

SHORT THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY (PHD)

**APPLICATION OF VIRTUAL PLANNING AND 3D PRINTING  
IN BONE SURGERY**

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## 1. Introduction

Additive manufacturing (commonly known as 3D printing) began its journey four decades ago, gradually rewriting the paradigms of industrial prototyping. Its development has kept pace with advancements in materials science, control engineering, and other technical disciplines, and today it has become a practical tool across numerous fields and scientific domains. Its use in medical practice is increasingly commonplace.

The visualization of unique anatomical conditions - achievable with all existing 3D printing technologies, albeit with varying compromises - was the entry point toward serving patient care. Beyond surgical simulation, additive manufacturing gained real, direct utility in surgery once sterilizable materials with some level of biocompatibility certification and compatible printers became available.

Orthopedics, musculoskeletal and neurotraumatology, and neurosurgery are among the specialties where 3D printing has offered solutions to challenges that were previously only addressable with significant compromises—or not at all. In collaboration with surgeons, it was recognized that incorporating 3D technologies enables the development of new methods and the design of instruments for cases that were previously unmanageable.

In the early years of my doctoral research, I focused on the technical support of re-prosthetization in patients with severe hip bone defects.

With increasing life expectancy and a growing demand for quality years, endoprosthetics has entered a new era over the past decade. The number of hip prosthesis revision surgeries is rising sharply, with a growing proportion of cases involving severe acetabular defects. Due to prosthesis wear, loosening, complications, or accidents involving prosthesis users, increasingly complex revision surgeries are required. In these cases, achieving stable fixation of the acetabular component is particularly challenging.

During my research, the Department of Orthopaedic Surgery at the Clinical Center of the University of Debrecen typically used the Waldemar Link (Hamburg, Germany) McMinn Type I stemmed cup for reconstructing extensive periacetabular bone defects classified as

Paprosky  $\geq$  2B. Targeting the stem posed technical difficulties due to the absence of reference points used by the manufacturer's instrumentation. To address this, a custom targeting technique was developed.

This required the design and production of a patient-specific targeting instrument using available 3D imaging, modeling, and printing tools. This instrument, sterilizable and biocompatible, could be used intraoperatively to accurately and safely position and prepare the conical bore for the stem of the acetabular cup.

The developed procedure involves the surgeon percutaneously inserting two titanium spongiosa screws into the anterior iliac crest during the first session, serving as reference points. A fine-slice CT scan of the operative hemipelvis is then performed using Metal Artifact Removal (MAR) mode. Based on this, the position of the implant is modeled, and a custom-designed, sterilizable, biocompatible 3D-printed targeting guide is created to safely guide the insertion of the targeting wire. This allows the operation to be performed with minimal radiation exposure.

The primary goal of the targeting method is the safe insertion of a guidewire to enable the planned directional insertion of cannulated surgical instruments, allowing the stemmed cup to be implanted with minimal radiation exposure and high reproducibility.

Another objective is to develop a repeatable workflow from CT imaging to surgery, facilitating reproducibility in future cases.

We hypothesize that the targeting method is suitable for the safe insertion of the guidewire used in the implantation of McMinn Type I stemmed cups in severe (Paprosky  $\geq$  2B) bone loss cases, ensuring proper prosthesis positioning without continuous use of fluoroscopy.

The complex cases discussed in this dissertation are characterized by the fact that they cannot be solved—or only with significant compromises—using standard, mass-produced products, despite the wide range of implants and surgical aids available on the market.

The experience gained from this method was later applied to the development of targeting guides for knee prostheses and adapted for shoulder prosthesis implantation as well.

Later, I became involved in the development of cranial bone reconstruction methods using CAD-CAM systems.

In cranioplasty - whether due to trauma or elective surgery - the primary task is to restore the morphology of the skull to protect the intracranial space, which is vital due to its unique physiological conditions. Beyond restoring the mechanical integrity of the skull, the aesthetic outcome of the reconstruction also plays a significant role. With the advancement of CT-based spatial modeling and rapid prototyping, anatomically accurate bone reconstruction planning has become widespread globally. In neurosurgery, even large cranial defects are now treated using 3D technology-supported cranial reconstruction.

In the cranioplasty procedure developed by our research group, a sterilized silicone mold is created based on a 3D-printed model of the implant, designed using postoperative CT scans. This mold is delivered to the operating room, where a PMMA-based bone cement implant can be cast and implanted under sterile conditions during surgery.

We hypothesize that custom implants made from poly(methyl methacrylate) (PMMA) bone cement, cast in silicone molds created from 3D-printed positive forms, are effective for reconstructing cranial bone defects.

My primary focus was on developing and refining modern design methods. This included implementing new capabilities offered by evolving software environments and introducing additional 3D printing technologies.

One objective was to replace manual post-processing of the positive model entirely with CAD modeling to improve implant quality and to enhance casting efficiency by introducing custom molds. This technical work was carried out in collaboration with the Neurosurgery Department of the University of Debrecen. The method was also supported and adopted by the Neurosurgery Departments of the Hungarian Defence Forces and the University of Szeged.

Since the implants are subjected to the same mechanical forces as the cranial bone after implantation, special attention must be paid to load-bearing capacity in addition to aesthetic and biocompatibility considerations.

We initiated a series of mechanical tests to evaluate the load-bearing capacity of the cranioplasties we designed and produced, which were conducted on 10 macerated calvaria. The symmetry of the skulls allowed us to create a defect on one side, reconstruct it using the described method, and compare the mechanical strength of the intact and reconstructed sides.

We hypothesize that the cranial implants possess sufficient strength to protect the underlying brain and that, upon failure, they will fracture without damaging the surrounding bone, thereby preventing more severe defects.

