A Novel High Strength and High Porosity Resorbable Scaffold

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Statement of Purpose: The challenge in developing a resorbable tissue scaffold using biologically active and resorbable materials is to attain load bearing strength with high porosity and pore morphology sufficient to promote the growth of bone tissue. Conventional bioactive bio-glass and bio-ceramic materials in a porous form are not known to be inherently strong enough to provide load bearing strength as a synthetic prosthesis or implant [1,2]. Similarly, conventional bioactive materials in a form that provides sufficient strength do not exhibit a pore structure that can be considered to be osteostimulative. The objective of this study was to develop a cost effective, resorbable load bearing scaffold. In this study, a novel scaffold structure utilizing bioactive glass fiber joined together by a bonding phase resulting in a unique highly porous and strong structural body is proposed.

Methods: Bioactive glass scaffolds were prepared using both powder and fibers. A unique process, Cross-Linked Microstructure (CLM^{TM}), originally developed for use in the ceramics industry was used for fiber scaffold preparation. In the CLM process bulk fibers are mixed with a binder and a liquid to form a plastically moldable material, which is then cured to form the bioactive tissue scaffold. The resulting structure is a three-dimensional, load bearing, osteoconductive matrix, Figure 1.
In order to determine the osteoconductive capabilities of tissue scaffolds made of bioactive glass fiber using the CLM process a 6 week *in-vivo* rabbit study was performed, with harvest points at 2 and 6 weeks. A 4mm diameter rod, 8mm in length was implanted into the distal femoral condyles of both legs of the rabbits, perpendicular to the long axis of the femur. This allowed for the implant to reside mainly in cancellous bone. The implanted scaffolds had a porosity of 60±10%, pore size distribution between 150-600 microns and a compressive strength between 13 and 23 MPa.

Results and Discussion: Fiber-based structures are generally known to provide inherently higher strength to weight ratios, given that the strength of a fiber-based structure can be significantly greater than powder-based or particle-based materials of the same composition. A fiber can be produced with relatively few discontinuities that contribute to the formation of stress concentrations for failure propagation. Our data, seen in Figure 2, demonstrate that our fiber-based structure exhibits superior mechanical strength properties over an equivalent size and porosity powder-based material of the same composition
Both MicroCT and histomorphometry confirmed that bone formation occurred between the implant surface and the host bone as well as in some of the interior pores of the implant over two and six weeks (Fig 3). We observed that throughout the implantation period the bone volume and thickness of the trabecular structure increased and the open space between the trabecular bone structures decreased. Histological slides of the specimens showed newly formed bone that is interlaced and webbed around the implant surface. The amount of the implantation region containing newly formed bone increased more than two times from Week 2 to 6, indicating ongoing bone ingrowth. By Week 6, large regions of lamellar type bone were seen in the implantation site. An increase in bone volume but a similar level of bone mineralization at 2 and 6 weeks indicated that new woven bone was growing in, while older formed bone was maturing into lamellar bone. The amount of residual implant materials was similar in the samples harvested at week 2 and 6, indicating a slow initial degradation rate.

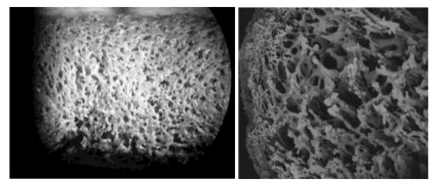

Figure 1: Bioglass scaffold with interconnected pores

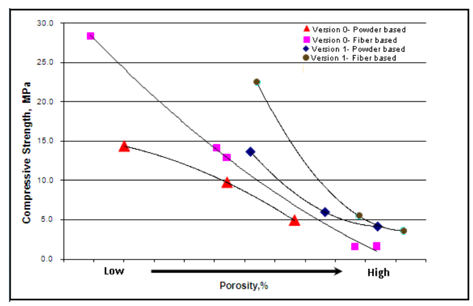

Figure 2: Relationship between porosity and compressive strength in powder and fiber-based scaffolds

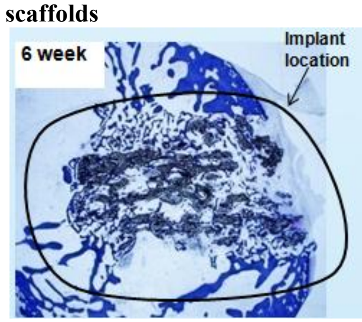

Figure 3: Stained thin section showing bone tissue present in the scaffold

Conclusions: Bioactive glass fabricated using the CLM process offers a promising solution for a load bearing resorbable scaffold. A follow-up study is being performed to better understand the bone ingrowth as well as the affect on the biomaterial over a longer duration.

References: [1] Hench L. J Am Cer Soc 1998, 81:1705-28. [2] Jone J. Elements 2007, 3[6]:393-399