



ORIGINAL RESEARCH ARTICLE

Patient-specific implants are accurate and cost-effective for blow-out fracture reconstruction: a retrospective case-control study

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ABSTRACT

Background: The volume of the bony orbit increases in facial trauma with a blow-out fracture and may lead to enophthalmos and double vision. The orbit's volume can be restored surgically. The authors aimed to determine the most accurate and cost-effective method for reconstructing blow-out fractures: virtual surgical planning (VSP) combined with patient-specific implants (PSI) or standard titanium stock implants.

Materials and methods: The authors conducted a retrospective study of patients who sustained a blow-out fracture requiring surgical reconstruction. Patients were categorized into two groups: the PSI group ($n = 13$) and the standard titanium stock implant group ($n = 36$). The primary aim was to analyze the total cost in each group, with a secondary aim to ensure volumetric restoration was achieved. Postoperative volume, operation time, need for reoperation, surgical and inpatient costs, and cost-effectiveness were calculated. The data were analyzed with Shapiro–Wilk, Mann–Whitney U test, and Fisher's exact test, using a significance level of 0.05.

Results: The operation time was significantly shorter in the PSI group than in the stock implant group, with an average of 89.77 and 122.69 min, respectively ($p = 0.008$), resulting in lower total costs in the PSI group. The PSI group had better postoperative volumetric restoration than the stock implant group compared to the contralateral side ($p = 0.01$). Four out of 36 patients (11%) needed reoperation in the stock implant group.

Conclusions: Preliminary results suggest that PSI requires a shorter operation time and is therefore cost-effective without compromising surgical outcomes.

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Craniofacial; trauma; cost effectiveness; blow-out fracture; patient-specific implant

Introduction

Fractures of the bony orbit, or blow-out fractures, represent a common type of craniofacial trauma in maxillofacial surgery. The thin floor of the bony orbit is easily fractured when blunt trauma transfers force to the orbital floor, which fractures while often preserving the surrounding bones and the orbital soft tissues from excessive damage. Not all blow-out fractures need reconstruction, but surgical intervention is required in some cases. Indications for operative reconstruction are still discussed [1], and no clear solution based on radiological data is found [2]. Computed tomography (CT) is the gold standard for imaging orbital trauma, and three-dimensional (3D) assessment is more accurate for measuring bony defects [3]. Clinical assessment is mandatory, and entrapment of soft tissue causing movement restriction of the globe, persistent diplopia, impaired vision, severe enophthalmos or hypoglobus, and poor aesthetics usually indicate surgery [4, 5]. The aim of the operation is to regain function and aesthetics.

Reconstruction replaces the paper-thin wall with an autologous graft or alloplastic implant. Autografts are associated with unpredictable resorption rates and donor site morbidity, so alloplasts are currently favored [4, 6]. Alloplasts also provide better clinical outcomes [7]. The goal is to restore the original volume and shape of the bony orbit without unnecessarily disturbing soft tissues. The

injured area is accessed surgically via transconjunctival, subciliary, mid-lower eyelid, infraorbital, and endoscopic trans sinusoidal approaches. Entrapment of soft tissue, a retrobulbar hemorrhage, or an oculocardiac reflex may need prompt intervention, but fracture reconstruction can usually be delayed up to 2 weeks [8]. This provides the opportunity to choose patient-specific implants (PSI) instead of standard stock implants. Surgical techniques have evolved to be more personalized, and PSI is becoming more common with the rise of 3D technologies [9]. Virtual surgical planning (VSP) is used, and the shape and volume of the unaffected orbit can be mirrored for the reconstruction. The PSI can be produced and delivered fast enough, even for primary trauma surgery [10].

Preoperative computer-assisted design/computer-assisted manufacturing (CAD/CAM) 3D planning is used in maxillofacial orthognathic surgery and in hard tissue reconstruction of tumor surgery [11–13]. VSP is used to facilitate surgery and achieve accurate results. The use of VSP and CAD/CAM is also gaining popularity in trauma surgery. Preoperative conebeam computed tomography (CBCT) or CT with 1 mm or less slice thickness and 0-degree gantry tilt is required for high-quality surface modeling for VSP in blow-out fracture surgery. The unaffected contralateral side is mirrored to the trauma side in the online planning session with the medical engineer and surgeon for CAD/CAM; the planned implant is further adjusted

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to fit exactly to reconstruct the fractured area according to the patient's anatomy and the surgeon's preferences. PSI itself is more expensive than the standard implant [14] but is thought to shorten operation time [13] and fit more accurately to restore the original anatomy [10].

