PROXIMAL SEGMENT POSITIONING USING PRE-BENT PLATES LOCATING SURGICAL GUIDES VERSUS CONVENTIONAL MANEUVER IN MANDIBULAR SETBACK SURGERY. A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

**Purpose:** Condylar orientation in the glenoid housing is a critical and most demanding step after proximal segment separation in mandibular setback surgery, as it affects postoperative skeletal stability and occlusion. This study aimed to assess the proximal segment position after fixation using surgical guides and pre-bent plates compared to the manual free hand proximal segment seating.

**Methods:** Twenty patients with skeletal class III malocclusion were randomly allocated to two groups. Both proximal and distal segments were repositioned using osteotomy/screw holes and plate locating surgical guides with pre-bent plates osteosynthesis in the intervention group, while manual free hand proximal segment positioning was performed in the control group.

**Results:** Proximal segment position after fixation was assessed using computed tomography. Bodily and angular condylar deviation was significantly lower for the intervention group (X-axis: 0.03±0.02, Y-axis: 0.02±0.03, Z-axis: 0.03±0.03 mm), (Axial: 0.24±0.28, Coronal: 0.24±0.19, Sagittal: 0.29±1.3°) compared to the control group (X-axis: 1.38±0.48, Y-axis: 1.35±0.51, Z-axis: 1.66±0.15 mm), (Axial: 2.79±1.51, Coronal: 3.14±2.28, Sagittal: 2.49±1.40°).

**Conclusion:** Computer guided approach significantly decreased proximal segment displacement compared to the manual free hand technique.

**KEYWORDS:** Computer guided surgery; Patient specific guides; Condylar positioning devices; Orthognathic Surgery; Mandibular set-back; Bilateral Sagittal Split Osteotomy.

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INTRODUCTION

Bilateral sagittal split osteotomy (BSSO) is one of the main orthognathic surgery procedures utilized for management of skeletal mandibular deformities. The maintenance of condylar position after BSSO is a major contributing factor for condylar function. The condylar position after BSSO is affected mainly by the intraoperative orientation of the proximal segment and the method of distal/proximal segments osteosynthesis [1]. Improper management of these factors could result in an unpredictable condyle to glenoid fossa relationship with subsequent sequelae of malocclusion, derangement of the condylar surface, condylar sage, and condylar resorption [2].

Epker and Wylie emphasized the importance of accurate mandibular proximal segment position to ensure stable surgical results and proper masticatory function with reduced adverse effects on the temporomandibular joint. Different condylar positioning devices and approaches have been used to maintain the preoperative condylar position after orthognathic surgery [3]. They have several drawbacks as extended surgical time and the need of stable intermaxillary fixation. Nevertheless, manual maneuvers are still considered as the conventional condylar repositioning techniques despite being technically arbitrary, and depending on the surgeon’s experience and hand skills [4-6].

After the revolution of computer guided technology, several computer guided approaches had been introduced to maintain the condylar position three-dimensionally after BSSO. These approaches utilized either real-time surgical navigation or rapid prototyping techniques. Surgical navigation transfers radiographic information to the surgical field and give great post-operative results, even so, it is considered to be expensive, sophisticated, and time-consuming. Rapid prototyping techniques using patient- specific surgical guides represents a simple method to overcome the real-time navigation limitations. In this approach, the virtual surgical plan is transferred to the surgical field using different CAD-CAM generated devices with positioning screws, pre-bent plates or custom-made plates osteosynthesis [7-10]. Despite the wide use of these devices in BSSO, limited comparative studies had been conducted to assess its accuracy in maintaining the condylar position versus the conventional manual maneuvers [11-16].

The aim of this study was to compare the accuracy of proximal segment position after BSSO using osteotomy/screw holes locating and plate locating surgical guides with pre-bent plates osteosynthesis versus conventional free hand proximal segment seating in management of patients with skeletal class III malocclusion.