Among the case collection of custom cranioplasties, several complex cases are included, but the most complicated situations are presented in a separate chapter. The separation of the Bangladeshi conjoined twins took place as part of the Operation Freedom surgical series, which began on February 28, 2018, and concluded on August 19 with the separation of the main cerebral vascular network. The procedure was performed endovascularly at the Dhaka Medical College Hospital, accessed via the femoral vein.

The second phase of the surgical series, involving plastic surgery, took place in Budapest. On January 25, 2019, tissue expanders were implanted between the skull bone and scalp at Semmelweis University to gradually generate sufficient native scalp tissue for coverage after separation. This phase involved 44 procedures over six months.

The third phase, the final separation surgery lasting over 30 hours, was performed on August 1, 2019, at the central military hospital in Dhaka, the capital of Bangladesh.

To support this extremely complex separation surgery, our laboratory team voluntarily created 3D designs of cranial implants and silicone molds for covering the bone defects, enabling on-site, sterile production of PMMA implants.

Although titanium implants were considered, due to time constraints, we opted for the well-established PMMA-based reconstruction method.

We hypothesize that our bone cement-based reconstruction method, utilizing 3D technologies, is applicable even in cases with severe deformities and significant bone and soft tissue loss. To support this, we created custom cranial implants based on postoperative CT

scans, considering individual anatomical features. The related chapters detail the experiences gained.

Many 3D printing methods are only suitable for producing molds or casting forms due to the lack of implantable materials. However, metal printing technologies now allow for the direct production of implants. These metal powder-based technologies can create trabecular lattice structures on implant surfaces that contact cut or fractured bone, promoting bone ingrowth and ensuring long-term, secure, and aesthetic fixation.

The objective is to develop a method for designing and directly 3D printing implants that include trabecular lattice structures promoting osseointegration, adapted to the available metal printing technologies. The design and printing conditions and experiences are detailed in the respective chapters.

If the Young's modulus of the implant differs significantly from that of the surrounding bone, the load distribution becomes uneven. This phenomenon, known as stress shielding, can lead to insufficient mechanical stimulation of the bone, resulting in bone quality deterioration. In non-solid implants, stiffness is reduced due to their hollow or porous structure.

We conducted compression tests to determine the Young's modulus of various bone-ingrowth-promoting lattice types found in the literature, aiming to identify which most closely matches that of bone to minimize stress shielding and promote healthy bone growth and maintenance.

We hypothesize that the different lattice types will exhibit varying elastic moduli, all lower than that of solid samples. Based on these findings, we aim to tailor implant design to the mechanical properties of the target bone region by adjusting the thickness and geometry of the lattice and solid sections.

Our findings will inform the selection of lattice types for future animal experiments and mechano-biological studies, as well as the design of custom bone-replacement implants.

## 2. Objectives

During my work, I formulated the following objectives:

### **Design and production of patient-specific cranioplasties based on CT imaging using 3D technologies**

- In the developed cranioplasty procedure, a sterilized silicone mold is created based on a 3D-printed model of the implant, designed using postoperative CT scans. This mold is delivered to the operating room, where a PMMA-based bone cement implant can be cast and implanted under sterile conditions during surgery.
- We hypothesize that custom implants made from poly(methyl methacrylate) (PMMA) bone cement, cast in silicone molds created from 3D-printed positive forms, are effective for reconstructing cranial bone defects.
- My primary focus was on developing and refining modern design methods. This included implementing new capabilities offered by evolving software environments and introducing additional 3D printing technologies.
- One objective was to replace manual post-processing of the positive model entirely with CAD modeling to improve implant quality and to enhance casting efficiency by introducing custom molds.
- Since the implants are subjected to the same mechanical forces as the cranial bone after implantation, special attention must be paid to load-bearing capacity in addition to aesthetic and biocompatibility considerations.
- We initiated a series of mechanical tests to evaluate the load-bearing capacity of the cranioplasties we designed and produced, which were conducted on 10 macerated calvaria.
- We hypothesize that the cranial implants possess sufficient strength to protect the underlying brain and that, upon failure, they will fracture without damaging the surrounding bone, thereby preventing more severe defects.

- The laboratory team created 3D designs of cranial implants and silicone molds to support the highly complex surgeries involved in the separation of the Bangladeshi conjoined twins, enabling on-site, sterile production of PMMA implants.
- We hypothesize that our bone cement–based reconstruction method, utilizing 3D technologies, is applicable even in cases with severe deformities and significant bone and soft tissue loss. To support this, we created custom cranial implants based on postoperative CT scans, considering individual anatomical features. The related chapters detail the experiences gained.

### **Support of complex endoprosthetic cases through custom targeting guide design**

- The primary task of the targeting method is the safe insertion of a guidewire to enable the planned directional use of cannulated surgical instruments, allowing the stemmed cup to be implanted with minimal radiation exposure and high reproducibility.
- The goal is to develop a repeatable workflow from CT imaging to surgery, facilitating reproducibility in future cases.
- We hypothesize that the targeting method is suitable for the safe insertion of the guidewire used in the implantation of McMinn Type I stemmed cups in severe (Paprosky  $\geq 2B$ ) bone loss cases, ensuring proper prosthesis positioning without continuous fluoroscopic guidance.

### **Design and mechanical testing of trabecular titanium implants**

- Metal powder–based technologies allow the creation of implant surfaces in contact with cut or fractured bone that feature trabecular lattice structures conducive to bone ingrowth, ensuring long-term, secure, and aesthetic fixation.
- The objective is to develop a method for designing and directly 3D printing implants that include trabecular lattice structures promoting osseointegration,

adapted to the available metal printing technologies. The design and printing conditions and experiences are detailed in the respective chapters.

