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A prospective multicenter study to compare the precision of posttraumatic internal orbital reconstruction with standard preformed and individualized orbital implants

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ABSTRACT

Purpose: A variety of implants are available for orbital reconstruction. Titanium orbital mesh plates are available either as standard preformed implants or able to be individualized for the patient. The aim of this study was to analyze whether individualized orbital implants allow a more precise reconstruction of the orbit than standard preformed implants.

Materials and methods: A total of 195 patients treated between 2010 and 2014 were followed up to 12 weeks after surgery. Of the patients, 100 had received standardized preformed and 95 individualized implants. The precision of orbital reconstruction with the different implants was determined by comparing the variances in the volume difference between the reconstructed and the contralateral orbit on the postoperative computed tomographic scans. Clinical volume-related parameters including globe position, vision, motility, and diplopia and surgical details including approach, timing and technique of implant modification, use of navigation, duration of surgery, as well as adverse events were documented.

Results: Orbital reconstruction was significantly more precise when individualized implants were used. The same was seen with intraoperative navigation. An overlap in the use of individualized implants and navigation makes it difficult to attribute the improved precision to a single factor.

Conclusion: This study demonstrated that individualization and navigation provide clinical benefit.

1. Introduction

Posttraumatic orbital defects are common injuries. Most are caused by direct blunt trauma to the orbits (Hosal and Beatty, 2002;

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Shere et al., 2004). Depending on the study, isolated involvement of the orbital floor occurs in 22%–47% of cases (Ellis et al., 1985; Antoun and Lee, 2008). Frequently, other orbital walls are also affected, in particular the medial orbital wall (Biesman et al., 1996). The main causes of orbital injuries are motor vehicle accidents and assaults (Cruz and Eichenberger, 2004; Shere et al., 2004; Chi et al., 2010). The most common injuries are the so-called blow-out fractures, in which the orbital wall and/or floor are affected but the orbital rim remains intact (Burm et al., 1999).

Patients with posttraumatic orbital defects present with a variety of clinical symptoms. Initial symptoms include swelling, hematoma, pain, motility disorders, sensory disturbances, and exophthalmos (Tong et al., 2001). Rarely, decreasing visual acuity secondary to orbital trauma may be caused by either sudden space-occupying intraorbital lesions, including retrobulbar hemorrhage (RBH), or direct damage to the prechiasmatic pathway (Zimmerer et al., 2014a, 2014b). When initial swelling and hematoma have disappeared and adequate treatment has not been rendered, serious complications may arise, including enophthalmos, hypoglobus, diplopia, restricted motility, and muscle entrapment. Enophthalmos can develop several weeks or months after surgery. It is usually caused by an increased orbital volume leading to a posterior displacement of the globe. Because initial clinical symptoms may vary and are sometime not reliable, three-dimensional (3D) imaging (computed tomography [CT], cone beam computed tomography [CBCT]) with 1-mm slices is advised to diagnose orbital fractures and to determine whether surgery is indicated. Following imaged-based diagnosis, a variety of different treatment algorithms are available.

For decades, a wide range of different resorbable and non-resorbable orbital implants have been used. Currently, titanium is regarded as the material of choice for orbital reconstruction due to its advantages including availability, biocompatibility, rigid fixation, and low susceptibility to infections (Tong et al., 2001; Ellis and Messo, 2004; Metzger et al., 2007). Its disadvantages are that it can be difficult to bend, to insert, and to contour.

