UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

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Comparative study of the effects of the fixed functional appliances Forsus Fatigue Resistant Device and MARA in treatment of Class II malocclusion through lateral cephalograms analysis

Estudo comparativo dos efeitos dos aparelhos propulsores mandibulares Forsus Fatigue Resistant Device e Mandibular Anterior Repositioning Appliance (MARA) no tratamento da má oclusão de Classe II através de análises cefalométricas

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Orientador: Prof. Dr. José Fernando Castanha Henriques

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FOLHA DE APROVAÇÃO

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À Faculdade de Odontologia de Bauru – Universidade de São Paulo.

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ABSTRACT

ABSTRACT

Comparative study of the effects of the fixed functional appliances Forsus Fatigue Resistant Device and MARA in treatment of Class II malocclusion through lateral cephalograms analysis

Introduction: Since the success of treatment through removable appliances depends mostly of patient cooperation, functional fixed appliances have been widely used in treatment of Class II malocclusion for a huge number of professionals. **Objective**: The purpose of this study is to analyze the effects of the Forsus Fatigue Resistant Device and to compare the findings with a well-matched group treated with the Mandibular Anterior Repositioning Appliance (MARA) for the correction of Class II malocclusion, and to compare with an untreated Class II malocclusion control group. **Methods:** The Forsus group was composed of 14 patients. The MARA group was comprised of 18 patients. The untreated control group was composed of 14 patients. Lateral cephalometric radiographs were taken of each subject at the pretreatment (T1) and posttreatment (T2). Posttreatment changes were calculated as T1-T2. Intergroup comparisons regarding treatment changes were performed using repeated measures analysis of variance (ANOVA) followed by Tukey's test. **Results:** During treatment, the Forsus group showed statistically significant decrease of maxillary protrusion and maxillomandibular sagittal discrepancy in relation to the control group. The MARA group showed statistically significant greater retrusion of maxillary incisors in relation to the Forsus and the control group. Overjet decreased significantly more in the treated groups in relation to the control group. The molar relationship improved significantly more in both treated groups, and both showed more correction than did the untreated control group. **Conclusion:** The Forsus and MARA associated with fixed appliances effectively correct the Class II malocclusion, mostly by means of dentoalveolar changes and maxillary growth restraint.

KEY WORDS: Orthodontics; Angle Class II malocclusion; Fixed functional appliances; Cephalometrics.

RESUMO

RESUMO

Estudo comparativo dos efeitos dos aparelhos propulsores mandibulares Forsus Fatigue Resistant Device e Mandibular Anterior Repositioning Appliance (MARA) no tratamento da má oclusão de Classe II através de análises cefalométricas

Introdução: O sucesso do tratamento da má-oclusão de Classe II com aparelhos funcionais removíveis depende principalmente da cooperação do paciente, portanto, aparelhos funcionais fixos têm sido amplamente utilizados por um grande número de profissionais. **Objetivo:** Analisar os efeitos do aparelho Forsus e comparar os achados com um grupo tratado com o aparelho MARA, comparando-os com um grupo controle de Classe II não tratada. **Métodos:** O grupo Forsus foi composto por 14 pacientes. O grupo MARA foi composto por 18 pacientes. O grupo controle foi composto por 14 pacientes. Telerradiografias em norma frontal foram tiradas de cada indivíduo no estágio pré-tratamento (T1) e pós-tratamento (T2). Alterações pós-tratamento foram calculadas como T1-T2. Comparações intergrupo em relação às alterações de tratamento foram realizadas utilizando ANOVA seguido de teste Tukey. **Resultados:** Durante tratamento, o grupo Forsus demonstrou maior diminuição da protrusão maxilar e da discrepância maxilo-mandibular sagital em relação ao grupo controle. O grupo MARA demonstrou maior retrusão de incisivos superiores em relação aos outros grupos. O overjet diminuiu estatisticamente mais nos grupos tratados do que no grupo controle. Houve melhora na relação molar em ambos os grupos tratados do que o grupo controle. **Conclusão:** O Forsus e o MARA associados ao aparelho ortodôntico fixo são eficazes no tratamento da má oclusão de Classe II, principalmente por alterações dentoalveolares e restrição de crescimento maxilar.

Palavras-chave: Ortodontia; Má oclusão de Classe II; Aparelhos funcionais fixos; Cefalometria.

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1 INTRODUCTION

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The Class II malocclusion is common a skeletal problem seen in orthodontics. According to Silva Filho et al, it is seen in 33,10% of individuals in deciduous dentition and 41% in permanent dentition;(SILVA FILHO et al., 2009) and it imposes limitations in Class II prognostic and treatment.

In the 1890's, Angle established the first definition of normal occlusion. He determined the mesiovestibular cuspid of the first upper molar should occlude in the first inferior molar's sulcus. This definition was based, therefore, on the first upper molar, which became the "key to occlusion".(ANDREWS, 1972) When diagnosing a malocclusion, Angle defined that we should consider first the mesio-distal relation of dental arches, and secondly the individual relations of each teeth. Therefore, we can define the Class II malocclusion as the abnormal position of dental arches, with inferior teeth occluding distally in relation to normal, producing lack of harmony in incisors and facial lines.(MCNAMARA JR, 1981)

Combinations of dental and skeletal factors ranging from mild to severe provide the multiple characters of this discrepancy.(BACCETTI; FRANCHI; KIM, 2009; BACCETTI; FRANCHI; STAHL, 2009) There are multiples approaches in treating Class II malocclusions. Among other factors, the treatment protocols can widely vary according to professional ability, malocclusion severity, and patient compliance. In a growing patient, a nonextraction approach with extraoral headgear or a removable functional appliance, associated with fixed appliances, is common.(BISHARA; CUMMINS; ZAHER, 1997; JANSON et al., 2013) Nonextraction correction of a complete Class II malocclusion requires more patient compliance in using the extraoral headgear and a removable functional appliance than treatment with 2 maxillary premolar extractions.(ARMSTRONG, 1971; MEHRA; NANDA; SINHA, 1998; JANSON et al., 2006)

In 1981, McNamara Jr. diagnosed the Class II etiology, where the most prevalent component was the skeletal mandibular retrusion.(MCNAMARA JR, 1981) In the last decades, the treatment with fixed appliances of Class II patients with mandibular deficiency has been widely approached in worldwide orthodontic literature.(BISHARA; ZIAJA, 1989) With the success of treatment through removable

appliances depend mostly of patient cooperation, functional fixed appliances have been used for a huge number of professionals. Functional appliances have been used since the 1930s. Despite this relatively long history, there continues to be much controversy relating to their use, method of action, and effectiveness.(BISHARA; ZIAJA, 1989) Among them, we may highlight the functional fixed appliance Herbst, brought for the first time at a Berlin conference in the year of 1905 from Dr. Emil Herbst. A long time later, in the 70's, this appliance was reintroduced with studies by Pancherz, who evaluated its action mechanism and its effects.(PANCHERZ, 1997)

Nowadays, the Forsus Fatigue Resistant device (3M Unitek, Monrovia, California) is a new fixed semirigid system, where its producer guarantees to be resistant against fractures and external forces.(CLEARY; WYLLIE, 2002) The FRD is a threepiece, semirigid telescoping system incorporating a superelastic nickel-titanium coil spring that can be assembled chair-side in a relatively short amount of time. It is compatible with complete fixed orthodontic appliances and can be incorporated into preexisting appliances. The FRD attaches at the maxillary first molar and onto the mandibular archwire, distal to either the canine or first premolar bracket.(FRANCHI et al., 2011) As the coil is compressed, opposing forces are transmitted to the sites of attachment.(JONES et al., 2008) Previous studies have investigated the posttreatment effects induced by the Forsus appliance. Sagittal maxillary growth restriction, correction in overjet, overbite and molar relation is expected during treatment with Forsus.(FRANCHI et al., 2011; CACCIATORE et al., 2014b) Therefore, this fixed functional appliance has proven to be effective in correcting Class II malocclusion mainly at the dentoalveolar level.

