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Preliminary study on the use of 3D printed biodegradable polymeric sheet for the manufacturing of medical prostheses by SPIF

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Abstract

Incremental Sheet Forming (ISF) and Fused Deposition Modelling (FDM) of polymers have both an edge over conventional manufacturing by their ability to directly get complex structures without the need of a mold or a die. Obtaining biocompatible polymer blanks for ISF is not always as easy as it could be expected. Concerning nowadays FDM offers a good opportunity to print biocompatible polymer sheets as blanks to next be formed by ISF. Exploring the combination of FDM and ISF for two biodegradable polymers (Polylactic acid (PLA) and Polycaprolactone (PCL)) is the objective of this work.

An analysis of the initial printed sheets in terms of thickness uniformity and surface roughness was carried out. Truncated cone shape with fixed slope angle geometries in a CNC machine were formed. The ISF process parameters modified were the traditional: step down, feed rate and spindle speed. As saved outputs there are: Forming Forces, Maximum Temperature, Surface Integrity, Surface Roughness and Shape Accuracy. After this first approach, a good feasibility process window was established for being used on prosthesis manufacturing of PCL. On the contrary, the feasibility window for PLA is limited because of its low formability. The first results of the combination of both additive manufacturing processes are interesting and deserve further studies to evaluate more in depth the behaviors and the forming mechanism of these materials.

Keywords: Incremental Sheet Forming, 3DPrinting, FDM, PLA, PCL, Polymers, Prostheses

1. Introduction

Medical prostheses consist of artificial components that are intended to replace damaged or lost parts of a body, whose lose can be due to different causes such as degenerative diseases, accidents, or tumors. In the recent years, the number of implanted prostheses has increased significantly due to the success of surgical procedures, increasing longevity of the population and earlier diagnosis of diseases, among other reasons. Consequently, prostheses are manufactured with the aim of repairing a patient's damaged area. To achieve this objective successfully, prostheses must include a series of characteristics that respond to a list of requirements [1]. In this sense, there exists nowadays a trend towards the use of customized implants for a number of reasons: (i) the evolution of digital modelling and the reconstruction of body parts, (ii) advances in manufacturing processes, (iii) the current ability for dealing with different types and geometries of bone fractures, and (iv) the desirable improvement of the patient's quality of life. In this way, prosthetics research worldwide is

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currently increasing, especially focusing on the development of customized medical implants rather than standard products produced in mass series. Advanced manufacturing processes included within the Rapid Manufacturing (RM) technologies implement suitably these requirements of the biomedical sector. To these regard, the use of Additive Manufacturing (AM) technologies [2,3] [6] as well Incremental Sheet Forming (ISF) processes [4,5] have demonstrated their potential for the manufacturing of actual customized medical prostheses in a near future.

AM processes using polymers such as Stereolithography (SLA) or Fused Deposition Modeling (FDM) have been advancing in recent years for allowing the production of biocompatible implants. This is due to the use of advanced biocompatible raw polymeric materials [6] in these technologies using advanced biocompatible polymers such as Polyethylene (PE) and its variants high density (HDPE) and ultra-high molecular weight (UHMWPE), or Polyetheretherketone (PEEK), widely used in dental implants.

Nevertheless, it is well known that the mechanical behaviour of parts and components printed via AM technologies is not that good as the resulted in conventional manufacturing as it is totally dependent on the layer-by-layer build approach, and there also exist other issues such as porosity or premature fracture, resulting in limitations for AM in the biomedical field.

ISF using polymers [7-9] and biocompatible polymers [10] sheets have drawn significant attention and interest, so a lot of progress has been done in the last decades. But on the one hand, one of the first barriers that must be overcome when working with ISForming of polymers is to obtain the polymer commercial blanks, so for some polymers is not as easy to get them as it could be expected. On the other, although there are prostheses that can be manufactured by AM technologies directly, layer-by-layer manufacturing interrupts the continuity of the fibers, affecting the mechanical properties of the prosthesis besides that surface roughness is also affected being generally worse and limiting its application (Fig. 1).

