



PATIENTS SATISFACTION FOLLOWING INTRAORAL VERTICAL RAMUS OSTEOTOMY AFTER MANDIBULAR SETBACK FIXED WITH PATIENTS-SPECIFIC OSTEOSYNTHESIS AND IMMEDIATE MOBILIZATION VERSUS VERTICAL RAMUS OSTEOTOMY FIXED WITH MMF IN PATIENTS WITH MANDIBULAR PROGNANTHISM (A RANDOMIZED CONTROLLED TRIAL)

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ABSTRACT:

Purpose: This study was designed to compare the effect of customized fixation plate following intraoral vertical ramus osteotomy versus vertical ramus osteotomy fixed with MMF in perception of patient satisfaction.

Materials and methods: This study was conducted on 20 patients aged from 20-30 years with skeletal class III Mandibular prognathism. All patients were treated with mandibular setback using intraoral vertical ramus osteotomy that was fixed using patient-specific customized plate in study group versus intermaxillary fixation in control group. The creation of the plate was performed by virtual planning using MIMICS and 3-Matic soft wares followed by milling. The plate was inserted and fixed to the osteotomized ramus segment with miniscrews. Evaluation of the patients was done before the procedure, immediately after the procedure, on postoperative month 1,3,6 months. Patients outcomes were recorded at each followup visit. Patient satisfaction was the outcome evaluated using questionnaire.

Results: All the patients underwent uneventful healing throughout the postoperative follow-up period. Regarding to patient satisfaction, there was statistically significant increase in the postoperative scores of overall satisfaction (all $P < 0.05$) in both groups.

Conclusions: Although patients benefitted from both techniques. Customized Titanium plates can be a reliable technique for fixation of vertical ramus osteotomy via intraoral approach in cases with skeletal class III mandibular prognathism. The procedure demonstrated excellent clinical outcomes with high level of patient satisfaction.

KEY WORDS: orthognathic surgery, mandibular prognathism, vertical ramus osteotomy, mandibular setback, customized titanium plates.



Introduction:

The prevalence of mandibular prognathism had been studied and found to be approximately 12% in skeletal class III (Lew et al., 1993). Mandibular prognathism was treated with different modalities such as sagittal split osteotomy or vertical ramus osteotomy (1). Orthognathic surgery and surgical orthodontic treatment are typically used to treat mandibular prognathism. Preoperative orthodontic treatment, orthognathic surgery, postoperative orthodontic treatment were the three phases of conventional surgical-orthodontic treatment (2). Incisor decompensation, dental alignment and arch coordination could be attained during preoperative orthodontic management, allowing for the development of a stable surgical occlusion (3).

Cone-beam computed tomography (CBCT) was being utilized more frequently in oral and craniofacial surgery as well as dentistry for diagnostic and treatment planning. In instance, for virtual surgical planning (VSP) and reconstruction utilizing 3D digital processing software, CBCT delivered a lower radiation dosage and a higher imaging resolution than traditional CT (4). Virtual computer-based planning with the use of direct patient-related three-dimensional imaging data. To increase the intraoperative reproducibility of the preoperative planning, A virtual surgical simulation was created using specialized software and placed onto a navigation system (5)

Intraoral VRO might be appropriate treatment for mandibular setback in certain circumstances when the mandibular canal located on, or embedded in the outer cortex of the mandibular ramus, the risk for injury to the IAN with a SSO was high. The advantages of IVRO included shorter surgical time, lower incidence of postoperative neurosensory deficit, lower incidence of temporomandibular disorders (6)

Maxillofacial surgery had undergone a revolution to the invention and success of piezoelectric bone cutting. It had a specific attraction for hard tissue due to the utilization of ultrasonic vibrations, and since it produced no heat, it did not harm soft tissue. Since its creation, it had gained popularity as a technique for making osteotomies for orthognathic surgery (7)

Complete immobilization of a patient's jaws for that length of time could be harmful to patients' health or even considered socially unacceptable. The most significant issue is that the position of the condyle cannot be adjusted during the operation. As a result, there was a risk that the condyle might sag or move out of place with 2.3% rate of condylar luxation which could be prevented with customized fixation plate and immediate mobilization (8).



