Use and Evaluation of Patient-Specific Titanium Implant for Delayed Repair of Posttraumatic Frontonasoethmoidal and Supraorbital Bone Defect

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Abstract

A 53-year-old female patient was referred to us with a posttraumatic frontoorbital deformity following motor vehicle accident after 2 months of her injury. Using the virtual surgical planning software, comprehensive analysis of the deformity, and preoperative planning was simulated. The reconstruction of the defect was then determined and approximated to the skull of the reference database. Patient-specific implant is manufactured by selected laser melting of titanium powder grade 2, which yielded a highly accurate personalized implant. The good postoperative outcome was satisfactorily achieved. The postoperative result was also comparable to the predicted outcome as showed via chromatographic analysis method. Not only being less invasive, the operative time was also remarkably reduced as compared with the conventional reconstruction method of similar cases.

Keywords
- virtual surgical planning
- patient-specific titanium implant
- craniomaxillofacial surgery
- computer-assisted surgery

Delayed frontoorbital bone reconstruction is a surgically challenging procedure. Conventionally, it may warrant an extensive and commonly, multidisciplinary approach involving both maxillofacial surgeon and a neurosurgeon. Compared with the relatively straightforward reconstruction of the almost flat surfaces of the anterior table of the frontal bones, the reconstruction of the depressed frontonasoethmoidal and supraorbital rim is surgically demanding. In this case report, we present and evaluate a case of the delayed frontoorbital reconstructive procedure using patient-specific, fully customized titanium by using virtual surgical planning (VSP) and rapid prototyping (RP) technology.

Historically, medical modeling technology started as early as 1980s when the two-dimensional computed tomography (CT) images in Digital Imaging and Communications in Medicine (DICOM) format were used to reconstruct three-dimensional (3D) model with computer numerically controlled (CNC) milling machines. Styrofoam or polyurethane block was then milled according to the 3D images.[1–3] This "near" life-sized medical model was preoperatively utilized, mainly to facilitate prebending of the reconstruction plate and a better understanding of the disease or injury. Nevertheless, the method used was not without its limitation as the production of the details largely depends on the size of the cutter.[4] Thus a conventional model reproduced is often incapable of capturing the complex and paper-thin internal structures of a skull.

The application later evolved into the production of more accurate models,[5] followed by the emergence of RP technology by using selective laser sintering and stereolithography apparatus.[6] Contrary to CNC, RP operates by deposition of biomaterial in layers, which allows production of a more precise final model with accurate external contour and internal geometries. Synergically, the vast development in both CT and cone-beam CT scanners provides higher resolution with considerably less radiation to the patient. More

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recently, the advancement of computer software programs, large random access memory and dedicated graphic capability allow virtual preoperative assessment and planning.[3]

It is of late that VSP has gained popularity in restoring facial symmetry, appearance and function in the maxillofacial region.[7] With the concurrent development in medical computer-aided design and manufacturing (CAD/CAM) technology, facial deformity can be quantified in a 3D milieu, while allowing not only simulation of the surgical osseous procedure[8] but also an alternative reconstruction method. A combination of both of the VSP and CAD/CAM system has been employed in designing the implant virtually,[3] resulting in a patient-specific, personalized implant.

In this case report, we present and evaluate a case of delayed frontonasoethmoidal with supraorbital reconstruction using patient-specific, fully customized titanium implant via VSP and RP technology.

Case Report

A 53-year-old female patient was referred to our team for reconstruction of the facial deformity 2 months after her facial injury following a motor vehicle accident. Clinical examination revealed a 10 cm healed laceration wound at mid forehead, which extended to the left upper eyelid. The frontonasoethmoidal region appeared severely depressed with palpable step deformity over the left supraorbital rim (►**Fig. 1**). Depressed fracture of the anterior table of frontal bone was confirmed by CT scan. Frontal sinus appeared healthy bilaterally with healed posterior table without dura or cerebrospinal fluid complication (►**Fig. 2**). She also sustained large, nonrepaired left orbital blowout fracture with a ruptured globe, and herniation of orbital contents into the left maxillary sinus (►**Fig. 3**). Left medial canthal attachment appeared slightly lower than that of the contralateral side. However, no telecanthus was observed. She also experienced intermittent pain on the left forehead region, which commonly causes a headache confined to the left frontal region and anosmia. In addition to facial injuries, she also sustained comminuted fractures of the left midshaft humerus and right lateral malleolus in which several surgeries were performed by an orthopedic colleague.

