



WHAT SOLID EVIDENCE DO SYSTEMATIC REVIEWS PROVIDE ABOUT POST-TRAUMATIC ORBITAL RECONSTRUCTION MATERIALS? AN OVERVIEW OF SYSTEMATIC REVIEWS

SYSTEMATIC REVIEWS

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ABSTRACT

Orbital fractures pose considerable challenges in the field of maxillofacial surgery. With advancements in materials engineering, various models and biomaterials have emerged for orbital reconstructions. Given the increasing number of systematic reviews (SRs) on orbital reconstructions, we aim to provide a comprehensive overview of SRs about biomaterials used in these procedures. Employing the PRIOR checklist, we scrutinized 14 SRs addressing materials for orbital reconstructions and their findings. The risk of bias was evaluated using the ROBIS tool, while the methodological quality of the reviews was assessed through the AMSTAR 2 tool. Our analysis revealed five low- or critically low-quality evidence, four of which had a strong recommendation for use and one that had a weak one. Despite the abundant literature on orbital reconstructions, high-quality evidence was notably absent. Still, this overview has generated pivotal and clear recommendations for surgical practice. We advocate for further randomized controlled trials featuring robust research designs to enhance the quality and reliability of evidence within this domain.

Key-words: Orbital Implants, Orbital Fractures, Absorbable Implants, Surgical mesh, Evidence-Based Practice.



1. INTRODUCTION

Orbital fractures represent significant challenges in maxillofacial surgery. Concerns such as the ideal time for the intervention, better surgical access, the use of customized implants, intraoperative navigation, and implant biomaterial are frequently debated issues.

As materials engineering advances, various models and biomaterials have been developed for orbital reconstructions. Evaluating these implants is crucial for clinical practice construction, and studies such as Randomized Controlled Trials (RCT), cohort studies, and Systematic Reviews (SR) play a critical role in this evidence-based process.

This practice should guide clinical decisions, and the critical analysis of SRs is a crucial step in this process. Every day, evidence-based practice gains more prominence, as it should be. Groups such as the Cochrane Collaboration¹, GRADE Collaboration²⁻⁴, Joanna Briggs Institute⁵, NICE⁶, and others produce a considerable effort to create and constantly update tools related to the quality of evidence, with the understanding that it is not enough to have data; the data must be strongly reliable^{7,8}.

Given the increasing number of SRs on orbital reconstructions, we aim to provide a comprehensive overview of SRs about biomaterials used in these procedures. Through this analysis, we propose evaluating the evidence's reliability and providing valuable insights for clinical practice.

2. MATERIALS AND METHODS

This SR overview was published on PROSPERO (CRD42023426823). We follow the PRIOR checklist, Preferred Reporting Items for Overview of Reviews⁹ (Appendix 1). The review question was: What solid evidence do systematic reviews provide about post-traumatic orbital reconstruction materials? The PECOS assessment is available in Table I.



2.1 SEARCH STRATEGY

The searches were conducted in May 2023 and repeated in March 2024. We used the databases PUBMED, COCHRANE, EMBASE, SCOPUS, WEB OF SCIENCE (via CAPES), LILACS (ENG, ESP, PT), Google Scholar (first 100 results), Science Direct, International Journal of Oral and Maxillofacial Surgery, and Journal of Oral and Maxillofacial Surgery. The complete search strategy descriptors can be found in Appendix 2. A manual search of the reference lists of the included articles was also conducted. Institutional repositories weren't included as the study aims to evaluate evidence published in SRs.

The searches were conducted using a filter for the type of study "systematic reviews." No other filters or restrictions were applied. The collected data was included in the EndNote platform for processing.

2.2 SCREENING PROCESS, DATA COLLECTION, AND OUTCOMES

Duplicate papers were identified and removed in EndNote; the remaining papers were added to the Rayyan platform¹⁰ to screen titles and abstracts and to apply eligibility criteria (Table I). Two independent and blinded authors (LHGM and LHST) performed this step, and a third author (MC) resolved the conflicts.

Two independent authors (LHGM and LHST) conducted the data collection, and it was reviewed by two other authors (CM and BDM) in a spreadsheet created for this purpose. A senior researcher (VAPF) supported the entire process.

We searched for results that presented safety and effectiveness in orbital reconstructions. Complications of interest were noted, including enophthalmos, diplopia, reduced ocular motility, and infection. No authors were contacted for unpublished data.

The primary studies used in the reviews have not been formally examined, which may result in overlap. Discrepant data found will be discussed in due course.



2.3 QUALITY OF REVIEWS AND BIAS ANALYSIS

LHGM and LHST conducted all steps of evaluating methodological quality and risk of bias, and the disagreements were resolved in consensus.

The systematic review quality was assessed using the AMSTAR 2¹¹. The final score can vary between high, moderate, low, and critically low quality. Bias analysis of the reviews was conducted using the ROBIS¹², which final bias score can be high, low, and uncertain.

The AMSTAR 2 and ROBIS inquire about the presence and clarity of various aspects of systematic reviews. When these aspects, methodological descriptions, results, or important caveats are absent or not clearly exposed in the text, the tendency is to classify them in that item as "high concern" or "low quality".

To answer the AMSTAR 2 and ROBIS tools, we considered statistical syntheses of data (e.g., pooled outcome analysis and the like) as meta-analysis. Our understanding is that if an analytical sum or treatment were used to support a conclusion, it would need to comply with some principles present in the meta-analysis, such as weighting of results by sample size, study design, methodological quality, risk of bias, or similar. We did this to distinguish reviews that chose not to treat the data (usually due to heterogeneity) from those that did.

Study design classification, bias analysis, or methodological quality analysis of primary studies has not been conducted or reviewed. When the SRs carry out this evaluation, it will be made available with their results. This information will be found in the text using the abbreviation BQAPS (Bias and Quality Assessment of Primary Studies). We considered "not available" when the reviewers did not separate the primary works in any way; "not adequately" if the reviewers only classified the primary studies according to their study design (e.g., RCT) or did not provide the evaluation of each study individually; "adequately" if there was an individual evaluation and the score was made available. We do not analyze whether the method or tool chosen by the SRs is



satisfactory/appropriate; we only analyze whether it has been made available to the reader adequately.

2.4 DATA SYNTHESIS, DATA CONFERENCE, AND CERTAINTY ASSESSMENT

No pooled or meta-analysis of the data was performed. The studies were approached separately and qualitatively assessed. If heterogeneity or sensitivity analysis is described in the SRs, they will be made available in due course.

We adopted the following for assessment:

1. We confronted the data, results, and discussion with the methodology used, and results BQAPS, ROBIS, and AMSTAR.
2. Authors CMJ, BDM, and MC reviewed the data for incorrect transcriptions, descriptive biases, and inconsistencies in descriptions.
3. These results were pooled and made available in a version of the GRADE tool that we adapted for quality of evidence and strength of recommendation.

3. RESULTS

3.1 SEARCH AND PATIENT CHARACTERISTICS

Figure I shows the PRISMA flowchart[13]. Overall, the studies evaluated more than 12,000 patients (with substantial overlap). Few of them described the patients' sex ($\geq 2:1$ M/H). Age was described in a heterogeneous method (Table II). The list of articles read and not included, with their justifications, is in Appendix 3.

The general and statistical summaries of the reviews are in Table II and Table III, respectively.

3.2 QUALITY AND BIAS ANALYSIS AND GUIDELINES

The final grades for AMSTAR 2 and ROBIS are in Figures II and III¹⁴, respectively.



Two reviews did not cite any tools to assess primary studies. Three (21.4%) were classified only according to the study design, one (7.1%) used Methodological items for non-randomized studies (MINORS), three New-Castle Ottawa Scale (NOS), and three used Cochrane tools. Twelve reviews (85.7%) followed the PRISMA checklist to describe the methodology. The PROSPERO registry was used in four (25.5%) reviews. Two reviews (14.2%) did not cite guidelines. Check Table II.

3.3 OUTCOMES

The observations BQAPS, AMSTAR 2, ROBIS, and notes in the "Enophthalmos" section should be extended by the reader in the other outcomes.

3.3.1 ENOPHTHALMOS

The results of Avashia *et al.* 2012¹⁵ were transcribed into Table III. **BQAPS:** not adequately. **AMSTAR 2:** critically low quality. **ROBIS:** high concern in bias.

The general data of Gunarajah and Samman 2013¹⁶ are available in Table III. Two primary studies were classified as quality level 1 (RCT); one compares Polydioxanone (PDS) (n=14) with Titanium mesh (n=14), and the postoperative enophthalmos was found in two patients in the PDS group; we found no mention of the statistical significance of this result. The other study compares PDS (n=12) with Collagen® (n=12); we did not find results on Collagen® in SR, and PDS did not present postoperative enophthalmos. **BQAPS:** not adequately. **AMSTAR 2:** critically low quality. **ROBIS:** low concern in bias.

Dubois *et al.* 2015¹⁷ suggested that combined floor and medial wall fractures have a higher chance of three-dimensional changes and enophthalmos, thus implying that patient-specific-implants (PSIs) may be more advantageous due to the accurate form. Four primary studies were classified as RCT, one of them multicentric*. One evaluated autologous auricular cartilage (n=8) vs. blade absorbable polyacid copolymer (n=12), another Collagen® membrane (n=12) vs. PDS foil 0.15 mm (n=12), another nasal autologous septal cartilage (n=11) vs. autologous conchal cartilage (n=11), and



another perforated PDS foil 0.15 mm (n=14) vs. titanium dynamic mesh (n=15)*. Only the study that evaluated autologous nasal septal cartilage found a statistical difference in favor of this implant. **BQAPS:** not adequately. **AMSTAR 2:** critically low-quality. **ROBIS:** low concern in bias.

Wan *et al.* 2015¹⁸ found five studies that evaluated enophthalmos; of these, 3-27% of patients in the Computer-Assisted Technology (CAT) group – mirror image overlay, intraoperative navigation, and individualized preformed CAD/CAM implant – and 10-50% of the control group continued with enophthalmos at the last follow-up. A retrospective cohort with 6 stars in NOS (equivalent to moderate quality) found statistical significance in favor of CAT but did not provide data on exophthalmometry. The other four studies found no statistical differences. SR showed no advantage of CAT in the prevention of postoperative enophthalmos. **BQAPS:** adequately. **AMSTAR 2:** low-quality. **ROBIS:** low concern in bias.

Ramesh *et al.* 2018¹⁹ evaluated only absorbable implants. Two studies, level 2 of evidence by the Oxford Criteria, found enophthalmos: one with a case of enophthalmos after self-reinforced PGA (overall n=12), with 12/16; 14/16 bias by MINORS*; another (overall n= 16) with 37% enophthalmos after use of PDO, 9/16; 15/16 bias*. The reviewers point out the use of PDO: "When patients were stratified by defect size, fractures less than 1 cm² had adequate reconstruction." They conclude that the absorbable implants show a late enophthalmos rate of 5% to 16% and that the PDO "may have slightly higher rates owing to rapid resorption in larger defects." **BQAPS:** adequately. **AMSTAR 2:** critically low quality. **ROBIS:** high concern in bias.

**Note: The three papers on level 2 of evidence received different scores during the SR; we provide the two scores found.*

Azzi *et al.* 2018²⁰ evaluated the use of orbital implants in a <16 years old population; the results are available in Table III. **BQAPS:** not available. **AMSTAR 2:** critically low quality. **ROBIS:** high concern in bias.



Oliver *et al.* 2020²¹ did not assess enophthalmos. **BQAPS:** not adequately. **AMSTAR 2:** critically low quality. **ROBIS:** high concern in bias.

Bourry *et al.* 2020²² found no statistical differences between the implants. The SUCRA ranking* has been transcribed into Table III. **BQAPS:** not available. **AMSTAR 2:** critically low quality. **ROBIS:** high concern in bias.

**Note: The SUCRA ranking should be interpreted cautiously since it has not been associated with the quality analysis of primary trials.*

Maher *et al.* 2021²³ evaluated the use of PSIs. The authors found heterogeneities in the descriptions; most studies do not mention the values of enophthalmos, only the presence or absence of clinical enophthalmos (>2mm), with no apparent statistical differences between conventional techniques or those aided by PSI. Only one RCT report enophthalmos: the control group (n=5) was treated with conventional titanium mesh vs. the intervention group (n=5) with 3D printed models and manually molded titanium implants. The mean preoperative in the intervention group was $2.6 \pm 0.8\text{mm}$, which improved postoperatively to $0.35 \pm 0.4\text{mm}$. The mean preoperative in the control group was $3.8 \pm 0.7\text{mm}$, which improved to $2.4 \pm 0.8\text{mm}$ postoperatively; the presence of statistical difference was not described in the review. Primary studies were not evaluated for bias. **BQAPS:** not adequately. **AMSTAR 2:** critically low quality. **ROBIS:** high concern in bias.

