The efficacy of Hybrid Hyrax-Mentoplate combination in early Class III treatment: a novel approach and pilot study

Vandana Katyal,* Benedict Wilmes,* Manuel Nienkemper,* M. Ali Darendeliler,† Wayne Sampson+ and Dieter Drescher*

Department of Orthodontics, The University of Düsseldorf, Düsseldorf, Germany,* Department of Orthodontics, The University of Sydney, Sydney, Australia† and Discipline of Orthodontics, The University of Adelaide, Adelaide, Australia+

Introduction: The aim of the present study was to assess the skeletal, dental and soft tissue effects of a specific treatment protocol in consecutively treated patients who presented with a Class III malocclusion. Treatment involved the use of a Hybrid Hyrax (HH) in the maxilla, a Mentoplate in the mandible and the application of continuous intra-oral Class III elastics.

Method: The treated group was comprised of seven males and seven females (mean pretreatment age 10.4 ± 1.7 yr, range 7.8 – 12.9 yr). Treatment changes were analysed on lateral cephalograms taken 6–12 months prior to commencing treatment (T1) and at the finish of the orthopaedic phase (T2). Where a normality assumption was met, a parametric paired-sample *t*-test was used to assess the change differences at T1 and T2. For non-normal data, a non-parametric Wilcoxon sign rank test for related samples was used to assess T1 and T2 differences. The level of statistical significance was set at $p < 0.05$ (2-tailed).

Results: The average sagittal changes showed an improved SNA angle of 2.1 ± 2° ($p = 0.002$), an ANB angle of 1.9 ± 1.8° ($p = 0.002$), a Wits improvement of 3.4 ± 2.7 mm ($p < 0.001$) and an overjet reduction of 2.0 ± 2.2 mm ($p = 0.005$). There were no statistically significant correlations found between the age at T1, age at treatment start and age at T2 and the changes identified in the cephalometric variables (T2-T1).

Conclusion: The HH-Mentoplate Class III treatment protocol induced a mean Wits improvement of 3.4 mm in the maxillary and mandibular sagittal base relationship at the functional occlusal level. This was primarily achieved by sagittal maxillary skeletal protraction with negligible effects on the mandible, facial vertical dimension and the incisor angulations. A controlled clinical study with larger sample sizes and longer follow-up times is needed.

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Vandana Katyal: vandykatyal@gmail.com; Benedict Wilmes: wilmes@med.uni-duesseldorf.de; Manuel Nienkemper: nienkemm@web.de; M. Ali Darendeliler: ali.darendeliler@sydney.edu.au; Wayne Sampson: wayne.sampson@adelaide.edu.au; Dieter Drescher: d.drescher@uni-duesseldorf.de

Introduction

A skeletal Class III malocclusion is characterised by either mandibular prognathism, a maxillary deficiency or a combination of the two features.[1] Approximately half of all skeletal Class III malocclusions are reported to result from maxillary retrognathia[2] and hence orthopaedic maxillary protraction is considered a viable treatment option for growing patients with a midface deficiency. However, early correction of maxillary retrognathia and the maintenance of the Class III skeletal correction still remains an orthopaedic challenge.[3,4]

Maxillary advancement in a growing child has been widely described and a protracting force may be applied via an extra-oral facemask or by intra-oral appliances anchored to either dentition,[4,5] ankylosed primary canines[6] or skeletal anchorage systems inserted in the zygomatic, palatal or mental areas.[7-11] To increase

Figure 1. The Hybrid Hyrax (HH) anchored to two mini-implants in the anterior palate and upper molars (Source: University of Düsseldorf, Germany).

skeletal maxillary advancement and to avoid the possible dental side-effect of mesial movement of the dentition resulting in dental crowding,[5] protraction therapy in growing children using skeletal anchorage has recently been advocated.[7-11] However, most studies have employed at least two or more surgical mini-plates or osseo-integrated implants, which involve invasive placement and removal procedures.

