Justus-Liebig-Universität Gießen

Fachbereich Medizin

Zentrum für Zahn-, Mund- und Kieferheilkunde - Poliklinik für Kieferorthopädie

Oral health effects, outcome quality and stability of orthodontic Class II:1 therapy

Mundgesundheitseffekte, Ergebnisqualität und Stabilität der kieferorthopädischen Klasse II:1-Therapie

Habilitationsschrift
zur Erlangung der Lehrbefähigung für das Fach Kieferorthopädie
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„Das Einzige, was auf Dauer zählt, sind die Menschen, die uns begleiten - die guten."

Fabian Sixtus Körner

Meinen Lehrern und Förderern

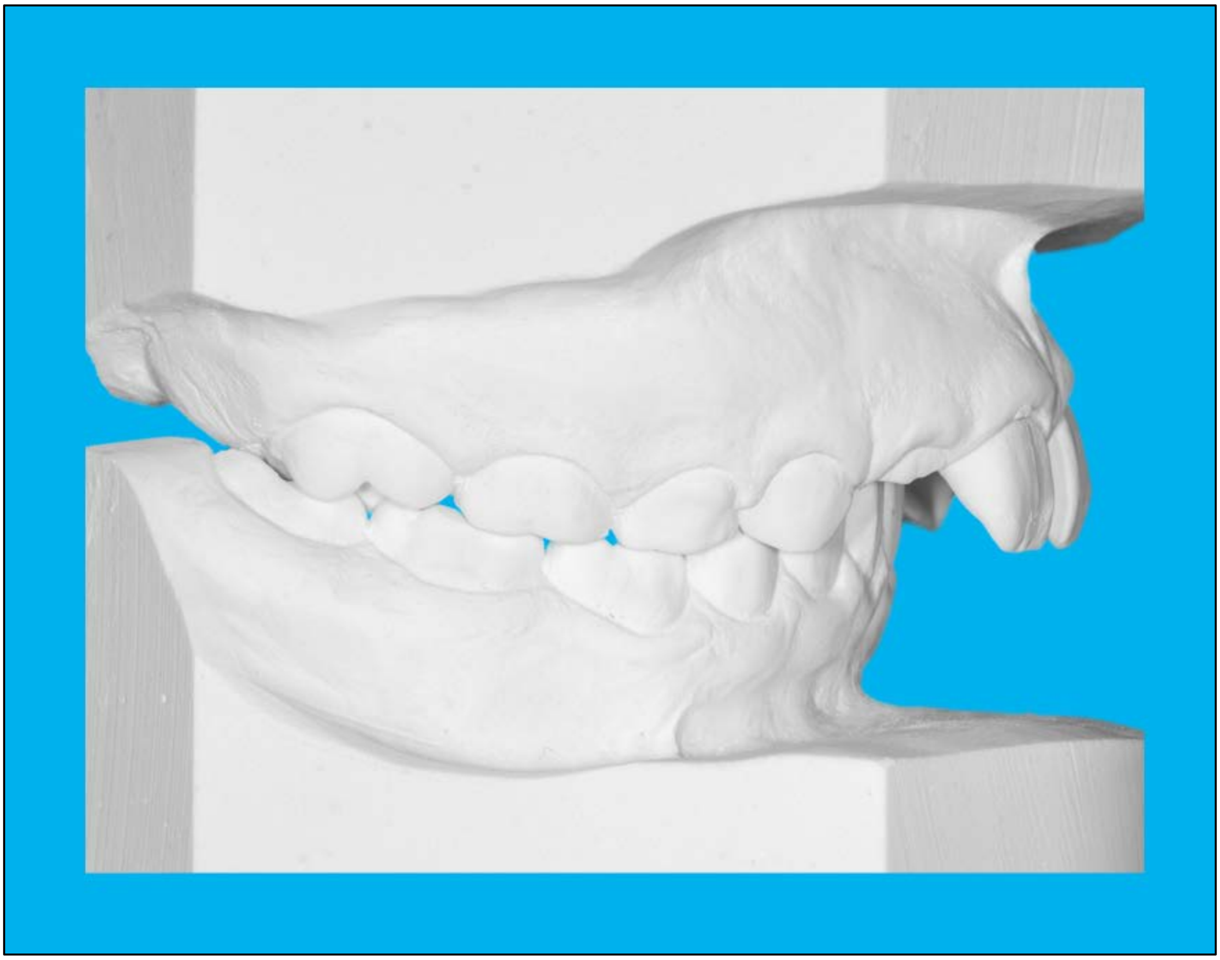
sowie meinen Eltern

1. Introduction

Class II:1 malocclusions - characteristics and prevalence

The prevalence for Class II:1 malocclusions ranges between 8.1 and 16.2% in Caucasians [182,455,460]. Class II:1 malocclusions (Figure A) are characterised by a sagittal discrepancy between the upper and the lower jaw resulting in an increased overjet as well as the lower teeth being positioned posteriorly compared to a "normal" Class I relationship. The original definition for this malocclusion was published by Edward Angle in 1899 [21].

Figure A Class II:1 malocclusion, characterised by a posteriorly positioned mandible resulting in an increased overjet (anterior-posterior distance between the labial surfaces of the upper and the lower incisors)



The underlying pattern of a Class II:1 malocclusion might be either skeletal or dental or a combination of both [271,285,338,401,402,496,497]. For the maxilla, this means that either the whole alveolar process including the dentition is located too far anterior in relation to the cranial base (maxillary protrusion), or that only the dentition is positioned too far anterior in a correctly located maxilla, which is often accompanied with notably proclined incisors. For the mandible, a posterior location of the jaw in relation to the cranial base (mandibular retrusion) might be seen or a correctly located jaw carrying a too far posteriorly positioned dentition. Of course, combinations of all kind are conceivable. Both, endogenous and exogenous factors may contribute to this aetiology [244,251,252,266,368,451,452] - with the detailed mechanisms still being unknown. In terms of possible endogenous causes, genetic influences of both hereditary and syndromic origin might be responsible for respective growth developments [106,124,266,451,452], while mainly functional, habitual influences like atypical swallowing or thumb-sucking are considered as exogenous causes [368].

Class II:1 malocclusions - treatment indications

The indications for treating the sagittal discrepancy in Class II:1 malocclusions treatment are diverse and the reasons can be divided into three main categories: functional, prophylactic and psychological/psychosocial.

In terms of functional reasons, the main treatment objectives are related to improving the ability to bite and chew [128,172,222,255,354,449,484], enabling lip closure and physiological breathing [471,498] as well as reducing temporo-mandibular joint overload [276,283,336]. Apart from that, prophylactic treatment indications as reducing the risks for incisor trauma [37,39,192,293,300, 350,461] and periodontal disease [9,13,43,404] as well as psychological/psychosocial treatment indications which are mainly about improving aesthetics and quality of life [90,109, 130,191,206,243,298,305,400,413,415,419-422,427,443] are of similar importance.

Class II:1 malocclusions - treatment options

Orthodontic Class II:1 correction has been undertaken since the late 19^{th} century. While several treatment approaches aimed at either restricting maxillary growth or compensating the skeletal features of the malocclusion, others aimed at stimulating mandibular growth. The treatment approach of "jumping the bite" was introduced in 1877 [216]. Multiple removable (Figure B) and fixed appliances have been designed and used since then and the term "functional appliances" developed. This was based on the fact that some of the appliances targeted at incorporating the whole stomatognathic system and its function including the musculature and the forces generated by them. Most of these appliances are removable appliances depending strongly on patient compliance [26,82,167,237,339,355], and as such being a factor of uncertainty in Class II therapy that can be eluded using fixed functional appliances like for example the Herbst appliance (Figure C) [174,317,334].

In addition, various treatment concepts focussing predominantly on orthodontic measures with or without tooth extractions as well as surgical interventions are commonly used.

Figure B Removable functional appliance for Class II:1 correction (Andresen-Activator)

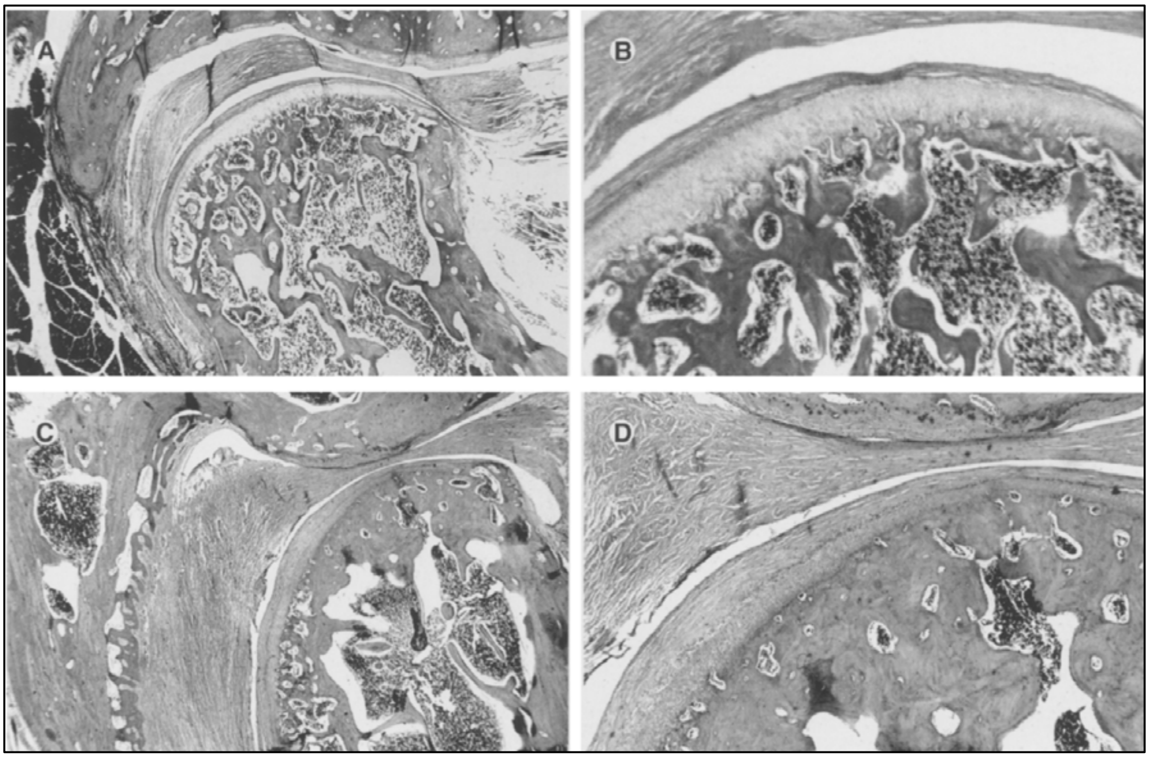
Figure C   Fixed functional appliance for Class II:1 correction (Herbst appliance)

Class II:1 malocclusions - Basic research

The possibility of growth stimulation in the temporomandibular joint (dentofacial orthopaedics) by continuous bite jumping has been shown in several animal experiments [38,73,177,270,272,273,349,365,442,480,481,493,494]. These studies demonstrated histologically that bone resorption occurs in the anterior part of the condyle while bone apposition takes place in the posterior part [127,272]. In monkeys (*Maccaca mulatta*), the initiation of appositional processes was seen after only two weeks, when hyperplasia of the prechondroblastic-chondroblastic zone occurred; the maximum was reached after 6 weeks of bite jumping [178]. After 12 weeks no more modelling changes could be detected when comparing to untreated controls (Figure D) [275,442].

Using magnetic resonance imaging technology, similar modelling changes were also shown in humans [336,388-390,392].

<u>Figure D</u> The temporomandibular joint regions of two adult 12-week experimental animals. Lower power views (A and C). Higher power views (B and D). Increased proliferation of the condylar cartilage can be observed in all views. Deposition of new bone can be observed along the anterior border of the postglenoid spine in C. This animal unintentionally had the largest amount of bite advancement (6 mm); reprinted from: “McNamara JA Jr, Peterson JE Jr, Pancherz H. Histologic Changes Associated With the Herbst Appliance in Adult Rhesus Monkeys (Macaca mulatta). Semin Orthod 2003;9:26-40” by permission of Elsevier



Animal experiments in rats confirmed the possibility of mandibular growth stimulation by dentofacial orthopaedics [359,364] and investigated the underlying cell-biological processes. For example it was found out that fibroblasts do organise in the temporomandibular joint disc’s posterior fibres’ force direction [364]. Furthermore, the protein Indian hedgehog (Ihh) is an essential mediator of mechanotransduction during mandibular advancement; therefore it is a major factor for stimulating cell proliferation in the condyle [454]. It was also shown that mandibular bite jumping triggers the expression of messenger parathyroid hormone-related protein (PTHrP) in condylar cartilage, which initiates the transformation of mesenchymal stem cells into chondroblasts [363].

The differentiation of chondrocytes is influenced by the transcription factor SOX9, which - upon mandibular advancement - is expressed at a higher level in the glenoid fossa. A similar mechanism exists for collagen II [359,360]. In addition, an elevated excretion of collagen X from hypertrophic chondrocytes was found in the hypertrophic layer [357]. At the same time an increased excretion of neovascularisation regulating vascular endothelial growth factor (VEGF) occurred [357,358,361], which seems to be significantly involved in bone formation in the posterior part of the glenoid fossa [361] and the condyle [358]. Core-binding factor alpha 1 (Cbfa1) and runt-related transcription factor 2 (Runx2) are also released at higher levels, indicating major roles of these factors in the coordination of osteoblasts, chondrocytes and osteoclasts in the condyle [362,453].

<u>Table A</u> Heretofore known cell-biological processes occurring in the temporomandibular joint during mandibular growth stimulation according to experiments in rats (significant changes in bold)

Parameter	Location			Experiment duration (days)														
				1	3	5	7	9	11	14	17	21	30	33	37	44	51	60
PTHrP expression	condylar cartilage				**↑**		**↑**			**↑**		↑	↑					
Collagen X	condylar cartilage				0		↑			**↑**		**↑**	**↓**					
Runx2 expression	condylar cartilage				↑		**↑**			**↑**		**↑**	**↑**					
Ihh expression	condylar cartilage				**↑**		**↑**			↑		↑	↑					
VEGF expression	condyle	anterior			↓		↓			↓		**↑**	**↑**	0	0	0	↑	↑
VEGF expression	condyle	middle			0		0			**↑**		**↑**	**↑**	↓	0	↑	↑	↑
Collagen II	condyle	posterior	not further specified	↑	↓	↑	**↑**	↓	↓	↓	↑							
VEGF expression	condyle	posterior	not further specified		↑		↑			**↑**		**↑**	**↑**	**↑**	↑	↑	↑	↑
SOX 9 expression	condyle	posterior	hypertrophic zone	**↓**	↓	↓	**↑**	↑	↑	0	0							
SOX 9 expression	condyle	posterior	proliferative zone	**↓**	**↑**	**↑**	**↓**	**↓**	**↓**	**↓**	↓							
VEGF expression	glenoid fossa	not further specified			↑		↑			**↑**		**↑**	↑	↑	0	**↓**	**↑**	↑
SOX 9 expression	glenoid fossa	posterior		↑	**↑**	**↑**	↓	↑	**↑**	**↑**	**↑**							
Collagen II	glenoid fossa	posterior		**↑**	**↑**	**↑**	**↑**	**↑**	**↑**	**↑**	**↑**							

However, continuing chronologically further, variations in post-treatment growth of the condyle and the fossa depending on the duration of mandibular advancement and growth stimulation, respectively, were discovered [85]. For example, comparing to untreated control animals, more newly formed bone was seen in rats undergoing

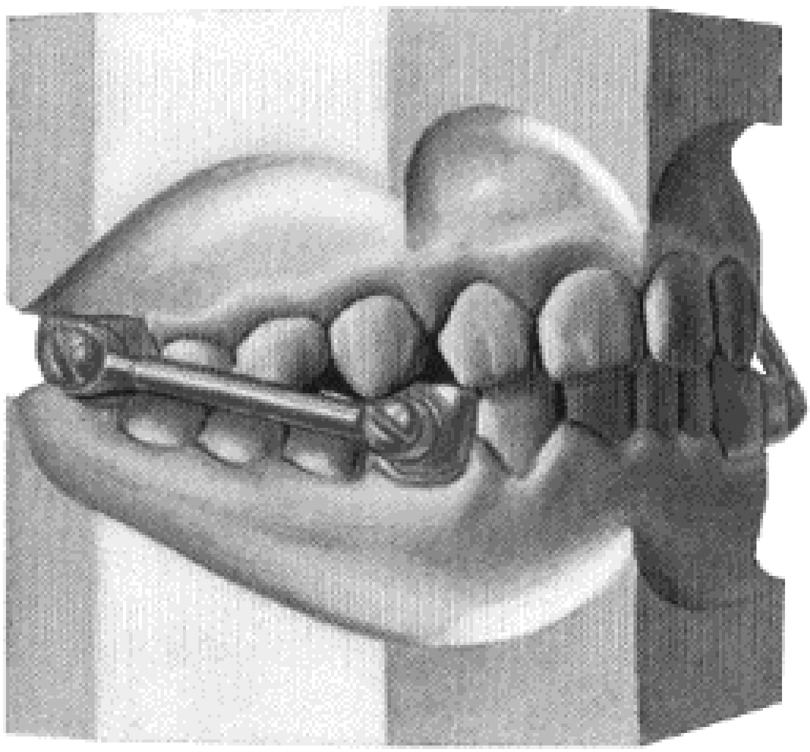
30 days of mandibular advancement. However, after a post-treatment phase of 14 days (without appliance-induced mandibular advancement), less bone formation was seen in the experimental animals than in the controls [85]. This subnormal growth behaviour might be the basis for relapse seen in clinical treatment of humans. Interestingly, no such behaviour was seen after a longer duration (44 days) of mandibular advancement. The authors suspected a difference in the collagen I (↑) to collagen III (↓) ratio to be responsible for a more stable bone configuration after a longer period of mandibular advancement [85]. Taking into account that other publications also considered collagen III as a kind of “less stable” repair collagen in the temporomandibular joint, the latter assumption seems to be reasonable. However, no further investigation of this topic has been undertaken so far.

Herbst appliance

As already mentioned above, the Herbst appliance is a fixed functional appliance. It was first introduced by Emil Herbst in 1909 (Figure E) [174,175].

During the first half of the 20th century, however, the appliance felt almost into oblivion until it was rediscovered by Hans Pancherz in 1977 [309]. Since then, it has been studied extensively concerning its effects on both skeletal and dental structures. Clinical and experimental studies demonstrated the general mode of action [16,33,40,80,92,94,99,102,140,154,156,161,218,223,232,259,274,292,309-315,329,332,334,342,386,387,390,403,426,464,473,488-491] in form of growth inhibition in the upper jaw [321] and growth stimulation in the lower jaw [311,331,342, 343,344,488] as well as tooth movements to the posterior in the upper jaw and to the anterior in the lower jaw [35,311,330]. In addition, the effects on the temporomandibular joint [31,34,86,162,179,328,335,336,388-390,392,432] as well as the musculature [179,240,319,320] were assessed. While Herbst appliance treatment is usually performed in the permanent dentition, skeletal maturity was shown to be of minor importance in terms of treatment success respectively treatment efficiency [367,383,475].

Figure E Herbst appliance as originally described by Emil Herbst in 1909; reprinted from: "Herbst E. [Atlas und Grundriß der Zahnärztlichen Orthopädie]. J.F. Lehmanns Verlag, München, Germany, 1910; p. 433"

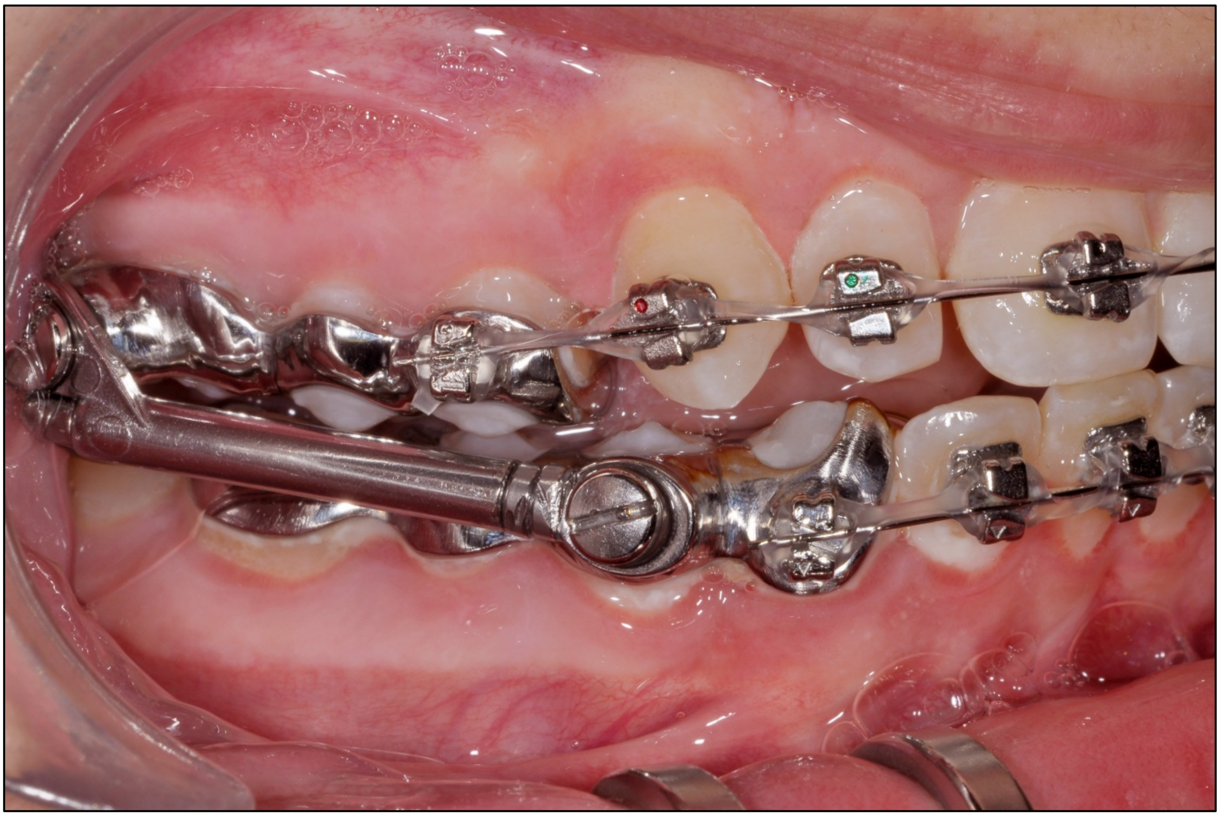


The appliance was shown to be effective in various Class II malocclusions including cases with severe underlying dentoskeletal features which are often expected to be difficult to treat [52,53,57,102,327,333,342,356,390,391,405] and to offer a respectable treatment alternative to surgical mandibular advancement in borderline cases [57,393]. Furthermore, recent studies have demonstrated positive effects regarding the influence on pharyngeal airway width [83,116,188-190,221,236,410].

While the design of the appliance used in the late 1970s was only slightly different from the original one described by Emil Herbst [174], a notable modification was introduced during the late 1980s. This modification, however, was supposed to primarily affect the attachment on the dentition in terms of anchorage and not the mode of operation as the Herbst telescoping mechanism was now attached to casted splints (incorporating teeth 4-6/7 of the upper and teeth 3-6/7 of the lower dentition) instead of bands on a few teeth per jaw only [317]. This modification proved to be less prone to breakages [156,398,408] as well as to reduce the unwanted side effect of anchorage loss [126,478,485]. In addition, the Herbst appliance can be combined with a headgear [117,153] or a rapid maxillary expansion screw [313]. Furthermore, Herbst appliance treatment has routinely been combined with/followed by a phase of multibracket appliance treatment since the mid-80s (Figure F) [334].

Nevertheless, the crucial advantages of the Herbst appliance in its current form are still the same as more than 100 years ago: as the appliance - which functions like an artificial joint between the upper and the lower jaw - is usually used as a fixed appliance, it is worn 24h/day and therefore continuous growth stimulation can be expected. In addition, patient compliance is of minor concern only [299]. Due to these advantages and the favourable research outcomes published since the early 1980s, the Herbst appliance became increasingly popular all around the world, making it the second most popular functional appliance in the US [211]. In Germany, the appliance is nowadays used by the majority (74%) of orthodontists as was determined in a recent survey [129]. In addition, numerous appliances which are based on a similar mechanism have been developed and introduced into the market during the last decades [41,66,340,409].

Figure F Herbst-Multibracket appliance: clinical situation with mandible advanced into an anterior edge-to-edge relationship



Outcome quality

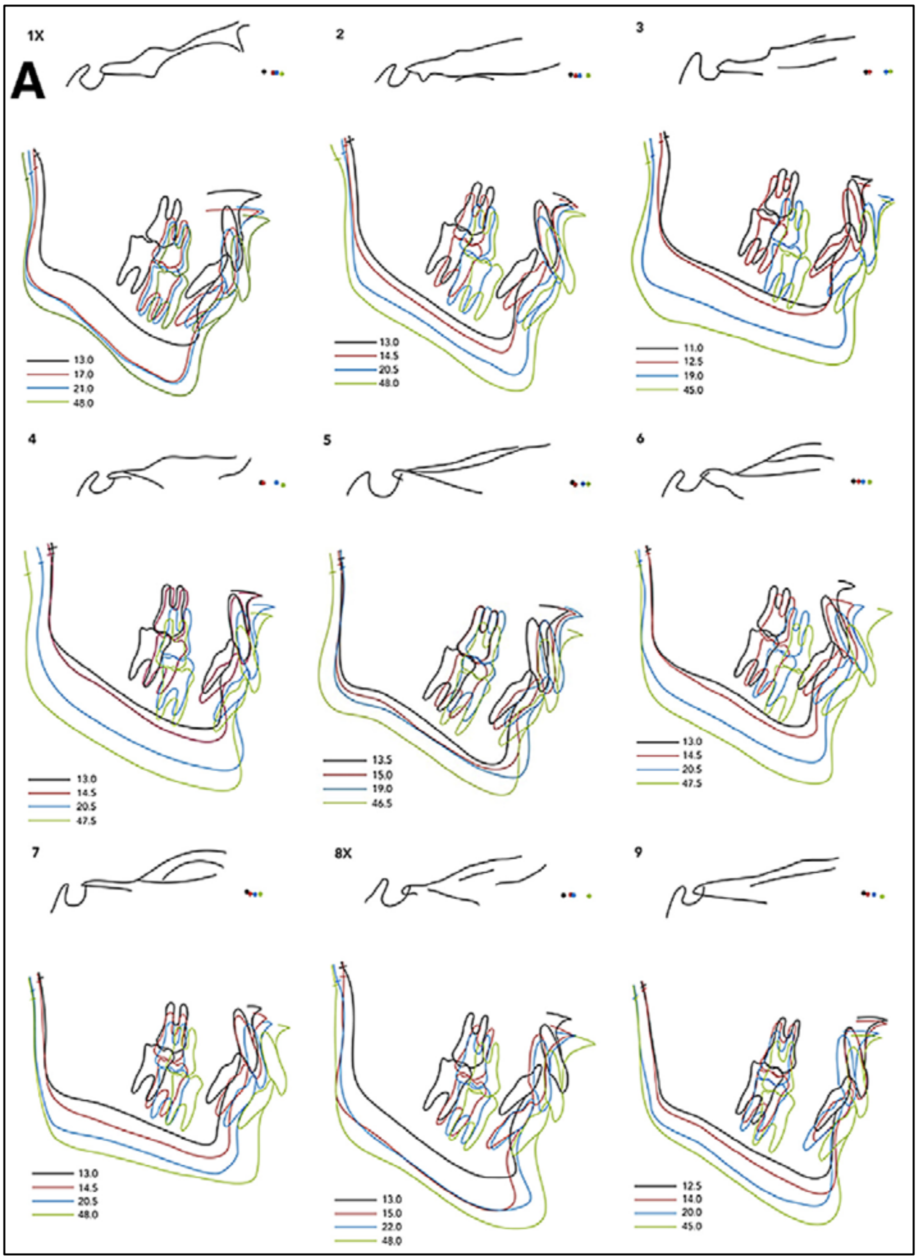
As in general medicine the outcome quality of orthodontic treatment is difficult to assess. According to the German Federal Social Court in 1998 “any kind of medical treatment procedure has to be based on a specific theoretical-scientific concept differentiating it from other procedures and justifying its systematic application in the examination and treatment of specific diseases” in order to qualify for cost coverage by the social security system [147]. However, there is no general agreement on definitions of success and failure in orthodontics. Aims like “achieving an individual, functional and aesthetic optimum” [18] and “establishing normal occlusion (as close to Angle’s ideal occlusion as possible)” [6] which are based on rather subjective judgement of clinicians can be found in the literature. Accordingly, the number of applicable tools is rather low with the majority being more subjective than objective

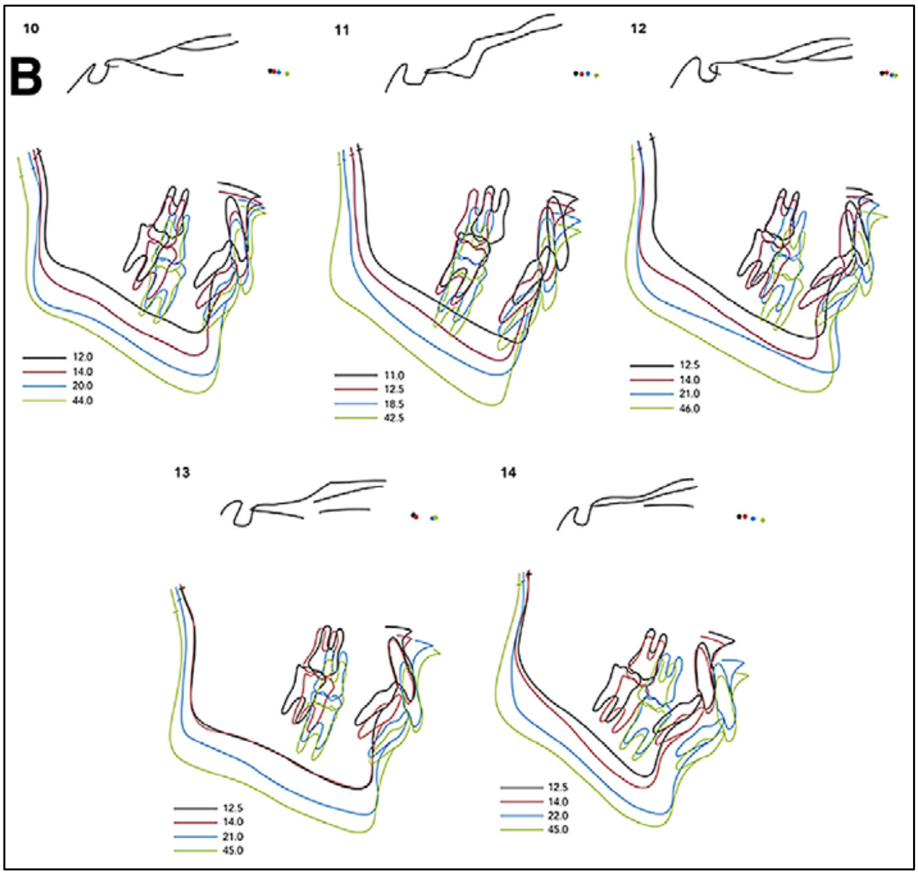
[302]. An early attempt to establish an objective assessment method was made by Summers when publishing the Occlusal Index [446]. The most popular method to determine objective data, however, is to apply the "Peer Assessment Rating" (PAR)-Index which was developed during the late 1980s/early 1990s [376]. While this method has been shown to be valid and reliable [77,103,120], the approach has also been criticised for its weighting system [158] and difficulties in terms of result interpretation [76]. Nevertheless, the PAR-Index allows for an uncomplicated comparison of data, particularly as operators are required to attend and pass a standardised calibration course before utilisation. Other evaluation tools like for example the Ahlgren-Scale [6] or standard study model measurements allow more specific and differentiated assessments of particular variables. Some of these ratings, however, are less objective than the PAR-Index. Another index which was established for rating orthodontic post-treatment study model is the Grading System for Dental Casts, which combines objective and subjective components [457]. Nevertheless, even if the outcome quality after orthodontic treatment of Class II:1 malocclusions has been investigated in some studies [14,48,78,132,167,215,269,297, 475], respective long-term data are scarce.

Stability of treatment results

The stability of orthodontic treatment results has always been of major interest for both researchers and clinicians. Statements like "If anyone would take my cases when they are finished, retain them and be responsible afterward, I would gladly give them half the fee" or "Retention is the most difficult problem in orthodontia; in fact, it is the problem" for example were made more than 80 years ago [378] and the earliest thoughts on orthodontic retention were expressed already in the 19th century [20,216]. On the other hand, it is known that orthodontic treatment results are prone to relapse to a certain extent during aging [15,374]. These changes, however, need to be appraised in relation to those occurring in untreated peers, as craniofacial growth has been shown to continue over decades [44,49,70,242,325,486] (Figure G) and tooth positions change throughout life [171,248,267,472] irrespective of orthodontic treatment. This in turn means that orthodontic treatment results have to persist in a rather dynamic environment of continuing skeletal changes, functional demands, and compensatory adaptations of the dentition [258]. Therefore, as the majority of patients receiving orthodontic treatment are adolescents, it is particularly difficult to predict post-treatment stability due to the residual growth and alveolar bone adaption potential. Nevertheless, as a matter of fact patients generally expect stability of the achieved treatment result for many years (if not forever) due to investing much effort and money over a long period.

Figure G A and B, Superimposed cephalometric tracings from the 14 patients with Class II Division 1 malocclusions treated with the Herbst appliance. The 4 times of examination were before treatment (*black*); after treatment, 12 months after the appliance was removed and the occlusion had settles (*red*); 6 years after treatment (blue) and 32 years after treatment (*green*). Note the pronounced posttreatment skeletofacial growth, especially between T3 and T4 (age ~20 years until ~46 years; reprinted from: "Pancherz H, Bjerklin K, Hashemi K. Late adult skeletofacial growth after adolescent Herbst therapy: a 32-year longitudinal follow-up study. Am J Orthod Dentofacial Orthop 2015;147:19-28" by permission of Elsevier





A systematic review [69] on long-term stability of orthodontic treatment results at least five years post-treatment led to the following conclusions:

- The correction of crowding resulted in successful alignment even if the mandibular arch length and width gradually decreased, and crowding of the lower anterior teeth reoccurred post-retention; this condition, however, was unpredictable at the individual level (limited evidence).
- Treatment of Class II:1 malocclusion with a Herbst appliance normalised the occlusion. Some relapse occurred but could not be predicted at the individual level (limited evidence).
- The scientific evidence is insufficient for conclusions on treatment of cross-bite, Class III, open bite, and various other malocclusions as well as on patient satisfaction in a long-term perspective.

In general, long-term observational studies investigating the effects after orthodontic treatment describe dental irregularities in up to 90% of the cases; these, however, exhibit large individual and unpredictable variations [15,69,119,205,245,248,458]. And while the absolute changes in locations of teeth might be considerable 10 to 15 years after treatment, these changes have been shown to be almost completely attributable to the growth of bony structures and not to dental changes per se [144]. But of course, the dental arches have also been shown to reduce in length over time resulting in anterior crowding [71,375,429,459,467]. In addition, continuous tooth eruption has been proven by increase of palatal and lower face height which cannot be explained by skeletal remodelling only [459]. On the other hand post-treatment growth might also be favourable and support outcome stability [47].

Therefore, in order to stabilise the achieved treatment result and to secure patient satisfaction for a long period, fixed and removable retention appliances have been widely used for decades. However, even if lifelong retention with bonded retainers (Figure H) continues to increase [307], little agreement exists regarding which retention regime is most effective [369]. In addition, the majority of these removable or fixed appliances stabilise only the teeth in their position within either the maxilla or the mandible. Therefore occlusal relapse may occur irrespective of long-term use of bonded retainers [440].

Figure H Bonded retainers in the upper and lower jaw

When it comes to the treatment approach of mandibular bite jumping in Class II:1 malocclusions and the intended growth stimulation, ongoing controversial discussions on stability prevailed during the last decades [100,105,199,304]. Like in other malocclusions, the basic sources of post-treatment changes are continuous reorganisation of the underlying structures and tissues as well as (neuro)muscular imbalances due to new potentially unstable situations [258]. Nevertheless, particularly for the treatment of Class II:1 malocclusions the differentiation of relapse from deficient growth or relapse independent tooth movements due to adaptation or aging hampers the evaluation of stability versus relapse. While relapse is known to occur in some Class II:1 patients but not in others, to date, no prediction seems to be possible at the individual level [213]. Likewise, little evidence exists regarding prognostic factors specifically in Class II:1 patients so far [69,263]. Nevertheless, in the literature, a severe pre-treatment malocclusion [45,114,194,263,288,301,492] , a lower pre-treatment maximal molar bite force [24], an unstable cuspal interdigitation post-treatment [315], a persisting lip-tongue dysfunction habit or other muscular/ functional dysbalances [107,108,308,309,318] and a short duration of the retention period [321] are described as predisposing factors for relapse after orthodontic Class II:1 treatment.

Orthodontic treatment and oral health

The most important goal of orthodontic treatment is to create functional occlusal conditions serving as a long-term preventive basis for oral health and oral health related quality of life. Particularly during recent years proof for a positive contributory effect of orthodontic treatment in terms of improvement respectively long-term maintenance of oral health has been demanded by the authorities as well as health insurances and the general public [142].

To date, however, the benefit of orthodontic interventions on oral health remains controversial. While an immediate association between the presence of malocclusion and periodontal disease was determined in a systematic review [67] and several trials [13,437], no positive impacts of orthodontic treatment on periodontal health [68] were found. In terms of caries, unfortunately inconsistent conclusions exist in literature. While according to one systematic review the scientific evidence indicates an association between malocclusion and dental caries [399], another systematic review concludes that there are no high-quality studies to resolve the possible association between dental crowding and the susceptibility to tooth decay [157]. An association between the presence of malocclusion and caries in adolescents was also described by Feldens et al. [133] while the findings by Stahl and Grabowski were partially opposite [436]. Nevertheless, a retrospective long-term observational study determined a history of more tooth-related problems in life in children who exhibited a malocclusion at age 8 years when compared to individuals who exhibited a normal occlusion [441]. Moreover, a long-term positive difference in self-rated dental appearance was seen when comparing treated and untreated cohorts [462].

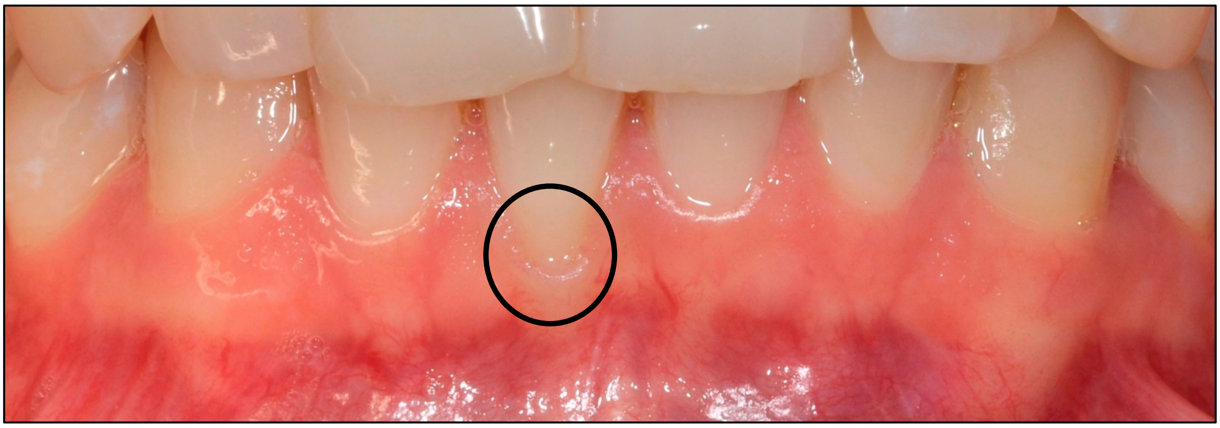
Why is it so difficult to scientifically prove, what is witnessed every day in clinical practice? First of all, the standard of oral health is undoubtedly influenced by multiple factors and does not only depend on the provision of an orthodontic therapy or its quality. In addition, the assessment of preventive orthodontic effects is impeded by the very long latency periods of various exposures (years to decades) and the generally slow progression of the most frequent oral diseases like tooth decay, periodontitis and mucosal disorders. Finally, from a research methodological perspective, a RCT design including untreated controls would be needed to prove a causal (preventive) effect of orthodontic treatment, which due to the long-term perspective would be virtually impossible to accomplish from both ethical and financial/administrative points of view. Last but not least, malocclusion is not a uniform condition; instead a wide variety of different malocclusions exhibiting various degrees of severity and countless options for combination with in turn different possible effects on oral health exists. The latter, however, has not been considered in the aforementioned trials and reviews. Therefore we might be able to determine effects if we focus on a very narrowly defined kind of malocclusion.

Numerous studies have been performed regarding the effectiveness of particular treatment approaches in terms of their corrective occlusal potential in Class II malocclusions in general [97,125,195,224,306,499,502]. The main focus of these studies is the active treatment phase, while data on long-term effects or stability are scarce [66,69,224,323,325,326]. And when it comes to data on long-term effects of Class II treatment on oral health, corresponding data are rare and equivocal [353,385].

Orthodontic treatment and gingival recessions

The role of orthodontic treatment with respect to the aetiology of labial gingival recessions (Figure I) remains controversial. It is unknown whether and to what extent the development of labial gingival recessions can be attributed to orthodontic interventions. As early as in the 1970s it was discussed that pronounced labial movement of teeth might predispose to the development of labial gingival recessions as a result of orthodontically induced bone dehiscences and periodontal attachment loss [36,439]. Similar findings have been made during the last decades. A higher prevalence for labial gingival recessions was found in orthodontically treated patients when compared to an untreated control group [370,430]. The proclination of lower incisors in particular has been referred to as risk factor [112,146,465]. This, however, could not be confirmed by other investigators [28,29,111,483] , not even in a recent study where patients wearing bonded retainers were assessed 5 years after fixed appliance treatment [373]. So, even nowadays no consensus exists in literature: controversial systematic reviews determined both little to no clinically relevant [341] or small detrimental effects [67] of orthodontic treatment on periodontal health.

Figure I Labial gingival recession on tooth 41



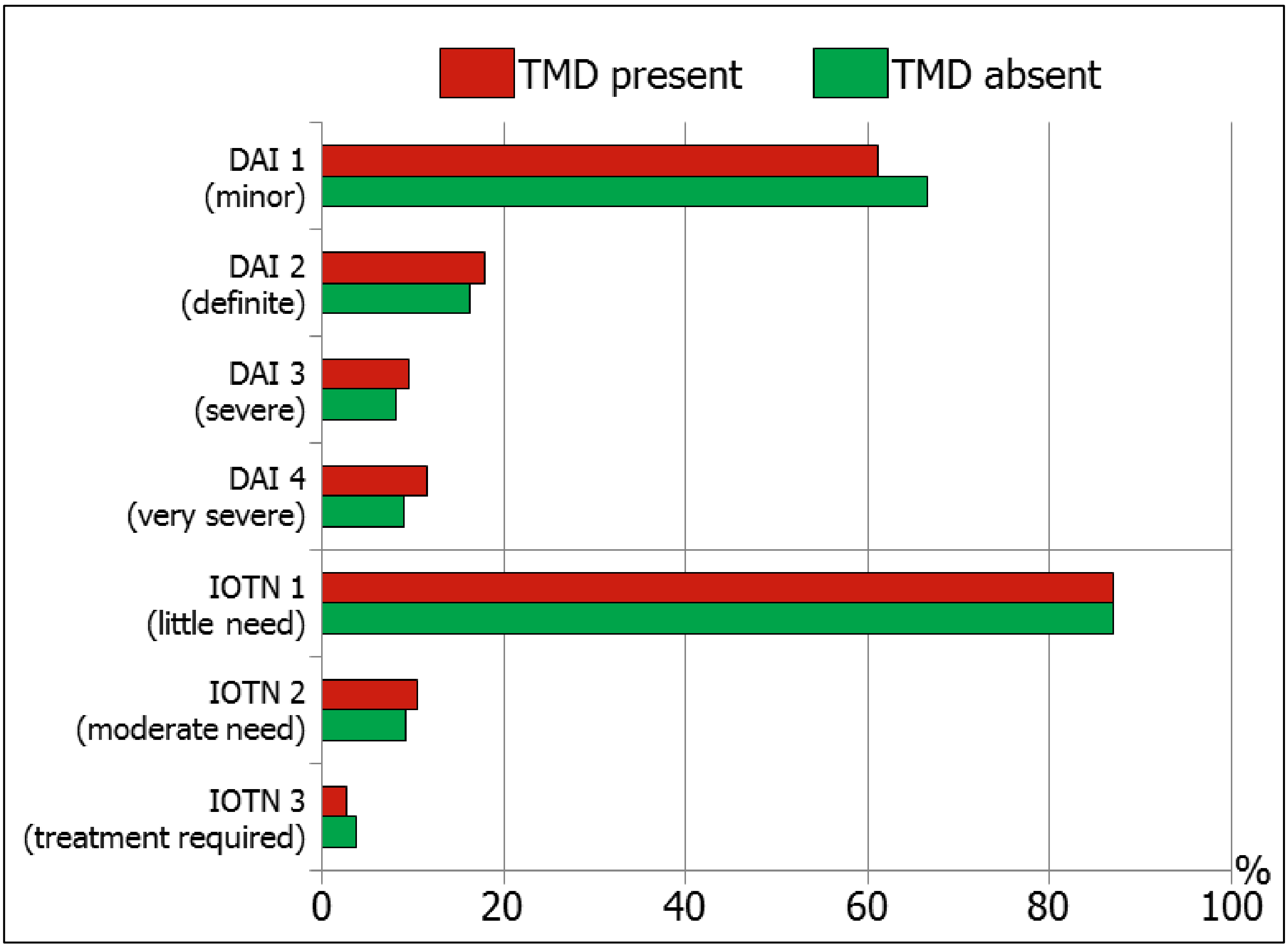
While it is known that a rather large amount of lower incisor proclination occurs during Herbst appliance Class II treatment [60,311,385] this unwanted side effect has been demonstrated to be unpredictable on the individual level - even when using additional skeletal anchorage [264,265]. The evaluation of three-dimensional radiographic post-Herbst data determined alveolar bone loss on the buccal surface of the lower incisors by ≤ 0.2 mm [412]. However, all the before mentioned studies assessed only the lower incisors and most studies included only patient samples fulfilling specific, rather strict criteria instead of unselected cohorts. Nevertheless, no trial has determined a clinically significant adverse short- or long-term effect of Herbst appliance treatment on periodontal health [60,323] or a direct relationship between the amount of proclination and the prevalence/incidence of labial gingival recession [385]. Nevertheless, a major frequent criticism with respect to Herbst treatment remains the side effect of lower incisor proclination, which has not been analysed in large cohorts so far.