Hartmann *et al.* 2022²⁴ also evaluated the PSIs in orbital reconstructions. One study was described in detail, and the same is referenced in the summary of results of the review by Maher *et al.* 2021; thus, the groups, patients, means, and standard deviations are identical. In the Hartmann *et al.* 2022 review, this study was classified as a prospective clinical study, with an unclear risk of bias as assessed by the Cochrane tool. The reviewers emphasized favorable statistical significance for using PSIs in this study. **BQAPS:** adequately. **AMSTAR 2:** low quality. **ROBIS:** high concern in bias.



Kotecha *et al.* 2022²⁵ did not find statistical differences between surgeries performed with or without the aid of PSIs, with substantial heterogeneity ($I^2= 82.3\%$). Two primary studies found statistical differences in favor of PSI; one is the same as the one cited by Maher *et al.* 2021 and Hartmann *et al.* 2022. The SR of Kotecha *et al.* 2022²⁵ was rated as "some concerns" in bias analysis by Cochrane RoB2. The other is a retrospective cohort, with a moderate risk of bias by NOS. In this one, the conventional group (n=27) was operated with MEDPOR Titan ® vs. PSI group (n=29) operated with MEDPOR TITAN® - 3D printed. We did not find further data on the study. **BQAPS:** adequately. **AMSTAR 2:** critically low quality. **ROBIS:** low concern in bias.

Murray-Douglass *et al.* 2022²⁶ showed that some 3D aids were effective in reducing enophthalmos (Table III), with small heterogeneity ($I^2= 11.33\%$), and that the quality of the study* did not interfere with the effect size or heterogeneity. The reviewers conclude that 3D printing can help reduce enophthalmos but cannot quantify how much of this benefit is conferred on 3D alone. **BQAPS:** not adequately. **AMSTAR 2:** low quality. **ROBIS:** low concern in bias.

**Note: It is worth noting that the reviewers acknowledged using a "simple tool" for quality assessment due to the variability of the articles and that articles with high scores may not necessarily be of high quality when evaluated by other tools.*

Singh *et al.* 2023²⁷ did not perform a meta-analysis of the data found on enophthalmos when comparing Manual Free-Hand-Shaped (MFS) vs 3D-Printed Model-Based (3DP). A retrospective study evaluating MFS (n=27) vs 3DP (n=29) showed statistical differences in favor of 3DP. The same RCT was described in the summary of results by Maher *et al.* 2021²³; here it was described with significance favorable to the 3DP. Another retrospective study comparing MFS (n=13) vs 3DP (n=17) found no differences between the groups. One RCT found significance favorable to 3DP (n=23) compared to MFS (n=16). All were classified as "high risk of bias" by RoB2. **BQAPS:** adequately. **AMSTAR 2:** critically low quality. **ROBIS:** low concern in bias.



The data described by Abukhder *et al.* 2024²⁸ were transcribed into Table III. All primary studies were classified as moderate quality by NOS. **BQAPS**: adequately. **AMSTAR 2**: critically low quality. **ROBIS**: low concern in bias.

3.3.2 DIPLOPIA

The data from Avashia *et al.* 2012¹⁵, Gunarajah and Samman 2013¹⁶, Azzi *et al.* 2018²⁰, and Abukhder *et al.* 2024²⁸ were transcribed in Table III. The SR of Gunarajah and Samman 2013¹⁶ showed no pre- or postoperative diplopia in the level 1 studies. Bourry *et al.* 2020²² and Kotecha *et al.* 2022²⁵ found no statistical differences in their meta-analyses. The SUCRA score ²² is made available in Table III.

Dubois *et al.* 2015¹⁷, of the four studies classified as RCT, two reported postoperative diplopia. One compared nasal septal cartilage (n=11) vs. conchal cartilage (n=11) and obtained 9% post-op diplopia in both groups; preoperative data are unavailable. The other study evaluated perforated PDS foil 0.15 mm (n=14) vs. titanium dynamic mesh (n=15); the preoperative diplopia rates were 75% and 88%, respectively, and postoperative diplopia was 50% for both. Statistical significance data for these results are not available.

Wan *et al.* 2015¹⁸ found four studies that reported postoperative diplopia. Three showed significant improvement in diplopia in the CAT vs. control groups: 51 vs. 60% (historically control trial with 8 stars in NOS, equivalent to high quality), 2 vs. 10% (prospective cohort study with 9 stars in NOS), and 17 vs. 88% (retrospective cohort study with 6 stars in NOS). A prospective cohort study with 7 stars in NOS found no significant difference. The reviewers conclude by suggesting an advantage of the use of CAT for the resolution of diplopia.

Ramesh *et al.* 2018¹⁹ found a paper level 2 of evidence and risk of bias 9/16; 15/16 who showed postoperative diplopia due to significant hypoglobus and enophthalmos after PDS reconstruction.

The SR of Maher *et al.* 2021²³ described a multicenter controlled trial: the Control Group – CG (n=84) – was reconstructed with titanium mesh, and the Intervention



Group – IC (n=61), received manually molded titanium implants in 3D printed models. The CG presented 65% of preoperative and 25% postoperative diplopia, and the IC presented 39% and 25%, respectively. This difference was not statistically significant.

Murray-Douglass *et al.* 2022²⁶ observed that, individually, contour model, mould, and surgical planning effectively reduce diplopia. In the general evaluation, 3D printing was also effective, with small heterogeneity ($I^2= 10.91\%$), and the quality of the study did not interfere with the effect size or heterogeneity. Although they found that 3D printing helped reduce diplopia, they could not quantify how much of this benefit is conferred on 3D alone.

Singh *et al.* 2023²⁷ did not perform a meta-analysis of data on diplopia in the MFS vs. 3DP groups. Primary studies – composed of retrospective (n=13 vs. 17), prospective controlled multicenter trial (n=95 vs. 100), and RCT (n=16 vs. 23) – showed, for the most part, no statistical differences favorable to the 3DP group. A retrospective study (n=12 vs. 12) showed a difference in favor of the 3DP group. All works in this SR are at high risk of bias by RoB2.

3.3.3 FRACTURE PATTERNS, SIZE, OR ORBITAL VOLUME

Gunarajah and Samman 2013¹⁶ provided an infographic indicating which materials would be indicated considering the size of the defect. We suggest reading it in the original paper.

Ramesh *et al.* 2018¹⁹ suggested that absorbable implants are indicated for isolated fractures of the medial wall and floor where the bony buttresses are intact, and the implants should serve as a barrier rather than load-bearing. They also suggest that PDO implants, pure PDLLA (faster resorption time), and PLLA (increased risk of delayed inflammation) are not indicated for orbital reconstructions.

Bourry *et al.* 2020²² provided an infographic indicating for Jaquiéry type 1 fracture: PL(DL/LA), PDS, and Polyglactin/PDS; Jaquiéry 2: PL(DL/LA); Jaquiéry 3, 4 and 5: Titanium, and Porous polyethylene.



In the SR of Maher *et al.* 2021²³, five papers reported the complete orbital volume data and were divided into three groups: Group 1(G1) - manual molding PSI on the 3D printed model; Group 2 (G2): fully individualized and manufactured from the 3D printer; and Group 3 (G3): fabrication of template from 3D printer. G1 has two prospective cohorts (n=12 and 104) and one retrospective cohort (n=104), G2 has one retrospective cohort (n=15), and G3 has one prospective cohort (n=11). In G1, the three studies analyzed observed a statistically significant improvement in the mean volume of the fractured orbit comparing the preoperative and postoperative CT scans, and the volume of the affected orbit after the intervention was similar to the volume of the unaffected orbit. In G2, a statistically significant improvement in volume was observed compared to the preoperative period, and the contralateral orbit presented a significantly larger volume than the operated one. G3 showed a statistically significant improvement compared to the preoperative moment and did not differ from the contralateral orbit.

Hartmann *et al.* 2022²⁴ cited two studies (a multicenter prospective controlled trial and retrospective case series) in which PSI was shown to be more accurate regarding orbital volume. We did not find data on the significance of this difference.

During the meta-analysis, Kotecha *et al.* 2022²⁵ found no statistical differences between the PSI and conventional groups. Five papers evaluated orbital volume, and only three provided volumetric data amenable to pooling in meta-analysis; they will be marked with "§. " Two studies did not find statistical differences between PSIs and conventional: a prospective cohort§ with a low risk of bias in NOS and a retrospective cohort§ with a moderate risk of bias. Three studies found statistical differences in favor of PSIs: A prospective cohort with a low risk of bias, a retrospective cohort with a low risk of bias, and a retrospective cohort§ with a moderate risk of bias. The PSI reconstructions were mainly performed with Titanium.

Murray-Douglass *et al.* (2022)²⁶ found no statistical differences when evaluating orbital volume between operated and non-operated orbits in favor of any 3D aids researched.



Singh *et al.* 2023²⁷ cited a multicenter trial supported by AO Foundation - CMF that compared MFS (n=95) vs. 3DP (n=100), where 3DP had statistically significantly higher accuracy compared to the MFS group. In a retrospective study (n=12 vs. 10), the authors compared the postoperative orbital volume with the non-traumatized orbit; the MFS group showed a significant difference in volume compared to the non-traumatized orbit, while the 3DP group did not show this difference. In another retrospective study (n=38 vs. 44), the authors found a statistically larger residual defect area in the MFS group. The first two studies were classified as having a high risk of bias and the last one as an unclear risk by the RoB2 tool.

3.3.4 FOLLOW-UP

We did not find a report of the follow-up time in only one SR²². The unweighted average among all articles was approximately 25 months. Some reviews found a follow-up time of a few hours.

3.3.5 INFECTION

We found an inconsistency between the "results" section and the table in the SR of Avashia *et al.* 2012¹⁵. The results show that the highest infection rates were for Polyglactin 910/PDS and Silastic Rubber, but the highest index in the table belongs to autologous mandible bone.

Gunarajah and Samman 2013¹⁶ found ten cases of infections in four studies that used porous polyethylene, two cases in studies that used PDS, one case in which titanium mesh was used, one case after using PLLA, P(L/DL)LA 70/30, PLLA/PGA. The SR classified all studies with cases of infection as level 4 of evidence (case series, poor-quality cohort, and case-control studies).

Azzi *et al.* 2018²⁰ reported only nine cases of infection, all from the same study that evaluated Titanium, Medpor, and Medpor/Titanium. It is unclear which implant(s) were not associated with infection or their proportion.



Oliver *et al.* 2020²¹ exposed three cases of infection. A retrospective cohort presented two cases after using smooth nylon foil, and a case study described delayed osteomyelitis after using porous polyethylene.

3.3.6 REDUCED OCULAR MOTILITY (ROM) OR ORBITAL SOFT TISSUE ENTRAPMENT (OSTE)

During ROM evaluation, the SR of Avashia *et al.* 2012¹⁵ described a contradiction between the results section and the table. In the results, we found the highest indices in lyophilized dura and PDS; however, in their table, a demineralized human bone, PDS, and allograft dura are cited as the highest indices.

According to Gunarajah and Samman 2013¹⁶, when evaluating OSTE, five implants remained with OSTE after reconstruction. Some studies, level 4 of evidence, have shown permanence of OSTE after reconstruction with porous polyethylene, polyglactin 910/PDS, allogenic lyophilized dura, and autogenous temporalis fascia, but with resolution > 90% in all. Only one study, level 4, verified the permanence of OSTE in 10 of the initial 60 cases after reconstruction with PDS. We could not find any more information about this paper.

In SR of Dubois *et al.* 2015¹⁷, when evaluating ROM, two of the four studies classified as RCT, and only one classified as CCT did not find postoperative ROM. An RCT found postoperative ROM when evaluating perforated PDS foil 0.15 mm (n=14) vs. titanium dynamic mesh (n=15), 75% and 88% preoperative and 50% postoperative for both. The other RCT did not provide the data but reported no statistical difference between the nasal septal cartilage vs conchal cartilage groups (n=11 both), pre- or postoperatively.

Singh *et al.* 2023²⁷ reported ROM in two studies. A retrospective study described the need for revision surgery in two cases that presented mobility restriction and enophthalmos in the manual free-hand-shaped – MFS (n=38). No re-approach was needed in the 3D-printed model-based – 3DP (n=44).



3.3.7 MISCELLANEOUS COMPLICATIONS

Gunarajah and Samman 2013¹⁶ found 18 cases of postoperative orbital dystopia, divided into iliac bone – all from the same study that measured 17 cases pre- and 7-permanence –, porous polyethylene and PDS. The low rate of improvement with PDS is noteworthy (only two of the initial 7). However, it is worth noting that current knowledge contraindicates PDS in the presence of preoperative dystopia. All studies that cited postoperative dystopia were classified as level 4 of evidence.

Wan *et al.* 2015¹⁸ found two studies that reported postoperative complications in both groups. No significance points to greater involvement in a specific group.

