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# Accuracy of CAD/CAM Cutting Guides and Customized Titanium Plates for Virtual Planning Transfer Compared to Classic Model Surgery in Bi-maxillary Orthognathic Surgeries. A Randomized Controlled Clinical Trial

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**KEYWORDS**

bi-maxillary orthognathic surgery, surgical plan, accuracy of transfer, CAD/CAM cutting guides, customized plates.

**ABSTRACT:**

**Purpose**: To evaluate the accuracy of CAD/CAM cutting guides and customized titanium plates in transferring the virtual plan in comparison to classic model surgery approach in bimaxillary orthognathic surgeries.

**Methods**: A total of 18 patients indicated for bi-maxillary orthognathic surgery were randomly assigned to 2 equal parallel groups; 9 patients were treated by CAD/CAM cutting guides and customized titanium plates (group 1) and 9 patients were treated using classic model surgery (group 2). Accuracy of transfer was assessed for each group.

**Results**: Maxillary mediolateral linear deviation in group 1 showed statistically significant lower values than that in group 2. While mandibular vertical and anteroposterior linear deviation in group 1 showed statistically significant lower values than that in group 2. While for other planes and measurements, the differences in accuracy between the two groups were statistically insignificant ($p>0.05$).

**Conclusion**: Computer-guided orthognathic surgery workflow provided more accuracy compared to classic model surgery. However both groups showed significant deviation from the virtual plan. Minor inaccuracies occurred in both groups did not affect the clinical outcome and patient quality of life in the included sample.

**Introduction:**

In patients undergoing bi-maxillary orthognathic surgeries to correct dentofacial disharmony, the accurate repositioning of the maxillary and mandibular segments is essential esthetically and functionally[1]. The accurate repositioning of the maxilla and mandibular distal segment requires accurate planning and precise transfer of this planning to the operating room. Orthognathic planning went through many evolutions over the past decades in order to avoid inaccuracy in surgical planning or planning transfer to the actual surgery[2]. This inaccuracy may result in less than ideal outcomes, especially in patients with major facial deformity or asymmetry[3].

Orthognathic planning began with the classic model planning which involves cephalometric analysis of 2D lateral radiographs, facial analysis, plaster dental casts mounted on articulator with face-bow transfer and

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surgical intermediate and final acrylic splints[2]. However, the conventional approach had many drawbacks including the 2D nature of the lateral cephalometric x-ray, time consuming and inaccuracy of the maxillary positioning up to 5 mm especially in the vertical direction[4], [5].

Bone-supported guides were introduced as an alternative to the surgical wafers. Bai et al described a new technique using two surface templates designed and manufactured by CAD/CAM technique. These templates controlled the vertical position of the maxilla. However, as fabrication of this template was considered relatively a sophisticated procedure, the drawback of this technique was the increased laboratory time and errors[6].

Then, with the introduction of the era of the PSIs and customized plates, Heufelder et al demonstrated a new method to place the maxillary segment in its correct vertical, transverse and anteroposterior position. This method depended on using CAD/CAM customized surgical cutting guides and patient specific osteosynthesis[7].

In the present study, the aim was to evaluate the accuracy of transfer of the surgical plan by using CAD/CAM surgical cutting guides and customized titanium plates in comparison to classic model surgery approach in bi-maxillary orthognathic surgery.

**Materials and methods:**

The present study is a double-blinded randomized controlled clinical trial conducted on 18 patients. Inclusion criteria were dentofacial misalignment requiring bi-maxillary orthognathic surgeries, patients more than 18 years old, absence of signs or symptoms of active TMDs and highly motivated patients. Exclusion criteria included patients who refused to be included in the research, patients with systemic diseases that may hinder the normal healing process or render the patient not fitting for general anesthesia and patients with intra-bony lesions or infections that may retard the osteotomy healing. The enrolled patients were allocated randomly into two equal groups; group 1 (Study or Intervention Group) comprised 9 patients who underwent computer guided surgery, and group 2 (Control Group) comprised 9 patients who underwent classic model surgery.

