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Customized Three-Dimensional Reconstruction of the Mandibular Segmental Defects with Built-in Dental Implants

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Abstract

Background: Reconstruction of the mandible including dental rehabilitation after segmental resection is considered challenging. Free and / or vascularized bone graft procedures are associated with multiple operations and co-morbidities. Patient specific implants have been proposed as an alternative treatment modality.

Purpose: The aim of this work was to evaluate the clinical and radiographic outcomes of customized three-dimensional reconstruction of the mandibular segmental defects using a full titanium prosthesis with built-in dental implants.

Methods: This is a prospective, interventional, longitudinal, single armed study was carried out on eight patients with planned or existing mandibular segmental defects. Six cases underwent segmental resection due to existing pathology and two patients underwent removal of complicated stock reconstruction plates. Accuracy of patient specific implant, manufacturing accuracy and position accuracy correlated to the clinical outcome was done.

Results: Radiographically, manufacturing accuracy of the patient specific implants ranged from (91-98 %) while position accuracy ranged from (41-91%). Temporomandibular joint function in terms of maximum mouth opening, lateral excursion and protrusive movements of the mandible of all cases showed no change all over the study. Postoperative occlusion was kept normal in 75% of the patients for one year follow up. 50% of our patients were strongly satisfied and 50 % were satisfied.

Conclusions: According to our findings position accuracy up to 61% has no effect on achieving postoperative centric relation of the condyles and subsequent stable occlusion. While when position accuracy reached 45% in bounded and 41% in disarticulation PSI ipsilateral, poorly accepted condylar position with subsequent malocclusion.

Keywords: Mandibular Reconstruction, Virtual Planning, Maxillofacial Pathology, Manufacturing Accuracy, Position Accuracy, Patient specific implant.

1. Introduction:

Mandibular defects after segmental resection have both functional and esthetic morbidities, accurate mandibular reconstruction aims to restore the form and function of the mandible, this requires achieving satisfactory cosmetic, functional and anatomical results, with a pain-free mandibular movement and accepted soft tissue relationships to facilitate articulation and swallowing and provide a base for dental rehabilitation [1-4].

Reconstruction of mandibular defects including dental rehabilitation after segmental resection is complex and challenging, different options of mandibular reconstruction include reconstruction plates, free bone graft and / or vascularized bone graft, these procedures are associated with multiple operations and co-morbidities with questionable outcomes [5, 6].

The use of the mandibular reconstruction plates as a primary reconstruction of anterior defects and larger lateral defects is associated with a higher incidence of complications, mainly extrusion. This can be attributed to the narrow profile of the mandibular reconstruction plates and contracture of the enveloping soft tissue leading to pressure necrosis. Other reported complications include fracture of the plate, dislodgement of the fixing screws and bone resorption of the remaining stump due to cyclic fatigue load during mastication. Thus, the need for secondary bone grafts should be planned [7].

The donor site morbid result bone grafting procedure either vascularized or non-vascularized together with long postoperative hospital stay, costly, highly operating rooms and special surgical skills that results in elevated operation cost of these operation and decreased availability increased the need for an easier method for reconstruction of mandibular segment defect [8].

Computer-generated models are the display of anatomic data obtained from medical imaging studies in physical form, stereolithography and the Three-dimensional (3D) printing are the Its principal applications used [9-11]. Mounir et al. [12] compared patient specific implant (PSI) and bone grafting in MSD with dental rehabilitation. They reported comparable outcomes of both procedures and an advantage of preserving donner sites in patients treated with well-designed and precisely fit PSI. Hence, the aim of this work was to evaluate the clinical and radiographic outcomes of outcomes of customized three-dimensional reconstruction of mandibular segmental defects using a full titanium prosthesis with built-in dental implants.

2. Patients and Methods:

2.1 Study design:

A prospective single- arm clinical trial was adopted in this study. The research was approved by the Research Ethics Committee (REC) at Faculty of Dentistry, Tanta University (Approval code: P-OS-3-20-10).

2.2 Study population:

2.2.1 Inclusion criteria

Patients with mandibular segmental defect larger than 6 cm after segmental resection, and\or in need for segmental resection due to benign mandibular lesions were the main inclusion criteria in this clinical research. All defects were unilateral and didn't cross the midline to allow mirror image step in PSI designing.

