Dentoskeletal Effects of Modern Hybrid Fixed Functional Appliances

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Abstract

AIM: This study performs an in-depth analysis of the literature to evaluate the dentoalveolar and skeletal effects of modern hybrid fixed functional appliances (HFFAs).
METHODS: An extensive literature search spanning from January 2010 to November 2023 was executed across three databases: PubMed, Cochrane Library, and Google Scholar. Additionally, a manual search was done by employing the names of relevant authors and screening the references within the included articles. The assessment for eligibility was based on the PICO approach: (P)articipants: Any patients exhibiting Class II division 1 malocclusion up to the age of 18; (I)ntervention: Treatment with HFFAs; (C)omparison: Untreated individuals; (O)utcome measures: (a) Amount of overjet reduction; (b) Changes in upper and lower incisor proclination/protrusion; (c) Skeletal maxillary/mandibular alterations (ANB, SNA, SNB values); (d) Mandibular growth (changes in mandibular length); and (e) Treatment duration.
RESULTS: Nine clinical trials were included in this study, representing a total of 584 adolescents with Class II division 1 malocclusion. Cephalometric measurements indicate pronounced dentoalveolar effects, including lower incisor proclination and upper incisor retroclination, to correct overjet and overbite. Skeletal effects, such as modest maxillary restriction and improvement in the maxillary-mandibular anteroposterior relationship, were less prominent.
CONCLUSION: Although successful at Class II dental malocclusion correction, HFFAs induce unwanted side effects such as significant lower incisor proclination and clockwise rotation of the occlusal plane. Further research, particularly focusing on HFFAs coupled with skeletal anchorage, is necessary.

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1 Introduction

Angle Class II division 1 malocclusion is a relatively common presenting complaint of patients seeking orthodontic treatment. Previous studies have indicated that this condition affects 40% of the population and has a complex etiology (Bilgic et al., 2015). Its distinct clinical features include mandibular retrognathism, resulting in disharmony of the maxillary-mandibular relationship, and prominent maxillary incisors with an associated enlarged overjet. Orthodontic treatment with functional (orthopedic) appliances aims to achieve both reduced maxillary incisor proclination and protrusion, and mandibular advancement. It is a clinically viable and proven option for adolescent patients, where improvement of facial aesthetics is a key factor in treatment satisfaction for the patient (van Wezel et al., 2015).

Functional appliances are classified as either removable or fixed. The advantage of Fixed Functional Appliances (FFAs) is the non-compliance factor. Recent innovations have led to FFAs being further classified by the force systems they use to position the mandible forward (Ritto and Ferreira, 2000). These sub-categories are rigid, flexible, and hybrid. The rigid type (e.g., Herbst appliance) produces large, consistent forces to the mandible but causes a restriction of mandibular range of motion. The flexible types (e.g., Jasper Jumper) permit greater mandibular movement but have an increased frequency of appliance breakages (Ritto and Ferreira, 2000).

Hybrid Fixed Functional Appliances (HFFAs) are a modern breed of appliances that claim to utilize the respective advantages of the rigid and flexible types while simultaneously nullifying their disadvantages (Moro et al., 2018). This has made them a more popular FFA choice in recent years, especially since recent literature has found one-phase orthodontic treatment in the permanent dentition to be more efficient than two-phase orthodontic treatment, as similar results are achieved in a shorter time (Cancado et al., 2008; Dolce et al., 2007).

The Twin Force Bite Corrector (TFBC), distributed by Henry Schein Inc. (Melville, NY, USA) consists of two telescopic tubes applied bilaterally. The nickel-titanium coil springs push the mandible forward. The dual-cylinder force system produces an average 210-gram force and does not require reactivation (Rothenberg et al., 2004). The appliance attaches to the arches by ball-and-socket joint fasteners, allowing free lateral mandibular movement. It is available in two sizes: small or standard. At full compression, the TFBC delivers the force that carries the mandible into an anterior edge-to-edge occlusion. The universal orientation design eliminates confusion over which TFBC is for the left or right side. The square screw attachment is reportedly superior to other HFF appliances' hex screw attachment, which are prone to stripping or loosening. The TFBC has no exposed springs or coils, reducing patient cheek mucosal irritation (Chhibber et al., 2013).