With the introduction of era of customized plates Mazzoni et al demonstrated that use of customized plates improved stability of environment for bone healing and reduced the time for bending and fixing the plate during operation when compared to a standard mini-plate and better osteosynthesis of bone with correct position of osteotomized segment of mandible(9)

The patient's assessment of facial appearance, occlusion, speech articulation, relief of jaw pain, and self-confidence were known variables that affect the patient-perceived treatment outcome.

Appearance was most often documented as the strongest motive to undergo surgery, and favorable aesthetic outcomes lead to more highly satisfied patients. The amount of pre- and postoperative information provided as well as the effective surgeon-patient communication regarding the operation and recovery had been linked to patient satisfaction. Despite overall success, inherent risks and complications of orthognathic surgery could decrease patient satisfaction.(10)(11)

It is well-known that satisfaction and the perception of surgical outcome were dependent upon preoperative expectations and the degree to which the procedure was explained by the operating staff patients needed to be realistically informed of their expectations and adequately informed of possible complications. Psychological preparation of patients also seemed to be an effective component for achieving final satisfaction(12)

In the present study, the aim was to compare the effect of customized fixation plate following intraoral vertical ramus osteotomy versus vertical ramus osteotomy fixed with MMF in perception of patient satisfaction.

Materials and methods:

The present study is a double-blinded randomized controlled clinical trial conducted on 20 patients. Inclusion criteria was skeletal class III mandibular prognathism required mandibular setback, patients more than 18 years old, free from any systemic disease that interfere with bone healing and highly motivated patients. Exclusion criteria included patients who had previous orthognathic procedures, degenerative disease of temporomandibular joint, patients with inferior alveolar nerve neurosensory dysfunction. The enrolled patients were allocated randomly into two equal groups; group 1 (Study or Intervention Group) comprised 10 patients who underwent IVRO fixed with customized plate, and group 2 (Control Group) comprised 10 patients who underwent IVRO fixed with intermaxillary fixation.



Randomization:

The twenty patients were randomly allocated into two equal groups using computer software. The numbers that generate randomly from the software were written in small folded opaque papers then inserted into envelope (Opaque sealed envelope and signed across seal), each participant grasped one envelop. The study is considered a double blinded clinical trial, as the participant and the statistician were blinded, while the operator and the assessor knew the allocation group from the plate design.

Acquisition of 3D images:

For every patient, preoperative pictures of the face in its natural head position were captured, including frontal at rest, frontal at smile, profile at rest, profile at smile. Cone Beam Computed Tomography (CBCT) data in digital Imaging and communications in Medicine (DICOM) format utilized for radiographic examination and virtual planning. The CBCT data was processed using Mimics software Mimics 21.0 (Materialise N.V., Leuven, Belgium). while the patient head was in its normal position. The scan was imported into a surgical planning software After segmentation the 3D reconstruction of the bony structures were carried out, the dental models were scanned separately and mounted on to each other in the desirable final occlusion using an optical scanner. The digitized dental models were used to replace the dentition, using interactive closest point registration followed by manual surface based registration to create an artifact free composite 3D model. The diagnosis of the maxillofacial deformity was carried out by combining the clinical examination and 3D cephalometric analysis of the virtual model. virtual osteotomies le forte I osteotomy on the maxilla, vertical ramus osteotomy on mandible and surgical movements were simulated. A definitive plan was then developed.

Study group:

Designing of surgical cutting guide using 3 matic . the plate composed of two parts in which the proximal part represented the final part of plate including housing bed for interlocking arm from other part which was the distal part with reference holes used for repositioning/fixation plates (figure 1). Then, the designed plates were manufactured in titanium and milled using 3 Axes, Milling machine. (MILLSTAR, made in Taiwan)

