EISSN 2148-9505

Turkish Orthodontic Society

Indexed in PubMed, Web of Science and Scopus

TURKISH JOURNAL of ORTHODONTICS

Original Articles

Review

Systematic Review

Volume 36
Issue 04
December 2023

galenos Publishing House

turkjorthod.org

TURKISH JOURNAL of ORTHODONTICS

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Web: www.galenos.com.tr **Publisher Certificate Number:** 14521
Printing Date: December 2023
E-ISSN: 2148-9505
International scientific journal published quarterly.

TURKISH JOURNAL of ORTHODONTICS

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Turkish Journal of Orthodontics publishes clinical and experimental studies on on all aspects of orthodontics including craniofacial development and growth, reviews on current topics, case reports, editorial comments and letters to the editor that are prepared in accordance with the ethical guidelines. The journal's publication language is English and the Editorial Board encourages submissions from international authors.

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TURKISH JOURNAL of ORTHODONTICS

Contents

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DOI: 10.4274/TurkJOrthod.2023.2022.124

Original Article

Has the COVID-19 Pandemic Affected Orthodontists' Interest in Various Orthodontic Appliances?

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Cite this article as: Eğlenen MN, Yavan MA. Has the COVID-19 Pandemic Affected Orthodontists' Interest in Various Orthodontic Appliances?. *Turk J Orthod.* 2023; 36(4): 216-223

Main Points

- Orthodontists' interest in brackets, functional appliances, orthognathic surgery, miniscrews, and retainers remained largely unchanged.
- There was a marked increase in the interest in clear aligners.
- Interest in standard metal brackets and fixed functional appliances decreased more in women than men.
- Interest in standard metal brackets decreased as respondents' work experience increased.

ABSTRACT

Objective: To determine the changes in orthodontists' interest in various orthodontic appliances during the coronavirus disease-2019 (COVID-19) pandemic.

Methods: A questionnaire probing respondents' interest in orthodontic appliances and techniques, including standard buccal metal brackets, self-ligating brackets, standard ceramic brackets, lingual brackets, clear aligners, orthodontic facemasks, removable functional appliances, fixed functional appliances, orthognathic surgery, orthodontic miniscrews, and lingual retainers, was prepared using Google Forms and then sent to the Turkish Orthodontic Society to invite all members of the society to participate in the survey. Of the 1903 members invited, 230 (response rate, 12.08%) orthodontists completed the questionnaire.

Results: The respondents' interest in brackets did not change among 70% of the respondents (standard buccal metal bracket 80%, self-ligating bracket 72.2%, standard ceramic bracket 77%, and lingual bracket 76.5%). A significant difference was observed between the genders only about the interest in standard metal brackets and fixed functional appliances ($p<0.05$ for both). Interest in standard metal brackets decreased as respondents' work experience increased ($p<0.05$). The interest in self-ligating brackets was higher among respondents with 1-5 years of experience than among other respondents ($p<0.05$). Interest in self-ligating brackets increased more among lecturers and residents than among clinicians ($p<0.05$).

Conclusion: The interest of orthodontists in clear aligners showed the highest increase during the COVID-19 pandemic among all orthodontic appliances, whereas their interest in other appliances, particularly standard buccal metal brackets, did not change.

Keywords: COVID-19, Orthodontic appliances, Orthodontists

INTRODUCTION

Coronavirus disease-2019 (COVID-19) has affected almost every aspect of life, and since its outbreak, people have tried to adapt to this unexpected change.[1] To prevent the spread of COVID-19, different types of lockdown measures with varying durations have been imposed in different regions across the world.[2] The dental setting is a unique environment in the COVID-19 pandemic because it potentially possesses all transmission risk factors for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). SARS-CoV-2 has been reported to be detected in

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Received: August 10, 2022
Accepted: January 03, 2023
Publication Date: December 29, 2023

alternative sites and specimens pertaining to dental practice.[3] In the first months of the pandemic, due to the inability to maintain social distance and the risk of infection through the inhalation of aerosol during dental procedures, these procedures were limited to treatments requiring emergency intervention.[4-7] With the increase in precautions, lockdown measures were loosened, and dental treatments were resumed.[1,8]

Orthodontic treatment mostly includes permanent or removable appliances, requiring patient compliance and months and years of regular follow-up.[9] Due to the COVID-19 pandemic, orthodontic treatment appointments are likely to be delayed or canceled, leading to various side effects.[4,7,10] In the literature, many orthodontic emergencies have been reported during the COVID-19 pandemic, including soft tissue irritation caused by brackets or wires and loosening or breakage of metal ligatures, elastic ligatures, chains, brackets, and retainers.[11] Accordingly, preventing orthodontic emergencies is important for reducing both patient discomfort and prolonged treatment.[12] This can be achieved by improving orthodontic materials and techniques[13] and incorporating new technologies.[11] Another effective orthodontic measure taken against COVID-19 is the minimization of chair time, which is useful for reducing aerosol transmission and has been enhanced with the emergence of new technologies and digital flow.[11] A scoping review by Kaur et al.[11] indicated that, in unpredictable times of crisis such as COVID-19, clear aligners are safer and provide more predictable and effective outcomes than fixed orthodontic treatments.

The literature indicates that COVID-19 is driving orthodontists toward treatment options that allow careful patient screening and collection of records, minimal physical visits, effective use of technology, virtual consultation instead of physical appointments using personal protective equipment (PPE), and less aerosol generation.[11] These requirements may change orthodontists' interest in orthodontic appliances. The aim of this study was to determine the impact of the COVID-19 pandemic on orthodontists' interest in various types of orthodontic appliances and techniques. Our null hypothesis is that the COVID-19 pandemic situation does not change orthodontists' appliance selection and treatment techniques.

METHODS

The study was initiated after obtaining ethical approval from the Adıyaman University Non-interventional Clinical Research Ethics Committee (approval no: 2021/10-7, date: 14.12.2021). A questionnaire was prepared using Google Forms and was sent to the Turkish Orthodontic Society to obtain the necessary permissions and approvals. Subsequently, all 1903 members of the society were invited via email to participate in the survey, and 230 (response rate: 12.087%) of them filled out the questionnaire. A total of 15 questions were included in the questionnaire to increase the efficiency of the research and the usefulness of the questionnaire. The questions followed a standard pattern (e.g. How has the COVID-19 pandemic affected your interest in the (any specified) appliance throughout your orthodontic treatments?) and a three-point Likert scale ("My interest has increased.", "My interest has not changed.", and "My interest has decreased."). The appliances and techniques probed in the questionnaire included standard buccal metal brackets, self-ligating brackets, standard ceramic brackets, lingual brackets, clear aligners, orthodontic facemasks, removable functional appliances, fixed functional appliances, orthognathic surgery, orthodontic miniscrews, and, in the forthcoming phase of treatments, the effect on the choice of clear and lingual retainers as retention devices. Additionally, the questionnaire probed their demographic characteristics, including gender, total work experience (1-5 years, 6-10 years, and 10 and more years), and academic position (resident, lecturer, clinician).

Statistical Analysis

Data were analyzed using SPSS for Windows version 22.0 (IBM Corp., Armonk, NY, USA). Descriptives are expressed as frequencies (n) and percentages (%). Categorical variables were compared using the chi-square test. A p value of <0.05 was considered significant.

RESULTS

The 230 participants comprised 144 women and 86 men. The overall response rate was 12.08%. The distribution according to total work experience revealed that 1-5 years constituted most respondents (40%). In terms of academic position, clinicians (45.7%) constituted majority of respondents, followed by residents (32.6%) and lecturers (21.7%).

Table 1 presents the changes in respondents' interest in orthodontic appliances. Accordingly, 80%, 72.2%, 77%, and 76.5% of the respondents indicated that their interest in standard buccal metal brackets, self-ligating brackets, standard ceramic brackets, and lingual brackets did not change. In contrast, the highest increase in interest was reported for clear aligners (62.2%). On the other hand, 92.2% and 90% of the respondents declared that their interest in facemask and orthognathic surgery remained unchanged. Interest in fixed functional appliances decreased among 10.9% of respondents, and interest in removable functional appliances increased among 6.1%. Interest in miniscrews remained unchanged among 83% of the respondents, whereas it increased among 15.2% of the respondents. Interest in fixed and removable retainers showed no change among 83% and 80% of the respondents, respectively. However, interest in fixed retainers decreased among 9.1% of respondents, whereas interest in removable retainers increased among 15.7% respondents.

Table 2 presents a comparison of responses according to gender. Accordingly, a significant difference was observed between genders only in terms of interest in standard metal brackets and fixed functional appliances ($p<0.05$ for both).

Table 3 presents a comparison of responses according to respondents' total work experience annually. A significant relationship was found between the length of total work experience and interest in standard buccal metal, self-ligating brackets, and fixed lingual retainers ($p<0.05$).

Table 4 presents a comparison of responses according to the respondents' academic positions. A significant difference was found among academic positions concerning the interest in self-ligating brackets, miniscrews, and fixed lingual retainers ($p<0.05$).

DISCUSSION

Studies have reported that orthodontic emergencies are encountered more frequently during COVID-19 lockdowns than during normal times.[14] The most common emergencies include bracket breakages, archwire breakages, and molar tube and band breaks.[15] Although these emergencies are not life-threatening, they require prompt treatment because they cause prolonged treatment periods, decrease patients' motivation, and reduce patients' trust in orthodontists.[16] The literature indicates that among fixed functional appliances, breakage of preadjusted stainless steel brackets has been the most common orthodontic emergency during the COVID-19 pandemic, with a rate of 74.7%.[15] Therefore, our null hypothesis was that orthodontists' interest in standard buccal metal brackets might decrease during the COVID-19 pandemic. Nevertheless, the results indicated that the interest in these appliances did not change among 80% of the respondents, while it showed a reduction among 17% of the respondents. Buccal metal brackets have been by far the most commonly used appliances in the last 30 years[15] and they are the gold standard for obtaining successful outcomes in orthodontic treatment.[17] The literature indicates that 45% of orthodontists consider that aligners limit the success of orthodontic treatment and thus prefer fixed treatments.[18] Given that standard buccal metal brackets are more accessible and economical[19] and that physicians have more experience and confidence in these appliances,[18,20] the absence of a remarkable change in the interest of orthodontists in these appliances, as revealed in our study, seems highly reasonable.

Table 1. Survey results

Appliances	Total (n=230)		
	Interest		
	Increased (n%)	Not changed (n%)	Decreased (n%)
Standard buccal metal braces	7 3%	184 80%	39 17%
Self-ligating braces	51 22.2%	166 72.2%	13 5.7%
Clear braces	3 1.3%	177 77%	50 21.7%
Lingual braces	7 3%	176 76.5%	47 20.4%
Clear aligners	143 62.2%	84 36.5%	3 1.3%
Orthodontic facemask	8 3.5%	212 92.2%	10 4.3%
Removable functional appliances	14 6.1%	206 89.6%	10 4.3%
Fixed functional appliances	14 6.1%	191 83%	25 10.9%
Orthognathic surgery	10 4.4%	206 90%	13 5.7%
Orthodontic miniscrews	35 15.2%	191 83%	4 1.7%
Lingual retainer	18 7.8%	191 83%	21 9.1%
Essix retainer	36 15.7%	184 80%	10 4.3%

Cotrin et al.[15] reported that the breakage of ceramic brackets was the second most common emergency reported during the COVID-19 pandemic (29.6%). In our study, the interest in clear brackets, which are more esthetic alternatives to metal brackets, did not change among 77% of orthodontists. In contrast, interest in clear brackets decreased among 21.7% of the respondents, which could be due to possible emergencies or increased interest in clear aligners. Similarly, Walton et al.[19] reported that their patients found clear aligners and lingual brackets esthetically more attractive than ceramic brackets and accepted them more easily.

A number of studies claim that self-ligating brackets have shorter total treatment and chair times and longer session intervals because they provide high patient comfort and allow faster wire replacement.[19,21] Moreover, because these appliances do not involve ligatures, they do not cause soft tissue injury or elastic ligature detachment.[19] Our null hypothesis was that interest in such appliances might increase during the COVID-19 pandemic because of these advantageous features. Nevertheless, it was observed that interest in these appliances increased only among 22.2% of orthodontists, whereas no change was observed among 72.2% of them. This finding could be explained by the difference in the costs of these appliances and standard metal brackets, as well as by the increased interest in clear aligners that have a lower risk of emergency orthodontic problems.[19]

Clear aligners have been reported to be highly advantageous during the COVID-19 pandemic because they have less chair time than fixed treatments, require minimal bonding, reduce appointment frequency (recall visit), and allow for remote/virtual planning. In addition, studies have shown that among all orthodontic appliances, clear aligners had the lowest rate of emergency conditions during the COVID-19 pandemic.[7,22] A scoping review by Kaur et al.[11] indicated that in unpredictable times of crisis such as COVID-19, clear aligners are safer and provide more predictable and effective outcomes than fixed orthodontic treatments. In line with the literature, our findings indicated that the interest in clear aligners increased among

Table 2. Comparison of survey results according to genders

Appliances	Female (n=144)			Male (n=86)			p value
	Interest			Interest			
	Increased (n%)	Not changed (n%)	Decreased (n%)	Increased (n%)	Not changed (n%)	Decreased (n%)	
Standard buccal metal braces	1 0.7%	115 79.9%	28 19.4%	6 7.0%	69 80.2%	11 12.8%	**0.015***
Self-ligating braces	34 23.6%	102 70.8%	8 5.6%	17 19.8%	64 74.4%	5 5.8%	0.794
Clear braces	2 1.4%	113 78.5%	29 20.1%	1 1.2%	64 74.4%	21 24.4%	0.745
Lingual braces	4 2.8%	112 77.8%	28 19.4%	3 3.5%	64 74.4%	19 22.1%	0.838
Clear aligners	95 66.0%	47 32.6%	2 1.4%	48 55.8%	37 43.0%	1 1.2%	0.286
Orthodontic facemask	2 1.4%	135 93.8%	7 4.9%	6 7.0%	77 89.5%	3 3.5%	0.075
Removable functional appliances	8 5.6%	131 91.0%	5 3.5%	6 7.0%	75 87.2%	5 5.8%	0.624
Fixed functional appliances	4 2.8%	121 84.0%	19 13.2%	10 11.6%	70 81.4%	6 7.0%	**0.012***
Orthognathic surgery	8 5.6%	127 88.2%	9 6.3%	2 2.4%	79 92.9%	4 4.7%	0.446
Orthodontic miniscrews	19 13.2%	121 84.0%	4 2.8%	16 18.6%	70 81.4%	0 0.0%	0.176
Lingual retainer	8 5.6%	124 86.1%	12 8.3%	10 11.6%	67 77.9%	9 10.5%	0.198
Essix retainer	22 15.3%	116 80.6%	6 4.2%	14 16.3%	68 79.1%	4 4.7%	0.962

n: number, α: chi-square test,
*Statistical significance: p<0.05.

62.2% of the respondents. In contrast, the interest in these appliances did not change among 36.5% of the respondents, which could be attributed to the fact that these orthodontists might have been using these appliances since before the COVID-19 outbreak or might have avoided them because of their limitations or high costs.[18-20]

Lingual suspenders constitute an esthetic treatment alternative. However, they prolong chair time.[23] Due to this disadvantage, we considered that its popularity might have decreased during the COVID-19 pandemic. However, 76.5% of the respondents indicated that their interest did not change, whereas only 20.4% reported a decrease in their interest. On the other hand, lingual braces are preferred only by a small number of orthodontists because they require substantial experience and training, are expensive, and involve technical difficulties.[23] These notions may explain the absence of a change in the interest of orthodontists who do not currently use these appliances. In our study, the interest in these appliances decreased among 20.4% of the respondents, which could be attributed to the characteristics of these appliances that could be important disadvantages, particularly during the COVID-19 pandemic, such as the technical difficulties of working indirectly in the lingual region, the availability of other aesthetic options such as clear aligners, and decreased cosmetic anxiety among the patients due to the routine use of disposable surgical face masks.

Given that broken brackets, bands, and wires were the leading orthodontic emergencies during the COVID-19 pandemic,[15] we considered that the interest in fixed functional appliances might decrease during this period and, conversely, the interest in removable functional appliances might increase. Nevertheless, in our study, the interest in both appliances did not show a remarkable change, which could be ascribed to the achievement of good compliance in only two-thirds of cases treated with removable appliances and clear aligners.[22]

Similarly, for orthodontic facemask appliances, regular follow-up is of prime importance for solving the compliance problem and preventing possible side effects.[16] In our study, we considered that the interest in these appliances might decrease because of the difficulty in achieving patient compliance and performing follow-up visits during the COVID-19 pandemic. Nonetheless, among all the appliances evaluated in the study, facemask showed the least change about respondents' interest, which

Table 3. Comparison of survey results according to work experience

Appliances	1-5 years (n=92)			6-10 years (n=64)			Over 10 (n=74)			p value[α]
	Interest			Interest			Interest			
	Increased (n%)	Not changed (n%)	Decreased (n%)	Increased (n%)	Not changed (n%)	Decreased (n%)	Increased (n%)	Not changed (n%)	Decreased (n%)	
Standard buccal metal braces	4 4.3%	81 88.0%	7 7.6%	3 4.7%	50 78.1%	11 17.2%	0 0.0%	53 71.6%	21 28.4%	**0.004***
Self-ligating braces	30 32.6%	57 62.0%	5 5.4%	12 18.8%	49 76.6%	3 4.7%	9 12.2%	60 81.1%	5 6.8%	**0.029***
Clear braces	0 0.0%	74 80.4%	18 19.6%	1 1.6%	48 75.0%	15 23.4%	2 2.7%	55 74.3%	17 23.0%	0.571
Lingual braces	5 5.4%	70 76.1%	17 18.5%	1 1.6%	48 75.0%	15 23.4%	1 1.4%	58 78.4%	15 20.3%	0.494
Clear aligners	59 64.1%	32 34.8%	1 1.1%	43 67.2%	20 31.3%	1 1.6%	41 55.4%	32 43.2%	1 1.4%	0.661
Orthodontic facemask	3 3.3%	84 91.3%	5 5.4%	5 7.8%	56 87.5%	3 4.7%	0 0.0%	72 97.3%	2 2.7%	0.129
Removable functional appliances	6 6.5%	84 91.3%	2 2.2%	5 7.8%	56 87.5%	3 4.7%	3 4.1%	66 89.2%	5 6.8%	0.573
Fixed functional appliances	9 9.8%	76 82.6%	7 7.6%	3 4.7%	50 78.1%	11 17.2%	2 2.7%	65 87.8%	7 9.5%	0.114
Orthognathic surgery	4 4.3%	82 89.1%	6 6.5%	4 6.3%	56 87.5%	4 6.3%	2 2.7%	68 93.2%	3 4.1%	0.815
Orthodontic miniscrews	15 16.3%	75 81.5%	2 2.2%	10 15.6%	53 82.8%	1 1.6%	10 13.5%	63 85.1%	1 1.4%	0.977
Lingual retainer	10 10.9%	76 82.6%	6 6.5%	7 10.9%	46 71.9%	11 17.2%	1 1.4%	69 93.2%	4 5.4%	**0.007***
Essix retainer	14 15.2%	73 79.3%	5 5.4%	12 18.8%	48 75.0%	4 6.3%	10 13.5%	63 85.1%	1 1.4%	0.496

n: number, α: chi-square test,
*Statistical significance p<0.05

could be explained by the fact that facemask, when applied at an appropriate time, is the gold standard in terms of efficiency when compared with its alternatives.[24]

In the first wave of COVID-19, at least 21 million elective surgical procedures were canceled worldwide because of postoperative SARS-CoV-2 infection concerns of the patients and the capacity of the hospitals.[25] Our null hypothesis was that interest in orthognathic surgery might decrease because of such cancelations and delays. However, the interest in this surgical procedure remained unchanged among 90% of the respondents, which could be attributed to the fact that the surgeries had returned to their normal routine at the time of the survey.

Miniscrews have been frequently used in orthodontic practice in recent years and can cause mucosal injuries because of their positioning and angulation in the mouth.[26] However, these mucosal injuries can be prevented by placing protective caps and taking utmost care during implantation. When miniscrews become loose, they can cause pain, discomfort, infection, facial swelling, and periodontal abscesses; therefore, they may need to be removed during an emergency follow-up visit.[16] Yavan et al.[14] evaluated patients who underwent orthodontic treatment during the COVID-19 lockdown period and reported that 8.16% of their patients experienced miniscrew failure.[27] In our study, the interest in miniscrews did not change among 83% of the respondents, whereas it increased among 15.2%. Respondents whose interest did not change might have considered the long-term advantages of miniscrews rather than their possible risk factors. In addition, in the increase in the interest in miniscrews could be ascribed to the fact that miniscrewss can reduce the side effects of conventional therapy, such as loss of anchorage, and can shorten the treatment period.[27]

Several studies indicated that during the COVID-19 pandemic, 15.9% of the patients visited the clinic with the complaint of a broken fixed retainer and less than 10% of the patients presented with the complaint of a broken removable retainer.[15] Some other studies suggested that during the COVID-19 pandemic,

Table 4. Comparison of survey results according to academic position

Appliances	Lecturer (n=50)			Clinician (n=105)			Resident (n=75)			p value$^{\alpha}$
	Interest			Interest			Interest			
	Increased (n%)	Not changed (n%)	Decreased (n%)	Increased (n%)	Not changed (n%)	Decreased (n%)	Increased (n%)	Not changed (n%)	Decreased (n%)	
Standard buccal metal braces	2 4.0%	36 72.0%	12 24.0%	2 1.9%	82 78.1%	21 20.0%	3 4.0%	66 88.0%	6 8.0%	0.114
Self-ligating braces	15 30.0%	34 68.0%	1 2.0%	11 10.5%	87 82.9%	7 6.7%	25 33.3%	45 60.0%	5 6.7%	**0.002***
Clear braces	2 4.0%	40 80.0%	8 16.0%	1 1.0%	78 74.3%	26 24.8%	0 0.0%	59 78.7%	16 21.3%	0.262
Lingual braces	1 2.0%	35 70.0%	14 28.0%	2 1.9%	86 81.9%	17 16.2%	4 5.3%	55 73.3%	16 21.3%	0.282
Clear aligners	33 66.0%	16 32.0%	1 2.0%	59 56.2%	45 42.9%	1 1.0%	51 68.0%	23 30.7%	1 1.3%	0.470
Orthodontic facemask	3 6.0%	46 92.0%	1 2.0%	1 1.0%	100 95.2%	4 3.8%	4 5.3%	66 88.0%	5 6.7%	0.243
Removable functional appliances	5 10.0%	44 88.0%	1 2.0%	3 2.9%	95 90.5%	7 6.7%	6 8.0%	67 89.3%	2 2.7%	0.203
Fixed functional appliances	3 6.0%	40 80.0%	7 14.0%	4 3.8%	90 85.7%	11 10.5%	7 9.3%	61 81.3%	7 9.3%	0.559
Orthognathic surgery	2 4.0%	44 88.0%	4 8.0%	4 3.8%	98 94.2%	2 1.9%	4 5.3%	64 85.3%	7 9.3%	0.242
Orthodontic miniscrews	13 26.0%	36 72.0%	1 2.0%	7 6.7%	96 91.4%	2 1.9%	15 20.0%	59 78.7%	1 1.3%	**0.018***
Lingual retainer	3 6.0%	37 74.0%	10 20.0%	6 5.7%	92 87.6%	7 6.7%	9 12.0%	62 82.7%	4 5.3%	**0.021***
Essix retainer	12 24.0%	36 72.0%	2 4.0%	12 11.4%	89 84.8%	4 3.8%	12 16.0%	59 78.7%	4 5.3%	0.355

n: number, α: chi-square test,
*Statistical significance p<0.05

thermoplastic retainers produced by 3D software should be preferred over fixed retainers to prevent aerosol emission caused by the aerator and to reduce the risk of breakage.[11] Our null hypothesis was that interest in lingual retainers might decrease because of prolonged chair time. However, the interest in these appliances did not change among 83% of the respondents, which could be due to poor patient compliance with removable retainers.[28]

In our study, the only difference detected between male and female respondents was the change in their interest in standard metal brackets and fixed functional appliances, whereby the interest in these appliances decreased more in women than in men. Women have greater anxiety than men during the COVID-19 pandemic,[4] which might explain the relative decrease in interest caused by possible side effects of fixed mechanical appliances.

An examination of respondents' interest in appliances concerning their total work experience indicated that interest in standard metal brackets decreased more in individuals with 10 years or more of experience. These findings could be explained by the fact that as orthodontists' experience increases, their ability to detect possible complications improved.[29] On the other hand, the interest in self-ligating brackets was higher among respondents with 1-5 years of experience. This finding could be associated with the fact that orthodontists who have low experience and hence longer learning curves spend more time on patient care,[30] which, in turn, might have led to an increased interest in self-ligating brackets due to their shorter chair times.[21]

In our study, the interest in self-ligating brackets increased more among lecturers and residents than among clinicians. This difference could be associated with the greater necessity of shortening the chair time in busy clinics such as university hospitals.[1,21] Similarly, these two groups also showed an increased interest in miniscrews, which could be explained by the fact that university hospitals are more affected by the COVID-19 lockdown procedures due to the large number of employees and the high number of patients, and the resulting long-term suspension of appointments.[1] On the other hand, these two groups might have increased their interest in miniscrews to reduce the side effects of orthodontic treatment, such as loss of anchorage, and to reduce the duration of treatment.[27]

It is commonly known that measures taken to prevent the spread of the COVID-19 pandemic have also resulted in serious economic consequences, which, in turn may cause financial issues to overshadow the potential side effects of orthodontic appliances.[28] A study conducted in Brazil reported that orthodontists were more more affected by the financial impact of the COVID-19 pandemic than its impact on orthodontic treatment.[15,31] We consider that one of the primary reasons for the absence of a change in the interest of orthodontists in the appliances might be their routine use of these appliances because of their habits.[18,20]

Study Limitations

Our study had several limitations. First it was a cross-sectional study that evaluated a certain population during a specific period of the COVID-19 pandemic. The COVID-19 pandemic continues to affect the world with new variants in numerous waves.[2,28,32] Moreover, the World Health Organization warns of possible future viral pandemics. Additionally, the number of cases diagnosed with COVID-19 varies with time and place, and vaccination rates vary widely across the world.[2] All these factors may lead to a change in the interest of orthodontists in appliances. Another limitation is the number of responses provided to the survey, which is a problem encountered in most surveys.[33] Because orthodontists have a busy schedule during the day, they cannot allocate enough time for surveys.[23,33] Further studies may investigate the interest of orthodontists in appliances during the COVID-19 pandemic in different countries or regions. This study may provide insight for orthodontists regarding possible new pandemics and lockdowns.

CONCLUSION

The results indicated that the interest of orthodontists in clear aligners showed the highest increase during the COVID-19 pandemic among all orthodontic appliances, whereas their interest in other appliances, particularly standard buccal metal brackets, did not change.

Ethics

Ethics Committee Approval: The study was initiated after obtaining ethical approval from the Adıyaman University Non-interventional Clinical Research Ethics Committee (approval no: 2021/10-7, date: 14.12.2021).

Informed Consent: Necessary permissions and approvals were obtained for this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - M.A.Y.; Design - M.A.Y.; Supervision - M.A.Y.; Materials - M.N.E.; Data Collection and/or Processing - M.N.E.; Analysis and/or Interpretation - M.N.E.; Literature Review - M.N.E.; Writing - M.N.E., M.A.Y.; Critical Review - M.N.E.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declared that this study has received no financial support.

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TURKISH JOURNAL of ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2023.2022.31

Original Article

Diode Laser versus Conventional Surgical Circumferential Supracrestal Fiberotomy in Preventing Relapse of Orthodontically Derotated Teeth: A Randomised Control Trial

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Cite this article as: Kharb S, Malhotra A, Batra P, Arora N, Singh AK. Diode Laser versus Conventional Surgical Circumferential Supracrestal Fiberotomy in Preventing Relapse of Orthodontically Derotated Teeth: A Randomised Control Trial. *Turk J Orthod.* 2023; 36(4): 224-230

Main Points

- Circumferential supracrestal fiberotomy significantly reduces the relapse tendency of orthodontically derogated anterior teeth.
- Circumferential supracrestal fiberotomy with a diode laser has results similar to the conventional surgical CSF method in reducing relapse potential.

ABSTRACT

Objective: To evaluate the effectiveness of a diode laser (810 nm) for circumferential supracrestal fiberotomy compared with conventional surgical circumferential supracrestal fiberotomy in preventing rotational relapse in orthodontically treated cases.

Methods: Seventy-six patients (age range from 18-25 years) with mandibular crowding ranging between 5-8 mm and rotation >10° (from the individualized arch form) treated non-extraction with a straight wire appliance (McLaughlin, Bennet, Trevisi; 0.022 inch) prescription were selected for the study. The patients were randomly allocated into 3 groups of 22 patients each: Group 1 (Control group-No circumferential supracrestal fiberotomy), Group 2 (Conventional circumferential supracrestal fiberotomy), and Group 3 (diode laser circumferential supracrestal fiberotomy). After leveling and alignment up to "0.019x0.025" stainless steel wire, the arch wire was removed for a period of 1 month. Impressions were made and the poured casts were scanned. The 3D models (.STL files) were evaluated for changes in the irregularity index and rotational relapse.

Results: One-way ANOVA and post-hoc Tukey's test were used for data analysis. Group 1 (Control group) showed greater relapse in both irregularity index and rotation angulations in comparison with Groups 2 and 3, which was statistically significant ($p<0.001$). There was no statistically significant difference in irregularity index and rotational relapse between Group 2 and Group 3 ($p=0.35$ for irregularity index, and $p=0.41$ for rotational relapse).

