Calcium Sulfate/Hydrogel Space-Making Composites for Bone Augmentation

B. R. Orellana[1], A.M. Hawkins[2], M. V. Thomas[3], J. Z. Hilt[2], and D. A. Puleo[1]
[1]Center for Biomedical Engineering
[2]Department of Chemical and Materials Engineering
[3]College of Dentistry
University of Kentucky, Lexington, KY, USA

Introduction

For dental implants to be successful, the jawbone needs to have a sufficient amount of bone to anchor the implant. Sometimes a loss of bone or narrow bridge is caused by severe periodontal disease, trauma, or birth defects. Bone augmentation is performed to build up these defects, may it be a large hole, back filling a ridge to make it wider, or however, bone will need to be 'added' to achieve a desired platform.

Calcium sulfate (CS)-based composites are being developed that will act as a 'tenting' barrier to soft tissue infiltration, while allowing the delivery of a growth factor from embedded poly(β-amino ester) biodegradable hydrogel particles to promote bone regeneration. These enhancements could improve CS's osteogenic properties and ability to be developed as a bioactive-delivery vehicle enriching augmentation. In this study, the structural integrity, mechanics, and morphology of CS combined with biodegradable hydrogel particles were studied.

Methods

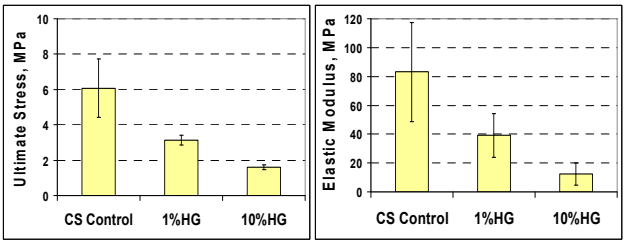
The composite consisted of calcium sulfate hemihydrate as the structural matrix and varying amounts of All-1.4 hydrogel (HG) particles [*Adv. Mater.* 18:2614, 2006] as the delivery component. CS control samples were produced by mixing 2g of CS powder with 2000µL of deionized (DI) water. The mixture was injected into a mold using a 5mL syringe. Each mixture produced 12-14 cylindrical samples. The mold, when filled, could yield up to 46 samples with an average diameter of 4.66 mm and a height of about 6.70 mm. The loaded mold was than placed in a 43ºC oven for 24 hrs to set.

CS samples with varying amounts of HGs (1 and 10 wt%) were produced. A mixture of 0.02g HG, 1.98g CS powder and 2250µL DI water for a 1 wt% HG solution was produced. The mixture was loaded into a mold using the same syringe method and left to set in a 43ºC oven for 24 hrs. Samples with 10 wt% HG, made with 0.2 g HG, 1.8 g CS, and 2500 µL DI water, were also produced.

Compression tests were performed using a Bose ELF 3300 testing apparatus to determine mechanical properties of the different composite formulations. Compressive modulus and ultimate compressive strength were measured. Destructive degradation testing was performed to understand degradation profiles of the composites. MicroCT imaging was used to determine distribution trends of HG particles throughout the CS matrix.

Results/Discussion

Ultimate compressive strength and compressive elastic modulus are shown in *Fig.1*. Samples with 1% HG had about half the strength and stiffness of the controls. At this loading, the composites will still provide some structural support during degradation and release. Addition of 10% HG resulted in less than 25% the strength and stiffness of the controls, raising concern that this ratio would have considerable structural integrity issues under loading conditions. The variability among samples seen in *Fig.*1 can be explained by differences in their microstructure, e.g., stress concentrators from voids, minor defects, and growth and propagation of crystals as CS sets.



a. b.

Figure 1: a) Ultimate compressive stress and b) compressive modulus of CS only (control) and CS-hydrogel composites. Data are mean ± standard deviation for n=10. Hydrogel particle size: 150-250µm.

All samples degraded with relative consistency and predictability compared to the controls, with higher loadings of hydrogel particles resulting in faster degradation (*Fig.2*). The HG loading-dependence of composite degradation rate allows for tuning to provide sufficient protection from soft tissue infiltration yet delivering HG particles to stimulate bone formation.

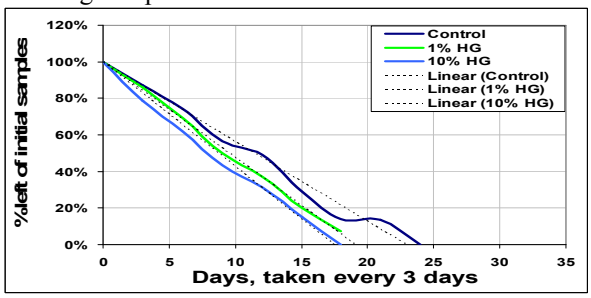


Figure 2: Mass loss of CS only (control) and CS-hydrogel composites. Hydrogel particle size: 150-250µm.

Preliminary microCT images showed a uniform distribution of hydrogel particles within the CS matrix. These results provide confidence for reproduction from sample to sample, as well as consistent release of HG particles as the composites degrade.

Conclusion

CS composites containing biodegradable hydrogel particles for delivering osteogenic biomolecules can be useful for bone augmentation. The composites must be carefully designed, however, because incorporation of particles in CS can drastically affect mechanical and physical properties. Ongoing release studies will provide information on dosage and loading of hydrogel particles needed to optimize the delivery capabilities of the composites.

Acknowledgement

This work was supported by NIH/NIDCR (DE019645).