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Primary reconstruction of combined orbital and zygomatic complex fractures with patient-specific milled titanium implants – A retrospective study

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A B S T R A C T

The aim of this retrospective study was to compare mid-facial symmetry and clinical outcomes between patients treated with patient-specific and standard implants in primary fracture reconstructions of combined orbital and zygomaticomaxillary complex fractures.

Patients who underwent primary reconstruction of orbital and zygomaticomaxillary complex fractures during the study period were identified and background and clinical variables and computed tomography images were collected from patient records. Zygomaticomaxillary complex dislocation and orbital volume were measured from pre- and postoperative images and compared between groups.

Out of 165 primary orbital reconstructions, eight patients treated with patient-specific and 12 patients treated with standard implants were identified with mean follow-up time of was 110 days and 121 days, respectively. Postoperative orbital volume difference was similar between groups (0.2 ml for patient-specific vs 0.3 ml for standard implants, $p = 0.942$) despite larger preoperative difference in patient-specific implant group (2.1 ml vs 1,5 ml, $p = 0.428$), although no statistical differences were obtained in symmetricity or accuracy between the reconstruction groups.

Within the limitations of the study it seems that patient-specific implants are a viable option for primary reconstructions of combined zygomaticomaxillary complex and orbital fractures, because with patient-specific implants at least as symmetrical results as with standard implants can be obtained in a single surgery.

1. Introduction

Dislocated zygomaticomaxillary complex fractures almost always cause some degree of internal orbit defect due to local anatomy (Ellis and Reddy, 2004). In cases with minimal to moderate internal orbital defect and soft tissue herniation, reduction of zygomaticomaxillary complex fracture is usually sufficient to restore the orbital volume (Ellis and Reddy, 2004; El-Mahallawy et al., 2020) but in patients with extensive internal orbit defect, reconstruction of the internal orbit may be required (Ellis and Reddy, 2004; Ellis and Perez, 2014). Achieving good primary reconstruction is important since late secondary reconstructions are known to be more difficult to perform (Hammer et al., 1995; Baumann et al., 2015). A favourable surgical outcome is desirable to achieve with a single surgery during the initial treatment of facial fractures.

Based on studies of postoperative imaging, the rate of refractory misalignment varies between 11 and 67% after surgical reduction of zygomaticomaxillary complex fracture (Ellis and Kittidumkerng, 1996; Ellis and Reddy, 2004; af Geijerstam et al., 2008). Correspondingly, misalignment rates up to 23% have been reported after orbital reconstructions with standard implants (Schlittler et al., 2020). Orbital fractures with combined zygomatico-orbital and orbital rim involvement have also been reported to require revision surgery more often than isolated fractures (Nikunen et al., 2021). Suboptimal reduction should be avoided whenever possible, as this is associated with increased risk of postoperative findings such as

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enophthalmos, cheek asymmetry, and double vision (Ellis and Kittidumkerng, 1996; af Geijerstam et al., 2008).

Computer-aided design and manufacturing (CAD-CAM) software and construction tools are increasingly used to plan patient-specific implants completely digitally before the surgery (Schreurs et al., 2017; Kärkkäinen et al., 2018; Chepurnyi et al., 2020). This provides more anatomically accurate plates than manually bent standard reconstruction plates (Rana et al., 2015) and reconstruction with patient-specific implants have also been shown to result in better implant position in postoperative imaging studies (Nikunen et al., 2021). Patient-specific implants for zygomatic or orbital reconstructions can be constructed using multiple techniques and materials, ranging from digital planning and computer-assisted milling of titanium (Kärkkäinen et al., 2018; Nikunen et al., 2021), polyetheretherketone (PEEK) (Chepurnyi et al., 2019) ceramic (Falkhausen et al., 2021) to pre-bending standard titanium implants using patient-specific bending guides (He et al., 2012; Lu et al., 2012; Blumer et al., 2021; Sigron et al., 2020; Osaki et al., 2020).

Most of the studies regarding patient-specific implants for patients with facial fractures have focused on internal orbit reconstructions after isolated orbital fractures (Rana et al., 2015; Kärkkäinen et al., 2018; Chepurnyi et al., 2019). Recent studies have also presented patient-specific implant use in secondary zygomaticomaxillary complex and orbit reconstructions (He et al., 2012; Schreurs et al., 2017; Falkhausen et al., 2021) but currently no previous studies exist concerning patient-specific milled titanium implants in primary reconstruction of zygomaticomaxillary complex fractures with significant orbital wall involvement that would include postoperative assessment of both orbital volume and zygomatic fragment dislocation with 3D analysis tools. The purpose of this retrospective study was to compare postoperative outcomes between patients treated with patient-specific milled titanium implants and standard implants for primary surgical reconstruction of combined orbital and zygomaticomaxillary fractures.

