

UNIVERSIDADE DE SÃO PAULO  
FACULDADE DE ODONTOLOGIA DE BAURU

SILVIO AUGUSTO BELLINI PEREIRA

**Three-dimensional evaluation of the maxillary dentoalveolar changes with three different intraoral distalization systems: Jones Jig, Distal Jet and First Class**

**Avaliação tridimensional das alterações dentoalveolares na maxila com três diferentes sistemas de distalização intrabucal: Jones Jig, Distal Jet e First Class**

BAURU

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Orientador: Prof. Dr. José Fernando Castanha Henriques

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# FOLHA DE APROVAÇÃO



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Aos meus pais Silvio e Inês, meus exemplos de vida e profissão.  
Obrigado por sempre acreditarem em mim e nos meus sonhos.

Ao meu Irmão Lucas, minha eterna inspiração.

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# ABSTRACT

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## ABSTRACT

### Three-dimensional evaluation of the maxillary dentoalveolar changes with three different intraoral distalization systems: Jones Jig, Distal Jet and First Class

**Introduction:** To compare the maxillary dentoalveolar changes of patients treated with three distalization force systems: Jones Jig, Distal Jet and First Class, using digitized models. **Material and Methods:** The sample comprised 51 patients with Class II malocclusion divided into three groups: Group 1 consisted of 17 patients treated with the Jones Jig appliance; Group 2 consisted of 17 patients treated with the Distal Jet, and Group 3 comprised 17 patients treated with the First Class. Initial and post-distalization plaster models of all patients were digitized and evaluated in the OrthoAnalyzer™ software. The initial and post-distalization measurements regarding sagittal, rotational and transverse changes were compared by the One-way Analysis of Variance (ANOVA) and Kruskal-Wallis tests, depending on normality. **Results:** All appliances presented similar amounts of distalization and anchorage loss. The Distal Jet appliance promoted significantly smaller mesial displacement of premolars and greater expansion of posterior teeth. The First Class presented the smallest rotation of the maxillary molars and treatment time. **Conclusion:** The distalizers were effective in correcting a Class II molar relationship, however, a palatal force seems to provide fewer undesirable effects. Additionally, the degree of rotation and expansion is associated with the side of force application.

**Keywords:** Imaging, Three-Dimensional; Rotation; Malocclusion, Angle Class II.

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# RESUMO

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## RESUMO

### **Avaliação tridimensional das alterações dentoalveolares na maxila com três diferentes sistemas de distalização intrabucal: Jones Jig, Distal Jet e First Class**

**Introdução:** Comparar as alterações dentoalveolares na maxila de pacientes tratados com três sistemas distalização: Jones Jig, Distal Jet e First Class, utilizando modelos digitalizados. **Material e Métodos:** A amostra foi composta por 51 pacientes com má oclusão de Classe II divididos em três grupos: o Grupo 1 consistiu de 17 pacientes tratados com aparelho Jones Jig; Grupo 2 formado por 17 pacientes tratados com Distal Jet; e o Grupo 3 compreendeu 17 pacientes tratados com First Class. Modelos de gesso iniciais e pós-distalização de todos os pacientes foram digitalizados e avaliados no software OrthoAnalyzer™. As medidas iniciais e pós-distalização referentes às alterações sagitais, rotacionais e transversais foram comparadas pelos testes de Análise de variância (ANOVA) e Kruskal-Wallis, dependendo da normalidade. **Resultados:** Todos os distalizadores apresentaram quantidades semelhantes de distalização e perda de ancoragem. O distalizador Distal Jet promoveu um deslocamento mesial significativamente menor dos pré-molares e maior expansão dos dentes posteriores. O distalizador First Class apresentou menor rotação dos molares maxilares e tempo de tratamento. **Conclusão:** Os distalizadores foram eficazes na correção da relação molar de Classe II, no entanto, uma força por palatina parece causar menos efeitos indesejáveis. Além disso, o grau de rotação e expansão está associado ao lado da aplicação da força.

**Palavras-chave:** Imagem Tridimensional; Rotação; Má oclusão de Angle Classe II.

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# **1 INTRODUCTION**

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## 1 INTRODUCTION

Class II malocclusion as defined by Angle in 1899 is characterized by a disharmonious mesiodistal relationship between the dental arches, with the lower teeth occluding distally in relation to the upper teeth, producing marked changes mainly in the incisor region. (BRODIE, 1931) Besides the dental characteristics, this malocclusion has a skeletal component related to maxillary protrusion, mandibular retrusion or association of both.

It has a considerable prevalence of approximately 24% for Class II division I and 3.5% for Class II division II, among children aged 11-14 years. (BORZABADI-FARAHANI *et al.*, 2009)

This higher prevalence in the population stimulated researchers to acquire information about its etiology. McNamara evaluated 277 individuals and postulated that Class II malocclusion is not a single clinical entity, but rather a result of the combination of several components. Only a small percentage of the cases studied by McNamara presented skeletal maxillary protrusion in relation to the base of the skull, the mean of the cases had the maxilla in a neutral position. Therefore, mandibular retrusion is the most common contributory factor for the development of this malocclusion. (MCNAMARA, 1981)

Because of its multifactorial etiology, the treatment of Class II malocclusion is challenging, especially when the presence of skeletal retrusion of the mandible and/or vertical growth overload is observed, thus the orthodontist must be aware of the various ways of treatment to achieve the patient's expectations. (MCNAMARA, 1981)

Many treatment approaches and protocols are available to clinicians and orthodontists to correct this anteroposterior discrepancy. They include a variety of extraoral force systems, functional or mechanical orthopedic appliances, intraoral distalizers, and mechanical distal systems with and without the extraction of teeth through the aid of intermaxillary elastics. However, each of these treatment choices differs in their effects on the skeletal and dentoalveolar structures. (KLOEHN, 1961; RUNGE *et al.*, 1999; DE ALMEIDA *et al.*, 2002; RODRIGUES DE ALMEIDA *et al.*,

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2002; JANSON *et al.*, 2004; ANTONARAKIS e KILIARIDIS, 2008; JANSON *et al.*, 2013)

Among the factors influencing these protocols, patient cooperation can be considered a determinant point to reach the goals of the treatment. Thus, systems that require minimal patient collaboration presents great value in orthodontic practice, since the lack of collaboration causes an increase in treatment time and may lead to results that are less than expected. Patient cooperation can be considered the exceptional parameter to the success of orthodontic therapy. (KLAUS *et al.*, 2017)

In this context, the intraoral distalizers present a system that requires minimum patient cooperation, becoming an alternative for the correction of the Class II molar relationship since the beginning of the 70s. These devices include magnetos, nickel-titanium springs and intraoral devices such as Pendulum, Jones Jig, Distal Jet, First Class, among others. (JONES e WHITE, 1992; CARANO *et al.*, 1996; FORTINI *et al.*, 1999; CHAQUES-ASENSI e KALRA, 2001)

These systems are exclusively indicated in cases where the Class II malocclusion is predominantly dental and is expected to be corrected by distalization of the molars with protrusion of the upper anterior teeth; and cases with small skeletal discrepancies where it is possible to perform a dental compensation. In general, they correct the molar relationship in a short period, are easy to install and inexpensive, but do not have orthopedic effects. (ANTONARAKIS e KILIARIDIS, 2008; GREC *et al.*, 2013)

Most of these devices have similar characteristics as they are supported on the upper arch and have an anchorage unit (usually premolars or deciduous molars) and an active unit that varies according to the appliance, but performs mild and continuous forces in the molars and consequently in the anchoring unit.

