UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

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Changes produced by the pendulum appliance with skeletal anchorage and comparison with conventional pendulum appliance

Alterações produzidas com o aparelho pêndulo com ancoragem esquelética e comparação com o aparelho pêndulo convencional

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Orientador: Prof. Dr. Guilherme Janson

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ABSTRACT

CHANGES PRODUCED BY THE PENDULUM APPLIANCE WITH SKELETAL ANCHORAGE AND COMPARISON WITH CONVENTIONAL PENDULUM APPLIANCE

The purposes of these investigations were firstly to evaluate the dentoalveolar, skeletal and soft tissue effects obtained with the bone-anchored pendulum appliance (BAPA) in patients with Class II malocclusion and secondly, to compare these effects with the conventional pendulum appliance (CPA). A sample of 18 patients (14 females; 4 males) with a mean age of 14.01 years (S.D 1.08) with Class II malocclusion treated with BAPA as distalizer device before fixed appliance in Orthodontic Department at the Dental School, University of São Paulo City. Lateral headfilms were taken at the beginning of treatment (T0) and at the end of distalization period (T1), measured and then statistically analyzed. Only the active distalization period was evaluated. The comparison group was composed by 18 patients (14 females; 4 males) with a mean age of 13.61 years (S.D 1.24) with the same malocclusion treated with CPA before fixed appliance in Orthodontic Department at Bauru Dental School, University of São Paulo. To evaluate the effects in this sample was used the same methodology abovementioned. Then, to compare changes between groups, the sample treated with CPA was named Group 1 (G1), and the sample treated with BAPA was named Group 2 (G2). The average distalization period was 5.76 and 6.16 months, respectively for G1 and G2. Both groups were compatibilized regarding initial age, treatment time, severity of Class II malocclusion and initial cephalometric characteristics. Intragroup comparisons were performed using dependent t tests and intergroup comparisons were performed using t tests. In G2 there was significant increase in the lower anterior face height, molar distalization, distal tipping and intrusion of the first and second maxillary molars. The first premolars had significant distalization and extrusion. Overbite significantly decreased and molar relationship was significantly improved. Comparing the groups, there were significantly greater maxillary first molar distalization, distal tipping and intrusion in G2 compared to G1. The maxillary incisors were labially tipped in G1 and lingually tipped in G2. The first premolars were distalized in G2 while were mesialized in G1. G1 showed a significantly greater overjet increase and smaller Class II molar relationship correction than G2. Distalization of the maxillary

molars was successfully achieved in both groups, but using the BAPA several advantages were observed including exclusive maxillary molars distalization, spontaneous distal movement of the maxillary premolars, no undesirable side effects in the maxillary incisors and lips and establishment of a Class I molar relationship.

Keywords: Molar distalization. Pendulum appliance. Skeletal anchorage.

RESUMO

ALTERAÇÕES PRODUZIDAS PELO APARELHO PÊNDULO COM ANCORAGEM ESQUELÉTICA E COMPARAÇÃO COM O APARELHO PÊNDULO CONVENCIONAL

Os propósitos destas pesquisas foram primeiramente avaliar as alterações esqueléticas, dento-alveolares e tegumentares obtidas com o aparelho pêndulo com ancoragem esquelética (BAPA) em pacientes com má oclusão Classe II e, posteriormente compará-los com os efeitos produzidos com o aparelho pêndulo com ancoragem convencional (CPA). A amostra composta de 18 pacientes (14 meninas;4 meninos) com idade média de 14.01 (D.P. 1.08) com má oclusão de Classe II tratados com BAPA como dispositivo distalizador antes do aparelho fixo, no Departamento de Ortodontia da Faculdade de Odontologia da Universidade Cidade de São Paulo. Telerradiografias laterais foram tomadas no início do tratamento (T0) e no final da distalização (T1), mensuradas e posteriormente analisadas estatisticamente. Apenas o período da distalização ativa foi avaliado. O grupo controle foi composto de 18 pacientes (14 meninas;4 meninos) com idade média de 13.61 (D.P. 1.24) com a mesma má oclusão tratados com CPA como dispositivo distalizador antes do aparelho fixo, no Departamento de Ortodontia da Faculdade de Odontologia de Bauru, Universidade de São Paulo. Para avaliar os efeitos desta amostra foi utilizada a mesma metodologia acima mencionada. Posteriormente, para comparar as alterações entre os grupos, a amostra tratada com CPA foi denominada Grupo 1 (G1), e a amostra tratada com BAPA denominada Grupo 2 (G2). O tempo médio de distalização foi 5.76 e 6.16 meses, no G1 e G2 respectivamente. Ambos os grupos foram compatibilizados em relação à idade inicial, tempo de tratamento, severidade da má oclusão de Classe II e características cefalométricas iniciais. A comparação intra-grupo foi realizada com teste t dependente, e a comparação inter-grupos foi realizada com o teste t. Em G2 houve aumento significante da altura facial anteroinferior, distalização molar, inclinação distal e intrusão significante dos primeiros e segundos molares superiores. Os primeiros pré-molares apresentaram distalização e extrusão significantes. A sobremordida diminuiu e a relação molar melhoraram significativamente. Comparando as alterações do tratamento entre grupos, foram significativamente maiores a distalização, inclinação distal e intrusão

dos primeiros molares no G2 comparados ao G1. Os incisivos superiores inclinaram para vestibular no G1, e ligeiramente retroinclinaram para lingual no G2, além disso os primeiros pré-molares foram distalizados no G2, porém foram mesializados no G1. O Grupo 1 apresentou aumento significativamente maior da sobressaliência, e menor correção da relação molar de Classe II do que G2. A distalização dos molares superiores foi obtida com sucesso em ambos os grupos, entretanto, utilizando o BAPA observou-se várias vantagens, tais como: Distalização exclusiva dos molares superiores; movimento distal espontâneo dos pré-molares superiores; sem efeitos colaterais indesejáveis nos incisivos superiores e nos lábios; e também o estabelecimento de uma relação molar de Classe I.

Palavras-chave: Distalização molar. Aparelho Pêndulo. Ancoragem esquelética.

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1 INTRODUCTION

1 INTRODUCTION

Class II is a type of dental or skeletal malocclusion, commonly found in 42% of children aged 7-11 years, and it's characterized by maxillary prognathism, mandibular retrognathism or a combination of both, with changes in occlusal, facial and neuromuscular relationships(SILVA FILHO OG, 1989).

The differential diagnosis leads to optimal treatment for each case. There are several techniques and appliances to treat Class II malocclusion, and maxillary molar distalization can be an effective method. There are different distalizing systems that vary according to the design and biomechanics, of which some options depend on patient compliance, such as Wilson bi-metric arch(WILSON, 1988a, 1988b), jigs associated with Class II elastics(TWEED, 1966; LUCATO AS, 2003), removable appliances with springs(CETLIN; TEN HOEVE, 1983) and extraoral headgear(GRABER, 1955, 1956; KLEIN, 1957; NEWCOMB, 1958; KLOENH, 1961; FUNK, 1967; MELSEN, 1969).

However, in the 90's, concerns on eliminating the cooperation factor in orthodontic treatments led to introduction of intraoral molar distalization appliances. Among these there are the jones jig distalizer(JONES; WHITE, 1992), the distal jet appliance(CARANO; TESTA, 1996), the devices with repelling magnets(GIANELLY et al., 1988), compressed coil springs(GIANELLY; BEDNAR; DIETZ, 1991), the pendulum appliance(HILGERS, 1992) and their modifications(CRAWFORD, 1974; MOYERS et al., 1980; MCNAMARA, 1981).

Given the diversity of devices, Scuzzo, Pisani and Takemoto(SCUZZO, 1999) showed that an ideal device for molar distalization must meet the following requirements: need of minimum patient compliance, acceptable esthetics and comfort, minimum anchorage loss, body movement of the molars and less chair-time.

Keeping these concepts in mind, Hilgers(HILGERS, 1992) designed an appliance for Class II correction in non-compliance patients, aiming to expand the maxilla and simultaneously distalize and rotate the first molar, the Pendulum appliance. The appliance consists in a palatal plate of acrylic resin fixed to the first and second premolars through occlusal fingers rest bonded on the mesial and distal marginal ridges in these dental elements, or welded bars in the bands of these teeth. In addition, titanium-molybdenum 0.032-inch springs are built into the palatal button and fit into the maxillary first molar bands palatal tubes.

The pendulum designed by Hilgers has been widely researched and partially meet the needs of an ideal device for maxillary molar distalization(GHOSH; NANDA, 1996; BYLOFF; DARENDELILER, 1997; BYLOFF et al., 1997; BUSSICK; MCNAMARA, 2000; TOROGLU, 2001; FUZIY et al., 2006). Therefore, its original design has been modified in order to give greater comfort to the patient and produce more controlled distal movement. Such modifications have proposed incorporation of telescopic tubes and removable springs(ALMEIDA, 1999).

Considering that the pendulum appliance is anchored on teeth and mucosa, it is observed that simultaneously with molar distalization, there is mesial movement of premolars and canines and incisor protrusion. This effect demonstrates that the space obtained between the first molar and the second premolar, results from 55 to 70% of molar distalization and from 45% to 30% of anchorage loss(BYLOFF; DARENDELILER, 1997; BYLOFF et al., 1997; BUSSICK; MCNAMARA, 2000; CHAQUES-ASENSI; KALRA, 2001; FUZIY et al., 2006).

In order to minimize the reciprocal forces, skeletal anchorage was introduced, to be used as absolute anchorage in orthodontics. Among these mechanisms, there is the use of palatal screws(BANTLEON, 2002; GIULIANO, 2002; KARAMAN; BASCIFTCI; POLAT, 2002; ONCAG et al., 2007; POLAT-OZSOY, 2008). Byloff e al.(BYLOFF et al., 2000) reported the use of the pendulum with implants, enabling distalization without anchorage loss. This method, although effective, requires invasive surgical procedures, during installation and removal, limiting therefore its acceptance by patients. This fact motivated the development of a simpler and cheaper Pendulum appliance, with removable springs attached to the palatal screws(FUZIY, 2008). Use of the screws has the advantages of convenience and comfort for the patient, the possibility of immediate loading, low cost, ease of insertion and removal and less trauma(COSTA; RAFFAINL; MELSEN, 1998; SMITH, 2000).

