Patient specific implants (PSI) in reconstruction of orbital floor and wall fractures

Gander, Thomas ; Essig, Harald ; Metzler, Philipp ; Lindhorst, Daniel ; Dubois, Leander ; Rücker, Martin ; Schumann, Paul

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*Title Page

Patient specific Implants (PSI) in Reconstruction of Orbital Floor and Wall Fractures

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Dear Reviewers,

Thank you very much for your constructive comments and for suggesting our paper for publication. According to your comments we made the following changes in our manuscript:

Reviewer #1: Thank you very much for your pleasant comment.

Reviewer #2: Thank you very much for your constructive comments. PSI can easily be manually bent, of course in a limited extent, compared with standardized titanium meshes. The goal of treatment planning should be the perfect fit of the implant. As mentioned, only two implants had to be corrected in their extent by pincers. An adjustment by bending was not necessary, although, as mentioned above, this could be performed but should be avoided by meticulous planning. Long-term results will follow and more patients will be included in future studies. The figures 5 and 7 have been removed.

All changes were highlighted in the text by using red color.   We hope that our manuscript is now suitable for publication and hope for acceptance.

Yours sincerely

Dr. Dr. Thomas Gander

Introduction

The orbital wall and floor are common sites of facial bone fracture and may cause serious functional impairment (Shin et al., 2013). Numerous cases of reconstructive implant use have been described in the literature (Strong et al., 2013; Gerressen et al., 2012). The repair of orbital wall and floor fractures is difficult due to the complexity of the anatomical region involved, and the limited intraoperative view. Meticulous imaging, and clinical examination, is indispensable for treatment planning, in order to restore orbital volume and shape. Ill-fitting implants and inaccurate surgical techniques may lead to visual disturbances and unaesthetic results (Ewers et al., 2005). Computer assisted three-dimensional (3D) treatment planning, and ready-to-use, individual titanium mesh implants, are routinely applied to achieve stable reconstruction and adequate postoperative results (Essig et al., 2013; Schramm et al., 2009). Contemporary standardized titanium meshes are manually adjusted to fit individual patients' polyamide models (Kozakiewicz and Szymor, 2013). We present a new approach employing customized, ready to use, patient-specific titanium implants (KLS Martin, Group, Germany), suitable for daily use. These easily manufactured and implemented, ready-made patient specific implants (PSI) allow for a more cost- and time-effective operating procedure.

Material and methods

Patients who underwent operations for orbital wall and/or floor fractures, between February 2014 and June 2014, were recruited, irrespective of their gender, age, trauma type or the presence of concomitant injuries. Informed consent was provided by all patients. Preoperative CT-scan data, with a slice thickness of 0.3 mm, were processed using the iPlan software package (ver. 3.0.5, Brainlab, Feldkirchen, Germany) to generate a 3D reconstruction of the affected orbit, using the mirrored non-affected orbit as a template. Correction of minor asymmetry was effected via the 3D smart shaper function. Accurate use of the 3D smart shaper is a key step in the planning process, and must be performed with caution to avoid discrepancies during subsequent implant placement (Figures 1-2). The parameters of the patient-specific implant are outlined, and three landmarks are positioned on the planned implants to allow for rapid and effective 3D control of the implant's position (Figures 3-5). Each planning step can be easily performed by any surgeon: no specialist, *a priori* knowledge of the software is beneficial.

Precise transfer of the 3D coordinates of the implant, from iPlan 3.0.5 to the manufacturing software (KLS Martin), represents an essential precondition of intraoperative control. STL data are then exported and approved for the purposes of implant manufacture. This procedure obviates the need for time-consuming integration of the dataset within the manufacturing software. Circumferential implant cushions should be created, although laser-sintered, individually manufactured implants (with a thickness of 0.3 mm) exhibit greater stiffness compared with manually adjusted titanium meshes and therefore allow for minor dimensioning of the implant (Ibrahim et al., 2009). Overextended implants can easily be reduced in extent by pincers and manual adjustment is still possible, although to a lesser degree compared with standardized implants. The need of manual adjustment should be avoided by meticulous preoperative implant planning.

Individually manufactured titanium implants are positioned using a retroseptal, transconjunctival approach (Figure 6). Application of a polydioxanon foil, which may improve the surgeon's view by preventing fatty tissues from encroaching on to the operative site, was utilized in certain cases. The polydioxanon foil is removed following placement of the implant and prior to wound closure. Dental arch splints in dentulous patients, and mini screws placed in the calvarian bones of edentulous patients, were used as registration markers. Postoperative CT-scans were performed to assess implant position. Quality management was effected by importation and superimposition of the postoperative dataset (Figure 7). All patients underwent a pre- and post-operative ophthalmological examination.

