UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

DEBORAH BRINDEIRO DE ARAÚJO BRITO

Treatment of Class II malocclusion with Forsus appliance: a long-term assessment

Tratamento da má oclusão de Classe II com aparelho Forsus: uma avaliação em longo prazo

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Tese constituída por artigos apresentada à Faculdade de Odontologia de Bauru da Universidade de São Paulo para obtenção do título de Doutor em Ciências no Programa de Ciências Odontológicas Aplicadas, na área de concentração Ortodontia.

Orientador: Prof.º Dr.º José Fernando Castanha Henriques

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"Percebe e entende que os melhores amigos
São aqueles que estão em casa, esperando por ti"

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(Amyr Klink)

ABSTRACT

Treatment of Class II malocclusion with Forsus appliance: a long-term assessment

Introduction: Successful treatment of Class II Division 1 malocclusion is implied to the long-term stability of treatment changes. **Objective:** The research aimed to evaluate the outcomes of Class II division 1 malocclusion correction with Forsus Fatigue Resistant Device (FRD) and the long-term stability of skeletal, dentoalveolar and occlusal changes produced by this therapy, associated to the patient satisfaction in the long-term. **Material and Methods:** 14 patients who were evaluated at 3 stages: pretreatment (T1), posttreatment (T2) and long-term posttreatment (T3) stages. The subjects also answered a satisfaction questionnaire at T3. Intragroup comparison of the cephalometric variables and the PAR index T1, T2 and T3 were were performed with ANOVA, followed by Tukey tests. Intragroup comparison of the OGS index at T2 and T3 were performed with dependent t tests. Intergroup comparisons of posttreatment changes and normal growth changes of the treatment group were performed with t tests. Results: There were dentoskeletal and soft tissue changes favorable for class II malocclusion correction. PAR index improved with treatment (T2-T1) and both PAR and OGS indexes remained stable at the long-term posttreatment period (T3-T2). Treatment has remained stable after 5 years follow-up. **Conclusions:** Treatment with the Forsus FRD appliance is efficient for patients with Class II malocclusion and changes obtained during treatment remained stable in the long-term posttreatment. The vast majority of patients were satisfied with the treatment and the current smile esthetics.

Keywords: Class II treatment; Fixed functional appliance; posttreatment; stability; relapse.

RESUMO

Tratamento da má oclusão de Classe II com aparelho Forsus: uma avaliação em longo prazo

Introdução: O tratamento bem-sucedido da má oclusão de Classe II Divisão 1 está implícito na estabilidade em longo prazo das alterações do tratamento. **Objetivo:** A pesquisa objetivou avaliar os resultados da correção da má oclusão de Classe II, divisão 1, com o Forsus Fatigue Resistant Device (FRD) e a estabilidade em longo prazo das alterações esqueléticas, dentoalveolares e oclusais produzidas por essa terapia, associadas à satisfação do paciente a longo prazo. **Materiais e Métodos**: 14 pacientes avaliados em três estágios: pré-tratamento (T1), pós-tratamento (T2) e pós-tratamento em longo prazo (T3). Os sujeitos também responderam a um questionário de satisfação em T3. A comparação intragrupo das variáveis cefalométricas e do índice PAR em T1, T2 e T3 foi realizada com ANOVA, seguido do teste Tukey. A comparação intragrupo do índice OGS em T2 e T3 foi realizada com teste t dependente. Comparações intergrupos de alterações pós-tratamento e mudanças do crescimento normal do grupo de tratamento foram realizadas com teste t. **Resultados:** Houve alterações dentoesqueléticas e de tecidos moles favoráveis à correção da má oclusão de classe II. O índice PAR melhorou com o tratamento (T2-T1) e os índices PAR e OGS permaneceram estáveis no período pós-tratamento a longo prazo (T3-T2). O tratamento permaneceu estável após 5 anos de acompanhamento. **Conclusões:** O tratamento com o aparelho Forsus FRD é eficiente para pacientes com má oclusão de Classe II e as alterações obtidas durante o tratamento permaneceram estáveis em longo prazo pós-tratamento. A grande maioria dos pacientes ficou satisfeita com o tratamento e com a estética atual do sorriso.

Palavras-chave: Tratamento de Classe II; Aparelho funcional fixo; Pós-tratamento; Estabilidade; Recidiva.

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1 INTRODUCTION

1 INTRODUCTION

Class II division 1 malocclusion affects 12-49% of the population[1] and comprises approximately one third of patients seeking for orthodontic treatment, due to its important esthetic effect. Class II malocclusion is characterized by an incorrect relationship between the maxillary and mandibular arches due to skeletal or dental problems or a combination of both.[2-4] Some studies have shown that the components of Class II malocclusion can be categorized into four main groups: anterior position of the maxillae, anterior position of the maxillary dentition, mandibular skeletal retrusion in absolute size or relative position, and excessive or deficient vertical development.[5,6] A number of studies have shown that Class II malocclusion is mainly characterized by mandibular retrognathia.[2,7-12]

The success of treatment of Class II malocclusion is related not only to a careful evaluation of these factors, as well as the timing and type of treatment proposed. The choice for a specific protocol is based on the benefits of the treatment along with its effectiveness and efficiency in correcting several aspects of the malocclusion.[13] Nevertheless, the decision as to which is the most effective technique for the treatment of growing patients with skeletal and dental Class II malocclusions has long been the source of considerable debate in the orthodontic literature.[14]

A common strategy in the treatment of Class II Division 1 malocclusions in growing patients is a 2-step approach. In the first phase of the treatment, the sagittal jaw relationship is normalized. Then Class II malocclusion is transformed into Class I malocclusion.[15] In the second phase of the treatment, tooth positions are adjusted, usually with fixed appliances.[9,15] However, there are also appliances that ideally allow the simultaneous (orthopedic and orthodontic) placement of a fixed orthodontic appliance in a single step, thereby speeding up the treatment length.[16]

Early intervention in cases of patients undergoing active growth using an association of orthodontic and orthopedic approach has been proven to be a successful therapy in the treatment of this malocclusion.[1]. Evidence has shown that the greatest effects of functional appliances, removable ou fixes, occur when the peak in mandibular growth is included in the treatment period.[17] The expected effects of

these appliances include alteration of maxillary growth, a possible change in mandibular growth and position, and an improvement in dental and muscular relationships.[18,19] Therefore, in order to be effective in treating Angle's Class II Division 1 malocclusion, an appliance should ideally generate the skeletal and dental effects necessary to correct the discrepancy between the basal bones while reducing overjet, thereby eliminating the need for patient compliance.[16,20]

Among the several fixed functional devices, since the introduction of Herbst appliance[21], the Forsus Fatigue Resistant Device (FRD), which has been used a lot nowadays. It is indicative to expect similar effects from all kinds of fixed functional appliances for Class II correction. However, it must be considered that the amount of dental and skeletal treatment effects for each, and thus the potential for relapse, may differ.[22] Thus, there is still insufficient stability data on them.[22-24] And as is important as obtaining these effects and correction of malocclusion is the stability of long-term changes. Furthermore, the Literature shows a shortcoming observed in the few studies on this subject was the absence of a control group of untreated subjects for analysis of the results.[25]

The maintenance of dental alignment after orthodontic treatment has been and continues to be a challenge to the orthodontic profession. The obtained resuts must translate a normal or ideal occlusion that is morphologically stable and esthetically and functionally well adjusted. Previous studies with functional appliances[22,24,26] have used cephalometry to assess changes, but occlusal indexes are rarely tested. Attempts have recently been made to evaluate treatments in a more objective way. In this context, the Peer Assessment rate (PAR index) and the American Board of Orthodontics Objective Grading System (OGS) are two of the most used indexes to evaluate treatment outcomes and stability.[27]

The PAR Index was developed to measure treatment outcomes in orthodontics[28] and its validity and it was improved by weighting the scores of some components to reflect their relative importance.[27] It evaluates tooth alignment, dental impaction, relationships of the buccal segments, overjet, overbite and midline discrepancies. The greater the mean percentage reduction in the PAR score, the greater the finishing achieved by the orthodontic treatment. More recently, in order to assess the adequacy of finished orthodontic results, The American Board of Orthodontics (ABO) developed a model grading system (Objective Grading System

OGS) as an occlusal index to evaluate posttreatment dental casts.[29] It assesses the final occlusion according to 8 different occlusal components: alignment, marginal ridges, buccolingual inclination, occlusal relationships, occlusal contacts, overjet, interproximal contacts, and root angulation.

Associated with that, an assessment of the long-term outcome of orthodontic treatment should also include patient satisfaction with respect to dental and facial appearance in treated as well as in untreated groups.[30,31]

Orthodontists should be familiar with different devices in order to accomplish this choice individually for each patient, aware of the advantages and limitations that each intervention will have, as well as its long-term outcomes. Observing the lack of researchs, the aim of this study was to evaluate the outcomes of Class II division 1 malocclusion correction with the Forsus FRD appliance and the long-term stability of skeletal, dentoalveolar and occlusal changes produced by this therapy, associated to the patient satisfaction in the long-term.

