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Original Article

Stability of Two Different Designs of Patient Specific Osteosynthesis for the Fixation of the Lefort 1 Osteotomy in Maxillary Orthognathic Surgery - A Randomized Clinical Trial

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Abstract

Aim: This RCT further explores maximizing the benefits of using PSIs in Orthognathic surgery. Does it improve the postoperative stability of the operated maxilla and does using different designs change affect that outcome?

Subjects and Methods:A Randomized clinical trial was done to compare the stability of the operated maxilla following orthognathic surgery. 34 patients were recruited from the Oral and maxillofacial surgery clinic and were divided into two groups: the first group a one-piece fixation plate was used, while a two-piece fixation plate was used in the second group. Immediate and four moths postoperative CT scans were done to evaluate the stability using seven dental and bony landmarks

Results: There were no statistically significant differences ($P \leq 0.05$) between the two groups in all seven landmarks used for stability measurements, indicating the absence of significant clinical stability between the two groups.

Conclusion: Based on this research findings, the two different fixation schemes proved to be very similar after 4 months of surgery. Further longer-term studies are indicated to reach final conclusions about the use of PSIs and the best use of VSP in orthognathic surgery.

Keywords: Orthognathic surgery, Stability, Virtual planning, PSIs.

Introduction

Orthognathic surgery is the detailed art and science of dealing with dentofacial deformities which affect many individuals. Dentofacial deformities can be defined as abnormal position of the lower third of the facial skeleton in all three dimensions of space resulting in dysfunctions affecting the patient's quality of life.(Posnick, 2013)

A plethora of corrective osteotomies have been advocated for both jaws to achieve an improved jaw relationship. The oldest osteotomy of the lower jaw was the one done by Simon Hullihen in the form of a dentoalveolar segmental osteotomy to correct a dysmorphology caused by burn scar contracture. (Bell, 2018)

Then came Hugo Obwegeser's milestone surgical techniques which included the use of a maxillary vestibular incision to expose the facial surface of the maxilla from one pterygoid plate to the other to achieve full downfracture of the maxilla with possible sacrifice of both descending palatine arteries without fear of loss of vascularity (Obwegeser, 2007).

After establishing the safety and the feasibility the Le Fort 1 osteotomy, which allowed the corrective surgeon complete control over the maxilla in all three dimensions of space, The next obvious pressing issue was to maintain the achieved position of the maxillary segment. What would be the benefit of putting the patient through strenuous surgery and recovery with their related morbidity and downtime and possible complications if these results were only short lived. Were these results stable on the long term? What is the expected amount of relapse? Which movements were more stable than the others? Which movements were too unstable to proceed with? What were the main factors associated with relapse? Was the type of fixation used with the advent of the LeFort 1 osteotomy a factor for relapse?

Relapse in orthognathic surgery is multifactorial and can be attributed to residual growth after surgery, the amount of movement, the type of movement, the type of fixation, condylar changes and muscle action and pull. Masticatory muscle activity, deficient preoperative and postoperative about the randomization process was asked about the specific group and treated; accordingly, the orthodontics, surgical complications, inefficient fixation of bone segments can lead to bone instability and hence treatment relapse.

When mentioning the significant advances in orthognathic surgery throughout the years, virtual surgical planning (VSP) must be mentioned as the most significant in recent years. A significant improvement in all aspects of diagnosis, treatment planning and guided execution have led to more predictable outcomes. (Tucker et al., 2010) (Xia et al., 2015) (Zhang et al., 2016).

This RCT takes advantage of VSP and Computer guided surgery to explore the added benefits of these entities regarding the post-surgical stability of the operated maxilla in orthognathic surgery.

Subjects and Methods

Study Design

This is a randomized clinical trial with two parallel arms and an allocation ratio of 1:1. The two arms are the control group and the intervention group. In the two groups, the intervention is done using different designs of patient specific osteosynthesis to try and determine the superiority of the intervention.