2.2.2 Exclusion criteria

Patients with uncontrolled systemic disease that may interfere with bone or soft tissue healing were excluded from this study.

2.2.3 Sample Size Calculation

The sample size calculation was calculated using Epi-info software statistical package created by WHO on CDC (center of disease prevention and control) Atlanta, Georgia USA. Version 2002.A sample of of 8 patients would be able to reject the null hypothesis that mean power measurement tool PMT change in the group is with probability of 75 % formula

2.3 pre-surgical evaluation:

The purpose of the present study was explained to the patients and informed consents were obtained according to the guidelines on human research adopted by the Research Ethics Committee of Faculty of Dentistry, Tanta University.

All patients were subjected to history taking, clinical examination [preoperative occlusion, maximum mouth opening, lateral excursion and protrusive movement], laboratory investigations [Complete blood count (CBC), liver and renal function tests, prothrombin time and activity, bleeding and coagulation time and viral profile] and radiological investigations.

2.4 Radiographic examination:

Panoramic X-ray film as a primary radiographic investigation was performed to investigate the lesion extension and teeth within the lesion. Multi axial computed tomography (CT) scan with 0.5 mm slice thickness was obtained to evaluate the extension of the lesion or the defect three dimensionally, and to obtain the digital imaging and communications in medicine dataset (DICOM) files used for software reconstruction, virtual planning and designing of a patient specific reconstruction prosthesis axial, coronal, sagittal and 3d reconstruction was ordered for every patient. **Figure 1**

