UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

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Class II malocclusion treatment with Twin Block and Mandibular Anterior Repositioning Appliance: a comparative study of dentoskeletal changes

Estudo comparativo das alterações dento-esqueléticas entre os aparelhos Twin Block e Mandibular Anterior Repositioning Appliance no tratamento da má oclusão de Classe II

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Dissertação constituída por artigo apresentada à 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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ABSTRACT

ABSTRACT

Twin Block and MARA appliances effects in Class II malocclusion correction

Background: The aim of this study was to compare the cephalometric changes in patients Class II division 1treated with Twin Block and MARA appliances. **Material and Methods:** The sample comprised 66 patients with Class II malocclusion divided into 3 groups: The Twin Block group consisted of 21 patients, the MARA group of 21 patients and the control group of 24 untreated subjects. Intergroup comparisons were performed at pre- (T1) and posttreatment (T2) stages. The initial and posttreatment measures concerning changes in angular and linear variables were compared using the analysis of variance (ANOVA) and Kruskal-Wallis tests. **Results:** Both appliances showed improvement of the relation Class II. MARA resulted in a significant increase in FMA and the occlusal plane, 1º more than control. Twin Block revealed significantly greater increase in LAFH than the others. MARA produced a significantly greater amount of labial tipping and protrusion of the mandibular incisors than the others groups. TB showed significant extrusion of the mandibular incisors compared to MARA and extrusion of the mandibular molars in relation to the control. Both treated groups showed improvement in the overjet, overbite and molar relationship. The treatment time for MARA almost was 1 year less than TB. **Conclusion:** The appliances were effective in the treatment of Class II malocclusion; however, the correction was mainly due to dentoalveolar effects.

Keywords: Twin Block; MARA; Functional Appliance; Class II malocclusion.

RESUMO

RESUMO

Os efeitos dos aparelhos Twin Block e MARA na correção da má oclusão de Classe II.

Proposição: O objetivo deste estudo foi comparar as alterações cefalométricas em pacientes Classe II divisão 1 tratados com os aparelhos Twin Block e MARA. **Material e Métodos**: A amostra foi composta por 66 pacientes com má oclusão de Classe II divididos em 3 grupos: o grupo Twin Block composto por 21 pacientes, o grupo MARA constituído por 21 e o grupo controle com 24 indivíduos não tratados. Comparações intergrupos foram realizadas nos estágios pré (T1) e pós- tratamento (T2). As medidas iniciais e pós-tratamento referentes as alterações nas variáveis angulares e lineares foram comparadas pelos seguintes testes: análise de variância (ANOVA) e Kruskal-Wallis. **Resultados**: Ambos os aparelhos apresentaram melhora na relação de Classe II. O MARA resultou em um aumento significante do FMA e do plano oclusal em relação ao controle. O Twin Block revelou um aumento significantemente maior na AFAI em relação aos outros grupos. O MARA produziu um aumento significantemente maior na inclinação vestibular e protrusão dos incisivos inferiores em relação aos outros grupos. O Twin Block promoveu significativa extrusão dos incisivos inferiores em relação ao MARA e significativa extrusão dos molares inferiores em relação ao controle. Ambos os grupos experimentais resultaram em melhora no trespasse horizontal, vertical e relação molar. O tempo de tratamento do MARA foi próximo de 1 ano a menos em relação ao Twin Block. **Conclusão**: Os aparelhos foram eficazes no tratamento da má oclusão de Classe II, porém a correção ocorreu em sua maior parte por efeitos dentoalveolares.

Palavras-chave: Twin Block; MARA; Aparelho Funcional; Má oclusão de Classe II.

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1 INTRODUCTION

1 INTRODUCTION

Class II malocclusion is characterized by a deficient relationship between the bone bases of the upper and lower arches. The changes observe int the anteroposterior direction is concentrated in skeletal and / or dentoalveolar structures of the maxilla and the mandible. These alterations caused by Class II malocclusion cause functional problems and alterations of soft tissue, influencing in the patient's facial esthetics.(BISHARA et al., 1995; BACCETTI et al., 1997)

This malocclusion may be related to a protrusion of the maxilla, a protrusion of the maxillary teeth, a retrusion of the mandible and / or mandibular teeth or a combination of these factors.(FUZIY et al., 2006)

Thus, there is an extensive search for the correction of this type of malocclusion.(ALMEIDA; ALMEIDA; BAJO INSABRALDE, 1999; DA SILVA FILHO et al., 2000; MIRANDA et al., 2016)

In orthodontics, there is an intense search about which would be the most effective treatment for Class II malocclusion seeking to relate variables such as age and / or gender. Actually, it is known that when the treatment of Class II malocclusion is performed during the growth phase the approach becomes more conservative, with excellent results and very low rate of relapse.(MCNAMARA JR, 1981)

An important ally of the orthodontist in the treatment of Class II malocclusion are functional appliances that can be mobile or fixed. The main objective of this type of appliance is to establish a more anterior position of the mandible, thus redirecting mandibular growth.(OLTRAMARI et al., 2007)

Within the many options available, o Twin Block (TB) is a consecrated mobile functional appliance. Due to its great efficiency in stimulating mandibular growth, it has been widely used in the last decades.(EHSANI et al., 2015)

Numerous authors have already discussed its efficiency in mandibular changes, overjet and Class II correction in European, American and Brazilian samples, since it is known that the same appliance used in different populations can lead to different

results, legitimizing their capacity of treatment.(JAMILIAN; SHOWKATBAKHSH; AMIRI, 2010)

In contrast, the fixed functional appliance MARA (Mandibular Anterior Repositioning Appliance) is considered a newer device, since it was in the years 2000 that Allen Noble (2002) and Eckhart White (2003) presented the model initially created by the German Dr. Douglas Tool in its improved form.(ECKHART; WHITE, 2003; FERGUS, 2008)

The mechanics of this appliance consists in not allowing the mandible to close in a more retruded position, this is possible because both upper and lower parts of the appliance come into contact and do not allow closure to occur in the usual occlusion. However, the design of the appliance enables movements to anterior of the mandible.

This study aims to evaluate how patients with Class II malocclusion treated with the mobile functional appliance TB and with the fixed functional appliance MARA behave, if there is a difference in the mandibular growth response and what the result is produced by each one.

2 ARTICLE

2 ARTICLE

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

Twin Block and MARA appliances effects in Class II malocclusion correction

Abstract

Background: To compare through cephalometric measures, the skeletal and dentoalveolar changes produced by functional appliances: Twin Block (TB) and MARA. **Material and Methods:** The sample comprised 66 patients with Class II malocclusion divided into three groups: The Twin Block group consisted of 21 patients, the MARA group consisted of 21 patients and the control group, comprised of 24 untreated subjects. Intergroup comparisons were performed at pre- (T1) and posttreatment (T2) stages. The initial and posttreatment measures concerning changes in angular and linear variables were compared using the analysis of variance (ANOVA) and Kruskal-Wallis tests. **Results:** Both appliances showed improvement of the relation Class II. MARA resulted in a significant increase in FMA and the occlusal plane, 1º more than control. Twin Block revealed significantly greater increase in LAFH than the others. MARA produced a significantly greater amount of labial tipping and protrusion of the mandibular incisors than the others groups. Twin Block showed significant extrusion of the mandibular incisors compared to MARA and extrusion of the mandibular molars in relation to the control. Both treated groups showed improvement in the overjet, overbite and molar relationship. The treatment time for MARA almost was 1 year less than Twin Block. **Conclusion:** Both appliances were effective to correct Class II malocclusion, mostly by means of dentoalveolar changes.

Keywords: Twin Block; MARA; Functional Appliances; Class II malocclusion.

Introduction

In the literature an extensive search has been observed to determine the most effective way to treat Class II malocclusion.[1,2]

Class II malocclusion refers to an anteroposterior discrepancy, characterized by an alveolar component, skeletal or combination of both, with mandibular retrusion being the predominant etiological factor.[3]

This malocclusion does not self-correct and its treatment is extremely necessary, both for functional reasons and for esthetic reasons. In view of this, the patients quest to treat this malocclusion is great.[4-6]

In orthodontics, there is an intense research about what would be the best treatment, observing variables such as age and gender. What is really know about the treatment of Class II malocclusion is that during the growth stage the approach is more conservative with excellent results and low recurrence rates. [7]

A great ally of the orthodontist in the treatment of Class II malocclusion during the growth stage are the functional orthodontic appliances. There are many functional appliances and their mechanisms of action are not very different. The main objective is to redefine a new posture of the mandible, a more anterior posture, giving a new direction to its growth.[8]

In view of so many functional appliances options, there is Twin Block. Its efficiency in the correction of Class II malocclusion is established in the literature.[9]

Several authors have already discussed its efficiency in mandibular changes, overjet, overbite and Class II correction in European, American and Brazilian samples. Because it is know that the same appliance used in different populations may bring different results.[10]

On the other hand, the Mandibular Anterior Repositioning Appliance (MARA) is considered a newer appliance, since it was in the years 2000 that Allen Noble (2002) and Eckhart; White (2003) presented the model initially created by German Dr. Douglas tool in its improved version.[11,12]

The mechanics of this appliance consists in not allowing the mandible to close in a posterior position, this is possible because both upper and lower parts of the appliance come into contact and does not allow the mandible to close in the usual occlusion. The design of the appliance allows more anterior movements of the mandible.

