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A method for accuracy of placement analysis on radiolucent polyether-ether-keton facial implants: A case series

M.C.P. Kortman [a], J. Jansma [b], R.H. Schepers [b], C.H. Slump [c], B.J. Merema [d,e], J. Kraeima [d,e,*]

[a] University of Twente, Technical Medical Centre, Multi-Modality Medical Imaging (M3i), Faculty of Science & Technology, Enschede, the Netherlands
[b] Dpt of Oral and Maxillofacial Surgery, Martini Hospital, Groningen, the Netherlands
[c] University of Twente, Technical Medical Centre, Robotics and Mechatronics, Faculty of Electrical Engineering Mathematics and Computer Science, Enschede, the Netherlands
[d] 3D Lab, University of Groningen, University Medical Center Groningen, Groningen, the Netherlands
[e] Dpt of Oral and Maxillofacial Surgery, University of Groningen, University Medical Centre Groningen, Groningen, the Netherlands

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ABSTRACT

Facial asymmetry is defined as a bilateral difference between facial components. Correction, often desired by the patient, can be performed with the aim of bone born patient-specific solid implants designed using 3D CAD software. This treatment is embedded in the daily practice of today's healthcare. However, an analysis of the implant's accuracy of placement has not been reported. This case series describes the accuracy analysis of bone born aesthetic facial implants manufactured out of polyether-ether-ketone (PEEK). The accuracy analysis was based on postoperative (cone beam) computed tomography ((CB)CT) data and preoperative 3D planning. The analysis showed a median entry point error of 0.7 mm (min: 0.1, max: 3.3, interquartile range: 0.78). The median maximal orientation error was 5.5° (min: 0.1, max: 36.8, interquartile range: 7.13). Both parameters showed an excellent intraobserver and interobserver agreement with an ICC above 0.84. The described cases show that the analysis method is an objective approach for determining the accuracy of PSI placement and indicates that these implants can be placed accurately on the osseous face.

1. Introduction

Facial asymmetry is defined as a bilateral difference between facial components and can be caused by trauma, disease or musculoskeletal factors (Choi, 2015; Thiesen et al., 2015). This asymmetry, with an osseous or soft tissue origin, can impair function, decrease facial aesthetics, and have psychological consequences, thereby patients often desire correction (Gerbino et al., 2015). In recent years there has been innovation in reconstruction methods of facial defects (Lv et al., 2022). Nowadays patient-specific implants (PSI), designed using computer-assisted design and manufacturing (CAD, CAM), facilitate correction (Copperman et al., 2021; Hierl et al., 2019). These aesthetic implants are often manufactured from polyether-ether-ketone (PEEK).

In CAD, preoperative computed tomography (CT) or cone beam computed tomography (CBCT) imaging is used to objectify the asymmetry or defect on bone level. From thereon, an implant is designed with a unique fit on the osseous structures. This enables the correct placement of the implant, resulting in the desired surgical outcome (Lv et al., 2022; Sharma et al., 2021). The use of CAD/CAM PSIs over standard implants results in a better fit and logically a better soft tissue response (Anabtawi et al., 2021).

The surgical outcome can be described using different parameters of which patient satisfaction levels, asymmetry metrics, and soft tissue gain are examples (Atef et al., 2021; Lv et al., 2022). These parameters describe the surgical outcome on an aesthetic and functional level. Atef et al. show that soft tissue response is not one-to-one translatable to implant size (Atef et al., 2021). So, the mentioned parameters are not suitable to address the placement accuracy of the PSI. A global analysis of PSI accuracy of placement was performed by van de Vijfeijken et al. (van de Vijfeijken et al., 2019). They calculated a distance map to visualise the deviation. This, however, is difficult due to the radiolucent properties of PEEK.

Precise accuracy of placement analysis has not been performed on PEEK implants. A method to do so has been described for temporomandibular joint (TMJ) implants. The method is more focused on postoperative placement and compares the postoperative screw position

* Corresponding author. 3D Lab, University of Groningen, University Medical Center Groningen, Groningen, the Netherlands.
E-mail address: j.kraeima@umcg.nl (J. Kraeima).