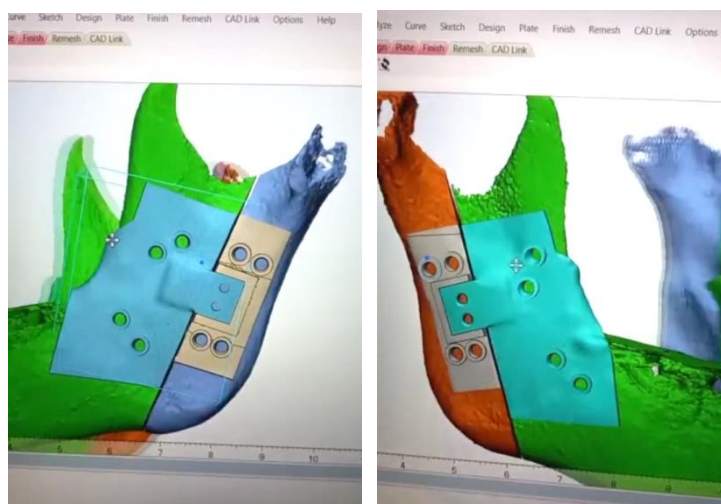


Figure (1): Designing of surgical cutting guide using 3 matic with the arrow pointed to the interlocking part connecting the guide with proximal part of plate.

- Custom made plate were designed to reposition and fix the distal segment of mandible to the proximal segment using 3 matic. The plates were constructed from titanium Then, the designed plates were milled using 3 Axes, Milling machine. (MILLSTAR, Taiwan).



Figure (2): Designing of mandibular custom plates in 3-matic



Figure 3: revealed the final plates and the guide

In operating room, intraoral incisions were created on external oblique ridge then mucoperiosteal flap reflected to expose the lateral mandibular ramus to the posterior border and the sigmoid notch. After that, Surgical guide was used to allocate the safe osteotomy site. The guide was fixed to the underlying bone through the preplanned drilling hole.



Figure4 :showing surgical guide adaptation to the anterior border of the ramus.

The anterior part of guide was removed leaving the proximal plate in place then utilizing the anterior border of plate as a guide for osteotomy .The intraoral vertical osteotomy line was accomplished by using piezoelectric (**Woodpecker DTE Surgery X**) positioned 5 mm anterior to mandibular posterior border and behind the antilingual prominence which was the mandibular foramen landmark in the mandibular ramus outer side In order to prevent damage to the inferior alveolar neurovascular bundle.

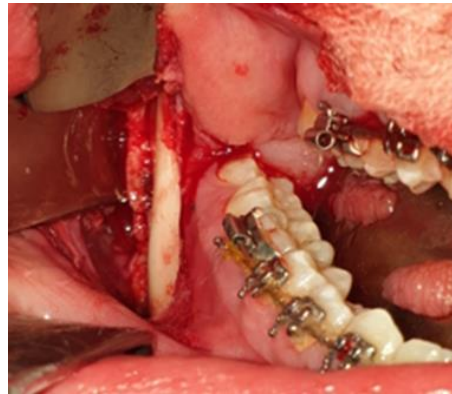


Figure (5): Vertical ramus osteotomy.

The setback was simulated according to pre-planned measure and occlusion stabilized with intermaxillary fixation. Then, customized titanium plates were screwed to ensured anatomical alignment of the mandible.

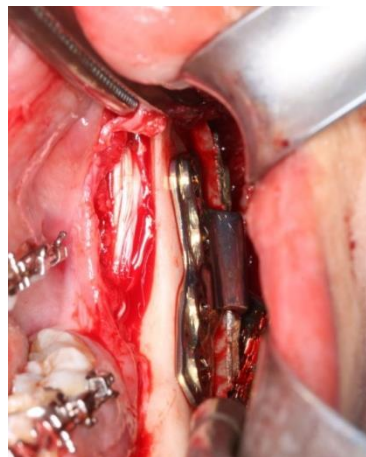


Figure (6): showing customized titanium plate fixation in place after mandibular set back according to the proposed plan

Regarding the maxilla, vestibular incision were made with mucoperiosteal reflection exposing anterior wall of maxilla with the use of piezoelectric to section the maxilla. After completing Le forte I osteotomy and down fracture of maxilla. Maxilla was oriented to final occlusion then ,Osteosynthesis of the maxilla was performed with four L-shaped 2.0 titanium miniplates .then checking of final occlusion was carried out. All incision were closed with 4-0 resorbable continuous sutures.

