

Manufacture of custom-made cranial implants from DICOM® images using 3D printing, CAD/CAM technology and incremental sheet forming

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Abstract Introduction: This work aims to pre-operatively manufacture custom-made low-cost implants and physical models ('biomodels') of fractured skulls. The pre-operative manufacturing of biomodels and implants allows physicians to study and plan surgery with a greater possibility of achieving the expected result. Customization contributes to both the esthetic and functional outcome of the implant because it considers the anatomy of each patient, while the low cost allows a greater number of people to potentially benefit. **Methods:** From CT images of a fractured skull, a CAD model of the skull (biomodel) and a restorative implant were constructed digitally. The biomodel was then physically constructed with 3D Printing, and Incremental Sheet Forming (ISF) was used to manufacture the implant from a sheet of pure grade 2 titanium. Before cutting the implant's final shape from a pre-formed sheet, heat treatment was performed to avoid deformations caused by residual stresses generated during the ISF process. **Results:** A comparison of the dimensions of the implant and its respective CAD biomodel revealed geometric discrepancies that can affect both functional and aesthetic efficiency. Nevertheless, the final shape preserved symmetry between the right and left sides of the skull. Electron microscopy analysis did not indicate the presence of elements other than pure titanium. **Conclusions:** Dimensional variability can be decreased with changes in the manufacturing process (i.e., forming and cutting) and the heating ramp. Despite biomedical characteristics, there was no contamination of the implant by harmful chemical elements. 3D Printing was effective in making the biomodel, enabling pre-operative planning and improving physician-patient communication. Current results indicate that ISF is a process that can be used to obtain custom-made implants.

Keywords Implant, Biomodel, Incremental sheet forming, Titanium, 3D printing, Custom-made.

Introduction

In medicine, customization is the new paradigm for this century, seeking to adapt to the specific requirements of each patient (Chulvi et al., 2007). The manufacture of custom medical devices (i.e., prostheses and implants) is an important medical field. According to Sicoli and Mrad (2010), the design and manufacture of orthotics, prosthetics and special materials (OPSM) used in medical procedures (e.g., reconstructive surgery) represent up to 80% of a hospital bill. Most (91.2%) of the implants are located in neurocranial and temporal regions (Eufinger et al., 2006). Skull injuries can occur due to tumors, traumas caused by decompression surgery, infections, and fractures typically arising from automobile accidents or physical assault. When the affected area exceeds 60 cm², it becomes necessary to use implants, as the bone layer loses the ability to regenerate and reintegrate. Figure 1 shows a recent case of injury to a skull: in 2010, Joseph (fictitious name) from Los Angeles lost almost half of his skull in a bar fight. The photo (from May 2013) shows an example of a severe loss of bone tissue and brain mass. In cases

like this, autologous bone regeneration does not occur, requiring an alloplastic implant to provide the necessary protection to the remaining brain mass and to restore the esthetics of the individual.

Graphic workstations, CAD/CAM systems, rapid prototyping and automated manufacturing processes for medical applications have been developed and refined since the latter half of the 1990s (Wehmoller et al., 1995), although manual processes currently remain (Goyal and Goyal, 2012). Hou et al. (2012), Lieger et al. (2010), Singare et al. (2004), Wei and Pallavi (2002) describe methodologies, flowcharts and procedures for the reconstruction of bone tissue using technological resources. These studies present the fabrication of implants using biocompatible polymers manufactured by different rapid prototyping processes (stereolithography, 3D Printing, selective laser sintering) as raw materials. However, pure grade 2 titanium exhibits the best long-term results, maintaining important features related to biocompatibility. Furthermore, according to Wang (1996), the mechanical properties of pure

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Figure 1. Severe cranial injury (NYDailyNews.com/us, December 10, 2013).

grade 2 titanium are superior to those of polymers; the elastic modulus is 4 to 5 times higher than that of human bone and exhibits high corrosion resistance. The use of computer-aided design and advanced manufacturing platforms provide a better fit for the implant and better esthetic results (Mazzoli et al., 2009). Moreover, the use of these methodologies and technologies confer the following advantages (Saldarriaga et al., 2011):

- Decrease surgical time by 85%;
- Restore the original appearance of the patient;
- Reduce the possibility of errors during surgery;
- Avoid modifications of the implant or the skull region around the injury during surgery;
- Biomodels act as an effective communication tool between neurosurgeons, patients and families when the surgical procedure is discussed.

