Primary reconstruction of resected proximal mandibular segments: a novel protocol using patient-specific poly ether-ether ketone (peek) condylar replicas

Original Article

Hesham El-Hawary[1], Mohamed Mounir[1], Samy Mounir[2] and Amr Gibaly[3]

Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, [1]Cairo University, Cairo, [2]MSA University, Sixth of October, [3]Beni-Suef University, Beni-Suef, Egypt

ABSTRACT

Purpose: This study aims to evaluate the efficiency of computer-aided design and computer-aided manufacturing (CAD/CAM), mirror-imaged Polyetheretherketone (PEEK) assembly that aimed to duplicate both of the exact anatomic position and the configuration of the resected mandibular condyle, post segmental proximal tumor resection.

Methods: Five patients were included in the study; diagnosed for mandibular ramus locally aggressive tumors, involving or markedly jeopardizing the mandibular condyles. All of the patients were subjected to a fully guided reconstructive protocol that implements guided resection, guided alignment of a pre-bent reconstruction plate, secured to a (CAD/CAM) fabricated, mirror-imaged (PEEK), looking forward to duplicating both of the anatomic location and the configuration of the amputated mandibular ramus and condyle.

Results: Clinical evaluation revealed acceptable recovery of the maximal mouth opening and limited postoperative malocclusion and mandibular deviation. The computed radiographic superimposition between the virtual plane and the one-week postoperative C.T. revealed decreased linear condyle displacement in both the mediolateral and anteroposterior directions versus an increased linear vertical displacement and decreased axial angular rotation versus increased sagittal angular rotation. The replication between the virtually planned condylar location and that surgically duplicated was judged as good to excellent among all the cases.

Conclusion: The novel simulation and allocation of the customized (PEEK) assembly represents a simple and efficient modality to reconstruct both of the lost condylar position and configuration. However, the anterior extension of the resected proximal mandibular segment deemed determinant to the success of the identical surgical execution of the virtual preplanned arrangement.

Key Words: CAD/CAM, Computer guided surgery, Patient specific cutting guides, PEEK, TMJ reconstruction.

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Corresponding Author: Hesham El-Hawary, Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University, Cairo, Egypt, **Tel.:** +201144446373, **E-mail:** elhawary.omfs@gmail.com.

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INTRODUCTION

Mandibular resection is, unfortunately, regularly carried out in the context of treatment of its aggressive tumors. The associated loss of mandibular continuity and condylar utilities contributes to the consequent disabled mandibular functions and defective occlusion, along with the impaired facial esthetics and the loss of the normal anatomic configurations[1].

The unique topographic configurations and functional features of the temporomandibular joint (TMJ) render its reconstruction one of the most sophisticated procedures among maxillofacial rehabilitation. Although costochondral grafts are widely harvested; graft fracture, successive ankylosis, an unreliable condylar behavior with a consequent unpredicted mandibular growth pattern, in addition to the morbidity of the donor site, represent common potential complications[2].

Risdon[3] in 1934 described the interposition of gold foils to underline the glenoid fossa, aiming to avoid the recurring ankylosis post condylectomy. Since then, the evolution of alloplastic reconstruction of the (TMJ) has begun. Several metals, polymers, and even TMJ full prosthetic systems were utilized, aiming to reproduce a nearby anatomic configuration that would restore the deficient facial vertical dimension and the disoriented occlusal relation, together with undisturbing a donor site and diminished subsequent ankylosis. However; almost all of them represented a mechanic solve, rather than a biological one; lacked either biocompatibility or geometric symmetry to the amputated condyles, regarding both shape and location in relevance to the glenoid fossae and the articular eminences[4, 5].