In 1992, Jones and White developed the Jones Jig appliance, which is a system that includes an active unit commonly called “jig” associated with a nickel-titanium spring and an anchoring unit corresponding to the Nance button. (JONES e WHITE, 1992) The jig is inserted into the first molar tube, in both rectangular and circular slots. The spring is activated to generate the necessary force for distalization of the molars. The system is efficient to promote molar distalization, but significant adverse effects such as linear and angular movement of the anchorage unit to mesial were observed,

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as well as the increase in overjet and lower anterior facial height, which many times are unfavorable for Class II resolution. (PATEL *et al.*, 2009; PATEL *et al.*, 2014) The reciprocal force of the spring sometimes causes a distolingual rotation of the molars, which if significant can produce a posterior crossbite. (RUNGE *et al.*, 1999)

Distolingual rotation of the molars and loss of anchorage led to the development of new devices to minimize these side effects. Carano and Testa in 1996 developed the Distal Jet appliance, which according to the authors, is able to distalize the molars bodily with less inclination because its system of forces is closer to the molar center of resistance. They also state that their anterior anchorage unit remains stable during distalization, and at the end of it, the apparatus itself can be modified in a Nance button as a retainer. (CARANO *et al.*, 1996; BOWMAN, 2016)

The union of the buccal force applied by the Jones Jig with the palatal force of the Distal Jet was idealized by Fortini in 1999, who developed the First Class appliance. An intraoral distalization system with an anchoring unit characterized by a modified Nance button, and a mechanism of forces in the buccal and palatal sides at the same time, in order to minimize rotation of the molars and loss of anchorage. (FORTINI *et al.*, 1999; FORTINI *et al.*, 2004)

The efficiency of these intraoral distalization appliances for Class II correction is well defined in the literature, however, while the distal movement of the molars occurs, inclination effects and anchorage loss are observed. It can be argued that the distal movement of the molars is always accompanied by a degree of inclination and undesirable effects, usually in the premolars. (CHIU *et al.*, 2005; GREC *et al.*, 2013)

The distal angulation of the molars is related to the distance between the point of force application and the center of resistance of the tooth. In the case of the molars, where the center of resistance is close to the trifurcation of the roots, a force applied closer to this center will cause a greater body movement. Therefore, it is possible to soften the inclination movement by positioning the molar tube closer to the cervical and/or applying forces from the buccal side. (KINZINGER *et al.*, 2008; BOWMAN, 2016)

Several studies report the effectiveness of the aforementioned devices in achieving molar distalization, with minimal patient cooperation. (FORTINI *et al.*, 1999; PAPADOPOULOS *et al.*, 2010; PATEL *et al.*, 2014; BOWMAN, 2016) In addition, other

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studies were performed with intraoral distalizers to compare the dentoskeletal effects between them and to find the system that achieved distalization effectively with less undesirable effects. (CHIU *et al.*, 2005; PATEL *et al.*, 2009; VILANOVA *et al.*, 2017)

These studies were based on cephalometric comparisons to obtain their results, however, the advent of three-dimensional imaging for occlusion evaluation stimulated a growing interest of professionals in the dental area about its usefulness in the clinic and research, and exhibited the same quality and accuracy of plaster models. (WAN HASSAN *et al.*, 2016)

The feasibility and accuracy of the digitized models, when compared to the plaster models, are already well described. Studies such as Fleming's in 2010 and Hassan's in 2016 state that the use of the digitized models is a diagnostic alternative with clinical validity when compared with the plaster models. It is reasonable to consider that measurements made by software in digital models are clinically acceptable, and slight differences with respect to measurements in plaster models are clinically insignificant. (WAN HASSAN *et al.*, 2016)

Although the dentoskeletal effects of the intraoral distalizers are well defined by the cephalometric analysis studies, there is still a deficiency in the evaluation of some clinically relevant variables promoted by distalizers, especially regarding rotation of the distalized molars and the transversal changes. (UZUNER *et al.*, 2016) In this context, this study aimed to compare the maxillary dentoalveolar sagittal, rotational and transversal changes of patients treated with three distalization force systems: Jones Jig, Distal Jet and First Class.

# **2 ARTICLE**

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## **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.

## Sagittal, rotational, and transverse changes with three intraoral distalization force systems: Jones Jig, Distal Jet and First Class

### Abstract

**Introduction:** To compare the maxillary dentoalveolar changes of patients treated with three distalization force systems: Jones Jig, Distal Jet and First Class, using digitized models. **Material and Methods:** The sample comprised 51 patients with Class II malocclusion divided into three groups: Group 1 consisted of 17 patients treated with the Jones Jig appliance; Group 2 consisted of 17 patients treated with the Distal Jet, and Group 3 comprised 17 patients treated with the First Class. Initial and post-distalization plaster models of all patients were digitized and evaluated in the OrthoAnalyzer™ software. The initial and post-distalization measurements regarding sagittal, rotational and transverse changes were compared by the One-way Analysis of Variance (ANOVA) and Kruskal-Wallis tests, depending on normality. **Results:** All appliances presented similar amounts of distalization and anchorage loss. The Distal Jet appliance promoted significantly smaller mesial displacement of premolars and greater expansion of posterior teeth. The First Class presented the smallest rotation of the maxillary molars and treatment time. **Conclusion:** The distalizers were effective in correcting a Class II molar relationship, however, a palatal force seems to provide fewer undesirable effects. Additionally, the degree of rotation and expansion is associated with the side of force application.

### Introduction

Class II malocclusion is characterized by an abnormal mesiodistal relationship between the dental arches, with the mandibular teeth occluding distally in relation to the maxillary teeth, producing marked changes.<sup>1</sup> In addition to the dental characteristic, this type of malocclusion may have a skeletal component related to maxillary protrusion, mandibular retrusion or association of both.<sup>2</sup>

Many treatment protocols are available to correct this sagittal discrepancy. They include extraoral traction,<sup>3</sup> functional orthopedic appliances,<sup>4,5</sup> intraoral distalizers,<sup>6-10</sup> and mechanics with and without teeth extraction associated with Class

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II intermaxillary elastics.<sup>11,12</sup> However, each of these treatment choices differ in their effect on the skeletal and dentoalveolar structures.

The intraoral distalizers requires minimum patient cooperation, becoming a common alternative to correct the Class II molar relationship. These devices include magnetos,<sup>13</sup> nickel-titanium (NiTi) springs,<sup>14</sup> Pendulum,<sup>15,16</sup> Jones Jig,<sup>10,17</sup> First Class,<sup>8</sup> Distal Jet,<sup>6</sup> among others.

