Long-term evaluation of pharyngeal dimensions and hyoid bone position in Class II Malocclusion patients treated with Herbst functional appliance

Avaliação em longo prazo das dimensões faríngeas e posição do osso hioide em pacientes com má oclusão de Classe II tratados com aparelho funcional de Herbst
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Dissertação constituída por artigo apresentada à Faculdade de Odontologia de Bauru da Universidade de São Paulo para obtenção do título de Mestre em Ciências no Programa de Ciências Odontológicas Aplicadas, na área de concentração Ortodontia.

Orientador: Prof. Dr. Marcos Roberto de Freitas

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ABSTRACT

Long-term evaluation of pharyngeal dimensions and hyoid bone position in Class II Malocclusion patients treated with Herbst functional appliance

Introduction: This study aimed to evaluate the long-term changes in the pharyngeal dimensions and hyoid bone position in Class II malocclusion patients treated with Herbst functional appliance. Methods: The sample was composed of 15 skeletal Class II malocclusion patients (13.00 years old ± 1.21) who had been treated with Herbst functional appliance and followed for a mean period of 10 years (10.73 years ± 3.67). Lateral cephalometric radiographs were used to evaluate the pharyngeal dimensions and hyoid bone position. Radiographic measurements were performed with Dolphin® Imaging 11.9. Intragroup comparison between the evaluation stages was performed with repeated measures ANOVA, followed by Tukey tests if necessary. Results were considered statistically significant at $p<0.05$. Results: Regarding the pharyngeal variables, only the lower airway space increased significantly in the treatment period and all of them remained stable in the long-term posttreatment period. The hyoid bone moved significantly forward and downward during the treatment period and even further forward during the long-term posttreatment period. Conclusion: The increase in the lower airway space may be related to the forward shift of the mandible plus the growth effect. The hyoid bone was moved forward and downward as a treatment effect. Only the horizontal position of the hyoid bone changed significantly in the long-term posttreatment period, moving forward.

Keywords: Malocclusion, Angle Class II. Orthodontic Appliances, Functional. Pharyngeal Airway. Hyoid Bone. Effects, Long-Term.
RESUMO

Avaliação em longo prazo das dimensões faríngeas e posição do osso hioide em pacientes com má oclusão de Classe II tratados com aparelho funcional de Herbst

Introdução: Este estudo teve como objetivo avaliar em longo prazo as alterações nas dimensões faríngeas e posição do osso hioide de pacientes com má oclusão de Classe II tratados com aparelho funcional de Herbst. Métodos: A amostra foi composta por 15 pacientes com má oclusão de Classe II esquelética (13.00 anos de idade ± 1.21) tratados com aparelho funcional de Herbst e acompanhados por um período médio de 10 anos (10.73 ± 3.67). Radiografias cefalométricas laterais foram utilizadas para avaliar as dimensões faríngeas e a posição do osso hioide. As medidas radiográficas foram realizadas com o software Dolphin® Imaging 11.9. A comparação intragrupo entre as fases de avaliação foi realizada com o teste ANOVA de medidas repetidas, seguido por Tukey teste quando necessário. Resultados: Em relação às variáveis faríngeas, apenas o espaço aéreo inferior aumentou significativamente no período de tratamento e todas permaneceram estáveis no período pós-tratamento de longo prazo. O osso hioide moveu-se significativamente para frente e para baixo durante o período de tratamento e ainda mais para frente durante o período pós-tratamento de longo prazo. Conclusão: O aumento do espaço aéreo inferior pode estar relacionado ao deslocamento para frente da mandíbula somado ao efeito do crescimento. O osso hioide foi movido para a frente e para baixo como efeito do tratamento. Apenas a posição horizontal do osso hioide mudou significativamente no período pós-tratamento de longo prazo, avançando.

Palavras-chave: Má Oclusão de Angle Classe II. Aparelhos Ortodônticos Funcionais. Remodelação da Vias Aéreas. Osso Hioide. Efeito a Longo Prazo.
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# LIST OF ABBREVIATIONS AND ACRONYMS

| Abbreviation | Description |
|--------------|-------------|
| BMI          | Body Mass Index |
| CAPES        | Coordination for the Improvement of Higher Education Personnel |
| CBCT         | Cone-Beam Computed Tomography |
| CBJ          | Cantilever Bite Jumper |
| OSAS         | Obstructive Sleep Apnea Syndrome |
| RME          | Rapid Maxillary Expansion |
| 3D           | Three-dimensional imaging |
| N            | Most anterior point of the frontonasal suture in the sagittal view |
| S            | Center of the pituitary fossa |
| A            | Point of maximum concavity in the midline of the alveolar process of the maxilla in the sagittal view |
| B            | Point of maximum concavity in the midline of the alveolar process of the mandible in the sagittal view |
| Me           | Most inferior point of the mandibular symphysis in the sagittal view |
| Go           | The deepest point of the curvature of the angle of the mandible between the inferior border of corpus and posterior border of the ramus of mandible in sagittal view |
| Gn           | The most downward and forward point on the mandibular symphysis, constructed by the intersection of the facial plane with the mandibular plane |
| U1           | Maxillary incisor tip |
| L1           | Mandibular incisor tip |
| U            | Lower end of the soft palate |
| V            | The most posteroinferior point on the base of the tongue |
| SPP          | Point of intersection of line from soft palate center perpendicular to posterior pharyngeal wall and posterior margin of soft palate |
| SPPW         | Point of intersection of line from soft palate center perpendicular to posterior pharyngeal wall and posterior pharyngeal wall |
| MPW          | Foot point of perpendicular line from point U to posterior pharyngeal wall |
| Abbreviation | Description |
|--------------|-------------|
| LPW          | Foot point of perpendicular line from point V to posterior pharyngeal wall |
| Hy           | Most anterior point on the hyoid bone |
| C3           | Most anteroinferior point on corpus of third cervical vertebra |
| SNA          | Angle between SN and NA |
| SNB          | Angle between SN and NB |
| ANB          | Angle between AN and NB |
| U1-NA        | Distance between NA line and the most anterior point of the maxillary incisor crown |
| U1.NA        | Angle between NA line and the long axis of the maxillary Incisor |
| L1-NB        | Distance between NB line and the most anterior point of the lower incisor crown |
| L1.NB        | Angle between NB line and the long axis of the mandibular Incisor |
| SPP-SPPW     | Superior airway space: Distance between SPP and SPPW (nasopharynx / palatopharynx) |
| U-MPW        | Middle airway space: Distance between U and MPW |
| V-LPW        | Inferior airway space: Distance between V and LPW |
| Hy-C3        | Distance between the most anterior point of the hyoid bone and the most anteroinferior point in the body of third cervical vertebra |
| Hy-MPerp     | Distance from the mandibular plane (Go-Me) perpendicular to the hyoid bone |
| T1           | Pre-treatment stage |
| T2           | Posttreatment stage |
| T3           | Long-term posttreatment stage |
| T3-T2        | Long-term posttreatment period |
| °            | Degree |
| mm           | Milimeter |
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1 INTRODUCTION
1 INTRODUCTION

