ORIGINAL ARTICLE

Secondary Reconstruction of Posttraumatic Enophthalmos

Prefabricated Implants vs Titanium Mesh

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Objective: To compare individually prefabricated computer-assisted designed/computer-assisted manufactured (CAD/CAM) glass-bioceramic implants with nonpreformed titanium meshes for orbital floor reconstruction in secondary correction of enophthalmos.

Methods: In a nonrandomized, comparative, prospective cohort study, 2 groups of 10 patients received secondary correction of enophthalmos with CAD/CAM implants in one group and titanium meshes in the other. Relative enophthalmometry and exophthalmometry data were assessed preoperatively, at the end of the operation, at day 90 postoperatively, and at day 365 postoperatively.

Results: In both groups, the globe position improved significantly at the end of the operation ($P = .005$ in both groups). At day 90, there was a significant tendency toward relapse of enophthalmos in both groups ($P = .005$ in the CAD/CAM group and $P = .008$ in the titanium mesh group). However, the globe position did not change significantly between postoperative days 90 and 365 in both groups ($P = .57$ in the CAD/CAM group and $P = .35$ in the titanium mesh group).

Conclusions: Individually prefabricated CAD/CAM glass-bioceramic implants and nonpreformed titanium meshes produce similar results in secondary enophthalmos correction. Because of higher costs, the use of CAD/CAM implants should be confined to selected cases in secondary enophthalmos correction.

Arch Facial Plast Surg. 2011;13(4):271-277

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ENOPHTHALMOS IS A SEVERE complication of inappropriate primary reconstruction of zygomatic fractures and fractures of the orbital floor.[1] The goal of secondary reconstruction procedures is restoring symmetry of globe positions for functional as well as aesthetic reasons.[2] Many different materials have been used for this purpose.[1]

Autogenous bone grafts are well-established material for orbital floor reconstruction.[3] However, their use is associated with many disadvantages. Harvesting of cells for these grafts requires additional operating time and leads to some donor site morbidity. Contouring the bone grafts to a proper size sometimes is difficult. The most important concern regarding this procedure—resorption of the grafts—leads to uncertainty regarding the long-term success of the enophthalmos correction.[4] As a consequence, alloplastic materials have been identified as alternatives to autogenous bone grafts. Titanium meshes have become popular alloplastic material for orbital floor reconstruction because of their relative ease of handling.[5]

For more than a decade, implants for orbital floor reconstruction have been built preoperatively in a computer-aided, individually shape-adapted technique.[6-10] Although many studies[3,5,11-17] have compared the use of different materials in the correction of orbital deformity, none of them has evaluated computer-aided, individually shape-adapted implants for use in secondary orbital floor reconstruction (**Table 1**). Therefore, the objective of the present prospective cohort study was to compare computer-assisted designed/computer-assisted manufactured (CAD/CAM) glass-bioceramic implants with nonpreformed titanium meshes in secondary correction of enophthalmos.

METHODS

Between January 1, 2004, and December 31, 2009, a total of 20 patients with unilateral enophthalmos of at least 2 mm were enrolled in

Table 1. Comparative Studies on Materials for Orbital Wall Reconstruction

Source	No. of Patients	Study Design	Treatment	Material	Follow-up Interval	Outcome
Scolozzi et al,[11] 2010	20	Prospective	Primary	Preformed and nonpreformed titanium mesh	6-12 mo	Similar results
Bayat et al,[12] 2010	22	Randomized	Primary	Conchal cartilage; nasal septal cartilage	6 mo	Better results with nasal septal cartilage
Guo et al,[13] 2009	61	Retrospective	Primary	Calvarial bone graft; preformed individually shaped titanium mesh	NR	Better results with preformed individually shaped titanium mesh
Al-Sukhun and Lindqvist,[14] 2006	39	Prospective	Primary	Anterior iliac crest; P(L/DL)LA	36 mo	Similar results
Nam et al,[15] 2006	405	Retrospective	Primary	Porous polyethylene; hydroxyapatite	NR	Better results with porous polyethylene
Ellis and Tan,[5] 2003	58	Retrospective	Primary	Calvarial bone graft; nonpreformed titanium mesh	NR	Similar results
Siddique and Mathog,[3] 2002	22	Retrospective	Primary	Calvarial bone graft; anterior iliac crest	24 mo	Similar results
Dacho et al,[16] 2002; Dietz et al,[17] 2001[a]	28	Randomized	Primary	Nonpreformed titanium mesh; PDS sheet	NR	Similar results

Abbreviations: NR, not reported; PDS, polydioxanone; P(L/DL)LA, poly-L/DL-lactide.
[a]The studies by Dacho et al[16] and Dietz et al[17] are identical.