It could be argued that the design of these appliances may be related to the amount of distalization promoted and possible undesirable effects. Therefore, different changes could be expected with the Jones Jig, that applies a buccal distalization force, the Distal Jet that applies a force from the palatal side, and the First Class which includes buccal and palatal forces.

Previous studies investigated the dentoskeletal effects of distalizers. However, most of them were performed using cephalometric measurements<sup>6,8,10,18,19</sup>. Thus, there is still a deficiency in the evaluation of some clinically relevant variables especially regarding rotation and transverse changes after the use of distalizing appliances.<sup>20</sup> Knowledge of these dentoalveolar effects and the extent of their possible undesirable effects could influence decision-making during treatment planning.

Therefore, the purpose of this study was to compare the maxillary sagittal, rotational and transverse changes of patients treated with three different distalization force systems: Jones Jig, Distal Jet and First Class, using digitized models.

## **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 71639017.0.0000.5417; decision number: 2.600.663).

The sample size calculation was based on an alpha significance level of 5% and a beta of 20%, to detect a mean difference of 2.04 mm, with a standard deviation of 1.41 mm in the sagittal displacement of the maxillary first molar, reported in a previous study.<sup>21</sup>

A minimum of 11 patients were required in each group based on the sample size calculation. Thus, to increase the power of the study 17 patients were included in each group.

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## Sample characteristics

The sample comprised 51 patients (18 male, 33 female) divided into 3 groups, treated at the Department of Orthodontics, Bauru Dental School, University of São Paulo, Brazil. The inclusion criteria were based on the following characteristics: 1. Presence of Class II malocclusion; 2. No severe skeletal discrepancies; 3. A minimum of a one-quarter cusp Class II molar relationship; 4. No severe maxillary and mandibular crowding; 5. No crossbite; 6. Absence of previous orthodontic treatment; 7. Patients with ages between 10 to 16 years.

Group 1 consisted of 17 patients (8 male, 9 female) with a mean initial age of 13.01 years (standard deviation [SD], 1.12 years), treated with the Jones Jig appliance (Fig. 1A). In order to exert a continuous force (125g) to the molars, the appliance was built with a nickel-titanium (NiTi) coil spring (American Orthodontics, Sheboygan, Wisc), activated 5mm every 4 weeks to maintain its effective length. The anchorage unit used was a Nance button attached to the second premolars.<sup>10</sup>

Group 2 comprised 17 patients (4 male, 13 female) with a mean initial age of 12.38 years (SD, 1.39), treated with the Distal Jet appliance (Fig. 1B). The open-coils springs of the appliance were selected to exert 240g of force in patients with the second molars erupted and 180g in those with absent of these teeth. The appliance was reactivated once a month, and after distalization, the Nance button was converted to a Nance holding arch.<sup>6</sup>

Group 3 consisted of 17 patients (6 male, 11 female) with a mean initial age of 13.14 years (SD, 1.41), treated with the First Class appliance (Fig. 1C). The appliance performed forces from the buccal and palatal sides, with activation screws and NiTi coil springs (10mm long) respectively. A modified Nance butterfly shaped button was used as the anchorage unit, and the appliance was activated rotating the screws in a counterclockwise direction once a day.<sup>8,22</sup>

In all three groups, distalization was performed aiming overcorrection until a super-Class I molar relationship was obtained.<sup>23</sup> The mean distalization time was 0.90 years (SD, 0.35); 0.97 years (SD, 0.34); and 0.69 years (SD, 0.21), for the Jones Jig, Distal Jet and First Class appliances respectively.

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## Digitized Models Analysis

Plaster models before (T0) and after molar distalization (T1) from all patients were submitted to 3D surface laser scanning by the 3Shape scanner model R700 (3Shape A/S, Copenhagen, Denmark). The scanner generated three-dimensional images of all plaster models (n=102). Therefore, pre- and post-distalization scans were analyzed with the OrthoAnalyzer™ software (3Shape Ltd, Copenhagen, Denmark), following an adapted method previously described.<sup>24</sup>

A frontal plane, perpendicular to the sagittal plane, and passing through the most anterior point of the incisive papilla was constructed by the software on the digitized models to determine the sagittal changes presented by the incisors, canines, premolars and molars<sup>24</sup> (Fig. 2A). Then, perpendicular lines from the centroid point<sup>25,26</sup> of the teeth to the frontal plane were drawn. Positive values indicated a mesial teeth displacement, while negative values indicated distal displacement.

To quantify the degree of molar rotation, two lines were constructed. One, passing through the most anterior point of the incisive papilla, to the tip of the distopalatal cusp of the maxillary first molar, and another line connecting the tips of the mesiobuccal and distopalatal cusps of the same molar (Fig. 2A). The angle formed by the intersection of these two lines was evaluated.<sup>24</sup> An increase of the angle indicated a distal rotation of the molar during treatment, and the decrease a mesial rotation.

To measure the amount of transversal changes, the sagittal plane was used.<sup>24</sup> Thus, the distance from this plane to the canines, premolars and molars centroids was measured (Fig. 2B). Positive values represented a buccal displacement, and negative values a palatal displacement.

All these measurements were performed on the digitized models before (T0) and after distalization (T1), and the differences (T1-T0) between them were compared.

## Error Study

After a month interval from the first measurements, 20 randomly selected models were redigitized and remeasured by the same researcher (S.A.B.P). The random errors were estimated according to Dahlberg's formula<sup>27</sup>, while the systematic errors were calculated with dependent t tests, at  $P < 0.05$ .<sup>28</sup>

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## Statistical Analysis

The presence of normal distribution was evaluated by Shapiro Wilk tests in the three groups and in both treatment stages (T0 and T1) for all teeth.

Comparability between the groups regarding sex, Class II molar relationship severity distributions and presence or absence of second molars (7s) were analyzed with Chi-square tests. Pre- and posttreatment ages and treatment time intergroup comparability were evaluated with One-way Analysis of Variance (ANOVA), followed by Tukey tests.

Intergroup initial teeth location and treatment changes (T1-T0) were compared with ANOVA, followed by Tukey tests for the teeth with normal distribution, and with Kruskal Wallis tests for those without normal distribution.

All the analyses were performed using Statistica for Windows 7.0 (Copyright Stat Soft, Inc. Tulsa, Okla, USA), with the level of significance set at  $P < 0.05$ .

## Results

The random errors ranged from 0.10 mm to 0.42 mm (sagittal displacement of teeth 24 and 22 respectively),<sup>29</sup> and from 0.89° to 0.92° (rotation of teeth 16 and 26), considered inside the acceptable limits for clinical implication<sup>30,31</sup> (Table I). No systematic errors were found.

The groups were comparable regarding sex, Class II malocclusion severity distributions, presence or absence of second molars (7s), pre- and posttreatment ages (Table II). However, the First Class group presented a significantly smaller treatment time when compared to the Distal Jet group.

Intergroup comparison before treatment showed the left first molar and second premolar significantly more palatally located in the Distal Jet group when compared to First Class group (Table III).