Other authors have also investigated the effects of Forsus compared to other fixed functional appliances. When compared to a sample treated with Herbst, Celikoglu(CELIKOGLU et al., 2016) found similar skeletal and soft tissue changes. However, maxillary and mandibular incisors were statistically significant more retruded in the Forsus group, when comparing to the Herbst group. This was also found on previous studies comparing Forsus with a Twin-block treated group.(GIUNTINI et al., 2015) The Twin-block appliance produced greater skeletal effects in terms of mandibular advancement and growth, while Forsus caused significant proclination of the mandibular incisors.

The MARA (Mandibular Anterior Repositioning Appliance) is a noncompliance device for Class II treatment, first proposed by Eckhart and Toll in 1998. It corrects a Class II malocclusion into Class I by displacing the mandibular condyles anteriorly and inferiorly, thereby resulting in remodeling of the temporal fossae and the condyles.(ECKHART; WHITE, 2003)

Treatment results with MARA include considerable distalization of maxillary molars, measurable forward movement of the mandibular molar and incisor, significant increase in mandibular length, and increase in posterior face height. (PANGRAZIO-KULBERSH et al., 2003; GHISLANZONI et al., 2011)

The effects of MARA have been compared to other fixed functional appliances. When compared to patients treated with Bionator, Herbst and Twin Block, all appliances showed statistically significant decrease of overjet, overbite and Wits.(SIARA-OLDS et al., 2010)

Even though the advantages, effectiveness, dentoalveolar and skeletal changes of fixed functional appliances are well defined through scientific research, there are still a lack in literature when comparing the effects between the Forsus and MARA directly among themselves.

2 ARTICLE

2 ARTICLE

The following article presented in this Dissertation was formatted according to the American Journal of Orthodontics and Dentofacial Orthopedics instructions and guidelines for article submission.

Comparative study of the effects of the fixed functional appliances Forsus Fatigue Resistant Device and MARA in treatment of Class II malocclusion

ABSTRACT

Introduction: Since the success of treatment through removable appliances depends mostly of patient cooperation, functional fixed appliances have been used in treatment of Class II malocclusion for a huge number of professionals. **Objective**: The purpose of this study is to analyze the effects of the Forsus Fatigue Resistant Device and to compare the findings with a well-matched group treated with the Mandibular Anterior Repositioning Appliance (MARA) for the correction of Class II malocclusion. **Methods:** The Forsus group was composed of 14 patients at an initial mean age of 12.4 years ± 1.3 years old, treated with the Forsus Fatigue Resistant Device followed by fixed orthodontic appliance, for a total mean period of 3,4 years ±1,2. The MARA group was comprised of 18 patients at an initial mean age of 12,1 years ±1,3 years, treated with MARA followed by fixed orthodontic appliance, for a total mean period of 3,4 years ±0,7 years. The untreated control group was composed of 14 patients and initial mean age of 11.54 years ±0.61 years, and final mean age of 14.64 years ± 1.28 years. Lateral cephalometric radiographs were taken of each patient at the pretreatment (T1) and posttreatment (T2). Posttreatment changes were calculated as T1-T2. Intergroup comparisons regarding treatment changes were performed using repeated measures analysis of variance (ANOVA) followed by Tukey's test. **Results:** During treatment, the Forsus group showed statistically significant decrease of maxillary protrusion and maxillomandibular sagittal discrepancy in relation to the control group. The MARA group showed statistically significant greater retrusion of maxillary incisors in relation to the Forsus and the control group. Overjet decreased significantly more in the treated groups in relation to the control group. The molar relationship improved significantly more in both treated groups, and both showed more correction than did the untreated control group. **Conclusion:** The Forsus and MARA associated with fixed appliances effectively correct the Class II malocclusion, mostly by means of dentoalveolar changes and maxillary growth restraint.

KEY WORDS: Orthodontics; Angle Class II malocclusion; Fixed functional appliances; cephalometrics.

INTRODUCTION

In 1981, McNamara Jr. diagnosed the Class II etiology, where the most prevalent component was the skeletal mandibular retrusion.[1,2] Among other factors, the treatment protocols can widely vary according to professional ability, malocclusion severity, and patient compliance.[3-6] In the last decades, the treatment with fixed appliances of Class II patients with mandibular deficiency has been widely approached in worldwide orthodontic literature.[7] With the success of treatment through removable appliances depend mostly of patient cooperation, functional fixed appliances have been used by a huge number of professionals. Among them, we may highlight the functional fixed appliance Herbst, brought for the first time at a Berlin conference in the year of 1905 from Dr. Emil Herbst. A long time later, in the 70's, this appliance was reintroduced with studies by Pancherz, who evaluated its action mechanism and its effects.[8] Many studies have proven the efficiency of Herbst for the treatment of Class II malocclusion[9-12], however, some authors have attributed several side effects to the use of functional appliances – eg, protrusion of mandibular incisors.[8,13]

Nowadays, the Forsus Fatigue Resistant device (3M Unitek, Monrovia, California) is a new fixed semirigid system, where its producer guarantees to be resistant against fractures and external forces.[14] The FRD is a threepiece, semirigid telescoping system incorporating a superelastic nickel-titanium coil spring that can be assembled chair-side in a relatively short amount of time.[15] It is compatible with complete fixed orthodontic appliances and can be incorporated into preexisting appliances. The FRD attaches at the maxillary first molar and onto the mandibular archwire, distal to either the canine or first premolar bracket.[15] As the coil is compressed, opposing forces are transmitted to the sites of attachment.[16]

The MARA (Mandibular Anterior Repositioning Appliance) is a noncompliance device for Class II treatment, first proposed by Eckhart and Toll in 1998. It corrects a Class II malocclusion into Class I by displacing the mandibular condyles anteriorly and inferiorly, thereby resulting in remodeling of the temporal fossae and the condyles.[17]

Even though the advantages, effectiveness, dentoalveolar and skeletal changes of fixed functional appliances are well defined through scientific research, there are still a lack in literature when comparing the effects between the Forsus and MARA directly among themselves. Therefore, the purpose of this study is to analyze the effects of functional appliances with different methods of action, through a group treated with the

Forsus Fatigue Resistant Device and to compare the findings with a well-matched group treated with the Mandibular Anterior Repositioning Appliance (MARA) for the correction of Class II malocclusion, evaluating and comparing through lateral cephalograms the skeletal dentoalveolar and soft tissue effects of both appliances.

