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ALTERAÇÕES TRIDIMENSIONAIS IMEDIATAS DA VIA AÉREA SUPERIOR APÓS CIRURGIA ORTGNÁTICA COM ROTAÇÃO ANTI-HORÁRIA EM PACIENTES RETROGNATAS

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Dissertação apresentada ao Programa de Pós-graduação em Clínica Odontológica, da Faculdade de Odontologia da Universidade Federal de Juiz de Fora, como requisito parcial para obtenção do título de Mestre. Área de concentração em Clínica Odontológica

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RESUMO

O presente estudo teve como objetivo a avaliação tridimensional da mudança imediata da orofaringe através da tomografia computadorizada de feixe cônico (TCFC) após cirurgia ortognática bimaxilar com rotação anti-horária, em diferentes avanços cirúrgicos. Os exames tomográficos foram realizados em 2 tempos distintos: T0 (pré-operatório) e T1 (pós-operatório com 15 dias). O total de 88 exames tomográficos de 44 paciente classe II (11 homens e 33 mulheres) foram selecionados e divididos em três grupos de acordo com avanço mandibular em milímetros (mm): G1 (< 5mm), G2 (entre 5 e 10 mm) e G3 (> 10mm). O programa Dolphin Imaging foi usado para mensurar a área sagital mediana (ASM), volume e área axial mínima (AAM) em cada grupo. Foi utilizado teste t de Student para amostras pareadas. O G1 não demonstrou diferença estatisticamente significativa, enquanto no G2 apenas a AAM demonstrou aumentos significativos ($p<0,05$). Nos avanços superiores a 10 mm (G3) houve aumento significativo em todas as medidas avaliadas, sendo a AAM a mais sensível. O presente estudo demonstrou que ao menos 10 mm de avanço no ponto B em rotações anti-horárias são necessárias para o aumento de toda a orofaringe.

ABSTRACT

The purpose of this study was to quantify, through cone beam computed tomography (CBCT), the immediate three-dimensional changes in the oropharynx following bimaxillary orthognathic surgery (OS) with counterclockwise (CCW) rotation, in different surgical advancements. CBCT were taken at two distinct time intervals, preoperative (T0) and immediately postoperative, up to 15 days after surgery (T1). A total of 88 tomographic scans of 44 class II patients (11 men and 33 women) were selected and divided into three groups according to the following mandibular advancement in millimeters (mm): G1 (< 5 mm), G2 (between 5 and 10 mm) and G3 (> 10 mm). Dolphin Imaging® software was used to measure the medial sagittal area (MSA), volume, and minimum cross-sectional axial area (CSA) in each group. Statistical analysis was performed using a paired Student's t-test for the samples. No significant difference was observed in patients from G1, while G2 presented statistical improvements in CSA only ($p < 0.05$). Remarkable changes in all measures were observed when the advancements were superior to 10 mm (G3), with the CSA showing the most prominent change. The present study demonstrated that an at least 10 mm B point advancement in CCW was needed to improve the entire oropharynx.

SÚMARIO

1 INTRODUÇÃO/JUSTIFICATIVA

O desenvolvimento correto e harmônico dos ossos da face está diretamente relacionado ao equilíbrio do sistema estomatognático, à presença de uma oclusão satisfatória, à estética facial e à morfologia das vias aéreas superiores. Quando este crescimento não ocorre de forma equilibrada, são encontradas as deformidades dentofaciais, como prognatismo ou retrognatismo maxilar e/ou mandibular, além das discrepâncias no sentido látero-lateral e vertical da face (TURNBULL e BATTAGEL, 2000).

Pacientes que possuem retrognatismo mandibular tendem a apresentar uma diminuição do espaço da via aérea superior (VAS) (RILEY *et al.*,1983), representada pela nasofaringe, orofaringe e hipofaringe (RAMA *et al*., 2002). Também são comumente encontrados em pacientes classe II, o comprimento vertical aumentado da VAS, o plano oclusal aberto e a retrusão do pogônio, que aumentam a resistência do fluxo de ar na região (ZINSER *et al*., 2013). A diminuição do espaço aéreo e o aumento da resistência à passagem de ar podem levar ao severo estreitamento ou até mesmo à obstrução transitória da passagem de ar durante o sono nas áreas de maior constrição, causando a apneia obstrutiva do sono (LI, 2011; BIANCHI *et al*., 2014).

A cirurgia ortognática é utilizada para correção das deformidades ósseas e discrepâncias de tecido mole da face (LOURO *et al*., 2018). Os avanços bimaxilares podem causar grandes modificações esqueléticas e como consequência alteram a área e o volume da cavidade bucal e nasal (BIANCHI *et al*., 2014), dependendo da região, da magnitude e direção do movimento (BRUNETTO *et al*., 2014). Grandes mudanças e melhoras na VAS ocorrem em pacientes com avanços bimaxilares médios de 10 milímetros (mm) (FAIRBURN *et al*., 2007; ABRAMSON *et al*., 2011; BOYD *et al*., 2013; BIANCHI *et al*., 2014), entretanto o avanço na região mandibular demonstra ser mais efetivo (HERNÁNDEZ-ALFARO *et al*., 2011). O avanço mandibular causa o estiramento da musculatura da faringe e supra hioidea que apresentam sua inserção nesta região (MEHRA *et al*., 2001; LI, 2011). Este avanço pode ser potencializado com a rotação anti-horária do plano oclusal mandibular, quando o pogônio e o ponto B avançam mais do que o incisivo inferior (MEHRA *et al*., 2001), maximizando o avanço do osso hioide, base de língua, e músculos genioglosso e geniohioide.

As mudanças nas VAS após a cirurgia ortognática podem ser avaliadas por exames de imagem em duas dimensões, com a utilização de radiografias cefalométricas (SAHOO *et al*., 2012), porém apresentam limitações, pois avaliam de forma linear apenas as modificações no plano sagital, considerando uma alteração bidimensional de uma estrutura tridimensional (ABOUDARA *et al*., 2009; CARVALHO *et al*., 2012; KOCHAR *et al*., 2016). A utilização de exames tridimensionais como tomografia computadorizada helicoidal para avaliação e reconstrução das vias aéreas pré e pós-operatórias também vem sendo utilizada em pacientes submetidos a cirurgias ortognática (FAIRNBURN *et al*., 2007; ABRAMSON *et al*., 2011; ZINSER *et al*., 2013; BIANCHI *et al*., 2014), porém há poucos relatos na literatura, com tomografia computadorizada de feixe cônico (TCFC) (HERNÁNDEZ–ALFARO *et al*., 2011; CANELLAS *et al*., 2016). Esta demonstra algumas vantagens sobre exames de TC helicoidal, com baixa dose de radiação, rápida aquisição e melhor custo-benefício (TSO *et al*., 2009).

Na literatura, a alteração das vias aéreas superiores causadas pela cirurgia ortognática geralmente são relatadas em avanços bimaxilares lineares, com análises em exames de duas dimensões e apenas citando a média de avanço de toda uma amostra (SAHOO *et al*., 2012; BIANCHI *et al*., 2014). Porém há a necessidade de estratificar esses avanços e avalia-los separadamente, analisando a repercussão na VAS, pois nem sempre esses grandes avanços são exequíveis devido à repercussão estética desfavorável, principalmente na região maxilar (ZINSER *et al*., 2013). Portanto, a repercussão de diferentes avanços com rotação anti-horária na via aérea superior em 3D pode ser uma importante avaliação para os profissionais da cirurgia maxilofacial (SAHOO *et al*., 2012).

2 PROPOSIÇÃO

O objetivo deste estudo foi avaliar tridimensionalmente as repercussões imediatas na VAS em diferentes avanços mandibulares após cirurgias bimaxilares com rotações anti-horárias em pacientes retrognatas.

3 MATERIAL E MÉTODO

Trata-se de um estudo observacional retrospectivo, onde foram analisados prontuários e exames de TCFC pré e pós-operatórias de cirurgia ortognática de pacientes retrognatas do Hospital Universitário Pedro Ernesto (HUPE) (Rio de Janeiro, RJ - Brasil), no período de janeiro de 2012 a janeiro de 2016. O estudo foi aprovado pelo comitê de ética e pesquisa da Universidade Federal de Juiz de Fora sob número de parecer 2.195.162 e pelo comitê de ética do HUPE sob número de parecer 2.450.559. Os critérios de inclusão adotados foram: exames de pacientes retrognatas (ângulo SNB < 78°), ambos gêneros, saudáveis (ASA I e ASA II), submetidos ao avanço do complexo bimaxilar com rotação anti-horária do plano oclusal. Foram excluídos pacientes submetidos a cirurgias ortognáticas prévias, com complicações trans-cirúrgicas, ou cirurgias prévias na região de cabeça e pescoço (MEHRA *et al*., 2001; HONG *et al*., 2011).

3.1 Exames de imagem

Foram avaliadas imagens pertencentes ao banco de imagens do HUPE, realizados no mesmo tomógrafo Kavo I-CAT (Imaging Sciences International, Hatfield, Pensilvânia, EUA), com “FOV” 22, rotação única de 360º para aquisição de imagens com cortes de 1 mm de espessura nos planos axial, sagital e coronal, com voxel de 0,3 mm, escala de 14 bits, tempo de varredura de 40 segundos, 120 kV e 5 mA e gravado em formato DICOM (Digital Imaging and Communication in Medicine). Os exames de TCFC foram realizados em dois intervalos de acordo com o protocolo do serviço de cirurgia maxilofacial da UERJ: pre-operatório (T0); pós-operatório imediato com 15 dias (T1). Não foi utilizado nenhum apoio para cabeça ou mento, com os pacientes sentados em posição natural de cabeça com o pescoço relaxado, sem causar hiperextensão ou hiperflexão (ARNETT *et al*., 1999). Os pacientes foram manipulados manualmente em relação cêntrica, com os lábios relaxados e instruídos a não sorrir, não engolir e permanecerem parados. Todas as imagens foram posteriormente comparadas aos exames clínicos para determinar o correto posicionamento da cabeça e a realização do planejamento cirúrgico, levando em conta o trespasse horizontal e o posicionamento da cabeça por meio de fotos clínicas (Figura 1 e 2).