Maxillary protraction is often started following a rapid palatal expansion procedure (RPE) because a proportion of Class III cases present with a narrowed maxilla.[12] Mobilisation of the midfacial sutures by RPE may be beneficial and induce a greater maxillary effect.[13] Even though there is controversy regarding the effectiveness of RPE for improved maxillary protraction,[14] its use is recommended in Class III treatment to enhance maxillary advancement.[10,15-17]

Wilmes and colleagues introduced a novel RPE device called a Hybrid Hyrax appliance (HH, Figure 1), which uses two mini-implants in the anterior palate to provide sagittal skeletal anchorage for maxillary protraction during simultaneous palatal expansion.[10,15-18] The mini-implants serve as an anterior skeletal anchorage unit, whilst deciduous or permanent molars are used as posterior dental anchorage (hybrid anchorage). In addition, Wilmes et al. described Class III management utilising a single Mentoplate (Figure 2) in the anterior mandible in combination with the HH.[10] Since the Mentoplate is inserted subapical to the lower incisors, it may be used in patients as young as eight years of age with developing lower canines.

It may be hypothesised that the use of a HH in the upper arch and a Mentoplate in the lower arch transfers an orthopaedic force primarily to the skeletal structures. Therefore, the aim of the present study was to assess the skeletal, dental and soft tissue effects in consecutively treated Class III patients, as a result of a treatment protocol that involved the placement of a Hybrid Hyrax in the maxilla, a Mentoplate in the mandible and the use of continuous intra-oral Class III elastics.

Figure 2. Class III intra-oral elastic forces as applied between the Hybrid Hyrax and Mentoplate arms bilaterally (Source: University of Düsseldorf, Germany).

Methods

The treatment group was comprised of 14 children, including seven males and seven females (mean pretreatment age 10.4 ± 1.7 yr, range 7.8 – 12.9 yr), who were consecutively treated for a skeletal Class III malocclusion (mean pretreatment Wits of -5.1 ± 2.1 mm, range -9.8 to -2.4 mm) requiring maxillary expansion and maxillary protraction. Standardised orthodontic pretreatment history, photographs and radiographs (lateral cephalogram and dental panoramic radiograph) were taken for all subjects at the University clinic, Düsseldorf, Germany.

Although patients were managed by different operators, the same protocol was followed for all of the treated group. At the commencement of treatment, two mini-implants (Benefit system, PSM Medical Solutions, Tuttlingen, Germany) for the HH and four bone screws for the Mentoplate (Promedia Medizintechnik, Siegen, Germany) were inserted under local anaesthesia. The HH device with a hyrax screw was subsequently fabricated in the laboratory and placed a week later. All patients were instructed to commence activating the hyrax screw (0.8 mm/day) until an upper midline diastema appeared. In addition, the application of Class III intra-oral elastics (3.5 oz., $^{3}/_{16}$") was commenced from hooks projecting intra-orally from the Mentoplate to hooks on the buccal arms bilaterally attached to the HH. The maxillary expansion and maxillary protraction occurred simultaneously. After the appearance of an upper midline diastema, the maxillary expansion rate was reduced to 0.4 mm/day. The clinical and surgical protocol for the placement and insertion of the HH-Mentoplate combination has been described previously by Wilmes and colleagues[10] and was followed for all children in the treatment group.

Pretreatment (T1) lateral cephalograms were taken 6–12 months prior to commencement. Post-treatment (T2) lateral cephalograms were taken at the completion of the orthopaedic phase and/or at the removal of the HH-Mentoplate combination. The two lateral cephalometric images for each subject were adjusted for magnification differences and digitised using the Image Collector software (copyrights owner and creator – author DD). Nine skeletal, five dental and two soft tissue variables were measured on each lateral cephalogram, as shown in Figure 3. The digitising and subsequent measurements were performed by one author (VK) and randomly repeated at least a week later on 10 radiographs to determine the error of the method.

