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POTENTIALITIES OF THE USE OF INCREMENTAL FORMING IN COMPUTER AIDED DESIGN AND MANUFACTURE OF CUSTOMIZED CRANIOFACIAL IMPLANTS

PhD Thesis

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Submitted by

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You can have any color as long as it’s black.

Henry Ford (1863 – 1947)

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SUMMARY

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LIST OF ABBREVIATIONS

ABNT	Associação Brasileira de Normas Técnicas (Brazilian Association of Technical Norms)
AM	Additive Manufacturing
ANVISA	Agência Nacional de Vigilância Sanitária (National Sanitary Surveillance Agency)
ASTM	American Society for Testing and Materials
3D	Three-dimensional
CAD	Computer-Aided Design
CAE	Computer-Aided Engineering
CAM	Computer-Aided Manufacturing
CFC	Calcium Phosphate Cement
CNC	Computerized Numerical Control
CP	Commercially pure
DICOM	Digital Imaging and Communications in Medicine
DMLS	Direct Metal Laser Sintering
EAS	Engineering Assisted Surgery
FLC	Forming Limit Curve
FLD	Forming Limit Diagram
IE	Incremental Forming
LACER	Laboratory of Ceramic Materials
LAMEF	Laboratory of Physical Metallurgy
LdSM	Laboratory of Design and Materials Selection
LDTM	Metal Forming Laboratory
MRI	Magnetic Resonance Imaging
PEEK	Poly-ether-ether-ketone
PMMA	Polymethylmethacriate
RP	Rapid Prototyping
SFF	Solid Freeform Fabrication
SLS	Selective Laser Sintering
SLM	Selective Laser Melting
SPIF	Single Point Incremental Forming
SPM	Specific Patient Modeling
STL	Stereolithography

TC	Computed Tomography
TMJ	Temporomandibular Joint
TUD	Technische Universität Dresden (Dresden Univeristy of Technology)
UFRGS	Universidade Federal do Rio Grande do Sul

ABSTRACT

Currently, craniofacial reconstruction surgeries are still a challenge for surgical teams due to the difficulty to define and repair bone defects. Defining the geometry of the implant is the first challenge, since each patient has an individual anatomy and, in case of bone defects due to trauma or tumors, each defect has a specific shape. The implant should then have a geometry that permits the replacement of the original structure and should consist of a material suitable for implantation. Moreover, the selected manufacturing process must be flexible enough to enable the production of a single piece, not requiring excessive cost with dyes and tooling. In the current scenario of flexible manufacturing processes, the process of incremental forming, which permits forming metal sheets to manufacture small batches, receives special emphasis. Thus, this study evaluates the feasibility of preoperative manufacturing of customized implants to repair defects in different regions of the craniofacial complex through the process of incremental forming. Different procedures were used for modeling implants obtained from CT data of patients and the parameters for forming different geometries of titanium implants were developed. Alternative techniques capable of producing such implants are also presented. The study shows that, although it has limited dimensional accuracy and restrictions regarding the geometric complexity of the implants that can be shaped, the single point incremental forming (SPIF) process represents a suitable alternative for the preoperative manufacturing of customized implants for the reconstruction of craniofacial defects.

RESUMO

Atualmente, cirurgias de reconstrução craniofacial ainda são um desafio à equipe cirúrgica devido às dificuldades em definir e reparar o defeito ósseo. A definição da geometria do implante é o primeiro desafio, uma vez que cada paciente possui uma anatomia individual e, em caso de defeitos ósseos devido a traumas ou tumores, cada defeito possui uma forma específica. O implante deve, então, possuir geometria tal que o possibilite substituir a estrutura original e ser constituído de material apto para a implantação. Além disso, o processo de fabricação selecionado deve ser flexível a fim de possibilitar a produção de uma peça única, dispensando custos excessivos com ferramental. No cenário atual de processos de manufatura flexível, um destaque especial recebe o processo de estampagem incremental, que permite a conformação de chapas metálicas para a fabricação de pequenos lotes. Neste sentido, este estudo ocorre no âmbito da fabricação pré-operatória de implantes personalizados para reparo de defeitos em diferentes regiões do complexo craniofacial através do processo de estampagem incremental. Foram utilizados diferentes procedimentos para modelagem dos implantes a partir de dados tomográficos e foram desenvolvidos parâmetros para a conformação de diferentes geometrias em titânio. São apresentadas, ainda, técnicas alternativas capazes de produzir tais implantes. O estudo mostra que, embora possua precisão dimensional limitada e restrições com relação à complexidade geométrica dos implantes que podem ser conformados, o processo de estampagem incremental apresenta-se como uma alternativa viável à fabricação pré-operatória de implantes personalizados para a reconstrução de defeitos craniofaciais.

ZUSAMMENFASSUNG

Operationen im Schädel- und Gesichtsbereich stellen nach wie vor eine große Herausforderung für die behandelnden Ärzte dar, weil sich oftmals die Abgrenzung des Knochendefekts und die Wiederherstellung der ursprünglichen Knochenstruktur als schwierig erweisen. Die erste Herausforderung dabei ist die Definition der Implantatgeometrie, da jeder Patient eine individuelle Anatomie und, im Falle eines Knochendefekts durch Traumata oder Tumore, jeder Defekt eine spezifische Form aufweist. Das Implantat sollte somit eine der originalen Knochenstruktur entsprechenden Geometrie besitzen und aus einem für die Implantation geeigneten Material bestehen. Weiterhin muss das für die Herstellung des Implantats gewählte Verfahren derart anpassungsfähig sein, dass auch die Erzeugung eines einzelnen individuellen Produktes möglich ist und keine übermäßigen Kosten im Werkzeug- und Formenbau verursacht werden. Im gegenwärtigen Szenario flexibler Herstellungsprozesse, die eine effiziente Blechumformung auch in kleineren Stückzahlen erlauben, liegt ein besonderer Schwerpunkt auf dem Verfahren der inkrementellen Umformung. In dieser Arbeit wird daher die Durchführbarkeit der präoperativen Herstellung individueller Implantate zur Wiederherstellung knöcherner Strukturen verschiedener Regionen im Schädel- und Gesichtsbereich mit dem Verfahren der inkrementellen Blechumformung untersucht. Dabei wurden unterschiedliche Methoden zur Modellierung von Implantaten aus patientenspezifischen CT-Daten angewendet und Prozessparameter für die Herstellung verschiedener Formen von Titanimplantaten entwickelt. Ferner werden alternative Techniken vorgestellt, mit denen es ebenfalls möglich ist, solche Implantate herzustellen. Gleichwohl es Einschränkungen hinsichtlich der Formgenauigkeit und Komplexität der zu formenden Geometrie des Implantates gibt, zeigt diese Arbeit, dass das Verfahren der inkrementellen Blechumformung eine geeignete Alternative für die präoperative Herstellung von individuellen Implantaten für den Schädel- und Gesichtsbereich darstellt.

1. INTRODUCTION

In order to develop new manufacturing technologies and new products, the combination of engineering and design in medical and biological sciences along with the cooperation of different areas of technical-scientific community has been pursuing the feasibility of working with quality in the segment of craniofacial implants. This interdisciplinary character brings solutions that target people's access to a better health care system coupled with quality and technology, providing thus, a better quality of life and social welfare.

The repair of cranial defects is necessary to provide brain protection and is aesthetically desirable. Tumors, trauma, diseases and birth defects generate the need for bone reconstruction. The treatment of craniofacial defects is a challenge to the surgical team, and often involves multiple surgeries, some of high cost, and yet, in some cases, the results are not satisfactory. In this sense, there is a continuous concern in the improvement and development of new treatment methodologies.

The rapid technological development of engineering and product design from the last half century has brought changes of great importance in Medicine regarding the treatment of bone fractures and rehabilitation. The use of CAD (computer-aided design), CAM (computer-aided manufacturing) and CAE (computer-aided engineering) enables the project, manufacturing and evaluation of specific prosthesis according to the needs of each individual patient. The additive manufacturing (AM), or rapid prototyping (RP) systems, which enable the manufacturing of medical implants in a fast, accurate and totally automated way, occupy a prominent role in this context. Therefore, it is possible to obtain, in short time, a 3D model that can be tested in practical situations.

The manufacturing of custom prosthesis has become a field of great interest in Biomedical Engineering. In fact, even when several products can be classified as similar, the natural difference among them in terms of anthropometric features of each individual leads research towards high customization in order to ensure the best performance possible for the product. The main arguments raised by proponents of the manufacturing of customized implants include the reduction of surgical time,

better aesthetic results, reduced risk of infection and better outcomes. Furthermore, the incorporation of functionality to the implant is also possible, as in the case of osteoconductive implants or controlled drug delivery. However, the manufacturing of prosthesis, according to the patient's needs, is costly and requires the domain of a still incipient technology, when compared to traditional methods such as *in situ* molding and standardized prostheses. The manufacturing technology for the production of customized prostheses comprises image processing and medicine, the use of CAD three-dimensional reconstruction, CAM systems, flexible manufacturing processes, CNC (Computerized Numerical Command) machinery, biomaterial processing technology, among others.

Thus, this study evaluates the main techniques currently available for the project and manufacturing of customized bone implants in craniofacial complex. CT images serve as the basis for the project of implants, manipulated in CAD software and transferred to CAM software, where strategies and parameters for the manufacture of the implant in the desired geometry are defined. In other words, a reverse engineering approach is used to produce a specific implant for the needs of each patient, also known as Specific Patient Modeling (SPM). The potential and limitations of each technique are assessed, as well as appropriate materials for each manufacturing process and anatomical function that the implant should perform.

Several techniques have been proposed and used for manufacturing customized implants - including incremental forming, rapid manufacturing, CNC machining, and manual conformation with the aid of physical biomodels (Goldsmit, Horowitz and Orentlicher, 2012; Staffa et al., 2012; Goh et al., 2010; abergmann et al., 2010; Mustafa et al., 2011; Neovius and Engstrand, 2009) . Specifically, using the single point incremental forming (SPIF) technique to form the implants to repair cranial defects has shown great potential. The possibility of extending the application of the technique for other more complex defects of the face, however, still remains unexplored. In this sense, the main issue to be investigated in this study is: which of the various flexible manufacturing processes available today can be used for the production of various types of implants needed for the repair of defects in the craniofacial region? The produced implants must fulfill geometrical and functional

requirements in order to be considered suitable for its use. Additionally, as an objective of this study, is to investigate whether single point incremental forming can effectively represent a suitable alternative to stamping of custom medical products.

This study aims to contribute to the advance of Biomedical Engineering, particularly that which relates to the design and manufacturing of craniofacial implants. The study was developed within the Graduate Program in Mining, Metallurgical and Materials Engineering in the Federal University of Rio Grande do Sul, and the Department of Mechanical Engineering in Dresden University of Technology.

2. OBJECTIVES

General objective: To evaluate the feasibility of preoperative manufacturing of customized implants for the repair of defects in different regions of the craniofacial complex through different manufacturing processes.

Specific Objectives:

1. Evaluate software currently available that allow the medical manipulation of implants.
2. Evaluate the materials and manufacturing processes available for the production of craniofacial implants with different geometries, functions and mechanical requirements.
3. Evaluate the technique of single point incremental forming as an alternative to the manufacturing of custom craniofacial implants, parameters, potentials and limitations.
4. Develop a technological route of manufacturing and evaluation of custom craniofacial implants, taking into consideration the structural, aesthetic and functional requirements of the implants, in addition to the prevailing relevant norms.

3. BIBLIOGRAPHIC REVIEW

3.1 The craniofacial skeleton

The anatomy of the cranio-maxillofacial skeleton is designed to give protection to soft tissue structures of vital importance and to allow the jaw movement, among other functions. Important systems that are protected include the central nervous system, eyes and respiratory system. A schematic representation of the bone structure of the skull is shown in Figure 1.

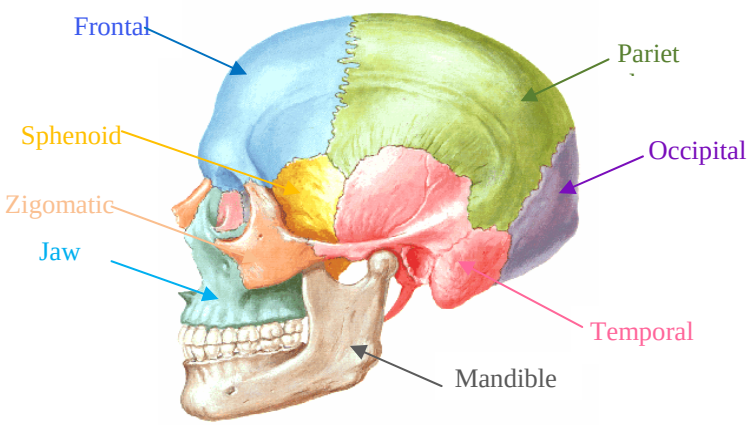


Figure 1: Schematic representation of the cranium bones.

Source: Adapted from Salgado (2010).

3.1.2 Cranioplasty

Cranioplasty is a procedure used in the totality of craniofacial surgeries of malformations and in surgeries of cancer and trauma, resulting in loss of substance of the cranium. The aesthetic-functional changes of the face and cranium require surgical specialties involving increasing technical and scientific improvement. The current trend, according to Rettore et al. (2000), is that patients are seen from a multidisciplinary perspective.

The fractures of the craniofacial skeleton are just one component of a spectrum of "maxillofacial injuries" and are associated with varying degrees of involvement of soft tissues and adjacent structures such as the eyes and nasal passages, paranasal sinuses and tongue. They can range in severity from a simple crack in the top alveolus to a major rupture in the internal facial skeleton. Important structural diseases in the

head form the basis of many medical, dental, and surgical specialties, such as oral-maxillofacial surgery, neurology, neuro-radiology, neurosurgery, ophthalmology, otology, rhinology, and psychiatry (Moore and Dalley, 2001).

Currently, craniofacial reconstruction surgeries are still a challenge for surgical teams due to difficulties in defining and repairing bone defects. The definition of the geometry of the implant is the first challenge, since each patient has an individual bone anatomy and in the event of bone defects due to trauma or tumors, each defect has a specific shape. The implant should then have such a geometry that allows for replacement of the original structure. The definition of the material of which the implant is made is another factor to be defined and generates divergent views among the various researchers of this subject (Quatela and Chow, 2008; Staffa et al., 2012; Goh et al., 2010; Neovius and Erik, 2010; Okazaki et al., 2014; Niinomi, 1998). According to Hench (2006), the challenge of the biomaterials field is that implant devices replace living tissues whose physical properties are the result of millions of years of evolutionary optimization, and have the capacity for growth, regeneration and repair. Thus, all materials used for repair or restoration of the body must have a specific set of characteristics and properties. The relative success or failure of a biomaterial reflects the scientific and engineering trial used in the evaluation of this adjustment.

The goals of modern bone surgery are rapid recovery of form and function. This must be the goal of every surgeon treating fractures and tumors causing craniofacial bone defects or performing osteotomies for correction of craniofacial deformities. When selecting the appropriate implant it is necessary to estimate the magnitude and expected duration of the charges for each specific case.

3.2 The materials and craniofacial reconstruction

Numerous implants, orthoses and prosthesis have been developed since the initial use of gold and silver as biomaterial. Most of them were used for a period of time and then discarded when their limitations became known and or new materials were provided. The use of implants to repair or replace parts of the human body has

grown tremendously in recent years, mainly due to increased life expectancy of the population, but also due to the increase of accidents related to transportation means , work and sports, and also wars and violence. According to Pereira et al. (2006), the demand for biomaterials grows 5-15% each year.

Historically, gold plates were used for cranioplasty by pre-Columbian Inca surgeons. In the sixteenth century, canine bone was used to repair a cranial defect in a human. In the early twentieth century, the use of autografts was quite popular. However, due to the devastation caused by war, the search for alternative metals to cover large craniofacial defects increased. Modern plastic and ceramic materials have replaced the metals in many cases for decades (Sanan and Haynes, 1997).

An implant according to Ernst, Herzog and Seidl (2009) describes any tissue or synthetic material that can be placed in a living organism. A graft describes a vital tissue or a body part which at least fulfills its function in the host tissue. Table 1 summarizes the classification of implants and grafts.

Table 1: Classification of implants and grafts.

TYPE	SOURCE
Autogenous (autologous)	Same individiual
Isogenous (homologous)	Monozygotic twin or same family tree
Allogenic (homologous)	Another individual of the same species
Xenogenous (heterologous)	From other species
Alloplastic	Inorganic, exogenous material

Source: Adapted from Ernst, Herzog and Seidl (2009).

A material, ideal to be used as an implant, must meet the following requirements (Ernst, Herzog and Seidl, 2009): good compatibility, no local or systemic toxicity, no reabsorption (early) of the implant material, readily available in adequate

quantity, sterilizable, must be pliable and conformable, have elasticity coefficient and Poison's ratio which corresponds to the tissue where it will be placed.

The main purpose of cranioplasty is to repair loss of substance and reconstruct the cranium, with a view to shelter and protect the brain and restore the aesthetics of the head. Tumors, trauma, disease, and birth defects generate the need for bone reconstruction. According to Neto and Zanini (2000), bone loss smaller than 2 cm in diameter, provided they do not compromise the aesthetics, will not usually be repaired because the ability of osteogenesis of the dura mater, pericranium, and bone edges is large. However, in cases where cranioplasty is required, there are alloplastic methods and bone transplant methods. Among the arguments used by teams who prefer bone transplants is the fact that they integrate into the recipient location by osteogenesis, osteoinduction and osteoconduction, and, apart from undergoing remodeling to restore the form, resist better to infections and stimulate vascularization of devitalized areas (Lee, Antonyshyn and Forrest , 1995). On the other hand, some critics say that the method, apart from being limited, always has some degree of reabsorption and always results in a lesser or greater morbidity for the patient, depending on the donor area. The donor most popular areas for removing material for bone grafts in cranioplasty are the skull cap, ribs and the iliac crest.

Ideally, in the cranioplastias in which it is necessary to have access to the brain, the cranial region that is removed is stored for later insertion. A bone cap, however, may not be available for the repair of defects where the fracture is composed of several fragments, tumors, congenital abnormalities, osteomyelitis or reabsorption of the bone fragment. Repairs using autogenous bones (rib or iliac) are often made, but sometimes do not provide adequate brain protection and may be associated with morbidity (Stoodley, Abbot and Simpson, 1996).

Authors that employ alloplastic materials defend their inexhaustible capacity to meet even the largest repairs without morbidity to the patient, in obtaining the material and ease of application and modeling. Quatela and Chow (2008) point out other advantages of alloplastic implants: lack of allergenicity and carcinogenesis; not corrosive nor toxic; not absorbable, are durable, resistant and lightweight, biocompatible and malleable. On the other hand, Neto and Zanini (2000) point out

that it is undeniable that the alloplastic inclusions, for being foreign bodies, have functional limitations and interfere with the diagnosis by image (especially metallic inclusions in magnetic resonance imaging).

3.2.1 Allografts (homologous)

The removal of bone from another part of the patient's own body for subsequent grafting (autogenous material) is still a widely used technique, especially in cases of small bone defects. Autogenous bone is usually the first choice, particularly for grafts. Its use is contraindicated for very large extent of the defect, patient in advanced age, previous failures in cranial reconstruction. Also, when autogenous implants are used, other considerations must be taken: risk of postoperative infection and resorption of the graft with loss of their physical properties and the need for another surgical procedure at the donor site. While xenografts (decalcified and dried animal bones) can pose immunological risks, allografts (obtained from cadavers and stored in bone banks) may be responsible for transmission of infections such as hepatitis B, hepatitis C and HIV. For xenografts, in particular bovine material, there is also concern about the possibility of disease transmission.

3.2.2 Alloplastic grafts

In the case of major defects, however, implants with alloplastic materials are preferred. A major advantage of the use of alloplastic materials is the possibility of manufacturing the prosthesis before surgery, thus reducing the time and complexity of the surgery. The use of alloplastic implants for reconstruction of damaged or missing parts of the human body has a long history, with different types of materials being used, some more successful, some less. Currently there are various materials (metals, polymers, ceramics and composites) suitable for use as an implant. Among these alternatives, three noteworthy materials that are widely used for craniofacial surgery: methylmethacrylate, calcium cement and phosphate (hydroxyapatite) and titanium. Each of these materials has its potential advantages, disadvantages and indications in contemporary craniofacial surgery. When used with good surgical technique and in the appropriate patient, each material can enable good clinical

response. The main materials used for craniofacial bone reconstruction are reviewed below.

- Polymers

Represent materials also often used as grafts. These are manufactured in the form of woven yarn and powders that, when mixed with proper liquids become mass serving to fill spaces from loss of tissues. In general, they produce a significant tissue reaction. Prominent polymeric materials currently used for alloplastic cranioplasty are polyethylene (PE) and polymethylmethacrylate (PMMA).

Polyethylene (PE)

Ultra high molecular weight polyethylene is also a polymer used to reconstruct the floor of the orbit and nasal cavity due to its hardness and strength. However, according to Rettore et al. (2000), the main contraindications to its use are: infected areas, regions with low blood flow, patients with systemic disease that hinder the healing process; regions that have undergone radiotherapy; areas where there is excessive pressure on the implanted material.

One of the main representatives of the polyethylene is Medpor® (Porex), which has high density linear polyethylene in its constitution. Its porous structure of interconnection stimulates bone cells to penetrate through these pores.

Polymethylmethacrylate (PMMA)

With a complex range of possibilities, the ideal synthetic material according to Chiarini (2004) must be biocompatible, inert, have low thermal conductivity, be radiotransparent, non-magnetic, light, rigid, simple to prepare, easily applicable and low cost. In this sense, the polymethylmethacrylate (PMMA) is among the inert materials that meet these requirements.

PMMA, commonly known as acrylics, is produced from esters of acrylic or methacrylic acids and has a long history of use in orthopedic surgery as bone cement for joint prosthesis. It has been adapted for cranioplasty procedures through a powder mixture of methylmethacrylate polymer and methylmethacrylate-styrene copolymer and a monomer benzyl peroxide. PMMA is polymerized in surgery by a mix of the liquid monomer to powder polymer. As a result of this mixture there is an exothermic

reaction, in which the temperature may reach 80°C in the curing time of the polymer (8-10 min). It forms a rigid and almost translucent polymer. As described by Eppley (2003), due to the fact that the liquid monomer is highly allergenic and cytotoxic, the mixture of the components and the beginning of the polymerization process occur outside the implantation local. Once hardened, the PMMA is inert, not resorbable and induces the formation of a fibrous capsule, which means that there is biological tolerance, but there is no capacity of tissue incorporation. The formation of capsules of fibrous tissue is usually attributed to surgical trauma, thermal shock caused by *in situ* polymerization, the exothermic reaction that may necrose the bone if its temperature reaches 56°C (Hench and Ethridge, 1082), and by the high toxicity of the unpolymerized monomers, a fact confirmed in cell culture (Pedersen, 1987).

PMMA also has several advantages. The material easily adapts to the contour of the defect in surgery (due to its pre-hardening moldability) and is quite durable, with high impact resistance. Because PMMA is rigid, it may have its tenacity to fractures increased by the joint use of wire mesh reinforcement, approaching the strength of the implant to the resistance of human cranial bone (Eppley, 2003). However, there are some disadvantages to the use of PMMA. The material releases volatile gasses when it is mixed (due to monomer), from which allergic reactions have already been reported in patients who were in the same place where the mixing was performed. Furthermore, the high temperatures reached during polymerization of the material require refrigeration to prevent the implant tissue from being damaged. Furthermore, as stated by Eppley (2003), the material exhibits ease of bacteria adhesion, which makes it poorly tolerated by the body once infected, or when in contact with tissues with recent infection. Still, thinning of the skin over the implant, implant exposure and infection may occur with a long period of implantation in pediatric cranioplasty.

- Metals

Metals were always used to reconstruct bone structures, as in the case of bone fractures or bone loss. The metals used are researched and approved by international organizations before their use is cleared (FDA, Anvisa, ISO, etc). As advantagesof metals it is worth to mention their inertia and structural stability, which allows them to

perform the functions for which they are indicated. The metallic materials of greater emphasis to craniofacial surgery are the stainless steels and titanium and its alloys.

Stainless steel

Stainless steel is used as wires of various diameters and plates and screws for rigid fixation in traumatology and orthognathic surgery. They cause mild foreign body reaction and small resorption in places where they are placed.

Despite its widespread use, its stability is being questioned by researchers, who claim all stainless steels to be susceptible to degradation by tissue fluids, causing, then, surface corrosion, and affecting the electrical neutrality (Rettore et al., 2000).

Titanium

Titanium has been available as an engineering material since 1950 and it is used for applications which require moderate resistance combined with good formability and corrosion resistance (Welsch, Boyer and Collins, 1994). Its production has greatly developed due to aerospace industry demands of a material lighter than steel and more resistant to high temperatures than the aluminum alloys. Commercially pure titanium is widely used when high corrosion resistance is required.

Commercially pure titanium is available in several grades that have varying amounts of impurities such as carbon, hydrogen, iron, nitrogen and oxygen. Some modified degrees may also contain small amounts of palladium (Ti-0, 2Pd), nickel and molybdenum (Ti-0,3Mo-0,8Ni). These additions occur when attempting to increase corrosion resistance and/or deformation.

Metallic materials are the source of success stories involving cranioplasty and alloplastic materials. Titanium is currently the most used material for craniofacial fixation, because, according to Rettore et al. (2000), it is considered the most acceptable metal in the body. The way its insertion in the body is recommended promotes the phenomenon of osseointegration, which, in studies of implants and bone grafts, is regarded as the best type of interface achieved between bone and implant material. Titanium is a material that has high corrosion resistance by forming a thin adherent layer of titanium oxide on its surface. As a result, it is highly biocompatible, with virtually no risk of hypersensitivity or allergic reactions. To

increase its resistance, it is usually manufactured as an alloy with small amounts of other metals (eg Ti-6Al-4V, 6% aluminum and 4% vanadium). This resistance, combined with the possibility of the material to be shaped and bent manually, makes it easy to adapt to the bone. Furthermore, the low density of titanium and its alloys allows for a minimum attenuation of the X-ray CT images.

Titanium wire meshes have been used for a long time and have a history of good results in cranioplasty, as a rapid method for restoring the external cranial shape. They are recommended for the support of materials of autogenous or alloplastic bone grafts. It can be used as surgical technique for rapid cranioplasty by intraoperative modeling of meshes or canvas of titanium (with a thickness that can vary from 0.15 to 2.0 mm). The mesh is placed over the defect and manually formed according to the anatomy of the patient. When the mesh is flat, it must be shaped so as to obtain a curvilinear surface, similar to the skull. The edges of the canvas are set to the bone next to the defect in with screws. Currently large pieces of titanium mesh are available already curved, which simplifies the process of adaptation to the shape of the cranium. When implanted in the outer surface of the cranium, it generates an excellent head contour, even in cases of large bone defects. The perforated nature of mesh and canvas allows for vascularization of the region.

- Ceramics

Calcium phosphate cements

Materials for implantation of calcium phosphate compounds (CFCs) have been commercially available for nearly 20 years as an alternative for bone replacement or augmentation. Unlike most other alloplastic biomaterials, which are inert, these materials are bioactive (enable osteoconduction) and have the potential to promote growth and osseous integration after implantation. As a result, these materials are very well tolerated, with minimum fibrous encapsulation and without negative effects on local bone mineralization. According to Santos (2002), due to its chemical similarity with human bone, calcium phosphate cements are osteoinductive themselves. They provide a physical substrate on which new bone tissue, from adjacent surfaces, can be deposited and potentially guided to areas occupied by the material.

The use of calcium phosphate cements has been increasing for applications in craniofacial surgery. Such material is available as a composition of a powder and liquid, which are mixed in surgery. The mixture is poured and formed in the cranial defect and subsequently converted *in vivo* to hydroxyapatite by direct crystallization, without generating heat. Various forms of these compositions are currently available, including various types of calcium phosphates.

3.3 Anatomical biomodels and craniofacial reconstruction

In many areas of applied science, there is great interest in reconstructing three-dimensional images (3D) from their cross sections, such as medical imaging, geological modeling, paleontology, and industrial manufacturing systems. In the case of medical images, special emphasis deserve Computed Tomography (CT) and Magnetic Resonance Imaging (MRI), which are two common techniques for capturing information of anatomical details of patients, stored as two-dimensional images. The data obtained from these medical imaging are in general a set of evenly spaced parallel slices representing cross sections of the object under investigation.

Developments occurring in computer graphics and manufacturing processes have allowed the patient data obtained from CT and MRI to be edited and processed to obtain from them, physical anatomical models, called biomodels. For the manufacturing of biomodels, an automated and flexible process is required, capable of producing organic complex forms. Nowadays, additive manufacturing has emerged in response to the need for designers to produce prototypes faster and more accurate than the manual method, and it is the most widely used technology. This process uses CAD (Computer-Aided Design) and CAM (Computer-Aided Manufacturing) software to manufacture parts directly from a virtual three-dimensional model. The key of the processes of additive manufacturing is the construction of the part by depositing material layer by layer, which enables the manufacture of single parts and complex geometries (Carvalho and Volpato, 2007).

The medical field has experienced different uses of additive manufacturing, initially as a mean to guide surgical procedures using anatomical models derived from

CT scans. In a classic application of additive manufacturing, James et al. (1998) used models produced through stereolithography for planning the surgical correction of a facial defect. Holle et al. (1996) discuss the use of stereolithography models to plan the shape and setting of autografts. Erickson et al. (1997) produced through casting custom titanium orbital implants from models of wax using anatomical models obtained from information of CT scans. Studies point to the potential of biomodels to reduce the overall cost of treatment, and lead to better results (Meurer et al., 2003).

According to D'Urso et al. (1998), biomodeling is a generic term that has been used to describe the ability to replicate the morphology of biological structures in solid material. Based on this concept, and extending the scope to include computational biomodels, Lohfeld et al. (2005) provides the following definition: "A biomodel is an entity that reproduces the geometry or morphology of a biological structure, which can be accomplished through both physical and computational models." From this definition, it is possible to define physical biomodels and computing information-based biomodels (this, in particular, may also have different settings according to its use).

