DOI: 10.2478/aucts-2018-0003

ACTA UNIVERSITATIS CIBINIENSIS – TECHNICAL SERIES
Vol. LXX 2018

A BRIEF REVIEW OF MANUFACTURING MEDICAL IMPLANTS BY SINGLE POINT INCREMENTAL FORMING

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Abstract: *SPIF is a relatively new process that can replace conventional deformation processes. Due to the use of generic tools only, the process is suited to achieving unique production or prototypes. The paper presents a brief literature review on current research of single point incremental forming with applications in obtaining medical implants regarding materials and metodology used.*

Keywords: single point incremental forming, medical implants, manufacturing methodology, cranial prosthesis

1. Introduction

One of the new technologies that has been developed due to the rapid advance of computer industry, often used to produce prototypes in full or small size, is Incremental Sheet Forming (ISF). ISF process consists of a gradual deformation of a raw material sheet or blank using a hemi-spherical die tool whose movement is controlled by a CNC machine (computer numerically controlled machine) or a robot. The technology of the process was patented by Leszak in 1967. In 1989, Iseki et al. [1] presented the first parts manufactured with a milling machine operated by CNC (fig.1).

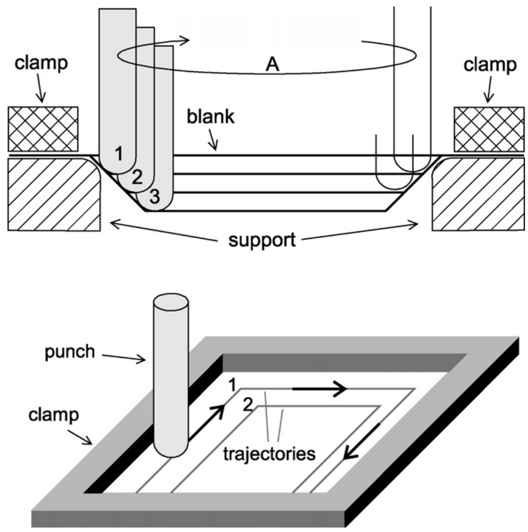

Figure 1. SPIF principle presented by Iseky et al. [1]

The main applications of ISF are in the automotive industry and aeronautic industry, but the technology has an important potential in other fields as well, such as biomedical one.

The ISF process offers advantages such as lower forming forces, improves formability, lower die tooling cost, flexible forming facilities, but has some limitations too, such as geometry accuracy, surface finish, process efficiency, excessive thinning [2].

Based on the number of points where deformation can be made, ISF can be single-point contact, single point incrementation forming (SPIF) and two-point contact, two point incremental forming (TPIF).

Last years research in manufacturing and bioengineering has been aimed at finding innovative solutions to improve real life expectancy. As the population grows, grows the demand for medical implants and devices. Medical implants must fulfill both functional and aesthetic aspects [3]. The primary purpose of medical implants was to mimic a part of the human body and also to support the normal functioning of the body by replacing an organ or a part thereof [4].

Some of the most researched applications of Single Point Incrementation Forming (SPIF) were medical implants because of the particularities of the human body shape, and consequently the making of parts in the form of a prototype or small series. Among the most studied medical implants in terms of SPIF are cranial plate, knee prosthesis, ankle support and facial implant [5].

From the materials used in making implants point of view, they can be divided into two groups: metallic and plastic [6]. The most commonly used metal material is titanium because of its biocompatibility. The disadvantage of titanium is the need for heating to increase formability.

2. Materials, manufacturing and methodolgy

2.1. Materials

The materials used to reconstruct the various organs of the human body must meet certain requirements such as biocompatiblity, easy to be shaped, strong but lightweight, low electric and thermal conductivity, low manufacturing costs and similar mechanical behaviour with a human bone [7].

In medical implants can be used synthetic materials (metallic, polymeric, ceramic materials) and non-synthetic materials like autografts (bones from the same body) and allografts (cadaver bone donation) [7]. Autografts are preferable for the bone replacement but cannot be always used because of pacient's health condition or because of a large quantity reguired [8], and allografts present high risk of infection and may have a limited strength [9].

