**UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU**

DEBORAH BRINDEIRO DE ARAÚJO BRITO

**A comparative study of the MARA appliance and the Activator-
Headgear combination in the treatment of Class II Division 1
malocclusion**

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DEBORAH BRINDEIRO DE ARAÚJO BRITO

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Headgear combination in the treatment of Class II Division 1
malocclusion**

**Estudo comparativo dos aparelhos MARA e Ativador combinado
com AEB no tratamento da má oclusão de Classe II Divisão 1**

Dissertação apresentada a Faculdade de Odontologia de Bauru da Universidade de São Paulo, para obtenção do título de Mestre em Ciências no Programa de Ciências Odontológicas Aplicadas, na área de concentração Ortodontia.

Orientador: Prof. Dr. José Fernando Castanha Henriques

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*“Percebe e entende que os melhores amigos
São aqueles que estão em casa, esperando por ti
Acredita nos momentos mais difíceis da vida
Eles sempre estarão por perto, pois só sabem te amar
E se por acaso a dor chegar, ao teu lado vão estar
Pra te acolher e te amparar
Pois não há nada como um lar”*

Aos melhores pais do mundo, Zenobio e Cléa, por
me guiarem com tanto amor e zelo!

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Vou persistir, e mesmo nas marcas daquela dor
Do que ficou, vou me lembrar
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***"Consagre a Deus tudo o que você faz, e
os seus planos serão bem-sucedidos."***

(Provérbios 16:3)

ABSTRACT

A comparative study of the MARA appliance and the Activator-Headgear combination in the treatment of Class II Division 1 malocclusion

The treatment of Class II Division 1 malocclusion using orthopedic devices combined with fixed orthodontic appliances has shown excellent results when used in growing patients. This study aimed to compare the treatment effects of Class II correction with MARA appliance (G1), AcHg combination appliance (G2), and an untreated control group (G3). Each experimental group was composed of 18 patients, with a baseline mean age of 11.70 (G1) and 10.88 (G2) years, treated for a mean time of 3.60 (G1) and 3.17 (G2) years. The control group (G3) consisted of 20 individuals with a baseline mean age of 11.07 years. The groups were evaluated before (T1) and after (T2) treatment. Lateral cephalometric radiographs were used to evaluate skeletal and dentoalveolar changes upon treatment (T2-T1), and a comparable period was used for the control group. Intergroup comparisons regarding treatment changes were performed using repeated measures analysis of variance (ANOVA) followed by Tukey's test. The dentoalveolar effects and maxillary restriction improved the maxillomandibular relationship in G1 and G2. Mandibular alterations were mainly due to natural craniofacial growth, with no significant alterations of soft tissues. It was concluded that both the appliances corrected similarly the Class II malocclusion.

Key words: Malocclusion, Angle Class II. Orthodontic Appliances, Functional. Orthodontics, Corrective.

RESUMO

Estudo comparativo dos aparelhos MARA e Ativador combinado com AEB no tratamento da má oclusão de Classe II Divisão 1

O tratamento da má oclusão de Classe II Divisão 1, usando aparelhos ortopédicos associados ao aparelho ortodôntico fixo, mostrou excelentes resultados, quando usado em pacientes em crescimento. Este estudo teve como objetivo comparar os efeitos do tratamento da correção de Classe II com os aparelhos MARA (G1) e o Ativador combinado ao AEB (G2) e um grupo controle não tratado (G3). Cada grupo experimental foi constituído por 18 pacientes, com idade média de 11,70 (G1) e 10,88 (G2), tratados por tempo médio de 3,60 (G1) e 3,17 (G2) anos. O grupo controle (G3) consistiu de 20 indivíduos com idade média de referência de 11,07 anos. Os grupos foram avaliados antes (T1) e após (T2) o tratamento. Telerradiografias laterais foram utilizadas para avaliar as alterações esqueléticas e dentoalveolares após o tratamento (T2-T1), sendo utilizado um período comparável para o grupo controle. As comparações intergrupos em relação às alterações do tratamento foram realizadas usando a Análise de Variância (ANOVA), seguidas pelo teste de Tukey. Os efeitos dentoalveolares e a restrição maxilar melhoraram a relação maxilomandibular em G1 e G2. As alterações mandibulares foram decorrentes principalmente do crescimento craniofacial natural, sem alterações significativas nos tecidos moles. Concluiu-se que ambos os aparelhos corrigiram similarmente a má oclusão de Classe II.

Palavras-chave: Má oclusão de Angle Classe II. Aparelhos ortodônticos funcionais. Ortodontia Corretiva.

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1 INTRODUCTION

1 INTRODUCTION

Class II malocclusion is the most common skeletal issue in orthodontics, (COZZA et al., 2006; CHIQUETO et al., 2013; CACCIATORE et al., 2014b; THIRUVENKATACHARI et al., 2015) with Class II division 1 malocclusion affecting 12 to 49% of the population (SARI et al., 2003). Although it is not the most prevalent malocclusion type in the population (GURGEL; ALMEIDA; PINZAN, 2001), there has been an increased influx of patients seeking orthodontic treatment to treat this condition, due to its important esthetic effect. (TRIVEDI et al., 2015)

Class II malocclusion is characterized by an incorrect relationship between the maxillary and mandibular arches due to skeletal or dental problems or a combination of both.(MCNAMARA JR, 1981; PROFFIT; FIELDS JR; MORAY, 1997; UPADHYAY et al., 2011) Some studies have shown that the components of Class II malocclusion can be categorized into four main groups: anterior position of the maxilla, anterior position of the maxillary dentition, mandibular skeletal retrusion in absolute size or relative position, and excessive or deficient vertical development.(RIEDEL, 1952; DE ALMEIDA; HENRIQUES; URSI, 2002) A number of studies have shown that Class II malocclusion is mainly characterized by mandibular retrognathia.(MCNAMARA JR, 1981; CHEN; WILL; NIEDERMAN, 2002; FLORES-MIR; MAJOR; MAJOR, 2006; FRANCHI et al., 2011; AL-JEWAIR, 2014; UNAL; CELIKOGLU; CANDIRLI, 2014; AL-SALEH et al., 2015)

Class II malocclusions can be treated with several appliances and treatment protocols based on some clinical features, such as anteroposterior discrepancy, age, as well as patient compliance.(CANÇADO et al., 2008) Numerous treatment approaches for Class II correction have been described over the last decades, including: selective extraction therapy, orthopedic forces delivered with headgear, functional jaw orthopedics using functional appliances, molar distalization with or without temporary anchorage devices (PANGRAZIO et al., 2012), as well as orthognathic surgery, have been described over the last decades.(KING et al., 1990; BOCK; VON BREMEN; RUF, 2015)

The choice for a specific protocol is based on the benefits of the treatment along with its effectiveness and efficiency in correcting several aspects of the malocclusion. (CANÇADO et al., 2008) Nevertheless, the decision as to which is the most effective technique for the treatment of growing patients with skeletal and dental Class II malocclusions has long been the source of considerable debate in the orthodontic literature. (PANGRAZIO et al., 2012)

