# Final Report
## OTKA K 113180

## Application of 3D printer in production of individual implants for human bone defects


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## Introduction

The 3D printing technology started its world-conquering journey 30 years ago, and it revolutionized the industrial segment dealing with prototype-preparation. However - unlike other “revolutions” – it is still in continuous evolution, similarly to computer science, and the technique of which utilization was strictly restricted to industrial application at the beginning, became an everyday tool in many other specialty and scientific area.

This adjoining application also presented itself in the medical area. Especially in the field of orthopaedics, neurosurgery, traumatology and neurotraumatology the 3D printing technology provides a very exciting and cost-sparing high-tech solution for previously unsolvable or expensively manageable problems.

A long-time challenge in neurosurgery is to precisely repair cranial defects and reconstruct the original form of the skull[1-7]. Several methods are used to solve this problem. The simplest of those, applicable for smaller defects at easily reached locations, is manual moulding, when during the surgery the replacement is moulded from PMMA by trying to shape it to the form of the defect while the bone cement is still ductile. The other possibility is to form the implant out of a titanium plate[8] or mesh[1], but these are rather complicated and costly to manufacture.

The appearance of 3D printing was a turning point in the area of individual osteoplasty and in particular for cranioplasty, since this technology allows the manufacturing of three-dimensional objects with complicated, irregular geometry, such as the skull or some part thereof. Kim et al. printed a special mould that, coated with plastic, allows the fabrication of the replacement in the surgery[5], however, applying the coating on the mould and securing its asepticity is not a simple task. Klammert et al. in their cadaver pilot experiments, used a material for powder based 3D printing that could in principle be suitable for direct implantation, but due to infection problems, the use of this method in living organisms is not yet feasible.

Most 3D printers are only suitable for printing a mould, however, metal printing processes, such as selective laser melting (SLM) and electron beam melting (EBM) also allow the direct fabrication of the implant.[3,10] Although these latter procedures facilitate the fabrication of precise and reliable implants, due to the extremely high cost of metal 3D printers, this method is practically available only for a select few institutes.

A cranioplasty procedure based on a special 3D printing method, well suited even for complicated geometries, has been in use at the University of Debrecen since 2005. In this procedure we print a sample exactly matching the shape and size of the intended replacement and based on this sample we produce a silicone mould that in turn can be used to fabricate the PMMA replacement during the surgery.[11,12]

The main goal of the project was to improve and develop the detailed usage protocol of 3D printing for bone reconstruction relying on basic research results.

## Progression and results

Following the work plan, at the beginning of the project we focused on the improvement of our moulding technique. We commissioned a vacuum system in the first months that was specially developed for silicone degassing and provides bubble-free water clean silicon mouldings that helps to track the bone cement inside the moulding. Besides, we developed and constructed a special, widely adjustable frame for the silicon moulding. Using the frame we can set up rectangular moulding pots with any edge size from 30x30 mm to 220x290 mm. Using this device, the amount of the consuming silicone and the size of the silicone moulding can be optimised for each case.

We developed the details of the packing and logistics and the application of these and the required packing materials (paper boxes with different sizes, filler materials etc.) were acquired. The work flow was developed that assures multiple feedback of the shape of the master model. Regarding this we plan to realise the fabrication and control processes based on the following steps (Figure 1.):

1. Receiving CT/DICOM files from the customer (by e-mail/mail).
2. Designing of the shape of the custom implant at the Laboratory of Biomechanics, UD.
3. Sending pictures and web-based 3d models (using http://www.sketchfab.com) from the designed implant plan to check and approve (e-mailing as a document called State report).
4. Modification of the 3d model when required based on the information gathered during the inspection/checking.

5. 3D printing of the bone replacement and the surrounding area of the bone and sending it for checking/approval (by mail).
6. The customer checks and inspects the models and the fitting of them and send them back with the modification/changing instructions when required.
7. Fabricating the silicone mould based on the approved final master model at the Laboratory of Biomechanics, UD.
8. Sending the silicone mould and the 3d models to the customer (by mail).
9. Sterilisation of the silicone mould at the customer's institute.
10. Moulding the bone cement to the silicone intraoperatively (video guide: http://www.tinyurl.com/koponyapotlas).
11. After hardening the last step is the implantation of the bone cement replacement.

