Applications of Rapid Prototyping in Cranio-Maxilofacial Surgery Procedures

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***Abstract*—** In the last decades, the technical field of additive layered manufacturing (ALM) has offered aid in medical reconstruction procedures in order to help surgeons reconstruct physical faults and anomalies of their patients. Using a combination of Computer Assisted Design (CAD), high medical skills and latest ALM technologies, it is now possible to help patients with birth defects or those suffering from craniofacial injuries of variable severities, retain aesthetic and functional properties of their bodies. Combined with traditional CT scanning techniques rapid technologies (prototyping and tooling) can be used as instruments for better (three-dimensional) visualization, simulation of procedures and treatment of patients. They also improve the overall performances of medical and nursing staff thus influencing the quality of medical service. Using a combination of Computer Assisted Design (CAD), high medical skills and latest rapid prototyping and manufacturing technologies, it is now possible to help patients with craniofacial deformities as birth defects, orthognathic deformities, deformities after malignancy treatment or the consequences of craniofacial injuries of variable severities, resulting in both aesthetic and functional alterations. This paper presents some clinical cases, carried out in cooperation of Faculty of Mechanical Engineering in Maribor and both University Clinical Centres in Slovenia, where virtual models have been used for surgical preparations and RP models for manufacturing of implants.

***Keywords*—** rapid prototyping, reverse engineering custom implant, maxillofacial, reconstructive surgery, Cranioplasty, CT scanning.

I. Introduction

DEFECTS in the craniofacial skeleton are of either congenital (birth defects), developmental (orthognathic deformities) or accidental (resulting from trauma, infection, tumour, etc.) cause. The purpose of reconstructing abnormalities is primary functional. The aesthetic rehabilitation is very demanding in the idea to approximate a normal appearance that is very difficult with patients' own tissues. Since they have a strong effect on the facial region, these types of alterations are highly visible, they affect the appearance, and thus the psychological state, social life, and possibility of the patient to found a family, to name a few.

Treatment of patients after injures or diseases resulting in deformational consequences usually require the implantation of either autologous tissues or biocompatible / biodegradable implants that replace missing parts of the tissue, usually bone. Autologous tissues are always the first choice of surgeons, if they are available. The bone defects in maxillofacial region can be replaced by patients' own bone by different surgical principles as bone grafts or by engineering bone by distraction osteogenesis [1]. These different autogenous bone grafts are "golden standard" for reconstruction procedures because they provide osteogenic cells, but they are of limited quantity and connected with risk of complications on donor site [2]. In cases where autologous material can not be obtained an artificial implant has to be made to fulfil physical, aesthetical and functional demands.

The implant market mainly covers areas of serial implant, and biocompatible material production. Serial implants are predominantly used in orthopedics (hip stems, knee joints…) where only functionality matters. In cranio-maxilo-facial treatments, implants also have to fulfill an aesthetic function, therefore, the possibilities of their prefabrication by means of serial production are very limited. Today there are modern synthetic implants like chin and mandible augmentation implants made of modern plastic materials (acrylates) available, in the shape of contoured two-piece chin implants and angular mandible augmentation implants [3]. A good synthetic material needs to have following properties: biocompatibility, inertness, bone-similar weight or even lighter, capability to generate no artefacts on CT and MRI scans, ease of manufacturing, enough strength to resist functional stress, not expensive and low or no thermal conductivity. The production of such implants starts by capturing a three-dimensional data set of the problematic area (skull, face, mandibular area...). The usual and the most common method is transforming sets of CT or MRI two-dimensional pictures into a three-dimensional, digital, model. This model is then used as the basis on which modelling of the defective – missing area takes place. If the defect is positioned in an area that has its mirror-image on another part of the body then relatively speaking the form of the implant can easily be produced by means of Boolean operators. In a case of mirror-less features some more sophisticated methods and dedicated

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software have to be used to finish the implant.

The finished digital model is then manufactured using one of the Rapid Prototyping (RP) or Rapid Manufacturing (RM) technologies. RM products are usually made of titanium or cobalt – chrome alloys, since these are, at the moment, the only biocompatible materials available for RM technologies that can be directly used as implants. RP products are used as patterns for further processing using one of the Rapid Tooling (RT) techniques. From among RT techniques, Silicone Rubber Moulding (SRM) is usually the first choice for making implants out of biocompatible PMMA, – Poly Methyl Meta Acrylate better known as bone cement among surgeons, or Plexiglas among engineers [4].

Another aspect of the described procedure is aimed for preparation of surgical treatment. Namely, the CAD, virtual model of a human body or a part of it can be used to study the problematic area before the actual operation starts. This is especially important in cases where functionality of the body part has to be re-established (orthopaedic surgery, blood vessel clogs, etc.) [5]. Besides the continuous flow and other FEA methods that are used to calculate required mechanical and physical properties of the implant, the virtual models can also be used to study the surgical procedures, like directions of implantation, required preoperational treatments and preparations, etc.

II. Uses of CAD and RP in Medicine

In last two years several trials have been made to show the potential of virtual modelling and rapid prototyping in medical praxis. Cranial and maxillofacial areas are very suitable for such development because of relatively low mechanical stresses that occur on them and because of very high aesthetical demands that have to be met in order to successfully finish the operation. The first trials were aimed to study the possibilities of three-dimensional construction and production tools in the medical praxis.

