Manufacturing Of Biocompatible Implant Component Using Rapid Prototyping Technology

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Abstract. The purpose of this research is to study the manufacturing of biocompatible implant component by using rapid prototyping technology, in particular of 3D printing process. The biocompatible material consist of 80% cobalt-chromium-HAP were prepared by mechanically blended with 10% maltodextrin and 10% polyvinyl alcohol as binding mechanism for 3D printing process. Test specimens were fabricated using experimental 3D printing machine followed by sintering process. The characteristic of the composites were studied using various techniques including Scanning Electron Microscope (SEM and EDS), hardness test, flexural test, porosity and density measurement. The results show that the biocompatible cobalt implant composite can be fabricated successfully using 3D printing process. Further investigation can be carried out on the samples to study the toxicity, chemical reaction and cell reaction for implant application.

Introduction

A number of medical case studies are presented, illustrating different uses of RP technology. These studies have been analyzed in terms of how the technology has been applied in order to solve related medical problems. A bone implant is a medical procedure in which a damaged or missing piece of bone is replaced with an implant. If the implant takes successfully, there is a good chance that the area will heal well, allowing the patient to use the bone as he/she normally would. The requirement of the implant structure is considering on the porosity of the specimens. To fulfill the requirement needed, the suitable technique is by using layer manufacturing technique. The implant components structure is originally in complex shape. In order to fabricated the design based on the structure, additive technique which is rapid prototyping technique is suitable than the subtractive technique. The main objectives of this research are to produce the implant specimen by using rapid prototype process from biocompatible materials and to evaluate the microstructure and the mechanical properties of the biocompatible material. This research focus on raw material preparation for 3DP process, followed by fabrication of 3D components from biocompatible implant material and evaluation of microstructure and physical properties of the implant component. The results show the new implants material that suitable by using 3DP with the result of microstructure and mechanical properties product that will be use for implant surgery. The focus is directly on the fabrication sample of the biocompatible material by using 3DP process and the evaluation is only involving on microstructure and mechanical properties.

There are many commonly commercial techniques in rapid prototype technologies. At least there are six different rapid prototyping techniques available and each with unique strengths [1]. Rapid prototyping is an additive process, combining layers of paper, wax, or plastic to create a solid object. RP's additive nature allows it to create objects with complicated internal features that cannot
be manufactured by other means [1]. Consequently, errors are minimized and product development costs and lead time substantially reduced. It has been claimed that RP can cut new product costs by up to 70% and the time market by 90% [2]. Biomaterials are artificial or natural materials used to in the making of implants, to replace the lost or diseased biological structure to restore form and function. Thus biomaterial helps in improving the quality of life and longevity of human beings and the field of biomaterials has shown rapid growth to keep with the demands of an aging population. Biomaterials are used in different parts of the human body as artificial valves in the heart, stents in blood vessels, bone plates, artificial ligaments and tendons, dental implants for tooth fixation, and replacement implants structure [3]. Different kinds of artificial tissues and organs are clinically under investigation. However, any materials are not always applicable to the medical system [4]. Development of new biomaterials is more than one branch of knowledge effort and it often requires a collaborative effort between material scientists and engineers, biomedical engineers, pathologists and clinicians. In order to serve for longer period without rejection an implant should have the following attributes which are mechanical properties, biocompatibility, high corrosion resistance and osseointegration. Bioactive materials are highly preferred as they give rise to high integration with surrounding bone. However, biocompatible implants are also accepted for implant manufacturing.

Experiment

For this research, there are three types of material are used which are cobalt implant composite, maltodextrin and polyvinyl alcohol. All those raw materials are powder based and the material needs to be prepared and for binder, cobalt used for 3DP process is maltodextrin and polyvinyl alcohol. Those cobalt implant composite and maltodextrin particle size are small and only polyvinyl alcohol particle size is much bigger than those particles. The SEM of the raw material as shown in Fig. 1, a) SEM raw cobalt implant composite, b) SEM raw maltodextrin and c) SEM raw polyvinyl alcohol. Sieving process has been used to get the particle size of polyvinyl alcohol. The particle size in this research should less than 50μm to get the best result [4]. The composition of cobalt powder was decided by using the Digital Balance (gram) with the optimum ratio of 80% cobalt, 10% maltodextrin and 10% polyvinyl alcohol [5]. After get the weight of the composition, it has been mix together by using the Planetary Ball Mill. Ball milling is an efficient and simple method for the fabrication of nanostructured powder materials especially for manufacturing some composite powders [6]. The mixing powders in planetary ball mill in this research use are at 600 RPM for 30 minutes. The comparison of mixed material manually (a) and mixed by planetary ball mill in 30 minutes (b) as shown in Fig. 2.

