Direct Digital Manufacturing as Communication and Implantation Tool in Medicine

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Abstract - **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. This method can also improve the overall performances of the medical and nursing staff thus influencing the quality of medical services available. 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 such 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 with the cooperation of Mechanical Engineering faculty members 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 - **Cranioplasty, CT Scanning, Custom Implant, Maxillofacial, Rapid Prototyping, Reconstructive Surgery, Reverse Engineering**

I. INTRODUCTION

Defects in the craniofacial skeleton are of either a result of congenital (birth defects), developmental (orthognathic deformities) or accidental (resulting from trauma, infection, tumor, etc.). The purpose of reconstructing abnormalities is primarily functional. The aesthetic rehabilitation is very demanding in the idea to approximate a normal appearance, which 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.

The treatment of the patients with deformational consequences usually requires 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 the 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 are connected with complications on the donor site [2]. In cases where autologous material can not be obtained an artificial implant has to be made to fulfill 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 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 should have the following properties: biocompatibility, inertness, bone-with a similar weight to generate no artefacts on CT and MRI scans, ease of manufacturing, enough strength to resist functional stress, inexpensive and with low or no thermal conductivity. The production of such implants begins 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 modeling 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 software have to be used to complete 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. In 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 focuses on the preparation of the surgical treatment. The CAD, virtual model of a human body or a part of it can be used to study the problematic area before the actual surgery This is especially important in cases where functionality of the body part has to be re-established (orthopedic surgery, blood vessel clogs, etc.) [5]. Besides the continuous flow and other FEA methods used to calculate required mechanical and physical properties of the implant, the virtual models can also be used to study the surgical procedures, such as implantation, required preoperational treatments and preparations.

II. PROBLEM STATEMENT - DIAGNOSIS

In last two years several trials have been made to show the potential of virtual modeling 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. In cooperation of engineers and doctors, two different types of implants were developed, clinically tested and implanted at the end. The first case was a cranial implant to relieve spontaneous intra cerebral hemorrhaging. The second case was a mandibular implant made to fulfill aesthetical function of the face. In the first case PMMA was used to manufacture the implant indirectly, using the silicone rubber molding to shape the PMMA. The second case was produced directly out of Titanium alloys, using selective laser melting equipment EOS M270 at Central University of Technology, Free State (South Africa).

A. Intra Cerebral Hemorrhaging

A thirty four year old male patient was admitted to a neurosurgical department because of spontaneous intra cerebral hemorrhaging. 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. Despite all efforts ICP could no longer be controlled by conservative measures. An angiograph was performed showing decreased blood-flow in the left hemisphere. Therefore a decision was made to perform a decompressive craniectomy. After intervention the intracranial pressure could be better controlled and patient's condition started to improve. His condition and awareness improved gradually. The Patient then was transferred to the rehabilitation institute where he received complex neuro-rehabilitation. After rehabilitation and preceding preparations, cranioplastic with PMMA in the form of bone cement, was carried out to replace the missing part of the skull [6].

B. Hemifacial Microsomia

A 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 a 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 orthognathic surgical procedures and with a modern surgical technology distraction osteogenesis of mandible. After the 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.

The treatment of an adult patient with hemifacial microsomia has the goal to achieve bone symmetry with good results. It is more difficult to compensate the soft tissue deficiency [7]. The patient's first surgery procedure was to produce the vertical part of his left lower jaw by distraction osteogenesis. Then his upper jaw was elongated and rotated by LeFort I osteotomy and his autogenous bone grafting (fig. 2).

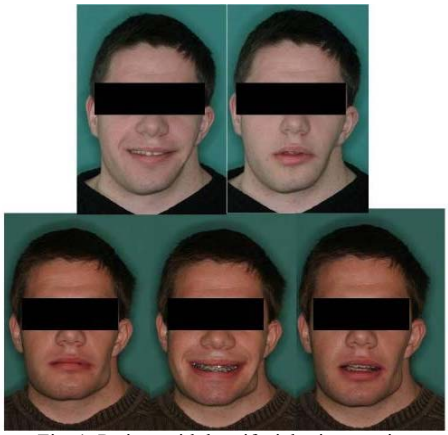

Fig. 1. Patient with hemifacial microsomia
before and after surgical treatment (bone surgery only)

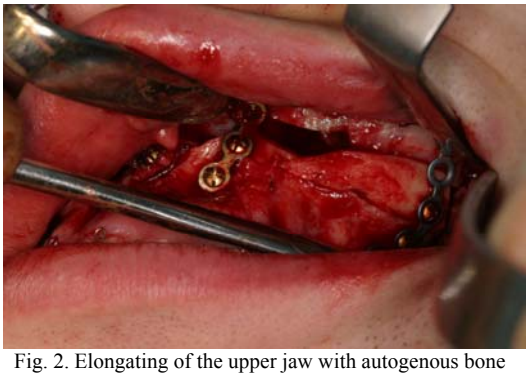

Fig. 2. Elongating of the upper jaw with autogenous bone graft.