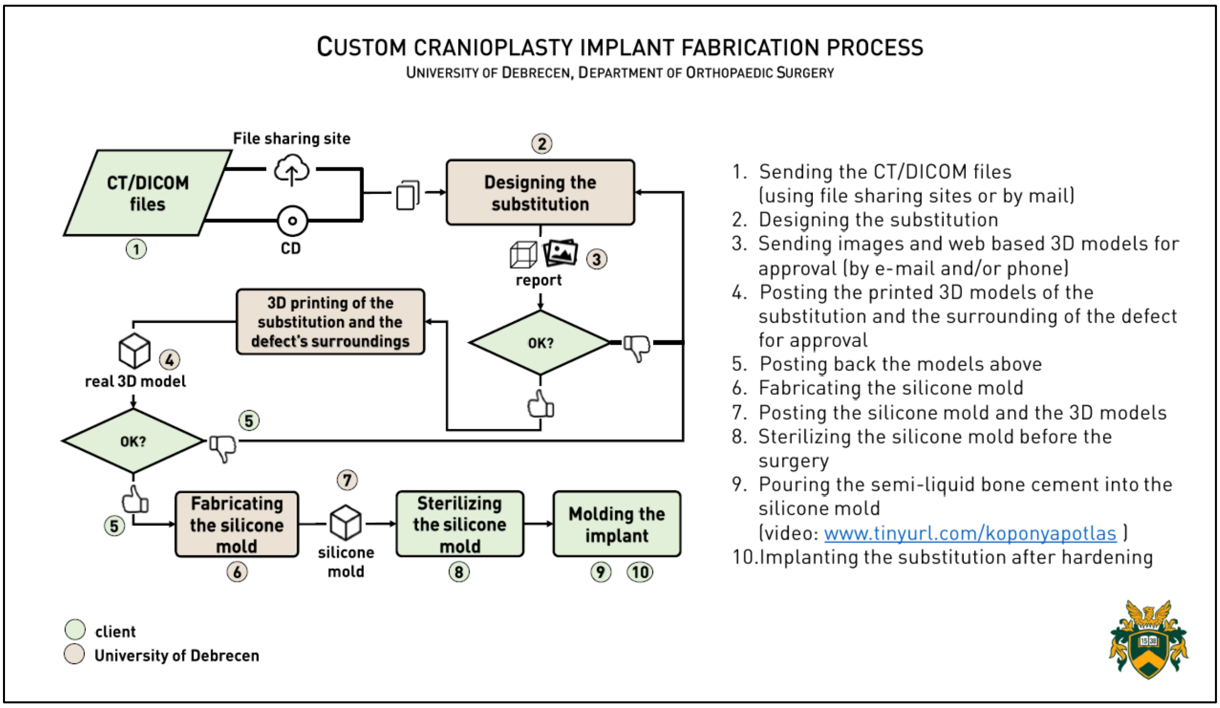


**Figure 1. Our 3D printing-based process for cranioplasty**

After the improvement of our protocol for cranioplasty we performed several tests to evaluate the materials we use and the overall technique from mechanical aspects.

Firstly we tested several silicone materials that could be applied as the base material of the moulding (Protosil RTV 245, Sorta Clear 40, Protosil RTV 23, HT 45 transparent 1:1, HT 45 transparent 2:1) and performed the pre-planned mechanical tests such as compression-, tensile-, and Shore hardness tests in room and increased temperature because of the exothermal reaction of the bone cement hardening process. Based on the test results we chose the material that is the most suitable for the base material of the silicone mould (Figure 2.). Protosil RTV240 has been proved to be the best from both mechanical and transparency point of view.

