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BRIGHT

Erasmus+ strategic partnership for Higher Education

BOOSTING THE SCIENTIFIC EXCELLENCE AND INNOVATION CAPACITY OF 3D PRINTING METHODS IN PANDEMIC PERIOD

TOOLKIT 1

SKULL IMPLANTS MADE BY SELECTIVE LASER SINTERING AND VACUUM CASTING TECHNOLOGIES

Project Title	**Boosting the scientific excellence and innovation capacity of 3D printing methods in pandemic period 2020-1-RO01-KA226-HE-095517**
Output	**IO2 – BRIGHT e-toolkit manual for digital learning in producing medical parts by 3D printing methods in the context of the pandemic**
Toolkit	**Toolkit 1** **Skull implants made by Selective Laser Sintering and Vacuum Casting technologies**
Date of Delivery	**30th of November 2021**
Authors	**TUCN**
Version	**Final variant**

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Contents

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1 Introduction. Presenting of the medical case study

The scientific literature refers to various cases in which customized implants are used. In general, all cases have the following layout:

- initial clinical condition containing images of the patient accompanied by a brief presentation of the defect cause (medical cause or accident)

- images with the virtual reconstruction and the physical model of the destroyed area, sometimes accompanied by short explanations regarding the manufacturing technology of the physical model (Additive Manufacturing technologies or conventional cutting technologies) and the location where this model was made

- in some cases, images of the implant without technical details of its realization sometimes mentioning a generic technology through which the implant can be made

- the post-operative image of the subject without complete details regarding the surgery technique used or the time necessary to obtain the presented result.

Recently, applications of medical models that are not intended for customized implants have been published more and more frequently. In this sense, there are cases of using medical models for planning very complex surgeries

Accidents, tumours of the skull bones and certain infections are the main causes of large cranial defects. The main reasons for the reconstruction of these defects are both aesthetic and the need to protect the intracranial structures against mechanical impacts.

The patient, presented in the Figure 1.1, due to an ischemic cerebral vascular accident in the right sylvian area, and with a history of persistent obliterative arteriopathy of the inferior limbs, was hospitalized. He was in a mild coma and had left hemiparesis at the time of his arrival. To treat the cerebral oedema, the patient received rigorous pharmacological therapy. The symptoms, on the other hand, did not go away. A growing cerebral oedema was discovered on repeated cranial CT examinations. The neurological state improved after a decompressive hemicraniectomy, which left a large bone defect in the right cranial vault. An infection forced the removal of a piece of the cranial vault that had been implanted within the subcutaneous abdominal tissue. The cranial deformity caused not just a cosmetic problem, but also the disadvantages of a craniectomy.

The patient had only a moderate motor loss on the left side, left lateral hemianopia, and short-term memory problems after a year of neurological recovery. He wasn't aphasic, didn't

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have any speech problems, and was completely self-sufficient. A customized cranioplasty was developed and a plate was created as specified to avoid the disadvantages of a craniectomy status.

The bone defect was revealed and prepared utilizing the old scar under general anaesthesia. The custom-made plate was installed, precisely fitting, and requiring no further processing. 2.0 silk sutures were used to close the wound.

There were no difficulties during the procedure, and the patient was discharged on the seventh day following surgery. There were no complications at the 1-month and 6-month follow-ups, and the patient tolerated the cranioplasty plate well.

The cranioplasty plate (Figure 1.2) was made by using a mould. The margins of the final custom-made cranioplasty plate were somewhat manually treated after removal from the mould to remove excess and drill holes for fixation [ROT06].

The result of the intervention is presented in Figure 1.3.

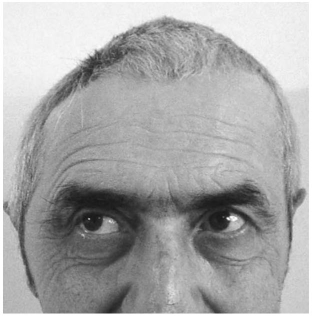

Figure 1.1 The patient's initial condition

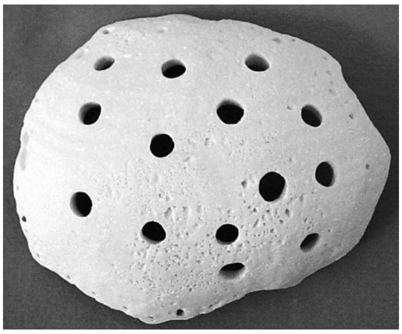

Figure 1.2. The cranioplasty plate

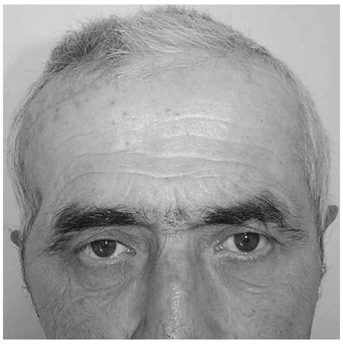

Figure 1.3 The result of the surgery

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The following steps must be followed in order to create personalized cranial plates:

- A spiral cranial CT scan was performed on the patient, from the Frankfurt horizontal to the vertex with a 01 tilt. The thickness of the axial slices was 2mm (continuous). A virtual 3D model of the vault and defect was generated using 3D reconstruction, and a cranioplasty plate was built using mirroring methods, superimposition, and algebraic Boolean operations.
- Both virtual models (defect and plate) were turned into real polyamide models using selective laser sintering (SLS) for rapid prototyping. The plate fit flawlessly into the defect after minimal manual polishing.
- A silicone rubber mould was created using the pattern of the polyamide cranioplasty plate (via SLS). By combining PEM powder with hydroxyapatite granules and liquid ethylmethacrylate, a thinner paste of PEM mixed with hydroxyapatite was created. This paste was pressed into shape after being cast in a silicone rubber mould (Figure 1.4). Silicone rubber moulds were first utilized in the industrial casting of liquid polymers. The casting procedure used a thin paste of PEM and a mould with larger walls to achieve an accurate model and avoid mould deformations. To drain extra material, large drainage canals were carved into the mould's edges. The mould’s cover was forced against its base with manual pressure, and it was kept in place when it was completely closed by placing the mould in a press without applying significant pressure. Following autopolymerization (an exothermic reaction), the entire piece was gently thermopolymerized for 24 hours at 60 degrees Celsius to remove all traces of monomer. The silicone rubber mould was retained in the press in the same position as during autopolymerization during thermopolymerization.
- The margins of the final custom-made cranioplasty plate were somewhat manually treated after removal from the mould to remove excess and drill holes for fixation. To prevent the development of an epidural haematoma, 5–7mm holes were bored in the centre.

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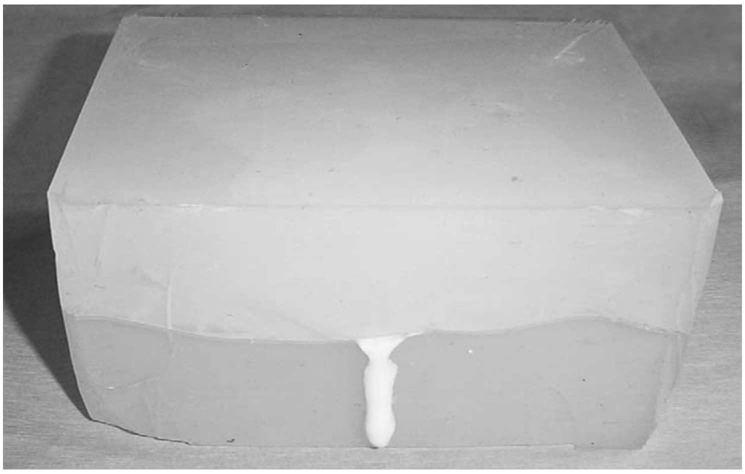

Figure 14. The silicone rubber mould

2 Medical imaging and data collection for CAD modelling

2.1 The image processing stages

To analyse structures inside the body, medical practitioners utilize computed tomography, generally known as a CT scan. This captures photographs of the bones, muscles, organs, and blood arteries in very tiny "slices" so that healthcare specialists may observe the body in exquisite detail.