Ramesh *et al.* 2018¹⁹ very briefly associated two studies, level 2 of evidence, with "inflammation" due to the use of Polydioxanone and Polycaprolactone, but this same citation also referenced study level 4 of evidence, so it was not possible to correlate reliably. They also mentioned 37.5% of delayed inflammation related to PLLA, but we did not find the baseline study of this data. Mucoïd cyst formation around Osteomesh was found in a study level of evidence 2, risk of bias 12/16; 13/16.

In Oliver *et al.* 2020²¹, it was possible to observe four epithelial cysts and four inflammations reported by a case series of four patients, two after hydroxyapatite implantation (after 2.5 and 8 years), one after the use of Titanium* and another after use of Medpor*. The most common complication was graft migration, with 11 cases from the same retrospective cohort that evaluated acrylic or silicone implants. Three cases of graft explantation were reported in two retrospective cohorts, one after the use of PPE + Titanium and the other two after the use of PLLA. Three cases of interest with hematoma were exposed: a retrobulbar hematoma after using u-HA/PLLA, a hematoma after using porous polyethylene, and the last one after using porous polyethylene + Titanium. In none of the cases of hematomas, we found a description in the SR that ruled out possible intervening variables. Except for graft migration (18%), the other complications represent $\leq 5\%$ of the study sample.



**Note: This statement does not appear explicitly in the text; it is possible to conclude it by connecting the author and title of the paper with another table where the implants used in each study are located.*

Bourry *et al.* 2020²² reported seven patients (0.74%) with "other complications," which may be hemorrhage, infection, or extrusion of the material. Of these, four were observed after titanium use, two after porous polyethylene, and one after iliac crest bone. After individual analysis, none of the materials presented a higher risk of complications.

Maher *et al.* 2021²³ cited a list of complications found but did not provide the number of cases or their correlation with the SR groups.

Hartmann *et al.* 2022²⁴ found complications only in primary studies with patients after tumor resection in their sample. Because they did not meet the eligibility criteria, they were not evaluated.

Singh *et al.* 2023²⁷ found a study reporting complications, but with patients who did not meet the eligibility criteria of this overview, so they were not evaluated.

4. DISCUSSION

4.1 QUALITY AND BIAS ANALYSIS OF SYSTEMATIC REVIEWS

Due to the heterogeneity of the primary trials, we noticed that some authors of the SRs needed to relativize important factors to gather some information that can be useful to readers. Such relativization impoverishes the methodological quality and, consequently, the reliability of the results.

The results observed in the AMSTAR 2 and ROBIS tools are worrying. Critical question nº7 of AMSTAR 2 received a negative score in all SRs. It questions whether the reviewers provided a list of the papers not included after complete reading and the justifications for doing so. Although unusual, this data is essential for transparency and reduction of selection bias.



During the ROBIS evaluation, we noticed that the major limitations were the inappropriate restriction of eligibility criteria (year of publication and language) and the lack of robustness of its methodology and results to affirm the conclusions presented. With today's advances in artificial intelligence, we need to rethink the necessity of restricting the language of publication.

4.2 SRS GUIDELINES' TOOLS

We observed low adherence of SRs authors to use robust tools for assessing methodological quality and analyzing bias in primary studies. We encourage the use of these tools, which, while not ridding us of flaws²⁹, bring greater transparency and less bias.

4.3 OUTCOMES

Figure 4 shows the levels of evidence and strength of recommendation. In general, we identified difficulties with the heterogeneity of data collection and description. Primary studies must provide the raw and measurable data to enable meta-analyses, in addition to statistical significance.

We highlight the insufficient description of complications in general, making it impossible to remove intervening variables.

The studies not mentioned in Figure 4 did not contribute to the discussion with evidence of a systematic review. Due to heterogeneity, most SRs could not synthesize the results and chose to present the raw data of the primary studies. In our interpretation, these results (even if included in the SRs) should be considered as evidence from primary studies, assigning a different weight to the evidence.

4.3.1 ENOPHTHALMOS

We found significant heterogeneity in its description. There seems to be a consensus that enophthalmos is clinical perception or a difference >2 mm between the operated



and non-operated orbit^{18,22,25}. SRs reported the absence of exophthalmometer data in the primary studies, and we reiterate the importance of such a description.

Because there are many cohorts, we emphasize the relevance of verifying and reporting the existence of "severe" traumas in the sample that may become a confounding factor in the final analysis, given the possibility of lipolysis caused by trauma, which may be independent of reconstruction or implantation.

The SRs of Gunarajah and Samman 2013¹⁶, Dubois *et al.* 2015¹⁷, Ramesh *et al.* 2018¹⁹, and Bourry *et al.* 2020²² converge in concluding the importance of mechanical support in extensive reconstructions.

The results of Murray-Douglass *et al.* 2022²⁶ point out that 3D-printed implants, contour models, and surgical planning effectively reduce enophthalmos, with no preference for implant biomaterial.

4.3.2 DIPLOPIA

The forms of evaluation/description of diplopia in the studies, when present, are even more heterogeneous. Several studies limit themselves to reporting its existence or not, and few mention in which visual field they find it. We reinforce the suggestion made by Dubois *et al.* 2015¹⁷ on using Goldman Screens.

We did not find a formal address by SRs about a possible association between the waiting time from trauma to surgery and the presence of postoperative diplopia. We support future authors to verify and report the period between trauma and surgery in cases with diplopia to avoid bias since Volkmann's contracture can occur regardless of the performance of surgery or the implant used.

Wan *et al.* 2015¹⁸ suggested that using CAT may provide better results for diplopia. Murray-Douglass *et al.* 2022²⁶ stated that contour models, moulds, and surgical planning also effectively reduce it.



4.3.3 FRACTURE PATTERNS, SIZE, OR ORBITAL VOLUME

Most studies have cited the importance of defect size, fracture pattern, or combined fractures in the choice of reconstruction method. The description in the primary studies was largely heterogeneous, such as mm, mm², cm, cm², cm³, % of orbital floor, Jaquiéry classification, and mL for volume. This makes it challenging to do a solid correlation. We corroborate the suggestion of Dubois *et al.* 2015¹⁷: it is necessary to create a three-dimensional model for the classification of defects

A SR by Ramesh *et al.* 2018¹⁹ concludes, among other topics, that although absorbable implants are suitable for isolated medial wall or floor fractures with intact bony buttresses, PDO, pure PDLLA, and PLLA are unsuitable for orbital reconstructions because they understand that other similar materials present fewer complications. In this SR or the others, we did not find a methodological substrate and quality results supporting these implant contraindications.

In the SRs of Maher *et al.* 2021²³ and Singh *et al.* 2023²⁷, it was found that manual molding of PSI on 3D printed models helps establish an orbital volume compatible with the non-traumatized orbit

4.3.4 FOLLOW-UP

It is worrisome that some reports involve only a few hours of follow-up. We know that sometimes trauma patients do not return to consultations, but postoperative follow-up for a few months is mandatory for data reliability. In cases where the patient has withdrawn from the treatment before this period, we discourage its maintenance in the sample at the risk of bias^{30,31}.

4.3.5 INFECTION

None of the implants appeared directly related to higher rates of postoperative infection, and the absence of data made it impossible to provide reliable evidence. The data provided by Avashia *et al.* 2012¹⁵ claim attention to the 9% of infections found after autologous grafting of the mandible. Although it is insufficient to be considered as



evidence, this information should be considered in clinical practice until new evidence is presented.

4.3.6 REDUCED OCULAR MOTILITY (ROM) OR ORBITAL SOFT TISSUE ENTRAPMENT (OSTE)

None of the types of implants appeared to be closely related to this outcome. We did not find a correlation between the waiting interval between the trauma and the surgery and the severity of the trauma. We support future authors to verify and report the period between trauma and surgery in cases with ROM or OSTE to avoid bias since Volkmann's contracture can occur regardless of the performance of surgery or the implant used.

4.3.7 MISCELLANEOUS COMPLICATIONS

Although several SRs report postoperative complications, few deepen the discussion to reduce the confounding variables.

Even without fulfilling some eligibility criteria, during the screening processes, the SR of Su *et al.* 2016³² reported a series of epithelial cysts after orbital reconstruction with silicone implants that caught our attention. Although this information does not constitute evidence, it should be considered in clinical practice until new evidence is presented.

5. CONCLUSIONS

Our limitations are available in Table IV, along with their stipulated risks and impacts.

Despite the significant amount of literature on orbital reconstructions, we did not find high-quality evidence. The concern of these results is that some implants have been overvalued or undervalued based on primary studies that have not had methodological validation and definition of statistical weight by the RS community, making these primary studies currently the highest level of evidence available, even if incompatible with this position.



Titanium's complete biocompatibility defends its safety compared to the other implant materials. Still, the concern regarding the permanence of the implant in the event of a new trauma should be considered, especially in young patients.

For the surgeon, this overview raised a series of important recommendations for the practice (Figure 4). We encourage further randomized controlled trials with a robust research design to increase the quality and reliability of evidence in the field.

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Figure 1. Flow diagram, based on PRISMA flowchart, with step-by-step searches and article selection

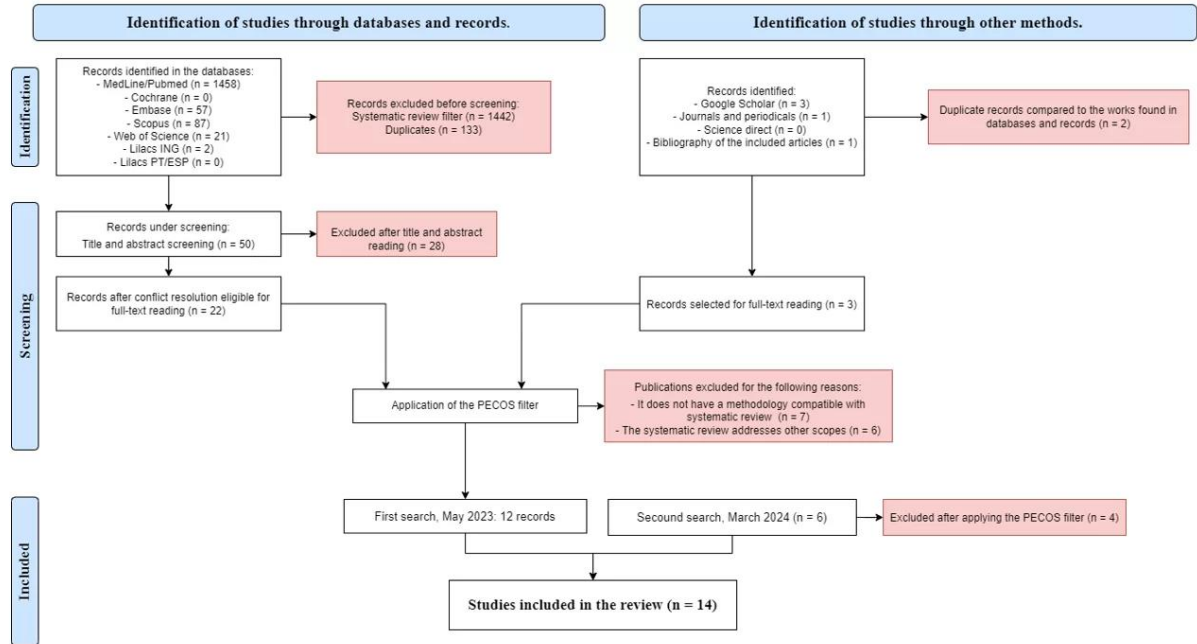


Figure 2. AMSTAR 2 summary plot [11,14]

	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	D11	D12	D13	D14	D15	D16	Overall
Avashia et. al 2012	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Gunarajah and Samman 2013	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Dubois et. al 2015	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Wan et. al 2015	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Ramesh et. al 2018	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Azzi et. al 2018	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Oliver et. al 2020	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Bourry et. al 2020	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Maher et. al 2021	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hartmann et. al 2022	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Kotecha et. al 2022	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Murray-Douglass et. al 2022	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Singh et. al 2023	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Abukhder et. al 2024	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

D1: 1 Did the research questions and inclusion criteria for the review include the components of PICO?
 D2: 2 Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?
 D3: 3 Did the review authors explain their selection of the study designs for inclusion in the review?
 D4: 4 Did the review authors use a comprehensive literature search strategy?
 D5: 5 Did the review authors perform study selection in duplicate?
 D6: 6 Did the review authors perform data extraction in duplicate?
 D7: 7 Did the review authors provide a list of excluded studies and justify the exclusions?
 D8: 8 Did the review authors describe the included studies in adequate detail?
 D9: 9 Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?
 D10: 10 Did the review authors report on the sources of funding for the studies included in the review?
 D11: 11 If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?
 D12: 12 If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?
 D13: 13 Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?
 D14: 14 Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?
 D15: 15 If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?
 D16: 16 Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

Judgement
 ● No
 ● Yes
 ● Not applicable
 ● Low quality review
 ● Critically low quality review

