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Radiographic Evaluation of the Accuracy of Computer-Assisted Design and Manufactured (Cad/Cam) Three-Dimensional (3d) Device for Condylar Positioning in Mandibular Bilateral Sagittal Split Osteotomy (Clinical Trial)

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Abstract: ***Introduction***: *Bilateral Sagittal split osteotomy (BSSO) is used to correct malocclusion by mobilizing the mandible during orthognathic procedures surgically. Although the use of condylar positioning devices (CPDs) seems prudent, theireffect on condylar position and relapse has not been studied deeply.* ***Aim of the study:*** *To radiographically assess the accuracy of CAD/CAM surgical guide for condylar positioning in the bilateral sagittal split osteotomy.* ***Materials and Methods****: The study recruited eight patients who had a nonsyndromic dentofacial deformity and underwent Bilateral Sagittal Split Osteotomy (BSSO). The surgery was planned according to (CAD /CAM) technology. After osteotomy, a preoperative guide was used, followed by a repositioning guide. Computed tomography scans were conducted on all patients one week preoperatively, immediately, and three months postoperatively to assess the condylar position.* ***Results:*** *The data are presented as median values with the 25th and 75th percentiles. Eight patients (37.50% females and 62.50% males) between the ages of 19 and 24 underwent BSSO with or without LeFort I maxillary advancement. The surgical procedure successfully corrected their skeletal deformities. Repeated measures analysis showed no statistically significant change in the Condylar Angle (°) among the different times of measurement (p=.233).* ***Conclusion:*** *The stability of the condylar head in position and patient postoperative occlusion is well assessed by 3D condylar positioning devices designed and manufactured by CAD/CAM technology in the mandibular BSSO.*

Keywords: *Computer-Aided Design, Computer-Aided Manufacturing, Mandibular Condyle, Osteotomy, Sagittal Split Ramus.*

I. INTRODUCTION

Orthognathic surgery is a proven method for correcting dentofacial deformities, but it can lead to complications such as relapse and temporomandibular joint disorders (TMD). Research has shown that alterations of the condyle during surgery can cause early or late relapse and serious TMD symptoms. [1-3]To prevent these issues, surgeons must maintain a stable and proper position of the mandible or condyle during the procedure. By doing so, post-operative relapse and TMJ dysfunction can be avoided. [4,5]

Researchers have been focusing on minimizing condylar displacement during surgery in the 20th century. They have aimed to keep the condyles within 1 mm of their pre-operative position when the mandible is fully interdigitated. [6,7] Different condylar positioning techniques have been presented and innovated.

While manual positioning is a convenient technique that requires no additional equipment, it can often be inaccurate as surgeons rely on their experience to determine the best condylar position. For inexperienced surgeons, this can pose a significant challenge due to the extensive training required to master this positioning method.[8]

Leonard initially reported a CPD in 1976 [9] which was then subsequently improved by Rotskoff and Herbosa[10] This CPD had a good result in avoiding the displacement in both vertical and horizontal planes beyond 1.2 mm, but it had no capability on the counterclockwise rotation of the proximal segment and mediolateral displacement. The discovery of a condylar positioning device (CPD) that can manipulate the condyle in three dimensions was initially documented by Luhr and Kubein-Meesenburg in 1985. This finding was later validated by Lin et al, who established its effectiveness in identifying and replicating the condyle's position along the sagittal axis. [11,12]

However, the TMJ may eventually displace due to the problem of autorotation, and displacement remained unsolved.Luhr's CPD lacked better functional improvement than manual positioning on skeletal stability. [13,14]

In addition to the CPDs mentioned earlier, scholars have expressed a greater interest in occlusal-based positioning splints. [15]According to Landes and Sterz, [16]the use of positioning splints significantly reduced postoperative dysfunction. However, some authors argue that manual positioning may have an even greater effect than occlusal-based splints in inhibiting short-term relapse and reducing condylar displacement. [7]

While positioning splints can be effective, it is important to acknowledge that the preparation process can be time-consuming. To streamline the process, digital technology applications like teeth-supported and bone-supported CAD/CAM CPDs have become increasingly popular in orthognathic surgery. [17] These tools allow for virtual pre-operative planning to be transferred to the actual operation, saving valuable time. [18]Research shows that CAD/CAM CPDs are particularly effective at stabilizing the proximal segment on the coronal plane, though they may not be as effective on the sagittal plane. [19] Benefiting from solid and detailed dental anatomy, the teeth-borne CPDs had higher accuracy in reproducing the pre-operative condylar position than bone-borne CPDs. [18] The CAD/CAM CPDs had obvious advantages: (1) eliminate the need for intraoperative measurements, face-bow, and intermediate splint in bimaxillary surgery; (2)reduce the exposure of surgeons to dust and toxic chemicals; and (3)eliminate pre-operative training and operation simulating. [18,20]

The goal of the study was to assess the precision of the CAD CAM surgical guide for condylar positioning in the bilateral sagittal split osteotomy through clinical and radiographic evaluation. The results of the study were analyzed to determine the accuracy of the guide.

In this study, we aim to test the hypothesis that the accuracy of the position of the condyles during bilateral sagittal split osteotomy is not significantly affected by the use of CAD/CAM 3D surgical guides.