- Another goal is to determine the Young's modulus of various bone-ingrowth-promoting lattice types through compression testing, comparing their values to each other and to solid structures, to identify which most closely matches that of bone.
- We hypothesize that the different lattice types will exhibit varying elastic moduli, all lower than that of solid samples. Based on these findings, we aim to tailor implant design to the mechanical properties of the target bone region by adjusting the thickness and geometry of the lattice and solid sections.

### **3. Materials and Methods**

#### **3.1. CT-Based Spatial Reconstruction**

All topics presented in this dissertation are based on low-slice-thickness CT scans of the relevant anatomical regions, supplemented with Metal Artifact Removal (MAR) mode in the presence of metallic materials. The 3D reconstructions were performed using the Mimics Innovation Suite (Materialise NV, Leuven, Belgium), an engineering software package for medical three-dimensional imaging.

#### **3.2. Anatomical 3D Design**

The 3D models were developed using the 3-matic (Materialise NV, Leuven, Belgium) anatomical CAD design software.

##### **3.2.1. Design of Custom Cranial Implants**

Based on cranial symmetry, the 3D model containing the defect was mirrored along the midsagittal plane. The resulting model was then aligned with the original skull using translational and, if necessary, rotational transformations. The alignment was optimized

around the defect area. The outer contour of the implant was constructed using curves along the boundary of the intact bone surface. To model the outer surface, cross-sections were drawn, aided by the mirrored skull model. The inner surface facing the brain ventricles was modeled using the “variable offset” function, based on manual measurements of bone thickness at multiple points. The bone-contacting surface was created by subtracting the surrounding bone model from the defect. The 3D printing and silicone molding were carried out as described in the physical implementation section.

### **3.2.2. Mechanical Testing of PMMA Cranioplasties**

We conducted a series of mechanical tests on 10 macerated calvaria to evaluate the load-bearing capacity of the cranioplasties. Based on cranial symmetry, a bone defect was created on one side, and a cranial implant was designed using the mirrored opposite side, following the procedure described earlier. Mechanical tests were then performed to compare the load-bearing capacity of the intact and reconstructed sides of the same skulls.

To prepare for the tests, identical circular defects (65 mm in diameter) were created on one side of each skull (left in five cases, right in five cases) at the junction of the temporal, parietal, and frontal bones. High-resolution, low-slice-thickness CT scans were taken of the defected skull halves. Cranial implant models were created according to our standard procedure. The 3D printing and silicone molding followed the same method as for other implants.

### **3.2.3. Design of Cranial Implants for the Bangladeshi Conjoined Twins**

The design process for the cranial implants for the conjoined twins began after the third phase of the Operation Freedom surgical series, based on postoperative cranial CT scans. Both skulls exhibited significant bone loss and asymmetry. Additionally, severe soft tissue deficiency necessitated prioritizing primary surgical goals over aesthetics. Instead of aiming for symmetry or ideal head shape, the focus was on covering the bone defect while minimizing the required skin surface. The 3D printing and silicone molding followed the same method as for other implants.

### **3.2.4. Design of Custom Implants for Osseointegration**

Bone-replacing implants that enable biological fixation are designed with spatial lattice structures at the bone-contacting surfaces, allowing for mechanical load transfer and tissue integration. Based on CT imaging, the digital model of the implant was created to match the exact geometry of the bone defect. Initially, the model was solid. The design process considered the specifications of the EOS M290 DMLS metal 3D printer (EOS GmbH, Krailling, Germany) and the Ti6Al4V biocompatible titanium alloy. The trabecular structures were modeled using the SpaceClaim CAD software (Ansys, Inc., Canonsburg, PA, USA). 3D printing was performed as described in the physical implementation section.

### **3.2.5. Material Testing of Trabecular Titanium Lattices**

For compression testing of titanium lattices suitable for bone ingrowth, we designed a test specimen in 3-matic CAD software. The specimen consisted of a 9 mm diameter, 35 mm high solid cylinder base and a 5 mm high, 10 mm diameter lattice head. In addition to the solid sample, we created stochastic, cylindrical, cubic, tetrahedral, and Schwarz-D and Schwarz-P lattice types. The lattice dimensions were based on literature data on bone ingrowth and the limitations of the metal printer. 3D printing was performed as described in the physical implementation section.

## **3.3. Tasks Related to Physical Implementation**

### **3.3.1. Surgical 3D Printing**

The positive models intended for silicone molding and the sterilizable master parts of the surgical targeting guides were printed using a Connex 260 (Stratasys Ltd, Rehovot, Israel) PolyJet 3D printer, with MED-610 (Stratasys Ltd, Rehovot, Israel), a rigid, transparent, biocompatible photopolymer, at a layer thickness of 16  $\mu\text{m}$ . According to the manufacturer's biocompatibility guidelines, the printed parts underwent high-pressure water jet and brush cleaning, followed by a three-hour bath in a 1% NaOH solution at room temperature. The loosened support material was then removed with another round of high-pressure water jet and brushing. Finally, the models were immersed in analytical-grade isopropanol at room

temperature for 30 minutes. To avoid alcohol residue absorption, the prints were dried in an oven at 50°C for 30 minutes before packaging and sterilization.

The surrounding anatomical areas of the defect and the outer shell of the silicone molds were printed using an F270 (Stratasys Ltd, Rehovot, Israel) FDM printer, typically with ABS material (Stratasys Ltd, Rehovot, Israel), at a layer thickness of 127  $\mu\text{m}$ . According to the manufacturer's instructions, the support-material-laden parts were placed in a 70°C NaOH bath for 210 minutes to remove the QSR support material. After rinsing with water, the prints were dried in an oven at 50°C for 120 minutes.