The pharyngeal airway anatomy and function is closely related with craniofacial development. (PRESTON; LAMPASSO; TOBIAS, 2004) As a result of the proximity between the pharynx and dentofacial structures, it is expected to exist an interrelation between the dentofacial pattern and respiratory changes and, therefore, different anteroposterior skeletal patterns seem to have an influence on airway dimensions. (CEYLAN; OKTAY, 1995; STELLZIG-EISENHAUER; MEYER-MARCOTTY, 2010; ZHONG et al., 2010)

About 2-10% of school-age children suffer from sleep-disordered breathing and these patients commonly experience constriction in the upper airway. (CEYLAN; OKTAY, 1995; KHAYAT; BIN-HASSAN; AL-SALEH, 2017; LAL et al., 2015; WILDHABER; MOELLER, 2007) The obesity is the main risk factor for Obstructive Sleep Apnea Syndrome (OSAS) in children, but when children with skeletal Class II malocclusion is compared with children with normal occlusion, they have significantly smaller nasopharyngeal dimensions, therefore it is also a risk factor for future respiratory problems. (GUILLEMINAULT et al., 1996; KIM et al., 2010; MERGEN; JACOBS, 1970; REDLINE et al., 1999; ZHONG et al., 2010)

Several environmental and genetic factors contribute to Class II malocclusion, but mandibular retrusion is the most common factor. (MCNAMARA JR., 1981) Functional orthopedic treatment with mandible position correction have been used in children to move the mandible forward, increase the upper airway and improve function in patients with respiratory problems, as well as the prevention of OSAS. (GHODKE et al., 2014; PAVONI et al., 2017; VILLA et al., 2002; VILLA; MIANO; RIZZOLI, 2012)

OSAS is characterized by repeated episodes of partial or complete upper airway obstruction during sleep and can affect lung ventilation, oxygenation, sleep quality, sweating and bedwetting. (PARK; RAMAR; OLSON, 2011) In children, untreated OSAS can cause behavioral problems, affect cognitive performance, and cause more serious morbidities, such as growth failure and systemic hypertension. (BENNINGER; WALNER, 2007)

Authors suggest that early treatment with mandibular advancement can permanently modify mouth breathing, avoiding upper airway obstruction and suggesting that in some
cases orthodontic treatment can be chosen that improves not only mandibular relationships but also reduce the risk of acquiring OSAS. (VILLA; MIANO; RIZZOLI, 2012)

The functional orthopedic appliances used to correct Class II malocclusion can be classified into flexible, rigid or hybrid, according to the system of forces they use to move the mandible forward. (RITTO; FERREIRA, 2000) The flexible fixed functional appliances allow for satisfactory mandibular movement, with lateral guidance being easily performed. The rigid fixed functional appliances are not elastic nor flexible and the mandible is in forward position 24 hours a day, with allows more stimulation for growth and, therefore, these appliances produce greater skeletal effects than those produced by flexible ones. (MORO et al., 2018; RITTO; FERREIRA, 2000)

The Herbst appliance is a rigid fixed functional appliance for treatment of Class II malocclusion with several advantages when compared to removable functional appliances, and it is probably the functional appliance most often used worldwide to correct Class II malocclusion with mandibular deficiency. (MORO et al., 2018; PANCHERZ, 1985) Many variations in the Herbst’s design have occurred over the years and the Cantilever Bite Jumper (CBJ; Ormco Corporation, Orange, Calif) was a variation introduced by Mayes in 1994, offering some advantages over other Herbst designs, such as easier dentition transition. (LAI; MCNAMARA, 1998; MAYES, 1994; 1996; WIESLANDER, 1984)

Some authors studied the effects of treatment with functional appliances in the upper airway and found that removable functional appliances were more efficient than fixed functional appliances in improving the dimensions of the pharyngeal airway. (ANUSUYA; JENA; SHARAN, 2019) Despite the large number of studies in the literature evaluating these changes, there is only one published study that researched about long-term effects of fixed functional appliances in the airway dimensions, which is essential for evaluating treatment efficacy. (DROSEN et al., 2018) Thus, the aim of this study was evaluating the long-term changes in the pharyngeal airway dimensions and hyoid bone position in Class II malocclusion patients treated with Herbst functional appliance.
2 ARTICLE
ARTICLE

The article presented in this Dissertation was formatted according to the American Journal of Orthodontics and Dentofacial Orthopedics instructions and guidelines for article submission.
LONG-TERM EVALUATION OF PHARYNGEAL DIMENSIONS AND HYOID BONE POSITION IN CLASS II MALOCCLUSION PATIENTS TREATED WITH HERBST FUNCTIONAL APPLIANCE

Introduction: This study aimed to evaluate the long-term changes in the pharyngeal dimensions and hyoid bone position in Class II malocclusion patients treated with Herbst functional appliance. Methods: The sample was composed of 15 skeletal Class II malocclusion patients (13.00 years old ± 1.21) who had been treated with Herbst functional appliance and followed for a mean period of 10 years (10.73 years ± 3.67). Lateral cephalometric radiographs were used to evaluate the pharyngeal dimensions and hyoid bone position. Radiographic measurements were performed with Dolphin® Imaging 11.9. Intragroup comparison between the evaluation stages was performed with repeated measures ANOVA, followed by Tukey tests if necessary. Results were considered statistically significant at $p<0.05$. Results: Regarding the pharyngeal variables, only the lower airway space increased significantly in the treatment period and all of them remained stable in the long-term posttreatment period. The hyoid bone moved significantly forward and downward during the treatment period and even further forward during the long-term posttreatment period. Conclusion: The increase in the lower airway space may be related to the forward shift of the mandible plus the growth effect. The hyoid bone was moved forward and downward as a treatment effect. Only the horizontal position of the hyoid bone changed significantly in the long-term posttreatment period, moving forward.

