

UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

THALES LIPPI CIANTELLI

**Comparison of direct skeletally anchorage distalization and
two premolar extractions for Class II treatment**

**Comparação entre distalização com ancoragem esquelética direta e
extração de dois pré-molares para o
tratamento da Classe II**

BAURU

2021

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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

COMPARISON OF DIRECT SKELETALLY ANCHORED DISTALIZATION AND TWO PREMOLAR EXTRACTIONS FOR CLASS II MALOCCLUSION TREATMENT

Introduction: to compare the dentoskeletal and soft-tissue effects of Class II malocclusion treatment using two different protocols: maxillary premolar extractions and skeletally anchored molar distalization using the Miniscrew-Anchored Distalizer with lateral radiographs and digitized models. **Material and Methods:** The sample comprised 35 patients with Class II malocclusion divided into two groups: Group 1 consisted of 15 patients treated with the Miniscrew-Anchored Distalizer (MAD), followed by fixed appliances. Group 2 consisted of 20 patients treated with maxillary first premolar extractions (XP2). Lateral radiographs were digitized with the ScanMaker i800 and analyzed with the Dolphin Imaging 11.9 software. The plaster models were digitized with the scanner 3Shape R700 and the digitized models were analyzed with the software OrthoAnalyzer. The intergroups treatment changes were compared with *t*-tests or Mann-Whitney tests, depending on normality. **Results:** The MAD group presented significantly greater intrusion of maxillary incisors, maxillary molar distalization and distal rotation, mandibular incisors labial tipping and mandibular molars mesialization. The XP2 group showed significantly maxillary molar mesial movement, greater reduction in the intermolar distance, arc perimeter, and arc length. **Conclusion:** Both protocols effectively treated Class II malocclusion promoting dentoalveolar changes. The MAD produced more mandibular incisor's labial tipping and accentuated molar distal rotation. The XP2 protocol promotes significantly greater reduction of the transversal arch dimensions.

Keywords: Imaging, Three-Dimensional; Malocclusion, Angle Class II; Orthodontic Anchorage Procedures.

RESUMO

RESUMO

COMPARAÇÃO ENTRE DISTALIZAÇÃO COM ANCORAGEM ESQUELÉTICA DIRETA E EXTRAÇÕES DE PRE-MOLARES SUPERIORES PARA O TRATAMENTO DA MÁ-OCCLUSÃO DE CLASSE II

Introdução: comparar os efeitos dento-esqueléticos e de tecidos moles do tratamento da má oclusão de Classe II utilizando dois diferentes protocolos: extrações de pré-molares superiores e distalização de molares com ancoragem esquelética direta com o Miniscrew-Anchored Distalizer a partir de radiografias laterais e modelos digitalizados. **Material e Métodos:** A amostra foi composta por 35 pacientes com má oclusão de Classe II divididos em dois grupos: Grupo 1 composto por 15 pacientes tratados com o Miniscrew-Anchored Distalizer (MAD), seguido de aparelhos fixos. O Grupo 2 consistiu de 20 pacientes tratados com extrações de primeiros pré-molares superiores (XP2). As radiografias laterais foram digitalizadas com o ScanMaker i800 e analisadas com o software Dolphin Imaging 11.9. Os modelos de gesso foram digitalizados com o scanner 3Shape R700 e os modelos digitalizados foram analisados com o software OrthoAnalyzer. As mudanças de tratamento intergrupos foram comparadas com testes t ou testes de Mann-Whitney, dependendo da normalidade. **Resultados:** O grupo MAD apresentou intrusão significativamente maior dos incisivos superiores, distalização e rotação dos molares superiores, inclinação labial dos incisivos inferiores e mesialização dos molares inferiores. O grupo XP2 apresentou significativamente movimento mesial dos molares superiores, maior redução na distância intermolar, perímetro do arco e comprimento do arco. **Conclusão:** Ambos os protocolos trataram efetivamente a má oclusão de Classe II, promovendo alterações dentoalveolares. A MAD produziu mais inclinação labial dos incisivos inferiores e rotação distal acentuada do molar superior. O protocolo XP2 promove redução significativa das dimensões do arco dentário.

Palavras Chaves: Imageamento Tridimensional; Má Oclusão de Angle Classe II; Procedimentos de Ancoragem Ortodôntica

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1 INTRODUCTION

1 INTRODUCTION

Orthodontics always aim for the most efficient treatment plan, that is, when the best performance is obtained with the least time spent, which is a fundamental issue for clinical success.(BARROS, 2004) Also, prolonged treatments, besides being susceptible to greater negative biological effects,(CONSOLARO; BIANCO, 2017) may require a higher cost to a national public health system.(GRABER; ELIADES; ATHANASIOU, 2005; MAVREAS; ATHANASIOU, 2008; SEGAL; SCHIFFMAN; TUNCAY, 2004)

In this context, Class II malocclusion usually has a negative psychosocial and facial impact, resulting in a greater demand of patients seeking orthodontic treatment. Given this, there is a constant evolution by orthodontic approaches of this occlusal disorder to be more efficient and with excellent aesthetic results. (ALMURTADHA; ALHAMMADI; FAYED; ABOU-EL-EZZ *et al.*, 2018; BERNEBURG; DIETZ; NIEDERLE; GOZ, 2010; CONSOLARO; BIANCO, 2017; JANSON; SATHLER; FERNANDES; ZANDA *et al.*, 2010; MCNAMARA, 1981; MENDES; JANSON; ZINGARETTI JUNQUEIRA-MENDES; GARIB, 2019; PAPADOPOULOS, 2008; PROFFIT; FIELDS; MORAY, 1998; SILVA FILHO; BERTOZ; CAPELOZZA FILHO; SANTOS, 2009) This malocclusion can be characterized by maxillary prognathism, mandibular deficiency, or involvement of both.(MCNAMARA, 1981) When the retrognathia is already exacerbated from deciduous or mixed dentition, the spontaneous forward jaw growth will not correct the bone discrepancy, which tends to stay for the entire life. In these cases, orthopedic/functional appliances, or even orthognathic surgery treatment, are more suggested.(BUSCHANG; TANGUAY; DEMIRJIAN; LAPALME *et al.*, 1988; CARVALHO; MARTINS; BARBOSA, 2007; GREC; JANSON; BRANCO; MOURA-GREC *et al.*, 2013; PROFFIT; FIELDS; MORAY, 1998)

However, when Class II presents greater dentoalveolar than skeletal involvement, with no major complaint of facial aesthetics, therapeutic possibilities with dental extractions or intraoral distalizers are considered efficient and require low patient compliance.(BARROS, 2004; BELLINI-PEREIRA; PUPULIM; ALIAGA-DEL