PATIENTS AND METHODS

This was a randomized controlled clinical study conducted on twenty patients. The patients were recruited consecutively at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University. Patients were selected according to the following clinical criteria: Adult patients complaining of skeletal class III malocclusion that require BSSO for correction of their deformity. Patients require bi-maxillary orthognathic surgery or patients with temporomandibular joint dysfunction were excluded from the study. Patients were allocated randomly into two equal groups using a simple random sequence with an allocation ratio of 1:1 generated by a web site (www.random.org). For the intervention group, two CAD/ CAM-generated surgical guides (osteotomy/screw holes locating surgical guide and plate locating surgical guide) together with a pre-bent titanium mini-plates were used for proximal and distal segments positioning, while for the control group, inter-occlusal wafer fabricated on a semi-adjustable articulator was used for distal segment positioning and the proximal segment was positioned manually using free hand technique.
Preoperative preparation and virtual planning

A thorough clinical examination was performed; preoperative photographs and plaster dental cast models were obtained for all enrolled patients. Patients were sent for orthodontic leveling, alignments and decompensation of malposed teeth. After orthodontic adjustment CT scan was requested using a multi-slice helical CT machine (I-CAT®PreciseTM from I-CAT®Technology, Hatfield, PA). DICOM files were utilized through mimic’s software (Mimics 19.0, Materialise NV, Leuven, Belgium). Stone dental models were fabricated, and scanned three dimensionally. Using the planning software digital dental models were aligned over the teeth of the CT skull model to obtain an artifact-free composite/dentition skull model. Using mimics, skeletal relations were analyzed, virtual surgical planning and simulation of the mandibular orthognathic surgery was performed for all patients. Distal interference appeared during the surgical simulation was planned for trimming with nerve preservation during the surgical procedure to prevent any change in proximal segment position.

Intervention group

The corrected mandibular model was exported in STL file format to the additive CAM machine (FORMIGA P 110 printer; EOS e-manufacturing solutions, Munich, Germany) and manufactured in white polyamide (PA2200; EOS e-manufacturing solutions, Munich, Germany) using fused deposition modelling (FDM) technology. Double Y titanium mini plates were bended and fixed over the virtually corrected 3D printed mandibular model. The printed mandible and the pre-bent plates in place were laser scanned for fabrication of two sets of surgical guides (osteotomy/screw holes locating guides and plate locating guides). Using the software, the corrected mandibular model with the plates over it was used to define the position of the screws on the mandibular segments. The mandible was then virtually moved to the preoperative position with the defined final screw holes. The osteotomy/screw holes locating surgical guides (right and left) was then virtually constructed. Each guide contained six screw holes corresponding to screws position on mandibular segments and two buccal vertical osteotomies guiding slits with the distance between them representing the amount of mandibular setback. The end of the ramal extension of the guide locate the position of the medial osteotomy, while the upper border of the guide locates the oblique osteotomy which connect the medial osteotomy with the two vertical osteotomies (Figure 1).

![Fig. (1). Snapshot of mimic’s software screen showing the osteotomy/screw holes locating guide.](image)

The plate locating guides (right and left) were then constructed on the scanned mandibular model with the fixed plates. Each plate locating guide contained housing trough on its medial aspect that house the pre-bent plate and place it exactly in the planned position. It also contained ramal extension that clip both proximal and distal segments together to the planned position (Figure 2). Formulated guides were sent to the additive CAM machine (FORMIGA P 110 printer; EOS e-manufacturing solutions, Munich, Germany) and manufactured in white polyamide (PA2200; EOS e-manufacturing solutions, Munich, Germany) using fused deposition modelling (FDM) technology.
Intraoperatively extended Ward’s incision was performed to expose the lateral and medial aspects of the mandibular ramus area. Osteotomy/screw holes locating surgical guide was seated and fixed in place (Figure 3). The medial, vertical and connecting oblique osteotomies were performed using reciprocating saw guided by the osteotomies’ markings, then the screw holes were performed guided by the reference screw holes. The osteotomy/screw holes locating guide was then removed and the splitting was completed (Figure 4). The plate locating surgical guide with the pre-bent plate accommodated inside was seated in place to engage the distal and proximal segments at the level of the anterior border of the ramus and to be coincident with the previously performed screw holes (Figure 5). Central screws were fixed, and the guide was removed to complete the screws fixation using mono cortical 2.0 screws (Figure 6). Finally, all incisions were sutured with 3-0 resorbable sutures (Polyglycolic acid coated braided suture, CFIRM esnet Kratznedel fabrik, Germany.)

**Control group**

Stone dental models were mounted on a semi-adjustable articulator using face-bow transfer record (Quick Master Semi-Adjustable Dental Articulator, Fag-Dentaire – France) and bite registration. Conventional cast surgery was prepared by mounting the mandibular plaster model in the desired final post-operative occlusion. Final wafer was made using self-cure acrylic resin.
Intraoperatively extended Ward’s incision was performed to expose the lateral and medial aspects of the mandibular ramus area. A reciprocating saw was used to perform the osteotomy. The osteotomized segments were split then the distal segment was positioned into the interocclusal wafer, followed by intermaxillary fixation. Osteosynthesis was performed using double Y titanium mini plates which was bended and adapted intraoperatively, while the proximal segment seated in place by light digital pressure extraorally at the angle region in conjunction with utilization of bone holding forceps to clamp the proximal and distal segments together to maintain the gained proximal segment position until fixation. Finally, all incisions were sutured with 3–0 resorbable sutures (Polyglycolic acid coated braided suture, CFIRM esnet Kratznedel fabrik, Germany).