Keywords: Malocclusion, Angle Class II. Orthodontic Appliances, Functional. Pharyngeal Airway. Hyoid Bone. Effects, Long-Term.
INTRODUCTION

Class II malocclusion is one of the most prevalent orthodontic problems in the world population and represents approximately one-third of the patients that seek orthodontic treatment.\(^1\) This malocclusion is present in about 15% of the total United States population,\(^1\) 27.2% of English adolescents,\(^2\) 36.3% of Italian adolescents,\(^3\) 27.0% of Chinese children\(^4\) and 38% of Brazilian children.\(^5\) The relationship between sagittal skeletal pattern and airway space has been subject of several studies, and different anteroposterior skeletal patterns seem to have an influence on airway dimensions.\(^6\) Compared to children with normal occlusions, children with skeletal Class II malocclusion has significantly smaller nasopharyngeal dimensions\(^6\) and has a higher risk of future respiratory problems.\(^7\)

Functional appliances (FAs) are routinely used to treat children with Class II skeletal malocclusion due to mandibular retrognathism\(^8\) and it may help to increase the airway dimensions, preventing respiratory disorders.\(^9\) Thus, in some cases, orthodontic treatment can be chosen that improves not only maxillomandibular relationship but also reduce the risk of acquiring Obstructive Sleep Apnea Syndrome (OSAS).\(^10\)

The Herbst appliance is a fixed functional orthopedic device for treatment of Class II malocclusion with several advantages when compared to removable functional appliances.\(^11\) Many variations in the Herbst's design have occurred over the years and the Cantilever Bite Jumper (CBJ; Ormco Corporation, Orange, Calif) was a variation introduced by Mayes in 1994,\(^12\) offering some advantages over other Herbst designs, such as easier dentition transition.\(^13\)

Previous studies have evaluated the association between fixed functional orthopedic appliances to treat Class II patients with mandibular retrognathism and changes in airway dimensions,\(^14,15\) and it is a controversial subject. Specifically about the association between airway and Class II malocclusion treatment with Herbst functional appliance, some studies showed dimension improvement of specific regions of upper airway\(^16-20\) and others showed no significant changes in any of them.\(^15,21\) Besides that, it is important to realize that some studies of airway dimensions changes by treatment of Class II malocclusion with Herbst appliance associated this protocol with rapid maxillary expansion (RME).\(^16,18\) Modification of pharyngeal airway by RME is described in the literature,\(^22\) then these results need to be carefully evaluated.
The literature reports that removable functional appliances are more efficient than fixed functional appliances in improving pharyngeal dimensions\textsuperscript{15,23}, but these findings need to be evaluated carefully. Although some authors have researched the long-term effects of the treatment with removable functional appliances in the upper airway, until the moment only one study researched the long-term effects of fixed functional appliances,\textsuperscript{21} which is essential for evaluating treatment efficacy. Therefore, this study aimed to evaluate the long-term changes in the upper airway dimensions and hyoid bone position in Class II malocclusion patients treated with Herbst functional appliance.

**MATERIAL AND METHODS**

The present study was approved by the Ethics Committee in Human Research of the Bauru Dental School, University of São Paulo, under protocol number CAAE: 22082219.0.0000.5417.

The sample size was calculated with a statistical power of 0.80 and an alpha of 5%, to detect a mean difference of 0.25 mm for the middle airway space (U-MPW) with a standard deviation of 0.32 mm, obtained in the study conducted by Göymen, Mourad and Güleç.\textsuperscript{14} The result showed the need for 15 patients.

The sample for the study group was taken retrospectively from the Department of Orthodontics, Bauru Dental School, University of São Paulo, Brazil and the patients selected had attended by graduate students. The inclusion criteria were: patients with initial Angle Class II, division 1 malocclusion and mandibular retrognathism; who underwent functional orthopedic treatment with Herbst, associated with fixed orthodontic appliance, aged between 11 and 15 years old; ANB angle > 4\textdegree; SNB angle < 80\textdegree; complete orthodontic records, including lateral cephalometric radiographs available in three moments: T1, pretreatment; T2, posttreatment (Herbst followed by orthodontic fixed appliances treatment); and T3, long-term posttreatment (at least 7 years posttreatment) (Fig.1, table I).

A total of 15 subjects (5 female; 10 male), with a mean age of 13.00 years (SD, 1.21) was selected. No subjects had a history of previous orthodontic/orthopedic treatment or any palatal/lip cleft symptom. At the time of anamnesis, the parents were questioned about their children’s medical history and any children with chronic mouth
breathing, permanent snoring, and tonsillectomy or adenoidectomy were excluded. Therefore, 45 lateral cephalometric radiographs (three of each patient) were obtained from T1, T2 and T3.

The patients selected were treated without extractions with Herbst variation - Cantilever Bite Jumper (CBJ - Ormco Corporation, Orange, Calif) orthopedic approach, followed by fixed appliances. The CBJ was used during a mean period of 1.18 years (SD, 0.19). After correcting the anteroposterior discrepancy, fixed orthodontic appliances were used to refine the occlusion (Roth prescription, Morelli, Sorocaba, Brazil). Class II intermaxillary elastics were used for finishing and as active retention. This second period lasted a mean time of 3.01 years (SD, 1.48). Patients wore a fixed mandibular canine-to-canine retainer for a minimum of 5-years or until the end of growth and a Hawley plate in the maxillary arch for 1-year after comprehensive treatment.

The lateral cephalometric radiographs were digitized and analyzed with Dolphin® Imaging 11.9 software (Patterson Dental Supply, Inc., Chatsworth, California, USA) by a single examiner (T.Y.). According to the respective X-Ray unit's settings and instructions, the software corrected the image magnification factors.

The cephalometric landmarks and analysis of the pharyngeal structures and hyoid bone position were based on the methods described previously by Liu et al.\textsuperscript{24} and Zhe Zong et al.\textsuperscript{24,25} (Table II, Fig 2). The cephalometric variables representing the dentoskeletal pattern were evaluated by Steiner analysis.\textsuperscript{26} A customized cephalometric analysis generated 13 variables, 6 angular and 7 linear, for each tracing (Table III).

**Error study**

Thirty percent of the lateral cephalometric radiographs was randomly selected, retraced and remeasured by the same examiner (T.Y.) after a 30-day interval. IntraClass Correlation Coefficient (ICC) was used for test reliability.

**Statistical analyses**

Normal distribution was evaluated and confirmed with Shapiro-Wilk tests.
Intraclass correlation coefficients for the two separate measurements on the cephalometric radiographs ranged between 0.968 (Hy-Mp perp) and 0.997 (L1.NB), indicating excellent reliability.