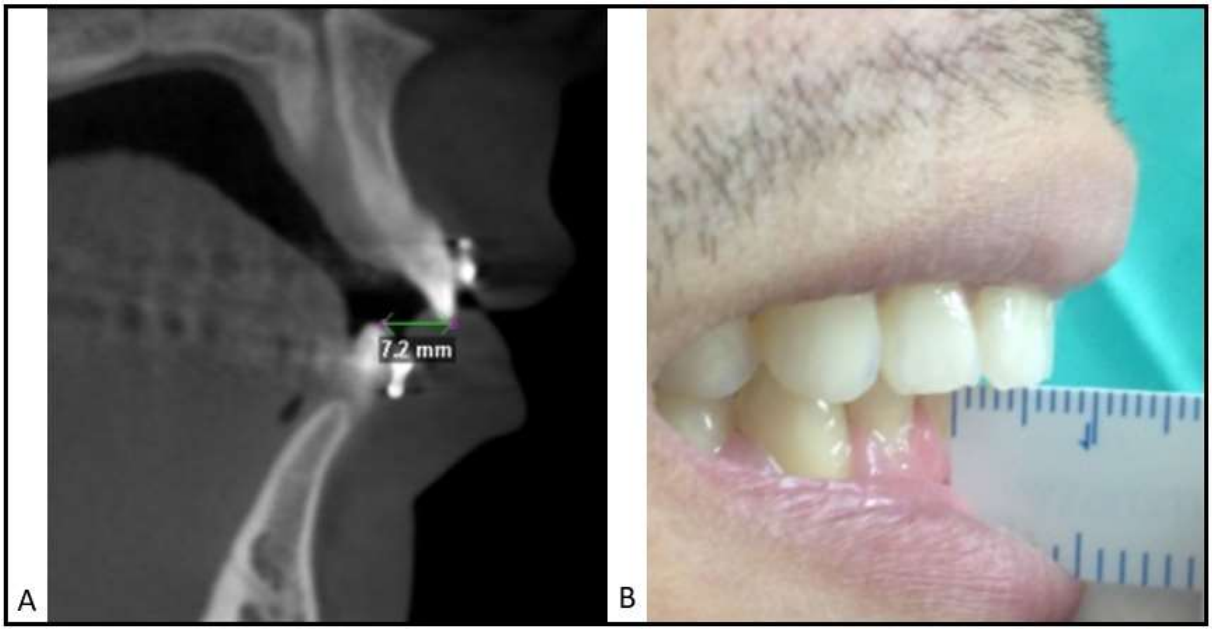

Figura 1 – (A) Reconstrução sagital ilustrativa da TCFC indicando o trespasse horizontal. (B) Foto clínica em vista lateral evidenciando o trespasse horizontal

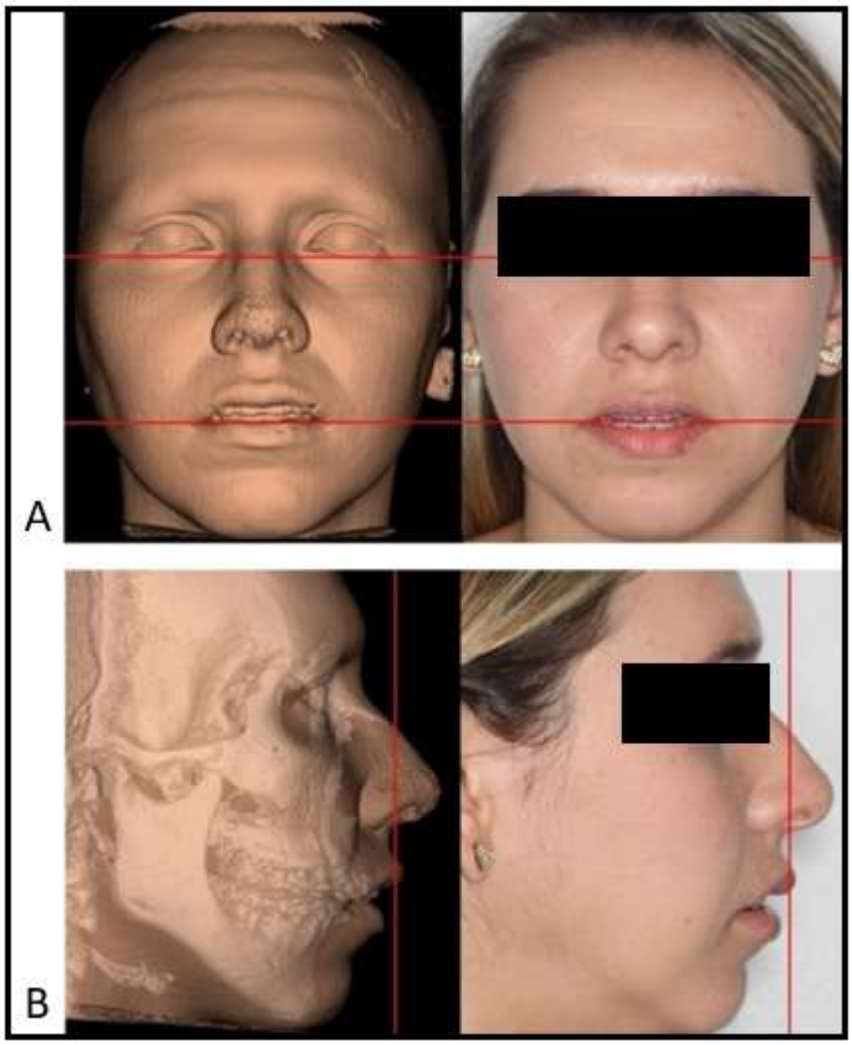

Figura 2 – Conferência do posicionamento da cabeça do paciente: (A) Reconstrução tridimensional da vista frontal seguindo como referência a foto clínica frontal; (B) Reconstrução tridimensional da vista lateral seguindo como referência a foto clínica de perfil

3.2 Procedimento cirúrgico

Foram realizadas cirurgias com avanços bimaxilares e rotação anti-horária do plano oclusal por meio de osteotomia Le Fort I e osteotomia sagital do ramo mandibular.

3.3 Sobreposição das imagens tomográficos

Os exames tomográficos T0 e T1 foram importados em formato DICOM para o Dolphin Imaging 11.7 (Dolphin Imaging and Management Solutions, Chatsworth, Calif., EUA). Em posição natural de cabeça, seguindo o protocolo do serviço da UERJ, foi utilizado a ferramenta “Superimpose Tool” na reconstrução sagital com 1 mm de espessura, e determinados os pontos fixos de referência como base de crânio, násion e sela túrcica em T0 e T1 que não sofreram alteração com a cirurgia para a sobreposição das imagens de forma automática no programa (Figura 3). A partir da sobreposição das imagens, utilizando a ferramenta “measure” foi mensurado de forma linear o avanço obtido em mm do ponto B em T0 e T1. De acordo com o avanço no ponto B, foram divididos em três grupos: G1 (avanço do ponto B < 5 mm), G2 (avanço do ponto B entre 5 e 10 mm) e G3 (avanço do ponto B > 10 mm). Utilizando a mesma ferramenta foram mensurados os avanços nos pontos: incisivo central inferior (ICI); incisivo central superior (ICS) e a espinha nasal anterior (ENA). Desta forma o avanço superior do ponto B em relação ao ICI e o maior avanço do ICS em relação a ENA caracterizou a rotação anti-horária do complexo em todos os casos (Figura 4).

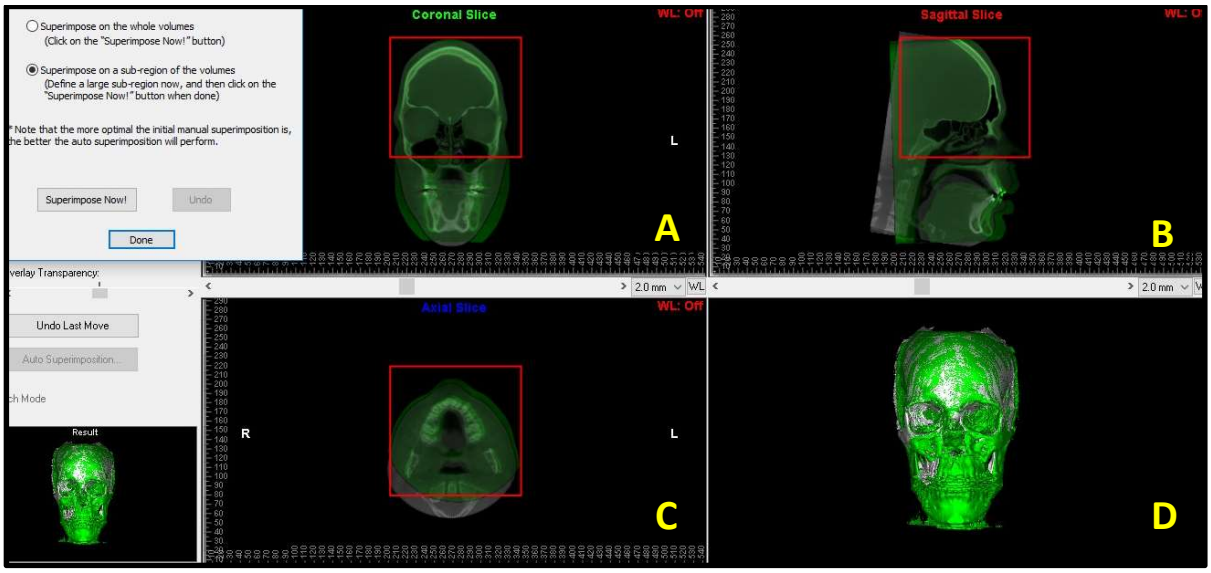

Figura 3 – Interface da ferramenta “superimpose” do programa Dolphin Imaging: (A), (B), (C): quadrado vermelho delimita a região com os pontos fixos que não sofreram movimentação cirúrgica, na vista coronal, sagital e axial respectivamente; (D) Reconstrução tridimensional das sobreposições de T0 e T1.