Conclusion: The control group showed significantly more relapse than both circumferential supracrestal fiberotomy groups. Both conventional and diode laser circumferential supracrestal fiberotomy decreased the relapse tendency.

Keywords: Diode laser, relapse, rotation, incisor

INTRODUCTION

Derotation of malaligned teeth is seldom considered a problem in modern orthodontic therapy. However, the maintenance of this derotation after the removal of orthodontic appliances remains a concern.[1] Orthodontic relapse is caused by the reorganization of the periodontal transseptal fibers and the gingival fibres.[1-3] Additionally, it is observed that the more severe the initial rotation, the greater the tendency for relapse.[4]

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Received: March 09, 2022
Accepted: January 10, 2023
Publication Date: December 29, 2023

Various methods have been utilized to minimize rotational relapse, such as early correction, overrotation, and long-term retention, but supracrestal fibrotomy is considered most efficacious.[5] This procedure, where the gingival fibers are severed with a surgical blade, was introduced by Edwards[6], and Crum and Andreasen.[7] Lasers have been used in the medical field since the 1970s and in dentistry since the 1980s. Since then, several developments have occurred in the field of lasers. The Food and Drug Administration approved the utilization of erbium lasers on hard tissue in 1997 and the diode laser on soft tissue in 1998. Since then, lasers have been used in many areas of orthodontic practice, such as orthodontic debonding, etching procedures, biostimulation, bone regeneration, and soft tissue surgical procedures.[8]

High - intensity lasers have become popular in orthodontics for the purpose of soft tissue surgical procedures. They provide a bloodless and atraumatic alternative to conventional surgical procedures. The laser allows for lesser postoperative pain as it inhibits pain receptors, lowers the risk of infection, and promotes healing.[9] Kim et al.[10] and Jahanbin et al.[5] noted a decrease in rotational relapse after using laser-assisted circumferential supracrestal fibrotomy.

Circumferential supracrestal fiberotomy utilizing a diode laser limits rotational relapse as the light energy from the diode laser (between 810-830 nm) is absorbed by soft tissue but poorly absorbed by hard tissue.[11] Although studies have been conducted on the efficacy of lasers in reducing relapse, not many human studies have been found where the efficacy of diode lasers, in particular, was tested.[12,13] The present study evaluated the effectiveness of 810 nm diode laser circumferential supracrestal fiberotomy versus conventional surgical circumferential supracrestal fiberotomy in the prevention of rotational relapse of mandibular anterior teeth.

Hypothesis being tested (N_o) were:

1) There exists no rotational relapse in cases treated with circumferential supracrestal fiberotomy and where no circumferential supracrestal fiberotomy was performed.

2) There exists no difference in the rotational relapse with conventional and diode laser circumferential supracrestal fiberotomy.

METHODS

Patients who reported in the department for treatment between January 2019 and July 2020 were included in the study. A priori sample size estimation was performed, where power was assumed to be at 90% and the confidence interval was maintained at 95%. Standard deviation and mean difference, as reported by a previous study was 1.5 and 1.5, respectively, and were used to calculate the sample size for the present study using SPSS Software version 28.[13] In this manner, sample size was calculated to be 66 patients. However, it was decided to keep a larger sample size in order to avoid the loss of the required sample in a situation where patients are unable to go through the complete study procedure.

After receiving approval from the Institutional Ethics Committee of Manav Rachna Dental College (ref no. MRDC/IEC/2019/16) for the study, 76 patients undergoing routine orthodontic treatment in the age range of 18-25 years were selected. Informed consent was obtained from all patients for their participation in the study. Patient consent was obtained to participate in the study. Six patients declined to participate in the study at this stage.

Randomization

The remaining 70 patients were randomly divided into 3 groups using the online Stat Trek software.

1. Group 1 (Control group- No circumferential supracrestal fiberotomy) =23 patients.

2. Group 2 (Conventional surgical circumferential supracrestal fiberotomy) =23 patients.

3. Group 3 (Diode laser circumferential supracrestal fiberotomy) =24 patients.

These patients had pretreatment mandibular anterior crowding of 5-8 mm from canine to canine, and mean rotation >10° as measured from the individualized arch form (Figure 1). Patients were assessed for clinical attachment loss, tooth mobility, probing depth, and alveolar bone loss with the help of standardized intraoral radiographs. Patients with clinical attachment loss, alveolar bone loss, or any systemic disease were excluded from the study.

Patients with gingival inflammation were referred to the department of periodontics for scaling and polishing, were advised chlorhexidine mouthwash and oral hygiene instructions. The patients were recalled to the department after one week for assessment for gingivitis before starting treatment. Scaling and

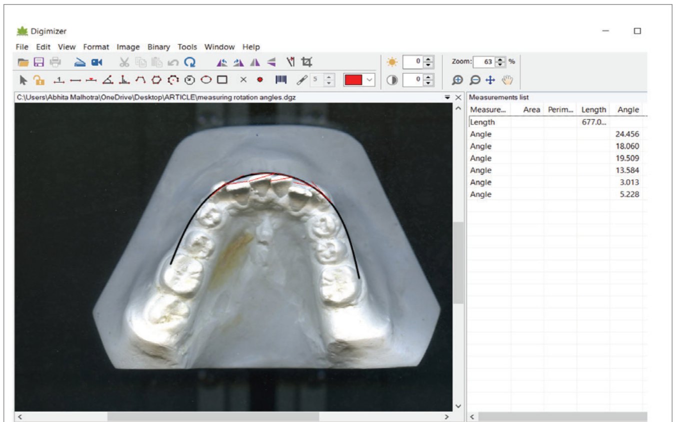

Figure 1. The degree of rotation of the anterior teeth was measured on the pretreatment cast, using the Digimiser software. A line was marked from the mesial-most point to the distal-most point for each of the 6 anterior teeth, and the angle of rotation was measured from this line to the tangent of the individualized arch form. Teeth with a mean rotation greater than 10° was included in the study sample

polishing were performed at 2-month intervals throughout the study period to ensure healthy gingival tissues.

Four patients were lost to follow-up. One patient from the control group, one patient from the conventional surgical group, one patient from the diode laser group discontinued treatment, and another refused to undergo the circumferential supracrestal fiberotomy procedure. These patients were removed from our study sample (Figure 2). The arches were leveled up to 0.019x0.025" stainless steel wire and kept in place for at least 3 months for the arch wire to express itself completely. The wire was subsequently removed, and circumferential supracrestal fiberotomy was performed using the conventional surgical method in Group 2 and diode laser in Group 3.

Study models were taken at three different time intervals: - T_0- Before treatment, T_1- After leveling and alignment, when the patient had been on 0.019x0.025" stainless steel wire for 3 months, T_2- One month after the removal of arch wire.

1. Measuring the irregularity in the lower anterior region: Little's irregularity index[14] was measured using the online software Meshmixer 3.5 (Autodesk, Inc.) The STL images of the casts, which were scanned utilizing the iTero 3D scanner, were transferred to the Meshmixer software, and the measurements were made with the help of the software (Figure 3).

The irregularity was assessed at T_0, T_1, and T_2.

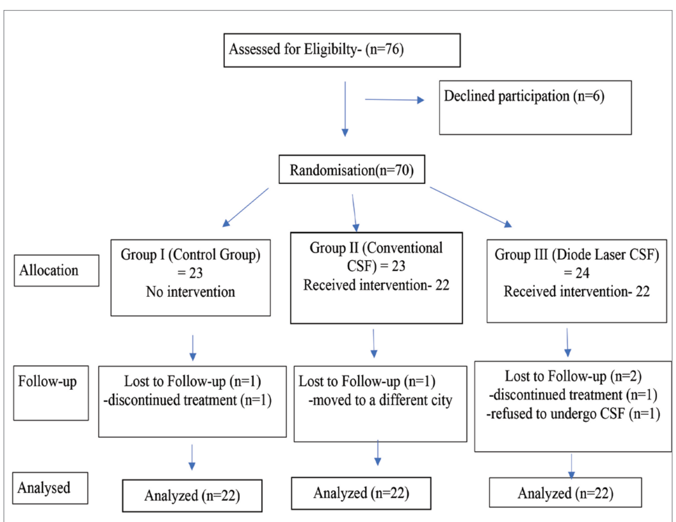

Figure 2. CONSORT flow chart of patients in each group during trial

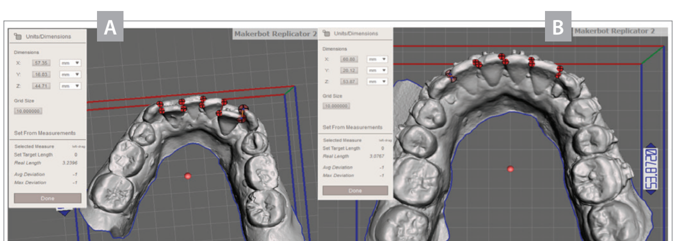

Figure 3. A) Little's irregularity index measured on the digital cast utilising Meshmixer software. B) Little's irregularity index on digital cast after removing archwire for 1 month

2. Measuring rotations:

a) Pretreatment (T_0):

The study model was scanned using an Epson Perfection V700 Photo Dual Analyser Lens System Scanner. The image received was then transferred to Paint 3D software (Microsoft, Version 6.2105.4017) and the individualized arch form was constructed. This image was then transferred to Digimizer Image Analysis software (Version 5.7.5; 2005-2021 MedCalc Software Ltd, Belgium) that allows precise manual measurements on an image. The teeth with a mean rotation >10°, were included in the sample (Figure 1).

b) Pre- and Post-Intervention (T_1 and T_2): The scanned images of casts were transferred to the Digimizer Image Analysis software. The midsagittal plane was constructed, and the six angles formed for each of the six anterior teeth were measured to the midsagittal plane (Figure 4).

Intervention

1) Conventional Surgical: Circumferential supracrestal fiberotomy was performed under infiltration anesthesia with 2% Lignocaine with 1:80000 Adrenaline (Lignocaine, Indoco Warren Lignox). Using a No. 12 surgical blade, intergingival, transgingival, transseptal, and semicircular fibers were transected (Figure 5).

2) Diode Laser: Gallium-aluminum-arsenide (Ga-Al-As) diode laser (AMD Picasso Diode Laser, 7405 Westfield Blvd., Indianapolis) with an 810-nm wavelength was used to do the CSF procedure.[11] A 15% Lignocaine surface anesthetic (Lidayn Surface Anaesthetic Spray, Global Dent Aids Pvt Ltd, Noida, Uttar Pradesh) was used and then the laser tip was inserted through the gingival sulcus, and the incision was extended around the tooth circumference keeping the laser at a setting of 1.2 W in repetitive pulsed mode (Figure 6).

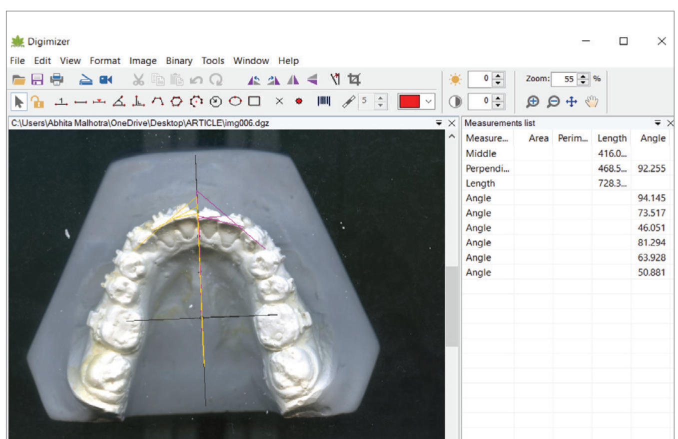

Figure 4. Measurement of the rotation angulation of anterior teeth was conducted using the Digimizer Image Analysis software. The scanned images of casts after alignment (T1), and after relapse (T2), were transferred to the software. The midsagittal plane was constructed by creating a line perpendicular to the line joining the mesial pit of the first molars on either side. The six angles formed for each of the six anterior teeth were determined by a line joining the mesial and distal contact points of each of the each tooth to the mid-sagittal plane. The inferior and inner angles were measured, and mean of all angles was calculated

Statistical Analysis

The data were analyzed with SPSS software (Version 28, Chicago, Illinois, USA). The amount of relapse seen in the irregularity index and rotation angulations (T_2-T_1) in the three groups has been tabulated (Table 1). The normality of the data was assessed and then groups were compared utilizing the ANOVA statistics test (Table 2). Intergroup comparison of relapses in crowding and rotation was also done using the post hoc Tukey's test (Table 2). A p value ≤0.05 was considered statistically significant.

All measurements of irregularity and rotational angulations were repeated after two weeks by the same observer. The interclass correlation coefficient (ICC) value was 0.9 with a 95% confidence interval for both rotational relapse values and for Little's irregularity index measurements.

Figure 5. Conventional CSF procedure

Figure 6. Laser aided CSF procedure

Table 1. Amount of relapse seen after CSF, as assessed by Little's irregularity index, and rotation, in each group

Patient No.	Group 1		Group 2		Group 3	
	LII (mm) (T_2-T_1)	R-Mean (Degree) (T_2-T_1)	LII (mm) (T_2-T_1)	R-Mean (Degree) (T_2-T_1)	LII (mm) (T_2-T_1)	R-Mean (Degree) (T_2-T_1)
1	4.8	8.3	3.7	4.2	1.8	3.2
2	6	9.5	2.8	4.5	2.5	2.3
3	1.1	5.7	2.2	4.4	1.5	2.5
4	3.6	6	2.4	6.3	2.9	4
5	2.9	6.2	0.9	3.7	3.4	6.3
6	4.1	13	2.2	3.8	3	4.3
7	7.6	7.5	2.8	2.7	1.6	5.7
8	4.9	8.2	2.4	5.7	3.3	4
9	7.4	7.3	3.9	5.5	3.9	6.2
10	6.2	9.2	2.2	6	1.5	5
11	4.3	7.4	2.8	3.7	2.3	3.3
12	3.7	6.8	3.2	4.2	1.5	2.5
13	5.7	9.5	2	6.5	1.3	3.8
14	5.8	8.7	1.4	5.3	2.3	4.2
15	5.7	7.9	2.6	4.7	1.4	3.6
16	4.6	6.5	3.4	3.4	1.2	2.4
17	5.3	8.3	1.6	3.4	0.7	3.1
18	7.6	5.5	3.1	2.8	1.3	3.5
19	4.7	6.9	2.3	3.1	2.5	2.7
20	3.7	5.8	1.5	5.7	1.6	4.3
21	5.0	8.7	3.6	2.4	2.6	3.5
22	4.4	5.3	2.7	3.3	1.2	2.8

Group 1- Control group, Group 2-Conventional CSF, Group 3- Laser-CSF
LII: Change in Little irregularity index (T_2-T_1) observed after relapse from the alignment, by the particular treatment modality (mm)
R-Mean- Change in rotation angulations (T_2-T_1) observed after relapse from the alignment, by the particular treatment modality (mm)

Table 2. Intergroup comparison (post-hoc Tukey's test) of change in irregularity Index and rotation after relapse (T_2-T_1)

Intergroup comparison		Little's irregularity index		Rotation	
		Mean difference	p value	Mean difference	p value[α]
Group 1	Group 1	2.4273	<0.001*	2.5773	<0.001*
	Group 2	2.9000	<0.001*	3.1273	<0.001*
Group 2	Group 1	-2.4273	<0.001*	-2.5773	<0.001*
	Group 3	0.4727	0.345	0.5500	0.308
Group 3	Group 1	-2.9000	<0.001*	-3.1273	<0.001*
	Group 2	-0.4727	0.345	-0.5500	0.308

*Statistical significance: p<0.05.

RESULTS

The intergroup statistical comparison for pretreatment values (T_0) for both Irregularity Index (p=0.08) and rotation (p=0.44), was found to be insignificant, suggesting that all the groups were comparable at the pretreatment stage, with no difference between the groups.

ANOVA test for relapse (T_2-T_1) revealed a statistically significant difference between the groups when both Little's Irregularity Index and Rotation values were compared (Table 2). After utilizing the post-hoc Tukey's test, it was observed that Group 1 (Control group- No circumferential supracrestal fiberotomy; irregularity index=4.96±1.54 mm, rotation=6.91±1.29˚) showed changes that were statistically significant (p<0.001) compared to both experimental groups i.e., Group 2 (Conventional circumferential supracrestal fiberotomy group; irregularity index=2.53±0.78 mm, rotation=5.16±3.78˚), and Group 3 (Diode Laser circumferential supracrestal fiberotomy group; irregularity index=2.06±0.86 mm, rotation=3.78±1.17˚). Thus the first null hypothesis, stating that there is no difference in the relapse tendency between cases treated with circumferential supracrestal fiberotomy and the control group, where no supracrestal fiberotomy was performed, is rejected. The post-hoc Tukey's test, however, did not reveal any significant difference between the experimental groups, Group 2 and Group 3, for both the irregularity index and rotational relapse (p>0.05). Therefore, the second null hypothesis is accepted, stating that there exists no difference in the rotational relapse tendency when conventional surgical supracrestal fiberotomy is performed and when diode laser fiberotomy is performed.

DISCUSSION

Gingival fiber elasticity, cheek, lip, and tongue pressure, and jaw growth are among of the major reasons for orthodontic relapse.[15] When observed under the scanning and transmission electron microscope, the stretched gingival fibers appear torn, disorganized, and laterally spaced.[16] An increased number of elastic fibers are also observed near these torn collagen fibers. It has been suggested that relapse occurs more due to the elastic fibers than the collagen fibres.[16,17] The relapse tendency decreases after the supraalveolar gingival fibers are severed.[18]

The evidence of progressive instability in a treated case following orthodontic retention was first noted by the relapse of mandibular incisor crowding. Post-retention malalignment is less prevalent in the maxillary than in the mandibular anterior segment.[19] Therefore, the area of observation was chosen to be the mandibular anterior region in our study to assess relapse after the correction of crowding.

The greatest amount of relapse is observed within 18 to 24 hours of the removal of fixed appliances.[20] In cases where extractions have been performed, 50% of relapse occurs within one week of closing the extraction space.[19,21] Therefore, the period immediately after removal of fixed appliances is crucial in preventing relapse, and measures must be taken to prevent relapse in the initial stages after appliance removal. Our study assessed relapse for a time period of 1 month after removal of the arch wire.

The results of our study indicated a greater relapse tendency in the control group where supracrestal fiberotomy was not performed, as opposed to when it was utilized. This suggests that supracrestal fiberotomy significantly aided in the prevention of rotational relapse of incisors. The control group in our study showed relapse (irregularity index=4.96±1.54 mm, and for rotation=6.91±1.29˚) during the 1-month observation period, which was statistically significant compared to the results achieved with either method of circumferential supracrestal fiberotomy (conventional and laser method) (p<0.001). Therefore, supracrestal fiberotomy significantly reduced the relapse. Several other studies have noted similar results.[13,22,23] Miresmæili et al.[13] reported significant relapse in the control group (11.28±2.93˚) compared to the fibrotomy groups (laser group 4.89±2.08˚, CSF group 5.09±1.59˚) (p<0.001). Al-Jasser et al.[22] observed a mean rotational relapse of 1.44º (14% of initial rotation) after circumferential supracrestal fiberotomy, which was statistically insignificant. Taner et al.[23] noted a significant increase in the irregularity index in the control group compared to the supracrestal fiberotomy group (p<0.01). Ahrens et al.[18] also observed greater relapse in the control group (5.75˚) than in the fibrotomy group (0.42˚) with statistical significance (p<0.01).

We attempted to comparatively assess the relapse tendency between two methods of circumferential supracrestal fiberotomy, i.e., the conventional surgical method, as suggested by Edwards[6], versus diode laser supracrestal fiberotomy. No statistical significance was found (p>0.05) between the conventional (irregularity index=2.53±0.78, rotation=5.16±3.78˚) and diode laser circumferential supracrestal fiberotomy (irregularity index=2.06±0.86, rotation=3.78±1.17˚). This held true for both the irregularity index (p=0.35) and rotation angulations (p=0.41). Similar results were observed by Miresmæili et al.[13]. They noted that circumferential supracrestal fiberotomy procedures decreased rotational relapse and there was no statistical difference between the laser group (4.89±2.08˚) and the conventional circumferential supracrestal fiberotomy group (5.09±1.59˚). This suggested that the decrease in relapse tendency of mandibular anterior teeth, achieved using either method of fibrotomy, was comparable.

Since there is insufficient literature reporting the efficacy of diode laser fiberotomy and comparing its effects with conventional surgical fiberotomy, our study was designed to bridge this prevalent gap. However, the sample size in this study is small, and it is necessary for future studies with a larger sample size and longer duration of relapse assessment to be conducted.

Several contributing factors to long-term relapse, such as the growth of the jaws,[24] third molars,[25] intercanine width changes,[26] and labial inclination of the incisors must be considered.[27] Circumferential supracrestal fiberotomy decreases the relapse tendency in the short term. Since early relapse and crowding can increase the severity of long-term relapse, it must not be ignored. Therefore, this study highlights the importance of circumferential supracrestal fiberotomy (whether surgical or laser) in alleviating the post-treatment rotational relapse.

Study Limitations

To accurately measure the amount of relapse occurring after alignment, the archwire must be removed for at least 6 months. However, this would raise serious ethical concerns not only in terms of allowing the relapse to occur but also for extending the treatment duration. Therefore, a future study could be designed where the relapse tendency is assessed for a longer duration after appliance removal. Furthermore, it is imperative that future studies are conducted with a larger sample size to report the results with greater accuracy.

CONCLUSION

The prevention of relapse of orthodontically derotated teeth is of great importance for successful treatment. Different methods have been utilized to decrease the relapse tendency of orthodontically derotated teeth, such as early correction, overcorrection of the rotation of teeth, and long-term retention. Circumferential supracrestal fiberotomy (whether done conventionally or with Diode Laser) is now routinely used and has proven to be a potent tool for successful treatment. Our study emphasizes the importance of circumferential supracrestal fiberotomy in decreasing the relapse tendency of derotated mandibular anterior teeth. It also asserts that, although soft tissue lasers are popular in orthodontics, they are not a superior procedure in preventing rotational relapse than the conventional surgical circumferential supracrestal fiberotomy.

Ethics

Ethics Committee Approval: Ethical approval was obtained from the Institutional Ethics Committee of Manav Rachna Dental College (ref no. MRDC/IEC/2019/16).

Informed Consent: Informed consent was obtained from all patients for their participation in the study. Patient consent was obtained to participate in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - S.K., A.M., P.B., N.A., A.K.S.; Design - S.K., A.M., P.B., N.A., A.K.S.; Supervision - S.K., A.M., P.B., N.A., A.K.S.; Fundings - S.K., A.M., P.B.; Materials - S.K., A.M., P.B., A.K.S.; Data Collection and/or Processing - S.K., A.M.; Analysis and/or Interpretation - S.K., A.M., P.B., N.A., A.K.S.; Literature Review - S.K., A.M.; Writing - S.K., A.M., P.B., N.A., A.K.S.; Critical Review - A.M., P.B., N.A., A.K.S.

Declaration of Interests: All authors declare that they have no conflict of interest.

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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DOI: 10.4274/TurkJOrthod.2023.2022.141

TURKISH JOURNAL of ORTHODONTICS

Original Article

Comparison of Rapid Maxillary Expansion and Alternate Rapid Maxillary Expansion and Constriction Protocols with Face Mask Therapy

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Cite this article as: Kayfaoğlu GE, Esenlik E. Comparison of Rapid Maxillary Expansion and Alternate Rapid Maxillary Expansion and Constriction Protocols with Face Mask Therapy. *Turk J Orthod.* 2023; 36(4): 231-238

Main Points

- Although Class III anomalies are an area known and researched by many orthodontists, we realized that the intraoral appliances used in their treatment were not investigated in the same way.
- The position of the incisors before and after the treatment is an important issue for the success and retention of the treatment; therefore, the intraoral appliances and the effect of these appliances on the skeletal and teeth are also important.
- Class III malocclusions/anomalies can be managed by improving facial profile and oral health with proper diagnosis and treatment methods.
- With the correct timing and appropriate treatment methods, anomalies can be eliminated in a shorter time period by avoiding unwanted tooth movements.

ABSTRACT

Objective: This study compared dentoskeletal and soft tissue changes with face mask (FM) therapy. Rapid maxillary expansion (RME) and alternate rapid maxillary expansion and constriction (Alt-RAMEC) protocols were used with the two different types of expansion appliance, and their effects on the treatment outcome were investigated.

Methods: The study consisted of 79 (37 and 42 patients in the RME and Alt-RAMEC groups with FM, respectively) patients who had received FM treatment. The effects of the RME/FM (20 female, 17 male) and Alt-RAMEC/FM (14 female, 28 male) protocols were evaluated using lateral cephalometric films. The chronological ages of the RME/FM and Alt-RAMEC/FM groups were 11.58 and 11.99 years, respectively. In addition, both groups were divided into two subgroups based on the design of the expansion appliance (Spolyar or full coverage type). Differences in all parameters were analyzed using Student's t-tests.

Results: The maxilla significantly moved forward in both the RME/FM and Alt-RAMEC/FM groups ($p<0.001$). No significant skeletal differences were observed between the groups. Sagittal movement of the upper incisors significantly increased, and the lower incisors significantly retruded in both groups. While similar skeletal changes were found between the Spolyar and full-coverage appliance groups, the upper incisors protruded significantly more in the full-coverage type.

Conclusion: RME/FM and Alt-RAMEC/FM therapies were found to be efficient for maxillary protraction and resulted in similar skeletal changes. A full-coverage expansion appliance produced a more upper incisor protrusion than a spherical-type appliance.

Keywords: Alt-RAMEC, Face mask therapy, Full coverage appliance, RME, Spolyar-type appliance

INTRODUCTION

Protracting (moving forward) the maxilla with rapid maxillary expansion (RME) and face mask (FM) therapy is a successful treatment method for correcting skeletal Class III anomalies with maxillary deficiency.[1-3] RME has been recommended before or during FM treatment as it stimulates maxillary movement by adjusting circummaxillary sutures. This eliminates transversal deficiency in the maxilla and prevents constriction of the anterior region

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Received: September 20, 2022
Accepted: February 10, 2023
Publication Date: December 29, 2023

that may occur during protraction.[2] Various modifications of maxillary expansion appliances have been introduced for intraoral anchorage of the FM. Haas[4] proposed designing an appliance for maxillary expansion to increase orthopedic effects while reducing dental side effects. He introduced the acrylic Haas-type expansion appliance, covering both teeth and palatal tissue, providing support for transferring expansion forces to the maxillary skeletal base.[4] Modifications of tooth- and tissue-supported expansion appliances have been reported to prevent molar tipping and ensure vertical direction control have been reported in previous studies.[5,6] Spolyar[7] designed an expansion appliance covering the buccal segments with acrylic while leaving the palatal side open for better hygiene. The posterior acrylic part served as a bite block to control the vertical direction. In 2005, Liou and Tsai[8] introduced a novel maxillary expansion method known as the "alternate rapid maxillary expansions and constrictions" (Alt-RAMEC), a recurrent weekly expansion and constriction protocol lasting 9 weeks. This method enables better separation of circummaxillary sutures better than the RME procedure, stimulating maxillary forward movement. Despite these advancements, there is no consensus on the comparative effects of Alt-RAMEC and RME protocols with FM therapy on maxillary protraction rates. Therefore, the present study aimed to compare the effects of the two expansion protocols, both with FM therapy and using two different appliance designs, on maxillary protraction.

METHODS

This retrospective study involved lateral cephalometric films of 79 patients with FM therapy for maxillary retrusion or a combination of maxillary retrusion and mandibular protrusion at the Akdeniz University, Department of Orthodontics. The study was approved by the University of Health Sciences Turkey, Antalya Training and Research Hospital Ethics Committee (approval no: 3/12, date: 08.02.2018). Using the G*Power 3.1 software,[9] determined a minimum of 16 patients per group were required with a power of 95% and a margin of error of 0.05 using the t-test. Lateral cephalometric films obtained before treatment (T0) and after maxillary protraction (T1) were evaluated. Inclusion criteria encompassed no syndrome or systemic disease, no history of of orthodontic treatment, Class III anomaly with maxillary retrusion or a combination of maxillary retrusion and mandibular protrusion, age between 7 and 14 years, maxillary protraction therapy with a Petit-type FM associated with RME or Alt-RAMEC, a bonded expansion appliance, and a minimum 3 mm overjet and a Class 1 relationship at the end of the facemask treatment.

All consecutively treated FM patients were evaluated, and those treated with a Petit-type FM and maxillary expansion were included. Exclusions were based on appliance type (Fan or banded types), FM type (Delaire or Nanda types), and the lack of radiographic records. The remaining 79 patients were divided into RME/FM (37 patients) or Alt-RAMEC/FM (42 patients) groups. (Table 1). A nine-week expansion and constriction protocol was used for the Alt-RAMEC group, as suggested by Liou and Tsai.[8] In the RME protocol, the screw was initially turned twice daily for 7 days to open the midpalatal suture and then once daily until, a 2-mm overcorrection transversely in maxillary and mandibular molars.

The effects of these two protocols were compared using cephalometric analysis. Subgroups were then divided based on the type of intraoral appliance: a full-coverage bonded expansion appliance or a spolyar-type bonded expansion appliance (Table 1). The effects of these appliances on skeletal, dental, and soft tissues were also compared using cephalometric analysis.

The bonded expansion appliance used in this study (Figure 1) resembled that designed by Dr. Spolyar.[7] In the Spolyar[7] appliance group, the buccal, palatinal, and occlusal sides of the premolar and molar teeth were covered with acrylic; leaving palatal tissue was acrylic-free. In the full coverage appliance group (Figure 2), all teeth and palatal tissue were covered with acrylic. Protraction elastics were facilitated with two hooks added between the lateral and canine in both appliance types.

