IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 23, Issue 4 Ser. 5 (April. 2024), PP 01-08
www.iosrjournals.org

Biomaterials for Orbital Fracture Repair in Adults: A Systematic Review

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Abstract
Aim*: This study aims to provide an overview and critical evaluation of reported applications and clinical outcomes associated with biomaterials utilized in the repair of post-traumatic orbital floor or wall defects in adults.*
Materials and Methods*: We conducted a systematic search of the English literature using PubMed/Medline and the Cochrane Library databases. The study selection process strictly followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement, leading to the inclusion of 32 articles that met the specified criteria. Primary outcome measures comprised assessments of diplopia, enophthalmos, reduced ocular motility, and infraorbital nerve paraesthesia. Secondary outcome measures encompassed any considerations related to aesthetics or complications associated with the implanted materials.*
Results*: Among the retrived 32 articles, 13 articles were retrospective cohort studies (40.62% of all the studies), 9 were clinical trials (28.12%), 7 were prospective cohort studies (21. 87%) and 3 were randomized clinical trials (9.37%). While some studies employed multiple materials, the materials in the retrieved studies were primarily separated into alloplastic materials either nonresorbable or resorbable in 21 studies, autologous graft materials in 12studies, composite materials in 3 studies and allogenic material in one study. A total of 197 postoperative complications were documented and the predominant complications included diplopia (47.7%, n=94), enophthalmos (23.85%, n=47), reduced motility (8.62%, n=17), infraorbital nerve disturbances (6.59%, n=13), thick scar formation (3.04%, n=6), and hypophthalmos (2.53%, n=5). The highest percentage observed in autogenous bone graft from an unspecified source (35.71%, n=5), iliac bone graft (28.20%, n=11) , titanium implants (26.07%, n=103) and bioactive glass (24.6% , n=16) while the lowest percentage associated with conchal cartilage graft (3.17% , n=2).*
Conclusion*: Various graft materials demonstrated varying degrees of success, as evidenced by the improvement reported across all studies in terms of the recorded outcome measures.*

Date of Submission: 11-04-2024 Date of Acceptance: 21-04-2024

I. Introduction:

Orbital fractures are prevalent in patients with facial trauma, constituting 18% to 50% of all craniomaxillofacial traumas, with incidence variations based on geographic region, injury mechanism, and the study population [1, 2]. The spectrum of orbital injuries ranges from nondisplaced linear fractures to intricate, comminuted fractures. While some fractures may be managed conservatively, the reconstruction of severely injured orbits presents technical challenges [3].

Accurate recognition and treatment of orbital injuries are imperative due to the potential for substantial functional and aesthetic issues, such as enophthalmos and persistent diplopia [4-6]. Orbital deformities primarily result from anatomic changes behind the eyeball and soft tissue alterations within the socket. Consequently, the selection of an appropriate reconstructive material is critical for restoring orbit volume, averting sequelae, and preserving ocular functions [7].

The choice of reconstructive materials varies based on the location and severity of the fracture, encompassing absorbable and non-absorbable options [8, 9]. While surgeons commonly rely on materials they believe yield satisfactory results with minimal complications, the ideal material remains a subject of ongoing debate in the literature [9]. Few studies provide a comprehensive review of the properties of different biomaterials and their associated complications. This review aims to analyze the literature concerning the use of reconstruction materials widely employed in the restoration of orbital floor or wall fractures in adults. By offering a comprehensive overview of materials used in post-traumatic orbital reconstruction, this review seeks to assist surgeons in making informed choices grounded in scientific evidence.

II. Materials And Methods:

Data source:

An electronic search was systematically conducted in the PubMed/Medline and Cochrane databases to identify evidence supporting the implant materials used for post-traumatic orbital floor or wall reconstruction in adults up to December 2022. The search was limited to English language articles.

Search Strategy:

Various text combinations were employed to search for relevant articles using the following terms:

- Orbital AND (Wall OR Floor OR Fracture) AND (Repair OR Reconstruction) AND (Outcomes OR Complications)
- Orbital AND (Wall OR Floor OR Fracture) AND (Repair OR Reconstruction) AND (Material OR Graft OR Implant)
- Orbital AND (Wall OR Floor OR Fracture) AND (Repair OR Reconstruction) AND (Diplopia OR Enophthalmos OR Infraorbital Paraesthesia)
- Orbital AND (Wall OR Floor OR Blowout) AND (Repair OR Reconstruction) AND (Autogenous OR Bone)
- Orbital AND (Wall OR Floor OR Blowout) AND (Repair OR Reconstruction) AND (Allogenic)
- Orbital AND (Wall OR Floor OR Blowout) AND (Repair OR Reconstruction) AND (Alloplastic)
- Orbital AND (Wall OR Floor OR Blowout) AND (Repair OR Reconstruction) AND (Titanium)
- Orbital AND (Wall OR Floor OR Blowout) AND (Repair OR Reconstruction) AND (Calvarial)
- Orbital AND (Wall OR Floor OR Blowout) AND (Repair OR Reconstruction) AND (Resorbable) AND (Implant)

Orbital AND (Wall OR Floor OR Blowout) AND (Repair OR Reconstruction) AND (Bioactive Glass)

- Orbital AND (Wall OR Floor OR Blowout) AND (Repair OR Reconstruction) AND (PDS OR Ethisorb)
- Orbital AND (Wall OR Floor OR Blowout) AND (Repair OR Reconstruction) AND (Teflon)
- Orbital AND (Wall OR Floor OR Blowout) AND (Repair OR Reconstruction) AND (Silicone)

Inclusion criteria:

- Studies published exclusively in the English language.
- Prospective and retrospective study designs.
- Clinical trials.
- Inclusion of adult participants only.
- Studies published up to December 31, 2022.
- Follow-up period of at least 3 months to 1 year.

