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Recent Approaches for the Manufacturing of Polymeric Cranial Prostheses by Incremental Sheet Forming

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Abstract

This paper presents recent research experiences developed with the aim of manufacturing cranial prostheses in polymeric sheet using Incremental Sheet Forming (ISF) technologies. With this purpose, different approaches have been carried out in Single-Point Incremental Forming (SPIF) and Two-Point Incremental Forming (TPIF) in order to produce customized cranial implants using different polymeric materials. In this context, this research work provides a methodology to design and manufacture polymer customized cranial prostheses using the ISF technologies starting from a patient’s computerized tomography (CT). The results demonstrate the potential of manufacturing polymeric cranial prostheses by ISF in terms of the high formability achievable and show the appropriate geometrical accuracy at affordable manufacturing costs provided by these processes.

Keywords: Incremental Sheet Forming (ISF); Cranial Prostheses; Formability Limits; Accuracy

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1. Introduction

Prostheses are artificial devices used to replace missed human body parts, which can occur due to degenerative diseases, traumatic accidents or tumors. The number of prostheses being implanted is increasing at a significant rate, with the success of the surgical procedure, the increased longevity of the population, the demand for increased quality of life and more active lifestyles, and the earlier onset and diagnosis of diseases meaning that the replacement is now undertaken in a wider age-range of patients.

In general, prostheses are manufactured with the aim of patching a patient's damaged area and so healing the injury. In particular, maxillofacial and cranial prostheses [1] have a series of characteristics that respond to a list of requirements, being these requirements a consequence of the functions that the customer expects from the device. Besides, cranio-maxillofacial prostheses have been used clinically for over 20 years [2] and today remain one of the most successful applications for reconstruction of an irreversibly damaged tissue. In the most complex and difficult cases, the surgeon may spend considerable time during surgery shaping the prosthesis replacement to fit the profile of the patient's bone, and these repeated manipulations to adapt them to difficult anatomical confines might make the prosthesis susceptible to fracture.

One solution to this problem is to use computer-guided surgical planning technologies to produce a passive fitting replacement designed for patient specific anatomical needs [3]. Progress in medical imaging and continued improvements in computer-processing power available for both three-dimensional patient data acquisition and subsequent image processing technologies make possible for clinicians to diagnose, simulate and treat more accurately their patients. In this sense, customised prostheses are in most cases related with manufacturing processes providing small-medium batches and making use of novel Rapid Prototyping (RP) processes taking into account the requirements within this particular sector [4,5].

On the one hand, Single-Point Incremental Forming (SPIF) is the simplest type within these ISF processes. This technology consists on a hemispherical end forming tool driven by a CNC machine that follows progressively a pre-established trajectory, deforming a peripherally clamped sheet blank into a final component without the use of any specific forming die. On the other hand, Two Point Incremental Forming (TPIF), another ISF variety, makes use of either a negative or a positive die is used. Furthermore, in TPIF it is possible to use a full or a partial die depending on the product complexity and accuracy required. The setups used in SPIF and TPIF are shown in Fig. 1.

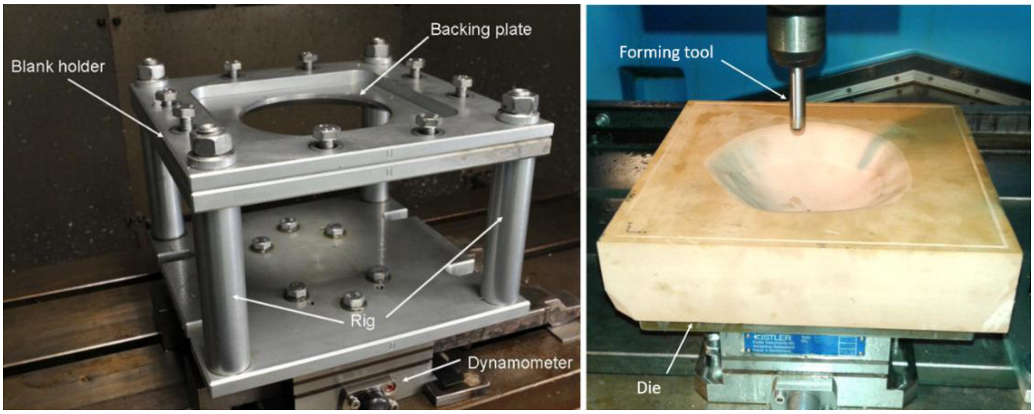


Fig. 1. Experimental setup of SPIF (left) and TPIF (right).