As the cost of the PSI may hinder its use, the authors conducted this study to clarify the total cost of the blow-out fracture reconstruction. Evidence regarding the cost of the blow-out fracture surgery, especially the expenses in different methods, is limited. This study aimed to determine, for inpatients undergoing post-traumatic orbital blow-out fracture reconstruction of the orbital floor (*population*), whether using a PSI (*intervention*) is beneficial over traditional titanium stock implants (*control*) as measured by operation time, reoperations, inpatient costs, and cost-effectiveness without compromising the postoperative orbital volume compared to the intact contralateral side (*outcomes*). The null hypothesis is that traditional stock implants are more cost-effective than PSI.

Materials and methods

All patients who presented with facial fractures (ICD-10 diagnosis code S02.xx) from 2008 to 2020 in our hospital were extracted from

the hospital medical data registry. Medical charts and X-rays were reviewed to identify patients with orbital blow-out fractures. Patients with a non-surgically treated blow-out fracture or surgical intervention but no reconstruction with a titanium implant, as well as patients needing other surgical intervention, were excluded.

All the patients were treated according to the standard of care. Three consultant surgeons performed the procedures. Fractures were surgically reconstructed to restore the orbit's original volume by replacing the floor with an implant with bony support. For the analysis, the patients were divided into a *stock implant group* who had reconstruction with a standard titanium stock implant and a *PSI group* who had a patient-specific titanium implant.

All the PSIs were designed with the Planmeca ProModel (Helsinki, Finland) system. The bony orbits were imaged with CT (GE Revolution CT, Siemens SOMATOM Definition AS+) with 1 mm or less slice thickness and a 0° gantry tilt. The DICOM data were uploaded, and virtual surgical planning was performed online with a surgeon and an engineer. The PSIs were designed using a mirroring technique from the unaffected side. The PSI design had at least 3-point bony support to prevent implant tilting, usually two points with extensions over the orbital rim and one on the posterior ledge (Figure 1), to facilitate accurate positioning and passive fitting. The PSI was made of titanium. Figure 2 shows the PSI and stock implants used.