X-ray machines that employ a fixed tube to point X-rays at a particular place are known as traditional X-ray machines. X-rays are absorbed in various amounts by different tissues as they pass through the body. Against the black background of the film, higher density tissue produces a whiter image than other tissues [www 02].

As it moves through an arc, a CT scanner emits a series of narrow beams into the human body. An X-ray machine, on the other hand, sends only one radiation beam. Compared to an X-ray image, a CT scan produces a more detailed final image.

The X-ray detector in a CT scanner can detect hundreds of different degrees of density. It has the ability to view tissues within a solid organ. This information is sent to a computer, which creates a 3-D cross-sectional image of the bodily component and presents it on the screen. A contrast dye is occasionally used to assist reveal particular structures more clearly.

If a 3-D imaging of the abdomen is needed, the patient may be required to consume a barium meal. On the scan, the barium appears white as it passes through the digestive system. If images of the lower body, such as the rectum, are needed, the patient may be

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given a barium enema. A contrast agent will be injected into the veins if blood vessel pictures are the goal.

The use of spiral CT, a relatively recent technique, may increase the accuracy and speed of CT scans. During scanning, the beam follows a spiral route, collecting continuous data with no pauses between images.

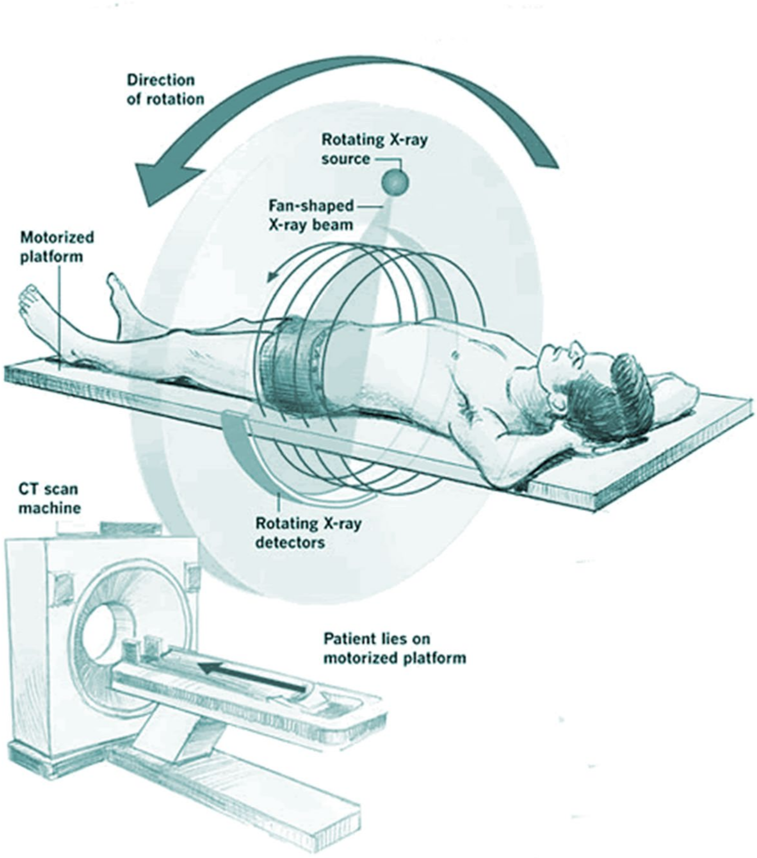

Figure 2.1 The working principle of a CT scan [www 04]

CT is a vital tool for assisting in medical diagnosis, however it emits ionizing radiation that has the potential to cause cancer.

CT scan can be used to get photographs of:

- soft tissues
- the pelvis
- blood vessels
- lungs

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- brain
- abdomen
- bones

Many cancers, such as liver, lung, and pancreatic tumours, are routinely diagnosed using CT scans. A clinician can use the image to confirm the presence and location of a tumour, as well as its size and the extent to which it has damaged neighbouring tissue.

A head scan can reveal critical information about the brain, such as whether there is any bleeding, artery swelling, or a tumour.

A CT scan of the abdomen can identify a tumour as well as any swelling or inflammation in the internal organs surrounding. It can reveal any spleen, kidney, or liver lacerations.

A CT scan is useful for planning locations for radiotherapy and biopsies because it detects abnormal tissue, and it can also provide significant data on blood flow and other vascular issues. It can aid a physician in determining bone disorders, bone density, and the condition of a patient's spine. It can also provide important information regarding a patient's injuries to their hands, feet, and other skeletal structures. Even little bones, as well as their surrounding tissue, are clearly apparent.

A CT scan exposes you to a little amount of radiation that is precisely focused. Even in persons who have had multiple scans, these levels of radiation have not been shown to be detrimental. The likelihood of developing cancer as a result of a CT scan is estimated to be less than one in 2,000. The level of radiation involved is considered to be similar to what a person might be exposed to in the environment over a period of few months to several years.

A scan is only performed if there is a compelling medical reason. The findings may lead to treatment for diseases that might otherwise be fatal. When deciding whether or not to get a scan, doctors will make sure that the advantages outweigh the risks.

Before the scan, the patient may be required to fast from food and perhaps drink for a period of time.

On that particular day, in most cases, the patient will be required to undress to their underwear and put on a gown provided by the health centre. If a gown is not provided by the hospital, the patient should dress loosely with no metal buttons or zippers. Some patients may be required to consume a contrast dye, which may also be administered through enema or injection. The image of some blood vessels or tissues is improved as a

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result of this. Any patient who has a reaction to contrast material should inform their doctor ahead of time. Certain drugs can help those who are allergic to contrast materials. Because metal interferes with the CT scanner's operation, the patient must remove all jewellery and metal fastenings.

The patient must lie down on a motorized examination table that glides into a doughnut-shaped CT scanning machine during the scan. The patient will most likely be lying on their back, facing up. They may, however, be required to lie face down or sideways on occasion. The couch will move slightly after one x-ray image, and the machine will take another image, and so on. For the best outcomes, the patient must lie completely still.

Everyone in the room except the patient will leave during the scan. An intercom will allow the radiographer and the patient to communicate in both directions. A parent or adult may be allowed to stand or sit near the patient if the patient is a youngster, but they must wear a lead apron to avoid radiation exposure [www 03].

2.2 Obtaining the medical models

In the early 1980s, models of the internal bone structures of the human body were made using thin sheets of aluminium that were cut out of the bone contours from images obtained by tomography. The three-dimensional model was obtained by assembling these sheets. The same technology has been used in the construction of moulds with the help of prostheses or implants made of biocompatible materials.

Later, numerically controlled milling machines were used to make the models, the complexity of the models increasing with the increase in the number of numerically controlled axes. These machines made the models directly in wax, polystyrene or polyurethane foam. The numerically controlled five-axis milling system developed in Kiel (Germany) produces models that are very close to the original structures. Taken as a whole, the realization of models by milling cannot be considered a complete solution for the realization of medical models due to technical limitations: the resolution of the models is limited, the presence on most models of complicated concave areas, with small dimensions, and with thin walls. In general, models are useful in very complex cases that are difficult to imagine with the help of 3D views, which is impossible to achieve by milling and leads to

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limited application of the method. Despite its limitations, this technology is still often used to make relatively simple models such as joints and long bones.

Currently, complex medical models are made using rapid prototyping technologies.

As stated before, the principle of operation of a computer-assisted tomograph is as follows: a tube that generates X-rays and a receiving analyser element are rigidly fixed on a rotor that rotates 3600 around the patient's axis. This allows to perform several thousand measurements from different angles through the patient. Starting from these measurements, a computer creates an artificial image of a cross section through the patient.