2. Materials and methods

2.1. Study design and data collection

The study was approved by the Internal Review Board of the Head and Neck Center, Helsinki University Hospital, Helsinki, Finland (HUS/356/2017). Patient consent was not required due to the retrospective nature of the study. The guidelines of the Declaration of Helsinki were followed in this study. Electronic patient records of all patients with orbital reconstructions from January 1, 2016 to June 30, 2020 were reviewed and all patients who underwent a primary reconstruction of a combined unilateral orbital and zygomaticomaxillary complex fracture with or without pyriform aperture involvement were selected. Inclusion criteria were computed tomography (CT) images with slice thickness <3 mm in pre- and postoperative CT images. Included patients were divided into the following groups: reconstruction with patient-specific milled titanium implants and reconstruction with standard titanium plates and orbital implants. Patients with dislocated bilateral fractures of zygomaticomaxillary complex and orbital areas were excluded. Sample CT images of a patient treated with patient-specific implants are shown in Fig. 1a–d.

2.2. Study variables

The following data were collected from patient records: age, sex, injury mechanism, associated injuries, delay between injury and surgery, used surgical approaches and reconstruction technique, number of fixation points used for the reconstruction, length of follow up and surgical complications during follow-up visits. All patients were followed by maxillofacial surgeons and all patients were also evaluated by ophthalmologists.

Surgical outcome variables were collected qualitatively from patient records and included resolve of preoperative symptoms, postoperative symptoms related to sensorimotor function and clinical assessment of facial symmetry. Measurement of enophthalmos was performed with a Hertel® exophthalmometer. Hypophtalmos was measured using examination spectacles with attached vertical millimetres scale.

Complications were graded using Clavien – Dindo classification for surgical complications (Dindo et al., 2004). Major complications were defined as Grade ≥ II including wound dehiscence, infections medication and/or surgical intervention and the need for revision surgery and/or secondary reconstruction for any reason, clinically significant malglobus (≥2 mm of enophtalmos or hypophtalmos) and disturbances in ocular motility impairing daily activities. Minor complications were defined as Grade I including problems related to scarring, eyelid malposition, disturbances of ocular motility not impairing daily activities.

To assess facial bony symmetry internal orbital and zygomaticomaxillary complex fracture components were evaluated based on the following measurements of the pre- and postoperative CT images: orbital defect volume (ml), orbital defect volume improvement (ml), orbital defect area (mm^2), and mean point-to-point dislocation (mm) and medial translation (mm) of the zygomatic fragment compared to the un-fractured side. The postoperative imaging studies were conducted within second day from surgery.

2.3. Virtual planning of patient-specific milled implants

All patient-specific implants were designed using virtual planning with the Planmeca Promodel™ system (Planmeca Ltd) by surgeons of Department of Oral and Maxillofacial Diseases, together with a biomechanical designer of Planmeca Ltd. Implants were designed by first segmenting displaced fracture fragments from bone surface model and then mirroring the anatomy of the uninjured side and manually repositioning fracture fragments to match the uninjured side anatomy using a CAD software suite. This was followed by localizing the fracture edges and extending implants over them. The fixation points for zygomaticomaxillary complex implants were selected by surgeon(s) who also confirmed the final designs of the implants on a 3D model. Care was taken to avoid fixation points in areas of comminuted fractures and the implants were extended to the area of the supporting bone. An example of a virtual design of a patient-specific implant is shown in Fig. 2.

2.4. Manufacturing of patient-specific implants and surgical procedures

Patient-specific implants were manufactured by milling from titanium alloy blocks by Planmeca Ltd using a similar workflow as described by Kärkkäinen et al. (2018) and were heat-sterilized before surgery. Patients in the standard implant group were treated with orbital and mid-facial implants manufactured by DePuySynthes, Stryker or KLS Martin. The used surgical approaches were chosen by the surgeon(s). The minimum timeframe for designing, manufacturing and delivering patient-specific implant to our unit is 24 h.

