Int. J. Oral Maxillofac. Surg. 2022; 51: 790–798
https://doi.org/10.1016/j.ijom.2021.08.027, available online at https://www.sciencedirect.com

International Journal of Oral & Maxillofacial Surgery

Clinical Paper

Trauma

Critical appraisal of patient-specific implants for secondary post-traumatic orbital reconstruction

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R. Schreurs, C. Klop, P. J. J. Gooris, T. J. J. Maal, A. G. Becking, L. Dubois: Critical appraisal of patient-specific implants for secondary post-traumatic orbital reconstruction. Int. J. Oral Maxillofac. Surg. 2022; 51: 790–798.

Abstract. In orbital reconstruction, a patient-specific implant (PSI) may provide accurate reconstruction in complex cases, since the design can be tailored to the anatomy. Several design options may be embedded, for ease of positioning and precision of reconstruction. This study describes a cohort of 22 patients treated for secondary orbital reconstruction with a PSI; one patient received two PSI. The preoperative clinical characteristics and implant design options used are presented. When compared to preoperative characteristics, the postoperative clinical outcomes showed significant improvements in terms of enophthalmos ($P < 0.001$), diplopia ($P < 0.001$), and hypoglobus ($P = 0.002$). The implant position in all previous reconstructions was considered inadequate. Quantitative analysis after PSI reconstruction showed accurate positioning of the implant, with small median and 90th percentile deviations (roll: median 1.3°, 90th percentile 4.6°; pitch: median 1.4°, 90th percentile 3.9°; yaw: median 1.0°, 90th percentile 4.4°; translation: median 1.4 mm, 90th percentile 2.7 mm). Rim support proved to be a significant predictor of roll and rim extension for yaw. No significant relationship between design options or PSI position and clinical outcomes could be established. The results of this study show the benefits of PSI for the clinical outcomes in a large cohort of secondary post-traumatic orbital reconstructions.

Key words: Orbital Fractures; Surgery; Computer-assisted; Reoperation; Patient-Specific; Modeling; Treatment outcome.

Accepted for publication 6 August 2021
Available online 8 November 2021

Enophthalmos, hypoglobus, and diplopia are frequently encountered in complex orbital fractures. These sequelae, or a combination of them, may indicate the need for surgical intervention[1,2]. The goal of orbital reconstruction is to alleviate these symptoms through the restoration of the pre-traumatized dimensions (shape and volume) of the orbit[3–5]. Preformed orbital implants are based on the average shape of the orbit and have the potential for adequate reconstruction[5–8]. In complex cases, pivotal anatomical structures such as the orbital process of the palatine bone may be affected. In secondary cases,

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remodelling may have distorted the anatomical relationships[7,9,10]. Further challenges in secondary cases may be the presence of reconstruction materials that need to be removed, extensive scarring of the soft tissue, and late soft tissue changes such as fat atrophy[11].

In these complex cases, a patient-specific implant (PSI) has the best potential for accurate reconstruction and alleviation of symptoms[12–14]. The shape of the implant can be tailored to the anatomy, while an exact and compulsory fit on the supporting bony structures can be incorporated into the design[15,16]. The volume of the orbit can be restored and may even be overcorrected in the implant design, for instance in patients suffering from severe atrophy. In difficult late or secondary reconstructions, a PSI may prevent the use of additional osteotomies or bone grafts[7]. In order to utilize the full potential of a PSI, positioning according to planning is required. Inaccurate positioning of a perfectly shaped implant may lead to a deviating shape of the bony anatomy and volume (over)correction in a different location than planned.

Several design choices may positively influence the ease and precision of intraoperative positioning. Recommendations regarding implant support, edge design, drainage possibilities, navigation implementation, and primary screw hole fixation have been described[17–20]. The effect of the design choices on the implant position and patient outcomes obtained has not been quantified. The aim of this study was to present the preoperative characteristics, design choices, implant position, and postoperative clinical outcomes of a cohort of patients treated with PSI for secondary orbital reconstruction. Secondary aims were (1) to assess the effect of the design choices on implant positioning, (2) to assess the effect of the design on clinical outcome parameters, and (3) to evaluate the effect of the implant position on clinical outcome parameters.