Data were analysed using statistical software SPSS (version 22, IBM Corp, NY, USA) and are presented as the mean and the standard deviation (SD) for continuous variables and as frequency or percentages for categorical variables. A normal distribution for all continuous variables was tested using the Shapiro-Wilk's test ($p > 0.05$). Where a normality assumption was met, parametric paired-sample *t*-test was used to assess the difference between the cephalometric measurements between T1 and T2. For non-normal data, a non-parametric Wilcoxon sign rank test for related sample was used to assess the difference between cephalometric measurements at T1 and T2. The level of statistical significance was set at $p < 0.05$ (2-tailed). Pearson's bi-variate correlation test ($p < 0.05$, 2-tailed) was used to assess associations between the patient's age at T1, at treatment commencement and age at T2 and the change in cephalometric variables (T2-T1).

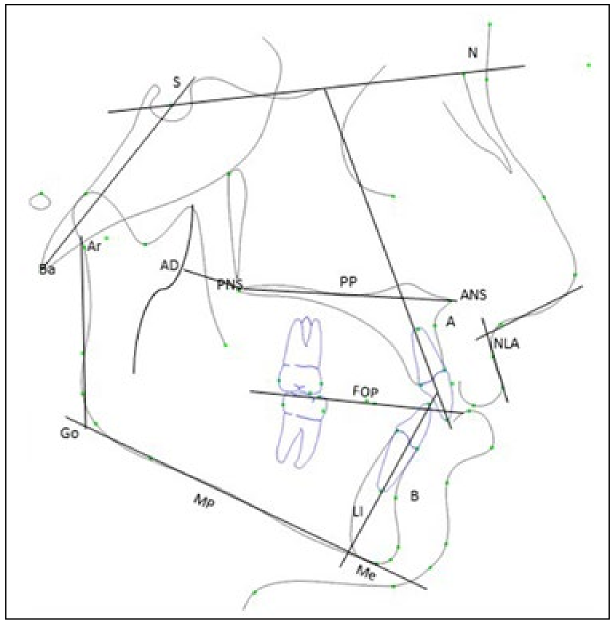

Figure 3. Lateral cephalometric reference landmarks, planes and angles analysed at pretreatment (T1) and post-treatment (T2).

Key: **SNA** (angle **S**ella-**N**asion-**A** point), **SNB** (angle **S**ella-**N**asion-**B** point), **ANB** (difference between angle SNB and SNA), **WITS** (sagittal discrepancy between A-point and B-point as measured on the functional occlusal plane FOP in mm), **NSBa** (cranial base flexure, angle **N**asion-**S**ella-**Ba**sion), **SN-PP** (angle between **S**ella-**N**asion line and the **P**alatal **P**lane), **SN-MP** (angle between **S**ella-**N**asion line and **M**andibular **P**lane), **PP-MP** (angle between **P**alatal **P**lane and **M**andibular **P**lane), **ArGoMe** (gonial angle, angle **Ar**ticulare-**Go**nion-**Me**nton), **UI-PP** (angle between long axis of **U**pper **I**ncisor and palatal plane), **LI-MP** (angle between long axis of **L**ower **I**ncisor to **M**andibular **P**lane), **UI-LI** (angle between long axes of **U**pper **I**ncisor and **L**ower **I**ncisor), **OJ** (overjet in mm), **OB** (overbite in mm), **AD-PNS** (distance most prominent anterior point on **Ad**enoidal mass and **P**osterior **N**asal **S**pine in mm) and **NLA** (nasolabial angle measured between the Nasal tip, Subnasale and the Upper Lip).

Intra-class correlation coefficients (ICC) were calculated to assess the error of the method using a two-way mixed model and absolute agreement type for all angular and linear cephalometric variables.

Results

The majority of the treated group were Caucasian and the average treatment duration was 0.88 ± 0.6 year. All mini-implants and Mentoplates showed high primary stability and remained stable throughout treatment.