Orthodontic treatment and temporomandibular disorders

The term temporomandibular disorder can be considered as a collective description characterising a number of clinical symptoms involving the temporomandibular joint, the masticatory musculature as well as associated structures [104]. Although temporomandibular disorders cannot be considered as life-threatening, they may have a substantial negative impact on patients' oral health related quality of life [260,425] and are a recognised disease listed in the 10th edition of the International Classification of Diseases (ICD-10) by the World Health Organisation [495].

The impact of occlusion and/or malocclusion on the aetiology of temporomandibular disorders, however, is controversial [122]. While numerous features like unstable occlusion, lateral forced bite, unilateral crossbite, large RCP/ICP discrepancy, Class II malocclusion, large overjet and anterior deep bite have been discussed as potential risk factors [122,123,203,256,276,381,416], no single occlusal factor seems to be of ultimate importance in terms of temporomandibular disorder development. However, the corresponding evidence is not conclusive [25,131,198,261,262] and seems to account for less than 20% of the variability in signs and symptoms of temporomandibular disorders (Figure J) [434]. A similar controversy also exists regarding the effect of orthodontic treatment on temporomandibular disorders. According to current agreement, however, orthodontic treatment neither increases nor decreases the risk for temporomandibular disorder development later in life [197,238,397].

Figure J Distribution of orthodontic treatment needs assessed by Dental Aesthetic Index (DAI) and Index of Orthodontic Treatment Need - Aesthetic Component (IOTN) in the group with and without TMD signs and symptoms; according to: Špalj S, Šlaj M, Athanasiou AE, Žak I, Šimunović M, Šlaj M. Temporomandibular disorders and orthodontic treatment need in orthodontically untreated children and adolescents. Coll Antropol 2015;39:151-158



The origin of temporomandibular disorders must be considered multifactorial. In addition, several factors hamper the investigation of both temporomandibular disorders in general and the influence of orthodontic treatment on them: the long latency times (years to decades) of orthopaedic disorders in general [254] and as such also for temporomandibular disorders, the generally slow progression and/or self-limiting nature of temporomandibular disorders [104,256] and the substantial fluctuation of signs and symptoms over time [256,282]. Finally, from a research methodological perspective, the proof of a causal/preventive effect of orthodontic treatment and/or a causative effect of malocclusion would require a RCT design with untreated controls, which would be impossible to conduct due to ethical and financial/administrative issues in combination with the long-term perspective.

In concordance with temporomandibular disorders, malocclusions are not a uniform condition. Furthermore, they can exhibit different degrees of severity. Countless options for combinations both within and between different Angle Classes with in turn different possible effects on temporomandibular disorders are possible. This factor, however, has rarely been taken into account in the previous studies/reviews existing in literature. So, concentrating on very narrowly defined types of malocclusions and high levels of severity, it might be possible to determine effects. It has been shown, for example, that orthodontic or combined orthodontic/surgical (orthognathic) treatment of severe malocclusions can improve oral health related quality of life by decreasing facial pain [428]. Furthermore, orthognathic treatment of severe malocclusions has been shown to both decrease signs and symptoms of temporomandibular disorders as well as improve masticatory ability and performance by increasing the number of occlusal contacts [1,2].

Looking particularly at Class II malocclusions, Herbst treatment was found to decrease the prevalence of temporomandibular disorder signs and symptoms short-term [392]. A favourable effect on the temporomandibular joint was also described in another independent investigation [377] as well as by Emil Herbst himself [175]. A different study, longitudinally (2 years) investigating 183 girls aged 11 to 15 (65 Class II treated, 58 Class II untreated, 60 normal occlusion untreated), found a decrease of reported temporomandibular disorder symptoms in the treated Class II sample when compared to untreated controls (both Class II and normal occlusion), even if an individual fluctuation of signs and symptoms was observed [173]. Nevertheless, long-term data on temporomandibular disorders in orthodontically treated Class II populations are scarce. An investigation of Class II patients 32 years (on average) after Herbst treatment determined only minor temporomandibular joint problems and a comparable prevalence of temporomandibular disorders as in the general population [337]. However, the sample comprised only 14 patients, and only a minority of 21% had received Multibracket appliance treatment after the Herbst phase, thus hampering the achievement of a perfect occlusion. Investigations in larger cohorts are lacking.

2. Objectives

The main focus of the present thesis are the post-treatment and long-term effects of orthodontic Class II:1 correction using a Herbst-Multibracket appliance. In detail, the following issues are addressed:

- A large variety of fixed functional appliances which are supposed to enable the correction of Class II:1 malocclusion are available on the market. Many of these appliances can be considered as derivatives of the original Herbst appliance. As a consequence, the data situation is rather unclear. While systematic reviews and meta-analyses regarding the immediate treatment effects of some of these fixed functional appliances are available in literature, no such evaluation on the stability of treatment results has been performed so far.

- Since the reintroduction of the Herbst appliance into modern orthodontics by Pancherz in 1977, a continuous scientific evaluation of the occurring treatment and post-treatment effects has been performed. For this purpose, diverse patient samples often exhibiting specific features as for example in terms of the severity of the malocclusion, the skeletal maturity or the craniofacial growth pattern, were analysed. However, the overall outcome quality has not been addressed deeply so far. In addition, many of the previous investigations are based on rather small sample sizes and the underlying therapy often comprised mere Herbst treatment only, and did not include a subsequent phase of Multibracket appliance treatment for finishing as it is general practice today. Therefore, the data available so far can only conditionally be transferred to a current basic population of Class II:1 patients.

- The effects of Herbst appliance therapy on periodontal health have not been addressed more than marginally yet. A few publications deal with the unwanted side effect of lower incisor proclination, however, neither possible post-treatment nor long-term complications have been assessed so far in a representative patient sample which had been treated according to the current treatment approach (Herbst-Multibracket appliance).

- Another issue to deal with is the long-term effect of Herbst-Multibracket appliance therapy. While some data on the stability of the treatment results exist in the literature, they were generated from a patient sample which was very small (n=14) on the one hand, and underwent Herbst treatment predominantly without additional Multibracket appliance treatment on the other hand. The respective patients were the very first who were treated with a Herbst appliance during the era of modern orthodontics in the late 1970s and hence experienced treatment under a different level of knowledge than patients in later years. Therefore, no long-term data regarding the current treatment approach (Herbst-Multibracket appliance) exists so far. In addition, any comparison of long-term Herbst data to a control group is lacking.

- The same is true for oral health; long-term data of orthodontically treated patients are generally scarce and research has not succeeded in proving a distinct beneficial effect of any orthodontic treatment on oral health yet. Hence the long-term effects of orthodontic Class II treatment in general and Herbst-Multibracket appliance therapy in particular on oral health in terms of tooth decay and periodontal health are vague.

- Regarding the temporomandibular joint, the treatment and short-term post-treatment effects of Herbst-Multibracket appliance therapy were assessed in studies involving both magnetic resonance imaging as well as clinical examinations. No deleterious impact in terms of temporomandibular disorders could be found and beneficial effects prevailed instead. However, no long-term data has been determined and published so far.

3. Results

This chapter contains the underlying six original articles of the present thesis. Each of them is accompanied by a brief summary and subsumption.

1) **Bock NC, von Bremen J, Ruf S. Stability of Class II fixed functional appliance therapy - a systematic review and meta-analysis.**
Eur J Orthod 2016;38:129-139

2) **Bock NC, Rühl J, Ruf S. Orthodontic Class II:1 treatment - efficiency and outcome quality of Herbst-Multibracket appliance therapy.**
Clin Oral Invest 2018;22:2005-2011

3) **Bock NC, Rühl J, Ruf S. Herbst-multibracket appliance treatment: Prevalence, magnitude and incidence of labial gingival recessions: a retrospective cohort study.**
Angle Orthod 2018; accepted for publication

4) **Bock NC, Saffar M, Hudel H, Evälahti M, Heikinheimo K, Rice DP, Ruf S. Long-term (≥ 15 years) post-treatment changes and outcome quality after Class II:1 treatment in comparison to untreated Class I controls.**
Eur J Orthod 2018;40:206-213

5) **Bock NC, Saffar M, Hudel H, Evälahti M, Heikinheimo K, Rice DP, Ruf S. Long-term oral-health effects of Class II orthodontic treatment.**
J Orofac Orthop 2018;79:96-108

6) **Ruf S, Bock NC. Long-term (≥ 15 years) effects of Class II treatment: A longitudinal and cross-sectional study on signs and symptoms of temporomandibular disorders.**
Eur J Orthod 2018;doi:10.1093/ejo/cjy040

1) Bock NC, von Bremen J, Ruf S. Stability of Class II fixed functional appliance therapy - a systematic review and meta-analysis.
European Journal of Orthodontics 2016;38:129-139

Fixed functional appliances for orthodontic (non-surgical) Class II correction have become very popular during the last decades [210,211]. Many different appliances have been introduced [41,180,340,409] since Pancherz's reintroduction of the Herbst appliance in 1977. Data on the respective treatment effects have been published [5, 10,33,35,91,136,137,139,148,152,200,217,223,229,277,296,309,311,318,321,334, 335,390,391,424,444,445,488], however, short- and long-term stability data are scarce.

Therefore, the objectives of this systematic review and meta-analysis were the following:

- to identify all fixed functional appliances for orthodontic Class II correction
- to perform a systematic literature search for scientific evidence on the stability after fixed functional Class II treatment
- to perform a meta-analysis for each appliance and assess eventual differences between the various appliances

In order to identify all fixed functional appliances for Class II treatment, a non-systematic search was performed using orthodontic textbooks [41,340], review articles [5,35,136,137,180,277] as well as internet pages, catalogues and conference exhibitions of dental/orthodontic suppliers.

For the systematic literature research, an electronic search of databases and orthodontic journals was conducted in addition to supplemental hand searching. The names of all previously identified appliances as well as the general term "fixed functional" were combined with each of the terms "long-term", "post-treatment", "relapse", "retention", "stability".

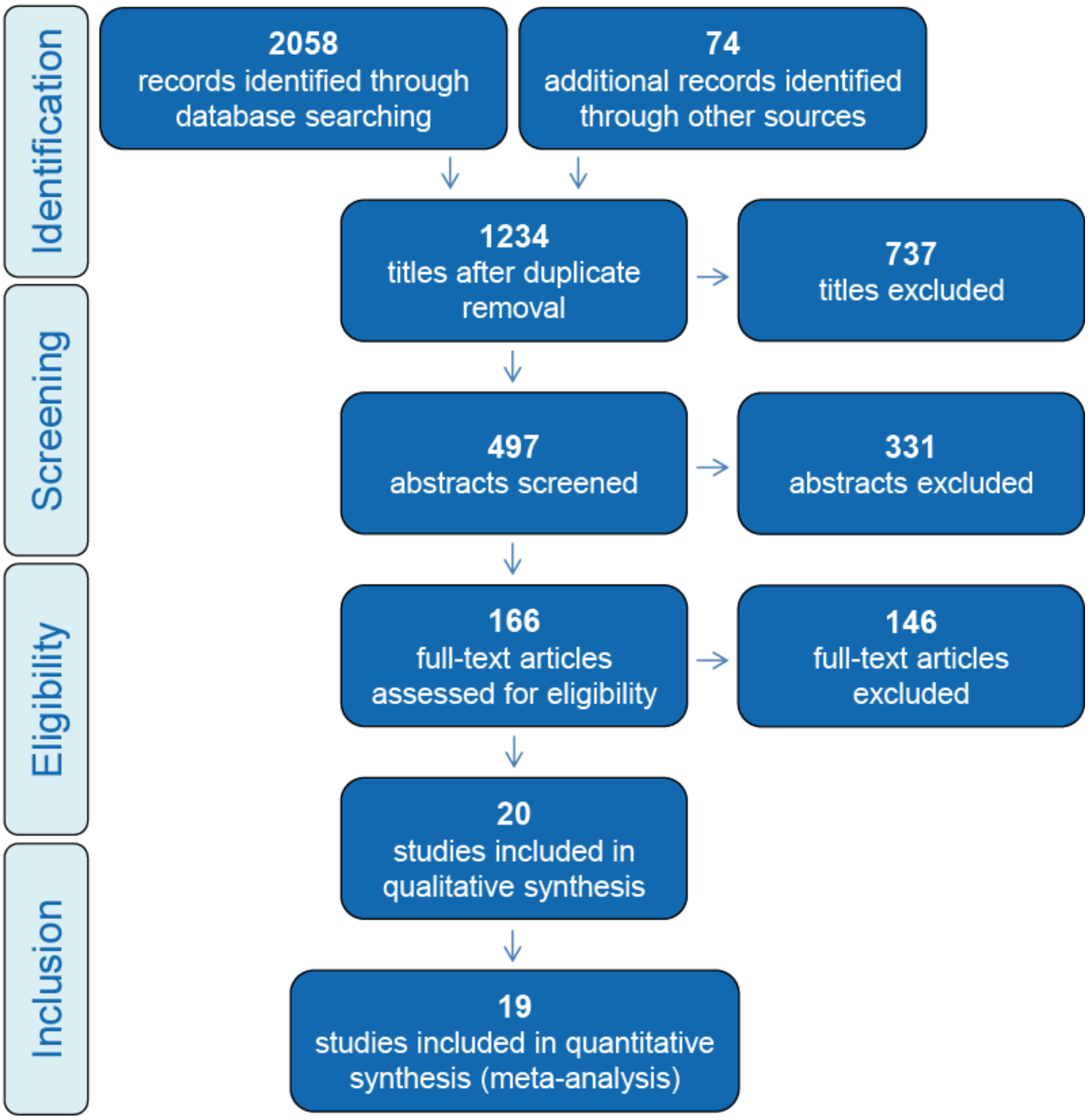
The selection criteria for articles to be included comprised of clear data on Class II treatment of ≥ 5 patients with a fixed functional appliance, post-treatment observation period of ≥ 1 year and numerical data reported on ≥ 1 of the variables “ANB angle”, “Wits appraisal”, “molar relationship”, “soft-tissue profile convexity excluding the nose”, “overjet”, “overbite”.

A three-step selection procedure according to the PRISMA statement (Figure K) [281] was carried out independently by two referees. The risk of bias was assessed using the checklist by Downs and Black [113]. A meta-analysis was performed if ≥ 3 publications were available for the same appliance and malocclusion. The respective mean values were weighted based on the sample size of each study. If the available data allowed a statistical test for heterogeneity and funnel plots, these were performed in order to determine eventual publication bias.

76 fixed functional appliances for Class II correction were identified. Many of these appliances must be considered derivatives of the Herbst appliance but some appliances use a different mode of action.

The systematic literature research revealed a total of 2132 hits, resulting in 497 abstracts and 166 full-text papers to be evaluated; 20 of them fulfilled the inclusion criteria. In all these articles both age and size of the sample as well as retention protocol and post-treatment observation period vary distinctly.

Figure K Flowchart outlining the systematic literature search according to the PRISMA guidelines; reprinted from: “Bock NC, von Bremen J, Ruf S. Stability of Class II fixed functional appliance therapy - a systematic review and meta-analysis. Eur J Orthod 2016;38:129-139” by permission of Oxford University Press/European Orthodontic Society



All 20 articles [52,56-58,64,65,84,89,159,160,291,310,315,322,326,330,351,413, 433], however, correspond to only 2 of the 76 appliances (Herbst appliance and Twin Force Bite Corrector). And, as only one publication was found for the Twin Force Bite Corrector, a meta-analysis could only be performed for the Herbst appliance. Most of the studies are case series and the assessment according to Downs and Black's checklist [113] revealed moderate methodological quality/risk of bias.

For Twin Force Bite Corrector (single study), a decrease of both ANB-angle (2.4°) and soft-tissue profile convexity angle including the nose (2.8°) were seen during treatment with further improvement by 46% and 86%, respectively, during the post-treatment period of 72 months.

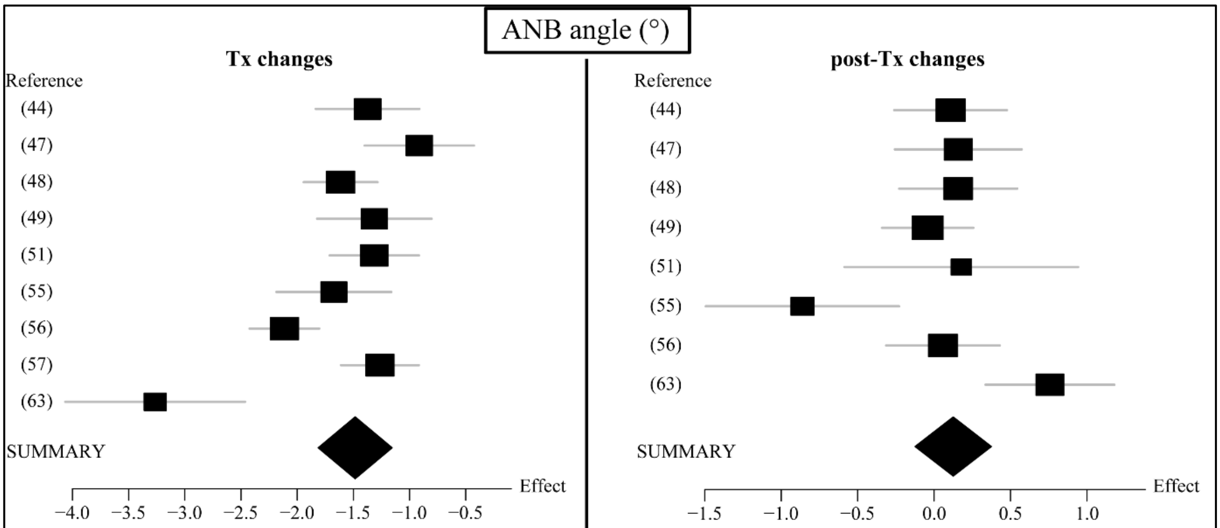
For Herbst appliance (meta-analysis of 19 studies), the average improvement during treatment was the following:

- ANB-angle: 1.5° (Figure L)
- Wits appraisal: 2.6 mm
- Sagittal molar relationship: 5.1 mm/0.8 cusp widths
- Soft-tissue profile convexity angle including the nose: 3.2°
- Overjet: 6.5 mm
- Overbite: 2.9 mm (Class II:1)/4.4 mm (Class II:2).

The mean percentages for post-treatment relapse were:

- ANB-angle: 12.4% (Figure L)
- Wits appraisal: 19.5%
- Sagittal molar relationship: 21.8% (mm)/6.5% (cusp widths)
- Soft-tissue profile convexity excluding nose: 1.0%
- Overjet: 26.2%
- Overbite: 44.7% (II:1)/22.2% (II:2).

Figure L Forest plot for the treatment and post-treatment changes of ANB angle. Reference numbers of the included studies, summary effects, confidence intervals (CI), estimated heterogeneity variances and P-values are given; reprinted from: "Bock NC, von Bremen J, Ruf S. Stability of Class II fixed functional appliance therapy - a systematic review and meta-analysis. Eur J Orthod 2016;38:129-139" by permission of Oxford University Press/European Orthodontic Society



Tx changes — Random-effects meta-analysis

Reference	Effect	lower	95% upper	weights
44	-1.3	-1.72	-0.80	1.0
47	-0.8	-1.29	-0.31	1.0
48	-1.5	-1.83	-1.17	1.1
49	-1.2	-1.71	-0.69	1.0
51	-1.2	-1.60	-0.80	1.1
55	-1.6	-2.07	-1.05	1.0
56	-2.0	-2.31	-1.69	1.1
57	-1.2	-1.50	-0.80	1.1
63	-3.2	-3.95	-2.35	0.7

Summary effect: -1.48; 95% CI (-1.81; -1.16)

Estimated heterogeneity variance: 0.2; p=0

post-Tx changes — Random-effects meta-analysis

Reference	Effect	lower	95% upper	weights
44	0.2	-0.22	0.52	1.1
47	0.2	-0.21	0.61	1.0
48	0.2	-0.19	0.59	1.1
49	0.0	-0.30	0.30	1.3
51	0.2	-0.54	0.98	0.6
55	-0.8	-1.45	-0.19	0.7
56	0.1	-0.27	0.47	1.1
63	0.8	0.38	1.22	1.0

Summary effect: 0.14; 95% CI (-0.11; 0.39)

Estimated heterogeneity variance: 0.079; p=0.007

This investigation identified a large variety of fixed functional appliances (n=76) and is the first systematic review to assess the post-treatment changes after fixed functional Class II treatment. In spite of wide-ranging inclusion criteria and almost no restrictions regarding publication date or language, the number of includable articles was rather low (n=20). In addition, the sample size was rather small in most investigations. Therefore, the opportunities in terms of detailed assessment were reduced and variables like age, skeletal maturity and retention regime as well as duration of the post-treatment observation period or use of a control group were not considered.

So, the results of this investigation revealed that the scientific evidence regarding the post-treatment stability of orthodontic fixed functional Class II treatment is inexistent for the vast majority of appliances - with the exception of the Herbst appliance. It might be tempting to expect similar treatment effects from all kind of fixed functional appliances but it should be remembered that the amount of dental and skeletal effects and thus the potential for relapse might differ.

For Herbst appliance treatment, however, the results based on the available data in the literature show only clinically irrelevant post-treatment changes. Even if the evidence level of most included studies is rather low, good dentoskeletal stability without clinically relevant changes was found for most variables. Therefore, on average, stability after Herbst treatment can be considered good. Nevertheless, it should be kept in mind that the available studies in the literature have limitations in terms of sample size and heterogeneity. In addition, the range of relapse is large for all variables, which is in concordance with a conclusion drawn from a systematic review on long-term stability of orthodontic treatment in general [69], where a certain amount of relapse was described to occur after Herbst appliance treatment - unpredictable on the individual level.

This article presents an overview of the vast amount of fixed functional appliances for Class II correction available in the literature and on the market. Since our research, additional appliances have appeared - like for example:

- Austro Repositioner [32]
- CS4® Class II Corrector [250]
- Jasper Vektor® Class II Corrector by TP Orthodontics, Inc.
- Sharma's Bite Corrector Appliance [418].

Additional stability data after fixed functional Class II treatment were published for the Forsus™ appliance [482] and the Jasper Jumper appliance [138] - both articles describe clinically irrelevant changes during a post-treatment period of approximately 2-5 years.

This is a pre-copyedited, author-produced version of an article accepted for publication in the ***European Journal of Orthodontics*** *following peer review. The version of record [Bock NC, von Bremen J, Ruf S. Stability of Class II fixed functional appliance therapy – a systematic review and meta-analysis. European Journal of Orthodontics, Volume 38, Issue 2, 1 April 2016, Pages 129-139] is available online at:* ***https://doi.org/10.1093/ejo/cjv009****.*

Stability of Class II fixed functional appliance therapy – a systematic review and meta-analysis

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Abstract

Objectives: To systematically search for scientific evidence concerning the stability of treatment (Tx) results achieved by means of Class II fixed functional appliance therapy and to assess possible differences between appliances.

Search methods: An electronic search of databases and orthodontic journals was carried out (until December 2013), with supplemental hand searching. In addition to the *names* of all identified appliances, the term *fixed functional* was used in combination with each of the following search terms: *long-term, post-treatment, relapse, retention, stability*.

Selection criteria: To be included in the review, the articles had to contain clear data on: *Class II Tx with a fixed functional appliance (> 5 patients), post-Tx period ≥ 1 year, assessment of ANB angle, Wits appraisal, molar relationship, soft-tissue profile convexity excluding the nose, overjet and/or overbite.*

Data collection and analysis: The literature search revealed 20 scientific investigations which corresponded to only 2 of the 76 identified appliances (Herbst and Twin Force Bite Corrector). As only one publication was found for the Twin Force Bite Corrector, a meta-analysis could only be performed for Herbst Tx. The data were extracted, pooled and weighted according to the number of patients in each study.

Results: The mean values for post-Tx relapse (percentages relative to the Tx changes) were: ANB angle 0.2° (12.4%), Wits appraisal 0.5 mm (19.5%), sagittal molar relationship 1.2 mm/0.1cusp widths (21.8%/6.5%); soft-tissue profile convexity excluding nose < 0.1° (1.0%), overjet 1.8 mm (26.2%), overbite Class II:1 1.4 mm (44.7%), overbite Class II:2 1.0mm (22.2%).

Conclusions: The scientific evidence concerning the stability of Tx results is inexistent for most fixed functional appliances for Class II correction except for Herbst appliance Tx. Even if the evidence level of most included studies is rather low, good dentoskeletal stability without clinically relevant changes was found for most variables.

Introduction

Class II malocclusion affects 12 to 32% of the caucasian population (1-4) and numerous treatment (Tx) approaches involving removable and/or fixed appliances with/without extractions have been described during the last decades. However, since the reintroduction of the Herbst appliance into modern orthodontics by Pancherz in 1977, fixed functional appliances have become the most popular tool for non-surgical Class II Tx (5). Many Herbst appliance derivatives, which all use the bite-jumping-mechanism but differ in appliance and/or anchorage design, have been introduced during the last 30 years (6-8).

Quite a number of papers analysing the dental, skeletal and facial changes taking place during the active Tx period of fixed functional appliance therapy have been published (9-37). However, data beyond the active Tx period seem to be scarce for most appliances and corresponding reviews are lacking.

Therefore, the purposes of the present study were 1) to identify all fixed functional appliances for Class II correction, 2) to systematically review the literature for scientific evidence concerning the stability of Tx results achieved by means of Class II fixed functional appliance therapy and 3) to perform a meta-analysis (if possible) as well as to assess possible differences between appliances.

Materials and Methods

Search strategy - fixed functional appliances

Before conducting the systematic literature review, a non-systematic search was performed in order to identify all fixed functional appliances for Class II correction ever described. For that purpose, orthodontic textbooks (6,8) and review articles (7,9,12,14,15,23,38-40) were screened. Furthermore, the internet pages and catalogues of all major dental/orthodontic manufacturers were consulted as well as the exhibitions of the 2012 annual meetings of the European Orthodontic Society and the German Orthodontic Society. In addition, for all appliances not found in current publications/catalogues, the last known manufacturer was contacted to gain information on whether the appliance was still available on the market.

Search strategy - literature

In the next step, a systematic electronic search strategy was conducted in two main databases (covering a total of 12 databases) as well as 10 international orthodontic journals to systematically search for literature published until (including) December 2013. A full list of all databases and journals is presented in Supplementary Table 1.

In addition to the term *fixed functional*, the *name* of each of the identified appliances, was used in combination with each of the following search terms: *long-term, post-treatment, relapse, retention, stability*. Furthermore, a hand search of the reference lists of the retrieved articles was performed. As an example, the search strategy which was applied onto the database of "NCBI-PubMed" for the term "fixed functional" is given: *(fixed functional[All Fields] AND retention[All Fields]) OR (fixed functional [All Fields] AND relapse[All Fields]) OR (fixed functional [All Fields] AND stability[All Fields]) OR ((fixed functional [All Fields]) AND (post[All Fields] AND treatment[All Fields])) OR ((fixed functional [All Fields]) AND (long[All Fields] AND term[All Fields]))*.

Inclusion criteria

The inclusion criteria were defined as papers describing *Class II treatment* with a *fixed functional appliance* (with or without subsequent Tx) of *at least five subjects* and containing numerical data on the changes occurring during a *non-active post-Tx period of at least one year* (group average).* In addition, study models and/or lateral head films had to have been assessed *for ANB angle, Wits appraisal, soft-tissue profile convexity excluding the nose, sagittal molar relationship, overjet and/or overbite*.

Studies had to be published either in English or one of the following languages: Danish, Finnish, French, German, Greek, Italian, Spanish, Swedish or Turkish. A three-step selection procedure (title-abstract-full text) was carried out independently by two reviewers according to the PRISMA statement (41). After each step, the cases of disagreement were discussed until a consensus was reached.

* *Comment: Basically there is no doubt that it would be desirable to include only studies with a high evidence level of I or II (42) in a review. However, for the present main parameter post-tx stability it is unrealistic. Thus, for clinical orientation, there is no alternative than to include studies with lower evidence levels.*

Data extraction

For all included studies, the sample's general data as well as the values given for measurements regarding the eligible variables were extracted. The methodological quality / risk of bias was assessed for each included study using the checklist by Downs and Black (43) consisting of 27 items categorized in 5 subgroups. For each item, one point was scored when the respective question was answered "yes".

In case of ≥ 3 articles available for the same appliance and malocclusion subtypes, a meta-analysis was performed. The respective mean values were weighted according to the number of patients in each study. For variables where the available data allowed a statistical test for heterogeneity and funnel plots, these were performed in order to identify possible publication bias (Figures 3a-3b, Supplementary Figures 2a-2e).

Results

This chapter consists of three sections – 1) identification of fixed functional appliances for Class II correction, 2) systematic review concerning the stability of Tx results and 3) meta-analysis.

76 fixed functional appliances for Class II correction were identified, of which the majority (n=59) is still available on the market (Supplementary Tables 2 and 3). A large number of these appliances are – at least in major part – derivatives of the original Herbst appliance, and some of them are even available in several different subtypes, which vary in appliance and/or anchorage design (Supplementary Table 2). Other appliances, however, differ concerning the mode of action (Supplementary Table 3).

Systematic Review

The number of studies identified through the search in the different databases and the selection procedure is detailed in Figure 1. Of the original 2132 hits, 497 abstracts were retrieved and 166 full-text papers were evaluated. The hand search did not deliver any additional material.

Excluded papers

146 of the 166 studies had to be excluded. The main reasons for exclusion were: overview article and/or no scientific study (n=40), appliance used was not a fixed functional (n=33), no post-Tx period (n=27), post-Tx period too short (n=8), no variable of interest assessed (n=19), < 5 patients (n=16). A full list of the 146 papers and the reasons for exclusion can be obtained from the authors.

Included papers

Finally, 20 publications remained, which were included in the present review (44-63). Most of these papers are case series, and none was on a higher evidence level than of a cohort study. The assessment according to Downs and Black's checklist (43) revealed moderate methodological quality / risk of bias with the following scoring results – Mean: 13.8, Median: 14.0, Minimum: 8, Maximum: 17 (detailed results for each separate paper can be found in Supplementary Table 4). Up to December 2013, no level I or II studies (meta-analysis, randomized clinical trial, or controlled clinical trial) on the stability of Class II fixed functional appliance therapy existed. The 20 scientific investigations (Table 1) correspond to only 2 of the 76 identified appliances (Herbst and Twin Force Bite Corrector).

The included studies report on Tx results and their stability in Class II division 1 and Class II division 2 malocclusions as well as other Class II subgroups. In all investigations, Tx had started with a fixed functional appliance which was – in some cases – accompanied or followed by multibracket appliance Tx conditionally in conjunction with Class II elastics for settling and/or tx result stabilisation. The number of patients included in the studies varied considerably between 5 and 69 individuals (Mean = 25, Median = 22). The same was true for the patients' mean age at start of Tx, which varied between 11 and 26 years (Mean = 15, Median = 14) and the average post-Tx period, which ranged from 12 to 382 months (Mean = 58, Median = 36). There was a large intra- and inter-study-variation concerning the retention protocol. This varied from removable retention devices to fixed bonded retainers or a combination of both, while some patients did not receive retainers at all.

The retrieved results are presented in detail in Table 2. Negative percentages of post-Tx changes correspond to a favourable development regarding Class II correction (= improvement).

Twin Force Bite Corrector – Single study results

One article describing a total of 5 patients with an average pre-Tx age of 11 years was found. The mean post-Tx observation period was 72 months. During Tx, a decrease of both the ANB-angle (2.4°) and the soft-tissue profile convexity angle excluding the nose (2.8°) was seen. Both variables showed further improvement during the post-Tx period; the ANB angle decreased by an additional 46% and the soft tissue profile convexity excluding the nose straightened by another 86% of the amount achieved during Tx.

Herbst appliance – Meta-analysis

19 studies on Herbst Tx were found. The meta-analysis for the post-Tx changes of the variables "ANB angle", "Wits appraisal" and "sagittal molar relationship" was performed irrespective of the type of Class II malocclusion. Due to the differences in dentofacial morphology between Class II division 1 and Class II division 2 malocclusions, the post-Tx changes of the remaining variables "soft-tissue profile convexity angle excluding the nose", "overjet" and "overbite" were performed separately for each malocclusion type. For sagittal molar relationship, separate calculations were performed for studies using millimetres (from assessing lateral cephalograms - LH) and cusp widths (from assessing study models - SM). In detail, the following data (averages – weighted according to the number of patients in each study) were extracted (Table 3, Figures 2a-2b, Supplementary Figures 1a-1e). However, due to the heterogeneity of both the patient samples and the length of the post-Tx period, large variations were seen for all changes.

The results of statistical testing for heterogeneity and the corresponding funnel plots are given in Figures 3a-3b and Supplementary Figures 2a-2e.

ANB angle (Figures 2a and 3a)
The mean ANB reduction during Tx was 1.5° and the average relapse during the post-Tx period was 0.2°. Looking at the net Tx reduction (mean: -1.3°), investigations in young patients showed notably large variations independent of pre-Tx age. Studies in adults on the other hand exhibit a tendency for generally smaller but still obvious changes.
Wits appraisal (Supplementary Figures 1a and 2a)
The average decrease during Tx was 2.6 mm and the mean post-Tx relapse amounted to 0.5 mm. The individual studies exhibited a large variation which did not seem to be related to pre-Tx age. The net Tx reductions were similar (mean: 2.1 mm) in all studies but the one with the highest mean pre-Tx age, which shows a considerably lower value.
Sagittal molar relationship (Supplementary Figures 1b, 2b-1 and 2b-2)

- Measuring unit mm:

The mean amount of correction during Tx was 5.1 mm and the average relapse during the post-Tx period amounted to 1.2 mm. A tendency of lower ranges was seen in the studies investigating children/early adolescents and adult patients. The net Tx reduction (mean: 3.9 mm) was largely independent of pre-Tx age.

• Measuring unit cusp widths (cw):

The mean amount of correction during Tx was 0.8 cw and the average relapse 0.1 cw with a net Tx reduction of 0.7 cw. No association of the changes with age was noted.

Soft-tissue profile convexity excluding the nose (Supplementary Figures 1c and 2c)

• Class II division 1:

During Tx, an average decrease of 3.2° occurred and the mean relapse during the post-Tx period was less than 0.1°. The Tx changes showed a clear decrease with increasing pre-Tx age. A large variation was also seen for the post-Tx changes: while the investigations in children/adolescents showed small amounts of further decrease, the studies in the older patients showed small amounts of relapse.

Overjet (Figures 2b and 3b)

• Class II division 1:

During Tx, an average overjet reduction of 6.5 mm was seen. The amount of relapse during the post-Tx period was 1.8 mm. Similar net Tx reductions (mean: 4.7 mm) were seen in all studies irrespective of age except for the one with the lowest mean pre-Tx age, which shows a considerably higher value.

Overbite

• Class II division 1 (Supplementary Figures 1d and 2d):

The average decrease of overbite during Tx was 2.9 mm and the mean amount of relapse during the post-Tx period amounted to 1.4 mm. The individual studies exhibited a large variation concerning the Tx changes showing a clear tendency towards less decrease in the youngest and the oldest patients. A large variation can be seen for the post-Tx changes as well; however, the investigations with the youngest and oldest patients show the most favourable development (further decrease or small amounts of relapse, respectively). Regarding net Tx reductions (mean: 1.5 mm) similar values were seen in all studies but the one with the lowest mean pre-Tx age, which shows a slightly more favourable value.

• Class II division 2 (Supplementary Figures 1e and 2e):

The mean reduction of overbite during Tx amounted to 4.4 mm and the average relapse during the post-Tx period was 1.0 mm. Similar values were seen in all investigations but the one with the lowest mean pre-Tx age which shows a slightly more favourable value for the Tx period. For the net Tx reductions (mean: 3.4 mm), again similar values were seen in all studies but the one with the lowest mean pre-Tx age showing a slightly higher value (Supplementary Figure 1e).

Discussion

In accordance with previous studies (7,8,33), the present review identified a large variety of fixed functional appliances (n=76). The current study is the first review to assess the post-Tx period.

Systematic Review

In order to avoid omitting any data on the stability after fixed functional Class II Tx, the inclusion criteria were defined quite wide-ranging. There were no limitations with respect to publication years and many languages were included. In spite of a rather high amount of hits at the beginning of the search, only 20 articles were finally included.

Similar difficulties were faced when searching for comparative literature. The data of the few studies identified are summarized in Supplementary Table 5.

Looking at the results of the present systematic review, one has to admit that the total number of available investigations (n=20), reporting stability data during a retention period of at least 1 year following fixed functional Tx, is low compared to the high amount of appliances available (n=76). This is especially true, when considering that these studies analyse the effects of only two of these 76 appliances: Herbst (n=19) and Twin Force Bite Corrector (n=1). Thus, for the vast majority of the Herbst appliance derivatives no treatment stability data exist. Even if it might be tempting to expect similar effects from all kinds of fixed functional appliances for Class II correction, it should be remembered, that the amount of dental and skeletal treatment effects, and thus the potential for relapse, may differ.

Meta-analysis (Herbst appliance)

As for natural reasons a meta-analysis could only be performed for the Herbst appliance, the following discussion will be restricted to the stability of Herbst treatment.

Quality of included papers

The evidence level of the 19 Herbst studies was rather low: case series without controls or with controls treated by a different protocol – *level III according to the "Levels of Evidence" by Shekelle et al. (42)*. In addition, a moderate risk for bias existed according to the Downs and Black's checklist. The partly asymmetrical data distribution in the funnel plots (Figures 3a-3b, Supplementary Figures 2a-

2e) as well as the calculated heterogeneity values and significances (Figures 3a-3b, Supplementary Figures 2a-2e) also indicated a moderate risk for bias. Due to the low number of studies and mainly small patient samples, however, this data must be interpreted carefully. Nevertheless, despite the fact, that it is ethically difficult or even impossible to obtain long-term stability data of untreated controls, it is also scientifically and clinically less important for the retention period than for the active treatment period, as only minor changes are expected to occur in untreated controls during the time period corresponding to the post-Tx phase.

Due to the low number of studies fulfilling the inclusion criteria, the assessment opportunities were limited and no differentiation regarding factors like age, skeletal maturity, duration of the post-Tx period or duration and mode of any subsequent Tx, type of retention regime and comparison to a control group was made. This, of course, must be considered when interpreting the results; a large range existed especially for the variables age and duration of post-Tx period. Furthermore, as some research groups published more than one of the included studies, some patients might have been included in more than one investigation; this however, was impossible to account for by looking at the data retrospectively.

<u>General patient characteristics</u>

The average pre-Tx age of the Herbst patients was around 15 years with a large amount of patients having completed most of their pubertal growth. The average stability data reported for Herbst Tx (Table 2) show only clinically irrelevant changes, hence on average stability can be considered as being good. However, the range of relapse seen for all analysed variables was large. This is in agreement with the conclusion drawn by Bondemark et al. (64) who performed a systematic review on long-term stability of orthodontic Tx (which included some of the studies being part of the present investigation) and also described a certain amount of relapse to occur after Herbst appliance Tx - which, however, cannot be predicted at the individual level.

<u>ANB angle/Wits appraisal</u>

For the evaluated skeletal variables (ANB angle/Wits appraisal) the post-Tx changes showed weighted mean values of 0.2° (ANB) and 0.5 mm (Wits), respectively (Table 2, Figure 2a, Supplementary Figure 1a). Looking at the literature (Supplementary Table 5), similar relapse values can be found in investigations by Fidler et al. (65: ANB = 0.2°; Wits = 1.4 mm) and Franchi et al. 2013 (66: Wits = 0.8 mm). While the data for the ANB angle (Figure 2a) showed similar amounts of post-Tx changes for the studies with a mean pre-Tx age of 13.8 years and above, the studies evaluating younger patients exhibited very large inter-study differences. It seemed as if the net Tx reduction was more predictable for older patients. To some extent, the same was true for Wits appraisal (Supplementary Figure 1a). While the post-Tx changes were quite similar in studies with a mean pre-Tx age ≥ 16.2 years, large inter-study differences exist in younger patients.

<u>Sagittal molar relationship</u>

Looking at sagittal molar relationship (Table 3, Supplementary Figure 1b), a weighted mean post-Tx relapse of 1.2 mm (measurements on LH) and 0.1 cw (measurements on SM) occurred. The minimal difference between the two methods might on the one hand be due to the differing pre-Tx age (LH =15.1 yrs.; SM = 16.5 yrs.) and thus, different post-Tx growth potential of the respective studies. On the other hand, the accuracy of the two methods differs – steps of 0.5 mm were used for LH-assessment while steps of 0.25 cw (≈ 2.0 mm) were applied during SM-assessment. The investigations by Fidler et al. (65) and Franchi et al. 2013 (66) show some slightly more favourable values for post-Tx relapse of sagittal molar relationship (Supplementary Table 5): 0.3 mm (SM-assessment) and 0.1 mm (LH-assessment). Comparing these results to the current findings, however, one has to bear in mind that the mean pre-Tx age of the patients (11.2 - Fidler et al.; 10.0 - Franchi et al.; 15.7 - current meta-analysis) as well as the Tx-changes (3.4 mm - Fidler et al.; 2.9 mm - Franchi et al.; 5.1 mm/0.7 cw - current meta-analysis) differ tremendously.

<u>Soft-tissue profile convexity</u>

The soft-tissue profile convexity excluding nose (Table 3, Supplementary Figure 1c) was the variable with the highest degree of stability in this meta-analysis: on average > 0.1° relapse of the Tx-changes. This favourable behaviour probably has to be attributed (at least partially) to favourable growth patterns of the craniofacial soft-tissues. On the other hand, most of the patients probably ended active Tx with only little remaining growth potential (average pre-Tx age 14.4 years). Looking at the detailed data of the four included studies, one can see that favourable post-Tx changes were especially seen in the younger patients while the studies involving older patients showed a moderate relapse of up to 0.6°.

Overjet

For overjet (Table 3, Figure 2b), an average post-Tx relapse of 1.8 mm occurred. Even if the range of both Tx and post-Tx changes was large – with a tendency for more uniform values in older patients (mean pre-Tx age ≥ 13.4 years) – the net Tx changes are quite similar in all studies included in the meta-analysis. Comparing the data to the literature (Supplementary Table 5), similar or slightly more favourable relapse values were seen (65-69: 0.1-1.1 mm). However, pre-Tx age and corresponding post-Tx growth potential differ between the investigations showing more favourable values for post-Tx development than the current meta-analysis, where the average pre-Tx age was quite high (14.4 years). Furthermore, some of the studies included in the present investigation - in contrast to the other studies cited above - contain data of patients who did not receive any subsequent Multibracket appliance Tx after removal of the Herbst appliance, which means that the post-Tx records were taken immediately after Herbst-Tx, and thus before settling. Consequently, these patients exhibited an overcompensation of overjet on the post-Tx records and thus larger tooth movements during the settling period, which was included in the amount of changes of the post-Tx/retention phase.

Overbite – Class II division 1

For overbite in Class II division 1 patients (Table 3, Supplementary Figure 1d), a moderate stability was found: 1.4 mm of the reduction seen during Tx (2.9 mm) relapsed during the post-Tx period. However, an effective overbite relapse of 1.4 mm seems to be of minor clinical relevance. Again, the studies with a higher mean pre-Tx age (≥ 13.4 years) showed a tendency for more uniform amounts of changes. The investigations in the literature (65-69) show a slightly less post-Tx overbite relapse (0.1-0.9 mm; Supplementary Table 5).

Overbite – Class II division 2

Looking at overbite stability in Class II division 2 patients (Table 3, Supplementary Figure 1e), however, a rather good stability showing 1.0 mm of relapse was found for the post-Tx period (reduction during Tx: 4.4 mm). Furthermore, all studies showed similar changes during both the Tx and post-Tx period resulting in resembling net Tx values. The relapse values described in the literature (70-72) are alike (0.5-1.4 mm; Supplementary Table 5).

On average the present meta-analysis shows minor, clinically irrelevant post-Tx changes for Herbst treatment. A tendency for more uniform Tx and post-Tx changes were seen in older compared to younger patients (Figures 2a-2b, Supplementary Figures 1a-1e). Even if some slightly more favourable post-Tx changes for overjet and overbite after other Tx protocols than Herbst/fixed functional Class II treatment are reported in the literature, it should be kept in mind that the use of fixed functional appliances is especially suggested and indicated in rather severe, challenging malocclusions and patients where other Tx protocols are unlikely to result in a successful Tx outcome. In daily practice and in accordance with the described large interindividual differences the predictability of Tx and post-Tx changes on the individual level seems to be limited.

