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Revolutionizing Reconstruction: The Role of Custom Implants in Orbital and Zygomatic Complex Fractures

Steven Steven[1], Jessica Oktavia[2], Irawan Wahyudi[3]
[1]Setio Husodo General Hospital, Indonesia
[2]PIK Pain Rehab Clinic, Indonesia
[3]Murni Teguh Sudirman Jakarta Hospital, Indonesia

ABSTRACT

Introduction: In the realm of orbital reconstruction following traumatic fractures involving the zygomatic complex (ZMC), the adoption of patient-specific implants (PSI) crafted through computer-assisted technology prompts inquiry into its comparative efficacy against conventional methods. This study investigates whether PSI enhances outcomes—such as orbital volume, enophthalmos, diplopia, implant malposition, and ZMC symmetry—in adult patients, compared to conventional approaches.

Methods: We conducted a systematic review following PRISMA guidelines, focusing on peer-reviewed articles published after 2014 that reported comparisons between implants based on computer-assisted technology and conventional methods for orbital bone and zygomatic complex fractures in adults. Databases and trial registries were systematically searched to identify relevant studies. The Newcastle-Ottawa Scale (NOS) was employed to assess the quality of studies included in this systematic review.

Results: Following a comprehensive literature search, 1,463 articles were initially identified and screened for relevance and duplication, resulting in a final selection of 3 articles. Orbital and zygomatic complex reconstruction using patient-specific implants (PSI) was performed in 61 patients, while 70 patients underwent conventional methods. The most common post-surgical complications included enophthalmos (n=23), diplopia (n=20), and implant malposition (n=13). PSI facilitated the restoration of orbital volume levels between injured and uninjured orbital bones and achieved ZMC symmetry. All studies included in this review were categorized as level 3 evidence.

Conclusion: This examination of published literature on PSI for orbital and ZMC fracture reconstruction underscores that, while PSI can effectively, precisely, and safely address orbital fractures, patient outcomes are largely comparable to those achieved with conventional methods, and PSI do not present a clear advantage over conventional implants.

KEYWORDS: Orbit Fractures, Patient-Specific Implants, 3-D Printing, CAD/CAM, Orbital Implants

ARTICLE DETAILS

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INTRODUCTION

Orbital wall defects, caused by isolated blowout fractures or zygomatic-maxillary fractures, are common injuries that lead to facial disfigurement and functional impairments.[1] Among these, zygomaticomaxillary complex (ZMC) fractures stand out as common consequences of midfacial trauma, often affecting the inferior orbital rim and orbital floor.[2] Displacement of ocular structures, soft tissues, or muscle entrapment caused by orbital bone defects often results in diplopia and enophthalmos, highlighting the need for careful management of orbital trauma.[1] The restoration of physiological anatomy and functional integrity in orbital defects depends on the severity of the trauma, thus highlighting the necessity for individualized treatment strategies.[3] Historically, the management of such fractures has predominantly relied on the expertise of the surgeon, albeit with variable outcomes in terms of facial contour, symmetry, and functional rehabilitation, occasionally yielding sub-optimal results.[4]

The controversies surrounding orbital reconstruction methods, particularly under diverse clinical conditions and varying orbital-defect topographies, remain subjects of ongoing debate within literature.[3] Facial reconstructive procedures are frequently performed due to injuries resulting from sports-related incidents and vehicular accidents, often requiring extensive reconstruction of the ZMC and orbital.[5] The fragile nature of the orbital floor renders it susceptible to damage in craniofacial trauma, particularly in regions medial to the infraorbital groove and canal, where fractures commonly occur.[1] These fractures pose significant challenges to plastic surgeons, given the potential for serious ophthalmic complications like visual disturbances, diplopia, and enophthalmos, along with aesthetic concerns such as facial asymmetry resulting from the injuries.[6]

Three-dimensional (3D) printing is extensively employed in orthopaedic and maxillofacial surgery to create customized medical tools and implants from digital models.[7] In orbital surgery, 3D printing aids in preoperative planning by producing models of the fractured orbit or mirror-images of uninjured orbits.[8] These models assist in shaping orbital implants tailored to individual patient anatomy, either through direct printing or preoperative manipulation. Computer-assisted surgery (CAS) and 3D printing are integral to various aspects of maxillofacial surgery, particularly in complex reconstructive procedures.[4] Advanced software tools enable surgeons to replicate pre-trauma anatomy effectively and affordably, enhancing surgical planning accuracy.[9]