Randomization:

The eighteen patients were randomly allocated into two equal groups using computer software. The numbers that generate randomly from the software were written in small folded opaque papers then inserted into envelope (Opaque sealed envelope and signed across seal), each participant grasped one envelop. The study is considered a double blinded clinical trial, as the participant and the statistician were blinded, while the operator and the assessor knew the allocation group from the plate design.

Acquisition of 3D images:

All selected patients had a CBCT scan in natural head position using Planmeca ProFace imaging machine (Planmeca Oy, Helsinki, Finland). The scan was imported into a surgical planning software Mimics 21.0 (Materialise N.V., Leuven, Belgium ). After segmentation and 3D reconstruction of the bony structures were carried out, the dental models were scanned separately and mounted on to each other in the desirable final occlusion using an optical scanner (Shera operating system 7Series; Dental Wings Inc., Mon-treal, Quebec, Canada). The digitized dental models were used to replace the dentition, braces and their artifacts using iterative closest point (ICP) registration followed by manual surface based registration to create an artifact free composite 3D model. The diagnosis of the maxillofacial deformity was carried out by combining the clinical examination and 3D cephalometric analysis of the virtual model. Virtual osteotomies and surgical movements were simulated. A definitive plan was then developed. From this point forward, the 18 patients were randomly allocated between the two groups.

**Study group:**

On Blender software (Ton Roosendaal, Blender Foundation, Holland), using the preoperative skull-dental composite model, cutting guides were designed on the maxilla and mandible to orient the osteotomy and mark reference holes to be used later by the repositioning/fixation plates (figure 1). Then, the designed guides were printed SLA 3D printing machine (Phrozen 3D printer, Taiwan).

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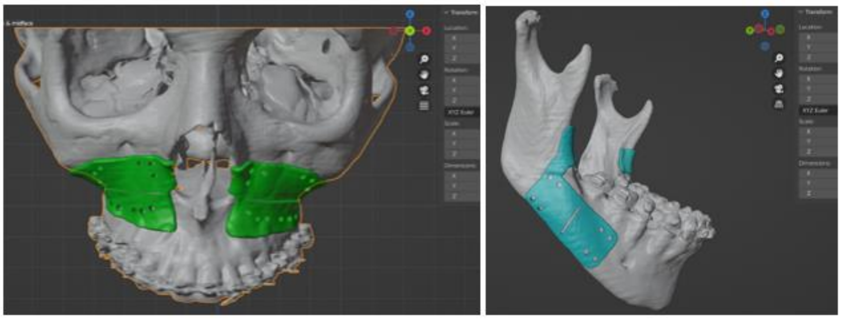

**Figure 1**: Designing of the maxillary and mandibular cutting guides.

Custom-made plates were designed to reposition and fix the maxilla and mandibular distal segment using the previously established reference holes (figure 2). Then, the designed plates were manufactured in titanium using a CNC milling machine (MILLSTAR, Made in Taiwan).

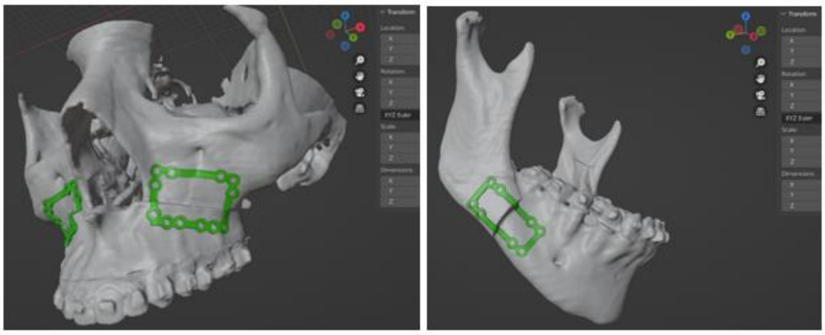

**Figure 2**: Designing of the maxillary and mandibular custom-made plates.

In the operating room, the maxillary cutting guides were inserted onto the exposed bony surface and manipulated to the best fit. 24 reference holes were established using the cutting guides; twelve on each side. Then, a reciprocating saw was used to section the lateral wall of the maxilla. After completing Le Fort I osteotomy and down fracturing of the maxilla, the maxilla was oriented to the planned position using the custom-made plate and fixed using sixteen 2.0 mm screws, eight on each side (figure 3).

