Research article

Evaluation of 3D printed PEEK and other 3D printed biocompatible materials as healthcare devices

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ABSTRACT

Introduction and Aim: Additive manufacturing has sought a widespread attention and higher rate of development which can also be modeled by processing of the data acquired by medical Computer Tomography scan. The object is built on a built plate of the printer in layers to form a final required model. Thus, a patient-specific model can be created from imaging data set. Materials available for such printing are elastomers, polymers, metals, or ceramics. The polymer, Polyether ether ketone (PEEK) has been used in health care applications, such as medical devices, and implants due to its high strength, biocompatibility, and light weight. Stainless steel (316L) is commonly used due to its strength, bio-tolerance, corrosion resistance and its formability. The aim of this study was to compare the mechanical strength and biocompatibility of medical grade PEEK and stainless steel.

Material and Methods: The test sample of PEEK was prepared using unreinforced PEEK (450G-Victrex Plc., Lancashire, UK) at the Prototyping Lab with a 3D-Printer - INTAMSYS - FUNMAT HT. Samples of stainless steel was printed using the iFusion SF1 Metal 3D Printer using Powder Bed Fusion (PBF) technology. The mechanical tests such as compressive, impact, and tensile tests were performed using an electromechanical universal testing machine (UTM) model- Zwick/Roell Z020 with a 20kN load cell. Biocompatibility tests were done using L929 cells to assess the cytotoxicity of the dental materials.

Results: The tensile strength of PEEK polymer was 70$\pm$1.6 and the impact strength of PEEK polymer was 289 J/m.

Conclusion: The tensile strength of stainless steel was higher compared to that of PEEK polymer, and the impact strength of PEEK polymer higher compared to stainless steel. Thus, it can be concluded that both biomaterial such as 316L stainless steel and PEEK are non-toxic to fibroblast.

Keywords: 3D printing; additive manufacturing; universal testing machine; PEEK polymer; 316L stainless steel.

INTRODUCTION

With technological development 3D printing also known as additive manufacturing has sought a widespread attention and higher rate of development in this century (1). It has been adopted by various streams of disciplines such as aerospace industry, automotive industry, healthcare, and biomedical industry, due to its ease of prototyping and possibility of reverse engineering in shorter duration, thus aiding in a rapid production of devices and help to plan treatment procedures easily and effectively (2). Three-dimensional modelling can create solid objects virtually of any shape. 3D design data can be converted to stereolithography (STL) format to fabricate objects by feeding the polymer and extruding it from the printer, by layers and thus printing the complex structures of the devices (3).

Polymer such as Polyether ether ketone (PEEK) is a new biomaterial which is gaining popularity in the 3D geometry can be modelled by processing of the data acquired by medical Computer Tomography scan, followed by selection of 3D printer, the material and optimization of the file for physical printing. This file represents the guidance for later printing, which digitally designs the pattern into cross-sections known as “slicing” which is then printed by given inputs for the 3D printer (4). The object is built on a built plate of the printer in layers to form a final required model. Thus, a patient-specific model can be created from imaging data set (5). The material wastage is significantly reduced when compared with computer aided milling (CAM) technique which is an advantage with 3D printing (6).

Additive manufacturing uses a variety of materials for printing such as elastomers, polymers, metals, and ceramics. Amongst metals, medical grade stainless steel is the commonly used material (7).
field of medical science as it is replaced by effected/ lost bone due to any medical condition such as trauma and most importantly cancer (8). PEEK polymer is

popular for its high strength, biocompatibility, light in weight and is also used in other health care applications, such medical devices, and implants (9).

The radiolucent property of PEEK aids in the diagnosis. Metal implants causes radiographic artifact on the X-ray image when taken for orthopedic, dental applications (10). One of the significant advantages of PEEK polymer is its tissue acceptability. Hence PEEK polymer has drawn its attention in the field of biomedical applications and research.

Stainless steel (316L) which is a common material used in fixation of bone fracture due to its strength, bio tolerance, corrosion resistance and its formability (11). This paper intends to compare the mechanical strength and biocompatibility of medical grade PEEK and stainless steel.

