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A CAD/CAM Maxillary Guiding for Osteotomy, Drilling and Maxillary Positioning in Orthognathic Surgery: Accuracy Analysis.

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HIGHLIGHTS

- Proposal of a new CAD/CAM guide technique for osteotomy, drilling, and maxillary positioning.
- Standard miniplate modeled on 3D print was used similarly a custom miniplate.
- Cutting and drill resin guide was modeled virtually using a 3D scan of the drilled model surface.
- The surgical accuracy test of the proposed technique supports its use.

Abstract: Resin CAD/CAM guides for the maxilla are widely used and differ from custom miniplates essentially in that they do not have drill guides for screw fixation and use miniplates that must be modeled in surgery. To solve this problem, we have developed a new Maxillary guide bone-supported indicated for osteotomy, drilling, and maxillary positioning in orthognathic surgeries using standard modeled miniplates. In this study were included sixteen patients who had bimaxillary orthognathic surgery. The technique for its manufacturing is described, and its surgical accuracy was analyzed using the planning image (CT0) superimposed on the computed tomography scan post-treatment (CT1). The mean positional differences between pre-treatment and post-treatment were obtained Tri-dimensionally on the X, Y, and Z axes using four landmarks points: one bone (SNA), and three dentals (CI, RM, and LM). At Sixty-four points analyzed on the X axis of the four landmarks, only eight points were greater than 1 mm; 87.5 % of the deviations were <1 mm. For the Y-axis 78.12% of the deviations were <1 mm and for Z-axis, 76.56 %. The mean and standard deviation of the error was 0.36 (0.28) mm, 0.93 (1.07) mm, and 0.73 (0.86) mm on the X, Y, and Z axes,

respectively. The X-axis demonstrated the best results among the three axes. The results of the accuracy and reliability tests were satisfactory and support the use of the proposed technique.

Keywords: Orthognathic Surgery; Osteotomy; Le Fort; Splints; Surgical Fixation Devices; Computer-Aided Design.

INTRODUCTION

Planning of three-dimensional (3D) positioning of the maxilla is essential for the success of orthognathic surgeries and requires complex control of the spatial axes. The Le Fort I procedure is challenging to perform. With the objective of obtaining greater surgical accuracy in this procedure, we use virtual planning and surgical guides for perforation, cutting, and bone fixation with customized miniplates [1,2,3]. A pioneering multicenter study, using computer-aided design/computer-aided manufacturing (CAD/CAM) guides, demonstrated that customized guides have greater surgical accuracy than the conventional method [4,5,6]. Several studies have performed virtual guide modeling with CAD/CAM technology and 3D printing of customized plates and guides using biocompatible photoactivated resin or titanium [1–3,7–22]. The translation of virtually planned movements to the operative field is more accurate with the use of these customized titanium devices. Custom-made miniplates are still state-of-the-art in the field of orthognathic surgery [6,7,8]. However, the logistics, the time required for industrial production, and the high manufacturing costs, which are rarely covered by health plans, may limit surgeons' access to customized titanium miniplates [6].

Three-dimensional CAD/CAM maxillary guides were developed, ensuring good surgical predictability, resulting in a more reliable method, as it reduces mandibular interference (centric relation) and lack of planning accuracy, particularly in asymmetrical cases [1,2].

Three-dimensional (3D) planning of maxilla positioning is essential for the success of orthognathic surgeries and requires complex control of the spatial axes. The Le Fort I osteotomy procedure is challenging to perform. In order to achieve greater surgical precision in this procedure, we use computer-aided design/manufacturing (CAD/CAM) guides to achieve better surgical precision than the conventional method [7].

In this context, some studies have evaluated low-cost alternatives [6]. Unfortunately, its high cost restricts the use in less developed countries. Cheaper alternatives such as customized resin guides, which are laser-printed using a biocompatible resin with the assistance of CAD/CAM technology, are also available. This technique has good surgical precision but does not present a perforation guide for screws [4]. Additionally, the miniplate is modeled during the surgical procedure, increasing the time of surgical intervention and the possibility of errors, which are consequential limitations [7,23].