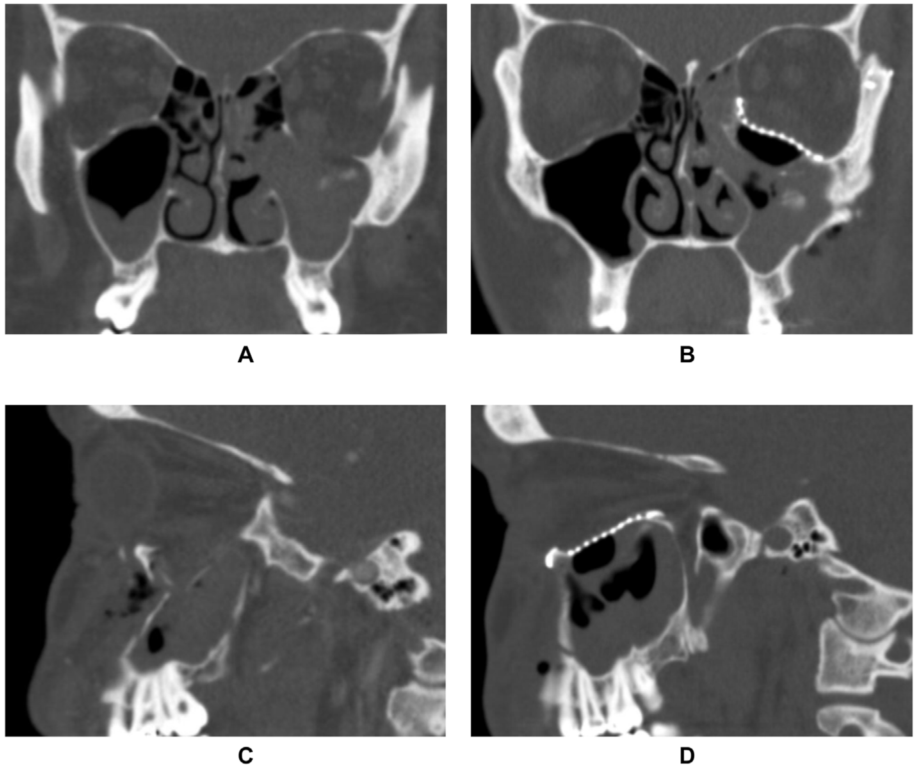

Fig. 1. Computed tomography images of a patient treated with patient-specific milled implants.
1A. Preoperative coronal series, 1B. Postoperative coronal series, 1C. Preoperative sagittal series, 1D. Postoperative sagittal series.

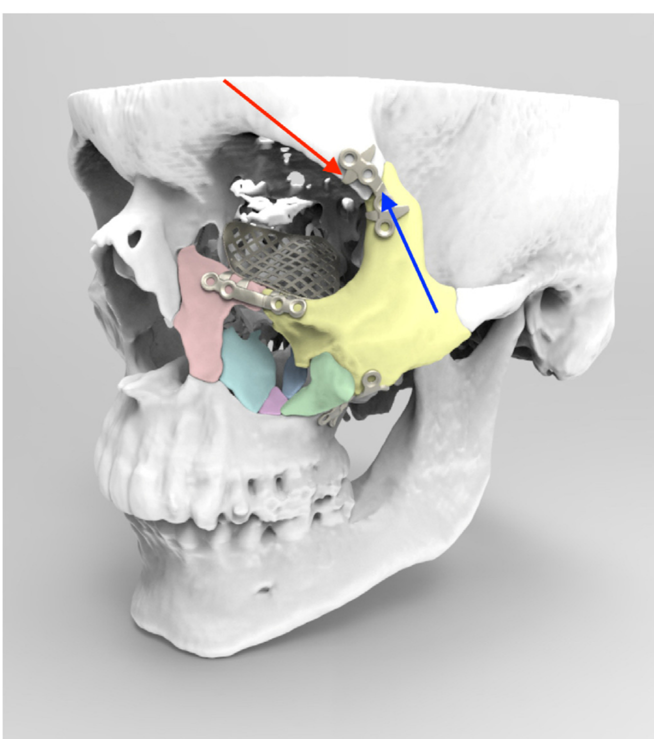

Fig. 2. Visualization of virtual design for patient-specific milled implants.
To help with fracture reduction and implant positioning, small marks for fracture edges (blue arrow) and bone edges (red arrow) were designed on zygomatic implants. Orbital implants were designed as screwless. Patient is the same as in Figure 1.

2.5. Computer-assisted analysis of zygomaticomaxillary complex fracture dislocation pattern

Axial series of pre- and postoperative CT images were exported in Digital Imaging for Communications in Medicine (DICOM) format for zygomaticomaxillary complex and orbital fracture analysis. Zygomaticomaxillary complex fracture analysis was conducted using Disior CMF Zygoma software (Disior Oy, Helsinki, Finland) using a workflow modified from Lehtinen et al. (2020) to semiautomatically determine the dislocation of zygomaticomaxillary complex fragment. Analysis consisted of 5 steps:

