Exposure of the orbital floor & Principles of Orbital Implant and Future of Orbital Floor Reconstruction

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Article History: Received 10th June, Accepted 5th July, published online 10th July 2023

Abstract

the orbital floor can be accessed via transcutaneous approach (which provide superior exposure, but the incisions carry a higher risk of visible scars and subsequent ectropion) or transconjunctival approach (which provides adequate visualization of the orbital floor, if further exposure is required, the access can be extended with a lateral canthotomy). The main objective of orbital floor reconstruction is to support the globe and periorbital soft, lifting the eyeball into its correct position and thereby avoiding enophthalmos. The choice of the implant is usually based on the size of the defect, availability of the products, and preference of the surgeon. No matter which material is used, however, certain principles should be kept in mind. Choice of implants in the growing orbit is to be taken into consideration by the surgeon who has to plan for the residual growth of the orbit and possible chances of migration of implants. To find a proper material for orbital floor reconstruction is not an easy task. This has been proved by the wide number of substances of biological or synthetic origin that have been tested over the last 50 years, in the hope that a truly functional biomaterial will eventually materialise. Today a myriad of implants is available on the market to treat orbital floor fractures as biological materials like auto graft (cartilage, bone), homograft, xenograft, and alloplastic materials as titanium, nylon, silicon.

Keywords: orbital floor, Orbital Implant

DOI: 10.53555/ecb/2023.12.Si12.266

The orbital floor can be accessed via transcutaneous approach (which provide superior exposure, but the incisions carry a higher risk of visible scars and subsequent ectropion) or transconjunctival approach (which provides adequate visualization of the orbital floor, if further exposure is required, the access can be extended with a lateral canthotomy)

Various modalities for fracture reduction/stabilization during fixation have been mentioned in literature, describing the use of custom made instruments or reduction forceps etc. This method is quick, simple and effective way of achieving initial reduction and stabilization of bone prior to final rigid fixation. The added advantages are reduced operating time, reduced instrumentation and assistance which in turn provide clear and more accessible surgical.

After the infraorbital rim has been exposed, subperiosteal dissection is carried out posteriorly. The dissection can be safely extended (25 mm) posteriorly from the inferior and lateral rim. The infraorbital nerves, the origin of the inferior oblique muscle, lacrimal apparatus, and optic nerves are special structures for which disruption should be avoided during operation. It is preferred to dissect from the lateral to medial side. This makes identification of the important anatomic structures and reduction of herniated fat tissue from the fracture site easy and safe. Care must be taken to avoid aggressive traction of the soft tissue because this may cause further bleeding deep in the orbit. Intraoperative bleeding can obscure the surgical field, which can be easily controlled by identification of the source and the use of bipolar or low-power electrocautery. The endpoint of dissection is reached when the surgeon has reduced all of the herniated tissue in the orbit and has exposed the bone of the unfractured orbit in a circumferential fashion. Even in a large fracture, the posterior ledge of the unfractured orbit can safely be identified by placing the elevator in the maxillary sinus and sweeping it upward and forward.nThe unfractured posterior ledge is usually the palatine bone. Once the size

and shape of the defect have been assessed, an autogenous graft or alloplastic implant is placed above the orbital shelf. In children under 8 years of age, autogenous bone graft or absorbable material should be used to accommodate growth of the orbital skeleton. A forced duction test is repeated after the implant has been placed to ensure eye mobility. The wound is inspected for hemostasis and then copiously irrigated. Then the released periosteum (arcus marginalis) is reattached to the orbit rim **(1).**

Because the objective of orbital reconstruction is to support the periorbital soft tissue and partition the maxillary or ethmoid sinuses from the orbit, any of the materials discussed will suffice. The decision is usually based on the availability of the products, preference of the surgeon and, most importantly, size of the defect. No matter which material is used, however, certain principles should be kept in mind **(2).**

* The size of the implant or transplant: As large an implant or transplant as necessary for covering the entire defect should be used. Before the placement of any implant or graft, one must be certain that its posterior edge is resting on sound bone. Perhaps the most common error in placement of an implant or transplant is leaving the posterior edge unsupported. To ensure proper placement, dissection back toward the orbital apex is necessary for establishing the posterior extent of the defect. If it is impossible to establish a sound posterior margin, the posterior edge of the material must be well supported laterally and medially. Alternatively, the material can be cantilevered to adjacent sound bone with the use of plate and screw fixation **(2).**

* Tension-free placement of the implant or transplant: The implant or transplant must be passive when inserted into the wound. In other words, there should be no tendency for an implant to buckle or for its edges to curl up or down, or for the implant to migrate when placed. If any of these occurs, the pocket is too small or the implant too large **(2).**