### **3.3.2. Silicone Mold Fabrication**

For casting the silicone molds, we used Neukasil RTV 230 (Antropol, Germany), a two-component silicone mixture that, after curing, is biologically inert, bubble-free after vacuum treatment, transparent, heat-resistant up to 200°C, and easily sterilizable. A key feature is that the cured bone cement detaches easily from it. After casting, the silicone mold was cured in a drying oven at 50°C for 24 hours. For test casting, we used Cemfix 3 (Teknimed, Vic-en-Bigorre, France), a low-viscosity PMMA-based bone cement in its “working phase.”

### **3.3.3. Mechanical Testing of Cranioplasties**

For mechanical testing, the skulls were sectioned and mounted in a custom fixture, which was clamped at a 45° angle to the testing machine. Minor angular deviations due to cutting inaccuracies were corrected by adjusting the clamp. The load was applied at a 45° angle to the midsagittal axis using a flat-surfaced loading element. In reconstructed samples, the load was applied to the center of the defect or implant.

The load-bearing tests were performed using an Instron 8874 (Instron, High Wycombe, UK) biaxial biomechanical testing machine. After positioning and angle adjustment, the machine applied gradually increasing pressure until damage occurred, while force and deformation were recorded. This provided data on compressive strength and deformation under continuous load.

Since we were comparing dependent groups, we used the Shapiro-Wilk test to analyze data distribution. Due to the small sample size and non-normal distribution, we used the Wilcoxon rank-sum test for statistical analysis.

#### **3.3.4. 3D Printing of Titanium Test Specimens**

Titanium test specimens were printed using an EOS M290 (EOS GmbH, Krailling, Germany) DMLS metal 3D printer with Ti64 titanium alloy. Sintering was performed in an argon atmosphere with a 30  $\mu\text{m}$  layer thickness, 280 W laser power, and an energy density of 55.56  $\text{J}/\text{mm}^3$ . The samples were removed from the solid titanium platform using a gravity-fed frame saw.

#### **3.3.5. Mechanical Testing of Porous Titanium Lattice Structures**

Compression tests were conducted on six different lattice types, with five samples per group. Each group was labeled with a number (1–6) and each sample with a letter (A–E). Testing was performed using the Instron 8874 biaxial testing machine in the Biomechanical Testing Laboratory.

A corrosion-resistant compression plate was mounted in the upper hydraulic grip. The lattice portion of the sample, fixed at its solid base in the lower grip, resisted the applied force. The testing speed was 1  $\text{mm}/\text{min}$ , and each test continued up to the machine's 25 kN limit.

The Young's modulus values of the solid group were compared to those of the lattice groups. The null hypothesis stated that the mean of each group significantly differed from that of the solid group. A one-sided t-test was used with a significance level of 0.05 to determine statistical differences.

## 4. Results

### 4.1. Patient-Specific 3D-Printed Cranioplasty Using Silicone Molds and PMMA

Over the years, our cranioplasty design practice has evolved based on feedback from numerous cases, including highly complex ones such as the separation of the Bangladeshi conjoined twins. Using the developed method, in collaboration with the Department of Neurosurgery at the University of Debrecen, the Department of Neurosurgery at the University of Szeged, and the Department of Neurosurgery at the Hungarian Defence Forces Medical Center, a total of 54 cranioplasty silicone molds were produced. No surgical complications related to the implants occurred.

Of these, 34 implants were placed after stroke, 4 after tumor removal, and 16 following traumatic brain injury. Two patients received bilateral implants; in one of these cases, a single-piece implant was used following bifronto-temporo-basal craniectomy. In the trauma group, two patients required reoperation due to wound infections, necessitating implant removal. In both cases, the same silicone mold was reused to produce a new implant three months later.

The patients were primarily young adults (mean age: 40.2 years, standard deviation: 13.4 years), with a male-to-female ratio of 37:17. The average defect dimensions were 91.5 mm and 101.4 mm, with the largest defect measuring  $125 \times 140$  mm.

In all cases, the implants fit perfectly, and the postoperative aesthetic outcomes were satisfactory. In one patient, who required reconstruction of the frontal skull base and part of the frontal sinus after a long-standing open craniocerebral injury, a brief episode of epidural pneumocephalus occurred two weeks postoperatively during nose blowing. The air was reabsorbed within days, but a similar event recurred three weeks later. In total, two patients experienced septic complications affecting three implants, unrelated to the implant manufacturing process, which necessitated implant removal.

## 4.2. Mechanical Evaluation of 3D-Printed PMMA Cranioplasties

The compression testing of cranial implants aimed to evaluate the mechanical performance of the reconstruction method, specifically its primary function: the protection of the underlying organ and the extent to which this is achieved. The force required to cause failure varied significantly across the 10 macerated skulls tested—both in the unaltered and reconstructed conditions.

In the reconstructed group, the lowest load-bearing capacity was 378 N, and the highest was 3079.4 N, with an average of 1510.4 N and a standard deviation of  $\pm 913.5$  N (60.5%). In the intact skulls, the minimum load-bearing capacity was 1537.5 N, and the maximum was 7162.8 N, with an average of 3152.4 N and a standard deviation of  $\pm 1929.6$  N (61.2%).

Fracture patterns in the reconstructed skulls were typically linear or T-shaped. Additionally, one edge fracture and two cases of cracking or fracture in the skull preceding implant failure were observed. In the intact skulls, fracture patterns were more varied.