During treatment, the second premolars in the Distal jet group moved distally, while in the Jones Jig and First Class groups a mesial displacement was observed, therefore, demonstrating significant differences (Table IV). The Jones Jig group presented significantly greater mesial displacement of the first premolars when compared with the Distal Jet group.

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There were significant differences during distalization regarding rotation of the first molars between the groups (Table IV). The Jones Jig and First Class groups presented distal rotation, while the Distal Jet group showed a mesial rotation. A significantly different behavior between the groups was also observed in the first molars transversal displacement, with the Jones Jig group resulting in a palatal displacement and the other two groups presenting a buccal displacement. Moreover, the second premolars in the Distal Jet group showed a significantly greater buccal displacement than the Jones Jig and First Class groups.

## Discussion

Previous studies evaluated the dentoskeletal effects of distalizers by means of cephalometric analysis after distalization<sup>7,18</sup> and after orthodontic treatment.<sup>32,33</sup> However, few studies<sup>20,34</sup> evaluated the rotational and transversal dental changes induced by these appliances, especially using distalizers with different sites of force application. Therefore, this study compared three distalization systems, with different characteristics, using digitized models to evaluate the dentoalveolar changes during distalization.

## Sample Characteristics

It could be considered that the retrospective design of this study may give rise to selection bias and other biases.<sup>35</sup> However, the presence of this inherent methodological limitation should be overcome by the great intergroup comparability. The groups were quite similar in terms of sex, Class II malocclusion severity distributions, presence and absence of second molars, pre- and posttreatment ages (Table II).

The treatment time of the groups was inside the limits suggested by previous studies.<sup>9,36</sup> Additionally, the shorter treatment time presented with the First Class appliance was similar to previous reports.<sup>8,37</sup>

At the pretreatment stage, the majority of dental characteristics regarding teeth location was also comparable between the groups (Table III). The first molar and second premolar significantly more palatal located in the Distal Jet group might not

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have interfered in the results since this difference could be considered without clinical significance and did not alter the performance of the distalizers.

### **Sagittal Changes**

The major objective of using intraoral distalizing appliances is to correct the molar relationship by distalizing the molars until a super-Class I is achieved. In this study, all the appliances tested were capable to perform molar distalization efficiently with amounts ranging from 2.93 to 3.78 mm (Table IV). These findings corroborate with other studies that presented similar amounts of distalization.<sup>37-39</sup>

Nevertheless, the effectiveness of these appliances is controversial since their use is commonly associated with undesirable effects such as premolars mesial displacement and incisors protrusion.<sup>9,40</sup> However, in the case of the second premolars, the groups behaved differently, since the second premolars in the Distal Jet group accompanied molar distal movement (Table IV). The anchorage unit of the Distal Jet appliance is supported on the first premolars, therefore, allowing the second premolars to drift distally under the pulling effect of the transseptal fibers.<sup>34,40</sup> Nonetheless, as expected, the first premolars from all groups presented a mesial displacement. The Jones Jig group presented the greater values, similar from other studies.<sup>17,41</sup>

The anterior teeth from all groups presented mild protrusion (Table IV). This anchorage loss can be reflected in a clinically significant increase in the overjet.<sup>37</sup> These findings are suggested in most studies with intraoral distalizing appliances conventionally anchored.<sup>7,17,18,37,40,42</sup> It could be possible that the anchorage unit of the appliances was insufficient to counteract the reciprocal distalization force, and the use of skeletal anchorage is the only possibility to reduce or even prevent anchorage loss.<sup>9,41</sup>

### **Rotational and Transverse Changes**

During distalization, the groups presented significant differences regarding rotation of the molars (Table IV). In the case of the Jones Jig, the force applied from the buccal side promoted a distal rotation.<sup>41,43</sup> Thus, a force from the palatal side promoted a mesial rotation, which was the case for the Distal Jet appliance.<sup>40</sup>

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Furthermore, the First Class group showed distalization without significant rotational effects since the force was applied from both sides. It is reasonable to state that the molars rotation is directly affected by the side of force application, whether from buccal, palatal or both sides.

A recent study compared the buccally acting Karad's Integrated Distalizing System (KIDS) with the palatally acting Frog appliance.<sup>20</sup> The first, promoted a maxillary molar distal rotation ranging from 5.5° to 6.3°, and the Frog appliance showed a mesial rotation ranging from 4.4° to 5.9°. Our findings are consistent with those and showed similar amounts of rotation with a force applied from the buccal (Jones Jig) and palatal (Distal Jet) sides (Table IV). Additionally, another study<sup>34</sup> obtained greater values of mesial rotation, ranging from 7.88° to 8.35° with a skeletonized Distal Jet appliance, suggesting that skeletal anchorage did not improve the control of the molars rotation in this case. Probably rotation is not affected by the type anchorage used.

The distal rotation promoted by the Jones Jig appliance may be a beneficial factor in correcting the Class II molar relationship (Table IV). However, it should be considered that this effect is not always desired. Therefore, using forces from the buccal and palatal sides might neutralize these rotational effects.

Regarding the transversal aspect, the significant changes during distalization were concentrated on the molars and second premolars (Table IV). The Jones Jig group showed a significant palatal displacement of the molars. Probably, the moment of force produced by the coil spring caused the distal rotation and this could reflect in a tendency of posterior crossbite in some teeth.<sup>41</sup> Nevertheless, these transversal changes on the molars did not exceed 1 mm, then it may have minimum clinical significance. On the other hand, the Distal Jet and First Class groups presented buccal displacement of the molars, representing mild expansion, as previously demonstrated.<sup>34,37,40</sup>

The Distal Jet group showed significantly greater buccal displacement of the second premolars when compared to the other groups (Table IV). This was already expected, since the anchorage unit is supported by these teeth in the Jones Jig and First Class appliances, resulting in no transverse changes. Differently, the second premolars in the Distal Jet groups were able to accompany molar distalization and expansion.<sup>34,40</sup>

This study quantified the dentoalveolar changes exclusively during distalization with different designed appliances and may complement the cephalometric studies

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previously performed. However, further research is also required to better understand the treatment effects after the end of the orthodontic treatment.

### **Clinical Relevance**

Orthodontists should understand the dentoalveolar effects promoted by distalizers and their undesirable effects, to comprehend the benefits of associating or not these appliances with skeletal anchorage. Therefore, knowing the effects of several distalizing appliances would facilitate decision making considering the patient's features. Selection of the appliance design must consider cost-effectiveness, fewer undesirable effects, and the patients' assumptions.

### **Conclusions**

- Correction of the Class II molar relationship was effectively obtained with the appliances tested. Similar amounts of distalization were promoted with some degree of undesirable effects.
- The Distal Jet appliance promoted smaller mesial displacement of premolars and greater expansion of posterior teeth.
- The First Class presented the smallest rotation of maxillary molars and treatment time.
- The degree of molar rotation and expansion was associated to the side of force application.

### **Acknowledgment**

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## Figure Legends

Fig. 1 – Pre- and post-distalization intraoral photographs: A) Jones Jig appliance; B) Distal Jet appliance; C) First Class appliance.