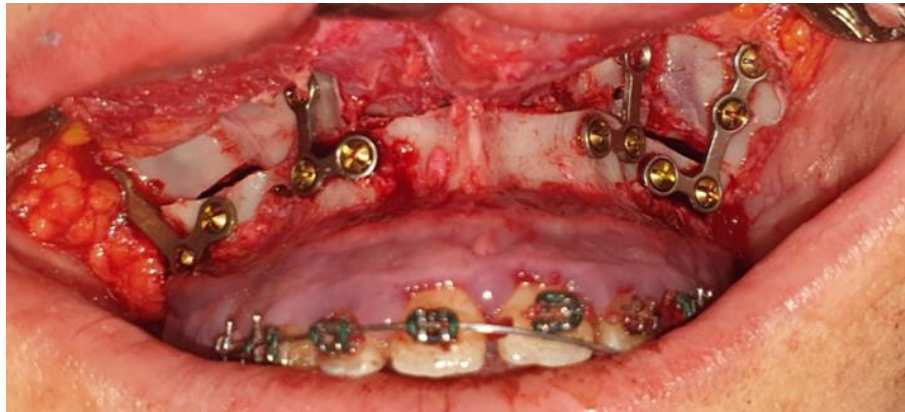


Figure (7): Fixation of maxilla with L- shaped plates 2-0

Control group:

In operating room, intraoral incisions were created on external oblique ridge then mucoperiosteal flap was reflected to expose the lateral mandibular ramus to the posterior border and the sigmoid notch. After that, Surgical guide was used to allocate the safe osteotomy site. The guide was fixed to the underlying bone through the preplanned drilling hole. The intraoral vertical osteotomy line was accomplished by using piezoelectric (Woodpecker DTE Surgery X) positioned 5 mm anterior to mandibular posterior border and behind the antilingual prominence which was the mandibular foramen landmark in the mandibular ramus outer side. In order to prevent damage to the inferior alveolar neurovascular bundle. The setback was simulated according to pre-planned measure and occlusion stabilized with intermaxillary fixation. Then, Regarding the maxilla, vestibular incision were made with mucoperiosteal reflection exposing anterior wall of maxilla with the use of piezoelectric to section the maxilla. After completing Le forte I osteotomy and down fracture of maxilla. Maxilla was oriented to final occlusion and fixed with 4 L shaped plate. then checking of final occlusion was carried out. Intermaxillary fixation was carried to stabilize the mandible with maxilla in final occlusion. All incision were closed with 4-0 resorbable continuous sutures.

Data collection method :

Patient were asked to complete a questionnaire measuring their level of satisfaction degree following surgery using a modified 10 cm visual analogue scale (VAS) with arrange of 0 to +10. Ten questions from "A" through "J" were included in the questionnaire, which were administrated verbally to the patients. It assessed patient's satisfaction regarding dental and facial appearance, their ability to smell, breathe, speech, chew and swallow food, as well as their overall satisfaction, the cost/benefit ratio of the surgery, and whether the benefits of the procedure outweighed the costs. Prior to and following surgery, the patient satisfaction data from the mentioned groups was examined.



Topics:

A) Are you satisfied with your facial aesthetics?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			

B) Are you satisfied with your dental aesthetics?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			

C) Are you satisfied with your perception of the smells?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			

D) Are you satisfied with your breathing?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			

E) Are you satisfied with your bite?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			

F) Are you satisfied with your perception during speech?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			

G) Are you satisfied with your perception when swallowing food?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			

H) Are you satisfied with the cost-benefit of the surgery?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			

I) The benefit of orthognathic surgery supplanted the sacrifice?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			

J) What's your overall satisfaction?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			

Are you satisfied?

1	2	3	4	5	6	7	8	9	10
Very Dissatisfied						Very Satisfied			



Results :

The early postoperative follows-up period for all patients went uneventful with no major complications with proper wound healing without any sign of infection or wound dehiscence. All patients experienced varying degrees of postoperative edema which resolved within 2-3 weeks after surgery. Most of the patients reported mild paraesthesia of the lower lip with varying degrees in one side in that was resolved completely by one year.



