DOI Number: 10.37506/v11/i1/2020/ijphrd/194016

Implant Materials Used for Orbital Floor Reconstruction

Mohamed Esmail Khalil[1], Mohamed Farag Khalil[2], Raafat Mohyeldeen Abdelrahman[2], Ahmed Mohamed Kamal Elshafei[3], Tamer Ismail Gawdat[4]

[1]Assistant Lecturer, [2]Associate Professor, [3]Professor, Ophthalmology Department, Minia University, Minia, [4]Professor, Cairo University, Ophthalmology Department, Cairo University, Cairo, Egypt

Abstract

Purpose: To review different available implant materials used for orbital floor reconstruction regarding their indications, advantages and disadvantages.

Summary: Review of literature revealed the presence of a wide variety of implant options for repair of orbital floor defects. They can be broadly classified into biological materials, metals and polymers which are further divided into resorbables and non resorbables. The choice could be based on an algorithm for the defect size, the anatomical location, or the remaining structural support. Small defects may heal solely by the formation of scar tissue, whereas larger defects, especially those associated with enophthalmos, need material of a sufficient strength to support the orbital contents.

Keywords: *Blow-out fractures, Titanium, resorbable polymers.*

Introduction

Fractures of the orbit are seen in many patients who have blunt trauma to the face and skull. The prominent position of the orbit in the craniofacial skeleton predisposes this region to injury. [1]

Blow-out fracture is a special type of fracture of the orbital floor. Rene Le Fort concluded that blow-out fractures occurred through force transmission from the more rigid infraorbital rim to the relatively weak orbital floor, known as the buckling theory. [2] This theory was challenged by Pfeiffer in 1948, who observed a case series of globe-directed trauma resulting in blowout fractures, leading him to propose the hydraulic theory, which states that hydraulic pressure from the globe is transmitted to the bony orbit resulting in fracture of the thin orbital floor.[3]

Corresponding Author:
Mohamed Esmail Khalil, MD
Assistant Lecturer of ophthalmology, Minia University, Ophthalmology Department, Minia University Hospital, Korneesh El Nile Street, Minia 61111, Egypt
e-mail: mismail.mi265@gmail.com
Telephone: 002-01224711107

In the repair of orbital fractures, the value of an implant is to regain function and aesthetic appearance by repairing the traumatic defect and bringing the globe into its correct position. In addition to the timing and method of reconstruction, a third essential factor in orbital fracture surgery is the choice of reconstruction material. [4]

Advances in biotechnology continue to introduce new implant materials for reconstruction of orbital floor fractures. Which material is best fit for orbital floor reconstruction has been a controversial issue. [5]

Characteristics of an ideal orbital reconstruction material [6]

1. **Stability and fixation:** The implant should be strong enough to support the orbital content and related forces, do not deform (sagging of material into maxillary sinus) under load and can be fixed to surrounding structures
2. **Contouring and handling:** Restores adequate volume to treat enophthalmos and diplopia, easy to shape to fit the orbital defect and regional anatomy and has smooth surface.
3. **Biological behavior:** Ideal implant is biocompatible with no infection, migration, foreign body reaction,

non-allergenic and non-carcinogenic. It should be osteosynthetic and shows high tissue incorporation but easily dissectable in implant removal during secondary reconstruction

4. **Drainage:** Spaces within the implant should be present to allow drainage of orbital fluids
5. **Donor site morbidity:** The implant should not increase surgical complication rate or donor site morbidity (pain, swelling, etc.)
6. **Radiopacity:** The implant should be radiopaque to enable radiographic evaluation without artifacts.
7. **Availability and cost-effectiveness:** Ideal implant should be readily available in sufficient quantities and acceptable costs

Types of materials used for orbital reconstruction:[6]

1. **Biological materials:**

- *Autografts/autogenous materials:*
  i. Autologous bone: calvarium, iliac crest, rib, mandibular symphysis, maxillary sinus wall
  ii. Autologous cartilage: nasal septum or concha, auricle, rib
  iii. Autologous fascia: Tensor fascia lata, temporal fascia
  iv. Autologous periosteum
- *Allografts*: Lyophilized dura mater; demineralized human bone, lyophilized cartilage, irradiated fascia lata.
- *Xenografts and animal-derived materials:* porcine sclera, porcine skin gelatin/Gelfilm, bovine bone or sclera
- *Biological ceramics (inorganic, non-metallic):* Porous hydroxyapatite (HA) and other calcium phosphates.