II. MATERIALS AND METHODS

The study was conducted following the ethical approval granted by the Research Ethics Committee of the Alexandria University Faculty of Dentistry.

Patients

This study involved eight patients from the Alexandria University Outpatients' Clinics of Oral and Maxillofacial Department, Faculty of Dentistry, Alexandria University, Egypt; the study involved individuals who presented with craniofacial deformities that necessitated BSSO with or without maxillary osteotomy. Before the surgery, all patients provided informed consentby signing the appropriate documentation at the Oral and Maxillofacial Surgery Department of Alexandria University's Faculty of Dentistry.

For three-dimensional (3D) planning, preoperative computed tomography (CT) images of the patient were acquired, and dental casts were taken. During CT, the condylar heads were positioned into the glenoid fossa by using a wax bite. Three-dimensional digital modeling of the mandible was performed by segmenting the acquired DICOM images using the MIMICS software (Materialise, Leuven, Belgium); surgery was planned virtually by using ProPlan CMF (Materialise); and guide modeling was performed using 3-matic (Materialise).

Patients suffering from dentofacial deformities not associated with any syndromes necessitating BSSO with or without maxillary osteotomywere included in the study, with ages between 20-40 years, no sex predilection, and good oral hygiene. Smokers, and alcohol or drug abuse patients were excluded.

Materials

Standard 2.0mm mini plates, mono-cortical screws measuring 2.0mm in diameter and 5 - 7mm in length (StemaMedizintechnik GmbH, Stockach, Germany), Orthognathic surgical instruments set, CT (a slice thickness of 0.5 mm), and CAD -CAM surgical guide: a) Preoperative guide (occlusal splint with holes positioning arm) (Fig.1A), b) Repositioning guide (preplanned occlusal splint with holes repositioning arm) (Fig.1B) were used.

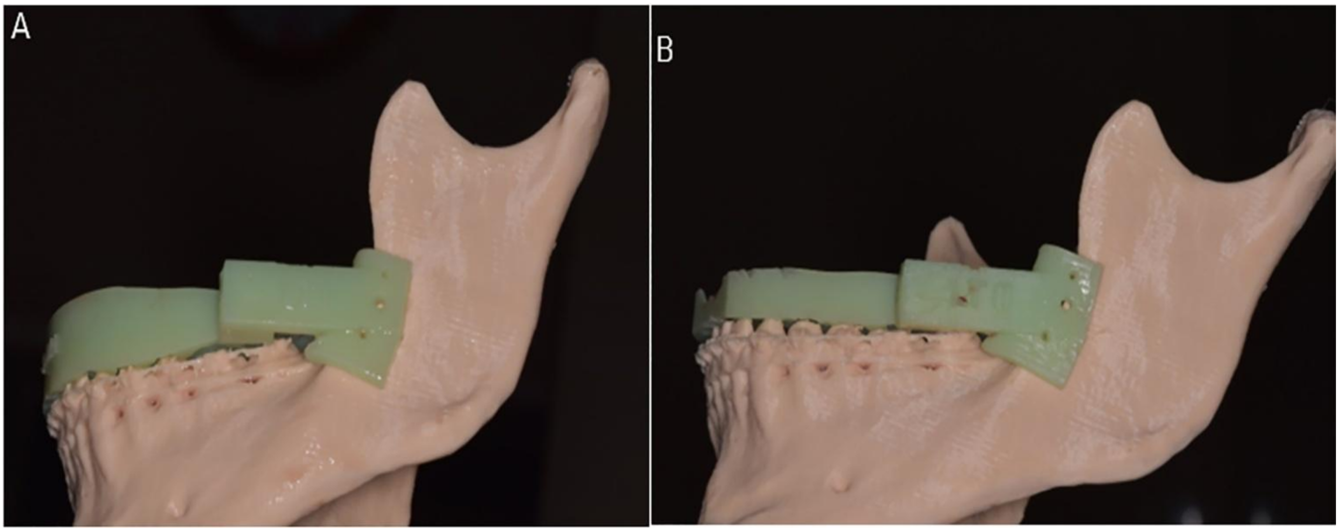


figure 1(A) Preoperative guide (occlusal splint with holes positioning arm), (B) Repositioning guide (preplanned occlusal splint with holes repositioning arm).

Methods

Preoperative Clinical examination

Complete medical and dental histories were taken, followed by extra-oral inspection to confirm the facial asymmetry and malocclusion and via palpation to assess any tenderness, teeth mobility, and condylar stability.The standard orthognathic evaluation encompassed an extensive preoperative data collection process, which involved clinical photographs, cephalometric analysis, dental models obtained through both traditional stone models and digital laser scanning, and registration of a centric relation (CR) bite in an upright position using an occlusal splint. Patients undergo all the necessary laboratory investigations to obtain clearance for operation from the anesthesia specialist. They were instructed to fast at least 8 hours before the surgery.

Preoperative Radiographic examination

For diagnosis and treatment planning, computerized tomography (CT) was performed for all patients. 3D CAD/CAM surgical guide fabrication by using a virtual plan: a) Preoperative guide (occlusal splint with holes positioning arm) b) Repositioning guide (occlusal splint with holes repositioning arm) was also done (Fig.2).

