 DOI: 10.21608/adjalexu.2021.98273.1220

# EVALUATION OF CUSTOMIZED POLYETHER ETHER KETONE IMPLANT IN RECONSTRUCTION OF ORBITAL FLOOR FRACTURES (CLINICAL TRIAL)"

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## ABSTRACT

**INTRODUCTION:** Orbital floor fracture is one of the most common maxillofacial fracture. Hence, many clinical methods were implemented for improvement of the techniques used in treating orbital floor fractures. Poly ether ether ketone had been widely used in reconstruction field due to its superb compatibility and proper mechanical properties.

**AIM OF THIS STUDY:** To evaluate the clinical efficacy and radiographic performance of customized PEEK implant in the treatment of patients with orbital floor fracture.

**MATERIALS AND METHODS**: 9 patients with recent orbital floor fracture were selected. All patients were treated using customized PEEK implants in orbital floor reconstruction. Patients were evaluated after 24-hours, one, four and six weeks for enophthalmos, diplopia, ocular motility and infraorbital nerve function in comparison with preoperative status. In addition, a radiographic investigation was performed immediately to confirm the proper placement of the implant and complete release of orbital soft tissue from the maxillary sinus.

**RESULT:** the study was conducted on seven patients with ZMC fracture and 2 patients with blow-out fracture. None of the enrolled patients showed postoperative diplopia. Six out of the enrolled nine patients in this study reported a subjective abnormal sensation in the course of the affected infraorbital nerve at the first follow-up period. However, all patients regained normal sensation by the end of the follow-up period. The difference of the rate of postoperative ocular complications was statistically significant over the follow-up periods (p=0.036).

**CONCLUSION:** The favorable clinical performance of the patient-specific PEEK sheet in the management of orbital floor defects makes it an exemplary reconstructive alternative with superb compatibility, great surgical precision and predictability.


**KEYWORDS:** polyether ether ketone, orbital floor fractures, reconstruction.

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## INTRODUCTION

The zygomatic maxillary complex fracture is one of the most frequently encountered fracture in personal violence, road traffic accidents, falls and sport injuries. Lateral wall, inferior rim and floor of the orbit are commonly involved in zygomatic maxillary complex fractures which make it considered as true orbital fracture (1).

Restricted eye movement altered globe level, diplopia, visual impairment, circumorbital ecchymosis and altered sensation over the distribution of infraorbital nerve are the most faced problems in orbital floor fractures. All these signs require urgent surgical intervention(2).

Orbital reconstruction is important to restore visual function and movement by freeing entrapped orbital tissue and enhance appearance. The literature contains a broad number of studies using many types of autologous materials, allogeneic materials, and alloplastic materials(3).

Autogenous grafts had been used for repairing orbital fractures years ago. biocompatibility and lower potential for infection, exposure, and foreign body reaction had been the gold advantages of them. however, there are many disadvantages of them such as morbidity of donor site, prolonged operation, variable degree of resorption and inability to reshape it to fit the concave-convex shape of the orbital floor(4).

Henceforth, ready-made titanium mesh has been widely used as it can be easily fitted to the shape of the orbital floor due to its malleability. Titanium is considered most compatible material however some adverse effects has been published in literature such as, difficulty of removal due to overgrowth of connective tissue around it (4).

Since its conception, Polyether Ether Ketone (PEEK) has been settled in the neurosurgical field as an implant material for cranioplasty and frontal bone reconstructions as an alternative material to titanium(5). PEEK is a semi-crystalline, thermoplastic, poly-aromatic linear polymer that displays an excellent blend of strength, stiffness, durability, environmental resistance, radiographic translucency, and in particular favorable biocompatibility(6).

PEEK can be designed with a cortical bone-like Young’s elastic modulus, which minimizes the risk of bone resorption and stress shielding (7). Furthermore, its high stiffness and fracture resistance permits its milling into complex designs without risking implant fracture or failure(8)

The recent development in computer-aided design and manufacturing (CAD/CAM) has substantially altered the craniomaxillofacial reconstruction field. The preoperative creation of a patient-specific (customized) reconstruction material can reduce the need for intraoperative modification and adaptation; hence, operation time is shortened(9).