Figure 1. Twin Force Bite Corrector appliance. Image source (CC BY-NC-SA): Abo-Elmahasen et al. (2024).

Sabbagh Universal Spring (SUS), distributed by Dentaurum (Ispringen, Germany), is a modern HFFA introduced to the market in 1997. There have been two modification release since Sabbagh Universal Spring 2 and 3. It shares some similarities to the rigid Herbst appliance. However, it has a different mode of activation with a telescopic rod fitted into a guide tube (Figure 2). There is also an adjustable coil spring within the tube to titrate the force levels for treatment of different severity of Class II malocclusions. The SUS now utilizes at eyelet for maxillary molar buccal tube attachment and a screw joint attachment at lower wire (Figure 2). A second coil spring inserted in combination with the internal spring permits a greater active extension of force than other functional appliances. The SUS is claimed to give predictable results, shorten treatment duration, and enable use of residual growth even beyond the pubertal growth spurt (Hanandeh and El-Bialy, 2010). It differs from the Forsus appliance (3M, Saint Paul, Minnesota, USA) by having the same left-side and right-side springs making it truly universal. It is applied after levelling and alignment with fixed multibracket appliances, unlike the Herbst appliance which is used before.

Figure 2. Sabbagh Universal Spring. Image source (CC BY-NC-SA): (Oztoprak et al. (2012).

The Powerscope (American Orthodontics, Sheboygan, WI, USA), was developed by Dr Andy Hayes. It exerts a constant 260 gram force via its fixed one-piece design when fully activated – see figure. One vital differentiating feature of the Powerscope 2 is its ability to connect directly to the maxillary and mandibular arch wires which eliminates the need for special molar band configurations - which are a requirement for other HFF applications. A magnetic sleeved driver is also supplied to aid the clinician with positioning and attaching the appliance to the archwires intra-orally.

Figure 3. Powerscope appliance. Image source (CC BY-NC-SA): Paulose et al. (2016).

Finally, the Advansync appliance (Ormco, Glendora, California, USA) is a more rigid style HFFA. It is a tooth-born functional appliance consisting of crowns cemented on maxillary and mandibular permanent first molars. It has significant advantage over other HFFAs in that it can be applied prior to the alignment of the arches and placement of heavy stainless steel wires. Hence arch alignment can commence simultaneously with orthopaedic growth modification. The telescoping mechanism helps the mandible adopt a forward posture upon closure.

The aim of this study is to analyze the current literature evidence on the dentoalveolar and skeletal effects of current HFFAs by summarizing the results of lateral cephalometric radiograph analyses. The goal is to provide clinically relevant information concerning orthodontic appliance treatment planning for Class II division 1 malocclusion.

Figure 4. Advansync appliance. Image source (CC BY 4.0): Hemanth et al. (2023).

2 Methods

A comprehensive literature search spanning from January 2010 to November 2023 was conducted across three databases: PubMed, Cochrane Library, and Google Scholar. In addition, a manual search was executed by employing the names of relevant authors and screening the references within the included articles.

The search focused on various terms associated with orthodontic devices and methodologies, yielding specific results as follows: "twin force bite corrector" led to 14 results, "SUS" combined with "class ii" resulted in 20 hits, and "sabbagh universal" fetched 5 entries. Broader searches for "Sabbagh" and "Advansync" produced 26 and 7 results respectively. The phrase "fixed functional" coupled with "class ii" and "control" generated 31 results. Notably larger result counts were observed for individual terms, with "control" returning 3,165,511 entries, "class ii" yielding 62,723, and "fixed functional" amounting to 219 results.