CASTILLO; HENRIQUES *et al.*, 2019; GRACIANO; JANSON; FREITAS; HENRIQUES, 2010; GREC; JANSON; BRANCO; MOURA-GREC *et al.*, 2013; KHAN; FIDA, 2010; PAPADOPOULOS, 2008) If the treatment is performed with two maxillary premolar extractions (XP2 protocol), the molars will finish in a complete Class II and the canines in Class I relationships, with good occlusal stability and satisfactory treatment time. Recent studies show not suffer damage related to long-term profile attractiveness.(ALMURTADHA; ALHAMMADI; FAYED; ABOU-EL-EZZ *et al.*, 2018; BARROS, 2004; GRACIANO; JANSON; FREITAS; HENRIQUES, 2010; MENDES; JANSON; ZINGARETTI JUNQUEIRA-MENDES; GARIB, 2019; PARK; KIM; YANG; BAEK, 2012)

Another treatment option would be the use of fixed intraoral distalizers, which decrease the degree of need for collaboration in the system's use, which has a primary function of the distalization of maxillary molars. As an anchor unit, traditionally, a cemented Nance button is used in the molars; however, there is loss of anterior anchorage with protrusion of these teeth, and consequently, increased treatment time. More recently, palatal miniscrew associated with these distalizing devices have been considered indirect anchor reinforcement, decreasing the total treatment time and side effects during distalization.(ESCOBAR; TELLEZ; MONCADA; VILLEGAS *et al.*, 2007; KINZINGER; GULDEN; YILDIZHAN; DIEDRICH, 2009; KIRCELLI; PEKTAS; KIRCELLI, 2006)

However, the use of miniscrew as an indirect anchorage, even reducing these side effects, was not sufficient for their complete solution. It is speculated that the possibility of using miniscrew in the form of direct anchorage, which receives the distalizing force directly on the miniscrew, would remove undesirable effects such as anterior teeth protrusion and premolar mesial movement.(KURODA; YAMADA; DEGUCHI; KYUNG *et al.*, 2009) Ideally, for pure molar translation, the force line should cross close to its center of resistance, exemplified as a body movement.(SMITH; BURSTONE, 1984; VIECILLI; BUDIMAN; BURSTONE, 2013) Thus, through the concepts of direct anchorage and body movement, it was developed in the Department of Orthodontics, University of São Paulo (FOB-USP), a device that is easy to make, low cost, simple to install, activated, and with force vector control to distalize the upper molars, allowing it to be individualized.(VILANOVA; HENRIQUES; PATEL; GREC *et al.*, 2017)

This device was associated with a miniscrew as a direct skeletal anchorage. The cantilever is made of 1.0 stainless steel wire with the aid of pliers 139, welded to the upper first molar band, and activated with a 200g-force nickel-titanium (NiTi) spring, anchored to a miniscrew between the roots of the second premolar and upper first molar. The results obtained with the device were satisfactory, with a Class I molar relationship, spontaneous distalization of premolars through transseptal fibers, and decrease anterior crowding, facilitating corrective orthodontic mechanics.

It is well established in the literature that the treatment for Class II malocclusion with two maxillary premolar extractions (XP2 protocol) presents satisfactory efficiency and final occlusal relationship.(JANSON; BARROS; DE FREITAS; HENRIQUES *et al.*, 2007; JANSON; DA COSTA BRAMBILLA; HENRIQUES; DE FREITAS *et al.*, 2004; PUPULIM; HENRIQUES; JANSON; HENRIQUES *et al.*, 2019) However, there is no evidence to compare this therapeutic protocol with treatment by molar distalization using direct skeletal anchorage. This study aims to compare class II correction techniques, exploring their positive consequences and possible side effects, to assist the orthodontist in deciding the best clinical approach and clarifying patients.

2 ARTICLE

2 ARTICLE

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COMPARISON OF DIRECT SKELETALLY ANCHORED DISTALIZATION AND TWO PREMOLAR EXTRACTIONS FOR CLASS II MALOCCLUSION TREATMENT

ABSTRACT

Introduction: to compare the dentoskeletal and soft-tissue effects of Class II malocclusion treatment using two different protocols: maxillary premolar extractions and skeletally anchored molar distalization using the Miniscrew-Anchored Distalizer with lateral radiographs and digitized models. **Material and Methods:** The sample comprised 35 patients with Class II malocclusion divided into two groups: Group 1 consisted of 15 patients treated with the Miniscrew-Anchored Distalizer (MAD), followed by fixed appliances. Group 2 consisted of 20 patients treated with maxillary first premolar extractions (XP2). Lateral radiographs were digitized with the ScanMaker i800 and analyzed with the Dolphin Imaging 11.9 software. The plaster models were digitized with the scanner 3Shape R700 and the digitized models were analyzed with the software OrthoAnalyzer. The intergroups treatment changes were compared with *t*-tests or Mann-Whitney tests, depending on normality. **Results:** The MAD group presented significantly greater intrusion of maxillary incisors, maxillary molar distalization, mandibular incisors labial tipping, mandibular molars mesialization and molar distal rotation. The XP2 group showed significantly maxillary molar mesial movement, greater reduction in the intermolar distance, arc perimeter, and arc length. **Conclusion:** Both protocols effectively treated Class II malocclusion promoting dentoalveolar changes. The MAD produced more mandibular incisor's labial tipping and accentuated molar distal rotation. The XP2 protocol promotes significantly greater reduction of the transversal arch dimensions.

Keywords: Imaging, Three-Dimensional; Malocclusion, Angle Class II; Orthodontic Anchorage Procedures.

INTRODUCTION

Class II malocclusion is usually related to a negative psychosocial and facial impact. This association explains the increased demand of patients seeking orthodontic treatment with this kind of malocclusion. In this context, a constant evolution of orthodontic approaches to treat this occlusal disorder was noticed through orthodontics history. Researchers and clinicians continuously searched for more treatment efficiency and greater esthetic results.¹⁻⁴

When Class II malocclusion is majorly skeletal, treatment with functional appliances or orthognathic surgery could be suggested.^{5,6} However, when greater dentoalveolar involvement is present, with no major complaint of facial esthetics, other therapeutic possibilities with dental extractions or intraoral distalizers are considered efficient and require minimum patient compliance.⁷⁻⁹

If treatment is performed with two maxillary premolar extractions (XP2 protocol), the molars and canines will finish in full-cusp Class II and Class I relationships, respectively. The literature describes acceptable occlusal stability and satisfactory treatment time with this approach.¹⁰ Additionally, recent studies showed that long-term profile attractiveness is not affected by extractions.^{1,3}