Radiographic Examination

All patients presented standardized baseline panoramic and lateral cephalometric X-rays._The panoramic X-ray serves as a scout radiograph for all the dentition and the condyles and to look out for impacted teeth and any pathology within the jaws.

Fine cuts (0.7mm) maxillofacial CT scans were ordered for all patients with the same specifications (0.7mm slice thickness – 0.4 mm slice spacing – zero gantry tilt) using the same medical Multislice CT machine **(Philips Spectral CT 7500)** for standardization purposes. The CT scan was done with the patient placed in Centric relation using a radiolucent bite record taken beforehand. All the DICOM data for each patient was obtained and processed using specialized medical viewing software for further diagnosis and treatment planning.

Preoperative Virtual Planning

After CT examinations, further processing of the DICOM files (Digital Imaging and Communications in Medicine) will be performed using the specialized DICOM image processing software **(ProplanCMF, Materialise, Leuven, Belgium)** and reconstructed 3D models of the skull will be made.

As the dentition portion of the generated skull model will usually be distorted to degrees by artifacts and restorations and orthodontic wire and brackets, additional accurate rendition of the teeth will be needed for the fabrication and intra-operative use of any occlusal based appliance. The final position of the mandible was achieved using a final occlusal wafer.

Stone models will be scanned using an optical scanner **(3shape F8 lab scanner)**. Registration of the STL files with the skull model will create a composite skull model suitable for the construction of necessary devices. The composite skull model consists of an accurate representation of both the skull bones and the dentition.

After the completion of the virtual surgery, all the bony segments are exported to a CAD software for the design of the fixation plates, cutting guides and the occlusal splints used for the fixation of the mandible in final position whenever it was done.

Surgical guides were fabricated using PLA 3D printing technology **(Phrozen Sonic Mini 4k, Taiwan)** using photopolymerized resin **(Proshape Digital solutions, USA)**.

All cutting guides designed for all patients were one piece bone supported guides to obtain the best fit and "one and only position" to match the virtual plan.

All the previously mentioned steps were the same for our two patients' groups. The only difference is the design of the patient specific fixation device used. In the first group a one-piece PSI was used versus a two-piece PSI in the second group. The two designs used were basically the same with plate holes placed below and above the LeFort osteotomies at the lateral nasal and zygomaticomaxillary buttresses. However, with the intervention group, the two sides were joined across the anterior nasal spine area. The two designs are shown in the pictures below.

The Patient specific implants were milled from titanium blocks **(Titanium grade5ELI)** using a five-axis milling machine **(HMU-800, HUAZHONGCNC, China)**. All PSIs in the two groups had a uniform thickness of 0.8 mm and were milled from grade 5 titanium disc.

Three-dimensional Data Acquisition

An immediate postoperative CT scan was ordered on the third postoperative day as a routine follow up of the procedure to assess the osteotomies and the fixation as well as the condylar positions. It was also used to assess the accuracy of the repositioned maxillary segment compared to the virtual plan.

The result of this step was one single ProPlan CMF file, in which there are two aligned skulls (preoperative skull from the planning file and the postoperative skull), and three different positions for the maxilla: the preoperative position, the simulated position as defined during the planning procedure, and the postoperative maxillary position as defined from the postoperative CT scan. The predicted results and obtained results were evaluated by comparing the seven landmarks:

1- The midline between the upper central incisors (U1)

2/3- The cusp tips of the upper canines bilaterally (U3R, U3L)

4/5- The mesiobuccal cusp tips of the upper first molars bilaterally (U6R, U6L)

6- The anterior nasal spine (ANS)

7- The posterior nasal spine (PNS)

The same procedure was repeated after 4 months to determine the stability.

Results

Stability Measurements (ΔT2: T2 – T1)

X, Y, Z values are the coordinate values of each of the reference points in the 3D environment. T0: The initial preoperative presentation. X0, Y0, Z0: the coordinate values of the reference point preoperatively.