The assessment for eligibility was based on the PICO approach: (P)articipants: Any patients exhibiting Class II division 1 malocclusion up to the age of 18; (I)ntervention: Treatment with HFFAs; (C)omparison: Untreated individuals; (O)utcome measures: (a) Amount of overjet reduction; (b) Changes in upper and lower incisor proclination/protrusion; (c) Skeletal maxillary/mandibular alterations (ANB, SNA, SNB values); (d) Mandibular growth (changes in mandibular length); and (e) Treatment Duration.

Using all the data from the included studies, two groups were formed, an intervention group and a control group. The following devices were used in the intervention group: Advansync, MARA, FRD, SUS, TFBC, Jasper Jumper and Powerscope. The control group consisted of untreated patients who were treated at a later date after the initial medical record had been prepared.

Preoperative and postoperative assessments for all subjects included the utilization of lateral cephalometric radiography. The analyses performed were heterogenous, however the extracted cephalometric parameters are presented in **Table 1**.

2.1 Statistics

Descriptive statistics and content analysis were used to systematically analyze the included studies. The extracted mean values and standard deviations from the individual studies were calculated as follows to produce a group-specific overall mean value with standard deviation. The overall mean ($\bar{x}$) is the weighted average of the individual means, where N_i is the number of data points in each set:

$$\bar{x} = \frac{\sum_{i=1}^{n} N_i \cdot \bar{x}_i}{\sum_{i=1}^{n} N_i}$$

The overall standard deviation (s) requires combining the variances of the individual data sets along with their means:

Table 1. Definition of extracted cephalometric values to describe dental and skeletal changes.

Variable	unit	Definition
Overjet	mm	Horizontal distance from the incisal edge of the most protruded lower incisor (LoInc) to the incisal edge of the most protruded upper incisor (UpInc).
Overbite	mm	Vertical distance from the incisal edge of the most protruded lower incisor to the incisal edge of the most protruded upper incisor.
UpIncInc	°	The angle formed by the long axis of the UpInc and the line drawn from point A to point Nasion (NA plane).
UpIncH	mm	The horizontal distance from UpInc edge to the NA plane.
LoIncInc	°	The angle formed by the long axis of the LoInc and the line drawn from point B to point Nasion (NB plane)
LoIncH	mm	The horizontal distance from LoInc edge to the NB plane.
SNA	°	The angle formed by the intersection of Sella, Nasion, and point A, assessing the relationship between the maxilla and the cranial base.
SNB	°	The angle formed between the Sella-Nasion line and the line extending from Nasion to the anterior shape of the mandibular symphysis (B point).
Co-Gn	mm	The distance from Condylion to Gnathion.
ANB	°	The angle formed by the intersection of the line drawn from point A to point Nasion, and the line drawn from point N to point B.
WITS	mm	The distance between a perpendicular line from point A to the occlusal plane, and another perpendicular line from the B-point to the same occlusal plane.

$$s^2 = \frac{\sum_{i=1}^{n}(N_i - 1) \cdot s_i^2 + \sum_{i=1}^{n} N_i \cdot (\bar{x}_i - \bar{x})^2}{\sum_{i=1}^{n} N_i}$$

Where: N_i is the number of data points in the i-th data set. $\bar{x}_i$ is the mean of the i-th data set. s_i is the standard deviation of the i-th data set. $\bar{x}$ is the overall mean. s is the overall standard deviation. The square root of s^2 equals the overall standard deviation s.

To determine if there were differences in the dental and skeletal cephalometric values between the intervention and the control group a Mann-Whitney-U-Test was calculated.

3 Results

Nine articles in total were used for this data synthesis. Three investigations were undertaken in Turkey, with two studies conducted in USA, one each in India, Canada, Egypt, and Brazil. All studies were published within the timeframe spanning 2012 to 2023. All included studies were retrospective controlled clinical trials with the exception of Guimaraes et al. (2012) which was a prospective controlled clinical trial.