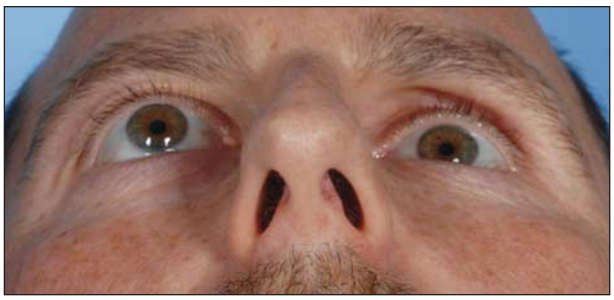

Figure 1. Patient 3 of the group receiving CAD/CAM (computer-assisted designed/computer-assisted manufactured) glass-bioceramic implants. Residual enophthalmos of the left eye after primary reconstruction of the orbital floor with a polydioxanone sheet.

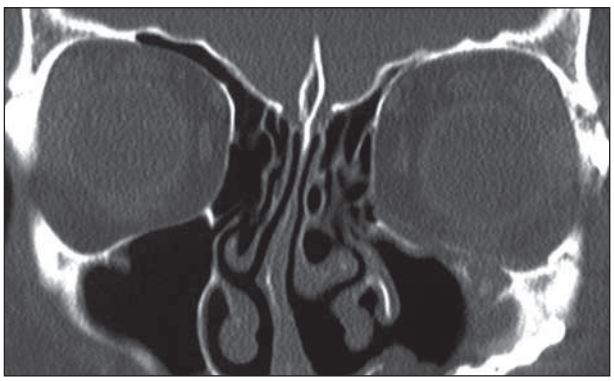

Figure 2. Preoperative computed tomographic scan of the patient in Figure 1.

a nonrandomized, comparative, prospective cohort study of secondary surgical intervention to correct enophthalmos. All patients had undergone an operation because of orbital fractures at least 6 months before they were included in the study. For primary reconstruction of the orbital floor, polydioxanone sheets had been used in all cases.

Before the second operation, orbital computed tomographic (CT) scans were performed (Somatom Sensation 16, 64, or 128; Siemens, Erlangen, Germany) using contiguous 1-mm-thick axial sections with a gantry tilt of 0°. The patients were examined routinely at the Department of Ophthalmology preoperatively and 2 days postoperatively. Clinically detectable disorders of ocular motility and diplopia were documented. Measurement of intraocular pressure was not included in the ophthalmologic routine examinations. Exclusion criteria included ocular hypotony, untreated nasal bone fractures, previous bilateral orbital fractures, reduced visual acuity, refractive errors, and intraocular trauma. All patients provided informed consent for participation in the study. The study was approved by the Institutional Ethics Committee of the University of Erlangen-Nuremberg (approval No. 2221).

Instead of Hertel measurements, enophthalmometry and exophthalmometry were carried out with an optical 3-dimensional sensor (CAM^{3D}; 3D-Shape, Erlangen, Germany) according to the method described by Kramer et al[18] and Nkenke et al.[19,20] Enophthalmometry and exophthalmometry data were assessed directly before the operation, at the end of the operation, and 3 months and 12 months after the procedure.

All operations were performed by the same surgeon (E.N.). In the first cohort of 10 consecutive patients, CAD/CAM individually shape-adapted glass-bioceramic implants (Bioverit II; 3di, Jena, Germany) were used for enophthalmos correction by reconstruction of the orbital floor (**Figures 1**, **2**, **3**, **4**, **5**, and **6**). If a correctly positioned implant caused exophthalmos intraoperatively, its size was reduced with a diamond burr. If a CAD/CAM implant did not correct for the enophthalmos sufficiently, the posterior aspect of the implant within the orbit was lifted to increase the volume restriction of the orbit.