To compare the load-bearing capacity of intact and reconstructed skulls, we calculated a ratio using the symmetry of the skulls: the numerator was the load-bearing capacity of the intact side, and the denominator was that of the reconstructed side. The resulting values showed significant variability (91.7%), and in two cases, the surrounding bone was weaker than the implant, yielding a ratio of 0.65. The most significant difference was observed in skull #9, with a ratio of 9.85. On average, the ratio of the two load-bearing capacities was 3.23, which decreased to 2.72 when the minimum and maximum values were excluded.

To account for actual cross-sectional area, we measured skull thickness along the fracture lines. We then divided the load-bearing capacity by the thickness to obtain a normalized value in N/mm. For intact skulls, the range was 100.8 to 548.7 N/mm (mean: 264.4, SD: 129.9). For reconstructed skulls, the range was 330.6 to 1590.4 N/mm, with a mean of 697.6 and a standard deviation of 448.53.

We also calculated the ratio of the normalized load-bearing capacities (thickness-adjusted) between reconstructed and intact skulls. The average ratio was 3.25, with a reduced standard deviation of 2.41. The p-value obtained from the significance test was  $p = 0.048$ , which is below the conventional threshold for statistical significance.

### **4.3. Cranioplasty of the Bangladeshi Conjoined Twins**

The final separation of the three-year-old Bangladeshi conjoined twins took place on August 1–2, 2019, in Dhaka, Bangladesh. During the surgery, the fused brain surfaces were manually separated under a microscope, and vascular redistribution was performed. This was followed by duraplasty and partial cranioplasty. The cranial implants were designed based on postoperative CT scans.

We consulted several times with Dr. András Csókay in the months and years following the bone reconstruction. According to his reports, the cranial reconstruction for Rukaya was highly successful, and long-term follow-up confirmed that the successful bone replacement significantly contributed to the child's rehabilitation. The on-site casting and fixation of the implant to the cranial bone in Rabeya's case also yielded similarly good initial results. However, from the beginning, inadequate skin distribution made tension-free coverage difficult. Despite further plastic surgical interventions, the desired outcome could not be achieved. After one year, a small section of the skin reopened, and due to the resulting infection, the previously well-functioning cranioplasty had to be removed.

### **4.4. Design of Custom Targeting Guides for McMinn Cups**

The biocompatible targeting guides designed for each case were delivered to the operating room after autoclave heat sterilization. In accordance with our clinic's standard practice, the surgeon exposed the hip joint using the Watson-Jones approach. After removing granulation tissue from the bony acetabulum, the surface was prepared for reaming, and the anchoring points for the targeting guide were cleared of any soft tissue adhesions. In cases of significant bone defects, this step did not involve classical reaming but rather the preparation of sclerotic bone to induce bleeding.

The locations of the two reference screws were also exposed, either through a separate incision or by extending the cranial part of the main incision. The targeting guides were securely fixed to the prepared reference points (two screws and a reliable bony landmark). Their correct positioning was aided by half-pelvis and targeting guide models placed outside the sterile field. Under fluoroscopic control, the surgeon then drilled the guidewire, which determined the orientation of the stem of the implanted prosthesis.

After removing the targeting guide, the next step was drilling. Using a cannulated drill provided by the manufacturer, the surgeon created the channel for the prosthesis stem, guided by the previously inserted wire. Then, using a self-positioning reamer, the acetabular cup bed was prepared within the drilled channel. The prosthesis was press-fit into the prepared cavity. In the surgeries presented in this chapter, McMinn-type cups (Waldemar Link GmbH & Co. KG, Hamburg, Germany) were used. The stemmed cups were implanted according to the manufacturer's recommendations. Proper planning, sizing, and execution were confirmed by achieving primary stability, which was monitored during follow-up by the attending physician.

The criterion for a successful procedure was the restoration of load-bearing capacity in the hip joint. Given the severity of these cases, postoperative rehabilitation was always tailored individually by the rehabilitation team.

In general, patients were allowed non-weight-bearing mobilization for 10 days, followed by gradual weight-bearing increases of 5 kg per week until full weight-bearing was achieved. Initially, walking was assisted with a walker or two crutches.

Between February 2018 and July 2021, we performed revision surgeries using stemmed prostheses in 17 patients with large periacetabular defects (Paprosky  $\geq$  2B), applying the method described above. Patient ages ranged from 35 to 77 years, with a gender distribution of 12 women and 5 men, and follow-up periods ranging from 10 to 34 months.

None of the patients had comorbidities that could have compromised the surgical outcome. No intraoperative complications occurred. In 16 cases, wound healing was uneventful, and the hips became load-bearing again after rehabilitation.

One septic complication occurred, which required implant removal, and the patient remained in a Girdlestone state. This complication rate is consistent with those reported for other revision techniques. No other complications or unexpected outcomes were observed.

Even in the case with the shortest follow-up period of 10 months, wound healing was uneventful, and the implant was securely fixed. Rehabilitation had already been successfully completed by that time. As with all such patients, regular follow-up continues. No prosthesis loosening was observed during the study period.

#### **4.5. Compression Testing of Trabecular Titanium Specimens**

The compressive strength tests conducted on six types of titanium lattice structures yielded results in line with expectations. In all cases, the lattice specimens exhibited some degree of deformation or damage under lower compressive forces than those required for solid specimens.

For the solid specimens, the average Young's modulus was 105.55 GPa, with a standard deviation of 1.09 GPa. In comparison:

- Stochastic lattice: average 80.16 GPa, SD 2.65 GPa
- Cylindrical lattice: average 97.72 GPa, SD 6.72 GPa
- Cubic-type lattice: average 72.04 GPa, SD 6.73 GPa
- Schwarz-D lattice: average 92.91 GPa, SD 1.74 GPa
- Schwarz-P lattice: average 90.42 GPa, SD 3.49 GPa
- Tetrahedral lattice: average 90.34 GPa, SD 2.35 GPa

All six lattice groups showed statistically significant differences from the solid group. The stochastic lattice exhibited the greatest deviation (lowest p-value,  $p = 0.000029$ ). This was followed by the Schwarz-D lattice ( $p = 0.000087$ ), the tetrahedral lattice ( $p = 0.000134$ ), and the cubic lattice ( $p = 0.000374$ ), despite its lowest average modulus, due to its high variability. The Schwarz-P lattice had a p-value of 0.000644, and the cylindrical lattice showed the least deviation with  $p = 0.038838$ .

