Saudi Journal of Oral and Dental Research

Abbreviated Key Title: Saudi J Oral Dent Res ISSN 2518-1300 (Print) |ISSN 2518-1297 (Online) Scholars Middle East Publishers, Dubai, United Arab Emirates Journal homepage: https://saudijournals.com

Review Article

Oral and Maxillofacial Surgery

Biomaterials for Orbital Reconstruction

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DOI: <u>10.36348/sjodr.2021.v06i12.008</u> | **Received:** 13.11.2021 | **Accepted:** 19.12.2021 | **Published:** 24.12.2021

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Abstract

Managing orbital floor injuries is often a multifaceted issue. Repair of these defects essentially aims to restore the continuity and stability of orbital floor providing an adequate support to the orbital contents. Several bio-materials and implants have been used over the years in the hope of achieving the best result. Traditionally autografts are considered to be the 'gold standard'. In order to overcome the drawbacks of autografts, researchers' and surgeons' attention has been progressively attracted by alloplastic materials which are commercially produced and can be easily tailored to fit a wide range of clinical needs. In this review the advantages and limitations of the various biomaterials proposed and tested for orbital floor repair are critically assessed and discussed. A thorough electronic search was carried out in February 2018 for pertinent English language literature without any time restrictions. The inclusion criteria were prospective or retrospective studies including randomized or quasi-randomized controlled trials (RCTs), controlled clinical trials (CCTs), retrospective studies and review articles with the aim of evaluating biomaterials for orbital reconstruction.

Key words: Biomaterials, Autografts, Allografts, Alloplastic materials, Orbital fracture, Blow out fracture.

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Introduction

Fractures of the midface pose a serious medical, functional and psychological problem due to their complexity, frequency, aesthetic and socioeconomic impact. Orbital floor fractures, alone or in combination with other facial skeletal injuries are one of the most commonly encountered midface fractures. They account for 10-25% of all cases of facial injuries. Approximately 5% of head injury cases have orbital injuries and 50% of them require surgical intervention [1-4]. Orbital fractures most often occur in middle aged males and in conjunction with assaults, motor vehicle accidents, sports injuries, fall etc [5].

It's commonly hypothesized that orbital deformities manifest due to the anatomic changes posterior to the eyeball i.e. an inferior dislocation of the orbital floor or a transverse expansion of medial or lateral walls [6]. Hence these defects are supposed to be repaired by an appropriate material to correct the anatomical position of the globe, to restore orbital volume restoring ocular motility. Small defects may heal spontaneously, whereas larger defects resulting enophthalmos and hypoglobus need reconstruction

using a bio-material of sufficient strength to support the orbital contents and to restore the contour.

Over the years a plethora of biological materials has been used for orbital floor reconstruction. These are human or animal derived tissues (autografts, allografts and xenografts) and could be used as transplants or suitably treated to be used as implants. In general, biological materials have certain limitations such as limited availability, morbidity at the harvest site (for autologous tissues), risk of disease transmission, unpredictable resorption rate etc.

The desired characteristics of an orbital implant include favorable biological behavior, contourability, radiopacity, permanent stability, minimum donor site morbidity, availability, cost-effectiveness etc. For smaller defects, choice of an implant is more dependent on biocompatibility. However in larger defects, mechanical properties, biocompatibility and the contour factor need particular consideration.

AIM & OBJECTIVES

Present review aims to furnish a comprehensive overview of the advantages and disadvantages of currently available materials used for reconstructing orbital defects.

Biomaterials may be naturally occurring or synthetic substances. They can be classified as autografts, allografts, xenografts and alloplastic materials. Physical properties of an ideal material should closely replicate those of the tissue it replaces as graphically presented in Fig. 1 [7]. The ideal properties of a biomaterial are represented in Table 1 [7].

DISCUSSION

Ideal properties

Table 1

Ideal properties for generic biomaterial

- 1. Chemically inert
- 2. Biocompatible
- 3. Non allergenic
- 4. Non carcinogenic
- 5. Cost-effective
- 6. Sterilizable
- 7. Easy handling
- 8. Ability to stabilize
- 9. Radio opaque

Table 2 Biologic reactions to foreign body

- Immediate inflammation with early rejection
- 2. Delayed rejection
- 3. Fibrous encapsulation
- Incomplete encapsulation with ongoing cellular reaction
- 5. Slow resorption
- 6. Incorporation

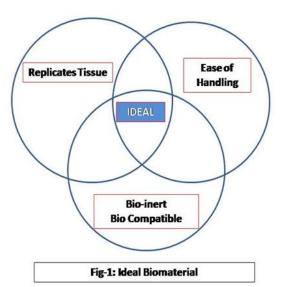
<u>Table 3</u> Factors influencing choice of biomaterial for use in the orbit

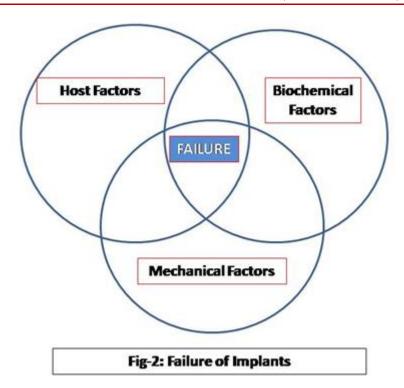
- 1. Size of defect
- 2. Involvement of multiple walls
- 3. Adaptation to internal contours
- 4. Restoration of proper volume
- Presence of adjacent sinus cavity
- 6. Prevention of displacement
- 7. Risk of further trauma
- Adhesions/restriction of ocular mobility
- 9. Early versus late repair

The long term biocompatibility of a material is dependent on the dynamic relationship between host and implant and is subjective to many factors. Calnan in 1963 [8] reported that alloplastic implants may initiate multiple types of tissue reactions (Table 2) [7]. Tissue reaction to an implanted material, as described by Coleman and colleagues [9], begins with an acute inflammatory reaction brought predominantly by PMNL cells. Lymphocytes and macrophages migrate then into the field attempting phagocytosis of the foreign material resulting chronic inflammatory reaction.

