



In-vitro studies of SS 316 L biomedical implants prepared by FDM, vapor smoothing and investment casting

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ABSTRACT

The function of biomedical implant is to replace the biological parts/limbs in body. Among various materials, metals and alloys like titanium, stainless steel (SS) are used as biomedical implants due to their superior mechanical properties, considerable bio-compatibility and easy manufacturing. In the present study, implants of SS 316L have been made with the combination of three processes namely fused deposition modelling, vapor smoothing and investment casting. Further, in-vitro test has been performed on the implants in order to analyze its corrosion behavior and bio-compatibility, to check its applicability and to verify the effect of manufacturing processes on its corrosion properties.

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1. Introduction

Biomedical implants are considered as boon for the medical industry and end users such as patients, suffering from serious injuries or ailments. Biomedical implants act as artificial replacements and expected to perform a function of original part. The primary requirement of any material to be used as an implant is its compatibility inside human body. So, the selection of material for implant is a matter of great concern. The other major concerns for good material are its mechanical properties (such as toughness, strength, hardness, surface roughness and dimensional accuracy etc.), simplicity in manufacturing of complex shaped parts in terms of design, production in less cost and time. Most commonly, implants are made of polymeric, metallic and ceramic materials or

combination of these materials. The demand for metallic materials is high in medical devices [1–3]. Specifically, SS alloys, Co–Cr alloys and titanium alloys are widely used as orthopedic implants materials. The SS 316L is one of the most widely used biomaterials for implants, because of its reasonable capability to resist corrosion, acceptable mechanical properties, ease of fabrication and cheaper price as compared to titanium alloys [4,5]. The performance of a biomaterial is determined by its chemical, physical and biological properties [6]. In the complex environment of the human body, biomedical materials are subject to electrochemical corrosion mechanisms, with body fluids acting as an electrolyte [7–10]. The corrosion is an important consideration taken into account while selecting the material which supposed to reside inside human body. In human body, the high concentration of Cl[−] and the temperature range of 36.7–37.2 °C are responsible for highly corrosive environment [11,12]. The presence of amino acids and proteins inside body fluids increases corrosion. Corrosion is responsible for unstable bone growth at interface of implant and bone. It may also release harmful ions of metal into body and excessive release of ions may lead to unfriendly reactions in body that may ultimately

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results into mechanical failure of the implant [2]. Chromium element in the stainless steels results in the evolution of thin, chemically stable and passive oxide film upon the surface. This oxide film controls the corrosion behavior of material, its relation with body and measure of material's biocompatibility [13,14]. Various studies suggested and it has been well acknowledged that the bearable corrosion rate for metallic implants should be about 2.5×10^{-4} mm/yr, or 0.01 mils/yr [15,16].

There is rapid evolution in the field of biomedical implants [17]. Compatibility i.e. (physically and chemically) with the body of human is the pre-requisite of implants [18]. Also, surface properties and close tolerances of implants cannot be neglected [19]. By implementing the additive manufacturing (AM) techniques, many researchers build up acceptable quality of biomedical joints for human body [20,21]. In the aim of creating surfaces with high finish and accurate dimensions, investment casting (IC) process is a favorable choice for the researchers [22–24]. Hence, IC is considered as one of the advanced metal casting process [25–27]. The physical models need to be used as pattern in IC process and can be obtained easily by fused deposition modelling (FDM) using CAD data [28]. The development of customized orthopedic implants became far easy by integrating the two processes such as; traditional lost wax IC process and FDM. This combination drastically shortens the build time of implant, by reducing the time requirements for building ABS pattern and the time required for a skilled craftsman to execute complex modifications, such as for wax pattern. Also, the cost of creating sacrificial patterns for IC using AM techniques is relatively less than the cost involved in designing and fabrication of metal tooling for wax pattern [29,30].

No doubt with the combination of these processes fabrication of implants became easy but, it faces crucial issues such as; the surface finish of ABS patterns produced by FDM process is inferior due to its inherent capability and staircase effect [31,32]. Consequently, the surface finish of casted implants is spoiled as a result of patterns with impaired finish. So, in this study a promising surface finishing technique known as vapor smoothing (VS) is added to existing processes to alleviate the troubles occurred before. The technique involves a use of chemical that vaporizes and penetrates the ABS parts, which in turn cause the peaks formed due to alternate layers on the surface to flow down into valleys due to surface tension forces and thus, improves the finish of the part by filling the gap [33].

