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## Performances analysis of Titanium prostheses manufactured by Superplastic Forming and Incremental Forming

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### Abstract

Titanium and its alloys are widely used in cranioplasty because they are biocompatible with excellent mechanical properties and favor the osseointegration with the bone. However, when Titanium alloys have to be worked several problems occurred from a manufacturing point of view: the standard procedure for obtaining Titanium prostheses is represented by the machining processes, which result time and cost consuming. The aim of this research consist to introduce alternative flexible sheet forming processes, i.e. Super Plastic Forming (SPF) and Single Point Incremental Forming (SPIF), for the manufacturing of patient-oriented titanium prostheses. The research activities have already highlighted the potentiality of the investigated forming processes that can be alternatively used taking into account both the damage morphology and the need of urgency operation. In the present work, the way of manufacturing the Ti prostheses by SPF and SPIF is described. A comparative analysis has been performed, thus highlighting the peculiarities of the investigated processes and the prostheses feasibility.

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## 1. Introduction

In the last years, researchers in Manufacturing and Bioengineering have been involved in proposing innovative solutions aimed at improving actual life expectancy and medical care quality. Moreover, they have tried to study better and customized answers for patients.

Cranioplasty is a kind of neuro-reconstructive surgery aiming at repairing structural or morphological problems due to congenital or accidental causes by means of a prosthesis. Cranioplasty is still a challenge for both surgeons and bioengineers. It can be described as a procedure not only for an anatomical reconstruction but also for the neurological improvement of underlying physiology [1].

Prostheses must be anchored to skull bone fulfilling both functional and aesthetic aspects. Different materials are available. Nowadays, standard procedures for prosthesis manufacturing consider mainly two types of materials: Polymethyl Methacrylate (PMMA) and Titanium Alloys. The first one is the most used material for cranioplasties due to its easier workability, whereas the prostheses made in Titanium alloy are manufactured by machining using CAD/CAM techniques [2]. Furthermore, Titanium alloys promote the osseointegration and is biocompatible, experimental and clinically tested, with excellent mechanical properties [3-4]. Customized prostheses have been recently used in order to improve aesthetics and to obtain a normal appearance [5-6], also because the craniofacial implants have a relevant aesthetic function, as well.

As concerns the manufacturing process, craniofacial prostheses could be made using the Incremental Sheet forming (ISF), an innovative technology characterized by significant advantages [6-9] such as the possibility of creating both patient-specific and generic prostheses and low set-up costs.

The aim of this paper is the design of a complete procedure that guides and integrates the jobs of surgeons and engineers during the cranioplasty process. Impact puncture and Cytotoxicity tests were performed in order to compare the behavior of two different prostheses.

## 2. Material and Method

### 2.1. Material

Ti6Al4V (thickness\_ 1.5mm) and Ti6Al4V-ELI (thickness\_ 1.0mm) have been used for the investigation of the prostheses manufacturing processes. The main difference between the two Ti alloys is the stricter control of both the composition and the mechanical properties of the Ti6Al4V-ELI. The attention was focused on these alloys largely used as implant materials because of good biocompatibility, low density, non-magnetic properties and the elastic modulus very similar to the bone's one.

The investigated alloys were preliminary characterized through an extensive experimental campaign based on tensile tests in a large temperature range (200 – 700°C) and free inflation tests in the range 800 – 900°C.

### 2.2. Case study

The case study definition can be divided into two distinct phases: the first goes from the damage identification up to the implant rebuilding (Phase I); the second, indeed, starts from the geometry of the needed prosthesis and ends with the design of auxiliary surfaces required for the processes execution (Phase II).

A simulacrum of the human skull has been adopted for the definition of the case study. A fracture in the frontal part of the skull has been produced in order to simulate the bone damage. After that, the damage reconstruction has been obtained starting from the DICOM image of the skull and implementing a mirroring technique for the rebuilding [10]. This phase of the study was carefully executed in order to have the geometry of the prosthesis very similar to the one of the missing anatomical part. Starting from the highlighted geometry, a second design phase has been conducted to comply the above specified shape at the technical requirement of the adopted manufacturing processes.

