Conical Biosilicate Implant for Volume Augmentation in Anophthalmic Sockets

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Abstract: The ideal implant for anophthalmic socket reconstruction has yet to be developed. Biosilicate, a highly bioactive glass-ceramic, has been used in the composition of conical implants, which were initially tested in rabbit orbits with excellent results. However, the use of this material and the conical shape of the implants require further study in the human anophthalmic socket. Thus, we propose the use of a new conical implant composed of Biosilicate for orbital volume augmentation in anophthalmic sockets. This prospective, randomized study included 45 patients receiving conical implants composed of either Biosilicate or polymethylmethacrylate (control). Patients were evaluated clinically before and 7, 30, 60, 120, and 180 days after implantation. Systemic evaluations, laboratory tests, and computed tomography of the orbits were performed preoperatively and 180 days postoperatively. Both groups had good outcomes with no significant infectious or inflammatory processes. Only 1 patient, in the Biosilicate group, had early implant extrusion. Laboratory tests were normal in both groups. Computed tomography scans showed that the implants in both groups were well positioned. The new conical implant composed of Biosilicate was successfully used for anophthalmic socket reconstruction. This implant may provide a good alternative to the only conical implant currently available on the market, which is composed of porous polyethylene.

Key Words: Anophthalmic socket, biosilicate, conical implant, polymethylmethacrylate

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The first implants effectively used for anophthalmic socket reconstruction were glass spheres.[1] In an attempt to find the optimal orbital implant, a number of other implants have been introduced over time, composed of materials such as rubber, ivory, wood, cork, silver, gold, polymethylmethacrylate (PMMA), silicone, hydroxyapatite, aluminum oxide, and porous polyethylene.[2] However, the ideal implant for anophthalmic socket reconstruction has yet to be developed.

Bioglass, the best known bioactive glass, has shown good integration with the host tissue when used as an anophthalmic socket implant.[3] Heat treatments can be applied for glass crystallization by combining glass with ceramics, thus promoting integration with biological tissues.[4] An example is Biosilicate, a highly bioactive glass-ceramic. When in contact with body fluids, the outer layer of Biosilicate undergoes chemical reactions that make the material biocompatible, with results similar to those of the gold standard Bioglass 45S5.[3–5]

Biosilicate has osteogenic and angiogenic potential, and conical implants composed of this material were initially tested in rabbit orbits with excellent results.[6,7] However, the use of this material and the conical shape of the implants require further study in the human anophthalmic socket. As the orbit is conical, conical implants would theoretically have greater contact with the extrinsic muscles. Although some conical implants have been previously suggested,[8–10] there is currently only 1 conical implant available on the market, composed of porous polyethylene (Medpor, Porex Surgical Inc., Fairburn, Georgia, USA), but there are no reports of its effectiveness.[8] Thus, the authors propose the use of a new conical implant composed of Biosilicate for orbital volume augmentation in anophthalmic sockets.

METHODS

This prospective interventional phase III study included 45 patients (23 men and 22 women) who underwent orbital volume augmentation in grade 1 or 2 anophthalmic sockets[11] from 2013 to 2016 at 2 university hospitals: Hospital de Clinicas of the State University of São Paulo (UNESP) and Hospital de Clinicas of the University of São Paulo (USP), both located in São Paulo, Brazil. Patients with grade 3 or 4 anophthalmic sockets, with other associated factors, such as orbital fractures and acute infectious diseases, and who refused to participate in the study were excluded.

Ethics committee approval was obtained from UNESP Medical School, and the study followed the tenets of the Declaration of Helsinki. Informed consent was obtained from all individual participants included in the study.

Patients were randomly assigned in a 2:1 ratio to receive a conical implant composed of either Biosilicate or PMMA (control), that is, 2 Biosilicate participants for each PMMA (control) participant. All implants were conical and identical in design, and manufactured in the Vitreous Materials Laboratory at the Federal University of São Carlos, São Paulo, Brazil, with an anterior diameter of 12 mm and length of 18 mm (18-mm implants) or with

