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Design and health care: a study of virtual design and direct metal laser sintering of titanium alloy for the production of customized facial implants

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CASE STUDY

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Abstract

The increase in life expectancy and a great number of accidents lead to higher demand for medical products, including corrective implants. Patients with tumors or traumas need to replace injured areas in order to restore their aesthetic and structural function. Currently, the available craniofacial implants present a standard geometry and seldom generate satisfactory results. Customized implants, on the other hand, are designed to conform exactly to individual patient's anatomy. This way, the use of customized implants can show beneficial effects to the patient and the surgical team. In this study, the design and manufacturing of customized implant prior to surgery were described. Implant shape and functional requirements were established by digital data based on CT-scans and mirroring operations. The design process of customized mandible prosthesis is illustrated as well as its manufacturing process (direct metal laser sintering) and quality control. Laser sintering process and its constraints for the production of customized implants in titanium alloy (Ti-6Al-4V) with complex geometry and internal structures are reported.

Background

Cranial defect repair is necessary to provide neural protection with aesthetic results. Tumors, traumas, disease, and congenital defects require bone reconstruction. Treating craniofacial defects has become a challenge for the surgical team and frequently involves multiple surgeries, some of them very costly, although in some cases the results are not satisfactory. Thus, there is great concern with the improvement and development of new treatment methodologies.

In engineering, the rapid technological development in the last half century brought about important changes in many different areas. One of the greatest advances refers to the design and the manufacturing of industrial models. The CAD (computer-aided design) consists of building figures with the computer to assist the professional during the process of creating a product. Presently, it is considered an essential tool for the technological industry. The association of CAD with CAM (computer-aided manufacturing) provided a revolution in procedures involving the conception and design of mechanical parts, architectural projects, among others. Through new rapid prototyping technologies (RP), it is possible to build real prototypes from a model created by the CAD system, quickly, automatized and totally flexible. Thus, the designer can have in his hands, in a short period of time, a physical model to be used in practical situations.

In the late 80s, the rapid prototyping techniques were combined with the biomedical images to obtain solid biomodels which could reproduce the anatomic structures, this way causing a revolution in the surgical procedures. The need for precisely fit prosthesis has impelled the development of several manufacturing methods of implants for computer-assisted cranioplasty. The design and manufacturing of anatomical prosthesis require a complete combination of all elements involved and require several phases.

Currently, rapid prototyping allows the manufacturing of customized implants and prosthesis prior to surgical procedures. Starting with the Computerized Tomography (CT) or Magnetic Resonance Imaging (MRI), the implants can be designed especially for a specific patient and with optimized forms and properties. For this, only digital information is used, disregarding all kinds of physical models and obtaining the final implant directly. Such advance was possible due to the rapid development of hardware and software for the acquisition and manipulation of images, improvement of new materials, and refinement of manufacturing processes. This allowed biocompatible materials to be used and processed as implants. When the implant geometry is well defined and presented in suitable format, an implant model can be manufactured and then reproduced with the use of desired material through a molding process. Yet, the final implant manufacture can also be prepared by rapid prototyping process directly with the selected material.

Engineering Assisted Surgery, EAS™ is a new research field currently being accepted worldwide by health institutions and is defined as the use of engineering and manufacturing technologies in health care services. The EAS™ process consists of the conversion of computerized tomography and potentially magnetic resonance, rapid prototyping, CAD 3D, robotic technology, rapid manufacturing, reverse engineering and finite element analysis (FEA) to improve surgical procedures. For medical applications, the use of EAS™ provided the improvement in services offered to patients through the evolution of areas such as 3D of anatomical parts, surgery planning, implant design, and prosthesis manufacturing [1, 2].

Popovic et al. [3] reported the development of a technique which involved a complete surgical process from planning, customized implants, robotic program option to intra-operative navigation and robot assisted performance. The study was especially related to 3D manipulation of the skull geometric data for planning and definition of the craniotomy. In addition to the aesthetic aspects, there was an attempt to reduce the patient's risks, the operation time, recovery as well as the treatment costs. The process started with computer-assisted planning, identifying the tumor, and planning the access and removal using CT and MRI data together with volumetric digital models. Following, the planning results were transferred to the CAD/CAM for the manufacturing of customized implants as well as intra-operative computer systems for navigation and robotic performance.

