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FERNANDO ANTONINI

ANÁLISE RETROSPECTIVA DO PLANEJAMENTO VIRTUAL TRIDIMENSIONAL SOBRE A ACURÁCIA NO MOVIMENTO MAXILAR NAS CIRURGIAS ORTOGNÁTICAS

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Tese apresentada como parte dos requisitos obrigatórios para a obtenção do título de Doutor em Odontologia, área de concentração em Cirurgia e Traumatologia Bucomaxilofacial, pela Pontifícia Universidade Católica do Rio Grande do Sul

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Orientador: Prof. Dr. Rogério Pagnoncelli

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LISTA DE ILUSTRAÇÕES E TABELAS

LISTA DE ABREVIATURAS E SIGLAS

CAD/CAM	Design Assistido por Computador/Fabricação Assistida por Computador
VSP	Planejamento Cirúrgico Virtual
CASS	Simulação Cirúrgica Assistida por Computador
Mandible first	Mandíbula primeiro
CBCT	Tomografia Computadorizada do Feixe Cônico
TMJ	Articulação Têmporo-Mandibular
BSSO	Osteotomia Sagital dos Ramos Mandibulares
U1 MIDLINE	Linha média entre os incisivos centrais superiores
RU6	Primeiro molar superior direito
LU6	Primeiro molar superior esquerdo
SPSS	Pacote Estatístico para Ciências Sociais

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SUMÁRIO

O objetivo deste trabalho foi investigar a acurácia do planejamento virtual tridimensional sobre o reposicionamento maxilar em cirurgias ortognáticas bimaxilares. Imagens de Tomografia Computadorizada Cone-Bean pré e pós-operatórias de cem pacientes submetidos a cirurgia ortognática bimaxilar foram sobrepostas e as distâncias lineares entre pontos de referência maxilares foram medidas em todos os três planos do espaço (eixos x, y e z). As mensurações de planejamento cirúrgico virtual e valores obtidos após a cirurgia foram então comparadas. Os pacientes foram divididos em cinco grupos, de acordo com o ano em que os procedimentos de planejamento e cirúrgicos foram realizados. Os resultados demonstram melhora da precisão na posição maxilar ao longo dos anos, com resultados mais precisos em pacientes submetidos à cirurgia ortognática bimaxilar nos anos de 2015, 2016 e 2017. A diferença linear média entre os resultados planejados e obtidos demonstra resultados mais precisos na direção horizontal, seguidos dos movimentos transversais e verticais, com uma discrepância média geral menor que 1 mm observada em 51,3% dos indivíduos. O tempo e a experiência do usuário desempenham um papel importante na precisão da maxila na cirurgia ortognática bimaxilar.

Palavras-chave: deformidade dento-facial; cirurgia ortognática; planejamento

The purpose of this study was to investigate accuracy of tridimensional virtual surgical planning over maxillary repositioning in bimaxillary orthognathic surgeries. Pre and postoperative CBCT images of one hundred patients were superimposed and linear distances between maxillary landmarks were measured in all 3 planes of space (*x, y,* and *z* axis). Virtual surgical planning and postoperative measurements were then compared. The patients were divided into five groups, according to the year in which virtual surgical planning (VSP) and surgical procedure was executed. Results show improved accuracy in maxillary position throughout the years, with more accurate results in patients that underwent bimaxillary orthognathic surgery in 2015, 2016 and 2017. Mean linear difference between planned and obtained results demonstrated more accurate results in horizontal direction, followed by transversal and vertical movements, with an overall average difference within 1mm observed in 51,3% of the subjects. Time seemed to play an important role in the accuracy of the maxilla in bimaxillary orthognathic surgery.

Key words: dentofacial deformity; orthognathic surgery, planning

3. INTRODUÇÃO

Pacientes com deformidades dentofaciais freqüentemente necessitam de correção cirúrgica de suas anormalidades esqueléticas para melhorar as limitações funcionais, principalmente a mastigação e a fala, e obter harmonia facial. A cirurgia ortognática é a intervenção cirúrgica mais comum nesses casos e o posicionamento correto da maxila é a base dos resultados bem-sucedidos[1,2]. Qualquer falha neste quesito pode levar a resultados estéticos insatisfatórios, assimetria facial e/ou má oclusão. Com o desenvolvimento da tecnologia e da odontologia virtual, o planejamento cirúrgico passou da cirurgia manual convencional dos modelos de gesso para o uso de princípios CAD/CAM (*Computer-aided design/Computer-aided manufacturing*) e o planejamento cirúrgico virtual (*Virtual Surgical Planning - VSP*) está sendo implementado cada vez mais no campo da cirurgia ortognática para auxiliar na criação de planejamentos cirúrgicos mais precisos, economizar tempo de planejamento pré-operatório e, no final, alcançar melhores e mais acurados resultados cirúrgicos. Pesquisadores anteriores demonstraram resultados precisos ao usar o VSP em cirurgias ortognáticas[3-4], embora a maior parte dos estudos apresenta pequena amostra e ainda focam na comparação entre o planejamento cirúrgico tradicional e o planejamento cirúrgico virtual. Ademais, nenhum estudo avaliou a precisão, ou a diferença na precisão, entre os diferentes eixos de movimentação do osso maxilar (horizontal, transversal e vertical). A realização de estudos que buscam avaliar a acurácia do planejamento cirúrgico virtual nas movimentações tridimensionais dos ossos maxilares em uma amostra de tamanho considerável e suprir as carências supracitadas é relevante. Soma-se a isto o fato de a literatura científica ainda ser escassa de informações sobre a obtenção de resultados mais precisos com base na atualização constante do software, bem como experiência de aprendizado e treinamento abrangente por mais de uma década por parte dos usuários (cirurgiões e engenheiros de empresas especializadas em planejamentos virtuais); e qualquer melhoria possível não foi ainda quantitativa ou qualitativamente documentada. Portanto, para superar deficiências passadas ou mesmo presentes, é imperativo confirmar como esse desenvolvimento tecnológico e humano determinou a precisão cirúrgica e o melhor resultado cirúrgico.

Em 2007, Xia et al. publicaram um estudo piloto avaliando a precisão de um protocolo de simulação cirúrgica auxiliado por computador (CASS - *Computer-aided surgical simulation*) no tratamento de pacientes com deformidade craniomaxilofacial complexa. Ao sobrepor tomografias computadorizadas pré e pós-operatória para avaliar a acurácia dos resultados, os autores encontraram resultados promissores[3]. Um estudo multicêntrico prospectivo realizado anos depois também confirmou resultados precisos. Hsu et al. avaliaram a precisão do protocolo CASS para cirurgia ortognática e relataram excelente acurácia para a posição da linha média dental maxilar. A diferença entre os resultados planejados e pós-operatórios na maxila foi de 0,8 mm para movimentos transversais (medio-laterais), 1,00 mm para movimentos horizontais (anteroposteriores) e 0,6 mm para medidas verticais (supero-inferiores)[4]. Zhang et al. também avaliaram a precisão do planejamento cirúrgico virtual em 30 pacientes consecutivos que foram submetidos à cirurgia ortognática de bimaxilar, medindo as diferenças médias nos pontos de referência maxilares entre tomografias computadorizadas com movimentos cirúrgicos virtualmente simuladas e pós-operatórias. Os resultados mostram que o *VSP* foi transferido com sucesso para a sala de cirurgia, levando a uma diferença média entre as medidas planejadas e pós-operatórias de 0,81 mm (0,79 mm para a maxila e 0,91 mm para a mandíbula)[5]. Resultados semelhantes também foram obtidos por Kwon et al, relatando discrepância média entre os resultados planejados e obtidos de 0,95mm para movimentos maxilares virtualmente planejados, demonstrando também acurácia satisfatória no reposicionamento maxilar ao usar o *VSP*[6]. Um artigo recente publicado em 2018 também comprova a precisão maxilar quando a cirurgia ortognática é virtualmente planejada. Os autores demonstraram uma diferença média entre o planejamento virtual e os resultados pós-operatórios de 0,79mm para a reposição maxilar[7]. Após 7 anos de experiência no uso de planejamento cirúrgico virtual (*VSP*) para cirurgia craniomaxilofacial, Adolphs et al. reportam diversas vantagens de tal tecnologia e enfatiza que uma melhoria adicional do fluxo de trabalho pré-operatório pode ser esperada ao longo dos anos[8].

O artigo 1, desenvolvido a partir de uma pesquisa voltada a avaliar a acurada do planejamento virtual 3D nos movimentos maxilares em cirurgias ortognáticas bimaxilares, tem como objetivo avaliar a atuação do planejamento cirúrgico virtual tridimensional, bem como a influência do tempo de uso desta tecnologia na acurácia da movimentação maxilar em cem pacientes submetidos à cirurgia ortognática bimaxilar ao longo de 5 anos de pesquisa. As hipóteses do estudo são: 1) apesar de excelentes resultados funcionais e estéticos geralmente serem obtidos com cirurgias ortognáticas, o movimento dos maxilares obtidos durante a cirurgia nem sempre se dá exatamente como planejado no período pré-operatório; 2) a acurácia dos movimentos pode ter sido influenciada pelo desenvolvimento do planejamento cirúrgico virtual, possivelmente por uma curva de aprendizado e/ou seu refinamento tecnológico.

Uma alternativa que vem sendo muito discutida na literatura para minimizar o erro de posicionamento maxilar em cirurgias ortognáticas bimaxilares é a alteração da técnica cirurgia tradicional para a técnica de sequencia invertida, popularizada com *mandible first*, na qual a mandíbula é o primeiro osso a ser reposicionado na cirurgia ortognática bimaxilar e, em seguida, a reposição maxilar. Tal sequência cirúrgica vem sendo incorporada cada vez mais na prática de muitos cirurgiões, uma vez que minimiza equívocos que podem levar a imprecisão no reposicionamento do osso maxilar, como casos de difícil reprodução de relação cêntrica pré-operatória ou dificuldade de reprodução da posição condilar pré-operatória durante a cirurgia propriamente dita, casos de cirurgia da articulação têmporo-mandibular concomitante e casos de difícil bloqueio maxilo-mandibular durante a fixação óssea maxilar (exemplo: avanços bimaxilares de ampla magnitude, especialmente em pacientes que já apresentam relação oclusal de classe II e grandes rotações anti-horárias do plano olcusal, nas quais o guia intermediário fica muito espesso na região anterior e dificulta o bloqueio maxilo-mandibular quando a cirurgia é iniciada pelo osso maxilar)[9]. Ainda, mesmo em casos de planejamento virtual tridimensional, há uma significativa imprecisão na eleição do correto eixo de rotação condilar durante o planejamento cirúrgico, e a não reprodução exata deste eixo de rotação condilar no paciente a ser operado pode levar a expressivos erros de posicionamento do osso maxilar, especialmente quando movimentos verticais são realizados. O artigo 1 explana de forma minuciosa esta relação do eixo de rotação condilar com a inacurácia do posicionamento maxilar.

Apesar de muito cirurgiões bucomaxilofaciais terem incorporado a técnica de operar inicialmente a mandíbula em sua prática, o planejamento cirúrgico ainda continua sendo realizado da maneira e em uma sequência tradicional, com a maxila sendo o primeiro maxilar a ter sua posição planejada. No entanto, a reposição do osso mandibular primeiramente durante o planejamento cirúrgico virtual tridimensional também apresenta vantagens, e pode ser considerada no casos em que o cirurgião elege iniciar a cirurgia ortognática bimaxilar pelo osso mandibular. O artigo 2 deste trabalho visa sugerir um protocolo de planejamento cirúrgico virtual no qual a mandíbula é o primeiro osso a ter sua posição planejada, discutindo possíveis vantagens do protocolo citado.

4. ARTIGO 1

Título: Acurácia do Planejamento Cirúrgico Virtual Tridimensional na Reposição Maxilar em Cirurgias Ortognáticas Bimaxilares: Existe uma Curva de Aprendizado?

Status: Em análise dos autores para submissão
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Resumo:
O objetivo deste estudo foi investigar a influência do tempo de uso sobre a precisão do reposicionamento maxilar em cirurgia ortognática bimaxilar. Cem pacientes submetidos à cirurgia ortognática bimaxilar preencheram os critérios de inclusão e foram investigados retrospectivamente. Os pacientes foram divididos em cinco grupos, de acordo com o ano em que o planejamento cirúrgico virtual e a cirurgia ocorreram: 2013 (n = 10); 2014 (n = 17); 2015 (n = 39); 2016 (n = 20) e 2017 (n = 14). O protocolo de planejamento cirúrgico virtual foi o mesmo para todos os indivíduos. Imagens de Tomografia Computadorizada Cone-Bean pré e pós-operatórias foram sobrepostas e as distâncias lineares entre os pontos de referência maxilares foram medidas em todos os três planos do espaço (eixos x, y e z). As medidas foram então comparadas aos registros do planejamento cirúrgico virtual e a diferença na acurácia entre todos os grupos foi analisada estatisticamente. Os resultados gerais mostram melhora da precisão na posição maxilar ao longo dos anos, com resultados mais precisos em pacientes submetidos à cirurgia ortognática bimaxilar em 2015, 2016 e 2017. A diferença linear média entre os resultados planejados e obtidos demonstra resultados mais precisos na direção horizontal (0,97 ± 0,04mm), seguidos dos movimentos transversais (1,09 ± 0,04mm) e verticais (1,52 ± 0,06mm). Uma discrepância média geral dentro de 1 mm foi observada em 51,3% dos indivíduos incluídos na amostra. O tempo e a experiência do usuário desempenham um papel importante na precisão da maxila na cirurgia ortognática bimaxilar.

Abstract:
The purpose of this study was to investigate the influence of time over the accuracy of maxillary repositioning in bimaxillary orthognathic surgery. One hundred patients who had undergone bimaxillary orthognathic surgery fulfilled the inclusion criteria and were retrospectively investigated. The patients were divided into five groups, according to the year in which virtual surgical plan and

the surgery itself occurred: 2013 (*n= 10*); 2014 (*n=17*); 2015 (*n=39*); 2016 (*n=2*) and 2017 (*n=14*). Virtual treatment planning protocol was the same for all subjects. Pre- and postoperative CBCT images were superimposed and linear distances between upper jaw reference landmarks were measured in all 3 planes of space (*x, y* and *z* axis). Measurements were then compared to virtual surgical plan records and the difference in accuracy among all groups was statistically analyzed. Overall results show improved precision in maxillary position throughout the years, with more accurate results in patients that underwent bimaxillary orthognathic surgery in 2015, 2016 and 2017. Mean linear difference between planned and obtained results demonstrates more accurate results in horizontal direction (0,97 ± 0,04mm), followed by transversal (1,09 ± 0,04mm) and vertical movements (1,52 ± 0,06mm). An overall average discrepancy within 1mm was observed in 51,3% of the subjects included in the sample. Time and users experience play an important role in the accuracy of the maxilla in bimaxillary orthognathic surgery.

Accuracy of Three-Dimensional Planning in Maxillary Repositioning in Double-Jaw Orthognathic Surgery: is there a learning curve?

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Keyword: Orthognathic surgery, virtual surgical planning, VSP, osteotomy

ABSTRACT

PURPOSE: The purpose of this study was to investigate the influence of time over the accuracy of maxillary repositioning in bimaxillary orthognathic surgery planned using virtual surgical planning (VSP).

MATERIALS AND METHODS: Patients who had undergone bimaxillary orthognathic surgery were retrospectively investigated, by comparison of maxillary position between pre-operative and post-operative CT scan, and divided into groups, according to the year in which VSP was executed. Linear distances between upper jaw reference landmarks were measured in all 3 planes of space (*x, y* and *z* axis).