The main advantage of utilizing ISF processes to deform metal sheet is the postponed failure by necking, which allows reaching stable deformation well-above the limiting strains achievable in conventional sheet metal forming processes, as has been widely discussed for the last few years [6-8]. Nevertheless, in the recent years there has been an increasing interest in using other materials within the ISF technologies. In this sense, after the use of polymers in ISF for the first time by Franzen et al. [9], it has been confirmed in recent research work [10,11] that the incremental forming processes have the same capability of enhancing formability above the conventional limits in polymeric sheets that they had widely proved to have in metals.

Focusing on the materials used to manufacture cranial prostheses, metals are the most utilised so far mainly because of their mechanical properties. However, polymeric prostheses have advantages such as biodegradation, lightness or providing easier bone fusion. Regarding cranial prostheses manufactured by ISF, there are some recent attempts to obtain prototypes made of metal that could replace cranial [12,13] and craniofacial areas [14]. With the purpose of manufacturing a customized cranial prosthesis in polymeric sheet by ISF, first attempts found in the literature are mainly focused on the evaluation of the accuracy of cranial prostheses in polycarbonate (PC) [15] and in biocompatible polymers such as Polycaprolactone (PCL) [16].

In this context, this paper presents recent research experiences developed with the aim of manufacturing cranial prostheses in polymeric sheet. With this purpose, different approaches have been carried out in SPIF and TPIF in order to produce customized cranial implants using different polymeric materials, including both not-biocompatible and biocompatible polymeric sheets, which were polycarbonate (PC) and ultrahigh molecular weight polyethylene (UHMWPE) respectively. In the case of the former material, a principal strain analysis was carried out in order to show the high capacity in terms of formability for manufacturing individualised polymeric prosthesis using SPIF. On the other hand, the latter case demonstrated that it is possible to manufacture successfully a customized bio-compatible polymeric cranial implant with improved geometric accuracy using TPIF with a negative die. The results demonstrate the huge potential of manufacturing polymeric cranial prostheses by ISF, showing that these processes provide high formability with appropriate geometric accuracy at affordable manufacturing costs.

2. Experimentation

This section is divided in two part. The first part focus on SPIF using PC sheets whereas the second one presents the experiments of TPIF using UHMWPE sheets. The methodology used for manufacturing customized cranial implants using ISF processes (either SPIF or TPIF) is shown in Fig. 2. The materials selected for the prostheses carried out by SPIF and TPIF as well as the experimental plan are discussed in previous research work [17,18].

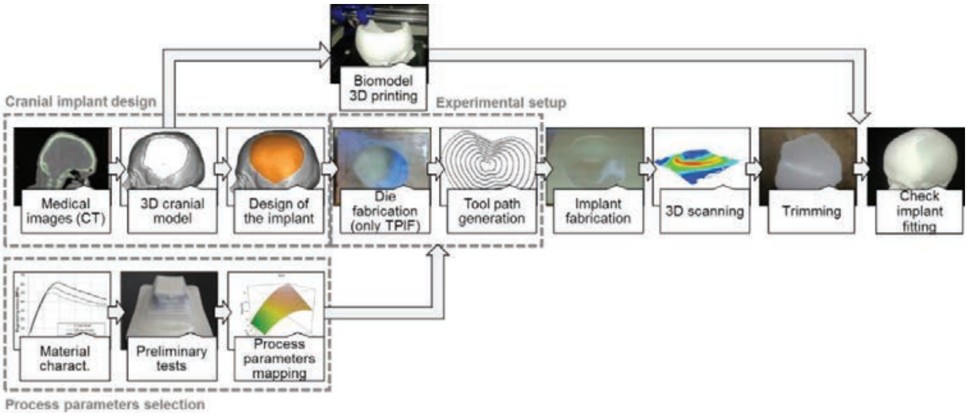


Fig. 2. Work flow showing methodology to be used for the manufacturing a customized cranial implant by ISF.