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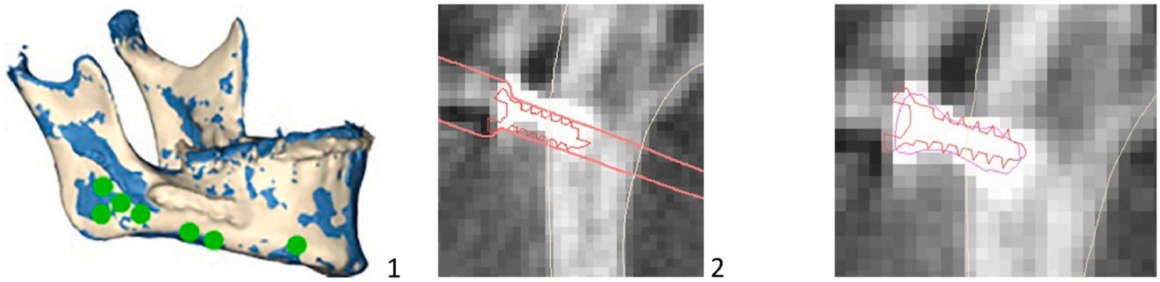


Fig. 1. 1: Visual representation of the postoperative model (blue) matched to the preoperative model (white). The green dots represent the screw positions. 2: Standard triangle language (STL) file of a 1.5 mm screw superposed on the planned screw position. The planned screw position is reassembled by two concentric cylinders. 3: STL file of a 1.5 mm screw superposed on the placed screw position. The placed screw position is reassembled by the purple line.

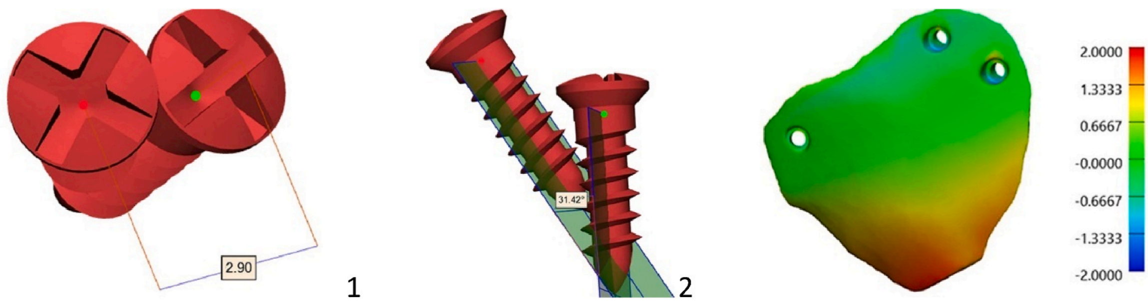


Fig. 2. 1: Entry point error (in mm.) in the plane orthogonal to the planned orientation. 2: Orientation error (in degrees) compared to planned orientation. 3: Distance map of an implant in mm.

and orientation to the 3D virtual planning data (Merema et al., 2021; Weijs et al., 2016).

The aim of this case series is to create literature on the placement accuracy of PEEK PSIs using an objective method for accuracy analysis implants using screw positioning and orientation.

2. Case series

From January 2019 through April 2022 eight patients underwent corrective implant surgery using PEEK implants at the department of oral- and maxillofacial surgery of the University Medical Centre Groningen (UMCG). With their consent the patients' medical records, operative reports, imaging studies, 3D planning, and follow-up data were used. Patients were excluded from the study when (CB)CT or clinical data was missing, the imaging data contained artifacts, or other materials than PEEK were used for the implant.

All patients underwent a preoperative planning CT or CBCT(voxel size 0.4*0.4*0.4 mm) for PSI design. The design was conducted in-house with the active participation of two Oral and Maxillofacial surgeons and under EU- MDR compliance. Initial screw positions were based on the local thickness of cortical bone. PSIs, manufactured by KLS Martin (Tuttlingen, Germany), were milled out of PEEK. During PSI implantation the implant is placed and thereafter fixated using 1.5 or 2.0 mm self-retaining screws (KLS Martin, Tuttlingen, Germany). The screws were placed using the PSI as references, without any further surgical guides.

