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Design, analysis and fabrication of polyamide/ hydroxyapatite porous structured scaffold using selective laser sintering method for bio-medical applications[†]

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Abstract

Both medical and engineering sciences play a vital role in human health diagnose and treatment. In this scientific world, the technology of alternative bone scaffold is one of the remedial sources for bone loss treatment. This research paper focuses on the design and analysis of porous scaffold made of additive manufacturing process. Various types of biocompatible materials with different characteristics are used for this bone scaffold. In order to have high load bearing capacity, a material composition of biocompatible Polyamide (PA) combined with Hydroxyapatite (HA) is used in this research work. HA has the character of greater cell seeding growth of tissue cells and hence added in the composition. The porous scaffold models with different configuration of cubical pore, spherical pore, shifted cubical pore, shifted spherical pore are designed using Solidworks software with a pore size of 800 microns and the porosity ranging from 40 % to 70 %. All the CAD models are analyzed using ANSYS software. Based on the static structural analysis, the shifted cubical scaffold posses lesser stress concentration, and thus selected for fabrication using Selective Laser Sintering machine. The specimens are fabricated in three different build orientations and the load bearing strength is found out using experimentation. The different material composition of 100 %PA, 95 %PA: 5 %HA, 90 %PA: 10 %HA and 85 %PA: 15 %HA are considered for this study.

Keywords: Polyamide (PA); Hydroxyapatite (HA); Selective laser sintering (SLS); Finite element analysis (FEA); Porous scaffold

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1. Introduction

The bone defects in femur bone are due to many causes like unexpected weight balancing, accident and bone defects of athletic people and aged persons. When we walk, play, run, jump or climb the stairs, huge amount of peak pressure is applied on the femur bone shaft. When this peak pressure is not tolerate by the bone shaft, the femur bone gets fracture as shown in Fig. 1. Major fracture in femur bone can be classified into four categories; transverse fracture, oblique fracture, comminuted fracture and segmental fracture [1].

In transverse fracture, the bone breaks as a straight parallel line moving beyond the femoral shaft region and oblique fracture progress crosswise along the femur bone. In comminuted fracture the bone breaks into three or more small parts and in segmental fracture, the bone breaks into several parts in the main portions of the fractured femur bone. When the above fractures are severe and not self curing nature, bone implants will be the only remedy. Even after implanted with bone scaffold, the injured persons cannot be confident and comfortable as there will be issues like numbness, restriction on overweight and mild irritation or pain. To avoid these kinds of issues, many researchers suggests porous scaffold made of biocompatible materials for bone substitute. The porous scaffold (Fig. 2) is a temporary structure capable of bearing load and supporting three-dimensional tissue cell growth formation in the injured bone region. For artificial bone scaffold there are different types of biocompatible materials available namely, polymers, composites, metals etc [2-4].

Polyamide (PA) is a biocompatible material with high load bearing capacity, but has a drawback of poor cell seeding behavior. Thus another suitable material HA is combined with PA for bone scaffold purpose. The HA will get along with the bone structure properties of the body and is most suitable for bone scaffold [5, 6]. HA has high compression strength and is brittle in nature and to overcome this drawback, PA is combined with HA [7, 8]. The bone scaffold CAD models are designed using solidworks software and are analyzed using ANSYS software to found the stress concentration. The best model is selected through FEA and fabricated using advanced SLS technique method with different build direction. This research work deals with computational design with different configuration models, finite element analysis, scaffold fabrica-

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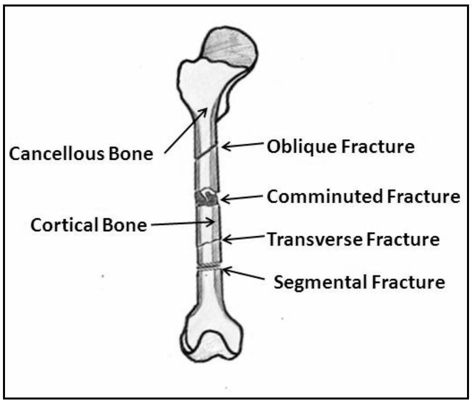


Fig. 1. Femur bone fractures.