She presented with a request for correction of the forehead defect and also prosthesis replacement of the ruptured left eyeball. Although consulted in several sessions, she refused the surgical plan for re-osteotomy and repositioning of the frontal and supraorbital bone to correct the deformity. Therefore, an alternative, less invasive treatment option was drafted, leading to decision for an "onlay" patient-specific titanium implant (PSTI) for reconstruction of the deformity. This correction was deemed possible due to the healthy status of the frontal sinus bilaterally. She consented to this surgical plan and subsequently, we approached Materialise (Leuven, Belgium) for the virtual 3D planning and simulation of the reconstruction. High-resolution CT data in DICOM format were uploaded onto the specialized image processing software, Mimics (Materalise) where data conditioning and segmentation were done to yield triangulated (STL) files. Following data interpolation, the anatomical data were imported to 3-matic (Materalise) which allowed precise 3D measurement and engineering analyses and design and fabrication of patient-specific implant.

Based on the surgeon's preference and recommendation, described by using the specific prescription form, the biomedical engineer next determined and approximated the

Fig. 1 Severe deformity of the frontonasoethmoidal and left supraorbital rim with the ruptured left eyeball.

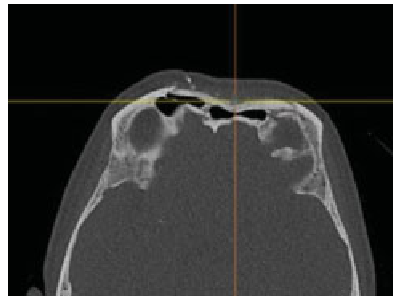

Fig. 2 Depressed fracture of the anterior table of frontal bone with bilaterally healthy frontal sinus.

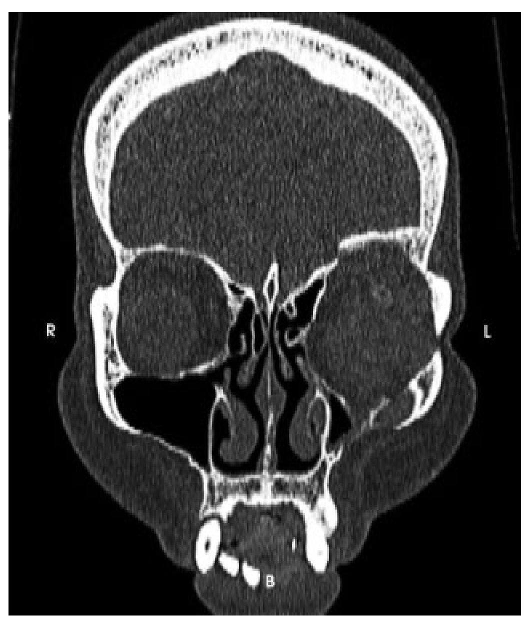

Fig. 3 A coronal section of CT scan showed the magnitude of left medial and inferior orbital walls fracture with disruption of the left supraorbital rim. CT, computed tomography.

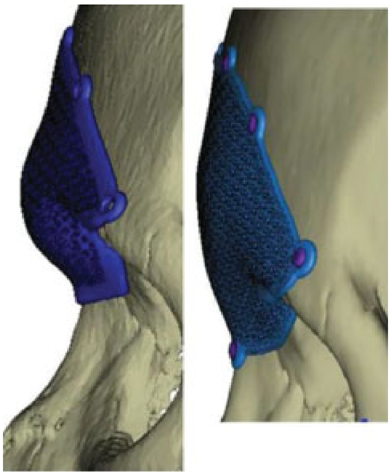

Fig. 4 Design modification to ensure precise projection and optimum fitness of the patient-specific titanium implant.

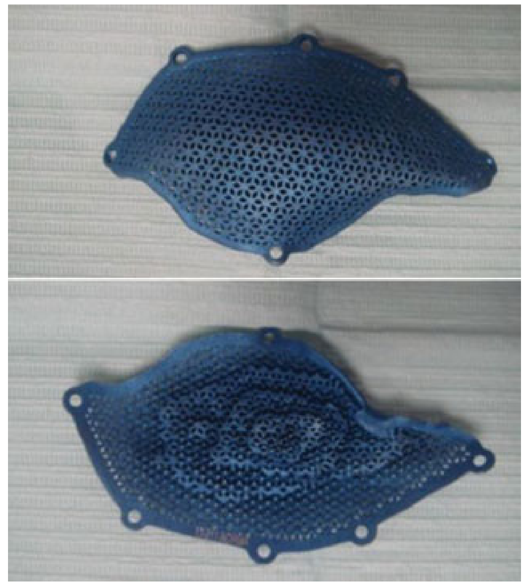

Fig. 5 Patient-specific titanium implant delivered in a nonsterile condition allowing further clinical inspection of surfaces.

defect to the skull of the reference database. Further design modification was undertaken following discussion with the surgeon to ensure precise projection and the fit of the implant while allowing the implant to rest passively on the frontal bone (►**Fig. 4**). Optimum screw locations were also determined through analyses of bone thickness and density while taking anatomical structures and surgical access into consideration.