Figure 1. Spolyar type expansion appliance; acrylic covers only the buccal, palatinal, and occlusal sides of the premolar and molar teeth

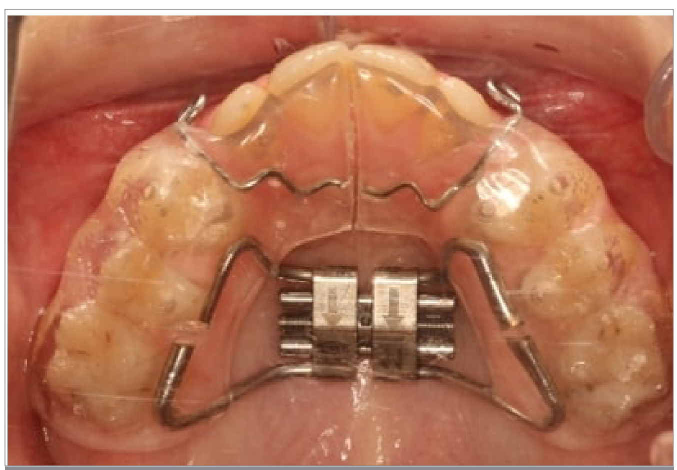

Figure 2. Full coverage type expansion appliance; acrylic covers the palatinal side of all the teeth and the buccal and occlusal sides of the premolar and molar teeth

Cephalometric analyses used in the study are shown in Figures 3 and 4.

The mean ages of the patients at the beginning and end of the orthopedic treatment, treatment duration, and gender distribution in the groups are shown in Table 1.

Statistical Analysis

Cephalometric landmark identifications, tracings, and measurements were conducted on 40 randomly selected radiographs with a 2-week period after the first measurements by the same author (first author) to determine the method error. The reliability of the measurements was assessed using Cronbach's alpha reliability test, yielding coefficients of reliability of 0.90 for all measurements. Changes between periods (T0 and T1) were analyzed for both groups. Differences in all parameters by the therapies were examined using Student's t-tests. A paired t-test was used for intragroup comparisons between T0 and T1, whereas an independent t-test was used for intergroup comparisons (treatment changes). A statistically significant p-value was considered as <0.05. All statistical analyses were conducted using the Statistical Package for the Social Sciences version 22 (IBM; Armonk, NY).

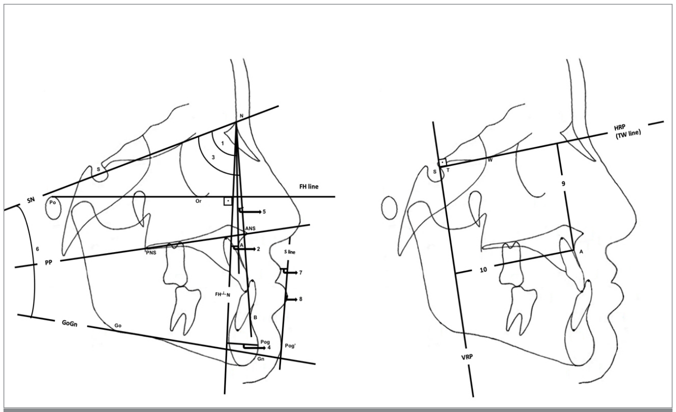

Figure 3. Skeletal and soft tissue cephalometric analyses. HRP indicates T-W line; VRP, perpendicular line to HRP; S line, line between the soft tissue S point and Pog'; SN, line between Sella and Nasion; PP (Palatal plane), line between ANS and PNS; GoGn, line between Gonion and Gnathion; FH, line between Porion and Orbitale; FH┴N, perpendicular line from Nasion to FH line; 1, SNA°; 2, FH┴N-A; 3, SNB°; 4, FH┴N-Pg; 5, ANB; 6, SN/GoGn°; 7, upper lip-S; 8, lower lip-S; 9, A-HRP; 10, A-VRP.
HRP, horizontal reference plane; VRP, vertical reference plane.

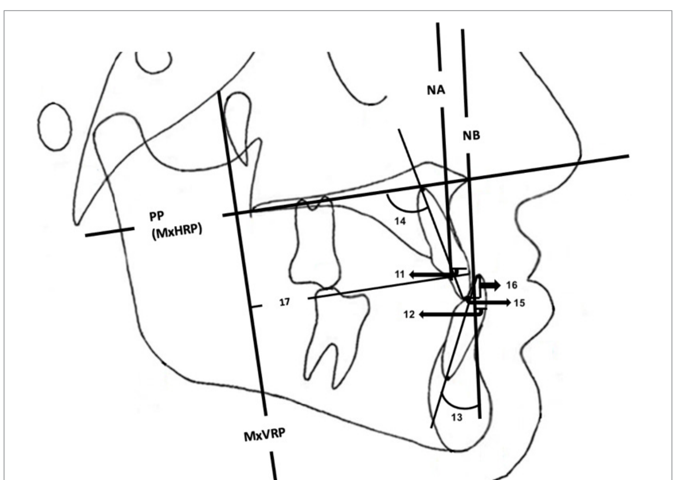

Figure 4. Dental cephalometric analyses. NA, indicates line between Nasion and A point; NB, line between Nasion and B point; Mx-VRP, perpendicular line to PP from distal point of the pterygomaxiller fissure; Mx-HRP (Palatal plane); 11, U1i-NA; 12, L1i-NB; 13, L1i/NB°; 14, U1/PP°; 15, overjet; 16, overbite; 17, U1-MxVRP.

RESULTS

Skeletal, Dentoalveolar, and Soft Tissue Changes in the RME/FM Therapy and Alt-RAMEC/FM Therapy Groups

The cephalometric changes between T0 and T1 for both groups are shown in Table 2. The maxilla significantly moved forward in both groups, and all maxilla-dependent measurements also significantly increased [p<0.001 for all measurements except A-horizontal reference plane (HRP) in RME/FM (p<0.01)]. Regarding mandibular parameters, the mandible displayed significant backward rotation in both groups. Similarly, there was a significant increase in the vertical plane angle (SN/GoGn°, p<0.001). Maxillomandibular measurement (ANB°) significantly increased in both groups (p<0.001).

In terms of dentoalveolar changes, both groups showed a statistically significant increase in overjet (p<0.001). Significant protrusions of upper incisors were observed only in the Alt-RAMEC/FM group [U1i-NA (mm), U1/PP°; p<0.05]. Both groups displayed significantly lower incisor retrusion [L1i-NB (mm), L1i/NB°]. Overbite was significantly reduced only in the Alt-RAMEC/FM group (p<0.01).

Soft tissue profile evaluation revealed increased facial convexity in both groups. The upper lip-S (mm) measurement significantly increased (p<0.001), and soft tissue facial angle (p<0.001) significantly decreased in both groups. The only significant differences between the groups following the treatment was in the upper lip-S (mm) measurement (p<0.05, Table 2).

Comparison of Spolyar and Full-Coverage Appliance Types in the RME/FM Group

Intra-group treatment changes in the Spolyar and full-coverage expansion appliance groups with the RME/FM protocol and their comparisons are shown in Table 3. FM treatment significantly

Table 1. Mean treatment duration, age, and sex distribution

Study groups		RME/FM (n=37)		Alt-RAMEC/FM (n=42)	
Appliance type		Spolyar type	Full coverage type	Spolyar type	Full coverage type
n		20	17	19	23
Gender	Female	10	10	6	8
	Male	10	7	13	15
Chronological age		11.85	11.27	11.93	12.04
Treatment duration		8.95	6.88	8.74	7.35

RME/FM, Rapid maxillary expansion/face mask; Alt-RAMEC/FM, Alternate rapid maxillary expansions and constrictions changed maxillary, mandibular, and maxillomandibular skeletal measurements. Vertical plane angle (SN/GoGn°) also changed in both appliance types.

A statistically significant difference in upper incisor dentoalveolar measurements was observed between the Spolyar and full coverage appliance groups. Upper incisors significantly protruded only in the full-coverage appliance group [U1i-NA (mm), U1/PP°, U1-MxVRP]. The only significant differences between the two appliance groups was in the U1/PP° parameter (p<0.05, Table 3).

Comparison of Spolyar and Full-Coverage Appliance Types in the Alt-RAMEC/FM Group

Intra- and intergroup treatment changes between the Spolyar and full-coverage expansion appliance groups in the Alt-RAMEC/FM protocol are shown in Table 4. Similar to the RME/FM group, no significant changes between the Spolyar and full coverage appliance groups were found in maxillary, mandibular, maxillomandibular, and vertical measurement.

Similar to the RME/FM group, significant differences between the appliance types were mainly observed in the upper incisor parameters [U1/PP°, U1i-NA (mm), U1-MxVRP (mm)]. As an effect of the upper incisor changes, upper lip protrusion was more prominent in the full coverage appliance group than in the Spolyar group [upper lip-S (mm), p<0.001]. The lower lip protruded only in the full coverage group, and these changes were statistically significant [lower lip-S (mm), p<0.01]. These soft tissue changes [upper lip-S (mm), lower lip-S (mm)] were also statistically significant between the Spolyar and full coverage groups (p<0.01, Table 4).

DISCUSSION

FM therapy with or without maxillary expansion is a common technique used in patients with skeletal Class III anomalies with maxillary retrognathia.[1-3,10,11] Although some studies have reported no significant difference in maxillary protraction rates[3,11] in FM therapy with or without RME, clinicians tend to combine it with RME.[1,2] As an alternative to this procedure, the Alt-RAMEC protocol has recently been utilized with FM therapy to enhance the effect of expansion on the maxilla, facilitate maxillary movement, and increase the rate of maxillary protraction.[8,12] In a prior study, Alt-RAMEC procedures demonstrated the ability to open both sagittal and coronal circummaxillary sutures more than conventional RME.[13] It was also claimed that Alt-RAMEC provided slight forward movement of the A point (mean, 0.89 mm) without an extra-oral force in a group of patients with Class III anomalies.[14] According to a randomized controlled trial conducted by Liu et al.,[15] the Alt-RAMEC protocol with FM therapy was compared with the RME protocol with FM therapy.

Table 2. Intra-group changes (T0-T1) by the face mask therapy and comparisons between the RME/FM and Alt-RAMEC/FM groups

	RME/FM n=37				Alt-RAMEC/FM n=42				p†
Variables	T0	T1	T1-T0	p value	T0	T1	T1-T0	p value	
	Mean ± SD	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	Mean ± SD		
SNA°	77.51±2.21	79.34±2.42	1.83±1.17	**<0.001**	77.73±1.92	80.04±2.38	2.3±1.6	**<0.001**	0.136
(FH┴N)-A (mm)	-1.78±2.33	-0.38±2.53	1.4±1.22	**<0.001**	-2.38±2.65	-0.49±2.8	1.89±1.11	**<0.001**	0.061
A-HRP	50.11±5.9	51.15±6.38	1.04±1.79	**0.001**	51.04±5.67	52.33±5.94	1.3±1.84	**<0.001**	0.541
A-VRP	49.66±6.11	51.56±6.15	1.89±2.38	**<0.001**	49.9±6.16	51.98±6.57	2.09±2.22	**<0.001**	0.71
SNB°	79.1±2.95	78.2±2.99	-0.9±1.3	**<0.001**	79.65±2.37	78.57±2.26	-1.08±1.32	**<0.001**	0.546
(FH┴N)-Pg (mm)	0.06±6.17	-2.09±5.64	-2.15±2.46	**<0.001**	-1.18±5.04	-3.36±4.56	-2.18±2.07	**<0.001**	0.958
ANB°	-1.59±1.63	1.14±1.86	2.73±1.58	**<0.001**	-1.91±1.65	1.47±1.41	3.38±1.4	**<0.001**	0.056
SN/GoGn°	35.68±4.88	37.46±4.67	1.79±1.54	**<0.001**	34.47±4.69	36.44±4.41	1.97±1.63	**<0.001**	0.608
U1i-NA (mm)	3.58±1.7	3.84±1.88	0.26±1.1	0.156	4.05±2.49	4.61±2.73	0.56±1.4	**0.013**	0.303
L1i-NB (mm)	3.59±1.56	3.33±1.62	-0.26±0.67	**0.023**	3.71±1.88	3.34±1.87	-0.37±0.88	**0.009**	0.538
L1i/NB°	17.91±4.33	16.75±4.18	-1.15±1.65	**<0.001**	19.69±5.57	18.16±5.91	-1.53±2.71	**0.001**	0.455
U1/PP°	110.11±5.98	110.32±5.50	0.21±3.39	0.689	111.93±5.23	113.19±6.26	1.26±3.53	**0.026**	0.189
Overjet (mm)	-1.07±1.43	3.18±0.85	4.25±1.36	**<0.001**	-1.12±1.17	3.7±1.1	4.82±1.53	**<0.001**	0.086
Overbite (mm)	0.94±2.08	0.43±1.76	-0.51±1.8	0.095	1.28±2.21	0.39±2.1	-0.89±1.91	**0.004**	0.362
U1-MxVRP	45.68±4.03	47.31±3.63	1.64±2.4	**<0.001**	46.76±4.32	48.8±4.52	2.05±1.72	**<0.001**	0.381
Upper lip-S (mm)	-1.82±2	-0.52±2.04	1.3±0.96	**<0.001**	-2.14±2.07	-0.26±1.93	1.88±1.28	**<0.001**	0.025
Lower lip-S (mm)	0.36±2.27	0.5±2.24	0.14±1.55	0.592	0.39±2.07	0.61±2.35	0.22±1.61	0.379	0.816
Soft tissue facial angle	170.85±5.24	166.68±5.14	-4.16±3.68	**<0.001**	171.51±3.67	166.76±3.51	-4.75±2.58	**<0.001**	0.416

T0, Before treatment; T1, After maxillary protraction treatment; T1-T0, Treatment period; SD, Standard deviation; p, Intragroup comparison, paired t-test; p†: Intergroup comparison, independent t-test. Statistically significant differences are written in bold (p<0.05)

Table 3. Mean changes in the RME/FM group by appliance type and their comparisons

RME/FM	Spolyar type appliance (n=20)				Full coverage type appliance (n=17)				p†
Variables	T0 Mean ± SD	T1 Mean ± SD	T1-T0 Mean ± SD	p value	T0 Mean ± SD	T1 Mean ± SD	T1-T0 Mean ± SD	p value	
SNA°	77.61±2.19	79.47±2.3	1.86±1.31	**<0.001**	77.39±2.29	79.19±2.63	1.81±1.02	**<0.001**	0.901
(FH┴N)-A (mm)	-1.07±1.78	0.51±2.22	1.58±1.36	**<0.001**	-2.61±2.66	-1.42±2.53	1.19±1.02	**<0.001**	0.342
A-HRP	52.27±6.48	53.7±6.91	1.43±1.72	**0.002**	47.57±3.96	48.16±4.18	0.59±1.82	0.197	0.163
A-VRP	49.15±7.04	51.08±7.5	1.93±2.24	**0.001**	50.27±4.95	52.12±4.2	1.85±2.61	**0.01**	0.924
SNB°	79.29±2.7	78.13±2.51	-1.16±1.36	**0.001**	78.88±3.29	78.29±3.55	-0.59±1.19	0.056	0.19
(FH┴N)-Pg (mm)	0.89±5.96	-1.11±5.43	-2±2.61	**0.003**	-0.92±6.45	-3.25±5.82	-2.34±2.34	**0.001**	0.686
ANB°	-1.68±1.86	1.34±2	3.02±1.73	**<0.001**	-1.49±1.37	0.91±1.72	2.4±1.36	**<0.001**	0.243
SN/GoGn°	34.5±5.16	36.17±4.89	1.67±1.14	**<0.001**	37.06±4.28	38.98±4.03	1.92±1.94	**0.001**	0.964‡
U1i-NA (mm)	3.41±1.86	3.36±2.19	-0.05±1.08	0.838	3.78±1.53	4.41±1.28	0.63±1.03	**0.023**	0.06
L1i-NB (mm)	3.34±1.65	3.17±1.7	-0.17±0.65	0.258	3.89±1.45	3.52±1.56	-0.36±0.69	**0.044**	0.209‡
L1i/NB°	17.86±4.49	16.94±4.53	-0.92±1.04	**0.001**	17.96±4.28	16.53±3.86	-1.44±2.16	**0.015**	0.821‡
U1/PP°	111.58±6.82	110.66±6.38	-0.92±3.52	0.26	108.35±4.41	109.91±4.41	1.56±2.77	**0.031**	0.024
Overjet (mm)	-0.73±1.41	3.37±0.97	4.1±1.39	**<0.001**	-1.48±1.4	2.95±0.65	4.43±1.33	<0.001	0.462
Overbite (mm)	0.74±2.05	0.32±1.91	-0.42±2.08	0.378	1.18±2.16	0.56±1.62	-0.61±1.47	0.105	0.752
U1-MxVRP	47.16±2.99	48.36±2.86	1.2±2.63	0.055	43.94±4.47	46.08±4.11	2.15±2.05	**0.001**	0.236
Upper lip-S (mm)	-2.1±1.94	-0.71±1.89	1.39±0.93	**<0.001**	-1.5±2.09	-0.31±2.24	1.19±1.02	**<0.001**	0.546
Lower lip-S (mm)	-0.13±2.07	-0.12±1.66	0.01±1.22	0.986	0.94±2.42	1.24±2.64	0.29±1.89	0.531	0.579
Soft tissue facial angle	169.54±5.6	164.86±5	-4.68±3.76	**<0.001**	172.39±4.45	168.83±4.56	-3.56±3.59	**0.001**	0.365

T0, Before treatment; T1, After maxillary protraction treatment; T1-T0, Treatment period; SD, Standard deviation; p, Intragroup comparison; paired t-test; p†: Intergroup comparison, independent t-test; ‡: Mann-Whitney U test. Statistically significant differences are written in bold ($p<0.05$)

Table 4. Mean changes in the Alt-RAMEC/FM group by appliance type and their comparisons

Alt-RAMEC/FM	Spolyar type appliance (n=19)				Full coverage type appliance (n=23)				p†
Variables	T0 Mean ± SD	T1 Mean ± SD	T1-T0 Mean ± SD	p value	T0 Mean ± SD	T1 Mean ± SD	T1-T0 Mean ± SD	p value	
SNA°	78.24±1.56	80.3±2.23	2.06±1.57	**<0.001**	77.32±2.12	79.82±2.52	2.5±1.63	**<0.001**	0.38
(FH┴N)-A (mm)	-1.6±2.61	0.44±2.83	2.04±1.29	**<0.001**	-3.03±2.56	-1.25±2.59	1.77±0.94	**<0.001**	0.45
A-HRP	53.69±4.5	55.44±5.02	1.74±2.21	**0.003**	48.84±5.68	49.77±5.48	0.93±1.42	**0.005**	0.175
A-VRP	48.19±6.77	50.16±7.38	1.97±2.47	**0.003**	51.3±5.35	53.49±5.53	2.19±2.04	**<0.001**	0.755
SNB°	79.42±2.2	78.45±2.07	-0.97±1.02	**0.001**	79.83±2.54	78.67±2.44	-1.17±1.54	**0.001**	0.389‡
(FH┴N)-Pg (mm)	-0.85±4.62	-2.48±4.39	-1.63±1.94	**0.002**	-1.46±5.45	-4.1±4.66	-2.63±2.11	**<0.001**	0.12
ANB°	-1.18±1.15	1.85±1.33	3.04±1.08	**<0.001**	-2.51±1.77	1.16±1.42	3.67±1.58	**<0.001**	0.146
SN/GoGn°	35.92±4.72	37.49±4.47	1.58±1.76	**0.001**	33.28±4.42	35.57±4.26	2.3±1.49	**<0.001**	0.16
U1i-NA (mm)	3.26±2.17	3.25±2.39	-0.01±1.75	0.979	4.7±2.59	5.73±2.51	1.03±0.82	**<0.001**	**0.025**
L1i-NB (mm)	3.6±1.83	3.02±1.8	-0.58±1.15	**0.039**	3.8±1.96	3.61±1.93	-0.19±0.54	0.104	0.713‡
L1i/NB°	18.96±5.24	16.89±5.22	-2.07±3.34	**0.014**	20.28±5.88	19.2±6.34	-1.08±2.02	**0.018**	0.264
U1/PP°	112±5.39	111.95±6.93	-0.05±3.99	0.955	111.87±5.21	114.21±5.6	2.34±2.74	**<0.001**	**0.027**
Overjet (mm)	-0.81±1.11	3.57±1.14	4.37±1.58	**<0.001**	-1.37±1.18	3.81±1.08	5.18±1.42	**<0.001**	0.088
Overbite (mm)	1.18±1.95	0.67±1.97	-0.51±1.7	0.212	1.37±2.44	0.16±2.21	-1.21±2.05	**0.009**	0.236
U1-MxVRP	47.91±4.52	49.31±4.91	1.4±1.82	**0.004**	45.81±4.01	48.39±4.24	2.58±1.47	**<0.001**	**0.025**
Upper lip-S (mm)	-2.08±1.97	-0.76±1.89	1.32±1.07	**<0.001**	-2.19±2.19	0.15±1.9	2.34±1.26	**<0.001**	**0.008**
Lower lip-S (mm)	0.17±2.15	-0.5±2.31	-0.67±1.66	0.097	0.58±2.03	1.53±1.98	0.96±1.16	**0.001**	**0.001**
Soft tissue facial angle	171.05±3.9	166.55±2.64	-4.51±2.72	**<0.001**	171.9±3.51	166.93±4.14	-4.96±2.5	**<0.001**	0.982

T0: Before treatment; T1: After maxillary protraction treatment; T1-T0: Treatment period; SD: Standard deviation; p: Intragroup comparison, paired t-test; p†: Intergroup comparison, independent t-test; ‡: Kruskal-Wallis test. Statistically significant differences are written in bold ($p<0.05$)

They found that the average maxillary forward movements were 3.04 mm and 2.11 mm in the Alt-RAMEC and RME groups, respectively. Although this difference was statistically significant, they stated that it might not be clinically relevant.[15] Some systematic reviews have suggested that Alt-RAMEC results in a small, but significantly greater increase in maxillary protraction.[16,17] However, there are some inconsistencies regarding its effects in the literature.[8,11-19] Therefore, the main purpose of the present study was to compare the effectiveness of RME/FM and Alt-RAMEC/FM procedures.

In this study, the maxilla exhibited significant protraction in both treatment protocols. Consistent with previous studies, there were notable increases in the maxilla-dependent variables [SNA°, (FH┴N)-A (mm), A-HRP, and A-VRP].[15,18,19] When assessing the amount of forward movement of the maxilla (A-VRP), it was observed that the A-point increased by 2.09 mm and 1.89 mm in the Alt-RAMEC/FM and RME/FM groups, respectively, a difference that is neither statistically significant nor clinically relevant. These protraction rates fell within the range of A-point (1.8-3.4 mm) movement reported in previous studies using the RME and Alt-RAMEC procedure with FM therapy.[15,18-21] However, it seems that our Alt-RAMEC/FM group had lower maxillary protraction rates than those reported in previous studies using the Alt-RAMEC procedure with FM therapy.[8,15,17,19] For instance, Liou and Tsai[8] found that the A point moved forward in the Alt-RAMEC group almost two times more than that in the RME group, indicating a significant increase in the protraction rate. However, Liou and Tsai[8] used a double-hinged expander in their study, whereas a Hyrax expander with acrylic coverage was used in this study. Their original design might have provided better maxillary protraction, as the double hinge could create torque movement on the maxillary sutures by facilitating a more stimulated adjustment response.[8] Overall, however, both RME/FM and Alt-RAMEC/FM protocols resulted in successful maxillary protraction and improvement of the maxillomandibular sagittal relationship; neither procedure demonstrated superiority over the other in the present study.

Skeletal modifications induced by FM therapy have been reported to included forward displacement of the maxilla, backward movement of the mandible, counterclockwise rotation of the maxilla, and clockwise rotation of the mandible.[11] Therefore, the vertical movement of the maxilla (A-HRP) was evaluated in the present study, and vertical displacements of 1.3 and 1.04 mm were determined in the Alt-RAMEC/FM and RME/FM groups, respectively.

The mandibular response to FM therapy is well known. Some clinicians have claimed that the mandibular effective length can be restricted due to the chincap of the FM.[1,2] Others have reported that the effective mandibular length increases because of growth and development during treatment in the pre-peak and peak growth periods.[10,22] The role of mandibular modification in maxillomandibular sagittal improvement results in part from mandibular restriction and in part from mandibular posterior rotation by the chincap. Maxillary protraction therapy and expansion results in extruded maxillary molar teeth that are tipped buccally, slight counterclockwise rotation of the maxilla, and clockwise rotation of the mandible.[3,11,15] Gallagher et al.[23] suggested that the backward rotation of the mandible is caused by the rotation effect of the maxillary protraction forces and the tipping and extrusion of the maxillary molar teeth created by maxillary expansion. In the present study, the SNB° and Pogonion protrusion [(FH┴N)-Pg] decreased, indicating a clockwise rotation of the mandible by the chincap of the FM, consistent with the results of previous studies.[1,11] These mandibular changes also contributed to the improvement of maxillomandibular discrepancy. Consistent with the results of previous studies, both the RME/FM and Alt-RAMEC/FM groups showed significant improvements in the maxillomandibular relationship.[15,19] The ANB° angle increased by 2.73° in the FM/RME group and 3.38° in the Alt-RAMEC/FM group; there was no significant difference between the two groups.

Rotation of the mandible is associated with increases in vertical dimensions.[24] Kwak et al.[24] reported that these vertical skeletal changes were related to the initial mandibular plane angle, severity of skeletal malocclusion, and the amount of growth during treatment. In the present study, SN/GoGn° increased in both groups (1.79° and 1.97° in the RME/FM and Alt-RAMEC/FM groups, respectively), and the difference between the groups was not significant. Although these increases were statistically significant, they may not be clinically relevant because the posterior acrylic blocks created a temporary interocclusal space. Similar to our study, Isci et al.[19] found a clockwise rotation in the mandibular plane angle resulting from the Alt-RAMEC and RME/FM procedures, and no significant differences between the groups were observed.

The second aim of this study was to compare two different types of intraoral appliances for FM anchorage. Both the RME/FM and Alt-RAMEC/FM groups included two different bonded intraoral appliances. Although these two appliances were designed similarly regarding the covering of the occlusal surfaces with acrylic, the coverage of the palatal surface and incisors differed. Maxillary protraction rates were similar between the two appliance groups. Studies on maxillary expansion have shown that A point moves forward and downward with the use of different kinds of RME appliances.[4,6,25] Regardless of these findings, Sarver and Johnston26 claimed that forward movement of the A point would be limited by Spolyar-type appliance. On the contrary to this we found the forward and downward movement of A point which resulted similar for each appliance that we combined with.

In the Spolyar appliance group, the upper incisors were covered by the appliance and were slightly retruded following treatment. The retrusion of the upper incisors in the Spolyar appliance group likely resulted from changes in the balance of pressure between the cheeks and upper lip following maxillary expansion and protraction. Some have claimed that the tongue is positioned more inferiorly than normal because of the acrylic blocks in the bonded expansion appliances, and the incisors are retruded by the muscles around the stretched mouth.[25] Sarver and Johnston[26] and Habeeb et al.[27] observed palatal tipping when using the Spolyar expansion appliance. They stated that these changes were due to the pulling forces of the transseptal periodontal fibers between the teeth; to mitigate this, they recommended extending the acrylic to the palatinal side of the incisors where retrusion was undesirable.[27] Similarly, Uzuner et al.[28] found upper incisor retrusion resulting from a Spolyar expansion appliance and FM therapy, whereas Ngan et al.[21] found protrusion with the same treatment protocol. In the second type of appliance group in the present study, the anterior teeth were covered by acrylic; therefore, the upper incisors protruded during expansion by opening the acrylic halves and by the protraction forces. Similarly, Arman et al.[20] reported a 2.6° increase in the angulation of the upper incisors when using a full-coverage expansion appliance with FM therapy. These anteroposterior movements of the incisor teeth were considered to be related to lip positions.[29]

In this study, the distance from the upper lip to the reference line (S line) increased significantly in all groups. The movement of the upper lip in the sagittal direction was associated with the forward movement of the maxilla and the protrusion of the upper incisors, consistent with the results of previous studies.[1,30] However, in the full-coverage appliance group (Alt-RAMEC/FM), the upper lip moved forward significantly more than in the Spolyar appliance group, probably resulting from increased upper incisor protrusion in the full-coverage appliance group. The lower lip to the S line significantly increased in the full-coverage appliance group when using the Alt-RAMEC/FM procedure. Kilicoglu and Kirlic[29] emphasized that the lower lip contacts both the lower and upper incisors following the elimination of the anterior crossbite. Therefore, the lower lip may not only be affected by the retraction of the lower incisors but also by the protracted upper incisors.[29] Therefore, in this study, for patients who underwent the Alt-RAMEC/FM procedure, changes in the upper and lower lip to S-line measurements were significantly different between the Spolyar and full coverage appliance groups. The findings of this study included only short-term results, which was one of the limitations of the study. Long-term studies regarding the stability of these two main protocols should be conducted.

CONCLUSION

RME and Alt-RAMEC combined with FM therapy resulted in similar maxillary protraction rates and mandibular skeletal changes. Spolyar and full-coverage expansion appliances did not lead to any differences in maxillary protraction. However, the upper incisors retruded and protruded in the Spolyar and full coverage appliance group. Therefore, the choice between these two types of appliances should be based on the pretreatment upper incisor positions.

Ethics

Ethics Committee Approval: The study was approved by the University of Health Sciences Turkey, Antalya Training and Research Hospital Ethics Committee (approval no: 3/12, date: 08.02.2018).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - E.E.; Design - E.E.; Supervision - E.E.; Materials - G.E.K.; Data Collection and/or Processing - G.E.K.; Analysis and/or Interpretation - E.E., G.E.K.; Literature Review - E.E., G.E.K.; Writing - E.E., G.E.K.; Critical Review - E.E., G.E.K.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declared that this study has received no financial support.

