Journal of Chemical Health Risks
www.jchr.org
JCHR (2024) 14(6), 2005-2014 | ISSN:2251-6727

# Skeletal Stability of Le Fort I Osteotomy Using Patient-Specific Osteosynthesis Compared to Mini-Plate Fixation for Patients with Dentofacial Disharmony. A Randomized Controlled Clinical Trial

**[1]Hassan Fahmy Hassan (corresponding author), [2]Prof. Maha Mohamed Hakam, [3]Prof. Adel Hamdy Abo El-Fotouh**
[1]PhD candidate, Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University, Cairo, Egypt, Postal address: 11 Saraya El Manial street Kasr El Einy, Cairo, Egypt.
[2]Professor, Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University, Cairo, Egypt.
[3]Professor, Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Cairo University, Cairo, Egypt.

***(Received: 16 September 2024 Revised: 11 October 2024 Accepted: 11 December 2024)***

**KEYWORDS**
stability of Le Fort I osteotomy, bi-maxillary orthognathic surgery, patient-specific osteosynthesis , CAD/CAM cutting guides, customized plates

**ABSTRACT:**
Purpose: to evaluate the skeletal stability of Le Fort I osteotomy using patient-specific osteosynthesis (PSO) compared to conventional mini-plate fixation in patients with skeletal class III malocclusion undergoing bimaxillary orthognathic surgery.

Methods: A total of 24 patients with skeletal class III malocclusion indicated for bi-maxillary orthognathic surgery were randomly assigned to 2 equal parallel groups. In 12 patients, computer-aided design and manufacturing (CAD/CAM) cutting guides and customized titanium patient-specific plates (PSPs) were used (group 1 or intervention group). In the other 12 patients, classic mini-plates were used (group 2 or control group). Skeletal stability of Le Fort I osteotomy was assessed for all patients in both groups after one year using CT scan.

Results: The mean horizontal relapse of maxilla after one year was 0.59±0.26 mm in group I (PSPs) and 0.69±0.27 mm in group II (conventional mini-plates). Intergroup comparisons of change in the coronal plane showed no statistically significant difference in relapse after 1 year between the intervention and control groups for (A point, ANS, PNS, RGBF, and LGBF), while for (IF and average) the change measured in the control group was significantly higher (more horizontal relapse) than that of the intervention group.

Conclusion: Both conventional mini-plates and PSPs provided stable and reliable fixation in small (<5mm) maxillary advancements via the Le Fort I osteotomy in class III patients who underwent bimaxillary surgery, with no clinically significant difference in relapse found between conventional mini-plates and PSPs fixation after one year follow up.

**Introduction:**
Skeletal stability after fixation of Le Fort I osteotomy cases in patients with dentofacial disharmony is widely discussed in the literature and it was shown that postsurgical relapse is one of the most common observations after surgery [1–7].

The use of Mini-plate fixation for Le Fort I osteotomy in patients with dentofacial disharmony is considered to be the gold standard technique [3]. Although they have been used for decades and have become the standard treatment, the materials used in these systems may fail due to excessive loading and other causal factors during the surgical procedure, including failure in plate adaptation and fixation to bone, material design, fabrication, and degree of purity of the plate material [1,4].

The bending of non-customized plates generate stresses that are minimized when using customized plates, because these plates are fabricated individually, with predetermined sizes for each patient [8].

Recently, the use of the computer-assisted orthognathic surgery systems is rapidly becoming a common practice in orthognathic surgery. Preoperative virtual surgical planning has become an important tool in orthognathic surgery. High-resolution computed tomography (CT) and cone beam computed tomography (CBCT) in addition to dental scans obtained during the work-up allow improved accuracy of planning and simulation of the result [9]. The benefits are clear in two-jaw surgery and in complex asymmetry cases in both planning and performing the surgery. Individually designed and manufactured surgical drill and cutting guides as well as patient-specific plates (PSPs) for osteosynthesis are now available for reasonable costs and within a short space of time. The development of three dimensional (3D) designed implants has been rapidly and continuously progressing [10].

The change from conventional mini-plates to individualized implants became possible when computer-aided design and manufacturing (CAD/CAM), including milling and printing techniques, started to develop [11–13]. Individually milled implants, combined with the use of drill guides also makes wafer free fixation of the maxillary segment possible, and ideal fitting of the osteosynthesis material is passive and tension-free.

