Manufacturing of Porous Polyethylene Ocular Implant by Three Dimensional Printing

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Abstract

In enucleation and evisceration, porous polyethylene ocular implants have been used to replace eyes of patients to restore function or aesthetic appearance effectively since they permit fibrovascularization and direct suturing of extraocular muscles. Traditionally, they are produced by sintering the particles below their melting temperature in a mould to create a porous structure. In this study, the feasibility of using new mould-less three dimensional printing process to manufacture high porosity and large pore size ocular implants was investigated and compared its properties with the traditionally manufactured sample.

Keywords*: Polyethylene, Three Dimensional Printing, Ocular, Medical, Porous*

1 Introduction

Polyethylene is one of biomedical polymers that have been successfully employed as implants for tissue replacement throughout the human body ranging from artificial hip to skull reconstruction [1]. Both dense and porous structures could be used depending upon the application requirement [2]. Porous structure is generally favorable where the in-growth of tissue is needed for long-term integrity [3]. In enucleation and evisceration, porous polyethylene implants has been used to replace eyes of patients to restore function or aesthetic [4]. This type of implant was found to permit fibrovascularization which offers several advantages for example reducing the incidence of infection, increasing the implant mobility and decreasing the incidence of implant extrusion and migration [5]. In addition, there is no need to use wrapping material and the extraocular muscles can be sutured directly to the implant [6]. Traditionally, this porous polyethylene implant is fabricated by powder sintering in the pre-shaped mould cavity. However, with the advance in manufacturing technology, mouldless freeform fabrication is increasing utilized for low-volume production which requires the production flexibility and controlled complexity of the products as in the case of implant. Three dimensional printing (3DP) is one type of rapid prototyping technology that additively builds three dimensional parts by using inkjet printhead. The technique starts with the spreading of a thin layer of a powdered raw material

mixture onto a building platform and is followed by a selective joining of powders through printing of an adhesive liquid through inkjet printhead at the area as specified by graphical data in computer. Subsequently, a platform containing the powder bed which is already printed is lowered at defined layered thickness, allowing for the spread of the next powder layer on top of the previous powder layer. These steps are repeated until the whole three dimensional structure is made. Figure 1 shows the schematic diagram of the process as described. Previously, this technology was studied as a new tool to directly produce porous material with reasonable properties [8]. In this study, the feasibility of producing the porous polyethylene ocular implant using powder printing was carried out and compared to the commercial Medpor® porous polyethylene implant in terms of density, porosity, microstructure and mechanical properties.