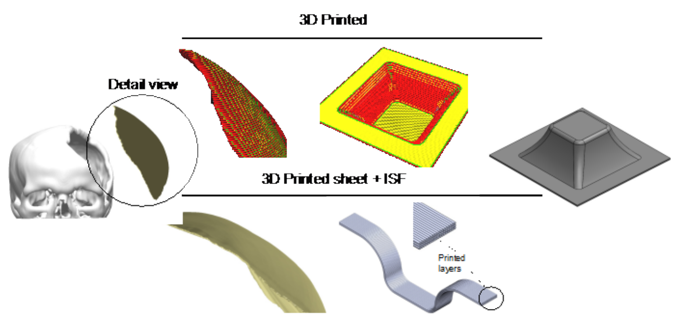


Fig. 1. 3D printed parts versus 3D printed part + ISF

By printing sheets, a print orientation can be decided and form it accordingly, creating stronger long formed fibers in some directions although continue being a layered structure.

Regarding these obstacles, FDM offers a good opportunity printing biocompatible/biodegradable polymer sheets as blanks to next be formed by ISF. And this work will explore this possibility. A possibility that can be also framed inside the concept of the hybridization of AM processes [11], which aims to integrate both AM with other manufacturing techniques, until the moment traditionally with subtractive ones as machining.

The hybridization of AM processes with forming technologies, or even more specifically with incremental sheet forming has been slightly explored. Esmaili et al. in [12] printed Poly Lactic Acid (PLA) sheets of 2- and 3-mm. thickness with triangular and rectangular infill geometry patterns and a density of 80%. They formed them under different conditions: room temperature and with air blowing heating until 70ºC, to investigate the effect the temperature could have on formability. Their best formability results were obtained with triangular infill on a sheet of 2 mm and with the hot conditions. Xiao's et al. study in [13] proposed the hybrid incremental sheet forming (HISF) technique for a CFRP sheet. This hybrid concept consists of forming a dummy sheet (made of mild steel) placed upon a CFRP sheet during the forming operation. CFRP sheet is deformed along with the dummy steel sheet (1mm) to achieve a pyramid shape with different prepreg combinations and thickness. The FE simulation results for the CFRP sheet HISFormed were close to their experimental results.

Each RM technique has its own strengths and weaknesses under the hybridization context, and the range of available materials varies dramatically. However, although the high potential that these kinds of hybrid processes seem to have, the scientific works for the establishment of complete hybrid manufacturing procedures (as it is the case of AM and ISF) are very limited, and the information is still scattered. In this overall context and according to the current state of knowledge, this paper will 3D print /by FDM technique) blank sheets using biodegradable polymers (PLA, and polycaprolactone, PCL), to be after formed by ISF and stablishing the first process windows for considering the AM-ISF manufacturing of customized and biocompatible medical prostheses and implants.

2. Methodology

This section will describe the methodology that was followed and the experimental equipment in detail.

2.1. Materials

The experimental material used was filament of poly lactic acid (PLA), supplied by Smartfilament and polycaprolactone (PCL) filament provided by 3d4makers.

2.2. 3D printed sheets

3D printed sheets were printed with PLA and PCL filament into sheet of 150x150 with a thickness of 1,5mm. The printer used for PLA printing was a 3NTR A4v4 and for PCL printing was an Ultimaker 3, both engineered for industrial applications with outstanding repeatability and dimensional accuracy, although the first one controls better the temperature into the printing chamber.

In terms of 3D printing there are many parameters to be controlled to ensure repeatability on print jobs. For the purpose

This is a resupply of March 2023 as the template used in the publication of the original article contained errors. The content of the article has remained unaffected.

