ACCURACY OF SPLINTLESS PATIENT SPECIFIC CAD-CAM OSTESYNTHESIS VERSUS COMPUTER GUIDED OCCLUSAL SPLINT IN BIMAXILLARY ORTHOGNATHIC PATIENTS; RANDOMIZED CONTROLLED CLINICAL TRIAL.

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ABSTRACT

Mohamed Mahmoud Mohamed Nagy; ACCURACY OF SPLINTLESS PATIENT SPECIFIC CAD-CAM OSTESYNTHESIS VERSUS COMPUTER GUIDED OCCLUSAL SPLINT IN BIMAXILLARY ORTHOGNATHIC PATIENTS; RANDOMIZED CONTROLLED CLINICAL TRIAL.

“Under the supervision of; Galal Behairy, Ramy El Beialy, Mohamed khashaba, Samer No’man”

Aim: The aim of the study was to determine if Splintless patient specific osteosynthesis are superior to computer guided splints regarding accuracy in bimaxillary orthognathic surgery.

Methodology: The study was performed on 20 patients indicated for bimaxillary orthognathic surgery. Patients randomized into two groups; Group I: Positioning guides &
patient-specific CAD-CAM osteosynthesis (PSI) have been used and **Group II:** Computer guided interocclusal wafers splints have been used with traditional mini plates, Radiographic assessment included superimposition of preoperative planning and postoperative CT scans.

**Result:** All patients expressed satisfaction with the aesthetic outcome. There were statistically significance differences between the two groups regarding maxillary, mandibular body, right and left proximal mandibular segments superimposition.

**Conclusion:** The results concluded that PSI and splints have adequate levels of accuracy. Although generally, PSI are more accurate in transmitting the virtual plan.

**KEYWORDS:** Bimaxillary Orthognathic, Patient-Specific CAD-CAM Osteosynthesis, PSI, Splintless Orthognathic Surgery, Waferless Orthognathic Surgery

**Introduction & Review of literature**

Orthognathic surgery (OGS) is a meticulous high precision surgical procedure, usually it is difficult to achieve high accuracy in orthognathic surgery (OGS). Intermaxillary splints have been in wide use since the 1980s to handle bone segments that have undergone osteotomy. (DAL PONT, 1961; Obwegeser, 1969; Epker and Bronson, 1978)

OGS planning has undergone a paradigm shift thanks to the integration of computer technology, which has revolutionised the practise, as well as providing the foundation for the development of new surgical solutions. This advanced CAD/CAM software enabled practitioner to model OGS procedure details with greater accuracy, especially when it comes to regulating the movement of the condyles and designating surgical splints. (Xia et al., 2007; Swennen, Mollemans and Schutyser, 2009; Aboul-Hosn Centenero and Hernández-Alfaro, 2012; Hernández-Alfaro and Guijarro-Martínez, 2013)

When it comes to successful orthognathic surgery, accuracy is first and foremost determined by how well the planning is transferred during the surgery, and second by the stability of the segments after surgery. Occlusal splints are the most commonly used method of the first step (surgical transfer). The chief disadvantage is inaccuracy and lack of control,
as the surgeon delegates most of the positioning to the surgical team. (Xia et al., 2007; Aboul-Hosn Centenero and Hernández-Alfaro, 2012)

When it comes to the second step, which is the stability, traditional osteosynthesis systems require plate bending and aren't always rigid enough to overcome the compressive muscular forces associated with extensive bimaxillary advancement surgeries. (Xia et al., 2007; Aboul-Hosn Centenero and Hernández-Alfaro, 2012)

We suggest that high-rigidity custom-made mini-plates (which are stiffer than standard-type mini-plates) designed from the final planning of an OGS contain all the relevant information for simultaneous surgical transfer and stabilisation. There is no longer need for intermaxillary occlusal splints and intra-operative measurements.

The study's goal was to demonstrate and assess the precision of a virtual orthognathic positioning system (OPS), based on bone-supported guides for positioning of high rigid, custom machined titanium miniplates produced by utilising CAD/CAM technology.

Many years ago (OGS) treatment planning has relied on plaster casts (mounted on semi adjustable articulators & face-bow transfer), and 2D cephalometric analysis, as well as model surgery to anticipate the direction and magnitude of the movement of the jaws. It unfortunately became believed that traditional planning was inaccurate and time-consuming. This is because it has multiple limitations including faulty landmark identification due to overlapping of anatomic structures on two dimensional radiographs (especially for patients with facial asymmetry), facebow registration, centric relation records, mock surgery using a semi-adjustable articulator and use of intermaxillary splints. In addition, it involves a systematic error resulting in inaccurate maxillary positioning. (Lin and Lo, 2015)

Orthognathic surgical planning has been significantly progressed in recent years. The initial concept was to do surgical planning using lateral cephalometric, photographs, & facial analysis, and plaster casts mounted on semi-adjustable articulator for the purpose of fabricating acrylic resin surgical splints.