The three-dimensional image is obtained by assembling the sections made by the tomograph and the 2D section package determines the geometric elements of the three-dimensional model. A first problem that arises when generating these images is the amount of radiation used. A high dose of radiation is needed to produce very good quality images. Thus, when performing a three-dimensional scan with the aim of obtaining very fine details, this dose may become critical. Another problem that occurs during a three-dimensional scan is the time the patient is immobilized, and a full scan can take up to 30 minutes.

Spiral scanning or continuous volume scanning can be a solution to the above problems. The procedure consists in the axial movement of the patient synchronized with a multitude of rotations performed by the receiver and the X-ray generator tube. In this case the received data no longer come from discrete sections, parallel to each other, but are presented in the form of a continuous film that consists of normal sections to an imaginary helical trajectory around the patient. Spiral CT scanners allow the user to choose both the pitch of the path and the thickness of the radiation beam that performs the scan. The proper choice of these parameters leads to the realization of helical spirals on spiral which is similar to the complete analysis of a volume.

Spiral CT scanners require special software packages to process data. These programs must be able to perform 3D reconstruction of the analysed models simultaneously with the removal of artifacts due to patient movement. The data must be stored in flat sections, and the model is made by assembling these sections. Due to the spiral scan, the flat sections are made by interpolating the analysed data. When performing a full spiral scan of a volume, the user can choose the distance between the parallel plane sections that will be calculated.

Nuclear magnetic resonance tomography is used to analyse and perform medical models of internal structures that are composed of soft tissues. Magnetic resonance imaging

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systems are based on the fact that odd-numbered nuclei rotate around their own axis, giving them a magnetic moment. When these nuclei are placed in an external magnetic field over which low-frequency radio waves overlap, the properties of these nuclei allow extremely detailed images of cross-sections to be obtained through the human body. The response frequencies are characteristic of each scanned tissue, which makes it possible to differentiate the analysed internal organs easily visually.

The process of 3D reconstruction of the analysed structures is similar to that of X-ray tomographs, in this case there is no possibility of spiral scanning. Although it seems to be a disadvantage, the absence of this facility does not affect the results of the analysis because exposure to magnetic fields is less harmful than exposure to X-rays.

2.3 Data acquisition and image processing for the case study

Three-dimensional data of the internal and external structures of the human body are obtained by using computed tomography (CT) systems for bone structures. In principle, it is possible to use any system that provides images of flat sections through the human body and that are able to make a mathematical correlation between these sections to make possible the 3D reconstruction of the analysed structure. Spiral scanning tomography was used in this case. The procedure consists in the axial movement of the patient synchronized with a multitude of rotations performed by the receiver and the X-ray generating tube. In this case, the received data no longer come from discrete sections, but are presented as a continuous film consisting of normal sections, to an imaginary helical trajectory around the patient. The image obtained by tomography is shown below, Figure 2.2:

Figure 2.2 Tomography image

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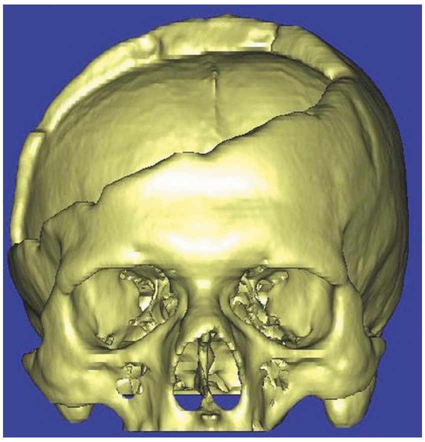
The three-dimensional image is obtained by "assembling" the sections made by the tomograph, and the 2D section package determines the geometric elements of the three-dimensional model.

Special software packages are used to process the data. This program is able to perform 3D reconstruction of the analysed model simultaneously with the removal of artefacts due to patient movement.

The interpretation of the images is performed by radiologists with the help of a 3D modelling program, namely the MIMICS program. During this stage, doctors determine the shape and size of the areas of interest in each section. The delimitation of the elements present in each section is called segmentation. Once the medical team has made the complete and correct segmentation at the level of each section, it is possible to proceed to the processing of the images provided by the tomograph.

3 CAD modelling preparation of the skull using specific software (Mimics)

The great advantage of using the CT - Modeler model provided by Materialize is that it interpolates the scanned sections without the need for the user to have advanced surface modelling knowledge. Basically CT - Modeler hides a very complex mathematical device, and the effect of processing the images provided by the tomograph can be visualized by displaying the three-dimensional model on the computer monitor, as seen in the figures below.



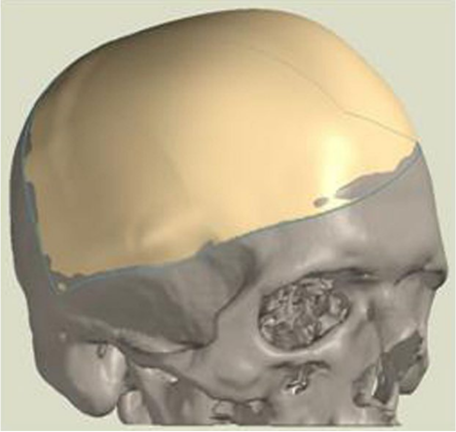


Figure 3.1 Virtual 3D reconstruction model of a patient’s skull

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3.1 Construction of the physical model of the destroyed (damaged) area

With the help of these technologies, objects are made by adding material in successive layers as opposed to classical technologies, where the models are made by removing material (cutting, EDM) or by redistributing material (injection, casting, forging, moulding).

The procedure behind obtaining the implant prototype is:

- starts from a virtual 3D model built on a computer system.

- this model is imported in specialized software packages, specific to each FRP system. In this software, the model is intersected with equidistant parallel planes and the intersection between the model and these planes is determined.

- the FRP system successively materializes these intersections, the piece being built sequentially layer by layer by selective laser sintering.

With this method the medical model is obtained, called the model of the destroyed area.

The model of the destroyed area means that part of a medical model, made on a 1: 1 scale, which includes the area on which the surgery will be performed.

To produce the custom-made cranioplasty implants, a spiral CT scan of the head (Siemens Somatom, Erlangen, Germany) was performed as the first step. A virtual 3D model of the skull was obtained using a 3D reconstruction program (MIMICS, Materialise NV, Leuven, Belgium). The virtual 3D model of the patient-specific implant was designed using FreeForm Modeling Plus 9.0 (Sensable, Wilmington, MA). Using selective laser sintering (Sinter Station 2000, 3D System, Darmstadt, Germany) or 3D printing (Eden 330, Objet Geometries, Rehovot, Israel), the virtual models (of the calvarial defect and the custom-made implant) were transformed into physical models. The designed implant was well suited for the defect, which was not needed for further manual processing [ROT12].

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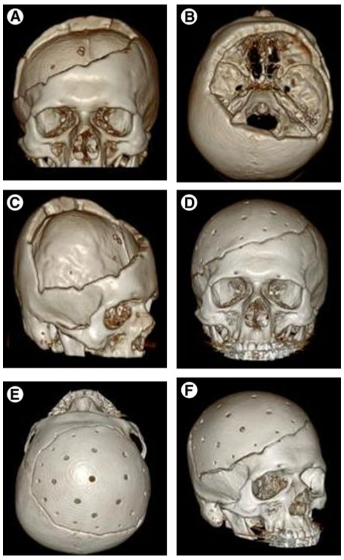

Figure 3.2 Three-dimensional computed tomographic images A-C, before versus D–F, after surgery show that the defect was successfully reconstructed.