Therefore, the purpose of this investigation was, firstly, to evaluate the dento-alveolar, skeletal and soft tissue effects obtained with the bone-anchored pendulum appliance (BAPA) in patients with Class II malocclusion and secondly to compare these changes with maxillary molars distalization with the conventional pendulum appliance.

2 ARTICLES

2 ARTICLES

2.1 ARTICLE 1

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

CHANGES CONSEQUENT TO MAXILLARY MOLAR DISTALIZATION WITH THE BONE-ANCHORED PENDULUM APPLIANCE

ABSTRACT

Introduction: This retrospective study aimed to evaluate the dentoalveolar, skeletal and soft tissue effects obtained with the bone-anchored pendulum appliance in patients with Class II malocclusion. **Methods:** The experimental group comprised 18 patients (4 male, 14 female) at a mean pretreatment age of 14.01 years (SD 1.08), treated with the bone-anchored pendulum appliance for 0.5 year. Only the active distalization period was evaluated with predistalization and postdistalization lateral cephalograms. Skeletal, dentoalveolar and soft tissue variables were obtained. The treatment effects on these variables were evaluated with dependent t tests. **Results**: Correction of Class II molar relationship resulted from distal movement and tipping of 11.24º and 12.62º of the first and second maxillary molars respectively. The premolars were distalized 1.65mm, accompanying the molars. Incisors, overjet and nasolabial angle remained stable. **Conclusions**: The bone-anchored Pendulum appliance proved to be an effective method for distalization of maxillary molars in cases that require maximum anchorage, avoiding the reciprocal mesial movement of premolars and incisors.

INTRODUCTION

Depending on the anteroposterior discrepancy severity, there are many resources to treat Class II malocclusions non-extraction.[1-3] An option is molar distalization; however, this alternative often requires patient compliance to achieve successful results, which may compromise treatment.[3,4] In order to eliminate patient compliance requirements, several intraoral distalizing devices were developed, such as the jones jig distalizer,[5] the distal jet appliance,[6] repelling magnets distalizers[7] coil springs on a continuous archwire,[8] the pendulum appliance,[2] and its variations.[9]

The pendulum appliance designed by Hilgers has been widely studied and partially satisfies the requirements of an ideal device for maxillary molars distalization.[10-16] The original design has been modified, incorporating telescopic tubes and removable springs, to provide greater patient convenience and to produce more controlled distal movements.[17]

The conventional pendulum appliance is anchored on the palate and premolars to produce distal movement of the maxillary molars. However, this type of anchorage also produces unfavorable side effects such as mesial movement of canines and premolars, and incisor protrusion. The space obtained between the first molar and the second premolar results in 55 to 70% of distal molar movement and in 30% to 45% of anchorage loss.[10,11,18,19]

To minimize the unfavorable side effects, a modified bone-anchored pendulum appliance with removable springs, was developed.[20] Therefore, the objective of this study is to evaluate the dentoalveolar, skeletal and soft tissue effects resulting from molar distalization with the bone-anchored pendulum appliance.

MATERIAL AND METHODS

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

The sample size was calculated based on an alpha significance level of 0.05 and a beta of 0.2 to achieve 80% of power to detect a mean difference of 2 mm in molar relationship change between the pre- and posttreatment stages, with a 2.27 mm of estimated standard deviation.[21] The sample size calculation showed that 12 patients were needed, and to increase the power even more it was decided to increase the sample to 20 patients. Two patients were excluded from the sample due to appliance loss by peri-implantitis.

Therefore, the sample consisted of 18 patients (14 female, 4 male), with an initial mean age of 14.0 years (SD 1.08), who were retrospectively treated at Department of Orthodontics at Dental School, University of São Paulo City. The criteria for sample selection were that the patients presented: good oral hygiene, complete permanent dentition with the second molars erupted or partially erupted, permanent molar relationship of at least half Class II, absence or a minimum crowding in the mandibular arch, and no history of previous orthodontic treatment. The group received intraoral molar distalization before fixed appliances treatment. Two serial cephalograms for each patient were taken at the beginning of treatment (T0) and at the end of distalization (T1). The mean time from T0 to T1 was 6.12 months. All patients and parents were informed about the surgical procedure to install the orthodontic implants and signed a consent form.

Appliance construction and activation

Initially, bands with triple buccal and palatal tubes were adapted on the maxillary first molars. After pre-drilling of 6 mm depth performed with a 2mm-diameter drill, bilateral titanium cortical screws type of 2.4 mm in diameter and 14 mm long were inserted into the palate, 6 to 9 mm posteriorly to the incisive papilla and 3 to 6 mm distant from the paramedian suture. The screw heads had an exposure of 4 mm in the oral cavity, which was enclosed by the Nance acrylic pad.

Sequentially, the Nance acrylic pads were constructed on duplicate dental casts, with spaces matching the implants inserted into the palate. These acrylic pads contained two stainless steel telescopic tubes of 12mm in length and 0.9mm of imbedded internal diameter (Figure 1).

Two 0.032-inch titanium molybdenum distalizing removable springs were constructed to fit into the telescopic tubes. The springs were pre-activated by means of a slight bend in the helicoid, keeping them parallel to the suture,[2] with an anti-bending inclination of 15° to avoid palatal molar movement and posterior crossbite,[11] and with 250g measured with force gauge dynamometer (Figure 1). Patients were monthly monitored, but maintained only the first activation during the active treatment period. The first molars were distally moved until overcorrection of 2 mm in molar relationship was achieved (Figures 2 and 3). At each appointment, the soft tissues around the Nance acrylic button were checked regarding compression of the palatal mucosa and local inflammation. After molar distalization (4-6 months), the Pendulum and screws were removed and a conventional Nance appliance was installed on first maxillary molars as anchorage to continue treatment.

Cephalometric analysis

Lateral cephalograms taken at T0 and T1 were digitized and had the landmarks identified by a single operator (A,O.) in the software Dolphin Imaging 11.5 (Dolphin Imaging and Management Solutions, Chatsworth, California, EUA). The software automatically corrected the 10% radiographic magnification of the headfilms and performed the measurements of the variables described in Table I.

Error study

Nine radiographs, representing 25% of the sample, were randomly selected, had the landmarks identified again and were remeasured by the same examiner. The random errors were calculated with Dahlberg´s formula ($Se^2= \Sigma d^2/2n$)[22] where Se^2 is the error variance and d is the difference between 2 determinations of the same variable. The systematic errors were evaluated with dependent t tests at $P<0.05$.[23]

Statistical analyses

Normal distribution of variables was evaluated with Kolmogorov-Smirnov tests, which demonstrated that all variables had a normal distribution.

Descriptive statistics were performed for all cephalometric variables at T0 and T1. Intragroup comparison of the treatment changes was performed with dependent t tests. Results were considered significant at $P<0.05$. All statistical analyses were performed with SPSS® Statistics for Mac, version 21.0 (IBM Corporation – Armonk, NY).

RESULTS

The random errors ranged from 0.25 (overbite) to 5.39 (Mx7.Sn), and most variables had errors below 1 degree or mm. No systematic errors were detected.

There was significant increase in lower anterior face height of 1.44mm, significant distalization of 3.45mm and 3mm, distal tipping of 11.24° and 12.62°, and intrusion of 0.74mm and 1.55mm of the first and second maxillary molars respectively. The first premolars had significant distalization of 1.45mm, and extrusion of 0.61mm. Overbite significantly decreased in 1.03mm and molar relationship was significantly improved in 3.09mm (Table II).

DISCUSSION

Use of only two calibrated operators to treat the 18 patients reduces the variability that would have been introduced by several operators. The strict inclusion criteria and treatment protocol resulted in this small sample size, which is however, greater than most similar articles,[21,24-28] except one.[9] Studies of the effects of the pendulum appliance usually do not use a control group because the observation period is short (6 months in this study) for normal growth changes to play a significant role in the changes.[7,10-12,18,19]

Bone Anchored Pendulum Appliance

Bilateral titanium screws were inserted into the palate, 6 to 9 mm posteriorly to the incisive foramen and 3 to 6 mm paramedian to the suture, according previous study.[29] Another important investigation confirmed that the thickest bone can be found in the anterior part of the palate, at the suture and in the paramedian areas, 4-8 mm distant from the incisive foramen.[30] Thus, the location chosen for screw insertion is in accordance with available data in the literature.

In this research, wider and longer cortical screws type than commonly used on the midpalatal region for BAPA[9,21,25,27,28] were purposely chosen for different reasons. Firstly, because they should be sufficiently exposed in the mouth to be encompassed by the Nance button. Secondly, because miniscrews do not remain static when undergoing orthodontic forces. Miniscrews (6mm length x 2mm diameter) in the midpalatal region moved 0.49 mm or less, on average, but some moved more than 1 mm when subjected to 250gf.[31] Even longer screws (11 mm length x 2 mm diameter) installed in the zygomatic region moved 0.4 mm on average, but up to 1.5 mm movements were detected after application of 400 gf.[32] In these investigations, screw displacement little influenced orthodontic treatment. However, with BAPA, contrary to the literature,[28] miniscrew displacement would lead to palatal mucosa compression, which may cause injury and inflammation.[21] Finally, it is important to install the screws before the pendulum. For this purpose, the acrylic buttons were made with windows for the screws. Later, acrylic resin was added to attach the screw head to the button. This procedure avoided pressure against the palatal mucosa during miniscrew installation. Thus, in order to minimize screw displacement after force application and consequent palatal compression, longer and wider screws were chosen. Figure 3 shows that this precaution had positive results with minimal palatal compression, as seen in all patients.