2 ARTICLES

2 ARTICLES

The articles presented in this Thesis were written according to the American Journal of Orthodontics and Dentofacial Orthopedics instructions and guidelines for article submission.

- **Article 1 -** Long-term stability of Class II treatment with the Forsus appliance

- **Article 2 -** Long-term comparison of occlusal changes and patients' satisfaction of Class II malocclusion treatment with the Forsus appliance

2.1 ARTICLE 1

Long-term stability of Class II treatment with the Forsus appliance

ABSTRACT

Objective: to evaluate the long-term posttreatment stability of the dentoalveolar and skeletal changes obtained from Class II malocclusion correction with the Forsus FRD associated with multibracket fixed appliances. **Methods:** The treatment group comprised 14 patients who were evaluated at 3 stages: pretreatment, posttreatment, and 5-years follow-up. The control group comprised 14 subjects with normal occlusion. Intratreatment group comparisons among the 3 stages were performed with ANOVA, followed by Tukey tests. Intergroup comparisons of posttreatment changes and normal growth changes of the treatment group were performed with t tests. **Results:** Improvement of apical base relationship and molar relationship and reduction of overjet and overbite obtained with treatment remained stable in the posttreatement period. As well as the labial inclination of the mandibular incisors. **Conclusions:** Treatment with the Forsus FRD, associated with fixed appliances, is an effective alternative for patients with Class II malocclusion since most of the changes obtained during treatment remained stable in a long-term period of 5 years.

Keywords: Malocclusion, Angle Class II; Orthodontic Appliances Functional; Orthodontics; Stability.

INTRODUCTION

Class II malocclusion is one of the most common irregularities in orthodontic practice.[1-3] It is characterized by an incorrect relationship between the maxillary and mandibular arches due to skeletal or dental problems or a combination of both, and mandibular retrognathia is the most dominant component of this malocclusion.[4]

Several types of removable and fixed functional appliances are used for Class II malocclusion treatment due to mandibular retrusion,[5-7] and an important discriminating factor between them is the need for patient compliance, since the success of functional therapy via removable appliances depends mainly on patient

cooperation.[7-9] Fixed functional appliances have been developed and chosen by numerous orthodontists,[7,10] and one of these devices is the Forsus Fatigue Resistant Device (FRD, 3M Unitek Corp, Monrovia, Calif.).

The Forsus FRD is a three-piece semirigid telescoping system incorporating a superelastic nickel-titanium coil spring and complete fixed orthodontic appliances. The device is compatible with other preexisting appliances and can be associated with them in a relatively short amount of time. Treatment with the device typically demonstrates mesial movement of the mandibular molars, labial tipping of the mandibular incisors, and variable effects associated with mandibular growth.[11]

However, studies report that changes obtained during the active treatment period, tend to dissipate after removal of the functional appliance.[12,13] The most in-depth analysis of functional appliance stability centered on the Herbst appliance with up to 32 years of retrospective follow-up.[14]

It could be argued that the majority of fixed devices are derived from the Herbst, as well as, the Forsus FRD. Therefore, similar effects might be expected with fixed functional appliances in Class II malocclusion correction. However, it must be considered that the amount of dental and skeletal treatment effects and the potential relapse may differ.[10] Thus, there is still insufficient data regarding treatment stability with these appliances.[1,8,10]

Based on the lack of investigations in this area, since stability is the key to success in orthodontic treatment, this study aimed to evaluate the long-term posttreatment stability of the dentoalveolar and skeletal changes obtained from Class II malocclusion correction with the Forsus FRD associated with multibracket fixed appliances.

MATERIAL AND METHODS

This study was approved by the Ethics in Research Committee of Bauru Dental School - University of São Paulo, Brazil (Protocol number: 71652217.1.0000.5417; decision number: 2.390.110), and all subjects signed informed consent.

The sample size calculation was based on an alpha significance level of 0.05 and a beta of 0.2, to detect a mean difference of 0.5° with a standard deviation of 0.5° in the ANB angle change between the posttreatment and long-term posttreatment stages, as previously suggested.[15]. Therefore, a minimum of 10 subjects in each group was required.

Based on the sample size calculation, this study comprised 42 lateral headfilms of 14 patients (10 male; 4 female), with Class II division 1 malocclusion initially, who were treated with the Forsus FRD combined with multibracket fixed appliances. This sample was retrospectively selected from the files of the Orthodontic Department at Bauru Dental School - University of São Paulo.

The treated group was selected according to the following inclusion criteria: Class II Division 1 malocclusion with bilateral Class II molar relationship (minimum severity of a half-cusp Class II molar relationship);[16,17] absence of agenesis, supernumerary or lost teeth, convex profile; mandibular retrognathism, mandibular arch with slight or no crowding, and without history of previous orthodontic treatment.[8] No cephalometric characteristics was considered as inclusion criteria. All patients were treated without extractions for a mean period of 3.32 years (SD, 1.24). The mean initial age of the patients was 12.60 years (SD, 1.32), and the mean final age was 15.92 (SD, 1.39). The mean age at the long-term posttreatment stage was 20.98 years (SD, 1.25). Thus, the mean long-term posttreatment period was 5.06 years (SD. 0.77; Table I).

All patients were treated by the same experienced orthodontist and the treatment protocol consisted on the use of the Forsus FRD associated with multibracket fixed appliances (Figs. 1A and B). Anchorage reinforcement was obtained by the installation of a transpalatal bar, resistant lingual torque and elastic chains on the lower incisors, and distal folds in the arch were performed. This mechanics was maintained until the correction of the Class II with an overcorrection of at least a quarter-cusp bilateral Class III molar relationship. Patients used the Forsus FRD for a mean period of 0.37 years (SD, 0.13). Then the device was removed for treatment completion and to obtain adequate intercuspation. Class II intermaxillary elastics were used as active retention in the nocturnal period during 4 months to preserve the favorable sagittal relationship obtained.[18] After comprehensive treatment, (Fig.1C) each patient was given a fixed mandibular canine-to-canine retainer, for a minimum period of five years or until the end of growth, and a Hawley plate for daily use during one year. Additionally, patients were recalled after an average period of 5 years to check treatment stability (Fig. 1D).

The control group comprised 14 subjects (8 male, 6 female) with normal occlusion and a initial mean age of 16.00 years (SD, 0.55), and a final mean age of 20.71 years (SD, 1.48) comparable to the treated group at the posttreatment and long-term posttreatment stages (Table I). This group was selected from the longitudinal

growth study sample of the "Iowa Facial Growth Study" (Department of Orthodontics, College of Dentistry, University of Iowa, Iowa City, USA) downloaded from the online American Association of Orthodontics Foundation (AAOF) Craniofacial Growth Legacy Collection (http://www.aaoflegacycollection.org).[19]

For the study group, three lateral headfilms (Fig. 2) were obtained of each patient in the following stages of orthodontic treatment: pretreatment (T1); posttreatment, when the multibracket fixed appliances were removed (T2) and long-term posttreatment (T3). For the control group, two lateral headfilms were selected from each patient matching the ages of the experimental group at T2 and T3. The headfilms were digitized (ScanMaker, model i800; Microtek, Hainchu, Taiwan), traced, and analyzed with the Dolphin software (version 11.5; Dolphin Imaging and Management Systems, Chatsworth, CA, USA). The software corrected the image magnification factors because the lateral headfilms were obtained from different x-ray machines. A customized cephalometric analysis generated 27 variables, 8 angular and 17 linear, for each tracing (Table II).

Error Study

Twenty-one lateral headfilms were randomly selected, redigitized, retraced, and remeasured by the same examiner (D.B.A.B.), after a 30-day interval. Random errors were calculated according to Dahlberg's formula ($Se^2 = \sum d^2/2n$),[20] and the systematic errors were evaluated with dependent *t* tests, for $P<0.05$.

Statistical Analyses

Kolmogorov-Smirnov tests were used to assess normal distribution, and all variables showed normal distribution.

Intergroup comparability regarding ages at T2 and T3 were performed with t tests and intergroup sex distribution comparison was performed with Chi-square tests.

Repeated measures analysis of variance (ANOVA), followed by Tukey tests was used for the intragroup comparisons among the treated group in the 3 treatment stages, and the intergroup treatment changes comparisons during posttreatment (T3–T2) were evaluated by t tests.

The analyses were conducted with Statistica© software (Statistica for Windows, version 7.0; Statsoft, Tulsa, OK). Results were considered statistically significant at $P<0.05$.

RESULTS

Only one variable (LAFH) had a significant systematic error. The random errors were within acceptable limits[8,21] and ranged from 0.27mm (Molar Relationship) to 1.57mm (Wits) and from 0.34º (SNB) to 1.57º (Mx1.PP) for the linear and angular variables respectively.

The groups were comparable regarding their chronological ages at the posttreatment and long-term posttreatment stages, posttreatment period and sex distributions (Table I).

