Reconstruction of Small Orbital Floor Fractures With Resorbable Collagen Membranes

Pasquale Piombino, PhD, MD, Alessia Spinzia, MD, Vincenzo Abbate, MD, Paola Bonavolontà, MD, Govanni Dell'Aversana Orabona, MD, and Luigi Califano, MD

Abstract: Orbital floor fractures are the most common facial fractures. The goals of orbital floor fracture repair are to free incarcerated or prolapsed orbital tissue from the fracture defect and to span the defect with an implant to restore the correct anatomy of the orbital floor and the pretrauma orbital volume. No consensus exists on the choice of implants to be used for orbital floor reconstruction, and several implant materials are available.

Our study intended to evaluate, for the first time, the effectiveness and complications related to the use of a resorbable collagen membrane in the reconstruction of small pure blow-out fractures. From October 2008 to November 2010, 23 patients who underwent reconstruction of the orbital floor using a resorbable collagen membrane following fracture were included in this study. At the 6-month follow-up, only 2 patients (9%) reported postoperative complications secondary to the operative procedure (surgical approach, orbital floor dissection), but these were not directly related to the use of the membrane. In 12 cases, a computed tomography scan revealed new bone formation beneath the membrane.

On the basis of this data, we believe that the use of a resorbable collagen membrane is a safe and effective alternative for reconstruction of small (<3 cm^2) pure orbital floor fractures.

Key Words: Orbital floor fractures, resorbable alloplastic materials, resorbable collagen membrane, pure orbital blow-out

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Orbital floor fractures are the most common facial fractures. They can be broadly classified as pure blow-out fractures (isolated orbital floor fracture) or impure blow-out fractures (associated with an orbital rim fracture).[1]

Two etiological mechanisms are accepted to be the cause of orbital floor fractures—the buckling mechanism and the hydraulic mechanism. In the case of the buckling mechanism, a traumatic force is transmitted by bony conduction through the orbital rim to the orbital floor, whereas in the case of the hydraulic mechanism, elevated hydrostatic pressure inside the orbital cavity causes disruption of the orbital floor, which is known to be the weakest region in the facial structure.[2]

Clinical findings related to orbital floor fractures include periorbital bruising and edema, and limitation of vertical and horizontal ocular movements resulting in diplopia, enophthalmos, and hypoesthesia or anesthesia of the area innervated by the infraorbital nerve in some cases.[3]

The goals of orbital floor fracture repair are to free incarcerated or prolapsed orbital tissue from the fracture defect and to span the defect with an implant to restore the correct anatomy of the orbital floor and the pretrauma orbital volume.[4]

No consensus exists on the choice of implants to be used for orbital floor repair, and several implant materials are available[5]; these can be classified as either autologous, allogenic, or alloplastic materials.

Autologous materials include nasoseptal and auricular cartilage, maxillary bone, mandibular symphysis, coronoid process, iliac crest, ribs, and calvaria.[6]

All of these materials share the problems associated with morbidity of a donor site and exhibit variable degrees of resorption.[7]

Allogenic materials such as lyophilized dura mater had been successfully adopted until cases of Creutzfeldt-Jakob disease coincident with its use were reported from different parts of the world; therefore, allogenic materials are no longer in use.[8] The use of lyophilized cartilage has also been reported.[5]

Alloplastic materials can be further subdivided into nonresorbable and resorbable materials. Silicone,[9] teflon, medpor (Porex, Newmann, GA, USA),[10,11] and titanium mesh are only some among the most well-known nonresorbable materials. Nonresorbable alloplastic implants are permanent foreign bodies, and late subsequent complications such as infection, extrusion, implant migration, recurrent hemorrhage, or residual diplopia have been reported to occur,[12,13] requiring subsequent implant removal, sometimes many years postoperatively.[9] These complications may be avoided by the use of resorbable alloplastic implants. Examples of resorbable materials include poly(L-lactide),[10,14] polydioxanone, vicryl mesh (polyglactin-910),[15] and polyglycolic acid.[16]

The resorbable collagen membrane used in our practice is a pure collagen membrane obtained by standardized, controlled manufacturing processes. Collagen is extracted from veterinary certified pigs and is carefully purified to avoid antigenic reactions. It is sterilized in double blisters by γ-irradiation. The membrane is made of collagen type I and type III without further cross-linking or chemical treatment. Two sizes of the membrane are available; we used the 30 × 44-mm size. The manufacturer did not provide us with information on the thickness of the membrane, but we estimated it to be less than 1 mm.