Compared to premolar extractions the use of intraoral distalizers is considered more conservative. These appliances present the primary function of maxillary molar distalization without patient compliance. Traditionally, a cemented Nance button is used as anchorage unit; however, anchorage loss and overjet increase have been reported with this mechanics.^{7,8,11} Skeletal anchorage with miniscrews was introduced to overcome these undesirable effects promoted during conventional distalization. Thus, palatal miniscrews were associated with intraoral distalizers as indirect anchorage reinforcement decreasing total treatment time and undesirable effects during distalization.¹²⁻¹⁴

Even though effective in reducing the undesirable effects during distalization, the use of miniscrews as indirect anchorage was not sufficient for their complete solution. Moreover, it is speculated that the possibility of using miniscrews in the form of direct anchorage, which receives the distalizing force directly on the miniscrew, would remove these undesirable effects completely.¹⁵ Directly anchored distalizers such as the bone-anchored pendulum appliance,¹⁴ the Miniscrew-Anchored Distalizer,

among others, were developed with this purpose.¹⁶ The Miniscrew-Anchored Distalizer is a device with low cost, easy to install and permits the force application closer to the molars center of resistance.

The effectiveness of Class II malocclusion treatment with two maxillary premolar extractions or skeletally anchored distalization is well-established in the literature.^{8,10,14,17} However, no evidence compared these treatment protocols to explore their effects and undesirable consequences. The present comparison would provide important findings for clinical decision-making. Therefore, this study aims to compare the dentoskeletal and soft-tissue effects of Class II malocclusion treatment using two different protocols: maxillary premolar extractions and skeletally anchored molar distalization using the Miniscrew-Anchored Distalizer with lateral radiographs and digitized models.

MATERIAL AND METHODS

This study was approved by the Ethics in Research Committee of Bauru Dental School, University of São Paulo, Brazil, and all subjects signed informed consent.

Sample size calculation was performed to detect a mean difference of 1.5 mm in the overjet, with a previously suggested standard deviation of 1.4 mm.¹⁸ An alpha significance level of 5% and a beta of 20% were considered. The sample size calculation showed that a minimum of 15 patients were needed in each group.

The sample selection was based on the following eligibility criteria: presence of Class II malocclusion with minimum severity of ¼ cusp Class II assessed using study models; malocclusion predominantly dental; presence of all permanent teeth up to the first maxillary molars; no supernumerary teeth; moderate dental crowding; absence of previous orthodontic treatment and satisfactory oral health.

The final sample of this retrospective clinical study comprised 70 lateral cephalograms and 70 digitized models of 35 patients with Class II malocclusion selected from the files of Bauru Dental School, University of São Paulo, divided into two groups:

Group 1 consisted of 15 patients (7 male, 8 female), with a mean initial age of 13.30 ± 1.54 years, treated with the Miniscrew-Anchored Distalizer (MAD), followed by fixed

appliances during a mean period of 2.66 ± 1.55 years. The appliance consisted of a cantilever welded in the molar bands and interradicular miniscrews (6.0-mm length, 1.5-mm diameter Morelli ® Sorocaba/SP) for direct anchorage inserted between the second premolar and first molar roots. A nickel-titanium (NiTi) spring was connected to the cantilever and miniscrew, applying 200g of force on each side. On average, molar Class I relationship was obtained in the first 6 months of treatment accompanied by a spontaneous distal migration of the maxillary premolars. After this phase, the distalizer was removed and fixed appliances 0.022" x 0.028" slot Roth prescription (Morelli ™ Sorocaba / SP) were bonded. Leveling and alignment followed the usual wire sequence characterized by an initial 0.014-inch or 0.016-inch NiTi archwires, followed by 0.016, 0.018, 0.020, and 0.019 x 0.025-inch stainless steel archwires. Deep overbite was corrected with accentuated and reversed curves of Spee. Class II intermaxillary elastics were used for finishing and as active retention.¹⁹ A Hawley plate in the maxillary arch and a fixed mandibular canine-to-canine retainer comprised the retention protocol posttreatment.

Group 2 consisted of 20 patients (6 male, 14 female), with a mean initial age of 13.89 ± 1.60 years, treated with maxillary first premolar extractions (XP2) during comprehensive orthodontic treatment, for a mean treatment period of 2.38 ± 0.51 years. Conventional fixed appliances 0.022" x 0.028" slot Roth prescription (Morelli ™ Sorocaba / SP) were used. Leveling and alignment and treatment of deep overbite followed a similar sequence of Group I. Maxillary en masse anterior retraction was performed with elastic chains, from the anterior hook (between lateral incisors and canines) to the hook of the maxillary first molars. An extraoral headgear and Class II elastics were used to reinforce anchorage when necessary. Both groups finished with very acceptable occlusions, normal overbite and overjet, Class I canine relationships, and no posterior crossbites. Figures 1 and 2 depict the intraoral changes in the MAD XP2 groups, respectively.

Each patient was evaluated in the following stages: pretreatment (T1) and posttreatment (T2). The lateral radiographs were digitized with the ScanMaker i800 scanner (Microtek, Hsinchu, Taiwan) and analyzed with the Dolphin Imaging 11.9 software (Patterson Dental Supply, Inc., Chatsworth, California, USA) by a single examiner (T.C.). The software also corrected the image magnification factors (ranging from 6% to 9.8%) since the lateral radiographs were obtained from different radiograph

machines between the evaluations. A customized cephalometric analysis generated 24 variables, 9 angular and 15 linear, for each tracing. Likewise, pre- and posttreatment plaster models of each patient were digitized with the scanner 3Shape R700 (3Shape Ltd, Copenhagen, Denmark). Therefore, the digitized models were analyzed with the software OrthoAnalyzer (3Shape Ltd, Copenhagen, Denmark) by a single examiner (G.Q.S.), following an adapted method previously published.²⁰

Initially, the transversal changes were evaluated measuring the intercanine and intermolar widths at the level of the cusp tips (Fig. 3A). Also, the arch perimeter and arch length were measured (Figs. 3B and C). To analyze the degree of molar rotation, an angle formed by the intersection of two lines was used: A line passing through the most anterior point of the incisive papilla to the tip of the distopalatal cusp of the molar; and another line connecting the tip of the mesiobuccal cusp of the molar with its distopalatal cusp (Fig. 3D).

Error study

After a 30 days interval, twenty-one lateral headfilms (30% of the sample) were randomly selected, retraced, and remeasured by the same examiner (T.C.); and twenty randomly selected models were redigitized and remeasured by the same researcher (G.Q.S.). Random errors were calculated according to Dahlberg's formula²¹ and systematic errors were evaluated with dependent t tests, at $P < 0.05$.²²

Statistical analyses

Normal distribution was evaluated with Shapiro-Wilk tests. Pre- and posttreatment ages and treatment times were compared between groups with t tests. The intergroup comparison regarding sex distribution and Class II malocclusion severity were performed with Chi-square tests.