Of the biocompatible materials used in reconstructive surgeries, according to TIG (Titanium..., 2013), titanium is widely used in bone tissue, joint and dental implants, cranio-maxillofacial reconstructions, cardiovascular devices (stents), temporary external prostheses and surgical instrumentation. More than 1,000 tons of titanium is implanted in patients worldwide yearly. Mechanical requirements for joint replacement increase with greater longevity. Bone can be worn down due to intense physical activity or lost due to traffic accidents or physical assault. Lightweight, strong and very biocompatible, titanium is one of the few materials that naturally match the requirements for implantation in the human body.

Methods

The development of implants is divided into seven steps:

- Biomodel computational modeling from DICOM images;

- Biomodel manufacturing by 3D Printing;
- Implant modeling by CAD 3D software;
- Implant manufacturing from a 0.5-mm titanium sheet by Incremental Sheet Forming;
- Heat treatment of titanium sheet;
- Dimensional analysis between the reference (CAD model) and titanium implant;
- Physical assembly of the implant and biomodel.

Step 1 – Biomodel computational modeling from DICOM images

The Digital Imaging and Communications in Medicine (DICOM) electronic format is a set of standards for imaging, storage and transmission of medical data, generating a common language between different equipment, devices and computers. These images are obtained from longitudinal sections of a damaged skull using Computed Tomography (CT) scans. The conversion of DICOM to a 3D CAD vector file (STL extension) is performed using InVesalius — free software developed by the Center for Information Technology Renato Archer (Campinas, São Paulo, Brazil) — that aids in diagnosis and surgical planning. From CT images, the program creates virtual models in 3D. A total of 724 DICOM images were processed with a slice thickness of 0.3 mm to generate a digital solid object, visualized in Figure 2b (in green).

Step 2 – Biomodel manufacturing by 3D Printing

Medical applications of 3D Printing have included the fabrication of replicas of broken bones and both broken bones and restorative alloplastic implants. Furthermore, 3D Printing is capable of creating models using several materials. Some examples include a) a model of a defective skull (Cui et al., 2014), b) a model of a defective skull with an implant, made with molding of poly-methyl-methacrylate (Goh et al., 2010; Rotaru et al., 2012); c) a model of a defective skull with an implant made with polyethylene terephthalate or laser melting thin layers of titanium powder (Klein et al., 2013) and d) a model of a defective skull with an implant made with acrylic (Werndle, 2012). Our work used 3D Printing technology to generate a physical model of a defective skull (see Figure 8) from thermoplastic aliphatic polyester (PLA), a renewable material derived from tapioca starch extracted from manioc (*manihot esculenta*), a very common root in Brazil. However, despite its natural origin, there are no studies to ensure that PLA is a biocompatible material.

Step 3 – Implant modeling by CAD 3D software

The peripheral contours (i.e., the contour lines of the implant) were designed based on the perimeter of the fracture. In addition to the contour, other CAD guidelines were designed to serve as the skeleton of the

implant surface based on the axial symmetry between the left and right sides of the skull. Figure 2a shows the digital model of the implant generated with an educationally licensed version of Solidworks software (Solidworks, CAD software developed by Dassault Systèmes S.A., Paris, France). Figure 2b shows the digital biomodel of a defective skull generated from CT images assembled with the implant model.

Step 4 – Implant manufacturing by Incremental Sheet Forming (ISF)

An alternative manufacturing processes was sought to avoid expensive manufacturing processes, such as milling, forging, conventional forming or multi-point forming (Chen et al., 2006; Tan et al., 2007). In addition, the manufacturing process had to be capable of producing custom models with simple tools. Incremental Sheet Forming (ISF) meets these requirements because it utilizes generic and low-cost tools and can be performed with machinery not specifically designed for ISF, such as those at CNC machining centers. This enables manufacturing of sheet metal parts for various geometries using the same tool;

CAD/CAM systems designed for machining can be used to design the geometry and tool paths. Tools with a generic profile (i.e. cylindrical or conical rod, with a semi-spherical border) without a cutting edges, are used to deform the sheet slowly in coordinated XYZ movements (see Figure 3). These movements produce a plastic deformation located in a small region of the sheet. This region changes according to the tool's movement and progressively causes deformation to occur, thus increasing the conformability of the sheet when compared with conventional forming processes (Martins et al., 2008).