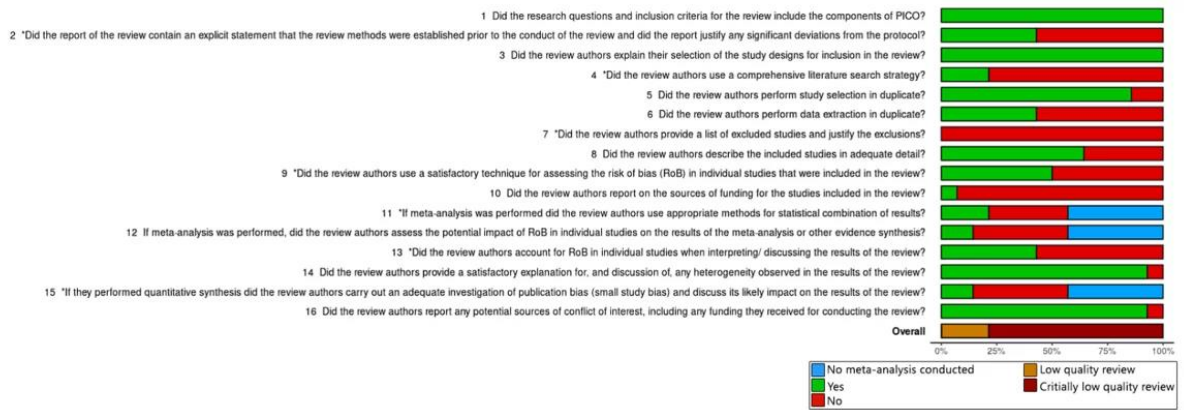


Figure 3. ROBIS summary plot [12, 14]

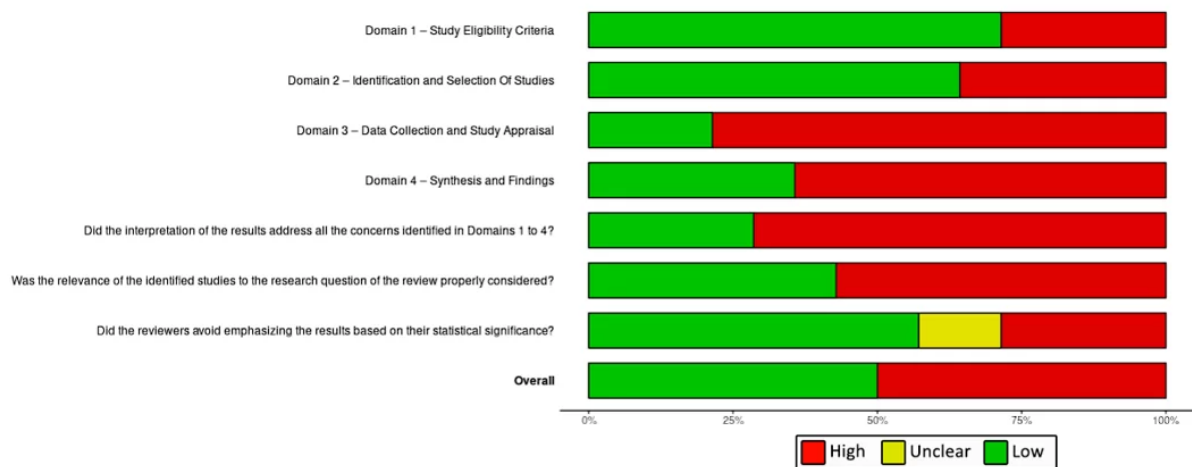
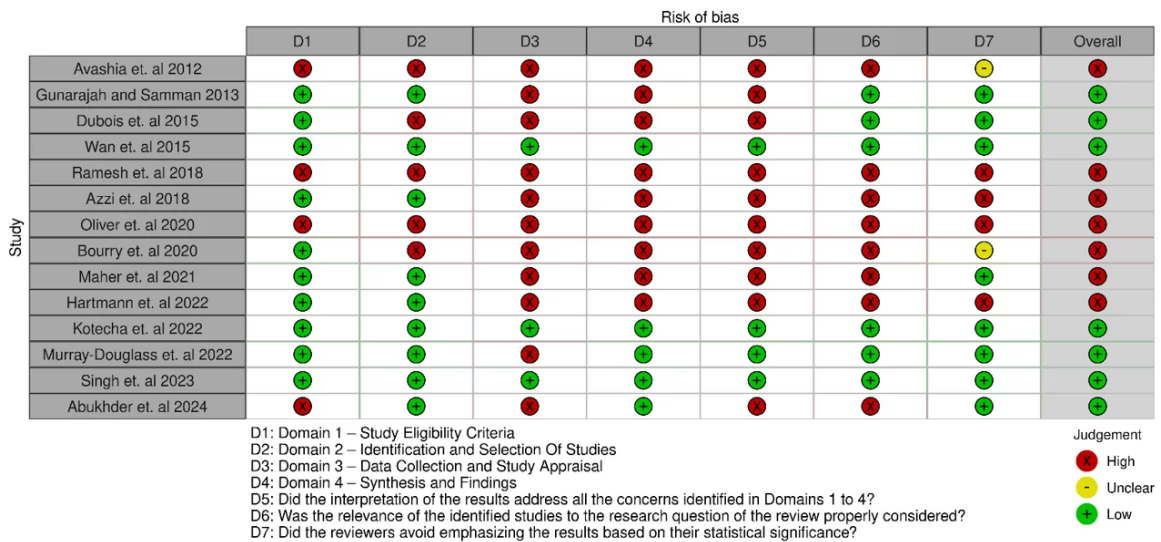


Figure 4. Summary of evidence

Outcomes	SRs	Evidence found	Quality of evidence	Strength of recommendation
Enophthalmos	Gunarajah and Samman 2013 [16], Dubois et. al 2015 [17], Ramesh et. al 2018 [19], Bourry et. al 2020 [22]	Combined orbital fractures or those involving bony pillar fractures benefit from more rigid, non-absorbable, and accurate orbital implants.	⊕⊕⊕⊖ LOW Reasons: Heterogeneities, bias in primary studies and SR, low-quality review and primary studies, and overlap of primary studies.	STRONG RECOMMENDATION Understanding the need for mechanical support in more extensive fractures has become an axiom in reconstructive surgeries. Despite the low quality of evidence in SRs, based on the knowledge available thus far, we understand this approach is safer for the patient. Furthermore, these implants are widely available in trauma centers.
	Murray-Douglass et. al 2022 [26]	3D printed implants, contour models, and surgical planning are effective in reducing postoperative enophthalmos	⊕⊕⊕⊖ VERY LOW Reasons: Heterogeneities, low-quality, and bias in primary studies, low-quality review, and the impossibility of isolating the benefit from other confounding variables.	STRONG RECOMMENDATION 3D printers have become increasingly accessible and cost-effective. As this laboratory step MAY improve postoperative outcomes, we see no reason not to recommend its use.
Diplopia	Wan et. al 2015 [18]	Mirror image overlay, intraoperative navigation, and individualized preformed CAD/CAM implant may improve diplopia.	⊕⊕⊕⊖ VERY LOW Reasons: small sample, studies heterogeneities, and low-quality review.	WEAK RECOMMENDATION Although we acknowledge the apparent benefits of these technologies, especially when we consider evidence from related fields, intraoperative navigation, and CAD/CAM still entail the high acquisition and routine use costs. At present, we do not find evidence to support the acquisition of these technologies for use in orbital reconstructions. However, if available in the institution, as it represents a stage that MAY improve postoperative outcomes, there is no reason to not use it.
	Murray-Douglass et. al 2022 [26]	Contour model, mould, and surgical planning effectively reduce postoperative diplopia.	⊕⊕⊕⊖ VERY LOW Reasons: Heterogeneities, bias in primary studies, low-quality review, and the impossibility of isolating the benefit from other confounding variables.	STRONG RECOMMENDATION 3D printers have become increasingly accessible and cost-effective. As this laboratory step MAY improve postoperative outcomes, we see no reason to not recommend its use.
Orbital volume	Maher et. al 2021 [23] ^a , Singh et. al 2023 [27] ^b	Manual molding of PSI on 3D-printed models is effective in maintaining postoperative orbital volume close to the contralateral orbit.	⊕⊕⊕⊖ LOW Reasons: unclear quality and bias in primary studies ^a , critically low-quality review ^{ab} , high risk of bias review ^a , overlap of primary studies.	STRONG RECOMMENDATION We understand that establishing the orbital volume of the untraumatized orbit in the traumatized one is a surgical goal. Moreover, the access and cost of 3D printers have become increasingly available as they involve a laboratory step that MAY improve postoperative outcomes; we see no reason to not recommend its use.
Infection	Avashia et. al 2012 [15]	Reconstructions performed with autogenous mandibular grafts showed a 9% infection rate.	⊖⊖⊖⊖ DID NOT MEET EVIDENCE CRITERIA. We do not consider it as evidence, merely as a warning.	NO RECOMMENDATIONS This systematic review revealed a series of weaknesses and, did not provide sufficient evidence to make any recommendations. It should serve only as a cautionary note.
ROM or OSTE	-	∅	∅	∅
Miscellaneous complications	Su et. al 2016 [32]	Series of epithelial cysts following orbital reconstruction with silicone implants.	⊖⊖⊖⊖ DID NOT MEET EVIDENCE CRITERIA. We do not consider it as evidence, merely as a warning.	NO RECOMMENDATIONS This systematic review has revealed a series of clinical case reports detailing predominantly silicone-based orbital reconstructions. However, it did not provide sufficient evidence to make any recommendations on this matter; it should serve only as a cautionary note.

∅: No reliable evidence found.
 ⊕⊖: Grades of evidence.
High quality: There is strong confidence that the evidence found is close to the truth.
Moderate quality: There is moderate confidence in the evidence found, with low uncertainty in the findings.
Low quality: There is low confidence in the evidence, with uncertainty in the findings.
Very low quality: Confidence in the evidence is very limited, with a significant degree of uncertainty in the findings.

Table I. PECOS criteria

	P (population)	E (exposure)	C (comparator)	O (outcomes)	S (study design)
Eligibility	Patients with orbital fractures and need for primary surgical approach	Need for fracture reconstruction with an implant (autogenous, heterogenous, xenogenic, alloplastic, or patient-specific implants - PSI), absorbable or non-absorbable	No restrictions	We should not restrict the inclusion of articles due to the existence of specific outcomes. Diplopia, enophthalmos, orbital volume, and complications were noted whenever available.	Systematic reviews
Exclusion	Patients with orbital fractures that did not require a surgical approach or in late reconstructions. Patients undergoing orbital reconstruction for other reasons than trauma*	Surgery without installing an implant (of any material) for reconstruction or where the review's focus was not on the reconstruction results. †	No restrictions	No restrictions	Papers that are not systematic reviews ‡

Justification:

* This study aims to raise the level of evidence about the materials used in primary surgeries of post-trauma orbital reconstructions.

† The objective is to qualify the level of evidence about the materials used for reconstructions.

‡ The goal is to understand the higher level of evidence of the claims found in current systematic reviews.

Table II. Overall characteristics of the selected reviews

Author and year	Research question or objective	N. and study design selected	Guidelines/ PROSPERO	Included studies	N° patients or orbits	Sex (cumulative)	Patient age	Quantity of articles and Orbital implants evaluated	Outcomes	Methods used for assessing methodological quality and bias analysis	Conflict of interest
Avashia et al 2012	"assess and analyze published evidence supporting the various materials used for orbital floor fracture reconstruction and develop a decision-making algorithm for clinical application."	12 level II (lesser quality RCT, prospective cohort, comparative study; or systematic review of these studies) 36 level III (Retrospective cohort or comparative study; case-control or systematic review of these studies)	NR	48	3475 orbits 3471 patients	NR	NR	Autologous bone 6 Calvarium 3 Ilium 3 Mandible 2 Maxilla Autologous cartilage 4 Auricular 4 Nasal septum Allografts 4 Dura 1 DHE Resorbable implants 2 PLA-PGA 4 P(DL)LA 1 PGA 3 PDS 3 Polyglactin 910 PDS Nonresorbable implants 3 Bioactive glass 6 Titanium mesh 2 Nylon 6 Porous polyethylene 1 Silastic rubber 1 Teflon	Immediate diplopia; follow-up diplopia; immediate enophthalmos; follow-up enophthalmos; reduced ocular motility; infection rate; and average follow-up	Quality of evidence: "American society of plastic surgeons level of evidence rating scale for therapeutic studies." The authors did not present the level of evidence for each study or implant individually; instead, they displayed the levels of evidence within each group based on the origin of the implant. In-depth assessments of methodological quality and bias were not found.	The authors report no conflicts of interest.
Gunaratnam and Sanman 2015	"The aim of this study is to review the available materials for the restoration of post-traumatic orbital floor defects and systematically evaluate the literature on their reported use and outcomes."	Published errata: 2 level I (Individual randomized controlled trial); 2 level II (Individual cohort study including low-quality randomized controlled trial; e.g., <80% follow-up); 1 level 3 (Systematic review of case-controlled studies or individual case-control studies) 50 level IV (Case series and poor-quality cohort and case-control studies) 41 retrospective case series 9 retrospective case-control studies	PRISMA	55 (only 21 were displayed in the table of "List of retrieved articles") In a published "errata", all 55 articles were described.	2483 orbits	NR	NR	Autogenous materials 4 Iliac bone 3 Cranial bone 1 Nasal bone 3 Maxillary bone 3 Mandibular bone 4 Nasoseptal cartilage 4 Conchal cartilage Temporalis fascia Allogeneic materials: 1 Irradiated fascia lata 2 Lyophilized dura mater 1 Irradiated cartilage Alloplastic materials: 9 Titanium mesh 9 Porous polyethylene sheet 2 BAG plate 1 Hydroxyapatite sheet 8 PLLA, PLLA-PGA, and PL-DLLA 70/30 plate 1 Polyglycolic acid membrane 7 PDS sheet 3 Polyglactin-910 mesh and Polyglactin-910 PDS sheet 1 Periosteum-polymer complex Xenograft materials 1 Collagen membrane	Diplopia; enophthalmos; infraorbital paresthesia; orbital dystopia; orbital soft tissue entrapment; graft extrusion/displacement; follow-up, sinus/orbital infection; donor site complications	Quality of evidence: "Oxford Centre for Evidence-based Medicine." In-depth assessments of methodological quality and bias were not found.	NR Published errata: Conflict of interest: Disclosures: None of the authors reported any disclosures.