Then computer algorithms for cephalometric analysis of lateral radiographs were developed with planning to utilise them in 2D for cephalometric assessment. While with the recent (CAOS), orthognathic surgery planning and the surgical intervention are both performed using software. During the planning phase, the 3D cephalometric analysis is applied & then (OGS) simulations of bone and soft tissue movement are done. These
Simulations are then used to generate the virtual plan which is transferred to the surgical setting by interocclusal splint and/or by intraoperative image-guided navigation.

The earliest virtual design and manufacture of flat-plane and full coverage occlusal splints with guidance ramps were first suggested by (Lauren and McIntyre, 2008). This made the digital splints commercially obtainable. Throughout the beta testing, one hundred and fifty cases were requested to provide feedback on the occlusal adjustments. Majority of the comments were positive in seventy-eight responses.

As an alternate to intermediate surgical wafer, the 3D CAD/CAM repositioning guides (surface template) has been utilized for transferring the simulated surgical plan to the operating theatre, several studies have evaluated the latter’s efficiency in comparison to the former one.

Patient specific titanium plates were introduced in 2015, to computer-aided orthognathic surgery through two publications (Gander et al., 2015; Mazzoni et al., 2015).

(Mazzoni et al., 2015) proposed an easy, yet accurate, patient specific osteotomy guides allowing the operating surgeon to accurately transfer the position and orientation of the osteotomy line from a virtual plan to the real surgical field. Osteotomy guides were virtually planned, using reference markings on both sides of the maxilla, and were planned to follow the natural topography of both the zygomaticomaxillary buttress and the anterior maxillary walls to enhance stability, adhesion, and accurate positioning translation during actual surgical phase. Furthermore, these cutting guides were placed with the help of a navigation system.

(Gander et al., 2015) reported on a different custom-made titanium plating called “Patient-Specific Implant” (PSI) in his case report. This involved a custom made cutting guide to position the osteotomy and make reference holes and a 3-piece patient-specific implant to reposition the maxilla into the virtually planned position while allowing for the osteosynthesis at the same time. Although this technique seemed promising, the study itself did not contain any qualitative or quantitative assessment.

Numerous authors explained the use of patient specific implants for maxillary osteotomy and repositioning (Mazzoni et al., 2015; Kraeima, Jansma and Schepers, 2016; Suojanen, Leikola and Stoor, 2016; Xue et al., 2018) On the other hand, quite few researchers, especially in recent years discussed using patient specific implants in (BSSO) (Brunso et al., 2016; Li et al., 2017; Suojanen, Leikola and Stoor, 2017; Savoldelli et al.,
Furthermore, much lesser publications report the use of patient specific implants in bimaxillary orthognathic surgery, although the possible conflict between maxillary and mandibular CAD/CAM fixation errors has not been well explored. (Li et al., 2017; Suojanen, Leikola and Stoor, 2017).

A randomised, controlled, multi-center study conducted by (Kraeima et al., 2020) aimed to assess if implementation of a PSI would lead to better maxillary translation accuracy. Included in the study were patients needing a Le Fort I osteotomy. PSI was applied to the intervention group while standard osteosynthesis & interocclusal splints was applied to the control group, Figure (10).

The final total for this research was 58 patients, 27 of whom participated in the PSI group and 31 of whom took part in the control group. The PSI group's median anteroposteroreal deviation was determined to be 1.05 mm, whereas the control group's was 1.74 mm. In the PSI group the cranial-caudal deviation was 0.87 mm, and 0.98 mm in the control group while the left-right translation deviation was 0.46 mm. In the control group, the left-right translation deviation was 1.07 mm. This PSI technique allows for improved precision in orthognathic surgery, especially when used in cases when anteroposterinallis projected translations exceed 3.70 mm.

Using the CAD/CAM intermediate splint and the customised surgical guide with PSI, (Karanxha et al., 2021) evaluated two transferring techniques for virtually planned orthognathic surgery. In this prospective clinical research, individuals were recruited and sequentially underwent bimaxillary orthognathic surgery. The participants were divided into two groups depending on the type of transfer utilised. Using a a (voxel based landmark) free registration technique, pre and postoperative CBCTs were aligned, and the relative differences in location between the chosen landmarks was calculated. Translation and rotation motions were examined individually, and the maxilla and mandible were independently evaluated.

