Investigations for mechanical properties and biocompatibility of SS-316L implant prepared as rapid investment casting for batch production

JASPREET SINGH¹, RUPINDER SINGH^{2,*} , HARWINDER SINGH³ and ANITA KAMRA VERMA⁴

¹Mechanical Engineering Department, Lovely Professional University, Phagwara 144411, India

²Production Engineering Department, Guru Nanak Dev Engineering College, Ludhiana 141006, India

³Mechanical Engineering Department, Guru Nanak Dev Engineering College, Ludhiana 141006, India

⁴Department of Zoology, Delhi University, Delhi 110007, India

e-mail: Rupindersingh78@Yahoo.Com

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Abstract. In this work, a detailed procedure for the development of biomedical implant (SS-316L) by combining fused deposition modeling (FDM), chemical vapor smoothing (CVS), silicon molding (SM) and investment casting (IC) for batch production has been outlined. In spite of being biocompatible and bioactive within the body, the implant must possess good surface quality and dimensional accuracy along with sufficient hardness in order to reduce the wear inside the body. So in this research work, investigations have been made on the surface finish, dimensional accuracy and hardness of the implants by varying two controllable factors of the IC process (drying time of primary coating and mould thickness). The tolerance grades for the selected dimension of the casted implants were within the allowable range as defined in UNI EN 20286-I (1995) standard of ISO. The process capability indices (C_p and C_{pk}) values greater than 1.33 for the surface hardness and radial dimension indicated that the proposed process is statistically controlled. Further, in order to evaluate the biocompatibility, an *in vitro* study was conducted to ensure the attachment of mouse embryonic fibroblasts cells (NIH-3T3) to the casted samples. The results of *in vitro* study indicated that samples were capable of supporting cell adhesion and cell proliferation and hence can be used for tissue engineering.

Keywords. Fused deposition modeling; chemical vapor smoothing; silicon molding; investment casting; biocompatibility; *in vitro* analysis.

1. Introduction

In the last two decades, the demand for tailor made biomedical implants had been increased at high rates all around the world [1]. These implants must be biocompatible and bioactive within the body [2]. Also, they must possess properties like good surface quality, dimensionally accurate and sufficient hardness in order to reduce the wear inside the body [3, 4]. Development of such implants using most appropriate route is the demand of today's world. Investment casting (IC) also known as 'precision casting' is the most widely used casting process to produce complex, intricate shaped and precision metallic components that require excellent surface finish and dimensional accuracy [5, 6]. In traditional IC process, a metallic die is used to

make the sacrificial wax patterns. However, the high cost and time associated for fabricating the die makes the IC process economical only for mass production [7]. If the volume is low, then the cost associated for making the die makes the IC process expensive [7, 8]. In these cases, additive manufacturing (AM) techniques prove to be a feasible solution for the synthesis of specialized and customized products with reduced product development time [9, 10]. Also, development in the area of rapid prototyping (RP) and image processing (IP) leads to the expansion of the applications of these technologies in the field of medical implantation [11].

Fused deposition modeling (FDM) is one of the most diffused RP techniques that bridged the gaps between conceptualization and realization of products [12]. In the process of FDM, materials like acrylonitrile butadiene styrene (ABS), polycarbonate or wax are heated to a semi-liquid state by the heaters present in FDM extrusion head [13] and then the head deposits the material in thin

