UNIVERSITY of VIRGINIA

ORTHOPAEDIC SURGERY

Novel Device for Suture Anchor Augmentation for Tendon Repair

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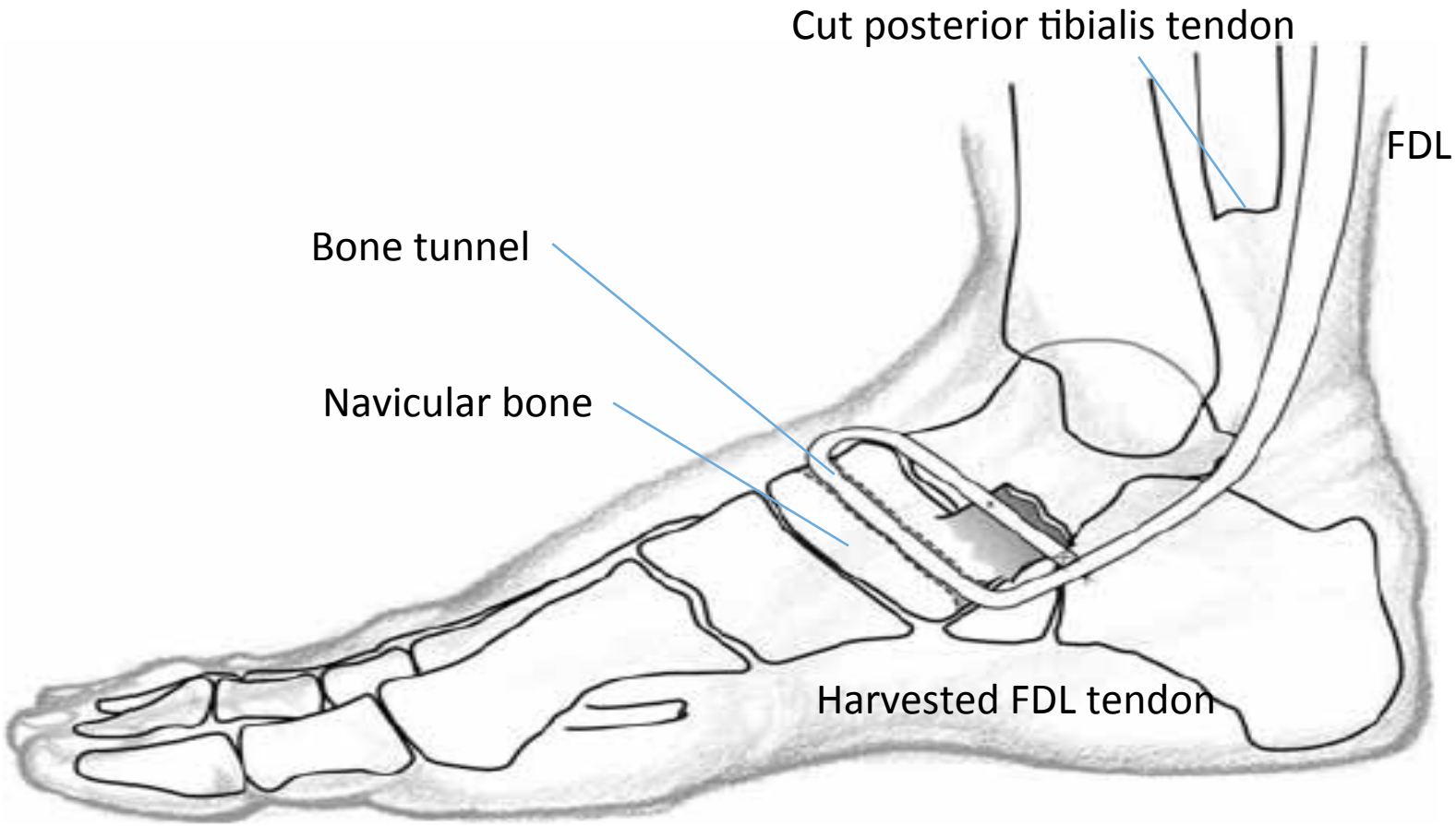
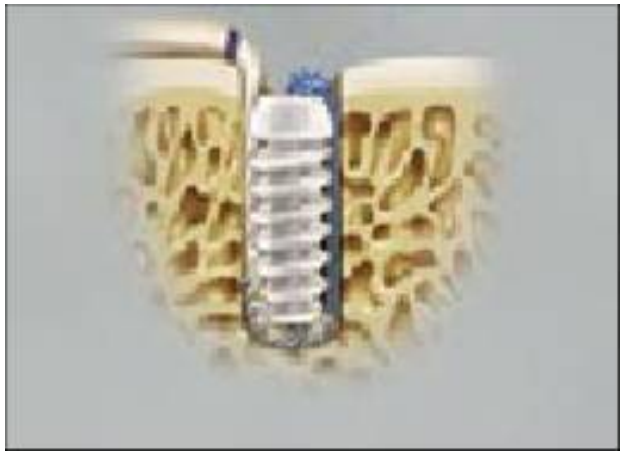
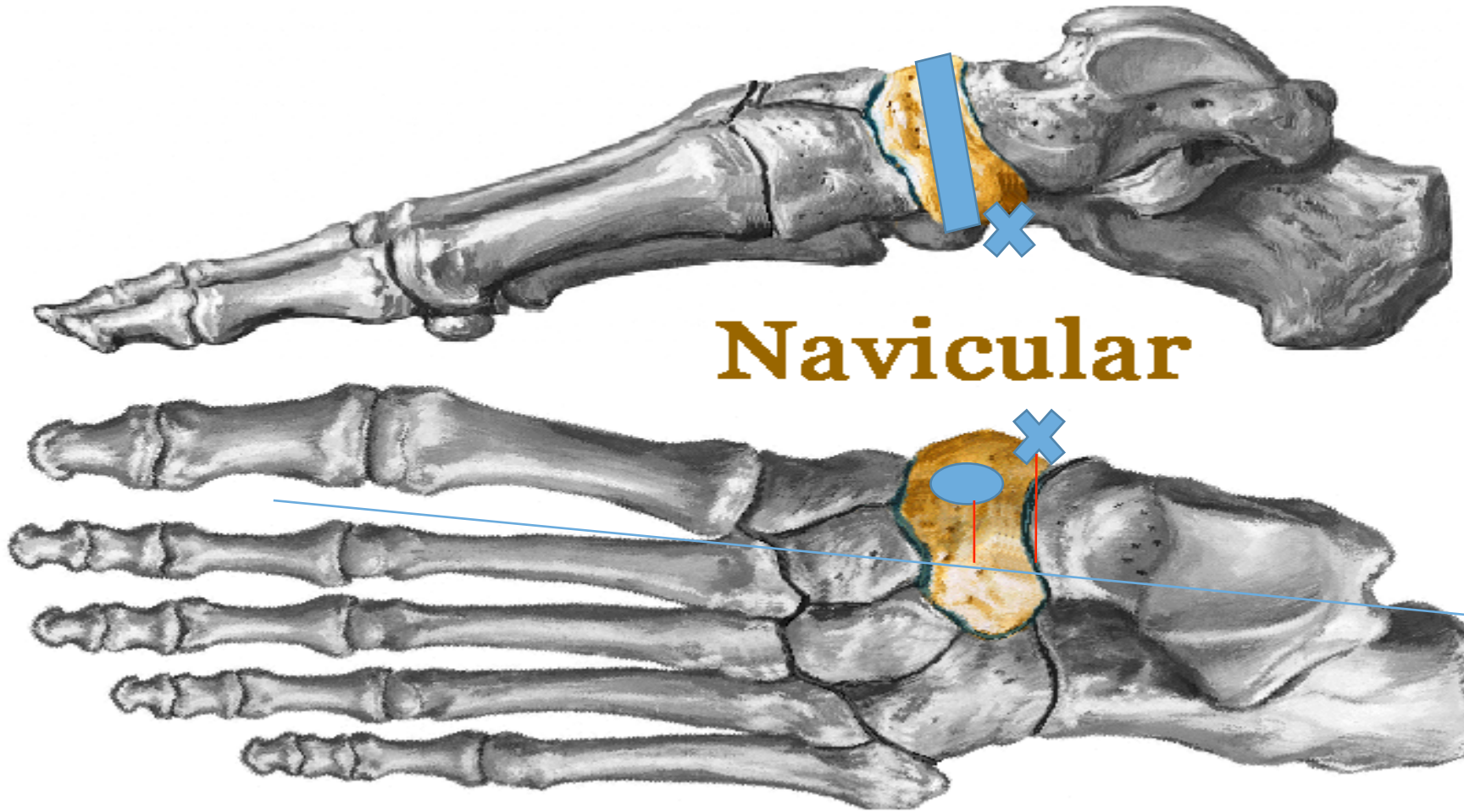
Clinical Problem:
Fixation of FDL Tendon to Navicular