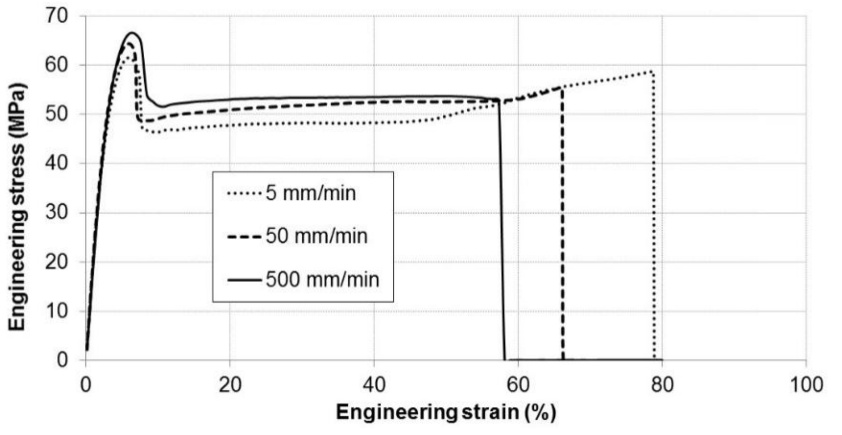
2.1. SPIF tests

The material characterization was carried out by mean of tensile tests in order to obtain experimentally their mechanical properties, as well as the stress-strain curves at different strain rates, and so providing the less favorable feed rates. Table 1 summarizes the main mechanical properties obtained for the transparent PC sheets of 1.5 mm thickness at different testing speeds (5, 50, and 500 mm/min).

As can be noticed from Table 1, when the testing speed was increased, the engineering yield stress (s_y) and strain (e_y) also increased while the Young modulus (E), and in this manner also the springback, decreased. This strain-rate behavior is very common for thermoplastic materials. It can also be concluded from the figure in Table 1 that the higher testing speed, the lower fracture strain, i.e. the lower formability of the material. Therefore, increasing feed rates during the manufacturing of the prosthesis in SPIF would decrease sheet formability. In order to explore the worse scenario a feed rate of 1000 mm/min was set in all the SPIF tests described below.

Table 1. Tensile tests at different testing speeds.

Testing speed	**E (MPa)**	**s_y (MPa)**	**e_y (%)**
5 mm/min	2153	61.58	6.05
50 mm/min	2250	63.11	6.12
500 mm/min	2017	66.97	6.22



After this material characterization, with the aim of determining its formability limits in SPIF the polymer sheet was tested by SPIF following a pyramidal frustum geometry (see Fig. 3), being the length of the pyramidal edges 105 mm with an initial wall angle of 45º, and 80 mm of generatrix radius Three replicates were carried out in order to provide statistical meaning. Indeed, in conventional sheet metal forming, local necking and ductile fracture are the two competitive modes of failure. In this case, failure usually starts with the onset of a neck, followed by an instable deformation process that develops until the ductile fracture takes place. On the contrary, in SPIF of metal sheets and particularly in polymeric sheets, necking seems to be postponed or even suppressed, and so traditional Forming Limits Curves (FLCs) are not applicable. Taking into account this behavior, Fracture Forming Lines (FFLs) are usually employed to establish the formability limits of polymeric sheets within the principal strain space.

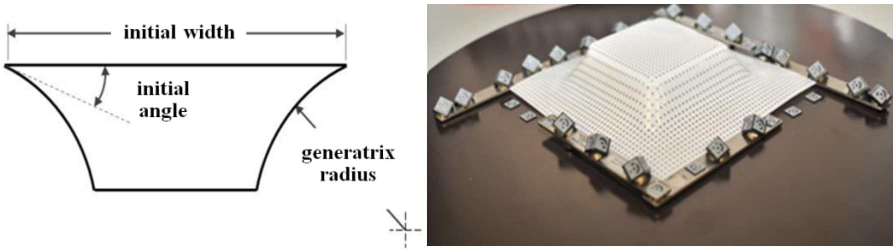


Fig. 3. Testing geometry for SPIF tests: design of the pyramidal frusta with circular generatrix (left) and final tested part (right).

The procedure for constructing the FFL, applied in previous research work on metals [8] and based in the work of Atkins [19], starts by measuring the thickness at fracture at several places along the crack in order to obtain the average thickness strain. This average thickness strain is evaluated at both sides of the crack for every tested specimen. In addition, some tested specimens were cut and polished perpendicularly to the crack and the thickness was measured from a profile view in order to validate the previous thickness measurements along the crack. The average minor strain is evaluated at a certain location at the outer sheet surface close to the crack appearance. Assuming that polymers in cold forming processes deform close to incompressible conditions, the major true strain was then calculated by volume constancy as follows:

$$\varepsilon_{1,f} = -(\varepsilon_{2,f} + \varepsilon_{3,f}) \qquad (1)$$

where $\varepsilon_{2,f}$ and $\varepsilon_{3,f}$ are respectively the average minor and thickness strains in a series of points along the crack.