TV: The virtual plan XV, YV, ZV: the coordinate values of the reference point in the virtual plan.

T1: The immediate postoperative CT scan X1, Y1, Z1: the coordinate values of the reference points in the immediate postoperative CT scan.

T2: The 4 months follow up CT scan X2, Y2, Z2: the coordinate values of the reference points in the 4 months follow up CT scan.

1. **Point: U1**

There was no statistically significant difference between ΔX2, ΔY2 and ΔZ2 regarding U1 point measurements in the two groups.

2. **Point: U3R**

There was no statistically significant difference between ΔX2, ΔY2 and ΔZ2 regarding U3R point measurements in the two groups.

3. **Point: U3L**

There was no statistically significant difference between ΔX2, ΔY2 and ΔZ2 regarding U3L point measurements in the two groups.

4. **Point: U6R**

There was no statistically significant difference between ΔX2, ΔY2 and ΔZ2 regarding U6R point measurements in the two groups.

5. **Point: U6L**

There was no statistically significant difference between ΔX2, ΔY2 and ΔZ2 regarding U6L point measurements in the two groups.

6. **Point: ANS**

There was no statistically significant difference between ΔX2, ΔY2 and ΔZ2 regarding ANS point measurements in the two groups.

7. **Point: PNS**

There was no statistically significant difference between ΔX2, ΔY2 and ΔZ2 regarding PNS point measurements in the two groups.

