EVALUATION OF THE EFFICIENCY OF CUSTOM-MADE THREE-DIMENSIONAL PEEK PLATES IN MANDIBULAR ANGLE FRACTURE FIXATION

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ABSTRACT

INTRODUCTION: Mandibular angle fracture management has always posed a dilemma for maxillofacial surgeons. Numerous treatment modalities and plate designs have been proposed. Three-dimensional (3D) plates have gained great acceptance since they can provide rigid and functionally stable fixation. Poly-ether-ether-ketone (PEEK) has lately emerged as a promising material of choice in the manufacturing of internal fixation devices.

AIM OF THE STUDY: To evaluate the efficiency of 3D custom-made PEEK plates in the management of mandibular angle fractures in terms of clinical and radiographic assessment parameters.

MATERIALS AND METHODS: The present study was conducted on nine patients with recent mandibular angle fractures indicated for open reduction and internal fixation. All fractures were fixed with custom-made 3D PEEK plates placed through an extraoral approach. The follow-up period was twelve weeks. Clinical assessment parameters included postoperative occlusion, interfragmentary mobility, and bite force recovery. Radiographic assessment was done with the aid of two computed tomography(CT) scans; one immediate postoperative scan and another one after twelve weeks, to evaluate the healing process and calculate the mean bone density at the fracture site.

RESULTS: By the end of the follow-up period, all patients showed satisfactory occlusion and zero interfragmentary stability. Bite force values showed a statistically significant difference across the follow-up period. Upon radiographic assessment, all fractures showed proper healing and the difference in mean bone density between baseline and final values was statistically significant.

CONCLUSION: Custom-made 3D PEEK plates can provide satisfactory clinical and radiographic outcomes in the treatment of mandibular angle fractures.

KEYWORDS: 3D plates, mandibular angle fractures, PEEK, bite force recovery.

RUNNING TITLE: Three-dimensional PEEK plates in angle fractures.

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INTRODUCTION

Reconstruction of facial bones following traumatic events represents one of the greatest challenges to maxillofacial surgeons(1). Due to its prominent position, the mandible is the most commonly fractured facial bone representing 36% to 59% of maxillofacial fractures(2), with the angle of the mandible being the first most commonly fractured region by sports incidents, the second most fractured region by interpersonal violence, and the third most fractured region in cases of road traffic accidents(3). This frequent involvement of the angle is possibly due to its thin cross-section and the possible existence of an impacted wisdom tooth that causes weakening(4).

Despite the widely accepted agreement nowadays regarding the necessity of open reduction and fixation of mandibular angle fractures, a wide array of treatment modalities has been designated. The debate is still going on in the literature about the most favorable type of fixation(5). Fixation of fractures of the mandibular angle is probably more critical than that of any other fracture in the mandible, where angle fractures feature unique biomechanical complexity because of the main stress-bearing trajectories of the mandibular bone being interrupted in this area(6).

Whether a single plate following Champy's recommendations of hardware fixation(7) was used, or two miniplates, (superior and inferior border plates)(8) were used, a high rate of complications was observed(9). To that purpose, an innovative plate design emerged in 1992, namely, three-dimensional (3D) plates, to combine the advantages of both techniques while overcoming their disadvantages (10). Such plates were found to have more resistance against torsional movements at the fracture line than conventional miniplates(11).

Nowadays, computers are being extensively used not only for diagnosis but also for designing surgical procedures in the craniomaxillofacial field. Advances in virtual surgery and 3D printing and milling techniques have significantly increased surgical precision and efficiency(12). They can be utilized alongside digital imaging techniques like computerized tomography (CT) to generate custom-made plates specifically tailored for each fracture. This can serve to shorten the operation time, eliminate the need to remove the plates and improve the fixation system stability(13).

Many materials can be employed in the process of manufacturing these custom-made plates; with Poly-ether-ether-ketone (PEEK) being one of the most recently used. PEEK is a semi-crystalline polyaromatic linear polymer that features exceptional strength, stiffness, biocompatibility, and environmental resistance(14). It is becoming very helpful and can provide very predictable and stable results, due to its resemblance to the cortical bone biomechanically(12).