Polyetheretherketone (PEEK); the synthetic, bio-inert polymeric material, that has been recognized as an

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attractive orthopedic biomaterial, was first introduced in-vivo, as spinal replacement implants in 2006 by Toth *et al.*[6] The current wide acceptance of the PEEK implants attributes to the favorable mechanical properties. The low modulus of elasticity that corresponds to that of the human bones, as well as stress shielding and stress distribution properties, had yielded admirable merge of firmness, rigidity, endurance, substantial persistence in addition to high resistance to degradation and fragmentation. Nevertheless, the applications of (PEEK) are still limited in the field of oral and maxillofacial surgery[7 - 9].

The inception of computer-assisted surgical simulation had enabled a convenience that yielded transferring a virtual plan into a surgical field feasible, through a pre-planned digital formulation and prefabricated surgical appliances[10]. This study aims to assess the accuracy of an innovated, prefabricated virtual arrangement to duplicate the exact resected mandibular ramus and condyle, regarding both anatomic configuration; utilizing mirror imaging and (CAD/CAM) (PEEK) transcripts, and anatomic location; via guided bone resection and guided fixation of reconstruction plates that would maintain the relation between the duplicated ramus and the patent mandibular segment.

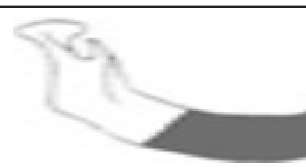
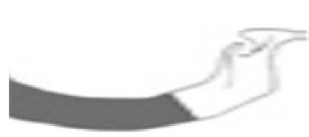
PATIENTS AND METHODS

Criteria of patient selection

Five patients; three females and two males, ranged in age from 24 to 39 years old were incorporated into this study, all expressed either mandibular swelling or paresthesia. The multilocular radiographic appearance, as well as the incisional biopsies, confirmed the initial diagnosis of locally aggressive tumors of the mandibular ramus; involving or markedly jeopardizing the mandibular condyle, disclosing three ameloblastic lesions, a central giant cell tumor, and an odontogenic myxoma. All the Patients were healthy and free from systemic diseases (Table 1).

The authors designated a guided protocol that implements guided resection, guided alignment of a pre-bent reconstruction plate, secured to a digitally manufactured, mirror-imaged (PEEK), duplicating both anatomic location and configuration of the amputated mandibular ramus and condyle.

Table 1: The descriptive clinical data of the five patients

Pt	Sex	Age	Pathology of the Lesion	Affected Area	Size of the Defect
1	Female	31	Cystic Ameloblastoma type III		7 cm
2	Male	39	Central giant cell tumor		4 cm
3	Male	24	Follicular Ameloblastoma		4.5 cm
4	Female	27	Follicular Ameloblastoma		9 cm
5	Female	29	Odontogenic myxoma		7.5 cm

Preoperative virtual planning

A preoperative CT scan of the mandible; in closed-mouth position, of each patient was introduced as DICOM (Digital Imaging and Communications in Medicine) files and illustrated on DICOM viewer software (Mimics 19.0; Mimics Medical 19.0, Materialise, Leuven, Belgium) to figure out 3-Dimensional reconstructed images of the affected mandibles (Figure 1), through which, trimming borderlines were sketched to define the intended plane of resection, considering a safety margin of at least 1.5 cm. Segmentation of the virtual construct was executed to isolate the tumor enclosing mandibular portion, followed by demarcating the virtual plan of resection.

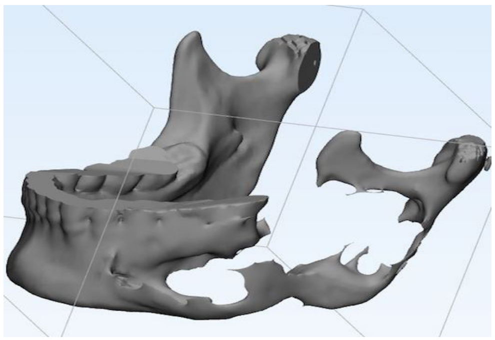


Figure 1: 3D reconstructed view of an affected mandible.