We proposal a new supported bone guide with the differential of being the only resin CAD/CAM guide to have a drilling guide for screw fixation, associated with previously modeled traditional miniplates; to simulate the fixation technique of customized plates, which automatically transpose the planned movements virtually to the intraoperative period.

The purpose of this research aims to demonstrate the surgical accuracy of a new CAD/CAM cutting and perforation guide.

MATERIAL AND METHODS

This study was approved by the Ethics Committee on Research in Human Beings of the Center for Tropical Medicine of the Institute of Health Sciences of the Federal University of Pará (ICS/UFGPA:87554218.0.0000.0018 under opinion number 2,903,830). All participants were individually informed about the research and agreed to participate by signing a free informed consent form. This series of cases was part of a quantitative and prospective clinical study reported according to the STROBE guidelines [24]. Patients who were operated on by the same Bucomaxillofacial Surgeon of the Federal University of Pará and Ophir Loyola Hospital in Brazil between March and December 2022 were included. Participants were selected for the study according to the following eligibility criteria: (1) they underwent bimaxillary orthognathic surgery and (2) they were operated on by the same surgeon. Exclusion criteria were the following: (1) unwanted bone fractures in the maxilla; (2) children aged under 16 years or adults aged over 60 years; (3) previous history of irradiation; (4) history of maxillary segmentation; (5) previous orthognathic surgery. Sixteen patients, (seven men and nine women, aged 21-42 years), who had bimaxillary orthognathic surgery were included in this study. Relating to the recruitment 16 patients are eligibility the allocation is at randomization attributed to chance and all participants were added to a single group.

Accuracy analysis methodology:

Immediately after the surgical procedure, the patients underwent a CT scan to check the outcome. The virtual skull was segmented, and we used the zygomatic, nasal, maxillary, and upper teeth bones for analysis: Point SNA (anterior nasal spine), point CI (left central incisor), point RM (mesiobuccal cusp of the right first molar), and point LM (mesiobuccal cusp of the first left molar). To align the preoperative STL file with the STL of the postoperative CT scan, we used Meshmixer (Autodesk, San Francisco, CA, USA). The overlap was performed automatically by the software using equal markings that do not shift after the Le Fort I osteotomy.

The accuracy of the points was measured using Cloud Compare (Cloud compare®, Boston, MA, USA). Two STL files were obtained from each patient: one from virtual planning (CT0) and the other from operated maxillary tomography (CT1). The two images were imported into the 3D alignment package software [8]. The overlap between CT0 and CT1 and the precision analysis were performed as follows: four fixed points (one bone and three dentals). 3D movement due to the Le Fort I osteotomy were marked in the initial planning (CT0): point ENA (anterior nasal spine), point CI (left central incisor), point RM (mesiobuccal cusp of the right first molar), and point LM (mesiobuccal cusp of the first left molar). To select the points, we considered the requirement of having three points distributed to orient an object in a 3D space (axes X,Y,Z) [9]. The same points were also marked in postoperative (CT1) and named R0, R1, R2, and R3, respectively, by the software. Since they are 3D images, for each of the points, three measurements were obtained, which referred to the three axes of maxillary movement: the mediolateral axis (X), anteroposterior axis (Y), and vertical axis (Z). Thus there were 12 measurements for the planning image and 12 equivalents for the postoperative period. (Figure 1)