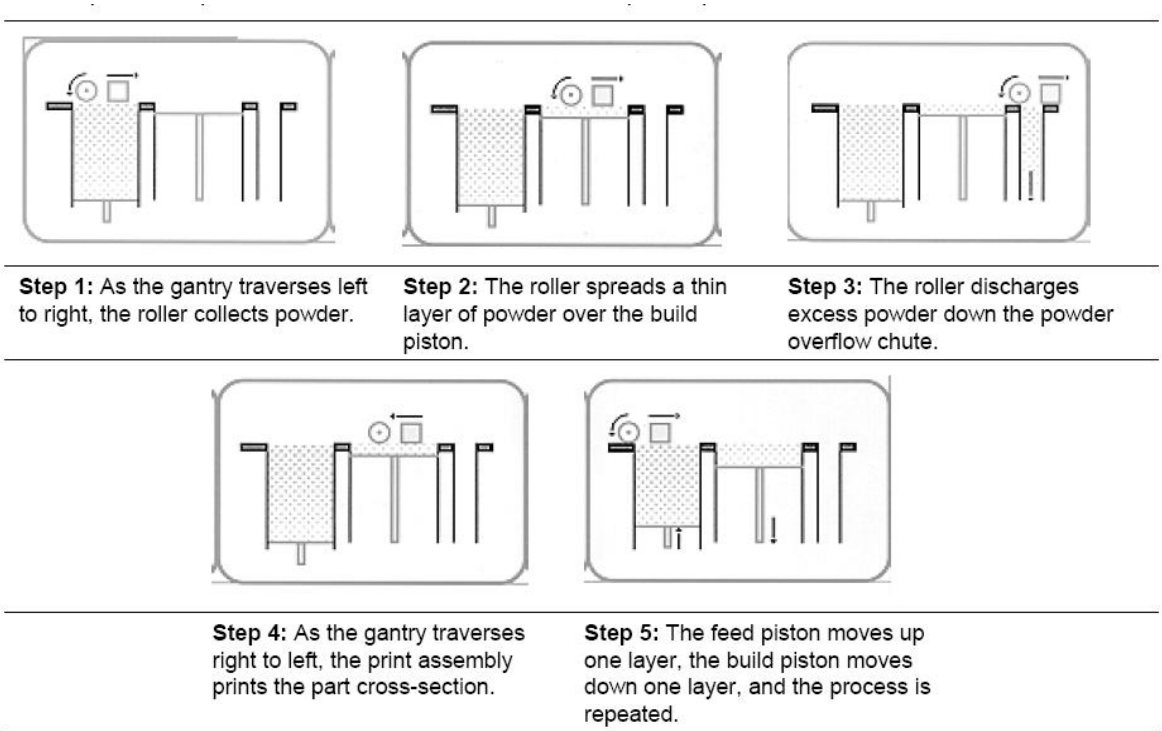


Figure 1: Schematic diagram of three dimensional printing process [7]

2 Materials and Method

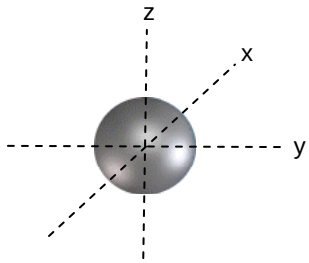
2.1 *Sample Preparation*

A mixture of raw material with 30 % w/w of water soluble binder and 70 % w/w of polyethylene was prepared by initially stirring in a plastic bag and then thoroughly mixed by a mechanical blender. The mixture was then loaded in the 3DP machine (Z400, Z Corporation). Rectangular specimens (80 mm x10 mm x4 mm) and spheres with 18 mm. in diameter were fabricated. After building, all specimens were left in the machine for 2 hours before removal and left in the laboratory atmosphere for 24 hours. The specimens were then air blown to remove any unbound powders and heat treated at 145 ^{o}C in an air-circulated oven for upto 3 hour. Specimens were subsequently cleaned by sonicating in distilled water for 1 hour. The sample was designated 3DP-PE. Commercially available porous polyethylene (Medpor®, Porex Surgical Products Group) in the form of orbital sphere with 18 mm in diameter and flexblock rectangular sheet were employed for comparative purpose.

2.2 *Dimensional accuracy*

Dimensional accuracy of as-purchased Medpor® sphere and fabricated 3DP-PE spherical samples were

determined by measuring diameter of the spherical samples by a Vernier caliper (Mitutoyo) with a reading resolution of 0.01 mm. Three readings were taken for each sphere in three directions and three spheres were used for each sample. Dimensional error was then calculated by the equation below:



$$Err_d = \left(\frac{d_m - d_t}{d_t} \right) x100 \quad (1)$$

2.3 *Bulk density and Porosity Determination*

Bulk densities of Medpor® and 3DP-PE samples were determined by dividing the weight of specimen which was measured by a digital balance (Mettler Toledo PB4002-S) by its volume which was calculated by multiplying the width, length and thickness of sample as measured by a Vernier caliper (Mitutoyo) with a reading resolution of 0.01 mm. Porosity was then calculated by the equation below:

$$P = \left(1 - \frac{\rho_p}{\rho_s} \right) x100 \quad (2)$$

2.4 *Mechanical Test*

Two types of mechanical test were carried out including tensile test and puncture test. Tensile test was performed on a universal testing machine (Instron 55R4502) equipped with a 10 kN load cell. The tests were carried out using a rectangular specimen and a constant crosshead speed of 2 mm min^{-1} and at 23 ^oC and 50 % RH. Puncture test was carried out to simulate the suturing procedure by measuring the force used to drive the suture needle into the specimen. This was done by securing the sphere sample on the base of universal testing machine (Instron 55R4502). The suture needle of Vicryl 6-0 suture was clamped by a machine's grip and driven to puncture the sample using a constant crosshead speed of 2 mm min^{-1}. The maximum force was recorded and reported. Five replicates were carried out and the average values were reported.