RESULTS: One hundred patients met eligibility for assessment and were allocated in groups according to the year of VSP: 2013 (*n= 10*); 2014 (*n=17*); 2015 (*n=39*); 2016 (*n=20*) and 2017 (*n=14*). Overall results demonstrated improved precision in maxillary position throughout the years, with more accurate results in patients that underwent bimaxillary orthognathic surgery in 2015, 2016 and 2017. Mean linear difference between planned and obtained results demonstrated more accurate results in horizontal direction, followed by transversal and vertical movements. An overall average difference within 1mm was observed in 51,3% of the subjects included in the sample.

CONCLUSIONS: Time seemed to play an important role in the accuracy of the maxilla in bimaxillary orthognathic surgery.

INTRODUCTION

Patients with dentofacial deformities often require surgical correction of their skeletal abnormalities to improve functional limitations, mainly chewing and speech, as well as to achieve facial harmony. Orthognathic surgery is the most common surgical intervention for such cases and correct positioning of the maxilla is important in acheiving successful results[1-2]. Failure to do so can lead to poor aesthetic results, facial asymmetry or malocclusion.

With the development of computer technology, in many centers, orthognathic surgical planning has shifted from conventional clinical and cephalometric planning with manual surgery of mounted casts to the use of computer aided design/computer aided manufacturing (CAD/CAM) principles and virtual surgical planning (VSP). The advantages include the creation of more precise surgical treatment plans, diminished surgical planning time, and better surgical outcomes. In 2007, Xia et al. published a pilot study assessing accuracy of computer-aided surgical simulation system in the treatment of patients with complex craniomaxillofacial deformity. By superimposing initial and postoperative CT scans to evaluate outcome accuracy, the authors found promising results[3]. A prospective multi-center study performed years later confirmed accurate results as well[4]. Hsu et al. assessed the accuracy of a computer-aided surgical simulation (CASS) protocol for orthognatic surgery and reported excellent accuracy for the maxillary dental-midline position. The difference between planned and postoperative outcomes in the maxilla were 0.8mm for mediolateral, 1.00mm for anteroposterior and 0.6mm for supero-inferior measurements[4]. Zhang et al. also evaluated the accuracy of virtual surgical planning in 30 consecutive patients that underwent two-jaw orthognathic surgery by measuring mean differences in maxillary landmarks between virtually simulated and post-operative CT scans. The results show that VSP was successfully transferred to the operating room leading to a mean difference between planned and post-op measurements of 0.81mm (0.79mm for maxilla and 0.91mm for mandible)[5]. Similar results were also obtained by Kwon et al, reporting mean discrepancy between planned and obtained results of 0.95mm for VSP, also showing satisfactory accuracy in maxillary repositioning when using VSP[6]. A recent study also proves maxillary accuracy when orthognathic surgery is virtually planned. Authors showed a mean difference between virtual plan and postoperative results 0.79mm for maxillary reposition[7]. After a 7 years experience in using virtual surgical planning (VSP) for craniomaxillofacial surgery, Adolphs et al. reported many advantages of such technology and emphasized that further improvement of the preoperative workflow can be expect throughout the years[8].

Previous investigators have demonstrated accurate results when using VSP in orthognathic surgery[3,9], although there is a lack of information regarding whether outcomes differed based on software updates as well as VSP learning experience and comprehensive training. To overcome past or even present deficiencies, we will assess how such technological and human expertise development has determined surgical accuracy and better surgical outcome. The hypothesis of the study are: 1) there are insignificant differences between planned and actual positioning of the maxilla, and 2) there has been no difference in the accuracy of virtual Orthognathic surgical planning over time.

MATERIALS AND METHODS

STUDY DESIGN AND SAMPLE

This retrospective study investigated consecutive 103 adult patients who received two-jaw maxilla first orthognathic surgery between March 2013 and September 2017. All cases were planned and performed by a single surgeon (MM) using VSP with a single third party biomedical engineering group (3D Systems, Rock Hill, SC, USA).

INLCUSION CRITERIA

Inclusion criteria for the study were as follows: (1) bimaxillary orthognathic surgery; and (2) availability of surgical planning records.

EXCLUSION CRITERIA

Subjects with missing or deficient immediate postoperative Cone-Bean Computed Tomography (CBCT) scans, concomitant TMJ surgery, and patients who underwent mandible-first sequence were excluded from the present study. The study was previously approved by UIC Institutional Review Board under protocol number 2108-0276 and was performed following the Declaration of Helsinki protocol.

SURGICAL TECHNIQUE

Surgical procedures involved a Le Fort I osteotomy according to the conventional method described by Bell et al.[10] A Kirschner wire inserted at nasion (without an incision) and a surgical splint were used to determine the vertical, anteroposterior, and transversal maxillary position. After the elimination of bony interferences, the maxilla was fixated with four L-shaped titanium miniplates (KLS Martin, Jacksonville, FL, USA). The mandible was then osteotomized, using a bilateral sagittal split osteotomy (BSSO) as proposed by Hunsuck[11]. The distal segment was positioned in final occlusion and fixated with one miniplate and 4 monocortical screws. Genioplasty was performed via inferior border osteotomy with chin advancement or setback when necessary. A preformed chin plate and monocortical screws were also used for chin fixation.

HEAD ORIENTATION AND CBCT SUPERIMPOSITON

Pre and postoperative CBCT scans of all selected cases were imported to Dolphin Imaging Software, version 11.9 (Dolphin Imaging and Management, Chatsworth, CA, USA). Preoperative CBCT scans had yaw orientation with nasion and basion aligned as the sagittal midline, roll orientation with orbital floors at the level of infraorbital canals aligned, and pitch adjusted with right porion and right orbitale at the same level forming the Frankfurt horizontal plane. Then, postoperative CT scans were registered onto previously aligned preoperative anterior cranial base by voxel-based matching methods present on Dolphin software[9].

ANALYSIS OF MAXILLARY POSITION ACCURACY

To evaluate the accuracy of maxillary repositioning, three landmarks were used as reference and marked on both pre and postoperative CBCT scans using sagital, axial and coronal images: 1) midline between upper central incisors (U1 midline); 2) upper right first molar mesiobuccal cusp (RU6) and 3) upper left first molar mesiobuccal cusp (LU6). Two cranial base landmarks were positioned as well and used only for operator calibration. The spatial position in all 3 axes (x, y and z) of all landmarks were then transferred to a Microsoft Excel (Microsoft, Redmond, WA, USA) spreadsheet by a software toll "copy landmarks coordinates". The numerical values for the preoperative coordinates were added/subtracted to/from VSP report transversal, vertical and horizontal measurements for maxilla repositioning, according to the planned movement for each case. A new value (pre-operative coordinates + VSP measurements) was obtained and composed the planned coordinate for each landmark. The numerical difference between postoperative coordinates and the planned coordinate of all 3 maxillary landmarks were used to define the accuracy of maxillary position. One single operator identified all landmarks and coordinates 2 different times, and the mean between the two values was used as final measurements for pre and postoperative coordinates.

OUTCOME ASSESSMENT

Primary outcome variable was defined by accuracy for orthognathic surgery for each year in all 3 axes (x,y and z). Time over accuracy assessment was determined after subjects included in the study were divided into groups, according to the year in which virtual surgical planning (VSP) was executed. Secondary outcome was determined by overall accuracy, including all landmarks in all axes, for each year of the study. Mean differences between planned and postoperative results were subdivided in below 1mm, between 1 and 2mm and above 2mm.

STATISTICAL ANALYSIS

Sample sized aimed a confidence level of 95% and a confidence interval of 0.05. All collected data were analyzed using IBM Statistical Package for the Social Sciences - SPSS (Armonk, NY, USA), version 22.0. Intra-oberver consistency was also evaluated and analyzed by a paired T-test. Quantitative variables are expressed by mean values and standard deviation. Qualitative variables are expressed by percentage and frequency. All statistical tests were performed considering a significance level at $p<0,05$. Mean measurements for quantitative variables between qualitative variables were compared by applying one-way variance analysis - ANOVA, followed by *post hoc* Games-Howell test when statistical significance were found.

RESULTS

Out of 103 eligible cases, 2 patients were excluded due to lack of immediate post-operative CBCT scan and 1 patient was excluded due to having mandible-first surgery. Of the 100 cases, there were 35 males and 65 females, with mean age of 22.1 years (range from 14 to 46 years). The sample size for a population of 103 subjects would require a minimum of 81 cases to meet a confidence level of 95% and a confidence interval of 0.05; therefore, final sample met sample size calculation criteria. Sample distribution into groups, according to the year in which VSP was performed composed 5 groups: year 2013 (n=10); year 2014 (n= 20); year 2015 (n= 39); year 2016 (n=20) and year 2017 (n=14).

Intra-observer accuracy, as determined by the consistency of the two distinct landmarks (basium and nasium) identification moments, displayed no statistical significant differences for all groups, except between years 2014 and 2015 in one reference landmark in a single direction (Basion in z axis) (Table 1).

Table 1 - Mean differences and standard deviation between pre- and postoperative measurements for Nasium and Basium landmarks (in millimeters).

	Mean ± Standard Deviation (mm)					
	Year					
Landmark - axis	2013	2014	2015	2016	2017	p-value†
	n=10	n=17	n=39	n=20	n=13	
Basion - X axis	0,41 ± 0,27	0,58 ± 0,28	0,52 ± 0,34	0,44 ± 0,20	0,49 ± 0,30	0,564
Nasion - X axi	0,59 ± 0,20	0,52 ± 0,30	0,48 ± 0,30	0,46 ± 0,42	0,41 ± 0,29	0,719
Basion - Y axis	0,17 ± 0,21	0,61 ± 0,36	0,61 ± 0,40	0,70 ± 0,45	0,24 ± 0,48	0,468
Nasion - Y axis	0,59 ± 0,26	0,52 ± 0,29	0,43 ± 4,70	0,71 ± 0,39	0,38 ± 0,35	0,864
Basion - Z axis	0,37 ± 0,18[a,b]	0,24 ± 0,15[a]	0,51 ± 0,36[b]	0,42 ± 0,33[a,b]	0,45 ± 0,34[a,b]	0,003
Nasium - Z axis	0,63 ± 0,28	0,26 ± 0,19	0,69 ± 2,53	0,45 ± 0,23	0,47 ± 0,35	0,508

The results of the overall linear measurement differences for each landmark in each year are shown in table 2. For the X axis, U1 landmark presented decreasing discrepancies from 2013 to 2017, with statistical significance of year 2013 from all other years while years 2014 and 2016 did not correlate to each other and years 2015 and 2017 correlated to all years except 2013. Landmarks RU6 and LU6 presented similar behavior, with decreasing mean values throughout the years, and with years 2013 and 2014 similar to each other but apart from years 2015, 2016 and 2017, which were similar to each other. For the Y axis, U1 landmark showed decreasing discrepancies from 2013 to 2017, except for a slight increase in mean values from 2015 to 2016, although this last difference was not statically significant. Statistical significance was found from year 2013 to years 2015 and 2017, while year 2014 was statistically different from 2015 only. No statistical significant difference was found among groups 2015, 2016 and 2017 for this landmark in Y axis.

Landmarks RU6 and LU6 presented similar behavior as well, showing decreasing discrepancies throughout the years, except for a modest increasing mean values between 2015 and 2016. For landmark RU6, year 2013 statistically correlated only to year 2014, which was also correlated to year 2016. Statistical significant correlation was found among years 2015, 2016 and 2017. In LU6 landmark, year 2013 only correlated to year 2014, which was also correlated to years 2016 and 2017. No statistical significant difference was found among years 2015, 2016 and 2017 in landmark LU6 as well.

Regarding Z axis, all landmarks presented decreasing mean discrepancies from year 2013 to year 2016. For U1 and RU6 landmark, discrepancies from year 2013 statistically correlated only to values from year 2014, while there was no statistical significance among years 2014, 2015, 2016 and 2017. Minor changes occurred for LU6 landmark, with year 2013 being correlated to years 2014 and 2015, while no statistical significance was found among years 2014, 2015, 2016 and 2017.

Table 2 - Mean differences and standard deviation between planned and postoperative results for all landmarks in all axes for each year of the study (in millimeters) - different letters represent statistical significance difference between values.

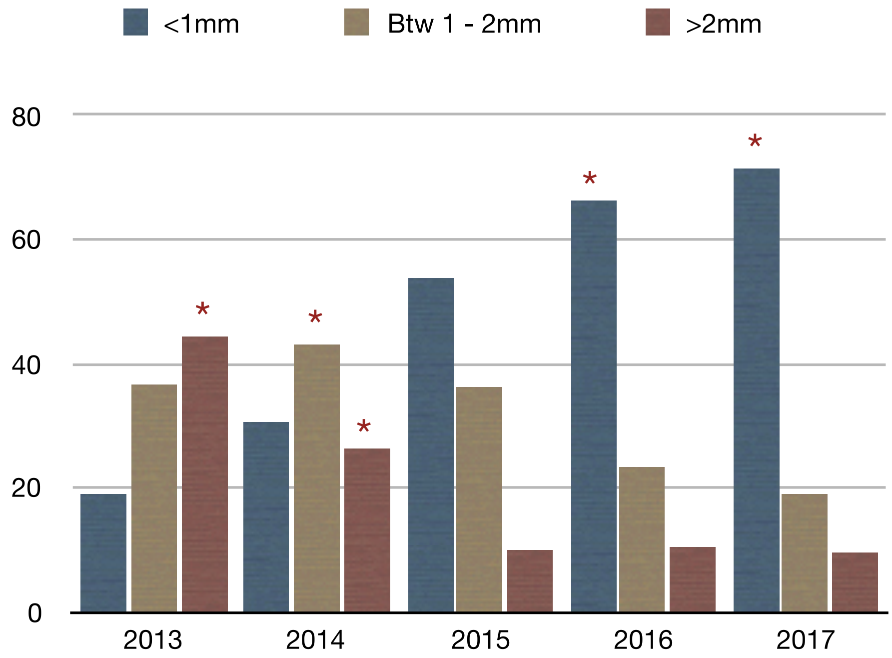
	Mean ± Standard Deviation (mm)					
	Year					
Landmark - axis	2013	2014	2015	2016	2017	p-value†
	n=10	n=17	n=39	n=20	n=14	
U1 Midline - X axis	1,79 ± 0,60^{a}	1,27 ± 0,83^{b}	0,87 ± 0,69^{b,c}	0,65 ± 0,83^{c}	0,69 ± 0,65^{b,c}	<0,001
RU6 - X axis	1,98 ± 0,33^{a}	1,50 ± 0,82^{a}	0,91 ± 0,62^{b}	0,76 ± 0,43^{b}	0,57 ± 0,66^{b}	<0,001
LU6 - X axis	1,93 ± 0,39^{a}	1,62 ± 0,70^{a}	0,96 ± 0,46^{b}	0,80 ± 0,72^{b}	0,73 ± 0,58^{b}	<0,001
U1 Midline - Y axis	2,07 ± 1,32^{a}	1,76 ± 0,92^{a,b}	1,02 ± 0,74^{c}	1,21 ± 0,94^{a,c}	1,05 ± 0,92^{b,c}	<0,001
RU6 - Y axis	2,11 ± 1,09^{a,d}	1,89 ± 1,02^{c,d}	1,33 ± 0,82^{b}	1,48 ± 0,78^{b,c}	1,35 ± 0,72^{b}	0,001
LU6 - Y axis	2,04 ± 1,32^{a}	1,88 ± 1,07^{a,c}	1,06 ± 0,85^{b}	1,40 ± 0,82^{b,c}	1,42 ± 0,68^{b,c}	0,001
U1 Midline - Z axis	1,53 ± 0,89^{a}	1,08 ± 0,69^{a,c}	0,90 ± 0,66^{b,c}	0,59 ± 0,48^{b,c}	0,58 ± 0,94^{b,c}	0,005
RU6 - Z axis	1,72 ± 1,07^{a}	1,22 ± 0,71^{a,b}	0,93 ± 0,64^{b}	0,58 ± 0,30^{b}	0,68 ± 0,90^{b}	0,001
LU6 - Z axis	1,56 ± 0,96^{a}	1,20 ± 0,66^{a,b}	1,01 ± 0,66^{a,b}	0,69 ± 0,35^{b}	0,66 ± 0,75^{b}	0,007

Overall accuracy defined as secondary outcome is shown in table 3 and graph 1. Among all axes (x, y and z), an overall average difference between planned and obtained outcomes within 1mm was observed in 51,3% of the measurements included in the sample, and an increasing accuracy is observed throughout the years. In 2013, a difference between planned and obtained results under 1mm was found only in 18,9% of all measurements, and this percentage increases throughout the years up to 71,4% of the measurements in 2017. Mean discrepancies between 1 and 2mm and above 2mm showed highest a incidence in 2014 (43,1%) and in 2013 (44,4%) respectively, and in both discrepancy limits the incidence decreased down to 19,1% and 9,5% respectively in year 2017. The incidence of mean discrepancies above 2mm was statistically higher in 2013 and in 2014, while that under 1mm was statistically higher in more recent years (2016 and 2017).