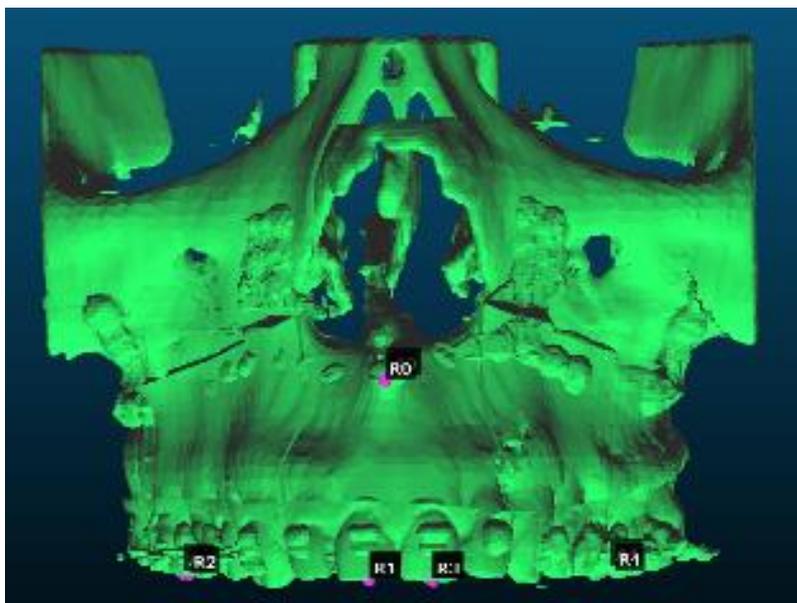


Figure 1. The overlap between CT0 and CT1 at Cloud Compare software.

Statistical analysis:

For accuracy analysis after the measurement of CT0 and CT1 data at all points (ENA, CI, LM, RM) and axes (X,Y,Z), the data were tabulated in a spreadsheet (Excel, Microsoft, Redmond, WA, USA). To determine the agreement between the planned and postoperative results, the Bland–Altman method was used. Student's t-test was used to compare the preoperative and postoperative groups, and the Dahlberg test was used to analyze the error of the method. The measurements and alignment were made by 3 different people to validate the methodology and the Anova test was used. There was no disagreement among the evaluators. The accuracy of the guide was evaluated separately for the three planes: midlateral (X), anteroposterior (Y), and vertical (Z), and at each of the maxillary points (SNA, CI, RM, and LM). The lack of agreement was estimated using differences (d) and standard deviations (SD) with a 95% confidence interval (CI). In this study, <1 mm positional differences between CT0 and CT1 were considered clinically insignificant, and differences up to 2 mm were considered acceptable. The software used for the calculation the Bland–Altman test, t-test, and Dahlberg Test was a spreadsheet preconfigured with the three test formulas in Microsoft Excel software. (Table 1 and 2).

Laboratory preparation of guide:

Two prebent miniplates for the maxilla were adapted and manually modeled on the 3D model of the virtual planning. The plates were placed on each side of the piriform aperture for the Le Fort I osteotomy. Holes were drilled in the 3D-printed model using a 702 surgical drill, with the holes of the modeled plate serving as a guide (Figure 2).



Figure 2. Prebent miniplates modeled on a 3D skull model. Holes were drilled.

The 3D model is inserted into its initial position. This can be done manually or aligned with the initial planning in the Meshmixer software (Autodesk, São Rafael, USA) (Figure 3).

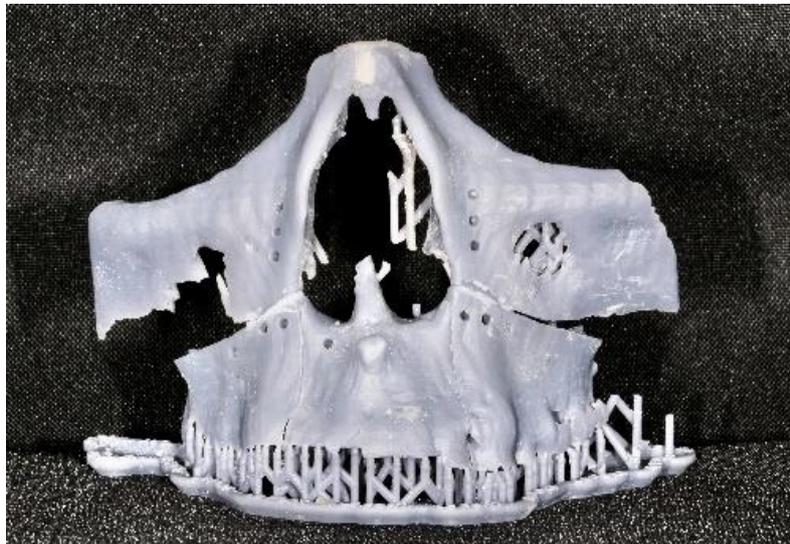


Figure 3. 3D model inserted into its initial position

To obtain the drill guide markings, a 3D scan of the model surface is performed. We used an intraoral scanner (Virtuo Vivo, Straumann, Switzerland). We designed the guide virtually in the Meshmixer software and used the holes previously made in the 3D printed model as the drill guide. We decided to make a single guide for drilling and cutting all the necessary markings, as it is easier and faster to position during surgery. The anatomy of the nasal fossa favors the correct positioning (Figure 4).