The use of PSPs for wafer-free fixation and osteosynthesis after Le Fort I osteotomy has proven reliable and accurate [13–15]. Whether this leads to better postoperative skeletal stability remains to be investigated.

In the present research, the aim was to evaluate the skeletal stability of Le Fort I osteotomy using patient-specific osteosynthesis (PSO) compared to mini-plate fixation for patients with skeletal class III malocclusion.

**Materials and methods:**

The present study is a double-blinded randomized controlled clinical trial conducted on 24 patients. Inclusion criteria were patients with skeletal class III malocclusion planned for traditional orthognathic approach and requiring bimaxillary orthognathic surgeries in which there will be Le Fort I osteotomy with maxillary advancement ranging from 2mm to 5 mm in addition to mandibular setback, patients more than 18 years old, patients with no signs or symptoms of active temporomandibular disorders (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. A total of 24 patients with skeletal class III malocclusion indicated for bi-maxillary orthognathic surgery were randomly assigned to 2 equal parallel groups. In 12 patients, CAD/CAM cutting guides and customized titanium PSPs were used (group 1 or intervention group). In the other 12 patients, classic mini-plates were used (group 2 or control group). Skeletal stability of Le Fort I osteotomy was assessed for all patients in both groups after one year using CT scan.

**Randomization:**

The 24 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 CT scan using multi-slice helical CT imaging machine (Toshiba Alexion 16, Toshiba Medical Systems Corporation, Otawara, Tochigi, Japan). The CT scan was acquired in a DICOM format and imported into a surgical planning software Mimics 21.0 (Materialise N.V., Leuven, Belgium). A segmentation process was then carried out; based on Hounsfield's units; to select only the bony structures out of it. A 3D reconstruction of the bony structures was then performed. Then, maxilla and mandible were separated using mask split.

Conventional plaster models were used to provide an accurate presentation of the dentition. The dental models were scanned separately and mounted 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 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 24 patients were randomly allocated between the two groups.

**Intervention group:**

Using the preoperative skull-dental composite model on Blinder software, 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). The thickness of the maxillary and mandibular guides was 2.5 mm. The maxillary cutting guides were designed to cover the eminences of the maxillary dental roots with extended

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arms on the zygomatico-maxillary buttress and piriform rim. The mandibular cutting guides were designed with an extended arm on the anterior aspect and lateral surface of the ascending ramus. Then, the designed guides were exported in the form of stereolithography (STL) file to be sent to a 3D printing machine (Phrozen 3D printer, Taiwan).

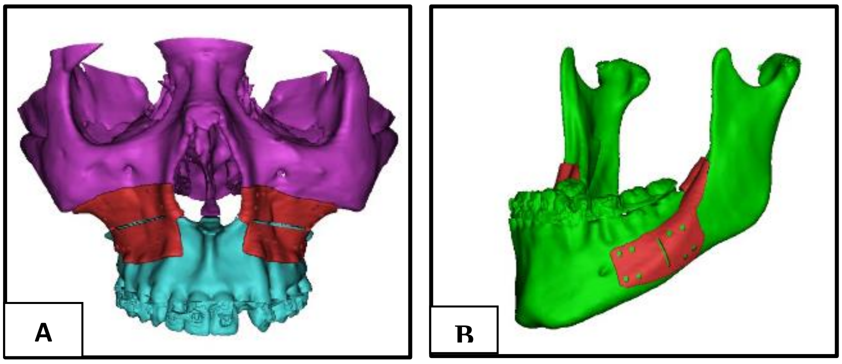

**Figure (1):** Designing of the maxillary (A) and mandibular (B) cutting guides.

A custom-made repositioning/fixation plates were designed to reposition and fix the maxilla and the mandibular distal segment in relation to the unmoved skull base and proximal segments of the mandible using the previously established reference holes (Figure 2). The design was composed of 2 maxillary plates, one on each side and 2 mandibular plates, one on each side. The thickness of the maxillary and mandibular plates was 0.8mm and their width was 2 mm. The maxillary plates were designed as a box shape with 12 holes for each plate. While the mandibular plates were designed as a box shape with 8 holes on each side. Then, the designed plates were exported in the form of STL files to be sent to a milling machine (MILLSTAR, Made in Taiwan).

