Evidenztabelle Abdalla et al. 2019

Original Article

Effects of rapid maxillary expansion on upper airway volume:

A three-dimensional cone-beam computed tomography study

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ABSTRACT
Objective: To compare changes in pharyngeal airway volume and minimal cross-sectional area (MCA) between patients undergoing rapid maxillary expansion (RME) and a matched control group and to identify markers for predicting airway changes using cone-beam computed tomography (CBCT).
Materials and Methods: Pre- and posttreatment CBCT scans were selected of children who had RME (14 girls and 12 boys; mean age, 12.4 years) along with scans of a control group (matched for chronological age, skeletal age, gender, mandibular inclination) who underwent orthodontic treatment for minor malocclusions without RME. Changes in airway volume and MCA were evaluated using a standardized, previously validated method and analyzed by a mixed-effects linear regression model.
Results: Upper airway volume and MCA increased significantly over time for both the RME and matched control groups (P , .01 and P 1⁄4 .05, respectively). Although the RME group showed a greater increase when compared with the matched controls, this difference was not statistically significant. A reduced skeletal age before treatment was a significant marker for a positive effect on the upper airway volume and MCA changes (P , .01).
Conclusions: Tooth-borne RME is not associated with a significant change in upper airway volume or MCA in children when compared with controls. The younger the skeletal age before treatment, the more positive the effect on the upper airway changes. The results may prove valuable, especially in RME of young children. (Angle Orthod. 0000;00:000–000.)

KEY WORDS: Maxillary expansion; Upper airway volume; Children; CBCT

Population *Setting* *Komorbiditäten*	**transversale Anomalie** • private practice in Victoria, Australia • Ethnecity - unspecific – probably Australian
Schweregrad	a unilateral or bilateral crossbite in habitual intercuspal position with an Angle Class I molar relationship
Einschluss-kriterien	• 1) RME treatment with a tooth-borne Hyrax expander due to a unilateral or bilateral crossbite, followed by fixed appliances; • (2) a minimum increase of 3 mm in the intermolar width between pre- and posttreatment scans, which would result in a minimum expected orthopedic change in the maxilla of 1.5 mm[20]; • (3) pretreatment and progress CBCT scans with complete imaging of the cranial base, maxilla, mandible, and first four cervical vertebrae and associated airways; • (4) children between 8 and 15 years of age; and • (5) biting in habitual intercuspal position with an Angle Class I molar relationship.

Ausschluss-kriterien	• (1) previous orthodontic treatment, • (2) previous adenotonsillec- tomy, • (3) known syndromic conditions, • (4) movement artifacts, • (5) swallowing during scan acquisition, and • (6) treatment plan requiring orthodontic extractions.
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** • expansion screw on a tooth-borne Hyrax-type expander • 0.25 mm per day for a minimum of 2 weeks. There was a retention period of 6 months, after which some of the RME patients continued with fixed appliances. • minimum increase of 3 mm in the intermolar width between pre- and posttreatment scans, which would result in a minimum expected orthopedic change in the maxilla of 1.5 mm20; • for a minimum of 2 weeks. There was a retention period of 6 months VERSUCHSGRUPPE: **RME group** N=26 (Anfang) / N=26 (Ende) / Alter = 12,4 Jahre (8-14 Jahre) / ♂:♀ = 12:14 • Gebissphase: frühes Wechselgebiss, spätes Wechselgebiss, permanentes Gebiss < 18 • KFO-Behandlung: frühe Behandlung, reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Control group** N=26 (Anfang) / N= 26 (Ende) / Alter = 12,4 ± 2,4 Jahre / ♂:♀ = 12:14 • Gebissphase: frühes Wechselgebiss, spätes Wechselgebiss, permanentes Gebiss < 18 • KFO-Behandlung: reguläre Behandlung

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)Subkategorie • Atmung und Luftraum (Airway space, Schlafapnoe), Schlucken und Sprechen PRIMÄRZIELGRÖßE: Upper airway volume (mm^3) SEKUNDÄRZIELGRÖßE: minimal cross- sectional area (MCA) (mm^2) TERTIÄRZIELGRÖßE: Maxillary width -Mx (mm) QUARTÄRZIELGRÖßE: Maxillary Intermolar width (mm) QUINTÄRZIELGRÖßE: Mandibular width –Go (mm)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. Despite increasing intermolar and maxillary widths, the tooth-borne rapid maxillary expander is not associated with a significant change in upper pharyngeal airway volume or minimum cross-sectional area when used in children. [L SEP] 2. Skeletal age was found to be a predictive marker for airway changes. [L SEP] 3. The results may prove valuable, especially in understanding the broader effects of RME in young children. [L SEP]
Zusammen-fassung der Ergebnisse	**GRUPPE RME group VS. GRUPPE control group** ***PRIMÄRZIELGRÖßE/SEKUNDÄRZIELGRÖßE:*** *Both groups showed a significant increase in the maxillary, mandibular, and molar widths as well as airway volume and MCA between T0 and T1 (Table 1)* ***No significant difference in the increase in the upper airway volume and MCA was found in the RME group when compared with the controls (Table 1).*** ***TERTIÄRZIELGRÖßE/ QUARTÄRZIELGRÖßE:*** *Both groups showed a significant increase in the maxillary, mandibular, and molar widths as well as airway volume and MCA between T0 and T1 (Table 1)* ***In the RME group, the increase in the maxillary and intermolar width was significantly greater compared with the controls (P 1⁄4 .05 and P , .001, respectively)*** ***QUINTÄRZIELGRÖßE: No intergroup difference – see Table 1.***

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: retrospektiv, Fall-Kontroll-Studie* *Durchführung:adequat* *Auswertung: korrekt* *Power der Studie/Patientenzahl: The power of the sample size was calculated, and it was determined that 21 subjects would be needed to achieve a power of 80% (a 1⁄4 .05).* *Funding: k.A.* *Interessenkonflikte: k.A.* *Bias* *Imbalance zwischen den Gruppen zu T0 :* *However, the maxillary intermolar width was significantly smaller in the RME group when compared with the matched control group (29.2 mm and 31.7 mm, respectively; P , .001).* *Vorauswahl der DVTs von 784 Fällen wurden 758 ausgeschlossen.*
Schluss-folgerung des Begutachters	methodische Qualität: PROBLEM: a wide range of age is included in the RME Group compared to the Control group – no real matching possible Allerdings insgesamt gute Bewertung
	Klinische Aussagekraft: Es ist davon auszugehen, dass oben genannte Effekte generalisiert auf die kieferorthopädische Therapie mit einer RME zu übertragen sind.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	Acceptable ⊕

Evidenztabelle Abu Alhaija, Elham S J, Al-Khateeb 2011

Skeletal, dental and soft tissue changes in Class III patients treated with fixed appliances and lower premolar extractions

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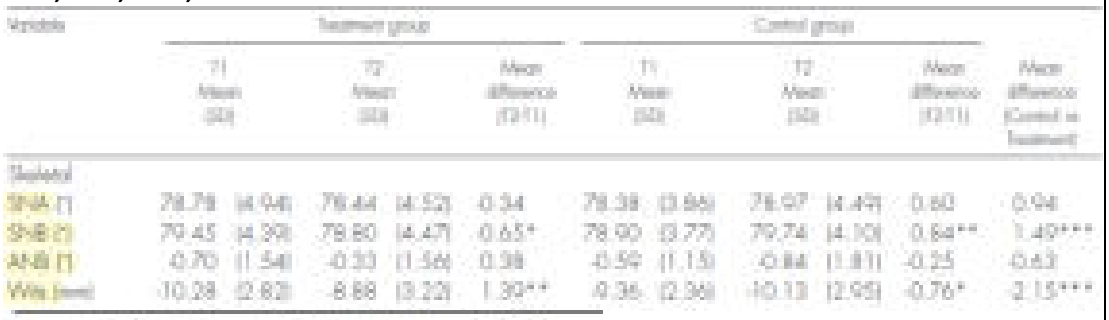
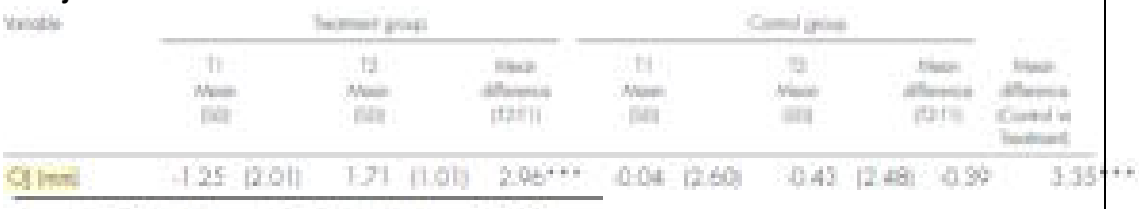
Background: Mild Class III malocclusions can be treated by upper incisor proclination and lower incisor retroclination following extraction of the lower first premolars.
Aims: To compare the skeletal, dental and soft tissue changes in Class III patients treated with fixed appliances, Class III traction and lower first premolar extractions with the changes in a group of untreated Class III patients.
Methods: The Treatment group consisted of 30 Class III patients (Mean age 13.69 ± 1.48 years) who were treated by upper and lower fixed appliances, Class III intermaxillary traction and lower first premolar extractions for 2.88 ± 1.12 years. The Control group consisted of 20 untreated Class III patients (Mean age 13.51 ± 0.95) matched for age and gender. The T1 to T2 changes in the treated and untreated groups were compared using a paired t-test while differences between the two groups were compared with an independent t-test.
Results: During treatment, the upper incisors were proclined about 1 degree and the lower incisors were retroclined 8 degrees. Small, but statistically significant changes in SNB, Wits and the overlying soft tissues accompanied the changes in incisor inclination. At the end of treatment a positive overbite and overjet were achieved. The increase in lower facial height in the Treatment group was comparable with the change in the Control group.
Conclusions: A range of mild to moderate Class III malocclusions can be treated by dentoalveolar compensation.
(Aust Orthod J 2010; 40–45)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** - Patients, with Class III incisor and molar relationship, overjet and therapy related extraction of the first premolars (Tretament group) • Irbid, Jordan
Schweregrad	Keine Angaben
Einschluss-kriterien	- Class III incisor and molar relationships - Overjet - (Therapy related extraction of the lower first premolar)
Ausschluss-kriterien	- reported mandibular functional shift at the start of treatment - poor quality of the lateral cephalogram. - inadequate data (lost data regarding age and treatment duration)

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **Class III (Treatment group):** Following extraction of the lower first premolars, the patients in the Treatment group were treated for an average duration of 2.88 ± 1.12 years with upper and lower fixed orthodontic appliances (preadjusted Roth prescription appliances with 0.022 inch slots). VERSUCHSGRUPPE 1: **Class III (Treatment group)** N= 30 (Anfang) / N=30 (Ende) / Alter = 13,69 ± 1,48 years ♂:♀ = 17:13 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** **untreated Class III (Control group)** KONTROLLGRUPPE 1: **untreated Class III (Control group)** N=20 (Anfang) / N=20 (Ende) / Alter = 13,51 ± 0,95 years ♂:♀ = 11:9 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • dentofaziale Ästhetik PRIMÄRZIELGRÖßE: **Skeletal: SNA, SNB, ANB, Wits** SEKUNDÄRZIELGRÖßE: **Dental: Overjet** TERTIÄRZIELGRÖßE: **Soft tissue: ALV**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	Both skeletal and dental changes occurred as a result of Class III treatment. However, dental movements accounted for most of these changes. Skeletal changes in the treated patients involved a slight reduction of mandibular prognathism and an improvement of the intermaxillary discrepancy (Wits appraisal). The dental changes were related to the lower arch extractions. Favourable soft tissue changes occurred in the Treatment group compared with the Control group. The soft tissues accompanied the skeletal changes. **Camouflage treatment using fixed appliances with Class III traction might be an option for mild to moderate skeletal Class III patients with little dentoalveolar compensation**.
Zusammen-fassung der Ergebnisse	**GRUPPE Class III (Treatment group) VS. GRUPPE untreated Class III (Control group)** T1 (pretreatment): 13,69, 1,48 years (Class III, Treatment group); 13,51, 0,95 years (untreated Class III, Control group) T2 (posttreatment/ observation): 15,71, 1,31 years (Class III, Treatment group); 15,93 years (untreated Class III, Control group **SNA, SNB, ANB, Wits**  $^{*}p < 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$ **Overjet**  $^{*}p < 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$ **ALV (distance from the lower lip to Sella-vertical line)**  $^{*}p < 0.05$, $^{**}p < 0.01$, $^{***}p < 0.001$

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die Äquivalenz von Versuch- und Kontrollgruppe gegeben (die beschriebenen Unterscheide sind für die Untersuchung nicht relevant). Eine Verblindung wurde nicht durchgeführt. Sample Size/ Power Berechnungen fehlen. Die retrospektive Studie hat einige methodische Schwächen. Allerdings ist die Population klinisch interessant (permanente Dentition, Extraktion, Therapie mit Multibracketapparatur – Camouflage treatment). Trotz der Schwächen besitzt die Studie daher klinische Relevanz. *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist gegeben. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Eine Verblindung fand nicht statt. Die retrospektive Studie besitzt deutliche Schwächen.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Die retrospektive Studie hat einige methodische Schwächen. Allerdings ist die Population klinisch interessant (permanente Dentition, Extraktion, Therapie mit Multibracketapparatur – Camouflage treatment). Trotz der Schwächen besitzt die Studie daher klinische Relevanz.
Evidenzlevel (SIGN)	**2+**
Qualität (RoB, SIGN)	**acceptable (+)**

Evidenztabelle Abu Alhaija, Richardson 1999

European Journal of Orthodontics 21 (1999) 291–298

Long-term effect of the chincap on hard and soft tissues

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SUMMARY The short- and long-term effects of the chincap used in combination with a removable appliance to procline upper incisors were analysed cephalometrically in 23 patients with Class III malocclusions. The overall changes were compared with growth changes in a closely matched control sample of untreated Class III patients. There was no evidence that the chincap retarded growth of the mandible. During treatment, there was an increase in mandibular length and facial height. The lower incisors retroclined and the upper incisors proclined. The incisor relationship was corrected. Soft tissue changes included an increase in nasolabial angle and improvement in soft-tissue profile, including the nose. Skeletal post-treatment changes included further mandibular growth associated with an increase in angle SNB and Wits measurement. Facial height also increased significantly. The Class I overjet was maintained, although slightly diminished. The soft tissue nose, upper and lower lip, and chin moved anteriorly, and the nasal tip and chin moved inferiorly.

At the end of the study period there were no significant skeletal or soft tissue differences between the treated and control groups. The only significant contrasts were in the overjet and the overbite.

Chincap therapy combined with an upper removable appliance to procline the upper incisors is effective in producing long-term correction of the incisor relationship by retroclination of lower incisors, proclination of upper incisors, and redirection of mandibular growth in a downward direction. The direction of growth at the chin is maintained subsequent to treatment, as are the changes in incisor inclination, although in diminished form. There are corresponding improvements in the soft tissue profile.

Population *Setting* *Komorbiditäten*	**Klasse III-Anomalie (inkl. LKG)** • Keine Angaben zum Setting • all subjects were in dental stage 1 (keine Angaben zu Komorbiditäten) ○ Störgrößen: An upper removable appliance for proclination of the upper incisors was added (only) when the incisors were retroclined at presentation
Schweregrad	Reverse Overjet
Einschluss-kriterien *Bei Review: PICOS*	• Class III Relationship • reverse overjet • Before treatment, all subjects were in dental stage 1 (eruption of first molars and incisors).
Ausschluss-kriterien	Keine Angaben

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung: mit Kopf-Kinn-Kappe (CC)** Chincap with low angulation were used in an attempt to restrain the growth of the mandible. An upper removable appliance for proclination of the upper incisors was added when the incisors were retroclined at presentation. VERSUCHSGRUPPE: **CC-Therapiegruppe** N=23 (Anfang) / N=23 (Ende) / Alter = 8.11 ± 0.96 Jahre / ♂:♀ = 14:9 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **untreated control group** N=23 (Anfang) / N=23 (Ende) / Alter = ?? ± ?? Jahre / ♂:♀ = k.A.:k.A. • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) **Subkategorie** Improvement in intermaxillary skeletal (and dental) variables PRIMÄRZIELGRÖßE: skelettale Parameterer SEKUNDÄRZIELGRÖßE: dentale Parmater TERTIÄRZIELGRÖßE: weichgewebige Parameter
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	The chincap, combined with an upper removable appliance, was effective in correcting the incisor relationship. The mandible continued to grow while the chincap was worn, and there was no improvement in mandibular protrusion as measured by SNB degrees or the jaw relation- ship as measured by Wits and ANB degrees.
Zusammen-fassung der Ergebnisse	**GRUPPE CC-Therapiegruppe VS. GRUPPE Bezeichnung** Chincap therapy combined with an upper removable appliance to procline the upper incisors is effective in producing long-term correction of the incisor relationship by retroclination of the lower incisors, proclination of the upper incisors, and a redirection of mandibular growth in a downward direction. The direction of growth at the chin is maintained subsequent to treatment as are the changes in incisor inclination, although in a diminished form. There are corresponding improvements in the soft tissue profile. The ideal case for the chincap, combined with an upper removable appliance to procline upper incisors, is a patient with diminished facial height, where a substantial overbite can be achieved, and where the antero-posterior skeletal discrepancy can be compensated or camouflaged by moderate proclination of the upper incisors and retro- clination of the lower incisors.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	Unklarer Studientyp Charakteristika der Kontroll- und Interventionsgruppe nicht angegeben Keine Interrater-Reliabilität bestimmt, Power-Analyse nicht gemacht Unterschiedliche Anzahl und unterschiedlicher Zeitpunkt der Datenerhebungen zwischen Kontroll und Therapiegruppe Nebeneffekte unzureichend untersucht Keine Interessenskonflikte angegeben Blinding nicht angesprochen Bias aufgrund teilweiser Behandlung mit OK-Platte
Schluss-folgerung des Begutachters	methodische Qualität: schlecht
	Klinische Aussagekraft: Es konnte trotz allem gezeigt werden, dass die Therapie mit Kopfkinn-Kappe bezüglich ihrer kieferorthopädischen/-orthodontischen Funktion als Therapie denkbar ist. Es wurden jedoch keinerlei Nebeneffekte wie Traumatisierung des Kiefergelenks untersucht, welche eine Behandlung mit einer Kopfkinn-Kappe reglementieren würden
Evidenz-level (SIGN)	**2+**
Qualität	**+**

Evidenztabelle Agirnasligil, Amuk et al 2019

The changes of self-esteem, sensitivity to criticism, and social appearance anxiety in orthognathic surgery patients: A controlled study

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Objectives: To evaluate the changes of psychologic parameters, such as self-esteem, sensitivity to criticism, and social appearance anxiety, in skeletal Class III patients undergoing orthognathic surgery and to compare the psychologic status of skeletal Class III patients with control subjects. **Methods:** The first group consisted of 60 patients with a mean age of 22.07 ± 1.30 years who did not need orthognathic surgery. The second group comprised 45 patients with skeletal Class III malocclusion (mean age 21.40 ± 2.02 years) who were evaluated in terms of psychologic changes from before to after surgery. A third group consisted of 50 Class III patients (mean age 20.09 ± 2.59 years) who were evaluated before surgery and a different 50 Class III patients (mean age 22.15 ± 2.03 years) who were investigated after surgery. The Rosenberg Self-Esteem Scale and the Social Appearance Anxiety Scale were used to evaluate psychologic parameters both before and after surgery. Analysis was carried out with the use of independent- and dependent-sample *t* tests, 1-way analysis of variance, and post hoc Tukey test. **Results:** Self-esteem of the patients with skeletal Class III malocclusion increased, and sensitivity to criticism and social appearance anxiety decreased significantly after the surgery ($P < 0.001$). In the patients with Class III malocclusion, self-esteem was significantly lower and social appearance anxiety significantly higher before orthognathic surgery than in the control group, and at the postoperative evaluation Class III patients had significantly higher self-esteem than the control group ($P < 0.001$). **Conclusions:** Through the improvement in facial appearance after surgery, patients' self-esteem increases and their sensitivity to criticism and social appearance anxiety decrease. (Am J Orthod Dentofacial Orthop 2019;155:482-89)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** • One hundred forty-five patients with Class III dentofacial deformity were invited to participate in this study who had applied to the Department of Orthodontics, Faculty of Dentistry, Erciyes University.
Schweregrad	Keine Angabe

Einschluss-kriterien *Bei Review: PICOS*	Patients were included in this study according to the following criteria: for subjects who were candidates for orthognathic surgery, 16 years of age or older; for subjects who underwent orthognathic surgery, age 18-25 years, having orthodontic treatment before and after orthognathic surgery, and undergoing doublejaw surgery with combination of advancement of the maxilla by the Le Fort I osteotomy procedure and setback of the mandible by bilateral sagittal split ramus osteotomy (BSSRO) for anterior/posterior and vertical skeletal corrections for Class III deficiency; and for control subjects, age 18-25 years, with Class I canine and molar relationship with well aligned dental arches, normal overjet and overbite, normal facial appearance, and no orthodontic/orthognathic surgery treatment needed.
Ausschluss-kriterien	Subjects with syndromes affecting the craniofacial anatomy, cleft lip or palate, or trauma-related malocclusion, and subjects who were mentally handicapped, psychologically ill, or had cognitive or behavioral impairment were not included in this study. Patients who underwent distraction osteogenesis, temporomandibular joint surgery, or resection due to malignancy present in the head and neck region, also were excluded from the study.
Intervention Versuchsgruppe	**kieferorthopädisch-kieferchirurgische Kombinationsbehandlung** According to the treatment plan, preoperative orthodontic decompensation procedures were completed by means of fixed orthodontic mechanics, and surgical splints were prepared on the plaster models. Osteotomies were performed with the use of Le Fort I and BSSRO osteotomy VERSUCHSGRUPPE: ***Longitudinal Group*** VERSUCHSGRUPPE: **Cross-Sectional group** N=95 (Anfang) / N=95 (Ende) / Alter = longitudinal group 21.68 ± 2.18 Jahre, cross-sectional group 19.75 ± 2.17 Jahre)/ ♂:♀ = longitudinal group 18:27; cross sectional group 27:23 • Gebissphase: permanents Gebiss <18 u. ≥ 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Klasse I-Non-Therapie-Gruppe** N=60 (Anfang) / N=60 (Ende) / Alter = ♂ 22.47± 1.46 y; ♀ 21.80± 1.12 y / ♂:♀ = 24:36 • Gebissphase: permanentes Gebiss Gebiss <18 u. ≥ 18. Lebensjahr • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • Reduktion der Belastung des Patienten PRIMÄRZIELGRÖßE: **Reduktion der Belastung des Patienten**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	Patients with Class III malocclusion had significantly lower self-esteem before orthognathic surgery than individuals of the control group. After surgery, patients' self-esteem was found to be higher than those of the control group. 2. The self-esteem of patients with Class III malocclusion increased after orthognathic surgery, and sensitivity to criticism and social appearance anxiety decreased significantly. 3. The social appearance anxiety levels of patients with Class III malocclusion was significantly higher before surgery than those of the control group. Through the orthognathic surgery, the social appearance anxiety levels of Class III patients reached close to the control group values. 4. Data on self-esteem, sensitivity to criticism, and social appearance anxiety of patients in longitudinal and cross-sectional study groups were found to be compatible with each other.
Zusammen-fassung der Ergebnisse	**GRUPPE Longitudinal Group VS. GRUPPE Klasse I-Non-Therapie-Gruppe** **GRUPPE Cross-Sectional group VS. GRUPPE Klasse I-Non-Therapie-Gruppe** 1. The patients with Class III malocclusion in both longitudinal and cross-sectional study groups had significantly lower self-esteem before surgery than the control group subjects (P <0.05), but there was no significant difference between the groups in terms of sensitivity to criticism. In the social anxiety evaluation, significantly higher anxiety values were found in the patients with Class III malocclusion in the longitudinal and cross-sectional study groups than in the control groups (P<0.05; Table II). 2. After surgery, self-esteem of the Class III patients in the longitudinal and cross-sectional study groups was significantly higher than the control group subjects (P<0.05), but there were no significant differences between the groups in the sensitivity to criticism and social anxiety level assessments (Table III). 3. According to the results of the longitudinal study group, self-esteem of patients increased significantly from before to after surgery (P<0.001). Also, sensitivity to criticism (P <0.001) and social appearance anxiety levels decreased significantly with surgery (P <0.001; Table V). 4. In the results of the cross-sectional study group, selfesteem of patients increased significantly with surgery (P <0.001), and the levels of sensitivity to criticism (P <0.05) and social appearance anxiety (P <0.001) decreased significantly, as in the longitudinal study group (Table VI). Correction of malocclusion through surgical intervention was shown to improve selfesteem and reduce social appearance anxiety and sensitivity to criticism levels significantly. 5. Patients in both longitudinal and cross-sectional study groups exhibited similar psychologic changes with surgical treatment. Comparing the self-esteem, sensitivity to criticism, and social appearance anxiety levels of patients with Class III malocclusion between the longitudinal and cross-sectional study groups, it was observed that there was no significant difference between the longitudinal and cross-sectional study designs in the presurgical and postsurgical psychologic evaluations. Self-esteem, sensitivity to criticism, and social appearance anxiety changed in both groups in the same way (Table VII).

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	- Gute Studie - Bias allerdings durch Kontrollgruppe möglich: Diese bestand aus Zahnmedizinstudenten im Studium und nicht wie die Behandlungsgruppen aus einer breiten Bevölkerungsschicht Unklar bleibt, ob psychische Veränderungen nur von kurzer Zeit durch Kontrasteffekt sind. Dieser Punkt wurde jedoch dadurch berücksichtigt, dass die Beurteilung von T1 erst nach 6 Monaten durchgeführt wurde
Schluss-folgerung des Begutachters	methodische Qualität: sehr gut
	Klinische Aussagekraft: hoch
Evidenz-level (SIGN)	**2++**
Qualität	**++**

Evidenztabelle Agostino et al. 2014

Cochrane Library

Cochrane Database of Systematic Reviews

Orthodontic treatment for posterior crossbites (Review)

Agostino P, Ugolini A, Signori A, Silvestrini-Biavati A, Harrison JE, Riley P

ABSTRACT

Background

A posterior crossbite occurs when the top back teeth bite inside the bottom back teeth. When it affects one side of the mouth, the lower jaw may have to move to one side to allow the back teeth to meet together. Several treatments have been recommended to correct this problem. Some treatments widen the upper teeth, while others are directed at treating the cause of the posterior crossbite (e.g. breathing problems or sucking habits). Most treatments have been used at each stage of dental development. This is an update of a Cochrane review first published in 2001.

Objectives

To assess the effects of orthodontic treatment for posterior crossbites.

Search methods

We searched the following electronic databases: the Cochrane Oral Health Group's Trials Register (to 21 January 2014), the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2014, Issue 1), MEDLINE via OVID (1946 to 21 January 2014), and EMBASE via OVID (1980 to 21 January 2014). We searched the US National Institutes of Health Trials Register and the World Health Organization (WHO) Clinical Trials Registry Platform for ongoing trials. We placed no restrictions on the language or date of publication when searching the electronic databases.

Selection criteria

Randomised controlled trials (RCTs) of orthodontic treatment for posterior crossbites in children and adults.

Data collection and analysis

Two review authors, independently and in duplicate, screened the results of the electronic searches, and extracted data and assessed the risk of bias of the included studies. We attempted to contact the first named authors of the included studies for missing data and for clarification. We used risk ratios (RR) and 95% confidence intervals (CIs) to summarise dichotomous (event) data, and mean differences (MD) with 95% CIs to summarise continuous data. We performed meta-analyses using fixed-effect models (we would have used random-effects models if we had included four or more studies in a meta-analysis) when comparisons and outcomes were sufficiently similar.

Main results

We included 15 studies, of which two were at low risk of bias, seven were at high risk of bias and six were unclear.

Fixed appliances with mid-palatal expansion

Nine studies tested fixed appliances with mid-palatal expansion against each other. No study reported a difference between any type of appliance.

Fixed versus removable appliances

Fixed quad-helix appliances may be 20% more likely to correct crossbites than removable expansion plates (RR 1.20; 95% CI 1.04 to 1.37; two studies; 96 participants; low-quality evidence).

Quad-helix appliances may achieve 1.15 mm more molar expansion than expansion plates (MD 1.15 mm; 95% CI 0.40 to 1.90; two studies; 96 participants; moderate-quality evidence).

There was insufficient evidence of a difference in canine expansion or the stability of crossbite correction.

Very limited evidence showed that both fixed quad-helix appliances and removable expansion plates were superior to composite onlays in terms of crossbite correction, molar and canine expansion.

Other comparisons

Very limited evidence showed that treatments were superior to no treatment, but there was insufficient evidence of a difference between any active treatments.

Authors' conclusions

There is a very small body of low- to moderate-quality evidence to suggest that the quad-helix appliance may be more successful than removable expansion plates at correcting posterior crossbites and expanding the inter-molar width for children in the early mixed dentition (aged eight to 10 years). The remaining evidence we found was of very low quality and was insufficient to allow the conclusion that any one intervention is better than another for any of the outcomes in this review.

Agostino P, Ugolini A, Signori A, Silvestrini-Biavati A, Harrison JE, Riley P.
Orthodontic treatment for posterior crossbites.
Cochrane Database of Systematic Reviews 2014, Issue 8. Art. No.: CD000979.
DOI: 10.1002/14651858.CD000979.pub2.

Population *Setting* *Komorbiditäten*	**transversale Anomalie** We conducted this review to assess the effects of different orthodontic treatments for correcting posterior crossbites.
Schweregrad	Posterior Crossbite
Einschluss-kriterien *PICOS*	1. RCTs 2. studies of any orthodontic or dentofacial orthopaedic (not surgical) treatment used to correct posterior crossbites or expand the top back teeth, or both, when compared against another such treatment or no treatment 3. children and adults with a posterior crossbite
Ausschluss-kriterien	1. Class III skeletal relationship 2. cleft lip or palate (or both) 3. other syndrome associated with craniofacial anomalies. 4. other studies than RCTs 5. studies investigating participants with systemic diseases

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: **orthodontic or dentofacial orthopaedic (not surgical) treatment used to correct posterior crossbites** N=671 (Anfang) / N=619 (Ende) / Alter = ? ± ? Jahre / ♂:♀ = ?:? • Gebissphase: jede • KFO-Behandlung: jede
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** VERSUCHSGRUPPE: **untreated control group** N=? (Anfang) / N=? (Ende) / Alter = ? ± ? Jahre / ♂:♀ = ?:? • Gebissphase: ? • KFO-Behandlung: keine Behandlung Für den Vergleich KREUZBISSBEHANDLUNG VS KEINE BEHANDLUNG wurde diese nicht klar definiert. Teilweise unbehandelte Kontrollen, teilweise Behandlung zum späteren Zeitpunkt. Die eigentliche Fragestellung des Reviews bezieht sich auf den Vergleich unterschiedlicher Behandlungsmittel.
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Okklusion, Kaufunktion, Funktion PRIMÄRZIELGRÖßE: Correction of the posterior crossbite SEKUNDÄRZIELGRÖßE: Expansion of the upper jaw/teeth measured as changes in the width between the molars or canines, or both. TERTIÄRZIELGRÖßE: Stability of crossbite correction QUARTÄRZIELGRÖßE: Signs and symptoms of temporomandibular joint dysfunction (e.g. pain, clicking, locking of the jaw joints, problems eating). Weitere Zielgrößen: • Signs and symptoms of respiratory disease (e.g. mouth breathing, nasal airway resistance). • Quality of life (using any validated measurement tool).
Studientyp	**Systematisches Review mit Meta-Analyse** • Inkludierte Studien: 15

Schluss-folgerungen der Autoren	**Implications for practice** There is a very small body of low- to moderate-quality evidence to suggest that fixed quad-helix appliances may be more successful than removable expansion plates at correcting posterior crossbites and expanding the inter-molar width in children with early mixed dentition (aged eight to 10 years). The remaining evidence that we found was of very low quality and was insufficient to allow the conclusion that any one intervention is better than another for any of the outcomes in this review. **Implications for research** More randomised controlled trials are required to address the question of what is the best treatment for posterior crossbites in children, adolescents and adults. The studies should be large enough to detect a difference, if one exists, and should assess appropriate outcomes. We believe that 'correction of crossbite' needs to be the primary outcome for all studies addressing this research question. In studies where all the crossbites were corrected (as with most studies in this review), 'time to correction' and 'pain' would be of increased importance as outcomes. High-quality work should be carried out to develop core outcome sets for orthodontics/areas of orthodontics. Such work should be carried out in association with the COMET (Core Outcome Measures in Effectiveness Trials) Initiative (www.comet-initiative.org), using robust methodology suggested by those working with the COMET Initiative so far (Williamson 2012). These core outcome sets should subsequently be the minimum set of outcomes that are measured in all clinical trials and systematic reviews (including this Cochrane review). Future randomised controlled trials must be well designed, well conducted and adequately delivered with subsequent reporting, including high-quality descriptions of all aspects of methodology. Reporting should conform to the Consolidated Standards of Reporting Trials (CONSORT) statement (www.consort-statement. org), which will enable appraisal and interpretation of results, and accurate judgements to be made about the risk of bias and the overall quality of the evidence. Although it is uncertain whether reported quality mirrors actual study conduct, it is noteworthy that studies with unclear methodology have been shown to produce biased estimates of treatment effects (Schulz 1995).
Zusammen-fassung der Ergebnisse	**GRUPPE orthodontic or dentofacial orthopaedic (not surgical) treatment used to correct posterior crossbites VS. GRUPPE untreated control group** **Leitlinienrelevante Ergebnisse:** Very limited evidence showed that treatments were superior to no treatment (Keine statistische Auswertung für diese Fragestellung dargestellt). **Andere Ergebnisse:** • The studies identified in this review are insufficient to address the question of what is the best treatment for posterior crossbites. • There is a very small body of low- to moderate-quality evidence to suggest that fixed quad-helix appliances may be more successful than removable expansion plates at correcting posterior crossbites and expanding the inter-molar width in children with early mixed dentition (aged eight to 10 years).

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding/Bias (AMSTAR II, Einzelstudien) Publikationsbias?	Review erfüllt die Cochrane-Standards Beschreibung der Einzelstudien Meta-Analyse für einzelne Fragestellungen Alle AMSTAR-Kriterien angewandt Risk-of-Bias-Analyse: *Overall risk of bias* • Two studies were at low risk of bias (Godoy 2011; Petrén 2008). • Seven studies were at high risk of bias (Asanza 1997; Lamparski 2003; Lippold 2013; Martina 2012; McNally 2005; Oshagh 2012; Thilander 1984). • Six studies were at unclear risk of bias (Garib 2005; Kilic 2008; Lagravere 2010; Mossaz-Joelson 1989; Oliveira 2004; Ramoglu 2010). *Power der Studie/Patientenzahl:* 287 Funding: **Internal sources** • Department of Surgical and Diagnostic Sciences, University of Genoa, Italy. Provision of IT support and open access to the university library. • Royal Liverpool and Broadgreen University Hospitals Trust (RLBUHT)/NHS, UK. • School of Dentistry, The University of Manchester, UK. • MAHSC, UK. The Cochrane Oral Health Group is supported by the Manchester Academic Health Sciences Centre (MAHSC) and the NIHR Manchester Biomedical Research Centre. **External sources** • National Health Service (NHS), UK. Jayne Harrison received research and development grant funding support for previous versions of this review. • Cochrane Oral Health Group Global Alliance, UK. All reviews in the Cochrane Oral Health Group are supported by Global Alliance member organisations (British Association of Oral Surgeons, UK; British Orthodontic Society, UK; British Society of Paediatric Dentistry, UK; British Society of Periodontology, UK; Canadian Dental Hygienists Association, Canada; Mayo Clinic, USA; National Center for Dental Hygiene Research & Practice, USA; New York University College of Dentistry, USA; and Royal College of Surgeons of Edinburgh, UK) providing funding for the editorial process (http:// ohg.cochrane.org/). • National Institute for Health Research (NIHR), UK. CRG funding acknowledgement: The NIHR is the largest single funder of the Cochrane Oral Health Group. Disclaimer: The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or the Department of Health. Interessenkonflikte: Paola Agostino, Alessio Signori, Armando Silvestrini-Biavati, Alessandro Ugolini, Jayne E Harrison, Philip Riley: no interests to declare.

Schluss-folgerung des Begutachters	methodische Qualität: höchste Qualität
	Klinische Aussagekraft: Die eigentliche Fragestellung des Reviews vergleicht unterschiedliche Behandlungsmittel zur Überstellung des posterioren Kreuzbisses. Diese Fragestellung ist nicht relevant für die aktuelle Leitlinie. Bezüglich der Leitlinie zeigt sich eine kleine Evidenz, dass die Behandlung des Kreuzbisses im Vergleich zu keiner Therapie überlegen ist.
Evidenz-level (SIGN)	**1++**
Qualität (Risk of Bias, AMSTAR II)	**Hoch** ⊕⊕⊕ - Keine oder eine unkritische Schwäche: Das systematische Review liefert eine genaue und umfassende Zusammenfassung der Ergebnisse der verfügbaren Studien zur Frage des Interesses.

Evidenztabelle Alali 2014

Original Article

A prospective controlled evaluation of Class II division 1 malocclusions treated with fixed lingual mandibular growth modificator

Osama H. Alali[a]

ABSTRACT

Objective: To assess the net dentofacial effects of the fixed lingual mandibular growth modificator (FLMGM).

Materials and Methods: The study sample comprised 38 patients with Class II/1 malocclusion and retrognathic mandible. All were in the pubertal growth spurt. Whereas FLMGM was applied to the treatment group (n = 21, mean age = 13.2 years), no treatment was performed on the control group (n = 17, mean age = 12.5 years). Skeletal and dentoalveolar changes were assessed on digital lateral cephalograms obtained at the beginning and end of the treatment/observation period of 8 months. Paired and independent *t* tests were used to assess the differences within and between groups.

Results: Maxillary growth was not affected by FLMGM treatment, which resulted in a significant overjet reduction of 4.1 mm, an increase in total mandibular length (Co-Gn) of 2.3 mm, chin advancement of 1.6°, and upper incisor retroclination of 4.0°. A reduction of 2.4° in ANB was largely due to an increase of 1.8° in SNB. Favorably, the lower incisors were obviously retroclined by 4.5°. The changes in the vertical skeletal relationships were negligible.

Conclusion: FLMGM was effective in treating growing Class II/1 patients and produced favorable dentofacial effects, with the matched untreated sample showing minimal changes. Lower incisor retroclination was a benefit of FLMGM treatment. (*Angle Orthod.* 2014;84:527–533.)

KEY WORDS: Fixed lingual mandibular growth modificator (FLMGM); Class II division 1 malocclusion; Mandibular retrusion; Dentofacial effects

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • University of Damascus, Department of Orthodontics, Syrien • 38 patients with Class II/1 malocclusion and retrognathic mandible. All were in the pubertal growth spurt.
Schweregrad	OJ > 4mm ANB > 4° APg/NL < 80° SNB < 76°
Einschluss-kriterien *Bei Review: PICOS*	1. Class II/1 malocclusion with (overjet > 4 mm) 2. Mild to moderate skeletal Class II (ANB > 4° and APg/NL > 80°) with retrognathic mandible (SNB < 76°) 3. Somatic maturation. The Fishman method was used to assess the hand-wrist radiographs, and only patients in the pubertal growth spurt peak, which occurs between stages 4 and 7, at the beginning of the treatment/observation period were invited.
Ausschluss-kriterien	Keine Angaben

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** Treatment group patients were treated with FLMGM. FLMGM consists of two separate and fixed parts (Figure 1). The maxillary part has four components: (1) an acrylic button similar to the Nance button, (2) two retention wires (1 mm) running posteriorly to enter into the headgear tube, (3) two retention hooks (0.8 mm) directed anteriorly and welded to the retention wire before entering the headgear tube, and (4) advancing loops (1 mm) consisting of two consecutive, long U loops. The mandibular part is similar to a standard lingual arch and welded to the lingual aspect of the molar bands. It includes an acrylic, anterior, inclined guiding plane seated on the lingual alveolar mucosa below the incisors; the plane is smooth to allow sliding against the advancing loops during mandibular closing movement to reach its anterior position. All appliances were fitted by the same orthodontist within 2 weeks of the patient’s initial records. After fitting, all treated patients were instructed to bite in the therapeutic anterior position, to keep their lips in touch as much as possible, and to return at 6-week intervals until the end of treatment duration. A construction bite registration was taken with the incisors in an edge-to-edge relationship where achievable. If this position was not attainable, then the bite was recorded in a comfortable anterior position, and, during treatment, the advancing loops were reactivated when necessary at the chair side. After a period of 8 months, the FLMGM was removed to record posttreatment findings, then the treatment was continued beyond this time point if the Class II malocclusion was not fully corrected and clinical objectives were not achieved. The observation period of 8 months was chosen in agreement with other articles studying fixed functional appliances. VERSUCHSGRUPPE: **FLMGM –Group (Fixed lingual mandibular growth modificator)** N=25 (Anfang) / N=21 (Ende) / Alter = 13,2 ± 0,9 Jahre / ♂:♀ = 11:14 (10:11 nach Dropouts) • Gebissphase: spätes Wechselgebiss (patients in the pubertal growth spurt peak) • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **untreated control group** N= 18 (Anfang) / N=17 (Ende) / Alter = 12,5 ± 2,1 Jahre / ♂:♀ = 8:10 (7:10 nach Dropouts) • Gebissphase: spätes Wechselgebiss (patients in the pubertal growth spurt peak) • KFO-Behandlung: keine Behandlung (Kontrollgruppe primär ohne Therapie, Mehrheit der Patienten mit späterer Therapie. “On the other hand, no orthodontic treatment was performed during the same period for the subjects of the control group and most of the control subjects were offered suitable treatment at a later date.” (S. 528))
Outcome	**Direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • dentofaziale Ästhetik PRIMÄRZIELGRÖßE: FRS-Werte (Table 3)

Studientyp	**RCT**
Schluss-folgerungen der Autoren	1. FLMGM was effective in treating Class II/1 growing patients and produced favorable and measurable dentofacial changes. 2. Overjet reduction was achieved by a combination of upper incisor retroclination and increase in total mandibular length associated with forward chin repositioning. 3. FLMGM appeared to be advantageous in terms of lower incisor retroclination. 4. Horizontal maxillary growth and vertical jaw relations were not statistically different.
Zusammen-fassung der Ergebnisse	**FLMGM –Group versus Untreated Control Group** In the maxilla, there were no statistically significant differences between groups in skeletal measurements. The upper incisors were retroclined overall by 4.0u (P <.001). In the mandible, there were great and significant differences observed for the sagittal mandibular skeletal measurements. Total mandibular length (Co-Gn) increased by 2.3 mm. With the chin moved forward, SNB and SNPg increased by 1.8° and 1.6°, respectively. Unexpectedly, the lower incisors of the FLMGM group retroclined significantly by 4.5° as a net effect. Overall, FLMGM treatment produced an overjet reduction of 4.1 mm. The sagittal relation was significantly enhanced: ANB decreased by 22.4°, APg/NL increased by 4.3°, and the profile convexity (NAPg) improved by 23.9°. Face-height index change was not statistically significant.
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • Ethikvotum fraglich (The protocol of study was approved by the council of scientific research and postgraduate studies. 528) • Handröntgenaufnahmen zu Beginn der Therapie und FRS 2x angefertigt, auch in Kontrollgruppe (“The Fishman method was used to assess the hand-wrist radiographs, and only patients in the pubertal growth spurt peak at the beginning of the treatment/observation period were invited.” S.528) • Nur Kurzzeiteffekt der Apparatur gemessen: Lastly, it must be stressed that the present trial reported the short-term FLMGM effects, and no conclusions can be drawn about longterm stability. S. 533 *Durchführung:* • Randomisierung nicht näher erklärt (“All subjects were randomized by the author at the beginning of the study to either the treatment or control group.” S. 528) *Auswertung:* • T-Test verwendet, aber keine Angabe, ob Normalverteilung getestet wurde: Pretreatment equivalence, changes occurring during the examination period in each group, and comparison of changes observed in both groups were tested for significance with t-tests using SPSS (ver.16.0; SPSS, Inc, Chicago, Ill) S. 528

	Power der Studie/Patientenzahl: • Based on that difference and standard deviation from previous investigations, a power analysis determined that, for a two-sided 5% significance level and a power of 80%, a sample size of 16 per group would be required. Accordingly, assignment continued until 25 patients had enrolled in the treatment group to compensate for any unexpected dropouts. In the control group, the enrollment continued until the minimum number of patients required to satisfy the statistical power was reached. S 528 *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe *Bias (SIGN):* • Baseline-Imbalancen in Versuchs- und Kontrollgruppe: The treatment and control groups are similar at the start of the trial. –NO (4 Parameter signifikant unterschiedlich) • Keine ITT-Analyse, sondern PP-Analyse (5 Drop-Outs wegen Umzugs): All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). – NO (SIGN) • Verblindung vorhanden: Cephalograms were digitized on screen and analyzed in a blind manner by the same orthodontist S. 529
Schluss-folgerung des Begutachters	methodische Qualität: gut
	Klinische Aussagekraft: Die FLMGM-Apparatur führt bei Patienten mit Klasse II/1 im puberalen Wachstums-Spurt verglichen mit einer unbehandelten Kontrollgruppe zu einer Reduktion des Overjets durch Kombination aus Retrusion der OKF und Vergrößerung der UK-Länge mit Anteriorverlagerung des Kinns. Zusätzlich wurde eine Retrusion der UKF beobachtet. Das Wachstum der Maxilla und vertikale Parameter wurden nicht signifikant beeinflusst.
Evidenz-level (SIGN)	**1+** Gut durchgeführte Metaanalysen, systematische Literaturübersichten oder RCTs mit einem niedrigen Biasrisiko
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable ⊕**

Evidenztabelle Alarcon, Bastir et al. 2011

Chincup treatment modifies the mandibular shape in children with prognathism

José Antonio Alarcón,[a] Markus Bastir,[b] Antonio Rosas,[c] and Julia Molero[d]
Granada and Madrid, Spain

Introduction: Although chincups are the preferred treatment for growing children with mandibular prognathism, the mechanism by which chincups improve this condition remains unclear. The aim of this study was to use geometric morphometrics to evaluate changes in the shape of the mandible of prognathic children treated with a chincup. Methods: Geometric morphometrics were used to evaluate the short-term mandibular shape changes in 50 prognathic children treated with chincups compared with 40 untreated matched controls. Twenty-one 2-dimensional mandibular landmarks from cephalograms taken before and after 36 months of treatment or observation were analyzed by Procrustes superimposition and thin plate spline. Results: Permutation tests of the treated patients showed highly significant differences in the mandibular shapes before and after treatment, and compared with the control group after the observation period. The thin plate spline grid deformations indicated more rectangular mandibular configuration, forward condyle orientation, condyle neck compression, gonial area compression, and symphysis narrowing. Conclusions: Early chincup treatment widely modifies the mandibular shape of prognathic children to improve Class III malocclusion. (Am J Orthod Dentofacial Orthop 2011;140:38-43)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** A group of 50 consecutive children (25 boys, 25 girls) with skeletal Class III malocclusions due to mandibular prognathism Details • were recruited from the Orthodontic Clinic of the School of Dentistry, Uni- versity Complutense, Madrid, Spain. • the children were chosen from a sample of 110 treated patients only if they had mandibular sym- physis narrowing (pretreatment symphysis-pogonion distance . posttreatment symphysis-pogonion dis- tance) as a sure sign of cooperation.
Schweregrad	1. ANB angle <0Grad 2. Wits appraisal < -2 mm 3. SNB angle> .82Grad 4. permanent first molar relationship of at least a half cusp Class III 5. anterior crossbite or edge-to-edge incisal relationship 6. accentuated mesial-step relationship of the deciduous second molars
Einschluss-kriterien *Bei Review: PICOS*	• s. unter Schweregrad

Ausschluss-kriterien	1. congenitally missing, supernumerary, or extracted teeth… 2. craniofacial anomalies; 3. temporoman- dibular joint dysfunction; 4. and previous or current orthopedic or orthodontic treatment
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** *(Therapie mit Kopf-Kinn-Kappe)* VERSUCHSGRUPPE: **Therapiegruppe** N=50 (Anfang) / N=50 (Ende) / Alter = 8,5 ± 0,5 Jahre / ♂:♀ = 25:25 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: unbehandelte Gruppe N=40 (Anfang) / N=40 (Ende) / Alter = 8,6 ± 0,4 Jahre / ♂:♀ = 20:20 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie Subkategorie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: *mandibular shape*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	These results imply that the chincup significantly affected the shape of mandibula. Chincup had strong effects on overall mandibular geometry…

Zusammenfassung der Ergebnisse

Gruppe Therapiegruppe T0 VERSUS Therapiegruppe T1

Mandibular shape

T0,T1

Significant differences in mandibular shape before and after chincup treatment in Procrustes distance (d = 0.035; P \0.001).

shape features could be identified as treatment effects:

- more rectangular relationship between the corpus and the ramus,
- anteroposterior compression of the relative distance between the condyle (landmark [lm] 5) and coronoid process (lm 2),
- relative vertical compression at the posterior ramus (between lms 5, 6, and 7),
- and gonial area compression (lms 8-10) that decreased the gonial angle and accentuated the preangular notch profile (lm 11)

Table. Cephalometric comparison of groups at T1

Cephalometric measurement	*Control group n = 40* *Mean*	*SD*	*Treated group n = 50* *Mean*	*SD*	*t test*
Cranial base					
S-N (mm)	65.1	1.7	64.5	1.2	NS
N-S-Ba (°)	129.5	2.3	130.3	2.5	NS
Po-PtV (mm)	−37.3	2.5	−36.6	1.1	NS
FH/Ba-N (°)	28.0	1.9	27.7	1.3	NS
Maxillary skeletal					
SNA (°)	81.0	0.9	80.8	0.7	NS
Co-Pt A (mm)	75.9	2.6	74.8	2.2	NS
ANS-PNS (mm)	48.1	2.4	47.3	1.8	NS
Mandibular skeletal					
SNB (°)	82.6	0.5	82.8	0.7	NS
Co-Gn (mm)	103.8	4.9	102.4	3.8	NS
Symphysis-pogonion (mm)	14.8	1.0	14.3	0.6	NS
Facial angle (°)	89.8	3.7	90.9	2.7	NS
Maxillary/mandibular					
ANB (°)	−1.4	0.7	−1.5	0.5	NS
Wits (mm)	−6.5	2.2	−7.5	2.1	NS
Maxillomandibular difference (mm)	27.9	3.0	27.6	3.5	NS
Vertical skeletal					
N-ANS (mm)	47.0	3.3	46.7	2.4	NS
S-Go (mm)	62.9	4.1	63.9	3.3	NS
N-Me (mm)	104.6	7.0	104.9	5.8	NS
(S-Go/N-Me) × 100 (%)	60.4	3.9	60.9	3.2	NS
FH to palatal plane (°)	1.0	1.2	−0.4	1.9	NS
Ar-Go-Me (°)	130.9	6.1	132.7	5.1	NS
Dental					
Molar relationship (mm)	−4.3	1.7	−4.5	2.1	NS
Overjet (mm)	−1.3	0.8	−1.8	0.8	NS
Overbite (mm)	1.0	1.3	0.9	1.5	NS
Interincisal angle (°)	140.4	7.1	145.2	8.8	NS
U1 to S-N (°)	97.9	7.6	97.4	6.8	NS
L1 to mandibular plane (°)	86.9	6.8	84.3	7.5	NS

NS, Not significant.

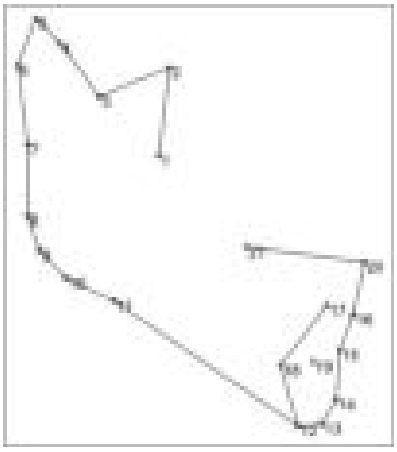

Fig 1. Twenty-one 2-dimensional landmarks on the mean shape (consensus of full sample): *1*, anterior ramus point (most posterior point on the anterior border of the ramus); *2*, coronoid tip; *3*, sigmoid notch; *4*, articulare anterior (anterior intersection of the condylar head and the posterior cranial base); *5*, condylion; *6*, articulare posterior (posterior intersection of the condylar head and the posterior cranial base); *7*, posterior ramus point (point of deepest concavity on the posterior border of the ramus); *8*, superior gonion (most superior aspect of the gonial curve); *9*, gonion; *10*, inferior gonion (most inferior aspect of the gonial curve); *11*, antegonial notch; *12*, menton; 13, gnathion; *14*, pogonion; *15*, B-point; *16*, infradentale; *17*, internal infradentale (most anterosuperior point on the lingual aspect of the mandibular alveolus); *18*, symphysis; *19*, mandibular incisor apex; *20*, L1 (incisal edge of the most prominent mandibular incisor); and *21*, mandibular molar mesial cusp tip.

Gruppe Kontrollgruppe T0 VERSUS Kontrollgruppe T1

no significant shape differences were obtained for the same interval in the control group (d 5 0.015; P 5 0.7).

Gruppe Therapigruppe T1 VERSUS Kontrollgruppe T1

The control and treated groups were significantly different in terms of their mean shapes after the treatment or observation period (d 5 0.04; P \0.001):

- the inferior basal border became curved in the treatment group compared with the control group.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Relativ hohes Dropout durch Eingrenzung der Probanden innerhalb des Studienverlaufs.* *Nebeneffekte wie eventuelle Kiefergelenksprobleme etc. wurden nicht untersucht.* *Ansonsten sehr gut durchgeführte Studie.*
Schluss-folgerung des Begutachters	methodische Qualität: sehr gut
	Klinische Aussagekraft: hoch
Evidenz-level (SIGN)	**2++**
Qualität	**++**

Evidenztabelle Al-Jewair, Preston et al. 2012

Original Article

A comparison of the MARA and the AdvanSync functional appliances in the treatment of Class II malocclusion

Thikriat S. Al-Jewair[a]; Charles B. Preston[b]; Eva-Maria Moll[c]; Terry Dischinger[c]

ABSTRACT

Objectives: To determine the skeletal and dentoalveolar effects produced by the MARA and the AdvanSync functional appliances in the treatment of growing patients with Class II malocclusion.

Materials and Methods: A retrospective study was conducted using lateral cephalograms of patients consecutively treated with MARA (n = 40) and AdvanSync (n = 30) during their skeletal growth spurt as evaluated by the improved cervical vertebral maturation method. A comparison was made with 24 untreated Class II control subjects obtained from the University of Michigan growth study and matched with the experimental groups for skeletal age, sex, and craniofacial morphology. Cephalograms were taken at three time points: (T1) pretreatment, (T2) postfunctional appliance treatment, and (T3) fixed orthodontic treatment completion. Treatment changes were evaluated between the time points using 35 variables. Data were analyzed using one-way analysis of variance and Scheffe's post hoc test.

Results: At the postfunctional appliances' phase (T2–T1), both appliances showed significant increases in total mandibular length, ramus height, and anterior/posterior facial height. The AdvanSync resulted in significant restriction of maxillary growth, 1° more than MARA. This effect continued during the fixed orthodontic treatment stage (T3–T2). The net changes (T3–T1) revealed significant mandibular growth enhancement with MARA (+2.7mm) and significant headgear effect with AdvanSync. Both appliances caused 5° flaring in mandibular incisors as well as significant decreases in overjet and overbite. The treatment time for AdvanSync was 1 year less than MARA.

Conclusion: The MARA and the AdvanSync resulted in normalization of the Class II malocclusion. The AdvanSync showed more headgear effect but less mandibular length enhancement than MARA did. Both appliances showed similar dentoalveolar changes. (*Angle Orthod.* 2012;82:907–914.)

KEY WORDS: Fixed functional appliance; Cephalometry; Class II malocclusion

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Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • United States: MARA patient records obtained from the cases treated by the developer of the appliance, Dr Douglas Toll, and AdvanSync [patients] obtained from one author (Dr Dischinger) were included. Results were compared with 24 untreated control individuals obtained from the University of Michigan Growth Study Center.38 patients with Class II/1 malocclusion and retrognathic mandible. All were in the pubertal growth spurt. • white healthy boys and girls (Versuchsgruppen)

Schweregrad	OJ < 10mm ANB ≥ 4° SNB ≤ 77° FMA° = 25 ± 5°
Einschluss-kriterien *Bei Review: PICOS*	• white healthy boys and girls presenting with Class II malocclusion • with the molars in at least an end-to-end relationship • presenting during the peak growth spurt as indicated by the improved version of the cervical vertebral maturation (CVM) method • Retrognathic mandible (SNB ≤77°), ANB angle ≥4° • Normal Frankfort to Mandibular plane angle (FMA°= 25 ± 5°) • overjet <10 mm • no missing teeth • a nonextraction treatment approach • crowns cemented on permanent maxillary and mandibular first molars • the appliance maintained for at least 6 months.
Ausschluss-kriterien	Keine Angaben
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** VERSUCHSGRUPPE 1: **MARA + MB simultan** The MARA (AOA, Sturtevant, Wis) and the AdvanSync (Ormco Co, Glendora, Calif) were designed to allow simultaneous fixed orthodontic appliance treatment (0.022” x 0.028” slot edgewise bracket system in the included samples fully bonded at T1) with the brackets on the mandibular incisors having a built-in labial root torque. Both functional appliances include stainless-steel crowns with single archwire tubes on permanent first molars. The MARA’s upper crowns are also attached to 0.062” square tubes to accommodate 0.060” upper elbows and lower crowns with soldered lower protruding arms. The crowns are attached to lower lingual holding arches (2–3 mm lingual to mandibular incisors) to prevent mesiolingual rotation of the molars. This side effect can also be prevented by bonding lower anterior brackets. The treatment protocols used by the MARA and the AdvanSync developers include stepwise activation as judged by the severity of the overjet. The appliances are activated 2 to 4 mm every 3 months over a 12- month (for MARA) duration until slight dental overcorrection is achieved with the MARA. Once the appliances are removed, edgewise fixed orthodontic treatment is continued to achieve correct anterior torque and occlusion and adequate finish. N=40 / Alter = 11,6 ± 1,9 Jahre / ♂:♀ = 22:18 • Gebissphase: spätes Wechselgebiss (during the peak growth spurt) • KFO-Behandlung: reguläre Behandlung

	VERSUCHSGRUPPE 2: **AdvanSync + MB simultan** The MARA (AOA, Sturtevant, Wis) and the AdvanSync (Ormco Co, Glendora, Calif) were designed to allow simultaneous fixed orthodontic appliance treatment (0.022” x 0.028” slot edgewise bracket system in the included samples fully bonded at T1) with the brackets on the mandibular incisors having a built-in labial root torque. Both functional appliances include stainless-steel crowns with single archwire tubes on permanent first molars. The AdvanSync did not include lower lingual holding arches, and the maxillary and mandibular crowns of this appliance are connected by telescoping rods. The treatment protocols used by the MARA and the AdvanSync developers include stepwise activation as judged by the severity of the overjet. The appliances are activated 2 to 4 mm every 3 months over a 6- to 12-month (for AdvanSync) duration until moderate overcorrection is achieved with the AdvanSync. The occlusion with the AdvanSync is overcorrected to an anterior crossbite and a Class III canine relationship with the maxillary canine in an end-to- end relationship with the mandibular first premolar or in a full-tooth relationship in the more severe cases. Once the appliances are removed, edgewise fixed orthodontic treatment is continued to achieve correct anterior torque and occlusion and adequate finish. N=30 (Anfang) / N=30 (Ende) / Alter = 12,3 ± 1,3 Jahre / ♂:♀ = 13:17 • Gebissphase: spätes Wechselgebiss (during the peak growth spurt) • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: unbehandelte **Kontrollgruppe** N=24 (Anfang) / N=24 (Ende) / Alter = 11,9 ± 1,9 Jahre / ♂:♀ = 13:11 • Gebissphase: spätes Wechselgebiss (aufgrund des Alters angenommen) • KFO-Behandlung: keine Behandlung
Outcome	**Direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: dentoskeletal treatment effects **Zeitpunkte der Datenerhebung:** (T1) pretreatment (T2) at functional appliance treatment completion (T3) at fixed orthodontic treatment completion
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	• Both the MARA and AdvanSync affect the skeletal and dentoalveolar craniofacial complex and are effective in normalizing the Class II malocclusion to Class I in patients treated during the skeletal growth spurt. • The MARA produced a significant elongation in the total length of the mandible. • The AdvanSync resulted in significant headgear effect when compared with MARA and controls and maintained the Class I relationship at T3–T1. • Both appliances resulted in similar dentoalveolar findings.
Zusammen-fassung der Ergebnisse	**GRUPPE Versuchsgruppen VS. GRUPPE Kontrollgruppe** **T2-T1 (Behandlung mit MARA bzw. AdvanSync und MB simultan)** The AdvanSync restricted maxillary growth ‘‘headgear effect’’ as indicated by SNA° (-2°). Both treatment groups showed significant increases in the total lengths of the mandible (Co-Gn), the ramus height (Co-Go), and the anterior and posterior facial heights. The dentoalveolar measurements revealed significant retroclination of the maxillary incisors relative to Frankfort horizontal in the AdvanSync group in addition to nonsignificant eruption and distalization of maxillary molars. The mandibular incisors proclined 5°, and the mandibular molars moved forward (+2 mm) with MARA and AdvanSync (P< .001) over controls. (Table 2) **T3-T2 (Follow-up/festsitzende Feinausformung)** The AdvanSync in comparison to controls showed a continued significant restraining in maxillary growth, less increase in ramus height (Co-Go; P< .001), and more relapse in the Wits appraisal and maxillary molars’ horizontal position. All interdental measurements were statistically significant for the same group. (Table 3) **T3-T1 (gesamte Behandlungsdauer)** The net treatment changes (T3–T1) showed a significant headgear effect in the AdvanSync group (Table 4). The mandibular growth enhancement (Co-Gn) was significant with MARA (+2.7 mm) and not significant with AdvanSync over controls. Figure 1 depicts the changes in the total mandibular length (Co-Gn) between the three time points. Both treatment modalities resulted in reduction in the ANB° and the angle of convexity and an increase in the anterior and posterior facial height over controls. The anterior/posterior facial height of the Advan- Sync group was less than MARA. The mandibular molars erupted and drifted forward more than 3 mm in both groups. Interdentally, significant decreases in overjet and overbite were observed. (Table 4)

Angaben auffälliger positiver und/oder negativer Aspekte
Studiendesign
Durchführung
Auswertung
Funding
Interessen-konflikte
Bias (SIGN, AMSTAR II, Einzelstudien)
	Studiendesign:
	• Ethikvotum fraglich (retrospektive Studie)
	• Nur Kurzzeiteffekt der Apparatur gemessen
	Durchführung:
	• S. Baseline-Imbalancen und s. Fallzahl
	• Beide Kl.II-Apparaturen von Beginn an mit MB kombiniert > keine eindeutige Zuweisung des Effekts möglich (u.a. Low-Torque-Brackets in UK-Front)
	Auswertung:
	• Keine Angabe des Tests, mit dem Normalverteilung geprüft wurde. Keine genaue Angabe des angewandten parametrischen Tests
	• Scheffe’s post-hoc-Analyse
	• FRS-Auswertung durch 2 Personen; 15 zufällig ausgewählte FRS nach zwei Wochen nochmals durchgezeichnet (Reliabilität erhöht)
	Power der Studie/Patientenzahl:
	• Keine Angabe zur Power
	• Zu geringe Fallzahl, um geschlechterspezifische Unterschiede zu bewerten
	Funding: keine Angabe
	Interessenkonflikte: keine Angabe
	Bias (SIGN):
	• Baseline-Imbalancen in Versuchsgruppen und Kontrollgruppe:
	  ○ Signifikanter Unterschied in 4 Messwerten
	  ○ Zu geringe Fallzahl, um geschlechterspezifische Unterschiede zu bewerten
	  ○ Historische Kontrollgruppe: keine Angabe zu Ethnie und lediglich „Annahme“, dass Wachstumsstadium der Kontrollgruppe mit Versuchsgruppen identisch
	• Have confidence intervals been provided? – NO (SIGN)

Schluss-folgerung des Begutachters	methodische Qualität: insgesamt gut
	Klinische Aussagekraft: Sowohl MARA als auch AdvanSync beeinflussen skelettale und dentale Parameter und sind effektiv in der Behandlung von Kl.II-Anomalien während des Wachstums. Allerdings beide Kl.II-Apparaturen von Beginn an mit MB kombiniert, d.h. Effekte nicht eindeutig zuweisbar. Durch MARA kam es zu einer signifikanten Zunahme der UK-Länge verglichen mit der Kontrollgruppe, allerdings zu Beginn schon größere UK-Länge in MARA-Gruppe verglichen mit Versuchsgruppe 2 und Kontrollgruppe. Durch AdvanSync kurzzeitiger HG-Effekt im Sinne einer signifikanten Wachstumshemmung des Oberkiefers. MARA und AdvanSync zeigen vergleichbare dentoalveoläre Effekte, allerdings Vergleichbarkeit eigentlich eingeschänkt, da beide mit MB mit gleicher Prescription kombiniert.

Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable ⊕**

Evidenztabelle Al-Khalifa et al. 2017

ABSTRACT

Introduction: Chin cup (CC) therapy has been used as the traditional appliance for treating class III malocclusion during mixed dentition period. The aim of this study was to investigate the effect of CC on the improvement of skeletal and dentoalveolar skeletal changes in class III patients during mixed dentition stage.

Materials and methods: A total of 30 patients (7–9 years old) with skeletal class III malocclusion were selected based on clinical and cephalometric examination. Out of 30 patients, 20 underwent CC therapy. All orthodontic records and measurements were taken before and after treatment. Similar records were collected from the control group. The lateral cephalometric films were traced before and after treatment and analyzed.

Results: There was a significant improvement in maxillary and the mandibular skeletal measurements after CC therapy. Improvement of ANB angle and an increase in wits appraisal have been detected in the treated group according to intermaxillary skeletal variables.

Conclusion: The study concluded that the CC therapy is effective for correcting skeletal class III malocclusion along with positive changes in the dentoskeletal variables during the mixed dentition stage.

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** **Class III patients during mixed dentition stage. Details** • 30 patients with skeletal class III malocclusion. Patients selected ranged from 7 to 9 years of age • Patients were selected from the Orthodontic Department of the Faculty of Dental Medicine in Al-Azhar University, Egypt • keine Angabe zu Komorbiditäten
Schweregrad	Overjet unter <0mm nicht explizit erwähnt, lediglich “average reverse overjet” angegeben
Einschluss-kriterien *Bei Review: PICOS*	• Skeletal class III relationship with normal maxilla and prognathic mandible • all patients had no transverse discrepancy between dental arches • no craniofacial anomaly • no history of previous orthodontic treatment • patients are all of class III malocclusion in the mixed dentition stage • patients and parents are cooperative with the dentist

Ausschluss-kriterien	Keine Angabe
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** *20 had undergone CC therapy with maxillary bite block* VERSUCHSGRUPPE: **CC-Therapiegruppe** N= 20 (Anfang) / N=20 (Ende) / Alter = 7-9 Jahre / ♂:♀ = 7:9 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Patients not treated with CC (Nicht-CC-Gruppe)** N=10 (Anfang) / N=10(Ende) / Alter = 7-9 Jahre / ♂:♀ = 7:9 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Reduktion eines weiteren Therapiebedarfs • **Subkategorie** Improvement in intermaxillary skeletal (and dental) variables Measured between Control and treatment group + Measured between treatment group T0 and treatment group T1
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	From the observations, it can be concluded that the CC therapy is effective for correcting skeletal class III mal- occlusion. It can significantly improve the dentoskeletal variables during the mixed dentition stage. Further lon- gitudinal long-term studies are required to fully ascertain the skeletal and dental changes of CC therapy.
Zusammen-fassung der Ergebnisse	**GRUPPE CC-Therapiegruppe VS. GRUPPE Patients not treated with CC (Nicht-CC-Gruppe)** • The sagittal maxillary position [SNA- AN□], showed significant changes at the end of CC therapy while Co-A and Co-ANS showed nonsignificant changes. • This study showed a significant increase in ANB and wits appraisal, • A significant increase in vertical angular variables (SN-Go Me, SN-Co GN) was also observed. This increase is due to the backward and downward rotation of the mandible. • Significant reduction of gonial angle was also observed in the study group • The study showed positive OJ in all patients at end of CC therapy. There was also a significant decrease in axial inclination of maxillary anterior teeth and interincisal angle at the end of CC therapy. However, mandibular anterior teeth and OB showed no significant changes at the end of treatmen

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Keinen wirklichen Schweregrad definiert, keine Angaben zu Komorbiditäten*. Keine genaue Angabe über anderweitige Therapie der Kontrollgruppe (lediglich “no treatment with CC” erwähnt, keine Ausschlusskriterien, kein Average Alter angegeben, lediglich “mixed dentition stage” und keine klare Angabe zur WGP/RP
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: gegeben, jedoch keine Aussage über mögliche Nebeneffekte wie Kiefergelenksschädigungen
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable** ⊕

Evidenztabelle Allen, Connolly et al. 1993

Early treatment of Class III incisor relationship using the chincap appliance

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SUMMARY Twenty-three patients (10 male, 13 female), with Class III relationships of the incisor teeth at the mixed dentition stage, were treated with the chincap appliance associated, where appropriate, with an upper removable appliance to procline upper incisors and to free the occlusion. Cephalometric analyses at the beginning and at the end of active treatment were compared with those in a carefully matched untreated control group selected from the Belfast Growth Study.

At the beginning of treatment patients differed significantly from the controls in that SNB was larger, ANB was negative, Wits' analysis was negative, and the intermaxillary angle significantly reduced. The overjet was reversed, the lower incisors were ahead of A–Po, and the upper lip was far behind the E line.

Significant changes brought about by the treatment were improvement in the Wits' relationship (but there was no significant change in the ANB angle), increases in the intermaxillary angle and lower facial height, improvement in the overjet, proclination of upper incisors and retroclination of lower incisors, backward movement of the lower incisors in relation to A–Po, and backward movement of the lower lip. The efficacy of the chincap appliance can be attributed to retroclination of lower incisors and downward movement of the mandible which may improve the jaw relationship without affecting the ANB angle. There were marked changes in the lip posture.

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** Twenty-three patients (10 male, 13 female), with Class III relationships of the incisor teeth at the mixed dentition stage, were treated with the chincap appliance associated, where appropriate, with an upper removable appliance to procline upper incisors and to free the occlusion. Cephalometric analyses at the beginning and at the end of active treatment were compared with those in a carefully matched untreated control group selected from the Belfast Growth Study.
Schweregrad	Overjet < 0mm
Einschluss-kriterien *Bei Review: PICOS*	Class III relationships of the incisor teeth
Ausschluss-kriterien	Class III relationships of the incisor teeth

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Each of 23 patients (10 male, 13 female) with Class III relationships of the incisor teeth, had a cephalometric radiograph (film 1) taken immediately before treatment with the chincap appliance. Forces between 200-450 g with low angulation were used in an attempt to retrocline lower incisors and restrain the growth of the mandible. In 17 of the patients, an upper removable appliance was used concurrently to separate the upper and lower teeth, and to procline the upper incisors. When the incisor relationship had been corrected, a second cephalometric film was taken (film 2) VERSUCHSGRUPPE: ***Chincup group*** • N=23 (Anfang) / N=23 (Ende) / Alter = ♂ 8.23± 1.48 years ♂:♀ = 10:13 • Gebissphase: Frühes und spätes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Klasse I-Non-Therapie-Gruppe** N=23 (Anfang) / N=23 (Ende) / Alter: Keine genaue Angabe: “Before treatment, the worst match was an age difference of 0.18 year and the best 0 year. After treatment, the worst match was a difference of 0.78 year and the best was a difference of 0.01 year” Verteilung Geschlecht: ♂:♀ = 10:13 • Frühes und spätes Wechselgebiss • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	The efficacy of the upper removable appliance/chincap system in treating Class III incisor relationships can be attributed to proclination of upper incisors, retroclination of lower incisors and downward movement of the mandible which may improve the antero-posterior relationship of the basal bones without affecting the ANB angle. There is an associated and dramatic improvement in the soft tissue profile brought about by backward repositioning of the lower lip. While there may be a posttreatment inclination of incisors which does not match normal standards, these discrepancies seem a small price to pay for the great improvement in soft tissue profile and dental function.
Zusammen-fassung der Ergebnisse	**GRUPPE Chincup group VS. GRUPPE Klasse I-Non-Therapie-Gruppe** **1. Skelett. Parameter** There were no statistically significant changes in the angles SNA, SNB, or ANB during treatment; Signifikante Änderungen jedoch in: - increases of Lower anterior face height (mm) - Wits (mm) - Intermaxillary angle (degrees) Genaue Werte siehe Tabelle unter “Notizen” **2. Dentale Parameter** Dentally, although the Class III incisor relationship had been corrected, the overjet was still diminished, the upper incisors significantly more proclined and the lower incisors more retroclined than normal. The latter finding corresponded with the incisal edge of the lower incisors being situated posterior to A-Po. At the end of treatment, the upper incisors were a little more proclined than normal, and the lower incisors appreciably retroclined. **3. weichgewebige Parameter** The upper lip remained significantly further behind the E line than normal and it is interesting to note that the position of the lower lip had been overcorrected in relation to normal standards.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	• k.A. über mögliche Interessenskonflikte oder Finanzierung • k.A. über Einschluss-/Ausschlusskriterien • Bias dadurch möglich, dass manche Patienten OK-Platte erhalten haben, manche nicht. • k.A. über Blinding • Kontrollgruppe besteht aus Klasse I-Patienten, statt Klasse III-Patienten-> sehr ungünstig, da kein wirklicher Vergleich gezogen werden kann.
Schluss-folgerung des Begutachters	methodische Qualität: befriedigend
	Klinische Aussagekraft: gegeben
Evidenz-level (SIGN)	**2+**
Qualität	**+**

Evidenztabelle Almeida, Flores-Mir et al. 2008

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SOFT TISSUE CHANGES PRODUCED BY A BANDED-TYPE HERBST APPLIANCE IN LATE MIXED DENTITION PATIENTS

Aim: This controlled trial cephalometrically compared soft profile changes during orthodontic treatment with a banded Herbst appliance against a control group. Methods: The sample consisted of late mixed dentition Class II division 1 malocclusion cases. The first group consisted of 29 consecutive patients (14 females and 15 males), selected prospectively and treated solely with a banded Herbst appliance; the second group consisted of 28 nontreated subjects (14 females and 14 males). Two lateral cephalograms were obtained from each patient at the beginning and immediately following the completion of the treatment/observation period (1 year). Soft tissue cephalometric variables were analyzed. Different t tests were used to compare the starting forms of the 2 groups and the changes that occurred after treatment (P < .05). Results: The present study showed a modest decrease in the facial convexity, retrusion of the upper lip, and an improvement in the mentolabial angle. All these changes were statistically significant. The profile improvement in the Herbst group was likely because of the changes observed in the upper lip and, to a minor degree, in the lower lip and soft tissue pogonion. Conclusions: It can be concluded that the changes in the soft tissue profile produced by a banded-type Herbst appliance were statistically different from the control group, but not likely clinically significant. The direction and magnitude of the changes were similar to those reported for permanent dentition cases. World J Orthod 2008;9:121–131.

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Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie**
Schweregrad	observed for a period of 1 year. Both samples presented with a bilateral distal molar relationship (> one-half cusp), mandibular deciduous second molars still present, and an ANB angle > 4.5 degrees.
Einschluss-kriterien *Bei Review: PICOS*	observed for a period of 1 year. Both samples presented with a bilateral distal molar relationship (> one-half cusp), mandibular deciduous second molars still present, and an ANB angle > 4.5 degrees.
Ausschluss-kriterien	Keine Angabe

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** months with a modified banded-type Herbst appliance (Fig 2).[15] A control sam- VERSUCHSGRUPPE: Herbst N=40 (Anfang) / N=29 (Ende) / Alter = 9y 11m max. 8,3y min. 11,1Y / ♂:♀ = 15:14 • Gebissphase: späte Wechselgebissphase • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine Therapie; Kategorie aus Einschlusskriterien** KONTROLLGRUPPE: **untreated control** N=28 (Anfang) / N=28 (Ende) / Alter = 9y 8m min. 8,0y-10,9y / ♂:♀ = 14:14 • Gebissphase: späte Wechselgebissphase • KFO-Behandlung: keine kieferorthopädische Therapie
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie Subkategorie** • **Dentofazial Ästhetik** PRIMÄRZIELGRÖßE: Soft tissue cephalometric variables *(Grad, Millimeter)*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	Significant changes, although not likely clinically significant, in the soft tissue profile of the banded Herbst group were found when compared to the control group. This was produced by a decrease in the facial convexity, a retrusion of the upper lip, and an increase in the mentolabial angle. No statistically significant changes in the nasolabial angle, lower lip position, or soft tissue pogonion were found.
Zusammen-fassung der Ergebnisse	**Herbst VS. Untreated Control** Changes between the groups from T_1 to T_2 The Herbst appliance produced a significant increase (8.8 degrees) in the mentolabial angle, a significant reduction (3.5 degrees) in the facial convexity, as well as a greater reduction in the protrusion of the upper lip (0.9 mm) compared to the mean changes of the control group ($P = .05$). There were no statistically significant differences between the Herbst and control groups in the NLA, lower lip, or pogonion (FHp-Pog') measurements. No changes were recorded for the remaining measurements (Table 4).

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • Prospektive Testgruppe • Historische Kontrollgruppe *Durchführung:* • Keine Angabe ob Verblindung bei Datenerhebung stattgefunden hat • Keine Angaben zum K-Biss • Keine Angaben zum genauen Aufbau der Herbst-Apparatur *Auswertung: genauen P-Wert angegeben* *Power der Studie/Patientenzahl: keine Angabe ob Poweranalyse erfolgt* *Funding: keine Angabe* *Interessenkonflikte: keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • *Test auf Normalverteilung vorhanden* *Siehe ROB:* • What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed: 16,2% • Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome: No • The main potential confounders are identified and taken into account in the design and analysis.: No
Schluss-folgerung des Begutachters	methodische Qualität: gut
	Klinische Aussagekraft: gering Kaum Veränderungen des Weichteilprofils feststellbar. Da davor auszugehen ist, dass die die gewählten Parameter sehr variabel sind und weiteren Umwelteinflüssen unterliegen, ist somit die klinische Aussagekraft gering.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN /AMSTAR II)	**acceptable ⊕**

Evidenztabelle Almeida, Henriques et al 2005

Original Article

Short-Term Treatment Effects Produced by the Herbst Appliance in the Mixed Dentition

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Abstract: This prospective clinical investigation evaluates the dentoalveolar and skeletal cephalometric changes produced by the Herbst appliance during treatment of mixed dentition patients with Class II division 1 malocclusion. Thirty individuals (15 male and 15 female individuals; initial mean age nine years 10 months) were treated with the Herbst appliance for a period of 12 months. For comparison, the records of 30 untreated Class II children (15 boys, 15 girls; initial mean age nine years eight months) were followed without treatment for a period of 12 months. The results indicated that the treatment effects produced in the mixed dentition patients were primarily dentoalveolar in nature. The mandibular incisors were tipped labially, and the maxillary incisors were retruded; a significant increase in mandibular posterior dentoalveolar height occurred, and there was a restriction in the vertical development of the maxillary molars. There was no difference in the forward growth of the maxilla between the two groups. In comparison with the controls, however, the Herbst treatment produced a modest but statistically significant increase in total mandibular length. This increase in total mandibular length, however, was less than that observed in adolescent Herbst patients in other studies. (*Angle Orthod* 2005;75:540–547.)

Key Words: Herbst appliance; Early treatment; Class II division 1 malocclusion; Functional orthopedics; Mixed dentition

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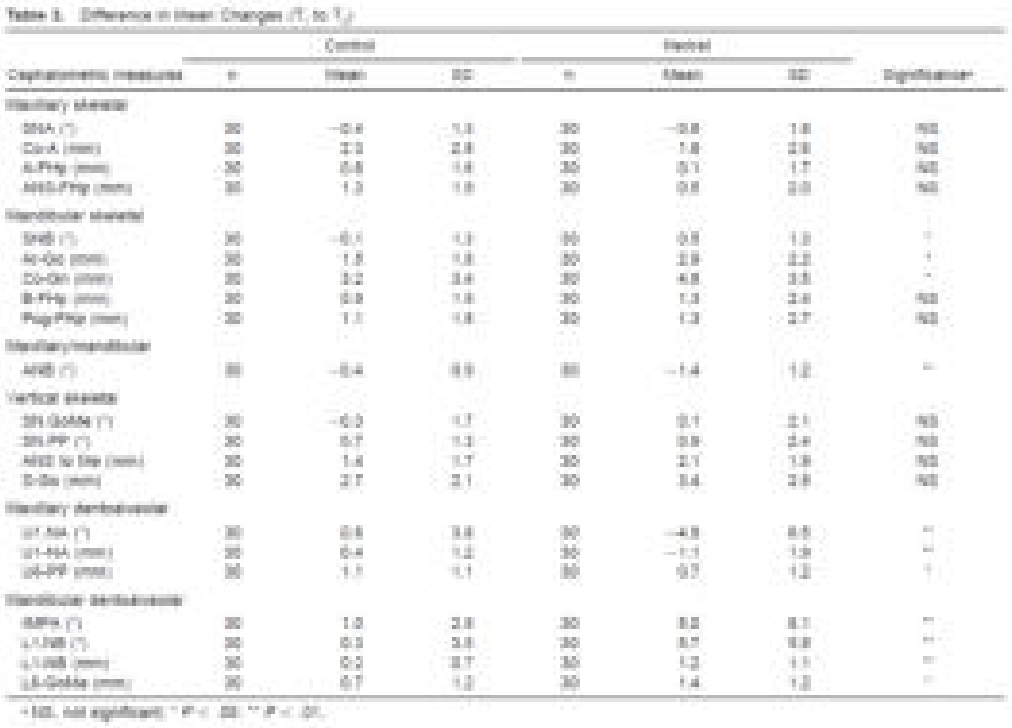
Based on research by Dr Almeida in partial fulfillment of the requirements for the Postdoctoral Program in Orthodontics, University of São Paulo, Bauru Dental School, Brazil.

