

PRELIMINARY STUDY ON ADDITIVELY MANUFACTURED PLASTIC LINER OF AN ACETABULAR CUP COMPONENT

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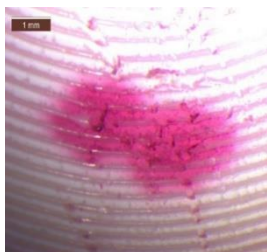
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Graphical abstract



Abstract

Additive manufacturing is extensively used in the medical field due to its flexibility in manufacturing implants based on the patient's requirements. This research study aims to investigate the additively manufactured plastic liner part, which is one of the parts of an artificial hip joint. In this study, fused deposition modeling (FDM) is used for fabricating the plastic liner from polylactic acid (PLA). The investigation was carried out to understand the manufacturability of dimensionally accurate, defect-free and better surface quality of the additively manufactured cup liner and to study the wear behaviour of the material chosen. The dimensions of the formed components were measured using a coordinate measuring machine (CMM). Non-destructive testing methods namely dye penetrant and radiography were carried out for identifying the existence of any surface or internal defects, respectively. The surface roughness values were measured to characterize the surface texture of the component made. The wear behaviour of the PLA material was studied by a pin-on-disc test. It is seen from the macrostructural images that some external surface defects exist. These observations are also confirmed by the dye penetrant test results. However, no internal defects were noticed by the radiography testing of the additively manufactured liner. The surface roughness measurements and macrostructural images have shown the poor surface finish of the part. The coefficient of friction of 0.302 and higher specific wear rate of PLA material were observed in pin-on disc test.

Keywords: Additive Manufacturing, Acetabular plastic liner, Polylactic acid, Non-destructive testing

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1.0 INTRODUCTION

Additive manufacturing (AM) is a revolutionary technology for the fabrication of customer-based and highly complex shaped products by adding the material layer-by-layer following the information received from the computer software. Even though AM is extensively used in many fields, it is considered the best candidate for the fabrication of orthopaedic implants [1]. The Total Hip Arthroplasty (THA), also

known as Total Hip Replacement, is an advanced surgery performed to replace the damaged or worn-out hip parts with artificial implants. The acetabular liner is one of the parts of the artificial hip implant which is fixed in the acetabular shell and has contact with the femoral head. Frederick J. Kummer *et al.* (2002) have reported that revision of damaged liner of a well-fitted metallic shell is common after some years of implantation [2]. Blom *et al.* (2005) stated that 3.4% of the liners needed revision due to wear and the risk

of dislocation after the revision of a liner was higher than the revision of complete acetabular components [3]. Harry S Hothi *et al.* (2015) carried out a study on the retrieved cobalt-chromium alloy acetabular cup liners which were used in conjunction with the titanium shell [4]. They reported that corrosion was observed on the backside of the liner and this corrosion was the primary reason for the higher rate of failure of the acetabular assembly. The corrosion caused due to the contact with biological solutions and the wear caused by the mechanical action have posed a lot of challenges to the researchers. Stellite 21, a low-carbon and cobalt-based alloy, was opted when compared with stainless steel and titanium due to its good wear and corrosion-resistant properties. Stellite 720, a high-carbon Stellite alloy, was coated on the Stellite 21 liners to improve the bearing capacity of metal-on-metal and also the wear properties in the hip implants [5]. It is observed from the literature survey on the total hip replacement of metal cup liner along with the metal shell that the corrosion caused at the outer and inner surfaces of the acetabular cup assembly as well as at the interface between the liner and shell was due to the contact with the biological solutions and the wear caused by the mechanical action. The small metal particles formed due to wear and corrosion of the acetabular cup assembly usually spread within the human body around the implant and caused osteolysis [5].

Many researchers have investigated the failure of the liner made of conventional polyethylene (PE) [6-10], cross-linked polyethylene (XLPE) [11], high-density polyethylene (HDPE) with ceramic particles [12], conventional ultra-high molecular weight polyethylene (UHMWPE) [13 - 15] and cross-linked UHMWPE [16 - 19].