The trials have shown a great potential as communication and surgery planning tools. Because of their overall usability first ideas of making usable implants arose. Their production started very soon after the first communication prototypes were made. The pioneering work in Slovenia was made in cooperation between the Faculty of Mechanical Engineering and University Clinical Centre in Maribor. Soon after the first successful clinical case in neurosurgical practice the cooperation was spread to University Clinical Centre in Ljubljana. In cooperation of engineers and doctors, two different types of implants were developed, clinically tested and implanted at the end. The first one was a cranial implant implanted to patient suffering from spontaneous intra cerebral haemorrhaging. The second case was a mandibular implant made to fulfil aesthetical function of the face. In the first case PMMA was used to manufacture the implant indirectly, using the silicone rubber moulding to shape the PMMA. The last was produced directly out of Titanium alloys, using selective laser melting equipment EOS M270 at Central University of Technology, Free State (South Africa).

III. Cranial Implant

On July, 27th 2006 a 34 year old male patient was admitted to a neurosurgical department because of spontaneous intra cerebral haemorrhaging. He was comatose and his Glasgow Coma Scale (GCS) score was 6. A CT scan showed extensive intra cerebral hematoma in the left temporal lobe with a shift of brain masses. The patient was immediately treated surgically with craniotomy, and evacuation of the intracerebral hematoma. At the same time an intracranial pressure (ICP) probe was inserted. ICP showed raised values and a controlled CT scan after the operation revealed brain edema. Therefore, an external ventricular drainage was inserted and he received all the conservative measures for lowering intracranial pressure and maintaining the CPP (cerebral perfusion pressure). Despite all efforts ICP started to rise again so that it could no longer be controlled by conservative measures. An angiograph was performed showing decreased blood-flow in the left hemisphere.

Therefore, on August 4th, 2006 a decision was made to perform a decompressive craniectomy. After intervention the intracranial pressure could be better controlled and patient's state started to improve. A controlled CT scan showed reduced edema, therefore, the drainage could be removed and the patient was brought to spontaneous ventilation. He was transferred from the ICU (intensive care unit) to the neurosurgical department, where we started early and complex neuro-rehabilitation. His condition and awareness started to improve gradually. Latter the Patient was transferred to the rehabilitation institute in Ljubljana. There he received complex neuro-rehabilitation, which was completed by the end of February 2007.

On March 23rd the patient was admitted to the neurosurgical department of University Clinical Centre of Maribor for a cranioplastic procedure. The patient was in a wheelchair, complient with the still present dysphasia and complete spastic plegia of the right upper extremity and serious paresis of the right lower extremity. After preceding preparations, cranioplastic with PMMA in the form of bone cement, was carried out. [6].

IV. Development of an Implant

The easiest way to reconstruct the structure of a patient's bones is to use those CT images that already exist from previous treatments of the patient. A set of CT images can be converted into a three-dimensional, digital model using one of the available conversion software, such as: Mimics (Materialise), RapidForm (Inus Technology), 3D doctor (Able Software), Amira (Marcury Computer), or others [8]. The input to this software is usually in the form of DICOM files and output is predominantly STL (Standard Tessellation Language), which can be directly used in most RP technologies to produce real models (Figure 1). In both presented cases the Materialise's software package Mimics was used, because of all the possibilities that it gives and because of its concept which is close to the engineers' as well as medical doctors' thinking.

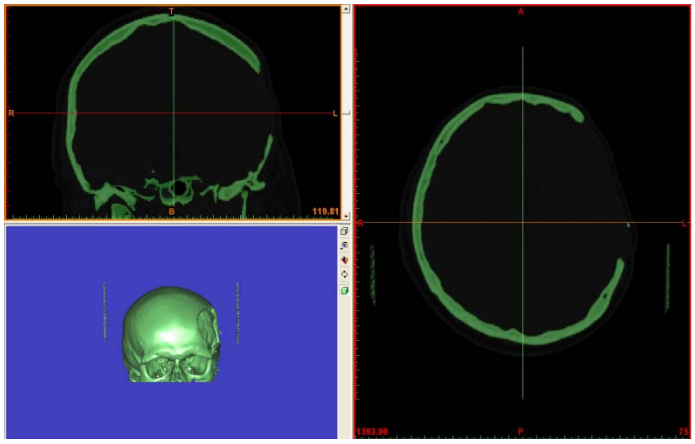

Fig. 1. 3D reconstruction of the skull from DICOM data

Three dimensional reconstruction of DICOM images in a form of STL file can be further manipulated by several CAD software. The usual 3D modelers based on parametric, volume modeling techniques are not very well suited to the task. Newer versions of these software packages (SolidWorks 2008, Delcam, etc.) enable manipulation of triangulated surface files, but using dedicated software, known from Reverse Engineering fields, such as Magics (Materialise), RapidForm, PolyWorks (InnovMetric), or others is much more effective in terms of time and effort. Using these software and STL models of scanned body parts, missing tissue can be modelled and saved as new STL files. These can be further processed or used for the production of real implant models by means of RP or RM technologies. CAD modelling of the implant was performed using several reverse engineering software packages.