**Postoperative follow up and outcomes**

Elastoplast strip was fastened to the cheek region for 48 h after the operation. The patients were informed to place ice-packs over the cheek region for twenty minutes every hour for 12 hours postoperatively and to use warm saline solution mouth wash starting on the 2\textsuperscript{nd} day after surgery. Soft diet intake was ordered for the 1\textsuperscript{st} two weeks. Postoperative anti-microbial, pain relieving, and anti-inflammatory drugs were ordered for 5–7 days. The patients were reviewed weekly in the 1\textsuperscript{st} two months after surgery for clinical assessment regarding; occlusal harmony, TMJ function and inferior alveolar nerve function. The final orthodontic adjustment was started at the beginning of the 1st month postoperatively.

A CT scan was acquired within one week postoperatively for all patients. Condylar/proximal segment movement was assessed through automatic software super-imposition of preoperative and postoperative CTs using fixed alignment points in the skull for registration and anatomical reference points and planes in the osteotomized segments for comparison \[17\]. The linear condylar movement was calculated by measuring the difference between the preoperative and postoperative position of the center of the condyle in mediolateral (X-axis), anteroposterior (Y-axis), and super-inferior (Z-axis). The angular condylar movement was assessed.
using 3D coordinates of condyle head lateral pole and medial pole in the axial view (inward rotation, outward rotation), and in the coronal view (downward, upward), while in the sagittal view was assessed using center of condyle head and tip of coronoid process (clockwise, anticlockwise) \(^\text{[18]}\). (Figure 7). Measures were evaluated by two assessors, and the final value was the average of the two readings. The absolute value of each measurement was used, and the positive/negative signs describing the direction was ignored to prevent masking of the true movement magnitude.

Mandibular distal segment deviation of the actual post-operative position from the preoperative virtual planning assessed through comparing postoperative CT with the virtual plane. Linear deviation was assessed using lower central incisors contact point (Inc), right mesio-buccal cusp tip (MB1) and left mesio-buccal cusp tip (MB2) as dental anatomical reference points in addition to menton (Me), pogonion (Po) and B-point as bony anatomical reference points regarding Frankfort (FHP), midsagittal (MSP), and coronal (CP) planes. Angular deviation was assessed using occlusal (OCCP), and mandibular (MP) planes with Frankfort (FHP), midsagittal (MSP), and coronal (CP) planes.

### Statistical analysis

SPSS (Statistical package for the social sciences-IBM® SPSS® Statistics Version 22 for Windows, IBM Corp., Armonk, NY, USA) was used to perform statistical analysis. Quantitative data were represented as mean±standard deviation. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. Student’s t-test was used to compare variables between the two groups for parametric data. Mann–Whitney U test was used to compare variables between the two groups for non-parametric data. Inter-observer agreement was evaluated using spearman correlation coefficient. The results were considered statistically significant if the p value was less than 0.05.

### RESULTS

This clinical trial was conducted on twenty patients with the mean age of 23.8±3.2 years for the intervention group, and 21.6±3.3 years for the control group. BSSO was performed in all patients. All cases were run uneventful with normal blood loss. Operative time was slightly longer for the intervention group (2 hours 4 minutes ±27.5 minutes) compared to the control group (1 hours 46 minutes ±32.1 minutes) and there was no statistically significant difference between the two
The proximal segment in only one case in the intervention group had an unfavorable split that was splinted by the aid of the plate locating guide till fixation. The magnitude of mandibular setback was comparable for both groups (4.9±1.3 mm in the intervention group, and 4.3±1.1 mm for the control group), and there was no statistically significant difference between the two groups (P-value 0.27). The follow up of all cases showed uneventful healing with no wound dehiscence, plate exposure, or infection. Edema resolved in all cases within 2 weeks. All cases showed temporary paresthesia immediately after the surgical procedures with complete resolution within two months postoperatively. All cases of the control group required post-operative orthodontic treatment to adjust the occlusal discrepancies. TMJ symptoms of pain and clicking was observed in four cases of the control group and resolved after completion of the post-operative orthodontics.