Wear and fracture caused by local stresses and oxidation are the main concern while choosing the polymer for orthopaedic implants [19]. Lars Weidenhelm *et al.* (2008) have reported that the rate of revision of uncemented polyethylene liners is higher when compared to cemented implants due to loosening of the implant and osteolysis [20]. Kyung Wook Kim *et al.* (2019) have concluded that more promising results can be obtained with the use of cross-linked PE when compared with the conventional one in the long term [8]. Cynthia A Kahlenberg *et al.* (2020) have experienced the early excessive wear of the cross-linked PE and declared that the exact reason for such unusual wear has not been identified. Oxidation degradation takes place in conventional UHMWPE during the process of sterilization in the air or in storage which reduces the mechanical properties of the liner [11]. To overcome this, the researchers used the following two alternatives: (i) gamma sterilization in inert conditions, vacuum or gas plasma, and (ii) the use of cross-linked UHMWPE [16]. No change in the failure due to damage of the conventional and cross-linked UHMWPE liners was observed by David T Schroder *et al.* (2011) [17].

The study on three different liners by Saverio Affatato *et al.* (2015) has revealed that the loss of mass

by wear due to the daily activities of a person was in the following order: Conventional PE, cross-linked PE stabilized using vitamin E and cross-linked PE [21]. The locking mechanism of the liner with the shell was one of the major reasons for the dissociation of the liner from the shell [10]. Richard J Napier *et al.* (2017) have discussed the various design modification made in generation-wise acetabular assembly to overcome the rim fracture and liner dissociation [7]. Backside wear produced by the micromotion between the metal shell and the polymer liner was another reason for the failure of the acetabular implant. Francisco Romero *et al.* (2007) have stated that a very rigid locking method helps in limiting this micromotion to a greater extent while the polishing of the shell prevents the motion fractionally [14].

The tribological behaviour of four different polymers namely conventional UHMWPE, crosslinked UHMWPE, conventional polyether ether ketone (PEEK) and PEEK reinforced with glass fibre was studied by Song Wang *et al.* (2015) to identify the alternate polymer as a bearing material in orthopaedic implants [22]. Based on tribological properties, it was concluded that the cross-linked PE is the best material for bearing surface when articulated with the titanium Ti6Al4V alloy based on the tribological properties. Sowmyajit Mojumder *et al.* (2017) have also carried out a similar study using stainless steel 304, brass, alumina, HDPE and UHMWPE materials and concluded that both the polymers show a much lower rate of wear compared with the experimented metal and alloys [23]. Additive manufacturing, an emerging manufacturing technology, is used to make 3D models that help to understand the anatomy and acetabular fractures so that the operative approach can be optimized [24, 25]. The layer orientation of the added material in the additive manufacturing process has an influence on the mechanical properties of a polymer and hence the performance of a manufactured component [26]. 3D printed custom-based implant and proper planning of pre-operative procedures are feasible choices for acetabular defects reconstruction [27].

In this preliminary study, to combine the benefits of AM manufacturing and thermoplastic polymers, the attempt has been made to fabricate a plastic liner part from conventional polymeric material. Polylactic acid, a bio-compatible and bio-degradable polymeric material, is one of the common thermoplastics used in additive manufacturing. Nonetheless, the thermal degradation of PLA is one of the limitations of PLA while processing in a molten state [28]. Yuhang Li *et al.* (2018) have expressed that there is a requirement for the improvement of mechanical properties of the fused deposition modeling method of additively manufactured thermoplastic parts [29]. It is obvious from the literature survey that the most extensively used polymeric material for the acetabular liner is PE and limited information is available concerning the usage of other polymers for liner. Since PLA is a biocompatible, cheap, easy to manufacture and widely used

polymer in additive manufacturing, it is chosen as a material for acetabular cup liner. Also, the use of additive manufacturing in the fabrication of custom-based implants has gained momentum due to its flexibility to manufacture any complexity in design. The dimensional accuracy and the surface quality of the additively manufactured component are very much necessary for determining the capability and reliability of the process. Further, the quality of the product manufactured is indicated by greater dimensional accuracy, non-existence of internal or external defects and better surface finish. For that reason, this research work aims to investigate the dimensional accuracy of the additively manufactured PLA liner, its defect-free manufacturing and surface texture as well as wear behavior of the PLA material to ascertain its suitability for implants.

