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3D printing of PEEK-based medical devices

M. Tafaoli-Masoule[1*], M. Shakeri[1], S. A. Zahedi[2], H. Seitz[3,4], M. Vaezi[1,5]

[1] *Mechanical Engineering Department, Babol Noshirvani University of Technology, Babol, Iran*
[2] *School of Engineering and Sustainable Development, De Montfort University, UK*
[3] *Department of Mechanical Engineering and Marine Technology, Chair of Microfluidics, University of Rostock, Rostock 18959, Germany*
[4] *Department Life, Light & Matter, University of Rostock, Rostock 18959, Germany*
[5] *BIEGLO GmbH, 242 Bahrenfelder St., 22765 Hamburg, Germany*
[*] *Email: mojtaba.tafaoli@yahoo.com*

Abstract: Polyether-ether-ketone (PEEK) is an excellent thermoplastic alternative to metallic biomaterials which is used for load-bearing applications due to its high strength and stiffness, and biocompatibility with no cytotoxic effects. However, a potential clinical concern is that PEEK alone is not bioactive enough, and thus has limited fixation to bone. To overcome this problem, bioactive materials and/or porosity are incorporated into PEEK medical devices. The latest developments in these two strategies are presented in this paper. Bioactive PEEK/hydroxyapatite (HA) prepared by integration of 3D printing and compression molding is presented in this paper. In addition, nozzle and build plate temperatures for 3D printing of porous PEEK were optimized using genetic algorithm (GA) to achieve the highest mechanical strength for load bearing applications such as spinal fusion cages.

I. Introduction

Polyether-ether-ketone (PEEK) is widely used in medical devices due to its good biocompatibility, and biological stability. However, it possesses insufficient osseointegration that can result in device/implant migration through reconstructive procedure. To improve PEEK's bioactivity, a lot of research has been put into development of PEEK compounds (e.g. PEEK/calcium phosphates), surface modification, coating PEEK devices with bioactive materials, and incorporating porosity into PEEK structures [1]. Among these routes, making bioactive PEEK compounds and porous PEEK are the two important strategies with proven effect on bone in-growth and osseointegration. Porous PEEK devices can be made through particulate leaching or additive manufacturing techniques (selective laser sintering or extrusion 3D printing) and bioactive PEEK compounds are normally prepared by injection or compression molding processes. The main focus of this paper is to present the latest developments in preparation of both bioactive PEEK compounds and porous PEEK.

PEEK devices with sophisticated shapes and controlled porosity can be currently produced using extrusion-based 3D printing. However, the effect of process parameters on mechanical strength of the 3D printed parts is still not well understood. There are different operational parameters that affect the strength of PEEK 3D-printed product such as extruder's temperature, feed rate, build plate's temperature, infill-type, etc. The extruder and build plate temperatures with significant effect on final strength of printed samples were optimized in this study.

On the other hand, the current bioactive PEEK compounding techniques doesn't allow control on distribution of bioactive phase within PEEK matrix. A new technique based on 3D printing and compression molding was recently proposed by Vaezi et al. [2], allowing a high level of control on incorporation of bioactive materials into PEEK. Updated information about the technique is presented in this paper.

II. Material and methods

Optimization of PEEK 3D printing

Dumbbell-shape samples based on international standard for tensile properties of plastics-specimen type 4 (Designation: D638-14) with different nozzle and bed temperatures were 3D printed. FIRE WIRE® PEEK 3D filament (3DXTECH, USA) and INTAMSYS 3D printer were used for producing the specimens. Search domain for nozzle and bed temperature were designed greater than suggested ranges by the manufacture as 130 to160 ºC and 375 to 440 ºC, respectively. Genetic Algorithm (GA) was used for finding the best values of operational parameters (Fig. 1).

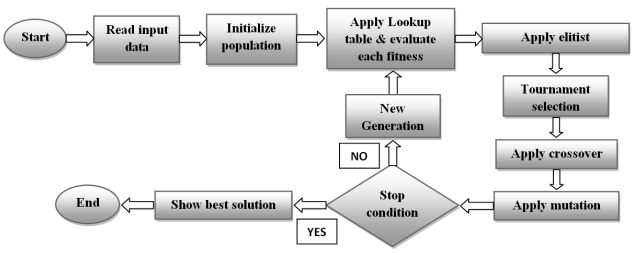

Figure 1. The genetic code to obtain the optimal parameters.

GA parameters were used as follows:

- Number of generations 150
- Population size 16
- Number of parameters 2
- Crossover rate 90%
- Mutation rate 10%

Producing numerous specimens and applying mechanical tests were so time-consuming and costly. So, lookup table in MATLAB software as Simulink design was used for calculating fitness function of each pair values of extruder

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and build plate's temperature. For training the lookup table 20 specimens were created in design space and a servo electro mechanical machine namely STM-250 as universal testing machine was used for uniaxial tension test.

