CHAPTER 7

CONCLUSION AND SCOPE FOR FURTHER RESEARCH

7.1 SUMMARY

The conventional method of scaffold fabrication takes long fabrication duration and has poor repeatability of size as well as connectivity of pores. Therefore, through conventional method a good quality customised scaffold cannot be modeled from the patient data. Thus to overcome the above mention limitations of conventional methods, automated controlled fabrication techniques are being explored by various researchers. Several advanced manufacturing processes are known in the literature such as Additive Manufacturing (AM) processes are being used in the fabrication of scaffold. By Magnetic Resonance Imaging (MRI) or CT scan we can obtain the most critical patient data, and by using AM processes we can easily create the 3D physical medical prototype.

This thesis describes the application of Additive Manufacturing in medical application. In this research work, two directions namely (i) porosity and stress analysis and (ii) in-vitro test are used to categorize the studies. One is to show that the customised bone scaffold with required porosity can be fabricated by AM technique. There are two types of stress analysis are also conducted; one allows wall shear stress analysis among the interconnected pores, the other compressive stress of the polyamide scaffolds. Wall shear stress simulation was carried out for the microfluid dynamics through the interconnected pores, using commercial CFD package, ANSYS CFX11.
Compressive testing and finite element analysis of samples were carried out to obtain the compressive stresses.

In the second part, an in-vitro test for the customised scaffold was conducted in laboratory. The current work achieves the pore size of 0.8mm diameter and inter pore distance of 1 mm produced 58.33 % of cell in-growth, as compared to the other customised scaffolds.

7.2 CONCLUSION

- A patient’s data of the tibia bone derived from the CT scan was used in MIMICS software, to convert two dimensional bone data in DICOM format into three dimensional bone data in the IGES format.

- The 3D data of the tibia bone in the IGES format was exported into solid works software, to develop the tibia bone solid model.

- The fifteen customised bone scaffolds with three different pore sizes of 0.6 mm, 0.7 mm and 0.8 mm diameter and inter pore distances ranging from 0.6 mm to 1 mm in steps of 0.1 mm were created using the modeling software.

- It can be observed that as the inter pore distance decreases, the porosity increases. It is also seen that when the pore size of the customised scaffold increases, the porosity increases.

- The fifteen customised bone scaffolds with pore sizes of 0.6 mm, 0.7 mm and 0.8 mm diameter, and inter pore distances ranging from 0.6 mm to 1 mm in steps of 0.1 mm were fabricated, using the Selective Laser Sintering Technique.
In this study, among these fifteen scaffolds it was found that for the small pore size of 0.6 mm and 0.7 mm diameter, the laser sintering process caused clogging of the pores, which is due to pores filled with unsintered polyamide powders. Hence, five scaffolds with pore size of 0.8 mm diameter and inter pore distances ranging from 0.6 mm to 1 mm in steps of 0.1 mm, were used for testing and analysis.

The experimental porosities of the fabricated scaffolds were determined and compared with the theoretical porosities. The average experimental porosity of the customised scaffold is 27.3 % against the theoretical porosity of 31.8 %, showing the reduction of 14 % compared to theoretical porosity. This can be attributed to the limitations of the Additive Manufacturing Process employed, where clogging of pores leads to an increase in the volume of the scaffold, and decrease in the experimental porosity.

Compression specimens were mechanically tested, using a TINNUS OLESAN Universal Testing Machine. The compressive stiffness and yield strength for polyamide cubic scaffolds varied in the ranges of 58.59 – 111 MPa and 4.63 -7.25 MPa, respectively.

Finite element analyses were carried out on five compressive test specimens, in ANSYS 13 software. Further, it was noted that the experimental results of the polyamide cubic specimens closely matches the theoretical results, with a maximum variation of 11 %.

It was found that the compressive stress values for the 0.8 mm pore size scaffold and inter pore distance of 0.6 mm to 1 mm varied from 20 MPa to 35MPa.
The Computational Fluid Dynamics analysis was performed to evaluate the local shear stress at the pore-level for the fifteen customised bone scaffolds.

The estimated Wall Shear Stress at fluid velocities from 0.2 mm/s to 1 mm/s lies in the range of $5.43 \times 10^{-4}$ Pa to $47.8 \times 10^{-4}$ Pa.

An *in-vitro* test for the customised scaffold with the pore size of 0.8 mm diameter and inter pore distances ranging from 0.6 mm to 1 mm in steps of 0.1 mm was conducted in laboratory. The customised scaffold with the pore size of 0.8 mm diameter and inter pore distance of 1 mm produced 58.33 % of cell in-growth, as compared to the other customised scaffolds.

From the above work, it is concluded that a customised bone scaffold with the required porosities can be modeled from the CT data of the patient. The Wall shear stress and compressive stress of the polyamide scaffolds can be determined using simulation tools. Also, the AM technique is most suitable to fabricate customised polyamide bone scaffolds, by virtue of their highly controllable pore structure, excellent mechanical strength, and in vitro biological response to osteoblast cells, with properties matching that of cancellous bone in the maxillofacial region and trabecular bone.

7.3 SCOPE FOR FURTHER RESEARCH

1. In this work, the pore size of scaffolds is uniformly distributed throughout the scaffold dimension. However, the scaffold may not need to be uniformly porous. Natural bone does not have a uniform distribution of porosity: it has higher porosity in the core with a strong and dense outer shell. A gradient distribution of porosity from the center to the periphery of the
scaffold can be achieved through complex design and manufacturing, that will ensure mechanical integrity and scaffold interconnectivity.

2. Although it is difficult to mimic nature, recent scientific and technological findings show potential to achieve bone scaffolds, that would encourage local and systemic biological functions. The proper selection of the scaffold materials, their geometry, pore size and size distribution, and ability to release biomolecules at a desired rate, will play critical roles in future development of bone scaffolds. Effective optimization of those properties towards scaffold development in the future can only be possible, using interdisciplinary approaches at multiple length scales.