2. **Metals:** Titanium, Cobalt alloys
3. **Polymers (plastics):**

- *Non-porous non-resorbable (permanent) implants*: Silicone, nylon (SupraFOIL; Supramid), polytetrafluoroethylene (PTFE; Teflon, Gore-Tex), hydrogels, PEEK (poly ether ether ketone)
- *Non-porous resorbable implants:* Hyaluronate/ carboxymethylcellulose (HA/CMC; Seprafilm).
- *Porous non-resorbable implants*:

Porous polyethylene (PE; Medpor)

- *Porous resorbable (absorbable) implants:* Poly (lactic acid) (PLA), poly (glycolic acid) (PGA), PLA/PGA implants Polydioxanone (PDS), polyglactin 910/PDS implants (Ethisorb).

4. **Composites:**

HA-reinforced high density composite

Titanium/PE composite implant (Medpor Titan)

HA/PLA/polycaprolactone (PCL) sheet

Bone morphogenetic protein-loaded gelatin hydrogel

Advantages and disadvantages of currently available reconstruction materials:

- **Biological materials:** Biological materials are defined as grafts harvested from the same or another human or animal and include autografts, allo-grafts, and xenografts. [6]

Since the 18th century, autologous bone has been the 'gold standard' biomaterial for the reconstruction of bony defects in the craniofacial area.[7] Autologous bone grafts are used in orbital surgery because of their strength, rigidity, vascularization potential, and incorporation into the orbital tissues with minimal acute and chronic immune reactivity (i.e. infection, extrusion, collagenous capsule formation, and ocular tethering).[8] Donor site morbidity remains a general drawback for autologous bone harvesting. [6]

Allografts (homografts) are transplanted tissues (e.g. lyophilized dura mater or banked (demineralized) bone) from another human being. Their advantages include a decreased surgical time, preoperative customizability, absence of donor site morbidity, and abundant availability of banked bone. [4] Lyophilized dura (Lyodura) was a standard in the past for the reconstruction of smaller orbital defects because of its strength and absence of tissue reactions. [9] However, it became controversial following a case of Creutzfeldt–Jakob prion disease in a patient who received dura originating from a cadaver.[10] Consequent to this report, lyophilized dura sterilization was no longer performed with gamma irradiation but with sodium hydroxide. [11] The disadvantages of allografts include a resorption rate substantially higher than that of autologous tissue,[8] the

need for immunosuppressive pharmacotherapy, and the risk of viral transmission, such as hepatitis C virus and HIV.[12]

- **Metals**

Titanium has been used extensively in craniofacial surgery and dentistry in the form of implants, plates, and screws. [13] With its high biocompatibility and physico-mechanical properties, it could be an ideal implant for covering large anatomical defects (categories III–V) and globe malposition if implant-stabilizing surrounding bone or a distal landmark (a 'bony ledge') is absent.[14]

Titanium mesh is strong, rigidly fixable, widely available, and is subject to osseointegration with minimal foreign body reaction.[15] However, titanium is costly and may have irregular edges if not cut properly, which may impinge soft tissue. Furthermore, fibrous tissue will incorporate the mesh-holes, which can make implant replacement technically complex.[15] Late unwanted effects such as infection, corrosion, and toxic metal ion release have been reported with the use of titanium implants.[13] One Randomized Control Trial (RCT) has evaluated the effects of titanium implants as compared to perforated (PDS) foil for small orbital floor fracture reconstruction, and found no significant differences in the clinical outcomes.[16] A pilot study without controls used a low-profile 0.25-mm titanium plate in large defects (categories II and III) and found successful clinical outcomes without complications in 93% of the cases; at the 6-month follow-up, no functional or aesthetic concerns were observed. [14]

- **Polymers:** Polymers (or plastics) are large molecules comprising multiple repeated subunits and can be categorized into absorbable and non-absorbable (permanent) types. [6]