In order to obtain the formability limits of the PC polymeric sheets, the tests were carried out until failure took place. The strain state of the tested polymeric sheets was measured off-line on the final part by using the 3D deformation digital measurement system ARGUS® via circle grid analysis. This allows representing the principal strains on the outer surface within the principal strain space, as represented in Fig. 4. It shows different strain paths along the fractured part labelled as S1, S2 and S3. Section S1, located in the middle of the side, coincides with plane strain, and S2 and S3, located close to the corner, correspond to biaxial strain and close to an equi-biaxial strain state respectively. As can be seen, the failure strains were analysed in two different sections along the fracture line, corresponding to plane strain and biaxial strain conditions.

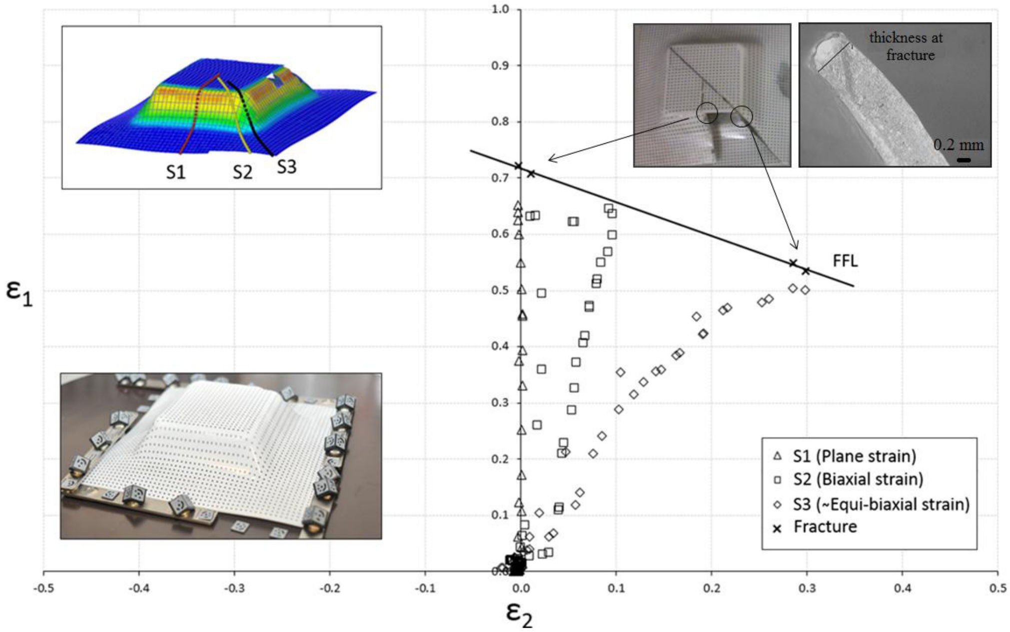


Fig. 4. Principal strains on the outer surface within the principal strain space and fracture strains defining the FFL.

2.2. TPIF tests

In the TPIF tests, 200x200 mm UHMWPE sheets of 2 mm thickness have been used in order to produce the desired cranial implant. The TPIF experimental tests have been carried out on a Kondia® HS1000 3-axis milling machine equipped with Fidia® numerical control. The cranial implant die is manufactured using wood agglomerate (Fig. 1 (right)), in a Deckel Maho 64V milling machine. This die is bolted in the machine work table. In order to reduce friction during the forming process, lubricant for cold forming has been applied over the upper surface of the blanks. The tool path has been generated considering a contouring tool trajectory.

The process parameters selection has been done according to results obtained in previous research works [18], where it was demonstrated that the variation of feed rate and step down does not significantly influence the material formability or the geometric accuracy obtained in polymers formed by ISF. Therefore, in order to manufacture the cranial implants the values are chosen aiming to reduce the forming time and costs, i.e. 3000 mm/min feed rate and 0.5 mm step down. As revealed in the same literature, the spindle speed is the factor with the major influence on the results concerning forming force, maximum temperature, surface roughness and formability. In this regard, two cranial implants in TPIF have been manufactured considering two different spindle speeds (free and 2000 rpm) to determine its influence on the geometric accuracy. Two replicas of each test have been carried out. A hemispherical tool of 10 mm diameter made of Vanadis 23 has been used for the tests.

