ACCURACY OF MAXILLARY REPOSITIONING USING 3D-CUSTOMIZED PLATE IN ORTHOGNATHIC SURGERY (CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: The key factors that determine the success of orthognathic surgery are the optimal diagnosis, treatment planning, and accurate surgical delivery of the preoperative simulation to the operating room. Recently, the development of virtual surgical planning (VSP) and computer-aided design/ manufacturing (CAD/CAM) technology has enabled preoperative virtual simulation to improve surgical outcomes.
AIM OF THE STUDY: to assess the accuracy of the (3D) customized titanium plate for maxillary repositioning in patients undergoing Le Fort I osteotomy in orthognathic surgery compared to the preoperative virtual surgical planning.
MATERIAL AND METHODS: This study was conducted on eight patients requiring Le Fort I osteotomy procedure using 3D customized titanium plates. The post-operative computed tomography (CT) scan images was compared to the pre-operative VSP by superimposition. Volumetric analysis was calculated to detect margin of error.
RESULTS: The mean superimposition deviation between the postoperative actual bone position and preoperative planned was 0.382 ±0.490 mm
CONCLUSION: using 3D customized titanium plates through CAD/CAM technologies and VSP bring out many advantages including reduced surgical intervention time, increased accuracy of maxillary repositioning and predictable outcomes.
KEYWORDS: 3D customized plate, Virtual planning, CAD/CAM surgical guide, LeFort I osteotomy.
RUNNING TITLE: Patient-Specific Plates for Maxillary Repositioning in Orthognathic Surgery

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INTRODUCTION

A successful orthognathic surgery should result in a balanced occlusion and a proportionate facial morphology for the patient (1). To attain this, traditional surgical planning for orthognathic surgery patients undergoes multidisciplinary inputs: thorough clinical examination, photography, orthodontic teeth alignment, two-dimensional radiographs and dental casts mounted on an articulator (2, 3). During two-dimensional analysis, inevitable errors may be introduced through diagnostic material or human factor error. The error may be extended during the construction of the surgical wafer (2, 4). Moreover, the lack of control of the third dimension is considered another limitation (5) along with the absence of the temporomandibular joint position changes evaluation (6).

During fixation process, construction of surgical wafers for orthognathic surgery using 3D printers and CAD/CAM technology may introduce errors intra-operatively as it uses stock mini-plates without any pre-marked drill holes causing inaccurate plate positioning (7).

One of the outstanding advantages of virtual surgical planning (VSP) is the ability to offer a 3D digital planning for surgical procedures (8). VSP is remarkbly applied in orthognathic surgical field. It enables surgeons to simulate various surgical schemes and evaluate potential outcomes (9). The advanced level of planning is essential in such complex surgical procedures as orthognathic surgery whenever millimeter-accuracy level can affect the functional and esthetic results significantly (10).

One of the significant benefits of VSP is high precision and accuracy level as proven by the systematic review by Chen et al. (9) The review concluded that VSP was significantly more accurate in predicting postoperative outcomes compared to traditional methods(9). Moreover, Alkhayer et al. (10) recorded that VSP could decrease the error limit to less than 2 mm, leading to more predictable outcome.

The quest for efficient surgical planning and predictable outcomes in orthognathic surgery has been always a challenge. The use of patient-specific titanium plates technique is one of the ways to increase accuracy of surgical outcome. The patient-specific titanium plates are customized for each individual patient, and are based on digitally-guided bone cuts, allowing bone segments repositioning in a splintless technique (11-13).

As concluded in the systematic review by AlKhayer et al.(10), virtual planning seems to be an accurate and reproducible method for orthognathic treatment planning. However, more clinical trials are needed to clearly determine the accuracy and validation of the virtual planning in orthognathic surgery.

The aim of this study was evaluation of the accuracy of maxillary repositioning using the 3D customized plate compared to the preoperative 3D VSP in patients undergoing Le Fort I osteotomy in orthognathic surgery.