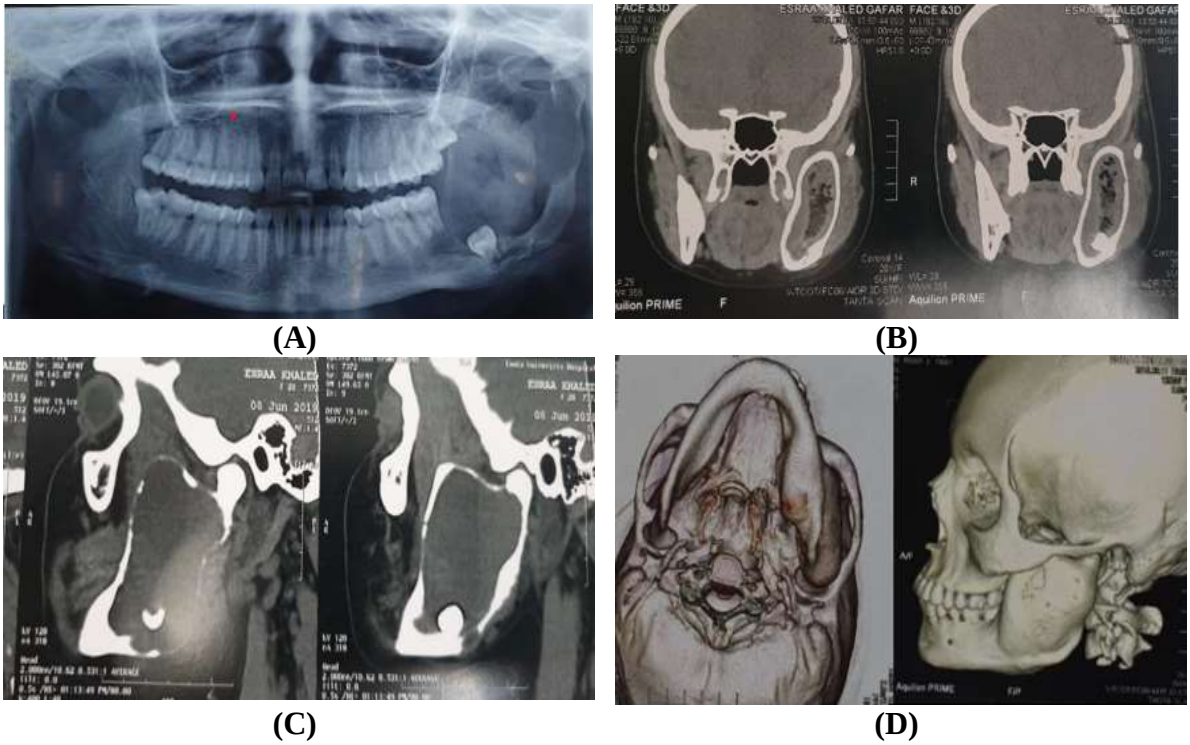

Figure 1: (A) Preoperative (A)panoramic photoradigraph showing well defined multilocular radiolucent lesion with impacted tooth inside the lesion and root resorption of lower left 2nd molar case 2, (B) Coronal CT scan showing disfigurement caused by the lesion expansion and position of impacted lower 3rd molar tooth case 2, (C) sagittal CT scan showing cranio-caudal extension of the lesion case 2, (D) A-3d reconstruction of CT Scan case 2 showing biocritical expansion of the left mandibular lesion and asymmetry of the mandible

2.5 Virtual planning and surgical setup:

Surgical planning, simulated osteotomies and designing of the PSI was processed using Mimics 10.01 (Materialise, Leuven, Belgium) and Dolphin Imaging 11.7 Premium software (Dolphin Imaging and Management Solutions, Chatsworth, CA). The virtual prosthetic design was planned on the computer model. PSI was designed following shape and form obtained from mirror image of the contralateral healthy side to achieve optimum facial symmetry and support

of soft tissue drop. PSI extended on the buccal side over the healthy side beyond the boundary of the segmental defect to accommodate for at least three fixation screws. It also extended below the inferior border of the healthy bone to accommodate at least two screws which were inserted perpendicular to the inferior border and help in primary stability of the PSI.
The PSI was produced by CAD CAM subtraction using a 5- axis milling machine. The PSI was made from titanium grade V alloy (Ti6Al4V). To transfer the virtual plan to the patient osteotomy site surgical guides were fabricated. Bone and tooth supported guides were designed to ensure 3D stability of the guide.

2.6 Surgical technique:

Arch bar was applied to the teeth on the contralateral side to preserve and maintain the centric relation of the mandibular condyle and preserve centric occlusion during PSI fixation. Exposure of the mandibular defect was done via intra and/or extra oral approach according to the accessibility and the defect site and size. The intended resection done through surgical cutting guides fabricated. After complete resection, Intermaxillary fixation (IMF) was done to preserve the centric relation of the condyle and centric occlusion of the contralateral side. PSI was applied and fixed using at least five 2.7 mm reconstruction bi-cortical screws. These screws were distributed at the buccal and inferior borders. Length and position of fixation screws was premeasured according to the virtual plan of each case. Following PSI fixation tie wires were removed. Passive centric occlusion, position of the condyles and mandibular movement were checked. Abutments for dental prothesis were screwed in place to check for proper alignment for the next stage i.e. dental rehabilitation. Abutments were then removed, and cover screws were inserted. Anatomical wound closure was done. Following PSI installation, all patients were observed on a weekly basis for the first month and then monthly for the subsequent five months. Six months later, the second stage surgery was done under general anesthesia with Naso endotracheal intubation. The site of the built-in abutment threads was exposed, the cover screws were removed, and the abutments were screwed in their position under 35 N / cm torque. Anatomical wound closure was done.

2.7 post-surgical evaluation:

2.7.1 Clinical evaluation:

After abutment installation regular follow-up was done weekly for 3 weeks and after insertion of the dental prothesis follow-up was done once monthly for 6 months after dental rehabilitation.

Occlusion: maximum intercuspation in centric relation was evaluated by three independent observers six months post PSI installation and six months post dental rehabilitation.

Maximum mouth opening: Interincisal distance was recorded preoperatively six months post PSI installation and 6 months post dental rehabilitation.

Lateral excursion: It was recorded preoperatively six months post PSI installation and six months post dental rehabilitation.

Protrusive movement: It was recorded preoperatively six months post PSI installation and six months post dental rehabilitation.

2.7.2 Radiographic evaluation:

Accuracy of the customized prosthesis

This was evaluated by obtaining post-operative multi-axial CT scan (0.5 mm slice thickness, 0.3–0.45 mm pixel size) in patient with the teeth in normal occlusion.