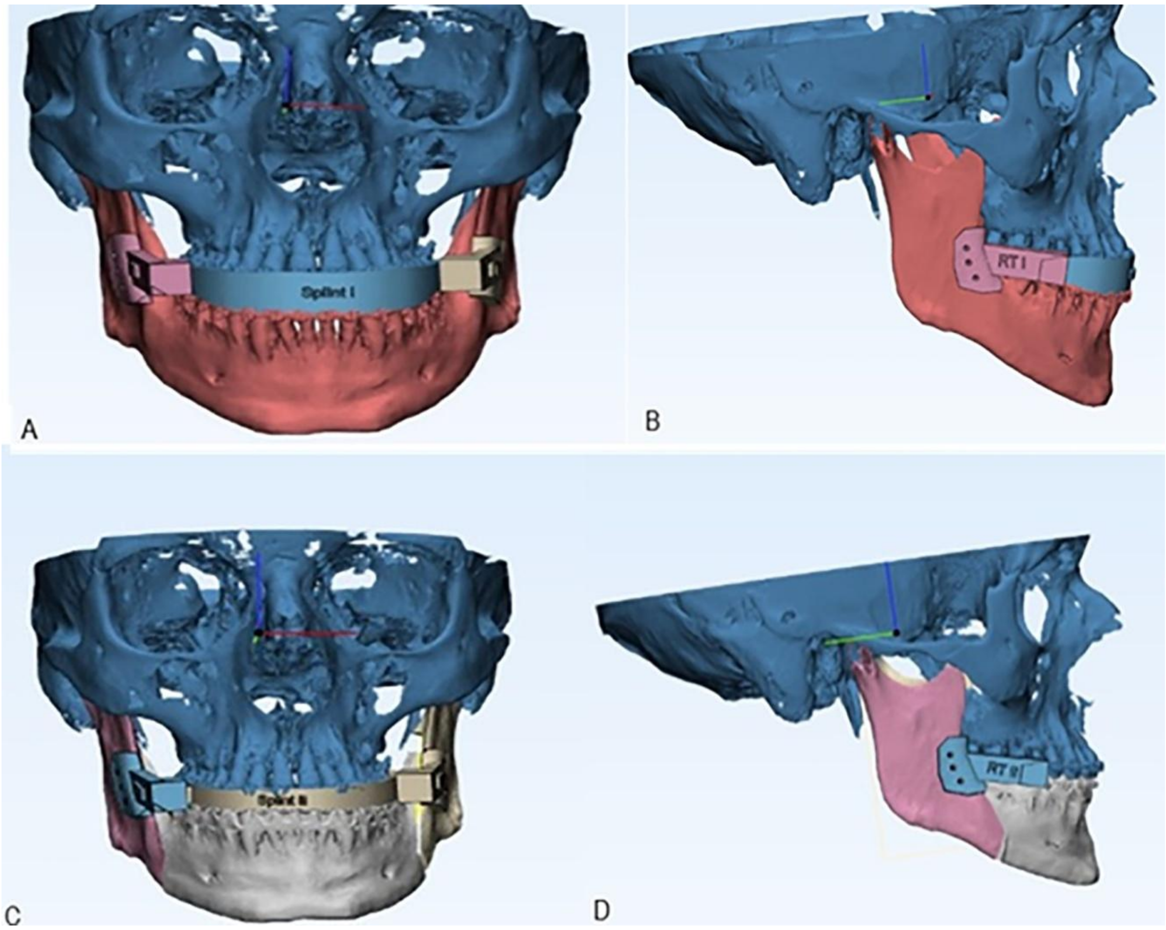


figure 2(A) Preoperative guide (occlusal splint with holes positioning arm frontal view),(B) Preoperative guide lateral view, (C) Repositioning guide (occlusal splint with holes repositioning arm frontal view), (D) Repositioning guide lateral view.

Preoperative preparations:

Placement of orthodontic brackets on the teeth with scaling and root planning was done for all patients.

Surgical phase

Preoperative medications

A prophylactic antibiotic was administered orally in Amoxicillin/Clavulanic acid (Augmentin 625 mg, GlaxoSmithKline, UK) three times daily for three days.

Surgical procedure

The surgical procedure was conducted with the patient supine under general anesthesia, utilizing nasotracheal intubation. Before the operation, thorough intraoral and extraoral scrubbing using povidone-iodine was performed.

Subsequently, sterile towels were used for draping, ensuring that only the surgical area was exposed. A mucoperiosteal intra-oral vestibular incision at the retromolar region was done. A preoperative guide (occlusal splint with holes positioning arm) was applied to make holes in the posterior ramus segment. The preoperative guide was removed to start (BSSO). A bilateral sagittal split ramus osteotomy (BSSO) procedure was carried out. The planned occlusion was obtained using a repositioning guide (occlusal splint with the same holes used before and repositioning arm), so a precise ramus position was obtained (Fig.3). Two mini plates and mono-cortical screws addressed the osteotomy sites' restricted bone contact area. The surgical wound was sutured using non -resorbable 3/0 silk suture material. Placement of orthodontic arch wire to the brackets, then activation started two weeks postoperatively. Placement of Inter Maxillary Fixation (IMF). Two days postoperatively, a computed tomography (CT) scan was conducted to assess the condyles' sagittal, vertical, and transverse positions and verify their placement within the glenoid fossae. Once measurements were done, the IMF was released.