A common strategy in the treatment of Class II Division 1 malocclusions in growing patients is a 2-step approach. In the first phase of the treatment, the sagittal jaw relationship is normalized. Then Class II malocclusion is transformed into Class I malocclusion. (DE LIMA et al., 2013) In the second phase of the treatment, tooth positions are adjusted, usually with fixed appliances. (FRANCHI et al., 2011; DE LIMA et al., 2013) However, there are also appliances that ideally allow the simultaneous (orthopedic and orthodontic) placement of a fixed orthodontic appliance in a single step, thereby speeding up the treatment length. (CHIQUETO et al., 2013)

Evidence has shown that the greatest effects of functional appliances occur when the peak in mandibular growth is included in the treatment period. (BACCETTI et al., 2000) The expected effects of these appliances include alteration of maxillary growth, a possible change in mandibular growth and position, and an improvement in dental and muscular relationships. Some of the most common removable devices are the Twin Block, Bionator, Activator, Frankel etc, whereas commonly used fixed appliances include the Jasper Jumper, Herbst, Twin Force Bite Corrector, Eureka Spring, MARA, among others. (KAYGISIZ et al., 2015)

Removable functional appliances, such as the activator, can change the Class II relationship through a transmission of soft-tissue tension to the dentition. (DE LIMA et al., 2013a) These appliances may be combined with extra-oral forces applied onto either the maxilla or the mandible. The use of the Activator-Headgear (AcHg) combination appliance has been recommended as a means of reducing vertical and sagittal maxillary displacement, achieving autorotation, increasing forward displacement of the mandible, and improving the maxillomandibular relationship. Additionally, the vertical dental effect of the AcHg appliance is to restrain the eruption of the maxillary molars and incisors. However, one major disadvantage lies in the need for patient compliance. (GÖNNER et al., 2007; KAYGISIZ et al., 2015)

Successful orthodontic treatment often relies heavily on patient cooperation in wearing the headgear, elastics, or removable appliances. Besides the lack of patient compliance to wearing the appliances, the severity of malocclusion is another likewise important factor.

Since the reintroduction of the Herbst appliance into modern orthodontics, (PANCHERZ, 1997) fixed functional appliances have become the most popular tools for nonsurgical treatment of Class II. The ideal appliance for correcting Class II skeletal problems would eliminate the need for patient cooperation, allow stimulation of the overall amount of mandibular growth, and direct such growth towards the appropriate direction. (PANGRAZIO-KULBERSH et al., 2003) Several studies have proven that fixed functional appliances are much more efficient in stimulating skeletal mandibular growth than are removable orthodontic appliances, (GÖNNER et al., 2007) and the first do not require patient compliance. (FRANCHI et al., 2011; CHIQUETO et al., 2013; CACCIATORE et al., 2014a; CACCIATORE et al., 2014b)

Among the fixed functional appliances recently available to treat Class II dentoskeletal malocclusion is the Mandibular Anterior Repositioning Appliance (MARA), (ECKHART, 1998; ECKHART; WHITE, 2003; PANGRAZIO-KULBERSH et al., 2003; BOCK; VON BREMEN; RUF, 2015) which works irrespective of patient cooperation. (CHIQUETO et al., 2013)

Patient compliance is one of the most important factors influencing the choice for a given appliance during the orthodontic treatment. Therefore, the purpose of this clinical study was to investigate the dentoskeletal changes in two groups of patients with Class II Division 1 malocclusion treated with either the MARA appliance, regardless of patient compliance, or with the AcHg combination, in which patient compliance is essential, both associated with fixed appliances. These groups were compared with a control group of untreated subjects with similar malocclusions.

2 ARTICLE

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A comparative study of the MARA appliance and the Activator-Headgear combination in the treatment of Class II Division 1 malocclusion

ABSTRACT

Introduction: The treatment of Class II Division 1 malocclusion using orthopedic devices combined with fixed orthodontic appliances has shown excellent results.

Objective: This study aimed to compare the treatment effects of Class II correction with the MARA appliance, followed by fixed orthodontic appliances (G1), AcHg combination appliance, followed by fixed orthodontic appliances (G2), and an untreated control group (G3). **Methods:** Each experimental group was composed of 18 patients, with a baseline mean age of 11.70 (G1) and 10.88 (G2) years, treated for a mean time of 3.60 (G1) and 3.17 (G2) years. The control group (G3) consisted of 20 individuals with baseline mean age of 11.07 years. The groups were evaluated before (T1) and after (T2) treatment. Lateral cephalometric radiographs were used to evaluate skeletal and dentoalveolar changes upon treatment (T2-T1), and a comparable period was used for the control group. Intergroup comparisons regarding treatment changes were performed using repeated measures analysis of variance (ANOVA) followed by Tukey's test. **Results:** The dentoalveolar effects and maxillary restriction improved the maxillomandibular relationship in G1 and G2. Mandibular alterations were mainly due to natural craniofacial growth, with no significant alterations of soft tissues. **Conclusion:** It was concluded that both the appliances corrected similarly the Class II malocclusion.

INTRODUCTION

Class II malocclusion is the most common skeletal issue in orthodontics¹⁻⁴, with Class II Division 1 malocclusion affecting 12 to 49% of the population.⁵ Although it is not the most prevalent malocclusion type in the population,⁶ there has been an increased influx of patients seeking orthodontic treatment to treat this condition, due to its important esthetic effect.⁷

The orthodontist can choose from an entire arsenal of different therapeutic means to correct Class II cases, namely headgear, Class II elastics, removable or fixed functional appliances, or orthognathic surgery.^{8,9,10}

As the most commonly found skeletal factor in Class II Division 1 is mandibular retrusion^{11,12}, and considering that maxillary protrusion is not often present, an approach able to redirect and stimulate mandibular growth with or without restriction of maxillary growth would be strongly recommended.¹³ Early intervention in patients with active growth using a combination of functional and fixed appliances can yield great treatment outcomes for Class II malocclusion.⁵

Removable functional appliances, such as the activator, change the Class II relationship by transferring soft tissue tension towards the dentition. This can be achieved by positioning the mandible anteriorly with the appliance.¹⁴ However, the use of removable devices, which depend heavily on patient compliance, is a recurrent concern of orthodontists during treatment, especially in adolescent patients.^{13,15-17}

In the therapy with MARA, the appliance prevents the mandible from closing more backwardly or in a Class II position. As a result, the patient is led to position their mandible anteriorly both during function and at rest, with the advantage of being a fixed device and not to depend on patient compliance for use.^{2,18}

Therefore, in order to be effective in treating Angle's Class II Division 1 malocclusion, an appliance should ideally generate the skeletal and dental effects necessary to correct the discrepancy between the basal bones while reducing overjet, thereby eliminating the need for patient compliance.²

Thus, the purpose of this clinical study was to investigate the dentoskeletal changes in two groups of patients with Class II Division 1 malocclusion treated either with the Mandibular Anterior Repositioning Appliance (MARA) or the Activator-Headgear (AcHg) combination, both associated with fixed appliances. These groups were compared with a control group of untreated subjects with similar malocclusions.

MATERIAL AND METHODS

This study was previously approved by the Research Ethics Committee of Bauru Dental School, University of São Paulo, Brazil, under the protocol 43929215.6.0000.5417. All subjects signed the informed consent to participate in the study.