In the second cohort of 10 consecutive patients, titanium meshes (MatrixMIDFACE orbital floor; Synthes, Oberndorf, Switzerland) were shaped and bent intraoperatively and fit into the orbit to position the globe in the intended direction (**Figures 7**, **8**, **9**, **10**, **11**, and **12**).

In all patients, the approach to the orbit was chosen according to the incision made during the primary surgical procedure. Ceramic implants, as well as titanium meshes, were fixed by 2.0-mm osteosynthesis screws (KLS Martin, Tuttlingen, Germany). The operation time was documented.

Postoperatively, for radiologic monitoring, Water views were obtained. Computed tomographic scans or cone beam CT scans (3D eXam; KaVo, Biberach, Germany) were per-

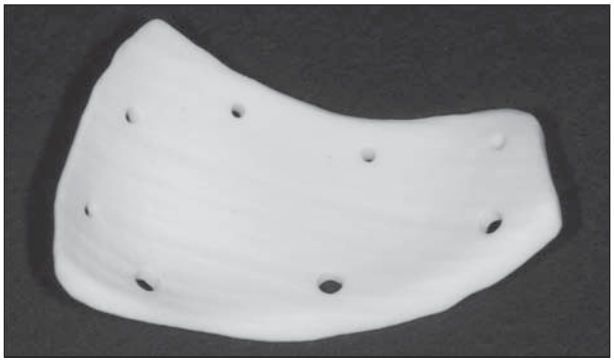

Figure 3. Computer-assisted design/computer-assisted manufacturing glass-bioceramic implant for orbital wall reconstruction of the patient in Figure 1.

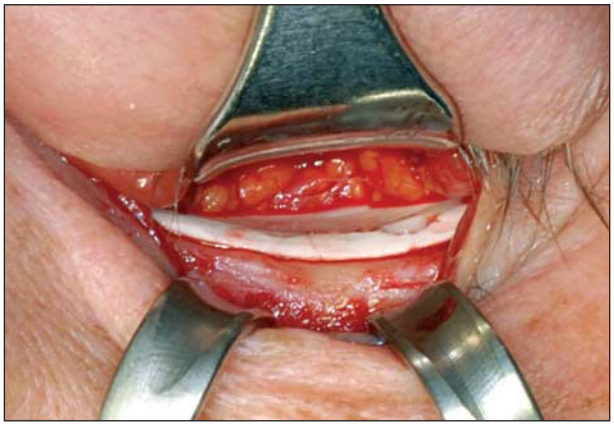

Figure 4. Intraoperative situation after insertion of the computer-assisted designed/computer-assisted manufactured glass-bioceramic implant in the left orbit of the patient in Figure 1.

formed only if they were deemed necessary during the postoperative ophthalmologic control examination.

Mean (SD) values are given. For comparison of continuous variables in paired samples, the Wilcoxon rank sum test was used; for unpaired samples, the Mann-Whitney test was used. *P* values ≤ .05 were considered significant. The calculations were made using commercial software (SPSS Version 14.0 for Windows; SPSS, Inc, Chicago, Illinois).

RESULTS

The group that received CAD/CAM glass-bioceramic implants included 9 men and 1 woman (mean age, 36.2 [15.5] years). In the titanium mesh group, all 10 patients were men (mean age, 33.6 [11.9] years). Age did not differ significantly between the groups (*P* = .76).

Preoperatively, the relative size of enophthalmos in the CAD/CAM group and the titanium mesh group was –3.6 (0.8) mm and –3.9 (1.0) mm, respectively (*P* = .45). The implants were placed in the orbit using a subciliary approach in 6 patients of the CAD/CAM group and 5 patients of the titanium mesh group and using a transconjunctival approach in 3 patients of the CAD/CAM group and 5 patients of the titanium mesh group. In the final patient of the CAD/CAM group, the transconjunctival approach was combined with a lateral canthotomy. Intraoperatively, the size of 6 of the CAD/CAM implants had to be reduced because the original shape caused exophthalmos. In 2 of the patients, the posterior aspect of the