*For correspondence

layers. Each layer bonds to the previous layer by particular material fabrication technology until the 3D physical model is built [14, 15]. Rapid investment casting (RIC) is one of the biggest applications of FDM, where castings are prepared by utilizing 3D plastic model fabricated by FDM as sacrificial patterns in the traditional IC process [15, 16] and thus eliminate the expensive tooling required for making the patterns [17]. This application can speed up the production processes in aerospace, medical and micro-manufacturing industry having requirement of flexible designs with lower cost and shorter lead times [18]. However, the major drawback of FDM process is the poor surface quality and dimensional inaccuracy even for basic part geometries [19]. The poor surface quality of sacrificial pattern definitely affects the final surface finish of the casting in RIC process. Also, the poor surface finish of castings may lead to dimensional inaccuracy and post-operative complications if used for biomedical applications [12]. So, in order to improve the surface finish and dimensional accuracy of FDM prototypes, researchers employed various techniques such as optimization of input parameters, optimizing part build orientations, utilization of optimum slicing strategy, barrel finishing, etc. [20–25]. Further, some of the researchers highlighted that chemical vapor smoothing (CVS) technique drastically improve the surface finish of FDM fabricated ABS replicas with minimal variation in part dimensions [11, 19, 26, 27]. Also, the dimensions of ABS replicas fabricated by the combined process of FDM and CVS has been found to be consistent with the permissible range of tolerance grades as per ISO standard UNI EN 20286-I (1995) and DIN 16901 for plastic materials [28]. Further, RP technologies are not preferred for batch production due to high cost involved and also have limited range in terms of material selection [29]. This requires the need of developing rapid tooling (RT), which is an extension of RP. It is the technology that utilizes the RP and applies them to the manufacturing of various tools [30, 31]. Silicon molding (SM) is an established prototyping technique widely used in industry to produce wax patterns [32, 33] and various types of plastic parts due to high chemical resistance of silicon rubber and low interfacial energy of its surface. SM is characterized by the use of a vacuum during the process of mould fabrication and the casting of plastic parts [34]. Some studies have been reported as an indirect approach for producing wax patterns via silicon rubber molding from RP based master pattern to reduce the costs associated with single-part or small-quantity production during the investment casting (IC) process [7]. Further, many researchers have successfully fabricated sacrificial wax patterns for IC process by room temperature vulcanized mould process [35–37] but hitherto, very less work has been reported to fabricate polyurethanes (PU) replicas that can be utilized as plastic based patterns in traditional IC process in order to

improve the dimensional accuracy for complex and intricate shapes.

Harun *et al* [38] fabricated ABS patterns (solid as well as hollow) using FDM technique for IC process and observed that hollow pattern construction proved to be more viable than solid pattern construction in terms of dimensional accuracy, mould cleanliness and pattern. Singh *et al* [39] compared the dimensional accuracy of the hip joint prepared by IC process by varying the pattern material (conventional wax and ABS) and number of slurry layers and concluded that ABS pattern with 8 number of slurry layers results into minimum deviation. Kumar *et al* [40] investigated the effect of selected parameters on the hardness of hip joint fabricated as hybrid IC and concluded that mold thickness and volume to surface area ratio of the casting play a significant role in deciding the microstructure and hardness of the castings. Singh *et al* [41] investigated the effect of mould thickness and drying time of primary coating on the dimensional accuracy of castings prepared as RIC and concluded that mould thickness affects the dimensional accuracy significantly. Further, the tolerance grades for the selected dimension of the castings were found to be acceptable as per the ISO standard UNI EN 20286-I (1995). In recent past some work has been reported to fabricate biomedical implant by combining FDM and IC in order to analyze its bio-compatibility. The samples prepared were also investigated for corrosion properties [42].

Also, literature review reveals that stainless steel (SS-316L) is the most widely used material for medical and dental applications due to its excellent mechanical and biomedical (bioactivity and biocompatibility) properties [43, 44]. In traditional IC process, wax is used as a material for sacrificial pattern whereas plastic based patterns are used in RIC process. Since steam cannot wash off plastic based patterns like it does with wax in the autoclave, hence no autoclave is done in RIC process. In order to remove the plastic based pattern, the shell is placed into a flash fire furnace where temperature reach upwards of 2000 °F (1093°C), and the pattern combusts, giving off gas and possibly leaving a small amount of ash in the hollow shell mould. Since the ash left in the mould is basically a form of carbon, it may affect the properties especially biocompatibility of the castings made of SS-316L material. So, investigations have to be performed to study the various properties of the casting produced from plastic based patterns. Further in this research work, experimental investigations had been carried out by varying two controllable factors of the IC process, namely drying time of primary coating and mould thickness on various properties such as surface roughness, dimensional accuracy and hardness of the castings prepared by this combined route. Also, the biocompatibility of the casted implants prepared by this route (FDM + CVS + SM + IC) had been evaluated by *invitro* testing.

Figure 1. Benchmark component.