2.0 MATERIALS AND METHODS

The acetabular liner component was fabricated using a polylactic acid filament with a diameter of 1.75 mm. The additive manufacturing method used for fabricating the desired component was fused deposition modeling (FDM) in Olivetti S2 – 3D Industrial Grade 3D Printer with 0.4 mm nozzle diameter as shown in Figure 1. The dimensions of the liner are presented in Figure 2. The selection of the process parameters for the preliminary study is based on the recommendation made by the PLA material manufacturer and the machine manufacturer. The following process parameters were used for printing; printing speed - 45 mm/s with an infill of 30%; infill pattern – rectilinear; layer height - 0.3 mm; bed temperature - 60°C; print temperature - 205°C. The infill density percentage has a significant effect on the mechanical properties of the component. Also, the lower percentage infill is used for rapid prototype models and higher percentage is used for end-user products. Based on the component shape, time and cost of printing material consumed and thereafter obtaining the considerable mechanical properties, the infill percentage is fixed at 30%. The physical and mechanical properties of the polymer used and comparison with UHMWPE are described in Table 1.

Table 1 Important Physical and Mechanical Properties of Experimented PLA and comparison with UHMWPE

Property	PLA	UHMWPE
Colour	White	-
Density	1.24 g/cm ³	0.925-0.945[30]
Melting Temperature	200 – 220°C	132-138 [30]
Vicat Softening Temperature	60°C	125-128 [31]
Tensile Strength	60 MPa	39-48 [30]
Impact Strength	7.5 KJ/m ²	95.2–105 [32]
Flexural Modulus	3800 MPa	1390 [30]



Figure 1 General View of the FDM Machine Used

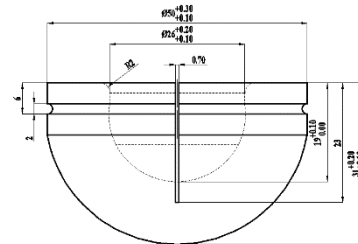


Figure 2 Acetabular Cup Liner Drawing

The fabricated liners were measured using a coordinate measuring machine (CMM) to ensure the accuracy of components produced. The CMM used for performing the dimension measurements was Helmel, U.S.A make (Model no:3020-164) with a measuring range of 400*400*350 mm; accuracy of 0.004 mm and a resolution of 0.001 mm. Zeiss O-Inspect 322 multi-sensor CMM was utilized for measuring the roundness of the component according to ISO 10360-7:2011. The important specifications are as follows: Measuring range 300 X 200 X 200 mm; Probe diameter = 3 mm; Maximum Probing speed = 5 mm/sec and Measurement error = 2.4 μm/L 150μm. Macrostructure images of the components were taken to study the surface characteristics. Dye penetrant test and radiography test were carried out to find the occurrence of any surface and internal defects, respectively in the FDM manufactured components. Dye penetrant (SKL-SP1) was applied by spraying at a component temperature of 35°C for a dwell time of 15 minutes. A solvent-based developer(SKD-S2) was applied for a dwell time of 15 minutes. In the radiography test, AGFA-D7 film with 5 mm equivalent thickness was exposed to 150 kV and 5 mA for 1 minute. Surface texture measurements were made using a surface roughness measuring instrument (Make: Kosaka Laboratory limited, Japan and Model: SEF 3500D) to reveal the degree of surface finish. The important specifications of the machine are (i) resolution = 0.0001 μm; (ii) Measuring range = 600 μm(vertical) and 100mm(horizontal); (iii)Magnification = 500,000 times Maximum(verticaly) and 5000 times(verticaly) in

accordance with ISO 4287:1997. Three samples were used for all measurements and tests and the average value of the three samples was presented. The measurements were made in CMM at four different locations in each sample and the average value was computed.

Pin-on-disc test was carried out using Ducom Tribometer to understand the wear behaviour of the PLA material. The specification of the tribometer is as follows: Maximum Load= 60 N; Rotational speed= 1500 rpm; Disk Diameter = 100 mm; Operating Temperature=Room Temperature to 1000° C. Three samples of 10 mm diameter pin of 25 mm length were made by FDM process using PLA material. The pin was pressed against the rotating EN31 steel disc at a track diameter of 60mm. The test was performed at a speed of 300 rpm with an applied normal load of 20N for 20min under dry conditions. The weight of the pin before and after the test was measured using a Mettler digital weighing machine having an accuracy of ±0.0001g for each sample. The specific wear rate (W) in mm³/N-m was calculated from the weight loss measured using Equation 1 and the average value was computed.

$$W = \Delta w / FLp \dots\dots (1)$$

Where Δw = Loss of weight in grams;

- F = Applied normal load in N;
- L = Sliding distance in m = πDNt;
- ρ = Density of the material in g/mm³;
- D = Mean diameter of the track in mm;
- N = Disc speed in rpm; t = Time of testing in min.