Manufacturing accuracy:

Using Mimics 10.01 (Materialise, Leuven, Belgium) the volume of the preoperative planned PSI on software project was measured. The volume of the PSI obtained from the postoperative CT was measured to detect manufacturing discrepancy. Fixation screws of the same length and diameter were scanned and calculated for each case. The net volume of the PSI was calculated

by subtraction the screw volume from the PSI volume gained from PSI volume obtained from postoperative CT scan. The net volume was necessary to evaluate the accuracy of the manufacturing procedure. It was calculated as the percentage of the result of dividing the net volume by the volume of the virtually planned PSI. **Figure 4**

Position accuracy:

The skull model super imposition of the virtually planned PSI in position over the skull model obtained from the patient post operative CT scan. The volume of intersection between PSI planning project and post operative CT of each patient before dental rehabilitation was measured to evaluate accuracy of the position of the PSI. **Figure 4**

2.8 Statistical analysis

Statistical analysis was done by SPSS v26 (IBM Inc., Chicago, IL, USA). Quantitative variables were presented as mean and standard deviation (SD) and compared between the two groups utilizing unpaired Student's t-test. Qualitative variables were presented as frequency and percentage (%) and analyzed using the Chi-square or Fisher's exact test when appropriate. A two-tailed P value < 0.05 was considered statistically significant.

3. Results

3.1 Patient demographic data:

This clinical study was carried out on 8 patients, among these 4 (50%) males and 4 (50%) females. The patient's age ranged from 15 to 42 years, with a mean of 24.25 ± 10.28 years. The causes of intervention were benign tumor in 6 (75%) patients no 1,2,4,5,6 &8, one patient (12.5%) case 3 presented with fractured reconstruction plate in and one patient (12.5%) case 7 presented with mal contoured and extra orally exposed reconstruction plate. **Table 1**

3.2 Occlusion

Six months post PSI installation five out of eight patients (62.5%) reported no significant difference in occlusion between preoperative and postoperative record case no 1,2,3,7 & 8. One patient case number 5 (12.5%) reported significant improvement of occlusion postoperatively. Two patients (25%) case no 4&6 showed post operative deterioration of occlusion but still accepted without midline shift. **Figure 2**

A **B**

Figure 2: Postoperative photograph showing A) improved occlusion in case no 5 post PSI installation and B) deranged occlusion in case no 4 after PSI installation

Six months post dental rehabilitation no significant difference observed regarding occlusion compared to post PSI installation records. There was insignificant difference in patient occlusion between pre and post dental rehabilitation. This stability in occlusion reflected the rigidity and stability of the fixation of the PSI and its ability to survive under occlusal cyclic load. **Figure 3**