Granulation tissue forms and subsequently matures forming an encapsulating connective tissue

sheath which isolates the implant from adjacent tissue. Once a fibrous capsule establishes around the implant, it is generally well tolerated by the body. However the relationship between host and implant can be influenced by several factors including various chemical, mechanical, geometric and physical factors. Generally a well-tolerated bio material shows an increased host reaction when the implant is chronically mobile, subjected to repeated trauma, or insufficiently surrounded by host tissue (Fig. 2) [7]. Each of these factors may lead to exposure and subsequent implant failure.





Geometric and physical factors include size, shape and form of the material. Scientific studies have clearly shown that physical form of a material influences the host response. Porous materials allow for variable degree of soft tissue ingrowth, decreased tissue contracture resulting enhanced long term stability. The acceptance of porous material is hypothesized to be through microscopic collagen fibrils and capillaries.

Optimal soft tissue compatibility is characterized by limited inflammatory reaction, thin fibrous encapsulation or mesenchymal ingrowth with minimal macrophage activity.

Several considerations inimitable to orbital reconstruction make the development of an ideal biomaterial particularly challenging. Because of the assorted challenges in orbital reconstruction, currently there is no ideal bio material suitable for all scenarios. Clinicians must therefore be cognizant of the properties of the various biomaterials available and to which each clinical situation is best suited. Specific considerations in reconstruction of the internal orbit are presented in Table 3[7].

Biomaterials for orbital floor reconstruction

Selection of a biomaterial has been and remains an ongoing debate. Autogenous bone is the standard against which other materials are compared, although its use has become less frequent over the past few decades. Newer biocompatible alloplastic implants (polymers, biological ceramics, and composites) added further options to the surgeon's armamentarium. In 1996, Neigel and Ruzicka [10] reviewed the allogenic materials used in orbital floor surgery, while Chowdry and Krause [11] gave some indications for material selection, focusing their attention on autografts and specifically on autologous bone. In 2004, Mok et al. [12] and Potter et al. in 2012 [7] reviewed both biologically derived and alloplastic materials for the management of orbital floor defects. In 2010 Betz et al. [13] published an excellent literature in which the potential of tissue engineered constructs for orbital floor regeneration was highlighted. Presently available biomaterials are discussed in subsequent paragraphs along with glimpses on recent advances and materials with future prospects. An overall summery of biomaterials is enumerated in Table 4.

Biological materials

(A) Autografts/autogenous materials

- a) Autologous bone
 - 1) Calvarium
 - 2) Iliac crest
 - 3) Rib
 - 4) Anterior wall of maxillary sinus
 - 5) Mandibular symphysis
 - 6) Mandibular coronoid process

b) Autologous cartilage

- 1) Nasal septum
- 2) Concha
- 3) Auricle
- 4) Costal cartilage

c) Autologous fascia

- 1) Tensor fascia lata
- 2) Temporal fascia

d) Autologous periosteum

(B) Allografts

- a) Lyophilized dura mater
- **b)** Demineralized human bone
- c) Lyophilized cartilage
- **d)** Irradiated fascia lata

(C) Xenografts and animal-derived materials

- a) Collagen membrane
- **b**) Porcine sclera
- c) Porcine skin
- d) Gelatin/Gelfilm
- e) Bovine bone or sclera

(D) Alloplastic materials

Biological ceramics (inorganic, non-metallic)

- 1. Porous hydroxyapatite (HA)
- 2. Calcium phosphates
- 3. Bioactive glasses (BAG)

Metals

- 1. Titanium
- 2. Cobalt alloys

Polymers (plastics)

a) Non-porous non-resorbable (permanent) implants

- 1) Silicone
- 2) Nylon (SupraFOIL, Supramid)
- **3**) Polytetrafluoroethylene (PTFE; Teflon, Gore-Tex)
- 4) Hydrogels
- 5) PEEK (poly aryl-ether ether ketone)
- **6)** PEKK (poly aryl -ether -ketone ketone)

b) Non-porous resorbable implants

- 1) Hyaluronate/carboxymethylcellulose (HA/CMC; Seprafilm)
- c) Porous non-resorbable implants
 - 1) Porous polyethylene (PE; Medpor)

d) Porous resorbable (absorbable) implants

- 1) Poly(lactic acid) (PLA)
- 2) Poly(glycolic acid) (PGA)
- 3) PLA/PGA implants
- 4) Polydioxanone (PDS)
- 5) Polyglactin 910/PDS implants (Ethisorb)

Composites

- 1. HA-reinforced high density composite (HAPEX)
- 2. Titanium/PE composite implant (Medpor -Titan)
- 3. HA/PLLA/polycaprolactone (PCL) sheet
- 4. Bone morphogenetic protein-loaded gelatin hydrogel
- 5. PLA-based polymer sheet
- 6. Periosteum/polymer complex
- 7. Gelatin hydrogel (dogs)
- 8. HA nanoparticles/cyclic acetal hydrogels
- Bone marrow-coated PCL scaffolds (pigs)

Newer materials and future prospects

- 1. Surface-treated titanium
- 2. Photoactive biocompatible conjugate polymers, such as chitosang- fluorescein (CHFL)
- 3. CAD-CAM based Bioactive glasses
- 4. Composites of bioactive glass and polymer
- 5. Polymeric hydrogels
- 6. BMP-2 loaded hydrogels

 Table 4: List of biomaterials available for orbital fracture repair (not exhaustive)

Autografts

The use of autografts requires harvesting an appropriate amount of autologous tissue from the patient's donor site which is then properly shaped in order to match the defect, thereby providing a rigid structural support to the defect. Various autografts have been tried successfully and recognized in the literature.