In the contemporary literature, only few records demonstrated the results of the orbital wall reconstruction with customized PEEK implant in the maxillofacial trauma field(10). This requires the need for evidence-based development of PEEK implant application in orbital floor fracture reconstructive surgery.

The aim of the study was to evaluate the clinical efficacy and radiographic performance of customized PEEK implant in the management of patients with orbital floor fracture

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## MATERIALS AND METHOD

The prospective clinical trial was conducted on nine patients suffered from orbital floor fracture who were indicated for surgical intervention over a period from august 2020 to June 2021. Patients were recruited from the Outpatient Clinic of Alexandria University Teaching Hospital and operated in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University. The Ethical Committee of the Faculty of dentistry Alexandria University approved the study protocol. Full detailed consents were collected from the patients who had been involved in the study.

Patients’ selection criteria

Participated patients suffered from unilateral or bilateral orbital floor fractures or associated with other orbito-zygomatic complex fracture and indicated for open reduction and internal fixation. This study involved adult patients with no gender predilection that agreed to present for follow-up visits for a minimum postoperative period of 3 months. Patients suffered from monocular diplopia or enophthalmos more than 2 mm were also included in the study. Patients with old orbital floor fracture, medically compromised patients, or patients with globe rupture were excluded from the study.

Sample size estimation

Sample size was estimated based on the following assumptions: alpha error= 5% and study power= 80%. Sample size was calculated to be 9 patients.

**Materials**

Polyetheretherketone (PEEK) Disk: it is a semicrystalline-polyaromatic linear polymer (breCAM disk by BioHPP®: Tapton Park Innovation, Brimington road, Germany)

2.0 mini screw, with lengths that range from 5 to 7 mm and plates if needed (JEIL Medical Corporation Company: Seoul, Korea).

Preoperative assessment

Full personal data was obtained, along with the circumstances of the traumatic event, like cause, time, place, and type of assault. Past medical and dental history were recorded for patients, along with a full appraisal for the general state of health. Patients were inspected for any swelling, flattened cheek, circumorbital ecchymosis, subconjunctival hemorrhage, or nose bleeding. This close inspection was to record any ocular problems such as restricted eye movements, altered globe level, lowering of the pupil level, diplopia, reduced visual acuity, and Enophthalmos. A subjective evaluation for the sensation in distribution of infraorbital nerve was performed. Preoperative Computed Tomography scan (CT-scan) was preformed to all patients to show orbital wall defects with herniation of orbital soft tissue into the maxillary sinus (Figure 1).

Preoperative virtual planning

Planning was accomplished using highly detailed CT, Digital Imaging and Communications in Medicine (DICOM) format, and segmentation software (Materialise innovation suite NV, Belgium).

The fracture segments were then virtually repositioned and reduced anatomically using the simulation module in the designing software. Virtual reduction of the anatomically reduced orbital floor was verified and checked in the axial and coronal planes. A patient specific implant was planned on the simulated reduced orbital floor with 0.6-0.9mm thickness with smoothening and roundation of the edges (Figure 2). The image was transferred in a Standard Template Library (STL) format to a specialized software that operates on a milling machine to mill the sheet from a PEEK disk. (MC X5: Dentsply Sirona Susquehanna Commerce. W. Philadelphia Street, USA)

Operative procedure

All patients were treated under general anesthesia using nasotracheal intubation, and in supine position. The surgical field was scrubbed with povidone-iodine surgical scrub solution, followed by draping of the patient with sterile towels exposing only the area of surgery. A forced duction test was done before releasing the entrapped tissue. Fracture line was exposed through transconjunctival or transcutaneous approach to gain access to the orbital floor and infraorbital rim according to the associated facial injuries and fractures. Dissection of the orbital floor up to the posterior edge of the floor fracture releasing the contents that was herniated into the maxillary sinus including inferior rectus muscle, followed by bone reduction into proper anatomical position. A forced duction test was done after release of entrapped tissue to ensure complete release. The customized PEEK implant was inserted and fixed using mini screws. Suturing of the wound was done (Figure 3).

All patients were instructed to apply ice pack extra-orally starting immediately postoperatively for 12 hours. Postoperative antibiotic, anti-inflammatory and analgesics were prescribed.