The aim of this research was to evaluate the effects of Twin Block and MARA appliances on the correction of Class II malocclusion, division1.Therefore, cephalometric measurements of patients treated with Twin Block and MARA were used at the initial and final stages of treatment.

Material and Methods

This retrospective study was approved by the Ethics in Research Committee of Bauru Dental School, University of São Paulo, Brazil (Protocol number 71651417.3.0000.5417; decision number: 2.332.806) and all parents or legal guardians provide informed consent.

Sample size calculation was performed based on an alpha significance level of 5% and a beta of 20% to reach a test power of 80%, to detect an intergroup difference of 2.7 mm with previously reported standard deviation of 2.43mm for the mandibular skeletal component Co-Gn. Thus, is necessary that each group has at least 18 subjects.[13]

Sample characteristics

The Twin Block group consisted of 21 subjects (08 female; 13 male) with initial and final mean ages of 10.59 years (SD, 0.94) and 12.69 years (SD,1.08) respectively. Treated for an average period of 2.10 years. This group was treated at the Department of Orthodontics, Bauru Dental School, University of São Paulo, Brazil. The MARA group included 21 subjects (06 female; 15 male) with initial and final ages of 11.98 years (SD, 1.19) and 13.15 years (SD, 1.23) respectively. The mean treatment time of the MARA appliance was 1.16 year. This group was derived from Department of Orthodontics, Bauru Dental School, University of São Paulo, Brazil.

The inclusion criteria used for the selection of patients in the sample was: with at least bilateral ¼ Class II molar relationship[14]; mandibular retrusion; presence of all permanent teeth up to the first molar; mandibular arches with slight or no crowding; moderate or severe overjet; no previous orthodontic treatment;

The control group consisted of 24 subjects (12 female; 12 male) with untreated Class II malocclusion. The records were obtained from Longitudinal Growth Study Center at Bauru Dental School, University of São Paulo, Brazil. The initial and final mean ages were 10.75 years (SD, 0.74) and 13.13 years (SD, 1.50) respectively. The mean time of analysis was 2.38 years (SD, 1.14) years.

The appliances were removed after the molar relation obtained a normal position.

Cephalometric Analysis

Initial (T1) and final (T2) lateral cephalograms of each patient were obtained in centric occlusion, with the lips at rest. Then, they were digitally and traced using Dolphin Imaging Software (Version 11.5, Dolphin® Imaging and Management Solutions, Patterson Dental Supply, Inc., Chatsworth, California, USA). A total of 29 cephalometric variables were used in this study. Bilateral structures of interest were averaged.[15]

Error Study

Thirty lateral cephalograms were randomly selected and retraced by the same operator (C.B.) after a 4-week interval. Random and systematic errors were calculated according to Dahlberg's formula and with dependent t tests, respectively; at $P<0.05$.[16,17]

Statistical Analysis

The chi-square test was used to compare the initial severity of malocclusion and sex distribution.

To verify the normal distribution and the equality of the variables was used the Kolmgorov-Smirnov test. For the variables that did not present normal distribution the Kruskal-Wallis test was used.

Group comparisons regarding initial and final ages, cephalometric status at pretreatment stage and the treatment/observation changes were compared with one-way analysis of variance (Anova) followed by Tukey tests.

All statistical analyses were done with Statistica software (Statistica for Windows, version 6.0, Statsoft, Tulsa, Okla), and the results were considered significant at $P< 0.05$.

Results

The random errors ranged from 0.37mm (Md1-NB) to 3.77mm (CoGn) and 0.79º (ANB) to 8.03º (ANL). These errors were considered within clinical acceptable limits. Four variables (Mx1.NA, Mx6-PP, molar relation, UL-E plane) presented significant systematic errors.

The groups were comparable regarding sex distribution, Class II malocclusion severity distribution, initial and final ages and treatment times (Table II).

At pretreatment, the Twin Block group presented significantly greater maxillary and mandibular effective length than the MARA group and significantly greater Class II relation than the control group (Table III). Furthermore, the MARA group showed significantly smaller FMA and significantly greater posterior facial height (S-Go) than the Twin Block group. The Twin Block group revealed significantly smaller vertical development of the maxillary molars than the MARA group. Besides that, the Twin Block group presented significantly greater labial tipping of the mandibular incisor than the others groups and significantly greater protrusion of the mandibular incisors than the control group. The control group showed significantly smaller vertical development of the mandibular incisors than the MARA group. The MARA group presented significantly greater overjet than the other groups and greater molar relationship discrepancy than the control group.

The treated groups showed significantly decrease in the Class II relation and maxillomandibular sagittal discrepancy while it increased in the control group (Table IV). The group MARA showed significantly increase in the FMA and occlusal plane while it decreases in the control group. The Twin Block group showed significantly greater increase in lower anterior facial height when compared to the other 2 groups. The MARA group presented significantly greater increase in the labial tipping and protrusion of the mandibular incisors than the others groups. The Twin Block group showed significantly greater increase in the extrusion of the mandibular incisors when compared the MARA group and significantly greater increase in the extrusion of the mandibular molars than the control group. The MARA group showed significantly greater decrease in the overjet and overbite than the Twin Block group, while it increases in the control group and significantly greater decrease in the molar relationship when compared the others groups.

Discussion

Many studies have already evaluated functional appliances and their effects, with many results still controversial. The Twin Block is an appliance established in the literature and MARA is a relatively new. The main difference between them is that one is mobile and the other is fixed. Therefore, this study has a main objective to compare the skeletal, dentoalveolar and soft tissue changes promoted by these appliances in Class II treatment.

Sample Characteristics

With the aim of detecting the changes promoted by the appliances of normal growth changes, the control group was added to the research. Because it is a retrospective study, the addition of a control group increases the quality of the research.

The three sample groups were equal in terms of sex distribution, Class II malocclusion severity and final ages (Table II). Regarding the initial ages, the MARA group presented the statistically greater mean in relation to the other groups, this occurred because the MARA is a fixed functional appliance and its treatment is recommended to be performed in the young permanent dentition during the peak of pubertal growth.[18]

On the other hand, the Twin-Block is a removable functional appliance and for its treatment to be effective the recommended initial age is during or just before the beginning of the pubertal peak.[19,20]

Regarding the time of treatment, the MARA group presented a significantly smaller time than the other groups (Table II). However, this did not interfere in any way in the research since the objective is to compare the effects of two different types of treatment protocols for Class II, being a treatment with the removable functional appliance (Twin Block) and another treatment with the fixed functional appliance (MARA).

One may criticize that due to the amount of variables compared between the groups, Bonferroni corrections (29) should have been used. However, this procedure would decrease the probability of detecting slight significant differences, which are very important in this comparison.[21]

Comparison of dentoskeletal and soft-tissue profile changes:

Maxillary component:

At pretreatment, the MARA group demonstrated a significantly greater maxillary effective length (CoA) than the Twin Block group (Table III). This difference between the groups was already expected, since the MARA patients were older than the Twin Block. Therefore, it is natural that due to the growth, the maxillary effective length was greater in MARA group.[22]

After the treatment, the appliances did not produce significant effects on the maxillary skeletal component (Table IV).

The effect of Twin Block on the maxillary skeletal component is controversial in the literature and the fact that it was not significant corroborates with other studies that evaluated its performance in the maxilla.[9,20,23-25]

However, other studies have shown that treatment with Twin Block may result in restriction of maxillary development.[19,26,27]

The fact that MARA also did not present a statistically significant effect on the maxilla was already reported another study.[28]

In the literature is suggested that in order to obtain the restrictive effect on maxillary development, MARA should be installed in the pre-peak growth stage.[18]

Mandibular component:

At pretreatment the MARA group showed a significantly greater mandibular effective length (Co-Gn) than the Twin Block group (Tabela III). As already reported above, the MARA group consisted of patients older than Twin Block group. As a result of the MARA having a longer growing time compared to Twin Block, the mandibular effective length was statistically greater in this group.[22]

At posttreatment, the Twin Block group presented the greatest increase in mandibular effective length (Co-Gn) when compared to the other groups, although this increase was not significant (Table IV). Since the treatment times between the two appliances are different, it is natural it has been treated for a longer period (2.10 years on average), presented a greater mandibular growth than the MARA group that received the treatment for less time (1.16 years on average). There was more time to grow in the Twin Block group when compared to MARA group.

