

RAPID TECHNOLOGIES SUPPORTING SURGICAL OPERATIONS CASE STUDY

DRSTVENSEK, Igor; STROJNIK, Tadej; BRAJLIH Tomaz & VALENTAN, Bogdan

Rapid prototyping and technologies that experienced a renaissance through rapid prototyping opened new possibilities in medical interventions. Combined with traditional CT scanning techniques rapid technologies (prototyping and tooling) can be used as an instrument for better (three-dimensional) visualization and treatment of a patient. They also improve overall performance of medical and nursing staff what influences a quality of medical service. Using a CT scan of a patient's injured skull, the skull has been reconstructed and the missing part of the skull modeled by use of CAD software. The skull and the implant were produced by SLS and PolyJet technologies to verify a fitting of both parts. Based on the printed model of the implant a silicone rubber mould was produced that was later used for molding the biocompatible material and forming the implant that was implanted into the patient's head.

Reconstruction by use of CT images

The easiest way to reconstruct structure of patient's bones in actual case study is to use the CT images that usually already exist from previous treatments of a patient. The set of CT images can be converted into a three dimensional, digital model using one of the available conversion software. The input to this software is usually in a form of DICOM files and output is predominantly STL, which can be directly used in most of the RP technologies to produce real models (Figure 1).

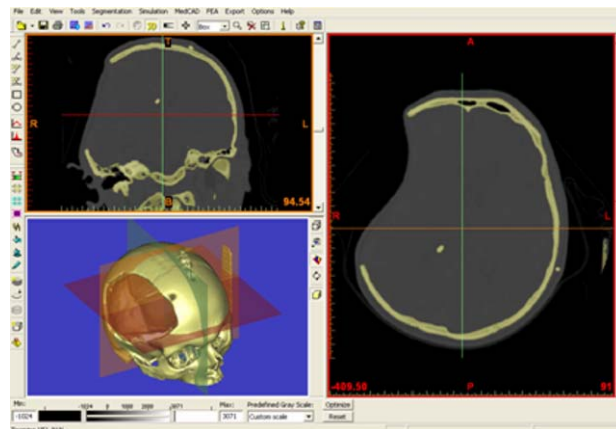


Fig.1. 3D reconstruction of the skull from DICOM data

The CAD modeling of the implant was performed with several reverse engineering software packages. The basic idea is to mirror the entire skull and then perform the Boolean operation of subtracting the original skull from the mirrored one. The result should be the three-dimensional model of the implant. However, during the modeling several problems appeared. Firstly, the orientation of the STL model of the skull in virtual space is exactly the same as was the position of the patients head during the CT-scanning.

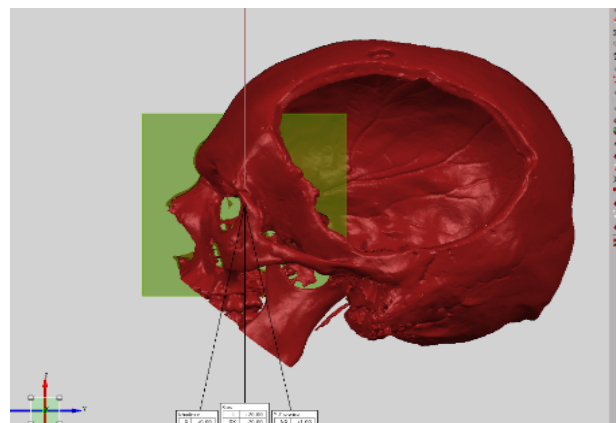


Fig.2. Definition of the vertical mid-plane

Therefore, definition of the mirror plane can be somewhat difficult. In this case, the approximate vertical mid-plane was determined by some well defined features on the skull (nose bone, eye cavities...) (Figure 2).

Then, the original and mirrored skulls were additionally oriented by best-fit registration method that is usually used in CAQ inspection (Figure 3).

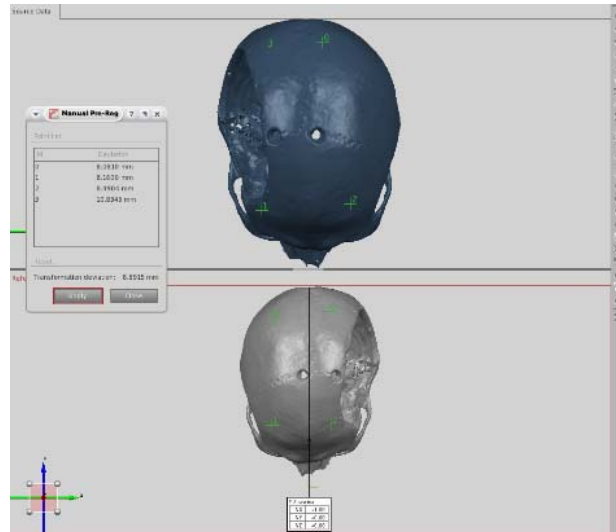


Fig.3. Best-fit registration of original and mirrored skull

Due to skull not being entirely symmetrical the subtracted part did not fit into original skull perfectly. Therefore some additional fine tuning was made to implant model by 3d animation software (Figure 4).