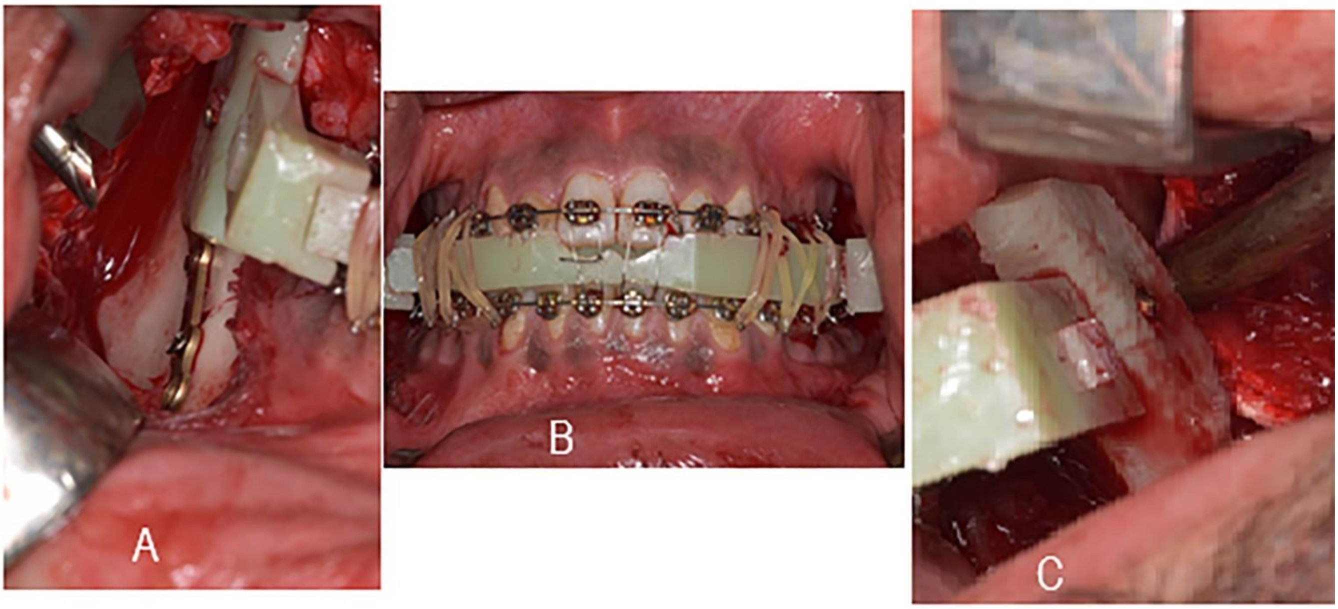


figure 3. (A) Right arm, (B) Fontal view of occlusal splint, (C) Left arm of the guide Intraoperative view with positioning segments and fixation of the proximal segment with mono-cortical screws.

Postoperative phase

All patients were instructed to apply ice packs extra-orally, starting immediatelypostoperatively for 12 hours. Patients were given strict instructions to maintain proper oral hygiene. Patients were instructed to eat a blenderizeddiet two weeks postoperatively.

2.5.1 Postoperative medications

All patients were given a 5 -days course of systemic antibiotics; 1 gm Amoxicillin + clavulanate tablets twice daily for the next seven days. Diclofenac potassium 50 mg tab every eight hours for five days and Chlorhexidine antiseptic mouthwash.

Follow-up phase

Clinical follow-up:

Pain, edema, wound healing, and facial symmetry were assessed. The pain was assessed by Visual Analogue Scale (VAS)[21]. Edema was evaluated by the Laskin scale. [22]

For assessment of wound healing, the intraoral incision was regularly assessed and monitored for any indications of dehiscence, infection, or inflammation during the postoperative period.

Facial symmetry was examined by clinical patient assessmentseven days, 14 days, and six weeks postoperatively. [23]

Radiological follow-up

CT scans were done for all patients to assess the position of the condylarangle immediately postoperatively and three months postoperatively (Fig. 4).

(a) (b) (c)

figure 4(a) Preoperative CT-scan (3D view) for condylar angle (b) Postoperative condylar angle immediate and (c) Postoperative condylar angle 3 months.

III. RESULTS

The eight patients recruited from the outpatient clinics of the Oral and maxillofacial department Faculty of Dentistry Alexandria University were operated in the same department's operating room.

The age of patients ranged from 19.00 to 24.00 years with a median [25th–75th percentile] of 20.00 [19.50-22.00], 95% Confident Interval of the median (CI) was 20.00-24.00.Males represented 5/8 (62.50% while females were 3/8 (37.50%)

Class II was indicated in 2/8 (25.00%) patients, while class III was indicated in 6/8 (75.00%).Every patient 1/8 (12.50%) underwent a different surgical procedure.