Exclusion criteria:

- Studies published in non-English language
- case reports
- Editorial or commentaries or reviews
- Animal or cadaveric studies
- Studies related to the surgical approaches but not related to the implant material.
- Studies with outcome measures and complications not reported objectively

Study Selection:

Studies were included according to the inclusion criteria and studies screening was done in three stages:

- First, a title screening was conducted to exclude studies clearly unrelated to this review.
- Second, all abstracts were thoroughly reviewed with the application of inclusion criteria.
- Lastly, articles identified through abstract screening underwent a detailed review, and their references were searched for any additional relevant articles.

Data collection and analysis:

Mendely software was used for screening and reference management and data extraction was done manually using Microsoft Excel. Data extracted from articles were: authors, year of publication, type of the study, number of cases, type of the defect, the implant for repair, follow-up period and complications (Table 1). Analysis of reconstructive material properties and complications was done.

Table 1: Findings reported in the included studies including the implant materials and postoperative complications

	Authors/ year	Number of cases	Age	Defect type	Reconstruction biomaterial(s)	Follow-up period	Postoperative complications
1	**Iizuka et al [12], 1991**	13	19-72 years	Orital floor fracture	Polydioxanone (PDS) implant	9-45 months	Diplopia (2 cases)
2	**Cordewener et al[13], ,1996**	6	18 -67 years	Orbital floor fracture	poly(L-lactide)	3.5-3.6 years	No postoperative complications
3	**Aitasol et al [14], 2001**	36	22 -73 years	Orbital floor fracture	Bioactive glass	1 year	Diplopia (5 cases) Infraorbital nerve paraesthesia(5 case) Removal (1 case)
4	**Kontio et al [15], 2001**	16	18–59 years	internal orbital wall (blow out fracture)	Polydioxanone (PDS) implant	3-9 months	Enophthalmos(6 cases) Fibrotic sinus with fluid around the PDS (1 case), Diplopia (4 cases) Thick scar formations (6 cases) Fibrotic sinuses filled with air or gas (3 cases)
5	**Jank et al[16], 2003**	435	18-60 years	Orbital floor fracture	Lyophilized dura patches (120 cases) PDS (81 cases) Ethisorb(136 cases) No implant (91 cases)	24 months	**Ethisorb group**: Diplopia (4 cases), enophthalmos (2 cases), reduced motility(5 cases) and exophthalmos (1 case) **PDS group**: Diplopia(1 case) , exophthalmos (1case) and reduced motility(3 cases) **Dura patch group:** Diplopia (3 cases), enophthalmos(1 case), exophthalmos (1case), reduced bulbous motility (6 cases)
6	**Schon et al[17], 2006**	19	Adults	Orbital floor and wall fracture	Individually preformed titanium-mesh implants	10 months	No postoperative complications
7	**Al-Sukhun et al [18], 2006**	39	≥18 years	Orital floor fracture	Anterior iliac crest graft (24 cases) P(L/DL)LA70/30 (15cases)	9 months	Enophthalmos: 3 cases with bone graft and 2 cases with P(L/DL)LA
8	**Kontio et al[19], , 2006**	15	37.3 years(mean)	Orbital floor and medial wall fracture	Iliac bone graft	7.8 months(mean)	Enophthalmos (1 case), hypophthalmos (5 cases) , hyperophthalmos (2 cases)
9	**Yilmaz et al[20] ,2007**	26	19-64 years	Orbital floor fracture	Porous polyethylene implants (Medpor)	6-24 months	Diplopia (3 cases), enophthalmos (5 cases), infraorbital paraesthesia (4 cases) , ectropion (2) , Infection (4)
10	**Talesh et al[21], , 2008**	20	22–48 years	Orbital floor fracture	nasoseptal cartilaginous graft	5–39 months	Enophthalmos (1 case)

Table 1(continued)

	Authors/ year	Number of cases	Age	Defect type	Reconstruction biomaterial(s)	Follow-up period	Postoperative complications
11	**Guo et al** [22]**, 2009**	61	21–65 years	Orbital floor fracture	Calvarial bone graft (26 cases) Titanium mesh(35cases)	8-22 months	**Calvarial bone group**: 2 diplopia, 3 enophthalmos **Titanium group** : 1 diplopia, 2 enophthalmos
12	**Liu et al** [23],**2010**	46	22-45 years	orbital wall fracture(old)	Mandibular outer cortex	3months-3 years	No postoperative complications
13	**Kruschewsky et al**[41],**2011**	20	Mean age: 42 years (copolymer group) 54 years (grafting group)	Orbital floor with or without medial wall fracture	Auricular cartilage graft (8 cases) Absorbable polyacid copolymer (12 cases)	6 months	4 cases of infraorbital nerve paraesthesia (2 in each group)) 2 cases of paralytic mydriasis in copolymer group
14	**Wajih et al** [24] **2011**	26	20-29 years	Orbital floor fracture	Autogenous graft (unspecified source, 14 cases) Medpore (12 cases)	1 year	**Medpore group:** Diplopia (3 cases), enophthalmos(4 cases), Reduced motility (2 cases) **Autogenous graft group:** Diplopia (1 case), enophthalmos (3 cases), Reduced motility (1 case)
15	**Chen et al** [25], **2012**	10	20-52 years	Orbital floor fracture	fibrin glue with osteoconductive scaffold	2-4 years	No postoperative complications
16	**Gerressen et al** [26],**2012**	22	21-53years	orbital floor fracture	Ethosorb patch (15 cases) Polydioxanone foil (16 cases)	27.4 months	4 cases of diplopia (2 in each group) (19 %)
17	**Kang et al** [27] **2012**	9	20-45 years	Old orbital wall fracture	T-shaped Medpore fabricated by mirror image	6-24 months	No postoperative complications
18	**Lieger et al** [28],**2012**	27	>18 years	Orbital floor and/or wall fracture	Low-profile titanium mesh	6 months	Enophthalmos (3 cases), buckling of the plate (2 cases)
19	**Kozakiewicz et al**[42],**2013**	57	20-48 years	Orbital wall fracture	Ti mesh (37 patients) UHMW-PE by CAM milling (20 patient)	6 months	Diplopia (5 cases with ti-mesh group , 3 cases with UHMW-PE)
20	**Morotomi et al** [29], **2013**	20	17-69 years	orbital floor and /or wall fracture	HA-P(LA/CL)	2 years	No complications

