

Repair of Orbital Floor Fractures With Bioactive Glass Implants

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Purpose: The ideal management of orbital floor fractures has been highly controversial. Many implants, both autogenous and alloplastic, have been used to span the defects. This study evaluated the use of bioactive glass implants (BAG-implant, S53P4; Abmin Technologies Ltd, Turku, Finland) for the repair of orbital floor defects caused by blunt facial trauma.

Patients and Methods: This retrospective review of 36 patients was carried out from 1995 to 1999. All patients were diagnosed with an orbital floor fracture or a large orbital blowout fracture. The BAG-implant was placed over the defect, using a subciliary or transconjunctival approach. No screw fixation was used when the implant was the correct size. Follow-up examination was done at 1 and 3 months after surgery. Twenty-eight (82%) of the patients were also seen at one-year follow-up (21 men and 7 women).

Results: The implants did not cause a foreign body reaction in the bone or soft tissue. There was no sign of resorption or infection, nor postoperative extrusion, hemorrhage, or displacement of the implant. Diplopia was seen preoperatively in 17 cases (61%) and postoperatively in 5 cases (18%). In 1 patient, the implant was removed 3 months after operation because of diplopia. Infraorbital nerve paresthesia was seen preoperatively in 9 patients (32%) and postoperatively in 5 patients (18%). The functional and cosmetic results were good at the 1-year follow-up.

Conclusion: The BAG-implant is a well-tolerated material in orbital floor reconstruction. It provides a favorable environment for an uncomplicated healing process because it is bioactive and biocompatible and because it causes new bone formation.

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Blowout fractures of the orbital floor or the medial wall of the orbit cause a well-known post-traumatic syndrome with characteristic clinical symptoms, of which the most serious is diplopia. The ideal management of such floor fractures has been highly controversial. Successful repair of fractures of the orbital and maxillary-zygomatic complex has 4 prerequisites: a

thorough understanding of the regional anatomy, accurate diagnosis, an unimpeded exposure and, in some cases, rigid fixation of the fracture.^{1,2}

Many implants, both autogenous and alloplastic, have been used to span the defects. These include autogenous grafts of bone, cartilage, and fascia,³⁻⁵ and alloplastic implants that are either nonresorbable, such as silicone, polytel, hydroxyapatite, and titanium, or resorbable, such as polylactin film or polylactide plates.^{6,7} Whether autogenous or alloplastic, the ideal implant should be nonreactive, provide good structural support, be easily positioned, and be readily available. Most alloplastic implants used today have these qualities. However, the reported incidence of early and delayed complications ranges from 0.4% to 7%.⁸

Traditionally, autogenous bone has been the implant material of choice for reconstruction of orbital blowout fractures. However, the harvesting and modeling of these grafts are time-consuming procedures. We have therefore used bioactive glass (S53P4) as an alloplastic implant material.

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Bioactive glasses (BAGs) are silicates containing sodium, calcium, and phosphate as their main components. They bind to bone by a surface layer of hydroxylapatite that forms through chemical reaction with the glass.⁹ This chemical bonding of BAG and bone has been shown by several investigators.^{10,11} BAG is biocompatible, bone-bonding, and osteoconductive in humans.¹¹ Good results have been achieved with this material in frontal sinus surgery.¹²⁻¹⁴ The long-term reactions between BAG and bone and its durability and stability in the sinuses are important for the success of the treatment.¹⁵ We report our experience with the use of BAG implants for repair of orbital floor defects.

Patients and Methods

The chemical composition of the BAG (S53P4) used was SiO₂, 53.0%; Na₂, 23.0%; CaO, 20.0%; and P₂O₅, 4.0% by weight, which was a kind gift of Abmin Technologies Limited, Turku, Finland. The rigid implants were of 3 sizes (20, 25, and 30 mm in diameter), supplied as round, heart, or kidney-shaped rigid plates approximately 1 to 1.5 mm thick with round edges (Fig 1). The implants were not reshaped in any way during the operation. One of the 3 types of prostheses was always used, and a template was used to determine the correct size. All surgical procedures were performed by the senior surgeon (K.A.).

