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"Smart Tools" for Orthopedic Surgery and Regenerative Medicine

Background: Injury to the Anterior Cruciate Ligament (ACL) is one of the most frequent sport injuries. ACL injuries are frequently associated with related damage to the knee, such as tears of collateral ligaments, menisci, and articular cartilage. Currently, most ACL tears cannot be repaired and require reconstruction using autograft or allograft tendon. In both of these cases, "interference screws" are used to anchor the repaired/replaced ligament to the adjacent bones. Even though the newer interference screws, used in ACL repair, are "biodegradable", they are still "passive" devices because they do not otherwise advance the healing process. Thus, there is a clear clinical need for novel technology-based tools that will aid in the healing process.

Technology Innovation: Our proposed biomedical technology solution for this poorly met clinical need is to develop "smart tools" and hardware that can actively participate in, and accelerate the healing processes. By combining innovative biomanufacturing techniques, such as solid freeform fabrication, gradient cellular structure (GCS), and injection molding with drug-encapsulation strategies, and by incorporating specific growth factors that promote tissue regeneration, we propose to produce novel bioactive and biocompatible smart surgical tools, such as smart screws and anchors. Our smart tools will exhibit mechanical strength comparable to/better than existing metal or plastic screws and, additionally, will contain locally released bioactive components to promote a much faster and more complete tissue healing. This will be achieved by incorporating growth factors tailored to specific applications and the personalized requirements of recipient patient. ***The combination of mechanical strength, bioactivity and patient-tailored drug-release competence is unique to our concept and distinguishes it from exiting products.***

Proposed Study: Based on our ongoing work, we propose to research, prototype, test, and eventually offer for manufacture and use a "medical device" *viz., a* smart screw/anchor for ACL repair using a blend of biodegradable polymers (e.g. polycaprolactone and/or polyglycolic acid and their derivatives) and calcium phosphate, thus optimally mimicking bone strength and structure. Using our newly developed, proprietary porogen- and GCS based techniques, we will generate "controlled voids" that will be filled with hydrogels containing sustained drug (e.g. BMP2) releasing microcapsules resulting in accelerated tissue in-growth and healing. After first testing the mechanical properties (e.g. pull-out strength) and drug release characteristics of these prototype "smart" screws/anchors first *in vitro*, we will proceed to test our devices in an animal model for the accelerated ACL repair. Two IP disclosures related to our concepts and procedures have been filed with the Technology Transfer Office of Drexel University. We anticipate that after the initial *in vitro and in vivo* proof-of–concept phase (2 years) our smart screws will undergo extensive animal testing (e.g. in dogs) and be ready for clinical implantation within 5 years.

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concept of porogen/GCS-based "smart tools", initially tailored to interference screws for ACL repair, can also be expanded the much large market of routine trauma screws promoting bone fracture healing. In addition our technologies could be used for designing and manufacturing personalized bone replacement parts and bio-cement, as urgently needed e.g., in filling large bone defects that are frequently encountered during revision surgery after knee or hip replacement.