4 Realizing of the part used as master model by Selective Laser Sintering technology

4.1 Possibilities of RP technologies to make models starting from CT (Computer Tomograph) and MRI (Magnetic Resonance Imaging) images

For selective laser sintering (SLS), the powders - the raw material must be coated with a thermoplastic polymer. During the laser beam sweeping of the successive layers (that by assembly generates the finished part), the thermoplastic polymer on two particles in contact must be welded to complete the strength of the metal-to-metal welding bridges. From the point of view of the resistance of the direct joint with laser radiation, the optimal shape of the particles is irregular, with marked peaks. This is the situation of titanium powders obtained by the process of hydration - grinding - dehydration. In addition to the metal peeks, the particles must have polymer-coated portions after conditioning. Presintered compacts made by SLS must have sufficient mechanical stability for the final sintering. In addition, the thickness of the metal-metal bridges must ensure sufficient mechanical stability during the

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removal of the organic binder. A too low sintering of titanium particles can compromise the shape of the final compact if the polymer-polymer welding bridges fail before making stable metal-to-metal "necks". Also, the adhesion of the metal substrate-coating polymer must be sufficient to ensure the mechanical strength of the precompact.

4.2 The manufacturing technology of customized implants

The creation of customized implants required a complex technology that includes six essential steps, namely:

- Acquisition and processing of tomographic images to obtain the virtual model of the destroyed area. The images obtained by tomography were processed on the computer with the help of the Materialize package which includes the 3D Mimics modelling program and the CAD system after which the STL, CT file is generated.
- After obtaining the data, the virtual generation of the implant was attempted using symmetry with the healthy part.
- The third stage in obtaining the customized implant consists in the construction of the physical model of the destroyed area and of the implant from materials specific to Rapid Prototyping (AM) technologies, namely in this case by selective laser sintering.
- After obtaining the implant, an adjustment is made to the physical model of the destroyed area.
- Construction of a silicone rubber mould for the formation of the real implant, made of biocompatible material.
- After a whole technology the real implant will be obtained.

The Sinterstation 2000 machine presented in figure 4.1, from the endowment of the National Centre for Rapid Manufacturing of Prototypes within the Technical University of Cluj-Napoca, works with several types of powder: metal powder, plastic powder (polyamide), polystyrene powders or powders from ceramic material.

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Figure 4.1 SINTERSTATION 2000 machine from the National Centre for Rapid Prototyping (UTC-N)

If this equipment were described in more detail, we could say that it is a control equipment, equipment that has the appropriate software characteristic of these systems, capable of taking over certain files for execution, files in ".stl" format, which the machine recognizes, as well as to effectively control the entire effective sintering process (through the indicated working parameters). The machine itself includes working chamber, mirrors, laser system, sensors, cartridges, adjusting elements, conveyor roller, etc.

The working space is limited to a 250 mm cylinder, but due to the deformations that occur on the edges due to the variation of the temperature in the enclosure, the working space is further limited to about 230 mm.

The characteristics of the SLS equipment are presented in the following table (Tab. 4.1)

Table 4.1 SLS equipment characteristics

Resolution	0.75 in the x / y plane, 0.005mm minimum layer thickness on Z
Overall dimensions	3937x 1499x 1905
Power supply	208/240VAC, 70A, 60Hz AND 120VAC, 20A
Laser	50W CO2 Laser
Working dimensions	203x254x152

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The working principle in the manufacture of parts by selective sintering with laser is shown in figure 4.2. As can be seen in this figure, the process of rapid prototyping by selective laser sintering (SLS) is based on the materialization of a virtual 3D model (built into a CAD system) by adding successive layers. It is not necessary to build supports because the previous layer of material (sintered or not) is a support for the current layer of material. The laser system generates laser radiation which is focused by means of lenses and is then directed through a system of mirrors to the surface of the work platform. At the beginning of the work process, the platform is in the upper (top) position. A feeding system deposits a thin layer of powder, of controlled thickness, on the surface of the platform. The laser beam scans the surface of the platform according to a trajectory corresponding to the geometry of the first section through the workpiece. Following the scanning process, the laser radiation sinters the powder layer locally. After the laser radiation has completely scanned the surface of the first layer, the work platform descends a distance equal to the thickness of a layer. The material supply system deposits a new layer of metal powder over the previous layer. Again, the laser radiation will scan the current layer of powder according to the geometry of the new section through the solid model of the workpiece. During the process, there will be a permanent control between the thickness of the powder layer deposited on the work platform, the distance between the sections made by the computer software through the solid part model and the size of the work platform movement after each layer processed. [www 05]

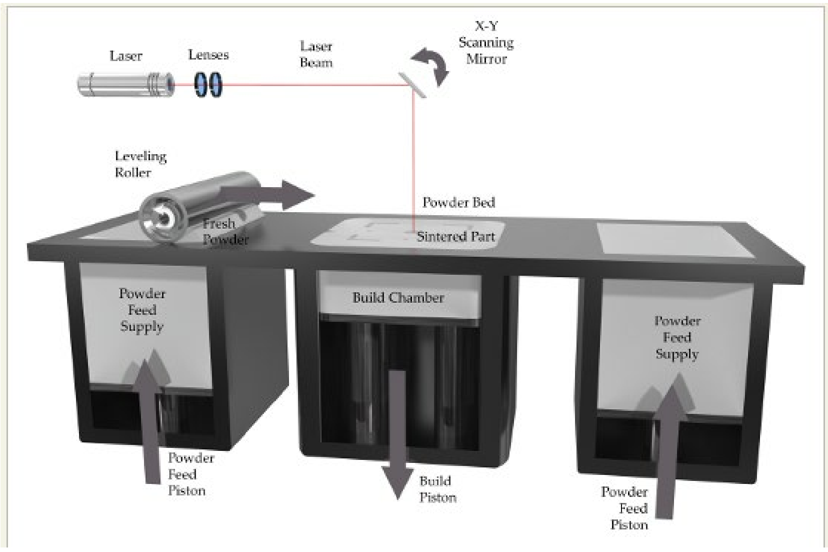

Figure 4.2 Working principle of laser selective sintering technology (SLS) [www 05]

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The characteristics of the material used to make the prototypes (Duraform Polyamide P6 plastic powder) are shown in Figure 4.3. [www 06]

TECHNICAL DATA

General Properties

MEASUREMENT	METHOD/CONDITION	VALUE
Specific Gravity	ASTM D792	1.00 g/cm^3
Moisture Absorption - 24 hours	ASTM D570	0.07 %

Mechanical Properties

MEASUREMENT	METHOD/CONDITION	VALUE
Tensile Strength, Yield	ASTM D638	N/A*
Tensile Strength, Ultimate	ASTM D638	43 MPa (6237 psi)
Tensile Modulus	ASTM D638	1586 MPa (230 ksi)
Elongation at Yield	ASTM D638	N/A*
Elongation at Break	ASTM D638	14 %
Flexural Strength, Yield	ASTM D790	N/A*
Flexural Strength, Ultimate	ASTM D790	48 MPa (6962 psi)
Flexural Modulus	ASTM D790	1387 MPa (201 ksi)
Hardness, Shore D	ASTM D2240	73
Impact Strength (notched Izod, 23°C)	ASTM D256	32 J/m (0.6 ft-lb/in)
Impact Strength (unnotched Izod, 23°C)	ASTM D256	336 J/m (6.3 ft-lb/in)
Gardner Impact	ASTM D5420	2.7 J (2.0 ft-lb)

Thermal Properties

MEASUREMENT	METHOD/CONDITION	VALUE
Heat Deflection Temperature (HDT)	ASTM D648	
	@ 0.45 MPa	180 °C (356 °F)
	@ 1.82 MPa	95 °C (203 °F)
Coefficient of Thermal Expansion	ASTM E831	
	@ 0 - 50 °C	62.3 μm/m-°C (34.6 μin/in-°F)
	@ 85 - 145 °C	124.6 μm/m-°C (69.2 μin/in-°F)
Specific Heat Capacity	ASTM E1269	1.64 J/g-°C (0.392 BTU/lb-°F)
Thermal Conductivity	ASTM E1225	0.70 W/m-K (4.86 BTU-in/hr-ft^2-°F)
Flammability	UL 94	HB

Figure 4.3 Mechanical and thermal characteristics of Duraform PA6 powder [www 02]

4.3 Manufacturing of Parts by Selective Laser Sintering (SLS)

Models designed with SOLID WORKS software are saved as ".stl" files, which are later recognized by the DTM SINTERSTATION 2000 machine software.