Fig. 2 – Measurements performed on the digitized models. Centroid points (black) and reference planes (green). A) Sagittal (blue) and rotational (red) measurements. B) Transverse measurements (yellow).

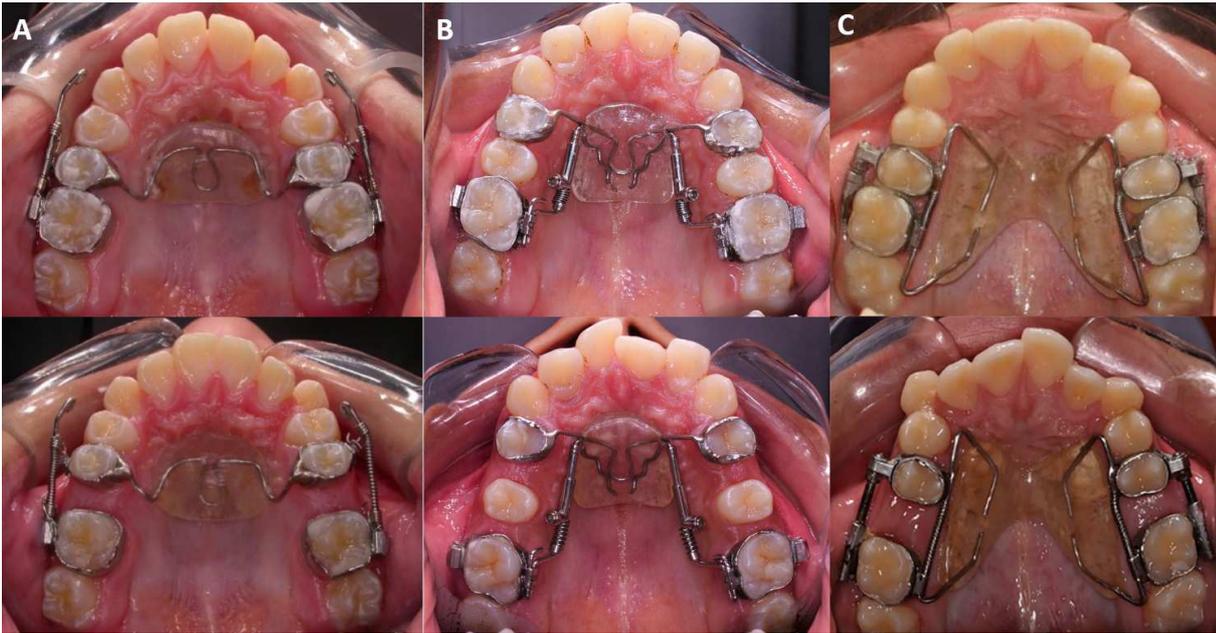


Fig.1

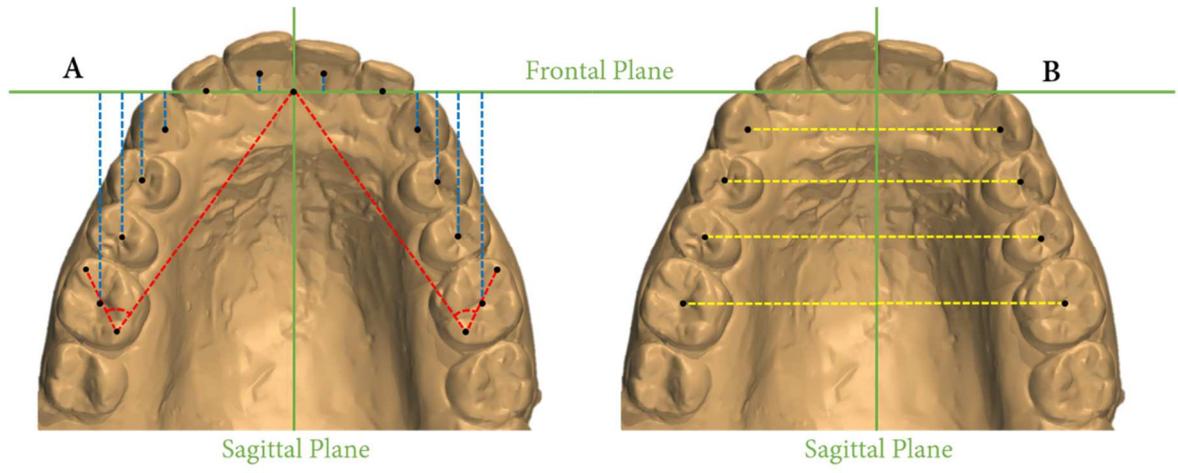


Fig. 2

Table I. Random and systematic errors (Dahlberg and t tests).

Measured Tooth <sup>¥</sup>	Measurement 1		Measurement 2		Dahlberg	P
	Mean	S.D.	Mean	S.D.		
Sagittal						
16	26.96	1.88	27.02	1.85	0.31	0.513
26	27.07	1.86	27.18	1.87	0.26	0.184
15	18.49	4.48	18.57	1.77	0.23	0.240
25	18.49	4.49	18.50	1.76	0.25	0.859
14	11.71	1.55	11.78	1.55	0.17	0.221
24	11.74	1.50	11.76	1.46	0.10	0.552
13	4.01	1.46	4.12	1.34	0.23	0.124
23	4.18	1.90	4.35	1.29	0.31	0.090
12	1.05	0.58	0.93	0.58	0.21	0.060
22	1.10	0.93	1.21	0.96	0.42	0.423
11	3.57	1.07	3.56	1.03	0.28	0.928
21	3.52	1.20	3.65	1.11	0.28	0.148
Rotational						
16	64.13	6.12	64.54	6.39	0.89	0.144
26	63.99	5.56	64.18	6.06	0.92	0.518
Transverse						
16	23.65	1.30	23.72	1.33	0.19	0.308
26	22.90	1.20	22.92	1.19	0.12	0.561
15	20.83	4.78	20.75	1.15	0.20	0.207
25	20.07	4.59	20.06	1.00	0.15	0.783
14	18.31	1.12	18.22	1.08	0.19	0.119
24	17.63	0.90	17.55	0.88	0.25	0.289
13	16.35	3.84	16.19	1.03	0.30	0.094
23	15.98	4.98	15.85	0.84	0.41	0.353

<sup>¥</sup>Teeth were numbered according to the Federation Dentaire Internationale (FDI) World Federation notation.<sup>29</sup>

Table II. Intergroup comparison of sex, Class II malocclusion severity distributions, presence or absence of second molars (7s), pre- and posttreatment ages, and treatment times.