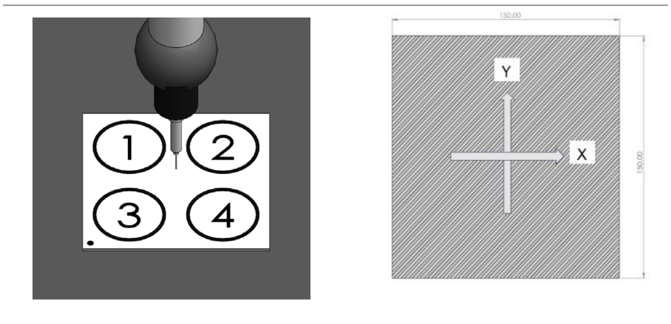
of this study, we fixed the additive manufacturing parameters, which can be seen in the Table 1.

Table 1. 3D printer parameters.

Parameter	PCL 3D printer parameters	PLA 3d printer parameters
Bed temperature	60ºC	60ºC
Nozzle temperature	160ºC	200ºC
Layer height	0.1mm	0.08mm
Speed	Slow	Slow
Infill	100%	100%
Pattern	45º	45º

These parameters were obtained from filament datasheet; however, some preliminary trials were carried out specially to decide about the raster angle and the temperatures. Two combinations of raster angle were printed (90º/0º and +45/-45) and incrementally formed, and the results showed more breakings with the first one. Regarding to PLA, all the sheets were printed with raft support beneath it to improve the adherence with the bed. And as it seen, for the PCL, the temperatures (bed and printing) were put high to guarantee the bed adherence and the interlayer fusion.

Considering the own limitations associated to additive manufacturing, about dimensional accuracy and layer-to-layer building, two issues were controlled from the printed sheets: thickness deviation and roughness. The thickness was measured in four regions of the sheet (Fig. 1) by a coordinate machine Mitutoyo model Crysta-Apex C544, and three measurements for each target area were taken, in order to have better accuracy. The roughness of the sheets was also evaluated before forming by a Mitutoyo Surftest SV2000, combined with the program Surfpack-SV v1.300. Two perpendicular directions (x,y) both on the front and back of the sheet, were considered, to evaluate the printed raster angle (+/- 45°) pattern of the printed sheets (Fig. 2).



(a) (b)

Fig. 2. 3D printed sheet: (a) Thickness deviation and (b) Roughness.

2.3. Incremental Sheet Forming

The geometry selected for the experiments was a truncated cone-shape with fixed slope angles (20°, 30°, 40°,50°, 60°) and an initial diameter of 45mm (the maximum allowed by the backing plate), Fig. 3. These values and the tool diameter conditioned the maximum depth of the final conus, which can be seen in Table 2. The ISF tests were carried out on a Kondia® HS1000 3-axis milling machine equipped with Fidia® numerical control.

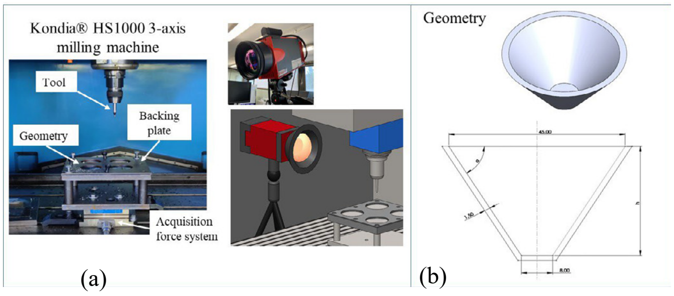


Fig. 3. (a) Experimental set up; (b) Geometry.

The experimental procedure was focussed on studding the influence of step down (SD), feed rate (FR) and spindle speed (SS) on the geometry proposed previously, because they have a direct influence on the formability of the material during forming. In this research was deployed the full factorial design for each slope angle (Table 2), what means a total of 24 experiments for each material. Although, some preliminary trials were done to stablish these values.