MATERIALS AND METHODS

The study was a clinical trial (ClinicalTrials.gov identifier: NCT06317012). The sample size was calculated using Power Analysis and Sample Size Software (PASS 2020) "NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass". A minimal total hypothesized sample size of eight eligible participants admitted to is needed to assess the accuracy of CAD/CAM guided osteotomy and customized plates in Le Fort I osteotomy; taking into consideration 95% confidence level and 80% power using Chi Square-test. The study was performed after gaining the ethical committee clearance from the Scientific Research Ethics Committee at the Faculty of Dentistry, Alexandria University (International No: IORG0008839, Ethics Committee No: 0407-03/2022).

Eight patients with dental and skeletal deformity requiring corrective orthognathic surgery were enrolled from the outpatient clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University, Alexandria, Egypt. Patients' inclusion criteria were non-syndromic dentofacial deformity requiring Le Fort I osteotomy with or without mandibular bilateral sagittal split osteotomy (BSSO) in class II or III patients age ranging from 17 to 30 years. The patients' exclusion criteria were previously performed orthognathic surgery or previous trauma in the maxillary or the mandible. Patients with systemic diseases contraindicating surgery or acute infection at the site of surgery were excluded.

Preoperative preparation

The recruited patients underwent virtual surgical simulation for 3D planning to set a precise plan. A comprehensive clinical examination of the patients was performed and their chief complaints were recorded. Extraoral and intraoral photographs were taken including different views **(Fig 1A)**.

Virtual Surgical Planning

For digital surgical planning, CT scans with centric relation were acquired. The optical scanner (Medit™ i600, Medit; MEDIT Co., Seoul, Korea) was used to digitize the dental models captured.

VSP was performed using Materialise-3-Matic 12.0 (Materialise, Leuven, Belgium) (14). 3D cephalometric analysis and scans of the dental model were virtually combined to achieve a definitive treatment plan. Virtual surgical simulation was performed to test the treatment objectives.

Using CAD software (Materialise-3-Matic 12.0; Materialise, Leuven, Belgium), the maxillary osteotomy lines were guided through cutting guides. Furthermore, these cutting guides aid reference hole marks to be further used for the plate repositioning/ fixation. The designed guide was then exported as (STL) file to the printer (Shenzhen Creality 3D Technology Co., Ltd, China) using liquid crystal display (LCD) technology.

3D customized plates were designed using Materialise-3-Matic 12.0 software (Materialise, Leuven, Belgium) for fixation of the maxilla after repointing on the new desired position **(Fig 2)**. The designed 3d customized plates were exported as STL file format to be milled in Medical Titanium Grade 4 alloy (ELI Titanium Alloy; Baoji INT Medical Titanium Co. Ltd, Shaanxi, China) using CNC machining.

Surgical Procedure

General anesthesia was used for treatment of all patients. surgical scrub solution as povidone-iodine (Betadine, The Nile Co. for Pharmaceuticals and Chemical Industries, Egypt) was used for scrubbing of the surgical field, then patient draping with sterile towels with only exposure the area of surgery. The surgical procedure starts by the incision from first molar to first molar and subperiosteal dissection superiorly till infraorbital foramen and posteriorly till pterygomaxillary fissure. The nasal mucosa was elevated using freer periosteal elevator. The cutting guide was manipulated to the best fit on the exposed bony surface **(Fig 3A)**. using 1.5 mm drilling bur, all the guide's holes had been drilled. Then, the guide was fixed using four 1.8mm diameter mini screws for immobilization during drilling of the reference holes. Guided Le Fort I osteotomy **(Fig 3B)** was performed using the Piezosurgery device (Woodpecker US-II, Guangxi, China). Next in sequence, the pterygomaxillary disjunction using pterygoid osteotome, septal, vomerine using bifid osteotome, and lateral nasal osteotomies bilaterally using side graded osteotome, then followed by down fracture and mobilization of the maxilla using smith spreader.