The sample size was calculated considering an alpha error of 0.05 and a beta error of 0.2 in order to achieve 80% power. The statistical power was set to detect a mean difference of 1.5 mm by using the overjet as a parameter and assuming detection of a minimum difference of 1.5 mm with a standard deviation of 1.57.¹⁹ The sample size calculation indicated that 18 patients were required to complete the study.

Therefore, the study sample comprised 56 subjects (36 treated, 20 untreated). Thirty-six treated patients were retrospectively selected from the files of the Orthodontic Department at Bauru Dental School, University of São Paulo. The sample was selected according to the following inclusion criteria: Class II Division 1 malocclusion with bilateral Class II molar relationship (minimum severity of one half Class II molar relationship;²⁰ absence of agenesis, absence of supernumerary or missed teeth; convex profile; mandibular arch with slight or no crowding; no history of previous orthodontic treatment.

The group treated with the MARA followed by a fixed appliance (G1) included 18 subjects (13 males, 5 females) with a baseline mean age of 11.70 years (SD, 1.11) and final mean age of 15.30 years (SD, 1.20). The subjects were treated for a mean period of 3.60 years (SD, 0.91), showing an initial mean ANB angle of 5.66 (SD, 1.49) and an initial mean overjet of 7.45 mm (SD, 1.34). All patients presented early permanent dentition with all permanent first molars, and first and second premolars erupted.

The MARA appliance (Fig. 1) comprises four steel crowns cemented on the permanent first molars. These crowns have loops that connect only when the patient occludes. A lingual arch and transpalatal bar are incorporated into the appliance to stabilize the upper and lower molars, respectively.^{2,21,22} Mandibular advancement can be accomplished by inserting steel bands in the loop of the upper crown. There are four band sizes ranging from 1 to 4 mm in length. Thus, advancement can be gradual, while the patient is given the opportunity to adapt to the appliance.²

The group treated with the AcHg combination followed by a fixed appliance (G2) consisted of 18 subjects (12 males, 6 females). All patients presented early permanent dentition with all permanent first molars, and first and second premolars erupted. This group had a baseline mean age of 10.88 years (SD, 0.80) and a final mean age of 14.06 years (SD, 1.35). The subjects were treated for a mean period of 3.17 years (SD, 1.50), showing an initial mean ANB angle of 5.98 (SD, 1.64) and an initial mean overjet of 7.70 mm (SD, 2.30 mm).

The AcHg combination appliance (Fig. 2) consisted of a bimaxillary acrylic block with a screw expander on the top, a maxillary labial bow (0.7 mm), and Adams clasps on the maxillary first molars. The incisal third of the mandibular incisors was capped with acrylic to prevent extreme labial tipping. Headgear bows were incorporated into the inter-occlusal acrylic in the premolar area. The construction bite was taken with the mandible protruded in an edge-to-edge incisor relationship, and the inter-occlusal space was increased to 7 mm. In patients with large overjets, a 2-step activation was performed. The outer bow was tilted 15° upwards from the occlusal plane, exerting 400 g of force on each side with an average wear of 15 hours per day.²³

The control group (G3) comprised 20 subjects (10 males, 10 females) with untreated Class II malocclusion. This group had a baseline mean age of 11.07 years (SD, 0.50) and a final mean age of 15.20 years (SD, 0.93) and was followed up for a mean period of 4.13 years (SD, 1.15). This group was selected from the longitudinal growth study sample of “The University of Toronto Burlington Growth Study” (Department of Orthodontics, Dental School, University of Toronto, Canada) obtained from the online American Association of Orthodontics Foundation (AAOF) Craniofacial Growth Legacy Collection. (http://www.aaoflegacycollection.org/aaof_home.html)²⁴

After obtaining a normal anteroposterior relationship in both experimental groups, fixed standard appliances were installed. Round nickel-titanium and steel wire and rectangular steel wire were used to make the ideal torques. During leveling and aligning, some patients used Class II elastic, when necessary, to maintain the anteroposterior relationship obtained with the appliances, and elastic intercuspation. After removal of the fixed orthodontic appliances, a Hawley plate was used in the maxillary arch, and a canine-to-canine bonded retainer was used in the mandibular arch. All patients were treated with no extractions.

Therefore, two lateral headfilms were obtained from each patient in the following stages of orthodontic treatment: 1- before the installation of orthopedic appliances (T1) and post-treatment - after the use of the orthopedic appliances and leveling and alignment (T2). The headfilms were digitized (MICROTEK ScanMaker, model i800), traced and analyzed with Dolphin Imaging 11.5 (Patterson Dental Supply, Inc., Chatsworth, California, USA). Imaging magnification factors were corrected since the lateral headfilms were obtained from different radiographic machines due to the long time between the evaluations. A customized cephalometric analysis generated 27 variables, being 8 angular and 19 linear, for each tracing (Table I; Fig. 4).

Error study

Fifty-six lateral headfilms were randomly selected, retraced and re-measured by the same examiner (D.B.A.B) within a 30-day interval. Random errors were calculated according to Dahlberg's formula ($Se^2 = \sum d^2 / 2n$)²⁵ and the systematic errors were evaluated with dependent *t* tests, at $p < .05$.

Statistical analyses

Normal distribution was evaluated using the Kolmogorov-Smirnov test and all variables showed normal distribution, therefore allowing the application of parametric statistical tests.

Chi-square tests were used to check for differences among the three groups regarding sex distribution and the severity of the initial Class II molar relationship. Analysis of variance (ANOVA) and Tukey's test were used for intergroup comparisons of (i) baseline and final ages; (ii) differences before treatment or before follow-up (control group); and (iii) differences between the cephalometric changes during the treatment period (T2 – T1) in the experimental groups with those occurring during a comparable period for the control group.

All statistical analyses were performed with Statistica software (Statistica for Windows, version 6.0, Statsoft, Tulsa, Okla). The results were considered statistically significant at $p < 0.05$.

RESULTS

Only 2 (SN.GoGn and LAFH) out the 27 study variables were found to show statistically significant systematic errors, and no variable showed random errors greater than 1.0 mm or 1.5°.

The groups were comparable regarding sex distribution (Table II).

The severity of the initial anteroposterior relationship was similar at baseline between the experimental groups and the control group (Table III).

The age of the subjects was significantly different in the three groups at T1 (pretreatment) and T2. The AcHg group had lower age at T1 and T2 than had the MARA and control groups. The total treatment length in the experimental groups and the follow-up period for the control group were similar (Table IV).

The experimental groups had significantly greater maxillary protrusion than the control group (Table V). The AcHg group showed significantly lower maxillary length than the other two groups. The control group presented significantly greater mandibular retrusion than the MARA group. The AcHg group had significantly lower mandibular length than the control group. The experimental groups showed significantly greater Class II anteroposterior discrepancies. The control group presented a significantly greater vertical growth pattern than the MARA group, and greater anterior facial height than the AcHg group. The maxillary incisors had significantly greater protrusion in the experimental groups, and the mandibular molars were found to be at a significantly higher vertical position in the control group. The experimental groups showed significantly greater overjet. The AcHg group showed nasolabial angle significantly lower than the control group in the beginning of treatment.