Preoperatively, Condylar Angle (°) ranged from 148.20 to 156.40 with a median [25th–75th percentile] of 152.85 [150.25-154.80], 95% CI of the median was 149.10-155.30. (Table1, Fig. 5).

Immediate post-operatively, the Condylar Angle (°) ranged from 148.10 to 156.70 with a median [25th–75th percentile] of 153.00 [150.30-155.10], 95% CI of the median was 148.80-155.80. (Table1, Fig. 5).

Three months postoperatively, the Condylar Angle (°) ranged from 148.50 to 156.50 with a median [25th–75th percentile] of 153.10 [150.30-154.90], 95% CI of the median was 148.90-155.20. (Table1, Fig. 5).

Repeated measures analysis showed no statistically significant change in the Condylar Angle (°) among the different times of measurement (*p*=.233)(Fig. 6).

Table 1: The Condylar Angle (°) at different times of measurements in the studied group.

Condylar Angle (°)	
Preoperative - n - Min-Max - Median - 95.0% CI of the median - 25th Percentile – 75th Percentile	8 148.20-156.40 152.85 149.10-155.30 150.25-154.80
Immediate post-operative - n - Min-Max - Median - 95.0% CI of the median - 25th Percentile – 75th Percentile	8 148.10-156.70 153.00 148.80-155.80 150.30-155.10

Three months post-operative	
- n	8
- Min-Max	148.50-156.50
- Median	153.10
- 95.0% CI of the median	148.90-155.20
- 25th Percentile – 75th Percentile	150.30-154.90
Friedman Test of significance ***p*-value**	$c^2_{(df=2)}$=3.00 *p*=.223 NS
Absolute change between immediate postop. And preop.	
- n	8
- Min-Max	-0.30 - 0.50
- Median	0.15
- 95.0% CI of the median	-0.10 - 0.40
- 25th Percentile – 75th Percentile	0.00 - 0.35
Absolute change between three months postop. and preop.	
- n	8
- Min-Max	-0.20-0.40
- Median	0.20
- 95.0% CI of the median	-0.10 - 0.30
- 25th Percentile – 75th Percentile	0.00 – 0.30

n: number of patients
Min-Max: Minimum to Maximum
CI: Confidence interval
df: degree of freedom
c^2 = Chi-Square
NS: Statistically not significant ($p \geq .05$)

