Self-Made Rapid Prototyping Technique for Orbital Floor Reconstruction: Showcases for Technical Description

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Background: Restoring the orbital cavity integrity in orbital floor defects is a challenging issue due to the anatomical complexity of the floor's surface. This is a showcase for technical description of a novel "in house" rapid prototyping protocol aimed to customize implant for orbital floor reconstruction.

Methods: The authors present 4 cases to show our Computer-aided-design and Computer-aided-manufacturing digital workflow. The system was based on a 3D-printed press that; through a virtually designed mold, was used to conform a patient specific titanium mesh for orbital floor reconstruction.

Results: The merging procedure analysis by iPlan Cranial 3.0 (Brainlab, Munich, Germany) highlighted a 0.71 ± 0.23 mm ($P < 0.05$) discrepancy in a point-to-point superimposition between the digital planned reconstruction and the real in vivo result.

Conclusions: The authors expect that this technique will reduce operative time and cost however further study and larger series may better define the applicability in everyday surgical practice.

Key Words: CADCAM, in house, orbital cavity, orbital floor, orbital floor reconstruction, rapid prototyping

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Orbital cavity may be affected by several diseases that require surgical reconstruction due to orbital floor displacement or disruption. Orbital structures may be affected in approximately 40% of all craniofacial trauma.[1] Maxillary dentigerous cysts arising from the canine region may extend in the maxillary sinus displacing the orbital floor.[2] Common routes of orbital invasion from the maxillary sinus include tumor spread through the posterior wall of the sinus into the pterygopalatine fossa, with subsequent invasion through the inferior orbital fissure or directly via the orbital floor or lamina papyracea.[3] Cranial malformations, such as congenital sphenoid dysplasia, may need floor reconstruction.[4] Despite several different surgical techniques have been described for orbital floor reconstruction, all of them result in a very narrow operating field. This makes the process of fitting and aligning implants within the orbit rather time-consuming,[5] and operator dependent. In addition, the anatomical complexity of the orbit makes the titanium mesh shaping and cutting process very difficult during the operation and it is almost impossible to achieve a "true-to-original" 3D shaping.

Several studies have highlighted how Computer-aided-design and Computer-aided-manufacturing (CAD-CAM) technologies, coming from aeronautical industry, may support the orbital reconstruction procedure, providing customized implant for reconstruction directly on the patient's anatomy. The CAD-CAM systems available on the market (work on: preformed plates, laser-synthesizing customized plates, or hand-crafting plates on a stereolitographic model) are burdened by high costs and/or long prototyping times.

The aim of our study was to describe an innovative technique based on an "in house" rapid prototyping CAD-CAM protocol that through a mold, virtually designed, should improve effectiveness to conform accurately titanium meshes for orbital floor reconstruction and orbital volume restoration, ensuring reproducibility and reduction of operatory time and costs.

METHODS

Clinical Presentations

From September 2016 to November 2018, 9 patients needing surgical treatment for orbital floor reconstruction were admitted on our hospital. Five cases were excluded because they did not complete at least 12 months of follow-up. Thus 4 cases met the inclusion criteria and were enrolled in the study. On our samples the orbital floor involvement was due to a case of silent sinus syndrome; a case of odontogenic keratocyst tumor in right maxillary sinus eroding the orbital floor; a case of orbital floor fracture; a case of maxillary fibrous dysplasia. All patient underwent ophthalmological assessment and a high-resolution computer tomography (CT) scan on admittance (Fig. 1).

Preoperative Digital Workflow

Orbital segmentation and mirroring: Our workflow started from DICOM files obtained by CT scans that have be uploaded in *iPlan Cranial 3.0* (Brainlab, Munich, Germany) so that users are able to segment the orbital bony walls bilaterally. The mirrored contralateral orbit was, then, used as a reference to reconstruct the bony defect (Fig. 2).