The manufacturing of custom-made prosthesis is drawing great interest in the field of Biomedical Engineering. Among the main arguments presented by the ones who follow it, some others can be mentioned such as the reduction of surgery time, better aesthetic results, and less risk of infection. However, the manufacturing of prosthesis according to the patient's need is more costly and requires knowledge of a still incipient technology, when compared to the traditional methods of molding in-situ and customized prosthesis. The manufacturing technology for custom-made prosthesis is still elementary demanding an interdisciplinary character, as it requires a synergic action from all the areas involved with the appropriate competence in the treatment of patients and their needs. Besides medicine, it involves image processing, the use of CAD systems for tri-dimensional reconstruction, simulations in Computer-aided Engineering (CAE) softwares, CAM systems, rapid prototyping, CNC machining and technology of biomaterial processing. Many related publications discuss the use of biomodels generated by the use of rapid prototyping for diagnostics, operation planning [4] and implant preparation [5, 6], even in a virtual environment [7, 8, 9, 10]. Several authors pointed out some advantages of using implants designed to attend the needs of each individual: improved operative planning and diagnosis, measurement accuracy, implant conforming the patient's anatomy, reduced surgery time, and more satisfactory aesthetic results [11, 12, 13]. In some studies, digital design and RP techniques were used for direct manufacturing of an implant model [14], but they do not make references to any suitable material for implantation. Lohfeld et al [15] demonstrated the generation of customized prosthesis using a standard digital design route and a manufacturing process. However, the literature review confirms that there have been no major publications involving design and manufacturing of customized prostheses with suitable materials used for implantation.

Based on that, the general objective of the present study was to show some methodologies which are currently being used to obtain customized implants for facial and cranial reconstruction. Engineering, design, and computer graphics tools were used to provide solutions for such cases related to the medical field. Techniques such as rapid prototyping, CAD/CAE/CAM system, material selection, 3D visualization software of medical images for the design and manufacture of customized exact-fit implants to conform to the patient's anatomy.

Materials and Methods

The case study involved a patient who developed an ameloblastoma in the left mandible. It is a benign odontogenic tumor which accounts for approximately 1% of all oral tumors [16, 17]. The tumor derives from several layers of the odontogenic epithelium together with the follicular epithelium of the teeth. Normally, it appears between the third and the fifth decades of life, but there are also reports including other age groups. The ameloblastoma is highly recurrent after inadequate treatment [18]. It is presently advisable to remove the total area affected by the tumor, which could reduce significantly the recurrence index. A 3D visualization of the patient's bone structure is illustrated in Figure 1. The dimensions of the virtual model correspond to the real dimensions of a human skull.

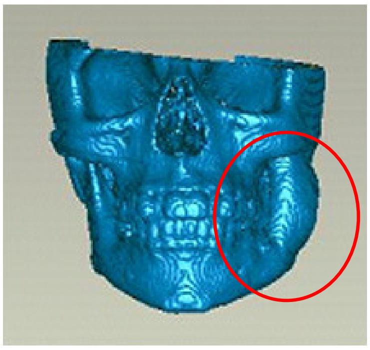

Figure 1: Virtual 3D model of the patient's bone structure. In the left side of the mandible, the incidence of ameloblastoma can be seen.

InVesalius Software was used to produce a virtual prototype of the patient's skull from his CT. However, these 3D images derived from CT data are files which require great space in the disk and great storage processing. All the skull parts considered useless for the study were excluded; only the part referring to the mandible remained. This way, the undesirable regions of the file can be removed to facilitate its processing (Figure 2). Also, part of the noise should be eliminated as well as small fragments, which are apart from the main structure.

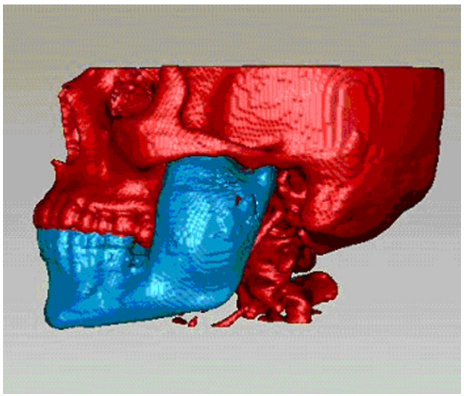

Figure 2: 3D model of the bone structure (in red) showing the region to be removed to facilitate image processing.