Concerning the prosthesis geometry, it is characterized by a severe curvature that makes difficult the workability of a Ti-Gr5 sheet. Starting from the CAD model of the prosthesis, the correct shape positioning on the sheet plane has to be performed since the technological constraints of the considered process have to be respected [11].

The results of Phase II is shown in the next Fig.1.

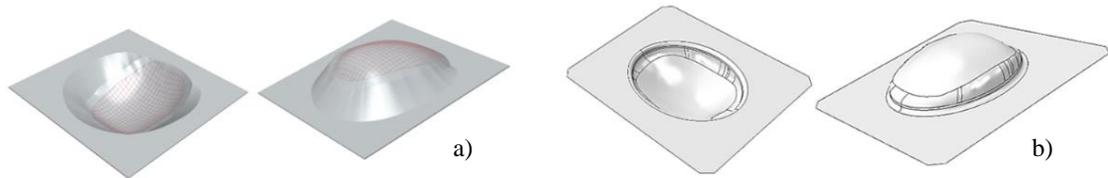


Fig. 1. Prostheses reconstruction for a) SPIF and b) SPF.

### 2.3. Experimental equipment

Established the part geometry, including the edge for the auxiliary material, the experimental analysis can be addresses in parallel for both the investigated processes.

#### 2.3.1. SPIF equipment

It has been assessed by the literature that Single Point Incremental Forming is a very suitable technology solution when highly customized products have to be manufactured. In fact, due to the very low set-up cost, the use of this manufacturing technique becomes strategic when a single part has to be manufactured [12]. After the shape positioning phase, a part program has been generated by using a CAD/CAM system, in which the tool path is defined for both the SPIF and cutting operation. The manufacturing steps have been performed on a 3-axes CNC work center, while a simple HSS tool having an hemispherical punch and a cylindrical cutter with 6mm of diameter have been used respectively to create the product by a continuous movement during the SPIF phase and to cut the edge of the sheet. More in detail, the sheet is deformed according to the designed tool trajectory and parameters: in this study a tool diameter of 12 mm, a constant tool depth step equal to 0,5 mm and a tool feed rate of about 2500 mm/min have been used. The working center has been additionally equipped by an innovative clamping set up that ensure the possibility to work in hot condition; indeed, taking into account the low formability of Ti-Gr5 at room temperature, the manufacturing step has to be performed in temperature. To do that, the conventional naked frame was properly changed and equipped with a chamber supplied with a circular electrical heater of 2kW. The chamber is additionally surrounded with an insulation to reduce heat losses with the environment and with the working table. The temperature in the chamber and on the sheet is continuously measured by thermocouples. A temperature of 650°C has been reached during the forming phase. Finally, a lower feed rate with respect to those used for the SPIF process has been adopted for material removal phase. In particular, the milling phase has been executed by using a feed rate of 500mm/min and a pitch of 0.2mm. An image of the utilized equipment is highlighted in the next Fig.2.



Fig.2. SPIF equipment.

### 2.3.2. SPF equipment

SPF tests were carried out using a 2500 kN electro-hydraulic press machine, adopting two levels of temperature (800 and 850°C) and two different types of pressure law. In particular, referring to the tests conducted at 800 °C, two constant pressure profiles (2 and 2.5 MPa) were conducted. Moreover, in order to ensure a constant strain rate (0.02 and 0.002 sec<sup>-1</sup>), the tests at 850 °C have been performed using variable and optimized pressure profiles obtained from the numerical simulation. In order to clamp the undeformed Ti sheet, a Blank Holder Force (BHF) equal to 480 kN was used. Four electric motors and electric cartridges (total power equal to 80 kW) ensure respectively the appropriate BHF and the correct value of temperature. The Fig.3a shows the setup adopted to perform the SPF tests.

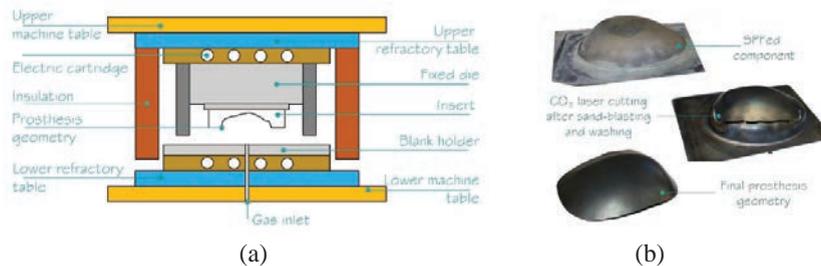


Fig.3. Scheme of setup for SPF tests (a) and final prosthesis obtained (b).