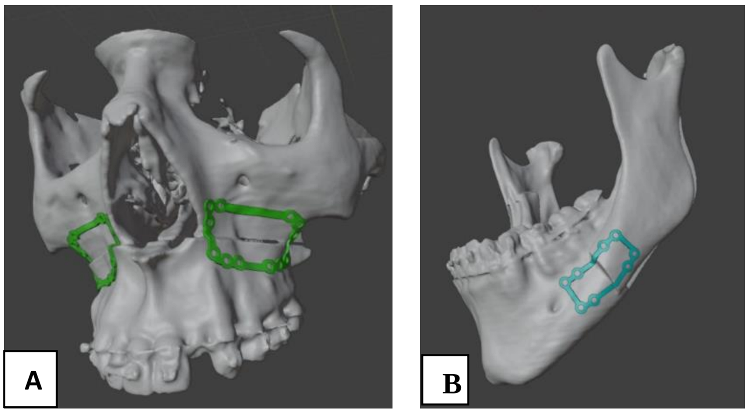

**Figure (2):** Designing of the maxillary (A) and mandibular (B) custom-made plates.

In the operating room, the cutting guides were inserted onto the exposed bony surface and manipulated to the best fit. The guides had extensions around piriform rim and root eminencies of the canine and premolars to ensure best accurate positioning and adaptation of the guide. Then, each guide was fixed using two 2.0 mm screws to avoid any mobilization during reference holes drilling. 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 from posterior to anterior through the planned slot in the cutting guide with the assistant retracting the buccal soft tissue. Then, the guides were removed. A reverse cut was made with the saw from inside out through the posterior wall of the maxilla, completing the osteotomy.

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 3A).

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JCHR (2024) 14(6), 2005-2014 | ISSN:2251-6727

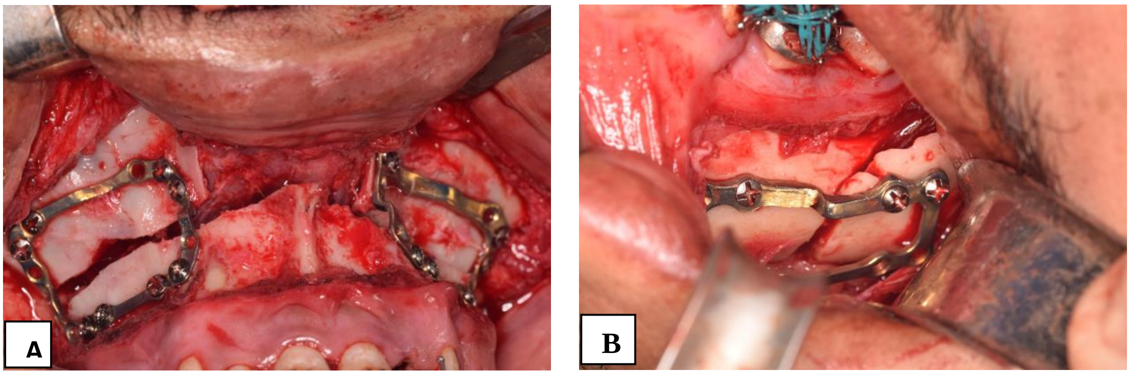


**Figure (3):** Maxillary (A) and mandibular (B) repositioning and fixation using custom-made titanium plates.

Regarding the mandible, the cutting guide was inserted onto the exposed bony surface and manipulated to the best fit. The guide had extension around the anterior border of the ramus to ensure best accurate positioning and adaptation of the guide. Then, each guide was fixed using two 2.0 mm screws to avoid any mobilization during reference holes drilling. 8 reference holes were established using the cutting guide on each side. Then, a fissure bur was used to mark the buccal cut on lateral border of the mandible. Then, the guides were removed and the bilateral sagittal split osteotomy (BSSO) was completed.

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

**Control group:**
After virtual planning, the desired occlusion was established then the maxillary and mandibular teeth were separated vertically, by approximately 1 mm through clock wise rotation of the mandible. This step aimed to avoid occlusal interferences and to create a final wafer with sufficient thickness to prevent unplanned premature tooth contacts, to provide sufficient surface area of material to positively locate the wafer on the teeth, and to enhance wafer strength. Digital intermediate and final interocclusal wafer splints were designed to guide the maxilla and mandible in the desired position using Blinder software.

The STL file representing the splints was transported to an additive 3D printing machine to be printed in resin.