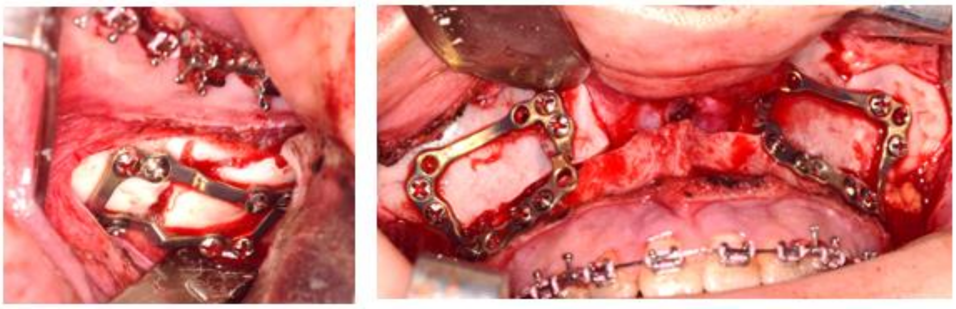

**Figure 3**: Maxillary and mandibular repositioning and fixation using custom-made titanium plates.

Regarding the mandible, the mandibular cutting guides were inserted onto the exposed bony surface and manipulated to the best fit. 8 reference holes were established using the cutting guide on each side. Then, the guides were removed and the bilateral sagittal split osteotomy was completed. Using the previously

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established reference holes and the custom-made plates, the distal segment was oriented to the planned position using the customized plate and fixed using 2.0 mm screws, eight on each side (figure 3). Then, checking of the final occlusion was carried out. All incisions were closed with 4-0 resorbable continuous sutures.

**Control group:**

Face bow record ((Bioart®, São Carlos- São Paulo, Brazil) was used to mount the maxillary cast to the top portion of A7Plus semi-adjustable articulator (Bioart®, São Carlos-São Paulo, Brazil) with mounting stone. The centric relation record was used to relate the mandibular cast in the appropriate centric relation. After marking the casts and taking measurements, the maxillary cast was repositioned to the planned position and intermediate wafer was fabricated. Then, the final wafer was fabricated after positioning of the mandibular cast in the desired final occlusion.

In the operating room, after completing the maxillary osteotomy and down fracturing, the maxilla was repositioned using the intermediate wafer, and fixed using four 2.0 mm titanium plates. Bilateral sagittal split osteotomy was then done, and the distal segment was repositioned using the final wafer and fixed with three 2.0 mm positional screws. All incisions were closed with 4-0 resorbable continuous sutures.

CBCT scans of all patients in both groups were taken within one week postoperatively.

**Data collection methods:**

The skull base in the virtual surgical plan CT was superimposed using point-based matching iterative closest point (ICP) registration with the skull base in the actual postoperative CT scans.

Linear deviation (ΔT) between the virtual plan (T0) and the actual postoperative position (T1) were measured using computer software (Mimics 21.0) by using maxillary teeth reference points (upper central, right and left maxillary first molar) and mandibular teeth reference points (lower central, right and left mandibular first molar) in relation to the three planes; FHP, coronal plane and midfacial plane MFP. The measurements from the reference points to the FHP indicated vertical deviation, to the coronal plane indicated anteroposterior deviation and to the MFP indicated mediolateral deviation.

**Results:**

All patients showed uneventful wound healing without any signs or symptoms of infection or wound dehiscence (figures 4 and 5). Postoperative edema was observed in all patients and resolved completely by the 8th week postoperatively.