The ICC varied from 0.873 to 0.911 for angular cephalometric measurements and from 0.872 to 0.901 for linear measurements. A satisfactory level of intra-observer reliability was established.

Descriptive statistics for the age of all subjects at T1, at treatment start and T2 are presented in Table I. All of the variables were normally distributed at T1 (Shapiro Wilk's test $p > 0.05$) except for ArGoMe ($p = 0.026$), OB ($p = 0.044$) and AD-PNS ($p = 0.005$). The statistical significance of differences between T2 and T1 variables analysed by non-parametric testing are presented in Table II. The average sagittal changes between T1 and T2 showed an improvement in SNA angle by 2.1 ± 2° ($p = 0.002$), ANB angle by 1.9 ± 1.8° ($p = 0.002$), Wits by 3.4 ± 2.7 mm ($p < 0.001$) and overjet by 2.0 ± 2.2 mm ($p = 0.005$). There were no statistically significant correlations found between the age at T1, age at treatment start and age at T2 and the changes identified in the cephalometric variables (T2-T1).

Discussion

Summary of key findings with clinical interpretation

The present study of Class III treatment in growing children managed by skeletal anchorage using a HH-Mentoplate combination provides evidence that the method is effective in maximising skeletal change while minimising unwanted dental effects.

Table I. Descriptive statistics for the treated group at pretreatment (T1) and post-treatment (T2).

Characteristics of treated group N = 14 (7 males, 7 females)	Mean ± SD	Median (50th percentile)	Range
Age at pretreatment (T1) lateral cephalometric radiograph (yr)	10.4 ± 1.7	10.5	7.8 – 12.9
Age at treatment commencement (yr)	11.2 ± 1.5	11.1	9.0 – 13.5
Age at treatment finish and post-treatment (T2) lateral cephalometric radiograph (yr)	12.1 ± 1.6	12.1	9.6 – 15.7

Table II. Statistical significance of differences between post-treatment (T2) and pretreatment (T1) cephalometric variables analysed.

Cephalometric variables (N = 14)	Mean (± SD) at pretreatment (T1)	Mean (± SD) at post-treatment (T2)	Mean (± SD) of the difference T2-T1	95% confidence intervals (lower, upper) of the difference T2-T1	Statistical significance of difference T2-T1 (*p* value)
SNA (°)	78.1 ± 4.0	80.2 ± 3.2	2.1 ± 2.0	0.9, 3.2	$p = 0.002$††
SNB (°)	78.9 ± 3.4	79.1 ± 3.2	0.2 ± 1.6	-0.8, 1.1	$p = 0.670$
ANB (°)	-0.8 ± 2.5	1.1 ± 2.1	1.9 ± 1.8	0.8, 2.9	$p = 0.002$††
WITS (mm)	-5.1 ± 2.1	-1.7 ± 1.6	3.4 ± 2.7	1.8, 4.9	$p < 0.001$††
NSBa (°)	128.8 ± 3.4	129.1 ± 3.2	0.4 ± 1.7	-0.6, 1.4	$p = 0.420$
SN-PP (°)	7.7 ± 3.9	6.9 ± 3.8	-0.8 ± 0.9	-1.4, -0.3	$p = 0.004$††
SN-MP (°)	36.6 ± 5.1	36.7 ± 4.3	0.1 ± 2.2	-1.9, 1.4	$p = 0.853$
PP-MP (°)	28.9 ± 5.1	29.8 ± 4.7	1.0 ± 2.3	-0.4, 2.3	$p = 0.145$
ArGoMe (°)	126.9 ± 6.1	127.3 ± 7.5	0.4 ± 3.8	-1.8, 2.7	$p = 0.681$
UI-PP (°)	112.6 ± 7.5	113.5 ± 6.0	0.9 ± 8.5	-4.0, 5.8	$p = 0.702$
LI-MP (°)	88.3 ± 5.2	88.1 ± 8.0	-0.2 ± 5.9	-3.6, 3.2	$p = 0.893$
UI-LI (°)	130.2 ±9.5	128.6 ± 9.8	-1.6 ± 10.7	-7.8, 4.5	$p = 0.578$
OJ (mm)	-0.7 ± 2.2	1.4 ± 1.4	2.0 ± 2.2	0.7, 3.3	$p = 0.005$††
OB (mm)	0.2 ± 2.2	0.2 ± 1.0	0 ± 2.1	-1.2, 1.2	$p = 0.955$
AD-PNS (mm)	15.2 ± 4.2	16.1 ± 4.4	0.9 ± 3.3	-1.0, 2.8	$p = 0.319$
NLA (°)	119.4 ± 7.2	118.2 ± 7.9	-1.2 ± 4.5	-3.8, 1.4	$p = 0.321$