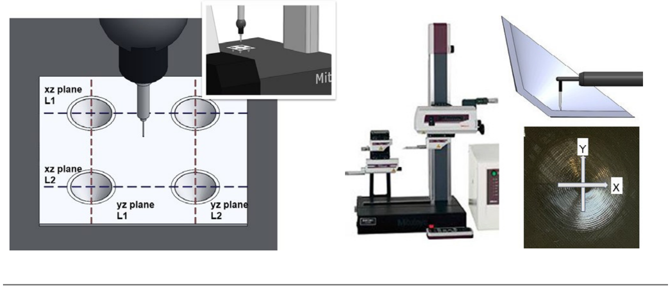
Table 2. Process parameters for PLA and PCL

	PLA			PCL		
Slope angle (º)	20	30	40	40	50	60
Depth to achieve (mm)	6.73	10.68	15.52	15.52	22.05	32.04
Δ*z* [mm]	0,1	0,3		0,3	0,5	
F[mm/min]	300	500		500	1500	
S [rpm]	500	1500		0	500	

During this experimental procedure, the experimental data that were recorded during the process included forming forces and temperature. Measurements of the forces in the X, Y and Z directions were performed with a Kistler Dynamometer with a frequency of 10 values per second, which sends an output voltage in response to a pressure or force applied (Fig. 2a). Forming forces in the vertical direction (Fz) were recorded since they are the predominant force in ISF. Following these magnitudes were filtered using Matlab® to obtain its maximum values. Regarding the temperature, as known, the friction between the tool and the blank increases the temperature during the forming process, thus the temperature was acquired using a thermographic camera IRBIS ImageIR® 3300 (Fig. 2a). This temperature may cause variations on the material properties, especially in polymer materials.

The 3D printed sheets formed incrementally were assessed three issues: surface roughness, shape accuracy and surface integrity. The surface roughness was measured on the two sides of the formed cones. The measurements were obtained with a Mitutoyo Surftest SV-2000 profilometer using the following parameters: (i) measured length: 8.8 mm; (ii) profile type: R; (iii) evaluation length: 0.8 mm; (iv) sampling length: 8.0 mm. Two directions (x,y) inside of the conus were measured (Fig.3b). The evaluation of shape accuracy, to quantify the influence of the process parameters to reproduce in the best way the theoretical profiles, was performed using the

Coordinate-Measuring Machine (CMM) Mitutoyo Crysta-Apex C544. Two directions (xz,yz) were measured (Fig. 4a). The surface integrity was assessed visually to identify defects commonly existing in ISF and new defects caused by the use of printed sheets as a raw material



(a) (b)

Fig. 4. (a) Shape accuracy measurements; (b) Roughness measurements.

3. Results

3.1. 3D printed sheet analysis

The results about thickness uniformity of the printed sheets are revealed in Fig. 4 and Table 3. The difference of thickness for the PLA printed sheets regarding the target thickness (1,5mm) is around 0,06mm on average, which is acceptable considering the capabilities of FDM process. For the PCL this difference is considerably higher, it is around 0,4mm, and sometimes the obtained thickness overcome the 35% of the expected one. This over-thickness is caused by the high temperatures (bed and printing) used for printing the PCL which guarantee the bed adherence and the interlayer fusion. Consequently, the material would need more time to become solid and the beads and polymer chains are able to move around. It justifies the reason why several sheets were measured. Although it can seem a drawback, this becomes an advantage for the forming process.

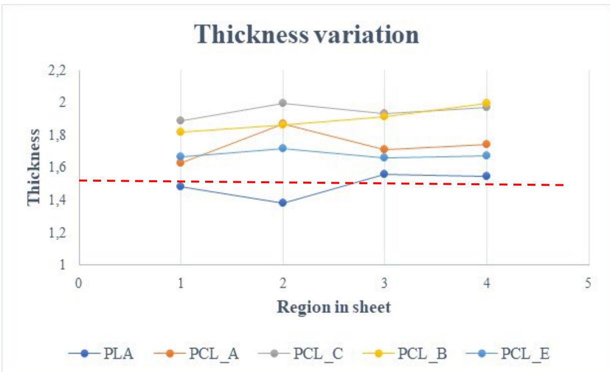


Fig. 5. Thickness uniformity of the printed sheets

Table 3. Initial sheet thickness of PLA and PCL [R=Regions, M=Mean (mm), D= Standard deviation (mm)]