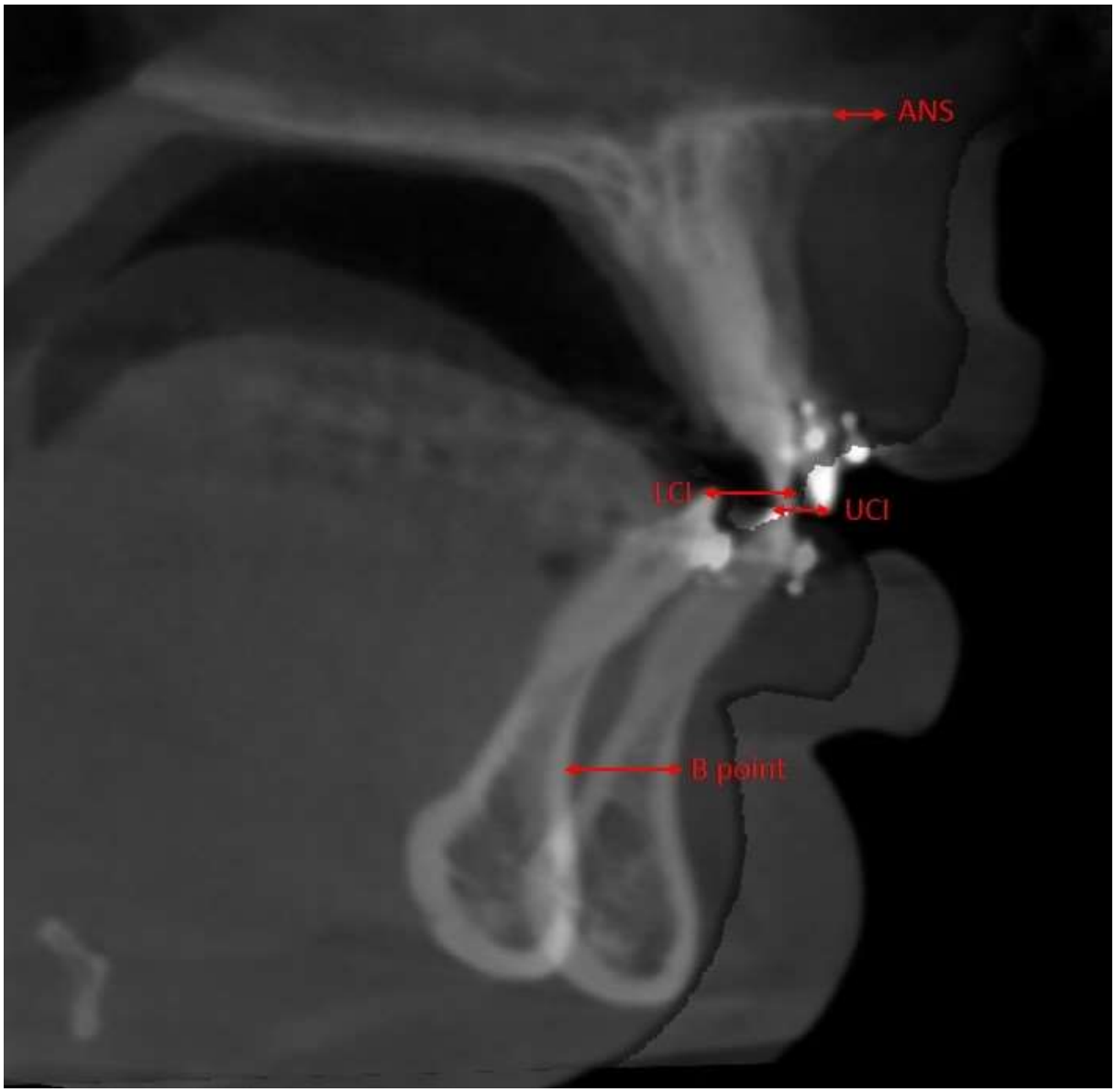

Figura 4 – Mensurações dos avanços nos pontos ENA, ICS, ICI e ponto B.

3.4 AVALIAÇÃO DA MUDANÇA DA VIA AÉREA SUPERIOR

O mesmo programa foi utilizado para reconstruir a VAS, com a ferramenta "Sinus/Airway Avaliation Tool", (CARVALHO *et al*., 2012; GONÇALVES *et al*., 2013; RAFFAINI e PISANI, 2013; BRUNETTO *et al*., 2014; MIRANDA *et al*., 2015; CANELLAS *et al*., 2016). A VAS foi delimitada na região da orofaringe a partir da reconstrução sagital mediana da mesma forma adota por Abramson *et al*., (2011). Foram demarcados os pontos da espinha nasal posterior e da parede posterior da

faringe, formando uma linha paralela ao plano horizontal, delimitando o limite superior da via aérea a ser avaliada. O limite inferior foi demarcado na mesma reconstrução em dois pontos, um anterior na base da epiglote e outro na parede posterior da faringe, formando assim, uma linha paralela ao plano horizontal. Desta forma, a via aérea se estendeu do palato duro à base da epiglote no sentido vertical e no sentido ântero-posterior e látero-lateral pela própria faringe (paredes anterior, posterior e laterais) (ABRAMSON *et al.*, 2011) (Figura 5).

Figura 5 – Interface da ferramenta “sinus/airway” do programa Dolphin Imaging delimitando a região da orofaringe avaliada

Definidos os limites da via aérea a ser avaliada, foi utilizado a ferramenta “add seed points” no local da VAS, com a sensibilidade de via aérea padronizada em 25% (CARVALHO *et al*., 2012). Selecionada a região da orofaringe e a sensibilidade padronizada, foi utilizada a opção “update volume” para calcular a área sagital mediana (ASM) e o volume (Figura 6 e 7) e a opção “enable minimum axial area” para localizar e calcular a área axial mínima (AAM) (Figura 8).

Figura 6 – Reconstrução sagital da TCFC evidenciando a área sagital mediana da orofaringe