Comparing T1-T2, the skeletal components showed a statistically significant increase in the SNB angle, a statistically significant improvement in the maxillomandibular relationship and a mandibular counterclockwise rotation (Herbst followed by fixed appliances). These variables were stable in the long-term posttreatment period. There were no significant changes in the dentoalveolar component between T1, T2 and T3 in the treated group.

About the pharyngeal airway variables, only the lower airway space increased significantly in the treatment period. No other of these variables has undergone significant changes.

The distance between the hyoid bone and the third cervical vertebra was statistically different between each one of the three stages, increasing over time. The mandibular plane distance perpendicular to the hyoid bone was increased in the treatment period and remained stable in the long-term posttreatment period (Table IV).

DISCUSSION

Although there are previous studies that evaluate the association between airway and functional appliances, the literature is scarce about long-term evaluations. In our study, we assessed upper airway dimensions and hyoid bone position changes in Class II patients with mandibular retrognathism treated with Herbst CBJ functional appliance for an average of 10 years (10.73y ± 3.67) of follow-up. It is important to discuss the effectiveness and stability of the treatment.
The sample size was sufficient to give reliability to the results. Statistical significance was achieved, indicating that the treatment effect was large enough to be detected in a limited sample. In addition, although a small sample size, it is substantial because the subjects were evaluated more than 10 years posttreatment. Several authors who have conducted similar researches showed similar samples.\(^{20,21}\)

For ethical reasons, it seems obvious the impossibility of long-term follow-up of untreated Class II individuals. Moreover, Mislik et al.\(^{28}\) studying the pharyngeal airway measurements of untreated patients, declared that most of the growth of airway structures finishes in early childhood and only a slight continuous increase of about 1 mm was detected between 6 and 17 years of age. Our treated group was on average 18 years old at the end of treatment; then, it was expected that there would be no increase in the upper airway dimensions from growth in the follow-up period. A similar long-term follow-up study\(^{21}\) of Class II treatment with fixed functional appliance and effects in the pharyngeal airway compared the treated group with untreated groups of individuals with Classes I and II malocclusion and observed that there were no significant differences between the groups regarding airway changes in the follow-up period. Therefore, our results were not affected by growth.

Although the three-dimensional imaging (3D) using cone-beam computed tomography (CBCT) to evaluate changes in airway dimensions is preferred to a lateral cephalometric radiograph, CBCT is not a standard diagnosis method in Orthodontics and routine use is not recommended for legal and ethical reasons because of radiation exposure.\(^{29}\) Furthermore, the total CBCT scanning time is about 20 seconds and the long exposure time can resulting blurring due to body movement, deglutition, and breathing, which can affect the measurements considerably.\(^{30}\) On the other hand, the 2D lateral cephalometric radiograph has a low radiation exposure and has been the standard tool for Orthodontic diagnostic and treatment planning.\(^{31}\)

The literature shows a significant correlation between sagittal cephalometric measurements of the airway and 3D analysis with CBCT imaging\(^{32}\) and, besides that, it was reported a high accuracy and reproducibility of airway measurements performed on lateral cephalometric radiographs.\(^{33}\) Hence, this method for analyzing the airway is still a valid tool as it is inexpensive, has minimal dose radiation and give accurate measurements.\(^{34}\)

In our study, we assessed upper airway dimensions and hyoid bone position changes in Class II patients with mandibular retrognathism treated with Herbst CBJ
functional appliance followed by a fixed orthodontic appliance in the long-term follow-up (10.73y ± 3.67).

Regarding the skeletal components changes in the posttreatment, the sample suffered an increase in mandibular protrusion, as previously reported for similar appliances,\(^{35,36}\) probably as a result of treatment, normal growth changes\(^ {37}\) and mandibular counterclockwise rotation that agree with the results of Manni et al.\(^ {38}\) There was a statistically significant improvement in the maxillomandibular relationship, as the literature has already shown,\(^ {39}\) represented mainly by the changes in the mandibular component and growth.\(^ {8}\)

There were no significant changes in the dentoalveolar variables between T1 and T2. According to Moro et al.\(^ {35}\), the Herbst CBJ variation causes less mandibular incisors protrusion when compared to other designs of this appliance.

Concerning the upper airway variables, during treatment, a significant increase was observed only in the lower airway space. This seems contradictory, as several studies that evaluated airway effects of Herbst appliance report an increase in the oropharyngeal region,\(^ {16,19}\) but it corroborates with the study by Koay et al.\(^ {17}\) that found that the greatest dimensional upper airway improvement with Herbst appliance was in the hypopharynx region. Moreover, other studies reported an increase in the hypopharynx as a consequence of this treatment.\(^ {16,18,20}\) This may be due to some treatment effect, probably related to the forward shift of the mandible, plus the growth effect.\(^ {17,18}\) A recent study reported improvement only in the oropharynx, but they did not include the hypopharynx in their evaluation.\(^ {19}\) In contrast, some authors concluded that the treatment of Class II malocclusion with the Herbst appliance does not improve significantly any linear dimension of the upper airway.\(^ {15,21,40}\)

In our study, the sample did not show statistically significant changes in the dentoalveolar variables, and it may explain the insignificant changes in the oropharynx. The dentoalveolar changes, especially the mandibular incisor protrusion by functional orthopedic appliances may be responsible for the expansion of the oral cavity and, consequently, the more anterior position of the tongue. This change can result in an increase in the size of the airways.\(^ {41}\)

The biggest part of the studies that evaluated the relationship between treatment with Herbst appliance and upper airway did not evaluate the hyoid bone position. Previous studies have shown that changes in hyoid bone position seem to be related to mandibular position changes.\(^ {42}\) In our study, the hyoid bone was moved
significantly forward in the treatment period, which corroborate with previous studies that evaluated functional appliances and that showed that the anterior displacement of the mandible by the functional appliances improve the horizontal position of the hyoid bone and, consequently, the position of the tongue, improving the upper airway.\textsuperscript{16,20,40,43} Also, the hyoid bone was moved in an inferior direction which is supporting by Zhou’s study,\textsuperscript{44} and Ulusoy’s study\textsuperscript{43} who showed a downward displacement of the hyoid bone after functional treatment, but do not corroborate with a previous study\textsuperscript{45} which declared that hyoid bone moved in a superior direction following functional mandibular advancement in the short-term, however, in the long-term, it moved downwards towards its original position as a compensatory action. Gul Amuk et al.,\textsuperscript{16} studying the Herbst appliance effects, found that the vertical position of hyoid bone did not exhibit a significant change with treatment.