Materials and methods

Patients

This study was approved by the local ethics committee of the Amsterdam UMC, Location AMC (W19_390). All patients who underwent orbital reconstruction with a PSI at the Academic Medical Centre Amsterdam, University of Amsterdam (AMC) between April 2014 and January 2020 were considered for inclusion. Secondary reconstruction was defined as surgical treatment after primary surgical intervention involving the soft tissue or hard tissue orbital structures (outer rim or inner walls). The occurrence and number of previous surgical reconstructions were noted, as well as wall involvement (number of walls affected, 1–4), rim involvement, naso-orbito-ethmoid (NOE) involvement, and involvement of the zygomatic complex. The amount of enophthalmos was assessed through Hertel exophthalmometry. Diplopia was expressed using the Bahn–Gorman diplopia score (0, no diplopia; 1, intermittent diplopia; 2, inconstant diplopia; 3, constant diplopia correctable with prisms; 4, constant diplopia not correctable with prisms)[21]. The existence of hypoglobus was registered, or evaluated afterwards on photographs. The orthoptic evaluation was repeated at follow-up, 3 months after surgery.

If a previous reconstruction of the orbit had been performed, the reconstruction material and its position were characterized. Since different reconstruction materials impair quantitative analysis, the following parameters were assessed: subjective judgement of position (bad, fair, good), size (too small, correct, too large), defect coverage (incomplete, partial, complete), position in relation to mirrored orbit (bad, fair, good), ledge support (yes, no), S-curve floor (yes, no), and reconstruction of the medial wall defect (yes, no). Deviations in rotation of the implant material in relation to the mirrored orbit were identified (roll, pitch, yaw) if this was feasible with the implant material used[22].

Design

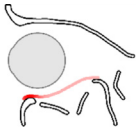
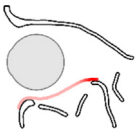
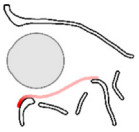
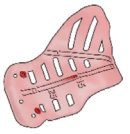
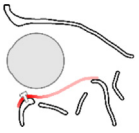
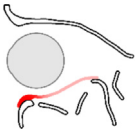
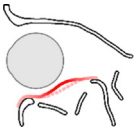
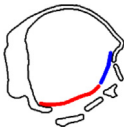
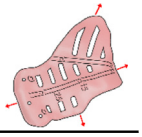
Preoperatively, a computed tomography (CT) scan with a slice thickness of 1.0 mm and bone reconstruction kernel was acquired. Preoperative planning was performed in iPlan software version 3.0.5 (Brainlab AG, Feldkirchen, Germany). A PSI was subsequently designed for all patients. For the first four patients, the method described by Gander et al. was used to design and fabricate the PSI[17]. From February 2015 onwards, all PSI designs were performed in-house, by one clinical technician (RS). An atlas-based segmentation of the contralateral hard tissue orbit and soft tissue orbit was performed, and both were mirrored to serve as the reference for the affected orbit. A segmentation of the bony structures surrounding the affected orbit was added and all objects were exported as stereolithography models (STL). A preliminary design was made in Meshmixer version 11.0.544 (Autodesk Inc., San Rafael, CA, USA), which was imported into the preoperative planning to evaluate the fit. Further adjustments to optimize the shape and fit of the implant could be implemented and re-evaluated. After the finalized design was acquired, the surface describing the implant and the desired screw positions were sent to the manufacturer (KLS Martin, KLS Martin Group, Tuttlingen, Germany) for further processing and additive manufacturing in titanium. Several design options could be implemented in the design based on the patient's anatomy and fracture morphology. These options are listed in Table 1 and discussed in more detail below.

Design properties

For each implant, the starting point of the design was to create support for the implant on the infraorbital rim, medial wall, and posterior ledge, if the existing anatomy allowed for this (rim support, medial support, ledge support). An extension over the orbital rim could be embedded in the design by extending the implant surface over the orbital rim curvature, with the goal of physically preventing rotation of the implant or translation posteriorly (rim extension). In cases with previous surgical intervention, the screw hole positions of the primary reconstruction could be reused to provide guidance for positioning the PSI. The screw positions were segmented and used as screw hole positions in the design of the PSI (fixation reuse). The final design option that could be incorporated into the design to possibly improve the implant position were markers to improve the quality of the feedback obtained through intraoperative navigation (navigation markers)[23].