Non-absorbable permanent polymer implants: Porous ultra-high density polyethylene **(PE; Medpor™)** sheets of various sizes and thicknesses (0.4–1.5 mm) have been used widely to cover smaller floor defects since the 1990s. This widespread use is a product of the ability to easily cut the sheets into various shapes and the ability of orbital tissue to move freely over the smooth surface. Connective tissue and vascular components grow into the pores with minimal foreign body reaction. [17] In a prospective cohort study of floor reconstructions, PE sheets showed satisfactory surgical outcomes and infection rates similar to autografts.[18]

Polytetrafluoroethylene (PTFE; Teflon) is biologically and chemically inert, non-antigenic with minimal foreign body reaction, sterilizable, and easily mouldable. However, this polymer has not yet been subject to comparative clinical studies.[6]

Relatively new in orbital floor repair is the use of nylon foil, a non-porous poly-amide. Nylon foil has provided favourable results in preliminary non-comparative studies.[19]

Resorbable Osteosynthesis implants: Although the performance and biocompatibility of metallic and titanium fixation in osteosynthesis has been reported as satisfactory, a number of disadvantages have been associated with its use, including stress shielding of bone or osteopenia[20], impairment in imaging evaluation[21] and its restricted use in certain specific circumstances such as pediatric craniofacial surgery.[22]

Resorbable materials have been used widely for over 30 years in many fields of surgical practice, [23] and are of interest because of their more predictable absorption rates than biological grafts, as well as their high level of customizability and control. [24]

Chemistry and mechanism of action: Bioresorbable polymers are mainly high-molecular-weight aliphatic polyesters with repeating units of α-hydroxy acid (HOCHR-COOH) derivatives manufactured by ring-opening polymerization. The absorption of these polymers begins with depolymerization through the hydrolysis of their ester bonds and subsequent metabolism, probably by macrophages, in the citric acid cycle into water and carbon dioxide. [25]

The first clinically used bioresorbable polymer was polyglycolic acid (PGA), a highly crystalline and high-molecular weight molecule with limited clinical use for osteosynthesis because of its susceptibility to rapid degradation. Approximately 4–7 weeks after implantation, a duration which is insufficient to allow complete bone healing, PGA loses its mechanical strength in vivo. In addition, the side effects of PGA have been detected during its clinical use; these are due to the difficulty in clearing the accumulated acid degradation products. These negative effects have resulted in the minimal use of pure PGA in osteosynthesis.[26]

Polylactic acid (PLA) is another high-molecular-weight bioresorbable polymer; its optically active carbon in lactic acid generates 2

stereoisomeric forms, namely poly- L -lactide (PLLA) and poly- D -lactide (PDLA). Since the early 1990s, PLLA has been used as an osteosynthesis material. [27] Due to its crystallinity and hydrophobicity, PLLA is fairly resistant to hydrolysis, and thus bioresorption with complete loss of its strength in vitro does not occur within the first 2 years of implantation. PDLA, on the other hand, has a lower crystallinity and is less resistant to hydrolysis. Because of its slower degradation rate, PDLA has been reported to be highly biocompatible, although crystalline particles resistant to degradation may elicit some inflammatory response. [27]

By copolymerization of different derivatives of α-hydroxy acids, a variety of different mechanical qualities and degradation rates can be achieved. Copolymers of L -, D -lactides, for example, SR-P(L/DL)LA 70/30, a copolymer composed of 70% PLLA and 30% PDLA, loses all its strength in vitro after 48 weeks of implantation.[28] Copolymers of L -lactide and glycolide (PLGA) have been extensively used owing to the wide range of physiochemical properties of the components.[29]

Advantages and disadvantages of resorbable implants: The main advantages are easy handling and contourability, smooth surface and smooth edge, do not necessarily require rigid fixation, ideal for pediatric fractures, thin and can be applied in multiple layers in larger orbital volume displacement and without late implant related complications as infection, migration and extrusion. [6]

On the other hand, these materials can be radiolucent on postoperative imaging. [6]Some authors believed it may not provide enough support to orbital contents in large fractures and demonstrated an increase in orbital volume as a late complication. [30]

In a RCT, the administration of an absorbable copolymer of PLA and PGA had functional and aesthetic outcomes and complications similar to auricular cartilage implants in orbital blowout fractures with or without medial wall involvement. [31] In addition, PLA 70/30 plates were studied in a controlled trial and showed similar surgical outcomes and complications as compared to autografts in category II and III floor defects, without MRI evidence of foreign body reaction.[32]

Discussion

Depending characteristics of the different materials of orbital implants, it was feasible to postulate clinical recommendations for materials in specific cases.