Finally, the patient-specific implant is fabricated using grade 2 titanium made by selected laser melting (OBL PorousiTi, patient-specific implant, France). Layer by layer deposition method was employed with an elementary porosity pattern to mimic the properties of surrounding bone. Each layer of titanium powder is fused by the laser beam in the fusion chamber. To ensure the even thickness of each layer, the powder delivery piston rises while the production piston descends concurrently in an equivalent and standard manner, as previously described.[9] Following fabrication, the PSTI was delivered in a nonsterile condition, allowing further clinical inspection prior for the usual autoclaving manner before the surgery (►**Fig. 5**).

Before the coronal flap, the remaining nonviable, ruptured left eye was enucleated and the intraoperative impression was taken in preparation for the orbital prosthesis. This was followed by the surgical exposure to the traumatic defect that was gained via a coronal flap (►**Fig. 6**). Following adequate surgical exposure, the PSTI was placed onto the defect in a passive fashion and fit snugly over the defect areas. Fixation screws were also placed as planned and an immediate, adequate frontal bone projection was reestablished (►**Fig. 7**). No manual implant adjustment was necessary during surgery that was completed within 85 minutes. The postoperative surgical period was uneventful and she was subsequently discharged 5 days later.

A postoperative CT scan was taken a month later to evaluate the accuracy of VSP and its final result. Heat map chromatographic analysis of the preoperative and postoperative CT scans shows that the mean distance, comparing the actual position of the implant to the planned one is accurately achieved (►**Fig. 8**). Around 98% of the points of the actual segmented implant are in a $\pm$ 2 mm range compared with the planning (77% in a $\pm$ 1 mm range and 44% in a $\pm$ 0.5 mm range). It was also important to note that the decrease in the value for 0.5 mm is strongly influenced by the fact that titanium segmentation is usually typically over-segmented. Also, regions of the large difference of more than 2 mm were hardly noticeable in the facial aspect of the analysis. Although not further explored, it could be postulated that these were located below the PSTI or in the "scaffold" areas beneath the implant that has minimal clinical relevance.

Overall, the morphology seems satisfying from both the computer analysis and importantly from the clinical or surgical outcome perspective (►**Fig. 9**). Also, it was apparent that less pain was experienced on the left forehead presumably secondary to the release of the tethered pericranium and/or overlying cutaneous tissue to the fracture site. She was still under review and is currently approaching almost 3 years review duration as we are also planning for the reconstruction of her left orbital walls to address the post-enucleation socket syndrome.

Fig. 6 Surgical exposure to the traumatic defect via a coronal flap.

Fig. 7 Immediate satisfactory frontal and profile projection reestablished intraoperatively.

Fig. 9 Follow-up picture of the patient at 2 years of surgery. Left postenucleation socket syndrome is evidenced for another patient-specific reconstruction.

Discussion

Traumatic craniofacial reconstruction is surgically demanding as it is usually complicated by soft tissue loss or scarring, comminuted bony fragments, and diminished blood supply.[10] Similarly, the frontonasoethmoidal and supraorbital rim that exclusively occupies nearly one-third of the facial aspect makes the reconstruction of traumatic deformity of this region aesthetically very demanding. Meticulous planning to achieve optimum and consistent aesthetic outcomes are mandatory. Although the flat surfaces of the outer table are a relatively straightforward reconstruction, the involvement of the supraorbital rim and nasoethomidal region are intricate and surgically demanding. Preservation of the vital structures such as the supraorbital nerves is also crucial.

Also, reconstruction of the traumatic nasal deformity has frequently been via harvesting an autogenous bone or cartilage, which carries a requirement for donor site and its associated morbidity. Synthetic material is also sometimes desirable to achieve a pleasing surgical outcome. Considering this, one can appreciate the complexities posed during and even before the surgery, with the uncertainties of the outcome despite the maximal efforts.

Before the advent of VSP and RP, the conventional method of reconstruction commonly relies on surgeons' experiences and often leads to less than expected intraoperative events and possible untoward complications. This gives rise to increased operative time and compromised surgical outcomes.[7] However, VSP enables detailed preoperative surgical planning and simulation using computer software, hence allowing surgeons to visualize and analyze the injuries in great details. The virtually controlled surgical simulation can also be done repeatedly, regardless of the complexity without the element of any harm to the patient.

In addition, 3D images further facilitate clearer communication between surgeons and patients, thus improving patient's understandings and perhaps acceptance toward the surgery. With virtual trial-and-error surgery made possible, a more predictable and satisfactory result can be attained.