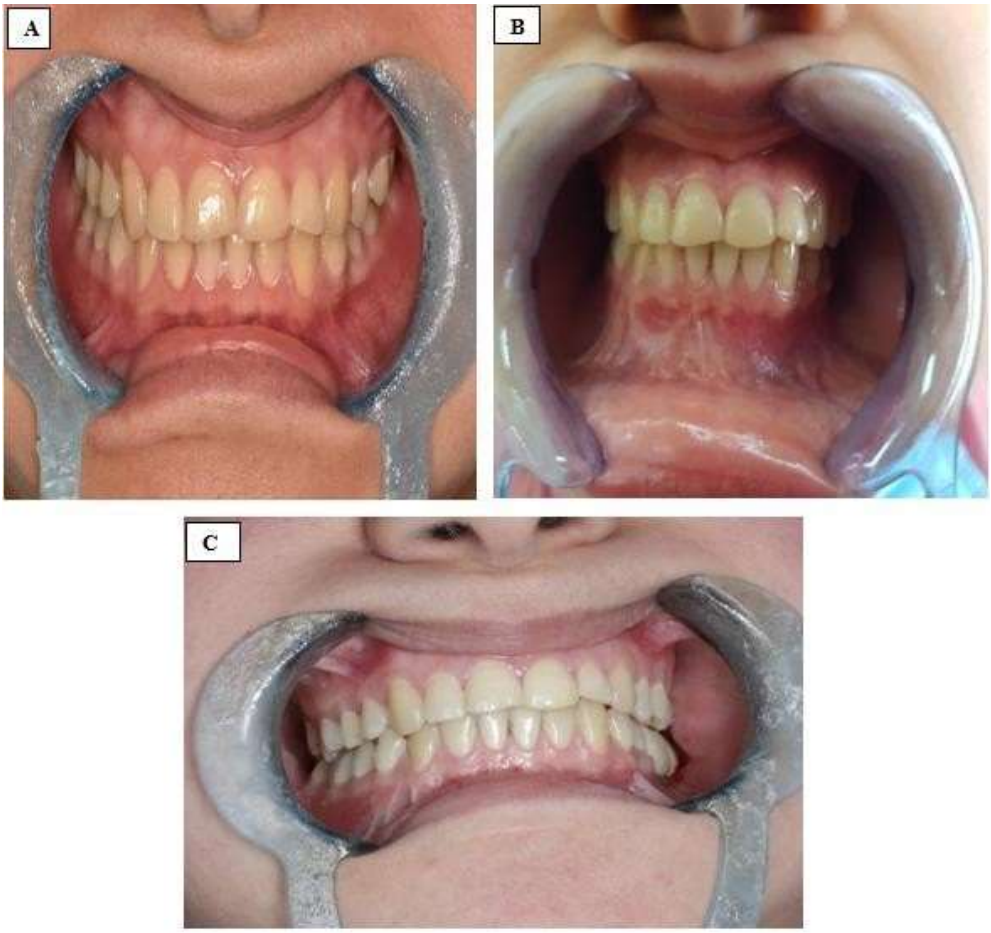

Figure 3: Photograph showing occlusion (A) preoperative (B) post PSI installation (C) post dental rehabilitation of lower left first and second molars

3.3 TMJ Function

There was insignificant difference between the maximum mouth opening, protrusive movement and lateral excursion of the mandible toward contralateral and toward the ipsilateral sides preoperatively, six months post PSI installation and six months post Dental rehabilitation. **Table 2**

3.4 Manufacturing and Position accuracy

The manufacturing accuracy of all cases was ranging from 91% to 98% with a mean value (± SD) of 95% (± 3%). This reflects good manufacturing procedure.Position accuracy of PSI ranged from 41% to 91% with a mean value (± SD) of 71% (± 20 %). **Table 3 & 4**

Table 1: Demographic data and type of defect of the studied patients

		N=8
Age (years)		24.25±10.28
Sex	**Male**	4(50%)
	Female	4(50%)
Type of defect	**HC**	4(50%)
	H	2(25%)
	L	1(12.5%)
	LC	1(12.5%)

Data are presented as mean± SD or frequency (%) or range.

Table 2: Maximum mouth opening, protrusive movement and lateral excursion of the mandible throughout the study

	Preoperative	6 m post PSI inst.	6 m post dental rehab.	P value
Maximum mouth opening (mm)	33.25 ± 3.24	32.25 ± 3.41	32.25 ± 3.41	
Protrusive movement (mm)	10.12 ± 2.57	11.5 ± 0.86	11.5 ± 0.86	0.219
Lateral excursion (mm)				
Towards healthy side	11 ± 2.73	11.3 ± 2.38	11.3 ± 2.38	0.973
Towards affected side	11.1 ± 2.3	11.4 ± 1.85	11.4 ± 1.85	0.960
P value for the same group	0.922	0.908	0.908	
Protrusive movement (mm)	10.12±2.57	11.5±0.86	11.5±0.86	0.219

Data are presented as mean± SD.

Table 3: Shows VP volume, CT (postoperative CT scan) volume, FS volume net volume and milling accuracy for each case in mm3

Case no	VP volume	CT volume	FS volume	Net volume	VP - Net volume	Manufacturing accuracy
1	17071.38	16721.65	712	16009.65	1061.73	94%
2	11979.99	11707.26	625	11082.26	897.73	93%
3	12017.35	11700.62	756	10944.62	1072.73	91%
4	13878.63	14652.42	1312.5	13339.92	538.71	96%
5	19619.78	20012.53	903	19109.53	510.25	97%
6	15983.35	16788.11	1103	15685.11	298.24	98%
7	24018.2	24701.47	1046	23655.47	362.73	98%
8	10381.64	10383.61	916	9467.61	914.03	91%

VP: virtual planning, FS: fixation screws. CT: computed tomography.

