Subacute Granulation Tissue of the Fornix after Resorbable Orbital Implant: An Unusual Case and Review of the Literature

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Abstract

Keywords

- orbital blow-out fractures
- resorbable implants
- L-lactide-co-glycolide
- granulation tissue

Orbital blow-out fractures are very common. Goals of surgical treatment are to reestablish form and function with excellent cosmetic results. Materials used for orbital floor repair include autologous grafts and a variety of alloplastic materials. In this article, we present a case of subacute granulation tissue of the fornix that developed as a foreign body reaction 4 months after placing a resorbable implant to repair an orbital floor fracture. The implant was removed and the patient continued to heal uneventfully. Management of the case and biomaterials employed are discussed in light of current research.

Causative factors associated with orbital fractures vary with social, demographic, and cultural characteristics of the studied population, as well as the timing of each study. However, epidemiologic data indicate that road traffic accidents, falls, sports injury, and assaults account for the great majority of such fractures in the urban population.¹ Depending on the type and nature of the forces involved in a facial trauma, fractures around the orbit can be subdivided into three main patterns: orbital-zygomatic, naso-orbito-ethmoid, and internal orbital fractures. This third pattern can be further classified into blow-in and pure blow-out (isolated orbital floor fracture) or impure blow-out (associated with an orbital rim defect) fractures.²

Orbital floor fractures can present as isolated fractures or as part of central, centrolateral, or lateral midfacial fractures.³ The objectives of surgical treatment for orbital floor fractures are to release entrapped orbital tissues and to reestablish both the shape and the volume of the bony orbit to achieve functional and cosmetic results.³ If left untreated or undertreated, functional and aesthetic issues may arise, such as enophthalmos, diplopia, visual loss, or limited ocular mobility. There are three important variables that contribute to the outcome of a case: surgical timing, surgical approach, and type of material employed for the reconstruction.⁴ The surgical approach and the type of material employed are

frequently dictated by the size of the defect. Smaller defects can be managed using resorbable materials. Even though complications with these materials are rare,⁴ adverse events such as infection, wound dehiscence, and clinically relevant foreign body reactions may occur.⁵

Foreign body reactions of mucous membranes take place in response to the presence of particles that are not promptly absorbable. From the histological standpoint, and regardless of the nature of the implant, all foreign body reactions exhibit the same essential features, that is, accumulation of chronic inflammatory cells and the formation of giant cells.⁶ Anderson⁷ detailed the cellular and molecular events that take place in living tissues when responding to materials, from injury/implantation of a biomaterial to fibrosis/fibrous capsule development. Anderson's study concluded that both local (tissue, blood supply, infection potential) and systemic (medical history, nutrition, immunological derangements) factors may play a role in the wound healing response to biomaterials or implants.⁷

The purpose of this article is to report a case of subacute granulation tissue of the fornix that developed as a foreign body reaction to a resorbable material employed to repair an orbital floor fracture. To the best of our knowledge, no similar clinical condition has been reported.

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Fig. 1 Clinical aspect of the pedunculated lesion of the left lower eyelid.

Case Report

A 39-year-old man presented during a routine follow-up with a complaint of a painless mass in the left eye of recent onset (►Fig. 1). The mass developed around 4 months after placement of a resorbable implant following an orbital floor fracture repair. The cause of the fracture was a fall of approximately 8 to 10 feet from a ladder which resulted in

an isolated left orbital floor blow-out fracture as well as a left nasal bone fracture (►Fig. 2a, b).

At the time of the initial injury, he had diplopia and difficulty with nasal breathing. He was taken to the operating room for an open repair of the orbital floor and a closed reduction of the nasal bone fracture. A transconjunctival approach was used to gain access to the orbital floor. Then, a bony defect was noted that was 1 cm × 1.5 cm. Dissecting around the defect established a posterior shelf, medial and lateral walls. A resorbable implant (Synthes Rapid Resorb, Synthes, West Chester, PA) was used to reestablish the orbital floor. Forced duction test was done after placement and there was no entrapment. The conjunctiva was closed using 6-0 fast gut sutures. A postoperative computed tomography (CT) of the face without contrast demonstrated good position of the implant and restoration of orbital volume (►Fig. 3a, b).

One month after the surgery, he was noted to have diplopia on extreme superior gaze; otherwise he was asymptomatic. He returned 4 months after the surgery, complaining of a flap of tissue that occasionally affected the vision in his left eye. On clinical examination, a red exophytic mass emanated from a stalk in the fornix of the left lower eyelid; his conjunctiva was mildly injected (►Fig. 1). A CT of the face with contrast was

Fig. 2 Preoperative CT image demonstrating the isolated orbital floor blow-out fracture. (a) Coronal view. (b) Sagittal view.

Fig. 3 Immediate postoperative CT. (a) Coronal view. (b) Sagittal view. Two fragments of bone are seen. The implant image corresponds to the thin line near the anatomic floor.