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DOI: 10.4274/TurkJOrthod.2023.2022.128

TURKISH JOURNAL of ORTHODONTICS

Original Article

Comparison of Pain Levels on Patients Undergoing Fixed Orthodontic Treatment with 2 Different Self-Ligating Bracket Systems

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Cite this article as: Dedeoğlu M, Özsoy ÖP. Comparison of Pain Levels on Patients Undergoing Fixed Orthodontic Treatment with 2 Different Self-Ligating Bracket Systems. *Turk J Orthod.* 2023; 36(4): 239-247

Main Points
- SmartClip group reported less pain at the 2nd and the 6th hours while chewing.
- Pain levels were the highest at the 6th h and the 2nd day for the Damon Q and SmartClip SL3 groups respectively.
- The SmartClip group reported more pain for the first two days, and after the 2nd day, pain scores were very similar to the Damon group.
- No statistically significant differences were reported between the groups at any time interval while biting on anterior or posterior teeth.

ABSTRACT

Objective: Comparison of pain levels of patients treated with 2 different passive self-ligating bracket systems right after initial archwire placement.

Methods: A total of 34 patients with mild crowding were allocated randomly to 2 groups to be treated using 2 different self-ligating brackets. 0.014 inch copper nitinol and 0.014 inch superelastic nitinol archwires were selected as the initial archwire for Damon Q and SmartClip SL3 systems respectively. Seven page questionnaires that consisted of 3 visual analogue scales were handled to patients to mark their pain levels while chewing, biting with anterior teeth, and biting with posterior teeth at 2nd hour, 6th hour, 2nd day, 3rd day, and 7th day time intervals. Pain scores were measured manually using a ruler and noted.

Results: The SmartClip group reported less pain at the 2nd and the 6th hours while chewing. Pain levels were the highest at the 6th h and the 2nd day for the Damon Q and SmartClip SL3 groups respectively. The SmartClip group reported more pain for the first two days, and after the 2nd day, pain scores were very similar to the Damon group. No statistically significant differences were reported between the groups.

Conclusion: The highest pain sensation was reported for the 2nd day and decreased toward the 7th day. The SmartClip SL3 group reported lower pain scores in the first two days, but the levels were equaled on the 2nd day and after.

Keywords: Pain, quality of life, self-ligating brackets

INTRODUCTION

According to the International Association for the Study of Pain, pain is an unpleasant emotional experience that can accompany or be associated with existing or possible tissue damage. The first week of orthodontic treatment does cause some degree of pain, which may be quite disturbing for some individuals.[1,2] The pain experienced by most of the orthodontic patients is a negative experience, which may even lead to the patient leaving the treatment. During the treatment, brackets and teeth are moved through the alveolar bone via the force generated by archwires. The applied force causes the vasospasm of the periodontium to compress, resulting in pain. This

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Received: August 25, 2022
Accepted: February 13, 2023
Epub: August 18, 2023
Publication Date: December 29, 2023

is a finding of hyalinized areas in the periodontal ligament. The use of light forces is recommended to reduce hyalinization and achieve a more physiological tooth movement. When it is considered biologically, applying a force that starts off slightly and resets itself to a lesser extent allows the tooth movement to occur more simply and physiologically.[3]

With self-ligating (SL) brackets, it is aimed to obtain less and more physiological force that will not irritate the periodontal tissues. By preventing indirect resorption, more effective tooth movement is obtained.[4] This may also reduce the pain sensation. In SL brackets, the bracket cap has two main tasks. The first is to lock the archwire by creating a slight force and less friction, and the second is to create a low force that controls the rotation, tipping and torque forces.[5] With SL systems, control appointment intervals are longer and appointments can be arranged in 8-10-week periods. The aim is to give acquired time to periodontal tissues for healing. SL brackets have been proposed to shorten the chair time and overall treatment duration.[6]

The most significant advantage of SL brackets compared to conventional brackets is believed to be reduced friction resistance.[7] Particularly passive SL brackets have been claimed to produce less friction force than those with active design. Thus, less force is required during tooth movement.[8] If less forces are generated with SL brackets, then one may assume that the discomfort and pain levels may also be less than expected. The aim of this study was to compare the pain levels of patients treated with 2 different passive SL bracket systems right after initial archwire placement. The null hypothesis is that the pain levels of patients treated with 2 different passive SL bracket systems right after initial archwire placement are the same.

METHODS

This study was approved by the Başkent University Non-Invasive Clinical Research Ethics Committee (project no: D-KA 16/13, date: 10.08.2016) that the rights of the human or animal subjects were protected and supported by the Başkent University Research Fund. Power analysis (GPower 3.1.0, Universität Düsseldorf, Düsseldorf, Germany), was performed to determine the sample size, and it was found that at least 10 patients for each group were needed to verify an effect with 80% power (α=0.05). Therefore, a total of 34 patients were included in the study.

Thirty four patients who sought orthodontic treatment with fixed appliances were selected. The inclusion criteria for this study were as follows: (1) absence of any systemic disease and/or allergy of the patient, (2) permanent dentition with no dental pathology (3) class I malocclusion with mild or moderate crowding (4) Non-extracion orthodontic treatment need (5) 10 to 19 years of age.

Detailed medical and dental history of all patients were taken before the beginning of the treatment. All patients were informed about this study verbally and in writing. Thirty four patients -17 in each group- who met the criteria were included in the study after reviewing the files of patients who were ready to start the treatment. Gender differences were not considered when creating groups. Each participant who agreed to participate in the study was asked to draw randomly one of the bracket systems.

Damon Q (Ormco, CA, USA) (Group 1) and Smartclip SL3 (3M, MN, USA) SL3 (Group 2) passive SL bracket systems, both with 0.022 inch slots and have standard torque values for MBT prescriptions were selected. All permanent teeth between the 2nd molar to 2nd molar in the upper and lower jaws were bonded at the same session using the direct bonding technique. Archwires were selected according to the recommendations of the manufacturers. In Group 1, a 0.014 inch Cu NiTi and for Group 2, a 0.014 inch HANT archwires were used for initial levelling and alignment. Apart from the closure mechanism differences of the Damon Q and SmartClip SL3 brackets, the slot dimensions of both brackets were the same. The CONSORT diagram displaying the flow of our work was shown in Figure 1.

As soon as the brackets were placed, a 7-page booklet was given to the patients. Each page of this form contained 3 visual analogue scales (VAS) of 100 mm. Patients were asked to mark these forms by drawing a vertical line that was closest to their pain levels during chewing, biting on the anterior teeth, and

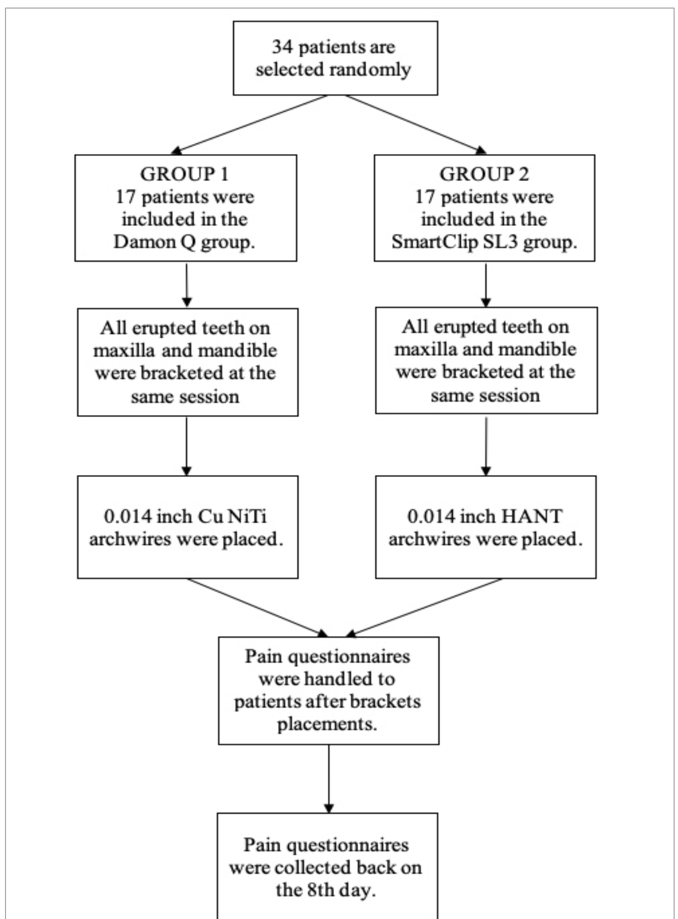

Figure 1. The CONSORT diagram shows the flow of the study

biting on the posterior teeth at 7 different time intervals. The evaluated time intervals were determined as the 2nd hour, the 6th h, the 2nd day, the 3rd day and the 7th day. Participants were asked to return their completed forms on the 8th day. The VAS scores collected from the patients were measured manually with a ruler and recorded by the same investigator. During the measurements, the names of the patients were covered to provide partial blinding.

Statistical Analysis

The data obtained in this study were analyzed with the IBM SPSS Statistics Version 20 (IBM Armonk,New York, USA) program. A Shapiro Wilk Test was used to determine the normal distribution of the variables. For pain intensity, non-parametric statistics (Mann-Whitney U test) were computed to determine any significance between the groups. To investigate repeated pain assessments, Friedman's two-way analysis of variance was calculated and the individual differences were estimated using Multiple Comparison Tests. Significant values were defined as $p<0.05$.

The VAS scores of 10 patients randomly selected for the determination of the reliability of the measurements were measured again after 2 weeks from the initial measurements. Correlation data of intraclass correlation coefficients for each variable was obtained, and it was seen that the lowest value was found to be 0.96.

RESULTS

The age distribution of Group 1 was 14.94±1.92; Group 2 was 13.65±1.66. The general age distribution was 14.29±1.88.

The perception of pain was assessed by three parameters: biting on the anterior teeth, biting on the posterior teeth, and chewing. The pain measurements that are reported according to these parameters at various time intervals are shown in Table 1.

In both groups, the pain started at the 2nd h and gradually increased, reaching the highest level in the parameters of chewing and biting on the anterior teeth on the 2nd day. The biting on the posterior teeth parameter reached the highest level at the 6th hour. According to all parameters, pain gradually decreased after 2nd day and reached the lowest values on 7th day (Table 1).

The results of the Mann-Whitney U test, that was used to assess differences between groups in terms of VAS values, are shown in Table 2.

There was a statistically significant difference between the groups in terms of the 2nd hour chewing parameter VAS values ($p<0.05$). The VAS values of Group 2 at the 2nd hour chewing and biting parameters were significantly lower than Group 1.

There was a statistically significant difference between the groups in terms of VAS values in the 6th h chewing parameter ($p<0.05$). The VAS value in the 6th h chewing parameter of Group 2 was significantly lower than that in Group 1.

There was no statistically significant difference between the groups in terms of other VAS values ($p>0.05$) (Table 2).

There was a statistically significant difference between the groups in terms of VAS values for chewing parameters in Group 1 ($p<0.05$).

In Group 1, the VAS value on the 7th day chewing parameter is significantly lower than VAS values of 6th hour and 2nd day chewing parameters and VAS value on the 3rd day chewing parameter is significantly lower than that of the VAS value on

Table 1. Distribution of VAS values

	n	Mean	Median	Min.	Max.	SD
2nd hour chewing	34	26.76	15.5	2	91	24.39
2nd hour biting on anterior teeth	34	23.93	12.5	1	92	26.25
2nd hour biting on posterior teeth	34	21.88	12.5	1	92	23.87
6th hour chewing	34	45.84	50	4.5	97	29.79
6th hour biting on anterior teeth	34	45.49	45.5	6.5	94	26.4
6th hour biting on posterior teeth	34	41.35	36.25	1.5	91	26.68
2nd day chewing	34	48.47	40.5	1	92	28.98
2nd day biting on anterior teeth	34	48.19	46.75	0.5	94.5	30.12
2nd day biting on posterior teeth	34	41.04	42.75	2	93	24.96
3rd day chewing	34	35.88	27.5	1	80.5	26.42
3rd day biting on anterior teeth	34	38.54	40	0.5	89	28.24
3rd day biting on posterior teeth	34	27.38	24.25	1	86	22.91
7th day chewing	34	15.13	9	2	70	16.52
7th day biting on anterior teeth	34	24.51	12	0	86	24.74
7th day biting on posterior teeth	34	12.38	6.25	1	60.5	14.65

Descriptive statistics of the overall VAS scores
VAS, visual analogue scale; SD, standard deviation; Min., minimum; Max., maximum

Table 2. Mann-Whitney U test regarding VAS score difference between groups

		Group						Mann-Whitney U test		
		n	Mean	Median	Min.	Max.	SD	Raw ave.	z	p value
2nd hour chewing	Group 1	17	36.62	29	5	91	28.15	21.47		
	Group 2	17	16.91	12.5	2	48	15.12	13.53	-2.32	0.02*
	Total	34	26.76	15.5	2	91	24.39			
2nd hour biting on anterior teeth	Group 1	17	24.26	15	1	92	25.87	17.79		
	Group 2	17	23.59	10	4	90.5	27.42	17.21	-0.17	0.86
	Total	34	23.93	12.5	1	92	26.25			
2nd hour biting on posterior teeth	Group 1	17	22.03	16	1	92	23.08	17.82		
	Group 2	17	21.74	11	2	90	25.34	17.18	-0.19	0.85
	Total	34	21.88	12.5	1	92	23.87			
6th hour chewing	Group 1	17	61.82	64.5	9.5	97	25.68	22.97		
	Group 2	17	29.86	19.5	4.5	79	25.06	12.03	-3.20	**0.001****
	Total	34	45.84	50	4.5	97	29.79			
6th hour biting on anterior teeth	Group 1	17	49.38	46	6.5	94	23.92	18.88		
	Group 2	17	41.59	45	7.5	91	28.86	16.12	-0.81	0.41
	Total	34	45.49	45.5	6.5	94	26.4			
6th hour biting on posterior teeth	Group 1	17	48.88	46	1.5	90	24.6	20.82		
	Group 2	17	33.82	24	4	91	27.26	14.18	-1.94	0.05
	Total	34	41.35	36.25	1.5	91	26.68			
2nd day chewing	Group 1	17	46.59	40	12	92	25.54	17.32		
	Group 2	17	50.35	50.5	1	91	32.75	17.68	-0.10	0.91
	Total	34	48.47	40.5	1	92	28.98			
2nd day biting on anterior teeth	Group 1	17	50.5	60	1	92	25.18	18.26		
	Group 2	17	45.88	45	0.5	94.5	35	16.74	-0.44	0.65
	Total	34	48.19	46.75	0.5	94.5	30.12			
2nd day biting on posterior teeth	Group 1	17	42.21	47	2	71.5	21	18.47		
	Group 2	17	39.88	35.5	2	93	29	16.53	-0.56	0.57
	Total	34	41.04	42.75	2	93	24.96			
3rd day chewing	Group 1	17	34.24	26	2	80.5	25.71	16.76		
	Group 2	17	37.53	34	1	79	27.79	18.24	-0.43	0.66
	Total	34	35.88	27.5	1	80.5	26.42			
3rd day biting on anterior teeth	Group 1	17	36.76	40	0.5	80	24.31	16.88		
	Group 2	17	40.32	33	1	89	32.36	18.12	-0.36	0.71
	Total	34	38.54	40	0.5	89	28.24			
3rd day biting on posterior teeth	Group 1	17	26.56	25.5	1	86	24.89	16.59		
	Group 2	17	28.21	23	1.5	69	21.48	18.41	-0.53	0.59
	Total	34	27.38	24.25	1	86	22.91			
7th day chewing	Group 1	17	18.09	9	2.5	70	20.23	18.65		
	Group 2	17	12.18	9	2	43	11.62	16.35	-0.67	0.50
	Total	34	15.13	9	2	70	16.52			
7th day biting on anterior teeth	Group 1	17	25.29	16	0	86	25.04	17.74		
	Group 2	17	23.74	11	2	74	25.17	17.26	-0.13	0.89
	Total	34	24.51	12	0	86	24.74			
7th day biting on posterior teeth	Group 1	17	14.09	6.5	1	60.5	17.43	18.18		
	Group 2	17	10.68	6	1	42	11.53	16.82	-0.39	0.69
	Total	34	12.38	6.25	1	60.5	14.65			

$p<0.05$ (*): Statistically significant, $p<0.001$ (**): Statistically significant. Mann-Whitney U test regarding VAS score difference between groups
VAS, visual analogue scale; SD, standard deviation; Min., minimum; Max., maximum

the 6th h chewing parameter. In Group 2, there was a statistically significant difference in time points between VAS values in chewing parameter (p<0.05). In Group 2, VAS values at 2nd hour and 2nd day chewing parameters were significantly lower than the VAS value at 2nd day chewing parameter (Table 3).

In Group 1, there was a statistically significant difference between the time points of VAS values for the biting on anterior teeth parameter (p<0.05). In Group 1, the VAS value of 2nd hour biting on anterior teeth parameters was significantly lower than that of the VAS value on the 6th hour and 2nd day biting on anterior teeth parameters and also the VAS value of 7th day biting on anterior teeth parameter was significantly lower than 2nd day biting on anterior teeth parameters. In Group 2, there was a statistically significant difference between the time points of VAS values in biting on anterior teeth parameter (p<0.05). In Group 2, VAS values at 7th h biting on anterior teeth parameters were significantly lower than the VAS value at 2nd day biting on anterior teeth parameter (Table 4).

In Group 1, there was a statistically significant difference between the time points of VAS values for the biting on anterior teeth parameter (p<0.05). In Group 1, the VAS value of 2nd hour and 7th day biting on posterior teeth parameters were significantly lower than that of the VAS values on the 6th hour and 2nd day biting on posterior teeth parameters. In Group 2, there is a statistically significant difference in time points between VAS values in biting on posterior teeth parameter (p<0.05). In Group 2, VAS values at 7th day biting on posterior teeth parameters were significantly lower than VAS values at 6th h, 2nd day, and 3rd day biting on posterior teeth parameters (Table 5).

DISCUSSION

Compared with conventional brackets, the most significant advantage of the SL brackets is assumed as the generation of low levels of friction.[9,10] Many *in vitro* studies have been carried out on the frictional resistance of SL brackets, and most of them showed that SL brackets in the laboratory environment generate less friction resistance than conventional brackets.[11,12] Therefore, it is argued that SL brackets may be more effective in lowering the pain sensation by producing less ischemia due to the low frictional force compared to conventional bracket systems.[13,14]

Two types of SL brackets were used in this study. These were selected according to the popularity of these systems. The first one was the Damon system, which consists of passive SL brackets. According to the claims of the manufacturer, the force generated by the special archwire used in the Damon bracket system is transmitted directly to the teeth and periodontium without being absorbed by the ligature due to the bracket cap structure. It has been suggested that this optimum force achieved with the tooth movement and the bone apposition, with the minimal interruption of blood flow during tooth movement shortens the patient's treatment duration and reduces pain complaints.[15] The second system was designated as SmartClip SL3. This bracket performs ligation with the help of C-shaped nickel titanium spring clips at the mesial and distal corners of the

Table 3. The Friedman's Two-Way ANOVA test on the difference between time points of VAS values for chewing parameter

								Friedman's Two-Way ANOVA			Multiple comparison
		n	Mean	Median	Min.	Max.	SD	Raw av.	Chi-square test	p value	
Group 1	2nd hour chewing	17	36.62	29	5	91	28.15	2.85	23.25	**0.001 (*)**	5-3 5-2 4-2
	6th hour chewing	17	61.82	64.5	9.5	97	25.68	4.21			
	2nd day chewing	17	46.59	40	12	92	25.54	3.62			
	3rd day chewing	17	34.24	26	2	80.5	25.71	2.38			
	7th day chewing	17	18.09	9	2.5	70	20.23	1.94			
Group 2	2nd hour chewing	17	16.91	12.5	2	48	15.12	2.26	23.77	**0.001 (*)**	5-3 1-3
	6th hour chewing	17	29.86	19.5	4.5	79	25.06	3.29			
	2nd day chewing	17	50.35	50.5	1	91	32.75	4.29			
	3rd day chewing	17	37.53	34	1	79	27.79	3.21			
	7th day chewing	17	12.18	9	2	43	11.62	1.94			

p<0.001 (*): Statistically significant. The Friedman's Two-Way ANOVA test on the difference between time points of VAS values for chewing parameter
VAS, visual analogue scale; SD, standard deviation; Min., minimum; Max., maximum

Table 4. Friedman's Two-Way ANOVA test on the difference between time points of VAS values for biting on the anterior teeth parameter

								Friedman's Two-Way ANOVA			Multiple comparison
		n	Mean	Median	Min.	Max.	SD	Raw av.	Chi-square test	p value	
Group 1	2nd hour biting on anterior teeth	17	24.26	15	1	92	25.87	2.18	19.67	**0.001** (**)	1-2 1-3 5-3
	6th hour biting on anterior teeth	17	49.38	46	6.5	94	23.92	3.74			
	2nd day biting on anterior teeth	17	50.5	60	1	92	25.18	4			
	3rd day biting on anterior teeth	17	36.76	40	0.5	80	24.31	2.85			
	7th day biting on anterior teeth	17	25.29	16	0	86	25.04	2.24			
Group 2	2nd hour biting on anterior teeth	17	23.59	10	4	90,5	27.42	2.44	13.79	**0.008** (*)	5-3
	6th hour biting on anterior teeth	17	41.59	45	7.5	91	28.86	3.53			
	2nd day biting on anterior teeth	17	45.88	45	0.5	94.5	35	3.85			
	3rd day biting on anterior teeth	17	40.32	33	1	89	32.36	3			
	7th day biting on anterior teeth	17	23.74	11	2	74	25.17	2.18			

p<0.01 (*): Statistically significant, p<0.001 (**): Statistically significant. Friedman's Two-Way ANOVA test on the difference between time points of VAS values for biting on the anterior teeth parameter
VAS, visual analogue scale; SD, standard deviation; Min., minimum; Max., maximum

Table 5. Friedman's Two-Way ANOVA test on the difference between time points of VAS values for biting on the posterior teeth parameter

								Friedman's Two-Way ANOVA			Multiple comparison
		n	Mean	Median	Min.	Max.	SD	Raw av.	Chi-square test	p value	
Group 1	2nd hour biting on posterior teeth	17	22.03	16	1	92	23.08	2.5	26.55	**0.001** (***)	5-2 5-3 1-2 1-3
	6th hour biting on posterior teeth	17	48.88	46	1.5	90	24.6	4.03			
	2nd day biting on posterior teeth	17	42.21	47	2	71.5	21	4.03			
	3rd day biting on posterior teeth	17	26.56	25.5	1	86	24.89	2.56			
	7th day biting on posterior teeth	17	14.09	6.5	1	60.5	17.43	1.88			
Group 2	2nd hour biting on posterior teeth	17	21.74	11	2	90	25.34	2.88	20.50	**0.001** (***)	5-4 5-2 5-3
	6th hour biting on posterior teeth	17	33.82	24	4	91	27.26	3.32			
	2nd day biting on posterior teeth	17	39.88	35.5	2	93	29	3.94			
	3rd day biting on posterior teeth	17	28.21	23	1.5	69	21.48	3.24			
	7th day biting on posterior teeth	17	10.68	6	1	42	11.53	1.62			

p<0.001: Statistically significant (***)
VAS, visual analogue scale; SD, standard deviation; Min., minimum; Max., maximum

bracket slot. SmartClip brackets offer both passive SL and active SL options when needed, with 4 distinct and easily accessible tie wings similar to conventional brackets. The archwires used in the current study were of the same dimension, but the material compositions were different due to the recommendations of the manufacturers.

One of the undesirable effects that can occur during fixed orthodontic treatment is pain. Pain, patient co-operation, the course of treatment, and the result can affect negatively. The sensation of pain is subjective, so it is impossible to precisely determine the duration, nature, or severity of the pain. Therefore, the patient's statement gives the most accurate information and is accepted as the gold standard.[2] Several methods have been developed for measuring pain severity. However, most of these methods are used in other medical fields rather than orthodontic studies due to various application difficulties. VAS are the most preferred for orthodontic studies. To evaluate the pain perception of the patients in our study, VAS of 100 mm lines were placed on each form which consisting of chewing, biting on the anterior teeth, and biting on the posterior teeth parameters for different time points. Patients were asked to mark their pain levels by drawing a vertical straight line on each scale for every parameter. The reason why we used VAS in our study was that it was a fast, simple and reliable method and it was easy to compare with the previous orthodontic pain studies.[16,17]

A through literature review showed that the pain reaches the highest level the day after the application of an active orthodontic force.[18,19] Erdinç and Dinçer[20] reported that the pain started to be perceived in the first 2 h, reached the highest level at the end of 24 h, continued for 3 days, and then gradually decreased. Polat and Karaman[21] reported that the orthodontic pain started at the first 2 h, reached the maximum value at 24 h, decreased afterwards, and reached very low levels at the end of the 7th day. Similar study by Scheurer et al.[22] Showed that very few patients continued to suffer from pain at the end of the 7th day.

Similar to the findings in the literature, our study found that the highest pain in chewing and biting on the anterior teeth was on the 2nd day. When biting on the posterior teeth, the pain reached the highest level at 6th hour, tended to decrease on the 3rd day and reached low levels on the 7th day. The pain felt in biting on the posterior teeth at all the time intervals evaluated in our study was felt lower by other movements and did not increase further after the first 6 h. The reason for this situation is; the force transmitted to the teeth may be too low, especially to create significant tooth movement in the posterior region since passive brackets are chosen in addition to being very thin and resilient.

The most important property of the nickel-titanium alloy (nitinol), which has a martensite stable structure and consists of 50% nickel and 50% titanium, shows low strength during the back spring.[23] Light and continuous force is applied due to its more flexible structure. The greatest advantage of nitinol is its good springiness and elasticity, which makes wide elastic deflections possible. When activated, it exhibits more springback properties than stainless steel and beta titanium wires and has higher energy. Thus, less arch-induced exchange or activation is required.[24] Sachdeva[25] claimed that the addition of copper element to nickel-titanium alloy creates more homogeneous force loads in the heat conduction, making more effective tooth movement possible. Cu NiTi wires are manufactured in three different types, at 27 °C, 35 °C and 40 °C, depending on the intended use of the orthodontic treatment. Damon claimed that using the sequence of 0.014 inches, 0.014x0.025 inches and 0.018x0.025 inches Cu NiTi at 35 °C, respectively, for more effective and rapid treatment would reduce the treatment time by 70% by applying slight forces at the bioone boundaries. Gravina et al.[26], on the other hand reported that, despite to Damon's claims, the loading forces of 35 °C Cu NiTi wires during deactivation and the percentage of deformation at the limit of neutrality were higher than 7 other types of NiTi archwires (superelastic or thermally shaped and NiTi or Cu NiTi) and they were less suitable for clinical use. They also reported that the thermoformed nitinol wires generated less deactivation force than the superelastic nitinol arch wires and that 27 °C Cu NiTi arch wires produced deactivation force of 1/3 of 35 °C Cu NiTi archwires.

In our study, pain levels for chewing parameter at 2nd hour and 6th h time points were lower in Group 2 than in Group 1. The highest pain in Group 1 was felt at 6th hour, and in Group 2, it was felt on 2nd day. According to this data, it can be said that the time to reach the highest pain level in Group 2 was shorter than Group 1. This situation is thought to be related to the structure of the archwires used. A number of research have been carried out which show that different archwire materials used in orthodontic treatment exhibit different friction characteristics.[26,27] In our study, the use of Cu NiTi archwires at 35 °C that generates more force than those of the HANT archwires could explain the significantly higher pain sensation in Group 1.

It can be considered that the surface roughness of the wire is also the effect of the applied force. Gravina et al.[26] studied 8 different archwires using SEM in terms of their chemical compositions and surface morphology. Because of the study, it was found that those with the lowest surface roughness were superelastic nitinol and those with the highest surface roughness were 27 °C and 35 °C Cu NiTi archwires. There are opinions in the literature that surface roughness increases the friction force.[28] In the same study, 35 °C Cu NiTi was found to have inadequate properties in terms of surface topography. This can be attributed to higher reported pain scores for the Damon brackets we obtained in our study.

Another reason for the highest pain level to be reached later in Group 2 may be the width difference between the Damon Q and SmartClip brackets. There are also studies in the literature that suggest that narrow brackets cause less friction between the wire and bracket, as well as those suggest that larger brackets cause less friction.[29] The bracket width has an important role in determining the interbracket distance. The interbracket distance increases as the width of the bracket-used decreases. Increasing the wire length of brackets increases the elastic deformation capability of the archwire.[30] The SmartClip SL3 brackets used in our work were wider mesiodistally than Damon Q brackets. The difference in pain perception results obtained in our study may be due to the width differences in the brackets.

Data collected in our study that the pain perception was evaluated using two different bracket systems according to their cap designs should be supported by other studies in which the number of participants is kept higher to increase the reliability of our findings.

Study Limitations

The most important limitations of this study is that the differences that may occur between genders were not examined when evaluating the sensation of pain. Females are traditionally thought to be "fragile" and sensitive to pain, whereas males are more tough and can withstand greater pain. However, there have been conflicting findings, with some indicating that men are more willing to withstand pain than women, while others claim that there are no differences between men and women when it comes to describe how much pain they feel. During fixed appliance therapy, girls experienced more discomfort/pain and ulcerations than boys, according to two studies that addressed this topic.[31] A future study must be designed considering gender - based pain sensation differences during orthodontic treatment.

CONCLUSION

The highest pain sensation was reported for the 2nd day for the patients participating in the study, and decreased toward the 7th day.

The SmartClip SL3 group reported lower pain scores in the first two days, but the levels were equaled on the 2nd day and after. Therefore, the null hypothesis is accepted.

