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ASSESSMENT OF THE ACCURACY OF THREE-DIMENSIONAL CAD-CAM CUSTOMIZED TITANIUM PLATES FOR LEFORT I OSTEOTOMY IN ORTHOGNATHIC SURGERY: A PROSPECTIVE CLINICAL TRIAL

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ABSTRACT

Objectives: The purpose of present research was to clinically and radiographically evaluate the accuracy and effectiveness of customized titanium plates in Le Fort I orthognathic surgery. **Subjects and Methods:** Ten participants who had dentofacial abnormalities were included. Preoperative CT scans were used for virtual surgical planning (VSP), as well as the design and fabrication of cutting guides and customized titanium plates. Clinical evaluations focused on the accuracy of the cutting guides and plates, dental occlusion, soft tissue dehiscence or infection, plate fractures, and screw loosening. Postoperative CT scans were used to assess the accuracy of the customized plates, with analysis performed using Mimics Medical 19.0 and 3-matic Medical 11.0 software through superimposition and measurement of discrepancies in millimeters. Written informed permission was acquired from all participants. Every participant underwent both clinical and radiographic evaluations. **Results:** There were no statistically significant variations amongst the virtual plan and postoperative outcomes at the five pre-selected reference points, with discrepancies of 0.80 ± 0.26 mm (MSP), 1.10 ± 0.23 mm (FHP), and 1.08 ± 0.25 mm (CP) ($p>0.05$). All patients achieved stable postoperative occlusion. One patient experienced transient upper lip numbness, which resolved within two months. No cases of plate loosening, infection, or soft tissue complications were reported. **Conclusion:** Customized titanium plates demonstrated high accuracy in translating the virtual surgical plan into the operating room. The observed variations amongst planned and postoperative results were minimal and clinically insignificant. Additionally, the use of customized plates significantly reduced operative time and facilitated surgical procedures, particularly during vertical repositioning.

KEYWORDS: Virtual surgical planning, patient-specific implants (PSI), customized titanium plates, POSG system.

INTRODUCTION

Dentofacial deformities are structural anomalies that primarily affect the jaws and teeth but may also involve various craniofacial components. These deformities often arise from moderate to severe genetic disturbances in normal craniofacial development, including conditions such as mandibular prognathism, bimaxillary prognathism or retrognathism, and maxillary vertical excess. Affected individuals commonly experience functional, aesthetic, and psychosocial impairments, resulting in significantly lower quality of life compared to unaffected populations [(1-3)].

Accurate surgical planning is essential for the successful correction of facial skeletal deformities.

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Historically, two-dimensional (2D) radiographic evaluation combined with surgical dental model has been the standardized approach for orthognathic surgical planning. Nevertheless, 2D techniques are inherently limited in their ability to represent complex three-dimensional (3D) craniofacial structures. The introduction of virtual surgical planning (VSP) has addressed many of these limitations, offering enhanced spatial visualization and reducing the time required for preoperative preparation [4-6].

Postoperative evaluation of skeletal and soft tissue changes has traditionally relied on 2D superimposition of lateral cephalograms using stable anatomical landmarks, such as the anterior cranial base[7, 8] or by comparing cephalometric measurements [9] With the advent of low-dose cone-beam computed tomography (CBCT), clinicians can now obtain accurate 3D representations of both hard and soft tissue morphology, providing a more comprehensive assessment of surgical outcomes[10-13] .

VSP has significantly advanced modern orthognathic surgery by enabling precise preoperative planning, improving intraoperative accuracy, and enhancing postoperative outcomes. Two major developments have contributed to these advances: improved methods for transferring virtual plans to the operating room and more accurate assessment of surgical results. Plan transfer systems are generally categorized into splint-based and splintless techniques. Splint-based systems rely on intermediate occlusal splints for jaw positioning, while splintless approaches—such as surgical navigation and customized fixation plates—directly guide bone repositioning without the need for splints [14-16].

Computer-aided design and manufacturing (CAD/CAM) technology has enabled the production of 3D-printed surgical splints that bypass conventional laboratory procedures, such as dental cast surgery and facebow transfer. These splints improve rotational control during maxillary repositioning; however, they offer limited vertical control and provide no guidance for osteotomy execution [15]. Moreover, their reliance on mandibular positioning to determine maxillary placement poses further limitations, prompting the exploration of alternative, more autonomous methods for plan transfer.