Skeletal components

Overall there were no statistically significant changes on the maxillary and mandibular sagittal skeletal components, because maxilla and mandible remained stable, corroborating other studies that evaluated the pendulum appliance effects with conventional[4,11,12,14,19] and skeletal anchorages.[26,27] On the other hand, LAFH significantly increased during treatment, probably because of the clockwise mandibular rotation caused by maxillary molar distalization, which agrees with findings of other studies.[2,10,14]

Dental components

The maxillary first and second molars had significant distalization, greater than observed in other studies with conventional[11,12,14,15] and with bone anchorage,[26,27] but smaller than others.[10,16,18] Such differences may occur due to different needs of molar distalization between samples. This distalization was achieved with distal tipping of the first maxillary molar, which was similarly observed in other studies.[2,10,11,14,15] However, most previous studies did not separately present the changes in distal tipping of the first and second molars, except one, [14] which reported greater distal second molar tipping. This is expected because the intraoral distalizer appliances forces act on the dental crowns at a distance from the center of resistance of the molars. The maxillary molars also experienced intrusion of the distal and extrusion of the mesial occlusal surface, which is normally consequent to the distal tipping experienced by these teeth.[10,11,14,15] The extrusion of the mesial occlusal surface consequent of distal tipping causes an increase in LAFH.

The maxillary incisors remained almost in the initial position without significant changes, agreeing with other studies.[9,21,33] This shows that bone-anchorage is an excellent option to avoid reciprocal unwanted movements in the incisors, described in other studies using conventional dental anchorage devices. [10,11,14,16]

There was significant distal movement of the first premolars (Table II). These were spontaneously obtained, without force application, as a result of the transseptal periodontal fibers action.[27,34,35] This conflicts with the side effects of mesial movement of the premolars, when conventional pendulum is used,[10,11,14-16] demonstrating that the use of skeletal anchorage with the Pendulum appliance is able to control this collateral effect.[26-28] Despite the spontaneous distalization and distal tipping, the premolars had also some extrusion, similarly reported in other study with skeletal anchorage.[9] Probably premolar extrusion is consequent to the extrusion of the mesial surface of the first molars, through the transseptal fibers action.

There was no significant overjet changes, the overbite significantly decreased and molar relationship was significantly improved. These results contrast with other studies with conventional pendulum appliances that observed overjet increase.[10,11,14-16,18] This shows that anchorage reinforcement with a Nance button is not enough to resist the reciprocal mesial force during molar distalization, leading to anchorage loss.[26-28,34,36,37]

Decrease in overbite was consequent to extrusion of the mesial occlusal surface of the maxillary molars, as previously discussed, and that may usually occur during distalization.[2,10,11,14,15,18] Molar relationship evidently improved with distalization of the molars and is the primary effect to be expected with this type of treatment.[2,10,11,14,18] This has been shown by the studies with intraoral distalizers.[2,5,6,8,9]

Soft tissue profile

There were no significant changes in the upper and lower lips, which means that the position of the maxillary incisors was not affected by the treatment, agreeing with one study [9] and differing with another study on the effects of the pendulum appliance, in which the NLA decreased due to anchorage loss.[10]

CONCLUSIONS

The results of this study showed that the bone-anchored pendulum appliance was effective as anchorage, producing:

- Distal movement of maxillary molars;
- Spontaneous distal movement of the maxillary first premolars;
- No undesirable side effects in the maxillary incisors and upper lip;
- Establishment of a Class I molar relationship.

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FIGURE LEGENDS:

Figure 1. Pretreatment lateral cephalometric radiograph and photographs of a patient with the Bone-Anchored Pendulum Appliance.

Figure 2. Post-distalization lateral cephalometric radiograph and photographs of a patient with the Bone-Anchored Pendulum Appliance.

Figure 3. Occlusal photograph after removal of the Bone-Anchored Pendulum Appliance.