Dubois et al 2015	"The aim of this study was to systematically review all prospective and retrospective clinical trials on orbital reconstruction. Particular focus was placed on the indication for surgery in relation to defect size and location in order to identify the reconstruction methods that show the best results for the different types of orbital fractures."	14 Prospective studies 3 Randomized controlled trial 1 Multicentric randomized controlled trial 1 Controlled clinical trial 4 Cohort 1 Matched control trial 1 Case series 2 Pilot without controls 1 Preliminary controlled clinical trial 217 Retrospective studies	PRISMA	231	14650 patients in retrospective studies ≈ 380 patients in prospective studies	NR	NR	Autogenous materials 1 Bone 1 Iliac cortex 1 Auricular cartilage 1 Nasal septal cartilage 1 Conchal cartilage Alloplastic materials 1 Polyacid copolymer 1 Collagen membrane 2 PDS foil implant 1 PDS foil perforated 1 PLA plate 70/30 1 Porous polyethylene 1 Polyethylene implant 3 Titanium mesh	Indication for surgery; Defect size; defect location; Reconstruction materials; Follow-up; Diplopia (any gaze) preop. and postop.; Enophthalmos/proptosis/dystopia preop. and postop.; Eye motility disorder preop. and postop.; infra-orbital hypoesthesia preop. and postop.	The authors categorized the articles according to their study design. In-depth assessments of methodological quality and bias were not found.	Funding: none. Competing interests: none declared.
Wan et al 2015	"We conducted a systematic review on the use of computer-assisted technology augmented surgery versus conventional surgery in post-traumatic orbital reconstruction to evaluate its functional and safety outcomes."	1 Historically control trial 4 Prospective cohort study 1 Retrospective cohort study	PRISMA	6	273 orbits 269 patients	NR	NR	1 Titanium mesh coated with high-density polyethylene 5 Titanium mesh 2 PDS 1 Calvarial bone plus PDS 1 Preformed glass-bioceramic 2 Preformed titanium mesh	Study objective; Fracture patterns; Primary or secondary reconstruction; Technique; Surgical approach; Implants; Diplopia; Enophthalmos; Complications; and Follow-up.	Observational studies: Newcastle-Ottawa Scale (NOS). The authors used two variations of the NOS, one specific to cohort studies and another for case-control studies.	The authors declare no competing financial interests.
Ramesh et al 2018	"This systematic review was undertaken to synthesize the literature and currently available products into a coherent resource for the orbital surgeon."	3 Level II (Systematic review of cohort studies or Individual cohort study (including low-quality randomized controlled trial, e.g., <80% follow-up); 21 Level IV (Case series and poor-quality cohort and case-control studies); 3 Level V (Expert opinion without explicit critical appraisal or based on physiology, bench research, or first principles)	PRISMA	27	1021	NR	NR	Primary articles: 3 PCI (Osteomesh) 4 FDO 1 PGA 8 PLLA/PDLLA (Rapidoorb, Polymax, Macropore) 6 PLGA (Lactosorb, Ethisorb) 4 PLGA/TMC 1 PDS Discussion Polyglycolide (PGA) Poly-L-lactide (PLLA) Poly-D, L-lactide (PDLLA) Poly(lactide Polyglycolide (PLGA) Polydioxanone (PDO) Polycaprolactone (PCL)	Enophthalmos; Diplopia; Peri-implant inflammation; Other complications; and Follow-up	Quality of evidence: Oxford criteria. Risk of bias: Methodological index for non-randomized studies criteria (MINORS).	None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this article.
Azzi et al 2018	"Evaluate the effectiveness and safety of resorbable implants in pediatric orbital floor reconstruction."	NR "... the vast majority of these studies were retrospective."	PRISMA	14	248 patients	NR	3-16 (range)	Autogenous 1 Nasoseptal cartilage 1 Pericranial shave graft 2 Calvarial graft "autoplast" cranium 1 Bone graft 1 Iliac bone graft 1 Lyophilized human dura Resorbable 1 Resorbable plates 1 Macroorb 1 PL-DL/LA plates 1 Lyodura 1 Lactosorb 1 Gelfilm 1 Polydioxanone Non resorbable 2 Titanium 4 Medpor	Follow-up; Diplopia; Enophthalmos and infection.	NR	The authors report no conflicts of interest.
Oliver et al 2020	"Conduct a comprehensive systematic review of alloplastic implant materials utilized in the repair of orbital floor fractures stratified by indication for surgery, and outcomes in all reported cases to date."	7 Retrospective cohort, 2 case series, 2 case study;	NR	11	585 patients* 239 males 107 females 242 NR	NR	120-68 (range)	Autogenous polyethylene (PPE) 1 PPE + titanium 3 Titanium 1 Titanium + PLLA-PGA 1 Ethisorb 1 Nylon foil 1 Acrylic 1 Silicone 1 Hydroxyapatite 1 Unsterile hydroxyapatite 1 PLLA 1 Iliac crest bone 2 P(L-DL/LA 70/30 1 Perosteum polymer complex 2 Titanium 1 PDS 3 Porous polyethylene 1 PDS + polyglactin 1 PDS Durapatrh 2 Calvaria 1 Caster oil-derived biopolymer	Infection; Inflammation; Graft explanation; Migration; Hematoma; Wound dehiscence; Follow-up;	The authors categorized the articles according to their study design. In-depth assessments of methodological quality and bias were not found.	The authors declare that they have no conflict of interest.
Bourry et al 2020	"Compare the clinical results regarding diplopia and enophthalmos obtained after primary reconstruction of OFF (orbital floor fracture) using a variety of materials."	NR "study was a comparative study of two or more materials"	PRISMA	9	946 patients 709 males 237 NR	NR	131-5 (range 24.5 – 41)	1 Titanium 1 PDS 3 Porous polyethylene 1 PDS + polyglactin 1 PDS Durapatrh 2 Calvaria 1 Caster oil-derived biopolymer	Diplopia; Enophthalmos; Hemorrhage; infection or extrusion equipment.	NR	The authors declare no conflict of interest
Maier et al 2021	"Summarize and present the current evidence for custom-made orbital wall implants." ..."Review studies of patients with traumatic orbital fractures repaired with PSI to assess the postoperative orbital volume, as well as review the safety of PSI by assessing postoperative complication rates."	8 Retrospective cohort, 1 retrospective case-control, 4 prospective cohort, 1 prospective case-control; 1 randomized controlled trials	PRISMA	15	597 patients	NR	NR	10 Titanium 2 Porous polyethylene with embedded titanium 1 Porous polyethylene 1 Polycaprolactone 1 Autogenous bone	Enophthalmos; Diplopia; Orbital volume; complications; and Follow-up	The authors categorized the articles according to their study design. In-depth assessments of methodological quality and bias were not found.	The authors have no financial or conflicts of interest to disclose.
Hartmann et al 2022	"Was to critically review the recent literature, present the state of the art in orbital fracture reconstruction, and evaluate current trends"	2 Retrospective case series; 1 Case series; 1 Prospective clinical study; 1 Case study; 1 CT 2 multicenter, prospective; 1 Prospective clinical study; groups randomized; 1 Randomized clinical trial	PROSPERO (CRD42020189284) And PRISMA-P	8	419 patients and orbits	NR	18 – 80	2 Titanium 1 PEEK 1 Titanium PSI 1 Titanium PSI vs. bent 1 TITANV ELL Titanium powder (grade 23) 1 Ultra-high-molecular-weight polyethylene vs titanium mesh 1 Intra-surgical bent mesh vs. custom-made devices vs. titanium mesh 1 MEDPOR TITAN 1 MEDPOR TITAN 3D printed 1 Autologous calvarial bone 1 Titanium mesh (OsteoMed CO) pre-contoured on PSI model	Recovery; Comparison; Remaining functional deficits; Complications; Therapy of complications; Benefit of navigation; Time of surgery; Hospitalization; Liquid infusion; Costs	Risk of bias: Cochrane Collaboration's tool In-depth assessments of methodological quality and bias were not found.	Conflict of interest: Dr. Marcus Seiler (one of the authors) is the owner of the patent of Ycoos CBR ®. Funding: This research did not receive any specific grant.
Kotecha et al 2022	"Do patient-specific implants, manufactured or designed using computer-assisted technology, improve outcomes (orbital volume change,	2 Randomized-controlled trials 6 Retrospective cohort 3 Prospective cohort	PRISMA	11	628 patients (by text) 403 males 151 females 78 NR 629 patients (by summing up)	NR	139-35 (SD 15.72)	1 Titanium mesh (OsteoMed CO) pre-contoured on PSI model	Orbital volume; Operative duration; Follow-up; Enophthalmos; Diplopia	Randomized trials: Revised Cochrane Risk-of-Bias Tool for Randomized Trials (RoB2). Observational studies:	The authors declare no competing interests.



	enophthalmos, diplopia, and operative duration) compared to conventional methods in orbital reconstruction following traumatic orbital injury in the adult patient population?"			the data in the tables)					2 Titanium mesh (manufacturer not disclosed) manufacturers pre-contoured on PSI model 1 Porous polyethylene (Biopora) sheet 1 Individualized polytetrafluoroethylene (Ecoflon) 1 Komet metal 1 Synthes 1 SynPOR titanium mesh (Synthes) 2 SynPOR PSI (Synthes) 3 Pre-formed orbital titanium mesh plates (Synthes) 3 Matrix MID-FACE pre-contoured on PSI model 1 Matrix MID-FACE/MODUS Midface pre-contoured on PSI model 1 Bioceramic glass individually shaped (Biovert II) 1 Titanium mesh (manufacturer not disclosed) 2 Orbital titanium mesh plate (manufacturer not disclosed) 2 SLM titanium PSI (KLS Martin) 1 Synker MEDPOR Orbital reconstruction implants	Newcastle-Ottawa Scale (NOS)	
Murray-Deouglas et. al 2022	"This study aims to determine, for patients undergoing post-traumatic orbital reconstruction, if using 3D printing provides benefit over traditional management with intraoperative implant contouring, as measured by functional and aesthetic clinical outcomes, postoperative orbital volume, and operation duration."	NR	PROSPERO (CRD42020134145) And PRISMA	58	906 patients	420 males 150 females 336 NR	†37.46 (SD 13.74)	NR	Enophthalmos; Diplopia; Orbital volume; and Follow-up.	Quality of reporting: "Appropriate use and reporting of uncontrolled case series in the medical literature."	The authors declare no conflicts of interest.
Singh et. al 2023	"This systematic review intends to compare the results of conventional manual freehand shaping (MFS) of orbital implants compared to pre-shaped implants on a 3D-printed model (3DP) in reconstructing traumatic orbital wall defects."	6 Retrospective 2 RCT 1 Prospective 1 Prospective controlled multicenter trial	PROSPERO (CRD42021261594) And PRISMA	10	564	NR	NR	NR	Accuracy of fit; Restoration of orbital defect and volume; Correction of orbital dystopia; Complications; Operative time.	Risk of bias: "A modified generic version of the Risk of Bias (ROB 2 tool)."	Conflicts of interest: "The authors declare no conflict of interest." Funding: "This research received no external funding."
Abukhder et. al 2024	"The primary aim of this systematic review is to report the type and frequency of complications which may arise in the use of autologous cartilage in the repair of orbital fractures."	NR	PROSPERO (CRD42022300402) And PRISMA	16	259	136 males 41 females 76 NR	06 - 87	6 Concha cartilage 5 Nasoseptal cartilage 2 Costal cartilage 2 Auricular cartilage 1 Conchal & Nasoseptal	Scleral show; Diplopia; Limitation in gaze; Enophthalmos; Sensitive disturbances; Entropion; Edema; Graft displacement; Retro-orbital hematomas;	Quality and risk of Bias: Newcastle-Ottawa Scale (NOS)	"This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. This research has no conflicts of interest."