16 patients participated in this research. Compared to the splint group, the PSI group was far more precise in translation along the (x) axes. For the mandible, the differences in accuracy were found to be significantly greater along the (x) axes in the PSI group. A substantial difference was observed between the maxilla's rotation accuracy in the (y) axis for the splintless group, but not for the mandible.
A systematic review to assess the precision of PSI in orthognathic surgery compared to conventional surgical methods was published in a recent study by (Figueiredo et al., 2021). Research papers were collected from 6 databases and two grey literature repositories. Also the descriptive clinical studies, using PSI in orthognathic surgery were analyzed. Only seven researchs of the 11,916 researches fulfilled the requirements for being included in the analysis, since all the others were found to be ineligible. They appeared between 2015 and 2019. According to the results, a large majority (57%) of the studies had a low risk of bias, whereas one study had high risk of bias. (74 patients in all): 63 had bimaxillary operations and 11 unimaxillary surgeries. Every study indicated an adequate level of accuracy in relation to previously established clinical standards.

In general, the virtual plan transmission to the operating room is more precise using the PSI method than of an intermediate CAD/CAM splint.

**AIM OF THE STUDY**

The aim of the study was to determine if Splintless patient specific osteosynthesis are superior to computer guided splints regarding the accuracy of surgical planning transfer in bimaxillary orthognathic surgery. (A randomized clinical trial).

**Material and methods:**

1. **Trial Design:**
   - Randomized clinical trial.
   - Single-blinded.
   - Parallel group study.
   - Superiority frame.
   - Allocation Ratio 1:1
   - The study protocol was approved by Oral & Maxillofacial Surgery Department – Cairo University. Evidence based committee and the ethical committee: Faculty Of Dentistry – Cairo University.

2. **Study Setting:**
The study was performed on 20 patients in the Oral & Maxillofacial Surgery Department – Cairo University indicated for bimaxillary orthognathic surgery. Patients randomized in equal proportions into two equal groups:

- **Group I (Study Group):** Consisting of 10 patients, a positioning guides & patient-specific CAD-CAM osteosynthesis have been used.
- **Group II (Control Group):** Consisting of 10 patients, computer guided interocclusal intermediate and final wafers splint have been used with traditional mini plates.

### 2.1. Eligibility Criteria:

#### 2.1.1. Inclusion Criteria:

- Patients who need bimaxillary orthognathic surgery due to skeletal maxillary & mandibular discrepancies.
- Patients should be clear from any systemic illness that may impair normal healing & expected results.
- Patients who are willing to provide consent and have agreed to attend follow-up appointments.
- Patients who do not have symptoms or findings consistent with TMJ dysfunction.

#### 2.1.2. Exclusion Criteria:

- Patients under the age of 18.
- Patients with any illness that may impair the healing process.
- Infections and lesions that may delay bone healing.
- Poor oral hygiene patients.
- Women who are pregnant.
- Patients who were not available for follow-up.
- Cleft lip and palate patients (may have an adverse impact on facial development).
- Patients receiving chemotherapy or radiotherapy.
- Patients who declined to participate in the study.
3. Patients Preparation:

Included study participants all received 3D planning, which were used to create a preliminary plan along with a virtual surgical simulation, to create the final plan prior to being assigned into research groups. The patient was examined in the natural head position where teeth in centric relation and the lips are relaxed. Patients were examined from frontal, lateral and three-quarters view. Standard set of photographs were taken for primary evaluation. “Frontal, Profile, 45°, smile, & dental occlusion” routine preoperative photos were taken.

For the chosen patients, primary upper and lower impressions were obtained using alginate impression material. Impressions were poured using dental stone to make dental models. The dental models were used to detect the desirable final occlusion.

3D Image Acquisition:

All selected patients had a CT scan, The CT data were exported as DICOM files and loaded into “Materialise ProPlan CMF” software version 3.0.

Then, a virtual model of CT reconstructed osseous volume were built to aid in 3D cephalometric analysis and diagnosis. A three-dimensional virtual hard tissue model of the patient was created. The three-dimensional virtual hard tissue models were oriented using the natural head position (NHP) principle, which was established from clinical evaluation and patient photographs.

To accurately show the dentition and produce surgical splints, traditional plaster models have been utilised. The dental models were scanned separately and mounted to each other in the desirable final occlusion using Shera® Dental wings operating system 7 series optical scanner.