Incremental sheet forming with lower support (also known as Two-Point Incremental Forming, or TPIF) uses a polymer support located under the sheet in addition to the forming tool. This support, which may be specific or semi-specific, is used to expand the geometric range and improve the accuracy of the parts (i.e. the correspondence between the CAD biomodel and the manufactured part). The use of the lower support is particularly important for organic and asymmetrical geometries. Therefore, considering

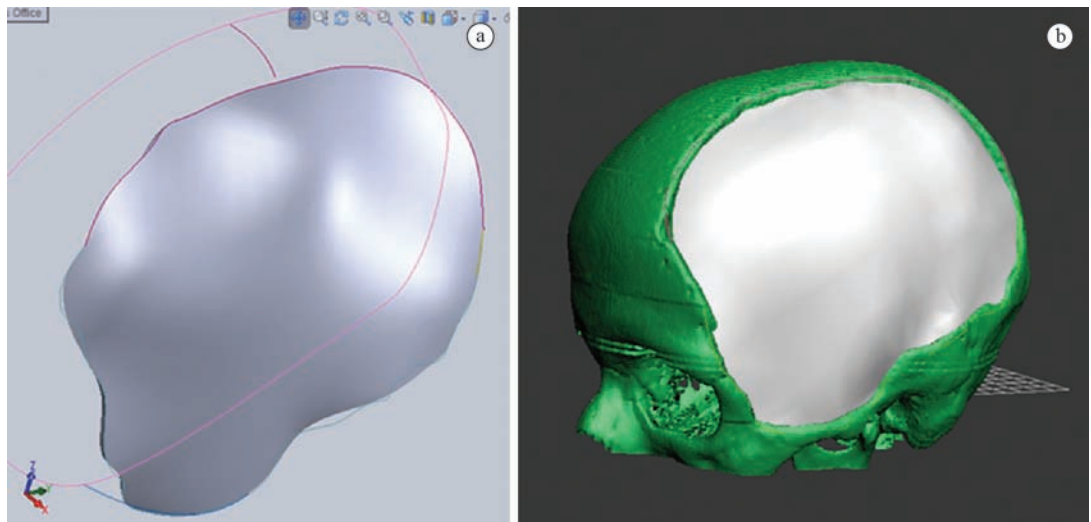


Figure 2. Finished 3D CAD biomodel: a) Generating the implant model - to generate the surface, we used advanced computational modeling techniques; b) Digital assembly of the defective skull model and modeled implant.

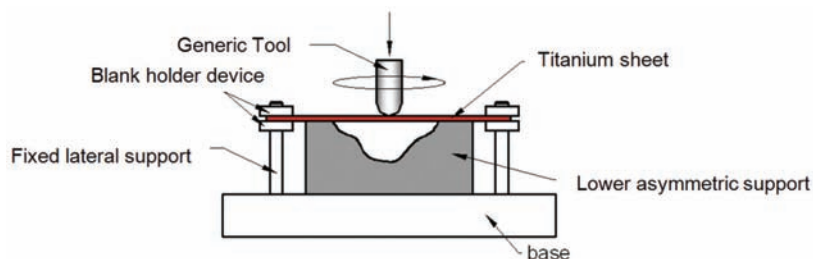


Figure 3. Incremental forming with lower support. The tool performs downward movements according to the programming in the CAD/CAM system.

that implants have precisely this type of geometry, TPIF is the ideal modality for their manufacture (Castelan, 2010).

The implant's manufacture was planned using EdgeCAM software, designed originally for the field of mechanics and specifically for metal machining. However, in this study, it was used for three specific purposes: a) machining of the lower support (see Figure 3), forming the titanium sheet (Figure 4a) and cutting the final product (Figure 4b). Before sending the implant CAD file (surface) to the CAM environment, an extra forming region must be generated because ISF starts on a flat and horizontal plane. As the implant perimeter is irregular, it is necessary to create a region that joins this perimeter to a horizontal surface.