Variable	Group 1 - Jones Jig n = 17 (%)		Group 2 - Distal Jet n = 17 (%)		Group 3 - First Class n = 17 (%)		P
Sex							
Male	8 (47)		4 (24)		6 (35)		0.351 <sup>€</sup>
Female	9 (53)		13 (76)		11(65)		
Class II malocclusion severity							
¼ Cusp Class II	7 (41)		7 (41)		8 (47)		0.843 <sup>€</sup>
½ Cusp Class II	4 (23)		7 (41)		4 (23)		
¾ Cusp Class II	3 (18)		1 (6)		3 (18)		
Full-Cusp Class II	3 (18)		2 (12)		2 (12)		
Second Molars (7s)							
Presence	15 (88)		14 (82)		13(77)		0.667 <sup>€</sup>
Absence	2 (12)		3 (18)		4(23)		
	Mean	S.D.	Mean	S.D.	Mean	S.D.	
Pretreatment age	12.99	1.12	12.38	1.39	13.14	1.41	0.217 <sup>†</sup>
Posttreatment age	13.89	1.27	13.35	1.38	13.83	1.41	0.457 <sup>†</sup>
Treatment time	0.90 <sup>AB</sup>	0.35	0.97 <sup>A</sup>	0.34	0.69 <sup>B</sup>	0.21	0.027 <sup>†*</sup>

Capital letters indicate statistically significant differences ( $P < 0.05$ ).

<sup>€</sup>Chi-Square tests.

<sup>†</sup>One-way Analysis of Variance tests.

Table III. Pretreatment intergroup comparison (One-way Analysis of Variance and Kruskal-Wallis tests).

Measured Tooth <sup>¥</sup>	Jones Jig		Distal Jet		First Class		P
	Mean	S.D.	Mean	S.D.	Mean	S.D.	
Sagittal							
16	27.00	2.61	27.31	2.11	27.54	1.91	0.780 <sup>†</sup>
26	27.49	1.98	27.43	1.94	28.00	2.04	0.656 <sup>†</sup>
15	18.36	2.33	18.97	1.65	18.90	1.92	0.628 <sup>††</sup>
25	18.82	1.77	19.12	1.53	19.34	2.14	0.717 <sup>†</sup>
14	11.74	1.97	12.23	1.42	11.89	1.68	0.698 <sup>†</sup>
24	11.99	1.48	12.29	1.28	12.32	1.82	0.793 <sup>†</sup>
13	3.96	1.64	4.24	1.34	4.27	1.82	0.843 <sup>†</sup>
23	4.38	1.22	4.51	1.49	4.82	1.71	0.696 <sup>†</sup>
12	1.23	1.11	0.81	0.53	1.20	1.16	0.660 <sup>††</sup>
22	0.90	0.74	0.76	0.57	1.15	0.93	0.424 <sup>††</sup>
11	3.50	1.22	3.26	1.11	3.54	0.95	0.717 <sup>†</sup>
21	3.75	1.00	3.03	1.09	3.42	0.87	0.119 <sup>†</sup>
Rotational							
16	61.69	5.93	60.70	4.17	63.75	5.83	0.191 <sup>††</sup>
26	61.94	6.54	62.65	3.54	64.38	3.58	0.317 <sup>†</sup>
Transverse							
16	23.10	1.62	22.66	1.57	23.64	1.28	0.173 <sup>†</sup>
26	22.71 <sup>AB</sup>	1.41	21.94 <sup>A</sup>	1.17	23.20 <sup>B</sup>	1.15	0.017 <sup>††*</sup>
15	20.46	1.50	19.90	1.26	20.78	1.24	0.169 <sup>†</sup>
25	20.06 <sup>AB</sup>	1.52	19.38 <sup>A</sup>	0.90	20.24 <sup>B</sup>	0.96	0.021 <sup>††*</sup>
14	17.80	1.54	17.46	1.20	18.32	1.29	0.187 <sup>†</sup>
24	17.63	1.51	17.15	1.00	17.91	0.99	0.078 <sup>††</sup>
13	16.58	1.20	16.11	1.20	16.21	1.25	0.542 <sup>†</sup>
23	16.12	0.93	15.75	0.96	15.99	0.97	0.556 <sup>†</sup>

<sup>¥</sup>Teeth were numbered according to the Federation Dentaire Internationale (FDI) World Federation notation.<sup>29</sup>

Capital letters indicate statistically significant differences ( $P < 0.05$ ).

<sup>†</sup>One-way Analysis of Variance tests.

<sup>††</sup>Kruskal-Wallis tests.

Table IV. Intergroup treatment changes comparison (One-way Analysis of Variance and Kruskal-Wallis tests).

Measured Tooth <sup>‡</sup>	Jones Jig		Distal Jet		First Class		P
	Mean	S.D.	Mean	S.D.	Mean	S.D.	
Sagittal							
16	-3.52	1.96	-3.42	1.50	-3.04	1.40	0.668 <sup>†</sup>
26	-3.78	1.50	-3.10	1.21	-2.93	1.03	0.222 <sup>††</sup>
15	2.58 <sup>A</sup>	1.37	-1.47 <sup>B</sup>	1.34	1.49 <sup>A</sup>	0.99	0.000 <sup>†*</sup>
25	2.57 <sup>A</sup>	1.19	-1.48 <sup>B</sup>	1.15	1.73 <sup>A</sup>	0.87	0.000 <sup>†*</sup>
14	2.43 <sup>A</sup>	1.10	1.33 <sup>B</sup>	1.23	1.68 <sup>AB</sup>	1.20	0.027 <sup>†*</sup>
24	2.45 <sup>A</sup>	1.05	1.40 <sup>B</sup>	1.28	2.01 <sup>AB</sup>	0.90	0.025 <sup>†*</sup>
13	1.62	0.79	1.15	1.34	1.52	1.48	0.570 <sup>†</sup>
23	1.98	0.94	1.37	1.27	1.92	1.02	0.245 <sup>†</sup>
12	0.68	0.85	0.67	1.03	0.67	1.48	0.801 <sup>††</sup>
22	0.91	0.97	1.13	1.37	0.78	1.09	0.690 <sup>††</sup>
11	0.28	0.67	0.28	0.96	0.32	0.79	0.984 <sup>†</sup>
21	0.56	0.69	0.21	0.80	0.30	0.48	0.297 <sup>†</sup>
Rotational							
16	6.47 <sup>A</sup>	4.76	-3.36 <sup>B</sup>	4.11	1.76 <sup>C</sup>	2.86	0.000 <sup>††*</sup>
26	5.65 <sup>A</sup>	5.56	-4.25 <sup>B</sup>	5.04	0.05 <sup>C</sup>	3.44	0.000 <sup>†*</sup>
Transverse							
16	-0.47 <sup>A</sup>	0.74	1.90 <sup>B</sup>	0.74	0.91 <sup>B</sup>	0.80	0.000 <sup>†*</sup>
26	-0.82 <sup>A</sup>	1.14	1.65 <sup>B</sup>	1.02	0.99 <sup>B</sup>	0.99	0.000 <sup>††*</sup>
15	0.09 <sup>A</sup>	0.50	0.93 <sup>B</sup>	0.48	0.08 <sup>A</sup>	0.72	0.000 <sup>†*</sup>
25	0.04 <sup>A</sup>	0.52	0.62 <sup>B</sup>	0.72	0.06 <sup>A</sup>	0.85	0.036 <sup>†*</sup>
14	-0.19	0.86	0.22	0.57	-0.26	0.71	0.111 <sup>†</sup>
24	-0.01	0.67	-0.14	0.63	-0.04	0.50	0.812 <sup>†</sup>
13	0.14	0.51	0.13	0.58	-0.17	0.94	0.360 <sup>†</sup>
23	-0.05	0.68	0.19	0.46	0.26	0.58	0.279 <sup>†</sup>

<sup>‡</sup>Teeth were numbered according to the Federation Dentaire Internationale (FDI) World Federation notation.<sup>29</sup>

Capital letters indicate statistically significant differences ( $P < 0.05$ ).