Treatment produced a statistically significant reduction of the maxillary protrusion in the long-term posttreatment period (Table III). The effective mandibular length significantly increased during the treatment and kept increasing during the long-term posttreatment period. During treatment, there was significant improvement in the maxillomandibular relationship, which remained stable in the long-term posttreatment. The lower anterior facial height showed a significant increase in the long-term posttreatment period. The maxillary molars showed a significant vertical development and mesialization in the long-term posttreatment period when compared to pretreatment. The mandibular incisors presented significant labial inclination, which remained stable in the posttreatment period. There was also significant increases in the mandibular molar vertical development in the long-term posttreatment period. Treatment also produced significant improvements in overjet, overbite, and molar relationship, which remained stable in the long-term posttreatment period. A reduction in the upper lip protrusion was observed in the long-term posttreatment period in relation to pretreatment.

Intergroup comparisons of the long-term posttreatment changes showed that the mandibular protrusion and the mandibular effective length were significantly more increased in the control group than in the treated group (Table IV). The maxillary incisors were retruded in the control group while the treated group presented protrusion, therefore, demonstrating significant differences. Also, the maxillary molars showed a significantly greater vertical development and mesialization in the control when compared to the treated group. Regarding the overjet and overbite, the groups behaved differently, with the treated group presenting an increase of these variables, while the control group showed reduction. In relation to the soft-tissue component, the upper and lower lips presented retrusion in both groups, nonetheless, it was significantly greater in the control group.

DISCUSSION

Sample and Methodology

Intergroup great comparability was essential to obtain reliable results[22] (Table II). Furthermore, it is important to emphasize that the majority of relapse occurs until first 6 years posttreatment,[14] and there are knowledge gaps about the stability of early treatment of Class II malocclusion in the long-term.[23] Thus, the follow-up time for this study was an important factor in assessing the main changes that may occur in the long-term posttreatment in young patients.

Maxillary component

The treatment produced a significant reduction of the maxillary protrusion, which remained stable on the posttreatment stage (Table III). This results are in agreement with previous studies that also found significant restrictions of maxillary growth with treatment.[9,24] There was no difference in long-term posttreatment compared to the control group. An acceptable explanation for this finding is the fact that point A is influenced by the dentition. When the upper incisors are retruded, labial tipping of the roots can shift the point A anteriorly, like this backward displacement of point A was masked because of the dental alterations.[24] Some authors conflicted with these findings.[3,25,26] Improvement in basal bone relationship during treatment resulted from the significant reduction of the maxillary protrusion and the mandibular growth.[24,26] Changes in the effective maxillary length showed soft increase in the long-term posttreatment stage on the experimental group that was similar to the increase observed on the control group due to normal growth and development (Table IV).

Mandibular component

There were no significant changes on the anteroposterior mandibular position in relation to the cranial base, however, a statistically significant increase in mandibular effective length was observed during treatment (Table III), which is in agreement with the results of a number of investigations involving the Forsus appliance and other functional devices.[3,5,8,21,24,26-28] This finding contributions to the improvement in basal bone relationship during treatment as previously discussed.

In the follow-up period, the position of the mandible becomes more anterior in control group, in addition to the increase in the effective size of the mandible in this

group (Table IV). This comparison with the treated group in this study confirms that the changes found in the mandibular component in the posttreatment period are related to the normal growth of individuals.[8,12,25,27] Although our study did not demonstrate the skeletal age of the individuals, the findings in the literature explain the changes related to position and size of mandible did not significantly differ when the treated subjects were compared with the controls for the overall effect estimate and for the pubertal and postpubertal.[29] That this fact is related to the individual's active growth during and after treatment.[8,27,30]

Maxillomandibular Relationship

There was a significant improvement of the maxillomandibular relationship, due to the skeletal beneficial effects of the Forsus therapy during treatment[24,31-34] (Table III). Improvement in basal bone relationship during treatment resulted from the significant reduction of the maxillary protrusion and the mandibular growth. The relationship remained stable during posttreatment period, showing a similar behavior to normal growth changes[8] (Table IV). Most important is that this effects and the maxillomandibular relationship achieved with treatment remained stable during the long-term posttreatment period, similarly to non-extraction Class II malocclusion treatment with other appliances.[35-39]

Vertical component

The facial pattern remained unaffected during treatment, but reduced not significantly in the long-term posttreatment period (Table III) suggesting a counterclockwise rotation and maintaining the growth pattern.[8] The lower anterior facial height showed a significant increase during both periods in experimental group, however it was statistically significant only in the long-term posttreatment period (Table III). There were no statistically significant changes in the long-term posttreatment for the experimental and control groups, showing that the changes are consequent to normal growth and development and that the control group possessed a potential for further mandibular growth then the experimental group.[8,40,41]

Maxillary Dentoalveolar component

There were a significant extrusion of maxillary molars during posttreatment period (Table III), due to growth and development due to growth and development

during posttreatment period[8,25,42,43] (Table III), and a similar extrusion as the observed on the posttreatment for the experimental group was presented by the control group (Table IV). In addition, there was mesialization of the upper molars during treatment, remaining stable in the posttreatment period. During treatment, the maxilla moved mesially, like this upper molars were moved mesially in similar movement, and after Class I molar occlusion is achieved and appliances are removed, mesial maxillary molar movement might be expected to keep pace with the mandibular molars[11] (Table III).

Mandibular Dentoalveolar component

Even though the mandibular incisors presented significant labial inclination during treatment this effect remained stable on the posttreatment stage[3,11,14,24,25,31,34,44] (Table III). Most functional appliances generate the anterior-directed force vector on the mandibular dentition, and although the Forsus appliance was used in a lower arch with resistant torque and tie together to reduce the labial tipping, there was a significant inclination of these teeth, as previously reported.[32,34,45,46] Other mechanical strategies can be used to reduce this undesirable effect on the lower incisors, such as the use of ~~a~~ mini implants for anchorage reinforcement.[33]

No significant changes in mandibular molar sagittal positions occurred during the treatment and posttreatment periods, while a significant vertical development was observed at posttreatment (Table III). That finding is probably related to growth and normal development, since more extrusion was observed on the comparable time by the control group[8,25] (Table IV).

Dental Relationship

Treatment produced significant improvements in the overjet, overbite and molar relationships (Table III). Similar results are found in the literature, and this study showed that the correction was maintained stable from a long-term perspective.[3,5,11,24,25,32,47]

Comparing with the long-term posttreatment changes presented by the control group, a modest tendency to relapse in treated group was noticed, characterized by a mild increase of the overjet and overbite (Table IV). This fact highlights the importance of active retention and overcorrection, which were performed in these patients. The

great stability presented by the molar relationships might also be related from these approaches.[8,42,47]

Soft tissue component

Despite the significant dentoskeletal changes related to the correction of the anteroposterior discrepancy with the Forsus FRD, there was no significant changes in the nasolabial angle.[8] The intragroup comparisons showed a modest retrusion in the upper lip[34] (Table III), however, the intergroup comparisons evidenced that the upper and lower lips retrusion were significantly greater in the untreated control (Table IV). Thus, probably, these soft tissue changes may not be attributed to treatment.

CONCLUSION

Based on these results, it can be concluded that treatment with the Forsus FRD, associated with fixed appliances, is an effective alternative for patients with Class II malocclusion since most of the changes obtained during treatment remained stable in a long-term period of 5 years.

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Figure legends:

Fig. 1.A: Pretreatment - Bilateral Class II malocclusion (T1). B: Forsus FRD appliance, associated with multibracket fixed appliances. C: Posttreatment (T2). D: Long-term posttreatment (T3). Five years of treatment completion.

Fig. 2.: Lateral headfilms at pretreatment (T1); posttreatment, (T2) and long-term posttreatment.