Conclusions

The scientific evidence concerning the stability of Tx results is inexistent for most fixed functional appliances for Class II correction except for Herbst appliance Tx. Even if the quality of most studies is rather low (evidence level III), good dentoskeletal stability without clinically relevant changes was found for most variables.

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Table 1
Scientific investigations fulfilling the inclusion criteria of the systematic review. The reference details, the appliance used, the malocclusion, the number of patients and the mean pre-Tx age are given.

	Reference	Appliance	Malocclusion	Number of patients	Pre-Tx age (mean)
44	Bock N, Pancherz H. Herbst treatment of Class II division 1 malocclusions in retrognathic and prognathic prognathic facial types. Angle Orthod 2006;76:930–941.	Herbst	II:1	26	13.8
45 a/b	Bock NC et al. Class II subdivision treatment with the Herbst appliance. Angle Orthod 2013;83:327–333.	Herbst	a) II subdivision b) II:1	22 22	15
46	Bock N, Ruf S. Post-treatment occlusal changes in Class II division 2 subjects treated with the Herbst appliance. Eur J Orthod 2008;30:606–613.	Herbst	II:2	37	16.1
47	Bock NC, Ruf S. Dentoskeletal changes in adult Class II division 1 Herbst treatment - how much is left after the retention period? Eur J Orthod 2012;34:747–753.	Herbst	II:1	15	25.6
48	Bock NC, Ruf S. Class II division 2 treatment - does skeletal maturity influence success and stability? J Orofac Orthop 2013;74:187–204.	Herbst	II:2	37	16.2
49	Bock NC et al. Facial profile and lip position changes in adult Class II, Division 2 subjects treated with the Herbst-Multibracket appliance. A radiographic cephalometric pilot study. J Orofac Orthop 2009;70:51–62.	Herbst	II:2	16	18.8
50	Bock NC et al. Occlusal stability of adult Class II Division 1 treatment with the Herbst appliance. Am J Orthod Dentofacial Orthop 2010;138:146–151.	Herbst	II:1	26	21.1
51	Chaiyongsirisern A et al. Stepwise advancement Herbst appliance versus mandibular sagittal split osteotomy. Treatment effects and long-term stability of adult Class II patients. Angle Orthod 2009;79:1084–1094.	Herbst	II	16	22
52	Chhibber A et al. Long-Term Stability of Class II Correction with the Twin Force Bite corrector. J Clin Orthod 2010;44:363–376.	Twin Force Bite Corrector	II:1	5	11
53	Hansen K et al. Long-term effects of the Herbst appliance on the dental arches and arch relationships: a biometric study. Br J Orthod 1995;22:123–134.	Herbst	II:1	53	12.5
54	Hansen K et al. Long-term effects of Herbst treatment on the mandibular incisor segment: a cephalometric and biometric investigation. Am J Orthod Dentofacial Orthop 1997;112:92–103.	Herbst	II:1	24	13.0
55	Nelson B et al. A long-term follow-up study of Class II malocclusion correction after treatment with Class II elastics or fixed functional appliances. Am J Orthod Dentofacial Orthop 2007;132:499–503.	Herbst	II:1	15	13.5
56	Pancherz H. The effect of continuous bite jumping on the dentofacial complex: a follow-up study after Herbst appliance treatment of Class II malocclusions. Eur J Orthod 1981;3:49–60.	Herbst	II:1	10	12.1
57	Pancherz H. The nature of Class II relapse after Herbst appliance treatment: a cephalometric long-term investigation. Am J Orthod Dentofacial Orthop 1991;100:220–233.	Herbst	II:1	29	12.4
58	Pancherz H, Anehus-Pancherz M. Facial profile changes during and after Herbst appliance treatment. Eur J Orthod 1994;16:275–286.	Herbst	II:1	69	12.6
59	Pancherz H, Bjerklin K, Lindskog-Stokland B, Hansen K. Thirty-two-year follow-up study of Herbst therapy: a biometrical dental cast analysis. Am J Orthod Dentofacial Orthop 2013;145:15–27.	Herbst	II:1	14	13.4
60	Pancherz H, Hansen K. Occlusal changes during and after Herbst treatment: a cephalometric investigation. Eur J Orthod 1986;8:215–228.	Herbst	II:1	40	12.5
61	Phan KL et al. Comparison of the headgear activator and Herbst appliance – effects and post-treatment changes. Eur J Orthod 2006;28:594–604.	Herbst	II:1	16	12.6
62	Schweitzer M, Pancherz H. The incisor-lip relationship in Herbst/multibracket appliance treatment of Class II, Division 2 malocclusions. Angle Orthod 2001;71:358–363.	Herbst	II:2	19	13
63	Soytarhan A, Isiksal A. Treatment of Angle Class II/1 malocclusions with the Herbst appliance. Turk Ortodonti Derg 1990;3:94–101.	Herbst	II:1	10	11.3

Table 2

Individual stability data of all 20 fixed functional appliance studies included in the systematic review for a) ANB angle, Wits appraisal, sagittal molar relationship and b) soft-tissue profile convexity excluding nose, overjet and overbite. The appliance used and the reference number are given as well as the means for duration of post-Tx period, changes during Tx and post-Tx (shown in mm, degree or cusp widths and %, respectively; standard deviations (SD) given if available). - indicates a favourable post-Tx change concerning Class II correction (=no relapse). For values in italic no meta-analysis could be performed (< 3 articles).

Fixed functional appliance used (Reference)	Type of malocclusion (Class)	Post-Tx period	ANB angle					Wits appraisal					Sagittal molar relationship								Soft-tissue profile convexity excluding nose					Overjet					Overbite				
			Tx changes		post-Tx changes			Tx changes		post-Tx changes			Tx changes			post-Tx changes					Tx changes		post-Tx changes			Tx changes		post-Tx changes			Tx changes		post-Tx changes		
		(months)	(°)*	SD	(°)*	%*	SD	(mm)*	SD	(mm)*	%	SD	(mm/cusp widths)*		SD	(mm/cusp widths)*		%	SD	(°)*	SD	(°)*	%	SD	(mm)*	SD	(mm)*	%	SD	(mm)*	SD	(mm)*	%	SD
Herbst (44)	II division 1	39	-1,3	1,20	0,2	-11,5	0,96						-5,8	mm	1,99	2,4	mm	-41,4	1,79	-2,8	2,28	0,6	-22,6	2,80	-8,3	2,86	3,4	-40,7	1,93					
Herbst (45b)	II division 1	36											-1,0	cusp widths	0,16	0,0	cusp widths	-3,0	0,11						-5,5	2,63	1,1	-19,2	1,06					
Herbst (47)	II division 1	36	-0,8	0,96	0,2	-25,0	0,82	-1,1	1,38	0,7	-63,6	1,35	-3,5	mm	2,11	0,3	mm	-8,6	0,84	-1,5	1,60	0,2	-13,3	1,11	-6,2	1,74	1,0	-16,1	0,64	-2,1	1,90	1,0	-47,6	0,91
Herbst (50)	II division 1	32											-0,8	cusp widths	0,26	0,1	cusp widths	-9,2	0,17						-4,8	2,06	0,7	-14,9	0,74	-2,3	1,42	0,9	-38,6	0,67
Herbst (53)	II division 1	74																							-6,8	2,80	2,0	-29,2		-3,3	1,69	2,3	-68,9	
Herbst (54)	II division 1	72	-1,8		-0,4	22,2																												
Herbst (55)	II division 1	72	-1,6	1,01	-0,8	52,6	1,25																		-4,3	2,60	0,5	-11,6	1,00	-2,3	1,80	0,5	-21,7	1,30
Herbst (56)	II division 1	12	-2,0	0,50	0,1	-5,0	0,60																											
Herbst (57)	II division 1	78	-1,2	0,95	0,8	-66,1							-6,3	mm	1,50	2,0	mm	-32,5							-7,5	3,42	3,1	-41,2		-4,2	1,77	2,1	-50,0	
Herbst (58)	II division 1	74																		-3,3	3,62	-0,3	7,6											
Herbst (59)	II division 1	382											-0,9	cusp widths		0,2	cusp widths	-22,2							-4,2		0,3	-7,1		-1,5		0,3	-20,0	
Herbst (60)	II division 1	12	-1,5		0,1	-6,7		-2,4		0,1	-4,2		-6,4	mm		1,8	mm	-28,1							-6,9		2,2	-31,9						
Herbst (61)	II division 1	24	-1,9		0,5	-26,3		-4,8		1,8	-37,5		-6,2	mm		0,9	mm	-14,5							7,7		2,7	35,1		-3,4		1,8	-52,9	
Herbst (63)	II division 1	12	-3,2	1,29	0,8	-25,4	0,68						-3,6	mm	1,78	0,9	mm	-25,0	4,44	-5,6	4,67	-0,8	14,3	3,06	-6,8	1,98	0,0	0,0	1,40	-2,1	2,06	-0,7	33,3	1,25
Herbst (46)	II division 2	27											-0,8	cusp widths	0,29	0,0	cusp widths	-3,6	0,15											-4,3	1,87	1,0	-22,0	1,29
Herbst (48)	II division 2	34	-1,5	1,02	0,2	-13,3	1,20	-1,9	1,71	0,4	-21,1	1,00	-3,5	mm	1,05	0,1	mm	-2,9	0,87	*-1,4*		*-0,4*	*28,6*		*-2,2*		*0,5*	*-22,7*		-4,1	1,78	0,9	-22,2	0,94
Herbst (49)	II division 2	24	-1,2	1,04	0,0	0,0	0,61													*-2,6*	*2,62*	*1,6*	*-61,5*	*2,02*	*-1,6*	*1,25*	*0,5*	*-31,3*	*0,38*	-4,7	1,33	1,1	-23,4	0,88
Herbst (62)	II division 2	12						-3,0	2,40	0,1	-3,3	0,40																		-5,6	3,30	1,2	-21,4	0,60
Herbst (45a)	II subdivision	36											-1,0	cusp widths	0,17	0,0	cusp widths	-2,0	0,13						*3,6*	*2,05*	*0,4*	*9,7*	*0,92*					
Herbst (51)	II	36	-1,2	0,81	0,2	-18,3	1,56	-3,4	2,14	0,5	-14,4	1,26	-3,7	mm	2,71	0,6	mm	-16,2	1,96	*-2,4*	*1,53*	*0,3*	*-10,4*	*1,48*	*-5,3*	*2,02*	*0,7*	*-13,2*	*1,41*	*-2,9*	*0,70*	*0,2*	-6,7	*0,47*
Twin Force Bite Corrector (52)	II division 1	72	*-2,4*	*1,71*	*-1,1*	*-45.8*	*0,55*													*-2,8*	*1,48*	*-2,4*	*-85,7*	*3,71*										

* negative Tx and post-Tx changes mean favourable development regarding Class II correction (= no relapse)

Table 3

Meta-analysis data for the stability of Herbst appliance treatment derived from 19 studies. The weighted data (weighted according to the number of patients of each individual study) for ANB angle, Wits appraisal, sagittal molar relationship (data from studies using millimetres and cusp widths shown separately), soft-tissue profile convexity excluding nose, overjet, and overbite are shown. The references, total number of patients, weighted mean pre-Tx age, Tx changes, duration of post-Tx observation period (months), post-Tx changes as well as final values are shown.

Variable		References		Number of patients	Pre-Tx age (weighted)	Tx changes* (weighted)	Duration of post-Tx observation period in months (weighted)			Post-Tx relapse* (weighted)			Final value (weighted)
				n	mean	mean	mean	min	max	mean	min	max	mean
ANB angle		n=12	44,47,48,49,51,54, 55,56,57,60,61,63	254	15.0 yrs	-1.5°	34,0	12	78	0.2°	-0.8°	0.8°	4.1°
Wits appraisal		n=6	47,48,51,60,61,62	143	16.0 yrs	-2.6 mm	24,2	12	36	0.5 mm	0.1 mm	1.8 mm	0.1 mm
Sagittal molar relationship		n=12	44,45a+b,46,47,48,50, 51,57,59,60,61,63	310	15.7 yrs	-5.1 mm -0.8 cw	49,7	12	382	1.2 mm 0.1 cw	0.1 mm 0.0 cw	2.4 mm 0.2 cw	-2.0 mm× 0.1 cw^
Soft-tissue profile convexity	- Class II:1	n=4	44,47,58,63	120	14.4 yrs	-3.2°	56,5	12	74	0.0°	-0.8°	0.6°	160.6°
Overjet	- Class II:1	n=11	44,45b,47,50,53,55, 57,59,60,61,63	266	14.4 yrs	-6.5 mm	63,1	12	382	1.8 mm	0.0 mm	3.4 mm	3.8 mm
Overbite	- Class II:1	n=8	47,50,53,55,57,59,61,63	178	14.9 yrs	-2.9 mm	81,4	12	382	1.4 mm	-0.7 mm	2.3 mm	3.7 mm
Overbite	- Class II:2	n=4	46,48,49,62	109	16.0 yrs	-4.4 mm	26,3	12	34	1.0 mm	0.9 mm	1.2 mm	2.8 mm

cw = cusp widths
* negative Tx and post-Tx changes mean favourable development regarding Class II correction (= no relapse)
× 0.0 mm means edge-to-edge Class II relationship (= 0.5 cw)
^ 0.0 cw means Class I relationship

Figure 1

Flow chart outlining the systematic literature search according to the PRISMA guidelines.

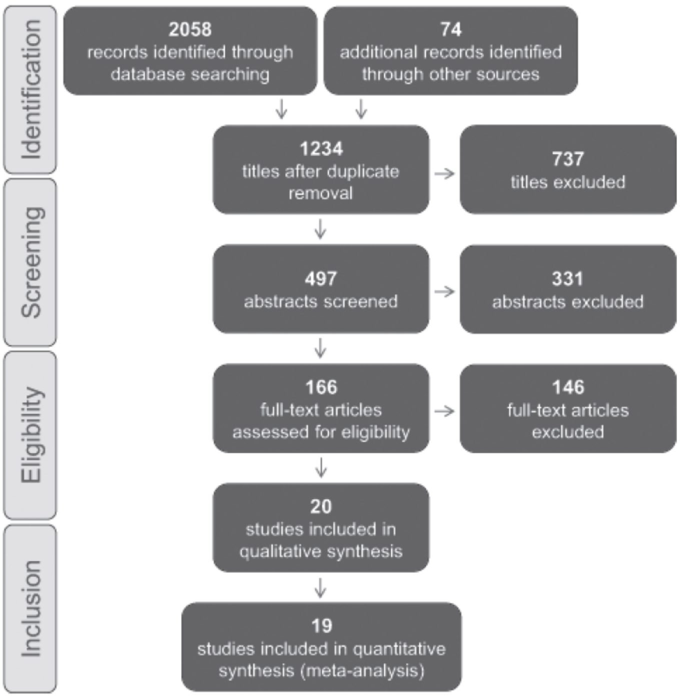
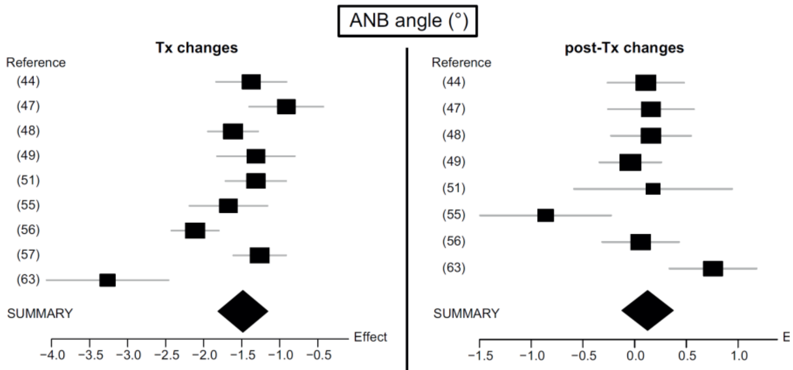


Figure 2a

Chart demonstrating the individual (article-based) Tx, post-Tx and net Tx changes of **ANB angle** as well as the weighted mean value (striped bars and grey shaded area) sorted according to mean pre-Tx age (ascending order). The reference of each article is given. Negative (-) changes indicate favourable development regarding Class II correction.



Random-effects meta-analysis

Reference	Effect	lower	95% upper	weights
44	-1.3	-1.72	-0.80	1.0
47	-0.8	-1.29	-0.31	1.0
48	-1.5	-1.83	-1.17	1.1
49	-1.2	-1.71	-0.69	1.0
51	-1.2	-1.60	-0.80	1.1
55	-1.6	-2.07	-1.05	1.0
56	-2.0	-2.31	-1.69	1.1
57	-1.2	-1.50	-0.80	1.1
63	-3.2	-3.95	-2.35	0.7

Summary effect: -1.48; 95% CI (-1.81; -1.16)

Estimated heterogeneity variance: 0.2; p=0

Random-effects meta-analysis

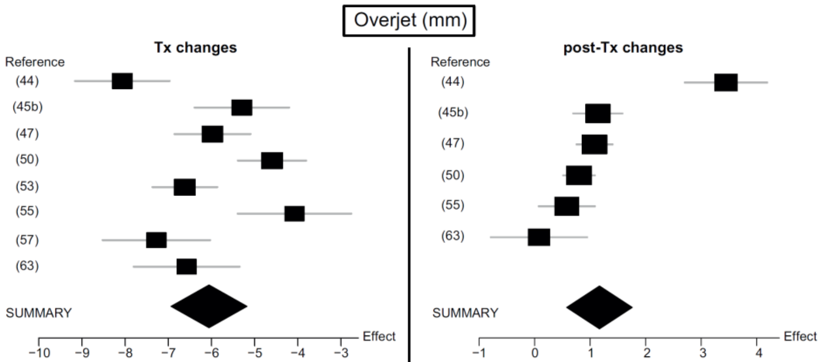
Reference	Effect	lower	95% upper	weights
44	0.2	-0.22	0.52	1.1
47	0.2	-0.21	0.61	1.0
48	0.2	-0.19	0.59	1.1
49	0.0	-0.30	0.30	1.3
51	0.2	-0.54	0.98	0.6
55	-0.8	-1.45	-0.19	0.7
56	0.1	-0.27	0.47	1.1
63	0.8	0.38	1.22	1.0

Summary effect: 0.14; 95% CI (-0.11; 0.39)

Estimated heterogeneity variance: 0.079; p=0.007

Figure 2b

Chart demonstrating the individual (article-based) Tx, post-Tx and net Tx changes of **overjet** as well as the weighted mean value (striped bars and grey shaded area) sorted according to mean pre-Tx age (ascending order). The reference of each article is given. Negative (-) changes indicate favourable development regarding Class II correction.



Random-effects meta-analysis

Reference	Effect	lower	95% upper	weights
44	-8.3	-9.39	-7.19	1.0
45b	-5.5	-6.62	-4.42	1.0
47	-6.2	-7.08	-5.32	1.1
50	-4.8	-5.61	-4.03	1.1
53	-6.8	-7.59	-6.09	1.1
55	-4.3	-5.62	-2.98	0.9
57	-7.5	-8.74	-6.26	0.9
63	-6.8	-8.03	-5.57	0.9

Summary effect: -6.28; 95% CI (-7.17; -5.4)

Estimated heterogeneity variance: 1.3; p=0

Random-effects meta-analysis

Reference	Effect	lower	95% upper	weights
44	3.4	2.63	4.11	0.9
45b	1.1	0.62	1.50	1.1
47	1.0	0.68	1.32	1.1
50	0.7	0.44	1.00	1.1
55	0.5	-0.01	1.01	1.0
63	0.0	-0.87	0.87	0.8

Summary effect: 1.09; 95% CI (0.5; 1.68)

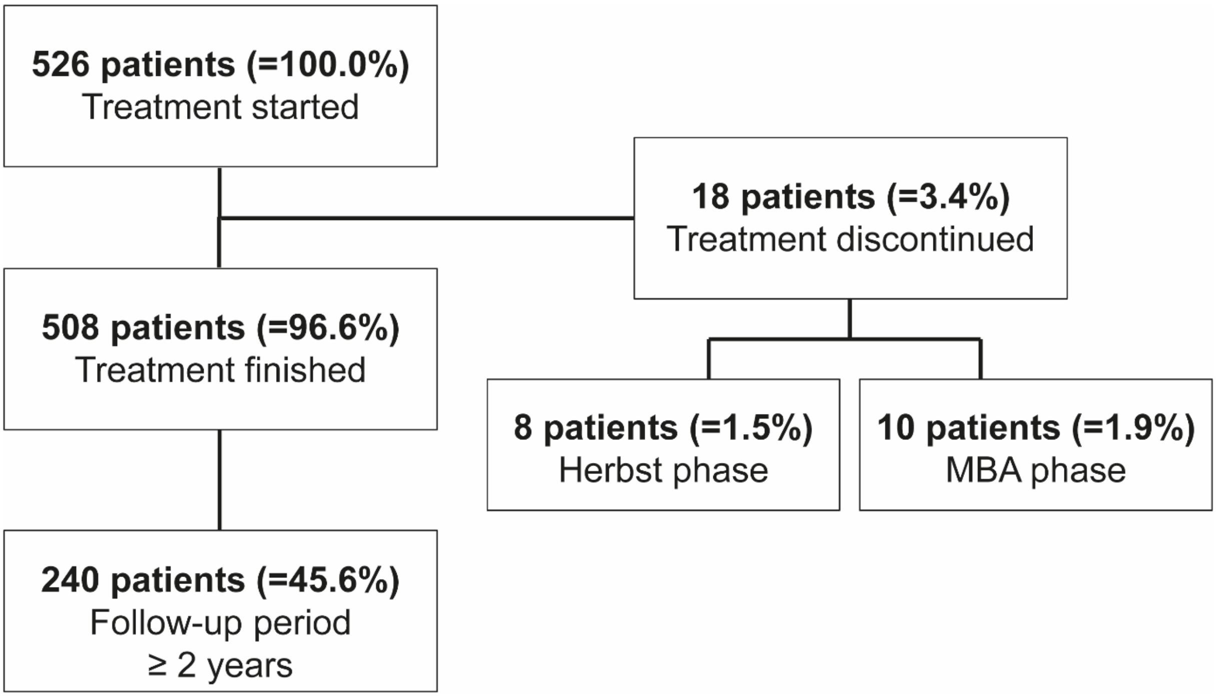
Estimated heterogeneity variance: 0.47; p=0

2) Bock NC, Rühl J, Ruf S. Orthodontic Class II:1 treatment - efficiency and outcome quality of Herbst-Multibracket appliance therapy.
Clinical Oral Investigations 2018;22:2005-2011

Herbst-Multibracket appliance treatment has been shown to be effective in Class II:1 patients for decades. And while possible outcome-influencing factors have been assessed since then [52,219,387,391,475,477,499,502], the respective studies represented rather narrow subgroup analyses respectively selected group analyses, making an extrapolation of the findings to Class II:1 samples in general impossible. Therefore, the present investigation aimed at determining representative data on the efficiency and the outcome quality of Herbst-Multibracket appliance treatment by assessing a large cohort of consecutively treated, unselected Class II:1 patients.

The archive of the Department of Orthodontics at the University of Giessen, Germany was screened for all Class II:1 patients in which Herbst-Multibracket appliance therapy had been performed between 1986 and 2014. 526 patients (53% females, 47% males) with a mean age of 14.4 years (range 9.8-44.4) at the start of treatment fulfilled these criteria. Treatment was discontinued prematurely in 18 of these 526 patients (3.4%). So, the treatment data of 508 patients were evaluated as well as the follow-up (≥ 24 months) data of 240 patients (Figure M).

Figure M Patient flowchart. The numbers and percentages of patients who started, discontinued and finished Tx as well as of those who fulfilled a follow-up period of ≥ 2 years are given; reprinted from: “Bock NC, Rühl J, Ruf S. Orthodontic Class II:1 treatment - efficiency and outcome quality of Herbst-Multibracket appliance therapy. Clin Oral Invest 2018;22:2005-2011” by permission of Springer Nature

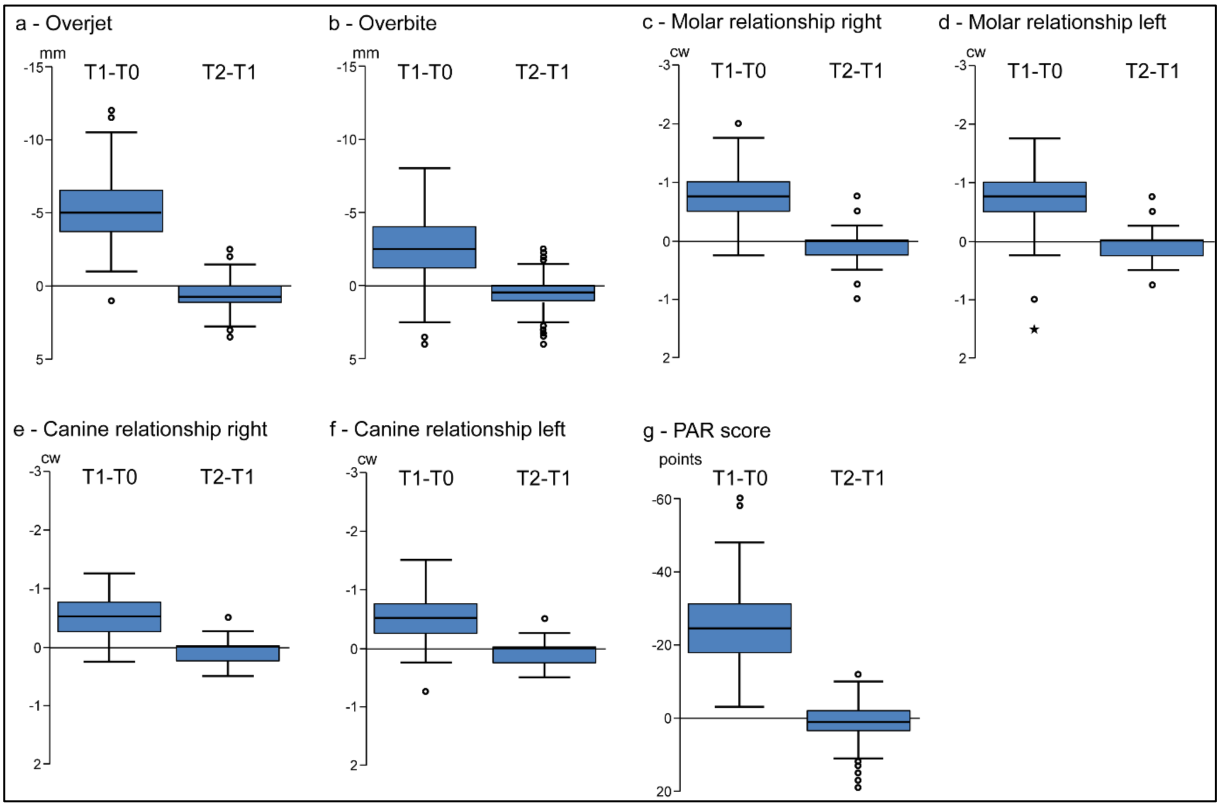


Study casts from before and after Herbst-Multibracket treatment as well as after at least 24 months of retention were evaluated. In addition to the occlusal variables overjet, overbite, sagittal molar relationship and sagittal canine relationship, the PAR-Index [376] and the Ahlgren-Scale [6] were used.

Visual ratings of the sagittal molar and canine relationships were performed to the nearest 0.25 cusp widths, linear measurements were made to the nearest 0.5 mm using a manual calliper. The same investigator assessed all standard occlusal variables and performed all PAR ratings as a calibrated and certified operator. The Ahlgren ratings were performed by two calibrated and experienced orthodontists according to the respective guidelines.

During on average 24.2±7.8 months of treatment, the overjet decreased from 7.0±2.3 mm to 2.0±0.9 mm; a slight increase of 0.7±1.0 mm occurred during retention (on average 32.7±15.9 months). For overbite, a decrease from 4.0±1.9 mm to 1.5±0.9 mm occurred during treatment and an increase of 0.5±1.1 mm was seen during retention. The sagittal molar relationship showed an overcorrection from 0.7±0.4 cusp widths Class II to -0.1±0.3 cusp widths Class III during treatment and settled to 0.0±0.23 cusp widths Class I during retention. For the sagittal canine relationship a decrease from 0.7±0.3 cusp widths Class II to 0.1/0.2±0.2 (right/left) cusp widths Class II occurred during treatment which settled to 0.2±0.2 cusp widths Class II during the follow-up period. Thus, on average the occlusal variables were normalised during treatment (Figure N).

<u>Figure N</u> Boxplots showing the changes of the occlusal variables (a-f) and PAR score (g); reprinted from: "Bock NC, Rühl J, Ruf S. Orthodontic Class II:1 treatment - efficiency and outcome quality of Herbst-Multibracket appliance therapy. Clin Oral Invest 2018;22:2005-2011" by permission of Springer Nature



The mean PAR score decreased from 32.4±8.8 to 8.0±4.5 during treatment; during retention an increase of 0.8±5.3 points occurred (Figure N). The outcome quality (PAR categories) at follow-up showed the following distribution: 57% “greatly improved”, 40% “improved” and 3% “worse/no different”. The categorisation according to the Ahlgren-Scale revealed the following occlusal outcomes: 17% “excellent”, 35% “good”, 45% “acceptable” and 3% “unsuccessful”.

As current systematic reviews and meta-analyses on fixed functional Class II treatment revealed deficits regarding the availability of efficiency and stability data [66,263,499,502], the findings of the present investigation seem to be of rather high value. While the underlying malocclusion and the treatment approach were similar in the entire patient sample, the overall severity and age varied pre-treatment. The same applies for the retention regime which was not uniform as the patient sample was generated during almost 30 years.

As the generally valid and reliable [103,121] PAR-Index has received criticisms for its weighting system and problems with interpretation [158], the Ahlgren-Scale was used as additional tool for outcome quality assessment.

The rather low discontinuation rate of only 3.4% and the rather short treatment duration of 24.2±7.8 months as well as the favourable and also stable treatment results give proof of Herbst-Multibracket appliance treatment as an effective and reliable treatment approach for Class II:1 malocclusions. This is also true when comparing the present findings to the few data available in literature for other treatment approaches. For other mainly unselected Class II:1 samples treated by diverse protocols (extraction, non-extraction) post-treatment PAR scores of 6.2-8.0 are described [15,48,269] while the present sample exhibited a score of 8.0±4.5. Looking at the follow-up period, the PAR score increase of 0.8±5.3 points in the present sample is in concordance with the literature, where PAR score increases of ≤ 1 point during follow-up periods of 2-3 years are described for patient samples where mainly bonded retainers were used [50,101]. Patients wearing bonded retainers (lower or both upper and lower) exhibited by on average 2.0-2.5 points lower PAR scores after the follow-up period.

Nevertheless, the present investigation included only a follow-up period of 32.7±15.9 months. Many of the patients were still adolescents or young adults with a remaining growth potential when assessed, so the long-term stability of the treatment outcome after Herbst-Multibracket therapy remains uncertain as it is also true for all other treatment approaches using fixed functional appliances for Class II correction [66].

*This is a pre-copyedited, author-produced version of an article published in **Clinical Oral Investigations** following peer review. The version of record [Bock N, Ruehl J, Ruf S. Orthodontic Class II:1 treatment - efficiency and outcome quality of Herbst-multibracket appliance therapy. Clinical Oral Investigations, Volume 22, Issue 5, 2018, Pages 2005-2011] is available online at: **https://link.springer.com/article/10.1007/s00784-017-2294-9**.*

Orthodontic Class II:1 treatment – efficiency and outcome quality of Herbst-Multibracket appliance therapy

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Abstract

Objectives: The aim of this retrospective investigation was to assess the efficiency and outcome quality of Class II:1 treatment (Tx).

Material & Methods: All Class II:1 patients that ever (1986-2014) started Tx with a Herbst appliance and subsequently a multibracket appliance (MBA) at the study center. Study casts from before Tx, after Herbst-MBA Tx and (if available) after ≥ 24 months of retention were evaluated using the PAR-Index, the Ahlgren Scale and standard occlusal variables.

Results: In total, 526 Class II:1 patients with a mean pre-Tx age of 14.4 years (range: 9.8-44.4) had received Herbst-MBA Tx; 18 patients discontinued Tx before completion. For 240 patients, data from ≥ 24 months of retention were available.

The pre-Tx PAR score of 32.4±8.83 was reduced to 8.0±4.51 during Tx. A slight increase to 8.8±5.11 occurred during retention. The percentage of patients which could be assigned to the category „greatly improved“ was 62% after Tx and 57% after retention; only 2-3% had to be assigned to the category „worse/no different“.

The outcome ratings according to the AHLGREN-Scale revealed 17% excellent, 35% good, 45% satisfactory and 3% unsuccessful results.

Conclusions: Class II:1 Tx using Herbst-MBA is an efficient approach in orthodontic care. During a mean active Tx period of 2 years high quality results can be obtained in the majority of patients

Clinical relevance: The present investigation is the first to investigate a large unselected cohort of consecutive Herbst-MBA patients to determine representative data on the efficiency and the outcome quality of this Tx approach.

Keywords: Humans; Malocclusion, Angle Class II; Orthodontic appliances, Functional; Orthodontic brackets; Mandibular advancement; Dental models

Introduction

Herbst appliance treatment (Tx) has been shown to be an effective approach in Class II:1 patients. While the Herbst appliance was conditionally followed by removable appliances [1] in the early period of modern Herbst appliance Tx, it has routinely been followed by a phase of multibracket appliance (MBA) Tx since the mid-80s [2].

Several investigations assessing possible outcome-influencing factors of this Tx approach in terms of effectiveness have been published during the last decades [3-10]. However, all these studies focused on very specific parameters (like age, skeletal maturity or growth pattern) and therefore rather small patient samples. Thus, they constitute very narrow subgroup analyses respectively selected group analyses and the results cannot be extrapolated to Class II:1 samples in general, even if the data are very valuable regarding the general scope and the possibilities of this Tx approach.

Therefore, it was the aim of the present investigation to assess a large cohort of consecutive, unselected Class II:1 Herbst-MBA patients to determine representative data on the efficiency and the outcome quality of this Tx approach.

Class II:1 classification was performed according to Angle's definition: maxillary anterior teeth are protruded as well as mandibular dentition being positioned posteriorly compared to the "normal" relationship with the mesiobuccal groove of the mandibular first molar occluding with the mesiobuccal cusp of the maxillary first molar.

Material and Methods

Study population

After ethical approval (Nr. 80/14), the archive of the Department of Orthodontics at the University of Giessen, Germany was screened for all Class II:1 patients in which Herbst-MBA Tx had been started since the introduction of this Tx approach at the study center in 1986 and was finished until 2014. The latter was true for 526 patients (53% females, 47% males) with a mean age of 14.4 years (range 9.8-44.4) at the start of Herbst-MBA Tx.

The Herbst appliance (Figure 1) is a so-called fixed functional appliance which is used for mandibular advancement. It consists of attachments (bands or casted splints) in the lateral segments of both jaws which are connected by a telescoping mechanism from the upper posterior to the lower anterior region resulting in mandibular "bite jumping". As the appliance is worn 24h/day, patient compliance is of minor concern. According to clinical and experimental studies both the upper and the lower jaws' skeletal and dental structures are affected [1, 2, 11]. During the last decades, the appliance has been shown to be effective in both Class II:1 as well as Class II:2 patients and to offer a respectable treatment alternative to surgical mandibular advancement in borderline cases [12].

Methods

The treatment charts and the respective data were available for all 526 patients. Study casts from before Tx (T0), after Herbst-MBA Tx (T1), and after at least 24 months of retention (T2) were evaluated using the PAR-Index [13] and the occlusal variables overjet, overbite as well as sagittal molar and canine relationships. In addition, the Ahlgren scale [14] was applied to assess the post-retention results (T2).

The PAR ratings were performed by a calibrated and certified operator according to the respective guidelines [13] and using an original PAR ruler. The same investigator assessed all standard occlusal variables. Visual ratings of the sagittal molar and canine relationships were performed to the nearest 0.25 cusp widths (cw) and classified as Class I, II or III. Linear measurements were made to the nearest 0.5 mm using a manual caliper. The ratings according to the Ahlgren Scale were performed by two calibrated and experienced orthodontists according to the respective guidelines [14].

To assess the observer reliability, all study models of patients 1-20 were evaluated twice, and Kendall's Tau correlation coefficient was calculated for the occlusal variables and the PAR index. The respective values range between 0.83 and 0.98, corresponding to a high consistency [15]. For assessments according to the Ahlgren-scale a conformity rate of 79-93% can be assumed according to previous investigations [16, 17].

The mean, standard deviation, minimum, maximum and median values are given for all variables. For the changes which occurred during Tx (T1-T0) and during retention (T2-T1), an explorative statistical analysis was performed. As the data did not show a normal distribution (Kolmogorov-Smirnov- and Chi-Square-tests), a nonparametric test (Wilcoxon signed-rank test) was used for data analysis. The level of significance was $p < 0.05$. In addition, to assess for possible correlations respectively associations, the Spearman-Rho- and the Kruskal-Wallis-tests were applied.

Results

Patient sample

While Tx was initiated in a total of 526 patients, it was discontinued prematurely in 18 patients (3.4%). So, the Tx data of 508 patients were evaluated as well as the follow-up (≥ 24 months) data of 240 patients (Figure 2). Study casts were available in most cases: n=492 (T0 and T1), n=232 (T2).

The most frequent pre-Tx skeletal maturity stage [18, 19] was shortly after the peak of the pubertal growth spurt: MP3-G/C3-S4 (Table 1).

39.4% of the patients had had a phase of previous orthodontic Tx (mainly with removable appliances; 25% at the study center, 75% elsewhere).

Treatment duration and retention

The mean Tx duration was 8.1±1.79 months for the Herbst phase and 16.0±7.4 months for the subsequent MBA phase, resulting in a total Tx duration (T0-T1) of 24.2±7.8 months. The mean follow-up period (T1-T2) was 32.7±15.9 months (Table 1). Retention was performed using bonded canine-to-canine, removable Hawley retainers or a combination of both. Most patients still wore the retainers at follow-up (Supplementary Table 1).

Occlusal variables (Table 2, Supplementary Table 2, Figures 2a-f)

The mean overjet decreased from 7.0±2.3 mm to 2.0±0.9 mm during Tx. During the retention period, a slight increase of 0.7±1.0 mm occurred. For overbite, a decrease from 4.0±1.9 mm to 1.5±0.9 mm was seen during Tx, while an increase of 0.5±1.1 mm occurred during the retention period. All these changes were statistically significant (p=0.000).

For the sagittal molar relationship (right and left), an overcorrection from 0.7±0.4 cw Class II to -0.1±0.3 cw Class III occurred during Tx and settled to 0.0±0.23 cw Class I during the retention period. The sagittal canine relationship showed a decrease from 0.7±0.3 cw Class II to 0.1±0.2(right)/0.2±0.2(left) cw Class II during Tx (p=0.000) which settled to 0.2±0.2 cw Class II during the follow-up period (p=0.002-0.044).

Thus, on average the occlusal variables were normalized by Tx.

Outcome quality (Table 2, Supplementary Table 2, Figure 3g and Supplementary Figure 1)

Before Tx, the mean PAR score was 32.4±8.8 points which decreased to 8.0±4.5 points during Tx (p=0.000). During the retention period a relapse of 0.8±5.3 points occurred (p=0.015). This PAR score increase was by 1.0/2.0 points lower (p=0.148) in subjects still wearing bonded lower/upper and lower retainers at T2.

The outcome quality (PAR categories) after Tx differed only minimally from the results at follow-up (T2) and showed the following prevalences (T1/T2): 62/57% "greatly improved", 36/40% "improved" and 2/3% "worse/no different". While no correlation was found between the PAR score reduction (T2) and pre-Tx skeletal maturity (r=0.057), a slight correlation was seen between the PAR score reduction and pre-Tx malocclusion severity in terms of Class II molar relationship (r=0.230).

The categorization according to the Ahlgren Scale revealed the following results at T2: 17% "excellent", 35% "good", 45% "acceptable" and 3% "unsuccessful" occlusal outcomes. No group difference for pre-Tx skeletal maturity was found (p=0.638), but a slight association seems to exist for pre-Tx malocclusion severity in terms of Class II molar relationship (p=0.031).

Discussion

The present investigation is the first to investigate a large unselected cohort of consecutive Herbst-MBA patients to determine representative data on the efficiency and the outcome quality of this Tx approach. The existence of such data seems to be particularly essential as the results of current systematic reviews and meta-analyses on the effectiveness and stability of fixed functional Class II Tx illustrate respective deficits [9, 10, 20].

Study population & Methods

The investigation is based on the evaluation of all Class II:1 patients who underwent Herbst-MBA Tx at the study center during a period of 28 years irrespective of Tx outcome. The patient sample was homogenous in terms of the underlying malocclusion (Class II:1) but the overall pre-Tx (T0) severity varied (total PAR score: 32.4±8.8) as did the pre-Tx age (14.4±3.4 years).

While the Tx approach was similar in all patients, Tx had been accomplished by several practitioners using different types of straight-wire MBAs. These issues might have had a minor impact on Tx outcome especially in terms of Tx duration and occlusal aspects such as rotation control or torque, but they do not really interfere with the aim of the study to get an overview of the Tx quality provided.

The same applies for the retention regime, which was not uniform as the patient sample was collected during a period of almost 30 years. While the standard retention protocol comprised of mainly removable appliances (predominantly Hawley retainers) during the early years of Herbst appliance treatment, fixed retention in both jaws had established during the later years. In between, combinations like for example fixed retention in the lower and removable retention in the upper jaw were considered appropriate. This also applies for additional night-time wear of an activator which had been recommended in a certain amount of patients. However, when looking at the literature, no relevant influence was found for a certain type of retention when comparing three different regimes in a RCT [21].

In 18 of the 526 patients Tx was discontinued prematurely (10x due to transfer to another place/disappearance, 7x due to unwanted MB Tx, 1x due to compliance during MB Tx). Unfortunately, however, in most cases no study model was available to assess the achieved Tx changes.

As it was the aim to determine objective data on the Tx outcome quality, the PAR Index was applied. While this index has been shown to be valid and reliable [22, 23], it has also been criticized due to problems in terms of interpretation [24] as well as its weighting system [25]. Therefore, a second index for outcome quality assessment [14] was used.

Results

Looking at the general Tx data, it seems to be worth mentioning that a premature discontinuation of Tx occurred in only 3.4% of the patients. This percentage is rather low when comparing it to the literature, where values between 9 and 17% are published for Class II fixed functional Tx [26-28]. For the remaining patients, the average Tx duration was 24.2±7.8 months (median 22.8). Unfortunately, no data from a comparable cohort of unselected Class II patients treated by fixed functional as well as MBA appliances exists, but a recent meta-analysis of 22 studies [29] describes a slightly lower mean duration (19.9 months) for fixed appliance Tx in general (Class I, II or III; no differentiation in terms of non-extraction/extraction protocols) without adjunctive use of functional appliances. In addition, the latter investigation did neither consider the severity of the underlying malocclusion nor the Tx outcome.

Overjet, overbite and the sagittal molar relationships were slightly overcorrected during active Tx and settled into normal Class I relationships during the follow-up period. For the canine relationships, a slight Class II relationship prevailed at T2. This is in concordance with the literature [30-32].

Outcome quality – active Tx

The outcome quality according to the PAR Index showed a mean post-Tx score of 8.0±4.5 in the present, fully unselected patient sample. Similar values of 6.2 to 8.0 are described by Al-Yami (n=1583) [33], Birkeland et al. (n=93) [34] and McGuiness et al. (n=207) [35] for other mainly unselected Class II:1 samples where diverse Tx protocols (extraction, non-extraction) were applied. In terms of PAR categorization, 62% respectively 36% of the current results were “greatly improved” or “improved” which is in concordance with the findings of Birkeland et al. (63% “greatly improved”, 33% “improved”) while the investigation by Al-Yami revealed slightly less advantageous results (46% “greatly improved” and 48% “improved”).

As most of these results are rather similar, the question arises whether the PAR Index is a sensitive enough tool to detect minor but clinically relevant differences at all.

When evaluating specifically those cases (n=10) which were categorized “worse/no different” according to PAR score reduction during active Tx, the mean pre-Tx PAR score was by 4.6 points lower compared to the remaining sample. Therefore, in terms of severity, these cases were below average. Nevertheless, as the mean post-Tx PAR score was by 14.2 points higher compared to the rest of the sample, the categorization “worse/no different” can probably be attributed to a combination of poor response/growth and poor cooperation.

Outcome quality – follow-up

Looking at the follow-up period, a slight PAR score increase by 0.8±5.3 points occurred. This is in concordance with a minor shift in the PAR categorization with slightly less patients becoming categorized as “greatly improved” (62->57%) and slightly more patients becoming categorized as “improved” (36->40%) or “worse/no different” (2->3%). Similar PAR score increases of ≤ 1 point for follow-up periods of 2-3 years can be found in the literature for patient samples where mainly bonded retainers were used [36, 37].

A comparison of the subjects wearing either a lower or both lower and upper bonded retainers to those not wearing any bonded retainer revealed by 2.0-2.5 points lower values in terms of PAR score increase during retention. While no statistical significance (p=0.148) was determined for this variation, it is certainly of clinical significance. In the literature, the final PAR score is described to be ~ 5 points less in patients with bonded retainers still in place 5 years post-Tx when compared to those without retainers [33, 38].

When considering the second, subjective outcome quality assessment – the Ahlgren scale – it is most interesting to discover that if we pool “excellent” and “good”, the percentage (52%) is similar as for the PAR category ”greatly improved” (57%). The same is true for “acceptable” (45%) and the PAR category “improved” (40%). Unfortunately, no data for direct comparison are available in the literature.

