

Can customized implants correct enophthalmos and delayed diplopia in post-traumatic orbital deformities? A volumetric analysis

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Abstract. The purpose of this study was to determine whether orbital reconstruction with customized implants can correct post-traumatic orbital deformities such as late enophthalmos and delayed diplopia. The hypothesis proposed was that an overcorrection of the orbital volume is needed to resolve enophthalmos. A retrospective observational descriptive study was conducted. Patients with a major trauma who required customized orbital implants for the delayed treatment of unilateral orbital fractures that had initially been operated on using titanium mesh and/or osteosynthesis plates were included. The orbital volumes of the unaffected contralateral side, of the affected orbit after initial reconstruction with mesh, and of the affected orbit subsequently reconstructed with the customized implant were calculated. All of the patients included in this study had diplopia in the gaze position prior to the installation of the implant. In addition, they all had severe enophthalmos. After surgery, no patient with a customized implant showed diplopia. The enophthalmos was corrected in all but one case. On average, orbits reconstructed with customized implants had lower volumes compared to the unaffected contralateral side. In cases where the enophthalmos was resolved, the volume was reduced by an average of 8.55%. Further studies using a larger number of cases and with controlled volumetric corrections using CAD/CAM are needed.

Key words: orbital fractures; orbital customized implant; patient-specific implant; enophthalmos; diplopia; post-traumatic orbital deformities.

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Orbital fractures are among the most challenging lesions for the surgeon. Given that they are part of one of the most prominent units of the face, patients

notice asymmetries, deviations, and even the smallest of defects.¹ They are among the most common fractures in the middle third of the face and can result in significant

complications, such as enophthalmos, persistent diplopia, and vertical dystopia.^{2,3} The cause of enophthalmos is a difference between the volume of soft tissue in the

orbit and the bones in the orbital cavity. Factors like muscular entrapment and atrophy, or necrosis of fat tissue, can cause enophthalmos as well as diplopia.⁴ Enophthalmos of more than 2 mm typically indicates the need for a surgical repair.^{1,4} For its part, diplopia in the primary gaze position or in the first 20° of the field of vision also requires a surgical intervention to resolve it. In particular, defects located in the connection between the orbital floor and the medial wall, or those produced by a deficient malar reduction, are the most likely to cause enophthalmos and diplopia.⁴

Delayed orbital reconstruction is sometimes necessary due to an insufficient primary reconstruction or untreated orbital defects. These cases are referred either on a delayed basis for the treatment of side-effects like diplopia and enophthalmos, or else because of the existence of other lesions whose seriousness prevents initial maxillofacial treatment being undertaken. The purpose of surgery to treat enophthalmos and delayed post-traumatic diplopia is to restore the orbital form and volume and also the function and aesthetics of the orbital region.^{1,4} Accurate reconstruction of the orbital walls and volumes is critical and therefore the materials used to restore major defects must ideally be easy to adjust and construct in order to precisely restore the bone contours of the orbital anatomy.¹ In general, thin materials do not properly correct dystopia of the ocular globe, nor do they reduce the orbital volume enough to correct cases of established enophthalmos.⁵ What is needed for a delayed repair are materials capable of taking up more space and which maintain stability and an adequate orbital volume over time.^{5,6} In addition, they should be individualized according to the magnitude of the damage, the type of fracture, and the clinical and imaging findings.¹

Titanium implants have biomechanical properties similar to those of bone, good biocompatibility, and they produce fewer radiographic artefacts,⁶ allowing even nuclear magnetic resonance imaging to be used to evaluate the content, volume, and reconstruction of the orbit.^{7,8} Titanium offers sufficient resistance to physiological loads and its stiffness is close to the modulus of elasticity of cortical bone.⁹ Such implants can reproduce the contours precisely and restore the orbital volume,¹⁰ allowing them to restore orbital functionality, and they improve facial aesthetics in cases of post-traumatic orbital deformities. Lastly, they allow the surgical time for post-traumatic reconstruction to be reduced.¹⁰

Fat atrophy and the loss of bone and ligament support in orbital fractures

causes the orbital soft tissue to recede and be redistributed by gravity and the forces exercised by the contraction of scars.¹ Thus, in cases with enophthalmos and delayed diplopia, overcorrection of the orbital volume may be necessary to correct these side-effects.³ In addition, an overcorrection of the globe projection in the sagittal direction has been proposed to correct the post-traumatic orbital deformity, because there is generally a degree of relapse in globe projection following the correction of enophthalmos.¹¹

The objective of this study was to determine whether orbital reconstruction with customized implants can correct post-traumatic orbital deformities such as late enophthalmos and delayed diplopia. The hypothesis proposed was that an overcorrection of the orbital volume is needed to resolve late enophthalmos. The specific objective was to measure the volumetric changes in the orbit during the reconstruction sequence and to determine the overcorrection needed to improve the enophthalmos.

Materials and methods

A retrospective observational descriptive study of patients who needed treatment for late enophthalmos and delayed diplopia with customized orbital implants was performed. The sample for this study was selected from the population of patients referred to the authors' service for the treatment of orbital fractures between 1 January 2011 and 1 August 2014. The information was compiled from a chart review by three independent researchers. This study was approved by the ethics

committee of the hospital, which abides by the Declaration of Helsinki.

The inclusion criteria were (1) patient age over 18 years, (2) orbital fractures that were operated on and required reconstruction with customized implants in a second surgery to treat post-traumatic enophthalmos and diplopia that was not initially resolved with the use of titanium mesh, and (3) at least 1 year of monitoring post installation of the customized implant. The exclusion criteria were (1) bilateral orbital fractures, (2) patients with amaurosis and/or ocular prosthetics, and (3) customized implants with an extension to more than one skeletal structure.

The orbital reconstruction of all patients included in this study was initially undertaken in the acute setting at the study hospital or at an external centre, with the installation of preformed two-dimensional (2D) mesh or anatomical three-dimensional (3D) mesh using the MatrixORBITAL system (both by Synthes, Switzerland); in one case, titanium mesh plus high-density porous polyethylene was used (MEDPOR TITAN, Stryker) (Figs 1 and 2). The choice of the initial type of mesh to be used was at the discretion of the surgeon (Table 1).

If the mesh was inadequate for the reconstruction and support of the soft tissue due to the extension, comminution, and/or position of the fracture (Fig. 2b), with the result being diplopia and/or enophthalmos, a customized orbital implant was installed in a second surgery. In addition, where there was a need to restore the zygomatic projection, a customized orbital implant with a zygomatic extension was planned, thus restoring facial symmetry (Fig. 2c). All operations



Fig. 1. Initial 3D CT reconstruction of a 72-year-old man (patient 1) with extensive zygomatic complex and naso-orbito-ethmoid fractures due to a fall from 2 m height.

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