3.0 RESULTS AND DISCUSSION

The acetabular cup liners fabricated by 3D printing process using PLA material are shown in Figure 3. The results of the representative dimensions measured by CMM are presented in Table 2.



Figure 3(a) External Surface View and (b) Internal Surface View of 3-D Printed Liners

It is observed from the results in Table 2, that the maximum percentage of deviation between the measured and actual dimensions is 1.1. Also, it is seen

that the outside dimensions are oversized and the inside dimensions are undersized. The minimum and maximum variations in dimensions observed are 0.01 and 0.5 mm respectively. This may be attributed to the oozing of material from the outside surface and shrinkage caused by heating and subsequent cooling of the material on the inside surface. The oozing of the material may be due to the low viscosity caused by the higher temperature of the material printing rather than the desired one.

Table 2 Representative Dimensions of the Liner Measured by CMM

Measured Parameter	Actual Dimension in mm	Average Measured Dimension in mm	% Deviation from the mean
Outside Diameter	50	50.17	+0.34
Inside Diameter	26	25.72	-1.08
Overall Height	31	31.14	+0.45
Inside Depth	19	18.83	-0.90

Thus, to get an accurate component, it is proposed to provide outside dimensions lesser and inside dimensions higher than the requirement in the design itself by the trial-and -error method and subsequently setting the optimum process parameters such as lowering the printing temperature, layer thickness and print speed to reduce these defects.

3.1 Non Destructive Testing

The additively manufactured PLA liner components do not exhibit any surface defects when subjected to visual inspection. The overall view of dye penetrant tested components is shown in Figure 4 (a). The surface defects like pores, voids and discontinuity visualized by dye penetrant test are shown in Figure 4 (b) & (c). These defects affect greatly the mechanical properties and hence the performance of the component. Porosity is a common occurrence in components produced by the additive manufacturing process. The presence of voids may be due to the shrinkage of the material, time of solidification and entrapped air or gas which is formed by the absorption of moisture from the surrounding air by PLA. Also, the voids may be formed due to the improper bonding of the newly laid layer with the layer already printed. The discontinuity can be because of the layer printing method and print speed and thus, by introducing the overlap in each layer or printing the multiple layers of different widths, it may be eliminated. Also, the study may be carried out by adopting different printing patterns and orientations to understand the occurrence of porosity and voids.

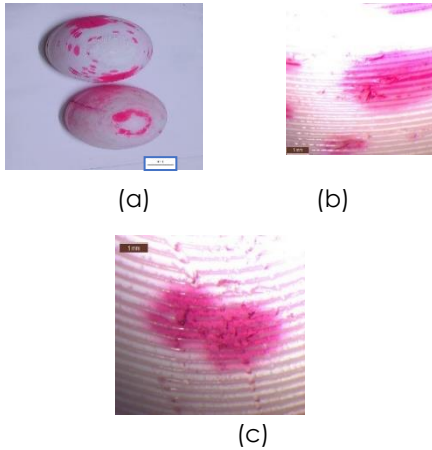


Figure 4 (a) Overall View of Dye Penetrant Tested Components and (b & c) Defects Observed

The macrostructure image of the liner is exhibited in Figure 5. The figure demonstrates the layers of formation of additively manufactured liner component which is a characteristic of the FDM process. Also, the oozing of material in each layer is noticed and it may be attributed to either the fact that the print temperature reduces the viscosity of the material and flows or the newly laid layer of molten material compresses the previously laid one and oozes. This may be the reason why the dimension measured is larger than the designed dimension at some locations and hence the dimension is seen to be oversized by 0.5 mm.



Figure 5 Macrostructure Image of a PLA liner

The radiography tested photos are captured in a film and some extracted images from the film are presented in Figure 6. There are no noticeable internal defects observed in the conventional radiography test and the manufactured component is acceptable as per ASTM E2662. Hence, it may be concluded that only surface defects and no appreciable internal defects are seen in the FDM printed PLA material. Warpage, one of the common defects in FDM due to the internal stresses produced by non-uniform cooling rates of different sections, is also not found noticeably in the printed component.