The pretreatment features and the cephalometric and digitized models' treatment changes (T2-T1) were compared between the groups. T tests were used for the variables with normal distribution, and Mann-Whitney tests were used for variables without normal distribution.

Statistical analyses were performed with SigmaPlot 12.0 software (Systat Software Inc., San Jose, CA), and the results were considered significant at $P < 0.05$.

RESULTS

The random errors of the cephalometric measurements ranged from 0.45° (ANB) to 1.78° (L6-MP $^\circ$) and from 0.22mm (L1-MP) to 0.78mm (U6-PP) for the angular and linear measurements, respectively. Moreover, the random errors of the digitized models analyses ranged from 0.02mm (Mx Arch Perimeter) to 0.23mm (6-6 Md), and from 0.36° (Rotation 26) to 0.65° (Rotation 16) for the transversal and maxillary molar's rotation measurements, respectively. These values indicate excellent reproducibility and can be considered inside the acceptable limits for clinical implication.¹⁷ No systematic errors were found.

The groups were comparable regarding pre- and posttreatment ages, treatment times, sex distribution, and Class II malocclusion severity (Table I). At pretreatment, the MAD group exhibited significantly greater overbite than the XP2 group (Table II). Additionally, no differences were found in the digitized model analyses at pretreatment (Table III).

The intergroup treatment changes comparison showed that the MAD group presented significantly greater intrusion of maxillary incisors (1-PP), mandibular incisors labial tipping (1-NB $^\circ$, IMPA), and mandibular molars mesialization (Table IV). The MAD group showed differences in maxillary molar distalization and improvement in molar relation, while the XP2 presented maxillary molar mesialization and decrease in molar relation (Table IV).

Concerning the digitized models intergroups comparisons the groups behaved differently: the XP2 group showed reduction of the intermolar distance, arc perimeter, and arc length while these variables increased in the MAD group; therefore, presenting significant differences (Table V). Moreover, the molars of the MAD group showed significantly greater distal rotation than the XP2 group (Table V).

DISCUSSION

In this retrospective clinical study, the patients were primarily selected regarding Class II malocclusion severity based on the plaster models analyses (Table I). Therefore, the groups were substantially comparable regarding their pretreatment features, skeletal and dental characteristics. Only the overbite was significantly greater in the MAD group compared to the XP2 group (Table II). Nonetheless, this small difference would not make the comparison unfeasible.

The incorporation of archwires with accentuated and reversed curves of Spee was used to correct the accentuated overbite on the MAD group.²³ This traditional orthodontic mechanics might explain the significantly greater maxillary incisors intrusion (1-PP°) in this group and may have contributed to the mandibular incisor's significantly greater labial tipping compared to the Xp2 group, as previously reported²³ (Table IV).

Another cause for the significant mandibular incisor's labial tipping on the MAD group, may be the use of Class II elastics for finishing purposes and active retention.²⁴ Additionally, the elastic force in the MAD group may likewise be responsible for the significant mandibular molar mesial movement (2.93 ± 2.26 mm) in contrast to the XP2 group (0.82 ± 2.92 mm), which concentrated the tooth movements predominantly in the maxilla (Table IV). The XP2 group showed significant maxillary mesial movement, and there were also significant differences in molar relationship changes because it improved toward Class I in the MAD group while it increased toward Class II in the XP2 group (Table IV).

In general, both approaches effectively obtained similar dentoskeletal effects; therefore, other aspects of the mechanics must be considered: the undesirable effects, patient compliance, and the orthodontists' ability.

The inclusion of digitized models in the present study brought important data regarding both treatments' undesirable effects. A reduction of the intermolar widths, arch perimeter, and arch length in the XP2 group was already expected in response to the molars mesialization and anterior retraction (Table V). It is possible to consider that arch width reduction could decrease the buccal corridors ratio and caused poor smile esthetics. Nonetheless, recent studies demonstrated no deleterious effects between smile esthetics in the extraction and non-extraction protocols.²⁵⁻²⁷

An additional treatment undesirable effect that should be highlighted was the accentuated distal rotation promoted by the MAD (Table V). This biomechanical rotation is explained by the unilateral buccal distal force applied as demonstrated in several distalizing appliances.²⁸⁻³¹ Nonetheless, it could be argued that most Class II patients have their maxillary first molars rotated mesially around their lingual roots and this undesirable effect may be considered beneficial in the final occlusal relationship.³⁰

Usually, the distalization methods apply the force at the crown level, which results in molar tipping and less root movement. Moreover, when the distalizing force is coincident or close to its center of resistance of the maxillary first molars, body movement will prevail, with less need of molar root change during the second phase with fixed appliances.^{11,13,14,17} The MAD was designed with the cantilever hook parallel to the miniscrew and as closest as possible to the center of resistance of the maxillary first molars. Thus, bodily distalization should be expected with the appliance. The final cephalometric results corroborate with this speculation (Table IV).

On the other hand, it has been posited that when the second molar has not yet completed erupted, distalization of the first molar occurs by tipping rather than by bodily movement.³² However, recent clinical studies and systematic review has shown that the effect of upper second and third molar eruption on molar distalization appears to be insignificant. Additionally, no evidence supports the enucleation or early removal of the upper third molars in an adolescent patient in the hope of facilitating molar distalization. Which cost and benefit are low and maybe exaggeratedly aggressive.^{30,33,34} In our clinical observations, patients with the second molar without completed erupted or not presented similar results in molar tipping and body movement (Fig.1). None impacted maxillary second molar was noticed at the posttreatment stage.

Although the tested treatment protocols showed acceptable results some improvements in both approaches could be satisfactory for the orthodontic clinical practice.

In relation to the XP2 protocol, a miniscrew between the posterior maxillary teeth for anchorage reinforcement would be an effective alternative with minimal undesirable effects, more comfortable, esthetic, and predictable than traditional anchorage reinforced with extraoral headgear or Class II elastics. Additionally, even less

requirement for patient cooperation would be necessary, and the screw stability is considerably high ranging from 80% to 95%.^{15,35,36} Likewise, the miniscrew success rate in the MAD group was 93.4%.