The software of the SLS machine contains two actual packages, one in which the model is prepared, indicating at the same time the working parameters depending on the material used, respectively the scaling factors necessary to compensate the contractions resulting from the manufacturing process, respectively a second package in which the actual manufacture takes place on the sintering machine (the control part of the machine).

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The preparation of the model is therefore done using a first software package of the SLS machine, namely the BUILD SETUP program.

The interface of this software is very similar to the interface of a design software, being easy to manipulate.

Thus, in a first phase, the saved ".stl" type models are imported into the machine program, thus building the package for the working session, so as to meet the minimum conditions on z, a condition that ultimately influences the cost price of the models, increasing or decreasing the working time, respectively the overall conditions, not exceeding 230 mm (cylinder diameter), otherwise the part suffering seriously from the point of view of precision, as well as qualitatively due to deformations.

Then select from the menu, the type of material from which the models will be made on the sintering machine, which will be the plastic powder type Duraform Poliamyde PA6 in our case.

Next, the parts are positioned for manufacture on the sintering machine, taking into account the shape of the models to be manufactured on this equipment in order to finally have a minimum package height in the direction of the Z axis (on height), which will reflect on the manufacturing time, respectively on the manufacturing costs using this equipment without affecting the quality and dimensional accuracy of the manufactured models (see figure 4.4).

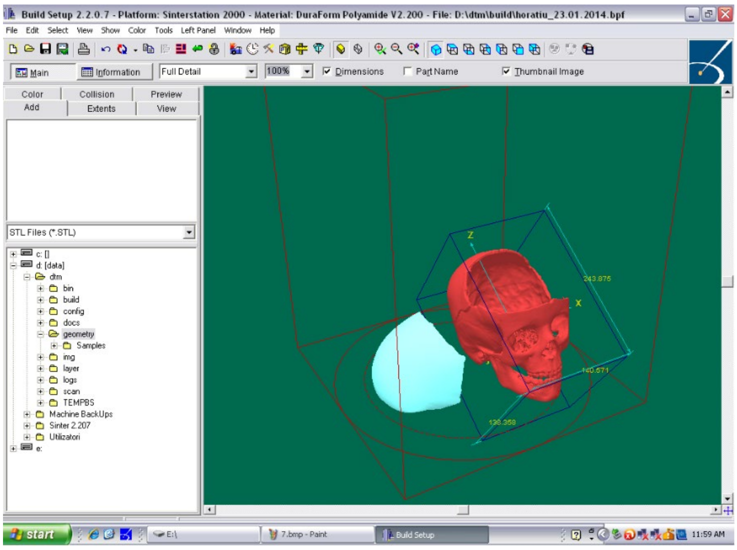

Figure 4.4 3D models imported in the Build Setup software

The working parameters are applied according to the chosen plastic powder. Thus, in a first phase, the scaling of the models to be manufactured takes place. These were each scaled in the direction of the X axis by 1.03510 mm, in the direction of the Y axis by 1.03310 mm, and in the direction of the Z axis by 1.01800 mm, in order to compensate for the contractions resulting from the sintering process itself (Figure 4.5).

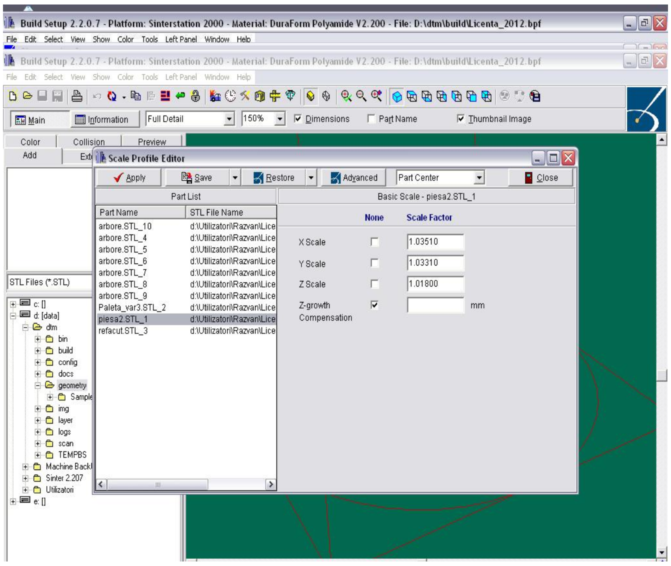

Figure 4.5 The used scaling factors

Next, the power of the laser that was used during the sintering process was set for all manufactured models. A laser power of 4.5 W was used for all the manufactured models, enough power to melt the plastic granules (Figure 4.6).

Also, as can be seen in Figure 4.7, a second parameter that was set was the temperature used during the manufacturing process. As can be seen in Figure 4.7, we have three temperature zones to be set, distinct on the machine, namely, a temperature value required for the area of the heating cycle, when the machine heats up to a set temperature of C, during which time the necessary base for the models to be manufactured is built. This base is necessary to maintain a constant temperature of the package containing the models throughout the manufacture. It is also possible to observe a second zone specific to the actual manufacturing, which comprises a temperature value of C, kept constant throughout the manufacturing process, followed by a third zone, on the cooling phase, when the process

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temperature drops sharply. controlled, at a value of C, at which point the process of selective laser sintering is considered to be completed.

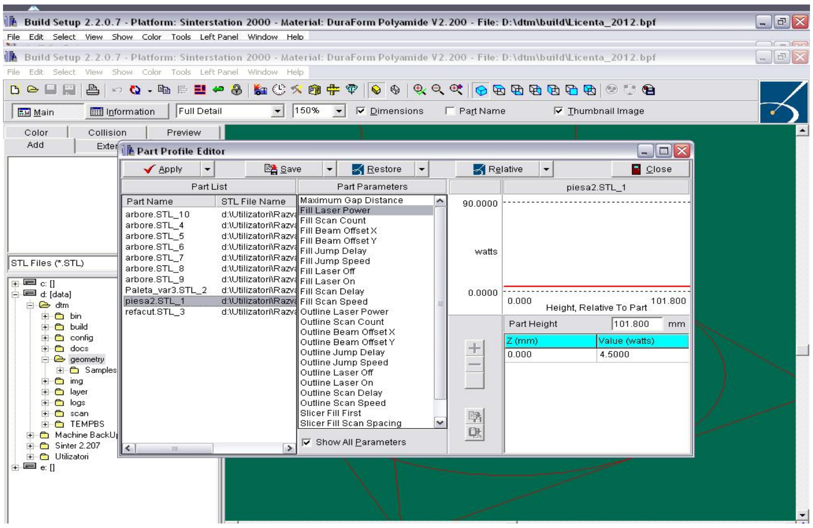

Figure 4.6 The laser power

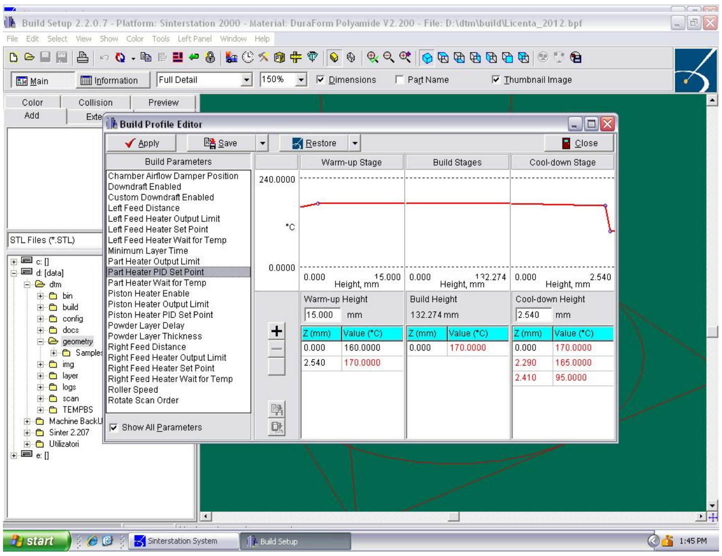

Figure 4.7 Working temperature on the three cycles

The thickness of the layers that was used in the selective sintering process with laser was 0.10 mm on all three areas mentioned above, as can be seen in the image in Figure 4.8.