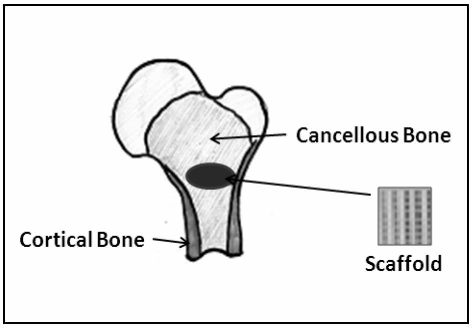


Fig. 2. Bone scaffold.

tion and mechanical testing.

2. Materials and methods

Bone scaffold, besides providing adequate mechanical strength, should also be biocompatible after implantation. Composite scaffolds perform better, rather than individual scaffold materials. Hence, a polymer/ceramic composite, comprising of Polyamide12 (USP class VI certified) supplied by Duraform 3D system and Hydroxyapatite [Ca10(PO4)$_6$OH2] synthesized by co-precipitation technique is used for the study.PA (Make: Duraform) has the average particle size of 58 µm and particle size distribution in which 90 % of particles are between 25-92 µm. Hydroxyapatite (HA) was chemically synthesized and finely crushed to match the particle size of PA. Polyamide offers good mechanical strength to the scaffold [9, 10], while Hydroxyapatite, being a bioactive ceramic, recruits osteoblast cells, facilitating rapid bone formation [11]. For the present study Polyamide/Hydroxyapatite composites in the ratio 95:5, 90:10 and 85:15 were prepared by manual blending and fabricated.

2.1 Synthesis of hydroxyapatite

Hydroxyapatite was synthesized using co-precipitation technique. Calcium nitrate tetrahydrate and di-Ammonium hydrogen orthophosphate were prepared separately. The mix is kept at 60 ^{o}C with constant stirring and the pH value was adjusted to 10 using liquid ammonia. The mixture was allowed to cure for 12 hours and was washed with distilled water till the ammonia residue is removed completely. The mixture was dried and sintered at 600 ^{o}C for 6 hours. The sintered material was finely crushed and tested using X-ray diffraction (XRD) to confirm the composition. The synthesized material was confirmed as Hydroxyapatite by its characteristic sharp peak at 32.2 (Fig. 3).

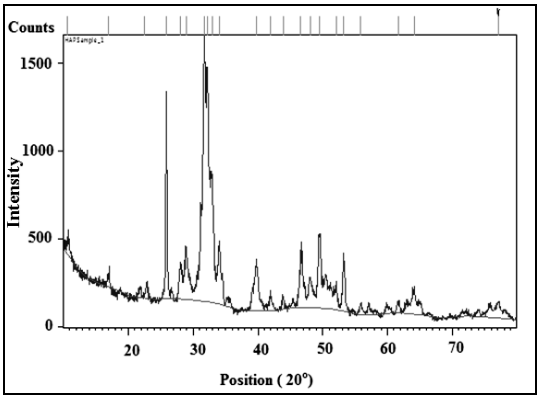


Fig. 3. XRD pattern of the synthesized Hydroxyapatite powder.

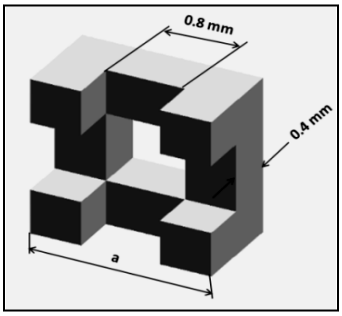
3. Design and analysis of porous scaffold

The design of scaffold models plays a major role in the performance of the scaffold. The following four bone scaffold models with different pore shape were designed.