Autologous bone

Autografts from patient's own bone are considered by the majority of surgeons as the 'gold standard' for osteogenic tissue repair (Fig. 3A). In the field of orbital floor repair favored donor sites include split calvarial bone, mandibular coronoid process, anterior maxillary wall, mandibular symphysis, rib. scapula and iliac crest [14-18]. Specifically, split calvarial bone seems to be the best option for orbital reconstruction because of its membranous embryonic origin and contour match. The graft can be positioned as-such, fixated by screws and/or plates or used in conjunction with an alloplastic material such as titanium mesh or porous polyethylene. The advantages of autologous bone are its intrinsic strength, rigidity and osteogenic potential. Most of the autografts exhibit excellent biocompatibility and tissue tolerance after implantation. However, the use of autologous bone is associated with several undesirable aspects. It is not always easy to contour the bone to the desired shape and size. The graft can shatter if it is bent beyond its natural limit. In case of large multiple defects involving disruption of bony buttresses, other biomaterials are preferred or combined with autologous bone [19]. Another major shortcoming is it's unpredictable resorption [20-22]. It is well accepted that the resorption rate of bone from membranous embryological origin is slower than that of endochondral bone [21, 22]. Further problems associated with the use of autologous bone grafts include donor site morbidity and significant increase in surgery time [23].

Autogenous cartilage

Costal cartilage, auricular cartilage and nasal septum are commonly used autologous cartilage grafts for orbital floor reconstruction [24, 25]. Cartilage is usually easier to harvest and contour when compared to autologous bone. It can provide long term support to the surrounding tissues without significant resorption even after several years. As recently highlighted by Bayat *et al.* [26], cartilage actually has immense potential as a graft material providing adequate support to the orbital floor as well as minimal donor site morbidity.

Other autogenous materials

B. Celikoz *et al.* [27] reported successful use of lyophilized tensor fascia lata in 1997. P. Dost [28] in 1996 used autogenous periosteum from mastoid region for repair of small orbital floor defects. The use of these grafts led to good clinical outcome, with complication rate similar to that of bone and cartilage autografts. The major drawbacks of these two grafts seem to be difficulties with harvesting and their limited strength which makes them suitable for the repair of only small orbital defects (<1 cm²).

Allografts

A partial solution to the drawbacks associated with autografts is the use of allografts i.e. the transplant of hard/soft tissue(s) from another living patient or from a cadaver of same species [10]. The advantages over autologous grafts include lack of donor site morbidity, decreased surgery time, the opportunity to pre form and customize the implant before surgery and quantity available. However, risk of disease transmission and incidences of immunological reactions are always there leading to requirement of extensive legislation, proper graft processing and strict monitoring [29]. Lyophilised dura (Lyodura) [30-32] and banked demineralized bone [10-33] are the most commonly employed allografts. Use of allogenic cartilage has also been reported [32]. The use of demineralized bone implants has been both advocated and castigated over the years. Neigel and Ruzicka [10] reviewed the use of demineralized bone orbital floor repair and found it to be osteoconductive too. However, recent studies have shown that demineralized bone grafts exhibit poor mechanical properties, insufficient to ensure adequate support. Another factor that often discourages the use of allografts is their high resorption rate [11].

Xenografts

Lyophilised porcine dermis was used by Webster [34] in the late 1980s and found it suitable for orbital floor repair. Bovine heterogonous bone has also been found suitable for the similar purpose. Both of them were clinically safe and biocompatible without any incidence of inflammatory reaction or infection. Successful use of bovine and porcine gelatin for small linear orbital fracture (<5 mm) has been reported but not too many clinicians used them till date [35]. Collagenous mesh has been successfully used in children without any post-operative complications [36]. Bovine sclera was considered by Costa et al. [37] to be biocompatible and suitable for orbital floor repair. Bovine sclera showed minimal resorption, ensured an adequate 'barrier effect' and allowed bony regeneration to some degree.

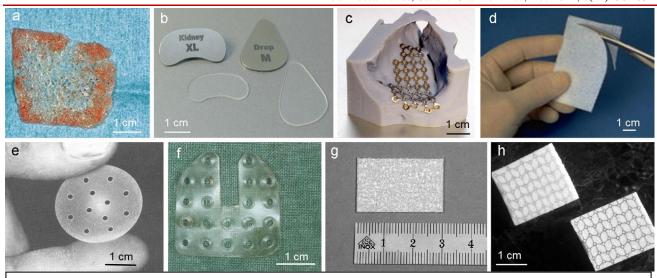


Fig. 3 (a) Iliac crest bone chips; (b) Bioactive glass with corresponding stainless steel templates (c) Titanium mesh on a 3D orbital model (d) Porous polyethylene sheet (Medpor) (e) Poly(L-lactide) (f) Poly(L-lactic) acid/polyglycolic acid composite implant (g) PGA910/PDO patch (h) Medpor-Titan

*Adopted from: Francesco Baino (2011) [82]

Alloplastic Materials

Bioceramics

Hydroxyapatite and other Calcium Phosphates

Hydroxyapatite (HA) is an excellent biomaterial due to its chemical and crystallographic similarity to bone mineral. HA and carbonated apatite cements are commercially available as moldable bone surrogate in the broader field of craniofacial reconstruction since early 1990s [38]. HA implants for orbital reconstruction are generally considered safe and an excellent alternative to autologous grafts. Porous biphasic beta-tricalcium phosphate (b-TCP)/HA plates (b-TCP: HA = 77:23 wt.%) has been proved to be highly biocompatible and their porous network allows fibrous tissue in-growth into the implant thereby enhancing its in-situ stability.