On the created skull-dental composite model, a virtual surgery was simulated according to the preliminary plan using “Materialise ProPlan CMF” software. According to a Le Fort I osteotomy & BSSO, the maxilla and the mandible were virtually osteotomized and the bony segments were mobilized according to the preliminary plan, the maxillary segment was virtually advanced to the preplanned final position. Consequently, the mandible was virtually advanced in centric relation. The mandibular ramus was virtually adjusted to fit precisely with the two osteotomy segments' lower border. In some cases, modifications of the
preliminary plan were made if there were concerns regarding the facial symmetry or collision of ramus segments. A definitive plan was developed.

**For the study group:**

The study group patients received the following steps

**CAD of the positioning & cutting guides**

In order to make the process of transferring the position and orientation of the osteotomy line from a virtual plan to the actual surgical environment more precise, customized cutting guides were created.

According to the intended final position of the maxilla and/or mandible, osteotomy guide with the design & location of osteotomy guide have been developed (Materialise, Leuven, Belgium).

**Maxillary guide;** Cutting guides created using a virtual model & almost based on the two maxilla sides and were intended for covering the vast majority of bone surfaces exposed during surgery. Following the natural curves of the maxillary/zygomatic buttress & the anterior wall of the maxilla the guides were designed. we thought this would provide the greatest stability, retention, & placement accuracy during the operation.

**Mandibular guide;** In relation with the vertical osteotomy line in the virtual 3d model, the position of the inferior alveolar nerve was determined. Two millimeters holes are made into various locations in order to fix the guide using titanium screws. To guarantee that root damage would not be impeded, every screw hole was carefully positioned. Osteotomy guides were built with screw hole that are incorporated inside the guide in positions that are readily accessible with enough bone available to enable the final fixation of the fixation plates to be implemented later on.

Thereafter STL file of the CAD-CAM guide & stent were exported to be used by the CAM machine. A Plastic material which is suitable for medical purposes is used in the manufacture of the wafers and guides.

**CAD of the custom-made repositioning/fixation plate (PSI):**

The second class of hardware included Customized repositioning/fixation plates (PSI). The plate permits simultaneously moving the upper jaw and lower jaw into the
preplanned proper place. The plates were constructed to provide the intended sagittal, transverse, & vertical movement of the upper jaw & lower jaw.

These PSI were developed to utilize the previously established reference holes to relocate the maxilla in relation to the unmoved skull base, also the distal & proximal mandibular segments in their planned positions, utilizing the previously 2mm drilled holes for screw fixation as a reference. The previously drilled holes to position the guides also were used to fix the PSI.

**CAM of the cutting guide**

The STL file representing the guide was transported to the Additive CAM machine to print the cutting guide in Polylactic acid (PLA) using “fused deposition modeling” (FDM), without finishing or polishing to preserve the accuracy. **Figure (1)**

![Fig(1): maxillary & mandibular cutting guide in place](image1)

**CAM of the plates**

The STL files representing the plates was transported to the 5 axis titanium milling machine to print the plates in type V titanium alloy. Finishing & polishing was performed in the outer surface as needed to eliminate any covering tissue irritation. **Figure (2)**

![Fig(2): maxillary & mandibular cutting guide in place](image2)
During the surgery, the cutting guide was inserted onto the exposed bony surface and manipulated to the best fit. Then, the guide was fixed using four 2.0 mm screws to avoid any mobilization during reference holes drilling. Reference holes & vertical cut position were established using the cutting guide, then the guide has been removed to complete the procedure. Using the previously established reference holes and the custom-made plates, the maxilla and mandible were oriented to the planned position and fixed using 2.0 mm screws.

**The Control Group:**

Virtual surgical planning was started by simulation of the Le Fort I osteotomy and Sagittal split osteotomies and the amount of translations and rotations were done according to the preoperative treatment plan that was previously defined. The osteotomy segments and the amount of movement were based on predefined analysis. Based on the planned final position of the maxilla/or mandible, an intermediate splint was designed instead of the cutting guides and PSI to transfer the location and orientation of maxillary/or mandibular segments from a virtual plan to the real surgical environment depending on maxilla first/ or mandible first technique, the final splint was designed to orient the other mobile segment based on the fixed maxilla/or mandible. The intermediate and final splints after they designed they were exported as STL files for 3D printing and sterilizing using the same protocol like the study group.

During the surgery, *vertical reference points have been marked*. 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 were identified by noting the bony eminence for the canine in addition to data gained from CT scans. The lateral maxillary walls above & below the planned osteotomy line were marked with internal reference points, and their vertical distance was measured using a caliper.

Following that, the mobilized maxillary segment was placed into the prepared intermediate occlusal splint and IMF was performed. Then, manual positioning of the maxillomandibular complex. The maxillomandibular complex then was passively seated until even bone to bone contact are established and the planned vertical relationship was reached.