Clinical follow-up

A thorough follow-up was performed after 24-hours, one week, four weeks and six weeks for the assessment of the following clinical parameters. Postoperative pain was assessed through a 10-point Visual Analogue Scale (VAS). (0-1= None, 2-4= Mild, 5-7= Moderate, 8-10= Severe). The sutured wounds were examined for signs and symptoms of infection including swelling, redness, hotness, pus discharge, and pain.

Subjective assessment of sensory function of the infra orbital nerve by asking the patient about any alteration in sensation in the cheek-midface region. Objective assessment by using a Pin prick test (nociceptive method). The specific sites included mid-way of the dimensions of lower eye lid, middle of the lateral part of the nose, middle portion of the upper lip and middle of zygoma. Postoperative edema was detected according to the presence or absence of occlusion of the palpebral fissure. Ocular motility and diplopia were assessed using the "follow my finger" test. Postoperative ocular complications were reported such as the presence of ectropion, entropion, enophthalmos, scleral show, corneal abrasion or impairment in eye movements.

Radiographic evaluation

Immediate postoperative CT scan was performed for the assessment of reduction and fixation accuracy, and to confirm the adequate anatomical implant placement and the complete release of the orbital content along with the lack of orbital soft tissue herniation into the maxillary sinus.

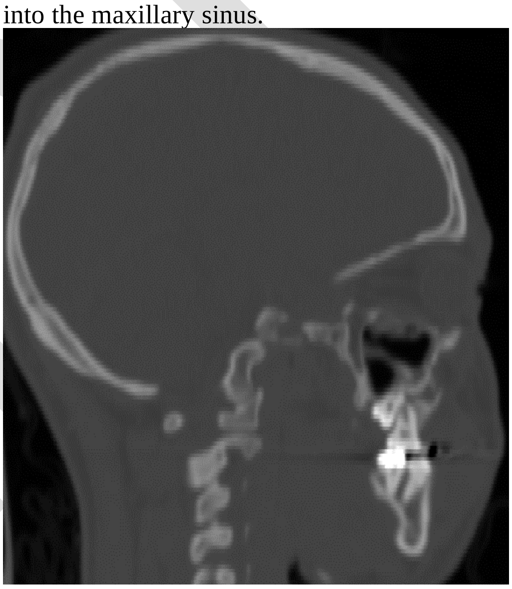

Figure (1): Radiographic picture showing preoperative Computed-Tomography Scan (sagittal Cut).

Figure (2): Radiographic picture the preoperative Virtual planning of the PEEK orbital sheet.

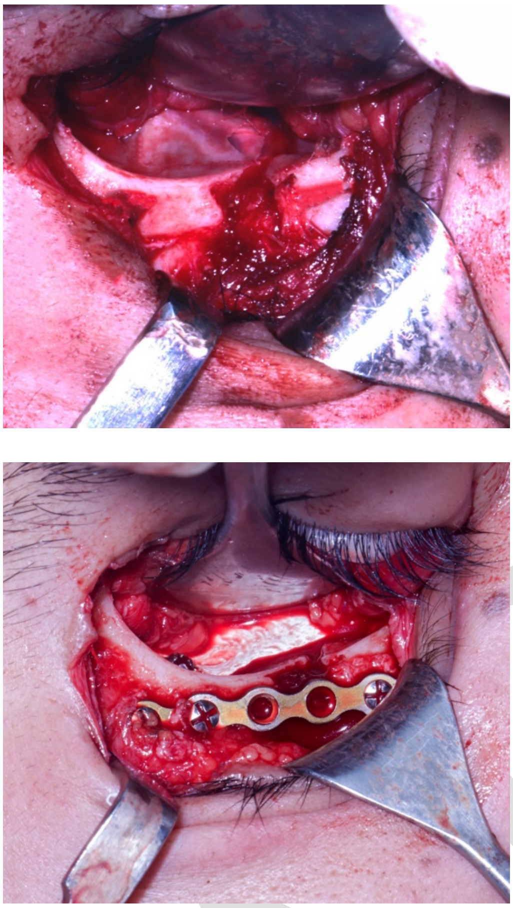

Figure (3): Photographic picture showing: A, a displaced inferior orbital rim with orbital floor defect. B, fixation of the fracture and placement of the PEEK sheet.