Condylar linear deviation was significantly lower for the intervention group (X-axis: 0.03±0.02, Y-axis: 0.02±0.03, Z-axis: 0.03±0.03 mm) compared to the control group (X-axis: 1.38±0.48, Y-axis: 1.35±0.51, Z-axis: 1.66±0.15 mm), and there was statistical significance difference between the two group at X, Y, and Z-axis (P-value <0.001). Condylar angular deviation was also significantly lower for the intervention group (Axial: 0.24±0.28, Coronal: 0.24±0.19, Sagittal: 0.29±0.13 mm) compared to the control group (Axial: 2.79±1.51, Coronal: 3.14±2.28, Sagittal: 2.49±1.40 mm), and there was statistical significance difference between the two group at axial, coronal, and sagittal planes (P-value <0.001) (table 1). Data showed perfect inter-observer agreement with correlation coefficient 0.98 (P value < 0.05).

Distal segment position in the intervention group showed linear deviation ranging from 0.02 to 0.13 mm and angular deviation ranging from 0.03 to 0.15°, while the distal segment position in the control group showed linear deviation ranging from 0.97 to 1.44 mm and angular deviation ranging from 1.41 to 1.52°. The intervention group showed higher accuracy compared to the control group, and there was statistically significant difference between the two groups in all linear and angular deviations (tables 2, 3).

### TABLE (1) Showing bodily and rotational deviations between the preoperative and postoperative proximal segment position.

<table>
<thead>
<tr>
<th>Movement</th>
<th>Bodily movement</th>
<th>Rotational movement</th>
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<tbody>
<tr>
<td>Side</td>
<td>Right</td>
<td>Left</td>
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<td>Axis/plane</td>
<td>X</td>
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<td>Study</td>
<td>Mean</td>
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<td>SD</td>
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<td>Control</td>
<td>Mean</td>
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<td></td>
<td>SD</td>
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<td>P value</td>
<td>0.001*</td>
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* Ax = Axial plane, Co = Coronal plane, Sg = Sagittal plane.  
* Statistical significance  
SD = Standard Deviation
DISCUSSION

TMJ problems, occlusal discrepancy, risks of relapse due to improper placement of the proximal segment following BSSO directed authors to develop several maneuvers and devices for accurate proximal segment repositioning. The conventional methods are considered an arbitrary and operator dependent method, while real-time surgical navigation is expensive and needs a steep learning curve. Thus, CAD-CAM generated devices are considered an accurate and more convenient solution for condylar repositioning [3,7]. This study aimed to compare accuracy of proximal segment position after BSSO using osteotomy/screw holes locating and plate locating surgical guides with pre-bent plates osteosynthesis versus conventional free hand proximal segment seating in management of patients with skeletal class III malocclusion.

CAD/CAM condylar positioning devices introduced in the literature were either bone supported, or tooth / bone supported (hybrid supported). Hybrid supported guides showed...
minimal deviation. However, these devices required accurate dental cast scanning, and added intra operative time during its application as it must be supplied in the form of assembled pieces [12-16]. In the current study, authors used two bone supported surgical guides (osteotomy /screw holes locating guide and plate locating guide). These guides together with the pre-bent plates were utilized to guarantee the exact condyle to fossa relationship, as the corrected mandibular model with the pre-bent plates fixed in place were laser scanned for exact plates and screw holes transfer [19]. Also, the pre-bent plate position was checked twice, first during virtual placement of the plates’ screw holes within the osteotomy /screw holes locating guide, and second during the creation of the plate housing within the plate locating guide.

The created osteotomy/screw holes locating guide was designed with wide anatomical surface to allow better anatomical adaptation. The upper extension of the guide allowed easy detection of the lingulae medially with subsequent inferior alveolar nerve protection. The guide has reference markings for the medial, vertical, and connecting oblique osteotomies that ensure the exact position of the osteotomy lines. It also has reference holes for the pre-bent plates’ screws position transfer.

Based on the literature, the firstly introduced bone supported condylar repositioning device utilized by Barakat et al. 2014 [13] was designed with reference holes for positioning screws location to position the proximal segment in its preoperative position in relation to the distal segment in its final position, unlike the current bone supported osteotomy/screw holes locating guide which contains reference markings for osteotomies in addition to the reference holes for the pre-bent plates’ screws position transfer. The utilization of bicortical positioning screws for segments fixation indicating the need of preoperative nerve tracing to avoid nerve injury. In the current study, authors used mono cortical screws for pre-bent plates fixation avoiding the risk of nerve injury and need of nerve tracing. Furthermore, authors used a plate locating guide as an additional condylar repositioning verification tool to maintain proximal segment preoperative position.