The emergence of CAS, including computer-aided design and manufacturing (CAD/CAM) processes, has led to the development of patient-specific implants (PSI).[10] These implants may be entirely customized externally based on mirror-image overlays derived from CT scans of the uninjured orbit or manipulated preoperatively on patient-specific 3D models created from CT imaging.[8] Printed models devoid of soft tissue offer comprehensive visualization of the fracture site, facilitating precise preoperative implant adaptation and potentially reducing operative time and soft tissue manipulation during surgery.[10]

This systematic review aimed to synthesize and clarify current evidence from comparative studies on PSI versus conventional reconstruction (CR) techniques regarding post-operative outcomes.

METHODS

The study was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) standards.[11] No approval from the Institutional Review Board was necessary for the present study. An extensive electronic search was conducted utilizing keyword search on the PubMed and Scopus databases, as well as the ClinicalTrials.gov, International Clinical Trials Registry Platform (ICTRP), and International Standard Randomized Controlled Trial Number (ISRCTN) registries. We employed a comprehensive search technique utilizing suitable descriptions and keywords. The search terms used were orbit fractures, zygomatic fractures, ZMC fractures, orbital implants, custom design, computer-assisted design, computer-assisted manufacturing, three-dimensional printing, and patient-specific implants. The Boolean operators "AND" and "OR" were used to narrow down the recovered texts to only those that discussed the specific topic of interest, which includes orbital fractures, ZMC fractures, and their reconstruction using PSI.

Eligible articles had to have a full-text available in English and specifically report the utilization of computer-assisted technology during the prefabrication or design process of implants intended for orbital reconstruction following fractures. The implants discussed in the selected articles were required to be patient-specific, achieved through either customized fabrication utilizing CAD/CAM technologies or through the pre-operative bending of plates using patient-specific 3D modeling.

Exclusion criteria encompassed articles where patients were blind preoperatively, duplicate patient datasets, utilization of computer-assisted technologies solely for diagnostic, pre-operative planning, or intra-operative navigation purposes, orbital and ZMC reconstruction conducted for non-traumatic indications, as well as animal and cadaveric studies, editorials, reviews, and observational studies lacking comparative treatment arms. Search restrictions were imposed, limiting the search to English-language content published from the year 2014 onwards, with the most recent search conducted on February 12, 2024.

Two reviewers conducted data selection based on predefined criteria, eliminating duplicate items in the initial screening stage. Each publication was meticulously evaluated to ensure compliance with inclusion criteria and exclusion of studies failing to meet standards. Any uncertainties were resolved through consultation with a senior researcher in the field. The selection process adhered to ethical standards and aimed to minimize bias through consistent and transparent procedures. The Newcastle-Ottawa Scale (NOS) assessed bias risk in relevant studies, categorizing them as high, moderate, or low risk across three dimensions.[10,12] Data extraction from eligible studies covered study characteristics (author, title, year, design, sample size, and follow-up period) and population details (mechanism of injury, fracture type, time from injury to surgery, surgical approach, implant material and manufacturing process, and whether the reconstruction was primary or secondary). Key outcomes included preoperative and postoperative diplopia, enophthalmos, orbital volume, facial symmetry, and complications.

RESULTS

A comprehensive search of databases, including PubMed, Scopus, and trial registries such as ClinicalTrials.gov, ICTRP, and ISRCTN, identified 1,463 studies. After removing 211 duplicates, 1,252 unique studies remained. Using ASReview LAB v1.5, titles and abstracts were screened against predefined inclusion and exclusion criteria, leading to the exclusion of 1,084 articles.[13] Full texts of the remaining 33 articles were then reviewed, with 30 excluded for not meeting the criteria. A manual search of reference lists from eligible articles did not identify any additional relevant studies. Ultimately, three articles met the inclusion criteria and are summarized in Table 1.