The corresponding tumor-free ramus and condyle constructed a mirror-image that was reversed to reflect the affected ramus. The mirror-image was imported to print out the simulated build of the plastic stereolithographic model; along which, an intimate adaptation of the bent reconstructive plate was accomplished (Figure 2).

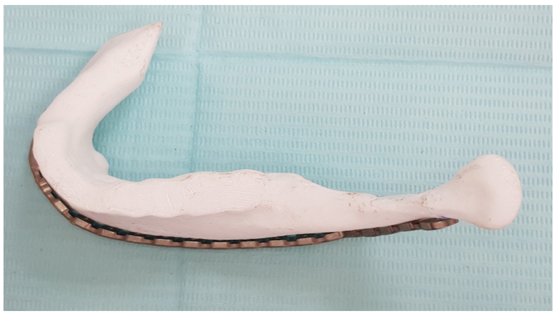


Figure 2: The bent reconstruction plate adapted to the printed plastic stereolithographic model.

Virtual formulation of a patient-specific cutting guide that combines the virtual allocation and fixation of the reconstruction plates to the undisturbed mandibular segment was designated by (Mimics 19.0; Mimics Medical 19.0, Materialise, Leuven, Belgium) and 3-D printed to guide the execution of the intended osteotomy and replicates the mirrored interrelation between the assumed reconstructive assembly and the patent mandibular segment (Figure 3 and 4). On the other hand, milling of the (PEEK) blocks was machinated with a five-axis milling mechanism, to imitate the virtually designed ramus and condyle. Finally, the plastic cutting guides, the stereolithographic model and the (PEEK) duplicates were chemically sterilized in a (2 %) glutaraldehyde solution (Cidex, Johnson and Johnson Co. NJ, USA), prior to surgery.

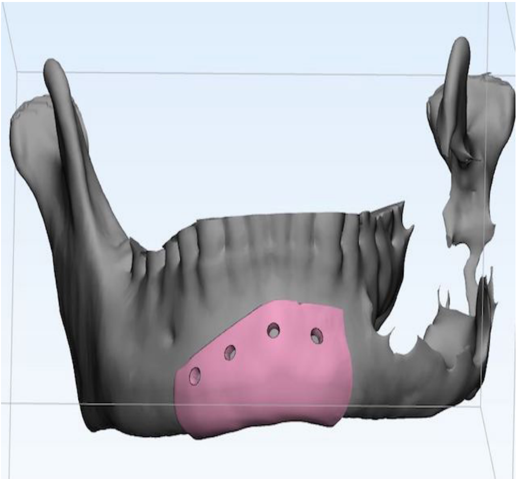


Figure 3: 3D view showing the virtual formulation of a patient-specific cutting guide.

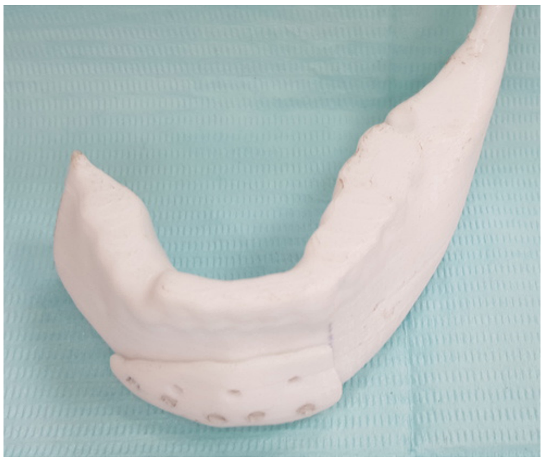


Figure 4: The printed cutting guide adapted to the stereolithographic model.

Surgical procedure

After a routine scrubbing and draping of the surgical site, a vasoconstrictor contained local anesthesia was infiltrated subcutaneously, the submandibular incision was labeled 2 cm beneath the mandible and fairly extended anterior to the planned bound of the bone osteotomy, blunt dissection progressed to widely expose the platysma muscle, which was violated inferior to the course of the marginal mandibular nerve. Dissection toward the inferior border of the mandible identified the submandibular salivary gland and the facial vessels, the gland capsule was detached and shielded and the vessels were ligated and severed, followed by sculpturing and elevating the mandibular periosteum.