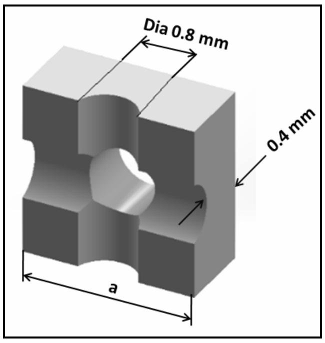
- Cubical model
- Shifted cubical model
- Spherical model
- Shifted spherical model.

The important parameters considered for designing scaffolds are porosity ranges, pore size, pore interconnectivity, load bearing capacity and ease of cell penetration [12-15]. The cubical models (Fig. 4(a)) have the internal pores in the shape of a cube of size 800 µm, and the unit cells are interconnected by square channels that are 800 µm in size. The wall thickness and unit cell sizes are kept constant as 400 µm and 1200 µm, respectively. Similarly, the spherical model have voids in the shape of spheres with diameter 800 µm and these voids are connected by square channels of size 800 µm. The spherical pore model (Fig. 4(b)) was designed with the idea of getting higher load bearing capacity in curved members [16]. The unit cells are repeated using linear pattern tool to create a 20x20x4 mm model for the mechanical studies. In addition, the porosity of the models was varied as 40 %, 50 %, 60 % and 70 %. The porosity is varied by altering the spacing between the pores 'x' as shown in Fig. 4(c).

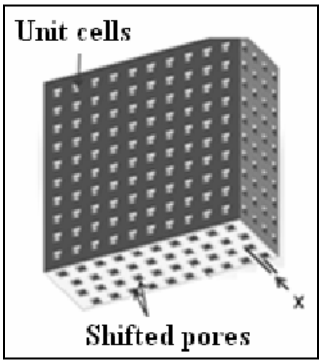
Shifting the pores of adjacent layers improves the interconnectivity and strength of the scaffold [17], so that a pore is



(a) Cubical pore



(b) Spherical pore

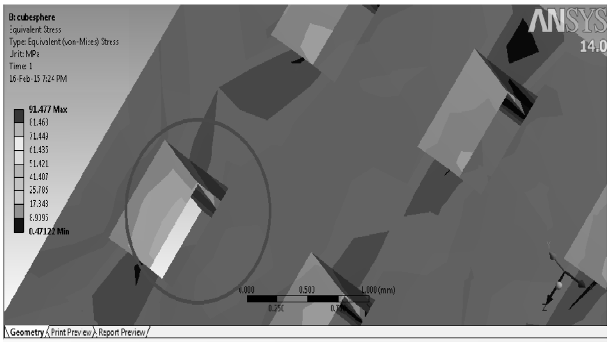


(c) Shifted cubical pore

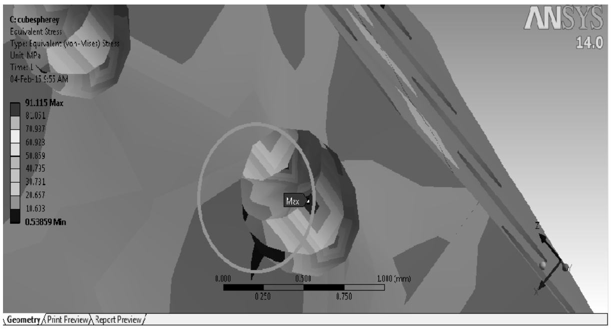
Fig. 4. Unit cell of porous scaffold with different pore geometries and porosities.

directly not below another pore. The cubical and spherical specimen was designed in shifted manner. The shift distance used is half the pore size i.e., 0.4 mm. The shifted cubical pore scaffold model is shown in Fig. 4(c).

The scaffold with different porosity and pore shape is analyzed through FEA [18]. All the models were analyzed using the ANSYS software to identify the best model with suitable porosity and factor of safety [19-21]. Usually the human femur bone is subjected to compressive load [22] and the compressive load of 15 MPa is applied to obtain the maximum deformation and stress in the scaffold [23, 24]. The cube model is fixed in one of the surface and the compressive load is applied in the opposite surface. The stress distribution in the spherical and cubical pore model is shown in Figs. 5(a) and (b). It was identified that the cubical shifted pore model posses lesser stress distribution compared with other models. The



(a) Shifted spherical



(b) Shifted cubical

Fig. 5. Stress distribution of shifted pore model.

scaffold with 70 % porosity is considered for the study to predict the minimum factor of safety compared to other values of porosities (50 % and 60 %).