Table 4: Shows the position accuracy for each case

Case no	VP volume	CT volume	FS volume	Net volume	intersection volume	Position accuracy
1	17071.38	16721.65	712	16009.65	13262.39	83%
2	11979.99	11707.26	625	11082.26	8010.28	72%
3	12017.35	11700.62	756	10944.62	9451.68	86%
4	13878.63	14652.42	1312.5	13339.92	6002.96	45%
5	19619.78	20012.53	903	19109.53	16841.03	88%
6	15983.35	16788.11	1103	15685.11	6382.15	41%
7	24018.2	24701.47	1046	23655.47	21556.32	91%
8	10381.64	10383.61	916	9467.61	5810.39	61%

VP: virtual planning, FS: fixation screws. CT: computed tomography.

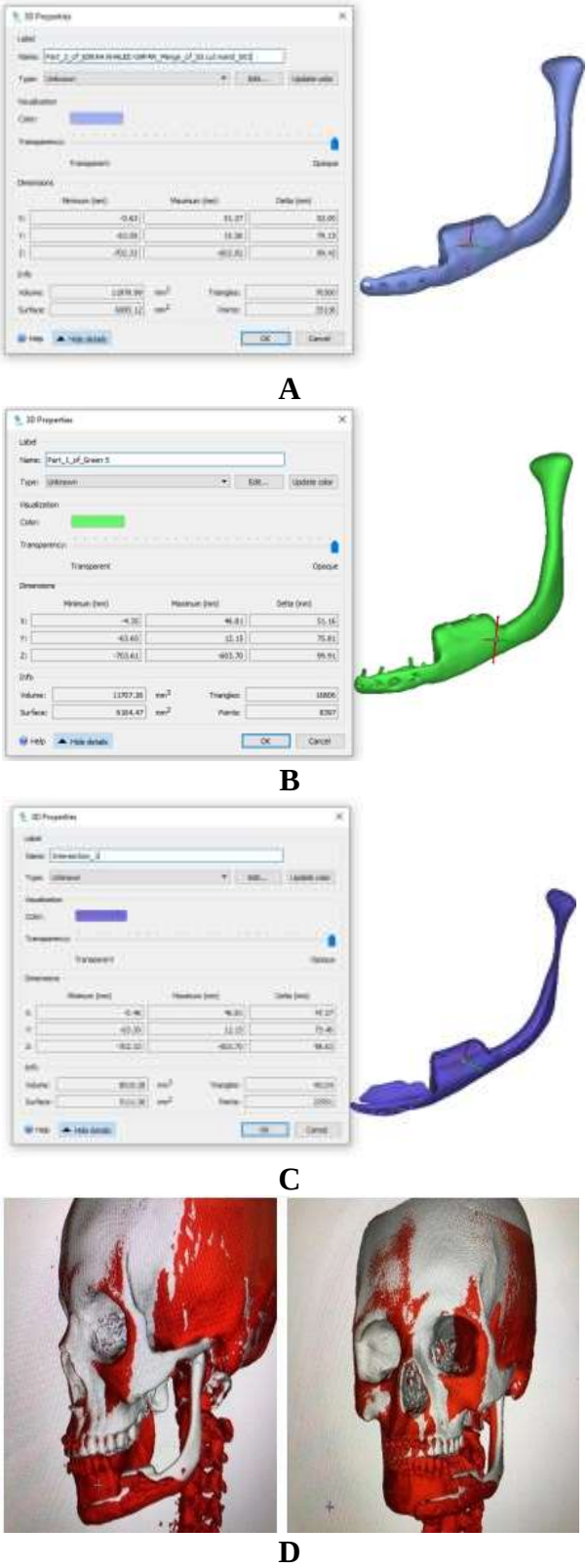

Figure 4: Photograph shows A) VP (vitually planned), B) CT (obtained from patient postoperative CT scan) volume of the PSI, C) intersection volume between the virtual and actual position of the PSI with position, E) superimposition of the planned PSI in gray color and Postoperative CT scan of the patient in red color which showed no significant difference

4. Discussion

Reconstruction procedures remain challenging for dental surgeons because it is difficult to maintain structure stability of the graft-site, to shape the bone for optimal configuration and symmetry of the mandible, and to restore facial contours and masticatory function. This agreed with Cheng et al. [13] concluded that a well- designed PSI would be an efficient method for mandibular segmental resections. An immediate, simultaneous and accepted function and esthetic outcomes were gained.