![Fig. 1: The SEM of the raw material](image)

The Canon Pixma IP1980 3D Printer used for the fabrication of the samples and prints the cross-section one after another from the bottom of the part to the top making a three dimensional
structure. Therefore, the sample size for this research is 100x8x4mm which fabricated layer by layer in about 45 layers. Distilled water is used to binding powder for making the 3D models. Based on the specimens that have been fabricated, the specimen has been used to measure the value of flexure test, hardness test, porosity and density test value. In this experiment, after the sample was produced, the green compact processes has a lack of strength and hardness, therefore it is easily crumbled under low stresses. Fig. 3 presents the microstructure of the specimens (SEM) before and after sintering process.

Fig. 2: The comparison of mixed material manually (a) and mixed by planetary ball mill (b)

(a)  
(b)

Fig. 3: SEM before (a) and after sintering process (b)

This sintering process used was the Horizontal Tube Furnace Elite with sintering profile as shown in Fig. 4. The samples were put in furnace at a heating rate of 15°C/min. The sintering process was performed in the furnace with the argon gas to prevent its oxidized. The sintering temperatures for the element are at 1196°C which are 80% of the melting temperature so that the liquid phase not presents.[?]
After the process was completed, the specimen was cooled at natural rate and removed from the tube furnace. Several of mechanical test on the sample of the engineering material are to measure their strength or other properties of interest specimen. There are wide variety standard methods have been developed for various material tests including all basic types of tests. The flexural strength of material is defined as ability to resist deformation under load. The testing accomplish by Autograph AG-I Shimadzu for 10kN UTM testing machine. The Vickers Hardness Test is one of the suitable tests used to test these hard materials. Good hardness generally means that the material is resistance to scratching and wears [8]. Porosity is defined as the ratio of the volume of the pores or empty spaces in the powder to the bulk volume [8]. The porosity of the specimen using Archimedes principle and was measured by using beaker, burner Bunsen, glass rod, and arbitrator for each specimen. Density can be determined by measuring the mass and volume of a sample particle and also can be defined as ratio of mass to volume.

Result and Discussion
From the SEM observation, there are different characteristic for the raw material use in maltodextrin, polyvinyl alcohol, pure cobalt implant composite, after mixed cobalt implant composite with maltodextrin and polyvinyl alcohol manually in gradual time, after mixed cobalt implant composite with maltodextrin and polyvinyl alcohol with planetary ball mill. In this research, the mixing time process by using ball mill is depending on the optimum time of mixing manually in gradual time. From the figure provided, there are some different when mixing manually and by using planetary ball milling process. Comparing to the manually mixing, the particle of the mixing material is scattered and uneven in some places. Meanwhile, by using planetary ball milling process, some of the particle can be seen to show an agglomerated form and the particle shape was expected to be necking spherical. The result shows the maximum stress is in the range which is 43.508MPa. In term of human being, the average of the mechanical properties of compact and spongy bone for flexural strength is 36MPa-152MPa [9]. Besides, the average elasticity value gathered is 11.529GPa also in the range of elasticity which has modal value 4-30Gpa for human being [10]. Even every human being has the same bones, but the characteristic of the bones is different and it also depends on food intake and increasing age [11]. The flexural result and average calculation shows in Table 1.

<table>
<thead>
<tr>
<th>Sample</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Force (N)</td>
<td>62.056</td>
<td>52.265</td>
<td>71.318</td>
<td>61.880</td>
</tr>
<tr>
<td>Max Stress (MPa)</td>
<td>43.633</td>
<td>36.747</td>
<td>50.146</td>
<td>43.508</td>
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<td>Max Strain (%)</td>
<td>0.522</td>
<td>0.318</td>
<td>0.530</td>
<td>0.456</td>
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<tr>
<td>Break Stress (MPa)</td>
<td>38.926</td>
<td>28.574</td>
<td>46.118</td>
<td>37.872</td>
</tr>
<tr>
<td>Break Strain (%)</td>
<td>0.592</td>
<td>0.393</td>
<td>0.590</td>
<td>0.525</td>
</tr>
<tr>
<td>Elasticity (MPa)</td>
<td>10220.2</td>
<td>12471.5</td>
<td>11897.4</td>
<td>11529.7</td>
</tr>
</tbody>
</table>