Fig. 4 Second postoperative CT. (a) Coronal view. (b) Sagittal view. Two fragments of bone are seen. The implant image corresponds to the thin line near the anatomic floor.

obtained to evaluate the orbit. This image revealed that the orbital implant was in good position (►Fig. 4a, b). The patient had consulted his optometrist, who documented no intraocular reason for the vision changes.

An excisional biopsy of the mass was performed under general anesthesia in an outpatient office setting (►Fig. 5). The tissue appeared to be soft granulation tissue and was sent for pathology testing. The histopathologic analysis revealed a fragment of granulation tissue containing a mixed inflammatory infiltrate composed of lymphocytes, plasma cells, histiocytes, and neutrophils. The diagnosis was “subacutely inflamed granulation tissue” (►Fig. 6). Following the biopsy, the patient was started on prednisolone ophthalmic 1% and erythromycin eye ointment (Romycin ointment, Valeant Pharmaceuticals North America LLC, Bridgewater, NJ). Over the next month, the mass returned to its previous size and location and an adhesion was found between the conjunctiva and the left lower eyelid that was noted (►Fig. 7). The patient’s conjunctival injection did not resolve despite regular application of the ophthalmic steroid. Exophthalmometer did not reveal abnormalities of the position of the left globe within the orbit.

Fig. 5 An oval-shaped, soft-tissue specimen measuring $1.4 \times 0.9 \times 0.2$ cm.

Fig. 6 Granulation tissue composed of a mixed inflammatory infiltrate containing lymphocytes, plasma cells, histiocytes, and neutrophils. Diagnosis: subacutely inflamed granulation tissue. Hematoxylin–eosin $\times 200$.

Fig. 7 A new lesion developed after excisional biopsy.

Fig. 8 The reassembled fragments of the removed rapid resorb plate; the anterior portion was encased with granulation tissue.

The patient was taken back to the operating room for open exploration and removal of the implant. A transconjunctival incision was used. Immediately prior to the incision, a sharp edge of a foreign body was noted. An incision was done in the conjunctiva following the foreign body; the anterior aspect of the implant was found to be fragmented and encased in granulomatous tissue (→Fig. 8). The base of the extraocular granuloma was traced to this fragmented piece of implant, and was easily removed. The rest of the implant was identified in the floor of the orbit. In attempting to remove this normal-appearing posterior implant, it fragmented as it was encased in healthy-appearing fibrous tissue. Not seeing any more granulation tissue, the removal of the rest of the plate was discontinued. The conjunctiva was closed with a single fast gut suture. At 1 and 4 weeks after surgery, he had persistent diplopia on extreme superior gaze, resolving conjunctival injection, and no evidence of granuloma recurrence.

Table 1 Grafting materials available for orbital fracture repair

	Autologous	Allogenic	Xenogenic	Alloplastic
Type of material	Bone Cartilage Periosteal Fascia lata	Irradiated bone Lyophilized cartilage Lyophilized dura Fascia lata	Bovine bone Lyophilized porcine dermis Denatured porcine collagen	<i>Resorbable</i> Poly(lactic/polyglycolic acid copolymer) Polydioxanone Polyglactin 910 <i>Nonresorbable</i> <i>Metallic</i> Titanium Vitallium <i>Nonmetallic</i> Silicone/Silastic sheets Bioactive glass Marlex mesh Porous polyethylene Teflon
Advantages	Biocompatibility, strength, rigidity, vascularization potential, minimum foreign body reaction	No donor-site morbidity, decreased surgical time, tissue availability, osteoconduction potential	Safe, no evidence of biologic incompatibility, inflammation, or infection	No donor-site morbidity, readily available, decrease surgical time, malleable, ease of handling, adequate support
Disadvantages	Difficult to reshape, breakable, graft resorption, donor-site morbidity, increase surgical time	Higher graft resorption rate, possibility of disease transmission	Limited availability, patient reluctance due to religious beliefs	Higher infection rates, increased costs

Source: Adapted from: Avashia et al.⁹

Discussion

The aim of this article was to present a case of subacute granulation tissue of the fornix that appeared as a reaction to a resorbable material employed to repair an orbital floor fracture and to review the literature on the subject. To our knowledge, a similar case has not been reported. The implant we employed in this particular case is manufactured from 85:15 Poly(L-lactide-co-glycolide; RapidSorb; Synthes Rapid Resorb, Synthes, West Chester, PA). By combining L-lactide and glycolide, it is believed that it maximizes the advantages of each material and makes it easier to the body to resorb it without toxic tissue accumulation. It is expected to resorb in approximately 12 months.⁸

Our experience with this case indicates that the reaction was to the resorbable implant. The mass, which started to be clinically noticeable 4 months after surgery, probably developed due to a combination of implant fracture and mobility. At initial placement, the implant was neither modified nor contoured, thus preserving its integrity at initial placement. Post-operative imaging revealed it was in the correct position with no signs of fracture. It is possible that it underwent accelerated resorption, resulting in fragmentation. Another possible explanation is that there was a subacute postoperative infection that led to chronic irritation and development of the granuloma. It is interesting to note that as soon as the conjunctiva was opened the second time, a mobile piece of implant that was covered with granulation tissue was observed before any orbital manipulation occurred. The fragments that were more posterior were unaffected by granulation tissue and were not initially fractured from the main implant; they broke off as the surgical team tried to manipulate the plate out of the fibrous tissue.