Ethics

Ethics Committee Approval: This study was approved by the Başkent University Non-Invasive Clinical Research Ethics Committee (project no: D-KA 16/13, date: 10.08.2016).

Informed Consent: All patients were informed about this study verbally and in writing.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - Ö.P.Ö.; Design - Ö.P.Ö.; Data Collection and/or Processing - M.D.; Analysis and/or Interpretation - M.D.; Writing - M.D., Ö.P.Ö.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declared that this study has received no financial support.

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TURKISH JOURNAL of ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2023.2022.154

Original Article

Comparison of Enamel Discoloration using Flash-Free and Conventional Adhesive Brackets with Different Finishing Protocols

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Cite this article as: Kaya A, Bilgiç Zortuk F. Comparison of Enamel Discoloration using Flash-Free and Conventional Adhesive Brackets with Different Finishing Protocols. *Turk J Orthod.* 2023; 36(4): 248-253

Main Points

- Tooth color alterations occurred following fixed orthodontic treatment.
- Flash-free brackets caused significantly less color change than conventional brackets.
- The lowest change in color was achieved in Flash-Free brackets using a tungsten carbide burr plus a Sof-Lex disk.

ABSTRACT

Objective: The aim of this study was to compare the effects of flash-free and conventional adhesive brackets and different finishing techniques on enamel discoloration.

Methods: Forty human premolar teeth were utilized and randomly divided into four groups based on the type of brackets and finishing technique: (1) Gemini® brackets were used for orthodontic bonding. After debanding, adhesive remnants were cleaned using a 12-blade tungsten carbide bur. (2) Gemini® suspenders were used for orthodontic bonding. After debanding the brackets, adhesive remnants were cleaned using12-blade APC™ Flash-Free brackets were used for orthodontic bonding. After debanding, adhesive remnants were cleaned a 12-blade tungsten carbide bur and polished with Sof-Lex disks. (4) APC™ Flash-Free brackets were used for orthodontic bonding. After debanding, the adhesive remnants were cleaned using a 12-blade tungsten carbide bur. A Vita Easyshade spectrophotometer was used to measure the color change values of the 40 teeth.

Results: The color change of the enamel surface in the Flash Free bracket group was significantly less than that in the conventional groups ($p=0.003$ $p<0.05$). The mean ΔE values obtained from the Sof-Lex groups were lower than those obtained from the groups without Sof-Lex, but these results were not statistically significant ($p=0.280$ $p>0.05$).

Conclusion: It is recommended to use Flash-Free brackets and polish with Sof-Lex disk following the clean-up procedures to minimize the possibility of discoloration of the teeth during orthodontic treatment.

Keywords: Teeth discoloration, adhesive precoated brackets, spectrophotometer

INTRODUCTION

One of the most frequent complications occurring during orthodontic treatment is the emergence of tooth color alteration, which remains a major complication that concerns orthodontists. Furthermore, the occurrence of enamel coloration would produce an unexpected financial burden on the patient.[1] Thus, it is a primary goal for a clinician to prevent color changes after orthodontic treatment by protecting the enamel surface.

In orthodontic treatment with fixed appliances, bonding agents can lead to tooth coloration because of the irreversible penetration of resin tags into the enamel structure.[2] Similarly, temporary or permanent damage may

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Received: October 19, 2022
Accepted: March 15, 2023
Publication Date: December 29, 2023

occur in enamel during the removal of brackets and residual adhesive materials after completing treatment, potentially leading to tooth coloration.[3] The finishing procedures employed and tools (such as tungsten carbide burrs, diamond burrs, abrasive disks and polishing disks) used to remove residual adhesives from the tooth surface may also affect tooth color differently.[3,4]

Adhesive Precoated (APC™) brackets, commonly used today, have an equal and sufficient amount of adhesive at the base. These brackets offer the advantages of no overflow and no need for adhesive clearance during bonding.[5] In *in vitro* studies, it was suggested that the APC™ bracket system provides adequate bonding strength and decreases micro-leakage compared with conventional bonding systems.[5-7] At this point, the choice of bonding and finishing procedures may be essential in aesthetically critical areas during orthodontic treatment. Therefore, the comparison of different brackets and finishing procedures will provide practical and useful information about tooth discoloration for clinicians.

Conflicting findings concerning enamel color changes caused by bonding and debanding processes have prompted us to investigate two different brackets and cleanup protocols.

The hypothesis tested in this study is that different finishing techniques and brackets will be effective in reducing color changes on enamel.

METHODS

The study received approval from the Hatay Mustafa Kemal University Tayfur Ata Sökmen Faculty of Medicine, Clinic Research Ethics Committee (approval no: 08, date 19.04.2018). The sample size was estimated using G Power (3.1.9.7) software with a confidence level of 80%, based on previous research.[8] Forty upper and lower premolars extracted for orthodontic reasons were collected from patients aged 12-30 years. Teeth with caries, cracks, white spot lesions, demineralization areas, or abrasions, those who previously underwent restorative treatment, and those exposed to trauma during extraction were excluded.

Immediately after extraction, teeth were cleansed from blood and tissue residues under streaming water and stored in distilled water at room temperature and in dark medium. Molds in the form of rectangular prisms sized 40 x 20 x 20 mm were prepared, and the teeth were placed in these molds using autopolymerizing acrylic. During this process, the acrylic did not touch the crowns of the teeth. The teeth were then randomly divided into two subgroups (n=20) and bonded with two types of brackets: adhesive precoated brackets (APC™ Flash-Free bracket; 3M Unitek) and conventional stainless steel brackets (Gemini; 3M Unitek). For the reliability and accuracy of the results, the teeth were allocated to the groups using a fixed-probability randomization method.

Before color testing, the teeth were randomly assigned to four groups of 10 specimens each and classified based on the type of brackets and finishing technique.

Specimen Preparation

A fluoride-free prophylaxis paste was utilized to polish the buccal surfaces of the teeth using low-speed soft-bristle brushes. Then, the teeth were rinsed with water and air-dried for 20 seconds. Each tooth underwent etcing with 37% orthophosphoric acid for 30-seconds, followed by a 15-second rinse, and then air-dried for 10 seconds. Afterward, the teeth were primed with a light cure adhesive primer (Transbond XT Primer, 3M Unitek). The Valo (Ultradent, South Jordan, Utah) light-curing device was used to cure the adhesives in Xtra power mode (3200 mW/cm^2) for 3 s in all groups.

Group 1: The orthodontic adhesive Transbond XT (3M Unitek, USA) was placed onto the conventional Gemini 3M ® brackets (3M Unitek, USA) base, and they were positioned on the buccal enamel surface. Finishing technique: The brackets were deboned and adhesive remnants were cleaned using a 12-blade tungsten carbide bur.

Group 2: Gemini 3M® brackets (3M Unitek, USA) were bonded with Transbond XT (3M Unitek, USA). Finishing technique: The brackets were debonded, and adhesive remnants were cleaned using a 12-blade tungsten carbide bur and polished with Sof-Lex discs.

Group 3: A preheated bracket system, APC Flash-Free (3M Unitek), was used. Since the adhesive resin was already in the bracket base, brackets were placed immediately after primer application. Finishing technique: The brackets were debonded, and adhesive remnants were cleaned using a 12-blade tungsten carbide bur and polished with Sof-Lex disks.

Group 4: APC Flash-Free Adhesive-Coated Brackets (3M Unitek) were placed immediately after primer application. Finishing technique: The brackets were deboned and adhesive remnants were cleaned using a 12-blade tungsten carbide bur.

All procedures were performed by the same operator (AK).

After bonding, the teeth in the four groups were placed into the thermal cycle device. In the device, 10,000 cycles were performed to simulate a 1 year oral cavity. Cycles were conducted by maintaining water bath temperatures between 5 °C and 55 °C. After thermal cycling, residual adhesive on the enamel after bracket debonding was removed.

The color determination procedure was conducted by the same operator (AK) before bracket bonding and after rthe emoval of adhesive residues from bracket debonding. Color determination was performed using a Vita Easyshade spectrophotometer (Vita Zahnfabrik, H. Rauter GmbH & Co, Germany). All teeth were measured from the same point, which is the middle third of the teeth. To standardize repeated measurements, calibration was performed before each measurement according to the manufacturer's instructions. To achieve standardization in color measurement, all teeth were measured by a single operator on the same day and in the same room under identical conditions. All measurements were performed three times, and the mean value was recorded. Color measurements were performed in a custom color special shade determination box with an inner surface covered with a neutral gray background. The box was illuminated using 6,500 Kelvin Philips daylight LED bulb, which mimics natural daylight, and the teeth were positioned at a 45° angle to the light source.

The CIE L*a*b* system was used to define color, which used three coordinates to represent color.[9] In the CIE (L* a * b *) color system, the L * axis represents the lightness (value) in black and white coordinates. A value of "0" corresponds to black, and a value of "100" corresponds to white (excellent reflector). The b* axis represents blue for negative values and yellow for positive values, while the a * axis indicates red (+ a *) and green (- a *), and the b * axis yellow (+ b *) -blue (-b *) value; they together express the saturation of the hue. The a* and b* coordinates are 0 in neutral colors and increase in more dense and saturated colors. The major advantage of the CIE L*a*b* system is that color difference can be expressed numerically. ΔE values mathematically express the color difference within the samples or between samples over time on L*a*b*. A single number from the formula defines the total difference rather than the nature and direction of color difference.[10] In the human eye, there is limited ability to perceive color differences, and it cannot perceive ΔE<1. The ΔE value of 2-3.7 represents the range that can be recognized clinically.[11,12] In this study, the ΔE threshold was set as 3.7 in agreement with literature.[13,14]

In the current study, discoloration was calculated using the following formula:

$$\Delta E = [(\Delta L)^2 + (\Delta a^*) + (\Delta b)^2]^{1/2} = (\Delta b)^2]^{1/2} = [(L_s - L_ö)^2 + (a_s - a_ö)^2 + (b_s - b_ö)^2]^{1/2}.$$

Clinical Color Match for Color Difference (ΔE)

0: Excellent

0.5-1: excellent

1-2: Good

2-3.5: Clinically acceptable

>3.5: Mismatch

Teeth were rated according to the above-mentioned values.

Statistical Analysis

Data were analyzed using SPSS (IBM Corp., Armonk, NY, USA) version 20.0. The normal data distribution was assessed using the Kolmogorov-Smirnov test, whereas data homogeneity was assessed using Levene's test. The ΔE differences was assessed using Tukey's multiple comparison test among groups. A p value<0.05 was considered statistically significant.

RESULTS

Table 1 presents the color change in the groups according to bracket type and finishing technique. Based on statistical analyses, both bracket types had significant effects on color change after bonding and finishing procedures independent of the finishing protocols used (p=0.003 and p<0.05). The finishing procedure had no significant effect on color change (p>0.05). In addition, there was no significant interaction between bracket type and finishing technique (Table 1).

Table 2 presents the mean color change in the groups and intergroup comparisons. When ΔE values were assessed: the ΔE value was >3.7 in all groups, indicating intense color change. The mean ΔE was found to be 11.22 in group 1 and 9.00 in group 2, indicating no significant difference between groups 1 and 2. Mean ΔE was found to be 5.83 in group 3. A significant difference was found in ΔE between group 1 and 3 (p<0.05). No significant difference was found in the remaining binary comparisons between groups (G1-G4, G2-G3, G2-G4, G3-G4) (p>0.05).

In the study, the highest ΔE value was observed in group 1 (ΔE=11.22) while the lowest ΔE value in group 3 (ΔE=5.83). For mean values, 95% confidence interval was calculated as 8.1406-14.3042 in group 1 and 3.7287-7.9236 in group 3 (Table 2).

When color change (ΔE) was assessed between groups, it was observed that the extent of color change was lower in group 3 where Flash-Free brackets were used than in group 1 where Gemini brackets were used, and that the mean value was lower in groups where Sof-Lex was used (Group 2 and Group 3) than in those where Sof-Lex were not used (Group 1 and Group 4). In conclusion, it was found that ΔE values in all groups were above the clinically acceptable level (ΔE: 3.7).

Table 1. Results of the 2-way ANOVA for the color parameters with respect to the effects of type of bracket and finishing type (p<0.05)

Source of variation	Sum of squares	DF	Mean square	F	p value
Corrected model	187.868	3	62.623	3.988	0.015
Intercept	2624.802	1	2624.802	167.141	0.001
Bracket type (A)	161.822	1	161.822	10.304	**0.003**
Finishing technique (B)	18.866	1	18.866	1.201	0.280
A X B	7.180	1	7.180	0.457	0.503
Error	565.349	36	15.704		
Total	3378.019	40			

Table 2. Mean color change (ΔE) values in the groups

	N	Mean	Std. deviation	Std. error	95% Confidence interval for mean value		Min.	Max.
					Lower Limit	Upper Limit		
Group 1	10	11.22a	4.31	1.36232	8.1406	14.3042	5.79	19.26
Group 2	10	9.00ab	4.93	1.55911	5.4746	12.5285	3.51	14.94
Group 3	10	5.83b	2.93	0.92719	3.7287	7.9236	0.51	9.77
Group 4	10	6.35b	3.37	1.06548	3.9421	8.7626	1.10	10.42
Total	40	8.1006	4.39469	0.69486	6.6951	9.5061	0.51	19.26

Different letter indicates statistical significance ($p<0.05$)

DISCUSSION

Color differences after orthodontic treatment can lead to dissatisfaction in patients and a reduction in treatment success. Thus, discoloration is an important issue in orthodontics. Although this study has an *in vitro* design, human teeth were used as samples to achieve maximal clinical compatibility. In the literature review, it was observed that human premolar teeth were used in majority of *in vitro* studies.[15,16] In the current study, teeth were cleansed by removing tissue residues and attachments under streaming water and stored in distilled water in a dark indoor area. Distilled water was renewed weekly to prevent bacterial infiltration. In previous studies, several solutions including normal saline, tirol solution, distilled water, alcohol solution at varying concentrations, formalin, and chloramine-T were used to store teeth.[2,17]

Measurement errors can occur because environmental and psychological factors may affect the sensitivity of human eyes during color determination. Thus, it is recommended to use color measurement devices to exclude human factors. The spectrophotometer is the most commonly used device for measuring tooth color, providing objective, consistent, and reproducible results. In addition, spectrophotometers are preferred due to their superiority in establishing color differences where the human eye will have difficulty identifying.[18] In clinical practice, many electronic color measurement devices have been used to measure tooth color. Kim-Pusateri et al.[19] compared four distinct dental color measurement devices (SpectroShade®, ShadeVision®, Vita Easyshade®, and ShadeScan®) regarding accuracy and reliability. The authors reported that ShadeScan® had significantly lower reliability, while there was no significant difference among the remaining three devices. When compared regarding accuracy, there were significant differences among devices, and Vita Easyshade® had the highest accuracy (96.4%. In the current study, Vita Easyshade® was preferred for the determination of changes in tooth color because of its accuracy and ease of use. To rule out intraobserver errors, each measurement was performed by the same operator (AK) in a triplet manner. The test materials were aged by simulating intraoral media in *in vitro* testing for biocompatible materials. This procedure is generally performed using a thermal cycle process. In this study, a thermal cycle process was used to simulate a variable temperature that mimicked intraoral media in the most realistic manner. This process plays an important role in performing an *in vitro* study in the most realistic manner.

In the literature, the intraoral temperature was reported as 36.4 °C during resting.[20] It was reported that intraoral temperature ranged from 0 °C to 70 °C for foods and beverages, whereas the inner surface temperature of restorations ranged from 9 °C to 52 °C. In addition, it has been reported that the intraoral temperature remained at 5-55 °C in most instances. The thermal cycle process is generally performed using cycles between 5 °C and 55 °C. The highest and lowest intraoral temperatures were recorded 20-50 times per day; thus, it was reported that 10,000 cycles corresponded to one year of oral function.[21] In the current study, tooth samples were subjected to 10,000 thermal cycles at 5-55 °C, corresponding to 1 year of intraoral use. In the color measurement phase, L*a*b* values were measured in each tooth in a triplet manner, and the mean value was recorded to minimize errors. In the literature, $\Delta E>3.7$ is accepted as the threshold value for the clinical perception of color change in orthodontics.[13,17] In the present study, the same threshold value was used for color assessment and measurements.

In orthodontics, many techniques have been used to remove residual adhesive from the enamel surface after debonding. It has been reported that cleansing with water-cooling and low-speed tungsten carbide burrs is the method associated with the least harm to enamel.[22] In a study, Eminkahyagil et al.[23] compared the effects of high-speed tungsten carbide burr, low-speed tungsten carbide burr, and Sof-Lex disk on enamel. The authors reported that the most rapid method was cleansing with a high-speed tungsten carbide burrs, but this technique was associated with the greatest harm to enamel. Sof-Lex disks had the longest duration for the cleaning procedure.[23] Although a smooth surface was achieved with Sof-Lex disks, significant residue was left on the enamel surface. Retief and Denys[24] and Zarrinnia et al.[25] recommend using 12-blade tungsten carbide with adequate air cooling at high speed, followed by polishing with ultra-fine grain Sof-Lex disks and smoothening with rubber and paste. In their study, Zachrisson and Arthun[26] evaluated the effects of distinct finishing techniques on enamel surfaces and suggested that the best result was achieved by low-speed tungsten carbide burr and polishing. Similarly, the least color change was achieved by the tungsten carbide burr plus Sof-Lex disks in this study.

It was seen that tungsten carbide burr followed by Sof-Lex disk polishing resulted in the least clinical color change in both brackets. The Sof-Lex disk group showed less color change because Sof-Lex causes less damage to enamel and provides a smoother surface than the tungsten carbide burr. In their study, Zachrisson and Arthun[26] reported that diamond burr use caused more extensive material loss from the enamel surface and greater damage to the enamel than a tungsten carbide burr. In a previous study, it was suggested that tungsten carbide burr, used to minimize damage in the enamel surface, provided a smoother end-face.[25] Some authors reported that there was no correlation between surface roughness and coloration,[27] whereas others reported that light reflection was increased with a reduction in surface roughness, thereby decreasing color changes.[28] In this study, it was observed that Sof-Lex application aiming to decrease surface roughness, led to less color change in both bracket types compared with the remaining groups.

In a study, Trakyali et al.[29] investigated the effects of reinforced composite and tungsten carbide burrs used in finishing and polishing procedures. The authors reported that there was no change in color between the two burr systems, but the reinforced composite burr provided a smoother surface. In a similar study, the effects of reinforced composite and tungsten carbide burrs on color change were investigated in orthodontic treatment. It has been reported that reinforced composite burrs provide a smoother end-face and fewer color change.[30] In contrast, in the current study, there was no significant color change with distinct finishing techniques. In the Flash-Free bracket groups, less color change was observed in both finishing protocols compared with the Gemini bracket group in this study. The self-adhesive in the Flash-Free bracket system ensures less composite overflow around the bracket. This may be the reason for less color change in Flash-Free brackets. Visible and clinically unacceptable tooth color alterations may occur following orthodontic treatment. Esthetic outcomes are as important as functional demands.[31] Orthodontic bonding with Flash-free systems and polishing with Sof-Lex disk following the clean-up procedures may reduce the color change of the enamel.

This study has some limitations due to its *in vitro* design. First, the color measurement process requires great sensitivity because it is affected by many environmental and operator-related factors. Thus, a color measurement box was used to provide artificial daylight to eliminate the adverse effects of ambient light, ensuring standardization. In addition, all baseline and final measurements were performed by a single operator.

CONCLUSION

It was observed that both the brackets and finishing techniques used in this *in vitro* study caused coloration at the tooth surface. There was a greater color change in teeth cleaned from adhesive residues using carbide burr alone compared with those cleaned using tungsten carbide burr plus Sof-Lex removed adhesive residues. The lowest change in color was achieved with the Flash-Free bracket, which underwent finishing procedure with a tungsten carbide burr plus Sof-Lex disk. Based on these results, Flash-free brackets, along with the finishing procedure using a tungsten carbide burr plus Sof-lex disk, which was associated with the least color change, may contribute to treatment success.

Ethics

Ethics Committee Approval: The study was approved by the Hatay Mustafa Kemal University Tayfur Ata Sökmen Faculty of Medicine, Clinic Research Ethics Committee (approval no: 08, date 19.04.2018).

Informed Consent: Not applicable.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - F.B.Z.; Design - F.B.Z.; Supervision - F.B.Z.; Funding - A.K.; Materials - A.K.; Data Collection and/or Processing - A.K.; Analysis and/or Interpretation - A.K.; Literature Review - A.K.; Writing - A.K., F.B.Z.; Critical Review - F.B.Z.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declared that this study has received no financial support.

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TURKISH JOURNAL of ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2023.2022.98

Original Article

Outcomes of Presurgical Nasoalveolar Molding using Modified Nostril Retainers in Patients with Unilateral Cleft Lip and Palate at an Average Follow-up of 2 Years

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Cite this article as: Titiz S, Oral E, Gelgör İE. Outcomes of Presurgical Nasoalveolar Molding using Modified Nostril Retainers in Patients with Unilateral Cleft Lip and Palate at an Average Follow-up of 2 Years. *Turk J Orthod.* 2023; 36(4): 254-260

Main Points

- Nasal molding was started without decreasing the cleft width to 5 mm.
- No patient developed a mega nostril.
- Treatment outcomes were stable for a mean of 2.2 years after surgery.

ABSTRACT

Objective: Presurgical nasoalveolar molding (PNAM) using a modified nostril retainer is a new treatment approach. This study aimed to evaluate the outcomes of early nasal molding using this approach with an average follow-up of 2 years in patients with severe unilateral cleft lip and palate.

Methods: This retrospective study included 18 patients with unilateral cleft lip and palate without genetic syndromes who underwent PNAM with modified nostril retainers. The Grayson technique was employed with an intraoral plate to approximate cleft segments. Nasal molding was initiated before reducing the cleft width to 5 mm. Measurements, including alar base height ratio (ABHR), nasal floor width ratio (NFWR), columellar length ratio (CLR), columellar angle (CA), and nostril axis inclination on the cleft and non-cleft sides (NAI-C and NAI-NC, respectively), were calculated from standard photographs taken before PNAM (T1), after PNAM (T2), after an average of 1.81 months post-surgery (T3), and after an average of 2.2 years after T3 (T4). Pairwise comparisons of values at the four time points were conducted.

Results: NFWR, CLR, CA, NAI-C and NAI-NC significantly increased after PNAM ($p<0.05$). However, no significant change was observed in ABHR ($p>0.05$) from T1 to T2. These outcomes were maintained at T4, and no patient developed a mega nostril.

Conclusion: The use of a modified nostril retainer for nasal molding appears to provide stability during the high probability of relapse reported in the literature.

Keywords: Unilateral, cleft palate, nostril retainers, presurgical molding

INTRODUCTION

Unilateral cleft lip and palate are one of the most common congenital craniofacial anomalies, often associated with various dentoalveolar anomalies, such as midface deficiency, distortion, displacement, and tissue deficiency of nasal structures.[1,2] Therefore, presurgical nasoalveolar molding (PNAM) is crucial, particularly in severe cases. Maternal estrogen passing through the placenta elevates the hyaluronic acid level in the fetal blood during pregnancy. Hyaluronic acid alters cartilage and connective tissue elasticity by breaking down the intercellular matrix; thus, increased plasticity and decreased elastic deformation of the cartilage lead to cartilage molding.[3-5]

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Received: June 29, 2022
Accepted: March 15, 2023
Publication Date: December 29, 2023

After birth, infants no longer receive maternal estrogen, causing a gradual decrease in hyaluronic acid levels in their blood. Consequently, cartilage can be more easily shaped within the six weeks following birth.[3]

Grayson recommended that nasal molding should start after achieving the laxity of the nasal soft tissue.[1,2] Inserting a nasal stent before achieving the laxity of the alar rim is sometimes impossible when the body of the nasal stent is rigid because the tension of the tissues reduces the space available for inserting the body of the stent. However, the modified nostril retainer is manufactured using soft acrylic; thus, it can enter the nose without any irritation before achieving the laxity of the nasal soft tissue. Therefore, the cleft width need not be decreased to 5 mm to achieve the laxity of the nasal soft tissue and start nasal molding.[6,7] This study aimed to evaluate the outcomes of this new approach in which nasal molding is started earlier than in the conventional method at an average follow-up of 2 years in patients with unilateral severe cleft lip and palate.

METHODS

This retrospective study received approval from the Clinical Research Ethics Committee of Uşak University Faculty of Medicine (approval no: 117-117-13, date: 02.06.2021). Informed consent was obtained from the parents of each patient after a detailed explanation of the procedures. The study protocol complied with the tenets of the Declaration of Helsinki. Patients treated consecutively Mersin and Uşak University selected based on the following criteria: (1) complete unilateral cleft lip-cleft palate with a cleft width exceeding 5 mm, (2) undergoing PNAM between 2017 and 2020, (3) absence of genetic syndromes or other congenital deformities, and (4) availability of clinical records and photographs suitable for analysis at four defined time points. Data were collected at the following time points: within two weeks of birth before the initiation of nasoalveolar molding (T1), after PNAM (T2), within an average of 1.81 months postsurgery (T3), and within an average of 2.2 years after T3 (T4). All surgeries were performed [Hacettepe University] by the same surgeon. The 18 patients (11 boys and 7 girls) included in this study met all the inclusion criteria.

Treatment Protocol

Nasal molding was carried out using a modified nostril retainer that was manufactured from soft acrylic (Vertex Soft, Vertex-Dental B.V., Soesterberg, The Netherlands), and cleft reduction was performed with an intraoral plate according to the Grayson technique (Figure 1A). In the initial session, an L-shaped tape was affixed to the alar groove of the non-cleft nose and lip, and then the tape was stretched until the columella was as upright as possible, and the band was attached to the cleft lip. The appliance was inserted and then secured in the mouth using rubber bands and tape.

Finally, the modified nostril retainer was placed on the nose and attached to the cheek using tapes. Weekly activation was performed adding soft acrylic to the cleft side of the modified nostril retainer. If columella lengthening was needed, soft acrylic was applied to the noncleft side as well (Figure 1B). The intraoral plate was selectively ground in areas expecting movement, while soft acrylic was added to regions requiring molding to reduce the cleft width. If the nose was asymmetrical after the greater and lesser alveolar segments touched each other, nasal molding was continued. When the modified nostril retainer is appropriately used, a reduction in tissue tension due to activation is expected after approximately one week. There might be two reasons for continued tension in the soft tissue: irregular use or the end of plastic deformation in the nasal cartilage. If no changes were observed in soft tissue tension, cleft and noncleft nostril heights were recorded, and the modified nostril retainer was not activated. If no changes were observed in soft tissue tension nostril heights during three subsequent visits, and family cooperation was ensured, it was concluded that the nasal cartilage's moldability was lost. All patients used modified nostril retainers as nasal stents for 3-6 months. Standardized digital photographs of all patients (frontal and basal views) were obtained, as recommended by Titiz and

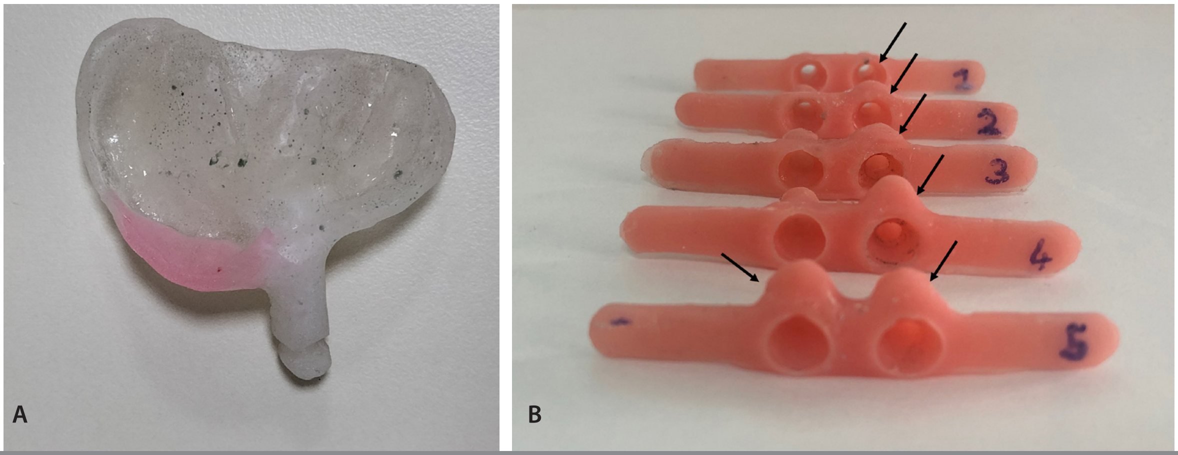


Figure 1. A: Intraoral appliance B: Modified nostril retainer activation: In the first visit, the non-activated appliance (1) is attached to the nose, and the appliance is activated using soft acrylic at each visit. If columella lengthening is required, bilateral activation is performed (5). One modified nostril retainer is used for each patient. For a better understanding of the method, each step is shown using a different modified nostril retainer

Aras.[8] From frontal view photographs, the alar base height ratio (ABHR)[9] was calculated. From basilar oblique view photographs, the columellar angle (CA),[10] nostril axis inclination on the cleft and noncleft sides (NAI-C and NAI-NC, respectively),[11] nasal floor width ratio (NFWR),[9] and columella length ratio (CLR)[9] were calculated (Figure 2).

Statistical Analysis

The minimum number of patients needed to compare pre-and post-treatment measurement values with a 95% confidence level was calculated using G Power analysis. (Version 3.1.9.2; Heinrich-Heine-Universität Düsseldorf, North Rhine-Westphalia, Germany). The effect size reported in a previous study, was 0.79.[12] Because of the analysis ($\alpha=0.05$), the standardized effect size was 0.79. The minimum sample size was determined to be 15, with a theoretical power of 0.80.