This model must be exported in STL file format, which consists of a mesh composed by triangles. The higher the number of triangles, the more precise and smooth is the mesh. However, some triangles can be superposed which could cause some problems in a subsequent manipulation of such files in CAD environment. For a more accurate processing of these images in CAD, these files must be in IGES format (Initial Graphics Exchange Specification). STL file format is adequate for the direct file prototyping, but the CAD software does not operate in STL files, it only provides their display. To perform operations such as Boolean, extrusion, and rotation, the file must be in IGES format.

Some experiments were carried out to analyze the viability and parameters of the process for prosthesis manufacture in Ti-6Al-4V through laser sintering process. Such experiments occurred in the Fraunhofer Institute (IFAM) in Germany. During the sintering process, metal powder was fused into a solid part by melting it locally and by using a laser beam directed by a computer, which scanned the powder surface horizontally (x-y-plane). The process operated on the layer-by-layer principle (Figure 3). After the last part of one layer was fused, the building platform was lowered vertically (z-direction) by one layer thickness and the next layer was prepared by a powder feeder and recoater. After recoating, the local fusing started again on the newly applied layer. The process was repeated until the part was completed. Afterwards, the building platform was removed from the machine and the part with its most necessary support structure was removed from it. Mandible prosthesis, for the patient described above, was carried out to verify the viability of producing parts with complex geometry. The materials used were: titanium, aluminum, and powdered vanadium, with medium particle size of 50µm.

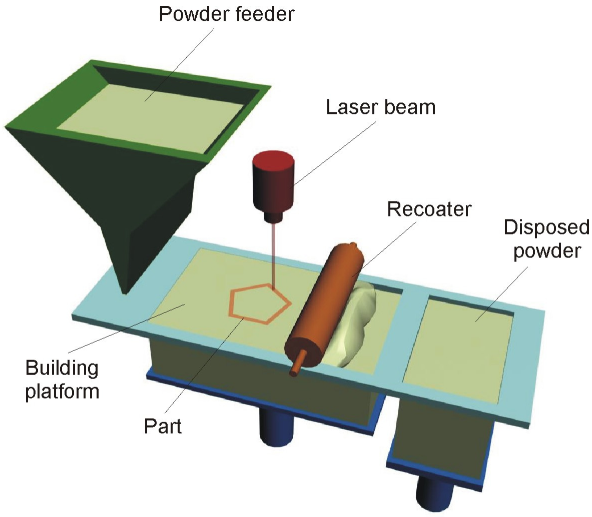

Figure 3: Principle of laser sintering process

The metallic powder tested for the laser sintering process used the master alloy concept in which pure titanium powder was mixed with powder containing 60% aluminum and 40% vanadium (in weight). The powder was mixed using a conventional tumbling mixer and placed in a mixing recipient that rotated diagonally; making the powder homogeneous. Mixing time was 1 hour in order to achieve homogeneous distribution of the alloy elements. The amount of powder used was 1.8Kg of Ti and 0.2Kg of Al-V mixture.

The platform surface was previously heated at 230ºC. It was sand-blasted and cleaned with acetone before being installed into the machine. All tests were performed using EOSINT M250X, running under argon atmosphere. The laser power was set constantly at 195W. Test specimens were laser sintered onto a pure Ti plate of size 100mm x 100mm x 10mm. The laser sintering parameters (hatch distance, laser scan speed) were varied in order to obtain optimized mechanical properties. The best combination of parameters was selected for the production of a Ti-6Al-4V prosthesis. Before starting any process, it was necessary to wait for approximately 20 minutes to achieve an oxygen level of 0.2%. In the meanwhile, the titanium platform was heating up to the set temperature.

Dimensional control is also an important phase of the method described here. As the prosthesis is produced before surgery, adjustment precision and mechanical stability are required. For the dimensional analysis, the Tecnodrill 3D laser scanner, model Digimill 3D was used.