Based on the preoperative clinical characteristics and advanced diagnostics in the virtual planning environment, an anterior elevation or overcorrection could be added to the implant. An anterior elevation was mainly used in patients with hypoglobus and a caudal displacement of the anterior orbital rim, to heighten the orbital rim to the desired level. An overcorrection of the reconstructed orbital volume could be designed to anticipate the effects of (repeated) orbital reconstruction on the soft tissue. The amount of soft tissue overcorrection was determined based on clinical characteristics and ophthalmological measurements; the volume of the mirrored soft tissue orbit was reduced with the predetermined volume using the ''smart shaper'' tool (iPlan software) posterior to the bulbus (Fig. 1). In the design software,

Table 1. Design choices and the primary parameter that is affected by the design choice.

Design option	Principal affected parameter	Description	Image
Rim support	Implant position	Support of the implant on existing (part of) infraorbital rim	
Medial support	Implant position	Support of the implant on existing (part of) infraorbital rim	
Ledge support	Implant position	Support of the implant on existing (part of) infraorbital rim	
Rim extension	Implant position	Extension of the implant over existing (part of) infraorbital rim	
Nav markers	Implant position	Navigation landmarks embedded in the implant	
Fixation reuse	Implant position	Overlap fixation with screw holes from primary reconstruction	
Anterior elevation	Hypoglobus	Plateau on infraorbital rim to raise rim height of implant	
Overcorrection	Enophthalmos	Raising implant shape within orbit to reduce orbital volume	
Two-piece	Positioning ease	Implant in two pieces	
Size	Positioning ease	Size of the implant	

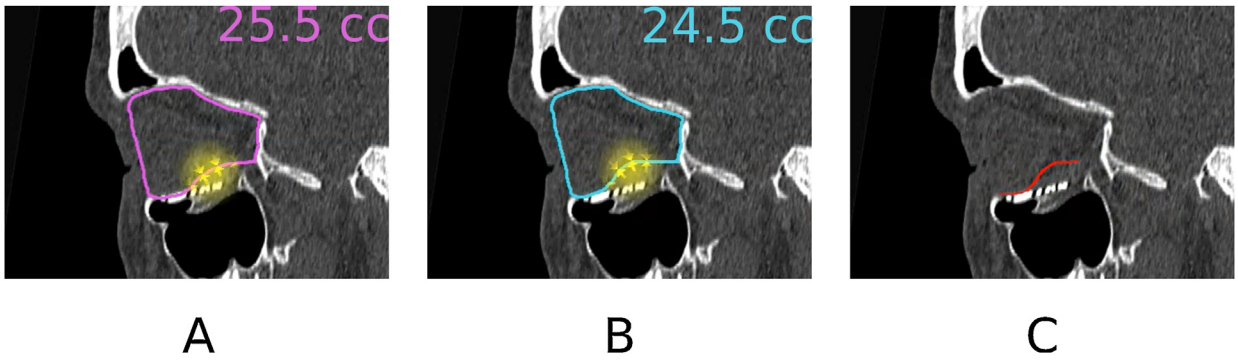


Fig. 1. Quantification of overcorrection. The ''smart shaper'' tool, indicated by the yellow arrows, is used to create an overcorrection behind the bulbus. The amount of overcorrection can be assessed in ''plan content'' as the difference in volume between the mirrored orbit (A) and overcorrected orbit (B). The PSI (C) follows the overcorrected contour. The sagittal view is visualized, but overcorrections are possible in any of the multiplanar views.

the adjusted soft tissue model was used as a reference for the implant shape.

Surgery

All reconstructions were performed by the same surgeon (LD). A transconjunctival incision was used as the standard approach in the majority of cases; medial and lateral extensions were used if necessary. During surgery, intraoperative navigation was available to the surgeon in all cases and the position of the implant was evaluated with the use of the embedded navigation markers. If available, intraoperative imaging was performed to assess the acquired implant position during surgery and make changes if necessary. Postoperative imaging (CT or cone beam computed tomography (CBCT)) was only acquired if intraoperative imaging was not available, or additional to intraoperative imaging on indication.