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** Patients: Lins Dental School, Methodist University, Kontrolle: University of Sa˜o Paulo (Bauru)
Schweregrad	>= ½ Prämolarenbreite / >= 4,5° ANB
Einschluss-kriterien *Bei Review: PICOS*	• Class II division 1 malocclusion • Bilateral distal molar relationship greater than ½ cusp • Presence of mandibular deciduous second molars • ANB >= 4,5°
Ausschluss-kriterien	Keine Angaben

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** The patients were treated with a modified Herbst appliance with reinforcement wires soldered to bands on the maxillary permanent first molars and the primary mandibular first molars region (Figures 1 and 2). No brackets or other appliances were used during Herbst therapy. The construction bite was registered with them mandible protruded 5.0 mm in only one step VERSUCHSGRUPPE: **Herbst** N=40 (Anfang) / N=30 (Ende) / Alter = 9y10m / ♂:♀ = 15:15 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Behandlung** KONTROLLGRUPPE: **Kontrolle** N=30 (Anfang) / N=30 (Ende) / Alter = 9y8m / ♂:♀ = 15:15 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: *skelettale FRS-Parameter* SEKUNDÄRZIELGRÖßE: *dentale FRS-Parameter* 

Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	The effects produced by the Herbst appliance in this study were: 1. no statistically significant changes in forward growth of the maxilla; 2. a modest, but statistically significant increase in mandibular length. This increase was less than that observed in adolescent Herbst patients in other studies; 3. a significant improvement of the anteroposterior relationship between the maxillary and mandibular dentition; 4. no statistically significant increase in LAFH; 5. labial tipping and protrusion of the mandibular incisors as well as a lingual inclination and retrusion of the maxillary incisors; 6. a significant increase in mandibular posterior dentoalveolär height and a slight extrusion of the upper molars >> ACHTUNG: Bei Punkt 6 muss es “Intrusion der oberen Molaren“ heißen! → Fehler in der Schlussfolgerung seitens der Autoren
Zusammen-fassung der Ergebnisse	**GRUPPE Herbst VS. GRUPPE Kontrolle** ***PRIMÄRZIELGRÖßE*** *(skelettale FRS-Parameter)* *Skeletal. There were no statistically significant differences between the Herbst and control groups in maxillary skeletal measurements (Table 3). The maxillae of the Herbst patients grew downward and forward at the same rate as the control group. The effective mandibular length (Co-Gn) increased significantly more in the Herbst group as compared with the control group (P<.05). These greater increases in mandibular length also were evident in the significant increases in Ar-Go and the SNB angle (P< .05).* *Maxillary mandibular relationship. The ANB angle was reduced significantly more in the Herbst group than the control group (P< .01). The mandibular plane and the palatal plane were unaffected by treatment. No differences in lower anterior facial height (LAFH) and in posterior facial height were present.* ***SEKUNDÄRZIELGRÖßE (dentale FRS-Parameter)*** *Dentoalveolar. The maxillary incisors were retracted significantly relative to NA both in millimeter and angulation (P < .01). In addition, the Herbst appliance produced more inhibition of maxillary molar eruption relative to the palatal plane (P < .05). The mandibular incisors were retracted significantly relative to IMPA as well as to NB both in millimeter and angulation (P < .01). The Herbst patients also showed more mandibular molar eruption relative to the mandibular plane (P < .05).* ➔ ***ACHTUNG: hier Fehler im Paper: gemäß der Ergebnisse müsste es hier “Protrusion der UK-Front heißen”***

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: Kontrollgruppe (obwohl „historisch“) passt sehr gut zur Patientengruppe.* *Durchführung: Statistische Verfahren adäquat, allerdings keine genauen p-Werte zu den Tests angegeben.* *Auswertung: Keine verblindete Auswertung. Reliabilität wurde überprüft und zeigte gute Ergebnisse.* *Power der Studie/Patientenzahl: nicht durchgeführt* *Funding: keine Angabe* *Interessenkonflikte: Keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* - *Moderates Biasrisiko (da fehlende Verblindung)* *Ethik: keine Aussage zum Ethikvotum („historische Kontrollgruppe mit Röntgenbildern)*
Schluss-folgerung des Begutachters	methodische Qualität: gut
	Klinische Aussagekraft: gut Die vorliegende Studie überprüfte die Effekte einer Herbst-Apparatur im späten Wechselgebiss im Vergleich zu einer unbehandelten Kontrollgruppe. Diese Kontrollgruppe war zwar eine „historisch vorhandene Gruppe“, die allerdings in nahezu allen Belangen (Ausnahme einzelne FRS-Parameter) gut zur Patientengruppe passte und somit eine gute Vergleichbarkeit aufwies. Die Gruppengrößen von 30 Probanden je Gruppe erscheinen adäquat und es wurden geeignete statistische Verfahren angewendet. Der Aufbau des Manuskriptes und die Darstellung der Studie sind übersichtlich, weitestgehend detailliert und verständlich. Es konnten sowohl skelettale, sowie überwiegend auch dentoalveoläre Effekte durch die Anwendung des Herbst-Scharniers beobachtet werden.
Evidenz-level (SIGN)	**2++**
Qualität **(RoB, SIGN /AMSTAR II)**	**High quality (++)**

Evidenztabelle Almeida-Pedrin et al. 2007

Treatment effects of headgear biteplane and bionator appliances

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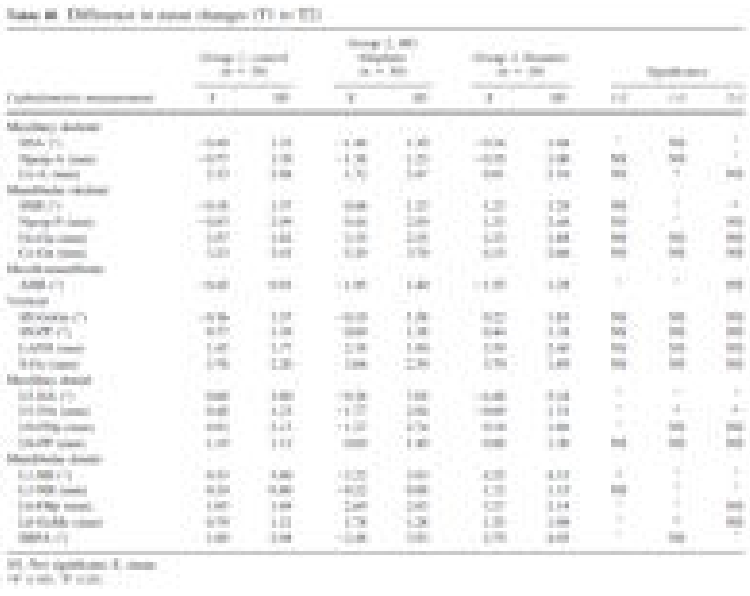
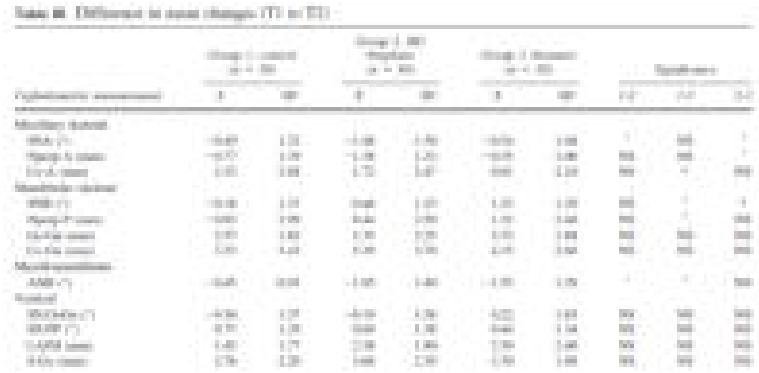
Introduction: The purpose of this investigation was to evaluate the dentoalveolar and skeletal cephalometric changes produced by headgear (HG) biteplane and bionator appliances in subjects with Class II Division 1 malocclusion. **Methods:** The sample comprised 60 patients with Class II Division 1 malocclusion: 30 (15 boys, 15 girls; mean age, 10.02 years) were treated with the HG biteplane for a mean period of 1.78 years, and 30 (15 boys, 15 girls; mean age, 10.35 years) were treated with a bionator for a mean period of 1.52 years. For comparison, a control group of 30 untreated Class II children (15 boys, 15 girls) with an initial mean age of 10.02 years, followed for 1.48 years, was established. Lateral cephalometric headfilms were obtained at the beginning and at the end of the treatment or observation period. **Results:** The results showed that forward growth of the maxilla was restricted in the HG biteplane group. Bionator treatment, however, produced a statistically significant increase in mandibular protrusion. Both appliances provided increases in total mandibular and ramus lengths. There were no statistically significant differences in craniofacial growth direction. The mandibular incisors were tipped labially with bionator treatment and lingually in the HG biteplane group. The maxillary incisors were retruded with both appliances; there also were a significant increase in mandibular posterior dentoalveolar height and a restriction in the vertical development of the maxillary molars. **Conclusions:** Class II treatment with HG biteplane and bionator appliances is efficient over the short term, with pronounced dentoalveolar movements and smaller but still significant skeletal effects. The stability of these results should be examined in a long-term study. (Am J Orthod Dentofacial Orthop 2007;132:191-8)

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** Skeletal and dental Class II malocclusion (Class-II-Division-1)
Schweregrad	bilateral distal molar relationships greater than one-half cusp and ANB angles >= 4.5°
Einschluss-kriterien *Bei Review: PICOS*	• bilateral distal molar relationships greater than one-half cusp • ANB angles >= 4.5°
Ausschluss-kriterien	Keine Angabe

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** *Keine genauen Angaben bezüglich der durchgeführten Interventionen* VERSUCHSGRUPPE: **HG** N=30 (Anfang) / N=30 (Ende) / Alter = 10,02 (8,2-11,0) Jahre / ♂:♀ = 15:15 • Gebissphase: späte Wechselgebissphase • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE: **Bionator** N=30 (Anfang) / N=30 (Ende) / Alter = 10,35 (8,2-11,0) Jahre / ♂:♀ = 15:15 • Gebissphase: späte Wechselgebissphase • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Kontrolle** VERSUCHSGRUPPE: **HG** N=30 (Anfang) / N=30 (Ende) / Alter = 10,02 (8,0-10,9) Jahre / ♂:♀ = 15:15 • Gebissphase: späte Wechselgebissphase • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis** PRIMÄRZIELGRÖßE: *skelettale FRS-Parameter* SEKUNDÄRZIELGRÖßE: *dentale FRS-Parameter* 
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	**CONCLUSIONS** Our results indicate that the skeletal and dental effects produced by HG biteplane and bionator appliances are as follows. 1. There was significant improvement of the antero-posterior relationship between the maxilla and the mandible with both therapies. 2. There were changes in forward growth of the maxilla only in the HG biteplane treatment group. 3. A statistically significant increase in mandibular protrusion was observed in patients treated with the bionator. 4. An increase in mandibular length was observed in the treated groups (an additional 0.92 mm [bionator] and 2.06 mm [HG biteplane] of mandibular length compared with control values) even though it was not statistically significant. 5. There were no statistically significant differences in craniofacial growth pattern or lower anterior and posterior facial heights among the groups. 6. The bionator produced labial tipping and linear protrusion of the mandibular incisors, whereas the incisors were retroclinated in the HG biteplane group. Both appliances produced lingual inclination and intrusion of the maxillary incisors compared with the controls. Horizontally, the first molars showed distal movement with HG biteplane treatment. In addition, there was significant extrusion of the mandibular molars and mesial movement in the treated groups.
Zusammen-fassung der Ergebnisse	**GRUPPE HG VS. GRUPPE Kontrolle** **GRUPPE Bionator VS. GRUPPE Kontrolle** ***PRIMÄRZIELGRÖßE***  ***SEKUNDÄRZIELGRÖßE*** 

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: Kontrollgruppe (obwohl „historisch“) passt sehr gut zur Patientengruppe.* *Durchführung: Statistische Verfahren adäquat – Normalverteilung wurde gezielt geprüft und die Auswertung mittels ANOVA mit post-hoc Analyse durchgeführt - allerdings keine genauen p-Werte zu den Tests angegeben.* *Auswertung: Keine verblindete Auswertung. Reliabilität wurde überprüft und zeigte gute Ergebnisse.* *Power der Studie/Patientenzahl: nicht durchgeführt* *Funding: keine Angabe* *Interessenkonflikte: Keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* - *Moderates Biasrisiko (da fehlende Verblindung), allerdings wurden die insgesamt 60 Patienten zufällig in die subgruppen „HG“ und „Bionator“ von einem Untersucher zugeteilt.* *Ethik: keine Aussage zum Ethikvotum („historische Kontrollgruppe mit Röntgenbildern)*
Schluss-folgerung des Begutachters	methodische Qualität: gut Klinische Aussagekraft: gut Die vorliegende Studie überprüfte die Effekte sowohl eines HG, sowie eines Bionators im Vergleich zu einer unbehandelten Kontrollgruppe. Diese Kontrollgruppe war zwar eine „historisch vorhandene Gruppe“, die allerdings in nahezu allen Belangen (Ausnahme einzelne FRS-Parameter) gut zur Patientengruppe passte und somit eine gute Vergleichbarkeit aufwies. Die Gruppengrößen von 30 Probanden je Gruppe erscheinen adäquat und es wurden geeignete statistische Verfahren angewendet. Der Aufbau des Manuskriptes und die Darstellung der Studie ist übersichtlich und verständlich. Allerdings geben die Autoren keine detaillierten Informationen zum Therapieablauf. Es konnten sowohl skelettale, sowie dentoalveoläre Effekte durch die Anwendung sowohl des HG als auch des Bionators beobachtet werden.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable (+)**

Evidenztabelle Altug-Atac, Erdem 2007

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Effects of three-dimensional bimetric maxillary distalizing arches and cervical headgear on dentofacial structures

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SUMMARY The aim of this study was to compare the dentofacial effects of an intraoral technique, the three-dimensional bimetric maxillary distalizing arch (3D-BMDA), with an extraoral technique, cervical headgear (CH), in subjects requiring maxillary molar distalization. Twenty-one patients (12 females, 9 males; mean age at the start of treatment: 14.7 years) were treated with 3D-BMDA and 18 subjects (11 females, 7 males; mean age at the start of treatment: 13.3 years) with CH. Since the treatment period was longer in the CH group, the results for this group were also compared with a separate 'untreated' control group of 17 subjects (12 females, 5 males; mean age at the start of observation: 13.1 years). The measurements were carried out on lateral cephalometric radiographs which were taken at two time points (T_1: start of treatment/control, T_2: end of molar distalization/control). Paired *t*-tests were performed within, and analysis of variance to determine the differences between the groups.

The total amount of distalization for the 3D-BMDA and CH was similar (3.55 and 4.56 mm, respectively). However, there were statistically significant differences in the total treatment period (3.4 and 10.2 months, respectively) and the monthly amount of distalization (1.11 and 0.55 mm, respectively). The 3D-BMDA system did not have a significant effect on mandibular rotation (an increase of 0.01 degrees), while the CH group showed a mean posterior rotation of the mandible of 1.08 degrees. The most significant differences between the two maxillary first molar distalization techniques were observed in the mandibular dental arches. Moderate anchorage loss in the mandibular dental arch was observed in the 3D-BMDA group. While the 3D-BMDA and CH techniques are both effective in distalizing maxillary molar teeth, the distalization time and rate of molar movement were significantly shorter with the 3D-BMDA than the CH.

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Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Department of Orthodontics of Ankara University, Turkey
Schweregrad	Keine Angabe
Einschluss-kriterien *Bei Review: PICOS*	1. A skeletal Class I or Class II malocclusion and a dental Class II relationship on both sides; 2. A non-extraction treatment plan; 3. SN/GoGn angle less than 40 degrees; 4. No or minimum crowding in the mandibular dental arch; 5. Erupted maxillary second molars in occlusion.

Ausschluss-kriterien	SN/GoGn < 40°
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** In the CH group, only the maxillary first molars were banded and no other orthodontic intervention was performed. The headgear was adjusted to exert a force of 450 – 600 g and the long outer bows were not angulated. The distalization period for the CH was 10.2 months. The patients were asked to wear their headgear daily for a period of 14 – 18 hours until a Class I molar relationship was achieved. VERSUCHSGRUPPE: **CH (cervical Headgear)** N=25 (Anfang) / N=18 (Ende) / Alter = 13,34 ± 1,47 Jahre / ♂:♀ = 7:11 • Gebissphase: spätes Wechselgebiss/bleibendes Gebiss (vermutet anhand Alter) • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** ‘untreated ’ subjects selected from the archives of the department using the same inclusion criteria as the treatment groups. Hand-wrist radiographs showed that the subjects in the control group had the same growth potential as the CH group. KONTROLLGRUPPE: **unbehandelte Kontrollgruppe** N=17 (Anfang) / N=17 (Ende) / Alter = 13,13 ± 1,68 Jahre / ♂:♀ = 5:12 • Gebissphase: spätes Wechselgebiss/bleibendes Gebiss (vermutet anhand Alter) • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Okklusion, Kaufunktion, Funktion PRIMÄRZIELGRÖßE: Dentoalveolar and skeletal changes Zeitpunkte der Datenerhebung: T1: at the start of treatment/control T2: after molar distalization was complete/end of control (nach 10,2 Monaten bei Versuchs-, nach 12,5 Monaten bei Kontrollgruppe)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. (…) and CH techniques are both effective in distalizing the maxillary molars. 2. A Class I relationship was achieved purely by maxillary molar distalization in the CH group (…) 3. To achieve successful results with either of these techniques, the effects of each treatment modality on dentofacial structures need to be taken into consideration for each individual patient.

Zusammen-fassung der Ergebnisse	**GRUPPE CH (cervical Headgear)-Gruppe VS. GRUPPEunbehandelte Kontrollgruppe** PRIMÄRZIELGRÖßE: Dentoalveolar and skeletal changes The differences between the groups are shown in Tables 3 and 4. Analysis of variance was used to determine the exact changes in the CH group (Table 5). <u>Dentoalveolar changes:</u> CH distalized the maxillary first molars (mean 3.54 ± 0.71 mm), but in the control group, mesial movement of the same teeth occurred (mean 0.88 ± 0.48 mm). Similarly, the second molars moved distally (mean 3.37 ± 0.59 mm) in the CH group and mesially (mean 0.97 ± 0.44 mm) in the control group. In the CH group, the first and second maxillary molars tipped distally (mean 6.16 ± 1.48, 6.97 ± 1.87 degrees, respectively) from T 1 to T 2 , which was statistically significant. In the control group, the first molars remained relatively stable, whereas the second molars tipped slightly in a mesial direction. The monthly changes for the maxillary first molars in the CH group showed a significant distal displacement (mean 0.45 ± 0.09 mm/month) while in the control group these teeth moved mesially (mean 0.08 ± 0.04 mm/month). While the maxillary molars moved distally in the CH group, the mandibular incisors and molars also moved significantly in a distal direction (mean − 0.75 ± 0.39, − 0.32 ± 027 mm, respectively). On the other hand, in the control group, the mandibular dentition moved mesially. The mandibular incisors tipped distally in the CH group, whereas they tipped slightly mesially in the control subjects. In addition, the decrease in overbite was greater in the CH group when compared with the control group. <u>Skeletal changes:</u> In the CH group, ANB showed a statistically significant decrease (mean 0.82 ± 0.24 degrees), but remained relatively stable in the control group. SN/GoGn angle increased in the CH subjects (mean 0.48 ± 0.28 degrees), while it decreased in the control group (mean − 0.49 ± 0.35 degrees). In addition, Co – Go increased significantly in the control group (mean 3.27 ± 0.39 mm), when compared with the CH group (mean 1.94 ± 0.26 mm).
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung <u>Funding</u> <u>Interessen-konflikte</u> <u>Bias</u> (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* ➢ Ethikvotum?: s. Handröntgen in Versuchs- und Kontrollgruppe bei T1 und T2 *Durchführung: -* *Auswertung:* ➢ T-Tests verwendet ohne Angabe, ob Normalverteilung (kleine Fallzahl) geprüft wurde ➢ PP-Analyse ohne Angabe der Daten vor Dropout in der Versuchsgruppe-Gruppe ➢ Keine Angabe der einzelnen p-Werte ➢ FRS-Auswertung erfolgte nur durch eine Person; zur Reliabilitätssteigerung wurden 35 zufällig ausgewählte FRS von derselben Person 1 Monat später erneut ausgewertet und der Reliabilitätskoeffizient bestimmt *Power der Studie/Patientenzahl:* keine Poweranalyse angegeben *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe

	Bias (SIGN): • Baseline-Imbalancen zwischen/innerhalb HG- und Kontrollgruppe: ▪ Unsicher, ob Versuchs- und Kontrollgruppe wirklich vergleichbar (“could be considered close”, “were closely matched” S.57) ▪ Keine genaue Angabe, wie Zuteilung in Versuchs-Gruppe erfolgte • attrition bias: In der Versuchs-Gruppe wurden 7 Patienten ausgeschlossen, die den HG nicht korrekt getragen haben • detection bias: The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable. – NO (SIGN)
Schluss-folgerung des Begutachters	<u>methodische Qualität:</u> insgesamt akzeptabel
	<u>Klinische Aussagekraft:</u> Dentoalveoläre Effekte: ➢ Die Anwendung des zervikalen HG führt zu einer Distalisation und Distalkippung von OK6/OK7 und zu einer simultanen Distalbewegung der UK-Front und UK-Molaren, während eine Nichtbehandlung mit einer Mesialisation der OK- und UK-Dentition einhergeht. ➢ Bei Anwendung des zervikalen HG kann der Overbite im Vergleich zur Nichtbehandlung stärker reduziert werden. Skelettale Effekte: ➢ Die Anwendung des zervikalen HG führt zu einer Abnahme des ANB und Zunahme des SN/GoGn (verstärkte Vertikalentwicklung des UK), wohingegen eine Nichtbehandlung zu einer Vergrößerung der Ramuslänge (Co-Go) führt (impliziert verstärkte Horizontalentwicklung des UK)
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable (+)**

Evidenztabelle Angelieri, Franchi et al. 2014

Long-term treatment effects of the FR-2 appliance: a prospective evalution 7 years post-treatment

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SUMMARY

AIM To examine the long-term effects induced by treatment with the function regulator (FR-2) appliance 7 years post-treatment compared with untreated class II subjects.

SUBJECTS AND METHODS The FR-2 sample was collected prospectively and comprised 17 subjects (10 boys and 7 girls, mean age 10.8 years) who were treated with the FR-2 appliance for 1.7 years and re-evaluated 7.1 years after treatment. The step-by-step mandibular advancement was performed gradually (increments up to 3–4 mm), until a 'super class I' molar relationship was obtained. The control group consisted of 17 class II subjects (9 boys and 8 girls, mean age 11.3 years) with class II malocclusion, excessive overjet, and class II molar relationship, matched to the treated group as to ages at all times, gender distribution, and stages of skeletal maturity (evaluated by the cervical vertebral maturation method). The lateral cephalograms were analysed at T1 (initial), T2 (final), and T3 (7.1 years post-treatment). The compatibility between the groups and the comparisons of their changes at T1–T2, T2–T3, and T1–T3 intervals were examined by independent sample *t*-tests ($P < 0.05$).

RESULTS FR-2 treatment provided a significant improvement in the maxillomandibular relationship due to an increase in mandibular length compared with controls, which remained stable over time. Also overjet, overbite, and molar relationship corrections demonstrated stability. Among dentoalveolar changes, only the increased mesial movement of the mandibular molars in the FR-2 group demonstrated stability.

CONCLUSIONS Correction of class II malocclusion remained stable 7 years after FR-2 treatment mainly due to the stability of the skeletal changes.

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** **Versuchsgruppe FR2-Group**: The FR-2 sample was collected prospectively and was comprised 17 Caucasian patients (7 girls and 10 boys) in the mixed dentition with a class II division 1 malocclusion. **Kontrollgruppe Untreated Control Group**: The cephalograms of the untreated subjects were obtained from the University of Michigan Growth Study and the Denver Child Growth Study.
Schweregrad	ANB (°); Overjet (mm); Okklusion ***FR2-Group:*** Eleven of them had fullcusp class II molar relationships and six had an end-to-end molar relationship. Each late mixed dentition patient was characterized by clinically mandibular skeletal retrusion, distal step, and excessive overjet (at least 5 mm). All patients had a skeletal class II malocclusion (ANB angle > 2 degrees) which defines the maxillomandibular relationship. ***Untreated Control Group:*** The untreated group consisted of 17 late mixed dentition subjects (8 girls and 9 boys) with skeletal class II malocclusion (ANB angle > 2 degrees), excessive overjet, and class II molar relationship (at least cusp-to-cusp molar relationship).

Einschluss-kriterien *Bei Review: PICOS*	***FR2-Group:*** The FR-2 sample was collected prospectively and was comprised 17 Caucasian patients (7 girls and 10 boys) in the mixed dentition with a class II division 1 malocclusion. Eleven of them had fullcusp class II molar relationships and six had an end-to-end molar relationship. Each late mixed dentition patient was characterized by clinically mandibular skeletal retrusion, distal step, and excessive overjet (at least 5 mm). All patients had a skeletal class II malocclusion (ANB angle > 2 degrees) which defines the maxillomandibular relationship. The mean age at the onset of treatment was 10.8 years, and the stages of skeletal maturity were either pre-pubertal or pubertal (Table 1). ***Untreated Control Group:*** The untreated group consisted of 17 late mixed dentition subjects (8 girls and 9 boys) with skeletal class II malocclusion (ANB angle > 2 degrees), excessive overjet, and class II molar relationship (at least cusp-to-cusp molar relationship).
Ausschluss-kriterien	Keine Angaben
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** The FR-2 appliances were fabricated according to Fränkel’s (1974) and McNamara and Huge’s (1981) principles. The step-by-step mandibular advancement was performed gradually with increments up to 3–4 mm (Cevidanes *et al.*, 2003), executed with a mean interval of 6 months, until a ‘super class I’ molar relationship was obtained. The FR-2 appliance was worn full-time (except at mealtimes and for oral hygiene) for 1.7 years and then only at night for 6 additional months. Patient compliance was adequate, as monitored by a home daily journal of hours of appliance wear. At the end of treatment, all patients had a class I molar relationship. VERSUCHSGRUPPE: **FR2 Group** N=17 (Anfang) / N=17 (Ende) / Alter = 10,8 ± 0,6 Jahre / ♂:♀ = 10:7 • Gebissphase: spätes Wechselgebiss (late mixed dentition) • KFO-Behandlung: reguläre Behandlung (anhand Alter)
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Behandlung** **KONTROLLGRUPPE: Untreated Control Group** N= 17 (Anfang) / N= 17 (Ende) / Alter = 11,3 ± 0,6 Jahre / ♂:♀ = 9:8 • Gebissphase: spätes Wechselgebiss (late mixed dentition) • KFO-Behandlung: Keine Therapie
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** • **Stabilität des Behandlungsergebnisses** PRIMÄRZIELGRÖßE: Long-term cephalometric effects (siehe Tabelle 2-4)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	The correction of class II malocclusion by the FR-2 appliance occurred mainly by the improvement of the maxillomandibular relationship due to the increase in mandibular length, with the stability of these changes observed over 7 years post-treatment. The dentoalveolar changes demonstrated lesser stability over time, with the exception of the greater mesial movement of the mandibular molars in the FR-2 patients than controls.

Zusammen-fassung der Ergebnisse	**GRUPPE FR2-Group VS. GRUPPE Untreated Control Group** *Analysis of treatment effects* The FR-2 treatment (T1–T2) produced an improvement of the maxillomandibular relationship, as shown by the ANB angle (−1.0 degree), Wits (−2.9 mm), and Mx/Md difference (2.4 mm) in comparison with control values (Table 2). The FR-2 group exhibited significantly greater increments in mandibular length (5.1 mm) in comparison with controls (3.2 mm), a difference that was statistically different. There was no significant difference in vertical skeletal relationships between the FR-2 and control groups. The dental relationships in the FR-2 group improved in comparison with controls. Overjet and overbite decreased significantly (−3.2 and −2.3 mm, respectively), whereas molar relationship increased significantly in the FR-2 group (4.4 mm). Moreover, the FR-2 appliance produced significant dentoalveolar effects represented by retroclination and retrusion of the maxillary incisors (−3.3 degrees and −1.2 mm, respectively), absence of the natural forward movement of the maxillary first molars (0.1 mm in the FR-2 group versus 1.3 mm in the control sample), and mesial movement and extrusion of the mandibular first molars (1.3 and 0.7 mm, respectively). *Post-treatment changes* The changes between the FR-2 and control groups in the post-treatment period (T2–T3) were small (Table 3). In the FR-2 group, there was a significant upward rotation of the palatal plane (FH-Palatal Pl. −1.6 degrees). The FR-2 patients demonstrated significantly greater protrusion and extrusion of the maxillary incisors (1.2 and 1.1 mm, respectively) and extrusion of the maxillary first molars (1.3 mm) compared with the control group. *Overall evaluation* In the overall evaluation (T1–T3; Table 4), there was stability in the correction of the maxillomandibular relationship (ANB −1.3 degrees, Wits −2.6 mm, and Mx/Md differential 3.3 mm), increase in total mandibular length (3.7 mm), and in the correction of overjet (−3.4 mm), overbite (−2.2 mm), and molar relationship (4.0 mm). The significant upward rotation of the palatal plane that occurred in the FR-2 group during T2–T3 interval was recorded also during the T1–T3 interval (−1.7 degrees). Among the dentoalveolar changes, only the increased mesial movement of the mandibular molars in the FR-2 group showed stability (1.7 mm). A significant extrusion of the maxillary incisors (1.1 mm) and a mesial movement of mandibular incisors (1.0 mm) also were recorded in the FR-2 group with respect to the control sample.
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *Prospektiv* • *Kontrollgruppe historisch (aber gut begründet:* Although historical control groups may present with limitations (Pandis, 2012), in the current study, the use of historical controls was necessary due to the lack of ethical rational to leave class II patients untreated during a longterm observation interval.) • *Ethikvotum* • *Viel Mühe auf Matching der Gruppen (z.B. Alter, Geschlecht)* *aber trotzdem statistisch signifikante Unterschiede bei zwei FRS-Werten (FR2 Gruppe vertikaler, labialere OK-Front)* • *keine Angaben zur Rekrutierung der Patienten (wo, wie viele)* *Durchführung:* • *ein Behandler, ein Techniker* • *ein Auswerter der FRS-Daten, zumindest Überprüfung durch zweiten Auswerter* • *keine Verblindung* • *Compliance-Überprüfung nur durch subjektives „Trage-Tagebuch“ (worn full-time fraglich?)*

	Auswertung: • *Keine ICC für Intra-Rater-Reliabilität gerechnet* • *Keine Angabe zu Konfidenzintervallen* • *Solide Statistik (Tests auf Normalverteilung vorhanden, Kolmogorov-Smirnov-Test; t-Test, chi-square-test)* *Power der Studie/Patientenzahl: Poweranalyse vorhanden* *Funding: This work was funded by São Paulo Research Foundation, Brazil.* *Interessenkonflikte: keine Angaben* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* *Siehe oben* • *Ggf. selection Bias durch Gruppen-Imbalancen* • *Detection bias (keine ICC, keine Verblindung bei FRS-Auswertung)* The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable. – NO (SIGN) • The study indicates how many of the people asked to take part did so, in each of the groups being studied. – NO (SIGN) • The main potential confounders are identified and taken into account in the design and analysis.- NO (SIGN) • Have confidence intervals been provided? – NO (SIGN)
Schluss-folgerung des Begutachters	<u>methodische Qualität:</u> sehr gut
	<u>Klinische Aussagekraft:</u> • Korrektur der Klasse-II-Anomalie mittels FR 2 durch Verbesserung der Kieferrelation durch Zunahme der UK-Länge • Stabilität des Behandlungsergebnisses nach 7 Jahren post-treatment v.a. durch Stabilität der skelettalen Parameter • Dento-alveoläre Effekte weniger langzeit-stabil außer Mesialwanderung der UK-Molaren
Evidenz-level (SIGN)	**2++**
Qualität (RoB, SIGN /AMSTAR II)	⊕⊕ High Quality

Evidenztabelle Atik, Görüncü-Coskuner 2017

Dentoskeletal and airway effects of the X-Bow appliance versus removable functional appliances (Frankel-2 and Trainer) in prepubertal Class II division 1 malocclusion patients

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Objectives: The aim of the present study was to evaluate the dentoskeletal and airway effects of three different functional appliances (Frankel-2, Trainer and X-Bow) in prepubertal Class II division 1 patients.
Methods: The sample consisted of 54 patients with a Class II relationship as a result of mandibular retrognathia and relative maxillary constriction. Group I included 13 patients treated with a Frankel-2 appliance. Group II consisted of 14 patients treated with a bite-block Trainer. Group III consisted of 13 patients treated with the X-Bow appliance. Group IV consisted of 10 untreated Class II patients who served as a control group. Pretreatment (T1) and posttreatment (T2) cephalograms were used to evaluate dentoskeletal and airway changes. Parametric one-way variance analysis (ANOVA) and a paired t test were used to perform statistical analysis.
Results: The decrease in SNA angle was significant in groups I and III, compared with the control group ($p < 0.05$). SNB angle and Co-Gn length changes from T1 to T2 were statistically significant in groups I and III ($p < 0.05$), but not relative to the control group. The upper and lower incisors were significantly retruded and protruded, respectively, in all treatment groups ($p < 0.05$). Except PNS-ANS and MAS measurements in group I, nasopharyngeal and oropharyngeal airway dimensions did not significantly change from T1 to T2 in all groups.
Conclusions: The Frankel-2 and X-Bow appliances were efficient in restricting the forward growth of the maxilla. The Frankel-2 and Trainer appliances produced a larger sagittal increase in mandibular length than the X-Bow appliance. Lower incisor proclination was more pronounced in the X-Bow group. The effect of the treatment protocols was similar and matched the control group with respect to the airway.
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Introduction

A Class II malocclusion originating from mandibular retrognathia may be treated by the use of functional appliances in an attempt to stimulate mandibular growth.[1] In company with the mandibular retrognathia, a constriction of the maxillary arch is encountered involving significantly reduced intercanine and intermolar widths.[2-4] Clinicians may therefore choose a functional appliance that offers maxillary expansion as one of its effects. Correspondingly, a popular removable functional appliance to manage mandibular deficiency and maxillary constriction is the functional regulator (FR-2).[5] A trainer is also claimed to correct a skeletal Class II malocclusion by providing a mandibular protrusive force.[6] The Frankel and Trainer appliances are also considered to produce transverse maxillary expansion by including buccal 'shields', which induce muscle relaxation of the dental arches.[7,8]

Besides removable functional appliances such as the

Population *Setting* *Komorbiditäten*	Klasse-II-Anomalie
Schweregrad	Siehe Einschlusskriterien
Einschluss-kriterien *Bei Review: PICOS*	• a skeletal Class II division 1 malocclusion with mandibular retrognathia (SNB<78°) and relative maxillary constriction • early or late mixed dentition period • prepubertal growth stage • overjet ≥ 4 mm • bilateral Class II or end-to-end molar and canine relationships • age at the start of treatment between 8 and 12 years, • no congenital craniofacial deformities
Ausschluss-kriterien	---
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** VERSUCHSGRUPPE 1: **Group I (Fränkel-2)** N=15 (Anfang) / N=15 (Ende) / Alter = 8.94 ± 1.28 Jahre / ♂:♀ = 4:11 • Gebissphase: frühes/spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung • Intervention: Treated with a Frankel-2 functional regulator appliance. A single-step mandibular advancement was conducted to an edge-to-edge incisor relationship with 2–3 mm of bite opening during wax-bite registration. The patients were instructed to wear the appliance full time (24 h/day) except for eating and oral hygiene measures. The patients were reviewed once every four weeks, and treatment was discontinued when the overjet and the overbite were reduced to 1–2 mm. VERSUCHSGRUPPE 2: **Group II (Trainer)** N=14 (Anfang) / N=14 (Ende) / Alter = 8.79 ± 0.72 Jahre / ♂:♀ = 8:6 • Gebissphase: frühes/spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung • Intervention: Treated with a preorthodontic T4-K (Myofunctional Research Co., QLD, Australia) Trainer. The patients were instructed to wear the appliance every day for three hours and overnight in accordance with the manufacturer’s instructions. The patients were reviewed every six weeks until the overjet and the overbite were reduced to 1–2 mm.

	VERSUCHSGRUPPE 3: **Group III (X-Bow)** N=15 (Anfang) / N=15 (Ende) / Alter = 10.58 ± 1.27 Jahre / ♂:♀ = 6:9 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung Intervention: Treated with the X-Bow appliance. The maxilla was expanded with a Hyrax screw attached to bands cemented on the first premolars and molars. The expander was part of the X-Bow fixed Class II corrector. After the maxillary expansion was achieved, a lower 1.10 millimetre round stainless steel anchorage arch and Guerin locks (3M Unitek large size) were placed, and 3M Unitek Forsus Fatigue-Resistant Device (FRD) with springs was inserted bilaterally and adjusted to supply 200 gm of force. The springs were reactivated every six weeks until the maxillary molars were in an overcorrected half-cusp Class III relationship. The springs were reactivated every six weeks until the maxillary molars were in an overcorrected half-cusp Class III relationship.
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Behandlung** KONTROLLGRUPPE: **Group IV (Control)** N=10 (Anfang) / N=10 (Ende) / Alter = 9.27 ± 0.89 Jahre / ♂:♀ = 6:4 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: ---
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie Subkategorie** - primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) - Atmung und Luftraum (Airway space, Schlafapnoe), Schlucken und Sprechen PRIMÄRZIELGRÖßE: *Skelettal Cephalometric measurements (SNA, Maxillary depth, SNB, Facial depth, CO-Gn, ANB, Overjet, Overbite, GoGnSN)* SEKUNDÄRZIELGRÖßE: *Dental Cephalometric measurements (U1-FH, U1-NA, U1-PTV, U1-FH, U6-PTV, IMPA, L1-NB, L1-PTV, L1-MP, L6-PTV, L6-MP)* TERTIÄRZIELGRÖßE: *Cephalometric measurements of the upper airway (PNS-AD2, PND-AD1, SPAS, MAS, IAS, Ba-PNS)*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	1. Removable and fixed functional appliance treatment was effective in significantly reducing the ANB angle, overjet and improving molar relationships. These results were considered to be clinically significant. 2. None of the appliances produced a significant increase in sagittal mandibular position change compared with the control group. 3. The Frankel-2 and Trainer appliances had a larger sagittal increase in total mandibular length compared with the X-Bow appliance. 4. The headgear effect of the functional appliances was significant in the Frankel-2 and X-Bow groups. 5. The most significant difference in the dentoalveolar effects in the treatment groups was the proclination of the mandibular incisors, which was greatest in the X-Bow group. 6. The maxillary incisors showed a significantly greater amount of retroclination in the Frankel-2 and Trainer groups compared with the X-Bow group. 7. Except for a significant increase in the PNS-AD2 and MAS measurements from the pretreatment to the post-treatment period in the Frankel group, the treatment protocols did not significantly differ from each other and the control group with respect to nasopharyngeal and oropharyngeal airway changes.
Zusammen-fassung der Ergebnisse	**Group I (Fränkel-2) vs. Group IV (Untreated Control Group)** **Group II (Trainer) vs. Group IV (Untreated Control Group)** **Group III (X-Bow) vs. Group IV (Untreated Control Group)** ***PRIMÄRZIELGRÖßE*** *Skelettal measurements* ***SEKUNDÄRZIELGRÖßE*** *Dental Cephalometric measurements* ***TERTIÄRZIELGRÖßE*** *Cephalometric measurements of the upper airway* The mandibular sagittal positional change related to the SNB angle and Co-GN measurements from T1 to T2 period was significant in groups I, II and IV (Table II, $p < 0.05$). The increase in Co-GN measurement was significantly greater in groups I (3.95 mm), II (3.41 mm) and IV (4.54 mm) than in group III (0.53 mm) (Table III, $p < 0.05$). Changes in the overbite and GoGn-SN measurements were not significant, and no differences were found in these changes between the groups (Tables II and III, $p < 0.05$). The upper incisors were significantly retruded, and the lower incisors were significantly protruded in all groups except the control group (Table IV, $p < 0.05$). The U1–FH and U1–NA angles showed a significant decrease in all treatment groups compared with the control group (Table III, $p < 0.05$). Changes in the lower incisor inclination were significantly different from each other between groups I and IV and III and IV (Table III, $p < 0.05$). U1–FH and L1–MP measurement changes significantly differed between groups I and IV and II and IV for U1–FH and between groups III and IV for L1–MP (Table III, $p < 0.05$). Except for the PNS-AD2 and MAS measurements, which increased significantly in group I, the nasopharyngeal (PNS-AD1, PNS-AD2 and Ba-PNS) and oropharyngeal airway dimensions (SPAS, MAS and IAS) did not significantly change from the T1 to T2 period in all groups (Table V, $p > 0.05$). Intergroup comparisons indicated that the changes in the airway dimensions did not differ between the groups (Table III, $p < 0.05$).

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *Eigene Kontrollgruppe* • *Kein suffizientes Matching* • *Retrospektiv* *Durchführung:* • *Keine Verblindung* • *Mehrere Behandler* *Auswertung:* • *Keine Reliabilitätstests* *Power der Studie/Patientenzahl: keine Poweranayse* *Funding: keine Angaben* *Interessenkonflikte: keine Angaben* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • *Selection Bias:* ○ *Eingeschränkte Vergleichbarkeit zwischen den Gruppen* ○ *Keine Aussage zur Teilnehmerrate* • *Performance Bias:* ○ *Keine Aussage zu Dropouts* • *Detection Bias* ○ *Keine Verblindung erfolgt* ○ *Fragliche Reliabilität der Behandlungsmethode* ○ *Keine Reliablitätsprüfung der Outcome-Erhebung* • *Keine Confounders erhoben* • *Keine Konfidenzintervalle angegeben*
Schluss-folgerung des Begutachters	methodische Qualität: befriedigend
	Klinische Aussagekraft: - Keine der Apparaturen führten zu einer signifikanten Verbesserung der sagittalen Unterkieferposition im Vergleich zur Kontrollgruppe - Herausnehmbare und festsitzende funktionskieferorthopädische Behandlungsmethoden zeigten signifikante Effektiviät bei Verringerung des ANBs, Overjets und bei der Verbesserung der Molarenrelation.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	⊕ Acceptable

Evidenztabelle Baccetti, De Clerck HJ et al. 2011

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Morphometric analysis of treatment effects of bone-anchored maxillary protraction in growing Class III patients

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SUMMARY The aim of the present morphometric investigation was to evaluate the effects of bone-anchored maxillary protraction (BAMP) in the treatment of growing patients with Class III malocclusion. The shape and size changes in the craniofacial configuration of a sample of 26 children with Class III malocclusions consecutively treated with the BAMP protocol were compared with a matched sample of 15 children with untreated Class III malocclusions. All subjects in the two groups were at a prepubertal stage of skeletal development at time of first observation. Average duration of treatment was 14 months. Significant treatment-induced modifications involved both the maxilla and the mandible. The most evident deformation consisted of marked forward displacement of the maxillary complex with more moderate favourable effects in the mandible. Deformations in the vertical dimension were not detected. The significant deformations were associated with significant differences in size in the group treated with the BAMP protocol.

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** Growing patients (mixed or permanent dentitions)with skeletal Class III with anterior crossbite • Italy
Schweregrad	Wits appraisal of −1 mm or less
Einschluss-kriterien	- Class III malocclusion in the mixed or permanent dentitions characterized by: - Wits appraisal of −1 mm or less (mean: −4.8 ± 2.8 mm), - anterior crossbite, or incisor end-to-end relationship and Class III molar relationship.
Ausschluss-kriterien	Not fullfilling inclusion criteria

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **BAMP** (bone-anchored maxillary protraction): In each treated patient, four miniplates were inserted on the left and right infrazygomatic crest of the maxillary buttress and between the lower left and right lateral incisor and canine (Figure 1). Small mucoperiosteal flaps were elevated and the modified miniplates (Bollard; Tita-Link, Brussels, Belgium) were secured to the bone by two (mandible) or three (maxilla) screws. Three weeks after surgery, the miniplates were loaded. Class III elastics applied an initial force of about 150 g on each side, increased to 200 g after 1 month of traction and to 250 g after 3 months. The patients were asked to replace the elastics at least once a day and to wear those 24 hours/day. In 14 cases after 2–3 months of intermaxillary traction, a removable bite plate was inserted in the upper arch to eliminate occlusal interference in the incisor region until correction of the anterior crossbite was obtained VERSUCHSGRUPPE 1: **BAMP** N= 26 (Anfang) / N=26 (Ende) / Alter = 11,9, 1,8 ♂:♀ = 12:14 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: untreated **Class III** N=15 (Anfang) / N=15 (Ende) / Alter = 9,6, 1,6 ♂:♀ = 8:7 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • dentofaziale Ästhetik PRIMÄRZIELGRÖßE: Skeletal: Morphometric Analyses, Thin plate splines (TPS)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	- TPS analysis allowed an appraisal of deformations in the craniofacial structures induced by BAMP independently from size changes. T - he morphometric evaluation of the therapeutical effects of the BAMP protocol in Class III growing patients revealed significant favourable deformations of both the maxillary and the mandibular structures that were associated with dimensional differences induced by treatment. - No appreciable vertical deformation was associated with treatment. The maxillary effects were particularly pronounced.

Zusammen-fassung der Ergebnisse	**GRUPPE BAMP VS. untreated Class III** T1 (pre-treatment): mean age 11,9 years, BAMP; 9,6 years, untreated Class III T2 (post treatment/ observation): mean age 13,1 years; BAMP, 11,4 years untreated Class III Morphometric Analyses, Thin plate splines (TPS) The analysis of the longitudinal deformations of the craniofacial structures in the treated and control Class III samples showed significant T1–T2 differences in the BAMP group ($P = 0.011$), while T1–T2 deformations in the controls did not reach statistical significance ($P = 0.88$) These significant deformations of the BAMP sample as well as the insignificant shape modifications in the controls were associated with significant differences in centroid size differences for both samples ($P < 0.05$). Allometry was significant for the BAMP sample ($F = 3.36$; $P < 0.01$), thus indicating dependence of size differences on shape differences in the treated group.
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die eigene Überprüfung der Äquivalenz von Versuch- und Kontrollgruppe ist aufgrund fehlender Daten nicht möglich. Es fand keine Verblindung statt. Eine Power/ Sample size Berechnung wurde nicht durchgeführt. Insgesamt aber akzeptabel durchgeführte Studie, die aufgrund des ungewöhnlichen Outcomes (TPS Morphometrie) möglicherweise eingeschränkte Vergleichbarkeit und daher eingeschränkte klinische Relevanz besitzt *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist nicht überprüfbar. Eine Power/ Sample size Berechnung wurde nicht durchgeführt.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Insgesamt aber akzeptabel durchgeführte Studie, die aufgrund des ungewöhnlichen Outcomes (TPS Morphometrie) möglicherweise eingeschränkte Vergleichbarkeit und daher eingeschränkte klinische Relevanz besitzt
Evidenzlevel (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Baccetti et al. 2001

Original Article

Treatment Timing for Rapid Maxillary Expansion

Tiziano Baccetti, DDS, PhD[a]; Lorenzo Franchi, DDS, PhD[a]; Christopher G. Cameron, DDS, MS[b]; James A. McNamara Jr., DDS, PhD[c]

Abstract: The aim of this study was to evaluate the short-term and long-term treatment effects of rapid maxillary expansion in 2 groups of subjects treated with the Haas appliance. Treatment outcomes were evaluated before and after the peak in skeletal maturation, as assessed by the cervical vertebral maturation (CVM) method, in a sample of 42 patients compared to a control sample of 20 subjects. Posteroanterior cephalograms were analyzed for the treated subjects at T_1 (pretreatment), T_2 (immediate post-expansion) and T_3 (long-term observation), and were available at T_1 and at T_3 for the controls. The mean age (years: months) at T_1 was 11:10 for both the treated and the control groups. The mean ages at T_3 also were comparable (20:6 for the treated group and 17:8 for the controls). Following expansion and retention (2 months on average), fixed standard edgewise appliances were placed. The study included transverse mea- surements on dentoalveolar structures, maxillary and mandibular bases and other craniofacial regions (na- sal, zygomatic, orbital, and cranial). Treated and control samples were divided into 2 groups according to individual skeletal maturation. The early-treated and early-control groups had not reached the pubertal peak in skeletal growth velocity at T_1 (CVM 1 to 3), whereas the late-treated and late-control groups were during or slightly after the peak at T_1 (CVM 4 to 6). The group treated before the pubertal peak showed significantly greater short-term increases in the width of the nasal cavities. In the long-term, maxillary skeletal width, maxillary intermolar width, lateronasal width, and lateroorbitale width were significantly greater in the early-treated group. The late-treated group exhibited significant increases in lateronasal width and in maxillary and mandibular intermolar widths. Rapid Maxillary Expansion treatment before the peak in skeletal growth velocity is able to induce more pronounced transverse craniofacial changes at the skeletal level. (*Angle Orthod* 2001;71:343–350.)

Key Words: Rapid maxillary expansion, Haas appliance, Posteroanterior cephalograms, Cervical ver- tebral maturation method

Population *Setting* *Komorbiditäten*	**transversale Anomalie** • in a single orthodontic practice, Cananda • Personen/ Patienten
Schweregrad	Keine Angabe
Einschluss-kriterien *Bei Review: PICOS*	• transverse maxillary deficiency as part of their over- all orthodontic problem
Ausschluss-kriterien	keine Angabe

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** These patients underwent Haas- type rapid maxillary expansion with 2 turns a day (0.25 mm per turn) until the expansion screw reached 10.5 mm (about 21 days). The Haas expander was kept on the teeth as a passive retainer for an average of 65 days (range: 42– 75 days). Immediately after the Haas expander was re- moved, fixed standard edgewise appliances were applied 1. VERSUCHSGRUPPE 1: **The Early-Treated Group (ETG) : N=29** N= 29(Anfang) / N=29 (Ende) / Alter = 11 Jahre / ♂:♀ =11:18 • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung 2. VERSUCHSGRUPPE 2: **The Late-Treated Group (LTG) : N=13** N= 13(Anfang) / N=13 (Ende) / Alter = 13,7 Jahre / ♂:♀ = 3:10 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **Early Control Group (ECG)** N= 11(Anfang) / N=11 (Ende) / Alter = 11 ± 3 Jahre / ♂:♀ = 9:2 • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: keine Behandlung KONTROLLGRUPPE 2: **Late Control Group (LCG)** N= 9(Anfang) / N=9 (Ende) / Alter = 12 ± 4 Jahre / ♂:♀ = 2:7 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** • **Okklusion, Kaufunktion, Funktion** • Atmung und Luftraum (Airway space, Schlafapnoe), Schlucken und Sprechen • Reduktion eines weiteren Therapiebedarfs • Stabilität des Behandlungsergebnisses PRIMÄRZIELGRÖßE: Maxillary Transverse dimension skeletal/dentoalveolar **Early** Treated Group *(kephalomerische Parameter in mm)* SEKUNDÄRZIELGRÖßE: Maxillary Transverse dimension skeletal/dentoalveolar **Late** treated group *(kephalomerische Parameter in mm)* TERTIÄRZIELGRÖßE: Maxillary Transverse dimension skeletal/dentoalveolar **Early** versus **Late** *(kephalomerische Parameter in mm)* QUARTÄRZIELGRÖßE: *Bezeichnung (gemessene Variable in Klammern)*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	Keine Angaben
Zusammen-fassung der Ergebnisse	**Early-Treated Group (ETG) VS. Early Control Group (ECG)** ***PRIMÄRZIELGRÖßE*** : Maxillary Transverse dimension skeletal/dentoalveolar **Early** Treated Group *Overall treatment changes in ETG (T□ T changes in 31 **ETG vs T□ T changes in ECG**) (Table 2) In the long-term, expansion therapy produced permanent increases in the transverse dimensions of both the dento- alveolar and skeletal components of the maxilla and cir-cummaxillary structures. There were significantly greater increments in the early-treated group compared to the con- trols for the following transverse measurements: lateroor-bitale width (□0.6 mm), maxillary width (□3.0 mm), la- teronasal width (□2.3 mm), and maxillary first molar width (□2.7 mm).* ***SEKUNDÄRZIELGRÖßE*** Maxillary Transverse dimension skeletal/dentoalveolar **Late** treated group *Overall treatment changes in LTG (T□ T changes in 31 LTG vs T□ T changes in LCG) (Table 3). The late-treated group presented with significantly greater increments for lateronasal width (□1.5 mm) and for both maxillary (□3.5 mm) and mandibular first molar widths (□2.3 mm) when compared to corresponding controls. Sig- nificant long-term changes in the late-treated group, therefore, involved primarily dentoalveolar structures, with no permanent increase in the skeletal width of the maxilla.* ***TERTIÄRZIELGRÖßE:*** Maxillary Transverse dimension skeletal/dentoalveolar **Early** versus **Late** *Comparison of treatment effects in ETG vs LTG (T□ T 21 changes in ETG vs T□ T changes in LTG) (Table 1). No statistically significant differences were found be- tween the 2 groups with the exception of a larger increase in lateronasal width in the early-treated group (□1.1 mm). Clinically favorable and similar changes in the transverse dentoalveolar measurements occurred in both groups. Though not significant, the increase in maxillary width was greater in the early-treated group (□0.6 mm).*
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:Fall-Konroll-STudie adequat zur Untersuchung der Thematik* *Durchführung: keine definierten Ein-/Aunsschulßkriterien, (Versuchsgruppe/ Kontrollgruppe ungleihce Gesclechterverteilun und Altersstruktur Early vs Late nicht stark voneinander abgegrenzt.* *Auswertung: keine Konfidenzinervalle, Fehlerberechnug OK* *Power der Studie/Patientenzahl: keine expilzite Fallzahlberechnung* *Funding:* Keine Angaben *Interessenkonflikte:* Keine Angaben *Bias .* *Baseline-Imbalancen in der Studienpopulation, d.h. Unterschiede zwischen den Gruppen oder Clustern keine Angabe* *NO - The main potential confounders are identified and taken into account in the design and analysis* *NO- Confidence intervals are provided.*

Schluss-folgerung des Begutachters	methodische Qualität: Overall a good design of the study
	Klinische Aussagekraft: Patients treated before the pubertal peak exhibit significant and more effective long-term changes at the skeletal level in both maxillary and circum- maxillary structures. Problem: only marginal differnces in the Early (11 years) vs. Late treated group (13,7 Years) according to their chronological age at T1.
Evidenz-level (SIGN)	**2++**
Qualität (RoB, SIGN /AMSTAR II)	⊕⊕

Evidenztabelle Baccetti, Franchi et al. 1999

SUMMARY An effective morphometric method (thin-plate spline analysis) was applied to evaluate shape changes in the craniofacial configuration of a sample of 23 children with Class III malocclusions in the early mixed dentition treated with rapid maxillary expansion and face mask therapy, and compared with a sample of 17 children with untreated Class III malocclusions. Significant treatment-induced changes involved both the maxilla and the mandible. Major deformations consisted of forward displacement of the maxillary complex from the pterygoid region and of anterior morphogenetic rotation of the mandible, due to a significant upward and forward direction of growth of the mandibular condyle. Significant differences in size changes due to reduced increments in mandibular dimensions were associated with significant shape changes in the treated group.

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** Children with Class III malocclusions in the early mixed dentition were treated with rapid maxillary expansion and face mask therapy, and compared with a sample of 17 children with untreated Class III malocclusions.
Schweregrad	1. Overjet in mm; 2. Verzahnung im 3er Bereich in Pb; 3. Verzahnung im 6er Bereich in Pb; 4. Wits in mm
Einschluss-kriterien *Bei Review: PICOS*	1. Overjet < 0 mm; 2. Class III canine relationship; 3. Class III permanent molar relationship; 4. Wits ≥ -2mm
Ausschluss-kriterien	k.A.
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Orthopedic face-mask therapy in the treated group comprised a face mask (according to the design of Petit 5; Fig. 1), a bonded maxillary acrylic splint expander with vestibular hooks, and heavy elastics VERSUCHSGRUPPE 1: facemask-group • N=23 (Anfang) / N=23 (Ende) / Alter = ♂ 6y9m± 7m ♂:♀ = 12:11 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe /Früh-Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **frühes Wechselgebiss-Kontrollgruppe** N=17 (Anfang) / N=17 (Ende) / Alter: 6y5m ± 8m ♂:♀ = 8:9 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Keine Behandlung

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** Outcome spezifisch: • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Okklusion, Kaufunktion, Funktion • Reduktion eines weiteren Therapiebedarfs **Primärzielgröße: Skelett. und dentoalveoläre Veränderungen**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	In this clinical study we evaluated the treatment effects produced by orthopedic face mask combined with a bonded maxillary expander. The records of 46 mixeddentition Class III patients were compared with those of 32 untreated subjects with Class III malocclusion. Two subgroups were established in each study group, according to stage of dentitional development (i.e., early vs. Late mixed dentition). The major findings were as follows: 1. Treatment of Class III malocclusion with maxillary expansion and a face mask in the early mixed dentition induced more favorable changes in the craniofacial skeleton compared with similar treatment started in the late mixed dentition. In particular, effective forward displacement of maxillary structures was achieved as an outcome of early treatment, whereas the late-treatment group showed no significant improvement in maxillary growth with respect to matched untreated controls. 2. Even though both early and late face-mask treatments reduced mandibular protrusion, significantly smaller increments in total mandibular length associated with more upward and forward direction of condylar growth were recorded only in the early-treatment group. 3. Discriminant analysis revealed that both maxillary and mandibular modifications concurred in the overall treatment effects of maxillary expansion and face-mask therapy.
Zusammen-fassung der Ergebnisse	**GRUPPE facemask-group VS. GRUPPE frühes Wechselgebiss-Kontrollgruppe**
Angaben auffälliger positiver und/oder negativer Aspekte	Sehr gut gemachte Studie. Kleinere Schwächen in der Methodik, wie bsw. die fehlende Angabe der Geschlechterverteilung innerhalb der Early- und Late-treatment Gruppen. Keine Angabe über: - Blinding bei Auswertung - Ein- und Ausschlusskriterien
Schluss-	<u>methodische Qualität:</u> sehr gut

folgerung des Begutachters	Klinische Aussagekraft: hohe klinische Aussagekraft. Im Vergleich zu anderen Studien eher kleineres Kollektiv, daher eventuell Effekt in late-treatment group nicht darstellbar.
Evidenz-level (SIGN)	**2++**
Qualität	**++**

Evidenztabelle Baccetti, Franchi et al. 2000a

Treatment and posttreatment craniofacial changes after rapid maxillary expansion and facemask therapy

Tiziano Baccetti, DDS, PhD,[a] Lorenzo Franchi, DDS, PhD,[b] and James A. McNamara, Jr, DDS, PhD[c]
Florence, Italy, and Ann Arbor, Mich

The aim of this study was to evaluate treatment and posttreatment dentoskeletal changes in 2 groups of subjects with Class III malocclusions. Subjects were treated with a bonded acrylic-splint expander and a face mask, and the optimal timing for this treatment protocol was assessed. The treated sample (29 subjects) was divided into 2 groups according to the stage of dental development. The early treatment group consisted of 16 subjects in the early mixed dentitional (erupting permanent incisors and/or first molars), whereas the late treatment group consisted of 13 subjects in the late mixed dentition (erupting permanent canines and premolars). Cephalograms were available at 3 time periods: T_1, pretreatment, T_2, end of active treatment, and T_3, posttreatment. The mean T_1–T_2 interval (active treatment period) and the mean T_2–T_3 interval (posttreatment period) were approximately 1 year each in both treatment groups. None of the patients wore any skeletal retention appliance during the posttreatment period (T_2–T_3). Groups of subjects with untreated Class III malocclusion were used as controls at both observation intervals. A significant increase in the sagittal growth of the maxilla was seen only when treatment was performed in the early mixed dentition. A restraining effect on mandibular growth rate associated with a more upward and forward direction of condylar growth was found in both treatment groups. An increase in vertical intermaxillary relationships was observed in Class III patients treated in the late mixed dentition. Posttreatment, the Class III craniofacial growth pattern was re-established in the absence of any skeletal retention appliance. Relapse tendency affects the sagittal growth of the maxilla in the early treated subjects and the sagittal position of the mandible in the late treated subjects. Orthopedic treatment of Class III malocclusion in the early mixed dentition is able to induce more favorable craniofacial adaptations than treatment in the late mixed dentition. (Am J Orthod Dentofacial Orthop 2000;118:404-13)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** Patients with class III malocclusion treated with maxillary expansion (bonded maxillary expander) and face-mask therapy was obtained from North American practitioners experienced in this type of treatment. The clinicians were asked to take cephalograms at the following time periods: pretreatment (T1), within 1 month after RME and facemask removal (T2), and at least 6 months later (T3). Therefore, for each patient an active treatment period (T1-T2) and a posttreatment period (T2–T3) could be evaluated.
Schweregrad	1. Overjet in mm 2. Verzahnung im 3er Bereich in Pb 3. Verzahnung im 6er Bereich in Pb 4. Wits in mm
Einschluss-kriterien *Bei Review: PICOS*	1. Overjet < 0 mm 2. Class III canine relationship 3. Class III permanent molar relationship 4. ≥ -2mm
Ausschluss-kriterien	k.A.

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Orthopedic face-mask therapy in the treated group comprised a face mask (according to the design of Petit 5; Fig. 1), a bonded maxillary acrylic splint expander with vestibular hooks, and heavy elastics VERSUCHSGRUPPE 1: early-treatment group • N=16 (Anfang) / N=16 (Ende) / Alter = ♂ 7y± 7m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe /Früh-Behandlung VERSUCHSGRUPPE 2: late-treatment group • N=13 (Anfang) / N=13 (Ende) / Alter = ♂ 8y8m± 1y ♂:♀ = k.A. • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **frühes Wechselgebiss-Kontrollgruppe 1** N=17 (Anfang) / N=17 (Ende) / Alter: 6y5m ± 8m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Keine Behandlung KONTROLLGRUPPE 2: **frühes Wechselgebiss-Kontrollgruppe 2** N=11 (Anfang) / N=11 (Ende) / Alter: 7y7m ± 7m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Keine Behandlung KONTROLLGRUPPE 3: **spätes Wechselgebiss-Kontrollgruppe 1** N=15 (Anfang) / N=15 (Ende) / Alter: 9y6m ± 1y6m ♂:♀ = k.A. • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: Keine Behandlung KONTROLLGRUPPE 4: **spätes Wechselgebiss-Kontrollgruppe 2** N=10 (Anfang) / N=10 (Ende) / Alter: 10y3m ± 1y5m ♂:♀ = k.A. • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: Keine Behandlung

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Okklusion, Kaufunktion, Funktion • Reduktion eines weiteren Therapiebedarfs **Primärzielgröße: Skell. Und dentoalv. Veränderungen im FRS durch Facemask/RME-Therapie** **Sekundärzielgröße: Skell. Und dentoalv. Posttherapeutische Veränderungen im FRS durch Facemask/RME-Therapie**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	The main findings of the present cephalometric study on treatment and posttreatment craniofacial alterations related to orthopedic therapy of Class III malocclusion by means of maxillary expansion and protraction in the early and late mixed dentitions are: 1. A significant increase in sagittal growth of the maxilla can be obtained only when treatment is performed in the early mixed dentition. Both early and late treatment of the malocclusion are able to induce a restraining effect on mandibular growth associated with a more upward and forward direction of condylar growth. 2. A backward positional rotation of the mandible associated with an increase in lower anterior facial height is observed in Class III patients treated in the late mixed dentition. 3. A Class III craniofacial growth pattern is re-established during 1 year of posttreatment observation in the absence of any skeletally based retention appliance. A significant relapse tendency affects the sagittal growth of the maxilla in the subjects who were treated early and the sagittal position of the mandible in the subjects treated later. 4. When considering combined outcomes of both active treatment and posttreatment periods, orthopedic treatment of Class III malocclusion in the early mixed dentition appears to induce more favorable overall craniofacial changes than treatment in the late mixed dentition.

Zusammen-fassung der Ergebnisse	**Early treatment group vs. Early-untreated group 1** Significantly greater increments in maxillary sagittal growth both at the skeletal (A-VertT) and dentoalveolar (Pr-VertT) levels. Midfacial length (Co-A) increments also were significantly larger in ETG. Significantly smaller increments for mandibular sagittal position (B-VertT), for total mandibular length (Co-Gn), and for the length of the mandibular body (Goi-Gn) were assessed in ETG and compared with those in ECG1. The direction of condylar growth as revealed by the change in inclination of the condylar axis in relation to both cranial base (CondAx-SBL) and the mandibular line (CondAx-ML) was significantly more upward and forward in ETG. **late treatment group vs. Late untreated group 1** Treatment performed in the late mixed dentition led to significantly smaller increments in the amount of mandibular growth along total mandibular length (Co-Gn), associated with significantly smaller increments in mandibular skeletal (B-VertT) and dentoalveolar (Id-VertT) protrusion. Increments in the inclination of the mandibular line in relation to cranial base (ML-SBL) and to nasal line(NL-ML) were significantly greater in LTG when compared with corresponding controls (LCG1). A significantly larger increase in lower anterior facial height (ANS-Me) was recorded in LTG as well. Measurements for the inclination of the condylar axis in relation both to the cranial base (CondAx-SBL) and to the mandibular line (CondAx-ML) showed a significantly more upward and forward direction of condylar growthin LTG when compared with LCG1. **Early treatment group vs. Early untreated group 1** Posttreatment increments in the anteroposterior position of the maxilla (A-VertT), in dentoalveolar maxillary protrusion (Pr-VertT), and in midfacial length (Co-A) were significantly smaller in ETG than in ECG2. Increments in lower anterior facial height (ANS-Me) were also significantly smaller in ETG during the posttreatment period. **Late treatment group vs. Late untreated group 1** Significantly greater increments in the anteroposterior position of mandibular base (B-VertT) and the mandibular dentition (Id-VertT) were found in LTG when compared with LCG2 during the posttreatment period.
Angaben auffälliger positiver und/oder negativer Aspekte	Sehr gut gemachte Studie, die die unterschiedlichen Behandlungsergebnisse verschiedener Therapiezeitpunkte aufzeigt. Eventuell gewisse Bias durch retrospektive Betrachtung. Das Alter der jeweiligen Gruppe zeigt, dass besonders früh in der Behandlung einer maxillären Protraktion begonnen werden sollte.
Schluss-folgerung des Begutachters	methodische Qualität: sehr gut
	Klinische Aussagekraft: hohe klinische Aussagekraft.
Evidenz-level (SIGN)	**2++**
Qualität	**++**

Evidenztabelle Baccetti, Franchi et al. 2000b

Treatment timing for Twin-block therapy

Tiziano Baccetti, DDS, PhD,[a] Lorenzo Franchi, DDS, PhD,[a] Linda Rather Toth, DDS, MS,[b] and James A. McNamara, Jr, DDS, PhD[b]
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This cephalometric study evaluated skeletal and dentoalveolar changes induced by the Twin-block appliance in 2 groups of subjects with Class II malocclusion treated at different skeletal maturation stages in order to define the optimal timing for this type of therapy. Skeletal maturity in individual patients was assessed on the basis of the stages of cervical vertebrae maturation. The early-treated group was composed of 21 subjects (11 females and 10 males). Mean age of these subjects at time 1 (immediately before treatment) was 9 years ± 11 months, and at time 2 (immediately after discontinuation of the Twin-block appliance) was 10 years 2 months ± 11 months. According to the cervical vertebrae maturation staging at times 1 and 2, the peak in growth velocity was not included in the treatment period for any of the subjects in the early group. The late-treated group consisted of 15 subjects (6 females and 9 males). Mean age of this group was 12 years 11 months ± 1 year 2 months at time 1 and 14 years 4 months ± 1 year 3 months at time 2. In the late group, treatment was performed during or slightly after the onset of the pubertal growth spurt. Both treated samples were compared with control samples consisting of subjects with untreated Class II malocclusions also selected on the basis of the stage in cervical vertebrae maturation. A modification of Pancherz's cephalometric analysis was applied to the lateral cephalograms of all examined groups at both time periods. Linear and angular measurements for mandibular dimensions, cranial base angulation, and vertical relationships were added to the original analysis. Annualized differences for all the variables from time 1 to time 2 were calculated for both treated groups and contrasted to the annualized differences in the corresponding untreated groups by means of nonparametric statistics. The findings of this short-term cephalometric study indicate that optimal timing for Twin-block therapy of Class II disharmony is during or slightly after the onset of the pubertal peak in growth velocity. When compared with treatment performed before the peak, late Twin-block treatment produces more favorable effects that include: (1) greater skeletal contribution to molar correction, (2) larger increments in total mandibular length and in ramus height, and (3) more posterior direction of condylar growth, leading to enhanced mandibular lengthening and to reduced forward displacement of the condyle in favor of effective skeletal changes. The importance of the biological evaluation of skeletal maturity in individual patients with Class II disharmony to be treated with functional appliances is emphasized. (Am J Orthod Dentofacial Orthop 2000;118:159-70)

Population *Setting* *Komorbiditäten*	Klasse-II-Anomalie Patienten mit Klasse-II-Anomalie ohne detaillierter Angabe; Patienten wurden alle mittels Twin-Block behandelt.
Schweregrad	Keine Angabe
Einschluss-kriterien *Bei Review: PICOS*	Patienten mit Klasse-II-Anomalie ohne detaillierter Angabe; Patienten wurden alle mittels Twin-Block behandelt.
Ausschluss-kriterien	1. absence of full Class II molar relationship; 2. poor film quality; 3. additional orthodontic treatment; 4.extractions of permanent teeth during the period of Twin-block therapy).

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** *Most of the Twin-block appliances used in this study were of the design originally developed by Clark. The appliance is composed of maxillary and mandibular appliances that fit tightly against the teeth, alveolus, and adjacent supporting structures (Fig 2). Delta clasps were used bilaterally to anchor the maxillary appliance to the first permanent molars, and 0.030 inch ball clasps (or arrow clasps) were placed in the interproximal areas anteriorly. The precise clasp configuration depended on the type (deciduous or permanent) and number of teeth present at the time of appliance construction. In the lower arch, Clark has recommended using a series of ball clasps that lie in the interproximal areas between the canines and lower incisors (Fig 2B). For a few of the appliances used in the study, the design was modified by placing a labial bow anterior to the lower incisors that has labial acrylic similar to that of a lower spring retainer as designed by Barrer. In contrast to the fabrication of a spring retainer, however, the positions of the lower incisors were not altered in the work model before appliance construction.* VERSUCHSGRUPPE 1: **ETG** N= nicht genau angegeben (Anfang) / N=21 (Ende) / Alter = 9y0m ± 0y11m / ♂:♀ = 10:11 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Frühbehandlung VERSUCHSGRUPPE 2: **LTG** N= nicht genau angegeben (Anfang) / N=15 (Ende) / Alter = 12y11m ± 1y2m / ♂:♀ = 9:6 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **ECG** N=16 (Anfang) / N=16 (Ende) / Alter = 9y1m ± 10m / ♂:♀ = 9:7 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: keine Behandlung KONTROLLGRUPPE 1: **LCG** N=14 (Anfang) / N=14 (Ende) / Alter = 13y7m ± 1y2m / ♂:♀ = 7:7 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: keine Behandlung

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: *diverse FRS-Parameter*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	Optimum treatment timing for Twin-block therapy of Class II disharmony appears to be during or slightly after the onset of the pubertal peak in growth velocity. Major favorable effects induced by functional therapy at this time in comparison with earlier phases are: • Greater skeletal contribution to the correction of the molar relation; • Larger and clinically significant increments in total mandibular length and in ramus height; • More posterior direction of condylar growth, a biological mechanism enhancing supplementary mandibular lengthening and reducing the amount of forward condylar displacement in favor of effective mandibular growth and reshaping.

Zusammen-fassung der Ergebnisse	**ETG VS. ECG** ***PRIMÄRZIELGRÖßE*** *Treatment with the Twin-block appliance before the pubertal peak produced an overjet correction of 4.6 mm and a correction in molar relation of 4.7 mm when compared with growth changes in the early-control group. The skeletal contribution to overjet correction was predominant (55%) due exclusively to mandibular changes. Mandibular base measurement showed significantly greater increments in ETG when compared with ECG. The dentoalveolar component of overjet correction was due mainly to mandibular changes. The mandibular incisors were proclined significantly by treatment, whereas the position of the maxillary incisors was not affected significantly. Skeletal and dentoalveolar contributions to molar correction were almost equivalent. Increments in mandibular base measurement completely accounted for the skeletal changes, whereas dental changes primarily were due to distal movement of the maxillary molars. The changes in the position of both maxillary and mandibular molars, however, were significant when compared with ECG.* *Early treatment produced a significant forward displacement of the condylar head in relation to the reference system (co/OLp) when compared with early controls. Total mandibular length (co-pg) showed significantly greater increments in ETG, whereas the height of the mandibular ramus (co-go) and the length of the mandibular body (go-pg) did not exhibit significant differences. The gonial angle (ar-goi-me) demonstrated significantly greater increments in ETG when compared with ECG, whereas the increments in the inclination of the condylar line in relation to the mandibular line (clml) were not significant. No significant differences between ETG and ECG were found as to cranial base angulation and vertical skeletal relationships.* **LTG VS. LCG** ***PRIMÄRZIELGRÖßE*** *Treatment with the Twin-block appliance during or slightly after the pubertal peak induced an overjet correction of 5.8 mm and a correction in molar relation of 4.8 mm when compared with growth changes in the LCG. The skeletal contribution to overjet correction was predominant (54%). Both skeletal and dentoalveolar components of overjet correction were due mainly to mandibular changes. Mandibular base measurement showed significantly greater increments in LTG when compared with LCG. Mandibular incisors were proclined significantly by treatment, whereas the position of the maxillary incisors was not affected significantly. Skeletal contribution to molar correction also was predominant (67%), and it was due mainly to significantly greater increments in mandibular base. Dentoalveolar changes were due primarily to mesial movement of the mandibular molars. The changes in the position of both maxillary and mandibular molars, however, were significant when compared with LCG. Late treatment induced a significant backward displacement of the condylar head in relation to the reference system (co/OLp) when compared with late controls. Treatment during or slightly after the pubertal peak also induced significantly greater increments in total mandibular length (co-pg), in the height of the mandibular ramus (co-go), and in the length of the mandibular body (go-pg). The increments in the inclination of the condylar line in relation to the mandibular line (cl-ml) and in the gonial angle (ar-goi-me) were significantly greater when compared with the corresponding control subjects. No significant differences between LTG and LCG were found as to cranial base angulation and vertical skeletal relationships.*

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: Patientenakquise über insgesamt 8 Zentren (7x Praxen und 1x Klinik),* *Durchführung: T2-FRS wurden unmittelbar nach der Entfernung des Twin Blocks angefertigt – daher möglicherweise Verfälschung durch rein muskuläre Adaption.* *Auswertung: Kein statistischer Vergleich zwischen früher und später Behandlung; zudem wurden die klinischen Behandlungseffekte linear auf „1 Jahr runtergerechnet“ (Siehe S. 163: „The T2 to T1 changes for all cephalometric variables in both treated and control groups were annualized.“* *Keine genauen Angaben (z.B. Tabelle) für den Vergleich der Gruppen zum Zeitpunkt T1.* *Keine genauen p-Werte angegeben.* *Power der Studie/Patientenzahl: Sehr kleine „n“ pro Gruppe (zwischen 14 und 21 Patienten je Gruppe) – Keine Poweranalyse* *Funding: Keine Angabe* *Interessenkonflikte: Keine Angabe* *Bias (SIGN/AMSTAR/Einzelstudien RoB – alle negativen Punkte aus Fragebogen auflisten):* *Publikationsbias (Reviews):* - *Wahrscheinlich hoch durch viele verschiedene Zentren und somit selection Bias!* *Ethik-Votum: keine Angabe*
Schluss-folgerung des Begutachters	methodische Qualität: moderat bis gut
	Klinische Aussagekraft: moderat Methodische Einschränkungen: Siehe “Angaben auffälliger positiver und negative Aspekte”. Der Titel der Untersuchung „Treatment timing for Twin Block“ suggeriert einen detaillierten statistischen Vergleich zwischen der ETG und der LTG. Dieser wird von den Autoren allerdings nicht präsentiert – ausschließlich Vergleich der beiden Untersuchungsgruppen zu den jeweiligen Kontrollgruppen. Dadurch die eigentlich geplante Aussage des Papers eingeschränkt.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable (+)**

Evidenztabelle Baccetti, Franchi et al. 2008

Introduction: The aim of this study was to investigate the role of treatment timing on the effectiveness of vertical-pull chincup (V-PCC) therapy in conjunction with a bonded rapid maxillary expander (RME) in growing subjects with mild-to-severe hyperdivergent facial patterns. **Methods:** The records of 39 subjects treated with a bonded RME combined with a V-PCC were compared with 29 untreated subjects with similar vertical skeletal disharmonies. Lateral cephalograms were analyzed before (T1) and after treatment or observation (T2). Both the treated and the untreated samples were divided into prepubertal and pubertal groups on the basis of cervical vertebral maturation (prepubertal treated group, 21 subjects; pubertal treated group, 18 subjects; prepubertal control group, 15 subjects; pubertal control group, 14 subjects). Mean change differences from T2 to T1 were compared in the 2 prepubertal and the 2 pubertal groups with independent-sample *t* tests. **Results:** No statistically significant differences between the 2 prepubertal groups were found for any cephalometric skeletal measures from T1 to T2. When compared with the untreated pubertal sample, the group treated with the RME and V-PCC at puberty showed a statistically significant reduction in the inclination of the mandibular plane to the Frankfort horizontal (−2.2 mm), a statistically significant reduction in the inclination of the condylar axis to the mandibular plane (−2.2°), and statistically significant supplementary growth of the mandibular ramus (1.7 mm). **Conclusions:** Treatment of increased vertical dimension with the RME and V-PCC protocol appears to produce better results during the pubertal growth spurt than before puberty, although the absolute amount of correction in the vertical skeletal parameters is limited. (Am J Orthod Dentofacial Orthop 2008;133:58-64)

Population *Setting* *Komorbiditäten*	**vertikale Anomalie** 39 treated subjects compared with 29 untreated subjects with similar vertical skeletal disharmonies (treated with a bonded RME combined with a V-PCC were)
Schweregrad	mandibular plane angle to Frankfort horizontal (MPA) of 25° or greater.
Einschluss-kriterien *Bei Review: PICOS*	(1) no permanent teeth extracted before or during treat- ment, (2) no functional appliance therapy, (3) 2 con- secutive quality lateral cephalograms with adequate landmark visualization and with minimal or no rotation of the head, taken before (T1) and after treatment (T2), (4) as derived from the cephalometric analysis at T1, a mandibular plane angle to Frankfort horizontal (MPA) of 25° or greater.
Ausschluss-kriterien	Keine Angaben

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE 1: **prepubertal-RME-/vertical-chincup-group** • N=21 (Anfang) / N=21 (Ende) / Alter = 8y8m±9m / ♂:♀ = ?:? • Gebissphase: Milchgebiss, frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung, Frühbehandlung VERSUCHSGRUPPE 2: **pubertal-RME-/vertical-chincup-group** • N=15 (Anfang) / N=15 (Ende) / Alter = 9y4m±1y1m / ♂:♀ = ?:? • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated prepubertal group** • N=18 (Anfang) / N=18 (Ende) / Alter: 8y5m±1y / ♂:♀ = ?:? • Gebissphase: Milchgebiss, frühes Wechselgebiss • Keine Behandlung: keine Behandlung KONTROLLGRUPPE 2: **untreated pubertal group** • N=14 (Anfang) / N=14 (Ende) / Alter: 9y10m±1y3m / ♂:♀ = ?:? • Gebissphase: Milchgebiss, frühes Wechselgebiss • Keine Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** • **Okklusion, Kaufunktion, Funktion** • **Reduktion eines weiteren Therapiebedarfs** Primärzielgröße: vertikale Parameter im FRS
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	Treatment of patients with increased vertical dimension with a bonded RME in conjunction with a V-PCC during the adolescent spurt in mandibular growth appeared to induce more favorable changes than prepubertal treatment. These changes included reduction in the inclination of the mandibular plane to the Frankfort horizontal, reduction in the inclination of the condyle to the mandibular plane, and increased growth of the mandibular ramus. The sizes of these favorable treatment effects were small (the greatest linear difference between the treated and untreated subjects was 2.2 mm; the greatest angular difference was 1.5°). Therefore, caution is recommended in the use of this treatment protocol at both prepubertal and pubertal stages. No statistically significant changes were found when treatment was performed at the prepubertal stage of skeletal maturity.
Zusammen-fassung der Ergebnisse	**GRUPPE prepubertal-RME-/vertical-chincup-group VS. GRUPPE untreated prepubertal group** **GRUPPE prepubertal-RME-/vertical-chincup-group VS. GRUPPE untreated pubertal group** **GRUPPE pubertal-RME-/vertical-chincup-group VS. GRUPPE untreated prepubertal group** **GRUPPE pubertal-RME-/vertical-chincup-group VS. GRUPPE untreated pubertal group** **Keine Vertikalen Veränderungen durch Therapie mit vertikaler Chincup bei prepubertären Patienten, lediglich sehr geringe Veränderungen bei pubertären Patienten.**
Angaben auffälliger positiver und/oder negativer Aspekte	- keine Angaben über Geschlechterverteilung innerhalb der Untergruppen
Schluss-folgerung des Begutachters	<u>methodische Qualität:</u> sehr gut
	Klinische Aussagekraft: klinische Aussagekraft hoch, wenn gleich eine Therapie durch mögliche Kiefergelenksschädigungen limitiert wäre. Die Frage stellt sich jedoch nur bedingt, da das Outcome für eine Therapie zu gering wäre.
Evidenz-level (SIGN)	**2++**
Quality	**++**

Evidenztabelle Baccetti, McGill et al 1998

The effectiveness of maxillary expansion and face-mask therapy in children with Class III malocclusion was studied in a sample of 46 subjects in mixed dentition and compared with a control sample of 32 subjects with untreated Class III malocclusion. Treated and untreated samples were divided into early and late mixed-dentition groups to aid identification of the optimum timing of the orthopedic treatment of the underlying skeletal disharmony. Cephalometric analysis was based on a stable basicranial reference system, appropriate for longitudinal studies started in the early developmental ages. The level of significance for intergroup comparisons was set at a *p* value of 0.01. Significant forward displacement of the maxillary complex was found in the early-treatment group. The region of the pterygomaxillary suture, in particular, showed significant changes in the subjects treated during early mixed dentition. No significant maxillary modifications were recorded in the late-treatment group. Both early and late groups exhibited smaller increments in mandibular protrusion and larger increments in the intermaxillary vertical relationship compared with their respective Class III control groups. Only children treated at an early age, however, showed a significant upward and forward direction of condylar growth, leading to smaller increments in total mandibular length. These results indicate that the combination of a bonded maxillary expander and face-mask therapy is more effective in early mixed dentition than in late mixed dentition, especially with regard to the magnitude of the protraction effects on maxillary structures. (Am J Orthod Dentofacial Orthop 1998;113:333-43.)

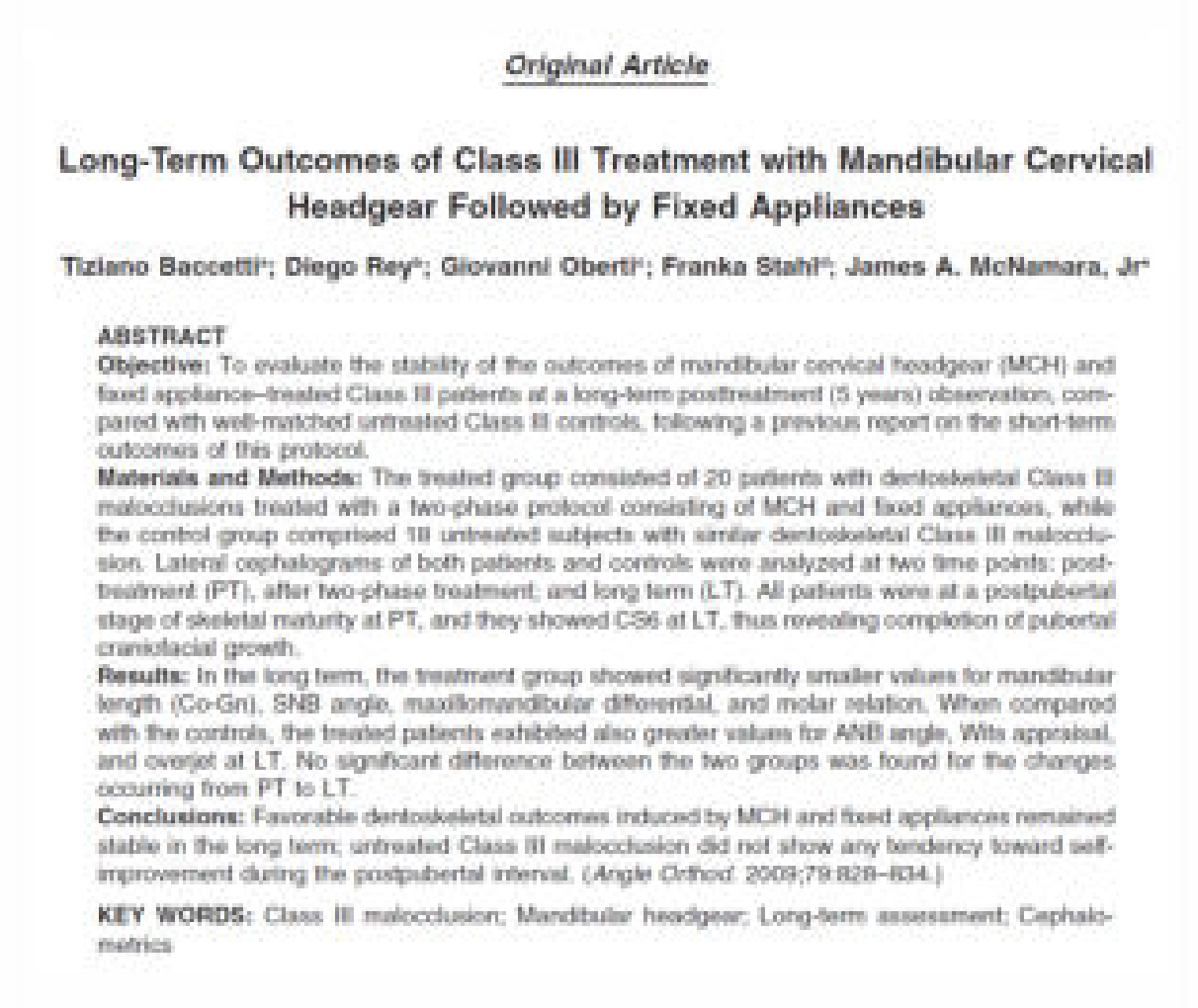
Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** Patients with class III malocclusion treated with maxillary expansion (bonded maxillary expander) and face-mask therapy was obtained from North American practitioners experienced in this type of treatment. The clinicians were asked to take cephalograms at the following intervals: before treatment (T1) and after treatment (T2). Generally, 1 or 2 months elapsed between the T1 cephalogram and the actual start of treatment. The T2 film was taken within 1 month of the discontinuation of face-mask wear and removal of the expander
Schweregrad	1. Overjet in mm 2. Verzahnung im 3er Bereich in Pb 3. Verzahnung im 6er Bereich in Pb 4. Wits in mm
Einschluss-kriterien *Bei Review: PICOS*	1. Overjet < 0 mm 2. Class III canine relationship 3. Class III permanent molar relationship 4. ≥ -2mm
Ausschluss-kriterien	k.A.