The orbital floor fractures were accessed using either a subciliary or transconjunctival incision, with a lateral canthotomy when necessary. The periorbita was then incised, and any prolapsed contents were lifted back into the orbit. After selection of the proper size, the implant was placed over the defect. None of the implants required screw fixation. The subciliary

or transconjunctival incision was closed using 6-0 nylon sutures, and the lateral canthotomy was closed with 5-0 nylon sutures. A postoperative forced duction test was carried out to ensure the mobility of the extraocular muscles. Postoperative antibiotics were administered only for 3 days.

A retrospective chart review of 36 patients who had received bioactive glass implants was carried out from 1995 to 1999 at the Department of Otorhinolaryngology, Turku University Central Hospital. All patients were diagnosed as having a complex maxillary fracture with an associated orbital floor or a large blowout fracture. There were 21 fractures of the right orbital floor and 15 of the left orbital floor. Six patients had a highly comminuted orbital floor and an orbital base fracture. A part of this material has previously been reported in a preliminary study.¹⁶

The patients were seen by the surgeon (K.A.) at 1 week, 1 month, and 6 months, which is the normal postoperative protocol in our clinic. An additional postoperative follow-up examination was carried out by the Ear Nose, Throat surgeon (I.K.), an ophthalmologist (J.P.), and a radiologist (M.V.) at 1 year. At each postoperative follow-up one of the otorhinolaryngologists examined the patient for infraorbital nerve paresthesia, signs of infection around the implant, signs of migration of the implant, and pain in the eye. Also, the aesthetic results after the operation were evaluated by photography. In ophthalmologic evaluation, the eye was examined for movements, diplopia, vision, signs of optic nerve lesions, and exophthalmos and enophthalmos. Standard radiographs, supplemented with computed coronal and axial tomography (CT) of the orbit, were obtained pre- and postoperatively in all patients. Sinus radiographs were taken before discharge from the hospital and 6 months after the operation. Laboratory tests for inflammatory parameters (C-reactive protein) and for liver (serum gamma-glutamyltransferase) and kidney function (creatinine) were also carried out at the postoperative follow-up visits.

The study plan was reviewed and approved by the Joint Commission on Ethics of Turku University and the Turku University Central Hospital.

Results

Of the 36 patients who underwent repair of an orbital floor fracture with a BAG implant, 28 (82%) were seen at the 1-year follow-up. Two patients could not be contacted, and 6 patients had had a 6-month follow-up. Of the 28 patients included in this study, 21 were men and 7 were women (age range, 22 to 73 years; average age, 32.6 years). The time to repair of the fractures ranged from 1 to 5 days. Fourteen of the 28 patients had pure blowout fractures (Fig 2) and the



FIGURE 1. View of an orbital floor BAG implant and a titanium template.