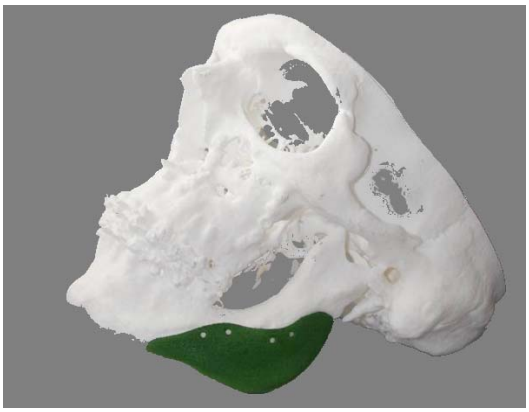

Fig. 3. Model of custom made angular implant on printed model of patient's head skeleton.

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 inflammation. The next step was a custom made titanium angular implant (fig. 3), which was prepared on the basis of computer tomography (CT) scans, Computer Aided Design (CAD) and Rapid Manufacturing technologies. (Laboratory for Intelligent Manufacturing Systems, of the University of Maribor, Faculty of Mechanical Engineering).

III. 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. A set of CT images can be converted into a three-dimensional, digital model using available conversion software, such as: Mimics (Materialise), RapidForm (Inus Technology), 3D doctor (Able Software), Amira (Marcury Computer), or an other [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 4). But it can also be manipulated by special software such Magics (Materialise), RapidForm, PolyWorks (InnovMetric)., Using these software and STL models of scanned body parts, missing tissue can be modelled and saved as new STL files. These information can be further processed or used for the production of real implant models by means of RP technologies.

Reconstructed models of the skull in both cases were manufactured using selective laser sintering. Selective laser sintering was chosen to produce skull models, since this technology produces rigid and resistible polyamide parts and the material is relatively inexpensive. 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.

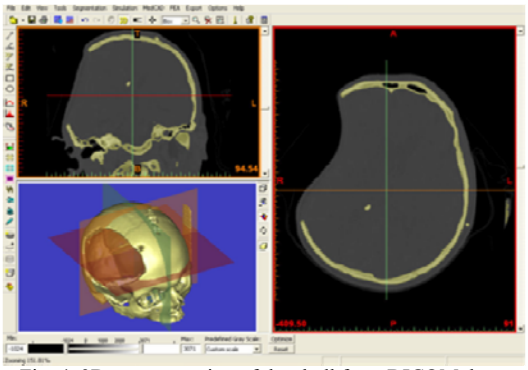

Fig. 4. 3D reconstruction of the skull from DICOM data

A. Cranial implant

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.

The initial 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, the 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…). Then, the original and mirrored skulls were additionally oriented by the best-fit registration method usually used in CAQ inspection (Figure 5).

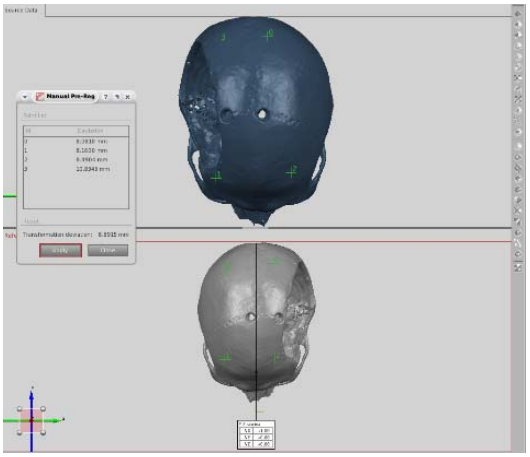

Fig.5. Best-fit registration of original and mirrored skull

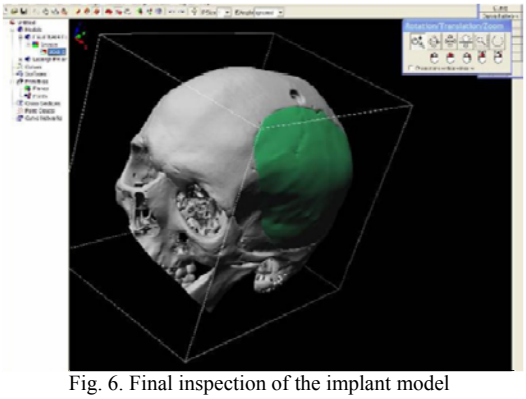

Fig. 6. Final inspection of the implant model

Because to the skull was not 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 6).