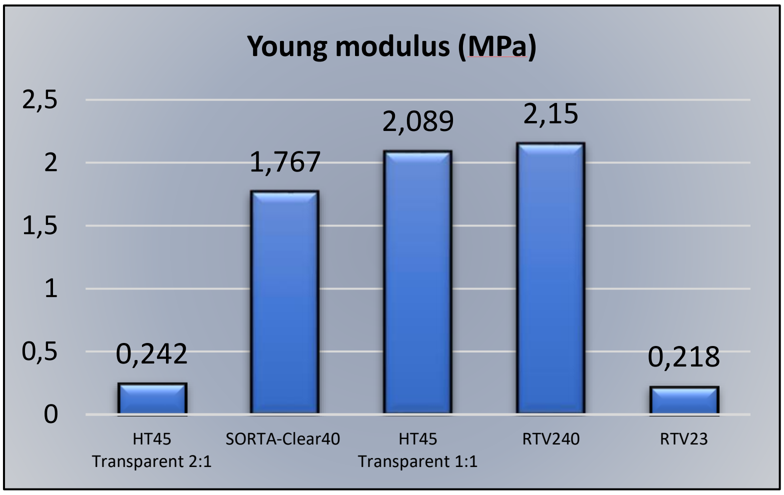


**Figure 2. The results and the samples of the mechanical test of different silicone materials**

As the second mechanical test series, biomechanical tests were carried out following these steps (Figure 3.):

1. Drilling an artificial (with 60 mm diameter) defect into 10 boiled human skull parts including parietal and frontal bone
2. Creating CT scans from the skull parts
3. Designing the shape of the substitutions for the defects based on the CT scans using mirroring and Boolean subtraction just like in usual real cranioplasty cases
4. 3D printing the substitution models
5. Creating silicone mouldings using the substitution models as master/positive models
6. Making the bone cement “implant” with the silicone mouldings
7. Cutting the skull parts in the midsagittal plane into two halves with the same size. The first contains the artificial defect and the second remains untouched
8. Pairing and fit together the damaged specimens and their substitutions
9. Placing the specimen on a rigid support and applying a perpendicular load with 5 mm/min to the skull part-substitution system until permanent damage (cracking or fracture)
10. Applying the same load condition to the untouched half of the skull part

**Figure 3. The test samples and set-up of the mechanical test of the skull-implant system**

Applying the method above we can compare the behaviour of the untouched "healthy" bone and the "damaged" bone with defect pair by pair.

The results showed that the average compressive strength of the substitutions was 1400 N, about the half of the compressive strength of the normal skull parts. Furthermore, the tests proved that in the case of bone cement the damaged material will be the substitution itself, not the surrounding bone.