Figure 8: profile view of patient no 2 in group preoperatively and 6 months postoperatively.



Figure 9: the occlusion of patient no 2 in group 1 preoperatively and 6 months postoperatively.



Regarding patient satisfaction, all included patients were evaluated and completed their questionnaire. Inter, intragroup comparisons and summary statistics for patient satisfaction score were presented in table (2) and in figures (45) and (46). there was statistically significant increase in the postoperative scores of overall satisfaction (all $P < 0.05$) in both group

A- Intergroup comparisons:

As regards satisfaction at all intervals, there was no significant difference between both groups ($p > 0.05$).

B- Intragroup comparisons:

For both groups, there was a significant difference between values measured at different intervals with value measured after 6 months being significantly higher than values measured pre-operatively and immediate postoperative and with value measured after 2 months being significantly higher than pre-operative value ($p < 0.001$).

Table (1): Inter, intragroup comparisons and summary statistics for patient satisfaction score.

Time	Median (IQR)		p-value
	Study	Control	
Pre-operative	0.00 (0.00) ^C	0.00 (0.00) ^C	1ns
Immediate posteroperative	3.00 (1.75) ^{BC}	2.50 (1.00) ^{BC}	0.117ns
2 months	8.00 (0.75) ^{AB}	7.00 (2.75) ^{AB}	0.149ns
6 months	10.00 (0.00) ^A	10.00 (0.00) ^A	1ns
p-value	<0.001*	<0.001*	

Values with different superscript letters within the same vertical column are significantly different



*; significant ($p \leq 0.05$) ns; non-significant ($p > 0.05$)

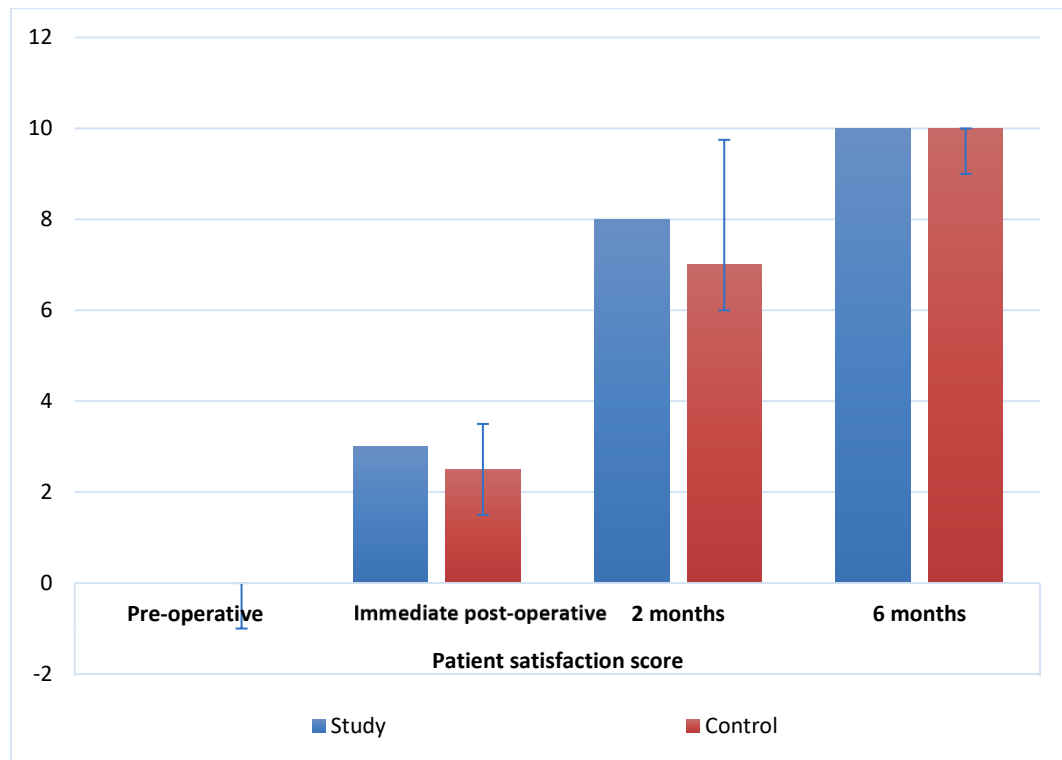


Figure 10: Bar chart showing median and IQR values for different groups.