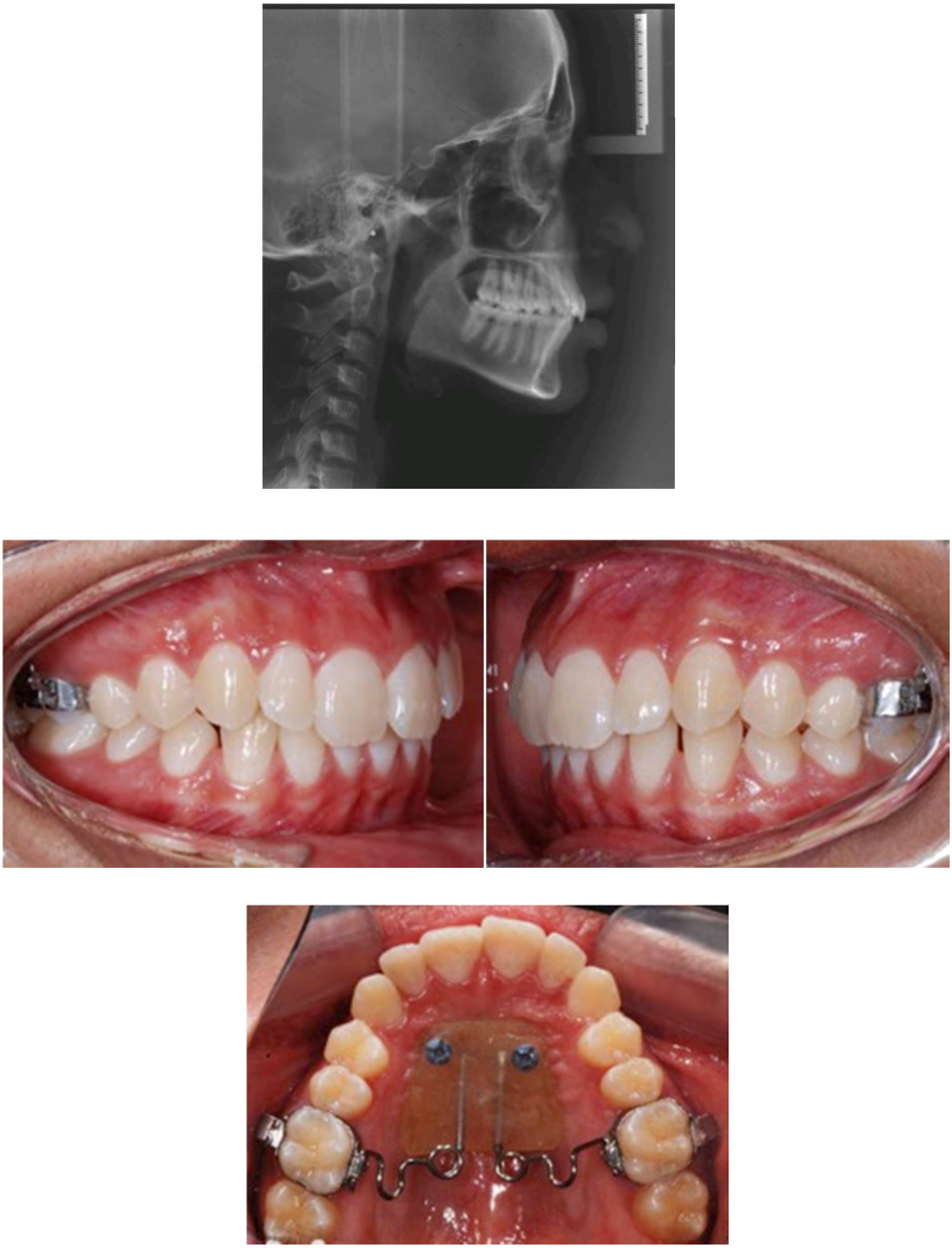

Figure 1

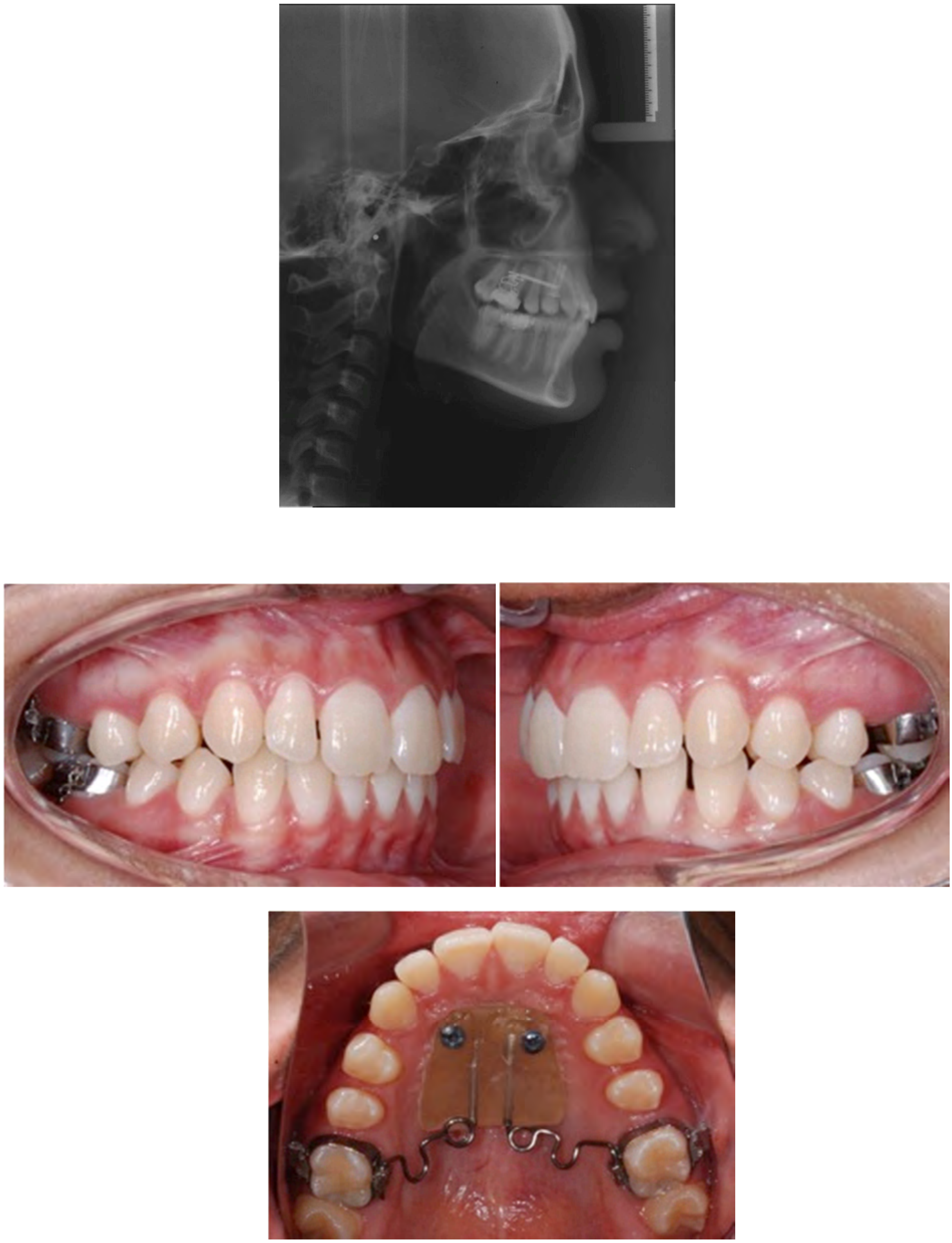

Figure 2

Figure 3

Table I – Definition of less usual cephalometric variables evaluated

MAXILLARY SKELETAL COMPONENTS	
A-PTM	Distance between A point and pterigomaxillary fossae (PTM)
Co-A	Distance between condylion (Co) and A point
S-A	Distance between Sella (S) and A point
MANDIBULAR SKELETAL COMPONENTS	
B-PTV	Distance between B point and pterigomaxillary vertical (PTV)
Co-Gn	Distance between condylion (Co) and gnathion (Gn)
S-B	Distance between Sella (S) and B point
VERTICAL SKELETAL COMPONENTS	
SN.PP	Angle between SN and Palatal plane
LAFH	Lower anterior face height - distance between ANS and Me
SN.GoGn	Angle between SN line and Go.Gn plane
SN.GoMe	Angle between SN line and Mandibular plane
FMA	Frankfort mandibular plane angle
NS.Gn	Angle between NS and SGn lines
MAXILLARY DENTAL COMPONENTS	
Mx6–PTV	Distance between the maxillary first molar long axis to pterigomaxillary vertical (PTV)
Mx6.SN	Angle between the maxillary first molar long axis to SN line
Mx6–PP	Distance between the maxillary first molar crown tip and palatal plane
Mx7–PTV	Distance between the maxillary second molar long axis to pterigomaxillary vertical (PTV)
Mx7.SN	Angle between the maxillary second molar long axis to SN line
Mx7–PP	Distance between the maxillary second molar crown tip and palatal plane
ANCHORAGE TEETH	
Mx1–PTV	Distance between the maxillary incisor long axis to pterigomaxillary vertical (PTV)
Mx1.SN	Angle between the maxillary incisor long axis to SN line
Mx1–PP	Distance between the maxillary incisor crown tip and palatal plane
Mx4-PTV	Distance between the maxillary first premolar long axis to pterigomaxillary vertical (PTV)
Mx4.SN	Angle between the maxillary first premolar long axis to SN line
Mx4-PP	Distance between the maxillary first premolar crown tip and palatal plane
SOFT-TISSUE PROFILE	
UL-EP	Distance between the upper lip to the Esthetic plane
LL-EP	Distance between the lower lip to the Esthetic plane
NLA	Nasolabial angle

Table II - Treatment changes (Dependent t tests).

	Initial (n=18) T0		Final (N=18) T1		Diference T1-T0	
	Mean	SD	Mean	SD		P
MAXILLARY SKELETAL COMPONENTS						
SNA (º)	85.55	4.65	85.65	5.11	0.10	0.864
A-PTM (mm)	49.81	3.62	49.42	2.53	0.39	0.367
Co-A (mm)	83.83	3.70	83.54	3.46	0.29	0.658
S-A (mm)	79.42	3.68	79.48	3.37	0.06	0.891
MANDIBULAR SKELETAL COMPONENTS						
SNB (º)	80.78	3.86	80.88	4.34	0.10	0.780
B-PTV (mm)	46.07	3.83	44.49	4.31	-1.58	0.083
Co-Gn (mm)	111.00	4.31	111.10	4.09	0.10	0.875
S-B (mm)	101.58	4.32	102.67	3.83	1.09	0.074
MAXILLOMANDIBULAR RELATIONSHIP						
ANB (º)	4.77	2.25	4.77	2.05	-0.20	0.986
NAP (º)	7.80	5.01	7.72	4.51	-0.08	0.911
VERTICAL SKELETAL COMPONENTS						
SN.PP (º)	5.45	3.66	5.09	3.67	-0.36	0.401
LAFH (mm)	61.38	4.33	62.82	4.40	1.44	0.003*
SN.GoGn (º)	28.68	6.15	28.26	6.77	-0.42	0.417
SN.GoMe (º)	31.46	6.03	30.99	6.78	-0.47	0.346
FMA (º)	23.53	4.77	24.39	5.53	0.86	0.186
NS.Gn (º)	65.92	3.91	66.02	4.00	0.10	0.782
MAXILLARY DENTAL COMPONENTS						
Mx6–PTV	21.75	5.75	18.30	3.14	-3.45	0.001*
Mx6.SN	64.18	13.31	52.94	6.02	-11.24	0.002*
Mx6–PP	16.67	2.15	15.93	1.91	-0.74	0.018*
Mx7–PTV	13.15	5.06	10.15	2.57	-3	0.003*
Mx7.SN	57.37	12.46	44.75	10.00	-12.62	0.001*
Mx7–PP	11.92	4.08	10.37	2.85	-1.55	0.027*
ANCHORAGE TEETH						
Mx1–PTV	55.61	4.34	55.08	4.22	-0.53	0.228
Mx1.SN	103.27	8.95	102.62	8.57	-0.65	0.427
Mx1–PP	27.23	2.42	27.67	2.01	0.44	0.070
Mx4-PTV	37.43	4.76	35.78	3.49	-1.65	0.018*
Mx4-SN	79.10	6.54	79.56	4.69	0.46	0.735
Mx4-PP	20.06	1.98	20.67	1.93	0.61	0.004*
DENTAL RELATIONSHIPS						
Overjet (mm)	4.46	1.53	4.55	1.86	0.09	0.670
Overbite (mm)	3.31	1.23	2.28	1.46	-1.03	0.001*
Molar relationship (mm)	-1.27	3.11	-4.36	1.64	-3.09	0.001*
SOFT-TISSUE PROFILE						
UL-EP	-0.48	1.68	-0.71	1.78	-0.23	0.325
LL-EP	0.65	2.00	0.69	2.18	0.04	0.876
NLA	108.21	9.24	107.87	9.02	-0.34	0.815

*Statistically significant at $P<0.05$

2.2 ARTICLE 2

CHANGES PRODUCED BY THE PENDULUM APPLIANCE WITH CONVENTIONAL AND SKELETAL ANCHORAGE

ABSTRACT

Introduction: The aim of this retrospective study was to compare the skeletal, dento-alveolar and soft tissue changes produced by the pendulum appliance with conventional and skeletal anchorage. **Material and method**: The sample consisted of 36 patients (28 female; 8 male) with Class II malocclusions and a mean initial age of 13.81 years (SD 1.16), divided into two groups: G1 (n=18) treated with conventional pendulum appliance (CPA), and G2 (n=18) treated with bone-anchored pendulum appliance (BAPA). Two serial cephalograms for each patient were obtained at the beginning (T0) and at the end of distalization (T1), measured and then statistically analyzed. Intragroup comparisons were performed using dependent t tests and intergroup comparisons were performed using t tests with significance level of 5%. **Results:** There were significantly greater maxillary first molar distalization, distal tipping and intrusion in G2 than in G1. The maxillary incisors were labially tipped in G1 and lingually tipped in G2 and the first premolars were distalized in group 2, but were mesialized in G1, therefore showing statistically significant different movements. G1 showed significantly greater overjet increase and smaller Class II molar relationship correction than G2. Both skeletal relationship such as soft tissue profile showed no difference between groups. **Conclusions:** The bone-anchored pendulum appliance showed greater efficiency in molar distalization by removing undesirable side effects associated with movement of anchorage teeth.

Keywords: Molar distalization; Pendulum appliance; skeletal anchorage.

INTRODUCTION

Nonextraction treatment of Class II malocclusion has been the tendency in contemporary orthodontics with a great number of techniques.[1-3] Whenever the etiology and severity of the discrepancy allows, and considering that extractions could negatively modify the soft tissue profile, a quite used option to avoid tooth extractions is molar distalization mechanics.[4]

There are several alternatives for molar distalization. The first devices introduced were based on extraoral anchorage, as the headgear appliance, which showed sucessfull results when patient compliance is good.[2,5] However in the 90s, in order to eliminate patient compliance requirements, several intraoral distalizing devices were developed, such as the jones jig distalizer,[6] the distal jet appliance,[7] repelling magnet distalizers,[8] coil springs on a continuous archwire,[9] the pendulum appliance[10] and its variations.[11]

Hilgers, in 1992 designed the pendulum appliance,[10] to correct Class II malocclusion, with molar distalization in non-compliant patients. This device was widely studied in its original and modified design with telescopic tubes and removable springs.[12] It shows excellent results, however, it is anchored on the premolars and hard palate to produce molar distalization. This fact results in mesial movement of premolars and canines as well as incisor protrusion.[13-16] Consequently, it was shown that the space obtained between the second premolar and the first maxillary molar during distalization mechanics results in 55 to 70% of distal movement of the molar and 30 to 45% of mesial movement of premolars, representing a considerable anchorage loss.[13]

To minimize the aforementioned side effects, it was found that the weak points of several distalizers are reaction forces dissipated in the anchorage tissue.[13] The introduction of skeletal anchorage in orthodontics offered a new alternative to reduce or eliminate undesirable effects in molar distalization mechanics.[17-19]

Therefore, the objective of this study was to compare the dentoalveolar, skeletal and soft tissue changes produced by the pendulum appliance with conventional and skeletal anchorage.

MATERIAL AND METHODS

This study was approved by the Ethics in Research Committee of Bauru Dental School, University of São Paulo.