## RESULTS

Cases epidemiology and demographic data

A total of 9 patients were enlisted in this study. The patient's mean age was 31.78 ± 13.38 years with a male to female ratio of 1.25:1. A cojoined prevalent fracture etiological factor was reported in this study, where each Road Traffic Accidents (RTA) and Inter-Personal Violence (IPV) were proclaimed in four cases respectively (44.4%). On the other hand, Claimed Fall was reported in only one case (11.1%). Seven of the enrolled cases in this study suffered from a zygomaticomaxillary complex fracture, while only two cases were presented with a blowout fracture (22.2%). Table 1 presents the summery of this study demographic data

Clinical Evaluation Data

Regarding the postoperative pain sensation, a highly statistically significant decrease in the level of the reported pain sensation across the follow-up period was recorded ($p<0.001$). Only one Patient complained from swelling and pus draining from the sutured wound at the second follow-up period. The patient was managed with draining of the entrapped pus, following by bacterial culture swab for specific antibiotic prescription, which was administered for 2 weeks. At the latter follow-up session, the wound was free from any signs of infection and the patient didn't report any symptom. The statistical analysis of the results over the whole study for all patients was statistically insignificant (Figure 4 a).

Six out of the enrolled nine patients in this study reported a subjective abnormal sensation in the course of the affected infraorbital nerve at the first follow-up period. This was objectively confirmed by pin prick nociceptive test in all of the specified points. All of the affected patients regained normal sensation by the end of the fourth postoperative week. The change in the function of the infraorbital nerve across the follow-up period was highly statistically significant ($p<0.001$).

The state of the postoperative edema was determined by the presence or absence of occlusion of the orbital fissure. In the immediate postoperative follow-up setting, 55.6% (n=5) of the patients were affected by totally occluded lateral orbital fissure. two out of the five affected patients regained normal fissure morphology in the consecutive follow-up period. All of the patients regained normal outline of the tarsal plates by the end of the fourth postoperative week.

The statistical appraisal showed that a 55.6 % (n=5) of the patients complained from discrete drawbacks. By the end of the follow-up, eight out of nine patient showed normal ocular signs and symptoms while only one subject retained impairment of ocular motility as a permeant ocular complication. This patient suffered from an impaired ocular motility since the preoperative assessment. An ophthalmic consultation was performed and confirmed an injury of the abducent nerve. The difference of the rate of postoperative ocular complications was statistically significant over the follow-up periods ($p=0.036$). A descriptive graph for the postoperative ocular complications is presented in Figure (5). The radiographic evaluation showed the proper reduction and peek implant outline in the immediate postoperative CT (Figure 4 b).

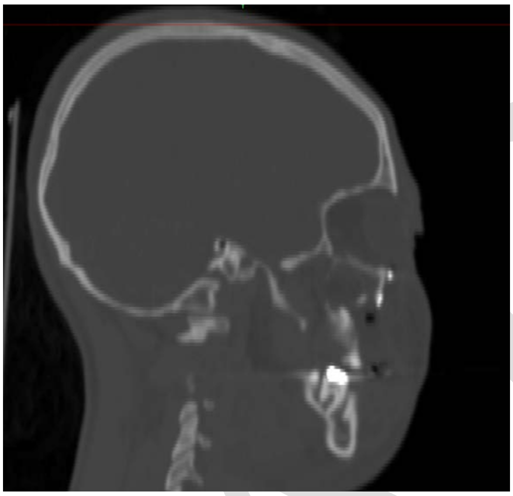

Figure (4): Photograph showing: A, six weeks postoperative clinical picture. B, Immediate postoperative radiographic picture (sagittal Cut).

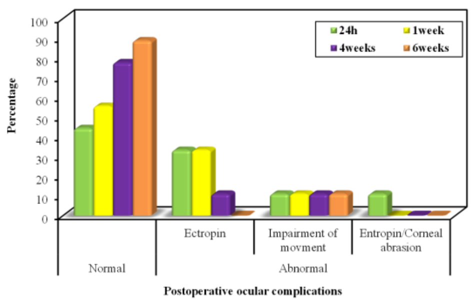


Figure (5): Comparison between the different studied periods according to Postoperative ocular complications (n = 9).