Infracrestal gingival incisions were scored through the lateral and medial aspects of the mandible, along the planned field of resection, and extended anteriorly to accommodate for an unrestricted application of the cutting guides. Both of the extraoral and intraoral incisions were connected along the buccal and lingual aspects of the mandible, widely exposing the expanse of resection.

The 3-D printed cutting guide was set into the exact virtually planned position, guided by the intimate fit of it's fitting surface to the underlying bone and curving around the inferior border of the mandible, and fixed in place by bi-cortical drilling and screw advent through three predetermined violated sleeves, that represent the guided entry of the bicortical screws that would later secure the reconstruction plate; attached to the PEEK assembly, to the undisturbed mandibular segment, hoping to allocate the duplicated ramus and condyle in the exact preplanned virtual anatomic position in relation to the glenoid fossa and the articular eminence (Figure 5).

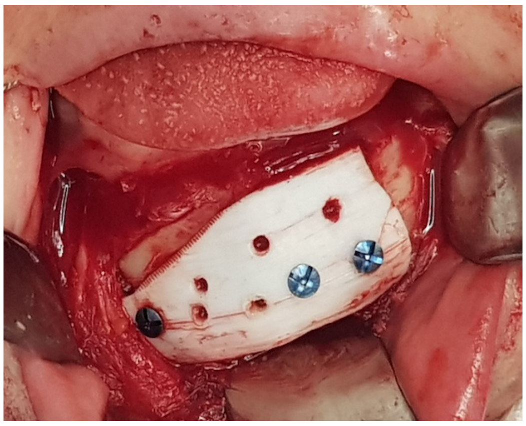


Figure 5: The CAD/CAM machinated (PEEK) block, secured to the reconstruction plate.

Guided by the anterior extension of the cutting guide, the preplanned osteotomy was carried out into the exact tract of bone cleavage; utilizing oscillating saws under profuse saline irrigation, followed by disarticulation and retrieval of the amputated segment. Following, an inter-maxillary fixation was secured, relating the residual mandible to the substantial maxillary occlusal plane.

The Peek assembly was then secured to the overlying, adapted posterior extension of the reconstruction plate, after drilling and screw-driving the selected screws into the exact preplanned advents. The integrated arrangement was then secured to the undisturbed mandibular segment by interrelating and bi-cortical interlocking the anterior holes of the reconstruction plate to the previously drilled holes "those guided by the sleeves of the cutting guide". (Figure 6, 7 and 8).

Figure 6: Intraoperative application of the cutting guide, fixed with the guided entry bi-cortical screws.

Figure 7: The reconstruction plate secured to the mandible through the guided entry bi-cortical screws.

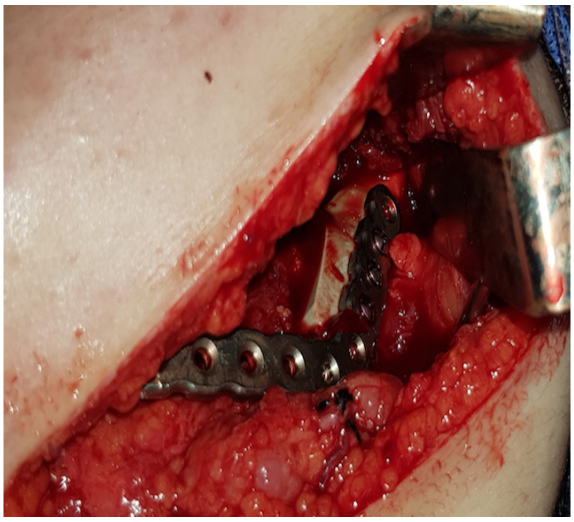


Figure 8: The reconstruction plate secured to the proximal PEEK assembly.