Table 1(continued)

	Authors/ year	Number of cases	Age	Defect type	Reconstruction biomaterial(s)	Follow-up period	Postoperative complications
21	**Bande et al**[30],**2014**	20	>18 years	orbital floor fracture	Autogenous graft from the anterior wall of the maxillary sinus	1 year	No complications
22	**Stoor et al** [31],**2015**	20	22-82 Years	Orbital floor fracture	Anatomically drop-shaped bioactive glass	1-4 years	Hyperophtalmos (1case) Enophthalmos (4 cases)
23	**Zimmer et al** [32],**2016**	195	18-80 Years	Orbital floor fracture	standard titanium preformed orbital implants (100 cases) individualized orbital implants (95 cases , navigation used)	3 months	Diplopia (15 cases with individualized group , 25 with the standard preformed group)
24	**Raisain et al**[43], **2017**	10	21-54 Years	orbital floor fracture	Customized Titanium Mesh Based on the 3D Printed Model (5 cases) Manually bended titanium (5cases	8 months	Enopthalmos(1 case in the custom-made group and 4 cases in conventional group)
25	**Uemura et al**[33],**2017**	22	17-68 years	Orbital floor and/ or wall fracture	Rib bone graft	8 months	Diplopia (2 cases)
26	**Al-Khdhairi et al**[34],**2017**	10	22-35 Years	Orbital floor fracture	Titanium mesh	12-22 months	Ectropion (1 case)
27	**Seven et al** [35],**2017**	55	17-54 Years	orbital floor fracture	Auricular Concha	1-3 years	No postoperative complications.
28	**Zavattero et**[36],**al 2017**	55	Navigation group: 22-58 years Conventional group: 22-62 years	Orbital floor and/ or medial wall fracture	Titanium mesh (with and without navigation)	6 months	Diplopia (4 cases in navigation group and 7 cases in conventional group)
29	**Kang et al**[37],**2018**	11	20-70	Orbital floor and medial wall fracture	3 D printed porous polyethylene with embedded titanium implants	3 months (average)	No postoperative complications.

Table 1(continued)

	Authors/ year	Number of cases	Age	Defect type	Reconstruction biomaterial(s)	Follow-up period	Postoperative complications
30	**Emodi et al[38].2018**	9	24-48 Years	orbital floor fracture	Anterior maxillary sinus bone graft	1-3 years	Infraorbital hypothesia (2 cases)
31	**Shin et al [39].2019**	111	control group: 18-68 years Combined group: 18-70 years	Medial wall fracture	porous polyethylene plates (control group,63 cases) resorbable meshed plate plus allogenic cancellous bone (combined group,48 cases)	12-30 months in control group 12-22 months in combined group	No postoperative complications.
32	**Yu et al[40] , 2021**	21	21-63 years	Orbital floor and medial wall fracture	Titanium mesh	7-15 months	No Postoperative complications

Quality assessment (critical appraisal):

The quality of each study was assessed by two assessment scales: the first scale for appraisal of potential risk of bias using the methodological index for non-randomized studies (MINORS) tool [10], the second scale was Jadad scale (the Oxford quality scoring system) for assessment of randomized clinical trials (RCT) [11] .

III. Results:

Study selection:

The study selection process adhered to the PRISMA flowchart. The initial search strategy in the two electronic databases resulted in 4661 articles. Following the screening procedure, 455 duplicate articles were excluded. Subsequently, 4117 articles were excluded based on screening of title and abstract, considering criteria such as animal or cadaveric studies, case reports or series, editorial or commentaries, and reviews. An additional 57 articles were excluded due to samples of mixed pediatric and adult patients or orbital defects unrelated to trauma. Finally, 32articles met the inclusion criteria and were included for data extraction (Fig.1).

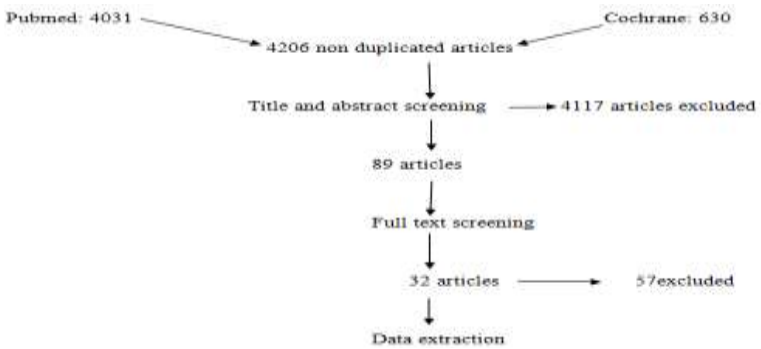

Figure 1. Study selection process following the PRISMA flowchart

Quality assessment:
Quality assessment was performed for non-randomized clinical studies and RCT as showing in table 1 and 2.

