INVESTIGATIONS ON DEVELOPMENT OF POROUS SCAFFOLD WITH BIOCOMPATIBLE MATERIALS USING RAPID PROTOTYPING

ABSTRACT

Submitted by

KUMARESAN T

in partial fulfillment of the requirements for the degree of

DOCTOR OF PHILOSOPHY

FACULTY OF MECHANICAL ENGINEERING

ANNA UNIVERSITY

CHENNAI 600 025

DECEMBER 2017

ABSTRACT

The whole world has been affected by musculoskeletal issues to a longer extent and the global burden of the disease reveals this significant information. A huge amount of money is spent on this musculoskeletal related treatment, which is at par with 3% of gross national product per year. Another important side is the aggregate life years of impairment that is said to be 6.8% for the last three decades and this has risen by 45%, currently.

As per universal statistics, people in the age group of 45-60 years are commonly affected by a bone related disease called osteoporosis, in which the bones become very weak and it is easily damaged. Most commonly, such fractures are possible at wrists, pelvis, hip joints, long bones, and spines. All around the world, men and women both get affected by this osteoporosis injuries and the risk factor being one out of three for men and one out of five for women. A study also revealed that for every three seconds, an occurrence of osteoporosis related issues is found.

In 2010, a study had been carried out and it is observed that 9 million people are affected by osteoporosis fracture all over the world that includes 1.4 million vertebral fracture, 1.7 million forearm fractures and 1.6 million hip fractures. It further states that about 7,00,000 people are affected by vertebral compression fractures which falls under the category of osteoporosis fracture, that occurs at spines.

Knowledgeable sources revealed that, about 27 million osteoporosis patients are found only in India and there has been a continual and rapid rise in this data every year. Compared to developed countries, Indian women, particularly those who belong to 30-60 age groups and possessing poor economic background, have very less density of inorganic substance in bones at all the necessary spots. To be exact, 52% osteopenia and 29% of osteoporosis

are found and the reason is lack of nutrients. According to the data recovered from the national crimes records bureau of ministry and the transport research branch of road transport and highways of the government of India, every year there has been a large number of road accidents and mishaps which resulted in very serious head, long bone injuries, and other fractures throughout the country. The volume of such accidents grows every year.

In a human body, femur bone is the most important and strongest bone, as almost the whole body weight is shared alone by femur bone. So, it is common that people especially athletics and aged people easily get affected by severe injuries and fractures in this area while running, jogging, jumping playing, climbing the stairs etc. During such occasions, the entire pressure would be on femur bone alone and such intolerable high volume of pressure may result in severe fractures. Under such conditions, the severe damages cannot be cured by simpler clinical treatments. So, there is no other alternative, other than moving for artificial scaffolds, which is a biocompatible support structure made up of a stainless steel and titanium. Till the damaged tissues or bones gets back to its original forms, such scaffolds withstanding the mechanical loads and support the tissue growth at any point of time.

After the fractured bones come back to its original form, these metal implants have to be removed and the surgical process is an expensive and a very tedious process. So, bioresorbable ceramic composites are imparted to overcome this hurdle. To set right the orthopedic fracture, scaffolds are manufactured using variety of biomaterials.

Fabrication of biomaterial into 3-D scaffold structures is the next vital step in the development of bone implants depending on bone injuries of individual patients and it is highly demanding among the Indian surgeons for treating those bone related defects. Therefore, the need for reliable and economically feasible design, better biomaterials, and efficient fabrication methods for scaffold to treat musculoskeletal defects has increased in the recent years.

Investigations of scaffold for porous structured bone implant is a recently emerging field in medicine and is involved in developing artificial bone like structures using materials like, Tricalcium Phosphate (TCP), polyetheretherketone (PEEK), Hydroxyapatite (HA), Polycaprolactone (PCL), poly(L-lactic acid) (PLLA) or Polyamide (PA) etc., by incorporating pores in the scaffold.

In order to have high mechanical strength, a biomaterial proportion of biocompatible PA mixed with HA is adopted in this research. HA has the function of preeminent cell formation of tissue cells on account of the combination in the proportion. The different material composition of 100%PA, 95%PA:5%HA, 90%PA:10%HA, 85%PA:15%HA, and 80%PA:20%HA are considered for this study.

The scaffold models are designed with interconnected pores with 30% to 70% porosity to facilitate the entry of the cells that ensures rapid bone formation. The interconnected pores also serve as a channel for the switch of nutrients and unwanted substances. Scaffold pores with cubical, spherical shapes, and their shifted arrangements are considered for this study. The minimum pore size used for the study is 800 μm and the porosity ranges from 30% to 70%. Based on the results of Finite Element Analysis (FEA), the best scaffold configuration of shifted cubical with 70% porosity model is identified and is fabricated with different build orientations using Selective Laser Sintering (SLS) process with different mix of PA/HA.

The fabricated test specimens are evaluated based on mechanical tests for its strength and *in vitro* studies with human osteosarcoma cell line for cell growth studies. From the load bearing evolution carried out on various proportions of PA:HA scaffold specimen provides a maximum strength of 24.3MPa and 28.1MPa during tensile and compression tests respectively for 80%PA:20%HA proportions. Also, the fabricated PA/HA biological test scaffold specimens are analyzed *in vitro* for the assessment of toxicity and the assessment shows beneficial outcomes for tissue cell growth.

The suitability of the porous scaffolds for bone repair is also ensured using FEA of a human femur bone under various physical activities. This FEA uses the Computed Tomography (CT) scan data of femur bone of a 75 kg healthy person and presents detailed information on the biomechanical analysis of the femur bone during various types of common physical activities using FEA. Based on the FEA performed on a normal human femur bone without scaffold, the von Mises stress is found to be higher in the mid shaft region of the femur bone. The porous scaffold with 70% porosity is introduced in the location of maximum stress, in the damaged femur by covering 25%, 50% and 75% of the shaft bone region. The stress induced in the implanted scaffold region during the different loading conditions is compared with the maximum strength value to decide the suitability of the corresponding scaffold configuration.

From the FEA results, it is observed that the femur implanted with the scaffold with 25% and 50% covering is suitable for slow and fast walking conditions. Increasing the scaffold covering area to 75% of the damaged area supports slow and fast walking and also withstands running condition

This research deals with the design, fabrication, and analysis of porous scaffold models with different configurations. The investigation on porous structured scaffold would be very much useful in bone tissue engineering, especially in bone tissue repair and regeneration.