4. Fabrication of the scaffold

SLS Method is one of the best additive manufacturing techniques which uses laser beam to build a layers of object on powdered base [25, 26]. The bone scaffold produced using this technique gives model with good quality, strength, fine accuracy and minimum strut size without any defects [27-31]. The designed models are fabricated using the DTM 2500 Plus SLS Machine. The PA/HA powder was uniformly spread over all the directions in the platform surface of the bed. Total filled powder quantity is 6 kg and the height of the powder bed surface is 75 mm. The standard part bed temperature of 123 °C was maintained during the fabrication process. In SLS technique, the object is built layer by layer forming in steps as shown in Fig. 6. The CO_2 laser beam creates an object on the top of the powder surface by fusion due to higher temperature. Then the sintered object portion is step down and the next layer is drawn on top, which enables the formation of the next build. The process continues, layer by layer, until the object is complete.

In the first trial run, the layer built was peeled off by the roller and then the chamber temperature was increased gradually by three degrees based on the PA/HA ratio. The process was continued till 132 ºC at which the build is good and no peel off was found. The models are fabricated in three build

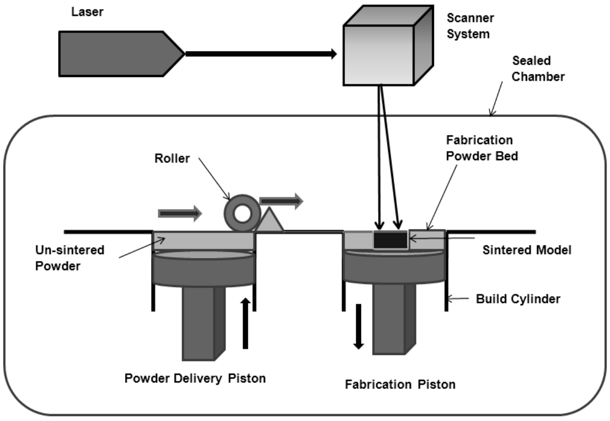


Fig. 6. Selective laser sintering.

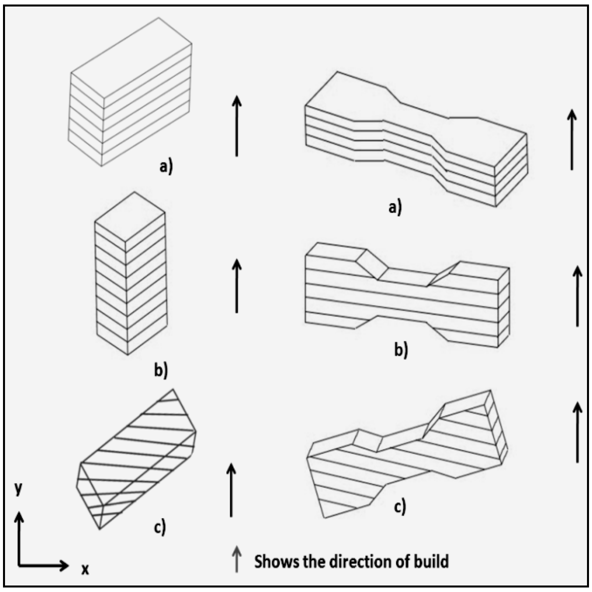
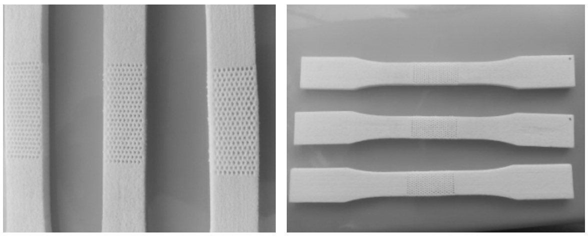