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

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

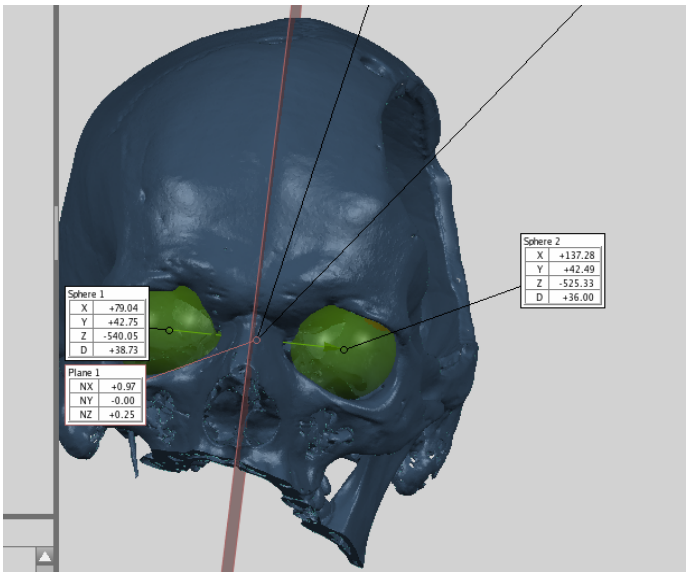

Fig. 2. Determination of mirror plane.

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

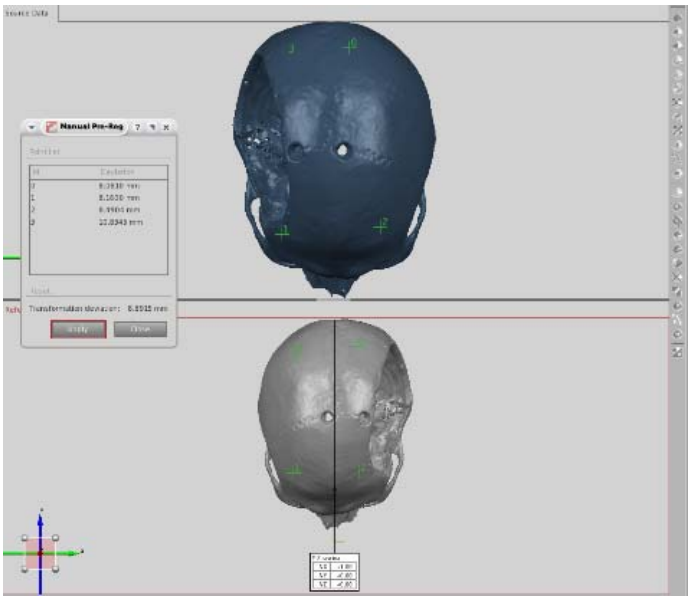

Fig. 3. Best-fit registration of original and mirrored skull

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

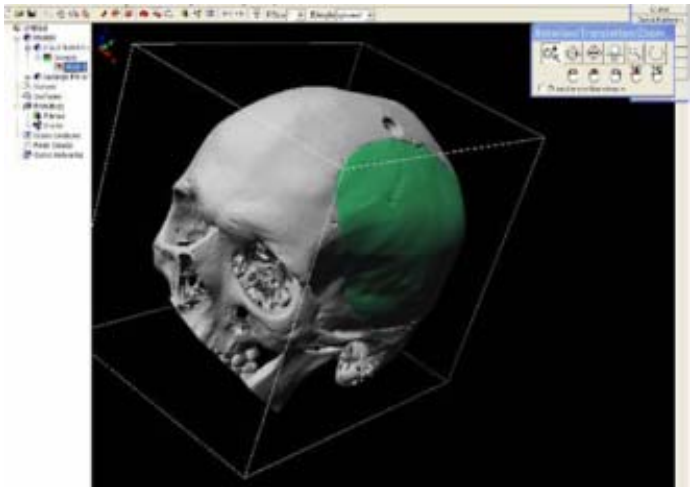

Fig. 4. Final inspection of the implant model

V. Implant Production

Reconstructed models of the skull and the implant were manufactured using two different additive layered technologies. These technologies are relatively new to the industrial market. Their use commercially began in 1987 with stereolitography being first sold by US company 3DSystems. The technologies are based on a layered principle, which starts by cutting a virtual model in a digital environment into a set of thin parallel slices. The slices, representing two-dimensional images of the model's cross sections are sent to a special device, popularly called a "3D printer" where they are "printed" one over another to form a real, three dimensional object. "Printing" principles are numerous but can be classified in one of four groups:

- Selective Consolidation,
- Selective Sintering and Melting,
- Aimed Depostition and
- Taylored sheets deposition.