Having defined the 3D CAD biomodel, it is possible to begin the manufacturing schedule step. On the schedule are defined features, speeds and dynamic tool strategies. There are two schedules: the first refers

to the lower support machining, which also serves to form the titanium sheet, and the second is used to cut the implant. Table 1 shows the technological data.

With simulations finalized, the programs were generated and transmitted to the CNC machine. The CNC Romi D 600 machine, originally intended for metal machining, has a robust configuration for serial production and intensive use in an industrial environment. A detail in Figure 4c shows the tool, composed of two parts: a rod (4340 steel, non-biomedical) and a tip (pure titanium grade 2). The use of a titanium insert is justified because AISI alloy 4340 contains chemical elements harmful to health (Mn, Si, Ni, and Cr). Another important issue concerning the contamination of the sheet is the lubrication. Due to the characteristics of the ISF process where the tool slides over the sheet, friction is generated. The friction causes premature wear of the tool and the displacement of material from the

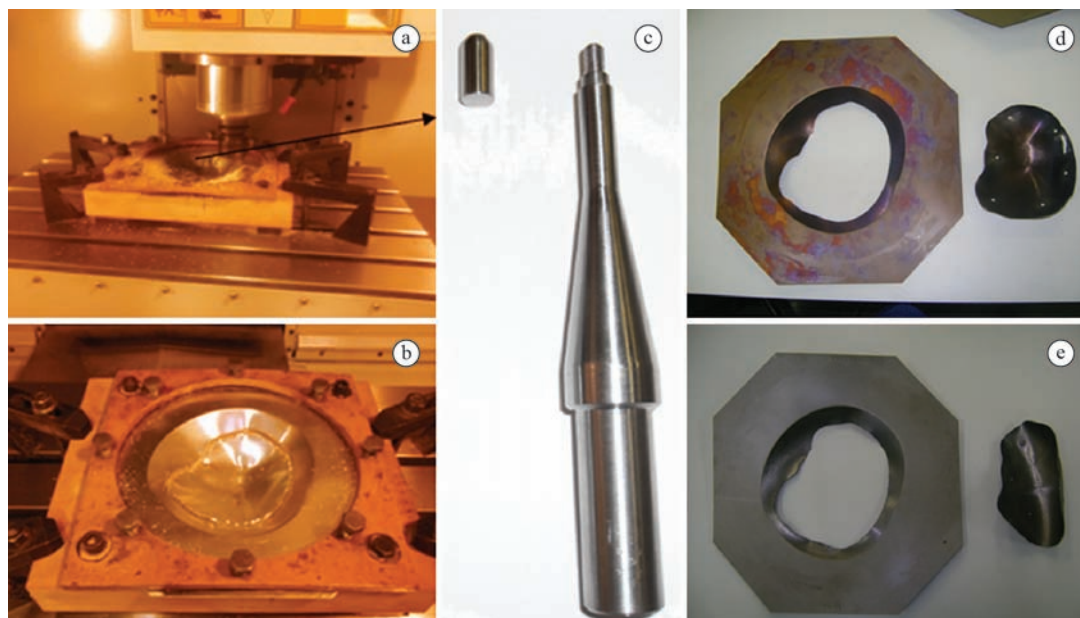


Figure 4. Incremental forming (a) and cutting (b) of a grade 2 pure titanium sheet; c) Tool shape made with 4340 steel and a tip made with pure grade 2 titanium; d) Cut profile after heat treatment (stress relief) of the formed sheet; e) Cut profile without heat treatment – note the drastic deformations due to internal stress.

Table 1. Manufacturing process.