Concerning treatment with the MAD appliance, it could be speculated that the use of an extra-alveolar miniscrew inserted in the infrazygomatic crest instead of the interradicular site may be a more effective without the physical barrier between the first molar and second premolar roots. Since much of the side effects were caused by Class II elastics and there would not need to use a Nance button as an anchorage reinforcement. Moreover, leveling and alignment with fixed appliances would be performed simultaneously with maxillary molar distalization, reducing total treatment time.^{37,38}

CONCLUSION

Based on the results of the present study, it can be concluded that:

- Both protocols effectively treated Class II malocclusion promoting dentoalveolar changes. Minimum skeletal and soft tissue effects can be expected.
- Treatment with the Miniscrew-Anchored Distalizer, followed by fixed appliances produced more undesirable effects related to the mandibular incisor's labial tipping and accentuated molar distal rotation. Although, the approach is more conservative since the premolars are maintained.
- Treatment with the XP2 protocol promotes significantly greater reduction of the transversal arch dimensions compared to the MAD protocol.

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FIGURE LEGENDS

Fig. 1 - Pre- and post-distalization and post-treatment intraoral photographs of the Miniscrew-Anchored Distalizer group.

Fig. 2 - Pre- and post-treatment intraoral photographs of the XP2 group.

Fig. 3 - Measurements performed on the digitized models. A) Transversal measurements; B) Arch length; C) Arch perimeter D) Rotational changes.

Fig.1



Fig. 2



Fig.3

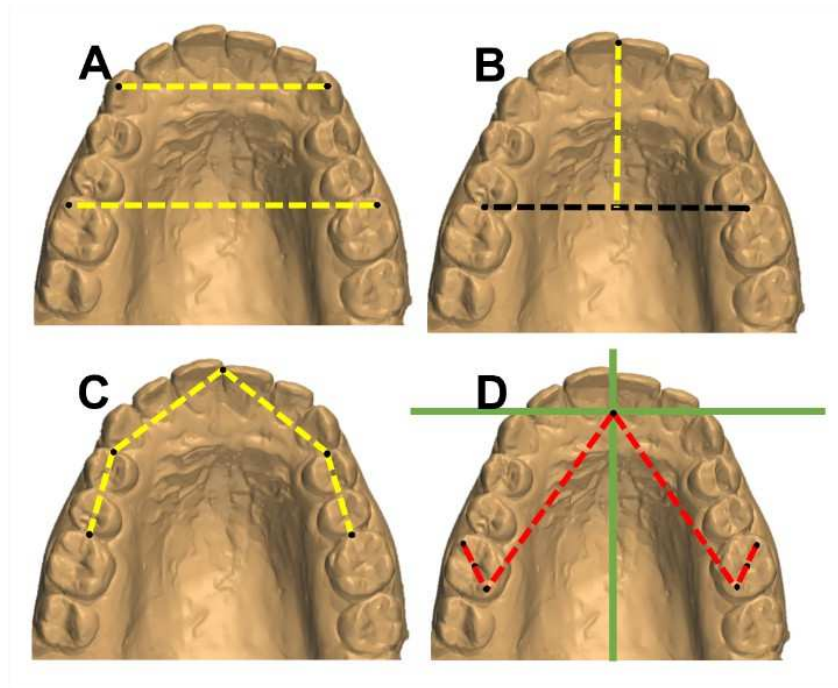


Table I. Intergroup comparison regarding pre- and posttreatment ages, treatment times, sex distribution and Angle Class II severity at pretreatment stage.

Variables	MAD Group n = 15		XP2 Group n = 20		P
	Mean	S.D.	Mean	S.D.	
Pretreatment age (T1)	13.30	1.54	13.89	1.60	0.270 [□]
Posttreatment age (T2)	15.97	1.55	16.27	1.63	0.930 [□]
Treatment time (T2-T1)	2.66	0.34	2.38	0.51	0.081 [□]
Sex					
Male	7		6		0.313 ^{##}
Female	8		14		
Class II malocclusion severity					
¼ Class II	1		2		0.914 ^{##}
½ Class II	7		7		
¾ Class II	5		8		
Full Class II	3		2		

*Statistically significant at $P < 0.05$; [□] *t* test; ^{##} Chi-square test.

Table II. Pretreatment intergroup comparison: Cephalometric measurements.

Variables	MAD Group		XP2 Group		P
	Mean	S.D.	Mean	S.D.	
Maxillary component					
SNA (°)	82.94	4.00	84.78	4.86	0.256 ‡
Co-A (mm)	84.02	4.48	81.46	3.72	0.064 □
Mandibular component					
SNB (°)	78.86	4.30	79.79	4.12	0.509 □
Co-Gn (mm)	111.01	7.07	109.53	4.57	0.676 ‡
Maxillomandibular relationship					
ANB (°)	4.22	1.80	5.11	1.63	0.124 □
Vertical component					
FMA (°)	22.14	5.01	24.20	5.64	0.258 □
Maxillary dentoalveolar component					
1.NA (°)	25.47	4.89	27.02	6.17	0.418 □
1-NA (mm)	4.80	2.27	5.47	2.56	0.414 □
1-PP (mm)	25.76	2.06	26.27	3.37	0.612 ‡
U6-SN (°)	75.51	7.11	74.77	6.04	0.733 □
U6-PP (mm)	16.59	2.18	17.77	1.51	0.058 □
U6-PTV (mm)	22.39	3.59	23.04	4.29	0.628 □
Mandibular dentoalveolar component					
1.NB (°)	27.14	5.26	28.07	5.61	0.611 □
1-NB (mm)	4.88	2.12	5.79	2.15	0.209 □
IMPA (°)	96.08	5.93	95.80	7.19	0.894 □
1-MP (mm)	1.58	0.73	0.89	0.91	0.517 □
L6.MP (°)	84.14	4.17	80.65	5.95	0.373 □
L6-MP (mm)	-1.57	5.92	-1.15	7.24	0.303 □
L6-PTV (mm)	14.58	3.59	15.99	4.06	0.283 □
Dentoalveolar relationships					
Molar Relation (mm)	1.68	1.30	1.10	0.91	0.164 ‡
Overjet (mm)	5.37	1.59	6.00	1.87	0.293 □
Overbite (mm)	3.10	1.40	1.80	1.83	0.025 □ *
Soft tissue profile					
Upper Lip Protrusion (mm)	5.05	0.97	5.13	1.89	0.731 ‡
Lower Lip Protrusion (mm)	2.89	2.04	4.47	2.26	0.036 □

*Statistically significant at $P < 0.05$. □ *t* test; ‡ Mann-Whitney test.