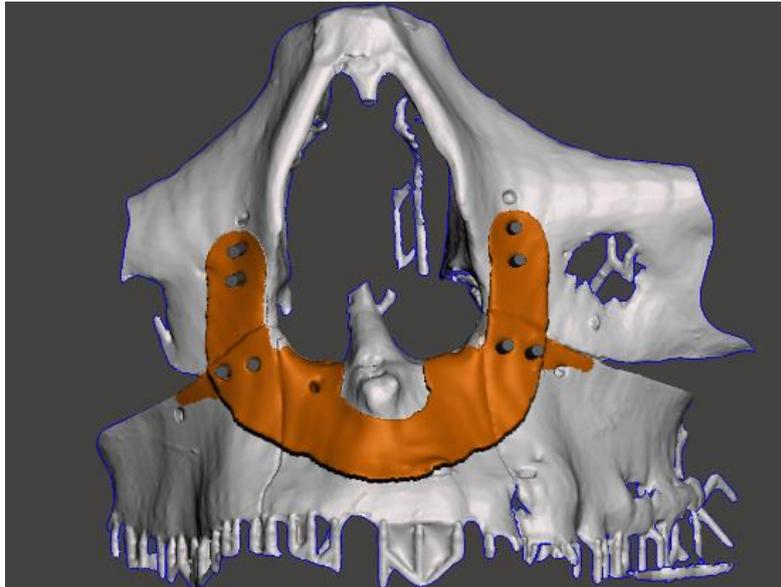


Figure 4. Guide, modeled in the Meshmixer software, fixed in the holes previously made in 3D printed model.

The CAD/CAM guide was 3D printed (Formlabs2, Somerville, USA), with biocompatible resin in 50 microns. (Surgical Guide Resin, Formlabs, USA).

Surgical procedure:

Access and detachment of the maxilla had to be sufficiently spacious for the guide to be passively seated and to avoid contact with the soft tissue. The bone guides were placed in position. As they were supported by bones, they passively adapted to the anatomy of the maxilla and nasal floor. The first drilling was performed using a monocortical drill (1.5 system), followed by the installation of a 6-mm screw. The sequence was repeated for installing the second screw, which ensured device stability. With the lower guide in position, the osteotomy site was marked using the upper edge of this guide as a reference. The guides were removed and discarded after drilling for plate fixation. Osteotomy was performed with a saw or piezo, with the osteotomy site previously marked by the guides. When we were installing the miniplate, to facilitate the fixation of the maxilla, we began with the lower perforations of the maxilla moving fragment in the planned position using an intermediate splint. This allowed us to check if the miniplate presented passivity and provided surgical confidence that the guides were made and used correctly. In this study, no patient underwent surgery without a surgical splint. Although surgery can be performed without a splint, we opted for the use of a traditional splint for better posterior control and to avoid any complications later.

The procedure involved auxiliary–maxillary positioning and the use of pre-modeled plates and guided perforations. This methodology provided surgical accuracy and helped with the evaluation of the reliability of the virtual planning

If there was found no passivity owing to bone contact, wear and tear were required until the installation was passive. After this step, the upper screws of the 1.5-mm system were installed in the previous perforations, which were made using the supported bone upper guide. The virtually planned steps were translated to the patient for the installation of the plate modeled for the maxilla (Figures 5, 6).



Figure 5. Maxillary fixation with prebent plate, system 1.5, modeled before surgery, using perforations previously made with miniplate guide.