<sup>†</sup>One-way Analysis of Variance tests.

<sup>††</sup>Kruskal-Wallis tests.



# **3 DISCUSSION**

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### 3 DISCUSSION

Most of the studies evaluating molar distalization were performed using cephalometric analysis. (FORTINI *et al.*, 2004; CHIU *et al.*, 2005; PATEL *et al.*, 2009; PAPADOPOULOS *et al.*, 2010; GREC *et al.*, 2013; VILANOVA *et al.*, 2017) However, this approach is incapable of evaluating some clinically relevant variables that may influence decision making in orthodontic treatment. Variables regarding rotation of teeth and transversal treatment changes may be better understood by means of models analyses. (NALCACI *et al.*, 2015)

Thus, this study compared with digitized models the dentoalveolar treatment changes during distalization promoted by three different distalization systems. To the author's knowledge, this is the first study to directly compare three different distalization force systems, with an applied force from the buccal, palatal or both sides using digitized models.

This clinical retrospective study evaluated a sample of 51 patients treated in the Department of Orthodontics of Bauru Dental School. It could be argued that the retrospective characteristic of the study may give rise to the inclusion of bias in the results. (DALZIEL *et al.*, 2005) Nonetheless, the study design limitation was overcome by the great intergroup comparability presented in the sample.

The groups were comparable regarding sex, Class II malocclusion severity distributions, presence and absence of second molars, pre- and posttreatment ages (Table II). Although, the groups presented significant differences in treatment time, with the First Class appliance presenting a significantly shorter treatment time. Similar findings have been previously reported. (FORTINI *et al.*, 2004; PAPADOPOULOS *et al.*, 2010)

At pretreatment, most of the dental characteristics were similar between the groups (Table III). The significant differences regarding the transversal position of the left first molar and second premolar may not affect the results of this study since this difference do not alter the performance of the distalizers.

All the appliances evaluated were able to perform molar distalization with average amounts of 3.62mm, 3.26mm, and 2.98mm for the Jones Jig (JJ), Distal Jet

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(DJ) and First Class (FC) appliances, respectively (Table IV). These values are similar to other studies that evaluated distalization with lateral radiographs. (CHIU *et al.*, 2005; PATEL *et al.*, 2009; PAPADOPOULOS *et al.*, 2010) Moreover, it is common knowledge that these distalizers promote undesirable effects, generally characterized by the premolars mesial displacement and loss of anchorage. (ANTONARAKIS e KILIARIDIS, 2008; GREC *et al.*, 2013)

In this study, the second premolars behaved differently between the groups (Table IV). In the Distal Jet group, the second molars accompanied distalization movement of the molars. Since the anchorage unit in the DJ is supported by the first premolars, the second premolars are able to drift distally, which is not observed in the JJ and FC appliances, as they use the second premolars to support the anchorage unit. (CARANO *et al.*, 1996; BOWMAN, 2016)

The reciprocal distalization force promoted in the anchorage unit also affects the anterior teeth. All groups presented mild protrusion of the incisors and canines (Table IV). These findings corroborate with other previous studies. (FORTINI *et al.*, 2004; KINZINGER *et al.*, 2008; PATEL *et al.*, 2009; PAPADOPOULOS *et al.*, 2010; BOWMAN, 2016) It can be argued that any conventionally anchored distalizer is not absent of undesirable effects.

During distalization, significant differences were encountered regarding the molars rotation and transversal changes (Table IV). The Jones Jig appliance promoted a distal rotation of the molars. Therefore, considering that the majority of the Class II patients present the maxillary molars mesially rotated, this effect was positive. (JONES e WHITE, 1992) However, in some cases the amount of force applied also delivered some undesirable constriction of the intermolar width. (JONES e WHITE, 1992; RUNGE *et al.*, 1999)

In this context, the Distal Jet appliance applies the force from the palatal side promoting molars distal rotation, increasing intermolar width, as previously reported. (CARANO *et al.*, 1996; CHIU *et al.*, 2005; BOWMAN, 2016)

Although the First Class group presented some degree of molar rotation and expansion, it was considered significantly smaller to present clinical implications. (PAPADOPOULOS *et al.*, 2010) It is reasonable to affirm that the amount of maxillary

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first molar expansion and rotation could be modulated by individualizing the appliance construction. (BOWMAN, 2016)

This recent findings associated with the cephalometric studies can improve the knowledge regarding the use of conventionally anchored intraoral distalizing appliances and suggest that new studies evaluating distalizers with skeletal anchorage should be performed. The skeletal anchorage devices may play an important role in the side effects reduction regarding the mesial displacement of premolars and loss of anchorage. (GREC *et al.*, 2013)

Orthodontists should understand the dentoalveolar effects promoted by distalizers and their undesirable effects, to comprehend the benefits of associating or not these appliances with skeletal anchorage. Therefore, knowing the effects of several distalizing appliances would facilitate the decision for the ideal treatment alternative considering the patient's features.

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# **4 CONCLUSION**

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## **4 CONCLUSIONS**

Based on the results of this study, it could be concluded that:

- Correction of the Class II molar relationship was effectively obtained with the appliances tested. Similar amounts of distalization were promoted with some degree of undesirable effects.
  - The Distal Jet appliance promoted smaller mesial displacement of premolars and greater expansion of posterior teeth.
  - The First Class presented the smallest rotation of maxillary molars and had the smallest treatment time.
  - The degree of molar rotation and expansion was associated to the side of force application.
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# APPENDIX

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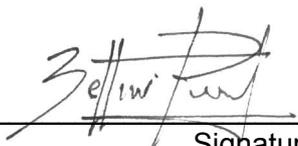


**APPENDIX A - DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN  
DISSERTATION/THESIS**

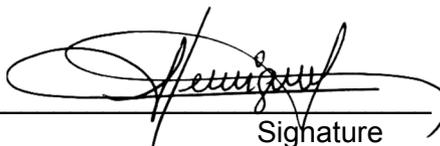
We hereby declare that we are aware of the article “Three-dimensional evaluation of the maxillary dentoalveolar changes with three different intraoral distalization systems: Jones Jig, Distal Jet and First Class” will be included in Dissertation of the student Silvio Augusto Bellini Pereira and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, December 2nd, 2018.