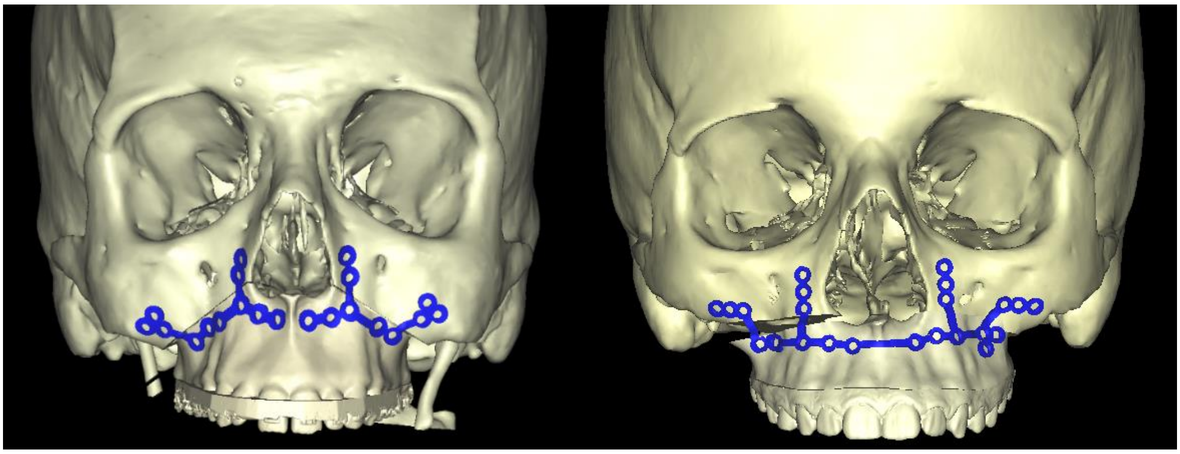

Figure 1: The two different PSI designs

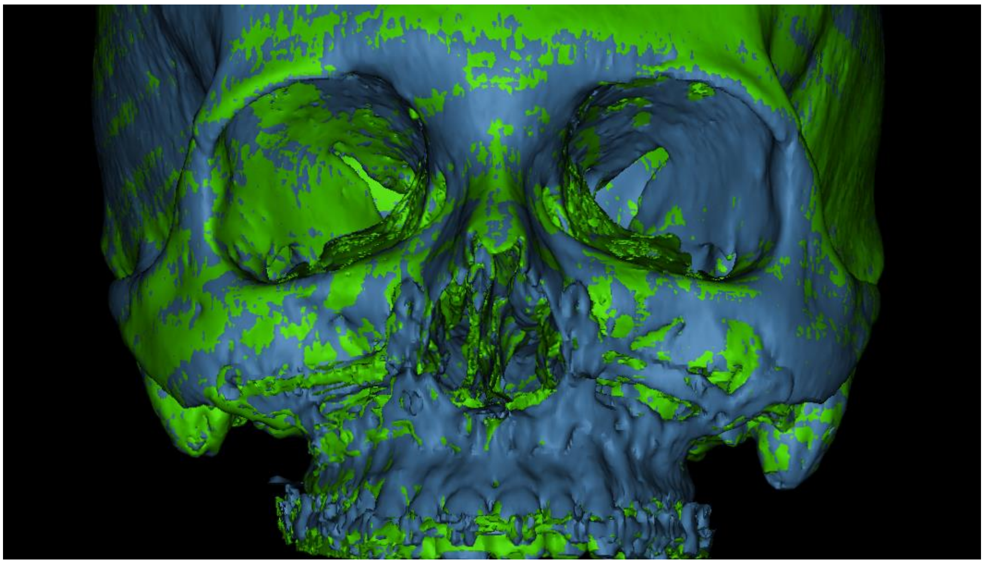

Figure 2: Immediate postoperative CT (Blue) over the 4 months Postoperative CT (Green) to determine the stability

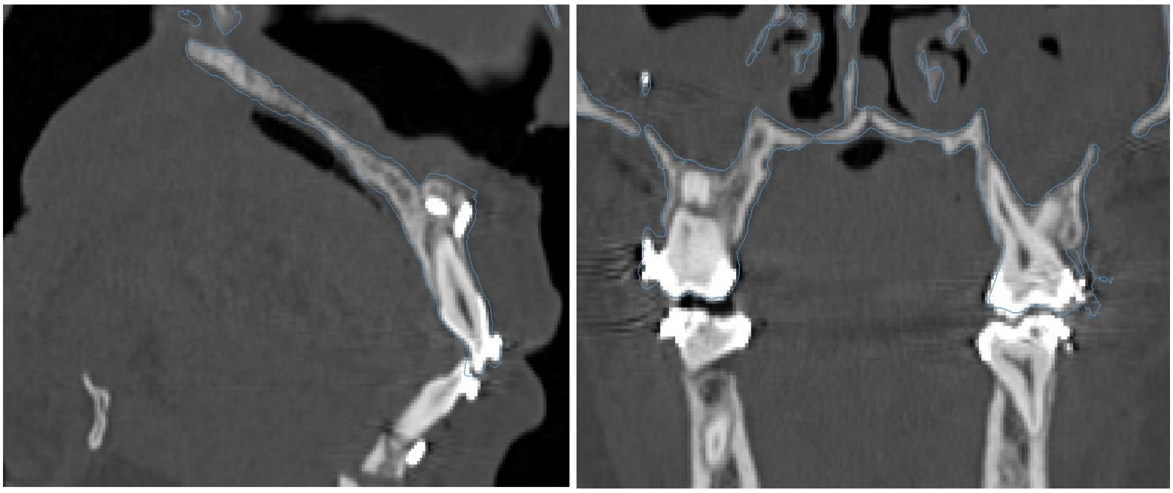

Figure 3: Immediate postoperative CT outline (Blue) overlapped Over the 4 months postoperative CT

Table (1): Descriptive statistics and results of Mann-Whitney U test for comparison between U1 measurements in the two groups

Measurement	Group	Median	Min.	Max	Mean	SD	P-value	Effect size (d)
ΔX2	Intervention	0.2	0.1	0.4	0.21	0.07	0.821	0.078
	Control	0.2	0	0.4	0.21	0.12		
ΔY2	Intervention	0.6	0.2	1.3	0.67	0.43	0.111	1.227
	Control	0.95	0.3	1.5	0.94	0.4		
ΔZ2	Intervention	0.85	0.1	1.7	0.81	0.43	0.799	0.096
	Control	0.85	0	2	0.77	0.5		