MATERIAL AND METHODS

The study was approved by the ethical committee of Bauru Dental School, University of São Paulo, Brazil (protocol number 71636617.0.0000.5417).

The sample size was calculated based on an alpha significance level of 0.05 and a beta of 0.2 to detect a mean difference of 2mm with a standard deviation of 1.5mm in the changes in mandibular length between the pretreatment and posttreatment stages[18]. The results showed that a minimum of 12 patients were needed in each group; to increase the test power even more, it was decided to select 32 patients for the treatment group.

Sample characteristics

Therefore, the sample consisted in 92 lateral cephalometric radiographs of 46 subjects (32 treated, 14 untreated). Thirty-two patients were selected from the files of the Orthodontic Department at _____. The patients were selected according to the following inclusion criteria: Class II division 1 malocclusion with bilateral Class II molar relationship (minimum severity of ½ Class II molar relationship)[19], in the permanent dentition; absence of agenesis or loss of permanent teeth; absence of supernumerary teeth; convex profile; dental arches with slight to moderate crowding; without history of previous orthodontic treatment; treatment nonextraction; presence of moderate to severe overjet. No cephalometric characteristic was considered as inclusion criteria.

The Forsus group (Group 1) comprised 14 subjects (9 male, 5 female) at an initial mean age of 12.4 years ± 1.3 years old, treated with the Forsus Fatigue Resistant Device followed by fixed orthodontic appliance, for a total mean period of 3.4 years ±1.2. Two patients presented ¾ cusp Class II malocclusion and twelve patients presented full cusp Class II.

The MARA group (Group 2) comprised 18 subjects (13 male, 5 female), at an initial mean age of 12.1 years ±1.3 years, treated with MARA followed by fixed orthodontic appliance, for a total mean period of 3.4 years ±0.7 years. One subject

presented ½ cusp Class II malocclusion, seven presented ¾ cusp Class II and ten presented full cusp Class II.

The control group (G3) comprised 14 untreated subjects (5 female; 9 male) with untreated Class II and initial mean age of 11.54 years ±0.61 years, and final mean age of 14.64 years ± 1.28 years. Seven patients presented ½ cusp Class II, two presented ¾ cusp Class II and five presented full cusp Class II. This group was selected from the files of the Department of Orthodontics, Bauru Dental School, University of São Paulo, São Paulo, Brazil, and from the longitudinal growth study sample of the "University of Toronto Burlington Growth Study" (Department of Orthodontics, College of Dentistry, University of Toronto, Canada), where groups of patients were radiographed and observed through the Orthodontics Department with the purpose to obtain a long-term sample of untreated Class II malocclusion, obtained from the online American Association of Orthodontists Foundation (AAOF) Craniofacial Growth Legacy Collection.

Treatment protocol

Before Forsus Fatigue Resistant Devices (Figure 1) were installed in all patients in G1, fixed standard preadjusted orthodontic fixed appliances were installed. After leveling and aligning, Forsus was placed with a 0.019 x 0.015-inch stainless-steel archwire at both arches. A transpalatal bar and a lingual arch were used in all subjects. The mean duration of the FRD active phase was 0.37 years ±0.13 years. After a slight overcorrection of the Class II dental relationship was achieved, Forsus was removed and treatment was continued to detail the occlusion.

Patients in the MARA group had the appliance (Figure 2) installed with a transpalatal bar and a lingual arch in all subjects. The patients in this group were not subjected in advance to tooth alignment and leveling, nor interproximal stripping. The mean duration of the MARA active phase was 1.10 years ± 0.16 years. The appliance was kept in place for 6 months as active retention after achieving Class I molar relationship. After treatment with MARA, fixed standard preadjusted orthodontic fixed appliances were installed and corrective phase took place for 1.95 years ± 0.95 years.

In all experimental groups, Class II molar relationship was corrected. Intermaxillary Class II elastics were used as active retention. At the end of the orthodontic treatment, all patients were instructed to wear a maxillary Hawley retainer

for a total of one year, with recommended use of 20 hours per day during six months, and additional six months of night wear. A fixed canine-to-canine lingual retainer was used for retention in the mandibular arch with recommended use of 3 years.

Cephalometric analysis

Lateral cephalometric radiographs were taken of each patient at the pretreatment (T1) and posttreatment (T2). They were digitized and had the landmarks identified by a single operator (C. Q. N.) in the Dolphin Imaging 11.5 software (Dolphin Imaging and Management Solutions, Chatsworth, California, USA), which also corrects the image magnification factors of the different radiographic machines where the lateral cephalograms were taken. The cephalometric variables are shown in Figure 3 and 4. Posttreatment changes were calculated as T1-T2. The lines and reference planes used in the study are shown in Table I.

Error study

30% of radiographs were randomly selected, re-digitized, retraced, and remeasured again by the same examiner (C.Q.N.), after a month of the first measurements. The random errors were calculated according to Dahlberg's formula ($Se2 = \sum d2/2n$),[20] where Se^2 is the error variance and d is the difference between two determinations of the same variable. The systematic errors were evaluated with paired t-tests, at $P<0.05$.[21]

Statistical analysis

Normal distribution was evaluated with Kolmogorov-Smirnov tests. In presence of normality, analysis of variance (ANOVA) was applied to compare changes among groups

Intergroup age and treatment time comparisons were evaluated through ANOVA followed by Tukey post-hoc tests. Intergroup sex distribution and pretreatment severity of the Class II malocclusion were compared with Chi-square tests. All statistical analyses were performed with Statistica software (Statistica for Windows, version 6.0, Statsoft, Tulsa, Okla), and the results were considered significant at P<.05.

RESULTS

The range of random errors varied from 0.28 (Mx1.PP) to 2.23 degrees (SNA) and from 0.15 (Co-A) to 1.46mm (Overjet) and were within acceptable limits.[22,23] Only 2 (SNA and ANB) of the 28 evaluated variables showed statistically significant systematic errors. The groups were comparable regarding ages at T1, T2, treatment period, sex distribution and initial Class II malocclusion severity (Tables II, III and IV).

Before treatment, the Forsus and MARA groups showed statistically significant greater maxillary protrusion and maxillomandibular sagittal discrepancy than the control group (Table V). The Forsus group showed significantly greater lower anterior face height compared to the control group. The MARA group showed significantly greater labial tipping of maxillary incisors compared to the Forsus group. The Forsus group presented significantly greater maxillary incisors extrusion than the other groups. The mandibular incisors in the experimental groups had significantly greater labial tipping and extrusion than the control group. The nasolabial angle was significantly greater in the control group than the experimental groups.

During treatment, the Forsus group showed statistically significant decrease of maxillary protrusion and maxillomandibular sagittal discrepancy in relation to the control group (Table VI). The MARA group showed statistically significant greater retrusion of maxillary incisors in relation to the Forsus and the control group. The experimental groups showed significantly greater labial tipping of the mandibular incisors and extrusion of mandibular molars in relation to the control group. Overjet decreased significantly more in the treated groups in relation to the control group. The molar relationship improved significantly more in both treated groups, and both showed more correction than did the untreated control group. The MARA group showed statistically significant greater upper lip retrusion in relation to the Forsus group and the control group. The Forsus group showed statistically significant greater lower lip protrusion in relation to the MARA and the control group.

