PEEK Patient-Specific Implants in Orbital Reconstruction: A Prospective Analysis of Accuracy

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ABSTRACT

The management of orbital wall fractures in maxillofacial surgery poses a challenge due to their frequent occurrence and complexity, resulting in both aesthetic and functional complications. Recent advancements in computer-aided design/computer-assisted manufacturing, virtual surgical planning, and 3D printing have streamlined the development of Patient-Specific Implants (PSIs). Among these materials, Polyetheretherketone (PEEK), a biocompatible thermoplastic polymer with properties resembling human cortical bone, proves particularly suitable for PSIs. Another technological solution, surgical navigation, has been reported to reduce overall operation time in complex anatomical areas, enhancing procedural reliability. This review aims to investigate the accuracy of patient-specific implant placement in orbital reconstructions using customized PEEK implants, with and without the use of a navigation system. A retrospective evaluation of 10 orbital fracture patients (5 with navigation and 5 with a freehand technique) demonstrated favorable outcomes, showcasing consistent accuracy. Both groups demonstrated satisfactory translational accuracy and mesh percentage with surface distance less than 2.00mm of PEEK implants, with no significant differences observed between navigation and freehand techniques. In terms of rotational accuracy, although the non-navigated group exhibited slightly higher differences in yaw and roll, these variances were not statistically significant compared to the navigated group. In conclusion, this review affirms that PEEK PSIs yield positive outcomes for reconstructing orbital defects according to the planned approach. Besides, use of navigation system was non-mandatory to satisfactory results due to “one-fit” characteristic of PSI, although non-detrimental and capable to enhance surgeon's confidence.

INTRODUCTION:

The management of orbital wall fractures poses a significant challenge in the field of maxillofacial surgery, given their high frequency and complexity, leading to aesthetic and functional disorders[1,2]. Surgeons face the crucial task of reconstructing these defects optimally while minimizing surgical time, to enhance patient outcomes and overall well-being[3].

Over the years, diverse procedures, therapeutic algorithms, and materials have been developed and tested in the realm of orbital reconstructions. Biomaterials employed in these procedures encompass autologous bone grafts[4], resorbable materials[5], and various form-stable alloplastic materials, with a particular emphasis on titanium[6].

Since 1995[7], the advent of computer-aided design/computer-assisted manufacturing (CAD/CAM), coupled with advancements in virtual surgical planning (VSP) and 3D printing, has facilitated the creation of patient-specific implants (PSI). These implants can be meticulously designed, produced, and precisely fitted into anatomical defects[8, 9]. Polyetheretherketone (PEEK), a biocompatible and bioinert semi-crystalline organic thermoplastic polymer, possesses mechanical properties similar to human cortical bone, making it well-suited for the fabrication of PSIs[10-12].

Regarding the aid of PSI implants and beneficial materials, the reconstruction of substantial defects may still present difficulties, especially when crucial anatomical landmarks are lost, such as the posteromedial orbital bulge and orbital apex[13]. This difficulty may arise, in part, from treatment by less-experienced surgeons, especially in cases where damage affects the posterior orbit. Reconstruction of this area is notably complicated, due the risks associated with manipulation and the limited visibility. In this context, surgical navigation (SN) has been reported to decrease the overall operation time in complex anatomical areas, thereby enhancing the reliability of the procedure[14-16].

Clinical outcome studies and accuracy comparisons have consistently affirmed the advantages of PSI in orbital wall reconstruction[17–21]. Additionally, the utilization of intraoperative navigation for the precise placement of PSI is recommended to attain optimal results[19, 22–24]. However, the assessment of prior studies primarily depended on comparisons of the restored orbital volume and/or angular deviations between the

reconstructed orbit and the unaffected contralateral orbit. These evaluations did not independently consider the positioning of PSI as a determining factor[25] or investigate this accuracy with the use or absence of a navigation system.

This review aims to investigate the accuracy of patient-specific implant placement in orbital reconstructions using customized PEEK implants, with and without the use of a navigation system.

METHODS

Ethics

This study adheres to the guidelines and code of conduct established for clinical reviews by the National Health Service of the United Kingdom Our study complies with the ethical principles outlined by the declaration of Helsinki published by the World Medical Association. This retrospective service evaluation was approved by the Sheffield Teaching Hospitals' Clinical Effectiveness Unit (project ref 9773).