Results

A total 12 patients were included. All patients underwent reconstruction of the orbital wall or orbital floor, via PSIs using intraoperative navigation, and in accordance with a transconjunctival, post-septal approach. In eight patients indication for surgery was imposed due to diplopia. Four patients underwent orbital reconstruction owing to profound defects or enophthalmos. The male to female ratio of the sample was 11:1, with a mean age of 53 years (range: 29-78 years). Major causes of orbital floor or wall fractures included industrial accidents and falls (Table 1).

In seven patients, dental splints were applied for intraoperative navigation purposes, in addition to dental cusps. In four patients navigation screws were employed in the calvaria, for intraoperative registration and navigation. CT scans were performed preoperatively, and the registration tools were introduced.
The time taken for digital planning ranged between 30-36 min: the manufacturing process took 4-6 days. All individually manufactured implants were placed without difficulty. Postoperative CT scans revealed accurate fitting of the PSI. No visual impairments were reported aside from double vision in terminal positions, which resolved during postoperative care. Reoperation was not required to reposition implants, or to correct displacement of the ocular bulb. In two cases intraoperative reduction of the implant, using pincers, was necessary due to overextension during computer-aided treatment planning. Manual adjustment by bending was not necessary in any case. Patients did not report sensations indicative of foreign bodies nor any visual impairment (Table 2).

Discussion

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Correct positioning of the PSI can be verified using intraoperative navigation, to support the three virtually planned indentations incorporated in the manufactured implant (Schramm et al., 2009). The three planned indentations and their stored coordinates also serve as measuring points during the virtual planning process, thereby improving overall accuracy. The implant is digitally planned by the surgeon, with a focus on its extent and the position of the three landmarks. The coordinate system of the digital plan must be conserved during the entirety of the manufacturing process, to allow for accurate superimposition of the pre- and postoperative implant positions. Although PSIs are dimensionally more stable compared with manually bent titanium implants, a circumferential cushion is nonetheless recommended. Furthermore, stiffness in PSIs prevents implant deformation during placement, but still allows for minor, intraoperative corrections by pincers. Due to the increased stiffness of laser-sintered PSIs compared with conventional titanium meshes, precise preoperative planning is required to avoid interference during insertion of the PSI.

Routinely incorporating postoperative results into preoperative virtual planning activities, and assessing implant positioning via superimposition, both represent ground-breaking advances in medical quality control.

Conclusion

PSIs simplify the reconstruction of orbital floor and wall fractures, and should be considered a more accurate alternative to manually bent titanium mesh implants. Automation allows for the application of safe, time-effective, daily procedures; accordingly, its use should be encouraged. Implant planning can be easily undertaken by any surgeon, and does not require specialized, software-specific knowledge.

As previously stated by the World Health Organization, PSIs should play a key role in daily routines, and furthermore should replace conventional implants by 2020. PSI for the reconstruction of orbital floor and wall fractures is now readily available.

More patients will be included in this study and long-term results will be gathered in the future to allow more funded statements.

Conflict of Interest Statement

All authors disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) this work.

Funding

None.

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Tables/Figures

Table 1 Patient data
Table 2 Results

The English in this document has been checked by at least two professional editors, both native speakers of English.

Table 1

Patient data	
Age in years, mean (Range)	53.08 (29-78)
Number of patients and gender	
Overall	12
Female	1
Male	11
Fracture types	
Orbital fracture simple*	5
Orbital fracture complex*	4
Combined Midface fracture	3
Course of accident	
Industrial accidents	3
Tumbles	4
Sport accidents	2
Syncopes	1
Road accidents	1
Violence	1

* Simple = single wall fracture, complex = more than one wall

Table 2

Table 2

Results	
Indication for surgery	
Double vision	8
Endophthalmos	3
Extent of defect without symptoms	1
Surgical access	
Transconjunctival, retroseptal	11
Transconjunctival, retrocaruncular	1
Navigation tool	
Dental splint	7
Dental cusps	1
Calvarian screws	4
Complications intra-/postoperative	
Misfitting implant	0
Overextent of implant	2
Underextent of implant	0
Orbital nerve injury	0
Foreign body sensation	0
Postoperative double vision temporarily	5
Postoperative double vision permanent	0
Variance implant position vs digital plan (mm)	
Minimal 0.3mm	
Maximum 1.6mm	