Some authors state that treatment with Twin Block promotes mandibular growth.[9,19,26,29,30]

Other authors state that patients treated with MARA during the growth spurt in the permanent dentition have a significant increase in mandibular length in relation to a control group.[18,28]

However, the fact that this research has showed that the changes int the treated groups were not significant relation to the control group, agree with recent studies. A systematic review with a meta-analysis has showed that functional removable appliances are effective in treating Class II by promoting dentoalveoalr rather than skeletal changes.[31]

Another systematic review demonstrated that the MARA appliance produced statistically significant changes in the mandibular dimensions, however, these alterations are not clinically significant, or simply did not produce significant changes in mandibular growth.[32-34]

Maxillomandibular relationship:

In pretreatment, the Twin Block group showed a significantly greater Class II relation to the control group (Table III).

In both treated groups there was a significant improvement in the discrepancy between the bone bases in relation to the control group (Table IV). It is probably that the restriction in maxillary development associated with increased mandibular length (even without being statistically significant) contributed to the decrease in Class II relation. This is mechanism of functional appliances to treat Class II malocclusion. Other authors have already reported this change.[12,35,36]

Vertical component:

Before the treatment, the Twin Block group presented significantly greater mandibular plane angle (FMA) than the MARA group (Table III). The Twin Block group also had significantly smaller posterior facial height (S-Go) when compared to MARA, since the Twin Block group consisted of significantly younger patients in relation to MARA.[22]

Three variables (FMA, OP.SN and LAFH) that evaluated the vertical component presented statistically significant differences (Table IV). The growth pattern (FMA) and the inclination of the occlusal plane (OP.SN) showed a significant increase in the experimental groups while those same variables decreased in the control group. These changes are more probable to be related to the dentoalveolar effects produced by the

devices, and there is no relationship with changes in the patients' craniofacial growth pattern. Some studies evaluating Twin Block also found the same effect.[25,37]

Another study evaluating MARA also reported similar results in relation to inclination of the occlusal plane.[33]

Though, other studies did not find significant changes in the angle of the mandibular plane and in the facial growth pattern.[38,39]

All groups showed an increase in lower facial height (LAFH), however this increase was statistically greater in the Twin Block group in relation to the other groups (Table IV). Possibly this increase was significant in the Twin Block group as a consequence of the greater extrusion of the mandibular molars that occurred in this group.

The increase in lower anterior facial height in patients treated with Twin Block is a consistent finding in the literature.[26,30,39,40]

Although, this same author states that increase in lower anterior facial heigth has no clinical relevance for the patient. Another study states that it did not find significant vertical changes with Twin Block treatment.[9]

Maxillary dentoalveolar component:

At the beginning of treatment, the MARA group demonstrated significantly greater vertical development of the maxillary molars than the Twin Block group (Table III). Because it was a group with an initial age older than Twin Block group, the MARA had a longer time to erupt the maxillary molars.[22]

After the conclusion of the treatments, no statistically significant changes were found in relation to the superior dentoalveolar component (Table IV). However, the treatment groups presented a palatal tipping of the maxillary incisors while in the control group there was a labial tipping. The fact that the maxillary incisors were retruded in the treated groups is related to the effect that the functional appliances exert on the maxilla. This palatal tipping effect of the incisors has been reported in another study that evaluated Twin Block, yet it was not statistically significant either.[25]

Other studies evaluating MARA performance also found no significant dentoalveolar changes in the maxilla.[9,18,20,33]

This finding contradicts other articles that affirm that the effect to Twin Block and MARA on the maxillary incisors is statistically significant.[24,25,28,34]

Mandibular dentoalveolar component:

In pretreatment, the Twin Block group had significantly greater labial tipping (Md1.PP) of the mandibular incisors than the others groups and significantly greater protrusion (Md1-PP) than the control group (Table III). Also, the MARA group had significantly greater vertical development of the mandibular incisors than the control group.

In posttreatment, all the variables used to measure the mandibular dentoalveolar component presented statistically significant differences (Table IV).

To evaluate the inclination and protrusion of the mandibular incisors, the variables used were Md1.NB, Md1-NB respectively. The greater significant increase in labial tipping occurred in the MARA group in relation to the other groups probably occurred because fixed functional appliance exerted forces of mesialization and intrusion in the mandibular incisors. This result as already been reported in other studies that evaluated the effects of MARA.[28,34,41]

As Opposite, another study found that the treatment with MARA during the growth spurt did not induce the proclination of the mandibular incisors.

This same study says dentoalveolar effects are greatest when MARA is installed after peak growth.[18]

Regarding the MARA to have presented a restriction in the vertical development of the mandibular incisors in relation to the Twin Block and control groups was an already expected finding (Table IV). As described above this is an expected effect to the fixed functional appliances. Other researches corroborate this finding.[18,41]

With respect to Twin Block showed a vertical development of the mandibular molars statistically greater than the control (Table IV). Possibly this occurred because the acrylic of the mandibular molars was wear performed so that the eruption was possible. This effect is beneficial in the correction of Class II malocclusion, since the functional appliances exert forces forward and downward in the anteroinferior region, as consequence of the increase of the vertical development and mesialization of the mandibular molar, besides helping in the leveling of the curve of Spee.[42,43]

The increase in the vertical development of the mandibular molars has already been described in other occasions in the literature.[20,24]

Dental relationship:

In the pretreatment, the fact that MARA showed a significantly greater overjet compared to the other groups and a significantly greater Class II molar relationship than the control may be associated with the fact that MARA group is composed of older patients compared to the other groups (Table III). Therefore, there was a greater growth of this group.[22]

In the posttreatment, the MARA group showed a significantly greater decrease in the overjet when compared the Twin Block group, while this variable showed a significant increase in the control group (Table IV). The MARA group also presented a significant correction of the overbite and Class II molar relationship than the other groups. The fact that the improvement in the correction of the overjet and overbite in the MARA group was significantly greater in relation to the Twin Block group could be associated with the greater dentoalveolar effect in the mandibular incisors produced by MARA. Another issue that may have contributed to the overbite correction being significantly greater in the MARA than in the Twin Block was the significant restriction in the vertical development that occurred in the mandibular incisors associated with the extrusion of the mandibular molars of this group.

There was a significant correction in the Class II molar relationship in the three groups, though, this correction was statistically greater in the MARA group in relation the other groups (Table IV). The Twin Block also presented a greater improvement in the Class II molar relation than the control, nevertheless was not significant. Correction of the Class II molar relation in the treated groups is related to a combination of dentoalveolar and skeletal effects, since even though it was not significant, there was a restriction in the development of the maxilla and there was a mandibular growth. In addition, dental effects such as the great labial tipping and protrusion of the mandibular incisors probably contributed to this correction. Other studies have already observed this improvement in dental relationships with Twin Block and MARA appliances.[9,18,20,25,28,30,33,34]

Soft tissue:

There were no statistically significant changes in soft tissue (Table IV). Although, it was observed that the treated groups showed a greater retrusion of the upper lips in relation to the control. This finding may be related to the restrictive effect that functional appliances exert on the maxillary component.[20,44-46]

Another alteration observed was that the mandibular lips presented a mild protrusion in the treated groups while the control presented retrusion. This finding is probably related (even without being significant) to the skeletal effects promoted by the appliances. This result corroborates with another study.[13]

Conclusions

- The Twin Block and MARA appliances demonstrated satisfactory results in the correction of Class II, division 1 malocclusion, nevertheless the main effect produced by the appliances was dentoalveolar.
- The MARA produced dentoalveolar effects in greater amount on the mandibular incisors, such as labial tipping and protrusion when compared the other groups.
- The Twin Block produced significantly greater extrusion of the mandibular incisors than the MARA and significantly greater extrusion of the mandibular molars in relation to the control.
- Both appliances promoted significant benefits in dental relationships (overjet, overbite and molar relation).

Acknowledgment

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Figure Legends

Fig. 1 – Photographs of installed appliances: A) Twin Block appliance in front view. B) Twin Block appliance in lateral view. C) MARA appliance in frontal view. D) MARA appliance in lateral view.

Fig. 2 – Cephalometric measures. A) Cephalometric Variables. B) Reference lines and planes horizontal. C) Reference lines and planes vertical.