2. Methodology

In this research work, the most commonly used biomedical implant (hip joint) as shown in figure 1 has been selected as the benchmark component. The CAD model of the component had been made using CREO 2.0 software and then converted into .STL file. The .STL file serves as an input to

the FDM machine to fabricate 3D model of acrylonitrile butadiene styrene (ABS) material followed by the CVS process to enhance the surface finish. It has been observed that CVS process dramatically improves the surface finish of ABS replicas. The results were in line with the observations made by other investigators [19, 26]. After that, multiple prototypes of PU material were produced by silicon molding (SM) process in order to reduce the cost of RP. IC process begins with joining the PU prototypes to a tree followed by number of layers of stucco coating of ceramic material for imparting strength to the mould (figure 2). Baking of the mould is then carried out in a furnace at around 900°C. During the baking process, the PU replicas suddenly come out of the mould in the gaseous state and leave the shell for pouring the molten metal. Before pouring, compressed air was passed through the shell for removing any ash content that left during the baking process. Castings were produced with a biocompatible grade of stainless steel (SS-316L). The complete methodology of the study has been shown in figure 3.

The literature related to IC process indicated that mould thickness and drying time of primary coating are the main factors that affect the properties of the castings [9, 40, 41]. In the IC process, the only way to control the thickness of the mould is by controlling the number of ceramic slurry layers. Higher the number of slurry layers more will be the thickness of the mould. Observation made from pilot experimentation indicates that by using less than 7 number of slurry layers, the IC shell gets cracked while pouring the molten metal. This was due to the thermal shock exerted by the molten metal on the walls of the mould. Further, as the number of layers increases beyond 9, the shells become too

Figure 2. PU prototypes attached to tree followed by stucco coating of ceramic.

Table 1. Parameters and their levels for IC process.

Parameters	Symbol	Unit	Levels		
			1	2	3
Drying time of primary coating	A	Min	330	360	390
Mould thickness	B	Number of layers	7	8	9

Table 2. Control log of experimentation.

Exp. no.	A (min)	B (number of layers)	Average surface roughness, R_a (μm)	Average dimensional deviation, ' Δd ' (mm)	Average hardness (HV)
1	330	7	2.148	0.262	186
2	330	8	2.246	0.192	169
3	330	9	2.104	0.137	151
4	360	7	1.898	0.252	189
5	360	8	1.805	0.205	175
6	360	9	1.756	0.142	158
7	390	7	1.634	0.234	221
8	390	8	1.515	0.190	177
9	390	9	1.593	0.124	161

heavy in weight and the heat transfer rate of molten metal reduces thus affecting the hardness of the castings. Similarly, during the pilot experimentation, moisture content was observed in the moulds when the drying time was set below 300 min. This results in lack of strength of the mould. Also, the moisture content causes formation of small pores and certain other defects during the baking of the moulds and thus affects the quality of the castings. Based on the results of pilot experimentation, levels selected for the two parameters in IC process have been shown in table 1. Full factorial approach has been used to plan and analyze the experiments.

3. Experimentation

Control log of experimentation along with the results of surface finish, dimensional accuracy and hardness of the castings have been shown in table 2. In this work, surface roughness (R_a) and dimensional deviation (Δd) has been taken to represent the surface finish and dimensional accuracy, respectively. Surface roughness (R_a value) of all the castings has been measured at femur part by Mitutoyo SJ-210 roughness tester at 0.5 mm/s stylus speed and cut-off length at 0.25 mm. One radial dimension (as shown in figure 1) of all the PU replicas and corresponding castings was measured by coordinate measuring machine (CMM) and deviation has been measured. The surface hardness of the casted hip joints was measured by using Vickers hardness tester (HVS-1000BVM) as per ASTM-E-384 standard. In order to minimize the variation, three readings were taken for each response and the average of the three

values was considered as the final output. Figure 4 shows the casted components and figures 5–7 indicate the variation of output response with the experiment number.

Figure 5 indicates that ' R_a ' value improves with increase in drying time of primary coating. This was due to the removal of moisture present in the ceramic shell with increase in drying time of primary coating. The minimum value of ' R_a ' was observed with drying time of 390 min. Mould thickness has very little influence on the surface roughness of the castings.