These differences are statistically reliable, confirming that the Young's modulus of the solid group significantly differs from all lattice groups.

## **5. Discussion**

### **5.1. Fabrication of PMMA-Based Cranial Implants**

Cranioplasty primarily serves to provide mechanical protection for delicate neural structures and also holds aesthetic significance for patients, contributing to improved neuropsychological outcomes. Studies show that restoring cranial defects leads to gradual functional improvement in patients. Not only can blood circulation return to normal, but cerebrospinal fluid dynamics may also be restored. Since antiquity, various techniques and materials have been used to achieve these goals, with varying degrees of success.

From a technical standpoint, neurosurgeons expect consistent availability, reproducibility, and ease of use in the operating room. For patients, the material and geometry of the implant are the most critical factors influencing outcomes.

Autografts are considered the best material for cranioplasty, but in cases of open cranio-cerebral injuries, preserving the bone is often not feasible. Additionally, subcutaneous temporal implantation can lead to significant resorption. Deep freezing appears promising, but resorption is still observed after reimplantation.

Metal implants offer several advantages in terms of durability and infection resistance. They are precise, reliable, and reduce surgical time. However, as described in earlier chapters, cranial reconstruction using metal printing is costly. Direct implant manufacturing using techniques such as selective laser or electron beam melting is practically limited to a few specialized institutions, and even for them, the MDR (Medical Device Regulation) approval process poses significant challenges.

Custom implants made from hydroxyapatite have a low complication rate. Their spongy ultrastructure resembles diploë bone, but high costs limit their widespread use.

In cadaver studies, Klammert and colleagues used calcium phosphate for powder-based 3D printing, which could theoretically be suitable for direct implantation. However, due to infection risks, its use in living organisms is not yet feasible.

Kim and colleagues developed a special plastic-coated mold that allows intraoperative implant fabrication. However, applying the coating and ensuring asepsis is highly complex.

PMMA is widely used in neurosurgery for covering cranial defects. It is available in sterile, low-viscosity form, making it suitable even for small, hidden defects, such as those following neurovascular decompression via a retromastoid approach. Custom fabrication techniques allow for more precise reconstruction in larger or more complex areas. 3D planning and preoperative printing of both the implant and surrounding area help identify fit issues. Unlike mesh implants, there is no “cactus effect,” and the implant can be securely fixed using standard clips.

Thanks to the use of silicone molds, the heat generated during PMMA polymerization is absorbed by the silicone, eliminating the risk of thermal damage to surrounding tissues. If casting issues arise, the implant can be recast during surgery, and if the mold is preserved, it can be reused for future implantation.

Today, thin-slice CT scans are readily available. By mirroring the midsagittal plane during computer-aided design, true symmetry and excellent aesthetics can be achieved. Printing the area surrounding the cranial defect along with the implant allows for preoperative verification of the result.

The 3D-printed silicone mold can be sterilized using standard hospital procedures. Surgical time is not longer than with other techniques, as the mold allows for instant shaping—only the polymerization time of the PMMA must be accounted for, and the process can be performed by a surgical assistant. The rough surface of PMMA ensures excellent adhesion to the skin.

Several factors can lead to complications, some of which are beyond our control, such as the patient’s general condition or the underlying pathology. To prevent surgical complications, the bony edges must be fully exposed, as the implant is designed accordingly. Any cerebrospinal fluid leakage must be addressed before implantation. Skin must be handled with

great care, both during the original surgery and during implantation. In open traumatic and infected cases, this is particularly challenging. Decompressive craniectomy should be planned in advance, assuming the patient will require cranial reconstruction.

In our cases, we placed great emphasis on infection prevention. If the skin was damaged or fragile, surgery was postponed. As an institutional standard, cranioplasty was typically indicated three months after craniectomy. Patients received an intravenous antibiotic bolus at the time of anesthesia, which could be repeated after four hours if necessary. If cranioplasty was anticipated, skin closure was performed using monofilament materials. In open trauma cases, dural closure can be problematic, so the dura is often left open during decompressive craniectomy. During cranioplasty, newly formed encephalomyosynangioses should be preserved as much as possible to prevent bleeding, CSF leakage, or delays in the recovery of cortical function. By mitigating all known risk factors, the risks associated with cranioplasty can be minimized.

This technique can also serve as a secondary option in cases where traditional cranioplasty has failed. In-house sterilization of the silicone mold and intraoperative preparation of PMMA from its original packaging both help minimize infection risk. Although we have not yet applied this technique in pediatric populations, the results are promising for future implementation.

## **5.2. Mechanical Testing of PMMA Cranial Implants**

According to the laws of statistics, the low sample size makes outliers and standard deviations more prominent. To gain a deeper understanding of the relationship between cranial load-bearing capacity and structural failure, additional samples would be necessary. Nevertheless, the current measurements already allow us to conclude that the load-bearing capacity of PMMA-reconstructed defects, as presented in this dissertation, is certainly lower than that of intact skulls. Therefore, in the event of trauma, fractures or cracks are almost certain to occur in the implant rather than in the surrounding bone.

It can also be concluded that accounting for skull thickness reduces the variability in the results.