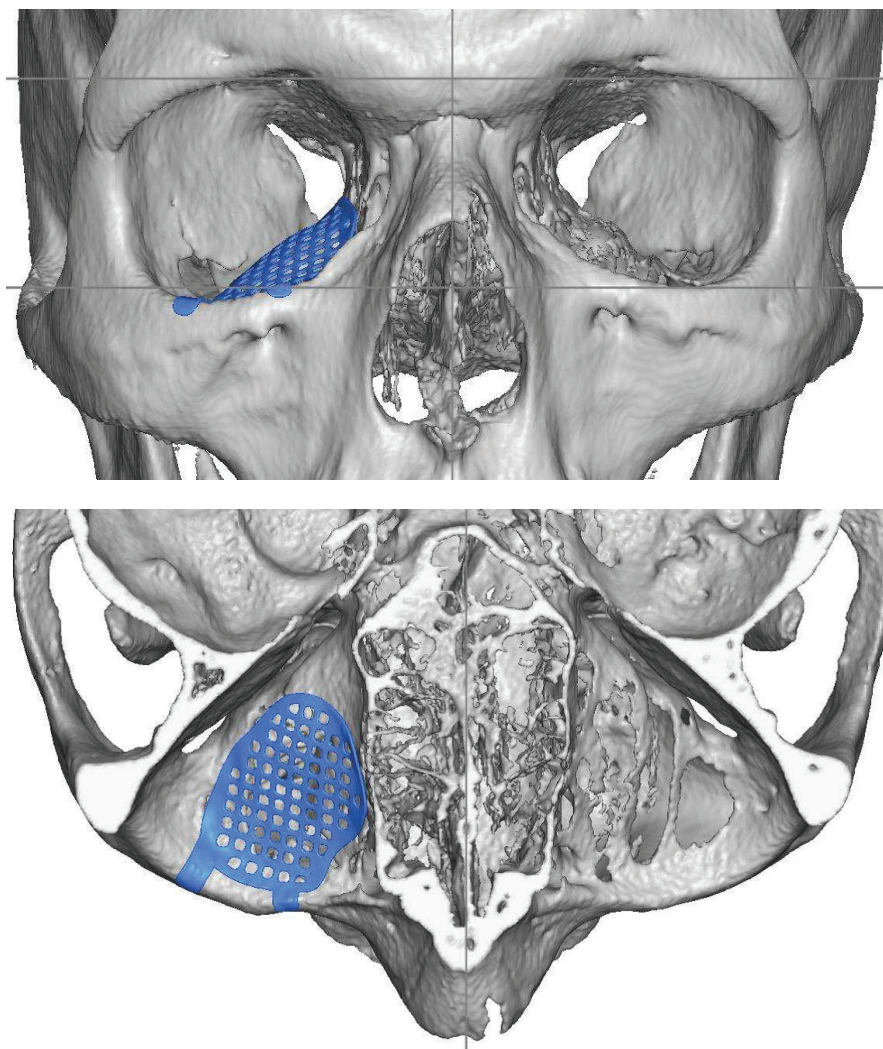


Figure 1. The patient-specific implant (PSI) design. Virtual surgical planning was performed online with a surgeon and an engineer. The PSI was designed by mirroring the unaffected side. The PSI had at least 3-point support to fit passively – usually two points with extensions over the orbital rim and one on the posterior ledge. 3D contouring facilitated accurate fitting. The PSI was made of titanium.

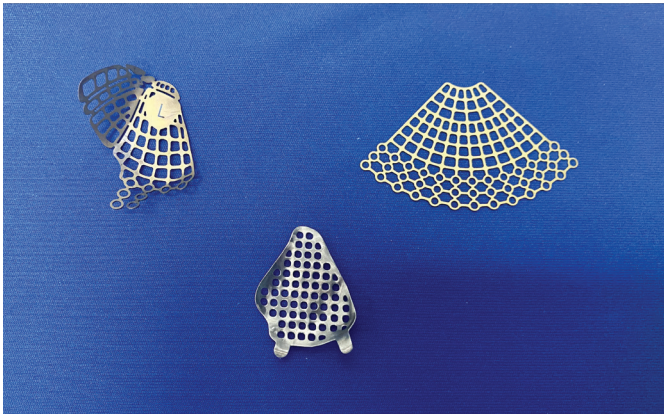


Figure 2. Implant types used in the study: preformed orbital plate (left), patient-specific implant (middle), titanium orbital mesh plate (right).

Preoperative data and surgeons' consultant experience in each study group were compared. To demonstrate the non-inferiority of the clinical outcome of the PSI compared to standard care (stock implants), the same radiologist (N.L.) measured the preoperative and postoperative volume of the bony orbit of the fractured side and the unaffected contralateral side for the analysis. Volume was measured using the automated volume analysis program CMF Orbital Software (Disior Ltd., Helsinki, Finland) to minimize measurement error. The program generates a virtual triangle mesh after the radiologist chooses a seed point inside the orbital vault (apex of the orbit), which iteratively expands until it meets the bony walls of the orbit and the orbital rims. For the fracture site, the shortest distance between the displaced fragment and the fracture rim limits the expansion. This system has been shown to be reliable (0.992, 95% confidence interval [CI]: 0.987–0.997; intraobserver ICC and 0.989, 95% CI: 0.983–0.993; interobserver ICC in intact orbit) [15]. The radiologist confirmed all volume analyses and the surface reliability of the software algorithm in all cases. The hospital radiologist workstations and GE HealthCare AW Server software were used for the analysis according to the manufacturer's instructions for quantitative analysis.

The postoperative volume difference in percent, compared to the contralateral, unaffected side, was calculated. The primary operation time was analyzed, as well as other inpatient costs. Operation time was defined as the interval from the incision to closure, and the time for patient preparation, anesthesia induction, and emergence from anesthesia was excluded to omit the effect of possible comorbidities. Data were assessed visually and tested for normality with the Shapiro–Wilk test. The PSI group was compared with the stock implant group with the Mann–Whitney test concerning volume difference and operation time. The missing data were excluded on a test-by-test basis. The need for reoperation was analyzed with Fisher's exact test. The significance was set to $p = 0.05$.