Limitations

The fact that follow-up data were available from only 45.6% of the patients certainly has to be considered as limitation. The same is true for the missing study models in some cases. Nevertheless, the T2 patient sample is still rather large. Besides that, in terms of consistency it might have been beneficial if all patients had been treated by the same practitioner using the same kind of MBA or to perform a randomized clinical trial, but due to the large sample and the long period of record collection such a study design is not realistic. This is also true for the favorable thought of having a comparable untreated control group available.

Conclusion

In summary, Class II:1 Tx using Herbst-MBA is an efficient approach in orthodontic care. During an active Tx period of on average 2 years high quality results can be obtained in the majority of patients.

Author Contributions

The study was designed by N. Bock and S. Ruf and all measurements were performed by J. Ruehl. All authors contributed to data analysis and interpretation while the manuscript was prepared and revised by N. Bock and S. Ruf. All authors gave final approval and agreed to be accountable for all aspects of the work.

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Compliance with ethical standards

Conflict of Interest:

Niko Bock declares that he has no conflict of interest.Julia Ruehl declares that she has no conflict of interest.Sabine Ruf declares that she has no conflict of interest.

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Ethical approval: The protocol for this retrospective investigation was approved by the ethical committee of the Faculty of Medicine, University of Giessen, Germany (80/14).

Informed consent: For this type of study, formal consent is not required.

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Table 1 General characteristics of the patient sample: pre-Tx age and skeletal maturity as well as the duration of the observation periods are given. The median (Med), mean value (Mean), standard deviation (SD), minimum (Min) and maximum (Max) are given for age and observation period duration, while the distribution in percent is given for the skeletal maturity stages.

		Med	Mean	SD	Min	Max
Pre-Tx age (years)		13.8	14.4	3.42	9.8	44.4
Pre-Tx skeletal maturity stages		%				
	MP3-E / C3-S1	9.1				
	MP3-F / C3-S2	15.0				
	MP3-FG / C3-S3	19.3				
	MP3-G / C3-S4	20.3				
	MP3-H – R-J / C3-S5 – C3-S6	35.6				
Observation periods (months)		**Med**	**Mean**	**SD**	**Min**	**Max**
Active Tx	Herbst phase	7.8	8.1	1.79	2.6	15.6
	MBA phase	14.3	16.0	7.36	4.0	47.0
	Total	22.8	24.2	7.76	8.5	54.7
Retention		27.1	32.7	15.93	24.0	190.0

Table 2 Overjet, overbite, sagittal molar and canine relationships (right/left) as well as PAR score at T0, T1 and T2. For each variable, the median (Med), mean value (Mean), standard deviation (SD), minimum (Min) and maximum (Max) are given. cw: cusp widths.

		T0 (n=492)					T1 (n=492)					T2 (n=232)				
		Med	Mean	SD	Min	Max	Med	Mean	SD	Min	Max	Med	Mean	SD	Min	Max
Overjet (mm)		6.5	7.0	2.28	1.5	15.5	2.0	2.0	0.91	0.0	7.3	2.5	2.7	0.93	0.5	7.5
Overbite (mm)		4.0	4.0	1.92	-4.0	9.0	1.5	1.5	0.89	-2.0	4.5	2.0	2.0	1.13	-2.0	5.0
Sagittal Molar Relationship (cw)	**Right**	0.8	0.7	0.36	-0.3	2.0	0.0	-0.1	0.25	-1.0	0.8	0.0	0.0	0.26	-0.8	1.0
	Left	0.8	0.7	0.40	-1.5	2.0	0.0	-0.1	0.27	-0.8	0.8	0.0	0.0	0.27	-0.5	1.3
Sagittal Canine Relationship (cw)	**Right**	0.8	0.7	0.27	-0.3	2.0	0.3	0.1	0.19	-0.8	1.3	0.3	0.2	0.19	-0.3	1.0
	Left	0.8	0.7	0.30	-0.3	2.0	0.3	0.2	0.19	-0.8	1.0	0.3	0.2	0.20	-0.3	1.0
PAR score		32.0	32.4	8.83	10.0	70.0	7.0	8.0	4.51	2.0	30.0	7.0	8.8	5.11	2.0	29.0

Table 3 Final PAR score at T2 and changes of the total PAR score during retention (T2-T1) in subjects with no retainer (n=42), a bonded lower retainer (n=71) and bonded upper and lower retainers (n=115) at T2.

	No fixed retainer n=42					Bonded lower retainer n=71					Bonded upper & lower retainer n=115					
	Med	SD	Min	Max	Mean	Med	SD	Min	Max	Mean	Med	SD	Min	Max	Mean	
Total PAR score at T2	8.0	6.32	3.0	29.0	10.1	7.0	5.00	2.0	24.0	9.0	6.0	4.66	2.0	23.0	8.2	0.149
PAR score changes during T2-T1	3.0	6.96	-10.0	19.0	2.9	1.0	5.45	-10.0	17.0	0.9	0.0	4.25	-12.0	15.0	0.4	0.148

Figure 1 Herbst appliance: Casted splints in the upper and lower jaw connected by telescoping mechanisms between the upper first molars and the lower first premolars. In addition, a lingual arch is placed between the lower lateral segments.

Figure 2 Patient flow chart. The numbers and percentages of patients who started, discontinued and finished Tx as well as of those who fulfilled a follow-up period of ≥ 2 years are given.

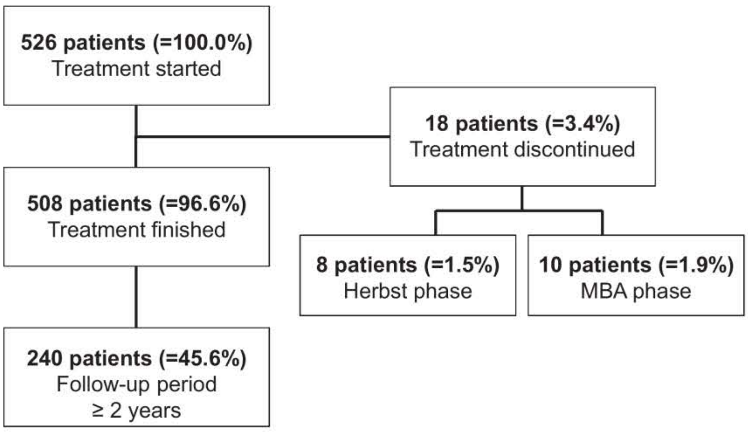
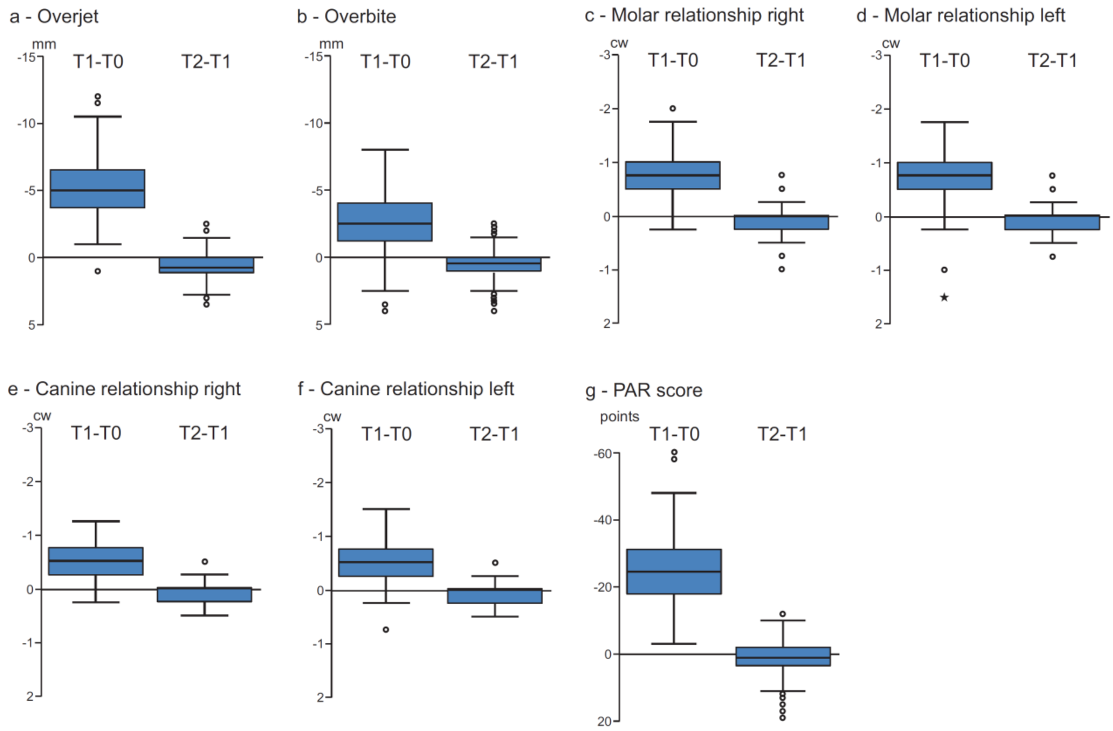


Figure 3 Boxplots showing the changes of (a) overjet, (b) overbite, (c-f) sagittal molar and canine relationships (right/left) as well as (g) PAR score during T1-T0 and T2-T1.



3) Bock NC, Rühl J, Ruf S. Herbst-multibracket appliance treatment: Prevalence, magnitude and incidence of labial gingival recessions: a retrospective cohort study.
The Angle Orthodontist 2018; accepted for publication

The literature on the impact of orthodontic treatment on labial gingival recessions' aetiology is controversial. Pronounced labial movement of teeth has been considered to be a respective predisposing factor since the 1970s [36,439]; systematic reviews, however, found little to no such effect [67,341].

Class II:1 Herbst-Multibracket appliance treatment is known to cause pronounced lower incisor proclination [60,311,385] which has been shown to be unpredictable on the individual level [476]. So far, however, only rather selected samples' lower incisors have been assessed for this unwanted side effect [60,323,385]. Therefore, it was the aim of the present study to investigate a large unselected sample of consecutive Class II:1 patients which had received Herbst-Multibracket appliance treatment, for the prevalence, incidence and magnitude of labial gingival recessions on all permanent teeth.

All Class II:1 patients who had been treated with a Herbst-Multibracket appliance at the Department of Orthodontics, University of Giessen, Germany were included in the present investigation if study models from before and/or after at least 24 months of retention were available.

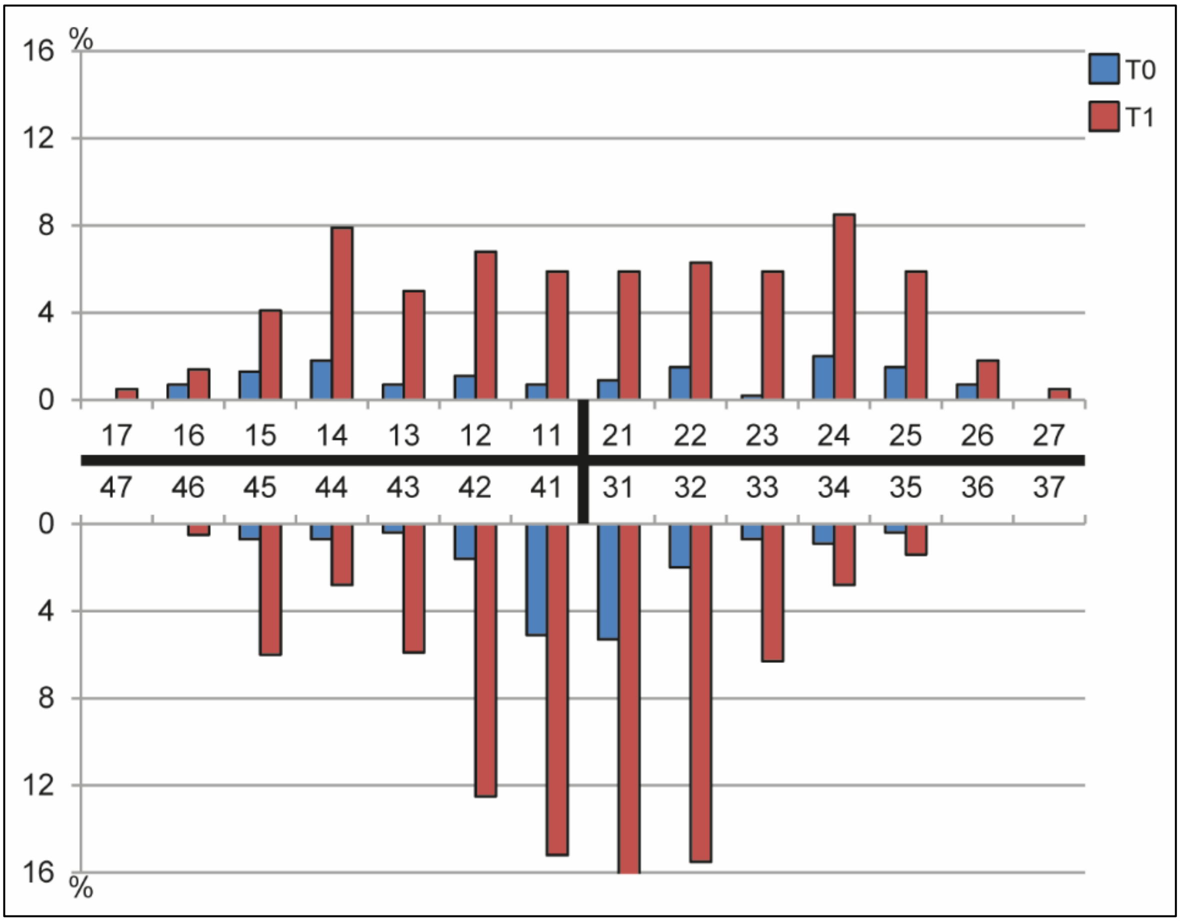
All study models were assessed by one single operator measuring the distance between the cemento-enamel junction and the deepest point of the gingival margin on all fully erupted teeth (except wisdom teeth) to judge for labial gingival recessions. A manual calliper was used and the values were rounded to the nearest 0.5 mm. The prevalence (%) and magnitude (mm) were assessed for the whole sample while the incidence (%) was only calculated for patients with study models available from both occasions.

From a total of 526 patients with a mean pre-treatment age of 14.4±3.4 years and a mean treatment duration of 24.2±7.8 months, 460 pre-treatment and 222 post-retention (on average 32.6±15.9 months after treatment) study models were available. A set of both study models was available for 187 patients with a mean total observation period of 60.0±15.1 months.

Before treatment, 1.1% of all teeth (n=12573) exhibited labial gingival recessions ≥ 0.5 mm (median magnitude: 0.0 mm). Lower central incisors showed the highest prevalence (5.1-5.3%) (Figure O). After retention, 5.3% of all 6131 teeth exhibited labial gingival recessions ≥ 0.5 mm (median magnitude: 0.0 mm). The highest prevalence (12.5-16.4%) was seen for the lower incisors (Figure O).

Looking at the incidence for labial gingival recessions (≥ 0.5 mm) during 60.0±15.1 months of treatment and retention, an overall value of 4.0% was determined. The highest value (10.4-11.4%) was seen for lower incisors.

Figure O Prevalence (%) of labial gingival recessions with a magnitude ≥ 0.5 mm for the teeth 17-47 before treatment (T0) and after Herbst-Multibracket appliance treatment and a retention period of ≥24 months (T1); from: “Bock NC, Rühl J, Ruf S. Prevalence and incidence of labial gingival recessions during Herbst-Multibracket appliance treatment. Angle Orthod 2018; accepted for publication” by permission of The Angle Orthodontist (open access)



This study is the first to assess the prevalence, incidence and magnitude of labial gingival recessions on all permanent teeth with regard to Herbst-Multibracket treatment. As this study was performed retrospectively, however, not all factors possibly influencing the development of recessions could be considered. However, the patient sample was rather homogenous in terms of the underlying malocclusion and the treatment approach. Another limitation is the large number of unavailable/not-assessable models due to gingival swelling (after Multibracket appliance treatment only) or yet incomplete retention period.

Comparing the present findings to the literature, similar pre-treatment prevalence values can be found [8,202,372] even if respective data are generally rare. The general post-retention prevalence is rather low whereas the respective values for the lower incisors are ~5-10% higher than those given in the literature for orthodontically untreated patients [8,151,249,284,372,417,430,448,456]. In terms of magnitude, all values including those for the lower incisors are in concordance with the literature [241,249,284,456]. The overall incidence, however, seems to be lower in the present sample when compared to the literature (10% in orthodontically treated adults; 8% in untreated adolescents) [8,202,278]. Looking specifically at the lower incisors, rather similar incidence and magnitude data can be found in the literature where, however, different treatment modalities were used [23,28,207,278,284,373].

Therefore, Herbst-Multibracket treatment should not be seen as a general risk factor for labial gingival recession development - at least short-term and not to a clinically relevant extent.

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Herbst-multibracket appliance treatment: Prevalence, magnitude and incidence of labial gingival recessions: a retrospective cohort study

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Abstract

Objectives: To assess the prevalence and magnitude of labial gingival recessions (LGR) before and after as well the incidence during Class II:1 Herbst-Multibracket appliance (Herbst-MBA) treatment (Tx) plus retention in a retrospective cohort study.

Materials and Methods: All Class II:1 patients who completed Herbst-MBA Tx (mean pre-Tx age: 14.4 years) at Department of Orthodontics, University of Giessen, Germany. Tx had consisted of a Herbst phase (mean 8.1 months) and a subsequent MBA phase (mean 16.1 months). Study casts from before and after Herbst-MBA Tx plus ≥24 months of retention were evaluated.

Results: A total of 460 pre-Tx and 222 post-retention study casts were available (total observation period: 59.2±14.8 months). The overall prevalence for teeth with LGR ≥0.5mm was 1.1% pre-Tx and 5.3% post-retention. The highest prevalences of up to 5.3% (pre-Tx) and 16.4% (post-retention) were seen for the lower incisors. Overall, the median magnitude of LGR was 0.0mm pre-Tx/post-retention (mean: 0.05mm/0.08mm). Incidence values of 4.0% (all teeth) and 10.0-11.4% (lower central incisors) were calculated for LGR ≥0.5mm.

Conclusion: The prevalence of LGR ≥0.5mm increased from on average 1.1% to 5.3% during ≈6 years of Herbst-MBA Tx plus retention. The highest incidence was seen in lower incisors (10.0-11.4%). However, due to the overall mean magnitude of 0.08mm post-retention, the clinical relevance can be considered as insignificant.

Key words: Herbst; Gingival recession

Introduction

The knowledge on whether and to what extent the development of labial gingival recessions (LGR) can be attributed to orthodontic treatment (Tx) is controversial. Already in the 1970s it was discussed that pronounced labial movement of teeth may predispose to the development of LGR as a result of orthodontically induced bone dehiscences and periodontal attachment loss[1,2]; and even today no corresponding consensus can be found in literature.

There are controversial systematic reviews testifying both little to no clinically relevant effect[3] and small detrimental effects[4] of orthodontic therapy on periodontal health. However, other studies determined a higher prevalence for LGR in orthodontically treated subjects when compared to untreated controls.[5,6] Particularly the proclination of lower incisors has been described as a risk factor[7]. This, however, was disconfirmed in a recent trial where patients were assessed 5 years after fixed appliance Tx and bonded retainer wear.[8]

A rather large amount of lower incisor proclination is known to occur during Class II correction using a Herbst appliance.[9-11] Three-dimensional radiographic evaluations determined alveolar bone loss on the buccal surface of the lower incisors after Herbst Tx by ≤0.2mm.[12] This undesired side effect has been shown to be unpredictable on the individual level even when using additional skeletal anchorage.[13] Nevertheless, so far no investigation has found a clinically significant negative short- or long-term effect of Herbst appliance Tx on periodontal health[9,14] nor could a direct relationship of the amount of proclination on the prevalence/incidence of LGR be established.[11] However, none of the before mentioned studies assessed other teeth than the lower incisors; in addition, most studies used only selected patient samples fulfilling specific, rather strict inclusion criteria instead of an unselected sample.

Therefore, the aim of the present investigation was to assess a large unselected (in terms of Tx outcome) sample of consecutive Class II:1 patients treated with a Herbst-Multibracket appliance (MBA) for the prevalence, incidence and magnitude of LGR on all permanent teeth.

Material and Methods

After obtaining ethical approval (Nr. 80/14), the records of all patients who had been treated with a Herbst-MBA since the introduction of this Tx approach in 1986 at Department of Orthodontics, University of Giessen, Germany were assessed regarding the following inclusion criteria and consecutively included in case of fulfilment:

- Class II:1
- Tx completed by 1st of January 2015
- Study casts available from before Tx (T0) and/or ≥24 months after Herbst-MBA Tx and retention (T1)

Tx had consisted of a Herbst phase (Figure 1, casted-splint Herbst appliance, Dentaurum GmbH, Germany) and a subsequent MBA phase (different types of labial straight-wire MBAs) including Class II elastics.

The study casts from T0 and T1 were evaluated for LGR on all fully erupted teeth except the wisdom teeth. The distance between the cemento-enamel junction and the deepest point of the gingival margin was assessed and – in case of a positive value – defined as LGR (Figure 2). These measurements were performed using a manual caliper (HSL247-52, Karl Hammacher GmbH, Solingen, Germany) and were rounded to the nearest 0.5mm. Descriptive statistics were performed separately for each kind of tooth.

All measurements were performed by one single operator (J.R.). To assess the observer reliability, all study casts of patients 1-20 were evaluated. The method error (Dahlberg Formula) was calculated as 0.03±0.07 and the Kendall's Tau correlation coefficient amounted to 0.71 which corresponds to a high consistency.[15]

While the prevalence (%) and magnitude (mm) were assessed for the entire study sample at T0 and T1, the incidence (%) for LGR during T0-T1 was analyzed for patients with available study casts from both occasions (T0 and T1) only.

All statistical analyses were performed using the software IBM® SPSS® Statistics Version 21 (IBM Corporation, Armonk, NY, USA). Due to the explorative character of the study no sample size calculation but a post-hoc power calculation was performed. Data of patients with study casts available from both T0 and T1 were compared: first in terms of LGR prevalence (McNemar test; power: 0.7±0.30) and second in terms of LGR magnitude (Wilcoxon signed-rank test; power: 0.6±0.29). The level of significance was P <0.05.

Results

While a total of 526 patients (53% females, 47% males) with a pre-Tx age of 14.4±3.4 years (range: 9.8-44.4) had received Herbst-MBA Tx between 1986 and 2015, Tx was completed in 508 patients (Figure 3). The mean active Tx duration was 24.2±7.8 months (range: 8.5-54.7). From T0 to T1 the overjet had changed from 7.0±2.3 to 2.7±0.9mm and the molar relationship from 0.7±0.4 cusp widths (Class II) to 0.0±0.3 (Class I). For retention, upper and/or lower bonded canine-to-canine retainers, removable upper and/or lower retention plates or a combination of both were used and still worn at follow-up by the majority of patients. For 48 of the 508 patients, however, the pre-Tx study casts had to be excluded due to the gingival situation looking somewhat "altered" (showing marked swelling, air blows or other artefacts) and preventing from reliable measurements. So, respective study casts (T0) were available for 460 patients. 240 patients fulfilled a retention period ≥24 months (mean duration: 32.6±15.9 months), respective study casts with an "unaltered" gingival situation were available for 222 of these 240 patients (mean total observation period: 59.2±14.8 months). A set of both, pre-Tx and post-retention study casts (T0 and T1) were available for 187 patients (mean total observation period: 60.0±15.1 months).

<u>Overall Prevalence and Magnitude of LGR (T0: n=460, T1: n=222)</u>

Looking at the overall situation before Tx (T0), the prevalence for LGR (magnitude ≥0.5mm) was 1.1% for all assessed 12573 teeth (Figure 4) and revealed a median magnitude of 0.0mm (mean: 0.05mm, minimum: 0.0mm, maximum: 2.5mm; Table 1). The highest prevalence (5.1-5.3%) was seen for the lower central incisors (Figure 4) of which 0.7-0.9% exhibited LGR with a magnitude ≥2.0mm.

After Tx plus a post-Tx retention period of ≥24 months (T1), 5.3% of all assessed 6131 teeth exhibited a LGR (magnitude ≥0.5mm). The median magnitude was 0.0mm (mean: 0.08mm, minimum: 0.0mm, maximum: 4.0mm; Table 1). The lower central and lateral incisors were most frequently affected (LGR prevalence: 12.5-16.4%; Figure 4). However, only 1.4-3.7% of the incisors exhibited LGR ≥2.0mm. In addition, LGR values of ≥2.0mm were relatively more frequent (prevalence >1.0%) in upper right lateral/left central incisors (1.4%; maximum: 2.0/2.5mm), upper left canines/first premolars (2.3/2.4%; maximum: 3.0mm) as well as in lower right/left canines (2.3/2.7%; maximum: 2.0/3.0mm).

<u>Incidence of LGR (T0 and T1: n=187)</u>

Looking at the patients with available study casts from both occasions (T0 and T1) an overall LGR incidence (magnitude ≥0.5mm) of 4.0% was seen for all teeth over the average observation period of approximately 5.5 years (T0-T1). For LGR ≥2.0mm, a respective value of 0.7% was determined.

Discussion

The present investigation is the first to evaluate the prevalence and magnitude of LGR in all teeth (17-47) before and after, as well as the incidence during Class II:1 Herbst-MBA Tx and retention.

<u>Subjects</u>

The investigation is based on the assessment of study casts of all Class II:1 patients who were treated with a Herbst-MBA at one single study center during a period of 28 years. Due to the retrospective study design it was not possible to control all variables that might have contributed to the multifactorial incident LGR development (i.e. amount of mandibular advancement, crowding, patient compliance, and periodontal morphology/susceptibility to gingival recession). However, the patient sample was homogenous regarding the underlying malocclusion and the general Tx approach which was non-extraction in all but few single cases. While the fact, that Tx had been performed by several practitioners using different types of straight-wire MBAs might have had an impact on torque, it should not interfere with the investigation's objective to assess the effect of Herbst-MBA Tx on the prevalence and magnitude of LGR. As severe gingival swelling/ hyperplasia is often present upon debonding, it was decided not to assess the study casts from immediately after debonding but those from the subsequent occasion (after retention) where marked swelling is less frequent. Nevertheless, the inclusion of patients was performed irrespective of Tx outcome.

<u>Method</u>

Linear measurements of the distance between the cemen-to-enamel junction and the deepest point of the gingival margin / recession were performed on all fully erupted teeth. All study casts were assessed by one single investigator showing a low method error (0.03±0.07) and high consistency (Kendall's Tau=0.71). Therefore, the generated data can be considered objective.

While respective measurements performed on study casts were found to show a high correlation with those made clinically16, factors like gingival swelling and artefacts emerging during study cast preparation might have had an impact on the accuracy of the measurements. However, in a similar investigation (assessment of pre- and post-Tx study casts, partially by two observers) an intraobserver reliability of 0.80 to 1.00 and an interobserver agreement of 0.67-1.00 (study casts 2 years post-Tx) were determined and demonstrate the method to be reliable.[17]

Results - Prevalence

Few data on the prevalence of LGR in young adolescents are available in literature. However, the pre-Tx overall LGR prevalence of 1.1% in the present investigation for 12573 teeth, is in concordance with the value of 1.7% determined pre-Tx (also by assessing study casts) in a resembling sample of 210 similarly aged orthodontic patients[17] and lower than the prevalence of 5.6% given for a non-orthodontic sample (n=100) of 12-year old Finns after clinical examination[18]. Whether these differences are due to the assessment method or a basic population difference is unknown.

Looking at the overall post-retention prevalence, a total value of 5.3% was determined (n=6131 teeth, LGR ≥0.5mm) in the present sample after roundabout 5 years of Tx and retention. In the literature, a value of 20.2% was described for a sample of 210 patients also after 5 years of Tx and retention.[17] However, the much higher LGR prevalence for lower incisors (12.5-16.5%) in the present investigation cannot be confirmed by the literature (7.0%).[17] A possible explanation for this difference might be the use of different Tx protocols/mechanics (Herbst-MBA vs. MBA only) or a difference in the underlying malocclusions (Class II:1 vs. a mix of 82% Class II, 17% Class I, 1% Class III), even if the proclination during Herbst-MBA has not been shown to be a long-term risk factor for LGR so far[11] as it is also true for proclination in general.[8,19]

For (mainly – according to the references) untreated samples of corresponding age, overall LGR prevalence values range between 1.6% and 13.8% in the literature (Table 4).[6,18,20-24] In contrast to the present investigation, these articles show lower LGR prevalence values for the lower incisors and do not identify them as the teeth with the highest prevalence values of the respective dentitions (Table 4).[6,17,22,24]

Results - Magnitude

In terms of mean post-retention LGR magnitude, the data from the present investigation (0.1±0.1mm) are similar as in other orthodontic patients (0.1±0.3mm, n=64; 4.6 years post-Tx at 18-26 years)[25] and even smaller than described for untreated populations (1.2/2.0mm, untreated 20-21 years old Norwegians/18-19 years old Sri Lankans).[20]

Looking specifically at lower incisors, very few data have been published so far. However, the current post-retention magnitude (mean: 0.1-0.2mm, maximum: 4.0mm) is lower than the corresponding values reported for an untreated sample (mean: 1.0-1.2mm, maximum: 3.0mm).[24]

Results - Incidence

In terms of incidence of LGR (magnitude ≥0.5mm), an overall value of 4.0% was calculated for those cases where both pre-Tx and post-retention study casts were available over the observation period of approximately 5.5 years. In the literature, overall LGR incidence rates of 10% (orthodontically treated adults, n=150)19 and 8% (untreated adolescents, period from 12 to 17 years, n=100)[18] are given.

For the lower central incisors an overall incidence of 10.4-11.4% for LGR (magnitude ≥0.5mm) was determined, which corresponds to data in the literature of 7.0-10.0% (adult patients)[19]. The same is true for respective magnitude data, which exhibited a mean increase of 0.1mm for all incisors in the current investigation and ranges between ≈0.6mm26, 0.6-1.1mm8 and 0.9-1.0mm[27] in the literature for patients who were orthodontically treated and observed for 4-9 years afterwards.

Therefore, with regard to the present findings and the data available in the literature, Herbst-MBA Tx cannot be considered as a general risk factor for LGR development, at least not to a clinically relevant extent. Of course single patients might develop lesions beyond average, but this is probably true for any kind of orthodontic Tx and in concordance with the finding that recessions probably are not induced by a single factor only.[14,20,28-30]

And while some studies in the literature conclude that orthodontic tooth movement might increase the risk for LGR development[5,6,25,31,32], the data of the present investigation including the comparison to the literature seem to disprove this suspicion for Herbst-MBA Tx.

Limitations

The limited numbers of post-retention study casts (compared to the pre-Tx sample) as well as patients with complete sets of study casts certainly are a limitation. This is also true for the retrospective study design resulting in the lack of well-matching data from treated/untreated controls and the fact that only study casts were analyzed limiting the reliability. However, due to the low overall incidence of LGR this issue seems to be negligible.

Conclusions

- During Class II:1 correction the prevalence of teeth with LGR ≥0.5mm increased from on average 1.1% before Tx to 5.3% after 24 months of Herbst-MBA Tx and a retention phase of 33 months.
- The highest prevalence after retention was found for the lower incisors (12.5-16.4%).
- However, due to the overall mean magnitude of 0.08mm after Herbst-MBA Tx plus retention, the clinical relevance can be considered as insignificant.

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Table 1 Overall magnitude (mm) of LGR for the teeth 17-47 at T0 (before Tx) and T1 (after Herbst-MBA Tx and a retention period of ≥24 months) in all included study casts (T0: n=460, T1: n=222). The mean value and standard deviation as well as the median, minimum and maximum values are given.

Max	mm	0.0	-1.0	-2.0	-2.0	-1.0	-1.0	-1.0	-2.0	-1.0	-2.0	-2.0	-2.5	-2.0	-2.0	-2.0	-2.0	-1.5	-2.0	-0.5	-3.0	-2.0	-3.0	-1.0	-2.0	-2.0	-2.0	0.0	-1.0
Min	mm	0.0																											
Median	mm	0.0																											
SD	mm	0.00	0.07	0.11	0.15	0.10	0.17	0.11	0.30	0.06	0.24	0.13	0.35	0.11	0.24	0.14	0.30	0.11	0.31	0.02	0.42	0.13	0.39	0.10	0.24	0.11	0.18	0.00	0.07
Mean	mm	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.0
Occasion		T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1
		17		16		15		14		13		12		11		21		22		23		24		25		26		27	
		Tooth																											
		47		46		45		44		43		42		41		31		32		33		34		35		36		37	
Occasion		T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1
Mean	mm	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.1	0.1	0.2	0.1	0.2	0.0	0.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD	mm	0.00	0.00	0.00	0.03	0.06	0.27	0.12	0.14	0.05	0.34	0.11	0.39	0.25	0.51	0.25	0.47	0.15	0.46	0.16	0.41	0.09	0.13	0.03	0.08	0.00	0.00	0.00	0.00
Median	mm	0.0																											
Min	mm	0.0																											
Max	mm	0.0	0.0	0.0	-0.5	-1.0	-3.0	-2.0	-1.0	-1.0	-2.0	-1.5	-2.0	-2.0	-4.0	-2.5	-4.0	-2.0	-4.0	-2.5	-3.0	-1.0	-1.0	-0.5	-1.0	0.0	0.0	0.0	0.0

Table 2 Prevalence (%) of LGR for the teeth 17-47 before Tx (T0) and after Herbst-MBA Tx plus a retention period of ≥24 months (T1) in 187 individuals. LGR categorised by magnitude: none (<0.5mm), 0.5-0.9mm, 1.0-1.9mm, ≥2.0mm. In addition, the p-value of the statistical comparison (T0 vs. T1) is shown for the category none (<0.5mm).

LGR prevalence	None (<0.5mm)	%	100.0	99.5	99.5	98.5	98.9	95.2	98.9	92.9	99.5	94.7	98.4	93.5	99.5	95.6	100.0	95.2	99.0	94.6	99.5	93.6	98.4	91.1	98.4	93.6	99.0	97.8	100.0	99.5
		%	p=1.000		p=0.500		p=0.016		p=0.001		p=0.008		p=0.004		p=0.016		p=0.008		p=0.008		p=0.003		p=0.000		p=0.012		p=0.500		p=1.000	
	≥0.5 - <1.0 mm	%	0.0	0.0	0.0	0.5	0.0	1.6	0.0	1.6	0.0	0.5	0.0	0.0	0.0	2.2	0.0	1.6	0.5	0.6	0.5	0.0	1.1	2.8	0.5	2.1	0.0	0.0	0.0	0.0
	≥1.0 - <2.0 mm	%	0.0	0.5	0.0	0.5	1.1	3.2	1.1	4.4	0.5	4.3	1.6	5.4	0.5	2.2	0.0	2.1	0.5	3.7	0.0	4.3	0.0	3.3	1.1	3.8	0.5	1.7	0.0	0.5
	≥ 2.0 mm	%	0.0	0.0	0.5	0.5	0.0	0.0	0.0	1.1	0.0	0.5	0.0	1.1	0.0	0.0	0.0	1.1	0.0	1.1	0.0	2.1	0.5	2.8	0.0	0.5	0.5	0.5	0.0	0.0
	Total	%	0.0	0.5	0.5	1.5	1.1	4.8	1.1	7.1	0.5	5.3	1.6	6.5	0.5	4.4	0.0	4.8	1.0	5.4	0.5	6.4	1.6	8.9	1.6	6.4	1.0	2.2	0.0	0.5
Occasion			T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1
			17		16		15		14		13		12		11		21		22		23		24		25		26		27	
			Tooth																											
			47		46		45		44		43		42		41		31		32		33		34		35		36		37	
Occasion			T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1
LGR prevalence	Total	%	0.0	0.0	0.0	0.5	0.0	3.3	1.1	2.8	1.0	5.9	2.2	12.2	4.4	14.8	5.4	16.8	3.8	14.1	1.0	4.9	1.2	3.4	0.5	1.6	0.0	0.0	0.0	0.0
	≥ 2.0 mm	%	0.0	0.0	0.0	0.0	0.0	1.1	0.0	0.0	0.0	2.1	0.0	2.2	1.6	3.3	1.1	1.6	0.0	1.1	0.5	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	≥1.0 - <2.0 mm	%	0.0	0.0	0.0	0.0	0.0	1.7	1.1	1.7	0.5	2.2	1.1	6.6	1.7	8.2	2.7	9.8	2.2	7.1	0.5	2.7	0.6	1.7	0.0	0.5	0.0	0.0	0.0	0.0
	≥0.5 - <1.0 mm	%	0.0	0.0	0.0	0.5	0.0	0.5	0.0	1.1	0.5	1.6	1.1	3.4	1.1	3.3	1.6	5.4	1.6	5.9	0.0	1.1	0.6	1.7	0.5	1.1	0.0	0.0	0.0	0.0
	None (<0.5mm)	%	100.0	100.0	100.0	99.5	100.0	96.7	98.9	97.2	99.0	94.1	97.8	87.8	95.6	85.2	94.6	83.2	96.2	85.9	98.9	95.1	98.8	96.6	99.5	98.4	100.0	100.0	100.0	100.0
		%	p=1.000		p=1.000		p=0.031		p=0.375		p=0.022		p=0.000		p=0.000		p=0.000		p=0.000		p=0.039		p=0.125		p=0.500		p=1.000		p=1.000	

Table 3 Magnitude (mm) of LGR for the teeth 17-47 before Tx (T0) and after Herbst-MBA Tx plus a retention period of ≥24 months (T1) in 187 individuals. The mean value and standard deviation as well as the median, minimum and maximum values are given. In addition, the p-value of the statistical comparison (T0 vs. T1) is given for each kind of tooth.

p		0.317		0.180		0.015		0.003		0.007		0.007		0.015		0.011		0.007		0.002		0.001		0.017		0.157		0.317	
Max	mm	0.0	-1.0	-2.0	-2.0	-1.0	-1.0	-1.0	-2.0	-1.0	-2.0	-1.0	-2.5	-1.0	-1.0	0.0	-2.0	-1.5	-2.0	-0.5	-3.0	-2.0	-3.0	-1.0	-2.0	-2.0	-2.0	0.0	-1.0
Min	mm	0.0																											
Median	mm	0.0																											
SD	mm	0.00	0.07	0.15	0.17	0.10	0.19	0.10	0.31	0.08	0.25	0.13	0.34	0.07	0.16	0.00	0.26	0.12	0.30	0.04	0.40	0.16	0.42	0.11	0.25	0.16	0.19	0.00	0.07
Mean	mm	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-0.1	0.0	-0.1	0.0	-0.1	0.0	0.0	0.0	-0.1	0.0	-0.1	0.0	-0.1	0.0	-0.1	0.0	-0.1	0.0	0.0	0.0	0.0
Occasion		T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1
		17		**16**		**15**		**14**		**13**		**12**		**11**		**21**		**22**		**23**		**24**		**25**		**26**		**27**	
		Tooth																											
		47		**46**		**45**		**44**		**43**		**42**		**41**		**31**		**32**		**33**		**34**		**35**		**36**		**37**	
Occasion		T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1
Mean	mm	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-0.1	0.0	-0.1	-0.1	-0.2	-0.1	-0.2	0.0	-0.1	0.0	-0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD	mm	0.00	0.00	0.00	0.04	0.00	0.30	0.11	0.14	0.08	0.34	0.12	0.39	0.29	0.51	0.27	0.49	0.16	0.36	0.16	0.28	0.08	0.14	0.04	0.90	0.00	0.00	0.00	0.00
Median	mm	0.0																											
Min	mm	0.0																											
Max	mm	0.0	0.0	0.0	-0.5	0.0	-3.0	-1.0	-1.0	-1.0	-2.0	-1.0	-2.0	-2.0	-4.0	-2.0	-4.0	-1.0	-2.0	-2.0	-2.0	-1.0	-1.0	-0.5	-1.0	0.0	0.0	0.0	0.0
p		1.000		0.317		0.026		0.334		0.010		0.000		0.001		0.001		0.000		0.083		0.063		0.180		1.000		1.000	

Table 4 LGR prevalence data available in the literature. The reference number, sample characteristics and LGR prevalence values (%) of comparable samples (age) are given.

Reference	**Sample**				**LGR prevalence**	
	Origin	Orthodontic Tx	n	age (years)	Type of teeth	%
6	Israel	27.4% treated	303	18-22	17-47	1.6
					31,41	4.5-6.8
					14,24,34,44	6.8-13.5
17	Netherlands	100.0% treated	302	19	17-47	20.2
					32-42	≈0.5-4.0
					14,24,34,44	≈4.0-6.5
					16,26	≈1.0-2.5
					36,46	≈1.5-2.8
18	Finland	no information	100	17	17-47	13.8
20	Norway	no information	n.a.	20-21	17-47	5.8
	Sri Lanka	no information	n.a.	18-19	17-47	1.6
21	Brazil	no information	263	14-19	17-47	2.9
22	Sweden	no information	n.a.	18-29	17-47	7.0
					32-42	≈2.0-6.0
					14,24,34,44	≈10.0-16.0
					16,26	≈12.0-24.0
					36,46	≈4.0-6.0
23	USA	no information	77	16-25	17-27	9.5
24	France	no information	100	19-26	17-27	11.9
					32-42	5.0-9.1
					14,24,34,44	28.1-40.2
					16,26	3.1-10.3
					36,46	3.3-6.5

Figure 1 Herbst appliance: Casted splints in both arches connected by telescoping mechanisms between upper 6 and lower 4 establishing an incisal edge-to-edge relationship. A lingual arch connects the lower lateral segments.

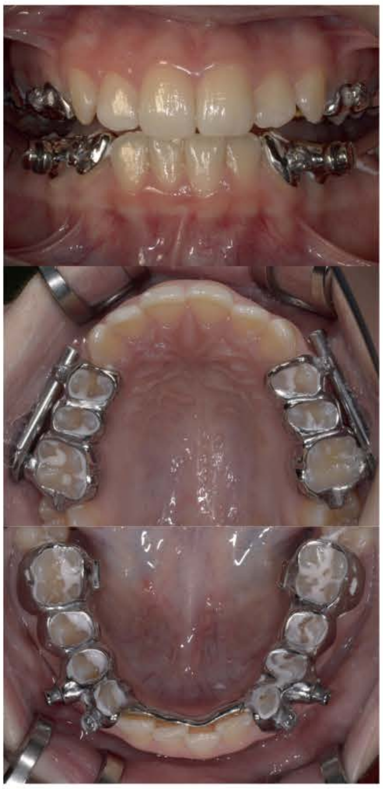


Figure 2 Measurement of the distance between the cemento-enamel junction and the deepest point of the gingival margin using a manual caliper.

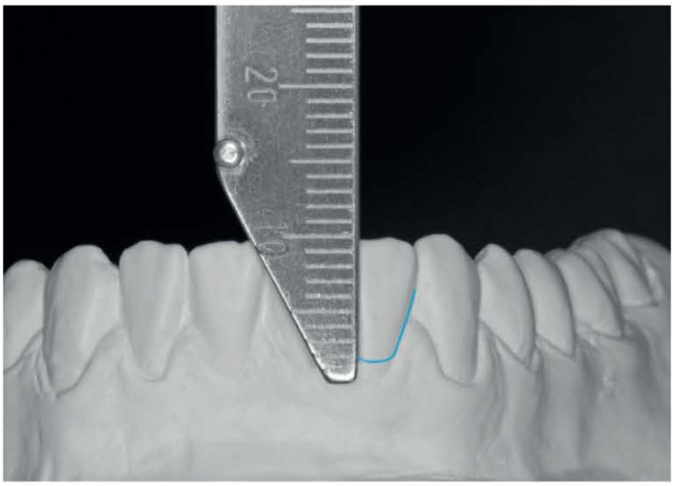


Figure 3 Patient flow chart. The numbers of Class II:1 patients who started/completed Herbst-MBA Tx and a retention period ≥24 months are given, as well as the numbers of included pre- and post-retention study casts.