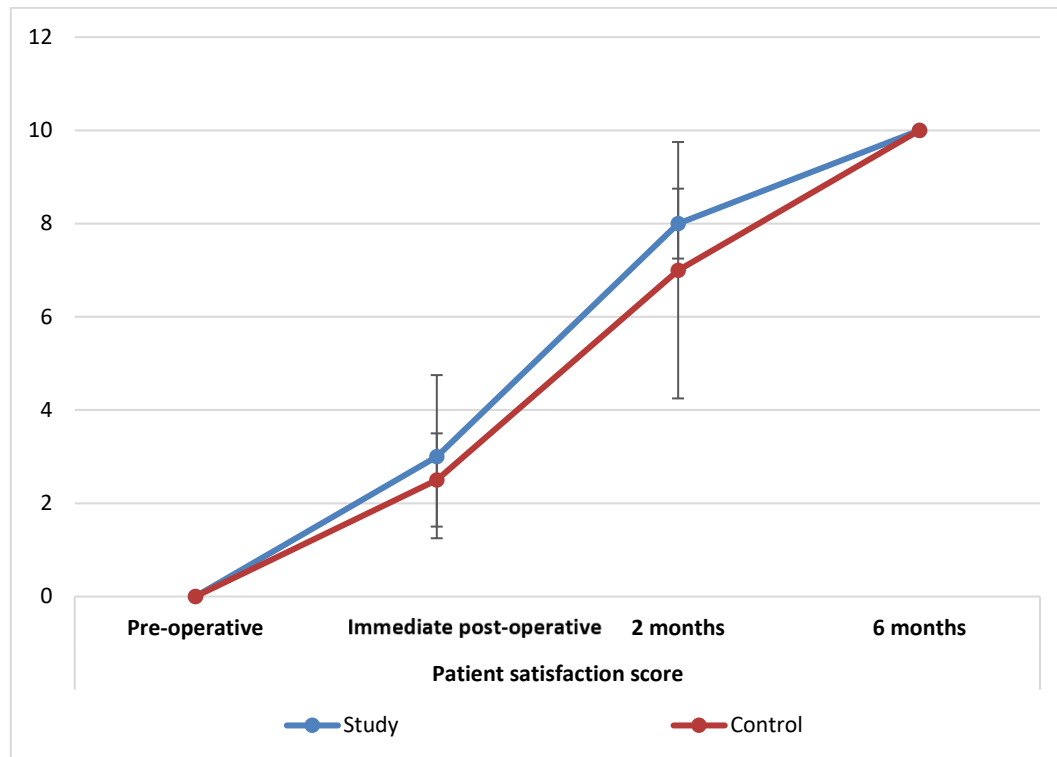


Figure (11): Line chart showing median and IQR values for different intervals.

Discussion:

In the current study we investigated Skeletal Class III mandibular prognathism patients who were generally characterized by overdeveloped mandible and aberrant occlusion with class III molar relationship as well as a reverse overjet in the incisor area. They needed both orthodontic and orthognathic surgical treatment to achieve a satisfying, optimal functional and esthetic relationship of musculoskeletal structures, the dentition, improvement in appearance and high patient satisfaction. Most of the cases required levelling and alignment of the teeth, dental compensation, coordination of dental arches which might been due to severity of malocclusion that prevent obtaining of tripoding needed for stabilized occlusion (13).