Key: †† Statistically significant at $p < 0.01$

There was a sagittal improvement of 2° (SNA - 2.1° ± 2°, ANB - 1.9° ± 1.8°). Since this was accompanied by negligible change in sagittal mandibular dentoalveolar base position (B-point) relative to the anterior cranial base, it suggested that the improvement was primarily produced by maxillary protraction at the dentoalveolar base (A-point). At the level of the occlusal plane, there was a mean improvement of 3.4 ± 2.7 mm in the Wits appraisal and 2.0 ± 2.2 mm improvement in overjet as a result of treatment. There no significant changes seen in the upper and lower incisor angulations, which suggested anchorage preservation, the prevention of unwanted mesial movement of the upper dentition and resultant anterior crowding. Hence, it is likely that overjet correction was primarily due to an enhanced maxillary sagittal projection. In the vertical plane, the palatal plane rotated counter-clockwise (upwards and forwards) relative to the cranial base by approximately 0.8° but no other vertical side-effects were seen. A change of 0.8°, although statistically significant, was relatively small and might not be clinically significant. Figure 4 depicts the cephalometric changes produced by the HH-Mentoplate protocol seen between T1 and T2.

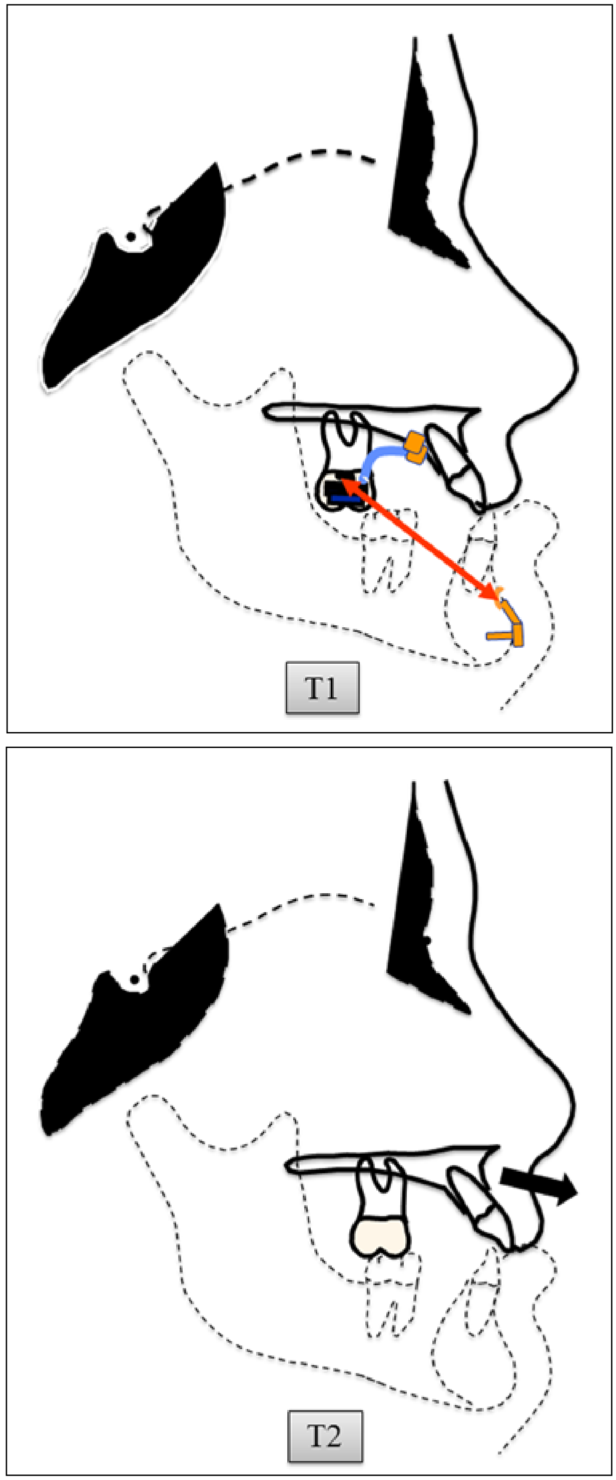

Figure 4. Cephalometric tracings depicting significant changes seen with Hybrid Hyrax-Mentoplate protocol before (T1) and after (T2) treatment.

Comparison to previous work

A meta-analysis published by Jäger et al.[19] described the mean skeletal and dental changes produced in Class III malocclusions treated with conventional maxillary protraction facemask or headgear. The composite effects showed mean improvements of SNA by 1.1° and ANB by 1.7°, which were lower than those reported in the present study.[19] Additionally, maxillary protraction using a conventional facemask can result in unwanted proclination of upper incisors, retroclination of the lower incisors, as well as an increase in the vertical facial dimension.[19] Interestingly, the effects reported in the present study, following the HH-Mentoplate protocol, did not show significant changes in incisor angulation or skeletal vertical dimension. Hence, the HH-Mentoplate protocol could benefit growing Class III patients who present with excessive proclination of the upper incisors, retroclination of the lower incisors and an increased vertical facial dimension.