The sample size was calculated based on an alpha significance level of 0.05 and a beta of 0.2 to achieve 80% of power to detect a mean difference of 2.65mm of mesial movement of premolar, between the pre- and post-treatment stages, with a 2.71mm of estimated standard deviation.[20] The sample size calculation showed that 17 patients per group were needed.

A sample of 36 patients, who were retrospectively treated in period 1998-2000 at Orthodontic Department at Bauru Dental School, University of São Paulo, and treated in period 2011-2013 at Orthodontic Department at the Dental School, University of São Paulo City. All patients received intraoral molar distalization before fixed appliances treatment. Patients were selected according to the following inclusion criteria: (1) Class II malocclusion with a minimum of half Class II molar relationship evaluated in dental models; (2) complete permanent dentition with second molars erupted or partially erupted. The sample was divided into 2 groups. The first group (G1) consisted of 18 patients (14 females; 4 males) treated with conventional pendulum appliances (CPA) with a mean age of 13.61 years (S.D 1.24) and the second group (G2) consisted of 18 patients (14 females; 4 males) treated with bone-anchored pendulum appliances (BAPA) with a mean age of 14.01 years (S.D 1.08). Two cephalograms for each patient were taken at the beginning of treatment (T0) and at the end of distalization (T1). The average distalization period was 5.76 and 6.16 months, for G1 and G2 respectively.

Appliance construction and activation

The Pendulum appliance used in G1 patients was similar to the original described by Fuziy.[21] Each appliance was anchored on the first premolars with bands and on the second premolars with wires bonded to the occlusal surface. The pendulum springs were activated parallel to the palatal midline, following the activation scheme suggested by Hilgers[10] (Fig. 1).

In G2, bands with buccal triple and palatal lingual tubes were adapted on the first maxillary molars. Then, bilateral titanium screws of 2.4x14mm (MaxLorenz Surgical, Rio Claro, São Paulo, Brazil) were inserted into the palate, 6 to 9mm posteriorly to the incisive papilla and 3 to 6mm away from the suture, with an anterior inclination of 45-60°.[22] The screw heads had an exposure of 3mm in the oral cavity.

After surgical healing, impressions were taken of the maxillary arch and screws to produce accurate dental models. For appliance construction, the screw heads were protected with wax. Sequentially, the Nance button was constructed with two stainless steel telescopic tubes of 12mm in length and 0.9mm of imbedded internal diameter[23] (Fig. 2).

Two 0.032-inch titanium molybdenum distalizing springs with the following dimensions were constructed: internal diameter of 4mm, horizontal handle adjustment of 4mm wide and 4mm length to fit into the telescopic tubes.[12] The springs were pre-activated by means of a slight bend in the helicoid, keeping them parallel to the suture,[10] with an anti-bending inclination of 15°,[15] and with 250g of force measured with dynamometer (Fig. 1). Construction of the appliance and activation of the springs was performed by a single operator (A.F.). Patients were monthly monitored by two operators. Only a initial activation during the active treatment period was maintained. At each appointment, the soft tissues around the Nance button were checked regarding compression of the palatal mucosa and local inflammation.

Cephalometric analysis

Lateral headfilms of both groups taken at T0 and T1 were digitized and had the landmarks identified by a single operator (A.O.) in the Dolphin Imaging 11.5 software (Dolphin Imaging and Management Solutions, Chatsworth, California, USA). The software automatically corrected the 10% radiographic magnification of the headfilms and performed measurements of 28 variables. The less usual cephalometric variables are shown in Table I. Treatment changes were calculated as T1-T0.

Error study

A month after the first measurements, nine radiographs, representing 50% of each group, were randomly selected, retraced and remeasured by the same examiner. The random errors were calculated with Dahlberg´s formula ($Se^2 = \Sigma d^2/2n$),[24] where Se^2 is the error variance and d is the difference between 2 determinations of the same variable. The systematic errors were evaluated with dependent t tests at $P<0.05$.[25]

Statistical analyses

Normal distribution of variables was evaluated with Kolmogorov-Smirnov tests, which demonstrated that all variables had a normal distribution.

Group comparability regarding Class II malocclusion severity was evaluated with Chi-square test. Regarding initial age, treatment time and initial cephalometric status, comparability was evaluated with t tests.

Intergroup treatment changes comparison was performed with t tests.

All statistical analyses were performed with SPSS® Statistics for Mac, version 21.0 (IBM Corporation – Armonk, NY). Results were considered significant at $p<0.05$.

RESULTS

The random errors varied from 0.18° (UL.EP) to 4.08° (Mx4.SN) and none of the variables showed a systematic error (Table II).

The groups were comparable regarding Class II molar relationship, initial age, treatment time and all pretreatment cephalometric variables, except NAP, where G2 showed significantly greater initial facial convexity than G1 (Table III).

There were significantly greater maxillary first molar distalization, distal tipping and intrusion in G2 compared to G1 (Table IV).

The maxillary incisors were labially tipped in G1 and lingually tipped in G2 and the first premolars were distalized in group 2, but were mesialized in group 1, therefore showing statistically significant different movements (Table IV).

G1 showed significantly greater overjet increase and smaller Class II molar relationship correction than G2 (Table IV).

DISCUSSION

To reduce or eliminate patient compliance,[10] intraoral devices have been developed to distalize the maxillary posterior teeth in Class II non-extraction treatment. With the advent of intraoral distalizers the compliance problem was solved, but there were undesirable effects, such as anchorage loss, represented by excessive maxillary incisor labial inclination, increase in overjet and in anterior maxillary crowding.

Skeletal anchorage revolutionized the paradigms of contemporary orthodontics with the introduction of new concepts to avoid undesirable movements within the mechanics. Intraoral distalizers associated with absolute anchorage currently represent the best option for distalization of maxillary molars.[17,19,26-28]

It is important to state that all patients presented a predominantly dental Class II malocclusion with at least half Class II molar relationship evaluated in dental models and all the second molars erupted or partially erupted. All the initial skeletal, dental and soft-tissue characteristics, initial age and severity of Class II molar relationship were comparable, showing similar features between the groups (Table III). In order to minimize the variability, all patients in the sample were treated by only 2 operators.

Quantifying molar distalization is difficult using 2-dimensional lateral cephalograms because of image superimposition. Cone beam computed tomography (CBCT) provides even better images resulting in more accurate data regarding teeth inclination or bodily dental movement, but to measure maxillary molar distalization, CBCT is not indicated because studies showed the reliability of both conventional two-dimensional and three-dimensional cephalometry [29,30]

The strict inclusion criteria and treatment protocol resulted in this sample size in G1, slightly smaller than other studies.[14,15,31] However in G2, the sample is greater than most similar articles.[17,19,26,27]

Bone Anchored Pendulum Appliance

As the conventional pendulum appliance has been widely described and studied, we focus on the details that made the difference of the bone-anchored pendulum appliance installed in this study. In G2 wider and longer screws were selected to install than commonly used on the midpalatal region for BAPA.[11,19,28] They were purposely chosen for different reasons. Firstly, they should be sufficiently exposed in the mouth to be encompassed by the Nance button. Secondly, because miniscrews do not remain static when undergoing orthodontic forces and stability of the screw is proportional to its length and diameter.[32]

Miniscrews (6mm length x 2mm diameter) in the midpalatal region moved 0.49mm or less, on average, but some moved more than 1mm when subjected to 250gf.[33] Even longer screws (11mm length x 2mm diameter) installed in the zygomatic region moved 0.4mm on average, but up to 1.5mm movements were detected after application of 400gf.[34] In these investigations, screw displacement little influenced orthodontic treatment. However, with BAPA, contrary to the literature,[19] miniscrew displacement will lead to palatal mucosa compression, which may cause injury and inflammation.[17] Finally, it is important to install the screws before the pendulum. For this purpose, the acrylic buttons were made with windows for the screws and embedded the telescopic tubes to insert distalizer springs. Later, acrylic resin was added to attach the screw head to the button. This procedure avoided pressure against the palatal mucosa during miniscrew installation and allows placement and activation of distalizing springs after the button has already been attached to the screws without any risk of palatal mucosa compression. Thus, in order to minimize screw displacement after force application and consequent palatal compression, longer and wider screws were chosen.

Skeletal components

Overall there were no statistically different changes on the maxillary and mandibular sagittal skeletal components between G1 and G2, corroborating other studies that compared the pendulum appliance effects with conventional[15,31,35-37] and skeletal anchorages.[26,28] The LAFH increased similarly during treatment in both groups probably because of the clockwise mandibular rotation caused by maxillary molar distalization which agrees with findings of other studies.[10,13,14]

Dental components

The first and second maxillary molars in both groups were distalized successfully without patient cooperation. Distal movement was greater than observed in other studies with conventional pendulum appliance[13,15,20,35] and with bone-anchored pendulum appliance.[26,28] There was significantly greater first and second molar distalization in G2 than in G1, according to the results demonstrated in a previous study.[11] Probably because the force of the appliance was transmitted in one direction, without impact on the anchorage unit. This distalization was achieved in both groups with distal tipping of the maxillary molars, which was similarly observed in other studies with conventional and skeletal anchorage.[10,11,13,14,16,20,35,38] However, tipping of the first and second molars in G2 was significantly greater than in G1. This is expected because the intraoral distalizer appliance forces act on the dental crowns at a distance from the center of resistance of the molars. The maxillary molars in both groups also experienced intrusion, which is normally consequent to the distal tipping shown by these teeth.[13,14,20,35]

In this study, both premolars and incisors were considered anchor teeth in G1, because their movement towards mesial or protrusion are associated with negative effects produced by intraoral distalizers with anchorage unit supported on the teeth.

Inclination of the maxillary incisors showed statistically significant difference between groups. In the first group the maxillary incisors were labially tipped, similar to several published studies.[13-15,39] This effect is probably due to the tendency to mesial movement of premolars and canines, and also might be the reactive force, which pushes the acrylic plate anteriorly. However, in the second group the incisors were slightly palatally tipped agreeing to other studies,[11,17] disagreeing with one[38] that showed labially tipped incisors, and another where the position of the incisors remained stable.[19] This shows that bone-anchorage is an excellent option to avoid reciprocal unwanted movements of the incisors, described in other studies using conventional dental anchorage devices.