1) Surface model of facial bones was created from an axial DICOM series using modified marching cubes algorithm and a threshold of 280 Hounsfield units.
2) The zygomaticomaxillary complex fragment was manually selected from the surface model along the fracture lines when it was fully detached from opposing surface and along sutures in places where there was a connection between fragment and opposing surface. For comminuted fractures the largest fragment containing zygomatic summit was selected for dislocation analysis. In cases where fracture edges were not clearly defined due to extremely small dislocation or impaction the fragment was segmented conservatively to prevent nonfractured areas from being included to dislocation analysis. Cranium and midface were semiautomatically selected with modified flood fill algorithm.
3) The central sagittal plane was initially determined by manually selecting the landmark points in the central sagittal plane (Di Angelo et al., 2019) of the surface model. Skull and zygomaticomaxillary complex fragment models were aligned to neutral rotation and lateral flexion using the initial central sagittal plane. The points used are visualized in Fig. 3c.

   a. Crista galli
   b. Nasion
   c. Incisive canal
4) Virtual repositioning of the zygomaticomaxillary complex fragment was performed by mirroring the non-injured side using the central sagittal plane first and then registering the fragment onto this mirrored non-injured surface using modified affine registration algorithm. In this iterative step, the position of central sagittal plane was also refined. Dislocation of the fragment was then calculated in relation to its centroid by measuring the difference between original and virtually repositioned locations using the iterative closest point (ICP) algorithm and rigid body kinematics. The medial translation component of the centroid was used as one of the outcome variables since it has been shown to correlate with the need for surgical treatment (Lehtinen et al., 2020).
5) Mean point-to-point dislocation distance was calculated by determining the minimum Euclidean distance for each surface point of the zygomaticomaxillary complex fragment between initial and repositioned location.

Successful virtual repositioning result was determined by author consensus. The workflow for virtual repositioning is shown in Fig. 3a–d. To assess repeatability of zygomaticomaxillary complex fracture analysis, the entire analysis procedure was repeated after 6 months by the same operator (V.L.) and also by a different operator (J.S.) to respectively measure intra- and interrater reliability of mean point-to-point dislocation distance and medial translation. Intraclass correlation coefficient (ICC) was used to assess the repeatability of the measurements.

2.6. Automatic analysis of orbital fracture components

Orbital fractures were analysed using Disior CMF Orbital version 1.9.11 (Disior Oy, Helsinki, Finland). The axial series of pre- and postoperative CT images were imported into the software and orbital volumes were segmented automatically using a proprietary algorithm that iteratively expands orbital volume segments until they encounter a sufficient Hounsfield unit contrast value, which indicates contact with orbital walls or the air inside paranasal cavities thereby defining the bony walls of the orbit. The saddle-shaped anterior closing of the orbit was then defined by an algorithm that iteratively contracts a mesh outside facial bones until it completely envelopes them. The final orbital volume was then defined by the software as the volume inside the bony orbit, limited by anterior closing. After segmentation of both orbital volumes, the