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Orthopedic face-mask therapy in the treated group comprised a face mask (according to the design of Petit 5; Fig. 1), a bonded maxillary acrylic splint expander with vestibular hooks, and heavy elastics VERSUCHSGRUPPE 1: early-treatment group • N=23 (Anfang) / N=23 (Ende) / Alter = ♂ 6y9m± 7m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe /Früh-Behandlung VERSUCHSGRUPPE 2: late-treatment group • N=23 (Anfang) / N=23 (Ende) / Alter = ♂ 10y3m± 1y ♂:♀ = k.A. • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **frühes Wechselgebiss-Kontrollgruppe** N=17 (Anfang) / N=17 (Ende) / Alter: 6y5m ± 8m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • Keine Behandlung KONTROLLGRUPPE 2: **spätes Wechselgebiss-Kontrollgruppe** N=15 (Anfang) / N=15 (Ende) / Alter: 9y6m ± 1y6m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • Keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** Outcome spezifisch: • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Okklusion, Kaufunktion, Funktion • Reduktion eines weiteren Therapiebedarfs **Primärzielgröße: Maxilläre und mandibuläre Formveränderungen**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	The effectiveness of early RME and face mask therapy of Class III malocclusions also included significant changes in size which can be ascribed mainly to a reduction in the mandibular dimensions. 1. Treatment of Class III malocclusion with maxillary expansion and a face mask in the early mixed dentition induced more favorable changes in the craniofacial skeleton compared with similar treatment started in the late mixed dentition. In particular, effective forward displacement of maxillary structures was achieved as an outcome of early treatment, whereas the late-treatment group showed no significant improvement in maxillary growth with respect to matched untreated controls. 2. Even though both early and late face-mask treatments reduced mandibular protrusion, significantly smaller increments in total mandibular length associated with more upward and forward direction of condylar growth were recorded only in the early-treatment group. 3. Discriminant analysis revealed that both maxillary and mandibular modifications concurred in the overall treatment effects of maxillary expansion and face-mask therapy.
Zusammen-fassung der Ergebnisse	**GRUPPE early treatment group VS. frühes Wechselgebiss-Kontrollgruppe** **GRUPPE early treatment group VS. späte Wechselgebiss-Kontrollgruppe** **GRUPPE late treatment group VS. frühes Wechselgebiss-Kontrollgruppe** **GRUPPE late treatment group VS. späte Wechselgebiss-Kontrollgruppe** Thin-plate spline analysis of shape changes in the treated group (Figure 4) ➔ extension in the horizontal axis in the maxillary region and ○ In particular, the shape change comprised maxillary advancement at points ANS, A, and Pr. A forward and slightly downward deformation at point PNS (moving from point Ptm) also was evident. ➔ a compression in the region of the anterior surface of the mandibular symphysis. ➔ a compression in the horizontal axis in the regions of the mandibular condyle and of the antero-inferior border of the symphysis. The component of maxillary advancement was still present. In the control group: ➔ little overall deformation and consisted of slight compression in the horizontal axis in the anterior region of the maxilla associated with a slight extension in the region of the mandibular condyle and of the antero-inferior portion of the mandibular symphysis. The partial warp with the largest magnitude (Table 1 and Figure 5B) confirmed the compression in the anterior part of the maxilla and the extension in the chin area. The effectiveness of early RME and face mask therapy of Class III malocclusions also included significant changes in size which can be ascribed mainly to a reduction in the mandibular dimensions.

Angaben auffälliger positiver und/oder negativer Aspekte	Sehr gut gemachte Studie, die über die Aussagen der meisten anderen Studien (Veränderungen im FRS) hinausgeht. Einzelne Angaben müssen aus vorheriger Studie entnommen werden.
Schluss-folgerung des Begutachters	methodische Qualität: sehr gut
	Klinische Aussagekraft: hohe klinische Aussagekraft.
Evidenz-level (SIGN)	**2++**
Qualität	**++**

Evidenztabelle Bacetti et al. 2009



Original Article

Long-Term Outcomes of Class III Treatment with Mandibular Cervical Headgear Followed by Fixed Appliances

Tiziano Baccetti[a]; Diego Rey[b]; Giovanni Oberti[c]; Franka Stahl[d]; James A. McNamara, Jr[e]

ABSTRACT

Objective: To evaluate the stability of the outcomes of mandibular cervical headgear (MCH) and fixed appliance–treated Class III patients at a long-term posttreatment (5 years) observation, compared with well-matched untreated Class III controls, following a previous report on the short-term outcomes of this protocol.

Materials and Methods: The treated group consisted of 20 patients with dentoskeletal Class III malocclusions treated with a two-phase protocol consisting of MCH and fixed appliances, while the control group comprised 18 untreated subjects with similar dentoskeletal Class III malocclusion. Lateral cephalograms of both patients and controls were analyzed at two time points: posttreatment (PT), after two-phase treatment, and long term (LT). All patients were at a postpubertal stage of skeletal maturity at PT, and they showed CS6 at LT, thus revealing completion of pubertal craniofacial growth.

Results: In the long term, the treatment group showed significantly smaller values for mandibular length (Co-Gn), SNB angle, maxillomandibular differential, and molar relation. When compared with the controls, the treated patients exhibited also greater values for ANB angle, Wits appraisal, and overjet at LT. No significant difference between the two groups was found for the changes occurring from PT to LT.

Conclusions: Favorable dentoskeletal outcomes induced by MCH and fixed appliances remained stable in the long term; untreated Class III malocclusion did not show any tendency toward self-improvement during the postpubertal interval. (*Angle Orthod.* 2009;79:828–834.)

KEY WORDS: Class III malocclusion; Mandibular headgear; Long-term assessment; Cephalometrics

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** • Fortsetzung der Studie **Rey et al. 2008** • In the current follow-up study, the treated group consisted of 20 patients with dentoskeletal Class III malocclusion treated consecutively with MCH followed by fixed appliances by one operator. Success of the therapy was not a determinant for selection of patients. One patient dropped out from the original treatment sample during the follow-up interval because he could not be located at recall. Lateral cephalograms were taken 2 years after the end of two-phase treatment (PT) and **about 5 years after the end of treatment as a long-term observation** (LT). • Treated Group (n=20): patients, who were consecutively treated with this protocol by 1 operator (D.R.). • Control Group (n=18): A control group of 18 untreated subjects with dentoskeletal Class III malocclusion was obtained from the Department of Orthodontics at the University of Florence and the University of Michigan Elementary and Secondary School Growth Study.

Schweregrad	Wits appraisal -1.5 mm or less.
Einschluss-kriterien *Bei Review: PICOS*	• Class III malocclusion characterized by anterior crossbite and Wits appraisal21 of -1.5 mm or less. • All patients were white. • No permanent teeth were congenitally missing or extracted before or during treatment.
Ausschluss-kriterien	Keine Angabe
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: **CLASS III treated with mandibular cervical headgear (MCH group)** N=21 (Anfang) / N=20 (Ende) / Alter = 10,4 ± 1,08 Jahre / ♂:♀ = 0,33:1 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **CLASS III untreated (control group)** N=20 (Anfang) / N=18 (Ende) / Alter = 10,08 ± 1,58 Jahre / ♂:♀ = 0,5:1 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: sagittal skeletal and dental parameters (ANB, Wits appraisal, overjet and molar relationship) SEKUNDÄRZIELGRÖßE: mandibular length (Co-Gn) TERTIÄRZIELGRÖßE: Mandibular plane angle MPA
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. Significant dentoskeletal outcomes in terms of improvement of mandibular prognathism, Wits appraisal, overjet, and molar relationship induced by MCH and fixed appliances **remained stable in the long term (5Y)**. 2. In the long term, the treatment protocol produced less anterior rotation of the mandibular plane than untreated Class III controls. (Weniger anti-clock wise Rotation der Mandibula vs. Kontrolle)

Zusammen-fassung der Ergebnisse	**GRUPPE Class III VS. GRUPPE CLASS III untreated (control group)** ***Rey et al. 2008*** ***[PRIMÄRZIELGRÖßE*** sagittal skeletal and dental parameters (ANB, Wits appraisal, overjet and molar relationship) Treatment with the MCH followed by fixed appliances induced significant dentoskeletal responses in terms of improvement in the sagittal skeletal (+4 mm for the Wits appraisal) and dental (+2.7 mm for overjet, -4.4 mm for molar relationship) parameters; these changes remained stable during the posttreatment period. ***SEKUNDÄRZIELGRÖßE*** mandibular length (Co-Gn) In the treated groupmandibular length (Co-Gn) significantly larger at T3 than at T2. ***TERTIÄRZIELGRÖßE:*** Mandibular plane angle MPA In the long-term skeletal relationship, significant backward rotation of the mandibular plane in relation to the Frankfort horizontal line was also recorded (2.8°).] HIER: The statistical comparison of the craniofacial forms at PT between the two groups showed several significant effects of two-phase therapy of Class III malocclusion followed by retention (Table 2). These results were already described by the previous report, Rey et al. 2008, which also showed the absence of significant pretreatment differences between the two groups. At PT, the treatment group showed significantly smaller values for Co-Gn, SNB angle, maxillomandibular differential, and molar relation. When compared with the controls, at PT the treated patients exhibited also greater values for ANB angle, Wits appraisal, and overjet. All of these differences remained statistically significant at LT (Table 3), with the addition of significantly smaller values for the distance from pogonion to the nasion perpendicular and of significantly greater values for the MPA in the treated group in the LT.
Angaben auffälliger positiver und/oder negativer Aspekte	*Studiendesign: Kohortenstudie* *Durchführung: Klasse III MCH gegen unbehandelte Klasse III Kohorte verglichen.* *Auswertung: Fehleranalyse durchgeführt, die Analyse valid und reproduzierbar* *Power der Studie/Patientenzahl: nicht kalkuliert,* *Funding: None.* *Interessenkonflikte: None.* *Bias (SIGN/AMSTAR/EinzelstudienRoB –): High quality (++) X*
Schluss-	<u>methodische Qualität:</u> insgesamt hoch

folgerung des Begutachters	Klinische Aussagekraft: Die Behandlung mit der MCH, mit anschließender festsitzender Apparatur, führte zu signifikanten dentoskelettalen Reaktionen in Bezug auf die Verbesserung der sagittalen (+4 mm für die Wits-Beurteilung) und dentalen (+2,7 mm für Overjet, -4,4 mm für die Molarenbeziehung) Parameter; diese Veränderungen blieben **5 Jahren nach Abschluss der Behandlung weiterhin** stabil. Desweiteren haben MCH und die Therapie mit festsitzenden Apparaten eine deutliche „Clockwise Rotation“ Unterkiefers verursacht, die in einer ähnlichen Studie von Westwood et al 2003 nicht gefunden wurde, bei der die langfristigen Auswirkungen von RME und Gesichtsmaskentherapie untersucht wurde. Daher scheint die MCH -im Gegensatz zur Gesichtsmaske- bei moderateren Formen der dentoskelettalen Klasse III Malokklusion und möglicherweise mit einem ausgeprägten horizontalem Wachstumsmuster indiziert zu sein.
Evidenz-level (SIGN)	**2++**
Qualität **(RoB, SIGN /AMSTAR II)**	**High quality (++)**

Evidenztabelle Baccetti, Tollaro 1998

A retrospective comparison of functional appliance treatment of Class III malocclusions in the deciduous and mixed dentitions

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SUMMARY This retrospective study compared the effectiveness of treatment of Class III malocclusions with the removable mandibular retractor in the deciduous and mixed dentitions.

A group of 20 children with Class III malocclusions started treatment at a mean age of 5 years 1 month ± 7 months (deciduous dentition), while a group of 18 children with Class III malocclusions started treatment at a mean age of 8 years 2 months ± 9 months (mixed dentition). The mean observation period was 2 years 3 months ± 6 months for the first group, and 2 years 4 months ± 7 months for the second group. Matched control groups of children with untreated Class III malocclusions in the deciduous and in the mixed dentition (16 subjects and 15 subjects, respectively) were used. The cephalometric analysis was based on a stable basicranial reference system appropriate for longitudinal studies that begin at early developmental ages.

The results showed that treatment of Class III malocclusions in the deciduous dentition produced a more significant anterior morphogenetic rotation of the mandible, due to a more upward and forward direction of condylar growth ($P < 0.01$). This leads to significantly smaller increments in mandibular total length (Co–Pg) in children with Class III malocclusions undergoing very early treatment ($P < 0.01$). On the contrary, maxillary dento-alveolar protrusion induced by therapy was greater in Class III subjects treated in the mixed dentition ($P < 0.01$). The optimum timing to improve skeletal relationships in Class III malocclusions by means of a functional appliance appears to be in the deciduous dentition.

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** Children with Class III malocclusion • Italy
Schweregrad	-
Einschluss-kriterien	- Class III malocclusion
Ausschluss-kriterien	- Not fullfilling inclusion criteria

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **RMR early/ late** RMR is constructed to work as a true functional appliance. The appliance consists of a resin plate which is attached to the upper jaw by Adams' clasps and which bears a labial arch extending to the cervical margin of the mandibular incisors. The labial arch is activated so as to be placed 2 mm in front of these teeth when the mandible is forced into maximum retrusion. Therefore, the arch is intended to work as a stop for sagittal movement of the mandible. Expansion screws and springs for the proclination of upper incisors were added to RMR in all treated subjects. VERSUCHSGRUPPE 1: **RMR early** N= 20 (Anfang) / N=20 (Ende) / Alter = 5,08, 0,58 ♂:♀ = 9:11 • Gebissphase: Milchgebiss • KFO-Behandlung: frühe Behandlung VERSUCHSGRUPPE 2: **RMR late** N= 18 (Anfang) / N=18 (Ende) / Alter = 8,16, 0,75 ♂:♀ = 11:7 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated Class III early** N=16 (Anfang) / N=16 (Ende) / Alter = 5,16, 0,66 ♂:♀ = 9:7 • Gebissphase: Milchgebiss • KFO-Behandlung: frühe Behandlung KONTROLLGRUPPE 2: **untreated Class III late** N=15 (Anfang) / N=15 (Ende) / Alter = 8,08, 0,75 ♂:♀ = 9:6 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: **Skeletal: NL-ML, ML-SBL, NL-SBL, A-VertT, B-VertT** SEKUNDÄRZIELGRÖßE: TERTIÄRZIELGRÖßE: QUARTÄRZIELGRÖßE:

Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. Treatment of Class III malocclusion in the **deciduous dentition is able to produce a more significant anterior morphogenetic rotation of the mandible** due to an upward-forward direction of condylar growth, leading to reduced mandibular protrusion and total length; 2. **Maxillary dento-alveolar protrusion induced by treatment is greater in subjects treated at later ages**, whereas **skeletal changes are significantly more evident in children treated in the deciduous dentition.**
Zusammen-fassung der Ergebnisse	**GRUPPE RMR early VS. GRUPPE untreated Class III early** **GRUPPE RMR early VS. GRUPPE untreated Class III late** **GRUPPE RMR late VS. GRUPPE untreated Class III early** **GRUPPE RMR late VS. GRUPPE untreated Class III late** T1 (pre-treatment): mean age 5,08, 0,58 years, RMR early; 5,16, 0,66 untreated Class III early; 8,16, 0,75 RMR late; 8,08, 0,75, untreated Class III late T2 (post treatment/ observation): mean age 7,33, 0,5 years, RMR early; 7,32, 0,66 untreated Class III early; 10,46, 0,58 RMR late; 10,08, 0,75, untreated Class III late **Skeletal: NL-ML, ML-SBL, NL-SBL, A-VertT, B-VertT** 
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung <u>Funding</u> <u>Interessen-konflikte</u> <u>Bias (SIGN)</u>	Die Äquivalenz von Versuch- und Kontrollgruppe wurde nachvollziehbar überprüft. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Eine Verblindung fand nicht statt. Es fehlen Prüfungen zur Reliabilität der Messungen. Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie noch akzeptabel. Die Untersuchung der von RMRs zu verschiedenen Entwicklungsphasen ist von klinischem Interesse, die methodische Qualität insgesamt noch akzeptabel, daher ist die klinische Relevanz dieser retrospektiven Studie mit Einschränkungen gegeben. *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist gegeben. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Eine Verblindung fand nicht statt.
Schluss-	<u>methodische Qualität: akzeptabel</u>

folgerung des Begutachters	Klinische Aussagekraft: Die Untersuchung von RMRs zu verschiedenen Entwicklungsphasen ist von klinischem Interesse, die methodische Qualität insgesamt noch akzeptabel, daher ist die klinische Relevanz dieser retrospektiven Studie mit Einschränkungen gegeben.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Baik, Jee et al. 2004

Treatment effects of Fränkel functional regulator III in children with Class III malocclusions

Hyoung S. Baik, DDS, PhD,[a] Sung H. Jee, DDS,[b] Kee J. Lee, DDS, MS,[c] and Tae K. Oh, DDS[d]
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The purpose of this study was to evaluate the skeletal and dental effects produced by the Fränkel functional regulator III appliance in growing children with Class III malocclusions. Thirty preadolescents (initial mean age, 8.6 ± 1.2 years; mean treatment duration, 1.3 ± 0.6 years) treated with the Fränkel functional regulator III appliance were compared with 20 matched untreated Class III controls (initial mean age 8.2 ± 1.1 years; mean observation period, 1.5 ± 0.6 years). The treatment effects were mainly from backward and downward rotation of the mandible and linguoversion of the mandibular incisors. (Am J Orthod Dentofacial Orthop 2004; 125:294–301)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** Thirty children (17 girls, 13 boys) with Class III malocclusions from the Department of Orthodontics, Yonsei University Dental Hospital, Seoul, Korea Keine Komorbiditäten
Schweregrad	mild or pseudo (functional) Class III malocclusion
Einschluss-kriterien *Bei Review: PICOS*	1. mild or pseudo (functional) Class III malocclusion, 2. minimal facial asymmetry (less than 3 mm of denture midline discrepancy) 3. primary or early mixed dentition, 4. no cleft lip and palate or other systemic disease, 5. no appliances used other than the FR III, and good cooperation during the treatment period (the patients wore the appliance for at least 14 hours per day).
Ausschluss-kriterien	k. A.
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** *FR3-Behandlung* VERSUCHSGRUPPE: **FR3-Gruppe** N=30 (Anfang) / N=30 (Ende) / Alter = 8.0 ± 1.2 Jahre / ♂:♀ = 13:17 • Gebissphase: frühes Wechselgebiss, Milchgebiss • KFO-Behandlung: frühe Behandlung

Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **unbehandelte Gruppe** N=20 (Anfang) / N=20 (Ende) / Alter = 8.2 ± 1.1 Jahre / ♂:♀ = 10:10 • Gebissphase: Milchgebiss, frühes Wechselgebiss • KFO-Behandlung: -
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** Primärzielgröße: Kephalometrisch messbare skelett. &dent. Veränderungen
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	The treatment effects found were mainly from backward and downward rotation of the mandible and linguoversion of the mandibular incisors.

Zusammenfassung der Ergebnisse

GRUPPE FR-3 GRUPPE VS. unbehandelte Gruppe

➔ Keine Signifikanz bezüglich der Parameter, welche einen Effekt auf die Maxilla zeigen könnten.

➔ There was a statistically significant difference between the 2 groups for the horizontal change but no significance in the vertical change (Table V).

➔ The increase in the mandibular plane angle and the decrease in SNB also support the redirection of the mandible

➔ In addition, there was no statistically significant difference in the lengths of the maxilla (MxL) and the mandible (MnL),

➔ There was also no particular significance in the comparison of the vertical changes between the 2 groups.

Dent. Parameter-Ergebnisse s. Tabelle

Table V. Comparison of changes between treatment and control groups

	Treatment group (n = 30)			*Control group (n = 30)*			*Significance*
	T1	*T2*	*T2-T1*	*T1*	*T2*	*T2-T1*	
Horizontal (mm)							
ANS	69.2	70.6	1.4	64.2	65.2	1.0	
A	62.8	64.1	1.3	61.7	62.6	0.9	
PNS	18.6	19.4	0.8	19.1	19.6	0.5	
B	60.3	59.5	−0.8	58.7	60.3	1.7	**
Mx.I	63.7	67.9	4.2	64.6	67.4	2.9	
Mx.M	31.8	33.7	1.9	34.8	36.4	1.6	
Mn.I	66.5	65.3	−1.2	65.8	68.2	2.4	**
Mn.M	38.1	38.3	0.2	37.3	39.7	2.4	*
Vertical (mm)							
ANS	46.6	47.9	1.3	43.8	45.0	1.2	
A	48.1	49.5	1.4	49.4	51.1	1.7	
PNS	10.5	11.9	1.4	41.9	43.6	1.6	
B	86.0	89.4	3.4	91.8	94.7	2.9	
Mx.I	67.8	70.7	2.9	70.9	73.7	2.8	
Mx.M	59.5	62.6	3.1	63.1	65.9	2.8	
Mn.I	66.5	68.8	2.3	69.9	72.7	2.8	
Mn.M	61.7	63.8	2.0	64.1	66.9	2.9	
Angular (°)							
SNA	80.0	81.1	1.1	79.9	80.0	0.1	
SNB	79.8	79.0	−0.8	79.8	80.3	0.5	*
ANB	0.2	2.0	1.9	0.1	−0.3	−0.4	**
PP	2.0	1.8	−0.2	3.3	3.2	−0.1	
MP	29.6	30.4	0.8	33.1	32.5	−0.5	*
UI to SN	103.1	107.8	4.7	105.2	108.7	3.4	
DaPA	89.2	85.8	−3.4	88.6	86.8	−1.8	*
Others (mm)							
MxL	47.2	48.7	1.5	45.2	46.8	1.6	
MnL	103.8	109.5	5.6	106.8	111.4	4.6	
Wits	−6.4	−4.0	2.4	−6.9	−7.3	−0.3	**
Overbite	1.8	1.5	−0.3	0.5	0.7	0.2	
Overjet	−2.2	1.9	4.1	−1.5	−0.9	0.6	**

*$P < .05$, **$P < .01$.
T1, Initial/start of control; *T2*, end of active treatment/end of control.

Angaben auffälliger positiver und/oder negativer Aspekte	*Keine genaue Aussage, ob Auswertung retrospektiv erfolgte oder NRCT vorlag* *Keine genaue Aussage, ob Kontrollgruppe ggf. anderweitige Therapie erhalten hat?* *keine Angabe über Start und End-Jahr bzw. Dauer der Studie* *Ethikvotum nicht erwähnt* *Keine Aussage über mögliche Verblindung bei Auswertung oder Randomisierung* *keine Angabe zu Interessenskonflikten* *keine Aussage, ob ggf. fehlende Compliance Ergebnisse verfälscht hat*
Schluss-folgerung des Begutachters	methodische Qualität: gut
	Klinische Aussagekraft: nicht 100%ig gegeben, da Compliance nicht wirklich überwacht werden kann. Tendenz jedoch auf Patienten übertragbar.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN /AMSTAR II)	**Acceptable (+)**

Evidenztabelle Barrett, Baccetti et al. 2010

ORIGINAL ARTICLE

Treatment effects of the light-force chincup

Aubrey A. F. Barrett,[a] Tiziano Baccetti,[b] and James A. McNamara, Jr[a]
Ann Arbor, Mich, and Florence, Italy

Introduction: The objective of this study was to evaluate the effectiveness of the light-force chincup appliance in correcting the skeletal and dentoalveolar components of Class III malocclusion compared with an untreated Class III control group. **Methods:** The treatment sample consisted of 26 patients (11 boys, 15 girls) treated with the light-force chincup (125-250 g). The mean age at the start of treatment in the chincup group was 8.5 years, with posttreatment cephalograms taken on average 2.6 years later. The control group consisted of 20 subjects. The mean age at the start of observation for the control group (6 boys, 14 girls) was 7.3 years, and the mean time of observation was 2.4 years. Lateral cephalograms were analyzed with a specific tracing regimen at the 2 time points for both groups. Treatment outcome were determined. The treatment group subsequently was subdivided into those treated simultaneously with a quad-helix appliance and those with the chincup only. Mann-Whitney U tests for independent samples were performed to evaluate the differences between the treated and untreated groups at both time points, the changes between the 2 time points, and the differences between the groups treated with the quad-helix and chincup, and the chincup only. **Results:** The chincup sample showed no significant skeletal changes in the mandible in either the vertical or horizontal direction, except for a slight decrease in SNB angle and an increase in ANB angle. There were significant dentoalveolar changes, particularly uprighting of the mandibular incisors. Significant positive Class III treatment outcomes were recorded in the quad-helix group, including a decrease in mandibular length of 1.9 mm compared with the chincup group. **Conclusions:** Fewer than 50% of the subjects treated with the chincup had favorable clinical outcomes. Correction of the initial Class III malocclusion occurred through significant dentoalveolar changes. The light-force chincup did not produce orthopedic changes in the mandible. Maxillary expansion with a quad-helix might aid in the correction of the Class III malocclusion in conjunction with the chincup. (Am J Orthod Dentofacial Orthop 2010;138:468-76)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** Children with occlusal signs of Class III malocclusion • USA
Schweregrad	Wits appraisal of –2 mm or more
Einschluss-kriterien	Occlusal signs of Class III malocclusion with a Wits appraisal of –2 mm or more.
Ausschluss-kriterien	Not fullfilling inclusion criteria

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **Light force CC (± Quad Helix Appliance, QHX):** The chincups and elastic straps were obtained from Summit Orthodontics (Munroe Falls, Ohio). The traction bands were obtained from Orthoband Company (Imperial, Mo). The chincup was fitted on each patient with about 1 in of slack, which resulted in force generation of approximately 150 to 250 g, as measured by a Correx force gauge (Haag-Streit, Koeniz, Switzerland) at the center of the chincup. The subjects in this study were instructed to wear the chincup at night only for at least 1 year. In addition, 12 of the 26 patients were treated with a quad-helix appliance for maxillary expansion. After 1 year, they were evaluated for Class III correction. If Class III correction had been achieved after a year (determined by lack of anterior crossbite and Class I molar and canine relationship), then the chincup was discontinued. If Class III correction was not achieved, chincup wear continued until Class III correction was achieved or the need for surgical intervention was determined. VERSUCHSGRUPPE 1: **Light force CC (± Quad Helix Appliance, QHX)** N= 26 (Anfang) / N=26 (Ende) / Alter = 8,5 ± 1,4 ♂:♀ = 11:15 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated Class III** N=20 (Anfang) / N=20 (Ende) / Alter = 7,3 ± 0,7 ♂:♀ = 6:14 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • dentofaziale Ästhetik PRIMÄRZIELGRÖßE: **Skeletal: SNA, SNB, ANB, Wits** SEKUNDÄRZIELGRÖßE: **Dental: Overjet** TERTIÄRZIELGRÖßE: **Soft tissue: UL- E plane; LL- E plane**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	- (1) The light-force chincupachieves Class III correction in less than 50% of the patients in the short term, and - (2) the **light-force chincup** produces most of its Class III correction through the **dentoalveolar change** of uprighting the mandibular incisors,but it **does not produce enough force for a significant orthopedic change in the mandible.** - **(3) Maxillary expansion with a quad-helix** might aid in the correction of the Class III malocclusion in conjunction with the chincup

Zusammen-fassung der Ergebnisse

GRUPPE Light force CC (± Quad Helix Appliance, QHX) VS. GRUPPE untreated Class III

T1 (pre-treatment): mean age 8,5 years, light force CC; 7,3 years, untreated Class III

T2 (post treatment/ observation): mean age 11,1 years, light force CC; 9,7 years, untreated Class III

Skeletal: SNA, SNB, ANB, Wits

Cephalometric measurement	Chin cup group n = 26		Control group (CG) n = 20		Chin cup vs CG		
	Mean	SD	Mean	SD	Mean difference	P value[1]	
SNA (°)	−0.9	2.1	−0.6	1.5	−0.4	0.406	NS
SNB (°)	−1.1	2.2	0.5	1.1	−1.5	0.010	*
ANB (°)	0.3	1.7	−0.7	1.1	1.1	0.016	*
Wits (mm)	1.5	2.5	−0.1	4.3	1.7	0.102	NS

SNA, SNB, ANB, Wits (QHX vs. CC alone)

Cephalometric measurement	QHX + CC n = 12		CC only n = 14		QHX + CC vs CC only		
	Mean	SD	Mean	SD	Mean difference	P value[1]	
SNA (°)	−0.7	2.3	−0.6	1.6	−0.1	0.876	NS
SNB (°)	−2.2	2.4	−0.6	1.9	−1.6	0.032	*
ANB (°)	0.5	1.8	0.3	1.9	0.2	0.587	NS
Wits (mm)	1.9	2.7	1.7	3.0	−0.2	0.402	NS

*P <0.05; †P <0.01; NS, not significant.
[1]Mann-Whitney U test.

Dental: Overjet

Cephalometric measurement	Chin cup group n = 26		Control group (CG) n = 20		Chin cup vs CG		
	Mean	SD	Mean	SD	Mean difference	P value[1]	
OJ (mm)	3.2	1.7	0.8	1.3	2.6	0.000	†

Overjet, (QHX vs. CC alone)

Cephalometric measurement	QHX + CC n = 12		CC only n = 14		QHX + CC vs CC only		
	Mean	SD	Mean	SD	Mean difference	P value[1]	
OJ (mm)	3.0	1.9	2.7	1.7	1.1	0.021	*

*P <0.05; †P <0.01; NS, not significant.
[1]Mann-Whitney U test.

Soft tissue: UL- E plane; LL- E plane

Cephalometric measurement	Chin cup group n = 26		Control group (CG) n = 20		Chin cup vs CG		
	Mean	SD	Mean	SD	Mean difference	P value[1]	
UL to E plane (mm)	−0.2	1.9	−0.2	2.4	−0.1	0.910	NS
LL to E plane (mm)	−1.5	1.6	0.0	1.6	−1.5	0.003	†

Cephalometric measurement	QHX + CC n = 12		CC only n = 14		QHX + CC vs CC only		
	Mean	SD	Mean	SD	Mean difference	P value[1]	
UL to E plane (mm)	−0.0	1.9	−0.3	2.4	−0.1	0.881	NS
LL to E plane (mm)	−1.5	1.6	−1.3	1.6	−0.2	0.725	NS

*P <0.05; †P <0.01; NS, not significant.
[1]Mann-Whitney U test.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die Äquivalenz von Versuch- und Kontrollgruppe wurde nachvollziehbar überprüft. Power/ Sample Size Berechnungen wurden durchgeführt. Eine Verblindung fand nicht statt. Die Kontrollgruppe ist allerdings aus Patienten der Universität Florenz sowie einer Wachstumstudie (University of Florence from clinic patients who initially refused treatment and subsequently returned seeking intervention and from the University of Michigan Growth Study) generiert, diese könnte zu einer heterogenen Gruppenzusammensetzung führen. Dies sollte bei der Beurteilung der Ergebnisse berücksichtigt werden. Die Subgruppenanalyse (QHX vs. no QHX) war nicht geplant und wurde nachträglich aufgrund der klinischen Beobachtung der Ergebnisse eingeführt. Dies könnte zu Verzerrung führen. Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie noch akzeptabel. Die Untersuchung der light force CC mit einer ergänzenden Quad Helix Apparatur ist von klinischen Interesse, die methodische Qualität insgesamt noch akzeptabel, daher ist die klinische Relevanz dieser retrospektiven Studie mit Einschränkungen gegeben. *Funding:* Supported in part by funds from the Thomas M. and Doris Graber Endowed Professorship in the Department of Orthodontics and Pediatric Dentistry at the University of Michigan. *Interessenkonflikte* The authors report no commercial, proprietary, or financial interest in the products or companies described in this article. *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist gegeben. Power/ Sample Size Berechnungen wurden durchgeführt. Eine Verblindung fand nicht statt. Die Subgruppenanalyse (QHX vs. no QHX) war nicht geplant und wurde nachträglich aufgrund der klinischen Beobachtung der Ergebnisse eingeführt. Dies könnte zu Verzerrung führen.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie noch akzeptabel. Die Untersuchung der light force CC mit einer ergänzenden Quad Helix Apparatur ist von klinischen Interesse, die methodische Qualität insgesamt noch akzeptabel, daher ist die klinische Relevanz dieser retrospektiven Studie mit Einschränkungen gegeben.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Basciftci, Uysal et al. 2003

The effects of activator treatment on the craniofacial structures of Class II division 1 patients

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SUMMARY The aim of the present study was to clarify the skeletal treatment effects induced by activator treatment. Fifty actively growing patients with Class II division 1 malocclusions were treated with an activator appliance. A control group consisting of longitudinal growth data from 20 patients (untreated Class II division 1 malocclusions) was used to eliminate possible differences in growth pattern. Lateral cephalograms of each patient were taken at the start and end of treatment. Final cephalograms were taken after a mean of 16.4 (±2.0) months activator treatment, compared with a mean of 14.2 (±2.4) months for the control group. Each cephalogram was traced and digitized by the same individual. The mean and standard deviations for linear and angular cephalometric measurements were analysed statistically, and intra- and inter-group changes were evaluated by paired- and independent-sample t-tests.

At the end of the study period, the overjet was decreased in all patients. Ramus height, corpus length, anterior and posterior face height all increased significantly ($P < 0.05$). In the treatment group, ANB angle decreased and the bite was opened. The activator appliance caused maxillary incisor lingual tipping and mandibular incisor labial tipping. The overjet was decreased as a result of the increased forward growth of the mandible and dentoalveolar changes. The results demonstrated that the activator appliance has a characteristic skeletal and dental effect on the developing craniofacial complex.

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Children with skeletal Class II malocclusions • Orthodontic Department of Selçuk University, Konya, Turkey
Schweregrad	Versuchsgruppe: ANB > 4 degrees and an overjet greater than 7 mm Kontrollgruppe: similar Class II division 1 malocclusions (ANB > 4 degrees) and an overjet greater than 5 mm
Einschluss-kriterien *Bei Review: PICOS*	Versuchsgruppe: ANB > 4 degrees and an overjet greater than 7 mm Kontrollgruppe: similar Class II division 1 malocclusions (ANB > 4 degrees) and an overjet greater than 5 mm
Ausschluss-kriterien	---

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** The activator appliance consisted of a maxillary block of acrylic with an upper labial wire (0.8 mm) passively contacting the incisal third of the upper central incisors. Acrylic capping covered the incisal third of the mandibular incisors in an attempt to avoid labial tipping of these teeth. The acrylic extended down to the lower lingual sulcus to provide stability and anchorage. The construction bite was taken with the mandible protruded by 4–5 mm and with an interocclusal space of 2–3 mm in the molar region. The interocclusal acrylic in the molar area was not trimmed until improvement of the sagittal jaw relationship was achieved. At the final stage, it was trimmed selectively, according to the desired occlusal movements of the lower molars. The patients were advised to wear the appliance 18 hours a day, but no active effort was made to measure co-operation. VERSUCHSGRUPPE: **Activator Group** N=50 (Anfang) / N=50 (Ende) / Alter = 12,55 ± 1,08 Jahre / ♂:♀ = 26:24 • Gebissphase: spätes Wechselgebiss (anhand Alter) • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** The subjects in the control group were informed about orthodontic therapy but refused treatment. KONTROLLGRUPPE: **Untreated Control Group** N=20 (Anfang) / N=20 (Ende) / Alter = 12,63 ± 0,98 Jahre / ♂:♀ = 10:10 • Gebissphase: spätes Wechselgebiss (anhand Alter) • KFO-Behandlung: keine
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: Skeletal cephalometric treatment effects (siehe Table 1) SEKUNDÄRZIELGRÖßE: Dental cephalometric treatment effects (siehe Table 2)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	This study compared 50 patients treated with an activator appliance with a matched untreated control group. A 16-month treatment period with the activator appliance was found to have significant effects on specific skeletal dimensions of growing individuals. The main findings were: 1. The treatment resulted in a transformation of the Class II molar relationship into a Class I molar relationship. 2. The appliance had little or no effect on the maxillary skeletal structures. No significant differences were observed according to the landmarks considered in both control and treated groups. 3. The growth in mandibular length, ramus height, and corpus length appeared to be significantly influenced by activator treatment. 4. The overjet was decreased by the increased forward growth of the mandible and dentoalveolar changes. Lingual tipping of the maxillary incisors and labial proclination of the mandibular incisors resulted in a significant reduction in overjet for the treated patients. 5. In terms of stability, the achieved results should be evaluated long-term.

Zusammen-fassung der Ergebnisse	Activator Group… VERSUS Untreated Control Group T1-T0 ***PRIMÄRZIELGRÖßE*** Skeletal cephalometric treatment effects *Intergroup comparisons*. The mean differences in the study group were compared with the mean differences in the control group using the Student's *t*-test for unpaired samples. The mean difference for the study group was larger than that for the control group for ramus height, Go–Ar, and Go–PC ($P < 0.01$), corpus length, N–Me, S–Go, Go–Me, and Co–Gn ($P < 0.001$), but smaller for ANB ($P < 0.05$) (Table 1). ***SEKUNDÄRZIELGRÖßE*** Dental cephalometric treatment effects *Intergroup comparisons*. The mean differences in the study group were compared with those in the control group using the Student's *t*-test for unpaired samples. The mean difference in the study group was smaller than in the control group for U1–NA (mm), U1–NA (º), U1–SN, overjet and overbite ($P < 0.001$), but larger for interincisal angle ($P < 0.01$) (Table 2).

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *Retrospektiv* • *Kein Ethikvotum angegeben* • *keine Verblindung bei der FRS-Auswertung angegeben* • *Abweichende Einschlusskriterien (Schweregrad des Overjets) zwischen den beiden Gruppen* • *Unterschiedliche Gruppengröße#* • *Keine Confounders erhoben* • *Keine Langzeiteffekte gemessen* *Durchführung:* • *1 Auswerter, Reliabilitätsprüfung durchgeführt* • *Keine Kontrolle der Compliance hinsichtlich beschriebener 18h-Tragedauer erfolgt* • *Fragliche Kointervention: ggf. MB als Kointervention bei einigen Probanden innerhalb des Erhebungszeitraumes: (*Individual tooth movements are difficult with functional appliances. Therefore, in some cases at the final phase **fixed appliances** were used to achieve bodily and rotational tooth movements and optimal functional occlusion. – 88) *Auswertung:* • *Keine Testung auf Normalverteilung* • *Keine Konfidenzintervalle angegeben* • *Keine näheren Angaben zu Matching zwischen den beiden Gruppen* *Power der Studie/Patientenzahl: keine Poweranalyse angegeben* *Funding: keine Aussage* *Interessenkonflikte: keine Aussage* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • The study indicates how many of the people asked to take part did so, in each of the groups being studied.- NO (SIGN) • The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis. – NO (SIGN) • The main potential confounders are identified and taken into account in the design and analysis.- NO (SIGN) • Have confidence intervals been provided?-NO (SIGN)
Schluss-	methodische Qualität: befriedigend

folgerung des Begutachters	Klinische Aussagekraft: • Die Aktivator-Therapie zeigte keinen signifikanten Einfluss auf skelettale Strukturen des OK. • Die Aktivator-Therapie scheint das Wachstum der UK-Länge, der Ramus-Länge und der Corpus-Länge signifikant zu fördern. • Die Aktivator-Therapie führt zu einer signifikanten Reduktion des Overjets durch Retrusion der OK-Front und Protrusion der UK-Front.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	⊕ Acceptable

Evidenztabelle Bassarelli, Franchi et al. 2016

Original Article

Dentoskeletal effects produced by a Jasper Jumper with an anterior bite plane

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ABSTRACT

Objective: The aim of this retrospective study was to evaluate the dentoskeletal effects produced by a modified Jasper Jumper with an anterior bite plane for the correction of Class II division 1 malocclusion.

Materials and Methods: A sample of 32 growing patients (mean age = 11.9 ± 1.4 years) with Class II division 1 malocclusion and increased overbite were treated with a modified Jasper Jumper (JJ) and anterior bite plane protocol and compared with a matched control group of 30 subjects with untreated Class II malocclusion (mean age 12.2 ± 0.8 years). Lateral cephalograms were taken before treatment (T1) and at the end of comprehensive treatment (T2). Mean treatment duration was 2.1 ± 0.4 years. The T1–T2 changes in the two groups were compared with Student's *t* tests for independent samples.

Results: The JJ group was successfully treated to a Class I occlusal relationship with a significant reduction in overjet (–3.9 mm, $P < .001$) and overbite (–3.1 mm, $P < .001$). The JJ group exhibited a significant increase in mandibular length and a significant improvement in maxillomandibular sagittal skeletal relationships. The lower incisors were significantly proclined, while the lower first molars demonstrated significant movement in a mesial direction.

Conclusions: Use of a modified JJ appliance and anterior bite plane is an effective protocol for the treatment of Class II malocclusion with increased overbite and greater skeletal (75%) than dentoalveolar (25%) effects mainly at the mandibular level. (*Angle Orthod.* 2016;86:775–781.)

KEY WORDS: Class II malocclusion; Jasper Jumper; Bite plane

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Growing subjects. All patients had Class II division 1 malocclusion and none underwent extraction. • JJ-Group: The present study was conducted in a private practice in Prato, Italy. • Untreated Control Group: selected from the American Association of Orthodontists Foundation Craniofacial Growth Legacy Collection (http://www.aaoflegacy collection.org, Michigan Growth Study, Denver Growth Study, and Oregon Growth Study).

Schweregrad	Okklusion: at least ½ cusp distal relation Overjet > 5mm Overbite > 4mm ANB > 4°
Einschluss-kriterien *Bei Review: PICOS*	1. Full permanent dentition 2. Overjet >5 mm 3. Overbite >4 mm 4. Class II molar relationship with at least ½ cusp distal relation 5. ANB greater than 4° 6. Lateral cephalograms available at the beginning and end of treatment
Ausschluss-kriterien	Keine Angabe
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** The JJ appliance was fitted only at the end of the aligning and leveling phase of orthodontic treatment, when a 0.019-inch 3 0.025-inch stainless steel archwire was inserted in both arches. Composite resin (extended up to 7 mm) was bonded on the palatal surface of the two upper central incisors at the same time the JJ was inserted, and debonded occurred at the same time the JJ was removed. The bite JJ appliance was activated with a stepwise advancement (every 60 days) rather than with one-step bite jumping. The size of the JJ appliance was determined following the manufacturer’s instructions. Each spring was attached to the maxillary first molar using a ball pin inserted into the headgear tube. In contrast to the usual JJ protocol, the lower end of the spring was engaged to the mandibular arch between the canine and the first premolar, thus avoiding any contact with the canine bracket, by an auxiliary 0.7 mm stainless steel jig inserted into the hook of the lower molar band on the distal end. This type of insertion at the lower molar allowed to express a single mesial sagittal force closer to the molar CR avoiding any undesirable moment (Figure 1). Patients were controlled at 4-week intervals. VERSUCHSGRUPPE : **JJ-Group** N=32 (Anfang) / N=32 (Ende) / Alter = 11,9 ± 1,4 Jahre / ♂:♀ = 18:14 • Gebissphase: spätes Wechselgebiss/ permanentes Gebiss < 18. Lebensjahr (anhand Alter und festsitzender Apparatur angenommen) („growing subjects“) • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** selected from the American Association of Orthodontists Foundation Craniofacial Growth Legacy Collection (http://www.aaoflegacy collection.org, Michigan Growth Study, Denver Growth Study, and Oregon Growth Study). KONTROLLGRUPPE: **untreated control group** N=30 (Anfang) / N=30 (Ende) / Alter = 12,2 ± 0,8 Jahre / ♂:♀ = 16:14 • Gebissphase: spätes Wechselgebiss / permanentes Gebiss < 18. Lebensjahr (anhand Alter angenommen) • KFO-Behandlung: keine

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Okklusion, Kaufunktion, Funktion PRIMÄRZIELGRÖßE: cephalometric dentoskeletal effects
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	The results suggested that in growing subjects a modified JJ appliance can be an effective device in the treatment of Class II division 1 malocclusions with somewhat deep overbite. The addition of an anterior bite plane could have a positive mandibular skeletal effect in both the sagittal and vertical planes. (In particular, 75% of the sagittal correction was due mainly to mandibular skeletal changes while the remaining 25% of the correction was due to mainly to lower incisor proclination.)
Zusammen-fassung der Ergebnisse	**JJ-Group VS. untreated control group** ***PRIMÄRZIELGRÖßE:*** cephalometric dentoskeletal effects The statistical comparison on the T1-T2 changes for the skeletal measurements between the two groups (Table 2) showed statistically significant differences both in the sagittal and vertical dimensions. While the mandibular base (Pg/OLp) increased significantly (+2.5 mm) together with the mandibular length (Pg/OLp+ Co/OLp, +2.0 mm) in the JJ group, the maxillary base remained unchanged in the control group. With regard to changes in vertical skeletal dimension the JJ group showed significantly greater increases of +1.2 mm in the inclination of the mandible both to the cranial base and to the palatal plane versus the untreated control subjects. When comparing the dentoalveolar changes, the JJ group showed a significant reduction in the overjet (–3.9 mm), the overbite (–3.1 mm), and the molar relationship (–3.5 mm). Significantly more protruded positions of the upper (mi/ OLP minus Pg/OLp) and lower (ms/OLP minus A/OLp) molars were found in the JJ group, but the sagittal positions of the upper and lower incisors presented no significant differences between the two groups. The lower incisors (L1-ML) in the JJ group showed a significantly greater proclination (+4.4°) than the control group.
Angaben auffälliger positiver und/oder negativer Aspekte	*Studiendesign:* • Keine Angabe zum Ethikvotum (retrospektiv) • Umfangreiches Matching erfolgt, keine Baseline-Imbalancen hinsichtlich dentoskelettaler Werte (s.Table 1) • Historische Kontrollgruppe aus USA vs. Versuchsgruppe aus Italien *Durchführung:* • Keine Verblindung angegeben • T2-Erhebung NICHT nach Entfernung des JJ, sondern am Ende der Gesamtbehandlung, d.h. nach Entfernung des JJ noch Finishing mit MB. Treatment time T2-T1 2,1 ± 0,4y, allerdings JJ nur 7 Monate in situ.

	• Multiband (The JJ appliance was fitted only at the end of the aligning and leveling phase of orthodontic treatment, when a 0.019-inch 3 0.025-inch stainless steel archwire was inserted in both arches.) + Turbobites (anterior bite plane) ➢ CAVE: T2-Erhebung nach Entfernung des JJ und Finishing mit MB ➢ CAVE: dies könnte dentale Effekte beeinflussen *Auswertung:* • Reliabilitätsprüfung bei FRS-Auswertung • Solide Statistik, u.a. Normalverteilung geprüft *Power der Studie/Patientenzahl:* • The power of the study was calculated on the basis of the sample size of the two groups and of a clinically significant change in overjet of 1.5 mm with a standard deviation of 1.6 mm. The power exceeded 0.95 at an alpha level of 0.05. *Funding:* This study was not supported by any internal or external funding. *Interessenkonflikte: keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • Selection bias: zwar gutes Matching hinsichtlich dentoskelettaler Paramter aber ggf. Baseline-Imbalance durch Kontrollgruppe amerikanisch vs. Versuchgruppe italienisch. • Siehe RoB: The main potential confounders are identified and taken into account in the design and analysis. NO - Where there is no mention of confounding. (wegen Multiband-Therapie parallel + T2 nicht bei Entfernung des JJ)
Schluss-folgerung des Begutachters	<u>methodische Qualität:</u> gut
	<u>Klinische Aussagekraft:</u> • Durch die Anwendung eines JJ+MB+Turbobites kann gegenüber einer Nichtbehandlung eine signifikante Zunahme der UK-Länge erzielt werden, wobei sich die OK-Basis nicht signifikant verändert. • Durch die Anwendung eines JJ+MB+Turbobites kommt es gegenüber einer Nichtbehandlung zu einer verstärkten Posterior-Rotation des UK. • Durch die Anwendung eines JJ+MB+Turbobites kommt es gegenüber einer Nichtbehandlung zu einer signifikanten Reduktion des Overjets, des Overbites und der Distalverzahnung im Molarenbereich. • Durch die Anwendung eines JJ+MB+Turbobites kommt es gegenüber einer Nichtbehandlung zu einer verstärkten Protrusion der UK-Front ohne signifikante Beeinflussung der sagittalen Position der OK-/UK-Schneidezähne sowie zu einem signikanten Mesialstand der OK- und UK-Molaren.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN /AMSTAR II)	**Acceptable (+)**

Evidenztabelle Batista, K. et al., 2018

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[Intervention Review]

Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children and adolescents

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ABSTRACT

Background

Prominent upper front teeth are a common problem affecting about a quarter of 12-year-old children in the UK. The condition develops when permanent teeth erupt. These teeth are more likely to be injured and their appearance can cause significant distress. Children are often referred to an orthodontist for treatment with dental braces to reduce the prominence of their teeth. If a child is referred at a young age, the orthodontist is faced with the dilemma of whether to treat the patient early or to wait and provide treatment in adolescence.

Objectives

To assess the effects of orthodontic treatment for prominent upper front teeth initiated when children are seven to 11 years old ('early treatment' in two phases) compared to in adolescence at around 12 to 16 years old ('late treatment' in one phase); to assess the effects of late treatment compared to no treatment; and to assess the effects of different types of orthodontic braces.

Search methods

Cochrane Oral Health's Information Specialist searched the following databases: Cochrane Oral Health's Trials Register (to 27 September 2017), the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library, 2017, Issue 8), MEDLINE Ovid (1946 to 27 September 2017), and Embase Ovid (1980 to 27 September 2017). The US National Institutes of Health Ongoing Trials Registry (ClinicalTrials.gov) and the World Health Organization International Clinical Trials Registry Platform were searched for ongoing trials. No restrictions were placed on the language or date of publication when searching the electronic databases.

Selection criteria

Randomised controlled trials of orthodontic treatments to correct prominent upper front teeth (Class II malocclusion) in children and adolescents. We included trials that compared early treatment in children (two-phase) with any type of orthodontic braces (removable, fixed, functional) or head-braces versus late treatment in adolescents (one-phase) with any type of orthodontic braces or head-braces, and trials that compared any type of orthodontic braces or head-braces versus no treatment or another type of orthodontic brace or appliance (where treatment started at a similar age in the intervention groups).

We excluded trials involving participants with a cleft lip or palate, or other craniofacial deformity/syndrome, and trials that recruited patients who had previously received surgical treatment for their Class II malocclusion.

Data collection and analysis

Review authors screened the search results, extracted data and assessed risk of bias independently. We used odds ratios (ORs) and 95% confidence intervals (CIs) for dichotomous outcomes, and mean differences (MDs) and 95% CIs for continuous outcomes. We used the fixed effect model for meta-analyses including two or three studies and the random effects model for more than three studies.

Main results

We included 27 RCTs based on data from 1151 participants.

Three trials compared early treatment with a functional appliance versus late treatment for overjet, ANB and incisal trauma. After phase one of early treatment (i.e. before the other group had received any intervention), there was a reduction in overjet and ANB reduction favouring treatment with a functional appliance; however, when both groups had completed treatment, there was no difference between groups in final overjet (MD 0.22, 95% CI −0.10 to 0.51, P = 0.18; 161 participants) (low-quality evidence) or ANB (MD −0.02, 95% CI −0.47 to 0.43; 147 participants) (moderate-quality evidence). Early treatment with functional appliances reduced the incidence of incisal trauma compared to late treatment (OR 0.56, 95% CI 0.33 to 0.95; 332 participants) (moderate-quality evidence). The difference in the incidence of incisal trauma was clinically important with 30% (51/171) of participants reporting new trauma in the late treatment group compared to only 19% (31/161) of participants who had received early treatment.

Two trials compared early treatment using headgear versus late treatment. After phase one of early treatment, headgear had reduced overjet and ANB; however, when both groups had completed treatment, there was no evidence of a difference between groups in overjet (MD −0.23, 95% CI −0.56 to 0.12; 208 participants) (low-quality evidence) or ANB (MD −0.27, 95% CI −0.80 to 0.26; 231 participants) (low-quality evidence). Early (two phase) treatment with headgear reduced the incidence of incisal trauma (OR 0.45, 95% CI 0.25 to 0.80; 297 participants) (low-quality evidence), with almost half the incidence of new incisal trauma (24/117) compared to the late treatment group (44/120).

Seven trials compared late treatment with functional appliances versus no treatment. There was a reduction in final overjet with both fixed functional appliances (MD −5.46 mm, 95% CI −6.63 to −4.28; 2 trials, 61 participants) and removable functional appliances (MD −4.02, 95% CI −5.33 to −2.82; 3 trials, 122 participants) (low-quality evidence). There was no evidence of a difference in final ANB between fixed functional appliances and no treatment (MD −0.50°, 95% CI −1.27 to −0.22; 3 trials, 89 participants) (low-quality evidence), but removable functional appliances seemed to reduce ANB compared to no treatment (MD −2.31°, 95% CI −3.01 to −1.74; 2 trials, 99 participants) (low-quality evidence).

Six trials compared orthodontic treatment for adolescents with Twin Block versus other appliances and found no difference in overjet (0.08 mm, 95% CI −0.60 to 0.76; 4 trials, 259 participants) (low-quality evidence). The reduction in ANB favoured treatment with a Twin Block (−0.56°, 95% CI −0.96 to −0.16; 6 trials, 320 participants) (low-quality evidence).

Three trials compared orthodontic treatment for adolescents with removable functional appliances versus fixed functional appliances and found a reduction in overjet in favour of fixed appliances (1.74, 95% CI 0.15 to 1.32; two trials, 154 participants) (low-quality evidence), and a reduction in ANB in favour of removable appliances (−1.84°, 95% CI −1.63 to −0.49; 3 trials, 185 participants) (low-quality evidence).

Authors' conclusions

Evidence of low to moderate quality suggests that providing early orthodontic treatment for children with prominent upper front teeth is more effective for reducing the incidence of incisal trauma than providing one course of orthodontic treatment in adolescence. There appear to be no other advantages of providing early treatment when compared to late treatment. Low-quality evidence suggests that, compared to no treatment, late treatment in adolescence with functional appliances, is effective for reducing the prominence of upper front teeth.

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Children (seven to 11 years old) and adolescents (usually 12 to 16 years old) receiving orthodontic treatment to correct prominent upper front teeth (Class II malocclusion).
Schweregrad	Nicht angegeben

Einschluss-kriterien *Bei Review: PICOS*	• Population: Children (seven to 11 years old) and adolescents (usually 12 to 16 years old) receiving orthodontic treatment to correct prominent upper front teeth (Class II malocclusion). • Intervention: o early treatment in children (two-phase) with any type of orthodontic braces (removable, fixed, functional) or head-braces o late treatment in adolescence with any type of orthodontic braces (removable, fixed, functional) or head-braces) • Comparison: o late treatment (one-phase) with functional appliance o late treatment (one-phase) with headgear o no treatment • Outcome: PRIMÄRZIELGRÖßE: Prominence of the upper front teeth **(Overjet** measured in mm or by any index of malocclusion) SEKUNDÄRZIELGRÖßE: Any injury to the upper front teeth (i.e. **incisal trauma**). TERTIÄRZIELGRÖßE: Relationship between upper and lower jaws measured, for example, by **ANB** angle. WEITERE ZIELGRÖßEN: Self-esteem and patient satisfaction Jaw joint problems. Number of attendances required to complete treatment. Harms such as health of the gums, damage to the teeth (e.g. tooth decay) Standard of orthodontic treatment. • Study type: Randomised controlled trials
Ausschluss-kriterien	1. participants with a cleft lip or palate, or both 2. participants with other craniofacial deformity/syndrome 3. trials that recruited patients who had previously received surgical treatment for their Class II malocclusion.

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: • **early treatment in children (two-phase) with any type of orthodontic braces (removable, fixed, functional) or head-braces** • **any type of orthodontic braces or head-braces** N=569 (Anfang) / N=?? (Ende) / Alter = 9-13,25 Jahre / ♂:♀ = ?:? • Gebissphase: frühes bis spätes Wechselgebiss, permanentes Gebiss (< 18. Lebensjahr) • KFO-Behandlung: Frühbehandlung (interzeptiv), reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie, kieferorthopädische Therapie zu anderem Zeitpunkt /Zeitraum /Gebissphase** KONTROLLGRUPPE: • **late treatment in adolescents (one-phase) with any type of orthodontic braces (removable, fixed, functional) or head-braces** • **no treatment** N=346 (Anfang) / N=?? (Ende) / Alter = 9-13 Jahre / ♂:♀ = ?:? • Gebissphase: frühes bis spätes Wechselgebiss, permanentes Gebiss (< 18. Lebensjahr) • KFO-Behandlung: keine Behandlung, reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** • **Okklusion, Kaufunktion, Funktion** • **Traumaprophylaxe (dentales Frontzahntrauma)** • **Reduktion eines weiteren Therapiebedarfs** PRIMÄRZIELGRÖßE: Prominence of the upper front teeth **(Overjet** measured in mm or by any index of malocclusion) SEKUNDÄRZIELGRÖßE: Any injury to the upper front teeth (i.e. **incisal trauma**). TERTIÄRZIELGRÖßE: Relationship between upper and lower jaws measured, for example, by **ANB** angle. WEITERE ZIELGRÖßEN: • Self-esteem and patient satisfaction. • Jaw joint problems. • Number of attendances required to complete treatment. • Harms such as health of the gums, damage to the teeth (e.g. tooth decay). • Standard of orthodontic treatment.

Studientyp	**Systematisches Review mit Meta-Analyse** Inkludierte Studien in Bezug auf PICO: Randomised controlled trials N=27 (N= 10 für LL-relevante Studien) Gesamt-Teilnehmerzahl in Bezug auf PICO: N=1251 (n = 915 für LL-relevante Studien)
Schluss-folgerungen der Autoren	**Implications for practice** Orthodontic **treatment for children, followed by a later phase** of treatment when in adolescence, may significantly **reduce the incidence of incisal trauma** as compared to treatment that is provided in one phase in adolescence. There seem to be **no other advantages for providing a two-phase treatment** in children compared to onephase in adolescence. Orthodontic treatment with functional appliances in **adolescents with prominent upper front teeth appears to significantly reduce the protrusion** of the upper teeth when compared to adolescents who are not treated. **Implications for research** Consideration needs to be given to forming a consensus on the **type of outcome measures** that are used in orthodontic trials; this is particularly relevant for cephalometric measurement and analysis. In addition, studies should be carried out at the same time points and reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Moreover, intention-to-treat analysis should be carried out properly, since attrition bias was the most common risk of bias in this review: it was considered 'high risk' in 8 of the 27 studies.
Zusammen-fassung der Ergebnisse	**1. early treatment in children (two-phase) with any type of orthodontic braces (removable, fixed, functional) or head-braces VERSUS late treatment in adolescents (one-phase) with any type of orthodontic braces (removable, fixed, functional) or head-braces** **2. any type of orthodontic braces or head-braces versus no treatment** ***Subgruppenanalyse:*** *1. early treatment (two-phase) with functional appliance VS late treatment (one-phase) with functional appliance* *2. early treatment (two-phase) with headgear VS late treatment (one-phase) with headgear* 3. *late treatment in adolescence with different types of functional appliances VS no treatment* ***Zeitpunkt des Vergleiches:*** *1. End of phase one for early treatment group, observation only in the late treatment group* 2. *End of phase two*

	Prominence of the upper front teeth (Overjet measured in mm or by any index of malocclusion): **End of phase one** (in case of early treatment: 1., 2.) 1. early treatment (two-phase) with functional appliance VS late treatment (one-phase) with functional appliance: The metaanalysis showed that there was a statistically **significant difference in the overjet in favour of the treated group at the end of phase one** (mean difference (MD) −4.17 mm, 95% confidence interval (CI) −4.61 to −3.73, Chi2 = 117.02, 2 degrees of freedom (df), P value < 0.00001, I2 = 98%; three studies, 432 participants) (Analysis 1.1). 2. early treatment (two-phase) with headgear VS late treatment (one-phase) with headgear: The comparison of the effect of treatment with headgear at the end of phase one (early treatment group), compared with observation (late treatment group), revealed a statistically **significant effect of headgear treatment**, in the reduction of the overjet (MD −1.07 mm, 95% CI −1.63 mm to −0.51 mm, Chi2 = 0.05, 1 df, P value = 0.0002, I2 = 0%; 278 participants **End of phase two** (in case of early treatment: 1., 2.) 1. early treatment (two-phase) with functional appliance VS late treatment (one-phase) with functional appliance: **no statistically significant differences in final overjet** (MD 0.21 mm, 95% CI −0.10 mm to 0.51 mm, Chi2 = 5.23, 2 df, P value = 0.18, I2 = 62%; 343 participants) 2. early treatment (two-phase) with headgear VS late treatment (one-phase) with headgear**: no statistically significant effects** of an early course of headgear treatment in childhood followed by treatment in adolescence with respect to final overjet (MD −0.22 mm, 95% CI −0.56 mm to 0.12 mm, Chi2 = 1.27, 1 df, P value = 0.20, I2 = 21%; 238 participants) 3. late treatment in adolescence with different types of functional appliances VS no treatment: There was evidence of **a reduction in overjet** with both removable functional appliances (MD −4.62, 95% CI -5.33 to -3.92, P < 0.00001; three trials, 122 participants) and fixed functional appliance (MD −5.46, 95% CI −6.63 to −4.28, P < 0.00001; two trials, 61 participants) when compared with no treatment **Any injury to the upper front teeth (i.e. incisal trauma):** **End of phase one:** 1. early treatment (two-phase) with functional appliance VS late treatment (one-phase) with functional appliance: Early treatment did **not show any significant difference in […] incidence of new incisal trauma at the end of phase 1** (odds ratio (OR) 0.72, 95% CI 0.35 to 1.49, P value = 0.38; two trials, 281 participants) (Analysis 1.2) when compared with untreated control group participants. 2. early treatment (two-phase) with headgear VS late treatment (one-phase) with headgear**: no statistically significant difference in new incisal trauma** (OR 0.76, 95% CI 0.37 to 1.54, Chi2 = 0.66, 1 df, P value = 0.44, I2 = 0%) between the two groups

	End of phase two: 1. early treatment (two-phase) with functional appliance VS late treatment (one-phase) with functional appliance: the incidence of new incisal trauma showed a **statistically significant difference, in favour of early functional appliance** treatment in childhood (two-phase) (OR 0.56, 95% CI 0.33 to 0.95, Chi2 = 1.98, 2 df, P value = 0.03, I2 = 0%; 332 participants) (Analysis 1.6) compared with late orthodontic treatment during adolescence (one-phase). The reduction in the incidence of new incisal trauma by the end of phase two **was clinically significant** with 30% (51/171) of participants reporting new trauma incidence in the late treatment group compared to only 19% (31/161) in the early treatment group. 2. early treatment (two-phase) with headgear VS late treatment (one-phase) with headgear: the incidence of new incisal trauma showed a **statistically significant reduction** in the earlier treatment (two-phase) group (OR 0.45, 95% CI 0.25 to 0.80, Chi2 = 1.15, 1 df, P value = 0.007, I2 = 13%; 237 participants) (Analysis 1.8). The group who had late treatment in adolescence (one-phase) suffered twice the incidence of new incisal trauma (44/120) as compared to the group who had early headgear treatment (two-phase) in childhood (24/117). **Relationship between upper and lower jaws measured, for example, by ANB angle:** **End of phase one:** 1. early treatment (two-phase) with functional appliance VS late treatment (one-phase) with functional appliance: When we evaluated the effect of treatment on final ANB, we found that there was a **statistically significant mean difference between the treatment and control groups in favour of functional appliance treatment** (MD −0.89°; 95% CI −1.38° to −0.40°, Chi2 = 9.17, 2 df, P value = 0.0004, I2 = 78%; three studies, 419 participants). 2. early treatment (two-phase) with headgear VS late treatment (one-phase) with headgear: headgear resulted in a statistically **significant reduction** of −0.72° (95% CI −1.18° to −0.27°, Chi2 = 0.34, 1 df, P value = 0.002, I2 = 0%; 277 participants) in final ANB **End of phase two** 1. early treatment (two-phase) with functional appliance VS late treatment (one-phase) with functional appliance: **no statistically significant differences in […] final ANB** (MD −0.02°; 95% CI −0.47° to 0.43°, Chi2 = 2.62, 2 df , P value = 0.92, I2 = 24%; 347 participants) 2. early treatment (two-phase) with headgear VS late treatment (one-phase) with headgear: **no statistically significant effects** of an early course of headgear treatment in childhood followed by treatment in adolescence with respect to […] final ANB (MD −0.27°, 95% CI −0.80° to 0.26°, Chi2 = 0.10, 1 df, P value = 0.32, I2 = 0%; 231 participants) 3. late treatment in adolescence with different types of functional appliances VS no treatment: **There was no evidence of a clear difference between use of the fixed appliance and no treatment for final ANB** (MD −0.53, 95% CI −1.27 to −0.22, P = 0.17; three trials, 89 participants) (Analysis 3.2). However, the **removable functional appliance reduced ANB significantly compared to no treatment** (MD −2.37°, 95% CI -3.01 to -1.74, P < 0.00001; two trials, 99 participants) ***für weitere Zielgrößen wurde keine Meta-Analyse erstellt***

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: nur RCTs eingeschlossen, umfangreiches Review mit 2 verschiedenen Verlgeichen (early vs. late treatment & late vs. no treatment)* *Durchführung: gute RoB-Analyse, umfangreiche Literaturrecherche, Methode der Literatursichtung & Datenextraktion & RoB-Analyse durch zwei unabhängige Auswerter, ausführliche Beschreibung der eingeschlossenen Einzelstudien* *Auswertung: Meta-Analyse nur bei vergleichbaren Outcomes durchgeführt, Subgruppenanalyse durch Aufteilung der verschiedenen KFO-Geräte, keine gleichmäßige Verteilung in Kontroll- & Versuchsgruppe (569 vs. 346)* *Power der Studie/Patientenzahl: 10/915 (LL-relevnat, insgesamt 27/1251)* *Funding:* **Internal sources** • The Royal Liverpool and Broadgreen University Hospitals NHS Trust, UK. • School of Dentistry, The University of Manchester, UK. • Manchester Academic Health Sciences Centre (MAHSC) and NIHR Manchester Biomedical Research Centre, UK. **External sources** • NHS National Primary Dental Care R&D programme PCD97-303, UK. • Cochrane Oral Health Global Alliance, Other. The production of Cochrane Oral Health reviews has been supported financially by our Global Alliance since 2011 (oralhealth.cochrane.org/partnerships-alliances). Contributors over the past year have been the American Association of Public Health Dentistry, USA; the British Association for the Study of Community Dentistry, UK; the British Society of Paediatric Dentistry, UK; the Canadian Dental Hygienists Association, Canada; the Centre for Dental Education and Research at All India Institute of Medical Sciences, India; the National Center for Dental Hygiene Research & Practice, USA; New York University College of Dentistry, USA; NHS Education for Scotland, UK; and the Swiss Society for Endodontology, Switzerland. • National Institute for Health Research (NIHR), UK. This project was supported by the NIHR, via Cochrane Infrastructure funding to Cochrane Oral Health. The views and opinions expressed herein are those of the review authors and do not necessarily reflect those of the Systematic Reviews Programme, the NIHR, the NHS or the Department of Health. *Interessenkonflikte:* Klaus BSL Batista: no interest to declare. Kevin O'Brien was involved in acquiring funding, running and reporting of the UK (11-14) 2003, UK (Mixed) 2009 and Banks 2004 trials; however, he was not involved in the quality assessment of these trials. Badri Thiruvenkatachari and Helen Worthington (author on previous versions) are among the authors of UK (Mixed) 2009; however, they were not involved in the risk of bias assessment of this trial. Helen V Worthington is a Co-ordinating Editor with Cochrane Oral Health. Badri Thiruvenkatachari and Kevin O'Brien were involved in running and reporting the Thiruvenkatachari 2010 (Dynamax) study; however, they were not involved in the quality assessment of this trial. Jayne E Harrison: no interest to declare. Dr Harrison is an Editor with Cochrane Oral Health.

	Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten): **2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?** **3. Did the review authors explain their selection of the study designs for inclusion in the re** **11. If meta-analysis was performed did the review authors use appropriate methods for st combination of results?** **14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?** **15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the resul review?** *Publikationsbias (Reviews):* we planned to examine the effect of including unpublished literature, but there were insufficient trials to undertake this.
Schluss-folgerung des Begutachters	methodische Qualität: Review gut, Einzelstudien z.T. mit hohem RoB (6/10 LL-relevanten Studien)
	Klinische Aussagekraft: Prominente obere Frontzähne scheinen in Klasse-II-Patienten, die sich entweder einer 2-Phasen-Therapie mit frühem Beginn im Kindesalter oder einer regulären 1-Phasen-Therapie im Jugendalter unterziehen, durch eine kieferorthoädische Behandlung korrigiert werden zu können. Bei einem Vergleich der 1- und 2-Phasen-Therapie scheint die umfangreichere 2-Phasen-Behandlung durch das reduzierte Frontzahntrauma-Risiko der späteren 1-Phasen-Therapie überlegen zu sein. Alle weiteren Korrekturen der Malokklusion werden aber wohl auch gleichermaßen durch einen späteren Behandlungsbeginn im jugendlichen Alter behoben.
Evidenz-level (SIGN)	**1+**
Qualität (RoB, SIGN /AMSTAR II)	**Moderat ⊕⊕**

Evidenztabelle Battagel, Orton 1991

Class III malocclusion: a comparison of extraction and non-extraction techniques

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SUMMARY A retrospective cephalometric study was made of the hard tissue changes in a group of 90 Class III, Skeletal III children, diagnosed as suitable for treatment by orthodontic means alone. Thirty-two were treated by a combination of upper incisor proclination and headgear to an intact mandibular dentition (Group 1), while in 28 the overjet was corrected with mid-arch extractions and Edgewise mechanics (Group 2). The remaining 30 children acted as controls (Group 3).

Children were initially examined as male and female subgroups, and where no significant differences were seen data were pooled. In order to standardize the results, treatment/observation effects were presented as average changes per year.

The three groups were essentially comparable pretreatment. Following overjet correction, the lower incisors uprighted in both groups, with an improved relationship to the A–Po line: the upper incisors were proclined in Group 1 only. Underlying skeletal changes were restricted to the mandible, which showed a downward and backward hinging, and an increase in lower face height. The improved mandibular position was significantly greater in the non-extraction group and was accompanied by an improvement in facial convexity. In addition, treatment could be started earlier and was completed in a significantly shorter time (Table 1).

It would, therefore, appear that, in the short term at least, a non-extraction/headgear approach has advantages over a standard mid-arch extraction/Edgewise technique.

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** - Patients with Class III malocclusion, deep overbite and reverse overjet and/ or forward mandibular displacement • UK
Schweregrad	a corrected ANB analysis showed a difference of less than 1.5 degrees
Einschluss-kriterien	(1) Class III (a corrected ANB analysis showed a difference of less than 1.5 degrees) (2) deep overbite and reverse overjet (3) forward mandibular displacement.
Ausschluss-kriterien	- Not fullfilling inclusion criteria

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **HG non extraction** The headgear was attached to a removable appliance as described by Orton *et al.* (1983) and no independent movement of the lower labial segment was attempted. **MB extraction** Patients were treated by the extraction of lower premolars and standard Edgewise mechanics to retract and align the lower labial segment, and align the upper arch. A few patients had upper extractions where this was necessary to relieve crowding. VERSUCHSGRUPPE 1 **HG non extraction** N= 32 (Anfang) / N=32 (Ende) / Alter = 12,66, 1,84 years ♂:♀ = 19:13 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE 1 **MB extraction** N= 28 (Anfang) / N=28 (Ende) / Alter = 13,33, 1,52 years ♂:♀ = 11:17 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** Untreated Class III Control group children (19 males and 11 females) were drawn from two sources. Some had declined therapy because they considered their occlusions satisfactory and/or did not wish to co-operate with the extra-oral appliances. Others had accepted therapy, but were still on a hospital waiting list pending the start of treatment. KONTROLLGRUPPE 1: **Untreated Class III (Control)** N=12 (Anfang) / N=18 (Ende) / Alter = = 12,38, 2,07 years ♂:♀ = 19:11 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: **Skeletal: SNA, SNB, ANB, Wits** SEKUNDÄRZIELGRÖßE: **Dental: Overjet**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren

Successful orthodontic treatment of the Class III, Skeletal III malocclusion is **accompanied by at least short-term dental and mandibular skeletal changes**. These effects are **greater when a nonextraction approach, using headgear to an intact mandibular dentition is used**, rather than a conventional extraction/Edgewise approach.

1. **Lower incisors move lingually during the application of headgear**, on average by 4.6 degrees. This facilitates overjet correction.

2. There **is a 1 degree per year improvement in ANB, when compared with a Class III control group.** This is due to a reduction in SNB in association with a downward and backward repositioning of the mandible.

3. There is **no improvement in the position of'A' point**.

4. The **facial convexity increases** as the chin point moves posteriorly.

However, this (**HG) approach** must normally be limited to those children whose lower arch **crowding is either absent or very mild**.

Zusammen-fassung der Ergebnisse

GRUPPE HG non extraction VS. Untreated Class III (Control)

GRUPPE MB extraction VS. Untreated Class III (Control)

T0 (pre-treatment) : 12,66, 1,84 years, HG non extraction; 13,33, 1,52 years, MB extraction ; 12,38, 2,07 years untreated Class III (Control)

T1 (post-treatment): 14,52, 0,72 years, HG non extraction; 15,64, 1,67 years, MB extraction ; 15,34, 2,56 years untreated Class III (Control)

Skeletal: SNA, SNB, ANB

Measurement	Group 1 (non-extraction)	Group 2 (extraction)	Group 3 (control)	Significance
Angular				
SNA	0.08 ± 0.77	−0.01 ± 0.80	0.04 ± 0.49	
SNB	−0.64 ± 1.13	−0.20 ± 0.67	0.21 ± 0.63	I (III)
ANB	0.73 ± 0.89	0.19 ± 0.90	−0.26 ± 0.56	I (II, III)

Dental: Overjet

Measurement	Group 1 (non-extraction)	Group 2 (extraction)	Group 3 (control)	Significance
Overjet	1.41 ± 1.57	0.59 ± 0.79	0.07 ± 0.33	I (II, III)

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Äquivalenz von Versuchs- und Kontrollgruppen möglicherweise eingeschränkt. Dies ist gezeigt für Alter und Therapie/ Beobachtungszeitraum. Baseline characteristics (skeletal, denta,l) sind angegeben aber statistisch verglichen. Die Zuordnung zu den Behandlungsgruppen erfolgte nach klinischen Kriterien. Dies bedeutet 1. Die Behandlungsgruppe war heterogen und 2. Es gibt selction bias. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Die Auswertung war nicht verblindet. Retrospektive Studie mit hohem Risiko für Bias (Alter, Behandlungs-/ Beobachtungszeitraum, Behandlung), daher mit sehr deutlichen Schwächen in der Durchführung. Die klinische Relevanz ist entsprechend sehr stark eingeschränkt. *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe *Bias (SIGN):* Äquivalenz von Versuchs- und Kontrollgruppen möglicherweise eingeschränkt. Dies ist gezeigt für Alter und Therapie/ Beobachtungszeitraum. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Eine Verblindung fand nicht statt.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel Klinische Aussagekraft: Retrospektive Studie mit Risiko für Bias (Alter, Behandlungs-/ Beobachtungszeitraum, Behandlung), daher mit Schwächen in der Durchführung. Die klinische Relevanz ist entsprechend eingeschränkt.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**acceptable (+)**

Evidenztabelle Battagel, Orton 1995

A comparative study of the effects of customized facemask therapy or headgear to the lower arch on the developing Class III face

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SUMMARY This retrospective, cephalometric study examined the effects of treatment in a group of 83 Class III, Skeletal III children, who were considered suitable for orthodontic correction of their malocclusions. All children completed therapy successfully: 44 individuals were treated with headgear to the mandibular dentition and for 39 a customized facemask was prescribed. These two groups were compared with 30 untreated Class III controls.

Data were examined at the beginning and end of active treatment for the treated groups, and over a similar time interval for the controls. Where differences between the sexes were apparent, data for each sex are given separately. Where no significant differences were seen, data are pooled. In order to standardize the results, treatment (or observation) effects are presented as average changes per year.

Surprisingly, despite the very different methods of applying the extra-oral force, the two treated groups showed strikingly similar therapeutic effects. The reverse overjet was corrected with little alteration in overbite. Upper incisors proclined whilst the lowers retroclined, becoming less prominent in relation to APo. The mandible hinged downwards and backwards, whilst the maxillary complex advanced. Lower face height increased more than would be expected by growth alone. Mirroring the hard tissue changes, the soft tissue profile improved and the relationship between the upper and lower lips became more harmonious.

For only three parameters did the facemask children demonstrate a significantly better performance than their headgear peers: the overjet and the antero-posterior position of the lower lip and chin in females.

It was concluded that, despite their differing approaches, the customized facemask and headgear to the mandibular dentition have very similar treatment effects. Both are clinically effective. However, treatment can begin earlier, and both the skeletal and profile changes are marginally superior when a facemask is worn.

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** - Patients with Class III malocclusion, deep overbite and reverse overjet and/ or forward mandibular displacement • UK
Schweregrad	a corrected ANB analysis showed a difference of less than 1.5 degrees
Einschluss-kriterien	1) Class III (a corrected ANB analysis showed a difference of less than 1.5 degrees) (2) deep overbite and reverse overjet (3) forward mandibular displacement.
Ausschluss-kriterien	- Not fullfilling inclusion criteria

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **HG:** Headgear, no details given **FM:** Facemasks with aremovable appliance and forces of 100-200 g per side. VERSUCHSGRUPPE 1 **HG** N= 41 (Anfang) / N=41 (Ende) / Alter = 12,4, 2,0 years ♂:♀ = 27:17 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE 1 **FM** N= 39 (Anfang) / N=39 (Ende) / Alter = 10,8, 1,8 years ♂:♀ = 19:20 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** Untreated Class III Control group children (12 males and 18 females) were drawn from two sources. Some had declined therapy because they considered their occlusions satisfactory and/or did not wish to co-operate with the extra-oral appliances. Others had accepted therapy, but were still on a hospital waiting list pending the start of treatment. KONTROLLGRUPPE 1: **Untreated Class III (Control)** N=12 (Anfang) / N=18 (Ende) / Alter = = 12,4, 2,1 years ♂:♀ = 12:18 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • dentofaziale Ästhetik PRIMÄRZIELGRÖßE: **Skeletal: SNA, SNB, ANB, Wits** SEKUNDÄRZIELGRÖßE: **Dental: Overjet** TERTIÄRZIELGRÖßE: **Soft tissue: Facial Convexity** QUARTÄRZIELGRÖßE:
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	1. **Both** the customized facemask and headgear to the mandibular dentition **are clinically effective techniques.** 2. **Both** types of therapy **have very similar treatment effects**. 3. The **mandible** shows an **anti-clockwise rotation** and the **lower incisors are uprighted**. This leads to a proportionate increase in lower facial height. 4. In the **facemask group** only, **forward development of the maxilla is seen**. This is associated with more positive labial development of the upper incisors. 5. Treatment with **the facemask can begin significantly earlier** than if headgear to the mandibular dentition is prescribed. 6. Further study is required to examine the behaviour of the facemask treated children once all treatment and retention have ceased..
Zusammen-fassung der Ergebnisse	**GRUPPE HG VS. GRUPPE Untreated Class III (Control)** **GRUPPE FM VS. GRUPPE Untreated Class III (Control)** T0 (pre-treatment) : 12,4, 2,0 years, HG; 10,8, 1,8 years, FM; 12,4, 2,1 years untreated Class III (Control) T1 (post-treatment): 14,5, 2,3 years, HG; 12,9, 2,2 years, FM; 15,3, 2,6 years untreated Class III (Control) **Skeletal: SNA, SNB, ANB** Lower arch headgear / Customized facemask / Controls Variable: Skeletal measurements SNA degrees: 0.3 (0.9) / 0.4 (0.8) / 0.0 (0.5) / none SNB degrees: −0.3 (0.8) / −0.6 (1.0) / 0.2 (0.6) / EOT & facemask from control ANB degrees: 0.5 (0.8) / 0.9 (1.0) / −0.2 (0.5) / EOT & facemask from control **Dental: Overjet** Lower arch headgear / Customized facemask / Controls Variable: Skeletal measurements Overjet mm: 1.4 (1.2) / 2.3** (1.5) / 0.1 (0.3) / EOT and facemask from control and EOT from facemask **Soft tissue: Facial Convexity** Lower arch headgear / Customized facemask / Controls Variable: Skeletal measurements Facial convexity (male) degrees: −1.7 (1.5) / −2.0 (1.4) / −0.3 (0.7) / EOT and facemask from control Facial convexity (female) degrees: −1.5 (1.6) / −2.2 (2.1) / −0.3 (0.9) / Facemask from control

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Äquivalenz von Versuchs- und Kontrollgruppen möglicherweise eingeschränkt. Dies ist gezeigt für Alter und Therapie/ Beobachtungszeitraum. Baseline characteristics (skeletal, dental soft tissue) sind angegeben aber statistisch verglichen. Die Zuordnung zu den Behandlungsgruppen erfolgte nach klinischen Kriterien. Dies bedeutet 1. Die Behandlungsgruppe war heterogen und 2. Es gibt selction bias. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Die Auswertung war nicht verblindet. Retrospektive Studie mit hohem Risiko für Bias (Alter, Behandlungs-/ Beobachtungszeitraum, Behandlung FM vs. HG), daher mit sehr deutlichen Schwächen in der Durchführung. Die klinische Relevanz ist entsprechend sehr stark eingeschränkt. *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe *Bias (SIGN):* Äquivalenz von Versuchs- und Kontrollgruppen möglicherweise eingeschränkt. Dies ist gezeigt für Alter und Therapie/ Beobachtungszeitraum. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Eine Verblindung fand nicht statt.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel Klinische Aussagekraft: Retrospektive Studie mit Risiko für Bias (Alter, Behandlungs-/ Beobachtungszeitraum, Behandlung FM vs. HG), daher mit Schwächen in der Durchführung. Die klinische Relevanz ist entsprechend sehr stark eingeschränkt.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**acceptable (+)**

Evidenztabelle Bavbek, Tuncer et al. 2016

Changes in airway dimensions and hyoid bone position following class II correction with forsus fatigue resistant device

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Abstract

Objective The objective of this study was to investigate the effects of fixed functional therapy on oropharyngeal airway dimensions and hyoid bone positions in Class II patients and make comparison with an untreated Class II group.

Materials and methods Eighteen patients (8 girls, 10 boys; mean age 13.62 ± 1.02 years) who were treated with Forsus Fatigue Resistant Device (FFRD) and 19 patients (11 girls, 8 boys; mean age 12.74 ± 0.91 years) who served as control were enrolled. Cephalograms were used to assess linear, angular, and area measurements. Intragroup comparisons were made by paired *t* and Wilcoxon tests and intergroup comparisons were performed by independent *t* test.

Results With respect to controls, FFRD group showed increased airway dimensions at soft palate ($P < 0.05$) and more forward positioning of the hyoid bone ($P < 0.05$). Dentoalveolar changes exhibited mesial movement of lower incisors and molars and reduction in overjet ($P < 0.001$) in FFRD group.

Conclusions Positive effects in oropharyngeal airway dimensions and increased values of hyoid bone displacement to a more forward position were found after fixed functional therapy.

Clinical Relevance Treatment with fixed functional appliances is mostly based on mesial movement of mandibular dentition, which might influence changes in tongue posture. The present results might indicate that oropharyngeal airway dimensions may be affected by postural changes of the hyoid bone in consequence of dentoalveolar changes. Clinically, these may be considered especially in Class II cases with reduced airway dimensions.