Repositioning guides have been developed to address these limitations by directly determining the post-osteotomy position of the maxilla and providing osteotomy guidance to enhance surgical precision[4]. Patient-specific implants (PSIs), typically fabricated from titanium, represent another advancement. These implants are designed to replicate the virtual plan with high fidelity by accurately transferring osteotomy lines and final segment positions to the surgical field. Cutting guides are contoured to the zygomaticomaxillary buttress and anterior maxillary wall for enhanced stability, and fixation holes are strategically placed to avoid damage to dental roots [17-19].

Custom titanium plates not only facilitate precise repositioning in all three spatial planes—sagittal, transverse, and vertical—but also simplify intraoperative workflow. These plates are often designed to use the same fixation holes as the cutting guides, ensuring consistency. Multiple fixation options are incorporated to allow flexibility during surgery. Studies have shown that CAD/CAM cutting guides and PSIs can accurately reproduce preoperative plans without the need for occlusal splints, streamlining procedures and improving efficiency[18, 20]. By eliminating steps such as manual plate bending, nasion reference screws, and occlusal splint wiring, this technique can reduce operative time and improve clinical outcomes.

Based on these developments, we hypothesize that customized titanium plate transfer systems will achieve greater accuracy in jaw repositioning and reduce operative time compared to conventional splint-based methods.

SUBJECTS AND METHODS

Patients and methods: A Prospective single arm Clinical Trial conducted on ten patients with dentofacial deformities requiring Le Fort I osteotomy orthognathic surgery were admitted and treated at the Oral and Maxillofacial Surgery Department, Sayed Galal University Hospital, Al-Azhar University, Cairo, Egypt.

Study design: A Prospective Clinical Trial

Inclusion Criteria: This research included participants who met the subsequent requirements:

1. Participants with dentofacial deformities requiring Le Fort I orthognathic surgery.
2. Participants aged between 18 and 30 years.
3. Based on the American Society of Anesthesiologists' (ASA) categorization system, healthy participants are categorized as ASA I or II.

Exclusion Criteria: patient who had one of the following conditions was excluded from this study

1. Participants requiring segmental Le Fort I osteotomy of the maxilla.
2. Participants who are pregnant, either proven or suspected.
3. Participants who have had orthognathic surgery in the past.
4. Participants have craniofacial anomalies or cleft palate.

Ethical Considerations:

The research objectives, treatment plans, and procedural steps were explained in detail to all participants. Written informed consent was obtained from each patient prior to the commencement of treatment. The study protocol was reviewed and approved by the Ethics Committee of the Faculty of Dental Medicine (Boys), Al-Azhar University, Cairo, Egypt (Approval Code: 887/1849).

Patient Assessment and Planning

Pre-operative clinical evaluation includes the following:

- Personal, medical, and dental history will be taken from each patient.
- Extraoral and intraoral clinical examination.
- Both extraoral as well as intraoral images.
- Dental casts for each patient were poured and scanned utilizing a desktop laser scanner (Medit T 310, Korea), for construction surface tessellation language (STL) files.

Radiographic evaluation

- An orthopantomography to evaluate patient's dentition.
- Lateral cephalometry to analysis of facial bone and planning of the orthognathic surgery
- Computed tomography (CT) scanning for the patients for Digital Imaging and Communications in Medicine (DICOM) file production.

Virtual planning:

A full skull CT scan was performed for each patient prior to surgery. The DICOM files obtained from the CT scan were imported into Mimics Medical 19.0 software (Materialise NV Technologielaan 15 3001 Leuven, Belgium). The data was then rendered into 3D models of the skull and mandible. These models were exported as STL files to 3-matic Medical 14.0(Materialise NV Technologielaan 15 3001 Leuven, Belgium) for virtual planning and surgical guide fabrication using the software's advanced tools. A 3D virtual hard tissue model of the patient was created and oriented using anatomical reference planes, including the Frankfort Horizontal Plane (FHP), the Midsagittal Plane (MSP) and coronal plane (CP).