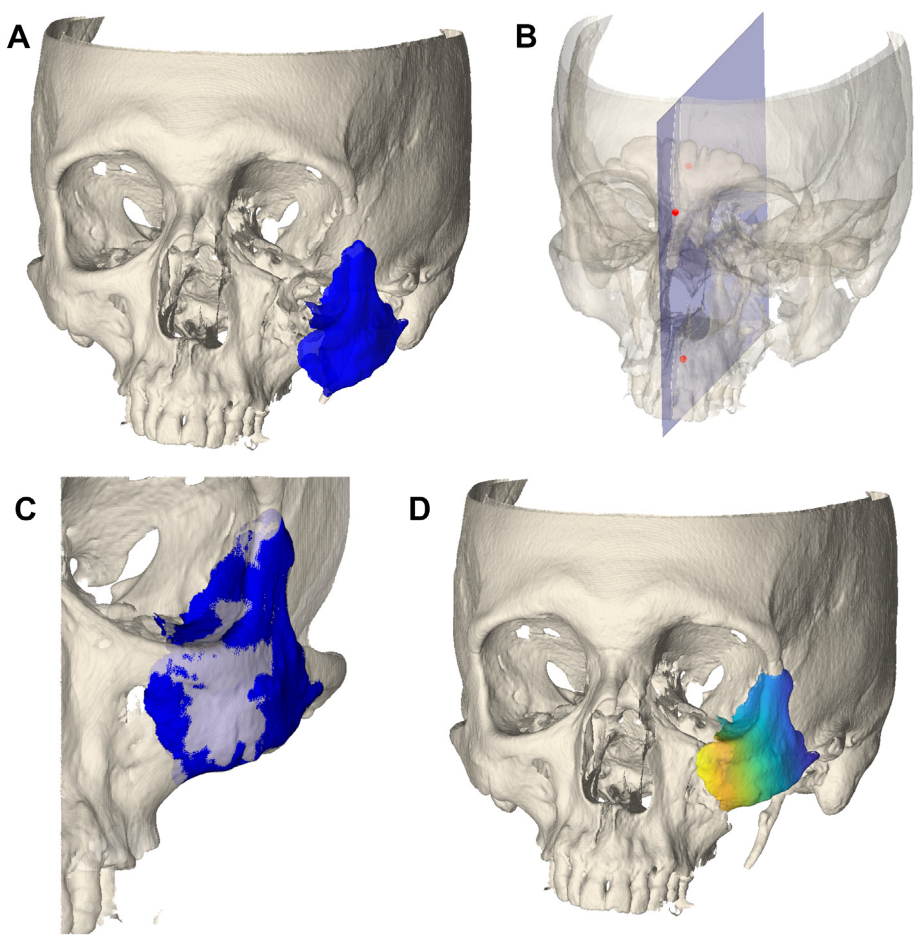

Fig. 3. Workflow for zygomaticomaxillary complex component dislocation analysis 3A. A surface model of facial bones created from computed tomography image and zygomaticomaxillary complex (ZMC) fragment (blue) that was manually segmented from the surface model. 3B. Initial approximation of the central sagittal plane (light blue), which was determined by manually selecting the landmark points in the central sagittal plane of the surface model. The points used are marked in the image in red: a. Crista galli (CG), defined as the most superior point of crista galli, b. Nasion, defined as the most anterior point of frontonasal suture, c. Incisive canal, defined as the most posterior point of opening for incisive canal in palate, 3C. The ZMC fragment (blue) is visualized after virtual repositioning, which was performed by mirroring the non-injured side (light grey) using the central sagittal plane and registering the fractured ZMC part onto this surface. 3D. The minimum Euclidean distance between initial and repositioned location was calculated for all surface points of ZMC fragment and is visualized here, with warmer hues indicating longer dislocation distance and colder hues indicating shorter dislocation distance.

defect volume(s) were calculated by registering the mirrored version of the non-injured orbit onto the injured orbit and finding the volumes of shape difference. The software reported the two largest shape differences that had a volume of >0,2 ml, which were either an increase or a decrease of the volume in comparison to reference side. The only input required by user is the definition of the injured side and the results provided by the software are always identical for the same image. Therefore, repeatability measures were not calculated for orbital fracture measurements.

In this study, the sum of decreased and increased components of volume change was used as the combined defect volume for each subject. Defect volume improvement between pre- and postoperative images was calculated in the software by registering pre- and postoperative fractured orbits onto each other and finding the shape difference between them. The defect surface area was calculated by CMF Orbital software by finding the elements of fractured volume in contact with mirrored non-injured orbital volume. Visualization of segmented volumes and orbital fracture component analysis is presented in Fig. 4.

2.7. Statistical analysis

Statistical analysis was conducted using SPSS Statistics for Windows version 25.0 (IBM Corp., Armonk, NY). The main outcome variables were compared between groups treated with patient-specific or standard implants using Student's *t*-test. Categorical outcome variables between groups were compared using Chi-squared test. P-values were calculated and the limit for statistical significance was set at $P < 0.05$. Missing data was handled by listwise deletion during statistical analyses.

3. Results

3.1. Patient characteristics, details of injury and surgery

Of the 165 primary orbital reconstruction surgeries performed during the study period, a total of 20 patients who fulfilled the inclusion criteria underwent a combined orbital and zygomaticomaxillary complex fracture reconstruction. Eight patients were treated with patient-specific implants and 12 patients with standard implants. Three maxillofacial surgeons of the Department of Oral and Maxillofacial Surgery, Helsinki University Hospital, performed all the surgeries.

Patient characteristics, injury details, number of used plates, and length of the follow-up period are shown in Table 1. The mean follow-up for the standard implant group 121 days, and 110 days for the patient-specific implant group. There were no statistically significant differences between the study groups in any of the variables related to group demographics, injury mechanisms, timing of surgery, or length of follow up.

The number of used zygomaticomaxillary complex fixation points was similar in both groups. The fractures were most often stabilized with two plates placed in the frontozygomatic suture and infraorbital rim in addition to orbital floor reconstruction.

3.2. Pre- and postoperative measurements of the fractures

Fracture measurements are shown in Table 2. In a single case in the standard implant group, the analysis software failed to perform the pre- and postoperative orbital volume measurements due to incompatible file format of DICOM images, and analysis of one postoperative image was rejected from orbital analyses due to inaccurate automatic segmentation of resorbing orbital implant. Zygomaticomaxillary complex fracture dislocation analysis was completed for all patients.

