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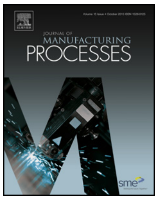

Technical Paper

# Experimental investigations on hardness of the biomedical implants prepared by hybrid investment casting

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ABSTRACT

In this paper for total hip replacement, a systematic procedure for development of primary (1°) implants of stainless steel has been outlined with fused deposition modeling (FDM) assisted hybrid investment casting process. As the suitability of the implant is mainly assessed by in vitro analysis, the change in microstructure and surface hardness is one of the important parameter/criterion for estimating the functional ability of 1° implants. In order to achieve the increased hardness and improved microstructure of the implants, process parameters of FDM and investment casting process have been identified and optimized in this research work. The analysis of variance has been used to find the percentage contribution of each factor. It has been observed that mold thickness and volume to surface area ratio of the casting plays a significant role in deciding the microstructure and hardness of the castings. Therefore, by controlling these parameters the required microstructure and hardness can be achieved for 1° implants. This study may be used as a yardstick for deciding the levels of coating as secondary (2°) implants (if required) for in vitro and in vivo analysis.

## 1. Introduction

Investment casting (IC) process is considered as suitable process to make complex metal parts with good dimensional accuracy [1]. In traditional method of IC, a metal die is used to make sacrificial wax patterns. The manufacturing of die is a costly and time consuming process but however, once the die is manufactured, it can make thousands of wax patterns. Thus, this method is economically suitable for mass production [2]. But, there are many applications where only one or very less number of pieces are required such as: during design iterations, making functional prototypes, making customized biomedical implants and making satellite parts [3–6]. In such situations the IC process proves to be costlier and more time consuming [7]. Moreover, with the traditional IC method any change in design is not possible after making the die. But frequent changes in dimensions may be required before getting the final design in many cases such as: during the manufacturing of a new product, making a patient specific customized biomedical implant or any other part with fit and functional testing etc. [8]. In such cases additive manufacturing technologies prove to be a feasible solution.

In recent past various additive manufacturing technologies have been emerged [9,10]. Some of these technologies are: fused deposition modeling (FDM), selective laser sintering, laminated object manufacturing, solid ground curing, electron beam melting and poly jet technology. The major benefit of these technologies is their capability to convert a three dimensional CAD model into a physical model directly without using any tool or die [11]. Among these technologies, the FDM can be used to produce three dimensional models by using plastic [12]. These models can be used for many applications. One important application is the use of these models as investment casting patterns instead of the traditional wax patterns with a little modification in the conventional IC process [13,14]. In conventional IC process steam is used to remove the wax pattern from the mold, but in FDM based patterns high temperature furnace is used to burn out the pattern and to produce a hollow shell [15]. The use of these FDM based patterns can overcome the limitations of the traditional IC process. First, it eliminates the requirement of costly and time consuming tooling for making dies [16]. Second, the change in design is easily possible by just applying the changes in the drawing only. In this way, this method can make the investment casting viable for low and very low volume projects [17]. FDM has potential to produce parts with locally controlled properties by changing deposition

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density and deposition orientation [18]. FDM assisted IC process can also be used to make functionally graded materials [19]. The only drawback of this process, as reported by some researchers is the incomplete burning of the pattern and/or mold cracking during the burning of the pattern due to thermal expansion of the plastic pattern [20–22]. However, these problems can be resolved by using suitable methods as suggested by [23,24]. The FDM assisted IC can be termed as hybrid investment casting.

Medical implants are devices or tissues that are placed inside or on the surface of the body. Many implants are prosthetics, intended to replace missing body parts. Other implants deliver medication, monitor body functions, or provide support to organs and tissues. Total hip replacement is a surgical procedure in which the hip joint is replaced by a prosthetic implant. This replacement is done in some hip fractures or in order to relieve arthritis pain. The IC process is generally used for manufacturing prosthetic implants [25]. These prosthetic implants are available in different sizes but sometimes patient specific custom sized implants are required for better performance and suitability. In such situations custom made 3-D freeform model of a required bone can be reconstructed by using magnetic resonance imaging (MRI) or computerized tomography (CT) image data [26,27]. In the process of implant development, firstly dimensions of implant are taken and visualized using MRI or CT scanners. Data collected from MRI/CT scans is then converted into '.STL' file using MIMICS or 3D-DOCTOR software packages. The '.STL' file is then further processed and converted into '.CMB' file (acceptable format to FDM system) using CatalystEX©® software [28]. The FDM machine makes the plastic patterns of the required dimensions. These plastic patterns are used to make the implant by using IC process.