In our study, aligning the teeth to ensure decompensation of the teeth axes, coordination the upper and lower arches, creating a situation where the teeth were in proper position relative to their



underlying skeletal bases level, and obtaining tripod for stable occlusion were the main objectives of pre-surgical orthodontic treatment.(14)

In this investigation, the imaging modality used was CBCT. Especially for 3D digital processing software that was chosen for virtual surgical planning (VSP) and reconstruction in spite of computed tomography or cephalogram. On the other hand, medical CT offered 3D data regarding the patients, improved image quality and resolution, and allowed physicians to take precise cephalometric measurements. It had some drawbacks. The medical CT scanner was large, it exposed the patients to increased radiation dose, and required them to be lying down, not in the standard position of cephalometry.(15)

CBCT get over the drawbacks of the earlier methods. the CBCT scanner was more compact than the medical CT scanner. It could be deployed in dental offices and offered 3D information with a reduced radiation dose while the patients were in the standard cephalometric position(15).

A paradigm shift in surgical planning for patients with cranio-maxillofacial abnormalities was brought about by the introduction of computer-aided surgical simulation, which enabled maxillofacial surgeons to overcome the majority of traditional techniques. The current work employed cephalometric analysis to find cephalometric landmark on the skull by constructing cephalometric planes. Next, to precisely depict the patient skeleton, teeth, facial soft tissue, computerized composite skull models were created(16).

On the PC, virtual osteotomies and orthognathic simulations were run. A rapid prototyping machine then processed and produced the surgical splints were utilized to precisely realign the bone segments in accordance with the findings of the investigations carried out (17)(18)

Serial preoperative and postoperative CBCT were obtained for each patient who was recruited. By computing changes at the B-point, menton and pogonion against horizontal axis (SNx) and vertical (SNy) reference lines on the lateral cephalogram, Postoperative dimensional stability alterations were measured. According to a study by (Kung & Leung, 2018), A positive score showed anterior displacement in the horizontal dimension and superior displacement in the vertical dimension.(19)

As the main goal in orthognathic surgery was to achieve more consistent postoperative patient's satisfaction through gained accepted general appearance, good functional occlusion and chewing. It was a primary factor in a study outcome as measured by (Magro-Filho et al., 2015).



Mandibular prognathism had different treatment modalities, vertical ramus osteotomy (VRO) was conducted in our study as the VRO might been selected for mandibular setback under certain conditions, when the mandibular canal located on or buried in the outer cortex of the mandibular ramus with high incidence of IAN injury during the osteotomy or in patients with thin ramus that were prone to bad splits during osteotomy (Cunha et al., 2020). The IVRO revealed some benefits included less surgical time, lower incidence of postoperative neurosensory deficit, lower incidence of temporomandibular disorders.

Despite of the easy access, good visibility and elimination of the need for post-operative Intermaxillary fixation provided by the use of extra oral vertical ramus osteotomy (EVRO), Intra oral vertical ramus osteotomy had been selected in the current study to get the benefit of hidden intra oral scar and avoid extraoral scarring series by (Öhrnell Malekzadeh et al., 2022) which reported by case.

In the present study, Two different modalities of fixation were utilized either complete immobilization of a patient's jaws for 4 weeks postoperatively in control group or used customized fixation in study group.

In the present study the use of customized fixation plate and immediate mobilization avoided prolonged immobilization which could be harmful to health or socially unacceptable and the position of condyle could not be controlled during the immobilization period, posing a risk of sag or displacement of the condyle with condylar luxation. So that the customized fixation system improved stable environment for bone healing and decreased the bend and fix time of the plate during operation when compared with the standard mini-plate and allowed the patients to attain normal jaw function immediately postoperative(20).

During the intraoperative procedure the visualization was so difficult due to limited surgical field to gained access for the surgical site. Especially during fixation of plate on the proximal segment that was enhanced by the use of channel retractors and trans-buccal trocar during drilling. Then the osteotomy cut was made by the aid of piezoelectric that had double angle tips under copious irrigation which was safer with easier application and accessibility, but it took more time in order to complete the cut that might been decreased with the use of reciprocating saw that had right angle and sharp end to get faster osteotomy. Despite of advantage of piezoelectric in osteotomy, the gained osteotomy cut was irregular that might been as a result of limited accessibility that could be overcome by use of reciprocal saw with right angle to obtain clean cut osteotomy(21).(22)

The minimal thickness of plates 1mm were selected to provide proper rigidity, better mechanical behavior and stable environment for bone healing and to avoided sense of palpable plate



that resulted in discomfort to the patient especially the posterior part of plate that was fixed on proximal segment.