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

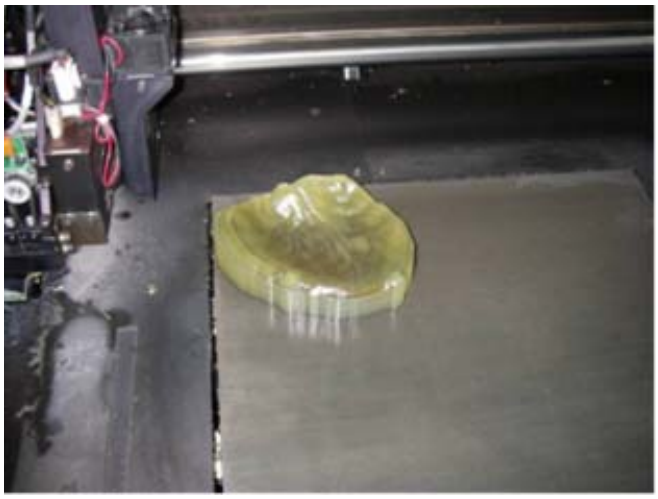

Fig.5. Implant model made by PolyJet Rapid Prototyping technology

SLS rapid prototyping technology builds parts from powder that is solidified in slices by a laser beam. The powder is usually one of the well-known plastic compounds (usually polyamide), but also metallic and ceramic powders are more and more frequently used. The powder is stored in special containers beside the machine's working surface. From here it is applied by a special device (roller) onto the working surface for each layer, separately. PolyJet rapid prototyping technology builds models from photo polymeric resins. Each layer is jetted on the work tray by a printing head and then cured by ultraviolet light. The support material is later removed by a water jet. Real models of the skull and the implant were then used for testing dimensional accuracy and as a communication tool between the engineer and the medical doctor during the phase of operation planning (Figure 6).

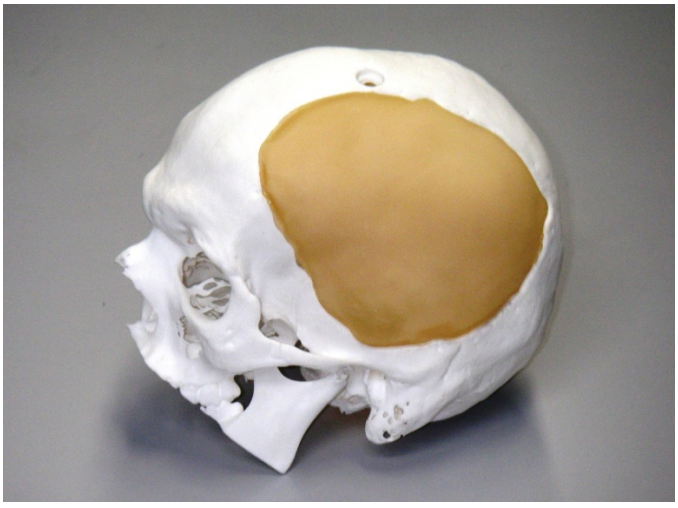

Fig.6. Model of the skull and implant.

A modified SRM procedure was used for the production of biocompatible implant. A SRM mould was made using a normal frame to hold the silicone and the pattern [9]. Pattern-holders were purposely made out of 5mm steel wires in order to make some room for excess PMMA compound (Figure 7). The usual casting of material through a round-gate was impossible because of its high viscosity.

Fig. 7. Manufacturing of SRM mould

The plan was to prepare a mixture in the lower part of the tool and then cover it with the upper part. Therefore the mould had to be modified in order to use it as a press. This required preparation of "glides" for improved leading of the tools and to prevent side movements that could lead to improper formation of the implant. At first, experiments showed that the initial release openings were miss-positioned and too small. The produced implant was too thick and uneven compared to the RP model. Therefore, the mould was modified with some extra release openings. Afterwards the experiment was repeated and the results were much better. Unfortunately, it is impossible to use an exact required amount of the material since the bone cement comes in preset quantities for both sterile components and require use of the whole amounts of both components to avoid lagging of residual monomers, as a consequence of insufficient mixing ratio. Residual monomers are highly poisonous and can, among other consequences, cause heart arrhythmia, as well as cardiac arrest.

The excess amount of material forms certain extra features in the parting plane of the mould that have to be manually removed after moulding (Figure 8).

Fig. 8. PMMA implant.

VI. Implantation

After preparation work and positive experimental results the whole setup e. g. the mold and the frame, as well as all required tools, were taken into an autoclave for sterilization. The implant was then produced by the surgeon in the sterile environment of the operation hall during the surgical procedure (Figure 9).

The surgical operation was performed traditionally with no alteration to standard procedure. The implant was inserted into the skull of the patient and fixed by titanium plates and screws (Figure 10). After the operation the patient recovered by a programme, staying neurologically unaltered. CT inspection showed good position of the bone cover, while some liquid, probably liquor had gathered under the cover. Later, this did not cause defection of the brain mass and additional surgical intervention was not needed. The patient was transferred to home nursing in settled and improved state. The whole duration of the operation was shortened for approximately 50%, due to the preparation work (planning, fit and function testing) done before the operation. This case study also showed some imperfections in the described procedure that could be avoided in the future. Besides the already-mentioned release openings that were too small in size and number, the mould production could also be improved. In the case study the mould was sterilized using autoclave in order to ensure sterile implant in the operation hall. Instead of sterilizing the tool by autoclave, the implant could be sterilized by means of gas sterilization.