The purpose of analyzing the fracture part after specimens break is to see the particle composition in specimen which cause it break. Considering on layer thickness manufacturing, the break point is due to the porosity and bonded particle in the structure. Besides, the composition of the bone tissue is more complicated than most engineering composites, especially the two-phase composite in which the mineral and collagen phase are bound in a complex manner. While in rapid prototype concept, as the layer setting is thinner, the quality strength of the part is much finer because the particles bonded well and the quality of performance also increases. As a result, these specimens
have shown the data of maximum stress and elasticity is in the range of natural implant component in human body. Hardness is to observe the questioned material's ability to resist plastic deformation from a standard source. The test used Vickers indentation since the samples only required small load and to prevent the samples from cracking. The measurement of hardness was highly influence by the porous structure. The average value for the testing has been calculated manually from each specimen in measured position. Then the total average data also have been calculated which result is 165HV. A suitable material for the bone plate is a metal with hardness 100 – 220 HV, and preferred in the range 120 – 200 HV [12]. Hence, the graph of the hardness result with in preferred range. When focusing on the concept layer by layer manufacturing, the problem that always in mind it the specimens will have great hardness value due to bonding particle from layer manufacturing and the effect of porosity in the specimens. Based on the result, it notes that the value of the specimens is in preferred range for human body. However when considering on the natural human component, some other discussion is about the osteoporosis will affect the hardness value of the implant component. It is because the common sense about the one who have the osteoporosis, their bones is easily loss. In fact, osteoporosis does not change the hardness of bones, but the density of bones [12]. Bones break more easily because they become thinner, and thus more fragile. Thus osteoporosis is not a change in the composition of the bone, but instead a reduction in total bone mass, and more importantly a loss of bone mass in important locations. This discussion shows that the hardness value is also rely on density besides porosity. Therefore, the suitable component for implant is tending to have great value of hardness with need some value of porosity and density.

The density measurement shows the influenced capability of the component to satisfy the mechanical demands of load bearing application such as standalone inter-body spinal devices and adjacent bones. The result shows that the average density for those specimens is 4.6/cm3. Meanwhile for the porosity, the result found that the average porosity of the specimens is 15.194%. This result value is shown in Table 2 and the estimation of average value of porosity and density. Therefore, this result means that the cobalt implant composite is suitable for undergo surgery because considering on the mechanical properties of the structure which are compact and spongy and needed for cell flow in the component. As it fulfills the requirement needed in implantation, the result shows the potential of biocompatible material in 3DP process to undergo implant surgery.

<table>
<thead>
<tr>
<th>No. of Sample</th>
<th>Porosity, P (%)</th>
<th>Density, (g/cm3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16.961</td>
<td>4.583</td>
</tr>
<tr>
<td>2</td>
<td>12.721</td>
<td>4.625</td>
</tr>
<tr>
<td>3</td>
<td>15.901</td>
<td>4.592</td>
</tr>
<tr>
<td>Average</td>
<td>15.194</td>
<td>4.600</td>
</tr>
</tbody>
</table>

**Summary**

This research is just focus on biocompatible material which has been decided as cobalt implant composite metal powder manufactured by 3DP. Hence, this research was used the optimum ratio of 80% Cobalt, 10% Maltodextrin and 10% Polyvinyl Alcohol based on previous research findings as reference [5]. The results of the test have been calculated and compared to the real bone for analysis. Based findings on the flexural test, hardness test, porosity and density measurement average data, the specimens have potential to undergo implantation due to have value in preferred range data in human body and have value of porosity which is preferred for cell flow in the implant component. Besides, studied about microstructure of the specimens also give more evidence as the bonding particle and porosity of the specimens can be clearly show. As conclusion, the implant
specimens have been successfully produce by using rapid prototype process from biocompatible materials regarding the result of the experiments findings is in the value range of natural human bone. The evaluation of the microstructure and the mechanical properties of the biocompatible material also shows that the material have potential and suitable in fabrication of implant by using 3DP machine. There are another experimental work is highly recommended especially with regard to toxicity, fatigue resistance and biocompatibility in vivo test as for a further research in this field.

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