Quantification of the implant position

The intraoperative or postoperative (CB) CT was matched on the preoperative plan in iPlan. The virtual model of the PSI was repositioned to overlap with the position of the implant in the matched postoperative (CB)CT. STL models of the unaffected orbit, mirrored orbit, and hard tissue reference model were exported and, along with a plane describing the floor of the PSI, imported into Blender software version 2.83.3 (Blender Foundation, Amsterdam, the Netherlands) to obtain a reference frame. A mirror for all models in right-sided reconstructions was generated, for consistency in setting up the reference frame. The frame was set up for each PSI using the following three landmarks: the most lateral point of the lacrimal duct of the mirrored orbit (Lac), the lowest point on the mirrored infraorbital margin (Orb), and the most posterior point of the PSI, indicating the position of the posterior ledge (Pos). The midpoint between the anterior landmarks – Ant – was calculated. The centre between Ant and Pos was calculated, and a projection of this landmark on the PSI (closest point) was regarded as the origin of the reference frame. The *x*-axis was defined as the axis through the origin parallel to the direction from Ant to Pos; the *z*-axis was perpendicular to the Lac–Orb–Pos plane, from the origin cranially. The *y*-axis was perpendicular to the *x*-axis and *z*-axis and thus had a lateromedial course. An example of this reference frame for a PSI is shown in Fig. 2. The roll (rotation around *x*), pitch (rotation around *y*), and yaw (rotation around *z*) and translation between the planned and acquired implant positions were calculated with the 'orbital implant positioning frame' methodology[22].

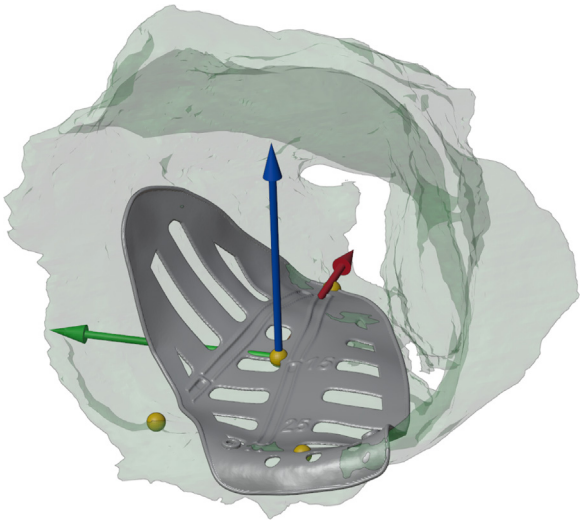


Fig. 2. PSI reference frame example. The mirrored orbit (green), PSI (grey), and landmarks (yellow) are shown. The red axis represents the *X*-direction, the green axis the *Y*-direction, and the blue axis the Z-direction.

Statistical analysis

Descriptive statistics were calculated for preoperative characteristics, previous reconstruction characteristics, design options, acquired implant position, and postoperative clinical outcomes. To assess the effect of the PSI reconstruction, preoperative and postoperative enophthalmos and Bahn–Gorman diplopia scores were compared using the paired samples Wilcoxon signed rank test; the existence of preoperative and postoperative hypoglobus was compared using the McNemar test. To assess the effect of the design choices on implant position, stepwise linear regression (addition) was performed for all implant position parameters (roll,

Table 2. Patient characteristics preoperative.

Characteristic and category	Number	%
Number of previous reconstructions		
1	18	78
2	3	13
3	2	9
Walls involved		
1	0	0
2	12	52
3	7	30
4	4	17
Bahn–Gorman diplopia score		
0	0	0
1–2	9	39
3–4	11	48
N/A	3	13
Enophthalmos (mm)		
$0 \leq x < 2$	2	9
$2 \leq x < 4$	11	48
$x \geq 4$	10	43
Hypoglobus	14	61
Rim involved	12	52
NOE involved	10	43
Zygoma involved	12	52

N/A,; NOE, naso-orbito-ethmoid.

Table 3. Previous reconstruction characteristics.

Characteristic and category	Number	%
Reconstruction material		
Autologous	1	7
Silicone	2	14
Pre-bent titanium	4	29
Preformed titanium	6	43
PSI	1	7
Subjective position		
Bad	11	79
Fair	3	21
Good	0	0
Size		
Too small	13	93
Correct	1	7
Too large	0	0
Defect coverage		
Incomplete	10	71
Partial	3	21
Complete	1	7
Mirror similarity		
Bad	11	79
Fair	2	14
Good	1	7
S-curve		
Yes	3	21
No	11	79
Ledge support		
Yes	3	21
No	11	79
Medial wall reconstructed		
Yes	0	0
No	14	100
Incorrect rotation identified		
Roll	7	
Pitch	12	
Yaw	6	