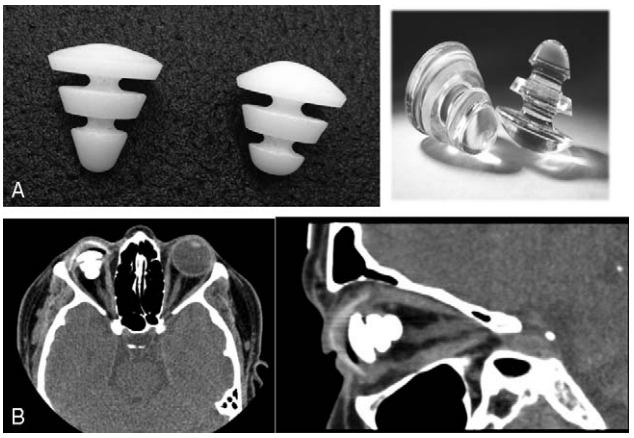

FIGURE 1. (A) Biosilicate tapered implants (left) and PMMA implants (right). Both implants are represented in the 2 sizes used in the study (18 mm and 16 mm). (B) CT scan of a patient with a 16-mm Biosilicate implant showing good implant positioning, without rotation, and the final maintenance of the orbital volume after 180 days of follow-up. CT, computed tomography; PMMA, polymethylmethacrylate.

an anterior diameter of 10 mm and length of 16 mm (16-mm implants) (Fig. 1A). The corresponding cone volume, calculated using Archimedes' principle, was $1.4 \pm 2\,cm^3$ for 16-mm implants and $1.75 \pm 0.2\,cm^3$ for 18-mm implants, and this volume was equivalent to a sphere of 14 mm and 16 mm, respectively. Implant size was selected based on the initial evaluation of the orbit using computed tomography (CT) and on socket grade.

Patients were evaluated before and 7, 30, 90, 120, and 180 days after implantation by slit-lamp examination. Clinical signs were classified as mild (+), moderate (2+), or severe (3+).[12] Systemic evaluations were performed preoperatively and 180 days postoperatively to assess liver function (bilirubin, glutamic oxaloacetic transaminase, and glutamic pyruvic transaminase), cardiac function (serum creatine phosphokinase), and renal function (urea, creatinine, and potassium). Computed tomography scan was performed preoperatively and 180 days postoperatively to evaluate orbital volume, implant position, and presence of fluid collections or inflammatory processes around the implant. Orbital volume (in cm^3) was measured on CT scans, using the orbital rim as the anterior border, running medial to the nasomaxillary suture, and the optic foramen as the posterior border. For the largest diameter of the orbit, the landmarks were the frontal bone superiorly and the maxillary bone/orbital process of the zygomatic bone inferiorly.[13]

SURGICAL TECHNIQUE

Evisceration, enucleation, and secondary implantation procedures were performed under general anesthesia and subconjunctival injection of lidocaine associated with 2% vasoconstrictor (Xylestesin, Cristália, São Paulo, Brazil) under aseptic and antiseptic conditions. Evisceration was performed by opening Tenon capsule and conjunctiva, completely removing the cornea and ocular contents and opening the sclera on the posterior aspect with a circular aperture around the optic nerve to facilitate the placement of the conical implant. The sclera and conjunctiva were closed with interrupted nonabsorbable 6-0 braided sutures (Mersilene 6-0, Ethicon, Johnson & Johnson, São Paulo, Brazil). Enucleation was performed by opening Tenon capsule and conjunctiva, identifying the extraocular muscles, which were disinserted, sectioning the optic nerve and removing the ocular bulb. The conical implants were wrapped in donor sclera, except for the posterior region of the implant. The extraocular rectus muscles were reattached to the donor sclera with interrupted nonabsorbable 6-0 braided sutures (Mersilene 6-0). Tenon capsule and conjunctiva were closed in the same manner as in evisceration. Secondary implants were wrapped in donor sclera, and the procedure followed the same steps previously described for enucleation. After any of the surgical procedures, patients received a subconjunctival injection of gentamicin (80 mg/2 mL) (Mentcorp, São Paulo, Brazil) and dexamethasone (2 mg/mL) (Aché, São Paulo, Brazil), and a pressure patch was applied to the operated eye for 12 hours.

RESULTS

The total sample consisted of 45 patients, with a mean age of 43.6 ± 19.2 years (median, 43 years; range, 6–80 years). The entire eye or its content was removed mainly due to ocular trauma (21%), absolute glaucoma (18%), phthisis bulbi (13%), uveitis (13%), endophthalmitis (8%), and retinal detachment (8%). Thirty-two (71%) patients had grade 1 anophthalmic sockets, while 13 (29%) had grade 2. Thirty-nine (87%) patients underwent evisceration, 5 (11%) underwent secondary implantation, and only 1 (2%) underwent enucleation. Orbital volume differed significantly according to the cause of eye loss, with decreased orbital volume in patients with phthisis bulbi and increased volume in those with glaucoma ($P = 0.019$; analysis of variance). There was no significant correlation between age, implant material, implant size, socket grade, or surgery type ($P > 0.05$; Fischer exact test).