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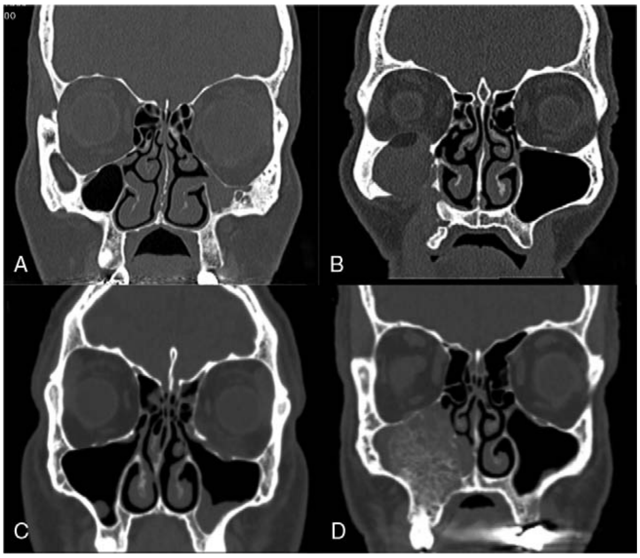

FIGURE 1. Preoperative CT scans showing: (a) a fibrous dysplasia involving the right maxillary sinus; (b) a case of KCOT in right maxillary sinus eroding the orbital floor; (c) a left orbital floor fracture; (d) a silent sinus syndrome. KCOT, keratocystic odontogenic tumor.

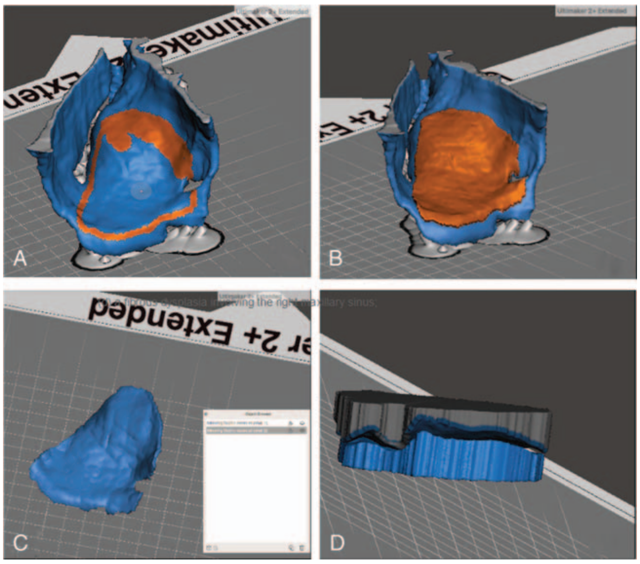

FIGURE 3. a) Digital surface selection for orbital floor reconstruction. b) "Extrude" tool. c) "Export" tool. d) Virtual mold—superior and inferior surfaces matching.

Meshmixer processing: The Standard Triangulation Language file (STL file) of the mirrored contralateral orbit was uploaded in the open source software *Meshmixer* (Autodesk, San Rafael, CA). The surface to be reconstructed was virtually selected and, through "Extrude" and "Export" tools, a virtual mold reproducing the area to be restored was obtained (Fig. 3).

123D Design processing: The STL file obtained was, then, imported in the open source software *123D Design* (Autodesk). Through editing tools, a virtual press with lateral inlays was created to perfectly superimpose the mold's superior and inferior surfaces (Fig. 4).

3D Slicing: Virtual press was exported as STL file, imported into *CURA 2.6.1* (Ultimaker, Utrecht, Netherlands) open-source software and optimized for Ultimaker 2 extended 3D printer. A 0.6 mm nozzle extruder for Bioflex medical polylactic acid (PLA) filament (ISO 10993–5:2009) was settled (Fig. 5).

Mesh modeling: A 0.6 mm titanium linear mesh was shaped inside the virtual mold by applying a manual pressure over the press to obtain a customized product (Fig. 6).