Table 3 - Overall accuracy of all differences between planned and postoperative results for all landmarks subdivided into 3 discrepancy limits (in millimeters) - different letters represent statistical significance difference between values.

	n (%)			
	Mean differences between planned and obtained outcomes (mm)			
	<1mm	Btw 1 - 2mm	>2mm	p-value
number of measured landmarks	n = 462	n = 292	n = 146	
Year				
2013	17 (18,9)	33 (36,7)	40 (44,4)[b]	<0,001[†]
2014	47 (30,7)	66 (43,1)[b]	40 (26,2)[b]	
2015	189 (53,8)	127 (36,2)	35 (10,0)	
2016	119 (66,1)[b]	42 (23,3)	19 (10,6)	
2017	90 (71,4)[b]	24 (19,1)	12 (9,5)	

Graph 1 - Percentage of measurements included in each discrepancy limit for each year (* represents statistical significant difference).



DISCUSSION

Most publications regarding VSP that have been published investigated the feasibility or emphasized the potential advantages over conventional methods[3,6,12]. However, differences in algorithms and rapid developments in software, and VSP operator learning curve have never been addressed in a chronological fashion. The results of the present study show a consistent increase in the accuracy of sagittal and anteroposterior movements from years 2013 and 2015 to years 2015, 2016 and 2017, although vertical movements were not as accurate.

When evaluating the literature, both early (Sun et al. and Hsu et al.) and more recent studies show satisfactory outcomes. In 2013, Sun et al. reported a mean difference between planned and obtained surgical movement of 0.50 ± 0.22mm in transversal axis, 0.57 ± 0.35mm in vertical direction and 0.38 ± 0.35mm in horizontal direction, although the authors investigated only 15 patients and only one maxilla landmark was analyzed (edge of central incisor)[13]. Similar outcomes were also reported by Hsu et al. in 2013, although the authors show the anteroposterior direction as the least accurate direction, showing 1mm difference between planned and obtained results[4]. More recent studies have shown a mean difference in maxillary position between planned and obtained results comparable to those of these studies as well as the present study. Ritto et al. [12] reported in 2017 mean linear difference of 0.90mm for transversal movements, 0.95mm for anteroposterior movements and 1.44mm for vertical movements. The sample of this study included patients from 2012 until 2015, although it did not mention the number of patients operated each year. In part, such results were consistent with those of this study in patients operated after 2014. Comparing the results of this study to those from the literature suggests software updates may not have impacted accuracy as much as other factors including the clinician's learning curve and inherent perioperative sources of error.

Regarding vertical discrepancies observed in this study as well as others, several perioperative sources could have played a role. Discrepancies in the condylar position during the CBCT and in surgery (whether from condyles not in centric relation during CBCT, or variations in condylar position during surgery, or both) could affect accuracy, mainly in the vertical and anteroposterior directions. Correct positioning of the condyle within the glenoid fossa in centric relation during preoperative registration as well as during CBCT scanning and during the surgery will help minimize such limitations. Poor appreciation for condyle placement on preoperative CBCT scans is one of the main reasons for surgeons to abandon VSP for orthognathic surgeries[14]. Perez and Ellis proposed that the occlusion should always be verified before surgery, with the patient under general anaesthesia, to check whether it is in agreement with the preoperative registration[15]. If not, new model surgery must be performed using an intraoperative bite registration and the surgery should be delayed or postponed. Borba et al. assessed occlusal measurements before and after general anaesthesia and the influence of gender and type of deformity on such changes. While in most instances centric occlusion can be adequately reproduced under general anaesthesia, significant changes in vertical direction for the mandible were found in class II patients. Another alternative to overcome such inaccuracies would be planning to initiate surgery at the mandible[15,16], or to use a waferless system to position the maxilla[17,18].

Another source of maxillary inaccuracy is related to the axis of condylar rotation when vertical movements are planned and executed. The current literature still lacks evidence about the precise position in which condylar hinge axis should be positioned during 3D landmarks placement as well as the degree and direction of mandibular autorotation. The “hinge axis concept” maintains that the mandible moves around a transverse horizontal axis through both condyles[19]. Difference in the position and the direction of autorotation significantly affects the position of the maxilla, mainly when large vertical movements are planned[20]. As the mouth opens for maxillomandibular fixation using the intermediate splint, both rotational and translational movements may occur, instead of the predicted pure hinge movement, which is what the VSP and splint fabrication is based on. Also, even if only pure rotational movement occurs, the hinge axis may very well differ between what was used during VSP and the actual axis in situ during surgery. Hellsing et al.[19] stated that pure rotation does not occur, and an increase in the occlusal vertical dimension results in positional change of the condyles in an unpredictable direction. As demonstrated by Travers et al.[21], healthy individuals may perform normal opening with highly variable amounts of condylar rotation and translation, which indicates that the lower incisor opening does not provide reliable information about condylar translation and its use to predict condylar movement should be limited. In an attempt to locate the center of mandible autorotation during maxillary surgical impaction and identify discrepancies between the resultant mandibular position following maxillary surgical impaction, Wang et al. demonstrated that the center of mandibular autorotation is located in average 2.5mm behind and 19.6mm below the radiographic condylar center of the mandible, with large individual variations[22]. There is no consensus regarding the location of mandibular autorotation center as reported in the literature and these authors do not mention maxillary positioning errors according to the rotation of the mandible. Mandibular rotation in 2D or 3D images may not represent real-life scenarios and determining the center of rotation could affect the accuracy of surgical prediction in any or multiple directions, therefore resulting in discrepancy of surgical outcomes in the maxilla and/or in the mandible[23].

The strengths of this study includes use of sound analysis techniques. A recent systematic review aiming to uncover a universal protocol to assess the accuracy of 3-dimensional virtually planned orthognathic surgery reports a lack of consensus between different centers regarding assessment and validation methods to research maxillary accuracy after VSP. Therefore the authors suggest three ideal criteria currently accepted to validate assessment of the accuracy of virtually planned orthognathic surgery: 1) voxel-based registration, on the cranial base, of planned and postoperative images; 2) automated or semi-automated evaluation of the outcome and 3) inter- and intra-observer reliability to validate results[24]. The study hereby presented followed voxel-based registration of pre and postoperative CBCT using the anterior cranial base, although assessment was performed by multiple landmarks registration and only one observer validated the results. Observer reliability was confirmed by measuring landmarks not affected by orthognathic surgery and statistical analysis on these landmarks confirmed its overall reliability.

One limitation of this study is that it was a single-center study. The results of this study may not be applicable to settings with different case volume, operator experience with VSP, and surgical technique. Also, it has been reported that the direction of surgical movement can influence the accuracy of maxillary surgery[25,26]. The present study did not divide patients into different groups according to the direction of movement, instead there was a large variation in maxillary direction and magnitude of movements in all groups, which contributes to the heterogeneity of the sample and reliability of the results. Also, although learning curve (which can be defined as improving performance over time or increasing experience or training), is thought to have played a substantial role in the improvement of surgical accuracy, a “learning curve cumulative sum analysis (LC-CUSUM)” was not performed. LC-CUSUM is a sequential analysis tool originally developed for quality control purposes that can be used to judge when an individual’s performance has reached a predefined level of competence. Other possible limitations of the study includes different sample size among all groups, single center study and inherent bias associated with retrospective studies.

In the authors’ collective experience, continuous learning from routine use of VSP resulted in improved understanding of the 3D relationships of the skeletal structures during the planned surgical movements. Describing his own experience with computer planning in orthognahtic surgery, Bell stated that initial obstacles of virtual planning software have been resolved and different software solutions have gained marketability in the meantime[27].

In conclusion, VSP is an accurate and reproducible method for treatment planning which is reliably transferred to the patient by means of surgical splints to accurately reposition the maxilla in the anteroposterior and transverse direction, while maxillary vertical movement accuracy still relies on some preoperative and surgical procedure parameters. User familiarity through continuous use of VSP seemed to have contributed to improved accuracy over time, and other factors such as software and miscellaneous technological updates could have contributed as well. Whether, and how much these factors contributed remains unknown. While continuous software development might occur, it is a duty for surgeons to fully understand the multiple steps of VSP, follow a rational protocol and aim for accuracy in each minor step along the process. Also, the surgeon must recognize inherent perioperative sources of error and aim to minimize them. More independent clinical trials may help to validate the accuracy and reproducibility of virtual surgical planning and seek more possible explanations for inaccuracies found and methods to overcome these errors.

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Título: Protocolo de Planejamento Cirúrgico Virtual para Cirurgias Ortognáticas Bimaxilares com Sequencia de Mandíbula Primeiro

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Resumo:
O planejamento tridimensional do tratamento virtual melhorou muito a eficiência e a precisão da correção da deformidade dentofacial por meio da cirurgia ortognática1. Além disso, o advento da fixação interna rígida permitiu uma mudança nesta seqüência clássica. A realização da cirurgia mandibular apresenta, inicialmente, diversas vantagens e os cirurgiões devem considerar algumas indicações para obter melhores resultados, sendo imprescindível a capacidade do cirurgião de reproduzir o plano de tratamento no centro cirúrgico. A maior parte do plano de tratamento da cirurgia ortognática foi realizada pela sequência tradicional, mas a cirurgia em si foi realizada usando uma sequência invertida. No entanto, reposicionar a mandíbula inferior primeiro durante o planejamento virtual tridimensional, assim como na cirurgia real, pode ser realmente vantajoso. O objetivo deste artigo é sugerir um protocolo para a cirurgia ortognática bimaxilar, reposicionando a mandíbula em primeiro lugar, tanto no planejamento virtual tridimensional quanto na própria cirurgia.

Abstract:
Three-dimensional virtual treatment planning has greatly enhanced the efficiency and accuracy of dentofacial deformity correction through orthognathic surgery[1]. Moreover, the advent of rigid internal fixation has allowed a change in this classical sequence. Performing mandibular surgery first presents several advantages and surgeons must consider some indications in order to achieve better results, and the ability of the surgeon to reproduce the treatment plan in the operating room is essential[2]. Most of orthognathic surgery treatment plan has been performed by the traditional sequence, but the surgery itself performed using an inverted sequence. However, repositioning the lower jaw first during three-dimensional virtual planning, as well as in actual surgery, can be really advantageous. The purpose of this paper is to suggest a protocol for double-jaw orthognathic surgery repositioning the mandible first in both three-dimensional virtual planning and surgery itself.

Tridimensional virtual planning protocol for double-jaw orthognathic surgery with mandible first surgical sequence

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Summary

Rigid fixation and three-dimensional virtual treatment planning has greatly enhanced outcomes in orthognathic surgery, allowing the surgeon to perform different surgical sequences and treatment protocols. The aim of this paper is to suggest a 3D virtual planning protocol for double-jaw orthognathic surgery when the mandible first sequence is indicated.

Key words: orthognathic surgery, dentofacial defomrity, virtual surgical planning

Tridimensional virtual planning protocol for double-jaw orthognathic surgery with mandible first surgical sequence

Introduction

Three-dimensional virtual treatment planning has greatly enhanced the efficiency and accuracy of dentofacial deformity correction through orthognathic surgery (*Schendel et al.*, 2013). Moreover, the advent of rigid internal fixation has allowed a change in this classical sequence. Performing mandibular surgery first presents several advantages and surgeons must consider some indications in order to achieve better results, and the ability of the surgeon to reproduce the treatment plan in the operating room is essential (*Ellis and Perez,* 2011). Most of orthognathic surgery treatment plan has been performed by the traditional sequence, but the surgery itself performed using an inverted sequence. However, repositioning the lower jaw first during three-dimensional virtual planning, as well as in actual surgery, can be really advantageous. The purpose of this paper is to suggest a protocol for double-jaw orthognathic surgery repositioning the mandible first in both three-dimensional virtual planning and surgery itself.

Tridimensional virtual planning protocol

Step 1: Clinical and CT-scan analyses of the patient in natural head position (NHP) and centric relation (CR).

During this first step, facial and dental analysis are performed under patient's NHP, jaws in CR and lips relaxed. Such position is recorded photographically and repeated during CT-scan afterwards. A technique for establishing NHP should follow a logical sequence, in which the patient stands in front of the photographer looking straight towards horizon. The photographer then first records the roll axis in a frontal view picture, followed by recording pitch axis in a profile view picture. It is very difficult to record yaw axis during facial pictures, hence the authors recommend to position yaw axis by the alignment of the ocular globe during CT-scan. One should be aware of enophthalmus, proptosis and other conditions that may alter the position of ocular globe. All photographs are taken using a tripod and professional SLR cameras. (Figure 1A, 1B and Figure 2)

Step 2: Treatment plan based on facial and dental analysis.

Such analyses follow traditional parameters as described by many authors and dictate the treatment plan (*Epker et al*., 1995; *Arnett and Bergmann*,1993) .

Step 3: Digital cephalometric prediction.

Digital prediction trancing allows direct evaluation of both dental and skeletal bidimensional movements and provides predicted profile images (*Kaipatur and Flores-Mir*, 2009). A lateral cephalogram is generated by CT-scan in NHP, with jaws in CR and lips relaxed. From this point there are two ways to predict the actual surgery. The first one is performed following the traditional method in which the maxilla is first positioned as planned, followed by placing the mandible in the desired final occlusion and then genioplasty if necessary. The second approach is initiated by first placing the mandible into the desired occlusion and next moving both maxilla and mandible together until desired final skeletal position as desired. At last, genioplasty can also be predicted if necessary. Both methods allow good prediction if soft tissue responses configuration is adequate. Also, having dental casts available to observe dental relationships can make it easier to place the mandible into the best occlusion.

Step 4: Identification of first dental contact between operated mandible and unoperated maxilla.