After the intraoperative justification of the location of the implanted condyle, the inter-maxillary fixation was released, the mouth opening and occlusion were assessed, homeostasis was assured, and the wound was properly cleaned and irrigated, drained and sutured in layers.

Postoperative care

Post recovery; inter-maxillary elastics were applied for all the patients, who were hospitalized for 48 hours, all of them received IM antibiotics (Ampicillin/Sulbactam 750 mg q8h) and NSAIDs (Diclofenac Sodium 75 mg IM q12h) for seven days; by the end of which, the sutures and the inter-maxillary fixation and elastics were removed and the patients were inspired to restore the normal jaw capacity and started a regimen of passive and active opening mouth exercises.

The patients were followed up regularly for two months postoperatively, through which the soft tissue healing, temporomandibular joint functions and the range of mandibular movements were assessed. The maximum mouth opening and the midline shift of the mandibular teeth were recorded one month postoperatively for all of the patients.

Digital interpretation

All the patients were subjected to C.T. scans; utilizing the same preoperative protocol, one-week post-surgery and importing the DICOM files into the same software, which was illustrated to evaluate the surgical construct and to figure out its vicinity to the virtual plan, through a computed superimpose of both of the pre-operative and the post-surgical C.T. scan views. The degree of discrepancy between the digitally formulated position of the condyle and that surgically executed was calibrated on the 2D images in the mediolateral, anteroposterior and vertical orientations.

The axial projections were illustrated to select the view with the greatest condylar mediolateral extension. An imaginary line representing the mid-sagittal plane was marked, and the horizontal distances were measured from this line to the medial pole of both of the resected condyle and the reconstructed condylar assembly, followed by calculating the linear differences. Demarcating the axial long axis was designated by labeling an imaginary line to cross the lateral and medial condylar poles. The angle between this line and the mid-sagittal line was measured and the angular differences were identified through both condyles (Figure 9).

A sagittal cut that delineates the head and neck of the condylar head and neck, as well as the slopes of the fixed glenoid fossa and the articular eminence, was chosen. The sagittal condylar long axes was demarcated by labeling the top of the condyle and extending a line that transects downward the neck of the condyle, followed by measuring the angles created between the virtual axis and the reconstructed one. Furthermore, the same view was employed to verify the vertical positional differences, by labeling and attaching both of the Frankfurt horizontal plane and marking lines that extended from the apices of the virtual and the reconstructed condyles, followed by comparing the length of both lines and reporting the linear differences (Figure 10).

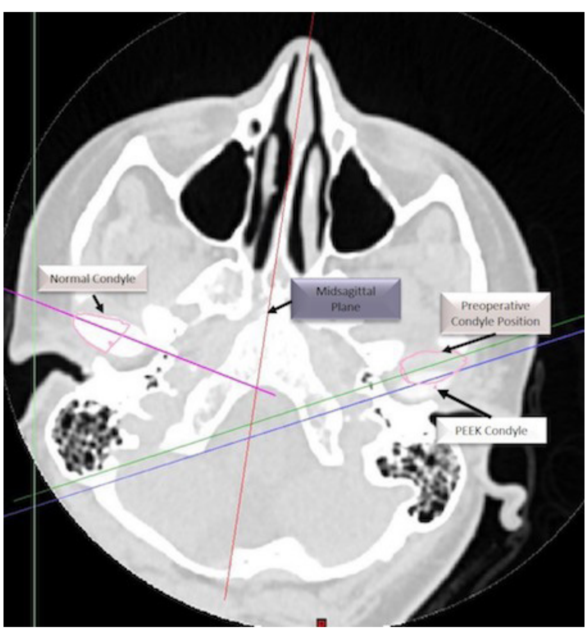


Figure 9: Axial C.T. view superimposing the resected and the reconstructed greatest mediolateral condylar dimension of the right mandibular condyle; showing the mid-sagittal line (in red), the preoperative condylar position (in pink), and the postoperative condyle position (in greyscale). Distances and angles (in relation to the mid-sagittal plan) were recorded as two parallel lines (green and blue) from the medial poles of the condyles to and perpendicular on the midsagittal line.