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Patients with class II malocclusion who were after the pubertal growth spurt or at the late stages of puberty • selected from the archives of the Department of Orthodontics, Gazi University, Turkey

Schweregrad	ANB > 4° SNB < 80° OJ > 5mm SN/GoGn 32 ± 6° CAVE: gilt nur für Versuchsgruppe, Kontrollgruppe lediglich in 3 Punkten gematched (were matched according to their chronological ages and sagittal (ANB°) and vertical (SN/GoGn°) skeletal patterns (Table 1)).
Einschluss-kriterien *Bei Review: PICOS*	1. Skeletal (ANB > 4°) and dental Class II malocclusion with mandibular retrusion (SNB < 80°) and increased overjet (>5 mm) 2. Optimal mandibular plane angle (SN/GoGn 32 ± 6°) 3. Patients who were after the pubertal growth spurt or during the late stages of puberty 4. No functional shift or dual bite 5. No congenital anomalies causing changes in airway dimensions 6. No medical history about a respiratory problem or an upper airway surgery 7. Presence of good quality lateral cephalograms and hand and wrist radiographs at the beginning (after alignment) and at the end of FFRD phase (after Class I molar and canine relationships were achieved) CAVE: Einschlusskriterien gelten nur für Versuchsgruppe, Kontrollgruppe lediglich in 3 Punkten gematched (were matched according to their chronological ages and sagittal (ANB°) and vertical (SN/GoGn°) skeletal patterns (Table 1)).
Ausschluss-kriterien	Keine Angabe
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Fixed orthodontic treatment with Roth metal brackets (0.018” slot size prescription); rods of FFRD placed from buccal tubes of the upper first molar bands to the arch wire between lower canines and first premolars (Fig. 1); no modifications during FFRD appliance (mini-implants, rapid maxillary expansion, lingual fixed appliances, extra root torque to lower incisors); FFRD was applied after alignment of teeth; and 0.017 × 0.025 in. stainless steel wires were inserted passively to both arches and cinched distal to the lower molars. Force is generated via the compression of the coil spring, and the force acts on both dental arches in opposite directions (distal force in maxilla and mesial force in the mandible) (Fig.1b). VERSUCHSGRUPPE : **FFRD group** N=18 (Anfang) / N=18 (Ende) / Alter = 13,62 ± 1,92 Jahre / ♂:♀ = 10:8 • Gebissphase: permanentes Gebiss < 18. Lebensjahr (anhand Alter und festsitzender Apparatur angenommen) (after the pubertal growth spurt or at the late stages of puberty) • KFO-Behandlung: reguläre Behandlung

Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated control group** N=19 (Anfang) / N=19 (Ende) / Alter = 12,74 ± 0,91 Jahre / ♂:♀ = 8:11 • Gebissphase: spätes Wechselgebiss / permanentes Gebiss < 18. Lebensjahr (anhand Alter angenommen) • KFO-Behandlung: keine
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Atmung und Luftraum (Airway space, Schlafapnoe), Schlucken und Sprechen PRIMÄRZIELGRÖßE: Cephalometric dentoskeletal changes SEKUNDÄRZIELGRÖßE: Cephalometric airway changes TERTIÄRZIELGRÖßE: Cephalometric hyoid bone position changes
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	In conclusion, findings of this study demonstrated prominent mesialization of the lower incisors and molars, forward positioning of the hyoid bone, and increased airway dimensions with the usage of FFRD appliance. In a clinical perspective, beneficial effects of these appliances on pharyngeal airway dimensions should be considered in Class II patients, especially for the ones with respiratory problems. However, since these findings represent the early effects of the appliance, studies are still needed to evaluate the long-term effects of fixed functional appliances on pharyngeal airway morphology.
Zusammen-fassung der Ergebnisse	**FFRD group VS. untreated control group** ***PRIMÄRZIELGRÖßE:*** cephalometric dentoskeletal changes In Table 3, comparisons of mean differences between groups are presented. Increases in vertical maxillary and mandibular measurements were more prominent in the control group when compared with those in FFRD group (S-ANS, N-PNS, P < 0.01; S-PNS, P < 0.05; S-Go, P < 0.01; N-Me, P < 0.001). The FFRD group displayed 2.81 mm mesial movement of lower incisors, while control group displayed only 0.44 mm mesialization, declaring a significant difference at 0.001 level between groups. There was also more mesial movement of lower first molars in FFRD group by 1.33 mm, relative to controls (P < 0.001). Reduction in overjet by 3.5 mm was prominent in FFRD group, when compared with that in the control group (P < 0.001). ***SEKUNDÄRZIELGRÖßE:*** Cephalometric airway changes Pharyngeal airway measurements showed group differences at several levels. SPS increased 1.06 mm and MPS increased 1.28 mm, while there were reductions in the control group at these levels (P < 0.05, respectively). ***TERTIÄRZIELGRÖßE:*** Cephalometric hyoid bone position changes Increase in the vertical movement of the hyoid bone was significantly higher in the control group by 2.05 mm in relation to FFRD group(H-SN, P < 0.001). However, forward movement of the hyoid bone was more prominent in FFRD group (1.68 mm) than in the control group (0.84 mm) (C3-H, P < 0.05).

Angaben auffälliger positiver und/oder negativer Aspekte
Studiendesign
Durchführung
Auswertung
Funding
Interessen-konflikte
Bias (SIGN, AMSTAR II, Einzelstudien)
	Studiendesign:
	• zwar Matching der Versuchs- und Kontrollgruppe erwähnt, jedoch nur hinsichtlich dreier Parameter, keine Matching für Parameter, die Aussagen über Airway-Space treffen (signifikante Unterschiede zwischen relevanten Paramtern?)
	Durchführung:
	• Keine Verblindung angegeben
	• T2-Erhebung nach Entfernung des FFRD, somit fließen keine Finishing-Effekte durch Multiband in Auswertung mit ein
	• Mulitband zwar parallel eingesetzt, jedoch passive Stahlbögen, sodass (bei Annahme kompletter Passivität) keine Zahnbewegungen durch MB alleine induziert
	• Beurteilung des Airway-Space lediglich anhand zweidimensionaler Auswertungen – daher keine Aussage in der Transversalen (dritten Raumdimension möglich)
	Auswertung:
	• Reliabilitätsprüfung bei FRS-Auswertung
	• Adäquate / geeignete Statistik, u.a. Normalverteilung geprüft
	Power der Studie/Patientenzahl: Sample size was calculated with a statistical power of 0.80, and the number of patients per group was required to be minimum 17.
	Funding: keine Angabe
	Interessenkonflikte: The authors declared that they have no conflict of interest.
	Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):
	• Selection bias: Einschlusskriterien gelten nur für Versuchsgruppe, Kontrollgruppe lediglich in 3 Punkten gematched (were matched according to their chronological ages and sagittal (ANB°) and vertical (SN/GoGn°) skeletal patterns (Table 1)). Kein Matching für Parameter, die Aussagen über Airway-Space oder Position des Hyoids treffen (Fragestellung der Studie)!
	• Siehe RoB:
	  ○ The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis. NO - Where no mention is made of this possibility. (Aufgrund von Matching der Versuchs- und Kontrollgruppe in nur 3 Parametern)
	  ○ The main potential confounders are identified and taken into account in the design and analysis. NO - Where there is no mention of confounding. (mögliche Störgrößen nicht genannt)

Schluss-	methodische Qualität: befriedigend

folgerung des Begutachters	Klinische Aussagekraft: Durch die Anwendung eines FFRD kommt es gegenüber einer Nichtbehandlung zu: • einer Zunahme des Vertikalwachstums von OK und UK • einer signifikant größeren Mesialbewegung der unteren Incisivi und unteren Molaren • zu einer signifikanten Reduktion des Overjets • einer Vergrößerung des Airway space, wohingegen die Kontrollgruppe eine Volumenabnahme des Airway space zeigt • zu einer Anteriorbewegung des Hyoids, wohingegen die Kontrollgruppe eine verstärkte Vertikalbewegung des Hyoids zeigt
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN /AMSTAR II)	**acceptable (+)**

Evidenztabelle Baysal, Ozturk et al. 2016

Original Article

Facial soft-tissue changes after rapid maxillary expansion analyzed with 3-dimensional stereophotogrammetry: *A randomized, controlled clinical trial*

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Population *Setting* *Komorbiditäten*	**transversale Anomalie, Klasse-III-Anomalie (inkl. LKG), Klasse-II-Anomalie** patients requiring RME as a part of their individual treatment plan in the initial examination were selected from the patient waiting list of the Orthodontic Department Clinics selected from the patient waiting list of the Orthodontic Department Clinics; Izmir Katip Celebi University
Schweregrad	Maxillary transverse deficiency, with posterior crossbite
Einschluss-kriterien *Bei Review: PICOS*	maxillary transverse deficiency, assessed both clinically and radiographically, with posterior crossbite; willingness of patient and parents to participate in the study; to be within normal range according to body mass index
Ausschluss-kriterien	1. Congenitally missing or extracted permanent tooth (except third molars); 2. Severe facial asymmetry determined by clinical examination; 3. Craniofacial syndrome; 4. Neuromuscular deformities; 5. History of trauma; 6. History of orthodontic treatment; 7. Poor oral hygiene; 8. Systemic diseases that might affect treatment results

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** All patients were submitted to the RME protocol established by a bonded acrylic splint expander (Figure 2). The screw was activated a quarter turn twice per day (0.5 mm) for the first week, then a quarter turn per day (0.25 mm), until the palatal cusps of the maxillary molar contacted the buccal cusps of the mandibular molar. Mean maxillary expansion achieved was 6.25 ± 2.9 mm, with a mean number of activations of 25 ± 11.6 turns. After the expansion completed, the appliance was kept in the mouth passively for the first month. The mean active expansion period was 0.7 ± 0.4 month in the treatment group. A Hawley retainer was delivered to all patients for the rest of the retention period. VERSUCHSGRUPPE: **Treatment Group RME** N=17(Anfang) / N=17 (Ende) / Alter = 13,4 ± 1,2 Jahre / ♂:♀ = 9:8 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**kieferorthopädische Therapie zu anderem Zeitpunkt /Zeitraum /Gebissphase** KONTROLLGRUPPE: C**ontrol** N=17 (Anfang) / N=17 (Ende) / Alter = 12,8 ± 1,3 Jahre / ♂:♀ = 9:8 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär),** • **dentofaziale Ästhetik** PRIMÄRZIELGRÖßE: Facial soft-tissue changes *(Table 3: Soft tissue landmarks Labiale Superius (ls) Crista Philtri (cph) Labiale Inferius (li) Subnasale (sn) Pronasale (prn) Cheilion (ch) Endocanthion (en) Pogonion (pog) Alare (al), Zygion (zyg))* SEKUNDÄRZIELGRÖßE: hard tissue and soft tissue relations *(Table 3: ZL-ZR ZA-AZ NC-CN MeAN JL-JR A6-6A B6-6B A3-3A B3-3B AG-GA)*
Studientyp	**Randomisiert-kontrollierte Interventionsstudie (RCT)**
Schluss-folgerungen der Autoren	1. After RME therapy, statistically significant hard tissue changes were observed compared with the untreated control group. 2. Soft tissue changes were similar in both groups, except the alar base, which became wider in the RME treatment group. 3. Soft tissue pogonion point was positioned backward in the treatment group. 4. Weak correlations were found between skeletal and soft tissue changes after RME therapy.
Zusammen-fassung der Ergebnisse	**GRUPPE treatment group RME VS. GRUPPE control** ***PRIMÄRZIELGRÖßE*** : Facial soft-tissue changes No statistically significant differences were found between groups, except for pogonion (P 5 .022), which was found to be posteriorly located in the expansion group, 21.33 mm), but forward movement (0.11 mm) was recorded in the control group. ***SEKUNDÄRZIELGRÖßE*** hard tissue and soft tissue relations Correlation coefficients were calculated; the only statistically significant correlation was found between the amount of expansion and maxillary intermolar distance (r 5 1.000, P 5 .001). The regression model was not used, as weak or no correlation existed between soft and hard tissue changes.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: stringent geführtes Studiendesign Randmisierung / klinisches Monitoring* *Durchführung: gutes Monitoring , valide und reialbe Messungen* *Auswertung:* *Power der Studie/Patientenzahl: The optimal sample size determination prior to the statistical analyses was performed based on the effect size (Cohen's d 5 0.99) reported by Johnson et al.,7 which indicated that group sizes of 17 (total 34) would provide at least 80% statistical power.* *Funding:* This work was supported by a research grants from The Scientific and Technological Research Council of Turkey (Pro- ject 112R033) and Izmir Katip Celebi University, Scientific Research Projects Unit (Project 2013-3-TSBP-32). *Interessenkonflikte: Keine* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten): KEINE*
Schluss-folgerung des Begutachters	methodische Qualität: insgesmat gut durchgeführte Studie
	Klinische Aussagekraft: Eine RME Therapie führt zu einer Verbreiterung der knöchernen nasalen Basis im Gegensatz zu einer unbehandelten Kontrollgruppe (Beobachtungszeitraum 6 Monate) Allerdings ist keine Korrelation auf die Gesichtsweichteile zu sehen.(Discussion: increase in hard tissue nasal width (2.42 6 1.28 .mm) was also found). Die RME Therapie bewirkt keine klinisch relevanten Veränderungen der Gesichtsweichteile im Vergleich behandleter vs unbehandelter jugendlicher Patienten (Discussion: The only statistically significant difference in soft tissue linear changes between groups was found for alar base width. In the treatment group, the difference was 1.41 6 0.95 mm, which was approximately 1 mm greater than in the control group.) Insgesamt ist keine KOrreltaion zwischen skelettaler Verbreiterung und Veränderung der Gesichtsweichteile unter RME-Therapie zu verzeichnen (Conclusion: Weak correlations were found between skeletal and soft tissue changes after RME therapy.)
Evidenz-level (SIGN)	**1++**
Qualität **(RoB, SIGN /AMSTAR II)**	**High Quality ⊕⊕**

Evidenztabelle Bernabe, Sheiham et al. 2008

The impact of orthodontic treatment on the quality of life in adolescents: a case–control study

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SUMMARY The aim of this case–controlled study was to assess the effect of orthodontic treatment on the quality of life of Brazilian adolescents. Two hundred and seventy-nine 'cases' (106 males and 173 females) and 558 controls (246 males and 312 females) were randomly selected from 15- to 16-year-old adolescents attending all secondary schools in Bauru, São Paulo, Brazil. A case was defined as having at least one condition-specific impact (CSI) attributed to malocclusion during the previous 6 months, based on the Oral Impact on Daily Performances index. Conversely, a control was defined as having no CSI attributed to malocclusion during the same period. Adolescents were also clinically examined for orthodontic treatment need using the Index of Orthodontic Treatment Need (IOTN) and asked about previous orthodontic treatment. Binary logistic regression was used for statistical analysis.

Females and adolescents with a definite normative orthodontic treatment need were more likely to report CSI than males and adolescents with no normative need [odds ratio (OR) = 1.48, 95 per cent confidence interval (CI) = 1.08–2.02 and OR = 3.02, 95 per cent CI = 2.09–4.47, respectively], whereas adolescents with a history of orthodontic treatment were less likely to report CSI than their counterparts (OR = 0.15, 95 per cent CI = 0.07–0.31). Furthermore, there was an interaction between a history of orthodontic treatment and the current level of normative need. Brazilian adolescents with a history of orthodontic treatment were less likely to have physical, psychological, and social impacts on their daily performances associated with malocclusion than those with no history of orthodontics. Gender was a confounding factor, whereas current level of normative orthodontic treatment need was an effect modifier. Prospective studies are needed to corroborate the present findings.

Population *Setting* *Komorbiditäten*	**„Malokklusion/Dysgnathie“ allg.** • Brazilian Adolescents (15- 16years of age) • São Paulo, Brazil
Schweregrad	The Index of Orthodontic Treatment Need (IOTN): ‘ no need ’ (IOTN 1 or 2), ‘ moderate need ’ (IOTN 3), or ‘ definite need ’ (IOTN 4 or 5) alle inkludiert
Einschluss-kriterien	- 15- to 16-year old adolescents - attending secondary schools in Bauru, São Paulo, Brazil
Ausschluss-kriterien	Not fulfilling inclusion criteria

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **With CSI “Case”** (condition-specific impact (CSI) as assessed by Oral Impact on Daily Performances (OIDP)). This index assesses serious oral impacts on eight daily performances, namely, eating, speaking, oral hygiene, relaxing, smiling, studying, emotion, and social contact. VERSUCHSGRUPPE 1 **With CSI „Case“** N= 279 (Anfang) / N=279 (Ende) / Alter = 15,24 years / ♂:♀ = 106:173 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** **Without CSI “Control”** (condition-specific impact (CSI) as assessed by Oral Impact on Daily Performances (OIDP))**.** This index assesses serious oral impacts on eight daily performances, namely, eating, speaking, oral hygiene, relaxing, smiling, studying, emotion, and social contact. KONTROLLGRUPPE 1: **Without CSI “Control”** N= 558 (Anfang) / N=558 (Ende) / Alter = 15,33 years / ♂:♀ = 246:312 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • mundgesundheitsbezogene Lebensqualität (MLQ), psychische Entwicklung PRIMÄRZIELGRÖßE: **Oral Impact on Daily Performances (OIDP)/ IOTN**
Studientyp	**Querschnittsstudie**
Schluss-folgerungen der Autoren	**The main finding of this study was that adolescents with a history of completed orthodontic treatment had fewer CSI on their daily lives attributable to malocclusion, than adolescents with no history of treatment.** Overall, adolescents **with a history of orthodontic treatment had an 85 per cent lower probability (OR = 0.15, 95 per cent CI = 0.07 – 0.31) of reporting CSI attributable to their current occlusal status** than their counterparts, after controlling for covariates. This association was **partly influenced by other variables, particularly gender and current level of normative orthodontic treatment need.** Adolescents who had completed orthodontic treatment were less likely to report CSI on their daily performances attributed to malocclusion than those who had not undergone treatment. The outcome was partly influenced by gender and the current level of orthodontic treatment need. Gender was a confounder, whereas current level of normative orthodontic treatment need was an effect modifier.

Zusammen-fassung der Ergebnisse	**GRUPPE With CSI „Case“ VS. GRUPPE Without CSI “Control”** T1: 15,34, years, With CSI; 15,33 without CSI **Oral Impact on Daily Performances (OIDP)/ IOTN** There was a **statistically significant association** between a history of orthodontic treatment and the presence of CSI attributed to malocclusion in the unadjusted model ($P < 0.001$). A history of orthodontic treatment was a protective factor against reporting CSI attributed to malocclusion. Furthermore, SES and current level of orthodontic treatment need were also significantly associated with the presence of CSI in the unadjusted model ($P = 0.004$ and $P < 0.001$, respectively). When a **multivariable analysis** was carried out, only a history of orthodontic treatment, current level of need for orthodontic treatment, and gender reached statistical significance to enter the model. **Main effects model-two factor interaction**: Among adolescents **with no current normative need**, **treated individuals were less likely to report CSI than those untreated** (OR = 0.15, 95 per cent CI = 0.07 – 0.31). However, the same pattern **was not found among adolescents with moderate or definite normative need** ($P = 0.059$ and 0.516, respectively). In addition, t**reated and untreated adolescents with a current definite need had a higher probability of reporting a CSI than adolescents with no need** (both $P < 0.001$), and **this probability was higher among treated (OR = 24.43, 95 per cent CI = 4.81 – 124.06) than among untreated adolescents** (OR = 3.06, 95 per cent CI = 2.09 – 4.47). However, there were no differences between adolescents with a current moderate need and those with no need, both among treated and untreated groups.
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung <u>Funding</u> <u>Interessen-konflikte</u> <u>Bias (SIGN)</u>	Große Gesamtpopulation und zufällige (Prozedur nicht spezifiziert) Auswahl der untersuchten Population. Falldefinition (CSI) durch OIDP nachvollziehbar. Prüfung der Behandlungsnotwendigkeit (IOTN, als potentieller Confounder) durch qualifizierten Experten mit Reliabilitätsprüfung. Signifikante Unterschiede zwischen den Untersuchungsgruppen hinsichtlich des soziökonomischen Status, und orthodontischer Behandlung sowie bestehender Behandlungsnotwendigkeit. Dies ist auf das Studiendesign zurückzuführen. Gut durchgeführte Fall-Kontroll-Studie. Studienabhängig fehlen longitudinale Vergleiche. Aufgrund des Studiendesigns ist die Aussagekraft eingeschränkt. Die ordentliche Durchführung sowie die Größe der untersuchten Population unterstützen jedoch die klinische und Leitlinienrelevanz. Power/ Sample Size Berechnungen wurden durchgeführt. Die Auswertung war nicht verblindet. Studie mit guter Durchführung und großer untersuchter Population. Bedingt durch das Studiendesign fehlen longitudinale Vergleiche. Daher ist die Aussagekraft eingeschränkt. Die ordentliche Durchführung sowie die Größe der untersuchten Population unterstützen jedoch die klinische und Leitlinienrelevanz. Die Übertragbarkeit auf die deutsche Bevölkerung ist möglicherweise nicht gegeben. *Funding:* Programme Al β an, the European Union Programme of High Level Scholarships for Latin America (E06D1000352PE). *Interessenkonflikte:* Keine Angabe *Bias (SIGN):* Auswahl der Studienpopulation aus der Gesmatpopulation nicht transparent. Eine Verblindung fand nicht statt. Power/ Sample Size Berechnungen wurden durchgeführt.

Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Gut durchgeführte Studie. Studienabhängig fehlen longitudinale Vergleiche. Aufgrund des Studiendesigns ist die Aussagekraft eingeschränkt. Die ordentliche Durchführung sowie die Größe der untersuchten Population unterstützen jedoch die klinische und Leitlinienrelevanz.
Evidenz-level (SIGN)	**3**
Qualität (RoB, SIGN)	**acceptable (+)**

Evidenztabelle Bicakci et al. 2004

Nasal Airway Changes Due to Rapid Maxillary Expansion Timing

A. Altug Bicakci, DDS, MS[a]; Ugur Agar, DDS, MS[b]; Oral Sökücü, DDS[b]; Hasan Babacan, DDS, MS[a]; Cenk Doruk, DDS, MS[a]

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Accepted: February 2004. Submitted: January 2004.

Population *Setting* *Komorbiditäten*	**transversale Anomalie, Malokklusion/Dysgnathie“ allg** • Patients of the Faculty of Dentistry, Cumhuriyet University, Sivas, Turkey
Schweregrad	• Bilateral crossbite
Einschluss-kriterien *Bei Review: PICOS*	• Transverse maxillary deficiency • Bilateral crossbite • the presence of an adequate nasal cavity space
Ausschluss-kriterien	• history of nasal disease

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** An acrylic-bonded fully tooth and tissue-borne RME appliance containing a Hyrax screw (GAC, Bohemia, NY) was used to correct the posterior crossbite in the treated subjects. The screw was activated two turns a day until the occlusal aspect of the maxillary lingual cusp of the upper first molars contacted the occlusal aspect of the facial cusp of the mandibular first molars. At that time, the screw was fixed with 0.014 ligature wire, and the appliance left for one week to minimize discomfort during removal. After removal, a new removable retention appliance was used for three months. VERSUCHSGRUPPE I: **Group I T (early-treated)** N= 16 (Anfang) / N=16 (Ende) / Alter = 11,8 Jahre / ♂:♀ = 8:8 • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE II: **Group II T (late-treated)** N= 13 (Anfang) / N=13 (Ende) / Alter = 14,1 Jahre / ♂:♀ = 5:8 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE I: **Group I C (early-control)** N=16 (Anfang) / N=16 (Ende) / Alter = 12,6 Jahre / ♂:♀ = 8:8 • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung KONTROLLGRUPPE II: **Group II C (late-control)** N=13 (Anfang) / N=13 (Ende) / Alter = 13,4 Jahre / ♂:♀ = 5:8 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **Atmung und Luftraum (Airway space, Schlafapnoe), Schlucken und Sprechen** • **Reduktion der Belastung des Patienten** • **Stabilität des Behandlungsergebnisses** PRIMÄRZIELGRÖßE: Effect of RME on nasal minimum cross-sectional area (MCA) SEKUNDÄRZIELGRÖßE: Relapse tendencies /stability - Difference Between Posttreatment and Postretention (T3–T2; MCA)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	1. The RME treatment is able to induce more pronounced transverse craniofacial changes at the skeletal level when the subjects were treated before the peak in skeletal maturation. 2. Although not statistically significant, patients treated before the pubertal peak exhibit more increase in MCA and the increase remained more stable 3. Besides expanding the maxilla, RME is effective in increasing MCA in nasal cavity, which is highly responsible for nasal resistance in both patients treated before the pubertal peak and after the pubertal growth spurt.
Zusammen-fassung der Ergebnisse	**GRUPPE Group I T (early-treated) VS. GRUPPE Group I C (early-control)** **GRUPPE Group I T (early-treated) VS. GRUPPE Group II C (late-control)** **GRUPPE Group II T (late-treated) VS. GRUPPE Group I C (early-control)** **GRUPPE Group II T (late-treated) VS. GRUPPE Group II C (late-control)** **PRIMÄRZIELGRÖßE:** Effect of RME on nasal minimum cross-sectional area (MCA) **Group I T (early-treated) VERSUS Group I C (early-control)** There were significantly greater increments (P < .05) in group I T compared with the controls (Table 3). Group I T(Early-treated) M 0.34 mm² (SD 0.26) Group I C (Early-control) M 0.08 mm² (SD 0.10). The difference between pretreatment and postretention in mean MCA between the group I T and group I C (P =.006) was statistically significant (P < .05). **Group II T (late-treated) VERSUS Group II C (late-control)** There were significantly greater increments (P , .05) in group II T compared with the controls (group II C) (Table3). Group II T(Late-treated) M 0.19 (SD 0.16) Group II C (Late-control) M 0.02 (SD 0.03) The difference between pretreatment and postretention in mean MCA between the group II T and group II C (P = .009) was statistically significant (P < .05). **Group I T (early-treated) VERSUS Group II T(late-treated)** Evaluation of the overall changes (T1–T3) revealed that in both group I T and group II T, RME produced an statistically significant increase of 0.34 cm2 (P > .05) and 0.19 cm2 (P > .05), and a significant gain over the controls of 0.26 cm2 (P > .05) and 0.17 cm2 (P > .05) in MCA, respectively. Although the increase in MCA was greater in group I the difference was not statistically significantly greater (P <.05). **SEKUNDÄRZIELGRÖßE:** Relapse tendencies /stability - Difference Between Posttreatment and Postretention (T3–T2; MCA) After the retention period (T2–T3), the increase in MCA in group I T remained almost stable (P > .05) and in group II T, MCA showed a statistically significant reduction (P < .05). This possibly means that in older patients the rigidity of articular bones to the midpalatal suture negatively affects the stability of the increase in MCA after RME. However, surprisingly, this difference between groups I T and II T was not statistically significant (P >.05).

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* *Durchführung: valide Methode der akustischen Rhinomanometrie, Keine Überprüfung der Reliabilität z.B. Berechnen des Messfehlers,* *allerdings Mehrfachmessungen durchgeführt, um reliable Daten zu erhalten (*AR measurements were taken at the same room temperature (20°C) and at constant humidity. The device was calibrated according to the manufacturer’s instruction during this period. This procedure was repeated four times for every measurement, and we used the mean values of all the measurements) *nur kurze Beobachtungszeit über insgesamt 3 Monate (errechnet)* *Kontrollgruppe nicht exakt definiert* *Power der Studie/Patientenzahl: keine Fallzahlberechnung, Anzahl der Patienten und Kontrollen im Manuskript nicht passend zum Abstract,* *Funding: KEINE* *Interessenkonflikte: KEINE* *Bias: NO - Comparison is made between participants and non-participants to establish their similarities or differences.* *It is NOT clearly established that controls are non-cases.* *NO Confidence intervals are provided.*
Schluss-folgerung des Begutachters	methodische Qualität: Methodik insgesamt durchdacht aber Unstimmigkeiten in der Durchführung
	Klinische Aussagekraft: Eine RME erreicht eine Vergrößerung des vorderen unteren Nasenganges mit Reduktion der Nasen-Luft-Widerstandes über eine Beobachtunsgzeitruam von 3 Monaten gegenüber einer unbehandelten Kontrollgruppe. Eine frühzeitige Erweitereung der Maxilla mittels RME (Patienten vor dem pubertären Wachstumsschub) scheint eine höheren Netto-Erweiterung des Nasenganges (Reduktion des MCA) zu erzielen als eine spätere Erweiterung (Patienten nach maximalen Wachstumsschub).
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable ⊕**

Evidenztabelle Bilbo, Marshall et al. 2018

Long-term skeletal effects of high-pull headgear followed by fixed appliances for the treatment of Class II malocclusions

E. Erin Bilbo[a]; Steven D. Marshall[b]; Karin A. Southard[c]; Venkata Reddy[d]; Nathan Holton[e]; Allyn M. Thames[f]; Marlene S. Otsby[g]; Thomas E. Southard[h]

ABSTRACT

Objectives: The long-term skeletal effects of Class II treatment in growing individuals using high-pull facebow headgear and fixed edgewise appliances have not been reported. The purpose of this study was to evaluate the long-term skeletal effects of treatment using high-pull headgear followed by fixed orthodontic appliances compared to an untreated control group.

Materials and Methods: Changes in anteroposterior and vertical cephalometric measurements of 42 Class II subjects (n = 21, mean age = 10.7 years) before treatment, after headgear correction to Class I molar relationship, after treatment with fixed appliances, and after long-term retention (mean 4.1 years), were compared to similar changes in a matched control group (n = 21, mean age = 10.9 years) by multivariable linear regression models.

Results: Compared to control, the study group displayed significant long-term horizontal restriction of A-point (SNA = −1.925°, $P < .0001$; FH-NA = −3.042°, $P < .0001$; linear measurement A-point to Vertical Reference = −3.859 mm, $P < .0001$) and reduction of the ANB angle (−1.767°, $P < .0001$), with no effect on mandibular horizontal growth or maxillary and mandibular vertical skeletal changes. A-point horizontal restriction and forward mandibular horizontal growth accompanied the study group correction to Class I molar, and these changes were stable long term.

Conclusions: One phase treatment for Class II malocclusion with high-pull headgear followed by fixed orthodontic appliances resulted in correction to Class I molar through restriction of horizontal maxillary growth with continued horizontal mandibular growth and vertical skeletal changes unaffected. The anteroposterior molar correction and skeletal effects of this treatment were stable long term. (*Angle Orthod.* 2018;88:530–537.)

KEY WORDS: Class II malocclusion; Headgear; Long-term stability; Orthopedics

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** Patients with class II malocclusion treated at the University of Iowa College of Dentistry and Dental Clinics, Department of Orthodontics Vergleich gegen eine unbehandelte historische Kontrollgruppe
Schweregrad	• Class II molar relationship (ohne weitere Angabe) • SN-MP > 28°

Einschluss-kriterien *Bei Review: PICOS*	Patientengruppe: 1. Class II molar relationship, 2. Late mixed dentition stage of tooth development 3. SN-MP angle >28° 4. One phase of orthodontic treatment beginning with high-pull headgear alone and directly followed by treatment with a complete fixed edgewise appliance 5. Treatment with high-pull headgear until Class I molar was achieved 6. Availability of complete records at four timepoints: prior to any treatment (T1), prior to beginning fixed edgewise appliance therapy (T2), at retention (T3), and at a minimum of 24 months post retention (T4). Kontrollgruppe: The subjects chosen for the control sample were matched as closely as possible by the gender, initial age, age at the three subsequent time points, initial cephalometric characteristics, and initial molar relationship of the study sample.
Ausschluss-kriterien	Patients with craniofacial anomalies or syndromes were not included in the study
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** *For all study group subjects, high-pull facebow headgear engaging the maxillary first molars was used as the primary means of anteroposterior dental and skeletal correction.* *Twelve patients wore Class II elastics at the end of fixed edgewise treatment, but only for a very short time: an average time period of 2.95 months between T3 and T4.* VERSUCHSGRUPPE: **HG + MB** N=21 (Anfang) / N=21 (Ende) / Alter =10,59 ± 1,04 Jahre / ♂:♀ = 12:9 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **unbehandelte Kontrolle** N=21 (Anfang) / N=21 (Ende) / Alter = 10,92 ± 0,50 Jahre / ♂:♀ = 10:11 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: *skelettale FRS-Parameter* *Subkategorien Outcome 1:* • *Δ T2-T1* • *Δ T3-T1* • *Δ T4-T1*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	1. Class II correction using high-pull headgear followed by fixed edgewise appliance results in restriction of maxillary horizontal growth during treatment that remains stable long term (average retention: 4.08 years). 2. ANB angle reduction with this treatment is achieved through a restriction of A-point forward growth and continued forward growth of the mandible. 3. ANB angle continues to decrease during retention via continued mandibular growth. 4. Treatment with high-pull headgear had no effect on vertical skeletal changes.
Zusammen-fassung der Ergebnisse	**HG + MB VS. unbehandelte Kontrolle** ***PRIMÄRZIELGRÖßE*** ship at all time points T1-T4. The results of the multivariable linear regression models, following adjustment for the effects of gender, age at T1, and difference in duration between time points, are summarized in Table 4. Those in the study group had negative changes (reduction) in the SNA angle from T2 to T1 (parameter estimate = –1.387, $P < .001$), T3 to T1 (parameter estimate = –2.373, $P < .001$), and T4 to T1 (parameter estimate = –1.925, $P < .001$), in the FH-NA angle from T2 to T1 (parameter estimate = –1.578, $P = .02$), T3 to T1 (parameter estimate = –2.875, $P < .001$), and T4 to T1 (parameter estimate = –3.042, $P = .001$), and in A-point horizontal from T2 to T1 (parameter estimate = –1.248, $P = .04$), T3 to T1 (parameter estimate = –2.687, $P < .001$) and T4 to T1 (parameter estimate = –3.859, $P < .001$) when compared to controls. This was accompanied by those in the study group showing negative changes in ANB from T2 to T1 (parameter estimate = –0.884, $P < .001$), T3 to T1 (parameter estimate = –1.501, $P < .001$), and from T4 to T1 (parameter estimate = –1.787, $P < .001$) when compared to controls. There was no significant difference in SNB changes between the study and control groups. There were no significant horizontal changes in B-point or Pogonion, nor were there significant changes in the angle FH-NPog between the study and control groups with the exception of the time period T3 to T1. Those in the study group had negative changes in B-point horizontal, in Pogonion Horizontal, and in angle FH–NPog from T3 to T1 (parameter estimate = –2.279, $P = .02$; parameter estimate = –2.279, $P = .02$; parameter estimate = –1.401, $P = .03$, respectively) when compared to controls. Long term (T4–T1) there were no significant differences in changes of these mandibular measurements between study and control groups. There were no significant changes in SN–MP angle or the FMA between the study and control groups with the exception of the time period T3 to T1. The study group had positive difference in SN–MP and FMA, from T3 to T1 (parameter estimate = 1.338, $P = .04$), and (parameter estimate = 2.067, $P = .02$), respectively, when compared to controls.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Durchführung:* - *Es wurde zwar eine historische Kontrollgruppe verwendet, diese passt aber bezüglich aller Parameter gut zur Probandengruppe. Zudem wurden multivariable lineare Regressionsanalysen zur Prüfung auf signifikante Unterschiede zwischen beiden Gruppen untersucht und dabei einige Parameter berücksichtigt: Geschlecht / Alter bei T1 / Dauer (T2 to T1, T3 to T1, or T4 to T1). Allerdings wurde zuvor nicht auf Normalverteilung geprüft, sodass streng genommen nicht sichergestellt ist, dass das verwendete statistische Verfahren angewendet werden darf.* - *Bei einige Patienten (etwa 50% der Patientengruppe) wurden teilweise zur Korrektur der Klasse-II-Anomalie zusätzlich Gummizüge eingesetzt.* *Auswertung:* - *Auswertungsverfahren wurde auf Reliabilität geprüft – es konnte eine gute Reliabilität nachgewiesen werden.* *Power der Studie/Patientenzahl: wurde adäquat durchgeführt* *Funding: Keine Angabe* *Interessenkonflikte: Keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* - *Moderate Gefahr von selection bias* - *Performance bias: Bei einige Patienten (etwa 50% der Patientengruppe) wurden teilweise zur Korrektur der Klasse-II-Anomalie zusätzlich Gummizüge eingesetzt.* *Ethikvotum liegt vor.*
Schluss-folgerung des Begutachters	methodische Qualität: gut
	Klinische Aussagekraft: gut Die Autoren präsentieren insgesamt eine gute Studie mit moderatem Biasrisiko. Ein positives Votum der Ethikkommission liegt vor. Vor Beginn der Studie wurde eine Poweranalyse durchgeführt. Die Outcomes wurden objektiv definiert und eine gute Reliabilität der Datenerfassung wurde nachgewiesen. Die Patientengruppe ist mit der Kontrollgruppe zu Beginn der Untersuchung gut vergleichbar. Die Korrektur der Klasse-II-Anomalie erfolgte bei einem Teil der Patienten unter Zuhilfenahme von Gummizügen, wodurch möglicherweise ein performance bias entsteht. Das statistische Verfahren ist, Normalverteilung vorausgesetzt, sehr gut geeignet, da durch die Anwendung der multivariablen linearen Regressionsanalysen wichtige Einflussfaktoren berücksichtigt werden konnten. Die eher kleinen Gruppengrößen schränken allerdings die allgemeine Aussagekraft etwas ein.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	Acceptable (+)

Evidenztabelle Borzabadi-Farahani, Lane et al 2014

The Cleft Palate-Craniofacial Journal 51(1) pp. e1–e10 January 2014

ORIGINAL ARTICLE

Late Maxillary Protraction in Patients With Unilateral Cleft Lip and Palate: A Retrospective Study

Ali Borzabadi-Farahani, D.D.S., M.Sc.D., M.Orth. R.C.S. (Ed.), Christianne J. Lane, B.S., Ph.D., Stephen L.-K. Yen, D.M.D., Ph.D.

Objectives: This retrospective study assessed the dentoskeletal effect of late maxillary protraction (LMP; reverse-pull headgear, Class III elastics, and maxillary sutural loosening) in unilateral cleft lip and palate (UCLP) patients versus a control group of untreated UCLP patients.

Materials and Methods: Cephalograms taken at age 13 to 14 years (T1) and 17 to 18 years (T2) were used for this study. The study group comprised 18 patients (10 male and 8 female, mean age at start of LMP therapy = 13.4 [0.45] years). A control groups of 17 patients (8 male and 9 female, mean age = 13.5 [0.44] years) was used for comparison.

Results: The repeated-measures analysis of variance showed statistically significant changes across time between groups for the following variables (mean difference [T2–T1] in the study group, 95% confidence interval): SNA (°) (1.95, 0.75 to 3.15), A ⊥ Na Perp (mm) (1.82, 0.86 to 2.77), CoA (mm) (2.92, 1.53 to 4.31), ANB (°) (3.13, 2.02 to 4.24), Wits (mm) (7.82, 5.01 to 10.54), Mx-Md Diff (mm) (0.62, −1.58 to 2.83), Occl P-SN (°) (−3.98, −5.99 to −1.98), overjet (mm) (8.82, 5.90 to 11.74), PMA (°) (4.05, −0.05 to 8.15), and BMPA (°) (−5.77, −9.74 to −1.80). Late maxillary protraction created a slight open bite (0.66 mm). Trends for overeruption of mandibular incisors and an increase in lower face height ($P = .07$ for both) were noted in the study group.

Conclusions: Late maxillary protraction produced a combination of skeletal changes (protraction of maxilla, improvement in the maxillo-mandibular skeletal relationship) and dental compensations (counterclockwise rotation of occlusal plane, retroclination of mandibular incisors) in patients with UCLP. Late maxillary protraction was also associated with some unwanted tooth movements (open bite tendency, mandibular incisors overeruption).

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** Patients with skeletal Class III malocclusion and UCLP • USA
Schweregrad	-
Einschluss-kriterien	- Class III malocclusion - UCLP
Ausschluss-kriterien	Not fullfilling inclusion criteria

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **LMP (late maxillary protraction** (LMP; reverse-pull headgear, Class III elastics, and maxillary sutural loosening) The Alt-RAMEC technique uses a two-hinged expander and intraoral springs for maxillary protraction.The intraoral springs and the two-hinged expander were substituted with a Hyrax expander. Class III elastics, and reverse-pull headgear Prior to maxillary protraction, 8 weeks of maxillary sutural loosening were applied with the Hyrax maxillary expander that alternates a week of maxillary expansion with a week of maxillary constriction. The maxillary constriction and/or expansion rate were set at 1 mm/d. The maxillary sutural loosening with the Hyrax was continued until the anterior crossbite was overcorrected into a Class II malocclusion with at least 3 mm of overjet. The 3 mm of overjet was achieved after 3 to 6 months (mean = 4.6 months) of maxillary sutural loosening. Three to four months after the point of overcorrection, the Hyrax expander was removed; the face mask wear was discontinued, and the maxillary arch was banded and bonded, proceeding into orthodontic alignment VERSUCHSGRUPPE 1: **LMP** N= 19 (Anfang) / N=18 (Ende) / Alter = 13,4, 0,45 ♂:♀ = 10:8 • Gebissphase: spätes Wechselgebiss/ permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: späte Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated Class III UCLP** N=17 (Anfang) / N=17 (Ende) / Alter = 13,5, 0,44 ♂:♀ = 8:9 • Gebissphase: spätes Wechselgebiss/ permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: Skeletal: SNA, SNB, ANB, Wits SEKUNDÄRZIELGRÖßE: Dental: Overjet
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	- The **LMP improved Class III malocclusions in UCLP** by a combination of skeletal changes (protraction of maxilla and improvement in maxillo-mandibular skeletal discrepancy) and dental compensations (counterclockwise rotation of occlusal plane and retroclination of mandibular incisors). - Late maxillary protraction was also associated with some **unwanted tooth movements** (open bite tendency, overeruption of mandibular incisors); future studies can investigate ways of eliminating or reducing these side effects. (Late maxillary protraction was associated with some dental compensations and unwanted tooth movement, such as proclination of maxillary incisors (Max Incisors-SN [°]; 7.42°), retroclination of mandibular incisors (IMPA [°];5.77°), open bite tendency (0.66 mm), and overeruption of and overeruption of mandibular incisors (Md Incisors - MP [mm]; 2.78 mm)).
Zusammen-fassung der Ergebnisse	**GRUPPE LMP VS. GRUPPE untreated Class III UCLP** T1 (pre-treatment): mean age 13,4 years, LMP; 13,5 years, untreated Class III UCLP T2 (post treatment/ observation): mean age 17,4 years; BAMP, 17,5 years untreated Class III UCLP Skeletal SNA, SNB, ANB, Wits  Dental Overjet 

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die Äquivalenz von Versuch- und Kontrollgruppe wurde nachvollziehbar überprüft. Hinsichtlich skeletaler Merkmale ist die Äquivalenz gegeben. Signifikante Unterscheide bestanden zu Behandlungsbeginn hinsichtlich des Overjets, dies ist zu berücksichtigen. Die retrospektive Studie hat im Verlauf eine Teilnehmer ausgeschlossen, dies ist unklar. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Eine Verblindung fand nicht statt. Trotz einer Anzahl von methodischen Schwächen ist das Gesamtdesign der Studie noch akzeptabel. Die spezielle, selten untersuchte Behandlungsgruppe, ist ausschlaggebend für die klinische Relevanz, die trotz der methodischen Schwächen ausreichend ist. *Funding:* This work was supported by research grants from the NIDCR (Dr. Yen, 1R21DE019164-01) and the European Orthodontic Society (Dr. Borzabadi-Farahani) as well as a post-doctoral research grant from the Children’s Hospital Los Angeles (Dr. Borzabadi-Farahani). *Interessenkonflikte:* keine Angabe *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist weitestgehend gegeben. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Eine Verblindung fand nicht statt
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Die spezielle, selten untersuchte Behandlungsgruppe, ist ausschlaggebend für die klinische Relevanz, die trotz der methodischen Schwächen ausreichend ist.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Bucci et al. 2018

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REVIEW

WILEY Oral Rehabilitation

Effects of maxillary expansion on the upper airways: Evidence from systematic reviews and meta-analyses

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Summary

Background: Constricted maxilla is frequently associated with reduced nasal airway dimensions. Whether or skeletal maxillary expansion (ME) is effective on the dimension of the upper airways is still a debated issue.

Objectives: This overview aimed to report the evidence provided by systematic reviews (SRs) on the effect of ME on the upper airways and to assess the methodological quality of the included SRs.

Methods: Six electronic databases have been explored up to November 2017. After title and abstract screening, SRs addressing the effects of fixed palatal expanders on the dimension and function of the nasal airways were included. The methodological quality of the included SRs was assessed using the updated version of A Measurement Tool to Assess Systematic Review (AMSTAR-2).

Results: Eight SRs were included. The methodological quality of most of the included SRs ranged between low and critically low. One SR was rated of high quality. A significant increase in nasal linear dimensions was reported both in the short and long term, but supported by low-/critically low-quality SRs. The significant increase in nasal cavity volume was the only outcome supported by a high-quality SR. Controversial results were found with regards to nasal function.

Conclusion: Whenever a constricted maxilla is present general dentists, paediatricians and ENTs should be familiar with the potential improvement provided by ME. However, due to the low/critically low quality of SRs supporting these results, ME cannot be indicated only for upper airways enhancement, but should be supported by an orthodontic indication.

Population *Setting* *Komorbiditäten*	**Transversale Anomalie / Malokklusion/Dysgnathie allg.** • growing patients with posterior crossbite
Schweregrad	Keine Angaben
Einschluss-kriterien *PICOS*	• systematic reviews (SRs) on the effect of maxillary expansion (ME) on the upper airways • growing patients with posterior crossbite

Ausschluss-kriterien	1.Dual publications, narrative reviews, updated publications 2.orthodontic treatment protocols other than fixed expander 3.expansion protocols in young adults and adults (ie, expansion with palatal anchorage on miniscrews or surgically assisted rapid maxillary expansion) 4.studies on syndromic patients and cleft lip and palate patients 5.studies on obstructive sleep apnoea syndrome 6.studies on other respiratory issues
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: ME N=?? (Anfang) / N=?? (Ende) / Alter = ?? ± ?? Jahre / ♂:♀ = ?:? • Gebissphase: Milchgebiss, frühes bis spätes Wechselgebiss (4-12 Jahre) • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **untreated control group** N=?? (Anfang) / N=?? (Ende) / Alter = ?? ± ?? Jahre / ♂:♀ = ?:? • Gebissphase: Milchgebiss, frühes bis spätes Wechselgebiss (4-12 Jahre) • KFO-Behandlung: reguläre Behandlung (keine ME)
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **Atmung und Luftraum (Airway space, Schlafapnoe), Schlucken und Sprechen** PRIMÄRZIELGRÖßE: the primary outcomes in most of the studies were nasal cavity width (NCW) and nasal cavity volume (NCV) SEKUNDÄRZIELGRÖßE: nasopharyngeal and oropharyngeal space TERTIÄRZIELGRÖßE: minimum cross-sectional area (MCA) QUARTIÄRZIELGRÖßE: nasal airflow
Studientyp	**Systematisches Review** • Inkludierte Studien in Bezug auf PICO: Systematische Reviews N=8 • Gesamt-Teilnehmerzahl in Bezug auf PICO: N=1189
Schluss-folgerungen der Autoren	Significant increase in nasal cavity width and volume is reported with both bi- and three-dimensional radiographic methods and the reduction in nasal resistance is observed with functional examinations. However, due the low/critically low quality of SRs supporting these results, this treatment cannot be indicated only for upper airways enhancement purposes, but must be supported by an orthodontic indication.

Zusammen-fassung der Ergebnisse	**GRUPPE ME- VS. GRUPPE Control (no therapy or not therapy with ME)** **Nasal cavity width and nasal cavity Volume, Nasophrayngeal and oropharyngeal spacel, Minimum cross-sectional area:** With regards to the outcome pointed out by radiographic studies based on bi-dimensional records, significantly favourable effects on the NCW, both immediately after treatment and in the long term were observed (at least 6 months after treatment). 22,23,25 The bone changes seemed to be more stable when treatment was started before the pubertal growth peak, probably because less calcification of the craniofacial sutures promotes less resistance to separation of the maxilla from adjacent structures. In threedimensional studies assessing the airway modifications by means of CBCT, the volume of the nasal cavities resulted to be significantly increased26,28 while the results of the oropharyngeal area are more controversial. Baratieri and colleagues pointed out on lateral cephalograms also changes in the head posture with a decrease in the craniocervical angulation, suggesting an improvement of nasal breathing rather than mouth breathing after ME.25 In threedimensional studies assessing the airway modifications by means of CBCT, the volume of the nasal cavities resulted to be significantly increased26,28 while the results of the oropharyngeal area are more controversial. The inconsistency of these results is probably due to the differences in the CBCT protocols used between studies where head posture, tongue position and segmentation procedures were not heterogeneous. Furthermore, the control of the position of the tongue and the soft palate are still factors that can influence the three-dimensional evaluation of the pharyngeal airways. **Nasal airflow:** Focusing on breathing function, it can be hypothesised that as ME creates additional space in the oral cavity, the tongue may be spontaneously positioning itself closer to the roof of the palate implementing the nasal breathing instead of the oral breathing
Angaben auffälliger positiver und/oder negativer Aspekte	Gut durchgeführtes Review. Einbezogen wurden zur finalen Auswertung 8 Systematische Reviews die jeweils einzeln nach AMSTAR II bewertet wurden, es zeigte sich eine überwiegend low bis zu critically low Qualität der inkludierten Reviews . Adaptiert an die vorliegende Methode (Review über Reviews) konnten die Studencharakteristika (PICOS) ermittelt werden. Bedingt durch die Heterogenität der Primärstudien in den jeweiligen Reviews konnten keine MA durchgeführt werden. Für die Leitlinie relevante Frage: ME und Veränderungen des Luftweges kann die Empfehlung der ME ausgesprochen werden, mit Rücksicht auf die eher niedrige Qualität der Studien. *Power der Studie/Patientenzahl: 8 Systematische Reviews, insgemamt 1189 Studienteilnehmer*
Schluss-folgerung des Begutachters	methodische Qualität: Review moderat, Einzelstudien nach AMSTAR II: low: 4 SRs, critically low: 3 SRs, high quality: 1 SR
	Klinische Aussagekraft: Eine maxilläre Expansion führt zu einer Expansion der oberen Atemwege. Die Position der Zunge, Neigung des Kopfes und Zeitpunkt der Expansion scheinen einen Einfluss auf dem Ergebnis zu haben.
Evidenz-level (SIGN)	**2+**
Qualität **(Risk of Bias, AMSTAR II)**	**Moderat ⊕⊕** Mehr als eine unkritische Schwäche: Das systematische Review hat mehr als eine Schwäche, aber keine kritischen Mängel. Es kann eine genaue Zusammenfassung der Ergebnisse von verfügbaren Studien liefern, die in die Überprüfung einbezogen wurden.

Evidenztabelle Cacciatore et al. 2014

Original Article

Treatment and posttreatment effects induced by the Forsus appliance
A controlled clinical study

Giorgio Cacciatore[a]; Luis Tomas Huanca Ghislanzoni[b]; Lisa Alvetro[c]; Veronica Giuntini[d]; Lorenzo Franchi[e]

ABSTRACT

Objective: To evaluate treatment and posttreatment dentoskeletal effects induced by the Forsus device (FRD) in growing patients with Class II malocclusion in a retrospective controlled clinical study.

Materials and Methods: Thirty-six Class II patients (mean [SD] age 12.3 [1.2] years) were treated consecutively with the FRD protocol and compared with a sample of 20 subjects with untreated Class II malocclusion (mean [SD] age 12.2 [0.9] years). Lateral cephalograms were taken at the beginning of treatment, at the end of comprehensive treatment (after 2.3 ± 0.4 years), and at a postretention period (after 2.3 ± 1.1 years from the end of comprehensive treatment). Statistical comparisons were carried out with the unpaired *t* test and Benjamini-Hochberg correction ($P < .05$).

Results: After comprehensive treatment, the FRD sample showed a significant restriction of the sagittal maxillary growth together with a significant correction in overjet, overbite, and molar relationship. During the overall observation interval, the FRD group exhibited no significant sagittal or vertical skeletal changes, while significant improvements were recorded in overjet (−3.8 mm), overbite (−1.5 mm), and molar relationship (+3.7 mm).

Conclusion: The FRD protocol was effective in correcting Class II malocclusion mainly at the dentoalveolar level when evaluated 2 years after the end of comprehensive treatment. (*Angle Orthod.* 2014;84:1010–1017.)

KEY WORDS: Class II treatment; Fixed functional appliances

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INTRODUCTION

Class II malocclusion is one of the most frequent problems in orthodontics, as it affects one third of patients seeking orthodontic treatment.[1] According to McNamara,[2] the most common characteristic of Class II malocclusion is mandibular retrusion, rather than maxillary prognathism. Thus, among the various orthodontic appliances introduced to treat Class II malocclusion, functional orthopedic appliances are widely used.[3–5] Contrary to removable appliances, fixed devices do not require the patient's collaboration and can be worn in association with multibracket therapy, so that Class II malocclusion can be corrected in a single phase treatment. Fixed functional appliances can be grouped into rigid or flexible devices.[3] The most commonly used rigid fixed functional appliances are the Herbst[6–11] and MARA.[12–14] Most popular flexible devices are the Jasper Jumper,[15,16] Eureka Spring,[17,18] and the Forsus device (FRD).[19–24]

The FRD is a three-piece (L pin module) or two-piece (EZ2 module) system, composed of a telescoping

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Details
Schweregrad	s. Einschlusskriterien
Einschluss-kriterien *Bei Review: PICOS*	• Class II dentoskeletal relationships • Overjet larger than 5 mm • full Class II or Class II tendency molar relationship • ANB larger than 3°
Ausschluss-kriterien	--
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** *36 subjects (21 male, 15 female), consecutively treated from August 2004 to September 2010 at a single private practice by one of the authors.* *All treated patients were in permanent dentition at T1, and they underwent a specific nonextraction treatment protocol with .022-inch slot preadjusted fixed appliances in combination with the FRD.* *The FRD was applied at the end of the aligning and leveling phase of orthodontic treatment, when a 0.019 x 0.025-inch stainless steel archwire was inserted in both arches.* *The mandibular archwire was consistently cinched distal to the molars. In addition, brackets on the lower incisors had a torque of -6° to limit the buccal inclination of the lower incisors. The rods of the FRD were placed on the mandibular archwire distal to the first premolars. No transpalatal arches were used in any phase of comprehensive treatment. The phase with the FRD was undertaken until Class II occlusion was overcorrected to an edge-to-edge incisor relationship. The mean duration of the FRD active phase was 4.8 ± 2.4 months.Thereafter, fixed appliances were maintained in order to finalize the occlusion. The retention protocol after removal of fixed appliance Consisted of a removable Hawley retainer in the upper arch used at nighttime for 2 years and a permanent fixed retention wire bonded from canine to canine in the lower arch.* VERSUCHSGRUPPE: **FRD Group (= Forsus)** N=36 (Anfang) / N=36 (Ende) / Alter = 12.3 ± 1.2 Jahre / ♂:♀ = 21:15 • Gebissphase: Permanentes Gebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated Control Group (historische Kontrollgruppe)** N=20 (Anfang) / N=20 (Ende) / Alter = 12.2 ± 0.9 Jahre / ♂:♀ = ?:? • Gebissphase: Permanentes Gebiss • KFO-Behandlung: keine

Outcome	direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie **T1 = beginning of treatment** **T2 = end of comprehensive treatments (MB + Forsus)** **T3 = postretention period** T1, T1-T2, T2-T3, T1-T3 PRIMÄRZIELGRÖßE: *Sagittal skeletal (SNA, SNB, Co-Gn, ANB, Wits)* SEKUNDÄRZIELGRÖßE: *Vertical skeletal (FH to palatal plane, MPA, Gonial angle)* TERTIÄRZIELGRÖßE: *Interdental (Overjet, Overbite, Molar relationship)* QUARTÄRZIELGRÖßE: *Maxillary dentoalveolar (U1 to FH)* QUINTÄRZIELGRÖßE: *Mandibular dentoalveolar (L1 to MPA)*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	• The FRD (=Forsus) protocol revealed to be effective in correcting Class II malocclusion mainly at the dentoalveolar level. • At the end of the treatment period, significant improvements in dentoalveolar sagittal intermaxillary relationships were found, together with a slight ‘‘headgear effect’’ on the maxilla. • At the end of the posttreatment period, only the dentoalveolar changes remained stable, while no significant sagittal or vertical skeletal change was present.

Zusammen-fassung der Ergebnisse	**FRD Group VS. Untreated Control Group** PRIMÄRZIELGRÖßE: *Sagittal skeletal (SNA, SNB, Co-Gn, ANB, Wits)* SEKUNDÄRZIELGRÖßE: *Vertical skeletal (FH to palatal plane, MPA, Gonial angle)* TERTIÄRZIELGRÖßE: *Interdental (Overjet, Overbite, Molar relationship)* QUARTÄRZIELGRÖßE: *Maxillary dentoalveolar (U1 to FH)* QUINTÄRZIELGRÖßE: *Mandibular dentoalveolar (L1 to MPA)* *T1 - T2* *During the T2-T1 interval, the maxilla exhibited a significantly greater decrease in the sagittal skeletal position (SNA 21.7u) in the FRD group than in the control group. No significant differences were recorded in mandibular sagittal skeletal changes. The FRD group showed significantly greater decreases in the intermaxillary sagittal skeletal relationships (ANB -1.8°). No statistically significant differences between the two groups were found for any of the vertical skeletal cephalometric variables. All interdental measurements showed statistically significant corrections in the FRD group vs the control group (overjet -5.1 mm; overbite -3.1 mm; molar relationship +3.5 mm). Upper incisors exhibited a significant retrusion (U1 horizontal -1.6 mm) in the FRD group vs the control group. On the contrary, the lower incisors showed a significant proclination (L1 to MPA +5.6u) associated with a significant protrusion (L1 horizontal +1.5 mm) and intrusion (L1 vertical -1.6 mm). No significant changes were detected in the horizontal or vertical position of the upper molars in the FRD group vs the control group, while the lower first molars showed a significant extrusion (L6 vertical +1.3 mm).* *T2 - T3* *During the posttreatment period (T2-T3), a significantly greater increase in the sagittal position of the maxilla (SNA +1.4°) occurred in the FRD group. Both overjet and overbite showed significant increases (+1.3 mm and +1.5 mm, respectively) in the FRD group. The upper incisors exhibited a significant intrusion (-1.2 mm) in the FRD group with respect to the control group.* *T1 - T3* *At the end of the comprehensive observation interval (T1-T3), no significant sagittal or vertical skeletal changes were detected. With regard to the interdental changes, the FRD group showed significantly greater decreases in both overjet (-3.8 mm) and overbite (-1.5 mm), as well as a significant improvement in molar relationship (+3.7 mm). The upper incisors exhibited a significantly greater retrusion (U1 horizontal, -1.1 mm) in the FRD group. As a result of therapy, the lower incisors demonstrated a significant intrusion (L1 vertical -1.2 mm). In terms of overall correction of Class II division 1 malocclusion, the success rate was 83.3%, which is very similar to that reported in a previous paper*

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: retrospektive Kohortenstudie* *Durchführung: Insgesamt ordentlich durchgeführte Studie mit einigen Angaben zur Methodik, allerdings insgesamt einer eher kleinen untersuchten Studienkohorte. Zudem handelt es sich bei der Kontrollgruppe um eine historische Kontrollgruppe.* *Auswertung: Die Auswertung der diagnostischen Unterlagen erfolgt verblindet und die FRS-Auswertungen werden durch einen zweiten Befunder begutachtet – bei Unklarheiten einigen sich beide Untersucher. Eine Methodenfehlerbestimmung anhand zufällig ausgewählter diagnostischer Unterlagen wurde durchgeführt.* *Power der Studie/Patientenzahl: vorhanden* *Funding: keine Angaben* *Interessenkonflikte: keine Angaben* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* - *Siehe zudem Datenextraktion!* - *Aufgrund der Tatsache, dass die Forsusapparatur ausschließlich in Kombination mit einer Multibracketapparatur eingesetzt werden kann, ist davon auszugehen, dass einzelne, insbesondere dentale Parameter durch die MB-Apparatur mitbeeinflusst werden. Zudem werden bewusst in der Unterkieferfront Brackets mit negativem Torque eingesetzt, um einer Protrusion der Front entgegenzuwirken.* - *Die untersuchte Kohorte ist recht klein. Die Kontrollgruppe besteht nur aus 20 Patienten.*
Schluss-folgerung des Begutachters	methodische Qualität: ausreichend bis gut Klinische Aussagekraft: moderat
Evidenz-level (SIGN)	**Acceptable (+)**
Qualität **(RoB, SIGN /AMSTAR II)**	**2+**

Evidenztabelle Chadwick, Aird et al. 2001

Functional regulator treatment of Class II division 1 malocclusions

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SUMMARY This controlled retrospective study aimed to identify the contribution of skeletal and dental changes in the correction of Class II division 1 malocclusions using Fränkel's functional regulator II (FRII), with reference to a concurrently recruited control group. One hundred and thirty-eight patients with Class II division 1 malocclusions were identified, those accepting treatment forming the study group and those declining treatment the control group. The study group ($n = 70$) were treated with a Fränkel appliance. Pre- and post-treatment observation cephalometric radiographs were analysed and compared. Mean values for both skeletal and dental variables in the control group were remarkably consistent throughout the study period; however, this masked individual variations in this group.

The skeletal variables in the study group that showed statistically significant differences from the control group were SNB, ANB, BaNA and ANS-Me, but none of these was sufficiently large to be regarded as clinically significant. Dental variables showed clinically and statistically significant differences, including a 10 degree reduction in UI-Max and 3.1 degree increase in LI-Mand. The Fränkel appliance was thus found to be effective in producing desirable occlusal and dental changes in the majority of patients treated.

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • growing patients • subjects with Class II division 1 malocclusions • The subjects for both the study and control groups were selected from those seen at a single centre by a single operator (JCA), Area Orthodontic Department, Dumfries and Galloway Royal Infirmary, Dumfries, UK (Scotland)
Schweregrad	OJ > 6mm
Einschluss-kriterien *Bei Review: PICOS*	1. Attended the centre consecutively from 1st January 1990; 2. Age 9–12 years; 3. Overjet greater than 6 mm on initial cephalometric radiograph; 4. Class II molar relationship on initial cephalometric radiograph; 5. Initial and follow-up cephalometric radiographs in occlusion; 6. Minimum 1 year and maximum 3 years between radiographs.
Ausschluss-kriterien	Keine Angabe

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Treatment instituted with a functional regulator (Fränkel II), as shown in Figure 1, regardless of outcome or co-operation. VERSUCHSGRUPPE : **FR-II Group** N=70 (Anfang) / N=70 (Ende) / Alter = 11,23 (min. 9,20, max. 12,92) Jahre / ♂:♀ = 33:37 • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr (anhand Alter angenommen) • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated control group** N=68(Anfang) / N=68 (Ende) / Alter = 10,89 (min. 9,0 max. 12,9 Jahre) / ♂:♀ = 31:37 • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr (anhand Alter angenommen) • KFO-Behandlung: keine kieferorthopädische Therapie
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: Treatment effects on mandibular growth SEKUNDÄRZIELGRÖßE: Treatment effects on maxillary growth TERTIÄRZIELGRÖßE: Treatment effects on the dentition
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. A remarkably stable mean facial and dental form during growth was seen in the untreated subjects; however, individual variation was masked. 2. The functional regulator of Fränkel does not produce clinically significant skeletal changes. 3. The functional regulator produces clinically and statistically significant changes in dental occlusion. 4. In this study, 62 per cent of subjects in the Fränkel group achieved reduction of overjet greater than 5 mm, while none of the control group achieved this change.

Zusammen-fassung der Ergebnisse	**FR-II Group VS. Untreated Control Group** Table 6 reports the changes observed for the two groups, and the results of a t-test for significant differences in that change. In view of the multiple comparisons, a Bonferroni correction was made, taking into consideration the correlation between some of the variables, indicating that a value of P < 0.025 was required to show a difference significant at the P < 0.05 level. The skeletal variables in the study group that showed a statistically significant difference from the control group were SNB, ANB, BaNA and ANS-Me. Dental variables showed clinically and statistically significant differences, including a 10 degree reduction in UI-Max and 3.1 degree increase in LI-Mand. PRIMÄRZIELGRÖßE: **Treatment effects on mandibular growth** Mandibular length increased by 4.2 mm in the study group which was not significantly different from the control group. This finding is in agreement with previous studies, most of which found changes in the region of 3–5 mm. The SNB angle increased by 1.1 degrees in the study group compared with 0.4 degrees for the control group. Although this was statistically significant it was not regarded as a clinically significant effect. A reduction in ANB of 1.4 degrees compared with 0.3 degrees for the control group, while statistically significant, is also of debatable clinical significance. SEKUNDÄRZIELGRÖßE: **Treatment effects on maxillary growth** The parameters used for assessing maxillary growth, SNA, maxillary length and N perpendicular to point A, all showed a trend towards decreased antero-posterior maxillary development in the study group, but this did not reach statistically or, in the opinion of the authors, clinically significant levels. TERTIÄRZIELGRÖßE: **Treatment effects on the dentition** The Fränkel appliance produced clinically and statistically significant changes in all the parameters used to assess the effects on the dentition. Lower incisors proclined by 3.5 degrees and the incisal tip moved forwards 2.6 mm relative to APog. The upper incisors retroclined by 9.7 degrees and upper incisor prominence was reduced by 2.7 mm. The net effect was a mean overjet reduction of 6.2 mm compared with no change in the control group. These findings perhaps indicate a greater contribution to overjet correction (5.3 mm) by incisor tipping. Overbite was reduced on average by 1.7 mm compared with a slight increase in the control group. This is an interesting finding, as the design of the Fränkel appliance does not incorporate a bite plane effect as seen in the activator type of functional appliances.
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte	*Studiendesign:* • Baseline-Imbalancen: signifikante Unterschiede bezüglich 5 Parametern zwischen Versuchs- und Kontrollgruppe, die anschließend zur Auswertung herangezogen werden (obwohl statistisch signifikant, nicht als klinisch relevant in Studie angesehen) • kein Behandlungs- und Beobachtungszeitraum angegeben (nur anhand der Altersangaben errechenbar) • Werte der Patienten, die nicht getragen haben oder bei denen der gewünschte Effekt ausblieb, trotzdem in Statistik aufgenommen (ITT-Analyse?): keine Verschleierung negativer Outcomes

Bias (SIGN, AMSTAR II, Einzelstudien)	*Durchführung:* • Verblindung bei FRS-Auswertung • **CAVE:** keine Informationen zur Intervention: nur Angabe, dass Fränkel II eingesetzt wurde, keine Angabe zu K-Biss/Bissverschiebung, Einschleifen, Instruktion der Patienten bzgl. Tragedauer etc. *Auswertung:* • Reliabilitätsprüfung bei FRS-Auswertung und Errechnung des Methodenfehlers, • Solide Statistik, Normalverteilung geprüft, Konfidenzintervalle angegeben, adjustiertes p (Bonferroni-Korrektur) *Power der Studie/Patientenzahl:* keine genauen Angaben. *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • Siehe RoB: ○ **performance bias:** The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis. – NO (kein klares Outcome definiert) **detection bias:** The outcomes are clearly defined. – NO (kein klares Outcome definiert)
Schluss-folgerung des Begutachters	methodische Qualität: ausreichend
	Klinische Aussagekraft: Durch die Anwendung eines FR II kommt es gegenüber einer Nichtbehandlung zu: • einer signifikanten Zunahme des SNB-Winkels • einer signifikanten Abnahme des ANB-Winkels • keiner signifikanten Veränderung des Oberkiefer-Wachstums (Veränderung von SNA nicht signifikant, Veränderung von BaNA signifikant) • einer signifikanten Protrusion der UK-Front, Retrusion der OK-Front und damit zu einer signifikanten Reduktion des Overjet • einer signifikanten Reduktion des Overbite
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN /AMSTAR II)	**Acceptable (+)**

Evidenztabelle Chatzoudi, Ioannidou-Marathiotou et al. 2014

Chatzoudi M et al. Progress in Orthodontics 2014, 15:62
http://www.progressinorthodontics.com/content/15/1/62

Progress in Orthodontics
a SpringerOpen Journal

RESEARCH Open Access

Clinical effectiveness of chin cup treatment for the management of Class III malocclusion in pre-pubertal patients: a systematic review and meta-analysis

Maria I Chatzoudi[1], Ioulia Ioannidou-Marathiotou[2] and Moschos A Papadopoulos[3*]

Abstract

Background: Chin cup is regarded as the oldest orthodontic appliance for the management of Class III malocclusion. To assess its clinical effectiveness in pre-pubertal patients, a meta-analysis on specific cephalometric values is attempted.

Methods: Detailed electronic and hand searches with no restrictions were performed up to July 2014. Only randomized controlled trials (RCTs) and cohort studies, i.e. prospective controlled trials (pCCTs) and (retrospective) observational studies (OS), were included. Analyses were performed by calculating the standard difference in means and the corresponding 95% confidence intervals, using the random effects model. Data heterogeneity and risk of bias assessment of the included studies were also performed. Study selection, data extraction and risk of bias assessment were performed twice. The level of significance was set at $P \leq 0.05$ for all tests, except for heterogeneity ($P \leq 0.1$).

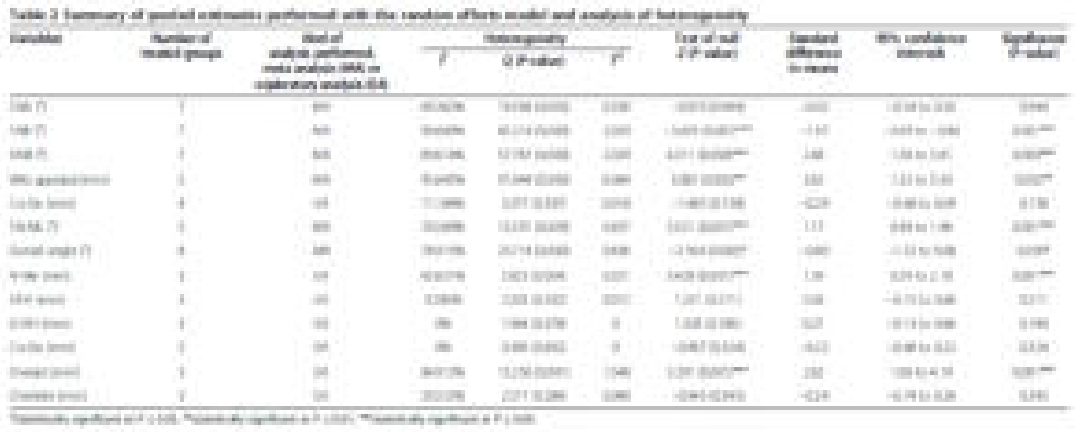
Results: Seven treated groups from five studies (no RCTs, four pCCTs, one OS) were eligible for inclusion, assessing only the short-term occipital pull chin cup effects. In total, 120 treated patients (mean age: 8.5 to 11 years) compared with 64 untreated individuals (mean age: 7.3 to 9.89 years) were assessed by means of 13 cephalometric variables. The overall quality of these studies was low to medium. In comparison to untreated individuals, the SNB and gonial angles decreased significantly following chin cup use, whereas ANB, Wits appraisal, SN-ML, N-Me and overjet increased. For the rest of the variables, no statistically significant differences were detected.

Conclusions: Although the occipital chin cup affects significantly a number of skeletal and dentoalveolar cephalometric variables, indicating an overall positive effect for the treatment of Class III malocclusion, data heterogeneity and between-studies variance impose precaution in the interpretation of the results.

Keywords: Class III malocclusion; Class III treatment; Chin cup; Systematic review; Meta-analysis

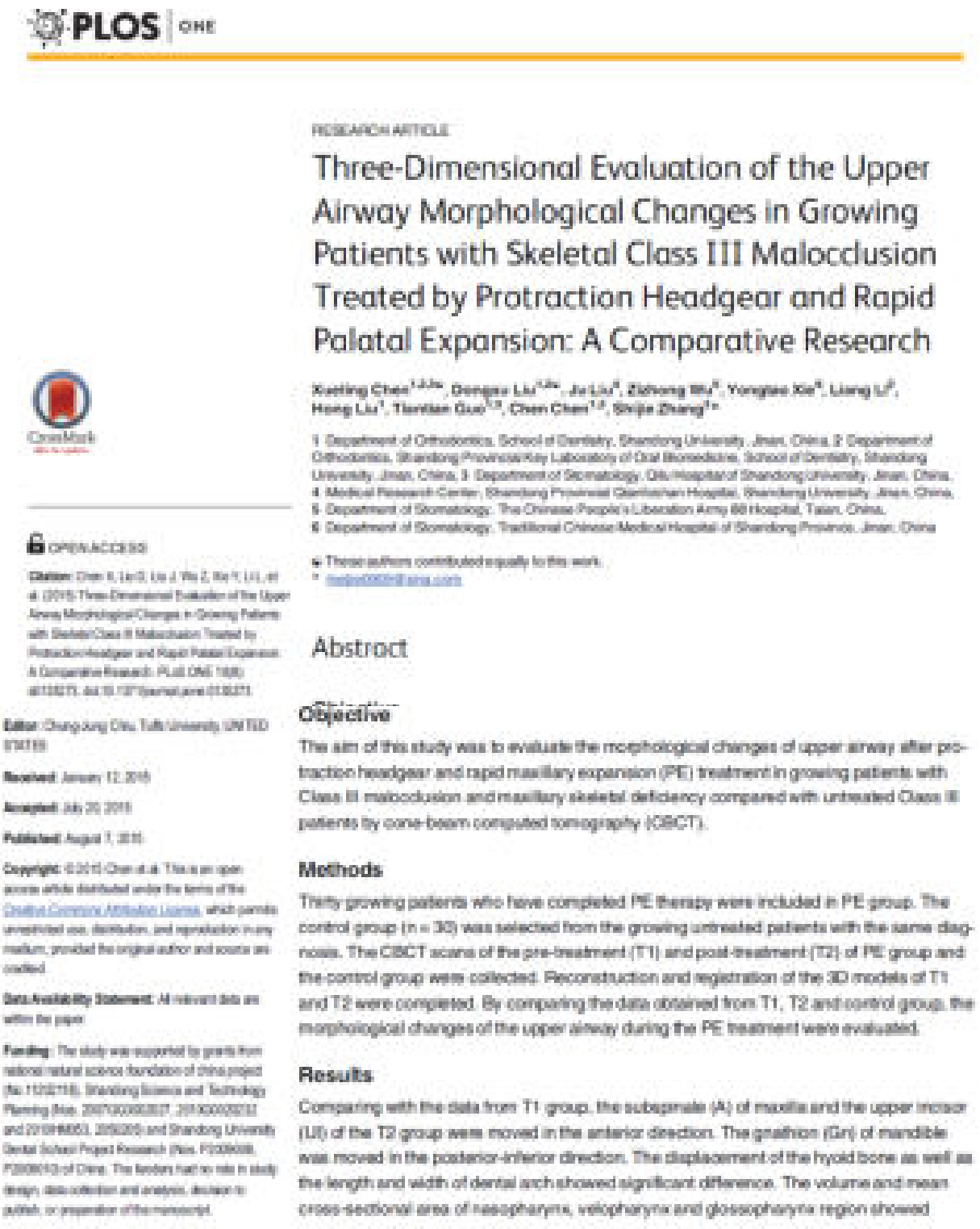
Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** • Patients with Class III malocclusion during/before pubertal growth spurt (6-14 years old) at the start of treatment; 3 der in die Meta Analyse eingegangenen Studien sind aus der Türkei, jeweils eine aus den USA und Ägypten
Schweregrad	Nicht spezifiziert

Einschluss-kriterien *Bei Review: PICOS*	Patients with Class III malocclusion during/before pubertal growth spurt (6-14 years old) at the start of treatment; Chin cup treatment; Untreated patients with Class III malocclusions; Effectiveness of chin cup on growing patients with Class III malocclusion (SNA, SNB, ANB Wits appraisal, Co-Go, SNB, Gonial angle, UFH, LAFH, SN-ML, overjet, overbite; RCTs, NRSI
Ausschluss-kriterien	Unsupported opinions of expert; Replies (to author/editor), Editor's choices, Books' abstract,s Conferences' abstracts ,Protocol of clinical procedures, Technique description, Cross-sectional surveys, Uncontrolled cohort studies (prospective or retrospective clinical trials), Case-control observational studies, Case series without a control, Case reports, Reviews Systematic reviews, Meta-analysis, In vitro studies, Animal studies/testing, Studies on molecular biology, histology, genetics or engineering, Studies on cleft lip and palate and craniofacial anomalies, Studies on Class I malocclusion, Studies on mandibular or maxillary protraction appliances with or without simultaneous use of chin cup, Treatment outcomes given after full orthodontic treatment including chin cup and fixed appliances, Geometric or morphometric assessment without cephalometric measurements, Studies with no English abstract or no abstract at all, studies of less than 10 participants , studies not reporting the size of the examined sample, Patients after the pubertal growth spurt (15+ years old) at the start of treatment, Studies with no matching control samples, Studies not providing measurements of skeletal, dental or soft tissue profile changes as recorded by means of lateral cephalometric analyses, dental cast analyses or electromyographic analyses before and after chin cup treatment in the short- and/or long-term
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: **Chin cup treatment** N=?? (Anfang) / N=120 (Ende) / Alter = 9,6 ± 0,95 Jahre / ♂:♀ = ?:? • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Frühbehandlung • (no restrictions concerneing force or suggested hours of wear, Chin cups were allowed to be used alone or in combination with removable dissocclusion or transversal expansion appliances)
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated Class III** N=?? (Anfang) / N=64 (Ende) / Alter = 9 ± 1 Jahre / ♂:♀ = ?:? • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)

Studientyp	**Systematisches Review** *Review:* Inkludierte Studien in Bezug auf PICO: **4 prospective controlled clinical trials(pCCTI), 1 retrospective observational study, (OS)** *Review:* Gesamt-Teilnehmerzahl in Bezug auf PICO: N=184
Schluss-folgerungen der Autoren	1. The skeletal Class III sagittal relationships of the maxilla and mandible are improved. 2. The skeletal Class III vertical relationships are also affected towards an increase of the vertical growth pattern, an increase of the anterior face height, and/ or posterior rotation of the mandible. 3. The antero-posterior relations of the maxillary and mandibular incisors, as indicated by the increase of overjet, are improved. 4. Nevertheless, the limited number of included studies, the high heterogeneity observed in most of the variables and the linear manner of many of them suggest some precaution in the interpretation of these conclusions. It seems that there is not enough evidence-based data to make definitive recommendations about the chin cup treatment.… … …
Zusammen-fassung der Ergebnisse	**Class III chin cup treated vs. Class III untreated** The pooled statistically significant increase of the SNB and ANB angles entails an improvement of the Class III skeletal relationship of the maxilla and mandible. The Wits appraisal of the treated patients presented a statistically significant increase in comparison to that of the untreated individuals The angular variable SN-ML also presented a statistically significant increase in patients treated with chin cup Statistically significant decrease of the gonial angle. The statistically significant increase of N-Me and overjet, as derived from the corresponding exploratory analyses ([10,13] and [9,11], respectively), further justifies the beneficial use of the chin cup towards the development of a Class I skeletal profile 

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Ordentlich durchgeführter Review. Lediglich die fehlenden Angaben zur Finanzierung und die altmodische RoB Analyse und vor allem die fehlende Evidenzbeurteilung der integrierten Einzelstudien sind einschränkend zu berücksichtigen. Die fehlende Verfügbarkeit von RCTS erlaubte nur den Einschluss von ausschließlich prospektiven nicht randomisierten kontrollierten Studien sowie einer Beobachtungsstudie und deren Heterogenität, schränkt die klinische Aussagekraft z.T. ein. Die Konzentration auf das primäre Behandlungsergebnis anhand numerischer Variablen ist dem Konzept (Meta-Analyse)geschuldet.*
Schluss-folgerung des Begutachters	methodische Qualität: ordentliche Durchführung
	Klinische Aussagekraft: *Die fehlende Verfügbarkeit von RCTS erlaubte nur den Einschluss von ausschließlich prospektiven nicht randomierten kontrollierten Studien sowie einer Beobachtungsstudie und deren Heterogenität, schränkt die klinische Aussagekraft z.T. ein.*
Evidenzlevel (SIGN)	**2+**
Qualität (RoB, SIGN /AMSTAR II)	**Moderat ⊕⊕**

Evidenztabelle Chen, Liu et al. 2015



PLOS ONE

RESEARCH ARTICLE

Three-Dimensional Evaluation of the Upper Airway Morphological Changes in Growing Patients with Skeletal Class III Malocclusion Treated by Protraction Headgear and Rapid Palatal Expansion: A Comparative Research

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Abstract

Objective

The aim of this study was to evaluate the morphological changes of upper airway after protraction headgear and rapid maxillary expansion (PE) treatment in growing patients with Class III malocclusion and maxillary skeletal deficiency compared with untreated Class III patients by cone-beam computed tomography (CBCT).

Methods

Thirty growing patients who have completed PE therapy were included in PE group. The control group (n = 30) was selected from the growing untreated patients with the same diagnosis. The CBCT scans of the pre-treatment (T1) and post-treatment (T2) of PE group and the control group were collected. Reconstruction and registration of the 3D models of T1 and T2 were completed. By comparing the data obtained from T1, T2 and control group, the morphological changes of the upper airway during the PE treatment were evaluated.