*: *Significant at* $P \leq 0.05$

Table (2): Descriptive statistics and results of Mann-Whitney U test for comparison between U3R measurements in the two groups

Measurement	Group	Median	Min.	Max.	Mean	SD	P-value	Effect size (d)
ΔX2	Intervention	0.3	0.1	0.4	0.3	0.09	0.188	0.492
	Control	0.2	0.1	0.5	0.26	0.12		
ΔY2	Intervention	0.7	0.1	1.9	0.74	0.57	0.503	0.254
	Control	0.9	0.1	1.8	0.91	0.53		
ΔZ2	Intervention	0.85	0.2	1.9	0.84	0.47	0.518	0.245
	Control	0.6	0.1	1.8	0.74	0.52		

*: *Significant at* $P \leq 0.05$

Table (3): Descriptive statistics and results of Mann-Whitney U test for comparison between U3L measurements in the two groups

Measurement	Group	Median	Min.	Max.	Mean	SD	P-value	Effect size (d)
ΔX2	Intervention	0.4	0	0.5	0.31	0.17	0.555	0.218
	Control	0.3	0.1	0.5	0.29	0.14		
ΔY2	Intervention	0.55	0.2	1.9	0.75	0.52	0.548	0.227
	Control	0.9	0.1	1.7	0.87	0.51		
ΔZ2	Intervention	0.7	0.1	1.8	0.79	0.5	0.595	0.201
	Control	0.6	0.2	1.6	0.71	0.41		

*: *Significant at* $P \leq 0.05$

Table (4): Descriptive statistics and results of Mann-Whitney U test for comparison between U6R measurements in the two groups

Measurement	Group	Median	Min.	Max.	Mean	SD	P-value	Effect size (d)
ΔX2	Intervention	0.2	0.1	0.6	0.28	0.13	0.373	0.316
	Control	0.2	0.1	0.4	0.23	0.08		
ΔY2	Intervention	0.75	0.2	2	0.76	0.48	0.853	0.07
	Control	0.7	0.1	1.6	0.71	0.42		
ΔZ2	Intervention	0.85	0.2	1.7	0.83	0.42	0.711	0.139
	Control	0.8	0.1	1.5	0.76	0.4		

*: *Significant at* $P \leq 0.05$

Table (5): Descriptive statistics and results of Mann-Whitney U test for comparison between U6L measurements in the two groups

Measurement	Group	Median	Min.	Max.	Mean	SD	P-value	Effect size (d)
ΔX2	Intervention	0.25	0.1	0.5	0.29	0.12	0.793	0.096
	Control	0.25	0.1	0.6	0.31	0.17		
ΔY2	Intervention	0.8	0.1	2.1	0.83	0.53	0.695	0.148
	Control	0.7	0	1.9	0.76	0.47		
ΔZ2	Intervention	0.95	0.2	1.5	0.84	0.38	0.403	0.316
	Control	0.9	0.1	1.7	0.74	0.45		

**: Significant at $P \leq 0.05$*

Table (6): Descriptive statistics and results of Mann-Whitney U test for comparison between ANS measurements in the two groups

Measurement	Group	Median	Min.	Max.	Mean	SD	P-value	Effect size (d)
ΔX2	Intervention	0.3	0.2	0.6	0.35	0.15	0.299	0.389
	Control	0.3	0.1	1	0.31	0.23		
ΔY2	Intervention	0.7	0.2	1.5	0.68	0.36	0.533	0.236
	Control	0.7	0.2	1.7	0.81	0.48		
ΔZ2	Intervention	0.65	0.2	1.9	0.78	0.45	0.982	0.009
	Control	0.65	0.2	1.8	0.78	0.42		