After free mobilization of the maxilla and removal of bony interferences, repositioning of the maxilla and fixation using the 3D customized titanium plate. Previously established holes guide the plate to the best fit then, fixed using 1.8-mm screws **(Fig 3C)**. continuous running closure fashion with 4–0 resorpable sutures was used.

Postoperative medication included cefotaxime ampoule 1 gm every 12 hours intravenous on the first day. For the next 5 days, Amoxicillin + clavulanate 1 gm every 12 hours (Augmentin, GlaxoSmithKline, UK), Metronidazole 500mg (Flagyl, GlaxoSmithKline, UK.) tablets every eight hours, α-chemo-trypsin 5 mg (Allzyme Max, Limitless, packed by Eva Pharma company, Egypt) tablets once every 24 hours and diclofenac potassium 50mg (Cataflam, Novartis, Switzerland) tablets three times daily. Strict instructions to rinse using 0.12% Chlorhexidine (Hexitol, ADCO, Egypt) antiseptic mouth to maintain good oral hygiene. All patients were instructed to consume soft, fully liquid, high protein, high calorie diet for 4 weeks after surgery.

Postoperative Follow-up Phase

Radioragphic Follow-up

Regarding the radiographic evaluation, the CT was obtained immediately postoperative for comparison with the preoperative digital virtual planned maxillary position using Mimics innovation suite software. the discrepancy or the magnitude of error between the post-operative object and the pre-planned object was illustrated with visual representation using (Materialise 3-Matic 14.0, Materialise NV, Leuven, Belgium) through a heat map **(Fig 4)**. The clinically acceptable range of discrepancies is 2.00 mm or less (15).

Clinical Follow-up

Post-operative pain evaluation via a 10-point Visual Analogue Scale (VAS). Evaluation at week 1, week 2 and week 4 (0-1= None, 2-4= Mild, 5-7= Moderate, 8-10= Severe).

Statistical analysis

Shapiro-Wilk normality test was used to verify the normal distribution of data. The superimposition scores data was non-parametric and violated the normal distribution. The pain data was parametric and normally distributed. The descriptive statistics including mean, standard deviation, median, minimum, and maximum. Repeated measures ANOVA was used to compare pain scale between observations followed by paired samples t-test for multiple comparisons. P value is significant if it is less than .05. The data was analyzed using SPSS (Statistical Package for social science, version 25).

RESULTS

Eight patients were recruited in this study. With age range from 17 to 25 years with a mean of 19 years of age. The deformities addressed were skeletal class II, skeletal class III, gummy smile and cleft lip and palate. The majority of the patients were class III skeletal deformity (75%). Class II skeletal deformity were the second in prevalence (25%). The majority underwent bimaxillary orthognathic surgery (87.5%) Additionally, gummy smiles (25%) were addressed in this study. Moreover, patient with cleft palate deformity (12.5%) was included in this study.

By 6–8 weeks, postoperative edema had totally subsided. Ordinary wound healing was seen in all patients without any wound dehiscence or signs of infection.

Superimposition

The mean error of superimposition discrepancy of preoperative planned bone position and postoperative actual bone position was 0.382 ±0.490 mm with a maximum of 1.251mm and a minimum of 0.095 mm. The descriptive analysis shown in **(Table 1 and Fig. 5)**. The mean of superimposition deviation between the preoperative planned bone position and postoperative actual bone position was 0.382 ±0.490 mm with a maximum of 1.251mm and a minimum of 0.095 mm

Pain:

- There was a significant difference in scores between 1 week and 2 weeks (paired t-test, p<.001), 1 week and 4 weeks (paired t-test, p<.001), and between 2 weeks and 4 weeks (paired t-test, p=.002).