The companies provided the data on the cost of the implants, which was considered the only non-routine fixed cost per patient. The financial services department of our hospital approximated the operating room minute cost. The average operating room cost was assessed to be 38 euros per min, covering the operating room personnel, maintenance and overhead, anesthesia, and routine equipment. The hospital ward cost per day was calculated, as well as the cost for imaging, operation-specific laboratory cost, specialty-specific materials, and general material cost. The engineer's work time was included in the PSI price. The authors calculated the cost of each method by adding the implant price to the average primary

Table 1. Demographic and orbital volume data.

Implant	Sex	Age	Consultant experience
	(female; male)	(years)	(years)
PSI	6 (46%); 7 (54%)	44	2.92
Stock	11 (31%); 25 (69%)	42	5.86
Sig.	$p = 0.135$ NS	$p = 0.874$ NS	$p = 0.377$ NS

PSI: patient-specific implant; NS: non-significant.

operation time, which was multiplied by the average operating room minute cost, and then added the hospital ward day cost, which was multiplied by the days as well as other inpatient costs. The reoperation rate and cost were calculated similarly, and the risk cost was added to the operation's total cost.

Ethics

The study protocol was approved by our hospital's Institutional Review Board (Permission D/18/07.01.04.05/2018 and D/2929/07.01.04.05/2020) and adhered to the principles outlined in the Declaration of Helsinki. This was an IRB-approved retrospective study; all patient information was de-identified, and patient consent was not required. Under Finnish legislation, patient consent was not required for this type of study.

Results

The data registry search identified 408 patients with facial trauma; 190 (46.56%) had a blow-out fracture. Forty-nine patients met the inclusion criteria, 13 (26.53%) of whom underwent reconstruction with PSI. Twenty-nine patients received preformed plates, and seven received titanium mesh implants, comprising the stock implant group of 36 (73.47%) patients. The study groups had no statistically significant differences in sex, age, or surgeons' consultant experience (Table 1). The patient registry contained no documented rationale for the implant selection. Thirteen in the stock implant group had insufficient radiological data and were excluded from the volume measurements. Preoperatively, the stock implant group had an average of 15.06% orbital volume difference between the trauma and contralateral side, and the PSI group had 7.17% ($p = 0.795$). The postoperative volume in the PSI group more closely matched the contralateral side (4.09%) than in the stock implant group (9.65%) ($p = 0.001$) (Table 2).

The price of a preformed plate ($n = 29$) was 667.60 €, that of a titanium mesh plate ($n = 7$) was 595.70 €, and that of a PSI ($n = 13$) was 917.60 € during the study period; the PSI cost 1.4 times the price of the mean control group plate. Operation time differed significantly between the groups ($p = 0.008$), with the PSI group having a shorter operation time. Consequently, operating costs were also lower in the PSI group (4328.86 vs. 5315.84 €) (Graph 1). The treatment protocol for patients with trauma did not differ according to implant type, and the other costs (materials, medical imaging, laboratory, and other inpatient costs) were similar across the study groups. Hospital ward days did not differ significantly ($p = 0.603$). Four patients (11.1%) in the stock implant group needed a reoperation, but none in the PSI group, although this difference was not statistically significant ($p = 0.562$). The reasons for reoperations were a radiologically ill-fitting plate with clinical complaints (3 patients) and persistent diplopia (1 patient). The total cost for reoperation was 6292.11 € (Table 3), adding to the total cost (Table 4).

The cost-effectiveness calculation showed that PSI had a lower total cost than standard stock implants (7573 vs. 8788.15 €).

Table 2. The pre- and postoperative orbital volume difference (%) between trauma and contralateral side in each study group.

Implant	Pre (%)	95% CI	SD	Post (%)	95% CI	SD
PSI	7.17	2.83–11.51	7.18	4.09	1.75–6.43	3.87
Stock	15.06	4.63–22.49	24.11	9.65	7.60–11.70	4.74
Sig.	$p = 0.795$, NS			$p = 0.001^*$		

CI: confidence interval; SD: standard deviation; PSI: patient-specific implant; NS: non-significant.

*significant ($P < 0.05$).

Discussion

This study aimed to assess whether titanium PSI is a cost-effective and accurate method to reconstruct blow-out fractures. The null hypothesis that stock implants are more cost-effective compared to PSI was rejected. Our findings show shorter operation time, no need for reoperations, lower total cost, and better postoperative volume correction.