Table 1: Average MINORS score of non-randomized studies

Study	Score
Iizuka et al [12	12/16
Cordewener et al [13]	13/16
Aitasol et al [14]]]	12/16
Kontio et al[15]	12/16
Jank et al [16]	18/24
Schon et al [17]	12/16
Al-Sukhun et al [18]	20/24
Kontio et al [19]	13/16
Yilmaz et al [20]	12/16
Talesh et al[21]	12/16
Guo et al [22]	20/24
Liu et al [23]	12/16
Wajih et al [24]	20/24
Chen et al[25]	12/16
Gerressen et al [26]	20/24
Kang et al [27]	12/16
Lieger et al [28]	12/16
Morotomi et al [29]	12/16
Bande et al [30]	12/16
Stoor et al [31]	12/16
Zimmer et al [32]	17/24
Uemura et al[33]	13/16
Al-Khdhairi et al [34]	12/16
Seven et al[35]	13/6
Zavattero et al [36]	19/24
Kang et al[37]	12/16

Table 1 (continued)

Study	Score
Emodi et al [38]	12/16
Shin et al[39]	20/24
Yu et al [40]	11/16

Table 2: Jadad scale of RCT studies.

Study	Score
Kruschewsky et al [41]	2/5
Kozakiewicz a et al [42]	2/5
Raisian et al [43]	2/5

Characteristics of the orbital fractures*:*

Among the retrieved studies, the distribution of orbital fractures was as follows: orbital floor fractures were documented in 18 studies (56.25%), the medial wall in 4 studies (12.5%), and the orbital floor with or without the orbital wall in 10 studies (31.25%).

Characteristics of the materials in the retrieved studies:

Some studies used more than one type of material, but the materials in the retrieved studies were primarily separated into alloplastic materials either nonresorbable or resorbable in 21 studies, autologous graft materials in 12studies, composite materials in 3 studies and allogenic material in one study.

Nonresorbable alloplastic materials*:*

Bioactive glass:

Bioactive glass (BAG) has surfaced as a promising implant material acknowledged for its biocompatibility and its capacity to promote new bone formation [14]. In a study conducted by *Aitasol et al*[14], bioactive glass was utilized in the reconstruction of orbital floor defects in 36 patients through round, heart-shaped, or kidney-shaped rigid plates. The outcomes revealed that 5 cases experienced diplopia postoperatively, while an additional 5 cases reported infraorbital nerve paraesthesia. Notably, there were no infection, foreign-body reaction, or extrusion associated with the BAG plates. However, one patient required reoperation due to postoperative diplopia, attributed to the implant being positioned too high in the orbital floor. Diplopia in other cases was addressed through the use of corrective eyeglasses or orthoptic rehabilitation, with potential causes including damage to the inferior oblique muscle or other associated orbital issues. The observed infraorbital nerve paraesthesia was linked to the traumatic event, with no toxic effects attributed to the implant itself, as minimal exploration during surgery confirmed nerve integrity.

Expanding on this, *Stoor et al*[31] took a unique approach by utilizing anatomically drop-shaped implants made of BAG S53P4 to reconstruct orbital floor fractures. In contrast to the round, kidney, or heart-shaped BAG implants, the drop-shaped design provided more substantial posterior medial or lateral bony support, particularly beneficial in severe blow-out fractures of the orbital floor. Out of 20 patients, 1 complained of hyperophthalmos, and 5 reported enophthalmos postoperatively. These complications were attributed to slight overcorrection of the bulbus position and the presence of associated zygomaticomaxillary fractures, respectively. Notably, this approach effectively maintained orbital volume and compensated for retrobulbar adipose tissue atrophy.

Titanium meshes and implants:

Titanium mesh emerges as a versatile material for reconstructing orbital defects, capable of accommodating both small and large defects without the need for simultaneous autogenous bone grafting [34]. *Al-Khdhairi et al*[34] highlighted its effectiveness in preserving globe position, ocular motility, and orbital volume. In their study involving 10 patients with large orbital floor fractures, there were no postoperative complications, except for one patient with ectropion, managed conservatively. The ectropion was attributed to skin damage during the trauma.

Supporting this, *Yu et al*[40] emphasized the security and reliability of titanium mesh for orbital defect reconstruction. They advocated the use of two titanium mesh plates to address unilateral concomitant orbital floor and medial wall fractures, highlighting advantages such as the restoration of the unique orbital shape, proper volume, diminished surgical complexity, and reduced complication risks. In their study involving 21 patients, no postoperative complications were reported.

Schon et al[17] reported increased precision, reduced time consumption, and less invasiveness with preformed titanium mesh implants in extensive orbital floor and medial wall fracture reconstructions compared to 'free hand' efforts using titanium mesh. Individually preformed implants were used to repair extensive orbital floor injuries in 19 patients, and none of the patients demonstrated diplopia or enophthalmos postoperatively.

Lieger et al[28] noted the reliability and safety of low-profile titanium mesh for orbital floor and/or orbital wall reconstruction, despite its insufficient stability. In their study involving 27 patients, postoperatively, three patients showed slight enophthalmos without any subjective functional or aesthetic concerns. Two patients showed buckling of the plate in the posterior edge region, necessitating replacement. The authors attributed this issue to the low profile of the mesh, leading to insufficient stability and intraoperative control. They recommended paying special attention to the plate borders after insertion and suggested increasing stability at the expense of a low profile

Zimmer et al[32] highlighted the precision achieved with computer-aided design (CAD)-based individualized orbital titanium mesh implants, especially with intraoperative navigation. They compared the use of standard titanium preformed implants with individually designed implants placed with navigation. The group treated with individually designed implants showed a lower incidence of postoperative diplopia, indicating enhanced precision.