In the operating room,the projected osteotomy line was demarcated by making drill holes 4 to 5 mm above the apices of the maxillary canine and the first molar. The location of the root apices was identified by noting the bony eminence for the canine in addition to data gained from CT scan. The osteotomy started from pyriform aperture and extended posteriorly on the lateral wall of maxilla through the holes to the pterygoid area.

After down fracturing of the maxilla, the mobilized maxilla was seated into the prefabricated intermediate occlusal splint and followed by intermaxillary fixation. Then, manual positioning of the maxillomandibular complex was achieved by applying digital pressure anterior to the mandibular angle in an upward and slightly anterior direction. The maxillomandibular complex then was seated passively until even bone contacts are observed and the planned vertical relationship was established. Once planned repositioning of the maxilla was achieved in anteroposterior, vertical, and transverse dimensions, osteosynthesis was achieved using 2.0 mm titanium plates with 1mm thickness and 2 mm width placed at the piriform area and the zygomaticomaxillary crest to secure the maxilla in its new position.

For the mandible, standard BSSO cuts were carried out. Then, the final surgical splint was placed and inter-maxillary fixation (IMF) was achieved using ligatures wires or power chain. Condylar positioning was achieved by gently moving and maintaining the proximal segment into the fossa using a ramus pusher. Care was taken to ensure that the segments remained passive during osteosynthesis, with no interferences or torquing of the condyles.

Osteosynthesis was achieved using three 2.0 mm positional screws inserted trans-buccally. Then the IMF was removed and occlusion was checked in reference to the planned final occlusion. All incisions were closed with 4-0 resorbable continuous sutures.

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CT scans of the patients were taken within one week after the surgery (immediate postoperative) and after one year.

**Data collection methods:**

The skull base in the immediate postoperative CT scans was superimposed using point-based matching ICP registration with the skull base in the one-year postoperative CT scans.

After establishment of the coronal plane, linear deviations (ΔT) between the immediate postoperative (T1) and the one-year postoperative position (T2) were measured using computer software (Mimics 21.0) using hard tissue reference points in relation to the coronal plane. Measurements from the reference points to the coronal plane indicated anteroposterior horizontal deviation.

Six hard tissue reference points were used:

- A point (maximum concavity on anterior surface of maxilla)
- Anterior nasal spine (ANS)
- Posterior nasal spine (PNS)
- Incisive foramen (IF)
- Right side Greater palatine foramen (RGPF)
- Left side Greater palatine foramen (LGPF)

**Results:**

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

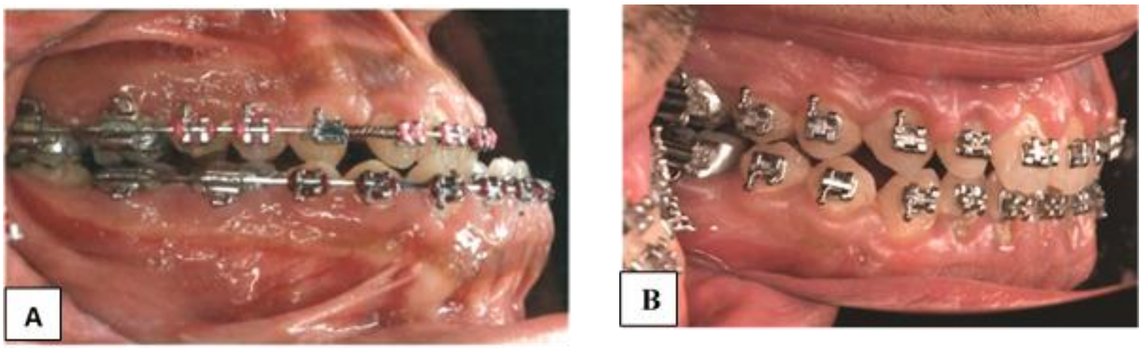


**Figure (4):** Intraoral lateral view of the occlusion of patient number 7 in group 2 preoperatively (A) and postoperatively (B).

All patients experienced limited mouth opening in the early postoperative phase that improved by active and passive mouth opening exercises. All patients had restored their maximum mouth opening one month postoperatively.

Regarding Intragroup comparisons in coronal plane, measured values of all points in both groups were significantly reduced after 1 year indicating horizontal relapse ($p<0.05$) (Table 1).