A virtual biomodel can be defined as a prototype that is generated based on computer information, created to enable the visualization of biological structures. An example for this case is a three-dimensional image of the human skeleton, generated from CT data and used for surgical planning (Figure 2). This definition also includes models able to be handled in a CAD environment, as occurs, for example, in the design of prostheses and implants.

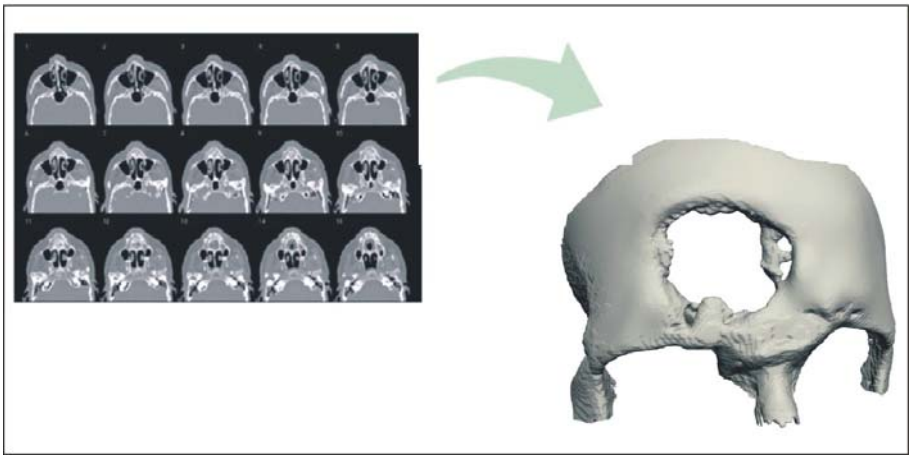


Figure 2: Virtual biomodel obtained from CT images, used to visualize the bone structure, surgical planning and implants design.

A computer biomodel is a prototype that is generated based on computer information in order to perform biomechanical analysis in biological structures and finite element models of bone structures used to simulate the distribution of tensions and strains. Within this definition, the material properties of the biological structure are extremely important for the generation of the model and its geometry.

A physical biomodel (Figure 3) is a biomodel materialized in a solid physical form that can be produced through technologies such as CNC (computer numerical control) or additive manufacturing. In general, physical biomodels are generated from virtual biomodels. They can be made in real size or scaled to obtain benefits in certain situations. In clinical practice, physical biomodels, in particular, have proven to be useful tools for the diagnosis and surgical reconstruction.

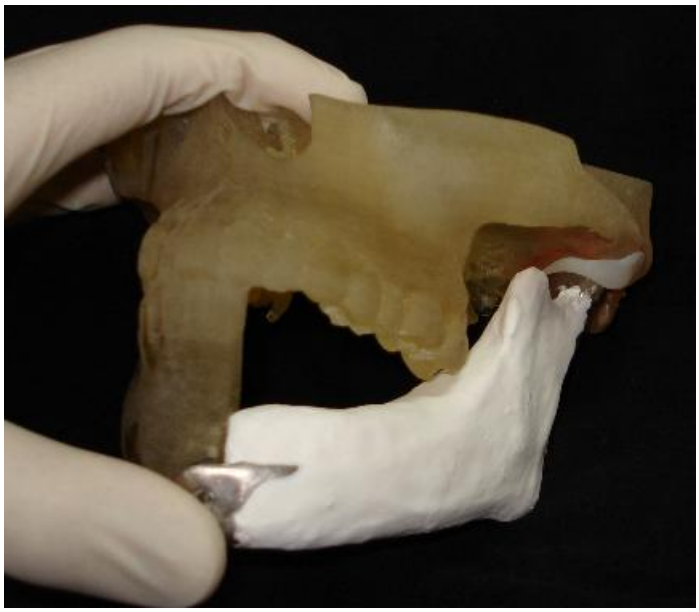


Figure 3: Physical biomodel, produced through additive manufacturing and used to the project of a mandibular prosthesis.

Currently, many softwares allow for the conversion of the series of CT slices of 3D volumetric models (MIMICS®, of Belgium Materialise, InVesalius®, from the Brazilian Institute Center of Information Technology Renato Archer - CTI). Shading tools and rendering of volumes have enhanced the visual realism of such images. In Figure 4, three-dimensional models generated with InVesalius reconstruction software, version 2.1 are illustrated. In (a), the image from the three-dimensional computerized tomography, without restriction of the tissue densities, in

(b), the three-dimensional image generated from the same tomography selecting density thresholds, covering only the denser tissues as the bone tissues. Some software also allow simulating the kinetics of bone and muscle and their behavior in various situations, as well as modeling and simulation of customized implants, such as the software Anybody®, of the Danish company Anybody Technology A/S.

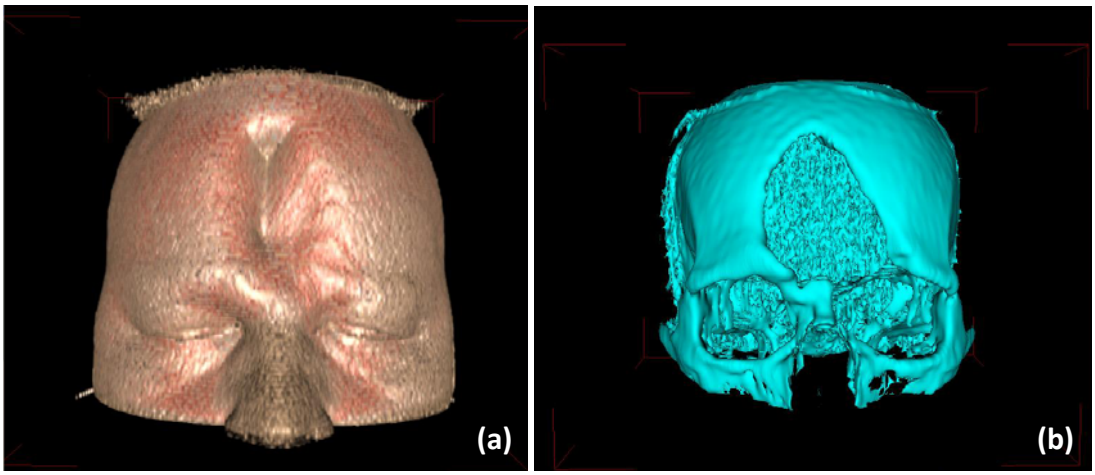


Figure 4: Interface of the software of three-dimensional reconstruction of medical images. a) Three-dimensional reconstruction of the skull, showing all tissues. b) Three-dimensional reconstruction of the same skull, but allowing the exhibition of bone tissues only.

Some advantages described by D'Urso (1998) regarding the use of biomodels are listed below:

- CT and MRI conventional images, in the form of slices, are complex and require a subjective 3D reconstruction. The accuracy of such reconstruction is dependent of experience and three-dimensional sense aptitude of the observer. Biomodels readily provide replicas of the anatomy of the patient.
- Biomodels optimize surgery planning because they allow for a realistic and interactive simulation to surgery.
- In surgery, biomodels may be used simply to guide the surgical approach and verify anatomic relations without the need to use complex equipment.

- Biomodels can be used as templates for the manufacturing of customized prostheses and implants, leading to improvements in the design and fitting of the implant, reducing risks and surgery time.
- Biomodels provide patients with an understanding of their pathology and the goals and limitations of surgery preoperatively.

3.4 Biomodels and design of custom prosthesis

The need for prosthesis that fit precisely lead to the development of various methods of implants manufacturing for computer-aided cranioplasty. The design and manufacture of anatomical prostheses require complete integration of all elements involved. However, custom prosthesis manufactured for specific patients are structures with complex geometry. The design and manufacture of such structures in a computer system require several steps. There are different methods for manufacturing custom implant, also the target of research work.

3.4.1 Manufacture of prosthesis through manual modeling

Manual modeling can be understood as the method of using biomodels manufactured through additive manufacturing to serve as the basis for the surgeon to manually sculpt or shape the prosthesis for reconstruction of the defect.

Traditionally, the clinical use of additive manufacturing relates to models that copy the structures original unchanged. In situations where the models require changes to perform the reconstruction, manual modeling technique is used. This method starts with the manufacture of a biomodel of the patient from the CT scan. The surgeon plans the surgical procedure, removing defective parts when necessary. To create the model of the implant, the biomodel is used as template and manual modeling is performed in the defect region, as shown in Figure 5. From this model of the implant, a mold is made, allowing that biomaterials are poured directly into the mold (calcium phosphate cements or PMMA, for example) or metal plates are shaped to fit the mold. The implant is then positioned over the biomodel for verification of the adjustment between the parts.

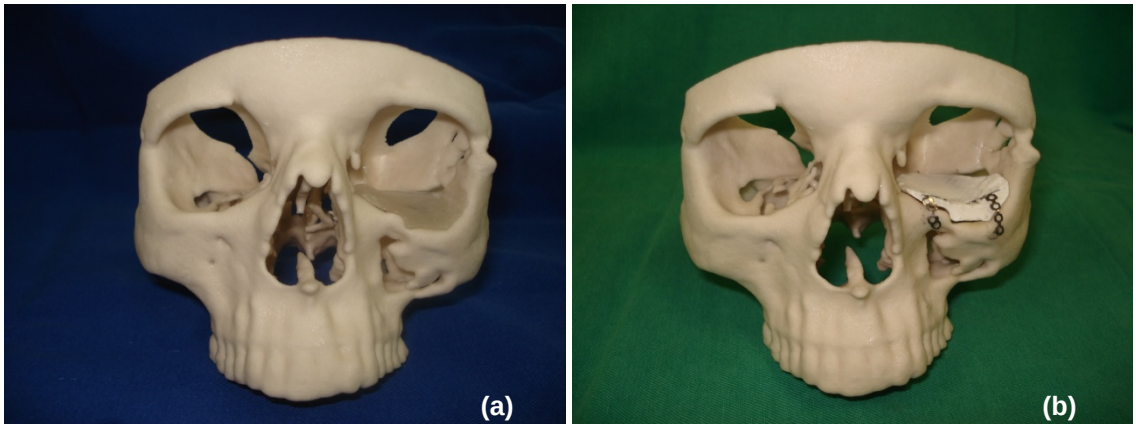


Figure 5: Figure 5: Manufacture of custom implant to repair defect in the region of the zygomatic bone. a) Biomodel used for making a model (resin) of the implant. b) Replicated model in calcium phosphate cement, adapted to biomodel.

Alternatively to the production of a molding defect, metal plates may be formed directly on the biomodel. Stoodley, Abbot, and Simpson (1996) use a skull biomodel that was manufactured in nylon using the technology of selective laser sintering (SLS). The model accurately reproduces the prominence in the left supra-orbital region, resulting from the healing of a frontal fracture outside the right position. The flare was removed from the biomodel and a titanium plate is shaped to fit the defect. Patients with fractures in the frontal region also underwent the same technique, succeeding. The positioning of the drain holes and screws and the exact length of the screws can be judged from the biomodel. Figure 6 illustrates a case of using a biomodel as a reference for the formation of a titanium plate for the correction of front bone defects. There are also reports of the use of manual modeling method for shaping wax prototypes of cranial implants (Figure 7), for further manufacture through casting (Maji et al., 2008).

Figure 6: Biomodel of the patient used as template for the conformation of a titanium plate to fit the defect. Source: Meurer (2003).

Figure 7: Prototype of the cranial implant manually modeled in wax. Source: Maji et al. (2008).

Although the method using manual modeling looks easy and proves suitable for many clinical situations, it has several limitations. Any change in the model can be permanent, which leaves little margin for error. The final result of manually altered model is highly dependent on manual skills of the professional, and might not be reliable.

Another approach is the use of acrylic or similar material, preoperatively, to create a model implant to serve as a guide so that, during surgery, the surgeon uses it to adjust the bone graft. This is especially appropriate when the graft requires a complex geometry. The surgeon can minimize the surgical time by preoperative molding of acrylic, in the exact form, using the biomodel as a guide (D'Urso, 2005).

3.4.2 Manufacture of prostheses through virtual modeling

In the traditional method, the biomodel is produced is then manually modified, cut, and sculptured to become symmetrical. However, a method has recently been developed, which uses virtual modeling and also, in which reconstruction precedes prototyping. Computational techniques are used to reconstruct the desired structures. In this method, the design of customized implants is developed in a virtual environment to eliminate frequent errors caused by the combined use of physical and virtual models. Moreover, a computer analysis of the implant can be designed to check the mechanical stability and a quality control system can also be established.

Engineering Assisted Surgery, as described by Lohfeld et al. (2007), is a new area of research now accepted internationally for healthcare institutions and defined as "application of engineering and manufacturing technologies in the delivery of healthcare." The EAS processes include conversion of CT scans and potentially MRI,

additive manufacturing, 3D CAD, robotics, reverse engineering, and finite element analysis (FEA), with the goal of improving surgical procedures. For medical applications, the use of EAS provided an improvement in services offered to patients through developments in areas such as 3D visualization of anatomical parts, surgical planning, design, and manufacturing of prosthetic implants (D'Urso and Redmond, 2000; Chelule, Coole, and Cheshire, 2000 Lethaus et al., 2011).

The design of custom implants for repair of defects in the region of the face and skull can also be accomplished through use of virtual reality environment and haptic devices (Figure 8), which assist the design of complex shapes. This technology allows the designer to have a sense of touch through tactile feedback provided by the haptic interface, allowing the user to have a sense of where the virtual 3D models that are being manipulated are. . Such feedback is in the form of a force in the opposite direction to the force exerted by the user along the axes x, y and z. Haptic interfaces can be used to simulate operations and actions as deformations and cuts. The three-dimensional haptic devices can be used in applications such as simulation of complex surgical procedures and the training of inexperienced surgeons. Furthermore, using haptic devices, designers can freehand model, using tools to cut, carve and deform a virtual simulated block of clay on the mesh, exploring the feedback, both tactile and visual. Thus, some stages of design of custom implants are facilitated by reducing the time required for modeling the implants bypassing some limitations in handling complex shapes experienced in CAD systems. This molding process is based on voxels, the 3D equivalent of pixels. The depiction of the geometry can be seen as a 3D extrapolation of binary images in space. In such a design process, as reported by Mazzoli et al. (2009), the designer models a virtual implant that fits precisely to the bone defect, stemmed from CT scans of the patient (Figure 9). Moreover, the force feedback adds tactile sensitivity, allowing the "sculptor" to feel virtual surfaces of both the defect and the implant model, key features in 3D modeling.

Figure 8: Phantom Omni haptic device, from the company SensAble, which causes a tactile feedback to the user.

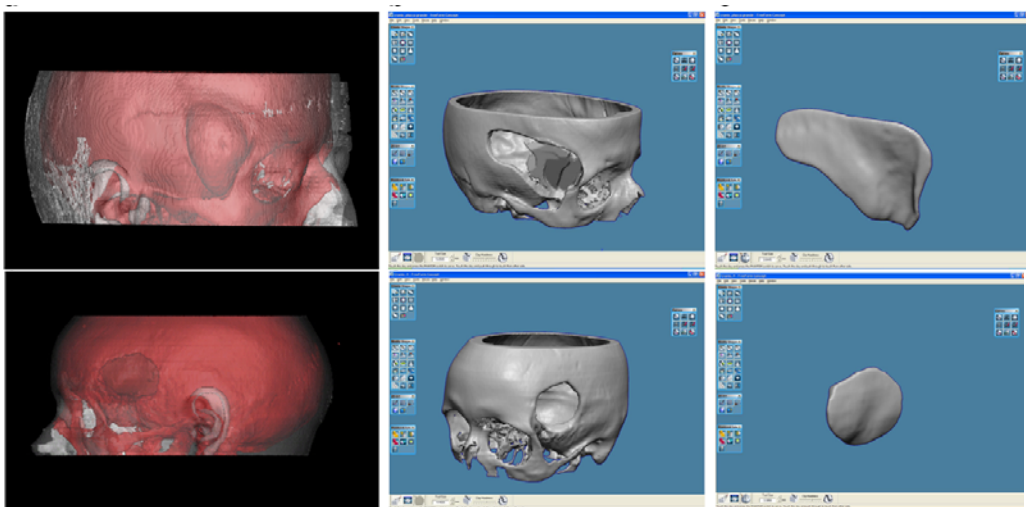


Figure 9: Cases studied by Mazzoli et al. (2009) and their respective modeled implants with haptic system.

Popovic et al. (2003) report the development of a technique that integrates the entire surgical process, from planning and manufacturing of customized implants, robotic programming option, to intra-operative navigation and robotic-assisted execution. The study is especially related to manipulating 3D geometric data of the cranium to planning and setting of craniotomy. Besides aesthetic aspects, we try to achieve the reduction of risks to the patient, reducing operation time and recovery, as well as treatment costs. The process starts with computer assisted design, identification of the tumor and planning of access, and removal of the region, using data from CT and MRI along with volumetric digital models. The results of planning are transferred to a CAM system (Figure 10) for the manufacturing of customized implants, as well as computer systems for intra-operative navigation and robotic execution.

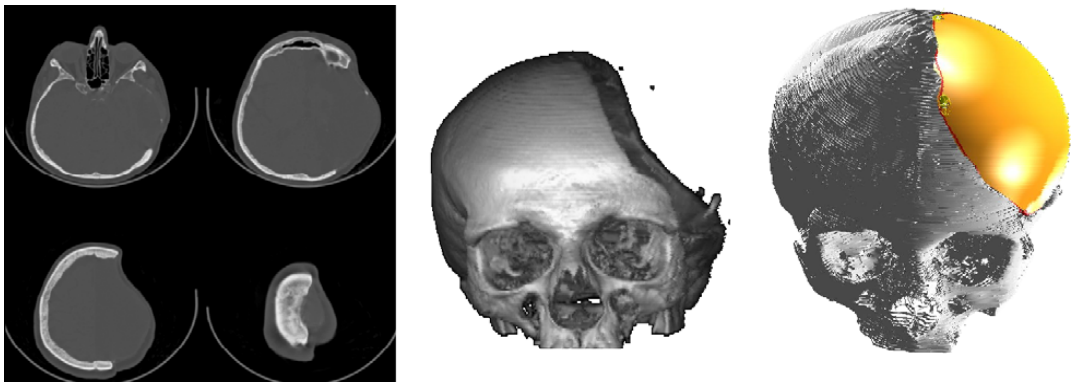


Figure 10: Design of the implant performed in virtual environment. Reconstruction of cranial defect planned from CT images, manipulated in CAD environment. Source: Adapted from Wehmöller et al. (2003).

Lethaus et al. (2011) report the design and manufacture of implants for large skull defects using virtual biomodels in CAD/CAM environment. The skull bone defects were repaired in this study using custom prosthesis in titanium or polyether-ether-ketone (PEEK), produced through CNC machining (Figure 11).

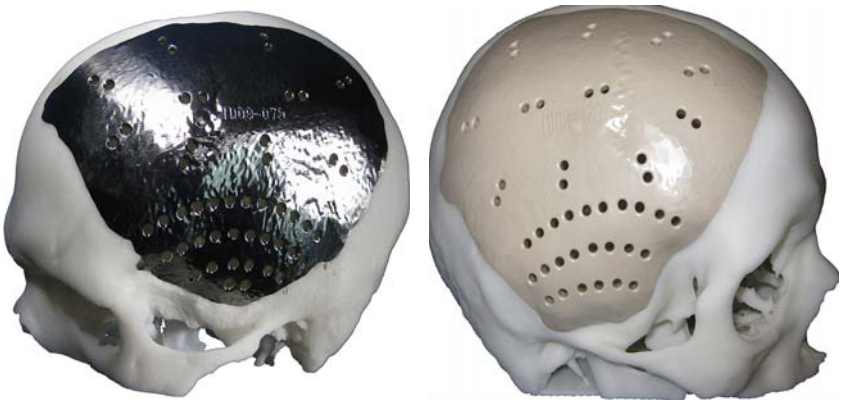


Figure 11: Custom prosthesis for reconstruction of cranial defects, modeled in CAD and manufactured through CNC machining.

New applications and prospects are seen in the areas of biomechanics for the implantation of bone structures. Using the direct manufacturing process such as laser sintering, titanium implants may be produced in unusual geometry, as described by Wehmöller (2005). Complex geometries and structures demonstrate the possibilities of this new technology, which in the close future will help in the revolution not only the geometric configuration, but also reduce the cost and time of manufacture of permanent metallic implants.

Wong et al. (2005) report a comparison between methods using manual and

virtual modeling. Both methods proved effective in surgical reconstruction of facial asymmetry for selected cases. The manual modeling method is preferred where backbones are already deformed, or when the reconstruction involves also soft tissues. In technical aspects, the virtual method was superior because of its versatility, predictability, accuracy, objectivity and convenience for data storage and documentation.

The virtual method, however, has some limitations. To be widely used, some requirements must be met. There is need for powerful image processing software and qualified professionals, good communication between surgeons and designers should be established, and a database with normal facial structures should be established.

An immediate advantage of the technique it the possibility of manufacturing the prosthesis or implant through an automated process, such as CNC machining, additive manufacturing and incremental forming. Thus, the component is manufactured directly in the material suitable for implantation.

3.4.3 Manufacture of prosthesis through incremental forming

In recent decades, the metal forming industry has been faced with new demands. Among them there is the production of small batches of components of metal sheets, the increasing demand for flexibility of the process and the need to reduce the time to bring the product to the market (Petek et al., 2009). The medical field is certainly one of these cases. The requirements listed are incompatible with the traditional processes of sheet metal forming. As a result, new forming processes, which have no intrinsic costs to traditional equipment has been recently proposed, usually classified as incremental forming processes, which have been developed and optimized in several research groups (Hirt et al, 2004; Jeswiet et al., 2005; Micari, Ambroglio and Filice, 2007; Duflou et al., 2010; Malhotra et al., 2011; Hussain et al., 2009; Hamilton and Jeswiet, 2011; Palumbo and Brandizzi, 2012; Robert et al., 2012).

Single point incremental forming (SPIF) is a process in which a simple geometry tool moves along an arbitrary trajectory over a sheet metal workpiece, fixed in a blank holder (Figure 12). In this way, locally controlled plastic deformations are inserted until

the target geometry is achieved. Unlike other processes, molds and dies are not necessary. It is also known as negative incremental forming process and is illustrated in Figure 13. Therefore, a CNC milling machine can be used to strain the plate plastically, placing the tool into specific path controlled by computer.

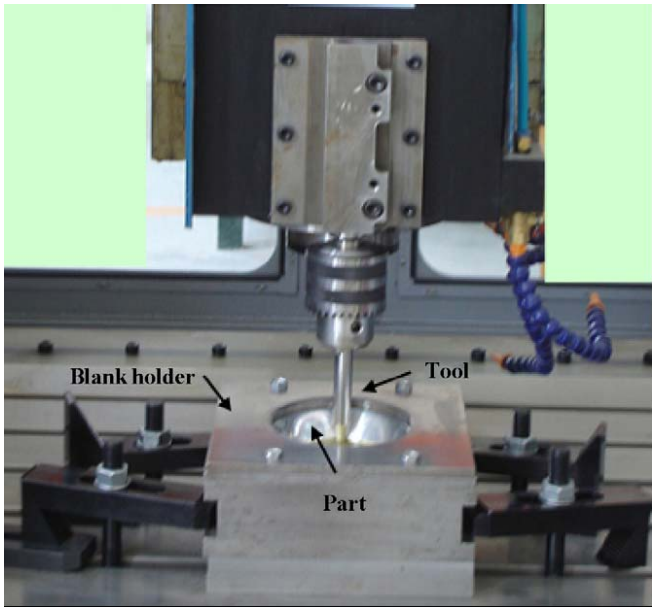
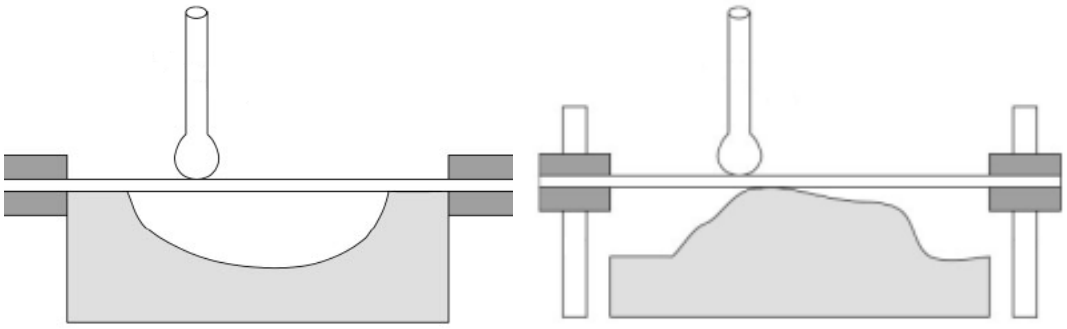


Figure 12: Tooling of the single point incremental forming process (SPIF). Source: Hussain et al. (2007).

Among the different types of incremental forming processes, the one which uses only one contact point is shown as the most advantageous from an economic standpoint because of its simplicity of tooling. Other types of incremental forming processes have been proposed by researchers in recent years. The most widely used can be classified into two categories: the first includes all processes in which a support is used below the plate to guide the deformation inhibiting some degrees of freedom (Figure 13 b). Traditionally, wood structures as well as layers of rubber of high strength were used in different research centers. The second class of processes uses different system deformation. Using more than one punch, for example, it may provide a local deformation with greater control over the rigid movements. Other studies are interested in using a different tool concept, replaced by water jet or pellets by making a kind of mix process between incremental forming and shot peening (Petek et al., 2009).



(a) **(b)**

Figure 13: Different systems used for incremental forming. a) Only one point of contact (SPIF - Single Point Incremental Forming), or process type negative. b) More than one point of contact, or positive incremental forming process. Source: Adapted from Hirt et al., 2004).

A simple tool is used for the product in a continuous movement of the trajectory usually automatically generated in a CAD/CAM system. In this analysis, the tool path starts on the outside of the form and will be moving towards the center and down incrementally in the Z direction, in a kind of spiral. Thus, the tangential motion of the tool forms the plate in accordance with the desired profile. The action of the punch is located in a small region located close to the point of contact. Indeed, a large numerical analysis of the process has shown that due to the progressive action of the punch, the path of deformation of a reference volume of material is characterized for a tendency of steps: each increment of deformation is only caused for the action of the punch during its action. In turn, increase in deformation does not occur when the tool moves back along the same lap, but spaced from the position of interest. This result confirms the idea of "localized deformation", in that any point of the material is not affected for the imposed deformation in the adjacent regions. In other words, the material exhibits its great deformation in small progressive increments.

This aspect results in a strong increase in formability [Kim and Yang (2000), Ambrogio et al. (2003), Shim and Park (2001), Hussain et al. (2009)]. Forming limit curves are higher compared to the curves obtained through traditional sheet metal processes, reaching values 2-3 times greater. Furthermore, the forming limit diagram does not have a curve with the same characteristic shape, but is represented for a straight line with a negative slope in the positive quadrant.

However, at the same time, the particular mechanics of the process introduce

certain disadvantages. Indeed, the zones of the plate where the punch does not act are subject to the presence of rigid motion that, when the force is released, generates undesired elastic return. This can negatively influence the final result in terms of dimensional accuracy and surface roughness. In other words, a large part of the plate is free to bend and therefore the final geometry may be different from what is desired. Discrepancies of a few millimeters are sometimes presented (Bambach, Hirt and Ames, 2004), making the process of incremental forming not so appropriate when aiming to produce very accurate parts. This undesired effect can be reduced using different strategies. For example, properly selecting the process parameters, among them the tool diameter and speed, the tool path and increase vertical, and lubrication highlight.

In summary, it is possible to list some relevant advantages offered through SPIF process as said by Micari et al. (2007):

- Set-up costs are virtually null [Jeswiet et al. (2005)];
- The movement of the tool is controlled by a CNC machine;
- High flexibility of the process to produce a new product. The minimum number of pieces to be considered for a batch is practically one;
- The process can be used for a rapid prototyping of new products, but it is also suitable to produce parts that need to be the reconstructed, for example, automotive components, whose matrices are currently out of service [Amino et al. (2002)];
- The forming limits are greater than typical processes of sheet metal forming. This is due to the favorable state of tensions punch-induced during deformation located.

On the other hand, some drawbacks can be mentioned:

- Incremental forming is a slow process. Indeed, deformation is locally imposed by the punch, which go a long trajectory to form complex geometries. Despite the most modern equipment allows high speed rate, the manufacturing time can reach several minutes;
- The accuracy obtained in the parts is low. Indeed, the plate is simply set

on a blank holder, and is free to bend during the process. However, when the force exerted by the punch is released, the elastic return can be significant.

Considering its great flexibility, the single point incremental forming process appears as a possibility for the manufacture of customized implants for craniofacial reconstruction. Strategic toolpaths are drawn to shape the implant in the desired geometry. In other words, a reverse engineering approach is used to produce a specific implant for the needs of each patient (Figure 14).

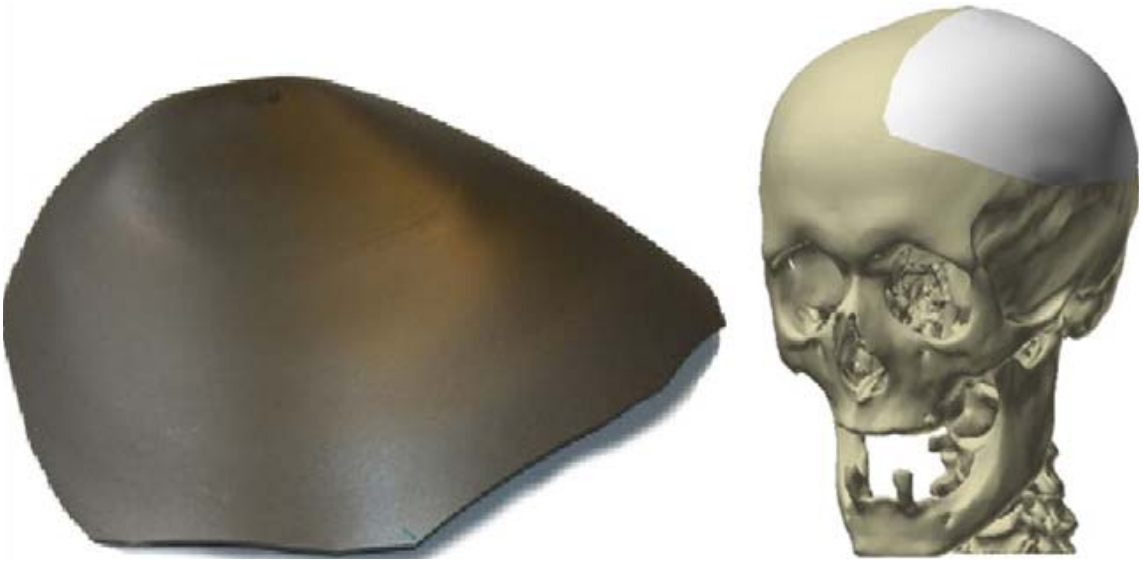


Figure 14: Titanium cranial implant projected in CAD environment and produced through incremental forming. Source: Duflou et al. (2008b).