Bioactive glass

First demonstrated by Hench and co-workers in early 1970s [39]. Bioactive glass exhibits the unique property of acquaintance to bone and stimulating neo-osteogenesis. It is slowly biodegradable, bioactive and biocompatible. Kinnunen *et al.* [40] compared bioactive glass with conventional cartilage graft for the repair of orbital floor defects and found it to be clinically comparable or better. However, Peltola *et al.* [41] found that glass plates were brittle, rigid and could not be molded, shaped or fixed with screws (Fig. 3B). Therefore, the primary challenge in using such implants in orbital reconstruction is selection of correct implant compatible with the bone defect. From the data published in recent studies, bioactive glass plate appears

to be a promising and reliable implant for orbital floor reconstruction.

Metals

Titanium

For many years titanium has been successfully and comprehensively used in orthopedics as well as in the field of craniofacial reconstruction including orbital floor repair (Fig. 3C). Titanium is highly biocompatible and an ideal candidate for the reconstruction of bone defects where high rigidity and strength are desirable. A striking feature of titanium is osseointegration. Titanium mesh seems to be particularly suitable for repairing large orbital defects. Gear et al. [42] used titanium mesh for reconstruction of orbital floor defect larger than 2 cm and achieved good functional outcome together with a low risk of infection after 44 months follow-up. In 2003 Ellis and Tan [19] evaluated the adequacy of internal orbital reconstruction in pure blow-out fractures using calvarial split bone grafts versus titanium mesh. The authors observed that titanium mesh resulted in overall better outcome. Although most of the studies showed that use of titanium mesh in orbital surgery can lead to highly satisfactory result, the incidence of serious postoperative complications has also been reported [43]. Lieger et al. developed a financially viable technique using CAD/CAM to manufacture titanium implants for orbital reconstruction [44].

Cobalt alloys

The most commonly used cobalt alloy is Vitallium. It's typical weight composition is 60.6% Co, 31.5% Cr, 6.0% Mo and 1.9% Residuum (Si, Mn and

C) [45]. In 1991 Sargent and Fulks [46] reconstructed 66 internal orbital defects with Vitallium meshes. There was no incidence of post-operative infections or implant failure. The authors found this material to be well tolerated in clinical practice and suitable for treating large orbital defects. Vitallium meshes produce significant artifacts on CT and MRI which makes it undesirable in clinical practice [47].

Polymers

Non absorbable

Silicone

Silicone is used as a appropriate material in various surgical fields since almost 50 years credit to its biological/chemical inertness, flexibility, ease of handling and cost effectiveness. In 1963 silicone was first used by Lipshutz and Ardizone [48] in the management of orbital floor fractures. Prowse *et al.* [49] in 2010 stated that the appropriate use of silastic implants for orbital reconstruction leads to satisfactory outcome with low complication rate and higher patient's fulfillment. However, over the years many studies highlighted an unacceptable incidence of various implant related complications, including infraorbital cyst formation, infection, extrusion and implant displacement [50, 51].

Polyethylene (PE)

Porous ultra-high density polyethylene (Medpor) has been successfully used in the surgical management of orbital defects worldwide for more than two decades. Sheets of various sizes and thicknesses (typically within 0.4–1.5 mm) are commercially available and they can be easily adapted to fit the need of individual case (Fig. 3D). The presence of pores promotes tissue ingrowth which reduces incidence of foreign body reaction and capsule formation [52]. Clinical outcomes after implantation of porous PE implants are generally good, however some authors reported a significant complication rate i.e. surgical site infection and implant extrusion [53, 54].

Polytetrafluoroethylene

Polytetrafluoroethylene (PTFE) is biologically and chemically inert, non-antigenic, sterilizable via autoclaving and easily moldable. It is a suitable implant material for orbital reconstruction. Breton *et al.* [[55] successfully used ePTFE (Gore-Tex) in 30 cases of orbital fractures with smaller defect (<1.5 cm). More recently Elmazar *et al.* investigated ePTFE grafts reinforced with fluorinated ethylene propylene (FEP-ePTFE) in animal studies. The efficacy and biocompatibility of ePTFE and FEP-ePTFE were found comparable with those of HA and autogenous bone grafts [56].

Nylon

Utilization of nylon (SupraFOIL, medical grade nylon 6) in orbital surgery is relatively recent. The smooth nylon foil implant has been found to be safe and effective with low complication rate in orbital floor reconstruction [57, 58].

Hydrogels

Betz *et al.* [13] described and demonstrated the use of EH–PEG hydrogels and BMP-2 loaded Hydrogels for the reconstruction of orbital floor with outstanding bone rejuvenation.

Absorbable implants

Absorbable polymeric plate—screw systems were commercially introduced for fixation of fractures in the craniomaxillofacial region including the field of orbital surgery in the 1990's [59]. Absorbable synthetic polymers exhibit some interesting features. They offer more convenient and predictable absorption pattern in compare to biological grafts. They can be easily tailored to desired size and shape without any donor site morbidities.

Poly Lactic acid based materials

The earliest clinical use of poly lactic acid (PLA) in the management of orbital floor fractures was reported in 1972 by Cutright and Hunsuck [60] demonstrating its appropriateness as an alternative to biological materials (Fig. 3E). De Roche et al. evaluated the suitability of poly L/DL-lactide for the reconstruction of orbital defects in animals. Bergsma *et al.* [61] observed an inconsequential tissue reaction around the implants and limited resorption even after 5 years of implantation. Cordewener *et al.* [62] evaluated the long term clinical outcome of PLLA implants in orbital floor defects and recommended PLLA as a safe implant material. However, a few issues regarding its biocompatibility and tissue reactions are also reported by some authors [63-64].