Patients treated with patient-specific implants had slightly larger orbital volume expansions caused by the fractures than patients treated with standard implants (2.1 ml vs 1.5 ml) preoperatively. However, patients treated with standard implants tended to have greater mean point-to-point dislocation (2.7 mm vs 2.2 mm) and medial translation (3.9 mm vs 2.6 mm) of zygomaticomaxillary complex fragments than patients treated with patient-specific implants. Postoperatively both groups exhibited comparable residual orbital volume difference (0.2 ml vs 0.3 ml for patient-specific and standard implants respectively) and zygomaticomaxillary fragment mean point-to-point dislocation (1.5 vs 1.7 mm for patient-specific and standard implants respectively). None of the differences between means of treatment groups in any of the pre- or postoperative measurements reached statistical significance. None of the patients had preoperative clinical signs of extraocular muscle impingement. Intraclass correlation coefficients for zygomaticomaxillary complex fracture analysis ranged between 0.843 and 0.991 (Table 4).

3.3. Postoperative clinical symptoms and complications

Surgical complications are listed in Table 3. No major (Clavien-Dindo Grade $\geq$ II) postsurgical complications occurred in either of the groups; no patients had wound dehiscence, surgical site infections or significant ($\geq$2 mm) globe malposition or diplopia that would have impacted daily activities or warranted further treatment. In the patient-specific implant group single patient had mild

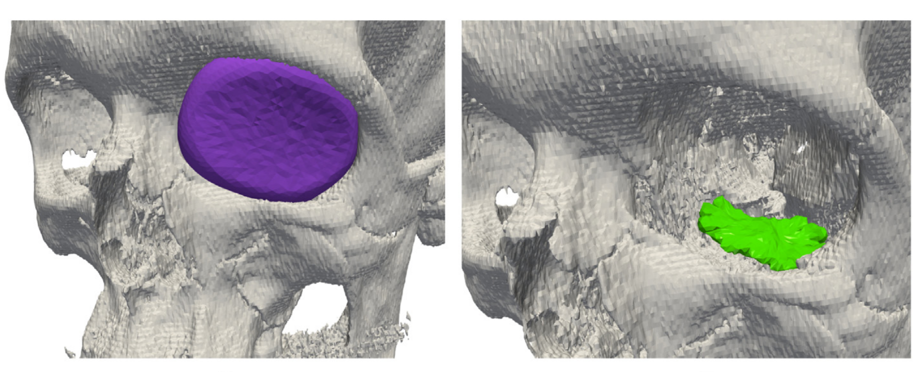

Fig. 4. Visualization of orbital fracture component analysis Orbital volume analysis from a preoperative CT image. Segmented orbital volume is shown in Figure 4A in purple and volume expansion caused by orbital floor fracture is shown in Figure 4B in green. Patient is the same as in Figure 1.

Table 1
Demographic and background variables of study samples.

	Patients with patient-specific milled implant reconstruction (n = 8)	Patients with standard implant reconstruction (n = 12)
Age, years (mean (95%CI))	55 (44–66)	56 (44–68)
Sex (male/female)	4/4	10/2
Injury mechanism, n		
Traffic Accident	3	3
Fall	4	6
Violence	0	1
Sports	0	2
Other	1	0
Associated injuries, n (% of total)		
Intracranial	3	1
Spine	1	1
Cervical arteries	0	2
Ocular	1	1
Chest	2	1
Extremities	4	4
Any associated injury	7	5
Days between injury and operation (n of days, median (range))	8 (5-9)	6 ; (2-14)
Number of fixation points (median (range))	3 (2-4)	3 (2-5)
Zygomaticomaxillary fixation point configurations, n (% of total)[a]		
2: FZ	1	3
3: FZ + IOR	7	8
4: FZ + IOR + ZMB	0	1
Additional implant to the medial maxilla, n	1	2
Surgical approach to the orbital floor, n		
Lower eyelid	5	7
Transconjunctival	3	3
Trauma laceration	0	2
Length of follow up, days, median (range)	121 (0[b] - 417)	110 (6–699)

Results are presented as number of patients (%).
Abbreviations.
FZ; Frontozygomatic suture; OF: Orbital floor; IOR: Infraorbital rim; ZMB: Zygomaticomaxillary buttress.
[a] in addition to the orbital implants.
[b] one patient in this group was transferred to another hospital for further treatment.

Table 2
Pre- and postoperative measurements of orbital fracture and ZMO fragment dislocation analyses.