Figure 1
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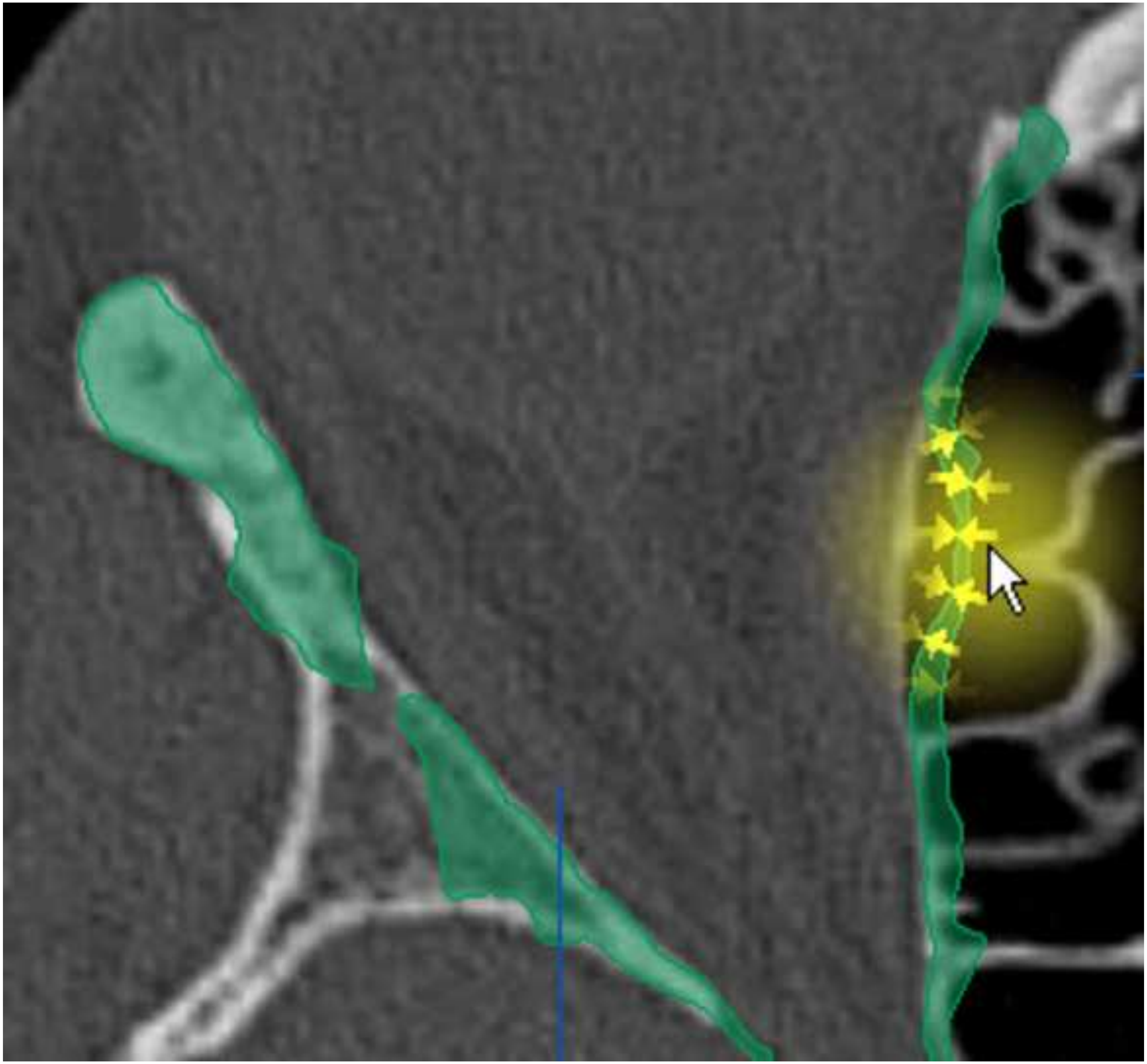