Treatment algorithm for orbital wall fractures[6]:

1. Small-sized, low-complexity defects (class I): Most materials are suitable; biological behaviour is most important and resorbables may be used in these cases.
2. Medium-sized, medium-complexity defects (class II): Apart from the bio-logical behaviour of an implant, the experience of the surgeon with specific types of orbital implants will benefit the outcome. Various materials can be used, from autologous materials to alloplasts.
3. Large-sized, high-complexity defects (classes III–VI): Stability and contour become more significant and pre-bent or patient-specific titanium mesh is the preferred reconstruction material.

Conclusion

The debate on the clinical recommendations for orbital reconstruction material will likely continue because of the absence of RCTs and best practice clinical studies. Controversy exists regarding the best material features, which can be defined broadly by whether the implant is: (1) autogenous or allogenic, (2) non-resorbable or resorbable material and (3) malleable or preformed anatomical plates.

Financial Disclosure: No financial support was received regarding this study.

Conflict of Interests: All authors declare that there is no conflict of interests.

Ethical Clearance: Taken from local research ethical committee of faculty of medicine, Minia University

References

1. Kuhn F and D P. ocular trauma : principles and practice. New york: Thieme, 2002, p. 385-8.
2. Tessier P. The classic reprint. Experimental study of fractures of the upper jaw. I and II. Rene Le Fort, M.D. Plast Reconstr Surg. 1972; 50: 497-506.
3. Pfeiffer RL. Traumatic Enophthalmos. Trans Am Ophthalmol Soc. 1943; 41: 293-306.
4. Baino F. Biomaterials and implants for orbital floor repair. Acta Biomater. 2011; 7: 3248-66.