In a similar context, *Zavattero et al*[36] found that intraoperative navigation significantly improved clinical outcomes in orbital floor fracture reconstruction using titanium mesh compared to freehand placement. The group treated with navigation demonstrated a lower incidence of diplopia compared to the group without navigation.

Raisian et al[43] demonstrated superior clinical outcomes with customized 3D-printed titanium mesh based on printed models compared to manually bent titanium mesh for orbital floor fractures. They reported a lower incidence of enophthalmos with custom-made titanium meshes compared to conventional manually bent ones, attributing this to the lack of reference landmarks and manual implant malposition.

Porous polyethylene (Medpor):

Yilmaz et al[20] reported the safety and effectiveness of Medpor implants in repairing orbital floor defects, encompassing both small and large defects, with the added benefits of no donor site morbidity and no requirement for implant fixation. They utilized ultra-thin porous polyethylene sheets (0.85 mm thick) for small defects and thin sheets (1.5 mm thick) for large defects (> 2x2 cm) in a total of 26 patients. Postoperatively, there were instances of complications, including 3 cases with diplopia, 5 cases with enophthalmos, 4 cases with persistent posttraumatic infraorbital hypoesthesia, 2 cases with ectropion, and 4 cases with infection. Notably, no implants extruded, and there were no signs of inflammatory reactions against the porous polyethylene. Both diplopia and enophthalmos were observed in patients who underwent surgery within 28-152 days after injury. The authors suggested that early repair is crucial in eliminating fibrous healing of the soft tissues, which could otherwise limit the dissection of the orbital floor and reduction of prolapsed orbital contents. Additionally, patients with persistent enophthalmos had accompanying complex facial fractures, posing challenges in correcting the orbital anatomy. In cases of postoperative infections in four patients, systemic antibiotics were administered, effectively controlling the infections without the need for implant removal. These patients presented with extensive facial lacerations, emphasizing the successful management of infections through intravenous antibiotic administration.

On the contrary, *Wajih et al*[24] presented conflicting findings, suggesting that autogenous bone grafts from an unspecified source achieved a higher success score compared to Medpor implants. In their study involving 26 patients with orbital floor fractures, they utilized Medpor in 12 patients and autogenous bone from an unspecified source in 14 patients. The outcomes reported better results in terms of diplopia, enophthalmos, and reduced orbital motility in individuals treated with autogenous bone grafts. However they reported that it is essential to consider the longer operative time and potential morbidity associated with the donor site when

opting for autogenous bone and autogenous grafts continue to play a role, especially in locations where cost is a significant consideration.

Kozakiewicz et al[42] suggested that individually shaped milled ultra-high-molecular-weight polyethylene (UHMWPE) is as effective as pre-bent titanium mesh for reconstructing orbital wall fractures. Their comparison of functional outcomes in individual orbital wall reconstructions using either titanium mesh or ultra-high molecular weight polyethylene revealed no statistically significant difference between the two groups. The authors emphasized a significant drawback of polyethylene implants, particularly their radiolucency, and recommended addressing this limitation by incorporating a radio-opaque agent with the polyethylene. This addition enhances visibility on computed tomography for postoperative assessments.

In an innovative approach, *Kang et al*[37] utilized 3D-printed customized orbital implant templates for shaping and refining porous polyethylene embedded with titanium. This innovative technique guarantees the formation of patient-specific contours and sizes, thereby enhancing optimal orbital wall reconstruction. They applied this method in 11 orbital wall reconstructions, consisting of 6 orbital floor and 5 medial wall fractures, all of which were successful with no postoperative ophthalmic complications.

Resorbable alloplastic materials*:*

Polydioxanone (PDS) implants:

Iizuka et al[12] reported that PDS is a well tolerated material that is totally absorbed and appears to be replaced by bone particularly in cases where defects are within the range of 1-2 cm in diameter. They assessed the efficacy of polydioxanone (PDS) plates for orbital reconstruction in 20 patients with various traumatic defects of the orbital floor and they demonstrated new bone formation in the orbital floor in the radiographic analysis and clinically most patients experienced temporary postoperative diplopia, lasting for an average of 29 days, primarily due to overcorrection. Only 2 patients had persistent diplopia, with one case attributed to abducens nerve paresis. are one of the inflammatory reactions that can occur due to the degradation of PDS implants.

Contrarily, *Kontio et al*[15] raised concerns about the use of polydioxanone (PDS) in internal orbital wall reconstruction, cautioning against potential complications. They highlighted issues such as the formation of fibrotic sinuses, the development of thick scar tissue, and fibrotic sinuses filled with air or gas. The prolonged retention of structural integrity by the PDS implant was identified as a factor contributing to the occurrence of a rigid and thick scar. Additionally, the formation of fibrotic sinuses around the implant was noted as one of the inflammatory reactions resulting from the degradation of PDS implants. In their study involving 16 patients treated with PDS implants, they reported postoperative complications, including 6 cases of enophthalmos, 6 cases of thick scar formation, 3 cases of fibrotic sinuses filled with air or gas, and 1 case of fibrotic sinuses filled with fluid. They attributed enophthalmos to weak resultant scarring.