Determination of the center of mandibular autorotation (CAR) should be performed as the very first action. Many CAR's have been described, but the most common method is to place CAR in the center of condyles (*Xia et al.,* 2015), although other authors have reported some other locations. In an attempt to locate the center of mandible autorotation during maxillary surgical impaction and identify discrepancies between the resultant mandibular position following maxillary surgical impaction, Wang et al. demonstrated that the center of mandibular autorotation is located 2.5mm behind and 19.6mm below the radiographic condylar center of the mandible in average, with large individual variations. Moreover, the authors reported that by using the radiographic condylar center of the mandible to predict the mandibular autorotation would overestimate the horizontal position of chin by 2 mm and underestimate the vertical position of chin by 1.3 mm following an average of 5 mm surgical maxillary impaction (*Wang et al*, 2006)**.** In a similar study Lou et al. reported that the mandibular rotation center is located outside the condylar head in all patients of the study, in average 15.64mm below and 0.82mm behind the center of the condylar head (*Lou et al*., 2014). Another technique is to individualize the CAR as described by Nasser Nadjmi et al. Both methods are available and present accurate results. Next, the mandible is rotated until first tooth contact between operated mandible and unoperated maxilla occurs (*Nadjmi et al*, 1998).

Step 5: Record of surgical movements obtained in step 3 and 4.

Surgical movements of both maxilla and mandible obtained in step 3 are initially recorded. Mandibular position obtained in step 4 is then recorded as well. Main landmarks registered are upper and lower incisors tips, upper and lower first molar cusps, anterior nasal spine and pogonium. Such landmarks must be individually documented horizontally and vertically. Moreover, both tooth contacts and distances between upper and lower jaws should also be recorded to allow best accuracy of mandibular position during virtual surgery.

Step 6: Virtual patient generation in NHP and CR.

CT-Scan clean-up is important to remove unnecessary data from scans. Dental casts superposition and generation of hard and soft tissue surface of patient’s face are very important actions as well. All softwares provide different tools to edit such images and the surgeon must be able to handle and coordinate skills to create the best image of the virtual patient in NHP and CR. Although the authors recommend to generate virtual patient in CR considering it a diagnostic and reproducible position, it is important emphasize that the actual surgery is also performed using an inverted sequence, hence patient generation in perfect CR is not mandatory and erros in such position will not affect treatment results. Virtual dental models superimposition on the virtual patient’s teeth is perhaps the most challenging procedure during virtual patient generation. Using a high-resolution laser scanner, digital dental models are generated by scanning patients' teeth or stone models and incorporated into the 3D CT reconstruction (Figures 3A, 3B, 3C and 3D).

Such superimposition could be performed automatically (auto superposition) or manually. If manually performed by the surgeon it should also follow a established sequence, as described bellow:

6.1) The very first action involves placing upper digital dental models in front of 3D CT model and rapidly pre-setting roll, pitch and yaw axis of such digital models in frontal, profile and axial views respectively. These steps should necessarily follow the mentioned adjustment order.

6.2) In a profile view superimpose the upper incisors of digital casts onto 3D CT reconstruction in vertical and horizontal position. A CT-scan sagital section can assist to enhance such superimposition.

6.3) In a tridimensional frontal view adjust the upper dental midlines. Different opacities patterns of dental casts and 3D CT reconstruction can be very helpful to assist such superposition.

The next steps encompasses refinement of digital dental models superimposition.

6.4) In CT-scan coronal section, adjust roll axis of superimposed teeth.

6.5) In CT-scan sagital section, adjust pitch axis of superimposed teeth.

6.6) In CT-scan axial section, adjust yaw axis of superimposed teeth.

6.7) Repeat steps 6.4, 6.5 and 6.6 until reaching a perfect superimposition.

6.8) Review and check perfect superimposition of upper dental cast in the 3D CT reconstruction with different opacities patterns as well as in CT-scan coronal, sagital and axial sections.

6.9) Repeat the same steps for lower cast superimposition.

Step 7: Virtual osteotomies generation

Virtual osteotomies design and length must be identical to the surgery itself in order to gather important information about bone segments contact area, bone interferences that may need adjustments and gaps that may need to be grafted (*Xia et al.*, 2010). Each software contains specific tools to generate preset classic midface and mandible osteotomies, including segmented osteotomies. Besides, it is possible to trace customized osteotomies which allows elaboration of a variety of treatment planning. The authors suggest to customize BSSO for each specific case according to patient's anatomy (i.e. inferior alveolar neurovascular bundle position, inferior teeth roots position and mandibular bone architecture), bony movement direction and magnitude.

Step 8: Setting the landmark points

Some tridimensional landmarks should be registered on the maxilla, mandible and soft tissue to allow understanding all tridimensional movements planned to reach the desired goals. Each software also contains a preset list of hard and soft tissue reference landmarks as well as specific tools to assist setting such landmarks. Special care should be taken to the CAR and reference landmarks registered, which should be coincident to the parameter used on digital cephalometric prediction in step 4 and 5 respectively.

Step 9: Virtual 3D surgery

9.1) Mandibular roll correction

Always start by leveling the mandibular cant. The rotation center should be positioned at the uppermost point of inferior dental midline and roll the mandible until the desired position. Any change in roll position will interfere in pitch and yaw position, as well as midlines alignment. Hence, misalignment in roll position will difficult to reach the desired occlusal contact between operated mandible and unoperated maxila needed in step 9.4.

9.2) Inferior midline correction

Inferior midline should be corrected in order to centralize the lower jaw. It also allows the next step to obtain the same occlusal contact between operated mandible and unoperated maxilla as reached in step 4.

9.3) Mandibular yaw correction

Yaw axis is aligned by rotating the mandible until the desired position. The rotation center for such procedure should be inferior dental midline. Yaw axis correction is best accomplished in a superior axial view in which gridlines will assist aligning the mandible in a suitable position. Any misalignment in yaw position will again difficult to reach the desired occlusal contact between operated mandible and unoperated maxila needed in step 9.4.

9.4) Find the first occlusal contact between operated mandible and unoperated maxilla

The mandible should be moved both horizontally and vertically until coincide occlusal contact obtained in step 4. The occlusion dental collision map is very helpful to reach the desired occlusal contact.

9.5) Mandibular pitch correction

After finding the first occlusal contact between operated mandible and unoperated maxilla, pitch axis is adjusted. To best adjust pitch axis the surgeon must place the rotation center on occlusal contact found on the previous step and rotate the mandible until the desired occlusal plane angulation and anteroposterior chin projection. After this manipulation all horizontal and vertical movements in lower incisors, lower molars and pogonium as well as eventual distances between upper and lower dental arches (i.e. distances between molars for counterclockwise rotations and between incisors for clockwise rotations) recorded on step 5 should coincide. Such maneuver carried previous to proximal segments orientation is imperative for appropriate segments alignment.

9.6) Proximal segments alignment

After all mandibular corrections the proximal segments can finally be appropriately aligned. The surgeon should take special care during this step in order to avoid temporomandibular disorders or condylar resorption caused by incorrect proximal segments alignment. According to Liu et al., maximum angulation in proximal segment positioning should not be more than 4º in pitch axis, 3º in roll axis and zero in yaw axis (*Liu et al.*, 2015). At this moment, all informations is saved into a new slot in the software before continuing the virtual planning. It allows access to all informations of intermediate occlusal relationships during the actual surgery.

Figures 4A, 4B, 4C and 4D show mandibular repositioning previous to any maxillary movement.

9.7) Maxillary reposition

The maxilla is repositioned on operated mandible according to the desired final occlusion. Softwares provide different tools for this purpose and such reposition could be performed either automatically or manually, according to the surgeon's preference. Manual positioning is performed by fitting virtual tridimensional teeth in a desired final occlusion. This maneuver is oriented and reviewed by direct view of 3D model in several perspectives (frontal, oblique, lateral, superior, inferior and posterior) as well as axial, coronal and sagital tomographic sections. Furthermore, it is assisted by a occlusion dental collision map that displays upper and lower teeth relationships and hence indicate possible area and magnitude of dental superposition. Having dental casts available to observe dental relationships will help to find the best final occlusion. Automatic position is driven by dental casts scanning mounted in the desired final occlusion. Digital superior and inferior dental casts are first superimposed in the desired occlusion and based on this superposition the maxilla will move until fitting into the desired occlusion.

9.8) Maxillomandibular complex rotation

After repositioning the maxilla the entire maxillomandibular complex is rotated for final vertical and horizontal correction. The upper incisors edges are the most useful vertical reference. Special care should again be taken to the CAR, which should be coincident to the parameter used before. After this rotation all horizontal and vertical movements in upper and lower incisors, upper and lower molars, anterior nasal spine and pogonium should coincide the prediction tracing.

9.9) Genioplasty

At last, genioplasty can also be simulated if necessary, according to treatment plan and surgery prediction.

10. Check list

Review all tridimensional movements and compare to the data obtained in steps 2 and 3. All horizontal and vertical movements and pitch axis correction are reviewed considering the prediction tracing as a guideline while roll and yaw axis as well as dental midlines are reviewed according to clinical analysis (Figures 5A, 5B, 5C, 5D and Figures 6A, 6B).

11. Construct surgical splint

Each software contains specific tools to generate the surgical splint , which should be designed on the computer and fabricated using a rapid prototyping machine. It is important that surgical splint has suitable thickness to provide resistance to deformation and fracture during its use, a highly detailed and precise surface and be free of interference with the orthodontic appliance. In addition, the surgical splint should be fabricated in fast and economic way to improve logistics in clinical practice.

Discussion

Accurate treatment planning and execution are essential for success in orthognathic surgery, regardless the method used to achieve its goals (*Sharifi et al.*, 2008). In order to accurately reproduce treatment plan and achieve the most reliable and predictable result, the protocol reported in this manuscript presents several advantages over a traditional tridimensional virtual treatment planning for inverted sequence in double-jaw orthognathic surgery in which treatment plan is based primarily on maxillary position.

Facial symmetry is essential for a desirable outcome after orthognatic surgery and such harmony is mainly attained by correct tridimensional lower jaw position. Correction of a facial asymmetry and, most important, avoid creating new asymmetries after orthognathic surgery become a challenge due to the geometric complexity of the jaws and other facial structures. These situations are best managed by first repositioning the mandible during tridimensional virtual surgical planning. This sequence simplifies the asymmetry correction and avoid establishing new asymmetries as the surgeon possesses much more control of tridimensional mandibular position during the virtual planning. In contrast, once the maxilla is first repositioned and this position guides mandibular replacement, facial symmetries may be under-corrected or even new asymmetries may be created since mandibular dentition has more skeletal bulk than the maxilla and any asymmetric repositioning is much more evident (i.e. contour of the inferior borders or asymmetry in mandibular angles).

Some of tridimensional virtual surgical planning softwares do not allow to reset the position of the maxilla if it is repositioned first. Therefore, if one chooses to first operate the mandible on actual surgery, the software will not accurately show intermediate occlusal relationships after mandible surgery. Other softwares allow to reset the position of the maxilla, but it is still a limited view. Therefore, if one chooses to first reposition the mandible during tridimensional virtual surgical planning all informations of intermediate occlusal relationships for inverted sequence double-jaw orthognathic surgery are available. The surgeon can use all the tools to check and measure the intermediate position and save these informations into a new slot in the software before continuing the virtual planning. Thus, during the actual surgery the surgeon will have full access to all measurements and references as well as ascertain the intermediate occlusion predicted in treatment plan.

Concomitantly, performing double-jaw orthognahic surgery with mandible first sequence presents several advantages over traditional “maxilla first” technique, as discussed by *Ellis and Perez*, 2008. Unlike the traditional maxilla first method, the mandible first protocol is not affected by interoclusal relationship discrepancies or vulnerable CR position. Although the authors seek CR position during surgical planning to gather as much information as possible, an accurate CR registration is not mandatory to achieve surgical accuracy[2]. Such protocol renders an increasingly attention in patients without a reliable centric relation in which the maxilla first method may be devastating for the final outcome, as presented by Posnick, Ricalde and Ng (*Posnick et al*, 2006).

Mandible first alternative to virtual planning and surgical sequence leads to improved results with good facial esthetics and more accurate occlusal outcomes. Both mandibular and maxillary surgical reposition show very accurate precision after a detailed and meticulous treatment plan, but mandibular surgical reposition is subject to many variables (i.e. temporomandibular joint individual position) and occasionally can lead to occlusal interferences. Aware that occlusal outcomes are more susceptible to these minimal “errors” than facial esthetics, a tradicional surgical sequence may cause unstable occlusal relationship while the mandible first protocol leads to a stable perfect occlusion without compromising facial esthetics, mainly when maxilla segmentation is required to achieve satisfactory esthetic and occlusal outcomes.

Potential disadvantages exist and should also be mentioned. The most important drawback of the protocol presented above is the fact that it is only suitable for bimaxillary orthognathic surgery in which the surgeon elects the mandible first sequence. In such sequence, complications such as unfavorable split of sagittal ramus osteotomy should be properly managed and rigidly stabilized prior to maxilla reposition, otherwise maxilla reposition might need to be delayed. As with all new approaches and techniques, such protocol also require previous training and a steep learning curve might be addressed as well. Although the sequence may seem complex at first, the entire process is actually simplified once the surgeon recognize its advantages.

Although the suggested protocol has been used by two authors of the study in two different centers in a fair number of patients and has been promoting suitable and satisfying outcomes, limitations of this paper and suggested protocol includes lack of validation testes and, most importantly, lack of clinical trials or prospective studies confirming its accuracy and reliability. The authors also acknowledge the inherent bias of reporting a protocol when the data are based on the clinician's surgical practice. Even so, pilot studies and clinical trials are suggested in order to certify its accuracy, endorse its reliability and establish itself as an alternative to uncertain traditional virtual surgical plan sequence.

Conclusion

In summary, the decision regarding the jaw to be operated on first in tridimensional virtual surgical planning and in the surgery itself depends on vantages and disadvantages of such protocol as well as surgeon's preference and experience. Although success depends on a host of factors, the authors firmly believe on the accuracy and reliability of the protocol presented to virtually plan double-jaw orthognathic surgery when the mandible first sequence is indicated and suggest to consider such planning sequence to reach outstanding short and long-term outcomes.

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None. All contributors of the manuscript are listed as the paper authors.