There is a lack of information about the long-term effects of fixed functional appliances in the airway dimension. Until the moment, only one study evaluated the long-term effects of fixed functional appliances on the upper airway and they did not analyze the changes in the hypopharynx dimension and hyoid bone position, besides that they included patients treated with the extraction in their sample.\textsuperscript{21} Some authors have researched long-term effects of treatment with removable functional appliances in the upper airway,\textsuperscript{46,47} but it is important noting that different functional appliances may result in different effects on the dentoalveolar and skeletal structures,\textsuperscript{48} as well in the upper airway and hyoid bone position.\textsuperscript{40,49}

In our study, in the long-term posttreatment period, only the horizontal position of hyoid bone changed significantly, moving forward, which is in agreement with the study by Ulusoy.\textsuperscript{43} All the other variables were stable in this period, corroborating with long-term follow-up studies with functional appliances.\textsuperscript{46,47}

Our study has some limitations and this needs to be reported. Because it is a retrospective study, we don't know if there was special instruction given to the patient about the tongue and head position in the lateral cephalogram records, affecting our findings. Another limitation of this study was that body mass index (BMI) could not be included in a retrospective study design. Body mass index has been shown to impact the dimensions of the airway in children\textsuperscript{50} and adults\textsuperscript{51} and may it influenced the airway measurements. Cephalograms are still widely used to assess pharyngeal airways. However, only the static position of airway structures can be assessed by lateral cephalometric radiographs. Further studies may be aimed at the long-term effects of
fixed functional treatment on the pharyngeal airway with three-dimensional imaging and a more controlled sample to confirm our results.

CONCLUSION

During treatment, the sample showed a significant change in the lower airway space, which may be related to the forward shift of the mandible, plus the growth effect. The hyoid bone was moved forward and downward as a treatment effect. Among all the variables studied, only the hyoid bone's horizontal position changed significantly in the long-term posttreatment period, moving forward.

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FIGURE LEGENDS

Fig. 1- A) Pretreatment (T1); B) During treatment with Herbst (CBJ); C) Posttreatment (T2); D) Long-term posttreatment (T3).

Fig. 2- Diagram of landmarks and variables associated with upper airway and hyoid bone.
Fig. 1
Fig 2.
Table I. Descriptive characteristics of the experimental group.

| X                                      | n = 15                |
|----------------------------------------|-----------------------|
| Stage/Period                           | Mean | S.D.   |
| T1 age                                 | 13.00 | 1.21   |
| T2 age                                 | 18.02 | 1.78   |
| T3 age                                 | 28.75 | 4.37   |
| Total treatment period (T2-T1)         | 5.02  | 1.55   |
| Long-term Posttreatment period (T3-T2) | 10.73 | 3.67   |
| Sex                                    | Male | Female |
|                                        | 10 (66.66%) | 5 (33.33%) |
Table II. Definitions of the cephalometric landmarks used in the present study.

| Cephalometric landmarks | Definition |
|-------------------------|------------|
| N                       | Most anterior point of the frontonasal suture in the sagittal view |
| S                       | Center of the pituitary fossa |
| A                       | Point of maximum concavity in the midline of the alveolar process of the maxilla in the sagittal view |
| B                       | Point of maximum concavity in the midline of the alveolar process of the mandible in the sagittal view |
| Me                      | Most inferior point of the mandibular symphysis in the sagittal view |
| Go                      | The deepest point of the curvature of the angle of the mandible between the inferior border of corpus and posterior border of the ramus of mandible in sagittal view |
| U1                      | Maxillary incisor tip |
| L1                      | Mandibular incisor tip |
| U                       | Lower end of the soft palate |
| V                       | The most posteroinferior point on the base of the tongue |
| SPP                     | Point of intersection of line from soft palate center perpendicular to posterior pharyngeal wall and posterior margin of soft palate |
| SPPW                    | Point of intersection of line from soft palate center perpendicular to posterior pharyngeal wall and posterior pharyngeal wall |
| MPW                     | Foot point of perpendicular line from point U to posterior pharyngeal wall |
| LPW                     | Foot point of perpendicular line from point V to posterior pharyngeal wall |
| Hy                      | Most anterior point on the hyoid bone |
| C3                      | Most anteroinferior point on corpus of third cervical vertebra |
Table III. Summary of the variables used for the cephalometric comparisons.

| Variable     | Interpretation                                                                 |
|--------------|--------------------------------------------------------------------------------|
| **Skeletal component**                                                                 |
| SNA          | Angle between SN and NA                                                        |
| SNB          | Angle between SN and NB                                                        |
| ANB          | Angle between AN and NB                                                        |
| SN.GoGn      | Angle between S-N and Go-Gn                                                    |
| **Dentoalveolar component**                                                            |
| U1-NA        | Distance between NA line and the most anterior point of the maxillary incisor crown |
| U1.NA        | Angle between NA line and the long axis of the maxillary incisor               |
| L1-NB        | Distance between NB line and the most anterior point of the lower incisor crown |
| L1.NB        | Angle between NB line and the long axis of the mandibular incisor              |
| **Pharyngeal airway**                                                                 |
| SPP-SPPW     | Superior airway space: Distance between SPP and SPPW (nasopharynx / palatopharynx) |
| U-MPW        | Middle airway space: Distance between U and MPW                                |
| V-LPW (mm)   | Inferior airway space: Distance between V and LPW                               |
| **Hyoid bone position**                                                                |
| Hy-C3        | Distance between the most anterior point of the hyoid bone and the most anteroinferior point in the body of third cervical vertebra |
| Hy-MPperp    | Distance from the mandibular plane (Go-Me) perpendicular to the hyoid bone      |
Table IV. Intragroup comparisons of the cephalometric variables among the three stages (repeated measures ANOVA, followed by Tukey tests).