Bioactive PEEK/HA

Bioactive HA scaffolds were 3D printed using a bespoke extrusion-based 3D printer. Analysis of variance (ANOVA) was performed using MINITAB's general linear model to determine the statistical significance and contribution of ram velocity (V), HA bioceramic solvent content, and nozzle length (L)/nozzle diameter (D) on extrusion pressure (P). To make PEEK/HA composite, different 3D printed bioactive HA scaffolds were overmoulded with PEEK OPTIMA®LT3 UF powder. The samples with average HA volume percentage of 40% were subjected to unconfined, uniaxial compression test using an Instron 8032 test machine at strain rate of 3×10^{-3} s^{-1}. Six samples were tested for reproducibility.

III. Results and discussion

Optimization of PEEK 3D printing

3D printing process was optimized for direct manufacturing of porous PEEK. At each generation of GA values of temperatures for build plate and extruder were created randomly in design space then the mechanical strength of each state is evaluated by lookup table. Tournament selection selects the more strength specimen and by following this trend, the best answers were remained and the poor ones were removed. Fig. 2 shows some tournament selection.

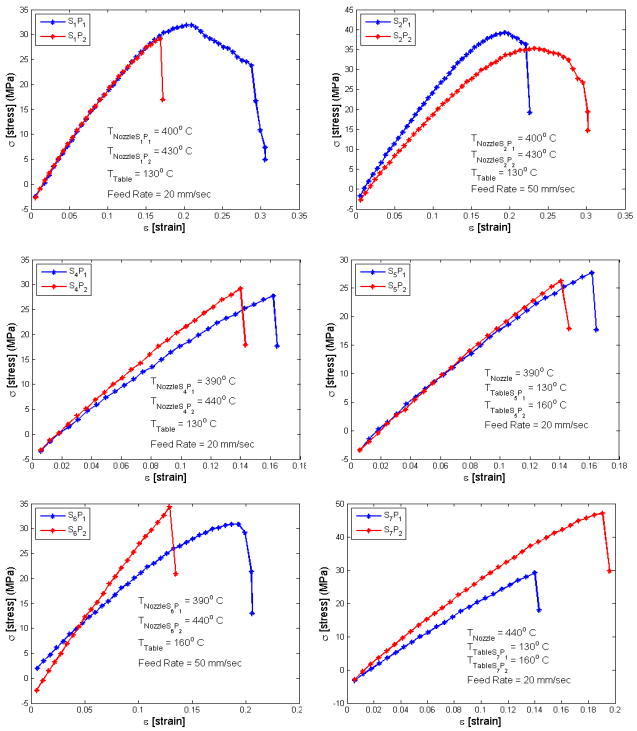

Figure 2 Stress-strain curves for different nozzle and build plate's temperatures

According to GA optimization the best values for extruder and build plate's temperature were 415 ºC and 155 ºC respectively. The optimum value for extruder's temperature is 14% and the optimum value for build plate's temperature is 66% higher than proposed domain by FIRE WIRE® PEEK. Totally the higher temperatures lead to higher mechanical strength but the values more than optimum state have reverse effect.

Bioactive PEEK/HA

According to the ANOVA results, L and V need to be selected as small as possible while solvent content should be increased sufficiently to have minimum effect on extrusion pressure by decreasing D. Taking this into consideration, HA scaffolds with filaments as fine as 50 µm could be printed for the first time (Fig. 3a). 3D printed HA scaffolds were fully infiltrated by PEEK in both vertical and lateral directions (Fig. 3b), while maintaining the HA network structure and uniformity. Fig. 3c depicts the results of compression tests on the biocomposites with average HA content of 40 vol% tested in two different directions and compared with unfilled PEEK samples. It was observed that the PEEK/HA in both directions had lower yield and compressive strength and moduli than the unfilled samples.

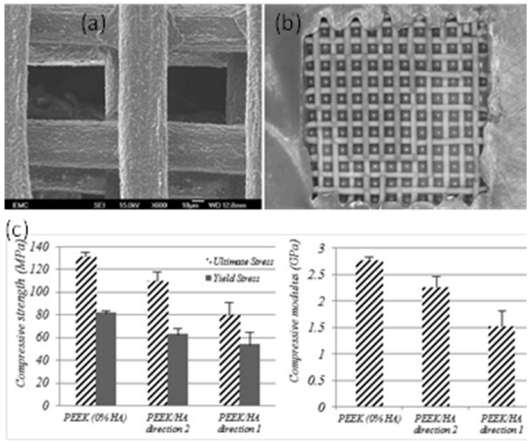

Figure 3 (a) 3D printed HA scaffolds with filament as fine as 50 µm, (b) produced bioactive PEEK/HA composite, and (c) the results of compression test on the PEEK/HA samples (c)

V. Conclusions

Bioactive PEEK/HA with fully interconnected HA network was produced through optimized 3D printing and compression molding processes. The mechanical property of 3D printed PEEK was also optimized through GA method. Optimum extruder and build plate's temperature were defined as 415 ºC and 155 ºC respectively.

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Author's statement

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