Once planned repositioning of the maxilla was achieved in anterior-posterior, vertical, and transverse dimensions, osteosynthesis was achieved using 2.0 mm titanium plates. For the
A prefabricated final stent was inserted and seated on the maxillary dentition and the lower teeth were allowed to fit passively into the occlusal stent and then the teeth were placed into maxilla-mandibular fixation (MMF) to fix the occlusion in the desired position. Condylar seating was performed with the conventional technique, by applying gentle pressure over the proximal segment in a superior posterior direction. Then fixation is made with conventional 4-hole mono-cortical mini plates and screws.

For all participants in both groups the mucosa was closed with continuous mattress absorbable 3/0 vicryl sutures, CT scan were taken within one week after the surgery using the same machine for all participants.

4. Data Collection: (Superimposition Of Preoperative CT Planning Data With Postoperative CT Data).

We based the primary outcome measure on a comparison of the preoperative plan and postoperative CT images. All planning and postoperative files will be anonymized. The planned preoperative data (the 3D Bimaxillary model surgery for both groups) were superimposed with the postoperative CT data (Postoperative 3D model) using “MATERIALISE PROPLAN CMF” software version 3.0 by combining:

1- Rigid point landmark based method registration (anatomical)
2- Segmentation based registration (surfaces)

The reference data was the preoperative CT scan (T0), & the superimposed data was the postoperative CT scan data (T1).

The combination of “landmark based segmentation method” & “surface based superimposition” is a semiautomatic technique, for that utilizing PROPLAN software for the segmentation process in order to create 3D surfaces of the skull. The 3D surfaces of the preoperative plan & postoperative data were exported as stereolithography (STL) files.

After each superimposition, we will construct colour-coded distance maps to measure the discrepancies using iterative closest point (ICP) surface matching, and calculated the mean distance of displacement for each patient, each surface deviation was analyzed using statistical methods and represented on a color-graded scale.

To make an assessment of “Interobserver Reliability” two assessors undertaken the CT analyses, while to make an assessment of “Intraobserver Reproducibility”, each assessor
collected two separate sets of records. The Pearson correlation coefficient was used to qualify both reliabilities.

5. Statistical Methods:

5.1. Intra-observer Reproducibility and Inter-observer Reliability Assessment

Intra-observer reproducibility and Inter-observer Reliability were qualified using the Pearson correlation coefficient. It has a value between +1 and −1, where 1 is total positive linear correlation, zero is no linear correlation, and −1 is total negative linear correlation

5.2. Statistical package used for this study:

Information was loaded into the computer and the programme “IBM SPSS Version 20.0 Armonk, New York: (The IBM Corporation)” was used to process it. Qualitative data were mentioned by numbers and percentage. “The Kolmogorov-Smirnov test” was performed to determine if the data followed a normal distribution. The use of range (minimum and maximum), mean, standard deviation, and median to represent quantitative data. The 5% significance threshold was used in the evaluation of the findings obtained.

The used tests were:

- **Chi-square test:** To categorical variables, for comparing the different groups.
- **Student t-test:** To normally distributed quantitative variables, for comparing the 2 groups in the study.

The significance level:

It was verified at $P \leq 0.05$. The results were deemed statistically significant if p-value was less than 0.05.

**RESULTS**

The study was conducted on 20 patients in the Oral and Maxillofacial Surgery Department – Cairo University indicated for bimaxillary orthognathic surgery. patients were randomly allocated into two groups; each included ten patients.

**Surgical results:**
No significant problems occurred during the surgeries for any of the patients. All (IAN) were either buried inside the mandibular distal segment or were visible within the same segment.

**Clinical results:**

- All patients had an uncomplicated immediate postoperative period with no major problems.
- None of the patients developed postoperative infection or wound dehiscence.
- All patients showed postoperative edema with variable degrees which resolved in 4 – 6 weeks.
- Both groups began early mandibular functioning after the removal of elastics.
- There was a neurosensory disturbance immediately after surgery for all patients in the form of temporary loss of sensation of the lower lip and chin which had resolved in 1:3 months.
- One patient had suffered from deviated nose after maxillary impaction due to insufficient trimming of nasal septal cartilage, the patient treated after one month and the nasal cartilage trimmed properly and the nose deviation had gone.
- All patients expressed satisfaction with the aesthetic outcome.

The mean age of **Group 1 (PSI)** was (22.60 ± 2.80 years), while the mean age of **Group 2 (Splint)** was (22.40 ± 3.10 years). The differences in proportions were statistically insignificant (p-value = 0.881).