Table 1. List of Retrieved Articles

Author	Year	Study Sample	Cause of Injury	Type of Fracture	Implant Type (Conventional; PSI)
Chepurnyi et al[3]	2020	Conventional: 45 PSI: 47	Not reported	Unilateral orbital fractures (isolated or combined with zygomatic and/or maxillary fractures)	Prefabricated titanium plate before/during operation (KLS-Martin or Titamed BVBA orbital plate). Patient Specific Machine-milled PEEK blocks (Merz Dental).
Lehtinen et al[9]	2022	Conventional: 12 PSI: 8	Assault= 1; fall= 10; traffic collision = 6; sport injury= 2; other= 1	Combined unilateral orbital and ZMC fracture	Standard orbital and mid-facial implants (Synthes, Stryker or KLS-Martin). Patient-specific milled titanium implants (manufacturer undisclosed).
Longeac et al[4]	2021	Conventional: 13 PSI: 6	Assault= 5; fall= 3; traffic collision = 3; sport injury= 7; other= 1	Comminuted unilateral ZMC fracture with associated orbital fracture	Titanium orbital meshes (SYNTHES® MatrixMIDFACE™) or PDS plate (ETHICON ZX5). Pre-bent titanium mesh and plate according to a 3D printed model (SYNTHES® Matrix MIDFACE™)

An overview of the article selection process is depicted in Figure 1. The total scores and risk of bias assessments for the three observational studies were determined using the NOS. Scores falling within the ranges of 0–3, 4–6, and 7–9 correspond to high, moderate, and low risk of bias, respectively. Notably, none of the three studies were identified as having a high risk of bias (Table 2).

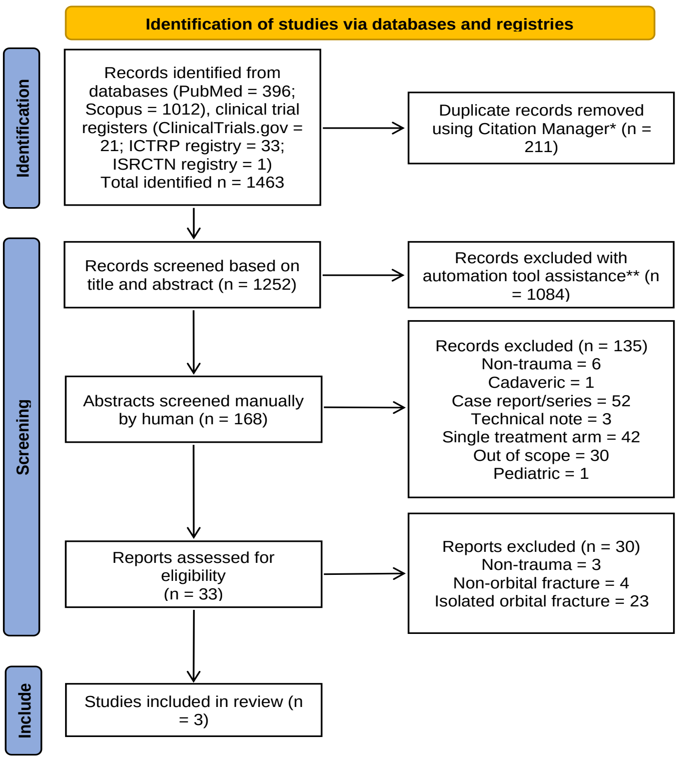

Figure 1. Overview of the process for selecting articles.

The systematic review evaluated the efficacy of PSI versus CR and the utilization of 3D printing technology in the reconstruction of orbital and zygomaticomaxillary complex (ZMC) fractures through analysis of three primary studies. Across the studies, sample sizes varied, ranging from 19 to 92 per cohort, with a mean patient age of 32.7 (SD 19.5) years across all reporting studies, encompassing a total of 131 patients. Notably, males constituted 76.33% of the cases, reflecting a disproportionate gender distribution. Mechanisms of injury were described in two of the three studies, with falls being the most common (33.3%), followed by traffic collisions (23.1%), sports injuries (23.1%), assaults (15.4%), and 'other' causes (5.1%).[3,4,9]

Regarding PSI materials, there was heterogeneity across the studies. One study utilized patient-specific machine-milled polyether-ether-ketone (PEEK) blocks,[14] while another employed pre-shaped titanium mesh and plate based on a 3D model.[4] The third study utilized patient-specific milled titanium implants.[9] This diversity highlights the range of material choices in orbital and ZMC fracture reconstruction, reflecting ongoing advancements in surgical techniques and technologies in the field.