A total of 584 adolescents presenting with Class II division 1 malocclusion (retrognathic mandible and associated overjet greater than 5mm) were included in this analysis. Three hundred and nine patients underwent treatment with hybrid fixed functional appliances, while the remaining 275 served as an untreated control group. The baseline characteristics are presented in **Table 2**. There is no significant difference between HFFA patients and controls concerning gender, age or observation time. According to Abbassi (1998), the age of the patient and control group at maximum height velocity is in the normal range of 11.5 years and 13.5 years.

Table 2. Baseline characteristics of the HFFA and the control group. Time denotes the treatment time in the HFFA group and the observation time in the control group.

	HFFA (n = 309)	control (n = 275)	p-value
females[1]	153	143	0.383
males[1]	156	132	0.419
age[2] (years)	12.75 ± 1.39	12.75 ± 1.20	0.960
time[2] (months)	11.19 ± 5.64	15.49 ± 4.81	0.406

[1] Chi-square
[2] Mann-Whitney-U

The HFFAs have a significant effect on dentoalveolar parameters. All HFFAs achieved correction of class II malocclusion by significant overjet and overbite reduction compared to matched untreated control groups. The respective reductions were related to a combination of maxillary and mandibular incisor changes (**Table 3**).

Table 3. Dentoalveolar effects.

	HFFA (n = 309)	control (n = 275)	p-value
overjet (mm)	-3.98 ± 2.16	-0.24 ± 0.89	0.001
overbite (mm)	-2.16 ± 1.75	-0.05 ± 1.19	0.001
UpIncInc (°)	-2.47 ± 6.72	0.01 ± 2.49	0.004
UpIncH (mm)	-0,21 ± 4.02	0.09 ± 0.98	0.630
LoIncInc (°)	5.43 ± 5.04	0.28 ± 2.72	0.001
LoIncH (mm)	2.04 ± 1.63	0.12 ± 0.86	0.001

As illustrated in **Figure 5**, the overbite in the HFFA group was corrected through a combination of horizontal anterior tooth movement. The horizontal values in the control group remained relatively constant during the observation period and represent the incisor relations during the growth phase. The values of the HFFA group are therefore exclusively attributable to the intervention. The horizontal values differ significantly, except for UpIncH (**Table 3**). This means that the overbite correction was essentially achieved by the lower anterior teeth.

Figure 6 confirms that the HFFAs have a disproportionate effect on the lower anterior teeth. The values for the lower anterior proclination are significantly greater than for the retroclination of the upper anterior teeth. The stable relation of upper and lower incisor inclination in the control group also confirms normal development during growth. The inclination change in the HFFA group is solely the effect of the appliances. With regard to the overbite, it can also be assumed that the greater proclination of the lower anterior teeth contributed significantly more to the correction of the deep bite than the retroclination of the upper anterior teeth.

The question now arises as to whether the HFFAs also have an effect on mandibular growth. Due to the Class II mechanics of the HFFAs, a forward displacement of the mandible can also be assumed, as with removeable functional appliances. An influence on growth can therefore not be ruled out. In order to measure this possible influence, the growth must also be set in relation to the skull and the maxilla. The studies included here therefore took the growth-stable Sella-Nasion plane into account in their measurements.