Silvio Augusto Bellini Pereira  
Author

  
Signature

José Fernando Castanha Henriques  
Author

  
Signature



# **ANNEXES**

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**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 DA EMENDA**

**Título da Pesquisa:** Avaliação tridimensional das alterações dentoalveolares na maxila com três diferentes sistemas de distalização intrabucais: Jones Jig, Distal Jet e First Class

**Pesquisador:** Silvio Bellini

**Área Temática:**

**Versão:** 2

**CAAE:** 71639017.0.0000.5417

**Instituição Proponente:** Universidade de Sao Paulo

**Patrocinador Principal:** Financiamento Próprio

**DADOS DO PARECER**

**Número do Parecer:** 2.600.663

**Apresentação do Projeto:**

Introdução: O tratamento conservador da má oclusão de Classe II por meio da distalização de molares superiores com aparelhos fixos intrabucais tem demonstrado excelentes resultados sem produção de efeitos ortopédicos e com mínima necessidade de colaboração do paciente. Sabe-se que efeitos indesejados estão associados a esta mecânica, como a angulação distal acentuada dos molares e a perda de ancoragem anterior. Porém, não há evidências quantificando a movimentação e rotação dos molares utilizando avaliação tridimensional dos modelos entre diferentes distalizadores intraorais. Objetivos: Avaliar e comparar, através da análise tridimensional (3D), as alterações dentoalveolares na maxila de jovens com má oclusão de Classe II tratados com três sistemas de distalização: Jones Jig, Distal Jet e First Class. Material e Métodos: A amostra consistirá de 51 pacientes com má oclusão de Classe II. Divididos em três grupos: O Grupo 1 (n=17) formado por pacientes tratados com o Jones Jig; o Grupo 2 (n=17) composto por pacientes tratados com o Distal Jet; e o Grupo 3 (n=17) por pacientes tratados com o First Class. Modelos de gesso iniciais e pós-distalização de todos os pacientes serão digitalizados através de um scanner 3D 3Shape R700 e em seguida será feita a mensuração e

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

Continuação do Parecer: 2.600.663

quantificação do deslocamento anteroposterior e transversal dos dentes e avaliada a rotação dos molares pelo software OrthoAnalyser™ 3D, seguida da comparação estatística entre os resultados obtidos.

**Objetivo da Pesquisa:**

Emenda - Avaliar e comparar, através da análise tridimensional (3D), as alterações dentoalveolares na maxila de jovens com má oclusão de Classe II tratados com três sistemas de distalização: Jones Jig, Distal Jet e First Class.

**Avaliação dos Riscos e Benefícios:**

Riscos: Riscos da perda de documentação e quebra de modelos de gesso também serão evitados pelo manuseio cuidadoso e sistemático por parte do pesquisador

Benefícios: Esta pesquisa trará como benefício principal apontar o distalizador intrabucal dentre os três testados, que soluciona a relação molar de Classe II de maneira mais eficiente (maior distalização em menor tempo) e com menos efeitos colaterais nos outros dentes. Facilitando a escolha de qual distalizador usar em âmbito clínico.

**Comentários e Considerações sobre a Pesquisa:**

A pesquisa está recebendo uma emenda com duas alterações:

- mudança do título
- acréscimo de 2 casos (prontuários) a mais em cada um dos três grupos analisados

**Considerações sobre os Termos de apresentação obrigatória:**

Todos os termos foram apresentados

**Conclusões ou Pendências e Lista de Inadequações:**

Retirar dos riscos, os que são relacionados ao pesquisador e deixar somente os relacionados aos dados de prontuário e modelo dos pacientes.

**Considerações Finais a critério do CEP:**

A emenda apresentada pelo(a) pesquisador(a) foi considerada APROVADA na reunião ordinária do CEP de 11/04/2018, com base nas normas éticas da Resolução CNS 466/12. No entanto sugere-se a adequação dos riscos, conforme mencionado 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.

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

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USP



Continuação do Parecer: 2.600.663

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_1086164_E1.pdf	22/03/2018 14:25:13		Aceito
Outros	CartaEncaminhamentoEmenda.pdf	22/03/2018 14:14:48	Silvio Bellini	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoDissertacaoEmenda.pdf	22/03/2018 14:13:55	Silvio Bellini	Aceito
Folha de Rosto	FolhaDeRostoEmenda.pdf	22/03/2018 14:06:38	Silvio Bellini	Aceito
Outros	Encaminhamento.pdf	18/07/2017 17:30:21	Silvio Bellini	Aceito
Outros	QuestionarioTecnico.pdf	18/07/2017 17:29:11	Silvio Bellini	Aceito
Declaração de Pesquisadores	DeclaracaoCompromisso.pdf	18/07/2017 17:27:49	Silvio Bellini	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	DispensaTCLE.pdf	18/07/2017 17:23:01	Silvio Bellini	Aceito

**Situação do Parecer:**

Aprovado

**Necessita Apreciação da CONEP:**

Não

BAURU, 16 de Abril de 2018

**Assinado por:**

**Ana Lúcia Pompéia Fraga de Almeida  
(Coordenador)**

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**ANNEX B. Patient's informed consent exoneration (front).****Universidade de São Paulo  
Faculdade de Odontologia de Bauru****Departamento Odontopediatria, Ortodontia e Saúde Coletiva  
Disciplina de Ortodontia****DISPENSA DE TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO E TERMO DE ASSENTIMENTO**

Solicitamos ao Comitê de Ética em Pesquisa, FOB-USP, a dispensa do Termo de Consentimento Livre e Esclarecido e Termo de Assentimento, do projeto de pesquisa **“Avaliação tridimensional das alterações dentoalveolares na maxila com três diferentes sistemas de distalização intrabucal: Jones Jig, Distal Jet e First Class”**, de autoria de *Silvio Augusto Bellini Pereira* sob a orientação do *Prof. Dr. José Fernando Castanha Henriques*.

Tal solicitação justifica-se pelo fato da amostra ser retrospectiva. Os prontuários estão sob os cuidados da disciplina de Ortodontia do Departamento de Odontopediatria, Ortodontia e Saúde Coletiva. Estes prontuários estão no acervo desde 1973, constituindo uma dificuldade o contato com os pacientes devido ao tempo decorrido desde o tratamento feito até a data presente. Vale ressaltar que os pacientes, quando atendidos da clínica de Ortodontia, assinam a “Autorização para Diagnóstico e/ou Tratamento Ortodôntico”, a qual aprova tanto a execução do tratamento quanto seu uso para “quaisquer fins de ensino e de divulgação em jornais e/ou revistas científicas do país e do exterior”, desta forma aprova-se também o uso dos dados do seu prontuário para o ensino em pesquisas científicas.

A dispensa do termo de Assentimento se deve ao fato de os pacientes da amostra, no momento da execução do exame, serem tanto menores de 18 anos quanto adultos, não sendo diferenciado para a pesquisa, como critério de inclusão ou exclusão. Tais pacientes também foram autorizados pelo responsável no documento “Autorização para Diagnóstico e/ou Tratamento Ortodôntico”. Os nomes e dados pessoais dos pacientes não serão divulgados em nenhum momento, mantendo desta forma o sigilo profissional (Artigo 9º do Código de Ética Odontológico) e a privacidade dos participantes da pesquisa durante todas as fases e assumimos o compromisso de cumprir as exigências contidas na Resolução CNS Nº 466, de 12.12.12.

Bauru, 07 de julho de 2017.

Silvio Augusto Bellini Pereira  
Orientado

Prof. Dr. José Fernando Castanha Henriques  
Orientador