The first premolars showed significantly different and opposite movements. In the first group the premolars presented mesial movement and tipping, representing anchorage loss. This was expected because the reactive force is dissipated in the palatal mucosa and anchoring teeth, which in this case are the first and second premolars.[13-16,20] Moreover, the premolars in the second group had spontaneous distal movement and distal tipping during molar distalization, agreeing with other studies.[17,19,26] This movement was probably caused by two distinct reasons: firstly because the device is not supported on any premolar, and secondly because they are free from any attachment, and this allows the transseptal fibers to distalize them. This spontaneous movement could reduce the treatment time, particularly in the post-distalization retraction phase.

Similar to the results of several pendulum studies,[13-16,20] in the first group the overjet increased significantly due to incisor proclination. This increase is considered as anchorage loss, and probably produces longer total treatment time. In the second group there was only a small increase, probably because the incisors had palatal tipping with the distalization, similar to the findings of other studies.[11,17,19]

The results of this study have shown that the maxillary first and second molars undergo intrusion during the distalization process. The variable used to show this was the measurement from the first molar crown tip to the palatal plane. However, as the molars tips distally, usually the mesial marginal ridges present some extrusion.[9-11,13-16,19,40] This may partially explain the similar decrease in overbite in both groups, with the consequent increase in LAFH.

Soft tissue profile

In both groups there were no significant differences in the changes of the upper and lower lips. However, it can be noticed that the first group showed a numerically greater labial displacement of the upper lip, probably due to the labial inclination of the maxillary incisors, as has been demonstrated in some studies.[13-16,39] In the second group the upper lip remained almost in the same position, which means that the position of the maxillary incisors was not affected by treatment, agreeing with other researches with skeletal anchorage.[11,19]

In spite of being a study shows interesting results, it could become more relevant by increasing the sample size and evaluating the effects of both devices in post treatment phase to compare the long-term stability. We recommend to compare effects between different types of bone anchored distalizers to conclude which one has more effective with fewer side effects.

CONCLUSIONS

Distalization of the maxillary molars was successfully achieved in both groups, but the bone-anchored pendulum appliance had the following advantages:

- Exclusive maxillary molars distalization;
- Spontaneous distal movement of the maxillary premolars;
- No undesirable side effects in the maxillary incisors and lips;
- Establishment of a Class I molar relationship.

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Figure Legends

Figure 1. Pretreatment occlusal photograph of the Conventional Pendulum Appliance.

Figure 2. Pretreatment occlusal photograph of the Bone-Anchored Pendulum Appliance.

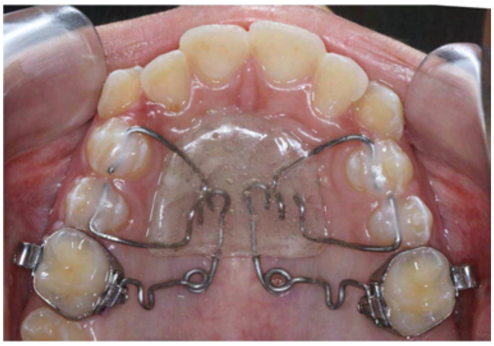

Figure 1

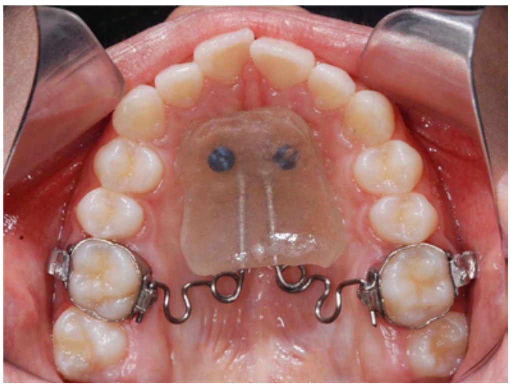

Figure 2

Table I – Definition of less usual cephalometric variables evaluated

MAXILLARY SKELETAL COMPONENTS	
SNA	Angle between SN and A point
S-A	Distance between Sella (S) and A point
MANDIBULAR SKELETAL COMPONENTS	
SNB	Angle between SN and B point
S-B	Distance between Sella (S) and B point
VERTICAL SKELETAL COMPONENTS	
SN.PP	Angle between SN and Palatal plane
LAFH	Lower anterior face height - distance between ANS and Me
SN.GoMe	Angle between SN line and Mandibular plane
FMA	Frankfort mandibular plane angle
MAXILLARY DENTAL COMPONENTS	
Mx6–PTV	Distance between the maxillary first molar long axis to pterigomaxillary vertical (PTV)
Mx6.SN	Angle between the maxillary first molar long axis to SN line
Mx6–PP	Distance between the maxillary first molar crown tip and palatal plane
Mx7–PTV	Distance between the maxillary second molar long axis to pterigomaxillary vertical (PTV)
Mx7.SN	Angle between the maxillary second molar long axis to SN line
Mx7–PP	Distance between the maxillary second molar crown tip and palatal plane
ANCHORAGE TEETH	
Mx1–PTV	Distance between the maxillary incisor long axis to pterigomaxillary vertical (PTV)
Mx1.SN	Angle between the maxillary incisor long axis to SN line
Mx1–PP	Distance between the maxillary incisor crown tip and palatal plane
Mx4-PTV	Distance between the maxillary first premolar long axis to pterigomaxillary vertical (PTV)
Mx4.SN	Angle between the maxillary first premolar long axis to SN line
Mx4-PP	Distance between the maxillary first premolar crown tip and palatal plane
SOFT-TISSUE PROFILE	
UL-EP	Distance between the upper lip to the Esthetic plane
LL-EP	Distance between the lower lip to the Esthetic plane
NLA	Nasolabial angle

Table II - Random and Systematic errors (Dalhberg´s formula and dependent t tests)

	First measurement n=18		Second measurement n=18		Dalhberg	P
	Mean	SD	Mean	SD		
MAXILLARY SKELETAL COMPONENTS						
SNA	84.51	4.32	84.48	4.16	0.90	0.943
SA	81.16	3.92	81.27	3.75	1.20	0.843
MANDIBULAR SKELETAL COMPONENTS						
SNB	80.58	3.92	80.48	3.92	0.49	0.671
SB	104.27	4.17	104.5	4.26	0.79	0.606
MAXILLOMANDIBULAR RELATIONSHIP						
ANB	3.94	2.23	4.01	2.33	0.71	0.831
NAP	5.62	4.83	5.84	5.40	1.59	0.764
VERTICAL SKELETAL COMPONENTS						
SN.PP	5.01	3.38	4.79	3.78	0.55	0.388
LAFH	63.84	3.40	63.89	3.62	0.11	0.413
SN.GoMe	31.27	6.33	31.41	5.98	0.57	0.597
FMA	23.79	4.87	23.94	4.75	1.19	0.784
MAXILLARY DENTAL COMPONENTS						
Mx6.PTV	20.17	3.46	19.88	3.68	0.67	0.336
Mx6.SN	64.9	6.00	62.46	5.39	2.49	0.011
Mx6.PP	17.98	2.01	17.96	2.00	0.39	0.911
Mx7.PTV	11.03	2.82	10.97	2.74	0.53	0.807
Mx7.SN	49.69	12.38	46.64	11.35	4.00	0.068
Mx7.PP	13.34	3.36	13.04	3.62	0.49	0.167
ANCHORAGE TEETH						
Mx1.PTV	58.04	4.68	58	5.08	0.78	0.911
Mx1.SN	110.33	7.80	110.3	7.83	1.45	0.964
Mx1.PP	27.44	1.67	27.48	1.84	0.22	0.699
Mx4.PTV	41.05	3.60	40.93	4.09	0.92	0.778
Mx4.SN	84	5.98	85.32	6.22	4.08	0.475
Mx4.PP	20.49	1.80	20.73	1.86	0.40	0.179
DENTAL RELATIONSHIPS						
Overjet	6.26	1.15	6.29	1.25	0.22	0.769
Overbite	2.61	0.99	2.6	0.98	0.25	0.931
MR	-2.5	1.05	-2.83	1.41	0.44	0.076
SOFT-TISSUE PROFILE						
UL.EP	-0.9	1.79	-0.84	1.66	0.18	0.468
LL.EP	0.7	2.24	0.73	2.31	0.21	0.763
NLA	106.14	10.02	105.65	9.68	1.22	0.374

*Statistically significant at *P*<0.05

Table III – Results of intergroup comparison at the pre-treatment stage (t - tests)

	G1 (n=18)		G2 (n=18)		P
MOLAR RELATIONSHIP SEVERITY					
½ Class II	11		14		$0.088^{‡}$
¾ Class II	7		4		
	Mean	SD	Mean	SD	
Initial age (Y)	13.61	1.24	14.01	1.08	0.306
Treatment time (Y)	0.48	0.83	0.51	0.85	0.350
MAXILLARY SKELETAL COMPONENTS					
SNA (º)	83.25	3.53	84.94	4.93	0.243
S-A (mm)	79.47	2.99	79.57	3.46	0.926
MANDIBULAR SKELETAL COMPONENTS					
SNB (º)	79.82	3.14	80.59	4.16	0.532
S-B (mm)	101.22	3.78	100.77	3.74	0.724
MAXILLOMANDIBULAR RELATIONSHIP					
ANB (º)	3.42	1.33	4.35	2.09	0.128
NAP (º)	4.05	3.53	7.12	4.75	0.036*
VERTICAL SKELETAL COMPONENTS					
SN.PP (º)	5.32	3.45	5.33	3.88	0.992
LAFH (mm)	61.42	3.20	60.97	4.21	0.721
SN.GoMe (º)	31.21	4.70	30.91	6.34	0.873
FMA (º)	23.05	3.26	23.09	4.46	0.972
MAXILLARY DENTAL COMPONENTS					
Mx6–PTV (mm)	22.91	2.67	24.03	3.71	0.270
Mx6.SN (º)	72.34	4.44	72.56	4.98	0.881
Mx6–PP (mm)	17.71	2.08	17.58	2.09	0.855
Mx7–PTV (mm)	13.52	2.33	14.67	3.71	0.216
Mx7.SN (º)	62.39	4.42	60.28	8.14	0.284
Mx7–PP (mm)	14.40	2.27	13.51	3.27	0.355
ANCHORAGE TEETH					
Mx1–PTV (mm)	55.22	3.60	55.60	4.21	0.763
Mx1.SN (º)	104.81	6.63	104.22	9.71	0.832
Mx1–PP (mm)	27.46	1.79	27.03	2.41	0.550
Mx4-PTV (mm)	38.07	2.91	38.76	3.49	0.490
Mx4-SN (º)	81.30	4.95	80.57	5.13	0.673
Mx4-PP (mm)	19.91	1.78	19.77	1.98	0.827
DENTAL RELATIONSHIPS					
Overjet (mm)	4.49	1.03	4.47	1.54	0.959
Overbite (mm)	3.71	1.49	3.40	1.14	0.493
Molar relationship	1.42	1.25	1.39	1.50	0.947
SOFT-TISSUE PROFILE					
UL-EP (mm)	-1.49	2.05	-0.71	2.00	0.257
LL-EP (mm)	-0.08	2.69	0.36	2.34	0.591
NLA (º)	107.07	6.45	106.56	10.61	0.862

*Statistically significant at $P<0.05$

‡Chi-square test.