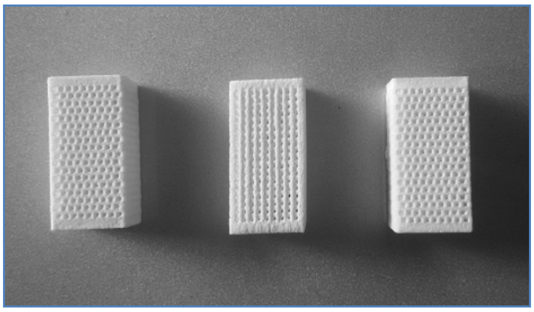
Fig. 7. Different build direction of RP Model for test specimen.

orientations as horizontal, vertical and inclined directions to predict its influence on the mechanical properties [32] as shown in Fig. 7. After the fabrication is completed the specimens are cooled for 8 hours and then they taken out. The support material attached to the specimen is removed by compressed air. The fabricated porous scaffold test specimens and the cross sectional view of the specimen is shown in Figs. 8 and 9, respectively. The scaffold with 95 %PA: 5 %HA, 90 %PA: 10 %HA and 85 %PA: 15 %HA composition is fabricated to predict the effect of HA % on mechanical and biomedical properties.

The mechanical test specimen were fabricated according to ASTM Standard 695 and D638 (Type I) for compression and tensile test and the cell culture test specimens are also fabricated in the dimensions of 0.9 x 0.9 x 4 mm. In total 57 test specimens were fabricated with different PA/HA compositions.



(a) Tensile test



(b) Compression test

Fig. 8. Fabricated test specimens.

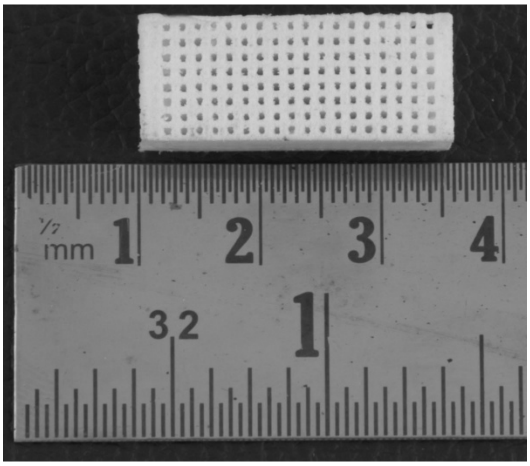
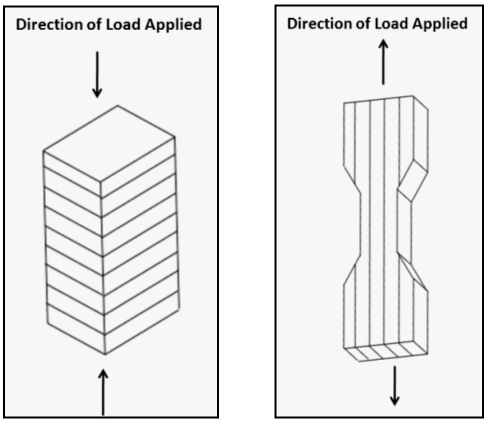


Fig. 9. Cross sectional view of the fabricated test specimen.

5. Mechanical testing

The machine used for testing the specimen is Universal testing machine - Zwick Roell make with 0-10 KN capacity. The UTM travel rate is set as 5 mm/min and 1mm/min for tensile and compression tests. The fabricated scaffold was evaluated by mechanical test to find the best build direction. Using PA scaffold and it is evident that the vertical build orientation yielded the best results compared with horizontal build and inclined build [33]. During compression test, the specimen made with layer orientation perpendicular to the applied load as (Fig. 10(a)) performs better than other orientation as expected. Also in tensile test, the specimen with layer orientation parallel to load direction as shown in Fig. 10(b), it performs better than other orientation. So the vertical build direction is found to be suitable for the fabrication both tensile and compression test specimen with different composition. So the



(a) Compression test (b) Tensile test

Fig. 10. Load applied in the build direction.

