

### 3D IMPLANTATION IN THE MAXILLOFACIAL REGION

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**Annotation.** The article considers the problem of combined facial trauma as a high-level diagnostic and surgical challenge, in particular the lower orbital wall. The article presents the results of clinical observation and describes the peculiarities and consequences of its manifestation.

#### Intraoperative feedback

During surgery, the surgeon strives to position the implant as close as possible to the ideal position that was established in the HSP. The presence of the VSP provides intraoperative feedback, which improves the outcome of the reconstruction. There are additional types of feedback that help with accurate positioning of the implant. Design options related to implant positioning provide static feedback through a unique and convincing PSI fit. In secondary cases, reuse of screw positions from the primary reconstruction will also help to find the planned position.

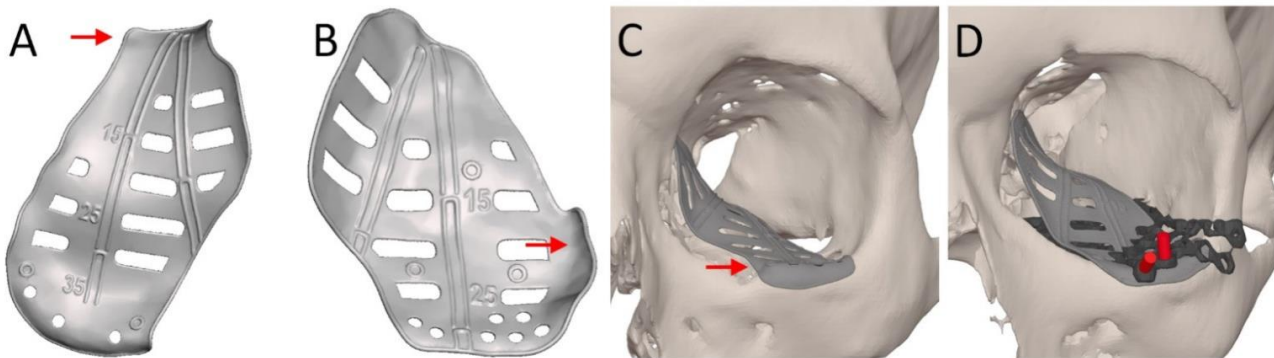


Figure 1: Illustration of the different feedback methods. Markers and vectors are visualized in (A) and (B). The convincing match of the patient-specific implant design is indicated by red arrows (A-C). Segmentation of the screw holes of the previous reconstruction is shown in red (D) and the previous implant is shown in dark gray.

Surgical navigation can be used to provide dynamic feedback of the implant position. During registration for surgical navigation, the patient's position in the operating room is linked to preoperative imaging data in virtual surgical planning. There are several methods of registration: soft-tissue registration, bone-fixed fiducials, and surgical splints. Splint registration methods used to require repeated radiographs with a fiducial splint in place, but combining intraoral scanning data during the in-depth diagnostic phase allows a registration splint to be fabricated without additional radiological imaging. The splint is designed taking

into account the individual features of the patient's dentition and contains fiducials that can be specified virtually in the planning software and physically in the operating room.

After registration, the position of the navigation pointer in the patient is visualized in the virtual surgical planning on the screen of the navigation system.

Once registered, the position of the navigation pointer in the patient is visualized in the virtual surgical planning on the navigation system screen. This provides the surgeon with feedback on the position of the pointer, representing the position of the specified location (a specific point on the implant surface). The quality and interpretability of the feedback can be improved with navigation markers embedded in the design.

The markers are indicated in the EP as navigational landmarks and are used in the operating room as a reference point. If the surgeon places a pointer in the navigational marker on the implant, visual and quantitative feedback about the position of the pointer in relation to the landmark is provided.



Figure 2: Illustration of the evaluation. (A) Three-dimensional model of the planned patient-specific implant (red) and the realized patient-specific implant (green) from different perspectives.

(B-D) Axial, sagittal, and coronal views of the postoperative CT scan with the planned contour of the patient-specific implant highlighted in red.

An optimally positioned orbital implant is no guarantee for a perfect clinical result. Restoration of the globe position can be achieved relatively well with PSI, even in secondary reconstructions. The treatment of diplopia is more difficult because it involves mechanical eye movement, combined visual perception and processing in the visual cortex. Visual processing can (partially) adapt over time. On discharge, the patient is informed that double vision will be present for the first 10-14 days, possibly longer.

Ocular mobility can be improved by training the extraocular muscles to prevent scarring and anticipate fibrosis. Instructions are given to mobilize the eye as much as possible: monocular orthoptical exercises six times a day for 6-12 weeks to prevent adhesions and to stimulate the reduction of orbital soft tissue edema, especially for the extraocular muscles. This protocol has a positive effect on clinical improvement in both primary and secondary cases.

Several larger comparative studies have demonstrated a positive effect of (components of) CAS on the accuracy of volumetric reconstruction, clinical outcomes, and the need for revision surgery. In practice, a combination of several CAS components is often used. This leads to heterogeneity of surgical approaches, which makes it difficult to compare results between studies. Differences in indications, patient and fracture characteristics, and implant materials used further complicate the comparison. Determining the effect of individual CAS techniques

on patient outcomes is difficult because of the overlap between the techniques in the groups studied. Individual effects of CAS techniques have been evaluated in a one-to-one comparison on a series of cadavers. Despite the limitations of the cadaveric model and the inability to estimate clinical outcome parameters, a positive effect of virtual planning, intraoperative imaging, and surgical navigation on reconstruction accuracy was found.