DISCUSSION

Previous studies have investigated the effects of Forsus and MARA.[24-29] However, a direct comparison of the treatment changes between these two fixed functional appliances and including an untreated control group has not been reported.

This clinical retrospective study examined a sample of 32 treated patients in the same institution under the same orientation. The sample size used in this study is similar or even greater than other previous studies.[15,30-32]

The control group was comprised of Class II untreated subjects, representative of a random population followed over the same period as the treated group. The main focus of this study was to compare the changes that occurred during treatment (T1-T2) with Forsus and MARA among themselves and in relation to a control group. Then, intergroup comparisons at posttreatment stage was not evaluated. Many previous studies have described the effects of these appliances at the posttreatment.[15,16,25,27,28,31,33-39] Therefore, this study evaluated only the changes that occurred during treatment with these appliances associated to a phase with comprehensive fixed orthodontic treatment, and compare these changes with the changes that occurred in an untreated control group.

The groups were comparable regarding pretreatment and posttreatment ages, treatment period, sex distribution and initial Class II malocclusion severity (Table II, III, IV).

The control group had slight smaller maxillary protrusion, Class II malocclusion and nasolabial angle at the pretreatment stage (Table V). Some other intergroup differences were found at T1 for the dentoalveolar variables. Because the focus of this study was to compare only the treatment changes, these initial differences are expected to do not alter our results.

Skeletal changes

Previous studies showed that in general, fixed functional appliances promote restriction in the sagittal maxillary growth[9,12,40], as it is expected with Forsus and MARA.[15,33-35,39,41] However, in this study, this restriction was observed only for the Forsus group (Table VI). This headgear effect could be caused by facial muscle tension occurred when trying to reposition the mandible back to its uppermost and posterior-most position. [9,28,40,42]

There were no statistically significant differences among groups regarding the mandibular component. Our results support the finding of previous studies, which stated that fixed functional appliances do not interfere significantly in the mandibular growth and development.[28,31,43] This was also demonstrated in this study; the mandibular growth and anterior displacement of the experimental groups were part of the normal growth and development when compared with the changes of control group. This could be related to the short period that these appliances are used.[15,34,44]

Maxillomandibular relationships

During treatment, the Forsus group showed statistically significant greater decrease of the maxillomandibular sagittal discrepancy. This could be expected due the significantly greater maxillary restriction of this group (Table VI), which is predictable at the end of orthodontic treatment with Forsus.[33] This could be associated to the headgear effect reported for this appliance.[15,41]

Vertical components

The vertical components showed a similar behavior among all three groups, which resulted on the lack of statistically significant differences (Table VI). The similar increase of the lower anterior face height between groups agrees with other studies that showed no statistically significant differences of this variable on treatment with fixed functional appliances in relation to untreated Class II subjects.[31,45,46]

This demonstrates that the expected growth after fixed functional therapy associated with fixed orthodontic appliances is similar to that expected from untreated Class II subjects.[46] This could be also explained due the short treatment period during the Forsus and MARA phases.[40,47]

Maxillary dentoalveolar component

The MARA group presented statistically greater maxillary incisor retrusion compared to the Forsus and the control groups (Table VI), as has been reported.[28] This may be expected due the smaller, but not statistically significant, maxillary growth restriction observed in this group compared to the Forsus. Then, the maxillary incisor has to be more retruded to obtain adequate overjet in this group.

Mandibular dentoalveolar component

Mandibular incisor labial tipping was similarly observed in the experimental groups (Table VI). This could confirm the greater maxillary incisor retrusion need observed on the MARA group to correct the overjet, as explained above. The experimental groups showed significantly greater labial tipping of the mandibular incisors compared to the control group. Since the resultant force is applied anteriorly, the effects of molars mesialization are reflected mostly in the incisors.[28] Those findings were similar to those reported by several other studies, as it is a consensus in literature that treatment with fixed functional appliances may cause mandibular incisor inclination.[15,16,37]

Forsus and MARA groups showed extrusion of mandibular molars in relation to the control group. This has been reported with the use of this fixed appliances. However, this extrusion could be associated to the use of Class II elastics during the active retention.[48]

Dental relationship

There was an improvement on the overjet and overbite in the treated groups compared to the control group (Table VI). The molar relationship improved significantly more in both treated groups, and both showed more correction than did the untreated control patients. These results show that both appliances are effective in the correction of the initial Class II molar relationship, mostly by means of dentoalveolar changes and minimal skeletal modifications.[7,16,24,27,28,45]

Soft tissue component

The nasolabial angle showed statistical similarity on all groups (Table VI). The MARA group showed statistically significant greater upper lip retrusion in relation to the Forsus group and the control group. This could be explained as a result of the significantly greater maxillary incisor retrusion observed in the MARA group.[31]

The Forsus group showed statistically significant greater lower lip protrusion in relation to the MARA and the control group. This could be associated to the greater, but not statistically significant, mandibular incisor labial tipping and protrusion that Forsus group showed in relation to the MARA group. These finding suggest that the lower lip would be no longer captured behind the maxillary incisors, as a result of both

retrusion of the maxillary incisors and the support of the proclined mandibular incisors,[31] associated to the correction of Class II malocclusion.

Clinical implications

Overall treatment with Forsus and MARA can both be considered effective. However, the MARA appliance requires the professional to acquire a full 30-piece kit with different crown sizes to incorporate the appliance into one patient. On the other hand, the Forsus appliance requires only one kit per patient, previously sided by the orthodontist for each patient. Since the access of Forsus by the professional nowadays has been incredibly easier, this factor should be taken in account when deciding which appliance to use.

CONCLUSIONS

Based on the results of this specific study:

- The Forsus showed greater maxillary growth restriction only than the control group and greater maxillomandibular discrepancy decrease than the other groups.
- The MARA group showed statistically significant greater maxillary incisor retrusion, which resulted in greater upper lip retrusion than the other groups.

- The Forsus group showed statistically significant greater lower lip protrusion than the other groups.

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Figure legends:

Figure 1: Forsus appliance.

Figure 2: MARA appliance.

Figure 3: Unusual cephalometric variables: 1, Mx1-PP; 2, Mx1.PP; 3, Mx1-Apo; 4, Mx6-PP; 5, Mx6-APerp; 6, Md1-MP; 7 Md6-MP; 8, Md6-PgPerp.

Figure 4: Dental Relationship measurements: A- Overjet; B- Overbite; C- Molar relationship.