2.5 *Microstructure analysis*

Microstructures of the spherical specimen was examined using a scanning electron microscope (JSM-5410, JEOL) at an accelerating voltage of 20 kV. The sample was gold sputtered prior to the observation.

3 Results and discussion

Figure 2 shows photographs of ocular implant (diameter 18 mm.) that was fabricated using three dimensional printing technique in comparison to the commercial Medpor® ocular implant. From this magnification, both samples appear similar. Dimensional error of 3DP-PE after manufacturing by mouldless technique is found to be approximately 1.9 %, table 1. In general, the dimensional accuracy in the range of 2-5 % is acceptable for implants depending on the location and type of tissue. The error values of the fabricated sample which is in the similar range of commercial product are found to be sufficient for this type of application.

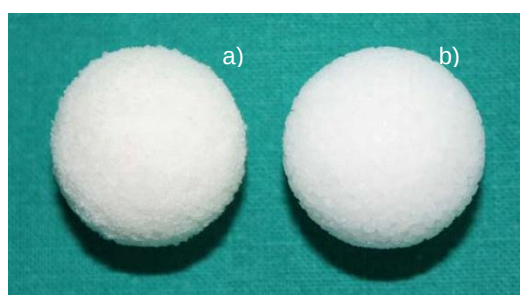


Figure 2: Images of spherical ocular implants; a) 3DP-PE fabricated by 3DP; b) Commercial Medpor®

Table 1: Comparison of dimensional error between Medpor® and fabricated 3DP-PE samples.

Samples	Dimensional error (%)
Medpor®	2.0±1.1
3DP-PE	1.9±1.3

Figure 3 shows the comparison of density and porosity between Medpor® and fabricated 3DP-PE samples. Fabricated 3DP-PE has a mean density of 384.3 kgm^{-3} and porosity of 61.9 % whereas Medpor® sample has a density of 493.3 kgm^{-3} and porosity of 48.4 %. Thus, the density of Medpor® is approximately 28 % greater than 3DP-PE while the porosity is 19 % lower. A comparison of microstructures between Medpor® and 3DP-PE spheres is shown in figure 4. It can be observed that Medpor® contains pores with pore sizes of about 200-500 microns. Correspondingly to the porosity result, 3DP-PE shows much greater porosity and the pore sizes are found to be about 150-800 microns. Individual polyethylene particles of Medpor® (~ 1,000 microns) are round and much larger than polyethylene struts of 3DP-PE (~100-200 microns).

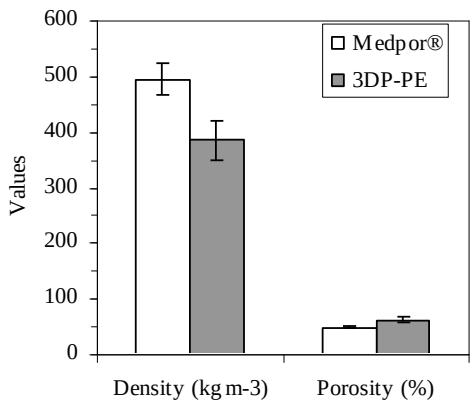


Figure 3: Comparison of density and porosity between 3DP-PE and Medpor® samples

This difference in microstructure is a result of using different processing techniques. The porous structure of Medpor® is produced by partial fusion at the surface of polyethylene particles under sub-melting temperature regime of polyethylene in the mould. Therefore, initial round particles are preserved. In contrast, 3DP-PE was processed by subjecting the green 3DP sample to the melt state sintering so the structure of 3DP-PE comprises connected struts caused by the melt and shrinkage of polyethylene particles. In the case of porosity, since Medpor® is produced by packing nearly spherical particles in the mould and subjected to partial fusion only at the surface, the theoretical prediction of maximum packing density would be between 0.56-0.74 which is corresponding to the theoretical porosity of 26-46 % [9]. In contrast, primary green structure of 3DP-PE is resulted from binding of polyethylene particles by the adhesive. This would cause the distantly connected porous framework. After subjected to heat treatment, the polyethylene fraction would thermally shrink and further increase the distance between particles. Higher porosity with large pore-sized structure is; thus, produced. The lower density and higher porosity of 3DP-PE is expected to decrease the weight to the eye lid and maintain the fibrovascularization.