Important advances for the use of incremental forming applications in the manufactuting of products for the medical field are described by many authors today. Such products have as features to require a high degree of customization without the need of low cost. Ambroglio et al. (2005) describes the fabrication of a customized an ankle support. The "round design", as described by the author, begins and ends in the patient's own body. The ankle of the patient is scanned, and from the scanner output information (point cloud), a virtual model is generated, for subsequent manufacture of an ankle support in the exact dimensions of the patient through incremental forming. Duflou et al. (2008) also shows the possibility of manufacturing customized to cranial implants through incremental forming.

3.4.4 Manufacture of prosthesis through additive manufacturing

Scientific studies of the applications of CAD/CAM systems in medicine and dentistry have been developed over the past 25 years, whose application is frequently associated with CNC machining or additive manufacturing (Bernard and Fischer, 2002; Schöne and Stelzer, 2005). In this case, in most approaches since 2006, it is focused on stents in Co-Cr and titanium alloys.

Additive manufacturing (AM), also commonly called rapid prototyping (RP), rapid manufacturing (RM) or solid freeform fabrication (SFF), allows for the fabrication of complex shapes, such as the forms found in the craniofacial region. Several SFF techniques are currently available, allowing the use of various materials, including metals and ceramics. Specifically for the manufacture of implants, additive manufacturing processes enable the manufacture of components in material suitable for implantation, as already experienced by several researchers (Singare et al., 2004, He et al., 2006; Lohfeld et al., 2007 ; Bertol et al., 2010, Zhou et al., 2010; Mazzoli et al., 2009)

The additive manufacturing processes are characterized for the generation of the component, previously designed in CAD environment, by material deposition, layer by layer. The physical principle that makes the layers overlapping and solidified to form the 3D object varies in additive manufacturing techniques, and is commonly characterized by the action of a laser beam that the melt the particles of powder (SLS, SLM), addition of a liquid which binds the powder particles (3D printing), incidence of light which solidifies a photopolymerizable resin (PolyJet). Among the advantages offered by the additive manufacturing systems compared to conventional methods are a wide variety of materials that can be used, including metals, ceramics and resorbable polymers can be mentioned; flexibility in shapes that can be produced; the potential of producing components of low weight, with optimized geometry and controlled roughness, the biocompatibility and the fact that it is a one-step process, which means no tools or additional steps in the process are required. Additive Manufacturing techniques for the production of implants in the material for suitable for implantation have been proposed to produce different anatomical structures, such as hip, cranium,

zygomatic bone, mandible, etc., illustrated in Figure 15.

Figure 15: Examples of prosthesis manufactured through additive manufacturing. a) Mandible implant, zygoma and intervertebral discs with reticular structure. Source: Rapidtech, 2011. b) Implant for repair of cranial defect in poly-lactic acid (PLA). Source: Fraunhofer Institu für Lasertechnik (ILT). c) Mandible Implant with optimized internal structure and topology. Source: Fraunhofer Geselschaft. d) Prosthesis for repair of cranial defect, in titanium. Source: University Maastricht, Netherlands. e) Replacement implant of knee joint in Co-Cr, with reticular structure. Source: Arcam AB, Sweden. f) Prosthesis for replacement of hip joint in titanium, with a gradient of porosity. Source: Neuner (2008).

3.4.5 Manufacture of prosthesis through three-dimensional laser scanning

Currently, aesthetic, ergonomic quality and product customization aspects are assuming a growing importance in manufacturing industries: a wide variety of products is designed and produced using these concepts. In this scenario, reverse engineering (RE*)* plays a key role since there is often a need to acquire important information for

existing products. RE potentially allows us to reconstruct, in a short process time, the complex geometric shapes known as free forms. Using the approach of reverse engineering, it is possible to create reliable three-dimensional models representing various objects, components, environments, animals and even human parts.

Several applications of reverse engineering techniques are disseminated worldwide in the areas of fine arts (to acquire virtual replicas of unique models), archeology (to rebuild old objects and even manufacture them again), in the industry, to provide models and craft products whose unique designs have been lost. Dentistry, specifically the area dedicated to the manufacture of dental prostheses, currently uses CAD/CAM systems based on three-dimensional laser scanning models. Dental crowns and bridges can be produced in a personalized and automated way from the dental arch molds of the patient and with the aid of a specific CAD/CAM system (Figure 16). The applications of three-dimensional laser scanning are also reported for the areas of health, assistive technology, archeology, jewelry, digital games, among others. Similar systems for the development of personalized products based on data of the digitized patient's body are also being developed, such as the development of custom seats [Smith (2011), Beretta (2011), Batista (2009)].

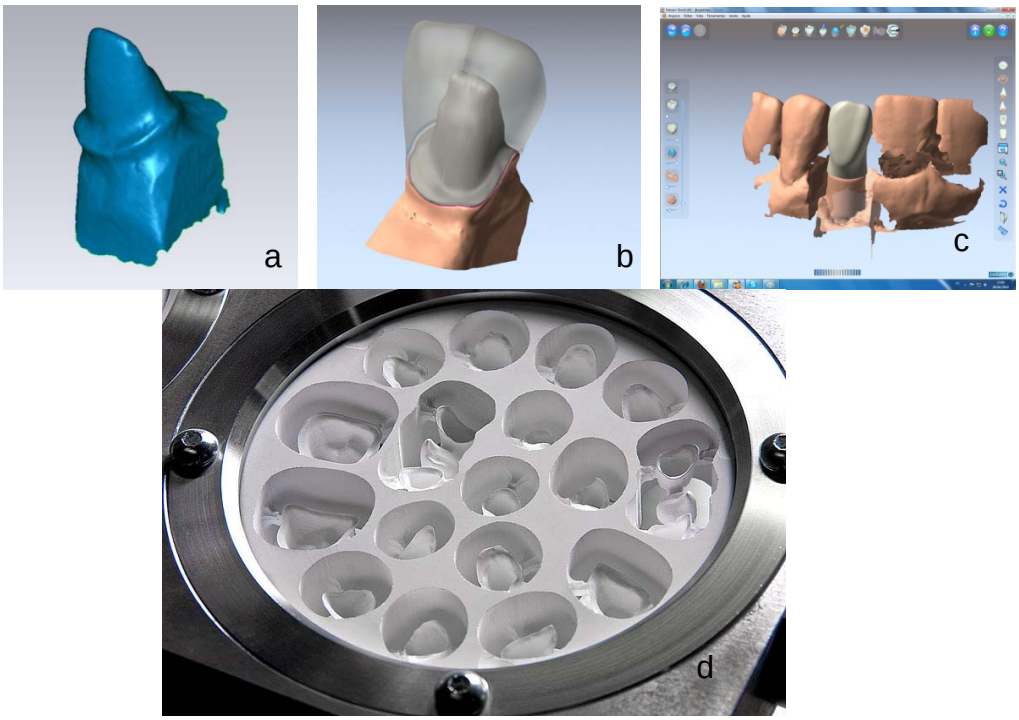


Figure 16: Process of manufacture of dental crowns and bridges based on Reverse Engineering. a) Scanning of the patient's dental mold. b) Part design. c) Visualization of the model projected on the patient's dental arch. d) CNC milling of zirconia parts.

In an analogous way to the manufacture of prosthesis using manual modeling, the method that uses the technique of dimensional laser scanning uses a physical model of a patient's skull, which acts as a template for manual modeling. A representative model of the prosthesis to be formed using a material suitable for shaping. Dental waxes, resins and polymeric plastic masses are among these materials.

After determining the area to be reconstructed and the geometry of the implant, the three-dimensional laser scanning of the part to be shaped is held. It should be noted that the model formed using physical biomodels must fit perfectly to the patient's bone structure, since it will be replicated in the material suitable for implantation.

The three-dimensional scan captures information from an existing physical model, generating three-dimensional information that can be exported to a CAD program, or directly to a prototyping device. This digital file that corresponds to a three-dimensional model to be manufactured implant is manipulable in a CAD environment and can easily communicate with CAM systems, allowing for manufacture of an automated manner. Different processes of manufacturing can be used such as CNC or additive manufacturing. Both processes can be performed directly with the material suitable for implantation.

The production of prosthesis for replacement of the temporomandibular joint (TMJ) has used the technique of three-dimensional laser scanning to capture data for the design and manufacture of custom components, as shown in Figure 17. The process consists basically of the CT scan of the patient, making an anatomical model of the bones of the patient through rapid prototyping. The model represents exactly the patient's bone structure, which allows for simulation of the regions of the mandible and/or joint that should be modified. The prototype of the prosthesis is manually patterned with the aid of resin or plastic masses and is subjected to three-dimensional scanning. This process allows the geometric data of the prosthesis to be saved in digital format, which allows its manufacturing through automated techniques such as CNC machining or additive manufacturing. As a result a prosthesis which fits precisely to the patient's bone structure is created.

Figure 17: Manufacture of custom TMJ prosthesis. a) CT scan of the patient. b) Anatomical biomodel showing the removal of region to be replaced. c) Prosthesis prototype. d) Scanning of the components of the prototype. e) Virtual model. f) Final prosthesis, manufactured through CNC milling.

3.5 Quality in orthopedic implants

Orthopedic implants and their quality are evaluated, in general, by factors such as the concept of the implant (function to be performed, patient characteristics, fixation technique to be used) design (dynamic evolutionary process, anatomical studies, distribution of load characteristics of the materials used, such as ductility, toughness, fatigue resistance, etc.). sterilization technique, the component characteristics and instrumentation (anatomical references, accuracy, testing, reliability, ergonomics, care and cleaning agents); control quality (raw materials, manufacturing processes, production processes, recording, packaging, sterilization, labeling, storage, transport) and R&D (accumulated knowledge, clinical experience/publications, records, risk analysis, study of failures, investments).

There are some causes that can lead to failure in orthopedic implants. Such failures may come from three different origins: the surgical technique, the patient or the implant itself. The wrong choice of technique, as well as its inadequate implementation are factors that can lead to implant failure and treatment failure. Factors such as osteoporosis, obesity, excess or lack of physical activity and incompatibility of the implant materials are assigned to the patient as possible causes of failure. The implant itself fails mainly due to the mechanical aspects, design errors,

fixing problems or sterilization.

Orthopedic implants are regulated by agencies and institutions that are responsible nationally and internationally. Internationally accepted standards are especially dictated by the Foods and Drug Administration (FDA), International Standards Organization (ISO), ASTM (American Society for Testing Materials (ASTM), Deutsches Institut für Normung (DIN), American National Standards Institute (ANSI), among others. In Brazil, orthopedic implants and their necessary quality requirements are regulated by Agência Nacional de Vigilância Sanitária (Anvisa).

Some important standards that deal with quality in orthopedic implants may be cited: ASTM F1440 (mechanical testing), ASTM F380 (passivation), ASTM F967.01 (passivation after laser recording), ASTM 138 (stainless steel), ASTM F74 (Co-Cr cast alloys), ASTM F67 (pure titanium), ASTM F136, F620 and F1108 (Ti-6Al-4V alloys), ASTM F648 (polyethylene, ultra high molecular weight), ASTM F799 (Co-Cr forged alloys), ASTM F603 (alumina heads for joints), ASTM F1185 (hydroxyapatite), ASTM D4169 (tests for packaging and transport), ASTM D4329 (UV packaging exposure). Besides these, other rules also regulate aspects such as sterilization, biocompatibility, aging tests, validity tests, standards for project design, environment, etc.

4. MATERIALS AND METHODS

The basic idea of this PhD study was to guide the process of design and manufacture of implants to repair defects in the craniofacial complex, avoiding the use of standardized plates and using implants designed and manufactured according to the needs of each patient, with geometry, accuracy and mechanical properties suitable for each case. The implants were produced using different design and manufacturing processes.

Reverse engineering was used in order to produce such custom implants for the reconstruction of human craniofacial bone structures. These products were chosen for two main reasons:

- require a high degree of customization
- the manufacturing process used is flexible

Initially it is necessary to make a distinction of different types of craniofacial implants that may be required to repair the craniofacial defects. These implants are located in different regions of the craniofacial complex and differ among themselves in terms of functions and geometric complexity. These characteristics guide and delimit the systematic selection of materials and manufacturing processes, since they require or dispense certain formal and mechanical requirements, and in turn, limit the selection to a few materials and manufacturing processes.

This study addressed five types of craniofacial defects with indication for customized implants, which might have different geometry and mechanical characteristics. The studied bone defects are located in distinct regions of the craniofacial complex with indication for alloplastic replacement.

The process involved the following steps, illustrated in Figure 18: acquisition of anatomical data through computed tomography, tomographic data manipulation; generation of a virtual or physical biomodel; modeling of the missing surface – implant; characterization of the implant to be produced in terms of geometric and mechanical requirements; selection of materials and manufacturing processes; manufacture of the implant; evaluation of produced implant.

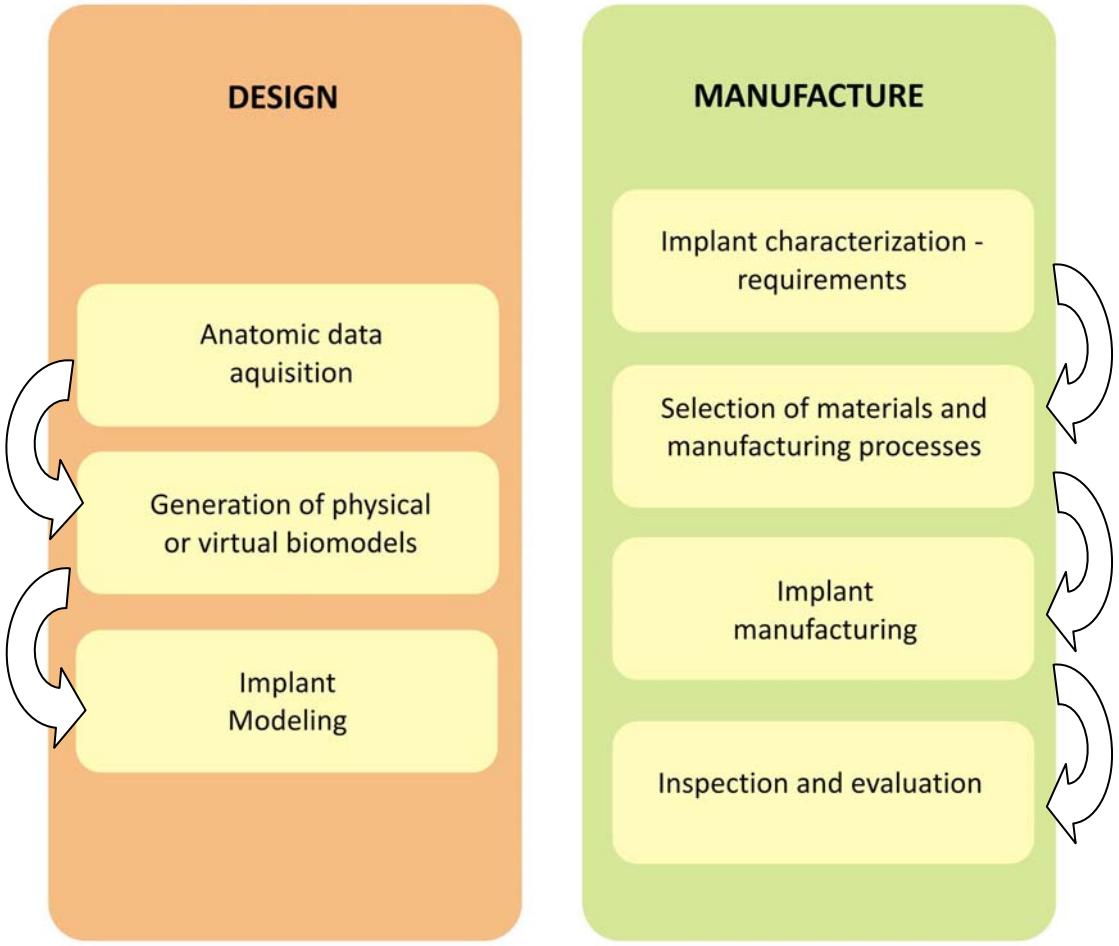


Figure 18: Steps involved in the project and manufacture of custom craniofacial implants covered in this study.

4.1 Design of implants

4.1.1 Characterization of the type of implant

The implant types selected for evaluation in this study are different from one another in terms of geometrical, mechanical and functional characteristics. For the design and manufacture of implants, five different regions of the craniofacial complex that are typically subjected to bone reconstruction surgeries were selected. There were selected regions with different degrees geometrical complexity and pronounced curvature, volumetric and articular regions, changing between each one, the degree of difficulty and complexity to the production of implants.

4.1.2 Acquisition of anatomical data of patients

The acquisition of anatomical data of cases of surgical indication for craniofacial reconstruction was performed using CT scans. The output files are images in DICOM format, corresponding to the transversal slices of the examined region. For the results of CT to be used in subsequent steps of the design and manufacturing of implants, some parameters were followed, according to Table 2.

Table 2: Requirements used to obtain tomographic data.

Matrix	**512x512**
Field of view	**Between 140 and 170mm**
Slice distance	**1.0mm**

4.1.3 Manipulation of tomographic data

Using InVesalius software version 3.0, DICOM images from CT scans were transformed into three-dimensional models. Thresholds were defined to exclude soft tissues and selection of densities corresponding to bone tissue. Next, the surfaces corresponding to the bone structure were generated and converted into STL format. The objective of converting the file to STL mesh format is the possibility to manipulate the file in other CAD, CAM and CAE commercial softwares, allowing the design of implants in the virtual environment and making a physical replica of the model through additive manufacturing.

4.1.4 Manufacture of biomodels

Physical anatomical models corresponding to the bone structure of patients were built using additive manufacturing processes. The STL files were converted into files corresponding to a series of transverse slices of the model, allowing the physical reconstruction of the models, layer by layer.

4.1.5 Modeling of the implants

The modeling of the implants was performed using computer

modeling software widely used in Product Design and Reverse Engineering. Among them there are the 3D Studio Max®, Rhinoceros®, Solidworks® and Raindrop Geomagic Studio®. The implants were designed in order to reconstruct the region of the skull and/or the patient's face that presented a bone defect.

The modeling of three-dimensional structures and patterns that add functionality to the implant was also assessed. The possibility of building internal structures of regular pattern in order to provide weight reduction and to stimulate the adjustment of the implant to the bone structure, as well as osteointegration, has been investigated.

4.1.6 Selection of materials and manufacturing processes

For each type of implant studied, materials and manufacturing processes were selected so that the produced implant could adequately meet the project requirements, whether they were formal, mechanical, or functional. Single point incremental forming (SPIF), CNC machining, additive manufacturing and modeling guide were evaluate as possible manufacturing processes. Each of the processes enables or restricts the use of certain materials which have, therefore, been selected. The requirement of biocompatibility of the material to be used to manufacture the implant was observed in all cases.

4.1.7 Characterization of the material

The implants were produced using commercially pure titanium sheets grade 2, 1mm thick. Prior to the production of implants, the characterization of the material was performed in terms of chemical composition and mechanical properties. For metallographic analysis, samples were taken in the transverse and longitudinal direction of the sheet. The analysis was used to evaluate the grain size and phases present in the material.

The analysis of the chemical composition was also carried out, verifying compliance with the standard 5832-2. The element Fe was determined by optical emission spectrometry with inductively coupled plasma, Vista model, Varian

brand. Carbon was determined by direct combustion in equipment Leco CS-444, while the oxygen and nitrogen were determined by absorption of infrared radiation and differential thermoconductivity, respectively, in device TC-436 Leco DR. Hydrogen was determined by difference of thermoconductivity, by equipment Leco HR-402

The titanium sheets used for the SPIF tests were characterized by metallographic analysis, tensile tests and bending tests based on NBR ISO 5832-2 (Characterization of material for surgical implants. Part 2: Pure titanium). Three specimens of 1 mm were subjected to tensile testing, three to the bend testing and a metallographic analysis to evaluate the microstructure and grain size.

The bending test was conducted based on ISO 7438:2005 (Figure 19, left) where three testing specimens in the same machine with 80 mm long, 10mm wide and 1 mm thickness were tested in the same testing machine before. The device was assembled based on Figure 19 , where the samples were folded at least 105 ° (α) in a 4 mm diameter mandrel (Figure 19, right) and with a distance between the supports (l) of 7.5 mm.

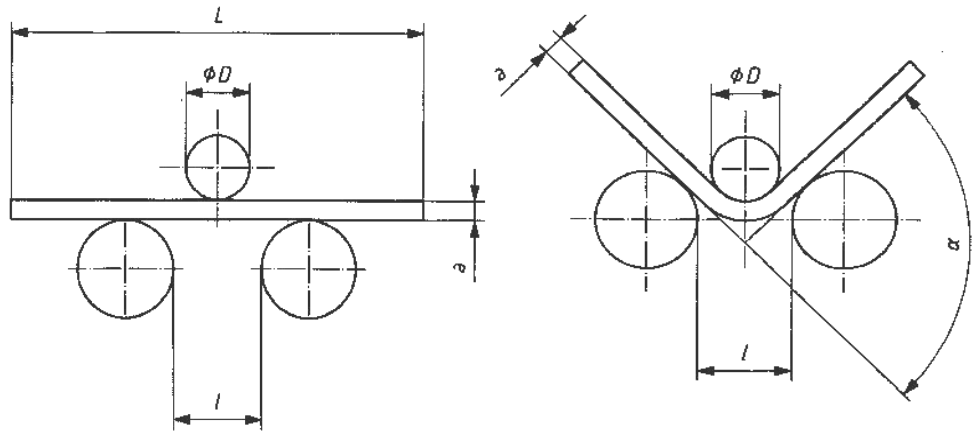


Figure 19: Schematic figure of the device mounting used for the bending test.

One of the tests used to determine a Forming Limit Curve (FLC) of the material is Nakajima. This test consists basically in stretching the specimens with different widths, keeping the other parameters constant. For the test, a clamping system and a punch are used. The specimens are fixed in the blank holder, and then the punch is forced into the specimen causing the stretch. If the force used to restrain the specimen

is insufficient, it seeps into the die, if it exceeds, it breaks. Eight test specimens were subjected to deformation by a punch to their rupture (Figure 20). The deformations were measured to the generation of FLC of the material.

Figure 20: Testing specimens submitted to a forming test to determine the Forming Limit Curve of the material.

FLC is a graph of the main deformation greater at the beginning of necking plotted for all values of the minimum main strain that can be supported. A typical curve for the steel can be seen in Figure 21.

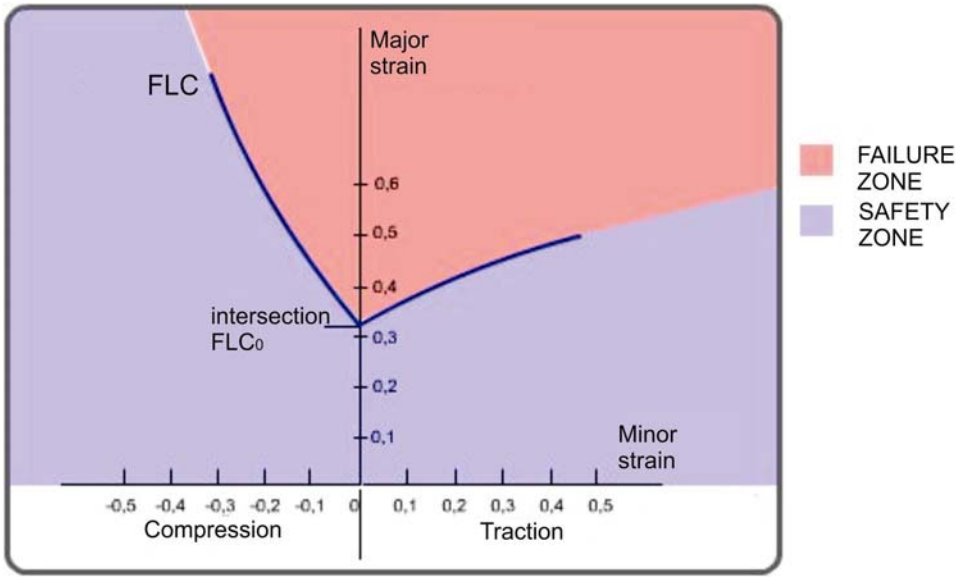


Figure 21: Example of forming limit curve (FLC).

Assuming that the curve represents the values of possible combinations of deformation of the specimen that indicate signs of early rupture, the curve can be interpreted as a boundary between regions of failure and safety. The region above the

curve is the region of failure or breakage. The region below the curve represents the safe region.

Furthermore, tests were performed on standard test specimens for determination of parameters which determine the limits for shaping the implant through SPIF. For this, a CNC machining equipment Tecnodrill Digimill 3D was used, belonging to the Laboratory of Design and Materials Selection (LdSM) from the Federal University of Rio Grande do Sul (UFRGS).

Besides titanium, implants were also produced using calcium phosphate cement. The bone cement used (α-TCP) was obtained using calcium carbonate as precursors ($CaCO_3$) - average particle size of 3.4 μm - and calcium pyrophosphate (Ca_2P2O_7-γ) - average particle size of 9.54 μm - that passed through stages of thermal treatment (calcination at 1300°C for approximately 15 hours and quenching of precursors), grinding (to obtain an average particle size of 850 μm) and dried (oven at 90° C for 72 hours). The solid part was mixed with the liquid part, which is an aqueous solution of Na_2HPO_4 to 2.5%.

4.2 Manufacture of implants

The designed implants were manufactured through one or more manufacturing processes that were considered appropriate. For all implants studied, the possibility of using the SPIF process for each case was evaluated and discussed. Parameters necessary for the process used to allow the manufacturing of every particular type of implant were studied and discussed.

4.2.1 Determination of the parameters of single point incremental forming

In this study, the process parameters were investigated in a systematic way for single point incremental forming of titanium sheets, aiming their application as implants for craniofacial reconstruction. SPIF tests with varied parameters were conducted in commercially pure titanium grade 2, 1mm thick plates. The tests intended to simulate different conditions and material stress for each mode, detect the various deformations which lead to fracture. For the lubrication system

molybdenum disulfide powder Z Molykote® was used.

A strategy similar to milling was used for computer-assisted manufacturing of implants. The programs determine the path that the tool will take to give the plate the desired shape. To determine the forming limits of the material through SPIF, geometries were formed into a cone shape, a diameter of 50mm, varying the forming angle to the material rupture. EdgeCAM Software® (Planit Software Ltd.) was used for the generation of strategies. The parameters used for the SPIF are summarized in Table 3.

Table 3: Forming parameters used for the tests.

Feedrate	1000mm/min
Plunge feedrate	800mm/min
Cusp height	0.01mm
Stepover	5%
Tool diameter	8 mm
Spindle	Tool free
Sheet thickness	1mm

Using the generated strategies, different geometries were formed. A clamping system of 200x200mm area was designed to fix the plate during the manufacturing process to be plastically deformed. Tools with a spherical tip were used as punch, locally pushing the plate according to the specified trajectory and parameters. HSS 10% Co tools were used, with 8mm diameter. The process was conducted in Tecnodrill Digimill 3D CNC machine. The tooling can be seen in Figure 22. It shall be noted that the process of forming the plate is fully automated.

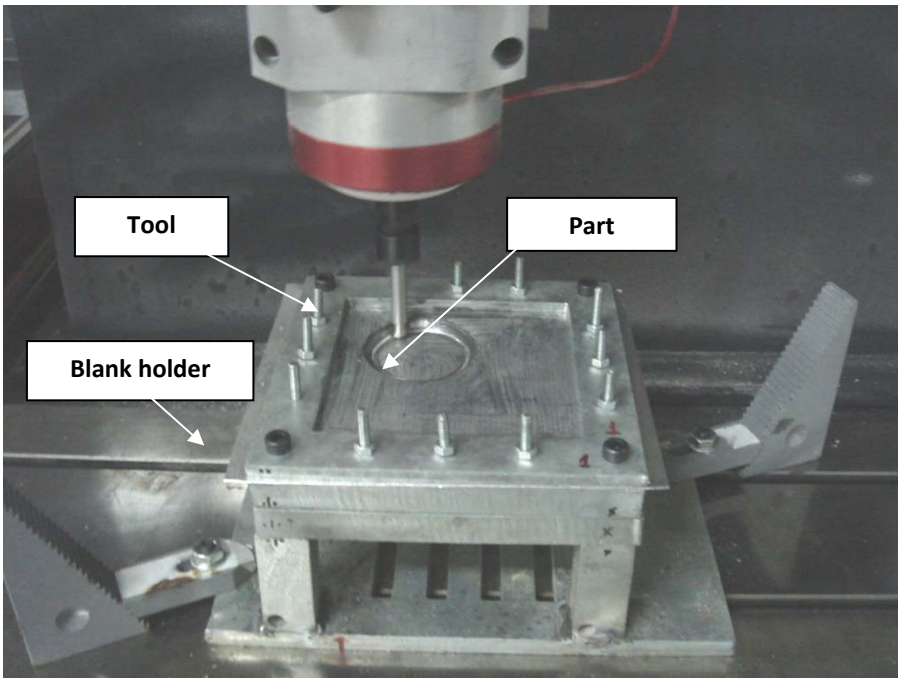


Figure 22: Tooling of the single point incremental forming process.

