A Novel High Strength and High Porosity Titanium Scaffold

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Statement of Purpose: The challenge in developing a tissue scaffold is to attain load bearing strength with high porosity and pore morphology sufficient to promote the growth of bone tissue. Conventional scaffolds with sufficient strength typically also are stiffer than bone which can cause stress-shielding, resulting in a reduction in bone density. Increasing the porosity and pore size of a scaffold, can reduce the elastic modulus yet may also reduce the strength of the scaffold. The objective of this study was to develop a cost-effective structural, load bearing scaffold that does not stress shield. The scaffold should have a compressive yield strength of 50MPa to be load bearing, be highly porous (≥70% porosity), with a pore range of 100-500µm and interconnected pores for optimal bone ingrowth and an elastic modulus of 0.6GPa to equal trabecular bone [1] so as to not cause stress shielding. The current metal scaffolds used in the orthopedic industry do not meet these standards. In this study, a novel scaffold structure utilizing fiber joined together by a bonding phase resulting in a unique highly porous and strong structural body is proposed.

Methods: Ti6Al4V scaffolds with porosities from 60% to 80% were prepared using a unique process used in the ceramics industry. The Cross-Linked Microstructure (CLM^{TM}) process consists of: 1) mixing Ti6Al4V fibers and organics (poreformer, binder) 2) forming the scaffold 3) heat treating the scaffold in a vacuum, resulting in simultaneous removal of the organics and heat treatment of the fiber/binder system to create a pore structure (Fig 1). The pore morphology of the samples were characterized by determining porosity and pore size using µCT. Mechanical properties including compressive yield and compressive modulus were measured on a Universal Testing Machine (Satec Inc.)
Scaffolds with a porosity of 70% and a pore size from 100µm to 500 µm (average of 200 µm) were made to evaluate the material *in-vivo* in New Zealand white rabbits. The rabbits were implanted with a scaffold into the distal femoral condyle by first drilling a hole and then press-fitting the scaffold. Rabbits were sacrificed at 4 and 8 weeks. The scaffolds were analyzed for bone ingrowth using both calcein fluorochrome labels and toluidine blue.

Results and Discussion: Figure 2 shows the relationship of porosity to compressive yield strength. There is a general trend that as porosity decreases, strength increases. This same trend can be seen with stiffness of the scaffold (Fig 3). The *in-vivo* study showed good bone ingrowth into the scaffolds at both 4 and 8 weeks. The microstructure produces a combination of high strength at high porosity for a given pore size distribution. The uniqueness of CLM is created by interconnections and bonds between fibers. For similar porosities, CLM has higher mechanical properties compared to particle based processes. The contact area between the fibers may result in this increased mechanical strength, as there is greater contact area with fiber based materials.

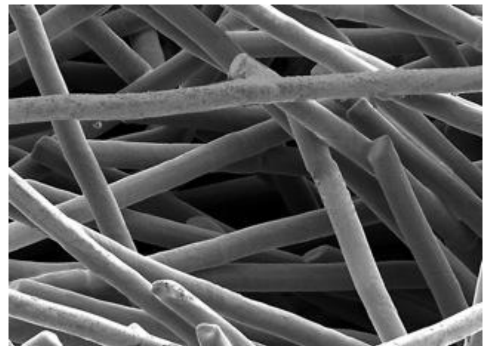

Figure 1: Pore structure created using the CLM process, using Ti6Al4V fibers.

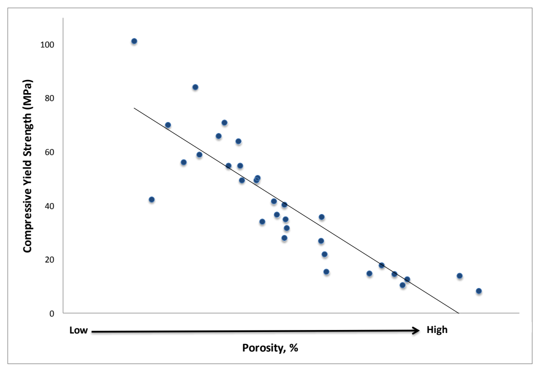

Figure 2: Compressive yield strength of scaffolds as a function of porosity.

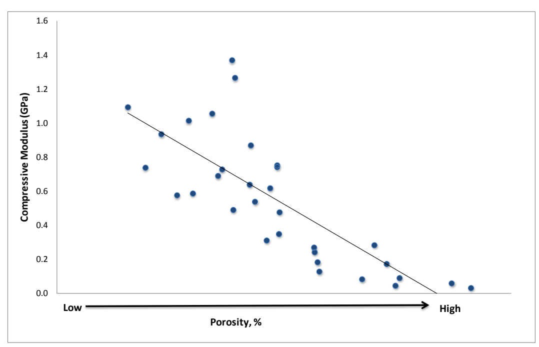

Figure 3: Compressive modulus of scaffolds as a function of porosity.

Conclusions: A cost-effective structural, load bearing scaffold that matches the modulus of cancellous bone was successfully fabricated using the CLM process. Analysis of the fatigue properties of the scaffold is currently under investigation.

References:

[1] Ding M. JBJS(Br), 1997;79B:995-1002