Table (1): A Summary of the study demographic data (n = 9).

| | No. | % | | No. | % |
|---|---|---|---|---|---|
| Sex | | | Etiology | | |
| Male | 5 | 55.6 | RTA | 4 | 44.4 |
| Female | 4 | 44.4 | IPV | 4 | 44.4 |
| | | | Claimed Falls | 1 | 11.1 |
| Age | | | Type of Fracture | | |
| Min. – Max. | 18.0 – 55.0 | | ZMC | 7 | 77.8 |
| Mean ± SD. | 31.78 ± 13.38 | | Blowout | 2 | 22.2 |
| Median (IQR) | 26.0 (21.0 – 43.0) | | | | |
| Site of Fracture | | | Utilized Incision | | |
| Right | 4 | 44.4 | Sub tarsal | 6 | 66.7 |
| Left | 5 | 55.6 | Transconjunctival | 3 | 33.3 |
| Associated Fracture | | | Peek Thickness | | |
| Negative | 6 | 66.7 | 0.70 | 7 | 77.8 |
| Positive | 3 | 33.3 | 0.90 | 2 | 22.2 |
| Right parasymphyseal | 1 | 11.1 | | | |
| Symphyseal & subcondylar | 1 | 11.1 | | | |
| Frontal bone | 1 | 11.1 | | | |

IQR: Inter quartile range
SD: Standard deviation
ZMC: Zygomaticomaxillary Complex
RTA: Road Traffic Accident
IPV: Inter Personal violence

## DISCUSSION

A scientific controversy on the clinical efficacy of a plethora of reconstructive material for orbital defects arises owing to the deficiency in randomized trials and the continuous evolution in the innovative Computer Aided Designing/Computer Aided manufacturing (CAD/CAM) and rapid prototyping technologies (11). The orbital floor has a unique topographic architecture that complicates the process of its reconstruction. The use of malleable hardware with a Pre-bending measure is one of the recent iterations in order to decrease the complexity of the reconstructive procedure. The use of a custom made, patient-specific orbital implant is a contemporary approach to the orbital reconstructive field with numerous advantages (12)

Poly Ether Ether Ketone (PEEK) is a thermoplastic polymer with various application in the medical field owing to its biocompatibility and favorable mechanical properties. Its capability to be milled into the desired geometrical configuration with minimal thickness without losing its properties makes PEEK a desirable material for the creation of Patient Specific Implants (PSI) (13). Hence, this work was aimed at clarifying the clinical and radiographic performance of customized PEEK orbital sheet in the management of floor fracture.

The interpretation of the demographic data in this study exhibited a mean age of 31.78 ± 13.38 years, and a male to female ratio of 1.25:1. These outcomes are comparable to the demographic analysis performed by Ellis et al (2004) in his assessment of zygomaticomaxillary complex fractures (14). In a similar manner, the demographic results are also analogous to those reported by Khojastepour et al (2020) regarding the prevalence of orbital blow-out fractures (15).A literature unanimity is found regarding the most prevalent age for facial trauma, ranging from 20-30 years old, which is the young adults age group (15, 16)The higher rate of day to day endeavors and the higher engagement in laborious activities may explain the susceptibility of this age group to traumatic events.

Despite having a higher male than female population in this study, the reported male to female ratio was lower than the published range, which spread between 2:1 to 4:1 (17-19). The high number of affected female patients in this study could be corelated with the study reported etiological factor, where more than half of the cases reported claimed falls and Interpersonal Violence (IPV) as the cause of the traumatic event.

Clark et al (2014) did a study to demonstrate an underappreciated orbital fractures etiological factor in the female population manifested as domestic violence. They reported a 20% of IPV as the reported orbital trauma etiology, among which 7.6% of the cases documented an intimate partner as the culpable factor(20). Goldberg et al (2000), states that the presentation of orbital fracture is one of the identifiable expression of domestic abuse (21) Furthermore, a high index of cynicism should be given to female trauma patients with IPV disclosure.

44.4% of the cases reported Road Traffic Accidents (RTA) as the trauma causative element. A higher reported prevalence of RTA, especially in ZMC fractures is reported in the literature (18, 19, 22, 23)Yamsani et al (2012) conducted an epidemiological appraisal for 101 cases with ZMC fractures, where RTA was the predominant etiological factor with 76 % (23).Concurrently, personal assaults and low-energy blunt traumas are a recurring orbital floor etiological factor (24).Sun et al (2015) reported that in 85% of cases with orbital floor fractures is manifested due to an assault incidence (25).