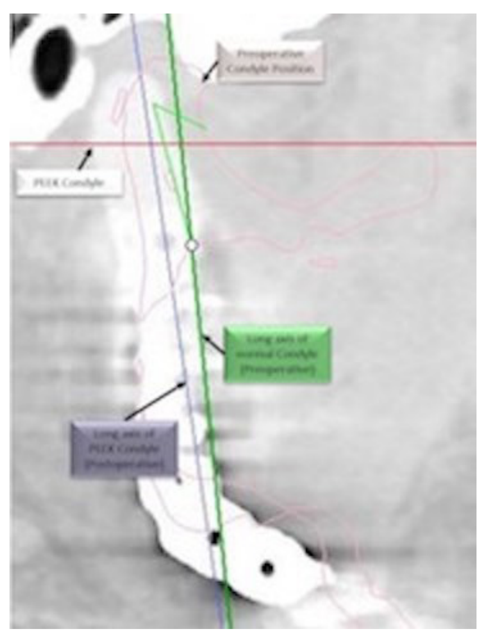


Figure 10: Sagittal C.T. view superimposing the resected and the reconstructed condyles; showing the mid-sagittal line (in red), showing the vertical distances and the sagittal angular rotation measured from the pre- and postoperative condyles, represented by the (green & blue) lines, to the Frankfurt horizontal plane (in red).

The anteroposterior positional changes were identified after formulating a coronal plane; perpendicular to both of the Frankfurt horizontal plane and the mid-sagittal plane. Parallel lines were portrayed from the condylar summits to the coronal plane and the linear differences were calibrated (Figure 11).

All of the numerical measurements were recorded by two different authors, and the mean of the recorded scores were calculated.

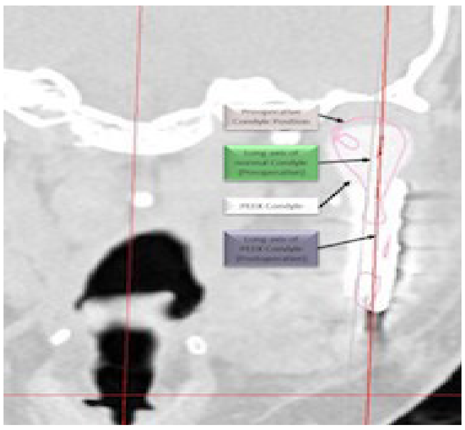


Figure 11: Coronal view superimposing the pre and post-operative condylar positions, demonstrating the anteroposterior positional changes in relation to the Frankfurt horizontal plane.

RESULTS

Five patients with aggressive tumors, compromising the ramus and condylar regions of the mandibles, where bone resection and disarticulation were proposed. The surgical interference employed a fully guided arrangement that directs guided resection and guided allocation of the reconstructive transcript.

All of the cutting guides properly fitted to the underlying bone; aided by their anchorage to the unde medial to the curved inferior mandibular border and guided the oscillating saws to transact a decent and rapid osteotomy, enhancing smooth separation of the compromised mandibular segments. The histopathological assessment of all the surgical specimens reported that the bone interfaces, along the whole planes of cleavage, were free from any tumor invasions. The integral guided drilling sleeves; successfully directed bicortical interlocking of the reconstruction plates to the exact preplanned adjoining mandibular buttress, throughout all of the screw advents. The pre-adjusted reconstruction plates were almost identical to the designated conformation; minimal intraoperative adaptation was required, the reconstruction plates were simply integrated to both of the residual mandible and to the reconstructive assembly, to span the resected gaps and to set the condylar duplicates into the assumed anatomic relationship within the glenoid fossae.