**Table (1):** Intragroup comparisons and summary statistics for different measurements in coronal plane.

| Time | Group | Mean ± SD (mm) | | p-value |
|---|---|---|---|---|
| | | Immediately | 1 year | |
| A point | Intervention | 72.22±2.80 | 71.60±2.84 | **0.003*** |
| | Control | 73.87±1.13 | 73.15±1.00 | **0.003*** |
| ANS | Intervention | 71.87±2.86 | 71.27±2.83 | **0.003*** |

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| Time | Group | Mean ± SD (mm) | | p-value |
|---|---|---|---|---|
| | | Immediately | 1 year | |
| | Control | 73.72±1.42 | 73.04±1.34 | **0.003*** |
| PNS | Intervention | 28.57±1.96 | 28.06±1.99 | **0.025*** |
| | Control | 29.77±0.85 | 29.02±0.93 | **0.003*** |
| IF | Intervention | 63.91±2.53 | 63.37±2.54 | **0.003*** |
| | Control | 64.95±0.87 | 64.23±0.81 | **0.003*** |
| RGBF | Intervention | 42.90±2.65 | 42.36±2.70 | **0.003*** |
| | Control | 43.56±1.00 | 43.00±0.87 | **0.003*** |
| LGBF | Intervention | 42.61±2.77 | 42.03±2.84 | **0.003*** |
| | Control | 43.92±0.98 | 43.22±1.01 | **0.003*** |

* Significant.

intergroup comparisons of change in the coronal plane showed no statistically significant difference in relapse after 1 year between the intervention and control groups for (A point, ANS, PNS, RGBF, and LGBF), while for (IF and average) the change measured in the control group was significantly higher (more horizontal relapse) than that of the intervention (Table 2).

**Table (2):** Intergroup comparisons and summary statistics for the change in different measurements in coronal plane

| Plane | Point | Mean ± SD (mm) | | p-value |
|---|---|---|---|---|
| | | Intervention | Control | |
| Coronal | A point | 0.62±0.30 | 0.72±0.26 | **0.371ns** |
| | ANS | 0.61±0.26 | 0.67±0.38 | **0.977ns** |
| | PNS | 0.65±0.18 | 0.75±0.31 | **0.285ns** |
| | IF | 0.54±0.18 | 0.72±0.22 | **0.028*** |

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| Plane | Point | Mean ± SD (mm) | | p-value |
|---|---|---|---|---|
| | | Intervention | Control | |
| | RGBF | 0.54±0.29 | 0.56±0.24 | **0.707ns** |
| | LGBF | 0.59±0.34 | 0.71±0.19 | **0.149ns** |
| | Average | 0.59±0.26 | 0.69±0.27 | **0.012*** |

**Discussion:**

Maxillary advancement via the Le Fort I osteotomy is a useful technique for the correction of maxillary hypoplasia cases in patients with dentofacial disharmony. Advances in anesthetic and surgical techniques over the past years have made the procedure safe and reliable.

Relapse rates for maxillary movements have been analyzed extensively [7]. In the literature, maxillary advancements and impactions have been considered the most stable, while maxillary transverse expansions and down-grafting have been considered the most unstable [16]. However it has been shown that postsurgical relapse in cases of maxillary advancement via the Le Fort I osteotomy is one of the most common observations after surgery [1–6].

Traditional rigid fixation relies on stabilization of the Le Fort I osteotomy bilaterally at the medial (nasomaxillary) and lateral (zygomaticomaxillary) buttresses. This is commonly accomplished using 2.0-mm mini-plates at each of the four sites, with at least two mono-cortical screws affixed to the plate on each side of the osteotomy.

The introduction of the new technologies such as CT and CBCT imaging, 3D computer virtual planning programs, rapid prototyping, CAD/CAM technology as well as surgical navigation system had changed the maxillofacial field in the last few decades. There has been a revolution in the 3D planning of the bi-maxillary orthognathic surgeries with paradigm shift in the accuracy of the virtual planning transfer to the actual surgery.

Designing the present study, it was hypothesized that PSPs provide more stable fixation than conventional mini-plates depending on many factors.

First, PSPs are 3D printed to rest intimately against the contour of the maxilla based on the bony morphology, while stock plates require the surgeon to bend the plate intraoperatively to fit best. Therefore, stock plates is subjected to more strain and micro movements from contour discrepancy, as well as weakening from intra-operative plate manipulation [17–19].