The skeletal parameters SNA, SNB and ANB differ significantly between the HFFA and the control group (**Table 4**). As can be seen in **Figure 6**, SNA and SNB of the control

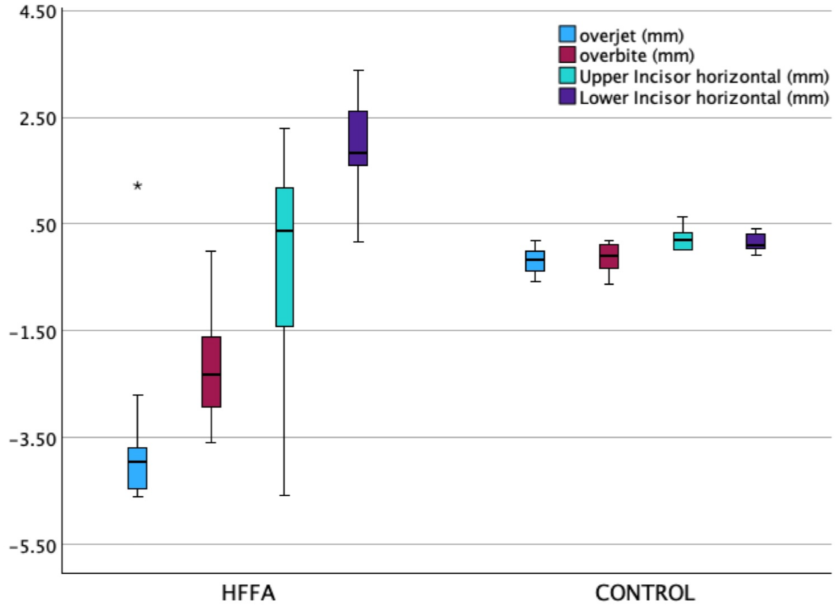

Figure 5. Dentoalveolar measurements of the HFFA and control group. Significant overjet and overbite changes were achieved in the treatment phase of 11.1 ± 5.5 month. The values of the control group remain stable during the observation period of 15.5 ± 4.8 month.

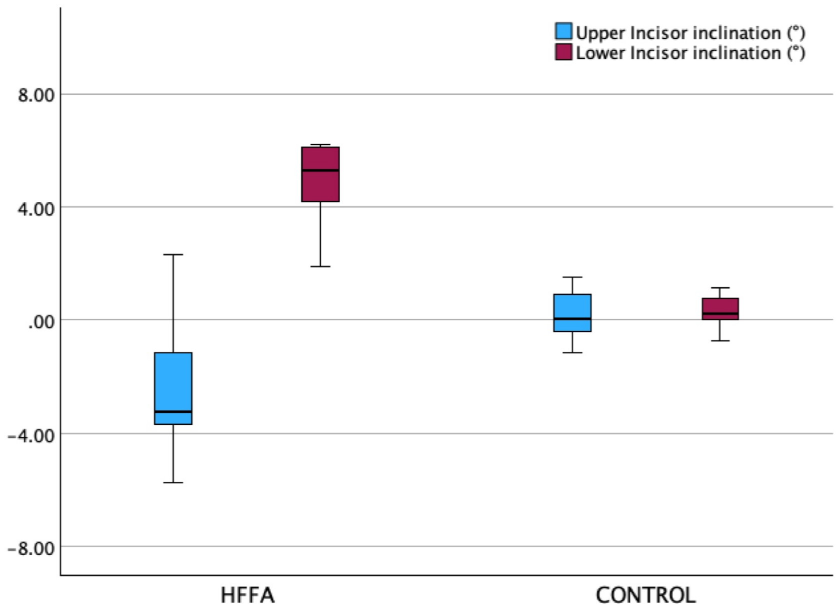

Figure 6. Incisor inclination change in the HFFA and control group.

group increase in anterior direction, whereby the value ANB is around zero, which indicates a uniform growth displacement of the maxilla and mandible. The values in the HFFA group deviate significantly from this pattern. The negative ANB and WITS values indicate a Class III relationship, where the mandible is positioned forward relative to the maxilla. This can be due to a backward position of the maxilla or a forward position of the mandible. Compared to the control group, the maxilla in the HFFA group is positioned posteriorly relative to the growth direction, while the mandible is positioned anteriorly, contributing to normal anterior growth. This pattern is typical for Class II mechanics.

Table 4. Skeletal effects.