The contiguous location of the orbital floor with the zygomatic-maxillary complex is responsible for several orbital complications and need for reconstruction when a ZMC fracture occurs. For this reason several authors prefer the alias orbito-zygomatic fracture (26). In a retrospective five-year analysis for ZMC fractures, ALI (2020) reported that 45% of the ZMC fracture patients suffered from orbital floor defects, however only 20% required reconstruction. Ellis demonstrates that orbital floor defects larger than 1 cm require a reconstructive mindset (27).

A concomitant facial fracture site was reported in 33.3% of the cases. Blumer et al (2018) reported 40% of their studied ZMC fracture cases to be presented with a supplementary fracture (28). The variance in the reported percentage of the associated fracture is probably as a result of the difference in the number of studied patients. In all of the three reported cases, the traumatic event was a cause of an RTA with a high energy of impact. The mechanism of impact clearly is reflected in the presentation of the sustained fracture in the body. High-energy RTA is consistent with the occurrence of devastating multiple facial fracture sites. Peltola et al (2014) reported that a multiple fracture line is encountered in 56 % of the trauma cases caused by a traffic-accident. Over and above, RTA are even consistent with the occurrence of associated non-maxillofacial fractures, which reached in the literature as high as 45.5% of the cases (29). Once again, this all could be correlated to the high-energy impact and sheer dragging force that occurs in RTA.

This study opted for a solid, non-porous, PEEK sheet design with a 0.70 to 0.90 mm range. This design was compatible to that proposed by Goodson et al (2012) and Chepurnyi et al (2021) (9, 30). The most commonly utilized alloplastic material for orbital reconstruction, the stock titanium mesh comes with a 0.4 mm thickness. However this minimal thickness is to allow the operator to preadapt the mesh to the innate and bizarre anatomical configuration of the orbit (31).On the other hand, a customized patient-specific hardware does not need an operative-modification, and they meticulously fit the anatomical configuration of the orbit.

Furthermore, the rigid nature of the polymer requires a minimum thickness in order to evade deformation.

There is a consensus about the minimum producible thickness of PEEK material using milling machines, which is based on the manufacture recommendation is 0.4 mm (9, 30, 31). Sharma et al (2021) conducted a computational finite element orbital model to test the durability and maximum deformation values for different thicknesses and porosity of PEEK orbital sheets (32). They conducted that the solid, non-porous, configuration possess the least deformation and maximum durability when compared to the different sheets with different porosity configurations. Regarding the sheet thickness, an inverse correlation was noted, where a less marked deformity is reported with gain in implant thickness (32). The chosen configuration in this study showed perfect fit in all of the cases while at the same time attain its shape and integrity across the recorded follow-up period, verified by its clinical and radiographic performance.

An excellent PEEK orbital sheet clinical performance was reported in this study. A similar outstanding clinical performance was observed by Chepurnyi et al (2021), where they reported a one-year follow-up period (9). PEEK own a distinguished inertness and chemical resistance which make it a compatible alloplastic material that could handle both the sinus mucosa and the orbital environment with great success (33). Wang et al (2021) even reported an antibacterial effect for the PEEK material, making it a more favorable reconstructive option for orbital defects (34). Furthermore, the PEEK sheet is capable of handling several cycles of the heat and moist sterilization process while attaining its convenient physical and mechanical properties (9, 31, 33)

Transient paresthesia in the ramification course of the infraorbital nerve was reported in the first follow-up period, however by the end of the follow-up period all of the investigated subjects regained normal sensation. The infraorbital nerve is in a vulnerable position to injury or entrapment within a collapsed infraorbital canal during orbito-zygomatic fracture. Beigi et al (2017) states that infraorbital nerve neuralgia is an overlooked symptoms in patients with traumatic disruption of the orbital skeleton. Risk of bony canal and nerve adhesion from neglected surgery comes with associated long-term behavioral changes and quality of life affection (35). Proper release of the entrapped orbital content and nerve decompression is an imperative procedure during orbital reconstruction.