Analyzing the data, we found that skull thickness and bone quality significantly influence load-bearing capacity. This is already evident in the wide variation observed among intact skulls. Since each implant is designed based on the thickness and curvature of the surrounding bone, this variability is also reflected in the implants.

Despite this, we concluded that the average load capacity of the implants corresponds to approximately 150 kg of force. Even the weakest skull in the study withstood a force equivalent to 38.58 kg, which is significantly higher than the forces encountered during everyday activities.

### **5.3. Solving Complex Endoprosthetic Cases with Custom Targeting Methods**

Hip joint prosthetics has entered a new era over the past decade. With increasing life expectancy and a growing demand for improved quality of life, the number of primary total hip arthroplasty (THA) procedures has risen significantly. Consequently, due to inevitable prosthesis wear, loosening, complications, and accidents involving prosthesis users, surgeons are increasingly faced with complex revision cases.

The appropriate solution always depends on the individual case: the pathological condition, the quantity and quality of the remaining bone stock, the patient's general health, expectations, and compliance, as well as the technical and human resources of the treating institution. Multiple approaches may lead to a viable solution. In severe cases, trabecular metal augments or anti-protrusion cages may be used, but there is currently no universally successful surgical solution.

The method presented here focuses on revision procedures using stemmed acetabular cups fixed into the pelvis. Since the targeting guide designed for the prosthesis was still under development, nearly every component of the instrument was modified case by case during the first few surgeries, as detailed in this dissertation. No inaccurate guidance occurred, and the developed procedure proved to be safe, reliable, and easy to apply.

The future directions of targeting techniques are already visible: research is focusing on developing systems that use augmented reality (AR) technology to significantly improve targeting accuracy during surgeries requiring high precision. AR systems would allow the surgeon to view the real-time surgical field through smart glasses, without the need for complex navigation systems, displaying the virtual model of the bone reconstructed from CT images and the surgical instruments (drill, screw, screwdriver) in the actual surgical environment.

Despite its relatively short history, augmented reality is already being used in numerous surgical applications to overlay the 3D virtual space onto real anatomical conditions. Several experimental solutions have been developed for spatial registration, but the accuracy is still typically within a few millimeters, which is insufficient for high-precision procedures. The method described above requires the registration process to be performed using a high-precision (sub-millimeter) 3D scanner.

This enables much more accurate alignment of the virtual and real bone than existing methods and eliminates the need for time-consuming manual registration, saving significant time.

We successfully achieved our dual objective. First, we managed to operate on these severe cases using a single implant instead of multiple components. Second, we solved the main technical challenge of inserting the stemmed cup in such complex cases. With the help of the targeting device, the prosthesis site can be safely prepared without continuous use of fluoroscopy.

Our results so far show that CT-based virtual surgical planning and the use of patient-specific 3D-printed targeting devices provide a reliable method for complex pelvic surgeries, allowing for significantly reduced radiation exposure compared to traditional methods.

Due to the relatively small number of cases and the highly variable follow-up periods, long-term conclusions cannot yet be drawn. However, our experience suggests that the method is promising for planning and safely executing complex surgeries. It opens the door to the design, production, and safe implantation of personalized implants.

A clear advantage of the procedure is that no ad hoc decisions are needed during implant placement. The targeting device ensures that the implant is positioned as planned, avoiding complications such as vascular, nerve, or bowel injuries due to misplacement. Thanks to CT-based 3D planning, the required implant size is also known in advance.

#### **5.4. Evaluation of Trabecular Titanium Implants**

The development of trabecular lattice-structured titanium implants and the investigation of their mechanical behavior served as preparation for a larger-scale research project. The results of the material testing laid the foundation for the structure of future studies.

With good statistical reliability, the stochastic lattice type showed the greatest deviation from the solid control group, followed by the Schwarz-D and then the tetrahedral lattice types. Although the cubic lattice group had the lowest average Young's modulus, its high standard deviation made the statistical difference less reliable. Since the t-test considers not only the difference in means but also the variance of the samples, the significance of the difference in this case was lower.

Given the relatively low elastic modulus of bone, these lattice types are recommended for further studies. With proper selection of implant geometry and lattice thickness, even better mechanical compatibility can be achieved for future applications.

To evaluate the mechanical and biological performance of lattice-structured implants in promoting bone ingrowth, we initiated a comprehensive study within the framework of the project titled "Research on Osteosynthesis of Implants and Development of Trabecular Structures Using Additive Manufacturing" (GINOP-2.2.1-15.2017-00055). In this animal study, we examined the bone integration of test specimens produced using metal 3D printing with different lattice geometries.

We used six different lattice types: gyroid, cubic, cylindrical, tetrahedral, double pyramid, and stochastic. The implants were manufactured from Ti6Al4V alloy using direct laser sintering with an EOS M290 metal 3D printer. The participating surgeons implanted the devices into the femoral condyles of sheep. The animals were euthanized 8 and 12 weeks postoperatively.

To assess the degree of bone ingrowth into the various lattice structures, we performed mechanical, histological, and image analysis on real samples extracted from the animals and on optical microscopy images of those samples.

The experimental conditions, the characteristics of the animal study, and the details and evaluation of the individual tests were presented by Ágnes Éva Kovács in her doctoral dissertation titled “Current Mechano-Biological Issues in Musculoskeletal Surgery.”

## **6. Summary**

In today’s surgical practice, a wide range of implants and instruments are available to surgeons for the treatment of numerous elective and traumatic procedures. However, surgeons are increasingly willing to take on cases involving severe defects that require custom design and additive manufacturing for modern solutions.

In my work, I focused on the technical development of real surgical problems across several distinct areas. For clarity and due to the thematic diversity, the dissertation is structured into three main parts.