Data Collection

Complex orbital trauma cases which were referred to the regional joint orbital trauma and managed with PEEK implant orbital reconstruction between January 2014 and February 2020 were reviewed. This reflects the period in which two surgeons (one Maxillofacial and one Ophthalmic surgeon trained in orbital surgery) worked collaboratively. Data was retrieved from patient records stored at Sheffield Teaching Hospitals NHS Trust. At all, 11 patients were identified. One case was excluded due to the patient receiving a magnetic resonance imaging (MRI) scan post-operatively, rather than CT scan. This was due to the discovery of a soft tissue lesion intraoperatively. A post-operative MRI scan was deemed more appropriate.

Implant design and manufacturing

All 10 patients included in the case series underwent either thin slice (0.9mm) CT scanning or cone beam computed tomography (CBCT) scanning of the orbits pre-operatively. The data was acquired in Digital Imaging and Communications in Medicine (DICOM) format. This was uploaded via secure server and the data subsequently tracked

using linked-anonymized planning numbers. Virtual surgical planning was undertaken through a collaborative approach between the operating surgeons and clinical engineer using ProPlan CMF (Materialise, Leuven, Belgium). During the VSP the unaffected orbit was digitally mirrored and used to restore the damaged anatomy on the affected side. This acted as a template on which an orbital patient-specific implant was designed. Implants were manufactured by DePuy Synthes, (Oberdorf, Switzerland) and shipped to the UK.

Prior to surgery, in 5 of 10 cases, the simulated implants were digitally imported in their CT-planned position as a segmented Standard Tessellation Language (STL) format file, for use in surgical navigation (SN) using the BrainLab Navigation System (BrainLab, Munich, Germany).

Surgical procedure and follow-up

All 10 operations were performed under general anaesthesia by the same two surgeons, both present for all cases. PEEK implants were sterilised as per manufacturer's instructions (DePuy Synthes, Oberdorf, Switzerland) prior to surgery. All patients received a single dose of intravenous co-amoxiclav 1.2g pre-operatively, and implants were soaked in gentamycin 80mg immediately before insertion. All implants were inserted via a transconjunctival approach which was extended retrocaruncularly and/or with lateral canthotomy for wider implants, except for a single interlocking implant, which was inserted via a transconjunctival and intraoral approach. The margins of the implants were adjusted intraoperatively, by using an acorn 4mm burr to shave the impante as necessary, although no modification was made on the VSP-planned fitting surface. Once the orbital implant was inserted, BrainLab navigation was used in 5 cases to confirm satisfactory positioning by comparing the surgically-achieved position to the VSP position. The implants were secured in place with Matrix Midface titanium screws (DePuy Synthes Oberdorf, Switzerland) through the pre-planned holes. Postoperatively, patients were kept under observation for at least 24 hours prior to discharge. All patients were discharged on a 5-day course of oral co-amoxiclav 625mg and topical chloramphenicol eye ointment used 4 times a day for 2 weeks and followed up for a minimum of 6 months.

PSI Accuracy:

The outcome describes the geometric deviation between the virtually planned and the postoperative PSI position and rotation, as previously performed[25]. Postoperative CT scans were segmented with Mimics (Materialise, Leuven, Belgium), and exported as STL files into 3-matic (Materialise, Leuven, Belgium), dedicated CAD analyzing software. Corresponding STL files representing the initial virtual planning were provided by the industrial partner (DePuy Synthes Oberdorf, Switzerland) and imported as well. The midfacial bone parts of the pre-and postoperative datasets were aligned using a semiautomatic fusion algorithm, initially through a 3-point alignment procedure before global alignment. The geometric deviation between the virtually planned and postoperative PSI position and rotation (Fig. 2) was assessed by surface distance as well as translational and positional differences:

Mesh with surface distance less than 2mm: Reported in percentage, representing the overall 3D geometric deviation. The "Part Comparison Analysis" command set in the 3-matic software was used for this measurement. This point-based algorithm assigned each surface point of a virtually constructed PSI to the closest point of the corresponding postoperative PSI model, measuring the respective Euclidean distances. Mean unsigned (absolute) distances were recorded. A separate evaluation determined the percentage of points with less than 2mm between the planned and achieved PSI.

Translational Accuracy: Reported in mm in the x-, y-, and z-axis at centroid corresponding point on the virtual PSI and the postoperative PSI model. This reference point is obtained as a mean of the coordinates of 4 extreme points at the implant margins: the anterior part, mid-lateral part, mid-medial part and posterior part. To avoid the observer bias, a “reversed” routine developed by Xia et al.[26] and Hsu et al.[27] was used to ensure the correspondence of landmarks between the planned and the postoperative The x-axis corresponded to transverse (lateral/medial), the y-axis to sagittal (anterior/posterior), and the z-axis to axial (cranial/caudal) alignment. Unsigned (absolute) values representing overall accuracy.