Parameter	Patient-specific implant reconstruction n = 8		Standard implant reconstruction n = 10/12[d]		p value for preop differences	p value for postop differences
	Preop analyses	Postop analyses	Preop analyses	Postop analyses		
Orbital defect volume (ml. mean (SD))[a]	2.1(1.9) ml	0.2 (0.8) ml	1.5 (1.5) ml	0.3 (0.9) ml	0.428[e]	0.942[e]
Defect volume improvement after operation (ml. mean(sd))[c]	−2.3 ml (1.4 ml)		−1.6 ml (1.27 ml)		0.300[e]	
Orbital defect area (mm2, mean, 95% CI)[b]	640 (320) mm2	340 (290) mm2	610 (360) mm2	380 (230) mm2	0.848[e]	0.728[e]
ZMC fragment mean point-to-point dislocation (mm, mean(SD))	2.2 mm (0.7 mm)	1.6 mm (0.8 mm)	2.7 mm (1.5 mm)	1.7 mm (1.3 mm)	0.402[e]	0.706[e]
ZMC fragment medial translation (mm, mean(SD))	2.6 mm (3.2 mm)	2.2 mm (2.2 mm)	3.9 mm (8.5 mm)	1.8 mm (2.2 mm)	0.638[e]	0.708[e]

Abbreviations.
SD = standard deviation.
ZMC = zygomaticomaxillary complex.
[a] Orbital volume increase compared to noninjured orbit.
[b] Combined area of orbital defect(s).
[c] Orbital volume change after comparing preoperative and postoperative segments.
[d] 2 cases were excluded for orbital volume analyses in standard implant group: 1 due to inaccurate segmentation of a resorbable plate and 1 due to incompatible DICOM images.
[e] Student's T-Test for independent samples.

eyelid malposition, and one patient had excessive tearing after intraoperative stretching of lower eyelid. In the standard implant group 2 patients had abnormal scarring, 2 patients had minor globe malposition and one patient had minor superior sulcus syndrome after lower eyelid incision. No patients required secondary surgery.

4. Discussion

The primary purpose of the present study was to compare the postoperative outcome between patients with combined zygomaticomaxillary complex and orbital fractures requiring internal orbit

Table 3
Surgical complications graded with Clavien-Dindo classification and minor complications not requiring intervention.

	Patient-specific implant reconstruction (n = 8)	Standard implant reconstruction (n = 12)
Grade I[a]		
Abnormal scarring	0	2
Eyelid malposition	1	0
Minor disturbance of ocular motility	0	0
Double vision	0	0
Minor globe malposition (<2 mm)	0	2
Other	1[b]	1[c]
Grade II	0	0
Grade III	0	0
Grade IV	0	0
Grade V	0	0

Abbreviations.
[a] Due to associated injuries sustained by most patients Grade I complications were recorded only if clearly related to midfacial reconstruction surgery.
[b] 1 patient had occlusal interference treated with selective occlusal grinding and lacrimal duct injury with increased secretion due to stretching during surgery.
[c] 1 patient had minor superior sulcus syndrome.

Table 4
Repeatability measures of zygomaticomaxillary complex dislocation analysis.

Measure	Intratester ICC[a]	p value	Intertester ICC[a]	
Medial translation Preop	0.983	<0.001	0.984	<0.001
Medial translation Postop	0.843	<0.001	0.991	<0.001
Mean dislocation Preop	0.964	<0.001	0.930	<0.001
Mean dislocation Postop	0.957	<0.001	0.974	<0.001

Abbreviations.
ICC = Intraclass correlation coefficient.
[a] ICC,two-way mixed effects model, single measurements.

reconstruction operated with patient-specific and standard implants. The hypothesis was that treatment with patient-specific implants leads to more symmetrical mid-facial anatomy compared to standard implant reconstruction. The main aim was to measure bony symmetry quantitatively using a computer-assisted workflow.

The results supported the hypothesis, as the reconstruction with patient-specific implants led to 0.1 ml smaller orbital defect volume difference between uninjured and reconstructed orbits when compared to standard implants, however without statistical significance. It should also be noted that preoperative defect volume was 40% greater in the group treated with patient-specific implants than with standard implants. The residual postoperative volume difference compared to healthy side in the group treated with patient-specific implants (0.2 ml) equals to results presented by Chepurnyj et al. (0.26 ml) (Chepurnyi et al., 2019).

Previous literature has mainly focused on late or secondary repair (He et al., 2012; Lu et al., 2012; Schreurs et al., 2012; Nkenke et al., 2011; Falkhausen et al., 2021), or solely orbital reconstruction (Kärkkäinen et al., 2018; Sigron et al., 2020; Gander et al., 2015; Rana et al., 2015). The present study reveals that a patient-specific implant is suitable for combined zygomaticomaxillary complex and internal orbital fracture surgery and symmetry can be achieved excellently with single surgery in primary fracture treatment.