B. Implant production

In a case of smaller parts such as the implant for cranioplastic or maxillofacial surgery SLS models are too rough especially if the model is intended to be used as a prime part for silicone rubber mould production. Because of its better performance in terms of surface and dimensional quality a PolyJet procedure was used to produce the implants' models. 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 7).

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].

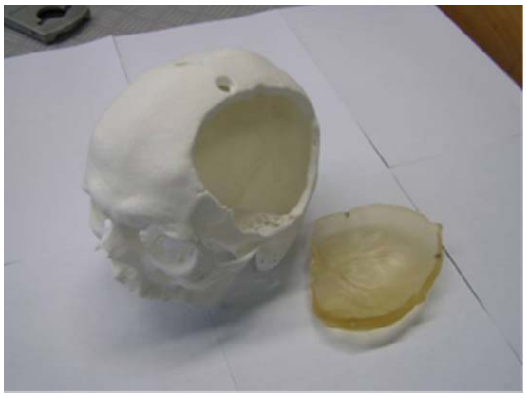

Fig. 7. Model of the skull and implant.

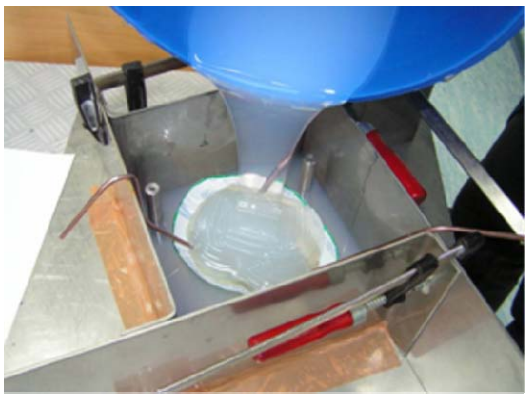

Fig. 8. Manufacturing of SRM mould.

Pattern-holders were purposely made out of 5mm steel wires in order to make some room for excess PMMA compound. The usual casting of material through a round-gate was impossible because of its high viscosity (Figure 8). 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 tool and to prevent side movements that could lead to improper formation of the implant.

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 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 9), but the whole duration of the operation was shortened for approximately 50%, due to pre-surgical preparation planning (fit and function testing).

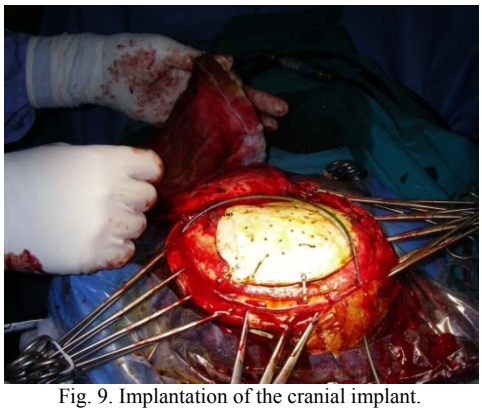

Fig. 9. Implantation of the cranial implant.

C. 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 would prevent 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. The most promising material was titanium, because of its anti-bacterial properties and toughness, while much lighter than steel, yet heavier than bone tissue. 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), laser sintered in a SLS machine. but only a few laboratories can be found that can successfully cast Ti alloys. The 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. After the good results with cranial implant the same idea, to split the skull in two parts was followed. But mirroring the right, healthy, side over the left one and obtaining the 3D model of the required implant through Boolean subtraction operations yielded only a picture of the huge facial bone asymmetry caused by the Goldenhar syndrome (Figure 10). Therefore a well-known type of angular implant was developed according to the shape of the distracted mandible and the reference shape of the mirrored healthy side (Figure 11).