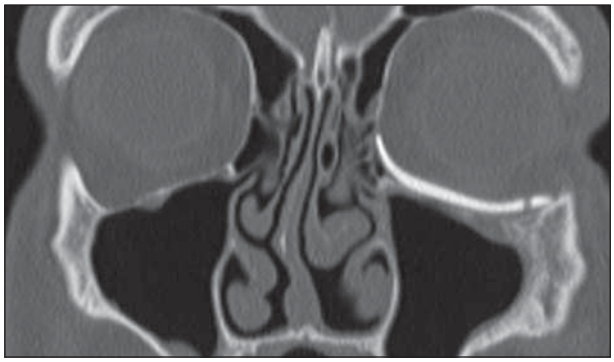

Figure 5. Postoperative computed tomographic scan of the patient in Figure 1 after insertion of the computer-assisted designed/computer-assisted manufactured glass-bioceramic implant in the left orbit.

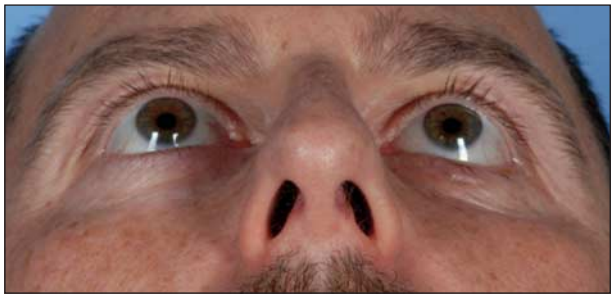

Figure 6. The patient in Figure 1 twelve months after correction of enophthalmos of the left eye.

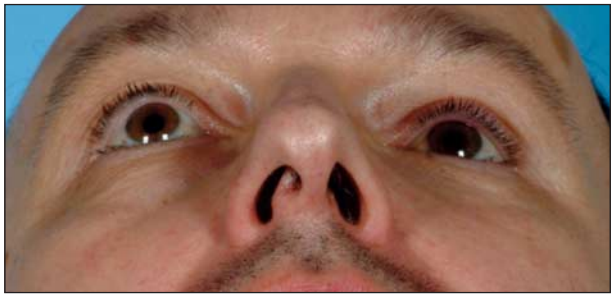

Figure 7. Patient 6 of the group receiving nonpreformed titanium meshes. Residual enophthalmos of the left eye after primary reconstruction of the orbital floor with a polydioxanone sheet.

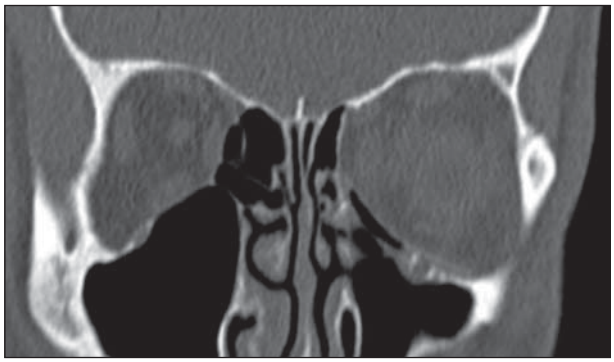

Figure 8. Preoperative computed tomographic scan of the patient in Figure 7.

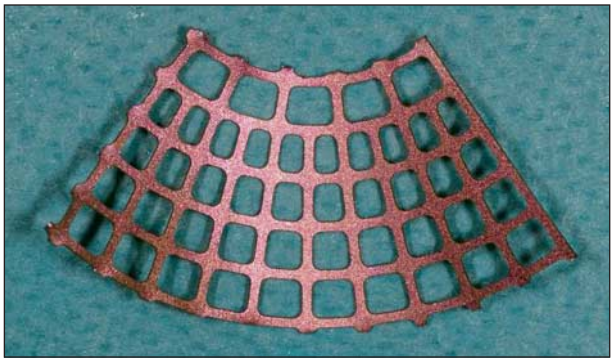

Figure 9. Intraoperatively formed titanium mesh for orbital wall reconstruction of the patient in Figure 7.