Once the parts have been fabricated, mobile 3D scanner which employs Structured Light technology (David SLS-2) is used to acquire the final dimensions and compare them with the theoretical CAD model. This comparison is done using SAL 3D software and the deviations between both surfaces (the real and the theoretical one) are analyzed in order to determine the geometric accuracy of the process.

3. Results

The section is again divided in two parts. The first part focus on the manufacturing of a partial prosthesis by SPIF in PC sheet, analysing in terms of formability the potential of this process to manufacture more complex prostheses. The second part deals with the production of cranial prostheses by TPIF using biocompatible UHMWPE sheets evaluating the improved accuracies attained by using this technology.

3.1. Cranial prosthesis manufactured by SPIF in PC sheet

In order to reproduce a specific cranial surface by SPIF, an artificial cranium was 3-D scanned in this case with the aim of carrying out a CAD/CAM process by using the software CATIA® in order to obtain the CNC trajectories in SPIF (Fig. 5a-b). This CNC code had to be post-processed in order to suit the specific ISO-code corresponding to the CNC machining centre where the prosthesis was manufactured. This process was carried out on a 3-axis milling machine EMCO VMC-200. The process parameters used in the SPIF process are summarized in Table 2.

Table 2. Process parameters used in the manufacturing process of the cranial prosthesis by SPIF.

Tool diameter (mm)	**Step down ΔZ (mm/pass)**	**Feed Rate (mm/min)**	**Spindle speed (rpm)**	**Manufacturing Time (min)**
10	0.2	1000	0	<10

Fig. 5c shows the forming zone, in terms of principal strains at the outer surface, in which the PC blank can be safely deformed by SPIF. Within this forming zone by SPIF, the principal strains reached at the outer surface of the cranial prosthesis manufactured are shown. As can be seen, above the level of strains reached on the prosthesis, an important extra formability is still attainable within this forming zone by SPIF before reaching the FFL of the material. This diagram justifies (1) the high potential of the process to obtain more complex geometries and (2) the importance of a strain analysis in order to determine formability limits.

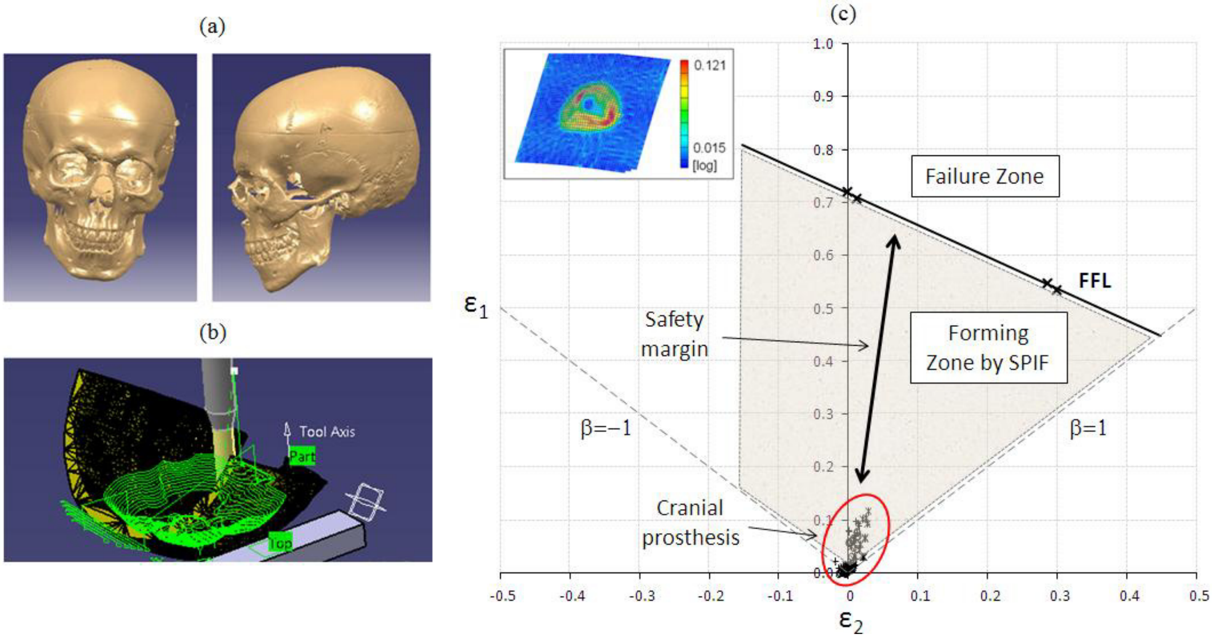


Fig. 5. (a) 3-D scanning of the artificial cranium, (b) 3-D geometry of the cranium in CATIA® and (c) Principal strains of the cranial prosthesis within the forming zone by SPIF.