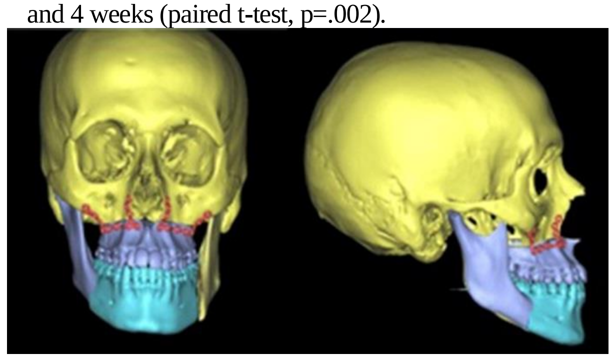

Figure 1: Pre-operative virtual surgical planning and customized titanium plate design.

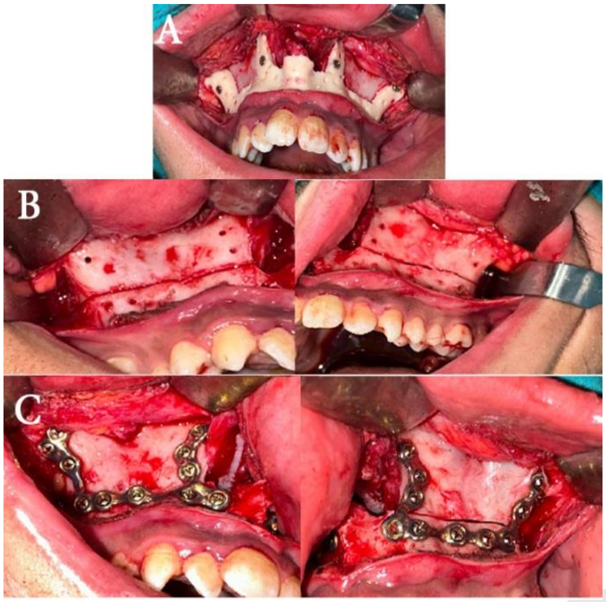

Figure 2: (A) The cutting guide was temporarily fixed in place using screws. **(B)** The cutting lines could guide the piezosurgery tip to accurately perform the osteotomy as planned. Once the cutting guides were removed, the screw holes left on the bony surface were preserved as the bony reference landmarks for the next step. **(C)** The maxillary custom plate was firmly fixed onto the maxilla using the screw holes above the osteotomy line on each side. Then, the predetermined locations of the screw holes on custom plates automatically brought the Le Fort I segment to its planned position as the screws were placed into the corresponding screw holes and tightened.

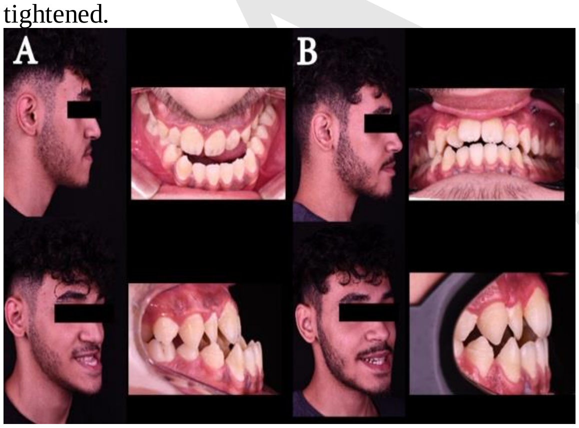

Figure 3: (A) Preoperative intraoral (lateral and occlusal views) and extraoral (lateral and 45 degree views) photos showing a class III skeletal deformity with protruded mandible, retruded maxilla and depressed nasolabial fold **(B)** postoperative intraoral (lateral and occlusal views) and extraoral (lateral and 45 degree views) photos for surgically corrected class III skeletal deformity (intraoral and extraoral) with mandibular setback and maxillary advancement.