Figura 7 – Reconstrução tridimensional evidenciando o volume total da orofaringe

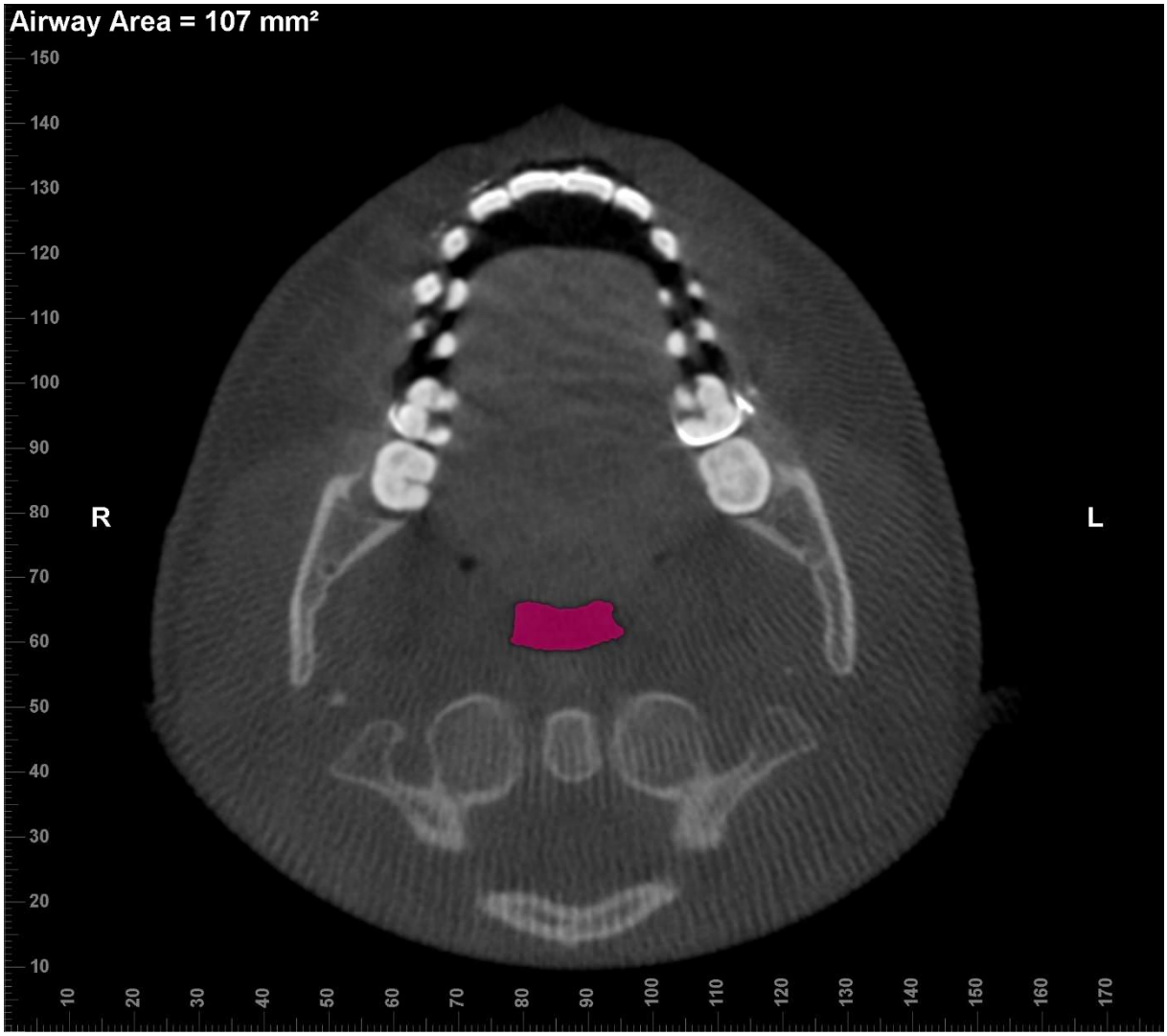

Figura 8 – Reconstrução axial da TCFC da área axial mínima da orofaringe na região de maior constrição

Todas as análises foram realizadas sob mesmas condições, pelo mesmo operador, limitando o número de imagens avaliadas por dia para evitar a fadiga visual (n = 5).

Para avaliar a reprodutibilidade de método, a amostra foi reavaliada após 1 mês, e foi aplicado o coeficiente de correlação de Pearson.

Para comparação das diferenças nos dois tempos (T0 e T1) das variáveis ASM, volume e AAM foi aplicado teste de normalidade da amostra e o teste T de Student pareado através do software IBM SPSS Statistics (versão 15,0; IBM Corp, Armonk, NY), com nível de significância de 95%.

4 ARTIGO

TITLE PAGE

Immediate three-dimensional changes in the oropharynx after different counterclockwise rotation advancements

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Key words: orthognathic surgery, three-dimensional image, airway remodeling

Running Heads: Impact of advances in the upper airway

ABSTRACT

The purpose of this retrospective study was to quantify, through cone beam computed tomography (CBCT), the immediate three-dimensional changes in the oropharynx following bimaxillary orthognathic surgery (OS) with counterclockwise (CCW) rotation, in different surgical advancements. CBCT were taken at two distinct time intervals, preoperative (T0) and immediately postoperative, up to 15 days after surgery (T1). A total of 88 tomographic scans of 44 class II patients (11 men and 33 women) were selected and divided into three groups according to the following mandibular advancement in millimeters (mm): G1 (< 5 mm), G2 (between 5 and 10 mm) and G3 (> 10 mm). Dolphin Imaging® software was used to measure the medial sagittal area (MSA), volume, and minimum cross-sectional axial area (CSA) in each group. Statistical analysis was performed using a paired Student's t-test. No significant difference was observed in patients from G1, while G2 presented statistical improvements in CSA only ($p \leq 0.05$). Remarkable changes in all measures were observed when the advancements were superior to 10 mm (G3), with the CSA showing the most prominent change. The present study demonstrated that an at least 10 mm B point advancement in counterclockwise was needed to improve the entire oropharynx.

INTRODUCTION

Patients presenting mandibular retrognathism tend to show a narrow upper airway (UA)[1]. Other factors commonly found in class II patients, such as increased vertical length of the UA, high occlusal plane and retruded pogonion, may increase airflow resistance[2]. The decreased airway space and the increased resistance to airflow may lead to a severe narrowing or to a transitory obstruction in the minimal axial area resulting in obstructive sleep apnea (OSA)[3,4].

Orthognathic surgery (OS) is performed to correct both bone deformities and facial soft tissue discrepancies[5]. Bimaxillary advancements may cause major skeleton modifications by increasing both UA area and volume[4]. Major changes in the UA are usually reported in patients subjected to bimaxillary advancements equal to or greater than 10 mm[4,6,7,8]. However, mandibular movements seem to be more important than maxillary advancement[9]. Since mandibular advancement stretches the pharynx and the suprahyoid muscles, airway gain may be enhanced with a counterclockwise (CCW) rotation of the mandibular occlusal plane[10]. This happens because the pogonion and B point move forward farther than the teeth, thus maximizing the advancement of the hyoid bone, base of the tongue, genioglossus, and geniohyoid muscles[10].

Two-dimensional lateral cephalograms have traditionally been used to evaluate airway parameters[11]. However, these exams present limitations because they provide a two-dimensional change evaluation of a three-dimensional structure[12,13,14]. Three-dimensional exams, such as computed tomographic (CT), have been used to reconstruct and evaluate airway spaces after orthognathic surgery[2,4,6,7]. Even though CBCT presents some advantages over CT, such as lower

radiation dose and better cost-benefit[15], there are still few reports in the literature evaluating UA changes using CBCT[9,16].

The few studies that evaluated UA changes after CCW rotation, using CBCT, only showed a mean advancement of 10 mm or more[17,18,19]. Therefore, it would be interesting to investigate the effects of specific amount of mandibular advancements over the UA space, by performing a stratification of advancement magnitude. In this way, the necessary movement to correct the airways can be better correlated with the amount of movement necessary to correct the facial esthetics. The purpose of this study was to evaluate the immediate effect on the oropharynx of different mandibular advancements through CCW rotations in retrognathic patients.

MATERIALS AND METHODS

A retrospective analysis of the medical records and pre- and postoperative CBCT scans of patients subjected to orthognathic surgery at the University Hospital in Rio de Janeiro State (HUPE), Brazil, from January 2012 to January 2016 was performed. The inclusion criteria were: retrognathic patients (angle SNB < 78º) submitted to ortho-surgical treatment by bimaxillary CCW rotation, with available pre- and post-CBCT scans. The exclusion criteria were: history of adjuvant surgery in the soft tissues of the head and neck region, any trans-surgical or postoperative complications, and incomplete records[10,16]. According to the advancement of B point, patients were divided into three groups: G1 (advancement < 5 mm), G2 (advancement between 5 and 10 mm) and G3 (advancement > 10 mm).

A standardized CBCT protocol was used according to the protocol of HUPE's Maxillofacial Surgery Department[16] at two distinct time points: preoperative (T0) and immediately postoperative (T1) up to 15 days after surgery. All exams were conducted in the same tomograph i-CAT (Imaging Sciences International, Hatfield, Pennsylvania, USA), with a FOV 22 x 13 cm, a rotation of 360º to capture images with 1 mm thick sections in the axial, sagittal and coronal planes, a voxel of 0.3 mm, a 14-bit scale, 120 kV, 5 mA, and data recording using DICOM (Digital Imaging and Communication in Medicine). Patients were instructed to sit upright with a natural head position[20] and asked to breathe slowly and not to swallow. The mandible was positioned in a centric relation without the use of any device and only with manual manipulation[16].

All the images preoperative and postoperative were imported to Dolphin Imaging 11.7 (Dolphin Imaging and Management Solutions, Chatsworth, Calif., USA) and were overlapped automatically in the same software with the "Superimpose

Tool". References used to superimpose both volumes included the skull base, nasion and sella turcica since they do not suffer from any changes with surgery.

After the superimposition, the “Measure Tool” was used to determine the linear advancement obtained at B point for each group division (G1, G2 or G3). Using the same tool, the linear advancement of the anterior nasal spine (ANS), upper central incisor (UCI), and lower central incisor (LCI) were also measured. A CCW rotation was configured when B point advanced more than the LCI, as well as in cases where the UCI advanced more than the ANS (Figure 1).