Maximum mouth opening, protrusive and lateral mandibular movement in this study didn`t show any significant change all over the study period. This reflects the ability of our design to mimic the behavior of patients' natural condyle in static position and under function. This also showed the adaptability of muscles of mastication to the PSI. The study results are confirmed by U V et al. [14] who reported that after reconstruction of complex mandibular defects using patient specific three-dimensional (3D) titanium implant, the occlusion was restored with adequate mouth opening, closing, and lateral movements of the mandible with no deviation of jaw during movements. They concluded that the patient specific implants appear to be very useful for precise reconstruction of mandible with greater accuracy. However, long-term follow- up is needed. This agreed with many studies such as Mounir et al. **[12]** Vingesh et al. [14] and Qassemyar et al. [15] who reported that PSI when fabricated meticulously, in most cases they provide stable function of the mandible. This was evident by stable post operative occlusion gained in most of the cases.

Supporting our findings, Xia et al. [16] examined the surgical efficiency and post-operative outcomes of patient-specific titanium mandibular reconstruction using additive manufacturing (AM). Furthermore, pre-operative preparations, surgical procedures and post-operative treatment outcomes were compared among patients who received mandibular reconstruction using a customized 3D titanium implant, titanium reconstruction plates or vascularized autologous fibular grafting. Use of a customized titanium implant significantly improved surgical efficiency and precision. When compared with mandibular reconstruction plates using the two conventional approaches, patients who received the customized implant were significantly more satisfied with their facial appearance and exhibited minimal post-operative complications in the 12-month follow-up period.

The manufacture process accuracy in this study ranged from 98 % to 91 % with mean value 95 % according to our finding this was excellent manufacture process. This was agreed with Kohn. [17] who reported that accuracy of CAD-CAM manufactured prothesis would be of high performance if the manufacturing accuracy achieved up to 90 %. However, from our point view the way we used to measure PSI milling accuracy through subtraction between patient preoperative virtual plan and postoperative CT scan needs to be refined. As it was depending on the CT scan accuracy. Also, it was very difficult to exclude the fixation screws from the PSI volume gained from the postoperative CT scan.

The PSI position accuracy in this study ranged from 83% to 41 % with a mean value 71 %. From our point of view, this due to the position of the PSI was not being fully guided. From our point of view, position screw drilling guide should be used to guide the PSI to its accurate position. To our knowledge, PSI position accuracy in mandibular segmental defects measurement on CT scan basis was not studied in literature in the same way. In our findings, position accuracy up to 71% in cases of disarticulation and 61% in bounded cases was able to keep facial symmetry and keep the patient occlusion and function. In bonded cases when position accuracy reached 45% obvious mal occlusion was recorded and midline shift was observed. In disarticulation cases when position accuracy reached 41% obvious mal occlusion reported and but without midline shift. From our point of view, this is due to the ability of the artificial condyle to change its position according to muscle pull. To our knowledge this finding was not studied in literature.

In the present study, four patients were (50%) strongly satisfied patients and 4 patients (50%) satisfied patients. This agreed with Carretero et al. [18] reported that all patients reported a good esthetic result and functional results, speech articulation was evaluated as intelligible language in all patients.

Limitations of this study including that small sample size may necessitate further research with a larger sample size. It was single center study. Short period of follow up for this technique. So, we recommended that more research should be performed to study the relation between size of the remaining bone stump and long-term stability of the PSI. More research should be done to explore the ideal design and length of the retentive part of the PSI. The relation between PSI- bone contact area and long-term stability of the whole procedure should be investigated. Methods of assisting manufacturing accuracy should on physical bases should be investigated. In addition, reactions of soft tissues surrounding the titanium mandible need further histological studies and investigations.

5. Conclusions:

Results from this study suggest that position accuracy up to 61% has no effect on achieving postoperative centric relation of the condyles and subsequent stable occlusion. While when position accuracy reached 45% in bounded and 41% in disarticulation PSI ipsilateral, poorly accepted condylar position with subsequent malocclusion.

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Conflict of interests: None to be declared.

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