Males were 40% of participants in **Group 1 (PSI)** vs. 60% in **Group 2 (Splint)**, while females were 60% of participants in **Group 1 (PSI)** vs. 40% in **Group 2 (Splint)**. The differences in proportions were statistically insignificant (p-value = 0.371). As for the total sample, males and females were equal in proportions.

There was very good Intra-observer reproducibility regarding all measurements, The Mean of intra-observer reproducibility scored (0.883) indicating almost prefect agreement.

Inter-observer reliability was assessed using the Pearson correlation coefficient. There was very good Intra-observer reliability regarding all measurements, The Mean of inter-observer reliability scored (0.879) indicating almost perfect agreement.
For Maxillary Segment Superimposition; There were statistically significance differences between the two groups regarding maxillary segment superimposition (p = <0.001*). The results of the Students’ t test showed that there were also statistically significance differences between the two groups (t-values = 7.219*). Table (1)

<table>
<thead>
<tr>
<th>Maxilla</th>
<th>Group 1 (PSI)</th>
<th>Group 2 (Splint)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min. – Max.</td>
<td>0.39 – 0.72</td>
<td>0.73 – 1.11</td>
<td>7.219*</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>0.53 ± 0.11</td>
<td>0.92 ± 0.13</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For Mandibular Body Segment Superimposition; There were statistically significance differences between the two groups regarding Mandibular Body (Distal Segment) superimposition (p = <0.001*). The results of the Students’t test showed that there were also statistically significance differences between the two groups (t-values = 8.716*). Table (2)

<table>
<thead>
<tr>
<th>Mandibular Body (Distal Segment)</th>
<th>Group 1 (PSI)</th>
<th>Group 2 (Splint)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min. – Max.</td>
<td>0.49 – 0.81</td>
<td>0.94 – 1.63</td>
<td>8.716*</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>0.64 ± 0.11</td>
<td>1.26 ± 0.19</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For Mandibular proximal Segment (RT & LT) Superimposition;

There were statistically significance differences between the two groups regarding Mandibular proximal Segment superimposition (p = <0.001*). The results of the Students’t test showed that there were also statistically significance differences between the two groups (t-values = 11.566*).

<table>
<thead>
<tr>
<th>Mandibular Proximal Segments</th>
<th>Group 1 (PSI)</th>
<th>Group 2 (Splint)</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min. – Max.</td>
<td>0.53 – 1.28</td>
<td>1.61 – 2.29</td>
<td>11.566*</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>0.74 ± 0.23</td>
<td>1.89 ± 0.22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min. – Max.</td>
<td>0.51 – 1.18</td>
<td>1.79 – 2.38</td>
<td>14.041*</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>0.69 ± 0.21</td>
<td>2.02 ± 0.21</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DISCUSSION

The goal of this study was to evaluate the accuracy of patient-specific CAD/CAM implants and CAD/CAM additively manufactured surgical splints in Bimaxillary orthognathic surgery. The results concluded that PSIs and splints have adequate levels of accuracy. Although generally, PSIs are more accurate in transmitting the virtual plan.

Recent years have seen the introduction of many new 3D treatment planning methods and technical devices designed to help with orthognathic surgery and increase the effectiveness of the operation while also increasing predictability and decreasing complications. Because of that there are vast diversity in surgical planning methods that are documented in the literature. The same applies to the evaluation of the postoperative skeletal changes and comparing the planned and final position of the bony segments.

Through our research, to illustrate differences between the intended and final location of the maxilla and mandible, we utilized colored distance maps. Preoperative & Postoperative CT images were segmented in the same manner, using the same procedure.

Once the segmented post-operative objects were loaded into the ProPlan CMF software file, which also included the original preoperative and planned simulation, the alignment tasks were performed and the results evaluated. ProPlan CMF’s alignment tool was used to register the preoperative and postoperative datasets before analysis. To ensure an exact anatomical registration during the initial surgical planning, the tool employs a “global registration” to achieve the “NHP” as established during the initial surgical planning. This registration was fine-tuned by choosing areas or landmarks such as the foramen magnum, orbit, and zygoma, which were the main features of the final product.

The single ProPlan CMF file from the last step included two aligned skulls, and three different positions for the maxilla and mandible: the preoperative position, the simulated position, and the postoperative position.

Additionally, each landmark that is planned for the item will be matched with a corresponding landmark in the preoperative position using ProPlan CMF, and those matchings will be used for later verification. Therefore, the data sets did not have individual landmarks manually tagged on them.

Further research is needed to examine the accuracy of auto-transfer of landmarks (Stokbro et al., 2014; Schouman et al., 2015). Yet, it is time saving and minimizes the
possibility of discrepancies to use the same software of virtual planning to analyze the results of the surgery in comparison to use different softwares. (Gander et al., 2015).