Resorbable collagen membranes are naturally broken down in the body by collagenases (enzymes) into amino acids by an inflammation-free process. Because it is derived from natural collagen without cross-linking, the host blood vessels are able to effectively penetrate through the layers of the membrane, increasing revascularization of the regenerating bone.

From the Department of Maxillofacial Surgery, Federico II University of Naples, Naples, Italy.
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Address correspondence and reprint requests to Dr Pasquale Piombino, MD, PhD, FEBOMFS, Via S. Pansini 5 (ed. 14), I-80131 Naples, Italy; E-mail: piombino@unina.it
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TABLE 1. Preoperative Ophthalmic Signs and Symptoms

Ophthalmic Signs and Symptoms	Patients
Subconjunctival hemorrhage	21 (92%)
Periorbital ecchymosis	17 (74%)
Dystopia	19 (83%)
Hypoglobus	14 (76%)
Enophthalmos	5 (24%)
Diplopia	13 (56%)
Infraorbital nerve hypoesthesia	10 (43%)
Periorbital swelling and/or edema	8 (35%)
Ocular injury	2 (9%)

Animal studies have demonstrated that collagen is resorbed in the bone cavities within 24–32 weeks.[17]

This type of membrane has already been used for a long time in the field of oral surgery for guided bone regeneration (GBR), and we believe that it could also be used for small orbital floor fractures because of its advantages.[18,19] Thus, our study intended to evaluate, for the first time, the effectiveness of the use of resorbable collagen membranes in the repair of small pure blow-out fractures.

PATIENTS AND METHODS

This study comprised 23 patients [19 male (83%), 4 female (17%); mean age, 39 years; range 18–60 years] who underwent repair of orbital floor fractures using resorbable collagen membranes from October 2008 to November 2010.

All subjects met the following inclusion criteria: (1) pure blow-out fractures, (2) a small orbital floor fracture (<3 cm^2), and (3) enophthalmos and/or diplopia. All patients provided their written informed consent before participating into the study. The study was conducted in accordance with the ethical principles provided by the Declaration of Helsinki and the principles of good clinical practice. Study design, inclusion and exclusion criteria, and treatment protocol were reviewed and approved by a council of senior specialists at the same department of our university.

The most common cause of fracture in this series was motor vehicle accidents (n = 18, 78%); other causes included sports injuries (n = 3, 13%) and falls onto the face (n = 2, 9%).

All patients underwent preoperative ophthalmological and radiological examinations. Ocular motility findings and diplopia were assessed on the basis of the Hess Chart, and enophthalmos was determined by Hertel exophthalmometry.

Clinical signs and symptoms included periorbital ecchymosis (n = 17, 74%), subconjunctival hemorrhage (n = 21, 92%), periorbital swelling and/or edema (n = 8, 35%), diplopia (n = 13, 56%), infraorbital nerve hypoesthesia (n = 10, 43%), and dystopia (n = 19, 83%) (Table 1).

Ocular injury was observed in 2 patients (9%) and involved corneal abrasion.

FIGURE 1. Preoperative high-resolution multislice computed tomography (CT) scans showing a typical small blow-out fracture on coronal (A) and sagittal (B) views.

FIGURE 2. The Synthes Orbital Retractor. This instrument accurately reproduces the orbital floor anatomy (A); the membrane was easily and accurately cut as a template using the same tool (B).

All patients were examined by high-resolution multislice computed tomography (CT), evaluated in coronal and sagittal views (Figs. 1A–B). CT scans were performed with 1-mm-thick contiguous slice sections under bone and soft tissue window settings. An open source image processing software (OsiriX; OsiriX Foundation, CA, USA) was used to reconstruct and manipulate CT scan data from each patient in order to obtain measurements of the bony defect area.