Results

Comparing with the data from T1 group, the subspinale (A) of maxilla and the upper incisor (UI) of the T2 group were moved in the anterior direction. The gnathion (Gn) of mandible was moved in the posterior-inferior direction. The displacement of the hyoid bone as well as the length and width of dental arch showed significant difference. The volume and mean cross-sectional area of nasopharynx, velopharynx and glossopharynx region showed

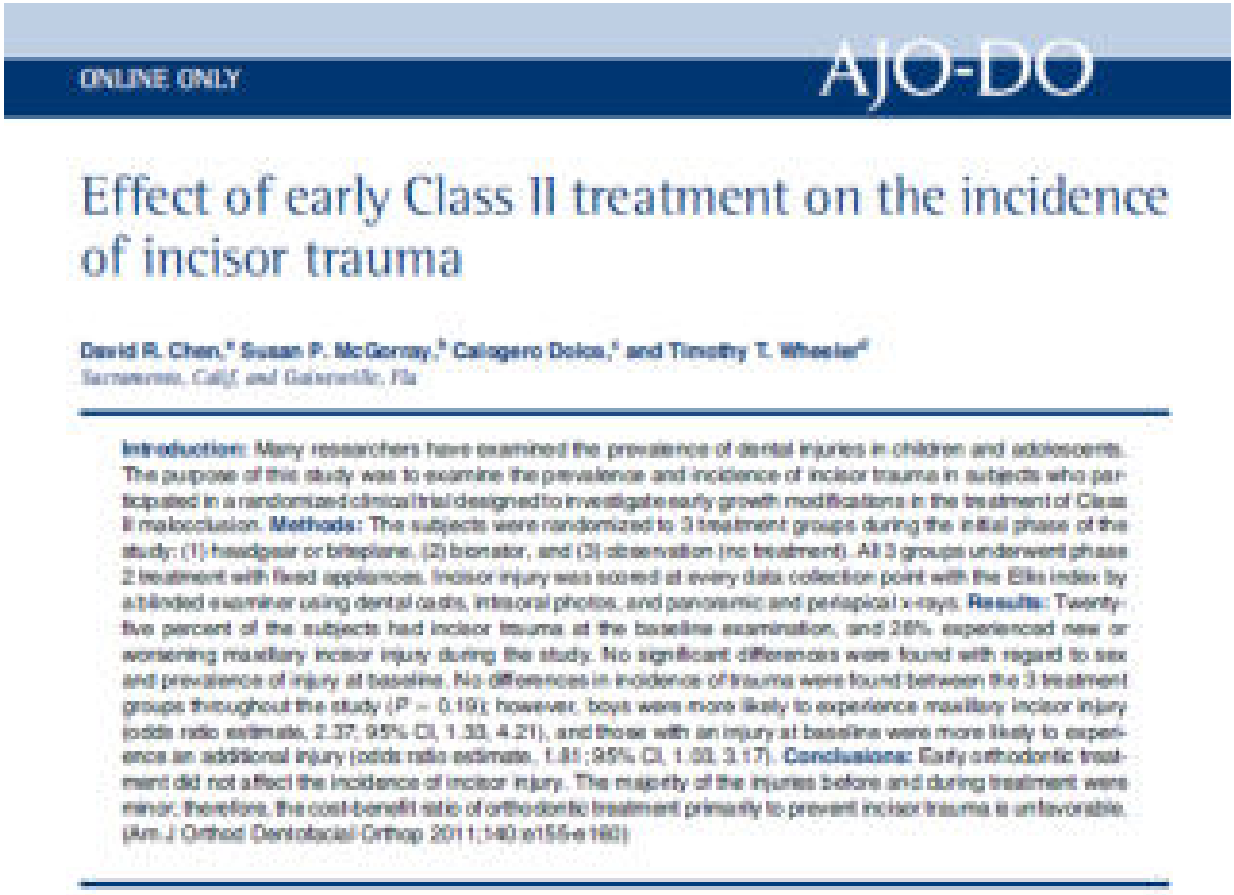
Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** Growing patients with skeletal Class III, dental ClassIII malocclusion with anterior crossbite in late mixed or early permanent dentition.. • China

Schweregrad	ANB angle was between 0° and -4°, SNA <78.8°, A-NP<0 mm, Wits appraisal was -2 mm or less
Einschluss-kriterien	1. At a prepubertal stage of skeletal maturity. The skeletal maturation age was assessed using their hand-wrist radiographs and the vertebral maturation method . 2. Class III molar relationship and anterior crossbite in late mixed or early permanent dentition. 3. Skeletal Class III malocclusion with maxillary deficiency. The ANB angle was between 0° and -4°, SNA <78.8°, A-NP<0 mm, Wits appraisal was -2 mm or less. 4. No mandibular forward functional displacement. 5. No other congenital anomalies, facial neoplasms, potential airway abnormalities or previous orthodontic treatment.
Ausschluss-kriterien	Not fullfilling inclusion criteria
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **PE (**protraction headgear and rapid maxillary expansion) A combination of maxillary protraction headgear and expansion device. An acrylic cap splint Hyrax was used as the expansion device. The screw of the rapid expansion appliance was activated twice a day for a period of 2 or 3 weeks. Maxillary protraction headgear was performed using a facemask. The elastics were oriented at an angle of approximately 30° relative to the occlusal plane. The forces of 500g on each side were used during the treatment. The patients were instructed to wear the appliance for at least 14 hours per day VERSUCHSGRUPPE 1: **PE** N= 30(Anfang) / N=30 (Ende) / Alter = 9,56, 0,22 ♂:♀ = 16:14 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated Class III** N=30 (Anfang) / N=30 (Ende) / Alter = 10,4, 0,42 ♂:♀ = 16:14 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • Atmung und Luftraum (Airway space, Schlafapnoe), Schlucken und Sprechen PRIMÄRZIELGRÖßE Airway Volume SEKUNDÄRZIELGRÖßE: TERTIÄRZIELGRÖßE: QUARTÄRZIELGRÖßE:
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	- Compared to the untreated patients, the **volume of nasopharynx and velopharynx of growing patients with Class III malocclusion and maxillary skeletal deficiency increases after the PE treatment.** - The **volume of glossopharynx and hypopharynx remains unchanged in a shortterm**. - In addition, the velopharynx becomes more circular and the hypopharynx becomes more elliptic in transverse shape after PE treatment
Zusammen-fassung der Ergebnisse	T1 (pre-treatment): mean age 9,56 years, PE; T2 (post treatment/ observation): mean age 10,32 years; PE, 10,41 years untreated Class III Airway Volume NA-V nasopharynx (NA, the top of the upper airway to hard palate plane) VE-V velopharynx (VE, the hard palate plane to the point of the uvula) GL-V glossopharynx(GL, the point of the uvula to the superior border of the epiglottic) HY hypopharynx (HY, the superior border of the epiglotticÐo the bottom of the epiglottic) 

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die Äquivalenz von Versuch- und Kontrollgruppe ist hier hinsichtlich der pharyngalen Volumina unklar. Die Volumenanlysen des Pharynx konnten nicht statistisch verglichen werden, da für die Kontrollgruppe aus ethischen Gründen nur eine Aufnahme zu T2 vorliegt, sodass unklar ist, ob die Äquivalenz der Untersuchungsgruppen zum Startzeitpunkt (T1) vollständig gegeben war. Aufgrund der durchgeführten echten 3D Analysen (CBCT) der Luftwege trotzdem interessante Studie. Weitere methodische Schwächen wie fehlende Verblindung, keine Power/ Sample Size Berechnung führen zu einer insgesamt noch akzeptabel durchgeführten Studie, die wegen der verwendeten Methode zur Erfassung des Outcomes noch klinische Relevanz besitzt. *Funding:* The study was supported by grants from national natural science foundation of china project (No.11202118), Shandong Science and Technology Planning (Nos. 2007GG3002027, 2010G0020232 and 2010HM053, 2050205) and Shandong University Dental School Project Research (Nos. P2009008, P2009010) of China. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. *Interessenkonflikte:* The authors have declared that no competing interests exist. *Bias (SIGN): Keine überprüftbare Äquivalenz von Versuchs- und Kontrollgruppe zu Untersuchungsbeginn. Keine Verblindung. Keine Sample Size/ Power Berechnung.* Aufgrund der durchgeführten echten 3D Analysen (CBCT) der Luftwege trotzdem interessante Studie. Weitere methodische Schwächen wie fehlende Verblindung, keine Power/ Sample Size Berechnung führen zu einer insgesamt noch akzeptabel durchgeführten Studie, die wegen der verwendeten Methode zur Erfassung des Outcomes noch klinische Relevanz besitzt.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel Klinische Aussagekraft: noch akzeptabel durchgeführten Studie, die wegen der verwendeten Methode zur Erfassung des Outcomes noch klinische Relevanz besitzt.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Chen, McGorray 2011



ONLINE ONLY AJO-DO

Effect of early Class II treatment on the incidence of incisor trauma

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Sacramento, Calif, and Gainesville, Fla

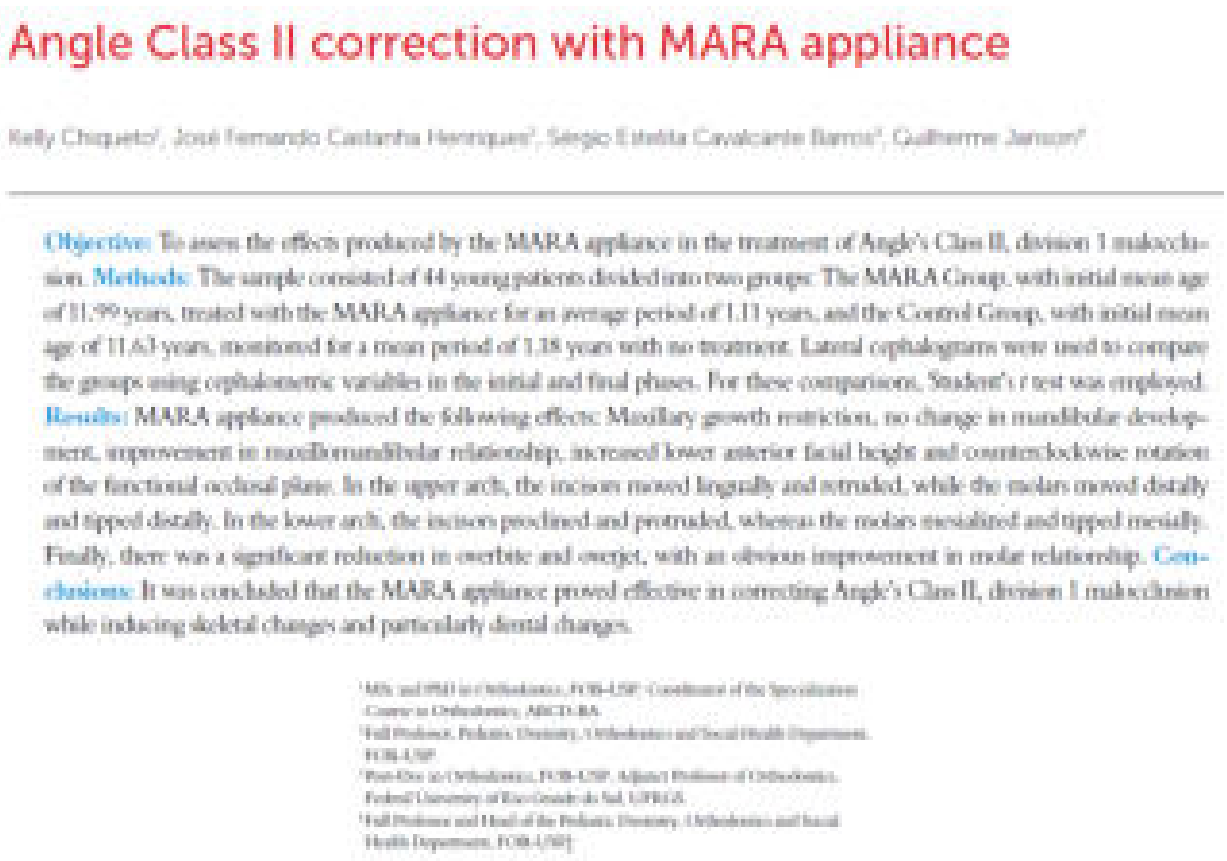
Introduction: Many researchers have examined the prevalence of dental injuries in children and adolescents. The purpose of this study was to examine the prevalence and incidence of incisor trauma in subjects who participated in a randomized clinical trial designed to investigate early growth modifications in the treatment of Class II malocclusion. **Methods:** The subjects were randomized to 3 treatment groups during the initial phase of the study: (1) headgear or bite plane, (2) bionator, and (3) observation (no treatment). All 3 groups underwent phase 2 treatment with fixed appliances. Incisor injury was scored at every data collection point with the Ellis index by a blinded examiner using dental casts, intraoral photos, and panoramic and periapical x-rays. **Results:** Twenty-five percent of the subjects had incisor trauma at the baseline examination, and 28% experienced new or worsening maxillary incisor injury during the study. No significant differences were found with regard to sex and prevalence of injury at baseline. No differences in incidence of trauma were found between the 3 treatment groups throughout the study ($P = 0.19$); however, boys were more likely to experience maxillary incisor injury (odds ratio estimate, 2.37; 95% CI, 1.33, 4.21), and those with an injury at baseline were more likely to experience an additional injury (odds ratio estimate, 1.81; 95% CI, 1.03, 3.17). **Conclusions:** Early orthodontic treatment did not affect the incidence of incisor injury. The majority of the injuries before and during treatment were minor; therefore, the cost-benefit ratio of orthodontic treatment primarily to prevent incisor trauma is unfavorable. (Am J Orthod Dentofacial Orthop 2011;140:e155-e160)

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Children and adolescents • third and fourth grade public school (Dolce et al. 2007)
Schweregrad	**mild:** bilateral half cusp **moderate:** at least 1 side three quarters cusp **severe:** at least 1 side full cusp
Einschluss-kriterien *Bei Review: PICOS*	• bilateral greater than or equal to one half-cusp Class II molars or unilateral greater than one half-cusp Class II molars • fully erupted permanent first molars • not more than 3 permanent canines or premolars • positive overjet and overbite • good general and dental health
Ausschluss-kriterien	Keine Angabe

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** *für genauere Beschreibung der Intervention* s. Wheeler et al. 2002, Dolce et al. 2007 VERSUCHSGRUPPE: **Bionator** N=87 (Anfang) / N= 87 (Ende) / Alter = 9.6 ± 1.1 Jahre / ♂:♀ = 60%:40% • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE: **HG/Biteplane** N=93 (Anfang) / N= 93 (Ende) / Alter = 9.7 ± 0.8 Jahre / ♂:♀ = 62%:38% • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Observation** N= 81 (Anfang) / N= 81 (Ende) / Alter = 9.5 ± 0.8 Jahre / ♂:♀ = 62%:38% • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung (MB ab DC7)
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • ***Traumaprophylaxe (dentales Frontzahntrauma)*** PRIMÄRZIELGRÖßE: *Frontzahntrauma (Inzidenz)*
Studientyp	**RCT**
Schluss-folgerungen der Autoren	1. We found that a significant number of children already had some incisor injury before early orthodontic treatment. Early treatment would need to be initiated at the eruption of the permanent incisors to determine its effectiveness in preventing dental trauma. 2. No correlation was found between initial overjet and the prevalence of trauma. 3. Early orthodontic treatment, begun on average between the ages of 9 and 10, did not significantly affect the incidence of trauma. Most injuries before and during treatment were minor and consisted of enamel fractures. Most injuries occurred in the maxillary central incisors. 4. Multivariate longitudinal analysis indicated that during the time periods of phases 1 and 2, boys were more likely than girls to incur trauma. Those with previous trauma were more likely to incur more, and the incidence of trauma decreased over time.
Zusammen-fassung der Ergebnisse	**Bionator VERSUS HG/Biteplane VERSUS Observation** ***PRIMÄRZIELGRÖßE*** As shown in Table III, there were no differences in the incidence of new trauma between treatment groups during any time interval.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *RCT* *Durchführung:* • *Durchführung an einem Zentrum* *Auswertung:* • *Verblindung bei der Auswertung* • *Ein Untersucher mit Reliabilitätsprüfung (hier aber keine genaueren Angaben)* • *Keine Konfidenzintervalle angegeben* *Power der Studie/Patientenzahl: keine Angaben* *Funding:* Supported by a grant from NIH/NICDR, DE08715 *Interessenkonflikte: keine Angaben* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • *Keine Verblindung in der Therapie*
Schluss-folgerung des Begutachters	methodische Qualität: sehr gut
	Klinische Aussagekraft: • Eine kieferorthopädische Behandlung im Alter von 9-10 Jahren hat keinen signifikanten Effekt auf die Inzidenz von Frontzahntraumata. • Keine Korrelation zwischen Overjet und der Inzidenz von Frontzahntraumata.
Evidenz-level (SIGN)	**1++**
Qualität **(RoB, SIGN /AMSTAR II)**	⊕⊕ High Quality

Evidenztabelle Chiqueto, Henriques et al. 2013



Angle Class II correction with MARA appliance

Kelly Chiqueto[I], José Fernando Castanha Henriques[II], Sérgio Estêvão Cavalcante Barros[III], Guilherme Janson[IV]

Objective: To assess the effects produced by the MARA appliance in the treatment of Angle's Class II, division 1 malocclusion. **Methods:** The sample consisted of 44 young patients divided into two groups: The MARA Group, with initial mean age of 11.99 years, treated with the MARA appliance for an average period of 1.11 years, and the Control Group, with initial mean age of 11.63 years, monitored for a mean period of 1.38 years with no treatment. Lateral cephalograms were used to compare the groups using cephalometric variables in the initial and final phases. For these comparisons, Student's *t* test was employed. **Results:** MARA appliance produced the following effects: Maxillary growth restriction, no change in mandibular development, improvement in maxillomandibular relationship, increased lower anterior facial height and counterclockwise rotation of the functional occlusal plane. In the upper arch, the incisors moved lingually and retruded, while the molars moved distally and tipped distally. In the lower arch, the incisors proclined and protruded, whereas the molars mesialized and tipped mesially. Finally, there was a significant reduction in overbite and overjet, with an obvious improvement in molar relationship. **Conclusions:** It was concluded that the MARA appliance proved effective in correcting Angle's Class II, division 1 malocclusion while inducing skeletal changes and particularly dental changes.

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Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Young patients • Orthodontics, FOB-USP (FOB –USP = Faculdade de Odontologia de Bauru – Universidade de São Paulo = Bauro School of Dentistry – University of São Paulo)
Schweregrad	Laut deskriptiver Statistik: • MARA Group: OJ = 9,12 ± 1,78mm, ANB = 5,23 ± 1,20° • Untreated Control Group: OJ = 7,99 ± 1,81mm, ANB = 4,69 ± 1,88°
Einschluss-kriterien *Bei Review: PICOS*	» Bilateral Angle's Class II, division 1 malocclusion. » Mandibular retrusion. » No agenesis or no permanent teeth missing. » No supernumerary teeth. » No crowding, or mild crowding in the upper and lower arches. » Moderate or severe overjet. » No previous orthodontic treatment.

Ausschluss-kriterien	Keine Angabe
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** The MARA was installed with a transpalatal bar and a lingual arch in all patients. Only one patient presented initially with posterior crossbite involving only the first molars and was then subjected to rapid maxillary expansion with a Hyrax appliance. The patients in this group were not subjected in advance to tooth alignment and leveling, nor interproximal stripping. All were treated until 2 mm, on average, beyond Class I molar relationship was obtained. Malocclusion correction was deemed successful when an occlusion in centric relation was achieved, i.e., when the mandible was positioned in a centric relation (CR) that matched the position of maximum intercuspation (MI). After achieving this relationship, the appliance was kept in place for 6 months for retention purposes. The MARA appliance was thereafter removed and the patient’s final radiograph taken. 1.00 year (minimum = 0.77, maximum = 1.25 years) VERSUCHSGRUPPE: **MARA Group** N=22 (Anfang) / N=22 (Ende) / Alter = 11,99 ± 1,20 Jahre / ♂:♀ = 15:7 • Gebissphase: spätes Wechselgebiss/permanentes Gebiss < 18 Jahre (anhand Alter) • KFO-Behandlung: reguläre Behandlung (anhand Alter)
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** The Control Group comprised 22 patients, 15 male and 7 female, who did not undergo any type of orthodontic or orthopedic functional treatment during the observation period evaluated in this study. The patients were selected from a sample provided by the Center for the Study of Growth, FOB-USP, where a group of children was X-rayed and checked annually by the Department of Orthodontics with the purpose of developing a longitudinal sample of occlusions in children spanning from primary to permanent dentition. Subsequently, all patients were referred for orthodontic treatment, but some either chose to postpone intervention to a later date, or showed no interest in the treatment, which allowed the authors to define a control group. KONTROLLGRUPPE: **Untreated Control Group** N=22 (Anfang) / N=22 (Ende) / Alter = 11,63 ± 1,03 Jahre / ♂:♀ = 15:7 • Gebissphase: spätes Wechselgebiss/permanentes Gebiss < 18 Jahre (anhand Alter) • KFO-Behandlung: keine Therapie

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: Cephalometric skeletal and dental effects The cephalometric tracing was performed on acetate tracing paper (Ultraphan) by the same researcher and then digitized (Numonics AccuGrid xnT, model A30TL.F - Numonics Corporation, Montgomeryville, Pa). Data were analyzed with Dentofacial Planner 7.2 software (Dentofacial Planner Software Inc., Toronto, Ontario, Canada); a 9.8% magnification factor was corrected in the radiographs of the MARA Group MARA and 6% in the radiographs of the Control Group, since they were taken by different X-ray machines. The lines and reference planes used in the study are shown in Figure 2A, comprising: A) Line SN. B) Frankfort plane. C) Palatal plane. D) Functional occlusal plane. E) Mandibular plane - GoGn. F) Mandibular plane - GoMe. G) Long axis of the upper incisor. H) Long axis of lower incisor. I) Long axis of the molar. J) Long axis of the molar. K) NA line. L) NB line. M) ANSperp line. N) Pogperp line. The skeletal cephalometric measures are shown in Figure 2B, the dental measures are shown in Figure 2C and the dental relations corresponding to overjet (OJ), overbite (OB) and molar ratio (MR) are shown in Figure 2D. Superimposition of initial and final tracings in the MARA group.
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	MARA appliance was effective in correcting Angle’s Class II, division 1 malocclusion, producing more dentoalveolar than skeletal effects, with skeletal changes occurring predominantly in the maxilla — where maxillary growth was restrained —, and no significant effects on the mandible. In addition, the MARA appliance increased the vertical dimension of the face. Regarding dental changes, the upper incisors were inclined lingually and retruded. The upper molars showed distalization and distal tipping. The lower incisors inclined labially and protruded. The lower molars showed mesialization and mesial tipping. The MARA caused some significant improvement in dental relations (overbite and overjet, and molar relationship).

Zusammen-fassung der Ergebnisse	**MARA Group VS. Untreated Control Group** ***PRIMÄRZIELGRÖßE*** To differentiate the effects produced by the functional appliance on the normal growth that occurred during the evaluation time, the changes found in cephalometric variables for MARA were compared with those of the Control Group (Table 2). As regards to skeletal changes, the results showed that in the MARA group, the maxilla showed a slight retrusion and less growth. The mandible showed no significant differences in length and position, the maxillomandibular relationship improved significantly, the growth pattern was not affected, the lower anterior facial height increased and the occlusal plane experienced a counterclockwise rotation. The dentoalveolar changes found in the MARA Group were: Greater lingual inclination and retrusion of upper incisors, crown distalization and distal tipping of the long axis of the upper molars, considerable buccal inclination and protrusion of the lower incisors, and mesialization and mesial tipping of mandibular molars. A reduction in overjet and overbite was noted in the dental relations as well as a significant improvement in the molar relationship in the MARA Group.
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *Kontrollgruppe aus „Center for the study of Growth“* • *Ethikvotum und Zustimmung vorhanden* • *Suffizientes Matching vorhanden* *Durchführung:* • *1 Behandler* *Auswertung:* • *Test auf Normalverteilung (Kolmogorov-Smirnov) vorhanden* • *1 Auswerter* • *Reliabilitätstest vorhanden, aber keine Ergebnisse angegeben* *Power der Studie/Patientenzahl: keine Angabe* *Funding: keine Angaben* *Interessenkonflikte: keine Angaben* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • *Selection bias: keine genauen Angaben über Rekrutierung; aber Matching vorhanden* • *Performance bias* • *Attrition bias: keine Angaben über Dropouts* • *Detection bias: keine Verblindung angegeben* • *Keine Konfidenzintervalle angegeben*
Schluss-	methodische Qualität: befriedigend

folgerung des Begutachters	Klinische Aussagekraft: Die MARA-Therapie führt im Vergleich zu Nicht-Therapie-Gruppe zu: • Keine signifikanten Effekte auf den Unterkiefer • Hemmung des Oberkieferwachstums • Retrusion der Oberkieferfront • Distalisation und Distalkippung der OK-Molaren • Protrusion der UK-Front • Mesialisation und Mesialkippung der UK-Molaren • Verbesserung von Overbite, Overjet und Bissstellung
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN /AMSTAR II)	⊕ Acceptable

Orthodontics & Craniofacial Research

REVIEW ARTICLE

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Efficacy of orthopedic treatment with protraction facemask on skeletal Class III malocclusion: a systematic review and meta-analysis

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Abstract

The objectives of this systematic review was to estimate the efficacy of protraction facemask on the correction of Class III malocclusion in the short term. A systematic review of articles was performed using different electronic databases (PubMed, Ovid, Cochrane Central Register of Controlled Trials, Web of Science, LILACS, and Google Scholar). Search terms comprised 'orthopedic treatment' and 'Class III malocclusion'. The selection criteria were set in order to include in this review only randomized clinical trials (RCTs) performed treating with facemask Class III growing patients. Studies' selection, data extraction, and risk of bias's assessment were executed independently by two authors using pre-defined data forms. All pooled analyses of data were based on random effects models. A pre-specified subgroup analysis was planned to evaluate the effect of preliminary rapid palatal expansion on facemask efficacy. Three RCTs met our inclusion criteria. In total, data from 166 patients (90 treated and 63 controls) were collected. The treated group showed the following significant changes: ANB° +3.08° [95%CI (2.58, 4.74)]; SNA° +2.10 [95%CI (1.14, 3.06)]; SNB° −1.54 [95%CI (−2.13, −0.95)]; SN-palatal plane −0.82° [95%CI (−1.62, −0.02)]; and SN-mandibular plane +1.51 [95%CI (0.61, 2.41)]. Heterogeneity varied from low to moderate (mean I^2 value: 41.4 ± 20.6). Facemask is effective correcting Class III malocclusion in the short term. The skeletal modifications induced by facemask are forward displacement of maxilla, backward displacement of mandible, clockwise rotation of the mandibular plane, and counterclockwise rotation of the maxillary plane.

Key words: human study; malocclusion; meta-analysis; protraction facemask; review article

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** • Patients with Class III malocclusion; Study settings: UK, USA (California), Turkey
Schweregrad	Nicht spezifiziert
Einschluss-kriterien *Bei Review: PICOS*	Patients with Class III malocclusion; Face mask or facemask ± RME; Untreated patients with Class III malocclusions; Sagittal and vertical skeletal effects of facemask: ANB, SNA, SNB, SN-palatal plane, SN-mandibular plane; RCTs, NRSI
Ausschluss-kriterien	1. No humanclinical trials; 2. No comparable untreated control; 3. subjects not allocated randomly; 4. no cenophalometric analysis performed before and immediately after treatment; 5. studies conductedon not on growing patients without any craniofacialdeformity; 6. orthognathic surgery; 7. confounding procedures (extractions, fixed appliances); 8. previous treatment for Class III malocclusion; 9. Non RCT
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: **Face mask or facemask ± RME** N=?? (Anfang) / N=54 (Facemask + RME; Ende) / Alter = 8 ± 0.98 Jahre / ♂:♀ = 63:93 N=?? (Anfang) / N=38 (Facemask alone; Ende) / Alter = 8.35 ± 0.35 Jahre / ♂:♀ = 63:93 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Frühbehandlung • Planned subgroup analyses: Facemask ± RME • Geschlechterverhältnis nur für die Gesamtpopulation darstellbar • Potentielles Bias Risiko: eine Studie (Ref. 3) hatte ausschließlich weibliche Teilnehmer
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated Class III** N=?? (Anfang) / N=63 (Ende) / Alter = 8.3 ± 1.4 Jahre / ♂:♀ = 63:93 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: keine Behandlung • Geschlechterverhältnis nur für die Gesamtpopulation darstellbar
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)

Studientyp	**Systematisches Review** *Review:* Inkludierte Studien in Bezug auf PICO: **RCT N = 3** *Review:* Gesamt-Teilnehmerzahl in Bezug auf PICO: N=155
Schluss-folgerungen der Autoren	1. Facemask therapy in growing subjects with Class III malocclusion is effective (Observation 12- 15 months) 2. Skeletal modifications induced by facemask are forward displacement of the maxilla, backward displacement of the mandible, clockwise rotation of the mandibular plane, and counterclockwise rotation of the maxillary plane … 3. When used with the intent to enhance anterior maxillary movement during facemask therapy, preliminary rapid palatal expansion does not seem to affect the effectiveness of the orthopedic treatment.
Zusammen-fassung der Ergebnisse	**GRUPPE Class III Face mask or facemask ± RME VS. GRUPPE Class III untreated** Protraction facemask therapy in growing Class III patients is effective in the short term. The skeletal modifications induced by facemask are forward dislocation of the maxilla, backward movement of the mandible, clockwise rotation of the mandibular plane, and counterclockwise rotation of the maxillary plane. Taking account of the protraction facemask's effects, it should ideally be used in Class III cases with counterclockwise rotation of mandibular plane. Preliminary rapid palatal expansion does not seem to improve the effectiveness of facemask.
Angaben auffälliger positiver und/oder negativer Aspekte	*Gut durchgeführter Review. Lediglich die fehlenden Angaben zur Finanzierung die fehlende Publication Bias Analyse und vor allem die fehlende Evidenzbeurteilung der integrierten Einzelstudien sind leider einschränkend zu berücksichtigen und verhinderen ein besseres Ergebnis. Die Fokussierung auf RCTs verbessert potentiell den Evidenzgrad des Reviews, allerdings konnten insgesamt nur 3 RCTs identifiziert warden, die den Einschlusskriterien genügten. Allerdings blieb die Heterogenität unter diesen jedoch gering bis moderat. Gute Studie mit klinischer Relevanz.*
Schluss-folgerung des Begutachters	methodische Qualität: Gute Durchführung
	Klinische Aussagekraft: *Durch den ausschließlichen Einschluss von RCTs hohe klinische Relevanz.*
Evidenzlevel (SIGN)	**1+**
Qualität (RoB, SIGN /AMSTAR II)	**Moderat ⊕⊕**

Evidenztabelle Cozza, Baccetti et al. 2010

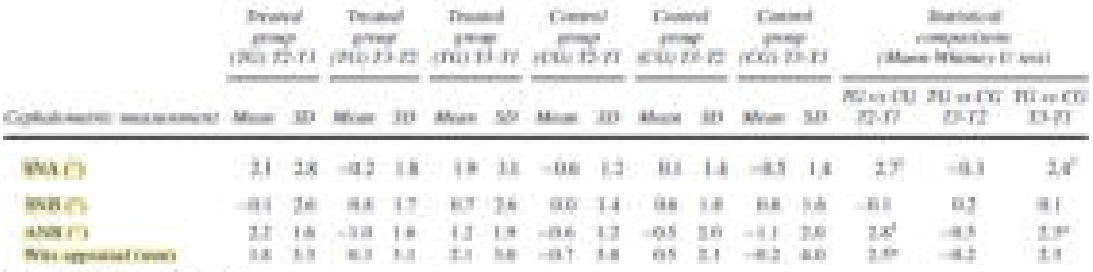
Treatment and posttreatment effects of a facial mask combined with a bite-block appliance in Class III malocclusion

Paola Cozza,[a] Tiziano Baccetti,[b] Manuela Mucedero,[c] Chiara Pavoni,[d] and Lorenzo Franchi[b]
Rome and Florence, Italy

Introduction: In this cephalometric investigation, we analyzed the treatment and posttreatment effects of an orthopedic protocol for Class III malocclusion consisting of a facial mask combined with a removable bite-block appliance. **Methods:** The treated sample consisted of 22 Class III patients treated with the facial mask and bite-block protocol before the pubertal growth spurt (mean age, 8.9 ± 1.5 years). Treated subjects were evaluated after facial mask and bite-block therapy and at a posttreatment observation in absence of retention. The treated group was compared with a matched control group of 12 untreated Class III subjects. All treated and control subjects were postpubertal at the final observation. Significant differences between the treated and control groups were assessed with the Mann-Whitney U test ($P < 0.05$). **Results:** Both angular and linear sagittal measurements of the maxilla showed significant improvements during active treatment. Significant improvements of SNA angle, ANB angle, overjet, and molar relationship remained stable during the posttreatment period. No significant effect was found in the mandibular skeletal measures. No significant protraction of the maxillary incisors or retraction of the mandibular incisors was observed. **Conclusions:** A bite-block appliance in the mandibular arch with a facial mask enabled effective control of mandibular rotation with progressive closure of the gonial angle. This added to the favorable maxillary outcomes of the treatment protocol. (Am J Orthod Dentofacial Orthop 2010;138:300-10)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** - Children with Class III malocclusion in the mixed dentition anterior crossbite or incisor end-to-end relationship, and Class III molar relationship. • Italy
Schweregrad	Wits appraisal of –2 mm or less
Einschluss-kriterien	- Class III malocclusion in the mixed dentition characterized by - Wits appraisal of –2 mm or less, - anterior crossbite or incisor end-to-end relationship, and - Class III molar relationship. - Prepubertal stage of skeletal maturity according to the cervical vertebral maturation method of CS 1 or CS 2.
Ausschluss-kriterien	- Missing or extracted permanent teeth before or during treatment - Transverse discrepancy between the dental arches.

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **FM-BB** The intraoral anchorage appliance for posteroanterior elastics connected with the FM was constructed with a 1-mm stainless steel arch (buccal and palatal), with 2 hooks in the maxillary canine region to attach the elastics. The intraoral appliance was soldered to bands placed on the maxillary first permanent molars, and the palatal arch was placed in contact with the gingival margins of the maxillary teeth. Maxillary protraction began with forward and downward traction directed approximately 30°to 40° to the occlusal plane. Hooks were soldered in the frontal part of the maxillary arch,between the lateral incisors and the deciduous canines. Elastics of increasing force were used during the first month of therapy until a heavy orthopedic force (600 g for each side) was delivered. A Delaire FM was used . The patients were instructed to wear the FM at least 14 hours a day; cooperation was good for all of them. During FM treatment, a BB appliance was used in all treated patients, The BB appliance was constructed in the form of a Schwarz plate for the mandibular arch with a vestibular arch, occlusal resin splints, and an expansion screw that was activated when needed. The patients were instructed to wear the BB for 24 hours a day, including during meals; cooperation was good for all of them. VERSUCHSGRUPPE 1: **FM-BB** N= 22 (Anfang) / N=22 (Ende) / Alter = 8,9, 1,5 ♂:♀ = 9:13 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated Class III** N=12 (Anfang) / N=12 (Ende) / Alter = 7,6, 1,4 ♂:♀ = 7:5 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: **Skeletal: SNA, SNB, ANB, Wits** SEKUNDÄRZIELGRÖßE: **Dental: Overjet**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	1. Treatment with the FM-BB protocol induced **significant dentoskeletal responses** in terms of improvement of SNA angle, ANB angle, OJ, and molar relationship; these changes remained **stable during the posttreatment period**. 2. **No modifications were found in vertical skeletal relationships**. The BB in the mandibular arch enabled effective control of mandibular rotation and facilitated progressive closure of the gonial angle. 3. As for the dental changes associated with orthopedic treatment, the FM-BB protocol caused no proclination of the maxillary incisors or retroclination of the mandibular incisors in the long term. The significant **improvement in OJ (2.5 mm) was entirely related to the amount of skeletal maxillary advancement**.
Zusammen-fassung der Ergebnisse	**GRUPPE FM-BB VS. GRUPPE untreated Class III** *Mean* *SD* *Mean* *SD* T1 8.9 1.5 7.6 1.4 T2 10.5 1.3 9.8 1.9 T3 12.6 1.9 11.9 2.2 T2-T1 1.6 0.8 2.2 1.3 T3-T2 2.1 1.3 2.0 1.7 T3-T1 3.7 1.3 4.3 2.0 **Skeletal: SNA, SNB, ANB, Wits**  **Dental: Overjet** 

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die Äquivalenz von Versuch- und Kontrollgruppe wurde nachvollziehbar überprüft. Power/ Sample Size Berechnungen wurden durchgeführt. Eine Verblindung fand nicht statt. Die Kontrollgruppe ist allerdings klein und retrospektiv rekrutiert. Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie ordentlich. Die Untersuchung des FM mit einem ergänzenden Bite Bloc ist von klinischem Interesse, die methodische Qualität insgesamt akzeptabel, daher ist die klinische Relevanz dieser prospektiv (FM-BB) /retrospektiven (Kontrollgruppe) Studie gegeben. *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist gegeben. Power/ Sample Size Berechnungen durchgeführt. Eine Verblindung fand nicht statt.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie ordentlich. Die Untersuchung des FM mit einem ergänzenden Bite Bloc ist von klinischem Interesse, die methodische Qualität insgesamt akzeptabel, daher ist die klinische Relevanz dieser prospektiv (FM-BB) /retrospektiven (Kontrollgruppe) Studie gegeben.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Cozza, De Toffol et al. 2004

European Journal of Orthodontics 26 (2004) 293–307

Dentoskeletal effects and facial profile changes during activator therapy

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**Private Practice, Rome, Italy

SUMMARY The aim of this retrospective study was to investigate cephalometrically the skeletal, dental, and soft tissue modifications induced by activator treatment in patients with Class II malocclusions caused by mandibular retrognathism. The subjects, all in the mixed dentition, were selected from a single centre and were divided into two groups: 40 patients treated with an incisor double capping activator (20 girls, 20 boys with a mean age of 10 years) and a control group of 30 subjects (15 girls, 15 boys with a mean age of 10 years). The dentoskeletal and aesthetic changes that occurred were compared on lateral cephalograms taken before treatment (T0) and after 18–24 months, when the activator was removed (T1). In the control group the radiographs were obtained before (T0) and after (T1) 21 months (standard deviation ±3 months).

Activator treatment in these growing patients resulted in a correction of the Class II relationship (ANB −2.14°), a restriction of maxillary growth (SNA −0.5°), an advancement of the mandibular structures (SNB +1.64°, FH°NPg +3.39°; OLp-B +5.17 mm, OLp-Pg +5.14 mm, OLp-Go +2.44 mm), a correction of the overjet (−5.03 mm), an improvement in overbite (−1.17 mm) and uprighting of the maxillary incisors (1°FH −5.64°).

The activator appliance was effective in treating growing patients with mandibular deficiency: activator therapy corrected Class II malocclusions by a combination of skeletal and dental changes and improved the soft tissue facial profile.

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Patients with Class II malocclusions • Mixed dentition, selected from the Department of Orthodontics, University of Rome “Tor Vergata”
Schweregrad	Overjet (mm), Okklusion (PB), ANB(°), SNB(°) OJ > 5mm; Klasse II > ½ PB; ANB >5°; SNB <78°
Einschluss-kriterien *Bei Review: PICOS*	1. 9-11 years of age 2. overjet greater than 5mm 3. Class II molar relationship with at least half a cusp width distal molar relationship 4. skeletal Class II malocclusion with ANB greater than 5 degrees 5. retrognathic mandible with SNB less than 78 degrees 6. no history of previous orthodontic therapy
Ausschluss-kriterien	---

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Acrylic monobloc attached to the upper jaw by Adams' clasps with a central screw. The screw was activated only to follow maxillary transversal growth. The activator was designed to avoid undesirable anterior dental movements. The incisal edges and 2mm of the labial surfaces of the maxillary and mandibular incisors were capped to prevent tipping. The activator was produced from a construction bite that positioned the mandible anteriorly in an edge-to-edge incisor relationship. The bite registration was obtained 3mm short of maximum protrusion, with care being taken to ensure that lateral displacement did not occur. The height of the bite exceeded the freeway space by 2-3mm. The patients were instructed to wear the appliance for a minimum of 14hurs in each 24 hour period. VERSUCHSGRUPPE: **Activator Group** N= 20 (Anfang) / N= 20 (Ende) / Alter = 10 ± ?? Jahre / ♂:♀ = 20:20 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated Control Group** N=30 (Anfang) / N=30 (Ende) / Alter = 10 ± ?? Jahre / ♂:♀ = 15:15 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: Cephalometric Analysis • Sagittal: SNA (º), SNB (º), ANB (º), Ao–Bo(mm), Nperp–A (mm), Nperp–Pg (mm), NSCo (º), CoA (mm), CoGn (mm), GoMe (mm), FH^NA (º), FH^NPg (º) • Vertikal: FMA (º), FH^OL (º), SN^PP (º), PP^GoMe (º), N–ANS (mm), ANS–Me (mm) • Dental: 1^FH (º), IMPA (º), interincisal angle (º), overjet (mm), overbite mm, 1¯-OL (mm) • Aesthetic: NCPgC^FH (º), UL–EL (mm), LL–EL (mm)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	The results indicate that the activator appliance is effective in treating mandibular deficiency. Functional therapy is of clinical benefit in actively growing patients and should be initiated during the middle to late mixed dentition period. Patient cooperation and the age at which functional appliance treatment is instituted are important for satisfactory correction of Class II malocclusions. When the activator patients were compared with the untreated controls subjects, the results showed that therapy promoted a combination of skeletal and dental changes and improved the soft tissue facial profile. Dentoalveolar effects seemed to play an important role in this correction, but a relative maxilla mandibular displacement, mainly a mandibular advancement, was also determinant. Further investigations on changes occurring in the condylar–glenoid fossa relationship might provide information concerning the remodelling processes responsible for Class II correction following activator treatment.

Zusammenfassung der Ergebnisse

Activator Group VERSUS Untreated Control Group

PRIMÄRZIELGRÖßE *keine genauere Beschreibung der unter den PICO-Kriterien relevanten Ergebnisse; nur Ergebnistabelle vorhanden*

Table 4 Changes in the control and treatment groups from before (T0) to after (T1) treatment.

Variables	T1–T0 control group ($n = 30$)	SD	T1–T0 treated group ($n = 40$)	SD	P
SNA (°)	0.33	0.49	−0.5	1	*
SNB (°)	0.17	0.41	1.64	1.3	***
ANB (°)	0.13	0.61	−2.14	1	***
Ao–Bo (mm)	0.4	0.51	−3.33	1.43	***
Nperp–A (mm)	−0.07	1.45	−0.39	1.22	ns
Nperp–Pg (mm)	−0.77	2.06	2.17	2.09	**
NSCo (°)	0.93	0.8	−0.39	2.95	*
Co–A (mm)	5.13	2.36	0.67	1.88	***
Co–Gn (mm)	3	3.68	5.67	4.85	ns
GoMe (mm)	2.17	1.71	2.36	1.76	ns
FH^NA (°)	−0.33	1.63	−0.44	1.2	ns
FH^NPg (°)	−0.67	1.76	3.39	4.16	***
FMA (°)	−1.33	5.22	0.47	1.83	ns
FH^OL (°)	−0.13	1.90	1.25	2.24	ns
SN^PP (°)	−0.67	1.29	1.58	2.38	**
PP^GoMe (°)	−0.73	1.71	−0.25	3.27	ns
N–ANS (mm)	3.33	2.97	2.44	2.07	ns
ANS–Me (mm)	2.67	1.95	2.11	2.64	ns
$\underline{1}$^FH (°)	−0.73	4.08	−5.64	4.12	**
IMPA (°)	−1.67	1.29	1.55	3.09	***
Interincisal angle (°)	5.33	4.17	3.42	6.4	ns
Overjet (mm)	−0.13	0.88	−5.03	1.45	***
Overbite (mm)	3.33	1.18	−1.17	2	***
$\overline{1}$–OL (mm)	1.7	1.49	−0.53	1.41	***
NCPgC^FH (°)	−0.03	1.8	1.75	2.73	*
UL–EL (mm)	−1.87	2.19	−2	1.77	ns
LL–EL (mm)	0.07	3.54	−0.39	2.3	ns
OLp–Co (mm)	0.80	0.82	−0.50	1.16	**
OLp–A (mm)	2.23	1.37	0.97	1.55	*
OLp–B (mm)	1.67	2.97	5.17	3.27	*
OLp–Go (mm)	0.17	3.55	2.44	2.26	ns
OLp–Pg (mm)	2	3.05	5.14	3.25	*
OLp–Ss (mm)	1.93	2.22	2.25	2.93	ns
OLp–UL (mm)	1.73	0.96	1.75	3.41	ns
OLp–LL (mm)	3.27	1.33	3.75	3.40	ns
OLp–Si (mm)	1.93	3.03	5.30	3.66	*
OLp–PgC (mm)	3.2	3.31	5.97	3.86	*
OLp–$\underline{1}$ (mm)	2	1.69	0.19	3.10	*
OLp–$\overline{1}$ (mm)	0.73	2.05	5.59	4.83	***
OLp–$\underline{6}$ (mm)	2.83	2	1.94	2.34	ns
OLp–6 (mm)	2.67	2.55	4.64	2.57	ns

ns, not significant; SD, standard deviation.
*$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

<table>
<tr><td>Angaben auffälliger positiver und/oder negativer Aspekte
Studiendesign
Durchführung
Auswertung
<u>Funding</u>
<u>Interessen-konflikte</u>
<u>Bias</u> (SIGN, AMSTAR II, Einzelstudien)</td><td>Studiendesign:
Keine Randomisierung, keine Verblindung
Keine Angaben, ob pro- bzw. retrospektiv
Keine Angabe zu Ethikvotum
Keine Angabe zu Einverständniserklärung
Durchführung:
Keine Hintergrundinformation zu Intervention (Therapeut?)
Auswertung:
Erhebung durch einen Untersucher
Reliabilitätsprüfung durchgeführt
Power der Studie/Patientenzahl: keine Poweranalyse
Funding: keine Angabe
Interessenkonflikte: keine Angabe
Bias (SIGN/AMSTAR/Einzelstudien RoB – alle negativen Punkte aus Fragebogen auflisten):
Attrition bias: Keine Angabe zu Dropouts/Rekrutierung
Detection bias: keine Verblindung; keine Angaben zur Reliabilität der Intervention
Keine Angaben von Konfounders
Keine Angabe von Konfidenzintervallen</td></tr>
<tr><td rowspan="2">Schluss-folgerung des Begutachters</td><td><u>methodische Qualität:</u> befriedigend</td></tr>
<tr><td><u>Klinische Aussagekraft:</u>
Die Aktivator-Apparatur ist eine effektive Methode, um ein mandibuläres Defizit zu behandeln
Funktionskieferorthopädische Therapie bei wachsenden Patienten hat einen klinischen Benefit und sollte im späten Wechselgebiss erfolgen.
Die Aktivatortherapie verbessert das Weichgewebsprofil.</td></tr>
<tr><td>Evidenz-level (SIGN)</td><td>2+</td></tr>
<tr><td>Qualität
(RoB, SIGN /AMSTAR II)</td><td>⊕ Acceptable</td></tr>
</table>

Evidenztabelle Croft, Buschang et al. 1999

A cephalometric and tomographic evaluation of Herbst treatment in the mixed dentition

Robert S. Croft, DDS,[a] Peter H. Buschang, PhD,[b] Jeryl D. English, DDS,[b] and Richard Meyer, DDS[c]
Vancouver, Wash, Dallas, Tex, and Rapid City, SD

This study describes combined treatment and posttreatment effects for patients treated with the Herbst appliance in the mixed dentition followed by retention with a prefabricated positioner. The sample included 24 female and 16 male patients with Class II malocclusions. Posttreatment lateral cephalograms were taken an average of 17 months after Herbst removal, when the patients presented for phase II comprehensive orthodontics. The cumulative treatment and retention effects were compared with a sample of untreated Class II controls matched for age, sex, and mandibular plane angle. The overjet and molar relationship were corrected by 3.4 and 3.3 mm, respectively. A headgear effect of Herbst therapy was observed, as anterior maxillary displacement was reduced by 1.2 mm. Condylar growth was redirected to produce 2.0 mm greater posterior growth in the treatment group. These effects produced significantly greater decreases in SNA (0.8°) and ANB (1.4°), and a tendency toward an increase in SNB (0.5°). Mandibular orthopedic effects resulted in an increase in anterior facial height (1.6 mm) and inferior displacement of the chin. Minimal changes in the displacement of condylion in relation to stable cranial base structures suggest that glenoid fossa displacement does not contribute in a clinically significant way to Class II correction. Pretreatment, immediate posttreatment, and postretention corrected temporomandibular joint tomograms demonstrated a tendency for the condyle to be slightly forward (0.2 mm) at the end of treatment and then to fall back after treatment. Statistically significant joint space changes were limited to the posttreatment period. We conclude that Herbst treatment in the mixed dentition, in combination with retention, produces significant long-term improvements in dental and skeletal relationships as a result of dentoalveolar changes and orthopedic effects in both jaws. (Am J Orthod Dentofacial Orthop 1999;116:435-43)

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Rekrutierung in Nordamerika (von Autoren geschlossen)
Schweregrad	ANB = 5,6 ± 1,8 °; OJ = 5,5 ± 1,9mm
Einschluss-kriterien *Bei Review: PICOS*	• initiated Herbst therapy in the mixed dentition in patients between 7 and 10 years of age • ANB ≥ 4° • molar relationship end-on or greater • average compliance with retention appliance
Ausschluss-kriterien	• Approximately 3% of the patients were excluded because they could not tolerate the retention appliance

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Herbst treatment consisted of three phases. All patients underwent rapid maxillary expansion (RME) with a banded RME appliance, followed by Herbst therapy, and retention. A cantilever Herbst appliance design was used and included upper and lower stainless steel crowns, a mandibular lingual arch, and occlusal rests extending from the lower crown to the occlusal surface of the lower primary molars. After the active treatment, patients were given a prefabricated positioner appliance (the Occlusal Guide, Orthotain) designed to support the orthopedic correction and guide tooth eruption between the mixed and permanent dentitions. VERSUCHSGRUPPE: **Herbst Group** N=40 (Anfang) / N=40 (Ende) / Alter = 8,5 ± 1,0 Jahre / ♂:♀ = 16:24 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: Untreated Control Group A control group of untreated Class II individuals was drawn from longitudinal data collected by the Human Growth Research Center, University of the Montreal, Quebec, Canada. Each control subject was matched to a patient in the treatment group based on age, sex, and mandibular plane angle. N=40 (Anfang) / N=40 (Ende) / Alter = 8,4 ± 1,1 Jahre / ♂:♀ = 16:24 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: ---
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: *Cephalometric Analysis* SEKUNDÄRZIELGRÖßE: *Cephalometric Superimposition*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. A significant Class II correction that was maintained throughout the transitional dental period. 2. A significant restraining effect on maxillary sagittal development. 3. A significant redirection of condylar growth. 4. No significant lower incisor flaring. 5. Significant vertical mandibular development, with no greater sagittal mandibular projection. 6. No significant changes in joint space during treatment. A significant posttreatment decrease in posterior joint space was observed. 7. Only minor changes in the displacement of the glenoid fossa that were unlikely to contribute to Class II correction.

Zusammen-fassung der Ergebnisse	**Herbst Group VS. Untreated Control Group** ***PRIMÄRZIELGRÖßE*** **Cephalometric Analysis** Mixed dentition Herbst therapy with retention resulted in significantly improved dental and skeletal relationships (Table II). At postretention, the molar relationship had improved by nearly 3.3 mm in the treatment group as compared to no change in the control group. Overjet and overbite worsened in the control group and improved in the treatment group. The net treatment effects for overjet and overbite were 3.4 mm and 2.0 mm, respectively. The lower incisor position of the Herbst group did not significantly change its relationship with the mandibular plane. Although skeletal angular measurements of SNA, ANB, and NAPg were reduced in both groups, they were reduced significantly more in the treatment group. The treatment effect differences on the jaw base relationship was –1.4°, whereas maxillary protrusion and facial convexity were reduced by 0.8° and 2.2°, respectively. The SNB angle showed a slightly greater increase for the treatment group, but differences were not statistically significant. There was a significantly greater increase in total facial height in the treatment group. The mandibular plane did not show a treatment effect, although it tended to open slightly in the treatment group and close slightly in the control group. ***SEKUNDÄRZIELGRÖßE*** **Cephalometric Superimposition** Sagittal orthopedic treatment effects were observed for the upper face. Treatment reduced the anterior displacement of A point by 1.2 mm (Table III). The control group had 0.5 mm more anterior growth at nasion. In contrast, the mandibular landmarks showed no significant sagittal group differences. The anterior mandibular landmarks (B point, pogonion, and menton) showed significantly greater inferior displacement (2.3 mm, 1.4 mm, and 1.5 mm, respectively) in the treatment than control group. Gonion demonstrated a tendency toward greater vertical displacement in the treatment group, but the differences were not statistically significant. There were no treatment effects on articulare. The dental landmarks (Table III) revealed significant treatment effects on the sagittal displacement of the upper molar and upper incisor. Treatment reduced the mesial movements of the upper molar by 2.2 mm and the upper incisor by 2.4 mm. Greater mesial movements of the lower dentition were observed for Herbst group, but differences were not significant. Significantly greater inferior displacement was observed after treatment for the lower molar (1.1 mm), the lower incisor tip (2.1 mm), and the lower incisor apex (1.4 mm). The mandibular superimposition showed increased posterior, vertical, and total condylar growth in the treatment group (Table IV). However, only the 2.1 mm increase in posterior growth was statistically significant. These orthopedic effects increased mandibular length, measured at Co-Pg and Ar-Pg, by less than 1.0 mm. Small group differences in glenoid fossa displacement (Table V) were observed. The fossa of the treatment group was displaced slightly more posteriorly and inferiorly. The combined effects of greater posterior and vertical displacement produced a significant 0.7 mm treatment effect for total fossa displacement.

<table>
<tr><td>Angaben auffälliger positiver und/oder negativer Aspekte
Studiendesign
Durchführung
Auswertung
<u>Funding</u>
<u>Interessen-konflikte</u>
<u>Bias</u> (SIGN, AMSTAR II, Einzelstudien)</td><td>Studiendesign:
kein Ethikvotum angegeben
historische Kontrollgruppe
TMJ-Tomogramme sind mehr up-to-date
Keine Angabe, ob pro- bzw. retrospektives Studiendesign
Vermeintlich gutes Matching zwischen Gruppen
Durchführung:
Keine Verblindung
Keine Randomisierung
Auswertung:
Keine Konfidenzintervalle angegeben
Power der Studie/Patientenzahl: keine zur statistischen Power
Funding: keine Angaben
Interessenkonflikte: keine Angaben
Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):
Selection bias: historische Kontrollgruppe
Performance Bias: keine Verblindung
Attrition Bias: Dropouts wurden statistisch nicht berücksichtigt
Detection bias: keine Verblindung; Reliablität der Intervention fraglich
Keine Konfounders erhoben</td></tr>
<tr><td rowspan="2">Schluss-folgerung des Begutachters</td><td><u>methodische Qualität:</u> befriedigend</td></tr>
<tr><td><u>Klinische Aussagekraft:</u>
Hemmender Effekt auf das Wachstum der Maxilla durch die Herbst-Therapie
Signifikant stärkerer vertikal Entwicklung der Mandibula unter Herbst-Therapie
Signifkante Steuerung des Kondylenwachstums unter Herbst-Therapie
Erfolgreich Korrektur der Klasse-II mit der Herbst-Apparatur möglich
Keine signifikante Protrusion der UK-Front</td></tr>
<tr><td>Evidenz-level (SIGN)</td><td>2+</td></tr>
<tr><td>Qualität
(RoB, SIGN /AMSTAR II)</td><td>⊕ Acceptable</td></tr>
</table>

Evidenztabelle Danaei, Ajami et al 2018

Assessment of the effect of maxillary protraction appliance on pharyngeal airway dimensions in relation to changes in tongue posture

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Abstract

Background:

Literature is controversial in regard with alterations in pharyngeal airway dimensions subsequent to maxillary protraction. The correlation between maxillary protraction and sagittal airway dimension was investigated in association with tongue and soft palate position in skeletal Class III children. The results were compared with those of an untreated Class III and a Class I malocclusion control group.

Materials and Methods:

In this cross-sectional study pre- and post-treatment cephalometric radiographs of 19 Class III patients (6 males, 13 females; mean age, 7.93 ± 0.96 years) treated with facemask were analyzed. The correlation between treatment changes in craniofacial morphology and those in the upper airway, tongue, and soft palate was evaluated. These results were compared with those of a group of 16 Class I malocclusion patients (1 male, 15 females; mean age, 7.31 ± 0.7 years) and a group of 15 untreated Class III patients (4 males and 11 females; mean age, 7.46 ± 0.1 years). A paired *t*-test, the Shapiro–Wilk test and Mann–Whitney U-test was used. The level of significance was established as $P < 0.05$.

Results:

Nasopharyngeal airway measurements PNS-ad1 and PNS-ad2 significantly increased by 2 mm and 2.1 mm, respectively. Statistical analysis revealed that maxillary protraction had a positive relationship with PNS-ad1 and PNS-ad2.

Conclusion:

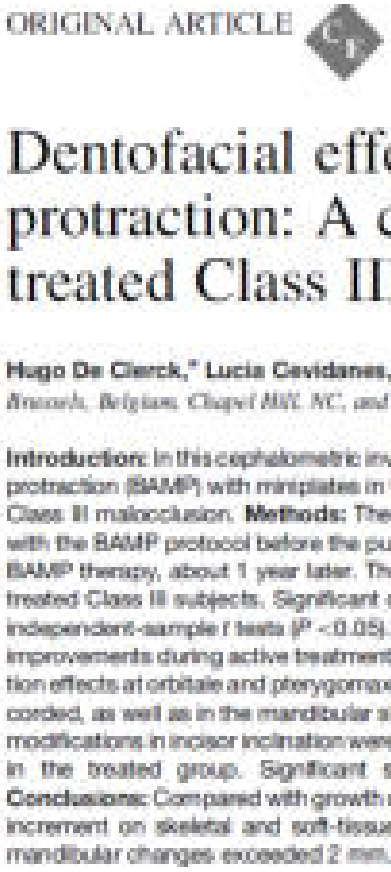
Nasopharyngeal airway dimensions can be improved in the short term with maxillary protraction in skeletal Class III children.

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** - Children aged between 5 and 9 years with skeletal Class III deformity, defined as maxillary retrusion with normally positioned mandible and anterior crossbite • Iran
Schweregrad	SNA <77, 76≤ SNB ≤80, ANB <1
Einschluss-kriterien	- aged between 5 and 9 years, - anterior crossbite, - straight or concave profile, - Class III molar relation, - skeletal Class III deformity, defined as maxillary retrusion with normally positioned mandible - SNA <77, 76≤ SNB ≤80, ANB <1 - availability of before (T1) and after (T2) treatment lateral cephalograms.
Ausschluss-kriterien	- History of trauma to the face and jaws, - apparent facial asymmetry, - presence of any syndrome related to orofacial region, cleft lip and/or palate, - obstructive sleep apnea or even habitual snoring, - chronic upper respiratory tract infections and diseases, - previous history of adenoidectomy/tonsillectomy, and vertical growth pattern
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **FM del w/o ME, Group 3** Maxillary protraction appliance (delaire-type facemask) and no maxillary expansion. VERSUCHSGRUPPE 1: **FM del w/o ME, Group 3** N= 19 (Anfang) / N=19 (Ende) / Alter = 7,93, 0,96 ♂:♀ = 6:13 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated Class III (Group 2)** N=15 (Anfang) / N=15 (Ende) / Alter = 7,46, 0,1 ♂:♀ = 4:11 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung KONTROLLGRUPPE 2: **Class I (Group 1)** N=16 (Anfang) / N=16 (Ende) / Alter = 7,31, 0,7 ♂:♀ = 1:15 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung

Outcome	• direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie • Atmung und Luftraum (Airway space, Schlafapnoe), Schlucken und Sprechen) PRIMÄRZIELGRÖßE: **Airway dimensions**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	I. The nasopharyngeal airway dimensions can be improved in short term with maxillary protraction in skeletal Class III children II. Pharyngeal airway space will not increase in untreated Class III patients III. Tongue attains a more forward position after maxillary protraction and nonextraction treatment of Class I malocclusion.
Zusammen-fassung der Ergebnisse	**GRUPPE FM del w/o ME, Group 3 VS. GRUPPE untreated Class III (Group 2)** **GRUPPE FM del w/o ME, Group 3 VS. GRUPPE Class I (Group 1)** T1 (pre-treatment): 7,93, 0,96 years, FM w/o ME; 7,46, 0,1 years, Class III untreated; 7,31, 0,7 years Class I T2 (post-treatment, observation): 8,68- 8,93 years, FM w/o ME; 8,21- 8,46 years, Class III untreated; 8,05- 8,31 years Class I **Airway dimensions** minimum airway dimension behind the base of the tongue (**MLA)**, airway dimension at the level of basion-PNS plane (**AD1 to PNS**) airway dimension at the level of PNS-So (**AD2 to PNS)** Among the airway parameters, minimum airway dimension behind the base of the tongue (MLA), airway dimension at the level of basion-PNS plane (AD1 to PNS) and airway dimension at the level of PNS-So (AD2 to PNS) significantly increased after treatment only in the treated Class III malocclusion group. In addition, both VRL to U and VRL to EP increased significantly after treatment in the treated Class I malocclusion group.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die Querschnittstudie hat deutliche methodische Schwächen. Es fehlen Sample Size/ Power Berechnungen. Die Studie war nicht verblindet und die Äquivalenz der Versuchsgruppen wurde nicht vollständig statistisch überprüft. Genaue Angaben zu den Behandlungsmodalitäten fehlen. Die exakten Behandlungs/ Observationszeiträume spezifisch für die einzelnen Gruppen wurden nicht angegeben. Das Ergebnis ist weitestgehend übereinstimmend mit ähnlichen Studien. Der Gesamtinformationsgehalt dieser Studie ist jedoch insgesamt eher gering. Die klinische Relevanz ist daher deutlich eingeschränkt. *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist nicht vollständig geprüft. Power/ Sample Size Berechnungen durchgeführt. Eine Verblindung fand nicht statt.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Das Ergebnis ist weitestgehend übereinstimmend mit ähnlichen Studien. Der Gesamtinformationsgehalt dieser Studie ist jedoch insgesamt eher gering. Die klinische Relevanz ist daher deutlich eingeschränkt.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle DeClerck et al. 2010



ORIGINAL ARTICLE

Dentofacial effects of bone-anchored maxillary protraction: A controlled study of consecutively treated Class III patients

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Introduction: In this cephalometric investigation, we analyzed the treatment effects of bone-anchored maxillary protraction (BAMP) with miniplates in the maxilla and mandible connected by Class III elastics in patients with Class III malocclusion. **Methods:** The treated sample consisted of 21 Class III patients consecutively treated with the BAMP protocol before the pubertal growth spurt (mean age, 11.10 ± 1.8 years) and reevaluated after BAMP therapy, about 1 year later. The treated group was compared with a matched control group of 18 untreated Class III subjects. Significant differences between the treated and control groups were assessed with independent-sample *t* tests ($P < 0.05$). **Results:** Sagittal measurements of the maxilla showed highly significant improvements during active treatment (about 4 mm more than the untreated controls), with significant protraction effects at orbitale and pterygomaxillare. Significant improvements of overjet and molar relationship were recorded, as well as in the mandibular skeletal measures at Point B and pogonion. Vertical skeletal changes and modifications in incisor inclination were negligible, except for a significant proclination of the mandibular incisors in the treated group. Significant soft-tissue changes reflected the underlying skeletal modifications. **Conclusions:** Compared with growth of the untreated Class III subjects, the BAMP protocol induced an average increment on skeletal and soft-tissue advancement of maxillary structures of about 4 mm, and favorable mandibular changes exceeded 2 mm. (Am J Orthod Dentofacial Orthop 2010;138:577-81)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** - Patients with skeletal Class III malocclusion in the mixed or permanent dentition, anterior crossbite or incisorend-to-end relationship, and Class III molar relationship, white ancestry, with a prepubertal stage of skeletal maturity • Belgium (BAMP), Italy (Control)
Schweregrad	Wits appraisal of –1 mm or less
Einschluss-kriterien	- Class III malocclusion in the mixed or permanent dentition characterized by a Wits appraisal of –1 mm or less (mean, –4.8 ± 2.8 mm), - anterior crossbite or incisor end-to-end relationship, and Class III molar relationship. - All patients were of white ancestry, with - a prepubertal stage of skeletal maturity according to the cervical vertebral maturation method (stage 1 or 2)
Ausschluss-kriterien	Not fullfilling inclusion criteria

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **BAMP** (bone-anchored maxillary protraction) 4 miniplates were placed on the left and right infrazygomatic crest of the maxillary buttress and between the mandibular left and right lateral incisors and canines. Small mucoperiosteal flaps were elevated, and modified miniplates (Bollard, Tita-Link, Brussels, Belgium) were secured to the bone by 2 (mandible) or 3 (maxilla) screws (diameter, 2.3mm; length, 5mm). Three weeks after surgery, the miniplates were loaded. Class III elastics applied an initial. force of about 150 g on each side, increased to 200 g after 1 month of traction, and to 250 g after 3 months. The patients were asked to replace the elastics at least once a day and wear them 24 hours per day VERSUCHSGRUPPE 1: **BAMP** N= 21 (Anfang) / N=21 (Ende) / Alter = 11,8, 1,6 ♂:♀ = 11:10 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated Class III** N=18 (Anfang) / N=18 (Ende) / Alter = 11,5, 1,5 ♂:♀ = 11:7 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • dentofaziale Ästhetik PRIMÄRZIELGRÖßE: Skeletal: Wits SEKUNDÄRZIELGRÖßE: Dental: Overjet TERTIÄRZIELGRÖßE: Soft tissue: Llip-VertT
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	- Compared with growth of the untreated Class III subjects, the BAMPprotocol induced an averageincrement on skeletal and soft-tissue advancement of maxillary structures of about 4 mm, and favorable mandibular changes exceeded 2 mm. - Changes in dental inclination were minor too, since the protocol was strictly skeletal. An interesting amount of mandibular incisor proclination was observed in the treated group; this is an original finding with respect to any previous study on orthopedic treatment of Class III malocclusion. - The treatment protocol actually led to decompensation of the lingual tipping of the mandibular incisors usually observed in untreated Class III subjects.

Zusammen-fassung der Ergebnisse	**GRUPPE BAMP VS. GRUPPE untreated Class III** T1 (pre-treatment): mean age 11,8 years, BAMP; 11,5 years, untreated Class III T2 (post treatment/ observation): mean age 12,1 years, BAMP; 12,0 years untreated Class III Skeletal Wits  Dental Overjet  Soft tissue Llip-VertT 
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die Äquivalenz von Versuch- und Kontrollgruppe wurde überprüft, die beobachteten Unterscheide sind nicht relevant. Power/ Sample Size Berechnungen wurden durchgeführt. Eine Verblindung fand nicht statt. Trotz einer Anzahl von methodischen Schwächen dieser retrospektiven Studie ist das Gesamtdesign der Studie akzeptabel. Die klinische Relevanz, ist gegeben. *Funding:* keine Angabe *Interessenkonflikte* The authors report no commercial, proprietary, or financial interest in the products or companies described in this article *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist gegeben, bestehende Unterscheide sind nicht von Relevanz. Power/ Sample Size Berechnungen wurden durchgeführt. Eine Verblindung fand nicht statt.

Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Trotz einer Anzahl von methodischen Schwächen dieser retrospektiven Studie ist das Gesamtdesign der Studie akzeptabel. Die klinische Relevanz, ist gegeben.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Defraia, Marinelli et al. 2008

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Dentoskeletal effects of a removable appliance for expansion of the maxillary arch: a postero-anterior cephalometric study

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SUMMARY The aim of this study was to evaluate the dentoskeletal effects of early treatment in the primary or early mixed dentition with a removable appliance with expansion springs, assessed on postero-anterior (PA) cephalograms, in patients with a unilateral posterior crossbite when compared with untreated subjects. The treatment group consisted of 23 subjects, 8 males, and 15 females treated with a removable appliance for the expansion of the maxillary arch. The mean age at the start of expansion (T_1) was 6 years 2 ± 17 months, and 8 years ± 18 months at the end of active therapy and after 1 year of retention (T_2), with an observation interval of 22 ± 7 months. The control group comprised 20 subjects (9 males and 11 females) with an untreated unilateral posterior crossbite. Their mean age was 5 years 9 ± 15 months at the first observation and 7 years and 4 ± 16 months at the second examination. The interval between the two observations was 18 ± 7 months. Nine skeletal and two dental measurements on the transverse plane were assessed. The data from the two groups were compared by means of a Student’s *t*-test for independent samples ($P<0.05$).

Positive dental and skeletal effects induced by the therapy were observed at T_2. The width of the upper dental arch and that of the skeletal maxillary transverse dimension were significantly greater ($P < 0.001$) in the treatment group when compared with the controls.

Population *Setting* *Komorbiditäten*	**transversale Anomalie** • selected from the files of the Department of Orthodontics, University of Florence • Unspecified, probably Italian , wo groups of subjects with a unilateral posterior crossbite
Schweregrad	unilateral posterior crossbite

Einschluss-kriterien *Bei Review: PICOS*	• presence of a unilateral posterior crossbite with a negative posterior transverse interarch discrepancy (PTID) • absence of previous orthodontic treatment and dental trauma and dental anomalies • two consecutive PA cephalograms of good quality with adequate landmark visualization and with minimal or absent rotation of the head, taken at T_1 and T_2 • absence of dentofacial abnormalities or syndromes
Ausschluss-kriterien	• previous orthodontic treatment and dental trauma and dental anomalies • dentofacial abnormalities or syndromes
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Active therapy lasted approximately 10 months and was followed by a retention period of about 1 year, when the appliance was worn at night. A removable appliance with two-shaped midpalatal wire springs was used. The springs were constructed of hard 0.6 mm round stainless steel– chromium alloy wire. The anterior spring consisted of two loops and was constructed on a 5-cm-long piece of wire, while the posterior spring comprised three loops constructed on a 6 cm long piece of wire; for both, springs 5 mm for each side, were embedded in the acrylic resin. Adams' hooks were placed on the second primary molars or, in the mixed dentition, on the first molars. Ball clasps were added if necessary to improve retention (Figure 1). The springs were activated every 3–4 weeks with Angle or Tweed pliers. The negative PTID was corrected. A slight over-expansion can be desirable in order to minimize relapse during the retention period. VERSUCHSGRUPPE: **herausnehmbaren Apparatur mit Expansionsfedern** N=23 (Anfang) / N=23 (Ende) / Alter = 6,2 ± 1,4 Jahre / ♂:♀ = 8:15 • Gebissphase: Milchgebiss, frühes Wechselgebiss • KFO-Behandlung: Frühbehandlung (interzeptiv)
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **control group** N=20 (Anfang) / N=20 (Ende) / Alter = 5,9 ± 1,3Jahre / ♂:♀ = 9:11 • Gebissphase: Milchgebiss, frühes Wechselgebiss • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)Subkategorie** PRIMÄRZIELGRÖßE Skeletal measurements *(***skeletal apical base of the maxilla (Mx – Mx** *mm)* SEKUNDÄRZIELGRÖßE: Dental measurements *(***upper dental arch (Um – Um)** *mm)*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	The correction of a posterior crossbite in the primary or early mixed dentition with a removable spring appliance was found to be effective on both dental and skeletal structures when studied on PA cephalograms.
Zusammen-fassung der Ergebnisse	**GRUPPE treatment group VS. GRUPPE control group** ***PRIMÄRZIELGRÖßE und SEKUNDÄRZIELGRÖßE*** Dental and skeletal effects induced by the therapy were observed. At T 2 , the transverse dimension of **the upper dental arch (Um – Um)** and the **skeletal apical base of the maxilla (Mx – Mx**) were significantly greater in the treatment group when compared with the controls. During the observation period, a significant increase was noted in the width of the upper dental arch (Um– U m): in the treatment group, there was an increase of 4.94 ± 1.55 mm, whereas in the controls this was 1.45 ± 1.24 mm. There was also an increase in the skeletal transverse dimension of the apical base of the maxilla (Mx – Mx): for the treatment group the increase in growth was 4.48 ± 1.96 mm
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: Studiendesign adequat zur Fragestellung.* *Durchführung: keine Unterschiede zu Beginn in den Gruppen* - Neither group showed any statistically significant difference at T_1 for any of the examined measurements (Table 1). *Bestimmung des Methodenfehlers.* *Auswertung: korrekt.* *Power der Studie/Patientenzahl: keine Fallzahlberechnung durchgeführt,* *Funding: k.A:* *Interessenkonflikte: k.A.* *Bias* NO - The main potential confounders are identified and taken into account in the design and analysis. NO - Confidence intervals are provided.
Schluss-folgerung des Begutachters	methodische Qualität: mit kleinen Einbußen (siehe oben) ist die Methodik adequate. Klinische Aussagekraft: Die Aussagekraft der Studie ist als gut zu bewerten. Positiv sind die beiden zu Beginn der Beobachtung/Intervention gleichen Grunddaten in den Gruppen. Die Alterskohorte ist als sehr interessant zu werten für die Aussagekraft eines größeren Zuwachses der transversalen Breite der Maxillla/des OK-Zahnbogens durch kieferorthopädische Behandlung im Gegensatz zu keiner Behandlung um den Faktor 2 auf der skelettalen Ebene bzw. Um den Faktor 4 auf dentaler Ebene.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable ⊕**

Evidenztabelle Deguchi, McNamara 1999

Craniofacial adaptations induced by chincup therapy in Class III patients

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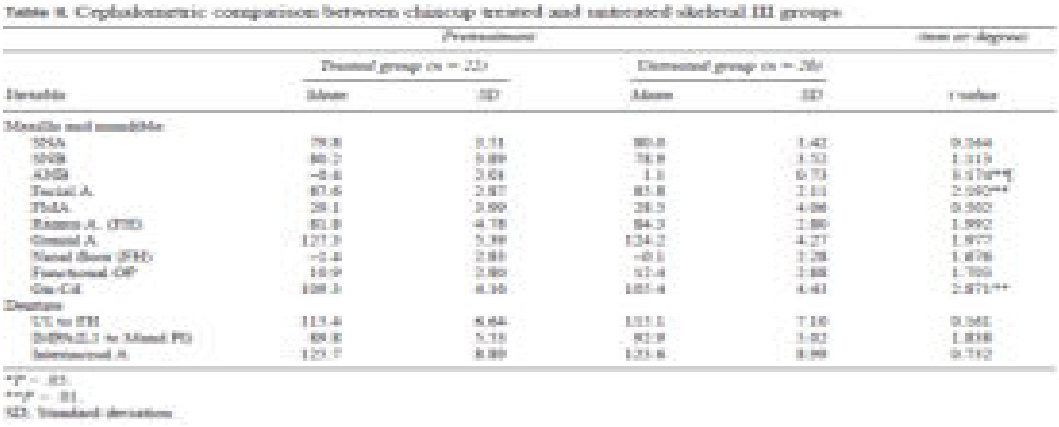
The purpose of the present study is to examine the effects of an orthopedic force produced by chincup treatment in patients with Class III malocclusion. Anteroposterior maxillary and mandibular changes were examined as were changes in the vertical dimension. Further, the possibility of posterior displacement of temporomandibular joints in treated Class III subjects was evaluated. Serial lateral headfilms of 22 young females (average age, 9 years), who had received chincup therapy were compared with those of 20 skeletal Class III subjects of similar age who received no treatment during the interval studied. A computerized x-y coordinate program was applied to analyze the cephalometric landmarks and measurements. The treated group showed improvement of the skeletal Class III pattern associated with a slight increase (0.8° per year) in SNA and a slight decrease (-0.7° per year) in SNB and also a decreased gonial angle. The distance from the condyle to the chin (Co-Gn or effective mandibular length) increased significantly less in the treated group in comparison with controls. Increases in lower anterior facial height were not different between the treated and untreated groups. In addition, the cranial base angles N-S-Ba and N-S-Ar showed no statistical difference between groups, but these angles tended to increase with time in both groups. Basion and Articulare showed almost the same amount of backward and downward movement in both groups. The results of this study indicate that the primary effect of chincup therapy was in producing a reduction in mandibular growth increments during the period studied. Maxillary growth was not affected during treatment. Further, the results of this study fail to support the hypothesis that chincup appliance significantly induces the posterior displacement of the glenoid fossa. (Am J Orthod DentofacialOrthop 1999;115:175-82)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** 42 females of Japanese ancestry with skeletal Class III malocclusion: Twenty-two were treated with a chincup, and an additional 20 subjects did not receive any orthodontic or orthopaedic treatment during the period studied. The records of the treated skeletal Class III subjects were obtained from the Department of Orthodontics, Matsumoto Dental Hospital, whereas the records of the untreated subjects were obtained from the files of a private clinic (Dr. Ryuzo Kanomi, Himeji city, Japan).
Schweregrad	--
Einschluss-kriterien *Bei Review: PICOS*	--
Ausschluss-kriterien	-

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** VERSUCHSGRUPPE: **Group 1 (chincup treated)** N=22 (Anfang) / N=22 (Ende) / Alter = 9,3 Jahre / ♂:♀ = 0:22 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Group 2 (untreated)** N= 20 (Anfang) / N=20 (Ende) / Alter = 9,6 Jahre / ♂:♀ = 0:20 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: Unbehandelt
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: intermaxillar parameter changes (ANB) SEKUNDÄRZIELGRÖßE: Maxillary parameter changes (ANS, A) TERTIÄRZIELGRÖßE: Mandibular parameter changes (B, Pg, Me)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. The present cephalometric study compared serial lateral cephalograms of Japanese children who were on average 9 years of age at the time the initial cephalogram was taken. A comparison of the two groups revealed that the primary effect of chincup therapy was a reduction in mandibular growth increments during the period studied. 2. Horizontal maxillary movement and lower anterior facial height were not affected during treatment. 3. Further, the results of this study fail to support the hypothesis that the chincup appliance significantly induces the posterior displacement of the glenoid fossa.

Zusammen-fassung der Ergebnisse	**Group 1 (chincup treated) VERSUS Group 2 (untreated)** **PRIMÄRZIELGRÖßE: intermaxillar parameter changes (ANB)** Table IV. Cephalometric comparison between chincup treated and untreated skeletal III groups Pretreatment Treated group (n = 22) — Untreated group (n = 20) — mm or degrees Variable — Mean — SD — Mean — SD — t value ANB — 1.2 — 1.91 — 1.3 — 1.08 — 0.126 **SEKUNDÄRZIELGRÖßE: Maxillary parameter changes (ANS, A)** Table VI. Cephalometric comparison between chincup treated and untreated skeletal III groups in horizontal (x) and vertical (y) landmarks changes (mm/year) Treated group (n = 22) — Untreated group (n = 20) Variable — Mean — SD — Mean — SD — t value ANS — x — 1.13 — 0.58 — 0.98 — 0.17 — 1.912 y — −0.18 — 0.53 — −1.40 — 0.53 — 1.327 A — x — 1.09 — 0.66 — 1.07 — 0.18 — 0.262 y — −1.36 — 0.87 — −1.47 — 0.61 — 0.187 **TERTIÄRZIELGRÖßE: Mandibular parameter changes (B, Pg, Me)** Table VI. Cephalometric comparison between chincup treated and untreated skeletal III groups in horizontal (x) and vertical (y) landmarks changes (mm/year) Treated group (n = 22) — Untreated group (n = 20) Variable — Mean — SD — Mean — SD — t value B — x — −0.26 — 1.50 — 1.14 — 0.80 — 3.259** y — −2.12 — 1.27 — −2.25 — 0.77 — 0.398 Pog — x — 0.10 — 1.56 — 1.15 — 0.94 — 1.501 * y — −2.93 — 1.80 — −2.41 — 0.71 — 1.567 Me — x — −0.09 — 1.74 — 1.42 — 1.04 — 3.209** y — −3.10 — 1.13 — −2.65 — 0.72 — 1.487 *P < .05. **P < .01. SD, Standard deviation.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: Kohortenstudie* *Durchführung: Group 1 (chincup treated) VERSUS Group 2 (untreated)* *Auswertung: The initial cephalometric radiographs* *Fehleranalyse wurde nicht durchgeführt* The two groups of Class III subjects were well matched at the beginning of the study except for a few variables (Table II). The maxillomandibular relationship, as indicated by the ANB angle, was greater in the untreated group (1.1°) than in the treated group (-0.4°), as was the facial angle (the angle between the FH plane and the N-Pg line). Effective mandibular length (Gn-Cd) also was greater in the treated group (109.3 mm) than in the controls (105.4 mm) before treatment.  *Power der Studie/Patientenzahl: nicht kalkuliert,* *Funding: None.* *Interessenkonflikte: None.* *Bias (SIGN/AMSTAR/EinzelstudienRoB –): Acceptable (+)*
Schluss-folgerung des Begutachters	methodische Qualität: insgesamt hoch
	Klinische Aussagekraft: Die Patientencharekteristika in der Ausgangssituation ist zur Diskussion offen. Beide Gruppen unterschieden sich damals bei dem wichtigen Parameter ANB statistisch signifikant (<0,01). Abgesehen davon, sprechen die Ergebnisse dieser Studie dafür, dass die Behandlung mit der Kopfkinn-Kappe primär den Unterkieferwachstum bremst. Die 3. Schlussfolgerung der Autoren können durch die Datenlage dieser Arbeit nicht unterstützt werden. Die Parameter zur Fossa mandibularis sind in deren anderen Arbeit in den Ergebnissen zu finden. (https://www.sciencedirect.com/science/article/pii/S088954069670063X?via%3Dihub)
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable (+)**

Evidenztabelle Dogan 2012

The effects of face mask therapy in cleft lip and palate patients

Servet Dogan

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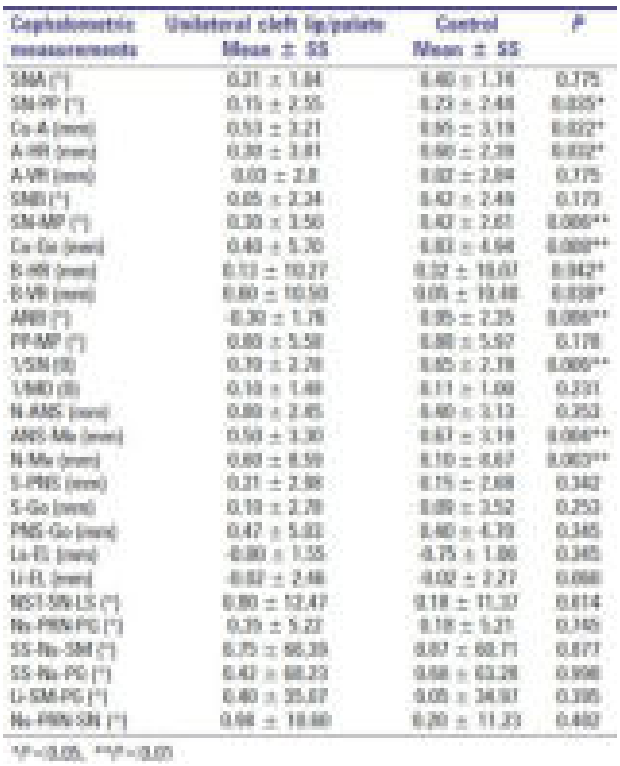
Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** Patients with unilateral cleft lip and palate (UCLP) The patients were treated by the same orthodontist using the same techniques and appliances (facemask). Mean pre- and posttreatment ages were 8.7 and 9.5 years, respectively. Each child was matched by ethnicity, age, sex, and the SN/MP angle to an untreated (noncleft) control. The treatment period with face mask was approximately 7 months and 5 days. All of the patients had RME treatment for maxillary transversal discrepancy before face mask therapy. After the completion of the RME treatment, the same appliance was used for protraction. It was an acrylic splint with expansion screw and traction hooks were soldered at the mesial aspect of the maxillary canines on both sides. The extraoral appliance was a Delaire type face mask, with a force of 800 g applied to each hook with vector force about 25° downward and forward to the occlusal plane [Figures 1 and 2]. Patients were instructed to wear the face mask for 16 hours a day and they changed the elastics every other day. Each patient received a timing record to register the number of hours of face mask therapy per day, which was useful to evaluate patient compliance. They were seen every 4 weeks for to control the adjustment of the face mask. Komorbiditäten: die Kontrollgruppe weist keine Spalten auf!
Schweregrad	u.a. anterior crossbite
Einschluss-kriterien *Bei Review: PICOS*	1. unilateral complete cleft lip and palate patients 2. only sagittally constricted maxilla, 3. anterior crossbite, and a Class III skeletal pattern with skeletal maxillary retrusion and all subjects had 4. mixed dentition
Ausschluss-kriterien	Keine Ausschlusskriterien definiert

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** *Therapie mit Facemask* VERSUCHSGRUPPE**: Facemask-Gruppe** N=20 (Anfang) / N= 20 (Ende) / Alter = Male: 8,7±2,64 Female: 8,69±1,64Jahre / ♂:♀ = 12:8 • Gebissphase: frühes Wechselgebiss, spätes Wechselgebiss • KFO-Behandlung: frühe Therapie
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **untreated non-cleft control-group** N=20 (Anfang) / N=20 (Ende) / Alter = Male: 8,22±1,54 Female: 8,14±2,04 Jahre / ♂:♀ = 20:20 • Gebissphase: frühes Wechselgebiss, spätes Wechselgebiss • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** Primärzielgröße: Kephalometrisch messbare Veränderungen
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. The UCLP group showed significantly anterior maxillary movements when compared with control group. The results showed definite protraction of the maxilla while the posterior part underwent manterior displacement for UCLP group ($P < 0.001$). The maxilla was displaced forward with a force of 800 g applied to each hook with vector force about 25 degrees downward and forward to the occlusal plane. Vertical changes of the maxilla showed no significant differences in cleft group. 2. There was a clockwise rotation of the mandible with an increase in the mandibular plane angle and movement of menton downward and backward in UCLP group. The mandible of the UCLP group was rotated inferiorly and posteriorly while control group showed inferior and anterior changes ($P <0.05$). 3. The maxillary incisors showed greater anterior movement than expected for untreated control group ($P < 0.01$). Overjet was improved, mainly as a result of skeletal changes rather than dental changes. The lower incisors were stable in the two groups. 4. Treatment results showed increasing convexity of the facial profile from anterior displacement of the maxilla and clockwise rotation of the mandible. It can be concluded that face mask is a safe and effective method for the orthopedic intervention of unilateral CLP patients before autogenous bone grafting in early mixed dentition.