The customized titanium plate system:

- The customized titanium plate system was included a pair of cutting guides with preplanned screws holes and a pair of custom titanium plates. The STL files of cutting guides have been sent for 3D printing using clear photopolymer resin on the Anycubic Photon Mono X (MSLA) 3D printer (Honkong Anycubic Technology Co., Ltd. 101-501, Building 111, Yinhai Industrial City, Shenzen, China)
- The STL files representing the plates was transported to the three-axis titanium milling machine (Arab Engineers for Designs and Medical Instrumentation Piece 940, Arab Elawamer industrial zone, Assiut, Egypt) to fabricate the plates from type IV titanium. Finishing and polishing was performed in the outer surface only to eliminate any covering tissue irritation.

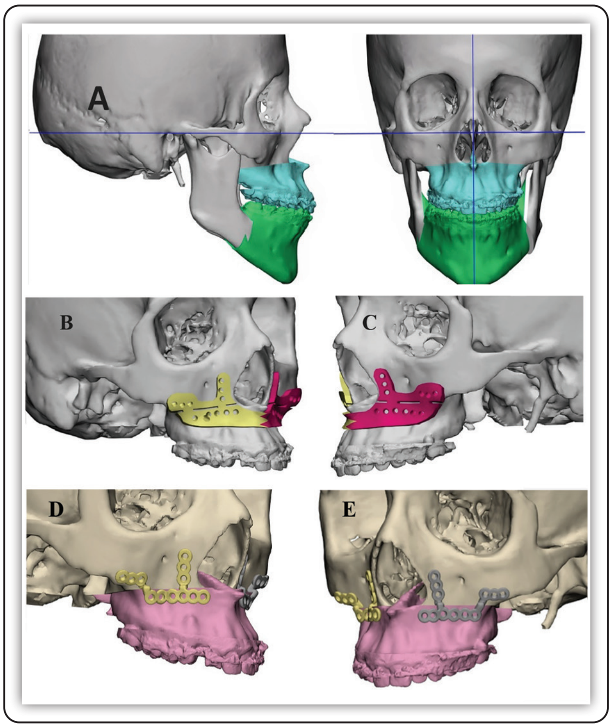

FIG (1) Virtual planning and design of guides and plates. (A) Virtual planning of osteotomy. (B&C) Virtual design of cutting guides. (C&D) right and left Customized titanium plates.

Surgical Procedures:

All procedures were performed under general anesthesia with nasotracheal intubation to allow for intraoperative occlusion checks. The endotracheal tube was secured using 2-0 silk sutures to prevent dislodgement during surgery.

Preoperative preparation included standard draping and scrubbing using povidone-iodine and surgical scrub solution. Intravenous administration of prophylactic antibiotics (Cefotaxime) and Dexamethasone sodium phosphate was performed in the operating room. For pre-emptive analgesia and hemostasis, submucosal infiltration of 0.25% bupivacaine hydrochloride with epinephrine (1:100,000) was administered.

Each patient underwent Le Fort I osteotomy in combination with bilateral sagittal split osteotomy (BSSO) to improve facial profile and achieve optimal occlusion. Four 11 mm intermaxillary fixation (IMF) screws were placed transmucosally between the canine and first premolar regions in each quadrant to facilitate IMF after BSSO.

A maxillary vestibular incision was made intraorally, extending from first molar to first molar about 5 mm above the mucogingival junction. Subperiosteal dissection was performed using to expose the anterior maxilla, including the infraorbital neurovascular bundle, piriform rim, and zygomaticomaxillary buttresses. Dissection was extended posteriorly toward the pterygomaxillary fissure via subperiosteal tunneling.

The two-piece cutting guide was positioned on the exposed maxillary surface and carefully adjusted for a precise fit, then secured using four 2.0 mm screws. Osteotomy lines were marked on the lateral maxillary wall using a reciprocating saw. The guide was then removed, and the osteotomies were completed along the lateral buttress, lateral nasal wall, nasal septum, and pterygomaxillary junction using a reciprocating saw and curved osteotomes.