This comparable modulus of elasticity of PEEK to that of compact bone causes any forces subjected to the bone-PEEK interface to be shared equally with the bone(15) thus abolishing the negative effects of the stress shielding phenomenon (16) and allowing an efficient and continuous bone remodeling process that can yield a higher quality bone. Moreover, PEEK is compatible with both computed tomography (CT) and magnetic resonance imaging procedures, it avoids harmful metal ion interactions, and can sustain its properties with most sterilization techniques (17).

In the contemporary literature, we found no records demonstrating the results of using custom-made 3D PEEK plates in mandibular angle fracture fixation. This requires the need for evidence-based development of 3D PEEK plates application in fractures of the mandibular angle.

MATERIALS AND METHODS

This study was a prospective clinical study, that was performed after gaining ethical clearance from the Research Ethics Committee, Faculty of Dentistry, Alexandria University.

Patients

Nine patients were selected from the Emergency Ward of Alexandria University Teaching Hospital in the period between February 2022 and July 2023 and were operated upon in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University. Only adult patients above 18 years old with no gender predilections, suffering from recent, uninfected, non-comminuted mandibular angle fractures that demand open reduction and internal fixation were included in the study. The exclusion criteria were medically compromised patients contradicting operation (ASA III, IV & V), patients receiving radiotherapy or chemotherapy, the existence of infection at the fracture line, pathological fractures, and old fractures. An informed consent was signed by all the patients after explaining all the procedures including all benefits and side effects in a simple and easy way.

Materials

1-Polyetheretherketone(PEEK)Disks (breCAM disk Manufactured by BioHPP®: Tapton Park Innovation, Brimington road, Germany.)

2- Piezoresistive force transduce sensor: FlexiForce A201 sensor (FlexiForce sensor, by Tekscan Boston, MA, USA. www.tekscan.com) (Figure 1) displaying a load range of 100 lb, equivalent to 440 N, and a sensitivity of 0.01 V/N. It is a flexible printed circuit planted within two polyester film layers reaching an ultimate thickness of 0.2 mm. The sensor's active zone is 1 cm in diameter at its end, which is made of pressure-sensitive ink. The output readings from the transducer are in Volt (V), accordingly, the sensor was initially pre-habituated according to the manufacturer-recommended equation to make the expressed reading in Newton (N)(18).

Methods

1) Pre-operative assessment and examination:

Detailed history taking was performed to collect the preoperative demographic data of the patients, including name, age, gender, occupation, address, onset, and cause of the fracture. This was followed by a thorough clinical, intraoral, and extraoral, examination to record swelling, ecchymosis, deformity of the bony contour and the occlusal plane, ecchymosis, and fracture hematoma in the buccal and lingual sulci, soft tissue laceration and deviation of the mandible during function by inspection and to detect the site of tenderness, step deformities, alteration of bony contour and bony crepitus by palpation. High-resolution CT of the mandible was performed (with a slice thickness of 1 mm) to show the extent of the fracture line, reveal the degree and direction of displacement, and show the relation of teeth involved in the fracture line.

2) Designing the PEEK plate

The computer-guided reduction was done using specialized software (MIMICS; Materialise NV, Belgium) with a surface-based rendering for surgical planning. CT images in a DICOM (Digital Imaging and Communications in Medicine) format were exported into the segmentation software (MIMICS). A segmentation process was carried out in the following steps: 2D section images were used to define the image thresholds to eliminate all the soft tissue and only highlight bone and dental tissues. Mandibular bone and teeth were further selected and a three-dimensional reconstruction of the segmented mandible along with the teeth was created. The reconstructed mandible was further segmented into distinct fracture segments (Figure 2). The fracture segments were then virtually reduced anatomically using the simulation module (repositioning option) of the designing software. Virtual reduction of the anatomically reduced angle is verified and checked in the axial and coronal planes and condylar position was checked in relation to the glenoid fossa. A three-dimensional custom-made plate of 1 mm thickness is then planned on the simulated reduced mandible (Figure 3). The image is then transferred in a ‘‘Standard Tessellation Language’’ (STL) format to a specialized software (INLAB CAM SW 16: Dentsply Sirona Susquehanna Commerce, W. Philadelphia Street, USA) that operates on a milling machine (MC X5: Dentsply Sirona, Susquehanna Commerce. W. Philadelphia Street, USA) to mill the plate from the PEEK disk. (bredent, breCAM.BioHPP, Germany). The plate was sterilized before the operation.