| Variables                  | T1     | T2     | T3     | p      |
|----------------------------|--------|--------|--------|--------|
|                            | Mean (s.d.) | Mean (s.d.) | Mean (s.d.) |     |
| **Skeletal components**    |        |        |        |        |
| SNA (°)                    | 81.76 (2.66) | 81.15 (2.99) | 81.32 (3.14) | 0.416 |
| SNB (°)                    | 76.22 (1.97) A | 77.85 (2.23) B | 78.32 (2.77) B | 0.008* |
| ANB (°)                    | 5.51 (1.77) A | 3.29 (1.89) B | 2.99 (1.95) B | 0.000* |
| SN.GoGn (°)                | 31.54 (4.95) A | 29.60 (3.77) B | 29.04 (5.48) B | 0.047* |
| **Dentoalveolar components** |        |        |        |        |
| U1-NA (mm)                 | 4.18 (3.02) | 4.61 (1.64) | 4.74 (1.86) | 0.672 |
| U1.NA (°)                  | 23.03 (10.20) | 25.32 (6.64) | 25.95 (7.29) | 0.380 |
| L1-NB (mm)                 | 4.64 (2.72) | 6.07 (1.87) | 5.74 (2.24) | 0.066 |
| L1.NB (°)                  | 25.45 (8.48) | 30.49 (5.81) | 28.72 (5.63) | 0.084 |
| **Pharyngeal airway**      |        |        |        |        |
| SPP-SPPW (mm)              | 11.68 (2.41) | 12.23 (2.12) | 10.99 (2.32) | 0.104 |
| U-MPW (mm)                 | 9.88 (2.63) | 9.43 (2.53) | 9.62 (2.58) | 0.758 |
| V-LPW (mm)                 | 15.94 (2.53) A | 18.32 (3.60) B | 19.09 (3.93) B | 0.007* |
| **Hyoid bone position**    |        |        |        |        |
| Hy-C3 (mm)                 | 31.45 (3.35) A | 34.65 (4.88) B | 36.48 (5.57) C | 0.000* |
| Hy-MPperp (mm)             | 15.14 (3.29) A | 18.58 (3.88) B | 21.07 (4.22) B | 0.002* |

* Statistically significant at p<0.05
Different letters in the same row indicate the presence of a statistically significant difference between the stages.
3 DISCUSSION
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Previous studies have evaluated the association between fixed functional orthopedic appliances to treat Class II patients with mandibular retrognathism and changes in airway dimensions and it is a controversial subject. (ARAS et al., 2016; BAVBEK; BAVBEK et al., 2016; GÖYMEN; MOURAD; GÜLEÇ, 2019; KANNAN; SATHYANARAYANA; PADMANABHAN, 2017) Specifically about the association between airway and Class II malocclusion treatment with Herbst functional appliance, some studies showed dimension improvement of specific regions of airway and others showed no significant changes in any of them. (CELIKOGLU et al., 2016; DROSEN et al., 2018; GU et al., 2019; GUL AMUK et al., 2019; KANNAN; SATHYANARAYANA; PADMANABHAN, 2017; KINZINGER et al., 2011; KOAY et al., 2016; MANNI et al., 2016; OLIVEIRA et al., 2020; SCHÜTZ et al., 2011)

Until the moment, only one study evaluated the long-term effects of fixed functional appliances on the pharyngeal airway. (DROSEN et al., 2018) Some authors have researched long-term effects of treatment with removable functional appliances, but it is important noting that different functional appliances may result in different effects on the dentoalveolar and skeletal structures, as well in the upper airway. (HAN et al., 2014; HÄNGGI et al., 2008; JENA; SINGH; UTREJA, 2012; PHAN et al., 2006; ULUSOY et al., 2014)

Three-dimensional imaging (3D) using cone-beam computed tomography (CBCT) to evaluate changes in airway dimensions is preferred to a lateral cephalometric radiograph, but this method has a long exposure time that can resulting blurring due to body movement, deglutition, and breathing which can affect the measurements considerably, and a high radiation exposure. (CHANG et al., 2013; GARIB et al., 2014; SILVA et al., 2008) Besides that, the literature shows a significant correlation between sagittal cephalometric measurements of the airway and 3D analysis with CBCT imaging and a high accuracy and reproducibility of airway measurements performed on lateral cephalometric radiographs. (FENG et al., 2015; KAUR; RAI; KAUR, 2014; MALKOC et al., 2005; VIZZOTTO et al., 2012) Thus, this method was used in our study.
For ethical reasons, it seems obvious the impossibility of long-term follow-up of untreated Class II individuals, and, besides that, most of the growth of airway structures finishes in early childhood and only a slight continuous increase of about 1 mm was detected between 6 and 17 years of age. (MISLIK et al., 2014) Our sample was on average 18 years old at the end of treatment; then, it was expected that there would be no increase in the upper airway dimensions from growth in the follow-up period.

In our study, regarding the skeletal components changes in the posttreatment, the sample suffered an increase in mandibular protrusion, as previously reported for similar appliances, and a statistically significant improvement in the maxillomandibular relationship, as the literature has already shown. (CHEUNG et al., 2015; LANCIA 2018; FRANCHI et al., 2012; GAO; LI; BAY 2014; MORO et al., 2009; PANCHERZ; ANEHUS-PANCHERZ, 1994; TOMBLYN et al., 2016) There were no significant changes in the dentoalveolar variables between the three stages.

Concerning the pharyngeal airway variables, during treatment, a significant increase was observed only in the lower airway space. This seems contradictory, as several studies that evaluated airway effects of Herbst appliance report an increase in the oropharyngeal region, but it corroborates with the study by Koay et al. that found that the greatest dimensional upper airway improvement with Herbst appliance was in the hypopharynx region. (GU et al., 2019; GUL AMUK et al., 2019; KOAY et al., 2016; MANNI et al., 2016; OLIVEIRA et al., 2020) Moreover, other studies reported an increase in the hypopharynx as a consequence of this treatment. (GUL AMUK et al., 2019; IWASAKI et al., 2014; MANNI et al., 2016; MOURA 2020; SCHÜTZ et al., 2011). This may be due to some treatment effect, probably related to the forward shift of the mandible, plus the growth effect. (KOAY et al., 2016; MANNI et al., 2016) A recent study reported improvement only in the oropharynx, but they did not include the hypopharynx in their evaluation. (OLIVEIRA et al., 2020) In contrast, some authors concluded that the treatment of Class II malocclusion with the Herbst appliance does not improve significantly any linear dimension of the upper airway. (CELIKOGLU et al., 2016; DROSEN et al., 2018; KANNAN; SATHYANARAYANA; PADMANABHAN, 2017; KINZINGER et al., 2011)