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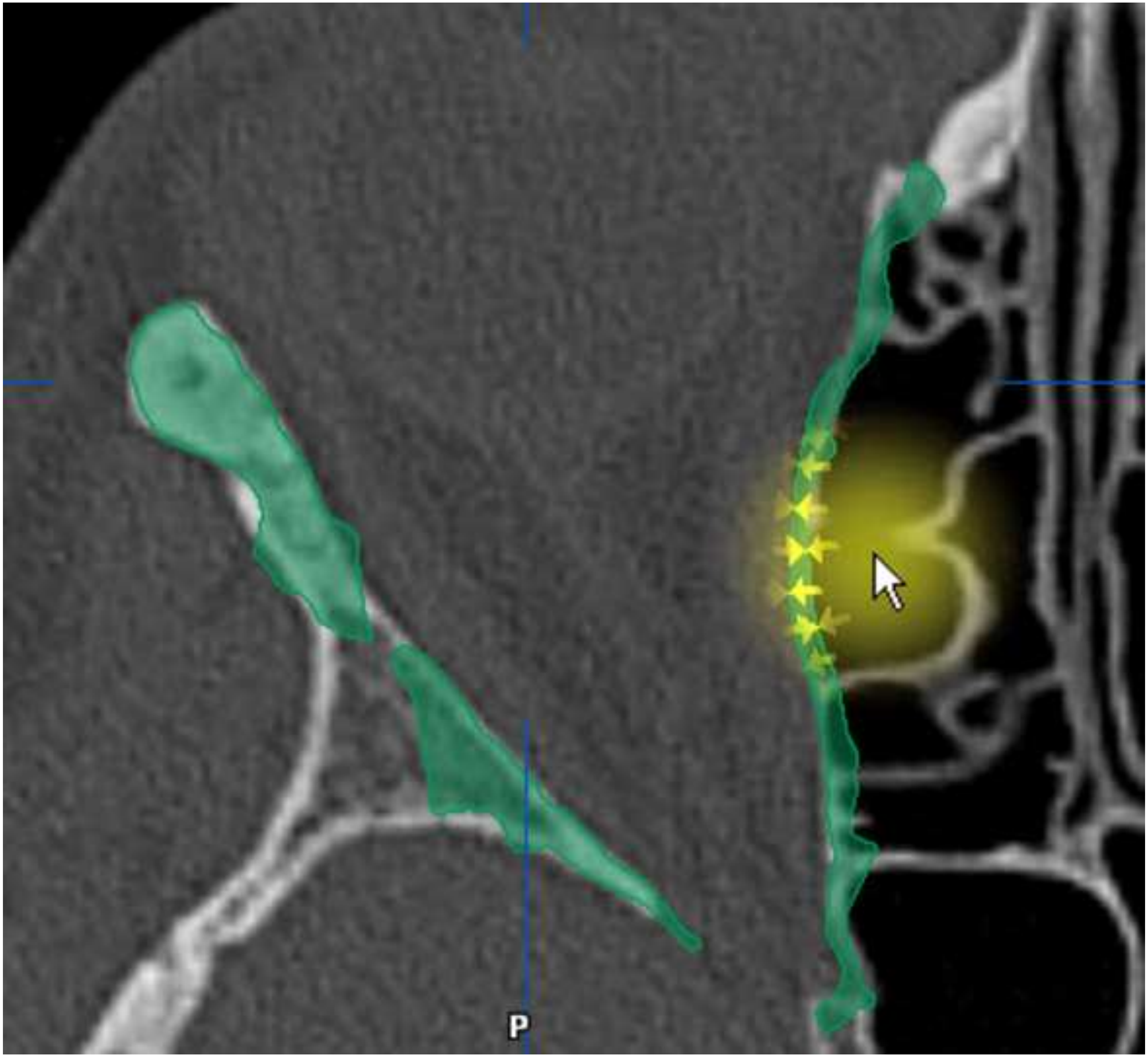

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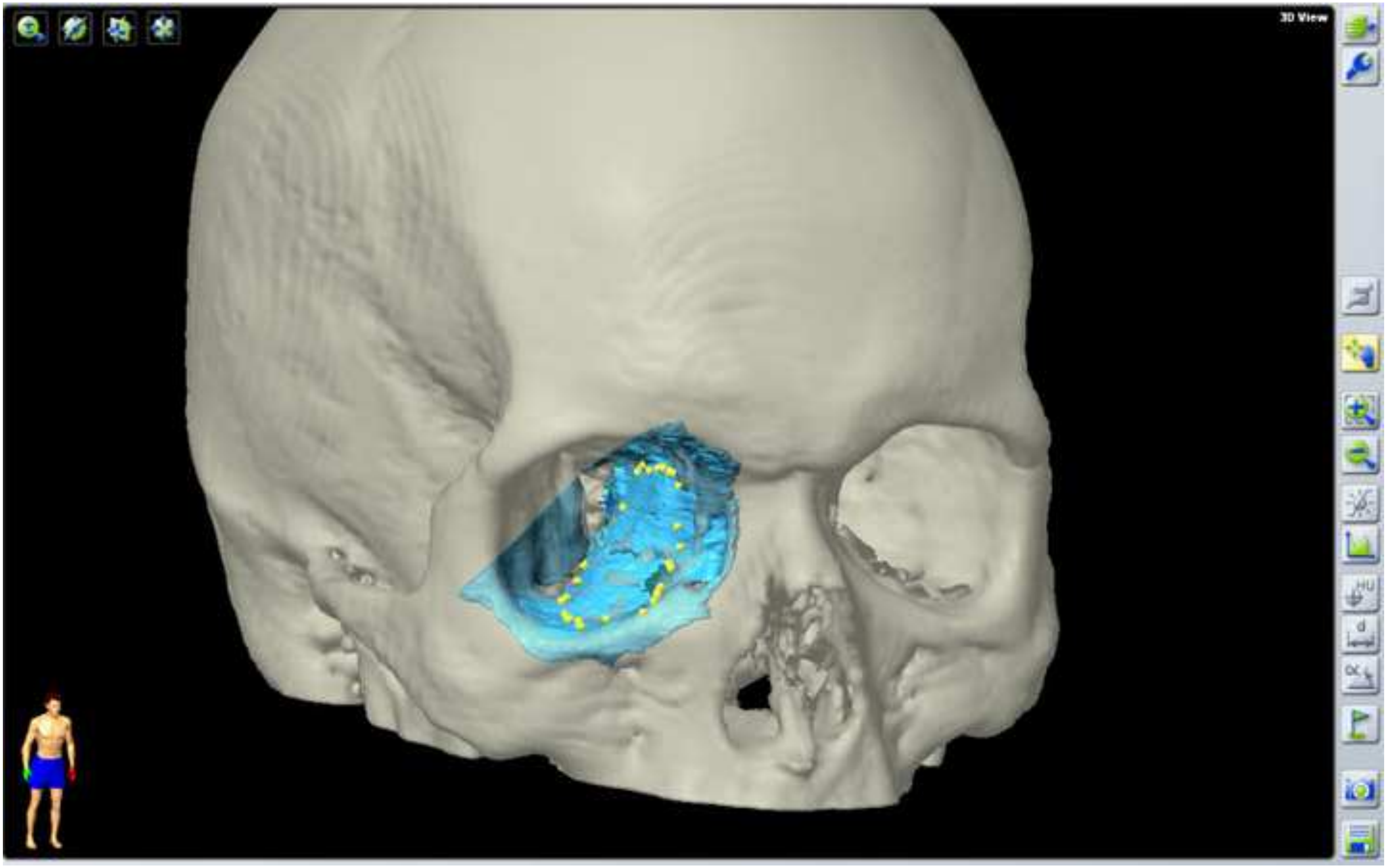