To enable the measurement of the deformation caused by the process, the plates were previously marked with circles of diameter defined by the electrochemical etching (Figure 23), performed with equipment belonging to the Metal Forming Laboratory (LdTM/UFRGS). To measure the deformations generated in the SPIF of the different specimens, a particular, flexible, transparent and graduated scale with deformations for the circular grating of 2.5 mm in diameter (Figure 24) was used. Thus, the strain values were read directly from the scale. Such scale, for being flexible, follows the shape of the testing specimen and its transparency allows the visualization of the mesh lines. For the measurement, the scale was overlaid on the ellipse to be measured and a reading was taken when the degree of transverse lines was over the axis that was being measured and the longitudinal lines of graduation were overlapped on the contour lines as the ellipse. The points were plotted on the measured strain limit graph, where ϕ_1 (major strain) corresponds to the axis of ordinates and ϕ_2 (minor strain) corresponds to the axis of abscissas.

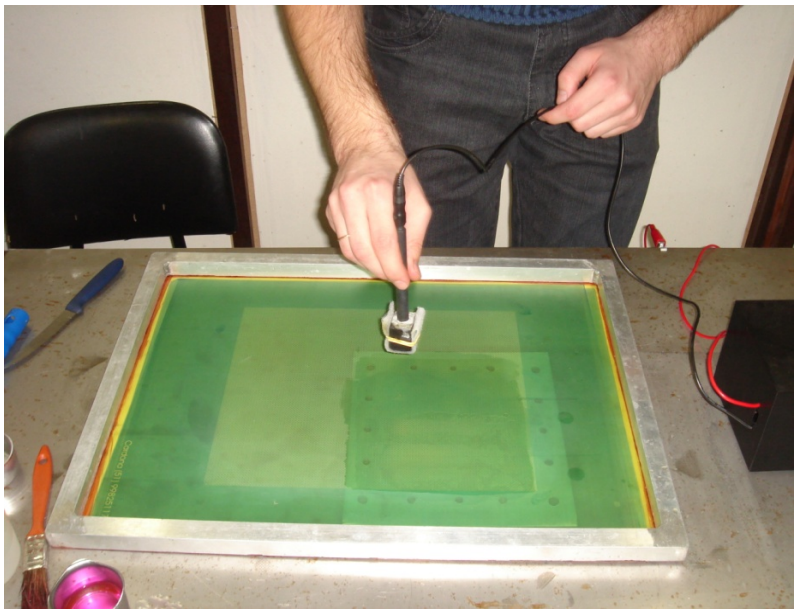


Figure 23: Device used for electrochemical etching of the circles grid on the metal plate.

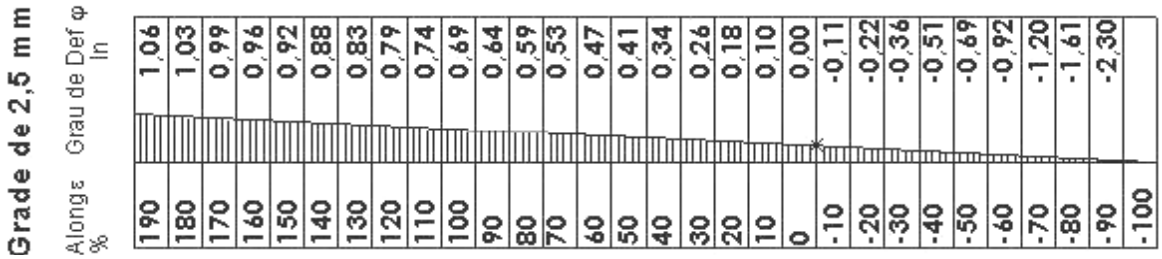


Figure 24: Graduated scale used for the measurement of deformations.

Furthermore, the temperature reached was monitored by the tool and by the plate during the SPIF, using the technique of thermography. The equipment used for the analysis was the Infrared thermography SAT, SAT-PHY6800, belonging to the Laboratory of Ceramic Materials (Lacer/UFRGS).

4.2.2 Dimensional inspection

In the case of production of customized implants, as well as in applications in which the fitting to other parts is necessary, the dimensional inspection gives a significant response over the performance of the process. To analyze the dimensional accuracy of the process the technique of three-dimensional laser scanner was used (Tecnodrill Digimill 3D). A comparison between the dimensions of manufactured parts and the designed parts, developed in a CAD environment was made. To this purpose,

the files resulting from scanning of formed parts and the virtual representations of the designed parts are overlapped, and the differences between them are measured. . Using the three-dimensional laser scanning the change in thickness experienced by the sheet during the forming process was also assessed.

The implants produced were evaluated according to the attendance or absence of formal, mechanical and functional requirements. The manufacturing process used was evaluated in terms of:

- **precision,** evaluated through the three dimensional laser scanning and/or adaptation of the implant to the patient's biomodel;
- **time** required to the execution of the various steps involved (set up of the equipment, manufacture, post-processing);
- **difficulties** encountered in the various steps involved (set up of the equipment, manufacture, post-processing);
- **cost,** also considering the level of technical skills of the operators involved and equipment needed.

In this sense, with the evaluation of the strengths and limitations of manufacturing processes studied, appropriate conditions for the development of criteria for the choice of manufacturing process (and, consequently, of the materials) for each case of manufacturing of customized implants in the craniofacial complex are created.

5. RESULTS AND DISCUSSION

5.1 Characterization of the types of implants

For the design and manufacture of implants, regions with different geometrical characteristics and different functional requirements were selected. As shown in Figure 25, they are located in distinct regions of the craniofacial complex:

- Defect in the parietal or frontal region (a);
- Defect in the frontal region of the skull, including the supra-orbital region (b);
- Defect in the region of the zygomatic bone (c);
- Defect in the region of mandible ramus (d);
- Defect in the temporomandibular joint (e).

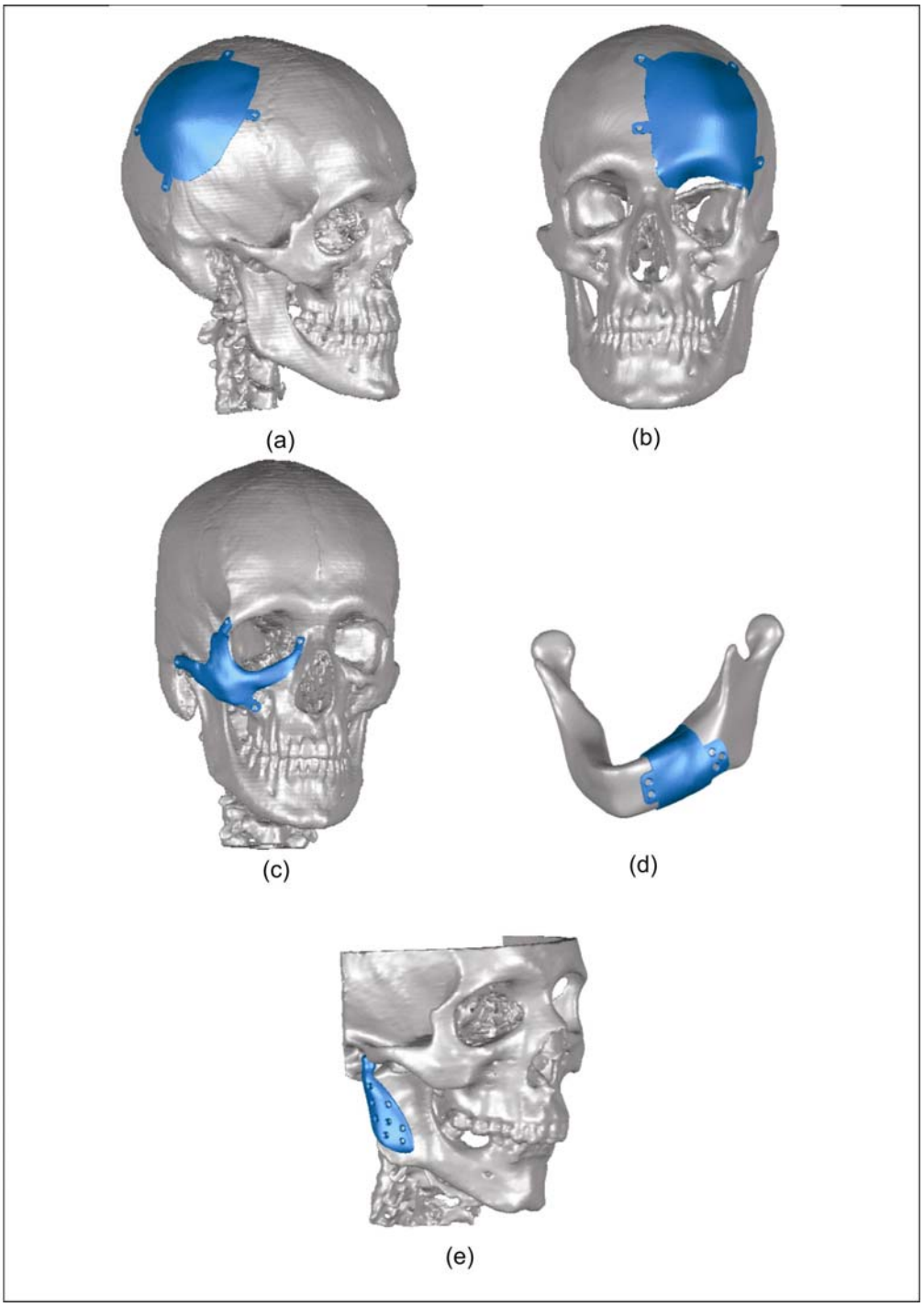


Figure 25: Different studied implant geometries.

5.1 Characterization of the material

Through the tensile and bending tests performed, the properties shown in Table 4 were determined and compared with the properties specified by the standard NBR ISO 5832-2.

Table 4: Results of tensile and bending tests.

Grade	Condition	Tensile strength [1] min. MPa	Yield strength min. MPa	Elongation [2] min. %	Mandrel diameter for bending test of strips [3] mm
2	Annealed	345	275	20	
RESULTS	Sample 1 1 mm	467	356	42	Did not crack
	Sample 2 1 mm	470	347	40	Did not crack
	Sample 3 1 mm	468	352	38	Did not crack
	Average	468	352	40	Did not crack

1) requirements for tesile, yielding and bending strength that plates shall apply to materials obtained longitudinally and transversely to the rolling direction.
2) Length of calibration = 5.65 mm or 50 √ S0, where S0 is the original area of cross section in square millimeters.
3) t = the thickness of the sheet or strip ≤ 2 mm

Findings through metallographic analysis demonstrate that the sample showed typical microstructure of pure titanium, with the average grain size ASTM 9, as shown in Figure 26. The tensile properties are in accordance with those specified in the standard for titanium grade 2.

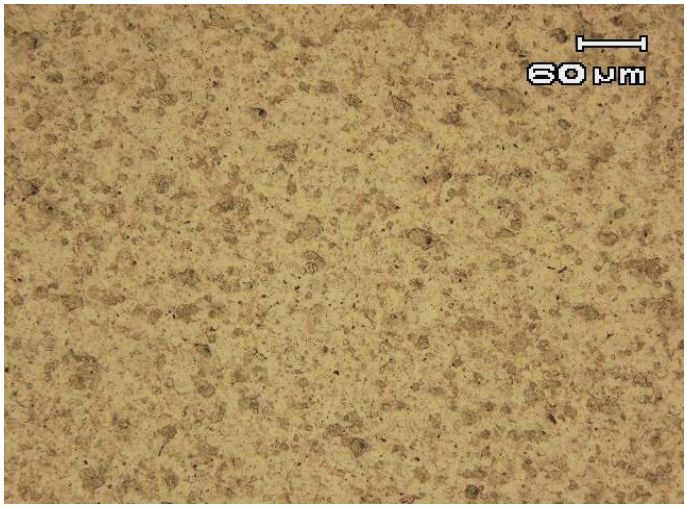


Figure 26: Metallographic analysis of titanium samples, showing equiaxed microstructure.

Table 5 shows the results obtained and the comparison to the requirement of the standard ISO 5832-2 to evaluate the chemical composition.

Table 5: Chemical composition of the plates.

Element	Pure titanium sheet grade 2 Thickness: 1mm % (m/m)	Specification Norma NBR ISO 5832-2 Grade 2 % (m/m)
Fe	0.08	0,30 max.
C	0.023	0,10 max.
O	0.104	0,25 max.
N	0.008	0,03 max.
H	0.0014	0,0125 max

A test was also performed to determine the forming limit curve (FLC) of the used plates of titanium. Using the markings etched on the plates, transverse and longitudinal strains to determine the FLC (Figure 27) were measured.

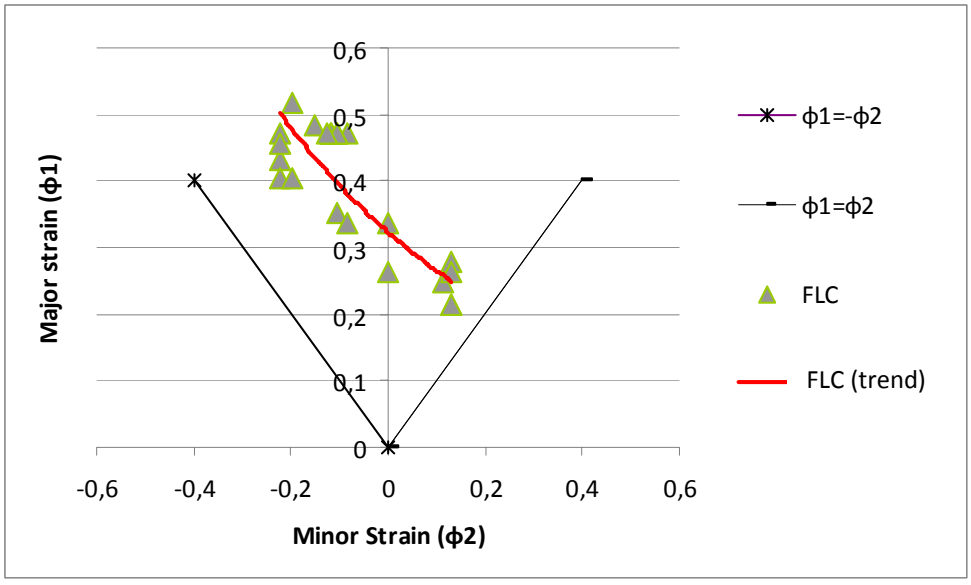


Figure 27: Forming Limit Curve of the titanium plates.

The FLC is particularly important because it determines, for conventional sheet metal forming processes, safe levels of deformation which can be imposed on the material. According to Folle et al. (2008), the factors that affect the forming limit curve for a given metal sheet are the thickness, the friction, the rolling direction, the anisotropy, the pre-deformation, grain size, the strain hardening and the punch speed. The effects on the curve, caused by each of these factors, are shown in Table 6.

Table 6: Influence of different parameters on the forming limit curve (FLC).

PARAMETER	EFFECT ON FLC
Sheet thickness	The increase in thickness causes greater deformation, ie, the curve moves upwards
Friction	The smaller the coefficient of friction, greater will be the deformations and the curve moves upwards
Rolling direction	Specimens cutted in the rolling direction present greater deformations and the curve moves upwards
Pre-deformation	Tractive pre-deformations: FLC moves down Compressive pre-deformation: FLC moves upwards
Grain size	The smaller the grain size, the curve is positioned upwards
Strain hardening	The smaller the strain hardening, the curve is positioned upwards
Punch speed	The smaller the speed, greater is the capacity of the material to be deformed: FLC upwards

5.2 Determination of parameters of the single point incremental forming

The single point incremental forming of cone specimens allowed the measurement of permitted and critic levels of deformation, where material fracture might occur.

Figure 28 shows the forming limit diagram (FLD) of the titanium sheets. The measures of the strain obtained from different samples and the FLC material are plotted on the graph.

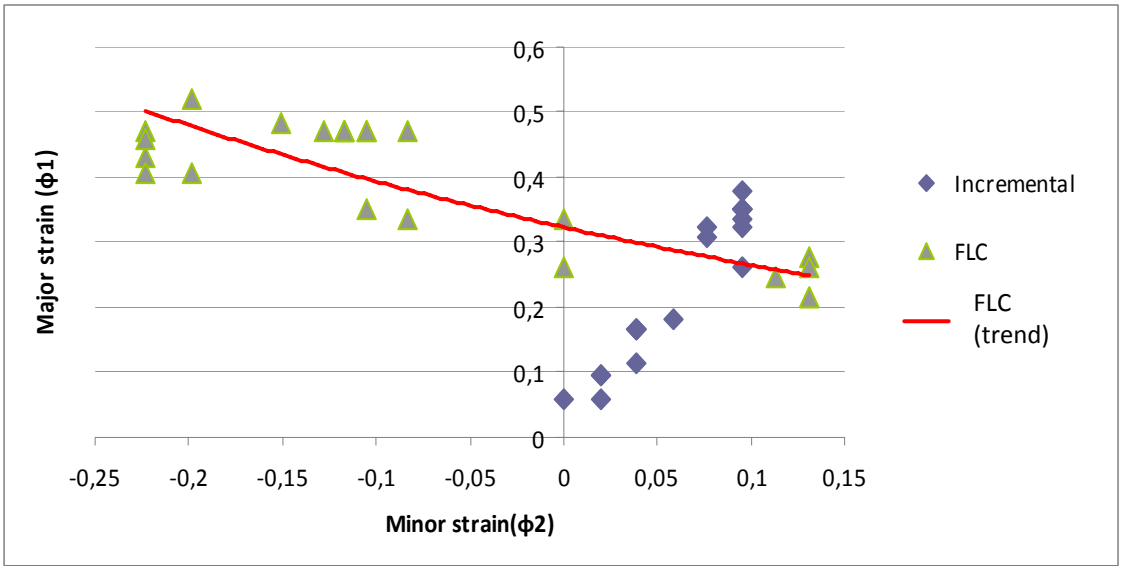


Figure 28: Forming limit diagram of the titanium plates used and strain values obtained for the SPIF tests.

For the SPIF process, however, it is observed that some strain values obtained are above the FLC. This can be explained by the fact that, in SPIF, the material is occasionally pushed in the direction of deformation. Each portion of the material is individually deformed, however, at the end of the process; the tension is applied in the entire area of the plate uniformly. In a conventional sheet metal forming process, the fracture mechanism occurs due to crack propagation, since the force is eventually concentrated in preferential regions, usually in parts of material that are defective or have micro-cracks. For the generated graph, the points that lie below the trend line correspond to deformations of the sheet in regions that were not in their maximum state of deformation. It is noted further that for forming through SPIF the points are in the region of the graph corresponding to positive deformations, which indicates an

increase in area in both the vertical and transversal direction of the deformed region. The increase in area in one direction and consequent reduction of the cross-sectional area, which occurs to the conventional forming process, indicates that there is a necking in the material, so the points are represented in the corresponding negative deformation area in the graph. Such behavior is not observed for the SPIF process.

For the determination of maximum angles that define the forming limits of the material, tests were conducted in specimens in the form of a cone with a diameter of 50mm, with angles of 30, 40, 45, and 50 degrees.

For different measured angles, it was found that the maximum angle to the conformation of titanium through SPIF was 45°. At this angle, the plate has undergone deformation, without showing cracks or micro-cracks (Figure 29). Above this value, the plate has an excessive deformation and decrease in thickness and consequently fails (Figure 30).

Once again using the angle 45°, SPIF was carried out in a larger cone, the apex plane with 120 mm diameter and 55mm height. The maximum amount of deformation measured in this test was 60%. It was observed the breaking of the plate during SPIF (Figure 31); however, the process was continued until its end. The fracture of the material occurred in a region that had 50% elongation, below the maximum shown in other regions of the material. This leads to the need to consider other important factors that affect the formability of the material in the process of SPIF. It is observed that fracture occurs in an intermediate region formed in the profile geometry. In this case, a conical geometry was used, with a flat basis and not pointed, as seen in Figure 29 . Considering that on the upper ends of the cone the plate thickness has its maximum, it decreases along the profile geometry. Upon arriving at the base of the cone, the plate thickness is again at a maximum. This event leads to the conclusion that the material is broken due to excessive reduction of sheet thickness and not due to deformation of the material above the limit. To prevent this type of breakdown, the use of a safety factor could be foreseen, forming only parts requiring lower levels of deformation or limit angles.

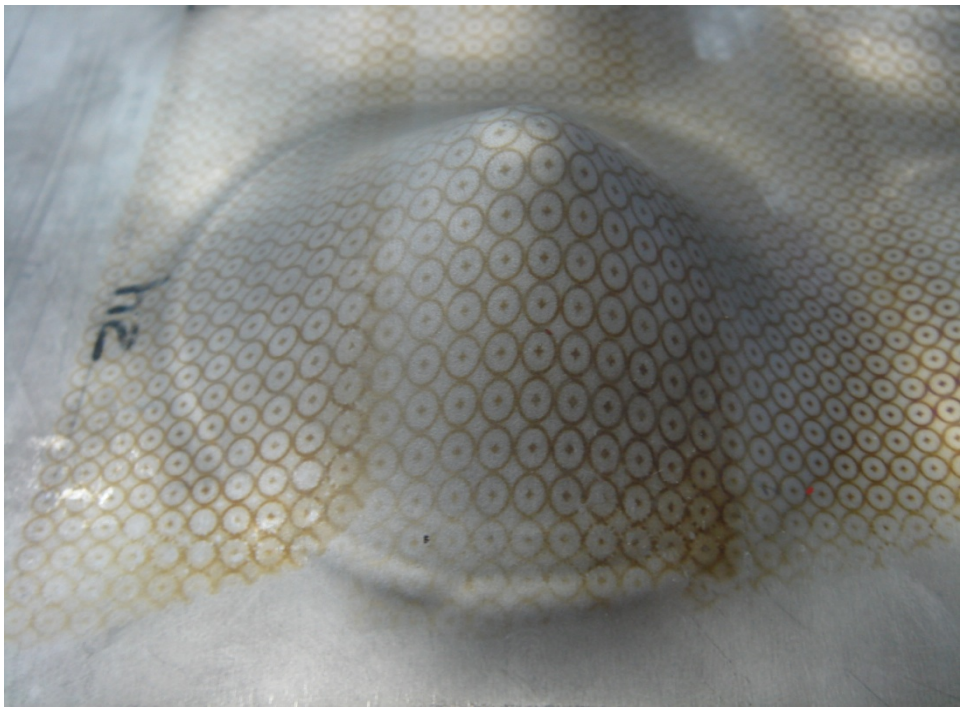


Figure 29: SPIF in titanium cone forming an angle of 45° with the plane of the plate.

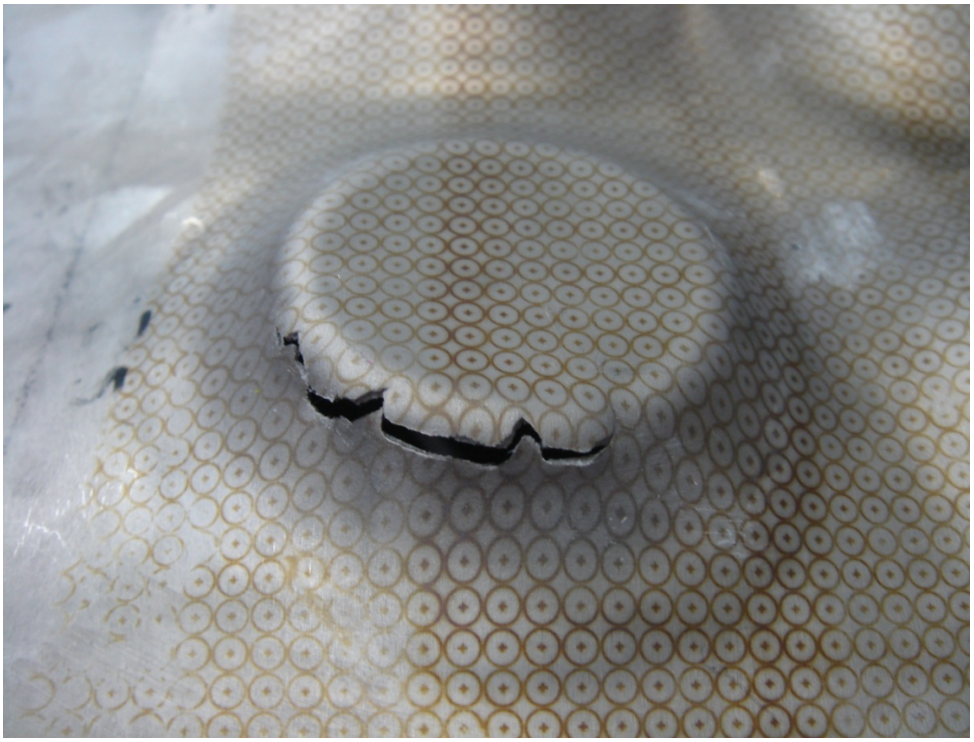


Figure 30: SPIF in titanium cone forming an angle of 50° with the plane of the plate, with disruption.

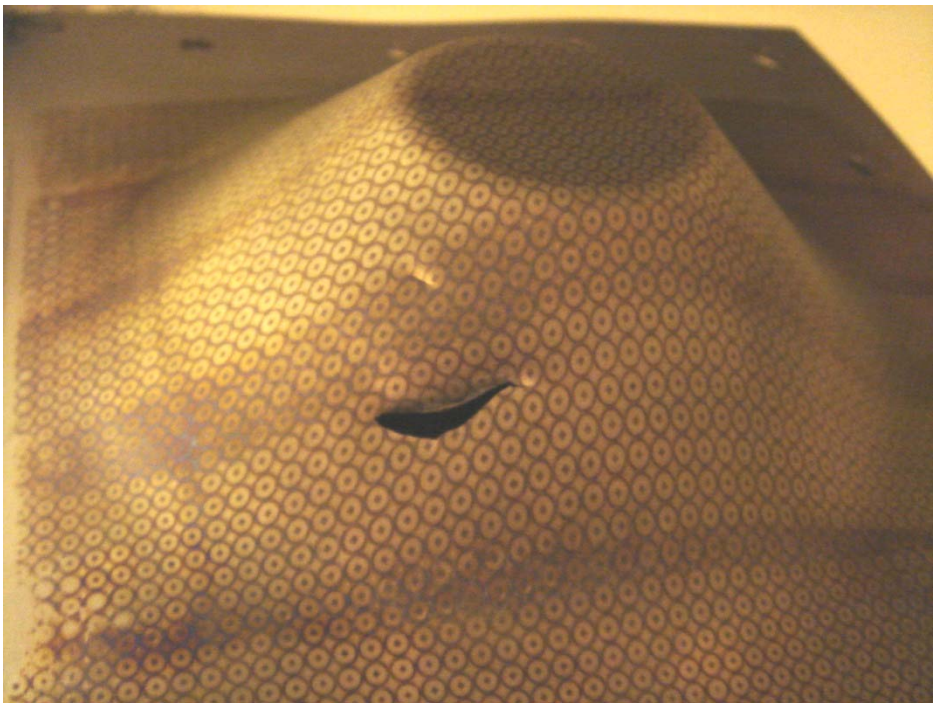


Figure 31: Fracture of the material presented in SPIF of cone with angle of 45°.

5.3 Dimensional inspection

The measurement of the variation of thickness of the sheets was performed using the technique of three-dimensional laser scanning, and after the capture of the point clouds, they were manipulated in the software Geomagic Qualify® (Figure 32). The plates were scanned in the two main faces with the aid of spheres for fixing the plate. The thickness variation was evaluated for the samples in the form of cone angles of 30° (Figure 33), 40° (Figure 34) and 50° (Figure 35). It is worth to remember that the initial thickness of the plates was 1 mm.