Authorship

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Declarations of Interests

None

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Figures

Figure 1A

Figure 1B

Figure 2

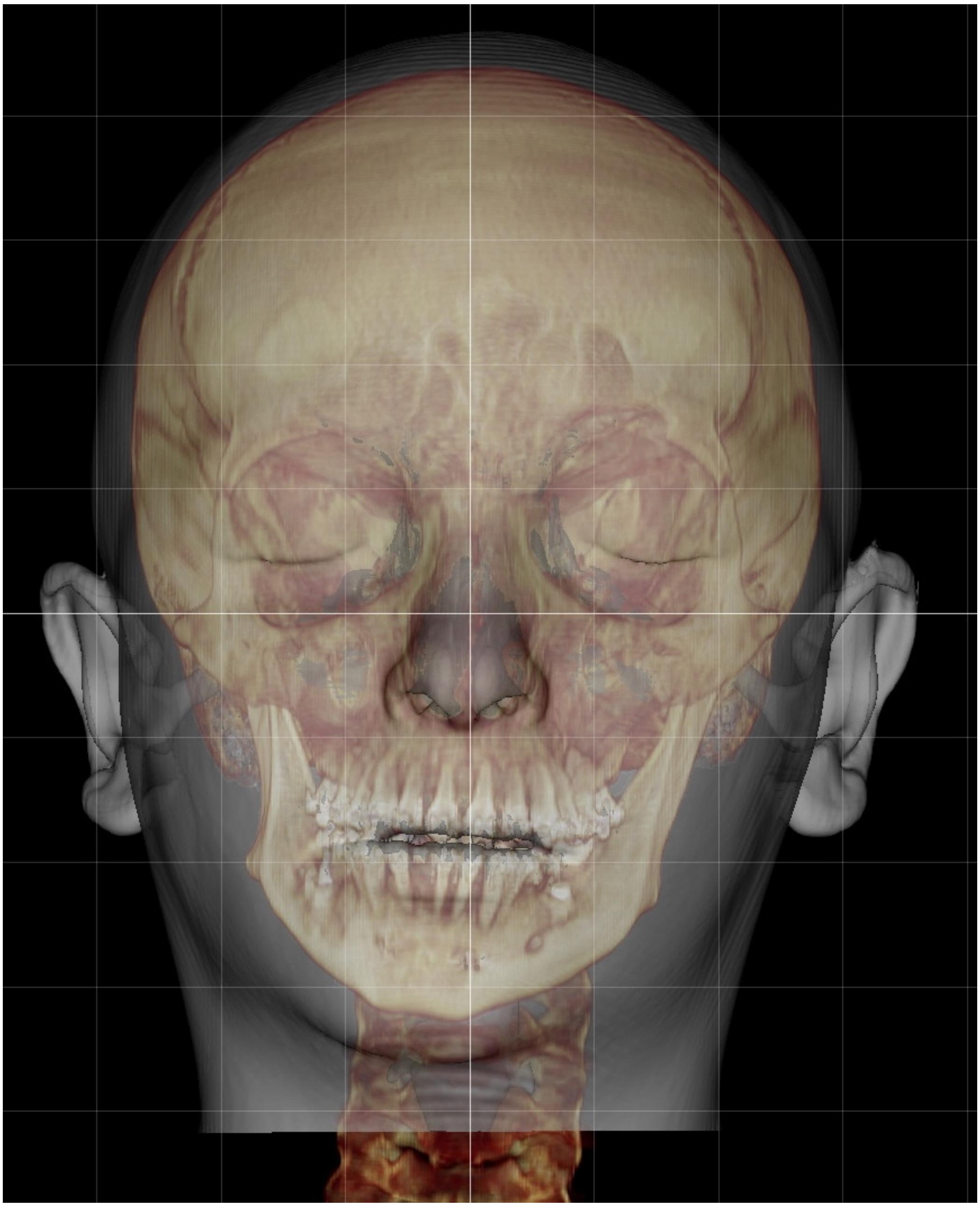


Figure 3A

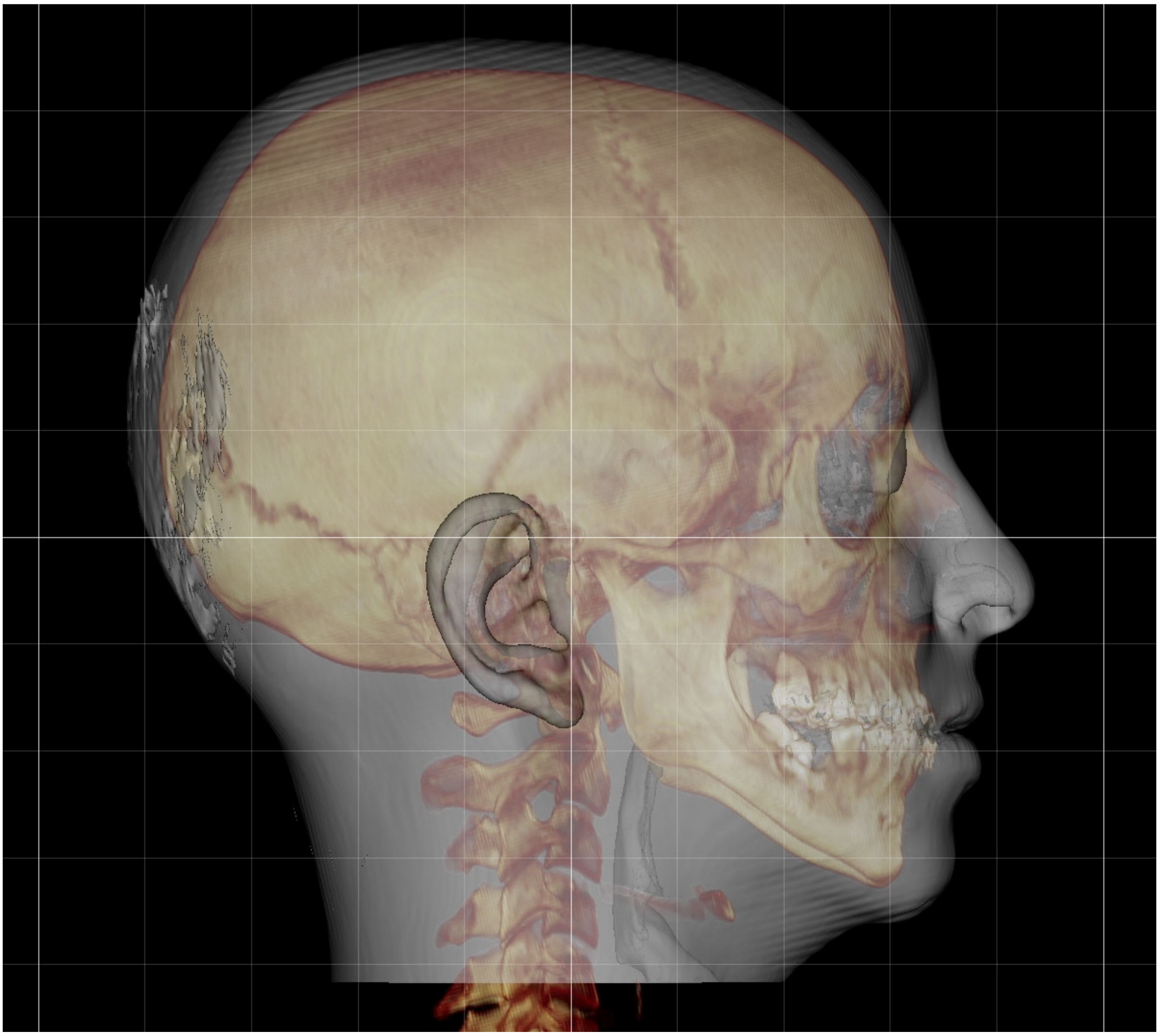


Figure 3B

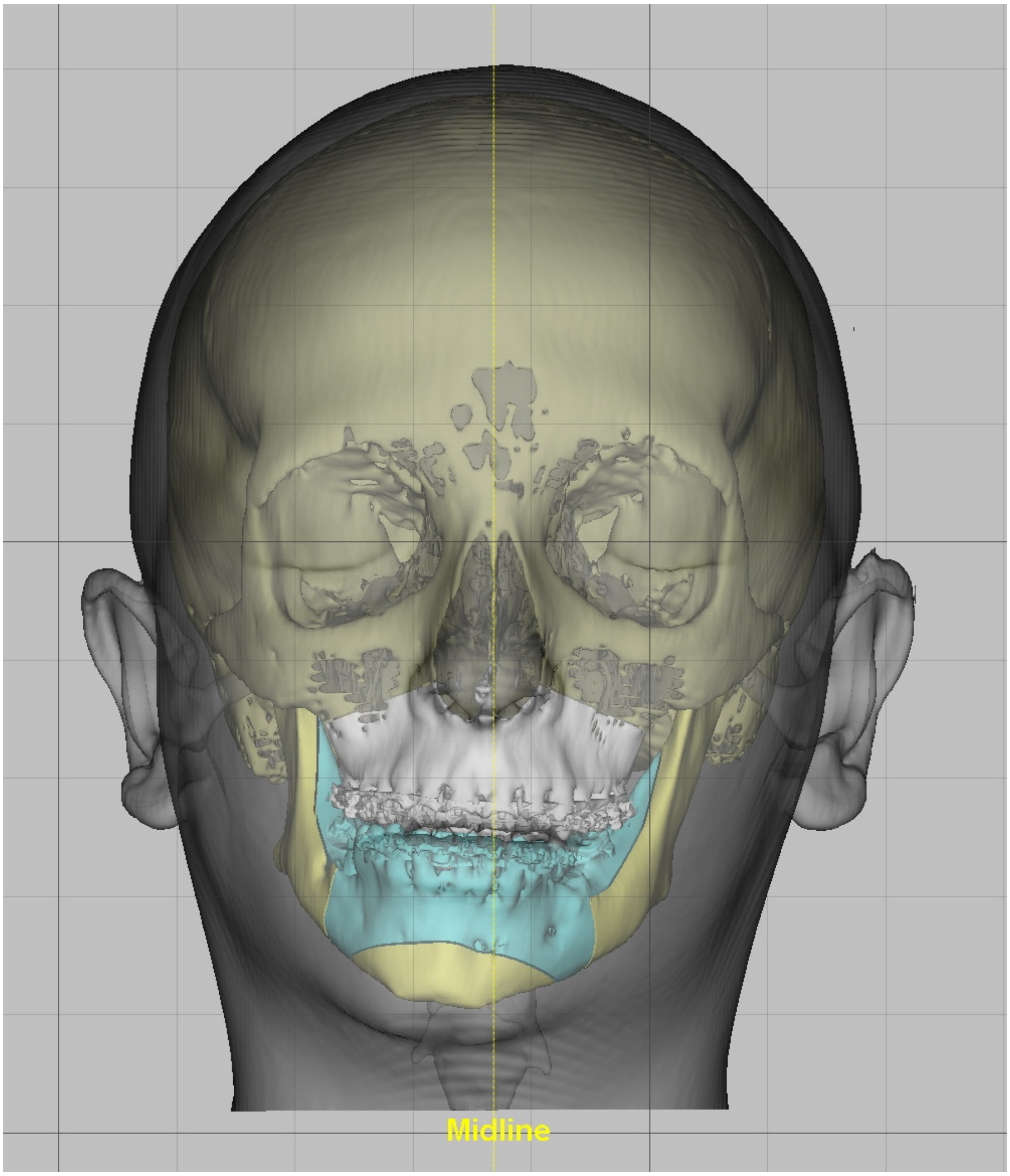


Figure 3C

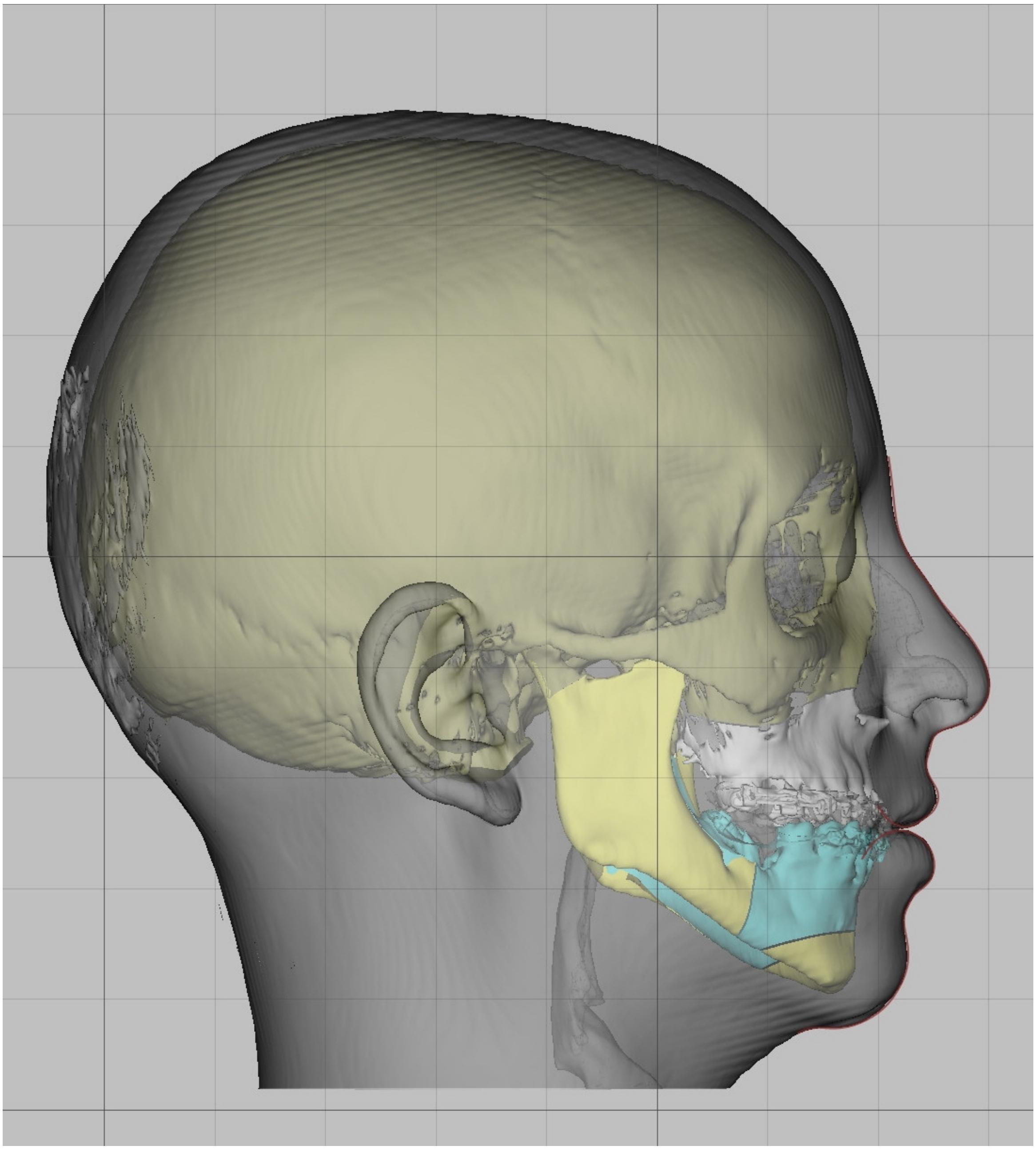
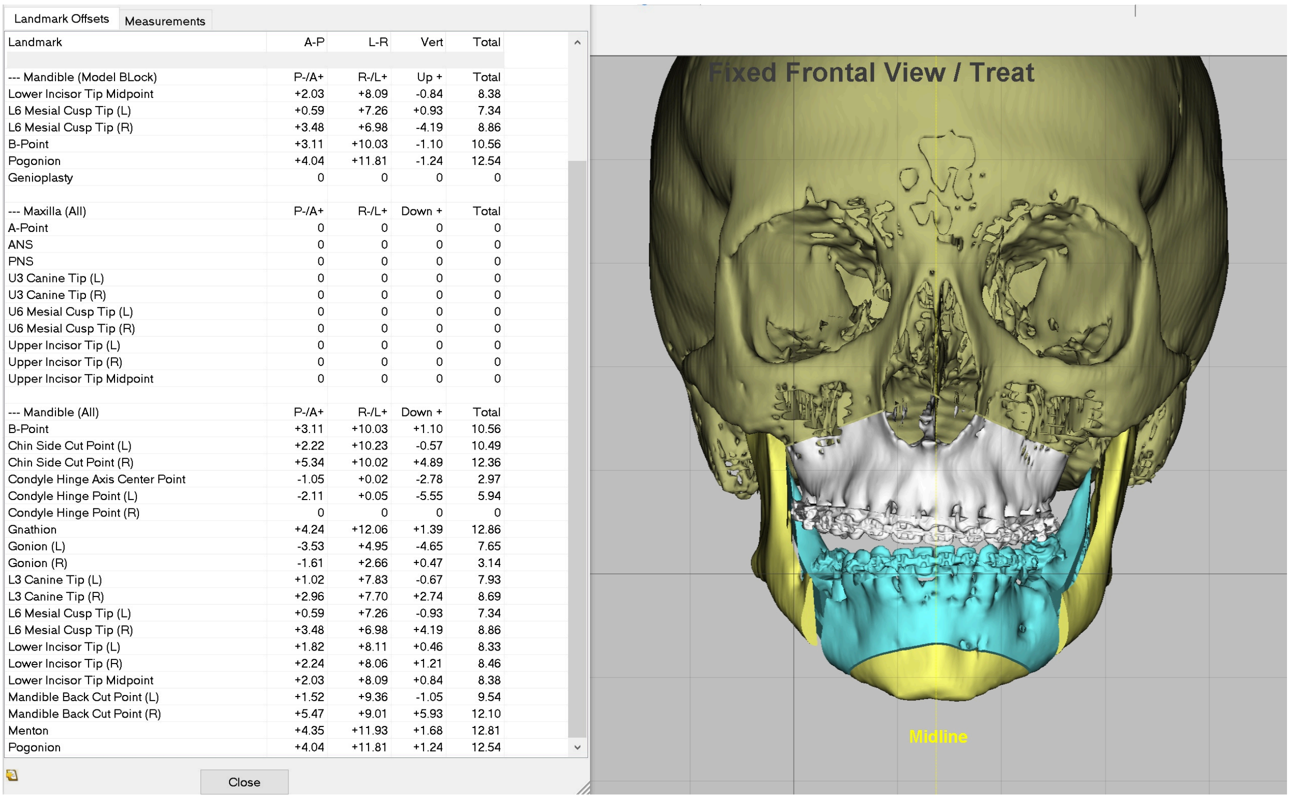