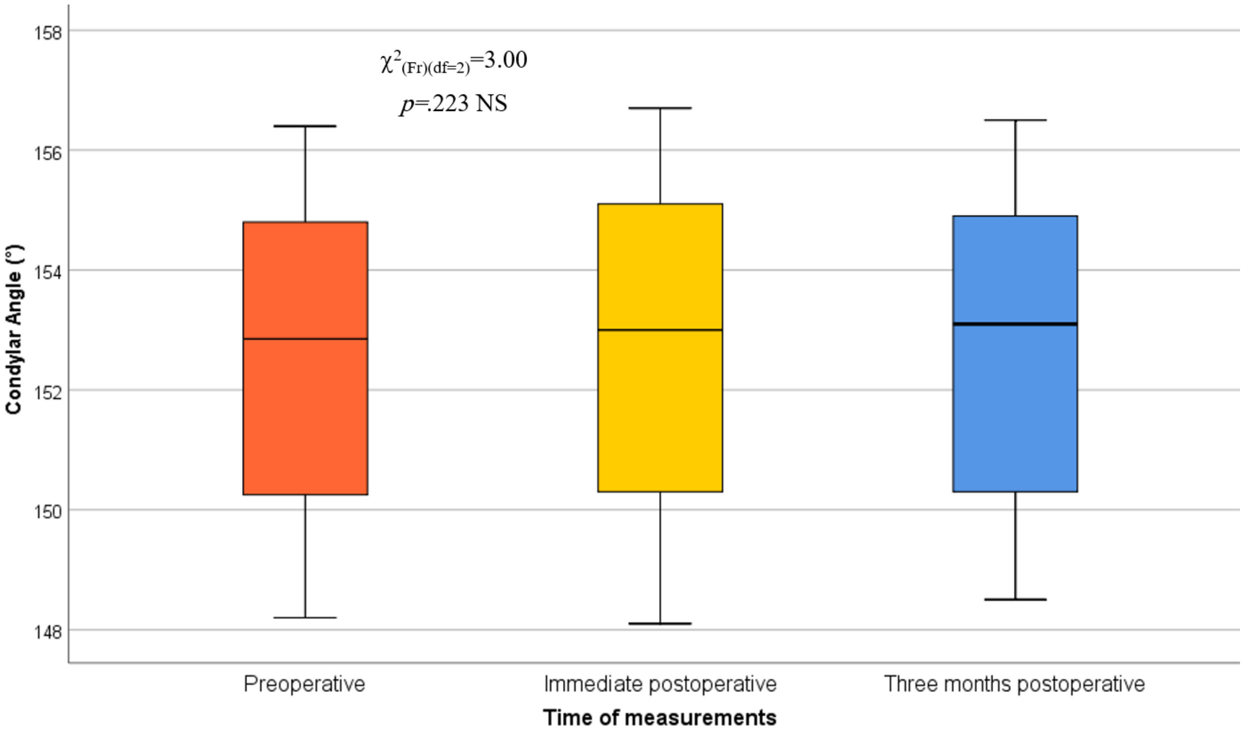
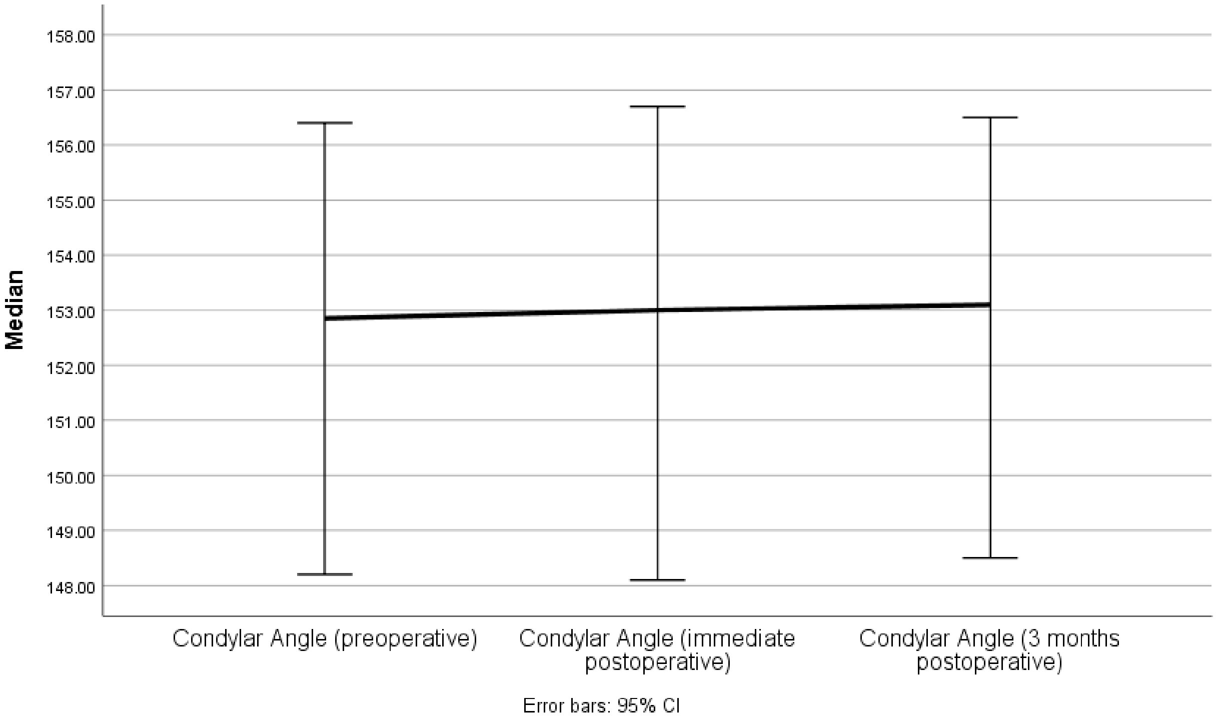
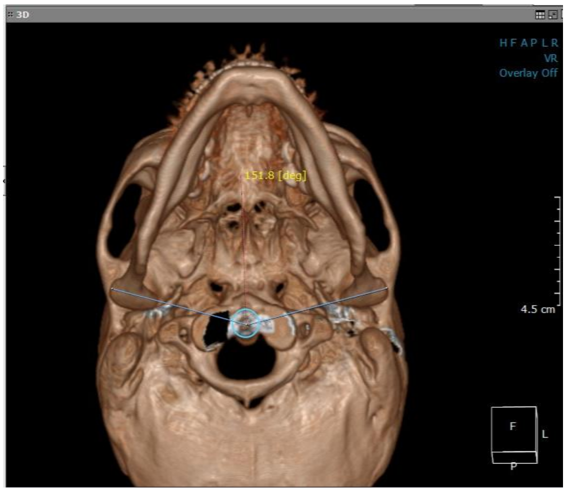
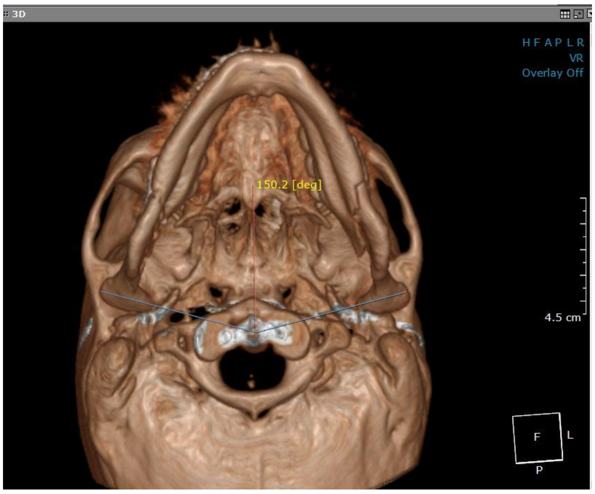


figure (5): Box and whisker graph of Condylar Angle (°) in the studied group, the thick line in the middle of the box represents the median, the box represents the inter-quartile range (from 25th to 75th percentiles), the whiskers represent the minimum and maximum.