Poly Glycolic acid based materials

In 1994 Hatton *et al.* [65] performed in-vitro tests on PGA membrane as a material for orbital floor repair. PGA was found to be appropriate for orbital floor repair without any significant occurrence of delayed infection or migration which is often reported with other nonabsorbable alloplastic implants. However PGA loses its structural integrity in less than 2 months after implantation and almost totally resorbed (>90%) by 9 months. Recent researches are directed towards materials having slower resorption kinetics such as PLA/PGA composites which can provide adequate structural and mechanical support for longer duration.

PLA/PGA implants

In the last two decades several studies have widely demonstrated the aptness of PLA/PGA implants for craniofacial reconstruction [59] including orbital floor repair (Fig. 3F). In 2007 Tuncer *et al.* [66]

reported the use of Biosorb PDX plates with a weight ratio of PGA to PLLA of 4:1 for the reconstruction of orbital floor with acceptable post-operative outcome. These implants are considered an excellent choice in children with a developing skeleton.

Polydioxanone (PDO)

Polydioxanone has been investigated in clinical practice as a material for orbital floor reconstruction. Some authors associate PDO with undesirable clinical outcomes [67, 68], but in other reports PDO performance was found to be comparable with that of other alloplastic materials [69]. Becker *et al.* [69] considered PDO foils to be very suitable for smaller orbital defect reconstruction (<2 mm).

Polyglactine 910/PDO

Polyglactin 910/PDO flexible membranes have been promoted worldwide under the commercial name of Ethisorb (Johnson & Johnson) for several years. In 1999 Piotrowsky and Mayer-Zuchi [70] originally reported the use of PG910/PDO patches for treatment of orbital fractures in 85 cases. In 2005 Buchel *et al.* [71] reviewed Ethisorb membrane (Fig. 3G) in 87 orbital fracture repair and concluded it to be very effective for small to moderate sized orbital floor defects (up to 4 cm²).

Composites (combination materials)

High density PE reinforced by HA (HAPEXTM)

HAPEX has been successfully introduced for orbital floor reconstruction since several years and commercially available [72]. This composite material is stiff, osteoconductive and biologically inert but brittle [73].

$\begin{array}{lll} \textbf{Titanium} & \textbf{plus} & \textbf{PE} & \textbf{composite} & \textbf{implant} & (\textbf{Medpor} \\ \textbf{Titan}^{TM}) \end{array}$

In the mid 2000s Medpor Titan was developed to overcome specific demerits of bare titanium mesh or Medpor alone. Commercially available in the trade name of Medpor-TitanTM and SynPOR, when implanted for orbital floor reconstruction concedes good clinical outcome [74] (Fig. 3H).

Periosteum and polymer complex (PCL)

In 2010 Asamura *et al.* conducted a pilot study [75] to explore the use of periosteum complexed with HA/PLLA/poly(Caprolactone) sheet and concluded that this material resulted an excellent clinical outcome and deemed to be a promising alternative to autologous bone.

BMP-2 loaded gelatine sheet

Asamura and co-workers [76] experimented the feasibility of BMP-2 loaded gelatine sheet with a biodegradable PLA foil as an orbital reconstruction implant. The authors grafted this composite into the bone defects of a model canine orbital floor. Post-operative radiological and histological findings showed

highly satisfactory bone formation and defect healing at 5 weeks.

Nanocomposites

Patel *et al.* [77] created nanocomposites incorporating HA nanoparticles (20–70 nm) within cyclic acetal hydrogels and used them to repair surgically formed orbital floor defects in an animal model. Preliminary histomorphometric outcome indicated the nanocomposites eliciting a positive invivo response in terms of bone growth.

Bone marrow coated PCL

Rohner *et al.* [78] tested PCL gallows coated with freshly collected autologous bone marrow chips for orbital defect reconstruction in animal model. Three months post-operative histomorphometric results showed that the bone marrow coated implants induced significantly superior bone in-growth in comparison to non-coated PCL scaffolds.

New advancements and future promises

Surface treated titanium

The bone bonding ability of surface treated titanium has been extensively studied over the last decade by several researchers [79]. Kokubo and coworkers suggested alkali treatment of titanium [79]. Ferraris *et al.* [80] proposed another approach inducing HA formation on the surface of titanium alloys. The authors performed a thermo-chemical treatment of titanium including first acid etching in HF acid and subsequent controlled oxidation in hydrogen peroxide.

Chitosang fluorescein (CHFL)

Chiono *et al.* [81] demonstrated the use of photoactive chitosang fluorescein (CHFL) which is a biocompatible conjugate polymers. CHFL was able to stimulate HA deposition upon visible light application. The authors suggested that the use of these polymers in clinical practice may be worth of extensive experimental work in the next few years.

3D printed bioactive glass

Bioactive glass has been proven to be osteoinductive and feasibility of 3D printed customized implants have the prospect to be a successful biomaterial for orbital reconstruction in near future [82].

Bioactive glass/polymer composites and polymeric hydrogels also have a great potential in orbital floor reconstruction [13].

Tissue engineering

Tissue engineered polymeric constructs such as BMP-2 loaded hydrogels have a promising prospect in the field of maxillofacial reconstruction including orbital reconstruction thanks to their excellent regenerative potential. BMP induced accelerated bone in-growth into the implant contributes to trounce the

restrictions related to polymeric matrix integrity over a period of time [83]. Promising results have also been reported by Betz *et al.* [13] and Asamura *et al.* [76] in animal models.