But up till now there is no single method that guarantee 100% accuracy of repeatable landmark identification, and point registration and without the intervention of human factor which may lead to false or unrepeatable readings resulting in unreliable data sets. The emphasis should be on using analytical techniques progressively, without placing manual landmarks to provide reliable results that can be counted on.

In the presented workflow, 3D image acquisition done by using a CT scan to gain benefits of high contrast ratio compared to CBCT especially in the thin anterior maxillary wall which restrict correct segmentation, and limits the quality of the 3D model, making it so difficult to produce a properly fit maxillary cutting guide because of this problem.

While the higher radiation dosage, scanning time, and expense associated with CT is a drawback, but in the current study there were just two scans needed one before the surgery and the other during one week post operatively which could reduce the problem of radiation doses and cost, both CT & CBCT scans may also not provide correct pictures of the patient's dental anatomy because of beam hardening artefacts “such as metal artefacts”. Scanning dental casts is necessary in order to ensure appropriate occlusal reproduction. To digitize dental models, an optical scanner was utilized in this study.

An innovative method has been suggested during the past few years, Using a cutting guide which assists the surgeon in determining the precise position and direction of the osteotomy, and a custom made fixation plate which fix the osteotomized jaw in its planned new position as in the virtual surgical plan, Every case has its specific design of both surgical guide and fixation plate, which have planned according to the virtual 3D surgical plan.

(Gander et al., 2015; Mazzoni et al., 2015) were the first to introduce a surgical guide and fixation plate system that was custom-made for each patient. A similar design & concept was developed by (Kraeima, Jansma and Schepers, 2016) in a case report, while (Suojanen, Leikola and Stoor, 2016) reported one of the largest sample sizes studies by 32 patients. All of these studies only for maxillary repositioning, they suggested a two-piece custom made fixation plate.

When it comes to plates designs in our study, maxillary custom made plates were designed as two pieces one for the right and one for the left with multiple holes more than needed we also added holes in the connecting bar between the anterior and posterior plate
(Nasal - Zygomatic) in each side to act as a backup in case of screw hole failure due to the thin walled anterior maxilla. **Figure (26)**

We suggested that designing the maxillary plate as one segment in each side is more reliable in maxillary segment repositioning than separated plates in each side. Also the design proposed by *(Heufelder et al., 2017)* connecting the right and left maxillary plates as a one piece we suggest is more preferable but we couldn’t achieve that design due to lack of the sophisticated machines that can manufacture that size of plates with that abrupt angulations so we separated the right and left plates from the midline.

The increased expenses of the PSI method are a disadvantage. But when doing our expenses estimate, we must also consider the time in the operation theatre will be reduced, since this is something we've seen over time.

The second drawback is that the virtual process plan and manufacturing the custom made plates and guides may take weeks to develop, resulting in a time delay before it can be used. To prepare for the whole operation, we must plan weeks in advance and make sure the method matches the treatment. However, for those opting for elective orthognathic surgery, this generally isn't an issue.

The results of the presented study concluded that PSIs and splints have adequate levels of accuracy, Although generally, PSIs are more accurate in transmitting the virtual plan. There were statistically significance differences between the two groups regarding maxillary, mandibular segments superimposition, Although the discrepancies between the planned design and postoperative results for both groups has no significant postoperative esthetical effects.

There are lack in researches in this field specially in mandibular PSI and Bimaxillary Orthognathic surgery, also there are difference in the assessing methods or difference in the comparator group, also the majority of the published literature are case series. Comparing our results to the other literature we found almost the same results indicating that the PSI is more accurate than the traditional method or computer guided splints.

Looking at the researches that used the same method of post-operative analysis Our results are similar to the results of *(Rückschloß et al., 2019)*, who compared PSI group and splint group in 18 class III bimaxillary orthognathic patients but they evaluated the maxillary accuracy only without mandibular accuracy in which they used traditional mini plates.
systems they used the same postoperative colour coded superimposition map analysis, they concluded the same results.

While (Mazzoni et al., 2015), in a ten patients case series to evaluate a single group of Maxiallary PSI using the colour coded post operative superimposition analysis they got 92.7% (the median) of accuracy in the post operative analysis when using a threshold of lesser than two mm, although they didn’t compare this technique to the conventional or computer guided interocclusal method and only used Maxillary PSI in a single jaw cases their results matching our finding and conclusion.