In that case the implant could be manufactured in a non-sterile environment before the operation, which would shorten the procedure by approximately 30 minutes, being the time needed for the polymer to set, and for the surgeon to manually finish the implant.

Fig. 9. Implant manufacturing inside a sterile operation room

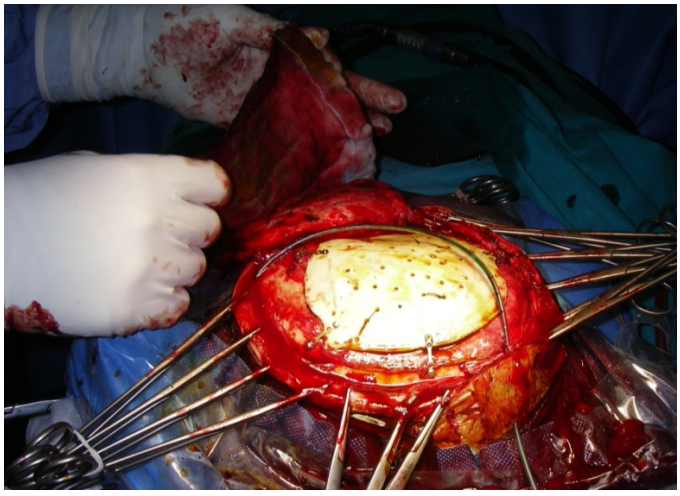

Fig. 10. Implantation of the cranial implant.

VII. Hemifacial Microsomia

Twenty four year old mentally healthy man was born with hemifacial microsomia. This is a severe asymmetry of facial bone and soft tissues in vertical, sagital and transverse plane combined with hearing impairment on the affected side. He wasn't treated before his adulthood; all surgical procedures were done in Clinical department of maxillofacial and oral surgery, University clinical centre Ljubljana. He was treated by classical ortognathic surgical procedures and by a modern surgical technology as distraction osteogenesis of mandible. After these bone surgical procedures the remaining defect of bone and soft tissues was partially compensated with on-lay xenogenic graft, later replaced with custom made titanium angular implant. His images before and after surgical procedures are presented in fig.1.

VIII. Method

The treatment of an adult patient with hemifacial microsomia has the goal to achieve bone symmetry as good as possible, more difficult is to compensate the soft tissue deficiency[7] (Figure 11). In presented patient the first surgery procedure was producing vertical part of his left lower jaw by distraction osteogenesis. Than his upper jaw was elongated and rotated by LeFort I osteotomy and his autogenous bone grafting (Figure 12). Because of the transverse discrepancy the on-lay xenogenic graft (Medpore mandible on-lay graft) was performed, but it was removed after more than one year because of the inflammation. Than we decided for custom made titanium angular implant (Figure 13), which was prepared on the basis of computer tomography (CT) scans, Computer Aided Design (CAD) and Rapid Manufacturing technologies [13]. (Laboratory for Intelligent Manufacturing Systems, of the University of Maribor, Faculty of Mechanical Engineering).

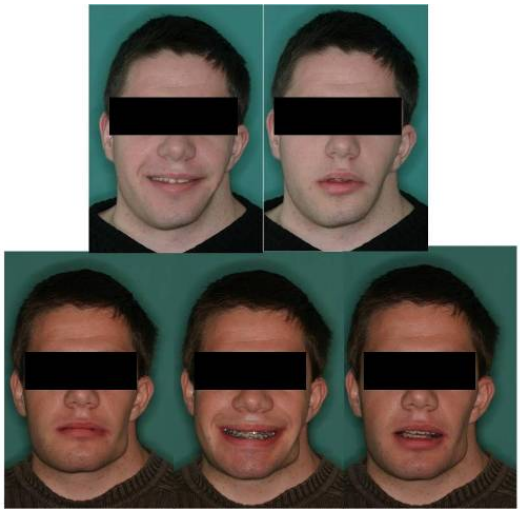

Fig. 11. Patient with hemifacial microsomia before and after surgical treatment (bone surgery only).

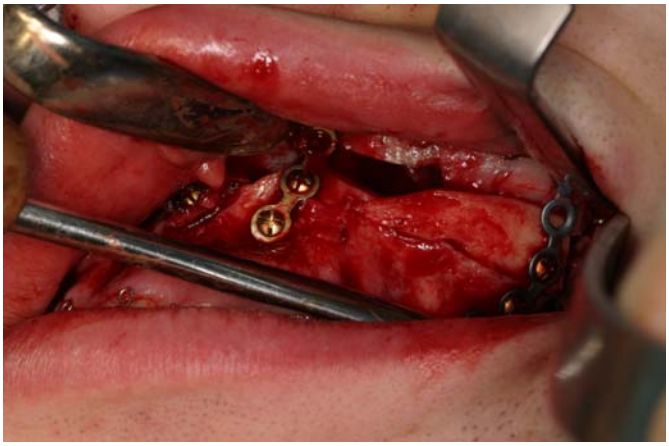

Fig. 12. Elongating of the upper jaw with autogenous bone graft.