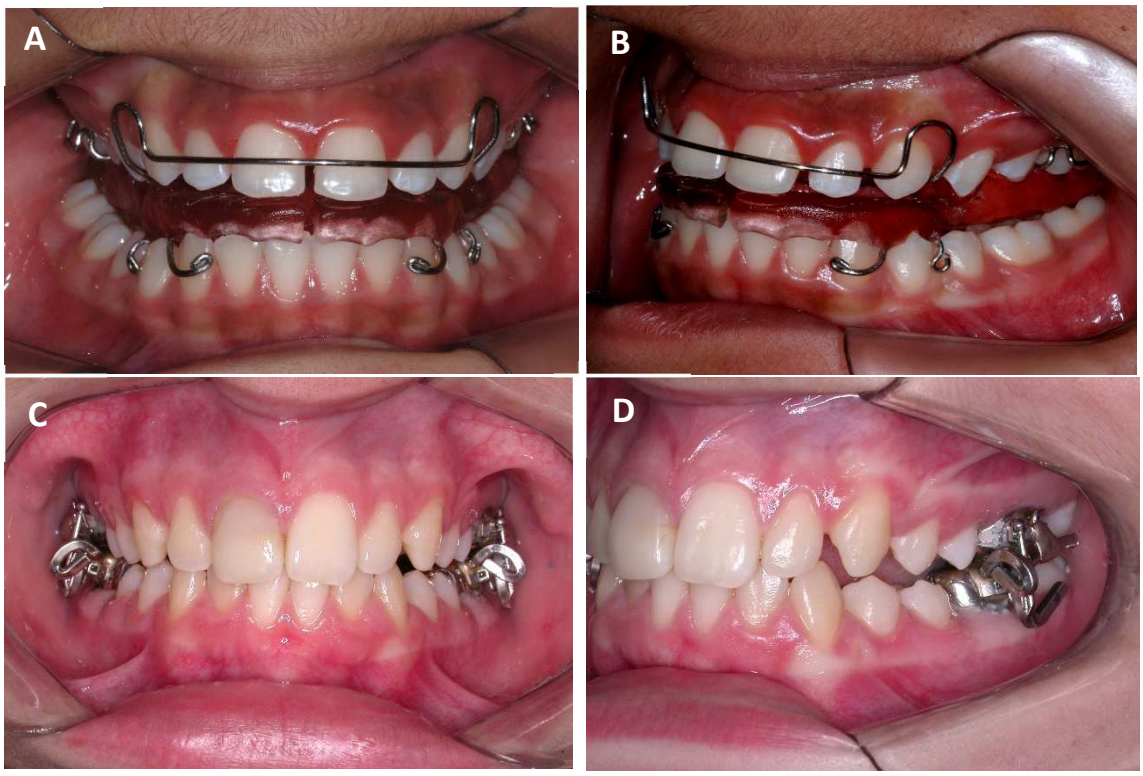

Fig.1

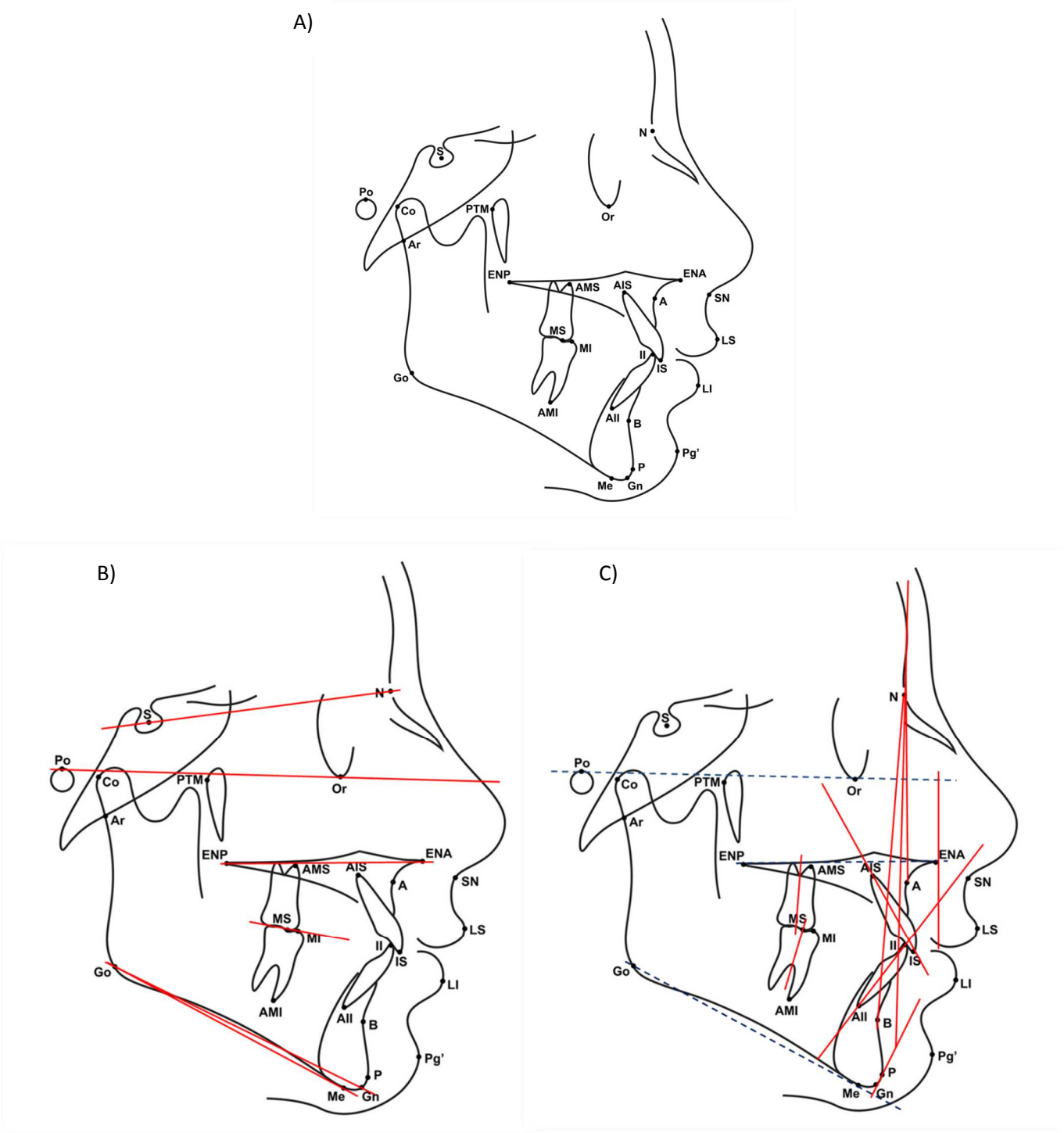
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Fig.2

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	
SN.GoGn (°)	SN to GoGn angle
OP.SN (°)	SN to occlusal plane angle
LAFH (mm)	Distance between ANS point and Me point.
S-Go (mm)	Sella turcica to gonion distance
Maxillary dentoalveolar component	
Mx1.NA (°)	Maxillary incisor long axis to NA angle
Mx1-NA (mm)	Distance between most anterior point of crown of maxillary incisor and NA line
Mx1.PP (°)	Maxillary incisor long axis to palatal plane angle
Mx1-PP (mm)	Distance between maxillary incisal edge and palatal plane
Mx6-PP (mm)	Mean perpendicular distance between mesial and distal cusp of maxillary first molar and palatal plane
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
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 comparison of sex and occlusal Class II malocclusion severity distribution, initial and final ages and treatment times

Variable	Group 1,TB (n= 21)		Group 2, MARA (n= 21)		Group 3, Control (n= 24)		P
Sex							
Male	13		15		12		0.333€
Female	8		6		12		
Occlusal malocclusion							
¼ cusp Class II			2		5		
½ cusp Class II	8		5		11		
¾ cusp Class II	6		7		4		0.975€
Full cusp Class II	7		7		4		
	Mean	SD	Mean	SD	Mean	SD	
Initial age	10.59A	0.94	11.98B	1.19	10.75A	0.74	0.000†*
Final age	12.69	1.08	13.15	1.23	13.13	1.50	0.427†
Treatment time	2.10A	0.37	1.16B	0.20	2.38A	1.14	0.000†*

Capital letters indicate statistically significant differences ($P < 0.05$).
€Chi-Square tests.
†One-way Analysis of Variance tests.