PSI, patient-specific implant.

pitch, yaw, translation), with the design options in Table 1 that have 'implant position' as the primary parameter affected included as predictive variables. The implant position data were transformed by taking the square root value to better resemble a normal distribution[24]. Two Fisher's exact tests were performed to evaluate the effect of design choices on the clinical outcome: one to assess the effect of incorporating an overcorrection (dichotomous) on postoperative enophthalmos, and one to assess the effect of anterior elevation on the postoperative existence of hypoglobus. Finally, the effect of implant position on the clinical outcome was assessed using three logistic regression models, with postoperative hypoglobus (yes/no), existence of postoperative enophthalmos >0 mm (yes/no), and postoperative Bahn–Gorman diplopia >1 (yes/no), respectively, as dependent variables and the square root implant position parameters as independent variables. All statistical analyses were performed in R[25].

Results

Patient characteristics

From April 2014 to January 2020, 23 PSI were used for secondary post-traumatic orbital reconstruction in 22 patients (one revision). The preoperative clinical characteristics (wall involvement, presence of diplopia, enophthalmos, and involvement of surrounding structures (NOE, zygoma, orbital rim)) are summarized in Table 2. Of these secondary cases, 22% had undergone more than one previous reconstruction. Clinically significant enophthalmos ($\geq$2 mm) was present in 21 cases (91%). Intermittent or inconstant diplopia was seen preoperatively in nine cases (39%) and constant diplopia in 11 cases (48%). Diplopia could not be determined in three cases, since the patient was blind in at least one eye before surgery.

Previous reconstruction

A previous reconstruction of the orbital floor or medial wall had been performed in 14 cases. Regarding the reconstruction material characteristics, most previous reconstructions were performed using titanium implants (79%) (Table 3). The single case of autologous reconstruction was performed during primary reconstruction of a panfacial defect, to obtain primary support for the globe in anticipation of secondary reconstruction with a PSI. The PSI case reported in Table 3 is the same revision case as mentioned in the Patient characteristics section above. This patient had undergone multiple previous reconstructions with a combination of implant materials, including silicone block, Teflon, and bone graft. These reconstruction materials had to be removed due to recurrent infections. Since the removed implant had provided an adequate reconstruction for over 25 years, a PSI was designed with a shape similar to that of the silicone implant (non-anatomical). This unfortunately led to an unsatisfactory clinical outcome; therefore, a second revision was performed with a PSI based on the anatomical shape of the orbit.

Overall, the previous reconstructions performed were inadequate. Nearly all implants were too small in size, and even correct positioning would not have led to an anatomical reconstruction of the defect. Support on the posterior ledge was only achieved in three reconstructions: the one with autologous bone and two reconstructions with preformed implants[26]. None of the pre-bent implants were positioned on the ledge; this was unfeasible in almost all pre-bent cases due to the size of the implant. The overall positioning scores of the four pre-bent implants were worse than the scores of the preformed implants: all pre-bent implants were too small, the similarity to the mirrored orbit was bad, no S-curve was present, no ledge support was present, and all pre-bent implants had incomplete coverage of the defect.

Table 4. Design and intraoperative characteristics.

Design/intraoperative option	Number	%
Rim support	19	83
Rim extension	20	87
Medial support	21	91
Ledge support	20	87
Fixation reuse	14	61
Anterior elevation	8	35
Overcorrection (cc)		
0	7	30
0.5	5	22
1	9	39
>1	1	4
N/A	1	4
Size (mm^2), mean ± SD	1052 ± 215	
Two-piece PSI	1	4
Intraoperative imaging	12	52
Intraoperative navigation	23	100

N/A,; PSI, patient-specific implant; SD, standard deviation.

PSI design and intraoperative characteristics

The design parameters and intraoperative characteristics are presented in Table 4. Rim support (83%) and a rim extension (87%) were feasible in the majority of cases, as were support on the medial wall (91%) and ledge support (87%). Fixation was reused in 14 of 18 cases (78%) that had a previous reconstruction with osteosynthesis screws fixed on the infra-orbital rim, either from fixation of orbital reconstruction material or reconstruction of the orbital rim (e.g., zygomatic reconstruction). An anterior elevation was designed in eight cases; in six of these cases the patient suffered from hypoglobus. One two-piece implant was designed. Navigation markers were embedded in every implant and intraoperative navigation was utilized in all cases. The utilization of intraoperative imaging was mainly dependent on the availability of this technology; it was always used if feasible. The positioning of 12 implants (52%) was evaluated with intraoperative imaging.