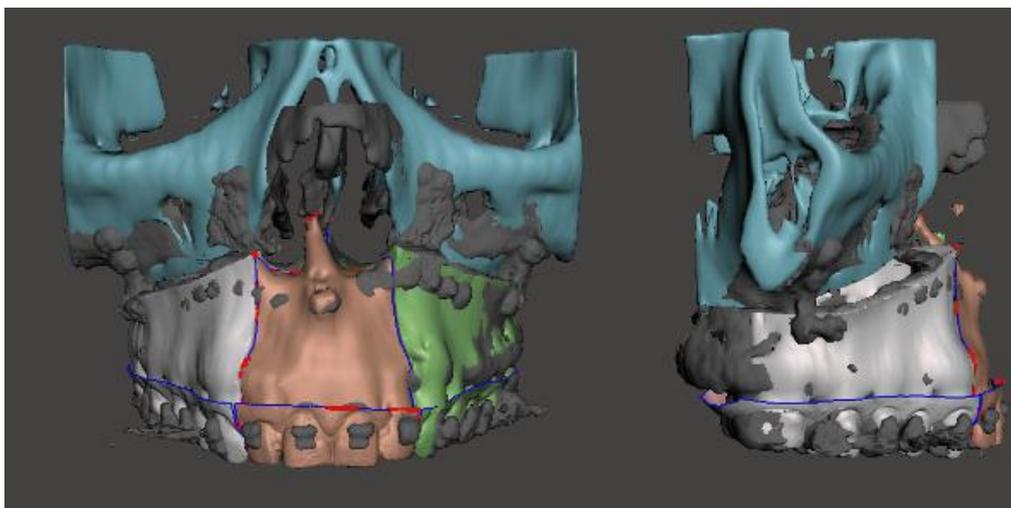


Figure 6. Front and side view of the overlap. Virtual planning with immediate postoperative tomography.

RESULTS

The results are presented in Table 1 and Table 2.

An analysis of the data in Table 1 indicated that the X-axis, which is related to lateral-lateral movement, demonstrated the best results among the three axes. In this axis, the lowest deviation recorded was at the incisal point (CI) of the right upper canine, with a bias and standard deviation of 0.00 and 0.45, respectively. The largest deviation recorded was at the right molar, with a bias and standard deviation of 0.32 and 0.65, respectively. On the X-axis (Table 2), the results of the mean and standard deviation at the four points (SNA, CI, RM, and LM) were 0.36 and 0.28 mm, respectively. The smallest and largest deviations were 0.01 and 1.56 mm, respectively. Of the 64 points analyzed on the X axis, only eight points were greater than 1 mm (that is, 87.5 % of the deviations were <1 mm). No point had a deviation >2 mm.

For the Y-axis (anteroposterior movement) (Table 1), the smallest deviation recorded was at the RM point with a bias and standard deviation of 0.01 and 0.96, respectively. The largest deviation had a bias and standard deviation of 0.54 and 1.01, respectively, at the CI point. The performance of the Y-axis at the four points (SNA, CI, RM, and LM) was 0.93 (1.07) (Table 2). The smallest and largest deviations were 0.03 mm and 2.19 mm, respectively. Of the 64 points analyzed on the Y-axis, 14 points were greater than 1 mm. Notably, 78.12% of the deviations were <1 mm. Three points had a deviation >2 mm, with 95.31 % of the total deviations being <2 mm.

For the Z-axis (vertical movement) (Table 1), the smallest deviation (0.03 mm) recorded was at the LM point, with a standard deviation of 0.90 mm. The largest deviation was at the CI point, with a mean and standard deviation of 0.79 mm. The performance on the Z axis (Table 2) shows the results of the mean (0.73 mm) and standard deviation (0.86 mm) for the four points (SNA, CI, RM, and LM). The smallest and largest deviations were 0.02 and 2.33 mm, respectively. Of the 64 points analyzed on the Z-axis, 15 points presented errors >1 mm. Therefore, 76.56 % of the deviations were <1 mm, and 5 points had a deviation >2 mm. Overall, 92.18 % of the deviations were < 2 mm on this axis.

No cases of infection or loss of miniplate or screw fixation were reported during the postoperative study period.

Table 1. Average in millimeters (mm) of the differences between the planning (CT0) and postoperative (CT1) images, in the three axes (x, y and z) and in each evaluated point (SNA, CI, RM, LM) by the Bland and Altman's agreement, Student's t-test and Dalberg's Formula.

