Clinical assessment of Open Reduction Internal Fixation (ORIF) of Mandibular Body Fractures Using Computer-Assisted Polyetherether Ketone (PEEK) Custom Made Plates Versus Conventional Titanium Plates: A Randomized Clinical Trial

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Abstract

Background and objective: This study aimed at clinical assessment of ORIF of mandibular body fractures using computer-assisted PEEK custom made plates versus conventional titanium plates.

Materials and Method: Sixteen patients were divided into 2 equal groups. Patients in both groups underwent ORIF of mandibular body fractures. In the study group, the fractures were stabilized using computer-assisted PEEK custom made plates. In the control group, the mandibular body fractures were stabilized using 2.3 & 2.0 titanium plating system. Each patient was assessed in terms of postoperative occlusion, wound dehiscence and mental nerve paresthesia. Moreover, operative time was evaluated in both groups.

Results: The postoperative recovery and healing phase were uneventful in all patients. No postoperative complications were observed except in one case in the study group (PEEK) where wound dehiscence & mental nerve paresthesia were experienced. Postoperative occlusion was satisfactory in both groups with an insignificant difference ($p>0.05$) regarding the assessment criteria. However, the custom made PEEK plates showed the advantage of decreasing operative time and accuracy of reduction.

Conclusion: Patient specific PEEK plate showed satisfactory clinical outcomes in ORIF of mandibular body fractures. Additional advantages include saving time & effort during the surgery.

Keywords: *PEEK, custom made plates, ORIF.*

Introduction

In the last decade, the rate of facial injuries increased, 25% of these injuries are mandibular fractures and 11-36% of these fractures are body fractures. A plenty of treatment choices is used for stabilization of mandibular body fractures including: 1-non surgical intervention and 2- surgical intervention using titanium plating system which is considered the gold standard yet.(1)

Several attempts were made to overcome the disadvantages of titanium plates, these disadvantages include: 1-sepsis with subsequent dehiscence accounted for 50% to 60% and 2-the need for 2nd surgery with documented rates 52-86% within 6 months to 12 months which is due to the significant difference between Young' modulus of elasticity of titanium & that of the cortical plate of bone with subsequent inefficient load transfer between bone and implant which is known as the stress shielding phenomenon. As a result bone loss

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will occur with subsequent risk of aseptic loosening of titanium plates.[2,3]

Accordingly, this trial will be held using polyether ether ketone (PEEK) to overcome such problems. PEEK is a linear semi-crystalline poly-aromatic polymer which has dimensional properties close to that of living bone in terms of strength and stiffness. The major beneficial property of PEEK is its lower Young's modulus of elasticity which is close to that of the cortical bone and therefore, it is likely to eliminate themajor problem encountered with titanium plating system which is the stress shielding phenomenon. It is highly durable, resists a high degree of temperature greater than 300 degree C and can be used without adverse tissue effects. Moreover, the computer-assisted custom made PEEK plates will make fracture reduction more accurate and will offer a great advantage of less time consuming.[3,4]

Materials and Method

Materials

Study Group: The plates used in this study were the patient specific PEEK plates manufactured by computer-aided design and computer-aided modeling (CAD/CAM) system. The plate was 4 mm thickness and consisted of 2 horizontalarms – a superior and an inferior one - connected together. The patient specific PEEK plates were fixed using titanium screws.

Control Group: Conventional 2.3 & 2.0 titanium plates on the superior and inferior borders respectively fixed using titanium screws.

Fig. 1: ORIF using patient specific PEEK plate

Study Population: 16 patients with mandibular body fractures were selected. The history and detailed medical examination data for each patient was collected. A preoperative computed tomography (CT) scan was taken. Fabrication of the custom made PEEK plate was carried out using (CAD/CAM) system.

Clinical Data: Postoperative occlusion, wound dehiscence and mental nerve paresthesia were evaluated for each patient. Also, the operative time was evaluated in both groups.

Radiographic Data: Immediate postoperative CT scan was obtained using the same machine and exposure parameters [Axial cuts, DICOM file, Gantry tilt zero and minimal thickness of 0.6mm] as for the preoperative CT scan. DICOM data processing, segmentation, 3D virtual model reconstruction, virtual reduction of the fractured segments and designing patient specific PEEK plates were obtained.

Results

Majority of both groups were males 7 (87.5%) with only one (12.5%) female. The mean age of the cases in the study group (PEEK) was (30.20±1.84) while for the control group (Titanium) was (29.17±1.37). Most of the cases had unilateral fractures in the right side [5 (62.5%), 4 (50.0%)] & didn't have associated fractures [6 (75.0%), 4 (50.0%)].