PSI itself is more expensive, but the total cost was reduced in our setting compared to the stock implant group. Operation time was significantly shorter when using PSI than stock implants in our study, and that is the crux of the matter. Shorter operation time was seen before in a small series of titanium PSI [13] or a PSI made of a variety of materials [16]. The precise fit and smooth rims of PSI facilitate surgery. PSI requires no perioperative bending during the operation and is easily inserted if designed properly, but other phases of surgery are similar. VSP also allows the surgeon to thoroughly orient to the surgery beforehand, and despite taking some time, the planning time is not as expensive as operating room time; some preoperative planning even occurs in stock implant surgery. The price of the implants varies. The PSI we used was less expensive (917.60 €) than that of the other study in the UK (approximately 2250€); however, the cost difference between the study groups would cover even the more expensive PSI [14].

The optimization of hospital efficiency is increasingly more important. In our study, the operating room cost was over two-thirds of the total cost of the patient treatment, but surgery is the cost-intensive part of hospital care. Operating rooms are estimated to account for approximately 35 to 40% of hospital costs [17]. Hospital ward time across the study groups did not differ significantly; other inpatient expenses were also similar.

A longer operation time is thought to carry a higher risk for postoperative complications, but this seems hard to specify because long operations and morbidity may be due to the procedure's

complexity and preoperative features. A longer operation time and more bleeding were found in blow-out reconstruction with intraoperative bending of titanium mesh compared to a variety of utilized preoperative CAD/CAM techniques [18]; surgery with 3D model molded implants versus traditional implants also carries a lower risk for bleeding [19].

The stock implant group had 11.1% reoperations, while PSI had none in our study. This result is a clinically important finding, although statistically non-significant. A previous study had 3.8% of reoperations on all isolated orbital floor fractures; the PSI and biomaterial also scored lowest in this [20]. In our study, three patients had radiologically misplaced implants, and one had persistent diplopia, needing reoperation. This parallels the findings of a previous study, claiming the reason for revising blow-out fracture surgery was usually radiologic malpositioning of the implant combined with clinical disturbance [21]. Patients with blow-out fractures treated at our institution also do not routinely meet with ophthalmologists; thus, no data on ocular pathologies nor their consequences are available for all patients. Reoperation cost was 6292.11 euros in our study, so reoperation is not only uncomfortable and burdensome to the patient, but a financial concern. Thus, the operation time and risk for reoperation remain the most important features reducing costs.

The cost-effectiveness in this study approximated the direct costs of the primary operation and inpatient care because other care and indirect costs were estimated to be similar across the study groups and not affected by implant choice, but this may be subject to inaccuracies. However, healthcare costs are always difficult to calculate precisely [22]. Neither the patient nor insurance in public hospitals in our country pays for healthcare costs; instead, taxes cover the inhabitants' healthcare, and the patient's charge does not depend on interventions or care received. However, with the current trends of increasing costs and lack of healthcare personnel, public healthcare is also under pressure to streamline the care and reduce the costs.

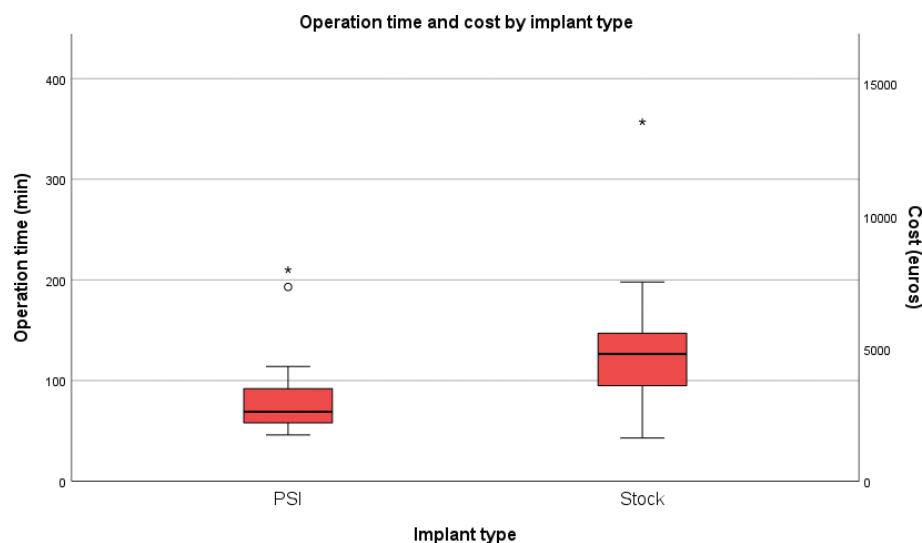
**Graph 1.** Operation time and cost in each study group.