The Biosilicate (n = 30) and PMMA (n = 15) groups did not differ in sex (51% male), laterality (53% of implants on the right side), or implant size (55% of 16-mm implants). Thirty-eight (84.5%) patients completed the 180-day follow-up, 25 (67%) in the Biosilicate group and 13 (33%) in the PMMA group. All preoperative and 180-day postoperative laboratory results were within normal limits. No patient developed inflammation or infection of the socket postoperatively. Twenty-seven (71%) patients underwent CT before and 180 days after implantation (Fig. 1B). There was no evidence of implant migration or signs of fluid collection or inflammatory processes in the sockets in either group. In the Biosilicate group, 1 (2.5%) patient had conjunctival dehiscence, which resolved spontaneously with favorable outcome. Another patient (2.5%) had conjunctival and scleral dehiscence, with severe chemosis (4+) and secretion (3+) shortly after surgery, leading to implant exposure on postoperative day 2, which progressed to implant extrusion within 30 days of implantation. After 30 days, 1 (2.5%) patient had conjunctival granuloma, which was removed without sequelae or recurrence, 2 (5%) patients who received 16-mm implants had orbital volume deficiency, and 1 (2.5%) patient died due to a complication unrelated to the procedure.

DISCUSSION

Overall orbital volume in grade 1 and 2 anophthalmic sockets was increased using the new conical Biosilicate implant proposed here. The implants used here were identical in weight, volume, and design and differed only in the composition, where Biosilicate implants had a mildly rough surface, due to the inherent roughness of the material, and PMMA (control) implants had a smooth surface. The implants were wrapped in donor sclera to reduce the risk of dehiscence.[11] The surgical technique involved a circular opening around the optic nerve or an opening on the posterior aspect of the sclera so that the conical implant could be "buttoned" in the sclera opening, thus facilitating placement and avoiding migration. Although the placement of Biosilicate implants was a little more difficult because of their mildly rough surface, both implant types were easy to place.

A number of ceramics, whether combined or not with glass, have been introduced over the years, with varying levels of bioactivity mainly due to their chemical nature and degree of crystallization.[1,6,14] Biosilicate was first described about 20 years ago and is considered a highly bioactive glass-ceramic material that interacts with the

biological system. It binds to bone and soft tissues by forming a hydroxycarbonate-apatite layer when in contact with body fluids, with no adverse reactions when implanted in the body, as confirmed by our results.[3,5,15] In addition, Biosilicate has antimicrobial properties that can facilitate tissue regeneration, with effects similar to those of Bioglass.[3,16–18]

Implants composed of inert materials, such as glass and PMMA, are nonintegrated implants used to augment volume in anophthalmic sockets. Because PMMA implants are the most common type of implants used in Brazil,[19] they were used as controls in our study. All patients, regardless of implant type, had satisfactory outcomes, except for 1 patient in the Biosilicate group who had early implant extrusion, probably related to a technical problem, and 1 in the Biosilicate group who had early suture dehiscence, with good subsequent evolution.[14–18,20]

The clinical signs observed in the postoperative period were those expected after a surgical procedure, with no significant difference between the groups. Postoperatively, there were no signs of inflammation in the sockets in either group. Although it is theoretically expected that PMMA implants will be more likely to rotate due to lack of integration,[14,20] none of the PMMA implants rotated probably because of their placement inside the scleral cavity or the conical shape of the implant with grooves on the surface, which increased implant contact with the host tissues, thus facilitating integration.

In conclusion, the authors have described the use of a new conical Biosilicate implant for orbital volume augmentation in anophthalmic sockets that can result in well-positioned implants, with few inflammatory signs and no systemic effects. The conical shape of the implant is another successful innovation. Therefore, the authors believe that conical Biosilicate implants may provide a good alternative to the implant currently available on the market, which is composed of porous polyethylene and, since it is not manufactured in Brazil, has to be imported at great cost. Based on the satisfactory outcomes without any severe complications, this new conical implant composed of Biosilicate represents a promising addition to the therapeutic arsenal for the treatment of the anophthalmic socket.

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