Surgical Procedure

All patients underwent a surgical reconstruction of the orbital floor under general anesthesia. The patient's head was fixed by navigated Mayfield skull clamp. Calibration of the navigator was made by soft-touch device. After infiltration of local anesthetic and

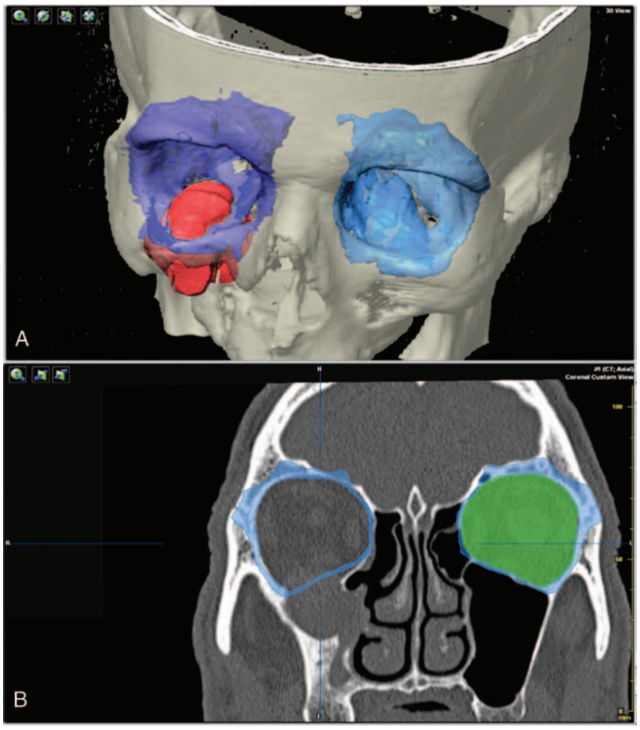

FIGURE 2. a) *iPlan Cranial 3.0* digitally processed DICOM files showing the cystic lesion (in red) involving the right orbit. b) The orbital cavity to be mirrored is highlighted in green.

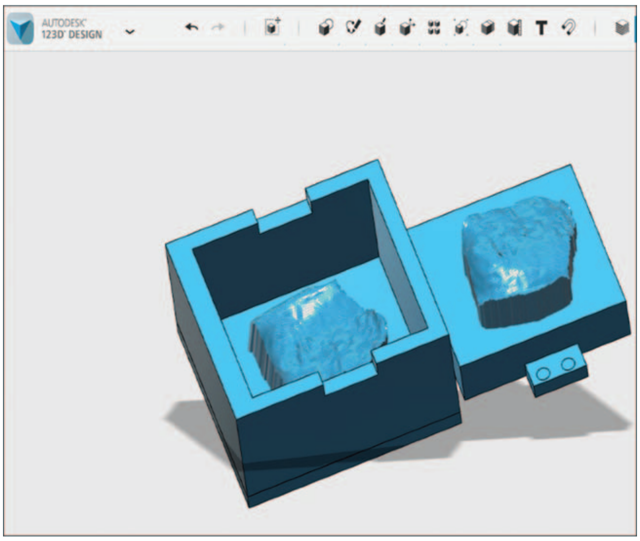

FIGURE 4. Virtual press design.

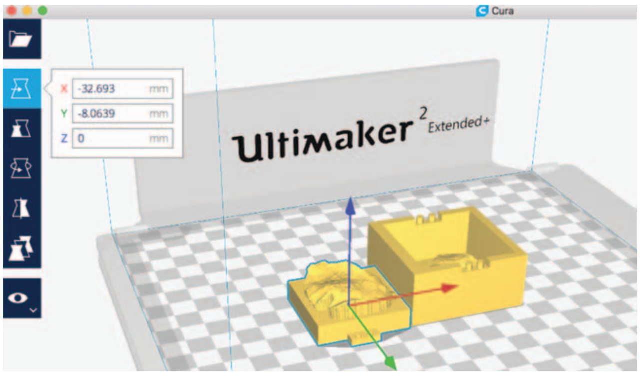

FIGURE 5. STL file sliced for 3D-printing.

vasoconstrictor, a right subciliar incision was practiced to expose the orbital floor. The mesh, previously shaped, was placed to fill the surgical gap. The correct placing of the mesh was tested under navigator control by probe device (Fig. 7).