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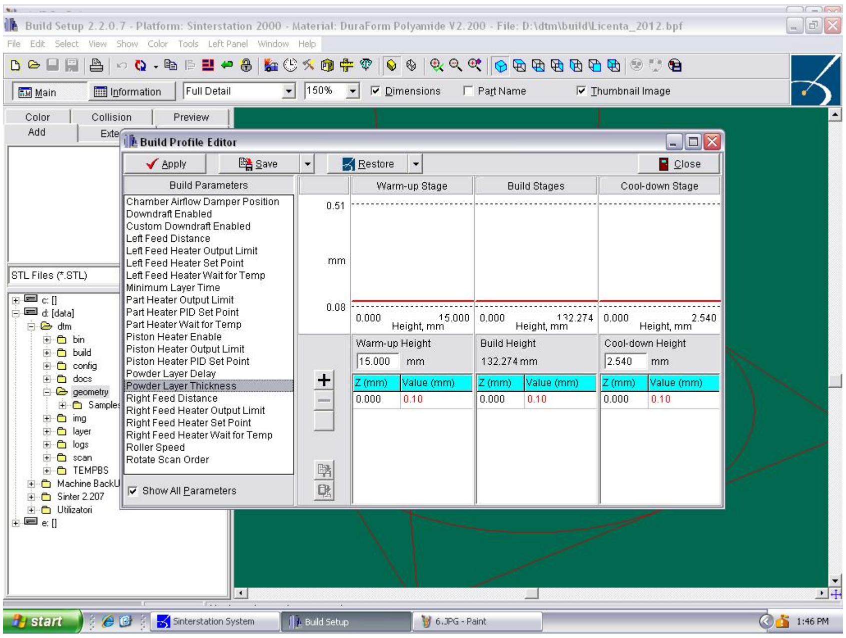

Figure 4.8 The used layer thickness

Finally, a last basic parameter that was set was the laser scanning speed, which has a value of 1257.30 mm / s. This parameter is particularly important, as a change in speed in the direction of its increase or decrease ultimately leads to improper sintering of the plastic powder granules, the parts becoming brittle, their tensile strength being significantly affected in this case (see Fig. 4.9).

Finally, all this information related to the manufacturing models is included in the analysis bulletins within the BUILD SETUP software, the package containing these settings can be accessed and manufactured at any time thereafter.

Thus, in these bulletins you can view information related to the material from which the package is made, the number of pieces of the models in the package, the number of facets of the models, the size in MB per disk drive (file size. * Stl), the required quantity of the material (powder) for the finalization of the package to be manufactured, respectively a particularly useful information regarding the time required for the manufacture of the package, which was estimated in this case of the models presented in Figure 4.4. at a total of 18 hours and 14 minutes (see Figure 4.10).

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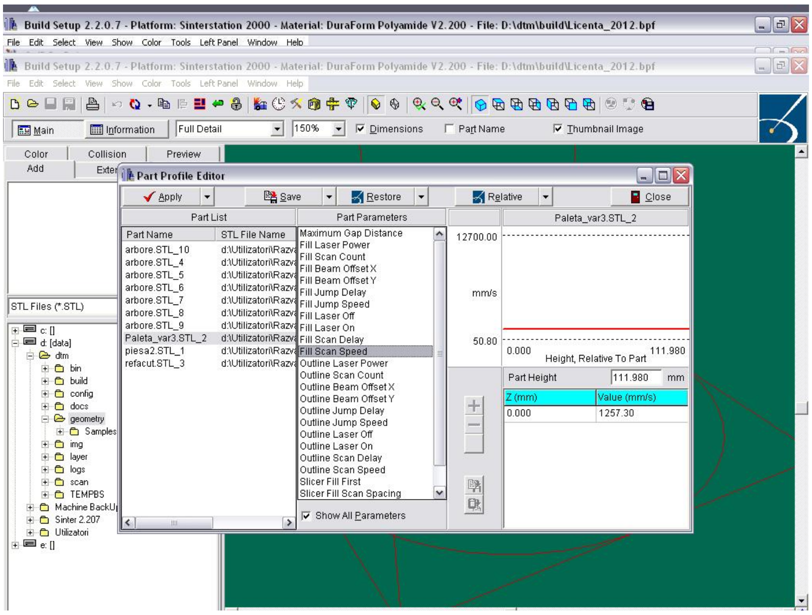

Figure 4.9. Laser scanning speed

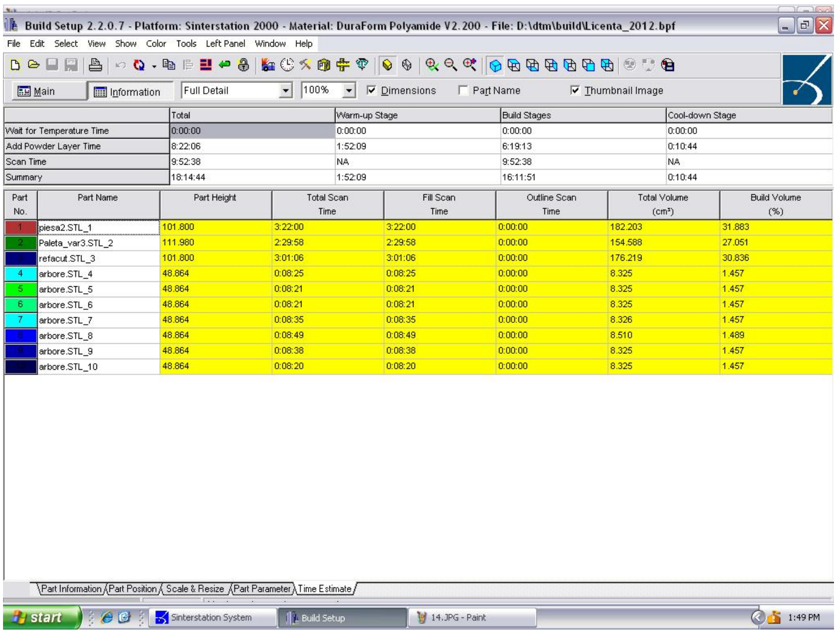

Figure 4.10 An example of an analysis bulletin related to model size and manufacturing time

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Once the pre-processing part of the models is finished, it can be move on to the actual manufacturing part, the models being loaded in BUILD SETUP, after which using the second software package of the Sinterstation machine, where the command and control parameters are set, such as operating temperature (the initial temperature of C for the heating zone will be set, as shown in Figure 4.7). The permissible oxygen level inside the machine's working chamber is also adjusted (5% is allowed inside the machine's oxygen chamber). The atmosphere in which plastic powders are treated is a controlled, being a nitrogen-based atmosphere. This is absolutely necessary to avoid the risk of ignition of plastic parts during the SLS manufacturing process. Once these conditions are met, layers of 0.10 mm are deposited, up to the total of 15 mm necessary to achieve the base of the package, as presented above.

After the deposition of these layers, the sintering process starts automatically, the actual manufacture of the package being carried out layer by layer until the maximum height of the package on the Z axis is reached.

Once the manufacturing package is completed, it enters the area of the last required cooling cycle, as shown in Figure 4.7, the temperature set for this cycle being C. In this phase no more layers of powder are deposited.

The models are finally buried in powder in the work area, being cleaned during a post-processing stage, with the help of special cleaning brushes, to avoid the risk of breaking certain fine details of the models, an exhaust system being permanently used at the same time for vacuuming the excess dust. The final parts that were made on the SLS machine, after their post-processing step are shown in the image in Figure 4.11.