(a) Compression test (b) Tensile test

Fig. 11. Test setup for mechanical testing.

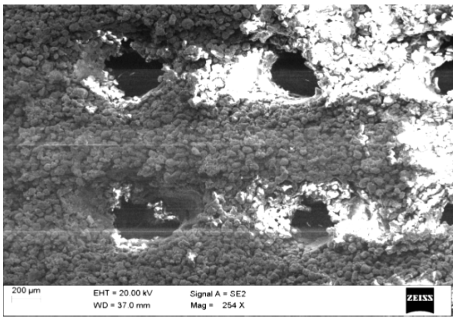
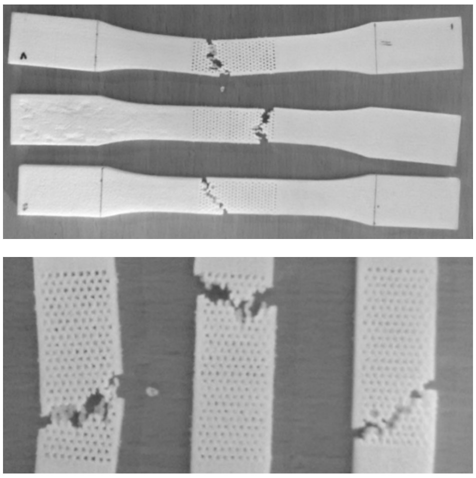
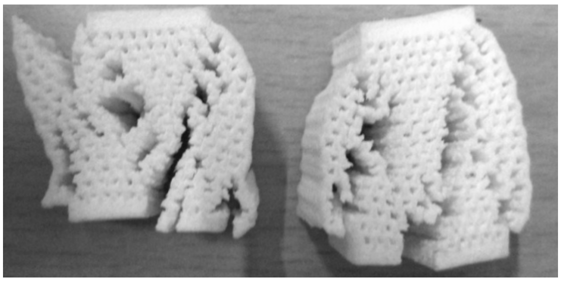


Fig. 12. SEM image of PA/HA porous scaffold.

tensile and compressive test models are fabricated in vertical build with 95 %PA:5 %HA, 90 %PA:10 %HA and 85 %PA: 15 %HA compositions. Three models each for tensile test and compressive test was tested in the test setup shown in Figs. 11(a) and (b). The sectional view of the PA/HA scaffold taken in scanning electron microscope is shown in Fig. 12 and the fractured specimens in tensile and compression test are shown in Figs. 13(a) and (b). The loading curves during tensile and compression test of PA:HA samples are given in Figs. 14(a) and (b).

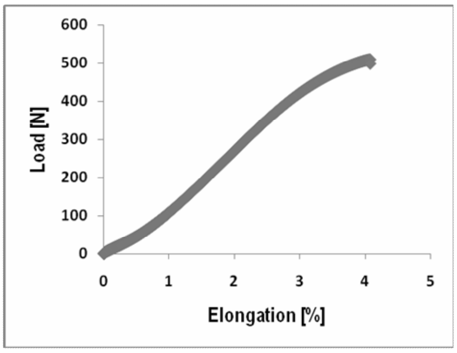


(a) Tensile test

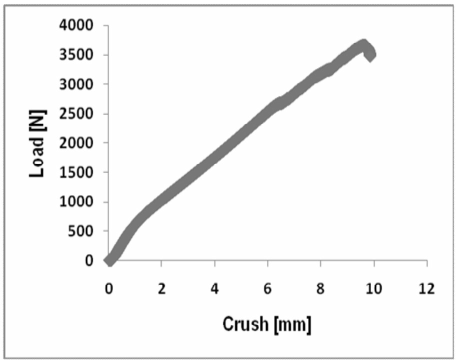


(b) Compression test

Fig. 13. Fractured test specimens.