The fully customized patient-specific implant also ensures precise fitting and rapid fixation intraoperatively while preserving surrounding vital structures. This can be made possible by choosing the best possible surgical access, reducing the unnecessary, sometimes extensive hard or soft tissue manipulation in an already compromised surgical site. Also, it significantly reduces the chances of unnecessary

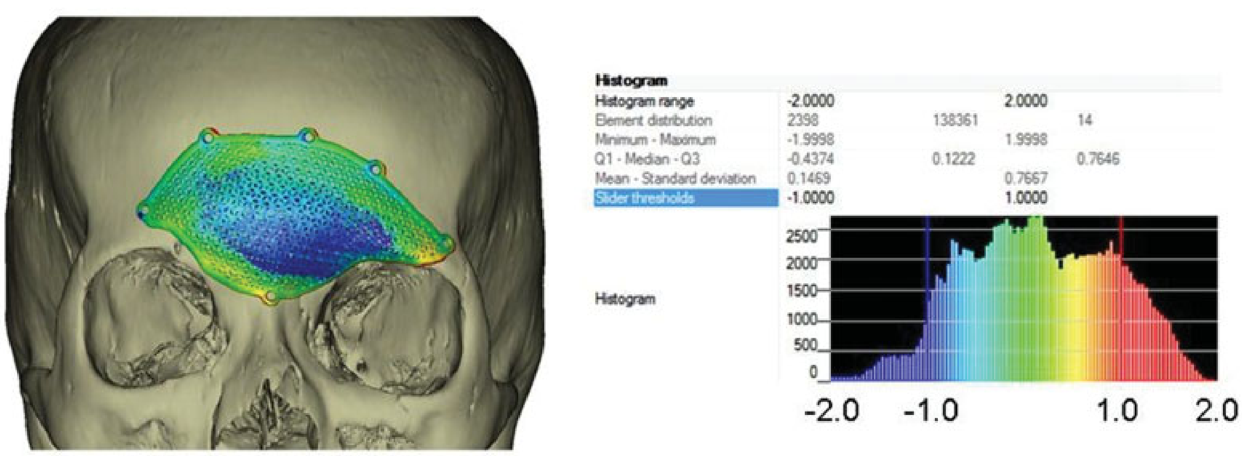

Fig. 8 Chromatographic analysis of the preoperative and postoperative CT scans. CT, computed tomography.

implant adjustment and participation of human-related errors and most importantly, minimize patients' morbidity and shortening the operating time.[9] As the clinical outcome can be "viewed" and objectively "measured" before the surgery, it can possibly reduce the large dependencies to the many other surgeons-related and surgical factors such as the surgeon's experience or inexperience, adequacy of access, the presence of cicatrization, and as well as minimizing the period of hospital stay. Coupled with other advances in surgery such as navigation surgery (which was not illustrated here), there is always a possibility to enhance the surgical precision further.

VSP is a promising technology that is gaining popularity owing to its superior precision, increased surgical efficiency and improved surgical outcome.[7,11] In this case, it is uniquely presented that it is also now possible for us not only for presurgical planning but also to objectively validate the surgical outcome with the use of the superimposition method of the preoperative and postoperative 3D CT scans. This method nurtures scientific evaluation and meaningfully contributes to the surgical outcomes and at the same time provides a detailed assessment of competency levels.

Nonetheless, VSP poses a steep learning curve in some nonsurgical aspect. Manipulating and familiarizing oneself with the computer software as well as in-depth discussion with a nonmedical or surgically trained biomedical personnel is an additional task to explore. This is paramount important as although the implant design aimed to restore the defect perfectly, some surgical limitations were worth discussed by both parties such as the surgical access method, the surrounding soft and hard tissue viability as well as alternative measures that can be taken in case of the need for unexpected intraoperative decision or findings such as the presence of infection or the apparent need for obliteration of frontal sinus. In the case illustrated here, none of these were required as the preoperative analyses were meticulously completed prior.

Some limitations to the method described are also worth being highlighted. The main limitation includes additional cost with the use of the 3D-printing, medical grade patient-specific implant technology, which possibly restrains the usage. It also, for the time being, possibly remains an exclusive option in a very complex and demanding surgical aspects. However, the added cost should be balanced as VSP enhances surgical outcomes, decreases operating time, diminishes the possibilities of complications, and the need for subsequent corrective surgeries. At present, there is still a lack of comparison of cost-effectiveness between this newer technology and conventional method, but it warrants further prospective studies and research.[7,10]

Conclusion

PSTI technique is a useful, alternative method for a complex, delayed frontonasoethmoidal and supraorbital rim reconstruction. Notably less invasive, it also provides promising surgical outcomes while reducing the operative time and should be considered in the management of complex posttraumatic deformity.

Conflict of Interest
The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter and/or surgical technique discussed in this article.

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