Quantification of the implant position

The median Euclidean distance between the planned and acquired implant positions was 1.4 mm, with a range of 0.2–3.3 mm. The 90th percentile Euclidean distance was 2.7 mm, meaning 90% of implants were positioned with a distance error <2.7 mm. The differences in the median roll, pitch, and yaw rotation were negligible: roll 1.3° (range 0.1–7.8°), pitch 1.4° (range 0.0–6.8°), yaw 1.0° (range 0.0–10.3°). The 90th percentile for pitch was the smallest, at 3.9°, compared to a 90th percentile of 4.6° for roll and 4.4° for yaw.

Postoperative clinical outcome

The postoperative clinical evaluation of the cohort in terms of diplopia, enophthalmos, and hypoglobus is provided in Table 5. The Bahn–Gorman diplopia score improved in 14 cases, remained the same in five cases and worsened in one case (by one grade). Enophthalmos remained 0 mm in one case, led to clinically insignificant exophthalmos in two cases (preoperative enophthalmos of 1 mm and 5 mm), and improved in 20 cases. The statistical analysis showed that there was a significant reduction in diplopia score (meaning less severe diplopia) (Wilcoxon signed rank test, $P < 0.001$) and enophthalmos (Wilcoxon signed rank test, $P < 0.001$) after surgical reconstruction with a PSI. The presence of hypoglobus was also significantly reduced after reconstruction (McNemar test, $P = 0.002$).

Table 5. Preoperative versus postoperative clinical characteristics.

Parameter and category	Preoperative		Postoperative		*P*-value
	Number	%	Number	%	
Bahn–Gorman diplopia score					<0.001
0	0	0	2	9	
1–2	9	39	16	70	
3–4	11	48	2	9	
N/A	3	13	3	13	
Enophthalmos (mm)					<0.001
$2 \leq x < 0$	0	0	2	9	
$0 \leq x < 2$	2	9	19	83	
$2 \leq x < 4$	11	48	2	9	
$x \geq 4$	10	43	0	0	
Hypoglobus					0.002
Present	14	61	3	13	
Absent	9	39	20	87	

N/A.

Relationship between design, position, and clinical outcomes

Table 5 shows that hypoglobus was resolved in 11 of 14 patients. An anterior elevation was designed in six of the 14 cases; hypoglobus was absent postoperatively in five of these six cases. Hypoglobus was resolved in six cases without an anterior elevation, while it was still present postoperatively in two cases without an anterior elevation. Fisher's exact test revealed no statistically significant difference in the existence of postoperative hypoglobus between the groups with and without an anterior elevation ($P = 1$). Of the three cases with postoperative hypoglobus, two had severe hypoglobus preoperatively (>10 mm) and one suffered from cachexia after perforation of the intestine, which led to postoperative orbital fat atrophy (verified using magnetic resonance imaging). To assess the effect of overcorrection on postoperative enophthalmos, the subset of patients with preoperative enophthalmos was analysed ($n = 22$). Fisher's exact test revealed no statistically significant difference in the postoperative enophthalmos score for patients treated with or without an overcorrection in the PSI ($P = 0.12$).

The linear regression model of $\sqrt{\text{translation}}$ and $\sqrt{\text{pitch}}$ yielded no significant prediction from rim support, medial support, ledge support, rim extension, or fixation reuse. For $\sqrt{\text{roll}}$, a final model with an adjusted R^2 of 0.27 was obtained that was statistically significant ($P = 0.01$); the variable included in the final model was rim support (estimate = −0.90). The use of a rim extension was found to be a significant predictor for $\sqrt{\text{yaw}}$ (adjusted $R^2 = 0.18$, $P = 0.03$). Stepwise binary logistic regression models for postoperative enophthalmos >0 mm, postoperative Bahn–Gorman diplopia >1, or postoperative hypoglobus, with independent variables comprising the transformed implant position parameters, yielded no significant results.