The hyoid bone is linked to tongue posture and function due to the associated muscles, and it influences their position, shape, and size. (SANTOS et al., 2009) In our
study, the hyoid bone was moved significantly forward in the treatment period, which corroborate with previous studies that studied functional appliances and that showed that the anterior displacement of the mandible by the functional appliances improve the horizontal position of the hyoid bone and, consequently, the position of the tongue, improving the upper airway. (GUL AMUK et al., 2019; JENA; SINGH; UTREJA, 2012; RIZK; KULBERSH; AL-QAWASMI, 2015; SAHOO et al., 2012; SCHÜTZ et al., 2011; ULUSOY et al., 2014) Also, the hyoid bone was moved in an inferior direction which is supporting by Zhou’s study, and Ulusoy’s study who showed a downward displacement of the hyoid bone after functional treatment, but do not corroborate with a previous study which declared that hyoid bone moved in a superior direction following functional mandibular advancement in the short-term, however, in the long-term, it moved downwards towards its original position as a compensatory action. (ZHOU; ZHAO; LU, 2000; ROBERTSON, 2000; ULUSOY et al., 2014) Gul Amuk et al., studying the Herbst appliance effects, found that the vertical position of hyoid bone did not exhibit a significant change with treatment. (GUL AMUK et al., 2019)

In the long-term posttreatment period, only the horizontal position of hyoid bone changed significantly, moving forward, which is in agreement with the study by Ulusoy. (ULUSOY et al., 2014) All the other variables were stable in this period, corroborating with long-term follow-up studies with functional appliances. (HAN et al., 2014; HÄNGGI, 2008; ULUSOY et al., 2014)

Because it is a retrospective study, we don’t know if there was special instruction given to the patient about the tongue and head position in the lateral cephalogram records and body mass index (BMI) could not be included in a retrospective study design. Therefore, may be aimed at the long-term effects of fixed functional treatment on the pharyngeal airway with three-dimensional imaging and a more controlled sample to confirm our results.
4 CONCLUSIONS
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During treatment, the sample showed a significant change in the lower airway space, which may be related to the forward shift of the mandible, plus the growth effect. The hyoid bone was moved forward and downward as a treatment effect. Among all the variables studied, only the hyoid bone’s horizontal position changed significantly in the long-term posttreatment period, moving forward.
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APPENDIX A- DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN DISSERTATION/THESIS

We hereby declare that we are aware of the article “LONG-TERM EVALUATION OF UPPER AIRWAY DIMENSIONS AND HYOID BONE POSITION IN CLASS II MALOCCLUSION PATIENTS TREATED WITH HERBST FUNCTIONAL APPLIANCE” will be included in Dissertation of the student Thagid Yasmin Leal Almeida Marques and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, January 14th, 2021

Thagid Yasmin Leal Almeida Marques
Author

Signature

Marcos Roberto de Freitas
Author

Signature
ANNEX A. Ethics Committee approval, protocol number 22082219.0.0000.5417 (front).

USP - FACULDADE DE
ODONTOLOGIA DE BAURU DA
USP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação em longo prazo das vias aéreas superiores em pacientes com má oclusão de Classe II tratados com propulsores mandibulares fixos

Pesquisador: THAGID YASMIN LEAL ALMEIDA MARQUES

Área Temática:

Versão: 1

CAAE: 22082219.0.0000.5417

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

Patrocinador Principal: Capes Coordenação Aperf Pessoal Nível Superior

DADOS DO PARECER

Número do Parecer: 3.642.036

Apresentação do Projeto:

Trata-se de um estudo observacional, analítico e retrospectivo, que empregará apenas informações de prontuários disponíveis na instituição sem previsão de utilização de material biológico. Estudo não intervencionista (sem intervenções clínicas).

O objetivo desse trabalho será avaliar em longo prazo as alterações nas vias aéreas superiores após o tratamento com aparelhos propulsores mandibulares fixos. A amostra será constituída das documentações ortodônticas de 40 indivíduos com idade variando entre 11 e 18 anos, portadores de má oclusão inicial de Classe II, divisão 1 de Angle e retrusognatismo mandibular, que foram submetidos a tratamento ortopédico funcional com aparelhos propulsores mandibulares fixos. Os sujeitos da pesquisa serão coletados dos arquivos do Departamento de Ortodontia da Faculdade de Odontologia de Bauru - Universidade de São Paulo. Serão avaliadas teleradiografias tomadas em três diferentes tempos: T1 (início do tratamento); T2 (final do tratamento); e T3 (observação em longo prazo). As teleradiografias serão digitais e por meio do software Dolphin serão realizadas medidas cefalométricas dentoesqueléticas e das vias áreas superiores. A normalidade dos dados será avaliada pelo teste de Shapiro-Wilk. A comparação intragrupo das fases inicial, final e longo prazo pós-tratamento será realizada pelo teste ANOVA de medidas repetidas e teste de Tukey quando necessário.
ANNEX A. Ethics Committee approval, protocol number 22082219.0.0000.5417 (front).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Objetivo da Pesquisa:
O objetivo desse trabalho será avaliar em longo prazo as alterações nas vias aéreas superiores após o tratamento com aparelhos propulsores mandibulares fixos.

Avaliação dos Riscos e Benefícios:
Riscos:
O desenvolvimento desta pesquisa oferece riscos mínimos pois empregará apenas informações de prontuários, disponíveis na instituição. Os riscos de contaminação cruzada do pesquisador principal pelo manuseio de prontuários antigos serão controlados por meio do uso de equipamentos de proteção individuais. Riscos da perda de documentação também serão evitados pelo manuseio cuidadoso e sistemático por parte do pesquisador.

Existe o risco de identificação do indivíduo, mas isso será evitado pelo cuidado do pesquisador em manejear e analisar de forma anônimo, sem identificação nominal dos participantes.

Se trata de um estudo sem intervenções clínicas) portanto sem alterações ou influências na rotina do participante da pesquisa.

Benefícios:
O benefício terapêutico do avanço mandibular precoce pode modificar permanentemente a respiração bucal e a respiração nasal, evitando assim a obstrução da via aérea superior. Comprovando-se a eficiência e eficácia do tratamento ortodontico com aparelhos propulsores fixos no aumento das dimensões das vias aéreas, o ortodontista poderá optar por um tratamento que melhore não apenas

Comentários e Considerações sobre a Pesquisa:
Descritas no item "Lista de Inadequações".

Considerações sobre os Termos de apresentação obrigatória:
Todos os documentos obrigatórios foram apresentados. Considerações descritas no item "Lista de Inadequações".

Recomendações:
Retificar os documento abaixo mencionado (gerado pela Plataforma Brasil), apresentando a respectiva "emenda".