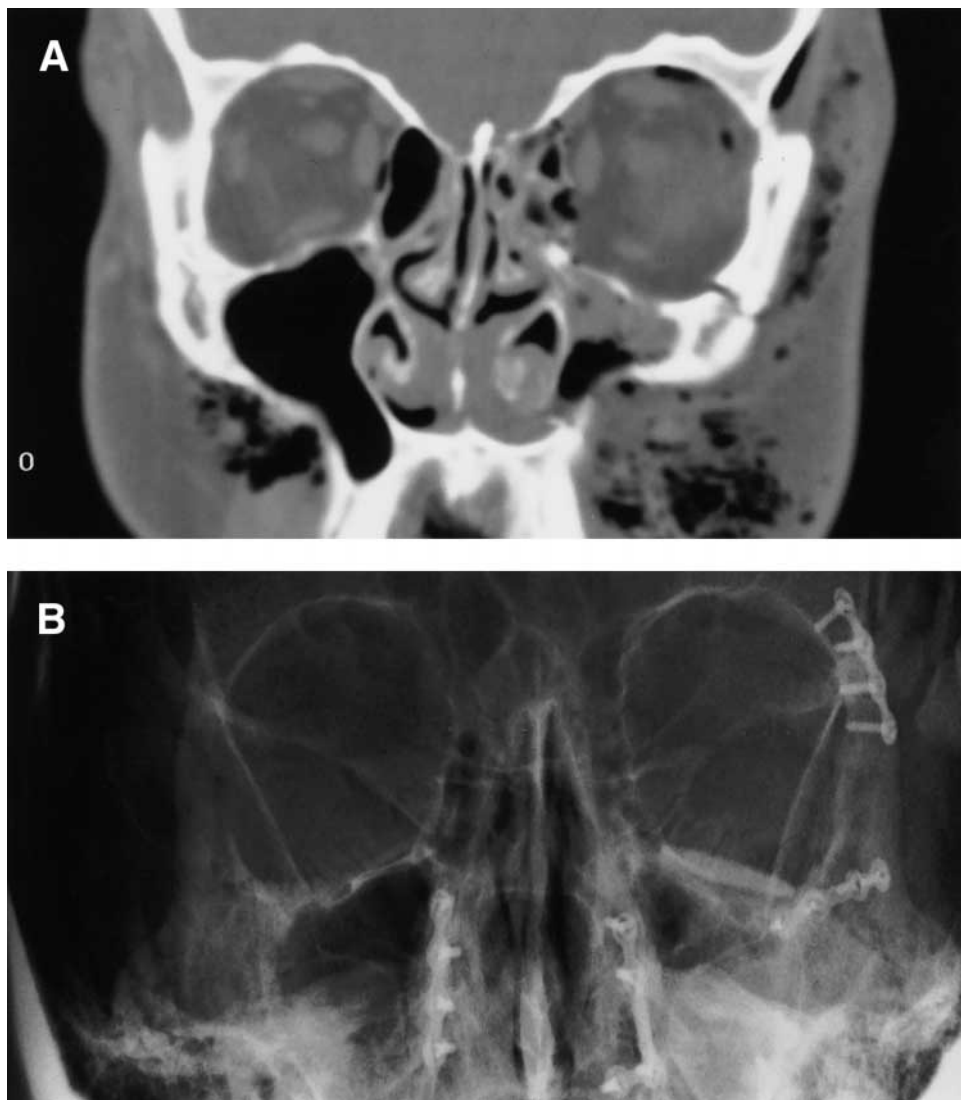


FIGURE 2. A, Coronal CT scan of a patient with a left orbital floor fracture. B, Scan of the same patient 12 months after left orbital floor reconstruction with a BAG implant and reconstruction of the maxillary fractures with titanium miniplates (Howmedica Leibinger GmbH & Co Kg, Freiburg, Germany).

other 14 had an associated zygomaticomaxillary or Le Fort fracture (Fig 3, Table 1). The size of the defects ranged from approximately 1 to 2 cm. Twenty-one of the patients underwent surgical repair through a transconjunctival incision and 7 patients through a subciliary incision.

Diplopia was seen preoperatively in 17 patients (47%). Nine patients (25%) had an enophthalmus, 3 had vertical dystopia, and 3 had an intraocular pressure (IOP) over 25 mm Hg (Table 1). Their increased IOP was decreased with medication. Three patients with complicated orbital base fractures had pathologic pupillary reflexes caused by optic nerve trauma. However, none of these patients had perforating ocular injuries.

Postoperatively, visual acuity was normal in all patients except for one whose acuity was 0.3, which was caused by a previous traumatic cataract. Intraocular pressure was normal in all patients. Four patients had diplopia (11%) (Table 1) when tested with a

Hess chart, but only 2 had diplopia when tested using red-green glasses. One of these patients still had esotropia 12 prism diopters (PrD), although this patient had undergone a strabismus operation. His affected eye was enophthalmic by 3 mm, and diplopia was present in both horizontal and vertical gaze, and even when looking straight ahead. The other patient had a damaged inferior oblique muscle. Partial infraorbital nerve paresthesia was present postoperatively in 5 cases (17%). One patient had minor dystopia and another had severe dystopia. Although the affected eye was 3 mm lower than the other, no subjective diplopia was reported. This patient could alleviate his inferior oblique muscle dysfunction by tilting his head. Two patients had optic nerve damage and a visual field defect. Both of them had macular lesions (macular pucker). Their primary ocular damage was probably severe. The transconjunctival incision caused some symblepharon in 2 patients. However, the eye movements were normal.