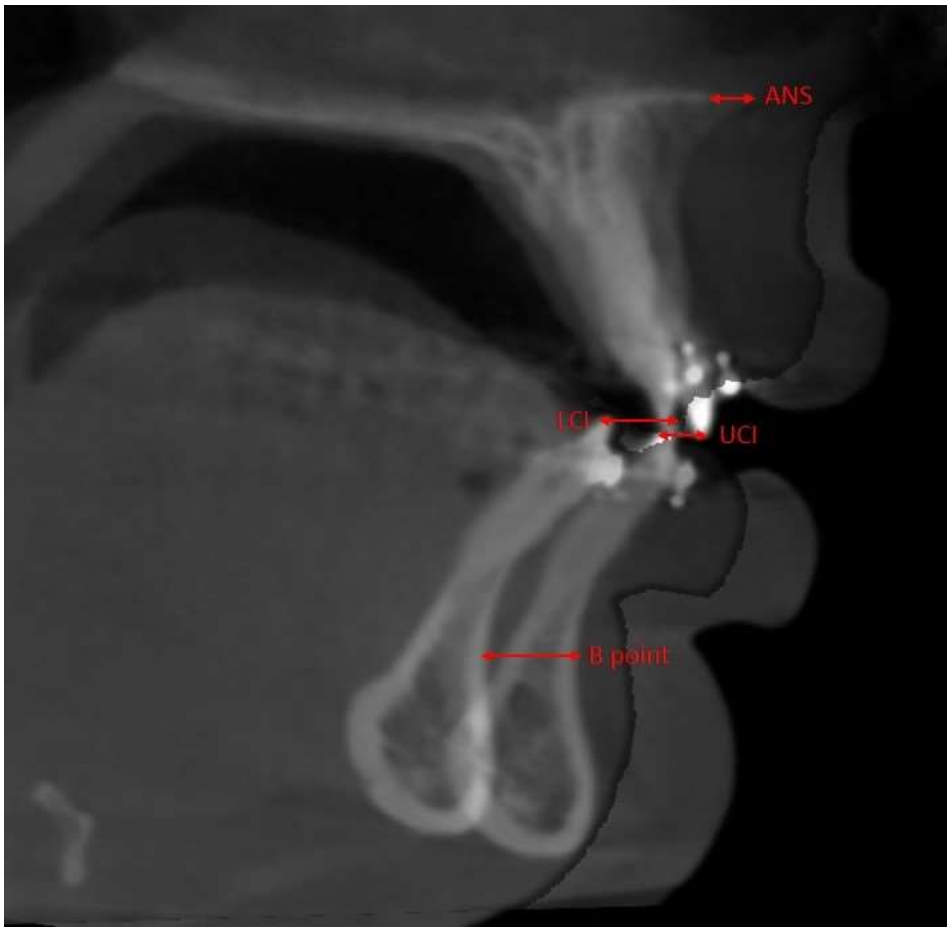

Figure 1. Superimposion of T0 and T1 and advancements at anterior nasal spine (ANS), upper central incisor (UCI), lower central incisor (LCI) and B point.

The "Sinus/Airway Evaluation Tool" in the Dolphin Imaging software was used for evaluation and reconstruction of the oropharynx[13,16,17,18,19,21]. The superior and inferior limits of the oropharynx were determined in the medial sagittal reconstruction[8] as a parallel line to the horizontal plane. The upper limit was defined at the level of the hard palate at the posterior nasal spine (PSA), and the inferior limit was set at the base of the epiglottis. Lateral and posterior limits were defined by the pharyngeal walls. Once these limits were defined, the "Add Seed Points Tool" was used to insert seed points inside this area. The detection sensitivity of the airway space was standardized at 25%, and the "Update Volume Tool" was used[13] to measure the volume and the MSA of the delimited airway space (Figure 2). The minimal CSA was determined using the option "Enable Minimum Axial Area" in the axial view (Figure 3). All analyses were performed under the same conditions by the same operator, limiting the number of images assessed per day in order to avoid fatigue (n = 5). The whole sample was measured again after 1 month, and the Pearson correlation coefficient was applied to assess reproducibility.

Figure 2. Oropharynx delimited in the CBCT: (A) Sagital reconstruction indicating the medial sagittal area (MSA); (B) Three-dimensional reconstruction indicating the volume of oropharynx.

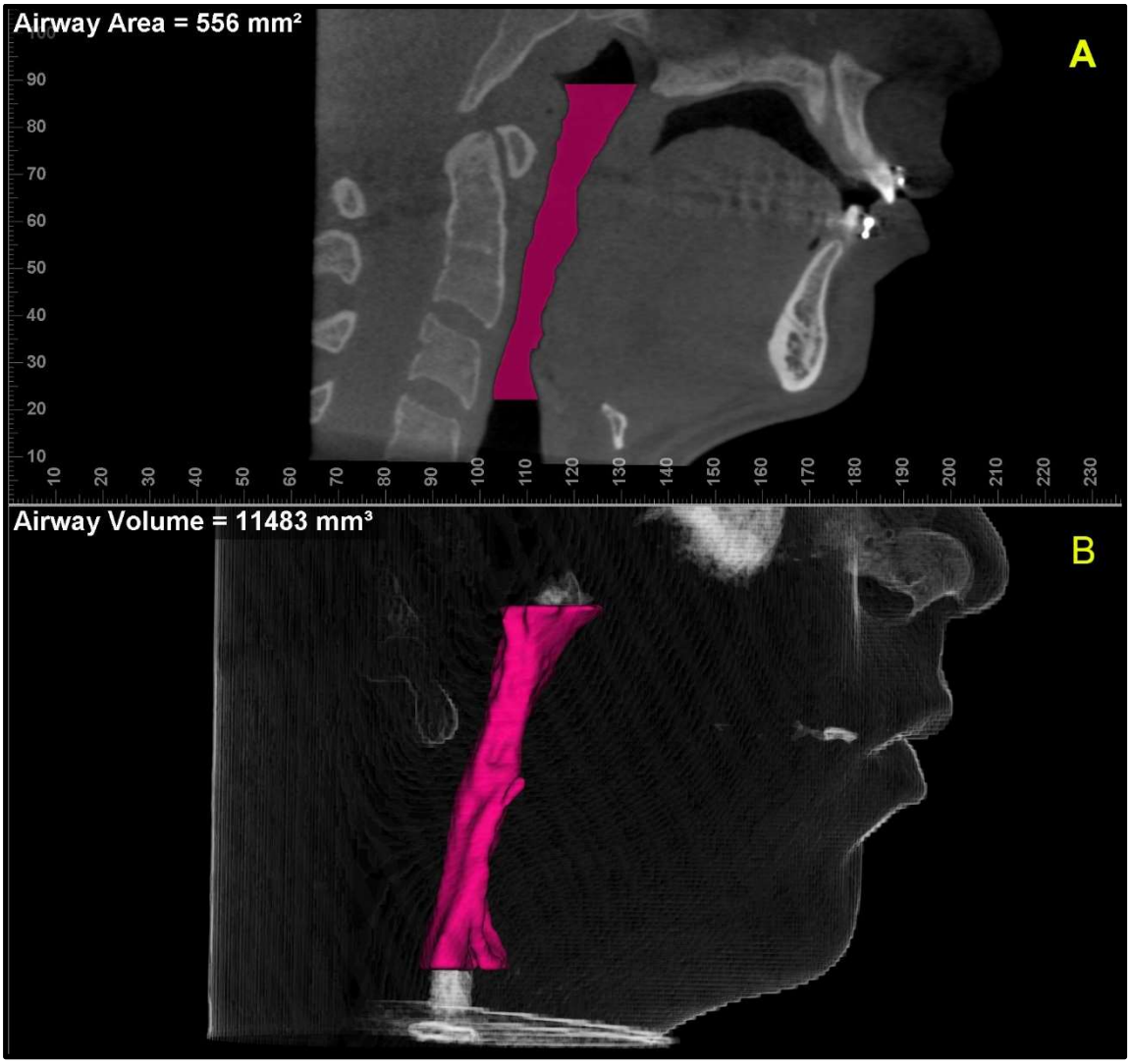

Figure 2. Oropharynx delimited in the CBCT: (A) Sagital reconstruction indicating the medial sagittal area (MSA); (B) Three-dimensional reconstruction indicating the volume of oropharynx.

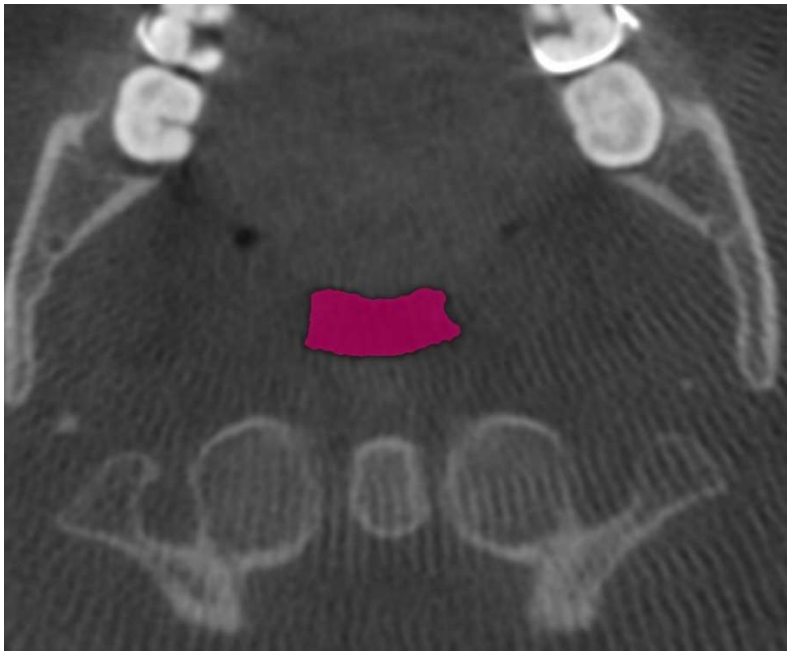

Figure 3. Axial reconstruction of CBCT indicating the minimum cross-sectional axial area (CSA)

Statistical analysis was performed using a paired Student's t-test to compare T0 and T1 MSA, volume and minimal CSA using SPSS (Statistics IBM software version 15.0; IBM Corp, Armonk, NY), with a significance level of 95%.

RESULTS

Of the total 138 pre- and postoperative images assessed, only 88 CBCT scans (44 patients) met the inclusion criteria for the study. In this sample, 33 patients were women and 11 were men, aged between 18 and 40 years. The Pearson correlation coefficient indicated an intra-examiner agreement of 0.93 in T0 and 0.96 in T1. Table 1 presents the mean, minimum and maximum values of the advances of the advancements at each point of the maxilla and mandible. Table 2 shows the comparison between T0 and T1 and the mean increase for the three variables studied (MSA, volume, and minimal CSA).