	HFFA (n = 309)	control (n = 275)	p-value
SNA (°)	-0.54 ± 1.49	0.37 ± 1.42	0.001
SNB (°)	0.99 ± 1.42	0.43 ± 1.05	0.005
Co-Gn (mm)	3.10 ± 2.24	2.37 ± 1.46	0.418
ANB (°)	-1.58 ± 0.87	-0.15 ± 0.90	0.001
WITS (mm)	-3.18 ± 2.80	0.67 ± 1.88	0.001

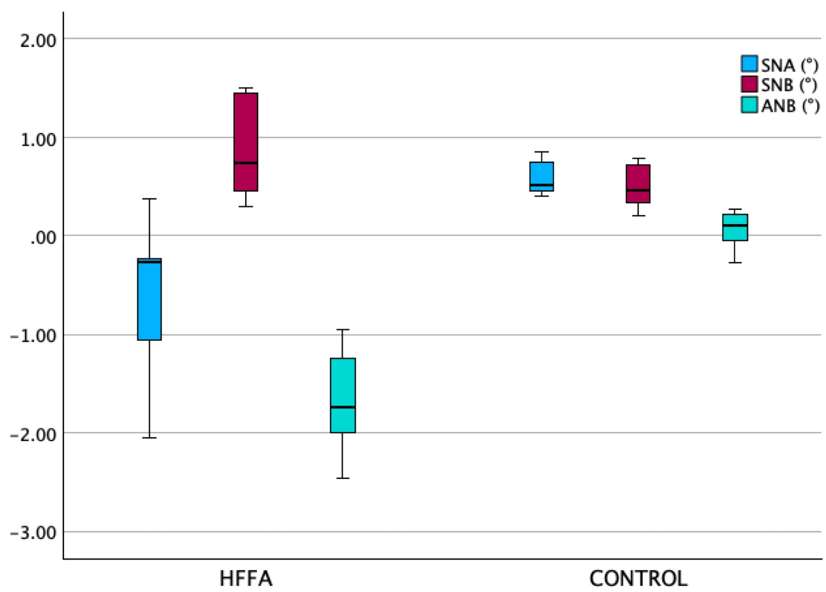

Figure 7. Skeletal parameters measured in the HFFA and control group.

Measurements based on the cephalometric points A and B do not represent the pure skeletal effects due to their position on the alveolar process, but are influenced by dentoalveolar effects. In contrast, the Co-Gn distance provides information on the change in size of the entire mandible, including the base, ramus ascendence and condylar region. Despite small differences in the mean value, the Co-Gn distance does not differ between the HFFA and control group (**Table 4**), i.e. the HFF appliances have no influence on the normal growth pattern of the mandible.

The average treatment time with each HFFA is listed in **Table 5**. There was significant heterogeneity in each study design and intervention protocol, making it impossible have direct comparisons for treatment efficiency.

4 Discussion

HFFAs are a combination of flexible and rigid fixed functional appliances. They position the mandible forwards via a telescopic mechanism with spring components. They are reported to produce skeletal and dentoalveolar effects similar to Class II intermaxillary elastics (Ritto & Ferreira, 2000). Recent literature suggests that treatment with flexible or hybrid appliances produces greater tooth movement than rigid appliances (Ishaq et al., 2016). However, rigid FFAs produce greater skeletal effects compared to hybrid and flexible FFAs (Moro et al., 2018).

This review article aimed to summarise the evidence of dentoskeletal effects of modern hybrid fixed functional appliances (HFFAs) in the treatment of Class II malocclusion patients by cephalometric analysis. All nine included studies were observational controlled trials. The average age of the included patient cohorts indicated that the interventions were performed on individuals in their peak growth phase.

According to our analysis, the prevailing trend was that HFFAs correct Class II malocclusion by predominantly dentoalveolar changes with only mild skeletal changes evident, which agrees with a recent systematic review on other fixed functional appliances (Zymperdikas et al., 2016).