Postoperative Workflow

After surgical procedure, all the patients underwent orbital CT scans. DICOM data were imported in *iPlan Cranial 3.0* and, by "Merging" tool the digital planning volume was superimposed to evaluate, with qualitative and quantitative measurements, the discrepancy between the digital planning and the in vivo result deriving from the postoperative CT scans. The distance between each of the 3 mesh's angles and the corresponding points on the digitally planned orbital floor surface were calculated using a digital meter tool on *iPlan* software (Fig. 8). The analysis of variance (ANOVA) by Fisher's method was carried out through One Way ANOVA Calculator. A value of $P < 0.05$ was considered significant.

All patients underwent regular clinical controls with a minimum 12 months follow-up.

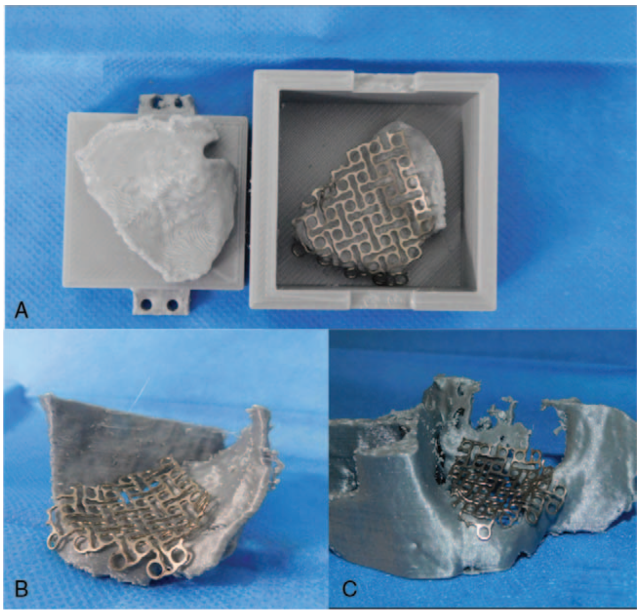

FIGURE 6. a) Shaping of the titanium mesh and its accurate fitting to the orbital floor printed model. b) Mirrored orbit model. c) Involved orbit model.

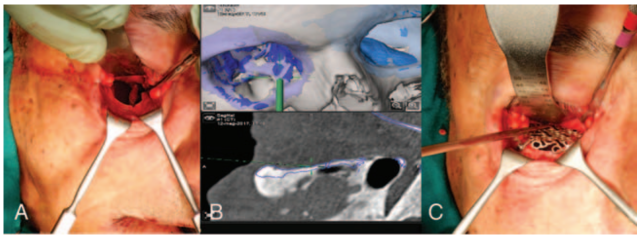

FIGURE 7. a) Right orbital floor defect; (b,c) Patient-specific mesh placement and checking under navigator control.

RESULTS

No postoperative complications were reported during the clinical follow-up period. In 3 cases in which anomalies in orbit positioning and/or in ocular mobility were highlighted by pre-operative ophthalmological examination, restoration of the ocular dystopia and absence of diplopia have been reported. The merging procedure analysis by *iPlan Cranial 3.0* was used to quantify the deviation between the real in vivo mesh positioning to that digitally planned. Good superimposition between preoperative digital planning over the postoperative result was highlighted in all the cases, testifying the mesh's optimal fitting. In detail, the mean distance between each of the 3 mesh angles and the corresponding points on the mirrored surface of the digitally programmed orbital floor was 0.71 ± 0.23 mm (respectively 0.566 mm, 0.533 mm, 0.766 mm, and 1 mm) (Fig. 9).

The ANOVA by Fisher's method showed a significant result at $P < 0.05$ (f-ratio value = 4.88848 P value = .007665) (Fig. 10 and Supplemental Digital Content, Table 1, http://links.lww.com/SCS/A943).