**Figure 4**: Profile view of patient number 2 in group 1 preoperatively and 6 months postoperatively.

**Figure 5**: The occlusion of patient number 2 in group 1 preoperatively and 6 months postoperatively.

Regarding difference in the accuracy of plan transfer of the maxilla between the two groups, U1, 26 and overall measurements made in the sagittal plane, group (I) had significantly lower values (i.e., was more accurate) than group (II). While for other planes and measurements, the difference in accuracy was not statistically significant (Table 1). For the difference in accuracy of plan transfer of the mandible between the two groups, overall measurements made in the FHP and coronal planes, group (I) had significantly lower values (i.e., was more accurate) than group (II). While for other planes and measurements, the difference in accuracy was not statistically significant (Table 2).

Table 1: Difference in accuracy between the two groups in the maxillary arch.

| Plane | Tooth | Group I Mean±SD | Group II Mean±SD | Test statistic | p-value |
|---|---|---|---|---|---|
| FHP | U1 | 0.88±0.80 | 0.92±0.70 | **26.00** | **0.722ns** |
| | 16 | 0.68±0.47 | 0.90±0.67 | **22.00** | **1ns** |
| | 26 | 0.89±0.48 | 1.11±0.62 | **13.00** | **0.529ns** |
| | Overall | 0.81±0.59 | 0.98±0.65 | **414.50** | **0.392ns** |
| Coronal | U1 | 1.29±1.00 | 1.78±1.30 | **16.00** | **0.477ns** |
| | 16 | 1.13±1.34 | 1.43±1.59 | **17.00** | **0.554ns** |
| | 26 | 1.37±1.19 | 1.65±0.91 | **17.00** | **0.554ns** |
| | Overall | 1.27±1.14 | 1.62±1.25 | **443.50** | **0.174ns** |
| Sagittal | U1 | 0.21±0.16 | 0.85±0.65 | **1.00** | **0.013*** |
| | 16 | 0.57±0.57 | 0.56±0.20 | **19.50** | **0.767ns** |
| | 26 | 0.37±0.26 | 0.68±0.32 | **3.00** | **0.024*** |
| | Overall | 0.38±0.39 | 0.69±0.43 | **551.00** | **0.001*** |

Table 2: Difference in accuracy between the two groups in the mandibular arch.

| Plane | Tooth | Group I Mean±SD | Group II Mean±SD | Test statistic | p-value |
|---|---|---|---|---|---|
| FHP | U1 | 0.90±1.00 | 1.61±0.59 | **8.00** | **0.097ns** |
| | 16 | 0.81±1.00 | 0.97±0.71 | **17.00** | **0.554ns** |

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| Plane | Tooth | Group I Mean±SD | Group II Mean±SD | Test statistic | p-value |
|---|---|---|---|---|---|
| | **26** | 0.85±0.43 | 1.04±0.73 | **15.00** | **0.407ns** |
| | **Overall** | 0.85±0.82 | 1.21±0.72 | **484.50** | **0.039*** |
| **Coronal** | **U1** | 1.55±1.09 | 1.55±0.73 | **21.00** | **0.906ns** |
| | **16** | 1.01±0.93 | 1.52±0.61 | **11.00** | **0.193ns** |
| | **26** | 0.83±0.74 | 1.45±0.86 | **13.00** | **0.286ns** |
| | **Overall** | 1.13±0.95 | 1.51±0.71 | **481.00** | **0.045*** |
| **Sagittal** | **U1** | 0.40±0.38 | 0.55±0.33 | **16.00** | **0.477ns** |
| | **16** | 0.73±0.42 | 0.65±0.23 | **23.00** | **0.529ns** |
| | **26** | 0.44±0.36 | 0.72±0.36 | **8.00** | **0.097ns** |
| | **Overall** | 0.52±0.40 | 0.64±0.30 | **456.00** | **0.115ns** |

**Discussion:**

In the present study, 3D virtual planning and simulation of the surgical movements were done for all patients in the two groups. The 3D virtual planning provides more diagnostic data including shape, size and position of the mandibular condyles, morphology and thickness of the bone at the osteotomy sites, location of the infra-orbital nerve and inferior alveolar nerve, as well as position of the dental roots[8].