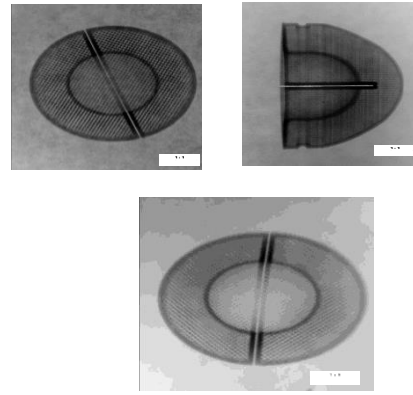


Figure 6 Images Extracted from the Radiograph Testing showing (a) Top View; (b) Side View and (c) Bottom View

3.2 Surface Roughness Measurement

The surface of the additively manufactured acetabular cup is rough, which is a characteristic of FDM process due to the staircase effect. The lines of layer formation in the FDM process are seen in Figures 4 & 5. The newly laid layer compresses the previous layer which distorts the circle into an oval shape, thus creating a wavy surface in the component. The waviness of the surface may be reduced by reducing the printing layer thickness which increases the time and cost of the component manufacturing. The Ra and Rz values measured by the surface roughness measuring instrument are shown in Table 3.

Table 3 Measured Average Surface Roughness Values

Parameter	Inner Surface	Outer Surface
R _a (μm)	18.42±0.52	4.15
R _z (μm)	68.96±0.84	27.11

The observed values indicate that the inner surface has higher roughness than the outer surface. This may be attributed to the occurrence of more non-homogeneous shrinkage in the interior surface than the exterior surface. This result is also supported by the CMM measurements. The measured roughness value of the PLA acetabular liner fabricated by FDM process is very high when compared to UHMWPE liner fabricated by different processes and part profile as shown in Table 4.

Table 4 Comparison of Ra values obtained from different processes and part profiles

Material	Manufacturing Process	Ra	Rz
PLA	FDM [Table 3]	18.42	68.96
PLA	FDM [33]	37.05	-
UHMWPE	FDM [34]	19.716	41.12
UHMWPE	Compression Moulding [35]	1.96	2.52
UHMWPE	Turning [34]	1.54	5.33

It is observed from Table 4 that the parts made with different processes other than FDM have a good surface finish and the parts produced with different part profiles using FDM have a poor surface finish which is a characteristic of FDM. The results of the measurement of roundness are presented in Figure 7. From the roundness measurements, it is noticed that the maximum and minimum deviations of 0.1231 and 0.1054 at a plane are 13.45 mm and 1.65 mm from the base respectively. This may be attributed to the existence of non-homogenous shrinkage and expansion during FDM process.

The results of surface roughness measurement claim the need for some post-processing such as Micro Machining Process MMP, Hard Cutter Machining (HCM), Vibratory Bowl Abrasion, Filling the gaps by Epoxy resin/ Part Painting etc. [36] to obtain smooth and accurate surfaces.

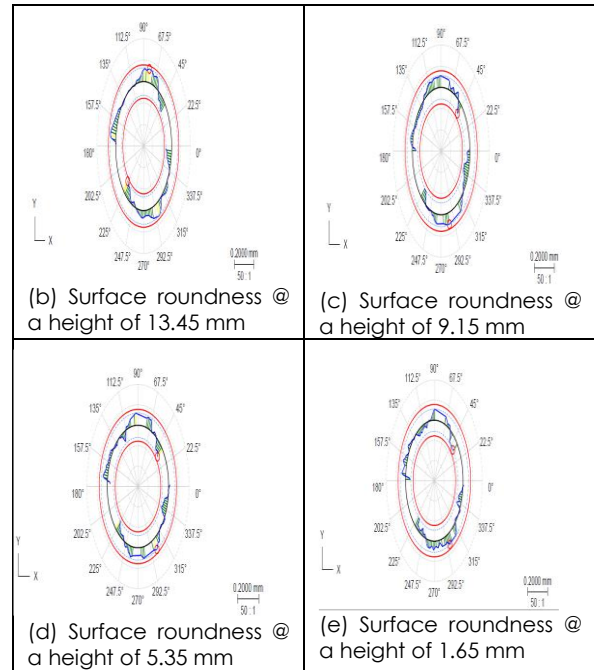


Figure 7 Roundness Deviation in the fabricated liner

3.3 Wear Measurement

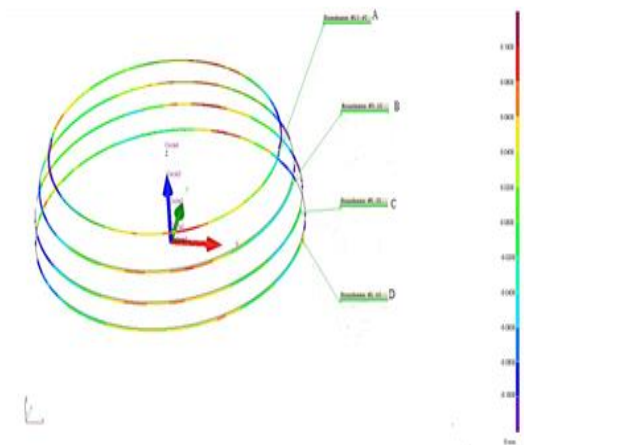
The average of the three test results from the pin-on-disc wear test is presented in Table 5 and the sample plot of the time versus the coefficient of friction obtained is shown in Figure 8.

