Mem|Mesh: Development of a novel shape memory functional surgical mesh

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Technology

We have developed a novel Shape Memory Polymer (SMP) integrated self-unrolling surgical mesh for ventral hernia repair applications. Many ventral hernia repair procedures are performed using laparoscopic minimally invasive techniques. The use of surgical mesh has been shown to reduce recurrence rates; however, with current technology, substantial skill is required to properly position and place surgical mesh. Further, such positioning make take substantial amounts of operating time, with concomitant morbidities, we believe our, novel, patent-protected SMP-integrated mesh will address this concern by greatly reducing the complexity and time for mesh placement. The SMP-integrated mesh can be sterilized, placed in a storage configuration, and later deployed using laparoscopic tools; the thermally-activated shape memory function allows the mesh to unroll automatically once it is introduced into the abdominal cavity. The SMP-integrated mesh can be manufactured on the large scale required for commercialization. We have optimized the SMP formulation, and performed *in vitro* and acute *in vivo* studies showing automated unrolling (Figure 1). We have also demonstrated excellent biocompatibility in a small animal model, and are currently investigating tissue ingrowth characteristics in a large animal model, with promising results.

Market

Ventral hernia repair surgery is a common surgical procedure, with approximately 400,000-500,000 hernia repair operations performed annually in the United States [1]. According to a recent report by Global Industry Analysts, Inc., the world market for hernia repair devices will reach $1.5 billion by 2015 [2]. Preliminary marketing research indicates there is a large unmet need for methods to improving mesh placement and reduce ventral hernia repair complexity.

Commercialization Strategy

Clinical interest amongst hernia surgeons has been high given the limited options and cumbersome devices available to address the issue. Our SMP technology provides a scalable, inexpensive, incremental yet clinically important improvement. This technology would involve a 510(k) regulatory pathway, with well-established regulatory criteria defined in an FDA guidance document, for a very large market. The added functionality intrinsic to the SMP-integrated mesh should command a 20 – 30% increase over base price both due to the deployment functionality but also the reduction in total surgical time. A reduction in total surgical time can substantially reduce operating room costs to the patient and improve hospital workflow. Further, given that there are a small number of large, well-established players in this area, and that our technology represents essentially a post-manufacturing step which does not require changes in the original manufacturing process, we believe there will be substantial acquisition interest or strategic alliance opportunities with this technology.

Our group has a proven track record of commercializing medical devices using similar SMP technology. Three companies (one in cardiovascular, two in ophthalmology) have been launched successfully from this material. The material now has a strong biocompatibility record. The key next steps are to generate FDA approval through a 510(k) pathway, and build the commercialization infrastructure to bring this promising technology to market.

Figures

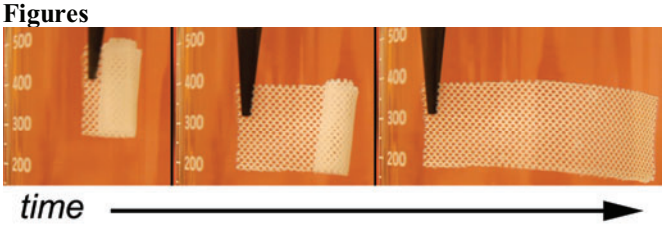

Figure 1 - *In vitro* SMP-mesh unrolling [3]

References

[1] J. W. A. Burger, R. W. Luijendijk, W. C. J. Hop, J. A. Halm, E. G. G. Verdaasdonk, and J. Jeekel, "Long-term Follow-up of a Randomized Controlled Trial of Suture Versus Mesh Repair of Incisional Hernia," Ann Surg, vol. 240, no. 4, pp. 578–585, Oct. 2004.
[2] Global Industry Analysts, "Hernia Repair Devices: A Global Market Report." Jun-2010.
[3] M. Zimkowski, M. Rentschler, J. Schoen, B. Rech, N. Mandava, and R. Shandas, "Integrating a novel shape memory polymer into surgical meshes decreases placement time in laparoscopic surgery: An in vitro and acute in vivo study," J Biomed Mater Res A, pp. 2613–2620, 2013.