Results and Discussion

Design process

After resection, the file was manipulated in the software Rhinoceros, CAD software largely used in the product design area. It provides the designer great freedom to handle complex geometric forms. Other softwares generally used in design could also be applied, for example, Solidworks and 3D Studio Max. CAD Software allows the use of images and changes in their dimensions, addition of materials, and removal of parts, creation freedom, and operations (Boolean, addition, union, extrusions and rotations). In case of regions with a symmetric side which need to be reconstructed, a mirroring operation can be performed. Thus, it is possible to obtain the missing symmetric part through some adjustments by using the original image. If necessary, some alterations may be made in the part obtained as the human structure is not exactly symmetric. Also, the original structure can be used to project the part that needs to be rebuilt. In this case, a simple mirroring operation (Figure 4) was enough to design in the left side a mirrored image of the right side, the portion which was not affected by the tumor. By doing so, it is possible to get to the adequate format of the patient's mandible (Figure 5). In Figure 6, a virtual 3D model of the prosthesis position is shown.

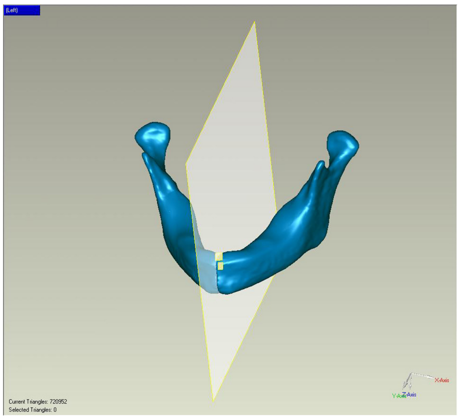

Figure 4: Mirroring operation used to copy the healthy side of the patient's mandible.

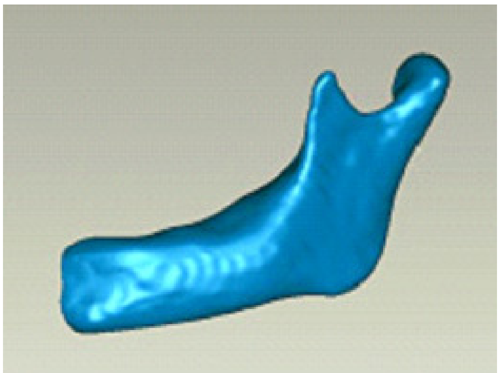

Figure 5: Prosthesis model obtained through a mirroring operation in relation to the right side of the mandible

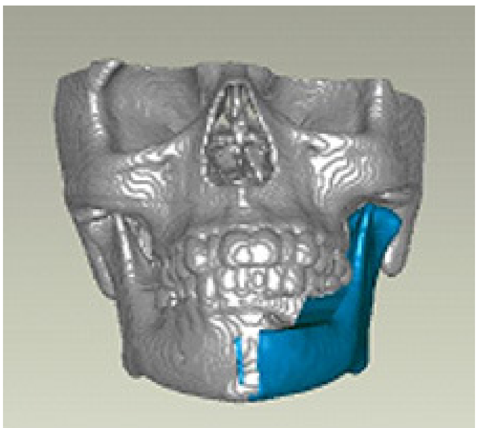

Figure 6: Prosthesis positioning (in blue) in the virtual model.

In order to study the laser sintering parameters, test specimens were produced varying hatch distance (0.05, 0.075 and 0,1mm) and scan speed (50 and 100mm/s). The obtained final densities (obtained using Archimedes principle) varied from 92.4 to 97.6%. The hardness values varied from 378 to 515 HV.

As it presented higher density and hardness values (97,6% final density and 515 HV), the combination of the parameters 0,05 mm (hatch distance) and 50 mm/s (scan speed) was chosen to the production of the Ti-6Al-4V prosthesis.

In order to evaluate the production of low weight parts, different internal structures were analyzed. Following, feasible structures were selected and inserted into the mandible model. This way, the model became lighter (as it was not completely filled up), presenting an internal modular structure. The viable possibilities of the internal structure were selected and the implant model was built; this time, it was not completely filled, but with an internal configuration with controlled porosity, as shown in Figure 7.