Table VI shows the changes during the total treatment length, including the use the orthopedic appliances, alignment of leveling, and alignment and use of the Class II elastics (T1-T2) in the experimental group. The same is shown during the comparable period for the control group. Among the 27 study variables, 10 measurements were found to have significant differences among groups. The experimental groups had restriction of maxillary forward displacement, with the AcHg group showing the greatest restriction. At the end of the treatment, there were significantly greater reductions in the maxillomandibular Class II relationship in both experimental groups. The experimental groups presented significant palatal inclination of the maxillary incisors. The AcHg group had significantly lower extrusion of the

maxillary molars in the total period. The experimental groups showed significant labial tipping and protrusion of the mandibular incisors, with greater values found in the AcHg group. Overjet and molar relationships had significantly greater improvements in the experimental groups until the end of the treatment, and the AcHg group still showed significant improvement of the overbite in relation to the control group. There were no statistically significant changes in soft tissue despite the significant dentoskeletal changes in the correction of the anteroposterior discrepancy in the experimental groups.

DISCUSSION

Sample and Methodology

Sex differences within groups were evaluated and were not statistically significant. (Table II) Comparability between the groups regarding distribution by sex is essential for this variable in order to avoid the effects of sexual dimorphism on craniofacial size and alterations.²⁸⁻³⁰

Concerning the severity of the initial anteroposterior discrepancy of the Class II malocclusion (Table III), no statistically significant difference was observed between the experimental and control groups. If the reduction of malocclusion severity is used to assess treatment effectiveness, then the comparability among groups regarding initial severity of the Class II molar relationship is essential.³¹⁻³³

The group treated with the AcHg combination had younger subjects at T1. This may be due to the fact that treatment with the AcHg combination can be performed in young people who should be ideally at the beginning of the pubertal growth spurt, which sometimes coincides with the second transitional period of the mixed dentition.^{14,34-36} In the MARA group, subjects were initially treated with orthopedics followed by fixed orthodontics. Treatment with the MARA can be performed either at the stage of mixed or permanent dentition.^{8,37} However, the groups showed no statistically significant difference with respect to treatment length or follow-up time. As a result, the groups showed difference in age at the end of treatment – T2 (Table IV).

The baseline cephalometric variables showed statistically significant differences between the experimental and control groups (Table V). Among the experimental groups, only the initial maxillary length, represented by Co-A variable, had a statistically significant difference. Thus, treatment groups with similar cephalometric

characteristics were compared. Statistically significant differences between the control group and both experimental groups simultaneously occurred in 8 out of the 27 variables evaluated. Overall, the differences reflect less severe measures in the control group. It is very difficult to find a suitable control group enabling a valid assessment of a long-term follow-up. Despite this limitation, a less-than-ideal control group is better than none. In addition, other studies have also shown initial differences between the experimental and control groups.^{28,38,39}

Maxillary component

The three groups were compared regarding treatment outcomes and growth changes. As seen in Table VI, the SNA angle decreased significantly only in the AcHg group. The MARA group showed a restriction of the anterior maxilla, which was not statistically significant for the SNA variable compared with the control group. The retrusion of the maxillary incisors during therapy reflected a change in the location of the A-point due to appositional changes in the alveolar area, which may have camouflaged the restrictive effect of the MARA on the maxilla (SNA). Another study also found slight growth restriction over time, but it was not significant in the control group.³⁷

There was a similar restriction of maxillary forward displacement in both experimental groups (A-Na Perp). However, this decrease was not sufficient to generate a statistically significant difference for the MARA group in relation to the control group. These results agree with previous studies that also found significant restrictions of maxillary growth upon treatment with the MARA appliance^{2,40-42} and AcHg combination^{23,38,43,44}.

A significant increase in the effective maxillary sagittal growth (Co-A) was observed in the experimental groups during the treatment period. Nevertheless, such increase was significantly lower than that of the control group, thus indicating a restriction in the maxillary sagittal growth. Similar results in relation to the maxillary effective length have been reported by other authors.^{2,14,17,35,45}

Mandibular component

The use of orthopedic appliances to stimulate and/or redirect mandibular growth is a common procedure. When changes in the mandibular components in relation to

the cranial base (SNB; Pg-Na Perp) were compared, no significant differences were observed between the experimental and control groups (Table VI). Despite the increase in such variables, mandibular changes were probably inherent to normal growth, corroborating some previous studies.^{19,23,46-48}

There was no statistically significant difference in the increase of mandibular effective length (Co-Gn) between the experimental and control groups. Hence, this study suggests that there may be a craniofacial growth embedded in these changes observed during treatment, diverging from some clinical studies that found no significant increase in mandibular length upon use of this device.^{2,23,49,50} In addition, some functional devices were also shown to be mainly active on the maxilla.⁵

Maxillomandibular Relationship

During treatment, there was a significant improvement in the maxillomandibular relationship in both treatment groups, although only Wits variable was statistically significant for the MARA group (Table VI). Improvement in the maxillomandibular relationship during treatment resulted primarily from maxillary retrusion, as previously discussed, in addition to normal mandibular growth and significant dentoalveolar effects. However, changes in the Wits appraisal must be carefully evaluated. It is not a reliable indicator of sagittal change since it is heavily influenced by alterations in the cant of the occlusal plane angle.²³ Most of the researchers who have studied the MARA appliance^{2,8,37,40-42,51} and the AcHg combination^{5,28,38,43,52}, as well as other therapies^{17,53,54}, have also reported similar findings.

Vertical component

The treatments with the MARA appliance and AcHg combined with fixed orthodontics did not alter significantly the existing growth pattern, allowing normal growth and changes to occur, however, there was a statistically significant difference for the SN-GoGn variable between the AcHg and control groups. (Table VI). This was also observed in the control group, due to normal growth, which is characterized by mandibular counterclockwise rotation in response to vertical redirection of condylar growth.^{55,56}

Maxillary dentoalveolar component

The experimental groups presented significant palatal inclination of the maxillary incisors. The AcHg group had significantly lower extrusion of the maxillary molars in the total period, but with no statistical significance (Table VI).

Only one variable (Mx1-Apo) was statistically significant between the experimental and control groups. This finding corroborates other studies which also showed a lingual inclination of the upper incisors as a common effect of all functional appliances^{2,14,19,37,48,50,60,61}

There was no statistically significant difference in the sagittal position of the maxillary molars, probably due to the use of anchorage control in the experimental groups, which is in line with several studies in the literature.^{19,62}

Mandibular dentoalveolar component

The experimental groups presented significant labial tipping and protrusion of the mandibular incisors, with greater values found in the AcHg group. At the end of the treatment, the mandibular incisors had significantly lower extrusion in the experimental groups as compared to those of the control group (Table VI).

This finding can be explained by the forces applied by the functional appliances, which work as vectors of mesialization and intrusion of mandibular incisors. Furthermore, the treatment effects on the mandibular incisors are a result of mandibular anchorage loss due to the anteriorly-directed force vector on the mandibular dentition. This corroborates with previous reports on functional appliances.^{2,8,17,19,23,61,63} During treatment, the experimental groups presented an extrusion of the mandibular incisors, a relapse that was also observed in other studies.^{58,64} Incisor extrusion was lower in the AcHg group than in the MARA group. The possible explanation for this may be the acrylic capping over the lower incisors. Extrusion is normal during the growth period, and the control group showed an even more significant extrusion during the comparable time (Table VI).