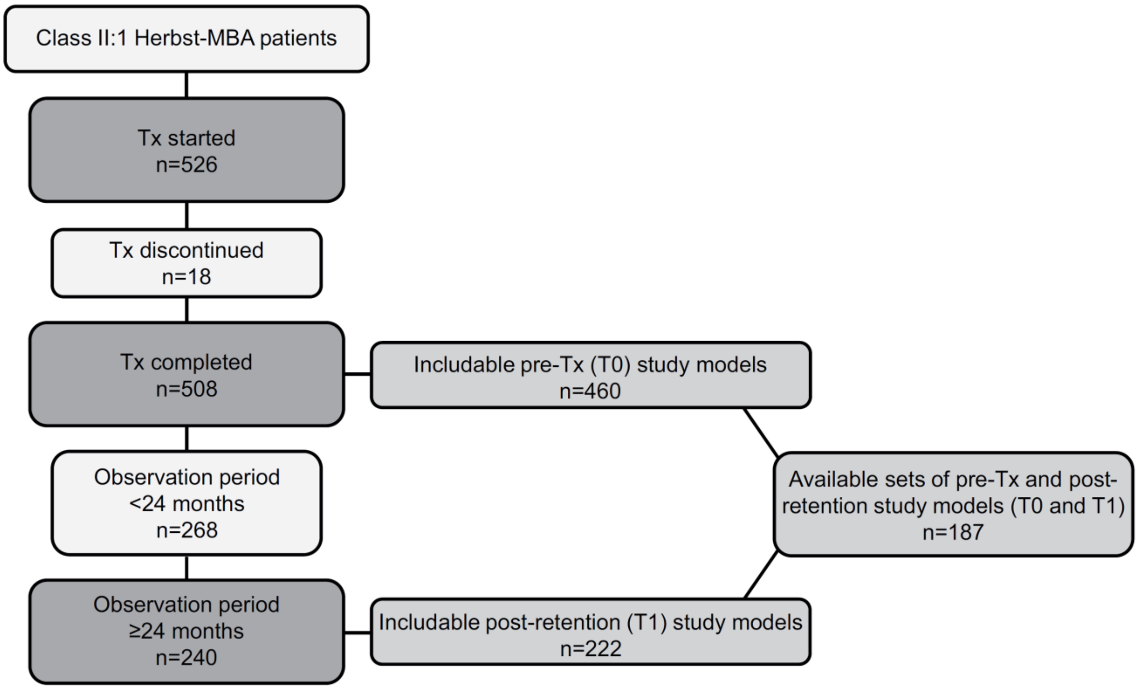
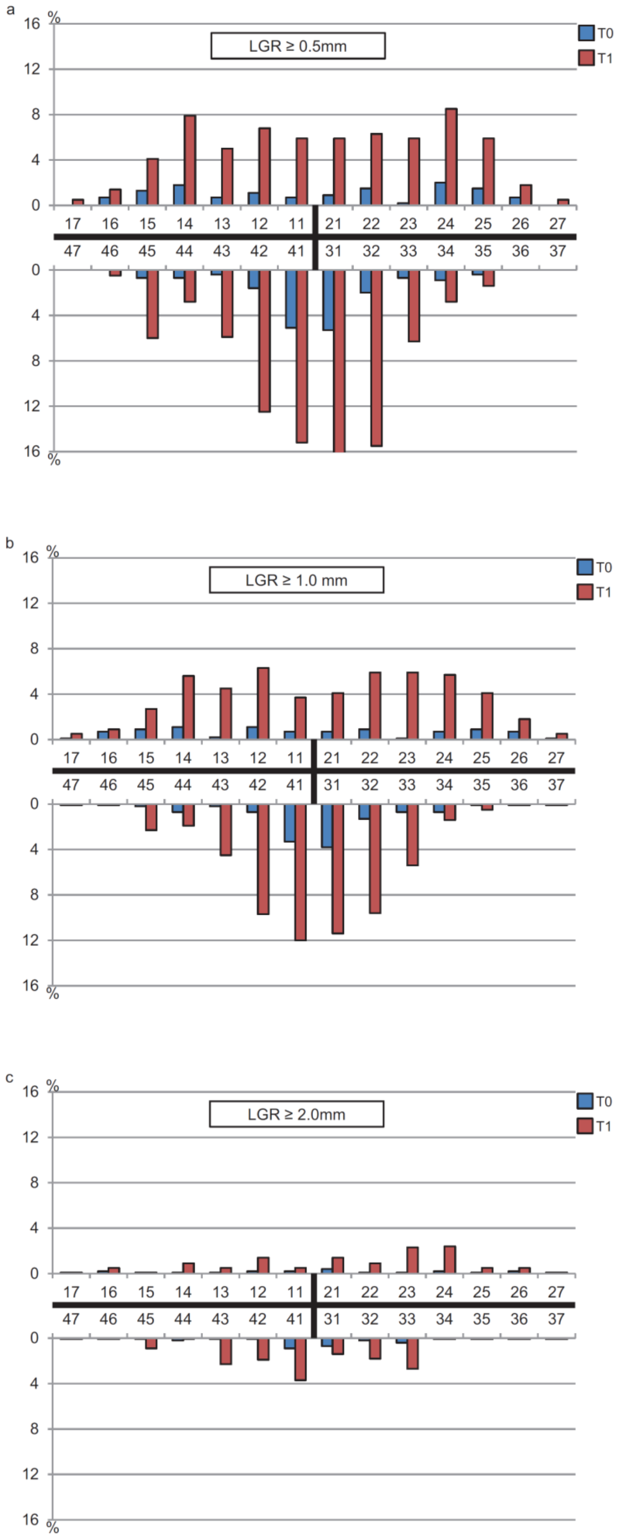


Figure 4 Prevalence (%) of LGR for teeth 17-47 before Tx (T0) and after Herbst-MBA Tx and a retention period ≥24 months (T1) for magnitude ≥ 0.5(a)/1.0(b)/2.0(c) mm in all included study casts (T0: n=460, T1: n=222).

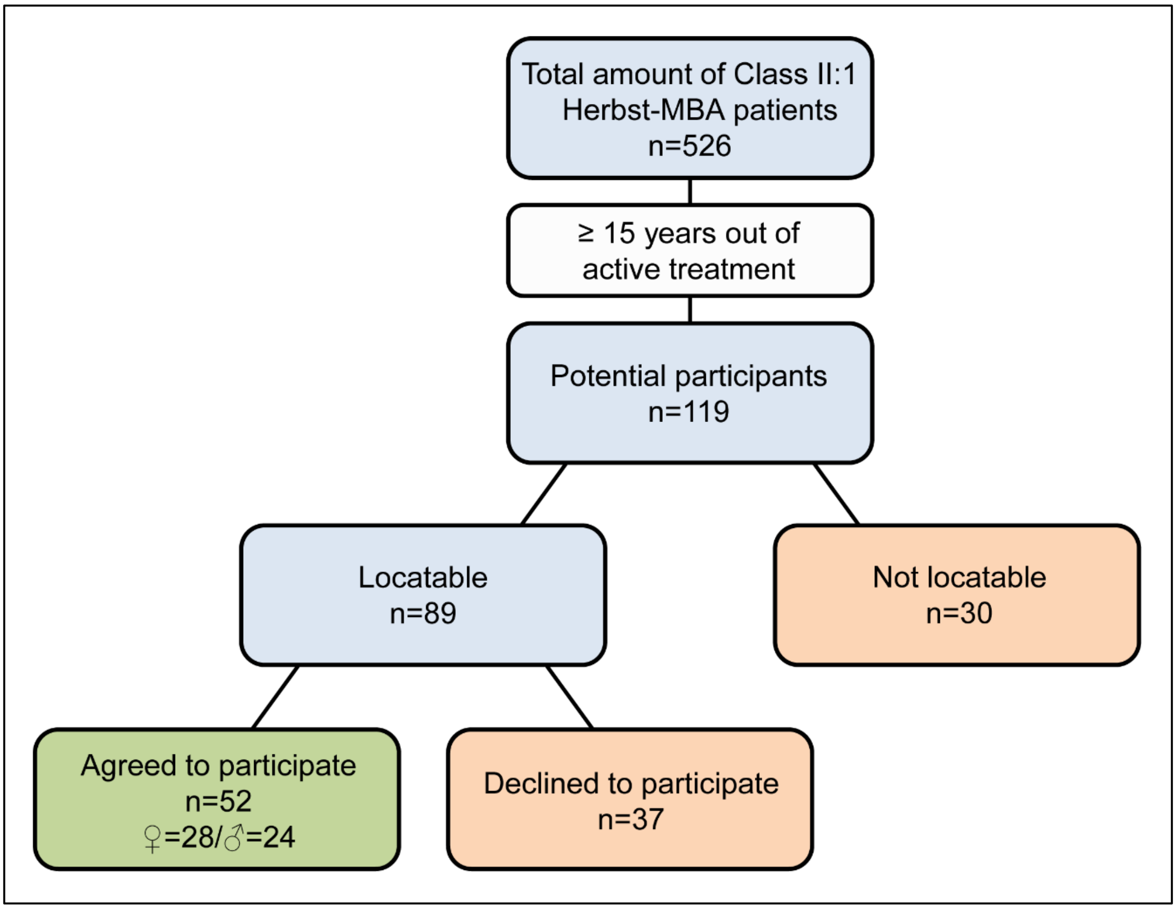


4) Bock NC, Saffar M, Hudel H, Evälahti M, Heikinheimo K, Rice DP, Ruf S. Long-term (≥ 15 years) post-treatment changes and outcome quality after Class II:1 treatment in comparison to untreated Class I controls. *European Journal of Orthodontics 2018;40:206-213*

The use of fixed functional appliances like the Herbst appliance is a common approach for non-surgical Class II:1 correction [211]. Several publications on respective treatment changes can be found in literature [187,502], but only little evidence exists in terms of long-term stability [66]. A series of five articles [323,324,325,326,337] describing the post-treatment changes during 32 years in the very first patients (n=14) who received Herbst appliance therapy in the era of modern orthodontics have been published, but no control group was used when assessing the long-term changes. In addition, most of these patients were only treated for six months of bite-jumping and eventually a retention period, while it has become common since the mid-80s and is now standard to add a subsequent phase of Multibracket appliance treatment to enable proper settling and alignment. For this modified approach, however, no long-term data (≥ 3 years) have been published so far. So, it was the aim of the present investigation to assess the long-term (≥ 15 years) occlusal stability and outcome quality of Herbst-Multibracket appliance treatment in comparison to untreated controls.

All Class II:1 patients who had received Herbst-Multibracket appliance therapy at the Department of Orthodontics, University of Giessen, Germany which was finished ≥ 15 years ago were asked to participate in a recall. While 119 potential participants were identified, 89 of them could be located. Out of them, 52 (58%) with a mean age of 33.6±3.1 years finally participated (Figure P); 21 still wore at least a lower bonded retainer.

Figure P Flowchart of the study participants/non-participants of the Class II:1 sample. The numbers of total Herbst-Multibracket appliance patients (active treatment completed by January, 1st 2015) as well as potential participants and the results of the recruitment process are given; reprinted from: "Bock NC, Saffar M, Hudel H, Evälahti M, Heikinheimo K, Rice DP, Ruf S. Long-term (≥ 15 years) post-treatment changes and outcome quality after Class II:1 treatment in comparison to untreated Class I controls. Eur J Orthod 2018;40:206-213" by permission of Oxford University Press/European Orthodontic Society



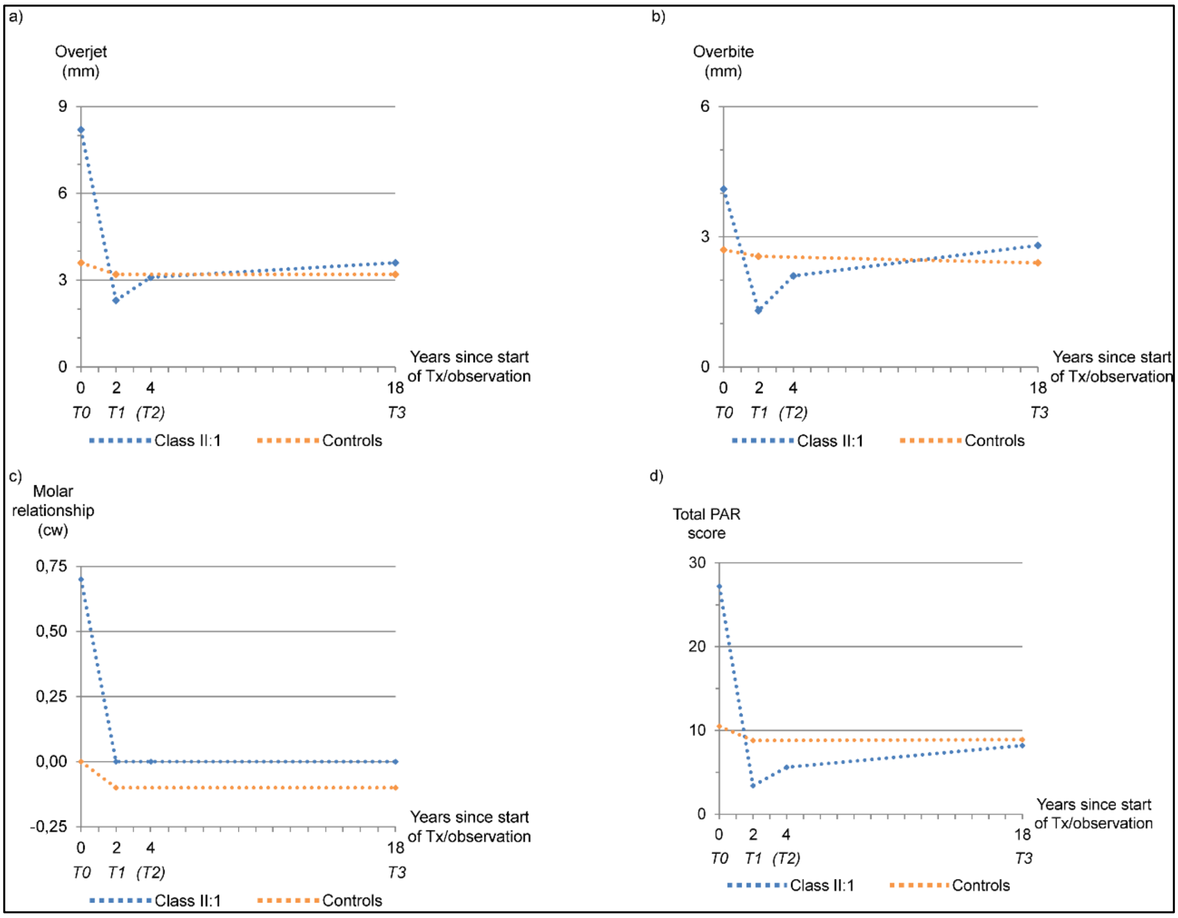
Study models were used to assess the changes which had occurred between the end of active treatment and the current situation. In addition to standard occlusal variables (sagittal molar and canine relationships, overjet, overbite), the PAR-Index was used for objective outcome quality assessment. While the molar relationship was evaluated visually to the nearest 0.25 cusp widths with a classification of Class I, II or III, overjet and overbite were assessed to the nearest 0.5 mm using a manual calliper. The PAR-Index [376] scoring was performed by a calibrated operator using an original ruler.

The control group used for comparison was considered “double negative, normal”. These untreated subjects (n=31) were participants of a longitudinal study on growth changes in Finland [168] and exhibited a Class I relationship with no orthodontic treatment need during childhood and adolescence. The respective study models from ages 12, 15 and 33 years were used.

The 52 participants and the 37 non-participants did not differ systematically in terms of age, treatment and retention duration; the occlusal variables showed slight differences. The PAR score, however, was lower (3.0-4.7 points) in the participants at all investigated occasions.

When comparing the 52 participants and the 31 controls, as expected, large differences existed for the occlusal variables and the PAR-Index data before treatment (Figure Q); immediately after treatment, more ideal values were seen in the Class II:1 sample compared to the untreated controls (Figure Q). During the follow-up period, slight recurring changes were noted in the Class II:1 sample resulting in rather similar values in both the Class II:1 sample and the untreated Class I controls at age 32/33 years (Figure Q).

Figure Q Development of a) overjet, b) overbite, c) sagittal molar relationship and d) total PAR score from T0 until T3 in the treated Class II:1 sample and the untreated Class I controls; reprinted from: “Bock NC, Saffar M, Hudel H, Evälahti M, Heikinheimo K, Rice DP, Ruf S. Long-term (≥ 15 years) post-treatment changes and outcome quality after Class II:1 treatment in comparison to untreated Class I controls. Eur J Orthod 2018;40:206-213” by permission of Oxford University Press/European Orthodontic Society



Comparing those Class II:1 participants still wearing a bonded retainer in the lower jaw at the time of recall to those not wearing a bonded retainer revealed a clear group difference in favour of retainer wear (PAR score increase: (+1.7±2.8 vs. +6.6±5.8).

The current investigation is the first to assess the long-term changes and outcome quality after Herbst-Multibracket appliance therapy in a Class II:1 sample with comparison to untreated controls. While the patient sample was rather homogenous with regard to the underlying malocclusion and treatment duration, the participation rate was only 58% and age/skeletal maturity as well as pre-treatment PAR score varied. To account for an eventual structural/selection bias, the non-participants' pre- and post-treatment data were considered as well.

The untreated controls (no orthodontic treatment need at age 15 years) were very homogenous in terms of age while minor crowding had developed in some patients. The group can be considered as "natural" gold standard for occlusal ageing. Thus, as the treated Class II:1 patients became Class I during treatment, at best they can be considered to share the same long-term occlusal ageing.

Comparing the present findings to those in other orthodontically treated and untreated populations, the long-term changes of overjet, overbite and sagittal occlusal relationship are very similar [27,115,119,163,164,267,287,411,459,470]. In terms of PAR score changes, less data can be found in the literature. Nevertheless, the changes in the treated Class II:1 patients were similar or lower than described for other populations [15,51,231,501]. However, it needs to be considered that 40% of the present sample still wore bonded retainers at the time of recall. The influence of retainer wear (PAR score by ~5 points lower) was alike in other investigations [15,231]. While the follow-up PAR scores seen in the untreated sample were slightly lower than in comparable samples in the literature, the long-term increase can be considered similar.

In conclusion, the outcome of Class II:1 Herbst-Multibracket appliance treatment showed very good long-term stability with a similar outcome as in untreated Class I controls. Thus, the present therapy can be recommended for patients exhibiting moderate to severe Class II:1 malocclusions. No comparable data have been shown for any other treatment approach using a fixed functional appliance for Class II correction nor respective orthognathic surgery or orthodontic camouflage procedures.

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Due to the journal self-archiving policy (European Journal of Orthodontics/Oxford University Press), it is only allowed to include the accepted manuscript of a publication in the thesis and not the printed/published version.

Long-term (≥ 15 years) post-treatment changes and outcome quality after Class II:1 treatment in comparison to untreated Class I controls

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Abstract

Aim: To investigate the long-term (≥ 15 years) post-treatment (Tx) occlusal changes and outcome quality after Class II:1 Tx.

Subjects and Methods: Herbst-MBA Tx had been performed at age 12.8±2.7 years in 119 patients. A recall was conducted and study models from before and after active Tx, after retention as well as after recall were evaluated using standard occlusal variables and the PAR index. These data were compared to 31 untreated Class I controls.

Results: 52 out of 119 patients could be located and participated at 33.6±3.1 years. Compared to the 67 patients who did not participate in the recall, the pre- and post-Tx occlusal data of the participants did not differ systematically; however, the PAR scores were higher by 3.0-4.7 points at all times.

Pre-Tx, the mean values of the 52 participants were: PAR = 27.2±7.6, Class II molar relationship (MR) = 0.7 cusp widths (cw), overjet = 8.2 mm, overbite = 4.1 mm. After Tx, the PAR score was 3.4±2.2. A Class I MR (0.0±0.1 cw) with normal overjet (2.3±0.7 mm) and overbite (1.3±0.7 mm) existed.

At recall, a mild PAR score increase to 8.2±5.5 points had occurred; this was mainly due to increased overjet and overbite values (3.6±1.1 and 2.8±1.6 mm) while the MR was stable (0.0±0.2 cw). For all these variables, similar findings were made in the untreated controls.

Conclusion: The occlusal outcome of Class II:1 Tx showed very good long-term stability. While mild changes occur post-Tx, the long-term result is similar to untreated Class I controls.

Introduction

12 to 32% of the Caucasian population exhibit Class II malocclusions (1, 2) and multiple treatment (Tx) strategies exist (3).

Fixed functional appliances are a widely used option for non-surgical Class II correction (4) and numerous scientific data on respective Tx changes have been published (5, 6). However, there is only little evidence regarding long-term post-Tx changes and outcome quality (7).

A recently published series of five articles describes the long-term changes (32 years) which occurred in a sample of the first patients (n=14) who were treated with a Herbst appliance during the era of modern orthodontics (8-12). However, no untreated controls were used for comparison, and most of these patients did not have any further Tx than just six months of mandibular bite jumping which was eventually followed by a period of activator wear for retention purposes. While this Tx approach was appropriate for its period in time, general developments in orthodontic Tx procedures and research changed the concept during the following years. So, from the mid-80s on Herbst Tx was generally followed by a subsequent phase of multibracket appliance (MBA) Tx. This modified Tx approach is supposed to promote a more stable occlusal relationship by enabling proper settling and alignment. Neither for this nor for any comparable Tx approach long-term data (≥ 3 years) have been published so far.

Therefore, the aim of the present investigation was to assess the long-term post-Tx occlusal stability and outcome quality after Class II:1 Herbst-MBA Tx compared to untreated controls.

Subjects and Methods

After ethical approval (Nr. 146/13) and registration (WHO: ID DRKS00006354), the archive of the Department of Orthodontics at the University of Giessen, Germany was screened for all patients (irrespective of Tx outcome) who had received Herbst-MBA Tx and whose active Tx was finished at least 15 years ago.

One hundred and nineteen patients with a mean age of 13.7 years at the start of Herbst-MBA Tx were identified. All these patients exhibited a severe Class II:1 malocclusion before Tx (median Class II molar relationship pre-Tx: 0.75 cusp widths, median overjet: 8.2 mm, median ANB angle: 5.5°, median ML/NSL angle 31.5°). Tx was carried out using a Herbst appliance (Dentaurum) as well as different types of labial straigt-wire multibracket appliances. The protocol usually started with the Herbst appliance being inserted and adjusted into an anterior edge-to-edge relationship. After 6-8 months, the appliance was removed and replaced by a full arch MBA in both jaws to achieve proper occlusal settling and finishing. Patient location and contact was attempted using the information in the patients' records and then the internet (search engines, online phone directories) as sources. While 89 of the potential 119 patients could be located and were asked to participate in the present study, 52 finally accepted and took part at age 33.6±3.1 years.

After obtaining informed consent, impressions of the upper and lower arch were taken of all participants (wax bite taken by the examining orthodontist). To assess occlusal and alignment changes that had occurred since the end of active Tx and to compare them to the pre-Tx situation, study models in centric occlusion were evaluated and compared to the current findings. While the examining orthodontist verified that no dual bite was present at recall, no such information was available for the earlier assessments. For all occasions (T0: before Tx, T1: after Tx, T2: after retention, T3: recall), the sagittal molar and canine relationship (right, left) as well as overjet and overbite were assessed. Visual ratings of the molar relationship were performed to the nearest 0.25 cusp widths (cw) and classified as Class I, II or III. Linear measurements were made to the nearest 0.5 mm using a manual calliper. In addition, the PAR Index (13) was applied. The PAR ratings were performed by a calibrated operator according to the respective guidelines (13) and using an original PAR ruler.

At recall (T3), 31 of the 52 participants wore no retainers at all. 11 of them had already been without retention at T2. All remaining 21 participants had a lower bonded canine-to-canine retainer (19 bonded on the canines only, 2 bonded on all six teeth) which was combined with an upper bonded retainer in 5 participants.

Control group

A “double negative, normal” control group (Class I, no orthodontic Tx need) was used for comparison. These untreated controls (n=31) were participants of a longitudinal study on growth changes in the dental arches in Finland (14), which followed the patients from age 7 until 33 years (32.9±1.2). The records obtained at age 12 (T0), age 15 years (T1) and age 33 years (T3) were considered to correspond best to the current Herbst-MBA sample regarding age (Table 2). From these untreated subjects, study models existed from both time points (n=31). All these subjects exhibited a Class I relationship at the age of 15 years which is more or less in concordance with the treated Class II:1 sample (Table 2).

Statistics

To minimize the error of the method, every single variable measurements was performed twice (N.B.) with a time interval of 2 to 4 weeks in between, and the mean value of both was used for further calculations.

Most of the data showed a non-normal distribution according to Shapiro-Wilk and Kolmogorov-Smirnov tests. Therefore, in addition to the descriptive statistical analysis, the Mann-Whitney-U test was used for most group comparisons. When more than two groups were compared, the Kruskal-Wallis-test was applied. Due to the explorative study design, multiple testing was performed and p-values ≤ 0.15 can be considered to suggest a group difference.

Based on the properties of the measured parameters the Intraclass Correlation Coefficient (ICC) was chosen to assess observer reliability. The decision was based on the ability of the ICC to be scaled for one observer and two observations. The ICC also allows for examination of reliability of repeated measurements based on the exact agreement of the measurements rather than consistency of measurements as would be measured by various correlation coefficients (e.g. Kendall’s W). While the ICC values were rather high for most measurements (mean: 0.8; standard deviation: 0.1; median: 0.8), values of as low as 0.4 were seen for a few single PAR-Index component measurements (category: contact point displacement).

Results

Participants (Table 1, Figure 1)

While 52 of the 119 potential patients agreed to participate, 37 patients were not available due to lack of interest or other reasons (Figure 1). Thus, with respect to the number of patients who could be located, the participation rate was 58%. However, to be able to rate an eventual structural / selection bias, the pre- and post-Tx data of the eligible patients who did not participate in the present study (non-participants), were considered where applicable.

The mean age of the Class II:1 participants and the controls differed slightly at T0, T1 and T3 (p≥0.15; Table 2). The observation periods differed by 9-10 months (T1-T0: 20.1 vs. 29.3 months, p=0.000; T3-T1: 18.3 vs. 17.5 years, p=0.873; Table 2).

Tx and long-term post-Tx changes (Tables 3 and 4, Supplementary Tables 1-4, Figure 2, Supplementary Figure 1)

As would be expected, at T0 marked differences were found between the Class II:1 participants and the untreated Class I controls for overjet, overbite, molar and canine relationships as well as for PAR score (Tables 3 and 4, Figure 2).

The mean overjet was by 0.9 mm smaller after Tx (T1) in the Class II:1 when compared to the controls (p=0.000), while the opposite was the case after the long-term observation (3.6 vs. 3.2 mm; p=0.091). For overbite, a similar situation was seen – slightly lower values at T1 in the Class II:1 compared to the controls (p=0.000) and a reverse situation existed at T3: 2.8 vs. 2.4 mm (p=0.056). The mean molar relationship was 0.0 cw at T1 and T3 in the Class II:1, while it was -0.1 cw in the controls (p=0.000-0.751). The canine relationship showed a mean value of 0.2 cw at both occasions and in both groups (p=0.058-0.450).

The detailed values for overjet, overbite as well as molar and canine relationships at T0, T1 and T3 are given in Table 3 (T2 in Supplementary Table 1). The respective changes during the observation periods T1-T0 and T3-T1 are shown in Supplementary Table 3 as well as Figure 2.

After Tx (T1), the mean total PAR score was notably lower by 5.4 points (p=0.000) in the Class II:1 than in the controls (Table 4). However, at T3 the difference had decreased to 0.7 points (p=0.139). Looking at the PAR components at T3, distinct differences were only seen for the maxillary and mandibular anterior segments showing lower scores and thus a better alignment in the Class II:1 when compared to the controls: 0.8 vs. 2.0 and 1.3 vs. 2.5 points (p=0.000).

The detailed scores for the PAR index (total score as well as contributing components) at T0, T1 and T3 are given in Table 4 (T2 in Supplementary Table 2). The respective changes during the observation periods T1-T0 and T3-T1 are shown in Supplementary Table 4.

Looking at the percentage of patients exhibiting “perfect” PAR component scores (=0), it is striking, that a perfect score for “occlusion” is nearly absent in both groups at all occasions (Supplementary Figure 1). In general, the lowest overall prevalences in both groups existed at T0 while at T1, most components in the Class II:1 showed a major improvement. After long-term observation, the Class II:1 group presented a perfect overjet slightly less frequent than the controls (62% vs. 71%). The same was true for overbite (46% vs. 61%). Almost identical prevalences were seen for perfect centrelines (88% vs. 90%). Significantly more perfect scores for maxillary/mandibular anterior segments were seen in the Class II:1 when compared to the controls (41%/38% vs. 6%/3%).

Influence of bonded retainers (Table 5)

As 21 of the 52 participants still wore a lower canine-to-canine retainer at T3, a separate comparison of these two subgroups and the controls was performed for the long-term changes (T3-T1) of the total PAR score as well as the components "mandibular anterior", overjet and overbite. For the total PAR score, a clear group difference (p=0.000) was seen. In the retainer group, an increase by 1.7±2.8 points was seen, while the group without retainers showed an increase by 6.6±5.8 points; in the controls, the total PAR score increased by 0.1±2.9 points. Similar observations (p=0.000-0.005) were made for the components "mandibular anterior", overjet and overbite (Table 5).

Class II:1 participants vs. non-participants (Table 1, Supplementary Table 2)

The 52 participants and the 37 non-participants of the Class II:1 sample did not differ systematically regarding age before Tx, after Tx and after retention (p≥0.15). The same was true for the period of active Tx (T1-T0) and the retention phase (T2-T1).

In terms of total PAR score, the mean values were by 3.0-4.7 points lower in the participants at all three occasions (p=0.000-0.050). However, regarding absolute occlusal values the differences were small and without clinical relevance (Supplementary Table 2). The overjet of the participants showed up to 0.5 mm higher mean values at all three occasions T0, T1 and T2 when compared to the non-participants (p=0.031-0.178). For molar relationship, the mean values differed by ≤ 0.1 cw (p=0.312-0.631) between the two groups.

Discussion

The current investigation is the first to assess long-term post-Tx changes and outcome quality of Class II:1 Tx and to compare the findings to an untreated control group. While long-term results (32 years) of Herbst Tx without subsequent MBA Tx have been described (8-12) for a small sample (n=14) and were found to be acceptable to good, a different outcome due to a more accurate post-Tx interdigitation and alignment might be seen after Herbst-MBA Tx.

As the primary aim of the study was to assess the post-Tx occlusal stability and not to evaluate the nature (dental/skeletal) of relapse, an analysis of the effects which occurred during each the Herbst and the subsequent MBA phase separately was considered irrelevant.

Subjects – participants vs. non-participants

The investigation is based on a recall of patients who had been treated at the study centre between 1986 and 2000 (active Tx). While the Tx approach was similar in all patients, Tx had been accomplished by several practitioners under supervision of two senior orthodontists. Nevertheless, all study model evaluations for this trial were performed by one investigator.

The patient sample was homogenous in terms of the underlying malocclusion (Class II:1) and the Tx approach (Herbst-MBA) but the overall pre-Tx (T0) severity varied (total PAR score: 27.2±7.6) as did the pre-Tx age (12.8±2.7 years). Post-Tx (T1), which can be considered as baseline for studying the long-term post-Tx changes, however, a more uniform occlusal situation existed (total PAR score: 3.4±2.2) while the age range (age: 15.3±1.9 years) was more or less unchanged indicating a similar Tx length irrespective of the pre-Tx age. At the time of the recall (T3), the homogeneity was moderate in terms of both severity (8.2±5.5) and age (33.6±3.1 years).

When comparing the data of the treated Class II:1 participants to those of the non-participants, both groups were similar in terms of age (T0, T1, T2), Tx duration (T1-T0), length of the retention period (T2-T1), overjet and molar relationship (T0, T1, T2). However, slight but statistically notable differences were seen for total PAR score (T0, T1, T2) while the absolute differences regarding the PAR components were rather small (Supplementary Table 2). In summary, it can be assumed that no relevant selection bias existed.

Subjects – untreated controls

The untreated Class I control group was quite uniform regarding age at both T0 (13.0±0.4 years) and T1 (15.4±0.4 years), as the sample comprised of participants of a longitudinal study on growth changes in the dental arches (14). They had no orthodontic Tx need when they were included in this original study at age 7 years; nevertheless at age 15 years (T1 in the present investigation) minor crowding had developed in some patients.

The variation in age was slightly larger at T3 (32.9±1.2 years), but the total PAR score was quite stable (T0: 10.5±4.2; T1: 8.8±3.7; T3: 8.9±3.3). The reduction during T1-T0 was mainly due to a decrease in overjet (Supplementary Table 4), which can be explained by the natural growth changes of the mandible during this period (age 13-15) which includes the peak of the pubertal growth spurt.

Validity of the control group

It might be debatable whether an untreated Class I group makes a valid control for treated Class II:1 patients. However, a Class I sample without orthodontic Tx need at adolescence and no orthodontic intervention can be considered as a "natural" gold standard for occlusal development and as such as a more realistic control group than a sample exhibiting an ideal occlusion (PAR score 0) which does neither correspond to nor reflects the natural aging process of the human dentition, as it was demonstrated when assessing dental arch form changes in subjects with "normal occlusion" from age 7 to 32 (14) and age 13 to 31 (15). In addition, it should be considered that the treated sample became Class I due to Tx, and thus shared the same long-term occlusal predispositions with the untreated control group.

Method

The PAR Index was used to gain objective data on the long-term stability and outcome quality. However, even if the validity and reliability of this assessment method have been shown (16, 17), the PAR Index has also been criticised – mainly for the weighting system (18) but also due to problems in terms of interpretation (19). Therefore, it was chosen to assess additional standard occlusal variables.

As several studies in the literature have already assessed both components of this Tx approach (Herbst phase and MBA phase) regarding their contributions towards Class II correction (20, 21), no separate analysis was undertaken in this investigation.

No age-based subgroup analysis was performed as the detected changes were generally small and without any obvious age trend.

Improvement of occlusal parameters during active Tx

Naturally, the occlusal variables as well as the total PAR index were notably lower in the untreated Class I controls at T0. Looking at the changes which occurred during active Tx (T1-T0), marked differences (p≤0.05) between the treated Class II:1 and the Class I controls can be seen for all variables. For the period of active Tx (T1-T0), these differences are obvious and probably do not need further discussion. As a result of Tx, the situation had reversed by T1, resulting in identical to lower PAR scores in the treated Class II:1 sample (p=0.000-0.765) when compared to the Class I controls, especially as a result of overjet and overbite reduction as well as dental arch alignment in the upper and lower anterior segments.

Long-term post-Tx changes

When looking at the post-Tx observation period (T3-T1), however, the situations at T1 and T3 should be taken into account. While the treated Class II:1 sample showed a more "ideal" and slightly overcompensated situation at T1 in terms of overjet, overbite and alignment when compared to the controls, the condition at T3 is more "normal" and similar to the controls. This is also confirmed by the p-values at T3. A statistically notable (p=0.000) but clinically irrelevant difference between the treated Class II:1 sample and the untreated Class I controls existed only for molar relationship: 0.0 cw (Class I) vs. -0.1 cw (Class III). So, even if the changes which occurred during the long-term observation period T3-T1 in the treated Class II:1 sample correspond to minor relapse and exceed those of the controls, the final values at age 33.6±3.1 and 32.9±1.2, respectively, are very similar in both groups. Nevertheless, when looking at the details, the treated Class II:1 sample presents higher values for both overjet and overbite (by 0.4 mm/0.5-0.7 PAR points) but lower values for the alignment (1.2 PAR points). When evaluating these changes, however, it has to be taken into account that 21 of the 52 study participants still wore fixed lower canine-to-canine retainers at T3 and no information on the underlying skeletal growth changes is available.

To compare the current data to respective changes in other populations, the literature was searched for data from long-term observations. Average increases in overjet of only up to 1.4 mm were reported for former Class I and II patients (treated by fixed appliances with or without extractions during adolescence) after ≥ 12 years post-Tx (22-28). These data correspond well with the mean overjet increase of 1.3 mm seen in the Class II:1 sample of the present investigation. The mean overjet change in the controls was lower (0.0 mm) but also similar to corresponding untreated populations (-0.2 to 0.1 mm; 23, 29).

In terms of overbite, the average long-term (≥ 12 years) post-Tx changes reported in the literature for Class I and II patients range between 0.5 and 1.6 mm increase (22-28) which is similar to the present findings (1.5 mm). The same applies for the untreated controls: -0.3 mm (current investigation) vs. -0.1 to -0.3 mm (23, 29).

Less data are available for the sagittal occlusal relationship. While changes of 0.1 to 1.1 mm towards Class II were found in 96 Class I and II patients treated with fixed appliances (with/without extractions) 12 to 35 years post-Tx (28), Class I molar relationship with a proper cusp-to-groove was found to be stable in 100% of 69 untreated subjects from age 20 to 55 (30). The findings of the current investigation were comparable (treated Class II:1 sample: mean 0.0±0.2 cw, controls: 0.0±0.1 cw). The long-term changes which occurred in the first sample of patients treated with a Herbst appliance but no further fixed appliance Tx amounted to 0.2±0.3 cw (9).

When looking at long-term PAR score changes, the literature provides only few data. An assessment of Class I subjects treated with fixed appliances (with/without extractions) revealed a mean increase of 5.7 to 7.6 points between age 15 (end of retention) and 30. While the findings of the present investigation seem to be slightly more favourable, it has to be considered that 21 of the 52 study participants (=40%) still wore fixed lower canine-to-canine retainers at T3, which wasn't the case in the previously mentioned investigation (31). Other similar investigations of unspecified patient samples (mixed Class I and II as well as Tx procedures with and without extractions) found mean increases of 5.1 points between age 15 and 31 (32) as well as 6.1 points between age 16 and 26 (33).

These studies also assessed the long-term influence of fixed retainers. Both of them found the final PAR score to be ~ 5 points less in patients with retainers still in place at the follow-up when compared to those without retainers (32, 33). These data correspond well to the difference of 4.9 points in the present investigation where long-term retention in the lower jaw was particularly beneficial for maintaining overjet, overbite and alignment stability in terms of PAR components (Table 5).

For untreated Class I subjects, a PAR increase from 11.9 points at age 12 to 12.9 points at age 22 can be found in the literature (33). The values seen in the present study were slightly lower (8.8 at age 15 and 8.9 at age 33) but the long-term increase can be considered comparable.

Limitations

Some issues regarding the patient sample of this study need to be regarded as limitations. First, the treated Class II:1 participants were neither treated at exactly the same age or skeletal maturity nor at the same time period and the retention protocol as well as the retainer wear until the current investigation was not uniform. However, the age range is rather narrow and the participants can be considered comparable. In addition, the participation rate was only 58%, which, however, seems to be acceptable due to the long-term design and the fact that no systematic differences existed in comparison to the non-participants. In terms of the untreated Class I control group, this sample was generated at a different site in Europe; however, the whole sample was of Caucasian descent as the treated Class II:1 sample. Furthermore, it would have been favourable to perform a more detailed analysis of the long-term post-Tx changes by assessing study models from additional in-between examinations as well as lateral cephalograms, which, however, did not exist. Furthermore, no blinding was performed as the study models of the two groups were generated at different locations and time periods making them identifiable. In addition it might be considered as a limitation, that no detailed analysis of the two Tx phases was performed and that ICC values of as low as 0.4 were seen for a few single PAR-Index component measurements.

Conclusion

The occlusal outcome of Class II:1 Tx showed very good long-term stability. While mild changes occur post-Tx, the long-term result is similar to untreated Class I controls.

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Conflict of interest

The authors declare no conflict of interest

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Table 1

Comparison of the Class II:1 participants' and non-participants' data: the mean value (Mean), standard deviation (SD) and p-value (p) of the respective group difference are given for age, duration of the observation periods, overjet, sagittal molar relationship and PAR score. cw: cusp widths

			Participants (28♀:24♂) Mean±SD	Non-participants (34♀:33♂) Mean±SD	p
Age	T0	years	12.8±2.65	13.0±3.60	0.801
	T1		15.3±1.91	15.6±3.05	0.904
	T2		17.8±2.18	18.0±3.27	0.935
Observation periods	T1-T0 (Treatment)	months	20.1±5.13	20.6±5.51	0.658
	T2-T1 (Retention)		30.7±14.19	28.4±16.64	1.000
Overjet	T0	mm	8.2±2.11	7.7±2.61	0.178
	T1		2.3±0.74	2.0±1.02	0.031
	T2		3.1±0.87	2.7±1.03	0.050
Molar relationship	T0	cw	0.7±0.24	0.8±0.31	0.312
	T1		0.0±0.14	-0.1±0.22	0.566
	T2		0.0±0.14	0.0±0.18	0.631
PAR	T0	total score	27.2±7.64	31.9±9.54	0.050
	T1		3.4±2.20	7.8±4.62	0.000
	T2		5.6±4.76	8.6±5.51	0.000

Table 2

Comparison of the Class II:1 and the controls: the mean value (Mean), standard deviation (SD) and p-value (p) of the respective group difference are given for age and the duration of the observation periods. -: data not available

			Class II:1 (28♀:24♂) Mean±SD	Controls (17♀:14♂) Mean±SD	p
Age	T0	years	12.8±2.65	13.0±0.42	0.566
	T1		15.3±1.91	15.4±0.36	0.243
	T2		17.8±2.18	-	-
	T3		33.6±3.11	32.9±1.22	0.429
Observation period	T1-T0 (Treatment)	months	20.1±5.13	29.3±3.61	0.000
	T2-T1 (Retention)		30.7±14.19	-	-
	T3-T1 (Long-term)	years	18.3±3.12	17.5±1.19	0.873

Table 3

Overjet and overbite as well as sagittal molar and canine relationships (mean left/right) in the Class II:1 and the controls at T0, T1 and T3. For each variable, the mean value (Mean), standard deviation (SD), minimum (Min), maximum (Max) and median value (Med) as well as the p-value (p) of the respective group difference are given. cw: cusp widths

			T0						T1						T3					
			Mean	SD	Min	Max	Med	p	Mean	SD	Min	Max	Med	p	Mean	SD	Min	Max	Med	p
Overjet	mm	Class II:1	8,2	2,11	4,3	12,5	8,0	0,000	2,3	0,74	0,5	4,5	2,3	0,000	3,6	1,08	1,8	8,0	3,5	0,091
		Controls	3,6	0,83	1,5	4,8	3,5		3,2	0,74	1,5	4,8	3,3		3,2	0,81	1,8	4,8	3,3	
Overbite	mm	Class II:1	4,1	1,61	-0,8	8,3	4,3	0,000	1,3	0,72	-0,8	3,8	1,3	0,000	2,8	1,55	-3,3	5,8	2,8	0,056
		Controls	2,7	0,88	1,3	4,0	2,8		2,7	0,96	1,0	4,8	2,5		2,4	1,21	0,5	4,5	2,3	
Molar relationship	cw	Class II:1	0,7	0,24	0,3	1,3	0,8	0,000	0,0	0,14	-0,3	0,4	0,0	0,751	0,0	0,18	-0,4	0,6	0,0	0,000
		Controls	0,0	0,16	-0,3	0,4	0,0		-0,1	0,15	-0,3	0,3	-0,1		-0,1	0,12	-0,3	0,3	-0,1	
Canine relationship	cw	Class II:1	0,8	0,18	0,3	1,1	0,8	0,000	0,2	0,14	-0,1	0,6	0,2	0,450	0,2	0,16	-0,3	0,8	0,2	0,058
		Controls	0,3	0,12	0,0	0,5	0,3		0,2	0,10	0,0	0,5	0,3		0,2	0,12	0,0	0,4	0,1	

Table 4

The total PAR score as well as the components (weighted) are given for the Class II:1 and the controls at T0, T1 and T3. For each variable, the mean value (Mean), standard deviation (SD), minimum (Min), maximum (Max) and median value (Med) as well as the p-value (p) of the respective group difference are given.

			T0						T1						T3					
			Mean	SD	Min	Max	Med	p	Mean	SD	Min	Max	Med	p	Mean	SD	Min	Max	Med	p
Total PAR score		Class II:1	27,2	7,64	13,5	43,0	26,0	0,000	3,4	2,20	0,0	16,0	3,0	0,000	8,2	5,50	1,5	25,5	7,3	0,139
		Controls	10,5	4,24	3,5	17,0	10,5		8,8	3,71	2,5	15,0	8,5		8,9	3,34	2,5	18,0	9,0	
Components	Occlusion	Class II:1	3,7	1,18	2,0	7,0	4,0	0,000	2,2	0,68	0,0	5,0	2,0	0,765	2,3	0,93	0,0	5,0	2,0	0,113
		Controls	2,5	0,53	2,0	3,5	2,5		2,2	0,58	1,5	4,0	2,0		2,1	0,90	0,5	6,0	2,0	
	Overjet	Class II:1	16,1	5,82	6,0	24,0	18,0	0,000	0,1	0,85	0,0	6,0	0,0	0,000	2,1	3,38	0,0	18,0	0,0	0,332
		Controls	3,0	2,68	0,0	6,0	0,0		1,7	2,43	0,0	6,0	0,0		1,4	2,30	0,0	6,0	0,0	
	Overbite	Class II:1	2,1	1,23	0,0	4,0	2,0	0,001	0,1	0,50	0,0	2,0	0,0	0,000	1,2	1,39	0,0	8,0	1,0	0,135
		Controls	1,1	0,96	0,0	2,0	2,0		0,8	0,93	0,0	2,0	0,0		0,7	0,94	0,0	2,0	0,0	
	Centreline	Class II:1	0,7	1,64	0,0	8,0	0,0	0,093	0,2	0,80	0,0	4,0	0,0	0,315	0,5	1,42	0,0	6,0	0,0	0,675
		Controls	0,1	0,50	0,0	2,0	0,0		0,2	0,60	0,0	2,0	0,0		0,2	0,60	0,0	2,0	0,0	
	Maxillary anterior	Class II:1	3,0	2,04	0,0	7,0	2,5	0,501	0,5	0,63	0,0	2,0	0,0	0,000	0,8	1,01	0,0	5,0	0,5	0,000
		Controls	2,5	1,44	0,5	6,0	2,0		2,2	1,23	0,5	5,0	2,0		2,0	1,27	0,0	5,5	2,0	
	Mandibular anterior	Class II:1	1,6	1,55	0,0	5,0	1,0	0,973	0,3	0,50	0,0	2,0	0,0	0,000	1,3	1,60	0,0	7,0	1,0	0,000
		Controls	1,3	0,84	0,0	3,0	1,0		1,7	0,99	0,0	3,0	2,0		2,5	1,52	0,0	5,5	2,5	

Table 5

Changes of the total PAR score as well as the (weighted) components mandibular anterior, overjet and overbite during long-term observation (T3-T1) in the Class II:1 with no retainer at T3 (n=52), the Class II:1 wearing a bonded lower canine-to-canine retainer at T3 (n=21) and the controls.

		Class II:1 no retainer at T3					Class II:1 bonded lower retainer at T3					Controls					p
		Mean	SD	Min	Max	Med	Mean	SD	Min	Max	Med	Mean	SD	Min	Max	Med	
Total PAR score		6,6	5,84	-3,0	23,0	5,8	1,7	2,78	-2,5	7,0	1,3	0,1	2,85	-5,5	8,0	-0,5	0,000
PAR components	Mandibular anterior	1,6	1,83	-1,0	6,0	1,5	0,2	0,41	0,0	1,0	0,0	0,9	1,03	-1,0	3,5	0,5	0,005
	Overjet	2,9	4,20	-6,0	18,0	3,0	0,6	1,57	0,0	6,0	0,0	-0,3	1,34	-6,0	6,0	0,0	0,000
	Overbite	1,1	1,37	0,0	6,0	0,5	0,8	0,95	0,0	2,0	0,0	-0,1	1,29	-2,0	1,0	0,0	0,000

Figure 1

Flow chart of the study participants/non-participants of the Class II:1 sample. The numbers of total Herbst-MBA patients (active Tx completed by January, 1st 2015) as well as potential participants and the results of the recruitment process are given.