Rotational Accuracy: Reported in degrees in the x-, y-, and z-axis as a difference between corresponding lines on the virtual PSI and the postoperative PSI model. One reference line is obtained between the mid-lateral and mid-medial points to evaluate the

roll and yaw discrepancies, another between the anterior and posterior point was used to evaluate the pitch discrepancies. To avoid the observer bias, the same “reversed” routine yet described was used. The x-axis corresponded to pitch (lateral/medial), the y-axis to roll (anterior/posterior), and the z-axis to yaw (cranial/caudal) rotation. Unsigned (absolute) values representing overall accuracy.

Statistical Analysis:

The data related to volumetric and accuracy analysis were tabulated using Microsoft Excel software (Microsoft Corporation. Microsoft Excel [Internet]. 2018) and subjected to statistical analysis using IBM SPSS Statistics 20 (SPSS Inc., Chicago, IL, USA). All variables present in each group underwent the Kolmogorov-Smirnov normality test to assess their distribution. Data were presented with timely descriptive statistics according to the normality test, with median and IQR for non-parametric data. In case of non-normal distribution in any variable during the same kind of analysis, all data were presented as non-parametric. Accuracy was assessed using Tukey-Hinges interquartile ranges (IQR) or 95% confidence interval. To compare groups with and without navigation, Mann-Whitney U test were utilized.

RESULTS

This cohort of 10 patients comprised 7 males and 3 females, with a mean age of 38 years (22 – 53). All 10 patients sustained trauma resulting in a unilateral large orbital floor fracture, causing significant globe displacement, cosmetic deficit and functional problems such as diplopia in primary position, which 8 were treated as isolated orbital floor fractures, 1 medial and orbital floor fracture and 1 zygomatic complex fracture – 8 affecting the right orbit and 2 affecting the left. About tomography acquisition, 8 patients had conventional CT scans and 2 had CBCT scans pre-operatively. Post-operatively 9 patients had conventional CT scans and one had a CBCT. Three patients had a different pre-operative/planning scan to their post-op scan (i.e. a CBCT pre-op and a conventional CT post-op or vice versa). Regarding the surgical intervention, in 7 cases the placement of a PEEK patient-specific implant was the primary surgery to repair the orbital floor fracture, 2 cases it was the secondary surgery and in 1 case it was a tertiary operation. As previously described in methodology, the position of the PEEK patient-specific orbital implant was confirmed with Brain Lab navigation at the time of surgery in 5 cases. The fracture complexity presented a mean of 5,11 cm^3, where the case with less complexity showed 1,70cm^3 of difference between the orbits and the most complex reveals 11,00cm^3 (Table 1).

About translational accuracy of peek implants, sagittal axis was that presented the biggest difference between VSP and final position, in the navigation group: 1.72 (IQR 0.76 – 1.87mm). Already, in the freehand group, the most imprecise results were found in transversal axis 1.06 (IQR 0.88 – 1.81mm). Rotational results of navigation group shown the worse result regarding yaw 2.13 (IQR 1.68 – 4.02°). Thus, the freehand group shows suboptimal results regarding roll 3.81 (IQR 2.77 – 5.73°) and yaw 5.37 (IQR 1,44 – 6,43°). The accuracy also was evaluated considering the mesh percentage with surface distance less than 2.00mm and both groups showed good results, 97 (IQR 97–99%) with use of navigation system and 95 (IQR 94–98%) without. Although the better results about rotational accuracy in navigated patients, when these two groups were compared regarding all PSI accuracy aspects, none statistical difference was realized (Table 2).

DISCUSSION

The primary objective in reconstructing the orbital walls is to restore the premorbid bony anatomy[24]. Advances in technology have enabled increasing degrees of accuracy in the treatment of orbital deformities, based on the anatomy of the unaffected side[28, 29], PSI provides the best chance for optimal reconstruction of the orbital anatomy[30].

To accurately restore the relief, it is crucial to place the PSI exactly in the position that was intended in the virtual setting. In 2021, Probst et al.[25] realized a study to assess the accuracy with which CAD/CAM-fabricated patient-specific titanium implants (PSI) are positioned for inferior and/or medial orbital wall reconstruction without the use of intraoperative navigation through single linear deviations in the x-, y- and z axis at corresponding reference points between virtually planned and postoperative PSI position. This cohort reveals for the orbital floor, unsigned (absolute) linear deviations (median values) between the planned and the postoperative implant position were 0.79 mm in the x-axis, 0.44 mm in the y-axis and 0.30 mm in the z-axis, which seems clinically acceptable compared to commonly assumed navigation and calibration errors approximately between 1 and 2 mm[31]. Our findings were the same, with all IQR bellow 2 mm in all directions, for both group, without any statistical difference with or without navigation.