Jank et al[16] reported no significant postoperative differences between PDS and Ethisorb implants in orbital floor reconstruction. However, they noted that Ethisorb is considered cost-effective. In their study, PDS implants were used in 81 cases, and Ethisorb was used in 136 patients. Postoperative complications in the Ethisorb group included 4 cases of diplopia, 2 cases of enophthalmos, 5 cases with reduced orbital motility, and 1 case of exophthalmos. In the PDS group, there were 1 case of diplopia, 1 case of exophthalmos, and 3 cases with reduced motility. The authors suggested that inflammatory reactions to the materials could be responsible for adhesions of the ocular muscles, potentially leading to reduced bulbous motility and causing diplopia.

Gerressen et al[26] suggested the use of PDS foils for moderate to extensive orbital floor fractures but acknowledged challenges in achieving complete restoration and recommended the use of prefabricated titanium mesh plates in cases of total or subtotal loss of the orbital floor to ensure safe support of the orbital content. . In their study comparing PDS implants in 16 patients with Ethisorb implants in 15 patients, no statistically significant differences were observed in any variable between the two groups. Postoperative complications included 4 cases of diplopia (2 in each group). The cases of persistent diplopia were associated only with extreme globe positions.

Ethisorb implants:

As previously mentioned, *Jank et al*[16] found no significant postoperative differences between Ethisorb and PDS implants in orbital floor reconstruction. However, they highlighted that Ethisorb is considered cost-effective. Interestingly, within just a 3-month postoperative period, the Ethisorb patches demonstrated a significantly lower incidence of exophthalmos compared to the PDS foils. This difference was attributed to the flexibility of the Ethisorb patches, allowing for better adaptation to the concave orbital floor compared to the rigid PDS foils.

Also, as mentioned earlier, *Gerressen et al*[26] reported that the reconstruction of moderate to extensive orbital floor fractures can be achieved with either the Ethisorb patch or PDS implants without significant changes in orbital geometry though complete restoration may not be universally achievable.

Polylactide and Poly-L/DL-Lactide implants:

Cordewener et al[13] advocated for the use of poly (L-lactide) (PLLA) implants in the repair of orbital floor defects, despite their slow resorption. They suggested enhancing the properties of PLLA implants to increase the degradation rate. Notably, they reported no postoperative complications in 6 cases treated with Poly (L-lactide) implants for orbital floor fractures.

Building on this, *Al-Sukhun et al*[18] reported that bioresorbable poly-L/DL-Lactide implants with a shorter degradation time and better strength properties are considered a good substitute for autogenous bone grafts in orbital floor defects, especially when considering availability and no donor site morbidity. In their comparison between the use of poly-L/DL-Lactide70/30 in 15 cases and autogenous bone graft from the iliac crest in 24 cases, 2 cases of enophthalmos were reported as postoperative complications in the poly-L/DL-Lactide group, compared to 3 cases in the autogenous graft group. The main cause for enophthalmos in both groups was attributed to the incorrect placement of the implant.

Absorbable Polyacid Copolymer:

Kruschewsky et al[41] reported that absorbable polyacid copolymer stands out as a biocompatible, absorbable, and easily moldable material, offering a successful alternative for autogenous graft in orbital wall reconstruction. In their study involving 20 patients with blow-out orbital fractures, with or without medial wall involvement, the authors compared the use of absorbable polyacid copolymer in 12 patients to auricular cartilage graft in 8 patients. The results indicated a 17% incidence of permanent postoperative paralytic mydriasis in the copolymer group, attributed to a firearm assault. Additionally, there was a 17% occurrence of persistent infraorbital paraesthesia in the copolymer group compared to 25% in the cartilage group, with both instances linked to traumatic infraorbital nerve laceration.

Furthermore, the study suggests that absorbable polyacid copolymer permits a fast surgery and serves as a suitable substitute for autogenous grafts, addressing the need for orbital wall reconstruction without donor site morbidity.

Autologous graft materials*:*

Autologous bone:

In the studies retrieved, various sources of autogenous bone were explored for orbital floor and wall reconstruction. These sources include the anterior iliac crest, calvarial bone, and mandibular outer cortex, anterior wall of the maxillary sinus, rib bone graft, and autogenous bone from unspecified sources.

Iliac Bone Graft:

As previously mentioned, *Al-Sukhun et al*[18] conducted a comparative analysis between autogenous bone from the anterior iliac crest and bioresorbable poly-L/DL-Lactide [P (L/DL) LA) 70/30] implants. They recommended poly-L/DL-Lactide implants due to reduced donor site morbidity and increased availability.

Kontio et al[19] recommended the use of iliac bone grafts for orbital floor and wall reconstruction. Despite the challenges associated with rigidity and accurate placement, iliac bone grafts demonstrated effectiveness in restoring orbital volume, accompanied by advantageous remodeling. Notably, partial resorption was observed in all iliac grafts, but new bone growth occurred in 75% of the orbits, indicating positive remodeling outcomes. However, challenges were reported, with 5 grafts and 4 grafts placed at incorrect angles coronally and sagittally, respectively, leading to an enlarged orbital volume in 20% of the cases.

Calvarial Bone:

Guo et al[22] highlighted the reliability of calvarial bone in fresh orbital floor reconstruction. However, in older fractures, compensating for atrophic soft tissue and accrescent bone value proved challenging and they recommended digitally designed titanium mesh for improved results in such cases of old fracture

Maxillary Sinus Anterior Wall:

Bande et al[30] and *Emodi et al*[38] reported reliable and successful reconstruction of small to moderate orbital floor defects using bone grafts harvested from the anterior wall of the maxillary sinus. This method demonstrated excellent cosmetic and functional outcomes with minimal or no complications.