CONCLUSION

Autologous bone i.e. split calvarial, rib or iliac crest bone grafts are currently considered to be the 'gold standard' by majority of surgeons as the preferred material for orbital reconstruction. Synthetic polymeric implants have also been shown to be highly biocompatible and to have lesser complication rate. However the most critical limitation of commercially available biomaterials for orbital floor repair is a lack of bioactivity. With respect to currently available commercial products, new generation innovative biomaterials are expected to cart a significant additional value in terms of biocompatibility, bioactivity and bone regenerating ability. They also have the potential for acting as matrices for in situ drug delivery. In the next decade an ever increasing collaborating contribution from material scientists, chemists, physicists, biologists, surgeons and researchers in the medical implant industry would be desirable to provide us more suitable and cost effective biomaterials for orbital floor reconstruction.

REFERENCES

- 1. Roth F, Koshy J, Goldberg J, Soparkar C. Pearls of Orbital Trauma Management. Semin Plast Surg. 2010;24(4):398–410.
- 2. Cruz AA, Eichengberger GC. Epidemiology and management of orbital fracture. Curr Opin Ophthalmol. 2004;15(5):416–21.
- 3. Erdmann D, Follmar KE, Debruijn M, Bruno AD, Jung S, Mukundan S. A Retrospective Analysis of Facial Fracture Etiologies. Ann Plast Surg. 2008;60(4):398–403.
- 4. Scherer M, Sullivan WG, Smith DJ Jr, Phillips LG RM. An analysis of 1,423 facial fractures in 788 patients at an urban trauma center J Trauma. 29((3):):388–90.
- 5. Kelley P, Crawford M, Higuera S, Hollier LH. Two Hundred Ninety-Four Consecutive Facial Fractures in an Urban Trauma Center: Lessons Learned. Plast Reconstr Surg. 2005;116(3):42e–49e.
- 6. Ramieri G, Spada MC, Bianchi SD, Berrone S. Dimensions and volumes of the orbit and orbital fat in posttraumatic enophthalmos. Dentomaxillofacial Radiol. 2000;29(5):302–11.
- 7. Potter JK, Malmquist M, Ellis EI. Biomaterials for Reconstruction of the Internal. Oral Maxillofac Surg Clin N Am. 2012;24:609–27.
- 8. Calnan J. The use of inert plastic material in reconstructive surgery. Br J Plast Surg. 1963;16(1).
- Coleman D, King R, Andrade J. The foreign body reaction: a chronic inflammatory response. J Biomed Mater Res. 1974;8:199.
- 10. Neigel J, Ruzicka P. Use of demineralized bone

- implants in orbital and craniofacial reconstruction and a review of the literature . Ophthal Plast Reconstr Surg. 1996;12(2):108–20.
- 11. Chowdhury K, Krause GE. Selection of Materials for Orbital Floor Reconstruction. Arch Otolaryngol Head Neck Surg. 1998;124:1398–401.
- 12. Mok D, Lessard L, Cordoba C, Harris PG, Nikolis A. A review of materials currently used in orbital floor reconstruction. Can J Plast Surg. 2004;12(3):134–40.
- 13. Betz MW. Orbital floor regeneration using cyclic acetal hydrogels through enhenced osteogenic cell signaling of mesenchymal stem cells. 2009. 1-213 p.
- BM R, Halli R, Mahindra U, Kharkar V, Saluja H. Autogenous mandibular symphysis graft for orbital floor reconstruction: a preliminary study. J Maxillofac Oral Surg. 2009;8(2):141–4.
- Sakakibara S, Hashikawa K, Tahara S. Reconstruction of the Orbital Floor With Sheets of Autogenous Iliac Cancellous Bone. J Oral Maxillofac Surg. 2009;67:957–61.
- 16. Iatrou I, Theologie-lygidakis N. Use of membrane and bone grafts in the reconstruction of orbital. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2001;91:281–6.
- 17. Ilankovan V, Jackson IT. Experience in the use of calvarial bone grafts in orbital reconstruction. Br J Oral Maxillofac Surg. 1992;30:92–6.
- 18. Cieślik T, Skowronek J, Cieślik M, Cieślik-Bielecka A. Bone graft application from anterior sinus maxillary wall in orbital floor reconstruction. J Craniofac Surg. 2009;20(2):512–5.
- 19. Ellis EI, Tan Y. Assessment of Internal Orbital Reconstructions for Pure Blowout Fractures: Cranial Bone Grafts Versus. J Oral Maxillofac Surg. 2003;61:442–53.
- Glassman R, Manson P, Vanderkolk C, Iliff N, Yaremchuk M, Petty P. Rigid fixation of internal orbital fractures. Plast Reconstr Surg. 1990;86:1103–11.
- Zins J, Whitaker L. Membranous versus endochondral bone. Implications for craniofacial reconstruction. Plast Reconstr Surg. 1983;72:778– 85.
- 22. Philips J, Rahn B. Fixation effect on membranous and endochondral onlay bone graft revascularization and bone deposition. Plast Reconstr. 1990;85:891–7.
- 23. Young V, Schuster R, Harris L. Intracerebral hematoma complicating split calvarial bone-graft harvesting. Plast Reconstr Surg. 1990;86:763–5.
- 24. Lai A, Gliklich RE, Rubin PAD. Repair of Orbital Blow-out Fractures With Nasoseptal Cartilage. Laryngoscope. 1998;108:645–50.
- Kraus M, Gatot A, Fliss D. Repair of traumatic inferior orbital wall defects with nasoseptal cartilage. J Oral Maxillofac Surg. 2001;59:1307– 401.
- 26. Bayat M, Momen-heravi F, Khalilzadeh O,