Table 1. Mean (mm), minimum (mm) and maximum (mm) values of the advances at different points

	G1 (n = 13)			G2 (n = 19)			G3 (n = 12)		
	Mean (SD)	Min	Max	Mean (SD)	Min	Max	Mean (SD)	Min	Max
UCI	1.85 (2.15)	0.0	5.4	3.10 (1.90)	0.0	6.8	4.00 (2.36)	2.5	7.9
ANS	0.08 (2.16)	- 3.5	3.2	1.46 (1.75)	-2.0	4.6	2.70 (2.11)	-1.6	5.1
LCI	2.11 (1.86)	0.0	4.3	5.41 (1.61)	2.8	8.5	7.67 (1.83)	5.1	10.3
Point B	3.34 (1.36)	1.5	4.8	8.05 (1.19)	6.2	9.9	12.55 (1.84)	10.4	16.5

UCI: upper central incisor; LCI: lower central incisor; ANS: anterior nasal spine

Table 2. Comparison of the means of T0 and T1 for the studied variables: MSA (mm^2), Volume (mm^3), and CSA (mm^2)

	G1				G2				G3			
	T0	T1			T0	T1			T0	T1		
	Mean (SD)	Mean (SD)	Mean increase	P	Mean (SD)	Mean (SD)	Mean increase	P	Mean (SD)	Mean (SD)	Mean increase	P
MAS	797.15 (239.77)	835.46 (195.28)	38.31 (4.80%)	0.174	715.31 (233.99)	783.57 (204.04)	68.26 (9.54%)	0.072	553.66 (151.92)	705.91 (227.43)	152.25 (24.5%)	0.007*
Volume	19117.61 (8213.01)	18337.84 (6719.45)	-779.77 (4.08%)	0.295	15684.89 (6791.12)	17944.42 (8152.94)	2259.53 (14.40%)	0.099	12124.91 (4126.74)	16029.25 (6662.44)	3904.34 (32.20%)	0.003*
CSA	164.23 (89.03)	147.23 (74.84)	-17.00 (10.35%)	0.238	119.10 (61.35)	141.63 (74.14)	22.53 (18.92%)	0.050*	91,58 (61.69)	139.16 (84.06)	47.58 (51.95%)	0.012*

MAS: medial sagital area; CSA: minimal cross-sectional area

*P≤0.05, statistically significant difference by paired T test.

DISCUSSION

Since mandibular movement seems to have a greater impact over the UA when compared to maxillary movements[9], the present study used B point as the discriminating factor for group division. The oropharynx area was selected for assessment[7] because it contains the greatest constriction region of the UA in retrognathic patients[22]. In addition, it is an area that seems to undergo major alterations due to mandibular movements following orthognathic surgery, particularly when compared to the nasopharynx and to the hypopharynx[2,6,14].

It is well established that CBCT is a simple and effective method to accurately analyze the airways[12], providing a more precise display of UA morphology and permitting measurements of MSA, minimal CSA, and volume[2]. The major effect of CCW rotation observed in the current study was the improvement both volume and minimal CSA. These are the most important clinical modifications, because volume shows the total gain capacity of the UA, whereas minimal CSA is the most physiologically relevant plane since it is perpendicular to the airflow[2,7,23].

Advancements inferior to 5 mm (G1) did not produce significant changes in the oropharynx in any of the assessed variables. The lack of change may be related to the small amount of advancement, which may have been insufficient to stretch the musculature[18,24]. Nevertheless, a significant increase in UA space with similar advancements has been reported. Ristow et al[25] found a significant difference in oropharynx volume and minimal CSA, with a mean value of mandibular advancement of 4.77 mm measured at three different points (left and right mental foramen and pogonion). The authors[25] used two different programs to evaluate mandibular advancement and the airways, instead of using Dolphin Imaging. According to El and

Palomo[26], the use of different software for assessing UA may generate differences among the results.

The literature presents significant improvements in minimal CSA and volume with mandibular advancements between 5 and 10 mm[14,18,21]. This is in partial accordance with the present study since G2 presented significant improvements in minimal CSA, but no significant difference was observed when the oropharynx volume was evaluated. This difference in volume can be explained by the different limits of the oropharynx, surgical advancements, and the time elapsed for evaluation. Brunetto et al[21] included part of the nasopharynx in the analysis and performed greater maxillary advancements (mean 4.71 mm). In the present study the mean maxillary advancement was 1.46 mm at ANS and 3.10 mm at UCI. Kochar et al[14], in addition to using different limits than the present study, evaluated the oropharynx in isolated mandibular surgeries through CT. The difference between patients sitting for CBCT and the supine position in CT may alter the UA due to the gravitational forces that displace the tongue and soft palate posteriorly[27,28]. Both studies[14,21] evaluated the UA at least 5 months of postoperatively, which may be different from an evaluation conducted during the immediate postoperative period[13,29]. Gonçalves et al[13] reported significantly increased absolute values similar to those of the present study in terms of both volume (1896 mm^3) and CSA (24 mm^2) after a mean CCW rotation mandibular advancement of 9.65 mm and using the same software to evaluate these modifications. One possible explanation is the individual differences in muscle tone around the pharyngeal airways[30].

Advancements greater than 10 mm are routinely related to an enlargement of the airways with linear bimaxillary advancement[4,6,7,8]. Nevertheless, these great maxillary advancements are not always possible from an esthetic point of view,

creating a biprotuse profile with a small naso-labial angle[2]. Thus, the CCW rotation, in addition to improving the airway[5], as shown in the present study (G3), enhances the esthetic profile of class II patients by optimizing the advancement of the pogonion[5] and avoiding the unpleasant protrusion of the maxilla in the patient.

CCW rotation with mandibular advancements superior to 10 mm has been related to significant increases in MSA, volume and minimal CSA in the oropharynx[2,13,17,19]. Raffaini and Pisani[17] showed gains in the oropharynx of 34% in MSA, 56% in volume, and 112% in minimal CSA. Additionally, Miranda et al[19] found gains of 178 mm^2 in surface area, 10.118 mm^3 in volume, and 76.67 mm^2 in CSA; these values are greater than those in the present study. However, Raffaini and Pisani[17] evaluated 10 patients with mandibular advancements ranging from 10 to 18 mm. Miranda et al[19] evaluated 23 patients with a mean advancement of 14 mm and did not report the sensitivity of the airway used in Dolphin. In agreement with the present study, the authors[2,17] found the minimal CSA to be most affected region in the oropharynx by CCW rotation.

Although the present study evaluated the immediate postoperative, the literature reports long-term stability of the skeletal movement after counterclockwise rotation with rigid fixation[31]. It has been reported that the surgical increased of the oropharyngeal airway space remained stable over the postsurgical follow-up of 34 months[32]. On the other hand, a long-term follow-up of the maintenance of the dimension of the UA after CCW rotation would require a strict control of all of the different variables that may predispose changes, such as an increase of the body mass index (BMI), muscle tone analysis, connective tissue flaccidity, and adipose tissue distribution[16].

As a limitation of the present retrospective study some important clinical evaluation could not be done and controlled, such as BMI, the Berlin questionnaire, the Epworth Sleepiness Scale and polysomnography. A prospective study including different CCW advancements and evaluating three-dimensional changes with a strict control of the external factors that influences the changes in the UA should be conducted

The literature presents studies with significant increases in the oropharynx[2,13,17,19], although they used a single group sample with mean advancements equal or greater than of 10 mm. Since the UA changes after orthognathic surgery depend on the magnitude and direction of the movement[7], the present study was able to demonstrate the effect that different ranges of advancement may have on the UA.

In conclusion, advancements of 5 – 10 mm at B point with a CCW rotation were able to increase MSA, volume, and minimal CSA; however, only the minimal CSA was significantly different. Mandibular advancements greater than 10 mm at B point were able to significantly improve the MSA, minimal CSA and the UA volume.

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Ethical approval:

This study was approved by the Juiz de Fora Federal University Committee (Number: 2.195.162)

This study was approved by the Pedro Ernesto University Hospital Committee (Number: 2.450.559)

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5 CONSIDERAÇÕES FINAIS

O presente estudo demonstrou a repercussão de diferentes grupos de avanços na orofaringe. Os avanços entre 5 – 10 mm no ponto B associado a rotação anti-horaria, foram capazes de aumentar ASM, volume e AAM, contudo, apenas a AAM foi estatisticamente significante. Os avanços mandibulares superiores a 10 mm no ponto B foram capazes de aumentar a orofaringe em ASM, volume e AAM.

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ANEXO A - REGRAS DA REVISTA DA SUBMISSÃO DO ARTIGO

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Would authors please note that the reference style for the journal has now changed. Please pay special attention to the guidelines under the heading "References" below

Authors wishing to submit their work to the journal are urged to read this detailed guide for authors and comply with all the requirements, particularly those relating to manuscript length and format. This will speed up the reviewing process and reduce the time taken to publish a paper following acceptance.

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PLEASE NOTE that all funding must be declared at first submission, as the addition of funding at acceptance stage may invalidate the acceptance of your manuscript.

Authorship
All authors should have made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data
(2) drafting the article or revising it critically for important intellectual content
(3) final approval of the version to be submitted.

Normally one or two, and no more than three, authors should appear on a short communication, technical note or interesting case/lesson learnt. Full length articles may contain as many authors as appropriate. Minor contributors and non-contributory clinicians who have allowed their patients to be used in the paper should be acknowledged at the end of the text and before the references.

The corresponding author is responsible for ensuring that all authors are aware of their obligations.