(Brunso et al., 2016), in a case series of six patients in need of bimaxillary orthognathic surgery they evaluated the accuracy of maxillary and mandibular PSI using the postoperative colour coded superimposition map using a threshold of 1 mm they got 92% accuracy in the maxillary segment superimposition and 86% accuracy in mandibular superimposition but they found lesser accuracy in cases that needed severe advancement greater than 10 mm which is quiet large number. They superimposed the mandible as a whole unit but in our research we analysed each mandibular segment separately or more accuracy.

(Li et al., 2017), in a case series of 10 patients undergoing bimaxillary orthognathic surgery they evaluated the accuracy of maxillary and mandibular PSI but used another method of analysis “linear and angular deviations” between manually set points, they concluded that using PSI method is reliable for preoperative planning transfer and splintless positioning of the maxillary and mandibular segments, due to using another method of analysis our finding cannot be compared in numbers but the final conclusion is the same.

There are more case series or RCT studies used another post-operative analysis methods, for maxillary PSI accuracy (Gander et al., 2015; Suojanen, Leikola and Stoor, 2016; Heufelder et al., 2017; Rückschloß et al., 2019; Hanafy et al., 2020; Kraeima et al., 2020). For mandibular PSI accuracy, (Suojanen, Leikola and Stoor, 2017; Badiali et al., 2020). And for bimaxillary PSI accuracy (Brunso et al., 2016, 2017; Kraeima, Jansma and Schepers, 2016; Li et al., 2017; Kim et al., 2019; Ho et al., 2020; Karanxha et al., 2021)

All of them concluded that PSI technique is reliable method and you can count on regarding splintless positioning of the segmented jaws and precise transferring of the preoperative plan to the operating theater.

The only paper had a negative feed back is the one published by (Suojanen, Leikola and Stoor, 2017) he evaluated the mandibular PSI in mandibular single jaw orthognathic
patients as aforementioned he had a problem in fitting the mandibular PSI and did not recommend the use of mandibular PSI alone without the interocclusal splint our explanation of their results are they sterilized their cutting and positioning polymer guides using an autoclave method which caused a dimensional change in the guides affecting the final seating of the mandibular PSI the unnoticeable effect on the guides may have caused the misalignment of the screw holes of the PSIs, resulting in small disparities between the predrilled screw holes and the actual screw holes of the PSIs. The other cause is the interference between the condylar segment and teeth bearing segment shouldn’t be conservatively removed it has a direct impact on the mandibular PSI fitting if they weren’t removed properly.

Since this research only included single piece maxilla cases, we cannot be confident whether or not the findings would be comparable for more than one piece maxilla cases.

Overall, both the transfer systems were reliable. PSI system was found to be more accurate than the intermediate CAD/CAM splint. Further studies into the reliability of the virtual plan transfer technique is strongly recommended due to the paucity of existing research in this subject, as well as the fact that only a limited sample size was used in this study.

**CONCLUSION**

Overall, both the transfer systems were reliable. PSI system was found to be more accurate than the intermediate CAD/CAM splint. Further studies into the reliability of the virtual plan transfer technique is strongly recommended due to the paucity of existing research in this subject, as well as the fact that only a limited sample size was used in this study.

CAOS improved the workflow, enabled the treatment of patients with skeletal asymmetry and minimised technical difficulties with the classic approach; in addition, CAOS approach deceased operation time associated with the traditional method, while enabling an inexperienced surgeon to perform the procedure with satisfying accuracy and minimal time requirements.

Using PSI and CAD/CAM surgical guides, a virtual simulation is transferred to the operating room with an exceptional degree of precision. Maxillary and mandibular placement
may also be changed using the present method in clinical practise, as long as training situations are taken into account.

With PSI technique, there is no relationship between the maxilla positioning and the condyle or mandible, add to that the fact that you don't need external reference points. A real-life Le Fort I osteotomy corresponds to the 3D simulated treatment plan with great accuracy.

The primary drawback of computer-assisted workflow is the expense and time required for planning. The anticipated technical improvements may enable more precise picture capture with no artefacts, substantially reducing planning time, and the availability of low-cost CAD/CAM technologies.

The PSI method may be especially beneficial in the following situations: 1) significant asymmetry with a significant vertical component; 2) anticipated postoperative occlusal instability, whether due to tooth loss or the adoption of a surgery-first strategy.

The PSI offered significant surgical precision for vertical control and proper condylar placement, as well as a technique for establishing final occlusion without the use of interocclusal splints, and afterwards allows the use of voxel-based registration. This removes a large number of potential causes of inaccuracy.

Only minor inaccuracies were present in both groups, and none of these discrepancies affected the clinical result or patient quality of life for the sample included in the study.

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**Patient consent:** Written patient consent was obtained to publish the clinical photographs.

**References**