	Bias and Standard deviation (n=16)	Positional Difference (IC 95%) <i>Minimum/Maximum</i>	t-test (p valor)	Dalberg's Formula
X Axis				
SNA point	-0,01 (0.42)	-0.85/0.82	p = 0.87	0.30
CI point	0.00 (0.45)	-0.89/0.88	p = 0.91	0.30
RM point	-0.32 (0.65)	-1.60/0.94	p = 0.12	0.49
LM point	-0.10 (0.63)	-1.34/1.13		0.45
Y axis				
SNA point	0.10 (0.96)	-1.78/2.00	p=0.80	0.65
CI point	-0.54 (1.01)	-2.50/1.42	p=0.11	0.71
RM point	0.01 (0.96)	-1.88/1.91	p=0.76	0.68
LM point	0.06 (0.96)	-1.81/1.95	p=0.53	0.69
Z axis				
SNA point	-0.08 (0.87)	-1.79/1.61	p=0.76	0.74
CI point	0.18 (0.79)	-1.37/1.75	p=0.26	0.56
RM point	0.21 (0.87)	-1.92/1.50	p=0.48	0.60
LM point	0.03 (0.90)	-1.75/1.80	p=0.78	0.61

Legend: Negative sign (-) = maxillary left positional difference; Positive sign (+) = maxillary right positional difference; X = mediolateral movement; Y = anteroposterior movement; Z = vertical movement; SNA = point 0 (skeletal); CI = point 1 (dental); RM = point 2 (dental); LM = point 3 (dental). IC = (95% confidence interval). (N = 16) = sample number. Dahlberg's formula = provides a method of quantifying measurement error. (p) Student's t-test = $p > 0,05$ was used to confirm that the sample groups are not different.

Table 2. Average of the differences obtained between CT0 (planning) and CT1 (postoperative), in the X, Y and Z axes, for each patient, in the 4 maxillary points analyzed.

Patients	Gender	Deviation					
		Axe X		Axe Z		Axe Y	
		Mean of all 4 points	Error <1 mm/<2mm (%)	Mean of all 4 points	Error <1 mm/<2mm (%)	Mean of all 4 points	Error <1 mm/<2mm (%)
1	F	0.32 (0.12-1.56)	75/100	0.25 (0.12-0.77)	100/100	0.24 (0.09-0.72)	100/100
2	F	0.26 (0.23-0.47)	100/100	0.07 (0.02-1.20)	100/100	0.17 (0.12-0.45)	100/100
3	M	0.54 (0.19-0.58)	75/100	0.17 (0.19-1.70)	75/100	0.12 (0.01-0.49)	100/100
4	F	0.32 (0.12-0.62)	100/100	0.27 (0.17-1.10)	100/100	0.45 (0.20-1.47)	75/100
5	F	0.15 (0.08-0.45)	100/100	0.96 (0.22-2.09)	50/75	0.64 (0.41-2.08)	50/75
6	M	0.56 (0.25-1.22)	75/100	1.19 (0.48-2.11)	50/75	0.43 (0.22-1.07)	75/100
7	F	0.41 (0.25-0.58)	100/100	0.71 (0.36-2.09)	75/100	0.32 (0.10-0.72)	100/100
8	F	0.19 (0.14-0.43)	100/100	0.50 (0.03-1.57)	100/100	0.45 (0.13-2.09)	50/75
9	M	0.44 (0.08-0.43)	100/100	0.34 (0.27-1.56)	100/100	0.79 (0.31-2.33)	75/75
10	M	0.55 (0.09-0.92)	50/100	0.56 (0.17-1.58)	75/100	0.45 (0.19-1.27)	75/100
11	F	0.23 (0.11-0.43)	100/100	0.19 (0.08-0.56)	100/100	0.34 (0.23-1.43)	75/100
12	M	0.64 (0.33-0.90)	100/100	0.88 (0.31-1.82)	75/100	0.82 (0.04-2.27)	75/75
13	M	0.72 (0.03-1.37)	50/100	1.45 (0.39-2.19)	50/75	1.22 (0.03- 2.02)	50/75
14	F	0.63 (0.37-1.38)	75/100	0.62 (0.07-0.90)	100/100	0.95 (0.59-1.47)	50/100
15	M	0.42 (0.06-0.42)	100/100	0.97 (0.19-1.56)	50/100	0.31 (0.02-0.81)	100/100
16	F	0.60 (0.16-0.60)	100/100	0.64 (0.01-1.44)	50/100	1.02 (0.44-2.15)	75/75

