Bone Allograft Degradable Polymer Composites

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The clinical use of intervertebral body fusion for relief of back pain and providing spinal stabilization has grown rapidly recently. Current materials used for interbody fusion include allograft bone, titanium, and PEEK. While each material can provide the structural demands of spinal loading, each is not without substantial tradeoffs. The development of a bone allograft composite (BAC) is an attempt to provide a biological alternative to these materials; our goal for the BAC is to provide for the structural demands of an interbody device material as well as the osteoconductive and osteoinductive capacity necessary for the fusion process.

The components of the bone allograft composite include a polymer matrix (polylactide (PLA)), demineralized bone matrix (DBM), and allograft bone particles. During manufacture of the composites, it is important that the polymer forms a continuous matrix in which polymer chains entangle with each other. The matrix encapsulates and holds the bone particles. Melt processing at high temperature is one of the common ways to form continuous matrix. However, bone components may be damaged at high temperature. Another option is to mix all the components at room temperature by the use of appropriate solvents. The solvents should be able to dissolve the polymer matrix but, in the same time, do not cause damages to the bone components.

In the present report, we used the second option, or the solvent aided mixing procedure to make BAC. Tetrahydrofuran (THF) was used to dissolve polymer, and the solution was mixed with the bone components. The BAC samples were dried in circulating nitrogen environment. Some of the dried samples were pressed at 60 to 70^{o}C to enhance the mechanical integrity. Our objectives were to investigate the mechanical influences of each component and explore the effects of various processing techniques.

The results from our initial rounds of testing (Table) show that the bone allograft composites can provide the mechanical strength necessary for biologically active interbody fusion devices. Future work on this study includes optimization of the composite recipe, improved processing methods, and small animal studies.

PLA (wt-%)	Bone (wt-%)	DBM (wt-%)	Ultimate Compression Strength (MPa)	Modulus (MPa)
10	45.0	45.0	39	327
10	80.7	9.2	44	647
11	89.0	0.0	54	790
20	50.0	30.0	45	401
20	80.0	0.0	42	902
20	72.5	7.3	41	838
30	62.7	7.5	42	616
30	40.0	30.0	42	505
30	70.0	0.0	42	689
39	54.9	5.7	34	244
39	60.6	0.0	30	284
40	30.2	29.8	46	596