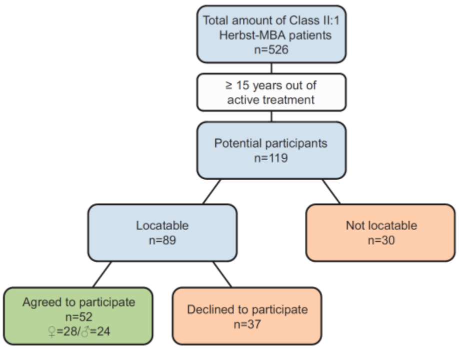
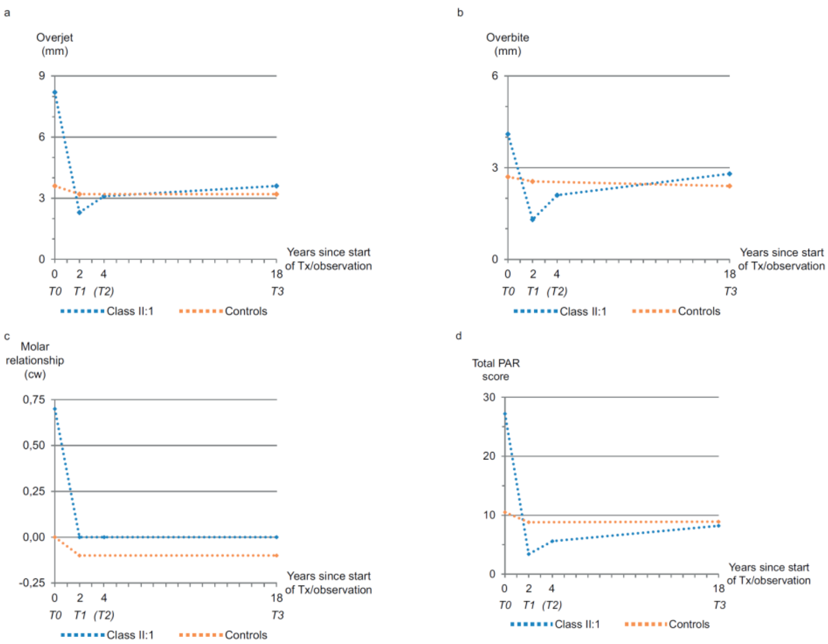


Figure 2

Development of a-overjet, b-overbite, c-molar relationship and d) total PAR score from T0 until T3 in the treated Class II:1 (Tx) and the controls. While the dotted lines suggest certain changes, it is unknown what exactly happened between the respective time points.



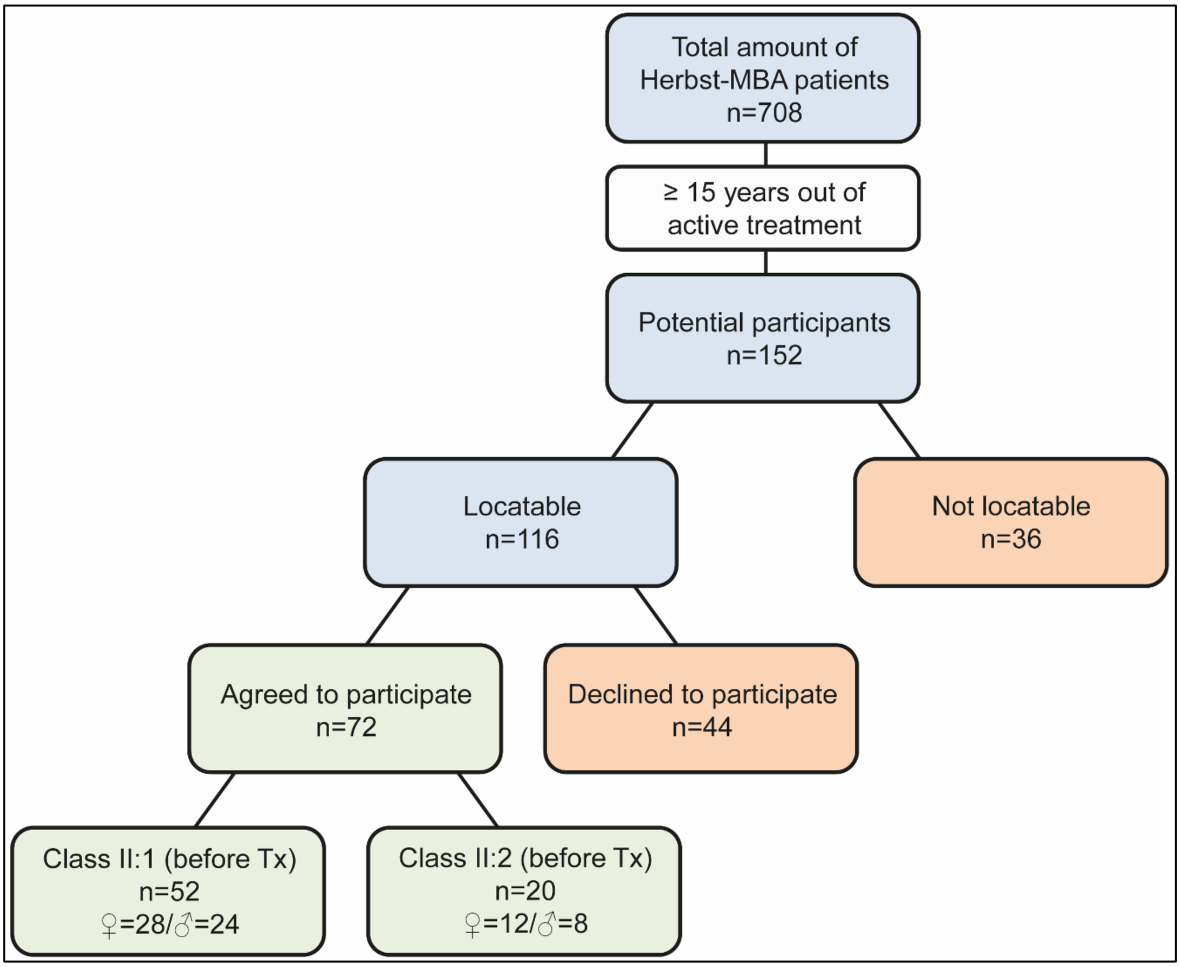
5) Bock NC, Saffar M, Hudel H, Evälahti M, Heikinheimo K, Rice DP, Ruf S. Long-term oral-health effects of Class II orthodontic treatment.
Journal of Orofacial Orthopedics 2018;79:96-108

Orthodontic treatment is supposed to generate an environment serving as preventive basis for excellent oral health and oral health related quality of life long-term. So far, however, investigations have not succeeded in demonstrating a clear positive effect, and it remains controversial whether orthodontic treatment is beneficial for oral health [67,68,157]. While numerous publications dealing with the effectiveness of Class II treatment in terms of occlusal changes are available, data on oral health is rare.

Therefore, it was the aim of the present investigation to assess the long-term effects of orthodontic Class II treatment on oral health.

All Class II patients who had received Herbst-Multibracket appliance therapy that had been ended ≥ 15 years ago at the Department of Orthodontics, University of Giessen, Germany, were asked to participate in a recall. 116 out of 152 potential participants could be located, and 72 finally agreed to take part in the study (Figure R). The data of the non-participants were considered as well for selection bias preclusion.

Figure R Flowchart of the treated Class II participants and non-participants. The numbers of total Herbst-MBA patients (active Tx completed by January, 1st 2015) as well as potential participants and the results of the recruitment process are given; reprinted from: “Bock NC, Saffar M, Hudel H, Evälahti M, Heikinheimo K, Rice DP, Ruf S. Long-term oral-health effects of Class II orthodontic treatment. J Orofac Orthop 2018;79:96-108” by permission of Springer Nature



The examination started with the anamnesis including complaints regarding teeth, occlusion and masticatory system’s function. Afterwards a clinical inspection of the oral cavity was performed and impressions as well as photographs were taken. To compare the current data to the situation immediately after treatment, the respective study models and panoramic radiographs were evaluated.

Oral health assessment was performed in terms of general dental status ("Decayed, Missing, Filled Teeth Index"/modified "Missing, Filled Teeth Index") [220] and gingival health ("Periodontal Screening Index"/"Community Periodontal Index") [7,233,279], including a gingival recession evaluation on study models.

Data from a "double negative, normal" control group (Class I, no orthodontic treatment need during adolescence) were applied for comparison. The respective sample (n=31) was part of a longitudinal trial on growth changes in Finland and was observed from age 7 until age 33 [168]. Anamnestic data, study models and data from clinical inspections acquired at ages 15 and 33 years were used as well as a panoramic radiograph from age 33 years.

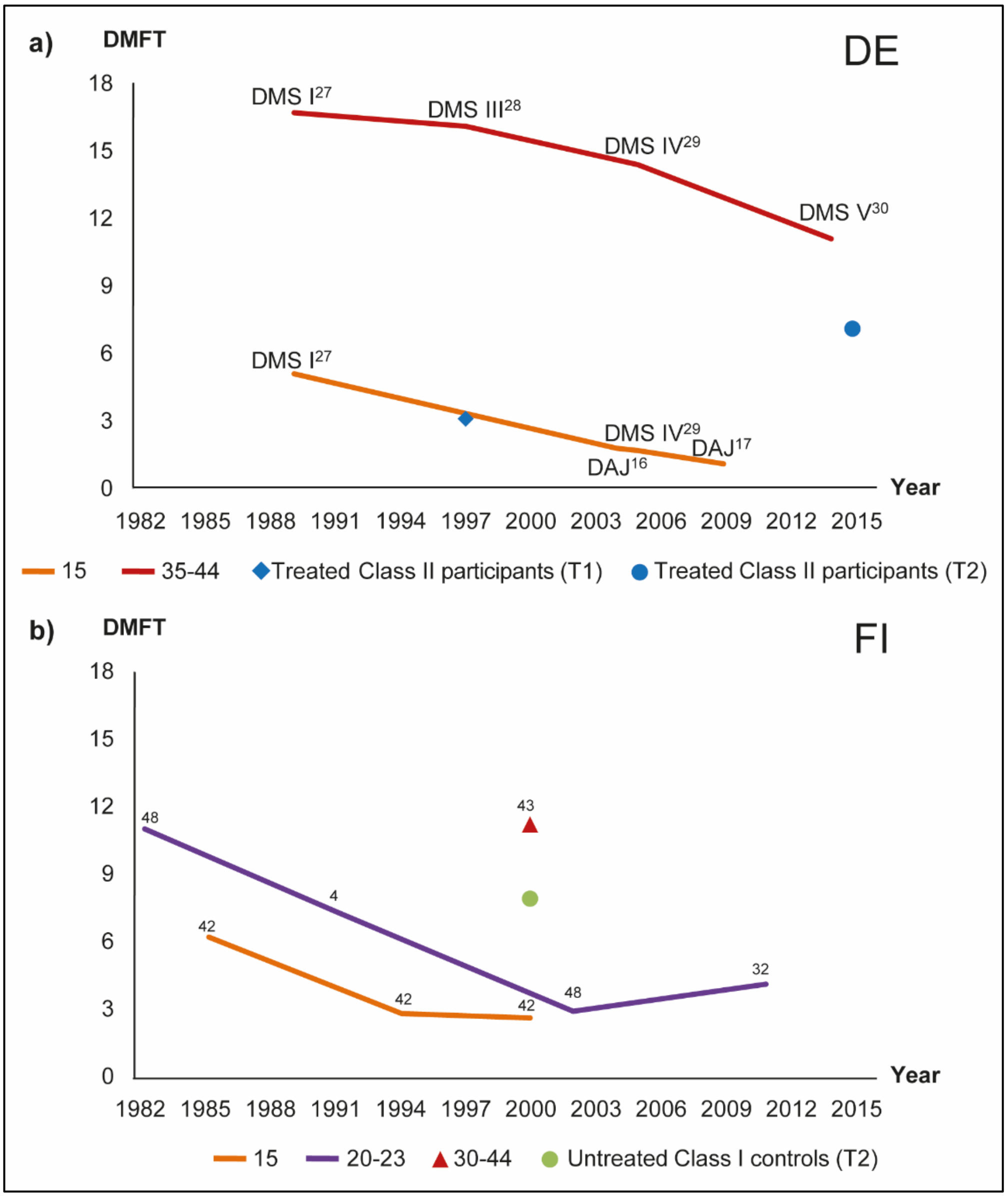
In addition, the German Oral Health studies (DMS I, III, IV and V) [183-186] were used as epidemiological oral health benchmark data from population-representative cross-sectional studies of different age cohorts.

No systematic difference existed between the participants and the non-participants for age and "Missing, Filled Teeth Index" after treatment; clinically irrelevant differences existed in terms of gingival recessions. Comparing the treated Class II sample and the untreated Class I controls, the mean age (15.4±1.9/33.7±3.0 vs. 15.3±0.6/32.9±1.2 years) and the duration of the observation period (18.3±2.9 vs. 17.6±1.2 years) were very similar.

The degree of patient satisfaction with the condition and appearance of their teeth as well as their masticatory system's function at recall was higher in the treated Class II participants than in the untreated Class I controls (70.8% fully satisfied/27.8% conditionally satisfied/1.4% unsatisfied vs. 48.3% fully satisfied/12.9% conditionally satisfied/38.8% unsatisfied).

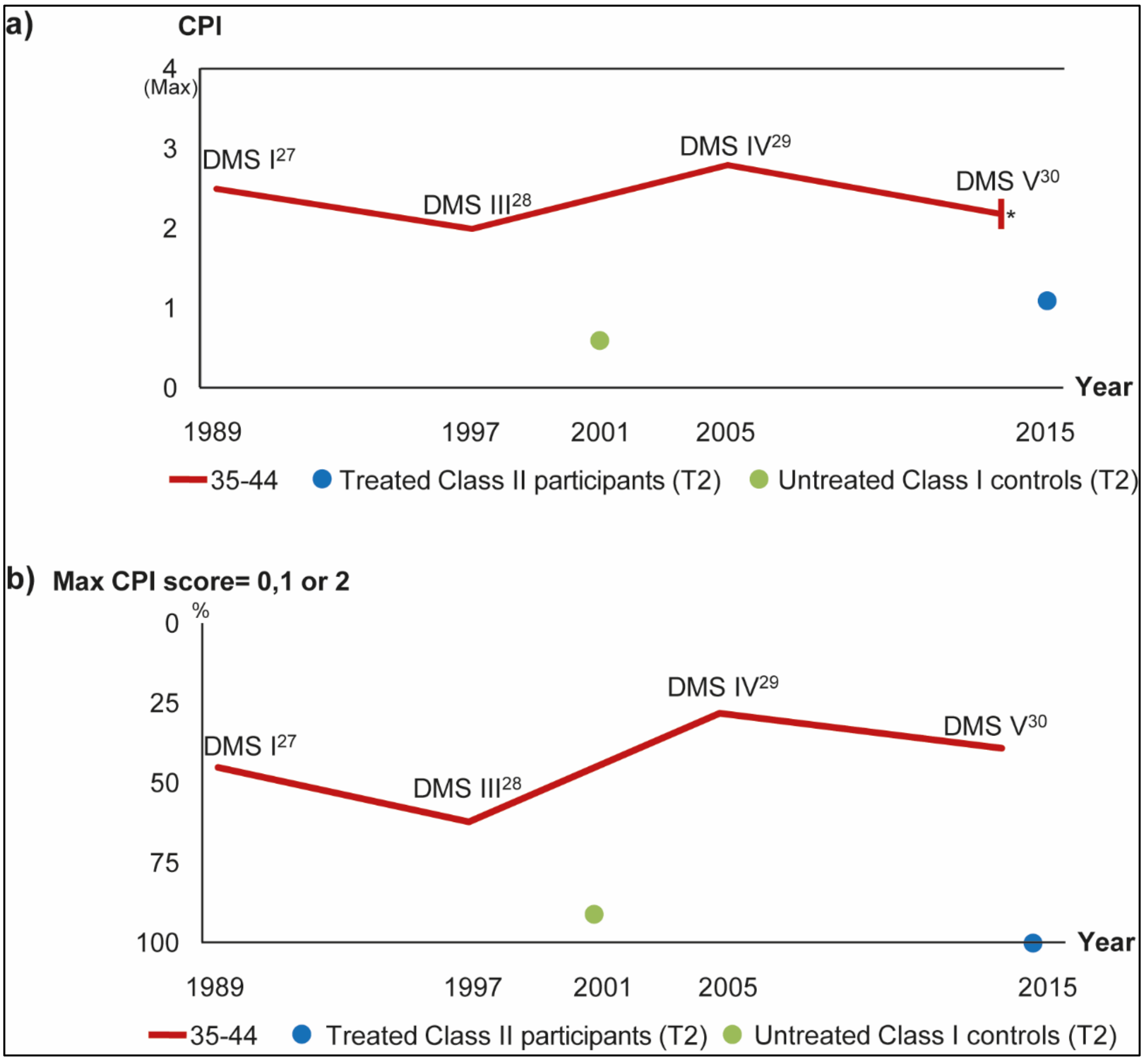
The general dental status ("Decayed, Missing, Filled Teeth Index") of the treated Class II participants exhibited a score of 7.1±4.8 at recall; the value of the untreated Class I controls ("Missing, Filled Teeth Index") was 7.9±3.6 (Figure S). The data of the corresponding population-representative age-cohorts showed by 56% (Germany)/43% (Finland) higher values [186,289] (Figure S).

Figure S Chart exhibiting the development of the mean (D)MFT scores of the population in a) Germany and b) Finland from the 1980s until today in different age groups; in addition, the respective values of the treated Class II participants (T1 and T2) as well as of the untreated Class I controls (T2) are given; reprinted from: "Bock NC, Saffar M, Hudel H, Evälahti M, Heikinheimo K, Rice DP, Ruf S. Long-term oral-health effects of Class II orthodontic treatment. J Orofac Orthop 2018;79:96-108" by permission of Springer Nature



In terms of periodontal health the mean “Periodontal Screening Index”/“Community Periodontal Index” maximum scores at recall were 1.6±0.6 in the treated Class II participants (100% with a maximum score 0, 1 or 2) and 1.7±0.9 in the untreated Class I controls (91% with a maximum score 0, 1 or 2) (Figure T); according to given prevalence data of the corresponding population-representative age-cohort (Germany), their respective mean value ranges between 1.9 and 2.3 (39% with a maximum score 0, 1 or 2) (Figure T) [186]. The mean extent of gingival recessions (teeth 32-42) measured on the study models obtained at recall was 0.1±0.2 in the treated Class II sample and 0.0±0.1 in the untreated Class I control group. Comparable benchmark data are lacking.

Figure T Chart exhibiting the CPI data (a: mean score, b: percentage exhibiting a maximum score of 0, 1 or 2) of the treated Class II participants and the untreated Class I controls at T2. In addition, the development of the CPI scores of the population in Germany from the 1980s until today in the same age group is shown (data in the figure are allocated to the respective years of investigation). * Exact value not known; best and worst possible value calculated; reprinted from: "Bock NC, Saffar M, Hudel H, Evälahti M, Heikinheimo K, Rice DP, Ruf S. Long-term oral-health effects of Class II orthodontic treatment. J Orofac Orthop 2018;79:96-108" by permission of Springer Nature



No significant influence of bonded retainers was seen for any of the assessed oral health variables.

The current study assessed the long-term effects of orthodontic treatment specifically in Class II patients which has not been done previously. While it might have been ideal to compare the data to an untreated Class II sample, it has to be considered that such a sample at least to our knowledge unfortunately does not exist. In addition, as the treated sample was Class I after treatment, an untreated Class I sample can be considered an even more realistic control group than an untreated Class II sample.

The lack of fully comparable data in terms of dental health must be considered as limitation as the respective data were partly generated clinically and partly derived from radiographs. In addition, only the lower incisors 32-42 were considered in terms of gingival recessions; in terms of Herbst-Multibracket appliance treatment, however, they seem to be the most relevant teeth.

While the degree of satisfaction was higher in the treated Class II subjects than in the untreated Class I subjects, it has to be remembered that the respective patients had not been treated orthodontically and did not wear any kind of retainers, which led to a certain natural amount of incisor malalignment. This assumption is in accordance with the literature [212,469].

For oral health both the treated Class II sample and the untreated Class I sample exhibited distinctly lower scores at recall than their corresponding population-representative age-cohorts; no such difference had existed at age 15 years [95,96,204,289,290]. As no previous investigations have been able to demonstrate a clear association between malocclusion and oral health, it might be assumed that the difference might be due to the intensive dental attendance both groups experienced over an extensive period during which they were repeatedly motivated to maintain good oral health with resulting greater dental awareness [88,98,134,149].

Comparable data in the literature are rare. For periodontal health, one long-term investigation found no significant difference between orthodontically treated and untreated patients [145] while another trial found the orthodontically treated patients to exhibit a greater prevalence for mild to moderate periodontal disease [396]. In terms of gingival recessions, another investigation of patients treated with a Herbst appliance revealed single gingival recessions 32 years after treatment, which were attributed to other impacts like mechanical trauma instead of proclination [249,326]. Lower bonded retainers were found to be without clinical relevance for oral health, which is in concordance with the literature [27,72,202,487]. When evaluating the present results, one should, however, consider that a certain part of the population-representative age-cohorts had orthodontic treatment as well which might increase the differences between the treated and untreated populations.

It can be concluded, that patients with orthodontically treated Class II malocclusions had a similar risk for oral health impairment as untreated Class I controls (without orthodontic treatment need during adolescence) and a lower risk than the general population. These results are rather unique and therefore of utmost importance in terms of long-term outcome and benefit of orthodontic Class II treatment.

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Long-term oral-health effects of Class II orthodontic treatment

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Abstract

Aim: To investigate the long-term (≥15 years) benefit of orthodontic Class II treatment (Tx) on oral health (OH).

Subjects and Methods: All patients (Dept. of Orthodontics, University of Giessen, Giessen, Germany) who underwent Class II correction (Herbst-Multibracket Tx, end of active Tx ≥15 years ago) and agreed to participate in a recall (clinical examination, interview, impressions and photographs). Records from after active Tx were used to assess the long-term OH effects. The data were compared to corresponding population-representative age-cohorts as well as to untreated Class I controls without orthodontic Tx need during adolescence.

Results: 72 out of 152 treated Class II patients could be located and participated at 33.7±3.0 years (pre-Tx age: 14.0±2.7 years). The majority (70.8%) were fully satisfied with their teeth and masticatory system. The "Decayed, Missing, Filled Teeth Index" (DMFT) was 7.1±4.8 and thus almost identical to the untreated Class I controls (7.9±3.6). In contrast, the DMFT in the population-representative age-cohort was by 56% higher.

The mean "Community Periodontal Index" (CPI) maximum score (1.6±0.6) was also comparable to the untreated Class I controls (1.7±0.9) but in the corresponding population-representative age-cohort it was by 19-44% higher.

The extent of lower incisor gingival recessions differed insignificantly between the treated Class II participants and the untreated Class I controls (0.1±0.2 vs. 0.0±0.1 mm).

Conclusion: Patients with orthodontically treated severe Class II malocclusions had a lower risk for oral health impairment than the general population. The risk corresponded to the one of untreated Class I controls (without orthodontic Tx need during adolescence).

Short title: Long-term oral-health effects

Key words: Class II treatment, oral health, caries, periodontal disease, long-term

Introduction

One of the most important aims of orthodontic treatment (Tx) is to create functional occlusal conditions which serve as a long-term preventive basis for excellent oral health (OH) and oral health related quality of life. Especially in recent years both the public and the authorities have demanded prove for such a positive contributory effect of orthodontic interventions in terms of an improvement respectively the long-term maintenance of OH.

Until to date the benefit of orthodontic Tx on OH remains controversial. Unfortunately, systematic reviews have been unable to prove associations between crowding and the susceptibility to caries [23] or positive effects of orthodontic Tx on periodontal health [11]. On the other hand, a direct relationship between the presence of malocclusion and periodontal disease was concluded from a systematic review [10]. In addition, more tooth-related problems in life compared to individuals showing normal occlusion during childhood were found in a long-term observational study [58]. In addition, a long-term positive difference in self-rated dental appearance was seen between treated and untreated cohorts [59].

Why can't we scientifically prove, what we witness clinically in our daily practice? First of all, the level of OH is no doubt influenced multifactorially and does not solely depend on the provision of an orthodontic Tx or its quality. In addition, the very long latency times of different exposures (years to decades) and the generally slow progression of the most common oral diseases like dental caries, periodontal diseases and mucosal disorders, hamper the investigation of preventive orthodontic effects. Finally, from a research methodological point of view, the proof of a causal (preventive) effect of orthodontic Tx would require a RCT design with untreated controls, which given the long-term perspective would be impossible to conduct both from an ethical and financial/administrative point of view. Last but not least, malocclusion is not a uniform condition. Instead there is a large variety of different malocclusions with different degrees of severity and countless possibilities for combination with in turn different possible effects on OH, the latter has however not been taken into account in the aforementioned studies/reviews. Thus, if we concentrate on a very narrowly defined type of malocclusion, we might see effects.

For Class II Tx in general, countless studies on the effectiveness of certain Tx procedures with respect to their corrective occlusal potential [18, 20, 31, 35, 41, 44, 62, 64] have been performed. These studies mainly concentrate on the active Tx period, while data on long-term effects or stability are scarce [7, 12, 35, 41, 45-47]. For long-term effects of Class II Tx on OH, respective data is rare and equivocal [49, 54, 55].

Aim

Therefore, it was the aim of the present investigation to assess the long-term OH effects of orthodontic Class II Tx.

Material and Methods

After ethical approval (Nr. 146/13) and registration (WHO: ID DRKS00006354), the archive of the Department of Orthodontics at the University of Giessen, Giessen, Germany was screened for Class II patients who had been treated with a Herbst-Multibracket appliance (MBA) and whose active Tx had been finished at least 15 years ago.

152 patients with a mean age of 14.0 years at the start of Herbst-MBA Tx fulfilled these criteria. All patients exhibited a severe Class II malocclusion before Tx - mean Class II molar relationship: 0.77 cusp widths, mean Peer Assessment Rating Index (PAR) [51]: 27.4 points. 116 patients could be located using the address data from the period of active Tx as well as the internet

and were asked to participate in the investigation. While 80 patients were not interested or unable due to other reasons (Figure 1), 72 patients agreed to take part in the study (group: "treated Class II participants"). Thus, with respect to the locatable patients, the participation rate was 62%.

The records (baseline data and general dental status) of the 80 patients who did not attend the recall (group: "non-participants") were used for comparison (Table 1) and preclusion of a selection bias.

After obtaining informed consent, the anamnesis and eventual complaints regarding the condition of their teeth, their occlusion and/or the function of the masticatory system were enquired. In addition, a clinical examination of the oral cavity including the gums and the teeth was performed. Furthermore, impressions of the upper and lower arches as well as a full set of standardised intraoral photographs were taken. To assess the changes regarding the dental status and gingival recessions that had occurred since the end of active Tx, panoramic radiographs, intraoral photographs and study models from after active orthodontic Tx (T1) were used for evaluation and comparison to the current situation (T2).

In detail, the following parameters were used for the assessment of oral health:

- General dental status: "Decayed, Missing, Filled Teeth Index" (DMFT) [34] and MFT Index (DMFT-modification assessed from panoramic radiographs)
- Gingival health: Periodontal Screening Index (PSI/PSR-Index) [36, 40], soft tissue abnormalities; in addition, the study models were assessed visually for the presence of gingival recessions on teeth 32-42, which were quantified in millimetres by measuring the labial crown height as distance from the centre of the incisal edge to the lowest point of the vestibulogingival margin to the nearest 0.5 mm using a manual calliper.

At recall (T2), 42 of the 72 treated Class II participants (58.3%) wore no retainers at all. 29 participants (40.3%) had a lower fixed canine-to-canine retainer (26 fixed on the canines online, 3 fixed on all teeth) which was combined with an upper fixed retainer in 5 participants. One participant (1.4%) wore an upper fixed retainer only.

Control group

A "double negative, normal" control group (Class I, no orthodontic Tx need) was used for comparison [24]. These untreated Class I controls (n=31) took part in a longitudinal study on growth changes in the dental arches in Finland, which followed the patients from age 7 until 33 (32.9±1.2). The records obtained at age 15 (T1) and age 33 (T2) were considered to correspond best to the treated Class II participants regarding age (Table 2).

Study models from both time points T1 and T2 existed and a panoramic radiograph from age 33 years (T2) were available for 28 of the 31 untreated Class I controls. Furthermore, data from a clinical inspection Community Periodontal Index (CPI) [3] and the anamnesis (eventual complaints regarding the condition of teeth, occlusion and/or function) from T2 were evaluated.

A detailed overview on the parameters used for the assessment and comparison of oral health is given in Table 3.

A remark on the assessment of gingival health: PSI [40] is the German version of PSR [36] and very similar to CPI, particularly the grades 0, 1 and 2 which are the most relevant in the current investigation can be considered equal. For ease of reading, only the term CPI will be used for all determined data in the respective tables and figures as well as for the description of the results and in the discussion.

Benchmark data

Epidemiological OH benchmark data from population-representative cross-sectional studies of different age cohorts (Tables 4 and 5) [4, 15-17, 27-30, 32, 42, 43, 48, 57] were used to account for population wide changes during the time interval of approximately 15 years between the T2 recall assessments in the treated Class II participants (2014/2015) and the untreated Class I controls (1998/1999).

In addition, the German Oral Health Studies (DMS I, III, IV and V; Supplementary Table 1) [27-30] were used as comparison to rate the OH effects of orthodontic Tx. If not otherwise indicated, comparisons were performed exclusively with age-corresponding cohorts.

To minimize the error of the method, all measurements were performed twice (X.X.) and the mean value of both measurements was used for further calculations.

In addition to a descriptive statistical analysis, the Shapiro-Wilk and Kolmogorov-Smirnov tests were applied to assess the data regarding normal distribution. In case of normal distribution, the t-test or an ANOVA were used, depending on the number of groups to be compared. In case of non-normal distribution, the Mann-Whitney-U test or the Kruskal-Wallis-test were applied, respectively. Due to the explorative study design, p-values ≤ 0.15 were considered to suggest a group difference. This procedure was chosen as explorative data analysis does not use a fixed threshold value of probability to search for "patterns" or "structure" in experimental data although robust inferential statistical procedures are utilised [60]. The 0.1-0.15 threshold was heuristically adapted from a selection process commonly used to screen for relevant factors in logistic regression and similar analytical procedures.

Results

Treated Class II participants vs. non-participants (Table 1)

The 72 treated Class II participants and the 80 non-participants did not differ significantly regarding age and MFT after Tx. The mean value of the total PAR score was higher in the non-participants by 6.5 points before Tx (p=0.000) and by 4.3 points after Tx (p=0.000). Regarding the magnitude of gingival recessions on lower incisors, clinically irrelevant group differences (p=0.058-0.277) were seen.

Treated Class II participants vs. untreated Class I controls (Tables 2-6, Figures 1-3)

The 72 treated Class II participants (40 females, 32 males) had a mean age of 15.4±1.9 years after Tx (T1) and 33.7±3.0 years at recall (T2). The mean post-Tx observation period was 18.3±2.9 years. The untreated Class I controls (17 females, 14 males) had a mean age of 15.3±0.6 years at T1 and 32.9±1.2 years at T2 resulting in an observation period of 17.6±1.2 years, which shows good comparability to the treated Class II participants.

All treated Class II participants had undergone Herbst-MBA Tx due to a severe Class II malocclusion (mean pre-Tx PAR score: 23.9±9.2) which was successfully treated (mean T1 PAR score: 3.2±2.0). Slight changes had occurred until the recall investigation (mean T2 PAR score: 7.5±5.1). At age 15 (T1) the untreated Class I controls exhibited a mean PAR score of 8.7±3.7 which remained stable (8.8±3.3) until age 33 (T2). The mean T2 PAR score in the untreated Class I controls did not differ significantly (p=0.196) from the treated Class II participants. More detailed data on the changes in occlusion and alignment have been published in two separate articles [8, 9].

Looking at the degree of patient satisfaction at recall, the majority of the treated Class II participants (70.8%) was fully satisfied with the condition and appearance of their teeth as well as masticatory system function at T2; 27.8% were conditionally satisfied and 1.4% (n=1) were unsatisfied. For the untreated Class I controls, a smaller amount of subjects (48.3%) could be categorized as fully satisfied; 12.9% were categorized as conditionally satisfied and 38.8% as unsatisfied.

In addition to the detailed findings described below, the clinical examination of the oral cavity and the gums in the treated Class II participants revealed minor anomalies in some patients: signs of local/superficial gingival inflammation (n=16), signs of pathology/purulence (n=2), atypical structure of the mucosa (n=6), cervical root/dentine exposure/tooth brushing defects (n=2).

The general dental status (Table 3) showed a mean MFT score of 3.1±3.8 immediately post-Tx (T1 – radiologic evaluation) in the treated Class II participants. For the untreated Class I controls no T1 data were available. At recall (T2), the treated Class II participants exhibited a mean DMFT score of 7.1±4.8 (clinical evaluation) while the DMFT score of the corresponding population-representative age-cohort (DMS V 2016) [30] is by 56% higher (11.1). The MFT score of the untreated Class I control group from ≈15 years earlier was 7.9±3.6 (radiologic evaluation), while the epidemiological age and year-corresponding Finnish control data [43] shows a value which is by 43% higher.

Looking at periodontal health (Table 5), the mean CPI maximum scores at recall (T2) were 1.6±0.6 in the treated Class II participants and 1.7±0.9 in the untreated Class I controls (p=0.479). The average value for the respective corresponding population-representative age-cohort (DMS V) [30] is not available, but according to the published prevalences of the CPI maximum scores it ranges between 1.9 (best possible scenario) and 2.3 (worst possible scenario); in the previous epidemiologic evaluation (DMS IV) [29] an average value of 2.8±0.9 was seen. While 100% of the treated Class II participants exhibited a maximum score of 0, 1 or 2, this was true for 91% of the untreated Class I controls but only 39% of the epidemiological age-cohort (DMS V) [30].

The mean extent of gingival recessions (on teeth 32/31/41/42) measured on the study models at T2 was 0.1±0.2 in the treated Class II participants and 0.0±0.1 in the untreated Class I controls (p=0.193). In both groups, the respective value had been 0.0±0.0 at T1. Comparable population benchmark data are lacking.

Evaluating the long-term influence of lower fixed retention, no significant group differences (with/without bonded retainer, controls) were seen neither for DMFT, CPI nor lower incisor gingival recessions (Table 7).

Discussion

The evidence supporting claims of significant dental health improvement following orthodontic Tx are tenuous [6]. The current investigation is the first to assess the long-term effects of orthodontic Tx on OH specifically in Class II patients. Before discussing the results in detail it seems important to reflect about what OH actually implies and what kind of findings might realistically be expected in patients many years after orthodontic Tx.

Undoubtedly, OH is a multifactorial condition with continuous development. While the definition by the WHO [OH is a state of being free from chronic mouth and facial pain, oral and throat cancer, oral sores, birth defects such as cleft lip and palate, periodontal (gum) disease, tooth decay and tooth loss, and other diseases and disorders that affect the oral cavity] is very comprehensive, the predominant factors which could potentially be influenced by orthodontic Tx procedures are tooth decay/tooth loss, periodontal disease and mouth/facial pain. So, in former orthodontic patients it would certainly be favourable to see good OH in terms of low DMFT scores, healthy periodontium and no report of OH related pain.

Ideally an untreated Class II sample should have been used for comparison. However, such a sample unfortunately does not exist. Nevertheless, it might be discussable whether the treated Class II participants should be compared to untreated Class I controls. However, the treated Class II participants were Class

I after Tx, and thus possibly predisposed to similar long-term OH effects as the control group. In addition, untreated Class I controls without orthodontic Tx need at adolescence and no orthodontic intervention represent a “natural” gold standard and therefore a more realistic control group than a sample with ideal occlusal characteristics (PAR score 0) which does not resemble the natural aging process of the human dentition [24, 26].

In terms of methodology, the lack of fully comparable data in terms of dental health must be considered as a limitation. While DMFT data from clinical assessment exist for the treated Class II participants at T2, the respective T1 data had to be determined from radiographs. Also the untreated Class I controls' data from T2 were based on a radiologic evaluation. Therefore, the respective score (MFT) might be slightly underrated in these cases. In addition, one might criticise that in terms of gingival recessions, only the lower anterior teeth 32-42 were considered. However, it has been shown that gingival recessions are no relevant issue after Herbst-MBA Tx on any other teeth than lower incisors [53, 54]. The prevalence of gingival recessions with a magnitude of >1 mm was found to be ≤2.8% when considering all teeth after a retention period of 32 months [53].

When comparing the data of the treated Class II participants to those of the non-participants, both groups were similar in terms of age (T0, T1), MFT (T1) and gingival recessions (T1). Therefore, it can be assumed that no relevant selection bias exists.

The degree of satisfaction with the condition and appearance of the teeth and the masticatory system function can be considered as rather high among the treated Class II participants (≈70% fully satisfied, ≈1% unsatisfied). In the untreated Class I controls less subjects were fully satisfied (≈48%) and more were unsatisfied (≈38%). However, evaluating these numbers, it has to be remembered that these controls filled out a questionnaire at a completely different setting. Nevertheless, the difference might be due to a higher degree of tooth - especially incisor - malalignment as neither orthodontic Tx nor retention had been performed in the untreated Class I controls. This is in concordance with the results of an investigation on subjective orthodontic Tx need where a significant association with perceived visible dental irregularity was seen [61]. According to a study from Finland [33], orthodontically treated subjects are also significantly more likely to be satisfied when compared to untreated subjects. The respective study comprised 281 subjects of which ≥ 89% were satisfied with their dental appearance/function of their occlusion. On the contrary, an investigation performed in Canada [50] determined 70% of 2184 participants to be satisfied with dental appearance, but found no relation to previous orthodontic Tx. Finally, a Brazilian study [38] found on long-term (≥5 years) patient satisfaction to be slightly associated with the stability of orthodontic Tx result. However, rating these numbers, it should also be considered that satisfied patients are more likely to participate in patient satisfaction surveys [39].

Looking at OH and especially the dental status, both the treated Class II participants and the untreated Class I controls exhibited similar (D)MFT scores at T2. For both groups, these values were distinctly higher (43-56%) in their corresponding population-representative age-cohorts. Furthermore, the treated Class II participants had been “fully normal” at T1 exhibiting similar values as the corresponding population-representative age-cohort at age 15 (Figures 2 a+b). How can this effect be explained? In literature, straight teeth are described to retain less plaque than irregular teeth [1, 2]; however, no significant difference regarding the incidence of caries between well-aligned and irregular teeth was found [2]. This was confirmed by a systematic review which did not find any high-quality study resolving an association between the presence of crowding and the susceptibility to caries in case of good oral hygiene [23]. A similar conclusion derived from a study which reassessed adolescents 20 years after an initial examination [25] and where no relationship was found between malocclusion and caries prevalence. So, the reason seems to be a different or an additional one. If we consider possible similarities between the treated Class II participants and the untreated Class I controls, both groups experienced an intensive attendance and/or Tx by the dental/orthodontic profession for quite an extensive period during adolescence, during which they were repeatedly motivated (kind of Hawthorne effect) to maintain good oral hygiene and health. So, by undergoing orthodontic Tx children might learn to appreciate the value of good oral hygiene, which is supported by the literature, as orthodontically treated children have shown to have lower plaque scores [19, 21] and caries [14]. This might be the major difference compared to the corresponding population-representative age-cohorts. In addition, a study from Sweden observed that alignment of the teeth seemed to have a positive psychological effect, motivating the patients and giving them greater dental awareness [22].

A similar explanation might account for the observations on periodontal health. Both the treated Class II participants and the untreated Class I controls exhibited similar and distinctly better CPI findings than the corresponding population-representative age-cohort for Germany (no data available for Finland). No other explanation than a difference in awareness due to constant motivation can be assumed.

Looking at the literature comparing the periodontal status of orthodontically treated and untreated patients, one investigation could not detect a significant difference for any periodontal variable at least 10 years after orthodontic Tx [49], while a similar long-term investigation revealed comparable results but found the orthodontic group to exhibit a greater prevalence of mild to moderate periodontal disease (by means of a tissue-destruction index) in the maxillary posterior and mandibular anterior regions than the untreated controls [55].

The mean magnitude of gingival recessions on the lower incisors was 0.1±0.2 mm in the treated Class II participants and 0.0±0.1 in the untreated Class I controls. The slightly larger value in the treated Class II participants might be due to the orthodontic Tx including proclination of the lower incisors. A three-dimensional radiographic evaluation determined alveolar bone loss on the buccal surface of the lower incisors after Herbst Tx by ≤ 0.2 mm and therefore without any clinical significance [56]. An investigation on long-term changes (32 years) after Herbst Tx only, revealed the occurrence of single gingival recessions during the long-term observation, but the authors attributed this finding to other factors like mechanical trauma from toothbrushing or gingival features rather than tooth inclination changes during and after Tx [37, 46].

The influence of lower bonded retainers on OH in the treated Class II participants was of no clinical relevance, which is in concordance with the literature [5, 13, 63], even if this issue remains controversial [52].

Finally, judging both dental and periodontal health one should keep in mind that a certain percentage of the population-representative age-cohorts underwent orthodontic Tx as well (40-60% according to DMS I, III and IV) [27-29]. In other words, the differences for DMFT and CPI can be expected to be even larger compared to the orthodontically untreated population.

Conclusion

Patients with orthodontically treated severe Class II malocclusions had a lower risk for oral health impairment than the general population. The risk corresponded to the one of untreated Class I controls (without orthodontic Tx need during adolescence).

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Table 1 Comparison of the treated Class II participants' and non-participants' data: the mean value (Mean), standard deviation (SD) and p-value (p) of the respective group difference are given for age, PAR, MFT and magnitude of gingival recessions (teeth 32-42).

			Treated Class II participants (40♀:32♂)	Treated Class II non-participants (39♀:41♂)	p
			Mean±SD	Mean±SD	
Age (years)		T1	15.4±1.9	15.9±3.2	0.216
PAR score (total)		T0	23.9±9.2	30.4±9.7	0.000
		T1	3.2±2.0	7.5±4.4	0.000
MFT		T1	3.1±3.8	3.4±3.5	0.499
Magnitude of gingival recessions (mm)	Mean (teeth 32-42)	T1	0.0±0.0	0.1±0.3	0.038
	Tooth 32		0.0±0.0	0.1±0.3	0.131
	Tooth 31		0.0±0.1	0.1±0.3	0.058
	Tooth 41		0.0±0.1	0.1±0.6	0.081
	Tooth 42		0.0±0.0	0.0±0.3	0.227

Table 2 Sex, age (in years) and duration of the observation period T1-T2 (in years) of the treated Class II participants and the "normal" untreated Class I controls. The mean value (Mean), standard deviation (SD) and p-value (p) of the respective group difference are given.

		Treated Class II participants 40♀:32♂	**"Normal" untreated Class I controls** 17♀:14♂	
		Mean±SD	Mean±SD	p
Age (years)	T1	15.4±1.9	15.3±0.6	0.329
	T2	33.7±3.0	32.9±1.2	0.219
Observation period (years)	T2-T1	18.3±2.9	17.6±1.2	0.877

Table 3 Parameters used for the assessment and comparison of oral health (dental status, gingival health) at T1/T2 and the mode of application in the treated Class II participants and the "normal" untreated Class I controls.

	Parameter	**Treated Class II participants**		**"Normal" untreated Class I controls**	
T1	Dental status	(D)MFT-Index	(radiograph)	no data available	
	Gingival health	Recessions teeth 32-42	(study model)	Recessions teeth 32-42	(study model)
T2	Dental status	DMFT-Index	(clinical examination)	(D)MFT-Index	(radiograph)
	Gingival health	PSI-Index^	(clinical examination)	CPI-Index#	(clinical examination)
		Recessions teeth 32-42	(study model)	Recessions teeth 32-42	(study model)

^ PSI-Index: Periodontal Screening Index [40]
# CPI-Index: Community Periodontal Index [3]

Table 4 General dental status: (D)MFT data of the treated Class II participants and the untreated Class I controls as well as comparative data from the literature.