Table III. Pretreatment intergroup cephalometric comparison (ANOVA, followed by Tukey tests)

	Group 1 (TB)		Group 2 (MARA)		Group 3 (Control)		P
	Mean	**S.D.**	**Mean**	**S.D.**	**Mean**	**S.D.**	
Maxillary skeletal components							
SNA (º)	82.84	4.19	81.91	4.30	81.67	3.54	0.599†
A-Nperp (mm)	1.95	2.87	1.74	3.15	1.58	2.68	0.808‡
Co-A (mm)	75.83^{A}	6.76	80.17^{B}	3.80	79.34^{AB}	4.57	0.019*†
Mandibular skeletal components							
SNB (º)	76.70	3.05	76.95	4.27	77.28	3.92	0.876†
Pg-Nperp	-5.29	5.22	-3.54	6.14	-2.77	4.84	0.292†
Co-Gn (mm)	100.37^{A}	9.69	106.52^{B}	5.48	105.36^{AB}	5.49	0.015*†
Maxilomandibular relationship							
ANB (º)	6.13^{A}	2.04	4.96^{AB}	1.91	4.39^{B}	1.80	0.012*†
Wits (mm)	2.94	2.38	3.62	2.90	1.88	2.34	0.075†
Vertical Component							
FMA	26.32^{A}	4.65	22.26^{B}	4.83	23.34^{AB}	3.63	0.010*†
SN.GoGn (º)	33.00	3.57	29.45	5.76	30.44	4.85	0.054†
OP.SN (º)	16.91	3,03	14.46	5.76	16.44	4.22	0.175†
LAFH (mm)	58.97	7.39	60.98	3.90	59.02	4.79	0.404†
S-Go (mm)	63.80^{A}	6.03	71.01^{B}	5.53	67.08^{A}	4.43	0.000*‡
Maxillary dentoalveoar components							
Mx1.NA (º)	24.19	6.38	26.13	4.92	22.94	6.51	0.211†
Mx1-NA (mm)	4.17	2.17	5.68	2.88	3.98	3.95	0.159†
Mx1.PP (º)	112.92	7.25	114.22	4.79	112.46	6.94	0.645†
Mx1-PP (mm)	26.01	3.33	27.04	2.75	25.66	2.76	0.283†
Mx6-PP (mm)	17.89^{A}	2.52	19.72^{B}	2.16	19.31^{AB}	2.19	0.029*†
Mandibular dentoalveolar components							
Md1.NB (º)	28.73^{A}	5.05	23.95^{B}	4.10	23.58^{B}	4.55	0.000*†
Md1-NB (mm)	5.82^{A}	2.04	4.70^{AB}	1.68	3.88^{B}	1.55	0.002*†
Md1-GoMe	36.31^{AB}	4.39	37.93^{B}	1.92	35.70^{A}	2.17	0.045*‡
Md6-GoMe	25.69	3.27	27.36	2.40	26.28	2.51	0.143†
Dental Relationships							
Overjet (mm)	6.00^{A}	2.32	7.51^{B}	1.42	5.22^{A}	2.05	0.001*†
Overbite (mm)	2.91	1.74	4.09	1.84	3.02	1.55	0.052†
Molar Relationship (mm)	1.33^{AB}	1.90	2.10^{A}	1.63	0.89^{B}	1.31	0.049*†
Soft tissue profile							
Nasolabial	119.23	13.48	119.24	10.41	119.51	7.53	0.995†
UL-E plane (mm)	0.19	2.24	-0.23	2.19	-1.29	2.23	0.076†
LL-E plane (mm)	1.08	2.29	-0.24	2.56	-0.27	1.61	0.070†

Capital letters indicate statistically significant differences ($P < 0.05$).
†One-way Analysis of Variance tests.
††Kruskal-Wallis tests.

Table IV. Intergroup treatment changes comparison (ANOVA, followed by Tukey tests)

	Group 1 (TB)		Group 2 (MARA)		Group 3 (Control)		P
	Mean	**S.D.**	**Mean**	**S.D.**	**Mean**	**S.D.**	
Maxillary skeletal components							
SNA (º)	-0.64	2.91	-0.53	2.85	1.03	1.88	0.053†
A-Nperp	2.60	4.40	2.21	5.23	0.55	2.77	0.270‡
Co-A (mm)	3.08	6.45	1.85	1.70	3.64	2.92	0.349†
Mandibular skeletal components							
SNB (º)	0.80	2.08	0.64	2.36	0.99	2.03	0.877†
Pg-Nperp	0.52	5.84	-2.01	4.17	1.93	4.22	0.025†
Co-Gn	7.41	8.85	3.43	4.53	5.85	4.16	0.115†
Maxilomandibular relationship							
ANB (º)	-1.45^{A}	1.82	-1.18^{A}	1.58	0.07^{B}	1.09	0.002*†
Wits (mm)	-1.95^{A}	2.23	-2.66^{A}	2.61	0.48^{B}	2.14	0.000*†
Vertical Component							
FMA (º)	0.51^{AB}	2.67	1.77^{B}	2.74	-0.81^{A}	3.00	0.012*†
SN.GoGn	0.27	2.31	0.02	2.40	-0.79	2.48	0.300†
OP.SN (º)	0.40^{AB}	3.00	1.96^{B}	3.56	-1.69^{A}	3.31	0.001*†
LAFH (mm)	4.50^{A}	4.66	2.04^{B}	2.13	2.12^{B}	2.56	0.026*†
S-Go (mm)	5.59	6.78	3.53	2.46	3.86	3.59	0.300‡
Maxillary dentoalveoar components							
Mx1.NA (º)	-2.67	5.74	-1.98	4.59	0.087	4.11	0.141†
Mx1-NA	-0.47	2.56	-0.83	2.32	0.38	3.53	0.863†
Mx1.PP (º)	-3.13	5.38	-1.02	5.37	0.05	4.06	0.100†
Mx1-PP	1.41	2.45	0.60	1.37	0.82	1.58	0.349†
Mx6-PP	1.56	2.23	0.73	1.51	0.49	2.41	0.219†
Mandibular dentoalveolar components							
Md1.NB (º)	0.31^{A}	3.05	6.68^{B}	3.51	0.81^{A}	2.93	0.000*†
Md1-NB	0.52^{A}	0.92	1.77^{B}	0.67	0.41^{A}	1.00	0.000*†
Md1-GoMe	2.24^{A}	3.01	0.30^{B}	1.99	1.83^{A}	1.42	0.001*‡
Md6-GoMe	2.66^{A}	2.19	1.11^{AB}	1.64	0.54^{B}	2.80	0.006*†
Dental Relationships							
Overjet (mm)	-2.32^{A}	2.05	-3.93^{B}	1.71	0.21^{C}	1.25	0.000*†
Overbite	-0.46^{A}	1.62	-1.84^{B}	1.60	0.53^{A}	1.38	0.000*†
Molar Relationship (mm)	-1.49^{A}	1.88	-3.47^{B}	1.74	-0.28^{A}	1.77	0.000*†
Soft tissue profile							
Nasolabial	0.43	15.72	1.00	9.20	2.19	12.76	0.895†
UL-E plane (mm)	-1.70	1.21	-1.58	1.22	-0.72	2.45	0.134†
LL-E plane (mm)	1.09	7.15	0.19	1.37	-1.01	2.24	0.266†

Capital letters indicate statistically significant differences ($P < 0.05$).
†One-way Analysis of Variance tests.
††Kruskal-Wallis tests.

3 DISCUSSION

3 DISCUSSION

In order to facility to simplify interpretation and analysis of the result obtained in this research, the discussion was divided as follows: characteristics related to the sample, compatibility between the groups and the methodology applied with observations about the method error. Next, the analyses of cephalometric measurements and intragroup comparisons in the initial and final stages of treatment and follow-up will be elaborated.

Many studies have already evaluated functional appliances and their effects, with many results still controversial. The Twin Block is an appliance established in the literature and MARA is a relatively new. The main difference between them is that one is mobile and the other is fixed. Therefore, this study has a main objective to compare the skeletal, dentoalveolar and soft tissue changes promoted by these appliances in Class II treatment.

Sample Characteristics:

The purpose of the selection of this sample was to verify the skeletal, dental and soft tissue effects resulting from the treatment of Class II, division 1 malocclusion with two types of functional appliances, the Twin Block and MARA. To detect the changes that occur from the growth of the changes promoted by the appliances, a control group of individuals with Class II division 1 malocclusion was instituted.

In order to constitute the sample, lateral cephalograms were used, in the initial stage of treatment (T1) and in the final stage the treatment (T2). These cephalograms were selected from the archive of the Department of Orthodontics at Bauru Dental School, University of São Paulo, Brazil. To achieve a legitimate comparison between the groups, the inclusion and exclusion criteria were severely followed.