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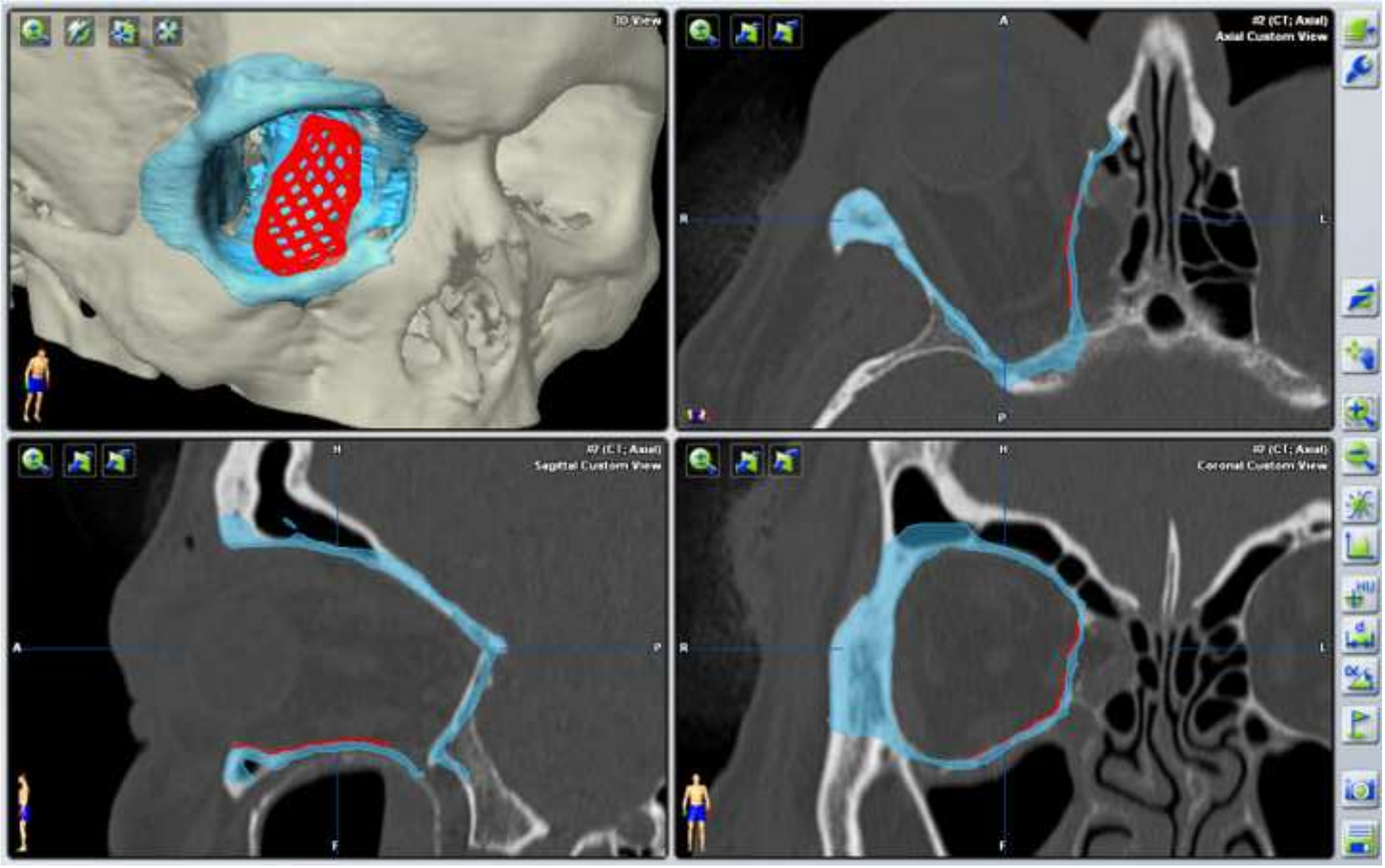