Moreover, virtual surgical planning allows the surgeon and engineer to determine the thickest available bone to fixate the hardware, while in stock plating the surgeon usually judge the quality of bone intraoperatively based on how the stock plates seats and where the screws could be fixed.

Another factor is that PSPs were designed as a single 3D box shape for each side of the maxilla and manufactured from grade 5 titanium alloys, in contrast to two separate straight and L-shape conventional mini-plates for each side of the maxilla that were manufactured form the less rigid grade 4 titanium alloys.

In this study, intragroup comparisons in the coronal plane showed that for all points measured in both groups, measured values were significantly reduced after 1 year indicating statistically significant anteroposterior horizontal relapse in both groups after one year. The mean horizontal relapse of maxilla after one year was 0.59±0.26 mm in group I (PSPs) and 0.69±0.27 mm in group II (conventional mini-plates).

However, these relapse values are considered clinically insignificant. Earlier previous studies assessing stability of orthognathic surgery agreed that relapse ≤2mm is considered acceptable, as this is within the realm of post-surgical orthodontic camouflage [16,20]. Therefore, it is fair to say that both groups (PSPs and conventional mini-plates) provided stable and reliable fixation.

In the current study, intergroup comparisons of change in the coronal plane showed no statistically significant difference in relapse after 1 year between the intervention and control groups for (A point, ANS, PNS, RGBF, and LGBF), while for (IF and average) the change measured in the control group was significantly higher (more horizontal relapse) than that of the intervention. However, the mean difference of horizontal relapse after one year between the two groups was only 0.1 mm which is definitely clinically insignificant.

These fore mentioned results were in accordance with previous studies done to assess skeletal stability of Le Fort I osteotomy [10,21,22]. A retrospective study conducted on fifty-one patients to compare the postoperative skeletal stability of the maxillary segment fixed by PSPs versus mini-plates after Le Fort I osteotomy using 2D cephalometric analysis found that the choice between the two fixation methods did not seem to affect the postoperative skeletal stability of the maxilla [10].

In another study, the 1-year skeletal stability of the osteotomized maxilla after Le Fort I surgery was assessed, comparing conventional osteosynthesis with PSO. The 3D translation analysis showed that the use of PSO did not result in a significant difference in 1-year skeletal stability compared to the conventional mini-plate osteosynthesis approach [21].

In patients with cleft lip and palate, the one-year skeletal stability of Le Fort I osteotomy was evaluated using PSPs versus stock conventional plates. In small (<5mm) and moderate horizontal advancements (5- 10mm), both PSPs and conventional plates provided similar stability; both groups had ≤0.4mm relapse with no statistically significant difference. While in patients who had large advancements (>10mm), PSPs had significantly less relapse than conventional plates (PSPs 0.105mm ± 0.317mm vs. conventional 1.888mm ± 1.125mm) [22].

Therefore, it may be fair to state that both conventional mini-plates and PSPs provide stable and reliable fixation in small (<5mm) maxillary advancements. However, for larger maxillary advancements (>10mm), PSPs might result in better postoperative stability than conventional plates. A separate study to compare the stability of maxillary advancements in patients with dentofacial disharmony using conventional versus PSPs with subgrouping according to amount of maxillary advancements (<5mm, 5-10mm, >10mm) might be useful to confirm this assumption.

Considering the cost, time, and complexity of preparation of PSPs, it may be beneficial to use them only in large maxillary advancements (>10mm).

## CONCLUSIONS

Both conventional mini-plates and PSPs provided stable and reliable fixation in small (2- 5mm) maxillary advancements via the Le Fort I osteotomy in class III patients who underwent bimaxillary orthognathic surgery. No clinically significant difference in relapse was found between conventional mini-plates and PSPs fixation after one year follow up.

The computer-assisted orthognathic surgery planning avoided technical obstacles with the classic model surgery. PSPs allowed surgeons to perform the maxillary procedure with minimal time frame especially in complex cases such as facial asymmetry.

The main disadvantages of the computer-guided planning and PSPs are the cost, and the longer time consumed in the planning.

**Funding:**

This research did not receive any specific grants from funding agencies in the public, commercial, or not-for-profit sectors.

**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 Hassan Fahmy Hassan and Adel Hamdy Abo El-fotouh. The first draft of the manuscript was written by Hassan Fahmy Hassan 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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