Following osteotomy completion, the maxilla was down-fractured using digital pressure and

Rowe's disimpaction forceps. The mobilized maxilla was then repositioned using prefabricated customized titanium plates as guides and fixed in place using 2.0 mm titanium mini-screws.

Subsequently, the BSSO was performed. The mandible was guided into the preplanned position using a 3D-fabricated occlusal wafer to ensure proper occlusion. Condylar positioning was confirmed via preauricular palpation. Rigid fixation was achieved using titanium miniplates and monocortical screws bilaterally. The incision was closed with a continuous 4-0 Vicryl suture to ensure a watertight seal. An alar cinch suture was placed to reattach the nasalis muscle and prevent alar base widening. A V-Y mucosal advancement flap was used to prevent upper lip flattening. The mandibular incision was closed in a single layer using a continuous 4-0 Vicryl suture. In select cases, postoperative guiding elastics were placed following extubation to support occlusal stability.

Data management and analysis: The gathered data underwent statistical processing, including tabulation and analysis, utilizing the SPSS software package. A criterion of $P < 0.05$ was used to establish statistical significance.

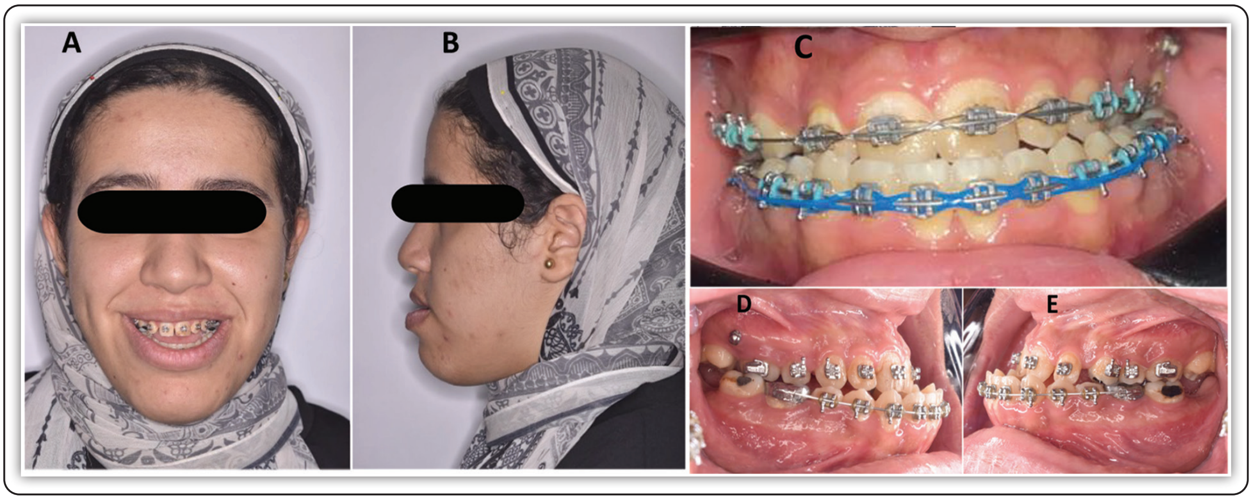

FIG (2) Preoperative photographs. (A&B) extra oral photographs frontal and profile views. (C&D&E): Preoperative intra-oral photographs: frontal view, right lateral view, and left lateral view