Zusammen-fassung der Ergebnisse	**Facemask-Group VERSUS untreated non-cleft control-group** 
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Kontrollgruppe besteht aus Patienten, welche keine Spalte aufweisen* *Keine genauen Angaben über Studiendesign (wahrscheinlich NRCT)* *Keine Fallzahlberechnung* *Keine Poweranalyse* *Keine Angaben über Rekrutierung der Patienten.* *Keine Angaben von Konfidenzintervall bezüglich Behandlungsdauer (duration of treatment: Approximately 7 months 5 days ?)* *Keinerlei Aussagen über Ethikvotum und Einverständnis* *Keine Ausschlusskriterien definiert* *Keine Aussage über Randomisierung und Blinding* *Vergleich einer Cleft-Gruppe zu einer Noncleft-Gruppe? Störgröße*
Schluss-folgerung des Begutachters	methodische Qualität: befriedigend Klinische Aussagekraft: ist gegeben, der Vergleich zu einer unbehandelten „Nicht-Spalten-Gruppe“ ist jedoch nicht ideal. Besser wäre ein Vergleich zu einer nicht behandelten Spaltengruppe gewesen.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Dorri 2015

Cochrane Clinical Answers

Question:

In children with prominent lower front teeth (class III malocclusion), how does orthodontic treatment affect outcomes?

Mojtaba Dorri

https://doi.org/10.1002/cca.996 | 27 December 2015

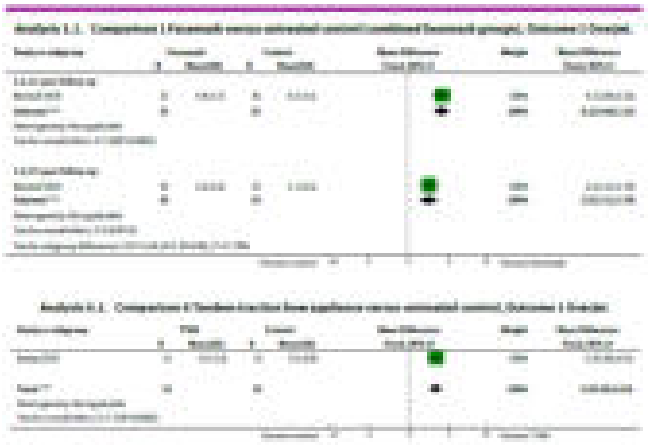
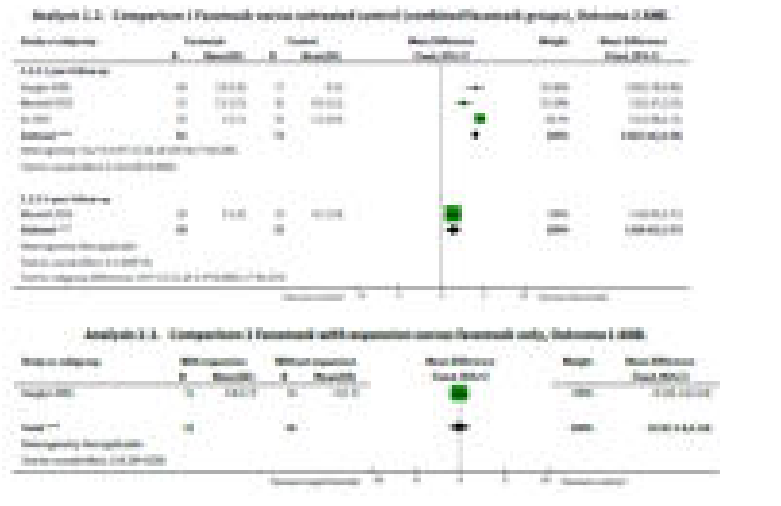
Answer

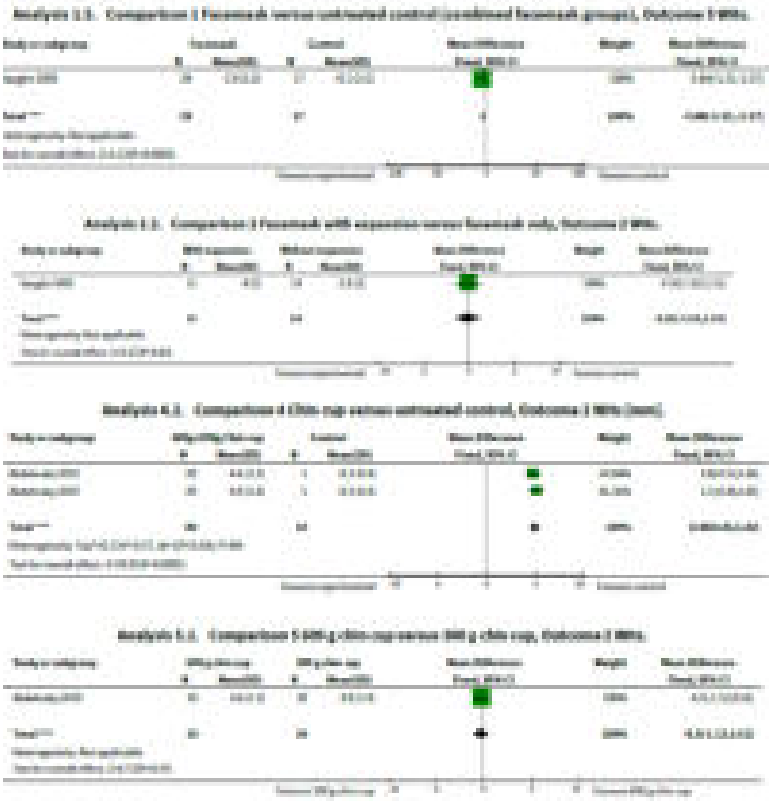
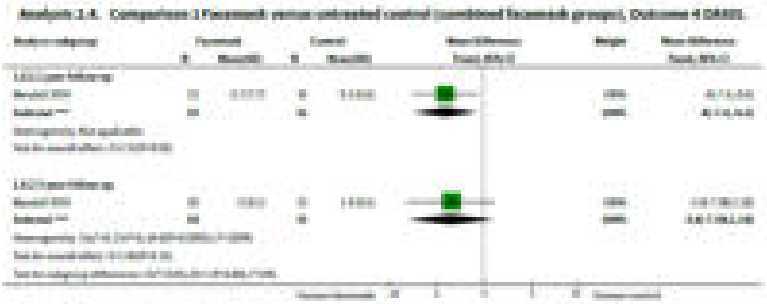
Moderate to low-quality evidence shows that the use of facemask therapy in children (mean age 8 years) may lead to short and medium term reductions in prominent lower front teeth and may improve self-esteem, compared with no treatment.

We cannot judge the effects of chin cup or tandem traction bow appliance as only very low-quality evidence is available.

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** • Primärliteratur. Einzelstudien mit individuellen Patienten • Single Center Studien aus der Türkei, China, und den USA
Schweregrad	Nicht definiert
Einschluss-kriterien *Bei Review: PICOS*	• Children or adolescents or both (aged 16 years or less) receiving any type of orthodontictreatment to correct prominent lower front teeth (Class III malocclusion • Class III treatment (Facemask, Chin Cup, tandem traction bow) • Orthodontic treatments were compared with control groups who received either no treatment, delayed treatment or a different active intervention • Orthodontic treatments were compared with control groups who received either no treatment, delayed treatment or a different active intervention
Ausschluss-kriterien	Non RCT

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: **Facemask (alone), Facemask with expansion, Nanda facemask, Chin Cup** N=?? (Anfang) / N=196 (Meta Analyse) (Ende) / Alter = 8 / ♂:♀ = ?? • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Frühbehandlung KFO-Behandlung: Class III treatment (Facemask, Chin Cup, tandem traction bow)
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** **kieferorthopädische Therapie zu anderem Zeitpunkt /Zeitraum /Gebissphase/** KONTROLLGRUPPE: ***Untreated Class II, Facemask (alone), Conventional facemask*** N=?? (Anfang) / N=148, / Alter = 8 / ♂:♀ = ?? • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: keine Behandlung untreated, Facemask (alone), Conventional facemask

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** **medizinischer Schaden, Nebenwirkungen** **bzw. Zunahme der Anomalie /Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • mundgesundheitsbezogene Lebensqualität (MLQ), psychische Entwicklung Overjet **Facemask compared with no treatment** **Tandem traction bow appliance versus untreated control** 1 year follow up, 3 years follow up (Facemask) 1 year follow-up (TTBA)  ANB **Facemask versus untreated control** **Facemask with expansion versus facemask only** **Nanda facemask versus conventional facemask** **Chin cup versus untreated control** 1 year follow up, 3 years follow up (Facemask) 1 year follow-up (others) 

Outcome	**Outcome** **Facemask versus untreated control (combined facemask groups)** **Facemask with expansion versus facemask only** **Chin cup versus untreated control** **Comparison 5 600 g chin cup versus 300 g chin cup** 1 year follow up  **OASIS** **Facemask versus untreated control (combined facemask groups)** 1 year follow up, 3 years follow up 

Studientyp	**Systematisches Review mit Meta-Analyse** RCT N= 7 *Review:* Gesamt-Teilnehmerzahl in Bezug auf PICO: Overjet, OASIS N= 69 (1year), N=63 (3 years), ANB N= 155 (1year), N= 63 (3 years) Wits N= 46
Schlussfolgerungen der Autoren	Moderate to low-quality evidence shows that the use of facemask therapy in children (mean age 8 years) may lead to short and medium term reductions in prominent lower front teeth and may improve self-esteem, compared with no treatment. We cannot judge the e_ects of chin cup or tandem traction bow appliance as only very low-quality evidence is available
Zusammen-fassung der Ergebnisse	**GRUPPE Facemask (alone), Facemask with expansion, Nanda facemask, Chin Cup VS. GRUPPE Untreaded Class II, Facemask (alone), Conventional facemask** Overjet 1 year: There was a statistically significant di_erence between groups, in favor of facemask (mean di_erence 4.10 mm, 95% CI 3.04 to 5.16) Overjet 3 years: There was a statistically significant di_erence between groups, in favor of facemask (mean di_erence 2.50 mm, 95% CI 1.21 to 3.79) ANB 1 year: There was a statistically significant di_erence between groups, in favor of facemask (mean di_erence 3.93°, 95% CI 3.46 to 4.39) ANB 3 years: There was a statistically significant di_erence between groups, in favor of facemask (mean di_erence 1.40°, 95% CI 0.43 to 2.37) Wits: There was a statistically significant di_erence between groups, in favor of face mask (mean di_erence -3.84 mm, 95% CI -5.31 to -2.37) OASIS 1 year: One RCT with 69 participants found that children wearing the facemask had a lower OASIS score (better selfesteem) compared with no treatment. OASIS 3 years: There was no statistically significant di_erence between groups (mean di_erence -3.40, 95% CI -7.99 to 1.19) Adverse Effects: One RCT with 73 children reported temporomandibular joint signs and symptoms: pain, clicking, crepitus, locking, and muscle tenderness. No quantitative data was reported but apparently the low prevalence of signs and symptoms precluded meta-analysis

Angaben auffälliger positiver und/oder negativer Aspekte	*Sehr gutes Review nach Cochrane Vorgaben. Die Einzelstudien von moderater bis guter Qualität, einzelne mit Schwächen in der RoB Analyse (Allocation, Blinding)*
Schluss-folgerung des Begutachters	methodische Qualität: Review: Sehr gutes review; Einzelstudien (Meta Analyse): moderat bis gut
	Technisch ist das Review von hoher niedriger Qualität (erfüllt Cochrane Standards. Zusammen mit der moderaten bis guten Qualität der Primärliteratur ergibt sich eine hohe klinische Rrelevanz.
Evidenzlevel (SIGN)	**1++**
Qualität **(RoB, SIGN /AMSTAR II)**	**Hoch ⊕⊕⊕**

Evidenztabelle Ehmer, Tulloch et al. 1999

Journal of Orofacial Orthopedics
Fortschritte der Kieferorthopädie

An International Comparison of Early Treatment of Angle Class-II/1 Cases

Skeletal Effects of the First Phase of a Prospective Clinical Trial

Ein internationaler Vergleich zur Frühbehandlung von Angle-Klasse-II/1-Dysgnathien

Skelettale Effekte der ersten Phase einer prospektiven klinischen Studie

Ulrike Ehmer[1], Camilla J. F. Tulloch[2], William R. Proffit[2], Celb Phillips[2]

Abstract: The University of North Carolina at Chapel Hill has established an extensive randomized trial to evaluate early treatment of Class-II/1 cases. As presented in this part of the study, a German treatment group was selected in parallel, based on identical prospective criteria, in the context of international cooperation with the Westfälische Wilhelms-Universität, Münster. One essential aspect of this study is the degree to which initially comparable groups can be established by careful alignment of selection criteria and of compilation and analysis of diagnostic records.
Nine skeletal analysis parameters initially indicated that it is possible to select very similar though not absolutely identical groups in the context of international cooperation. The further results of the initial 15-month phase comprising functional orthodontic treatment in severe Class-II/1 cases showed significant mandibular effects in both treatment groups (USA UNC, Chapel Hill: modified Balters appliance; Germany WWU Münster: U-bow activator Type I). The groups were compared to a randomized control group with similar untreated malocclusions, established at Chapel Hill (USA UNC, Chapel Hill).
The results of this cooperative study reveal opportunities for critical evaluation of different treatment methods through international cooperation, utilizing existing prospective randomized studies.

Key Words: Dentofacial orthopaedics · Angle Class-II/1 treatment · Prospective clinical trials

Zusammenfassung: An der University of North Carolina Chapel Hill ist eine umfangreiche randomisierte Studie zur Bewertung der Frühbehandlung von Angle-Klasse-II/1-Dysgnathien etabliert. In der hier vorgestellten Teilstudie konnte im Rahmen einer internationalen Kooperation mit der Westfälischen Wilhelms-Universität Münster nach identischen prospektiven Selektionskriterien eine deutsche Behandlungsgruppe parallel selektiert werden. Ein wesentlicher Gesichtspunkt der Untersuchung besteht in der Fragestellung, inwieweit sich bei sorgfältigem Abgleichen von Standards zur Selektion, Unterlagenerstellung und -analyse initial vergleichbare Gruppen etablieren lassen.
Neun skelettale Analyseparameter zeigen initial an, daß es möglich ist, zwar keine absolut gleiche, aber eine sehr ähnliche Gruppe im Rahmen einer internationalen Kooperation zu selektieren. Die weiterführenden Ergebnisse der initialen, 15 Monate dauernden funktionskieferorthopädischen Therapiephase bei ausgeprägter Angle-Klasse II/1 dokumentieren signifikante mandibuläre Effekte für beide Behandlungsgruppen (USA UNC, Chapel Hill: Balters-Modifikation; Deutschland WWU Münster: U-Bügel-Aktivator Typ I). Der Vergleich erfolgte zu einer dysgnathieadäquaten, nicht therapierten, in Chapel Hill randomisiert etablierten Kontrollgruppe (USA UNC, Chapel Hill).
Die Ergebnisse dieser Kooperationsstudie weisen auf Möglichkeiten hin, unter Ausnutzung prospektiv vorhandener randomisierter Studien unterschiedliche Behandlungsmethoden durch internationale Kooperation kritisch zu überprüfen.

Schlüsselwörter: Dentofaziale Orthopädie · Angle-Klasse-II/1-Behandlung · Prospektive klinische Studien

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Submitted: 31 May 1999

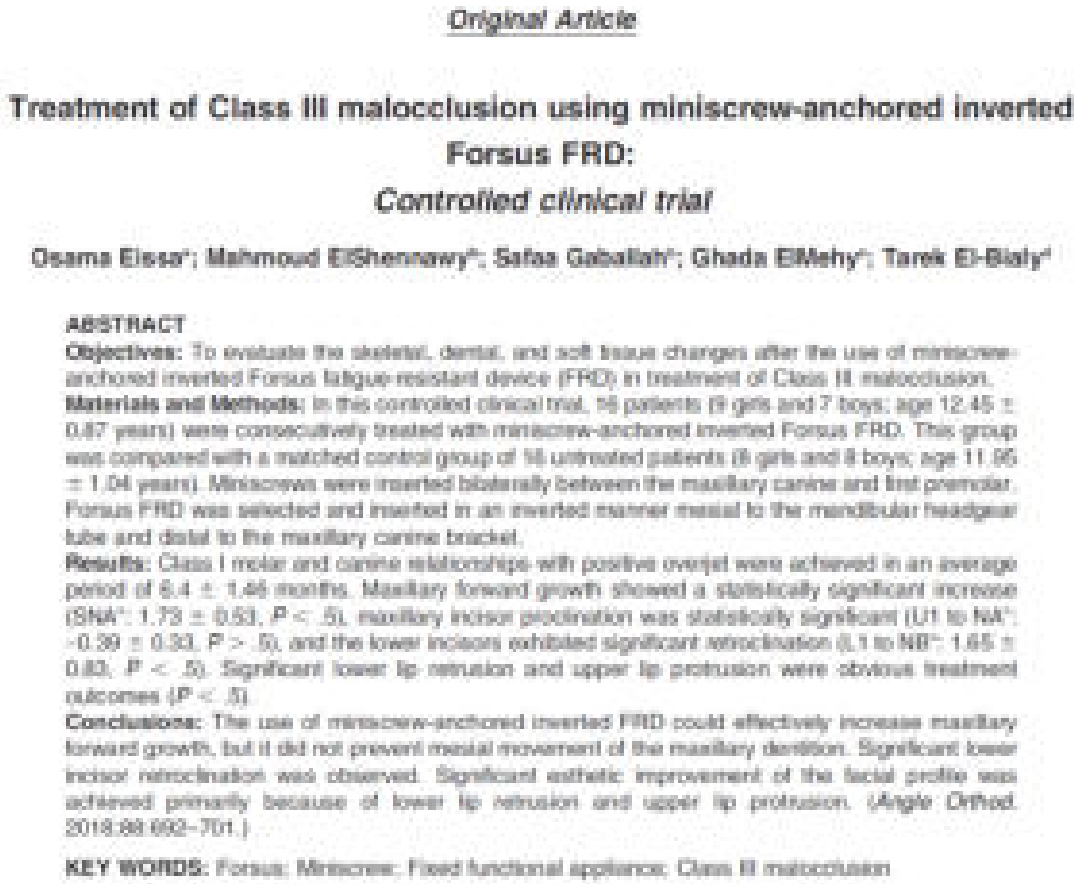
Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** 1. Aktivator-Gruppe: Münster, Deutschland 2. Kontroll- / Bionator-Gruppe: Chapel Hill, North Carolina
Schweregrad	Bionator: Overjet = 8,3 ± 2.2 mm; Overbite = 5,3 ± 2,3 mm Aktivator: Overjet = 9,9 ± 1,7 mm; Overbite = 4,6 ± 2,2 mm Kontrolle: Overjet = 8,5 ± 2,0 mm; Overbite = 5,2 ±1,9 mm
Einschluss-kriterien *Bei Review: PICOS*	1. Caucasian 2. Negative overjet > 7 mm 3. First molar and incisors erupted 4. > 1 year before pubertal growth maximum (hand X-ray, Bowden analysis)
Ausschluss-kriterien	1. Other ethnic group 2. Syndromes, malformations 3. Facial asymmetries 4. Extreme vertical disproportiones (> 2 standard deviations) 5. Extremely accelerated skeletal maturity 6. Previous orthodontic treatment

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE 1: **Bionator Group (US)** *The prospective planning stipulated that preparation of all initial documents (models, lateral ceph, opg, hand X-ray, photo status and others) and insertion of the appliance were to take place within 1 month. The construction bite for the modified Balters appliance was to be taken with 4 to 6 mm sagittal advancement and minimal vertical distance.* *In cases treated with the modified Balters appliance, a new appliance with further mandibular advancement was constructed after clinical evaluation.* N=53 (Anfang) / N=53 (Ende) / Alter = 9,5 ± 1,0 Jahre / ♂:♀ = 30:23 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE 1: **U-bow-activator Group (GER)** *The prospective planning stipulated that preparation of all initial documents (models, lateral ceph, opg, hand X-ray, photo status and others) and insertion of the appliance were to take place within 1 month. The construction bite for the Ubow activator with 4 mm sagittal advancement and 4 mm vertical distance. A successive sagittal advancement can be induced by activating the U-bow to permit further advancement after condylar adaptation.* N=26 (Anfang) / N=26 (Ende) / Alter = 9,8 ± 0,7 Jahre / ♂:♀ = 13:13 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung Patients were treated by an orthodontist experienced with the specific appliance in each centre.
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated Control Group (US)** N=61 (Anfang) / N=61 (Ende) / Alter = 9,5 ± 1,2 Jahre / ♂:♀ = 35:26 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: keine Therapie
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: Skeletal cephalometric treatment effects Skeletal sagittal mandibular (SNB, Md Un Len, Pg-N Perp) Skeletal sagittal maxillary (SNA, Mx Un Len, A-N Perp) Skeletal sagittal relationship (ANB, A-B Diff, Unit Diff) Skeletal vertical relationship (SN-GoGn, y axis, PP-SN)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	• Even proband selection based on standardized criteria over the same period of time may not eliminate inter-group differences. These must be carefully tested and documented. • Given these requirements and in view of the difficulties involved in selecting large groups of patients prospectively at 1 center by specified criteria, defined prospective inter-center comparisons of treatment effects offer obvious advantages. • Without large, prospectively and carefully selected patient and control groups, the question of whether and to what extent different appliances do in fact have specifically different treatment effects is difficult to answer. The problem is in the inter-individual morphological variability at baseline and in growth and reaction to treatment. • The results of this inter-center study show that the effects of 2 differently designed functional appliances (modified Balters appliance: UNC Chapel Hill, U-bow activator Type I: WWU Münster) applied by different orthodontists in America and in Europe for correction of Angle Class-II/1 cases led to surprisingly similar results. These are interesting findings. The underlying reasons require further investigation.
Zusammen-fassung der Ergebnisse	**Bionator Group (US) VS U-Bow-activator Group (GER) VS Untreated Control Group (US)** ***Skeletal cephalometric treatment effects*** *The results of the 15-month phase of treatment with functional orthodontic appliances such as the U-bow activator (Ger Func), the modified Balters appliance (UNC Func) compared with the untreated control group (UNC Cont) are shown in the form of boxplots in Figures 4 to 7. In general, significant reductions in the skeletal mandibular Class-II parameters were recorded for both treatment groups compared to the control group. A significant increase in SNB angle was found during the treatment phase. The positive influence of treatment on mandibular length seemed more differentiated: this parameter showed significant differences between the control group (UNC Cont) and the UNC Func group but not so for the Ger Func group, given the high level of significance defined above, although the trend was the same. The effects of treatment concerning the improved chin projection showed virtually identical increases for both treatment groups; the parameter evaluated was the distance between pogonion and nasion perpendicular. As documented in Figure 4, however, the results fell short of significance level. The effects on the maxilla were non-significant in both functional treatment groups. The boxplots in Figure 5 show a slight inhibition of the parameters analyzed: SNA angle and distance of landmark A to nasion perpendicular. The development of the maxillary length during the treatment phase was not significantly inhibited (Figure 5). A trend towards an increase in the UNC Fuac and a decrease in the Ger Func group compared to the untreated control group (UNC Coat) was recorded.*

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *Prospektives Design* • *NRCT* • *Multizentrische Datenerhebung* • *Gutes Matching der Gruppen* • *Große Studienpopulation* • *Keine Angabe zu Dropouts* • *Wenig Angaben zur initialen Rekrutierung* *Durchführung:* • *Intervention durch nur einen Behandler in jedem Zentrum* *Auswertung:* • *Reliabilitätsprüfungen durchgeführt* • *Keine Angabe von Konfidenzintervallen* *Power der Studie/Patientenzahl: keine Angabe* *Funding: keine Angabe* *Interessenkonflikte: keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten)*
Schluss-folgerung des Begutachters	methodische Qualität: gut
	Klinische Aussagekraft: • Die beiden untersuchten funktionskieferorthopädischen Geräte zur Korrektur der Klasse II/1 führten zu überraschend gleichen Ergebnissen. • Die Resultate weisen damit sehr ähnliche skelettale Behandlungseffekte für beide apparative Varianten aus, wobei ein signifikant positiver therapeutischer Einflug auf die mandibuläre Entwicklung im Vergleich zur Kontrollgruppe dominierte.
Evidenz-level (SIGN)	**2++**
Qualität **(RoB, SIGN /AMSTAR II)**	⊕⊕ High Quality

Evidenztabelle Eissa, ElShennawy et al 2018



Original Article

Treatment of Class III malocclusion using miniscrew-anchored inverted Forsus FRD:

Controlled clinical trial

Osama Eissa[a]; Mahmoud ElShennawy[b]; Safaa Gaballah[c]; Ghada ElMehy[c]; Tarek El-Bialy[d]

ABSTRACT

Objectives: To evaluate the skeletal, dental, and soft tissue changes after the use of miniscrew-anchored inverted Forsus fatigue resistant device (FRD) in treatment of Class III malocclusion.

Materials and Methods: In this controlled clinical trial, 16 patients (9 girls and 7 boys; age 12.45 ± 0.87 years) were consecutively treated with miniscrew-anchored inverted Forsus FRD. This group was compared with a matched control group of 16 untreated patients (8 girls and 8 boys; age 11.95 ± 1.04 years). Miniscrews were inserted bilaterally between the maxillary canine and first premolar. Forsus FRD was selected and inserted in an inverted manner mesial to the mandibular headgear tube and distal to the maxillary canine bracket.

Results: Class I molar and canine relationships with positive overjet were achieved in an average period of 6.4 ± 1.46 months. Maxillary forward growth showed a statistically significant increase (SNA°: 1.73 ± 0.53, $P < .5$), maxillary incisor proclination was statistically significant (U1 to NA°: -0.39 ± 0.33, $P > .5$), and the lower incisors exhibited significant retroclination (L1 to NB°: 1.65 ± 0.83, $P < .5$). Significant lower lip retrusion and upper lip protrusion were obvious treatment outcomes ($P < .5$).

Conclusions: The use of miniscrew-anchored inverted FRD could effectively increase maxillary forward growth, but it did not prevent mesial movement of the maxillary dentition. Significant lower incisor retroclination was observed. Significant esthetic improvement of the facial profile was achieved primarily because of lower lip retrusion and upper lip protrusion. (*Angle Orthod.* 2018;88:692–701.)

KEY WORDS: Forsus; Miniscrew; Fixed functional appliance; Class III malocclusion

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** Children during the circumpubertal phases of skeletal development (cervical vertebrae maturation index [CVMI] 2 and 3 with skeletal Class-III malocclusion, Angle Class III molar relationship with or without anterior crossbite • Egypt
Schweregrad	-4°<, ANB < 0° SNA <78° SN/MP angle 28°–36° Crowding < 5mm
Einschluss-kriterien	- Skeletal Class III malocclusion (-4°<, ANB < 0°), maxillary deficiency (SNA <78°) with or without mandibular prognathism, - Angle Class III molar relationship with or without anterior crossbite, - Normal vertical growth pattern (SN/MP angle 28°–36°), - Minimal or no crowding in the maxillary and mandibular arches (0–5 mm), - no extracted or missing permanent teeth (third molars excluded), - immediately before and during the circumpubertal phases of skeletal development (cervical vertebrae maturation index [CVMI] 2 and 3).
Ausschluss-kriterien	- medical history or systemic disease that could affect normal growth of the body and/or the jaws

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **Forsus FRD (**miniscrewanchored inverted Forsus fatigue-resistant Mini Diamond Twin brackets (Ormco Corporation, Orange, Calif), with a 0.022-inch slot and low-torque maxillary incisors and high-torque mandibular incisors, were bonded to both arches.. Miniscrews (1.6 x 10 mm; MCT Tech, South Korea) were inserted bilaterally between the maxillary canine and first premolar root areas at the level of mucogingival junction. The Forsus FRD was inserted in an inverted fashion: the mandibular end of the FRD was inserted into the headgear tube of the mandibular first molar by means of EZ2 module clips. The pushrod was inserted onto the maxillary arch wire distal to the canine brackets and crimped around the arch wire. While having the patient keep his or her mouth open, the spring was compressed until the push rod was inserted. Patients were observed every 3–4 weeks. During follow-up visits, if the spring module was compressed more than 2.5 mm above the stop on the push rod, reactivation was performed by cinching a crimp onto the push rod to provide an additional 1.5 mm of activation. The Forsus FRD and miniscrews were removed when normal overjet and overbite had been achieved. The fixed appliances were then left in place using light Class III elastics to stabilize the results and avoid relapse. To finalize the occlusion, light intermaxillary box elastics were used, and the mandibular arch wire was replaced with a lighter, more flexible wire. VERSUCHSGRUPPE 1: **Forsus FRD** N= 16 (Anfang) / N=16 (Ende) / Alter = 12,45, 0,87 ♂:♀ = 7:9 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated Class III** N=16 (Anfang) / N=16 (Ende) / Alter = 11,95, 1,04 ♂:♀ = 8:8 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • dentofaziale Ästhetik PRIMÄRZIELGRÖßE: **Skeletal: SNA, SNB, ANB, Wits** SEKUNDÄRZIELGRÖßE: **Dental: Overjet** TERTIÄRZIELGRÖßE: **Soft tissue: UL- E plane; LL- E plane**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	- The use of miniscrew-anchored inverted FRD could effectively increase maxillary forward growth and result in counterclockwise rotation of the occlusal plane. - Clinically non significant proclination of the maxillary dentition was observed. - Distalization of the mandibular dentition together with intrusion of mandibular molars and maxillary incisors were inevitable treatment results. - Significant esthetic improvement of the facial profile, mainly due to lower lip retrusion and upper lipprotrusion, could be achieved.
Zusammen-fassung der Ergebnisse	**GRUPPE Forsus FRD VS. GRUPPE untreated Class III** T1 (pre-treatment): mean age 12,45 years, Forsus FRD; 11,95 years, untreated Class III T2 (post treatment/ observation): mean age 12,98 years, Forsus FRD; 12,48 years, untreated Class III **Skeletal: SNA, SNB, ANB, Wits**

Measurement	Treatment Time	Treated Group Mean	SD	Significance	Control Group Mean	SD	Significance	Comparison Between Treatment and Control Groups T	Significance
SNA	T1	77.720	1.543		79.000	1.652		7.168	.000
	T2	79.460	1.698		79.080	2.007			
	T2-T1	1.730	0.540	<.001**	0.080	0.554	.740		
SNB	T1	78.720	1.536		80.700	1.403		-1.521	.140
	T2	78.640	1.591		80.810	1.467			
	T2-T1	-0.080	0.276	.405	0.110	0.269	.027		
ANB	T1	-2.080	0.970		-1.670	0.606		7.653	.000
	T2	-0.190	1.292		-1.520	0.596			
	T2-T1	1.890	0.995	<.001**	0.150	0.341	.197		
Wits	T1	-5.070	1.031		-4.650	1.732		12.582	.000
	T2	-1.740	0.892		-4.790	1.758			

Dental: Overjet

Measurement	Treatment Time	Treated Group Mean	SD	Significance	Control Group Mean	SD	Significance	Comparison Between Treatment and Control Groups T	Significance
Overjet	T1	2.080	2.207		2.860	1.171		12.608	.000
	T2	2.590	0.601		2.710	1.211			
	T2-T1	4.610	1.815	<.001**	0.140	0.285	.116		

Soft tissue: UL- E plane; LL- E plane

Measurement	Treatment Time	Treated Group Mean	SD	Significance	Control Group Mean	SD	Significance	Comparison Between Treatment and Control Groups T	Significance
UL-E plane	T1	-1.960	2.319		-2.980	1.555		4.998	.001
	T2	-1.010	2.147		-3.050	1.394			
	T2-T1	0.950	0.743	.997	-0.070	0.383	.578		
LL-E plane	T1	3.240	3.018		2.980	1.848		-6.809	.000
	T2	1.680	2.564		3.130	1.768			
	T2-T1	-1.560	0.738	<.001**	0.150	0.466	.329		

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die Äquivalenz von Versuch- und Kontrollgruppe wurde nachvollziehbar überprüft. Power/ Sample Size Berechnungen wurden durchgeführt. Eine Verblindung fand nicht statt. Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie akzeptabel. Die Untersuchung einer Forsus FRD ist noch relativ selten, die methodische Qualität insgesamt akzeptabel, daher ist die klinische Relevanz dieser prospektiven Studie gegeben. *Funding:* keine Angabe *Interessenkonflikte* keine Angabe *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist gegeben. Power/ Sample Size Berechnungen wurden durchgeführt. Eine Verblindung fand nicht statt. Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie akzeptabel. Die Untersuchung einer Forsus FRD ist noch relativ selten, die methodische Qualität insgesamt akzeptabel, daher ist die klinische Relevanz dieser prospektiven Studie gegeben.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Die Untersuchung einer Forsus FRD ist noch relativ selten, die methodische Qualität insgesamt akzeptabel, daher ist die klinische Relevanz dieser prospektiven Studie gegeben.
Evidenzlevel (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Eissa et al. 2017

Treatment outcomes of Class II malocclusion cases treated with miniscrewanchored Forsus Fatigue Resistant Device: A randomized controlled trial

Osama Eissa[a]; Mahmoud El-Shennawy[b]; Safaa Gaballah[b]; Ghada El-Meehy[c]; Tarek El Bialy[d]

ABSTRACT

Objective: To evaluate the skeletal, dental, and soft tissue effects of the Forsus Fatigue Resistant Device (FRD) used with miniscrew anchorage and compare them with those of the conventional Forsus FRD.

Materials and Methods: This study was carried out on 38 patients. These patients were randomly allocated into three groups. The 14 patients in group 1 (aged 12.76 6 1.0 years) were treated with the FRD appliance. In group 2, the 15 patients (aged 12.52 6 1.12 years) received treatment with FRD using miniscrew anchorage, and the 9 patients in group 3 (aged 12.82 6 0.9 years) received no treatment as a control group. Linear and angular measurements were made on lateral cephalograms before and immediately after Forsus treatment. Data were analyzed statistically using paired t-, ANOVA, and Tukey tests.

Results: Class I molar relationship and overjet correction were achieved in both treatment groups. Although mandibular growth was statistically nonsignificant, there was a significant headgear effect on the maxilla. Mandibular incisor proclination, maxillary incisor retroclination, and distalization of maxillary molars were significant in both treatment groups. However, no significant differences were found between the treatment groups.

Conclusions: Class II correction was mainly dentoalveolar in both treatment groups. Use of miniscrews with Forsus did not enhance mandibular forward growth nor prevent labial tipping of the mandibular incisors. (Angle Orthod. 2017;87:824–833.)

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie**
Schweregrad	1. Skeletal Class II malocclusion with mandibular retrognathia (ANB > 4.58, SNB < 76,8°) 2. Normal vertical growth pattern (SN-MP angle in 258–358 range) 3. Minimal or no crowding in the mandibular arch (0–5 mm), based on Little’s irregularity index
Einschluss-kriterien *Bei Review: PICOS*	1. Skeletal Class II malocclusion with mandibular retrognathia (ANB . 4.58, SNB , 768) 2. Normal vertical growth pattern (SN-MP angle in 258–358 range) 3. Minimal or no crowding in the mandibular arch (0–5 mm), based on Little’s irregularity index 4. No extracted or missing permanent teeth (third molars excluded) 5. Undergoing circumpubertal phase of skeletal development (CVMI 2–4) 6. No medical history or systemic disease that could affect normal growth of the body or jaws.

Ausschluss-kriterien	Keine Angabe
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE 1: Forsus N=15 (Anfang) / N=14 (Ende) / Alter = 12,76 ± 1,0 Jahre / ♂:♀ = 6:9 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE 2: Forsus with miniscrews N=15 (Anfang) / N=15 (Ende) / Alter = 12,53 ± 1,12 Jahre / ♂:♀ = 5:10 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: untreated control N=15 (Anfang) / N=9 (Ende) / Alter = 12,82 ± 0,9 Jahre / ♂:♀ = 6:9 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: keine kieferorthopädische Therapie
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis** PRIMÄRZIELGRÖßE: Skelettal und dentale FRS Parameter SEKUNDÄRZIELGRÖßE: Soft tissue FRS Parameter
Studientyp	**Randomisiert-kontrollierte Interventionsstudie (RCT)**
Schluss-folgerungen der Autoren	1. The Forsus FRD effectively corrected Class II malocclusion in both the conventional and miniscrew- anchored treatment groups, mainly through dentoalveolar changes. Due to the short treatment duration of the FRD (6 months), which may be not enough for mandibular growth to take place, a longer use of the appliance might have resulted in more skeletal effects. 2. The use of miniscrews as a means of anchorage with FRD did not enhance forward mandibular growth or limit proclination of the lower incisors…

Zusammen-fassung der Ergebnisse	**GRUPPE Forsus (group 1) VS. GRUPPE untreated control (group 3)** ***PRIMÄRZIELGRÖßE*** Skelettal und dentale FRS Parameter*: Ergebnisse nicht im Text beschrieben, sondern nur tabellarisch aufgeführt* ***SEKUNDÄRZIELGRÖßE*** Soft tissue FRS Parameter: *Ergebnisse nicht im Text beschrieben, sondern nur tabellarisch aufgeführt.* **GRUPPE Forsus with miniscrews (group 2) VS. GRUPPE untreated control (group 3)** ***PRIMÄRZIELGRÖßE*** Skelettal und dentale FRS Parameter*: Ergebnisse nicht im Text beschrieben, sondern nur tabellarisch aufgeführt* ***SEKUNDÄRZIELGRÖßE*** Soft tissue FRS Parameter: *Ergebnisse nicht im Text beschrieben, sondern nur tabellarisch aufgeführt.* Table 4. Comparison of Cephalometric, Skeletal, Dental, and Soft Tissue Mean Changes Among Groups 1, 2, and 3 ANOVA | Tukey's Post Hoc Tests (Grps 1 & 2 | Grps 1 & 3 | Grps 2 & 3) Measurements | F | P | Diff | P | Diff | P | Diff | P SNA (°) | 11.284 | <.001** | -0.279 | .532 | 1.081 | .002* | 1.360 | <.001** SNB (°) | 1.195 | .315 | 0.018 | .998 | 0.421 | .348 | 0.404 | .368 ANB (°) | 6.429 | .004* | -0.273 | .600 | .700 | .042* | .973 | .003* MP-SN (°) | 4.101 | .025* | 0.152 | .953 | -1.421 | .054 | -1.573 | .028* LFH (ANS-Me) (mm) | 0.441 | .647 | 0.423 | .834 | 0.850 | .996 | -0.273 | .777 N-Me (mm) | 1.475 | .243 | 0.600 | .544 | 1.460 | .209 | 0.860 | .720 Co-Gn (mm) | 4.219 | .022* | 1.550 | .208 | 2.967 | .018* | 1.407 | .357 LFH/TFH (%) | 1.111 | .341 | -0.110 | .950 | 0.994 | .330 | -0.884 | .467 Wits appraisal (mm) | 20.060 | <.001** | 0.066 | .936 | 4.341 | <.001** | 3.875 | <.001** U1-NA (mm) | 17.840 | <.001** | -0.940 | .210 | 3.777 | <.001** | 3.737 | <.001** U1-NA (°) | 19.236 | <.001** | -1.214 | .693 | 8.719 | <.001** | 9.933 | <.001** L1-NB (mm) | 4.851 | .014* | -0.207 | .823 | -1.168 | .014* | -.962 | .045* L1-NB (°) | 8.213 | .001** | -1.300 | .548 | -6.922 | .001** | -6.622 | .006* Overjet (mm) | 55.585 | <.001** | -1.075 | .115 | 5.091 | <.001** | 6.166 | <.001** Overbite (mm) | 8.561 | .001** | -0.971 | .231 | 1.713 | .030* | 2.684 | .001** U6/PT vertical (mm) | 12.238 | <.001** | 3.048 | .896 | 2.952 | <.001** | 2.808 | <.001** Lower lip to E-plane (mm) | 0.443 | .645 | -0.235 | .963 | 0.621 | .771 | 0.827 | .625 Upper lip to E-plane (mm) | 9.784 | <.001** | -1.036 | .784 | 1.887 | .027* | 2.933 | <.001** Nasolabial angle (Col-Sn-UL) | 5.019 | .012* | 4.968 | .216 | -5.367 | .263 | -10.36 | .009* P > .05 (nonsignificant) * P < .05 (significant) ** P < .001 (highly significant)

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *prospektive Studie* • *randomisierte Gruppenzuteilung ohne historische Kontrollgruppe* *Durchführung:* • *Detaillierte Beschreibung der Studiendurchführung* • *FRS Punkte wurden nicht definierte* *Auswertung:* • *bei FRS Auswertung zum Zeitpunkt T2 ist für den Auswerter das MB in situ bei den Therapiegruppen sichtbar* *Power der Studie/Patientenzahl:* • *Poweranalyse wurde durchgeführt und eine Dropout rate wurde berücksichtigt* *Funding: keine Angabe* *Interessenkonflikte: keine Angabe* *Bias (SIGN/AMSTAR/Einzelstudien RoB – alle negativen Punkte aus Fragebogen auflisten):* *Performance bias nicht auszuschließen, da für den Behandler die Intervention sichtbar war* *Attrition bias durch höhere Dropoutrate in der Kontrollgruppe im Vergleich zu den Testgruppen*
Schluss-folgerung des Begutachters	methodische Qualität: gut
	Klinische Aussagekraft: hoch
Evidenz-level (SIGN)	**1++**
Qualität **(RoB, SIGN /AMSTAR II)**	**High quality ⊕⊕**

Evidenztabelle Hanem Younes Elfeky et al., 2018

Three-dimensional skeletal, dentoalveolar and temporomandibular joint changes produced by Twin Block functional appliance

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Abstract

Introduction The aim of this study was to three-dimensionally analyze the net skeletal, dental, and temporomandibular joint (TMJ) treatment changes using Twin Block functional therapy in comparison to untreated subjects.

Materials and methods The study (Twin Block) group comprised 22 female patients with skeletal Class II malocclusion due to mandibular retrusion. A total of 18 skeletal Class II untreated female subjects were included as controls. Skeletal, dental, and TMJ changes were evaluated using pre- and posttreatment/observational by cone beam computed tomography (CBCT) images. The treatment changes were compared with the growth changes observed in the control group using independent t-tests.

Results Compared to the changes induced by normal growth, the effective mandibular length, ramus, and corpus lengths increased by 3.19, 3.47, and 2.69 mm ($P < 0.001$ for all), respectively. The maxillary and mandibular incisors inclination and position were significantly reduced and increased, respectively ($P < 0.001$). The maxillary first molars were significantly moved distally and intruded by 1 and 0.36 mm, respectively, while the lower first molars moved mesially and intruded by 2.18 and 0.59 mm, respectively. There was a significant change in the condylar dimensions: increase in length, width, and height by 1.28, 0.88, 1.59 on the right and by 1.60, 0.53, and 1.10 mm on the left sides, respectively. There was significant forward positioning of the right and left condyle by 1.5 and 1.3 mm, respectively.

Conclusions Treatment with the Twin Block functional appliance results in significant skeletal, dentoalveolar, and condylar changes in both dimensions and positions.

Keywords Class II malocclusion · Functional orthopedic appliance · Twin Block · Temporomandibular joint · Cone beam computed tomography

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Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Female patients • Outpatient clinic of the Department of Orthodontics Nicht klar definiert, entweder Ägypten oder Saudi-Arabien
Schweregrad	≥½ unit Class II molar and canine relationship overjet ≥5mm
Einschluss-kriterien *Bei Review: PICOS*	(1) females with a chronological aged between 10–13 years (2) convex profile with retruded mandible, (3)≥½ unit Class II molar and canine relationship (4) overjet ≥5mm (5) skeletal age: stage 3 cervical vertebrae maturational indicators (CVMI) (6) vertical growth pattern as verified clinically by steep mandibular plan (7) no history of orthodontic Treatment (8) no history or clinically diagnosed TMJ disorders, (9) free from any systemic disease or chronic medication use.
Ausschluss-kriterien	---

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: **Twin block group** N=22 (Anfang) / N=18 (Ende) / Alter = 11,89 ± 1,85 Jahre / ♂:♀ = 0:22 • Gebissphase: spätes Wechselgebiss (anhand Alter) • KFO-Behandlung: reguläre Behandlung (anhand Alter) The treatment group subjects were treated with a standard Twin Block appliance according to Clark [8]. The patients were instructed to wear the appliance 24h/day, especially during mealtimes and they were followed once every 4 weeks. The anteroposterior dental arch relationship was checked with and without the appliance during each appointment. When no difference existed and the mandible could not be retruded, the active treatment period was then finished, retention period started with the appliance for another 3 months
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **untreated control group** N=18 (Anfang) / N=18 (Ende) / Alter = 11,27 ± 2,19 Jahre / ♂:♀ = 0:18 • Gebissphase: spätes Wechselgebiss (anhand Alter) • KFO-Behandlung: keine CBCT images of 18 untreated clinically matching control patients were obtained from a control databank created by three research projects in the same institute. All subjects in the control group were orthodontically treated after completion of the observational period.
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: *Three-dimensional skeletal, dentoalveolar and temporomandibular joint changes*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	• Twin Block appliance therapy increase dimensions of mandibular condyle in the three planes of space and reposition toward a more forward position. • Increased posterior and superior and decreased anterior and medial joint spaces are another indication of anterior and inferior positioning of the condyle. • Significant improvement of the skeletal profile in anteroposterior and vertical direction; most of these changes were due to an increase in the effective mandibular, ramus, and corpus lengths and increase in posterior facial height, respectively. • Palatal displacement of maxillary incisors, labial displacement of mandibular incisors, forward migration of the mandibular first molars, and backward migration of the upper molars were responsible for correction of overjet and molar relation, respectively

Zusammen-fassung der Ergebnisse	**Twin block group VS. untreated control group** ***PRIMÄRZIELGRÖßE***: *Three-dimensional skeletal, dentoalveolar and temporomandibular joint changes* Mean and standard deviation (SD) values of all skeletal, dental, and TMJ outcomes in starting form of the Twin Block/control group are presented in Tables 3 and 4, respectively. Mean and SD values of pre- and posttreatment and pre- and postobservational measurements of both groups are listed in Tables 5 and 6. The mean changes and differences between both groups for the same outcomes are presented in Tables 7 and 8. Compared to the changes induced by normal growth, Table 7 showed a net significant increase in both linear and angular anteroposterior facial profile measurements as indicated by ANB°, A-B diff Nv (P<0.001), and increase in the vertical facial profile measurements as demonstrated by AFH (P<0.05) and PFH (P<0.001), and subsequently the jarabak ratio; S-Go/N-Me (P<0.001). The sole effect of the Twin Block on the maxillary base showed that there were no statistically significant changes in vertical position, effective maxillary length, maxillary base tipping, and maxillary base width. There was a significant increase in the palatal plane length (ANS-PNS) and minimal reduction in linear anteroposterior position of point A (P<0.01). Comparison of the two groups showed that the net treatment effect on the mandibular base indicated that there was significant movement in anteroposterior position by 1.53°, 1.87mm (P< 0.001 for all) as showed by SNB and both Nv-B and Nv-Pg, respectively. Similarly, the mandibular effective length, ramus length, and corpus length increased significantly by 3.19, 3.47, and 2.69mm (P< 0.001 for all), respectively. The vertical mandibular position, mandibular width, and mandibular plane inclination were not affected. Regarding the dentoalveolar effects, compared to the minimal changes induced by normal growth, the maxillary incisors inclination and position were significantly reduced (P< 0.001) by 7.98° and 2.57mm, respectively. The mandibular incisor inclination and position was significantly increased by 3.32° and 1.82mm, respectively. The net effect of the Twin Block showed that both overjet and overbite were significantly decreased by 4.89 and 2.11mm, respectively. The maxillary first molars were significantly (P< 0.001) moved distally and intruded by 1 and 0.36mm, respectively, while the lower first molars moved mesially and intruded by 2.18 and 0.59mm, respectively. Results of the net effect of the Twin Block on the osseous TMJ components and joint spaces presented in Table 8 that showed a significant change in the condylar dimensions (increase in length, width, and height by 1.28, 0.88, 1.59 on the right and by 1.60, 0.53, and 1.10mm on the left sides, respectively). There was significant forward positioning of the right and left condyle by 1.5 and 1.3mm, respectively. This dimensional and positional change of the condyles results in a net decrease of the anterior (0.77 and 0.84mm in the right and left side, respectively) and medial joint spaces (0.65mm and 0.67 in the right and left side, respectively) and a net increase of the posterior (0.80 and 1.11mm in the right and left side, respectively) and superior joint spaces (0.79 and 0.90mm in the right and left side, respectively).

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • Historische Kontrollgruppe • Ethikvotum und Zustimmung vorhanden • Suffizientes Matching *Durchführung:* • Mehrere DVT-Auswerter • Behandlung nach Protokoll • Keine Überprüfung der Tragedauer angegeben *Auswertung:* • Reliabilitätsprüfung vorhanden aber kein statistisches Ergebnis aufgeführt • Keine Prüfung auf Normalverteilung • PP-Analyse, attrition bias *Power der Studie/Patientenzahl:* Sample size was calculated with an alpha value of 0.05 and a power of 90% based on the study conducted by Toth and McNamara. *Funding:* --- *Interessenkonflikte:* H.Y. Elfeky, M.S. Fayed, M.S. Alhammadi, S.A.Z. Soliman and D.M. El Boghdadi declare that they have no competing interests. *Bias (SIGN/AMSTAR/Einzelstudien RoB – alle negativen Punkte aus Fragebogen auflisten):* • Comparison is made between full participants and those lost to follow up, by exposure status. – No (sign) • The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable. – No (sign) • Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.- No (sign) • The main potential confounders are identified and taken into account in the design and analysis.- No (sign) • Have confidence intervals been provided? – No (sign)
Schluss-folgerung des Begutachters	methodische Qualität: befriedigend
	Klinische Aussagekraft: Die Behandlung mit einem Twin-Block-Funktionsgerät führte zu signifikanten skelettalen, dentoalveolären und temporomandibulären Veränderungen.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable (+)**

Evidenztabelle Elkordy, Abouelezz et al. 2016

Original Article

Three-dimensional effects of the mini-implant–anchored Forsus Fatigue Resistant Device: *A randomized controlled trial*

Sherif A. Elkordy[a]; Amr M. Abouelezz[b]; Mona M. Salah Fayed[c]; Khaled H. Attia[b]; Ramy Abdul Rahman Ishaq[a]; Yehya A. Mostafa[a]

ABSTRACT

Objective: To detect three-dimensionally the effects of using mini-implant anchorage with the Forsus Fatigue Resistant Device (FFRD).

Materials and Methods: The sample comprised 43 skeletal Class II females with deficient mandibles. They were randomly allocated into three groups: 16 patients (13.25 ± 1.12 years) received FFRD alone (Forsus group), 15 subjects (13.07 ± 1.41 years) received FFRD and mini-implants (FMI group), and 12 subjects (12.71 ± 1.44 years) were in the untreated control group. Three-dimensional analyses of cone beam computed tomographic images were completed, and the data were statistically analyzed.

Results: Class I relationship and overjet correction were achieved in 88% of the cases. None of the two treatment groups showed significant mandibular skeletal effects. In the FMI group, significant headgear effect, decrease in maxillary width, and increase in the lower facial height were noted. In the FMI group, retroclination of maxillary incisors and distalization of maxillary molars were significantly higher. Proclination and intrusion of mandibular incisors were significantly greater in the Forsus group.

Conclusions: FFRD resulted in Class II correction mainly through dentoalveolar effects and with minimal skeletal effects. Utilization of mini-implant anchorage effectively reduced the unfavorable proclination and intrusion of mandibular incisors but did not produce additional skeletal effects. (*Angle Orthod.* 2016;86:292–305.)

KEY WORDS: Forsus Fatigue Resistant Device; Mini-implants; Class II malocclusion; Fixed functional; Anchorage

Population *Setting* *Komorbiditäten*	**Kl. II Anomalie** • Female patients with deficient mandibles • Cairo, Egypt
Schweregrad	SNB ≤ 76°; OJ ≥ 5mm
Einschluss-kriterien *Bei Review: PICOS*	• Females 11–14 y of age • Skeletal Angle Class II division 1 malocclusion with a deficient mandible (SNB ≤ 76°) • Horizontal or neutral growth pattern (MMP ≤ 30°) • Increased overjet (minimum 5 mm) with Class II canine relationship (minimum of half unit) • Erupted full set of permanent teeth with mandibular arch crowding less than 3 mm • At the time of insertion of the FFRD, the patients had to be in the MP3 G or MP3 H stage according to Rajagopal

Ausschluss-kriterien	1. Systemic disease 2. Any signs or symptoms of temporomandibular dysfunction 3. Extracted or missing permanent tooth/teeth 4. Facial asymmetry 5. Parafunctional habits 6. Severe proclination or crowding that requires extractions in the lower arch
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** *The 0.022-inch slot 3M MBT brackets were bonded to maxillary and mandibular arches, and a passive transpalatal arch was cemented to the maxillary first molars. Brackets of the mandibular canines and first premolars were bonded with exaggerated bracket tip to allow root divergence. Levelling and alignment proceeded until treatment reached a phase including 0.019 x 0.025-inch stainless-steel archwires. Wires were cinced distal to the maxillary and mandibular first molars. Periapical radiographs were taken for middle phalanges of the middle fingers of left hands of the patients at this stage to detect the MP3 stage of skeletal maturation according to Rajagopal. Cone beam computed tomographic (CBCT) images were obtained with an i-CAT CBCT unit (Imaging Sciences International, Hatfield, Pa). The first Image (T1) was obtained immediately before insertion of FFRD and mini-implants in the two treatment groups. In both groups, selection of the proper size of the FFRD was done according to the manufacturer’s instructions. The pushrods of the appliance were inserted onto the mandibular archwires distal to the mandibular canines* *Follow up visits occurred every 3–4 weeks, and at these visits, the mini-implants and wire segments were checked for stability and the appliance was checked for activation. Split crimps were used for appliance activation, according to the manufacturer’s instructions. Treatment was continued until overcorrection to an edge-to-edge incisor relationship was reached. The appliances and mini-implants were then removed and the second set of CBCT images (T2) was obtained.* VERSUCHSGRUPPE 1: **Forsus Group** N=16 (Anfang) / N=16 (Ende) / Alter = 13,25 ± 1,12 Jahre / ♂:♀ = 0:16 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE 2: **FMI Group** N=16 (Anfang) / N=16 (Ende) / Alter = 13,25 ± 1,12 Jahre / ♂:♀ = 0:16 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung *In the FMI group mini-implants (1.6 x 10 mm; 3M Unitek) were inserted under local anesthesia between the mandibular canines and first premolars according to AlSamak et al.,25 and 0.019 3 0.025-inch stainlesssteel wire segments were used for fixation of the mini-implants to the mandibular arch and were bonded to the labial surface of the mandibular canines.*

Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Bezeichnung** N=15 (Anfang) / N=12 (Ende) / Alter = 12,71 ± 1,44 Jahre / ♂:♀ = 0:12 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: CBCT Changes The analysis was done using Invivo Anatomage version 5.2 (Anatomage, San Jose, Calif). The analysis included skeletal and dental measurements. The measurements were performed by the same observer twice and by another observer. *Siehe Tabelle 2 in der Evidenztabelle*
Studientyp	**RCT**
Schluss-folgerungen der Autoren	• FFRD was successful in treatment of Class II division 1 malocclusion through dentoalveolar changes and minimal significant skeletal changes. • The use of mini-implants with FFRD could not produce significant additional sagittal skeletal effects. • The incorporation of mini-implants with FFRD decreasedthe mandibular dentoalveolar side effects and increased the distalizing effects of the appliance on the maxillary arch.
Zusammen-fassung der Ergebnisse	**Forsus VS FMI VS Control Group** ***PRIMÄRZIELGRÖßE*** ***Skeletal Changes*** *Most of the vertical skeletal measurements did not change significantly with treatment in both groups. The lower facial height and MP/SN increased significantly only in the FMI group. SNA decreased significantly only in the FMI group. SNB, B-FP, and right and left effective mandibular lengths increased significantly in the three groups. The ANB and A-B difference decreased significantly in all groups. As for the transverse plane, maxillary and mandibular widths did not show statistically significant differences. Upon comparing the three groups, the FMI group showed statistically significant maxillary retrusion (AFP decreased by -0.33 ± 0.63 mm) and significant reduction in the maxillary width (-0.68 ± 1.35 mm).* ***Dentoalveolar Changes*** *Statistically significant retroclination of the maxillary incisors was evident in the FMI and Forsus groups as compared to the control group (-11.17° ± 3.51° and -9.15° ± 3.01°). The maxillary incisors were significantly extruded in the FMI group only. The maxillary first molars significantly moved mesially in the control group in contrast to the FMI and Forsus groups, in which they significantly moved distally. The maxillary first molars showed significant extrusion in the control group and significant intrusion in the FMI and Forsus groups. The mandibular incisors were significantly proclined (5.26° ± 2.71° and 9.05° ± 2.91° in the FMI and Forsus groups, respectively) and intruded in the treatment groups, as compared with the control group. In the Forsus group the mandibular incisors moved significantly forward more than in the other two groups (0.66 ± 1.42 mm, 0.81 ± 1.49 mm, and 2.55 ± 0.88 mm in the control, FMI, and Forsus groups, respectively). The mandibular first molars were significantly extruded and moved in a mesial direction in the three groups. The mesialization was shown to be most significant in the Forsus group.*

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *RCT* • *Homogene Gruppengrößen* • *Nur Mädchen* • *Gute Randomisierung* • *Ethikvotum vorhanden* • *ALARA fraglich (2 DVTs in Kontrollgruppe)* *Durchführung:* • *Keine Verblindung in der Intervention (nicht wirklich möglich)* • *Reliabilitätstest* • *Reliabilität der Intervention fraglich (keine Angaben zum Behandler)* *Auswertung:* • *Verblindung in der Outcome-Erhebung* • *Konfidenzintervalle angegeben* • *Solide Statistik (Test auf Normalverteilung; Bonferoni-Korrektur)* • *Keine Aussagen zur Validität der Vermessung der DVTs* *Power der Studie/Patientenzahl: vorhanden* *Funding: keine Angabe* *Interessenkonflikte: keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):*
Schluss-folgerung des Begutachters	methodische Qualität: sehr gut
	Klinische Aussagekraft: • Der Forsus ist ein geeignetes Gerät zur Behandlung der Klasse II/1. Wobei von dento-alveoläre und weniger skelettale Effekte erzielt werden. • Mit der Verwendung von Mini-Implantaten in Kombination mit dem Forsus konnten keine zusätzlichen skelettalen Effekte erzielt werden. • Die Verwendung von Mini-Implantaten verringerte die dento-alveolären Nebenwirkungen im UK (Protrusion der Front) und verstärkte den Headgear-Effekt im OK.
Evidenz-level (SIGN)	**1++**
Qualität **(RoB, SIGN /AMSTAR II)**	⊕⊕ High Quality

Evidenztabelle ElKordy, Abouelezz et al. 2019

Evaluation of the miniplate-anchored Forsus Fatigue Resistant Device in skeletal Class II growing subjects: *A randomized controlled trial*

Sherif A. Elkordy[a]; Amr M. Abouelezz[b]; Mona M. S. Fayed[c]; Mai H. Aboulfotouh[d], Yehya A. Mostafa[e]

ABSTRACT

Objectives: To evaluate the use of direct miniplate anchorage in conjunction with the Forsus Fatigue Resistant Device (FFRD) in treatment of skeletal Class II malocclusion.

Materials and Methods: Forty-eight females with skeletal Class II were randomly allocated to the Forsus plus miniplates (FMP) group (16 patients, age 12.5 ± 0.9 years), Forsus alone (FFRD; 16 patients, age 12.1 ± 0.9 years), or the untreated control group (16 subjects, age 12.1 ± 0.9 years). After leveling and alignment, miniplates were inserted in the mandibular symphysis in the FMP group. The FFRD was inserted directly on the miniplates in the FMP group and onto the mandibular archwires in the FFRD group. The appliances were removed after reaching an edge-to-edge incisor relationship.

Results: Data from 46 subjects were analyzed. The effective mandibular length significantly increased in the FMP group only (4.05 ± 0.78). The mandibular incisors showed a significant proclination in the FFRD group (9.17 ± 2.42) and a nonsignificant retroclination in the FMP group (−1.49 ± 4.70). The failure rate of the miniplates was reported to be 13.3%.

Conclusions: The use of miniplates with the FFRD was successful in increasing the effective mandibular length in Class II malocclusion subjects in the short term. The miniplate-anchored FFRD eliminated the unfavorable mandibular incisor proclination in contrast to the conventional FFRD. (*Angle Orthod.* 2019;89:391–403.)

KEY WORDS: Class II malocclusion; Forsus; Miniplates; Anchorage; Growth; Fixed functional appliance

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • 48 Mädchen (10-13 Jahre) • Faculty of Dentistry, Cairo University outpatient orthodontic clinic
Schweregrad	SNB ≤ 76°; MP/SN ≤ 39°; OJ ≥ 5mm
Einschluss-kriterien *Bei Review: PICOS*	• Chronologically; 10–13 y of age • Skeletally, the patients had to be in the cervical maturational stage 3 or 4 as detected by the lateral cephalometric radiograph • Skeletal Angle Class II malocclusion with a deficient mandible (SNB ≤ 76°) and a horizontal or neutral growth pattern (MP/SN ≤ 39°) • Class II division 1 incisor relation • Increased overjet (minimum of 5 mm) • Class II canine relationship. (minimum of half unit) • Mandibular arch crowding less than 3 mm

Ausschluss-kriterien	• Systemic diseases • Facial asymmetry • Any signs or symptoms or previous history of temporomandibular disorders • Parafunctional habits • Extracted or missing upper permanent tooth/teeth (except for third molars) • Class II division 2 incisor relation • Severe proclination or crowding that requires extractions in the lower arch
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** A passive, soldered transpalatal arch was cemented to the maxillary first permanent molars. MBT prescription brackets with 0.022-inch slots (3M Unitek) were bonded to both arches in the FFRD group and to the maxillary arch only in the miniplates (FMP) group. Leveling and alignment progressed until reaching 0.019x0.025-inch cinched-back stainless-steel wires. The patients were then referred for the T1 CBCT scan. CBCT scanning was performed in maximum intercuspation with the next-generation i-CAT CBCT unit (Imaging Sciences International, Hatfield, Penn). The selected parameters were voxel dimension 0.3 mm, field of view 17 cm at 120 kV, and 18.54 mAs. In both treatment groups, the proper FFRD size was selected according to the manufacturer’s instructions. The pushrods were inserted onto the mandibular archwires distal to the mandibular canines in the FFRD group and into the miniplate heads in the FMP group (Figure 2a,b). Follow-up visits were every 4 weeks, during which the miniplates were checked for stability and the appliance for activation. The FFRD was planned to be removed either after 10 months or after reaching an edge-to-edge incisor relationship, whichever occurred first. T2 CBCT scan was obtained afterwards. VERSUCHSGRUPPE 1: **Forsus Group (FFRD)** N=16 (Anfang) / N=15 (Ende) / Alter = 12,1 ± 0,9 Jahre / ♂:♀ = 0:16 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE 2: **Forsus/Mini-plates Group (FMP)** In the FMP group, surgical procedures were performed under local anesthesia. A single horizontal incision was made in the alveolar mucosa and the underlying muscle immediately below the mucogingival line from the mandibular canine on one side to that of the other using blade No. 15. Two long Y-shaped miniplates (Stryker, Leibinger, GmbH & Co, Freiburg, Germany) were adapted to the underlying bone (Figure 1). They were fixed by three titanium mini-screws (diameter 2 mm, lengths 8 and 10 mm). The flap was closed using resorbable (4/0) sutures, leaving the miniplate heads perforating the attached gingiva at the mandibular canine region. Postoperative anti-inflammatories and analgesics were prescribed; ice packs and soft diet were advised. N=16 (Anfang) / N=15 (Ende) / Alter = 12,5 ± 0,9 Jahre / ♂:♀ = 0:16 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung

Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated Control Group** The control group subjects were sent for the T1 CBCT after their random allocation. The observation period was 7.26 6 1.74 months. Afterward, they were sent for the T2 CBCT that was considered their pretreatment record. Orthodontic treatment was then performed for all control patients. N=16 (Anfang) / N=16 (Ende) / Alter = 12,1 ± 0,9 Jahre / ♂:♀ = 0:16 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: keine Therapie
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: CBCT Treatment Effects CBCT analysis was done using Invivo Anatomage version 5.2 (San Jose, Calif). The landmarks and included measurements are described (Figure 3a–c; Table 2).
Studientyp	**RCT**
Schluss-folgerungen der Autoren	• The addition of miniplates to the FFRD (FMP group) enhanced the skeletal outcome of Class II malocclusion treatment in the short term. • Miniplate-anchored FFRD (FMP) resulted in a significant lengthening of the mandible that was coupled with clockwise mandibular rotation, reducing the apparent sagittal correction. • In contrast to the conventional FFRD, miniplateanchored FFRD (FMP) showed retroclination of the mandibular incisors and no anchorage loss.

Zusammen-fassung der Ergebnisse	**Forsus Group (FFRD)**… VERSUS **Forsus/Mini-plates Group (FMP)** VERSUS **Untreated Control Group** ***PRIMÄRZIELGRÖßE*** ***Skeletal Changes*** *A significant increase was found in the effective mandibular length (4.05 ± 0.78), SNB, and B-FP in the FMP as compared with the FFRD and control groups, even after data annualization (Tables 7 and 8). The gonial angle was significantly decreased in the controls (-0.88 ± 0.76) and increased in the FMP group (1.15 ± 0.85). The effective maxillary length and A-FP showed no significant difference between groups. The ANB angle showed a significant decrease in the FMP group only (-1.62 ± 1.37), indicating the skeletal Class II improvement. No significant differences were reported regarding the maxillary and mandibular widths. In the vertical plane, there was a significant increase in the MP/SN (2.06 ± 1.44), indicating a clockwise mandibular rotation in the FMP group, which was confirmed after data annualization.* ***Dental Changes*** *The maxillary incisors were significantly retroclined in the FFRD (-8.98 ± 2.55) and FMP (-10.03 ± 4.39) groups (Tables 7 and 8). In the FFRD group, the mandibular incisors showed significant proclination (9.17 ± 2.42) and advancement relative to the Apogonion line (2.96 ± 0.95). The FMP and control groups showed no significant difference in the mandibular incisor position; retroclination (-1.49 ± 4.70) occurred in the FMP group. The FFRD also showed significant mandibular incisor intrusion (-1.76 ± 0.64), while the FMP showed significant extrusion (1.14 ± 1.52). Maxillary molars were significantly distalized and intruded in the FFRD and FMP groups. Mandibular molars were mesialized and extruded in all groups. The highest mesialization was found in the FFRD group (2.83 ± 1.31), while the maximum extrusion was found in the FMP group (2.75 ± 0.78).*

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *RCT* • *Homogene Gruppengrößen* • *Nur Mädchen* • *Gute Randomisierung* • *Ethikvotum vorhanden* • *ALARA fraglich (2 DVTs in Kontrollgruppe)* • *Gute Beschreibung der Rekrutierung* *Durchführung:* • *Keine Verblindung in der Intervention (nicht wirklich möglich)* • *Reliabilitätstest* • *Reliabilität der Intervention fraglich (keine Angaben zum Behandler)* *Auswertung:* • *Verblindung in der Outcome-Erhebung* • *Konfidenzintervalle angegeben* • *Solide Statistik (Test auf Normalverteilung; Bonferoni-Korrektur)* • *Keine Aussagen zur Validität der Vermessung der DVTs* *Power der Studie/Patientenzahl: vorhanden* *Funding: self-funded* *Interessenkonflikte: keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):*
Schluss-folgerung des Begutachters	methodische Qualität: sehr gut
	Klinische Aussagekraft: • Durch die zusätzliche Verwendung von Miniplates zum Forsus konnte während des Beobachtungszeitraums die skelettale Wirkung der Apparatur verstärkt werden. • In der Miniplate-Gruppe kam es zu einer signifikanten Verlängerung der Mandibula zusammen mit einer clockwise-Rotation des UK. • Im Vergleich zum konventionellen Forsus kam es in der Miniplate-Gruppe zu weniger Verankerungsverlust und einer Retrusion der UK-Frontzähne.
Evidenz-level (SIGN)	**1++**
Qualität **(RoB, SIGN /AMSTAR II)**	⊕⊕ High Quality

Evidenztabelle Entrenas et al. 2019

Evaluation of changes in the upper airway after Twin Block treatment in patients with Class II malocclusion

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Abstract

The purpose of this prospective case control study is to describe in growing patients with mandibular hypoplasia, treatment outcomes following functional therapy in terms of volumetric changes in nasopharynx and oropharynx, that is, upper and lower pharynx. We recruited 60 study participants aged between 8 and 12 years having mandibular Class II malocclusion and a reduced upper airway (UA) size, as determined by McNamara cephalometric analyses. Forty patients received Twin Block treatment, whereas the remaining 20 patients did not receive treatment, thus constituting the control group. The control group included patients who did not start treatment after their first visit but returned for a consultation one or 2 years later. All patients underwent an initial teleradiography examination of the skull and a final teleradiography examination to measure changes using McNamara cephalometric analysis of the UA. Pretreatment and posttreatment changes were assessed using Student's *t* test for independent samples with a significance level of 0.05. Both anatomical structures analyzed—the upper pharynx (nasopharynx) and lower pharynx (oropharynx)—showed significant increases after treatment regardless of whether the patients were boys or girls. The controls showed a decrease in UA size on average after approximately 2 years of growth. A clear relationship exists between the mandibular advancement achieved with TB treatment and an increased UA size. Therefore, the appliance is considered suitable for improving the respiratory quality of growing patients with a decreased UA size.

KEYWORDS
Class II malocclusion, mandibular hypoplasia, sleep breathing disorders, twin block, upper airway

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Patients with a decreased UA size and mandibular Class II malocclusion • Asturian Institute of Dentistry (IAO for its acronym in Spanish)
Schweregrad	Keine genauen Angaben: …with a decreased UA size and mandibular Class II malocclusion.

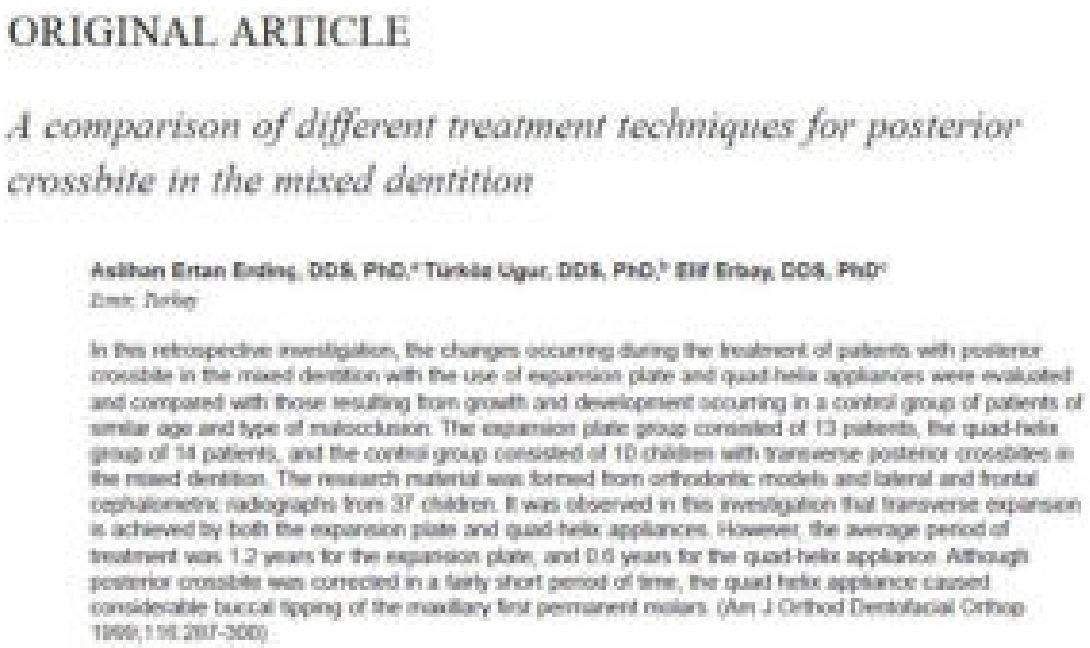
Einschluss-kriterien *Bei Review: PICOS*	1. aged between 8 and 12 years 2. a decreased UA size 3. mesofacial and brachyfacial growth patterns 4. mandibular Class II malocclusion (nur für Versuchsgruppe angegeben)
Ausschluss-kriterien	Patients with a very vertical pattern and a tendency towards an open anterior bite were excluded because although one benefit of TB appliances is control of the vertical dimension (without trimming bite blocks to avoid favoring posterior tooth extrusion), another type of functional appliance is better suited for these patients.
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** The TB appliance is a functional device used for early treatment of children with Class II malocclusion that advances the jaw and stimulates jaw growth. The appliance was developed by William J Clark in 1970 in Scotland and is currently one of the most common and popular functional appliances due to its effectiveness in correcting skeletal Class II malocclusion. The appliance is well accepted by patients and can produce rapid changes. The appliance should be worn 24 hours a day, although use of the appliance for approximately 14–18 hours per day also yields positive effects after 12–18 months of treatment. However, treatment should be ideally initiated before or during peak growth to produce more favorable results. The appliance should be retained—either the TB itself or a Hawley plate with an advancement splint—until the end of growth to ensure long-term stability. VERSUCHSGRUPPE: **Twin Block group** N=40 (Anfang) /N=40 (Ende) / Alter =9,83 Jahre / ♂:♀ = 20:20 • Gebissphase: frühes und spätes Wechselgebiss • KFO-Behandlung: Frühbehandlung/reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE : **untreated control group** N=20 (Anfang) /N=20 (Ende) / Alter 9,65 Jahre / ♂:♀ = 10:10 • Gebissphase: frühes und spätes Wechselgebiss • KFO-Behandlung: keine kieferorthopädische Therapie

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • Atmung und Luftraum (Airway space, Schlafapnoe), Schlucken und Sprechen PRIMÄRZIELGRÖßE: Cephalometric changes in the upper pharynx (nasopharynx) SEKUNDÄRZIELGRÖßE: Cephalometric changes in the lower pharynx (oropharynx) Twin Block group: T1: at the start of treatment T2: after 12-18 months of TB treatment Untreated control group: T1: first visit T2: one or two years later
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	A significant increase in UA size was observed in both the nasopharynx and oropharynx after early treatment with TB appliances in patients with mandibular Class II malocclusion. The effectiveness of TB treatment was demonstrated in patients with clinical manifestations suggestive of SAHS, mouth breathing, and/or snoring as all patients showed improved respiratory quality. Patients with mandibular Class II malocclusion show a decrease in UA size with growth and may therefore become future SAHS patients if not treated with functional appliances. TB devices are some of the most common and popular functional appliances due to their effectiveness in skeletal Class II correction, thus improving the facial profile. In addition, these devices may be effective for treating children with RSDs and mandibular retrognathia, thus decreasing the risk of SAHS development in adulthood. Whenever CBCT is performed in orthodontic practice, the clinical benefits to the patient must be weighed against the potential risk of radiation. Currently, more research is being conducted on the benefits of intraoral orthopedic appliances for the treatment of SAHS and other RSDs; however, few studies have demonstrated the long-term stability of such devices.
Zusammen-fassung der Ergebnisse	**Twin Block group vs. untreated control group** PRIMÄRZIELGRÖßE: Cephalometric changes in the upper pharynx (nasopharynx) T2-T1: The control group showed a tendency for a decreased nasopharynx, whereas the experimental group exhibited a tendency for an increased nasopharynx. Similar results for only boys/only girls. SEKUNDÄRZIELGRÖßE: Cephalometric changes in the lower pharynx (oropharynx) T2-T1: The control group showed a tendency for a decreased oropharynx, whereas the experimental group exhibited a tendency for an increased oropharynx. Similar results for only boys/only girls.

Angaben auffälliger positiver und/oder negativer Aspekte
Studiendesign
Durchführung
Auswertung
Funding
Interessen-konflikte
Bias (SIGN, AMSTAR II, Einzelstudien)
	Studiendesign:
	• Ethikvotum vorhanden
	• unterschiedliches T2 innerhalb der Twin Block Gruppe (12-18 Monate) und der Kontrollgruppe (ein oder zwei Jahre)
	• unterschiedliches T2 zwischen Twin Block Gruppe und Kontrollgruppe
	• Baseline-Imbalancen (größerer Oropharynx in Kontrollgruppe zum Zeitpunkt T1, 10.56 vs 8.93)
	• keine Angabe zu signifikanten Unterschieden zwischen den Gruppen zum Zeitpunkt T1
	• keine genaue dentale Ausgangssituation beschrieben
	• kein genaues Behandlungsziel definiert
	Durchführung:
	• Keine Verblindung angegeben
	• keine Angabe zum Untersucher
	• keine Angabe zu tatsächlichen Tragezeiten/Compliance
	Auswertung:
	• keine Reliabilitätsprüfung bei FRS-Auswertung
	• Normalverteilung geprüft
	• Varianztests durchgeführt
	• Einheiten nicht genau definiert (mm angenommen)
	Power der Studie/Patientenzahl: keine Power Analyse
	Funding: keine Angabe
	Interessenkonflikte: The authors have no conflicts of interest to declare.
	Bias (SIGN/AMSTAR/Einzelstudien RoB – alle negativen Punkte aus Fragebogen auflisten):
	• evtl. performance bias: keine Angabe zu Behandlern (Anzahl/Erfahrung)
	  ○ The main potential confounders are identified and taken into account in the design and analysis - NO
	  ○ Have confidence intervals been provided? - NO

Schluss-folgerung des Begutachters	methodische Qualität: ausreichend
	Klinische Aussagekraft: Eine Behandlung mit Twin Block Apparatur führt im Vergleich zu einer unbehandelten Kontrollgruppe zu einer signifikanten Vergrößerung des Naso- und Oropharynx. Die Kontrollgruppe zeigt eine Tendenz zur Verkleinerung des Naso- und Oropharynx. Es existieren keine geschlechterspezifischen Unterschiede innerhalb der Versuchsgruppe.
Evidenz-level (SIGN)	**2+**
Qualität	**Acceptable (+)**

Evidenztabelle **Erdinc et al. 1999**



ORIGINAL ARTICLE

A comparison of different treatment techniques for posterior crossbite in the mixed dentition

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In this retrospective investigation, the changes occurring during the treatment of patients with posterior crossbite in the mixed dentition with the use of expansion plate and quad-helix appliances were evaluated and compared with those resulting from growth and development occurring in a control group of patients of similar age and type of malocclusion. The expansion plate group consisted of 13 patients, the quad-helix group of 14 patients, and the control group consisted of 10 children with transverse posterior crossbites in the mixed dentition. The research material was formed from orthodontic models and lateral and frontal cephalometric radiographs from 37 children. It was observed in this investigation that transverse expansion is achieved by both the expansion plate and quad-helix appliances. However, the average period of treatment was 1.2 years for the expansion plate, and 0.6 years for the quad-helix appliance. Although posterior crossbite was corrected in a fairly short period of time, the quad helix appliance caused considerable buccal tipping of the maxillary first permanent molars. (Am J Orthod Dentofacial Orthop 1999;116:287-300)

Population *Setting* *Komorbiditäten*	**Transversale Anomalie (Patienten mit uni-/bilateralem Kreuzbiss)** Patienten der Abteilung für Kieferorthopädie der Universität Istanbul. Alter: 9.3-9.7 Jahre
Schweregrad	Uni- oder Bilateraler Kreuzbiss
Einschluss-kriterien *Bei Review: PICOS*	Morphologic posterior crossbite on one or both sides due to transverse maxillary deficiency; Angle Class I or Class II molar occlusion; the mixed dentition period
Ausschluss-kriterien	keine Angabe

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** VERSUCHSGRUPPE 1: **Expansion plate group** Beschreibung: Martin Schwartz developed the expansion plate used in this investigation. This plate had a midline screw for symmetric expansion and clasps on the teeth N=13 (Anfang) / N=13 (Ende) / Alter = 9.3 ± 1.1 Jahre / ♂:♀ =2:11 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Frühbehandlung, interzeptiv ---------- VERSUCHSGRUPPE 2: **Quad helix group** Beschreibung: The quad-helix appliance with a lock and key mechanism used in this investigation was a modification of the “W” appliance developed by Rickets. The quad-helix appliance, made of a 0.9 mm stainless steel wire, was activated 1 week after its application. N=14 (Anfang) / N=14 (Ende) / Alter = 9.7 ± 1.4 Jahre / ♂:♀ =2:12 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Frühbehandlung, interzeptiv
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Behandlung** KONTROLLGRUPPE: **Control group** N=10 (Anfang) / N=10 (Ende) / Alter = 9.4 ± 1.3 Jahre / ♂:♀ = 3:7 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Frühbehandlung, interzeptiv
Outcome	**Direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: Orthodontic cast measurements *(* Maxillary intermolar width, Maxillary intercanine width, Mandibular intermolar width, Mandibular intercanine width) SEKUNDÄRZIELGRÖßE: Frontal cephalometric measurements (Upper molar axial inclination angle, Lower molar axial inclination angle, Maxillary intermolar angle, Maxillary apical base width, Nasal width)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	Dentally maxillary intermolar width and intercanine width have been found to increase as a result of treatment with expansion plate after a period of approximately 1.2 years. Dentally maxillary intermolar and intercanine widths and axial Inclinations of maxillary first molars have increased while the intermolar angle decreased with quad-helix appliance. Skeletally maxillary apical base width has increased with the quad-helix appliance after a treatment period of 0.6 year. It was observed that transverse expansion was achieved by both the expansion plate and the quad-helix appliance. However, the period of treatment was 1.2 years for the expansion plate and 0.6 year for the quad-helix appliance. Although posterior crossbite was corrected by the quad-helix appliance in a fairly short period of time, the appliance caused considerable buccal tipping in the maxillary first permanent molars.
Zusammen-fassung der Ergebnisse	**GRUPPE Expansion plate VS. Control group** **GRUPPE Quad helix group VS. GRUPPE Control group** **PRIMÄRZIELGRÖßE** Nach 0.6/0.7 Jahren: The maxillary intermolar, maxillary intercanine, and maxillary apical base width increased more in the expansion plate group than in the control group (siehe Tabelle). Nach 1.2 Jahren: The maxillary intermolar and maxillary intercanine widths increased more in the expansion plate group than in the control group. **SEKUNDÄRZIELGRÖßE** Nach 0.6 Jahren: SNB increased more in the expansion plate group than in the control group (siehe Tabelle). **GRUPPE Quadhelix group VS. Control group** **PRIMÄRZIELGRÖßE** The maxillary intermolar, maxillary intercanine, and maxillary apical base widths and the axial inclination of the first maxillary molars exhibited a greater increase in the quad-helix than in the control group and a greater decrease was observed in the maxillary intermolar angle (siehe Tabelle). **SEKUNDÄRZIELGRÖßE** Siehe Tabelle **GRUPPE Quadhelix group VS. Expansion plate** **PRIMÄRZIELGRÖßE** Nach 0.6 Jahren: The maxillary intermolar widths, axial inclination of the maxillary left, and right first permanent molars and maxillary apical base width exhibited a greater increase in the quadhelix group than in the expansion plate group, and a greater decrease was observed in terms of the maxillary intermolar angle (siehe Tabelle). Nach 1.2 Jahren Expansion plate und 0.6 Jahren Quadhelix: The maxillary intermolar width and axial inclination of the maxillary left and right first molars showed a greater increase in the quad-helix group than in the control group. Greater decrease was observed in terms of the maxillary intermolar angle in the quad helix group, whereas in the expansion plate group the mandibular intercanine width showed a greater increase (siehe Tabelle). **SEKUNDÄRZIELGRÖßE** **Siehe Tabelle**

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: Retrospektive Studie, keine Fallzahlberechnung vorliegend, Anzahl der Behandler unklar, Methodenfehler nach Dahlberg für Primärzielgröße berechnet, für Sekundärzielgröße keine Berechnung, nicht verblindet, keine klaren Ein-/Auschlusskriterien definiert, Ausmaß der Dysgnathie nicht definiert.* *Insgesamt klinisch relevante Ergebnisse. QH verursacht mehr Bukkalkippung als Dehnplatte.* *Funding: Keine Angabe* *Interessenkonflikte: Keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* - *Can’t say if the same exclusion criteria are used for both cases and controls* - *Can’t say if comparison is made between participants and non-participants to establish their similarities or differences.* - *Cases are not clearly defined and differentiated from controls.* - *Can’t say if the methods used to define or identify controls are mentioned, but no details or justification are provided.* - *Confidence intervals are not provided.*
Schluss-folgerung des Begutachters	methodische Qualität: Akzeptabel
	Klinische Aussagekraft: Dentally maxillary intermolar width and intercanine width have been found to increase as a result of treatment with expansion plate after a period of approximately 1.2 years. Dentally maxillary intermolar and intercanine widths and axial inclinations of maxillary first molars have increased while the intermolar angle decreased with quad-helix appliance. Skeletally maxillary apical base width has increased with the quad-helix appliance after a treatment period of 0.6 year. It was observed that transverse expansion was achieved by both the expansion plate and the quad-helix appliance. However, the period of treatment was 1.2 years for the expansion plate and 0.6 year for the quad-helix appliance. Although posterior crossbite was corrected by the quad-helix appliance in a fairly short period of time, the appliance caused considerable buccal tipping in the maxillary first permanent molars.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable ⊕**

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Original article

Bone-anchored maxillary protraction in unilateral cleft lip and palate: a cephalometric appraisal

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Summary

Objectives: The aim of this study was to evaluate the cephalometric outcome of bone-anchored maxillary protraction (BAMP) in individuals with unilateral complete cleft lip and palate (UCLP).