Conclusões ou Pendências e Lista de Inadequações:
O projeto analisado não possui impedimentos éticos, podendo ser iniciado, porém, deve a pesquisadora retificar o documento intitulado "PB_INFORMAÇÕES": os benefícios da pesquisa estão incompletos; Informa que não haverá uso de dados secundários e que serão recrutados 40

Endereço: DOUTOR OCTAVIO PINHEIRO BRISOLLA 75 QUADRA 9
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Telefone: (14)3235-8356 Fax: (14)3235-8356 E-mail: cep@fob.usp.br
ANNEX A. Ethics Committee approval, protocol number 22082219.0.0000.5417 (verse).

participants.
Assim, sou de parecer que o projeto seja APROVADO com a recomendação acima mencionada.

Considerações Finais a critério do CEP:
Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 09/10/2019, 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.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

| Tipo Documento                  | Arquivo                                      | Postagem          | Autor                      | Situação  |
|---------------------------------|----------------------------------------------|-------------------|---------------------------|-----------|
| Informações Básicas do Projeto | PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1417353.pdf | 19/09/2019 13:01:50 | THAGID YASMIN LEAL ALMEIDA MARQUES | Aceito    |
| Outros                          | checklist.pdf                                | 19/09/2019 13:01:14 | THAGID YASMIN LEAL ALMEIDA MARQUES | Aceito    |
| Outros                          | termodeaquiescencia.pdf                      | 19/09/2019 13:00:46 | THAGID YASMIN LEAL ALMEIDA MARQUES | Aceito    |
| Folha de Rasto                  | folhaderoasto.pdf                            | 19/09/2019 10:17:24 | THAGID YASMIN LEAL ALMEIDA MARQUES | Aceito    |
| Cronograma                      | cronograma.pdf                               | 19/09/2019 10:08:32 | THAGID YASMIN LEAL ALMEIDA MARQUES | Aceito    |
| Projeto Detalhado / Brochura Investigador | projeto.pdf                               | 19/09/2019 10:07:21 | THAGID YASMIN LEAL ALMEIDA MARQUES | Aceito    |
| Outros                          | usodoarquivo.pdf                             | 14/09/2019 10:39:46 | THAGID YASMIN LEAL ALMEIDA MARQUES | Aceito    |
| TCLE / Termos de Assentamento / Justificativa de Ausência | isencaotcle.pdf                            | 14/09/2019 10:35:59 | THAGID YASMIN LEAL ALMEIDA MARQUES | Aceito    |
ANNEX A. Ethics Committee approval, protocol number 22082219.0.0000.5417 (verse).

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 3.642.036

| Declaração de Pesquisadores | declaracaopesquisador.pdf | 14/09/2019 10:35:36 | THAGID YASMIN LEAL ALMEIDA MARQUES | Aceito |
|-----------------------------|---------------------------|---------------------|-----------------------------------|--------|
| Declaração de Instituição e Infraestrutura | declaracaoinstituicao.pdf | 14/09/2019 10:34:59 | THAGID YASMIN LEAL ALMEIDA MARQUES | Aceito |

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 15 de Outubro de 2019

Assinado por:
Ana Lúcia Pompéia Fraga de Almeida
(Coordenador(a))
Universidade de São Paulo
Faculdade de Odontologia de Bauru
Departamento Odontopediatria, Ortodontia e Saúde Coletiva
Área Departamental de Ortodontia

Solicitação de isenção do Termo de Consentimento Livre e Esclarecido

Referência: "Avaliação em longo prazo das vias aéreas superiores em pacientes com má oclusão de Classe II tratados com propulsores mandibulares fixos"

Pesquisador Responsável: Thagrid Yasmin Leal Almeida Marques

Ao Comitê de Ética em Pesquisa da Faculdade de Odontologia de Bauru da Universidade de São Paulo:

Venho por meio deste documento solicitar a dispensa de obtenção de um Termo de Consentimento Livre e Esclarecido (TCLE) para o estudo intitulado "Avaliação em longo prazo das vias aéreas superiores em pacientes com má oclusão de Classe II tratados com propulsores mandibulares fixos" proposto por Thagrid Yasmin Leal Almeida Marques.

A dispensa do uso de TCLE se fundamenta: I) por ser um estudo observacional, analítico e retrospectivo, que empregará apenas informações de prontuários disponíveis na instituição sem previsão de utilização de material biológico; II) porque trata-se de documentações antigas, sendo impraticável o contato com a maioria dos pacientes da amostra; III) porque todos os dados serão manejados e analisados de forma anônima, sem identificação nominal dos participantes de pesquisa; IV) porque os resultados decorrentes do estudo serão apresentados de forma agregada, não permitindo a identificação individual dos participantes; e V) porque se trata de um estudo não intervencionista (sem intervenções clínicas) e sem alterações ou influências na rotina do participante de pesquisa, e consequentemente sem adição de riscos ou prejuízos ao bem-estar dos mesmos.

O investigador principal e demais colaboradores envolvidos no estudo acima se comprometem, individual e coletivamente, a utilizar os dados provenientes deste, apenas para os fins descritos e a cumprir todas as diretrizes e normas regulamentadoras descritas na Res. CNS N° 466/12, e suas complementares, no que diz respeito ao sigilo e confidencialidade dos dados coletados.

Bauru, 10 de setembro de 2019.

Thagrid Yasmin Leal Almeida Marques
RG 15084282-12
ANNEX C. Patient’s informed consent exoneration (verse)

UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU
CLÍNICA DE ORTODONTIA

AUTORIZAÇÃO PARA DIAGNÓSTICO E/OU EXECUÇÃO DE
TRATAMENTO ORTODÔNTICO

Por este instrumento de autorização por mim assinado, dou pleno consentimento à FACULDADE DE ODONTOLOGIA DE BAURU-USP para, por intermédio de seus professores, assistentes e alunos devidamente autorizados, fazer diagnóstico, planejamento e tratamento em minha pessoa ou meu filho menor de idade _____, de acordo com os conhecimentos enquadrados no campo dessa especialidade.

Concordo também, que todas radiografias, fotografias, modelos, desenhos, históricos de antecedentes familiares, resultados de exames clínico e de laboratório e quaisquer outras informações concernentes ao planejamento de diagnóstico e/ou tratamento, constituem propriedade exclusiva desta FACULDADE, à qual dou plenos direitos de retenção, uso para quaisquer fins de ensino e de divulgação em jornais e/ou revistas científicas do país e do exterior.

Bauru, ____ de ____________ de 19 __

__________________________
Assinatura do paciente ou responsável
R.G. Nº: ______________________
Nome: ______________________________
Endereço: ______________________________
CEP: ________________ Telefone: ________________