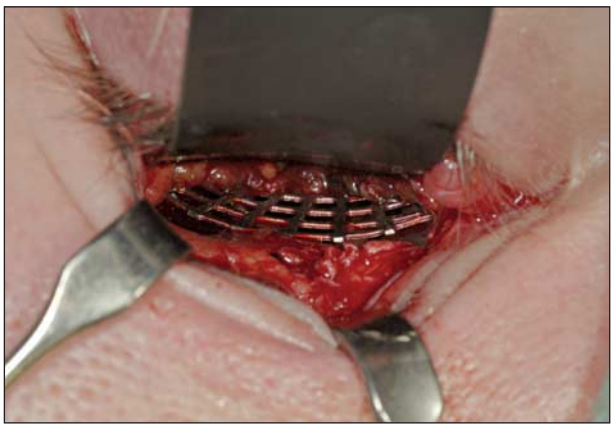

Figure 10. Intraoperative situation after insertion of the titanium mesh in the left orbit of the patient in Figure 7.

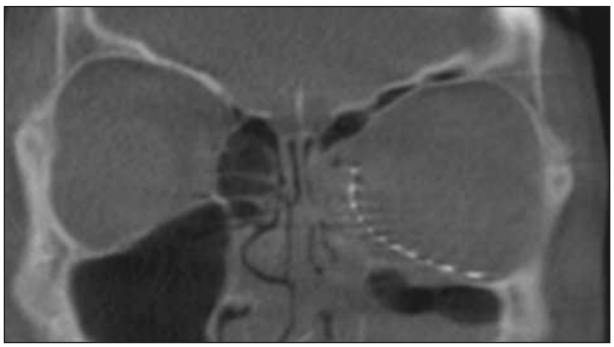

Figure 11. Postoperative cone beam computed tomographic scan of the patient in Figure 7 after insertion of the titanium mesh in the left orbit.

implant had to be lifted more than originally planned to gain additional projection of the globe in an anterior direction. The operation time was 58.5 (17.8) minutes and 65.8 (14.6) minutes in the CAD/CAM and titanium mesh groups, respectively ($P = .38$).

At the end of the operation, both groups demonstrated slight exophthalmos of the corrected side (**Table 2**). The globe position was changed significantly ($P = .005$ in both groups). In 3 patients of the CAD/CAM group and 2 patients of the titanium mesh group, postoperative CT or cone beam CT scans were performed because of reduced vision (1 patient of the CAD/CAM group) and suspected retrobulbar hematoma (2 patients of the CAD/CAM group and 2 patients of the titanium mesh group). None of the patients required additional surgical intervention.

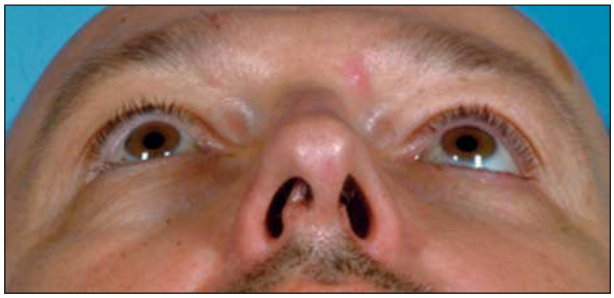

Figure 12. The patient in Figure 7 twelve months after correction of enophthalmos of the left eye.

During the follow-up examinations, there was a tendency toward relapse of enophthalmos in both groups when the enophthalmometry and exophthalmometry data at the end of the operation and at postoperative day 90 were compared (Table 2; $P = .005$ in the CAD/CAM group and $P = .008$ in the titanium mesh group). However, the enophthalmometry and exophthalmometry data assessed at day 90 and day 365 did not differ statistically significantly for either group ($P = .57$ in the CAD/CAM group and $P = .35$ in the titanium mesh group). In both groups, the globe position of the affected side was improved significantly at day 365 compared with the preoperative status ($P = .005$ for both groups). At the end of the follow-up period, none of the patients in either group had developed diplopia. There was no need for additional revisional operations.

COMMENT

Disfiguring enophthalmos after orbital trauma is a common problem in clinical practice. After primary surgical repair of orbital fractures, the incidence of residual enophthalmos has been reported[21] to be high, independent of early or late orbital floor repair. The large number of studies[2,7,9,10] on secondary correction of postoperative residual enophthalmos reflects a significant incidence of treatment failure with the primary surgical procedure. Enophthalmos occurs in up to 10% of the cases of primary reconstruction of the orbital floor.[15] All patients in the present study had received polydioxanone sheets during the primary operation. This material dissolves over time. The development of enophthalmos might have been avoided by using a material for primary reconstruction of the orbital floor that does not dissolve. Additional studies are needed to clarify this possibility.