Fig. 1

Fig. 2

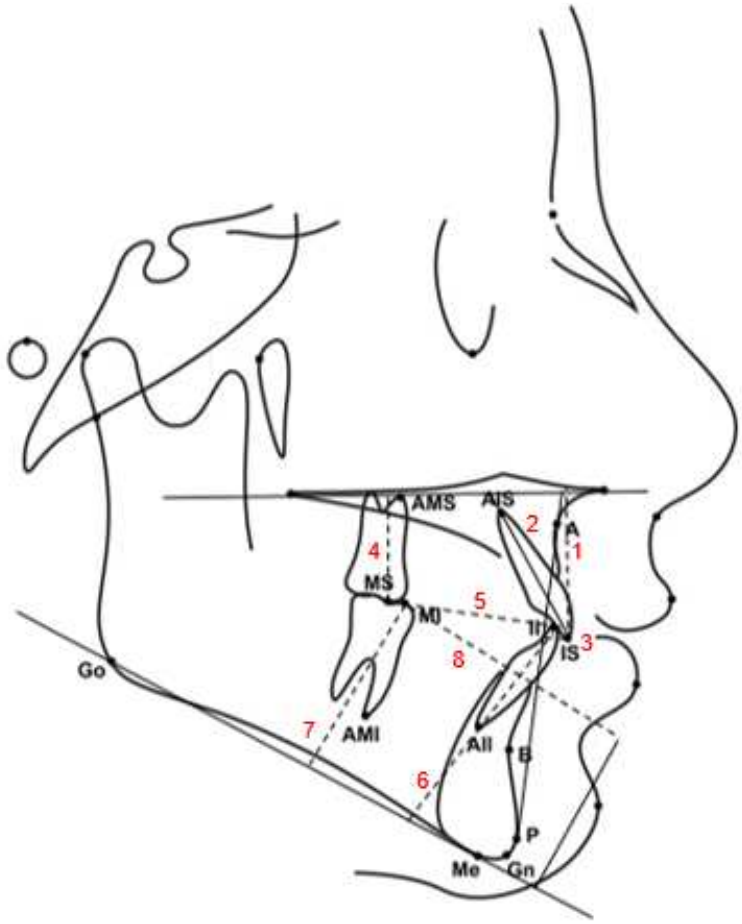

Fig. 3

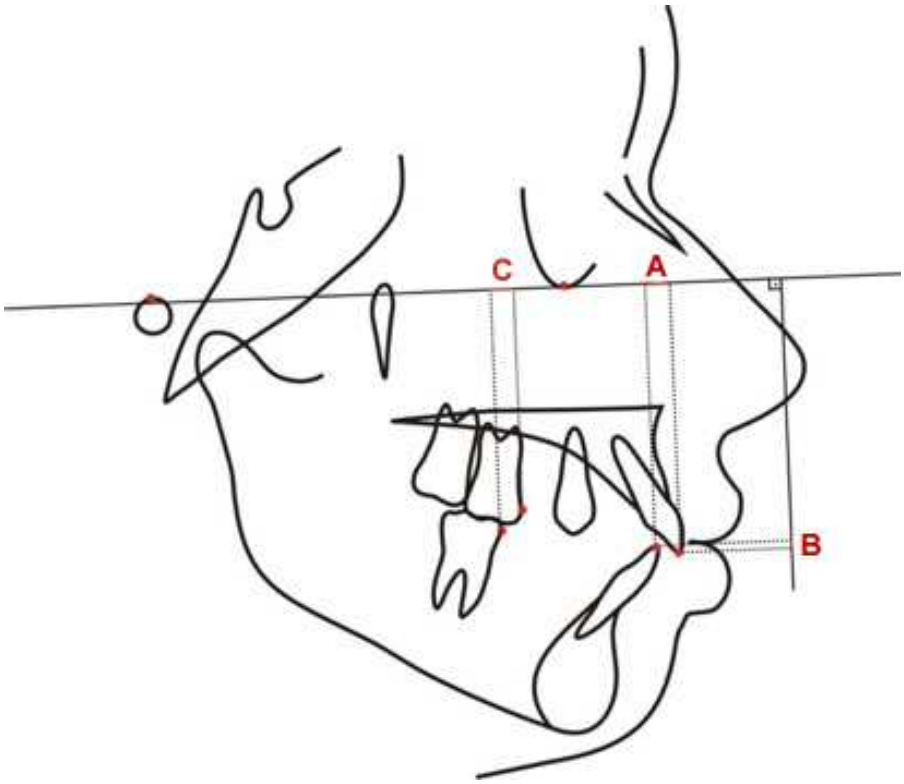

Fig. 4

Table I. Skeletal, dental and soft-tissue cephalometric variables

Maxillary skeletal component	
SNA (°)	SN to NA angle
A-Nperp (mm)	A-point to nasion-perpendicular
Co-A (mm)	Condylion to A-point distance
Mandibular skeletal component	
SNB (°)	SN to NB angle
Pg-Nperp (mm)	Pogonion to nasion-perpendicular distance
Co-Gn (mm)	Condylion to gnathion distance
Maxillomandibular relationship	
ANB (°)	NA to NB angle
Wits (mm)	Distance between the perpendicular projections of A and B points on the functional occlusal plane (FOP).
Vertical component	
FMA (°)	Frankfurt mandibular plane angle
SN.GoGn (°)	SN to GoGn angle
LAFH (mm)	Distance between ANS point and Me point.
Maxillary dentoalveolar component	
Mx1.PP (°)	Maxillary incisor long axis to palatal plane angle
Mx1-PP (mm)	Distance between maxillary incisal edge and palatal plane
Mx1 – Apo (mm)	Distance between incisal edge of maxillary incisor and A-Pg line
Mx6-PP (mm)	Mean perpendicular distance between mesial and distal cusp of maxillary first molar and palatal plane
Mx6-Aperp (mm)	Distance between maxillary first molar occlusal and line perpendicular to palatal plane, tangent to A point
Mandibular dentoalveolar component	
Md1.NB (°)	Mandibular incisor long axis to NB angle
Md1-NB (mm)	Distance between most anterior point of crown of mandibular incisor and NB line
Md1-GoMe (mm)	Distance between mandibular incisal edge and mandibular plane
Md6-GoMe (mm)	Mean perpendicular distance between the mesial and distal cusp of mandibular first molar and mandibular plane
Md6-Palatal Plane	Perpendicular distance between mandibular first molar occlusal and mandibular plane
Md6-PgPerp (mm)	Distance between mandibular first molar occlusal and line perpendicular to mandibular plane, tanget to Pg point
Dental relationship	
Overjet (mm)	Distance between incisal edges of maxillary and mandibular central incisors, parallel to occlusal plane
Overbite (mm)	Distance between incisal edges of maxillary and mandibular central incisors, perpendicular to occlusal plane
Molar relationship (mm)	Linear distance from the mean of the most distal points of maxillary first molar crowns to the mean of the most distal points of mandibular first molar crowns. Negative values means more favorably Class I molar relationship. Positive values or zero means class II tendency.
Soft-tissue profile	
Nasolabial angle (°)	Angle formed by lines columella to Subnasal and from Subnasal to upper lip
UL-E plane (mm)	Distance from the upper lip to the esthetic plane of Ricketts (line from soft tissue pogonion to pronasale)
LL-E plane (mm)	Distance from the lower lip to the esthetic plane of Ricketts (line from soft tissue pogonion to pronasale)

Table II - Intergroup age comparison at T1 and T2 and treatment/observation period (ANOVA followed by Tukey tests).

	Forsus Group N= 14		MARA Group N = 18		Control Group N= 14		P
Stage/Period	Mean	SD	Mean	SD	Mean	SD	
T1 age	12.47	1.32	12.06	1.28	11.54	0.61	0.105
T2 age	15.77	1.26	15.53	1.30	14.64	1.28	0.590
Treatment period (T1-T2)	3.4	±1.2	3.4	±0.7	3.1	±1.22	0.711

Table III - Intergroup sex comparison (Chi-square tests).