Before a paper is accepted all the authors of the paper must sign the Confirmation of Authorship form. This form confirms that all the named authors agree to publication if the paper is accepted and that each has had significant input into the paper. Please

download the form and send it to the Editorial Office. (pdf version or word version) It is advisable that to prevent delay this form is submitted early in the editorial process.

Acknowledgements

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Role of the funding source

All sources of funding should be declared as an acknowledgement at the end of the text. Authors should declare the role of study sponsors, if any, in the study design, in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. If the study sponsors had no such involvement, the authors should so state.

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Registration in a public trials registry is a condition for publication of clinical trials in this journal in accordance with International Committee of Medical Journal Editors recommendations. Trials must register at or before the onset of patient enrolment. The clinical trial registration number should be included at the end of the abstract of the article. A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.

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• technical notes (surgical techniques, new instruments, technical innovations) - no more than 1500 words, 10 references and 2 figures
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• book reviews
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• IAOMS announcements
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• Please include a paragraph in your cover letter where you explain what is new about your study and why it will have an impact on your field of research.

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• text
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• references
• tables
• captions to illustrations.
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• name and address of the department or institution to which the work should be attributed
• name, address, telephone and fax numbers, and e-mail address of the author responsible for correspondence and to whom requests for offprints should be sent
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If the title is longer than 40 characters (including spaces), a short title should be supplied for use in the running heads.

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Introduction

• Present first the nature and scope of the problem investigated
• Review briefly the pertinent literature
• State the rationale for the study
• Explain the purpose in writing the paper
• State the method of investigation and the reasons for the choice of a particular method
•; Should be written in the present tense

Materials and Methods

• Give the full details, limit references• Should be written in the past tense• Include exact technical specifications, quantities and generic names• Limit the number of subheadings, and use the same in the results section• Mention statistical method• Do not include results in this section

Results

• Do not describe methods
• Present results in the past tense
• Present representations rather than endlessly repetitive data
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• Discuss - do not recapitulate results
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All references cited in the text must be included in the list of references at the end of the paper. Each reference listed must include the names of all authors. Please see section "Article Types" for guidance on the maximum number of reference for each type of article.

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4. Please include any financial disclosures at the end of the letter. This would include the potential conflicts of interest not just related to the specific content of your letter but also the content of the IJOMS article and other related areas.
5. Please recognize that letters that are essentially in agreement with the author's findings and offer no additional insights provide little new information for publication. Likewise, letters that highlight the writer's own research or are otherwise self promotional will receive a low publication priority.
6. There may be a need for additional editing. Should editing be required the letter will be sent back to the author for final approval of the edited version.
7. It is important to use civil and professional discourse. It is not advisable that one adopt a tone that may be misconstrued to be in anyway insulting.
8. Finally, it is not advisable to provide a letter that is anecdotal. While personal experiences can have great value in patient care, it is generally not strong evidence to be placed in a letter to the editor.

ANEXO B - PARECER DO COMITÊ DE ÉTICA DA UFJF

UFJF - UNIVERSIDADE FEDERAL DE JUIZ DE FORA - MG

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação das mudanças morfológicas na via aérea superior de pacientes retrognatas submetidos à cirurgia ortognática com avanços maxilomandibulares

Pesquisador: Bruno Salles Sotto Maior
Área Temática:
Versão: 2
CAAE: 70597917.0.0000.5147
Instituição Proponente: FACULDADE DE ODONTOLOGIA
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.195.162

Apresentação do Projeto:
Trata-se de um estudo clínico retrospectivo, a ser composto por 40 pacientes provenientes do serviço de Cirurgia e Traumatologia Bucomaxilofacial de um Hospital Universitário Estadual do Rio de Janeiro.Serão avaliadas as mudanças da morfologia da via aérea destes pacientes no período pré-operatório (T0) e pós-operatório imediato de no máximo 10 dias (T1), através de exame de tomografia computadorizada de feixe cônico, que foram necessários para o correto planejamento e avaliação do tratamento cirúrgico executado. Os exames serão avaliados em uma Universidade Pública de Juiz de Fora, através do software de imagem Dolphin Imaging (Dolphin Imaging and Management Solutions, Chatsworth, Calif., EUA), sem a necessidade de qualquer identificação dos pacientes para a realização da pesquisa. Apresentação do projeto esta clara, detalhada de forma objetiva, descreve as bases científicas que justificam o estudo, de acordo com as atribuições definidas na Resolução CNS 466/12 de 2012, item III.

Objetivo da Pesquisa:
Objetivo Primário:
O objetivo deste estudo retrospectivo será avaliar a alteração da área em milímetros quadrados (mm²) vista no plano sagital, do volume em milímetros cúbicos (mm³) da via aérea como um todo, a área em milímetros² na vista axial no ponto de maior constrição ântero-posterior e a mudança

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ântero-posterior do osso hioide que está diretamente relacionado a via aérea superior.
Objetivo Secundário:
Avaliar se há diferença significativa entre os grupos G1 e G2 na alteração da área (milímetros ²), no volume (milímetros³) e na área da região de maior constrição na vista axial em milímetros².
O Objetivo da pesquisa está bem delineado, apresenta clareza e compatibilidade com a proposta, tendo adequação da metodologia aos objetivos pretendido, de acordo com as atribuições definidas na Norma Operacional CNS 001 de 2013, item 3.4.1 - 4.

Avaliação dos Riscos e Benefícios:

Os riscos envolvidos na pesquisa consistem em riscos mínimos e restringe-se ao sigilo a identificação e as informações referentes ao participante,no entanto, todos os cuidados serão tomados para preservar a sua identidade.A forte associação entre pacientes classe II esqueléticos com retrusão mandibular e a via aérea mais estreita, fazem da cirurgia ortognática um procedimento com potencial de mudança na morfologia desta área, através do avanço das estruturas para correção da harmonia facial e oclusal. O estreitamento da via aérea está relacionado a distúrbios sistêmicos e piora na qualidade de vida de determinado grupo de pessoas, podendo estar fortemente associado como um fator de risco para o desenvolvimento de doenças sistêmicas como a síndrome da apena obstrutiva do sono. Desta forma é importante avaliar, a alteração na via aérea após o avanço mandibular, e a magnitude do movimento necessário para que ocorram tais mudanças de forma significativas, auxiliando no planejamento dos cirurgiões para pacientes que apresentam características de via aérea estreita. Riscos e benefícios descritos em conformidade com a natureza e propósitos da pesquisa. O risco que o projeto apresenta é caracterizado como risco mínimo, considerando que os indivíduos não sofrerão qualquer dano ou sofrerão prejuízo pela participação ou pela negação de participação na pesquisa e benefícios esperados estão adequadamente descritos. A avaliação dos Riscos e Benefícios estão de acordo com as atribuições definidas na Resolução CNS 466/12 de 2012, itens III; III.2 e V.

Comentários e Considerações sobre a Pesquisa:

O projeto está bem estruturado, delineado e fundamentado, sustenta os objetivos do estudo em sua metodologia de forma clara e objetiva, e se apresenta em consonância com os princípios éticos norteadores da ética na pesquisa científica envolvendo seres humanos elencados na resolução 466/12 do CNS e com a Norma Operacional Nº 001/2013 CNS.

Considerações sobre os Termos de apresentação obrigatória:

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O protocolo de pesquisa está em configuração adequada, apresenta FOLHA DE ROSTO devidamente preenchida,com o título em português, identifica o patrocinador pela pesquisa, estando de acordo com as atribuições definidas na Norma Operacional CNS 001 de 2013 item 3.3 letra a; e 3.4.1 item 16. Apresenta o TERMO DE DISPENSA DO TCLE de acordo com a Resolução CNS 466 de 2012, item: IV.8. O Pesquisador apresenta titulação e experiência compatível com o projeto de pesquisa, estando de acordo com as atribuições definidas no Manual Operacional para CPEs. Apresenta DECLARAÇÃO de infraestrutura e de concordância com a realização da pesquisa de acordo com as atribuições definidas na Norma Operacional CNS 001 de 2013 item 3.3 letra h.

Conclusões ou Pendências e Lista de Inadequações:

Diante do exposto, o projeto está aprovado, pois está de acordo com os princípios éticos norteadores da ética em pesquisa estabelecido na Res. 466/12 CNS e com a Norma Operacional Nº 001/2013 CNS. Data prevista para o término da pesquisa:Junho de 2018.