	PLA-A		PCL-A		PCL-B		PCL-C		PCL-D	
R	M	D	M	D	M	D	M	D	M	D
1	1,48	0,031	1,62	0,019	1,89	0,002	1,82	0,010	1,66	0,003
2	1,38	0,016	1,86	0,004	1,99	0,002	1,86	0,003	1,71	0,008
3	1,56	0,033	1,71	0,012	1,93	0,001	1,91	0,065	1,66	0,004
4	1,54	0,034	1,74	0,026	1,9	0,002	1,99	0,012	1,67	0,006

The roughness results of the printed sheets are shown in Table 4. These results are the roughness average of two different sheets, in two perpendicular directions (x, y) on the front and back of the sheet. For the PLA, the roughness on the back side it's significantly worse than in the front side, due to the raft support in this face. The front values are acceptable according to FDM capabilities and in comparison, to an injected commercial sheet. For the PCL, it's possible to see that the roughness on the front it's better than the one on the back. This is because the back side is built on the bed plate of the 3d printer, while the front is the one subjected more to the 3d printed filaments, hence a worst surface finish.

Table 4. Initial roughness PCL sheet

	Ra (μm) - Front		Ra (μm) - Back	
	X	Y	X	Y
PLA	1,133	1,175	10,137	8,937
PCL	1,447	1,286	0,547	0,864

3.2. ISF results for the PLA

Fig. 6 shows the PLA results for the extreme values of SA and Δz, and the most conservative conditions for S. Actually, although there is not much difference with the variations of S and F, it notices that higher values of S and F create small defects on the formed parts (burns or too much deformation due to the increase of temperature). Changes in SA and Δz affects strongly on the results; thus, as lower they are better the results are achieved.

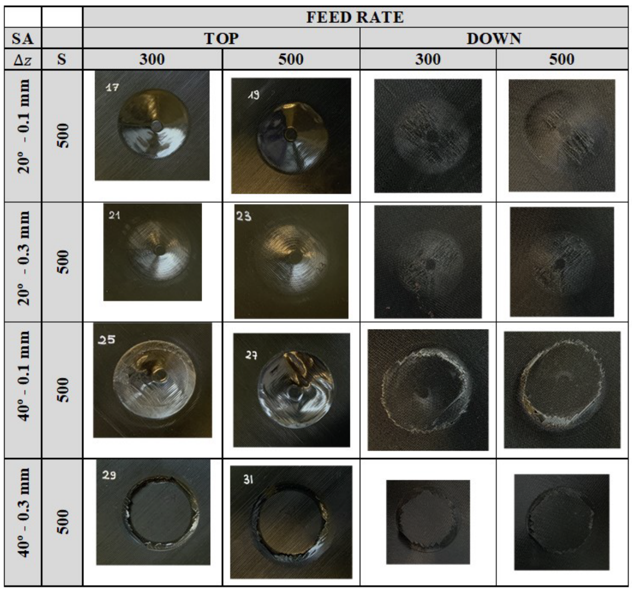
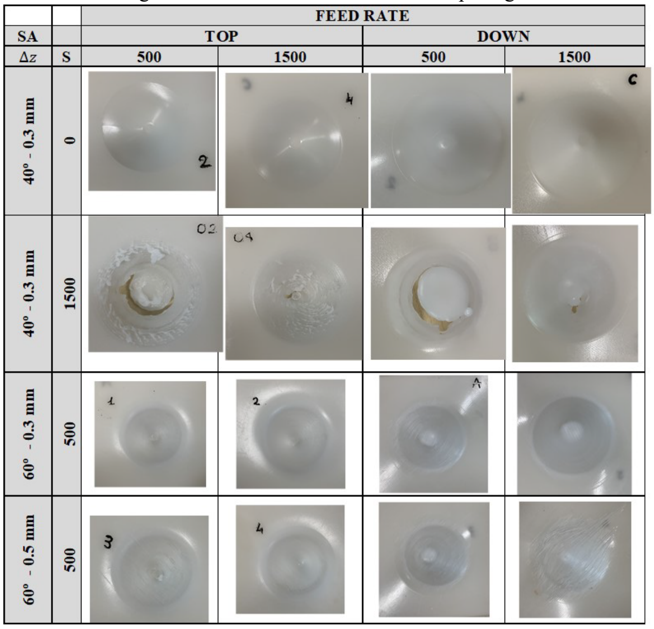