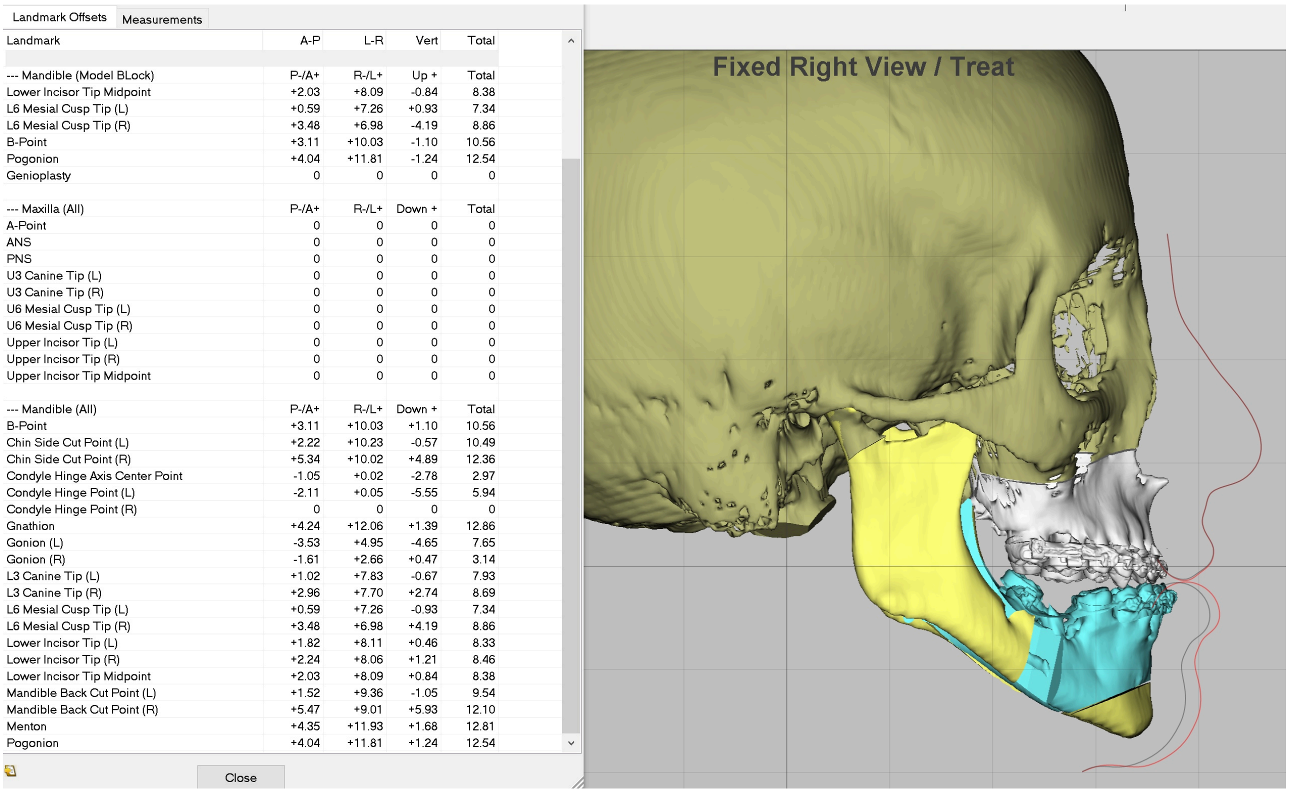
Figure 3D

Figure 4A



Landmark	A-P	L-R	Vert	Total
--- Mandible (Model BLock)	P-/A+	R-/L+	Up +	Total
Lower Incisor Tip Midpoint	+2.03	+8.09	-0.84	8.38
L6 Mesial Cusp Tip (L)	+0.59	+7.26	+0.93	7.34
L6 Mesial Cusp Tip (R)	+3.48	+6.98	-4.19	8.86
B-Point	+3.11	+10.03	-1.10	10.56
Pogonion	+4.04	+11.81	-1.24	12.54
Genioplasty	0	0	0	0
--- Maxilla (All)	P-/A+	R-/L+	Down +	Total
A-Point	0	0	0	0
ANS	0	0	0	0
PNS	0	0	0	0
U3 Canine Tip (L)	0	0	0	0
U3 Canine Tip (R)	0	0	0	0
U6 Mesial Cusp Tip (L)	0	0	0	0
U6 Mesial Cusp Tip (R)	0	0	0	0
Upper Incisor Tip (L)	0	0	0	0
Upper Incisor Tip (R)	0	0	0	0
Upper Incisor Tip Midpoint	0	0	0	0
--- Mandible (All)	P-/A+	R-/L+	Down +	Total
B-Point	+3.11	+10.03	+1.10	10.56
Chin Side Cut Point (L)	+2.22	+10.23	-0.57	10.49
Chin Side Cut Point (R)	+5.34	+10.02	+4.89	12.36
Condyle Hinge Axis Center Point	-1.05	+0.02	-2.78	2.97
Condyle Hinge Point (L)	-2.11	+0.05	-5.55	5.94
Condyle Hinge Point (R)	0	0	0	0
Gnathion	+4.24	+12.06	+1.39	12.86
Gonion (L)	-3.53	+4.95	-4.65	7.65
Gonion (R)	-1.61	+2.66	+0.47	3.14
L3 Canine Tip (L)	+1.02	+7.83	-0.67	7.93
L3 Canine Tip (R)	+2.96	+7.70	+2.74	8.69
L6 Mesial Cusp Tip (L)	+0.59	+7.26	-0.93	7.34
L6 Mesial Cusp Tip (R)	+3.48	+6.98	+4.19	8.86
Lower Incisor Tip (L)	+1.82	+8.11	+0.46	8.33
Lower Incisor Tip (R)	+2.24	+8.06	+1.21	8.46
Lower Incisor Tip Midpoint	+2.03	+8.09	+0.84	8.38
Mandible Back Cut Point (L)	+1.52	+9.36	-1.05	9.54
Mandible Back Cut Point (R)	+5.47	+9.01	+5.93	12.10
Menton	+4.35	+11.93	+1.68	12.81
Pogonion	+4.04	+11.81	+1.24	12.54

Figure 4B



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PNS	0	0	0	0
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U3 Canine Tip (R)	0	0	0	0
U6 Mesial Cusp Tip (L)	0	0	0	0
U6 Mesial Cusp Tip (R)	0	0	0	0
Upper Incisor Tip (L)	0	0	0	0
Upper Incisor Tip (R)	0	0	0	0
Upper Incisor Tip Midpoint	0	0	0	0
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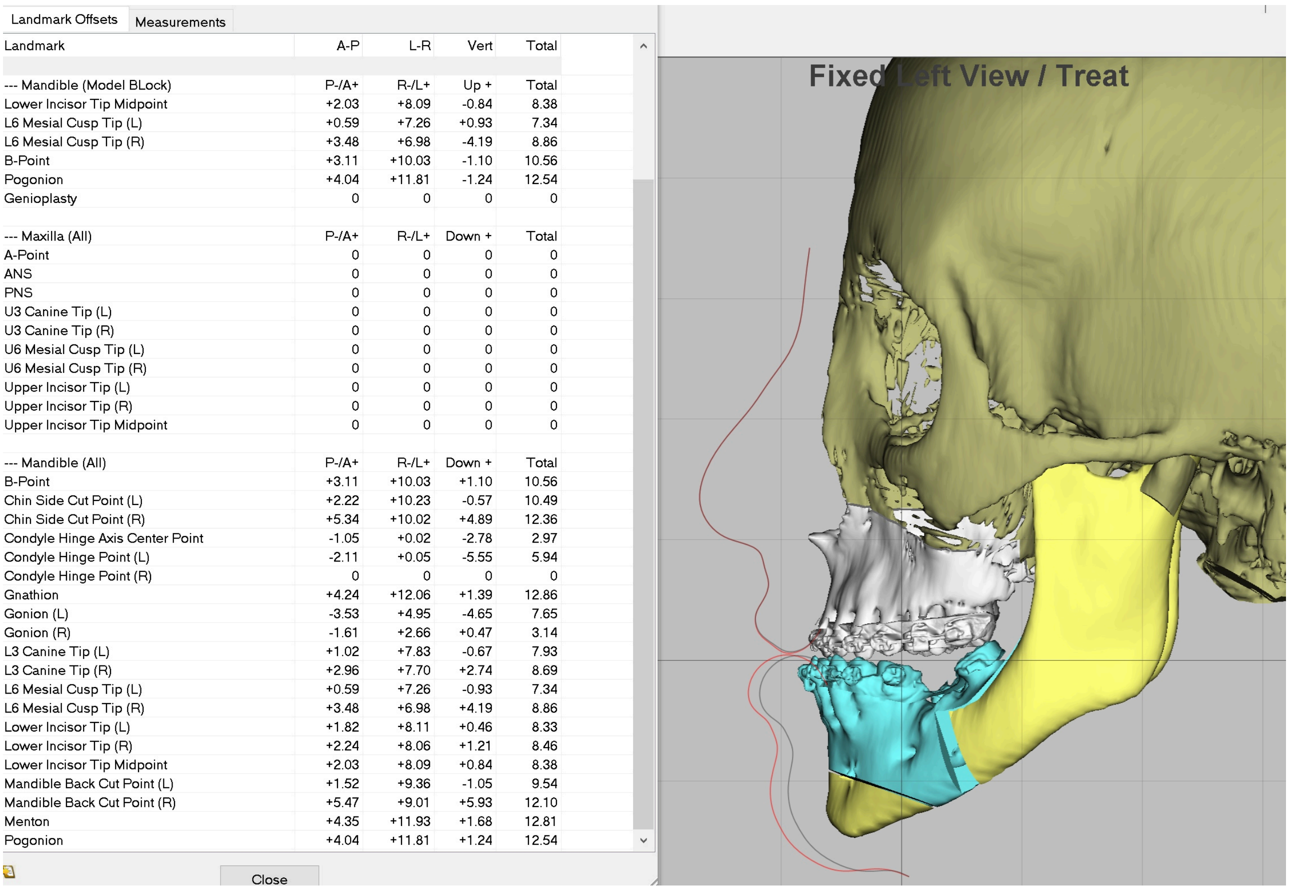
Figure 4C



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U6 Mesial Cusp Tip (R)	0	0	0	0
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Mandible Back Cut Point (L)	+1.52	+9.36	-1.05	9.54
Mandible Back Cut Point (R)	+5.47	+9.01	+5.93	12.10
Menton	+4.35	+11.93	+1.68	12.81
Pogonion	+4.04	+11.81	+1.24	12.54