Uneventful healing was expressed by all the patients, with no incidences of infection or wound dehiscence. The postoperative edema was resolved after ten to fourteen days. Although the occlusion of all the cases deemed reliable intraoperatively and during the first week; while the inter-maxillary elastics were attached, mild malocclusion, mandibular deviation as well as marked limitation of mouth opening were observed, following the removal of the unifying elastics through all of the patients, the capacity of mouth opening improved shortly after the initiation of the active and passive mouth opening exercises.

One month postoperatively, the maximum patient's mouth opening recorded a mean of 33.4 mm and the mandibular deviation toward the unaffected side, represented by the shift of the dental midline enumerated a mean of 2.7 mm.

The computed Superimposition of the DICOM files of the preoperative CT and those of the one-week post-surgery; distinguished by (Mimics 19.0; Mimics Medical 19.0, Materialise, Leuven, Belgium), have demonstrated variable angular and linear discrepancies among all of the axial, coronal and sagittal planes, between the virtual condylar position and that surgically executed.

The Superimposition revealed variable mediolateral inconsistency, two condylar head assemblies were deviated laterally by 1.1 mm and 3.2 mm (with a mean of 2.15 mm) while the other three were medially displaced by 0.8, 3.7 and 4.2 (with a mean of 2.9 mm) All the reconstructed condyles revealed vertical displacement; positioned inferiorly by 0.2 mm to 5.4 mm (with a mean value of 4.38 mm). Antro-posteriorly, all the condyles were anteriorly displaced by 0.4 mm to 3.9 mm (with a mean value of 2.7 mm) (Table 2).

Table 2: The minimum, maximum and mean values of the linear mediolateral, vertical and anteroposterior displacement.

	N	Minimum (mm)	Maximum (mm)	Mean value (mm)
		Lateral		
Mediolateral Displacement	2	1.1	3.2	2.15
		Medial		
	3	0.8	4.2	2.9
Vertical Displacement	5	0.2	5.4	4.1
Anteroposterior Displacement	5	0.4	3.9	2.7

The angular rotation along the axial long axis followed the direction of the linear displacement, the two laterally displaced condyles demonstrated lateral rotation with 1.5^{o} and 2.8^{o} with (a mean of 2.15^{o}). The medially disoriented condyles followed the same medial rotational alignment with 0.9, 3.9 and 4.5 (a mean of 3.1 mm). On the other hand, all the condyles rotated anteriorly and inferiorly along the sagittal long axis; ranging from 3° to 9.5° with (a mean of 6.25°) (Table 3).

The degree of accuracy between the virtually planned condylar location and that surgically executed was judged as good to excellent among all the cases.

Table 3: The minimum, maximum and mean values of the angular rotation around both of the axial and sagittal long axis.

	N	Minimum (⁰)	Maximum (⁰)	Mean value (⁰)
Rotation around the Axial long axis		Lateral		
	2	1.5	2.8	2.15
		Medial		
	3	0.9	4.5	3.1
Rotation around the Sagittal long axis	5	3	9.5	6.25

DISCUSSION

The unique architecture of the mandibular topography with the distinct heterogeneous composition, yields renovating the resected segments and the pre-surgical occlusion, not only demands the span of the discontinuity but also duplicating the missing constitute. The digital surgical simulation, coupled with CAD/CAM custom manufacturing has enabled fashioning of a biocompatible material to simulate the resected mandibular condyles and guided its alignment to a nearby anatomic location[11, 12].

The authors of this study planned for designating a single virtual guide that would ensure the complete enclosure of the tumor mass within the resected segment and precisely relates a pre-adapted reconstruction plate to the residual mandible, hoping to assign the (PEEK) proximal duplicate to occupy the same anatomic location and hence, reproduce the lost condylar function. The authors are referring the simplicity of performing the virtual osteotomy along with the favorable histopathological results to the precision of the fabrication of the cutting guides and their intimate adaptation and ease of fixation. Furthermore, the firm interlocking of the reconstruction plates to the patent mandibular segment, through the pre-stationed screw advents contributed to the proximate accuracy of the proximal reconstruct. By virtue of the whole preoperative arrangements, the intraoperative time was markedly reduced as the regular manual manipulations were replaced by fine adjustments.