Table III. Pretreatment intergroup comparison with *t* tests: Digitized models

Transversal					
Transversals Distances	XP2 group		DG group		<i>P</i>
	Mean	S.D.	Mean	S.D.	
3-3 Mx (mm)	33.47	2.6	34.35	3.29	0.397
3-3 Md (mm)	27.04	1.43	26.82	2.04	0.711
6-6 Mx (mm)	50.23	3.85	50.09	2.9	0.908 [□]
6-6 Md (mm)	45.09	2.98	44.39	2.68	0.478 [□]
Arch Dimensions					
Mx Arch Perimeter (mm)	74.32	4.32	74.89	4.79	0.715 [□]
Md Arch Perimeter (mm)	64.65	2.9	66.46	4.52	0.159 [□]
Mx Arch Length (mm)	27.79	2.33	27.62	2.76	0.838 [□]
Md Arch Length (mm)	22.98	2.04	23.9	1.98	0.190 [□]
Maxillary Molar's Rotation					
Rotation 16 (°)	63.48	5.35	64,37	5,86	0,646 [□]
Rotation 26 (°)	65.33	5.12	66,96	4,91	0,350 [□]

measurements.

*Statistically significant at $P < 0.05$.

Table IV. Intergroup treatment changes comparison (T2-T1): Cephalometric measurements.

Variables	MAD Group		XP2 Group		P
	Mean	S.D.	Mean	S.D.	
Maxillary component					
SNA (°)	-0.04	1.35	-0.75	0.85	0.060 [□]
Co-A (mm)	1.17	2.70	-0.07	1.39	0.085 [‡]
Mandibular component					
SNB (°)	0.68	1.55	0.27	0.69	0.293 [□]
Co-Gn (mm)	2.47	1.26	2.05	1.17	0.320 [□]
Maxillomandibular relationship					
ANB (°)	-0.54	0.93	-0.76	1.02	0.520 [□]
Vertical component					
FMA (°)	1.20	0.90	1.40	2.77	0.785 [‡]
Maxillary dentoalveolar component					
1.NA (°)	-1.51	7.10	-3.56	5.88	0.358 [‡]
1-NA (mm)	-0.85	2.16	-1.79	2.23	0.220 [□]
1-PP (mm)	1.31	0.98	0.15	1.09	0.003 ^{□*}
U6-SN (°)	1.06	2.37	1.25	5.25	0.895 [□]
U6-PP (mm)	1.26	1.02	1.50	1.37	0.566 [□]
U6-PTV (mm)	-0.6	2.57	3.41	3.24	0.002 ^{□*}
Mandibular dentoalveolar component					
1.NB (°)	6.30	3.00	3.73	3.97	0.044 ^{□*}
1-NB (mm)	1.34	1.34	1.14	1.76	0.708 [□]
IMPA (°)	6.11	4.71	2.22	5.75	0.040 ^{□*}
1-MP (mm)	-0.78	0.50	-0.36	0.85	0.095 [□]
L6.MP (°)	-1.57	5.92	-1.70	7.36	0.957 [□]
L6-MP (mm)	1.95	1.45	1.18	1.79	0.182 [□]
L6-PTV (mm)	2.93	2.26	0.82	2.92	0.027 ^{□*}
Dentoalveolar relationships					
Molar Relation (mm)	-3.18	1.48	2.45	1.50	0.001 ^{‡*}
Overjet (mm)	-2.80	1.75	-3.66	2.27	0.233 [□]
Overbite (mm)	-1.64	1.07	-0.77	1.72	0.095 [□]
Soft tissue profile					
Upper Lip Protrusion (mm)	-1.13	1.24	-0.73	2.02	0.502 [□]
Lower Lip Protrusion (mm)	0.44	1.05	-0.26	1.94	0.210 [□]

*Statistically significant at $P < 0.05$. [□] *t* test; [‡] Mann-Whitney test.

Table V. Intergroup treatment changes comparison (T2-T1) with *t* tests: Digital models measurements.

Transversal					
Transversals Distances	XP2 group		DG group		<i>P</i>
	Mean	S.D.	Mean	S.D.	
3-3 Mx (mm)	0.81	1.98	1.02	2.27	0.773
3-3 Md (mm)	-0.52	1.26	0.22	1.52	0.124
6-6 Mx (mm)	-2.50	2.75	1.21	1.62	0.001 *
6-6 Md (mm)	-0.73	1.84	-0.08	2.09	0.333
Arch Dimensions					
Mx Arch Perimeter (mm)	-13.04	3.54	1.33	2.25	0.001 *
Md Arch Perimeter (mm)	0.59	2.39	0.09	2.44	0.548
Mx Arch Length (mm)	-6.91	2.00	0.44	1.76	0.001 *
Md Arch Length (mm)	0.44	1.70	0.18	1.34	0.633
Maxillary Molar's Rotation					
Rotation 16 (°)	4.26	6.79	8.64	5.97	0.036 *
Rotation 26 (°)	2.25	6.26	7.02	5.31	0.023 *

*Statistically significant at $P < 0.05$.

3 DISCUSSION

3 DISCUSSION

Nowadays, the decision for orthodontic treatment or orthodontic device to be used is increasingly linked to the wishes of the patient or parents. The treatment options to obtain functional and aesthetic results for the same malocclusion in permanent dentition are more comprehensive compared to the past and can be conducted with fixed appliances or removable aligners and associated or not with dental extractions. However, it is the duty of the orthodontist to know scientifically and clinically the skeletal, dental and soft tissue effects of them. So that the decision for proper treatment is made with clarification of the adverse effects of each approach.(PROFFIT; FIELDS; MORAY, 1998)

There are several comparative studies related to the treatment of Class II malocclusion.(HERRERA; HENRIQUES; JANSON; FRANCISCONI *et al.*, 2011; JANSON; DA COSTA BRAMBILLA; HENRIQUES; DE FREITAS *et al.*, 2004; KHAN; FIDA, 2010; MENDES; JANSON; ZINGARETTI JUNQUEIRA-MENDES; GARIB, 2019; PINZAN-VERCELINO; JANSON; PINZAN; DE ALMEIDA *et al.*, 2009) However, few presents cephalometric and model results in the same study. The main purpose of this study was to improve the practice of orthodontic clinic with the results related to cephalometric changes (skeletal, dental and soft tissue), as well as through model analysis (transversal, arc width and rotational).

Considering the study as retrospective, It could be argued that the retrospective characteristic of the study may give rise to the inclusion of bias in the results.(DALZIEL; ROUND; STEIN; GARSIDE *et al.*, 2005) Nevertheless, the sample selection was carried out with the compatibility between age and initial severity of Class II malocclusion as similar as possible to reduce this study design model's inherent biases (table I). This compatibility was confirmed with the results of the pretreatment intergroup comparison, with only the overbite variable showing significant differences between groups (table II).