HFFAs produce similar lower incisor effects as Class II intermaxillary elastics, including the unwanted proclination of lower incisors (Aras and Pasaoglu, 2016). However, the retraction of upper incisors is less significant in HFFAs compared to Class II elastics and flexible FFAs, which could be related to the greater skeletal changes achieved by HFFAs. (Jayanchadran et al. 2016) These findings match those of a recent systematic review by Thiasos et al. (2022). HFFAs appear to have greater upper incisor control and overjet correction than class II elastics due to the disclusion effect of the appliance. This may suggest that they are better at correcting a more severe class II dental relationship.

The lower incisor changes could be attributed to the anterior direction of pushing force exerted by the HFFA spring mechanism. Patients with thin tissue biotype should be assessed for the severity of lower incisor crowding and the risk of periodontal attachment loss from HFFA-induced proclination of lower incisors. (Amid et al. 2020) Caution is also advised for HFFA treatment in patients with a high smile line as upper incisor retroclination may increase the appearance of an undesirable gummy smile.

Interestingly, HFFAs produced more upper incisor retroclination compared to rigid FFAs. (Al-Jewair et al. 2012) This may be explained by the greater mandibular length increase achieved by rigid FFAs. The HFFAs do not produce significant upper incisor torque control as evidenced by the non significant horizontal position change of the upper incisor. This would indicate they are better suited for large overjet correction with proclined upper incisors.

The incisal changes induced by HFFAs also resulted in another undesirable effect – the clockwise rotation of the occlusal plane. These results are similar to other fixed functional

Table 5. Appliance duration time.

HFFA Type	N	average appliance time (months)
TFBC	53	3.36
SUS	45	5.87
Advansync	101	13.76
Powerscope	30	21.8

appliances (Linjawi et al., 2018; Zymperdikas et al., 2016; Bilgic et al., 2011; Bozkurt et al., 2020; Khan et al., 2021).

There was a small but statistically significant contribution by HFFAs to the improvement of skeletal Class II relationships (as seen by the average annualised decrease of the ANB angle of the treated patients in comparison to untreated controls). However, there was no significant effect by HFFA on the growth pattern of the mandible, hence the skeletal changes may be due more to a maxillary restriction effect.

4.1 Critical appraisal of the results in the context of other evidence

Skeletal correction in the sagittal plane by HFFAs can be considered clinically small, in agreement with other reviews on fixed functional appliances (Zymperdikas et al., 2016). A recent randomised controlled trial by Kochar et al. (2023) found that upper premolar extractions produced more desirable dentoskeletal and soft tissue changes than FFA therapy for skeletal Class II malocclusions.

Skeletal maxillary changes were determined by the SNA angle; however, the A point is a dentoalveolar cephalometric landmark rather than a true skeletal point. Hence, the observed maxillary restraint may not necessarily indicate skeletal modification. It is also proposed that the upper incisor retroclination impacts on the position of the A point (Jena et al., 2006).

The inability of HFFAs to effectively change mandibular position and growth may not be significant as another study on fixed functional appliances found these effects to not have a long-term impact (Ishaq et al., 2016). Functional appliances have been reported to position the mandible more anteriorly and stimulate growth in mandible length (Covell et al., 1999; Kucukkeles et al., 2007). However, recent systematic reviews dispute the magnitude and clinical relevance of these effects (Cozza et al., 2006; Flores-Mir et al., 2007).

The heterogeneity of the included studies prevented an analysis of treatment duration with each appliance. HFFAs are fixed devices that remove the requirement for patient compliance and are integrated into the fixed multi-bracket appliance treatment phase. Previous systematic reviews have identified poor intermaxillary elastic use and/or compliance as a significant factor in prolonging treatment duration (Skidmore et al., 2006). This could indicate that treatment protocols including HFFAs would have a shorter treatment duration compared to those with inter-maxillary elastics for Class II correction. However when using any type of FFA, additional chairside time, emergency appointments for breakages and laboratory support must be considered. (Moro et al., 2018)

The TFBC's reported appliance phase treatment duration (average 3.4 months) was exceptionally rapid compared to other functional appliances. (O'Brien et al., 2003) Long term follow-up investigation is needed to determine the stability of such rapid correction.

