Fabrication and Characterization of Poly(*para*-phenylene) for use as a Porous Scaffold Biomaterial

Amy L. DiRienzo[1.], Christopher M. Yakacki[2.], David L. Safranski[3.], Carl P. Frick[1.]

1. University of Wyoming, Department of Mechanical Engineering, Laramie, WY 82071, USA
2. University of Colorado Denver, Department of Mechanical Engineering, Denver, CO 80217, USA
3. MedShape Solutions Inc., Department of Research & Development, Atlanta, GA 30318, USA

Statement of Purpose: Primary care physicians report that back pain is the second most common complaint next to the common cold. Many techniques of vertebral fusion have been developed to treat instability and low-back pain. Often this involves replacing the nucleus of the intervertebral disc with a bone graft and offering decompression via an interbody cage device. In a recent review, it was found that these procedures have an average complication rate of 36.4%, with implant subsidence ranked as the 2nd most frequent complication. Subsidence occurs when the implant body damages and cuts into the vertebral endplate (e.g. Fig. 1). As a result, there is a loss of restored disc height and in turn an altered state of mechanics. There presumably exists an optimal level of implant/construct stiffness that would promote fusion, more closely mimic the native physiology, and lower the rates of subsidence. We believe that the current cage materials are unable to meet these requirements and that new approaches should be explored. We hypothesize that a porous fusion cage mad from an advanced polymer system can be developed to better distribute stresses across the endplate, promote fusion, and reduce the rates of subsidence.

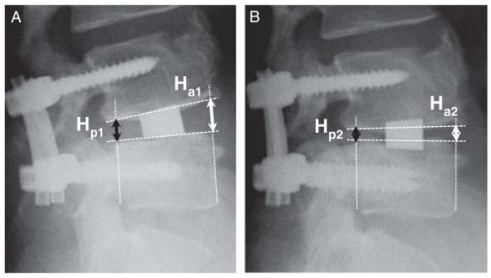

Fig. 1: *X-ray showing cage subsidence over time.* H_a *and* H_p *represent anterior and posterior heights.*

The goal of this study was to fabricate and mechanically characterize a high-strength porous polymer scaffold for use as spinal cage device. Poly(*para*-phenylene) (PPP) is a newly developed polymer that is an excellent candidate for an orthopedic device due to its exceptional strength, stiffness, and relative inertness; but has never been investigated for use as a biomedical device. PPP has strength values 3 to 10 times higher and an elastic modulus nearly and order of magnitude higher than traditional biomedical polymers such as poly(methyl methacrylate) (PMMA), polyurethane, and ultra-high molecular weight polyethylene (UHMWPE) and is significantly stronger, stiffer, and easier to process than poly(etheretherketone) (PEEK). By utilizing PPP we can overcome the mechanical limitations of traditional porous polymeric scaffolds since the outstanding stiffness of PPP allows for a highly porous structure appropriate for osteointegration that can match the stiffness of bone (100-250 MPa), while maintaining suitable mechanical properties for soft-tissue fixation. Our approach was to derive knowledge of PPP's potential for biocompatibility, its mechanical behavior under physiological conditions, and its properties as a porous construct.

Methods: Bulk PPP samples were manufactured by powder-press sintering. The biocompatibility was characterized using ISO 10993-5 and the material was determined to be non-toxic. Samples were soaked in phosphate buffered saline (PBS) for up to six months in an incubator at 37°C and 30 rpms then mechanically tested. Porous samples were manufactured by powder-press sintering followed by particle leaching. The pore volume fraction was systematically varied over a broad range from 50–80 vol.%, for pore sizes of 150-250 µm & 420-500 µm, indicated by previous studies as optimal for osteointegration.

Results: Dry, the yield strength of PPP is 151.2±4.6 MPa and elastic modulus is 5.7±0.4 GPa. After soaking in PBS a minimal absorption of 0.67±0.08 wt% was observed, and no significant change in mechanical behavior was measured. The porous elastic modulus was compared to established porous foam theory, as shown in Fig. 2.

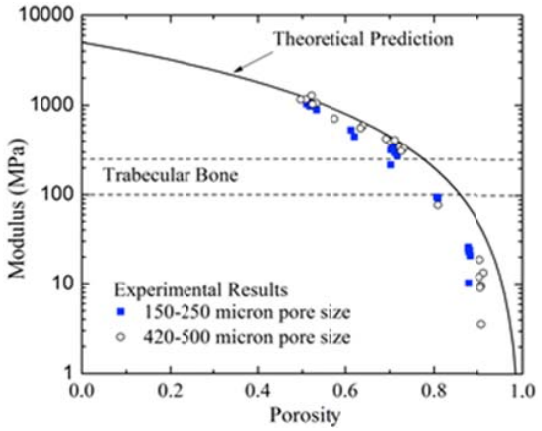

Fig. 2*: Experimental and theoretical elastic modulus of porous PPP. To match the stiffness of trabecular bone, traditional polymers must be between 43-64 vol.% porosity, whereas experimental data shows PPP can be almost 80 vol.% porous.*

Conclusions: PPP is biocompatible, its mechanical properties are virtually unaffected by soaking, it exhibits low absorption, and it is capable of being manufactured into a porous scaffold with optimal pore sizes for osteointegration and 70-80 vol.% porosity matching the stiffness of trabecular bone.