3.2. Cranial prosthesis manufactured by TPIF in UHMWPE sheet

Figure 6 depicts the geometric accuracy obtained for the cranial implants manufactured by TPIF, using free spindle speed (Fig. 6a) and spindle speed fixed at 2000 rpm (Fig. 6b). The colors represent zones which have different deviation ranges of the real part referred to the theoretical one (in mm). Negative values indicate that the manufactured part has not reached the designed depth while positive values indicate that the real part has overpassed the desired profile. As it can be observed in both cases, the deviation varies from -4.5 to 4.5 mm, which is still inacceptable considering that the tolerance process window for ISF when using metallic materials is 2 mm [20]. It is worth noting that in the case of using a higher spindle speed (Fig. 6b) there are less extreme regions (dark blue or red), meaning that the implant is closer to the desired geometry and that the springback effect, which appears when the sheet is released form the clamping system, can be slightly reduced. It should be considered that the excess material shown must be cut in order to finally obtain the implant which is marked as dashed line. This post-process operation will eliminate some of the zones with higher deviations. Figure 4c shows the geometric deviations measured after trimming the TPIF cranial implant manufactured at 2000 rpm spindle speed. It has been possible to improve the global accuracy of the implant, from ±4.5 mm to ±1.5 mm.

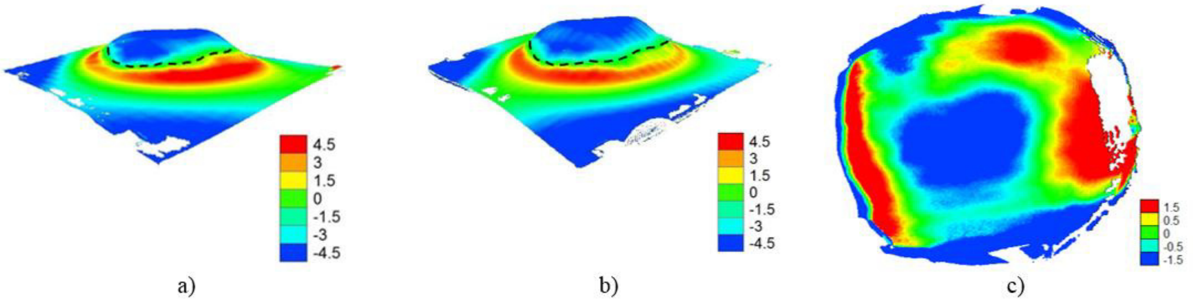


Fig. 6. Geometric deviation (in mm) for the TPIF cranial implant at a free spindle speed (a) and at 2000 rpm spindle speed (b). Geometric deviation for the trimmed cranial implants manufactured at 2000 rpm spindle speed (c).

4. Conclusions

This paper presents the application of a new class of materials, i.e. 2 different polymer sheets (PC and UHMWPE), to the manufacturing of cranial prostheses by ISF making use of SPIF and TPIF respectively, which so far have been mainly making use of metallic materials, especially titanium, due to its bio-compatible properties.

On the one hand, the successful manufacturing of a partial cranial prosthesis by SPIF in PC sheet shows the high potential in terms of formability of manufacturing individualised bio-compatible polymeric prosthesis using ISF.

On the other hand, it has been demonstrated the viability of producing a customized cranial implant using a biocompatible polymer (UHMWPE) with the TPIF variant. The geometric tolerances for this kind of application are usually wide, because one of the implant’s objective is to repair the damaged area ensuring an appropriate aesthetic finishing, considering the anatomic lines of the patient and being as symmetric as possible. Therefore, even though the deviations of the manufactured implant respect to the designed one are around ±1.5 mm in some parts of the geometry, it could still be suitable for cranioplasty, since the aesthetical differences to the human eye will be practically negligible and the psychological and emotional repercussions for the patient will be improved.

However, in order to establish a more general procedure for manufacturing medical prosthesis by ISF, a series of issues should be studied in more detail, such as the characterization of a number of polymer materials in order to have a materials properties library, determining safe forming zones in ISF for those polymer material, bio-integration aspects, or the establishment of an aseptic medical manufacturing environment, among others.

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