Figure 6 indicates that ' Δd ' decreases with increase in mould wall thickness and was minimum with 9 number of layers. This was due to the fact that lesser mould wall thickness results in higher heat transfer rate and ultimately more shrinkage occurs. As the number of layers increases, heat transfer rate as well as shrinkage decreases which results in lesser deviation. Drying time of primary coating has negligible effect on dimensional deviation. The maximum shrinkage of approximately 2.2% has been observed in the selected radial dimension of the castings produced with 7 number of layers.

Figure 7 indicates that hardness value decreases with increase in mould wall thickness i.e., as the number of layers of ceramic material increases, the hardness value decreases. This was due to the fact that with increase in number of slurry layers, heat transfer rate and ultimately cooling rate of the casting decreases which in turn reduces the hardness value. Higher the cooling rate more will be the hardness of the casting. Further, with increase in drying time of primary coating, the hardness value increases slightly. This was due to the fact that by increasing the drying time, the moulds were strengthened properly due to

Figure 3. Methodology of the study.

the removal of any moisture present in them and consequently increases the hardness value. However, the effect on hardness with increases in drying time was not significant.

4. *In-vitro* study

Further, in order to evaluate the biocompatibility of casted samples, an *invitro* study was conducted to ensure the attachment of fibroblast cells to the fabricated structures. The specimens of size 5 mm x 0.5 mm were first sterilized in autoclave conditions at 15 psi, 121°C for 15 min and thereafter under ultraviolet light for 30 min prior to start of the experiment. Mouse embryonic fibroblasts cells (NIH-3T3) were maintained in adherent cultures. Cells of a 90 per cent confluency were trypsinized and re-suspended in serum-containing medium and these first passage cells were seeded at a density of 10×10^3 cells/well in a six-well plate for designed specimens and placed in a 5 percent CO₂-humidified 37°C incubator. Briefly, cells were maintained in fully supplemented medium, i.e., Dulbecco's modified Eagle's medium with 10 per cent fetal bovine serum, 2 mM l-glutamine and antibiotics (100 U/ml penicillin and 100

g/ml streptomycin). Culture medium was changed every two to three days for one week, till cells became confluent. The specimen was transplanted to a new, well-supplemented with complete media (second passage) and checked for proliferation. This is performed to estimate the number of adherent cells in a culture well to estimate the proportion of the surface which is covered by cells. Figure 8 shows growth of NIH3T3 cells in designed specimens. Fluorescently labeled cell samples were imaged using a Nikon Eclipse TE2000 inverted laser scanning confocal microscope with operating software. The results exhibit growth of fibroblast cells and were found to be proliferating over the designed specimens. They were found capable of supporting cell adhesion and cell proliferation. These results suggest that these carriers are suitable for cell culture and can be used for tissue engineering.

5. Results and discussion

5.1 Calculation of tolerance grades

In today's manufacturing scenario, the calculation of the tolerance (IT) grade becomes very important when one has to commercialize a manufacturing process. In order to find

Figure 4. Specimens after casting.

Figure 5. Variation of surface roughness.

Figure 6. Variation of radial dimension.

Figure 7. Variation of hardness.

Figure 8. Growth of NIH-3T3 cells at 10X.

the tolerance grades, first the measured dimensions have been utilized to calculate the tolerance unit ‘n’ that derived from fundamental tolerance ‘i’, as outlined in UNI EN 20286-I (1995) standard of ISO. The fundamental tolerance ‘i’ and tolerance unit ‘n’ is calculated as follows [10]:

$$i = 0.45 \sqrt[3]{D} + 0.001 D \quad (1)$$

$$n = 1000 \left(\frac{D_N - D_M}{i} \right) \quad (2)$$

where ‘D’ is the geometric mean of range of nominal size, D_N is the nominal dimension, D_M is the measured dimension, ‘i’ is the fundamental tolerance in μm .

Table 3. Calculations of IT grades.