* Stabilization of the implant or transplant: The implant or transplant must be fashioned so that it cannot be displaced or must be secured with sutures, wires, or bone screws. Usually, orbital implants migrate anteriorly. This tendency is probably because the implant is improperly sized and placed under tension. The implant should not extend over the infraorbital rim. It usually can be placed so that its anterior end is behind the rim. Stabilization with bone screws and/or bone plates will prevent migration **(2).**

* Careful closure of the wound: The periorbita must be carefully closed with resorbable sutures. This closure is extremely important because it ensures the proper positioning of the orbital septum and helps adapt the tissue over the implant or transplant **(2).**

Pediatric consideration in orbital trauma necessitates the discussion of important aspects which clearly delineate the management principles from adults.

The face to cranium ratio of an infant is (1:8), while that of a child who is between 4 and 6 is about (1:4). This clearly establishes the fact that the cranium in an infant or a child is much larger than the face and is more exposed to potential trauma. The orbit completes almost 80% of its growth within the first 2 years of life and another 10% within the next 2–3 years **(3).**

As maxillary sinus pneumatization undergoes significant expansion from 6 to 12 years of age, fractures of the orbital floor are relatively rare in children younger than 5 years old. Orbital floor and medial wall fractures in small children are therefore actually less common than fractures of the orbital roof **(4).**

Trapdoor fractures are an anatomic subtype of orbital floor fracture, seen almost exclusively in children **(4).**

The management of most pediatric orbital floor fractures should be similar to that of adults. The repositioning of herniated orbital tissue, the lysis of adhesions, and proper positioning of the implant are far more crucial than the type of implant employed for successful operation **(5).**

Choice of implants in the growing orbit is to be taken into consideration by the surgeon who has to plan for the residual growth of the orbit and possible chances of migration of implants (**3**).

Pediatric orbital floor fracture reconstruction should be delayed until edema and inflammation have mostly resolved, and repair undertaken if there is residual, clinically significant diplopia. An exception to this rule is a trapdoor fracture which should be repaired within 24 h from the time of diagnosis. Enophthalmos resulting from an orbital floor fracture does not need to be prevented with early surgery. Enophthalmos can be allowed to develop over time allowing the parents and/or patient decide if they want the operation if the degree of enophthalmos is cosmetically unacceptable for them **(4).**

The use of nonresorbable material is not ideal in the pediatric patient, as it subjects the patient to a second procedure, increasing cost and risk of peri-operative complications. According to Azzi et al., autologous grafts and absorbable materials have no significant benefit over each other in pediatric orbital floor defect reconstruction **(5).**

Basically, the goal of an orbital floor implant is to repair the traumatic defect, lifting the eyeball into its correct position and thereby avoiding enophthalmos. This ideal reconstructing material of the orbital floor fracture in the presence of bony defect should be thin, light, force bearing, easily contoured, radiopaque, resistant to infection and MRI compatible, and also it should be non-carcinogenic and have no potential for transmission of disease **(6).**

To find a proper material for orbital floor reconstruction is not an easy task. This has been proved by the wide number of substances of biological or synthetic origin that have been tested over the last 50 years, in the hope that a truly functional biomaterial will eventually materialise. Today a myriad of implants is at the surgeon's disposal and available on the market to treat orbital floor fractures **(7).**

1-Biological materials

Over the years a wide range of biological materials has been tested in the field of orbital floor repair. They have been derived from human or animal tissues and could be used as transplants (autografts, allografts and xenografts) or treated to obtain suitable substances to be used as implant materials. In general, biological materials have problems, such as limited availability and morbidity at the harvest site for autologous tissues and the risk of viral infection and disease transmission (especially in the past) by the donor (living or cadaver) tissue. In addition, the resorption rate of such materials can vary greatly depending on their origin **(7).**

A-Autografts

Autografts have been traditionally considered as the ''gold standard'' choice due to the absence of an adverse immunological response. The use of autografts requires an appropriate amount of autologous patient tissue, harvested from a donor site, which is properly shaped in order to match the defect dimensions, thereby providing a rigid structural support to the surrounding tissues and structures **(7).**

***Autologous bone:**

Historically, In the field of orbital floor repair the most common source was the iliac crest. However, split ribs, the anterior surface of the opposite maxilla, the buccal or lingual cortex of the mandible and the calvarium have also been used with good success. When bone is used, it should be borne in mind that some resorption will eventually take place, so adequate volume should be transplanted to offset this eventuality **(2).**

The graft can be placed as-such, fixated by screws and/or plates, or used in conjunction with an alloplastic material, such as titanium mesh or porous polyethylene **(8).**