	Population	Year(s) of investigation	Type of evaluation	Location	N=	Mean age	Mean (D)MFT	(D)MFT =0
Current investigation	Treated Class II participants	1988-2000 (T1)	Radiographic	DE	68	15.4	3.1±3.8	34%
		2014-2015 (T2)	Clinical		72	33.7	7.1±4.9	7%
	Untreated Class I controls	1998-2002 (T2)	Radiographic	FI	28	32.9	7.9±3.6	4%

Publication	Year of publication	Year(s) of investigation	Type of evaluation	Location	N=	Age	(D)MFT	(D)MFT =0
DMS I[27]	1991	1989	Clinical	DE (West)	452	13-14	5.1	12%
					451	35-44	16.7	1%
DMS III[28]	1999	1997	Clinical	DE (West)	516	35-44	16.1±5.7	1%
DMS IV[29]	2006	2005	Clinical	DE (West)	1012	15	1.7±2.5	48%
					755	35-44	14.4±5.8	1%
DMS IV[30]	2016	2014	Clinical	DE (West)	814	35-44	11.1±5.6	3%
DAJ[16, 17]	2005	2004	Clinical	DE (Hessen)	1987	15	1.8	46%
	2010	2009			2656	15	1.1	62%
Splieth et al.[57]	2003	1997-2001	Clinical	DE	699	25-34	7.6	-
National Public Health Institute[43]	2008	2000	Clinical	FI	2148	30-44	11.3	-
National Institute for Health and Welfare[42]	2010	1985	Clinical	FI	>10000	15	6.2	-
					>10000	18	9.4	2%
		1994			>10000	15	2.8	-
					>10000	18	4.7	14%
		2000			>10000	15	2.6	-
					>10000	18	4.0	16%
		2003			>10000	17	-	20%
Ankkuri and Ainamo[4]	1997	1991	Clinical	FI	4057	20,3	7.3±5.1	7%
Peltola et al.[48]	2006	1982	Radiographic	FI	176	19,8	11.0±4.2	0%
		2002			231	20,2	2.9±3.2	28%
Kämppi et al.[32]	2013	2011	Clinical	FI	13304	21-23	4.1±4.2	21%
Crocombe et al.[15]	2009	2004-2006	Clinical	AUS	5505	16-19	-	24%
						20-34	-	4%
						35-49	-	0%

DE: Germany
FI: Finland
AUS: Australia
-: Data not available

Table 5 Gingival health: CPI and gingival recession data of the treated Class II participants and the untreated Class I controls as well as comparative data from the literature.

	Population	Year(s) of investigation	Type of evaluation	Location	N=	Age	CPI Maximum score				
							Mean	=0	=0,1,2	=3	=4
	Treated Class II participants	2014-2015 (T2)	Clinical	DE	72	33,7	1.6±0.6	4%	100%	0%	0%
	Untreated Class I controls	1998-2002 (T2)	Clinical	FI	31	32,9	1.7±0.9	16%	91%	6%	3%

Publication	Year of publication	Year(s) of investigation	Type of evaluation	Location	N=	Age	CPI Maximum score				
							Mean	=0	=0,1,2	=3	=4
DMS I[27]	1991	1989	Clinical	DE (West)	451	35-44	2,5	6%	45%	40%	15%
DMS III[28]	1999	1997	Clinical	DE (West)	509	35-44	2,0	18%	62%	29%	9%
DMS IV[29]	2006	2005	Clinical	DE (West)	740	35-44	2.8±0.9	0%	28%	53%	19%
DMS V[30]	2016	2014	Clinical	DE (West)	806	35-44	1.9-2.3*	-	39%	51%	10%

DE: Germany
FI: Finland
*: Exact value not known; best and worse possible value calculated

Table 6 Mean magnitude of gingival recessions on lower incisors. Results of study model assessment in mm are given for each of the teeth 32-42 as well as mean (teeth 32-42). The data is shown for the treated Class II participants and the untreated Class I controls. In addition the group difference (p-value) is given where applicable.

			Tooth 32	p	Tooth 31	p	Tooth 41	p	Tooth 42	p	Mean (teeth 32-42)	p
T1	Treated Class II participants	n=70	0.0±0.1	0.136	0.0±0.1	0.288	0.0±0.1	0.392	0.0±0.0	0.145	0.0±0.0	0.585
	Untreated Class I controls	n=31	0.0±0.1		0.0±0.0		0.0±0.0		0.0±0.1		0.0±0.0	
T2	Treated Class II participants	n=72	0.1±0.2	0.469	0.1±0.4	0.267	0.2±0.5	0.903	0.0±0.1	0.845	0.1±0.2	0.193
	Untreated Class I controls	n=31	0.0±0.1		0.0±0.1		0.1±0.4		0.0±0.1		0.0±0.1	

Table 7 (D)MFT, CPI and mean gingival recessions (teeth 32-42) after long-term observation (T2) in the treated Class II participants with (n=29) or without (n=43) a bonded lower canine-to-canine retainer at T2 as well as the untreated Class I controls. The mean value (Mean), standard deviation (SD), median (Med) and p-value (p) of the respective group difference are given.

	Treated Class II participants						Untreated Class I controls		
	Bonded lower retainer at T2			No retainer at T2					
	Mean	SD	Med	Mean	SD	Med	Mean	SD	Med
(D)MFT	5.9	4.7	7.0	7.9	4.9	7.0	7.9	3.6	8.0
	p=0.210								
CPI	1.6	0.6	2.0	1.6	0.5	2.0	1.7	0.9	2.0
	p=0.090								
Mean gingival recessions (teeth 32-42; mm)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	p=0.227								

Figure 1 Flow chart of the treated Class II participants and non-participants. The numbers of total Herbst-MBA patients (active Tx completed by January, 1st 2015) as well as potential participants and the results of the recruitment process are given.

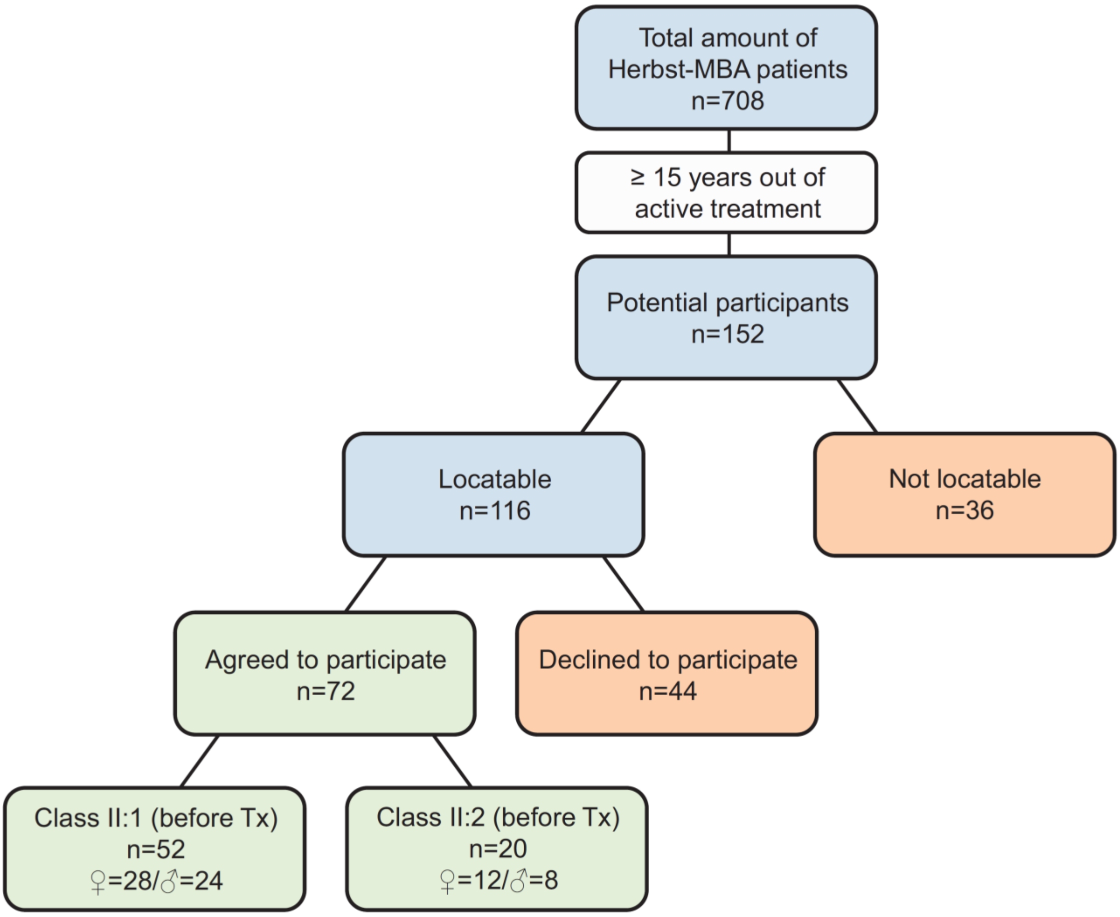


Figure 2 Chart exhibiting the development of the mean (D)MFT scores of the population in a) Germany (West) and b) Finland from the 1980s until today in different age groups; in addition, the respective values of the treated Class II participants at T1 and T2 as well as of the untreated Class I controls (T2) are given (data in the figure are allocated to the respective years of investigation). For a), the names of the respective references are used as in Table 4; for b), the reference numbers are given.

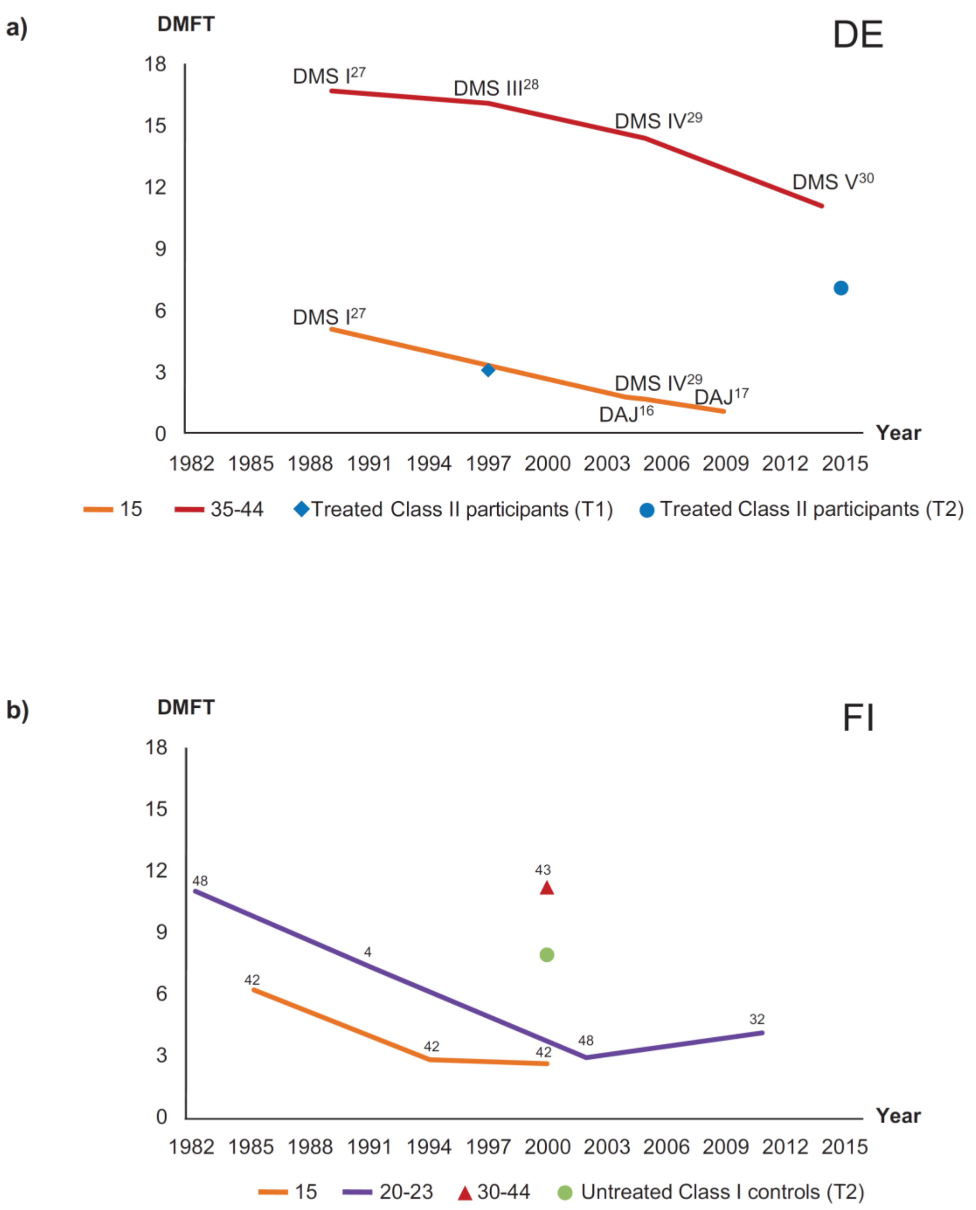
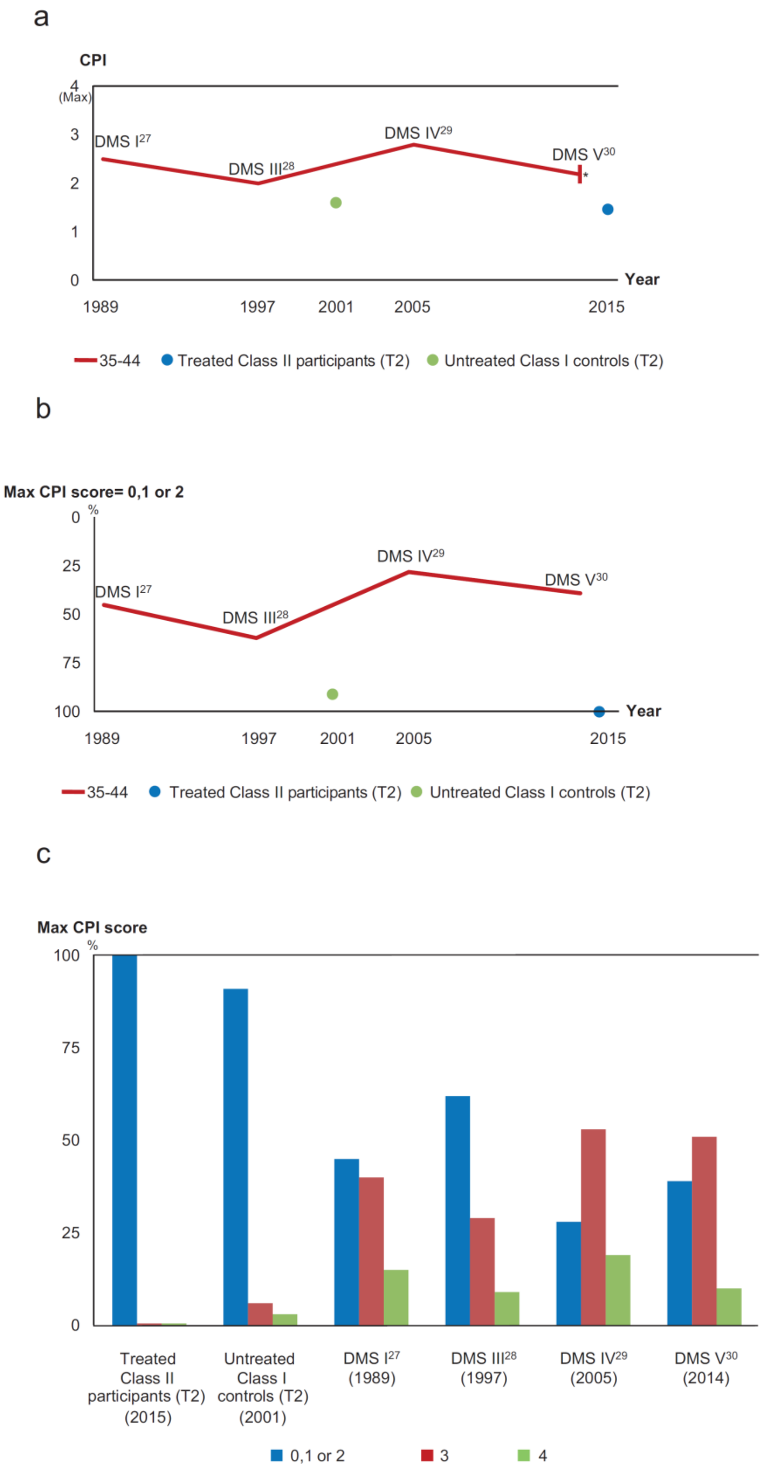


Figure 3 Chart exhibiting the CPI data (a: mean score, b: percentage exhibiting a maximum score of 0, 1 or 2; c: distribution of maximum scores 0-4 in percent) of the treated Class II participants and the untreated Class I controls at T2. In addition, the development of the CPI scores of the population in Germany (West) from the 1980s until today in the same age group is shown (data in the figure are allocated to the respective years of investigation). The names of the respective references are used as in Table 5. *Exact value not known; best and worst possible value calculated



6) Ruf S, Bock NC. Long-term (≥ 15 years) effects of Class II treatment: A longitudinal and cross-sectional study on signs and symptoms of temporomandibular disorders.
European Journal of Orthodontics 2018; accepted for publication

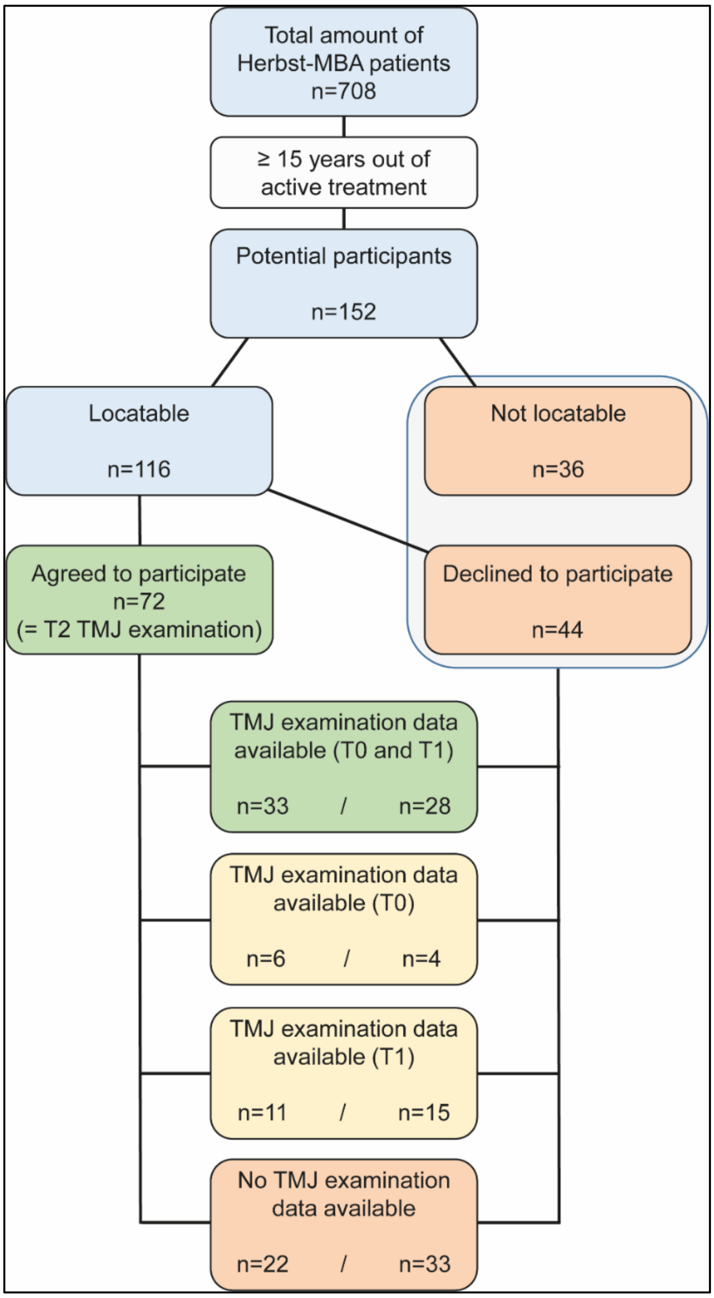
Temporomandibular disorder is a collective term for a number of clinical problems of multifactorial origin [104] that might negatively impact patients' oral health related quality of life [12,425,481]. While several occlusal factors [122,123,203,256,276,417] have been discussed to be associated with temporomandibular disorder development [295], the evidence in the literature is controversial [25,131,198,260-262]; the same is true for the effects of orthodontic treatment on temporomandibular disorders [197,238]. Unfortunately, any such investigation is impeded by the diversity of malocclusion, long latency times (years to decades) [104,254,256] as well as the fluctuation of signs and symptoms over time [256,282].

For Class II treatment a prevalence decrease of signs and symptoms of temporomandibular disorder was found [173,392]. Long-term data on the effects of orthodontic Class II treatment, however, are scarce.

The objective of this longitudinal, cross-sectional investigation was the analysis of the long-term effects of Class II Herbst-Multibracket appliance treatment on the prevalence and incidence of signs and symptoms of temporomandibular disorder.

The archive of the Department for Orthodontics at the University of Giessen was screened for all Class II patients whose Herbst-Multibracket appliance treatment was finished at least 15 years ago. From a total of 152 patients, 116 could be located and were asked to participate in a recall; while 72 patients (56% females, 44% males) agreed, 44 declined (Figure U). The mean age was 13.6±1.9 years before treatment, 15.4±1.9 years after treatment and 33.7±3.0 years at recall.

Figure U Flowchart showing the patient selection procedure of the Herbst-Multibracket appliance sample. In addition, the numbers of participants/non-participants with available temporomandibular disorders data are given; reprinted from: "Ruf S, Bock NC. Long-term (≥15 years) effects of Class II treatment: a longitudinal and cross-sectional study on signs and symptoms of temporomandibular disorders. Eur J Orthod 2018;doi:10.1093/ejo/cjy040" by permission of Oxford University Press/European Orthodontic Society



Before undertaking a functional examination of the temporomandibular joint, the masticatory musculature and associated structures, the anamnesis and potential complaints of the participants were gathered. RDC/TMD [118] and DC/TMD [407] as well as the Helkimo-Index [169] were used to classify the findings.

Previous data on temporomandibular disorder from before and/or after treatment were available for more than 54% of the participants and were compared to the present findings. Findings for all three assessment time points were available for 33 of the 72 participants. If available, non-participants' data were used to appraise for selection bias.

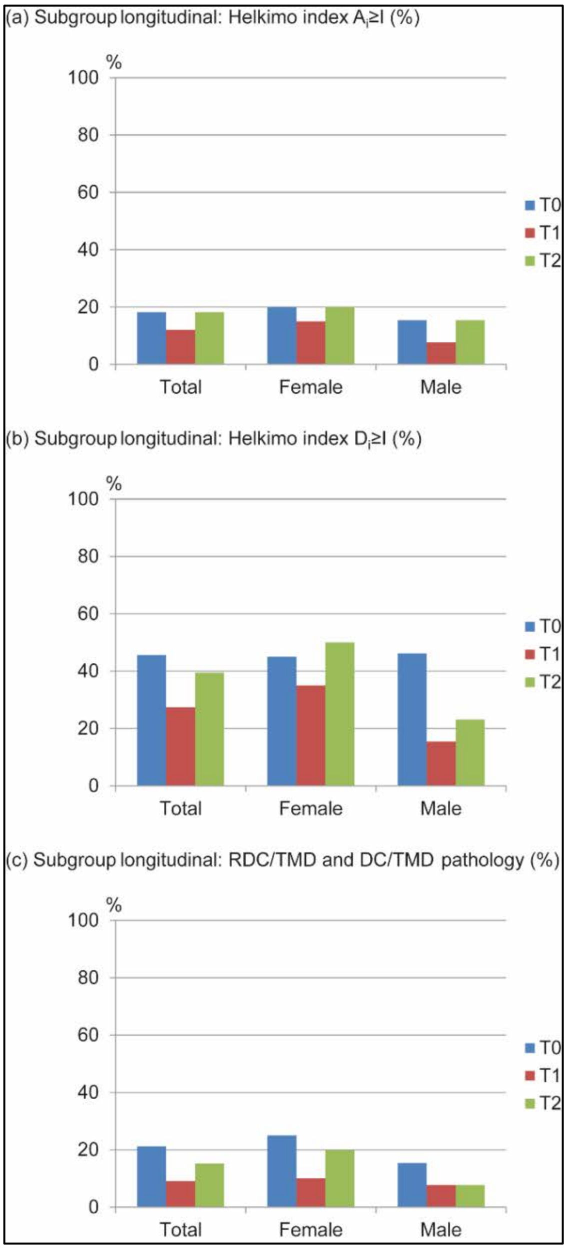
Herbst-Multibracket appliance treatment led to successful Class II correction. No systematical differences existed between the participants and the non-participants as well as the participants with complete and incomplete data-sets.

Regarding temporomandibular disorder, no systematical difference was found between the 72 participants and the 80 non-participants. The same was true for the comparison of the 33 participants with complete data-sets and the 39 participants with incomplete data-sets; therefore, this group was considered representative for the whole sample.

The majority of patients (82-88%) did not report any anamnestic temporomandibular disorder symptoms (Helkimo-Index A_i) at any time-point. Mild symptoms were described by 9-12% and severe symptoms by 6-9% of the patients (Figure V).

Time point dependent, no clinical dysfunctions (Helkimo-Index D_i) were seen in 55-73% of the patients while mild/moderate dysfunctions existed in 21-33%/3-21% (Figure V). Severe dysfunction was seen in one patient (3%) but only before treatment. The classification according to RDC/TMD and DC/TMD revealed similar data: the prevalence was 21% before treatment, 9% after treatment and 15% at recall (Figure V).

Figure V Overall prevalence and prevalence per gender (%) of patients with temporomandibular disorders before treatment (T0), after treatment (T1) and ≥ 15 years follow-up (T2) in 33 Herbst-Multibracket appliance patients. The percentages are given for patients with (a) a Helkimo anamnestic dysfunction index (A_i) > 1, (b) a Helkimo clinical dysfunction index (D_i) > 1 and (c) a positive RDC/TMD or DC/TMD; reprinted from: "Ruf S, Bock NC. Long-term (≥15 years) effects of Class II treatment: a longitudinal and cross-sectional study on signs and symptoms of temporomandibular disorders. Eur J Orthod 2018;doi:10.1093/ejo/cjy040" by permission of Oxford University Press/European Orthodontic Society



For both Helkimo-Indexes A_i and D_i as well as RDC/TMD and DC/TMD a fluctuation between the time-points with a non-significant trend for improvement during active treatment and recurrence thereafter was seen. The non-significant trend for prevalence decrease during active treatment was more pronounced in males than in females. The trend for prevalence recurrence after treatment was less pronounced in males.

The current investigation assessed the longitudinal effects of Herbst-Multibracket appliance treatment over ~20 years from adolescence until adulthood. While the sample was still rather small, it was relatively large compared to literature; in addition, it was homogenous and can be considered representative for the entire sample.

Both the classifications according to RDC/TMD and DC/TMD as well as the Helkimo-Index were used to enable a wider comparison with the literature. However, the non-availability of any kind of imaging data at the time of recall due to the screening character of the study design have to be considered as limitation. So, the prevalence/incidence values for temporomandibular disorder might objectively be higher.

The prevalence and gender distribution for temporomandibular disorder in the present sample is in concordance with the literature [173,256,282,428]. While no publications contain respective data exclusively for Class II patients, the present prevalence data seems to be at the lower range with respect to prevalence when compared to values of other orthodontically treated/untreated samples of similar age [122,253,256,395]. So, there might be a positive effect which could neither be proven in previous nor in the present study.

However, in overall concordance with the literature [197], the current findings seem to confirm that orthodontic treatment neither decreases nor increases the risk for temporomandibular disorder development in later life [197,238,397].

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Long-term (≥ 15 years) effects of Class II treatment: A longitudinal and cross-sectional study on signs and symptoms of temporomandibular disorders

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Abstract

Background: The aetiology of temporomandibular disorders (TMD) is controversial and post-orthodontic long-term TMD data of Class II populations are scarce.

Objectives: To analyse the long-term (≥ 15 years) effects of Herbst-MBA Class II treatment (Tx) on signs and symptoms of TMD.

Subjects and Methods: All patients (University of Giessen, Germany) who underwent Herbst-MBA Tx (end of active Tx ≥ 15 years ago), could be located and agreed to participate in a recall. Available records from before (T0) and after (T1) active Tx were used for comparison with the recall data (T2). All findings were classified according to RDC/TMD (Dworkin and LeResche 1992) and DC/TMD (Schiffman et al. 2014) as well as the Helkimo index (Helkimo 1974).

Results: 72 out of 152 patients participated at age 33.7±3.0 years. Complete TMD data-sets (T0+T1+T2) were available for 33 participants. Participants and non-participants did not differ significantly at T0 or T1 in terms of general clinical data, occlusal relationship or TMD prevalence.

At all time-points, 79-91% of the patients were free of TMD signs and symptoms (RDC/TMD and DC/TMD). The TMD prevalence fluctuated: 21% (T0), 9% (T1), 15% (T2). Similar findings with a trend towards improvement during T0-T1 and recurrence during T1-T2 were seen for the Helkimo index. There were no statistically significant differences.

Limitations: The participation rate of only 62%, the disparate availability of records (T0, T1), the fact that the patients were not treated at exactly the same time period and that no untreated control group is available.

Conclusion: In the long-term (≥ 15 years) Herbst-MBA Class II Tx neither seems to increase nor decrease the risk for developing TMD.

Introduction

Temporomandibular disorder (TMD) is a collective term that describes a number of clinical problems involving the masticatory musculature, the temporomandibular joint (TMJ) and associated structures (1). Although TMD is not life-threatening, it may have a substantial negative impact on the patients' Oral Health Related Quality of Life (OHRQoL) (2, 3) and is a recognized disease listed in the International Classification of Diseases, 10th edition (ICD-10) by the World Health Organization.

The role of occlusion and/or malocclusion in the aetiology of TMD remains controversial (4). No single occlusal factor seems to be of utmost importance for the development of TMD although unstable occlusions, lateral forced bites, unilateral crossbites, large RCP/ICP discrepancies, Class II malocclusion, large overjets and deep bites have been discussed as potential risk factors (5-10). However, the corresponding evidence is not conclusive (11-15) and seems to account for less than 20% of the variability in TMD signs and symptoms (16). Controversy also exists for the effect of orthodontic treatment (Tx) on TMD for which it is currently agreed upon, that it neither increases nor decreases the risk for developing TMD later in life (17).

TMD are multifactorial in origin. In addition, the long latency times (years to decades) of orthopaedic disorders in general (18) and as such also for TMD, the generally slow progression and/or self-limiting nature of TMD (1, 9) and the substantial fluctuation of both signs and symptoms over time (9, 19) hamper the investigation of orthodontic effects. Finally, from a research methodological point of view, the proof of a causal/preventive effect of orthodontic Tx and or a causative effect of malocclusion would require a RCT design with untreated controls, which given the long-term perspective, would be impossible to conduct both from an ethical and financial/administrative point of view.

Malocclusion is not a uniform condition and may additionally have different degrees of severity. There are countless possibilities for combination both within and between different Angle Classes with in turn different possible effects on TMD. However, this factor has rarely been taken into account in the previous studies/reviews existing in literature. Thus, if we concentrate on very narrowly defined types of malocclusion and high levels of severity, we might see effects. For example it has been shown, that Tx of severe malocclusions by orthodontic or orthodontic/surgical Tx improves OHRQoL via a decrease in facial pain (20). Furthermore, it was demonstrated, that orthognathic Tx of severe malocclusions not only decreases signs and symptoms of TMD but also improves masticatory ability and performance via an increase in the number of occlusal contacts (21, 22).

With respect to Class II malocclusions, Herbst Tx was described to result in a decrease of prevalence regarding signs and symptoms of TMD from before to after Tx (23). A longitudinal (2 years) study investigated 183 girls aged 11 to 15: 65 Class II treated, 58 Class II untreated, 60 with normal occlusion (24). Despite an individual fluctuation of signs and symptoms of TMD, a decrease of reported TMD symptoms was seen in the treated Class II group compared to the untreated controls (both Class II and normal occlusion). However, long-term TMD data for an orthodontically treated Class II population are scarce. Class II patients analysed an average of 32 years after Herbst Tx reported only minor TMJ problems and their TMD prevalence was comparable to the general population (25). However, in this sample of 14 patients, only three (21%) got multibracket appliances (MBA) thus hampering the achievement of a perfect occlusion.

Objectives

The aim of this longitudinal and cross-sectional study was to analyse the long-term effects of Herbst-MBA Tx of Class II malocclusions on the prevalence and incidence of signs and symptoms of TMD.

Material and Methods

After ethical approval (University of Giessen - No. 146/13) and study registration (WHO: ID DRKS00006354), the archive (Department of Orthodontics, University of Giessen, Germany) was searched for Class II patients who finished Herbst-MBA Tx $\geq$ 15 years ago.

A total of 152 patients fulfilled these criteria (Figure 1). Out of these 152 patients – 116 patients could be located using the address data from the period of active Tx as well as the internet and were asked to participate in the study. While 44 patients were not interested or unable to participate for other reasons, 72 patients agreed to take part. Thus, with respect to the amount of locatable patients, the drop-out rate was 38%.After obtaining informed consent, the anamnesis and eventual complaints regarding TMD of the 72 participating patients were gathered. Thereafter, a functional examination of the TMJ and the masticatory musculature and associated structures was performed. In addition, the mandibular border movements were measured to the nearest 0.5 mm using a manual calliper. All findings were classified according to the Helkimo index (26) (Table 1) as well as RDC/TMD (27) and DC/TMD (28).

All clinical TMD follow-up examinations were performed by one of the two authors. Both investigators were blinded for the corresponding previous (pre- and post-Tx) examination results.

<u>Cross-sectional data: total group of participants (n=72)</u>

The total sample comprised of 40 females (56%) and 32 males (44%); the mean age was 13.6±1.9 years pre-Tx (T0) and 15.4±1.9 years post-Tx (T1). The average age at follow-up (T2) was 33.7±3.0 years.

For more than 54% of the participants and more than 40% of the non-participants (Figure 1) previous TMD data from pre-Tx and/or post-Tx (0-47 months after active Tx) were retrievable from the patient's files and were compared to the present findings. For this purpose the former TMD data recorded according to RDC/TMD (27) were examined together with the data recorded according to DC/TMD (28). The main differences (28) between the former RDC/TMD and the actual DC/TMD (concept of "familiar pain", a reduced number of muscle palpation sites, changes in myofascial pain diagnoses) could be overcome because of the specific registration in the former TMD data.

The data of the non-participants were used for preclusion of a selection bias.

<u>Longitudinal data: subgroup of participants with complete data-sets from pre-Tx, post-Tx and follow-up (n=33)</u>

For 33 out of the 72 participating patients TMD data were available for all three observation time-points: before Tx (T0), after Tx (T1) and after follow-up (T2). All clinical examinations of this longitudinal subsample were performed by the same calibrated investigator (S.R.) with long-term TMD experience that had performed the clinical analysis of the subjects $\geq$ 15 years ago (23, 29).

The mean pre-Tx age of the subgroup was 13.4±2.7 years. The gender distribution was 61% females and 39% males. The average age at follow-up was 32.6±2.1 years.

Statistical analysis

In addition to a descriptive statistical analysis, the Chi-square test respectively the Fisher's exact test were used to analyse group differences, while the McNemar test was employed to compare changes. A p-value $\leq$ 0.05 was considered statistically significant.

Results

The general clinical and occlusal characteristics of all 152 patients (participants and non-participants) at pre-Tx and post-Tx as well as conditionally their longitudinal changes have been described in detail elsewhere (30, 31). A summary of the data is given in Table 2. The group comparison showed that for both participants and non-participants Herbst Tx had resulted in a successful correction of the Class II malocclusion. There were no statistically significant group differences, neither between the participants and non-participants nor between the participants with complete and incomplete data-sets.

This also applies for all data of the present investigation. All p-values were > 0.1 with one exception: p=0.065 was determined for Helkimo clinical dysfunction index (D_i) before Tx when comparing the participants (incomplete vs. complete TMD data-sets). Therefore, as no further comparison reached the level of statistical significance, for ease of reading no p-values are given in the tables/figures.

<u>Cross-sectional data: participants vs. non-participants (Table 3)</u>

The 72 participants and the 80 non-participants did not differ significantly regarding the prevalence of positive anamnestic and dysfunctional Helkimo index scores or pathologic RDC/TMD and DC/TMD findings.

<u>Cross-sectional data: participants with complete vs. incomplete data-sets (Table 3)</u>

The sample of the 39 participants with incomplete TMD data-sets and the 33 participants with complete TMD data-sets (T0+T1+T2) did not differ significantly regarding the prevalence of positive anamnestic and dysfunctional Helkimo index scores as well as pathologic RDC/TMD and DC/TMD findings for all observation time-points. Only the pre-Tx prevalence of positive Helkimo clinical dysfunction index scores (D_i > 1) came close (p=0.065) to a significant difference, indicating a trend for more pre-Tx dysfunction in the group with complete data-sets. In addition, no statistically significant differences were seen for age, gender distribution and occlusal characteristics. Therefore, the subgroup with complete data-sets was considered representative for the entire sample, and in the following only the results of the subgroup with complete data-sets will be described in detail.

Longitudinal data: subgroup of participants with complete data-sets (Table 3, Figures 2 and 3)

At all time-points, the majority (82-88%) of the patients were free of anamnestic TMD symptoms (Helkimo index A_i; Figure 2a). Mild anamnestic dysfunction symptoms were found in 9-12% of the sample and severe anamnestic symptoms were reported by 6-9% of the patients (T0 and T2 only). There was a fluctuation of anamnestic symptoms between all three index categories with a trend towards improvement between T0 and T1 and a trend for recurrence between T1 and T2. However, there weren't any statistically significant differences.

No clinical dysfunctions (Helkimo index D_i; Figure 2b) were seen in 55-73% of the patients (Figure 2b). The highest prevalence of dysfunction-free individuals existed after Tx (73%). Mild dysfunction could be detected in 21-33% of the patients and moderate dysfunction in 3-21% of the patients. Severe dysfunction was only present in one patient (3%) and exclusively before Tx. There was a fluctuation of signs between all four index categories with a trend towards improvement between T0 and T1 and a trend for recurrence between T1 and T2. Nevertheless, from T0 to T2 the frequency of moderate and severe dysfunctions decreased in favour of mild dysfunctions. No statistically significant differences were found.

The prevalence of TMD according to RDC/TMD and DC/TMD is given in Figure 2c. At all time-points, the majority (79-91%) of patients were free of TMD. The prevalence of TMD decreased from 21% (T0) over 9% (T1) to 15% (T2). A similar fluctuation as for the Helkimo index (A_i and D_i) with a trend towards improvement between T0 and T1 and a trend for recurrence between T1 and T2 was seen. However, there weren't any statistically significant differences.

The specific TMD diagnoses according to RDC/TMD and DC/TMD found in the present sample are given in Table 4. They underline the abovementioned trend towards milder dysfunction with age. From T0 to T2, the prevalence of arthralgia decreased from 9% to 6%. Also, the number of patients with clinically detectable disc displacements decreased from 18% to 9%. One "new" pathology appeared at T2 – it was a very mild form of the subgroup "others" (DC/TMD) respectively "stylalgia" (RDC/TMD).

Looking at possible gender differences for the Helkimo index (A_i and D_i) as well as the RDC/TMD and DC/TMD categories (Figure 3), two gender-specific trends could be recognized. First, the decrease in prevalence between T0 and T1 was more pronounced in males compared to females for A_i and D_i as well as RDC/TMD and DC/TMD. Second, the trend for recurrence/increase between T1 and T2 was less pronounced for males (D_i as well as RDC/TMD and DC/TMD). Both trends lead to a lower prevalence for D_i as well as RDC/TMD and DC/TMD at T2 compared to T0 for males but not for females. There was, however, no statistically significant group difference.

Discussion

The present study analysed the longitudinal effects of fixed functional Class II malocclusion Tx over an average period of about 20 years from adolescence to adulthood. Over such a long period, although desirable, a dropout of patients/loss of data is unfortunately inevitable. Nevertheless, 62% of the locatable patients could be recalled and analysed, which given the length of the observation period seems acceptable. The sample size in the present study was 72 respectively 33 subjects. Therefore, although the patient sample is very homogenous, the sample size was rather small compared to other non-selected longitudinal studies on TMD (9, 19).

The data of the participants did not differ significantly from the data of the non-participants, neither in terms of age, occlusal characteristics nor in terms of signs and symptoms of TMD. Thus, the recalled patients seem to be representative for the entire sample of Class II patients treated with Herbst-MBA at least 15 years before.

From a methodological point of view, the proof of a causal/preventive effect of orthodontic Tx would require a RCT design with untreated controls, which given the long-term perspective, was impossible from both an ethical and a financial/administrative point of view. Unfortunately, also an untreated historical Class II control group with comparable TMJ data, at least to our knowledge, does not exist.

The analysis of TMD was performed according to the Helkimo index (26) as well as RDC/TMD (27) and DC/TMD (28). While the Helkimo index does not provide specific information on the TMJ (for both the anamnestic and the clinical indices muscle and joint signs and symptoms are intermixed), it was used to allow for a wider comparison with literature. The DC/TMD criteria have been shown to have a high level of reliability (32) comparable to the former RDC/TMD criteria (27), nevertheless they have also been criticised (33). Given the long time interval between the examinations ($\leq$ 15 years) in the present study, it cannot be ruled out that, despite the basically high reliability of RDC/TMD respectively DC/TMD, the investigator's evaluation of TMD signs and symptoms has evolved over time.

A limitation of the present study is the fact, that no imaging modalities were used to underline and conditionally complement the clinical diagnosis. Both CT and CBCT have been shown to have a high validity to assess degenerative TMJ disease (34) but are also clearly not recommended for screening purposes. With respect to disc disorders and especially disc displacements without reduction the sensitivity and specificity of the clinical examination (RDC/TMD) are clearly inferior to MRI analysis (35). In other words, RDC/TMD respectively DC/TMD are appropriate for clinical/research screening, but a final diagnosis for intra-articular disorders requires imaging (36). Therefore, it cannot be ruled out, that the reported prevalences/incidences of TMD in the present sample were not objectively higher.

The prevalence of patients with TMD (RDC/TMD and DC/TMD) in the present sample decreased from 21% (T0 ~ age 13 years) over 9% (T1 ~ age 15.5 years) to 15% (T2 ~ age 33 years). A similar trend, showing a development towards milder symptoms of dysfunction was detected using the D_i component of the Helkimo index. These trends, although statistically not significant, are in line with previous results (20, 24) showing that Tx of severe malocclusions decreases signs and symptoms of TMD from before to three years after Tx. The findings are also supported by other reports in literature, demonstrating that with increasing age signs and symptoms of TMD reduce, respectively that they increase until young adulthood and tend to level-out thereafter (9, 19).

With regard to the overall prevalence of signs and symptoms of TMD, the only clinically relevant question is whether the patients had a higher prevalence of TMD at the time-point of recall. The present study analysed the longitudinal effects of fixed functional Class II malocclusion Tx over an average period of about 20 years from adolescence to adulthood with an endpoint at ~ 33 years. During this period the prevalence changed from 21% (T0 ~ age 13 years) over 9% (T1 ~ age 15.5 years) to 15% (T2 ~ age 33 years). In literature, there are no other publications reporting the changes in TMD exclusively in Class II patients over a corresponding period of time. Reports, that do cover a corresponding period in time analysed either orthodontically treated samples with a full range of malocclusion (5, 37), a mixed sample of orthodontically and non-orthodontically treated subjects (9) or a national cohort (38). Clinical analyses were not performed in all studies. The prevalence of patients with TMD signs and symptoms at the age ~ 30 years ranged from 9.9-45%. Thus, the prevalence of signs and symptoms in the present sample of Class II patients after Herbst-MBA Tx and at the age ~ 33 years was definitely at the lower range with regard to other reports in literature (5, 9, 37, 38). Thus, there might be some positive effect of orthodontic Tx, which could however not be proven with the present investigation.

Overall, the results of the present study showed no significant changes in signs and symptoms of TMD from before Tx to long-term follow-up (Helkimo as well as RDC/TMD and DC/TMD) in the present population of severe Class II malocclusions treated with Herbst-MBA. Both signs and symptoms fluctuated unforeseeably over time. These findings support the currently accepted fact that orthodontic Tx neither decreases nor increases the risk for developing TMD later in life (17, 39). In other words, no basically new knowledge could be generated from the present investigation, despite the fact that a very specific and homogenous malocclusion group of severe Class II patients with a uniform Tx approach was analysed. This clearly underlines the fact that occlusion/malocclusion has been found to account for a very limited (16) if not any percentage of the variability in TMD signs and symptoms.