The most used metallic materials are titanium alloys, especially grade 5 Ti6Al4V. The titanium alloy has the advantage of biocompatibility and corrosion resistance, but also the disadvantage of conducting the heat and mechanical properties superior to human bones. Titanium is also used in other commercial applications such as aircrafts, jet engines or sporting goods. Ambrogio et al. [3] have made impact test and cytoxicity test on titanium alloys deformed by SPIF and concluded that the prostheses biocompatibility is not affected by the manufacturing process.

The polymeric materials used in medical implants are absorbable and nonabsorbable polymers. Absorbable polymers are polylactic acid and polycaprolactone. Nonabsorbable polymers are polyethylene, polyetheretherketone and polymethylmethacrylate [9]. Of these, nonabsorbable polymers are the most used in medical procedures. Compared to metallic materials used in implants, polymeric implants have the advantage of a lower density than titanium (3 to 5 times), mechanical properties similar to human bone, more lightweight and low heat conductivity.

Another category of materials used in medical implants is ceramics. One of the most used in medical implants are hydroxyapatite, who has the advantage of very good osteointegration, but it's fragile meaning poor mechanical properties.

Some of the most used materials are presented in table 1 [10].

Table 1: Materials used in incremental sheet forming [10]

Material	Alloy	Thickness
Aluminium	1xxx 3xxx 5xxx	0.5 to 3.0mm 0.5 to 3.0mm 0.5 to 3.0mm
Steel	low carbon DPxxxx	0.5 to 2.0mm 0.5 to 1.5mm
Brass	-	0.5 to 1.5mm
Cooper	-	0.5 to 1.5mm
Titanium	grade 2	0.5 to 1.5mm
PE	-	1.0 to 5.0mm
PA	-	1.0 to 5.0mm

2.2. Manufacturing

Racz et al [11] presents a manufacturing process diagram (fig.2). Medical implants and cranioplasty plates in particular can be manufactured using a manually approach or a computer aided approach.

The manual approach consists of several manual operations from physical templates, negative cast and reaching the medical implant.

The digital approach is based on processing a computer tomography (CT) scan or another scanning technologies such as magnetic resonance imaging (MRI), which will be processed and converted to a 3D stereolithography (3D STL) file. After the import to a CAM software the code is generated the code and then sent to CNC machine or industrial robot. In the final stage, implants are subject to some operations which are specific to medical act like for example the sterilization.

The cranioplasty plates can be made by cutting, SPIF [18], SPIF with heating, double-side incremental forming [11] or by super plastic forming [12].