Similar to the study by Probst, orbital floor PSI without navigation showed the highest unsigned (absolute) deviations in the x-axis (lateral/medial direction), presumably due to uncertain transversal positioning along the infraorbital rim[25]. This lack of a bony “stop” in the mediolateral plane may allow the implant to rotate into a less accurate rotational position too, without being visually noticeable at the time of surgery. To tackle this issue, the use of tools like intraoperative navigation could be beneficial.

Previous research has not compared angulation with navigation system to the conventional method when using PSI. Although no statistically significant differences were found, this review revealed consistently higher IQR for roll 3.81 (2.77 – 5.73°) and yaw 5.37 (1.44 – 6.43°) rotations in the non-navigation group, exceeding 4 degrees. This 4-degree threshold, established for orthognathic surgery accuracy[32,33], serves as a reference due to the absence of defined limits for rotational accuracy in orbital reconstructions in the existing literature. The pitch rotation, however, exhibited a similar error pattern in both groups. A hypothesis for this is that, even in a correct position, the

implant may be susceptible to pitch rotations due to a lack of passivity during the screw fixation process[6].

CONCLUSION

The findings of this review allow us to assert that PEEK patient-specific implants are an optimal solution for reconstructing orbital defects, proved effective in achieving clinically acceptable accuracy in all directions. While the use of a navigation system could enhance rotational accuracy, it did not show any statistical differences in all comparisons with freehand technique group. Although use of navigation system is non-detrimental and may be beneficial in improving surgeon confidence of correct intra-operative implant placement, it is not deemed essential for achieving satisfactory results when utilizing patient-specific implants due to its well-know “one-fit” characteristic.

FUNDING

Funding was provided by Johnson and Johnson for the postoperative analysis to be performed.

CONFLICT OF INTEREST

The authors declare that there were no conflicts of interest.

ACKNOWLEDGMENTS

The authors acknowledge Katrijn Michielsen of Materialise, Belgium, for her acquisition and analysis of data. Additionally, Razvan-Alexandru Gheorghe of Synthes GmbH, Switzerland for design and manufacture of implants. Finally, they acknowledge IBRA (Basel, Switzerland) for sponsoring the visit of one of these authors, Luis Fernando de Oliveira Gorla, to the Sheffield Maxillofacial department, with this work being analyzed and written as part of the activities related to the fellowship.

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TABLES AND FIGURES

Table 1 – Sample Characteristics. UK, 2023

ID	Age	Sex	Side	Diagnosys	Surgery	Fracture Complexity (mm^3):
1	22	M	R	Orbital floor	Primary	3
2	51	F	L	Orbital floor	Secondary	3,2
3	38	M	R	Orbital floor	Primary	5,3
4	49	M	R	Medial wall and orbital floor	Primary	4,8
5	53	M	R	Zygomatic complex	Secondary	9,3
6	30	F	R	Orbital floor	Primary	1,7
7	44	M	R	Orbital floor	Primary	11
8	23	M	L	Orbital floor	Primary	5,9
9	45	F	R	Orbital floor	Tertiary	4,8
10	27	M	R	Orbital floor	Primary	2,1

M: Male; F: Female; R: Right; L: Left; mm: millimeters

Table 2 – PEEK Accuracy – System Navigation and Free Hand Technic. UK, 2023

Delta	**Axis**	**Navigation System**		**Free Hand**		***p-value*[1]**
		Median	IQR	Median	IQR	
Translational (mm)	Transversal	0,19	0,15 – 0,24	1,06	0,88 – 1,81	0,076
	Sagital	0,88	0,20 – 0,96	0,66	0,14 – 1,22	0,917
	Vertical	1,72	0,76 – 1,87	0,49	0,33 – 0,55	0,175
Rotational (**°**)	Roll	1,97	1,08 – 3,31	3,81	2,77 – 5,73	0,175
	Pitch	2,08	1,34 – 2,71	1,90	1,13 – 2,22	0,917
	Yaw	2,13	1,68 – 4,02	5,37	1,44 – 6,43	0,347
< 2mm** (%)	-	97	97 – 99	95	94 – 98	0,596

[1]Mann-Whitney test, alpha = 0,05.
IQR: Turkey's Hinges interquartile range

FIGURE 1

Fig.1: PEEK Accuracy – Planned vs Postoperative position.