The HH-facemask combination used by Nienkemper et al.[20] for Class III maxillary protraction improved mean SNA by 2.0°, ANB by 1.9° and Wits by 4.1 mm without increasing the vertical facial dimension or upper incisor angulation, which is similar to the findings of the present study. Although the HH-Mentoplate is slightly more surgically invasive

Figure 5. Pretreatment photographs of a female patient treated with the Hybrid Hyrax-Mentoplate protocol from the present study.

compared with the HH-facemask protocol, it could benefit children who prefer to have an intra-oral elastic force over the bulkiness of the extra-oral facemask.

Reports of maxillary orthopaedic protraction using skeletal anchorage and intra-oral forces are rare in contemporary orthodontic literature. Three-dimensional imaging studies by De Clerck and co-workers have shown that bone-anchored maxillary protraction stimulates forward displacement and modelling of the maxillary and zygomatic bones as well as affecting mandibular shape.[21,22] It was evident that the treated groups in the present study and those of De Clerck et al.[9] were similar in relation to age at commencement and pretreatment Wits value. However, a slightly higher improvement in Wits value of 4 mm was reported by De Clerck et al. at the end of treatment (3.4 ± 2.7 mm). It may be argued that the difference in Wits improvement between the two studies is negligible and could have been due to variations in the sample size, demographics, compliance or the measurements obtained on three-dimensional images compared with two-dimensional imaging. An advantage of the HH-Mentoplate protocol is that only one surgical miniplate is inserted rather than four miniplates in the studies reported by De Clerck et al.[9,10] The Mentoplate may be surgically inserted at younger ages because it does not encroach upon the developing mandibular canines due to its anterior and subapical placement. Additionally, the HH component of the HH-Mentoplate combination provides versatility when rapid palatal expansion is desired and can be performed simultaneously during protraction. Masucci et al.[23] and Wilmes et al.[16] reported increased maxillary advancement when using the Alt-RAMEC protocol (alternating rapid maxillary expansion and constriction) with a facemask

Figure 6. Post-treatment photographs of a female patient treated with the Hybrid Hyrax-Mentoplate protocol from the present study.

in comparison with a conventional RPE-facemask protocol and untreated controls.