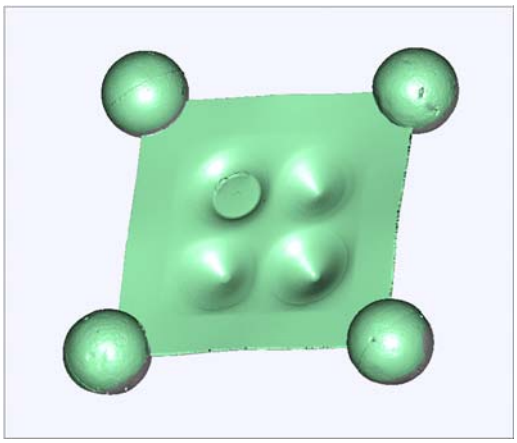
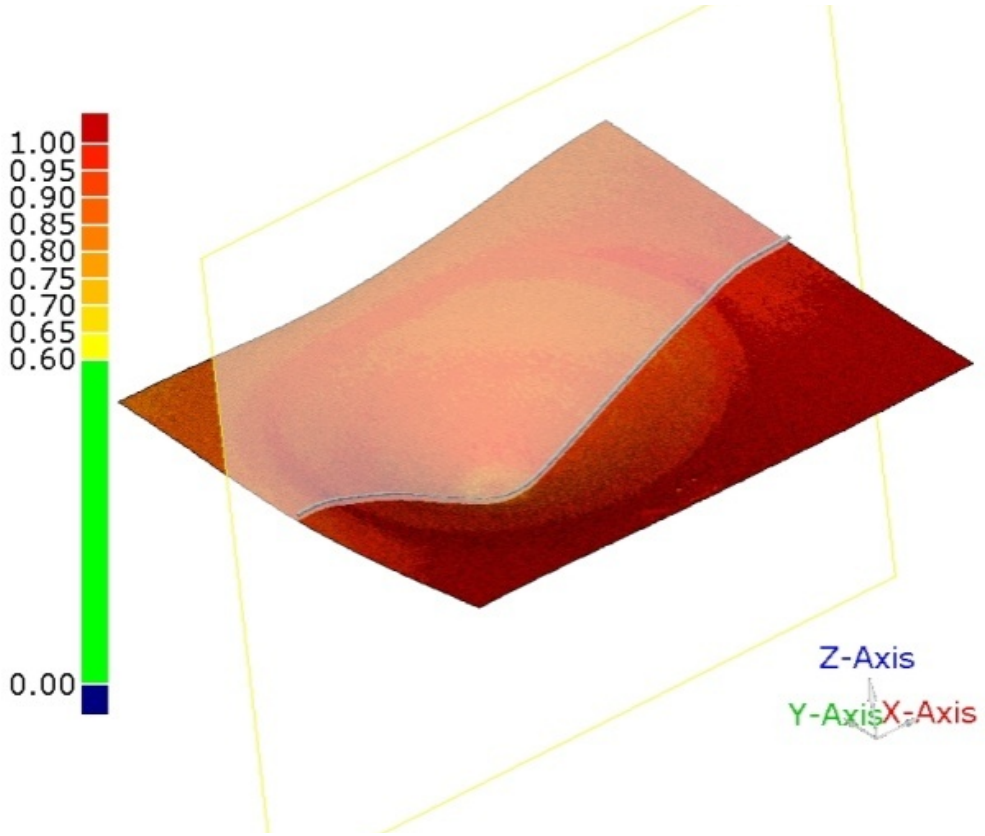
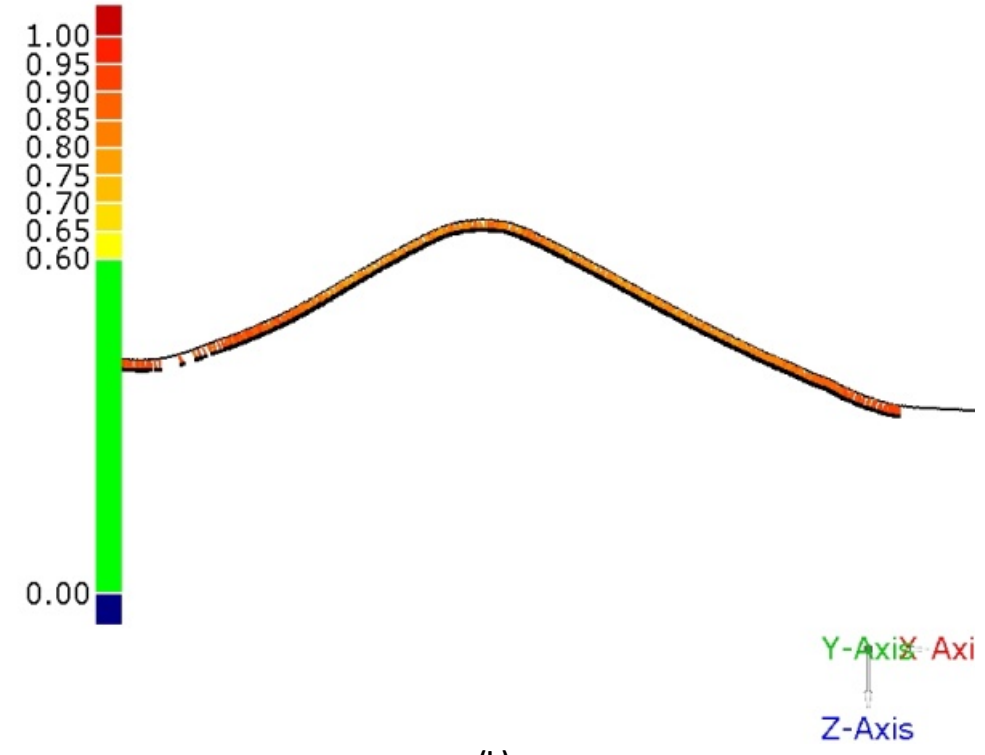


Figure 32: Three-dimensional laser scanning of the testing specimens in the cones of 30 and 40° manufactured through SPIF in plate of 1mm.

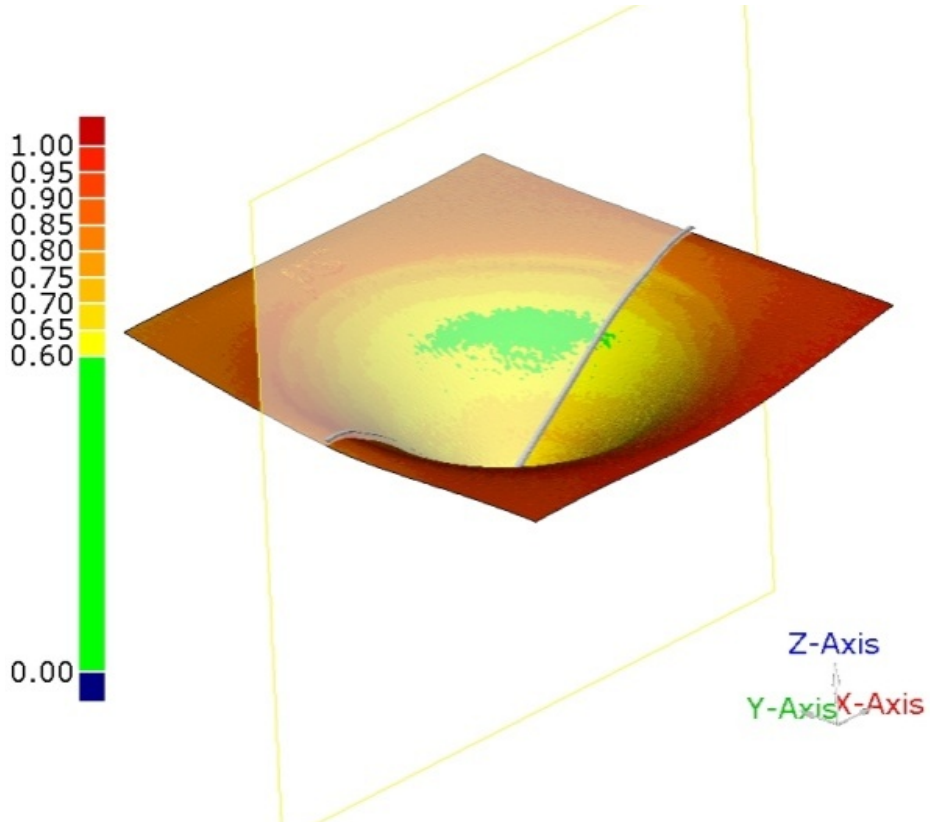


(a)

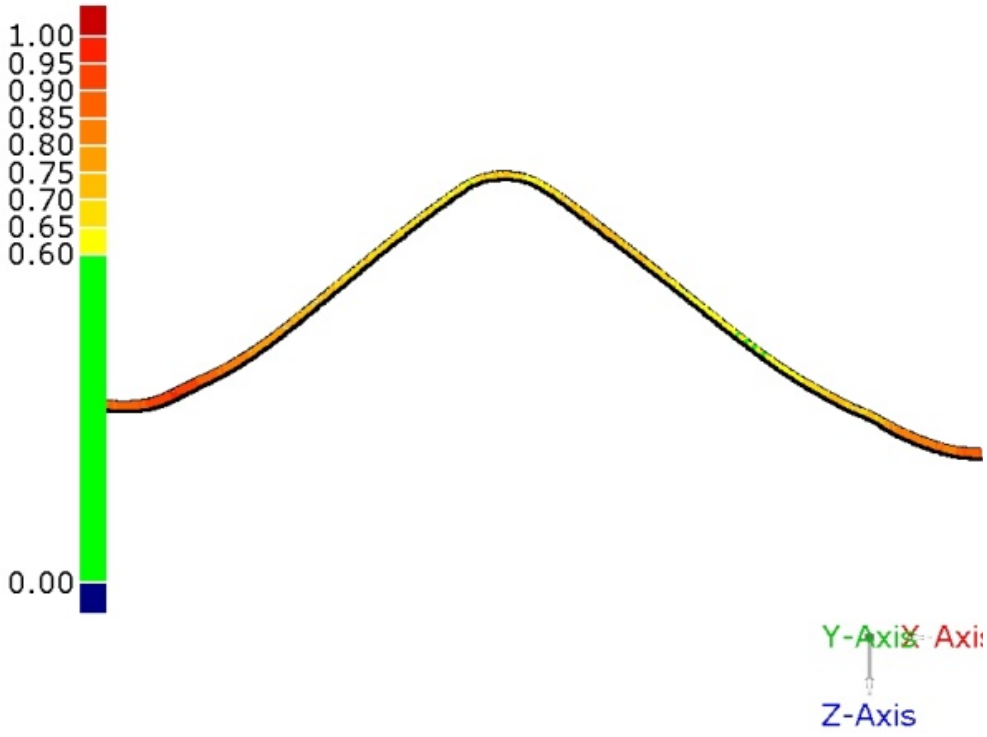


(b)

Figure 33: Variation of the thickness of the formed plate into the conformation of the 30° cone. a) Top view. b) Cross section view.

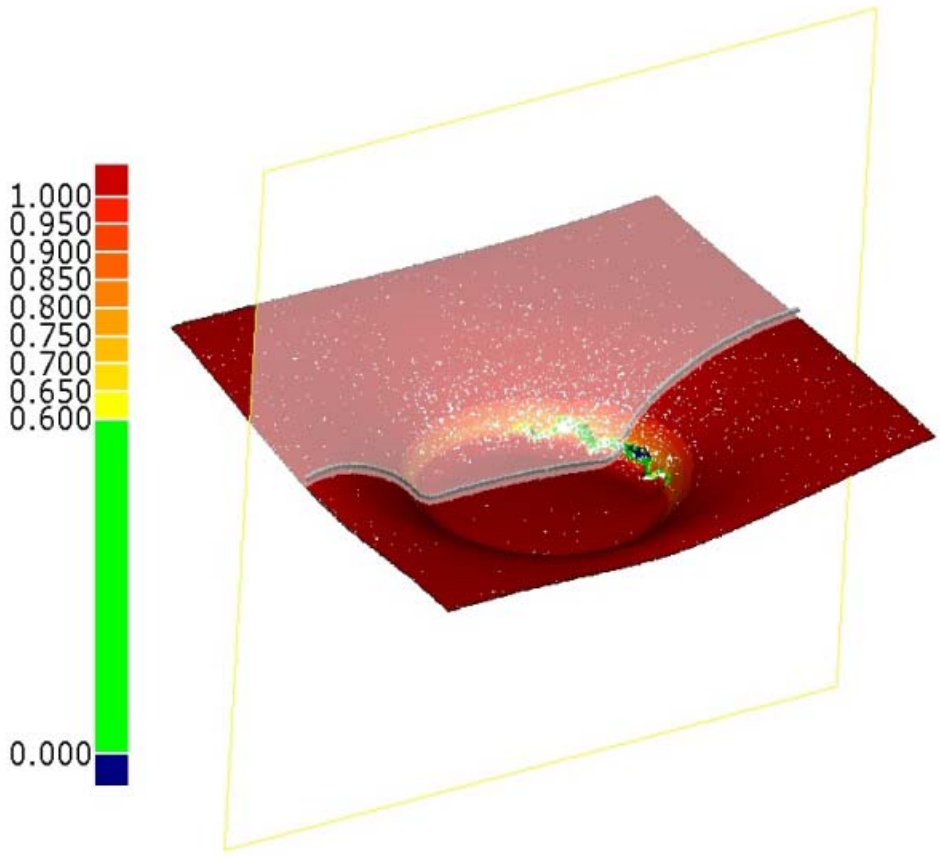


(a)

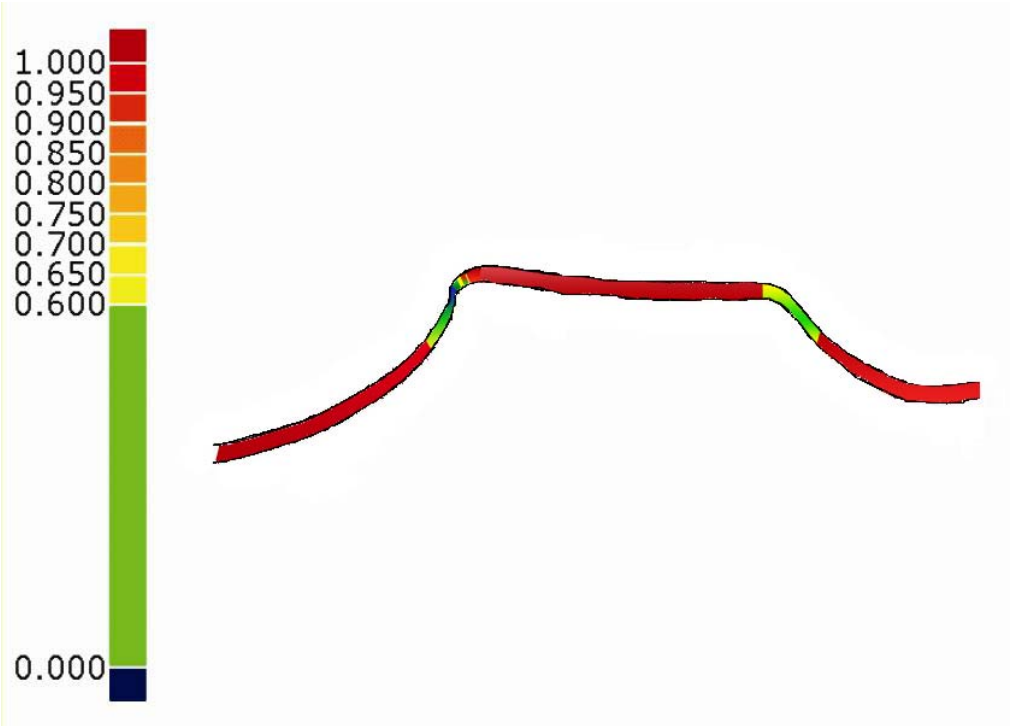


(b)

Figure 34: Variation of the thickness of the formed plate into the conformation of the 30° cone. a) Top view. b) Cross section view.



(a)



(b)

Figure 35: Variation of the thickness of the formed plate into the conformation of the 50° cone. a) Top view. b) Cross section view.

The variation of thickness of the sheets can be understood considering the law of conservation of volume: since the plate is attached to the blank holder and the material is plastically deformed, the increased surface area which occurs in the region of the plane of the plate is offset by decreasing the thickness. Through these tests a significant variation of thickness for the cones of 40 and 50 degrees can be observed, as a consequence of this fact. The region of the material to fracture would theoretically be attained when the thickness of zero was reached, as in the case of Figure 35. However, other factors end up affecting the formability of the metal sheet, such as material defects or cracks and lubrication failures.

The accuracy of the SPIF process of the test specimens was also evaluated by means of three-dimensional laser scanning. The formed geometries were compared with their original models, designed in CAD. The result can be seen in Figure 36.

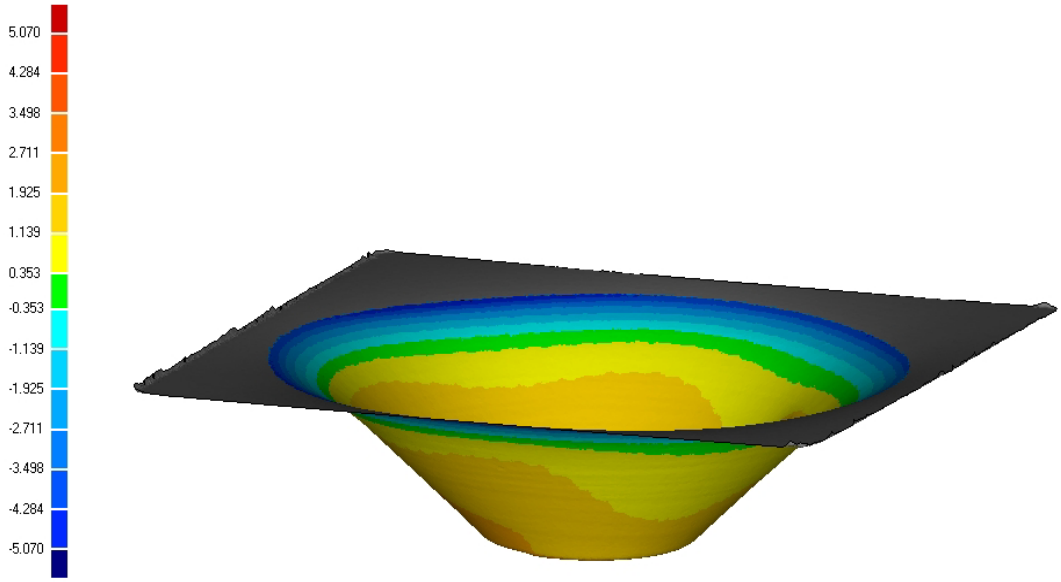
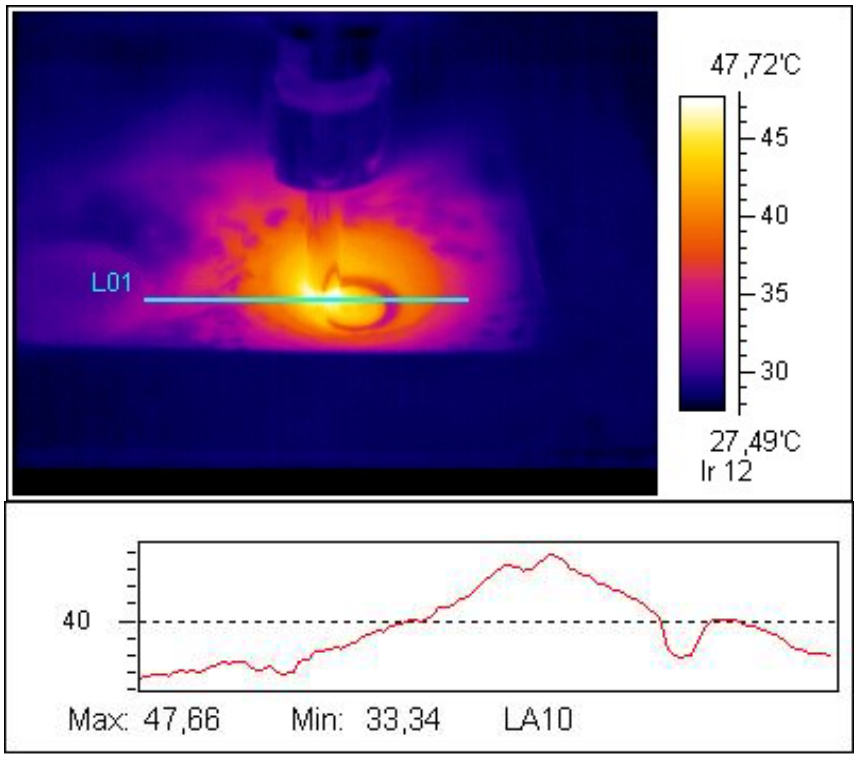


Figure 36: Three-dimensional comparison of CAD designed model and the model formed through SPIF.

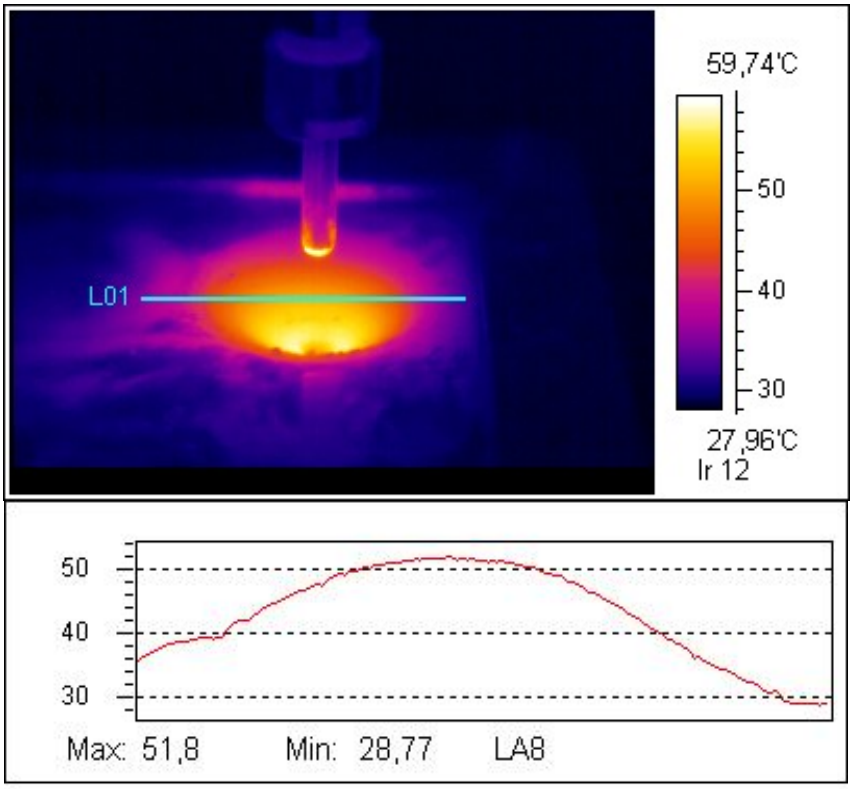
Poor accuracy of the process is observed, especially in regions near the edges of the plate and regions experiencing geometric variations over abrupt or sharp edges, such as the bottom end of the figure illustrated in Figure 36. This difference can also be seen in the cross section of the cones with 30 and 40 degrees shown in Figure 33 , Figure 34 and Figure 35. The region of contact between the edges of the sheets and formed parts are rounded, as well as their bottom extremities.

5.4 Thermography

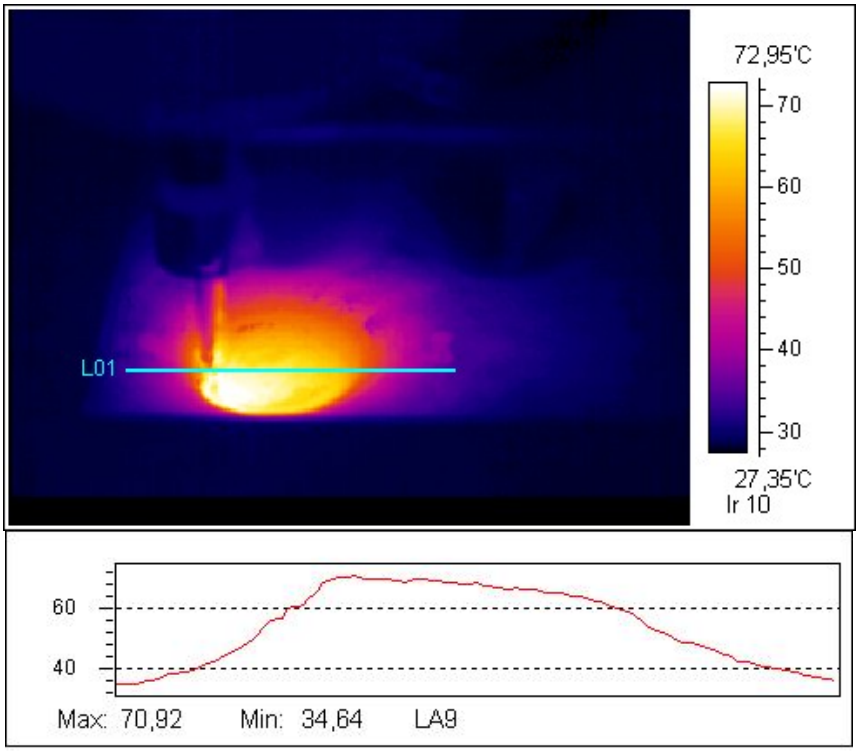
The temperature experienced by the material and the tool during the SPIF is shown at different angles in the thermography of Figure 37 . The formed cones of 30, 40 and 50 degrees were evaluated.



(a)



(b)



(c)

Figure 37: Thermography performed during the SPIF of cones with different angles. a) 30 degrees. b) 40 degrees. c) 50 degrees.

The titanium plate and the tool, in turn, had heating, evidenced in the thermography, especially the cone angle of 50 degrees, experiencing temperatures around 70^{o}C. The heating of the titanium plate can be attributed to several factors, such as the release of energy due to plastic deformation and friction. However, it is not possible to consider the temperature rise a cause of the fracture of the material which occurs in the cone of 50 degrees. In this case, it can be inferred that the fracture has occurred due to deficiencies of the process, such as the deficiency in lubrication, as evidenced by elevated temperature, or by local defects in the material.

5.5 Design and manufacture of implants

As proposed, cases of reconstruction of craniofacial bone defects in five different regions of the craniofacial complex were studied: the frontal or parietal region, the frontal region, including the supra-orbital, the zygomatic bone region, the temporomandibular joint; the mandible ramus. For each case, one or more modeling possibilities were investigated, whether manual or virtual. All cases involved the use of biomodels, whether physical or virtual, derived from CT images. The ability to manufacture implants through SPIF and other alternative processes was evaluated.

5.5.1 Frontal region

A typical case of defect repair in the frontal region of the cranium was selected (Figure 38). To this purpose, two strategies of modeling and manufacturing were used. The first approach (method 1) was based on manual modeling of the prototype of the implant. The second (method 2) was performed using virtual modeling and single point incremental forming.

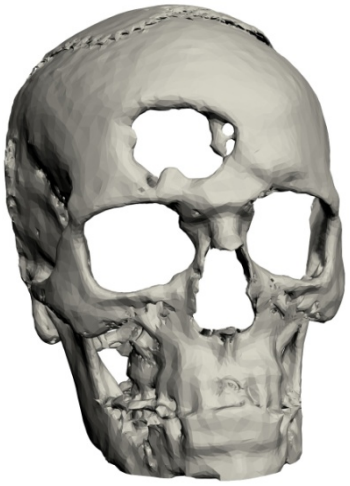


Figure 38: Three-dimensional image obtained from CT data. Defect in the frontal region of the skull.

METHOD 1

An anatomical biomodel containing the cranial defect to be repaired was produced though CNC machining process. The defect was filled manually with epoxy resin, and from this template, a silicone rubber mold was generated and a suspension of calcium phosphate cement was poured into it. Furthermore, inside the mold, a titanium mesh grade 2 cp thickness 0.7 mm was positioned, to ensure structural stability of the cement and allow its attachment to the cranium of the patient with the use of screws. After pouring into the mold, the calcium phosphate cement remained in the oven for 24 hours until it has acquired the necessary rigidity to be demolded. Figure 39 illustrates the steps involved in this procedure. For the evaluation of costs involved to produce the implant, however, the cost of commercial bone cement was considered.

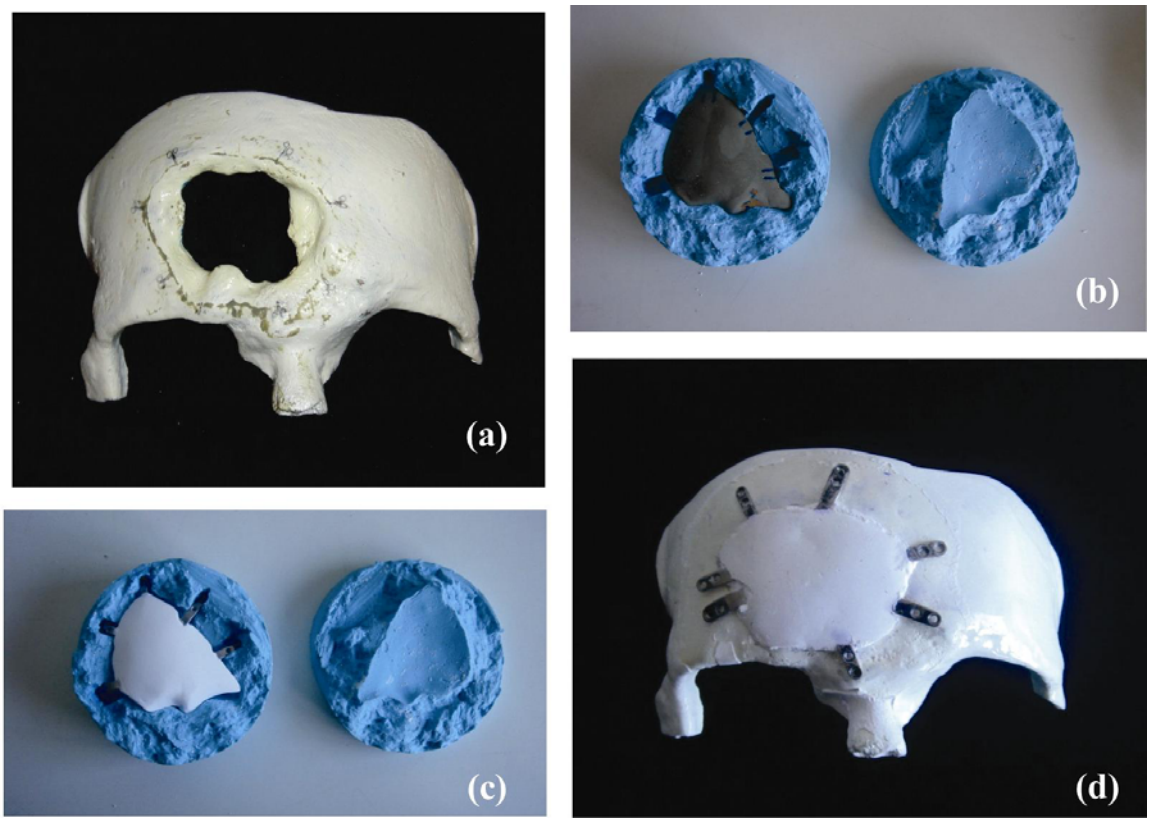


Figure 39: Figure 39: Procedure for manual modeling of implant to repair the bone defect in the frontal region. a) Biomodel showing the defect. b) Implant model, molded in epoxy resin in a silicon mold. c) Implant cast in calcium phosphate cement with titanium mesh inside. d) Implant positioned in the biomodel.

The process time to obtain the implant considering the steps described above is shown in Table 7.

Table 7: Time required to manufacture the cranium implant with calcium phosphate cement.

Step	Used time (h)
Manufacturing biomodel	10
Modeling the plastic mass (including the cure time)	10
Manufacture of silicone mold (including curing time)	25
Cutting and shaping the titanium mesh	1
Filling with calcium phosphate cement (including curing time)	25
TOTAL TIME	**71**

The handling time of the materials for making the mold and the implant (excluding the curing time) was estimated at 5 hours. Among the manufacturing costs of the implant, the manufacture of biomodel, the materials for making the model of the implant and template, the implant materials (cement of calcium phosphate and

titanium) and manpower (Table 8) are included.