Fig. 6. PLA results for max and min slope angle for a S=500rpm

3.3. ISF results for the PCL

Fig. 7 contains the images from the obtained results for PCL material. The results reveals that any SA can be achieved using almost all the manufacturing conditions, although certainly some delamination defects started to appear for the combination SA=60º and Δz=0.5 mm, and some burnings when 1500 rpm in spindle seep (S) is used.

Fig. 7. PCL results for max and min slope angle



3.4. ISF Analysis

- *Shape accuracy and roughness*

Fig. 8 compares the profiles shape of the geometries incrementally formed with the target geometry to achieve. As expected, when smaller the slope angle of the geometries is, better adjusted the geometry is achieved. Although there is detected the springback phenomenon on the bottom of the part and bending on the connection between the geometries, which can be caused by the forming forces or temperature effect due to the small geometry dimensions.

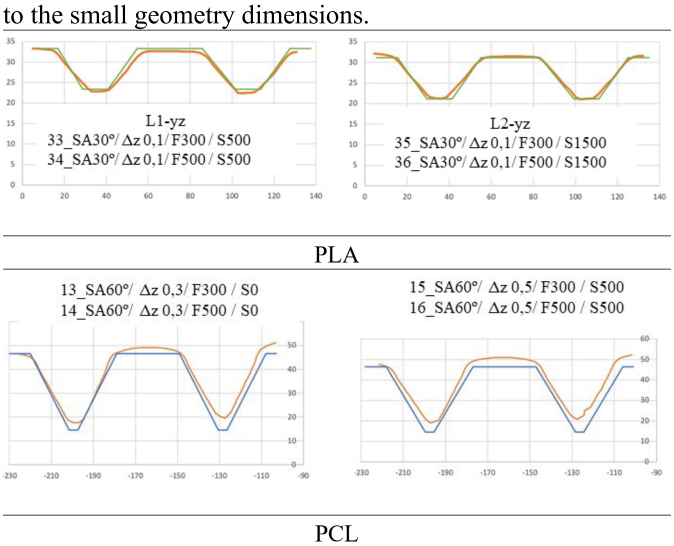


Fig. 8. Shape accuracy

The roughness is affected by the step down, being it better for smaller value of step down [8]. This trend is clearly obtained for the PLA but less evident for the PCL. The processing of the PCL sheets is done with a temperature higher than required one for this material, the printing layers fused better with each other and therefore the sheet had a similar behavior to an injected sheet. Thus, this increase on step down is not enough to appreciate this difference on the roughness result.

Table 5. Final roughness PCL and PLA parts

	Δz (mm)	Ra (µm)
PLA	0,1	0,359
	0,3	1,155
PCL	0,3	1,256
	0,5	1,388

- *Forming forces and Temperature*

Forming force trends obtained for PLA and PCL (Fig. 9) follow the expected trend observed in [14]: "after the completion of one contour the Fz drops when the tool moves to the next contour, reaches its peak value at the step down and finally stabilizes when the tool moves along the contour [8].