Fig. 1

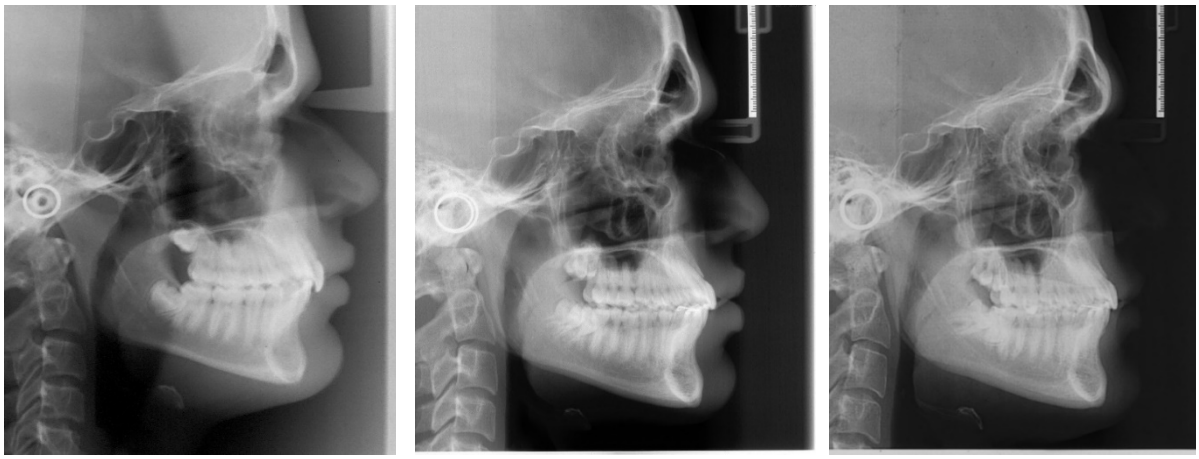

Fig. 2

Table I - Intergroup comparability regarding ages at T1, T2, and T3, treatment and long-term posttreatment periods (t tests) and sex distributions (Chi-square tests)

	Treatment group (n=14)		Control group (n=14)		*P*
Stage/Period (Years)	Mean	S.D.	Mean	S.D.	
T1 age	12.60	1.32	---	---	
T2 age	15.92	1.39	16.00	0.55	0.858£
T3 age	20.98	1.25	20.71	1.48	0.606£
Treatment period (T2-T1)	3.32	1.24	---	---	
Long-term Posttreatment period (T3-T2)	5.06	0.77	4.71	1.20	0.377£
Sex	Male 10 (71.42%)	Female 4 (28.57%)	Male 8 (57.14%)	Female 6 (42.85%)	0.430†

T1, Pretreatment; T2, posttreatment; T3, long-term posttreatment.

£t test; †Chi-square test.

Table II - Skeletal and dental cephalometric variables.

Maxillary component	
SNA angle (˚)	Angle formed by the intersection of SN line and NA line
A-NPerp (mm)	A-point to nasion-perpendicular
Co-A (mm)	Condylion to A-point distance
Mandibular component	
SNB angle (˚)	Angle formed by the intersection of SN line and NB line
Pg-NPerp (mm)	Pg-point to nasion-perpendicular
Co-Gn (mm)	Condylion to gnathion distance
Maxillomandibular relationship	
ANB angle (˚)	Angle formed by the intersection of NA line and NB line
Wits (mm)	Distance between perpendicular projections of Points A and B on functional occlusal plane
Vertical component	
FMA (˚)	Angle formed by the intersection of Frankfurt plane and Go-Me
SN.GoGn (˚)	Angle formed by the intersection of SN line and Go-Gn
LAFH (mm)	Distance from ANS to menton
Maxillary dentoalveolar component	
Mx1.PP (˚)	Angle formed by the maxillary incisor long axis to the palatal plane (PP)
Mx1-PP (mm)	Perpendicular distance between incisal edge of maxillary incisor and PP
Mx1-APo (mm)	Distance between incisal edge of maxillary incisor and A-Pg line
Mx6-PP (mm)	Perpendicular distance between maxillary first molar occlusal and PP
Mx6-APerp (mm)	Distance between maxillary first molar occlusal and line perpendicular to PP, tangent to A point
Mandibular dentoalveolar component	
Md1.NB (˚)	Angle formed between the mandibular incisor long axis to NB
Md1-NB (mm)	Distance between the most anterior crown point of the mandibular incisor and NB line
Md1-MP (mm)	Perpendicular distance between incisal edge of mandibular incisor and mandibular plane
Md6-MP (mm)	Perpendicular distance between mandibular first molar occlusal and mandibular plane
Md6-PogPerp (mm)	Distance between mandibular first molar occlusal and line perpendicular to mandibular plane, tangent to Pg point
Dental relationship	
Overjet (mm)	Distance between incisal edges of maxillary and mandibular central incisors, parallel to functional occlusal plane
Overbite (mm)	Distance between incisal edges of maxillary and mandibular central incisors, perpendicular to Frankfort plane
Molar Relationship (mm)	Distance between mesial points of maxillary and mandibular first molars, parallel to Frankfort plane
Soft-tissue component	
Nasolabial angle (º)	Angle formed by the Prn'-Sn line and UL-Sn' line (Prn' pronasal point, Sn subnasal point, UL upper lip)
Upper Lip (mm)	Distance between point of the upper lip to S line (Pg' 'point to nose)
Lower Lip (mm)	Distance between point of the lower lip to S line (Pg' 'point to nose)

Table III- Intragroup comparison of the cephalometric variables at the 3 stages (repeated measures ANOVA followed by Tukey tests)

Variable	Unit	T1		T2		T3		*P*
		Mean	S.D.	Mean	S.D.	Mean	S.D.	
Maxillary component								
SNA angle	^{0}	84.17^A	3.02	82.24^{AB}	2.85	81.90^B	4.26	0.017*
A-NPerp	mm	2.17	3.12	0.86	2.84	0.51	4.12	0.070
CoA	mm	81.17	4.34	81.42	4.25	82.52	4.26	0.222
Mandibular component								
SNB angle	^{0}	78.40	3.40	78.40	3.70	78.57	3.74	0.935
Pg-NPerp	mm	-3.92	6.10	-3.22	7.15	-2.80	8.32	0.566
Co-Gn	mm	108.75^A	7.32	113.72^B	7.40	116.02^C	7.61	<0.001*
Maxillomandibular relationships								
ANB angle	^{0}	5.76^A	1.63	3.86^B	2.57	3.31^B	2.50	0.001*
Wits	mm	4.61^A	2.44	0.20^B	2.41	0.07^B	3.13	<0.001*
Vertical component								
FMA	^{0}	23.97	4.94	23.17	4.71	22.82	5.53	0.207
SN-GoGn	^{0}	29.37	4.96	29.17	4.95	28.87	4.79	0.796
LAFH	mm	64.49^A	4.98	66.15^{AB}	4.22	67.72^B	4.76	<0.001*
Maxillary dentoalveolar component								
Mx1.PP	^{0}	105.81	10.06	108.80	5.30	110.54	5.04	0.193
Mx1-PP	mm	29.05	2.12	29.16	2.00	29.95	2.36	0.214
Mx1-APo	mm	6.95	2.88	5.90	1.71	6.44	1.49	0.132
Mx6-PP	mm	17.35^A	2.52	18.35^{AB}	2.56	19.83^B	2.42	0.002*
Mx6-APerp	mm	28.38^A	2.06	26.32^B	2.44	25.52^B	2.51	<0.001*
Mandibular dentoalveolar component								
Md1.NB	^{0}	28.47^A	4.40	32.84^B	5.56	32.44^B	4.76	0.011*
Md1-NB	mm	5.47	1.82	6.25	1.94	6.30	2.21	0.212
Md1-MP	mm	36.50	3.36	36.12	3.92	37.45	3.61	0.065
Md6-MP	mm	28.80^A	4.87	30.97^{AB}	2.67	32.00^B	3.47	0.012*
Md6 - PogPerp	mm	31.61	2.64	30.63	3.17	30.67	3.49	0.388
Dentoalveolar relationship								
Overjet	mm	5.54^A	2.40	2.70^B	0.89	3.07^B	0.90	<0.001*
Overbite	mm	3.89^A	1.24	1.44^B	0.72	1.81^B	1.01	<0.001*
Molar Relationship	mm	2.67^A	1.32	-0.22^B	0.85	-0.25^B	0.62	<0.001*
Soft-tissue Component								
Nasolabial angle	^{0}	110.84	8.42	109.62	8.35	110.76	7.51	0.945
Upper lip	mm	4.30^A	1.91	4.07^{AB}	1.74	3.41^B	2.14	0.030*
Lower lip	mm	2.40	1.85	3.55	1.80	2.72	2.16	0.096

Different letters indicate statistically significant differences;
*Statistically significant at $P<0.05$.