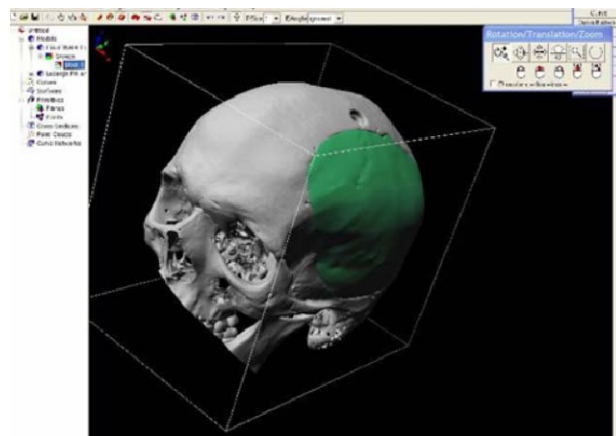


Fig.4. Final inspection of the implant model

Production of real models

Reconstructed models of the skull and the implant were manufactured using selective laser sintering and PolyJet™ procedure. Selective laser sintering was chosen to produce a skull since the technology produces a rigid and resistable polyamide parts and because the material is relatively cheap and consumption is much lower compared to FullCure series of materials used in PolyJet procedure. On the other hand price difference in case of smaller parts like the implant for cranioplastic does not substitute PolyJet's better performance in terms of a surface and dimensional quality. Because the printed model of the implant has latter on been used as a pattern for Silicone rubber molding, PolyJet was chosen for its production (Figure 5).

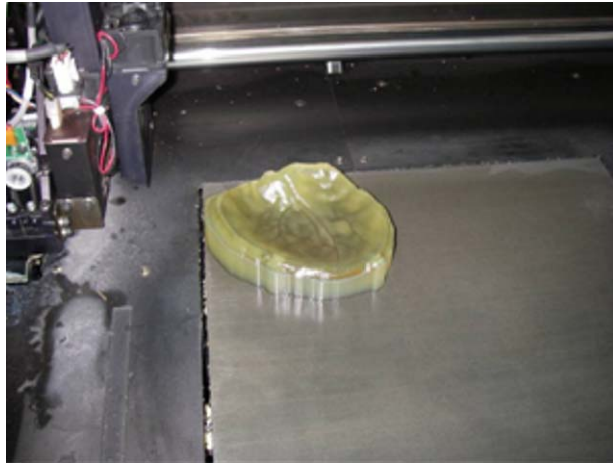


Fig.5. Implant model made by PolyJet Rapid Prototyping technology

Real models of the skull and the implant were then used for testing of the dimensional accuracy and as a communication tool between engineer and medical doctor in a phase of operation planning (Figure 6).

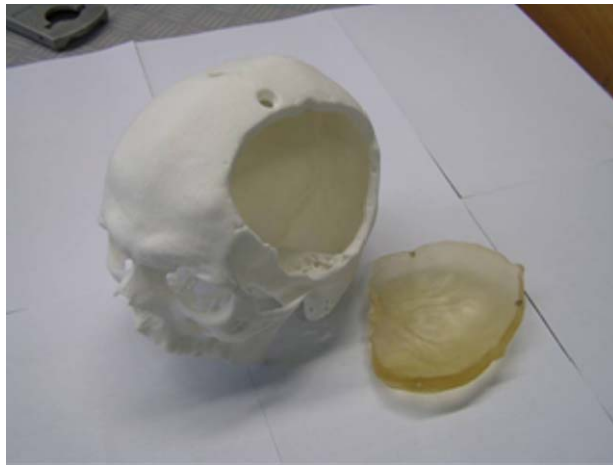


Fig.6. Model of the skull and implant.

Production of biocompatible implant

For production of biocompatible implant a modified SRM procedure was used. A SRM mold was made using a usual frame to hold the silicone and the pattern. Pattern holders were purposely made out of 5mm steel wires in order to make some room for excess PMMA compound (Figure 7). Because of its high viscosity usual casting of material through a round gate was not possible.



Fig.7. Manufacturing of SRM mould

The plan was to prepare a mixture in the lower part of the tool and then cover it with the upper part. Therefore the mold has to be modified in order to be used as a press. This required preparation of “glides” for improved leading of tools and to prevent side movements that could lead to improper forming of the implant. For pressing and holding the tool together for the time of polymer setting an additional press frame was manufactured consisting of two stainless plates and four screws to hold the parts of the mold together.