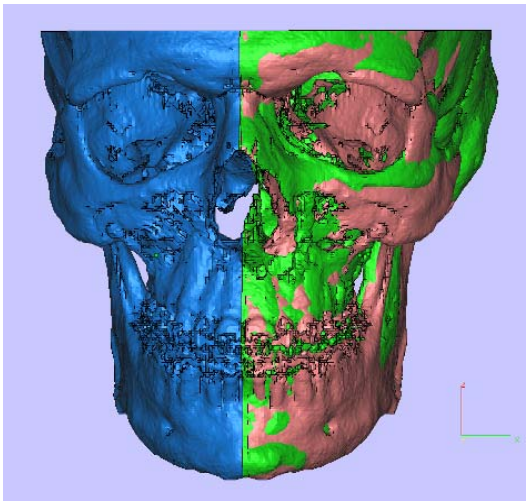

Fig. 10. Asymetry of the left face side. Red – mirrored right face side (blue), Green – original bone.

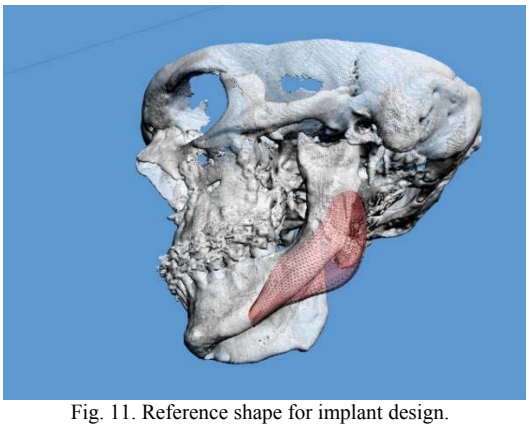

Fig. 11. Reference shape for implant design.

It was then equipped with the holes for fixing it to the mandible since it would be an awkward and lengthy procedure to drill the holes in the operation room.

Following the final inspection of the 3D model, real models of the skull and implant were produced out of polyamide using the SLS process. The models were used for testing dimensional accuracy and to be analyzed by the surgeon (Figure 12). The CAD model of the implant was later changed to the specifications of the surgeon who considered the muscle positions and practical demands of the surgical procedure. For that purpose fixing holes were replaced to avoid nerves in the mandible and resized to enable better handling. It was then

sent to the SLM machine to be produced out of Ti6Al4V ELI alloy. To keep the implant light the planed wall thickness was 0,2 mm, which would result in 6 g of its total weight. But since the desired 0,2 mm walls were too thin for the state of the art SLM procedure [10], the compromise was providing it with cca 0,7 mm thin walls.

New files were later sent to the EOSINT M270 and the implant was built.

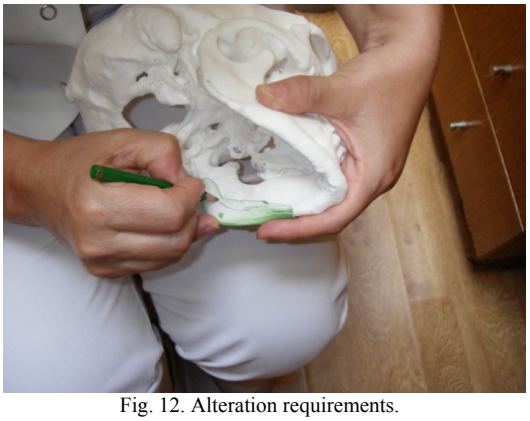

Fig. 12. Alteration requirements.

To prevent bacteria from lagging on the implant's surface, the finished implant was polished in a dental laboratory on both sides. Although it is generally desirable to have a rough surface of the implant to enable better osteointegration, in such cases the prevention of the bacterial film buildup is more important.

The implant was implanted extra orally (Figure 13), again to assure a sterile local environment, which is almost impossible to obtain at intraoral implantation. The implantation procedure finished in one hour, which is mostly due to the extensive preoperative planning and perfect fit of the custom made mandibular implant.

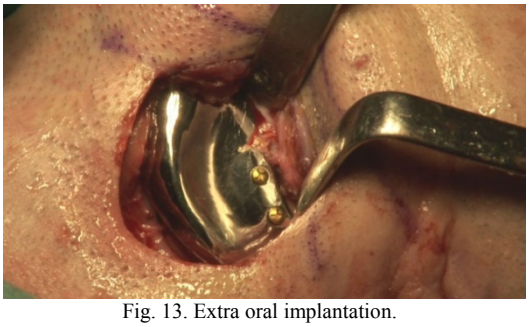

Fig. 13. Extra oral implantation.

IV 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 the surgeon and the patient can benefit from custom-made implants. Custom-made bespoke implants not only technically improve the procedure; they can also release some of the stress by enabling effective pre surgical planning and simulation as well as reduce costs and, most importantly, shorten the time of anesthesia.

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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