MATERIAL AND METHODS

The samples were designed virtually for the mechanical testing using Autodesk Fusion 360. The test sample of PEEK was prepared using unreinforced PEEK (450G-Victrex Plc., Lancashire, UK) at the Prototyping Lab with a 3D-Printer - INTAMSYS - FUNMAT HT (Fig. 1). Samples of stainless steel was printed using the iFusion SF1 Metal 3D Printer using Powder Bed Fusion (PBF) technology which uses IPG laser of 500, high-energy laser melts the fine metal powders layer by layer and by lowering the build plate of the printer forming 3Dimensional object. (Fig. 2).

The mechanical tests such as compressive, impact, and tensile tests were performed using an electromechanical universal testing machine (UTM) model- Zwick/Roell Z020 with a 20kN load cell. Fig. 3-A, B, C depicts specimen and test fixture for mechanical tests. Izod method with a pendulum weight = 5.5J was used to test impact strength using Zwick/Roell HIT 50P impact tester (Fig 3-D) (12). The digital 3D representation of designed test specimens for mechanical tests is shown in Fig. 4.

Fig. 1: (A) INTAMSYS - FUNMAT HT 3D printer. (B) 3D printed specimen of PEEK

Fig. 2: iFusion SF1 Metal 3D Printer

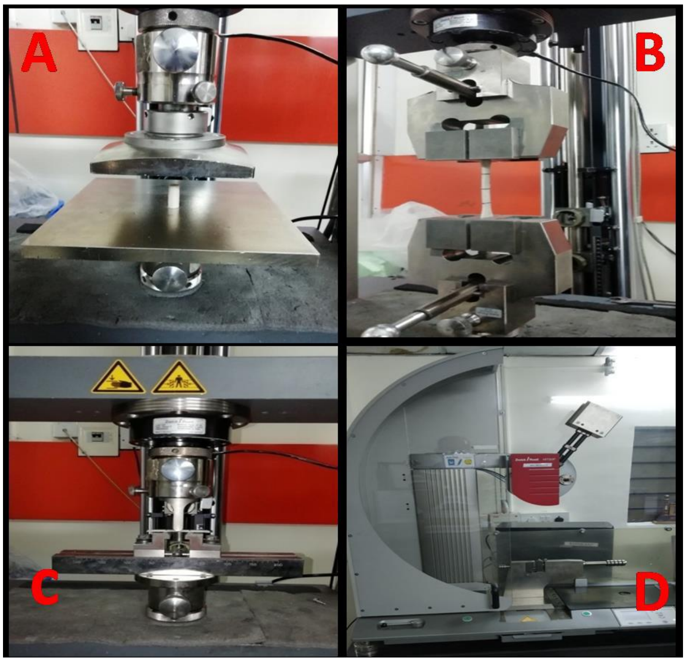

Fig. 3- Universal mechanical testing (A, B, C, D)

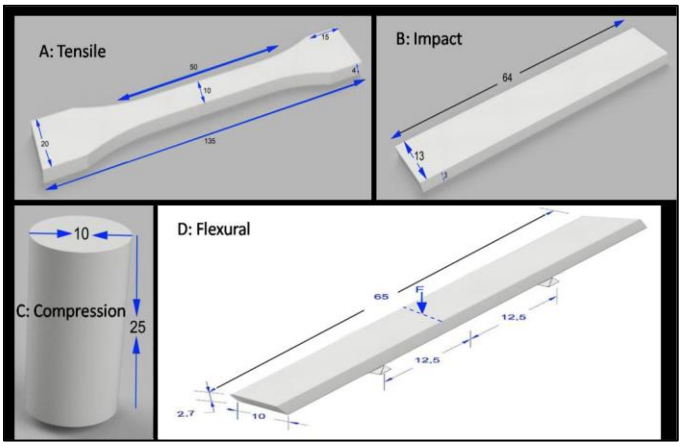

Fig. 4: Designed test specimens

Biocompatibility testing of 3D printed PEEK polymer

From normal subcutaneous areolar and adipose tissue of a male mouse, L929 murine fibroblast was derived. The cells are heterogeneous and adherent in morphology, epithelial- like, spindle-like, stellate, and round shape. the L929 cells often been experimentally used to assess the cytotoxicity of the dental materials with respect to the clinical relevance of the test results.