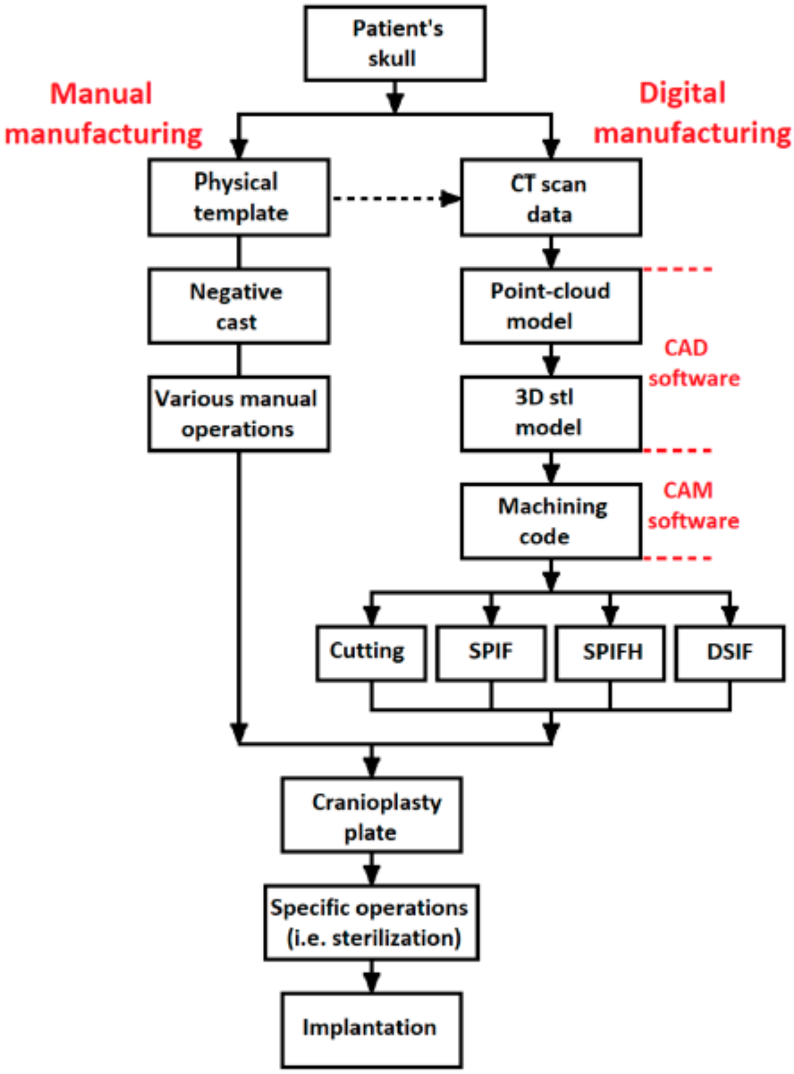

Figure 2. Processes diagram for cranioplasty plates [11]

The development of computer systems has led to the emergence of new technologies in the expansion of medical implants. One of these technologies is additive manufacturing (AM) whose principle consists in adding material layer by layer and resulting a 3D object. In this category can be mentioned selective laser sintering, direct metal laser sintering, fused deposition modeling, stereolitography apparatus and 3D printing (3DP). Jardini et al. [12] reconstruct a 3D biomodel from the 3DP manufactured skull. Then they verify the adjustment on the 3D biomodel by using a titanium implant manufactured with DMLS.

Bagudanch et al. [7] and Centeno et al. [15] present another process diagram for manufacturing a cranial implant using the ISF process (figure 3 and figure 4). Medical images optained from CT are software processed to obtain the 3D model. After that, model exported as StL file was used to obtained the CAD model.

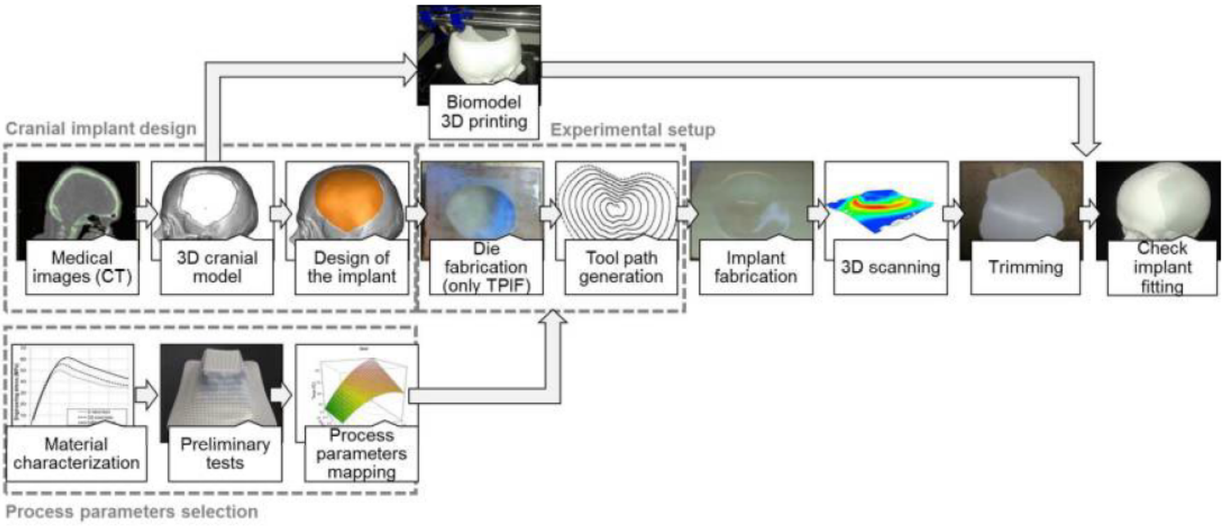

Figure 3. Methodology for manufacturing a customized cranial implant by ISF presented by Bagudanch et al [7] **and Centeno et al** [15]