Table IV - Intergroup treatment changes comparison (t - tests)

	Group 1 n=18		Group 2 n=18		
	Mean	SD	Mean	SD	P
MAXILLARY SKELETAL COMPONENTS					
SNA	0.93	1.31	0.74	2.40	0.771
SA	1.12	1.93	1.88	8.38	0.710
MANDIBULAR SKELETAL COMPONENTS					
SNB	0.22	1.25	0.21	1.67	0.991
SB	1.72	2.37	4.30	10.71	0.325
MAXILLOMANDIBULAR RELATIONSHIP					
ANB	0.72	0.61	0.52	1.41	0.583
NAP	1.49	1.28	0.87	2.93	0.414
VERTICAL SKELETAL COMPONENTS					
SN.PP	-0.19	1.43	-0.12	2.16	0.899
LAFH	1.73	1.64	3.52	6.48	0.264
SN.GoMe	-0.06	1.63	0.23	2.30	0.660
FMA	0.55	1.85	1.51	1.86	0.129
MAXILLARY DENTAL COMPONENTS					
Mx6.PTV	-3.11	1.97	-5.53	2.40	0.002*
Mx6.SN	-8.02	5.18	-18.74	7.22	0.000*
Mx6-PP	0.39	1.30	-1.28	2.03	0.006*
Mx7.PTV	-2.88	1.77	-4.68	1.83	0.005*
Mx7.SN	-13.74	6.68	-14.70	10.12	0.739
Mx7-PP	-1.31	1.14	-3.06	2.16	0.005*
ANCHORAGE TEETH					
Mx1.PTV	1.88	2.22	0.69	6.07	0.438
Mx1.SN	3.72	4.91	-1.38	5.13	0.004*
Mx1.PP	0.02	0.80	1.29	3.04	0.097
Mx4.PTV	2.80	1.61	-2.24	4.32	0.000*
Mx4.SN	2.57	4.00	-1.03	6.83	0.062
Mx4.PP	0.83	1.01	1.53	2.44	0.270
DENTAL RELATIONSHIPS					
Overjet	1.59	1.32	0.23	1.01	0.001*
Overbite	-1.08	1.17	-1.07	1.25	0.967
Molar relationship (mm)	-3.93	0.83	-5.77	2.63	0.008*
SOFT-TISSUE PROFILE					
UL.EP	0.49	0.79	0.11	0.88	0.183
LL.EP	0.36	0.82	0.44	1.36	0.825
NLA	0.79	4.58	0.78	5.65	0.995

*Statistically significant at $P<0.05$

3 Discussion

3 DISCUSSION

Conventional intraoral distalizers have usually side effects as distal tipping and rotation of the distalizing molars and undesirable effects associated with anchorage loss(BYLOFF; DARENDELILER, 1997; CHAQUES-ASENSI; KALRA, 2001; FUZIY et al., 2006). Nowadays, maxillary molar distalization mechanics associated with absolute anchorage currently represent a great option for distalization of maxillary molars(KIRCELLI; PEKTAS; KIRCELLI, 2006; ESCOBAR et al., 2007; ONCAG et al., 2007; OBERTI et al., 2009; SAR et al., 2013).

The use of mini-implants allows control of most of the adverse effects. Wider and longer screws than commonly used on the palatal region for BAPA(KIRCELLI; PEKTAS; KIRCELLI, 2006; ESCOBAR et al., 2007; POLAT-OZSOY, 2008; KAYA et al., 2013; SAR et al., 2013), were used in this investigation, to be sufficiently exposed in the mouth and encompass the Nance button to better support the orthodontic forces.

In the first study, only the effects produced after the active distalization period were evaluated, and therefore, the use a control group was not necessary. In the second study, a group with similar characteristics but treated with the conventional pendulum was selected to compare the skeletal, dento-alveolar and soft tissue changes consequent to maxillary molars distalization with the pendulum appliance with skeletal anchorage. Despite the fact that this study included a retrospective selection of patients, strict inclusion criteria and treatment protocol were applied. It is important to state that all patients presented a predominantly dental Class II malocclusion with at least half Class II molar relationship and all the second molars erupted, and the majority of published studies consider the effects of distalization mechanics with absolute anchorage until the first maxillary molar(KELES; ERVERDI; SEZEN, 2003; KIRCELLI; PEKTAS; KIRCELLI, 2006; ESCOBAR et al., 2007).

In the first article, there are no statistically significant changes sagittal maxilla and mandible relative to the skull base, which indicates that both the maxilla and mandible were stable in anteroposterior direction agreeing with other studies that prove that the distalizers did not produce skeletal effects(HAYDAR; UNER, 2000; PAPADOPOULOS; MAVROPOULOS; KARAMOUZOS, 2004; ONCAG et al., 2007; POLAT-OZSOY, 2008; PATEL et al., 2009).

The most significant changes to the BAPA were evaluate in the maxillary dental components. The maxillary first and second molars had significant distalizations, greater than observed in other studies with bone anchorage(ONCAG et al., 2007; SAR et al., 2013). The distalization occurred simultaneously with distal tipping and intrusion of the first maxillary molar, which was similarly observed in other studies(HILGERS, 1992; GHOSH; NANDA, 1996; BYLOFF; DARENDELILER, 1997; BUSSICK; MCNAMARA, 2000; CHAQUES-ASENSI; KALRA, 2001; FUZIY et al., 2006).

The maxillary incisors remained without significant changes, agreeing with other studies(ESCOBAR et al., 2007; GELGOR; KARAMAN; BUYUKYILMAZ, 2007; POLAT-OZSOY, 2008). This probably occurred because the palatal plate is fixed with skeletal anchorage, therefore, there are no undesirable movements like protrusion of incisive sector, such as was found in other studies using conventional dental anchorage devices(GHOSH; NANDA, 1996; BYLOFF; DARENDELILER, 1997; BUSSICK; MCNAMARA, 2000; TOROGLU, 2001; FUZIY et al., 2006).

There were spontaneously significant distalization, distal tipping and extrusion of the first premolars, as a result of the transseptal periodontal fibers action(KELES; ERVERDI; SEZEN, 2003; ONCAG et al., 2007; KINZINGER et al., 2009; SAR et al., 2013), demonstrating that the bone-anchored Pendulum appliance is able to control this collateral effect, such as mesial movement of premolars and canines called anchorage loss.

The molar relationship was significantly improved, and the overbite significantly decreased contrasting with other studies with conventional pendulum appliances that observed overjet increase.

Regarding the second article comparing the Pendulum appliance with different anchoring systems, there were no statistically significant changes in the maxillary and mandibular sagittal skeletal components between the Pendulum with conventional and skeletal anchorages. This result was expected since the effects of these distalizers are restricted to the dento-alveolar complex, as observed in other studies that showed no skeletal effects in the maxilla and mandible(BRICKMAN; SINHA; NANDA, 2000; HAYDAR; UNER, 2000; PAPADOPOULOS; MAVROPOULOS; KARAMOUZOS, 2004; ONCAG et al., 2007; POLAT-OZSOY, 2008; KINZINGER et al., 2009; PATEL et al., 2009).

Regarding the dental changes, the maxillary first and second molars in both groups were distalized successfully without patient cooperation, and distal movement was greater than observed in other studies with CPA(GHOSH; NANDA, 1996; BYLOFF; DARENDELILER, 1997; BYLOFF et al., 1997; FUZIY et al., 2006) and BAPA(ONCAG et al., 2007; SAR et al., 2013). There was significantly greater first and second molar distalization in G2 than in G1, coinciding with what has been demonstrated in another study(POLAT-OZSOY, 2008). Probably because the force of the appliance was transmitted in one direction, without impact on the anchorage unit. This distalization was achieved in both groups with distal tipping of the maxillary molars, which was similarly observed in other studies with conventional and skeletal anchorage(HILGERS, 1992; GHOSH; NANDA, 1996; BYLOFF et al., 1997; BUSSICK; MCNAMARA, 2000; CHAQUES-ASENSI; KALRA, 2001; FUZIY et al., 2006; POLAT-OZSOY, 2008; SAR et al., 2013). However, tipping of the first and second molars in G2 was significantly greater than in G1. This is expected because the intraoral distalizer appliance forces act on the dental crowns at a distance from the center of resistance of the molars, however, some studies have reported that the side effects observed during the distal movement mechanics are corrected during orthodontic treatment and return to starting treatment values(MILLS; HOLMAN; GRABER, 1978; BRICKMAN; SINHA; NANDA, 2000; BURKHARDT; MCNAMARA; BACCETTI, 2003; CHIU; MCNAMARA; FRANCHI, 2005). The maxillary molars in both groups also experimented intrusion, which is normally consequent to the distal tipping shown by these teeth(GHOSH; NANDA, 1996; BYLOFF et al., 1997; BUSSICK; MCNAMARA, 2000; FUZIY et al., 2006).