Rib Bone Graft:

Uemura et al[33] reported the reliability and safety of rib bone grafts, obtained using in situ splitting techniques, for reconstructing narrow, localized, and uncomplicated defects of the orbital floor and medial wall. In their study involving 22 patients, only 2 exhibited postoperative diplopia, and revision surgery was necessary for one patient. The authors attributed these outcomes to the increased difficulty in repairing oversized and large defects that involve both the orbital floor and medial wall.

Unspecified Source:

As mentioned earlier *Wajih et al*[24] reported a higher success score with autogenous bone grafts from unspecified sources compared to Medpor implants, emphasizing the need for further exploration into different autologous sources.

Autologous cartilage:

In the studies retrieved, nasoseptal cartilaginous graft and conchal cartilage graft were explored for orbital floor and wall reconstruction.

Nasoseptal Cartilaginous Graft:

Talesh et al[21] advocate for the utilization of nasoseptal cartilaginous grafts in orbital floor reconstruction. These grafts exhibited minimal to no resorption, exceptional adaptability to orbital walls, and easy accessibility in the surgical field with minimal donor site morbidity. The authors specifically endorse the use of a double-layered graft in cases of large defects. In their study involving 20 patients, the use of autogenous nasoseptal cartilage resulted in no donor site morbidity, and no grafts became infected or extruded. Notably, only one patient experienced enophthalmos, attributed to insufficient reduction of the periorbital bone during the operation.

Conchal Cartilage Graft:

Kruschewsky et al[41] and *Seven et al*[35] employed conchal cartilage grafts for the reconstruction of orbital floor, with or without associated orbital wall fractures. The use of conchal cartilage proved successful, offering minimal donor site morbidity and presenting advantages such as ease of use, wide acceptance, biocompatibility, and straightforward harvest, providing adequate structural support.. Notably, *Kruschewsky et al*[41] implemented a posterior auricular incision rather than anterior one, resulting in an excellent cosmetic outcome due to the concealed scar

Composite materials:

Fibrin glue with osteoconductive scaffold:

Chen et al[25] proposed a novel approach using single-donor platelet fibrin glue combined with an osteoconductive scaffold as a promising alternative to autogenous bone for orbital floor reconstruction. The combination of hydroxyapatite (HA) and beta-tricalcium phosphate (β-TCP) with platelet glue exhibited favorable tissue compatibility, mechanical stability, and demonstrated potential for replacement by newly formed bone. However, it was acknowledged that this HA/β-TCP platelet glue composite was thicker and more costly than traditional titanium mesh, potentially leading to slight vertical dystopia. The study, conducted on 10 patients with a follow-up of up to 4 years, reported normal ocular motility, with no observed diplopia or enophthalmos in the reconstructed orbits. Coronal computed tomography scans confirmed successful restoration of the orbital floor defect in all 10 patients.

Hydroxyapatite-poly (L-lactide-ε-caprolactone):

Morotomi et al[29] reported the successful surgical treatment of orbital blowout fractures using bioabsorbable osteo-inductive copolymer hydroxyapatite-poly (L-lactide-ε-caprolactone) (HA-P (LA/CL)). The material proved useful in linear and trap-door fractures, with no significant postoperative complications. The authors suggested enhancing its rigidity to address limitations in punched-out fractures

Resorbable meshed plate plus allogenic cancellous bone:

Shin et al[39] described and introduced a combination material consisting of a resorbable meshed plate and cancellous bone allograft for medial wall blowout fractures. The method showed successful and long-lasting results, simplifying surgery compared to porous polyethylene plates. Despite some advantages, such as rigidity, flexibility, and elasticity, coupled with easy trimming, the authors noted limitations, including cost and applicability restricted to medial wall blowout fracture reconstruction due to the materials' design to fill ethmoid air cell-formed bony defects.

Allogenic materials:

Lyophilized dura patches:

Among the retrieved studies, *Jank et al*[16] conducted a study endorsing the suitability of lyophilized dura patches for the reconstruction of orbital floor defects. However, caution is advised due to the potential risk of slow viral infection associated with the use of dura patches. As an alternative material, Ethisorb has been suggested as a viable option.

These findings underscore the diverse options available for the different materials available for reconstruction, each with its unique considerations and advantages. The choice among these sources depends on factors such as defect size, patient characteristics, and surgical preferences.

Postoperative complications:

The type and number of postoperative complications reported in studies are presented in table 4.

A total of 197 postoperative complications were documented and the predominant complications included diplopia (47.7%, n=94), enophthalmos (23.85%, n=47), reduced motility (8.62%, n=17), infraorbital nerve disturbances (6.59%, n=13), thick scar formation (3.04%, n=6), and hypophthalmos (2.53%, n=5). Complications falling below the 2% threshold encompassed various issues.

Primary causes for most complications were linked to traumatic events or surgical techniques, including overcorrection or improper reconstruction. Notably, complications such as thick scar formation and fibrotic sinuses around Polydioxanone (PDS) implants were associated with the prolonged structural integrity of PDS, leading to rigid scar development, and inflammatory reactions due to PDS degradation, respectively. Additionally, insufficient stability of low-profile titanium mesh was attributed to its low profile, resulting in buckling.

Diverse materials exhibited varying complication rates, with the highest percentage observed in autogenous bone graft from an unspecified source (35.71%, n=5), iliac bone graft (28.20% , n=11) , titanium implants (26.07%, n=103) and bioactive glass (24.6% , n=16) while the lowest percentage associated with conchal cartilage graft (3.17% , n=2). Intriguingly, no complications were reported with mandibular outer cortex bone graft, hydroxyapatite-poly (L-lactide-ε-caprolactone), fibrin glue with osteoconductive scaffold, and resorbable meshed plate plus allogenic cancellous bone. Interpretation of these results should be approached cautiously due to the limited number of patients in some categories.