* Note: Results from the "included studies" and "N and Orbital implants evaluated" columns may not be equivalent because several studies assess more than one implant.
 † Discrepancy of three patients between the overall count and the sum of the sexes.
 ‡ The reviewer has already added these data as the average age.
 ‡ We believe this acronym refers to "controlled trial." We did not find this definition in the text.
 §: Approximately
 NR: not related; NC: not clear, used when the data was not directly disclosed; RCT: Randomized controlled trials



Table III. Analytical characteristics of the selected reviews

Author and year	Enophthalmos	Diplopia	Other Outcomes / Complications	Follow-up, overall range (months)	Data Synthesis Technique
Avasha et. al 2012	% improvement: § 83.9% Autologous nasal septum cartilage 71.9% Porous polyethylene 53.9% Titanium mesh 50.6% Autologous auricular cartilage 30.5% Autologous calvarium bone 16.1% Bioactive glass 11.8% Allograft Dura 10.9% Teflon 10.9% DHB 9.1% Autologous maxilla bone 8.3% PLA+PGA 6.6% PDS 5.3% Polyglactin 910 + PDS 3.5% P1(d)LA NR Autologous mandible bone, Silastic rubber, PGA, Autologous ilium bone, Nylon	% improvement: § 60.0% Teflon 59.0% PGA 57.5% Autologous auricular cartilage 56.3% Autologous nasal septum cartilage 53.9% Titanium mesh 48.1% Bioactive glass 32.3% Allograft Dura 32.2% Autologous ilium bone 25.0% PLA+PGA 24.3% PDS 23.7% DHB 23.4% Porous polyethylene 21.9% Polyglactin 910 + PDS 20.0% Autologous maxilla bone 17.7% P1(d)LA 13.9% Autologous calvarium bone NR Nylon, Silastic rubber	PO Reduced Ocular Motility: § 20.0% Allograft DHB 8.1% PDS 5.7% Allograft Dura 4.0% Polyglactin 910 + PDS 1.8% Autologous maxilla bone 1.7% Porous polyethylene 1.4% Autologous calvarium bone 1.0% Titanium mesh 1.0% Nylon 0.0% Autologous ilium bone, Autologous auricular cartilage, Autologous nasal septum cartilage, PLA+PGA, P1(d)LA, Bioactive glass, Teflon NR Autologous mandible bone, Silastic rubber, PGA PO Infection: § 9.0% Autologous mandible bone 6.7% Silastic Rubber 3% Polyglactin 910 + PDS 1.6% Autologous calvarium bone 1.4% Porous polyethylene 1.0% Titanium mesh 1.0% Nylon 0.4% Teflon 0.0% PDS, Autologous maxilla bone, Autologous ilium bone, Autologous auricular cartilage, Autologous nasal septum cartilage, PLA+PGA, P1(d)LA, Bioactive glass NR PGA, DHB, Allograft Dura	3 – 30	Unweighted cumulative synthesis.
Gunarajah and Samman 2013	N pre/post (% of improvement) ◊ 57/5 (91.2%) Autogenous cartilage 32/4 (87.5%) Autogenous temporalis fascia 21/4 (80.9%) Allogenic lyophilized dura mater 77/18 (76.6%) Autogenous bone 113/28 (75.2%) Porous polyethylene 70/19 (72.8%) PDS 7/2 (71.4%) Polyglactin, Polyglactin 910/PDS 11/4 (63.6%) BAG plate 55/28 (49.1%) Titanium NR Polyglycolic acid membrane, Allogenic irradiated fascia, Allogenic lyophilized cartilage, Hydroxyapatite sheet, Periosteum-polymer, Collagen, PLLA, P1(DL)LA 70/30, PLLA/PGA	N pre/post (% of improvement) ◊ 10/0 (100.0%) Polyglycolic acid membrane 55/4 (92.0%) Allogenic lyophilized dura mater 104/9 (91.4%) Polyglactin, Polyglactin 910/PDS 32/3 (90.6%) Autogenous temporalis fascia 35/5 (85.7%) BAG plate 188/27 (85.6%) Autogenous bone 53/10 (81.1%) Autogenous cartilage 18/5 (72.2%) Allogenic irradiated fascia 48/14 (70.8%) PLLA, P1(DL)LA 70/30, PLLA/PGA 200/37 (68.0%) Porous polyethylene 46/15 (67.4%) Titanium 41/18 (53.1%) PDS NR Allogenic lyophilized cartilage, Hydroxyapatite sheet, Periosteum-polymer, Collagen	Orbital dystopia ◊ N pre/post (% of improvement) 23/0 (100%) Autogenous cartilage 3/0 (100%) BAG plate 4/0 (100%) PLLA, P1(DL)LA 70/30, PLLA/PGA 43/6 (86.0%) Porous polyethylene 47/7 (85.1%) Autogenous bone 7/5 (28.6%) PDS NR others implants. Orbital soft tissue entrapment ◊ N pre/post (% of improvement) 46/0 (100%) Autogenous bone 40/0 (100%) Autogenous cartilage 10/0 (100%) PLLA, P1(DL)LA 70/30, PLLA/PGA	2 – 78	In one table, there was an unweighted sum of the patient quantity per biomaterial rather than per study. Raw quantity of patients;
			54/3 (94.4%) Porous polyethylene 79/3 (93.7%) Polyglactin, Polyglactin 910/PDS 72/5 (93.1%) Allogenic lyophilized dura mater 32/3 (90.6%) Autogenous temporalis fascia 101/24 (76.2%) PDS -0 BAG plate, Collagen membrane NR others implants. Graft extrusion/displacement ◊ N found/all 1/529 Porous polyethylene 1/455 PDS Sinus/orbital infection ◊ N found/all 10/529 Porous polyethylene 2/455 PDS 1/174 Titanium mesh		
Ramesh et. al 2018	12.5% PLLA 8.3% PGA 4.8% PLGA 3.5% PLLA/PDLLA 3.2% PDO 1.2% PCL	3.0% PDO 2.3% PLGA 2.3% PCL <1.0% PLLA/PDLLA 0.0% PLLA 0.0% PGA	Delayed inflammation 37.5% PLLA 3.3% PLGA 1.7% PLLA/PDLLA 1.2% PDO 0.0% PGA, PCL	1.5 – 96	Unweighted cumulative synthesis.
	"Statistical significance cannot be inferred from these percentages, as these are compilations of case series with varying methodologies in surgical technique and clinical assessment."	"Statistical significance cannot be inferred from these percentages, as these are compilations of case series with varying methodologies in surgical technique and clinical assessment."	"Statistical significance cannot be inferred from these percentages, as these are compilations of case series with varying methodologies in surgical technique and clinical assessment."		
Azzi et. al 2018	Affected / All patients (%) 14/102 (3.7%) Nonabsorbable 12/83 Titanium, or Medpor, or Medpor/Titanium 2/6 Medpor 4/36 (11.1%) Autogenous 4/13 Iliac or calvarial bone graft 3/52 (5.8%) Absorbable 3/9 Gelfilm	Affected / All patients (%) 19/72 (26.4%) Absorbable 8/20 Lyodura or Lactosorb 8/34 Polydioxanone 3/9 Gelfilm 12/54 (22.2%) Autogenous* 5/14 Lyophilized human dura 4/13 Iliac or calvarial bone graft 3/17 Pericranial shave graft 5/122 (4.1%) Nonabsorbable 2/20 Medpor; 1/5 Medpor 1/6 Titanium 1/85 Titanium, or Medpor, or Medpor/Titanium	Affected / All patients (%) Infection 9/102 (8.8%) Nonabsorbable 9/83 Titanium, or Medpor, or Medpor/Titanium 0/33 (0.0%) Autogenous 0/43 (0.0%) Absorbable	1 – 61	Unweighted cumulative synthesis.
Oliver et. al 2020	NR	NR	N (%) Inflammation: 2/2 (100%) Hydroxyapatite 1/51 (2.0%) PPE 1/52 (1.9%) Titanium Infection: 1/51 (2.0%) PPE 2/181 (1.1%) Nylon foil Graft explant 2/34 (5.9%) PLLA	8.5h – 49 months	Unweighted cumulative synthesis.



			1/24 (4.2%) PPE + Titanium Hemostats 1/20 (5.0%) Titanium + PLLA/PGA 1/24 (4.2%) PPE + Titanium 1/51 (2.0%) PPE 1/70 (1.4%) u-HA/PLLA (The implants not mentioned did not show complication rates)		
Bourry et al 2020	No statistical significance when assessed separately. SUCRA (better results first): 1° PDS/Polyglactin 2° PDS 3° Durapatch 4° Titanium 5° P(L/DL)LA 6° PP 7° Calvaria 8° PFC 9° ICB 10° CODB	No statistical significance when assessed separately. SUCRA (better results first): 1° P(L/DL)LA 2° Porous polyethylene 3° Durapatch 4° Titanium 5° PDS 6° PDS/Polyglactin 7° CODB 8° PFC 9° ICB 10° Calvaria	"Other complications, defined as hemorrhage, infection, or extrusion of the material, were noted in 7 patients (0.74%) for all the materials combined. When analyzed separately, none of the materials studied presented a higher risk of complications than the others."	≥ 3 via eligibility criteria	Meta-analysis with treatment for heterogeneity, but without weighting the results by the methodological quality/bias analysis of each primary study.
Kotecha et al 2022	Despite two [†] of the five primary articles revealing statistically favorable differences for PSL, the meta-analysis outcome did not show statistical differences between "favorable to conventional reconstruction" and "favorable to PSL-guided reconstruction."	There are no statistical differences between "favorable to conventional reconstruction" and "favorable to PSL-guided reconstruction."	Operative duration: Despite two [†] of the five primary articles revealing statistically favorable differences for PSL, the meta-analysis outcome did not show statistical differences between "favorable to conventional reconstruction" and "favorable to PSL-guided reconstruction." Orbital Volume: Despite one [†] of the three primary articles revealing statistically favorable differences for PSL, the meta-analysis outcome did not show statistical differences between "favorable to conventional reconstruction" and "favorable to PSL-guided reconstruction." "Important clinical outcomes, such as hypoglobus, ION hypoesthesia, ocular motility restriction, and procedure-related complications could not be included in the current study due to insufficient reporting."	3 – 60	Meta-analysis was conducted with treatment for heterogeneity but without weighting the results by each primary study's methodological quality/bias analysis.
Murray-Douglass et al 2022	Is there a reduction in enophthalmos in the postoperative period? Indication: 3D printed implant: SS† Contour model: SS† Mould: NS† Surgical guides: NS† Surgical planning: SS† Navigation: No: SS† Yes: SS† Overall: SS	Is there a reduction in diplopia in the postoperative period? Indication: 3D printed implant: NS† Contour model: SS† Mould: SS† Surgical guides: NS† Surgical planning: SS† Navigation: No: SS† Yes: SS† Overall: SS	Orbital volume: Is there a volume difference between the operated and non-operated orbit? Indication: 3D printed implant: NS† Contour model: NS† Mould: NS† Surgical guides: NS† Surgical planning: NS† Navigation: No: NS† Yes: NS† Overall: NS	9.6 (SD 5.20)	Meta-analysis was conducted with treatment for heterogeneity. Sensitivity analysis indicated that the study quality did not affect the outcomes' overall effect size or heterogeneity. Although the reviewers recognized the need for a simple tool with few criteria to assess quality, they acknowledged that this was necessary due to the heterogeneity of the primary studies.
Singh et al 2023	NR	NR	Operative time: Statistical significance was found in favor of implants previously modeled in 3D models. Substantial heterogeneity was observed.		Meta-analysis was conducted with treatment for heterogeneity. Funnel plots and formal tests to account for biases were not performed because there were fewer than ten studies. Unweighted cumulative synthesis.
Abukhder et Al 2024	Affected / All patients (% of involvement) † 4/72 (5.6%) Nasoseptal cartilage 1/22 (4.5%) Auricular cartilage 2/148 (1.4%) Conchal cartilage 0/17 (0.0%) Costal cartilage	Affected / All patients (% of involvement) † 4/17 (23.5%) Costal cartilage 3/22 (13.6%) Auricular cartilage 6/72 (8.3%) Nasoseptal cartilage 10/148 (6.8%) Conchal cartilage	NR	0.25 – 40 meses	