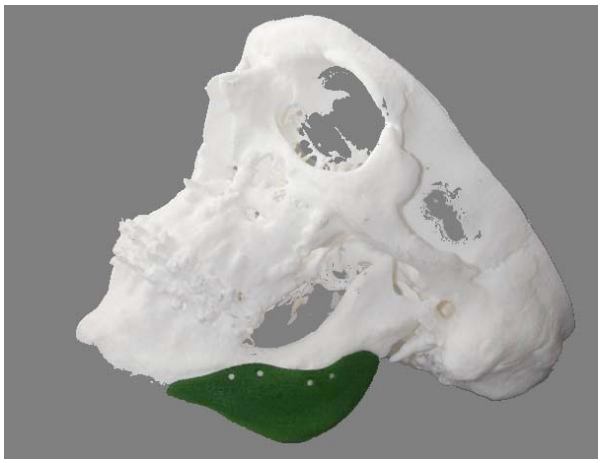

Fig. 13. Model of custom made angular implant on printed model of patient's head skeleton.

IX. Design of the Mandibular Implant

Because of the inflammation that developed on Medpore mandible on-lay graft, a solution was required to manufacture a similar implant out of a material that wouldn't allow for bacteria to develop and still successfully provide for a symmetric reconstruction of the person's appearance, while keeping the implant light enough to be functional [12].

The most promising material was titanium, since it is anti-bacterial and strong, while a lot lighter than steel, yet heavier than bone tissue and very expensive. The problems that had to be solved were keeping a low weight and finding a method to manufacture the implant. The indirect way similar to the production of the cranial implant could be performed by using an investment casting procedure and polistyrole core (prime-model of the implant). The problem is that only a few laboratories can be found that can successfully cast Ti alloys besides, a much better solution exists already. Therefore a decision was made to design an implant in approximately the same way as the cranial one, but producing it directly by means of Selective Laser Melting.

Following the DICOM to STL data conversion, CAD modelling of the implant was performed using several 3D modelling and STL manipulation software packages [14]. The idea was to split the skull in two parts in the middle, mirror the right, healthy, side over the left one and obtain the 3D model of the required implant through Boolean subtraction operations (Figure 14). However, due to the facial bone asymmetry the subtracted model could only be used as a reference for further modelling using 3D software. After the final inspection of the 3D model (Figure 15), real models of the skull and implant were produced out of polyamide using the SLS and PolyJet processes. The models were used for testing dimensional accuracy and to be analysed by the surgeon (Figure 16.) [15].The CAD model of the implant was later changed as required by the surgeon who considered the muscle positions and practical demands of the surgical procedure. It was then sent to the SLM machine to be produced out of Ti6Al4V ELI alloy. The weight of the implant will measure approx. 6 g, which is quite acceptable, but the compromise was providing it with cca 0,7 mm thin walls, since the desired 0,2 mm walls were too thin for the state of the art SLM procedure [10].

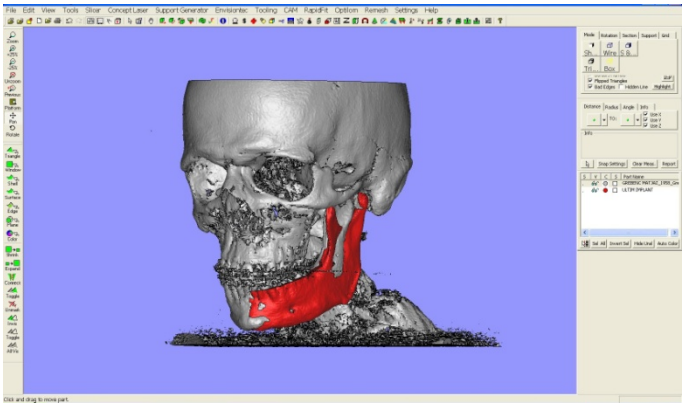

Fig. 14. Reference shape for implant design.

X. Production of the Implant

The implant was produced in the EOSINT M270 selective laser melting machine out of Ti64 ELI material, certified for medical use. EOSINT M 270 builds metal parts using Direct Metal Laser-Sintering (DMLS). The technology fuses metal powder into a solid part by melting it locally using a focussed laser beam. The parts are built up additively layer by layer. Even highly complex geometries are created directly from 3D CAD data, fully automatically, in just a few hours and without any tooling. Its production took place in Central University of Technology, Free State (South Africa) in a frame of cooperation between the scientists. Producing an implant out of PMMA is ethically clear and not problematic because the material is well known in surgical praxis.

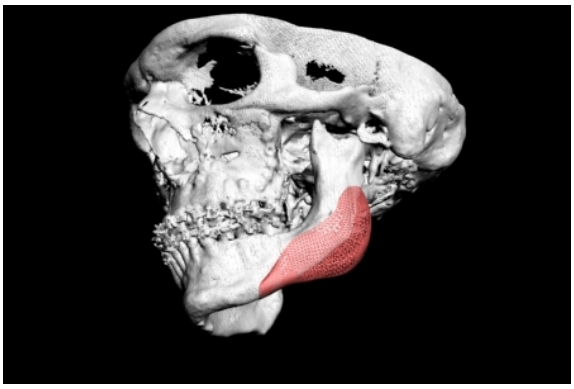

Fig. 15. Virtual model of the implant.