Table 8: Costs associated in manufacturing the cranium implant with calcium phosphate cement.

Description of the expense	Cost (€)
Biomodel	500,00
Model of the implant material	10,00
Mold material (silicone rubber)	40,00
Calcium phosphate cement (30g)	3.440,00
Titanium mesh (100x100x1mm)	30,00
Manufacture of mold and implant (5h) *	40,00
TOTAL COST	**4.655,00**

* Value considered for the cost of an employee's hours with technical training to assist production.
** Values considering the price of the Euro on 30/04/2012, equivalent to R$ 2.50.

As further requirements necessary to perform the proposed method, an oven, a additive manufacturing equipment and manpower to assist the technical level of production can be mentioned.

METHOD 2

A second alternative tested to the production of an implant to repair the defect was the use SPIF. Do to the fact that is an automated process, it required that the implant model was in digital format, thus providing input for a conformation strategy generated using CNC equipment. The digital model of the implant (Figure 40) was generated using the software Geomagic Studio® using the tool for filling holes following the alignment of adjacent surfaces.

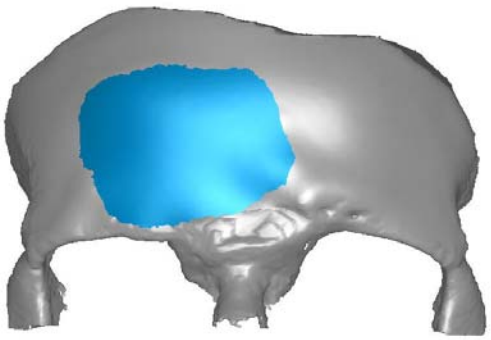


Figure 40: Virtual model of the implant (in blue) for repair of cranial defect.

For the virtual model of the implant it was possible to use the feature of filling holes of Geomagic Studio® software, since the area to be repaired is an extension of the adjacent surfaces, without complex curvatures. Thus, the mathematical approach provided by the software proved to be visually suitable. Such tool is limited, however, to the case of implants modeling in non-complex regions of the cranium, such as the parietal or frontal region; in the case of complex geometries, however, it is necessary to design it in CAD environment.

Using EdgeCAM® software, a strategy to form the implant through SPIF of cp titanium sheet was generated. A strategy that defines a constant cusp of 0.01 mm and step over (horizontal advancement) of 5% was selected. The result of the conformation of the implant, prior to cutting the implant from the sheet is shown in Figure 41.

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Figure 41: Incremental forming of implant for repair of cranial defect.

After the SPIF, the part was scanned in order to verify the accuracy of the process. The comparative result between the virtual designed model and the formed model can be seen in Figure 42 . The deviations are shown in millimeters.

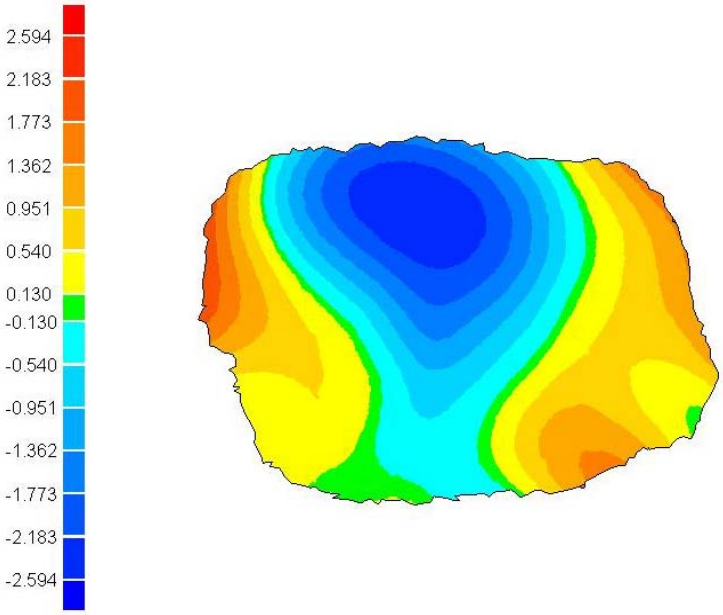


Figure 42: Three-dimensional comparison between the designed and produced model (in mm).

It must be noted that the low accuracy of the process in some specific regions such as regions near the edges of the implant and in the central region. This can be attributed to the return due to elastic properties of the material and the geometry itself, where it is observed a greater springback effect at approximately the center of the part. The elongation was calculated and showed values ranging from 10 to 20%.

According to Table 8 and Table 9, the time and costs associated with the manufacture of the implant through SPIF can be listed.

Table 9: Time required to manufacture the titanium cranial implant through single point incremental forming.

Step	Used time (h)
Biomodel Manufacture	3
Programming in CAM	1
Set up of the equipment	1
SPIF	2
Cutting plate according to the contour of the implant	3
Deburring, cleaning	2
TOTAL TIME	**12**

Table 10: Costs associated with the manufacture of titanium cranial implant through single point incremental forming.

Description of the expense	Cost (€)***
CAD modeling (3 hours) *	48,00
CAM Programming (1 hour)	16,00
Time machine CNC machining center (3 hours)	120,00
Cutting plate and finishing (5 hours) **	40,00
Titanium sheet cp grade 2 (200x200x1mm)	42,00
Lubricant (MoS_2)	40,00
TOTAL COST	**306,00**

* Values considered for the cost of an employee's hours with technical training in design and programming.
** Values considered for the cost of time for an employee with technical training to assist production.
*** Values considering the price of the Euro on 30/04/2012, equivalent to R$ 2.50

As operational requirements, the demand of this process are also a 3-axis CNC machining, CAD and CAM softwares. As manpower, a professional with aptitude for CAD modeling and CNC programming is necessary.

EVALUATION OF PROPOSED METHODS

Both procedures used for modeling and manufacturing of the implants were suitable for the studied cranial defect. The implant manufactured through manual modeling, and the one which was virtually designed and manufactured through SPIF adapted well to the bone structure. If necessary, dimensional changes (such as removal of excess material, shaping external titanium mesh) could still be done in the manually modeled implant to allow adaptation to the biomodel. The implant manufactured through SPIF also proved to be capable of use, although some springback has been experimented by the sheet, decreasing the implant accuracy. However, as the geometry of the implant is simple and follows the cranial curvature, there is no impediment to the use of the technique. In the case of complex geometries, however, the elastic return, and therefore, the inaccuracy of the process may prevent its use.

The time required for manufacturing the implant through manual modeling is mostly derived from the cure time of the materials. The material for the construction

of the prototype of the implant requires about 10 hours to achieve the stiffness required to be molded. The mold material (silicone rubber) and the implant material (calcium phosphate cement), in turn, require about 24 hours. The lack of precision which may perchance be associated with this method arises from the fact that it is manually performed and, for this reason, depends on motor skills and practice of the operator.

The calcium phosphate cements (hydroxyapatite) present different characteristics for use as a biomaterial. They are biocompatible and, in addition, bioactive, inducing formation of bone tissue in regions where it is located, causing its regeneration. It is therefore bioassimilable. This feature comes against what was thought until recently about biomaterials: that they should remain inert when implanted in the human body. The calcium phosphate cement may be cured "in situ", allowing greater ease of handling. However, its "caught" reaction does not present elevation of temperature, being favorable for intraoperative manipulation, excluding possible complications that can occur from exposure to implant tissue at high temperatures. Although being suitable for intraoperative handling, manufacture of the implants of calcium phosphate before the surgery appears to be very advantageous. Due to the limitations that the metallic and polymeric materials present, the production of custom craniofacial implants using calcium phosphate cements show significant advantages. Unlike most other alloplastic biomaterials, which are inert, these materials are bioactive (enable osteoconduction) and have the potential to promote osseous growth and integration after implantation. As a result, these materials are very well tolerated, with virtually no inflammation, minimum fibrous encapsulation and without negative effects on bone mineralization site. According to Santos (2002), calcium phosphate cements provide a physical substrate on which new bone tissue, with adjacent surfaces, can potentially be deposited and guided to areas occupied for the material.

The time required to manufacture the implant through SPIF is, in turn, significantly lower. This is due to the fact that the SPIF process allows the direct manufacture of the implant in the suitable material and in its final geometry, without the prior manufacture of prototypes. The advantage provided by this method to the

manufacture of skull defects is evident from these data, regarding the time necessary to complete the process. Some manual finishing operations such as cutting of the plate, removal of burrs and cleaning are necessary, however.

The SPIF process also showed a reduced cost to manufacture skull implants when compared to manual shaping. This fact can be explained analyzing the composition of the cost of the manual modeling process, which is mostly derived from the cost of biomodel and the implant material. Eliminating the need for a prototype of the cranium to provide a basis for the modeling, the cost of the process is significantly reduced. The material used for manual modeling (calcium phosphate cement) has also a higher market value, being eliminated from the SPIF method. In turn, it provides the advantage that, being initially fluid, it can be used to fill bone holes and has also properties of osteoconduction.

Other authors also suggest the manufacture of cranial implants using other procedures. Wirtz (2005) evaluates the manufacture of a cranial implant in titanium by means of additive manufacturing and compares process variables with CNC milling, in the case of the same implant. Table 11 shows the comparative costs involved for both processes. Furthermore, the production of such a custom implant is currently commercially available. The time required for the manufacture (excluding the steps of pre-and post-processing) is estimated at 12 hours, using laser melting equipment. The division Cranial Construct®, from the German company Digital Medical Design GmbH, designs and manufactures customized implants for cranial defects using additive manufacturing and deliveries it to the applicant in approximately one week.

Table 11: Comparison between the costs of making cranial titanium implants through CNC machining and additive manufacturing (laser melting). Source: Adapted from Wirtz, 2005.

Step	**CNC Machining**		**Additive manufacturing**	
Programation in CAM	300€	CNC Programation	50€	Positioning of support structures, division of the 3D file in layers
Manufacture	3000€ 200€	CNC machining Deep drawing	1200€	Laser sintering
Post-processing	200€	Deburring, cleaning	250€	Removal of supports, Deburring, cleaning
Total cost	**3700€**		**1500€**	

In the costs raised by Wirtz (2005), a significant difference appeared compared

to the costs involved in the studied processes. This difference is particularly significant regarding the costs arising of steps that involve the direct interference of the operator, as it is the case of manual operations to remove burrs and cleaning. This difference is mainly due to the comparison of labor costs of resident employees in Germany and Brazil, among other costs involving taxes and fees. The costs of raw materials can also be strongly influenced by the geographical region where it will be used.

5.5.2 Frontal and supra-orbital region

One case of typical defect in the frontal and supra-orbital region of the skull with indication of bone reconstruction was investigated. For the design and manufacture of the implant, two different approaches were used. For the first method, a physical biomodel of the skull was used for the direct manual modeling of the implant (method 1). For the second method, a virtual modeling approach was chosen, in which a virtual flat editable mesh has been distorted according to the 3D model of the skull. The part was formed through single point incremental forming (method 2).

METHOD 1

In the first case of front and supra-orbital bone defect (Figure 43 a), a physical biomodel was used to shape the implant manually (Figure 43 b). The implant was made manually using the biomodel manufactured through additive manufacturing. To this purpose, a predrilled titanium plate was formed with the aid of pliers. The result is shown in Figure 44 .

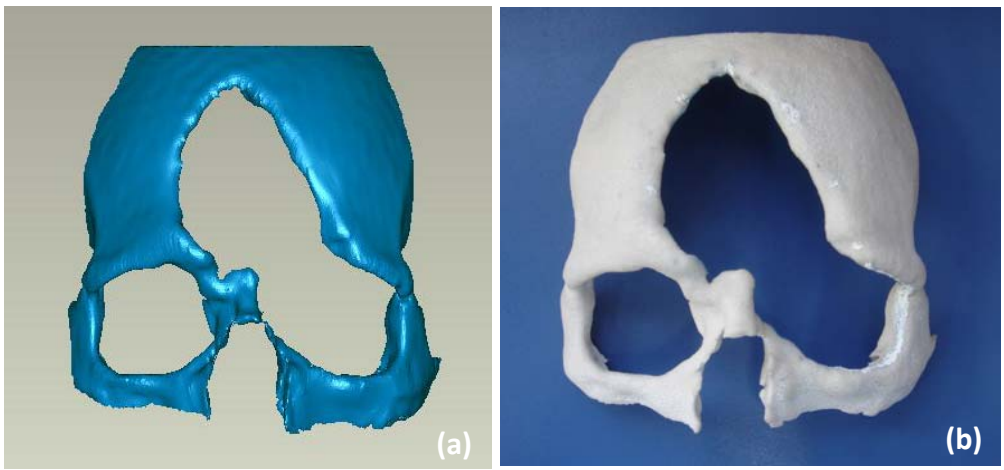


Figure 43: Bone structure of the case of bone defect studied. a) Virtual biomodel, showing the defect in the frontal and supra-orbital region. b) Physical biomodel used for the manual modeling.

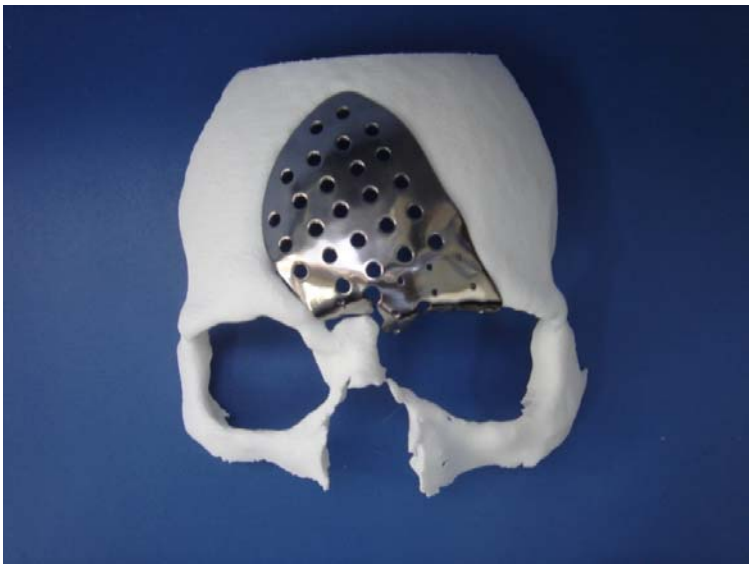


Figure 44: Resulting cranial implant produced through manual shaping.

The implant fitted well to the bone structure, as evidenced by its proper adaptation to the biomodel. The bone defect was completely hidden by the implant, which thus enables the resumption of aesthetic functions and neural protection. Time data and cost required for the manual shaping of the implant are presented in Table 12 and Table 13.

Table 12: Time required for the manual manufacture of the cranium implant in titanium plate.

Step	Used time (h)
Biomodel manufacture	10
Drilling titanium plate	1
Cutting and shaping titanium plate	4
Deburring, cleaning	2
TOTAL TIME	**17**

Table 13: Costs associated with the manual manufacture of cranial implant in titanium plate.

Description of expense	Cost (€)**
Biomodel manufacture	500,00
Titanium sheet cp degree 2 (100x100x1mm)	30,00
Drilling, forming, shaping and finishing of the plate (6 hours) *	48,00
TOTAL COST	**578,00**

* Value considered for the cost of an employee's hours with technical training to assist production.
** Values considering the price of the Euro on 30/04/2012, equivalent to R$ 2.50.

METHOD 2

The second variant of bone defect in the frontal and supra-orbital is shown in

Figure 45a. An implant was virtually designed in order to restore the shape of the cranium and the orbit. The process started from a surface that was virtually distorted and shaped to adapt to the anatomy of the cranium and fill the area with missing bone material. The modeling was performed in 3ds Max® software and is shown in Figure 45b. The final virtual implant model is illustrated in Figure 45c.

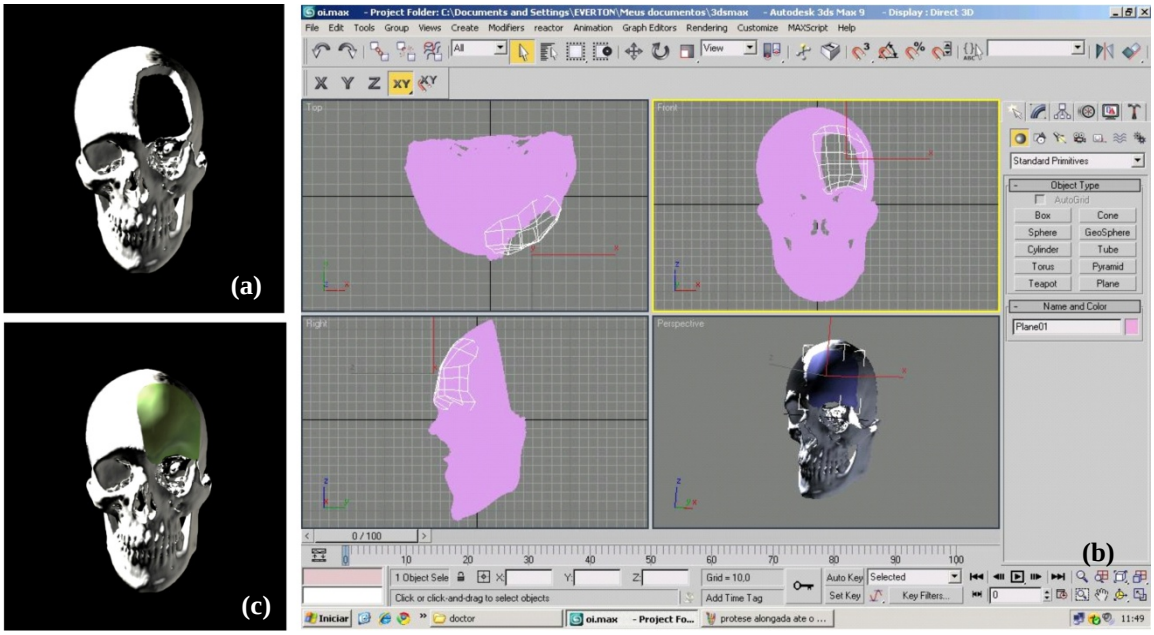


Figure 45: Three-dimensional model of the cranium of the patient, (a) showing the bone defect to be reconstructed, (b) modeling and (c) bone defect repaired with the shaped implant (green).

The designed implant model was manufactured from titanium sheet cp 1mm thick, through SPIF. For shaping the implant, a strategy was used so that the defined toolpath in the CAM software did not exceed the limits of angle and maximum deflection determined in preliminary tests with cone geometries. A reference plane was constructed (representing the plate) and polygons were modeled joining the lower regions of the implant to the reference plane. A maximum angle of 40° between the polygon and track the reference plane was established, in order to ensure that the plate does not exceed the limits and the material fails (Figure 46).

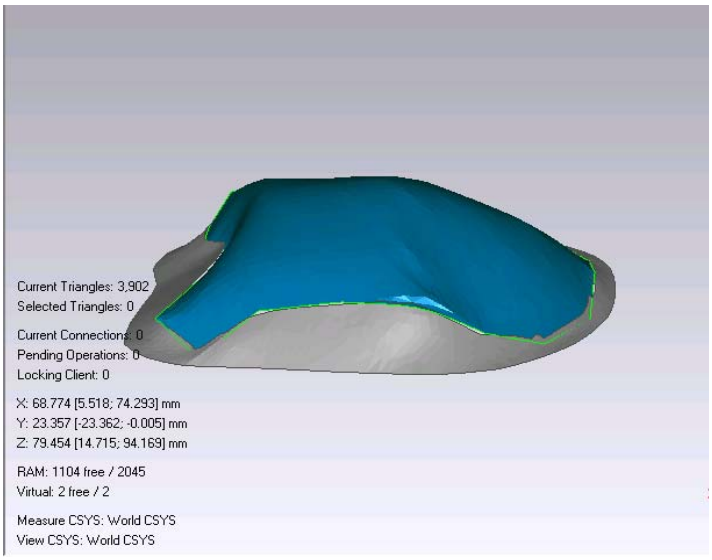


Figure 46: Virtual implant model, with adjacent polygons with a maximum angle of 40° to the plane of the plate.

The need for further shaping of surfaces adjacent to the ends of the implant is evident. With the exception of the hypothetical situation in which all the implant edges coincide with the plane of the plate at low angles (below 45°), certain regions to be shaped are positioned at distances above the deformation limit of the material. Thus, if the tool goes down directly to this position, the plate would break due to the extrapolation of the limit angle. In this regard, the forming is sought in deeper regions by gradual material forming at an allowed angle, until it reaches regions of the edges which lie below the plane of the plate. The modeling of the implant, due to the need of the inclusion of adjacent areas to follow the curvature of the implant and allow its conformation, required a longer time compared to the modeling of the cranial implant from the previous case (item 5.5.1).

With the area to be shaped defined in compliance of the limit angles of forming, a conformation strategy was generated in a CAM software (Figure 47). In this case, also a strategy defining a cusp constant of 0.01 mm and stepover of 5% was used. Care should be taken so that the increase is small enough to ensure that only a small point of the tool finds the surface of the metal to be shaped, to maximize the pressure. The process for forming titanium implant to repair the front and supra-orbital defect is illustrated in Figure 47.

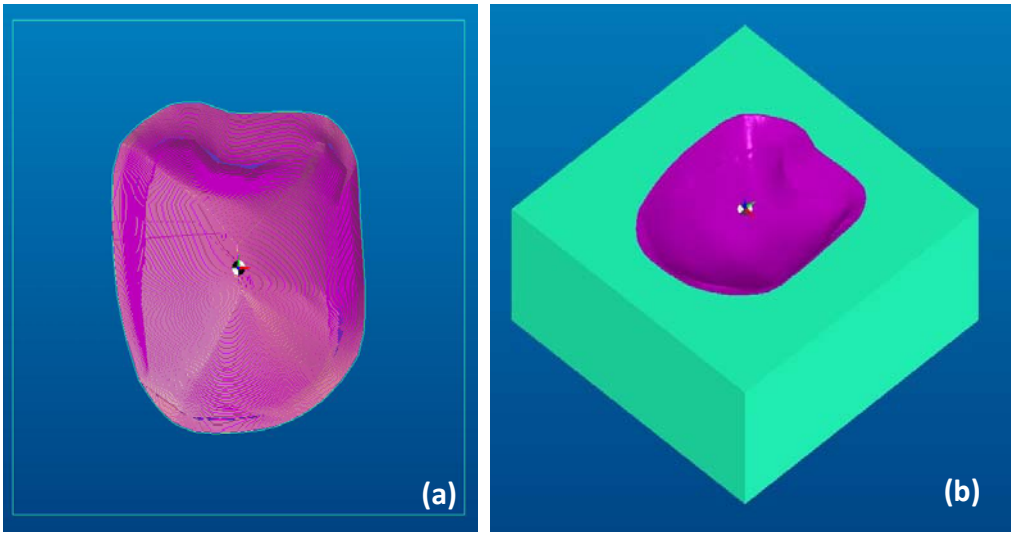


Figure 47: Forming strategy defined in CAM software. a) Toolpath. b) Process simulation.

The implant was then produced in titanium. Using the etched grid in the plate it was possible to measure the deformation experienced by the material. The highest value found of elongation, measured using the graduated scale (Figure 24), was 72% and can be seen in Figure 49.

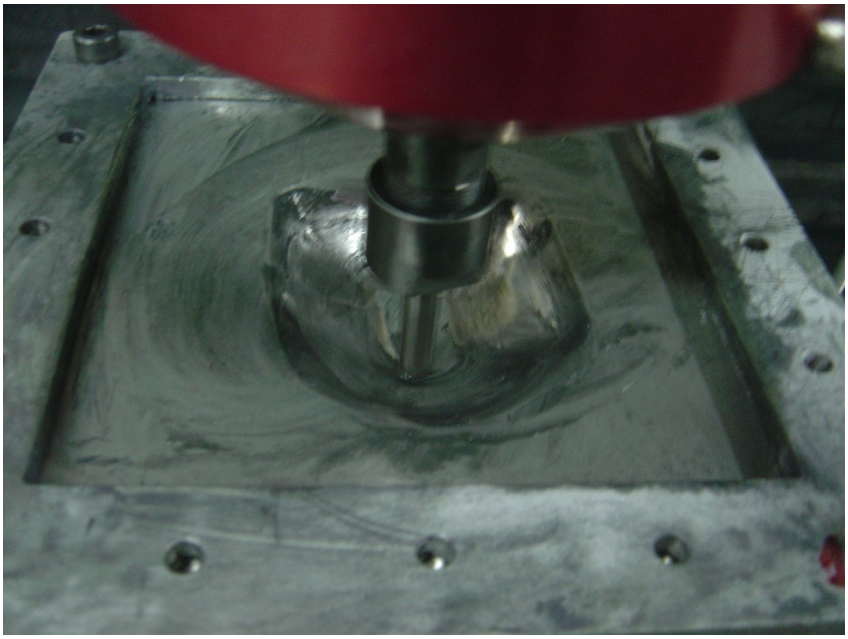


Figure 48: SPIF of the implant.

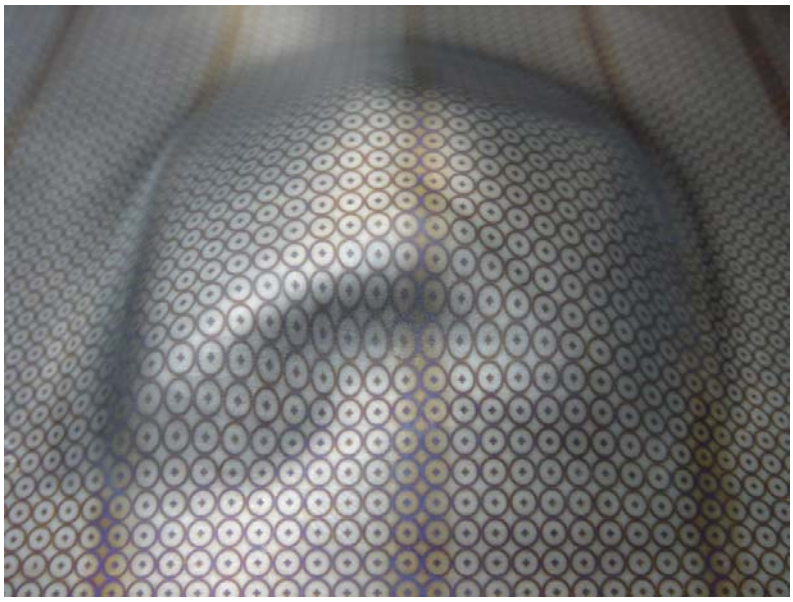


Figure 49: Implant manufactured of titanium, showing the etched grid used for the measurement of the deformation.

The difference between the designed and the final part, formed through SPIF, can be seen in Figure 50 . This analysis was carried out using three dimensional laser scanning, and provides important information about the accuracy of the process. For the fabrication of customized implants, as it is the case studied, such precision is particularly important, since the implant must be exactly adapted to the patient's bone structure. As seen in the dimensional analysis of deviations, the region corresponding to the orbit has not been properly reproduced.

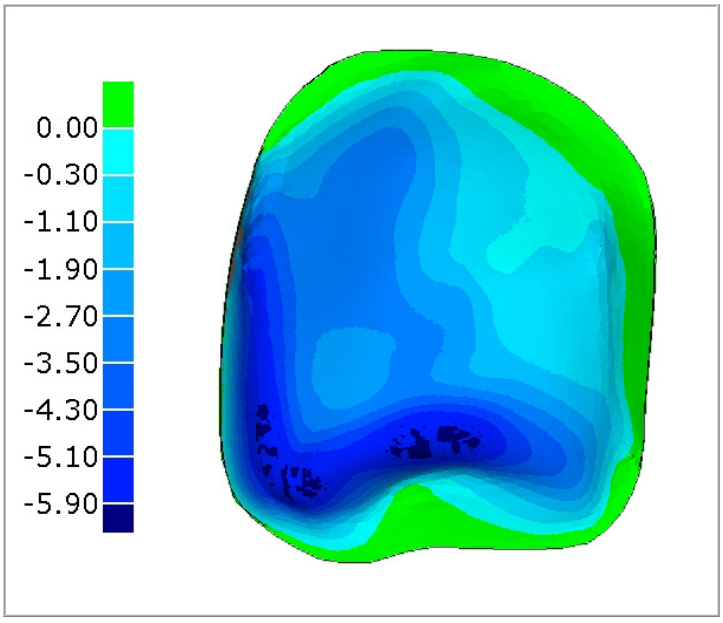


Figure 50: Differences, in millimeters, between the designed implant and the implant produced through SPIF.

The differences found between the designed part and the effectively performed implant range from zero to a maximum of 5.9 mm. This difference can be explained for the elastic return experienced by the material, after releasing the pressure exerted by the punch. For the application of this methodology, considering the material, process parameters and tooling, the accuracy should give better results, since the implant must fit exactly to the patient's bone anatomy. Dimensional deviations would be aesthetically viable for up to 2 mm for the region. The use a scale factor can be shown as an alternative, giving the desired part larger dimensions than it really should have. It may be possible to compensate the springback effect experienced by the material. The quantification of the exact amount to be increased in the model, however, should be determined.

The time consumed and cost associated with manufacture of the implant through SPIF is listed in Table 14 and Table 15.

Table 14: Time required to manufacture the implant to repair front and supraorbital defects in titanium through single point incremental forming.

Step	Used time (h)
Modeling of implant in CAD	5
Programming in CAM	1
Set up of the equipment	1
SPIF	2
Cutting plate according to the contour of the implant	3
Deburring, cleaning	2
TOTAL TIME	**14**

Table 15: Costs associated with the manufacture of the implant to repair frontal and supra-orbital defects in titanium through single point incremental forming.

Description of the expense	Cost (€)***
CAD modeling (5 hours) *	80,00
Programming in CAM (1 hour)	16,00
Time machine CNC machining center (3 hours)	120,00
Cutting and finishing plate (5 hours) **	40,00
Titanium sheet cp grade 2 (200x200x1mm)	42,00
Lubricant (MoS_2)	40,00
TOTAL COST	**338,00**

* Values considered for the cost of an employee's hours with technical training in design and programming.
** Values considered for the cost of time for an employee with technical training to assist production.
*** Values considering the price of the Euro on 30/04/2012, equivalent to R$ 2.50.