Reconstruction of the small orbital floor fractures (<3 cm^2) was performed with the help of a unique, 30 × 40-mm, resorbable, bilayer collagen membrane (Bio-Gide; Geistlich Biomaterials, Wolhusen, Switzerland) recommended by the manufacturer for all maxillofacial reconstructions. A subciliary incision was used in all patients. Once the infraorbital rim was exposed, the orbital floor was subperiosteally dissected to reach the fracture area. The size of the orbital floor defect was determined after freeing the soft tissue and removing the small bony fragments. In order to model and correctly fit the membrane onto the bone defect, we used a special instrument (Orbital Retractor; Synthes Maxillofacial, Paoli, PA, USA) that accurately reproduces the shape of the orbital floor anatomy. After positioning this instrument in place and ensuring it adhered to the fractured floor, the membrane was easily and accurately cut as a template using the same tool (Figs. 2A–B). The collagen membrane was then inserted to reconstruct the orbital floor defect (Fig. 3). No fixation was performed, but the periosteal edges were brought together on the infraorbital rim to prevent implant displacement. After confirmation of free eye movement by the forced duction test, the skin was closed using a nonabsorbable 5-0 suture.

Every patient underwent postoperative clinical and radiological follow-up (mean follow-up duration, 14 months; range, 2–21 months). Bone formation was radiologically assessed at follow-up using the OsiriX image processing software. This software allowed us to estimate the density values (Hounsfield scale, HU) in very restricted areas on the CT scans. It was therefore possible to compare the values obtained in the membrane apposition area with those of the surrounding

FIGURE 3. Intraoperative view: collagen membrane apposition to reconstruct the orbital floor defect.

TABLE 2. Postoperative Ophthalmic Signs and Symptoms

Ophthalmic Signs and Symptoms	Preoperative	Postoperative	% Resolution
Subconjunctival hemorrhage	21	0	100%
Periorbital ecchymosis	17	0	100%
Dystopia	19	2	89.4%
Hypoglobus	14	0	100%
Enophthalmos	5	2	66%
Diplopia	13	2	84.6%
Infraorbital nerve hypoesthesia	10	2	80%
Periorbital swelling and/or edema	8	0	100%
Ocular injury	2	0	100%

bone. These values were found to be overlapping, indicating that the 2 areas had the same bone density.

RESULTS

At the 6-month follow-up, 11 of the 13 patients (84.6%) with preoperative diplopia exhibited resolution of all symptoms postoperatively. Eight of the 10 patients (80%) with infraorbital nerve hypoesthesia exhibited resolution postoperatively, while 2 patients (20%) experienced residual infraorbital nerve hypoesthesia. Hypoglobus resolved postoperatively in all of the 14 (100%) patients, while enophthalmos resolved in 3 (66%) of the 5 patients who initially presented with it (Table 2).

Only 2 patients (9%) experienced postoperative complications, but these were secondary to the operative procedure (surgical approach or orbital floor dissection) and not directly related to the resorbable collagen membrane.

In 12 cases, a CT scan revealed new bone formation beneath the membrane within the fracture site at the 12-month follow-up (Fig. 4).

DISCUSSION

In order to prevent tardive sequelae such as enophthalmos,[20] persistent diplopia, orbital dystopia, reduced globe mobility,[4] vertical strabismus with double vision,[21] anisocoria, and permanent Volksmann ischemic contracture particularly of the inferior rectus muscle,[22] it is important to have a correct approach to the treatment of orbital floor fracture. In the treatment of blow-out fractures, it is important to repair and maintain the accurate anatomical structural support of the orbit against herniation forces during the initial phase of healing to obtain functional and esthetic results.[22]

The main purpose of the surgical repair of orbital fractures is achieved by releasing the incarcerated soft tissue contents by bridging the defect with autogenous or alloplastic materials and by restoring the original anatomy and orbital volume. A wide variety of materials have been utilized for this purpose, each with its own advantages and disadvantages, but there is still no consensus on which material is the most effective.[3] An ideal material should be biocompatible, noncarcinogenic, easy to maintain in position, and free of any potential for disease transmission.[12]

Since 1996, new absorbable alloplastic materials have been available in the market. During the last few years, these materials have greatly contributed to the technical advances in surgical treatment of orbital trauma.[23]