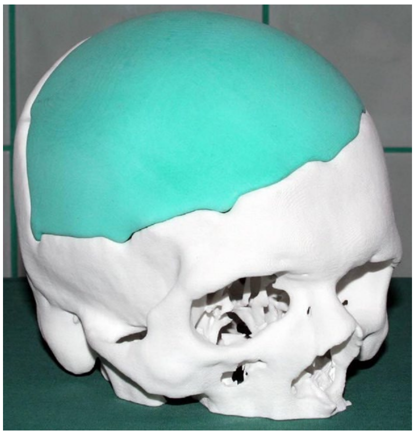

Figure 4.11. Medical model made of polyamide material on SLS machine using Sinterstation 2000 equipment (UTC-N)

5 Realizing of silicone rubber moulds by Vacuum Casting method

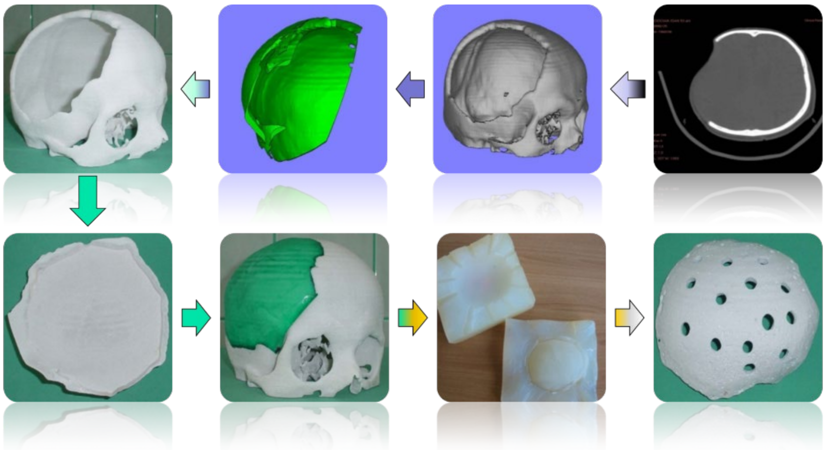

Fig. 5.1. Required steps for obtaining a customized implant using indirect

Manufacturing a silicone rubber mould (Figure 5.1) for a customized implant requires the following steps:

1) Checking the master model which was obtained using an Additive Manufacturing Technology. In this example, the model was obtained through Selective Laser Sintering Process, using Polyamide, PA6 material.
2) Cleaning the master model and applying chemical substances to prevent sticking of the silicone on model's surface. For this purpose, a green coloured Release Agent was used. The dried process of the model took 2 hours, at room temperature.
3) Manufacturing of a shaped box, using MDF as a building material (wood with glossy surface), in which the master model can fit and to it can be casted the silicone rubber (CS) in a liquid state. For economic reasons this box must be made approximately 20-25 mm larger than the size of the master model, Figure 5.2.

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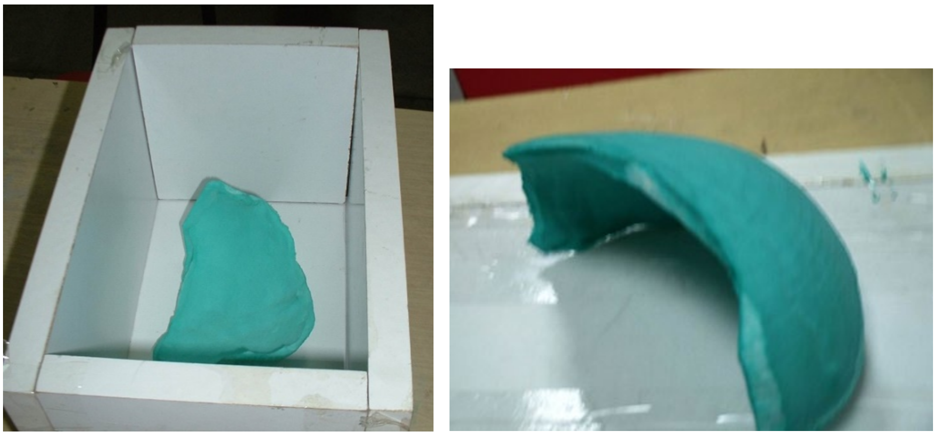

Fig. 5.2. The box shaped from wood and the physical model of the destroyed area

4) Suspension of the model into the box. The model must be suspended into the box and to not touch the bottom of the box. There are many ways to suspend the model. Due to the small size of this master model, it was chosen to anchor the model with the help of nylon threads, in walls of wooden box after its previous drilling. Drilling was done with a helical drill with a cylindrical shaft, Drill 2 STAS 573-80/Rp 3. Due to the small size of the holes, the future implant that will be casted into the silicone mould will not be affected.
5) Preparation of the silicone rubber mixture. Silicone rubber which has been casted over the model was obtained by mixing silicone "ESSIL 291 RESIN" (Figure 5.3a) and catalyst "ESSIL 291 CATALYSEUR" (Figure 5.3b). The catalyst had role for hardener.

Figure 5.3.a)cESSIL 291 RESIN b) ESSIL 291 CATALYSEUR

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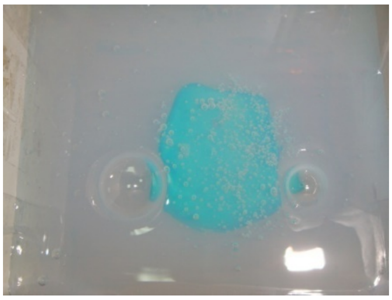
By determining the volume of the box (9 cm x 8 cm x 8 cm = 576 cm3) was obtained by approximating, the quantities of silicone, respective catalyst, which must be used (600 g silicon and 60 g catalyst). The ratio of silicone and catalyst was 10:1. The two components were mixed in a container whose volume is at least 5times larger (Figure 5.4. a, b, c).

a) b) c)

Figure 5.4.a,b,c Mixing of the components

6) Introducing the mixture into a vacuum chamber (MCP-001 Machine PLC) for degassing, where it stayed until most of the air bubbles are gone.
7) Casting the mixture in the box over the model. The model must be covered, so the mixture was casted onto with approximately 5 cm over the model (Figure 5.5 a,b).

a)



b)

Figure 5. 5.a,b Casting the silicone over the model

8) As shown the Figure 5.6 during the casting have been formed many air bubbles. If these are located close to the model, may lead to deviations from its original shape of the master model and will influence the shape of the future implant too. Therefore,

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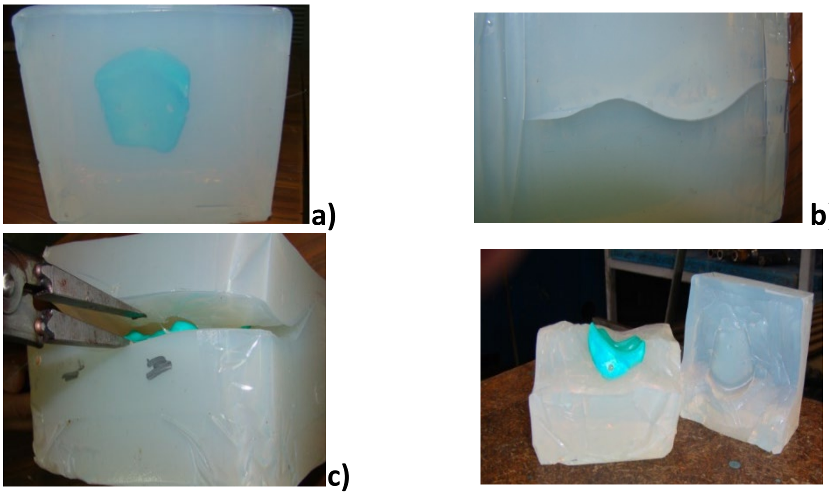
the forming box with silicone rubber is inserted again into the vacuum chamber to remove air bubbles accumulated at casting proces, around the master model.