After the SPF process, the component obtained is subjected to the subsequent processes of polishing, sandblasting and washing; finally, by means of a laser cutting, the final geometry of the prosthesis is obtained (Fig. 3b).

### 2.4. Impact test

Impact puncture tests have been performed on the two prostheses using an Instron CEAST 9350 drop tower. This machine is capable of impacting samples at energies up to 1800 J by using a spring assist. An instrumented striker equipped with a 20 mm hemispherical nose impactor with a mass of 2.295 kg was employed for experiments. Due to the non-standard shape of the samples, a proper clamp system was designed to firmly fix the prostheses in order to minimize vibrations during the test. After the first impact of the specimen, a break mechanism was activated to prevent a second strike. During the impact, the resistive impact force exerted by the specimen was measured by a 45 kN strain gauge load cell. The striker was dropped from a height of 200 mm with a speed of 2 m/s corresponding to a nominal impact energies of 4.5 J. From the basic force–time information, important parameters such as maximum force and absorbed energy have been obtained.

### 2.5. Cytotoxicity test

Titanium alloys are known to be biocompatible when in contact with bone tissues. However, in order to assess if the adopted manufacturing procedures could induce a change in the biocompatibility of the material, cytotoxicity tests according to ISO 10993-5 standard have been performed using osteoblast-like cells SAOS-2 cultured in an appropriate medium (McCoy cell culture medium 1x, 15% fetal bovine serum, 1% glutamine 200mM, 1% sodium pyruvate, 1% penicillin / streptomycin).

Rectangular specimens (approximately 20x20 mm) were cut directly from the sheets after the forming phase; specimens were disinfected in ethanol solution 70% v/v for 2 hours then dried under sterile hood overnight; specimens were finally sterilized for 20 minutes under UV lamp ( $\lambda=254$ ). Eluates have been extracted at different time points (Ti-1, Ti-3 and Ti-7 at 1, 3 and 7 days respectively): at every timepoint three specimens have been immersed in a multiwell plate into 7.5 ml of culture medium while three more wells were filled with the same quantity of medium without specimens to be used as control (TCPS-1, TCPS-3 and TCPS-7 at 1, 3 and 7 days respectively). After a proper culture, SAOS-2 cells were seeded in each well of the plate with a density of  $10^4$

cells/well for 24h. The culture medium was then replaced by the same volume of eluates that were in contact with the titanium specimens at Ti-1, Ti-3 and Ti-7 and cells have been maintained in incubator for 24h: after that, the culture medium was substituted by an Almar-blue solution and cell viability has been evaluated by measuring the fluorescence through a spectrophotometer (Tecan, Genius Plus plate reader).

### 3. Discussion of the results

The results of impact tests, in terms of force and energy vs. time are shown in Fig. 4. In particular Fig. 4a reports data obtained concerning the prosthesis manufactured by SPIF, whereas Fig. 4b reports data obtained from impact tests on the prosthesis manufactured by SPF.