As operational requirements for this process, a 3-axis CNC machine, a workstation, CAD and CAM softwares are also required. As manpower, able professionals are necessary for CAD modeling and CNC programming.

EVALUATION OF PROPOSED METHODS

The methods for the manufacture of custom implant to repair cranial defects which also involve the supra-orbital region proved to be suitable, albeit with some limitations.

For applications requiring very complex form, the SPIF process could be considered impractical because of the limited angle conformation (45° in this case). The craniofacial skeleton in turn, has regions, especially in the face, that present a complex geometry which would require the conformation of the plate at an angle exceeding the material limits, which would make the process unfeasible. The skull, on the other hand, has a smooth curvature, which can be manufactured through SPIF. In this case, the orbit, for presenting a complex geometry and high forming angle, was partially formed through SPIF, however it showed deviations from the desired shape. The region of the frontal bone defect, nevertheless, was entirely made up through SPIF.

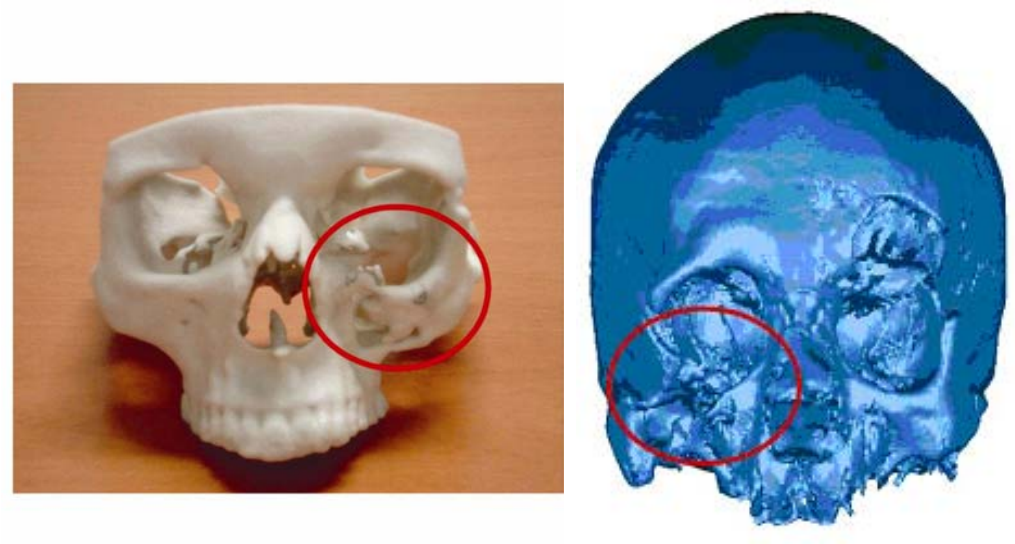
The implant formed through manual modeling showed suitable accuracy, fitting well to biomodel of the patient. The manual forming process requires, however, some manual skill of the operator and the geometry of the implant is defined visually. Furthermore, the extent of this application to other cases of cranial defects must be carefully evaluated. As the area of the defect increases, it becomes more difficult to form the plate in order to follow the spherical curvature of the head. Assuming that a hypothetic defect covers one entire side of the skull, it is difficult to imagine manual shaping of the plate without difficulty.

The implant generated through the method of SPIF had its main demand of time in the virtual modeling stage, while for the other process, the main demand is the manufacture of the the biomodel. With regard to costs for the material, although both implants are made of titanium and presumably have the same dimensions, for SPIF, a sheet dimension corresponding to the area provided to be attached to the blank

holder must always be considered. For the system used in this study it was 200x200mm.

5.5.3 Zygomatic bone region

To evaluate the modeling of implants for bone reconstruction in the region of the zygomatic bone, two methods were also used, seeking the restoration of function in two typical cases of trauma to the zygomatic bone region. The approach used for the implant modeling of the first case involved manual modeling through the use of physical biomodel (method 1), using titanium mesh and calcium phosphate cement. For the second case, the CT image was transformed into a virtual three-dimensional model, serving as a basis for performing mirroring operation. The implant was then formed using SPIF (method 2).



(a) **(b)**

Figure 51: Bone defects in the zygomatic bone region. a) Physical biomodel used for modeling of the implant to the first case. b) Virtual biomodel used in the second case.

METHOD 1

The implant of calcium phosphate cement and titanium was developed using a replica of the cranium base (biomodel), produced through additive manufacturing from CT data. To define the implant geometry, a deformable plastic material was manually shaped on the biomodel. Thus, the defect was filled with material to obtain a replica of the implant. From this prototype, a silicon rubber mold was made aiming to

reproduce the region of the defect and allow the manufacture of the implant, suitable in size and curvature. A titanium mesh was cut according to the edges of the defect and then shaped following the anatomy using the biomodel manufactured as template. The implant design also predicted the hypothetical region where it must be fixed with screws. The shaped titanium mesh was inserted into the mold. Next, the calcium phosphate cement, initially fluid, was poured into the mold cavity containing the titanium mesh.

The mold filled with cement was placed in an oven for a period of 24 hours, so the material can acquire mechanical strength and dry. Then, the implant was removed from the mold. The Figure 52 illustrates the manufacturing steps of the implant.

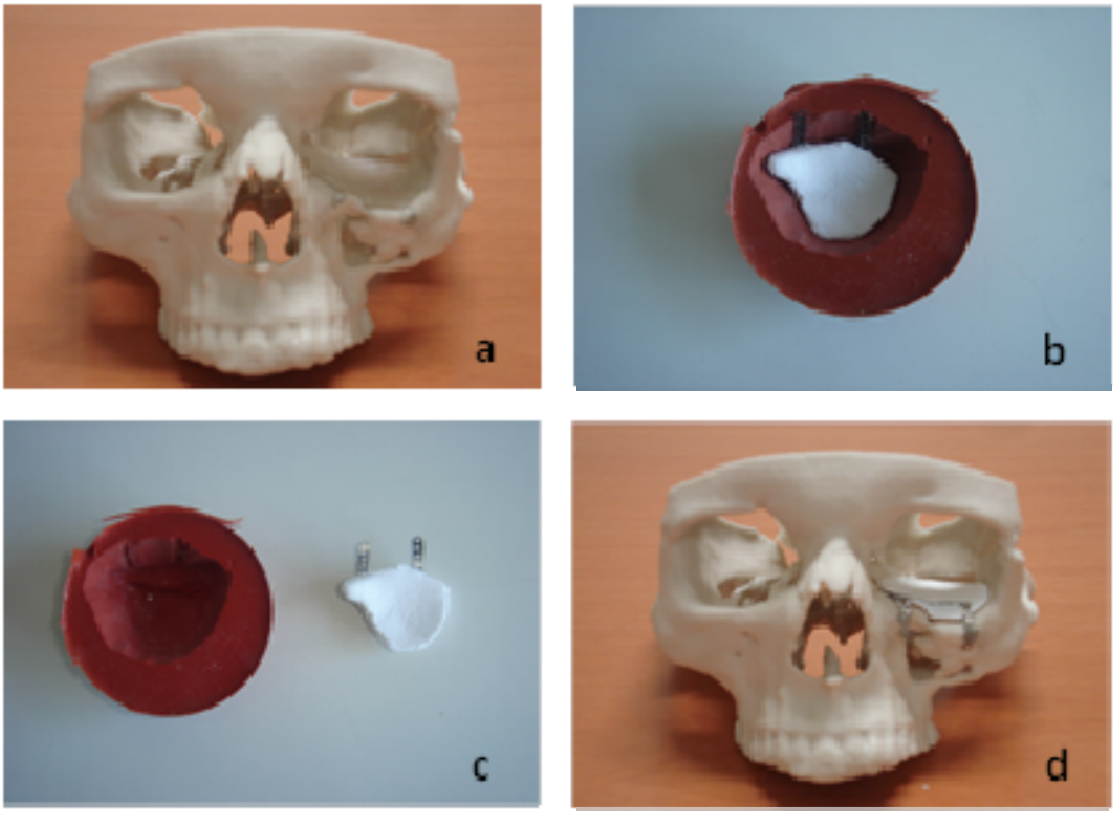


Figure 52: Manufacture of custom implant to repair defects in the region of the zygomatic bone. a) Biomodel used to make a model (resin) of the implant. b) Model replicated in calcium phosphate cement in silicone mold. c) Implant removed from the mold. d) Checking of the fitting of the implant to biomodel.

Part of the titanium mesh that is intentionally out of the cemented structure has been bended according to the biomodel. The mesh, with holes, allows the fixing with screws, with no need of drilling the implant during surgery. Moreover, the

surgeon can predict how and where the fixing is performed.

Summarized in Table 16 is the description of steps to manufacture the implant to repair a defect in the zygomatic bone region and the associated time. Table 17 shows the costs involved for this procedure. The time required to prototype the model of the implant with a plastic resin, excluding the hardening time, was 5 hours.

Table 16: Time required to manufacture the zygomatic bone implant in calcium phosphate cement.

Step	Used time (h)
Biomodel manufacturing	10
Modeling of the plastic mass (including the cure time)	10
Manufacture of silicone mold (including curing time)	25
Cutting and shaping the titanium mesh	1
Filling with calcium phosphate cement (including curing time)	25
TOTAL TIME	**71**

Table 17: Costs associated with the manufacture of the zygomatic bone implant in calcium phosphate cement.

Description of the expense	Cost (€)**
Biomodel	500,00
Implant model material	10,00
Mold material (silicone rubber)	40,00
Calcium phosphate cement (30g)	3.440,00
Titanium mesh (100x100x1mm)	30,00
Confection of mold and implant (5h)	40,00
TOTAL COST	**4.060,00**

* Value considered for the cost of an employee's hours with technical training to assist production.
** Values considering the price of the Euro on 30/04/2012, equivalent to $ 2.50.

As other requirements necessary to perform the proposed method, an oven, a additive manufacturing equipment and manpower to assist the technical level of production can be mentioned.

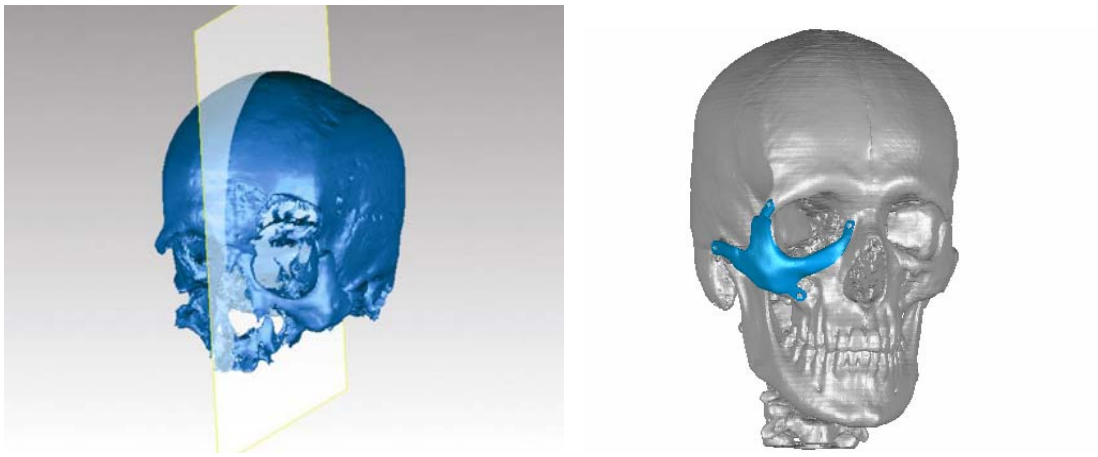
METHOD 2

The three-dimensional model obtained from computed tomography was saved in STL format, a standard file that represents a three-dimensional surface composed of a triangle mesh. A mirroring operation in relation to the vertical axis (YZ plane) of the cranium of the patient was performed using the software Geomagic Studio® (Figure

53 a). After the mirroring operation and the generation of a new virtual biomodel (this time with a symmetrically mirrored model and using the software features which allows the boolean operations) there was an intersection between the two models, with a subtraction of the regions in common. It results, as remaining structure, the region corresponding to the missing defect located in the zygomatic bone, which is exactly the implant model that fits to the patient's bone defect (Figure 53 b). Also, adjustments were made to keep only the outer surface to enable sheet metal forming, and adjacent shaped surfaces were designed to predict how the implant would be fixed.

The virtual model was then formed through SPIF. The strategy was generated with the software EdgeCAM®. In Figure 54, the implant after forming through SPIF is observed. After the forming, the implant must be cut from the sheet along its contour.

The strain experienced by the formed implants was measured with the aid of a graduated scale (Figure 24). The dimensional deviations produced between the formed implant and its respective CAD are shown in millimeters, in Figure 55.



(a) **(b)**

Figure 53: Modeling of the zygomatic implant. a) Mirroring operation. b) Final model (in blue).

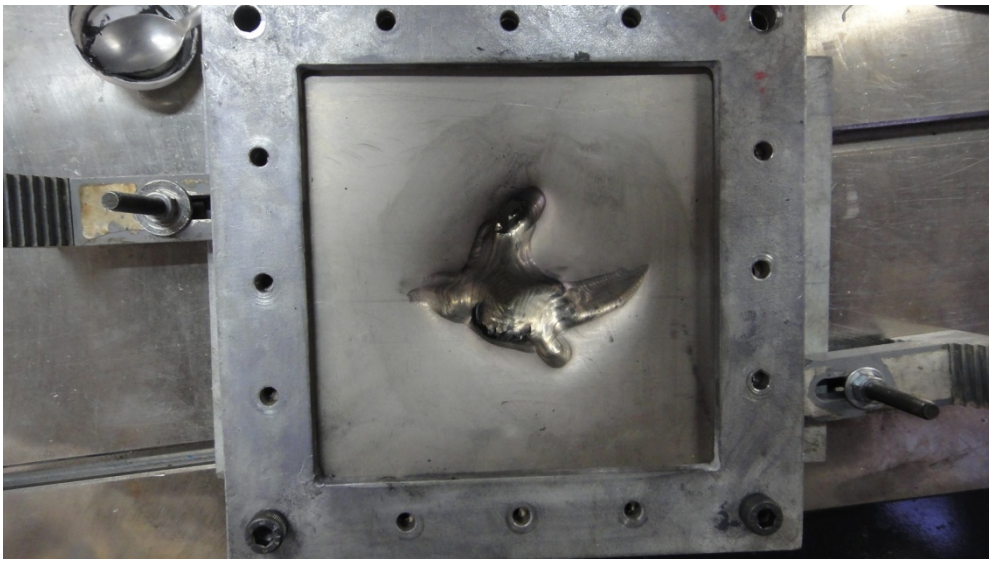


Figure 54: Single point incremental forming of the zygomatic Implant.

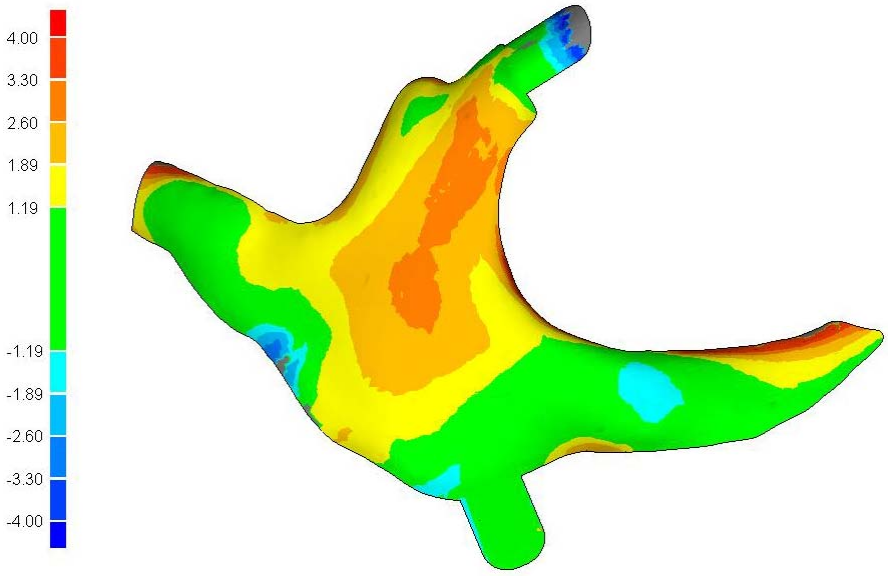


Figure 55: Dimensional comparison between the CAD designed implant and the implant produced through single point incremental forming (in mm).

Some regions of the implant whose dimensional deviations deserve highlight are the regions that have more pronounced deformations, such as the case in the region along the contours of the orbit, with values close to 4mm.

Below are presented values in terms of time (Table 18) and costs (Table 19) associated with the manufacture of the implant for the reconstruction of the zygomatic bone through incremental forming.

Table 18: Time required to manufacture the zygomatic bone implant through single point incremental forming.

Step	Used time (h)
Modeling of implant in CAD	5
Programming in CAM	1
Set up of the equipment	1
SPIF	2
Cutting plate according to the contour of the implant	3
Deburring, cleaning	2
TOTAL TIME	**14**

Table 19: Costs associated with the manufacture of the implant to repair the zygomatic bone in titanium through single point incremental forming.

Description of the expense	Cost (€)***
CAD modeling (5 hours) *	80,00
Programming CAM (1 hour)	16,00
Time machine CNC machining center (3 hours)	120,00
Cutting and finishing plate (5 hours) **	40,00
Titanium sheet cp grade 2 (200x200x1mm)	42,00
Lubricant (MoS_2)	40,00
TOTAL COST	**338,00**

* Values considered for the cost of an employee's hours with technical training in design and programming.
** Values considered for the cost of time for an employee with technical training to assist production.
*** Values considering the price of the Euro on 30/04/2012, equivalent to R$ 2.50.

EVALUATION OF PROPOSED METHODS

The manual modeling technique proposed enabled the construction of a custom implant for the reconstruction of the zygomatic bone, including the region of the orbit floor, with good adaptation to biomodel. As initially fluid, the calcium phosphate cement allows the filling of holes and small defects and provides great freedom with respect to the geometries that can be molded. It should be noted that due to the fact that craniofacial defects present a very individual geometry, varying significantly from case to case, some forms of implant would be impossible to be obtained directly during the surgery with the aid of standardized plates.

Through SPIF it is also possible to obtain an implant to repair a defect in the zygomatic bone with good adaption to the anatomical bone structure. The application of SPIF for the reconstruction of defects in the zygomatic bone would be limited, however, if it should also involve the reconstruction of the orbit floor area. Due to the

fact that they include regions of complex geometry, they would require the conformation of the plate above the allowed limit angles (45˚, for the used system parameters). For forming the outer surface of the zygomatic bone, however, the SPIF technique proves to be appropriate, despite its significant elastic return.

5.5.4 Mandible ramus

For the modeling of implants for the reconstruction of mandibular bone defects, two typical cases were studied. One corresponds to a patient with need of complete removal of the mandible. The second is a case of resection of part of the mandible. To obtain implants to repair these defects, two different modeling and manufacturing methods were investigated: laser sintering (method 1) and SPIF (method 2).

METHOD 1

The first studied case is illustrated in Figure 56. The implant design was made using mirroring operations in relation to a symmetry plane of the face. The softwares Geomagic Studio® and Solidworks® were used for such operation.

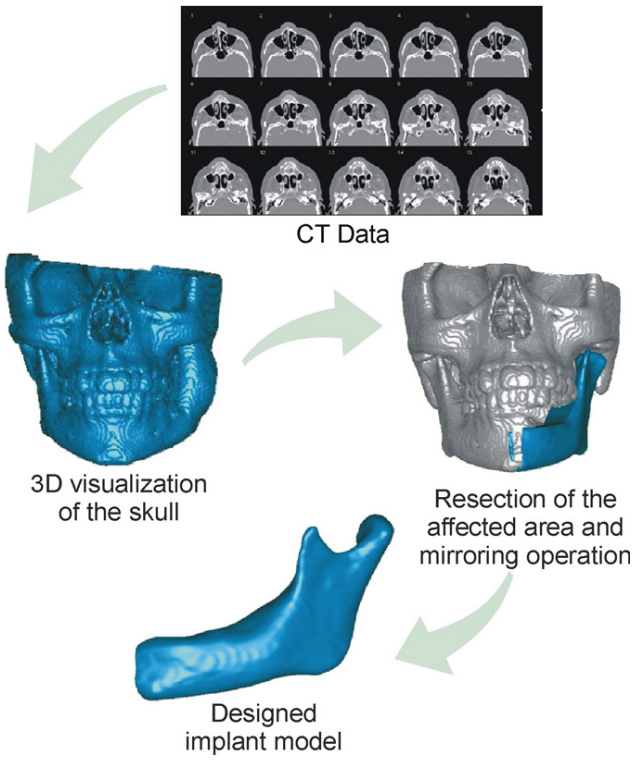


Figure 56: Design of the implant performed in a virtual environment. Mandibular reconstruction planned from CT images using mirroring operations. Source: Adapted from Bertol et al. (2010).

The implant to repair the mandibular defect generated in CAD was

manufactured through selective laser sintering (Direct Metal Laser Sintering, DMLS), EOS equipment M250X, using powder Ti-6Al-4V, 50µ particle size. The values of time and cost for such implants are summarized in Table 20 and 21. The produced implant, as well as the dimensional comparison between the designed and the manufactured model, are shown in Figure 57. The model was manufactured at the Fraunhofer Institute IFAM in Bremen, Germany.

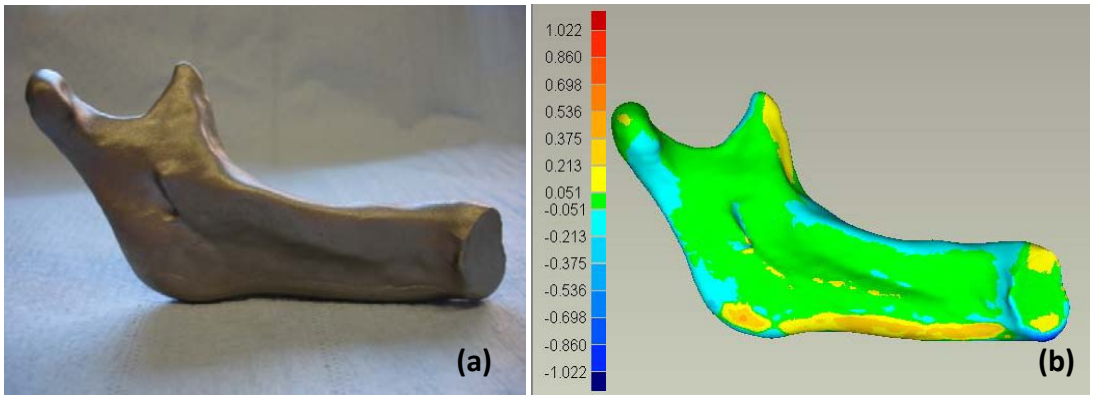


Figure 57: Implant to repair the mandibular defect. a) Model produced in Ti-6Al-4V through selective laser sintering. b) Differences (in millimeters) between the CAD model and the produced model.

Table 20: Time required to manufacture the mandibular implant through laser sintering Ti-6Al-4V.

Step	Used time (h)
Modeling of implant in CAD	2
Mechanical simulation of the implant via FEM, optimization of the internal structure	10
Positioning support structures, converting the 3D file into slices	1
Laser sintering	36
Removal of support structures	6
Deburring, cleaning	4
TOTAL TIME	**59**

Table 21: Costs associated with the laser sintering of the mandibular implant.

Description of the expense	Cost (€)***
Preparation of the implant in CAD, CAE and CAM (13 hours) *	208,00
Laser sintering (36 hours), material included	3.600,00
Removal of supports and burrs, cleaning (10 hours) **	80,00
TOTAL COST	**3.888,00**

* Values considered for the cost of an employee's hours with technical training in design and programming.

** Values considered for the cost of time for an employee with technical training to assist production.

*** Values considering the price of the Euro on 30/04/2012, equivalent to R$ 2.50.

The time required for the sintering of such implant (36h) is considerably longer compared to the manufacture of implants previously discussed. An implant for cranial reconstruction, as described by Wirtz (2005), can be produced in titanium through laser sintering in approximately 12h. This difference in time is due to the implant volume of the manufactured model in question.

The time required to obtain the laser sintering implant is also dependent on the orientation of the model. It is possible to rotate the geometry in order to reduce the Z height, which would reduce the process time. However, the reorientation of model means, in some cases, the need to insert extra amount of structures for supporting the part to allow its manufacture. As a result, increased complexity in supports removal is added to the process, a step manually performed with the aid of a cutting tool.

The long time required to complete the process (59h) also causes an increase in cost, due to the high time of use of the equipment and the need for skilled labor to perform the simulation and optimization of the geometry. The proposed method also requires a additive manufacturing equipment capable to sinter titanium powder with a controlled atmosphere (in this case, the EOS DMLS equipment M250X with argon), a workstation, software CAD, CAE and CAM. In addition, trained manpower to perform such functions is also required.

The model produced through the described method has high accuracy, meeting the necessary geometrical requirements. The regions of lower precision, shown in Figure 57 b, refer mainly to the regions on which support structures were removed, requiring some kind of manual finishing.

To add functionality to the implant, internal structures were also included. The insertion of internal reticular patterns in the implant is performed to reduce the weight of the implant and allows, if the case of the surface be open in any of the extremities, vascularization and bone tissue growth within the implant. These patterns, this time designed in a CAD environment, can be combined with complex 3D shapes, to permit to fill the 3D model with certain internal structure. Different pattern geometries, and also size and spacing of repetition patterns can be configured. For the generation of the internal structures, different elements that were later replicated in the form of patterns for subsequent insertion into a 3D shape (Figure 58) were

modeled in Solidworks® software (Dassault Systems). There are some currently available commercial softwares capable of inserting internal repeating structures automatically to the desired 3D geometry, such as the software VisCam® (Marcam Engineering GmbH).

As described by Lohfeld (2007), prosthesis with pores in its interior not only brings benefits to provide a reduction in weight, but can also make the production faster, in the case of using a rapid manufacturing process. The manufacturing time of this process is strongly dependent on the area to be scanned for the laser in each layer. The disadvantage of manufacturing an internal structure lies in the way the dust is removed from the interior of the part, which must be previously designed.

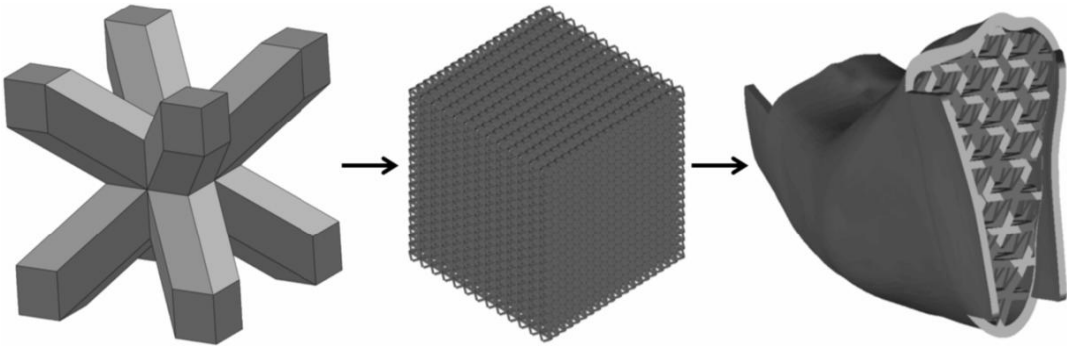


Figure 58: Internal structure. a) Unitary element of the reticular pattern. b) Reticular structure. c) 3D shape filled with the developed pattern.

The difficulty for modeling the patterns in CAD environment is the size that the files can achieve. In this way, one is limited to the hardware processing capacity. As the unitary elements are being replicated in order to create an internal structure large enough to fill a 3D structure corresponding to a mandibular bone defect, for example, the file size will also increase significantly. Thus, it is sometimes impossible to save the patterns developed as STL files, precluding its combination with the 3D shape to be filled. Table 22 describes the size of network structures that were modeled with their respective values of surface area, volume and size of the generated file. A symmetrical unit element of length 1 mm and wall thickness of 0.3 mm was used as reference. To this element, it was found that the designing in CAD environment of a block with dimensions 12x15x45 mm was not possible due to hardware restrictions. The processing capacity prevents even the file corresponding to half this size be saved as a

triangle mesh file. Thus, it was not possible to design and save in STL the internal structure able to completely fill the proposed 3D shape (25x45x30mm). The tests were performed with the software Solidworks® 2010 on a DualCore processor with 64-bit operating system.

Table 22: Possibility to block modeling with reticular structure in the CAD system.

Block size (mm)	Surface area (mm^2)	Volume (mm^3)	CAD file size (KB)	Possibility to save in STL
12x15x12	3952	560	7077	Yes
12x15x24	7864	1120	13559	Yes
12x15x27	8842	1260	15029	No
12x15x30	9820	1400	16913	No
12x15x33	10798	1540	18590	No
12x15x36	11776	1680	20215	No
12x15x39	12754	1820	21598	No
12x15x42	13732	1960	23381	No
12x15x45	14710	2100	24809	No

The limitation found in the process of repeating unit elements for the generation of reticular structures in the CAD system was circumvented using unitary elements modeled in CAD, that have already been saved as triangle mesh file (surface file, STL). Thus, the file size was significantly smaller, making possible the building blocks of reticular structure of sufficient size to fill the 3D shapes present in the craniofacial complex. For such, mirroring operations using the software Geomagic Studio® were carried out with the same hardware configuration.

With the reticular block structure as STL and the 3D shape to be filled, features of the Geomagic Studio® software, which allows Boolean operations (addition, subtraction, intersection) were used. Thus, the first block of the network structure and the 3D shape of the implant were appropriately positioned and overlapped (Figure 59a). So, the block is cut in the following the 3D form of the implant (Figure 59b) and the 3D surface of the implant and the resulting reticular structure were attached (Figure 59 c), resulting in an implant completely filled with the designed pattern. An implant with such reticular internal structure, although it has not been manufactured, could be produced in the material suitable for implantation using rapid manufacturing

processes such as selective laser melting.