The best solution to achieve an optimal result and in the future can be accurately adapted to the individual patient, provided the above knowledge gaps are filled. Cost, turnaround time, and logistical requirements are disadvantages of using PSI. Pricing can vary depending on geography, but typically the process costs between 1,500 and 6,000 euros. Making the implant takes about 3-5 business days; this amount does not include sterilization or the time required for virtual surgery planning and design. Korn et al. described the average communication time between the surgeon and the PSI technician during virtual surgical planning, which was nearly nine days for isolated wall fractures and 16 days for multi-wall fractures. Adjustments to the original design proposed by the technician were required in nearly three-quarters of cases, but implants placed by technicians trained by the company required fewer adjustments. Improved communication and understanding are believed to be the reasons for the increased efficiency. Complete in-house planning and design by a dedicated technician on site can improve planning efficiency and ultimately significantly reduce preparation time (assuming the surgeon and technician are experienced and have collaborated on previous cases). In-house design is supposed to reduce costs because the commercial partners rely only on production. These advantages of in-house design may be why surgeons using in-house planning feel less of the disadvantages of using PSI.

Although this paper focuses on posttraumatic orbital reconstruction, other orbital-related applications of PSI have also been described. In cheekbone reconstruction after trauma, ablative surgery or congenital deformity, PSI has been found to accurately restore anatomy without the need for additional bone grafts. In secondary posttraumatic reconstruction of the orbit and zygomatic bone, PSIs allow for a one-stage surgical procedure in which the order of operations is reversed: if the orbit is operated on first, the functional result of orbital reconstruction does not depend on repositioning of the zygomatic complex [54]. PSIs can also be used to create an artificial rim and orbital floor to support the globe after maxillectomy [84,85]. The most extensive orbital reconstructions using PSI have been described after resection of a sphenoid-orbital meningioma or neurofibroma. In these cases, reconstruction of all four orbital walls with multiple PSIs allowed predictable reconstruction of the internal orbital structure under the same surgical conditions as the resection. The design of PSI in the aforementioned cases may differ significantly from that of posttraumatic reconstruction of single orbital fractures. Nevertheless, the point of using PSI is the same: freedom of design to adapt PSI to the patient's anatomy and a predictable and accurate end result.

Extended diagnostics seeks to maximize the information extracted from the available image data. For this purpose, CT scans are imported into a virtual surgical planning software. The CT scan is divided into voxels (three-dimensional pixels), each with a gray value corresponding to the absorption of X-rays in a given volume. These voxels can be segmented (grouped) based on the type of tissue or anatomical structure to which they belong. Anatomical

structures of interest in orbital trauma are the orbit, the orbital cavity, and possibly the surrounding

bony structures, such as the zygomatic complex. The segmentation is visualized as supra- in a multiplanar view and as a 3D model. Additional information can be gathered Through quantification (e.g., volume measurement) or manipulation (e.g., mirror image) Segmented anatomy. The unaffected contralateral orbit and orbital cavity in unilateral fractures can serve as a reference for the affected orbit, giving an idea of the extent of the fracture and the displacement of the orbital walls or the surrounding bony structures. The volume of the affected orbit can be compared with the volume of the unaffected healthy side to determine the relative change in volume, because it has been proven that the orbits are very symmetrical. These volume changes can be incorporated into the treatment plan. Information can also be extracted from several sets of images. Image Image fusion allows multiple datasets of the same modality to be aligned over time or sets of images from different modalities. Image sets can be simultaneously visualized and evaluated after image fusion. The segmentation process can also be based on information from several merged modalities.

Orbital reconstruction with PSI is the final step in individualizing orbital reconstruction. The PSI is virtually modeled from scratch using information from the (advanced) diagnostic stage and exported virtual models. A prototype of the implant is created in special design software. The prototype is imported into virtual surgical planning and its fit is evaluated. The prototype position is not adjusted in virtual surgical planning to improve the fit, but the prototype design is adjusted and the new prototype is re-imported. Although the PSI design is not fixed in the protocols, various design variants have been described in the literature. An overview of the variants is given in Table 1. This overview is not exhaustive, and new design variants regularly appear in the literature.

Structural considerations can be categorized according to their intended effect: stability, ease of positioning, accuracy of implant placement, or relief of clinical symptoms. The size and shape of the implant depend on the extent of the defect. The defect must be covered by the implant, and its shape should reflect the intended reconstruction of the affected orbital walls. Reliance on existing bone structures is taken into account to ensure stability of the reconstruction. Similar to pre-formed implants, support is most often at three points in the orbit. Fixation is recommended to ensure the stability of the PSI. Possible screw positions can be evaluated in virtual planning, considering the patient's anatomy and local bone quality. Implant thickness and the presence of an atraumatic cord around the edge are factors that affect both implant stability and ease of positioning during surgery. Thanks to the rigidity of additively manufactured titanium, the implant thickness of 0.3 mm combined with the atraumatic cord provides a good balance between rigidity and ease of positioning. The accuracy of positioning of the implant can be controlled by extending over the unaffected bone supports. Extension of the implant over the bony structures creates a secure fixation. Extension of the infraorbital rim limits rotation and translation in the anteroposterior direction. Additional flaps may be placed on the posterior lateral wall to prevent unwanted movement of the implant. The screw positions from the fixation material of the previous reconstruction can be reused in the secondary reconstruction to provide guidance and thus increase the accuracy of the implant positioning. Another design option is the inclusion of

navigation markers and vectors that can improve the interpretation of feedback from the intraoperative navigation system.

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