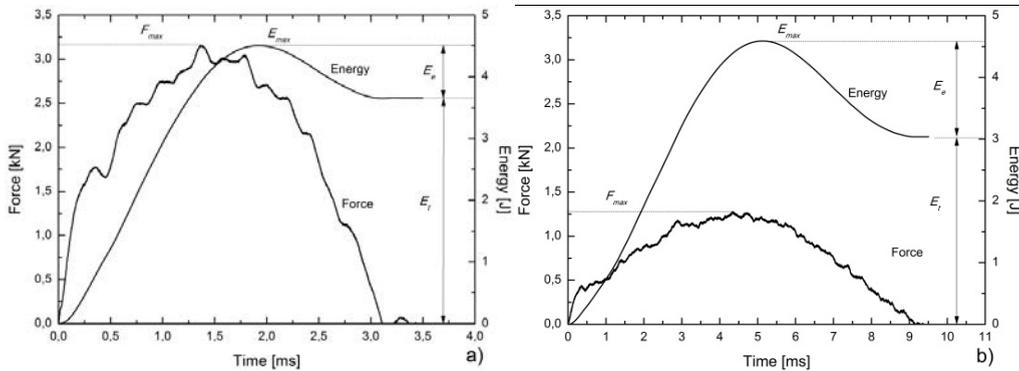


Fig. 4 results, in terms of load and energy vs. time, obtained from the impact experiments; a) data obtained from the prosthesis realized using the SPIF technique, b) data obtained from the prosthesis realized using the SPF technique.

Results show that the perfectly elastic rebound of the striker did not take place for any of the investigated case studies. This means that the kinetic energy was transferred to the prostheses during the contact, and consumed in the generation of small deformations generated by the very localized impact point. Furthermore figures show that the sample obtained by SPIF got the highest maximum force ( $F_{max}$ ), the highest absorbed total energy ( $E_t$ ) and the lowest energy absorption time. In other words, sample obtained by SPIF seems to be stiffer than the one obtained by SPF which highlighted a more ductile response. This behavior can be justified by (i) the geometrical differences between the tested shapes; (ii) the different thickness distribution, both the initial one and the one determined by the forming process (for example SPF determines larger thinning in the formed part).

In addition, it is important to underline that force vs time data exhibited several load drops. In general such events can be attributed to damage initiations, but in this case they are related not only to instability phenomena, induced by the particular shape of the samples, but also to vibrations of the non-standard clamping system.

Concerning the cytotoxicity tests, from the observations done using the optical microscopy, no qualitative difference is noted between the morphology of the cells that have been in contact with the titanium specimens and the control ones; moreover, no dead cells have been noted and this aspect indicates the absence of cytotoxic products released by the titanium specimens.

Cells viability has been calculated at each timepoint comparing the viability of the cells in contact with the titanium specimens with the one of the control wells containing only the culture medium. Cells were observed through an optical microscope (Olympus BX51W1) at 80x magnification to qualitatively evaluate the morphology of the cells adherent to the well floor. Results are expressed in terms of mean value  $\pm$  standard deviation. Satisfactory results have been obtained for both the investigated samples obtained by SPIF and SPF. Cell viability is high for all the considered timepoints: the decrease of viability in time is present and statistically significant but anyway the absolute value is high enough to guarantee that the material biocompatibility has not been affected by the manufacturing procedures adopted. In Fig. 5 the optical microscopy observation and quantitative results of the cell viability for the Ti6Al4V-ELI after SPF process is reported.

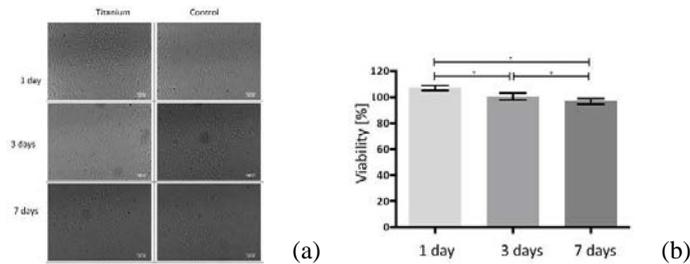


Fig. 5. (a) optical microscopy observation and (b) cell viability measurements for the Ti6Al4V-ELI.

#### 4. Conclusion

Both the processes investigated in the present work have confirmed to be suitable for producing custom made prostheses. The mechanical behaviour of the prostheses is satisfactory with a higher stiffness highlighted by the component obtained by SPIF due to the larger sheet thickness. In addition, the cytotoxicity testes have shown that the manufacturing processes do not affect the biocompatibility of the prostheses. The investigation addressed in this work highlighted the good performances of both the processes and the satisfactory results from a mechanical and a biocompatibility point of view. The differences of shapes and materials did not allow executing a full benchmarking of the processes; however, the strength to impact and the cytotoxicity results suggested the opportunity to include SPIF and SPF in the surgical protocols for a fast and cheap custom made manufacturing of implants.

#### Acknowledgements

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