Table IV - Intergroup comparisons of the long-term posttreatment changes and normal growth changes (*t* tests)

Variable	Unit	Treatment Group (n=14)		Control Group (n=14)		*P*
		Mean	S.D.	Mean	S.D.	
Maxillary component						
SNA angle	^{0}	-0.33	2.05	0.30	3.03	0.517
A-NPerp	mm	-0.35	2.13	0.73	3.92	0.272
CoA	mm	1.09	1.77	0.68	2.59	0.632
Mandibular component						
SNB angle	^{0}	0.17	1.82	1.56	1.92	0.060
Pg-NPerp	mm	0.42	3.19	5.37	4.75	0.003*
Co-Gn	mm	2.29	3.24	6.22	4.05	0.008*
Maxillomandibular relationships						
ANB angle	^{0}	-0.55	1.54	-1.27	2.12	0.308
Wits	mm	-0.12	2.75	0.03	1.86	0.861
Vertical component						
FMA	^{0}	-0.34	1.89	-4.48	7.93	0.068
SN-GoGn	^{0}	-0.30	2.45	-1.75	2.25	0.114
LAFH	mm	1.57	2.22	2.90	1.91	0.102
Maxillary dentoalveolar component						
Mx1.PP	^{0}	1.74	5.19	0.33	5.33	0.485
Mx1-PP	mm	0.78	1.08	0.62	1.04	0.699
Mx1-APo	mm	0.53	1.39	-2.00	2.02	<0.001*
Mx6-PP	mm	1.48	2.12	4.04	2.17	0.004*
Mx6-APerp	mm	-0.80	1.45	-4.42	3.04	<0.001*
Mandibular dentoalveolar component						
Md1.NB	^{0}	-0.40	2.89	-0.97	5.92	0.748
Md1-NB	mm	0.04	0.99	-1.18	2.37	0.085
Md1-MP	mm	1.33	1.65	2.16	1.93	0.234
Md6-MP	mm	1.02	1.94	1.89	1.60	0.211
Md6 - PgPerp	mm	0.03	1.81	-1.62	2.75	0.070
Dentoalveolar relationship						
Overjet	mm	0.25	0.81	-1.10	1.32	0.003*
Overbite	mm	0.37	0.75	-0.66	1.20	0.011*
Molar Relationship	mm	-0.08	0.88	-0.74	1.14	0.101
Soft-tissue Component						
Nasolabial angle	^{0}	1.14	6.16	0.93	9.35	0.945
Upper lip	mm	-0.65	1.19	-1.97	1.65	0.023*
Lower lip	mm	-0.82	1.13	-2.59	2.19	0.012*

*Statistically significant at $P<0.05$.

2.2 ARTICLE 2

Long-term comparison of occlusal changes and patients' satisfaction of Class II malocclusion treatment with the Forsus appliance

ABSTRACT

Objective: The aim of this study was to evaluate the outcomes and the long-term occlusal stability of Class II malocclusion correction with the Forsus Fatigue Resistant Device (FRD), associated to the patient satisfaction in the long-term. **Methods:** The sample comprised 12 patients treated with Forsus FRD evaluated with the PAR and OGS indexes in dental casts and panoramic radiographs obtained at pretreatment (T1), posttreatment (T2) and long-term posttreatment (T3) stages. The subjects also answered a satisfaction questionnaire at T3. Intragroup comparison of the PAR index at T1, T2 and T3 were performed with ANOVA and Tukey tests. Intragroup comparison of the OGS index at T2 and T3 were performed with dependent t tests. **Results:** PAR index improved with treatment (T2-T1) and both PAR and OGS indexes remained stable at the long-term posttreatment period (T3-T2). **Conclusions:** Occlusal changes obtained during treatment with Forsus FRD remained stable in the long-term posttreatment, according to PAR and OGS indexes. The vast majority of patients were satisfied with the treatment and the current smile esthetics.

Keywords: Functional Orthodontics; Posttreatment; Objective grading system; Stability; Relapse.

INTRODUCTION

Class II malocclusion is considered one of the most encountered problems in the orthodontic practice, accounting for approximately one third of the patients seeking orthodontic treatment.[1] Among the factors that contribute to the development of Class II malocclusion, mandibular retrognathism is the most common.[2] The use of functional appliances during the growth period allows to redirect this pattern of mandibular growth in a beneficial way.[3,4]

In this context, the Forsus Fatigue Resistant Device (FRD) (3M Unitek Corp, Monrovia, Calif) stands out as an excellent alternative of compliance-free fixed interarch appliance typically demonstrate mesial movement of the mandibular molars,

tipping of the mandibular incisors, and variable effects associated with mandibular growth.[4-7]

Previous studies with functional appliances[8-10] have used cephalometry to assess changes, but occlusal indexes are rarely tested, as Peer Assessment Rating (PAR) and the Objective Grading System (OGS).[11,12] Evaluation of efficacy and difficulty of treatment, quality of completion and stability of long-term posttreatment of esthetic and occlusal results possible are investigations recommended for a long time in the literature.[13]

The PAR index was developed to assess treatment outcome in a quantitative manner. I provides a summary score for occlusal anomalies and an estimate of how far a malocclusion deviates from normal alignment and occlusion. It was weighted to match the judgment of a panel of British orthodontists and general dentists on the deviation of a case from normal and has been used to evaluate treatment standards. The PAR index offers uniformity, objectivity, standardization in assessing the outcome of orthodontic treatment and easy to apply.[14,15]

The American Board of Orthodontics (ABO) currently helps set standards of excellence for orthodontists and instituted the model and radiographic portions of the objective grading system (OGS) to be officially used to grade these portions of candidates' clinical case reports. The ABO's OGS (ABO-OGS) attempts to assess the outcome of orthodontic treatment to provide the candidate a goal toward which to strive and to establish a standard for orthodontists throughout the world.

The maintenance of dental alignment after orthodontic treatment has been and continues to be a challenge to the orthodontic profession. The obtained results must translate a normal or ideal occlusion that is morphologically stable and esthetically and functionally well adjusted. Associated with that, an assessment of the long-term outcome of orthodontic treatment should also include patient satisfaction with respect to dental and facial appearance in treated as well as in untreated groups.[16,17]

Thus, the objective of the present study was to evaluate the outcomes and the long-term occlusal stability of Class II malocclusion correction with the Forsus FRD, associated to the patient satisfaction in the long-term.

MATERIAL AND METHODS

This research was approved by the Ethics in Research Committee of the Bauru Dental School - University of São Paulo, Brazil (Protocol number:

71652217.1.0000.5417; decision number: 2.390.110), and all subjects signed informed consent.

The sample size calculation revealed that based on an alpha significance level of 0.05 and a beta of 0.2, to detect a mean difference of 1.5mm with a standard deviation of 1.4 in the alignment component of the OGS as previously suggested [18], a minimum of 9 subjects was required.

Patients were selected based according to the following inclusion criteria: Class II Division 1 malocclusion with bilateral Class II molar relationship (minimum severity of one half Class II molar relationship)[19,20]; at least symmetric, absence of agenesis, supernumerary or lost teeth, convex profile; mandible retrognatistm, mandibular arch with slight or no crowding, and without history of previous orthodontic treatment.[9]

Thus, 12 patients (8 male; 4 female), who were treated with Forsus FRD combined with multibracket fixed appliances, for a mean period of 3.43 years (SD, 1.29), were retrospectively selected from the files of the Orthodontic Department at Bauru Dental School - University of São Paulo (Table I). For each patient, three dental cast models (Fig. 1) were obtained in the following stages of orthodontic treatment: pretreatment (T1); posttreatment, when the multibracket fixed appliances were removed (T2) and long-term posttreatment (T3). A total of 36 cast models were selected in good condition, without fractured cusps or severe attrition. The mean initial age of the patients at T1 was 12.60 years (SD, 1.44), and the mean final age at T2 was 16.04 (SD, 1.43). The mean age at T3 was 21.20 years (SD, 1.42). The mean long-term posttreatment period was 5.15 years (SD. 0.56).

The Peer Assessment Rate (PAR) Index was developed to record the malocclusion at any stage of treatment.[12] The individual scores are summed to obtain an overall total, representing the degree a case deviates from normal alignment and occlusion.[15] The following occlusal features are evaluated in both arches: Buccal occlusion on the right and left sides (antero-posterior relationship, vertical and transverse), overjet, overbite, crowding, spacing, impacted teeth and centerline. A score of zero means that a perfect occlusion was reached; a score from one to nine indicates that good dental relationships are present; a score above 10 indicates that there are a residual malocclusion and above 40, severe malocclusion.[13,15] In this study, the American PAR model was followed, validated with weightings, which were: 5 for overjet, 3 for overbite and midline discrepancy, 2 for buccal occlusion and 1 for

maxillary anterior alignment; it eliminates mandibular anterior alignment.[12,13] The measurements were performed with the PAR ruler (Fig. 2).

Quality of the orthodontic outcomes was evaluated with the Objective Grading System (OGS), of the American Board of Orthodontics.[11] The OGS evaluates eight criteria: alignment, marginal ridge levels, buccolingual inclination, overjet, anteroposterior occlusal relationships, occlusal contacts, interproximal contacts, and root parallelism.[21] To evaluate the subcomponents in dental casts, a specific metal gauge with 0.5-mm thickness and 1.0-mm height was used (ABO Measuring Gauge, St. Louis, MO) (Fig. 3), and to evaluate the item root parallelism, a panoramic radiograph was used (Fig. 4). A score of 0 indicates ideal alignment and occlusion; scores of 1 and 2 show deviations from the normal. The final individual OGS index corresponded to the sum of lost points in each factor, and it was noted in a paper sheet. The critical score for the ABO clinical examination is 30.[11] As the OGS is an index used to assess the quality of treatment completion, we measure only the difference from the long-term posttreatment stage with the final stage of the OGS (T3-T2).

The patients answered a satisfaction questionnaire, containing 5 questions, which was sent by a messaging application and followed a structured pattern, as shown in Table II. It was based on a questionnaire used for patients with normal occlusion,[22] about their self-appraisal of occlusal function and aesthetics, at long-term posttreatment.