The regain of normal sensation in all of the cases reported in this study is indicative of a proper surgical reduction and manipulation during the release of the orbital floor content, along with the nerve-compatible behavior of the PEEK sheet. This is further clarified by Ozer et al (2016), where they stated that an accurate reduction is needed to achieve infraorbital nerve recovery (36).

In this study both the subtarsal and the transconjunctival approaches was utilized to access the orbital floor. In an electronic literature search, Bronstein et al (2020) found that both the transconjunctival and the transcutaneous approaches are safe to be used in orbital floor reconstruction with non-significant difference regarding the rate of complications (37).

Postoperative periorbital edema was assessed by the degree of occlusion of the palpebral fissure. All of the patients reported sever edema in the first follow-up period, where five of them appeared with total occlusion of the palpebral fissure. In a study regarding the lymphatic drainage of the periorbital tissues, Dickinson and Gausas (2006) declared that the main superficial and deep lymphatic draining ports assembles at the canthus lymphatic vessels, which causes the postoperative edema to be manifested as occlusion of the palpebral fissure (38).

A correlation could be found between the degree of immediate postoperative edema and the approach utilized. In this study, all the patients in which a transconjunctival approach was utilized developed an occluded fissure in the first postoperative follow-up period which was prolonged for the first postoperative week and showed improvement by the end of the observational period. A similar statement was reported by El-Anwar et al (2017), where they reported a severe postoperative edema with the transconjunctival approach that didn’t persist across the follow-up period (39). The increased retraction rate and the need for lateral canthotomy which may transverse the lymphatic derange of the periorbital tissues may be culpable for the slower rate of edema resolution.

A high rate of postoperative ocular complications was reported in the first follow-up period (55.6 %), however since the majority of the complications were related to the tarsal plate position, ectropion or entropion, only 11.1 % persisted past the observational follow-up period. This reported 11.1 % was as a result of a globe motility disorder. An approximate report was declared by Chepurnyi et al (2019), 15.8%, and Zieliński et al (2017), 13% (40). Despite that, the only reported case with impairment of eye movement in this study was as a result of neurological affection of the abducent nerve and not as a result of any mechanical impairment.

In this study, none of the patients showed postoperative diplopia at any interval across the follow-up period. This comes in dispute with the outcome reached by Zimmerer et al (2016), 24.6%, and Chepurnyi et al (2020) 29.4% (24,35). Proper release of the entrapped tissue is crucial for the management of patients with entrapment-diplopia. In the sample collected in this study, none of the patients showed a preoperative diplopia and the placement of the less than 0.9 mm PEEK sheet seems to possess no detrimental effect on the action of the extraocular muscle.

PEEK owns a convenient characteristics for the PSI manufacturing processes, with either a milling machine or an extrusion additive rapid prototyping technology (32). PEEK is a contemporary reconstructive option for the management of orbital defects. It is a thermoplastic, semicrystalline, non-porous alloplastic material with favorable mechanical characteristics, easy manufacturing and high biocompatibility (9). PEEK as orbital floor substitute offers a plethora of advantages, such as its durability, chemical resistance, and radiographic translucency. In comparison to the most common alloplastic orbital substitute, PEEK offers a lighter weight and compatible modulus of elasticity. However its main added benefit is its easy of manufacturing and customized nature (9),(31)

The patient specific PEEK orbital implant as a reconstructive option is not free from drawbacks. The long preoperative processing time makes its use in primary orbital reconstruction more difficult, as several trauma centers recommend prompt management of traumatic orbital events. This may explain the long-proven popularity of the customized PEEK hardware in the management of delayed entrapment orbital complications and enophthalmos correction (13, 30) . Furthermore, the use of a CAD/CAM manufactured PEEK alloplastic material comes with added financial load on the patient when compared to the stock titanium mesh.

Conclusion

Taking this study limitations in consideration and based on the favorable clinical and radiographic performance, it may be conducted that the utilization of the patient-specific PEEK sheet in the management of orbital floor defects is an exemplary reconstructive alternative with superb compatibility, great surgical precision and predictability. A customized PEEK orbital implant showed a comparable clinical efficacy to the commonly utilized alloplastic materials in orbital floor reconstruction. On the other hand, the use of customized orbital implant comes with an increase in the processing time and financial burden on the patient.

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