The sample calculation was performed, ensuring a minimum number of patients for each of the groups. The achieve 80% test power, the sample calculation was based on an alpha significance level of 5% (0.05) and a 20% (0.20) to identify a mean difference of 2.77 mm with a standard deviation of 2.43 change in mandibular effective

length (Co-Gn). The result obtained through the sample calculation was 18 individuals for each group.(PIERI et al., 2012)

The sample consisted of a total of 66 patients, dived into 3 groups: group 1 consisted of 21 patients treated with Twin-Block appliance; group 2 consisted of 21 patients treated with MARA appliance and group 3, being this the control group with a total of 24 individuals.

The three sample groups were almost equal in terms of sex distribution, Class II malocclusion severity and final ages (Table II). Regarding the initial ages, the MARA group presented the statistically greater mean in relation to the other groups, this occurred because the MARA is a fixed functional appliance and its treatment is recommended to be performed in the young permanent dentition during the peak of pubertal growth.(HUANCA GHISLANZONI et al., 2012)

On the other hand, the Twin-Block is a mobile functional appliance and for its treatment to be effective the recommended initial age is during or just before the beginning of the pubertal peak.(BACCETTI et al., 2000; BAYSAL; UYSAL, 2013)

Regarding the time of treatment, the MARA group presented a significantly smaller time than the other groups (Table II). However, this did not interfere in any way in the research since the objective is to compare the effects of two different types of treatment protocols for Class II, being a treatment with the mobile functional appliance (Twin Block) and another treatment with the fixed functional appliance (MARA).

One may criticize that due to the amount of variables compared between the groups, Bonferroni corrections (29) should have been used. However, this procedure would decrease the probability of detecting slight significant differences, which are very important in this comparison.(ARMSTRONG, 2014)

Methodology:

The choice of the method to evluate the dentoskeletal and soft tissue alterations provided by Class II malocclusion treatments was the cephalometric analysis. It is reliable technique that has been in use for decades.(VASSOLER, 2011; PIERI et al., 2012)

As a consequence of the great progress and reliability of the digital programs for cephalometric analyses, they are increasingly being used in studies that evaluate the results of the changes provided by different types of treatments.

The program chosen to carry out this study was Dolphin Imaging, due to its great precision in the measurement of cephalometric measures and together with the fact of correcting the magnification values of the lateral cephalograms.(PAIXÃO et al., 2010)

In order to achieve maximum accuracy in the demarcation of anatomical structures, this phase was always performed by the same examiner in a darkened room.(HOUSTON, 1983)

The demarcation of anatomical structures is a complex stage of research and subjectivity in its realization can lead to the ambiguity of the values obtained.(CANÇADO et al., 2009)

Thirty lateral cephalograms were randomly selected and retraced by the same operador (C.B.) after a 4-week interval. Random and systematic errors were calculated according to Dahlberg's formula and with dependet t tests, respectively; at $P<0.05$.(DAHLBERG, 1940; HOUSTON, 1983)

The random errors ranged from 0.37mm (Md1-NB) to 3.77mm (CoGn) and 0.79º (ANB) to 8.03º (ANL). These errors were considered within clinical acceptable limits. Four variables (Mx1.NA, Mx6-PP, molar relation, UL-E plane) presented significant systematic errors.

Comparison of dentoskeletal and soft-tissue profile changes:

Maxillary component:

At pretreatment, the MARA group demonstrated a significantly greater maxillary effective length (CoA) than the Twin Block group (Table III). This difference between the groups was already expected, since MARA was older than Twin Block. Therefore, it is natural that due to the growth, the maxillary effective length was greater in MARA group.(BEHRENTS, 1985)

After the treatment, the appliances did not produce significant effects on the maxillary skeletal component (Table IV).

The effect of Twin Block on the maxillary skeletal component is controversial in the literature and the fact that it was not significant corroborates with other studies that evaluated its performance in the maxilla.(CLARK, 1988; BAYSAL; UYSAL, 2013; EHSANI et al., 2014, 2015; GIUNTINI et al., 2015)

However, other studies have shown that treatment with Twin Block may result in restriction of maxillary development.(TOTH; MCNAMARA, 1999; BACCETTI et al., 2000; O'BRIEN et al., 2009)

The fact that MARA also did not present a statistically significant effect on the maxilla was already reported another study.(AL-JEWAIR et al., 2012)

In the literature is suggested that in order to obtain the restrictive effect on maxillary development, MARA should be installed in the pre-peak growth stage.(HUANCA GHISLANZONI et al., 2012)

Mandibular component:

At pretreatment the MARA group showed a significantly greater mandibular effective length (Co-Gn) than the Twin Block group (Tabela III). As already reported above, the MARA group was older than Twin Block. As a result of the MARA having a longer growing time compared to Twin Block, the mandibular effective length was statistically greater in this group.(BEHRENTS, 1985)

At posttreatment, the Twin Block group presented the greatest increase in mandibular effective length (Co-Gn) when compared to the other groups, although this increase was not significant (Table IV). As the treatment time between the two appliances is different, it is natural that the Twin Block for having stayed for a longer period (2.10 years on average) had a greater mandibular growth than MARA (1.16 years on average).

Some authors state that treatment with Twin-Block promotes mandibular growth.(MILLS; MCCULLOCH, 1998; TOTH; MCNAMARA, 1999; BACCETTI et al., 2000; LEE et al., 2013; EHSANI et al., 2015)

Other authors state that patients treated with MARA during the growth spurt in the permanent dentition have a significant increase in mandibular length in relation to a control group.(AL-JEWAIR et al., 2012; HUANCA GHISLANZONI et al., 2012)

However, the fact that this research has shown that the changes int the treated groups were not significant relation to the control group, agree with recent studies. A systematic review with a meta-analysis has shown that functional removable appliances are effective in treating Class II by promoting dentoalveoalr rather than skeletal changes.(KORETSI et al., 2014)

Another systematic review demonstrated that the MARA appliance produced statistically significant changes in the mandibular dimensions, however, these alterations are not clinically significant, or simply did not produce significant changes in mandibular growth.(PANGRAZIO et al., 2012; CHIQUETO et al., 2013; AL-JEWAIR, 2014)

Maxillomandibular relationship:

In pretreatment, the Twin Block group showed a significantly greater Class II relation to the control group (Table III).

In both treated groups there was a significant improvement in the discrepancy between the bone bases in relation to the control group (Table IV). It is probably that the restriction in maxillary development associated with increased mandibular length (even without being statistically significant) contributed to the decrease in Class II relation. Other authors have already reported this change.(COVELL JR et al., 1999; ECKHART; WHITE, 2003; SIARA-OLDS et al., 2010)

Vertical component:

Before the treatment, the Twin Block group presented significantly greater mandibular plane angle (FMA) than the MARA group (Table III). The Twin Block group also had significantly smaller posterior facial height (S-Go). As previously argued, this occurred because the MARA group had a greater time of growth in relation to the Twin Block group when compared the MARA group.(BEHRENTS, 1985)

Three variables (FMA, OP.SN and LAFH) that evaluated the vertical component presented statistically significant differences (Table IV). The growth pattern (FMA) and the inclination of the occlusal plane (OP.SN) showed a significant increase in the experimental groups while those same variables decreased in the control group. These changes are more probable to be related to the dentoalveolar effects produced by the devices, and there is no relationship with changes in the patients' craniofacial growth pattern. Some studies evaluating Twin Block also found the same effect.(SINGH et al., 2010; GIUNTINI et al., 2015)

Other studies evaluating MARA also reported similar results in relation to inclination of the occlusal plane.(PANGRAZIO et al., 2012)

Though, other studies did not find significant changes in the angle of the mandibular plane and in the facial growth pattern.(LUND; SANDLER, 1998; BURHAN; NAWAYA, 2014)

All groups showed an increase in lower facial height (LAFH), however this increase was statistically greater in the Twin Block group in relation to the other groups (Table IV). Possibly this increase was significant in the Twin Block group as a consequence of the greater extrusion of the mandibular molars that occurred in this group.