Figure 5

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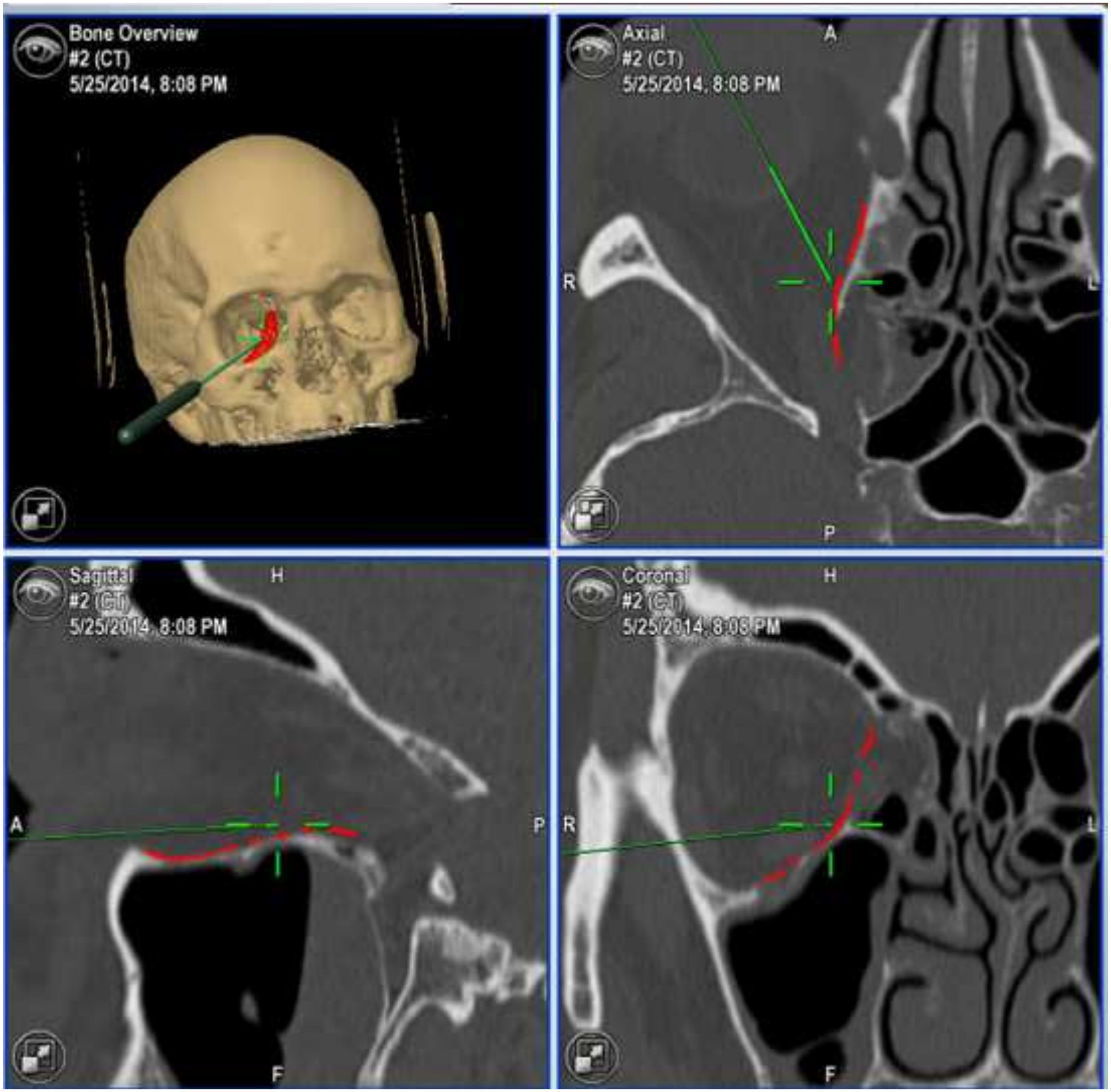