Growth studies of untreated Class III malocclusions are rare in the literature and most are historical in nature. However, a relatively recent, semi-longitudinal study with a large Caucasian-based sample size has indicated that, on average, untreated Class III malocclusions worsen with age.[24] Hence, once a Class III growth pattern is established, it rarely self-corrects without dentofacial orthopaedics or orthognathic surgery.

In agreement with previously reported studies,[25,26] the presented protocol failed to find any significant changes in the linear dimension of the nasopharyngeal airway at the adenoidal level. Interestingly, Lee et al.[27] reported an approximate increase of 1.4 mm in the sagittal dimension of the nasopharyngeal airway following maxillary protraction with a facemask. This may have been due to different characteristics of the examined sample compared with the subjects of the present study.

No complications or failures in relation to the HH-Mentoplate appliance protocol were reported for any of the patients, which suggested good compliance and acceptability. Pre- and post-treatment photographs of a patient treated with the HH-Mentoplate from the present study are shown in Figure 5 and 6.

Limitations

A limitation of the present study relates to its retrospective design, although attempts were made to include all consecutively treated cases along with the availability of T1 and T2 radiographs. Although 15 consecutive patients had been treated with the HH-Mentoplate protocol at the university hospital, one patient was excluded due to migration out of the area and unavailability of the T2 radiograph.

Additional limitations include the small sample size, relatively short longitudinal follow-up and reliance on lateral cephalograms for treatment efficacy. Most cephalometric measurements have inherent problems with landmark identification, measurement errors and the representation of three-dimensional anatomical patterns by two-dimensional analyses.[28] Nevertheless, the lateral cephalogram is a valid radiograph for orthodontic screening and diagnosis with a lower radiation dose in comparison with computed tomography.[29] To overcome some of the errors that are inherent when analysing a lateral cephalogram, only one author (VK) digitised all radiographs in a standardised manner and the error of the method indicated that intra-examiner reliability was acceptable.

Future research directions

Future research aims to focus on increasing the current sample size and to compare treatment efficacy of the HH-Mentoplate Class III protocol with that of a conventional Class III treatment and matched untreated controls. Additionally, an extended follow-up is desired due to challenges reported with long-term maintenance of the results and re-establishment of an initial unfavourable growth pattern.[4,30] It may also be beneficial to acquire three-dimensional study models or intra-oral scans for the assessment of changes after the RPE phase of the HH-Mentoplate protocol. Future studies should also report on patient compliance, pain perception and complications.

Masucci et al.,[23] utilising a conventional RPE device, facemask and the Alt-RAMEC protocol in the early treatment of Class III malocclusion, reported enhanced sagittal maxillary protraction when compared with a conventional protocol. It may be hypothesised that the HH-Mentoplate with an Alt-RAMEC protocol could provide even greater efficacy and efficiency in the early treatment of a Class III malocclusion.[24] However, a controlled clinical study with a larger sample size is required to test the study hypothesis.

Conclusion

The HH-Mentoplate Class III treatment protocol produced a mean Wits improvement of 3.4 mm in the sagittal base discrepancy between maxilla and mandible at the functional occlusal level. This was primarily achieved by sagittal maxillary skeletal protraction with negligible effects on the mandible, facial vertical dimension and the incisor angulations. A controlled clinical study with a larger sample size and longer follow-up times is needed.

Corresponding author

Dr Vandana Katyal or Professor Dieter Drescher
Department of Orthodontics
The University of Düsseldorf
Moorenstrasse 5, 40225
Düsseldorf
Germany

Email: vandykatyal@gmail.com /
d.drescher@uni-duesseldorf.de

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