Table 2. The Nos Scores And Bias Ratings For The Three Observational Studies.

NOS criteria	Studies (year)		
	Chepurnyi et al (2020)	Lehtinen et al (2022)	Longeac et al (2021)
A. Selection			
Representativeness of the exposed cohort	★	☆	☆
Selection of the non-exposed cohort	★	☆	☆
Ascertainment of exposure	★	★	★
Demonstration that outcome of interest was not present at start of study	★	★	★
B. Comparability			
Comparability of cohort based on the design or analysis	★☆	★☆	★☆
C. Outcome			
Assessment of outcome	★	★	★
Was follow-up long enough for outcomes to occur	★	★	★
Adequacy of follow-up of cohorts	★	★	★
Total	8	6	6
Overall risk of bias	Low	Moderate	Moderate

The synthesis of findings from three distinct studies comparing the efficacy of patient-specific implants (PSI) versus conventional reconstruction (CR) in orbital and zygomaticomaxillary fracture reconstruction provided valuable insights into postoperative outcomes. Chepurnyi et al. found that PSI offered greater accuracy in reconstructing orbital shape, with a significant difference in mean orbital volume post-surgery (0.137 ± 0.8 cm^3 for PSI vs. 1.05 ± 1.9 cm^3 for CR, p=0.007).[3]

Similarly, Longeac et al. demonstrated a substantial improvement in orbital volume restoration, with a postoperative volume discrepancy of 0.4 mL in the PSI group compared to 2.1 mL in the CR group (P=0.004), highlighting the superior outcomes associated with 3D printing technology.[4] However, Lehtinen et al. found no significant advantage of PSI over conventional implants regarding volume correction, reporting similar postoperative orbital volume differences (0.2 mL for PSI vs. 0.3 mL for CR), despite a larger preoperative orbital volume difference in the PSI group (2.1 mL vs. 1.5 mL). This suggests that while PSI may be more effective in managing more severe fractures, its impact on volume restoration is comparable to conventional methods.[9]

Lehtinen et al. noted minor complications in both groups, signaling a low overall complication rate, with no major issues like wound dehiscence or significant globe malposition observed. In the PSI group, occurrences included one case of eyelid malposition and another involving occlusal interference and lacrimal duct injury, while the CR group experienced two instances of abnormal scarring, two of minor globe malposition, and one case of minor superior sulcus syndrome. These findings indicate that while complications were present, they were predominantly minor and controllable, with PSI exhibiting a marginally lower complication rate compared to CR.[9]

Chepurnyi et al. found that while PSI provided a better fit, the incidence of diplopia post-surgery was similar between PSI and CR patients, suggesting that the choice of implant may not significantly influence the resolution of diplopia. However, PSI patients had a significantly lower incidence of enophthalmos (10.6% vs. 35.6%, p=0.001), suggesting an advantage in preventing this complication. The incidence of diplopia at the three-month follow-up did not show a significant difference between the two groups (14.9% for PSI vs. 28.9% for CR), indicating that the implant type may not substantially affect the recovery from diplopia.[3]

Longeac et al. observed a trend towards fewer complications and negative outcomes during surgery, suggesting potential benefits associated with the utilization of 3D printed models and pre-bent plates, which could contribute to a reduction in postoperative issues. Notably, the absence of reported complications during the surgery implies a smooth procedural experience devoid of unexpected challenges. Despite a small sample size, the study found a significantly lower incidence of complications in the study group (P = 0.03).[4]

When assessing facial symmetry, Longeac et al. found no significant differences in the anterior and posterior width of the zygomaticomaxillary complex (ZMC) between the injured and uninjured sides after surgery, even with pre-bent titanium plates. However, zygoma projection was significantly improved in the study group (P=0.04), with a variation of 0.1 cm compared to 0.2 cm in the control group.[4,15]

In a separate study, Lehtinen et al. assessed the mean point-to-point dislocation of the ZMC to evaluate facial symmetry. Patients treated with conventional implants showed greater mean dislocation (2.7 mm compared to 2.2 mm) and medial translation (3.9 mm compared to 2.6 mm) compared to those treated with PSIs. However, post-surgery, both groups demonstrated similar dislocation (1.5 mm for

PSI vs. 1.7 mm for CR), indicating comparable results in facial symmetry after reconstruction.[9,16]