Conclusion

In the long-term (≥15 years) orthopaedic Tx of severe Class II malocclusions using a Herbst-MBA neither seems to increase nor decrease the risk for developing TMD.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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Table 1 Categories of the Helkimo anamnestic (Ai) and clinical (Di) dysfunction index. (26)

A_i0	No anamnestic dysfunction	- No symptoms
A_iI	Mild anamnestic dysfunction	- TMJ sounds (clicking or crepitation)
		- Jaw fatigue or jaw stiffness
A_iII	Severe anamnestic dysfunction	- Difficulty in mouth opening or jaw locking
		- Difficulty in mouth closure or jaw luxation
		- Painful TMJ region or masticatory musculature
		- Painful jaw movements

Clinical dysfunction index (D_i= A+B+C+D+E)		
D_i0	No dysfunction	No clinical symptoms
D_iI	Mild dysfunction	1-4 points
D_iII	Moderate dysfunction	5-9 points
D_iIII	Severe dysfunction	>10 points

A	Impaired mobility	1P	≤39mm opening or ≤ 6mm lateral
		5P	≤29mm opening or ≤ 3mm lateral
B	Altered function	1P	Uni- or bilateral clicking or crepitation or mandibular deviation ≥ 2mm
		5P	Luxation or locking
C	Muscle Pain	1P	Sensitivity to pressure 1-3 places
		5P	Sensitivity to pressure ≥ 4 places
D	TMJ pain	1P	Sensitivity to lateral pressure
		5P	Sensitivity to posterior pressure
E	Painful function	1P	1 painful movement
		5P	≥2 painful movements

Table 2 Age and occlusal characteristics of the non-participants, the total group of participants, the participants with incomplete TMD data (=missing TMD data at one or more observation time-points) and the participants with complete longitudinal TMD data (T0+T1+T2). *Please note: None of the group differences was statistically significant.*

			Non-participants (cross-sectional)	Participants (cross-sectional) complete/incomplete data-sets (n=72)	Participants (cross-sectional) incomplete data-sets (n=39)	Participants (longitudinal) complete data-sets (n=33)
Age (years)	Pre-Tx	T0	14.1±3.16	13.6±1.87	13.3±1.47	13.9±2.23
	Post-Tx	T1	15.9±3.20	15.4±1.90	15.1±1.54	15.8±2.20
	Recall	T2	-	33.7±3.00	34.7±3.26	32.6±2.14
Sagittal molar relationship (cusp widths)	Pre-Tx	T0	0.8±0.29	0.8±0.26	0.8±0.27	0.7±0.25
	Post-Tx	T1	0.0±0.21	-0.1±0.13	0.0±0.14	-0.1±0.13
	Recall	T2	-	0.0±0.17	0.0±0.16	0.0±0.19
Overjet (mm)	Pre-Tx	T0	7.1±2.79	7.1±2.70	7.3±2.76	6.8±2.66
	Post-Tx	T1	1.9±1.01	2.1±0.75	2.1±0.75	2.2±0.75
	Recall	T2	-	3.2±1.20	3.4±1.02	3.1±1.37
Overbite (mm)	Pre-Tx	T0	4.0±2.29	4.4±1.61	4.5±1.64	4.3±1.60
	Post-Tx	T1	1.3±0.89	1.3±0.73	1.4±0.79	1.2±0.64
	Recall	T2	-	2.7±1.53	3.0±1.48	2.4±1.53

Table 3 Number (n) and percentage (%) of patients with TMD pre-Tx, post-Tx and at the ≥15 years recall for the non-participants, the total group of participants, the participants with incomplete TMD data-sets (=missing TMD data at one or more observation time-points) and the participants with complete longitudinal TMD data (T0+T1+T2). The percentages are given for patients with a Helkimo anamnestic dysfunction index (A_i) ≥1, a Helkimo clinical dysfunction index (D_i) ≥1 and a positive RDC/TMD or DC/TMD. *Please note: None of the group differences/differences between time-points was statistically significant.*

		n	Helkimo index		RDC/TMD and DC/TMD
			Anamnesis ≥AiI	Dysfunction ≥DiI	Pathology
Non-participants (cross-sectional)					
Total	Pre-Tx T0	32	12.5% (n=4)	46.9% (n=15)	12.5% (n=4)
	Post-Tx T1	43	7.0% (n=3)	27.9% (n=12)	4.7% (n=2)
Female	Pre-Tx T0	17	23.5% (n=4)	58.8% (n=10)	23.5% (n=4)
	Post-Tx T1	25	12.0% (n=3)	32.0% (n=8)	8.0% (n=2)
Male	Pre-Tx T0	15	0.0% (n=0)	33.3% (n=5)	0.0% (n=0)
	Post-Tx T1	18	0.0% (n=0)	22.2% (n=4)	0.0% (n=0)
Participants (cross-sectional)			**complete/incomplete data-sets**		
Total	Pre-Tx T0	39	15.4% (n=6)	38.5% (n=15)	17.9% (n=7)
	Post-Tx T1	44	11.4% (n=5)	27.3% (n=12)	9.1% (n=4)
	Recall T2	72	23.6% (n=17)	38.9% (n=28)	15.3% (n=11)
Female	Pre-Tx T0	24	16.7% (n=4)	37.5% (n=9)	17.9% (n=5)
	Post-Tx T1	25	16.0% (n=4)	32.0% (n=8)	9.1% (n=3)
	Recall T2	40	27.5% (n=11)	47.5% (n=19)	25.0% (n=8)
Male	Pre-Tx T0	15	13.3% (n=2)	40.0% (n=6)	17.9% (n=2)
	Post-Tx T1	19	5.3% (n=1)	21.1% (n=4)	9.1% (n=1)
	Recall T2	32	18.8% (n=6)	28.1% (n=9)	9.4% (n=3)
Participants (cross-sectional)			**incomplete data-sets**		
Total	Pre-Tx T0	6	0.0% (n=0)	0.0% (n=0)	0.0% (n=0)
	Post-Tx T1	11	9.1% (n=1)	27.3% (n=3)	9.1% (n=1)
	Recall T2	39	28.2% (n=11)	38.5% (n=15)	15.4% (n=6)
Female	Pre-Tx T0	4	0.0% (n=0)	0.0% (n=0)	0.0% (n=0)
	Post-Tx T1	5	20.0% (n=1)	20.0% (n=1)	20.0% (n=1)
	Recall T2	20	35.0% (n=7)	45.0% (n=9)	25.0% (n=4)
Male	Pre-Tx T0	2	0.0% (n=0)	0.0% (n=0)	0.0% (n=0)
	Post-Tx T1	6	0.0% (n=0)	16.7% (n=2)	0.0% (n=0)
	Recall T2	19	21.1% (n=4)	31.6% (n=6)	10.6% (n=2)
Participants (longitudinal)			**complete data-sets**		
Total	Pre-Tx T0	33	18.2% (n=6)	45.5% (n=15)	21.2% (n=7)
	Post-Tx T1		12.1% (n=4)	27.3% (n=9)	9.1% (n=3)
	Recall T2		18.2% (n=6)	39.4% (n=13)	15.2% (n=5)
Female	Pre-Tx T0	20	20.0% (n=4)	45.0% (n=9)	25.0% (n=5)
	Post-Tx T1		15.0% (n=3)	35.0% (n=7)	10.0% (n=2)
	Recall T2		20.0% (n=4)	50.0% (n=10)	20.0% (n=4)
Male	Pre-Tx T0	13	15.4% (n=2)	46.2% (n=6)	15.4% (n=2)
	Post-Tx T1		7.7% (n=1)	15.4% (n=2)	7.7% (n=1)
	Recall T2		15.4% (n=2)	23.1% (n=3)	7.7% (n=1)

Table 4 Categories of RDC/TMD (27) and DC/TMD (28) and the prevalence of the different diagnoses among the 33 Herbst-MBA patients at the three observation time points: before Tx (T0) to after Tx (T1) and ≥15 years follow-up (T2). *Please note: Patient numbers highlighted in red indicate multiple diagnoses per patient. Prevalence fields shaded in grey correspond to 0%.*

ICD-10	Diagnosis	Subdiagnosis	Prevalence n (%)		
			T0	T1	T2
M79.1	Myalgia	- local myalgia			
		- myofascial pain			
		- myofascial pain with referral (ICD-9 729.1)			
M26.62	Arthralgia	-	1+2 (9%)		1+1 (6%)
G44.89	Headache attributed to TMD	-			
M26.63	Disc displacement	- DDwR* without locking	4 (12%)	2 (6%)	2+1 (9%)
		- DDwR* with intermittent locking			
		- DDnoR** without limited opening	2 (6%)		
		- DDnoR** with limited opening			
M19.91	Degenerative joint disease	-		1 (3%)	
SO3.OXXA	Subluxation	-			
None	Other TMD	- stylalgia (RDC/TMD) / others (DC/TMD)			1 (3%)

* DDwR = Disc displacement with reduction
** DDnoR = Disc displacement without reduction

Figure 1 Flow chart showing the patient selection procedure of the Herbst-MBA sample. In addition, the numbers of participants/non-participants with available TMD data are given.

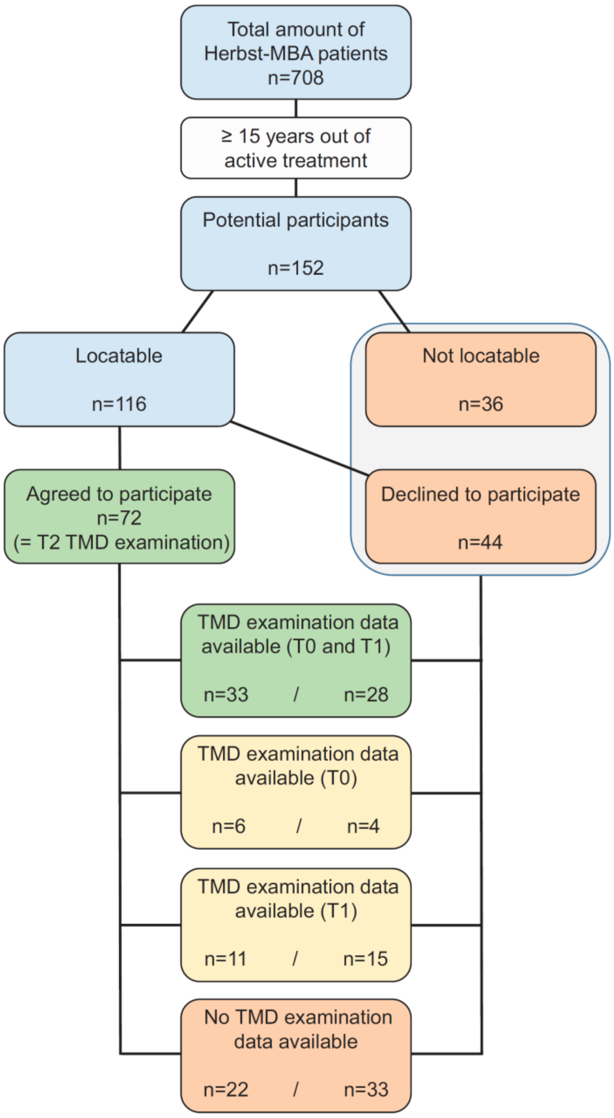


Figure 2 Longitudinal changes of TMD from before Tx (T0) to after Tx (T1) and ≥15 years follow-up (T2) in 33 Herbst-MBA patients. The number (n) and percentage (%) of patients corresponding to the different categories of **(a)** the Helkimo anamnestic dysfunction index (A_i), **(b)** the Helkimo clinical dysfunction index (D_i) as well as **(c)** the RDC/TMD and DC/TMD are given. The number of patients and their direction of change between the observation time-points is given above the arrows. *Please note: None of the changes/differences between the time-points was statistically significant.*

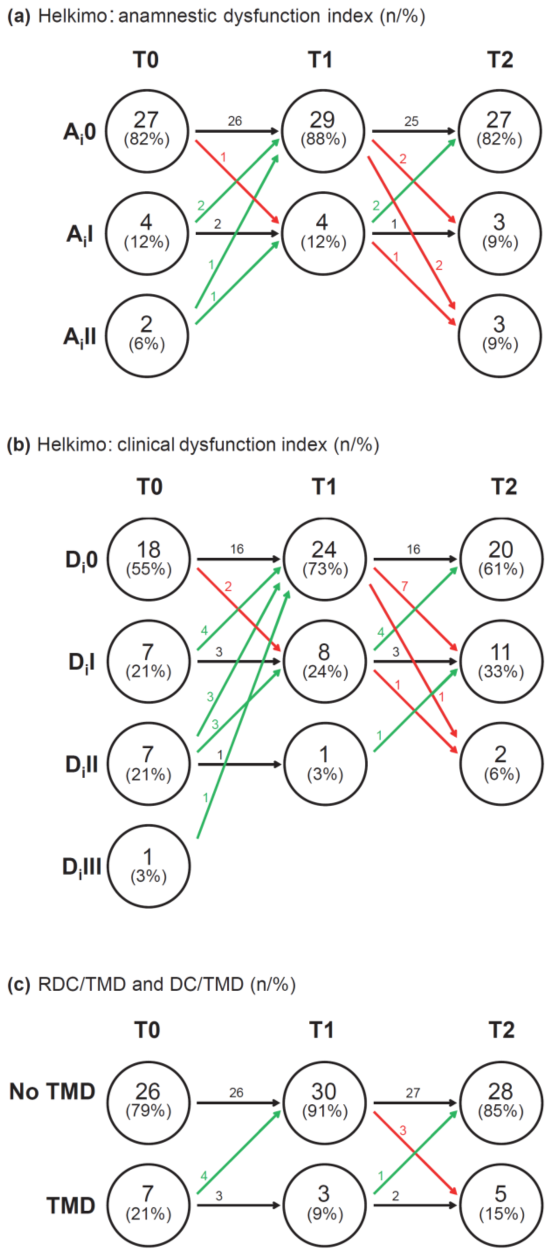
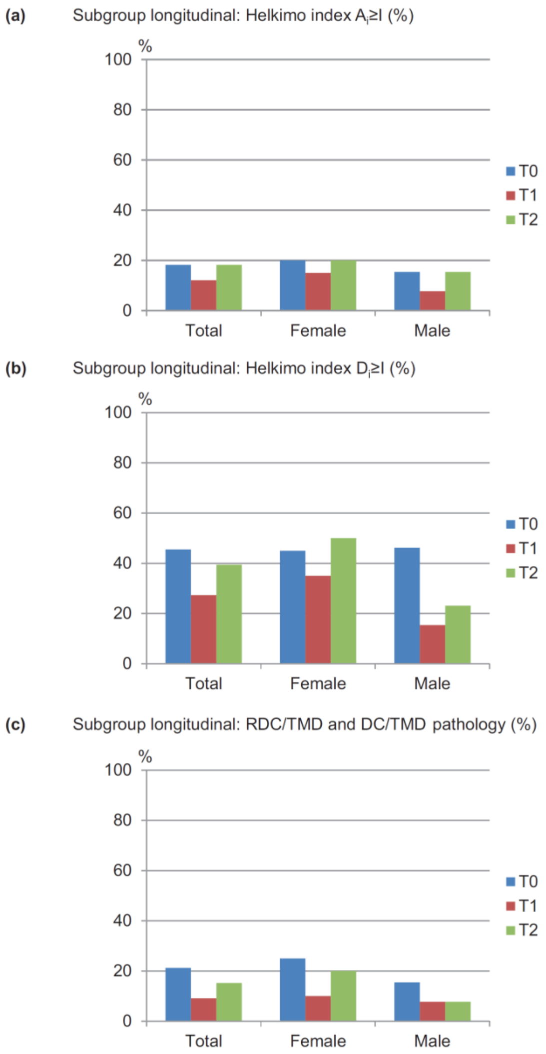


Figure 3 Overall prevalence and prevalence per gender (%) of patients with TMD before Tx (T0), after Tx (T1) and ≥15 years follow-up (T2) in 33 Herbst-MBA patients. The percentages are given for patients with **(a)** a Helkimo anamnestic dysfunction index (A_i) ≥1, **(b)** a Helkimo clinical dysfunction index (D_i) ≥1 and **(c)** a positive RDC/TMD or DC/TMD. *Please note: None of the changes/differences between the time-points was statistically significant.*



4. Discussion & Limitations

The present investigations which systematically assessed an approach for Class II:1 malocclusion treatment in terms of oral health effects, effectiveness and outcome quality both short- and long-term came to the following results:

- The scientific evidence regarding the post-treatment stability of orthodontic fixed functional Class II treatment is inexistent for the vast majority of appliances - with the exception of the Herbst appliance.
- Herbst-Multibracket appliance treatment of Class II:1 malocclusion is an efficient and reliable approach in orthodontic care.
- The outcome of Herbst-Multibracket appliance Class II:1 treatment shows very good long-term (≥ 15 years) stability with similar findings as in untreated Class I controls (without orthodontic treatment need during adolescence).
- Herbst-Multibracket appliance treatment should not be seen as a general risk factor for labial gingival recession development - at least not to a clinically relevant extent.
- Patients with orthodontically treated Class II malocclusions have a similar risk for oral health impairment as untreated Class I controls (without orthodontic treatment need during adolescence) and a lower risk than the general population.
- In the long-term (≥ 15 years) Herbst-Multibracket appliance treatment of Class II:1 malocclusions neither decreases nor increases the risk for temporomandibular disorder development in later life.

While some Class II:1 long-term data after Herbst appliance treatment had been published before, the present investigations are the first to assess the respective effects after Herbst-Multibracket appliance treatment as the now common approach.

The already available data as well as the results from the present investigation show generally good occlusal stability with a favourable long-term outcome for the majority of cases. However, in single patients a partial or even a full relapse develops after mandibular bite jumping. The general mechanism has been shown to be based on both dental and skeletal changes in most cases.

In addition, the present investigations are the first to assess the short- and long-term effects of orthodontic Class II therapy on oral health.

Herbst treatment has been known to result in slightly detrimental periodontal effects in some patients, which was confirmed in the present investigation for a fraction of patients. However, these effects were determined to probably not result in clinically relevant harm long-term - particularly when compared to an orthodontically untreated sample.

Oral health in terms of tooth decay and periodontal health respectively the influence of orthodontic therapy on their condition have been discussed for decades. Particularly during the recent years with respective discussions on costs and benefits, the perspective seems to have changed. Of course, orthodontic treatment should help to establish and maintain excellent oral health; and as the results of the present investigations demonstrate - it might even have the potential to generate some kind of oral health literacy in our patients. These data seem to be of utmost importance in terms of medical care research. Nevertheless, it has to be kept in mind that the generated data were not collected in a prospective setting, but this also applies for respective control values from corresponding population-representative age-cohorts.

Herbst appliance treatment has also been blamed by critics to negatively affect the temporomandibular joint. The present investigation, however, could not detect any negative long-term effects on the temporomandibular joint even if a general fluctuation of symptoms between the different time-points with a trend for improvement during treatment and recurrence thereafter was observed.

However, an effect which has only marginally been looked at in the present investigations is oral health related quality of life. This parameter has caught both the general population's and the research community's attention during recent years. As a consequence, the impacts of malocclusion respectively orthodontic treatment on oral health related quality of life have received attention. While one review article found malocclusion in general to have a significant impact on oral health related quality of life [191,447], separate investigations confirmed this association specifically for children [225] and young adults [87,209]. In addition, a large overjet as typical feature of Class II:1 malocclusions, was determined to have a significant impact on oral health related quality of life in children [130,206], adolescents [130] and adults [130]. On the other hand, one recent trial could not confirm an association between malocclusion and oral health related quality of life in adolescents [110]. Looking at the effects of orthodontic treatment in general on oral health related quality of life, several recent review articles concluded that orthodontic treatment improves oral health related quality of life in children and adolescents [196,230,352,500] as well as adolescents and young adults [17,87,193,294]. No results, however, have been published for orthodontic treatment of Class II:1 malocclusions in particular. The long-term recall of our treated Class II:1 sample revealed predominantly satisfied patients. This satisfaction covered both function and aesthetics. Therefore, the present data confirm orthodontic Class II:1 malocclusion treatment as a tool for oral health related quality of life improvement.

Nevertheless, even if the present investigations revealed favourable data in many aspects, it has to be kept in mind that the outcome of Herbst-Multibracket appliance treatment is not fully successful and stable in all patients. In some cases partial or - seldom - even total relapse occurs. So far, however, neither the predisposition for the development of relapse on the individual level nor the biologic basis for relapse after mandibular bite jumping in general are known with certainty.
According to the literature, attempts have been made to identify genetic characteristics (polymorphisms) contributing to the development of the mandible respectively its size; for example polymorphisms of the following genes have been

determined to be involved: CYP19A1 [166], MYO1H [30] and RANK [228]. However, in contrast to Class III malocclusions, where several studies have already been undertaken (probably due to the generally more complex and often surgery-involving therapy), research in terms of Class II malocclusions is still at the very beginning.

As mentioned before, another category of individual relapse promoting factors after Class II treatment is related to musculature and function. While the influence of these factors has been addressed in several articles [24,107,108,213,316], it has not been feasible to investigate the immediate effects of lip-tongue dysfunctions and other muscular dysbalances so far. However, some promising findings on the effectiveness and reliability of ultrasound for diagnosing respectively monitoring tongue posture in children have been published [286,303,346,347,348,474].

Looking at the biologic basis for relapse after mandibular bite jumping, very little information exists. Variations in post-treatment growth of the condyle and the fossa depending on the duration of mandibular advancement/growth stimulation were seen in rats [85]. While the collagen I (↑) to collagen III (↓) ratio was suspected to be responsible, no further and detailed analysis of the complex mechanisms was performed.

Limitations

The participation rate/number of drop-outs must be considered as a limitation as well as the unavailability of certain previously obtained records in single patients as it is not uncommon in studies including retrospective material. On the other hand, it seems most unrealistic to perform a long-term prospective study with a duration of 15-20 years.

The same is true in terms of an untreated control group. While such a sample (Class I) could be used for part of the investigations, the validity of the results might have profited from an untreated Class II:1 sample. A Class II:1 sample with corresponding data does, however, not exist; and generating such a sample would be unethical.

Due to the unavailability of radiographic follow-up data, the analysis of the long-term recurring/relapsing changes was limited. The clinical assessment with the support of study casts only allowed to judge if recurring/relapsing changes had occurred but not whether the underlying mechanism of these changes were mainly skeletal or dental.

The validity of oral health assessment would also have been enhanced by the availability of radiographic follow-up data. However, for ethical reasons no such records were taken.

5. Conclusion & Prospect

Conclusion

Herbst-Multibracket appliance treatment can be recommended as a standard procedure for Class II:1 therapy. The treatment approach has been shown to be effective as well as reliable and to generate long-term stable outcomes. In addition, positive long-term effects on oral health could be determined.

Prospect

As the present investigations have shown Herbst-Multibracket appliance not to be fully successful and stable in all patients, further investigations should aim at analysing the biologic basis as well as the influence of individual predispositions (genetic and/or functional) on the development of relapse after mandibular bite jumping.

- Therefore, it is planned to experimentally analyse the histologic and moleculogenetic mechanisms of relapse following mandibular bite jumping.

- In addition, the genetic characteristics affecting the development of the mandible and its size should be further investigated.

- To complement, the influence of lip-tongue dysfunctions could be investigated in a prospective long-term study using ultrasound technique.

Finally, as mentioned before, the parameter oral health related quality of life has been considered only marginally in the present investigations - a respective long-term study, planned in a prospective design should be carried out in future.

6. Summary

The present thesis covers the post-treatment and long-term effects of orthodontic Class II:1 Herbst-Multibracket appliance treatment.

First, due to the large variety of derivatives of the original Herbst appliance which are available on the market, a systematic review and meta-analysis on the stability of treatment results after fixed functional appliance treatment of Class II:1 malocclusions was performed. The results of this investigation revealed that for the majority of respective appliances no scientific evidence regarding the post-treatment stability of treatment results exists - with the exception of the Herbst appliance. For Herbst appliance treatment, good dentoskeletal stability without clinically relevant changes for most variables was determined from the available data in the literature. However, the evidence level of most included studies is rather low and the available studies in the literature have limitations in terms of sample size and heterogeneity. In addition, the range of relapse is large for all variables making the amount of relapse after Herbst appliance treatment unpredictable on the individual level.

While the treatment and post-treatment effects of Herbst appliance treatment have been investigated extensively since the late 1970s, the available data can only partly be transferred to a current basic population of Class II:1 patients. In addition, the overall outcome quality has not been addressed more than marginally so far. Therefore, it was the aim to determine representative data on the efficiency and the outcome quality of Herbst-Multibracket appliance treatment by assessing a large cohort of consecutively treated, unselected Class II:1 patients. 526 patients with a mean age of 14.4 years (range 9.8-44.4) at the start were assessed. In 3.4% of these patients treatment was discontinued prematurely, but the treatment data of 508 patients as well as the follow-up (≥ 24 months) data of 240 patients were evaluated. While the overjet decreased by 5.0±2.2 mm during 24.2±7.8 months of treatment, a slight increase of 0.7±1.0 mm occurred during the follow-up period (32.7±15.9 months). For overbite, a decrease of 2.5±2.0 mm and an increase of

0.5±1.1 mm were seen during treatment respectively follow-up. The sagittal molar relationship improved from 0.7±0.4 cusp widths Class II to -0.1±0.3 cusp widths Class III during treatment and settled to 0.0±0.23 cusp widths Class I during follow-up. The mean PAR score decreased by 24.4±9.2 points (treatment) and increased by 0.8±5.3 points (follow-up). Thus, the occlusal variables were normalised during treatment.

As the effects of Herbst appliance treatment on periodontal health have not been investigated more than marginally so far, the representative patient sample of consecutive Class II:1 patients (n=526) which had been treated according to the current treatment approach (Herbst-Multibracket appliance) was to be assessed for the occurrence of labial gingival recessions on all permanent teeth. 460 pre-treatment and 222 follow-up study models were available; a set of both was available for 187 patients (total observation period of 60.0±15.1 months). The distance between the cemento-enamel junction and the deepest point of the gingival margin was measured on all fully erupted teeth (except wisdom teeth) using a manual calliper. 1.1% of all teeth (n=12573) were found to exhibit a labial gingival recession ≥ 0.5 mm before treatment, and 5.3% of all teeth (n=6131) were affected after the follow-up period. The median magnitude was 0.0 mm at both occasions. The lower incisors showed the highest prevalence of 5.1-5.3% pre-treatment respectively 12.5-16.4% at follow-up. Looking at the incidence for labial gingival recession ≥ 0.5 mm during 60.0±15.1 months of treatment and follow-up, an overall value of 4.0% was determined. The highest values of 10.4-11.4% were seen for the lower incisors.

In addition to the so far described treatment and short-term post-treatment effects of Herbst-Multibracket appliance therapy, the long-term effects (≥ 15 years post-treatment) were to be assessed for the present thesis. The available data on long-term stability after Herbst treatment in the literature were generated from a very small patient sample (n=14) which had undergone Herbst treatment without additional Multibracket appliance treatment. In addition, any comparison to a control

group is lacking. Therefore, the long-term (≥ 15 years) occlusal stability and outcome quality of Herbst-Multibracket appliance treatment were to be assessed and compared to untreated controls. Out of 119 potential participants 52 with a mean age of 33.6±3.1 years participated in a recall. The changes which had occurred between the end of active treatment and the current situation were assessed on study models. The control group used for comparison was considered "double negative, normal". These untreated subjects (n=31) were participants of a longitudinal study on growth changes in Finland and exhibited a Class I relationship with no orthodontic treatment need during childhood and adolescence. Both the occlusal variables and the PAR-Index data showed large differences before treatment when comparing the 52 Class II:1 participants and the 31 Class I controls. Immediately after treatment the Class II:1 sample exhibited more ideal values in comparison to the untreated Class I controls. During the long-term follow-up period, slight recurring changes were noted in the Class II:1 sample resulting in rather similar values as in both samples at age 32/33 years.

Long-term data of orthodontically treated patients are generally scarce and especially for oral health no distinct beneficial effect of any orthodontic treatment has been proven so far. So, it was an aim of this thesis to assess the long-term effects of orthodontic Class II treatment on oral health in terms of tooth decay and periodontal health. 72 out of 116 potential participants who had received Herbst-Multibracket appliance therapy which had been ended ≥ 15 years ago participated in a recall. The examination comprised of an anamnesis (including complaints regarding teeth, occlusion and masticatory system's function), a clinical inspection of the oral cavity and taking of impressions as well as photographs. Study models and panoramic radiographs from immediately after treatment were used for comparison. Again, respective data from the before mentioned "double negative, normal" control group (n=31, Class I, no orthodontic treatment need during adolescence) from Finland were applied for comparison. In addition, the German Oral Health studies (DMS I, III, IV and V) were used as epidemiological oral health benchmark data from population-representative cross-sectional studies of different age cohorts. The results

at recall show a higher degree of satisfaction in the treated Class II sample than in the untreated Class I controls. The general dental status exhibited a score of 7.1±4.8 ("Decayed, Missing, Filled Teeth Index" - treated Class II sample) respectively 7.9±3.6 ("Missing, Filled Teeth Index" - untreated Class I controls). The corresponding population-representative age-cohorts showed higher values: +56% (Germany)/+43% (Finland). For periodontal health, the mean "Periodontal Screening Index"/"Community Periodontal Index" maximum scores were 1.6±0.6 (treated Class II sample; 100% with a maximum score 0, 1 or 2) respectively 1.7±0.9 (untreated Class I controls; 91% with a maximum score 0, 1 or 2). According to the available data of the corresponding population-representative age-cohort (Germany), the respective mean value ranges between 1.9 and 2.3 (39% with a maximum score 0, 1 or 2). The extent of gingival recessions (teeth 32-42) measured on study models obtained at recall was 0.1±0.2 (treated Class II sample) and 0.0±0.1 (untreated Class I controls). Comparable benchmark data are lacking.

In terms of the temporomandibular joint, both treatment and short-term post-treatment effects of Herbst-Multibracket appliance therapy were assessed in clinical as well as magnetic resonance imaging studies. While no deleterious effect in terms of temporomandibular disorders could be found and beneficial effects prevailed instead, no long-term data has been generated so far. Therefore, the effects of Class II Herbst-Multibracket appliance treatment on the long-term prevalence and incidence of signs and symptoms of temporomandibular disorder were to be investigated cross-sectionally. The respective data was determined in the before mentioned 72 patients whose Herbst-Multibracket appliance treatment was finished at age 15.4±1.9 years and who participated in a recall at age 33.7±3.0 years. After gathering the anamnesis, a functional examination was performed and the findings were classified using RDC/TMD and DC/TMD as well as the Helkimo-Index. Previous data from before and/or after treatment were available for more than 54% of the participants and were compared to the present findings. Findings for all three assessment time points were available for 33 of the 72 participants. Most patients (82-88%) did not report any anamnestic symptoms (Helkimo-Index A_i) at any time-point. Mild symptoms were described by 9-12% and severe symptoms by 6-9%. Time point dependent, no clinical dysfunctions (Helkimo-Index D_i) were seen in 55-73% of the patients while mild/moderate dysfunctions existed in 21-33%/3-21%. Only one patient (3%) exhibited a severe dysfunction, but only before treatment. The RDC/TMD and DC/TMD classifications revealed similar prevalence data: 21% before treatment, 9% after treatment, 15% at recall. A general fluctuation between the time-points with a trend for improvement during treatment and recurrence thereafter was determined. A more pronounced trend for prevalence decrease during treatment was seen in males while a more pronounced trend for prevalence recurrence after treatment was seen in females.

Therefore, the following conclusions can be drawn:

- The scientific evidence regarding the post-treatment stability of orthodontic fixed functional Class II treatment is inexistent for the vast majority of appliances - with the exception of the Herbst appliance.
- Herbst-Multibracket appliance treatment of Class II:1 malocclusion is an efficient and reliable approach in orthodontic care.
- The outcome of Herbst-Multibracket appliance Class II:1 treatment shows very good long-term (≥ 15 years) stability with similar findings as in untreated Class I controls (without orthodontic treatment need during adolescence).
- Herbst-Multibracket appliance treatment should not be seen as a general risk factor for labial gingival recession development - at least not to a clinically relevant extent.
- Patients with orthodontically treated Class II malocclusions have a similar risk for oral health impairment as untreated Class I controls (without orthodontic treatment need during adolescence) and a lower risk than the general population.
- In the long-term (≥ 15 years) Herbst-Multibracket appliance treatment of Class II:1 malocclusions neither decreases nor increases the risk for temporomandibular disorder development in later life.

7. Zusammenfassung

Die vorliegende Arbeit beschäftigt sich mit den posttherapeutischen Langzeiteffekten der kieferorthopädischen Klasse II:1-Behandlung mittels Herbst-Multibracket-Apparatur.

Aufgrund der großen Anzahl von auf dem Markt erhältlichen Derivaten der originalen Herbst-Apparatur wurde zunächst eine systematische Übersichtsarbeit und Metaanalyse zur Stabilität der Behandlungsergebnisse nach Klasse II:1-Therapie mittels festsitzender funktionskieferorthopädischer Apparaturen durchgeführt. Die Ergebnisse dieser Untersuchung ergaben, dass für die Mehrheit der entsprechenden Apparaturen keine wissenschaftliche Evidenz hinsichtlich der posttherapeutischen Stabilität der Behandlungsergebnisse existiert - mit Ausnahme der Herbst-Apparatur. Für die Therapie mit der Herbst-Apparatur konnte für die meisten Variablen aus den in der Literatur verfügbaren Daten eine gute dentoskelettale Stabilität ohne klinisch relevante Veränderungen abgeleitet werden. Allerdings ist das Evidenzniveau der meisten eingeschlossenen Publikationen eher niedrig, und die in der Literatur verfügbaren Studien weisen Limitationen hinsichtlich der Größe und der Heterogenität der Probandengruppen auf. Außerdem ist das Spektrum der posttherapeutisch aufgetretenen Veränderungen bei allen Variablen relativ groß, wodurch das individuelle Ausmaß eines Rezidivs nach einer Herbst-Behandlung nicht vorhersagbar ist.

Die therapeutischen und post-therapeutischen Effekte der Herbst-Behandlung sind seit den späten 1970er Jahren intensiv untersucht worden; dennoch können die vorhandenen Ergebnisse nur teilweise auf die allgemeine Population von Klasse II:1-Patienten übertragen werden. Außerdem ist die generelle Ergebnisqualität bisher nur marginal untersucht worden. Daher war es das Ziel, repräsentative Daten zur Effizienz und zur Ergebnisqualität der Herbst-Multibracket-Behandlung anhand einer großer Kohorte konsekutiv behandelter, unselektierter Klasse II:1-Patienten zu generieren. 526 Patienten mit einem Durchschnittsalter von 14,4 Jahren (Spanne:

9,8-44,4) zu Behandlungsbeginn wurden untersucht. Bei 3,4% dieser Patienten wurde die Therapie vorzeitig beendet, doch die Behandlungsdaten von 508 Patienten sowie die Nachbeobachtungsdaten (≥ 24 Monate) von 240 Patienten konnten ausgewertet werden. Während sich der Overjet während 24,2±7,8 Monaten Behandlung um 5,0±2,2 mm reduzierte, kam es während der Nachbeobachtung (32,7±15,9 Monate) zu einer geringen Vergrößerung um 0,7±1,0 mm. Der Overbite zeigte eine Reduzierung von 2,5±2,0 mm während der Therapie und eine Zunahme von 0,5±1,1 mm während der Nachbeobachtung. Die sagittale Molarenrelation verbesserte sich während der Behandlung von 0,7±0,4 Prämolarenbreiten Distalokklusion auf -0,1±0,3 Prämolarenbreiten Mesialokklusion und „setzte" sich während der Nachbeobachtung in eine Neutralokklusion (0,0±0,23 Prämolarenbreiten). Der durchschnittliche PAR-Wert reduzierte sich während der Therapie um 24,4±9,2 Punkte und nahm während der Nachbeobachtung um 0,8±5,3 Punkte zu. Es kam also während der Behandlung zu einer Normalisierung im Bereich der okklusalen Variablen.

Die Effekte der Herbst-Behandlung auf die parodontale Gesundheit wurden bisher nur marginal untersucht. Daher sollte ein repräsentatives Patientengut konsekutiver Klasse II:1-Patienten (n=526), welches gemäß des aktuellen Therapiestandards (Herbst-Multibracket-Apparatur) behandelt worden war, hinsichtlich des Auftretens labialer gingivaler Rezessionen an allen bleibenden Zähnen untersucht werden. Studienmodelle von vor der Behandlung konnten von 460 Patienten einbezogen werden, Studienmodelle von nach der Nachbeobachtungsphase von 222 Patienten; Studienmodelle beider Zeitpunkte lagen von 187 Patienten vor (Gesamtbeobachtungsdauer: 60,0±15,1 Monate). Die Distanz zwischen der Schmelz-Zement-Grenze und dem tiefsten Punkt des Gingivalrandes wurde an allen vollständig durchgebrochenen Zähnen (mit Ausnahme der Weisheitszähne) mittels manueller Schieblehre ermittelt. 1,1% aller Zähne (n=12573) zeigten vor Behandlung eine labiale gingivale Rezession ≥ 0,5 mm, 5,3% aller Zähne (n=6131) waren zum Nachuntersuchungszeitpunkt betroffen. Das Ausmaß betrug zu beiden Zeitpunkten im Median 0,0 mm. Die unteren Schneidezähne zeigten die höchste Prävalenz von

5,1-5,3% (vor Behandlung) bzw. 12,5-16,4% (Nachuntersuchung). Es wurde eine Inzidenz von insgesamt 4,0% für labiale gingivale Rezessionen ≥ 0,5 mm während 60,0±15,1 Monaten Behandlung und Nachbeobachtung ermittelt. Die höchsten Werte von 10,4-11,4% wurden an den unteren Schneidezähnen beobachtet.

In Ergänzung zu den bisher beschriebenen therapeutischen und kurzzeitig posttherapeutischen Effekten, sollten im Rahmen der vorliegenden Arbeit auch die Langzeiteffekte (≥ 15 Jahre) nach Herbst-Multibracket-Behandlung untersucht werden. Die existierenden Daten zur Langzeitstabilität nach Herbst-Behandlung in der Literatur wurden anhand eines sehr kleinen Patientenkollektivs (n=14) generiert, welches lediglich eine Behandlung mittels Herbst-Apparatur erhalten hatte, ohne anschließende Multibracket-Behandlung. Außerdem wurde bisher kein Vergleich zu einer Kontrollgruppe vorgenommen. Entsprechend sollten die okklusale Langzeitstabilität (≥ 15 Jahre) und die Ergebnisqualität der Herbst-Multibracket-Behandlung untersucht und mit einer unbehandelten Kontrollgruppe verglichen werden. 52 von 119 potentiellen Teilnehmern mit einem Durchschnittsalter von 33,6±3,1 Jahren partizipierten an einer Nachuntersuchung. Die Veränderungen, welche zwischen dem Ende der aktiven Behandlung und der aktuellen Situation aufgetreten waren, wurden anhand von Studienmodellen untersucht. Die zum Vergleich genutzte Kontrollgruppe wurde als „doppelt negativ, normal" erachtet. Diese unbehandelten Probanden (n=31) waren Teilnehmer einer Longitudinalstudie zu Wachstumsveränderungen in Finnland und wiesen in der Kindheit bzw. Jugend eine Klasse I-Relation ohne kieferorthopädischen Behandlungsbedarf auf. Sowohl die okklusalen Variablen als auch der PAR-Index zeigten vor der Behandlung große Unterschiede zwischen den 52 Klasse II:1-Teilnehmern und den 31 Klasse I-Kontrollen. Unmittelbar nach der Behandlung lagen in der Klasse II:1-Kohorte vorteilhaftere Werte als bei den unbehandelten Klasse I-Kontrollen vor. Während der Nachbeobachtungsphase traten bei den Klasse II:1-Patienten geringfügige rezidivierende Veränderungen auf, welche dazu führten, dass im Alter von 32/33 Jahren in beiden Gruppen ähnliche Werte vorlagen.

Langzeitdaten kieferorthopädisch behandelter Patienten sind generell selten und insbesondere hinsichtlich der allgemeinen Mundgesundheit wurden bisher nicht eindeutig förderliche Effekte irgendeiner kieferorthopädischen Maßnahme nachgewiesen. Daher war es ein Ziel dieser Arbeit, die Langzeiteffekte der kieferorthopädischen Klasse II-Behandlung in Bezug auf die Mundgesundheit (Karies und parodontale Gesundheit) zu untersuchen. 72 von 116 potentiellen Teilnehmern welche eine Herbst-Multibracket-Behandlung erhalten hatten, die vor ≥ 15 Jahren beendet worden sein musste, nahmen an einer entsprechenden Nachuntersuchung teil. Die Untersuchung umfasste eine Anamnese (inklusive Beschwerden zu Zähnen, Okklusion und Funktion des Kausystems), eine klinische Untersuchung der Mundhöhle und die Anfertigung von Abdrücken und Fotos. Studienmodelle und Orthopantomogramme von unmittelbar nach der Behandlung wurden zum Vergleich herangezogen. Außerdem wurden erneut die Daten der bereits zuvor genannten „doppelt negativen, normalen” Kontrollgruppe (n=31, Klasse I, kein kieferorthopädischer Behandlungsbedarf während der Jugend) aus Finnland zum Vergleich verwendet. Des Weiteren wurden die Deutschen Mundgesundheitsstudien (DMS I, III, IV und V) als epidemiologische Referenzwerte verschiedener Alterskohorten aus bevölkerungsrepräsentativen Querschnittsstudien hinzugezogen. Bei der Nachuntersuchung konnte eine höhere Zufriedenheit in der behandelten Klasse II-Kohorte als in der unbehandelten Klasse I-Kontrollgruppe erfasst werden. Der generelle Dentalstatus zeigte einen Wert von 7,1±4,8 („Decayed, Missing, Filled Teeth Index” - behandelte Klasse II-Kohorte) respektive 7,9±3,6 („Missing, Filled Teeth Index” - unbehandelte Klasse I-Kontrollgruppe). Die korrespondierenden bevölkerungsrepräsentativen Alterskohorten zeigten höhere Werte: +56% (Deutschland)/+43% (Finnland). Hinsichtlich der parodontalen Gesundheit lagen die Maximalwerte des „Periodontal Screening Index”/„Community Periodontal Index” im Durchschnitt bei 1,6±0,6 (behandelte Klasse II-Kohorte; 100% mit einem Maximalwert von 0, 1 oder 2) respektive 1,7±0,9 (unbehandelte Klasse I-Kontrollgruppe; 91% mit einem Maximalwert von 0, 1 oder 2). Gemäß der verfügbaren Daten der korrespondierenden bevölkerungsrepräsentativen Alterskohorte (Deutschland), liegt der entsprechende Wert 1,9 bzw. 2,3 (39% mit einem Maximalwert von 0, 1 oder 2). Das anhand von Studienmodellen ermittelte Ausmaß gingivaler Rezessionen (Zähne 32-42) betrug zum Nachuntersuchungszeitpunkt 0,1±0,2 mm (behandelte Klasse II-Kohorte) und 0,0±0,1 mm (unbehandelte Klasse I-Kontrollgruppe). Vergleichbare Referenzwerte sind nicht existent.

In Bezug auf die Funktion/Dysfunktion des Kiefergelenks wurden sowohl die während der Herbst-Multibracket-Behandlung als auch die während eines Kurzzeit-Nachuntersuchungszeitraumes aufgetretenen Effekte in klinischen und magnetresonanztomografischen Studien untersucht. Es existieren diesbezüglich jedoch bisher keinerlei Langzeitdaten. Daher sollten die Effekte der Klasse II Herbst-Multibracket-Behandlung auf die Langzeit-Prävalenz und -Inzidenz von Zeichen und Symptomen temporomandibulärer Dysfunktionen im Querschnitt untersucht werden. Die entsprechenden Daten wurden anhand der bereits zuvor beschriebenen 72 Patienten, deren Herbst-Multibracket-Behandlung im Alter von 15,4±1,9 Jahre beendet worden war, und die im Alter von 33,7±3,0 Jahren an einer Nachuntersuchung teilnahmen, generiert. Nach Erfassung der Anamnese erfolgte eine funktionelle Untersuchung; die Befunde wurden gemäß RDC/TMD und DC/TMD sowie Helkimo-Index klassifiziert. Frühere Daten von vor/nach der Behandlung waren für mehr als 54% der Teilnehmer verfügbar und wurden zum Vergleich mit den aktuellen Befunden herangezogen. Befunde für alle drei Untersuchungszeitpunkte lagen von 33 der 72 Teilnehmer vor. Bei den meisten Patienten (82-88%) lagen anamnestisch zu keinem Untersuchungszeitpunkt Symptome vor (Helkimo-Index A_i). Schwache Symptome wurden von 9-12% und schwerwiegende Symptome von 6-9% beschrieben. In Abhängigkeit vom Untersuchungszeitpunkt wurden keine klinischen Dysfunktionen (Helkimo-Index D_i) bei 55-73% der Patienten und schwache/moderate Dysfunktionen bei 21-33%/3-21% diagnostiziert. Nur ein Patient (3%) zeigte eine schwerwiegende Dysfunktion, doch lediglich vor Behandlung. Die Klassifikationen nach RDC/TMD und DC/TMD ergaben ähnliche Prävalenzwerte: 21% vor Behandlung, 9% nach Behandlung, 15% zum Nachuntersuchungszeitpunkt. Es zeigte sich analog zu anderen Berichten in der Literatur eine Fluktuation der Befunde zwischen den Zeitpunkten mit einem Trend zu einer Verbesserung während der Behandlung und einem Trend zu einem Wiederauftreten danach beobachtet. Bei männlichen Patienten war der Trend zur Verbesserung während der Behandlung deutlicher, bei weiblichen Patienten hingegen war der Trend für das Wiederauftreten nach der Behandlung ausgeprägter.

Entsprechend können die folgenden Schlussfolgerungen formuliert werden:

- Mit Ausnahme der Herbst-Apparatur existiert für die Mehrheit der festsitzenden funktionskieferorthopädischen Apparaturen keine wissenschaftliche Evidenz hinsichtlich der posttherapeutischen Stabilität der Behandlungsergebnisse.
- Die Behandlung von Klasse II:1-Malokklusionen mittels Herbst-Multibracket-Apparatur stellt eine effiziente und zuverlässige Methode in der kieferorthopädischen Versorgung dar.
- Das Ergebnis der Klasse II:1-Behandlung mittels Herbst-Multibracket-Apparatur zeigt eine sehr gute Langzeitstabilität (≥ 15 Jahre) mit ähnlichen Befunden wie bei unbehandelten Klasse I-Kontrollen (ohne kieferorthopädischen Behandlungsbedarf in der Jugend).
- Die Herbst-Multibracket-Behandlung sollte nicht als grundsätzlicher Risikofaktor für das Entstehen von labialen gingivalen Rezessionen betrachtet werden - zumindest nicht in einem klinisch relevanten Ausmaß.
- Patienten mit kieferorthopädisch behandelter Klasse II-Malokklusion haben ein ähnliches Risiko für eine Beeinträchtigung der Mundgesundheit wie unbehandelte Klasse I-Kontrollen (ohne kieferorthopädischen Behandlungsbedarf in der Jugend) und ein geringeres Risiko als die Allgemeinbevölkerung.
- Gemäß Langzeitbeobachtung (≥ 15 Jahre) wird durch die Behandlung von Klasse II:1-Malokklusionen mittels Herbst-Multibracket-Apparatur das Risiko, zu einem späteren Zeitpunkt eine temporomandibuläre Dysfunktion zu entwickeln, weder erhöht noch reduziert.

8. List of figures and tables

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