**: Significant at $P \leq 0.05$*

Table (7): Descriptive statistics and results of Mann-Whitney U test for comparison between PNS measurements in the two groups

Measurement	Group	Median	Min.	Max.	Mean	SD	P-value	Effect size (d)
ΔX2	Intervention	0.35	0.1	0.7	0.33	0.16	0.640	0.174
	Control	0.3	0.1	1	0.4	0.25		
ΔY2	Intervention	0.85	0.2	1.9	0.91	0.54	0.982	0.009
	Control	0.75	0.3	2	0.91	0.49		
ΔZ2	Intervention	0.95	0.1	1.6	0.94	0.44	0.782	0.104
	Control	1	0.2	2	0.99	0.52		

**: Significant at $P \leq 0.05$*

Discussion

Stability following orthognathic surgery is one factor that affects all aspects of orthognathic surgery, starting from the planning stage all the way to evaluating long term success. Acknowledging its importance are the new studies performed to determine what leads to best stability of the performed surgery throughout the years.

This prospective clinical study investigated the stability, and efficiency of virtual preoperative simulation combined with patient-customized osteotomy guides and plates and compared two different designs of customized plates in these regards.

Many factors have been shown to affect the stability of the LeFort 1 osteotomy for the correction of dentofacial deformities. These include: the type of surgical movement, the amount of surgical movement, the type of fixation used, the condition of the soft tissue envelope of the maxilla, the health of the temporomandibular joints, the obtained occlusion and whether the treatment was a surgery first or orthodontics first approach. (Dowling et al., 2005) (Brandtner et al., 2015) (Takahara et al., 2020)

Wire osteosynthesis used in the early phases of the procedure was one of the main culprits accused for the relapse frequently seen at that time. Such basic fixation schemes lead to many compromised outcomes, reoperations, and patient dissatisfaction. (Drommer, 1986) (Proffit et al., 1996) With the advent of plate and screw fixation, a more rigid form of fixation was obtainable to assure a better chance of the osteotomized and repositioned segment to remain in place in the future years.

The stock plates used for fixation usually come in different shapes. They are bent and placed using fixation screws. The most common fixation scheme used is two miniplates on either side of the maxilla at the lateral nasal wall and zygomaticomaxillary buttresses, on either side of the maxillary sinus. (Ueki et al., 2012)

The expected improvement in surgical stability was immediately seen with the use of plate and screw osteosynthesis. However, relapse still existed in many cases and there was a big space for improvement. Maxillary Downgrafting to increase the vertical height of the maxilla was deemed quite unstable, together with transverse widening. (Proffit et al., 2007)

With the advances in all aspects of orthognathic surgery, none is more important than virtual surgical planning together with the emergence of CAD/CAM technologies. Treatment planning can be done more accurately, and execution of this improved plan was achieved.

Two different methods were created to transfer the virtual plan to the operating theatre: Static and dynamic methods. Static methods included the use of CAD/CAM generated occlusal wafers, repositioning guides, and Patient Specific Implants. The dynamic method included the use of intraoperative navigation and augmented reality methods. (Jo et al., 2021)

The use of custom-made plates and cutting guides has been proven to be more accurate, efficient and more time saving inside the operating room. Many studies using different plate designs have all lead the way for their use. (De Riu et al., 2018) (Steinhuber et al., 2018) (Suojanen et al., 2018)

With multiple studies proving the accuracy and the benefits of the use of PSIs over stock plates, the question was raised next if improving the stability of the outcome can be added as a major benefit. The freedom to design PSIs in many shapes and the ability to plan the fixation screws in the points with the best bone quality (Neo et al., 2021) (Karanxha et al., 2021).

Joining the plates placed in the buttress areas theoretically improves the strength of the fixation unit. Multiple designs were used in different studies either joining all the fixation together as one entire unit, while others divided the fixation scheme into two, one plate on each side spanning the lateral nasal wall and zygomaticomaxillary buttress area.