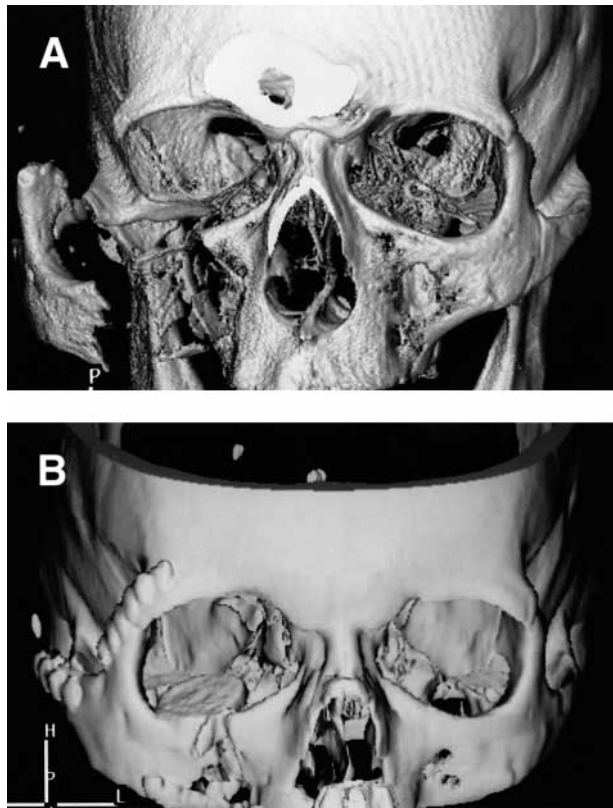


FIGURE 3. A, Spiral CT scan of a patient with complicated maxillo-orbital fracture. B, Scan of the same patient after reconstruction and BAG implant placement in the orbital floor.

Postoperative CT scans and/or sinus radiographs showed adequate maintenance of orbital floor and maxillary sinus volume. Only in 4 cases in which there was complicated maxillary trauma was there partial deformation of sinus volume. However, there was no evidence of infection. Furthermore, new bone formation was seen in the anterior wall of the operated maxillary sinus in the axial views. The BAG implants showed no signs of resorption; their status was the same 1 year after operation as it was imme-

diately after operation. There was no cosmetic deformity, infection, rhinosinusitis, postoperative or long-term extrusion, hemorrhage, or displacement of the implant (Table 2). In 1 patient, the implant was removed 3 months after operation because the patient reported diplopia (Table 1). In this case, the implant had been placed too high in the orbit floor. The cosmetic results were good at the 1-year follow-up. Only 3 patients had enophthalmos without any evidence of diplopia, and 1 had entropion (Table 1).

Discussion

A traumatized orbital floor fracture can cause severe symptoms, such as diplopia, intraorbital nerve damage, and exophthalmos or enophthalmos, with radiographic evidence of herniation of orbital fat into the antrum. The primary goal of this study was to show that BAG implants are a safe and useful material for use in orbital floor surgery. This study also showed that bioactive glass fulfills all the essential criteria for an ideal orbital floor reconstruction material (Table 2). There were no problems in the earlier use of BAG in frontal sinus obliteration or orbital surgery.^{13,14} No infections, resorption, or foreign body reactions were seen.

Bioglass is not only bioactive, but it is also bacteriostatic,¹⁵ which may be one reason why there were no acute or late infections after frontal sinus obliteration or orbital floor reconstruction. The implants are rigid and therefore one must choose the correct size to fit the internal orbital anatomy. Although the implants are not molded during the operation, when they are of the correct size and in the correct place, they do not need any specific fixation to prevent migration (Table 2). When the internal orbital volume is correct, there should be normal postoperative globe position. Thus, there are 3 different sizes and shapes of implants available. The correctly sized im-

Table 1. CLINICAL FINDINGS BEFORE AND AFTER SURGICAL RECONSTRUCTION OF ORBITAL FLOOR DEFECTS IN 28 PATIENTS TREATED BETWEEN 1995 AND 1999

