## 217f Porous Polyurethane Foam Scaffolds for Bone Tissue Engineering

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In the US an estimated 643,000 bone graft procedures were performed in 2002 at a cost of \$750 million, thereby making bone the second most frequently transplanted tissue after blood. Autogenous bone transplanted from a donor site in the patient to the recipient site has the best outcome for repair of tissue defects due to its osteogenic, osteoinductive, and osteoconductive properties. However, availability of donor tissue is limited and explantation introduces a significant risk of donor-site morbidity. Due to the increasing frequency (e.g., 10% per year) of bone graft procedures, the demand for new clinically effective materials that have the availability of synthetics and the efficacy of autograft will continue to grow.

Polyurethanes synthesized from aliphatic polyisocyanates and polyester polyols have been reported to support the attachment, proliferation, and differentiation of osteoprogenitor cells in vitro. We postulate that polyurethanes have unique properties making them potentially useful as synthetic injectable bone void fillers: (1) the material can be injected as a two-component reactive liquid mixture which gels in situ, and (2) porosity and pore size can be controlled by tuning the surface chemistry. We are currently synthesizing biocompatible and biodegradable polyurethane foam scaffolds that have controlled reactivity and porosity. The clinical goal is to prepare polyurethane scaffolds that deliver biologically active molecules to enhance the healing of open bone fractures.

We have synthesized two-component polyurethane foams from lysine methyl ester diisocyanate (LDI) and a hardener comprising a polyester polyol, water, catalyst, stabilizer, and pore opener. We present initial physical, mechanical, chemical, and biological analyses of the materials. Pore size was determined by SEM. The density and the compressive stress required to generate a 50% deflection were measured according to ASTM D3574. The in vitro degradation rate in PBS at 37oC was also measured. In vivo biocompatibility was evaluated by implanting the materials in the hamstring muscle of a mouse followed by harvesting of experimental sites after 4 weeks. Our results demonstrate that the porosity and pore size distribution can be controlled by varying the amount of water and stabilizer in the hardener. The foams are degradable and lose approximately 5 - 10% of their initial mass after 8 weeks in PBS. Finally, the materials induce a mild inflammatory response at 4 weeks post-implantation in the hamstring muscle of a mouse. Considering these preliminary results, the polyurethane foams are promising candidates for future development as biocompatible and biodegradable bone void fillers.