Statistical analysis was performed using IBM SPSS version 25.0 (IBM Corp., NY, USA). The normality assumption was checked using the Shapiro-Wilk test in the first step of data analysis. Pearson's chi-square correlation analysis was performed when data were determined to be normally distributed to determine measurement error and similarity between measurements. Spearman rank difference correlation analysis was performed in cases in which the normality assumption was not met. The two-way Friedman test was applied to analyze the difference between the means of variables that were nonnormally distributed and had three or more dependent groups. The adjusted Bonferroni test was used to determine whether the groups were distinct. P-values <0.05 were considered statistically significant.

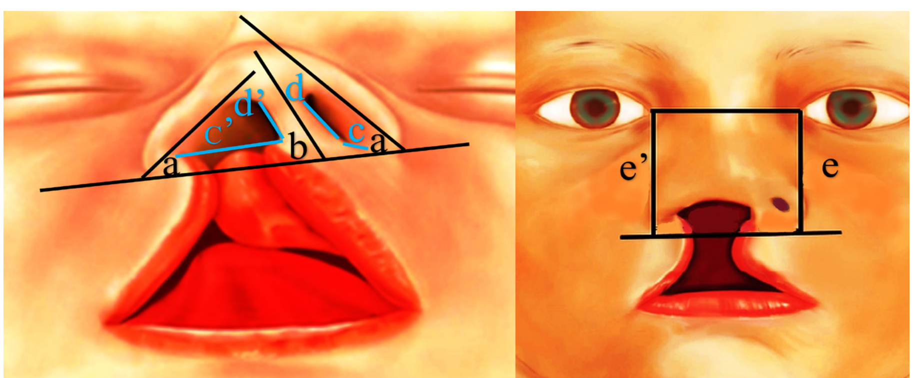
Method Error

Measurements were repeated by the same researcher using 10 randomly selected facial photographs at 1-month intervals under standard conditions to facilitate intraobserver reliability testing. Correlation coefficients between measured values were 0.85, which suggested that the method error was clinically acceptable.

RESULTS

The alveolar cleft width varied between 7 and 16 mm, with a mean of 10.6 mm. The timing of the treatment stages is shown in Table 1. During the examination of patient clinical follow-up cards, no information was found regarding soft tissue nasal problems such as large nostrils, nasal epithelial compression, columellar deformation, or bleeding. However, band-induced irritation was observed on the cheeks in some patients. The progressive stages of modified PNAM in an infant are illustrated in Figure 3. Columellar angle (CA) increased after PNAM (Table 2, T1-T2, $p<0.05$), approached a right angle after primary lip surgery (T2-T3, $p<0.05$), and remained stable at T4 (Table 2, T3-T4, $p>0.05$). Nostril axis inclination on the cleft (NAI-C), nostril axis inclination on the noncleft side (NAI-NC) nasal floor width ratio (NFWR), and columella length ratio (CLR) increased after PNAM (Table 2, T1-T2, $p<0.05$) and were found to be stable at T4 (Table 2, T3-T4, $p>0.05$). Treatment did not result in an improvement in alar base height ratio (ABHR), as the mean ABHR remained similar at all time points (T1, T2, T3, T4).

A



B

Figure 2. Measurements used in the study. A: a. Nostril axis inclination cleft (NAI-C) and noncleft (NAI-NC), angular measurement between the longitudinal plane of the nostril and the nasal width plane; b. columellar angle (CA), angular measurement between the columellar axes and nasal width plane at the subnasale; c/c': nasal floor width ratio (NFWR), nasal floor width on the non-cleft side/nasal floor width on the cleft side; d'/d: columellar length ratio (CLR), columellar length on the cleft side/columellar length on the non-cleft side. B: e/e' alar base height ratio (ABHR), alar base height on the noncleft side/alar base height on the cleft side

Table 1. Timing of treatment

Timepoint	n	Minimum	Maximum	Mean	Standard deviation
T1 (days)	18	2.00	12.00	6.38	3.01
T2 (months)	18	2.00	4.00	2.97	0.55
T3 (months)	18	3.00	5.00	4.02	0.52
T4 (years)	18	1.50	3.00	2.20	0.68

T1: Within 2 weeks of birth, before initiation of nasoalveolar molding; T2: After presurgical nasoalveolar molding; T3: Within an average of 1.81 months after primary lip surgery; T4: Within an average of 2.2 years following T3 time point

Figure 3. Progressive stages of modified presurgical alveolar nasoalveolar molding treatment. A: Pre-treatment basal view (10 days); B: during PNAM treatment; C: post-treatment basal view (6 weeks); D: Post-treatment basal view 1.5 months after primary lip surgery; E: Post-treatment basal view 3 years after primary lip surgery.

Table 2. Comparison of measurements assessed at T1-T4 timepoints

	T1 SD	T2 SD	T3 SD	T4 SD	T1/T2	T1/T3	T1/T4	T2/T3	T2/T4	T3/T4
CA	29.66±13.68	79.05±6.28	85.72±3.46	85.77±3.05	0.012*	0.000*	0.000*	0.033*	0.0367*	1.00
NAI-C	16.88±9.83	45.72±4.19	48.61±4.88	47.77±4.50	0.001*	0.000*	0.000*	1.000	0.639	1.00
NAI-NC	38.72±9.24	46.16±3.14	47.61±3.92	46.83±3.91	0.000*	0.000*	0.001*	1.000	1.000	1.00
NFWR	31.50±6.34	74.94±8.43	89.88±3.77	89.61±4.13	0.05*	0.000*	0.000*	0.005*	0.027*	1.00
ABHR	91.66±2.42	91.72±2.19	91.55±2.09	91.33±2.37						
CLR	32.33±9.75	76.72±7.10	84.22±6.94	84.66±6.38	0.012*	0.000*	0.000*	0.233	0.059	1.00

*Significant difference ($p<0.05$). The two-way Friedman test was applied to analyze the difference between the means of the variables. The adjusted Bonferroni test was used to identify the group or groups that made the difference. No statistically significant differences were found between the average ABHR values over time. For this reason, no pairwise comparisons were made

CA: columellar angle; NAI-C and NAI-NC: Nostril axis inclination on the cleft and non-cleft sides respectively; NFWR: nasal floor width ratio; ABHR: alar base height ratio; CLR: columella length ratio; T1: within 2 weeks of birth, before initiation of nasoalveolar molding; T2: after presurgical nasoalveolar molding; T3: within an average of 1.81 months after primary lip surgery; T4: within an average of 2.2 years after T3

DISCUSSION

High-quality photographs are essential for evaluating treatment outcomes. In patients with CLP, two-dimensional (2D) facial photographs are commonly employed for documentation. However, the utilization of three-dimensional photographs is increasing. Digital stereophotogrammetry is a noninvasive technology with several advantages, including accurate measurements, reproducibility, and quick image acquisition.[13] However, the restricted portability and high cost of the system restrict its use as a recording standard; therefore, 2D photographs remain important for evaluating treatment outcomes.

Photogrammetry is the art, science and technology of obtaining reliable information about objects and their immediate surroundings through measurement on photographs.[14] The mathematical model of photogrammetry is based on central prospective projection, with the photograph serving as the projection plane. Titiz[15] determined the effects of positioning errors on ratio and angle measurements in patients with unilateral CLP. The study showed that using 2D photographs acquired according to the central projection rules specified by photogrammetry can yield reliable results for ratio and angle measurements.

A nasal molding device not attached to an intraoral plate offers several advantages. Some patients with cleft lip and palate may be fed using a specialized bottle system designed to help babies with serious sucking difficulties, such as a cleft palate. This may lead to poor parental compliance with the use of an intraoral appliance. Moreover, the use of intraoral plates may occasionally lead to sores or fungal infections, requiring the removal of the intraoral plate for some time. To overcome these limitations, a modified nostril retainer was manufactured using a special mold, enabling nasal molding independent of an intraoral appliance. In our previous work, we only used modified nostril retainers for patients with UCLP, without maxillary collapse, and with a cleft width of less than 6 mm.[16] However, in severe cleft cases, intraoral plates are necessary for properly aligning the alveolar segments because uncontrolled forces are more likely to occur without an intraoral plate.[17] In this study, the cleft width was from 7 to 16 mm (mean 10.6 mm); thus, an intraoral plate manufactured according to the Grayson alveolar aligning technique was preferred to reduce the cleft width.

The Grayson technique is a well-known method that has undergone several modifications. Grayson recommends adding a nasal stent when the width of the cleft is reduced to 5 mm to achieve laxity of the nasal soft tissues and to avoid increasing the nostril circumference.[1,2] In 2009, Southmedic produced a ready-made nasal elevator with a special flexible tape called Dyna-Cleft protocol (Canica Design Inc., Ottawa, Canada). In the Dyna-Cleft protocol, both alveolar and nasal molding were initiated from the first day without waiting for the reduction of the cleft width to 5 mm, which is similar to our technique. No study has reported the occurrence of a mega nostril using the Dyna-Cleft protocol[17,18] as a result of early shaping, as claimed by Grayson. Jahanbin et al.[19] evaluated the effect of immediate versus delayed addition of the nasal stent to the nasoalveolar molding plate on the nose shape in infants with unilateral cleft lip and palate. In the early treatment group, nasal molding was started without reducing the cleft width to 5 mm. In the late-onset group, nasal molding was initiated after the cleft width was reduced to 5 mm. The results showed that early use of nasal stents provided more desirable results concerning decreasing the width of the nostrils, increasing their height, and correcting the angle of the columella without any adverse effects on the nostrils after treatment. However, nasal stents fabricated using orthodontic acrylic, even if it has a soft acrylic outer surface, may increase the risk of mucosal injury in cases with wider clefts. The stretched soft tissue reduces the space available for inserting the stent body. Therefore, a modified nostril retainer fabricated using only soft acrylic may lead to fewer complications in the nasal soft tissue in patients with severe clefts.

Similar to our study, Matsuo et al.[3] and Matsuo and Hirose[5] reported the use of symmetrical or asymmetrical silicone nostril retainers for nasal molding. However, our technique used nostril retainers made of soft acrylic that had wings that facilitated taping. These wings ensured that the modified nostril retainer remained stable within the nose without requiring support from the nasal base. In contrast, Matsuo et al.[3] used silicone nostril retainers that did not have wings. In such silicone nostril retainers, the resistance from the nasal soft tissue must be overcome by the anchorage support provided by the nostril floor.[3] The size of the cleft may lead to an inability of the nostril base to provide adequate support. Additionally, maintaining the position of silicone nostril retainers might be problematic.[20] Also, the addition of silicone for activation is more difficult than that of soft acrylic. Furthermore, tape adheres to soft acrylic more easily than to silicone.[7,8]

Doruk and Kiliç[21] and Larson et al.[22] introduced external devices to improve alveolar position and nasal septum symmetry. In both techniques, the nostril molding device was attached to a head cup. Although these systems separate the intraoral plate from the nasal molding device, anchoring the nasal molding device on the infant's head may disturb the baby's comfort and sleep patterns.

In PNAM, the modified nostril retainer provides some advantages for the physician and the family. Family cooperation is critical to the success of PNAM. According to our clinical observations, the motivation of families increased when they observed visual changes in their children in a short time as nasal molding was started in the first visit. The air holes in the modified nostril retainers also reduced the anxiety of the families regarding proper breathing of the infants. In the Grayson method, adding a nasal stent to the intraoral plate requires a sensitive laboratory step. The fit of the nasal stent is crucial for the correct molding force and stability of the intraoral plate. Manufacturing the modified nostril retainer does not involve a sensitive laboratory step.

The columella is located centrally at the base of the nose, is a prominent aesthetic component of the nasal midline, and has a pivotal role in determining the shape of the nasal base. Deviations in the columella and variations in its width and height lead to distortion of the nostril shape and frequently compromise function.[23] In patients with unilateral cleft lip and palate, deformation is observed not only on the cleft side of the nose but also on the noncleft side. Another advantage of PNAM using a modified nostril retainer is that it can lengthen the columella if necessary. Ruíz-Escolano et al.[24], Titiz and Aras[8], Abhinav et al.[17], and Monasterio et al.[25] reported a correction of columella deviation of 23.68°, 28.5°, 22°, and 25.9°, respectively, in patients with unilateral cleft lip and palate treated using the Grayson technique. In this study, correction of the columella deviation was 49.84°. In the Grayson technique and in our technique, an L-shaped tape is attached from the alar groove of the noncleft nose and lip to the cheek of the cleft side until the axis of the columella is corrected to the maximum extent permitted by the soft tissues. Taping from the noncleft side to the cleft side applies rotational force to the columella at the rotational center of the nasal stent in the nostril. In the Grayson technique, this force is mostly absorbed by the soft tissue of the noncleft nostril; however, with the presented technique, the modified nostril retainer in the noncleft nostril transmits the force generated by the tape and pushes the columella to the midline. In this study, more effective transmission of the force generated by the tape may have resulted in more uprighting of the columella than that with the classical method.

Previous studies recommended using a nasal stent to retain the corrected nostril shape after primary lip surgery. In our clinic, patients use the modified nostril retainer as a nasal stent after primary lip surgery, potentially contributing to long-term stability. However, as this is a retrospective study, conducting a prospective study were to be planned, it would be unethical to recommend not using a nasal stent to evaluate the efficacy of nasal molding with a modified nostril retainer. Cartilage memory and scar contraction are key factors in the long-term deterioration of the cleft nose.[26] Cartilage memory is defined as a tendency of cartilage to revert to its original position over time due to elasticity.[27] Starting nasal cartilage molding as early as possible might achieve more long-lasting molding of the relatively plastic immature cartilage and avoid the elastic deformation that occurs in the older, more mature, and less plastic cartilage. Early cartilage shaping reduces cartilage memory.[27] Thus, early shaping may have a more significant effect on stability than using a nasal stent after primary lip surgery.

According to Roux's concept of orofacial orthopedics and the functional matrix theory put forward by Melvin L. Moss in the 1960s, there is an intimate relationship between shape, structure, and function. Modified nostril retainers used during PNAM may enhance nasal breathing, aligning with the functional matrix theory, where evolving function contributes to the permanence of molding and more normal development of the nasal airway.

Chang et al.[28] observed varying degrees of relapse in nasal cleft deformity after primary rhinoplasty. Tang et al.[29] found significant asymmetry in the nose nine months after primary lip repair. In this study, with an average follow up of 2.2 years after primary lip surgery, no relapse was observed. Initiating nasal molding with modified nostril retainers before reducing the cleft width to 5 mm is likely advantageous for maintaining symmetry, especially in patients with large clefts.

Study Limitations

First, being a retrospective study, we could only investigate routinely collected data, limiting the scope of data collection. More data could be obtained from 3D photographs. Feasibility issues in the clinic prevented their inclusion. Another method for evaluating the nasolabial region is impressions of the nasoalveolar region. However, obtaining such impressions requires general anesthesia for the infant and the use of unpressurized techniques.[30] The ethical concerns and impracticality of sedating infants solely for impressions at the initial stage limit their use to primary lip surgery. Moreover, recording impressions without applying pressure to the soft tissues, which can cause distortion, is challenging.[30] Another limitation is the evaluation period of approximately 2.2 years for treatment outcomes. Future studies with longer follow-up periods are necessary. Further studies with a control group, including patients treated with the Grayson technique, will offer valuable evidence to precisely determine the effectiveness of early nasal molding before reducing the cleft width to 5 mm in patients with severe cleft lip and palate.

CONCLUSION

No relapse occurred within a maximum of one year after primary lip surgery, which is reported in the literature as the period with a high probability of relapse. Moreover, early treatment did not lead to the formation of meganails.

Ethics

Ethics Committee Approval: The study was approved by the the Clinical Research Ethics Committee of Uşak University Faculty of Medicine (approval no: 117-117-13, date: 02.06.2021).

Informed Consent: Informed consent was obtained from the parents of each patient following a detailed explanation of the procedures.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - S.T., E.O., İ.E.G.; Design - S.T., E.O., İ.E.G.; Data Collection and/or Processing - S.T., E.O., İ.E.G.; Analysis and/or Interpretation - S.T., E.O., İ.E.G.; Literature Review - S.T., E.O., İ.E.G.; Writing - S.T., E.O., İ.E.G.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: The authors declared that this study has received no financial support.

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DOI: 10.4274/TurkJOrthod.2023.2022.131

TURKISH JOURNAL of ORTHODONTICS

Review

Orthodontic Localization of Impacted Canines: Review of the Cutting-edge Evidence in Diagnosis and Treatment Planning Based on 3D CBCT Images

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Cite this article as: Farha P, Nguyen M, Karanth D, Dolce C, Arqub SA. Orthodontic Localization of Impacted Canines: Review of the Cutting-edge Evidence in Diagnosis and Treatment Planning Based on 3D CBCT Images. *Turk J Orthod.* 2023; 36(4): 261-269

Main Points

- A thorough clinical and radiographic assessment is a prerequisite for a successful treatment of impacted canines.
- 3D imaging such as cone-beam computed tomography provides more detailed information regarding the location of impacted canines and more precise estimation of the space conditions in the arch.
- Accurate localization of the three-dimensional position of impacted canines is the key in planning the most efficient biomechanical approach for their traction.

ABSTRACT

A thorough clinical and radiographical assessment of an impacted maxillary canine's location forms the basis for proper diagnosis and successful treatment outcomes. Implementing a correct biomechanical approach for directing force application primarily relies on its precise localization. Poor biomechanical planning can resorb the roots of adjacent teeth and result in poor periodontal outcomes of the canine that has been disimpacted. Furthermore, treatment success and time strongly rely on an accurate assessment of the severity of impaction, which depends on its 3D spatial location. The evolution of cone-beam computed tomography (CBCT) radiographs provides more detailed information regarding the location of the impacted canines. In addition, the literature has shown that CBCT imaging has enhanced the quality of diagnosis and treatment planning by obtaining a more precise localization of impacted canines. This review article highlights current evidence regarding comprehensive evaluation of three-dimensional orientations of impacted canines on CBCT images for precise diagnosis and treatment planning.

Keywords: Impacted canines, 3D localization, CBCT

INTRODUCTION

When an impacted maxillary canine is present, it often presents challenges in diagnosis, localization, and management. Mandibular canine impaction is less than half as likely to occur than maxillary canine impaction, and of the patients who belong to the latter group, 8% have bilateral impaction.[1] About two-thirds of the impactions are located palatally, while one-third are set buccally.[2,3] Therefore, the literature is abundant in studies that investigated maxillary impacted canines. Buccal canine impaction is considered a result of crowding. Jacoby had evidence to support that only 17% of buccal impactions have adequate eruption space, compared to 85% for palatal impactions. Nonetheless, with sufficient space and time, buccally impacted canines will typically erupt.[4] Two major theories were proposed to be associated with palatally impacted maxillary canines. The

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Received: August 31, 2022
Accepted: February 21, 2023
Publication Date: December 29, 2023

guidance theory, which mentions that canine eruption depends on the lateral incisor's root, and deviation in the development of the latter can hinder canine eruption.[4] In contrast, Becker[4,5] suggested the genetic theory, which supports a genetic etiology for palatally impacted canines and proposes a potential link to related anomalies, including absent or irregular lateral incisors.

Treatment of impacted canines generally involves surgical exposure and subsequent orthodontic bonding to guide it into the proper position in the arch.[6] Considerable debate surrounds the choice of the exposure technique for ectopic canines. Those advocating the closed eruption approach cite benefits in terms of patient comfort and long-term periodontal health. On the other hand, clinicians who support the excision of the overlying mucosa and spontaneous eruption of the canine mention advantages in terms of fewer repeated operations.[7] However, the most common complications that pose a challenge during treatment include bone loss, root resorption, and compromised periodontal outcomes of the impacted canine and surrounding teeth.[8] Therefore, accurate assessment of the position of the impacted maxillary canine is an essential aid in determining the severity of impaction, difficulty in management, adequate surgical exposure procedure, and overall prognosis of treatment.[9,10]

Localization of impacted maxillary canines relies on both clinical and radiographic evaluation.[2] For a practitioner to achieve proper diagnosis and successful treatment outcomes, it is imperative to accurately assess the exact location of the impacted tooth and determine its severity to define the treatment duration and complexity. Clinical evaluation alone is not conclusive of an accurate diagnosis or localization, especially that impacted canines vary greatly in their inclination and location, which might contribute to cystic degeneration or root resorption for neighboring teeth.[11] Therefore, it is essential for the clinical evaluation to be supplemented by radiographic analysis.

Numerous (2D) radiographic images have been used to evaluate the position of impacted canines, including panoramic, periapical, occlusal, and lateral cephalometric views.[12] However, these traditional radiographic images are (2D) representations, and the canine's position can be confounded with distortion and overlapping structures. Approximately 80% of clinicians should use two or more supplemental traditional radiographs to localize an impacted tooth.[13] Therefore, cone-beam computed tomography (CBCT) and CT were introduced as an aid in diagnosis.[14] The introduction of CBCT marks a profound advancement in dental radiology. This innovation in [three-dimensional (3D)] imaging appears to offer the potential for improved diagnosis in a wide range of clinical applications, and radiation is usually at lower doses compared to medical CT.[15] Additionally, the literature has shown that CBCT imaging has enhanced the quality of diagnosis and treatment planning by obtaining a more precise localization of impacted canines.[16] This review article highlights current evidence regarding the comprehensive evaluation of 3D orientations of impacted canines on CBCT images, for precise clinical diagnosis, treatment planning, and implementation of a proper biomechanical approach for traction based on their 3D location.

3D Localization of Impacted Maxillary Canines using CBCT versus 2D Conventional Methods

The diagnostic value of (3D) images lies in their ability to precisely locate impacted canines in three planes of space. Furthermore, the choice of the surgical orthodontic management and determination of the direction of traction relies primarily on the location of the impacted tooth relative to adjacent structures and its depth and inclination in the jaw.[17] Limitations encountered with the use of conventional radiography, such as the superimposition of adjacent structures, magnification, distortions, and the need for more than one radiographic image to accurately localize an impacted canine, hinder their diagnostic ability to precisely localize impacted canines.[18] CT scans were used initially as an alternative. Even though they offered more efficient information than conventional radiographs, limitations related to their radiation dose, cost, risk/benefit, access, and expertise in their evaluation, restricted their use in localizing impacted teeth.[19] CBCT images require lower radiation doses compared with CT scans.[15] They also appear to accurately delineate the spatial location of impacted canines and their surrounding structures, hence ensuring optimal orthodontic surgical management. Walker et al.[16] were among the first to use images from NewTom QR-DVT 9000 (QR Sri, Verona, Italy) to depict the positioning of impacted canines. They showed that the implementation of CBCT radiography-improved detection rates of root resorption adjacent to the impaction up to 66.7%.

Studies that compared the diagnostic efficacy of the two imaging modalities, conventional radiographs vs. CBCT scans, in localizing the impacted maxillary canines have illustrated the superiority of the latter. Haney et al.[20], used a questionnaire to compare the differences in diagnosis and treatment planning of impacted canines between CBCT images and various conventional radiographic modalities (panoramic, occlusal, and periapical radiographs). They concluded that the use of these two image modalities produced different diagnoses and treatment plans for the same patient. In another questionnaire-based study, respondents found that the 2D conventional and 3D CBCT images had different diagnostic capabilities with regard to localize impacted canines. In addition, observers had greater agreement when using CBCT images for variables related to impacted maxillary canines.[21] In a subsequent CBCT study, a model was established to predict canine impaction. The factors included in this model were crown position of the canine, angulation of the canine with respect to the lateral incisor, and cusp tip of the canine in relation to the plane of occlusion. They determined that reliability was high when CBCT imaging was used to predict canine impaction.[22]

Multiple studies have compared the radiation doses between 2D and 3D radiological examinations. The average effective dose for panoramic and lateral cephalometric X-rays were around 22.0 μSv and 4.5 μSv, respectively. Comparatively, the effective dose for a CBCT examination ranged between 61 and

134 µSv.[23] For that reason, the American Academy of Oral and Maxillofacial Radiology (AAOMR) recommend CBCTs only for certain cases where conventional 2D methods cannot provide enough diagnostic information, such as cleft cases, impacted teeth, and orthognathic surgery planning.[24]

In a recent systematic review, Eslami et al.[25] reviewed observational, experimental, and diagnostic accuracy studies that compared the efficacy of CBCT images to conventional radiography in localizing maxillary impacted canines. They illustrated the improved accuracy of CBCT scans in localizing impacted canines. However, they mentioned that evidence is weak to support their use as a first-line imaging method for evaluating canine impaction. However, they can be indicated when conventional radiography does not provide sufficient information. Therefore, the supporting evidence seems to indicate that the CBCT system is a reliable method for detecting impacted canines, and the current literature illustrates the supremacy of CBCT images over other conventional radiographic techniques as an aid for the diagnosis and visualization of impacted maxillary canines and adjacent structures.[26]

Use of CBCT Images in Assessing the Location and Severity of Impacted Maxillary Canines

Initial attempts to localize an impacted canine and determine the degree of its severity were based on analyzing (2D) radiographs. Among the pioneers in the field, Ericson and Kurol[2] classified the position of impacted canines in both frontal and transverse sections using orthopanthograms and axial vertex views. They used an angle (α) to denote the relationship between the long axis of the canine and the mid sagittal plane of a panoramic radiograph. Frontal and transverse planes were divided into five sectors, and the medial position of the crown in relation to these sectors was evaluated. The perpendicular distance (d) was measured from the impacted cuspid's tip to the occlusal plane (Figure 1A). They concluded that the probability of lateral incisor root resorption increases by 50% if the canine cusp tip is closer to the midline (within sectors 4 or 5) and the angle exceeds 25°. Furthermore, the duration of treatment was longer if the canine was in sector 3 and shorter for impaction in sector 1 (further away from the midline).[2]

Ericson and Kurol's[2] sector classification was redefined by Lindauer et al.[27]. Who located the canine's cusp tip relative to its proximal lateral incisor. He determined the likelihood of impaction using the sector classification. Sector I was classified as a region distal to the distal border of the lateral incisor. Sector II is the distal half of the lateral incisor when bisected through its long axis. Sector III denoted the mesial half of the lateral incisor when bisected through its long axis. Sector IV represents the area mesial to the mesial border of the lateral incisor. With this approach, it is estimated that 78% of unerupted canines located in sectors II, III, and IV would be impacted. Warford et al.[28], found 82% of impacted canines were in sectors II, III, and IV. They suggested that the sector approach had stronger reliability than angulation and provided canine impaction risk assessment from sectors and angles (Table 1).

In another attempt, Power and Short[29] investigated the success of the eruption of palatally impacted canines after removing their deciduous predecessor. Panoramic radiographs were used to evaluate the severity of impaction. They recorded the following: canine-incisor overlap, its angulation relative to the midline, eruptive level relative to the nearest incisor root, and the vertical height from the canine tip to a horizontal line drawn tangent to the central incisal edges. The authors concluded that the treatment outcome depends on these radiographic variables, of which canine-incisor overlap had the most significant impact (Figure 1B).[29]

On the other hand, Fleming et al.[30] used panoramic radiographs to extrapolate the appropriate duration for orthodontic alignment. They assessed radiographic variables related to the vertical displacement of the impacted canine, long axis angulation, proximity of the canine cusp tip to the midline and proximal incisors, and the anteroposterior apex location. The location of the impacted canine with respect to the midline influenced the treatment time the most. Furthermore, the treatment time could not be associated with the anteroposterior position of the apex, mesiodistal location, or long axis-midline angulation (Figure 1C).[30]

Eventually, with the introduction of CBCT scans, profound comprehension of impacted canines and an efficient biomechanical approach for their management became feasible. Kau et al.[31] were the first to suggest an index (KPG) that used information provided by CBCT imaging to evaluate the complexity in treating impacted canines. Based on the canine's anatomical location, its cusp tip and root tip were scored (0-5) in three dimensions (X,Y,Z). The sum of these scores in two views (frontal and axial) dictated the anticipated difficulty of treatment.[31] Despite the good level of agreement between the clinician's perception and the KPG index score for the difficulty of impaction,[32] reliability in using this index varied between different software used for the analysis.[33] In addition, this index did not take into consideration the sagittal view and did not evaluate the angulation of the longitudinal axis of the impacted canine relative to a standard reference plane (Figure 2).