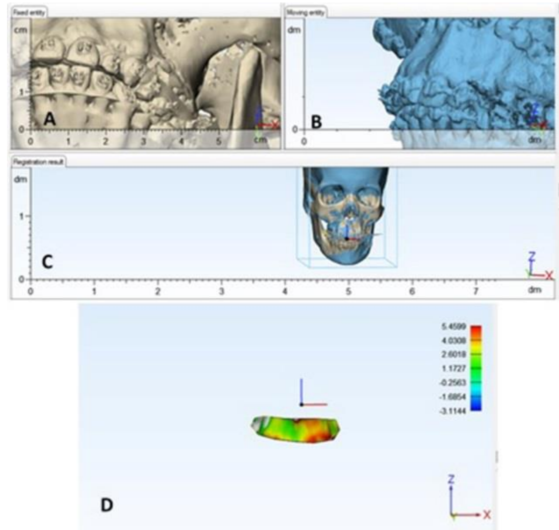

Figure 4: A) Preoperative virtual surgical planning **(B)** Postoperative CT **(C)** Superimposition of virtual surgical planning and postoperative CT **(D)** Heat map to illustrate the discrepancy between the postoperative object and pre-planned object.

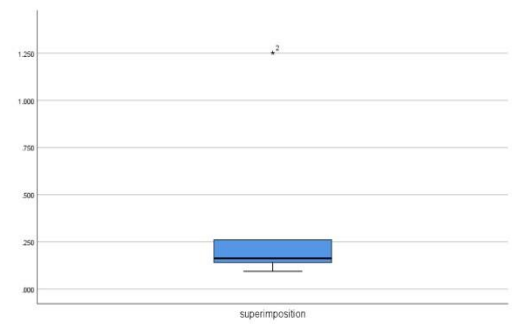

Figure 5: Boxplot graph presenting median, minimum, and maximum values of superimposition (mm).

Table1. Descriptive statistics of Superimposition (mm).

	Superimposition (mm)
Mean	.382
Standard deviation	.490
Median	.163
Minimum	.095
Maximum	1.251

Table 2. Descriptive statistics of pain scores at different observation times

	1 week	2 weeks	4 weeks	Repeated measures ANOVA (p value)
Mean	9.00	6.20	.40	<.001*
Standard deviation	.71	.84	.55	
Median	9.00	6.00	.00	
Minimum	8.00	5.00	.00	
Maximum	10.00	7.00	1.00	
Maximum	<.001*			
Paired samples t-test (p value)		.002*		
	<.001*			

DISCUSSION

Previously, maxillary repositioning in orthognathic surgery using surgical acrylic wafers depended on cast analysis and inconsistent intra- and extraoral measurements. Apparently, many errors have occurred with unpredictable outcomes leading to maxillary malpositioning up to 5 mm (16). In 2010, the authors' sought to overcome this problem they introduced simulation-guided navigation device showing reproduction of the preoperative surgical plan with 86.5% (error, <2 mm) (17).

Later authors have described the use of transferring 3D VSP to the surgical site using CAD/CAM occlusal wafers lacking to proof increased accuracy in maxillary positioning (6, 18, 19). In a previous study, Li et al. (20) used a new CAD-CAM template to guide the osteotomy and maxillary reposition in orthognathic surgery. Maxillary fixation was done by pre-bent plates. The obtained results of superimposition of postoperative CT scans on virtual plan showed that error was less than 1 mm (20). Moreover, Modabber et al. (21) conducted a survey regarding subjective evaluation of functional and aesthetic outcomes. It concluded that patients who underwent VSP reported more favorable outcomes than who underwent traditional surgery (21).

In our study, maxillary positioning accuracy has been determined in the studies through superimposition of VSP pre-operative images and images of post-operative CT to determine the differences between virtually planned maxillary movement and the actual maxillary surgical movement. Previous studies reported that less than 2 mm discrepancy in the maxillary repositioning is clinically insignificant (15, 22). Other studies reported that inaccurate discrepancies more than 1mm in anterior maxilla result in malposed maxillary center line which may lead to undesirable esthetic outcome (12, 13, 23, 24). Fortunately, our study showed the mean of superimposition deviation between the preoperative planned bone position and postoperative actual bone position as 0.382 ±0.490 mm, confirming the predictability of this technique.