DISCUSSION

The primary etiological factors contributing to trauma, namely traffic collisions, sports injuries, and falls, align with commonly reported mechanisms of injury in existing literature.[17,18] The management of complex orbital-ZMC fractures presents a significant challenge due to the pivotal role of the ZMC in facial structure and function, posing risks such as facial deformity or compromised facial projection.[14,19,20] Evaluating the efficacy of orbital fracture repair involving orbital-ZMC using implants relies on objective assessments of key outcomes, including rates of ophthalmic complications such as diplopia and enophthalmos, as well as the quantification of orbital volumes.[21]

In orbital-ZMC reconstruction, the pursuit of improved surgical techniques has driven efforts to develop fully customized patient-specific implants (PSI) that can accurately replicate the complex anatomy of the orbital region. At the same time, the emergence of computer-assisted surgery (CAS) has transformed surgical approaches, providing advancements in pre-operative planning and intra-operative guidance.[7,10,19] These innovations encompass the utilization of stereolithography to generate detailed 3D models of patient anatomy and intra-operative guidance. However, despite these technological advancements, these methods have not yet become standard practice in clinical settings.[22] The current study, which included 131 patients across three studies, aimed to gather comparative data to assess whether there are differences in outcomes between patients undergoing orbital and ZMC reconstruction post-trauma, specifically comparing patient-specific implants (PSI) with conventional implants

Chepurnyi et al. highlighted the superior fit and accuracy of custom-made implants for repairing eye socket injuries compared to standard ones. Several studies regarding the use of PSI also support the idea that custom implants offer a more effective and predictable means of restoring the eye socket's shape, crucial for preventing a sunken appearance and improving post-injury vision problems.[23–26]

Lehtinen et al.'s study compared PSI to CR for reconstructing facial fractures, focusing on symmetry and clinical results. Despite initial conditions being more severe in patients receiving PSI, outcomes did not significantly differ from those treated with CR. This indicates the effectiveness of patient-specific implants in managing complex fractures.[27,28] Additionally, patient-specific implants might offer advantages in reducing postoperative complications, requiring less manipulation during surgery, potentially leading to better recovery outcomes.[29,30]

Longeac et al. discussed the benefits of using 3D printing and virtual planning for accurate treatment of ZMC fractures involving orbital bone, resulting in improved facial symmetry and shape post-surgery. However, challenges remain in addressing zygoma rotation during surgery.[21,31,32] While promising, the study's small sample size warrants further research to confirm these results. Moreover, combining 3D printing with navigation systems could enhance surgical outcomes, indicating a promising avenue for future research.[33,34]

Overall, the systematic review underscores the potential of customized implants and advanced surgical techniques in improving outcomes for patients undergoing orbital and ZMC fracture reconstruction. However, further studies with larger sample sizes and prospective designs are needed to validate these findings and explore additional advancements in surgical technology.

CONCLUSION

Based on the results, it can be concluded that patient-specific implants (PSI) offer several benefits in managing orbital fractures, particularly those involving the zygomaticomaxillary complex. First, PSIs provide improved precision, leading to more accurate reconstruction of the orbital shape compared to conventional plates, which enhances the restoration of orbital anatomy. Additionally, PSIs are effective in preventing enophthalmos, a common complication of orbital trauma, improving both aesthetic and functional outcomes for patients. While PSIs offer better precision and fit, their postoperative outcomes in terms of symmetry and clinical results are like those of standard implants, suggesting that PSIs are a viable option for treating complex orbital fractures. Finally, the use of PSIs may reduce postoperative complications due to their better fit and less manipulation during surgery, leading to improved patient outcomes and faster recovery.

Overall, the utilization of patient-specific implants in managing orbital fractures involving the zygomaticomaxillary complex appears promising, offering improved precision, reduced complications, and comparable outcomes to standard implants. However, the absence of robust comparative studies underscores the need for further research in this nascent field. Future investigations should aim to fill this gap by conducting well-designed comparative studies that directly compare the outcomes of PSI-based approaches with conventional methods. These studies would contribute significantly to our understanding of the efficacy, safety, and comparative effectiveness of PSIs in orbital-ZMC fracture management.

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CONFLICT OF INTEREST

There are no conflicts of interest.

AUTHOR CONTRIBUTION

All authors contributed equally to the research, writing, and editing of the manuscript.

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