Hydrophilic Soft-tissue Replacements

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Statement of Purpose:

Most of the existing biomaterial technology is limited to materials such as silicones, Teflon®, polyethylene, metal and polyurethanes that do not exhibit the mechanical and physical properties of natural tissue. These materials are stiff, difficult to manufacture, and not initially developed for medical implants. Artificial tissue substitutes have not been found to withstand the rigors of repetitive motion and associated forces of normal life. Cadaver tissue is limited in supply and due to the risk of infection is coming under increased scrutiny by FDA.

An alternative biodevice may be a soft tissue replacement. For example, arthritis stems from damage to cartilage, the soft tissue between the bones. Biodevices that replace the soft tissue would restore diarthroidal joint function much better and protect further damage by a more natural stress distribution. A similar problem exists for heart valves. Prosthetic heart valves are made from metal and pyrolitic carbon which do not function like native heart valves. An alternative would be to design a biodevice with soft tissue flexibility and endothelial cell covering to provide a wide-open central flow and low-thrombogenic surface.

Soft tissue replacements should start with a biomaterial that has compliance ranges similar to human soft tissue, be strong and wear resistant, manufactured to personal shapes, and have long-term biocompatibility. Cellular in-growth or preloading of cells can then be performed on this established scaffold. These features are demonstrated in a new biomaterial described in this paper.

Methods:

Soft tissue-like devices can be made from polymers such as poly vinyl alcohol as thermoset materials. As an example, a PVA cryogel can be made according to the full descriptions in US Patent U.S. Patent Numbers 5,981,826 and 6,231,605.

A new biomaterial, commercially available as Salubria® from SaluMedica, LLC, Atlanta, GA is similar to human tissue in its mechanical and physical properties. The biomaterial was subjected to a full complement of biocompatibility tests in accordance with ISO 10993-1 and FDA Blue Book Memorandum #G95-1. Salubria biomaterial was also tested for particulate toxicity or inflammatory reaction in rabbit joints.

Results:

Biocompatibility: The material was tested for ability to produce cytotoxicity, intracutaneous irritation, sensitization by Kligman maximization, Ames mutagenicity, chromosomal aberration, and chronic toxicity. The material passed all required biocompatibility testing.

Salubria particulates in rabbit joints were biologically well-tolerated. The biomaterial particulate was deposited on the superficial synovium with minimal inflammatory reaction. There was no evidence of migration from the joint space or toxicity in the knee or at distant organ sites. There was no evidence of third body wear or osteolysis. Furthermore, the biomaterial has stable, durable physical properties over the period of implantation in joints and would be suitable for use as structure deceives such as a soft-tissue cartilage replacement.

Materials Mechanical Testing:

Plots of stress versus strain in tension (Figure 1) show a non-linear response. Due to the non-linearity of the loading curve, tangent modulus values at a defined percent strain are used to characterize the material stiffness.

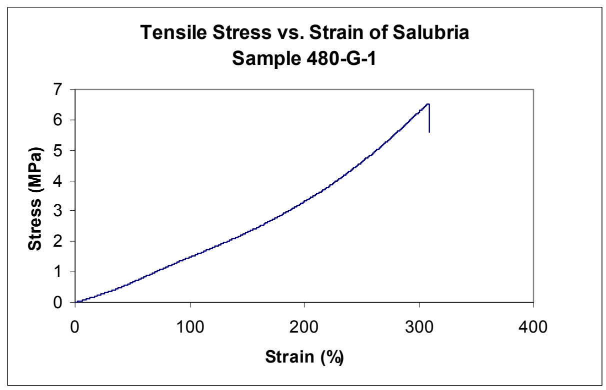

Figure 1: Representative Tension Curve

Tangent modulus ranges from 1.2-1.6 MPa. Ultimate tensile strength is 8-10 MPa. The stress-strain curve exhibits a non-linear elastic behavior similar to natural soft tissue.

Conclusions:

The biomaterial presented here opens the potential for soft tissue replacements that more closely match the anatomic and physiologic requirements for human soft tissue replacements. The biocompatibility of this hydrophilic biomaterial makes implants generally possible. The strength of the material covers the range of typical human soft-tissue without requiring months of remodeling or non-uniform results. The manufacturing process using cast molding techniques is inexpensive but allows for surface texturing to the nanometer level of detail. New medical devices such as cartilage and heart valve replacements may be possible through the judicious use of biomaterials with hydrophilic soft-tissue properties.