3) Surgical phase

Prophylactic antibiotic therapy was administered preoperatively in the form of Cefotaxime 1 gm/12 hours (Cefotax, E.I.P.I.C.O, Egypt) intravenously to prevent postoperative infection. All of the patients underwent open reduction and internal fixation of mandibular fractures under general anesthesia administered through naso-endotracheal intubation. The surgical field was scrubbed with povidone-iodine surgical scrub solution (Betadine 7.5%; Purdue Products L.P), followed by draping of the patient with sterile towels exposing only the area of surgery. The fracture line was exposed through an extra-oral submandibular approach using a 4 cm long skin and subcutaneous incision placed 1.5-2 cm below the inferior border of the mandible. Exposure of the fracture site was obtained by standard layered dissection through platysma muscle, investing layer of the deep cervical fascia, pterygomasseteric sling, and periosteum. This was followed by mobilization of the fracture, removal of any soft tissue entrapped within the fracture line, and management of teeth in the fracture line either by extraction or preservation. Intermaxillary fixation (IMF) was temporarily secured to provide proper occlusion that served as a guide for fracture reduction. The bone was then reduced into proper anatomical occlusion and the reduction was confirmed visually by verifying the alignment of the buccal cortex and inferior border. Placement of the custom-made PEEK plate in position and fixed by mini screws followed (Figure 5). The IMF was removed and the surgical field was irrigated with Povidone-iodine and saline and wound closure in layers was performed, using Vicryl suture material (Johnson & Johnson Int. European Logistics Centre, Belgium)

4) Post-operative phase :

All patients received intravenous Cefotax 1 g/12 h for one day postoperatively followed by oral antibiotics in the form of Amoxicillin + Clavulanic acid(Augmentin 1gm; GlaxoSmithKline, UK) twice daily for 5– 7 days after discharge. Analgesic and anti-inflammatory medication in the form of diclofenac potassium 50 mg tablets (Cataflam50 mg, Novartis, Switzerland) was given every 8 hours for five days, and the patients were instructed to follow a soft diet for one month along with careful oral hygiene.

5)Follow-up phase

A-Clinical evaluation:

A postoperative clinical assessment was executed after 24 hours, one week, two weeks, four weeks, six weeks, and twelve weeks. A postoperative clinical evaluation for the interfragmentary mobility and the state of occlusion was performed.

B- Radiographic evaluation:

A postoperative radiographic evaluation was performed using an immediate postoperative CT scan to assess the adequacy of fracture line reduction, then another scan was taken after 12 weeks to show the healing progression and estimate the mean bone density at the fracture line in comparison to the immediate postoperative scan (Figure 5).

C- Bite Force Measurements

Using the piezoresistive force transduce sensor, to measure the bite force at molar and premolar area. This was done at 1, 6, and 12 weeks postoperatively on the fracture side in all patients (19). In each sitting, the patients were settled with the head upright, looking forward, and in an unsupported natural position. The patients were instructed to bite on the sensor as forcefully as they could for 5 seconds. The 1 cm diameter active zone was inserted in the first molar area and then in the first premolar area on the ipsilateral side. The sensor was inserted into a disposable transparent plastic sheet to dodge its contact with the patient’s saliva, as the sensor doesn’t endure immersion or heat sterilization.

D- Statistical Analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Quantitative data were expressed as range (minimum and maximum), mean, standard deviation **Paired t-test** for normally distributed quantitative variables, to compare between two periods while **ANOVA with repeated measures** for normally distributed quantitative variables, to compare between more than two periods or stages and Post Hoc Test (adjusted Bonferroni) for pairwise comparisons**.** The significance of the obtained results was judged at the 5% level.