Table 3. Reoperation total cost per patient ($n = 4$).

Cost components	Cost (Euros)
Operation cost (38 € per min)	3676.5
New implant (2 PSI, 2 stock)	785.61
Other specialty-specific materials (per operation)	619
General materials (per operation)	260
Hospital ward (844 € per day)	844
Imaging (107 € per CT)	107
Total cost €	6292.11

PSI: patient-specific implant; CT: computed tomography.

Although the cost was our study's main aim, the care provided should not be inferior compared to the gold standard treatment [4, 6, 7]. Orbital volume in the normal population is rather symmetric [23, 24], and this should be the aim to avoid surgical complications [25–27]. The postoperative volume of the bony orbit more closely matched the volume of the contralateral side in our study's PSI group. Thus, the shorter operation time was not achieved with lower standards; rather, the outcome exceeded the control group's. Previous studies have shown the PSI volume correction [16, 27–29]. Prefabricated mesh provided rather poor radiological symmetry outcomes [30]. A standard implant may provide inadequate support to orbital contents or disturb delicate structures of the orbit that require readjustment or even reoperation. This was especially true in larger fractures [31]. A meta-analysis found 3D printing to be better in volume, diplopia, and enophthalmos, but the study combined all kinds of 3D printing methods and compared them to traditional reconstruction of blow-out fractures [29]. Larger defects were better reconstructed with PSI, but the difference was non-significant compared to standard implants in smaller defects [18]. VSP is shown to reproduce well in real-life surgery, and the implant's postoperative position was proven to be very accurate as planned [10, 28].

A limitation of this study is its rather small study population. Our study's retrospective nature also provided limited data, so a prospective randomized controlled trial would verify the results. Moreover, more than one surgeon operated on patients, introducing potential variability in techniques. Stock implants were the standard routine in our hospital before 2018, and the shift to the PSI method happened gradually; however, the rationale for selecting the implant type was not documented in the patient registry. As the study was not randomized, the surgeons' preferences or the presumed difficulty of the operation may have influenced implant selection. Combining

Table 4. Operation total cost. Stock implant price used in this analysis is calculated as the average price of the prices of preformed plates ($n = 29$, 667.60 €) and mesh plates ($n = 7$, 595.70 €).

Cost components	PSI ($n = 12$)	Stock ($n = 36$)	<i>P</i>
Operation cost (38 € per min)	4328.86	5315.84	
Operation time (min)	89.77	122.69	0.008*
Implant (€)	917.60	653.62	
Other specialty-specific materials and laboratory (€ per operation)	619	619	
General materials (€ per operation)	260	260	
Hospital ward and laboratory cost (844 € per day)	1233.54	1027.33	
Hospital ward (days)	1.46	1.28	0.603 NS
Imaging (107 € per CT)	214	214	
Reoperations	0	4	0.562 NS
Calculated reoperation risk cost	0	698.42	
Total cost €	7573	8788.15	

PSI: patient-specific implant; CT: computed tomography; NS: non-significant.

*significant ($P < 0.05$).

different kinds of implants in the stock implant group may affect the results, as the orbital mesh seems to perform worse than preformed plates, despite being less expensive [32].

A new technology implementation should consider both quality and cost. The authors are not claiming the overall superiority of PSI over standard implants but rather emphasize the comprehensive approach for cost management. The results are not applicable to all countries because settings, personnel, material, maintenance costs, and requirements vary.

Conclusion

This investigation's results imply that PSI is a more cost-effective method to reconstruct orbital floor fractures, mainly due to reduced operation time. PSI provides more accurate reconstruction than titanium stock implants and requires no reoperations. However, this study addresses only some aspects of the treatment for blow-out fractures and may not show PSI's overall superiority. Further studies, preferably prospective controlled trials, are needed to confirm the results.

Conflicts of interest

The authors report no competing interests to declare.

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