Table 5 Measured Weight Loss and Specific Wear Rate

Sample No	Initial Weight (gms)	Final Weight (gms)	Δw (gms)	Specific Wear Rate ($\text{mm}^3/\text{N}\cdot\text{m}$)
1	2.1724	2.1212	0.0512	0.001825
2	2.1552	2.1056	0.0496	0.001768
3	2.1578	2.1122	0.0456	0.001626

The observed average value of the coefficient of friction is 0.302 and the computed mean specific wear rate is $0.001740 \pm 0.0001 \text{ mm}^3/\text{N}\cdot\text{m}$. When compared with the results obtained by Song Wang *et al.* [22], this coefficient of friction value for PLA material (0.302) is more than the conventional PE (0.116) and less than the conventional PEEK (0.388). The higher specific wear rate may be due to softening effect of PLA material during the additive manufacturing process. The worn PLA material surface after the pin-on-disc test is shown in Figure 9.

It can be seen from the figure that the small wear particles formed due to the abrasive action are distributed throughout and there seems to be no existence of cracks and voids.



(a) CAD representation of Surface roundness measurement at four surface

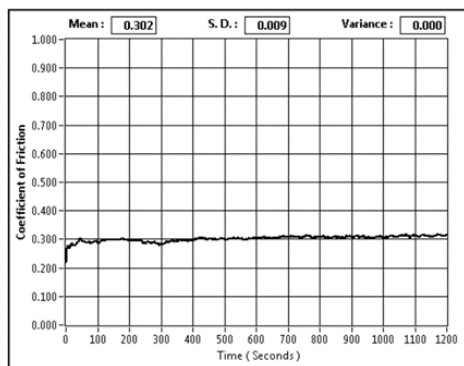


Figure 8 Sample Plot Showing the Coefficient of Friction Vs Time

To obtain the wear behaviour of a liner, it is suggested to carry out the test using hip simulator. To improve the wear characteristics of PLA liner, the surface modification either by coating of a wear resistant material or by techniques such as cladding, friction stir processing etc. may be experimented to ascertain the applicability of PLA as a suitable candidate for acetabular cup liner.

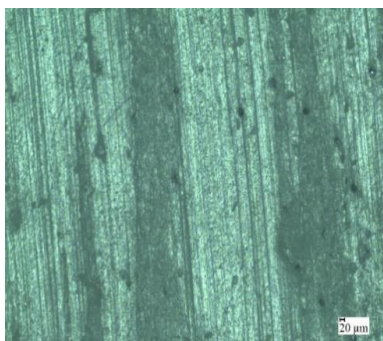


Figure 9 Surface after the Pin-on-Disc Wear Test

4.0 CONCLUSION

The FDM processed acetabular cup liner was fabricated using PLA material. According to the results obtained from various tests and measurements, the following conclusions can be drawn. The maximum variation observed from CMM measurements is 0.47% in outside dimensions and 1.10% in inside dimensions. The minimum and maximum variations in the measured dimensions are equal to 0.01 and 0.5 mm respectively. The maximum variation is attributed to the non-uniform shrinkage and oozing of PLA material. This effect may be overcome by providing proper shrinkage allowance in design and using optimum process parameters. Surface defects such as pores, voids and discontinuities are visualized through dye penetrant testing while the conventional radiography tests demonstrate no internal defects. The outside surface of the additively manufactured cup liner is

relatively smoother than the inside surface. Post-processing of the manufactured liner is recommended to attain a better surface finish. The observed coefficient of friction of PLA material is 0.302 which lies between the coefficient of friction of PE and PEEK and has a higher specific wear rate. It is suggested to perform the surface modification of the acetabular cup liner to improve its wear characteristics. Bio-degradation of a PLA is a main concern when using it for acetabular cup liner. Further research that can protect PLA from degradation is in progress.

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