DISCUSSION

The orbit has such a complex anatomy that ideal reconstruction is still now considered a challenging issue. Unless the orbital wall is repaired very accurately, postoperative enophthalmos or diplopia can occur. Limited surgical field in a narrow space is the major drawback in orbital surgery, which may result in failing orbital reconstruction.

A solution may be represented by computer-aided-surgery (CAS) that is today successfully applied in maxillofacial surgery.[6,7,13–15] Computer-aided-design technologies and computer-aided-manufacturing methods allow to plan osteotomy guides,

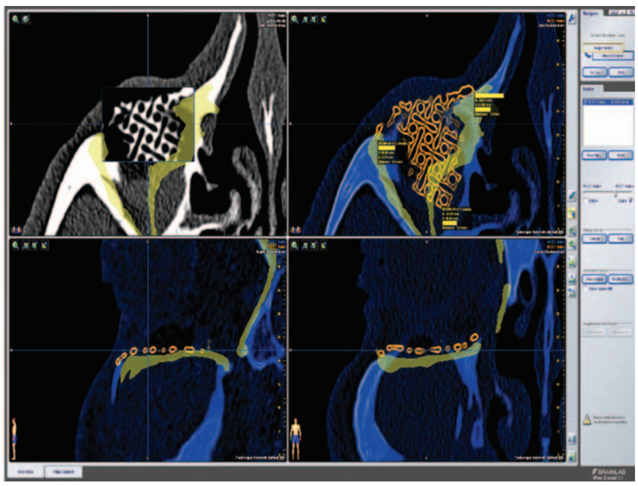

FIGURE 8. Point-to-point discrepancy measurement on the overlap analysis in *iPlan Cranial 3.0.*

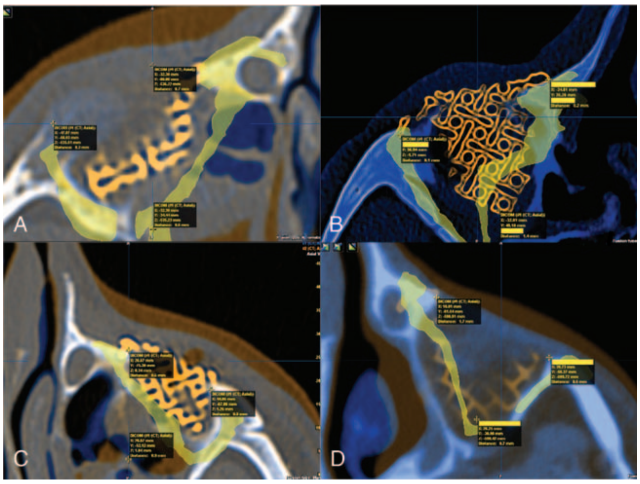

FIGURE 9. Merging procedure analysis by *iPlan Cranial 3.0* in each case: a) fibrous displasia b) KCOT; c) orbital floor fracture; d) silent sinus syndrome.

titanium meshes, and plates, customized on patient's anatomy. These systems are already successfully applied nowadays in orbital floor reconstruction.[10] Several authors[10–12] described the efficacy of customized, laser-synthesized titanium meshes produced by specialized companies. Unluckily, these methods are burdened by high costs and long prototyping times.

In this study, an "in house" laboratory rapid prototyping protocol was applied in order to virtually plan the orbital reconstruction. The new technique we describe is based on a virtually planned mold that reproduces accurately the patient's orbital floor's anatomy. The mold, inserted in a 3D-printed press,