Figure 6

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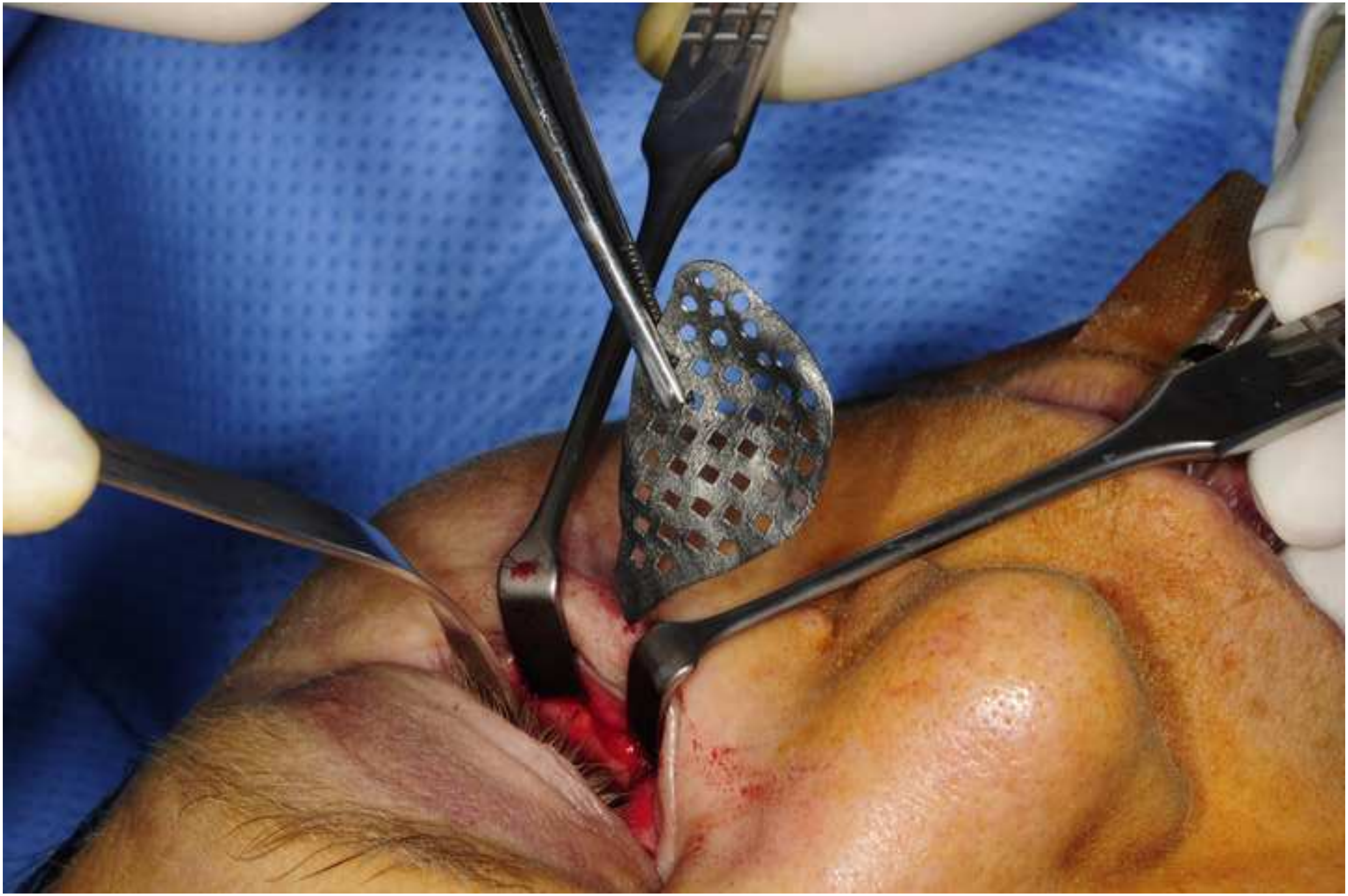