Considerações Finais a critério do CEP:

Diante do exposto, o Comitê de Ética em Pesquisa CEP/UFJF, de acordo com as atribuições definidas na Res. CNS 466/12 e com a Norma Operacional Nº001/2013 CNS, manifesta-se pela APROVAÇÃO do protocolo de pesquisa proposto. Vale lembrar ao pesquisador responsável pelo projeto, o compromisso de envio ao CEP de relatórios parciais e/ou total de sua pesquisa informando o andamento da mesma, comunicando também eventos adversos e eventuais modificações no protocolo.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_843615.pdf	31/07/2017 15:17:55		Aceito
Projeto Detalhado / Brochura Investigador	ProjetoCaioCEP.docx	31/07/2017 15:17:36	Caio Bellini Lovisi	Aceito
Outros	CurriculoCaio.pdf	01/07/2017 17:23:02	Caio Bellini Lovisi	Aceito
Outros	Curriculo_Neuza.pdf	01/07/2017 17:22:48	Caio Bellini Lovisi	Aceito
Outros	Curriculo_BrunoSallesSottoMaior.pdf	01/07/2017 17:22:23	Caio Bellini Lovisi	Aceito

Endereço: JOSE LOURENCO KELMER S/N
Bairro: SAO PEDRO **CEP:** 36.036-900
UF: MG **Município:** JUIZ DE FORA
Telefone: (32)2102-3788 **Fax:** (32)1102-3788 **E-mail:** cep.propesq@ufjf.edu.br

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Continuação do Parecer: 2.195.162

Declaração de Instituição e Infraestrutura	Declaracao_Infraestrutura_UERJ.pdf	19/04/2017 22:53:17	Caio Bellini Lovisi	Aceito
Declaração de Instituição e Infraestrutura	Declaracao_Infraestrutura_UFJF.pdf	19/04/2017 22:53:04	Caio Bellini Lovisi	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Dispensa_do_TCLE.pdf	19/04/2017 22:51:44	Caio Bellini Lovisi	Aceito
Folha de Rosto	Folha_de_Rosto_CEP.pdf	19/04/2017 22:50:09	Caio Bellini Lovisi	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

JUIZ DE FORA, 01 de Agosto de 2017

Assinado por:
Patrícia Aparecida Fontes Vieira
(Coordenador)

Endereço: JOSE LOURENCO KELMER S/N
Bairro: SAO PEDRO **CEP:** 36.036-900
UF: MG **Município:** JUIZ DE FORA
Telefone: (32)2102-3788 **Fax:** (32)1102-3788 **E-mail:** cep.propesq@ufjf.edu.br

ANEXO C - PARECER DO COMITÊ DE ÉTICA DA UERJ / HUPE

UERJ - HOSPITAL UNIVERSITÁRIO PEDRO ERNESTO/ UNIVERSIDADE DO

PARECER CONSUBSTANCIADO DO CEP

Elaborado pela Instituição Coparticipante

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação das mudanças morfológicas na via aérea superior de pacientes retrognatas submetidos à cirurgia ortognática com avanços maxilomandibulares

Pesquisador: Bruno Salles Sotto Maior
Área Temática:
Versão: 1
CAAE: 70597917.0.3001.5259
Instituição Proponente: Hospital Universitário Pedro Ernesto/UERJ
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.450.559

Apresentação do Projeto:
Trata-se de um estudo clínico retrospectivo, a ser composto por 40 pacientes provenientes do serviço de Cirurgia e Traumatologia Bucomaxilofacial do Hospital Universitário Pedro Ernesto da Universidade Estadual do Rio de Janeiro (UERJ), que foram tratados cirurgicamente para correção de deformidade dentofacial do tipo classe II de Angle (retrognatas). Serão avaliadas as mudanças da morfologia da via aérea destes pacientes no
período pré-operatório (T0) e pós-operatório imediato de no máximo 10 dias (T1), através de exame de tomografia computadorizada de feixe cônico, que foram necessários para o correto planejamento e avaliação do tratamento cirúrgico executado. Os exames serão avaliados na Faculdade de Odontologia da Universidade Federal de Juiz de Fora, através do software de imagem Dolphin Imaging (Dolphin Imaging and Management Solutions, Chatsworth, Calif., EUA), sem a necessidade de qualquer identificação dos pacientes para a realização da pesquisa.

Objetivo da Pesquisa:
O objetivo deste estudo retrospectivo será avaliar a alteração da área em milímetros quadrados (mm²) vista no plano sagital, do volume em
milímetros cúbicos (mm³) da via aérea como um todo, a área em milímetros² na vista axial no ponto de maior constrição ântero-posterior e a
mudança ântero-posterior do osso hioide que está diretamente relacionado a via aérea superior.

Endereço: Avenida 28 de Setembro 77 - Térreo
Bairro: Vila Isabel **CEP:** 20.551-030
UF: RJ **Município:** RIO DE JANEIRO
Telefone: (21)2868-8253 **E-mail:** cep.hupe.interno@gmail.com

Avaliação dos Riscos e Benefícios:

Riscos:

Os riscos envolvidos na pesquisa consistem em riscos mínimos e restringe-se ao sigilo a identificação e as informações referentes ao participante,
no entanto, todos os cuidados serão tomados para preservar a sua identidade.

Benefícios:

A forte associação entre pacientes classe II esqueléticos com retrusão mandibular e a via aérea mais estreita, fazem da cirurgia ortognática um
procedimento com potencial de mudança na morfologia desta área, através do avanço das estruturas para correção da harmonia facial e oclusal.

O estreitamento da via aérea está relacionado a distúrbios sistêmicos e piora na qualidade de vida de determinado grupo de pessoas, podendo estar
fortemente associado como um fator de risco para o desenvolvimento de doenças sistêmicas como a síndrome da apena obstrutiva do sono.

Desta forma é importante avaliar, a alteração na via aérea após o avanço mandibular, e a magnitude do movimento necessário para que ocorram
tais mudanças de forma significativas, auxiliando no planejamento dos cirurgiões para pacientes que apresentam características de via aérea
estreita.

Comentários e Considerações sobre a Pesquisa:

O objetivo deste estudo retrospectivo, será a avaliação da mudança da morfologia da via aérea em pacientes que foram submetidos a avanço
mandibular para correção de deformidade dentofacial do tipo classe II de Angle. Serão selecionados pacientes aleatoriamente e de forma
randomizada que foram submetidos a cirurgia ortognática com avanço de mandíbula para correção estética e funcional (oclusão) entre o período de
janeiro de 2012 e janeiro de 2016 e divididos em 2 grupos G1 (avanços de mandíbula menores que 5 milímetros) e G2 (avanços de mandíbula
maiores que 5 milímetros). Previamente ao procedimento cirúrgico foi realizado exame tomográfico de feixe cônico em posição natural de cabeça
para o planejamento virtual dos movimentos cirúrgicos necessários. O exame foi repetido com os mesmos equipamentos no pós-operatório imediato
entre 7 e 10 dias de pós-operatório, com intuito de avaliar os cortes cirúrgicos e a fixação

realizada. Para a avaliação da mudança na morfologia da
via aérea, será realizada a sobreposição dos exames tomográficos pré e pós-operatórios utilizando a ferramenta “Superimpose Tool” do software de
manipulação de imagem Dolphin Imaging (Dolphin Imaging and Management Solutions, Chatsworth, Calif., EUA). Após a sobreposição das
tomografias será avaliada o avanço mandibular obtido durante a cirurgia para correta divisão dos grupos, e através da ferramenta “Airway/Sinus
Avaliation Tool” verificar a mudança da área em milímetros quadrados (mm ²) e o volume em milímetros cubico (mm³) no período T0 e T1. Todos os
dados coletados serão analisados estatisticamente com significância de 5% utilizando teste t de Student para amostras pareadas.

Considerações sobre os Termos de apresentação obrigatória:

Todos os documentos de apresentação obrigatória foram enviados a este Comitê, estando dentro das boas práticas e apresentando todas dados necessários para apreciação ética. A pesquisa está bem estruturada e o referencial teórico e metodológico estão explicitados, demonstrando aprofundamento e conhecimento necessários para sua realização. As referências estão adequadas e a pesquisa é exequível.

Recomendações:

Não há

Conclusões ou Pendências e Lista de Inadequações:

O projeto pode ser realizado da forma como está apresentado. Diante do exposto e à luz da Resolução CNS nº466/2012, o projeto pode ser enquadrado na categoria – APROVADO.

Considerações Finais a critério do CEP:

Tendo em vista a legislação vigente, o CEP recomenda ao Pesquisador: Comunicar toda e qualquer alteração do projeto e no termo de consentimento livre e esclarecido, para análise das mudanças; Informar imediatamente qualquer evento adverso ocorrido durante o desenvolvimento da pesquisa; O Comitê de Ética solicita a V. Sª., que encaminhe relatórios parciais de andamento a cada 06 (seis) Meses da pesquisa e ao término, encaminhe a esta comissão um sumário dos resultados do projeto; Os dados individuais de

todas as etapas da pesquisa devem ser mantidos em local seguro por 5 anos para possível auditoria dos órgãos competentes.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_843615.pdf	31/07/2017 15:17:55		Aceito
Projeto Detalhado / Brochura Investigador	ProjetoCaioCEP.docx	31/07/2017 15:17:36	Caio Bellini Lovisi	Aceito
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_843615.pdf	01/07/2017 17:27:32		Aceito
Projeto Detalhado / Brochura Investigador	ProjetoCaioCEP.docx	01/07/2017 17:27:11	Caio Bellini Lovisi	Aceito
Outros	CurriculoCaio.pdf	01/07/2017 17:23:02	Caio Bellini Lovisi	Aceito
Outros	Curriculo_Neuza.pdf	01/07/2017 17:22:48	Caio Bellini Lovisi	Aceito
Outros	Curriculo_BrunoSallesSottoMaior.pdf	01/07/2017 17:22:23	Caio Bellini Lovisi	Aceito
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_843615.pdf	20/04/2017 17:03:36		Aceito
Declaração de Instituição e Infraestrutura	Declaracao_Infraestrutura_UERJ.pdf	19/04/2017 22:53:17	Caio Bellini Lovisi	Aceito
Declaração de Instituição e Infraestrutura	Declaracao_Infraestrutura_UFJF.pdf	19/04/2017 22:53:04	Caio Bellini Lovisi	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Dispensa_do_TCLE.pdf	19/04/2017 22:51:44	Caio Bellini Lovisi	Aceito
Folha de Rosto	Folha_de_Rosto_CEP.pdf	19/04/2017 22:50:09	Caio Bellini Lovisi	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

RIO DE JANEIRO, 20 de Dezembro de 2017

Assinado por:
DENIZAR VIANNA ARAÚJO
(Coordenador)