The report of this case is in agreement with those researchers who believe that there is no ideal material.^{4,9} The

Fig. 9 (a–d) Fundamental aspects of tissue response to biomaterials (adapted from Anderson).⁷

ideal material for orbital floor fracture repair should be resorbable, osteoconductive, resistant to infection, minimally reactive, does not induce capsule development, has a half-life allowing for bony ingrowth, is readily available, and economical.⁴ These characteristics, without question, indi-

cate that the development of the ideal material is far from being available. Nevertheless, most of the materials used today for reconstructive purposes are reliable and useful.

Was the initial surgery indicated and was the correct material chosen for this patient? Indications for surgical

intervention include visual impairment, persisting diplopia, enophthalmos greater than 2 mm, increased orbital pressure, radiologic findings of extraocular muscular entrapment, reduced sensitivity of the infraorbital nerve, and patient symptoms.^{9–11} Our patient had diplopia documented shortly after the initial trauma. When surgical management is necessary, the reconstructive goal is to restore form and function. Concurrent with the restoration of function is minimizing complications related to the surgical approach or the grafting materials. The wide variety of materials introduces an even wider listing of their indications, contraindications, advantages, and disadvantages (►Table 1).

In general, the choice of the material depends on its extension and complexity of the fracture. While small fractures are usually reconstructed with autologous grafts or resorbable biomaterials, larger defects necessitate nonresorbable materials due to the massive loss of substance and herniation into the maxillary antrum.¹⁰ In our case, we thought the defect was small enough that it could be approached by a transconjunctival incision. We also thought that the defect could be isolated with bony shelves on all sides.

A resorbable plate acts as a biological template during the healing process, thus guiding the ossification process.¹¹ The pores present in nonresorbable materials permit angiogenesis and bone ingrowth, which ultimately stabilizes the implant, therefore minimizing the chances of extrusion or migration.¹² It is possible that the defect was larger than this restorable material was meant to be used for. While the postoperative CT scan appeared to show good placement, there may have been increase load on the central portion of the implant leading to early fragmentation.

Although autologous bone grafts remain the “gold standard” for orbital floor reconstruction,¹³ materials and techniques used for orbital floor repair will continue to evolve as biotechnology advances and innovative alloplastic materials become available. In light of current research,^{5,14} the size of the bony defect of this case (1.5×1 cm) is classified as small; therefore, it is suitable for resorbable implants such as poly-L-lactide, poly-D, L-lactide, trimethylene carbonate, and polyglycolide. Applying a mathematical formula ($\text{width} \times \text{length} \times \pi$) to coronal and sagittal CT scans to calculate the size of the orbital floor defect, Piombino et al⁵ classified orbital floor fractures as small (<3 cm²) and large (>3 cm²). They concluded that the use of resorbable materials for the first and nonresorbable for the later defects provides reliable and reproducible stabilization of orbital wall defects, granting satisfactory outcomes from the aesthetic and functional standpoints.

Reported complications with resorbable alloplastic materials include poor incorporation at the cellular level, production of a fibrous capsule, infection, and inflammatory reactions to the foreign implant that can cause ocular muscle adhesions and diplopia. Although there are no studies documenting the cellular and molecular events that take place at the resorbable implant–orbital floor defect interface, the fundamental aspects of tissue responses to biomaterials are schematized in ►Fig. 9(a–d).⁷ The proposed sequence of host reactions following implantation of biomaterials/medical devices is as follows: injury, blood–material inter-

actions, provisional matrix formation, acute inflammation, chronic inflammation, granulation tissue, foreign body reaction, and fibrosis/fibrous capsule development.

When complications arise, it is accepted that the management is challenging; often the solution is to remove the implant.^{9,15} In the present case, the main complication consisted of an oval, 1-cm pedunculated mass localized at the fornix, which arose 4 months after orbital floor reconstruction with a resorbable material. This subacute granulation tissue of the fornix created functional and cosmetic inconveniences for the patient. After excisional of the mass, it returned within 1 month. This recurrent complication called for removal of the resorbable plate, a clinical decision supported by the literature.^{9,15} The exact cause for this complication is unknown.

Conflict of Interests

None.

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