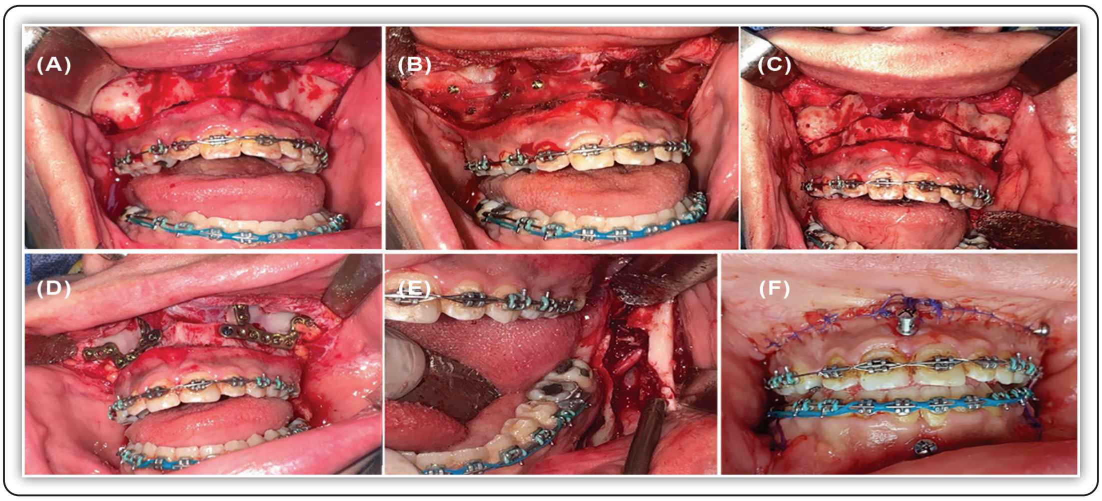

FIG (3) Surgical steps for lefort I. (A) Mucoperiosteal flap incised and elevated. (B) Custom-made cutting guide in place. (C) Lline of osteotomy and screw holes. (D) Customized titanium plates fixation (E)BSSO. (F) Suturing of the flap post-operative occlusion.

RESULTS

Following superimposition of the postoperative 3D model of the virtual plan with the postoperative CT scan the linear deviations were measured at five anatomical landmarks: (the most inferio-mesial point of upper central incisor, bilateral canine tips and the bilateral mesiobuccal cusp tip of first molars) For each landmark, three-dimensional discrepancies between planned and achieved positions were quantified relative to all three spatial planes (sagittal, coronal, and axial). Mean positional errors were then calculated and compared to assess the precision of transferring the virtual surgical plan to the operative procedure.

TABLE (1) Comparison between Virtual plan and Post surgery according to Superimposition results in MSP.

Superimposition results	Virtual plan	Post-surgery	Paired Sample t-test		
			Delta	t-test	p-value
MSP (mm)					
Mean±SD	17.64±4.35	17.49±4.22	0.80±0.26	0.744	0.463
Range	0.61-30.78	0.12-30.73	0.05-3.27		

*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

There is no statistically significant variation between the virtual plan and post-surgery according to superimposition results about MSP (mm) with a p-value (p > 0.05).

TABLE (2) Comparison between Virtual plan and Post surgery according to Superimposition results FHP.

Superimposition results	Virtual plan	Post-surgery	Paired Sample t-test		
			Delta	t-test	p-value
FHP (mm)					
Mean±SD	51.33±4.40	51.10±4.22	1.10±0.23	0.788	0.437
Range	44.75-60.44	45.39-61.08	0.02-4.12		

*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

There is no statistically significant variation between the virtual plan and post-surgery according to superimposition results about FHP (mm). p-value (p > 0.05)

TABLE (3) Comparison between Virtual plan and Post surgery according to Superimposition results in CP.

Superimposition results	Virtual plan	Post-surgery	Paired Sample t-test		
			Delta	t-test	p-value
CP (mm)					
Mean±SD	49.61±12.96	49.78±12.17	1.08±0.25	-0.669	0.508
Range	15.36-100.47	15.78-101.09	0.06-2.93		

*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

There is no statistically significant variation between the virtual plan and post-surgery according to superimposition results about CP (mm) with a p-value (p > 0.05).

Patients' satisfaction.

All patients expressed their satisfaction to the functional and aesthetic outcomes.

Fabrication accuracy of surgical guides and custom-made plates.

The surgical guides and customized titanium plates were evaluated for fabrication accuracy by assessing their adaptation and fit to the preplanned positions.

DISCUSSION

Achieving optimal aesthetic and functional outcomes in orthognathic surgery hinges on the precise repositioning of the maxilla in accordance with the preoperative plan. Despite advances in surgical techniques and digital planning, the most effective method for three-dimensional (3D) intraoperative control of maxillary positioning remains under debate[18].A successful surgical outcome depends on the accurate transfer of the preoperative plan to the patient through the operation [21, 22].