Similarly, Liu et al.[34] also attempted to three-dimensionally localize impacted canines and assess the amount of adjacent incisors' root resorption. Angular and linear measurements were undertaken in axial and paraxial sections. Their classification

Table 1. Warford et al.[28] classification of impacted canines (probability of canine impaction based on sector and angle classification)

Angle (degrees) classification	Sector classification			
	I	II	III	IV
40-54°	0.11	0.53	0.91	0.99
55-69°	0.08	0.43	0.87	0.98
70-84°	0.05	0.33	0.81	0.98
85-99°	0.04	0.25	0.75	0.96
Angle not considered	0.06	0.38	0.87	0.99

was descriptive and not related to standardized measurements. They found that the displacement of impacted maxillary canines is widely variable and is usually associated with the resorption of proximal incisors.[34] More recently, Zeno and Ghafari[35] hypothesized that the severity of impaction and treatment required can be specified based on the location of the palatally impacted canine in relation to its expected final position in the dental arch. Their objective was to evaluate the impaction severity by three-dimensionally assessing the position of palatally impacted canines. The angulation of impacted canines was measured relative to its final expected position, midline, and palatal plane. Their measurements also included cusp tip to apex length. The highest severity of impaction was seen when the canine tip point was medial, and the apex was posterior. They noted that further research is needed to take other variables, such as treatment duration, into account when performing severity scoring (Figure 3).[35]

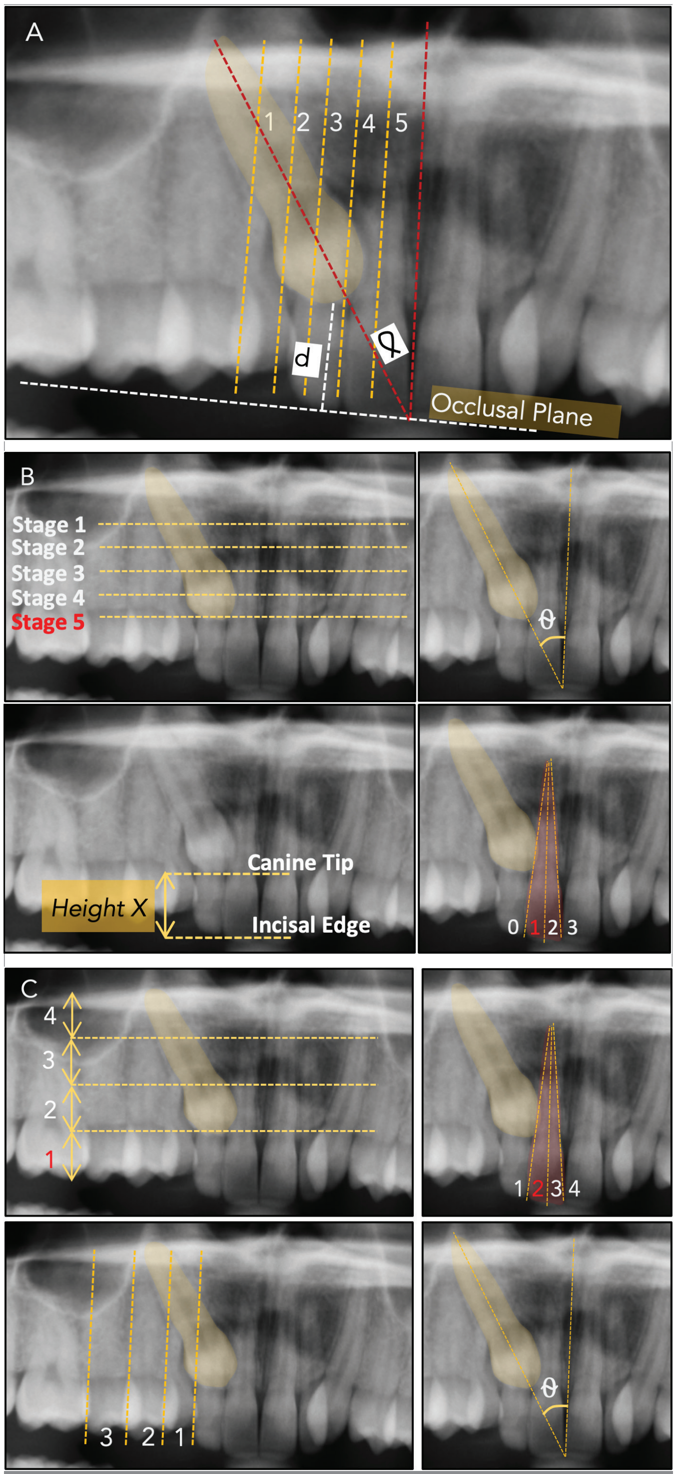

Figure 1A-C. Initial attempts to assess the location of impacted canines. A) Ericson and Kurol,[2] **B)** Power and Short,[29] **C)** Fleming et al.[30].

Despite the previous attempts, a comprehensive standardized and objective analysis of (3D) locations and orientations of impacted canines was lacking.[14,16,17,36] The previous classifications were not based on a standardized vertical, horizontal, and angular analysis of impaction. They lacked an objective scoring system to assess the severity of impaction. Severity assessment will help determine the treatment duration and mechanics necessary to resolve the impaction. Furthermore, it will assist in choosing the best surgical exposure technique to resolve the impaction.

Recently, Ross et al.[37] developed a comprehensive standardized index that quantified the (3D) location of impacted canines in the three planes of space (sagittal, coronal and axial). Specifically, it included angular measurements of the long axis of the canine relative to adjacent teeth. They also assessed the linear distances to standardized reference planes in the sagittal, coronal, and axial views using CBCT scans. This index was adopted to evaluate the severity of the impaction (mild, moderate, or severe) based on the impacted canine's (3D) location. Scores were given for each category of severity. A nomenclature that indicates the location of the canine was suggested to enhance the communication between the clinicians. In their study, they concluded that the majority of the severely impacted canines had their crowns buccal in relation to the maxillary arch, closer to the occlusal plane and mesial to the distal border of the central incisor with more than 45° buccal inclination and an exaggerated mesial tip. They concluded that the sagittal angle of the impacted canine had a significant effect on the severity of impaction (Figure 4).[37]

Clinical Significance of the Radiographic Predictors and Precision of Locating an Impacted Canine Using 3D Radiographs

Variations in the spatial location of the impacted canines define the complexity of the impaction and help assess the treatment duration. Additionally, 3D radiographs serve as an aid to the clinician in the decision-making process regarding management and prognosis (Figure 5).[35,38] Several factors were reported in the literature and can be associated with the duration of traction of an impacted canine, among which are: number of impaction, accurate pretreatment radiographic evaluation using (2D) radiographs, and indices computed, and proposed in the literature from (2D) radiographs and more recently (CBCT) images.[2,5,11,35,38]

Previous studies in grading the severity of impacted canines using (2D) radiographs illustrated four major radiographic

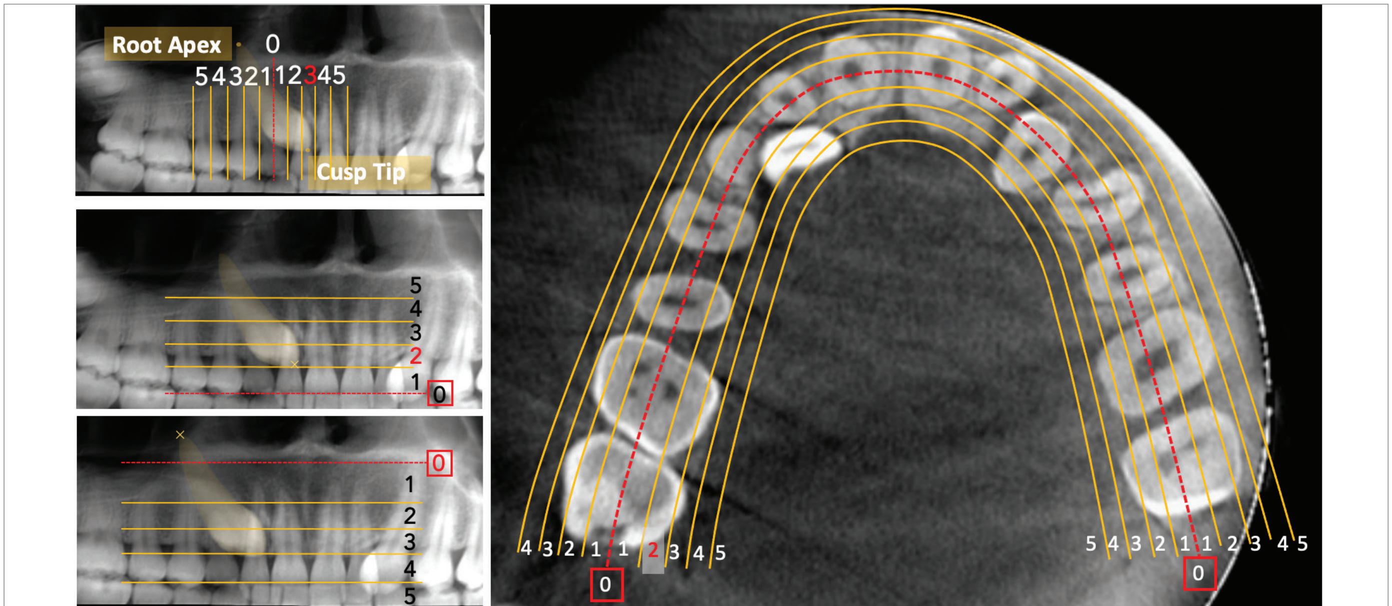

Figure 2. Clinical example of the Kau index

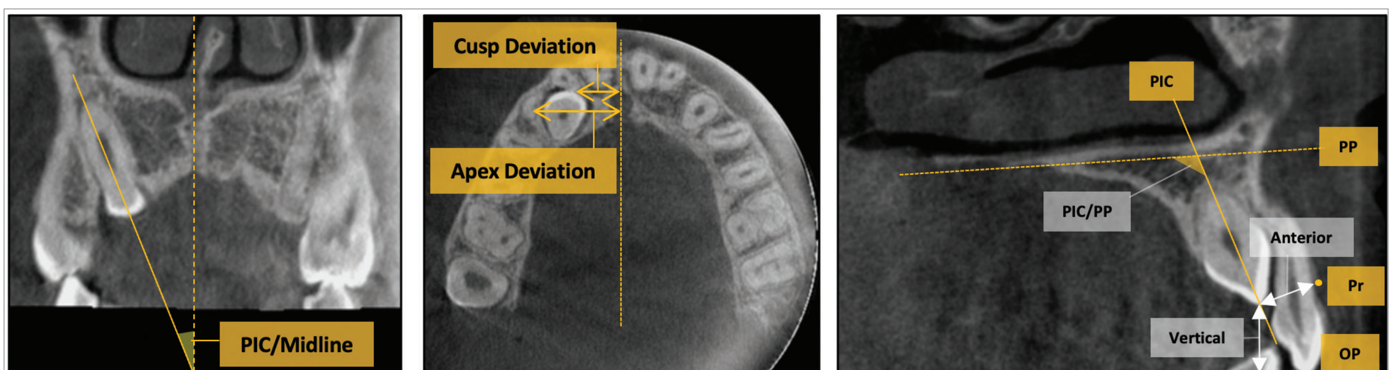

Figure 3. Clinical example of a measurement from Zeno and Ghafari[35]

predictors that showed some evidence correlated with the complexity of managing an impacted canine. The predictors included overlap with the proximal incisor, long axis-midline angulation, sagittal position of the apex, and vertical displacement of the crown tip.[39]

Regarding vertical displacement of the canine tip in association with severity found that when the impacted canine crown was at a distance of less than 14 mm from the occlusal plane, treatment time averaged 23.8 months; a distance of more than 14 mm required an average treatment time of 31.1 months.[39] Historically, Ericson and Kurol[2,40] were the first to illustrate the significance of this vertical distance as a predictive factor during treatment. This distance also dictated the outcomes of their suggested interceptive treatment i.e. extraction of the deciduous canine and maintaining the space in the maxillary dental arch.[41,42] On the other hand, Fleming et al.[43] reported that vertical height did not influence the treatment duration.

The horizontal mesiodistal location of the canine is a predictive factor for its severity of impaction and duration of traction. Fleming et al.[30] demonstrated that canine crown location in relation to proximal teeth and midline is associated with treatment duration. Alternately, Zuccati et al.[38] indicated a strong direct correlation between the horizontal mesiodistal location of the canine and treatment duration.

Moreover, the influence of impacted canine angulation on the midsagittal plane in panoramic radiographs on treatment duration has been previously studied.[39,43] Due to the limitations of the (2D) radiographs, assessment of the influence of sagittal angle on treatment complexity and duration was not feasible. The sagittal angle is critical in evaluating the severity of the impacted canine. The severity of this angle indicates a more challenging path of eruption and reflects the difficulty in moving the root buccally during orthodontic treatment.[44] A greater mesio-distal tip, will increase the risk of damaging adjacent roots during canine traction. Consequently, the more severe these angles, the greater the need for the canine to be uprighted and distanced from the incisors' roots; once uprighted can be pulled toward the arch. Therefore, uprighting with orthodontic traction on the opposite side would be required.[42] Additionally, the torque correction for the roots will increase the treatment duration to finally be able to engage the canine into a rectangular SS archwire. And even if the canine was close to the occlusal plane, the non-linear biomechanics of traction based on the severity of the sagittal and coronal angulation play a crucial role in predicting the severity and traction duration.[10] Hence, the clinical significance of CBCT scans in evaluating both angles.

The controversy in the literature regarding the influence of some of the above-mentioned radiographic predictors on the severity of impaction and duration of treatment can be

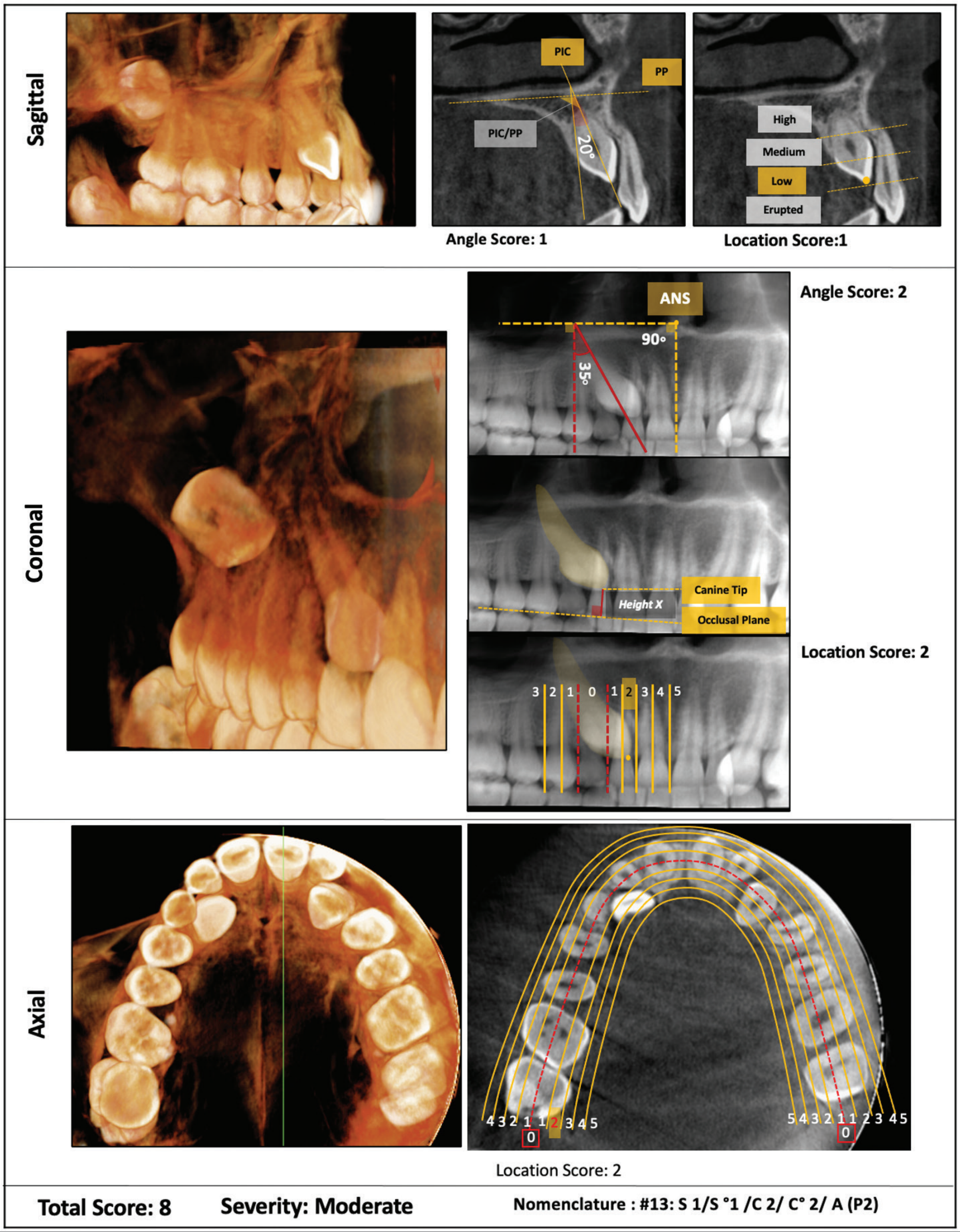

Figure 4. Clinical example for the application of the current index to evaluate the severity of impaction

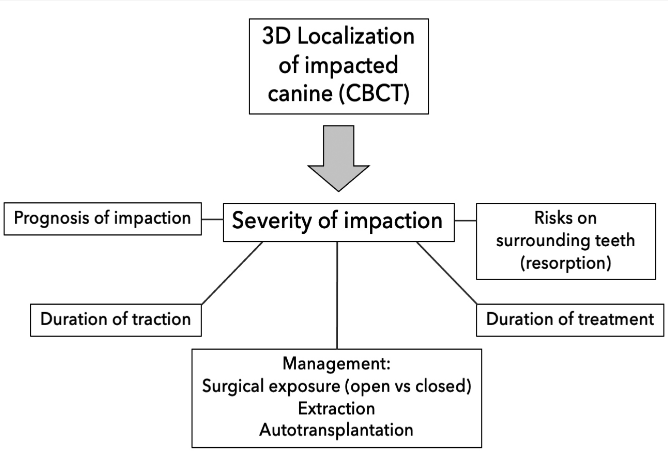

Figure 5. Illustration of the factors that are influenced by the severity of impaction based on 3D localization
CBCT, Cone-beam computed tomography

attributed to the fact that these variables were each assessed independently using (2D) radiographic images. Therefore, combining these predictive variables in one comprehensive classification system would clearly signify their value. A single predictive radiographic parameter does not necessarily illustrate the severity of impaction, but rather a combination of these variables assessed in all three planes of space–would be a reliable pretreatment estimate of orthodontic treatment duration, risks, and success rate. Moreover, with the use of a single (2D) image, a comprehensive evaluation of all these predictors at once is impossible. A combination of several (2D) images will be required. In addition, the diagnostic validity for locating impacted canines is often compromised by the drawbacks associated with (2D) images related to magnification, superimposition of adjacent structures, and the deformative nature of conventional radiographs.[45] However, with a single CBCT scan, reconstruction of the area of interest in (3D) views became a feasible and precise method to analyze all the above-mentioned radiographic predictors.[16,31,35,37]

Finally, the various proposed mechanisms for traction mentioned in the literature include the use of power chains, ligature wires, cantilever springs, accessory wires,[46] and more recently traction with the aid of temporary anchorage devices.[47] The initial eruption can be easily achieved with the use of any previously mentioned auxiliary, while, bringing the impacted canine into the line of the arch requires careful attention to the direction of pull, amount of force applied, and amount of available space in the dental arch.[48] Therefore, the implementation of a careful biomechanical approach would prevent adverse events related to root contact, periodontal health, and loss of anchorage.[43] The success in planning proper biomechanics for traction depends on using a standardized 3D analysis for localizing the impacted canine.[37] For instance, attempting to pull a palatally impacted canine with buccally directed forces without careful assessment of its 3D location in relation to the surrounding structures, might introduce unwanted side effects related to resorption and obstruction, which might hold back the eruption process and delay the treatment or lead to the loss of the impacted canine. Additionally, an optimal force system within the physiological range is needed. It was recommended that 0.6 N (61.1 grams) is the ideal force for canine traction.[1] Yadav et al.[49] discussed the forces applied in the Kilroy spring, ligature wire, and elastomeric chain systems. They concluded that the three systems produced excessive forces beyond the physiological limits 2.7 N (275.3 grams).

Interestingly, the latest literature focused on studying the influence of other factors such as the contact of the roots to the cortical plates of the nasal cavity and/or sinus, and shape of the canine's root on the success of orthodontic eruption and treatment duration. The closer the proximity of the canine's root to the cortex and the presence of a bend in the roots had a great influence on orthodontic treatment duration.[50] Therefore, many variables play a role in lengthening the treatment duration for impacted canines, all of which should be taken into consideration when evaluating treatment.

CONCLUSION

Precision in localizing an impacted maxillary canine is the key to assess its severity of impaction, which plays a main role in decision-making related to prognosis, diagnosis, treatment planning, and estimating the duration of traction. The current evidence proves the superiority of CBCT scans over conventional radiography in detection, visualization, and precisely localizing impacted canines. With a single CBCT scan, that permits reconstruction of the area under investigation in (3D) views, previously investigated radiographic predictors for the severity of impaction assessed with multiple (2D) radiographic views can now be evaluated comprehensively immediately.

An inclusive and objective analysis of (3D) locations and orientations of impacted canines based on a standardized vertical, horizontal, and angular analysis and a scoring system to determine the degree of severity is the future foundation for an accurate estimate of the duration of traction and application of proper mechanics and surgical exposure procedures necessary to resolve the impaction.

There is evidence that the impacted canine's location is the most crucial factor in determining the severity of impaction, and validation of the newly proposed severity classification using CBCT images is needed. A comprehensive nomenclature for the spatial localization of impacted canines using CBCT scans is a turnover step to facilitate communication between clinicians and aid in proper diagnosis and treatment mechanics. Despite the positive effects on treatment planning, which justifies the use of CBCT images as a routine examination for some of the impacted canine cases, it should be kept in mind that CBCT results in a higher radiation dose compared to 2D radiographs; therefore, before choosing the proper radiographical examination, both clinical benefit and radiation dose must be taken into consideration.

Ethics

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - S.A.A.; Design - P.F., S.A.A.; Supervision - S.A.A., D.K.; Data Collection and/or Processing - P.F., S.A.A.; Analysis and/or Interpretation - P.F., D.K.; Writing - P.F., S.A.A., M.N., C.D.; Critical Review - P.F., M.N., D.K., C.D., S.A.A.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: No financial assistance was received to support this study.

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TURKISH JOURNAL of
ORTHODONTICS

DOI: 10.4274/TurkJOrthod.2022.2022.110

Systematic Review

Effectiveness of Functional Mandibular Advancer in Patients with Class II Malocclusion: A Systematic Review and Meta-analysis

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Cite this article as: Kumar MD, Sathyanarayana HP, Kailasam V. Effectiveness of Functional Mandibular Advancer in Patients with Class II Malocclusion: A Systematic Review and Meta-analysis. *Turk J Orthod.* 2023; 36(4): 270-279

Main Points

- The functional mandibular advancer is a rigid, fixed functional appliance with bilateral protrusive bars and inclined planes which directs the mandible to anterior position.
- The design of the appliance is quiet simple and it has similar effects compared to other fixed functional appliances in Class II correction with a combination of skeletal and dentoalveolar effects.
- Evidence regarding the soft tissue and airway changes is limited to draw definitve conclusions.

ABSTRACT

Objective: We aimed to evaluate the effectiveness of functional mandibular advancer (FMA) in treating growing patients with Class II malocclusion.

Methods: Electronic searches were conducted in MEDLINE (via PubMed), Cochrane Library, Web of Science, Scopus, Embase, and Lilacs from 1945 to 30th November 2021. Studies were selected based on the following inclusion criteria: human studies, Class II growing patient treated with FMA, untreated control group or a comparable group treated with another fixed functional appliance, pre- and post-treatment lateral cephalograms/magnetic resonance imaging/cone-beam computed tomography, randomized clinical trials, prospective studies, and retrospective studies. Data extraction of the included articles was independently performed independently by two authors. The risk of bias was assessed using the ROBINS-I tool. Meta-analysis was performed using the inverse generic model.

Results: Seven articles met the criteria and were included in the systematic review and three articles were included in the meta-analysis. Three studies had at low risk of bias and four studies had a moderate risk of bias. All articles reported anterior positioning of the mandible along with an increase in mandibular length. The meta-analysis results indicated a negligible difference between FMA and other functional appliances for the parameters SNA [0.11, 95% confidence interval (CI) of -1.07 and 1.29] and ANB (-1.00, 95% CI of -1.34 and -0.65). The evidence was limited for soft tissue changes.

Conclusion: Class II correction with FMA involved a combination of skeletal and dentoalveolar changes and was similar to other fixed functional appliances.

Keywords: Mandibular retrognathism, functional mandibular advancer, Class II malocclusion, systematic review

INTRODUCTION

The primary treatment objective for correcting mandibular retrognathism in a growing patient is to induce supplementary lengthening of the mandible through functional appliance therapy.[1] Functional appliances are broadly categorized into removable functional appliances (RFAs), fixed functional appliances (FFAs), and hybrid appliances.[2] The key difference among these appliances is patient compliance, with RFAs and hybrid variants relying on patient cooperation, whereas full-time wear is ensured with the fixed type.[2]

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Received: July 23, 2022
Accepted: January 11, 2023
Publication Date: December 29, 2023

FFAs may be further sub-classified as fixed rigid, fixed flexible, and fixed hybrid.[3] Fixed rigid functional appliances provide constant horizontal forces, particularly when the mouth is closed, and they exhibit an additive headgear effect.[4] The consensus is that condylar growth can be effectively stimulated when functional treatment is performed during the adolescent growth spurt using rigid FFAs.[5]

The functional mandibular advancer (FMA) (Forestadent®, Pforzheim, Germany) is a rigid FFA introduced by Kinzinger et al.[6] in 2002 that resembles the mandibular anterior repositioning appliance.[7,8] The FMA relies on the mechanical principle of an inclined plane, which is inclined at 60° to horizontal, and the guide pins that direct the mandible to the anterior position.[6] Based on biomechanical considerations, the FMA has a more vertical intergnathic force vector and a remarkably shorter lever arm compared with the Herbst appliance.[6]

Studies have evaluated the skeletal, dentoalveolar effects and soft tissue changes in patients with Class II malocclusion treated with FMA, reporting varying conclusions.[9-11] Therefore, the aim of this systematic review was to evaluate the treatment effectiveness of FMA in patients with Class II malocclusion.

METHODS

Protocol and Registration

This systematic review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[12] The proposal was registered on the International Prospective Register of Systematic Reviews (PROSPERO: CRD42021227317). The research question was, "How effective is the Functional Mandibular Advancer in treating growing patients with Class II malocclusion in terms of skeletal, dental, soft tissue, and airway changes?"

Eligibility Criteria

Inclusion criteria were as follows: human studies, involving growing patients with Class II malocclusion (defined by an ANB angle greater than 4 degrees or an overjet greater than 6 mm) treated with FMA with or without fixed appliances, untreated control group or a comparable group treated with other FFA; pre- and post-treatment lateral cephalograms/magnetic resonance imaging (MRI)/cone-beam computed tomography (CBCT), lateral cephalograms and CBCT-derived lateral cephalograms were used to assess skeletal, dental, and soft tissue changes, whereas lateral cephalograms and MRI were used to assess the airway changes; randomised clinical trials, prospective and retrospective studies. The exclusion criteria were adult patients, patients with craniofacial syndromes, systematic reviews, meta-analysis, case series, case reports, expert opinion, and editorials.

Information Sources and Search Strategy

Electronic searches in MEDLINE (via PubMed), the Cochrane Library, Web of Science, Scopus, Embase, and Lilacs were conducted from 1945 to 30th November 2021. Search terms were based on both Medical Subject Headings (MeSH) and free text with combinations and were prepared for MEDLINE via PubMed and adapted for LILACS, Web of Science, Scopus, Ovid, Embase, and Cochrane electronic databases. The keywords and the search database summary are presented in Table 1.

Table 1. Summary of the search database

Keywords	Database	No of articles
((Class II malocclusion)) [Title/Abstract] AND ((Fixed Functional Appliance)[Title/Abstract] OR (Functional Mandibular Advancer))[Title/Abstract] AND ((Skeletal)[Title/Abstract] OR (Dental)[Title/Abstract] OR (Soft tissue)[Title/Abstract]OR (Airway)[Title/Abstract]OR (Condyle)[Title/Abstract]OR (Mandibular fossa) [Title/Abstract]OR (TMJ)[Title/Abstract])	Pubmed (From 1980 to 30th Nov 2022)	785
(Class II malocclusion) AND (Fixed Functional Appliance)	Lilac (From 1980 to 30th Nov 2022)	39
((Class II malocclusion)) AND ((Fixed Functional Appliance) OR (Functional Mandibular Advancer)) AND ((Skeletal) OR (Dental) OR (Soft tissue) OR (Airway) OR (condyle) OR (Mandibular fossa) OR (TMJ))	Ovid (From 1946 to 30th Nov 2022)	1550
"Class II malocclusion" in Title Abstract Keyword AND "Fixed Functional Appliance" in Title Abstract Keyword OR "Functional Mandibular Advancer" in Title Abstract Keyword AND "Skeletal" in Title Abstract Keyword AND "Dental" in Title Abstract Keyword.	Cochrane (From 1945 to 30th Nov 2022)	25
TITLE-ABS-KEY((Class II malocclusion)) AND TITLE-ABS-KEY ((Fixed Functional Appliance) OR TITLE-ABS-KEY (Functional Mandibular Advancer)) AND TITLE-ABS-KEY ((Skeletal) OR TITLE-ABS-KEY (Dental) OR TITLE-ABS-KEY (Soft tissue) OR TITLE-ABS-KEY (Airway) OR TITLE-ABS-KEY (condyle) OR TITLE-ABS-KEY (mandibular fossa) OR TITLE-ABS-KEY (TMJ))	Scopus (From 1960 to 30th Nov 2022)	308
ALL FIELDS:((Class II malocclusion)) AND ALL FIELDS: ((Fixed Functional Appliance) OR ALL FIELDS:(Functional Mandibular advancer)) AND ALL FIELDS: ((Skeletal) OR ALL FIELDS:(Dental) OR ALL FIELDS:(Soft tissue) OR ALL FIELDS:(Airway) OR ALL FIELDS:(Condyle) OR ALL FIELDS:(Mandibular fossa) OR ALL FIELDS:(TMJ))	Web of science (From 1952 to 30th Nov 2022)	161
TOTAL		2868
DUPLICATES		118
TOTAL AFTER DUPLICATES REMOVAL		2750

Study Records

The selection of the studies consisted of two phases. The initial screening of articles identified in the databases involved independent screening of titles and abstracts by two reviewers based on the research question and against the inclusion and exclusion criteria. In cases where the title and abstract failed to provide sufficient information, the full text was reviewed to assess relevance. In the second phase, full-text articles were retrieved from these potentially eligible studies. To ensure that no relevant studies were missed, the reference lists of the remaining articles were hand-searched. Articles identified using this process were added to the pool of full-text articles for evaluation. This pool was then assessed for eligibility for both quantitative and qualitative reviews.