Figure 4D

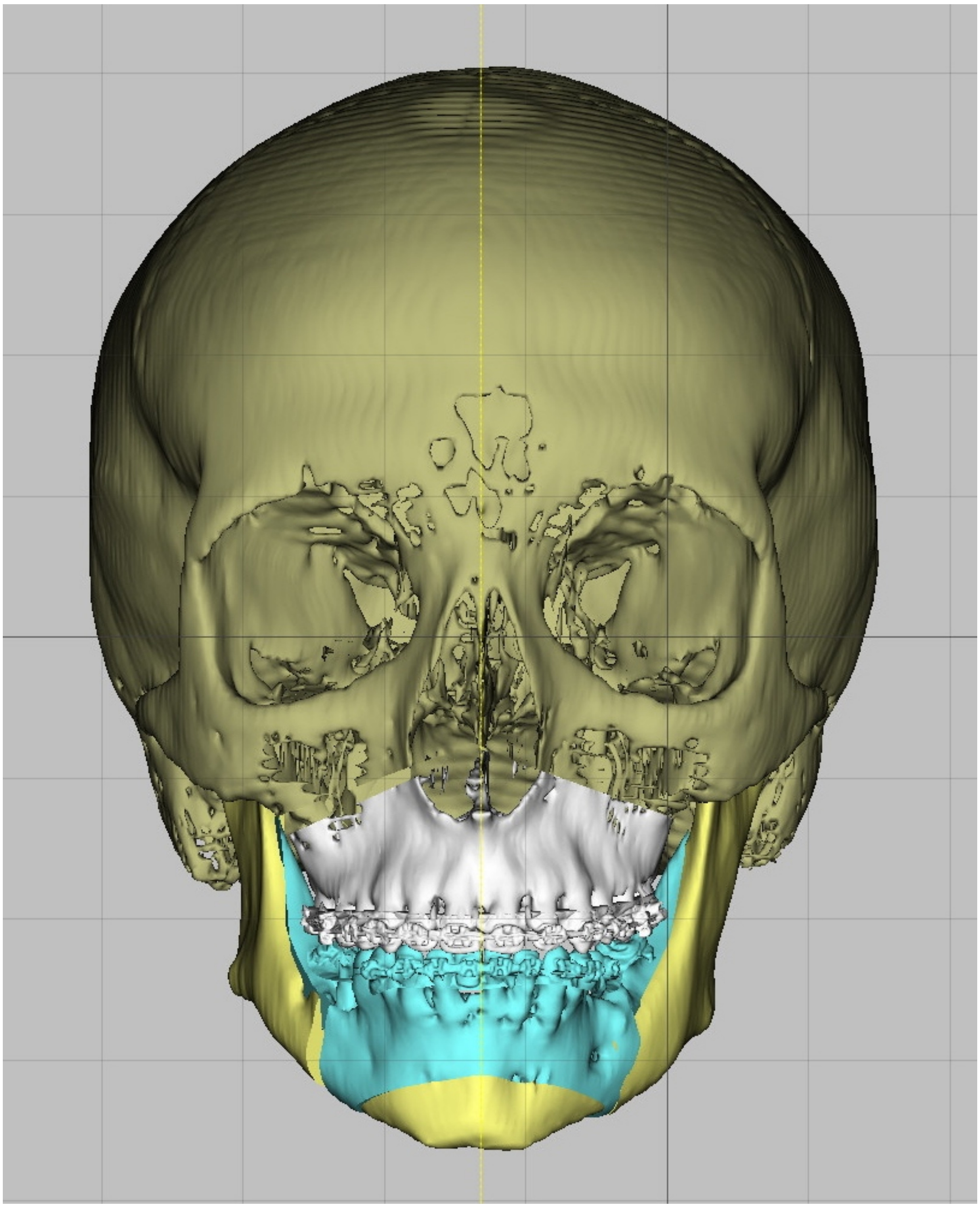

Figure 5A

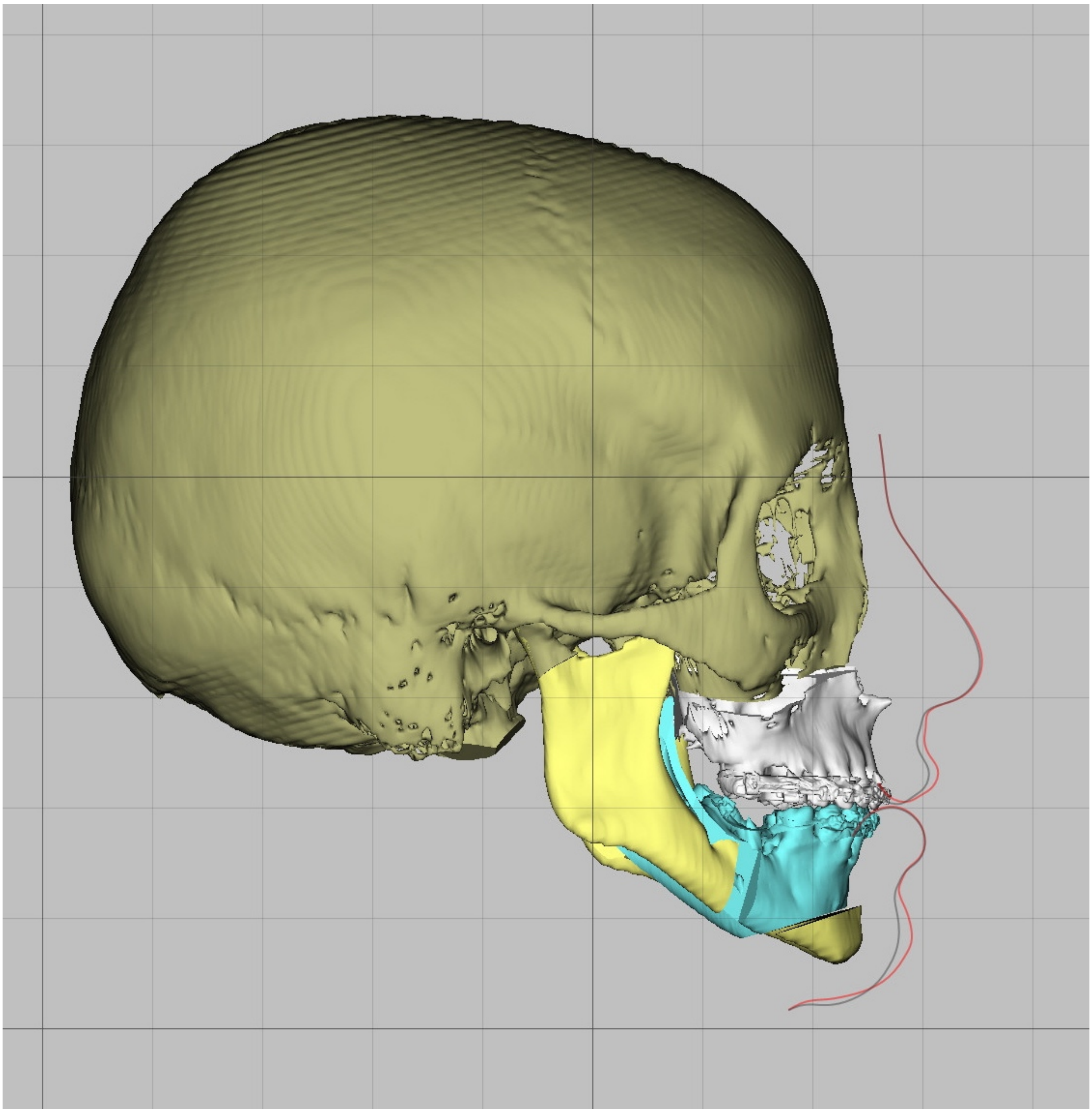

Figure 5B

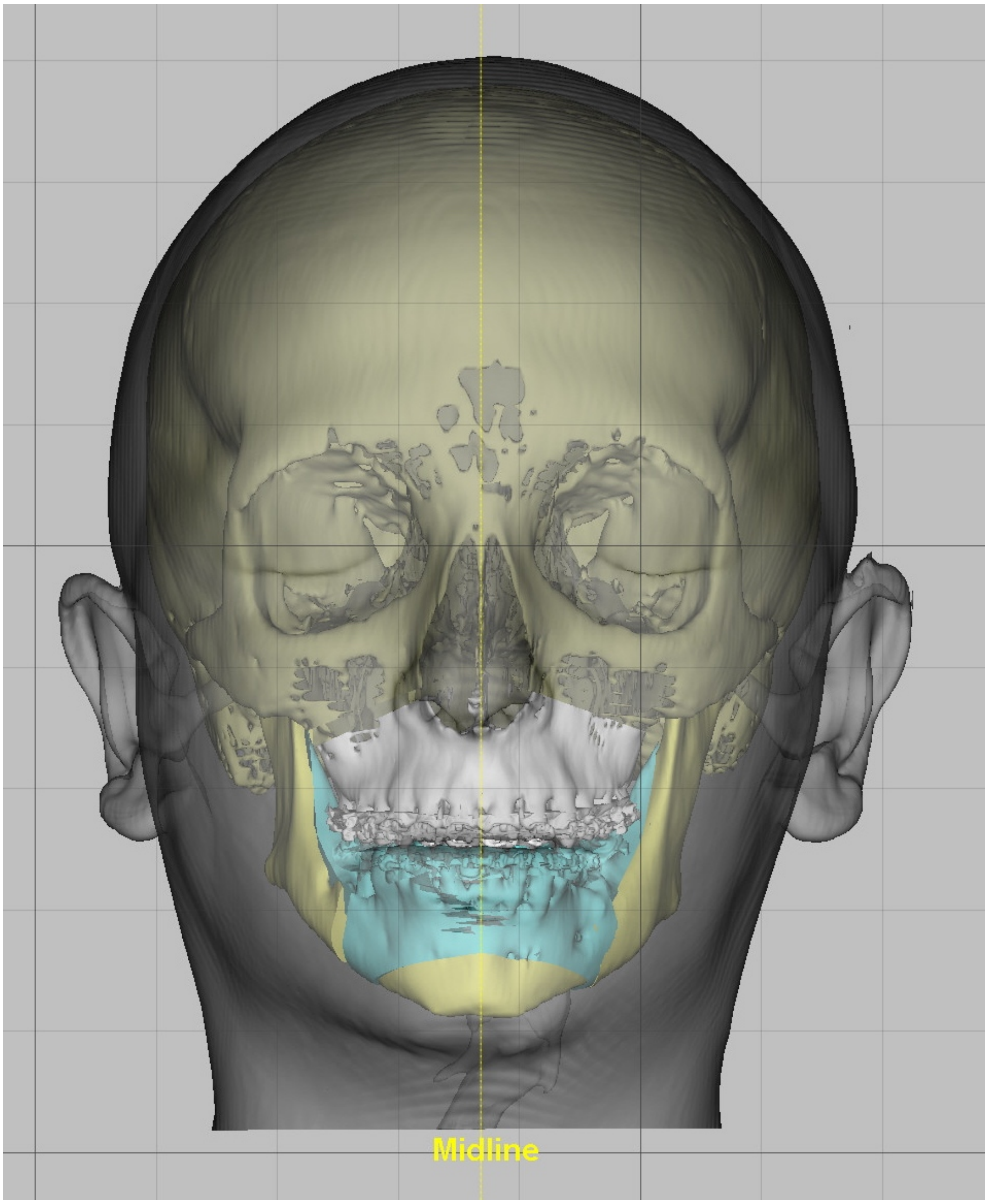

Figure 5C

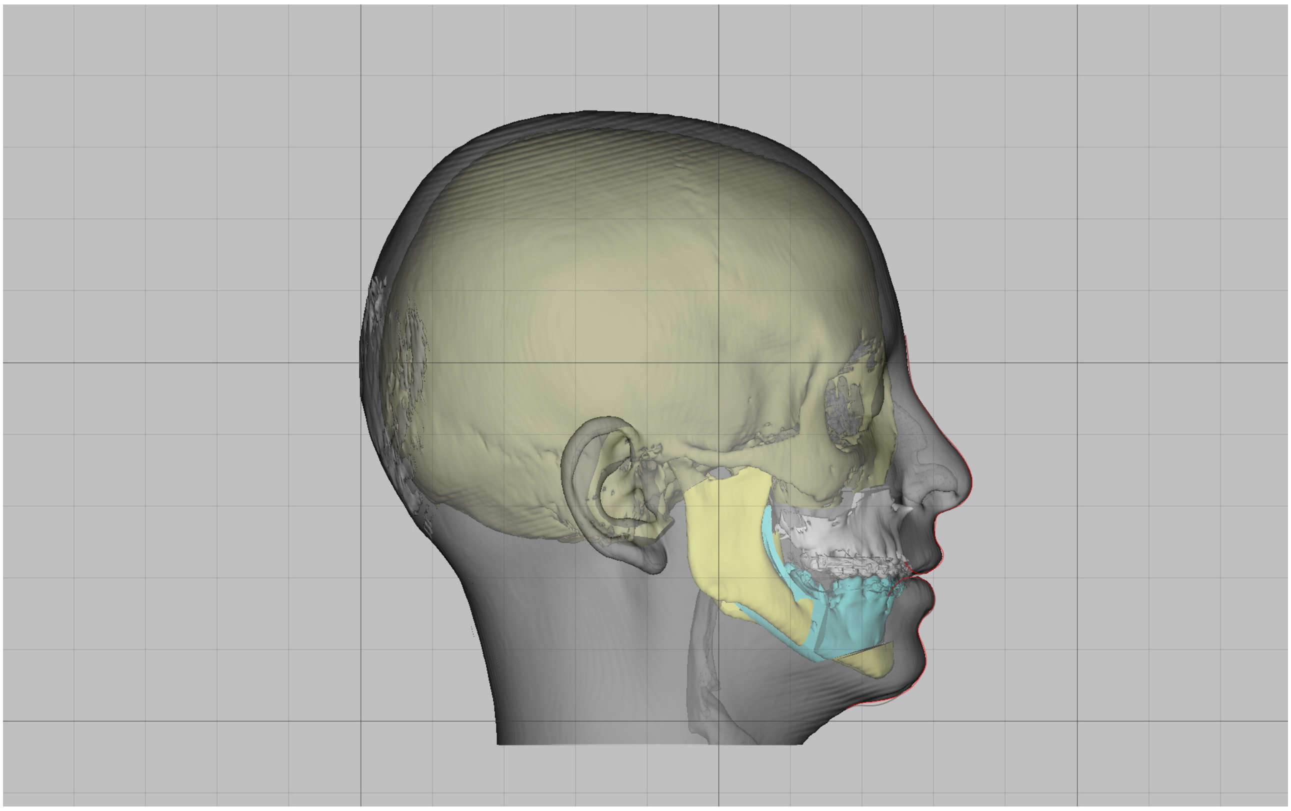

Figure 5D

Figure 6A

Figure 6B

Figure legends

This is a 20-year-old female patient with a development dentofacial deformity characterized by an mandibular asymmetry due to active condylar hyperplasia and maxillary deficiency. The patient underwent combined condylar hyperplasia resection and orthognathic surgery. The orthognathic procedures included BSSO and Le Fort I osteotomies for mandibular and maxillary advancement and correction of jaw asymmetries as well as oblique osteotomy of the chin. Septoplasty and turbinectomy surgeries were performed as well.

Figures 1. 1A. Preoperative facial frontal view. 1B. Preoperative facial profile view.

Figure 2. Yaw axis positioning by the alignment of the ocular globe on CT-scan.

Figures 3. Establishing NHP (3A. frontal view; 3B. lateral view) and virtual patient generation in NHP and CR after digital dental models superposition onto 3D CT reconstruction (3C. frontal view; 3D. lateral view).

Figures 4. 4A. Prediction tracing of mandibular movement identifying first dental contact between operated mandible and unoperated maxilla. Note that in the case presented there was no contact between upper and lower teeth. Such relationship between upper and lower dental arches are common in asymmetries correction since bidimensional prediction trancing does not consider roll adjustment. Hence it must be adjusted during 3D virtual planning in order to reach the desirable outcome; 4B. Frontal view of complete mandible first reposition on 3D virtual planning; 4C. Right lateral view of complete mandible first reposition on 3D virtual planning; 4D. Left lateral view of complete mandible first reposition on 3D virtual planning. In this specific patient there are very similar movements measured on lower incisors, B-point and pogonium while considerable difference could be measured between lower molars due to roll adjustment and correction during such 3D virtual planning.

Figures 5. Final tridimensional treatment simulation (5A. hard tissue frontal view; 5B. Hard tissue profile view; 5C. Hard and soft tissue frontal view. D. Hard and soft tissue profile view.

Figures 6. 6A. Postoperative facial frontal view; 6B. Postoperative facial profile view.

6. CONSIDERAÇÕES FINAIS

Os resultados da pesquisa realizada no intuito de investigar a acurácia do reposicionamento maxilar em cirurgias ortognáticas bimaxilares planejadas sob os conceitos do *Virtual Surgical Planning (VSP)* demonstram que o reposicionamento maxilar é acurado, principalmente em seus movimentos horizontais (eixo z) e transversais (eixo x), e que ainda ocorre uma imprecisão maior que 1mm na direção vertical (eixo y).

No entanto, a comparação entre os grupos do estudo demonstram que os resultados obtidos foram significativamente mais precisos nos planejamentos/procedimento cirúrgicos mais recentes, demonstrando um aumento de acurácia nas reposições maxilares ao longo do tempo. Tal aprimoramento ocorreu a partir do ano de 2015, e os autores acreditam que alguns fatores associados ao planejamento cirúrgico virtual contribuíram para esta melhora; modalidades de exames de imagem, escaneamento e visualização de superficies foram aperfeiçoados ao longo do tempo e nortearam um melhor entendimento de elementos anatômicos e relação entre as estruturas do crânio e dos maxilares. O desenvolvimento dos *softwares* de planejamento e a inclusão de novas ferramentas, bem como a evolução das impressoras e impressões tridimensionais supostamente também favoreceram para as diferenças clínicas e estatísticas encontradas ao longo do artigo 1. Ainda, a experiência dos autores sugere que um melhor entendimento de imagens tridimensionais bem como uma avançada visualização interativa da mobilização e movimentação dos segmentos maxilares e mandibulares foram alcançados ao longo dos anos como resultado de um aprendizado continuo derivado da utilização contínua e repetitiva desta nova tecnologia, caracterizada como curva de aprendizado.