(a) Tensile test

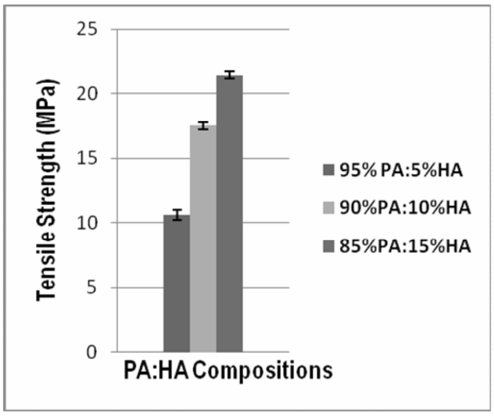


(b) Compression test

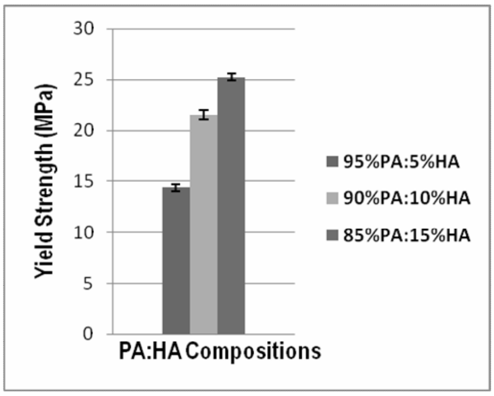
Fig. 14. Loading curves of mechanical test on PA/HA samples.

Table 1. Results of tensile and compression specimen.

Material compositions	Tensile test	Compression test
	Tensile strength (MPa)	Yield strength (MPa)
95 %PA:5 %HA	10.6	14.3
90 %PA:10 %HA	17.5	21.5
85 %PA:15 %HA	21.4	25.2



(a) Tensile test



(b) Compression test

Fig. 15. Results of mechanical testing.

6. Results and discussions

The mechanical test was carried on the PA/HA scaffold with different composition. A maximum strength of 21.4 MPa and 25.2 MPa was obtained during tensile and compression test respectively for 85 %PA:15 %HA specimen. The results of mechanical test on the PA/HA specimens are shown in Figs. 15(a) and (b) and given in Table 1. It is evident that the strength increases proportional to the increase in the composition of ceramic composites particles with PA [34, 35].

7. Conclusion

Bone injury that occurs due to accidents when severe demands for bone repair. Stainless steel and titanium are well known and established scaffold materials used for bone repair. The scaffold materials should have good load bearing capability in the injured region till the native bone is formed. The metals implants are removed most of the times during subsequent surgery which is painful and expensive treatment.

To combat the above situation, bioresorbable ceramic composites are being developed. Such material when implanted into the body gets resorbed (degraded synchronously with the new bone formation). Polyamide/Hydroxyapatite is a recently developed partially resorbable biocompatible scaffold material investigated in this study.

The scaffold specimens with different porosities and pore shapes were designed and analyzed to predict the better configuration. The results of FEA analysis of the different scaffold configuration showed that the shifted cubical pore scaffold model has minimum stress concentration, so the shifted cube model was fabricated and used for further analysis.

PA/HA scaffold specimens using shifted cube models were fabricated using Selective Laser Sintering method. It is also found that the models fabricated in vertical build direction performs better during both tensile and compression tests. The mechanical load bearing test showed the maximum strength of 85 %PA:15 %HA of 21.4 MPa and 25.2 MPa during tensile and compression test, respectively.

The investigation also proves that the SLS method provide the feasibility of fabricating components with complex architectures with good quality. The SLS method gives the greater mechanical strength and fine accuracy of scaffold as per the requirement. The SLS method also provide excellent control over the geometry of the scaffold and assures 100 % interconnected pores. The investigation on porous structured scaffold manufacturing would be very much useful in tissue engineering applications especially in bone tissue engineering to replace fractured bones and aids in new bone regeneration.

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