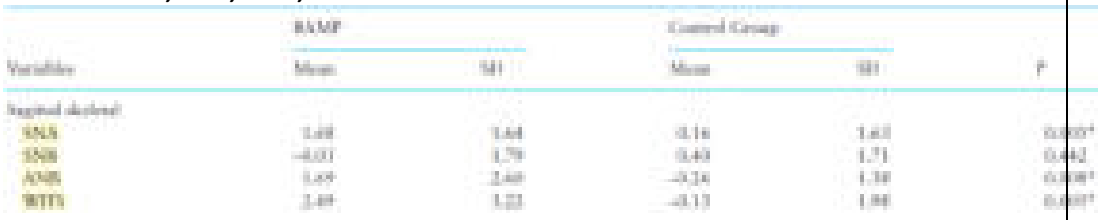
Material and methods: The experimental group (EG) comprised 23 individuals (17 males and 6 females) with UCLP and a mean age of 11.7 years. At least 6 months after secondary alveolar bone grafting, Bollard miniplates were installed in the posterior region of the maxilla and in the anterior region of the mandible. Class III elastics were recommended to be worn for 24 hours/day for a mean time of 18 months. Cone beam computed tomography (CBCT) was obtained before (T1) and after treatment (T2). The control group (CG) consisted of 23 individuals with UCLP matched by initial age and gender with the EG and without any orthopaedic or surgical intervention performed between T1 and T2. The interval between T1 and T2 observations was 18 months for both groups. Twenty-one cephalometric variables were analysed. Intra- and intergroup comparisons were performed using paired and independent *t*-tests, respectively ($P < 0.05$).

Results: BAMP caused a greater maxillary protrusion (SNA) and a greater decrease of Class III maxillomandibular discrepancy (ANB and Wits appraisal) compared with the CG. BAMP also caused a counterclockwise rotation of the occlusal plane (Occ Plane to FH) and an improvement in the molar relationship compared with controls.

Conclusions: BAMP therapy demonstrated a significant orthopaedic maxillary protraction and an improvement in the Class III skeletal pattern in UCLP.

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** - Patients with UCLP and moderate-to-severe maxillary deficiency (Goslon Index 3, 4, or 5) or mesial step in the mixed or permanent dentition and secondary alveolar bone graft performed at least 6 months before • São Paulo, Brasil
Schweregrad	Goslon Index 3, 4, or 5
Einschluss-kriterien	Treatment group/ Control group (1) moderate-to-severe maxillary deficiency (Goslon Index 3, 4, or 5), (2) age between 10 and 13 years (3) late mixed dentition or permanent dentition;, (4) mandibular permanent canines already erupted (5) secondary alveolar bone graft performed at least 6 months before the study onset (6) good oral hygiene.
Ausschluss-kriterien	Treatment group/ Control group (1) associated syndromes, Control group (1) history of orthopaedic/orthodontic intervention between T1 (2) bad quality cephalometric images.
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **BAMP** (boneanchored maxillary protraction) **CLASS III UCLP (BAMP)** Two miniplates (Bollard type, Tita-Link, Brussels, Belgium) were placed in the maxilla at the infrazygomatic crest bilateraly. In the mandible, two other miniplates were placed on both sides between the roots of the permanent canine and lateral incisor. Three weeks after surgery, full-time Class III intermaxillary elastics (G&H Orthodontics, Franklin, Indianapolis, USA) connecting the maxillary and mandibular miniplates were inserted. The traction was started with 75 g on each side, increased to 150 g in the second month, and 250 g in the third month further maintained until the end of active therapy. The elastics were changed twice a day, in the morning and in the evening. Bite plates with finger springs lingual to the maxillary incisors were used to open the bite and to ‘jump’ the bite when reaching an edge-to-edge incisor relationship. VERSUCHSGRUPPE 1 **BAMP CLASS III UCLP (BAMP)** N= 23 (Anfang) / N=23 (Ende) / Alter = 11,7 years ♂:♀ = 17:6 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung

Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** **untreated Class III UCLP (Control group)** The control group (Control group) consisted of 23 patients with UCLP paired by gender and initial age with the final BAMP group KONTROLLGRUPPE 1: **untreated Class III UCLP (Control group)** N=23 (Anfang) / N=23 (Ende) / Alter = = 11,5 years ♂:♀ = 17:6 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • dentofaziale Ästhetik PRIMÄRZIELGRÖßE: **Skeletal: SNA, SNB, ANB, Wits** SEKUNDÄRZIELGRÖßE: **Dental: Overjet** TERTIÄRZIELGRÖßE: **Soft tissue: Nasolabial angle** QUARTÄRZIELGRÖßE:
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	**BAMP** therapy demonstrated **a significant orthopaedic maxillary protraction** and an improvement in the Class III skeletal pattern in UCLP. Compared with a untreated Class III UCLP(Control group), BAMP therapy in individuals with UCLP demonstrated a **- significant orthopaedic maxillary protraction,** **- an improvement in the Class III skeletal pattern,** **- a counterclockwise rotation of the palatal plane, and** **- an improvement in the molar relationship**.

Zusammen-fassung der Ergebnisse	**GRUPPE CLASS III UCLP (BAMP) VS. GRUPPE untreated Class III UCLP (Control group)** **Skeletal: SNA, SNB, ANB, Wits**  **Dental: Overjet**  **Soft tissue: nasolabial angle** 
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung <u>Funding</u> <u>Interessen-konflikte</u> <u>Bias (SIGN)</u>	Die Äquivalenz von Versuch- und Kontrollgruppe Äquivalenz ist nur eingeschränkt gegeben. Die baseline Charakteristika sind angegeben, und statistisch verglichen. Es bestehen signifikante Unterscheide in wesentlichen skeletalen Kriterien. Es fehlt eine Verblindung. Es wurden Power/ Sample Size Berechnungen durchgeführt. Insgesamt ordentlich durchgeführte Studie, die aber nicht deutlich genug auf die Äquivalenzproblematik eingeht (Bias, Confounding). Die retrospektive Kohortenstudie hat daher nur ein noch akzeptables Risiko für Selection Bias. Die klinische Relevanz ist durch die methodischen Mängel allerdings deutlich eingeschränkt. *Funding:* Authors thank São Paulo Research Foundation (FAPESP, process #2013/19.880-0) for the financial support *Interessenkonflikte:* The authors declare that they have no conflict of interest *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe Äquivalenz ist nur eingeschränkt gegeben. Power/ Sample Size Berechnungen wurden durchgeführt. Eine Verblindung fand nicht statt.
Schluss-folgerung des Begutachters	<u>methodische Qualität: acceptable (+)</u> <u>Klinische Aussagekraft:</u> Insgesamt ordentlich durchgeführte Studie, die aber nicht deutlich genug auf die Äquivalenzproblematik eingeht (Bias, Confounding). Die retrospektive Kohortenstudie hat daher nur ein noch akzeptables Risiko für Selection Bias. Die klinische Relevanz ist durch die methodischen Mängel allerdings deutlich eingeschränkt.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Falck, Zimmermann-Menzel 2008

Cephalometric Changes in the Treatment of Class III Using the Fränkel Appliance*

Kephalometrische Veränderungen bei der Behandlung von Klasse III mit dem Fränkel-Gerät*

Friedrich Falck, Kristina Zimmermann-Menzel

Abstract

Aim: In this retrospective clinical study, we aimed to evaluate skeletal changes following treatment of Class III malocclusion by means of the Function Regulator (FR-3) appliance.

Material and Methods: The group of patients we treated with the FR-3 exclusively consisted of 56 subjects (20 boys and 36 girls). Fifteen subjects (7 boys and 8 girls) of approximately the same age and presenting almost identical characteristics of a Class III malocclusion of skeletal etiology served as a control group (between the ages of 7 and 15 years). Lateral cephalograms were compared using the occipital reference structures as proposed by Fränkel.

Results: Cephalometric analysis showed that maxillary landmarks (point A, nasospinale), and the upper incisor (root included) did move significantly farther forward in the treated group than in the control group ($p < 0.05$). We also found that the gonial angle decreased by 7.17° in the FR-3 group, as opposed to 2.07° in the untreated group ($p < 0.001$). No significant differences were noted in mandibular-length growth (Ar-Pog, Ar-Go, Go-Pog).

Conclusion: According to these study results, FR-3 treatment has an obvious effect on maxillary development, and affects the shape and, to a certain degree, the position of the mandible.

Key Words: Class III treatment · Function Regulator appliance · Cephalometric analysis

Zusammenfassung

Ziel: Mit dieser retrospektiven klinischen Studie sollten skelettale Veränderungen bei der Behandlung der Klasse III mit dem Funktionsregler (FR-3) festgestellt werden.

Material und Methodik: Die ausschließlich mit FR-3 behandelte Gruppe bestand aus 56 Kindern (20 Jungen und 36 Mädchen). Als Kontrollgruppe von etwa 8. bis 16. Lebensjahr dienten 15 Kinder (7 Jungen und 8 Mädchen) mit nahezu gleichem Alter und fast gleichem skelettalen Aufbau der Klasse III. Laterale Fernröntgenaufnahmen wurden unter Benutzung der von Fränkel vorgeschlagenen okzipitalen Referenzstrukturen miteinander verglichen.

Ergebnisse: Die Analyse der Fernröntgenaufnahmen zeigte, dass sich die maxillären Messpunkte (A-Punkt, Nasospinale) und der obere Schneidezahn einschließlich Wurzel in der behandelten Gruppe signifikant weiter nach vorn bewegten als in der Kontrollgruppe ($p < 0,01$). Des Weiteren verringerte sich der Gonionwinkel in der FR-3-Gruppe um 7,17° im Gegensatz zu 2,07° in der unbehandelten Gruppe ($p < 0,001$). Keine signifikanten Unterschiede konnten in der Zunahme der Länge des Unterkiefers (Ar-Pog, Ar-Go, Go-Pog) festgestellt werden.

Schlussfolgerung: Nach den Ergebnissen dieser Studie hat die FR-3-Behandlung einen deutlichen Effekt auf die maxillare Entwicklung und beeinflusst die Form und zu einem gewissen Grad die Position des Unterkiefers.

Schlüsselwörter: Klasse-III-Behandlung · Funktionsregler · Fernröntgenanalyse

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** Children Angle Class-III molar relationship and an Overjet of ≤ 0 mm of the upper and lower incisors • Germany
Schweregrad	Overjet of ≤ 0 mm of the upper and lower incisors
Einschluss-kriterien	- Angle Class-III molar relationship - Overjet of ≤ 0 mm of the upper and lower incisors.
Ausschluss-kriterien	Not fullfilling inclusion criteria

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** FR-3: The children in the FR-3 group were instructed to wear the appliance fulltime for 12–24 months, and thereafter while sleeping and 4–5 hours during the day for another 2–3 years. VERSUCHSGRUPPE 1: **FR-3** N= 56 (Anfang) / N=56 (Ende) / Alter = 7,6 (5,0- 11,3) ♂:♀ = 20:36 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated Class III** N=15 (Anfang) / N=15 (Ende) / Alter = 8,0 (5,6- 10,0) ♂:♀ = 7:8 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: **Skeletal: SNA, SNB, ANB, maxillary length, point A, nasospinale, gonial angle**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	FR-3 treatment **stimulates horizontal maxillary skeletal development**, and leads to reduction of the gonial angle with a tendency to **backward repositioning of the mandible**.

Zusammen-fassung der Ergebnisse

GRUPPE FR-3 VS. GRUPPE untreated Class III

T1 (pre-treatment): mean age 7,6 years, FR-3, 8,0 years, untreated Class III

T2 (post treatment/ observation): mean age 15,8 years, FR-3, 16,0 years, untreated Class III

Skeletal:
SNA, SNB, ANB, maxillary length, point A, nasospinale, gonial angle
SNA, SNB, ANB

Variables (°)	Untreated group x̄	SD	FR-3 group x̄	SD	Significance p
SNA	1.3	2.07	1.49	1.79	n.s.
SNB	3.6	1.62	1.61	2.37	< 0.01
ANB	−2.37	2.01	−0.13	1.96	< 0.001

Maxillary lenght

Variables (mm)	Untreated group x̄	SD	FR-3 group x̄	SD	Significance p
Maxillary length (A – PNS)	2.93	1.76	4.40	2.09	< 0.05

A-point

Variables (mm)	Untreated group x̄	SD	FR-3 group x̄	SD	Significance p
A-point (A)					
horizontal	6.90	2.19	9.02	2.90	< 0.01
vertical	−3.37	3.97	−2.62	3.17	n.s.

Nasospinale

Variables (mm)	Untreated group x̄	SD	FR-3 group x̄	SD	Significance p
Nasospinale (Nsp)					
horizontal	6.70	1.81	8.69	2.53	< 0.01
vertical	−1.90	3.65	−2.40	2.65	n.s.

Gonial angle

Variables (°)	Untreated group x̄	SD	FR-3 group x̄	SD	Significance p
Ar-Go / Go-Me	−2.07	5.48	−7.17	4.05	< 0.001

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die Äquivalenz von Versuch- und Kontrollgruppe wurde nachvollziehbar überprüft. Hinsichtlich der untersuchten Merkmale ist die Äquivalenz gegeben. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Die Versuchs- und Kontrollgruppen sind deutlich unterschiedlich in der Größe. Eine Verblindung fand nicht statt. Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie akzeptabel. Die retrospektive Studie hat klinische Relevanz. *Funding:* keine Angabe *Interessenkonflikte* keine Angabe *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist gegeben. Relevanz. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Eine Verblindung fand nicht statt. Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie noch akzeptabel. Die retrospektive Studie hat klinische Relevanz.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie noch akzeptabel. Die retrospektive Studie hat klinische Relevanz.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle Faltin, Faltin et al 2003

Long-term Effectiveness and Treatment Timing for Bionator Therapy

Kurt Faltin Jr, DDS, PhD;[a] Rolf M. Faltin, DDS, MSc, PhD;[b] Tiziano Baccetti, DDS, PhD;[c] Lorenzo Franchi, DDS, PhD;[c] Bruno Ghiozzi, DDS;[a] James A. McNamara Jr, DDS, PhD[d]

Abstract: The aim of the present investigation was to provide information about the long-term effects and optimal timing for class-II treatment with the Bionator appliance. Lateral cephalograms of 23 class-II patients treated with the Bionator were analyzed at three time periods: T1, start of treatment; T2, end of Bionator therapy; and T3, long-term observation (after completion of growth). T3 includes a phase with fixed appliances. The treated sample was divided into two groups according to their skeletal maturity as evaluated by the cervical vertebral maturation (CVM) method. The early-treated group (13 subjects) initiated treatment before the peak in mandibular growth, which occurred after completion of Bionator therapy. The late-treated group (10 subjects) received Bionator treatment during the peak. The T1–T2, T2–T3, and T1–T3 changes in the treated groups were compared with changes in control groups of untreated class-II subjects by nonparametric statistics ($P < .05$). The findings of the present study on Bionator therapy followed by fixed appliances indicate that this treatment protocol is more effective and stable when it is performed during the pubertal growth spurt. Optimal timing to start treatment with the Bionator is when a concavity appears at the lower borders of the second and the third cervical vertebrae (CVMS II). In the long term, the amount of significant supplementary elongation of the mandible in subjects treated during the pubertal peak is 5.1 mm more than in the controls, and it is associated with a backward direction of condylar growth. Significant increments in mandibular ramus height also were recorded. (*Angle Orthod* 2003;73:221–230.)

Key Words: Class-II malocclusion; Functional jaw orthopedics; Cephalometrics; Cervical vertebral maturation

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • class-II malocclusion patients consecutively treated with the Bionator (Versuchsgruppen); untreated class-II malocclusions (Kontrollgruppen) • collected from a single orthodontic practice (Versuchsgruppen); selected from the University of Michigan Elementary and Secondary School Growth Study (Kontrollgruppen)
Schweregrad	OJ > 6mm; Okkl ≥ 1 PB distal
Einschluss-kriterien *Bei Review: PICOS*	• class-II-malocclusion • treated with Bionator
Ausschluss-kriterien	Keine Angaben

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** The treatment protocol consisted of class-II correction by a Bionator constructed without coverage of the lower incisors, followed by approximately one year of fixed appliance therapy to refine occlusion. After the comprehensive phase, each patient was given a fixed lower incisor retainer. VERSUCHSGRUPPE 1: **Early Bionator Group** N=13 (Anfang) / N= 13 (Ende) / Alter = 9y 8m ± 1y 3m Jahre / ♂:♀ = 6:7 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE 2: **Late Bionator Group** N=10 (Anfang) / N= 10 (Ende) / Alter = 10y 9m ± 1y 8m Jahre / ♂:♀ = 4:6 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Behandlung** KONTROLLGRUPPE 1: **Early Untreated Control Group** N=11 (Anfang) / N=11 (Ende) / Alter = 9y 5m ± 1y 3m Jahre / ♂:♀ = 6:5 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: keine Therapie KONTROLLGRUPPE 2: **Late Untreated Control Group** N=11 (Anfang) / N=11 (Ende) / Alter = 11y 2m ± 1y 6m Jahre / ♂:♀ = 5:5 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: keine Therapie
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: Cephalometric dental and skeletal treatment effects
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	The findings of the present long-term study on Bionator therapy followed by fixed appliances in class-II patients indicate that this treatment protocol is effective and stable when it is initiated immediately before the pubertal growth spurt. Optimal timing to start treatment with the Bionator is when a concavity is evident at the lower borders of both the second and the third cervical vertebrae (CVMS II). In the long term, the amount of significant supplementary elongation of the mandible in subjects treated with the Bionator during the pubertal growth spurt is 5.1 mm more than that in untreated subjects with class-II malocclusion. Similar favorable findings can be recorded for the significant increments in mandibular ramus height and for a significantly more backward direction of condylar growth.

Zusammen-fassung der Ergebnisse	**Early Bionator Group vs. Early untreated control group** ***PRIMÄRZIELGRÖßE*** *T1-T2:* Treatment with the Bionator appliance before the pubertal peak produced a significant overjet correction of 3.2 mm and a significant sagittal correction in molar relation of 2.6 mm when compared with growth changes in the ECG. *T2-T3:* no significant modification was found *T1-T3:* No significant difference **Late Bionator Group vs. Late untreated control group** ***PRIMÄRZIELGRÖßE*** *T1-T2:* Treatment with the Bionator appliance when the pubertal peak was included in the active treatment period induced a significant overjet correction of 4.4 mm and a correction in molar relation of 1.8 mm when compared with changes in the LCG. A significant mesial advancement of the mandibular dentition at both the molar and incisor regions occurred in LTG. At the skeletal level, supplementary increases in total mandibular length and in ramus height (of 4.3 mm both), along with a significant opening of the gonial angle and of the angle between the condylar line and the mandibular line, were found in LTG when compared with LCG. *T2-T3:* no significant modification *T1-T3:* In the long term, the patients treated during the pubertal growth spurt showed a significant overjet correction of 4.2 mm and a correction in molar relation of 2.1 mm when compared with changes in the LCG. Significantly greater increments in total mandibular length (15.1 mm) and in ramus height (14.8 mm) were assessed in LTG when compared with LCG. These changes were associated with a significantly greater growth increment of the mandibular condyle in a backward direction in LTG, and with a significant opening of the gonial angle and of the angle between the condylar line and the mandibular line in the group that received treatment during the pubertal growth spurt.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *historische Kontrollgruppe* • *kleine Studienkohorten* *Durchführung:* • *Reliabilität der Intervention fraglich; kaum Angaben zum Behandler* • *Keine Testung der Compliance* • *Keine Verblindung weder bei Outcome noch bei Intervention* *Auswertung:* • *Reliabilität der Outcome-Erhebung fraglich; keine definitiven Angaben, nur Verweise auf andere Publikation* • *Keine Angabe von Konfidenzintervallen* *Power der Studie/Patientenzahl: keine Angaben* *Funding: keine Angaben* *Interessenkonflikte: keine Angaben* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • *Detection bias: keine Verblindung* • *Keine Erhebung von Confounders*
Schluss-folgerung des Begutachters	methodische Qualität: gut
	Klinische Aussagekraft: • Bionator-Protokoll ist effektiv bei Behandlungbeginn direkt vor dem puberalem Wachstum • Der optimale Behandlungszeitpunkt ist im CVMS II. • In der puberalen Wachtumsgruppe waren die sagittale Verlängerung des Unterkiefers und Vergrößerung der Raumushöhe signfikant größer als in der unbehandelten Kontrollgruppe.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	⊕ Acceptable

Evidenztabelle Feng, Li et al 2012

Review Article

Effectiveness of TAD-anchored maxillary protraction in late mixed dentitio
A systematic review

Xiaoxia Feng[a]; Jianhua Li[b]; Yu Li[b]; Zhihe Zhao[c]; Sen Zhao[c]; Jue Wang[d]

ABSTRACT

Objective: To evaluate the effectiveness of temporary anchorage device (TAD)-anchored maxillary protraction (MP) in terms of the skeletal and dentoalveolar changes and to compare it with traditional tooth-anchored MP.

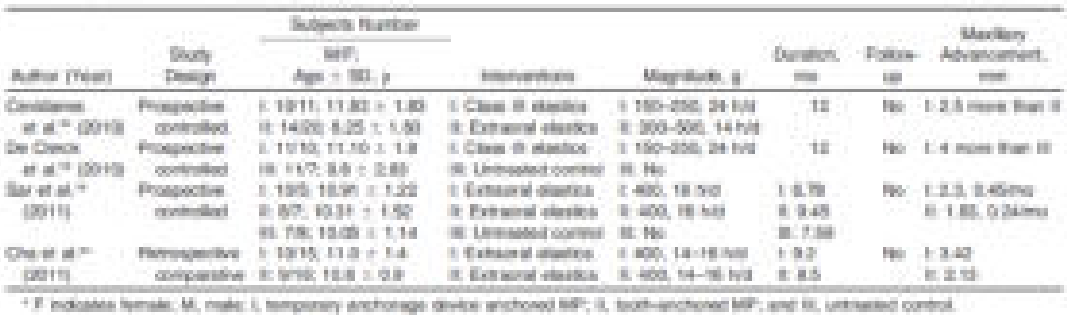
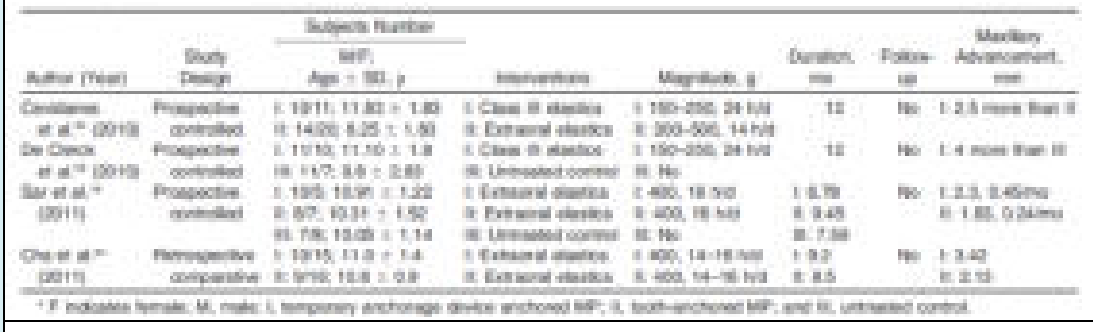
Materials and Methods: A computerized literature search for relative randomized controlled trials and prospective controlled trials was performed in PubMed, MEDLINE, Cochrane Central Register of Controlled Trials, Embase, CNKI, and Google Scholar, complemented with manual search. Data extraction and quality assessment were carried out by two reviewers independently. Meta-analysis was followed when possible; otherwise, description was done.

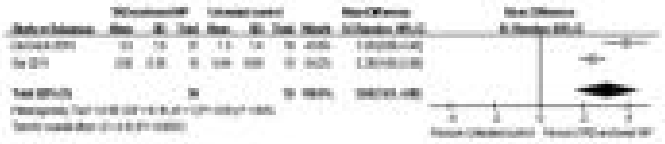
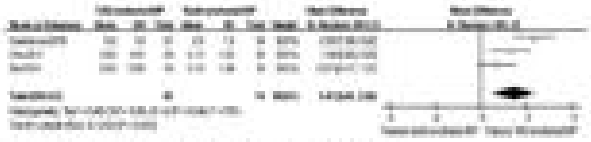
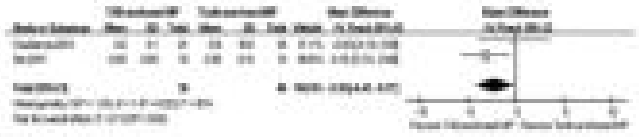
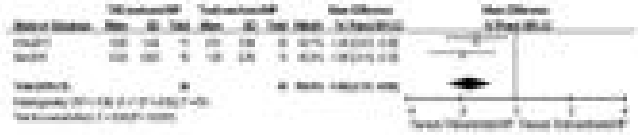
Results: Forty articles were found, among which four trials were qualified for meta-analysis. The results showed that there was significant difference between TAD-anchored MP and untreated control in terms of maxillary advancement (weighted mean differences (WMD) 3.08 mm; 95% CI: 1.81 to approximately 4.56; $P < .0001$), but there were no consistent points in terms of mandibular rotation. Also, there were significant differences between both treatment patterns regarding maxillary advancement (WMD 1.41 mm; 95% CI: 0.47 to approximately 2.35; $P = .003$), mandibular rotation (WMD −1.39°, 95% CI: −2.47 to approximately −0.31; $P = .01$), proclination of maxillary incisors (WMD −2.29°; 95% CI: −4.41 to approximately −0.17; $P = .03$), and extrusion of maxillary molars (WMD −1.68 mm; 95% CI: −2.51 to approximately −0.85; $P < .0001$).

Conclusions: According to the present results, TAD-anchored MP might have a greater maxillary advancement effect and might reduce skeletal and dental side effects, compared with tooth-anchored MP. (*Angle Orthod.* 2012;82:1107–1114.)

KEY WORDS: Systematic review; Maxillary deficiency; Maxillary protraction; Temporary anchorage device

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** • Children or adolescents or both (aged 16 years or less) receiving orthodontic treatment involving TAD to correct Class III malocclusion • Singel Center Studien aus der Türkei, Südkorea und den USA
Schweregrad	Nicht definiert
Einschluss-kriterien *Bei Review: PICOS*	• Children or adolescents or both (aged 16 years or less) receiving orthodontic treatment involving TAD to correct Class III malocclusion • Class III treatment involving temporary anchorage device (TAD) maxillary protraction • A- VR (mm) , maxillary advancement, MP-HR (degree), mandibular plane angle, U1-PP (degree), inclination of maxillary incisors, U6-VR (mm, extrusion of the maxillary first molars) • 1. Studies analyzing the effectiveness of temporary anchorage device (TAD) maxillary protraction • 2. Randomized clinical trials (RCTs), controlled clinical trials (CCTs), and prospective studies • 3. Cephalometric measurements about the skeletal and dentoalveolar changes • 4. Sample size > 10

Ausschluss-kriterien	1. Animal studies 2. Case reports, descriptive studies, review articles, letters, and opinion articles 3. No control groups
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: **temporary anchorage device (TAD) maxillary protraction** Class III treatment involving temporary anchorage device (TAD) maxillary protraction • N=?? (Anfang) / N=?? (Ende) / Alter = ?? ± ?? ♂:♀ = ?? • Gebissphase: ?? • KFO-Behandlung: ?? 
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **untreated control group** Orthodontic treatments were compared with control groups who received either no treatment, or a different active intervention. • N=?? (Anfang) / N=?? (Ende) / Alter = ?? ± ?? ♂:♀ = ?? • Gebissphase: ?? • KFO-Behandlung: keine Behandlung 

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** **medizinischer Schaden, Nebenwirkungen** **bzw. Zunahme der Anomalie /Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: A- VR (mm) , maxillary advancement SEKUNDÄRZIELGRÖßE: MP-HR (degree), mandibular plane angle TERTIÄRZIELGRÖßE: U1-PP (degree), inclination of maxillary incisors QUARTÄRZIELGRÖßE:U6-VR (mm, extrusion of the maxillary first molars) A- VR (mm) , maxillary advancement TAD-anchored MP vs untreated control  TAD-anchored MP vs tooth-anchored MP  MP-HR (degree), mandibular plane angle TAD-anchored MP vs tooth-anchored MP  U1-PP (degree), inclination of maxillary incisors TAD-anchored MP vs tooth-anchored MP  U6-VR (mm, extrusion of the maxillary first molars) 

Studientyp	**Systematisches Review mit Meta-Analyse** *Review:* Inkludierte Studien in Bezug auf PICO: N=4 *Review:* Gesamt-Teilnehmerzahl in Bezug auf PICO: N=189
Schluss-folgerungen der Autoren	1. Based on the present results, TAD-anchored MP might have greater effect of maxillary advancement. 2. Some side effects are reduced by TAD-anchored MP, such as mandibular rotation, extrusion of maxillary molars, and proclination of maxillary incisors....
Zusammen-fassung der Ergebnisse	**GRUPPE Class III treatment involving temporary anchorage device (TAD) maxillary protraction VS. GRUPPE Orthodontic treatments were compared with control groups who received either no treatment, or a different active intervention** The total pooled WMD value (95% CI) of A-VR was 3.08 mm (1.61, 4.56; P , .0001) in comparison 1 and 1.41 mm (0.47, 2.35; P 5 .003) in comparison 2, which was in accordance with previous studies.[8–25] However, the maxillary advancement ranged from 1.61 to 8 mm, which depended on the severity of maxillary deficiency and treatment objective.[16–20] In any case, TAD-anchored MP showed a larger maximum potential for maxillary advancement than tooth-anchored MP. Interestingly, Sar et al.[19] found that TAD-anchored MP was more efficient than tooth-anchored MP, as the rate of maxillary advancement in TAD-anchored MP was nearly twice that in tooth-anchored MP (0.45 vs 0.24 mm per month). A possible reason for this was that TAD-anchored MP imposed the orthopedic force directly on the maxillary sutures without being hampered by periodontal ligament or being consumed by tooth movement..
Angaben auffälliger positiver und/oder negativer Aspekte	*Das Review ist weitestgehend ordentlich durchgeführt. Überraschenderweise fehlen Angaben zum Funding und zu Interessenskonflikten. Soweit möglich wurden Meta-Analysen durchgeführt. Heterogenität wurde berücksichtigt und diskutiert.*
Schluss-folgerung des Begutachters	<u>methodische Qualität:</u> Review und Einzelstudien: durchschnittlich bis gut <u>Klinische Aussagekraft:</u> Durch die ordentliche Durchführung des Reviews bei mittlerer bis guter Qualität der Primärliteratur sowie durch die Berücksichtigung und Einschätzung aufgetretener „side effects“ ist die klinische Aussagekraft gut.
Evidenzlevel (SIGN)	**2+**
Qualität (RoB, SIGN /AMSTAR II)	**Moderat ⊕⊕**

Evidenztabelle Firouz, Zernik et al. 1992

American Journal of ORTHODONTICS and DENTOFACIAL ORTHOPEDICS

Founded in 1915 Volume 102 Number 3 September 1992

SPECIAL ARTICLES

Dental and orthopedic effects of high-pull headgear in treatment of Class II, Division 1 malocclusion

Maurice Firouz, DDS,[a] Joseph Zernik, BDS, PhD,[b] and Ravindra Nanda, BDS, MDS, PhD,[c]
Fountain Valley, Calif., and Farmington, Conn.

In the present study a prospective cephalometric investigation was undertaken to examine the skeletal and dental effects of the high-pull extraoral appliance, when the resultant force was directed through the level of trifurcation of the maxillary molars. Twelve adolescent patients with Class II, Division 1 malocclusions were selected for the study. Each patient wore the headgear for a 6-month period, an average of 12 hours a day. A group of untreated adolescent patients with Class II, Division 1 malocclusions who were in a similar age range, as well as skeletal and dental characteristics were chosen as controls. Lateral cephalometric films were taken before and after the 6-month treatment period, and before and after the observation period in the control group of patients. Our data indicate that by directing the force of the headgear approximately through the center of resistance of the maxillary molars, it is possible to accomplish simultaneously a substantial distal movement of the molars (2.6 ± 0.6 mm), as well as significant intrusion (0.54 ± 0.54 mm). In addition, our results demonstrate that the applied force of 500 gm was sufficient to initiate maxillary orthopedic changes in the treated patients. These changes include relative restriction of horizontal and vertical maxillary growth, as well as distal movement (mean: 0.6 mm) of the maxillary anterior border in the treatment group relative to an untreated control group. Such orthopedic changes have been previously described only in association with much higher force levels. (Am J Orthod Dentofac Orthop 1992;102:197-205.)

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Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalien** • White adolescent patients • Vermutlich: Professor, Department of Orthodontics, School of Dental Medicine. University of Connecticut Health Center, Farmington, Conn.
Schweregrad	Their molar occlusions were between 3.0 to 7.0 mm Class II at the onset of treatment. All the patients had at least a 2.0 mm interlabial gap and increased lower facial height.

Einschluss-kriterien *Bei Review: PICOS*	Class II, Division I malocclusion
Ausschluss-kriterien	---
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** VERSUCHSGRUPPE: **Headgear** N=12 (Anfang) / N=12 (Ende)/ Alter = ?? ± ?? Jahre (9,5-12,5)/ ♂:♀ = ?:? (keine Angabe) • Gebissphase: spätes Wechselgebiss (anhand Alter) • KFO-Behandlung: reguläre Behandlung An Interlandi type high-pull headgear (Orthoband Co. Inc., Barnhart, Mo.) was used for all of the patients, and the outer bows were attached to the head straps of the headgear with IA-inch latex elastics. The direction of the applied force was modified by changing the point of attachment of the elastics. The level of buccal trifurcation of the maxillary first molars was clinically and radiographically determined, and the headgear force was directed through that point as an approximation of the center of resistance of these teeth.' The inner bow was made parallel to the occlusal plane, and the length of the outer bow was reduced so that it did not extend distal to the maxillary first molar. A force of 500 gm was used for each side, as measured by a force gauge. Thus the appliance generated a force including intrusive, as well as distally directed components. The headgear bow position and the line of force are shown in Fig. 1. An 0.032 x 0.032 stainless steel transpalatal arch (Ormco Corp., Glendora, Calif.) was fabricated and tied to welded lingual brackets. This arch was made to fit these brackets passively, and its main function was to maintain symmetry and arch widths and prevent molar rotation, t7 To examine the possibility that the elastics might lose some of their force after the 12-hour required wear, individual elastics were stretched on a spring tester to generate 500 gm of force. The distance was then held constant, and the force measured periodically. Mean force decay over a 15-hour period was relatively small and probably clinically insignificant. Every effort was made to keep the activation and the direction of the force of the elastic constant throughout the treatment. Patients were asked to change elastics at least once a day. In the current study elastics were used to deliver the headgear force.
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated control** N = 12 (Anfang) / N=12 (Ende) /Alter = ?? ± ?? Jahre (9,5-12,5) / ♂:♀ = ?:? (keine Angabe) • Gebissphase: spätes Wechselgebiss (anhand Alter) • KFO-Behandlung: keine the remaining patients served as controls
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: Dental and orthopaedic effects

Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	The following conclusions are based on significant trends and findings in the present study: 1. By directing the force of the headgear approximately through the center of resistance of the maxillary molars with the high-pull headgear, it is possible to translate the molars in the direction of the applied force. One can therefore accomplish both instrusion and distal movement of the molars at the same time. 2. An average of 500 gm of force is sufficient to translate the molars distally, and at the same time initiate maxillary changes that are normally associated with higher force levels. 3. If the headgear is used for a short period of 6 months and the patient is cooperative, one can expect a significant dental improvement in the Class II molar relationship.
Zusammen-fassung der Ergebnisse	**Headgear VS. Untreated control** ***PRIMÄRZIELGRÖßE*** Dental and orthopaedic effects All 12 patients selected for treatment with the highpull headgear completed the 6-month course of treatment without any discomfort or complications. The headgear was worn by all the patients an average of 12 hours a day. Figs. 2 to 10 show dental and skeletal changes in two patients representative of the treatment group. The most significant changes were noted in the maxillary molars. After the 6-month period, the maxillary molars in the treatment group were distally displaced (mean 2.56 mm, Table I). In contrast, the maxillary molars in the control group were mesially displaced (mean 0.23 mm). At the end of the 6-month headgear wear, the maxillary molars in the treatment group were intruded an average of 0.54 mm. No vertical eruption of the maxillary molars was noted in any of the treatment patients. The maxillary molars in the control group erupted on the average by 0.23 mm. Thus the maxillary molars in the treatment group were displaced in accordance with the distal and intrusive direction of the applied headgear force. The changes in tooth position during the treatment period were clinically and statistically significant ($p < 0.01$). The distal molar movement in the treatment group significantly contributed to the correction of the Class II molar relationship. Overall, the displacement of the maxillary molars was in the form of translation-like tooth movement. In fact, the roots of these molars were displaced slightly farther distally than the crowns (Table I). Significant skeletal changes were observed in the maxilla. Anteroposterior growth of the maxilla during the 6-month treatment period, as measured by changes at ANS and PNS, in reference to constructed FH plane, was reduced in the treatment group relative to the control group by approximately 0.5 mm ($p < 0.01$). Horizontally, the maxilla in the treatment group moved posteriorly by an average of 0.33 nun, as measured by the position of A point. In controls, A point moved forward in all 12 control patients (mean 0.5 mm). The headgear not only restricted or redirected the anteroposterior growth of the maxilla, but also exerted an orthopedic effect by moving the maxilla distally. A significant difference was observed also in the downward growth of the maxilla between the control and the treatment groups. In the treatment group, both the ANS and the PNS grew downward less than half the amount of downward growth that was observed in the controls, ($p < 0.01$ and $p < 0.05$, respectively, Table II). There were no clinical or statistical differences in measurements of the nasal floor, mandibular plane, skeletal convexity, soft tissue convexity, and other soft tissue measurements between the treatment and the control groups (Table II).

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • retrospektiv • sehr weit gefasste Einschlusskriterien • kein Matching erfolgt, keine Aussage über Baseline-Imbalancen mgl., auch keine Angabe der Geschlechterverteilung bzw. genaue Altersangabe (nur range) • Sehr ausgiebige Überprüfung der Patientencompliance beschrieben und durchgeführt *Durchführung:* • Ausführliches standardisiertes Behandlungsprotokoll • Keine Angabe über Behandlerzahl *Auswertung:* • Angabe, dass keine Dropouts vorhanden waren • Keine Angabe zur Anzahl der FRS-Auswerter • Keine Prüfung auf Normalverteilung • keine Reliabilitätsprüfung *Power der Studie/Patientenzahl:* keine Poweranalyse angegeben *Funding:* --- *Interessenkonflikte:* --- *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation. – No (Sign) • The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis. – No (Sign) • The main potential confounders are identified and taken into account in the design and analysis. – No (Sign) • Have confidence intervals been provided? – No. (Sign)
Schluss-folgerung des Begutachters	methodische Qualität: befriedigend
	Klinische Aussagekraft: Durch die Behandlung mit einem High-Pull-Headgear über 6 Monate mit Kraftverlauf durch das Widerstandszentrum der OK6er kommt es zu einer simultanen Intrusion und Distalbewegung der OK6er sowie Korrektur einer Distalbissstellung. Zudem kommt es zu einer Hemmung des ventrokaudalen Wachstums der Maxilla.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable (+)**

Evidenztabelle Flores-Mir, C. et al., 2007

Review Article

Skeletal and Dental Changes in Class II division 1 Malocclusions Treated with Splint-Type Herbst Appliances

A Systematic Review

Carlos Flores-Mir[a,b]; Abenaa Ayeh[c]; Ashim Goswani[c]; Shouresh Charkhandeh[c]

ABSTRACT

Objective: To evaluate skeletal and dental changes in growing individuals through lateral cephalograms obtained after the sole use of the splint-type Herbst appliances in Class II division 1 malocclusions.

Methods: Several electronic databases (Pubmed, Medline, Medline In-Process & Other Non-Indexed Citations, Cochrane Library Database, Embase, Web of Sciences, Scopus, and Lilacs) were searched with the help of a health sciences librarian. Abstracts that appeared to fulfill the initial selection criteria were selected by consensus. The original articles were then retrieved. Their references were also hand-searched for possible missing articles. Clinical trials that assessed, through lateral cephalograms, immediate skeletal and dental changes with the use of splint-type Herbst appliances without any concurrent orthodontic appliances, surgical intervention, or syndromic characteristics were considered. A comparable untreated Class II division 1 malocclusion control group was required to factor out normal growth changes.

Results: Three articles were finally selected and analyzed. An individual analysis of these articles was made and some methodological flaws were identified. The selected studies all showed statistically significant changes in the anteroposterior length of the mandible, vertical height of the ramus, lower facial height, mandibular incisor proclination, mesial movement of the lower molars, and distal movement of the upper molars. Posttreatment relapse in overjet and molar relationship was also observed.

Conclusions: Dental changes are as important as skeletal changes to attaining the final occlusal results. Long-term, prospective, double-blinded, randomized clinical trials are needed to support these conclusions.

KEY WORDS: Functional appliances; Herbst; Orthodontics; Systematic review; Dental changes; Skeletal changes

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • growing individuals Class II division 1 malocclusions.
Schweregrad	unbekannt

Einschluss-kriterien *Bei Review: PICOS*	• Population: growing individuals Class II division 1 malocclusions. • Intervention: splint-type Herbst appliances • Comparison: comparable untreated Class II division 1 malocclusion control group • Outcome: immediate skeletal and/or dental changes through lateral cephalograms; only linear or angular measurements PRIMÄRZIELGRÖßE: **skeletal changes** (cranial base, facial portion and growth direction: gonion angle/ condylar position/ facial growth axis/ facial profile/ anterior & posterior facial heights, mandibular measurements: mandibular protrusion/ mandibular plane inclination/ mandibular dimensions, maxillary measurements: antero-posterior position, intermaxillary relationships) SEKUNDÄRZIELGRÖßE: **dental changes** (overjet, overbite, vertical & sagittal changes of upper incisors, vertical & sagittal changes of upper molars, vertical & sagittal changes of mandibular incisors, vertical & sagittal changes of mandibular molar) • study type: human clinical trials
Ausschluss-kriterien	1. concurrent orthodontic appliances 2. simultaneous surgical intervention 3. syndromic characteristics 4. individual case reports or series of cases
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** VERSUCHSGRUPPE: **splint-type Herbst appliances** N=?? (Anfang) / N=?? (Ende) / Alter = ?? ± ?? Jahre / ♂:♀ = ?:? • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Behandlung** KONTROLLGRUPPE: **comparable untreated Class II division 1 malocclusion control group** N=?? (Anfang) / N=?? (Ende) / Alter = ?? ± ?? Jahre / ♂:♀ = ?:? • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: keine Behandlung

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** • **Okklusion, Kaufunktion, Funktion** PRIMÄRZIELGRÖßE: **skeletal changes** (cranial base, facial portion and growth direction: gonion angle/ condylar position/ facial growth axis/ facial profile/ anterior & posterior facial heights, mandibular measurements: mandibular protrusion/ mandibular plane inclination/ mandibular dimensions, maxillary measurements: antero-posterior position, intermaxillary relationships) SEKUNDÄRZIELGRÖßE: **dental changes** (overjet, overbite, vertical & sagittal changes of upper incisors, vertical & sagittal changes of upper molars, vertical & sagittal changes of mandibular incisors, vertical & sagittal changes of mandibular molar)
Studientyp	**Systematisches Review** Inkludierte Studien in Bezug auf PICO: human clinical trials (not randomized) N=3 Gesamt-Teilnehmerzahl in Bezug auf PICO: N=?
Schluss-folgerungen der Autoren	• The studies selected all showed that use of the splint-type Herbst appliance in treating adolescents with Class II division I malocclusion resulted in **increased anteroposterior length of the mandible, increased vertical height of the ramus, increase in lower facial height, mandibular incisor proclination, mesial movement of lower molars, and distal movement of upper molars.** • The magnitudes of the reported differences were significant in several cases, but were not likely clinically significant. It is the **combination of several small changes in different skeletal and dental areas that produces the overall r**eported positive change.

Zusammen-fassung der Ergebnisse	**splint-type Herbst appliances VERSUS comparable untreated Class II division 1 malocclusion control group** **skeletal changes (cranial base, facial portion and growth direction: gonion angle/ condylar position/ facial growth axis/ facial profile/ anterior & posterior facial heights, mandibular measurements: mandibular protrusion/ mandibular plane inclination/ mandibular dimensions, maxillary measurements: antero-posterior position, intermaxillary relationships):** Regarding cranial base changes, no selected study reported significant changes except with regard to the cranial base angle (1°), and this change is not likely clinically significant.33 No changes in the facial growth axis were reported, but a **decrease in the facial profile was found** (3°).33 **Significant changes in the vertical dimensions were reported for the posterior (1.4 to 2.5 mm)31,33 and lower anterior facial heights** (1.2 to 3 mm).31,33 **Significant decreases in the intermaxillary discrepancy** were found (-1.5 to -2.1° and -4.2 to -4.9 mm).31,33 Some significant changes in the maxillary anteroposterior position were reported, but these are not likely clinically significant (<1 mm).31,33 A **significant increase in the mandibular protrusion** was found (1.2 to 2.9°).31,33 No significant changes for the mandibular plane inclination,31,33, gonial angle,31–33 or condylar position31 were reported. **Mandibular dimensions were shown to be significantly increased** (0.7 to 2.7 mm).31–33 **dental changes (overjet, overbite, vertical & sagittal changes of upper incisors, vertical & sagittal changes of upper molars, vertical & sagittal changes of mandibular incisors, vertical & sagittal changes of mandibular molar): significant decreases for the overjet (-4.6 to 5.6 mm)31,32 and overbite** (-2.5 mm)31 were reported. No significant changes were reported for the upper incisors. The **upper molars were significantly more retruded (1.5 to 5.4 mm),31,33, slightly intruded (-0.9 mm),33 and retroclined** (5.6°)31, after treatment. In general**, mandibular incisors were protruded (1.5 to 4 mm),31–33 3.2 to 4.5°),33 and extruded** (5.3°)31 after treatment. The **mandibular molars were also protruded** (0.8 to 3.6 mm)31–33 but not proclined or clinically significantly extruded.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: keinea priori Registrierung, keine Meta-Analyse (geringe Studienzahl)* *Durchführung: explizite Suchstrategie. Keine RCTs. Keine Beschreibung der Studiencharakteristika der inkludierten Studien. Gute kritische Diskussion.* *Auswertung: Zusammenfassung der Ergebnisse der einzelnen Studien, aber keine einheitlichen Messparameter/ Kontrollgruppen.* *Power der Studie/Patientenzahl: nur drei eingeschlossene Studien, Teilnehmerzahl unbekannt* *Funding: -* *Interessenkonflikte: -* *Bias (SIGN/AMSTAR/Einzelstudien RoB – alle negativen Punkte aus Fragebogen auflisten):* **2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?** **3. Did the review authors explain their selection of the study designs for inclusion in the review?** **8. Did the review authors describe the included studies in adequate detail?** **10. Did the review authors report on the sources of funding for the studies included in the review?** *Publikationsbias (Reviews): -*
Schluss-folgerung des Begutachters	methodische Qualität: Review ermöglicht keine quantitative Aussage, sondern nur eine Zusammenfassung der (verschiedenen) Messwerte der Einzelstudien. Einzelstudien von mittlerer Qualität.
	Klinische Aussagekraft: Die Splint-Herbst-Apparatur scheint in heranwachsenden Klasse-II/1-Patienten das skelettale Ausmaß der Dysgnathie zu verbessern, wobei dentale Nebenwirkungen nicht ausgeschlossen werden können. Aufgrund der vielen verschiedenen Messparameter im FRS und den unterschiedlichen Kontrollgruppen der Einzelstudien sind diese Feststellungen nicht eindeutig zu verallgemeinern.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**moderat ⊕⊕**

Evidenztabelle Flores-Mir, Barnett et al. 2009

Short-term skeletal and dental effects of the Xbow appliance as measured on lateral cephalograms

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Introduction: Our objective was to determine the short-term skeletal and dental effects of the Xbow appliance when compared with an equivalent untreated control group as measured on lateral cephalograms. **Methods:** A prospective sample of 68 consecutive Class II patients treated with only the Xbow appliance was compared with 30 historical Class II untreated controls. Standardized lateral cephalograms were used. **Results:** Two patients from the treatment group did not complete treatment. The 2 groups appeared similar at pretreatment with the exception of the positions of the maxillary central incisor (2.9 mm more protruded in Xbow group), the mandibular incisor (1.7 mm more protruded with the Xbow group), and Point A (2.8 mm forward restriction in Xbow group). There were statistically significant differences for 9 of the 14 evaluated cephalometric variables when normal growth changes were factored out. Those differences favoring the Xbow for changes in the direction of Class II correction include SNA, ANB, L1-MP, L1 minus Pg, overjet, U6 minus A, L6 minus Pg, and A-OLp. Meanwhile, the control group showed a statistically significant decrease in the mandibular plane angle compared with the Xbow group. **Conclusions:** Skeletally, a diminution of maxillary protrusion without mandibular advancement and an increase of the vertical dimension were found. Dentally, overjet correction was accomplished by an increase in mandibular incisor protrusion without maxillary incisor movement. The maxillary molars were distalized whereas the mandibular molars were mesialized. (Am J Orthod Dentofacial Orthop 2009;136:822-32)

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The Xbow appliance design is patented. Duncan W. Higgins has a commercial interest in Xbow appliances. He receives royalties when Xbows are fabricated in licensed dental laboratories. The other authors have no commercial interest in the Xbow or any other conflict of interest.

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Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Private practice of the inventor of the Xbow appliance (D.W.H.) (Xbowgroup) • Burlington Growth Centre, Faculty of Dentistry, University of Toronto, in Ontario, Canada (Untreated control group)
Schweregrad	Keine Angabe

Einschluss-kriterien *Bei Review: PICOS*	Xbow group: 1. Class II 2. Therapy started with the appliance having both pretreatment (T1) and posttreatment (T2) lateral cephalograms taken between September 26, 2002, and September 30, 2006. Untreated control group: an untreated, age-matched Class II control group with skeletal and dental characteristics as similar as possible
Ausschluss-kriterien	Keine Angabe
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** The Xbow is a fixed Class II corrector that consists of 3 main components: a maxillary hyrax expander, a mandibular labial and lingual bow, and Forsus fatigue resistant device (FRD) springs (3M Unitek, Monrovia, Calif) connecting the 2 bilaterally or unilaterally. The maxillary hyrax included bands on the first molars and first premolars. The Forsus spring is placed in the headgear tube of the maxillary first molar band and hooked around the labial bow near the mandibular canine-first premolar area, contained anteriorly by a Gurin lock (3M Unitek). This lock allows for reactivation of the Forsus device without the need for a longer push rod or split tubing shims. The mandibular labial and lingual bows are in passive contact with the mandibular incisors and are retained in the mouth by bands on the first molars and occlusal rests bonded to the first premolars. Forsus FRD springs do not rigidly hold the mandible forward and allow the patient to function in centric occlusion. It could thus be categorized as a nonprotrusive interarch Class II corrector (Fig 1).The ends of the springs can be protected by spring caps (Comfort Solutions, Langley, British Columbia, Canada). The hyrax jackscrew allows posterior expansion for constricted arches or compensatory maxillary expansion. Maxillary incisor teeth can be bracketed and aligned in a 2 3 4 arrangement. In this case, the archwire is segmented from lateral incisor to lateral incisor while the Forsus springs are active. The mandibular labial bow precludes the placement of orthodontic brackets on mandibular anterior teeth. The treatment protocol begins with the Forsus springs inserted bilaterally, even if 1 side is Class I. The springs are completely compressed every 6 weeks until the maxillary first premolars are in an overcorrected Class III relationship where they are end on with the mandibular second premolars. The spring is left on 1 side longer in a patient with an asymmetric Class II relationship. This was common in our study. Once the springs are removed, the hyrax screw is activated if compensatory maxillary expansion is required. The expansion is retained for 5 months, while the physiologic recovery of the Class II overcorrection is monitored once springs have been removed. If too much relapse occurs, the spring is replaced on 1 side or both sides, as necessary. This happened in only a few patients in the study. The Xbow framework is left in place for the entire treatment period to allow for replacement of the springs. As noted in Table I, a mean of almost 6.5 months elapsed between spring removal and the T2 cephalograph. No retention appliances were used during this time to help hold the Class II correction. VERSUCHSGRUPPE: **Xbow group** N= 69 (Anfang) / N=67 (Ende) / Alter = 11,11 ± 1,3 Jahre,Monate / ♂:♀ = 30:39 • Gebissphase:spätes Wechselgebiss bzw. permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung

Kontrolle Kontrollgruppe	**Keine kieferorthopädische Behandlung** KONTROLLGRUPPE: untreated control group N=30(Anfang) / N=30 (Ende) / Alter = 11,9 ± 0,9 Jahre, Monate / ♂:♀ = 20:10 • Gebissphase: spätes Wechselgebiss bzw. permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: keine Therapie
Outcome	**Direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: Cephalometric skeletal and dental effects T1: pretreatment T2: posttreatment T1-T2: 14, 67 months (Xbow group) bzw. 21,9 months (Untreated control group)
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. Treatment with the Xbow appliance in Class II patients resulted in favorable dental and skeletal changes in the direction of Class II correction. 2. Skeletally, a diminution of maxillary protrusion without mandibular advancement and an increase of the vertical dimension were found. 3. Dentally, overjet correction was accomplished by an increase in mandibular incisor protrusion without maxillary incisor movement. The maxillary molars were distalized, and the mandibular molars were mesialized. 4. Although some of these changes were statistically significant, the magnitude of the differences may not likely have clinical significance in some patients. 5. From the samples used in this investigation, Xbow treatment appears to be equally effective for both male and female patients.

Zusammen-fassung der Ergebnisse	**Xbow group vs. Untreated control group** All variables except Ar-OLp were significant at the α = 0.05 level based on MANOVA with only 1 factor—group. The MANOVA was run a final time with group as a factor and months between cephalograms remaining as a covariate. Estimated marginal means (EMM) were calculated for the 2 treatment groups based on the analysis with the months between cephalograms as a covariate, and the group differences for this is shown in the column labeled ‘‘EMM group difference’’ in Table VI. There were statistically significant differences over the observation period for 9 of the 14 variables at the α = 0.05 level when the difference in observation period (months between cephalograms) was taken into account. The differences favoring the Xbow for changes in the direction of Class II correction included SNA, ANB, L1-MP, L1 minus Pg, overjet, U6 minus A, L6 minus Pg, and A-OLp. Meanwhile, the control group showed a statistically significant decrease in mandibular plane angle compared with the Xbow group, as measured by MP-SN (–1.3° for control, –0.1° for Xbow). Neither group showed a significant difference in SNB, U1-SN, U1 minus A, Pg-OLp, or Ar-OLp. Examples of the clinical changes obtained with Xbow appliance can be found in Figure 5. Subgruppenanalyse: The MANOVA was again run for comparison of the groups, first with the interaction for group and sex. The interaction term was not significant, so it was omitted.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • historische Kontrollgruppe • große zeitliche Unterschiede zwischen T1 und T2 zwischen den Gruppen • Baseline-Imbalancen zwischen den Gurppen *Durchführung:* • keine Angaben zum Behandler *Auswertung:* • keine Angabe zur auswertenden Person • solide Statistik, Normalverteilung geprüft, MANOVA *Power der Studie/Patientenzahl:* • keine Power-Analyse *Funding: keine Angabe* *Interessenkonflikte:* The Xbow appliance design is patented. Duncan W. Higgins has a commercial interest in Xbow appliances. He receives royalties when Xbows are fabricated in licensed dental laboratories. The other authors have no commercial interest in the Xbow or any other conflict of interest. *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • detection bias: große zeitliche Unterschiede zwischen T1 und T2 zwischen den Gruppen *Sh. ROB:* • The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable – NO • Have confidence intervals been provided? - NO
Schluss-folgerung des Begutachters	methodische Qualität: ausreichend
	Klinische Aussagekraft: Die Behandlung mit der Xbow-Apparatur führt zu gewünschten dentalen und skelettalen Korrekturen der Klasse II: • Skelettal konnten eine Verringerung des OK-Prognathiegrades ohne Ventralentwicklung des Unterkiefers sowie eine Bisshebung beobachtet werden. • Die Reduktion des Overjets wurde durch Protrusion der UKF ohne Bewegung der OKF erreicht. Die OK-Molaren wurden distalisiert, die UK-Molaren mesialisiert. • Es zeigten sich keine Unterschiede bezügloch der Therapieeffekte der Xbow-Apparatur zwischen Mädchen und Jungs.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable (+)**

Evidenztabelle Flores-Mir und Major 2006

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A systematic review of cephalometric facial soft tissue changes with the Activator and Bionator appliances in Class II division 1 subjects

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SUMMARY The objective of the present systematic review was to evaluate, through lateral cephalograms, facial soft tissue changes after the use of the Activator and Bionator appliances in Class II division 1 malocclusion subjects.

Several electronic databases (PubMed, Medline, Medline In-Process & Other Non-Indexed Citations, Cochrane Database, Embase, Web of Sciences, and Lilacs) were searched with the assistance of a senior health sciences librarian. Abstracts, which appeared to fulfil the initial criteria, were selected by consensus. The original articles were then retrieved. Their references were also hand searched for possible missing articles. Clinical trials, which assessed facial soft tissue changes with the use of either an Activator or a Bionator appliance without any surgical intervention or syndromic characteristics, were considered. A comparable untreated control group was required to factor out normal growth changes.

Five articles using the Activator and six using the Bionator fulfilled the selection criteria and quantified facial soft tissue changes. An individual analysis of these articles was undertaken and some methodological flaws were identified.

Based on the available evidence, a significant amount of controversy regarding the soft tissue changes produced by the Activator and the Bionator exists. Soft tissue changes that were reported as being statistically significant were of questionable clinical significance. Long-term, double-blinded, prospective randomized clinical trials are needed to confirm the findings. Three-dimensional quantification is also required to overcome current limitations in our understanding of the soft tissue changes obtained with the use of removable functional appliances.

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • subjects with Class II division 1 malocclusions
Schweregrad	Nicht angegeben

Einschluss-kriterien *Bei Review: PICOS*	• population: subjects with Class II division 1 malocclusions • intervention: Activator and/or Bionator functional appliances • comparison: comparable untreated control group • outcome: Facial soft tissue changes evaluated through lateral cephalograms PRIMÄRZIELGRÖßE: Face (Subnasale: SnLsSnNBt/ SnPg'SnNBt/ GlSnSnPg'/ N'SnSnPg', ST pogonion: N'Pg'TrOrpS, Sulcus inferious: SiLLtSiMt/ N'Pg'Pg'Ls, Face heights: Gl-Sn/ Sn-M'/ Pg'N'/ Sn-StS/ StI-M') SEKUNDÄRZIELGRÖßE: Nose (Pronasale horizontal: Pm-NA, Subnasale horizontal: Sn-TrSN*pS/ Sn-SN*pS, Subnasale vertical: Sn-TrOr) TERTIÄRZIELGRÖßE: Upper Lip (Sulcus superious horizontal: Ss-OpS/ Ss-SN*pS/ Ss-SNpS/ Ss-SN*Gl, Sulcus superious vertical: Ss-TrOr, Labrale superious horizontal: Ls-SN*pS/ Ls-PrnPg'/ Ls-OpS/ Ls-SNpS/ Ls-SNpS/ Ls-Pg'Sn/ Ls-SN*pGl, Labrale superious vertical: Ls-TrOr, Upper lip thickness: LsU/ SsA, Upper lip length: SnSts/ SsLs) QUARTÄRZIELGRÖßE: Lower Lip (Labrale inferious horizontal: Li-SN*pS/ Li-PrnPg'/ Li-OpS/ Li-SNpS/ Li-Pg'Sn/ Li-SN*pGl, Laberale inferious vertical: Li-TrOr, Sulcus inferious horizontal: Si-OpS/ SiSN*pS/ SISN*PGl, Sulcus inferious vertical: Ssi-TrOr, Lower lip thickness: SiB/ StiM, Lower lip length: LiLI SiLi, Lower Lip heigh: StiM') WEITERE ZIELGRÖßEN: Menton (ST pogonion horizontal: Pg'OpS/ Pg'-NA/ Pg'-SN*pS/ Pg'-SNpS/ Pg'-SN*pGl, ST pogonion thickness: Pg ' Pg, Pg'-TrOr) • study type: Human clinical trials
Ausschluss-kriterien	1. syndromic or medically compromised patients 2. individual case reports or series of cases 3. surgical intervention 4. Simultaneous use of fixed appliances
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: **Activator and/or Bionator functional appliances** N=297 (Anfang) / N=?? (Ende) / Alter = 10,0-11,8 Jahre / ♂:♀ = ?:? • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: Frühbehandlung (interzeptiv), reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **comparable untreated control group** N=243 (Anfang) / N=?? (Ende) / Alter = 10,0-11,8 Jahre / ♂:♀ = ?:? • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: keine Behandlung

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **dentofaziale Ästhetik** PRIMÄRZIELGRÖßE: Face (Subnasale: SnLsSnNBt/ SnPg'SnNBt/ GlSnSnPg'/ N'SnSnPg', ST pogonion: N'Pg'TrOrpS, Sulcus inferious: SiLLtSiMt/ N'Pg'Pg'Ls, Face heights: Gl-Sn/ Sn-M'/ Pg'N'/ Sn-StS/ StI-M') SEKUNDÄRZIELGRÖßE: Nose (Pronasale horizontal: Pm-NA, Subnasale horizontal: Sn-TrSN*pS/ Sn-SN*pS, Subnasale vertical: Sn-TrOr) TERTIÄRZIELGRÖßE: Upper Lip (Sulcus superious horizontal: Ss-OpS/ Ss-SN*pS/ Ss-SNpS/ Ss-SN*Gl, Sulcus superious vertical: Ss-TrOr, Labrale superious horizontal: Ls-SN*pS/ Ls-PrnPg'/ Ls-OpS/ Ls-SNpS/ Ls-SNpS/ Ls-Pg'Sn/ Ls-SN*pGl, Labrale superious vertical: Ls-TrOr, Upper lip thickness: LsU/ SsA, Upper lip length: SnSts/ SsLs) QUARTÄRZIELGRÖßE: Lower Lip (Labrale inferious horizontal: Li-SN*pS/ Li-PrnPg'/ Li-OpS/ Li-SNpS/ Li-Pg'Sn/ Li-SN*pGl, Laberale inferious vertical: Li-TrOr, Sulcus inferious horizontal: Si-OpS/ SiSN*pS/ SISN*PGl, Sulcus inferious vertical: Ssi-TrOr, Lower lip thickness: SiB/ StiM, Lower lip length: LiLI SiLi, Lower Lip heigh: StiM') WEITERE ZIELGRÖßEN: Menton (ST pogonion horizontal: Pg'OpS/ Pg'-NA/ Pg'-SN*pS/ Pg'-SNpS/ Pg'-SN*pGl, ST pogonion thickness: Pg ' Pg, Pg'-TrOr)
Studientyp	**Systematisches Review** Inkludierte Studien in Bezug auf PICO: human clinical trials (1 davon RCT) N=11 (davon 5 Activator, 6 Bionator) Gesamt-Teilnehmerzahl in Bezug auf PICO: N=540
Schluss-folgerungen der Autoren	1. Based on the available evidence, there is **significant controversy** regarding the soft tissue changes produced by the Activator and the Bionator. 2. For the studies that supported significant changes, the nature of reported changes was of questionable clinical significance.

Zusammen-fassung der Ergebnisse	**Activator and/or Bionator functional appliances VERSUS comparable untreated control group** ***Subgruppen: 1. Activator, 2. Bionator*** **Face (Subnasale: SnLsSnNBt/ SnPg'SnNBt/ GlSnSnPg'/ N'SnSnPg', ST pogonion: N'Pg'TrOrpS, Sulcus inferious: SiLLtSiMt/ N'Pg'Pg'Ls, Face heights: Gl-Sn/ Sn-M'/ Pg'N'/ Sn-StS/ StI-M'):** **1.** Activator: No changes in the naso-labial (SnLs SnNBt) and labio-mental (SiLiSiM') angles were observed (Looi and Mills, 1986) **2.** Bionator: Contradictory results were reported for the facial angles. One of the studies (Henriques *et al.* , 2001) did **not report any** changes in facial convexity, one a diminution (− 2.2 degrees; Morris *et al.* , 1998), and **one augmentation** (2.7 degrees; Lange *et al.* , 1995). Regarding the **labio-mental angle, a large increase** (17 degrees; Lange *et al.* , 1995) **and no change** (Morris *et al.* , 1998) were observed**. No studies reported a significant naso-labial angle change** (Lange *et al.* , 1995 ; Oliveira *et al.,* 1997 ; Almeida *et al.* , 2001 ; Henriques *et al.* , 2001). **Total face height and lower face thirds were augmented** (Morris *et al.* , 1998 ; Henriques *et al.* , 2001). **Nose (Pronasale horizontal: Pm-NA, Subnasale horizontal: Sn-TrSN*pS/ Sn-SN*pS, Subnasale vertical: Sn-TrOr):** 1. Activator: Neither the tip (Forsberg and Odenrick, 1981) nor the base (Looi and Mills, 1986) of the nose underwent any change. 2. Bionator: not reported **Upper Lip (Sulcus superious horizontal: Ss-OpS/ Ss-SN*pS/ Ss-SNpS/ Ss-SN*Gl, Sulcus superious vertical: Ss-TrOr, Labrale superious horizontal: Ls-SN*pS/ Ls-PrnPg'/ Ls-OpS/ Ls-SNpS/ Ls-SNpS/ Ls-Pg'Sn/ Ls-SN*pGl, Labrale superious vertical: Ls-TrOr, Upper lip thickness: LsU/ SsA, Upper lip length: SnSts/ SsLs):** 1. Activator: Contradictory results were found regarding the position of the upper lip,[…]. Some studies (Forsberg and Odenrick, 1981 ; Looi and Mills, 1986 ; Gogen and Parlar, 1989) reported upper lip **retrusion (− 1.1 to − 3 mm) but others no change** (Mamandras *et al.* , 1989 ; Cozza *et al.* , 2004). Contradictory changes in upper lip thickness and length were also reported (Looi and Mills, 1986). 2. Bionator: Contradictory results were found for the antero-posterior position of the upper lip […]. **Retrusion of the upper lip** (− 0.89 to − 1.4 mm; Lange *et al.* , 1995 ; Almeida *et al.* , 2001) or **no change** (Morris *et al.* , 1998 ; Henriques *et al.* , 2001) was reported. A vertical increase was reported for upper lip […] (Lange *et al.* , 1995).

	Lower Lip (Labrale inferious horizontal: Li-SN*pS/ Li-PrnPg'/ Li-OpS/ Li-SNpS/ Li-Pg'Sn/ Li-SN*pGl, Laberale inferious vertical: Li-TrOr, Sulcus inferious horizontal: Si-OpS/ SiSN*pS/ SISN*PGl, Sulcus inferious vertical: Ssi-TrOr, Lower lip thickness: SiB/ StiM, Lower lip length: LiLI SiLi, Lower Lip heigh: StiM'): 1. Activator: Contradictory results were found regarding the position of the […] lower lip. […] **no changes** in the lower lip (Looi and Mills, 1986). Bionator: Contradictory results were found for the […] lower lip. For the lower lip, **a protrusion** (2.2 – 4.9 mm; Almeida *et al.* , 2001 ; Henriques *et al.* , 2001) or **no significant change** (Lange *et al.* , 1995 ; Morris *et al.* , 1998) was observed. A vertical increase was reported for […] lower lip measurements (Lange *et al.* , 1995). **Menton (ST pogonion horizontal: Pg'OpS/ Pg'-NA/ Pg'-SN*pS/ Pg'-SNpS/ Pg'-SN*pGl, ST pogonion thickness: Pg ' Pg, Pg'-TrOr):** **1.** Activator: mild **protrusion (1.8 degrees) of menton** was reported (Cozza et al., 2004)**.** Contradictory results were found regarding the position of […] menton. […] no changes […] soft tissue menton were noted (Looi and Mills, 1986). 2. Bionator: Contradictory results were found for the antero-posterior position of […] soft tissue pogonion. Finally, soft tissue pogonion was found to be **more protrusive** (0.9 mm; Lange *et al.* , 1995 ; Henriques *et al.* , 2001) **or unchanged** (Morris *et al.* , 1998).**A vertical increase** was reported for […] soft tissue menton measurements (Lange *et al.* , 1995).
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: keine a priori Registrierung, gute Suchstrategie, keine Meta-Analyse, nur 1 RCT. Kontrollgruppe nur als unbehandelt definiert (k.A. ob auch Klasse-II-Anomalie)* *Durchführung: methodische Qualität der Einzelstudien analysiert, aber nicht validierte Vorgehensweise. Literatursichtung durch zwei unabhängige Auswerter* *Auswertung: Eingeschlossene Studien messen unterschiedliche FRS-Parameter.* *Power der Studie/Patientenzahl: 11 Studien/540 Patienten mit ungefähr gleichmäßiger Aufteilung in Kontroll-/ Versuchsgruppe & Aktivator/Bionator-Intervention.* *Funding: -* *Interessenkonflikte: -* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* *Insgesamt niedrige Qualität der EInzelstudien (nur 2/11 Studien >50% erreicht).* **2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?** **3. Did the review authors explain their selection of the study designs for inclusion in the review?** **6. Did the review authors perform data extraction in duplicate?** **10. Did the review authors report on the sources of funding for the studies included in the review?** **13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?** *Publikationsbias (Reviews): -*

Schluss-folgerung des Begutachters	methodische Qualität: Review in Ordnung, Einzelstudien meist eingeschränkte methodische Qualität
	Klinische Aussagekraft: Werden Aktivatoren oder Bionatoren in Klasse-II/1-Patieten eingesetzt, kann die Veränderung im Weichteil zur Zeit nicht mit großer Wahrscheinlichkeit prognostiziert werden.
Evidenz-level (SIGN)	**2+**
Qualität (RoB, SIGN /AMSTAR II)	**moderat ⊕⊕**

Evidenztabelle Flores-Mir et al., 2006

Review Article

Soft Tissue Changes with Fixed Functional Appliances in Class II division 1

A Systematic Review

Carlos Flores-Mir[a]; Michael P. Major[b]; Paul W. Major[c]

ABSTRACT

Objective: To evaluate facial soft tissue changes after the use of fixed functional appliances in Class II division 1 malocclusion cases using a systematic review of the literature.

Materials and Methods: Several electronic databases (PubMed, Medline, Medline In-Process & Other Non-Indexed Citations, Cochrane Database, Embase, Web of Sciences, and Lilacs) were searched with the help of a senior Health Sciences librarian. Abstracts that appeared to fulfill the initial selection criteria were selected by consensus. The original articles were then retrieved. Their references were also hand-searched for possible missing articles. Clinical trials assessing facial soft tissue changes with the use of fixed functional appliances without any surgical intervention or syndromic characteristics were considered. A comparable untreated control group was required to factor out normal growth changes. Four articles using Herbst and one using Jasper Jumper fulfilled the selection criteria. An individual analysis of these articles was made and some methodological flaws were identified.

Results: Although fixed functional appliances produce some significant statistical changes in the soft tissue profile, the magnitude of the changes may not be perceived as clinically significant.

Conclusions: The conclusions from this systematic review should be considered with caution because only a secondary level of evidence was found. Long-term double-blinded prospective randomized clinical trials are needed. Three-dimensional quantification of the soft tissue changes is required to overcome current limitations in our understanding of the soft tissue changes obtained with the use of fixed functional appliances. (*Angle Orthod* 2006;76:712–720.)

KEY WORDS: Functional appliances; Soft tissue; Profile; Facial changes

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Class II division 1 malocclusions
Schweregrad	Nicht angegeben

Einschluss-kriterien *Bei Review: PICOS*	• Population: Class II division 1 malocclusions • Intervention: fixed functional appliances • Comparison: comparable untreated control group • Outcome: evaluation of soft tissue changes through lateral cephalograms PRIMÄRZIELGRÖßE: Face (Pronasale: N‘Prn^PrnPg‘/ TrOrpN^PrnPg‘, Subnasale: SnPg‘^SnNBt/ SnLs^SnNBt/ N‘Sn^SnPg‘, Sulcus superious: N‘Ss^SsPg‘) SEKUNDÄRZIELGRÖßE: Nose (Pronasale horizontal: Prn-TrOrpN, Subnasale horizontal: Sn-TrOrpN) TERTIÄRZIELGRÖßE: Upper lip (Labrale Superious horizontal: Ls-PrnPg‘/ Ls^TrOrpN/ Ls-TrOrpN/ Ls-TrOrpS) QUARTÄRZIELGRÖßE: Lower lip (Labrale Inferious horizontal: Li-PrnPg‘/ Li-TrOrpN/ Ls-TrOrpS) WEITERE ZIELGRÖßEN: Menton (ST Pogonion horizontal: ST Pogonion horizontal) • Study type: human clinical trials
Ausschluss-kriterien	1. syndromic or medically compromised patients 2. individual case reports or series of cases 3. surgical intervention 4. Simultaneous use of fixed banded appliances
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE: **fixed functional appliances** N=160 errechnet aus Tabelle 6 (Anfang) / N=?? (Ende) / Alter = 9-26 Jahre / ♂:♀ = ?:? • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr, permanentes Gebiss ≥ 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung, Spätbehandlung (Erwachsenenbehandlung)
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **comparable untreated control group** N=?? (Anfang) / N=?? (Ende) / Alter = ?? ± ?? Jahre / ♂:♀ = ?:? • Gebissphase: spätes Wechselgebiss, permanentes Gebiss < 18. Lebensjahr, permanentes Gebiss ≥ 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung, Spätbehandlung (Erwachsenenbehandlung)

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **dentofaziale Ästhetik** PRIMÄRZIELGRÖßE: Face (Pronasale: N‘Prn^PrnPg‘/ TrOrpN^PrnPg‘, Subnasale: SnPg‘^SnNBt/ SnLs^SnNBt/ N‘Sn^SnPg‘, Sulcus superious: N‘Ss^SsPg‘) SEKUNDÄRZIELGRÖßE: Nose (Pronasale horizontal: Prn-TrOrpN, Subnasale horizontal: Sn-TrOrpN) TERTIÄRZIELGRÖßE: Upper lip (Labrale Superious horizontal: Ls-PrnPg‘/ Ls^TrOrpN/ Ls-TrOrpN/ Ls-TrOrpS) QUARTÄRZIELGRÖßE: Lower lip (Labrale Inferious horizontal: Li-PrnPg‘/ Li-TrOrpN/ Ls-TrOrpS) WEITERE ZIELGRÖßEN: Menton (ST Pogonion horizontal: ST Pogonion horizontal)
Studientyp	**Systematisches Review** Inkludierte Studien in Bezug auf PICO: retrospective (4) & prospective (1) clinical trials N=5 Gesamt-Teilnehmerzahl in Bezug auf PICO: N=228 (aber 2/5 (aber in 2/5 Studien “not aaplicable”: diese Studien untersuchen nichtwachsende Patienten)
Schluss-folgerungen der Autoren	The following systematic review conclusions should be considered with caution because only a secondary level of evidence was found. Long-term prospective double-blinded randomized clinical trials are needed to support these conclusions. • An improvement of the facial convexity was found. • Changes produced by fixed functional appliances seem to restrict the forward movement of the upper lip. • No change in the anteroposterior position of the lower lip and soft tissue menton was found. • Soft tissue changes are similar between nongrowing young adult and growing adolescent samples.

Zusammen-fassung der Ergebnisse	**fixed functional appliances VERSUS comparable untreated control group** **Subgruppen: 1. Jasper Jumper, 2. Herbst, 3. Growing patients, 4. Nongrowing patients** **Face (Pronasale: N‘Prn^PrnPg‘/ TrOrpN^PrnPg‘, Subnasale: SnPg‘^SnNBt/ SnLs^SnNBt/ N‘Sn^SnPg‘, Sulcus superious: N‘Ss^SsPg‘):** 1. Jasper Jumper: An **increase in the nasiolabial angle**, was found. **No changes were found in the H-angle**.1 2. Herbst: **Subnasale**, but not the nose tip, was **more retrusive** after treatment.15 3. Growing patients: A significant improvement of the facial profile after Herbst appliance use. The selected articles15,35 consistently report an increase in different facial angles, which is correlated to an improvement in the facial profile. 4. Nongrowing patients: - **Nose (Pronasale horizontal: Prn-TrOrpN, Subnasale horizontal: Sn-TrOrpN):** 1. – 2. Herbst: Regarding the nose-base angulation, no significant changes were found.15 **(Subnasale, but**) not the nose tip, was **more retrusive** after treatment.15 3. Growing patients: A significant improvement of the facial profile after Herbst appliance use. The selected articles15,35 consistently report an **increase in different facial angles, which is correlated to an improvement in the facial profile**. 4. Nongrowing patients: - **Upper lip (Labrale Superious horizontal: Ls-PrnPg‘/ Ls^TrOrpN/ Ls-TrOrpN/ Ls-TrOrpS):** 1. Jasper Jumper: a **more retruded** position of Labrale Superious relative to the vertical reference plane was found. **No changes were found in the upper lip relative to the E-plane**.1 2. Herbst: **Contradictory** results have been reported regarding the anteroposition of the upper lip. Whereas one study4 reported a retrusion, another14. reported a protrusion. Studies4,14,15. 3. Growing patients: This improvement is not the product of a more forward position of the lower lip but more likely **a retrusion of the upper lip**. the anteroposterior position of the upper lip gets less prominent but the inclination of the lip per se does not change,15 which is explained by a similar posterior reposition of both Subnasaleand Labrale Superious. 4. Nongrowing patiens: An improvement in the facial profile was associated with a **retrusion of the upper lip** but not a forward position of the lower lip

	Lower lip (Labrale Inferious horizontal: Li-PrnPg‘/ Li-TrOrpN/ Ls-TrOrpS): 1. Jasper Jumper: a **protrusion of Labrale Inferious relative to Esthetic Plane (E-plane**) were found. No changes were found in the lower lip relative to the vertical reference plane.1 2. Herbst : consistently reported **no change** to the lower lip and the soft tissue menton 3. Growing patients: **No significant changes** were reported for the lower lip in any of the two selected studies,15,35 Nongrowing patients: An improvement in the facial profile was associated with a retrusion of the upper lip **but not a forward position of the lower** lip **Menton (ST Pogonion horizontal: ST Pogonion horizontal):** 1. – 2. Herbst: All studies reported significant changes in the facial angles related to a **soft tissue menton protrusion.** consistently reported **no change** to the soft tissue menton 3. Growing patients: **No significant changes were reported for the soft tissue Pogonion** in any of the two selected studies,15,35 **4.** Nongrowing patients: -

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: keine Meta-Analyse. Viele verschiedene Messwerte der Einzelstudien. Keine RCTs. Methodische Qualität der Einzelstudien zwar untersucht, aber nicht mit validierten Analyse-Techniken.* *Durchführung: gute Literatursuche. Keine genaueren Angaben zur Kontrollgruppe bzgl. der skelettalen Klasse. 2/5 Studien ohne Kontrollgruppe da hier ausgewachsene Patienten untersucht wrden* *Auswertung: 2/5 Kontrollgruppen ohne Angaben (Größe, Alter etc.). Z.T. große Unterschiede im Patientenalter (9-26 Jahre) & Behandlungsdauer (7 Monate bis 10 Jahre)* *Power der Studie/Patientenzahl: 5 Studien. Keine Gesamtteilnehmerzahl der Kontrollgruppe bekannt* *Funding: -* *Interessenkonflikte: -* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* **2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?** **3. Did the review authors explain their selection of the study designs for inclusion in the review?** **6. Did the review authors perform data extraction in duplicate?** **10. Did the review authors report on the sources of funding for the studies included in the review?** **14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?** **16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?** *Publikationsbias (Reviews): -*
Schluss-folgerung des Begutachters	methodische Qualität: Einzelstudien mit insgesmat niedriger Evidenz (45-60%), Review mit guter Konzeption
	Klinische Aussagekraft: Eine festsitzende Klasse-II-Mechanik bei Klasse-II/1-Patienten scheint die Weichgewebs-Konvexität zu verbessern. Dabei scheint das Patientenalter bzw. die Unterscheidung in wachsende und ausgewachsene Patienten keinen großen Einfluss auf die Veränderung zu nehmen.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Moderat ⊕⊕**

Evidenztabelle Franchi, Alvetro et al. 2011

Original Article

Effectiveness of comprehensive fixed appliance treatment used with the Forsus Fatigue Resistant Device in Class II patients

Lorenzo Franchi[a]; Lisa Alvetro[b]; Veronica Giuntini[c]; Caterina Masucci[c]; Efisio Defraia[d]; Tiziano Baccetti[e]

ABSTRACT

Objective: To assess the dental, skeletal, and soft tissue effects of comprehensive fixed appliance treatment combined with the Forsus Fatigue Resistant Device (FRD) in Class II patients.

Materials and Methods: Thirty-two Class II patients (mean age 12.7 ± 1.2 years) were treated consecutively with the FRD protocol and compared with a matched sample of 27 untreated Class II subjects (mean age 12.8 ± 1.3 years). Lateral cephalograms were taken before therapy and at the completion of comprehensive therapy. The mean duration of comprehensive treatment was 2.4 ± 0.4 years. Statistical comparisons were carried out with the Student's *t*-test ($P < .05$).

Results: The success rate was 87.5%. The FRD group showed a significant restraint in the sagittal skeletal position of the maxilla (also at the soft tissue level), a significant increase in mandibular length, and a significant improvement in maxillo-mandibular sagittal skeletal relationships. The treated group exhibited a significant reduction in overjet and a significant increase in molar relationship. The lower incisors were significantly proclined and intruded, while the lower first molars moved significantly in a mesial and vertical direction.

Conclusions: The FRD protocol is effective in correcting Class II malocclusion with a combination of skeletal (mainly maxillary) and dentoalveolar (mainly mandibular) modifications. (*Angle Orthod.* 2011;81:678–683.)