During designing, the plates were constructed from two parts joined together by interconnecting part that positioned above the inferior dental canal. The use of two parts allowed easy and single time handling of proximal part of plate during adaptation and drilling of screws through the limited access intraorally and got the advantage of use the anterior part of proximal plate as a guide to completed the osteotomy. After osteotomy and set back of distal segment, the interconnecting part acted as guidance for reposition of distal part plate until fixation to the pre-drilled holes thus ensured accurate fitting of the plates.

After setback of distal segment into the preplanned position, some cases revealed minimal interference between the proximal and distal segment that prevented the proper position of the segments. This problem was managed by removed the interference on the expense of distal segment especially at the area of sigmoid or at the inferior border that might be due to the difference between planning and accurate mobility of proximal segment.

There were two difficulty faced during fixation of plate intraorally, the first one while drilling the screws in the proximal segment especially the most posterior two holes that was overcome by designing the hole with a slight lip superiorly to guide the drill in the correct pass. The other difficulty was the length of two micro screws that was too short about 3-4mm long enough to fall several times during screwing or unscrewing. These was overcome by the use of trocar while holding the screw with good retraction and proper visualization with cautious handling of screws.

All of the patient, early postoperative follows-up period went smoothly and without any major issues. Every patient had varying degrees of postoperative edema which went away after 2-3 weeks postoperatively that might been due to prolonged time of retraction with extended operation time. That was minimally due to the use of piezoelectric technology with the cavitation effect of the ultrasonic vibration.

Concerning the soft tissue healing with the presence of customized plate, all cases in the study showed excellent healing process with no sign of dehiscence or any serious complication as the IVRO appeared to be safer , simple technique especially with the aid of piezoelectric this as in the same study demonstrated by(Peleg et al., 2022)

In the present study, for all dimension the results were much less than clinically acceptable limit 2mm as demonstrated by previous study. As the success criteria proposed by previous authors(Stokbro et al., 2014)(De Riu et al., 2018b) demonstrated that the surgical goal in recruited



patients was a maximum 2mm discrepancy between the virtual planned surgery and the actual surgical outcome. It might be advantageous to slightly overcorrect SNA and SNB (around 2°) during virtual planning.

In order to assess patients satisfaction and potential long term consequences of the treatment, the patients in the current study answered a questionnaire. The study included visual analogue scales to assessed the degree of self-perceived changes in oral function and appearance. The primary motivations for obtaining treatment were to enhance the appearance, functionally of chewing, regarding look and profile, the treatment had led to statistically significant chewing in the study group in the early postoperative period that became significant improvements in overall satisfaction (all $P < 0.05$) in both groups later on.

In summary, the patients expressed satisfaction, and there was an improvement in their quality of life connected to dental health. Despite of the intermaxillary fixation period in control group through which there was difficult feeding while the patients in the study group attained immediate postoperative function but both groups were less satisfied in early postoperative period. These might been due to that the patients in control group were aware and informed about the possible line of treatment, difficulties and limitations. Furthermore difficult feeding in study group might be due to prolonged surgical time and extensive surgical procedure that resulted in variant degree of edema and swelling.

In general the condylar sag occurred because part of masseter muscle and medial pterygoid muscle were stripped during the procedure, losing their ability to contract. Consequently, upon the removal of IMF, the condyles might repositioned posteriorly to the fossa, resulting in an overall clock-wise rotation and posterior migration of the proximal segments. Those were comparable to other studies by (Kawase-Koga et al., 2016)(Yoshioka et al., 2008)(C. M. Chen et al., 2008)

In our study, the relation between magnitude of postoperative relapse with the amount of setback could not be considered a single variant affected the degree of stability which in accordance with (Jung et al., 2013)

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Ethical approval: The Ethics and Research Committee, Faculty of Dentistry, Cairo University approved the study and patient consent was obtained.

Patient consent: Written patient consent was obtained to participate in the study.

Consent to publish: The authors affirm that human research participants provided informed consent for publication of the clinical photographs.

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