Note: When applicable, the data are arranged from the highest complication rate to the lowest.
 § We found an inconsistency in data between the results section and the table. These data were extracted from the systematic review table. The authors presented the data in separate columns, and we calculated the difference between pre-op and post-op involvement.
 * There may be uncertainty surrounding the inclusion of five patients in this group, who should be classified under the 'absorbable' category.
 † These data were extracted from the unweighted sum conducted by the reviewers. In the original SR, the reviewers provided the data per study.
 ≈: Approximately
 ‡ Considering only the results where the confidence interval does not touch the '0 line' on the forest plot.
 †: Complication percentages are calculated as the number of complications reported divided by the total number of cases reported in the SR. We carried out this calculation only to be able to classify the order in which the implants appear.
 NR: Not reported; NS: Non-Significant; SS: Significant; PPE: porous polyethylene; u-HA: unsintered hydroxyapatite particles; PLLA: poly-L-lactic acid; PGA: polyglycolic; DHB: demineralized human bone; PDS: polydioxanone; PPC periosteum polymer complex; ICB iliac crest bone; CODB castor oil-derived biopolymer;

Table IV. Limitations

Limitation	Risk of changing the conclusions	Impact of the change	Information
The primary studies were not evaluated for methodological quality.	Low	Low	Whenever available, we used the quality and bias assessment performed by the SRs. A dataset culminated in classifying the evidence found as low quality.
The overlap of primary studies has not been formally assessed.	Low	Low	The evidence was analyzed considering the methodological quality of the statements, not the quantity of studies affirming the same effect.
The AMSTAR and ROBIS questionnaires and the evidence qualification system have subjectivities.	Moderated	Low	The subjectivity of the questions can lead to variations in the results when answered by different teams, which can impact the quality of the evidence in the end. However, the analysis of the evidence was for the benefit of the doubt about biomaterials already used and not in the affirmation of quality. We understand that this practice does not put the patient at additional risk.
When completing the AMSTAR and ROBIS tools, we consider all statistical data synthesis a "meta-analysis."	Moderated	Low	This option may be responsible for the decrease in the final grade of some papers. However, the importance of these questions is diluted as other essential items had to be evaluated until we arrived at the quality of the evidence.
Some patients outside the eligibility criteria may have been inadvertently included.	Moderated	Low	Some papers have not made clear the reason and extent of the reconstruction. Larger and more complex reconstructions (e.g., after tumor resections) tend to develop more complications and unfavorable outcomes, which may be independent of the biomaterial. However, we did not compare the overall results of all implants to determine lower complication rates; instead, we compared the quality of the data surrounding them.



APPENDICES

Appendix 1. PRIOR checklist

SECTION TOPIC	ITEM NO	ITEM	LOCATION WHERE ITEM IS REPORTED
Title			
Title		Identify the report as an overview of reviews.	✓
Abstract			
Abstract	2	Provide a comprehensive and accurate summary of the purpose, methods, and results of the overview of reviews.	✓
Introduction			
Rationale	3	Describe the rationale for conducting the overview of reviews in the context of existing knowledge.	✓ "Introduction" section
Objectives	4	Provide an explicit statement of the objective(s) or question(s) addressed by the overview of reviews.	✓ "Introduction" section
Methods			
Eligibility criteria	5a	Specify the inclusion and exclusion criteria for the overview of reviews. If supplemental primary studies were included, this should be stated, with a rationale.	✓ Table I. PECOS criteria
	5b	Specify the definition of "systematic review" as used in the inclusion criteria for the overview of reviews.	✗
Information sources	6	Specify all databases, registers, websites, organizations, reference lists, and other sources searched or consulted to identify systematic reviews and supplemental primary studies (if included). Specify the date when each source was last searched or consulted.	✓ "Search strategy" section
Search strategy		Present the full search strategies for all databases, registers and websites, such that they could be reproduced. Describe any search filters and limits applied.	✓ Appendix
Selection process	8a	Describe the methods used to decide whether a systematic review or supplemental primary study (if included) met the inclusion criteria of the overview of reviews.	✓ "Screening process, data collection and outcomes" section
	8b	Describe how overlap in the populations, interventions, comparators, and/or outcomes of systematic reviews was identified and managed during study selection.	▲ Table IV. Limitations
Data collection process	9a	Describe the methods used to collect data from reports.	✓ "Screening process, data collection and outcomes" section
	9b	If applicable, describe the methods used to identify and manage primary study overlap at the level of the comparison and outcome during data collection. For each outcome, specify the method used to illustrate and/or quantify the degree of primary study overlap across systematic reviews.	▲ Table IV. Limitations
	9c	If applicable, specify the methods used to manage discrepant data across systematic reviews during data collection.	✓ "Screening process, data collection and outcomes" section
Data items	10	List and define all variables and outcomes for which data were sought. Describe any assumptions made and/or measures taken to identify and clarify missing or unclear information.	✓ "Screening process, data collection and outcomes" section
Risk of bias assessment	11a	Describe the methods used to assess risk of bias or methodological quality of the included systematic reviews.	✓ "Quality of reviews and bias analysis" section
	11b	Describe the methods used to collect data on (from the systematic reviews) and/or assess the risk of bias of the primary studies included in the systematic reviews. Provide a justification for instances where flawed, incomplete, or missing assessments are identified but not reassessed.	✓ "Quality of reviews and bias analysis" section
	11c	Describe the methods used to assess the risk of bias of supplemental primary studies (if included).	▲ We use the evaluations carried
Synthesis methods	12a	Describe the methods used to summarize or synthesize results and provide a rationale for the choice(s).	out by systematic reviews ✓ "Data synthesis, data conference and certainty assessment" section
	12b	Describe any methods used to explore possible causes of heterogeneity among results.	✓ "Data synthesis, data conference and certainty assessment" section
	12c	Describe any sensitivity analyses conducted to assess the robustness of the synthesized results.	✓ "Data synthesis, data conference and certainty assessment" section
Reporting bias assessment	13	Describe the methods used to collect data on (from the systematic reviews) and/or assess the risk of bias due to missing results in a summary or synthesis (arising from reporting biases at the levels of the systematic reviews, primary studies, and supplemental primary studies, if included).	✓ "Quality of reviews and bias analysis" section; Figure 2. AMSTAR 2 summary plot Figure 3. ROBIS summary plot
Certainty assessment	14	Describe the methods used to collect data on (from the systematic reviews) and/or assess certainty (or confidence) in the body of evidence for an outcome.	✓ "Data synthesis, data conference and certainty assessment" section
Results			
Systematic review and supplemental	15a	Describe the results of the search and selection process, including the number of records screened, primary study selection assessed for eligibility, and included in the overview of reviews, ideally with a flow diagram.	✓ Figure 1. Flow diagram based on PRISMA.
		Provide a list of studies that might appear to meet the inclusion criteria, but were excluded, with the main reason for exclusion.	✓ Appendix.
Characteristics of systematic reviews and supplemental primary studies	16	Cite each included systematic review and supplemental primary study (if included) and present its characteristics.	✓ "Results" and "Discussion" section.
Primary study overlap		Describe the extent of primary study overlap across the included systematic reviews.	▲ Table IV. Limitations.
Risk of bias in systematic reviews, primary studies, and supplemental primary studies	18a	Present assessments of risk of bias or methodological quality for each included systematic review.	✓ "Quality of reviews and bias analysis" section. Figure 2. AMSTAR 2 summary plot. Figure 3. ROBIS summary plot.
	18b	Present assessments (collected from systematic reviews or assessed anew) of the risk of bias of the primary studies included in the systematic reviews.	✓ "Results" section.
	18c	Present assessments of the risk of bias of supplemental primary studies (if included).	✓ Not included.
Summary or synthesis of results	19a	For all outcomes, summarize the evidence from the systematic reviews and supplemental primary studies (if included). If meta-analyses were done, present for each the summary estimate and its precision and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	✓ Figure 4. Summary of evidence.
	19b	If meta-analyses were done, present results of all investigations of possible causes of heterogeneity.	✓ Statistical analyses will not be performed.
	19c	If meta-analyses were done, present results of all sensitivity analyses conducted to assess the robustness of synthesized results.	✓ Statistical analyses will not be performed.
Reporting biases	20	Present assessments (collected from systematic reviews and/or assessed anew) of the risk of bias due to missing primary studies, analyses, or results in a summary or synthesis (arising from reporting biases at the levels of the systematic reviews, primary studies, and supplemental primary studies, if included) for each summary or synthesis assessed.	✓ "Results" section.
Certainty of evidence	21	Present assessments (collected or assessed anew) of certainty (or confidence) in the body of evidence for each outcome.	✓ Figure 4. Summary of evidence.
Discussion			
Discussion	22a	Summarize the main findings, including any discrepancies in findings across the included systematic reviews and supplemental primary studies (if included).	✓ "Discussion" section.



	22b	Provide a general interpretation of the results in the context of other evidence.	✔ "Discussion" section.
	22c	Discuss any limitations of the evidence from systematic reviews, their primary studies, and supplemental primary studies (if included) included in the overview of reviews. Discuss any limitations of the overview of reviews methods used.	✔ "Discussion" section and Table IV. Limitations
	22d	Discuss implications for practice, policy, and future research (both systematic reviews and primary research). Consider the relevance of the findings to the end users of the overview of reviews, e.g., healthcare providers, policymakers, patients, among others.	✔ Figure 4. Summary of evidence, and "Conclusion" section.
Other information			
Registration and protocol	23a	Provide registration information for the overview of reviews, including register name and registration number, or state that the overview of reviews was not registered.	✔ "Materials and methods" section.
	23b	Indicate where the overview of reviews protocol can be accessed, or state that a protocol was not prepared.	✔ "Materials and methods" section.
	23c	Describe and explain any amendments to information provided at registration or in the protocol. Indicate the stage of the overview of reviews at which amendments were made.	✔ "Materials and methods" section.
Support	24	Describe sources of financial or non-financial support for the overview of reviews, and the role of the funders or sponsors in the overview of reviews.	✔ In the designated area for this purpose.
Competing interests	25	Declare any competing interests of the overview of reviews' authors.	✔ In the designated area for this purpose.
Author information	26a	Provide contact information for the corresponding author.	✔ In the designated area for this purpose.
	26b	Describe the contributions of individual authors and identify the guarantor of the overview of reviews.	✔ In the designated area for this purpose.
Availability of data and other materials	27	Report which of the following are available, where they can be found, and under which conditions they may be accessed: template data collection forms; data collected from included systematic reviews and supplemental primary studies; analytic code; any other materials used in the overview of reviews.	✔ Appendices.