Data Items and Collection

Data extraction from the included articles was independently performed by two authors using a pre-determined and standardized table. The predefined data to be extracted included the title, author, study type, age, gender, population, sample size, assessment method, skeletal and dental cephalometric findings, including mandibular and maxillary dimensions, mandibular and maxillary anteroposterior positions, vertical dimensions, sagittal intermaxillary relationship, mesiodistal position of maxillary and mandibular first molars, inclination of maxillary and mandibular incisors, and P values.

Outcome

The outcomes for which data would be sought included skeletal, dental, soft tissue, and airway changes.

Risk of Bias/Quality Assessment

For non-randomized studies the risk-of-bias was assessed using the ROBINS-I tool for non-randomized studies (risk of bias in non-randomised studies of interventions).[13] The following domains were evaluated; 1. Confounding bias, 2. Selection bias, 3. Bias in classification of interventions, 4. Bias due to deviation from intended interventions, 5. Missing data, 6. Measurement of outcomes, 7. Bias in selection of reported result.

Two reviewers independently assessed all included studies, and disagreements were resolved through discussion and consensus, or the decision of the third reviewer.

Data Synthesis

The studies were grouped based on the assessed data. For each article that met the inclusion criteria, data were extracted and compiled into a table of evidence. Analysis was performed according to the Cochrane Handbook for Systematic Reviews. Data were analyzed using Review Manager (RevMan) 5.3.[14] Continuous data are presented as mean difference and 95% confidence interval. An inverse variance method for pooling the data with a random-effects model was used for the meta-analysis. Heterogeneity was assessed with I2 statistics that ranged from 0% to 100%.[15] An I2 index less than 25% is indicative of low heterogeneity, between 25% and 75% represents average heterogeneity, and more than 75% indicates considerable heterogeneity.[16] The coefficient of efficiency of FMA was assessed by dividing the supplemental elongation of the mandible obtained during the overall active treatment period with the functional appliance by the number of months of active treatment.[5]

RESULTS

Study Selection

The search selection process is depicted in the PRISMA flowchart (Figure 1). According to the electronic search, 2,868 records were screened across all databases. After removal of duplicates, 2750 records were screened, of which 2,728 articles were eliminated after reading the title and abstracts. Of the 22 full-text articles, 15 studies were excluded from the review, and the reasons for exclusion are depicted in the PRISMA flow chart (Figure 1).

Study Characteristics

Of the seven included studies that met the inclusion and exclusion criteria, Kinzinger et al.[17] compared the airway and skeletal changes caused by FMA. Three studies[11,18,19] have evaluated the skeletal and dental changes caused by FMA and compared them with other FFAs. Hourfar et al.[10] compared soft tissue changes, Kinzinger et al.[9] evaluated the skeletal and dental effects caused only by FMA, and Aras et al.[20] evaluated the airway changes produced by the type of advancement (either single step or stepwise) of FMA.

Four studies were prospective[9,11,19,20] and three were retrospective.[10,17,18] The total number of FMA patients across the seven studies was 163 (81 males and 82 females), with a minimum sample of 16 patients[9] and a maximum sample of 21 patients.[18] In five studies,[9,10,17,18,20] participants were selected based on chronologic age, and their age ranged from a minimum of 13.15 years to a maximum of 16.2 years. One study was based on the cervical vertebral maturation index by Baccetti et al.[21] with 20 participants at cervical stage 2 and 18 participants at cervical stage 3.[19] Another study was based on hand-wrist radiographs by Hagg and Taranger[22] with a growth period just before or at the peak of pubertal growth.[11] The summarized results of individual studies are shown in Table 2.

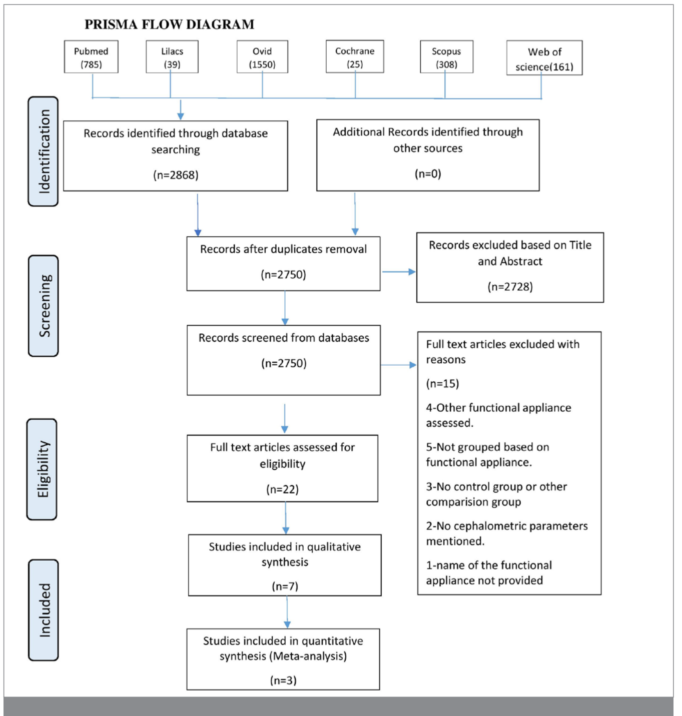

Figure 1. Literature search Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram

Table 2. Characteristics of the included studies

	Journal name/year	Study type	Participants	Mean age of participants	Treatment duration for participants	Control/ comparision group	Mean age of control/ comparision	Treatment duration for control/ comparision
Kinzinger et al.[9]	J Orofac Orthop 2005	Prospective study	FMA-16 patients	15 years and 5 months males-16 years, 1 month females-14 years, 9 months	7.5 months	Bhatia & Leighton in 1993	No data	No data
Kinzinger et al.[17]	J Orofac Orthop 2011	Retrospective study	FMA-18 patients	15 years and 7 months	FMA and MBA treatment= 18 months.	HERBST-25 patients	13 years and 8 months	Herbst and MBA treatment- 19.5 months
Aras et al.[11]	Angle Orthodontist 2017	Prospective study	FMA SSG-17 patients	Hand-wrist radiographs-just before or at the peak of pubertal growth	10 months	FMA SWG-17 patients	Hand-wrist radiographs-just before or at the peak of pubertal growth	10 months
Kinzinger et al.[18]	Clin Oral Invest 2018	Retrospective study	FMA-21 patients	Male-16 years and 2 months female-15 years and 9 months	1.32 ± 0.71 years.	HERBST-21 patients	Males-12 years and 1 month females-13 years and 2 months	1.46±0.38 years
Bozkurt et al.[19]	AJODO 2020	Prospective study	FMA-19 patients	Cervical Stage 2- 9 patients (5 boys and 4 girls) Cervical Stage 3-10 patients (6 boys and 4 girls)	2±0.2 years	FORSUS-19 patients	Cervical Stage 2- 11 patients (5 boys and 6 girls) Cervical Stage 3- 8 patients (5 boys and 3 girls)	2.3±0.5 years
Aras et al.[20]	J Orofac Orthop 2016	Prospective study	SSG-17 patients SWG-17 patients	SSG- 13.15±0.77 years SWG- 13.48±0.88 years	Functional phase-10 months second phase-SSG-20.48±2.15 months SWG-19.16±2.67 months	Untreated-17 patients	13.76±0.62 years	18.9±3.8 months
Hourfar et al.[10]	Clin Oral Invest 2018	Retrospective study	FMA-21 patients	Males-16 years and 2 months Females-15 years and 9	1.32 ± 0.71 years.	HERBST-21 patients	Males-12 years and 1 month. Females-13 years and 2 months	1.46±0.38 years

Three studies compared FMA with the Herbst appliance,[10,17,18] one study compared FMA with the Forsus appliance,[19] two other studies had untreated Class II patients as control group[9,20] and one study compared the single-step and step- wise advancement of FMA.[11] The study duration was until the end of the functional appliance phase in five studies ranging from a minimum of 7.5 to a maximum of 13.2 months.[9-11,18,20] The study duration was until the end of the fixed appliance phase in two studies, ranging from a minimum of 18 to a maximum of 24 months[17,19] (Table 3).

Risk of Bias in the Studies

The ROBINS-I tool was used to assess the risk of bias.[13] In terms of overall risk of bias, four of these studies were assessed as having a moderate risk of bias.[10,17,18,20] Lower scores were obtained from these studies in the domains of confounding bias, selection bias, and intervention classification. Three studies had a low risk of bias[9,11,19] (Table 4).

Synthesis of the Results

Skeletal Changes

The maximum and minimum sagittal increases in mandibular length (Co^{dorsal}-Pog) were 3.4 3.4±4.69 mm (18 months) and 0.69±3.5 mm (13.2 months) respectively.[17,18] The maximum increase in the SNB angle was 2.41±0.91°[19] and the minimum increase in the SNB angle was 1.29±1.34°.[17] The maximum decrease in the ANB angle was -2.64±0.61°[19] and the minimum decrease in the ANB angle was -0.98±1.34°.[17] Kinzinger et al.[17] reported an increase in the SNA angle by 0.32±1.44° whereas Bozkurt et al.[19] reported a decrease by -0.23±0.46°. The maximum

Table 3. Risk of bias in studies-the table displays for each included study the risk-of-bias judgement for each of six domains of bias and for the overall risk of bias with ROBINS 1 tool

No	Author	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall bias
1	Kinzinger et al.[9]	Moderate	Moderate	Low	Low	Low	Low	Low	Low
2	Kinzinger et al.[17]	Moderate	Moderate	Moderate	Low	Low	Low	Low	Moderate
3	Aras et al.[11]	Moderate	Low	Low	Low	Low	Low	Low	Low
4	Kinzinger et al.[18]	Moderate	Moderate	Moderate	Low	Low	Low	Low	Moderate
5	Bozkurt et al.[19]	Moderate	Low	Low	Low	Low	Low	Low	Low
6	Arasl et al.[20]	Moderate	Moderate	Low	Low	Low	Low	Low	Moderate
7	Hourfar et al.[10]	Moderate	Moderate	Moderate	Low	Low	Low	Low	Moderate

Table 4. Results of individual studies

Kinzinger et al.[9]	**SKELETAL EFFECTS**			**DENTAL EFFECTS**	
	Maxilla	**Mandible**		**Maxilla**	**Mandible**
	No treatment effect on the maxilla occurred and the position of the maxillary base remained stable	Effective increase in mandibular length sagitally and sagittal-diagonally. Bony chin advanced significantly (N-Pog on FH). Gonial angle changes also significant		Central incisors were retracted. Molars were distalized.	Central incisors had protruded. Molars tipped mesially. Reduction in overjet.
Kinzinger et al.[17]	**SKELETAL EFFECTS**				
	Maxilla	**Mandible**	**Pharyngeal distance**		
	Significant increases in the vertical length of the maxilla (S-ANS, S-PNS and N-ANS). No significant changes in the position of the anterior maxillary base relative to the anterior cranial base (SNA).	Linear: S-Go, N-Gn, N-Pog, and N- Me increased. Diagonal: Ba-Pog and Codorsal-Pog increased. Forward development of the mandible (SNB, SN-Pog). No significant difference in gonial angle ANB angle statistical decrease in FMA group.	No significant changes.		
Aras et al.[11]	**SKELETAL EFFECTS**			**DENTAL EFFECTS**	
	Mandible			**Maxilla**	**Mandible**
	Positioned anteriorly. SNB, mandibular length and ramus height increased, Pg and ANB angle decreased horizontally. Gonial angle no significant difference.			Palatal tipping of maxillary incisors. No distal movement of maxillary molars (due to palatal arch).	Mesial movement of mandibular molars, labial tipping of the mandibular incisors, and decrease in overjet and overbite. No significant intergroup differences were found for dental changes.
Kinzinger et al.[18]	**SKELETAL EFFECTS**			**DENTAL EFFECTS**	
	Maxilla	**Mandible**		**Maxilla**	**Mandible**
	Increased N-ANS and N-PNS. NO change in maxillary length (N-ANS on FH and Ba-PNS).	S-Go and N-Me increased. Codorsal-PTV - decreased		Greater retroclination of upper incisors. Mesial tipping of Upper molars. Greater antero-caudal cant of the occlusal plane.	Greater proclination of lower incisors, and mesial tipping of lower first molars.

Table 4. Continued

Bozkurt et al.[19]	**SKELETAL EFFECTS**			**DENTAL EFFECTS**	
	Maxilla	**Mandible**		**Maxilla**	**Mandible**
	No skeletal maxillary effect	Increase in SNB and Co-Gn. Co-Go and SNGoGn no significant change. ANB and WITS - decreased.		No significant change in position of maxillary incisors, horizontal and vertical position of maxillary molars.	Significant changes in proclination of mandibular incisors, overjet, overbite and mesial movement of mandibular molars.
Aras et al.[20]	**AIRWAY**				
	Nasopharyngeal	**Oropharyngeal**	**Hypopharyngeal**		
	Increased significantly in the SSG and SWG (p<0.05)	Oropharyngeal airway, minimal distance between the base of the tongue and the posterior pharyngeal wall (PASmin) in the SWG and SSG increased significantly (p<0.05).	Hypopharyngeal airway, soft palate length and thickness- NOT SIGNIFICANT		
Hourfar et al.[10]	**SOFT TISSUE**				
	Significant lower lip protrusion (Li-Sn on FH) (p<0.01) Straightening of the profile (N'-Sn-Pog', soft tissue profile excluding nose) (p<0.05)				

and minimum sagittal decreases in anterior maxillary length (N-ANS on FH) were 0.38 -0.38±2.63 mm and -0.07±0.24 mm.[18,19] The average coefficient of efficiency for FMA was 0.19 mm per month.[9] The results are depicted in Tables 5 and 6.

Dental Changes

The maximum retraction of the upper incisors and distalization of the upper molars were 1.79±2.58 mm and 2.24±3.47 mm respectively.[18] The minimum retraction of upper incisors and distalization of upper molars were 1.76±1.81 mm and 1.62±1.38 mm respectively.[9] The maximum proclination of lower incisors and mesialization of lower molars were 2.66±1.85 mm and 2.26±2.05 mm respectively.[9] The minimum proclination of lower incisors and mesialization of lower molars were 2.42±2.69 mm and 1.62±3.2 mm respectively.[18]

Soft Tissue Changes

Hourfar et al.[10] was the only study evaluating soft tissue changes. There was an improvement in the lower lip position and facial convexity angle by -0.14±1.93 mm and 2.72±4.69°, respectively.

Airway Changes

Aras et al.[20] assessed airway changes with single-step and stepwise advancement of FMA. The mean improvements in the nasopharyneal, oropharyngeal, and hypopharyngeal airways in the single step group were 1.39±2.31 mm, 1.59±2.01 mm and 1.05±2.24 mm respectively. The mean improvements in the nasopharyneal, oropharyngeal, and hypopharyngeal airways in the stepwise group were 1.35±2.51 mm, 1.69±2.08 mm and 0.98±2.04 mm respectively. Kinzinger et al.[17] assessed the posterior airway space at six levels [palatal plane (P1), occlusal plane (P2), second cervical vertebra (P3), mandibular plane (P4), third cervical vertebra (P5), and fourth cervical vertebra (P6)] and reported a decrease in posterior airway space at P1, P2, P3, and P4 levels by 0.47±2.8 mm, 0.85±2.56 mm, 0.32±3.25 mm and 0.4±2.58 mm respectively. The posterior airway space increased at P5 and P6 levels by 0.63±3.28 mm and 1.85±5.32 mm respectively.[17]

Quantitative Analysis

A meta-analysis was planned for homogeneous data. There was an increase in the SNA angle by 0.11 degrees in the FMA group when compared with other FFAs (95% CI of-1.07 to 1.29). The I^2 was 67%, showing moderate heterogeneity. The N-ANS distance increased by 0.14 mm in the FMA group when compared with other FFAs (95% CI of -0.77 to 1.04). The I^2 was 47%, showing low heterogeneity. The N-PNS distance decreased by -0.17 mm in the FMA group compared with other FFAs (95%

Table 5. The table displays maxillary changes achieved with functional mandibular advancer

	SNA			N - ANS on FH			Ba - PNS		
	MD	SD	p-value	MD	SD	p-value	MD	SD	p-value
Kinzinger et al.[9]	NA	NA	NA	-0.07	0.24	0.262	-0.08	0.41	0.435
Kinzinger et al.[18]	NA	NA	NA	-0.38	2.63	0.517	0.19	2.04	0.6674
Kinzinger et al.[17]	0.32	1.44	0.3633	NA	NA	NA	NA	NA	NA
Bozkurt et al.[19]	-0.23	0.46	0.018	NA	NA	NA	NA	NA	NA

Student's t-test, NA, not applicable; MD, mean difference; SD, standard deviation; NA, not applicable; SNA, Sella-Nasion-A, Statistical significance p<0.05

Table 6. The table displays mandibular changes achieved with functional mandibular advancer

	Horizontal distances									Diagonal distances						Gonial angle					
	SNB			N - Pog on FH			Co^{dorsal} - PTV			Co^{dorsal} - Pog			Co^{superior} - Gn			Ar - Go - Me			Co^{dorsal} - Go - Pog		
	MD	SD	p-value	MD	SD	p-value	MD	SD	p-value	MD	SD	p-value	MD	SD	p-value	MD	SD	p-value	MD	SD	p-value
Kinzinger et al.[9]	NA	NA	NA	1.28	0.52	0	0.43	0.93	0.084	1.42	1.51	0.002	1.53	2.15	0.012	1.14	1.34	0.004	0.97	1.51	0.022
Kinzinger et al.[17]	1.29	1.34	0.0008	NA	NA	NA	NA	NA	NA	3.4	4.69	0.0069	NA	NA	NA	-1.29	6.35	0.399	NA	NA	NA
Kinzinger et al.[18]	NA	NA	NA	0.58	4.42	0.5534	-0.66	1.98	0.1451	0.69	3.5	0.3757	0.66	2.81	0.296	1.55	3.47	0.054	1.19	3.26	0.1115
Bozkurt et al.[19]	2.41	0.91	0.001	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

(Student's t test, MD, mean difference; SD, standard deviation; NA, not applicable; SNB, Sella-Nasion-B., Statistical significance $p<0.05$)

CI of -1.49 to 1.14). I^2 was 60%, showing moderate heterogeneity (Figure 2).

The ANB angle brought about a greater reduction by 1 degree in FMA group compared with other FFAs (95% CI of -1.34 to -0.65). I^2 was 0%, showing low heterogeneity (Figure 3).

The SNB angle had a greater increase by 0.81 degrees in FMA group when compared with other FFAs (95% CI of -0.78 to 2.39). The I^2 was 89%, showing considerable heterogeneity. The Co^{dorsal}-Pog distance decreased by -1.00 mm in the FMA group when compared with other FFAs (95% CI of -2.65 to 0.65). The I^2 was 0%, showing low heterogeneity. The gonial angle brought about a greater increase by 0.74 degrees in FMA group when compared to other FFAs (95% CI of -1.22 to 2.71). The I^2 was 0%, showing low heterogeneity. The S-Go distance brought about a greater decrease by 0.29 mm in the FMA group when compared to other FFAs (95% CI of -1.46 to 0.88). The I^2 was 0%, showing low heterogeneity. The N- Me distance brought about a greater decrease by -0.74 mm in the FMA group when compared with other FFAs (95% CI of -2.66 to 1.17). The I^2 was 0%, showing low heterogeneity (Figure 4).

DISCUSSION

In this systematic review, the study group consisted of patients with Class II malocclusion treated with an FMA appliance, and

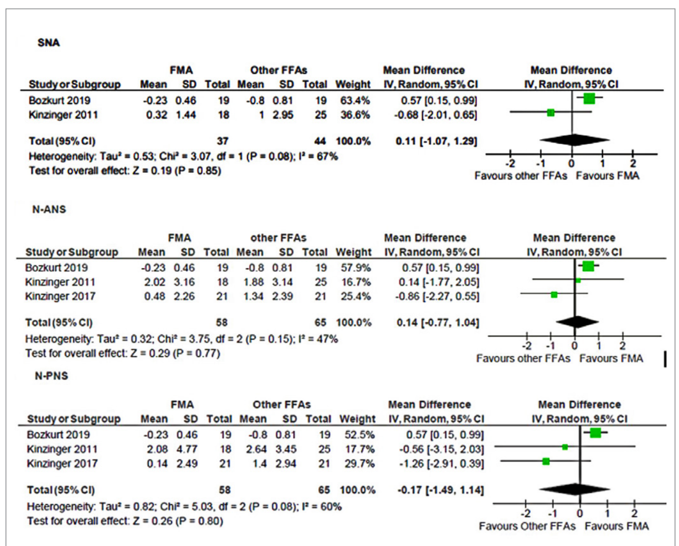

Figure 2. Forest plots comparing Maxillary changes- SNA angle, N-ANS, N-PNS for FMA versus other FFAs

df, degrees of freedom; CI, confidence interval.

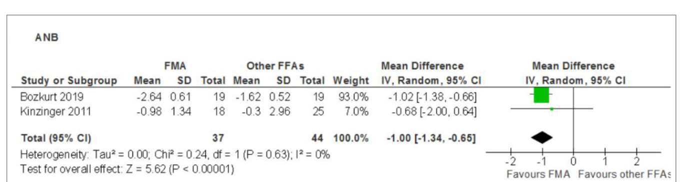

Figure 3. Forest plots comparing maxillo-mandibular changes- ANB angle for FMA versus other FFAs

df, degrees of freedom; CI, confidence interval.

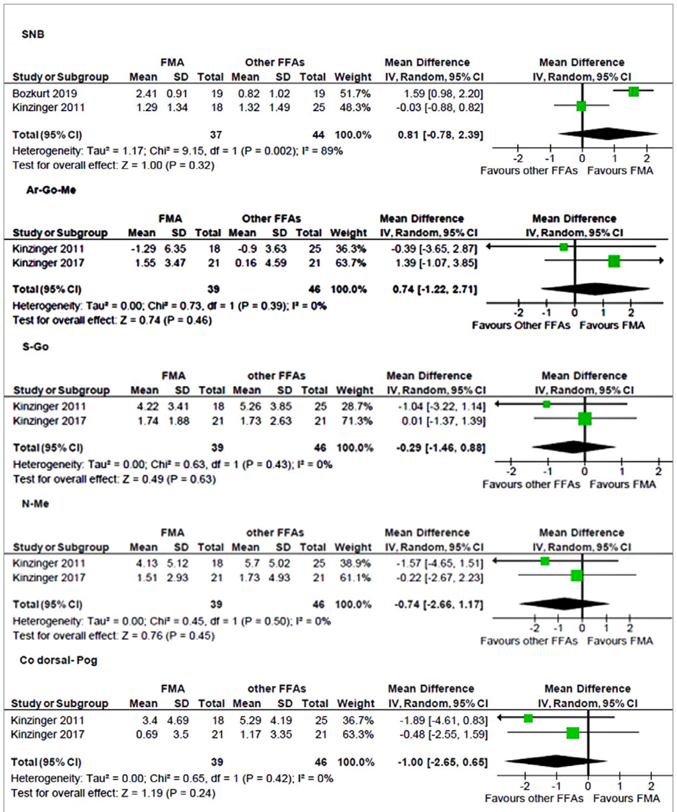

Figure 4. Forest plots comparing Mandibular changes-SNB angle, Gonial angle (Ar-Go-Me), S-Go, N-Me, Codorsal-Pog for FMA versus other FFAs
df, degrees of freedom; CI, confidence interval.

the control group consisted of patients with either untreated Class II malocclusion or those treated with a fixed appliance or with other FFAs. The research question of this systematic review was to evaluate "how effective is the FMA in treating growing patients with Class II malocclusion?".

The risk of bias in the seven selected articles was assessed by two authors using the ROBINS-I tool for non-randomized studies.[13] Three studies[9,11,19] were graded as having a low risk of bias and four studies[10,17,18,20] were graded as having a moderate risk of bias due to the risk of confounding, selection of participants into the study, and classification of interventions. Seven studies were included in the systematic review[9-11,17-20] and three studies were included in the meta-analysis.[17-19] Four studies were excluded from the meta-analysis because two studies[9,11] did not have a control group and two studies[10,20] had no comparable data to be combined for a meta-analysis.

Skeletal Changes

The meta-analysis of the maxillary and mandibular changes showed no significant difference between FMA and other FFAs. The studies included in the above meta-analysis evaluated effects only with FFAs and a combination of FFAs and FAs; hence, the results should be interpreted with caution.

The meta-analysis with maxillomandibular changes showed a significantly greater reduction by 1 degree, indicating a better Class II correction with the FMA group. This conclusion of the meta-analysis is further strengthened, more reliable, and less prone to bias as the phase of FAs would be common to both groups. Subgroup/sensitivity and GRADE analyses were planned but could not be performed. Subgroup and Sensitivity analysis could not be performed because none of the included studies were classified as high risk of bias.[23] GRADE analysis could not be performed because the studies included in the meta- analysis were non-randomized clinical trials, and the GRADE baseline rating for non-RCTs starts with low.[24]

Kinzinger et al.[18] reported an increase in the gonial angle with FMA, leading to clockwise rotation of the mandible. There was a greater improvement in the mandibular position, as shown by SNB. However, FMA had a lesser effect on mandibular length than other FFAs. The increase in the gonial angle displaces the cephalometric reference point pogonion caudally and dorsally, which would have influenced the treatment-related change in the length of the mandible.[18]

Five studies reported that there was no treatment-induced effect of FMA on maxillary length, and the position of the maxilla remained stable even after treatment.[9,11,17-19] Similar findings were reported in systematic reviews of RFAs.[25,26] On the contrary, systematic reviews of FFAs showed a restraining effect on maxilla.[27,28] Kinzinger et al.[9] was the only study to assess the total mandibular length after active treatment with FMA when compared with the untreated control group, and the coefficient of efficiency was 0.19 mm per month. This was lesser when compared with the Herbst appliance (0.28 mm per month) and twin block (0.23 mm per month) but greater than bionator (0.17 mm per month), activator (0.12 mm per month), and Frankel appliance (0.09 mm per month), which were reported by Cozza et al.[5]. Because all the studies were conducted on growing patients, the skeletal changes were always based on the cumulative effect of natural growth processes and treatment-induced effects.[9]

Dental Changes

In the mandibular arch, four studies reported proclination of the incisors with mesial tipping of molars and a decrease in overjet.[9,11,18,19] In the maxillary arch, three studies reported retroclination of incisors.[9,11,18] Bozkurt et al.[19] reported that there was no change in the position of maxillary incisors and molars in the FMA group. The probable reason could be that the measurements were a combination of functional and fixed appliance therapy, which would have influenced the position of the maxillary incisors and molars.[19] Kinzinger et al.[18] reported that the maxillary molars tipped mesially in contrast to another study by the same author where the molars tipped distally.[9] These findings suggest that dentoalveolar changes also contribute to Class II correction. This was in accordance with systematic reviews on FFAs, which showed that maxilla-mandibular correction is a combination of skeletal and dental changes with proclination of mandibular incisors, mesial movement of lower molars, retroclination of maxillary incisors, and distal movement of maxillary molars.[25,26,29,30]

Soft Tissue and Airway Changes

Hourfar et al. reported straightening of the profile, retrusion of the upper lip and protrusion of the lower lip, an increase in lower lip thickness, and an increase in lower facial height in patients with patients.[10] The lip changes were evaluated using the E line as the reference line, which might have contributed to the difference in the results.[21] A recent systematic review also reported straightening of the soft tissue profile after treatment with FFAs.[29]

Aras et al.[20] showed that the nasopharyngeal and oropharyngeal airway increased in both the SWG and SSG groups because of the forward positioning of the mandible without any change in the hypopharyngeal airway. Kinzinger et al.[17] reported that there was no change in the pharyngeal distance in patients treated with FMA. Both studies assessed the airway using lateral cephalograms, which permits only a two-dimensional evaluation of the three-dimensional object. Because the airway possesses an oval, non-rigid three-dimensional cross sections, it limits the reliability of conclusions about airway space.[17]

Study Limitations

While the included studies had standardized their measurements for each radiograph to a real size in order to correct the radiographic magnification, there were a few limitations to this systematic review. Only English studies were included. There was variation in the study designs of participant characteristics, treatment duration, and growth pattern. Most of the studies included participants based on chronologic age rather than skeletal maturity, which allows only a limited assessment of growth status. The literature search revealed the absence of randomized clinical trials in this area of research. RCTs are considered the gold standard among all research designs in the evidence pyramid. Therefore, the results must be viewed with caution.

CONCLUSION

FMA has the following effects:

- The quality of the included studies ranged from low to moderate, with three studies at low risk of bias and four studies at moderate risk of bias.
- Class II correction was a combination of skeletal and dentoalveolar changes.
- The SNA and SNB angles increased by 0.11 and 0.81 degrees, respectively, and there was a greater reduction in the ANB angle by 1 degree compared with other FFAs.
- Maximum proclination of the lower incisors by 2.66mm, retroclination of the upper incisors by 1.79 mm, and mesial movement of the lower molars by 2.26 mm with a decrease in overjet by 5.06 mm were observed. The position of the upper molars is inconclusive because of varying results from the included studies.
- Analyzing the soft tissue and airway changes, the evidence is limited and further studies are required.

Ethics

Ethics Committee Approval: Not applicable.

Informed Consent: Not applicable.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - M.D.K.; Design - M.D.K., H.P.S., V.K.; Supervision - H.P.S., V.K.; Data Collection and/or Processing - M.D.K.; Analysis and/or Interpretation - M.D.K.; Literature Review - M.D.K., H.P.S., V.K.; Writing - M.D.K., Critical Review - H.P.S., V.K.

Declaration of Interests: All authors declare that they have no conflict of interest.

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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