Fig.1 Flexiforce sensor

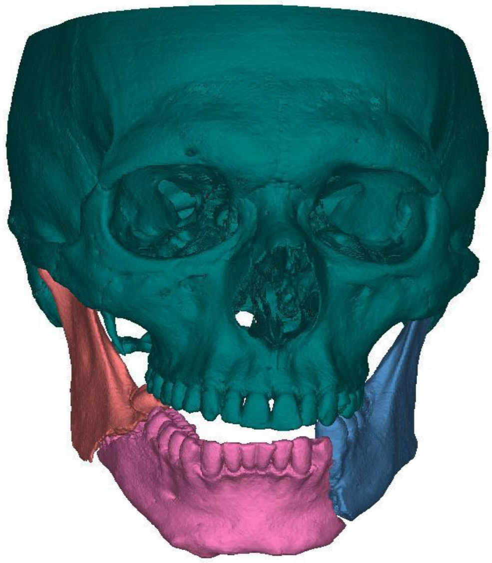
Fig.2 Segmentation of the fractured segments

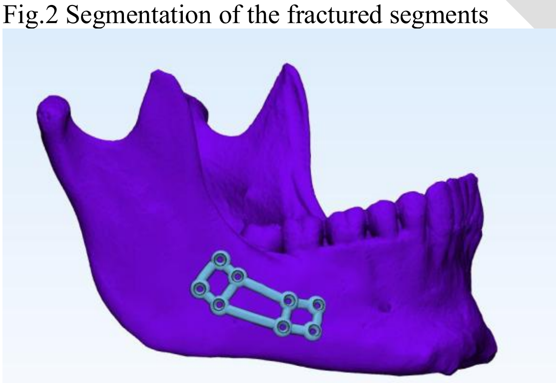
Fig.3 Virtually reduced mandible and design of the PEEK plate

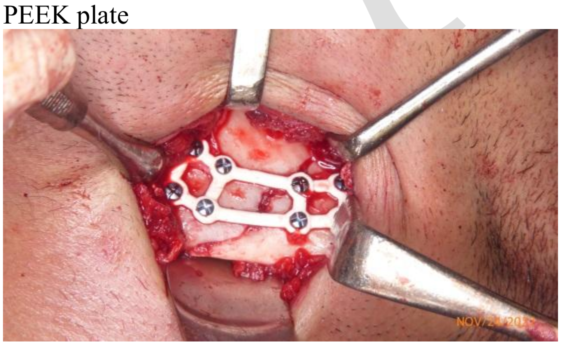
Fig.4 PEEK plate in place

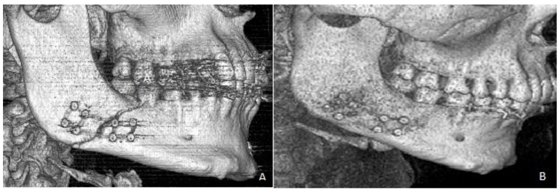

Fig.5 Postoperative CT scans. A: Immediate postoperative , B: 12 weeks postoperative

RESULTS

Demographic Data

The present study was conducted on nine patients selected from those admitted to the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University suffering from mandibular angle fractures. Their ages ranged from 22 - 42 years old. All the patients were males. Eight patients had left mandibular angle fractures and one patient had right mandibular angle fracture. The cause of the trauma was road traffic accidents in six patients and assaults in three patients. Six cases had solitary angle fractures while three cases had contralateral fractures. The diagnosis of mandibular angle fracture was based on clinical examination and radiographic findings. Teeth in the fracture line were extracted in 4 cases (44.4%).

Clinical Assessment Data

All of the studied cases were monitored for 12 weeks postoperatively. There were no cases of infection or wound dehiscence. No interfragmentary mobility was noticed in any of the cases. The occlusal examination showed a normal occlusal and intercuspal relation in all of the cases. There was no need for selective grinding in any case during the follow-up period.