Accuracy analysis of all implants was performed using a predetermined protocol. First, the osseous area of the implants and surrounding bone and screws were segmented from postoperative imaging data (voxel size 0.4*0.4*0.4 mm) using a multi-threshold-based method in Mimics 24.0 (Materialise, Leuven, Belgium). The lower values ranged from 337 to 696 HU and the upper values from 1447 to 3095 HU. The values were chosen to include the outer border of the osseous structures and exclude the inserted screws. The preoperative and postoperative 3D models of the patient's skull or mandible (with CAD implants) were matched using 3-Matic 16.0's (Materialise, Leuven, Belgium) built-in point-based matching method. Subsequently, the available global match function with a decreasing distance threshold was applied. A 3D model of a 1.5 or 2.0 mm screw was superposed on the location of the planned and placed screws. As can be seen in Fig. 1. The centre of the screwhead was used to determine the entry point error in a plane orthogonal to the planned orientation. The maximum angular displacement was determined using two planes characterising the screw orientation. Finally, a distance colour map was calculated to visualise global displacement. A visual representation of the method is provided in Fig. 2.

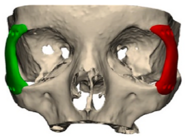
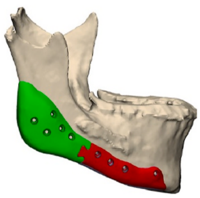
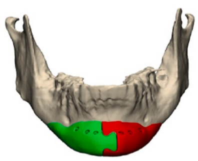
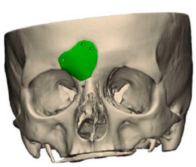
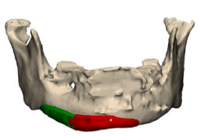
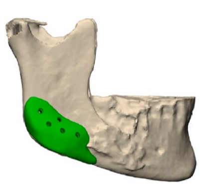
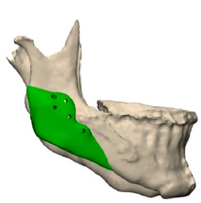
Intra- and interobserver variability was calculated. The observers both superposed the screws on the postoperative scan after which the placement accuracy was determined. The correlation between entry point deviation and angular displacement was calculated.

In this case series eight patients were included. Patient details can be found in Table 1. All but one intervention were uneventful. Before the frontotemporal PSI of patient 5 could be placed the newly formed bone had to be removed. There were no post operative complications described among the included patients. A summary of the results can be found in Table 2. The median entry point error was 0.7 (min: 0.1, max: 3.3, interquartile range: 0.78). The ICC (two-way mixed) of the intra-observer variability was 0.97 with a median difference of 0.1 mm. The median maximal orientation error was 5.5° (min: 0.1, max: 36.8, interquartile range: 7.13). The ICC (two-way mixed) of the intraobserver variability was 0.85. The median difference was 3.3°. Kendall's tau correlation coefficient for the relation between angular and translational displacement was −0.2 ($p = 0.024$). A distance map of all implants was created to study the effect of screw displacement on implant displacement.

3. Discussion

This case series reports the accuracy of PEEK PSI placement using an objective method to assess its accuracy of placement. The analysis shows that the median entry point deviation is less than one mm and that the median orientation error is less than 6°, meaning that it can be applied predictably and accurately in a clinical setting (Kraeima et al., 2018;

Table 1
Patient details.

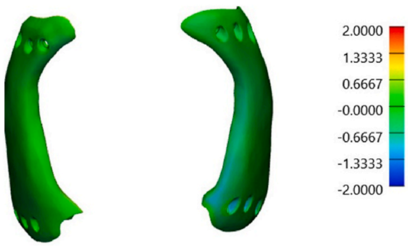
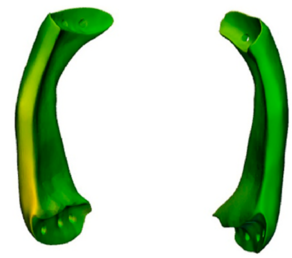
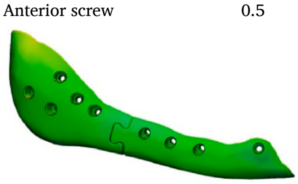
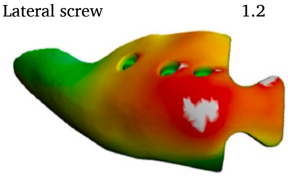
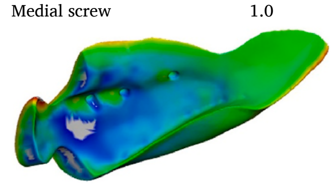
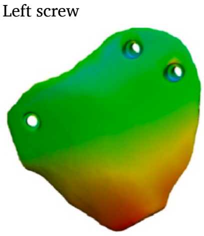
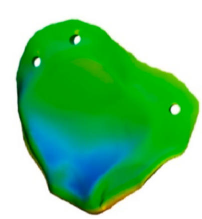
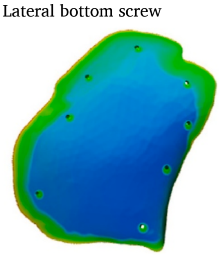
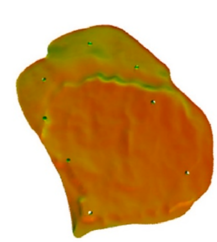
Patient	PSI location	Number of screws	Intervention details and/or indication	Preoperative imaging modality	Number of months to postoperative imaging
1		12	Lateral orbital reconstruction after multiple orbital decompressions.	CT	<1 mo
2		7	Right mandible angle reconstruction after orthognathic surgery.	CBCT	12 mo
3		4	Chin PSI after chin osteotomy.	CBCT	12 mo
4		3	Reconstruction of frontal sinus after complicated frontal sinusitis with Potts Puffy	CT	8 mo
5		5	Frontotemporal PSI after silastic implant removal. The bone at the edges of implant site was rounded	CT	<1 mo
6		5	Chin reconstruction after trauma and reconstructive surgery	CBCT	<1 mo
7		4	Right mandible angle reconstruction after orthognathic surgery.	CBCT	<1 mo
8		4	Right mandible angle reconstruction after orthognathic surgery.	CBCT	8 mo