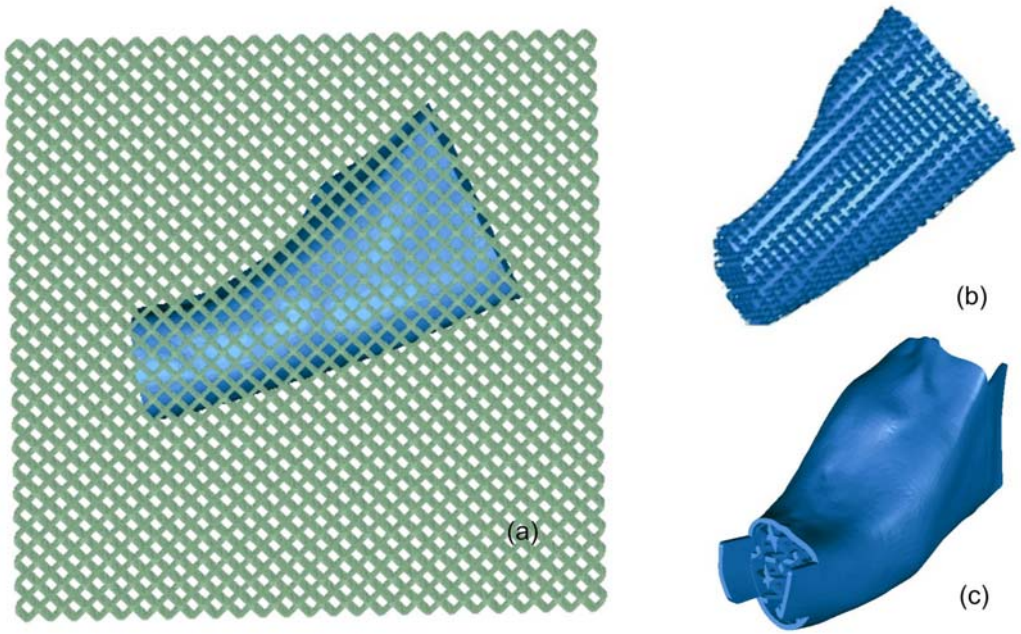


Figure 59: Operations performed in the surface files for the insertion of network structure in the 3D shape of the implant. a) Positioning and overlapping. b) Intersection and exclusion of the rest of the reticular block. c) Union of the implant surface and its respective internal structure.

METHOD 2

The implant for reconstruction of mandibular defect, proposed in the second method, was designed to be divided into two components and enable its manufacture from a metal sheet (in the case of SPIF). In this way, the interior is not massive, generating a low weight implant. The result of this modeling is shown in Figure 60 . The software Geomagic Studio® was used to select the region of interest in the structure (obtained from CT data) and Solidworks® for modeling the surface corresponding to the implant. In the designing process, additional surfaces are also provided for fixation of the implant by means of screws.

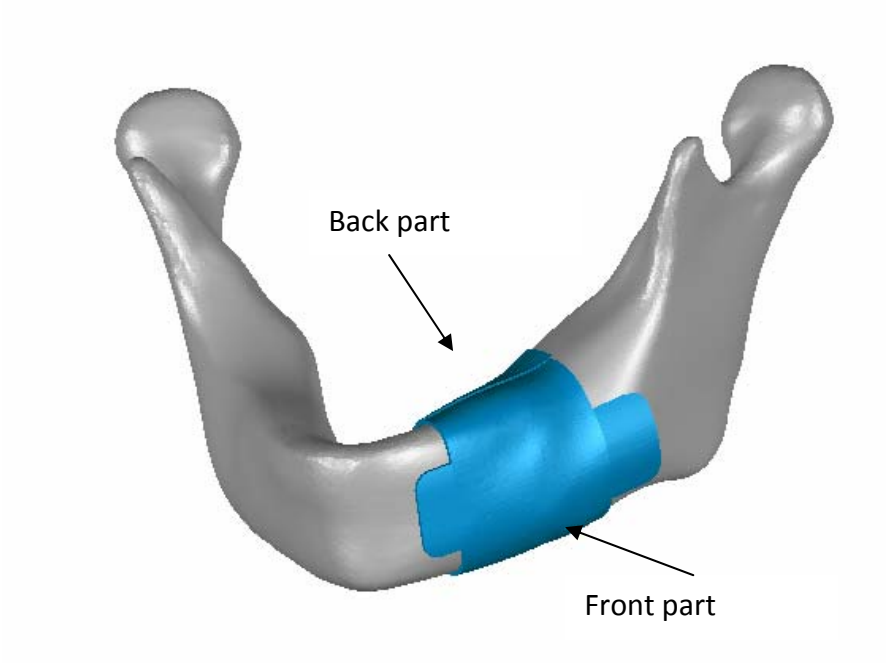


Figure 60: Mandible implant modeled in two parts.

Each of the parts of the implant was formed though SPIF. The result of the forming of the back part of the implant is shown in Figure 61 . The deviations found in the formed geometry in relation to the designed CAD model are shown in Figure 62 for each of the parts of the implant (front and back).

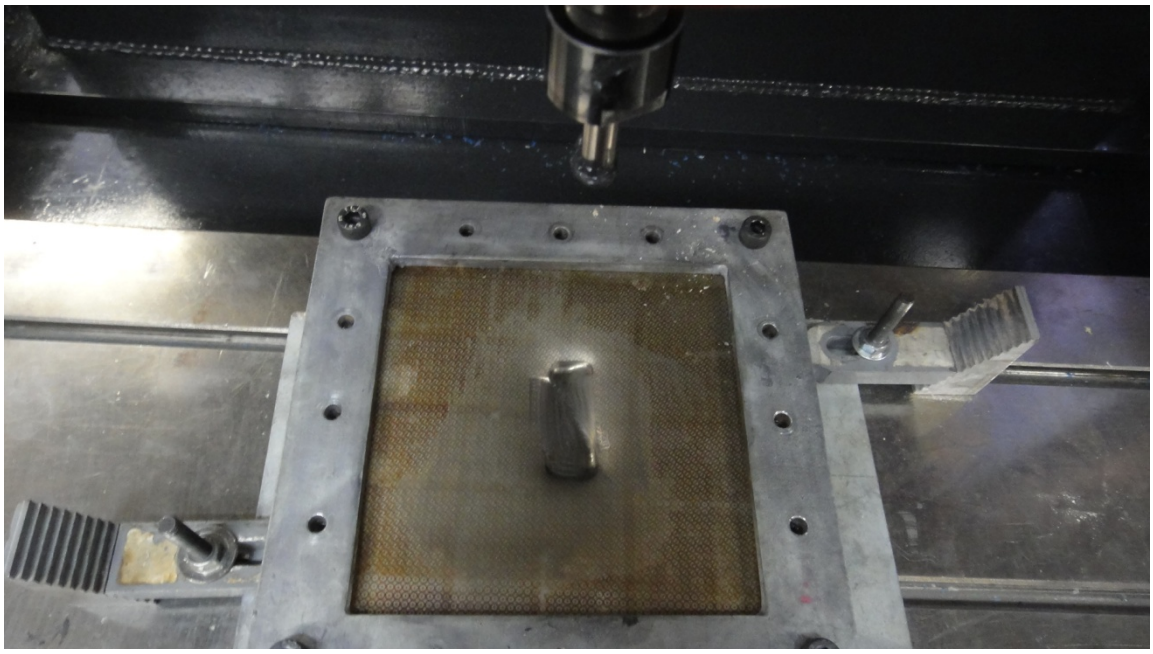


Figure 61: Component of the mandibular implant produced through single point incremental forming.

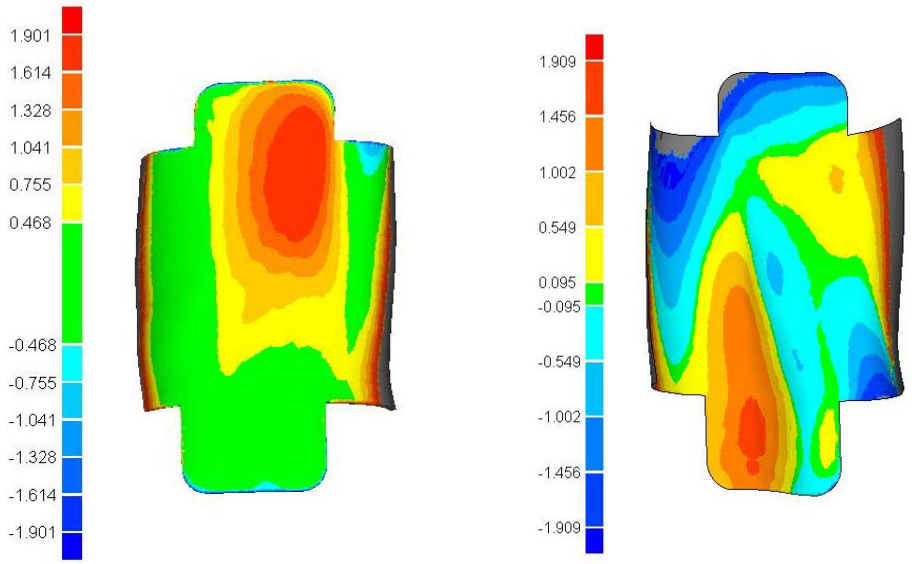


Figure 62: Variation in dimensions (in mm) presented by the formed parts in relation to the CAD model. a) Front part. b) Back part.

The dimensional deviations presented in the mandible implant formed through SPIF are quite significant in the edge regions. This fact emphasizes the high elastic return presented by the material, which makes this technique unfeasible in the present case. The region of the edges represents precisely rounded geometry, which gives the cylindrical/oval form of the mandible. With such dimensional deviation, the implant, as it is designed (two parts), does not complete the full circumference of the mandible, and the composition of both sides remain open in the central region. Adaptations in the design of the implant should be implemented to make the manufacture of the mandible implant possible though SPIF.

The time and cost variables of the manufacturing process though SPIF of the mandibular implant are summarized in Table 23 and Table 24.

Table 23: Time required to manufacture the mandible implant through SPIF.

Step	Used time (h)
Modeling of implant in CAD	5
Programming in CAM	1
Set up of the equipment	1
SPIF	2
Cutting plate according to the contour of the implant	3
Deburring, cleaning	2
TOTAL TIME	**14**

Table 24: Costs associated to the SPIF of the mandibular implant.

Description of the expense	Cost (€)***
CAD modeling (5 hours) *	80,00
Programming CAM (1 hour)	16,00
Time machine CNC machining center (3 hours)	120,00
Cutting and finishing plate (5 hours) **	40,00
Titanium sheet cp grade 2 (200x200x1mm) - 2 sheets	84,00
Lubricant (MoS_2)	40,00
TOTAL COST	**380,00**

* Values considered for the cost of an employee's hours with technical training in design and programming.
** Values considered for the cost of time for an employee with technical training to assist production.
*** Values considering the price of the Euro on 30/04/2012, equivalent to R$ 2.50.

EVALUATION OF PROPOSED METHODS

The implants produced by means of rapid manufacturing showed good adaptation to biomodel, given the necessary geometrical requirements. The rapid manufacturing also allows internal structures of high geometric complexity to be inserted into the implant, adding functionality. Such formal freedom is not observed in SPIF, in which limits the geometry only to an outer surface shaped according to the virtual three-dimensional model. The laser sintering process, however, although flexible to create complex geometries, still uses equipment often restricted to a few companies, universities and research centers. Antagonistically, SPIF uses CNC machining centers, 3-axis and simple tooling, which are easily found. The time required to manufacture the implant is also significantly lower (14 hours, compared to the laser sintering, which requires 59 hours). However, it has limited dimensional accuracy, that in the case of the implant in question, makes its manufacture unfeasible. Other strategies for improving the accuracy and/or increasing the forming limits of the material should be used.

5.5.5 Temporomandibular joint (TMJ)

Three basic requirements for a system for full reconstruction of ATM can be listed, which are: to reproduce the movements of the original system function, to

provide adequate adjustment to the cranium and to achieve sufficient service life. Such requirements may still develop into others, such as the reproduction of condylar translation during opening of the mouth, unrestricted mandible movements; correct fit to the skull; correct fit to the mandible; stable fixation of bone structures, life expectancy of more than 20 years, low wear rate, particles tolerated for the body, biocompatible materials, adequate mechanical strength, simple and achievable deployment procedures.

Due to the foregoing requirements, prosthesis for replacement of TMJ should copy the movement of the joint. Therefore, two surfaces in contact are needed (one attached to the skull, another attached to the mandible) and that permit relative movement. Thus, it would not be feasible the use this prosthesis with two components titanium, due to the imminence of excessive wear between the surfaces. Still, the standard ISO 7206-2: 2012 (Implants for surgery - Partial and total prosthesis hip joint, part 2: articulating surfaces made of metallic materials, ceramic and plastic) provides a list of materials which may be articulated against each other, in which titanium is not included. Therefore, SPIF was not performed for the manufacture of prosthesis for replacement of TMJ. It has been considered only the manufacture through CNC machining, described in Section 3.4.5, in which the mandible component is made of titanium and the cranial component, ultra- high- molecular- weight- polyethylene.

Commercially available and approved for implantation systems can be mentioned, such as Promm (Brazil), called Arthroplasty System Promm, TMJ Concepts (USA) called TMJ Patient-Fitted TMJ Reconstruction Prosthesis System and the system W. Lorenz Surgical Inc. (USA) called Biomet Microfixation TMJ Replacement System. Both manufacturers use the CNC machining process for the production of custom TMJ prosthesis. The time spent on each step for the manufacture of a custom system for TMJ replacement TMJ through manual modeling, laser scanning and CNC-machining are summarized in Table 25.

Table 25: Time required to manufacture the custom system for TMJ replacement.

Step	Used time (h)
Biomodel manufacturing	10
Modeling the plastic mass for implant prototyping (including curing time)	10
Scanning of the prototypes (cranial and mandibular components)	4
STL file generation	4
CNC Programming	4
Set up of the equipment	1
Machining of the jaw component (titanium)	12
Machining of the cranial component (in UHMWPE)	4
Deburring, cleaning	4
TOTAL TIME	**53**

The material handling time for prototyping the implant (excluding the curing time) is estimated at 5 hours. The estimated costs associated with manufacturing of the implant are presented in Table 26.

Table 26: Costs associated with the manufacture of custom system to replace the TMJ.

Description of expenses	Cost (€)***
Biomodel	500,00
Modeling of the prototypes of the implant (5 hours) **	40,00
Material of the implant model	10,00
Scanning of the prototypes	320,00
STL file generation (4 hours) *	64,00
CNC Programming (4 hours) *	64,00
Titanium sheet cp grade 2 (120x80x12mm)	100,00
Ultra high molecular weight polyethylene block (40x40x25mm)	50,00
CNC Machining (17 hours)	680,00
Deburring, cleaning (4 hours) **	32,00
TOTAL COST	**1.860,00**

* Values considered for the cost of an employee's hours with technical training in design and programming.
** Values considered for the cost of time for an employee with technical training to assist production.
*** Values considering the price of the Euro on 30/04/2012, equivalent to R$ 2.50.

The implant produced using this process is well adapted to the biomodel, and its precision is limited by factors related to the multiple steps of the process, such as the resolution used for scanning and the machining strategy. The geometric complexity that can be achieved for customized TMJ implants manufactured through this method is, however, limited by the intrinsic characteristics of the CNC machining process, where the material is removed only from the regions where the tool can reach. The

indexing of the extra axis to the CNC equipment tends to enable the manufacture of parts with more complex geometry.

5.5.6 Summary of the proposed methods

Several processes that allow the manufacturing of customized implants to repair defects in the craniofacial complex are available today. Methods based on manual modeling with the use of anatomical biomodel of the patient, single point incremental forming, additive manufacturing and CNC machining highlight among them. As it has been noted, each process has its more or less limited extent regarding the potential for the manufacture of craniofacial implants. Limitations for the application of each process reside in aspects such as the desired accuracy, geometric complexity, availability of equipment and tooling, automation, process time. The processes studied in each typical case craniofacial reconstruction are summarized in Table 28, with the variables of materials, time, cost, advantages, limitations and operational requirements.

Methods based on manual modeling are already being used in craniofacial surgery. Osteosynthesis plates for reconstruction are commercially available and can be shaped in the desired geometry intraoperactively or previously to the surgery, with the aid of biomodels, as performed in this study for reconstruction of defects in frontal and supra-orbital regions. The freedom that the surgeon has, considering the geometry that can be formed, is, however, limited. Furthermore, the conformation depends on manual skills of the operator and cannot be performed in defects covering large areas. Furthermore, when performed intraoperactively, the conformation of osteosynthesis plates can increase the time of surgery, increasing patient risk and costs to the health system. The use of an initially fluid material (as is the case of calcium phosphate cements) appear as an alternative for the reconstruction of complex defects, since small bone holes can be filled. For those cases assessed using the calcium phosphate cement (reconstruction of frontal defect and zygomatic bone), the aesthetic effect obtained was satisfactory. Additionally, the calcium phosphate cements have properties of osteoconduction, guiding the bone growth and providing a stable interface between implant and bone.

The rapid manufacturing processes able to produce implants directly using the material suitable for implantation, such as those based on laser melting, allow the reproduction of the designed models with high accuracy, and unlimited geometric flexibility. As discussed herein, for the case of manufacture of the mandible implant, organic geometries, reticular structures, or even internal optimized geometries can be produced. However, although very versatile and flexible in terms of geometries to be manufactured and capable of generating implants directly into the material suitable for implantation, additive manufacturing processes based on laser sintering of metals is not yet widely available. Notably, there is a rapidly growing market worldwide, improvement and diffusion of technical innovations in hardware and software and increasing of the range of materials suitable for the process. However, most of the equipment currently in operation is still restricted to large companies, universities and research centers. Thus, using the technique for manufacturing custom implant is still limited and expensive.

Single point incremental forming, in turn, although it has limitations considering the accuracy of the process, uses simple tooling and widely available equipment. CNC machining centers are easily found and can be easily adapted to the SPIF process for implant manufacturing. The titanium implants manufactured through SPIF can be seen in Figure 63.

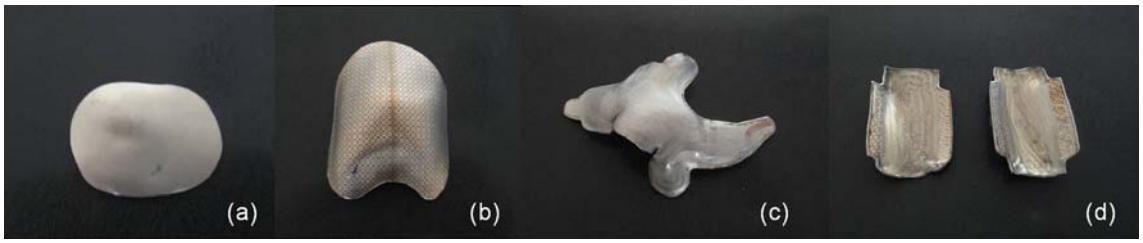


Figure 63: Titanium implants for different craniofacial regions produced through single point incremental forming. (a)Frontal; (b) frontal and supraorbital; (c) zygomatic bone; (d) mandible.

SPIF has proposed, as one of its strengths, the possibility to achieve degrees of deformation not achievable through conventional sheet metal forming methods. This statement can be confirmed when comparing the strains obtained through SPIF with the forming limit curve of the material (shown in Figure 28). To the formed implants of this study, the analysis of deformation is shown in Figure 64.

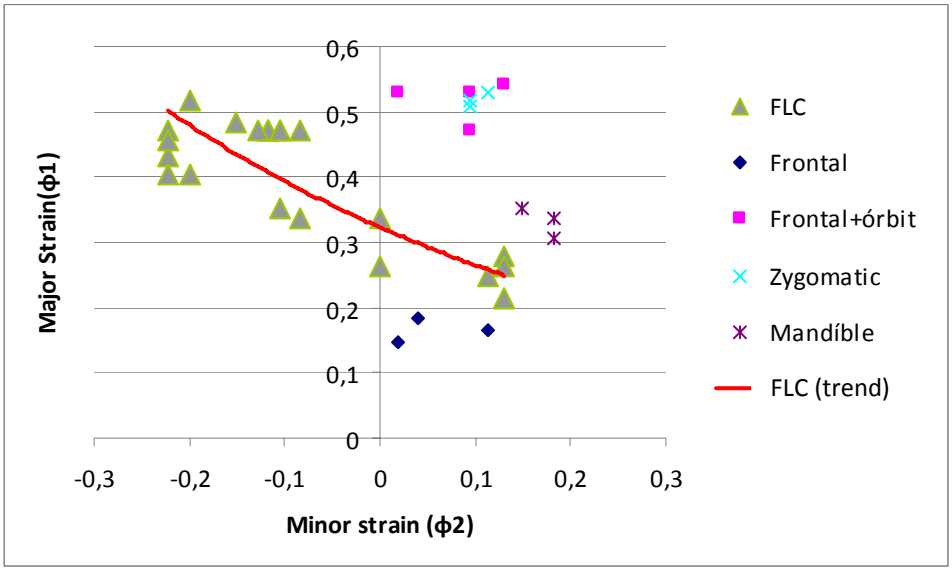


Figure 64: Deformations presented in implants produced through SPIF and comparison with the material FLC.

For implants, analogously to the specimens formed into a cone shape, the points on the graph are found above the FLC of the material. This means that the degree of deformation reached in SPIF is greater than the degree of deformation obtained through conventional sheet metal forming. The points that appear below the FLC correspond to the implant to repair a defect in the frontal region, which due to its simple geometry, required low degrees of deformation. Special attention must be given to frontal defect implants + orbital and zygomatic, which experienced high degrees of deformation without rupture.

However, due to the low accuracy presented by SPIF, some authors have investigated some strategies that can circumvent, or at least lessen the negative springback effects of the plate. In this sense, Ambrogio et al. (2004) showed that it is possible to improve the accuracy of the final product, reducing the gap by 70% through proper selection of these parameters. A very promising concept for reducing inaccuracy of the parts is based on the design of "addicted trajectories" of the tool and, thereby, create an intermediate form which approach the desired shape only when the motion of the plate is relaxed. These paths should be designed before the start of the process, using both numerical simulation and sensors that detect the actual shape of the plate and introduce the appropriate correction to the part program taking into

account the springback effect. According to Ambrogio et al. (2005), this area of research will probably be the challenge of coming years.

Mohammadi et al. (2012) and Duflou et al. (2008a) have developed a system capable to generate heat dynamically directly in the vicinity of the tool by means of a laser beam, creating a ductile area of low elastic modulus. Effects obtained with this strategy are the reduction of the forces applied by the tool, greater localized deformation and, thus, an increase in the accuracy of the process. It was also demonstrated that the incremental forming using multiple passes (Duflou et al., 2008b), or mixed strategies (Malhotra et al., 2011) enhance the formability of the sheet, also generating positive effects on the accuracy of the process. Further, the use of counter parts under the plate to be shaped can also be used for such purpose (Ambrogio et al., 2004). Other studies indicate, as a strategy to increase the accuracy, the reduction in diameter of the tool and reducing the vertical increment. Another factor that affects the accuracy of the process is the distance between the location on the plate where the part is being formed and where it is fixed (clamping system). The distance must be minimized in order to reduce unwanted effects of elastic deformation of the plate (Micari et al., 2007). Behera et al (2011) reported also an increase in the accuracy of the process by means of optimized toolpaths and compensated trajectories, anticipating the deformation that the material would suffer and making up for it.

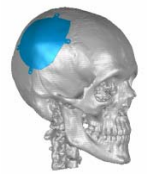
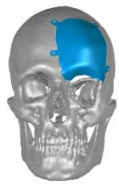
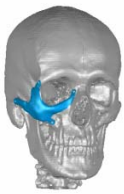
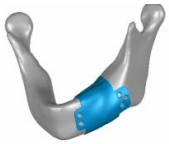
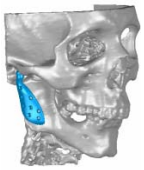
Besides the aspects discussed about the accuracy, when a strategy for incremental forming is utilized, according to the conservation of volume, the thinning of the sheet is another important problem (Hussain and Gao, 2007). The thinning is generally governed by geometric thickness that leads to zero on the vertical walls. As a result, this type of surface must be carefully avoided. Sometimes, the problem can be solved performing a rotation in the model to be formed by positioning the walls, first vertical, aligned with the horizontal plane as much as possible. From a purely industrial point of view, the thickening phenomenon is usually avoided with use of thicker plates. Anyway, when the weight of the component is a variable to be optimized, a specific study should be performed.

The increase in formability of the material itself, and the resultant viability of

forming parts exceeding the limit forming angles (45 degrees, for the material used for this study) are aspects that are currently being discussed. Strategies are proposed, such as localized heating of the material in regions where the deformation occurs [Duflou et al. (2008a), Palunbo and Brandizzi (2012)] and the use of multiple steps or intermediate geometries in order to increase the formability of the material [Duflou et al. (2008b), Malhora et al. (2011)].

For the various cases of patients requiring craniofacial reconstruction addressed in this study, the possibility of manufacturing the implant through SPIF was evaluated. The result is summarized in Table 27.

Table 27: Possibility of manufacturing through single point incremental forming and meeting of the formal requirements for the reconstruction of the different regions of the craniofacial complex.

Region of the craniofacial complex to be reconstructed	Possibility of establishing the desired geometry	Accuracy (reproduction of the desired geometry)	Potential of application of the technique in the craniofacial complex region
Frontal or parietal 	Yes	Suitable	Can be applied
Frontal and supra-orbital 	Yes	Good for the frontal region, does not satisfactorily reproduce the orbital area.	Inadequate for supra-orbital reconstruction
Zygomatic bone 	Yes	Suitable	It can be applied, except for the reconstruction of orbital floor.
Mandible ramus 	No	Inadequate	It can not be applied for geometrical constraints
Temporomandibular joint 	No	Inadequate	It can not be applied for regulatory requirements

6. CONCLUSIONS

This study examined methods of manufacture of customized implants currently used with potential for craniofacial reconstruction surgery. The anatomical information and, consequently, the regions to be reconstructed were obtained from CT scans. Methods were evaluated based on manual modeling using different materials, such as titanium meshes and calcium phosphate cements, and automated methods, such as CNC machining, additive manufacturing and single point incremental forming.

For all cases investigated in this study, implants were designed based on CT images. The softwares used are commercially available and offer various resources for the virtual three-dimensional reconstruction and visualization of the anatomical structure of the patients. For the design of the implants, commercially available CAD software can also be used to manipulate the files.

The methodology presented and discussed for the manufacture of craniofacial customized implants using calcium phosphate cement meets the requirements for use in bone reconstruction. The implants manufactured through the manual modeling method with the aid of rapid prototyping biomodels have formal and functional characteristics suitable for specific types of fractures investigated in this study. Likewise, the manual sheet conformation for the reconstruction of front and orbital defect, although being dependent on motor skills of the operator, provided a suitable reproduction of the desired geometry.

The mandibular implant produced through rapid manufacturing (the laser sintering, more specifically) on Ti-6Al-4V presented appropriate geometric precision. The manufacture of complex shapes with high dimensional accuracy demonstrated the high flexibility of the process. However, the high cost of the materials and equipment restricts the access to this technology to few end users that have appropriate resources.

Implants of titanium grade 2, 1mm thickness, whose geometries were designed in advance in a CAD, were produced through single point incremental forming. The manufacture of implants to repair complex craniofacial defects introduced restrictions due to the accuracy limitations of the technique and the geometries that could be

formed. Through trials in cone specimens, the forming limit angle of the material was determined to be 45˚. This finding limited the achievable cranial and facial geometries using this process, so only implants with curvature below this angle can be successfully formed. The implants produced for the correction of defects in the frontal, parietal and zygomatic regions clearly show satisfactory geometry. The implant to repair frontal and supra-orbital defects was satisfactorily fitted to the frontal region; the characteristic curve of the orbit was, however, not adequately reproduced. The implant produced to repair the mandibular defect has not fitted to the anatomical structure and may be considered inappropriate. The increase in the formability of the material itself, and the consequent feasibility of parts with angles higher than 45 degrees are aspects that are being currently discussed. Strategies are being proposed for the localized heating of the material in regions where the deformation occurs as well as the use of multiple steps and/or intermediate geometries for incremental forming.

A relevant characteristic of SPIF, which was observed in the produced implants, was the low precision. The elastic recovery presented by the plate is substantial and may, as in the case of the mandible implant, destabilize the process. As it has been demonstrated, strategies such as the use of more than one point of contact or backing plates for incremental forming, as well as multi step incremental forming, may help to improve the precision of the process. It is also possible to improve the dimensional accuracy of parts produced through incremental forming through the development and use of optimized forming strategies, which undertake compensation in regions that are slightly warped or deformed in excess.

The analysis of deformation on the implants produced through SPIF demonstrates an increase in the capacity of elongation of the material when compared to a conventional sheet metal forming. For the implants to repair the frontal and parietal orbital and the zygomatic regions, the strain values are found above the forming limit curve of the material.

Despite its limitations in geometric and dimensional accuracy, the single point incremental forming process enabled the production of a preoperactively manufactured custom implants with a simple automated set up. As system

requirements, there are CAD and CAM software and widely used equipments such as 3-axis CNC milling machines, clamping systems, backing plates and spherical tools. The processing time is also low compared to other investigated processes (such as additive manufacturing and manual modeling using calcium phosphate cement), and is mainly due to the design steps in CAD and CAM programming. Likewise, the costs of manufacture of implants through SPIF are also significantly lower.

Considering the flexibility and potential provided by the SPIF process, it can be stated that the process presents itself as a viable alternative for the manufacture of customized titanium craniofacial implants. They are, however, subjected to the intrinsic limitations of the process and the material once the geometry to be formed is defined.

Implants intended for the reconstruction of complex craniofacial defects have, as fundamental requirements for the most part, the protection and restoration of form. Thus, this study contributes to the systematic knowledge of design tools, materials and manufacturing processes that allow the flexible production of craniofacial implants that meet its formal, functional and aesthetic requirements.

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