The sagittal position of the mandibular molars showed no significant changes in the experimental groups as compared to the control group. Nevertheless, mesialization of these mandibular molars is a desirable event for correction of the Class II malocclusion.

Dental relationship

The treatments led to significant improvement in the molar relationship and reduction of overjet and overbite (Table VI). Similar results can be found in the literature.^{2,5,28,41,64} These corrections can be attributed to a combination of skeletal and dental effects promoted by the functional appliances.

Soft tissue component

There were no statistically significant changes in soft tissues (Table VI). All favorable skeletal alterations were not associated with a significant improvement in soft tissue in the experimental groups compared to the control group. These findings corroborate those by other studies evaluating soft tissue in therapies with other functional appliances.^{19,45,50,55}

CONCLUSIONS

The effects of the treatment with the MARA appliance and the AcHg combination followed by fixed orthodontic appliances were found to be similar concerning correction of the Class II malocclusion. Their main effects are as follows:

- A restrictive effect on the maxilla;
- Palatal inclination of maxillary incisors;
- Labial tipping of mandibular incisors;

Both appliances provided significant improvement of maxillomandibular relationship, overjet, overbite, and molar relationship.

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Figure legends:

Fig. 1. MARA appliance installed.

Fig. 2. AcHg combination appliance.

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

Fig. 1

Fig. 2

Fig. 3

Table I - Skeletal and dental cephalometric variables.

Skeletal cephalometric variables	
<i>Maxillary component</i>	
SNA (°)	SN to NA angle
A-NPerp (mm)	A-point to nasion-perpendicular
Co-A (mm)	Condylion to A-point distance
<i>Mandibular component</i>	
SNB (°)	SN to NB angle
Pg-NPerp (mm)	Pg-point to nasion-perpendicular
Co-Gn (mm)	Condylion to gnathion distance
<i>Maxillomandibular relationship</i>	
ANB (°)	NA to NB angle
Wits (mm)	Distance between perpendicular projections of Points A and B on functional occlusal plane
<i>Vertical component</i>	
FMA (°)	Frankfort mandibular plane angle
SNGoGn (°)	SN to GoGn angle
LAFH (mm)	Distance from ANS to menton
<i>Soft-tissue component</i>	
Nasolabial angle (°)	Angle formed by the Prn'-Sn line and UL-Sn' line (Prn' pronasal point, Sn subnasal point, UL upper lip)
Upper Lip (mm)	Distance between point of the upper lip to S line (Pg' 'point to nose)
Lower Lip (mm)	Distance between point of the lower lip to S line (Pg' 'point to nose)
Dental cephalometric variables	
<i>Maxillary dentoalveolar component</i>	
Mx1.PP (°)	Maxillary incisor long axis to palatal plane angle
Mx1-PP (mm)	Perpendicular distance between incisal edge of maxillary incisor and palatal plane
Mx1-APo (mm)	Distance between incisal edge of maxillary incisor and A-Pg line
Mx6-PP (mm)	Perpendicular distance between maxillary first molar occlusal and palatal plane
Mx6-APerp (mm)	Distance between maxillary first molar occlusal and line perpendicular to palatal plane, tangent to A point
<i>Mandibular dentoalveolar component</i>	
Md1.NB (°)	Mandibular incisor long axis to NB angle
Md1-NB (mm)	Distance between the most anterior point of the crown of the mandibular incisor and NB line
Md1-MP (mm)	Perpendicular distance between incisal edge of mandibular incisor and mandibular plane
Md6-MP (mm)	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, tangent to Pg point

<i>Dental relationship</i>	
Overjet (mm)	Distance between incisal edges of maxillary and mandibular central incisors, parallel to functional occlusal plane
Overbite (mm)	Distance between incisal edges of maxillary and mandibular central incisors, perpendicular to Frankfort plane
Molar Relationship (mm)	Distance between mesial points of maxillary and mandibular first molars, parallel to Frankfort plane

Table II - Comparability among the groups for sex distribution (Chi-square test)

Sex	G1, MARA (n=18)	G2, AcHg (n=18)	G3, Control (n=20)	p value
Female	5 (27.77%)	12 (66.66%)	10 (50.00%)	0.064
Male	13 (72.22%)	6 (33.33%)	10 (50.00%)	

*Statistically significant at $p < 0.05$.

Table III - Comparability among the groups for severity of the initial anteroposterior relationship of the dental arches (Chi-square test)

Severity of Class II	G1, MARA (n=18)	G2, AcHg (n=18)	G3, Control (n=20)	p value
½ Class II	4 (22.22%)	6 (44.44%)	6 (30.00%)	0.850
¾ Class II	7 (38.88%)	4 (22.22%)	6 (30.00%)	
Complete Class II	7 (38.88%)	8 (44.44%)	8 (40.00%)	

*Statistically significant at $P<0.05$.

Table IV - Intergroup comparisons of the ages at T1 and T2 and values of the treatment length (T1-T2) (ANOVA followed by Tukey test)

	G1, MARA (n=18)		G2, AcHg (n=18)		G3, Control (n=20)		
Variable	Mean	S.D.	Mean	S.D.	Mean	S.D.	p value
T1 age (yrs)	11.70 ^A	1.11	10.88 ^B	0.80	11.07 ^{AB}	0.50	0.012*
T2 age (yrs)	15.30 ^A	1.20	14.06 ^B	1.35	15.20 ^A	0.93	0.003*
Treatment or observation time (yrs) (T1-T2)	3.60	0.91	3.17	1.50	4.13	1.15	0.059

*Statistically significant at $p < 0.05$.

Table V- Comparability before treatment among the groups (ANOVA followed by Tukey test)

	G1, MARA (n=18)		G2, AcHg (n=18)		G3, Control (n=20)		
Variable	Mean	S.D.	Mean	S.D.	Mean	S.D	p value
Maxillary component							
SNA	82.23 ^A	3.84	82.35 ^A	2.91	79.78 ^A	3.58	0.041*
A-Na Perp	2.46 ^A	3.67	1.17 ^A	2.95	-2.53 ^B	3.09	0.000*
Co-A	81.21 ^A	3.95	77.63 ^B	3.55	81.99 ^A	3.70	0.001*
Mandibular component							
SNB	76.57	3.65	76.37	2.51	76.51	2.93	0.980
Pg-Na Perp	-3.86 ^A	5.73	-6.45 ^{AB}	4.77	-8.56 ^B	6.24	0.045*
Co-Gn	106.09 ^{AB}	5.51	102.02 ^A	4.47	109.65 ^B	5.80	0.000*
Maxillomandibular relationships							
ANB	5.66 ^A	1.49	5.98 ^A	1.64	3.26 ^B	2.55	0.000*
Wits	3.45 ^A	2.57	3.94 ^A	1.78	-0.14 ^B	4.14	0.000*
Vertical component							
FMA	22.15 ^A	4.55	25.21 ^{AB}	3.94	25.87 ^B	5.06	0.037*
SN-GoGn	31.31	5.52	32.84	4.21	32.94	4.88	0.533
LAFH	60.36 ^{AB}	3.89	58.17 ^A	3.94	61.64 ^B	4.12	0.033*
Maxillary dentoalveolar component							
Mx1.PP	112.82 ^A	5.02	115.48 ^A	7.86	104.93 ^B	7.83	0.000*
Mx1-PP	27.43 ^{AB}	2.29	25.98 ^A	2.02	28.28 ^B	2.28	0.008*
Mx1-APo	8.56 ^A	1.88	8.55 ^A	2.35	5.87 ^B	3.18	0.001*
Mx6-PP	15.91	2.39	15.29	2.03	16.05	2.43	0.568
Mx6-APerp	32.38	1.50	31.78	2.30	32.25	2.23	0.541
Mandibular dentoalveolar component							
Md1.NB	27.03	3.10	26.53	4.48	23.98	7.37	0.178
Md1-NB	4.84	1.57	4.65	1.48	3.72	2.46	0.163
Md1-MP	31.96	3.02	31.18	2.99	30.75	2.22	0.403
Md6-MP	26.25	2.28	24.67	2.42	25.98	2.10	0.090
Md6-PogPerp	35.68 ^A	1.55	35.09 ^A	3.51	39.00 ^B	4.19	0.000*
Dentoalveolar relationship							
Overjet	7.45 ^A	1.34	7.70 ^A	2.30	5.12 ^B	2.29	0.000*
Overbite	3.23	2.20	3.40	1.50	2.48	1.62	0.249
Molar Relationship	2.59	1.27	2.50	1.66	2.75	1.98	0.103
Sof-tissue component							
Nasolabial angle	111.23 ^{AB}	12.78	110.32 ^A	11.16	118.89 ^B	8.30	0.033*
Upper lip	5.28	1.66	4.76	1.96	4.04	2.02	0.134
Lower lip	3.23	2.62	3.08	2.53	1.57	2.46	0.087