Inclination of the maxillary incisors showed statistically significant difference between groups. In the second group with BAPA the incisors were slightly palatally tipped agreeing to other studies(ESCOBAR et al., 2007; POLAT-OZSOY, 2008), disagreeing with one(SAR et al., 2013) that showed labially tipped incisors, and another where the position of the incisors remained stable(KIRCELLI; PEKTAS;

KIRCELLI, 2006). In the first group the maxillary incisors were labially tipped, similar to several published studies(BYLOFF; DARENDELILER, 1997; BUSSICK; MCNAMARA, 2000; TOROGLU, 2001; FUZIY et al., 2006). This effect is probably due to the tendency to mesial movement of premolars and canines, and also might be the reactive force, which pushes the acrylic plate anteriorly. These results show that bone-anchorage is an excellent option to avoid reciprocal unwanted movements of the incisors, described in other studies using conventional dental anchorage devices.

The first premolars showed significantly different and opposite movements. In the first group the premolars presented mesial movement and tipping, representing anchorage loss. Probably because the reactive force is dissipated in the palatal mucosa and anchoring teeth, which in this case are the first and second premolars(GHOSH; NANDA, 1996; BYLOFF; DARENDELILER, 1997; BUSSICK; MCNAMARA, 2000; CHAQUES-ASENSI; KALRA, 2001; FUZIY et al., 2006). In the second group they had spontaneous distal movement and distal tipping during molar distalization, agreeing with other studies(KIRCELLI; PEKTAS; KIRCELLI, 2006; ESCOBAR et al., 2007; ONCAG et al., 2007). This movement was probably caused by two distinct reasons: firstly because the device is not supported on any premolar, and secondly because they are free from any attachment, and this allows the transseptal fibers to distalize them. This spontaneous movement could reduce the treatment time, particularly in the post-distalization retraction phase.

Similar to the results of several pendulum studies(GHOSH; NANDA, 1996; BYLOFF; DARENDELILER, 1997; BUSSICK; MCNAMARA, 2000; CHAQUES-ASENSI; KALRA, 2001; FUZIY et al., 2006), in the first group the overjet increased significantly due to incisor proclination. This increase is considered as anchorage loss, and probably produces longer total treatment time. In the second group there was only a small increase, probably because the incisors had palatal tipping with the distalization, similar to the findings of other studies(KIRCELLI; PEKTAS; KIRCELLI, 2006; ESCOBAR et al., 2007; POLAT-OZSOY, 2008).

Another interesting aspect of the maxillary molar distalization is the possibility to treat non-extraction and with minimal changes in the upper lip, which remained almost in the same position with the bone-anchored pendulum appliance. This means that the position of the maxillary incisors was not affected by treatment, agreeing with other researches with skeletal anchorage(KIRCELLI; PEKTAS; KIRCELLI, 2006; POLAT-OZSOY, 2008).

4 CONCLUSIONS

4 CONCLUSIONS

- The bone-anchored pendulum appliance was effective as anchorage, producing: exclusively maxillary molars distalization; spontaneous distal movement of the maxillary first premolars; no undesirable side effects in the maxillary incisors and lips and establishment of a Class I molar relationship.
- When compared with the conventional pendulum appliances, distalization of the maxillary molars was successfully achieved in both groups, but the bone-anchored pendulum appliance showed greater efficiency in molar distalization by removing undesirable effects associated with anchorage loss.

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ANNEX

FACULDADE DE ODONTOLOGIA DE BAURU-USP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação cefalométrica das alterações esqueléticas e tegumentares produzidas com o distalizador pêndulo com ancoragem convencional e esquelética

Pesquisador: ALDO OTAZU CAMBIANO

Área Temática:

Versão: 1

CAAE: 43924015.1.0000.5417

Instituição Proponente: Universidade de Sao Paulo

Patrocinador Principal: MINISTERIO DA EDUCACAO

DADOS DO PARECER

Número do Parecer: 1.051.387

Data da Relatoria: 29/04/2015

Apresentação do Projeto:

O projeto de pesquisa "Avaliação cefalométrica das alterações esqueléticas e tegumentares produzidas com o distalizador pêndulo com ancoragem convencional e esquelética" apresenta como pesquisador responsável o pós-graduando Aldo Otazu Cambiano e tem como integrante da pesquisa o Prof. Dr. Guilherme dos Reis Pereira Janson (orientador). Seu desenho visa comparar cefalometricamente as alterações dentoesqueléticas e tegumentares decorrentes da distalização dos molares superiores com o aparelho pêndulo com ancoragem convencional e modificado associado à ancoragem esquelética a curto prazo. Para isso, 2 grupos serão analisados: Grupo 1: Serão selecionados 18 casos de pacientes de Classe II (14 mulheres e 4 homens) tratados ortodonticamente com distalização de molares superiores com o aparelho pêndulo associado à ancoragem esquelética, com idade inicial entre 11 e 16 anos. Grupo 2: Com o intuito de diferenciar as alterações esqueléticas, dentoalveolares e tegumentares produzidas pelo mesmo aparelho com ancoragem convencional dentomucossuportada, serão selecionados 18 pacientes de Classe II (14 mulheres e 4 homens) tratados ortodonticamente com distalização de molares superiores com o aparelho pêndulo com ancoragem convencional. Método: Foram obtidas duas telerradiografias em norma lateral de cada paciente estudado, de ambos os grupos. Estes foram realizados ao início do tratamento (T0), e imediatamente após a distalização

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dos molares superiores (T1). Serão analizadas cefalométricamenta as radiografias e serão comparadas as variáveis cefalométricas das fases inicial e final do estudo, e para verificar as diferenças entre os grupos G1 e G2, quanto às alterações cefalométricas e tempo de tratamento.

Objetivo da Pesquisa:

Este estudo comparará cefalometricamente as alterações dentoesqueléticas e tegumentares decorrentes da distalização dos molares superiores com o aparelho pêndulo com ancoragem convencional e modificado associado à ancoragem esquelética a curto prazo.

Avaliação dos Riscos e Benefícios:

O pesquisador informa que:

Riscos:

A pesquisa não envolve risco aos pacientes uma vez que as documentações e as radiografias necessárias já foram realizadas.

Benefícios:

Aqueles pacientes que utilizaram o aparelho pêndulo associado à ancoragem esquelética e não apresentaram efeitos colaterais de perda de ancoragem poderiam ser tratados sem extrações dentárias de pré-molares.

Comentários e Considerações sobre a Pesquisa:

A pesquisa apresenta metodologia descrita corretamente com objetivos condizentes. Não apresenta comprometimento ético. Solicita dispensa de TCLE pois não será realizada nenhuma intervenção nos indivíduos da amostra da pesquisa. As documentações necessárias já foram realizadas (análise de arquivo).

Considerações sobre os Termos de apresentação obrigatória:

Foram apresentados os termos: Projeto detalhado, dispensa de TCLE, critérios de encerramento, folha de rosto e ciência do departamento.

Recomendações:

Não há recomendações.

Conclusões ou Pendências e Lista de Inadequações:

Sem pendências. Sugiro aprovação do projeto.

Situação do Parecer:

Aprovado

FACULDADE DE ODONTOLOGIA DE BAURU-USP

Continuação do Parecer: 1.051.387

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 29.4.2015, com base nas normas éticas da Resolução CNS 466/12. Ao término da pesquisa o CEP-FOB/USP exige a apresentação de relatório final. Os relatórios parciais deverão estar de acordo com o cronograma e/ou parecer emitido pelo CEP. Alterações na metodologia, título, inclusão ou exclusão de autores, cronograma e quaisquer outras mudanças que sejam significativas deverão ser previamente comunicadas a este CEP sob risco de não aprovação do relatório final. Quando da apresentação deste, deverão ser incluídos todos os TCLEs e/ou termos de doação assinados e rubricados, se pertinentes.

BAURU, 06 de Maio de 2015

Assinado por:
Izabel Regina Fischer Rubira Bullen
(Coordenador)

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Table A. Initial data of the CPA group

Grupo	**Nome**	**Sexo**	**Idade**	**Má Ocl.**	**T. de Tto.**
1	AO	F	12,58	½ Classe II	0,4
1	AV	F	12,97	¾ Classe II	0,6
1	AB	F	14,52	½ Classe II	0,5
1	AG	F	13,18	½ Classe II	0,4
1	BB	F	15,12	¾ Classe II	0,6
1	BF	M	12,81	½ Classe II	0,5
1	CD	F	14,41	¾ Classe II	0,5
1	CR	M	13,78	½ Classe II	0,4
1	DU	M	12,89	¾ Classe II	0,6
1	FG	M	14,5	¾ Classe II	0,4
1	HC	F	14,25	½ Classe II	0,5
1	JD	F	13,11	½ Classe II	0,6
1	LP	F	13,24	½ Classe II	0,5
1	LI	F	13,15	½ Classe II	0,4
1	MO	F	13,51	¾ Classe II	0,5
1	RI	F	13,18	½ Classe II	0,4
1	SH	F	14,12	¾ Classe II	0,5
1	TQ	F	13,68	½ Classe II	0,5

Table B. Initial data of the BAPA group

Grupo	Nome	Sexo	Idade	Má Ocl.	T. de Tto.
2	AB	F	14,08	½ Classe II	0,4
2	AB	F	14,33	½ Classe II	0,6
2	AM	F	15,25	½ Classe II	0,5
2	AO	F	14,08	½ Classe II	0,5
2	BR	F	14,55	¾ Classe II	0,6
2	DC	F	12,65	½ Classe II	0,5
2	DS	F	14,08	½ Classe II	0,5
2	GH	M	15,41	½ Classe II	0,4
2	GR	M	15,3	¾ Classe II	0,6
2	JC	M	14,5	½ Classe II	0,4
2	MM	F	13,91	½ Classe II	0,5
2	NS	F	13,83	½ Classe II	0,6
2	PF	F	13,58	¾ Classe II	0,5
2	PO	F	12,83	½ Classe II	0,4
2	RF	M	13,5	½ Classe II	0,5
2	TJ	F	12,91	¾ Classe II	0,6
2	TN	F	13,15	½ Classe II	0,5
2	VR	F	14,74	½ Classe II	0,6