Sample preparation

PEEK polymer sample was cut into pieces of size 3mm width and 3mm length. Material was sterilized by ethanol followed by UV exposure for 20 minutes. The sterilized sample was processed immediately for testing.

Cells and culture conditions

In this study L9292 murine fibroblast cells were used and cultured in Dulbecco's Modified Eagle Medium (DMEME) supplemented with 10% Fetal bovine serum (FBS), 1% glutamine and 1% antibiotic-antimycotic solution. Cells were maintained at 37^0C and 5% CO_2 in a humidified atmosphere throughout the experiments (13).

Cell viability assessment by MTT assay

Cell viability of the test compound was assessed using Methyl Thiazolyl Tetrazolium (MTT) assay (14). Cells were seeded onto 96 well microtiter plate at a seeding density of 5000 cell/well. Allowed it to attach for overnight at 37˚C and 5% CO_2 in a humidified condition (15). After adherence, sterilized material was placed onto wells and incubated for 24 hrs 37˚C and 5% CO_2 in a humidified condition. After 24 hrs of incubation material was removed from the wells carefully and media was decanted, MTT reagent (1 mg/ml) was added to the wells and incubated at 37˚C for 4 hrs. MTT solution was removed from the wells and formazan crystals formed were solubilized using DMSO and absorbance was recorded at 570 nm using multimode reader (FluoSTAR omega, BMG Labtech).

Percentage of viable cells of the sample d was calculated with respect to untreated cell control.

RESULTS

The result of the study for tensile test is shown in (Table 1). The tests were performed using an electromechanical universal testing machine (UTM) model- Zwick/Roell Z020 with a 20kN load cell. The tensile strength of PEEK polymer was 70±1.6. The impact strength of PEEK polymer was 289 J/m (Table 1). There was a significant increased number of living fibroblast following exposure time to PEEK polymer (Table 1) suggesting the PEEK polymer is biocompatible.

Table 1: Test results of PEEK polymer

SL No	Parameters	Material PEEK polymer
1	Tensile strength	70±1.6 MPa
2	Impact strength	289 J/m
3	Cell viability	95.81±2.47

DISCUSSION

Mechanical and biocompatible tests were done in respect to PEEK and stainless steel. The samples that have been tested were of those products/samples which were 3D printed as these products/samples (Fig 1) of PEEK have to go through high temperature close to 450˚C (9).

The tests for tensile strength, impact strength and compressive strength were done using an electromechanical universal testing machine (UTM) model- Zwick/Roell Z020 with a 20kN load cell (Fig 3). and the results showed that the tensile strength for stainless steel was better than that of PEEK, but PEEK showed a better impact strength in comparison to that of stainless steel (Table 1), which is an important for the durability of the device.

Biocompatibility is the ability of a material to perform its desired function while in contact with the tissue, without eliciting any undesirable local and systemic effects on the subject for any therapy (16). Biocompatibility is important because the surface in contact with the tissue can undergo corrosion which undergo degradation into cytotoxic substances and loss of strength, and harm to the tissue (17). Hence the study of biocompatibility is important before conducting any treatment. In this study the results of biocompatibility tests (Table 1) show that cell viability in PEEK sample after 24 hours was 95.81±2.47 and 61.58±3.1 for stainless steel (7).

CONCLUSION

The results collected in this paper are focused on the mechanical and biocompatibility test of PEEK polymer and 316L stainless steel manufactured by additive manufacturing technique. The tensile strength of stainless steel was higher compared to that of PEEK polymer, and the impact strength of PEEK polymer was higher compared to the stainless steel. It can be concluded that both biomaterial such as stainless steel and PEEK were non-toxic to fibroblast thus concluding that additive manufacturing is a promising method in fabrication of biocompatible alloys for various needs in biomedical application but these processes need to be extensively studied before clinically applied.

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CONFLICT OF INTEREST

Authors declare no conflict of interest.

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