Novel Polysaccharide-derived Fixation Device for Anterior Cruciate Ligament (ACL) Reconstruction

Team #13
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Outline

- Background and Market Need
- Client’s Statement of Need
- Optimal Design
  - Tendon Casing
  - Interference Screw
- Surgical Integration
- Finite Element Analysis
- Conclusions
- Acknowledgements
Background

- ACL connects articulating surfaces of the femur and tibia
- Prevents forward translation of femur over tibia
- Provides rotational stability to knee joint
Market Need for ACL Injury

- Approximately 50% of the 200,000 annual ACL injuries in the U.S. require surgery
  - $5,694 average procedure cost (Cole 2005)
- Inadequate fixation devices on the market
  - Current load capability: 800 N
  - Native ACL load: 2000 N
- 10-15% of patients have continued instability and/or discomfort
Issues with Current Devices

- **Interference Screws**
  - **Benefits:**
    - Biodegradable
    - Stability
  - **Drawbacks:**
    - Too rigid
    - Limited range of motion
    - May break during placement

- **Endobutton (2007)**
  - **Benefits:**
    - Flexibility of motion
  - **Drawbacks:**
    - Too much graft tunnel motion
    - Knee instability
Statement of Need

- Use novel polysaccharide-derived biodegradable material from UCHC
- Integrate current surgical procedure
- Fixation device satisfies the following:
  - Withstand necessary loading experienced in knee
  - Balance stability and flexibility of current devices
Optimal Design Features

- Threaded Design (Stability)
  - Prevent rotational device movement
  - Improved Healing

- Suspension System (Flexibility)
  - Prevent translational device movement
  - Limit Knee Stiffness
Optimal Design Components

1) Tendon Casing – Femoral
2) Biodegradable Interference Screw - Tibial
Component #1: Tendon Casing

- **Height:**
  - 17mm

- **Width:**
  - 15mm

- **Tendon Width:**
  - 4mm
Component #1: Tendon Casing

**Threaded Exterior**
- Increased surface area
  - Osteoconduction
  - Rotational stability

**Hexagonal Drive**
- Standard Size
- Easy insertion during surgery

**Interior Tendon Canal**
- Prefer hamstring graft
- Surgical integration
- No graft-tunnel slippage
Component # 2: Interference Screw

- Extreme example of length and width:
  - Mechanical testing to evaluate material
- Length: 30mm
- Width: 8mm
- Unique thread shape
Component # 2: Interference Screw
Interference Screw Mold
Surgical Procedure – Step 1

- Harvesting Hamstring Graft
- Dimensions

Source: Immersion Media - IMSports

Surgical Procedure – Step 2

- Double strand tendon pulled through tendon casing with 5/8 circle suture needle
Surgical Procedure – Step 3
Surgical Procedure – Step 4
Surgical Procedure – Final Placement
Loading and Moments in the Knee

Left Knee Joint

ACL injuries occur when bones of the leg twist in opposite directions under full body weight.
Loading Requirements of the Knee

- Native ACL
  - Ultimate Load: $1994 \pm 206\text{N}$ (Scheffler 2002)

- Endobutton with hamstring tendon
  - Ultimate Load: $572 \pm 105\text{N}$ (Woo 2006)

- Biodegradable screws with BPTB (bone-patellar tendon-bone) graft
  - Ultimate Load: $830 \pm 168\text{N}$

- Our Device
  - Ideally: $>2000\text{N load}$ and $10\text{Nm torque}$
Loading on Tendon Casing

- 2000N to tendon cavity
- 10 Nm torque to threads
High Stress Environment of Knee

Equivalent Stress:

Max Stress Experienced by Device
• 5.5526*10^7 Pa

Material Yield Strength
• 1.9-5.1*10^7 Pa (Ave. 3.26*10^7)
Tendon Casing Prototype

- 3D Printing photos
- Fabricated from PLA
  - similar to cellulose acetate

- Left: Highlights the threads and hexagonal drive
- Right: Shows the two openings of the tendon tunnel
Loading on Interference Screw

- 6 Nm moment applied at hex drive
- Exceeds rotational failure of current interference screws
ANSYS Results

B: Static Structural
Equivalent Stress
Type: Equivalent (von-Mises) Stress
Unit: Pa
Time: 1
4/24/2013 6:28 PM

7.1114e8 Max
6.3213e8
5.5311e8
4.7409e8
3.9508e8
3.1606e8
2.3705e8
1.5803e8
7.9016e7
0.020838 Min
Interference Screw Prototype
Mold Prototype
Mold Assembly
Prototype in Knee Model

- Step #1: Loop graft tendon through Tendon Casing
- Step #2: Insert graft tendon and Tendon Casing into femur
- Step #3: Fix graft tendon with Interference Screw in tibia
- Result: Reconstructed ACL
## Budget

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Conclusions

- FEA shows tendon casing is suitable for ACL reconstruction application
  - Yield strength of device is significantly greater than other devices currently on market
- Molding tool will allow for fast production of interference screws for further testing
Acknowledgements

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