The increase in lower anterior facial height in patients treated with Twin Block is a consistent finding in the literature.(LUND; SANDLER, 1998; TOTH; MCNAMARA, 1999; ŠIDLAUSKAS, 2005; LEE et al., 2013)

Although, this same author states that increase in lower anterior facial heigth has no clinical relevance for the patient. Another study states that it did not find significant vertical changes with Twin Block treatment.(EHSANI et al., 2015)

Maxillary dentoalveolar component:

At the beginning treatment, the MARA group demonstrated significantly greater vertical development than the Twin Block group (Table III). Because it was a group with an initial age older than Twin Block group, the MARA had a longer time to erupt the maxillary molars.(BEHRENTS, 1985)

After the conclusion of the treatments, no statistically significant changes were found in relation to the superior dentoalveolar component (Table IV). However, the treatment groups presented a palatal tipping of the maxillary incisors while in the control group there was a labial tipping. The fact that the maxillary incisors were retruded in the treated groups is related to the effect that the functional appliances exert on the maxilla. This palatal tipping effect of the incisors has been reported in another study that evaluated Twin Block, yet it was not statistically significant either.(GIUNTINI et al., 2015)

Other studies evaluating MARA performance also found no significant dentoalveolar changes in the maxilla.(HUANCA GHISLANZONI et al., 2012; PANGRAZIO et al., 2012; BAYSAL; UYSAL, 2013; EHSANI et al., 2015)

This finding contradicts other articles that affirm that the effect to Twin Block and MARA on the maxillary incisors is statistically significant.(AL-JEWAIR et al., 2012; CHIQUETO et al., 2013; EHSANI et al., 2014; GIUNTINI et al., 2015)

Mandibular dentoalveolar component:

In pretreatment, the Twin Block group had significantly greater labial tipping (Md1.PP) of the mandibular incisors than the others groups and significantly greater protrusion (Md1-PP) than the control group (Table III). Also, the MARA group had significantly greater vertical development of the mandibular incisors than the control group.

In posttreatment, all the variables used to measure the mandibular dentoalveolar component presented statistically significant differences (Table IV).

To evaluate the inclination and protrusion of the mandibular incisors, the variables used were Md1.NB, Md1-NB respectively. The greater significant increase in labial tipping occurred in the MARA group in relation to the other groups probably occurred because fixed functional appliance exerted forces of mesialization and intrusion in the mandibular incisors. This result as already been reported in other studies that evaluated the effects of MARA.(PANGRAZIO-KULBERSH et al., 2003; AL-JEWAIR et al., 2012; CHIQUETO et al., 2013)

Opposite this, another study found that the treatment with MARA during the growth spurt did not induce the proclination of the mandibular incisors nor did it produce effects on the horizontal and vertical positions of the mandibular molars.

This same study says dentoalveolar effects are greatest when MARA is installed after peak growth.(HUANCA GHISLANZONI et al., 2012)

Regarding the MARA to have presented a restriction in the vertical development of the mandibular incisors in relation to the Twin Block and control groups was an already expected finding (Table IV). As described above this is an expected effect to the fixed functional appliances. Other researches corroborate this finding.(PANGRAZIO-KULBERSH et al., 2003; HUANCA GHISLANZONI et al., 2012)

With respect to Twin Block showed a vertical development of the mandibular molars statistically greater than the control (Table IV). Possibly this occurred because the acrylic of the mandibular molars was made so that the eruption of the same occurred. This effect is beneficial in the correction of Class II malocclusion, since the functional appliances exert forces forward and downward in the anteroinferior region, as consequence of the increase of the vertical development and mesialization of the mandibular molar, besides helping in the leveling of the curve of Spee.(HARVOLD; VARGERVIK, 1971; LEE et al., 2016)

The increase in the vertical development of the mandibular molars has already been described in other occasions in the literature.(BAYSAL; UYSAL, 2013; EHSANI et al., 2014)

Dental relationship:

In the pretreatment, the fact that MARA showed a significantly greater overjet compared to the other groups and a significantly greater Class II molar relationship than the control may be associated with the fact that MARA is older than the others (Table III). Therefore, there was a greater growth of this group.(BEHRENTS, 1985)

In the posttreatment, experimental groups presented a significant improvement in the correction of overjet, overbite and molar relationship (Table IV). The MARA group showed a significantly greater increase in the correction of dental when compared the other groups. The fact that the improvement in the correction of the overjet and overbite

in the MARA group was significantly greater in relation to the Twin Block group could be associated with the greater dentoalveolar effect in the mandibular incisors produced by MARA. Another issue that may have contributed to the overbite correction being significantly greater in the MARA than in the Twin Block was the significant restriction in the vertical development that occurred in the mandibular incisors associated with the extrusion of the mandibular molars of this group.

There was a significant correction in the Class II molar relationship in the three groups, though, this correction was statistically greater in the MARA group in relation the other groups (Table IV). The Twin Block also presented a greater improvement in the Class II molar relation than the control, nevertheless was not significant. Correction of the Class II molar relation in the treated groups is related to a combination of dentoalveolar and skeletal effects, since even though it was not significant, there was a restriction in the development of the maxilla and there was a mandibular growth. In addition, dental effects such as the great labial tipping and protrusion of the mandibular incisors probably contributed to this correction. Other studies have already observed this improvement in dental relationships with Twin Block and MARA appliances.(AL-JEWAIR et al., 2012; HUANCA GHISLANZONI et al., 2012; PANGRAZIO et al., 2012; BAYSAL; UYSAL, 2013; CHIQUETO et al., 2013; LEE et al., 2013; EHSANI et al., 2015; GIUNTINI et al., 2015)

Soft tissue:

There were no statistically significant changes in soft tissue (Table IV). Although, it was observed that the treated groups showed a greater retrusion of the upper lips in relation to the control. This finding may be related to the restrictive effect that functional appliances exert on the maxillary component.(PANCHERZ; ANEHUS-PANCHERZ, 1993; URSI et al., 2000; BAYSAL; UYSAL, 2013; TSIOULI et al., 2017)

Another alteration observed was that the mandibular lips presented a mild protrusion in the treated groups while the control presented retrusion. This finding is probably related (even without being significant) to the skeletal effects promoted by the appliances. This result corroborates with another study.(PIERI et al., 2012)

4 CONCLUSION

4 CONCLUSIONS

Based of the methodology used for the comparison of the cephalometric effects promoted by the Twin Block and MARA appliances compared to a Control group, we conclude that:

The two appliances used showed satisfactory results in the correction of Class II division 1 malocclusion, however, most of its effects were dentoalveolar.

The experimental groups promoted an increase in FMA and inclination of the mandibular plane while these values decreased in the control group.

The Twin Block group promoted a greater increase of lower anterior facial height.

The MARA produced dentoalveolar effects in greater amount on the mandibular incisors, such as labial tipping and protrusion when compared the other groups.

The Twin Block produced significantly greater extrusion of the mandibular incisors than the MARA and significantly greater extrusion of the mandibular molars in relation to the control.

Both appliances promoted significant benefits in dental relationships (overjet, overbite and molar relation).

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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 "CLASS II MALOCCLUSION TREATMENT WITH TWIN BLOCK AND MANDIBULAR ANTERIOR REPOSITIONING APPLIANCE: A COMPARATIVE STUDY OF DENTOSKELETAL CHANGES." will be included in Dissertation of the student Cristina Bastiani and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, December 05th, 2018.

Cristina Bastiani
Author

Signature

José Fernando Castanha Henriques
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Signature

ANNEXES

ANNEX A. Ethics Committee approval, protocol number 71639017.0.0000.5417 (front).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Estudo comparativo das alterações dento-esqueléticas entre os aparelhos Twin-Block e Mandibular Anterior Repositioning Appliance no tratamento da má oclusão de classe II.

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Versão: 2
CAAE: 71651417.3.0000.5417
Instituição Proponente: Faculdade de Odontologia de Bauru
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.332.806

Apresentação do Projeto:
Trata-se de um projeto intitulado "Estudo comparativo das alterações dento-esqueléticas entre os aparelhos Twin-Block e Mandibular Anterior Repositioning Appliance no tratamento da má oclusão de classe II.", de autoria de Cristina Bastiani com a orientação do Prof. Dr. José Fernando Castanha Henriques. Trata-se de um estudo retrospectivo sobre a comparação das alterações dento-esqueléticas entre 2 tipos de aparelhos - Twin-block e o Mandibular Anterior Repositioning Appliance (MARA)- e um grupo controle onde os pacientes não receberam nenhum tipo de intervenção ortodôntica. O grupo Twin Block será composto por 19 indivíduos, destes 12 são do sexo masculino e 7 são do sexo feminino com má oclusão inicial de Classe II, divisão 1. Este grupo tem idade média inicial de 8,18 anos, tratados com o aparelho Twin Block por um período total médio de 17,8 meses. O grupo que foi tratado com o aparelho MARA (mandibular anterior repositioning appliance) será formado por 20 indivíduos, destes 12 são do gênero masculino e 8 são do gênero feminino. Todos possuíam inicialmente má oclusão de Classe II, divisão 1 e idade média inicial de 11,96 anos, eles foram submetidos ao tratamento com o aparelho MARA por um período total médio de 12,5 meses. Os indivíduos do grupo controle serão selecionados da amostra do Centro de Estudo de Crescimento da Faculdade de Odontologia de Bauru, Universidade de São Paulo. Esta amostra é composta por jovens que foram radiografados e controlados pela disciplina de ortodontia, com intuito de obter um modelo de amostra longitudinal de oclusão