Na comparação entre os movimentos pode-se considerar que os movimentos horizontais, no sentido ântero-posterior são os mais precisos, enquanto os movimentos verticais demonstraram diferenças acima do limite de 1mm quando comparados os resultados planejados e obtidos. Tais discrepâncias são provenientes de inacurácias que ocorrem ainda no planejamento pré-operatório ou no procedimento cirúrgico propriamente dito. A relação incorreta dos côndilos mandibulares com as cavidades glenóides durante a tomada tomográfica ou mesmo durante o reposicionamento maxilar certamente afetará a acurácia do procedimento, principalmente nos sentidos horizontal e vertical. A correta relação destas estruturas em relação cêntrica durante todo o planejamento pre-operatório, bem como a coincidência entre a relação pré-operatória e trans-operatória (após anestesia geral) superará esta limitação. Uma alternativa para solucionar esta possível discrepância é iniciar a cirurgia pela mandíbula, abordado no artigo 2. Ainda, o eixo de rotação condilar está associado a inacurácias dos movimentos maxilares, e a literatura científica corrente ainda é isenta de evidências sobre a precisão do ponto de rotação condilar. Diversos autores já objetivaram localizar o ponto exato de rotação condilar, porém, com resultados incosistentes e com o consenso que a rotação mandibular em imagens bi ou tridimensionais podem não representar o cenário real dos pacientes, resultando em discrepâncias entre valores planejados e resultados obtidos. Um melhor entendimento sobre o eixo de rotação condilar e o desenvolvimento continuo dos *softwares* de planejamento virtual podem guiar cirurgiões a resultados mais precisos ao longo dos próximos anos. No entanto, como a técnica cirúrgica atual ainda permite que o cirurgias altere a quantidade de movimentação vertical da maxila durante o procedimento cirúrgico, tal condição também consiste em um fator para as imprecisões de resultados, principalmente no sentido vertical.

Os resultados do artigo demonstram que 51,3% das mensurações realizadas apresentaram uma diferença entre valores planejados e obtidos ≤1mm, sendo este valor (≤1mm) considerado o limite para a precisão dos resultados. A maior parte dos outros estudos consideraram os resultados obtidos precisos quando a diferença entre resultados planejados e obtidos for ≤2mm. Apesar de ser comum considerar este limite de ≤2mm como fator de sucesso para os resultados, os autores do artigo 1 propõe que estudos que avaliam a acurácia com imagens tridimensionais não devem mais se basear no limite de 2mm e sim no limite abordado no artigo 1, com uma tolerância de 0,5mm relacionada a resolução espacial dos voxel do exame tomofráfico e 0,5mm a limitação do olho humano[9].

O planejamento cirúrgico virtual é um método acurado e reproduzível para o planejando de cirurgias ortognáticas. Ao que tudo indica, a acurácia do planejamento cirúrgico virtual foi influenciada pelo tempo de experiência com esta tecnologia, apesar de não haver certezas para justificar tal afirmação. Apesar do contínuo desenvolvimento dos *softwares*, o cirurgião usuário desta tecnologia deve entender e dominar todos os detalhes do processo de planejamento virtual afim de obter resultados cada vez mais precisos. Além disso, outros estudos clínicos randomizados podem auxiliar na validação a acurácia e reprodutibilidade do método e encontrar novas explicações que justificam as imprecisões ainda encontradas, e ainda encontrar métodos que superam tais limitações.

Conforme já mencionado, uma das alternativas para controlar e/ou evitar possíveis imprecisões de reposicionamento do osso maxilar e/ou mandibular, é iniciar a cirurgia pelo osso mandibular. Apesar de a maioria dos cirurgiões iniciar não apenas a cirurgia, mas também todo o planejamento cirúrgico virtual tridimensional pela maxila, o reposicionamento do osso mandibular de forma primária, durante o planejamento cirúrgico virtual e durante o procedimento em si pode apresentar diversas vantagens. O artigo 2 sugere um protocolo de planejamento cirúrgico virtual 3D no qual a mandíbula é reposicionada primeiramente, seguido então do reposicionamento maxilar. Trata-se de um protocolo detalhado que engloba o passo a passo do planejamento bidimensional e tridimensional, discutindo características, vantagens e limitações do protocolo apresentado.

Simetria facial é essencial para resultados satisfatórios após cirurgias mandibulares, e tal harmonia é principalmente determinada pelo correto posicionamento tridimensional do osso mandibular. A correção de assimetrias faciais, bem como a prevenção de novas assimetrias é um desafio para os cirurgiões e tal situação é mais facilmente manejadas quando a mandíbula é reposicionado primariamente durante o planejamento cirúrgico. Ainda, como já mencionado acima o protocolo de planejar e operar a mandíbula primeiro não é afetado por discrepâncias interoclusais após anestesia geral ou relação cêntrica vulnerável durante a tomada tomográfica ou durante a cirurgia, e também não gera imprecisões de reposicionamento de acordo com o eixo de rotação condilar. Caso o cirurgião decida iniciar o planejamento cirúrgico pelo osso maxilar e o procedimento cirúrgico pela mandíbula, a visualização da oclusão intermediária pode ser limitada, uma vez que alguns *softwares* não permitem resetar a posição da maxila após seu reposicionamento, limitando a visão da oclusão e consequentemente gerando dúvidas quanto a acurácia deste reposicionamento mandibular. No entanto, desvantagens do protocolo citado também existem; porém, apesar de parecer inicialmente complexo, os autores acreditam que o processo todo é simplificado tão logo o cirurgião aprenda as vantagens oferecidas.

Sumariamente, a decisão de qual osso maxilar deve ser abordado primeiramente nos planejamentos cirúrgicos e nas cirurgias ortognáticas bimaxilares depende das vantagens e desvantagens que cada método fornece e na preferência e experiência do cirurgião. Apesar de o sucesso e a precisão dos reposicionamentos maxilares dependerem de vários fatores, os autores acreditam firmemente que, em casos selecionados, o protocolo apresentado no artigo 2 pode gerar resultados promissores com relação a precisão dos movimentos maxilares realizados.

Por ser ainda um protocolo recente, não há estudos comparativos na literatura que evidenciam a acurácia do método apresentado nem estudos que comparam a acurácia deste método de planejamento em relação ao método tradicional utilizado para o estudo do artigo 1. Da mesma forma, estudos pilotos e ensaios clínicos são recomendados para certificar a acurácia deste método bem como comparar com métodos tradicionais de planejamento virtual tridimensional,

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8.1) PARECER COSUBSTANCIADO DO COMITÊ DE ÉTICA EM PESQUISA

PONTIFÍCIA UNIVERSIDADE CATÓLICA DO RIO GRANDE DO SUL - PUC/RS

Plataforma Brasil

Continuação do Parecer: 3.106.910

projeto de pesquisa ANÁLISE RETROSPECTIVA DE PLANEJAMENTO VIRTUAL TRIDIMENSIONAL SOBRE A ACURÁCIA NO MOVIMENTO MAXILAR NAS CIRURGIAS ORTOGNÁTICAS proposto pelo Rogerio Miranda Pagnoncelli com numero de CAAE 05071418.7.0000.5336.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1244906.pdf	21/12/2018 13:05:15		Aceito
Outros	CARTA_SIPESQ.pdf	21/12/2018 13:04:47	Rogerio Miranda Pagnoncelli	Aceito
Outros	SISPESQDocumentoUnificado.pdf	21/12/2018 13:04:17	Rogerio Miranda Pagnoncelli	Aceito
Outros	Pesquisadores.docx	21/12/2018 13:03:50	Rogerio Miranda Pagnoncelli	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoDetalhado.pdf	26/10/2018 15:16:05	Rogerio Miranda Pagnoncelli	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	JustificativaTCLE.pdf	26/10/2018 15:11:41	Rogerio Miranda Pagnoncelli	Aceito
Declaração de Instituição e Infraestrutura	Carta_Autorizacao.pdf	26/10/2018 15:01:49	Rogerio Miranda Pagnoncelli	Aceito
Folha de Rosto	FolhaRosto.pdf	26/10/2018 15:01:05	Rogerio Miranda Pagnoncelli	Aceito
Orçamento	Orcamento.pdf	25/10/2018 10:05:52	Rogerio Miranda Pagnoncelli	Aceito
Declaração de Manuseio Material Biológico / Biorepositório / Biobanco	Autorizacao_manuseio_material_biologico.pdf	25/10/2018 09:59:27	Rogerio Miranda Pagnoncelli	Aceito
Declaração de Instituição e Infraestrutura	Autorizacao.pdf	25/10/2018 09:42:59	Rogerio Miranda Pagnoncelli	Aceito
Brochura Pesquisa	Projeto.pdf	25/10/2018 09:41:57	Rogerio Miranda Pagnoncelli	Aceito
Declaração de Instituição e Infraestrutura	Termos.pdf	25/10/2018 09:20:28	Rogerio Miranda Pagnoncelli	Aceito
Cronograma	Cronograma.pdf	25/10/2018 09:18:11	Rogerio Miranda Pagnoncelli	Aceito

Endereço: Av.Ipiranga, 6681, prédio 50, sala 703
Bairro: Partenon **CEP:** 90.619-900
UF: RS **Município:** PORTO ALEGRE
Telefone: (51)3320-3345 **Fax:** (51)3320-3345 **E-mail:** cep@pucrs.br

8.2) CARTA DE APROVAÇÃO DO PROJETO DE PESQUISA NO SISTEMA DE PESQUISAS DA PUCRS

S I P E S Q

Sistema de Pesquisas da PUCRS

Código SIPESQ: 8912

Porto Alegre, 8 de outubro de 2018.

Prezado(a) Pesquisador(a),

A Comissão Científica da ESCOLA DE CIÊNCIAS DA SAÚDE da PUCRS apreciou e aprovou o Projeto de Pesquisa ""ANÁLISE RETROSPECTIVA DO PLANEJAMENTO VIRTUAL TRIDIMENSIONAL SOBRE A ACURÁCIA NO MOVIMENTO MAXILAR NAS CIRURGIAS ORTOGNÁTICAS"".

Atenciosamente,

Comissão Científica da ESCOLA DE CIÊNCIAS DA SAÚDE

8.3) CARTA DE APROVAÇÃO PARA USO DE DADOS OBTIDOS EM UNIVERSIDADE PARCEIRA

UIC UNIVERSITY OF ILLINOIS AT CHICAGO

Department of Oral and Maxillofacial Surgery
801 South Paulina Street Room 110
Chicago, Illinois 606 12-72 11

Chicago, June 18th 2018.

Ao Comitê de Ética e Pesquisa da PUCRS

Ilma. Coordenadora do Comitê de Ética
Profa. Dra. Denise Cantarelli Machado

Authorization Letter

After reviewing the proposed research project, I hereby authorize Fernando Antonini to conduct the research titled Retrospective Analysis of Virtual Surgical Planning on Maxillary Accuracy in Bimaxillary Orthognathic Surgeries in the Oral and Maxillofacial Surgery Department at the University of Illinois at Chicago.

I also give Fernando Antonini permission to access and analyze all patients records and CBCT's exams required for the above mentioned project , as well as, using the collected data during a research project for PhD program thesis at Pontifícia Universidade Católica do Rio Grande do Sul.

All research materials (data, records, documents or exams) will be protected according HIPPA and CEP-PUCRS protocols during the complete development of the research.

If you have any concerns about the permission being granted by this letter, please contact me at the [phone number &/or email address] listed below.

Sincerely,

Dr. Michael Miloro, DMD, MD, FACS
Professor and Head, Oral and Maxillofacial Surgery
University of Illinois, College of Dentistry
801 S. Paulina St., Room 110
Chicago, IL 60612
(312)996-1052
mmiloro@uic.edu

8.4) DOCUMENTO DE APROVAÇÃO DO INSTITUTIONAL BOARD REVIEW (IRB) - *UNIVERSITY OF ILLINOIS AT CHICAGO*

UIC

Approval Notice
Initial Review (Response To Modifications)

April 18, 2018

Michael Han, DDS
Oral and Maxillofacial Surgery
801 S. Paulina Street
Oral and Maxillofacial Surgery
Chicago, IL 60612
Phone: (312) 996-7409 / Fax: (312) 996-5987

RE: Protocol # 2018-0276
"Accuracy of virtual surgical planning of orthognathic surgery over time"

Dear Dr. Han:

Your Initial Review (Response To Modifications) was reviewed and approved by the Expedited review process on April 18, 2018. You may now begin your research

Please note the following information about your approved research protocol:

Protocol Approval Period: April 18, 2018 - April 17, 2021
Approved Subject Enrollment #: 100
Additional Determinations for Research Involving Minors: The Board determined that this research satisfies 45CFR46.404, research not involving greater than minimal risk. Wards of the State may not be enrolled unless the IRB grants specific approval and assures inclusion of additional protections in the research required under 45CFR46.409. If you wish to enroll Wards of the State contact OPRS.
Performance Sites: UIC
Sponsor: None
Research Protocol(s):

a) Chronological accuracy of orthognathic virtual surgical planning, Version 2, 04/03/2018

Recruitment Material(s):

a) No Recruitment Materials will be Used

Informed Consent(s):

a) Waiver of Informed Consent Granted Under 45 CFR 46.116(d)

Assent(s):

a) Waiver of Child Assent Granted Under 45 CFR 46.116(d)

Parental Permission(s):

a) Waiver of Parental Permission Granted Under 45 CFR 46.116(d)

HIPAA Authorization(s):

a) HIPAA Waiver of Authorization Granted Under 45 CFR 164.512(i)(1)(i)

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1) under the following specific category:

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Please note the Review History of this submission:

Receipt Date	Submission Type	Review Process	Review Date	Review Action
03/05/2018	Initial Review	Expedited	03/19/2018	Modifications Required
03/28/2018	Response To Modifications	Expedited	04/18/2018	Approved

Please remember to:

→ Use your **research protocol number** (2018-0276) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the guidance:
"UIC Investigator Responsibilities, Protection of Human Research Subjects"
(http://research.uic.edu/irb/investigators-research-staff/investigator-responsibilities)

Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 355-5438. Please send any correspondence about this protocol to OPRS via OPRS Live.

Sincerely,

Tina S. Johnson, MA
IRB Coordinator, IRB # 1
Office for the Protection of Research Subjects

cc: Michael Miloro, Oral and Maxillofacial Surgery, M/C 835
Privacy Office, Health Information Management Department, M/C 772

UNIVERSITY OF ILLINOIS AT CHICAGO
Office for the Protection of Research Subjects
201 AOB (MC 672)
1737 West Polk Street
Chicago, Illinois 60612
Phone (312) 996-1711

9.1) CARTA DE ACEITE PARA PUBLICAÇÃO ARTIGO 2

View Letter

Close

Date:	05 Feb 2019
To:	"Fernando Antonini" antonini.ctbmf@gmail.com;antonini_fernando@hotmail.com
From:	"Henning Schliephake" Schliephake.Henning@med.uni-goettingen.de
Subject:	OMFS: Your manuscript entitled Tridimensional virtual planning protocol for double-jaw orthognathic surgery with mandible first surgical sequence

Ref.: Ms. No. OMFS-D-18-00139R1
Tridimensional virtual planning protocol for double-jaw orthognathic surgery with mandible first surgical sequence
Oral and Maxillofacial Surgery

Dear Dr Antonini,

I am pleased to tell you that your work has now been accepted for publication in Oral and Maxillofacial Surgery.

It was accepted on 05 Feb 2019.

Thank you for submitting your work to this journal.

With kind regards

Henning Schliephake, M.D., D.M.D., PhD
Editor-in-Chief
Oral and Maxillofacial Surgery

Reviewer #1: Authors have added to discussion, enhancing integrity of the manuscript
No further objections to publications, need for some technical revision, not on content

****

MARISTA PUCRS

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