Error study

One calibrated examiner (DBAB) performed all measurements and remeasured them in 30% of the sample, randomly selected, after a 30-day interval. Random errors were calculated according to Dahlberg's formula ($Se^2 = \sum d^2/2n$),[23] and the systematic errors were evaluated with dependent *t* tests, for $P<0.05$.[24,25].

Statistical analysis

The normal distribution of the data was checked using Kolmogorov-Smirnov tests. Intragroup comparison of the PAR index studied at the three stages evaluated (T1, T2, and T3) were performed with ANOVA and Tukey tests. Intragroup comparison of the OGS index at T2 and T3 were performed with paired t tests.

All statistical analyses were performed with Statistica software (Statistica for Windows, version 10.0, StatSoft Inc., Tulsa, Okla, USA), at $p<0.05$.

RESULTS

PAR and OGS indexes evaluation

The random errors varied from 0.58 (PAR Index) to 1.00 (OGS) and were within the acceptable ranges.[18,26] There was no significant systematic error (Table III).

PAR index showed a statistically significant and expressive improvement with treatment, which remained stable in the follow-up period (Table IV). The components of the PAR index individually improved significantly with treatment. The posterior occlusion, the overjet and the displacement showed a modest recurrence in long-term posttreatment, although insignificant. The components, overbite and medium line, further reduced the score in long-term posttreatment.

For the total OGS index, there were no statistically significant changes from the end of treatment to the long-term posttreatment (Table V). Although there was also no statistically significant difference, when separately evaluating the 8 components of the OGS, we detail that: alignment, occlusal relationship and interproximal contacts showed a slight relapse in long-term posttreatment. Conversely, the marginal ridges, buccolingual inclination, overjet, occlusal contacts and root angulation showed a improvement in long-term posttreatment.

Questionnaires

One patient of the sample did not answer the questionnaire. Nine patients (81.8%) were very satisfied with the smile. Only two patients (18.2%) noticed changes in the smile during the follow-up period. Changes in the alignment were reported by two patients. Two patients demonstrated desire for new orthodontic treatment. Five patients (45.4%) would change nothing in their smiles. Six patients (54.5%) presented complaints as: tooth color (3), general clinical procedures (2), could not explain what would change (1) and teeth position (1). Eighty-one percent of the sample gave an excellent score for the smile attractiveness. Only two patients gave a good score for smile attractiveness.

DISCUSSION

Twelve participants attended for posttreatment review at a follow-up of more than 5 years (Table I). There is still great difficulty in recruiting patients for long-term

follow-up posttreatment, however the number of patients reached is representative,[13] considering the methodology of this study and the lack of investigations in this area.[9]

In recent years, occlusal indexes provide a more objective, reliable, and reproducible way of assessing occlusal relationships.[13] Occlusal indexes should be widely used by orthodontists for evaluation factors related to occlusal stability in the short and long-term. However, no method is entirely satisfactory. Many methods are limited to assess occlusal relationships, due the importance of skeletal and soft tissue outcomes.[27,28]

The PAR index was used in stage T1, with an average initial score of 26.58 (Table IV). Although our study does not have a comparative group, previous studies presented similar severity, for cases treated with and without extraction.[13,14,26] At T2, the PAR index was established to quantify malocclusion improvements after treatment, thus posttreatment and long-term posttreatment PAR scores were, respectively, 4.33 and 4.66, that is, in both stages they were less than 5, which is considered an excellent outcome.[15] Overall PAR index had an average percentage of improvement of 87.70% immediately posttreatment, and at a mean of 5.15 years posttreatment, it had a percentage of recurrence of 1.43%, without statistical significance. PAR Index was designed specifically to provide a more objective assessment of a percentage of treatment success, but it becomes less sensitive to assess the quality of treatment completion. This index has certain limitations as it measures only occlusal changes which, although important, are not the only factors in orthodontic treatment. Factors like decalcification, root resorption, gingival recession, inclination of the incisors, and facial aesthetics undoubtedly contribute to the quality of treatment.[26]

PAR and OGS indexes were used for posttreatment evaluation to analyze the quality of the finished cases, however the precision of the ABO-OGS system is unparalleled, detecting subtle inadequacies in occlusion.[27] There was no statistically significant difference in the total OGS score at T2 and T3, with both scores not exceeding 30 points, which is considered to be the average e proper quality of finished cases.[11,29] An interesting and relevant finding is that the score for OGS in the long-term posttreatment decreased, suggesting an improvement in completion, which can be explained as better adaptation of the treated occlusion. In other words, it is suggested that some aspects of occlusion "settle" after treatment, even if ideal relationships have been established. Evaluation systems can be extremely critical for some posttreatment results.[27] We found 5 subcomponents of OGS index reduced the

long-term posttreatment score (Table V), which shows us that deviations in these criteria tend to self-correct in the posttreatment period. In this study, posttreatment assessments were made on cast models immediately after removal of the fixed appliance, however ABO[28] allows final models to be taken up to 1 year after debonding.

The criterion of "alignment" in the quality indexes of completion is very critical in all stages. Initially, as assessed by the PAR it is of great value to assess the initial severity[27], and the orthodontist has little control over these biologic processes, which act on this aspect, and who make an important clinical decision: use of retainer after the case is concluded.[26] In addition, it was shown in a study that evaluates normal occlusion that the aging process deteriorates some occlusal characteristics of individuals.[22] In this study, the permanence of the use of a fixed canine-canine mandibular retainer may have contributed to the satisfactory score on the OGS index.

On the other hand, during an evaluation, it was noticed that some cases did not include the second molars in orthodontic treatment. This fact may explain the increase in the final score for PAR and OGS indexes in this study.[27] Other authors argue that there is a tendency to self-correction of maxillary second molar distoangulation with time, thus the correction of this feature in orthodontic patients during the early permanent dentition might constitute an overtreatment and should be avoided to decrease treatment time.[22]

However, it is worth considering that well-finished orthodontic treatment minimizes relapse[15,30] and still had absolute better postretention occlusal relationships.

An interesting aspect, which should be added to studies that evaluate long-term results, is the patient's satisfaction with the treatment. There is a strong tendency for research to present patient satisfaction questionnaires at the end of treatment, however there are still few records of these data in the literature.[16]

A satisfaction questionnaire was applied in this study, at the long-term follow-up stage, when patients could assess their current smile, their complaints with the smile are rarely related to orthodontic treatment. This questionnaire was adapted from Miranda et al, 2019[22] which aimed the evaluation in a normal occlusion sample who were highly satisfied with the smile before the aging process, which deteriorated some normal characteristics of the occlusion. In our study, it was found that patients are more vigilant with possible changes that can occur in the smile, however the current complaints are not associated with occlusal and functional aspects, but with aesthetics.

Patient satisfaction with the current smile, in this study, may be related to the final quality obtained in the occlusion. The orthodontist should provide general guidance on what patients should expect in relation to the gains achieved with treatment in terms of oral performance, aesthetics and oral health as a whole.[31]

Research about patient satisfaction with treatment should be a routine practice. The assessment of the patients' satisfaction with the treatment, in addition to the technical ability to assess quality completion indexes, makes the clinical orthodontist even more discerning.

CONCLUSIONS

In the present study, it was shown that occlusal changes obtained during treatment with Forsus FRD were remained stable in the long-term posttreatment, according to PAR and OGS indexes. The vast majority of patients were satisfied with the treatment and the current smile.

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Figure legends:

Fig.1: Cast models at pretreatment (T1); posttreatment, (T2) and long-term posttreatment.

Fig.2: Par ruler.

Fig.3: OGS metal gauge.