In 2019, a Korean group of orthognathic surgeons published their first paper using PSIs evaluating both accuracy and stability and demonstrated good results in both regards. (Kim et al., 2019)

A most recent study by the same group related to the use pf PSIs in the field of orthognathic surgery showed improved stability of the new maxillary position with the use of PSIs compared to conventional stock plates. (Kim et al., 2023)

However, there are no studies in recent literature assessing the stability of these improved PSIs and whether the different designs used had an effect.

This study was designed to directly compare two different designs of patient specific implants in terms of stability following surgery. Adding newer insights into the ever-growing trend of computer guided surgery can only help us reach better outcomes and stable results for all patients.

The two arms of the study are:
- a two-piece Patient Specific osteosynthesis for the control group with each place on one side of the maxilla extending on the lateral nasal and zygomaticomaxillary buttresses.
- a one-piece PSI spanning along the entire length of the maxilla.

The surgical procedure performed was essentially the same for all patients in both the intervention and control groups: similar surgical technique, similar design of cutting guides with predictive holes, similar downfracture and mobilization techniques. The only difference was the design of the PSIs as mentioned earlier.

Also, all PSIs were manufactured using the same titanium alloy, milling machine and same thickness through the plates to maintain the uniformity of the procedures.

The stability in the two groups was assessed using the position of 7 landmarks which were compared in the 3D environment using their coordinate system values in all three axises. All seven landmarks were compared at the immediate postoperative phase and after four months.

The least amount of relapse in both groups was the x-axis, correlating with the fact it was the vector with least amount of surgical movement.

The highest amount of relapse in a single case in the vertical vector (y-axis) was 1.8 mm for all seven landmarks in the control group, a case with 4 mm inferior repositioning done at the incisor level. For the intervention group, in the same vector, the highest relapse in a single case was 1.7mm.

The maximum amount of relapse in the Y-axis was 21 mm seen at the UL6 point.

All cases with maxillary impaction were found to be stable with an average of 0.7mm relapse in all cases. At the incisal midpoint, considered a very important esthetic point, the average relapse was 0.67 mm for the intervention group and 0.94 for the control group. Both amounts of relapse considered to be clinically acceptable.

Also, the average relapse was nearly the same for all points used, showing good stability of the osteotomized LeFort segment in all three dimensions of space.

The uniformity of the comparison was also boosted as there was no statistically significant differences between the two groups regarding the different types and the amount of surgical movement done.

However, mixing between different types of maxillary movements is a source of inaccuracy and restricting the study to a single vector of movement in a certain type of dentofacial deformity will be more favorable for the uniformity of the study.

There was no statistically significant difference regarding the relapse/ change in position of all seven landmarks used, which leads us in the direction that the two different plate designs did not have a significant effect on the 4 months stability. Also a longer period of stability assessment is preferred for more accurate results.

The obtained stability numbers for the operated patients were considered great considering the clinically significant difference of 2mm. However, unstable movements produced a higher degree of relapse.

The relative rigidity and great fixation obtained with the two-piece fixation scheme might be all that was needed in most cases, hence the absence of any statistically significant difference when compared with the one-piece PSI.

Conflict of Interest:

The authors declare no conflict of interest.

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Ethics:

This study protocol was approved by the ethical committee of the Faculty of Dentistry - Cairo university on: 25/10/2022, approval number: 13-10-22

Data Availability:

Data will be available upon request.

Clinical Trial Registration:

This trial was registered in clinical trials.gov with ID: NCT05277506.

Credit Statement:

Author 1: Data curation, Writing - review & editing, Writing-original draft, Methodology, Conceptualization, Resources

Author 2: Data curation, Conceptualization, Project administration, Supervision, Methodology, Writing - review & editing, Writing - original draft

Author 3: Methodology, Writing - original draft, Writing - review & editing, Investigation, Formal analysis, Supervision, Data curation.

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