- Mirhosseni Z, Sadeghi-tari A. Comparison of conchal cartilage graft with nasal septal cartilage graft for reconstruction of orbital floor blowout fractures & Br J Oral Maxillofac Surg. 2010;48:617–20.
- 27. Çeliköz B, Duman H, Selmanpakoğlu N. Reconstruction of the orbital floor with lyophilized tensor fascia lata. J Oral Maxillofac Surg. 55(3):240–4.
- 28. Dost P. Orbital floor reconstruction with autologous periosteum transplant. Laryngorhinootologie. 1996;75:57–8.
- 29. Directive of the EU Parliament and the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. In: Commission of the European Union. 2004. p. 23/EC.
- 30. Waite P, Clanton J. Orbital floor reconstruction with lyophilized dura. J Oral Maxillofac Surg. 1988;46:727–30.
- 31. Munoz-Guerra M, Sastre-Perez J, Rodriguez-Campo J, Naval-Gias L. Reconstruction of orbital fractures with dehydrated human dura matter. J Oral Maxillofac Surg. 2000;58:361–6.
- 32. Chen J, Zingg M, Laedrach K, Raveh J. Early surgical intervention for orbital floorfractures: a clinical evaluation of lyophilized dura and cartilage reconstruction. J Oral Maxillofac Surg. 1992;50(92):341–6.
- 33. Sallam M, Hashem H, Shokier H. Use of demineralised bone sheets in reconstruction of orbital floor trap door fracture. J Appl Sci Res. 2010;6:653–8.
- 34. Webster K. Orbital floor repair with lyophilized porcine dermis. Oral Surg Oral Med Oral Pathol. 1988;65:161–4.
- 35. Burres SA, Cohn AM, Mathog RH. Repair of orbital blow out fractures with marlex mesh and gelfilm. 1981. p. 1881–6.
- 36. Chrobok V, Pellant A, Novak J, Brozik J. Reconstruction of an orbital floor fracture in a 4-year-old child. Acta Med. 2008;51:229–31.
- 37. Costa J, Patrocínio L, Rossi R, Amorim A, Patrocínio J, ., et al. Bovine sclerae graft for orbital floor fracture in rabbits. Arq Int Otorrinolaringol. :181–8.
- 38. Mathur KK, Tatum SA, Kellman RM. Carbonated Apatite and Hydroxyapatite in Craniofacial Reconstruction. Arch Facial Plast Surg. 2003;5:379–83.
- 39. Hench LL. Bioactive materials: The potential for tissue regeneration. J Biomed Mater Res. 1998;41(4):511–8.
- Kinnunen I, Aitasalo K, Pollonen M, Varpula M. Reconstruction of orbital fractures using bioactive glass. J Craniomaxollofac Surg. 2000;28:229–34.
- Peltola M, Kinnunen I, Aitasalo K. Reconstruction of Orbital Wall Defects With Bioactive Glass Plates. J Oral Maxillofac Surg. 2008;66:639–46.

- 42. Gear A, Lokeh A, Aldridge J, Migliori M, Benjamin C, Schubert W. Safety of titanium mesh for orbital reconstruction. Ann Plast Surg. 2002;48:1–9.
- 43. Mackenzie D, Arora B, Hansen J. Orbital floor repair with titanium mesh screen. J Craniomaxillofac Trauma. 1999;5(3):9–16.
- Lieger O, Richards R, Liu M, Lloyd T. Computer-Assisted Design and Manufacture of Implants in the Late Reconstruction of Extensive Orbital Fractures. Arch Facial Plast Surg. 2010;12(3):186– 91.
- 45. Dobbs H, Robertson J. Heat treatment of cast Co-Cr-Mo for orthopaedic implant use. J Mater Sci. 1983;391–401:391–401.
- 46. Sargent L, Fulks K. Reconstruction of internal orbital fractures with Vitallium mesh. Plast Reconstr Surg. 1991;88(1).
- Sullivan P, Smith J, Rozzelle A. Cranio-orbital reconstruction: safety and image quality of metallic implants on CT and MRI scanning. Plast Reconstr Surg. 1994;94:589–96.
- 48. Lipshutz H, Rohlo AA. The use of silicon rubber in the immediate reconstruction of the fractures of the orbit. 1963. p. 563–8.
- Prowse S, Hold P, Gilmour R, Pratap U, Mah E, Kimble F. Orbital floor reconstruction: a case for silicone, a 12 years experience. J Plast Reconstr Aesthet Surg. 2010;63:1105–9.
- 50. Laxenaire A, Levy J, Blanchard P, Lerondeau J, Tesnier F, Scheffer P. Silastic implants and reconstruction of the orbital floor: review of twenty year's experience. Ann Chir Plast Esthet. 1996;41(6):631–8.
- Morrison AD, Sanderson RC, Moos KF. The use of silastic as an orbital implant for reconstruction of orbital wall defects - Review of 311 cases treated over 20 years. J Oral Maxillofac Surg. 1995;53(4):412–7.
- 52. Romano JJ, Iliff NT, Manson PN. Use of medpor porous polyethylene implants in 140 patients with facial fractures. J Craniofac Surg. 1993;4(3):142–7.
- 53. PM V, AJ M, LM J. Porous polyethylene implants in orbital floor reconstruction. Plast Reconstr Surg. 2002;109(3):877–85.
- Fialkov J, Holy C, Forrest C, Philips J, Antonyshyn O. Postoperative infections in craniofacial reconstructive procedures. J Craniofac Surg. 2001;12:362–8.
- 55. Breton P, Crezoit E, Blachard P, Fiere A, Freidel M. The role of Gore-Tex in orbital injuries: apropos of 30 cases. Rev Stomatol Chir Maxillofac. 1990;91:52–4.
- Elmazar H, Jackson I, Degner D, Miyawaki T, Barakat K, Andrus L. The efficacy of Gore-Tex vs hydroxyapatite and bone graft in reconstruction of orbital floor defects. Eur J Plast Surg. 2003;25:362–8.
- 57. Majmundar M V., Hamilton JS. Repair of Orbital Floor Fractures With SupraFOIL Smooth Nylon