The plate locating guide ensures the exact preplanned plate position through its plate housing together with the wide anatomically adapted extensions. It engages the proximal and distal segments at the level of the anterior border of the ramus to ensure the proximal /distal segments relationship and to clamp the proximal segment in place until plate fixation. Moreover, the plate locating surgical guide could be utilized as a template that splint the proximal and distal segments in case of unfavorable splits until fixation, the benefit of this splinting function was utilized in one case in the intervention group.

In the current study, authors utilized plate osteosynthesis instead of bicortical screw osteosynthesis. Plates osteosynthesis provides direct inferior alveolar nerve protection through utilization of mono cortical screws, and indirect protection through preservation of the planned distal proximal segment distance without nerve compression. Furthermore, the plate osteosynthesis depends on lateral surface fixation using monocortical screws allowing for fixation of the segments even after large distal interference trimming, which is considered as a limitation of condylar positioning device’s depending entirely on the bicortical positioning screws as the devices utilized by Barakat et al [13] and Harada et al [20]. In the current study, authors utilized double Y-shaped miniplate with 6 holes and 9.0 mm spacing for both groups following Hasanein and Alfakhry [21] who emphasized that this plate configuration had greater resistance to displacement and provided more favourable biomechanical behaviour than the conventional straight miniplates.

The postoperative assessment in this study was depending on surface-based registration between pre- and post-operative CT following the protocol of Almukhtar et al. who proved that there are no statistical differences between
Mohammed Omara, et al.

E.D.J. Vol. 69, No. 3

The voxel-based registration and surface-based registration methods\(^{(22)}\). The condylar deviation was accurately measured in the current study following the mathematical calculations protocol introduced by Takasu H et al which effectively reduced the assessment errors\(^{(18)}\), moreover the direct measurements are subjective and inaccurate while the mathematical method is accurate but more sensitive, the faced limitations in the mathematical methods was the long computational steps and data that was subjected to mathematical errors which mandated several revisions for the steps to assure its accuracy.

The condylar linear and angular deviation for the intervention group (X-axis: 0.03±0.02, Y-axis: 0.02±0.03, Z-axis: 0.03±0.03 mm, Axial: 0.24±0.28, Coronal: 0.24±0.19, Sagittal: 0.29±0.13 mm) was statistically significantly lower than the control group (X-axis: 1.38±0.48, Y-axis: 1.35±0.51, Z-axis: 1.66±0.15 mm, Axial: 2.79±1.51, Coronal: 3.14±2.28, Sagittal: 2.49±1.40 mm). It was also significantly lower than the minimum deviation range for the computer assisted condylar positioning studies reported in the literature (1mm/1° deviation\(^{(12-16)}\). However, the conventional method is still considered comparable to the acceptable clinical range\(^{(23)}\).

Distal segment position in the intervention group also showed statistically significant lower deviation compared to the control group, and these results were reflected post-operatively in terms of clinical outcomes as all cases of the intervention group showed accurate postoperative occlusion with no signs of TMDs. While all cases of the control group showed slight post-operative occlusal discrepancy that mandated post-operative orthodontics. The occlusal discrepancy of the control group is a clinically detectable consequence of the high condylar deviation. This condylar deviation either happened due to proximal segment mal-positioning or when the proximal segment is seated correctly in the glenoid housing while the inter-occlusal wafer is in place with the teeth in occlusion; however, the intraoperative plates bending may induce flexural stresses in the proximal segment. Once the inter-maxillary fixation is loosened, induced forces on the proximal segment are released and the condylar deviation occurred and this deviation is reflected clinically as distal segment mal-positioning with occlusal discrepancies\(^{(2)}\).

On the other hand, intervention group showed slightly longer intraoperative time (2 hours 4 minutes) compared to the intraoperative time of the control group (1 hours 46 minutes). Nevertheless, operative time is still comparable with no statistically significant difference between the two groups. This can be attributed to the placement and removal of the two surgical guides in the intervention group that lengthen the intraoperative time compared to the control group.

**CONCLUSION**

The use of osteotomy/screw holes locating and plate locating surgical guides with pre-bent plates osteosynthesis significantly decreased proximal segment displacement after BSSO compared to conventional free hand proximal segment seating. The additional cost for the surgical guides construction can be considered as a limitation factor compared to the conventional free hand approach. Nevertheless, this can be overwhelmed by the benefits of the digital approach especially for less experienced surgeons.

**REFERENCES**