In the case of cranial implant only the technology of shaping the implant was new, while the producer and the material were the same as in conventional procedures. But in case of SLM made Ti64 implant several ethical as well as legal issues could be raised. Having the certified material makes the living a lot easier but still one wants to be sure about the quality issues of the implant. Therefore several probes were made in the same job with the implant [11]. 6 of them were tensile test probes and 3 of them were metallographic probes [16]. Tensile probes were taken in all three building directions of the machine (X, Y, Z) in order to test the physical homogeneity of the produced implant.

Fig. 16. Alteration requirements.

The tensile probes were tested on the tensile machine and showed very promising results. Tensile strength of all probes reached beyond 1100 MPa at elongation at break over 11%. The elongation curves showed no hardening effect and a satisfactory ductility (Figure 17).

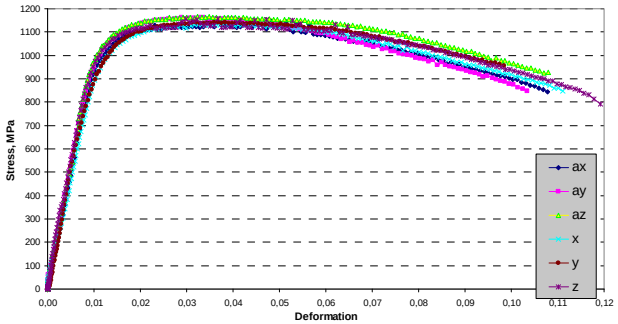

Fig. 17. Results of tensile tests.

Another problem is surface roughness which is approx. 26 microns (Ra) and still too rough for the aimed application [17]. Namely the Mandibular area where the implant has to be situated has relatively low density of blood vessels. Therefore blood can hardly reach it what makes a good environment for development of bacteria. A rough surface of the implant would even improve the environment for bacteria development, therefore the implant had to be grinded and polished to achieve the best possible surface that would prevent a development of bacteria film (Figure 18).

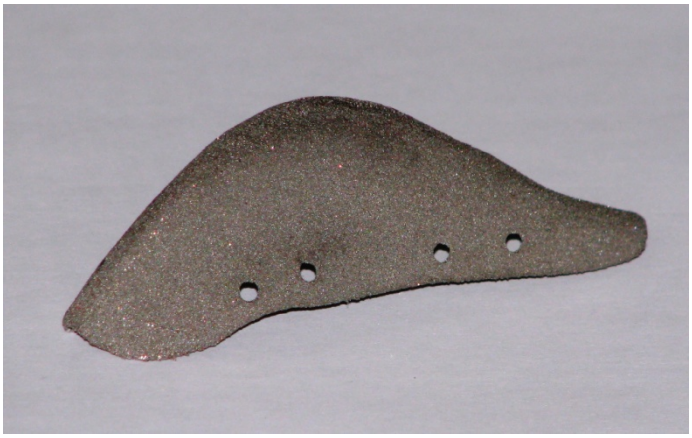

Fig. 18. Ti64 ELI implant

XI. Implant Accuracy Inspection

In this chapter a method of cranial implant inspection is presented in order to establish any manufacturing inaccuracies and possible post-processing deformations prior to implementation. Due to implants complex three-dimensional geometry an appropriate measuring method must be used. There are several factors that make three-dimensional optical scanning a favourable inspection method compared to coordinate measuring machine. The CAD data of a cranial implant is usually (due to the established modelling method) a polygon mesh in the STL file format. This fact can make an accurate importation of CAD data (that is essential for inspection) into CMM software somehow difficult. On the other hand an STL mesh can be considered as a native format for three-dimensional scanner software, making an inspection with STL CAD data much easier. Also, the accuracy demands for a cranial implant are within the limits of ±0,5 mm making higher accuracy of a CMM (compared to a high-end optical scanner) unnecessary. There is also a possibility of measuring probe damage especially in a case of continuous scanning due to an implants usual surface roughness.

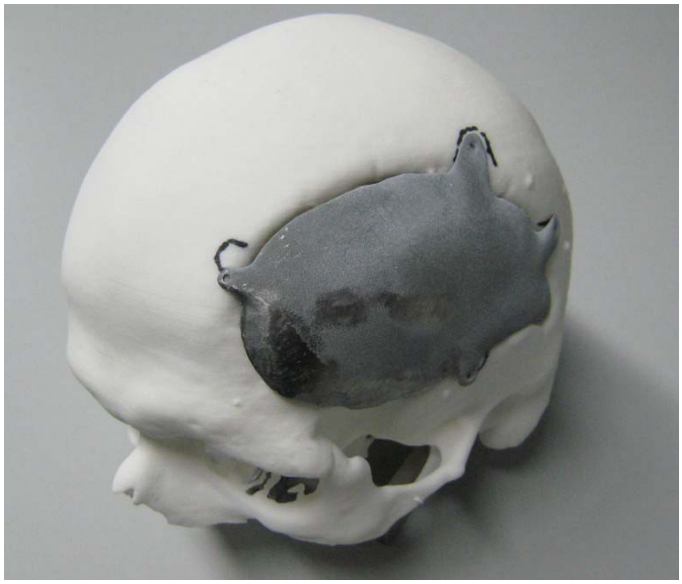

Fig. 19. Implant and skull model

This particular implant was manufactured with selective laser melting method (on EOSINT M270™ rapid manufacturing machine) from titanium alloy. For a rough inspection and engineer-surgeon communication a physical model of the patient skull was also manufactured (from polyamide) (Figure 19). However, an additional inspection prior to operation was made by means of ATOS II optical scanner (Figure 20).