There are 2 major categories of orbital titanium implants. The first is standard preformed orbital plates. Standard preformed orbital plates have been launched to overcome the difficulties with bending, insertion and creation of contours. They are available in different sizes, with the goal of providing a good anatomic fit and a stable reconstruction as long as they are in the correct position. The second category is individualized orbital implants. Titanium orbital implants can be individualized either digitally (computer-aided design [CAD]-based individualized orbital implants) or manually (non-CAD-based individualized orbital implants). All CAD-based individualized orbital implants share a virtual plan based on the patient's 3D scan, which is transferred into either a physical biomodel (custom-made model) or a digital blueprint, both serving for fabrication processes of the implant. Thus, all types of CAD-based individualized orbital implants require preoperative computerized planning. Using 3D planning software, the unaffected orbit can be mirrored to fit the affected side (Gellrich et al., 2002). Physical biomodels of the virtually reconstructed orbit provide bending templates for pre- and intra-operative use. This way, titanium meshes can be designed, bent, and sterilized preoperatively, together with the biomodel for intraoperative application (Metzger et al., 2006). Alternatively, the digital blueprint can be used to manufacture patient-specific titanium orbital implants. Recently, the process of selective laser melting (SLM; KLS Martin, Tuttlingen, Germany) has been introduced to generate patient-specific titanium orbital implants (Rana et al., 2015b). This method is currently considered the most accurate technique for orbital reconstruction (Rana et al., 2015a).

On the other hand, the design and shape of non–CAD-based individualized orbital implants can be free-handed, based on the intraoperative findings and the surgeon's experience. These orbital implants need to be adapted to the patient's anatomy intraoperatively and typically do not require preoperative planning.

Additional tools for quality assessment of implant shape and position include intraoperative navigation and/or intraoperative imaging (CBCT or Hybrid-CT). Like CAD-based individualized implants, intraoperative navigation also requires preoperative virtual planning. This allows matching implant position and shape with the preoperative virtual planning using infrared-based navigation without further radiation (Schramm et al., 2007; Schramm and Gellrich, 2010; Essig et al., 2013). This is particularly helpful in challenging cases. Moreover, intraoperative imaging, preferably using CBCT-based 3D C-arm devices, provides a tool for intraoperative evaluation of orbital reconstruction (Wilde et al., 2013). Particularly in complex trauma cases, this technique helps to reduce the number of secondary interventions (Wilde and Schramm, 2014).

To date, there has been no study comparing the precision of internal orbital reconstruction using individualized or preformed orbital implants. The purpose of this study was to do this by measuring both orbital volumes and volume-related clinical parameters in patients treated with either implant.

2. Materials and methods

2.1. Ethical and legal background

The trial was carried out following approval of the local ethical committee of each of the participating hospitals. The study was funded by AOCMF and sponsored by AOCID (AO Clinical Investigation and Documentation). The study was registered at ClinicalTrials.gov with the identifier NCT01121159.

2.2. Study design and enrollment

This study was designed as a prospective, controlled, multicenter trial. A total of 211 patients from 10 cranio-maxillo-facial centers in Germany, Spain, the United States, Singapore, and Austria were initially enrolled between 2010 and 2014.

Study inclusion criteria were as follows: (a) patient at least 18 years old, (b) fracture of the orbital floor and/or medial wall, (c) fracture not older than 21 days, (d) patient scheduled for reconstruction surgery with one of the following implants: Matrix MIDFACE™ Preformed Orbital Plate, SynPOR Titanium Reinforced Fan Sheet, Orbital Floor Mesh Plate, Stryker MEDPOR®, or custom-made orbital implant, (e) at least partial sight in both eyes before the accident, (f) written patient informed consent, and (g) the ability to understand and read local language at an elementary level. Study exclusion criteria were as follows: (a) fracture of the orbital roof, (b) complex fracture of the zygomatic bone (those affecting orbital volume), (c) previous dislocated orbital fractures on either side, (d) vision or diplopia not assessable, (e) injury to the globe that restricts surgical reconstruction (e.g., retinal detachment, globe rupture, etc.), (f) neurological diseases with influence on eye motility or sight, (g) legal incompetence, (h) active malignancy, (i) life-threatening condition, or (j) alcohol and drug abuse preventing the patient from reliable study participation.

After exclusion of 7 patients who were not eligible, 8 patients who had not received any of the study implants and another patient who had received both standard preformed and individualized plates in the same orbit, 195 patients were included in the study after written informed consent was obtained. Treatment allocation was based on surgeon's preference.