The advantages of autologous bone are its inherent strength, rigidity and vascularization potential. Most of all, autografts exhibit excellent biocompatibility and tolerance after implantation. Because autologous bone grafts are incorporated into the tissue, as living tissue and elicit no immune reaction to self-antigens, foreign body reactions such as infection, extrusion and ocular tethering are minimized. **(9).**

However, the use of autologous bone is associated with several less favourable aspects. First, it is not always easy to contour bone to the desired shape and size, which may depend on the graft harvest site. Furthermore, the graft can break if it is bent beyond its natural capacity. In the case of large defects involving multiple fractures and disruption of bony buttresses other biomaterials are preferred or combined with autologous bone. In such a context Ellis and Tan, demonstrated that a better accuracy of reconstruction can be achieved using titanium mesh rather than cranial bone grafts **(2).**

Further problems associated with the use of autologous bone grafts concern material harvesting from the donor site, including a significant increase in surgery time and patient time under general anaesthesia **(9).**

For the most part the donor graft is harvested without particular complications, but general risks include infection and haematoma at the donor site and/or injury to the healthy tissue, increased time of recovery and additional postoperative pain. Furthermore, extra surgery creates a bony defect at the patient donor site and an additional scar. Certain donor sites are associated with possible site-specific complications **(10).**

*** Cartilage*:***

As already described for autologous bone, post-operative complications such as infection, extrusion and chronic inflammatory reactions are less prevalent than with alloplastic materials **(9).**
Compared with autologous bone, cartilage is usually easier to harvest and shape and it can provide long-term support to the surrounding tissues without undergoing resorption, even after several years **(7).**
Autologous cartilage grafts have a favorable application in orbital floor reconstruction owing to ease of access, malleability, and reliable support without evidence of resorption. Autologous cartilage grafts are still used for small orbital floor fractures. The predominant sources for cartilaginous grafting are auricular concha and nasal septum. Nasal septum is advantageous over other forms of cartilage including rib cartilage due to quick harvest and minimal cosmetic and functional morbidity. auricular cartilage is anatomically better suited; this is secondary to its natural curve. It allows an improved inset in the inferior orbit. Autologous cartilage graft is used for small orbital floor defects **(11).**

B- Homografts

A partial solution to the patient drawbacks associated with autografts is the use of homografts, i.e. the transplant of hard/soft tissue(s) from another living patient or from a cadaver, such as Irradiated homologous fascia lata, lyophilized human dura mater or irradiated cartilage **(12).**
The advantages over autologous grafts include lack of donor site morbidity, decreased surgery time, the opportunity to preform and customize the implant before surgery and, at least virtually, unlimited availability of graft material, with particular reference to banked bone **(7).**
The main concern, however, involves the potential spread of infectious diseases, known and as yet unknown, such as transmissible spongiform encephalopathy that may be fatal **(12).**

c-Xenografts and animal-derived materials

In other fields within the broad world of bone reconstruction, however, the use of xenografts has sometimes been associated with worrisome complications, such as disease transmission, a severe immunogenic response and unpredictable resorption rates, usually higher than that of autologous bone. All these factors have discouraged the use of animal grafts in recent years, as has the wide range of other materials and implant options available to surgeons. **(7).**

Alloplastic materials

A- Metals

***Titanium:**

Titanium is highly biocompatible and thanks to its physico-mechanical properties, is an ideal candidate for the reconstruction of bone defects requiring substitutes with high rigidity and strength. An attractive feature of titanium is its ability to be incorporated into the surrounding tissues and to osteointegrate. **(13).**
Titanium mesh seems to be particularly suitable for repairing large orbital fractures. **(14).**
Although the majority of reports showed that the use of titanium in orbital surgery can lead to highly satisfactory results, the occurrence of serious post-operative clinical complications has occasionally been reported. **(7).**
It has also been underlined that titanium, even if incorporated into the surrounding tissue, is a non-absorbable material and, therefore, it cannot be replaced by new soft or bone tissue and will remain in situ indefinitely, causing possible late side-effects (infection, implant corrosion and toxicity due to metal ion release**. (15).**
Another non-negligible disadvantage of titanium implants, is the high cost. **(15).**

B. Polymers

(Non-absopable)

*** Nylon**

The use of nylon in orbital floor surgery is relatively recent. In 2007, Majmundar and Hamilton reported preliminary clinical experiences involving the repair of limited orbital floor fractures using smooth nylon sheets (*SupraFOIL*), medical grade nylon **(16)**.
One year later Nunery et al. reported excellent clinical outcomes obtained after implanting a single 0.4 mm thick nylon foil (SupraFOIL), medical grade nylon in 102 human patients. In 101 orbits a normal globe

position and full extraocular motility without diplopia was accomplished, however, one orbit had persistent enophthalmos requiring a second procedure **(17)**.

