Development of Shape-Memory Polymer Medical Devices – From Academia to Industry

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Statement of Purpose: Shape-memory polymers (SMPs) have increasingly been proposed for biomedical applications for their ability to change shape or exert force *in vivo*; however, despite the number of proposed applications, limited commercial development has been achieved with SMP medical devices.

One of the underlying reasons SMPs have yet to break through the medical device marketplace is the difficulty in transferring from laboratory conditions to the operating room (OR). Conditions that seem commonplace in the research environment can become enormous practical challenges for the clinician. For example, controlling the temperature of a SMP sample and monitoring strain recovery hardly seem like a technical feat in the laboratory; however, doing so in an arthroscopic procedure where OR-temperature saline is constantly being pumped through a joint while under significant time restraints poses a much more difficult problem. As a benchmark, the average time it takes for an orthopedic surgeon to implant soft tissue fixation devices is between 4 and 6 minutes.(*1*) SMP must be implanted, activated, and functioning within these time limits in order to gain clinical acceptance.

Recently, the first SMP medical devices have been approved by the FDA for soft-tissue fixation applications. This presentation aims to discuss the discovery and development pathway of these SMP materials and devices from laboratory to clinical use. The authors also wish to share their experience with transitioning academic research into industry.

Methods and Results: SMP acrylate networks were first explored for the ability to tailor the shape-memory effect. The glass transition temperature (T_g) and rubbery modulus of the networks were shown to tailorable by controlling the ratio of the linear and crosslinking monomers as well as the molecular weight of the crosslinkers. Both T_g and rubbery modulus were shown to directly affect the free- and fixed-strain recovery of the networks.

Thermal and mechanical activation mechanisms of the shape-memory effect were investigated in relation to the time dependence of surgical operations. The rate of free strain recovery was tested under isothermal conditions for thermally activated SMPs. Mechanical activation achieved by supplementing mechanical force (energy) to SMPs below T_g and was found to nearly eliminate the time dependence of thermal activation.

SMP networks were prototyped into several biomedical devices such as cardiovascular stents, but were focused on orthopedic interference devices and suture anchors. Figure 1 is a developed concept utilizing SMPs to fixate soft-tissues in a bone tunnel such as in anterior cruciate ligament (ACL) reconstructions.

Figure 1: A cylindrical SMP sample is placed within a glass tunnel and expanded to lock a tendon in place.(2)

The biocompatibility of a SMP material was evaluated under ISO 10993 standards, leachable/extractable testing, and an animal model (Figure 2). Histological analysis showed similar healing between the tendon-bone interface compared to screw-based devices (Figure 3). Results lead to a Material Master File being submitted to the FDA.

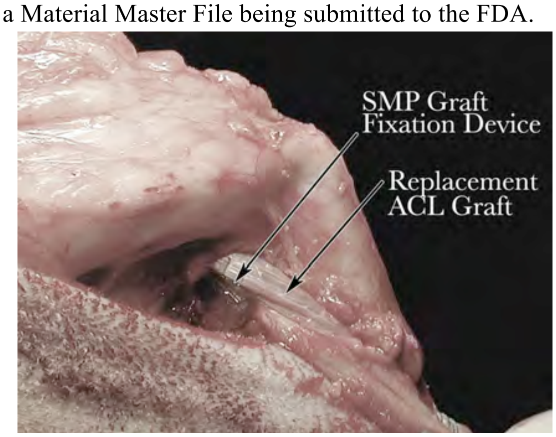

Figure 2: A cylindrical SMP sample is used as a graft fixation device in a sheep ACL reconstruction.

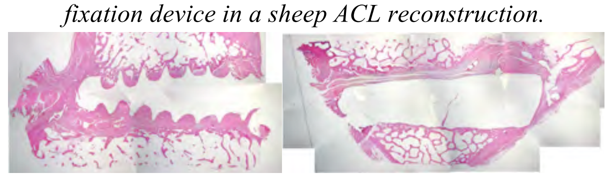

Figure 3: Histological results ACL reconstructions using a screw (left) and a SMP plugs (right).

SBIR grant mechanisms were used to fund the development of the initial research ideas. NSF 0750247 and NIH/NIAMS 2R44/AR056154 were received to support development of the SMP ACL fixation device and SMP suture anchor, respectively.

Conclusions: The authors have demonstrated that an acrylate-based SMP can be developed from laboratory research into a FDA cleared medical device.

References:

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2. C. M. Yakacki *et al.*, *Advanced Functional Materials* 2008;18: 2428.

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