- Foil. Arch Facial Plast Surg. 2007;9:64-5.
- 58. Park DJ, Garibaldi DC, Iliff NT, Grant MP, Merbs SL. Smooth Nylon Foil (SupraFOIL) Orbital Implants in Orbital Fractures: A Case Series of 181 Patients. Ophthal Plast Reconstr Surg. 2008;24(4):266–70.
- 59. Enislidis G. Treatment of Orbital Fractures: The Case for Treatment With Resorbable Materials. J Oral Maxillofac Surg. 2004;62(1):869–72.
- 60. Cutright DE, Hunsuck EE. The repair of fractures of the orbital floor using biodegradable polylactic acid. Oral Surgery, Oral Med Oral Pathol. 1972;33(1):28–34.
- 61. Bergsma J, Rozema F, Bos R, De Brujin W, Boering G. Poly(L-lactic) acid implants in repair of defects of the orbital floor. A five-year animal study. Cells Mater. 1994;4:31–6.
- 62. Cordewener F, Bos R, Rozema F, Houtman W. 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.
- 63. Balogh C, Lucas R, Kraft T, Breton P, Freidel M. Lactic acid polymer implants in the repair of traumatic defects of the orbital floor. Rev Stomatol Chir Maxillofac. 2001;102:109–14.
- 64. Lieger O, Schaller B, Jürgen Z, Kellner F, Iizuka T. Repair of Orbital Floor Fractures Using Bioresorbable Poly-L/DL-Lactide Plates. Arch Facial Plast Surg. 2010;12(6):399–404.
- 65. Mcvicar I, Hatton P V, Brook IM. Self-reinforced polyglycolic acid membrane: a bioresorbable material for orbital floor repair. Initial clinical report. Br J Oral Maxillofac Surg. 1995;33:220–3.
- Tuncer S, Yavuzer R, Kandal S, Demir Y, Ozmen S, Latifoglu O. Recontruction of traumatic orbital floor fractures with resorbablemesh plate. J Craniofac Surg. 2007;598–605.
- 67. Baumann A, Burggasser G, Gauss N, Ewers R. Orbital floor reconstruction with an alloplastic resorbable polydioxanone sheet. Int J Oral Maxillofac Surg. 2002;31:367–73.
- 68. Kontio R, Suuronen R, Salonen O, Paukku P, Konttinen YT. Effectiveness of operative treatment of internal orbital wall fracture with polydioxanone implant. Int J Oral Maxillofac Surg. 2001;30:278–85.
- 69. Becker ST, Terheyden H, Fabel PM, Kandzia C. Comparison of Collagen Membranes and Polydioxanone for Reconstruction of the Orbital Floor After Fractures. J Craniofac Surg. 2010;21(4):1066–8.
- 70. Piotrowski W, Mayer-Zuchi U. The use of polyglactine 910-polidioxanon in the treatment of

- defects of the orbital roof. J Oral Maxillofac Surg. 1999;75:1301–5.
- 71. Buchel P, Rahal A, Seto I, Iizuka T. Reconstruction of orbital floor fracture with polyglactine 910–polydioxanon patch (Ethisorb): a retrospective study. J Oral Maxillofac Surg. 2005;63:646–50.
- 72. Tanner T, Downes R, Bonfield W. Clinical applications of hydroxyapatite reinforced polyethylene. Br Ceram Trans. 1994;93:104–7.
- 73. Tanner KE. Bioactive ceramic-reinforced composites for bone augmentation. J R Soc Interface. 2010;7(June):541–57.
- 74. Merbs S, Iliff N, Grant M, Garibaldi D. Use of MEDPOR TITAN Implants in Orbital Reconstruction. Invest Ophthalmol Vis Sci. 2005;46:2–3.
- Asamura S, Ikada Y, Matsunaga K, Wada M, Isogai N. Treatment of orbital floor fracture using a periosteum–polymer complex. J Craniomaxillofac Surg. 2010;38:197–203.
- Asamura S, Mochizuki Y, Yamamoto M, Tabata Y, Isogai N. Bone Regeneration Using a Bone Morphogenetic Protein-2 Saturated Slow-Release Gelatin Hydrogel Sheet Evaluation in a Canine Orbital Floor Fracture Model. Ann Plast Surg. 2010;64(4):496–502.
- 77. Patel M, Betz MW, Geibel E, Patel KJ. Cyclic Acetal Hydroxyapatite Nanocomposites for Orbital Bone Regeneration. Tissue Eng. 2010;16(1):55–65.
- 78. Rohner D, Hutmacher D, Cheng T, Oberholzer M, Hammer B. In vivo efficacy of bone-marrow-coated polycaprolactone scaffolds for the reconstruction of orbital defects in pigs. 2003;66: J Biomed Mater Res. 2003;66:574–80.
- 79. Nishiguchi S, Kato H, H F, Oka M, Kim H, Kokubo T. Titanium metals form direct bonding to bone after alkali and heat treatment. Biomaterials. 2001;22:2525–33.
- 80. Ferraris S, Spriano S, Pan G, Venturello A, Bianchi C, Chiesa R. Surface modification of Ti–6Al–4V alloy for biomineralization and specific biological response: part I, inorganic modification. J Mater Sci Mater Med. 2011;22:533–45.
- 81. Chiono V, Gentile P, Boccafoschi F, Carmagnola I, Ninov M, Georgieva V. Photoactive chitosan switching on bone-like apatite deposition. Biomacromolecules. 2010;11:309–15.
- 82. Baino F. Biomaterials and implants for orbital floor repair. Acta Biomater. 2011;7:3248–66.
- 83. Haidar ZS, Hamdy ARC. Delivery of recombinant bone morphogenetic proteins for bone regeneration and repair. Part A: Current challenges in BMP delivery. Biotechnol Lett. 2009;31:1817–24.