Therefore, it is important to know which material for orbital floor reconstruction performs best in secondary correction of enophthalmos. To our knowledge, no comparative trials have been performed (Table 1). Therefore, our goal in conducting this prospective cohort study was to compare CAD/CAM glass-bioceramic implants with nonpreformed titanium meshes in secondary correction of enophthalmos.

To perform enophthalmometry and exophthalmometry in a precise and reproducible way, we selected a method that is based on the use of an optical 3-dimen-

Table 2. Results of Optical Enophthalmometry and Exophthalmometry in Patients Undergoing Secondary Correction of Unilateral Enophthalmos

Patient No.	Relative Enophthalmometry and Exophthalmometry Data, mm			
	Preoperative	At the End of Surgery	Postoperative Day 90	Postoperative Day 365
Group Receiving CAD/CAM Glass-Bioceramic Implants				
1	–2.4	1.2	0.2	0
2	–3.8	0.8	0	0
3	–5.1	1.4	0.9	0.9
4	–3.2	–0.4	–1.1	–0.5
5	–4.5	0.5	–0.2	–0.7
6	–2.3	0	–0.8	0
7	–4.7	0.9	0.2	–1.0
8	–3.3	1.5	0.6	0.4
9	–2.9	–0.7	–1.2	0.8
10	–4.2	–1.0	–1.8	–0.8
Mean (SD)	–3.64 (0.97)	0.42 (0.90)	–0.32 (0.87)	–0.39 (1.06)
P Value		.005[a]	.005[b]	.57[c]
Group Receiving Nonpreformed Titanium Meshes				
1	–3.5	2.1	0.8	0.5
2	–2.3	0.7	0.6	0.3
3	–2.8	–0.3	–0.8	–0.8
4	–4.6	–0.7	–0.7	–0.7
5	–3.6	0.3	0.0	–0.2
6	–2.9	1.4	1.3	0.9
7	–5.2	0.2	–0.7	–0.5
8	–4.8	1.1	0.5	0.6
9	–4.7	–0.9	–1.1	–0.8
10	–5.1	0.2	–0.3	0.0
Mean (SD)	–3.95 (1.06)	0.41 (0.94)	–0.04 (0.81)	–0.07 (0.63)
P Value		.005[a]	.008[b]	.35[c]

Abbreviation: CAD/CAM, computer-assisted designed/computer-assisted manufactured.
[a] Compared with preoperative data.
[b] Compared with data at the end of surgery.
[c] Compared with data at postoperative day 90.

sional sensor and has been used for several different indications.[18-20,22,23] Although the technique is complex, optical enophthalmometry and exophthalmometry can be used not only for preoperative diagnosis and postoperative follow-up but also within the operating room.

Among the many different materials that are used for orbital floor reconstruction, titanium meshes are very popular. One of the reasons seems to be that they provide good reconstruction because of the ease with which titanium meshes can be manipulated to adapt to the intricate contours of the internal orbit.[5] The CAD/CAM individually prefabricated implants are also widely accepted for orbital floor reconstruction and show good functional and aesthetic results.[8] These implants are thought to reduce the need for intraoperative adaption.[1] However, in the present study, as well as in previous trials,[8] additional intraoperative shaping of the implants or altering of their preoperatively planned position within the orbit was frequently necessary. There are several reasons for this problem that reduce the effectiveness of CAD/CAM implants. First, although CT scans are very accurate, virtual reconstruction as the basis for planning the implant still differs slightly from the real situation.[24] This is one reason that intraoperative correction of the shape of the implant may become necessary. Another aspect is that a relative deficiency of orbital tissue resulting from bony volume expansion is not the only cause of posttraumatic enophthalmos; an absolute deficiency of tissue content resulting from fat loss or cicatricial contraction may also be responsible.[14] If this latter factor is present, anatomically adequate reconstructed orbital floor will not resolve enophthalmos. Therefore, it becomes clear that implants designed by mirroring reference data from the intact orbit, as in the present study, do not guarantee perfect correction of enophthalmos. As a consequence, it is most important that the surgeon is closely involved in the production process of the CAD/CAM implants. He or she must check the design of the implant and change it if it does not seem to be appropriate. A crucial aspect is the dorsal extension of the implant. Compression of the optic nerve by the implant should be avoided; however, if an implant is too small, it will not allow sufficient reduction in the volume of the orbit and enophthalmos will not be corrected adequately. Therefore, especially with cases in which a loss of soft tissue in the orbit has to be assumed, a more pronounced extension of the implant will be chosen to allow perfect correction of enophthalmos. This sometimes results in a nonsymmetrical anatomic reconstruction. However, the primary goal of the reconstruction is correction of enophthalmos. For this reason, symmetry of the supporting bone does not play a major role.