	Forsus Group N= 14	MARA Group N = 18	Control Group N= 14	P
Sex	Mean	Mean	Mean	
Female	5	5	5	0.853
Male	9	13	9	

Table IV. Intergroup comparison of occlusal Class II malocclusion severity distribution (Chi-square tests).

Occlusal malocclusion severity	Forsus Group N= 14	MARA Group N = 18	Control Group N= 14	p
¼ cusp Class II	0	0	0	0.570
½ cusp Class II	0	1	7	
¾ cusp Class II	2	7	2	
Full cusp Class II	12	10	5	

Table V - Comparability before treatment among the groups

	G1, FORSUS (n=14)		G2, MARA (n=18)		G3, Control Group (n=14)		
Variable	**Mean**	**S.D.**	**Mean**	**S.D.**	**Mean**	**S.D**	**p value**
Maxillary component							
SNA (°)	83.86	2.67	83.99	4.53	82.76	3.32	0.608
A-N Perp (mm)	3.09^{A}	3.20	4.47^{A}	5.53	0.34^{B}	3.27	0.008*
Co-A (mm)	82.61	3.98	82.47	4.53	83.31	4.65	0.857
Mandibular component							
SNB (°)	78.19	3.79	78.06	4.18	79.20	3.40	0.676
Pg-N Perp (mm)	-2.42	6.82	0.33	7.33	-3.36	6.17	0.289
Co-Gn (mm)	109.98	6.50	107.69	5.07	110.12	5.53	0.394
Maxillomandibular relationships							
ANB (°)	5.67^{A}	3.12	5.93^{A}	1.79	3.57^{B}	2.26	0.019*
Wits (mm)	4.48^{A}	3.21	4.26^{A}	2.66^{A}	0.65^{B}	4.25	0.005*
Vertical component							
FMA (°)	21.31	5.94	19.25	4.50	23.20	3.70	0.077
SN.GoGn (°)	28.23	6.82	28.17	5.36	28.69	3.96	0.961
LAFH (mm)	65.05^{A}	5.19	61.73^{AB}	4.21	59.03^{B}	3.68	0.003*
Maxillary dentoalveolar component							
Mx1.PP (°)	109^{A}	10.94	116^{B}	5.22	111.2^{AB}	6.67	0.043*
Mx1 – PP (mm)	28.76^{A}	2.50	26.4^{B}	3.55	26.09^{B}	2.61	0.041*
Mx1 – Apo (mm)	6.68^{A}	2.58	7.93^{B}	2.04	5.58^{A}	1.68	0.013*
Mx6 – PP (mm)	19.81	2.57	18.34	2.43	17.97	2.33	0.116
Mx6 – Aperp (mm)	30.95	2.23	31.43	3.25	30.03	3.34	0.428
Mandibular dentoalveolar component							
Md1.NB (°)	28.44^{A}	3.60	27.71^{A}	3.85	22.43^{B}	7.71	0.007*
Md1 – NB (mm)	4.87	2.18	4.82	1.66	3.49	1.75	0.086
Md1-MP (mm)	39.05^{A}	2.89	37.61^{A}	3.50	33.99^{B}	2.48	0.000*
Md6 – MP (mm)	27.75	2.78	26.52	3.06	26.68	2.92	0.467
Md6-PP (mm)	22.48	3.01	20.94	2.32	21.87	2.21	0.230
Md6 – PogPerp (mm)	35.13	3.52	35.13	2.94	37.47	4.13	0.127
Dentoalveolar relationship							
Overjet (mm)	5.82	2.57	7.12	1.49	5.29	2.92	0.083
Overbite (mm)	3.58	1.50	3.81	1.94	2.94	1.73	0.376
Molar Relationship (mm)	1.49	1.51	1.73	1.58	2.38	2.40	0.421
Sof-tissue Component							
Nasolabial angle (°)	108.75^{A}	5.64	109.3^{A}	13.75	121.71^{B}	8.22	0.002*
Upper lip – E (mm)	-1.34	2.79	-0.08	2.23	0.02	3.75	0.388
Lower lip – E (mm)	-0.24	2.79	0.33	3.03	0.00	2.23	0.833

*Statistically significant at $p<0.05$.
ANOVA followed by Tukey tests
Note: different letters in a row represent statistically significant differences among stages.

Table VI - Intergroup comparison of treatment and growth changes (T2-T1)

	G1, FORSUS (n=14)		G2, MARA (n=18)		G3, Control (n=14)		
Variable	**Mean**	**S.D.**	**Mean**	**S.D.**	**Mean**	**S.D**	**p value**
Maxillary component							
SNA (º)	-1.35 ^{A}	2.79	-0.81^{AB}	2.65	1.23^{B}	2.20	0.025*
A-Na Perp (mm)	-1.52^{A}	3.47	0.48^{AB}	4.07	1.84^{B}	2.91	0.047*
Co-A (mm)	3.28	2.12	4.32	3.17	5.41	2.10	0.105
Mandibular component							
SNB (º)	0.79	1.50	0.38	2.44	0.91	2.33	0.764
Pg-N Perp (mm)	0.99	6.74	1.29	6.94	2.66	5.05	0.757
Co-Gn (mm)	7.90	3.26	9.11	4.33	8.79	3.26	0.654
Maxillomandibular relationships							
ANB (º)	-2.15^{A}	2.26	-1.2^{AB}	1.70	0.33^{B}	1.50	0.003*
Wits (mm)	-4.08^{A}	2.39	-1.4^{B}	2.27	0.36^{B}	2.19	0.000*
Vertical component							
FMA (º)	-0.71	3.75	-0.02	4.08	-1.04	3.55	0.742
SN.GoGn (º)	-1.34	2.37	-0.04	3.04	-0.55	1.99	0.371
LAFH (mm)	3.84	3.99	5.39	2.86	3.99	1.79	0.284
Maxillary dentoalveolar component							
Mx1 – PP (º)	2.86	10.86	-4.11	7.04	1.56	6.27	0.050
Mx1 – PP (mm)	1.87	1.76	1.72	3.01	1.80	1.21	0.981
Mx1 – Apo (mm)	-0.30^{A}	1.94	-2.95^{B}	2.28	-0.20^{A}	1.12	0.000*
Mx6 – PP (mm)	2.11	2.47	3.67	2.80	1.61	2.46	0.072
Mx6 – Aperp (mm)	-1.54	4.85	-0.11	3.38	0.16	3.74	0.475
Mandibular dentoalveolar component							
Md1.NB (º)	4.97^{A}	6.30	4.51^{A}	5.78	0.17^{B}	3.70	0.041*
Md1 – NB (mm)	1.69	1.60	1.04	1.73	0.49	1.33	0.142
Md1-MP (mm)	1.11	2.10	1.97	3.70	2.67	1.57	0.331
Md6 – MP (mm)	3.78^{A}	2.70	3.71^{A}	2.64	0.98^{B}	2.93	0.012*
Md6 – PP	3.11	2.14	4.11	2.11	1.66	4.09	0.066
Md6 – PogPerp (mm)	-1.34	5.57	-0.60	3.37	-0.40	5.07	0.851
Dentoalveolar relationship							
Overjet (mm)	-2.92^{A}	2.51	-4.15^{A}	1.99	-0.61^{B}	2.34	0.000*
Overbite (mm)	-2.17^{A}	1.43	-2.53^{A}	2.03	0.23^{B}	1.50	0.000*
Molar Relationship (mm)	-2.66^{A}	1.77	-2.66^{A}	1.99	-0.3^{B}	2.44	0.004*
Sof-tissue Component							
Nasolabial angle (º)	0.65	7.64	3.29	8.19	-0.63	10.02	0.425
Upper lip – E (mm)	-1.3^{A}	0.96	-2.91^{B}	1.69	-1.11^{A}	3.13	0.034*
Lower lip – E (mm)	0.72^{A}	1.84	-1.32^{AB}	1.94	-1.92^{B}	3.26	0.014*

*Statistically significant at $p<0.05$.
ANOVA followed by Tukey tests
Note: different letters in a row represent statistically significant differences among stages.