Table 4. Reconstruction materials and Postoperative complications

Implant material	Authors	Patients	Complications	Total
Bioactive glass	Aitasol et al [14] Stoor et al[31]	56	Diplopia (5) Nerve disturbance(5) Removal (1) Enophthalmos (4) Hyperophthalmos (1)	16
Titanium	Schon et al[17] Guo et al [22] Lieger et al [28], Kozakiewicz et al[42] Zimmer et al [32] Raisain et al[43] Al-Khdhairi et al[34] Zavattero et[36] Yu et al[40]	409	Diplopia(57) Enophtalmos (10) Ectropion (1) Buckling of the plate (2)	70

Table 4 (continued)

Implant material	Authors	Patients	Complications	Total
Porous polyethylene	Yilmaz et al [20] Wajih et al [24] Kang et al [27] Kozakiewicz et al [42] Kang et al [37] Shin et al[39]	141	Diplopia(9) Enophthalmos (9) Nerve disturbance (4) Reduced motility (2)	24
Polydioxanone (PDS)	Iizuka et al [12] Kontio et al[15] Jank et al [16] Gerressen et al [26]	126	Diplopia (9) Enophthalmos (6) Fibrotic sinuses (4) Thick scar formation (6) Reduced motility (3) Exophthalmos (1)	29
Ethisorb	Jank et al [16] Gerressen et al [26]	151	Diplopia (6) Enophthalmos (2) Reduced motility (5) Exophthalmos (1)	14
Polylactide and Poly-L/DL-Lactide	Cordewener et al [13] Al-Sukhun et al [18]	21	Enophthalmos (2)	2
Absorbable Polyacid Copolymer	Kruschewsky et al [41]	12	Paralytic mydriasis (2)	2
Iliac bone graft	Al-Sukhun et al [18] Kontio et al [19]	39	Enophthalmos (4) Hypophthalmos (5) Hyperophthalmos (2)	11
Calvarial bone graft	Guo et al [22]	26	Diplopia (2) Enophthalmos (3)	5
Mandibular Outer Cortex bone graft	Liu et al [23]	46	No complications	0
Maxillary Sinus, Anterior Wall bone graft	Bande et al [30] Emodi et al [38]	29	Nerve disturbance (2)	2
Rib Bone Graft	Uemura et al [33]	22	Diplopia (2) Reoperation (1)	3

Table 4(Continued)

Implant material	Authors	Patients	Complications	Total
Bone graft(Unspecified Source)	Wajih et al [24]	14	Diplopia (1) Enophtalmos (3 cases) Reduced motility (1)	5
Nasoseptal Cartilaginous Graft	Talesh et al [21]	20	Enophthalmos (1)	1
Conchal Cartilage Graft	Kruschewsky et al [41] Seven et al [35]	63	Nerve disturbance (2)	2
Hydroxyapatite-poly (L-lactide-ε-caprolactone)	Morotomi et al [29]	20	No complications	0
Fibrin glue with osteoconductive scaffold	Chen et al [25]	10	No complications	0
Resorbable meshed plate plus allogenic cancellous bone	Shin et al [39]	48	No complications	0
Lyophilized dura patches	Jank et al [16]	120	Diplopia(3) Enophthalmos (1) Exophthalmos (1) Reduced motility (6)	11

IV. Discussion:

Treatment of orbital fractures debate is never ending and ever-evolving. Multiple and different reconstruction materials are available and many of these materials can achieve satisfactory results when used appropriately but there is no one ideal material that is universally successful [44] .

This systematic review was conducted to overview the materials used to post-traumatic orbital reconstruction with the goal of assisting surgeons to make a better choice based on evidence practice. All the included studies had to include preoperative and postoperative CT scans as it is the diagnostic method of choice for orbital fractures [45]in addition to being useful in the assessment of the orbital volume and contour after reconstruction [46]. Included studies also had reported preoperative and postoperative ophthalmological examinations, as diplopia and enophthalmos are shown to be important indications for surgical intervention [47]and also they can persist after inadequate surgical treatment [48].

The results of this review showed that there is no an ideal material to be used in all cases of orbital fractures, this is due to the diversity in the individual characteristics of the materials and the various factors controlling the choice of the materials and generally, the use of technological innovations in addition to a suitable material help to obtain good results in the posttraumatic orbital reconstruction.

V. Conclusion:

The choice of material for orbital reconstruction is multifaceted, involving considerations of the distinctive properties of each material, defect size, surgeon preferences and expertise; implant cost, and the integration of modern tools and computer-assisted surgery. This article underscores the significance of a comprehensive understanding of these materials and emphasizes that judicious material selection can play a pivotal role in minimizing the risk of complications in orbital reconstruction procedures. The complexity of these considerations highlights the need for continued research and prospective studies to further refine guidelines and best practices in this evolving field.

VI. Recommendation:

This study underscores the need for additional randomized clinical trials (RCTs) to address the ongoing debate surrounding the clinical efficacy of orbital reconstruction materials. The current scarcity of RCTs and comprehensive clinical studies highlights a crucial gap in the existing literature. Future research endeavors should prioritize well-designed RCTs and rigorous clinical investigations to provide more robust evidence and insights into the optimal selection of materials for orbital reconstruction. Such endeavors will not only contribute to resolving the existing controversies but also enhance the overall understanding of the field, guiding clinicians toward evidence-based and best-practice approaches in orbital reconstruction procedures.

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