CBCT scan was used in the current study for 3D image acquisition with less radiation doses, cost and exposure time compared to CT. However, CBCT scanners even with flat panel detectors which are less prone to beam hardening artifacts as metal artifacts didn't provide enough accuracy and resolution[9], [10].

Moreover, accurate acquisition of the dental morphology is still a limitation in the CBCT imaging and even CT scan. In order to overcome this limitation, the dental casts were scanned to provide accurate dental morphology and reproduction[11], [12]. Another limitation in the image acquisition using CBCT and even with CT scan is poor segmentation of the thin anterior maxillary wall resulting in low quality of the 3D model, so the design of the cutting guide that precisely fit the anterior maxillary wall becomes impossible. To overcome this problem, the anterior wall of the maxilla was segmented separately and then augmented with the entire 3D model.

In the present study, additional holes were added in the design of the maxillary plates so that if a hole fails and the screw become loose, another hole could be used to ensure sufficient screw tightening and subsequently stable fixation of the plates.

Regarding the fitting accuracy of the cutting guides, Mazzoni et al. described the use of image-guided navigation to verify the position of the cutting guides and reported that 30 % of the guides required small adjustments[13]. Some authors preferred to design the maxillary cutting guide in one-piece crossing the midline to confirm the precise seating and positioning[7], [14]. In the current study, in order to guarantee the maximum fitting and the accurate positioning of the cutting guides, each maxillary guide was designed with extensions to three anatomical areas; the zygomatico-maxillary buttress, around the piriform rim and scalloped part covering the dental roots eminences. While the design of

each mandibular guide had an extending arm covering the anterior border and part of the lateral surface of the ascending ramus.

When analyzing the linear deviation of the maxillary and mandibular landmarks, the maxillary linear deviation didn't exceed 1.37 mm in group 1, while in group 2 was up to 1.78 mm, and the maximum mandibular linear deviation in group 1 was 1.55 mm, while in group 2 was 1.61 mm.

These results were comparable to those of Zinser et al. in 2013 who reported statistically insignificant linear deviation between computer-guided group and classic inter-occlusal wafer group. However, the mean linear deviation reported by Zinser et al, did not exceed 0.23 mm vertically, 0.14 mm anteroposteriorly and 0.04 mm mediolaterally for the computer-guided group, while the classic wafer gruop had deviation up to 1.3 mm vertically, 0.61 mm anteroposteriorly and 0.43 mm mediolaterally[15].

When the linear deviation in the current study was compared to results reported by other authors[16]–[18], it was apparent that the current workflow achieved more precise plan transfer. The more accurate results could be attributed to use of the customized plates that provide bone-to-bone guidance, while other studies with less accuracy results used inter-occlusal wafers and tooth-to-bone guidance.

**Conclusion:**

Computer-guided orthognathic surgery workflow provide more accuracy than classic model surgery. The main disadvantages of the computer-guided workflow are the cost, and the long duration of the planning. The foreseeable technological advances may allow more accurate image acquisition with no artifacts that would significantly reduce planning time and the CAD/CAM technology at a cut-price to be available.

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**Declaration of Competing Interest:**

No conflict of interest declared.

**Author Contributions:**

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Mohamed Ali Zain, Adel Hamdy Abo El-fotouh and Mahmoud Hanafy Mahmoud. The first draft of the manuscript was written by Mohamed Ali Zain and Maha Mohamed Hakam, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

**Ethical approval:**

The Ethics and Research Committee, Faculty of Dentistry, Cairo University approved the study and patient consent was obtained.

**Patient consent:**

Written patient consent was obtained to participate in the study.

**Consent to publish:**

The authors affirm that human research participants provided informed consent for publication of the clinical photographs.

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