Symptoms	Preoperative		Postoperative	
	Blowout Fracture (N = 14)	Zygomaxillary Fracture (N = 14)	Blowout Fracture (N = 14)	Zygomaxillary Fracture (N = 14)
Diplopia	11 (79%)	6 (43%)	2 (14%)*	2 (14%)*
Infraorbital nerve paresthesia	7 (50%)	2 (14%)	3 (21%)†	2 (14%)
Enophthalmos	4 (29%)	5 (36%)	1 (7%)	2 (14%)
Vertical dystopia	1 (7%)	3 (21%)	—	2 (14%)
Optic nerve lesion	—	3 (21%)	—	2 (14%)
Infection	—	2 (14%)	—	—

*Two patients had diplopia when tested using red-green eyeglasses.

†The infraorbital nerve paresthesia was only partial.

Table 2. CT FINDINGS IN THE ORBITAL FLOOR, MAXILLARY SINUS, AND BAG IMPLANT 1 YEAR AFTER IMPLANT PLACEMENT IN 28 PATIENTS

State of Sinus Before and After Operation and BAG-Implantation	Preoperatively		Postoperatively	
	Blowout Fracture (N = 14)	Zygomaticomaxillary Fracture (N = 14)	Blowout Fracture (N = 14)	Zygomaticomaxillary Fracture (N = 14)
Deformation				
Infraorbital nerve	In fracture line (10)	In fracture line (4)	No compression of bone (14)	No compression of bone (14)
Lateral wall of maxillary sinus	No	Deformed (14)	No	Partial deformation (4)
Hematoma	Yes (14)	Yes (14)	No	No
Orbital floor deformed	Yes (14)	Yes (14)	No	No
Herniation of orbital fat	Yes (14)	Yes (10)	Yes (1)*	No
BAG implant				
Placement/size			Optimal (13)†	Optimal (12)‡
Stability			Unchanged	Unchanged
Migration			No	No
Resorption			No	No
Infection of implant			No	No
Position of implant to infraorbital nerve			Lower side of implant (14)	Lower side of implant (14)

*BAG implant was too small in AP-dimension.

†One BAG implant was too small and one too large.

‡The BAG implant was not optimally placed in 2 cases.

plant must extend over the stable bone in the orbital floor.

Persistent enophthalmos occurred in 4 patients, and they required reoperation. There was preoperative total nerve paresthesia in 9 patients (32%) and partial postoperative nerve paresthesia in 5 patients (17%) (Table 1). This persisted in 5 patients (18%) at 1 year. Minimal exploration of the infraorbital nerves at the time of BAG implantation showed that the nerves were intact, and any loose or sharp bone fragments were judiciously removed from the perimeter of the intraorbital foramen. The implants did not appear to have any toxic effect on the nerves.

Primary reconstruction of the orbit was carried out in all cases of diplopia (17) not regressing within 2 to 3 days of injury. Postoperatively, only 2 of the patients had diplopia when tested using red-green eye-glasses, whereas 3 others had other problems associated with diplopia (Table 1), which were corrected using eye-glasses or orthoptic rehabilitation.

Access to the orbital floor for implant surgery was obtained by a transconjunctival or subciliary incision for access and aesthetic reasons. In all cases of orbital floor defects where BAG implants were used, the size and position of the implant depended on the degree of enophthalmos and the size of the defect. The implant was placed over the stable edge of the fractured orbital bone (Figs 2, 3). In all patients except one, the correct size implant for the defect was used according to the opinion of the surgeon during the operation. In the 1 patient, the implant had to be removed because

it was not a correct size (Table 2). There were no postoperative complications, such as eyelid distortion, displacement of the implant, or any complications caused by the implant material. The BAG material did not cause any changes in laboratory studies, such as inflammatory parameters or liver and kidney function.

The results of this study show that BAG is a promising alloplastic implant material for the reconstruction of orbital floor defects. It is bioactive, bacteriostatic, thin, and nonresorbable. Because of its biocompatibility, bioactivity, and lack of donor site morbidity, it shows great promise as a well-tolerated material for use in orbital floor surgery. It provides a favorable environment for an uncomplicated healing process and new bone formation in the orbital floor.

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