Manufacturer instructions for HFFAs advise that they are to be used in conjunction with lower incisor brackets with negative torque values, lingual crown torque at the lower anterior segment, and full lower arch ligation. (Oztoprak et al., 2012; Franchi et al., 2013) These measures prevent anchorage loss at the lower anterior segment and subsequent lower incisor over-proclination.

The utilisation of skeletal anchorage mini-plates at the mandibular symphysis in conjunction with the Forsus appliance has reportedly induced significant skeletal effects including mandibular forward movement and maxillary restriction (Unal et al., 2015). Future studies are needed to analyse the combination of other HFFAs with skeletal anchorage mini-plates at the mandible. The current trend shows that undesirable dentoalveolar effects such as proclination of lower incisors can be reduced (Arvind & Jain, 2021).

A recent systematic review on the long-term effects of functional appliances (Cacciatore et al., 2019) suggested there are long-term skeletal effects induced by FFAs. The follow-up period was 3-5 years after completion of comprehensive orthodontic treatment. The greatest maxillary restriction effect was induced by the Herbst and Forsus appliances. This suggests that the small skeletal changes of HFFAs may have long-term significance. However, Bock et al. (2016) disagreed with this and found the evidence for long-term stability of the treatment result from FFA treatment to be nonexistent.

Class II elastics and HFFAs produced similar dentoalveolar effects via differing mechanisms - the former produce an intermittent force while the latter produce a continuous and mostly consistent force. Elastics exert traction force while HFFAs exert an impulsion force (Janson et al., 2013). A previous systematic review comparing functional appliances and Class II elastics found no long-term differences in treatment effects. (Nelson et al., 2007)

This study presents both significant strengths and notable limitations, which are important to consider. There is no existing review of the dentoskeletal effects of HFFAs that includes multiple modern HFFAs. The findings of this review will optimise selection criteria for HFFA treatment and appliance factors.

This review only included skeletal change values in the sagittal plane. A more in-depth analysis of vertical change would assist practitioners in selecting HFFAs for Class II malocclusion with high or low angle discrepancy. Additional cephalometric values could not be extracted for dentoalveolar changes due to inconsistent reporting and analyses undertaken amongst the included studies.

Conclusions

HFFAs are proficient Class II division 1 malocclusion correction appliances. They majority of correction was by dentoalveolar changes, specifically lower incisor proclination and position changes as well as upper incisor retroclination. The evidence suggests that skeletal effects induced by these appliances are mild and clinically insignificant. HFFAs do not modify growth of the mandible, unlike other functional appliances.

Although successful at Class II dental malocclusion correction, the HFFAs induce unwanted orthodontic side effects such as significant lower incisor proclination and clockwise rotation of the occlusal plane.

Further research is needed to confirm the effect of HFFAs used in conjunction with skeletal anchorage devices. This may help to reduce the aforementioned unwanted side effects. Further reviews on the soft tissue and facial profile effects of HFFAs are also warranted.

Acknowledgements

Not applicable.

Ethical approval

No ethical approval was required for this study as it did not involve human participants, animal subjects, or sensitive data. This study falls under the category of data collection without participant identification.

Consent for publication

Not applicable.

Authors' contributions

The author(s) declare that all the criteria for authorship designated by the International Committee of Medical Journal Editors have been met. More specifically, these are: (a) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND (b) Drafting the work or revising it critically for important intellectual content; AND (c) Final approval of the version to be published; AND (d) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Competing interests

The author(s) declare that there are no competing interests related to this work.

Author notes

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