According to what stated by Throckmorton[13], "The ideal total joint reconstruction, is one that closely mimics the form and function of the original joint it replaces", the authors are believing that the favorable condylar alignment was attributed to the mirror-imaged assembly; that reproduced a nearby approximation to the lost mandibular architecture, as well as the guided virtual arrangement that restored the lost mandibular curvatures to simulate the native interrelation between the reconstructive transcript and the undisturbed mandibular segment; established by the execution of the traced alignment of the pre-bent reconstruction plate to the (PEEK) assembly, that demonstrated outstanding capability of being tailored to exact the configurations of the amputated mandibular condyles, which coincided with Liang *et al*.[14], who considered that stereolithographic model aided bending of reconstruction plates was crucial for proper condylar positioning, and Scolozzi[12] who considered the application of the mirror imaging technicality crucial to duplicate the missing anatomic figurations.

The authors of this study are referring the favorable postoperative mouth openings and the acceptable postoperative malocclusion and mandibular shift to both of the alignment and the mechanical properties of the (PEEK) assemblies, matching what stated by Kim *et al*.[15] "PEEK implants are customizable, easily workable, inert, and nonporous, they represent an ideal alloplastic material for maxillofacial reconstruction".

The fixed occlusal relation between the mobile mandible and the fixed maxilla is maintained by the attached mandibular muscles and ligaments. Unfortunately, proximal segmental resection with the associated loss of the muscular and ligamentous attachment is combined with an established dislocating rotational forces; induced by the normal patent's contralateral anatomic organization[16]. Liang *et al*.[14] believed that these forces would undoubtedly alter the reconstructed condylar position, particularly with short residual mandibular segments, matching what reported by the authors of this study, as both of the degrees of post-surgical malocclusion and condylar displacement were proportional to the expanse of the proximal resection, which seemed particularly true with the extent of the vertical displacement and the associated angular rotation around the sagittal axis, which reported minimal when only the mandibular ramus was resected, and markedly increased with extending the resection margin toward the midline. The authors are believing that the post-surgical neuromuscular imbalance ; generated by the loss of the muscles, ligaments and the tendinous attachments to the bone of the resected proximal mandibular segment, as well as the stretching effect of the muscular apparatus of the contralateral undisturbed mechanism, is a crucial antagonistic factor in the execution of the exact post-surgical condylar position, the resultant extent and pattern of post-operative mandibular movements and would also contributes to the incidence of the postoperative relapse.

CONCLUSIONS

Although this study was restricted by a short follow-up period, the authors are relating the minute discrepancy of the condylar orientation; especially in the sagittal plane, to the size of the resected proximal mandibular segment with the related extent of muscle detachment. The authors of this study are planning to provide long term follow-up, even after consolidating the planned autogenous free bone graft.

The authors of this are considering that the novel simulation and allocation of the customized (PEEK) assembly represents a simple and efficient modality to reconstruct both of the lost condylar position and configuration. However, the anterior extension of the resected proximal mandibular segment deemed determinant to the success of the identical surgical execution of the virtual preplanned arrangement.

RECOMMENDATION

Coupling the (PEEK) favorable chemical and mechanical properties with the booming technology of the virtual planning and computer-assisted designing and manufacturing, represents a promising potential advance for the reconstruction of the complex temporomandibular joint. However, the mood by which the detached apparatus of muscles, ligaments and the tendinous attachments would correspond to the implanted (PEEK) is undefined, which needs to be explored by further studies.

CONFLICT OF INTEREST

There are no conflicts of interest.

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