Process	Operation	Tool	Feed speed (XY axis, mm/min)	Plunge Speed (Z axis, mm/min)	Rotation (RPM)	Strategy	Increment Z (mm)
Polymer machining	Rough	End mill Ø10	4.000	2.000	3.000	Parallel	1.00
	Finish	ballnose Ø8	2.000	2.000	4.000	Helical	0.10
Forming and cutting of sheet	Forming	Special* Ø10	1.500	1.500	50	Helical	0.10
	Cut	End mill 4 mm	1000	500	7000	Groove	1

*Tool with Ti insert, semi-spherical tip, without cutting edges, Ø10 mm.

sheet surface. Thus, lubrication is essential for sliding and to distribute the pressure of the tool on the sheet, preserving the integrity of both. Industrial mineral-based lubricants have excellent mechanical properties. However, their chemical components are harmful to health (Zn, Pb, Ni, Cu), preventing their use in the present work. Thus, it is necessary to use alternative inert lubricants, such as Vaseline, glycerin, propylene glycol, or an animal-based lubricant, such as swine grease (also known as lard, used in this work), which is widely used in the machining of screws and internal threads with excellent functional results.

Step 5 – Heat treatment of titanium sheet

Before cutting, it is necessary to perform a heat treatment for stress relief on the formed titanium sheet to avoid unwanted deformations (Göttmann et al., 2013). Figure 4e shows what happens in the absence of heat treatment; deformations are so large that it is unnecessary to compare the dimensions from the reference model (CAD). Figure 4d shows a profile cut from a thermally treated sheet. The heat treatment progressed as follows: heating for 2 h up to 400 °C, maintaining that temperature for 4 h and then cooling for 18 h to room temperature.

Step 6 – Dimensional analysis between the reference (CAD model) and titanium implant

To evaluate the dimensional concordance between the CAD model and titanium implant, a 3D Scanner (Material Selection and Design Laboratory, Federal University of Rio Grande do Sul, Brazil) was used. The scanner ran a sweep along the titanium sheet, generating a CAD surface. This surface was assembled with the original CAD model of the implant, and its dimensions were compared (see Figures 5 and 6).

Step 7 – Physical assembly implant-biomodel

Finally, the biomodel-implant physical assembly was performed (see Figure 7). This procedure can be useful to a physician to plan surgery, predict

movements, and evaluate the implant fixation and explain to the patient and/or the patient's family what will be performed during surgery.

Results

The analysis of dimensional discrepancies between the reference (CAD) model and manufactured implant revealed values in the range of +6.5 mm to -7.2 mm (Figure 6). The positive value indicates that in the negative Z direction (see Figure 5b), the titanium implant exceeded the respective CAD model; the negative value indicates that in the same direction, the titanium implant showed smaller dimensions than the respective CAD model. In the first case (positive discrepancy), the unwanted deformation occurred due to the remaining stresses following heat treatment, indicating that this process needed to be adjusted (ramp, ultimate temperature or both) to minimize these stresses post-treatment to decrease this discrepancy. In the second case, the negative discrepancy occurred as a result of the cutting operation, which was completed with an End Mill Ø4-mm tool (described in Table 1). The tool's rotation causes the deformation of the sheet, which was larger on one side than the other (see Figure 6, left side) due to concordant/discordant tool rotation relative to the cutting profile. The ideal solution would be laser-based cutting because the deformations would be smaller and more uniform, and the surface finish of the cutting area (sheet thickness) would be improved without the need for the manual polishing that was performed in this work. Indeed, the evaluated dimensional discrepancies indicate that the process is efficient, but new studies and experiments should be performed to improve results.

Another important characteristic is the maintenance of symmetry between healthy and recovered sides. Due to dimensional discrepancies, the symmetry was