KEY WORDS: Class II malocclusion; Fixed functional appliances; Cephalometrics

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • 32 subjects with Class II division 1 malocclusion • Vermutlich: Italy
Schweregrad	Overjet > 5mm, ANB > 3°
Einschluss-kriterien *Bei Review: PICOS*	• overjet larger than 5 mm • full Class II or Class II tendency molar relationship • ANB larger than 3
Ausschluss-kriterien	Keine Angaben

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** All treated patients were in the permanent dentition at the start of treatment, and they underwent a specific treatment protocol with preadjusted fixed appliances in combination with the FRD. The FRD was applied at the end of the aligning and leveling phase of orthodontic treatment, when a 0.019 X 0.025–inch stainless-steel archwire was inserted at both arches. The mandibular archwire was consistently cinched distal to the molars. In addition, brackets on the lower incisors presented with a torque of -6° to limit the buccal inclination of the lower incisors. The management of the maxillary archwire varied according to the individual need in terms of upper molar distalization. The rods of the FRD were placed on the mandibular archwire distal to the first bicuspids. The phase with the FRD was undertaken until Class II occlusion was overcorrected to an edge-to-edge incisor relationship. The mean duration of the FRD active phase was 5.2 ± 1.3 months. Thereafter, fixed appliances were maintained in order to finalize the occlusion. Comprehensive treatment of Class II malocclusion was performed during the circumpubertal phases of skeletal development, as assessed with the cervical vertebral maturation method. VERSUCHSGRUPPE: **Forsus Group** N=32 (Anfang) / N=32 (Ende) / Alter = 12,7 ± 1,2 Jahre / ♂:♀ = 19:13 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated Control Group** A sample of 27 subjects was selected from the files of the University of Michigan Growth Study (12 subjects) and of the Denver Child Growth Study (15 subjects) N=27 (Anfang) / N= 27 (Ende) / Alter = 12,8 ± 1,3 Jahre / ♂:♀ = 13:14 • Gebissphase: permanentes Gebiss < 18. Lebensjahr • KFO-Behandlung: keine Therapie
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: *Cephalometric Treatment Effects* A customized digitization regimen and analysis provided by cephalometric software (Viewbox, ver 3.0, dHAL Software, Kifissia, Greece) were utilized for all of the cephalograms that were examined in this study. The customized cephalometric analysis containing measurements from the analyses of Steiner, Jacobson, Ricketts, and McNamara was used and generated 33 variables, 11 angular and 22 linear, for each tracing. For the analysis of the soft tissue profile changes the method of Arnett et al. was used, with modifications.
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	1. The FRD protocol led to a successful correction of Class II malocclusion in 87.5% of the patients. 2. The protocol had a greater skeletal effect on the maxillary structures by restraining the sagittal advancement of the maxilla. 3. The effects on the mandible were mainly at the dentoalveolar level, with a large amount of mesial movement of the lower incisors and first molars.
Zusammen-fassung der Ergebnisse	**Forsus Group… VERSUS Untreated Control Group** ***PRIMÄRZIELGRÖßE*** Results for statistical comparisons on the T2-T1 changes for the FRD group and the Class II untreated controls are shown in Table 2. The statistical comparison showed a significant restraint in the sagittal skeletal position of the maxilla (SNA, Pt A to Nasion perp, and Co-A). The increase in effective mandibular length (Co-Gn) was significantly greater in the FRD group when compared to natural growth changes in Class II controls. Comparison of changes in intermaxillary relationships revealed a significantly greater decrease in ANB angle and Wits appraisal as well as a significant increase in the maxillo-mandibular differential in the treatment group. With regard to changes in vertical skeletal relationships, the increase in lower anterior facial height (ANS to Me) was significantly greater in the treatment group compared to the untreated controls. With regard to the interdental changes, the treatment group exhibited a significant reduction in overjet, overbite, and interincisal angle, as well as a significant improvement in molar relationship. A significantly more retruded position of the upper incisors (U1 to Pt A vertical and U1 horizontal) was assessed in the treated group, as was a greater vertical eruption of the upper incisors (U1 vertical). All of the changes in the mandibular dentoalveolar parameters were statistically significant in the FRD group when compared with the untreated control group. As a result of therapy the lower incisors were significantly proclined and intruded, while the lower first molars extruded significantly and moved significantly in a mesial direction. The analysis of the changes in the soft tissue measurements between treated Class II patients and untreated controls showed significantly greater backward movement of the soft tissue A point in the FRD group.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *Keine Ethikvotum* • *Vermutlich retrospektives Vorgehen* • *Historische Kontrollgruppe* • *Matching fraglich (ausgeprägter Geschlechterunterschiede zwischen den Gruppen)* *Durchführung:* • *Keine Details zum Behandler ➔ Reliabilität fraglich* • *Keine Angaben zur Compliance des Patienten/der Behandler* *Auswertung:* • *Wenige Information zum Auswerter* • *Verblindung der Auswertung garantiert* • *Keine Konfidenzintervalle angegeben* • *Solide Statistik (Kolmogorov-Smirnov, t-Test)* *Power der Studie/Patientenzahl: retrospektiv vorhanden; keine Fallzahlplanung* *Funding: keine Angabe* *Interessenkonflikte: keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • *Selection bias: historische Kontrollgruppe, wenige Angaben zur Rekrutierung* • *Attrition bias: keine Angabe zu Dropouts* • *Keine Erhebung von Confounders*
Schluss-folgerung des Begutachters	methodische Qualität: befriedigend
	Klinische Aussagekraft: • Das Forsus-Protokoll führte zu einer erfolgreichen Korrektur der Klasse-II in 87,5% der Patienten. • Der skelettale Effekt war im OK durch eine Hemmung des sagittalen Wachstums stärker ausgeprägt. • Die Effekte im UK waren hauptsächlich dento-alveolärer Natur (v.a. Mesialwanderung der ersten Molaren und Protrusion der Inzisiven)
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	⊕ Acceptable

Evidenztabelle Franchi, Baccetti et al 1998

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The aim of this study was to evaluate maxillary and mandibular shape/size changes by means of Bookstein's shape-coordinate and tensor analysis in children with Class III malocclusions treated with rapid maxillary expansion and a facial mask in order to define optimum timing of intervention for this type of therapy. The treated group (46 subjects, 26 females and 20 males) was divided into two subgroups according to the stage of dentitional development. The early-treated group consisted of 23 subjects treated in the early mixed dentition (mean age at Time 1, 6 years 9 months ± 7 months); the late-treated group included 23 subjects treated in the late mixed dentition (mean age at Time 1, 10 years 3 months ± 1 year). The mean treatment period was about 11 months. The control group (32 subjects with untreated Class III malocclusion, 18 females and 14 males) also was divided into two subgroups (an early control group, 17 subjects in the early mixed dentition, and a late control group, 15 subjects in the late mixed dentition). Maxillary triangles (point T, the most superior point of the anterior wall of sella turcica, point FMN, the fronto-maxillary-nasal suture, and point A) and mandibular triangles (point Condylion, point Gonion, and point Pogonion) were digitized on cephalograms in both groups at Time 1 and Time 2. Combined facial mask and rapid maxillary expansion therapy produced a significant enhancement of the forward growth of the maxilla and significantly more upward and forward direction of growth of the mandibular condyle (leading to smaller increments in mandibular total length, Co-Pg) in the early-treated group when compared with controls and to the late-treated group. Both maxillary size and mandibular size were significantly affected by treatment in the early mixed dentition. The results of this study indicate that orthopedic treatment of Class III malocclusion induces favorable size and shape changes both in the maxilla and mandible, and that this combined treatment approach is more effective in the early mixed dentition than in the late mixed dentition. (Am J Orthod Dentofacial Orthop 1998;114: 418-26)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** Patients with class III malocclusion treated with maxillary expansion (bonded maxillary expander) and face-mask therapy was obtained from North American practitioners experienced in this type of treatment. The clinicians were asked to take cephalograms at the following intervals: before treatment (T1) and after treatment (T2). Generally, 1 or 2 months elapsed between the T1 cephalogram and the actual start of treatment. The T2 film was taken within 1 month of the discontinuation of face-mask wear and removal of the expander
Schweregrad	1. Overjet in mm 2. Verzahnung im 3er Bereich in Pb 3. Verzahnung im 6er Bereich in Pb 4. Wits in mm
Einschluss-kriterien *Bei Review: PICOS*	1. Overjet < 0 mm 2. Class III canine relationship 3. Class III permanent molar relationship 4. ≥ -2mm
Ausschluss-kriterien	Keine Angaben

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Orthopedic face-mask therapy in the treated group comprised a face mask (according to the design of Petit 5; Fig. 1), a bonded maxillary acrylic splint expander with vestibular hooks, and heavy elastics VERSUCHSGRUPPE 1: early-treatment group • N=23 (Anfang) / N=23 (Ende) / Alter = ♂ 6y9m± 7m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung / FrühBehandlung VERSUCHSGRUPPE 2: late-treatment group • N=23 (Anfang) / N=23 (Ende) / Alter = ♂ 10y3m± 1y ♂:♀ = k.A. • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **frühes Wechselgebiss-Kontrollgruppe** N=17 (Anfang) / N=17 (Ende) / Alter: 6y5m ± 8m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Keine Behandlung KONTROLLGRUPPE 2: **spätes Wechselgebiss-Kontrollgruppe** N=15 (Anfang) / N=15 (Ende) / Alter: 9y6m ± 1y6m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** Outcome spezifisch: • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Okklusion, Kaufunktion, Funktion • Reduktion eines weiteren Therapiebedarfs **Primärzielgröße: Morphologische Veränderungen der Maxilla und Mandibula**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	The findings of the present study showed that FM and RME therapy were able to induce a significant enhancement of the forward growth of the maxilla and a significantly more upward-forward direction of growth of the mandibular condyle (leading to smaller increments in mandibular total length) in the earlytreated group when compared to the late-treated group and to untreated controls. Orthopedic treatment of Class III malocclusion is more effective in the early mixed dentition than in the late mixed dentition.

Zusammen-fassung der Ergebnisse	**GRUPPE early-treatment group VS. GRUPPE frühes Wechselgebiss-Kontrollgruppe** **GRUPPE late-treatment group VS. GRUPPE späte Wechselgebiss-Kontrollgruppe** ➔ Im Zuge der Frühbehandlung mit einer Delairemaske ist ein Wachstum der Maxilla nach ventrokranial zu beobachten. Gleiches gilt mandibulär für den Condylus. Der Gonionwinkel wird kleiner. ➔ Die maxillären Auswirkungen einer späten Behandlung sind ähnlich, jedoch deutlich geringer ausgeprägt. ➔ Fazit: Die Frühbehandlung ist signifikant effektiver als die späte Behandlung
Angaben auffälliger positiver und/oder negativer Aspekte	Sehr gut gemachte Studie. Zeigt sehr schön die morpholigschen Veränderungen während der maxillären Protraktion auf und weist auf den Vorteil einer frühen Behandlung hin.
Schluss-folgerung des Begutachters	methodische Qualität: sehr gut
	Klinische Aussagekraft: sehr hohe klinische Aussagekraft.
Evidenz-level (SIGN)	**2++**
Qualität	**++**

Evidenztabelle **Franchi et al. 2002**

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Thin-plate spline analysis of the short- and long-term effects of rapid maxillary expansion

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SUMMARY The aim of this study was to investigate the short- and long-term effects induced by rapid maxillary expansion (RME) on the shape of the maxillary and circummaxillary structures by means of thin-plate spline (TPS) analysis. The sample consisted of 42 patients who were compared with a control sample of 20 subjects. The treated subjects underwent Haas-type RME, followed by fixed appliance therapy. Postero-anterior (PA) cephalograms were analysed for each treated subject at T_1 (pre-treatment), T_2 (immediate post-expansion), and T_3 (long-term observation), and were available at T_1 and T_3 for the control group (CG). The mean age at T_1 was 11 years and 10 months for both groups. The mean chronological ages at T_2 were 20 years, 6 months for the treated group (TG) and 17 years, 8 months for the control group. The study focused on shape changes in the maxillary, nasal, zygomatic, and orbital regions.

TPS analysis revealed significant shape changes in the TG. They consisted of an upward and lateral displacement of the two halves of the naso-maxillary complex as a result of active expansion in the short-term, and normalization of maxillary shape in the transverse dimension in the long-term (the initial transverse deficiency of the maxilla in the treated group was eliminated by RME therapy both in the short- and long-term). At the end of the observation period, the nasal cavities were larger when compared with both their pre-expansion configuration and the final configuration in the controls. RME with the Haas appliance appears to be an efficient therapeutic means to induce permanent favourable changes in the shape of the naso-maxillary complex.

Population *Setting* *Komorbiditäten*	**Transversale Anomalie** • Patienten aus einer privaten Praxis, Ort unklar • Alter: 11 Jahre und 10 Monate • Kaukasier
Schweregrad	Keine Angabe
Einschluss-kriterien *Bei Review: PICOS*	RME Group • treated with Haas-type RME • non-extraction edgewise appliance therapy • transverse maxillary deficiency Control Group • aged matched control group with no orthodontic treatment

Ausschluss-kriterien	keine Angabe
Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** VERSUCHSGRUPPE 1: **RME Group (TG)** A sample of 42 subjects (25 females, 17 males) treated with Haas-type RME and non-extraction edgewise appliance therapy in a single orthodontic practice were investigated. N=42 (Anfang) / N=42 (Ende) / Alter = 11 Jahre und 10 Monate / ♂:♀ =17:25 • Gebissphase: spätes Wechselgebiss/permanentes Gebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Control group (CG)** N=20 (Anfang) / N=20 (Ende) / Alter = 11 Jahre und 10 Monate / ♂:♀ = 11:9 • Gebissphase: spätes Wechselgebiss/permanentes Gebiss • KFO-Behandlung: keine Behandlung
Outcome	**Direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** ***PRIMÄRZIELGRÖßE:*** Shape differences (Thin-plate spline analysis) Gemessen an folgenden Strukturen: 1. Medio-orbitale (Mo)—the most medial point of the orbital orifice. 2. Orbitale (Or)—the lowest point of the orbital orifice. 3. Ectoconchion (Ek)—the most lateral point of the orbital contour. 4. Latero-orbitale (Lo)—the intersection of the lateral wall of the orbit and the greater wing of the sphenoid (the oblique line). 5. Supra-orbitale (So)—the highest point of the orbital orifice 6. Zygomatic (Zyg)—the most lateral point of the zygomatic arch 7. Maxillare (Mx)—the point located at the depth of the concavity of the right lateral maxillary contour, at the junction of the maxilla and the zygomatic buttress. 8. Lateronasal (Ln)—the most lateral point of the nasal cavity. 9. Inferonasal (In)—the most inferior point of the nasal cavity. In addition, the following midline points were included in the analysis: 10. Nasal septum (Ns)—the point located at the intersection of the nasal septum with the floor of the nose. 11. Prosthion (Pr)—the tip of the alveolar crest between the maxillary central incisors. After hand-tracing posterior-anterior cephalograms the average craniofacial configurations were subjected to thin-plate spline (TPS) analysis to make comparisons on differences in shape both within the RME treatment group, and between the RME treatment group and the control group.

Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	RME is an effective therapeutic procedure to induce significantly favourable morphological changes in the craniofacial region. The shape modification consists of the displacement of the two halves of the naso-maxillary complex in an outward and upward direction. The fulcrum of the bilateral displacement appears to be located between the medial ridges of the two orbits. RME is able to normalize the maxillary complex in the long term.
Zusammen-fassung der Ergebnisse	**GRUPPE RME Group (TG) VS. GRUPPE control group (CG)** ***PRIMÄRZIELGRÖßE:*** Shape differences (Thin-plate spline analysis) The maxilla was significantly narrower (P= 0.003) in the TG when compared with CG before treatment. This was due to compression in the horizontal plane at point Mx bilaterally. The difference was associated with compression of the midface in the vertical plane because of a downward displacement of point Or bilaterally. A vertical extension of the lateral portions of the face in an upward direction was also detectable as a consequence of an upward displacement of point Zyg bilaterally. Treatment with RME induced significant alterations in the naso-maxillary complex in the transverse plane. A permanent enlargement of the base of the nose was achieved as revealed by the significant bilateral extension in the horizontal plane of the nasal region (P< 0.01) in the TG. The initial transverse deficiency of the maxilla in the TG was eliminated by RME therapy both in the short- and long-term. The position of point Mx did not show any difference in the TG when compared with the controls at both T2 and T3. The initial shape differences in the orbital and zygomatic areas persisted at T2 and T3. Treatment with RME induced significant alterations in the naso-maxillary complex in the transverse plane. A permanent enlargement of the base of the nose was achieved as revealed by the significant bilateral extension in the horizontal plane of the nasal region (P< 0.01) in the TG. The initial transverse deficiency of the maxilla in the TG was eliminated by RME therapy both in the short- and long-term. The position of point Mx did not show any difference in the TG when compared with the controls at both T2 and T3. A horizontal extension of the nasal area in TG could be detected at T3. The initial shape differences in the orbital and zygomatic areas persisted at T2 and T3.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: Skelettale Veränderungen nach RME wurden mit thin-plate-spline Analyse untersucht. Die Methode wurde bereits mehrfach in vorangegangenen Untersuchungen verwendet. Die Auswertung aller Röntgenbilder wurde von zwei Untersuchern verifiziert und 10 Bilder wurden wiederholt durchgezeichnet. Quantitative Werte (deskriptive Statistik) wurden in der Studie nicht angegeben. Die Kontrollgruppe hatte initial keinen Kreuzbiss. Ein möglicher Selbstausgleich der Anomalie wurde daher nicht untersucht.* *Power der Studie/Patientenzahl: Keine Fallzahlberechnung* *Funding: keine Angabe* *Interessenkonflikte: keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* *Publikationsbias (Reviews):* - *Can’t say if the same exclusion criteria are used for both cases and controls.* - *Can’t say if comparison is made between participants and non-participants to establish their similarities or differences.* - *Can’t say if cases are clearly defined and differentiated from controls.* - *The main potential confounders are not identified and taken into account in the design and analysis.* - *Confidence intervals are not provided.*
Schluss-folgerung des Begutachters	methodische Qualität: Akzeptabel
	Klinische Aussagekraft: mittel Die transversale Erweiterung der Maxilla mittels GNE führt zu skelettalen Veränderungen des nasomaxillären Komplexes.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable ⊕**

Evidenztabelle Franchi, Baccetti et al. 2004

In this cephalometric investigation, we evaluated the correction of Class III malocclusion in subjects who had attained postpubertal skeletal maturity and considered whether treatment timing influenced favorable craniofacial modifications. All subjects (n = 50) were treated with an initial phase of rapid maxillary expansion and protraction facemask therapy, followed by a second phase of preadjusted edgewise therapy. The treated sample was divided into an early treated group (early mixed or late deciduous dentition, 33 subjects) and a late treated group (late mixed dentition, 17 subjects). Mean treatment duration times were 7 years 2 months for the early treatment group and 4 years 5 months for the late treatment group. The treated patients were matched to untreated controls (early control group, 14 subjects; late control group, 10 subjects) on the basis of race, sex, mean age at first observation, mean age at second observation, mean observation intervals, and type of malocclusion. A modified version of Johnston's pitchfork analysis, with additional angular and linear measures for mandibular size and shape and for vertical skeletal relationships, was performed. Analysis of variance was used to evaluate the difference in means for each cephalometric variable in the treated groups compared with the corresponding control groups. The findings showed that orthopedic treatment of Class III malocclusion was more effective when it was initiated at an early developmental phase of the dentition (early mixed or late deciduous) rather than during later stages with respect to untreated Class III control groups. Patients treated with rapid maxillary expansion and facemask therapy in the late mixed dentition, however, still benefited from the treatment, but to a lesser degree. Early treatment produced significant favorable postpubertal modifications in both maxillary and mandibular structures, whereas late treatment induced only a significant restriction of mandibular growth. Significant changes in mandibular size were associated with significant changes in mandibular shape only in early treated subjects. The main contribution to overall occlusal correction was related to skeletal modifications rather than dental changes in both early and late treated groups. (Am J Orthod Dentofacial Orthop 2004;126:555-68)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie (inkl. LKG)** The parent sample of class III maxlocclusion patients consisted of cephalometric records of 102 Class III subjects treated with RME/FM followed by comprehensive preadjusted edgewise therapy collected from 3 private orthodontic practices experienced in this treatment modality. The records of additional patients were obtained from the University of Michigan Graduate Orthodontic Clinic.
Schweregrad	1. Overjet < 0 mm; 2. Wits ≥ -1,5mm
Einschluss-kriterien *Bei Review: PICOS*	(1) European-American ancestry (white), (2) Class III malocclusion at the first observation (T1) characterized by an anterior crossbite or edge-to-edge incisal relationship and a Wits appraisal of -1.5 mm or less, (3) 2-phase treatment consisting of RME/FM therapy followed by comprehensive preadjusted edgewise appliance therapy, (4) no permanent teeth congenitally missing or extracted before or during treatment, (5) cephalograms of adequate quality available at T1 and at the final observation (T2) after the 2-phase treatment, and (6) postpubertal skeletal maturation at T2 based on the CVM method of developmental staging20 (CVMS IV or V, Fig 1).
Ausschluss-kriterien	k.A.

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Orthopedic face-mask therapy in the treated group comprised a face mask (according to the design of Petit 5; Fig. 1), a bonded maxillary acrylic splint expander with vestibular hooks, and heavy elastics. All subjects underwent a second phase of preadjusted edgewise therapy immediately after the RME/FM treatment or after an interim period during which a removable maxillary stabilization plate typically was worn. On average, fixed appliance therapy lasted 27 months and did not involve extraction of permanent teeth. VERSUCHSGRUPPE 1: **early-treatment group** • N=33 (Anfang) / N=33 (Ende) / Alter = ♂ 7y5m± 1y3m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe /Früh-Behandlung VERSUCHSGRUPPE 2: **late-treatment group** • N=17 (Anfang) / N=17 (Ende) / Alter = ♂ 10y9m± 1y4m ♂:♀ = k.A. • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **frühes Wechselgebiss-Kontrollgruppe** N=14 (Anfang) / N=14 (Ende) / Alter: 7y0m ± 1y5mm ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • Keine Behandlung keine Behandlung KONTROLLGRUPPE 2: **spätes Wechselgebiss-Kontrollgruppe** N=10 (Anfang) / N=10 (Ende) / Alter: 10y8m ± 1y10m ♂:♀ = k.A. • Gebissphase: frühes Wechselgebiss • Keine Behandlung keine Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** Outcome spezifisch: • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Okklusion, Kaufunktion, Funktion **Primärzielgröße: Skelett. und dentoalveoläre Veränderungen**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	Treatment with RME/FM is most effective when it begins at an early developmental phase of the dentition (early mixed or late deciduous) rather than during later stages with respect to untreated Class III control groups. Patients treated with RME/FM therapy in the late mixed dentition, however, still benefit from the treatment, but to a lesser degree. Early treatment produces significant favorable postpubertal modifications in both maxillary and mandibular structures, whereas late treatment induces only a significant restriction of mandibular growth. Regardless of treatment timing, the correction of occlusal relationships in Class III patients treated with RME/FM therapy followed by fixed appliances is due almost entirely to adaptations in the skeletal bases rather than to dentoalveolar movements.
Zusammen-fassung der Ergebnisse	**GRUPPE early treatment group VS. GRUPPE frühes Wechselgebiss-Kontrollgruppe** **GRUPPE late treatment group VS. GRUPPE späte Wechselgebiss-Kontrollgruppe** ➔ The maxilla showed a significant forward movement of 1.8 mm more in the treated subjects (P < .05), and the mandible expressed a significantly smaller anterior projection (5 mm) in the same patients when compared with the untreated Class III controls (P < .01) ➔ The overall molar relationship improved by 1.7 mm for patients treated early, but worsened by more than 5 mm in the untreated controls. ➔ A significant overjet correction of more than 7 mm (P <.001) was achieved in the ETG when compared with the ECG during a similar ➔ Early treatment induced significantly smaller increases in total mandibular length with respect to the controls (-3.6 mm in about 7 years), along with significantly greater decreases of the gonial angle (-2.6°). Äquivalente Ergebnisse auch in late treatment group, jedoch mit geringerem Ausmaß, sodass eine frühere Behandlung in ihrer Therapieeffizienz überlegen ist.
Angaben auffälliger positiver und/oder negativer Aspekte	Sehr gut gemachte Studie, die wie schon die vorherigen Studien der Arbeitsgruppe die Notwendigkeit eines möglichst frühen Beginns der Behandlung widerspiegelt.
Schluss-folgerung des Begutachters	methodische Qualität: sehr gut Klinische Aussagekraft: hohe klinische Aussagekraft.
Evidenz-level (SIGN)	**2++**
Qualität	**++**

Evidenztabelle Franchi, Pavoni 2013

Original Article

Long-term skeletal and dental effects and treatment timing for functional appliances in Class II malocclusion

Lorenzo Franchi[a]; Chiara Pavoni[b]; Kurt Faltin Jr[c]; James A. McNamara Jr[d]; Paola Cozza[e]

ABSTRACT

Objective: To analyze the long-term skeletal and dentoalveolar effects and to evaluate treatment timing of Class II treatment with functional appliances followed by fixed appliances.

Materials and Methods: A group of 40 patients (22 females and 18 males) with Class II malocclusion consecutively treated either with a Bionator or an Activator followed by fixed appliances was compared with a control group of 20 subjects (9 females and 11 males) with untreated Class II malocclusion. Lateral cephalograms were available at the start of treatment (mean age 10 years), end of treatment with functional appliances (mean age 12 years), and long-term observation (mean age 18.6 years). The treated sample also was divided into two groups according to skeletal maturity. The early-treatment group was composed of 20 subjects (12 females and 8 males) treated before puberty, while the late-treatment group included 20 subjects (10 females and 10 males) treated at puberty. Statistical comparisons were performed with analysis of variance followed by Tukey's post hoc tests.

Results: Significant long-term mandibular changes (Co-Gn) in the treated group (3.6 mm over the controls) were associated with improvements in the skeletal sagittal intermaxillary relationship, overjet, and molar relationship (−3.0–3.5 mm). Treatment during the pubertal peak was able to produce significantly greater increases in total mandibular length (4.3 mm) and mandibular ramus height (3.1 mm) associated with a significant advancement of the bony chin (3.9 mm) when compared with treatment before puberty.

Conclusion: Treatment of Class II malocclusion with functional appliances appears to be more effective at puberty. (*Angle Orthod.* 2013;83:334–340.)

KEY WORDS: Functional jaw orthopedics; Class II malocclusion; Cervical vertebral maturation; Cephalometrics; Puberty

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • 40 patients (22 females and 18 males) with Class II division 1 malocclusion • orthodontic practice and from the records of patients treated in the Department of Orthodontics of the University of Rome Tor Vergata
Schweregrad	OJ > 5mm; maxillomandiblar differential < 23mm
Einschluss-kriterien *Bei Review: PICOS*	• Overjet > 5mm • full Class II or end-to-end molar relationships • maxillomandibular differential smaller than 23 mm
Ausschluss-kriterien	Keine Angabe

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** The late-treatment group (LTG; Table 1) included 20 subjects (10 females and 10 males) presenting with CS3 at T1. Stages in CVM atT2 were either CS4 or CS5. Therefore, the peak in growth velocity was included in the period of treatment with functional appliances for all of the subjects in LTG. Stage in CVM at T3 was CS6 for all the subjects of the LTG. treated consecutively either with the Bionator (21 subjects) or Activator (19 subjects) were reviewed. The subjects were collected from an orthodontic practice (Bionator) and from the records of patients treated in the Department of Orthodontics of the University of Rome Tor Vergata (Activator). The study project was approved by the Ethical Committee at the University of Rome Tor Vergata, and informed consent was obtained from the subjects’ parents. The nonextraction treatment protocols consisted either of a Bionator constructed without coverage of the lower incisors or of an acrylic monobloc attached to the upper arch by Adams clasps and with capping of the upper and lower incisors. Treatment with functional appliances finished with the achievement of Class I molar relationship and was followed by fixed appliance therapy in the permanent dentition. VERSUCHSGRUPPE 1: **Early Functional Treatment Group** N=20 (Anfang) / N= 20 (Ende) / Alter = 9,3 ± 1,3 Jahre / ♂:♀ = 8:12 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE 2: **Late Functional Treatment Group** N=20 (Anfang) / N= 20 (Ende) / Alter = 10,7 ± 1,3 Jahre / ♂:♀ = 10:10 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Behandlung** **Des Weiteren: Kieferorthopädische Therapie zu anderem Zeitpunkt /Zeitraum /Gebissphase (zusätzliche Statistik zwischen den beiden Versuchsgruppen)** KONTROLLGRUPPE: **Untreated Control Group** N=20 (Anfang) / N=20 (Ende) / Alter = 10,1 ± 0,5 Jahre / ♂:♀ = 11:9 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: keine Therapie

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: Cephalometric Treatment Effects All lateral cephalograms of each patient were hand traced at a single sitting. Cephalograms were traced by one investigator. Landmark location and the accuracy of the anatomical outlines were verified by a second. Any discrepancies as to landmark placement were resolved by mutual agreement. A customized digitization regimen (Viewbox, version 3.0, dHAL Software, Kifissia, Greece) was created and used for the cephalometric evaluation. Lateral cephalograms for each patient at T1, T2, and T3 were digitized, and a custom cephalometric analysis was used. Twenty variables (13 linear and 7 angular) were generated for each tracing. Lateral cephalograms of treated and control groups at T1, T2, and T3 were standardized as to magnification factor (8%).
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. A significant long-term elongation of the mandible over the controls associated with improvements in the skeletal sagittal intermaxillary relationship, the overjet, and sagittal molar relationship. 2. A significant reduction of the overbite associated with an increase in lower anterior facial height and mandibular ramus height. 3. Significantly greater increases during the pubertal peak in total mandibular length and mandibular ramus height associated with a significant advancement of the bony chin when compared with treatment before puberty.
Zusammen-fassung der Ergebnisse	**Overall Functional Treatment Group VERSUS Untreated Control Group** ***PRIMÄRZIELGRÖßE*** When compared with the controls, the treated group presented with a significant increase of 3.6 mm in mandibular length (Co-Gn) both in the short term (T1– T2 interval) and in the long term (T1–T3 interval; Table 3). There were no significant between-group differences for skeletal sagittal maxillary measures. The treated group showed a significant decrease in the Wits appraisal and a significant increase in the maxillomandibular differential with respect to the control sample both in the T1–T2 (23.4 mm and 3.4 mm, respectively) and in the T1–T3 intervals (23.7 mm and 3.5 mm, respectively). Lower anterior facial height (ANS-Me) was increased significantly in the treated group both in the short term (2.7 mm) and in the long term (2.8 mm), while the mandibular ramus (Co-Go) was significantly increased in the treated group in the T1–T3 interval (3.2 mm). Both overjet and overbite exhibited significant decreases both during the T1–T2 interval (23.3 mm and 21.7 mm, respectively) and during the T1–T3 interval (23.1 mm and 21.6 mm, respectively). The sagittal relationship of the maxillary and mandibular molars improved significantly in the treatment group both in the short-term interval (3.0 mm) and in the long-term interval (2.8 mm). The treated group exhibited also a significant retroclination of upper incisors in the T1–T2 interval (U1 to FH, 26.1°).

	Early Functional Treatment Group VERSUS Late Functional Treatment Group ***PRIMÄRZIELGRÖßE*** The comparisons between the ETG and the LTG (Table 5) revealed that the chin was significantly more protruded in LTG both in the T1–T2 and in the T1–T3 intervals (Pg to Nasion perpendicular 4.5 mm and 3.9 mm, respectively). Total mandibular length showed significantly greater increases in the LTG vs ETG both in the short-term interval (5.5 mm) and long-term interval (4.3 mm). The LTG showed a significant increase in the maxillo-mandibular differential during the T1–T2 interval (3.1 mm). The mandibular ramus (Co-Go) was significantly increased in the LTG both in the T1–T2 and in the T1–T3 intervals (4.8 mm and 3.1 mm, respectively). Overjet exhibited significant decreases in LTG vs ETG during the T1–T2 interval (22.4 mm). The distal molar relationship was significantly improved in the LTG both in the short term (2.1 mm) and in the long term (1.9 mm).
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *Ethikvotum vorhanden* • *Historische Kontrollgruppe* *Durchführung:* • *Wenig Angaben zu Behandlern* • *Multizentrisches Vorgehen mit wenig Beschreibung der Qualitätssicherung* • *Suffiziente Verblindung* *Auswertung:* • *Wenig Angaben zu den Auswertern* • *Keine statistische Reliabitätsprüfung* • *Suffiziente Verblindung* • *Keine Konfidenzintervalle angegeben* • *Solide Statistik (ANOVA, post-Hoc Test)* *Power der Studie/Patientenzahl:* *Funding: keine Angaben* *Interessenkonflikte: keine Angaben* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • *Selection bias: historische Kontrollgruppe, keine Angaben zur Rekrutierung* • *Attrition bias: keine Angaben zu Dropouts* • *Keine Erhebung von Confounders*
Schluss-	methodische Qualität: befriedigend

folgerung des Begutachters	Klinische Aussagekraft: • Durch die funktionskieferorthopädische Behandlung und die anschließende festsitzenden Behandlung kam es zu einer signifikanten Verlängerung des Unterkiefers mit Verbesserung der sagittalen Kieferrelation und Verringerung des Overjets im Vergleich zur Kontrollgruppe. • Es kam zu einer signifikanten Vergrößerung der unteren Gesichtshöhe mit einer Reduktion des Overbites im Vergleich zur Kontrollgruppe. • Der spätere Therapiebeginn zum Zeitpunkt des puberalen Wachtumspeaks war mit einer signifikant stärkeren Zunahme der UK-Länge assoziiert.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	⊕ Acceptable

Evidenztabelle Freeman et al. 2009

Long-term treatment effects of the FR-2 appliance of Fränkel

David C. Freeman,[a] James A. McNamara, Jr,[b] Tiziano Baccetti,[c] Lorenzo Franchi,[c] and Christine Fränkel[d]
Ann Arbor, Mich, Fresno, Calif, Florence, Italy, and Zwickau, Germany

Introduction: The objective of this study was to evaluate the long-term effectiveness in a group treated with the FR-2 appliance of Fränkel compared with an untreated Class II control group. **Methods:** The sample consisted of 30 patients (17 boys, 13 girls) treated exclusively with the FR-2 by Rolf Fränkel. The mean age at the start of treatment was 8 years (T1), with a posttreatment cephalogram (T2) taken 10 years later. The control group included 20 subjects (11 boys, 9 girls) with untreated Class II malocclusion. Their mean ages at T1 and T2, and the mean times of observation, matched the treatment group closely. Lateral cephalograms were analyzed with a specific tracing regimen at both T1 and T2 in both groups. The Student *t* test was used to compare changes between the groups. **Results:** The FR-2 group maintained stable correction of the initial Class II malocclusion over the evaluation period. Significant mandibular and intermaxillary changes and dentoalveolar changes were noted in the treated group, with a 3-mm long-term increase in mandibular length compared with the untreated Class II controls. **Conclusions:** This study suggests that correction of a Class II malocclusion with the FR-2 appliance maintains favorable results over the long term with both skeletal and dentoalveolar changes. (Am J Orthod Dentofacial Orthop 2009;135:570.e1-570.e8)

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Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Patients • Interventionsgruppe: Private practice , Zwickau, Germany Kontrollgruppe: University of Michigan Elementary and Secondary School Growth Study and the Denver Growth Study
Schweregrad	Excessive overjet and full-cusp Class II molar relationship
Einschluss-kriterien *Bei Review: PICOS*	Class II
Ausschluss-kriterien	---

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** VERSUCHSGRUPPE: **FR2** N=30 (Anfang) / N=30 (Ende) / Alter = 8,1 ± 1,3 Jahre / ♂:♀ = 17:13 • Gebissphase: frühes Wechselgebiss, spätes Wechselgebiss (anhand Alter) • KFO-Behandlung: Frühbehandlung (interzeptiv), reguläre Behandlung (anhand Alter) All FR-2 subjects were treated by Rolf and Christine Fränkel, using Rolf Fränkel's specified appliance design and treatment protocol; The FR-2 appliance was used according to the following protocol: full-time wear (with a gradual increase in wearing time) for 2 to 2.5 years, an initial retention phase of 1.5 to 2 years during which the FR-2 was worn in the afternoon and at night, and a second retention phase of 1.5 years with the FR-2 worn only at night. All patients were treated exclusively with the FR-2 appliance; no fixed appliances were used.
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **untreated control** N= 20 (Anfang) / N=20 (Ende) / Alter = 8,5 ± 1,2 Jahre / ♂:♀ = 11:9 • Gebissphase: frühes Wechselgebiss, spätes Wechselgebiss (anhand Alter) • KFO-Behandlung: keine The untreated group included 20 subjects with Class II malocclusion. These subjects had excessive overjet and full-cusp Class II molar relationship (matching the initial characteristics of the FR-2 group). The cephalograms of the untreated patients were obtained from the University of Michigan Elementary and Secondary School Growth Study and the Denver Growth Study.
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: Long-term treatment effects
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. These results refer to successfully treated patients; therefore, they represent a gold standard for the FR-2 appliance. 2. The FR-2 appliance, over a long period, has a minor restraining effect on the position of the maxilla and a significant enhancing effect on mandibular length and sagittal position. 3. The FR-2 has its greatest long-term effects on anteroposterior intermaxillary measurements, as shown by the ANB angle and the Wits appraisal, as well as by significant improvements in overjet (4.5 mm) and molar relationship (4 mm). 4. Treatment with the FR-2 has no discernible effects on the skeletal vertical dimension. 5. FR-2 treatment results in significant lingual tipping of the maxillary incisors and, to a lesser degree, proclination of the mandibular incisors.

Zusammen-fassung der Ergebnisse	**FR2 VS. untreated control** ***PRIMÄRZIELGRÖßE*** Long-term treatment effects From T1 to T2 (Figs 1 and 2), the FR-2 group had a significant reduction of about 1.5 mm in Point A, as measured from nasion perpendicular, when compared with the control group (Table III). There was a net statistically significant increase (3 mm) in mandibular length (Co-Gn) when comparing the FR-2 group to the Class II control group. SNB angle increased significantly in the FR-2 group compared with the Class II control group. The values for ANB angle and the Wits appraisal also were significantly decreased in the FR-2 group compared with both controls. A significant clockwise rotation of the palatal plane was found in the FR-2 group. The mandibular plane angle decreased in both groups by about 2° to 3°, with no difference between the groups. Overjet and overbite were reduced significantly in the FR-2 group when compared with the controls. The molar relationship change in the FR-2 group was significantly different than in the control group, with a significant improvement of molar relationship in the treated group. The variables U1 to SN and Point A vertical decreased significantly in the FR-2 group compared with untreated controls, indicating significant palatal inclination of the maxillary incisors in the treated group. L1-APg increased significantly in the FR-2 group compared with the controls, signifying proclination of the mandibular incisors in the treated group.
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • retrospektiv/historische Kontrollgruppe • Sehr gutes Matching • nicht klar definierte Einschlusskriterien • kaum Baselineimbalancen, siehe Matching *Durchführung:* • Standardisiertes Durchführungsprotokoll • reliabel (nur 1 Patient von anderem Behandler betreut) *Auswertung:* • standardisierte FRS-Analyse • nur 1 Auswerter, Reliabilitätsprüfung vorliegend • keine Prüfung auf Normalverteilung • keine p-Werte angegeben *Power der Studie/Patientenzahl:* Due to sample size and standard deviation of examined cephalometric variables, the power of the study exceeded 0.85. *Funding:* --- *Interessenkonflikte:* The authors report no commercial, proprietary, or financial interest in the products or companies described in this article. *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • Have confidence intervals been provided?- No (sign)
Schluss-	methodische Qualität: sehr gut

folgerung des Begutachters	Klinische Aussagekraft: Bei Einhaltung des standardisierten Protokolls führt die FR2-Therapie im Vergleich zur unbehandelten Patienten zu geringer Wachstumshemmung der Maxilla und zur Vergrößerung der Mandibula-Länge und Vorverlagerung in der Sagittalen. Zudem erfolgt eine Reduktion des ANB, des Wits mit Verbesserung von OJ, OB und Okklusion. Die OK-Front retrudiert unter Therapie, die UK-Front protrudiert. Es zeigen sich keine nennswerten Effekte auf die skelettal-vertikale Dimension.
Evidenz-level (SIGN)	**2++**
Qualität **(RoB, SIGN /AMSTAR II)**	**High quality (++)**

Evidenztabelle Garattini, Levrini et al 1998

ORIGINAL ARTICLE

Skeletal and dental modifications produced by the Bionator III appliance

Giovanna Garattini, MD, DDS,[a] Luca Levrini, MD,[b] Paolo Crozzoli, MD, DDS,[a] and Aurelio Levrini, MD, DDS[c]
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The therapeutic results of a functional orthopedic treatment with a Balters' Bionator III appliance were evaluated. The sample group included 39 white growing subjects with a dentoskeletal Class III malocclusion. A 2-year study compared results with a control group. The results showed that the Bionator III is effective, especially when the malocclusion is mainly the result of a midfacial deficiency and when there is a hypodivergent growth pattern. (Am J Orthod Dentofacial Orthop 1998;114:40-4.)

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** - Patients with Class III molar relationship, anterior crossbite and concave profile - Italy
Schweregrad	Keine Angaben
Einschluss-kriterien	Bionator III group (1) angle Class III molar relationship; (2) edge-toedge incisor position or anterior cross bite; (3) concave profile; (4) head hyperextension posture (5) static and dynamic Class III neuromuscular attitude4; (6) hypertonic upper lip; (7) low and forward tongue rest position.cts Control group (Class I) (1) Class I Occlusion
Ausschluss-kriterien	(1) Not fulfilling inclusion criteria

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** Treatment with a modified Balters' Bionator III. The modified Balters' Bionator III differs from the original in the following characteristics: deeper and wider lingual wings; acrylic vestibular lateral shields extending deeply into the upper fornix, upper labial buttons; upper incisor inclined plane. Patients had to wear this appliance for at least 22 hours a day. In order to check their compliance parents had to undersign a form on which the daily wearing time was recorded by the patient. VERSUCHSGRUPPE 1 **Bionator III** N= 55 (Anfang) / N=39 (Ende) / Alter = 7,9, 1,67 years / ♂:♀ = 15:24 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: frühe Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** **Class I:** Patients from the longitudinal study of the London King's College matched according to sex and age. KONTROLLGRUPPE 1: **Class I** N=39 (Anfang) / N= 39 (Ende) / Alter = 7,83, 1,67 years / ♂:♀ = 15:24 • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: **Skeletal: ANS, SNB, ANB, Wits**
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	The Bionator III **failed to show an effective control on vertical growth**. The use of this appliance should be preceded by a careful evaluation of patient skeletal and growing patterns as it is **not indicated for use in patients with increased facial height.** The Bionator III is **helpful** in Class III malocclusion treatment in **growing patients with midfacial deficiency, hypodivergent growth pattern, and reduced facial height.** The Bionator III may also be considered a **valid appliance in patients with favorable skeletal features**. **A correct diagnosis is necessary** to stress facial and skeletal variables and the extent of the malocclusion in order to rationally use this appliance. **Patient compliance needs to be good**.
Zusammen-fassung der Ergebnisse	**GRUPPE Bionator III VS. GRUPPE Class I** Initial (T1) (pretreatement/ observation): 7,9, 1,67 years, Bionator III; 7,83, 1,67 Class I (Control group) Final (T2) (post treatment/ observation): 9,9 years Bionator III; 9,83, (Control group) **Skeletal: ANS, SNB, ANB, Wits** **Table III.** Comparison of Bionator III group and control group *Variables* / *Mean difference* / *SD* / *SE* / *Significance of difference* ANS / 1.3 / 2.4 / 0.4 / S.** SNB / −0.7 / 2.6 / 0.4 / S* ANB / 2.5 / 2.0 / 0.3 / S.*** Wits / 2.4 / 2.1 / 0.3 / S.*** SD, Standard deviation. SE, Standard error. *p < 0.05; **p < 0.01; ***p < 0.001.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Äquivalenz von Versuchs- und Kontrollgruppen nicht gegeben (Klasse III vs. Klasse I). Die Daten sind ausschließlich als Differenzen zwischen den Untersuchungszeitpunkten dargestellt und auch als solche verglichen. Daher ist der Vergleich mit der Klasse I Kontrollgruppe (Wachstumsstudie) nur eingeschränkt sinnvoll. Interessant ist die Studie durch die Untersuchung des Bionators. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Die Auswertung war nicht verblindet. Attrition rate 30 % (Bionator group). Retrospektive Studie mit, aufgrund des unvollständigen Vergleichs (nur Differenzen) mit der Klasse I Kontrollgruppe sehr stark eingeschränkter klinischer Relevanz. *Funding:* keine Angabe *Interessenkonflikte:* keine Angabe *Bias (SIGN):* Äquivalenz von Versuchs- und Kontrollgruppen nicht gegeben. Power/ Sample Size Berechnungen wurden nicht durchgeführt. Eine Verblindung fand nicht statt. Attrition rate 30 % (Bionator III)
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel Klinische Aussagekraft: Retrospektive Studie mit, aufgrund des unvollständigen Vergleichs (nur Differenzen) mit der Klasse I Kontrollgruppe sehr stark eingeschränkter klinischer Relevanz.
Evidenzlevel (SIGN)	**2+**
Qualität (RoB, SIGN)	**acceptable (+)**

Evidenztabelle Gencer, Kaygisiz et al. 2015

Original Article

Comparison of double-plate appliance/facemask combination and facemask therapy in treating Class III malocclusions

Deniz Gencer[a]; Emine Kaygisiz[b]; Sema Yüksel[c]; Tuba Tortop[d]

ABSTRACT

Objective: To compare the treatment effects of double-plate appliance/facemask (DPA-FM) combined therapy and facemask (FM) therapy in treating Class III malocclusions.

Materials and Methods: The material consisted of lateral cephalometric radiographs of 45 children with skeletal and dental Class III malocclusion. The first treatment group comprised 15 patients (mean age = 11 years) treated with FM. The second treatment group comprised 15 patients (mean age = 10 years 9 months) treated with DPA-FM. The third group comprised 15 patients (mean age = 10 years 5 months) used as controls. The paired *t* test was used to evaluate the treatment effects and changes during the treatment and observation period in each group. Differences between the groups were determined by variance analysis and the Duncan test.

Results: With the DPA-FM and FM appliances, the SNA and ANB angles increased significantly. These changes were statistically different compared with the control group. Lower facial height showed a greater increase in both treatment groups than in the control group. Molar relation showed a greater increase in the DPA-FM group than in the FM group. The increase in U6/ANS-PNS angle in the FM group was significantly different from the DPA-FM and control groups. The L1/NB angle and Pg-T increased significantly only in the FM group, but no significant difference was found between the treatment groups.

Conclusions: In the treatment of Class III malocclusion, both appliances were effective. The significant sagittal changes in the lower incisors and pogonion in the FM group compared with the nonsignificant changes in the DPA-FM group might be due to the restriction effect of acrylic blocks in the DPA-FM group. (*Angle Orthod.* 2015;85:278–283.)

KEY WORDS: Class III malocclusion; Double-plate appliance; Facemask; Functional

Population *Setting* *Komorbiditäten*	**Klasse-III-Anomalie** Patients with skeletal Class III malocclusion with anterior crossbite, • Turkey
Schweregrad	ANB angle<0°; SNA <82°
Einschluss-kriterien	- Angle Class III malocclusion characterized by an anterior crossbite and/or Class III molar relationship with - skeletal Class III malocclusion(ANB angle<0°) due to maxillary retrusion (SNA <82°) or a combination of maxillary retrusion (SNA <82°)) and mandibular protrusion (SNB >80°)
Ausschluss-kriterien	Congenital anomalies in the craniofacial region

Intervention Versuchsgruppe	**kieferorthopädische Behandlung** **FM Del** Delaire type FM with removable intraoral appliances. The removable intraoral appliance had two Adams clasps at the molars and two F clasps between the upper lateral incisors and canines. The force of the protraction was 350–400 g per side, the angle between the occlusal plane and the direction force applied by the FM was approximately 20°, and the patients were instructed to wear the appliance 16 hours a day. The average treatment time was 9.6 months. **DPA + FM Del** (double-plate appliance/facemask) Construction bites for DPA were taken without sagittal activation and with a 5–6 mm vertical opening at the molar region. The appliances had modified Adams clasps at the molar region and F clasps between the upper lateral incisors and canines. Inclination between the acrylic blocks was 30°. The protraction elastics were attached to the F clasps, a force of 350–400 g was applied per side, and the patients were instructed to wear the mask approximately 16 hours a day. Trimming was done to facilitate the free sliding of the upper and lower pieces of the appliance along the angulated surfacesThe average treatment time was 10.6 months. VERSUCHSGRUPPE 1: **FM Del** N= 15 (Anfang) / N=15 (Ende) / Alter = 11 ♂:♀ = 8:7 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE 2: **DPA + FM Del** N= 15 (Anfang) / N=15 (Ende) / Alter = 10,75 ♂:♀ = 7:8 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE 1: **untreated Class III** N=15 (Anfang) / N=15 (Ende) / Alter = 10,4 ♂:♀ = 6:9 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen** **bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) PRIMÄRZIELGRÖßE: **Skeletal: SNA, SNB, ANB** SEKUNDÄRZIELGRÖßE: **Dental: Overjet**

Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	- In the treatment of Class III malocclusion, both appliances were effective - The changes in molar relationship, overjet, and ANB angle in both treatment groups showed significant differences compared with the control group, so it could be concluded that both appliances are effective in treating subjects with Class III malocclusion. - The removable appliance without the guidance of the angulated surfaces might cause upper molar tippingduring FM therapy. - Significant sagittal changes in lower incisors andpogonion in the FM group compared with the nonsignificant changes in the DPA-FM group might be due to the restriction effect of acrylic blocks in the DPA- FM group - Vertical skeletal changes were similar between the DPA-FM and FM groups
Zusammen-fassung der Ergebnisse	**GRUPPE FM Del VS. untreated Class III** **GRUPPE DPA + FM Del VS. untreated Class III** T1 (pre-treatment): mean age 11 years, FM Del; 10,75 years, DPA+ FM Del; 10,4 years untreated Class III T2 (post treatment/ observation): mean age 11,8 years, FM Del; 11,6 years, DPA+ FM Del; 11,25 years untreated Class III **Skeletal:** **SNA, SNB, ANB**  **Dental:** **Overjet** 

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN)	Die Äquivalenz von Versuch- und Kontrollgruppe wurde nachvollziehbar überprüft. Hinsichtlich der untersuchten Merkmale ist die Äquivalenz gegeben. Power/ Sample Size Berechnungen wurden zwar durchgeführt, deren Aussagekraft sind jedoch möglicherweise eingeschränkt, da von einer Power „very close to 0,80“ gesprochen wird. Eine Verblindung fand nicht statt. Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie noch akzeptabel. Die retrospektive Studie hat klinische Relevanz. *Funding:* keine Angabe *Interessenkonflikte* keine Angabe *Bias (SIGN):* Die Äquivalenz von Versuch- und Kontrollgruppe ist gegeben. Relevanz. Power/ Sample Size Berechnungen wurden unorthodox durchgeführt. Eine Verblindung fand nicht statt. Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie noch akzeptabel. Die retrospektive Studie hat klinische Relevanz.
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: Trotz einiger methodischer Schwächen ist das Gesamtdesign der Studie noch akzeptabel. Die retrospektive Studie hat klinische Relevanz.
Evidenzlevel (SIGN)	**2+**
Qualität (RoB, SIGN)	**Acceptable (+)**

Evidenztabelle **Geran et al. 2006**

A prospective long-term study on the effects of rapid maxillary expansion in the early mixed dentition

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Introduction: The aim of this prospective longitudinal clinical study was to evaluate the short-term and long-term changes in dental-arch dimensions in patients treated with the acrylic splint rapid maxillary expander in the early mixed dentition followed by fixed appliances in the permanent dentition. **Methods:** The dental casts of 51 consecutively treated patients (TG) were compared with those of 26 untreated controls (CG) at 3 different times: pretreatment (T1), after expansion and fixed appliance therapy (T2), and at long-term observation (T3). The mean ages for the TG were 8 years 10 months at T1, 13 years 10 months at T2, and 19 years 9 months at T3. Arch widths, arch depth, arch perimeter, and molar angulation were assessed in all subjects at all observation times. T1-T2, T2-T3, and T1-T3 changes were compared statistically in the TG with respect to the corresponding CG. **Results:** Treatment with an acrylic splint RME followed by fixed appliances produced significantly favorable short-term and long-term changes in almost all maxillary and mandibular arch measurements. The amount of change in both maxillary and mandibular intermolar and intercanine widths fully corrected the initial discrepancies. Approximately 4 mm of long-term relative increase in maxillary arch perimeter, and 2.5 mm additional maintenance of mandibular arch perimeter were observed in the TG compared with the CG. **Conclusions:** These results suggest that this protocol is effective and stable for the treatment of constricted maxillary arches, and can relieve modest deficiencies in arch perimeter. (Am J Orthod Dentofacial Orthop 2006;129:631-40)

Population *Setting* *Komorbiditäten*	**Transversale Anomalie** • The patients examined were part of a prospective clinical investigation, the Michigan Expansion Study, of mixed dentition patients who underwent RME in a private faculty practice.
Schweregrad	keine Angabe
Einschluss-kriterien *Bei Review: PICOS*	• The decision to use RME therapy was based on at least 1 preexisting criterion: crowding, lingual crossbite, esthetics, or tendency toward Class II malocclusion • Before treatment, the following teeth were present: erupted maxillary and mandibular first permanent molars, erupted maxillary and mandibular permanent central incisors, and deciduous second molars
Ausschluss-kriterien	keine Angabe

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** VERSUCHSGRUPPE 1: **RME Group (TG)** Beschreibung: The 51 patients underwent RME with bonded acrylic splints (Fig 1) that covered the maxillary first and second deciduous molars and the maxillary permanent first molars. The midline expansion screw was attached to the appliance with a heavy (.045 in) wire framework and routinely was expanded a quarter turn per day until a buccal crossbite was approached. The transverse molar relationship obtained in most instances involved approximating the lingual cusps of the maxillary posterior teeth and the buccal cusps of the mandibular posterior teeth in the transverse dimension. After expansion, the bonded appliance usually remained in place for an additional 5 months, followed by stabilization with a simple palatal plate with posterior clasps bilaterally. The plate typically was worn full time for 12 months or more and then at night; in a few patients, however, the plate was discontinued after 1 year of retention. A transpalatal arch typically was placed before the loss of the second deciduous molars. In addition, over half of the patients had their maxillary incisors bracketed temporarily for alignment. After the eruption of the permanent teeth, the patients underwent comprehensive nonextraction orthodontic treatment with preadjusted edgewise appliances (phase II). The transpalatal arch was left in place for the duration of treatment in most patients. After phase II, a positioner usually was used to fine-detail the dentition for 3 weeks to 2 months. Then impressions for invisible retainers typically were taken; the patients were instructed to wear the retainers full time for a year. The patients then were advised to wear the invisible retainers at night for an additional year; then they were encouraged to wear them intermittently at night. Most patients were no longer wearing their retainers at the T3 records N=51 (Anfang und Ende) / Alter = 8 Jahre und 10 Monate / ♂:♀ =22:29 • Gebissphase: frühes Wechselgebiss/ spätes Wechselgebiss/permanentes Gebiss <18 • KFO-Behandlung: Frühbehandlung/ reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Control group (CG)** N=26 (Anfang und Ende) / Alter = 8 Jahre und 9 Monate / ♂:♀ = 18:8 • Gebissphase: frühes Wechselgebiss/ spätes Wechselgebiss/permanentes Gebiss <18 • KFO-Behandlung: keine Behandlung
Outcome	**Direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär) • Stabilität des Behandlungsergebnisses ***PRIMÄRZIELGRÖßE:*** Arch width ***SEKUNDÄRZIELGRÖßE*** : Arch depth ***TERTIÄRZIELGRÖßE:*** Arch perimeter ***QUARTÄRZIELGRÖßE:*** Molar angulation

Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	Therapy with an acrylic splint RME in the early mixed dentition followed by fixed appliances in the permanent dentition can be considered an effective treatment option to correct transverse deficiencies of both maxillary and mandibular arches when evaluated in the long term. No active expansion of the mandibular dental arch was undertaken during the mixed dentition. RME followed by fixed appliances can also be considered an option to relieve modest tooth size-arch length discrepancies. Approximately 4 mm of long-term relative increase in maxillary arch perimeter and 2.5 mm additional maintenance of mandibular arch perimeter were observed in the TG when compared with the CG.

Zusammen-fassung der Ergebnisse	***GRUPPE* RME Group (TG) *VS. GRUPPE* Control group (CG)** ***PRIMÄRZIELGRÖßE:*** Arch width At T1, both the maxillary and mandibular dental arches of the patients in the TG were significantly narrower than the corresponding dental arches of the subjects in the CG (Table I). All measurements for maxillary and mandibular arch width (except mandibular intercanine width). The T2-T1 treatment changes with RME followed by fixed appliances produced significantly greater increments in all variables for maxillary and mandibular arch widths (Fig 4) when compared with the controls (Table II). For the T3-T2 changes in the TG vs the CG, no significant differences in the post-treatment changes were found with respect to the CG, except for maxillary first premolar widths (measured both at the centroid and lingually), which showed significantly greater decreases in the TG, and mandibular intermolar arch width (measured both at the centroid and lingually), which increased in the TG and decreased in the CG (Table II). Mandibular arch width measured at the canines (lingually) showed significantly larger decreases in the TG. No statistically significant differences were found between the final forms of the TG and the CG (Table III). The only exception was a slightly larger width in mandibular arch measured at the second premolars (centroid) in the TG with respect to the CG. ***SEKUNDÄRZIELGRÖßE*** : Arch depth Maxillary arch depth showed significantly greater decreases in the TG with respect to the CG. Significantly smaller decreases were recorded in the TG for changes in maxillary arch depth and maxillary arch perimeter when compared with the CG. No statistically significant differences was found between the final forms of the TG and the CG (Table III). ***TERTIÄRZIELGRÖßE:*** Arch perimeter Arch perimeters were significantly smaller in the TG than in the CG. Significant differences in maxillary and mandibular arch perimeters were found in the TG when compared with the CG. For example, maxillary arch perimeter increased 0.9 mm in the TG but decreased 1.8 mm in the CG. Mandibular arch perimeter decreased less in the TG (–2.4 mm) than in the CG (– 4.4 mm). Significantly smaller decreases were recorded in the TG for changes in maxillary arch depth and maxillary arch perimeter when compared with the CG. The statistical comparison of the changes in the overall observation period from T1 to T3 in the TG vs the CG for the most part replicated the results of active treatment changes (T1-T2) (Table II). For example, by contrasting the overall change in maxillary arch perimeter in the TG (0.0 mm) with the same measurement decreases in the CG (–3.8 mm), 3.8 mm more arch perimeter was recorded in the TG. In the mandibular arch, arch perimeter decreased –3.6 mm in the TG and –6.2 mm in the CG, leading to a difference of 2.8 mm more in the TG. No statistically significant differences was found between the final forms of the TG and the CG (Table III). ***QUARTÄRZIELGRÖßE:*** Molar angulation The maxillary permanent first molars also had a significantly greater buccal angulation in the TG than in the CG. As for the changes in molar angulation (Fig 6), in the TG, the maxillary first permanent molars showed a significant tendency for more lingual inclination. No statistically significant differences was found between the final forms of the TG and the CG (Table III).

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign: Fall-Kontroll-Studie, Kontrolle stammt aus* University of Michigan Elementary and Secondary School Growth Study, unklar ob Kontrollgruppe lateralen Kreuzbiss aufwies, Kontrollgruppe deutlich kleiner als Fallgruppe. *Power der Studie/Patientenzahl: Keine Fallzahlberechnung* *Funding: keine Angabe* *Interessenkonflikte: keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* *Publikationsbias (Reviews):* - *Can’t say if the same exclusion criteria are used for both cases and controls.* - *Can’t say if comparison is made between participants and non-participants to establish their similarities or differences.* - *The main potential confounders are not identified and taken into account in the design and analysis.* - *Confidence intervals are not provided.*
Schluss-folgerung des Begutachters	methodische Qualität: akzeptabel
	Klinische Aussagekraft: mittel Transversale Erweiterung mittels GNE führt zu signifikant mehr Vergrößerung der Zahnbogenbreite als reines Wachstum in einer Kontrollgruppe.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**Acceptable ⊕**

Evidenztabelle Ghislanzoni, Baccetti 2013

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Treatment timing of MARA and fixed appliance therapy of Class II malocclusion

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SUMMARY The objective of this study is to evaluate the effect of timing on Mandibular Anterior Repositioning Appliance (MARA) and fixed appliance treatment of Class II malocclusion in a prospective clinical trial. The treated sample consisted of 51 consecutively treated patients at prepubertal (n = 21), pubertal (n = 15), and postpubertal (n = 15) stages of development. Control groups for the three treated groups were generated from growth data of untreated Class II subjects. Lateral cephalograms were digitized and superimposed via cephalometric software at T1 (pre-treatment) and T2 (after comprehensive treatment). The T1–T2 changes in the treated groups were compared to those in their corresponding control groups with Mann–Whitney tests with Bonferroni correction. Mandibular elongation was greater at the pubertal stage (Co–Gn +2.6 mm, with respect to controls). Headgear effect on the maxilla was greater in the pre-peak sample (Co–A −1.9 mm, with respect to controls). Dentoalveolar compensations (proclination of lower incisors, extrusion and mesialization of lower molars, and reduction in the overbite) were significant in the pre-peak and post-peak groups. Optimal timing for Class II treatment with MARA appliance is at the pubertal growth spurt, with enhanced mandibular skeletal changes and minimal dentoalveolar compensations.

Population *Setting* *Komorbiditäten*	**Klasse-II Anomalie** • Details • Details
Schweregrad	wits > 2°, full Class II or end- to- end molar relationships,overjet > 4 mm
Einschluss-kriterien *Bei Review: PICOS*	Keine Angaben
Ausschluss-kriterien	Keine Angaben

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** The MARA (AOA, Sturtevant, Wisconsin, USA) was used according to the original design. Fixed appliances were started together with the MARA or after a few months of active treatment. The developers of the appliance (Toll et al., 2010) recommend at least a 12 month treatment time to achieve a bite jumping or orthopaedic effect. A stepwise advancement protocol with 2 – 3 mm enhancement steps (Du et al. , 2002; Hägg et al., 2008) was used up to a slight overcorrection of Class II dental relationship. VERSUCHSGRUPPE 1: **MARApre Group** **CVM:** CS1 or CS2 at T1 N=21 (Anfang) / N=21 (Ende) / Alter = 9,7 ± 1,2 Jahre / ♂:♀ = ?:? • Gebissphase: frühes Wechselgebiss • KFO-Behandlung: Frühbehandlung VERSUCHSGRUPPE 2: **MARApeak Group** **CVM:** CS3 at T1 N=15 (Anfang) / N=15 (Ende) / Alter = 11,4 ± 1,6 Jahre / ♂:♀ = ?:? • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung VERSUCHSGRUPPE 3: **MARApost Group** **CVM:** CS4 or CS5 at T1 N=15 (Anfang) / N=15 (Ende) / Alter = 14,9 ± 1,8 Jahre / ♂:♀ = ?:? • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Behandlung** The control group consisted of data calculated on longitudinal series of untreated Class II subjects selected from the University of Michigan and Denver Child Growth Studies (Stahl et al. , 2008). The longitudinal series were derived from Class II subjects who matched the treated subjects for Class II dentoskeletal features, age, and skeletal maturation at T1 and T2. The use of historical controls was due to the lack of ethical reasons to leave Class II patients untreated at the developmental period (puberty) that is known to represent the optimal time for orthopaedic modifcations KONTROLLGRUPPE: **Untreated Control Group** N=?? (Anfang) / N=?? (Ende) / Alter = ?? ± ?? Jahre / ♂:♀ = ?:? • Gebissphase: ??? • KFO-Behandlung: ???

Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: *Cephalometric Treatment Effects*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	1. Optimum treatment timing for MARA and fixed appliance therapy of Class II malocclusion appeared to be during the pubertal growth spurt in the permanent dentition. 2. Mandibular length increments were larger and clinically significant at this time. 3. The amount of dentoalveolar compensation (proclination of lower incisors, extrusion and mesialization of lower molars, and reduction in the overbite) was minimal when treatment was performed at puberty, while it was significant in patients treated before or after puberty
Zusammen-fassung der Ergebnisse	**MARA Group (pre, peak, post) VS Untreated Control Group** ***PRIMÄRZIELGRÖßE*** <u>MARApre group</u> Significantly smaller increases in maxillary sagittal position and length were recorded in the MARApre group versus respective controls, while no significant changes occurred in the mandibular skeletal measures. Therefore, the significant improvements in maxillary/mandibular parameters in the MARApre group versus controls were due mainly to the favourable maxillary skeletal changes. As to the vertical skeletal parameters, a significant downward rotation of the palatal plane relative to Frankfort plane was found in the treated group, which led to a significant decrease in the intermaxillary vertical skeletal relationships. All interdental measurements revealed statistically significant differences between the treated group and the controls. In particular, both overjet and overbite were reduced by over 3 mm, and molar relationship showed an improvement of 3 mm as well. No significant maxillary dentoalveolar changes were assessed in the treated group, while most of the mandibular dentoalveolar changes were significant. Lower incisors were significantly proclined, While lower first molars extruded and moved mesially by a significant amount. <u>MARAPeak group</u> No significant changes were recorded for the maxillary skeletal parameters while a significantly greater increase in mandibular length (2.6 mm) was recorded in the group treated at the peak with respect to the controls. This latter significant change led to significant improvements in both the Wits and the maxillo/mandibular differential (− 2.5 and 3.2 mm, respectively). No significant changes were assessed for the vertical skeletal parameters with the exception of a significant decrease in the intermaxillary vertical skeletal relationships. The overjet was significantly reduced by 3 mm and molar relationship showed a significant improvement of 2.8 mm. No significant maxillary dentoalveolar changes were assessed in the treated group.

	MARAPost group No significant changes were recorded either for the maxillary or for the mandibular skeletal parameters in the sagittal plane. However, the maxillary/mandibular parameters presented with significant improvements. No significant changes were found for the vertical skeletal parameters. The overjet was significantly reduced by 1.9 mm, the overbite was reduced significantly by 2.6 mm, and molar relationship showed a significant improvement of 2.7 mm. No signifiant maxillary dentoalveolar changes were assessed in the treated group while most of the Mandibular dentoalveolar changes were significant. Lower incisors were proclined and intruded while first molars extruded significantly.
Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* - *Wenig Angaben zu Studienpopulation, Keine Altersangaben* - *Kaum Aussagen über Kontrollgruppe, Historische Kontrollgruppe* *Durchführung:* - *Wenig Angaben zu Behandler, Keine Angaben zu Compliance* *Auswertung:* - *Test auf Normalverteilung vorhanden, Bonferroni Korrektur erfolgt* *Power der Studie/Patientenzahl: vorhanden* *Funding: keine Angaben* *Interessenkonflikte: keine Angaben* *Bias (SIGN/AMSTAR/Einzelstudien RoB – alle negativen Punkte aus Fragebogen auflisten):* • *Selection bias: historische Kontrollgruppe; wenig Angaben zur Rekrutierung* • *Attrition bias: keine Angabe über Dropouts* • *Detection bias: keine Verblindung* • *Keine Erhebung von Confounders*
Schluss-folgerung des Begutachters	methodische Qualität: befriedigend
	Klinische Aussagekraft: • Der optimale Behandlungszeitpunkt für die MARA-Therapie war das puberale Wachstumsmaximum. • Die Zunahme der UK-Länge war hier am größten und zeigte signifikante Effekte. • Die dentoalveolären Nebenwirkungen (Protrusion der UK-Front; Mesialisation und Extrusion der UK-Molaren; Verringerung des Overbites) waren zum Zeitpunkt des puberalen Wachstumsmaximum minimal. Zu den beiden anderen Zeitpunkten (davor und danach) zeigten sich signifikante dentoaleveoläre Kompensationen.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	**+ Acceptable**

Evidenztabelle Ghislanzoni, Toll et al. 2011

Original Article

Treatment and posttreatment outcomes induced by the Mandibular Advancement Repositioning Appliance; A controlled clinical study

Luis Tomas Huanca Ghislanzoni[a]; Douglas Edward Toll[b]; Efisio Defraia[c]; Tiziano Baccetti[d]; Lorenzo Franchi[d]

ABSTRACT

Objective: To evaluate the treatment and posttreatment dentoskeletal effects induced by the Mandibular Advancement Repositioning Appliance (MARA) in the treatment of Class II malocclusion.

Materials and Methods: The treated sample consisted of 23 consecutively treated patients at prepubertal or pubertal stages, as assessed by the cervical vertebral maturation method. A control group of untreated Class II subjects was generated from published normative growth data. Lateral cephalograms were digitized and superimposed via cephalometric software at three different times: T1, pretreatment; T2, post-MARA treatment; and T3, at least 1 year after T2. The T1–T2, T2–T3, and T1–T3 changes in the treated group were compared to those in the control group with independent-sample Student's *t* tests.

Results: Skeletal and dentoalveolar effects of MARA were assessed after the active phase of the treatment (T1–T2). Mandibular elongation in length (Co-Gn, +2.2 mm) was evident together with lower incisor proclination (IMPA, +5.8 mm). A relapse tendency for IMPA was noticed after removing the appliance (IMPA, −2.1° during T2–T3). Significant skeletal effects (Co-Gn, +2.0 mm) and headgear effects on the maxilla (SNA, −1.2°) were significant in the long term (T1–T3).

Conclusions: The MARA appliance provides an effective correction of Class II malocclusion, which is maintained at a posttreatment observation with a moderate skeletal effect. (*Angle Orthod* 2011;81:684–691.)

KEY WORDS: Fixed functional appliances; Class II malocclusion; Cephalometrics

Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • 23 Patienten mit MARA-Therapie
Schweregrad	ANB ≥ 4°; Okklusion ≥ ½ PB distal
Einschluss-kriterien *Bei Review: PICOS*	• ANB greater than or equal to 4° • full Class II end-to-end molar relationships • follow-up observation at least 1 year after the end of comprehensive treatment with MARA and fixed appliances
Ausschluss-kriterien	Keine Angabe

Intervention Versuchsgruppe	**Kieferorthopädische Behandlung** All patients were consecutively treated by the same operator with MARA (AOA, Sturtevant, Wis) and fixed appliances followed by removable retention in a private practice setting. No subjects underwent extraction of teeth as part of the treatment protocol, nor did any undergo maxillary expansion concurrent with the use of the MARA appliance. The MARA inclined plane works as an obstacle to be avoided during closure, inducing the lower jaw to move forward. This is supposed to favor a neuromuscular re-education during correction of the Class II dentoskeletal relationship. During treatment with the MARA it is also possible to use other appliances (like fixed appliances or rapid palatal expander) to better address specific patient needs and to shorten treatment duration. The developers1 of the appliance recommend a 12-month treatment time to achieve a bite-jumping or orthopedic effect. Stabilization of the lower molars is assisted by the fitting of a lingual arch, which is constructed at a 2-mm to 3-mm distance from the lingual surface of the lower incisors in order to prevent proclination of these teeth. This appliance does not require the placement of attachments on teeth other than the first molars. A stepwise advancement protocol with 2–3-mm enhancement steps 17–19 was used up until the point that a slight overcorrection of the Class II dental relationship was achieved. Fixed appliances were initiated together with the MARA or after a few months of active treatment. The T1–T2 interval provided information about the active treatment with the MARA appliance. The T2–T3 interval gave data about posttreatment changes that included a phase of finishing treatment with fixed appliances. The T1–T3 interval provided information about the overall effects induced by MARA during treatment and posttreatment intervals. VERSUCHSGRUPPE: **MARA Group** N=23 (Anfang) / N=23 (Ende) / Alter = 10,2 ± 1,5 Jahre / ♂:♀ = keine Angabe • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung
Kontrolle Kontrollgruppe	**Keine kieferorthopädische Therapie** KONTROLLGRUPPE: **Untreated Control Group** The control ‘‘group’’ comprised data calculated on longitudinal series of 17 untreated Class II subjects selected from the University of Michigan and Denver Child Growth Studies.16 The longitudinal series consisted of Class II subjects who matched the treated subjects for Class II dentoskeletal features at T1, sex distribution, age, and skeletal maturation (CVM stages) at T1, T2, and T3. The use of historical controls was due to the lack of ethical reasons to leave Class II patients untreated at the developmental period (puberty), which is known to represent the optimal time for orthopedic modifications. N=17 (Anfang) / N=17 (Ende) / Alter = keine Angabe / ♂:♀ = keine Angabe • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: keine Therapie
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: *Cephalometric Treatment Effects*
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**

Schluss-folgerungen der Autoren	• When compared to matched untreated Class II controls, the MARA produces favorable skeletal changes (mandibular elongation, maxillary growth restriction, ANB decrease), although modest in entity, and dentoalveolar changes (overjet and overbite decrease, molar relationship correction) are maintained at an average 1-year posttreatment observation. • Lower incisor proclination is limited, probably as a result of fixed appliance treatment used concurrently with MARA.
Zusammen-fassung der Ergebnisse	**MARA Group VERSUS Untreated Control Group** ***PRIMÄRZIELGRÖßE*** All cephalometric variables contributing to Class II correction showed significantly favorable changes (ANB angle, 21.4°; Wits, 22.1 mm; overjet, 22.8 mm). A ‘‘headgear effect’’ was observed in the maxilla (A to Nasion perpendicular, 20.8 mm), while total mandibular length (Co-Gn) and ramus height (Co-Go) increased significantly more in cases than in controls (+2.2 mm and +2.3 mm, respectively), thus enhancing a favorable differential growth pattern (Max/Mand differential, +2.8 mm). The lower incisors exhibited sagittal advancement and proclination (+5.8°) relative to the mandibular plane. The lower molars were also significantly advanced (+1.0 mm) and showed some extrusion (+0.9 mm). There were no adverse effects on the vertical dimension with any significant change on vertical measures. T2–T3 interval changes and statistical comparison are reported in Table 2. Only minor posttreatment changes were noted as a slight, but significant, relapse (22.2°) in the excessive proclination of the lower incisors. The ‘‘headgear effect’’ on the maxilla (SNA, 20.9°) continued during this phase. The headgear effect (SNA, 21.2°; A to Nasion per, 21.4 mm) on the maxilla was associated with mandibular supplemental elongation (Co-Gn, +2.0 mm). ANB angle (21.8°), Wits (21.8 mm), overjet (23.3 mm), and overbite (21.4 mm) showed significantly greater decreases in MARA patients when compared to Class II controls. A vertical effect was present, with a slight opening of the Frankfurt to palatal plane angle (+1.3°) and an increase of the lower third of the face (ANS-Me, + 1.8 mm) in the MARA group. The lower incisors were proclined (+3.7°), with a tendency for the mandibular first molar to extrude (+1.6 mm) in the MARA group vs controls.

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • *Retrospektiv* • *Historische Kontrollgruppe (mit guter Begründung, dass heute aufgrund Ethik nicht mehr möglich)* • *Wenig Angaben zur Demographie (Alter, Geschlechtsverteilung)* • *Aufgrund der fehlenden Angaben ist Matching nicht beurteilbar* *Durchführung:* • *Reliabiliät der Intervention unklar, da wenig beschrieben* • *Compliance der Patienten nicht erfasst* • *Keine Verblindung in Intervention/Outcome-Erhebung* *Auswertung:* • *Reliabilitätstest vorhanden* • *Solide Statistik (Shapiro-Wilk, t-Test)* • *Keine Konfidenzintervalle* *Power der Studie/Patientenzahl: vorhanden* *Funding: keine Angabe* *Interessenkonflikte: keine Angabe* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • *Selection bias: historische Kontrolle, wenig Angaben zur Rekrutierung* • *Detection bias: keine Verblindung* • *Keine Erhebung von Confounders*
Schluss-folgerung des Begutachters	methodische Qualität: befriedigend
	Klinische Aussagekraft: Im Follow nach 1 Jahr führte die MARA im Vergleich zur unbehandelten Kontrollgruppe zu: • Einer Verlängerung des UK • Wachstumshemmung im OK • Verkleinerung des ANB-Winkels • Dentoalveoläre Veränderungen (Verkleinerung OJ/OB; Korrektur der Molarenrelation) Die Protrusion der UK-Frontzähne wurde vermutlich durch die parallel eingesetzte MB-Apparatur in geringem Maße gehalten.
Evidenz-level (SIGN)	**2+**
Qualität **(RoB, SIGN /AMSTAR II)**	⊕ Acceptable

Evidenztabelle Giuntini et al. 2015

Treatment effects produced by the Twin-block appliance vs the Forsus Fatigue Resistant Device in growing Class II patients

Veronica Giuntini[a]; Andrea Vangelisti[a]; Caterina Masucci[a]; Efisio Defraia[b]; James A. McNamara Jr[c]; Lorenzo Franchi[d]

ABSTRACT

Objective: To compare the dentoskeletal changes produced by the Twin-block appliance (TB) followed by fixed appliances vs the Forsus Fatigue Resistant Device (FRD) in combination with fixed appliances in growing patients having Class II division 1 malocclusion.

Materials and Methods: Twenty-eight Class II patients (19 females and 9 males; mean age, 12.4 years) treated consecutively with the TB followed by fixed appliances were compared with a group of 36 patients (16 females and 20 males; mean age, 12.3 years) treated consecutively with the FRD in combination with fixed appliances and with a sample of 27 subjects having untreated Class II malocclusion (13 females and 14 males; mean age, 12.2 years). Mean observation interval was 2.3 years in all groups. Cephalometric changes were compared among the three groups by means of ANOVA and Tukey's post hoc tests.

Results: The FRD produced a significant restraint of the maxilla compared with the TB and control samples (SNA, −1.1° and −1.8°, respectively). The TB sample exhibited significantly greater mandibular advancement and greater increments in total mandibular length than either the FRD or control groups (SNB, 1.9° and 1.5°, respectively; and Co-Gn, 2.0 mm and 3.4 mm, respectively). The FRD produced a significantly greater amount of proclination of the mandibular incisors than what occurred with the TB or the control samples (2.9° and 5.6°, respectively).

Conclusion: The TB appliance produced greater skeletal effects in terms of mandibular advancement and growth stimulation while the Forsus caused significant proclination of the mandibular incisors. (Angle Orthod. 2015;85:784–789.)

KEY WORDS: Functional jaw orthopedics; Class II malocclusion; Cephalometrics

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Population *Setting* *Komorbiditäten*	**Klasse-II-Anomalie** • Class II division 1 malocclusion patients • The two treatment groups were derived from two private practices (Dr Forbes Leishman of Auckland, New Zealand, and Dr Lisa Alvetro of Sydney, Ohio, for having provided the samples treated with the Twin-block and the Forsus) • Kontrollgruppe aus verschiedenen Growth studies (of the University of Michigan Growth Study, the Denver Child Growth Study, the Bolton-Brush Growth Study)
Schweregrad	Class II dentoskeletal relationships having an overjet larger than 5 mm a full cusp or end-to-end Class II molar relationship and an ANB angle larger than 3°
Einschluss-kriterien *Bei Review: PICOS*	• Class II dentoskeletal relationships having an overjet larger than 5 mm • a full cusp or end-to-end Class II molar relationship • an ANB angle larger than 3°

Ausschluss-kriterien	---
Intervention Versuchsgruppe	**kieferorthopädische Behandlung** VERSUCHSGRUPPE 1: **Twin Block (TB)** N= 28 (Anfang) / N=28 (Ende) / Alter = 12,4 ± 1,0 Jahre / ♂:♀ = 9:19 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung *All patients underwent a specific nonextraction treatment protocol with 0.0220-slot after the TB.* VERSUCHSGRUPPE 2: **Forsus Fatigue Resistant Device (FRD)** N= 36 (Anfang) / N=36 (Ende) / Alter = 12,3 ± 1,2 Jahre / ♂:♀ = 20:16 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: reguläre Behandlung *All patients underwent a specific nonextraction treatment protocol with 0.0220-slot, preadjusted fixed appliances in combination with the FRD*
Kontrolle Kontrollgruppe	**keine kieferorthopädische Therapie** KONTROLLGRUPPE: **untreated control** N=27 (Anfang) / N=27 (Ende) / Alter = 12,2 ± 0,8 Jahre / ♂:♀ = 14:13 • Gebissphase: spätes Wechselgebiss • KFO-Behandlung: keine
Outcome	**direkter oder schadenspräventiver medizinischer Nutzen bzw. Korrektur/Prävention der Anomalie/Malokklusion/Dysgnathie** • **primäres kieferorthopäd. Behandlungsergebnis (skelettal/dentoalveolär)** PRIMÄRZIELGRÖßE: Cephalometric skeletal and dentoalveolar treatments effets
Studientyp	**Beobachtungsstudie (Kohortenstudie oder Fall-Kontroll-Studie)**
Schluss-folgerungen der Autoren	• Both treatment protocols (TB and FRD) were effective in correcting Class II malocclusion, with over an 80% success rate noted in consecutively treated patients in both groups. • The TB produced greater skeletal effects than did the FRD in terms of mandibular advancement and growth stimulation. • The Class II correction induced by the FDR was more dentoalveolar than was the TB, with a large amount of proclination of the mandibular incisors.

Zusammen-fassung der Ergebnisse	**TB VS. untreated control** ***PRIMÄRZIELGRÖßE*** Cephalometric skeletal and dentoalveolar treatments effets The TB sample exhibited significantly greater mandibular advancement as measured by the SNB angle compared with the control groups (1.5°). These changes led to significantly greater decreases in the ANB angle in the TB sample with respect to the control groups (-0.2°) The TB sample showed significantly greater increments in total mandibular length (Co-Gn) than did the control groups (3.4 mm). As for the changes in vertical skeletal relationships, no statistically significant differences were found among the three groups for any of the angular measurements except for the FH to mandibular plane angle, which showed a significantly greater increase (1.5u) in the TB sample compared with the control group. The TB produced significantly greater decreases than in the controls in both overjet (-7.9 mm) and overbite (-3.2 mm). Both the TB induced significantly greater increases in molar relationships than in the controls (4.8 mm). The maxillary incisors showed a significantly greater amount of retroclination in the TB group compared with the control groups (-6,3°). **FRD VS. untreated control** ***PRIMÄRZIELGRÖßE*** Cephalometric skeletal and dentoalveolar treatments effets With respect to the T1–T2 changes (Table 3), the FRD produced a statistically significant restraint in the sagittal skeletal position of the maxilla (SNA) compared with the control samples (-1.8°). Greater decreases in the ANB angle in the FRD sample compared with the control groups (-1,4°). The FRD produced significantly greater decreases than in the controls in both overjet (-5.0 mm) and overbite (-3.0 mm). The FRD induced significantly greater increases in molar relationships than in the controls (3.3 mm). The FRD produced a significantly greater amount of mandibular incisor proclination with respect to the control sample (5.6°).

Angaben auffälliger positiver und/oder negativer Aspekte Studiendesign Durchführung Auswertung Funding Interessen-konflikte Bias (SIGN, AMSTAR II, Einzelstudien)	*Studiendesign:* • Retrospektiv • Suffizientes Matching • Baseline-Imbalancen, vor allem in Bezug auf Overjet *Durchführung:* • Versuchsgruppen aus unterschiedlichen Praxen, 1 Behandler pro Praxis • Standardisiertes Behandlungsprotokoll *Auswertung:* • Reliabel • Verblindung der auswertenden Personen • p-Wert-Adjustierung auf Mehrfachvergleich erfolgt (post-hoc-test) *Power der Studie/Patientenzahl:* Poweranalyse vorhanden, ausreichende Patientenzahl *Funding: ---* *Interessenkonflikte: ---* *Bias (SIGN/AMSTAR/EinzelstudienRoB – alle negativen Punkte aus Fragebogen auflisten):* • Have confidence intervals been provided?- No (sign)
Schluss-folgerung des Begutachters	methodische Qualität: gut
	Klinische Aussagekraft: Behandlung mittels Twin block und nachfolgender Multibracketapparatur führt im Vergleich zu ausbleibender Behandlung bei Kl-II-Patienten zu UK-Vorverlagerung, ccw Rotation des UK, Verringerung des OJ und OB, Verbesserung der Okklusion und Retrusion der OK-Frontzähne. Behandlung mittels Forsus und Multibracketapparatur führt im Vergleich zu ausbleibender Behandlung bei Kl-II-Patienten zur Verringerung des OJ und OB, Verbesserung der Okklusion und Protrusion der UK-Frontzähne. Ausbleibende signifikante skelettale Effekte eventuell aufgrund von zu kurzen Therapiedauer mit Forsus (6 Monate)
Evidenz-level (SIGN)	**2++**
Qualität **(RoB, SIGN /AMSTAR II)**	**High quality (++)**

Evidenztabelle **Godoy et al. 2010**

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Treatment of posterior crossbite comparing 2 appliances: A community-based trial

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Introduction: The aim of this community-based trial was to compare the effectiveness of the quad-helix appliance and removable plates for treating posterior crossbite. **Methods:** Ninety-nine patients were randomly divided into 3 groups: quad-helix, expansion plate, and untreated. All subjects were in the mixed dentition, had posterior crossbite, no sucking habits, no previous orthodontic treatment, and no Class III malocclusion. The following aspects were evaluated: posterior crossbite correction, maxillary and mandibular intermolar and intercanine expansions, length of treatment, cost-benefit analysis, success rate, and number of complications. **Results:** The length of treatment and the costs were higher in the expansion plate group than in the quad-helix group. The success rates were similar for the quad-helix and the expansion plate groups, and the number of complications was higher in the quad-helix group. No self-correction was observed in the untreated group, and relapses occurred in both experimental groups. **Conclusions:** The average treatment time was significantly shorter and 11% less expensive than in the quad-helix group, making it the more cost-effective choice for treatment. (Am J Orthod Dentofacial Orthop 2011;139:e45-e52)

Population *Setting* *Komorbiditäten*	**Transversale Anomalie** Community-based trial; Santa Amaro favela, Recife, Brazil
Schweregrad	Keine Angabe
Einschluss-kriterien *Bei Review: PICOS*	skeletal posterior crossbite
Ausschluss-kriterien	sucking habit; previous orthodontic treatment; Class III malocclusion