The advantages of resorbable alloplastic materials include the following: (1) unlimited availability of the material, (2) decreased operative time, (3) no donor-site morbidity or complications, (4) no risk of infectious disease transmission, and (5) avoidance of subsequent complications associated with nonresorbable alloplastic materials (infection, migration, and extrusion).[4] A resorbable implant simply acts as a scaffold to establish a supportive structure on which the periorbital wall heals. The implant is gradually resorbed and replaced completely by fibrous collagenous tissue.[7]

Our study is the first to use Geistlich Bio-Gide resorbable collagen membrane to repair small orbital floor fractures. GBR has long been in use in the field of oral implantology and periodontology (including procedures such as socket extraction, ridge preservation, sinus floor elevation, and correction of intraosseous defects). Several studies have shown that predictable and successful bone regeneration can be achieved using this osteopromotive membrane method.[18,19]

GBR involves placement of a barrier membrane over a bony defect and close adaptation of this membrane to the surrounding bone surface, creating an enclosed space between the bone and the membrane. This is necessary to achieve a sealing effect, preventing the in-growth of soft tissue cells, because these cells can compete with bone-forming cells in the bony defect below the membrane. Because of its characteristics, a resorbable collagen membrane used for GBR has the potential to be a perfect product for use in orbital floor repair. Its main feature is the unique bilayer collagen membrane (source animal: pig) composed of a smooth and a rough layer. The smooth upper layer placed in contact with the periocular tissues is an ideal basis for the attachment of fibroblasts leading to favorable healing of the orbital tissue. In accordance with GBR, this layer acts as a barrier, protecting the newly formed bone from potential invagination of the periorbital soft tissue (the GBR principle).[24] The dense porous layer used to cover the bony defect acts as a guide for osteoblasts, thereby supporting optimal bone healing. Thus, soft tissue is prevented from growing into the defect, and the membrane also acts as a guide for bone, soft tissue cells, and blood vessels. Endogenous tissue forms a bond with the porous collagen mesh, and blood vessels grow between the fibers and along the membrane surface, providing ideal conditions for the development of healthy soft tissue and bone.

The implant will be gradually resorbed (within 6–8 months) and eventually replaced completely by a fibro-osseous matrix. Bone formation at the membrane apposition site after resorption has been widely demonstrated with respect to the use of this membrane in GBR in the field of implantology.[17,18]

Based on this experience, we indirectly assessed bone formation in the membrane apposition site. In the area of membrane resorption, we detected the CT density (Hounsfield scale, HU)[25] values overlapping the bone area.

One of the essential advantages of the use of this membrane is the excellent wound healing resulting from good vascularization. In addition to the features that make this membrane suitable for GBR, we believe that it can also be successfully applied in small orbital floor reconstructions because it offers valuable support to the orbital content preventing its herniation throughout the critical pre-regeneration period of the floor.

In our study, only 2 patients (9%) experienced postoperative complications, but these were secondary to the operative procedure (surgical approach or orbital floor dissection) and not directly related

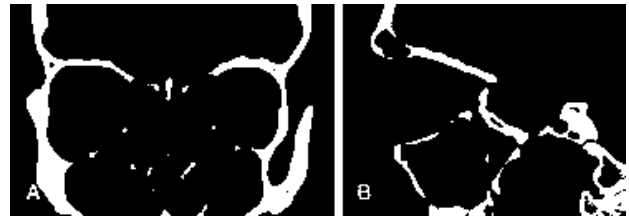

FIGURE 4. The 6-month follow-up computed tomography (CT) scans (A: coronal view; B: sagittal view) showing orbital volume restoration and new bone formation in the membrane apposition area.

to the resorbable collagen membrane. These favorable results demonstrate the effectiveness of this type of membrane in the reconstruction of orbital floor fractures. It is important to note that such a resorbable collagen membrane implant can be used only in small defects (<3 cm^2). In fact, a surgeon must always ensure that the membrane spans the entire defect and, more importantly, rests on the stable bone all around the edges of the defect.

In 3 cases, a CT scan revealed new bone formation beneath the membrane within the fracture site during the 6-month follow-up. Based on these results, we believe that a resorbable collagen membrane can be used to repair small orbital floor fractures and to support new bone formation. Its unique osteopromotive features, which foster new bone formation, make this membrane suitable for other surgical or medical applications in future, wherever bone formation is required. We conclude that the use of this resorbable collagen membrane is a safe and effective alternative for reconstruction of small pure orbital floor fractures.

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