Splintless technique decreases the surgical time through diminishing plate-bending, intermaxillary fixation and intraoperative measures (11, 12, 25). This technique allows maxillary positioning independent to the mandibular autorotation or condylar position (11, 13, 23, 25, 26).

To overcome the high cost and complex production of titanium osteotomy guides, resin was selected for printing the osteotomy guides in this study(27). Titanium osteotomy guides are bulky and need more periosteal stripping and elevation for adequate positioning of the guide. This leads to a less conservative surgical procedure (28, 29).

Ho et al and Kraeima et al claimed that splintless technique may be unsuitable for cleft lip and palate (CLP) patients regarding the osteotomy guides' size in the presence of tight soft tissues (26, 30). On the other hand, Imai et al proved no diffuculties to such technique as the osteotomy guides and the prebent plates were small enough to adapt the tight soft tissues (28). This goes in line with our study as an enrolled CLP patient showed satisfactory outcomes with acceptable challenges regarding soft tissue handling while using osteotomy guides and customized plate.

One of the significant drawbacks of this system is the increased cost of the pre-operative VSP and milling of the patient-specific titanium plates. This is rationalized through reduced surgical operating time leading to conservation in blood loss and decreased hospitalization time (25, 31). Moreover, other authors claim reduced pre-operative errors and fewer appointments improving the cost-effectiveness of the splintless osteotomy procedure (12, 28, 30).

Use of 3D customized titanium plate requires accurate osteotomies and surgical technique as its fit is contingent and unmodifiable. It avoids incorrect osteotomies and imprecise screw hole placement or over-preparation (11, 13). Although we haven't encountered such situations, we acknowledge the consequences of such errors and pursued to decrease them by including more screw-holes than required.

In vitro studies proved that customized plates have greater rigidity in comparison to preformed plates (32, 33). The customized titanium plates production may be by machining(26) or layer-by-layer sintering (13). In this study, the plates were machined to avoid the limitations of layer-by-layer sintering: decreased rigidity and increased contamination risk (11). Moreover, the machining was preferred considering the availability in our region regardless its higher cost.

In our study, the volumetric analysis was the best method to evaluate the superimposition. This technique decreases the need for definite landmark identification and eliminates the dependence on dental landmarks that may be susceptible to orthodontic movement. Additionally, skeletal landmarks such as the anterior nasal spine are often altered intraoperatively and the change in position cannot be evaluated whether it is secondary to movement or reduction. Moreover, the use of volumetric analysis facilitates the 3D post-surgical evaluation of the shape and position of the maxilla in relation to the pre-surgical plan (34).

Pain is expressed as an unpleasant emotional and sensory experience that is associated with potential tissue damage (6). The Visual Analogue Scale (VAS) was used to measure the postoperative pain as it is considered to be a reliable tool for measuring acute pain in adult patients (35, 36). VAS is considered a precise and highly sensitive methodology in pain assessment (37). The VAS evaluates intensity of pain and individual's pain perception as a recent complex experience.

Regarding the pain measures, our study represented a statistically significant decrease in scores between week 1 and 2 weeks ($p<0.001$), and between week 2 and week 4 ($p=0.002$). This coincides with Phillips (38) who reported that most patients declared that pain persisted for 2 to 3 weeks postsurgically. Less than 5% of patients reported experiencing 'substantial' pain 1 month postsurgery, but approximately 20% reported taking analgesics for pain relief (38). Other studies showed that vast majority of patients believe that analgesics prescribed were sufficient for pain management while many patients reported that their pain persisted longer than expected (39). in our study, no patient reported persistent pain 4 weeks postsurgically.

To conclude, using VSP and CAD/CAM technologies bring out many advantages including, increased accuracy of maxillary repositioning and increased patient satisfaction (21, 40). Preoperative surgical simulation along with customized plates leads to superior reconstructive and aesthetic outcomes in comparison to traditional 2-dimensional (2D) modeling and cephalometric tracing. The main limitation is adapting to new technology and shifting the standards to performing orthognathic surgery more efficiently.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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