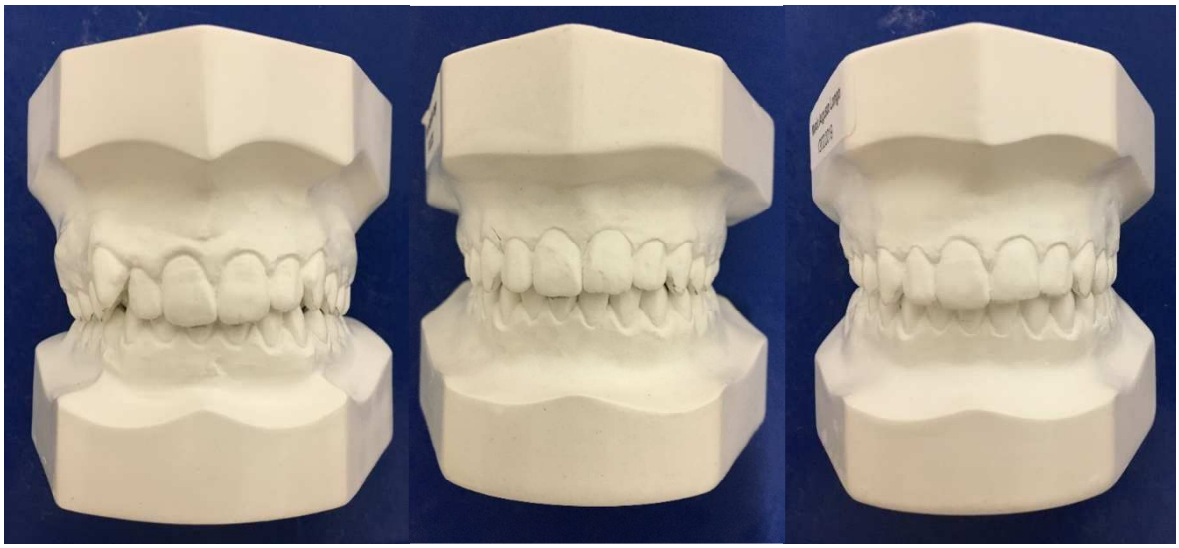
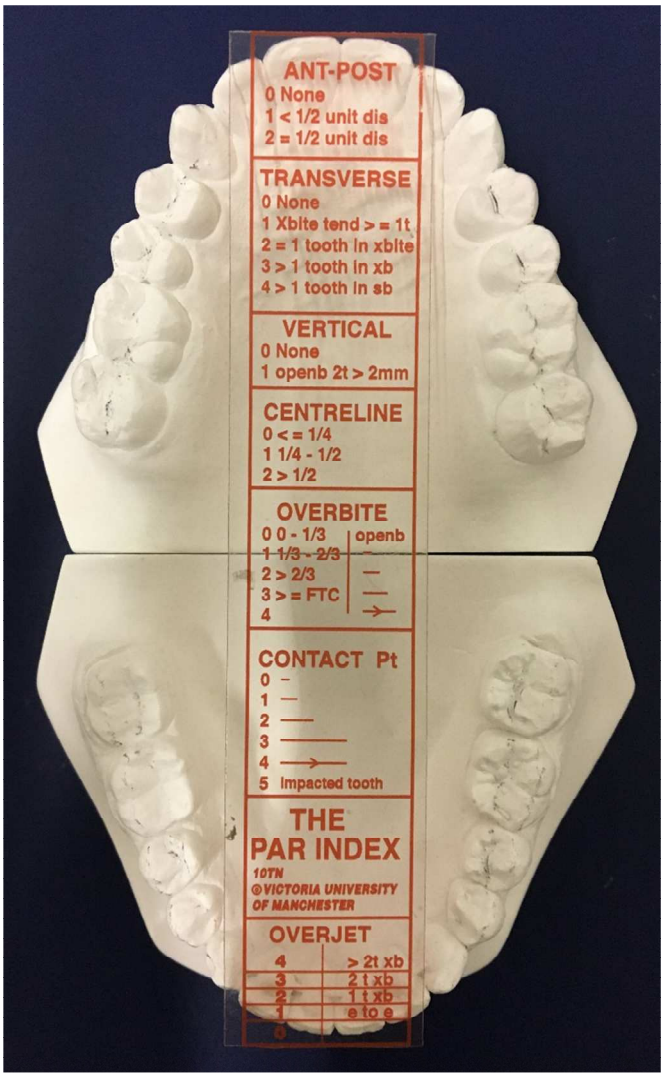


Fig.1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TRANSVERSE
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2 = 1 tooth in xbite
3 > 1 tooth in xb
4 > 1 tooth in sb
VERTICAL
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1 openb 2t > 2mm
CENTRELINE
0 < = 1/4
1 1/4 - 1/2
2 > 1/2
OVERBITE
0 0 - 1/3
1 1/3 - 2/3
2 > 2/3
3 > = FTC
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THE PAR INDEX
10TN
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Fig. 2

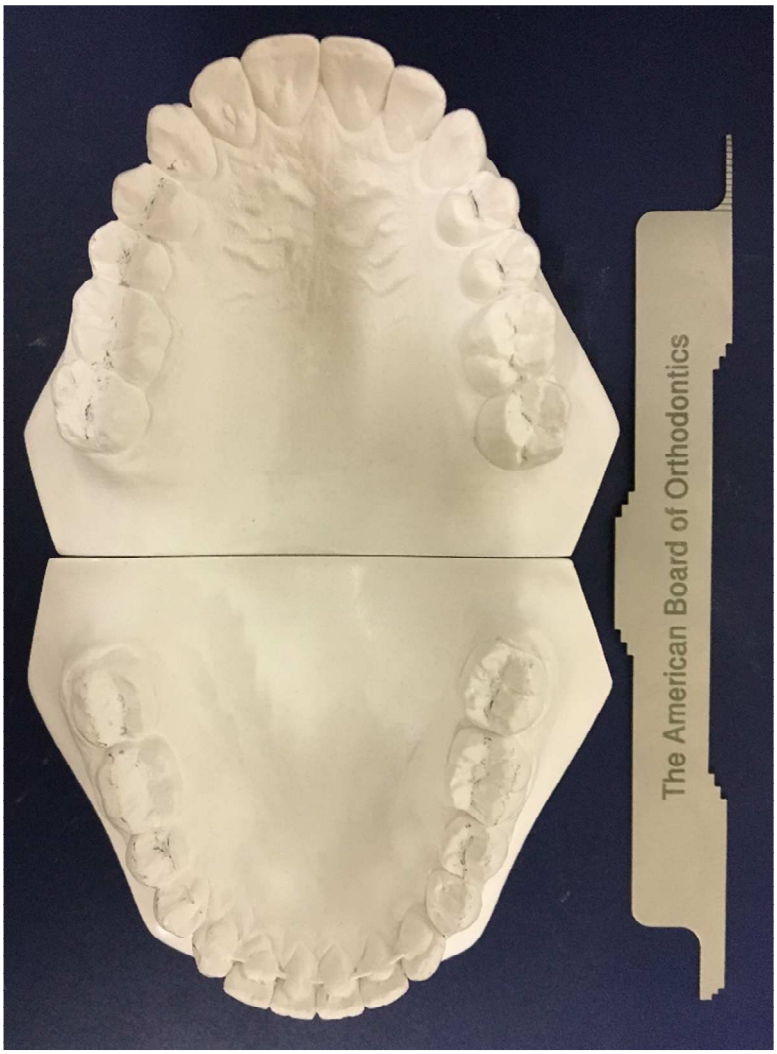

Fig. 3

Table I- Sample characterization regarding ages at T1, T2 and T3, treatment and long-term posttreatment periods, and sex distribution

Sample group (n=12)		
Stage/period	**Mean**	**S.D.**
T1 age (y)	12.60	1.44
T2 age (y)	16.04	1.43
T3 age (y)	21.20	1.42
Treatment period (T2-T1) (y)	3.43	1.29
Posttreatment period (T3-T2) (y)	5.15	0.56
Sex	Male 8 (66.66%)	Female 4 (33.33%)

Table II – Smile satisfaction questionnaire

Question	Possibility of response
1- Are you satisfied with your smile?	YES or NO.
2- Have you perceive any changes in your smile since you finished your orthodontic treatment until today?	YES or NO.
3- Are your teeth crowded ("crooked")?	YES or NO.
4- Would you like to have a new orthodontic treatment?	YES or NO.
5- Would you change something in your current smile?	Briefly explain what.

Table III - Results of the error study (Dahlberg's formula for casual errors and dependent t tests for systematic errors)

Variables	1st Measurement (N=32)		2nd Measurement (N=32)		Dahlberg	P
	Mean	s.d.	Mean	s.d.		
PAR	10.55	11.37	10.11	10.93	0.58	0.104
OGS	30.00	9.52	30.20	9.55	1.00	0.678

Table IV - Intragroup comparison of the PAR Index at initial (T1), final (T2) and long-term posttreatment (T3) stages (repeated measures ANOVA followed by Tukey tests)

	T1		**T2**		**T3**		
Variable	**Mean**	**SD**	**Mean**	**S.D.**	**Mean**	**S.D.**	***P***
PAR Total	26.58^{A}	4.67	4.33^{B}	4.94	4.66^{B}	5.29	<0.001*
PAR Index Components							
Posterior occlusion	5.41^{A}	3.62	0.66^{B}	1.30	0.83^{B}	1.33	<0.001*
Overjet	10.00^{A}	3.69	1.66^{B}	2.86	2.08^{B}	2.32	<0.001*
Overbite	5.25^{A}	2.59	1.25^{B}	2.00	0.75^{B}	1.86	<0.001*
Medium Line	0.75^{A}	1.35	0.25^{B}	0.86	0.00^{B}	0.00	<0.001*
Displacement	5.16^{A}	2.20	0.50^{B}	0.67	1.00^{B}	0.85	<0.001*

Different letters indicate statistically significant differences;

*Statistically significant at P<0.05.