Merema et al., 2020, 2021).

Looking at the retrieved data there is a negligible correlation between the screw orientation and entry point displacement. Research does suggest that the error when using drilling guides is of the same order of magnitude (Merema et al., 2021). So, there seems no indication for the use drilling guides, provided the surgeons are experienced.

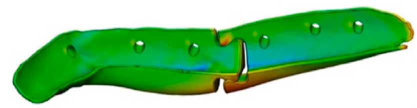
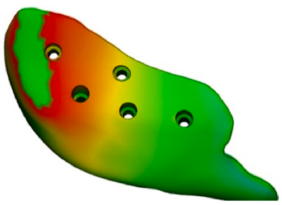
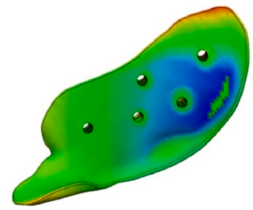
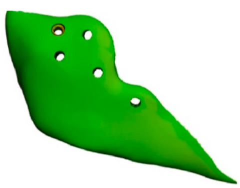
The use of PEEK PSIs is a recent innovation in the field of craniomaxillofacial surgery (Narciso et al., 2021). To analyse the clinical performance of the intervention postoperative assessment of patient satisfaction and soft tissue response was performed by several researchers (Alasseri and Alasraj, 2020; Brandicourt et al., 2017; Guevara-Rojas et al., 2014). However, these evaluations did not include the

Table 2
Results of translational and angular displacement assessment. [a] C: converging screw orientation D: diverging screw orientation. The images are the calculated distance maps of the implants. The legend in the first picture is applicable to all implant distance maps.

Screw position	Entry point error (mm)	Orientation errors		Screw position	Entry point error (mm)	Orientation errors	
Patient 1 right implant							
Lateral top screw	0.5	11.4°	D	Middle top screw	0.4	0.1°	D
Medial top screw	0.4	5.6°	C	Lateral bottom screw	0.4	5.4°	C
Middle bottom screw	0.5	9.8°	D	Medial bottom screw	0.4	7.3°	D
Patient 1 left implant							
Lateral top screw	0.4	4.59°	D	Middle top screw	0.7	4.2°	C
Medial top screw	0.4	5.73°	C	Lateral bottom screw	0.9	12.3°	C
Middle bottom screw	1.0	3.25°	C	Medial bottom screw	1.0	3.4°	D
							
Patient 2 posterior implant							
Posterior top screw	0.7	4.09°	D	Middle screw	0.5	2.6°	D
Posterior bottom screw	0.4	2.39°	D	Anterior screw	0.2	3.7°	D
Patient 2 anterior implant							
Posterior screw	0.1	0.5°	C	Middle screw	0.1	0.5°	D
Anterior screw	0.5	5.7°	C				
							
Patient 3 right implant							
Lateral screw	2.8	26°	C	Medial screw	2.6	15.2°	C
Patient 3 left implant							
Lateral screw	1.2	36.8°	D	Medial screw	1.0	15.2°	D
							
Patient 4							
Right screw	3.3	3.0°	C	Middle screw	1.4	12.3°	D
Left screw	1.1	8.9°	D				
							