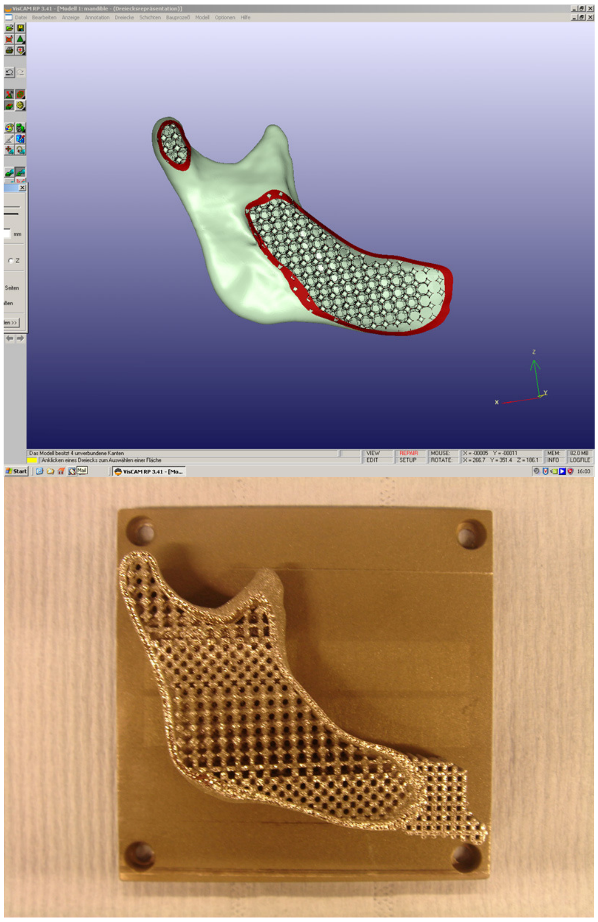

Figure 7: Implant internal view; a) virtual model; b) physical model.

As described by Lohfeld et al. [15], a hollow prosthesis not only benefits from being light weight, but can be produced more rapidly. The production time of this process strongly depends on the area to be scanned with the laser in each layer. The disadvantage of manufacturing an internal structure is that the way to remove the powder out of the part must be previously designed. In order to validate the dimensional precision of the implant obtained through laser sintering process (Figure 8), the model surface was scanned in a 3D scanning system. Through this analysis, it was possible to compare the model dimensions produced with the CAD model, as shown in Figure 9. Differences in dimension are given in millimeters.

Figure 8: Physical model produced by laser sintering based on CT data.

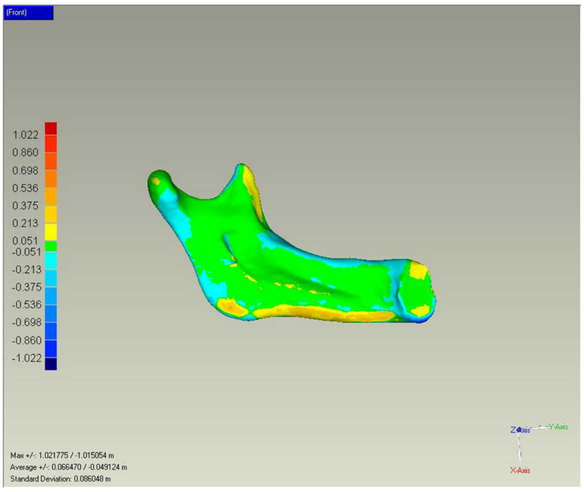

Figure 9: 3D comparison between the physical model produced and the CAD model.

Most part of the scanned area had a difference of no more than 0.05 mm (green area) when compared with the original CAD model. Some specific regions found in the borders presented higher values, which could be explained by the imperfection in the superficial finishing due to the manual removal of the support structures.

The manufacturing process of customized implants for the craniofacial reconstruction presents great applicability potential through the process of direct metal laser sintering. The specific bone structure of the patient can be reproduced with great dimensional precision. Further studies should, however, verify the adequacy of the mechanical properties of the prosthesis produced in relation to the international norms for craniofacial implants.

Conclusions

This study analyzed how the CAD/CAE/CAM systems, especially rapid prototyping, and traditionally used techniques for industrial application may contribute for the improvement of orthopedic implants. A case involving a patient who needed facial bone reconstruction caused by tumors was studied. The mandible prosthesis design and manufacturing were performed following a virtual method for the production of state of the art customized implants in the area. Such method disregarded the use of physical models of the patient's skull, allowing the prosthesis to be designed in virtual environment and produced with adequate material to be implanted. The technique used for implant manufacture was the selective laser sintering and alloy Ti-6Al-4V. The results obtained were positive for the manufacture of customized craniofacial implants in addition to having intrinsic advantages with the technique, like the possibility of manufacturing models of great geometric complexity and reducing weight, since it allowed the construction of hollow parts in it.

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CONFLICTS OF INTEREST
The authors declare that they have no competing interests