3 DISCUSSION

3 DISCUSSION

Previous studies have investigated the effects of Forsus and MARA.(PANGRAZIO-KULBERSH et al., 2003; COZZA et al., 2006a; ARAS et al., 2011; CHIQUETO et al., 2013; CACCIATORE et al., 2014b; BAYRAM, 2017) However, there are no previous studies directly comparing treatment changes between these two fixed functional appliances.

This clinical retrospective study examined a sample of 32 treated patients in the same institution under the same orientation. The sample size used in this study could be considered satisfactory since it is within limits recommended by Houston(HOUSTON, 1983) in a sample size calculation.

The control group was comprised of Class II untreated subjects, representative of a random population followed over the same period as the treated group. Since the main focus of this study was to compare the changes that occurred between pretreatment and posttreatment stages (T1-T2) after treatment with Forsus and MARA among themselves in relation to a control group, intergroup comparability regarding the posttreatment stage was not evaluated. Many previous studies have described the effects of these appliances at the end of treatment.(PANGRAZIO-KULBERSH et al., 2003; GONNER et al., 2007; JONES et al., 2008; FRANCHI et al., 2011; GHISLANZONI et al., 2011; GUNAY; ARUN; NALBANTGIL, 2011; GHISLANZONI et al., 2012; PANGRAZIO et al., 2012; CHIQUETO et al., 2013; CACCIATORE et al., 2014a; CACCIATORE et al., 2014b; TARVADE et al., 2014; GIUNTINI et al., 2015) Therefore, the changes that occurred at the end of comprehensive fixed appliance therapy with Forsus and MARA separately were analyzed to assess whether they could contrast from one another.

The groups were compatible regarding pretreatment and posttreatment age, treatment time, sex distribution and initial Class II malocclusion severity (Table III, IV and V).

Skeletal changes

Previous studies showed that in general, fixed functional appliances promote restraint in the sagittal maxillary growth(PANCHERZ, 1979; CROFT et al., 1999; KUCUKKELES; ILHAN; ORGUN, 2007), as it is expected with Forsus and MARA.(FRANCHI et al., 2011; GHISLANZONI et al., 2011; CACCIATORE et al., 2014a; HEINRICHS et al., 2014; TARVADE et al., 2014; GIUNTINI et al., 2015) Likewise, in this study, this was also observed when comparing to a control group, where a greater anterior displacement was observed for the same period of time (Table VII). Therefore, both of these appliances presented a restrictive effect on the maxilla with greater anterior repositioning of the maxillary component. This headgear effect is caused by facial muscle tension when trying to reposition the mandible back to its uppermost and posterior-most position. (PANCHERZ; ANEHUS-PANCHERZ, 1993; CROFT et al., 1999; KUCUKKELES; ILHAN; ORGUN, 2007; CHIQUETO et al., 2013)

There were no statistically significant differences among groups regarding the mandibular component (Table VII). Our results support the finding of previous studies, which stated that fixed functional appliances do not interfere in the mandibular growth and development.(GUNAY; ARUN; NALBANTGIL, 2011; CHIQUETO et al., 2013; ASLAN et al., 2014) This was also demonstrated in this study; the mandibular growth and anterior displacement of the experimental groups were part of the normal growth and development when compared to a control group. According to Franchi et. Al (2011) this could be related to a short period of use of these functional appliances.(PHAN et al., 2006; FRANCHI et al., 2011; GIUNTINI et al., 2015)

Maxillomandibular relationships

During treatment, the Forsus group showed statistically significant decrease of maxillary protrusion and maxillomandibular sagittal discrepancy in relation to the control group (Table VII), which is predictable at the end of orthodontic treatment with Forsus.(CACCIATORE et al., 2014a)

Vertical components

The vertical components showed a similar behavior among all three groups, which resulted on the lack of statistically significant differences (Table VII). The increase of the lower anterior face height agrees with other studies that demonstrated no statistically significant differences of this variable on treatment with fixed functional appliances in relation to other untreated subjects.(DE OLIVEIRA et al., 2007; GUNAY; ARUN; NALBANTGIL, 2011; OZTOPRAK et al., 2012)

This was expected due the short treatment period with the Forsus and MARA. Our findings confirm those reported by previous studies(PANCHERZ, 1982; KUCUKKELES; ILHAN; ORGUN, 2007), and could explain why we cannot expect great changes on these components since there was not enough time for growth and, consequently, significant vertical alterations.

Maxillary dentoalveolar component

All three groups appeared to have similar results regarding the maxillary dentoalveolar component, as they were not statistically significant (Table VII). Those outcomes could be explained by the fact that patients started fixed orthodontic treatment after the removal of these fixed functional appliances. Therefore, the non-significant alteration of inclination and protrusion of maxillary incisors could be attributed to the effects of the fixed orthodontic appliance prescription.(COVELL et al., 1999)

Mandibular dentoalveolar component

The experimental groups showed significant greater labial tipping of the mandibular incisors (Table VII). Since the resultant force is applied anteriorly, the effects of molars mesialization are reflected mostly in the incisors.(CHIQUETO et al., 2013) Those findings were similar to those reported by several other studies, as it is a consensus in literature that treatment with fixed functional appliances cause lower incisor inclination.(GONNER et al., 2007; JONES et al., 2008; FRANCHI et al., 2011)

Treatment with Forsus and MARA both showed extrusion of mandibular molars in relation to the control group, as it is an expected result with fixed functional appliances(DE OLIVEIRA et al., 2007; JONES et al., 2008) as well as a side-effect of Class II elastics(JANSON et al., 2013) used as contention after orthodontic treatment.

Dental relationship

There was great improvement on overjet and overbite in the treated groups in relation to the control group (Table VII). The molar relationship improved significantly more in both treated groups, and both showed more correction than did the untreated control patients. These results show that both appliances are effective in the correction of the initial Class II molar relation, mostly by means of a combination of both dentoalveolar and skeletal modifications.(BISHARA; ZIAJA, 1989; PANGRAZIO-KULBERSH et al., 2003; DE OLIVEIRA et al., 2007; JONES et al., 2008; ARAS et al., 2011; CHIQUETO et al., 2013)

Soft tissue component

The nasolabial angle showed statistical similarity on both three evaluated groups (Table VII).