Patient 5							
Medial bottom screw	0.9	7.7°	D	Medial middle screw	1.4	0.5°	D
Top screw	1.6	2.8°	C	Lateral middle screw	1.0	4.0°	C
Lateral bottom screw	0.7	0.8°	D				
							

(continued on next page)

Table 2 (*continued*)

Screw position	Entry point error (mm)	Orientation errors		Screw position	Entry point error (mm)	Orientation errors	
Patient 6 posterior implant							
Posterior screw	1.4	2.6°	D	Anterior screw	1.5	0.1°	D
Patient 6 anterior implant							
Posterior screw	1.5	9.0°	D	Middle screw	1.4	0.0°	D
Anterior screw	0.7	9.2°	D				
							
Patient 7							
Posterior screw	0.7	34.3°	D	Posterior middle screw	0.7	29.5°	D
Anterior middle screw	0.6	9.0°	C	Anterior screw	0.5	9.5°	D
							
Patient 8							
Posterior top screw	0.7	13.3°	C	Posterior bottom screw	0.4	6.8°	C
Middle screw	0.2	6.8°	D	Anterior screw	0.2	14.5°	D
							

numerical accuracy of the placement of the implant in these cases.

No prior studies that have evaluated the placement accuracy of aesthetic PEEK implants, using screw positions, were found. So, no directly comparable studies were found. However, some studies assessed the accuracy and surgical outcome using other methods. The first study was performed by van de Vijfeijken et al. (van de Vijfeijken et al., 2019). In their paper, they compared a continuous distance map of one implant to the planned position. They did not elaborate on the method of creating the distance map.

Atef et al. assessed the surgical outcome of PEEK implant surgery by quantifying the soft tissue gain (Atef et al., 2021). They reported a soft tissue gain of 109.2% compared to the implant thickness on the chin side and 65.57% on the side of the ramus. Their paper underlines the importance of accuracy is dependent on the anatomical area in which the implant is placed, as it affects the soft tissue response.

A limitation of this study is the lack of uniformity in preoperative imaging modality, both CT and CBCT were used. The use of different modalities, and thus a non-standardized segmentation protocol, can cause discrepancies in postoperative measuring. A study by Rathankaya et al. shows that a multi-threshold-based segmentation method on CT scans has a deviation between 0.15 and 0.20 mm. from the ground truth, which was determined with a microCT scanner (voxel size 30 μm^3) (Rathnayaka et al., 2011). Fourie et al. performed a similar study for CBCT (voxel size 3 mm^3) data and found that manual segmentation results in an average mean deviation of 0.763 mm (Fourie et al., 2012). This difference is known and accepted. However, for future studies, it is recommended to use the same pre- and postoperative imaging protocol to prevent measurement inaccuracies.

A second limitation of this case series that measurement error has not been quantified. Discrepancies could occur through manual superposing of the screws and implants. This method, however, is already described in the literature by Merema et al. (2021) and deemed most suitable for our data. It is unknown whether inaccuracies in the manufacturing process play a significant role in the placement accuracy. To assess this problem volume analysis could be performed. This, however, is still dependend on the accuracy of the imaging modality.

A third limitation is the time to follow-up. There is a range from leas than 1 month to 12 months. A short follow-up period can underestimate the effect of the fixation screws on the bone. Bone resorption around fixation screws is reported by several studies(Feng et al., 2019; Kumar et al., 2021; Schulten et al., 2003). Bone resorption can result in loosening of the implant and can be caused by radial stress or friction. For implant surgery the frictional component is most relevant. Van de Vijfeijken et al. wrote a review of implant safety, which included 250 cranioplasties with PEEK implants and reported no implant migration (van de Vijfeijken Sophie et al., 2018). Keeping this in mind it is recommended to set the postoperative scanning interval to 3–6 months to allow for wound healing and reduce the effect of bone resorption. For future studies, a longer follow-up period could be indicated to assess the effect of the PEEK implants and screws on the bone.

Despite the limitations this case series shows that PEEK PSIs can be placed accurately. The next step in this research is to combine the accuracy of PSI placement with the soft tissue outcome and patient satisfaction. A prospective study has to be designed in which the follow-up moments are set and one imaging modality is used.

4. Conclusion

The described cases show that the analysis method is an objective approach for determining the accuracy of PSI placement and indicates that these implants can be placed accurately on the osseous face.

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