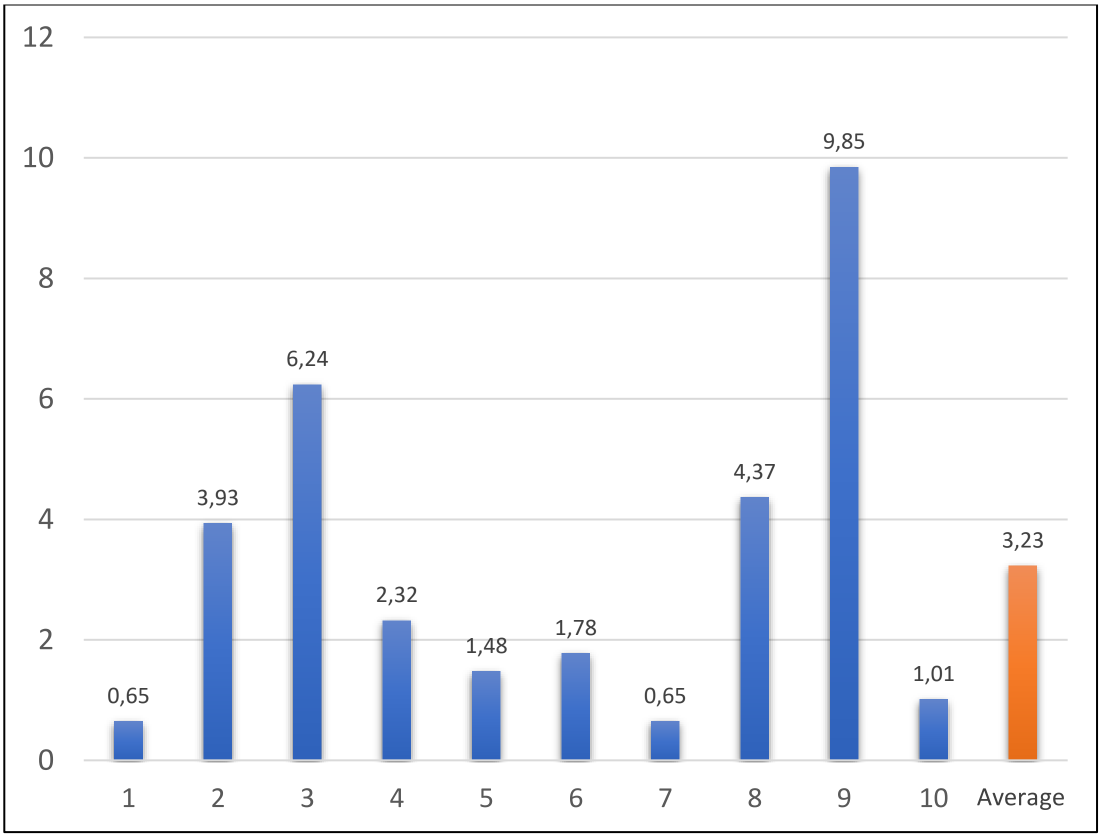


**Figure 4. The results of the skull biomechanical tests: the ratio between the load required to permanent damage in the case of untouched and substituted skulls**

At the last years of the project we improved the technology of the moulding process. Our goal was to develop a better and more effective mould-shaping and cutting arrangement that can provide better filling and easier handling. The result is a mould with two hinged halves with a special coating that prevents the PMMA sticking to the mould (Figure 5.).

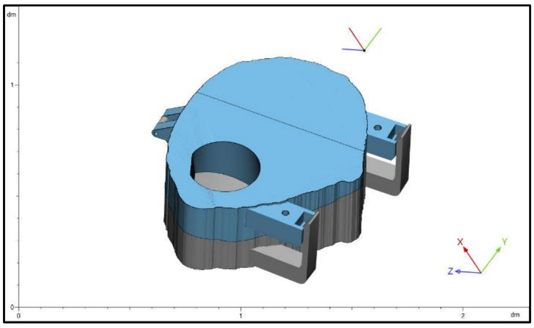

**Figure 5. The hinged construction of the mould**

Between 2015 and 2019 we performed cranioplasty in 44 cases using the procedure we developed in the frame of the project. The publication of the first processed 29 cases is in progress (under review at Journal of Neurotrauma). Most of the patients belonged to the young adult age group (mean age 39.01 years, standard deviation 12.96 years) and the gender ratio was 21:8 (male: female). The average size of the defect in two perpendicular directions was 91.5 and 101.35 mm, while the largest defect had the size 125x140 mm. Complications were observed in the case of two patients and three cranioplasties. In these three cases the patients developed wound infections that necessitated the removal of the implant. However, these complications are not related to the 3D manufacturing technology in any way, we interpret them as results of the standard septic risk of the surgery.

## Discussion

In those cases when 3D printing of metal implants is not possible or for other reasons metal implants cannot be used, individual implants fabricated of bone cement in silicone moulds can be utilized with good results. In the course of this procedure the implanted material is bone cement that has been successfully used for bone replacement for over 40 years. Compared to the manual moulding technique, the present technique allows more precise replacement to be used for more extended areas and in more problematic locations. A further advantage of this procedure is that the polymerization and the accompanying heat generation does not happen in the living organism but in the silicone mould. If any technical problem arises, the moulding, i.e. the fabrication of the implant can be repeated during the surgery and if the mould is kept, later it can be reused for replantation if necessary.

Summarizing, we can say that the overall project was successful. In the end we managed to develop an easy-to-handle bone substitution method and fabrication process and the application was proved with nearly 50 successful cases.

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