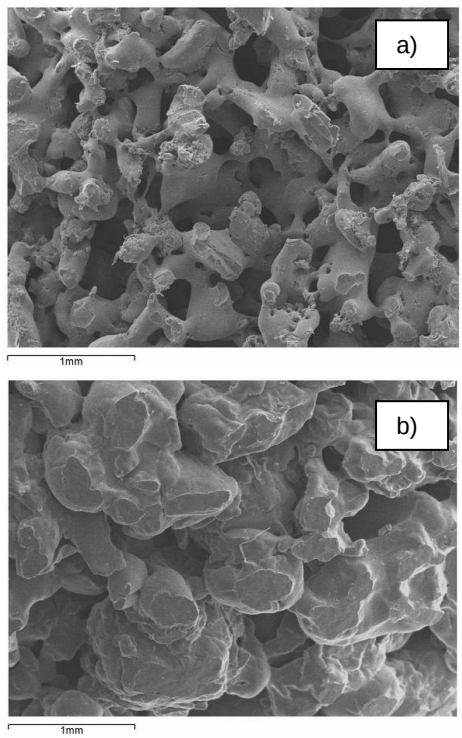


Figure 4: SEM micrographs showing the microstructure of samples: a) 3DP-PE; b) Medpor®

Figure 5 shows the comparison of tensile properties between both samples. Medpor® has greater tensile modulus, strength and elongation at break than 3DP-PE. This difference is possibly due to the higher porosity and larger pore sizes found in 3DP-PE. In general, mechanical properties of porous material would decrease with increasing porosity since the load bearing area is diminished [10]. In addition, pore size also plays a role in mechanical properties. Sample containing larger pores was also reported to have lower strength than smaller pore-sized sample [11]. Furthermore, the larger particles which formed the connected framework as observed in Medpor®

would also form a more rigid and stronger connection for load-bearing than smaller struts founded in 3DP-PE. These all could lead to the lower tensile properties of 3DP-PE compared to Medpor®. However, this cannot be stated to be a major disadvantage of 3DP-PE since its use in evisceration and enucleation applications are not load bearing applications. In contrast, lower tensile modulus may be favorable since high stiffness ocular implant can contribute to the development of complication such as exposure through a compliance mismatch between the implant and overlying conjunctiva and soft tissue [5]. Therefore, lower modulus 3DP-PE may be more advantageous in this aspect. In the case of toughness, 3DP-PE still exhibited ductile failure with numerous fibrillar extension at the tensile fractured surface similarly to Medpor® (data not shown). In the case of puncture test, no samples broke during the pushing the suture needle through. Table 2 shows the average maximum force that was recorded during the puncture test. It can be seen that approximate 60 % lower in force is required to push the suture needle to pass through the spherical 3DP-PE sample than Medpor®. This can contribute to the comfort of ocularist during suturing of extraocular muscles procedure since less force is needed to suture the implant.

Table 2: Comparison of puncture force between Medpor® and 3DP-PE by using a Vicryl 5-0 suture needle

Samples	Maximum force (N)
Medpor®	1.74±0.50
3DP-PE	0.69±0.15

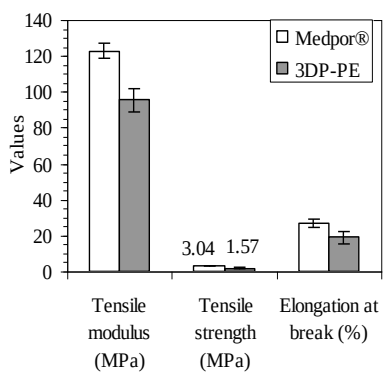


Figure 5: Comparison of tensile properties between 3DP-PE and Medpor® samples

4 Conclusions

Three dimensional printing is demonstrated here as a new processing route to fabricate porous polyethylene ocular implant with comparable properties in terms of pore size to its commercial Medpor® counterpart, but lower in density, less stiff and needs lower force in suturing. The proposed process in this study is foreseen as an aid to the rapid development and manufacturing of ocular implants.

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Symbols

Err_d = Dimensional error (%)
d_m = Average measured diameter of sample (mm.)
d_t = Designated diameter of sample (18 mm.)
P = Porosity (%)
ρ_s = Theoretical density of high density polyethylene (956 kg m^{-3})
ρ_p = Experimental bulk density of polyethylene samples (kg m^{-3})