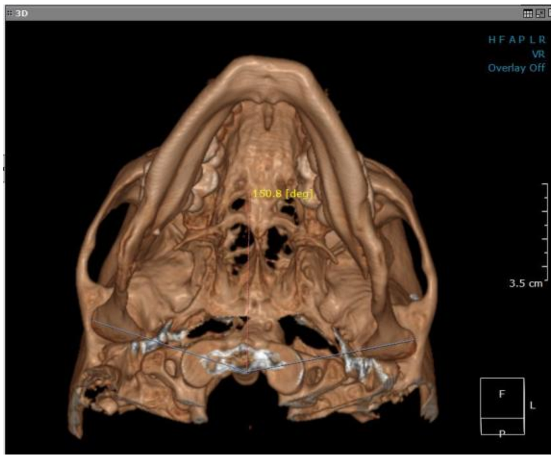




(a)



(b)



(c)

figure (6)(a) Preoperative CT-scan (3D view) for condylar angle (b) Postoperative condylar angle immediate and (c) Postoperative condylar angle 3 months.

IV. DISCUSSION

Achieving the optimal placement of the condyle is crucial for ensuring its proper function and promoting stable occlusion and ideal temporomandibular joint (TMJ) function. Although the Condylar Positioning Device represents a significant advancement, it is cumbersome too. It causes the conversion of non-rigid fixation to rigid fixation. But at the same time, very scarce scientific evidence is available in the literature supporting their routine use in orthognathic surgery. Therefore, this paper attempts to hoard some of the important narratives. The manual positioning technique was the preferred method of choice for Gerressen et al. (2007) [13] and Costa et al. (2008) [7] due to its ease of use and cost-effectiveness. They advocated for alike stable results using the manual technique in orthognathic surgery. Hirjak D et al. (2017) [24] conducted a retrospective study to evaluate the effectiveness of the manual condylar positioning method and bicortical fixation in achieving optimal postoperative condylar position and TMJ function following BSSO. Their findings indicate that the manual condylar positioning method, in combination with bicortical fixation, results in ideal condylar placement, proper TMJ function, and optimal occlusion. In 2008, Costa F et al. [7]conducted a review on the effectiveness of Condylar Positioning Devices (CPDs) in orthognathic surgery, finding that their use can prevent skeletal instability and TMD. Before the introduction of CPDs, achieving an ideal mandibular-condylar fossa segmental relationship following sagittal split osteotomy required manual repositioning. However, since 1995, research has indicated that investigating both skeletal/occlusal stability and TMJ function following orthognathic surgery is crucial. To improve the process of identifying a malpositioned condyle during surgery, the researchers recommended simpler and cost-effective methods, such as intraoperative patient awakening. Despite reviewing 11 studies with 1,313 patients, none of them mentioned the use of CPDs. Therefore, based on current literature, there is no scientific evidence to support the routine use of CPDs in orthognathic surgery.

In contrast to previous studies, Shah PD and Mukherji S (2014) [25] focused on the benefits and use of condylar positioning devices. Despite acknowledging the device's difficulties and time-consuming nature, the authors emphasized its effectiveness in achieving precise and stable results, preventing TMD complications, and promoting long-term harmony. Additionally, they noted that any malpositioning could be easily corrected through condyle adaptability, making the device a recommended tool for achieving optimal outcomes. In 2012, Lee CY et al. [26]conducted an in-vivo study on the effectiveness of a condylar-repositioning device for mandibular condyle displacement. Their findings suggest that this procedure is a viable and effective method for repositioning condyles due to its simplicity.While the three-dimensional examination is useful, additional computed tomography investigations are needed due to its limitations. In 2019, Cortese A et al. [27]developed a new technique for accurately positioning the condyle and ramus segments through CAD-CAM technology.

Their findings suggest that incorporating CAD-CAM guidance during BSSO ensures precise regulation of the condyle for a stable centric occlusion.

V. CONCLUSION

3D condylar positioning devices (CPDs), designed and manufactured by CAD/CAM technology in a mandibular bilateral sagittal split osteotomy, assess the stability of condylar position and postoperative occlusion.

REFERENCES:

[1] Kim YK. Complications associated with orthognathic surgery. J Korean Assoc Oral Maxillofac Surg. 2017;43(1):3-15.

[2] Jung HD, Kim SY, Park HS, Jung YS. Orthognathic surgery and temporomandibular joint symptoms. MaxillofacPlastReconstr Surg. 2015;37(1):14.

[3] Zaroni FM, Cavalcante RC, João da Costa D, Kluppel LE, Scariot R, Rebellato NLB. Complications associated with orthognathic surgery: a retrospective study of 485 cases. J Craniomaxillofac Surg. 2019;47(12):1855-1860.

[4] Helm G, Stepke MT. Maintenance of the preoperative condyle position in orthognathic surgery. J Craniomaxillofac Surg. 1997;25(1):34-38.

[5] Berger M, Nova I, Kallus S, et al. Electromagnetic navigated condylar positioning after high oblique sagittal split osteotomy of the mandible: a guided method to attain pristine temporomandibular joint conditions. Oral Surg Oral Med Oral Pathol Oral Radiol. 2018;125(5):407-414.