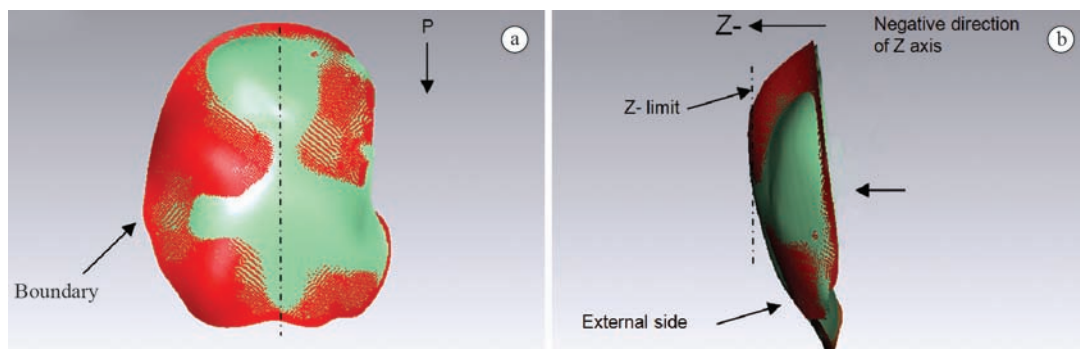


Figure 5. Dimensional analysis between the CAD model (red) and scanned formed implant (green). a) Top view indicates that in the boundaries, the implant showed smaller dimensions in relation to the CAD model, while the implant's external regions exceeded the CAD model shapes near the Z-limit (see figure 5b) and in a non-uniform way to the left and right sides (see 5a). b) Projected view from 'P'.

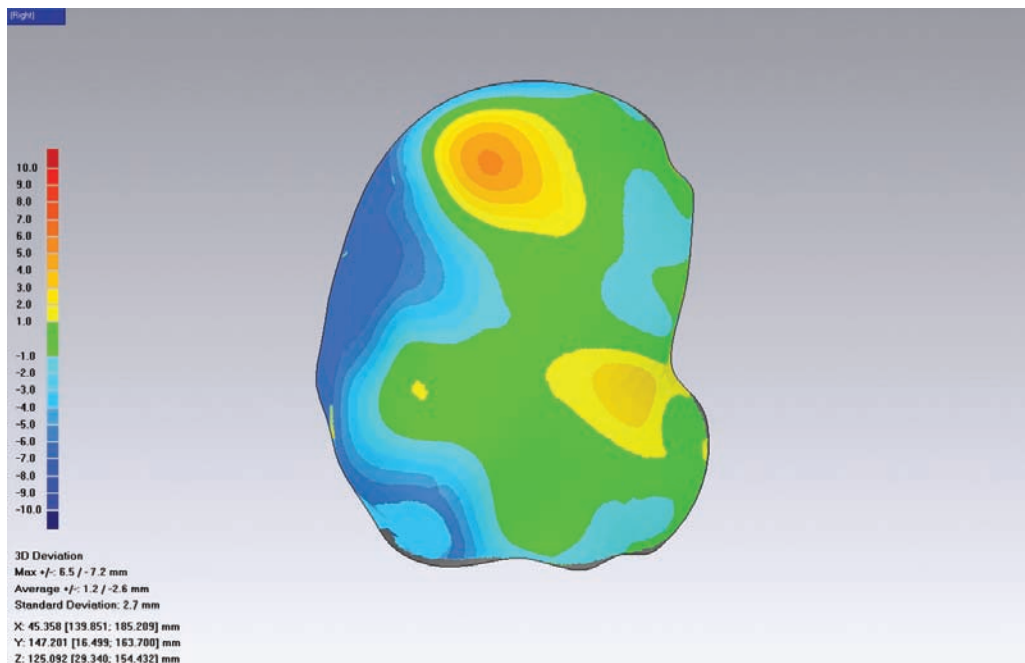


Figure 6. Dimensional analysis. The colors indicate the differences between the reference (CAD Model) and formed implant. There were significant dimensional discrepancies in the left side (-7.2 mm) and in the upper region ($+6.5$ mm). The negative difference (i.e., where the implant is less than the CAD model) was caused by the cutting tool (milling cutter); the positive difference (i.e., where the implant is greater than the CAD model) may have been caused by deformations that occurred during heat treatment.