Different letters indicate statistically significant differences;

*Statistically significant at $p < 0.05$

Table VI - Intergroup comparison of treatment and growth changes (T2-T1) (ANOVA followed by Tukey test)

	G1, MARA (n=18)		G2, AcHg (n=18)		G3, Control (n=20)		
Variable	Mean	S.D.	Mean	S.D.	Mean	S.D	p value
Maxillary component							
SNA	0.03 ^A	2.55	-1.87 ^B	2.18	0.79 ^A	1.78	0.001*
A-Na Perp	-0.57 ^B	2.13	-1.94 ^A	3.30	0.59 ^B	1.86	0.010*
Co-A	2.24 ^A	4.08	2.28 ^A	2.93	6.01 ^B	3.84	0.002*
Mandibular component							
SNB	0.99	2.22	0.55	1.76	1.12	1.53	0.619
Pg-Na Perp	0.55	4.32	0.36	5.27	1.74	4.57	0.621
Co-Gn	8.22	4.62	8.38	2.94	9.79	4.64	0.444
Maxillomandibular relationships							
ANB	-0.99 ^A	1.32	-2.43 ^B	1.65	-0.33 ^A	1.27	0.000*
Wits	-1.36 ^A	2.76	-2.92 ^A	1.08	1.25 ^B	2.17	0.000*
Vertical component							
FMA	0.05	2.36	0.60	4.38	-1.60	2.86	0.107
SN-GoGn	-1.23 ^{AB}	3.05	0.04 ^A	3.12	-2.24 ^B	2.13	0.048*
LAFH	5.31	2.07	4.47	2.39	4.70	2.57	0.551
Maxillary dentoalveolar component							
Mx1.PP	-4.22	7.33	-4.19	7.98	0.79	9.01	0.099
Mx1-PP	1.32	1.98	1.61	1.61	1.38	1.46	0.539
Mx1-APo	-3.15 ^A	2.02	-2.39 ^A	2.47	0.04 ^B	1.05	0.000*
Mx6-PP	2.97	1.22	2.11	2.01	2.99	1.77	0.212
Mx6-APerp	-0.74	1.82	-1.12	1.79	-1.69	2.07	0.309
Mandibular dentoalveolar component							
Md1.NB	3.37 ^A	6.76	4.07 ^A	4.72	-1.85 ^B	4.55	0.002*
Md1-NB	1.04	1.47	1.26	1.65	0.32	1.12	0.112
Md1-MP	2.47 ^{AB}	3.30	1.29 ^A	1.83	3.60 ^B	1.64	0.014*
Md6-MP	3.23	1.73	2.47	1.33	2.57	1.46	0.263
Md6-PogPerp	-1.17	1.28	0.26	2.21	-1.33	3.37	0.110
Dentoalveolar relationship							
Overjet	-4.42 ^A	1.76	-4.47 ^A	2.50	-0.45 ^B	2.21	0.000*
Overbite	-1.33 ^{AB}	1.93	-2.03 ^A	1.49	-0.19 ^B	2.17	0.014*
Molar Relationship	-2.76 ^A	1.75	-3.10 ^A	2.03	-0.66 ^B	1.74	0.000*
Sof-tissue component							
Nasolabial angle	5.14	8.19	3.24	9.22	1.21	6.75	0.332
Upper lip	-1.89	1.87	-1.88	1.68	-1.31	1.89	0.532
Lower lip	-0.62	1.65	0.01	2.77	-0.94	2.26	0.428

Different letters indicate statistically significant differences;

*Statistically significant at $p < 0.05$.

3 DISCUSSION

3 DISCUSSION

3.1 Skeletal component

According to the results found in this study, treatment with the MARA appliance and AcHg combination led to very similar alterations in the correction of Class II malocclusion. These systems restrained maxillary growth and development, with little influence on mandibular growth, despite producing a significant improvement in the maxillomandibular relationship (Table VI). These results are in agreement with those reported by previous studies, which also found significant restriction of maxillary growth.(COPE et al., 1994; WEILAND et al., 1997; KÜÇÜKKELES; İLHAN; ORGUN, 2007; CHIQUETO et al., 2013; DE LIMA et al., 2013b; KAYGISIZ et al., 2015) Increase in SNA angle and A-Na Perp in the AcHg group was significantly greater than that in the MARA and control groups. This consistent finding may be related to the fact that AcHg presents the headgear component in the system.(LAGERSTRÖM et al., 1990; CURA et al., 1996; JANSON et al., 2004; MARŞAN, 2007)

The use of orthopedic appliances to stimulate and/or redirect mandibular growth is common. In this study, even though small differences in these variables were found among the experimental groups, they were not significantly greater than those of the control group concerning mandibular effective length. Nevertheless, it is likely that the mandibular length continues to increase after treatment as a consequence of normal growth, which may contribute to the stability of the Class II correction.(STUCKI; INGERVALL, 1998) It is important to know the correct indication of these functional devices. In some cases, combined orthopedic-orthodontic therapy for Class II division 1 malocclusion with mandibular retrognathism - as described by some authors(GRABER; RAKOSI; PETROVIC, 1997; TULLOCH et al., 1997; ZYMPERDIKAS et al., 2015), may not be a primary indication for wearing appliances, since there are cases in which greater growth and mandibular protrusion are much more due to normal growth.(COVELL JR et al., 1999; WEST; MCNAMARA, 1999; NALBANTGIL et al., 2005; COZZA et al., 2006; DE LIMA et al., 2013a)

Furthermore, the great benefit of orthopedic appliances lies in the use of the patient's natural growth to correct Class II malocclusion. If no treatment is instituted, then the patient will present greater anterior displacement of their maxillary component (KÜÇÜKKELES; İLHAN; ORGUN, 2007; STAHL et al., 2008; BACCETTI; FRANCHI; STAHL, 2009; HENRIQUES et al., 2009; FRANCHI et al., 2011), indicating therefore that these devices promote a restrictive skeletal effect in the maxilla (COPE et al., 1994; JASPER; MCNAMARA, 1995; WEILAND et al., 1997; COVELL JR et al., 1999; NALBANTGIL et al., 2005; FRANCHI et al., 2011; HERRERA et al., 2011; PANGRAZIO et al., 2012; DE LIMA et al., 2013a) and improve the relationship between the apical bases. (ECKHART; WHITE, 2003; KARACAY et al., 2006; KÜÇÜKKELES; İLHAN; ORGUN, 2007; SIARA-OLDS et al., 2010; FRANCHI et al., 2011; HERRERA et al., 2011; PANGRAZIO et al., 2012) As previously discussed, the improvement in the maxillomandibular relationship is a result of maxillary retrusion, normal mandibular growth, and significant dentoalveolar effects.