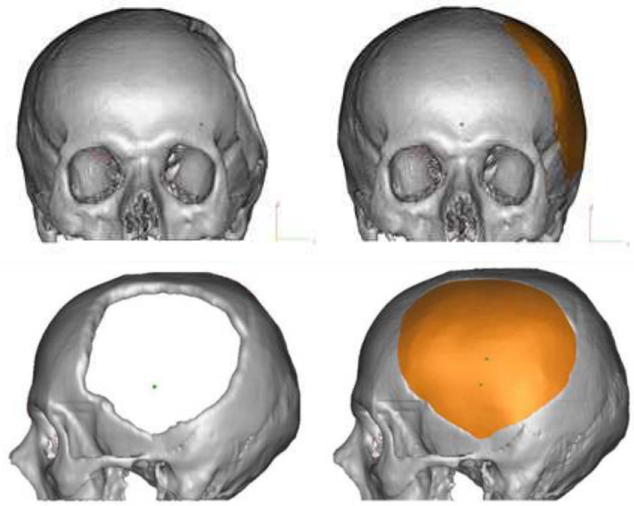

Figure 4. Cranial fracture and prosthesis [7]

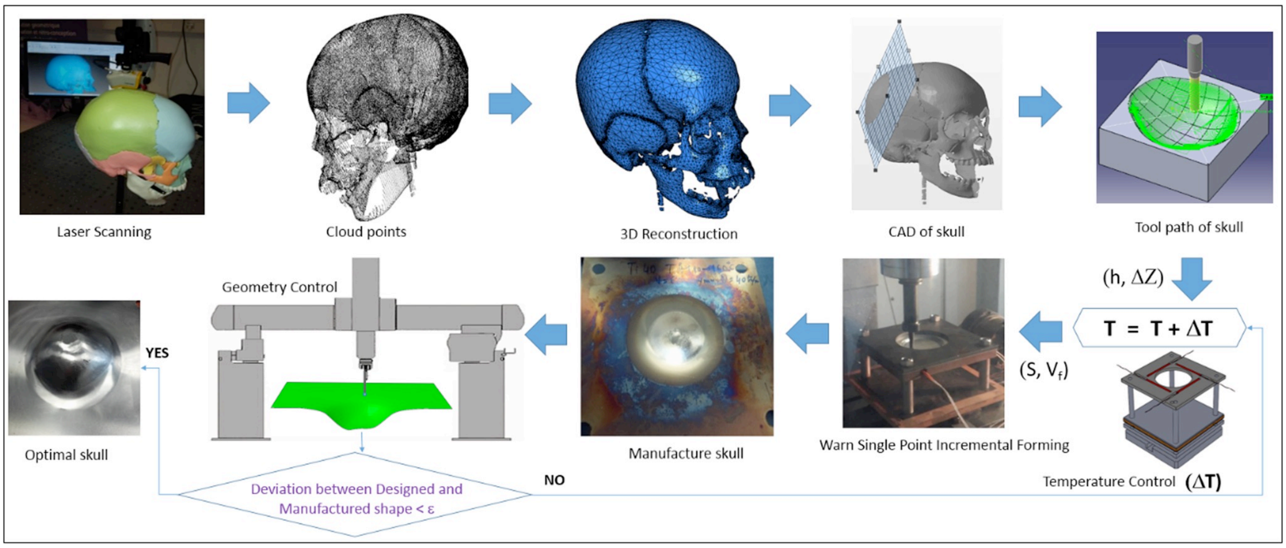

Figure 5. Human skull manufacturing by reverse engineering application [16]

Saidi et al. describe the reverse engineering approach [16]. In this approach, the cranial implant is designed from an anatomic model, created form a cloud of points obtained by laser scanning. Based on this detailed scan, the CAD model is created for chirurgical reconstruction. The whole process is presented in figure 5.

Conclusions

The use of SPIF in the manufacturing process by companies such as Ford and Arcel makes it have a promising future. Nowadays, SPIF is achieving a 5/6 technology readiness in industrial environment [17].

SPIF is a leading candidate for the production of small series or prototypes or as way to personalize the products for large series manufacturing. Mass production can be achieved if the process is associated with other production techniques.

SPIF can be used not only for prototyping, but also for single or small series products adding more value to them. It also takes advantages of the aesthetic features. Unlike other rapid prototyping techniques that reproduce non-functional parts, SPIF can make functional parts that can be used both as prototypes but also as regular production and spare parts.

SPIF is ready for industry with feasible results and is possible to obtain real implants for the human body organs.

Lower forming forces, lower die tooling cost, greater formability have made the SPIF process a strong competitor to conventional forming processes. There are still disadvantages as well geometric accuracy and process efficiency.

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