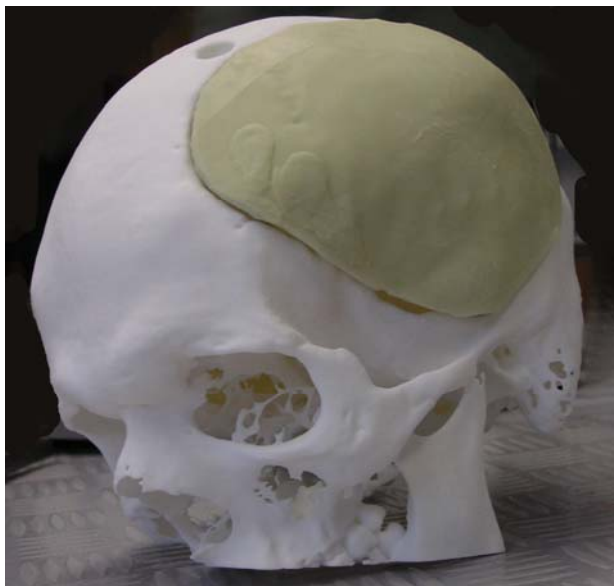


Fig.8. Verification of the PMMA implant fitting

First experiments showed that the initial release openings were miss positioned and too small. The produced implant was too thick and uneven compared to the RP model (Figure 8). Therefore the mold was modified with some extra release openings. Afterwards the experiment was repeated and results were much better. Unfortunately it is impossible to use an exact amount of the material since the bone cement comes in preset quantities of both components that are sterile and require a use of a whole amount of both components to avoid lagging of residual monomers as a consequence of insufficient mixing ratio. Residual monomers are highly poisonous and can among other consequences cause heart arrhythmia as well as cardiac arrest. The excess amount of material forms some extra features in the parting plane of the mold that have to be manually removed after the molding. This requires some cutting and grinding of the implant to achieve the initial shape and satisfactory fitting of the implant.

4. IMPLANTATION

After the preparation work and positive experimental results the whole setup e. g. the mold and the frame as well as all required tools were taken into an autoclave for sterilization (Figure 9).



Fig.9. Final mould setup

The implant was then produced by surgeon in the sterile environment of the operation hall during the surgical procedure (Figure 11). The implant was inserted into the skull of the patient and fixed by titanium plates and screws (Figure 10).

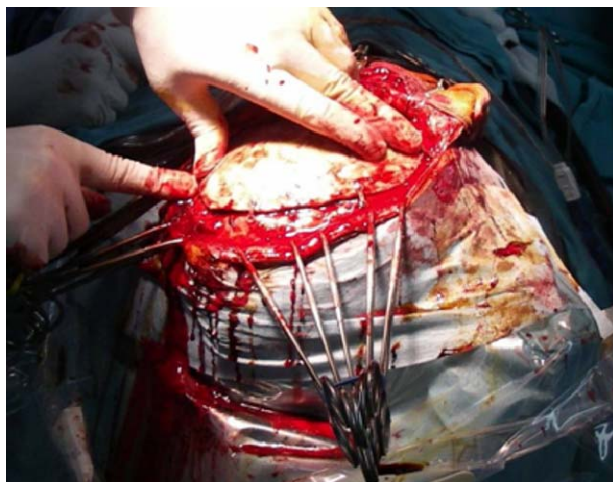


Fig.10. Insertion and fastening of the implant

After the operation the patient recovered by a program, staying neurologically unaltered. Inspection CT showed good position of the bone cover, while some liquid, probably liquor gathered under the cover. Later did not cause deflection of the brain mass and additional surgical intervention was not needed. Patient was released to a home nursing in settled and improved state.

9. CONCLUSION

Presented case study shows a great potential of RP and RM technologies in medical applications. This was the first case of RP&T implant production and implantation in Slovenia. Although the procedure itself is not new it opens new possibilities for medical staff as well as for engineers and industrial applications. Cranioplastic is not the only intervention where both, surgeon and patient can benefit from custom made implants. Custom made “bespoke” implants not only “technically” improve the procedure, they can also release some stress by enabling effective pre surgical planning as well as reduce costs and most important shorten the time of anesthesia.



Fig.11. Implant manufacturing inside sterile operation room

The case study also showed some imperfections in the described procedure that could be avoided in the future. Besides already mentioned release openings that were too small in size and number, also the production of mould could be improved. In the case study the mold was sterilized using autoclave in order to make a sterile implant in the operation hall. Instead of sterilizing the tool by autoclave the implant could be sterilized by means of gas sterilization. In that case the implant could be manufactured in non sterile environment before the operation, what would shorten the procedure for approximately 30 minutes, which is the time needed for polymer to set and for surgeon to manually finish the implant (Figure 11).