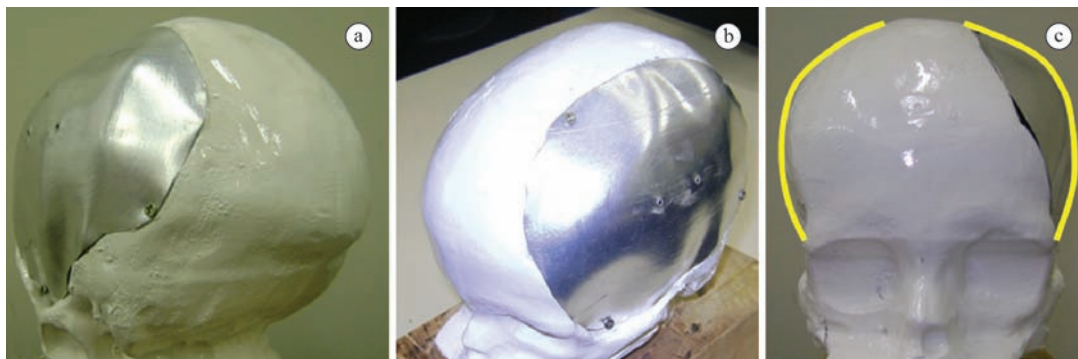


Figure 7. Implant-biomodel assembly: a) Back view; b) Isometric view; c) Front view, with indication of symmetry lines between left and right sides of the skull.

affected (see Figure 7), although discreetly according to a visual analysis.

Furthermore, chemical analysis of the forming titanium sheet was performed (see Figure 8). The EDS analysis showed that there was no contamination by harmful elements and that cleaning and degreasing procedures were effective.

Discussion

The use of a lower support polymer with the specific format of the implant (TPIF) contributes to decreased dimensional discrepancies between the CAD model

and the formed implant. Previous experiments with Single Point Incremental Forming (SPIF) showed that this process is contraindicated for organic shapes. The heat treatment after forming is indispensable for maintaining the dimensional correlation with the CAD model. In this work, we applied TPIF and heat treatment to improve the dimensional aspects. However, the results remain unsatisfactory and there are ways to improve these results. Changes in the heat treatment parameters (ramp and ultimate temperature), forming parameters (feed and plunge speed, tool movement strategy and Z-increment) and laser-based cutting profile can generate substantial improvements in the dimensional aspects.