Treatment of the experimental groups led to changes in the mandibular component, although no significant differences were observed when compared with the control group (Table VI). It is likely that the mandibular alterations may have been also camouflaged by other important changes, such as increase in the lower anterior facial height, which is a normal effect of treatments with functional appliances. (HÄGG; DU; RABIE, 2002; SIARA-OLDS et al., 2010; CHIQUETO et al., 2013; FRANCISCONI et al., 2013) The MARA and Achg appliances caused the vertical relationships to be practically unchanged. However, there were clockwise mandibular rotations in the experimental groups as compared with the control group due to force vectors of orthopedic devices that move the jaw forward and downward.

3.2 Dentoalveolar component

The ideal time to carry out a treatment with functional appliances is in the phase of young permanent teeth, i.e. approaching patients in the growth phase. In the absence of such devices, the dental movements may be slightly impaired as intercuspation may "lock" the occlusion. (FRÖHLICH, 1962) In addition to that, important dental changes may also occur, such as those observed in this study:

restriction of the vertical development of maxillary molars; vestibularization, protrusion and limitation of the vertical development of lower incisors, and extrusion of the lower molars (Table VI).

Both treatment regimens proved to be effective concerning occlusal parameters (overjet, overbite, and molar relationship). Similar results were also found in the literature. (COELHO, 1995; STUCKI; INGERVALL, 1998; SARI et al., 2003; BACCETTI; FRANCHI; STAHL, 2009; GHISLANZONI et al., 2012; CHIQUETO et al., 2013; DE LIMA et al., 2013b) These corrections can be attributed to a combination of skeletal and dental effects promoted by the functional appliances.

It is also worth noting that one of the advantages of fixed functional appliances, for instance, the MARA appliance, is that the devices can be used even in patients whom do not show further growth potential because of their predominantly dentoalveolar effects. (COPE et al., 1994; COELHO, 1995; KÜÇÜKKELES; İLHAN; ORGUN, 2007; CHIQUETO et al., 2013; NEVES et al., 2014)

3.3 Soft tissue component

Upon treatment with functional appliances, it is common that the soft tissue profile also suffers favorable changes as a result of improved dentoalveolar and skeletal positioning. Some studies have also reported an increase in the nasolabial angle, retrusion of the upper lip, and lower lip advance (NALBANTGIL et al., 2005; KÜÇÜKKELES; İLHAN; ORGUN, 2007). Despite the significant dentoskeletal changes to correct the Class II malocclusion with the MARA and AchHg appliances, there was no significant change in soft tissues as compared to the control group (Table VI). These findings corroborate those of other studies evaluating the effects of therapies with other functional appliances on soft tissues. (PANCHERZ, 1984; NALBANTGIL et al., 2005; KÜÇÜKKELES; İLHAN; ORGUN, 2007; FRANCISCONI et al., 2013) A study using different parameters from those used herein found a significant improvement in the sagittal position of maxillary soft tissues in the treated group. (FRANCHI et al., 2011)

3.4 Suggestion for upcoming surveys

- To compare the cephalometric changes of the Class II division 1 malocclusion treatment with the MARA device and the Forsus device, associated to the fixed appliance;
 - To evaluate the long-term stability of dentoskeletal and in plaster cast models changes in the treatment of Class II division 1 with the MARA device associated to the fixed appliance;
 - To compare the long-term stability of the occlusal results obtained with the MARA and Forsus devices associated with the fixed appliance in the treatment of Class II division 1.
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4 CONCLUSION

4 CONCLUSION

According to the results found in this study, the MARA appliance and the AcHg combination associated with a fixed appliance were effective in the correction of Class II malocclusion. These devices promoted (i) significant improvements in the relationship of the apical bases, with a restriction in maxillary development and non-statistically significant mandibular growth; (ii) improvements in the dentoalveolar relationship, with reduction of overjet and overbite; as well as (iii) improvements in the molar relationship.

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APPENDIX

APPENDIX – Declaration of exclusive use of the article in Dissertation**DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN DISSERTATION**

We hereby declare that we are aware of the article “A COMPARATIVE STUDY OF THE MARA APPLIANCE AND THE ACTIVATOR-HEADGEAR COMBINATION IN THE TREATMENT OF CLASS II DIVISION 1 MALOCCLUSION” will be included in the Dissertation of the student Deborah Brindeiro de Araújo Brito and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, 05 de dezembro de 2016.

Deborah Brindeiro de Araújo Brito
Nome do autor

Assinatura

José Fernando Castanha Henriques
Nome do autor

Assinatura

ANNEX

ANNEX A – Ethics Committee approval, protocol number 43929215.6.0000.5417

FACULDADE DE
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PARECER CONSUBSTANCIADO DO CEP**DADOS DO PROJETO DE PESQUISA**

Título da Pesquisa: Estudo comparativo das alterações do tratamento da má oclusão de Classe II, 1ª divisão com os aparelhos Mandibular Anterior Repositioning Appliance e Ativador combinado à ancoragem extrabucal, seguidos do aparelho fixo

Pesquisador: Deborah Brindeiro de Araújo Brito

Área Temática:

Versão: 1

CAAE: 43929215.6.0000.5417

Instituição Proponente: Universidade de São Paulo

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.051.497

Data da Relatoria: 29/04/2015

Apresentação do Projeto:

O projeto de pesquisa "Estudo comparativo das alterações do tratamento da má oclusão de Classe II, 1ª divisão com os aparelhos Mandibular Anterior Repositioning Appliance e Ativador combinado à ancoragem extrabucal, seguidos do aparelho fixo" apresenta como pesquisador responsável a pós-graduanda Deborah Brindeiro de Araújo Brito e como integrante da pesquisa o Prof. Dr. José Fernando Castanha Henriques (orientador). Seu desenho consiste em comparar os efeitos promovidos pelos aparelhos Mandibular Anterior Repositioning Appliance (MARA) e Ativador associado à Ancoragem Extrabucal (AEB), seguidos do aparelho fixo, no tratamento da má oclusão de Classe II, 1ª divisão. A amostra retrospectiva será constituída de pacientes, divididos em três grupos: Grupo MARA composto por 18 pacientes com idade inicial média de 11,96 anos, tratados com o aparelho MARA associado ao aparelho fixo; Grupo ATIVADOR, composto por 22 pacientes com idade inicial média de 11,07 anos, tratados com o aparelho Ativador associado à AEB, seguidos do aparelho fixo; e Grupo Controle com 20 indivíduos com idade média de 12,54 anos e observado por um período médio de 2,19 anos, sem nenhum tratamento. Para tanto, serão realizadas mensurações através de análise cefalométrica de telerradiografias iniciais e finais, bem como de modelos de estudo iniciais e finais.