It is unquestionable the efficiency of the headgear appliance to distalize molars.(BOECLER; RIOLO; KEELING; TENHAVE, 1989; HUBBARD; NANDA; CURRIER, 1994; MELSEN, 1978) However, nowadays, it is no longer esthetically

acceptable, and the total patient compliance in using the appliance, in several cases, could create an uneasy relationship between parents, patient, and doctor. To achieve similar results, as the headgear effects, intraoral distalizers utilizing conventional or indirect skeletally anchorage has been proposed as noncompliance and esthetic alternative, albeit with undesirable anchorage loss effects.(BELLINI-PEREIRA; PUPULIM; ALIAGA-DEL CASTILLO; HENRIQUES *et al.*, 2019; DE ALMEIDA-PEDRIN; HENRIQUES; DE ALMEIDA; DE ALMEIDA *et al.*, 2009; GREC; JANSON; BRANCO; MOURA-GREC *et al.*, 2013) In our finds, the Miniscrew-Anchored Distalizer with direct bone anchorage produced a distal movement of molars and premolars at the same time, with no anchorage loss during molar distalization (Fig. 1 and Table IV).

Furthermore, studies show that treatment with two maxillary premolars extraction is more efficient than that with the extraction of 4 first premolars or the distalization of molars with conventional intraoral distalizers.(DE ALMEIDA-PEDRIN; HENRIQUES; DE ALMEIDA; DE ALMEIDA *et al.*, 2009; JANSON; BARROS; DE FREITAS; HENRIQUES *et al.*, 2007; JANSON; DA COSTA BRAMBILLA; HENRIQUES; DE FREITAS *et al.*, 2004; PINZAN-VERCELINO; JANSON; PINZAN; DE ALMEIDA *et al.*, 2009; PUPULIM; HENRIQUES; JANSON; HENRIQUES *et al.*, 2019) This efficiency could be related to a shorter treatment time because the molar Class II is maintained, with less tooth movement. In our finds, after treatment, the overjet and canine Class I relationship was achieved with no significant differences in treatment time, independent if the mechanics were conducted with direct bone anchorage molar distalization or XP2 protocol.

At pretreatment, Intergroup comparison showed only that the MAD group had a greater overbite than the XP2 group before treatment (Table II). The incorporation of archwires with accentuated and reversed curves of Spee was used to correct the accentuated overbite in more intensity on the MAD group.(CHIQUETO; MARTINS; JANSON, 2008) This traditional orthodontic mechanics could might explain the significantly greater maxillary incisors intrusion ($1-PP^\circ$) in the MAD group at intergroup treatment changes and may have contributed to a the mandibular incisor's labial tipping, as previously reported(CHIQUETO; MARTINS; JANSON, 2008) (Table IV).

An additional treatment side undesirable effect that should be highlighted was the accentuated distal rotation promoted by the MAD, even after the comprehensive treatment with molar distalization. The significant impact of mesiobuccal molar rotation

could not be annulated by the second phase of treatment with fixed appliances compared with the XP2 protocol (Table V). This biomechanical rotation is explained provided by the unilateral buccal distal force applied as demonstrated in several distalizing appliances.(CARRIÈRE, 2004; FORTINI; LUPOLI; GIUNTOLI; FRANCHI, 2004; GHOSH; NANDA, 1996; KELES; SAYINSU, 2000) Nonetheless, it could be argued that usually most Class II patients have their maxillary first molars rotated mesially around their lingual roots and this undesirable effect may be considered a benefit management of the final occlusal relationship.(GHOSH; NANDA, 1996)

Both treatments have no significant skeletal and soft tissue changes, with a slight reduction in SNA ($^{\circ}$), ANB ($^{\circ}$), and Upper Lip Protrusion (mm). The buccal tipping and retraction of the maxillary incisors is related to a posterior displacement of A point.(ANGELIERI; ALMEIDA; ALMEIDA; FUZIY, 2006) The mandibular and vertical components changes could be related to normal growth (Table IV).(RIOLO, 1974)

According to this study's results, Class II patients with greater dentoalveolar than skeletal involvement, with no major complaint of facial esthetics, can be safely treated with the Miniscrew-Anchored Distalizer or XP2 protocol.

4 CONCLUSION

4 CONCLUSIONS

Based on the results of the present study, it can be concluded that:

- Treatment with the Miniscrew-Anchored Distalizer protocol produced more side effects related to maxillary molar's distal rotation (unilateral buccal distal force) and mandibular incisor's vestibular tipping (Class II elastics for finishing procedures and active retention stage).
 - Treatment with XP2 protocol was slightly faster and presented a more significant reduction in the intermolar distance, arc perimeter, and arc length.
 - Both protocols effectively treated Class II malocclusion, and no skeletal or soft tissue changes can be expected.
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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 "COMPARISON OF DIRECT SKELETALLY ANCHORED DISTALIZATION AND TWO PREMOLAR EXTRACTIONS FOR CLASS II TREATMENT" will be included in Dissertation of the student Thales Lippi Ciantelli and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, January 26th, 2021

Thales Lippi Ciantelli
Author

Signature 

José Fernando Castanha Henriques
Author

Signature 

ANNEXES

ANNEX A. Ethics Committee approval, protocol number 24927319.8.0000.5417 (front).

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PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Comparação entre distalização com ancoragem esquelética direta e extração de dois pré-molares para o tratamento da Classe II

Pesquisador: Thales Ciantelli

Área Temática:

Versão: 2

CAAE: 24927319.8.0000.5417

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

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.834.723

Apresentação do Projeto:

Idem parecer 3.718.138

Objetivo da Pesquisa:

Idem parecer 3.718.138

Avaliação dos Riscos e Benefícios:

Idem parecer 3.718.138

Comentários e Considerações sobre a Pesquisa:

Idem parecer 3.718.138

Considerações sobre os Termos de apresentação obrigatória:

Idem parecer 3.718.138


Recomendações:

Recomendações:

1) O CONEP determina que nenhuma pesquisa envolvendo seres humanos seja dispensada de TCLE. Este CEP entende a dificuldade de contato com alguns participantes, especialmente aqueles que terminaram seu tratamento há mais de 2 anos. Assim sendo, recomendo que seja elaborado um TCLE para aqueles participantes que puderem ser contactados pela equipe de pesquisa. Caso não seja possível entrar em contato com algum participante devido à morte, mudança de endereço ou outro motivo, os pesquisadores devem apresentar a justificativa ao CEP nos relatórios de

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Bairro: VILA NOVA CIDADE UNIVERSITARIA **CEP:** 17.012-901
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ANNEX A. Ethics Committee approval, protocol number 24927319.8.0000.5417 (verse).