Implants can be placed permanently or they can be removed once they are no longer needed. Therefore, on the basis of function of the implant the doctors estimate the desirable life of the implant. Many implants like chemotherapy ports, bone plates, rods and nails are used only for inter fixation of fractures. These are used for holding the broken pieces of the bone together and generally these implants are removed after healing of the bones in proper position. Some other implants like knee joint, hip joint, stents, etc. are permanent and required to work for longer time. Different types of surface coatings are provided on permanent implants in order to ensure their longer life. Whereas the temporary implants produced by using biocompatible materials can work satisfactorily without surface coating. The in vitro studies are conducted on the primary implants in order to find their suitability for the human body. The decision about requirement of coating depends upon the microstructure and properties of the 1° implant. Moreover, in many types of implants, there is direct metal to metal contact and there is relative motion between two metal parts of the implant. Therefore, over the time some wear of the implants occur. This wear produces some debris which is harmful for the human body. In order to minimize the wear of the implant, there must be a good surface hardness of the implant [25]. Also the wear resistance of the implant increases the life of the implant.

In addition to making implants, the IC process is used to make many other engineering components which work under direct metal to metal contact between two moving parts. Therefore refined microstructure and adequate surface hardness is required to minimize the wear of such engineering components. Moreover, the improved microstructure can provide more strength, more corrosion resistance and more resistance to deformation.

Many attempts have been made in the past to obtain the required microstructure and hardness. Guemmaz et al. [29] showed that nitrogen implantation in stainless steel 316L leads to important microstructural modifications of the subsurface layer. It is found that multiple energy implantation induces new phases that change the micro mechanical surface properties. Yamada et al. [30] used aging for improvement of microstructure and mechanical properties of SCS14A cast duplex stainless steel. It is found that with 3000 h at 400 °C aging ferrite hardness increases to 600 VHM. The ferrite hardness can be further increased by increasing the aging time. Ganesh et al. [31] used hard facing method in order to improve the hardness. A bi-metallic tube used in fast breeding reactor manufactured with different material on internal and outer surfaces, Stellite was used in inner side whereas stainless steel 316L was used on outer side. Asgari et al. [32] found that the surface hardness and tribology behavior of austenitic stainless steel can be improved by using pulsed plasma nitriding treatment. By this method an extended austenite phase can be formed which provides a unique combination of wear and corrosion properties. Chandra et al. [33] found that low temperature thermal aging of stainless steel 304L and 316L can be used to increase the hardness. The microstructure study showed a larger increase in hardness of ferrite phase whereas there is no change in hardness of austenite phase. Roath [25] used electron beam melting process to make specimens of Ti6Al4V biocompatible alloy. It is found that EBM can be used directly for making custom implants and hardness obtained by this method is also comparable to casted components.

Elmer et al. [34] found that the microstructure that develop during the solidification of stainless steel alloys are related to the solidification conditions and the specific alloy composition. The precipitation morphology of the primary phase plays an important role in the solid phase transition, the final microstructure and the mechanical properties. The solidification conditions are determined by the parametric variation of the processing method and processing conditions. The microstructural morphology and residual ferrite content depend on the cooling rate. Abhilash et al. [35] observed that secondary dendritic arm spacing (SDAS) has inverse relation with cooling rate and solidification velocity. Calik [36] investigated the effect of cooling rate on microstructure and mechanical properties of AISI 1020, 1040, 1060 steels. The experimental results show that the microstructure of these steels can be changed and significantly improved by varying the cooling rate. Dobrzanski et al. [37] conducted a study on AlSi9Cu cast alloy in order to determine the effect of cooling rate on the size of grain, SDAS, size of beta precipitation and thermal characteristics. It is found that increasing cooling rate refines all microstructural features including SDAS and intermetallic compounds and improves silicon modification level. Martins and Casteletti [38] worked on duplex and super duplex stainless steels found that during solidifications of thick sections, the cooling rate reduces which leads to precipitation of intermetallic and carbide phases with presence of sigma phase. It is reported that the microstructure of the duplex stainless steel can be controlled by solution annealing heat treatment followed by water quenching. Cronemberger [39] investigated the microstructure evolution process of the duplex stainless steel SAF 2205 after solution annealing treatment. The ferrite volume fraction obtained in microstructure increased with the cooling rate whereas the volume fraction of austenite phase increased with a lower cooling rate. It is found that cooling rate is an important factor in defining steel microstructure. Mehr [40] conducted experiments to examine the cooling conditions, solidification microstructure and interfacial heat transfer in A319 aluminum alloy. Different cooling rates were obtained by using chills. It is found that the cooling rate and time has potential to improve the mechanical fatigue performance and reduction in SDAS. Liang [41] performed quenching experiments at different cooling rates on AISI 301 austenitic steel pieces. Morphological variations, variation of primary phase, phase transition temperature and hardness change were investigated. The experimental results show that with decrease in cooling rate the process is more close to equilibrium solidification and the temperature of phase precipitation is almost not changed. The hardness of samples gradually