Secondly, complications were slightly more frequent in standard implant group when compared to the group treated with patient-specific implants. The usage of patient-specific implants in mid-facial fracture surgery can reduce postoperative complication due to the individually designed shape requiring smaller incisions and less intraoperative manipulation of fixation plates and intraorbital soft tissue (Metzger et al., 2007; Zielinski et al., 2017). In addition, patient-specific implants are considered to minimize the risk of secondary repair (Rana et al., 2015) and implant malposition (Nikunen et al., 2021) which is more common particularly in complex midfacial fractures (Nikunen et al., 2021).

In the current study, none of the patients had diplopia that interfered with daily life. One patient in the standard implant group had clinically nonsignificant (<2 mm) globe malposition and one patient in the standard implant group had mild eyelid malposition. None of the plates were removed due to infection as no infections occurred. Surgical site infections and wound dehiscence has been shown to occur in 8–14% of patients with zygomaticomaxillary complex fractures (Calderoni et al., 2011; Snäll et al., 2014; Starch-Jensen et al., 2018), whereas plate removal is needed between 6 and 11% of cases (Eski et al., 2006; Starch-Jensen et al., 2018). The incidence of globe malposition after surgical treatment of zygomaticomaxillary complex fractures has varied up to 22% and diplopia up to 23% (Zingg et al., 1992; Ellis and Kittidumkerng, 1996; Eski et al., 2006; af Geijerstam et al., 2008; Calderoni et al., 2011; Starch-Jensen et al., 2018; Schneider et al., 2020), whereas eyelid malposition has been found to occur in 1–6% of patients (Zingg et al., 1992; Ellis and Kittidumkerng, 1996; Eski et al., 2006; Ridgway et al., 2009; Calderoni et al., 2011; Starch-Jensen et al., 2018). The limited number of patients can explain the low complication rate observed in this study, but the favoring for exclusively extraoral approaches for fixation points can also affect this since surgical wound infections and dehiscence have been shown to occur more often with intraoral approaches (Snäll et al., 2014).

The use of patient-specific implants did not delay surgical treatment due to the close affiliation with our department and the company providing customized implants. Most of the patients had sustained multiple associated injuries (Table 1) and surgery timing and duration was also affected by other injuries, thus the duration of surgeries could not reliably be estimated from this data. However, in previous literature, the use of customized implants has decreased surgery duration compared with standard implants in isolated orbital floor fracture reconstructions (Sigron et al., 2020).

Based on the current results, patient-specific implants may be recommended particularly in zygomaticomaxillary complex fractures with extensive orbital involvement. However, optimal virtual implant design requires familiarity with the typical features of these fractures. For example, fracture borders that are too slender or prone to fracture during surgery should not be designed as supporting edges for an implant. The exact visual reduction of the fracture and especially orbital reconstruction was easier with patient-specific implants than with standard implants and the rigidity of the milled implant guaranteed the stability of the reconstruction. Therefore, patient-specific implants may provide a way to avoid the typical perioperative challenges to achieve correct fracture and implant positions.

The strength of the present study was the use of a quantitative, computer-assisted 3D methods to measure pre- and postoperative volume and symmetry of the internal orbit and zygomatic bone. Additionally, the study showed the usability of patient-specific implants even in reconstruction of larger zygomatico-orbital defects requiring both zygomatic and internal orbit reconstruction at primary stage surgery. Limitations of the current study include the small size of the study population, which reflects the rare nature of combined extensive zygomaticomaxillary complex and orbital wall fractures compared to isolated zygomaticomaxillary complex and orbital fractures, and particularly the retrospective nature of the study. As the decision to use patient-specific implants was dependent on the clinical evaluation of the surgeon, the indications for using patient-specific or standard implants were not standardized.

Moreover, the method to analyze orbital volume difference and zygomatic fragment dislocation was based on the paradigm of facial mirror symmetry as optimal reconstruction outcome, which may be considered as a weakness. Fracture reduction analysis based on fracture surfaces has been demonstrated with mandibular fractures (Voss et al., 2016), but midfacial fractures are more difficult to analyze with this kind of approach due to thin bones, small comminuted fragments and complex anatomy.

5. Conclusions

Within the limitations of the study it seems that patient-specific implants are a viable option for primary reconstructions of combined zygomaticomaxillary complex and orbital fractures, because with patient-specific implants at least as symmetrical results as with standard implants can be obtained in a single surgery.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: One of the authors (V.L.) was a part-time employee of Disior® during the analysis process. No other financial engagements existed between the authors and Disior® and Disior® did not take part in the data selection, analysis or reporting of results.

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