Shape Memory Polymers for Soft Tissue Fixation in ACL Reconstruction

Ken Gall[1,2,3], Chris Yakacki[3], Jack Griffis[3]
School of Materials Science and Engineering[1], Woodruff School of Mechanical Engineering[2]
Georgia Institute of Technology, Atlanta, GA
[3]MedShape Solutions, Atlanta, GA

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Statement of Purpose: The fixation of tendons and ligaments to bone remains a central challenge in joint reconstruction and tissue engineering. The overarching goal of this work is to assess the use of shape memory polymer networks in soft-tissue orthopedic reconstructions. Shape memory polymers are materials than can transition between temporary and permanent shapes through thermo-mechanical processing and via exposure to external stimuli[1,2]. As such, they have potential use in biomedical applications when simple, reliable, and minimally invasive delivery of devices is advantageous[1,2]. In this work we undertake a series of studies ranging from fundamental materials characterization to a benchtop pullout model to assess the feasibility of shape memory polymers as anchors in soft tissue fixation. Although several potential applications exist, this work focuses on tendon graft fixation in ACL reconstruction.

Methods: PMMA-co-PEG networks were synthesized by free radical polymerization using 0.2 - 0.4 wt% of a 2,2-dimethoxy-2-phenylacetophenone photoinitiator. Polymerization was performed under 365 nm UV irradiation for 30 minutes. Polymer networks were synthesized with PEGDMA compositions ranging from 25 - 100 wt% and molecular weights ranging from 330 - 1000. Tensile dynamic mechanical analysis (DMA) on flat strips was used to determine the glass transition temperature and rubbery modulus of the networks on a TA Q800 DMA. Free strain and constrained stress recovery were measured as a function of increasing temperature on compression cylinders on an MTS Insight mechanical tester equipped with an environmental chamber. ISO 10993 biological testing (*in vitro* and *in vivo*) was performed by AppTec laboratories. Finally, pullout testing was performed on prototype shape memory polymer devices compared to Ti interference screws using a sawbone based benchtop model for fixation in ACL reconstruction.

Results: After basic characterization of the polymer system, six tailored networks were created to independently test the influence of T_g and rubbery modulus on shape-memory behavior. Three of the networks had T_gs of 56, 76, and 92°C with approximately equal rubbery moduli of 12.8 MPa. The alternative networks had increasing rubbery moduli of 9.3, 12.8, 17.2, and 23.0 MPa with approximately equal T_gs of 76°C.

Free-strain recovery is defined as unconstrained polymer shape change as a function of temperature during transient heating or time during isothermal hold. Constrained-stress recovery is defined as the polymer's generation of stress under full deformation constraint as a function of temperature during transient heating or time during isothermal hold. Free-strain and constrained stress recovery, were studied from a 30% stored compressive strain for all six polymers under transient and isothermal conditions. The results demonstrated that free-strain recovery was highly dependent on the glass transition temperature of the networks while crosslink density had a negligible effect. On the other hand, constrained-stress recovery was dictated by the crosslink density (rubbery modulus) of the networks. This understanding facilitates design of a specific composition to optimize the generation of force required for soft tissue fixation in ACL reconstruction.

A proprietary network with thermomechanical properties that fall within the range of the six tested networks characterized was subsequently tested for biocompatibility and capacity for soft tissue fixation in a saw bone model. The network was tested for cytotoxicity, sensitization, irritation, acute and subchronic toxicity, and genotoxicity under ISO 10993 guidelines and performed with multiple extracts including normal saline, cottonseed oil, and dimethylsulfoxide. The networks received the highest passing scores possible for all tests. The prototype devices made from this biocompatible composition demonstrated pullout strengths statistically equivalent to a FDA cleared predicate Ti interference screw device.

Conclusions: Tailored shape-memory polymer networks can be photopolymerized from methyl methacyrlate and poly(ethylene glycol)$_n$ dimethacrylate. The measured thermomechanical properties, biocompatibility, and fixation strength of the networks make them a strong candidate for soft tissue reconstruction.

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