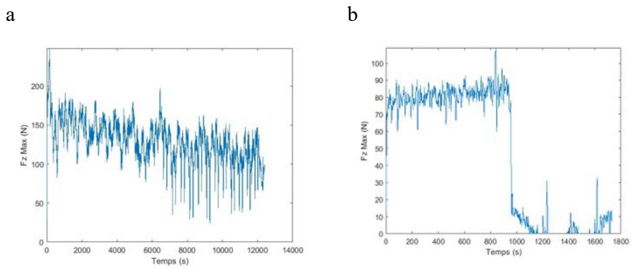


Fig. 9. (a) PLA Force (test 40º,0.1mm,300mm/min,500rpm) (b) PCL Force (test 40º,0.5mm,1500 mm/min, 0 rpm).

The steep descent in Fig. 9b corresponds to a failure due to a rupture in the sheet. An increase of the step down resulted in an increase of the magnitude of the forming force. Regarding temperature influence, highest values of temperature were reached with the highest values of spindle, and consequently the value of forming force decreased. All the attained results were according to the ones in literature, f.i. Bagundach et al. works [8,10].

PLA maximum force values are bigger (average value from all experiments around 100 N) that the ones obtained for PCL (average value from all experiments around 165 N).

- *Surface Integrity and defects*

The surface integrity of the sound cones was correct in terms of roughness. But some defects also appeared. Classical defects [15] for ISFormed polymer sheets related to the deformation's mechanisms and modes of failure have appeared in PLA and PCL sheets, it is to say: cracking, wrinkling and oblique cracking. But due to the 3D printed feature of the sheet because its layer-upon-layer nature, other defects appeared: delamination (layers rupture and appearance of a hat in PLA sheets, Fig.10a), circumferential cracking (PLA sheets, Fig.10b), burnouts because of bad combination of process parameters, (high spindle speed 1500 rpm in PCL sheet, Fig.10c), defilamentation (PCL sheets, Fig. 10d) and porosity or crazes as in [16] (for PCL sheets, Fig. 10e).

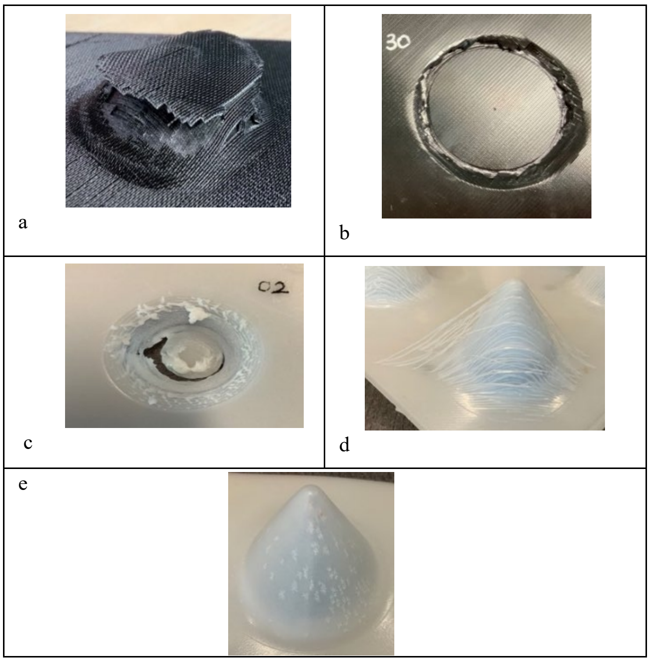


Fig. 10. Defects: (a) delamination (b) circumferential cracking (c) burnouts (d) defilamentation (e) porosity/crazing

4. Conclusions

The results provided a promising starting point to develop further and deeper studies for determining process parameters windows for both technologies FDM and ISF.

As it could be anticipated, process parameters have a great influence on the results of the variables studied (accuracy, thickness, roughness, force, and temperature) and the expected trends have been also fulfilled. For example, how formability is improved by the increase of temperature by means of the spindle speed during ISF processes.

Therefore, the proposed global methodology must be extended to turn more consistent these first attempts.

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