Legend: **M** =male;**F** =female; **4 points** =(SNA, CI, RM and LM); **X** =mediolateral axis; **Y** =anteroposterior axis; **Z**=vertical axis. **mm**=millimeter

DISCUSSION

The results of our cases were analyzed using postoperative tomography and compared with preoperative planning. The analysis and comparison proved the accuracy and applicability of the technique. We use the basic principles of customized orthognathic surgery that are already widely practiced and scientifically proven. In addition, a surgeon can manually confirm the measurements during the surgical procedure and make any necessary changes [1,6,7,9,10,13].

The results of the maxillar positioning differences comparing the before and after of Le Fort I surgery indicate mean deviation <1mm in 87% of points in X-axis, 78% in the Y-axis and 77% in the Z-axis. Of the analyzed points in the X, Y and Z-axis, 100%, 95% and 82%, respectively show mean deviation <2mm. When comparing results of the literature, these accuracy indicates that the observed deviation in our cases study, are nearer of the deviation obtained with customized guide. As an example of the accuracy of these guides, a multicenter study obtained an average movement of 3D planning for the surgery performed of only 0.73 mm, thereby reaching the conclusion that the customized guide is more accurate than the conventional method (1.63 mm) [9]. Three years later (2016), Li and coauthors used a sample of nine patients with CAD-CAM guides and obtained a mean deviation of 0.6 mm [19]. In these studies, a movement smaller than 2 mm was defined as an acceptable standard, proving that the CAD-CAM guides provide good surgical accuracy. The results of current customized guides are so highly accurate that the acceptable mean and standard deviation used in similar studies is ≤ 1 mm and for conventional guides is <2 mm [1,3,5,8,10,18,19].

It can be observed that the results with poorer accuracy were in the anteroposterior and vertical movements (Y and Z-axes), with similar results in the molar region. However, the results were better for the canine region. This can be explained by the muscular action and tension created by the surgical splint at the time of modeling and trans operative conventional fixation of the miniplates in the zygomatic pillar. The better results could also be because the guides and pre-circumvented plates are made only for the anterior region of the maxilla. These results demonstrate, and further emphasize, the importance of the guides and the customization of miniplates [2,8].

A critical point in the laboratory setting is the preparation of the drilling guide. Any failure will result in unwanted movement. Because of this the guides are currently printed in titanium, since they do not distort when drilled in an undesirable angle, which can otherwise cause a position error [8,20,22,23,24]. The contribution of this work is an improvement of the thermoplastic 3D CAD-CAM guide. This technique uses drilling guides similar to that of customized miniplates [1,2,8,9,13,18,25]. It is common to bend or model miniplates from 3D-printed models before the surgery. However, there are no reports in the literature explaining how to do a cutting and drilling guide to transform the conventional folded plates into customized plates that can transfer the planned movements from the virtual state to the surgical procedure [6,8,9,22]. We create and describe thoroughly the step addition to the procedures that allowed this transfer accurately without titanium materials. This step consists of drill previously the 3D model of the maxillary and then scanning that surface with the perforation to allow the confection of a drilling and cutting guide of compatible resin using CAD/CAM.

This publication is the first one to describe this innovation that reproduce a complex technique, that requires professional 3D modeling and customized plate printing in titanium, in a simpler and cost-effective manner, and demonstrated the utility of our proposed technique to obtain results that are accurate and reliable.

In the cases reported in this article, the cutting and drilling guides were performed at software 3D instead of 3D virtual modeling of the drilling guides.

In the future, we will analyze the accuracy of the guide for comparison with CAD-CAM guide and miniplate customized guides and we will also study the application of this technique in sagittal osteotomies of the mandible and chin.

CONCLUSION

The results of the accuracy and reliability tests were satisfactory and support the use of the proposed technique.

Conflict of interest: The authors declare no conflict of interest.

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