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Continuação do Parecer: 3.834.723

acompanhamento e final."

Conclusões ou Pendências e Lista de Inadequações:

Sugiro pendência.

Considerações Finais a critério do CEP:

O CEP, reunido ordinariamente no dia 05/02/2020, acata por unanimidade, o parecer COM PENDÊNCIA emitido pelo relator. Encaminha ao pesquisador para as modificações necessárias e atualização do cronograma.

De acordo com a Res. CNS 466/12 e com as Normas Operacionais internas deste CEP, as pendências devem ser respondidas exclusivamente pelo pesquisador responsável no prazo de 30 dias, a contar da data de envio do parecer deste CEP. Após esse prazo o protocolo será arquivado. Solicita-se ainda que as respostas sejam enviadas por meio de ofício, de forma ordenada, conforme os itens das considerações deste parecer, destacando a localização das possíveis alterações realizadas nos documentos do protocolo, com realce no texto, inclusive no TCLE, se for o caso.


Diante do exposto, este CEP manifesta-se por aguardar o atendimento às questões acima para emissão de seu parecer final.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_P ROJETO_1433725.pdf	02/12/2019 11:58:17		Aceito
Outros	Oficio_do_Projeto.pdf	02/12/2019 11:52:43	Thales Ciantelli	Aceito
Outros	TermodeusoArquivo.pdf	02/12/2019 11:49:48	Thales Ciantelli	Aceito
Projeto Detalhado / Brochura Investigador	Projeto.pdf	02/12/2019 11:27:18	Thales Ciantelli	Aceito
Parecer Anterior	PB_PARECER_CONSUBSTANCIADO_ CEP_3718138.pdf	02/12/2019 11:26:13	Thales Ciantelli	Aceito
Declaração de Pesquisadores	declaracao_de_compromisso.pdf	04/11/2019 17:26:37	Thales Ciantelli	Aceito

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

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Continuação do Parecer: 3.834.723

TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	01/11/2019 09:11:35	Thales Ciantelli	Aceito
Declaração de Instituição e Infraestrutura	Estrutura.pdf	01/11/2019 09:06:39	Thales Ciantelli	Aceito
Outros	CheckList.pdf	31/10/2019 10:56:16	Thales Ciantelli	Aceito
Folha de Rosto	folhaderostro.pdf	19/09/2019 18:13:33	Thales Ciantelli	Aceito

Situação do Parecer:
Pendente

Necessita Apreciação da CONEP:
Não

BAURU, 12 de Fevereiro de 2020

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

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ANNEX B. - Random and systematic errors (Dahlberg and t tests): Cephalometric measurements.

Variables	1 ^a Measurement		2 ^a Measurement		Dahlberg	P
	Mean	S.D.	Mean	S.D.		
Maxillary component						
SNA (°)	82.95	5.07	83.03	4.97	0.929	0.789 [□]
A-NPerp (mm)	1.97	3.21	2.11	3.21	0.486	0.925 [□]
Co-A (mm)	83.77	5.43	83.55	5.18	0.613	0.247 [□]
Mandibular component						
SNB (°)	78.14	5.36	78.01	5.05	0.627	0.514 [□]
Pg-NPerp (mm)	-3.90	7.56	-4.10	7.39	0.9	0.473 [□]
Co-Gn (mm)	112.12	5.22	111.98	5.09	0.584	0.436 [□]
Maxillomandibular relationship						
ANB (°)	4.95	1.47	4.94	1.74	0.450	0.922 [□]
Vertical component						
FMA (°)	24.95	6.61	24.87	3.4	0.709	0.967 [□]
Maxillary dentoalveolar component						
1.NA (°)	24.60	6.59	24.77	6.32	0.986	0.583 [□]
1-NA (mm)	3.86	2.19	3.76	2.35	0.545	0.555 [□]
1-PP (mm)	26.58	2.29	26.40	2.44	0.587	0.303 [□]
U6-SN (°)	73.98	7.03	74.11	7.33	1.543	0.784 [□]
U6-PP (mm)	18.09	1.73	17.87	2.10	0.780	0.375 [□]
U6-PTV (mm)	23.31	4.39	23.36	4.21	0.499	0.770 [□]
Mandibular dentoalveolar component						
1.NB (°)	32.00	5.37	32.12	5.93	0.969	0.673 [□]
1-NB (mm)	6.86	2.01	6.77	2.02	0.298	0.349 [□]
IMPA (°)	96.08	5.93	95.80	7.19	0.894 [□]	0.654 [□]
1-MP (mm)	0.60	0.64	0.65	0.68	0.226	0.476 [□]
L6.MP (°)	80.71	4.94	79.90	5.38	1.789	0.137 [□]
L6-MP (mm)	30.07	3.58	29.99	3.62	0.551	0.614 [□]
L6-PTV (mm)	16.13	4.41	16.28	4.26	0.541	0.386 [□]
Dentoalveolar relationships						
Molar Relation (mm)	0.91	2.36	0.78	2.46	0.296	0.159 [□]
Overjet (mm)	3.54	1.95	3.56	1.87	0.279	0.794 [□]
Overbite (mm)	1.20	1.27	1.30	1.20	0.345	0.348 [□]
Soft tissue profile						
Upper Lip Protrusion (mm)	4.24	1.77	4.56	1.69	0.446	0.098 [□]
Lower Lip Protrusion (mm)	4.06	2.43	4.19	2.36	0.331	0.193 [□]

ANNEX C. - Random and systematic errors (Dahlberg and t tests): Digitalized models measurements.

Variables	1 ^a Measurement		2 ^a Measurement		Dahlberg	P
	Mean	S.D.	Mean	S.D.		
Transversal						
Transversals Distances						
3-3 Mx (mm)	34.64	3.76	34.57	3.80	0.12	0.121
3-3 Md (mm)	27.02	1.80	27.02	1.82	0.06	0.926
6-6 Mx (mm)	49.61	4.25	49.52	4.26	0.13	0.061
6-6 Md (mm)	43.95	2.85	43.90	2.69	0.23	0.631
Arch Dimensions						
Mx Arch Perimeter (mm)	71.94	8.46	71.93	8.47	0.02	0.607
Md Arch Perimeter (mm)	66.06	4.11	66.05	4.12	0.03	0.508
Mx Arch Length (mm)	26.39	4.04	26.37	4.04	0.06	0.513
Md Arch Length (mm)	26.94	1.85	23.93	1.85	0.04	0.544
Maxillary Molar's Rotation						
Rotation 16 (°)	65.20	9.93	65.06	6.98	0.65	0.618
Rotation 26 (°)	67.63	6.14	67.59	5.99	0.36	0.780