Discussion

In this study, a cohort of 23 orbital reconstructions with a PSI was analysed. While there were substantial differences in the preoperative clinical characteristics, the cohort may best be summarized as solely secondary post-traumatic cases with a large orbital defect (≥2 walls), and with clinically significant enophthalmos and

diplopia. In 61% of the cases, a previous reconstruction of the orbital walls had been attempted, but in all of these cases the previous reconstruction had been unsuccessful; implant positioning of the previous reconstructions could be considered inadequate in nearly all cases. The PSIs were positioned accurately according to planning, as can be seen from the implant positioning analysis, with median rotations $<1.5°$ and median translation of 1.4 mm. The postoperative clinical outcomes show that this cohort of patients with large orbital defects and, frequently, a previous surgical reconstruction of the orbit can benefit from accurate reconstruction with a PSI.

A positive clinical outcome with successful reduction or resolution of enophthalmos and/or diplopia has been described in several smaller ($n < 20$) PSI case-series[7,13,14,20,27–29]. Kozakiewicz and Szymor compared 20 PSI reconstructions with ultra-high-molecular-weight polyethylene to 37 reconstructions with pre-moulded mesh[30]. Similar diplopia outcomes were described for the groups, but the PSIs had been used in more complex defects. Spalthoff et al. focused on the use of spacers ($n = 25$), which were often combined with PSIs ($n = 22$, 16 secondary)[31]. Improvements in diplopia was seen in nine of 11 patients and globe position improved in 20 of 25 patients. Zieliński et al. described an improvement in vision for a combined PSI ($n = 23$) and pre-moulded mesh ($n = 16$) group[32]. Schönegg et al. also analysed a combined group, but focus was much more on PSIs (41/44 PSI reconstructions)[33]. Diplopia in primary gaze was resolved in 23 of 25 patients. The presence and severity of enophthalmos (but not of exophthalmos) seemed reduced postoperatively. Chepurnyi et al. described a reduction in diplopia from 82.1% preoperatively to 17.9% at 3 months postoperative in a PEEK PSI group ($n = 28$)[34]. Persistent enophthalmos >2 mm was present in 3.7% of patients, which was significantly less than the 29.4% in the pre-moulded implant group ($n = 17$) and is comparable to the findings of the present study (enophthalmos >2 mm in one patient). The analysis of a larger cohort by the same group (47 PSI, 45 pre-moulded) focused more on implant position: preoperative clinical characteristics were not described but postoperative ratios were comparable to those of the smaller cohort[16]. The largest cohort ($n = 92$) was described by Rana et al., in a study that focused on reconstruction accuracy. Clinical information was provided on indication for operation (enophthalmos in 10 patients, diplopia in 15 patients) and adverse events directly postoperative (none for globe position or diplopia)[3].

Larger cohort studies that provided information on timing focused primarily or solely on primary orbital reconstruction[3,34]; other studies that lacked timing information seemed to focus on primary orbital reconstruction as well[16,30,32,33]. Of the cohorts mentioned above, only that described by Spalthoff et al. had mainly secondary patients[31]. The present study is novel in presenting a large sample of patients who had undergone secondary orbital reconstruction with a PSI. The increased difficulties in secondary orbital reconstruction relating to scarring, distorted bony anatomy, soft tissue deformity, and the presence of pre-existing hardware has been described extensively in the literature[10,35–39]. Several case studies describing PSI in secondary reconstruction have advocated their use specifically for secondary reconstruction[7,13,14,27,28]. The results of the present study confirm the benefits of PSI in a large cohort and establish PSI as an important addition to the surgical armamentarium for secondary orbital reconstruction.

The key to success in orbital reconstruction with a PSI may lie in the freedom in design it provides. A unique, compelling fit can be designed, and positioning according to the plan may be further controlled by navigation rulers and markers, the use of positioning guides, or a rim extension[17–19,29,40]. Other design options can be used to tailor the implant to the pathology of the patient, such as a volume overcorrection, or can enable zygomatic reduction and orbital reconstruction in a one-stage orbitozygomatic reconstruction[19,20,31,41]. The list of design choices presented in Table 1 is not exhaustive, and ongoing development in PSI design will lead to novel design options. A possible pitfall is that implants may be designed that cannot be positioned during surgery and the size has to be reduced. In this cohort, this proved necessary in two cases.