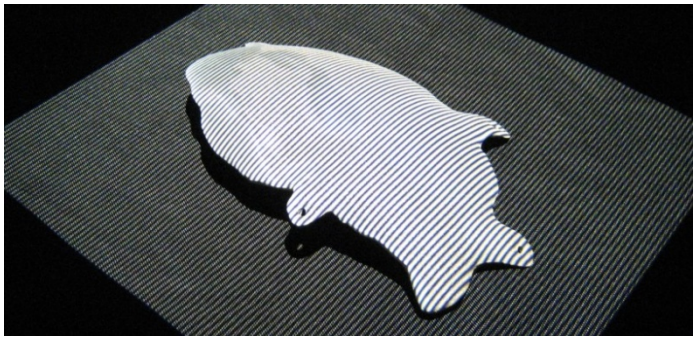

Fig. 20. Optical scanning of the implant.

Inspection was based on implants STL file used in its manufacturing. Two independent scans of each side of the implant were taken and polygonized into an independent mesh. Essential step in part inspection is a mutual registration of the scanned and CAD data (Figure 21).

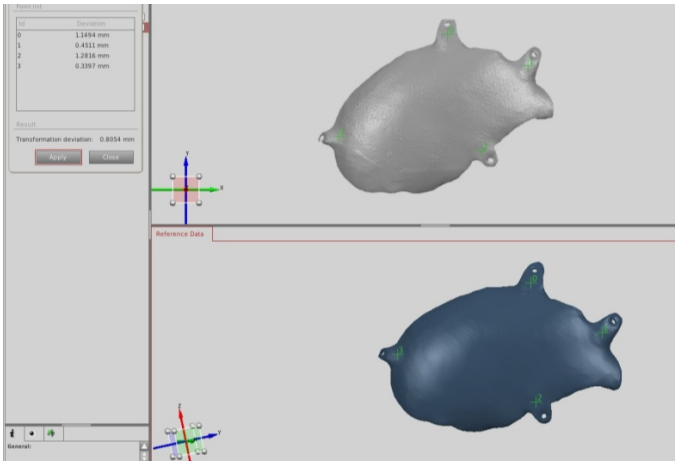

Fig. 21. Mutual registration of scanned and CAD geometrical data

In ATOS software the registration is usually performed in two steps. Firstly, the meshes are manually registered by marking four (or more) common points on each mesh [18]. Due to two independent meshes being the result both were registered separately In the next step a semi-automatic best–fit registration is performed. Deviation results (Figure 22) are useful in a final verification of the manufactured implant, which is basically an engineer and surgeon mutual go/no go decision prior to operational implantation.

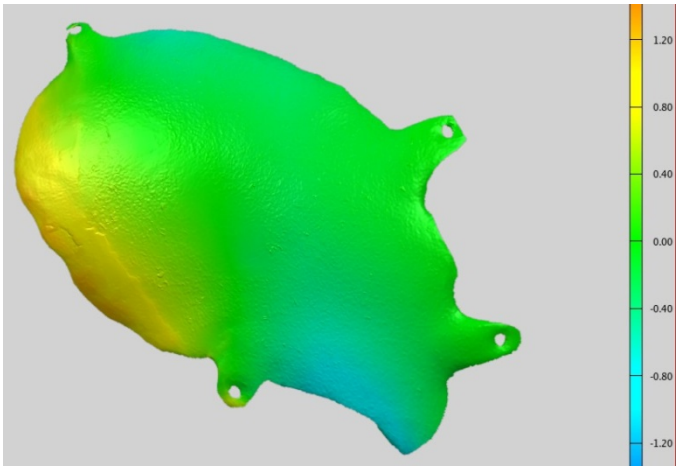

Fig. 22. Geometrical inspection results

By observing the inspection results we can note some problematic areas on the part (especially areas where a support structure had to be removed), where deviation are larger than desired ±0,5mm limits. However, due to this areas not being critically located, the implant was approved and later successfully implanted at University Clinical Centre of Maribor.

XII. Conclusion

The presented case studies show the great potential of RP and RM technologies in medical applications. These were the first cases of RP&T implant production and implantation in Slovenia. Although the procedure itself is not new it opens new possibilities for medical staff as well as for engineering and industrial applications. Cranioplastic and maxillofacial operations are not the only interventions where both, surgeon and patient can benefit from custom-made implants. Custom-made bespoke implants not only technically improve the procedure, they can also release some stress by enabling effective pre surgical planning and simulation as well as reduce costs and, most importantly, shorten the time of anaesthesia. The medical needs and contemporary technological development are the fields that will be in close relation in the future in many fields of the medicine. For facial deformities, in spite of different surgical approaches, there is still a need for development of materials for xenogenic bone grafts and the technologic facilities can nowadays prepare custom made bone implants to achieve better esthetical results.

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