Figure 5.6. Removing the air bubbles from the mould

9) Further, the box containing silicone rubber mould, was introduced into a polymerization oven, where the solidification process of the silicone rubber block was occurred. The mould remained in the oven 2 hours, at 50° C temperature. Another possibility for polymerization is to let it at room temperature for 24h.
10) After full polymerization, the silicone rubber block was removed from the box. With the help of a cutter, following the separation plane between the two half moulds (which was made considering the complex shape of the part) the block was cut. This has been facilitated by the use of a transparent silicone rubber. By opening the silicone rubber mould, the master model was extracted (Figure 5.7 a,b,c,d).



a) b) c) d)

Figure 5.7. Silicone rubber mould

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6 Realizing of the real implant made of PMMA material using silicone rubber moulds

The pattern of the implant was used to build a silicone rubber mould after the CT scan and 3D model were completed. PMMA-based radiopaque bone cement was placed into the silicone rubber mould and pushed into place. The final custom-made implant's margins were modestly and manually processed after unmoulding to remove any excess. To prevent the development of an epidural hematoma, holes were drilled into the plate's surface. Ethylene oxide was used to sterilize the plates.

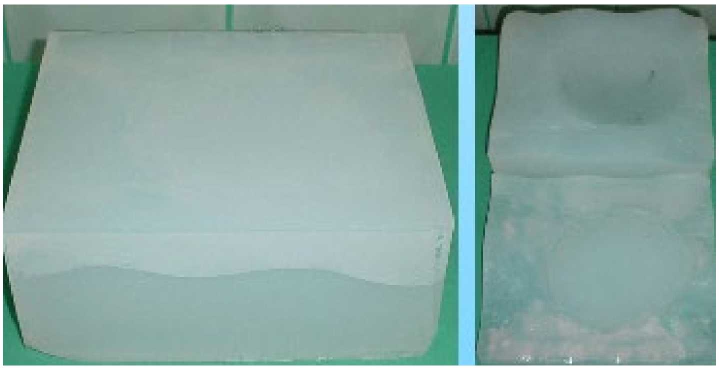

Figure 6.1. Silicone rubber mould in which the PMMA-based radiopaque bone cement was cast. The thickness of the mould's walls and the excess material appearing at one of the drain channels

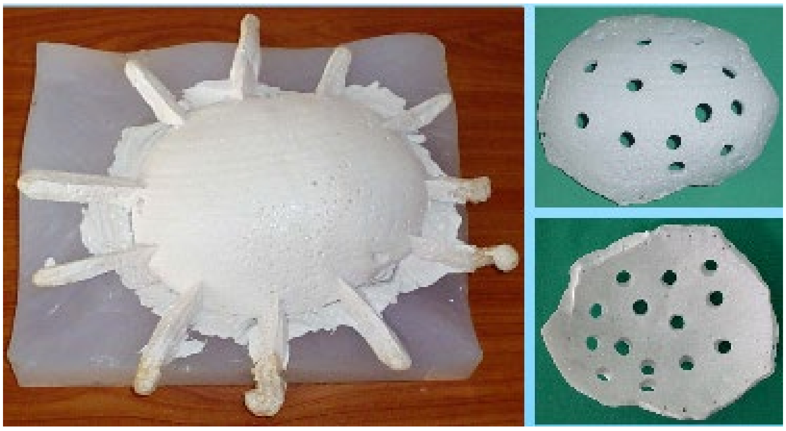

Figure 6.2. Custom made cranioplasty plate (before implantation).

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The bone deficiency was disclosed, and custom-made implants were placed under the patient's general anaesthesia. To add stability, the plates were sutured to the defect's bony edges with 1-0 silk sutures. Additional CT scans of the patient were acquired postoperatively to assess the symmetry restored by the surgery. The calvaria, the roof of the neurocranium, and the cranial base make up the neurocranium, which is the covering of the brain. The frontal, parietal, and occipital bones make up the calvaria. The volume of the neurocranium (calvaria) was measured in this study. The rebuilt cranial volume was calculated from postoperative CT images using Xelis (INFINITT Healthcare, Seoul, Korea).

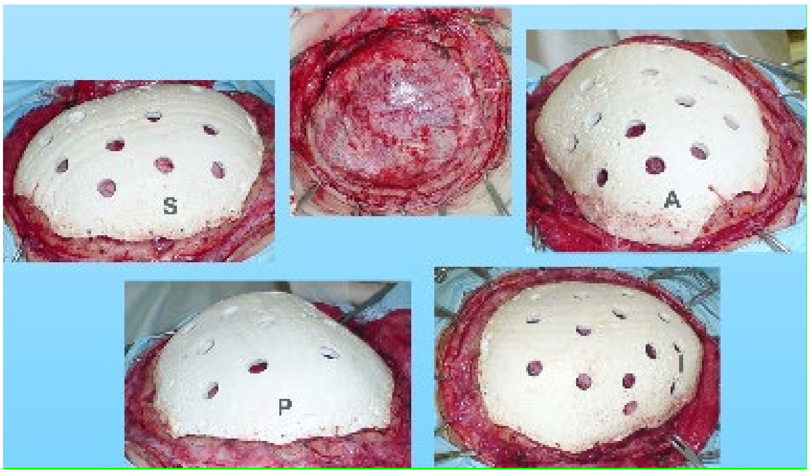

Figure 6.3. Intraoperative view (the plate is exactly positioned into the defect)

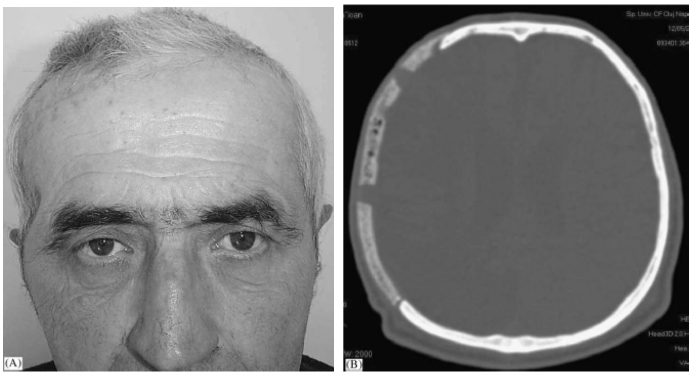

Figure 6.4. Postoperative aspect revealing the restored symmetry and (B) postoperative CT, note the perfect marginal adaptation of the reconstruction plate

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7 Conclusions

To correct major skull deformities, either intra-operative vault reconstruction or a "custom manufactured cranial implant" might be chosen before surgery. Time, greater risk to the patient, insufficient protection from trauma and infection, and generally suboptimal cosmesis are among downsides of intra-operative repair. Custom-made cranioplasty implants, on the other hand, have the advantages of a shorter operative time, less invasive surgery, better cosmetic results, faster recovery, and lower expenses due to the shorter operative time.

Custom-made implants should be explored for cranioplasty because to the several advantages of custom-made implants, including reduced surgical times, no donor site morbidity, and enhanced cosmetic results.

RP techniques have been used to create custom-made implants in numerous cases. A silicone rubber mould was utilized in this procedure. Because of its fluidity, the silicone rubber enables for the retention of the plate's surface morphology and marginal features during the impression process. The implant's stability has enhanced thanks to the precision of the marginal replicas. The graft can be created accurately if the PMMA graft is allowed to polymerize in the bone defect. During the polymerization of PMMA, however, the temperature rises, causing damage to the critical structure nearby.

Finally, custom-made cranial implants created by 3D modelling, rapid prototyping, and additive manufacturing were particularly useful for fixing big deformities. There was a significant improvement in morphology and function. Infection, plate rejection, or major long-term consequences were not found. This approach could be used to repair bones at additional locations.

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