[6] Ellis E 3rd. Condylar positioning devices for orthognathic surgery: are they necessary? J Oral Maxillofac Surg. 1994;52(6):536-554.

[7] Costa F, Robiony M, Toro C, Sembronio S, Polini F, Politi M. Condylar positioning devices for orthognathic surgery: a literature review. Oral Surg Oral Med Oral Pathol Oral RadiolEndod. 2008;106(2):179-190.

[8] Park JC, Kim UK, Hwang DS. Three-Dimensional Analysis of Perioperative Condylar Displacement After Mandibular Setback Surgery With Intended Manual Condylar Positioning. J Craniofac Surg. 2018;29(8):e767-e773.

[9] Leonard M. Preventing rotation of the proximal fragment in the sagittal ramus split operation. J Oral Surg. 1976;34(10):942.

[10] Rotskoff KS, Herbosa EG, Villa P. Maintenance of condyle-proximal segment position in orthognathic surgery. J Oral Maxillofac Surg. 1991;49(1):2-8.

[11] Luhr HG, Kubein-Meesenburg D. Rigid skeletal fixation in maxillary osteotomies. Intraoperative control of the condylar position. Clin Plast Surg. 1989;16(1):157-163.

[12] Lin Y, Pape HD. Use of condyle positioning plate in sagittal split ramus osteotomy of mandible. Zhonghua Kou Qiang Yi Xue Za Zhi. 1996;31(3):165-168

[13] Gerressen M, Stockbrink G, Smeets R, Riediger D, Ghassemi A. Skeletal stability following bilateral sagittal split osteotomy (BSSO) with and without condylar positioning device. J Oral Maxillofac Surg. 2007;65(7):1297-1302.

[14] Gerressen M, Zadeh MD, Stockbrink G, Riediger D, Ghassemi A. The functional long-term results after bilateral sagittal split osteotomy (BSSO) with and without a condylar positioning device. J Oral Maxillofac Surg. 2006;64(11):1624-1630.

[15] Harada K, Okada Y, Nagura H, Enomoto S. A new appliance for condylar positioning (clamp system). Int J Oral Maxillofac Surg. 1995;24(5):342-343.

[16] Landes CA, Sterz M. Proximal segment positioning in bilateral sagittal split osteotomy: intraoperative controlled positioning by a positioning splint. J Oral Maxillofac Surg. 2003;61(12):1423-1431

[17] Zinser MJ, Mischkowski RA, Sailer HF, Zöller JE. Computer-assisted orthognathic surgery: feasibility study using multiple CAD/ CAM surgical splints. Oral Surg Oral Med Oral Pathol Oral Radiol. 2012;113(5):673-687

[18] Cortese A, Chandran R, Borri A, Cataldo E. A Modified Novel Technique for Condylar Positioning in Mandibular Bilateral Sagittal Split Osteotomy Using Computer-Assisted Designed and Computer-Assisted Manufactured Surgical Guides. J Oral Maxillofac Surg. 2019;77(5):1069.e1-1069.

[19] Kim HM, Baek SH, Kim TY, Choi JY. Evaluation of threedimensional position change of the condylar head after orthognathic surgery using computer-aided design/computer-aided manufacturing-made condyle positioning jig. J Craniofac Surg. 2014;25(6):2002-2007

[20] Polley JW, Figueroa AA. Orthognathic positioning system: intraoperative system to transfer virtual surgical plan to operating field during orthognathic surgery. J Oral Maxillofac Surg. 2013;71(5):911-920.

[21] Seymour RA, Simpson JM, Charlton JE, Phillips ME. An Evaluation of Length and End-Phrase of Visual Analogue Scales in Dental Pain. Pain 1985;21:177-85.

[22] Laskin DM. CirugiaBucal Y Maxilofacial: MédicaPanamericana; 1987.

[23] Savoldelli C, Vandersteen C, Dassonville O, Santini J. Dental Occlusal-Surface-Supported Titanium Guide to Assist Cutting and Drilling in Mandibular Bilateral Sagittal Split Osteotomy. J Stomatol Oral Maxillofac Surg 2018;119:75-8.

[24] Hirjak D, Beno M, Kupcova I, Branislav G. The position of the condyles and functional results after bilateral sagittal split osteotomy. Int J Oral Maxillofac Surg. 2017;46(1):159. doi:10.1016/j.ijom.2017.02.546.

[25] Mukherji S, Shah PD. A Dependable Device to Secure Condylar Position into Glenoid Fossa during Orthognathic Surgery. J Contemp Dent. 2014;4(3):178–80

[26] Lee CY, Jang CS, Kim JW, Kim JY, Yang BE. Condylar repositioning using centric relation bite in bimaxillary surgery. Korean J Orthod. 2013;43(2):74–82.

[27] Cortese A, Chandran R, Borri A, Cataldo E. A Modified Novel Technique for Condylar Positioning in Mandibular Bilateral Sagittal Split Osteotomy Using Computer-Assisted Designed and ComputerAssisted Manufactured Surgical Guides. J Oral Maxillofac Surg. 2019;77(5):1069.