Product Design Specification

Version 3.2

Title: Bioactive Interference Screws for ACL Reconstruction

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Client: William Murphy, Ph.D.

Function:

Currently, during an ACL reconstructive surgery, titanium or partially degradable plastic interference screws are used to secure the graft within the femur and tibia. These screws or parts of these screws will remain in the patient's knee for the rest of his or her life and can potentially cause problems. The current screws are also not conducive for tissue re-growth. It is therefore our client's desire to develop an interference screw for ACL reconstruction that will promote and foster the growth of surrounding bone tissue, as well as limit any potential problems a patient may incur due to these screws in his or her body.

The interference screw that we will design should be biphasic and bioactive. A biphasic screw consists of a thermoplastic that is strong enough to withstand the stress during implantation and post-operative activity, and a mineralized hydrogel phase that acts as a scaffold for and promotes bone growth. The screw must also be bioactive. It must promote tissue growth at a rate that is comparable to the degradation of the screw. The screw must also secure the ACL graft just as its predecessors, and it must be biocompatible, in other words it must not cause an inflammatory or immune response in the body.

Client Requirements:

The screw must be:

- Biphasic, in that one half is bioactive alginate hydrogel that effectively promotes and fosters bone tissue re-growth, and the other half is PLGA/PLLA thermoplastic which provides mechanical strength, however, ultimately degrades
- Biocompatible in that it does not evoke an immune response when implanted and is relatively inert with respect to the body
- Biodegradable in that it is biologically absorbed over time without producing harmful byproducts in the process
- Easily sterilized or autoclaved
- Must be able to withstand the stresses involved during surgery and post-operative activity

Design Requirements

1. Physical and Operational Characteristics

a. *Performance requirements*: The screw must withstand the stresses involved with the surgery and activities performed by the patient post-surgery. More specifically, the screw must withstand a pullout-strength of 1300 N and shear failure strength of 430 N.

b. *Safety*: The screw should allow bone tissue to re-grow and anchor the graft within the bone. The material of the screw should not be harmful to the body. The threads of the screw should not shear the graft.

c. *Accuracy and Reliability*: The screw should successfully anchor the graft, and stay secure until sufficient bone tissue re-growth has occurred. The screw should be able

to be manufactured with a high rate of precision and accuracy with room allowed for only minor error.

d. *Life in Service*: The PLGA/PLLA portion of the screw must structurally support the graft until enough tissue has grown to support the graft. Ideally, the screw will degrade at a rate equal to the tissue growth rate. This is typically on the order of several months but could last up to one year. Thus in order to include an adequate factor of safety, the screw should be able to last for two full years after implantation.

e. *Shelf Life*: Optimal shelf life would be between six months and one year due to the maintenance of chemicals within the hydrogel. The screw should also be stored in a secure, cool place out of direct sun-light.

f. *Operating Environment*: The screws need to be kept in a sterile, possibly cool storage area before being used. After surgery, the screw will be secured in the knee, anchored in bone and must not interfere with homeostatic conditions.

g. *Ergonomics*: The screw must not interfere with the motion of the tibia, femur, patella, or graft.

h. *Size*: The screw will be between 22-30 mm long and will have diameter of 6-10 mm.

i. *Weight*: The weight of the screw will be dependent on the materials chosen and their relative densities. Care should be taken, however, to minimize the weight of the screw.

j. *Materials*: The threads and main components of the screw will be fabricated out of a PLGA/PLLA composition. The semi-circle pockets will be composed of mineralized alginate.

k. *Aesthetics, Appearance, and Finish*: The screw should be uniform in shape and density and have minimal amounts of rough edges, increasing the ease for insertion into the bone.

2. Production Characteristics

a. *Quantity*: Current mechanical testing requires a small quantity of surgically sized prototypes as well as a scaled-up model, diameter approximately larger by a factor of 2.5. Ideally, 10-15 screws should be manufactured for both sizes used in testing.

b. *Target Product Cost*: The cost of the screw will be dependent on the mold and the materials used in the screw. The PLGA/PLLA will be the most expensive.

3. Miscellaneous

a. *Standards and Specifications*: All nations have strict rules and regulations pertaining to medical devices. In the United States, the Food and Drug Administration (FDA) is mainly responsible for product safety and performing regulatory actions. They have very detailed and thorough regulations for medical devices, especially implantable ones, which requires additional research to attain the details. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=888.3040

b. *Customer*: The customer will be the surgeons that will be using the interference screws during surgery. The consumer (patient) should be unaware of the screw after it has been inserted.

c. *Patient-related concerns*: The screw must not initiate an immune system response. The screw will need to be sterilized before it is secured in the body. The doctors should make sure the patient is not allergic to any of the materials in the screw. The doctor must advise the patient on proper care during post-surgical recovery. Excessive force on the screw before full healing could cause damage to the screw and to the patient.

d. *Competition*: There are many health care companies that manufacture interference screws for orthopedic applications. The size geometry of the current products are somewhat similar, but can have small differences. These include the amount of

tapering, the size and angle of the threads, and the shape of the tip. Many designs are patented and further research is needed to investigate the various patents and screw geometries in general.

The original material standard for interference screws was metal, usually a titanium alloy because of its biocompatibility. Many companies currently offer titanium interference screws, including Stryker (www.stryker.com), Sulzer Medica (www.sulzerorthoeu.ch), and DePuy Mitek (a Johnson & Johnson company, www.mitek.com). However, there have been recent advances in the materials used to fabricate interference screws. Newer materials are not just biocompatible, but bioabsorbable, where they will break down starting 6 weeks to 6 months after surgery. Following is a list of companies and the bioabsorbable interference screw they offer:

- Stryker Corporation (www.stryker.com)
  - Bioabsorbable Wedge Interference Screw
    - 100% Poly-L Lactic Acid (PLLA)
  - Biosteon™ (HA/PLLA) Wedge Interference Screw
    - 25% Hydroxyapatite
    - 75% PLLA
    - Patented wedge design
    - Osteo-conductive potential of bone
- Arthrotek, Inc. (www.arthrotek.com)
  - LactoSorb® resorbable copolymer
    - 82% PLLA
    - 18% glycolic acid
    - Retains most of its strength for 6-8 weeks
- Steiner & Martins, Inc. (www.steminc.com)
  - DrixMed™ PLDL TB bioabsorbable interference screw
    - Poly (L-DL-Lactide) 70-30
    - Total resorption at more or less 2 years
- Sulzer Medica (www.sulzerorthoeu.ch)
  - Sysorb – bioresorbable interference screw

        - Poly (D,L-Lactide)
- DePuy Mitek (www.mitek.com)
    - Milargo interference screw
        - 30% osteoconductive β TriCalcium Phosphate (TCP)
        - 70% faster resorbing poly(lactide-co-glycolide) (PLGA)
    - ABSOLUTE Absorbable Interference Screw
- Atlantech Medical Devices LLC (www.atlantech-md.co.uk)
    - Bilok® ceramic/polymer interference screw
        - PLLA and β-Tricalcium phosphate
- Linvatec (a ConMed Company) (www.linvatec.com)
    - SmartScrew®
        - ACL – self reinforced 96L/4D copolymer
    - BioScrew®
        - PLLA