

What Is the Incidence of Implant Malpositioning and Revision Surgery After Orbital Repair?

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Purpose: Postoperative radiographic examinations are the gold standard in maxillofacial surgery, except in orbital reconstruction. Therefore, the purpose of this study was to estimate the frequency of implant malposition and revision operation after orbital repair.

Materials and Methods: This retrospective cohort study was conducted in a level I trauma center at the University Hospital in Bern, Switzerland. To assess the incidence of malpositioning, a qualitative analysis of postoperative computed tomography scans, as well as comparative volumetric measurements of the orbits, was conducted. Furthermore, the incidence of and reason for secondary revision procedures were evaluated.

Results: From September 2008 to December 2015, a total of 71 emergency patients (73 implants) were treated at the Department of Cranio-Maxillofacial Surgery with a titanium mesh (49 male patients; mean age, 56 years). The implant position was rated as poor in 17 cases (23%) by the qualitative analysis. The volumetric assessment showed no significant results. Revision intervention was needed in 12 patients (17%) because of an unsuccessful treatment outcome causing relevant clinical symptoms.

Conclusions: Patients with large orbital defects who require surgical treatment with a titanium mesh are at risk of implant malposition. Because in this study, poor positioning of the implant is the main reason for surgical revision, we postulate that a postoperative radiographic control should be obtained routinely. Only then can long-term sequelae due to inadequate reconstruction be avoided.

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In craniofacial trauma the involvement of the orbital structures is noted in up to 40% of cases.¹ Post-traumatic orbital deformities caused by incorrect reconstruction of orbital dimensions are severe complications causing enophthalmos, diplopia, and visual acuity disturbance. To prevent such complications, immediate repair of orbital injuries with the restoration of normal anatomy is indicated in orbital floor fractures. The aim of such an

intervention is to free incarcerated tissue that could cause a restriction in the eye movement and to restore the architecture of the bony orbit. To achieve this result, defects need to be bridged with the help of implants. Consequently, the correct position of the inserted implants plays a crucial role in restoring the functional and normal anatomic structure of the orbital cavity. Computer-assisted preoperative planning and intraoperative

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navigation are very effective tools for primary and secondary reconstruction of the orbit and have become more popular in the past decade. However, because of higher costs and limited availability, these methods have not yet become standard procedures. Therefore, most maxillofacial surgeons still use freehand bent titanium mesh or synthetic implants for orbital reconstruction.

In facial bone surgery, it is common practice to obtain postoperative radiographs to judge the outcome. In the postoperative assessment of the orbit, however, many surgeons avoid performing control computed tomography (CT) scans to reduce the risk of damaging the ocular lens. Therefore, it has not yet become a standard procedure to evaluate the position of the orbital implant. Because of this circumstance, to our knowledge, no data on the incidence of malpositioning of implants are available in the literature. However, only with the help of these data could the potential need for postoperative evaluations be estimated.

The purpose of this study was to retrospectively assess the incidence of implant malpositioning and revision surgery after orbital repair in a large trauma center, in which postoperative CT assessments are performed routinely. We hypothesized that the rate of poor surgical outcomes would be more than 10% in large orbital fractures ($>2 \text{ cm}^2$). The specific aim of this study was to qualitatively and quantitatively evaluate the surgical outcome with the help of preoperative and postoperative CT scans.

Materials and Methods

STUDY DESIGN

To address the research purpose, we designed and implemented a retrospective cohort study. The study population was composed of all patients treated for orbital repair with either a Medartis (Modus OPS; Medartis, Basel, Switzerland) or DePuy Synthes (Matrix Orbital; DePuy Synthes, Bettlach, Switzerland) titanium device. The operations were performed at the Department of Cranio-Maxillofacial Surgery at the University Hospital in Bern, Switzerland, between September 2008 and December 2015. The selection criteria for this retrospective study were adult patients (>18 years) who had been treated for an orbital blowout fracture with a titanium mesh. The primary indication for surgical repair was the presence of an isolated or combined orbital fracture causing an actual or expected functional or esthetic deficit. This included all defects of more than 2 cm^2 in size. Patients routinely underwent surgery within 2 weeks after trauma. The exclusion criteria included missing preoperative or postoperative follow-up documentation and/or CT scans, as well as missing consent for study participation. The indication for revision was determined for symptomatic patients presenting with

malpositioning of the orbital mesh on the postoperative CT control. Their clinical symptoms included double vision, ocular motility disturbance, or obvious enophthalmos. This study followed the Declaration of Helsinki on medical protocol and ethics, and the regional Ethical Review Board of Bern, Switzerland, approved the study.

SURGICAL PROCEDURE

All operations were performed with general anesthesia. For orbital repair, a titanium mesh was applied. The orbital floor was exposed via a transconjunctival, subtarsal, or subciliary incision or via a pre-existing skin laceration. The type and size of the mesh, the surgical approach, and any intraoperative problems were recorded.

VARIABLES

To evaluate the accuracy of reconstruction, postoperative CT scans were performed routinely. The maxillofacial surgeon evaluated the accuracy of the titanium mesh according to a qualitative assessment of the implant position as described by Ellis and Tan.² The position in the anterior, middle, and posterior locations of the defect was rated as ideal, adequate, or poor. The worst rating of the 3 was used for further evaluation. Every surgical revision required was documented and the postoperative assessments reanalyzed.

In addition, an independent radiologist compared the volume of the healthy orbit with that of the reconstructed orbit by a manual segmentation process (as discussed later). This procedure was performed on both orbits in all patients, and the volume of the contralateral uninjured orbit served as a control for comparison. Furthermore, the volume ratio of the injured and healthy orbits was assessed.

Because the size as well as the location of the orbital defect is most likely a predicting factor for the surgical outcome, an analysis of the preoperative situation was conducted using preoperative 1-mm CT scans. Given the complex 3-dimensional osseous structure of the internal orbit, a simple radiologic description of orbital fractures is insufficient. To classify the severity of the defect regarding size and location, we used a score introduced by Jaquiéry et al³ (Table 1). Their classification describes a 2-dimensional model, aiming to visualize the third dimension and displaying the volume-relevant areas of the internal orbit.³ Another advantage of this score is the differentiation between isolated and complex orbital fractures.

DATA COLLECTION METHODS

All imaging studies were performed with a Siemens CT scanner (Somatom Definition Edge; Siemens Healthcare, Erlangen, Germany). We used only non-enhanced CT studies of the orbits. The standard examination protocol

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