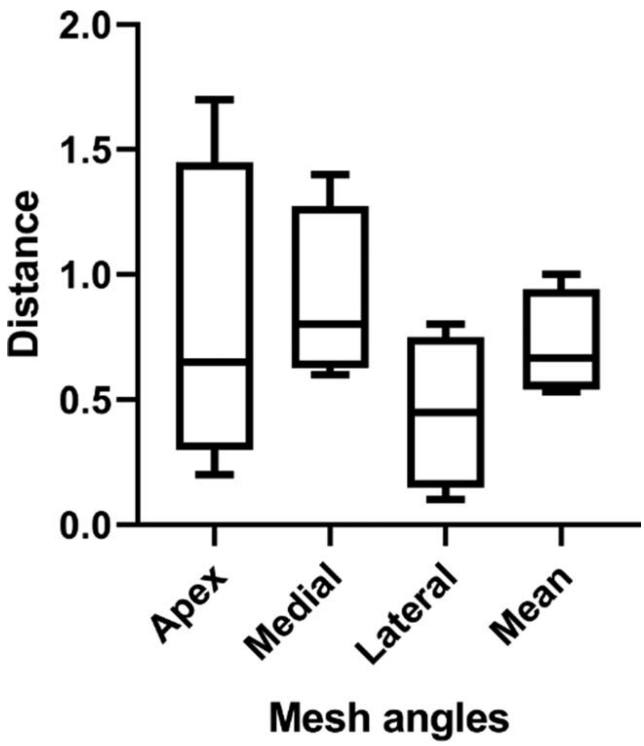

FIGURE 10. Variance of distance between mesh angles and the corresponding points on surface of the digitally programmed orbital floor. The greatest variability is found at the apex of the mesh.

was used to conform accurately the titanium mesh over the patient's floor anatomy, ensuring reproducibility and reduction of operatory time.

The CAD/CAM algorithm proposed is based on the use of free open-source software for digital planning and 3D layer plastic deposition printer with biocompatible polylactic acid (Bioflex medical PLA) as raw material. Merging between the post-operative CT scan and the preoperative design showed an excellent overlapping imaging with an accuracy (measured as average distance between points) of almost 0.71 ± 0.23 mm ($P < 0.05$). 3 meters of plastic wire were used with a cost of about 3 Euros.

Most of this time is spent on surgical planning with consistent gain during surgery. As already said, preoperative design of surgery is not easy and our workflow has some critical points:

The CAD software used in our protocol was not developed for orbital reconstruction intent, and it was daunting to use this the first time without any references books. However, once we became accustomed to it, we encountered no difficulties in using the software.

In general, 3D printer accuracy would depend on the accuracy of CT scans, especially of which thickness should be as thin as possible (1 to 2 mm is a good compromise for a skull study as reported by Olszewski et al).[8] Actually, mayor difficulty in the proposed technique is obtaining an accurate orbital segmentation. Sometimes a manual segmentation is needed to improve the digital result. Because the segmentation process in computer simulations is time consuming, it needs to be more automated.[9]

Another important drawback of our method is the accuracy deriving from mirroring procedure. How reliable is the damaged orbit reconstruction based on the mirrored, contralateral one? This argument is still very debated in literature. Sozzi et al's work[16] showed that anatomically between the 2 orbits a significant surface difference persists, as the contralateral healthy orbit may not be a sufficient reference for guiding the reconstruction protocol. Anyhow Zavattero et al experienced on 55 operation,[17] a significant orbital volume restoration using the navigation protocol based on the healthy mirrored orbit compared with the conventional group.

Such results are confirmed by Gui et al's experience on 138 operations performed using the navigation protocol.[18] The mean discrepancy was confirmed to be less than 1.0 mm by comparing postoperative computed tomography with the preoperative plan. Significant decreasing of the operation time, improvement in safety and accuracy, restoration of the function, high patient satisfaction and remarkable aesthetics improvement via long-term follow-up were assessed.

Our paper did not show that the "in house" protocol we propose was better or worse than those provided by commercial system but demonstrated that our algorithms provide overlapping results. With this in-house procedure, the time required to manufacture the customized, patient-specific implant was much shorter when compared to the time taken by commercial system and could potentially be reduced within 24 hours. This is especially important when we treat malignant diseases.

CONCLUSION

The protocol we proposed allowed to produce low-cost, patient-specific implants in an "in-house" way with an accuracy comparable to that of the currently available systems on market.

The encouraging results obtained with the described method suggest the implementation of this technique to improve accuracy in orbital floor reconstruction. Further studies on larger series are needed to confirm the encouraging results obtained and better define the applicability in everyday surgical practice.

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