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jovens, desde a dentadura decídua até a dentadura permanente, após a obtenção desses dados os indivíduos foram encaminhados para o tratamento ortodôntico, contudo alguns optaram por tratar mais tarde ou não fazer o tratamento por enquanto, possibilitando a formação do grupo controle. Este grupo é composto por 20 pessoas, sendo 10 do gênero masculino e 10 do gênero feminino e serão observados os seguintes critérios: Idades iniciais e finais; Tempo médio de avaliação; Gênero. Estes serão os dados avaliados com o objetivo de harmonizar esse grupo com os grupos experimentais. O método radiográfico empregado para esta pesquisa será a telerradiografia em norma lateral. Cada indivíduo terá duas radiografias, a primeira no início do tratamento e a segunda no caso do grupo 1, será realizada após o tratamento com o aparelho Twin Block. No grupo 2 a segunda radiografia será realizada após o paciente ter sido submetido ao tratamento com o aparelho MARA. As telerradiografias dos grupos experimentais serão obtidas em diferentes Centros de Radiologia Odontológica da cidade de Bauru – SP e na Clínica de Radiologia da Faculdade de Odontologia de Bauru – Universidade de São Paulo (FOB-USP). As telerradiografias do Grupo Controle serão tomadas na Clínica de Radiologia da FOB/USP.

Objetivo da Pesquisa:

Os objetivos deste trabalho são analisar pacientes portadores da má oclusão Classe II divisão 1 tratados com dois diferentes tipos de aparelhos, o Twin Block e o MARA e avaliar simultaneamente um grupo controle onde os indivíduos não serão submetidos a tratamento algum. Nesta análise será verificado as medidas cefalométricas iniciais e finais e as medidas iniciais e finais dos modelos de gesso, podendo assim, avaliar o desempenho de cada um dos aparelhos citados acima e o comportamento do grupo controle.

Avaliação dos Riscos e Benefícios:

Riscos:

Os riscos que envolvem essa pesquisa diz respeito ao fato de que será necessário manipular os modelos de gesso dos pacientes com todo o cuidado mas existe a possibilidade de acontecer algum acidente e o modelo de gesso quebrar causando algum dano a documentação. Outro risco que pode ocorrer é o de perder alguma documentação do paciente, mas serão tomados todos os cuidados necessários para que isso não ocorra de forma alguma. E por último, existe uma preocupação com relação a contaminação cruzada pois os modelos de gesso serão manipulados para que seja possível realizar a análise, devendo desta forma tomar todos as precauções de biossegurança para que esse risco seja diminuído o máximo que for possível.

Benefícios:

Através deste estudo - será possível analisar se algum dos dois tipos de aparelhos é mais efetivo

no tratamento da má oclusão de Classe II.

Comentários e Considerações sobre a Pesquisa:

Trata-se de uma pesquisa bem interessante aonde a pesquisadora pretende fazer um estudo comparativo em pacientes portadores de má oclusão de classe II num período antes e depois de serem tratados com 2 tipos de aparelhos ortodônticos funcionais fixos o Twin-block e o Mandibular Anterior Repositioning Appliance (MARA). Através deste estudo - será possível analisar se algum dos dois tipos de aparelhos é mais efetivo no tratamento da má oclusão de Classe II.

Considerações sobre os Termos de apresentação obrigatória:

Foram apresentados todos os documentos necessários para que seja avaliada a presente pesquisa. Ou seja: O projeto, carta de encaminhamento, orçamento, cronograma, folha de rosto, termo de aquiescência autorizando a pesquisadora a ter acesso aos prontuários e moldes de gesso e a justificativa para a dispensa do TCLE.

Recomendações:

Não se aplica.

Conclusões ou Pendências e Lista de Inadequações:

A presente pesquisa foi analisada por este CEP na reunião do mês de Agosto de 2017. Naquela ocasião a pesquisa foi considerada com pendencias para sua aprovação. A pesquisadora retornou a pesquisa para uma nova análise e observa-se que praticamente a totalidade das pendencias foram esclarecidas ou corrigidas. Entretanto, ainda a questão dos benefícios desta pesquisa não nos parece resolvida. Novamente questionamos a pesquisadora em relação aos benefícios que ela nos elenca aos participantes da pesquisa. Veja a resposta que nos foi enviada, presumivelmente, pela pesquisadora (uma vez que o ofício veio sem assinatura e data): "Ao participar desta pesquisa, os pacientes receberam benefícios como a gratuidade dos exames, do planejamento ortodôntico, do tratamento das más oclusões (posicionamento incorreto dos dentes) e do acompanhamento clínico. O grupo controle teve o seu crescimento craniofacial observado durante o período de 2,19 anos, desta forma colaborando para que fosse obtida uma amostra longitudinal de oclusão jovens, desde a dentadura decídua até a dentadura permanente e após a obtenção destes dados, os indivíduos foram encaminhados para o tratamento ortodôntico tendo a sua má oclusão corrigida. Caso esses pacientes apresentassem algum outro tipo de cuidado bucal,

sistêmico geral ou psicológico, eles foram devidamente encaminhados para outros Departamentos da Faculdade de Odontologia de Bauru ou hospitais, para tratamento integral e ao final do estudo tiveram por tempo indeterminado acesso gratuito aos melhores métodos preventivos, diagnósticos e terapêuticos que se demonstrarem eficazes, por parte da Instituição patrocinadora. Outro benefício é que através do estudo destas amostras retrospectivas será possível analisar se algum dos dois tipos de aparelhos é mais efetivo no tratamento da má oclusão de Classe II." Mais uma vez reiteramos a necessidade da pesquisadora separar os benefícios dos participantes desta pesquisa dos benefícios que eles já receberam por participarem de outra pesquisa (não nesta). Nesta pesquisa eles não estarão participando diretamente, apenas seus dados colhidos em seus prontuários é que servirão para esta pesquisa. Portanto, nos parece que o único benefício desta pesquisa seria que "através deste estudo - seja possível analisar se algum dos dois tipos de aparelhos (Twin-Block e o MARA) é mais efetivo no tratamento da má oclusão de Classe II" e não todos aqueles benefícios elencadas pela pesquisadora que são benefícios que os participantes tiveram por participarem de outras pesquisas. Entretanto, apesar dessa observação, podemos aprovar este projeto, mas sugerimos a pesquisadora que corrija os benefícios dos participantes desta pesquisa e envie uma emenda a este CEP.

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 11/10/2017, com base nas normas éticas da Resolução CNS 466/12, no entanto solicita-se envio de uma EMENDA, conforme descrito no item Conclusões ou Pendências e Lista de Inadequações. 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_932185.pdf	14/09/2017 17:18:52		Aceito
Outros	respostaspendencias.docx	14/09/2017 17:14:33	CRISTINA BASTIANI	Aceito

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 2.332.806

Declaração de Instituição e Infraestrutura	termoaquiescencia.docx	14/09/2017 16:36:55	CRISTINA BASTIANI	Aceito
Projeto Detalhado / Brochura Investigador	PROJETO.docx	13/09/2017 17:10:47	CRISTINA BASTIANI	Aceito
Outros	quetionario2.pdf	20/07/2017 10:40:22	CRISTINA BASTIANI	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	dispensaTLCE.docx	19/07/2017 21:58:17	CRISTINA BASTIANI	Aceito
Declaração de Pesquisadores	declaracaopesquisador.JPG	18/07/2017 22:02:00	CRISTINA BASTIANI	Aceito
Declaração de Instituição e Infraestrutura	infraestrutura.JPG	18/07/2017 21:59:50	CRISTINA BASTIANI	Aceito
Folha de Rosto	FolhaCris.pdf	18/07/2017 21:56:07	CRISTINA BASTIANI	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 17 de Outubro de 2017

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, 12 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 das alterações dento-esqueléticas entre os aparelhos Twin Block e Mandibular Anterior Repositioning Appliance no tratamento da má oclusão de Classe II."** tendo como responsável principal Cristina Bastiani, sob orientação do Prof. Dr. José Fernando Castanha Henriques.

A pesquisa prevê a dispensa de TCLE e Termo de Assentimento, devido ao fato de 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 inicio e no final do tratamento ortodontico, e já possuem TCLE assinados pelos pacientes autorizando a nos utilizarmos dessa documentação em pesquisas.

Atenciosamente,

Cristina Bastiani
Responsável Principal

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