In regard to in-vitro studies of the implants, majority of the work is reported to study the corrosion behavior of the different materials by applying coatings on them. But, the main aim of this research paper is to check the applicability of biomedical implants prepared with the combination of three processes, in terms of biocompatibility (corrosion and cell culture) with human body by providing simulated environment. The focus is to observe the effect of parameters of FDM, VS and IC on the corrosion properties of the implants.

2. Experimentation

In present work, hip joint as shown in Fig. 1 has been prepared as the biomedical implant with the help of FDM, VS and IC process. Two main controlling parameters were selected from each process, with two or three levels of each input factors by referring literature and performing pilot experiments. The experiments were designed with Taguchi L_{18} ($2^1 \times 3^7$) orthogonal array. The L_{18} orthogonal array along with independent variables and their selected levels used for the experiments is shown in Table 1.

In experimentation work, 3-D drawing of hip joint as an input data to FDM machine, ABS replicas were obtained at two different orientations 0° and 90° , having densities such as low, high and

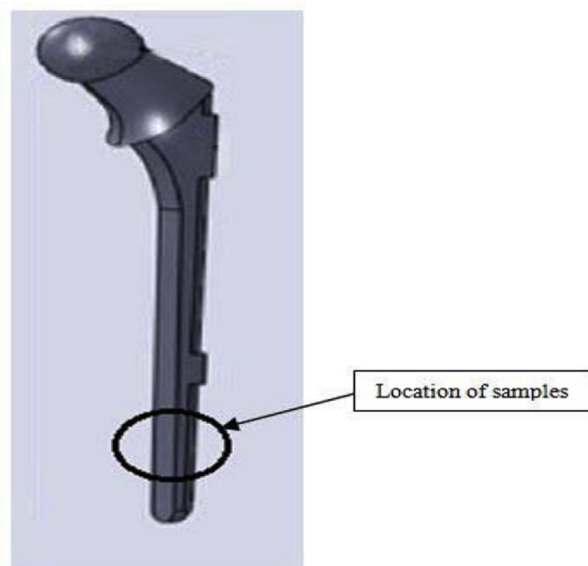


Fig. 1. 3-D view of hip joint.

solid. Then, patterns undergoes a finishing process i.e. vapor smoothing, to reduce the irregularities on the surface. The input factors in finishing process are vapor exposure time and no. of repeated cycles.

The number of repeated cycles indicates that the no. of times pattern is placed in smoothing chamber as shown in Fig. 2, and pattern can be exposed to chemical vapors for different time periods in the aim to enhance its finish. The 1,2,3 cycles have been selected for this factor. While, vapor exposure time is expressed as the variation in time for which the patterns are exposed to the vapors in the smoothing chamber in each cycle. In every cycle, the exposure time in cooling chamber remain fixed. Three different exposure times represented as 10, 15, 20 s have been elected for this study. Finally, after finishing ABS replicas were used as pattern in investment casting process.

Patterns were coated with different combinations of slurry layers i.e. 7,8 and 9 to vary the mould thickness and in later stage, baking time is important for proper burnout of the pattern from the investment casting mould so that there should not any remains of ash left inside mould. Baking time was selected as 30, 40 and 50 min. And, cavities in the mould were filled with molten SS 316L.

3. In-vitro corrosion studies

3.1. Materials and preparation

For In-vitro testing, samples were collected from the location as shown in Fig. 1. Samples for corrosion test have dimensions $6 \times 4 \times 10$ mm. Before experiment, each sample is mechanically abraded with emery paper of 150–2000 grit size. The electrolyte used for simulating human body fluid conditions was Ringer's solution at pH-7.2, with chemical composition as shown in Table 2.

The temperature of Ringer's solution was kept at $37 \pm 1^\circ\text{C}$ as this is the normal temperature of the human body. The exposed area of sample into ringer's solution was 0.30 cm^2 .

3.2. Electrochemical tests

All electrochemical experiments were performed in Gamry electrochemical cell with three electrodes connected to Gamry

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