Radiographic assessment Data

The immediate post-operative CT scans showed proper reduction and accurate alignment of the fractured segments and the inferior border of the mandible in all cases. After twelve weeks, CT scans showed proper bony union, with anatomic vertical and horizontal alignment of the mandibular bone. Bone healing was attained and the fracture line couldn't be detected in all the cases. In any case, there was no radiographic evidence of the presence of plate fracture, malunion, or nonunion.

The mean immediate postoperative bone density was 811.1 ± 68.24 HU, while the mean bone density after twelve weeks was 1225.1 ± 111.7 The difference between these values was found to be statistically significant ($p<0.001$) (Table 1) (Figure 6).

Bite force Measurements

After the first week postoperatively, the mean bite force was 113.6 ± 14.22 N. After six weeks postoperatively, the mean bite force was 202.7 ± 18.75 N. After the twelve weeks postoperatively, the mean bite force was 304.1 ± 14.50 N. And so, the difference in bite force values in all cases across the follow-up period was statistically significant (p<0.001) (Table 2).

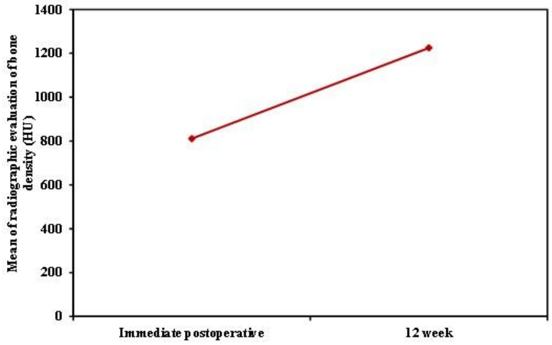

Fig.6 Graph showing the radiographic evaluation of the mean bone density at the fracture line

Table 1: Descriptive analysis of the mean bone density values in Hounsfield Unit (HU) throughout the follow-up period

Radiographic evaluation of bone density (HU)	(n = 9)
Immediate postoperative	
Min. – Max.	709.7 – 917.1
Mean ± SD.	811.1 ± 68.24
12 weeks	
Min. – Max.	1052.2 – 1367.7
Mean ± SD.	1225.1 ± 111.7
p_1	<0.001*

SD: Standard deviation
p: p value for comparing between immediate postoperative and 12 weeks postoperative
*: Statistically significant at $p \leq 0.05$

Table 2: Descriptive analysis of mean bite force values in Newton across the follow up period

Bite force recovery (postoperative)	1week	6week	12week	P
(n = 9)				
Min. – Max.	89.0 – 132.0	181.0 – 233.0	281.0 – 324.0	<0.001*
Mean ± SD.	113.6 ± 14.22	202.7 ± 18.75	304.1 ± 14.50	
Sig. bet. periods.	p_1<0.001*, p_2<0.001*, p_3<0.001*			

SD: Standard deviation
F: F test (ANOVA) with repeated measures, Sig. bet. periods was done using Post Hoc Test (adjusted Bonferroni)
p: p value for comparing between the studied groups
p1: p value for comparing between 1 week and 6 weeks
p2: p value for comparing between 1 week and 12 weeks
p3: p value for comparing between 6 weeks and 12 weeks

DISCUSSION

Despite the significant advancement in the techniques used for the fixation of fractures of the maxillofacial skeleton, mandibular angle fractures continue to be among the most complex and unpredictable fractures to treat comparing to other areas of the mandible. This is due to the thin cross-section of the angle and the attachment of the powerful elevator muscles of mastication, which creates complex biomechanical forces at the angle during function, thus leading to a high incidence of postoperative complications. This emphasizes the importance of rigid fixation in this area to maintain postoperative stability.(20)

The literature on the management of fractures of the mandibular angle points out the fact that no single approach was found to be ideal; therefore, the controversy will remain. Several osteosynthesis techniques have been tested starting from Champy's technique (21), to the application of two miniplates through an extraoral approach (22), then to the rise of three-dimensional (3D) plates (23) as a solution to the drawbacks of the older methods.