The conventional approach to maxillary repositioning using interocclusal splints and manual techniques is associated with several limitations, including measurement inaccuracies, errors in splint fabrication, and procedural variability[23].In contrast, the use of customized titanium plates offers simultaneous guidance and fixation, eliminating the need for intraoperative adaptation and thereby reducing surgical time [24].

In the present study, we assessed the accuracy of maxillary positioning by comparing the planned and postoperative outcomes using linear measurements from fixed anatomical landmarks to the axial, coronal, and sagittal planes. This evaluation was performed following superimposing the virtual surgical plan with postoperative skull data using N-point and global registration tools to ensure optimal alignment and accuracy.

The surgical guides and custom-made plates were evaluated for fabrication accuracy by assessing their adaptation and fit to the preplanned positions. In all cases, all appliances surgical guides and custom-made plates demonstrated accurate fitting. However, exceptions were noted in one case where the last hole of the upper right customized plate did not fit the bone and this hole left without screw.

The customized titanium plates demonstrated no statistically significant differences in positioning accuracy across the midsagittal plane (mediolateral direction), Frankfurt horizontal plane (cephalocaudal direction), and coronal plane (anteroposterior direction). This high level of accuracy may be attributed to the ability of customized guides and plates to facilitate precise repositioning of the maxilla across all spatial planes, particularly in the vertical dimension, without reliance on interocclusal splints or external landmarks. Moreover, this approach allows maxillary fixation to occur independently of condylar positioning, avoiding the risk of condylar sag and its associated misalignment.

Postoperative occlusion was evaluated after IMF removal and plate fixation. Canine and Angle classifications of occlusion were used to compare outcomes with the preoperative plan. In all cases, acceptable occlusal relationships were achieved, demonstrating the clinical reliability of customized plates in translating surgical plans to intraoperative execution.

Notably, customized plates offered significant advantages in controlling vertical repositioning, which is typically the most challenging vector to manage. By eliminating the dependence on intraoral or extraoral reference points, the system minimizes the potential for human error. Additionally, it allows maxillary placing to be achieved autonomously of the mandible or condylar position, which is especially advantageous in complex or asymmetrical cases.

Patient-specific implants (PSIs) further enhanced surgical precision, particularly in anterior–posterior translational movement and in case of unstable occlusion, such as surgery-first approaches or patients with multiple missing teeth, where interocclusal splints and intermaxillary fixation (IMF) are unreliable or unfeasible[25]. Furthermore, the utilize of CAD/CAM-designed guides and plates enabled accurate preoperative planning for screw placement, optimizing their position relative to bone thickness and tooth roots [26].

The integration of customized surgical guides and fixation plates contributed to a significant reduction in surgical time by eliminating the need for nasion reference screws, manual plate bending, and splint wiring, thereby streamlining the procedure [20].

Postoperative outcomes were favorable, with no reported cases of soft tissue dehiscence, infection, plate fracture, or screw loosening. One patient reported a transient foul odor during breathing and was referred to an ENT specialist. All individuals who had bilateral sagittal split osteotomy (BSSO) experienced lower lip paresthesia, which resolved within three months in most cases and within six months in one case. One patient experienced mild upper lip numbness, which subsided within two months. These outcomes agreed with those of Suojanen et al., who discovered no significant differences in complication rates, plate removal, or soft tissue issues with the use of PSIs [27].

Despite these advantages, customized titanium plates present some limitations. The increased cost associated with the design and fabrication of patient-specific guides and plates can be a barrier. Dependence on third-party companies for virtual planning, validation, and manufacturing may lead to logistical delays. Additionally, the use of customized plates requires more extensive soft tissue dissection, which may increase the risk of postoperative edema or neurovascular injury. Furthermore, intraoperative flexibility is reduced, as rigid prefabricated plates are challenging to modify if anatomical discrepancies or unexpected changes are encountered during surgery.

CONCLUSION

This study concluded that using cutting guides and special constructed titanium plates helps converting the virtual surgical plans to the actual surgery with accuracy. The plates were easy to use, improved accuracy, and reduced the time needed for surgery. These results support using CAD/CAM technology regularly in orthognathic surgery to make procedures more precise and efficient.

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