

<sup>1</sup>Peter I. Lelkes, <sup>2</sup>Norman Johanson, <sup>2</sup>Fredric Kleinbart, <sup>3</sup>Ari D. Brooks, <sup>4</sup>Jack Zhou and <sup>5</sup>Barry Waterhouse.  
<sup>1</sup>School of Biomedical Engineering, Science & Health Systems, <sup>2</sup>Department of Orthopaedic Surgery, College of Medicine, <sup>3</sup>Department of Surgery, College of Medicine, <sup>4</sup>Department of Mechanical Engineering and Mechanics, College of Engineering, <sup>5</sup>Office of Graduate Studies, College of Medicine, Drexel University, Philadelphia, PA

## Abstract

As part of Drexel University's College of Medicine (CoM) strategic plan, under the heading of Outstanding Applied Biotechnology, a surgical engineering initiative is being developed tentatively termed *Surgical Engineering Enterprise (SEE)*. The initial translational goal for SEE is to develop, through collaboration between clinicians and scientists/engineers in the CoM, the School of Biomedical Engineering and the College of Engineering, tissue engineering and biotechnology-based tools for regenerative joint repair, such as bioactive interference screws, and porogen-based personalized bone constructs. These smart tools will aid in the repair and healing of some of the most common musculoskeletal problems, including anterior cruciate ligament (ACL) and rotator cuff injuries, and failed total joint replacements. While initially focusing on developing this single class of products, the long-term research goal of SEE is to develop a portfolio of a variety of surgery-related clinically relevant devices, which may rapidly enter the clinical realm and enhance the quality of life for the patients. As a forward-thinking initiative, the SEE includes research and development, education, and patient care components. In addition to yielding tangible deliverables with significant commercial and clinical prospects, the project fosters interdisciplinary research between the CoM and the rest of the University and also entails novel educational components. Importantly, the SEE represents a prime example of applied biotechnology programs that draw on existing Drexel strength to achieve specific goals. Because of existing pockets of excellence in these domains, the CoM is poised to take a leadership role in multiple facets of surgical engineering.

## CoM Strategic Plan (2007 – 2012) Objective III.3: Surgical Engineering: Develop Biotechnology-based Tools for Regenerative Joint Repair

□ The CoM will develop a research and training program in surgical engineering. Barry Waterhouse, Ph.D. will oversee and coordinate the activities of this program. The scientific director will be Peter Lelkes, Ph.D., the School of Biomedical Engineering and the Department of Pathology, CoM.

□ The lead program in this initiative is biotechnology-based regenerative joint repair, and effort that includes research, education, and translational. The unique environment at Drexel provides surgeons and other clinicians the opportunity to collaborate with engineers and biologists in the development of novel devices and minimally-invasive procedures that aid in the diagnosis, treatment and repair of diseased or injured tissue.

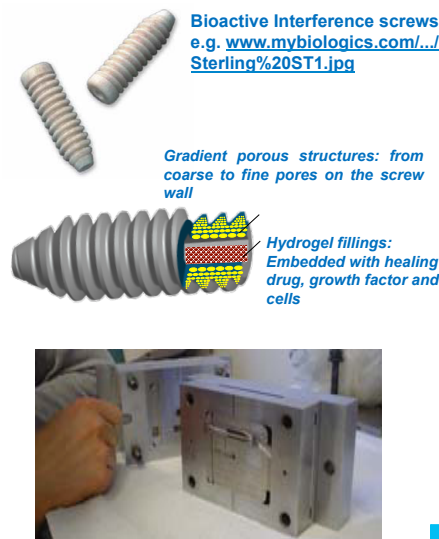
□ Components and one that provides the blueprint for development of other seminal advances in the surgical area.

□ In focusing on regenerative musculoskeletal tissue engineering, this project is unique in its clinical outlook, in which the proposed goal-oriented research and its implementation are driven by the need for accelerated and successful healing of some of the most frequent injuries to the musculoskeletal system.

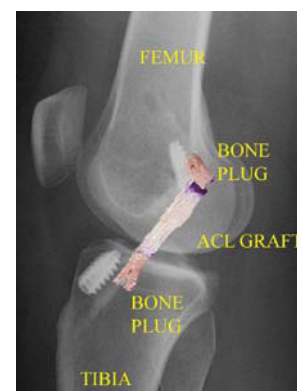
□ The clinically-oriented agenda, combining basic and applied investigations, will be complemented by an urgently needed, integrated educational agenda, which will attract students from both the CoM and the rest of the University.

□ In addition to yielding tangible deliverables with significant commercial and clinical prospects, the project fosters interdisciplinary research between the CoM and the rest of the University and also entails novel educational components (curricula, seminars, hands-on lab courses).

□ A tentative business plan suggests that this project will be self-sufficient and profitable by the fourth year. It is anticipated that revenue from patents, licensing of intellectual and tuition for clinical training should be substantial.



Custom-built mold for screw manufacturing



Post-operative X-ray after ACL patellar tendon reconstruction (with picture of graft superimposed) shows graft position and bone plugs fixation with metal interference screws. [orthoinfo.aaos.org/figures/A00297F12.jpg](http://orthoinfo.aaos.org/figures/A00297F12.jpg)

## Research Goals

1. Manufacture "smart scaffold" based "surgical tools" (screw/anchor) and "personalized allografts", test mechanical properties (in years 1-2).
2. Use suitable small animal models to assess biocompatibility and bio-absorbability, and enhanced bone-in-growth (years 2-3).
3. Test the regenerative effectiveness and safety of the product in large animals (years 3-4).
4. Clinically test the developed products in ACL, rotator cuff, and major bone defects encountered in total hip and knee revisions (~20 patients; year 5 and extend for 1-2 additional years).

## Summary and Conclusion

1. With this new surgical engineering enterprise (SEE), clinicians and scientists in the CoM and the School of Biomedical Engineering will collaborate and, as a first target jointly develop biotechnology-based tools, for example for regenerative joint repair. These will aid in the repair and healing of some of the most common musculoskeletal problems including anterior cruciate ligament and rotator cuff injuries, and failed total joint replacements.
2. The proposed program for advancements in regenerative musculoskeletal tissue engineering will serve as the model for achieving similar favorable outcomes in other areas of surgical engineering, e.g. targeted drug delivery systems, cold plasma sterilization of living tissue, vascular grafts, and other novel materials and devices for measurement and enhancement of wound healing, and surgical robotics.