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Continuação do Parecer: 1.051.497

Objetivo da Pesquisa:**Objetivo Primário:**

Este trabalho tem como objetivo comparar por meio de telerradiografias em norma lateral e de modelos de estudo, as alterações dentoalveolares e esqueléticas promovidas no tratamento de pacientes com má oclusão de Classe II, 1ª divisão, tratados na clínica de pós-graduação da disciplina de Ortodontia da Faculdade de Odontologia de Bauru, por meio dos aparelhos MARA e Ativador associado ao AEB, seguidos do aparelho ortodôntico fixo.

Objetivo Secundário:

Verificar a confiabilidade dos métodos de análise que estão sendo testados.

Avaliação dos Riscos e Benefícios:

O pesquisador informa que:

Riscos:

Como se trata de um estudo a partir da análise de uma documentação já existente, o presente estudo não apresenta riscos.

Benefícios:

Oferecer novas alternativas de tratamento para os pacientes portadores de má-oclusão Classe II, 1ª divisão, que ofereçam menor tempo de tratamento, que seja mais confortável para o paciente.

Comentários e Considerações sobre a Pesquisa:

A pesquisa não apresenta comprometimento ético. A metodologia está detalhada e exequível. Propõe dispensa de TCLE pois justifica-se pelo fato da amostra ser retrospectiva. Os prontuários estão sob os cuidados da disciplina de Ortodontia do Departamento de Odontopediatria, Ortodontia e Saúde Coletiva. Estes prontuários são do acervo desde 1973, constituindo uma dificuldade o contato com os pacientes devido ao tempo decorrido desde o tratamento feito até a data presente. Vale ressaltar que os pacientes, quando atendidos da clínica de Ortodontia, assinam a "AUTORIZAÇÃO PARA DIAGNÓSTICO E/OU EXECUÇÃO DE TRATAMENTO ORTODÔNTICO" (modelo anexo) a qual aprova tanto a execução do tratamento quanto seu uso para "quaisquer fins de ensino e de divulgação em jornais e/ou revistas científicas do país e do exterior", desta forma aprova-se também o uso dos dados do seu prontuário para o ensino em pesquisas científicas. A dispensa do termo de Assentimento se deve ao fato de os pacientes da amostra, no momento da execução do exame, serem tanto menor de 18 anos quanto adultos, não sendo diferenciado para a pesquisa, como critério de inclusão ou exclusão. Tais pacientes também foram autorizados pelo responsável no documento "AUTORIZAÇÃO PARA DIAGNÓSTICO E/OU EXECUÇÃO DE TRATAMENTO ORTODÔNTICO". Os nomes e dados pessoais dos pacientes não serão divulgados em nenhum

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Continuação do Parecer: 1.051.497

momento, mantendo desta forma o sigilo profissional (Artigo 9º do Código de Ética Odontológico) e a privacidade dos participantes da pesquisa durante todas as fases e assumimos o compromisso de cumprir as exigências contidas na Resolução CNS Nº 466, de 12.12.12.

Considerações sobre os Termos de apresentação obrigatória:

Foram apresentados os termos: Projeto detalhado, autorização do uso do acervo, dispensa de TCLE, folha de rosto e ciência do Departamento.

Recomendações:

Não há recomendações.

Conclusões ou Pendências e Lista de Inadequações:

Não há pendências. Sugiro aprovação.

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 29.4.2015, 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.

BAURU, 06 de Maio de 2015

Assinado por:
Izabel Regina Fischer Rubira Bullen
(Coordenador)

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ANNEX B – Ethics Committee approval with amendment, protocol number 43929215.6.0000.5417

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PARECER CONSUBSTANCIADO DO CEP

DADOS DA EMENDA

Título da Pesquisa: Estudo comparativo das alterações do tratamento da má oclusão de Classe II, 1ª divisão com os aparelhos Mandibular Anterior Repositioning Appliance e Ativador combinado à ancoragem extrabucal, seguidos do aparelho fixo

Pesquisador: Deborah Brindeiro de Araújo Brito

Área Temática:

Versão: 2

CAAE: 43929215.6.0000.5417

Instituição Proponente: Universidade de São Paulo

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.632.980

Apresentação do Projeto:

Idem ao parecer substanciado nº 1.051.497, emitido em 06/05/2015.

Objetivo da Pesquisa:

Idem ao parecer substanciado nº 1.051.497, emitido em 06/05/2015.

Avaliação dos Riscos e Benefícios:

Idem ao parecer substanciado nº 1.051.497, emitido em 06/05/2015.

Comentários e Considerações sobre a Pesquisa:

Idem ao parecer substanciado nº 1.051.497, emitido em 06/05/2015.

Considerações sobre os Termos de apresentação obrigatória:

Adequados.

Conclusões ou Pendências e Lista de Inadequações:

A pesquisadora responsável encaminha Emenda solicitando a alteração na seleção do Grupo Controle; anteriormente seria selecionada a partir da amostra do Centro de Estudo do Crescimento da Faculdade de Odontologia de Bauru (Universidade de São Paulo), e agora será obtida amostra do "Burlington Growth Centre" (Departamento de Ortodontia da Universidade de Toronto -

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Continuação do Parecer: 1.632.980

Canadá). Para isso anexou dois documentos: 1) BGC_RULES_APPLICATION.pdf e 2) BGC_RULES_APPLICATION_2014_Traduzido.pdf

A pesquisadora se compromete anexar referido documento, após a assinatura daquele Centro.

Não havendo impedimentos éticos, sou de parecer favorável.

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 15.06.2016, 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
Declaração do Patrocinador	BGC_RULES_APPLICATION_2014_Traduzido.pdf	20/06/2016 08:18:28	Izabel Regina Fischer Rubira Bullen	Aceito
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_738171E1.pdf	13/06/2016 23:26:54		Aceito
Outros	BGC_RULES_APPLICATION.pdf	13/06/2016 23:09:53	Deborah Brindeiro de Araújo Brito	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_CEP_Emenda.pdf	13/06/2016 23:08:56	Deborah Brindeiro de Araújo Brito	Aceito
Outros	Dispensa do Termo de Consentimento.pdf	09/04/2015 21:21:05		Aceito
Outros	Encaminhamento departamento.pdf	09/04/2015 21:18:43		Aceito
Projeto Detalhado / Brochura Investigador	Projeto CEP Final.pdf	09/04/2015 21:17:55		Aceito
Declaração de Instituição e Infraestrutura	Uso do arquivo.pdf	09/04/2015 21:09:04		Aceito

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Continuação do Parecer: 1.632.980

Folha de Rosto	FOLHA DE ROSTO.pdf	09/04/2015 21:03:33		Aceito
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Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

BAURU, 24 de Junho de 2016

Assinado por:**Izabel Regina Fischer Rubira Bullen**
(Coordenador)

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