Surgical Results: For all patients, the surgical procedures were performed without any major complications. However, in onecase in the study group,mental nerve injury was occurred during reduction and fixation of the fractured segments

Clinical Results: The postoperative recovery and healing phase were uneventful in all patients. No postoperative complications were observed except in one case in the study group (PEEK) where wound dehiscence was noted 1 week postoperatively and treated by irrigation and wound care .Moreover, in the same patient, chin paresthesia was noted which was attributed to mental nerve injury. None of the patients included in the study were necessitated second surgical intervention. **Table (1).**

Table (1): Complications of all patients included in the study

	Group I (PEEK)	Group II (Titanium)
Wound dehiscence	1	-
Mental nerve injury	1	-
The need for 2nd surgery	-	-

The postoperative occlusion was evaluated via Visual analogue scale (VAS) utilizing University of Washington Quality of Life Questionnaire (UW-QOL v4). The parameters included in this study were activity, chewing & swallowing. All patients included in the study enjoyed good postoperative occlusion regarding the mentioned parameters. For different occlusal parameters, there was no significant difference between both groups (p>0.05). **Table (2).**

Table (2): Mean and standard deviation (SD) values for VAS scores in both groups

Feature	VAS scores (Mean±SD)		p-value
	Group I (PEEK)	Group II (Titanium)	
Activity	9.56±8.16	9.62±2.93	0.985ns
Chewing	8.92±6.35	8.75±8.877	0.966ns
Swallowing	9.33±3.22	9.50±3.02	0.915ns

The average operative time in the control group (Titanium) was significantly higher than that of the study group (PEEK) (p=0.002).

Radiographic Results: The immediate postoperative CT data revealed proper reduction & alignment of the fractured fragments in the study group (PEEK). The patient specific PEEK plates were perfectly adapted to the fractured segments.

(a) **(b)**

Fig. 2(a) Post-operative clinical photograph & (b) Post-operative reformatted lateral reconstruction of CT data of the patient specific PEEK plate in study group (PEEK)

Discussion

Open Reduction Internal fixation (ORIF) of mandibular body fractures using titanium plating systems had several drawbacks including sepsis with subsequent wound dehiscence and the need for 2nd surgery which is attributed to bone loss as a result of the elevated modulus of elasticity of titanium hardware. Accordingly, attempts were made to overcome problems encountered with the titanium plating system.[2,5]

In this study, custom made PEEK plates were used in ORIF of mandibular body fractures. The main beneficial property of PEEK material is its lower modulus of elasticity that is close to that of living bone with subsequent elimination of the problem of stress shielding phenomenon encountered with titanium plating system. PEEK material has other advantages including biocompatibility, mechanical strength, durability, resistance to high degree of temperature without dimensional alteration.[3][4]

No postoperative complications were observed except in one patient in the study group (PEEK) where wound dehiscence was noted 1 week postoperatively and treated by irrigation and wound care. Moreover, in the same patient, chin paresthesia was noted which was attributed to mental nerve injury as a result of handling of the fractured segments during reduction & fixation. This is inconsistent with the results reported by **Yang et al.**[6] **(2014)** who reported there was no wound dehiscence occurred in the 12 patients included in their studies who underwent PEEK cranioplasty.

In agreement with the results obtained in this study, **Thien A et al.**[7] **(2015)** reported that the complication rate for PEEK cranioplasty was 25% and wound dehiscence was 4.2%. Similar results were obtained by **Jonkergouw et al.**[8] **(2016)**.

In the control group (Titanium), there were no infection or wound dehiscence and need for 2nd surgery which are inconsistent with the results obtained by **Bakathir et al.** [9] (2008), **O'Connell et al.**[10] (2009) & **Pan et al.**[2] (2013) who concluded that infection/wound dehiscence was the main reason for plate removal in the mandible upon using the titanium plating system.

The postoperative occlusion was evaluated via Visual analogue scale (VAS) utilizing University of Washington Quality of Life Questionnaire (UW-QOL v4). The parameters included in this study were activity, chewing & swallowing.

All patients included in the study enjoyed good postoperative occlusion regarding the mentioned parameters. For different occlusal parameters, there was no significant difference between both groups ($p>0.05$).

There was a significant difference regarding the operative time between both groups ($p=0.002$) which is consistent with the studies performed with **Scolozzi et al.**[11] (2012) and **Yang et al.**[6] (2014) where a significant decrease in the operating time was noticed in the computer-assisted custom made PEEK plates which was attributed to minimal to none intraoperative adjustments of the custom made plates.

In this study, the patient specific PEEK plates offered optimum reduction & alignment of the fractured segments (proximal & distal) which was the key for successful reduction of both segments and subsequently the key for optimum functional results post-operatively which is in agreement with **Voss et al.**[12] (2016).

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Competing Interests:

Conflict of Interest: No

Ethical Approval: The Ethics and research committee, Faculty of Dentistry, Cairo University approved the study and patients' consent was obtained.

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