The thesis begins with the description of a cranioplasty technique using PMMA material, produced with a silicone mold based on a 3D-printed positive model. The design and manufacturing process developed over the years is illustrated through the case of a conjoined twin separation. Dedicated chapters also address the mechanical testing of these bone cement implants on cadaver skulls, allowing for the evaluation of their mechanical behavior in situ, compared to surrounding bone structures.

The next section focuses on the technical support of complex endoprosthetic cases involving severe bone loss. The targeting method developed is presented through cases where the surgical team opted for stemmed hip prostheses. The described procedure enables the safe creation of the prosthesis stem cavity in the defective hip bone with minimal radiation exposure.

The design-related chapters are complemented by the modeling steps of custom implants with trabecular lattice structures suitable for bone ingrowth, forming the foundation for the development of next-generation personalized implants.

These lattice structures were used to create experimental cranial implants, custom hip replacements, and mechanical test specimens, which were later subjected to compression testing. The test series helped identify which lattice types had an elastic modulus closest to that of bone, thereby reducing stress shielding on the surrounding bone.

As a result of my work, including the case of the Bangladeshi twins, a total of 56 well-documented cranioplasty cases were completed, along with many more since the publication of the dissertation's foundational articles. Custom targeting guides were developed for 18 hip revision surgeries, 4 knee surgeries, and 3 shoulder surgeries, offering a repeatable and safe targeting method. Over the years, these techniques have been integrated into the surgical practice of the Orthopedic Clinic in Debrecen, and thanks to the positive experiences gained from numerous cases, they are now confidently used in the treatment of complex conditions.

## **7. New Scientific Results**

### **7.1. Design and Production of Custom Cranioplasties Using 3D Technologies**

- A well-functioning workflow was developed, from the initial request to the delivery of a sterilizable surgical aid.
- A design process was established for cranial implants based on CT-reconstructed 3D models, taking into account the thickness of the bone surrounding the defect.
- The silicone molding process was further refined to produce the final physical product.
- In collaboration with neurosurgeons, we applied our developed method in 54 cranioplasty cases.

## **7.2. Mechanical Testing of PMMA-Based Cranial Implants**

- Measurements confirmed that PMMA cranial implants, designed to match the thickness of the surrounding bone, withstand expected loads and only fail under significantly greater forces.

## **7.3. Cranioplasty for the Bangladeshi Conjoined Twins**

- In collaboration with the surgeons of the Foundation for the Support of the Vulnerable (Cselekvés a Kiszolgáltatottakért Alapítvány), the design method was adapted for cases with severe bone and soft tissue loss and significantly altered anatomy.
- Silicone molds were created for the twins to enable on-site casting of PMMA implants, and titanium alloy-based cranial implants were also produced.

## **7.4. Solving Severe Endoprosthetic Cases Using 3D Technologies**

- A repeatable procedure was developed for revision surgeries involving severe (Paprosky  $\geq 2B$ ) bone loss, enabling the implantation of stemmed hip prostheses.
- The method was applied in 18 cases to assist in the implantation of McMinn-type hip prostheses.

## **7.5. Development and Mechanical Testing of Trabecular Titanium Implants**

- A design process was developed for bone-ingrowth-promoting lattice structures and their application in custom cranial and large joint bone implants.
- Through material testing, we identified the lattice type with mechanical properties most closely matching those of bone, to guide future biological studies.

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### A PhD értekezés alapjául szolgáló közlemények

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To whom it may concern

**DE KK RKEB/IKEB No. 6173-2022**

(UD CC REC/IEC No. 6173-2022)

Dec. 10, 2022

This is to certify that the Regional and Institutional Ethics Committee /REC/IEC) of the Clinical Centre (University of Debrecen) has been contacted by **Prof. Zoltán Csernátóy, MD, DSc.** (University of Debrecen, Clinical Centre, Department of Orthopedics) asking for ethical permission for the proposal entitled **"ICCS Cup Insertion for Acetabular Revision and Severe Dysplasia Using a Patient-Specific Aiming Device "**. We have had the opportunity to read and study this proposal, curriculum vitae of the participants and the informed consent. The REC/IEC proposed the approval of the protocol and assured the follow-up for the subjects.

The Regional and Institutional Ethics Committee of the University of Debrecen is organized and operates according to the IHC-CGP and the applicable Hungarian laws and regulations. The Committee will continually oversee, evaluate and enforce the fulfillment of all national, European and international ethical regulations/conventions/legislations.

Sincerely Yours,

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President of REC/IEC of UD



József Szentmiklósi, MD, PhD  
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**DE KK RKEB/IKEB No. 6371-2023**

(UD CC REC/IEC No. 6371-2023)

Feb. 10, 2023

This is to certify that the Regional and Institutional Ethics Committee /REC/IEC) of the Clinical Centre (University of Debrecen) has been contacted by **Prof. Zoltán Csernátóy, MD, DSc.** (University of Debrecen, Clinical Centre, Department of Orthopedics) asking for ethical permission to the proposal entitled **“Custom-made 3D printing-based cranioplasty using a silicone mold and PMMA ”**. We have had the opportunity to read and study this proposal, curriculum vitae of the participants and the informed consent. The REC/IEC proposed the approval of the protocol and assured the follow-up for the subjects.

The Regional and Institutional Ethics Committee of the University of Debrecen is organized and operates according to the IHC-CGP and the applicable Hungarian laws and regulations. The Committee will continually oversee, evaluate and enforce the fulfillment of all national, European and international ethical regulations/conventions/legislations.

Sincerely Yours,

Sándor Szántó, MD, PhD, DSc  
Professor of Rheumatology and Sport Medicine  
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