The MARA group showed statistically significant greater upper lip retrusion in relation to the Forsus group and the control group, which is predictable most likely as a result of both retrusion of the maxillary incisors and the proclined lower incisors.(GUNAY; ARUN; NALBANTGIL, 2011)

The Forsus group showed statistically significant greater lower lip protrusion in relation to the MARA and the control group. The lower lip was no longer captured behind the upper incisors as a result of both retrusion of the upper incisors and the support of the proclined lower incisors(GUNAY; ARUN; NALBANTGIL, 2011) as a result of the correction of Class II malocclusion.

Clinical considerations

It is important to understand the various appliances designed to correct the Class II malocclusion. According to the results of this study, the correction of the Class II malocclusion are similar with Forsus and MARA. It was observed that the Forsus and the MARA appliance associated with fixed appliances were effective in correcting the Class II malocclusion division 1 with maxillary protrusion, mostly by means of dentoalveolar changes. This way, it is expected in this treatment protocol greater dentoalveolar alterations than skeletal, even though they were not statistically significant among themselves.

These devices promoted the overjet, overbite and molar relation. Besides that, there was an improvement on patients' profile after therapies. However, treatment did not produce significant mandibular changes, implying the lack growth of this component. These effects could be limiting factors of this treatment protocol in Class II division 1 patients with mandibular retrusion. Thus, according to the results of this study, mandibular retrusion should not be the main indication of treatment with Forsus and MARA, and not to expect greater mandibular growth than the normal patters.

The ideal age for fixed functional appliance is in the permanent dentition, in growing patients.(COZZA et al., 2006b) However, since the effects are predominantly dentoalveolar, these devices could be used even on patient without growing potential.

Even though the Forsus and MARA are both used in treatment of Class II division 1, they are different regarding installation protocol.

Considering this, the decision for treating with Forsus or MARA should be based upon factors such as the relation of costs, benefits of treatment, and the professional and patients' preferences.

4 CONCLUSION

4 CONCLUSION

Based on the results of this specific study:

- The Forsus and MARA associated with fixed appliances effectively correct the Class II malocclusion, mostly by means of dentoalveolar changes and maxillary growth restraint.
- The Forsus showed greater maxillary growth restriction only than the control group and greater maxillomandibular discrepancy decrease than the other groups.
- The MARA group showed statistically significant greater maxillary incisor retrusion, which resulted in greater upper lip retrusion than the other groups.
- The Forsus group showed statistically significant greater lower lip protrusion than the other groups

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REFERENCES

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APPENDIX

APPENDIX A - DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN DISSERTATION/THESIS

We hereby declare that we are aware of the article "Comparative study of the effects of the fixed functional appliances Forsus Fatigue Resistant Device and MARA in treatment of Class II malocclusion through lateral cephalograms analysis" will be included in Dissertation of the student Cinthya Quagliato Nogueira and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, December 5th, 2018.

Cinthya Quagliato Nogueira
Author

Signature

José Fernando Castanha Henriques
Author

Signature

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ANNEXES

ANNEX A. Ethics Committee approval, protocol number 2.505.541 (front).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Estudo comparativo dos efeitos dos aparelhos propulsores Forsus Fatigue Resistant Device e MARA no tratamento da má oclusão de Classe II por meio da análise cefalométrica

Pesquisador: Cinthya Quagliato Nogueira

Área Temática:

Versão: 3

CAAE: 71636617.0.0000.5417

Instituição Proponente: Universidade de São Paulo - Faculdade de Odontologia de Bauru

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.505.541

Apresentação do Projeto:

Idem ao Parecer 2.337.142

Objetivo da Pesquisa:

Idem ao Parecer 2.337.142

Avaliação dos Riscos e Benefícios:

Idem ao Parecer 2.337.142

Comentários e Considerações sobre a Pesquisa:

Pendência descrita no Parecer 2.337.142: os autores devem corrigir o número de participantes necessários para a realização do estudo na Folha de Rosto ou nas informações básicas do projeto.

A PENDÊNCIA FOI RESOLVIDA.

Considerações sobre os Termos de apresentação obrigatória:

Termos devidamente apresentados

Recomendações:

Sem recomendações

Conclusões ou Pendências e Lista de Inadequações:

Sem pendências

Endereço: DOUTOR OCTAVIO PINHEIRO BRISOLLA 75 QUADRA 9
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ANNEX A. Ethics Committee approval, protocol number 2.505.541 (verse).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 2.505.541

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 07/02/2018, com base nas normas éticas da Resolução CNS 466/12. Ao término da pesquisa o CEP-FOB/USP exige a apresentação de relatório final. Os relatórios parciais deverão estar de acordo com o cronograma e/ou parecer emitido pelo CEP. Alterações na metodologia, título, inclusão ou exclusão de autores, cronograma e quaisquer outras mudanças que sejam significativas deverão ser previamente comunicadas a este CEP sob risco de não aprovação do relatório final. Quando da apresentação deste, deverão ser incluídos todos os TCLEs e/ou termos de doação assinados e rubricados, se pertinentes.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_943438.pdf	20/11/2017 15:18:35		Aceito
Folha de Rosto	Folha.pdf	20/11/2017 15:15:49	Cinthya Quagliato Nogueira	Aceito
Declaração de Instituição e Infraestrutura	PENDENCIACEP.pdf	15/09/2017 00:16:19	Cinthya Quagliato Nogueira	Aceito
Projeto Detalhado / Brochura Investigador	Projeto.pdf	19/07/2017 13:45:54	Cinthya Quagliato Nogueira	Aceito
Outros	QUEST.pdf	13/07/2017 10:13:56	Cinthya Quagliato Nogueira	Aceito
Declaração de Pesquisadores	DECLARACAO.pdf	13/07/2017 10:08:55	Cinthya Quagliato Nogueira	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	13/07/2017 10:07:39	Cinthya Quagliato Nogueira	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

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ANNEX A. Ethics Committee approval, protocol number 2.505.541 (verse).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 2.505.541

BAURU, 21 de Fevereiro de 2018

Assinado por:
Ana Lúcia Pompéia Fraga de Almeida
(Coordenador)

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ANNEX B. Patient´s informed consent exoneration (front).

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva

Bauru, 01 de Julho de 2017.

Dispensa de Termo de Consentimento Livre Esclarecido e Termo de Assentimento

Como parte da documentação solicitada pelo Comitê de Ética em Pesquisa para a avaliação de projetos de pesquisas envolvendo seres humanos, encaminho justificativa para a dispensa de TCLE e Termo de Assentimento no Projeto de Pesquisa **"Estudo comparativo dos efeitos dos aparelhos propulsores Forsus Fatigue Realstant Device e MARA no tratamento da má oclusão de Classe II por meio da análise cefalométrica"** tendo como Responsável Principal Cinthya Quaglato Nogueira, sob orientação de por José Fernando Castanha Henriques.

A pesquisa prevê dispensa de TCLE e Termo de Assentimento, devido não ser uma pesquisa que requer participação direta dos indivíduos. Nela se utilizarão dados secundários do arquivo do departamento de Ortodontia, no caso, telerradiografias de pacientes previamente tratados, tomadas no início e no final do tratamento ortodontico, e já possuem TCLE assinados pelos pacientes autorizando a nos utilizarmos dessa documentação em pesquisas.

Atenciosamente,

Cinthya Quaglato Nogueira
Responsável Principal

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