Exp. no.	Radial dimension (mm)	Tolerance value ‘n’ in (μm)	IT grade
1	11.788	241.99	IT13
2	11.858	177.33	IT13
3	11.913	126.54	IT12
4	11.798	232.75	IT13
5	11.845	189.34	IT13
6	11.908	131.15	IT12
7	11.816	216.13	IT13
8	11.860	175.49	IT13
9	11.926	114.53	IT12

In this research work, the selected radial dimension has been taken as nominal dimension. The standard basic step for dimension ($D_1 = 12.050$ mm) is 10–18 mm. In experiment 1 (see table 2), the value of ‘n’ for the selected linear and radial dimension is calculated as follows:

$$D = (10 \times 18)^{1/2} = 13.416 \text{ mm}$$

$$i = 0.45 (13.416)^{1/3} + 0.001 (13.416) = 1.0827 \mu\text{m}$$

$$n = 1000 (12.050 - 11.778) / 1.0827 = 241.99$$

Similarly, the tolerance unit for all the experiments (as per table 2) has been calculated and the obtained IT grades have been shown in table 3. Further, it has been observed that (see table 3) the measured dimension in all the experiments is less than the nominal dimension. This was due to the shrinkage that occurs during solidification of the casting as the metal changes state from liquid to solid. The shrinkage is generally compensated by providing shrinkage allowance to the pattern. The results indicate that the IT grades of the castings prepared by this RIC process are within the allowable range as defined in UNI EN 20286-I (1995) standard of ISO.

5.2 Process capability analysis

In order to ensure that the process is repeatable and statistically controlled, 12 samples were casted by taking drying time of 390 min and number of layers as 9. These levels were selected only for the reason that the radial deviation was minimum (refer table 2) at these parameter settings. The observations of surface hardness and radial dimension of castings have been shown in table 4. After that the C_p and C_{pk} values of the process and histogram of observed values for surface hardness and radial dimension have been obtained by ‘Process Capability Wizard 2016’ software. Figures 8 and 10 indicate the histogram of the observed values along with C_p and C_{pk} values for the surface hardness and radial dimension, respectively. The prerequisite for computing C_p and C_{pk} is that the process is required to be under statistical control and that the data are

Table 4. Observations of selected dimension.

Sl. no.	Surface hardness (HV)	Radial dimension (mm)
1	167	11.924
2	164	11.926
3	163	11.923
4	159	11.919
5	164	11.922
6	166	11.925
7	170	11.925
8	168	11.921
9	167	11.920
10	163	11.923
11	164	11.921
12	164	11.925

Figure 9. Histogram of observed values for surface hardness.

normally distributed [45, 46]. Since the value of both C_p and C_{pk} for the hardness as well as radial dimension has been found to be greater than 1.33, it indicated that the process is statistically controlled [47]. Further, normal probability plot for the selected responses (see figures 9–12) indicates that the data are normally distributed. The observed values are plotted on the X-axis against a theoretical normal distribution (z-scores) on the Y-axis [46]. A regression line is drawn from these XY pair which shows points closer to the regression line and thus indicating a good fit. These results are in line with the observations made by other investigators [48, 49].

6. Conclusions

From this research work, the following conclusions have been drawn.

Figure 10. Normal distribution curve of observed values for surface hardness. **Figure 11.** Histogram of observed values for radial dimension. **Figure 12.** Normal distribution curve of observed values for radial dimension.

- The combined route of FDM, CVS, SM and IC has been found to be feasible for the development of biomedical implant for batch production.
- Drying time of primary coating affects the surface finish significantly and 'R_a' value improves with increase in drying time of primary coating.

- Dimensional deviation decreases with increase in mould wall thickness due to the fact that as the number of layers increases, heat transfer rate as well as shrinkage of the castings decreases which results in lesser deviation.
- Surface hardness decreases with increase in mould wall thickness due to the fact that with increase in number of slurry layers, heat transfer rate and ultimately cooling rate of the casting decreases which in turn reduces the hardness value.
- The tolerance grades for the selected dimension of the casted implants were within the allowable range as defined in UNI EN 20286-I (1995) standard of ISO.
- The C_p and C_{pk} value greater than 1.33 for the surface hardness and radial dimension indicated that the proposed process is statistically controlled.
- Further, the samples casted by this combined route (FDM+CVS+SM+IC) were found to be capable of supporting cell adhesion and cell proliferation and hence can be used for tissue engineering.

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