***Silicon**

Silicone has been extensively proposed for almost 50 years as a suitable material for various surgical applications due to its attractive properties, including biological/chemical inertness, flexibility, ease of handling and low cost **(7).**

In 1963 silicone was introduced by Lipshutz and Ardizone in the management of orbital floor fractures **(18).** However, over the years some reports have described an unacceptable incidence rate of various implant-related complications, including infra-orbital cyst formation, infection, extrusion and implant displacement **(19).**

As reported by Morrison et al, the majority of silicone-related complications generally occurs in the early post-operative period and the chance of complication decreases with longer asymptomatic period. **(7).**

***Polyethylene:**

Porous ultra-high density polyethylene (PE), marketed under the commercial name Medpor (Porex Surgical, USA), has been successfully used for almost 20 years in the surgical management of orbital defects worldwide. Sheets of various sizes and thicknesses (typically within 0.4–1.5 mm) are commercially available, and they can be easily adapted by the surgeon to fit the needs of each case. The presence of pores promotes tissue in growth and implant vascularization and reduces foreign body reactions and capsule formation **(7).**

Patel et al. reported excellent integration of the synthetic implant with the host tissues due to Fibrovascular tissue in-growth into porous PE sheets **(20).**

Even if the clinical outcomes after implantation of porous PE implants were generally good, some authors reported a non-negligible complication rate associated with the use of such materials **(20).** specifically It was registered that a higher infection rate associated with porous PE compared with other alloplastic implants.

***Polytetrafluoroethylene (Teflon):**

Polytetrafluoroethylene (PTFE), being biologically and chemically inert, non-antigenic, sterilizable via autoclaving and easily mouldable to conform to various solid shapes, is an ideal implant biomaterial in the context of repairing post-traumatic orbital floor defects. **(7).**

(Absorbable)

Absorbable synthetic polymers exhibit interesting features, as they offer more controllable and predictable absorption kinetics than those of biological grafts and can be easily tailored to obtain an implant of the desired size and shape **(21).**

Polyglycolic acid

PGA was found to be highly suitable for orbital floor repair as it did not induce long-term infection or migration, which is sometimes associated with non-absorbable alloplastic implants. **(7).**

***Polydioxanone**

Polydioxanone (PDO) has been adopted in clinical practice as a material for resorbable sutures that disappear 6 months postoperatively, but its use as an orbital implant has also been documented. There is controversy about its use in orbital floor surgery: some authors associate PDO with unacceptable clinical outcomes**,** but in other reports PDO performance was found to be comparable with that of other alloplastic materials **(22).**

The first clinical use of polylactic acid (PLA)in the management of orbital floor fractures was reported in 1972 by Cutright and Hunsuck, who demonstrated its suitability as an alternative to biological material **(7).**

In 2001 Balogh et al. reported a study on 18 patients with fractured orbits treated with PLA implants. No post-operative complications were observed at 24 –43 months follow-up, except for a transient eyelid inflammation that resolved spontaneously. The authors also underlined that the material could be easily remodelled once heated, thereby allowing precise adaptation of the implant to the orbital structures **(23).**

The present literature is still divided regarding which material should preferably be used to reconstruct the orbit since no material only has advantages. Furthermore, it is unclear up to which defect size which material should be used **(24).**

Many studies showed promising results of many materials used for orbital floor reconstruction.

In a study done by Castellani et al. they used *auricular cartilage* to reconstruct the orbital floor defect in which the bone gap was relatively small up to (2 x 2 cm) with all of the cases had clinical findings. The follow up of the cases showed good improvement of clinical signs except 1 case of entropion that may be attributed to adhesion caused by the miniplate used to fix the orbital rim; the condition resolved spontaneously, and 1 case of palpebral edema as this patient had had very extensive injuries to the lower and upper eyelids, which they used for access to the orbit.

The positive findings for some clinical signs at follow-up are also quantitatively comparable to those reported in the literature, independent of the type of reconstruction used. This study proved the effectiveness of auricular cartilage is reconstruction of small size defect as it provided an optimal support function for the globe with minimum donor-site morbidity **(25).**

In an extensive case report on 55 patients Gear et al., used a *titanium mesh* to repair orbital defects larger than (2 cc) and reported the achievement of good functional results together with a minimal risk of infection after 44 months follow-up. **(26).**

In 2010 Prowse et al. conducted a detailed retrospective review of 81 patients who had orbital floor reconstruction from 1995 to 2007 and compared the performance of *silicone* implants (58 patients) with that of non-silicone (autografts, titanium mesh and resorbable plates) materials (23 patients). Statistically significant advantages were found in the silicone group compared with the other, especially in the number of patients with palpable implants (24% vs. 63%), without any post-operative complaints (67% vs. 32%), or requiring subsequent surgery for complications related to their implants (5% vs. 23%).