The specifics of the cohort evaluated here make it difficult to draw conclusions about the secondary goals in this study: assessing the effect of design choices on implant position and clinical outcomes, and evaluating the effect of implant position on clinical outcomes. The occurrence of most design choices was not equally distributed across the cases: for instance, rim support, a rim extension, ledge support, and medial support were all encountered in approximately 90% of cases. For optimal statistical analysis, the use of these design parameters would have been randomized, with equal group sizes, but this of course would not have been justifiable in terms of patient care. The absence of large deviations from the planned implant position and adverse postoperative clinical outcomes make it difficult to assess a possible negative effect of implant position on the clinical outcomes. This is the rationale behind the choice for grouping the clinical outcomes based on a cut-off value. Finally, many confounders may be identified in this group: the extent of the fracture, involvement of the surrounding structures, number of previous reconstructions, preoperative severity of the diplopia, enophthalmos, and hypoglobus, soft tissue damage during trauma, and iatrogenic damage during previous reconstructions or during the PSI reconstruction.

In light of these disclaimers, it may not be surprising that, in this cohort, no significant relationships were found between clinical outcome parameters and implant design options or (small) differences in implant position parameters. The effect of implant position on the clinical outcome has been the subject of debate in the literature, with some authors regarding this as a key factor determining the clinical outcome[42,43], while others have hypothesized that its role is not as important as previously believed[44]. Differences in confounding factors, especially defect size, make it difficult to reach any definitive conclusions based on the literature. The fact that the implant position of the previous reconstruction was judged as poor for all patients in this cohort might substantiate the importance of accurate implant positioning in the clinical outcome. A tentative conclusion may be that not every inaccuracy in implant position will lead to an adverse clinical outcome, but if revision is required, there is a high chance that the implant was malpositioned in the previous reconstruction. Remarkably, Schlittler et al. identified the same main reason for revision as can be concluded from Table 3: treating a defect with a mesh that is too small[45]. This can easily be avoided if preoperative surgical planning is conducted. The fact that surgical planning is required to design a PSI may also explain the improved implant positioning with these implants[17].

A significant relationship was found between some implant design options and implant position parameters. The most significant effect was found for rim support on roll. As well as rim support, a significant effect for the use of a rim extension on yaw was observed. Several design options have a specific hypothesis

for their course of action to improve implant position: a rim extension limits large deviation in yaw by physical obstruction at the infraorbital rim, and fixation reuse would limit unwanted movement of the implant because a fixed location is introduced in the positioning process. The rim extension had a significant effect on implant position, but fixation reuse did not have a significant effect in this cohort. Again, caution is warranted because of the composition of this dataset. In this study, at least one screw hole position was designed not to overlap with the existing screw hole positions, in order to guarantee proper fixation in the case of failure at existing positions due to the release and reinstallation of screws in the same location.

In summary, a series of 23 secondary post-traumatic orbital reconstructions with a PSI was analysed in this study. Preoperatively, all patients had a multiple wall defect and suffered from clinically significant enophthalmos and diplopia. Previous reconstruction attempts had been unsuccessful; the implant position of the previous reconstruction could be considered poor in all cases. Several implant design options were presented that may be implemented in the PSI to possibly obtain improved positioning or improved clinical outcomes. The postoperative clinical outcome was significantly improved in terms of enophthalmos, diplopia, and hypoglobus when compared to the preoperative clinical characteristics. This study confirms the benefits of PSIs for patients with large defects and, frequently, a previous reconstruction, who require secondary post-traumatic orbital reconstruction. A significant effect of overcorrection on enophthalmos, and of anterior elevation on hypoglobus, was not found in this cohort. The use of rim support or a rim extension seemed effective in controlling implant positioning: a significant positive effect could be established on roll and yaw, respectively. The hypothesis that implant position affects the clinical outcome could not be established in this cohort, which could be due to the cohort specifics with accurate implant positioning and positive clinical outcomes overall.

Funding

Funding for this research was received by KLS Martin and Brainlab AG. None of the funding parties had any involvement in the contents or decision to submit the manuscript.

Competing interests

None to declare.

Ethical approval

Ethical approval was considered by the local ethics committee of the Amsterdam UMC, Location AMC (W19_390). An exemption letter was provided by the ethics committee.

Patient consent

An opt-out procedure was followed for inclusion in the cohort. No clinical photographs are included.

Declaration of Competing Interest

The authors report no declarations of interest.

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