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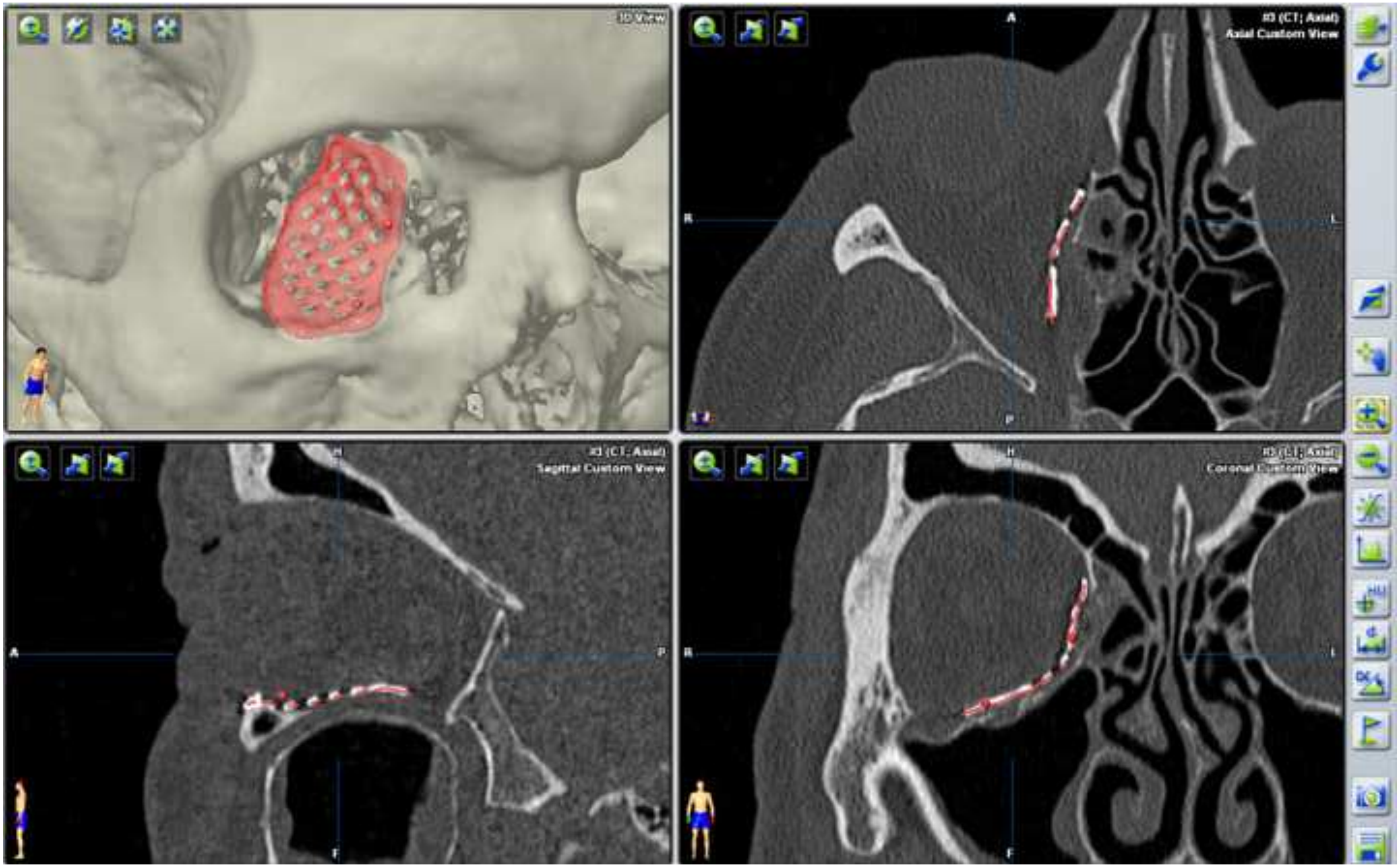

Highlights (for review)

Summary

Fractures of the orbital wall and floor can be challenging due to the demanding three-dimensional anatomy and limited intraoperative overview. Misfitting implants and inaccurate surgical technique may lead to visual disturbance and unaesthetic results. A new approach using individually manufactured titanium implants (KLS Martin, Group, Germany) for daily routine is presented in the current paper. Preoperative CT-scan data were processed in iPlan 3.0.5 (Brainlab, Feldkirchen, Germany) to generate a 3D-reconstruction of the affected orbit using the mirrored non-affected orbit as template and the extent of the patient specific implant (PSI) was outlined and three landmarks were positioned on the planned implant in order to allow easy control of the implant's position by intraoperative navigation. Superimposition allows the comparison of the postoperative result with the preoperative planning. Neither reoperation was indicated due to malposition of the implant and the ocular bulb nor visual impairments could be assessed.
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Tables/Figures

Table 1 Patient data

Table 2 Results

Figure 1 Placement of the smart shaper in the required area.

Figure 2 Adaptation of the selected area with the smart shaper.

Figure 3 Determination of the prospective implant's extent.

Figure 4 Implant design.

Figure 5 Intraoperative navigation for implant position control.

Figure 6 Transconjunctival, post-septal patient-specific implant (PSI) placement.

Figure 7 Superimposition of the preoperative planning position upon the postoperative patient-specific implant (PSI) position.

The English in this document has been checked by at least three professional editors, all native speakers of English.