When the volume of orbital contents is reduced as a consequence of previous trauma and the anatomically correct reconstruction of the orbital floor does not lead to a sufficient correction of enophthalmos intraoperatively, an additional maneuver to neutralize this discrepancy is necessary. When this problem occurred in the present study, the prefabricated CAD/CAM implants were positioned within the orbit so that the posterior aspect was lifted more than originally planned to increase the volume restriction of the reconstructed orbit.

If an individually shaped prefabricated CAD/CAM implant is too large and produces exophthalmos, its size must be reduced. With the glass-bioceramic implants used in the present study, the shape can be corrected without major problems because of the good filing and milling properties of the material.[8] Water-cooled carbide or diamond drills should be used with 5000 to 10 000 rpm. However, this procedure can be time-consuming and might need to be repeated until the optimal shape of the implant has been achieved. As a consequence, although the reconstruction of the orbital floor was carried out slightly faster with CAD/CAM glass-bioceramic implants, the difference in operative time compared with the time needed for nonpreformed titanium meshes was not statistically significant. Considering these results, the report[8] that use of individually shaped CAD/CAM implants shortens operative time seems not to be realistic. Other studies[5] have documented that titanium meshes can be easily contoured to adapt to the intricate shape of the internal orbit, thereby providing good reconstruction without a pronounced increase in operative time.

Another problem specific for glass-bioceramic implants is the fact that a minimum thickness of 3 mm has been recommended for this material.[8] It has been shown that, to achieve a 1-mm advancement of the globe, a volume restriction of approximately 1.5 cm^3 is needed.[21] This aspect has to be considered while planning and designing a CAD/CAM glass-bioceramic implant when only small distances of advancement of the globe are necessary. In such cases, it sometimes will be impossible to generate a glass-bioceramic implant that restricts the intended volume reduction to the planned extent. In such circumstances, glass-bioceramic implants are not an alternative to titanium meshes.

Additional limitations of glass-bioceramic implants are production time and costs. It takes, on average, 2 days for a CAD/CAM glass-bioceramic implant to be planned and milled. However, this is a minor problem because secondary enophthalmos correction is an elective, rather than emergency, procedure. More important, the expenses for 1 CAD/CAM glass-bioceramic implant are 4- to 5-fold higher than those for a titanium mesh. These high costs for CAD/CAM implants limit their use to selected cases. Considering these limitations, as well as the lack of significantly improved effectiveness of CAD/CAM implants observed in this study, it seems that nonpreformed titanium meshes should be preferred in clinical practice.

Accepted for Publication: March 15, 2011.
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Author Contributions: All authors had full access to all the data in the study. Dr Stelzle takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Nkenke, Vairaktaris, and Holbach. *Acquisition of data:* Nkenke, Spitzer, Holbach, Knipfer, and Stelzle. *Analysis and interpretation of data:* Nkenke, Kramer, Stamminger, and Stelzle. *Drafting of the manuscript:* Spitzer and Knipfer. *Critical revision of the manuscript for important intellectual content:* Nkenke, Vairaktaris, Kramer, Stamminger, Holbach, and Stelzle. *Statistical analysis:* Nkenke, Kramer, Stamminger, Knipfer, and Stelzle. *Obtained funding:* Nkenke and Stamminger. *Administrative, technical, and material support:* Spitzer, Knipfer, and Stelzle. *Study supervision:* Nkenke, Vairaktaris, Kramer, and Holbach.
Financial Disclosure: None reported.
Funding/Support: The study was supported by grant NK 453/2-1 from the Deutsche Forschungsgemeinschaft and by the Erlangen Graduate School in Advanced Optical Technologies.

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