Appendix 2. Complete Search Strategy

DATABASES	TERMS	RESULTS
MEDLINE PUBMED	((((((((("Orbital Fractures"[Mesh]) OR ("Orbital Fracture") OR ("Fracture, Orbital") OR ("Fractures, Orbital") OR ("Blow-Out Fractures") OR ("Blow-Out Fracture") OR ("Fracture, Blow-Out") OR ("Fractures, Blow Out") OR ("Blow Out Fracture") OR ("Blow Out Fractures") OR ("Fracture, Blow Out") OR ("Fractures, Blow Out") OR ("Out Fractures, Blow") OR ("Out Fractures, Blow")) AND (((((((((((("Orbital Implants"[Mesh]) OR ("Absorbable Implants"[Mesh]) OR ("Prostheses and Implants"[Mesh]) OR ("Bone Transplantation"[Mesh]) OR ("Surgical mesh" [Mesh]) OR ("Implant, Orbital") OR ("Implants, Orbital") OR ("Orbital Implant") OR ("Implants and Prostheses") OR ("Prosthetic Implants") OR ("Prostheses and Implant") OR ("Implant and Prostheses") OR ("Prosthetic Implant") OR ("Implant, Prosthetic") OR ("Implants, Prosthetic") OR ("Endoprosthesis") OR ("Endoprostheses") OR ("Prostheses") OR ("Prosthesis") OR ("Implants, Artificial") OR ("Artificial Implant") OR ("Artificial Implants") OR ("Implant, Artificial") OR ("Biodegradable Implants") OR ("Biodegradable Implant") OR ("Implant, Biodegradable") OR ("Implants, Biodegradable") OR ("Bioabsorbable Implants") OR ("Bioabsorbable Implant") OR ("Implant, Bioabsorbable") OR ("Implants, Bioabsorbable") OR ("Implants, Absorbable") OR ("Absorbable Implant") OR ("Implant, Absorbable") OR ("Meshes, Surgical") OR ("Surgical Meshes") OR ("Mesh, Surgical") OR ("orbital reconstruction") OR ("orbital defect") OR ("Biocompatible Material") OR ("Material, Biocompatible") OR ("Biomaterials") OR ("Bioartificial Materials") OR ("Bioartificial Material") OR ("Material, Bioartificial") OR ("Biocompatible Materials"[Mesh]))	1458
COCHRANE	"Orbital Fractures" OR "Orbital Fracture" OR "Fracture, Orbital" OR "Fractures, Orbital" OR "Blow-Out Fractures" OR "Blow-Out Fracture" OR "Fracture, Blow-Out" OR "Fractures, Blow Out" OR "Blow Out Fracture" OR "Blow Out Fractures" OR "Fracture, Blow Out" OR "Fractures, Blow Out" OR "Out Fracture, Blow" OR "Out Fractures, Blow" in Title Abstract Keyword AND "Orbital Implants" OR "Absorbable Implants" OR "Prostheses and Implants" OR "Bone Transplantation" OR "Surgical mesh" OR "Implant, Orbital" OR "Implants, Orbital" OR "Orbital Implant" OR "Implants and Prostheses" OR "Prosthetic Implants" OR "Prostheses and Implant" OR "Implant and Prostheses" OR "Prosthetic Implant" OR "Implant, Prosthetic" OR "Implants, Prosthetic" OR "Endoprosthesis" OR "Endoprostheses" OR "Prostheses" OR "Prosthesis" OR "Implants, Artificial" OR "Artificial Implant" OR "Artificial Implants" OR "Implant, Artificial" OR "Biodegradable Implants" OR "Biodegradable Implant" OR "Implant, Biodegradable" OR "Implants, Biodegradable" OR "Bioabsorbable Implants" OR "Bioabsorbable Implant" OR "Implant, Bioabsorbable" OR "Implants, Bioabsorbable" OR "Implants, Absorbable" OR "Absorbable Implant" OR "Implant, Absorbable" OR "Meshes, Surgical" OR "Surgical Meshes" OR "Mesh, Surgical" OR "orbital reconstruction" OR "orbital defect" OR "Biocompatible Material" OR "Material, Biocompatible" OR "Biomaterials" OR "Bioartificial Materials" OR "Bioartificial Material" in Title Abstract Keyword	0
EMBASE	('orbit fracture'/exp OR 'orbit fracture' OR 'orbit'/exp OR 'orbit' OR 'blowout fracture'/exp OR 'blowout fracture') AND ('orbit implant' OR 'implant' OR 'bone transplantation' OR 'bone graft' OR 'biomaterial' OR 'biodegradable implant' OR 'surgical mesh' OR 'orbit reconstruction') AND ('meta analysis'/de OR 'systematic review'/de)	57
SCOPUS	TITLE-ABS-KEY (("Orbital Fractures" OR "Orbital Fracture" OR "Fracture, Orbital" OR "Fractures, Orbital" OR "Blow-Out Fractures" OR "Blow-Out Fracture" OR "Fracture, Blow-Out" OR "Fractures, Blow Out" OR "Blow Out Fracture" OR "Blow Out Fractures" OR "Fracture, Blow Out" OR "Fractures, Blow Out" OR "Out Fracture, Blow" OR "Out Fractures, Blow") AND TITLE-ABS-KEY ("Orbital Implants" OR "Absorbable Implants" OR "Prostheses and Implants" OR "Bone Transplantation" OR "Surgical mesh" OR "Implant, Orbital" OR "Implants, Orbital" OR "Orbital Implant" OR "Implants and Prostheses" OR "Prosthetic Implants" OR "Prostheses and Implant" OR "Implant and Prostheses" OR "Prosthetic Implant" OR "Implant, Prosthetic" OR "Implants, Prosthetic" OR "Endoprosthesis" OR "Endoprostheses" OR "Prostheses" OR "Prosthesis" OR "Implants, Artificial" OR "Artificial Implant" OR "Artificial Implants" OR "Implant, Artificial" OR "Biodegradable Implants" OR "Biodegradable Implant" OR "Implant, Biodegradable" OR "Implants, Biodegradable" OR "Bioabsorbable Implants" OR "Bioabsorbable Implant" OR "Implant, Bioabsorbable" OR "Implants, Bioabsorbable" OR "Implants, Absorbable" OR "Absorbable Implant" OR "Implant, Absorbable" OR "Meshes, Surgical" OR "Surgical Meshes" OR "Mesh, Surgical" OR "orbital reconstruction" OR "orbital defect" OR "Biocompatible Material" OR "Material, Biocompatible" OR biomaterials OR biomaterial OR "Bioartificial Materials" OR "Bioartificial Material" OR "Material, Bioartificial" OR "Biocompatible materials") AND (LIMIT-TO (DOCTYPE , "re"))	87



WEB OF SCIENCE	"Orbital Fractures" OR "Orbital Fracture" OR "Fracture, Orbital" OR "Fractures, Orbital" OR "Blow-Out Fractures" OR "Blow-Out Fracture" OR "Fracture, Blow-Out" OR "Fractures, Blow Out" OR "Blow Out Fracture" OR "Blow Out Fractures" OR "Fracture, Blow Out" OR "Out Fracture, Blow" OR "Out Fractures, Blow" (topic) AND "Orbital Implants" OR "Absorbable Implants" OR "Prostheses and Implants" OR "Bone Transplantation" OR "Surgical mesh" OR "Implant, Orbital" OR "Implants, Orbital" OR "Orbital Implant" OR "Implants and Prostheses" OR "Prosthetic Implants" OR "Prostheses and Implant" OR "Implant and Prostheses" OR "Prosthetic Implant" OR "Implant, Prosthetic" OR "Implants, Prosthetic" OR endoprosthesis OR endoprotheses OR prostheses OR prosthesis OR "Implants, Artificial" OR "Artificial Implant" OR "Artificial Implants" OR "Implant, Artificial" OR "Biodegradable Implants" OR "Biodegradable Implant" OR "Implant, Biodegradable" OR "Implants, Biodegradable" OR "Bioabsorbable Implants" OR "Bioabsorbable Implant" OR "Implant, Bioabsorbable" OR "Implants, Bioabsorbable" OR "Implants, Absorbable" OR "Absorbable Implant" OR "Implant, Absorbable" OR "Meshes, Surgical" OR "Surgical Meshes" OR "Mesh, Surgical" OR "orbital reconstruction" OR "orbital defect" OR "Biocompatible Material" OR "Material, Biocompatible" OR biomaterials OR biomaterial OR "Bioartificial Materials" OR "Bioartificial Material" OR "Material, Bioartificial" OR "Biocompatible materials" (topic) AND review article (document type)	21
LILACS (ING)	("Orbital Fractures") AND ("Orbital Implants" OR "Absorbable Implants" OR "Prostheses and Implants" OR "Bone Transplantation" OR "surgical mesh" OR "Biocompatible Materials") AND (do:("LILACS") AND type_of_study:(("systematic_reviews"))	2
LILACS (ESP)	("Fracturas Orbitales") AND ("Implantes Orbitales" OR "Implantes Absorbibles")	0
LILACS (PT)	(Fraturas Orbitárias) AND ("Implantes Orbitários" OR "implantes Absorvíveis")	0
GOOGLE SCHOLAR (FIRST 10 PAGES)	(Orbital Fractures OR Blow-Out Fractures AND Orbital Implants OR Biocompatible Materials AND Systematic Review)	100 results, 3 selected for full-text reading 52 results, 0 selected for full-text reading
SCIENCE DIRECT	"Orbital reconstruction" and "systematic review"	1: 136 results, 0 article with inclusion criteria.
JOURNALS: 1: JOURNAL OF ORAL AND MAXILLOFACIAL SURGERY	"Orbital reconstruction" and "systematic review"	2: 91 results, 1 article with inclusion criteria.
JOURNALS: 2: INTERNATIONAL JOURNAL OF ORAL AND MAXILLOFACIAL SURGERY		

Appendix 3. Articles excluded after full-text assessment

Articles	Reason
Bratton EM, Durairaj VD. Orbital implants for fracture repair. <i>Curr Opin Ophthalmol</i> . Set 2011. Available: https://doi.org/10.1097/icu.0b013e3283499409	Non-systematic review of the literature
Chang EL, Bernardino CR. Update on orbital trauma. <i>Curr Opin Ophthalmol</i> . Oct 2004. Available: https://doi.org/10.1097/01.icu.00000137854.37950.fb	Non-systematic review of the literature
Cheung K, Voineskos SH, Avram R, Sommer DD. A Systematic Review of the Endoscopic Management of Orbital Floor Fractures. <i>JAMA Facial Plast Surg</i> . Mar 2013. Available: https://doi.org/10.1001/jamfacial.2013.595	The SR focuses on evaluating the endoscopic approach for orbital reconstruction
Dubois L, Steenen S, Gooris P, Mourits M, Becking A. Defect driven orbital reconstruction: a systematic review. <i>Int J Oral Maxillofac Surg</i> . Oct 2013. Available: https://doi.org/10.1016/j.ijom.2013.07.178	Abstract published in conference proceedings
Dubois L, Steenen SA, Gooris PJ, Mourits MP, Becking AG. Controversies in orbital reconstruction—II. Timing of post-traumatic orbital reconstruction: A systematic review. <i>Int J Oral Maxillofac Surg</i> . Apr 2015. Available: https://doi.org/10.1016/j.ijom.2014.12.003	The SR focuses on the timing of the approach
Dubois L, Steenen SA, Gooris PJ, Bos RR, Becking AG. Controversies in orbital reconstruction—III. Biomaterials for orbital reconstruction: a review with clinical recommendations. <i>Int J Oral Maxillofac Surg</i> . Jan 2016. Available: https://doi.org/10.1016/j.ijom.2015.06.024	The SR performed a technical review of the materials, but no clinical cases were conducted.
Dubois L, Dillon J, Jansen J, Becking AG. Ongoing Debate in Clinical Decision Making in Orbital Fractures. <i>Atlas Oral Maxillofac Surg Clin</i> . Jan 2021. Available: https://doi.org/10.1016/j.exom.2020.10.004	Non-systematic review of the literature
Esmail Khalil M, Farag Khalil M, Mohyeldien Abdelrahman R, Mohamed Kamal Elshafei A, Ismail Gawdat T. Implant Materials Used for Orbital Floor Reconstruction. <i>Indian J Public Health Res Amp Dev</i> . Jan 2020. Available: https://doi.org/10.37506/v11/i1/2020/ijphrd/194016	Non-systematic review of the literature
Fries PD. Controversies: Autogenous, alloplastic, integrated and resorbable implants for orbital blow-out fracture repair: A review. <i>Orbit</i> . Jan 1994. Available: https://doi.org/10.3109/01676839409031149	Non-systematic review of the literature
Goh EZ, Bullis S, Beech N, Johnson NR. Intraoperative computed tomography for orbital reconstruction: a systematic review. <i>Int J Oral Maxillofac Surg</i> . May 2023. Available: https://doi.org/10.1016/j.ijom.2023.05.002	The SR focuses on the use of intraoperative CT for orbital reconstructions
Jazayeri HE, Khavanin N, Yu JW, Lopez J, Ganjawalla KP, Shamlivan T, Tannyhill RJ, Dorafshar AH. Does Early Repair of Orbital Fractures Result in Superior Patient Outcomes? A Systematic Review and Meta-Analysis. <i>J Oral Maxillofac Surg</i> . Apr 2020. Available: https://doi.org/10.1016/j.joms.2019.09.025	The SR focuses on evaluating the different time intervals for surgery
Mast G, Ehrenfeld M, Cornelius CP, Tasman AJ, Litschel R. Maxillofacial Fractures: Midface and Internal Orbit—Part II: Principles and Surgical Treatment. <i>Facial Plast Surg</i> . Sep 2015. Available: https://doi.org/10.1055/s-0035-1563693	Non-systematic review of the literature
Schlund M, Lutz JC, Sentucq C, Bouet B, Ferri J, Nicot R. Prediction of Post-Traumatic Enophthalmos Based on Orbital Volume Measurements: A Systematic Review. <i>J Oral Maxillofac Surg</i> . Nov 2020. Available: https://doi.org/10.1016/j.joms.2020.05.049	The SR focuses on evaluating the different time intervals for surgery
Su Y, Sun J, Fan X. Epithelial cysts associated with alloplastic implants after repair of orbital fractures: a systematic review and four new cases. <i>Br J Oral Maxillofac Surg</i> . Jul 2016. Available: https://doi.org/10.1016/j.bjoms.2016.03.028	The SR brings a series of clinical cases with only one specific complication
Udhay P, Bhattacharjee K, Ananthnarayanan P, Sundar G. Computer-assisted navigation in orbitofacial surgery. <i>Indian J Ophthalmic</i> . Mar 2019. Available: https://doi.org/10.4103/ijo.ijo_807_18	The SR focuses only on intraoperative navigation
Vargas-Buratotvic JP, Uribe-Monasterio M, Ortuño-Borroto D, Verdugo-Paiva F, Pinedo-Henriquez FJ. Abordaje transconjuntival en comparación con abordaje subciliar para el tratamiento de fracturas orbitarias. <i>Int J Interdiscip Dent</i> . Aug 2020. Available: https://doi.org/10.4067/s2452-55882020000200105	The focus of the SR is on surgical access
Verbiat M, Dubron K, Bila M, Jacobs R, Shaheen E, Willaert R. Accuracy of surgical navigation for patient-specific reconstructions of orbital fractures: a systematic review and meta-analysis. <i>J Stomatol Oral Maxillofac Surg</i> . Nov 2023. Available: https://doi.org/10.1016/j.jormas.2023.101683	The SR focuses on the efficacy of intraoperative navigation



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