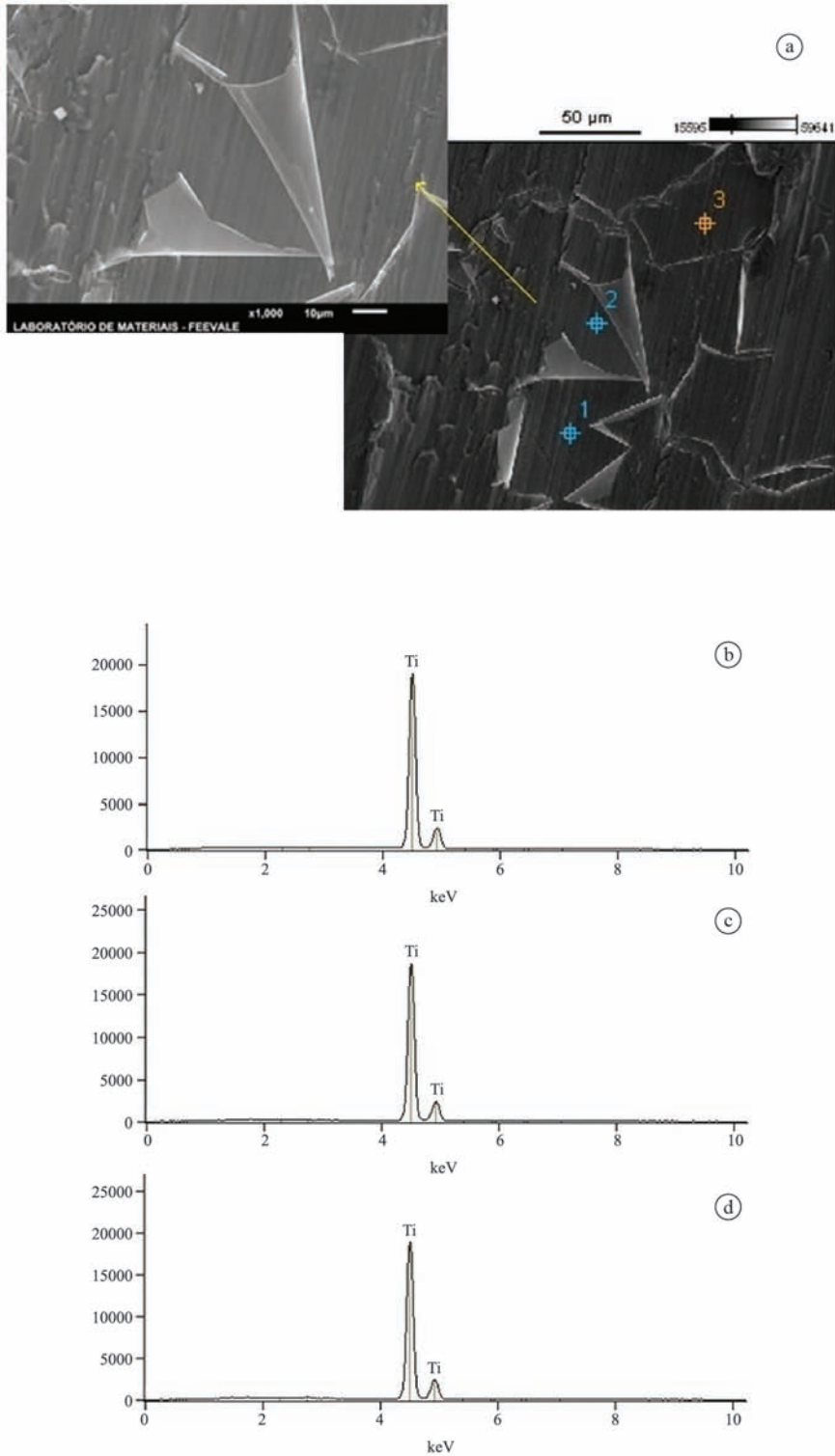


Figure 8. Electron microscopy images (EDS analysis) of the forming titanium sheet did not indicate the presence of harmful chemical elements. Places: 1(b), 2(c) and 3(d). (from LAPEC/UFRGS, collaboration by Leonardo Marasca Antonini).

Independent of the current results, this work presents two important contributions: a) the development of design procedures and manufacturing planning by adapting existing resources (CAD/CAM mechanical software and CNC milling machinery) and b) the reduction of production costs of implants. According to neurosurgeon Dr. Sandro de Medeiros (São José Hospital, Criciúma, Santa Catarina, Brazil), the cost of cranial implants manufactured in biocompatible polymer or titanium may reach 40-50,000.00 USD depending on the area, shape and manufacturing process (molding vs. machining from a solid block). The costs of these method are estimated to be between 7-8,000.00 USD, which include a) the time spent making the CAD biomodels, b) the time spent machining and programming (to control the XYZ movements of the CNC machine), c) the manufacture of the titanium implant, d) the cost of the titanium sheet, and e) the cost of using the machining center's machinery.

Other researchers have developed preoperative implant manufacturing systems. Bertol et al. (2010) conducted a study regarding the fabrication of custom implants, focusing on different alloplastic biomaterials (polymethylmethacrylate, titanium and calcium phosphate cements) and presented results similar to this study, although in that study, the implants were manufactured manually. In that case, the implant quality is dependent on the manual skill of the biomodeler. The purpose of this study was to develop a mechanized and parametric manufacturing system that could increase the possibility of producing implants with esthetic-functional efficiency.

In Lieger et al. (2010), the methodology (based on CT images to manufacture biomodels and implants) is similar to this study's, though it is different in two ways: a) the resources used (software and hardware) and b) the implant manufacturing process. Lieger used stereolithography to generate the implant, which is an expensive process mainly due to the cost of acquiring the equipment.

Alternatively, the use of computational resources allows for the early planning of surgery by means of visual analysis and the digital assembly of parts. The pre-visualization and the customized and mechanized manufacturing process contribute to the reduction of surgical time and minimize shape errors that may affect the esthetic-functional efficiency of the implant. Furthermore, the implant can be manufactured in a few hours.

The limitations of the study are related to the aseptic aspects of the environment used to perform the experiments, which is not suitable for the production of implants. The machinery, tools and other devices are

dispersed in an open academic room (manufacturing laboratory), presenting a high risk of contamination. Although there are procedures for cleaning, disinfecting and sterilizing implants, it is ideal to have a closed, aseptic environment with controlled temperature and humidity and certified by ANVISA for production and utilization in humans.

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