5. Avashia YJ, Sastry A, Fan KL, Mir HS and Thaller SR. Materials used for reconstruction after orbital floor fracture. J Craniofac Surg. 2012; 23: 1991-7.
6. Dubois L, Steenen SA, Gooris PJ, Bos RR and Becking AG. Controversies in orbital reconstruction-III. Biomaterials for orbital reconstruction: a review with clinical recommendations. Int J Oral Maxillofac Surg. 2016; 45: 41-50.
7. Tessier P, Woillez M, Lekieffre M and Asseman R. [Posttraumatic diplopia and osseous grafts. Observations]. Bull Mem Soc Fr Ophtalmol. 1960; 73: 271-91.
8. Chowdhury K and Krause GE. Selection of materials for orbital floor reconstruction. Arch Otolaryngol Head Neck Surg. 1998; 124: 1398-401.
9. Luhr HG and Maerker R. Transplantation of homologous dura in reconstruction of the orbital floor. Trans Int Conf Oral Surg. 1973; 4: 340-4.
10. Prichard JV, Thadani R and E. K. Rapidly progressive dementia in a patient who received a cadaveric dura mater graft. MMWR Morb Mortal Wkly Rep. 1987; 36: 49-50.
11. Guerra MF, Perez JS, Rodriguez-Campo FJ and Gias LN. Reconstruction of orbital fractures with dehydrated human dura mater. J Oral Maxillofac Surg. 2000; 58: 1361-6.
12. Aho AJ, Hirn M, Aro HT, Heikkila JT and Meurman O. Bone bank service in Finland. Experience of bacteriologic, serologic and clinical results of the Turku Bone Bank 1972-1995. Acta Orthop Scand. 1998; 69: 559-65.
13. Mackenzie DJ, Arora B and Hansen J. Orbital floor repair with titanium mesh screen. J Craniomaxillofac Trauma. 1999; 5: 9-16.
14. Dubois L, Steenen SA, Gooris PJ, Mourits MP and Becking AG. Controversies in orbital reconstruction--I. Defect-driven orbital reconstruction: a systematic review. Int J Oral Maxillofac Surg. 2015; 44: 308-15.
15. Schubert W, Gear AJ, Lee C, et al. Incorporation of titanium mesh in orbital and midface reconstruction. Plast Reconstr Surg. 2002; 110: 1022-30.
16. Dietz A, Ziegler CM, Dacho A, et al. Effectiveness of a new perforated 0.15 mm poly-p-dioxanon-foil versus titanium-dynamic mesh in reconstruction of the orbital floor. J Craniomaxillofac Surg. 2001; 29: 82-8.
17. Dougherty WR and Wellisz T. The natural history of alloplastic implants in orbital floor reconstruction: an animal model. J Craniofac Surg. 1994; 5: 26-32.
18. Wajih WA, Shaharuddin B and Razak NH. Hospital Universiti Sains Malaysia experience in orbital floor reconstruction: autogenous graft versus Medpor. J Oral Maxillofac Surg. 2011; 69: 1740-4.
19. Park DJ, Garibaldi DC, Iliff NT, Grant MP and Merbs SL. Smooth nylon foil (SupraFOIL) orbital implants in orbital fractures: a case series of 181 patients. Ophthalmic Plast Reconstr Surg. 2008; 24: 266-70.
20. Paavolainen P, Karaharju E, Slatis P, Ahonen J and Holmstrom T. Effect of rigid plate fixation on structure and mineral content of cortical bone. Clin Orthop Relat Res. 1978; 136: 287-93.
21. Fiala TG, Novelline RA and Yaremchuk MJ. Comparison of CT imaging artifacts from craniomaxillofacial internal fixation devices. Plast Reconstr Surg. 1993; 92: 1227-32.
22. Orringer JS, Barcelona V and Buchman SR. Reasons for removal of rigid internal fixation devices in craniofacial surgery. J Craniofac Surg. 1998; 9: 40-4.
23. Francel TJ, Birely BC, Ringelman PR and Manson PN. The fate of plates and screws after facial fracture reconstruction. Plast Reconstr Surg. 1992; 90: 568-73.
24. Lyu S and Untereker D. Degradability of polymers for implantable biomedical devices. Int J Mol Sci. 2009; 10: 4033-65.
25. Pietrzak WS. Principles of development and use of absorbable internal fixation. Tissue Eng. 2000; 6: 425-33.
26. Vasenius J, Vainionpaa S, Vihtonen K, et al. Comparison of in vitro hydrolysis, subcutaneous and intramedullary implantation to evaluate the strength retention of absorbable osteosynthesis implants. Biomaterials. 1990; 11: 501-4.
27. Pihlajamaki H, Bostman O, Hirvensalo E, Tormala P and Rokkanen P. Absorbable pins of self-reinforced poly-L-lactic acid for fixation of fractures and osteotomies. J Bone Joint Surg Br. 1992; 74: 853-7.
28. Tormala P, Pohjonen T and Rokkanen P. Bioabsorbable polymers: materials technology and surgical applications. Proc Inst Mech Eng H. 1998; 212: 101-11.

29. Pietrzak WS and Kumar M. An enhanced strength retention poly(glycolic acid)-poly(L-lactic acid) copolymer for internal fixation: in vitro characterization of hydrolysis. J Craniofac Surg. 2009; 20: 1533-7.
30. Cordewener FW, Bos RR, Rozema FR and Houtman WA. Poly(L-lactide) implants for repair of human orbital floor defects: clinical and magnetic resonance imaging evaluation of long-term results. J Oral Maxillofac Surg. 1996; 54: 9-13.
31. Kruschewsky Lde S, Novais T, Daltro C, et al. Fractured orbital wall reconstruction with an auricular cartilage graft or absorbable polyacid copolymer. J Craniofac Surg. 2011; 22: 1256-9.
32. Al-Sukhun J and Lindqvist C. A comparative study of 2 implants used to repair inferior orbital wall bony defects: autogenous bone graft versus bioresorbable poly-L/DL-Lactide [P(L/DL)LA 70/30] plate. J Oral Maxillofac Surg. 2006; 64: 1038-48.