Table V - Intragroup comparison of the OGS at final (T2) and long-term posttreatment (T3) stages (dependent t tests)

	T2		T3		
Variable	**Mean**	**S.D.**	**Mean**	**S.D.**	***P***
OGS Total	29.75	5.10	28.16	10.18	0.381
OGS Components					
Alignment	6.91	1.50	8.58	3.50	0.101
Marginal ridges	4.75	2.34	3.75	1.86	0.059
Buccolingual inclination	5.41	2.23	4.83	1.58	0.253
Overjet	3.91	2.99	2.83	2.12	0.232
Occlusal contacts	1.83	1.74	1.25	1.76	0.131
Occlusal relationship	2.41	3.55	2.83	4.54	0.609
Interproximal contacts	0.75	1.76	0.83	2.88	0.838
Root angulation	3.75	2.13	3.25	1.65	0.256

3 DISCUSSION

3 DISCUSSION

Sample and Methodology

Despite the stability is known to be the fundamental key to successful outcome of orthodontic treatment, most studies are limited to assessing short-term effects of the Forsus Fatigue Resistant Device (FRD).[9,20,32-34] Present studies investigated the stability of dentoskeletal and occlusal changes more than 5 years after treatment with Forsus FRD associated with multibracket fixed appliances. In our study, the sample was not divided by skeletal age, however, it is interesting to obtain more information about this, to show the changes that occur in growth and post-growth, with samples that followed the same treatment protocol.[32] An intergroup comparison of the cephalometric variables between the Forsus sample was performed in the post-treatment period with patients with normal occlusion. However, comparisons with control groups must still be performed during the treatment period with cephalometric and occlusal changes.

Skeletal component

Maxilla is known that the maxilla is more protruded in Class II division 1 [35], although there are controversies in the literature. Treatment produced a statistically significant reduction of maxillary protrusion in the long-term posttreatment period. Other studies[34,36-39] with functional devices have had similar results.

The mandibular advancement, and the consequent redirection and/ or stimulation of mandibular growth, promoted by the functional devices still maintains a great question of discussion about this therapy.[20,40] Beneficial effect of mandibular advancement was not observed in this study with the Forsus FRD appliance, however in this our adolescent sample, significant increase in mandibular length was observed. Mandibular length continued to significantly increase in the posttreatment period consequent to normal growth [41], which can contribute to the stability of Class II relationship correction, however it did not contribute to further significant increase in mandibular protrusion. The increase of the mandibular effective length was

significantly bigger on the control group, this is in agreement with other studies that showed a decrease on the mandibular growth on Class II malocclusion patients [25,42-44].

The present study also observed a significant improvement of the maxillomandibular relationship that did not present statistically significant changes on the post treatment period. Since Class II, Division 1 patients tend to present similar late dentofacial growth to the presented by young people with normal occlusion, the maxillomandibular discrepancy observed at the end of growth won't suffer any significant changes.[45] Most important is that this effects and the maxillomandibular relationship achieved with treatment remained stable in the long-term posttreatment period, similarly to non-extraction Class II malocclusion treatment with other devices [46-50].

Nearly 70% of patients with Class II malocclusion showed an increased lower facial height [51]. The lower anterior facial height showed a significant increase during both periods evaluated on this study. This is a normal effect of treatment with functional appliances [39,48,52-54]. Although the control group showed an increase bigger, there were no statistically significant changes in the long-term posttreatment for the groups groups, showing that the changes are consequent to normal growth and development and that the control group possessed a potential for further mandibular growth then the experimental group.[24,55,56]

Dentoalveolar component

There was mesialization of the upper molars during treatment, remaining stable in the posttreatment period. During treatment, the maxilla moved mesially, like this upper molars were moved mesially in similar movement.[20]

During treatment period, mandibular incisors presented significant labial inclination and protrusion, which remained stable on the posttreatment stage. Treatment effects on the mandibular incisors are a result of mandibular anchorage loss, due to the anterior-directed force vector on the mandibular dentition, this corroborates with previous reports of other functional appliances [39,41,57-64]. Even though some proclination occurs not only this effects were stable, but were also similar to the findings observed in the control group during the comparable period. Recently, use of the Forsus FRD appliance with miniplates inserted in the mandibular symphysis was

shown to be an effective method for eliminating mandibular incisor protrusion and increasing the skeletal contribution.[34]

The extrusion of the mandibular molars is a common side effect of the use of intermaxillary elastics as active retention during the fixed appliances phase,[65] in the present study we observed significant vertical development of the mandibular molars during both periods.

In consequence of the dentoalveolar changes produced by the Forsus FRD appliance combined with multibrackets fixed appliances therapy, the dentoalveolar relationships as the overjet, overbite and molar relationship presented a significant improvement as well, this was previously reported by other studies.[24,65,66]

Soft tissue component

Despite the significant dentoskeletal changes on the correction of the anteroposterior discrepancy with the Forsus FRD appliance, there was no significant change in the nasolabial angle[24]. In the post-treatment period, there was a modest reduction in the protrusion of the upper lip,[9] however, compared to the control group, there was a statistically lower reduction in the protrusion of the upper and lower lips, as well as changes in soft tissue cannot be attributed to treatment.

PAR and OGS Evaluation

The assessment of orthodontic treatment outcomes has traditionally been accomplished using the subjective opinion and experience of clinicians. Several indices have been devised in an attempt at providing a more objective assessment of malocclusion severity.[67]

The treatment results with Forsus FRD appliance were considered greatly improved according to PAR Index.[28] There was no significant difference in the PAR and OGS indexes in the posttreatment and long-term posttreatment stages for the scores obtained, indicating stability of occlusal changes. In addition, the averages for the OGS achieved in both observed stages indicate good quality of case completion,[29,68] which may also explain stability of changes in the correction of Class II malocclusion.

Pacient's satisfaction

Patient satisfaction with the current smile, in this study, may be related to the final quality obtained in the occlusion. The orthodontist should provide general guidance on what patients should expect in relation to the gains achieved with treatment in terms of oral performance, aesthetics and oral health as a whole.[69]

Limitations

The main limitation of this study is related to the sample size, however considering the follow-up period, it is a representative sample. Also, the retrospective nature of this study made it dependent on the accuracy and availability of orthodontic records. Additional studies, using different fixed functional appliances with larger samples, should be performed to discuss and compare these findings.

4 FINAL CONSIDERATIONS

4 FINAL CONSIDERATIONS

Based on the methodology used and the results obtained is valid to conclude that the treatment with the Forsus FRD appliance is efficient for patients with Class II malocclusion and changes obtained during treatment remained stable in the long-term posttreatment. As this is a retrospective study, it is not possible to increase the sample size, however it is interesting to compare the results of this treatment with other similar devices. This study reinforces the importance of using criteria for orthodontists to evaluate their completed cases and become more perfectionists. Added to this, patient satisfaction, assessed in self-assessment questionnaires, must be taken into account and this research must be a routine clinical practice.

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ANNEXES

ANNEXES

ANNEX A – Research Institutional Board approval, decision number: 2.390.110 (front)

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação da estabilidade em longo prazo da correção da má oclusão de Classe II divisão 1 com aparelho Forsus

Pesquisador: Deborah Brindeiro de Araújo Brito

Área Temática:

Versão: 3

CAAE: 71652217.1.0000.5417

Instituição Proponente: Universidade de Sao Paulo

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.390.110

Apresentação do Projeto:

Idem ao parecer numero 2.337.155

Objetivo da Pesquisa:

Idem ao parecer numero 2.337.155

Avaliação dos Riscos e Benefícios:

Idem ao parecer numero 2.337.155

Comentários e Considerações sobre a Pesquisa:

Idem ao parecer numero 2.337.155

Considerações sobre os Termos de apresentação obrigatória:

Idem ao parecer numero 2.337.155

Conclusões ou Pendências e Lista de Inadequações:

As pendencias foram atendidas de acordo com o parecer numero 2.337.155, considero aprovado.

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 08/11/2017, 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,

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cronograma e quaisquer outras mudanças que sejam significativas deverão ser previamente comunicadas a este CEP sob risco de não aprovação do relatório final. Quando da apresentação deste, deverão ser incluídos todos os TCLEs e/ou termos de doação assinados e rubricados, se pertinentes.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_949022.pdf	20/10/2017 00:53:59		Aceito
Outros	CartaOficio.pdf	20/10/2017 00:53:30	Deborah Brindeiro de Araújo Brito	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoCEPDeborah.pdf	20/10/2017 00:51:40	Deborah Brindeiro de Araújo Brito	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Deborah.pdf	20/10/2017 00:50:06	Deborah Brindeiro de Araújo Brito	Aceito
Outros	DeclaracaoCompromissoPesquisadorResultadosPesquisa.pdf	15/09/2017 15:29:47	Deborah Brindeiro de Araújo Brito	Aceito
Outros	QuestionarioTecnicoPesquisador.pdf	15/09/2017 15:29:25	Deborah Brindeiro de Araújo Brito	Aceito
Folha de Rosto	Folha_Deborah.pdf	19/07/2017 14:13:46	Deborah Brindeiro de Araújo Brito	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 21 de Novembro de 2017

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

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ANNEX B - One of the patients that illustrates the sample patients treated with the Forsus FRD appliance