Therefore, the authors concluded, in good agreement with the majority of surgeons, that the appropriate use of silicone implants for orbital floor reconstruction can lead to good results, with low complication rates, including an accept ably low rate of infection and extrusion, as well as high patient satisfaction. The good in vivo behaviour of silicone has commonly been attributed to its biochemical inertness and to the fact that a smooth collageneous capsule forms around the material, decreasing the chance of later infection and migration of the implant **(27).**

Lupi et al, used *porous polyethylene* sheets for orbital floor reconstruction in both post-traumatic (27 cases) and post-oncologic (five cases) patients. There were no cases of implant migration, extrusion or enophthalmos; diplopia persisted in only two patients after 6 months follow-up. The implant was considered safe and represented a stable platform for orbital soft tissues growth. In addition, with respect to other alloplastic materials, porous PE was deemed to be more suitable in the case of large defects requiring extensive support. **(28).**

There are more studies showing the effectiveness of other materials used in orbital floor defect reconstruction, and the researchers do their best to find the most appropriate reconstructive material with least complications. Basically, the goal of an orbital floor implant is to repair the traumatic defect, lifting the eyeball into its correct position and thereby avoiding enophthalmos. To find a proper material for orbital floor reconstruction is not an easy task. This has been proved by the wide number of substances of biological or synthetic origin that have been tested over the last 50 years, in the hope that a truly functional biomaterial will eventually materialise. Today a myriad of implants is at the surgeon's disposal and available on the market to treat orbital floor fractures **(7).**

In 1996 Neigel and Ruzicka reviewed the allogenic materials used in orbital floor surgery, while 2 years later Chowdry and Krause gave some indications for material selection, focusing their attention on autografts and, specifically, on autologous bone. In2004 Moketal and Potter and Ellis reviewed both bio logically derived and alloplastic materials for orbital floor fracture management. In 2010 Betz et al. published an excellent contribution to the maxillofacial and ophthalmic literature, in which the potential of tissue engineered constructs for orbital floor regeneration was highlighted **(7).**

The endogenous response to bone healing is not adequate for proper regrowth of the orbital floor, resulting in a number of associated problems. In addition, current clinical solutions are not without their share of disadvantages **(29).**

Tissue engineering and regenerative medicine have been recently begun to be explored for the treatment of orbital bone defects. In bone tissue engineering in general, cells act as the osteogenic stimulate for the

formation of new bone. In contrast, specific growth factors and cytokines can act as the osteoinductive stimulation, recruiting and inducing osteoprogenitor cells to grow into mature bone tissue through chemotaxis, mitosis, and differentiation. Finally, a scaffold acts as an osteoconductive medium where the scaffold serves as a surface on which the cells can attach, migrate, grow, and divide, and new blood vessels can invade **(29).**

The key feature in any orbital bone regeneration strategy should be the support of the globe (a scaffold in bone engineering). To regenerate bone tissue an appropriate cell population needs to be delivered or recruited to the injured area. While some progress has been made with periosteal cells and calvarial osteoblasts, the most widely investigated cell type in craniofacial tissue engineering is bone-marrow-derived mesenchymal stem cells (MSCs). To induce MSCs down the osteogenic differentiation pathway, a sufficient and appropriate amount of extracellular signals must be available. Bone morphogenetic proteins (BMPs) are members of the transforming growth factor-β (TGF-β) superfamily and are known to be secreted signaling molecules and present in adults during fracture repair. 16 BMPs have been identified. BMP (2) and BMP (7) are currently the only BMPs with recombinant human products developed for clinical applications. The family of BMPs is known to induce formation of cartilage, bone, and other like tissues of the skeleton through recruitment, commitment, and differentiation of osteoprogenitor cells **(29).**

Scaffold design is critical to the success of an engineered construct. In orbital bone tissue engineering, scaffolds act as a temporary framework for cells to grow and produce new matrix and functional tissue. The scaffold should be easily modified to fit the defect. In addition, as the target tissue is regenerated, the scaffold should degrade to allow space for the new tissue to grow. There are many parameters involved in scaffold design, including polymer composition, biodegradation, biocompatibility, and mechanical strength **(29).**

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