With the current advances in virtual surgical planning, patient-specific plates have started to emerge as a solution with perfect adaptability and a quite predictable outcome (12). Various materials can be used to fabricate internal fixation devices, with poly-ether-ether-ketone (PEEK) being a recognized choice for its superior strength, biocompatibility, and biomechanical resemblance to bone (24).

To our knowledge, this is the first study to assess the efficiency of custom-made three-dimensional PEEK plates in the fixation of fractures involving the angle of the mandible. Through a twelve-week postoperative follow-up period, patients were assessed for interfragmentary mobility, postoperative occlusion, bite force recovery, and estimated bone density at the line of fracture.

None of the patients suffered postoperative interfragmentary mobility. This was in accordance with Xue et al.(25) who showed that the three-dimensional plates revealed better initial interfragmentary stability compared to miniplates. A biomechanical study by Alkan et al.(26) observed that the 3D strut plate design has a more advantageous biomechanical behavior compared to other plating techniques employed in mandibular angle fractures. This is due to the fact that when screws are placed in the configuration of a box on either side of the fracture line rather than in a linear configuration, this creates broad platforms that may increase the plate's capacity to resist torsional forces, resulting in better interfragmentary stability

(23), which in turn results in less postoperative complications (25).

Regarding the postoperative occlusion, all patients had a satisfactory occlusion. This is accordant with the literature where studies with 3D plates reported occlusal derangement ranging from 0- 20% (11, 23, 27). This is attributed to the superior stability of the fractured segments provided by the 3D design of the plate, thus offering a stable occlusion. It also comes in accordance with Abaas et al.(28) who compared PEEK plates to titanium plates in the fixation of mandibular body fractures and found no significant difference in postoperative occlusion, suggesting that PEEK plates can provide adequate fracture stability, just as good as titanium plates.

In this study, a statistically significant difference ($p<0.001$) *was detected between the values of the mean bite force recorded at the fracture side at 1, 6, and 12 weeks postoperative. This was in agreement with Pepato et al.(29) who reported a good functional recovery in patients two months following open reduction and fixation of fractures of the mandibular angle. When comparing 3D threadlock plates to conventional miniplates in fractured mandibular angles, Melek et al.(30) discovered a statistically significant difference with regard to the mean bite force at the fracture side between the two groups at two and four weeks after the operation, with higher values detected in 3D plate group. At 6 weeks postoperatively, the difference was not statistically significant. Saxena et al.(31) too has found a statistically significant difference between the mean bite force values at 1 and 3 months postoperative when comparing 3D plates to standard mini plates. This too can be explained by the excellent mechanical behavior of 3D plates that provide superior stability and better force distribution.

As for the radiographically estimated bone density at the fracture line, a statistically significant difference was found between the immediate postoperative bone density and the 12-weels postoperative numbers ($p<0.001^*$). This was in accordance with Dessouky et al.(12) who used PEEK plates to fix displaced mandibular body fractures and Abdelmoneim et al.(17) who used PEEK plates to fix mandibular fractures in the pediatric population, both reporting a statistically significant difference in the estimated bone density through the postoperative follow-up period. This might be attributed to the fact that PEEK has adequate strength and stiffness to maintain functional stability during the healing period. These findings are also in accordance with the recent review of literature published by Chrcanovic and Ramos (32) who stated that 3D plates in general show better clinical outcomes and higher fracture stability in the treatment of mandibular angle fractures. Melek et al.(30) too has performed a radiographic appraisal for the use of 3D plates in angle fractures and revealed a statistically significant increase in estimated bone density across the follow-up sessions ($P<0.001$). This may indicate that combining the 3D plate design with the high mechanical properties of the PEEK material can result in superior fracture stability and better clinical outcomes regarding postoperative occlusion and bite force recovery.

CONCLUSION

Mandibular angle fracture fixation with custom-made three-dimensional PEEK plates placed through an extraoral approach can provide satisfying clinical and radiographic outcomes. This can be attributed to the exceptional combination of the resistance to torsional forces provided by the 3D design of the plate in addition to the excellent biomechanical properties and the near-to-bone modulus of elasticity of the PEEK.

Conflict of interest

The authors declare that they have no conflict of interest.

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