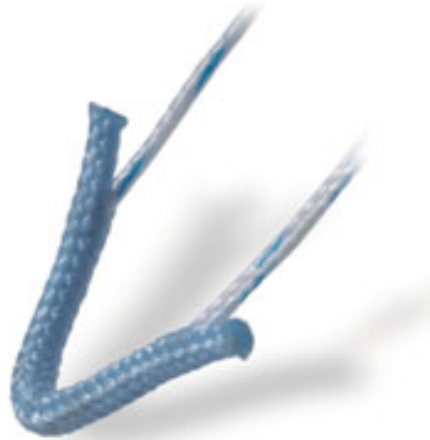


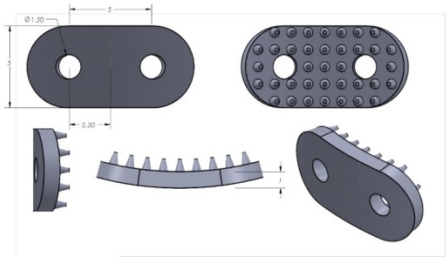


Consequence of shifting the effective insertion is loss of moment arm

- ~33-50% loss in moment arm







Research Aims

- Aim 1 is to test strength of compression with:
  - Suture anchor alone
  - Suture anchor plus suture button prototype
  - Suture anchor plus porous metal spiked button prototype

  In rabbit achilles tendons and bone substitute

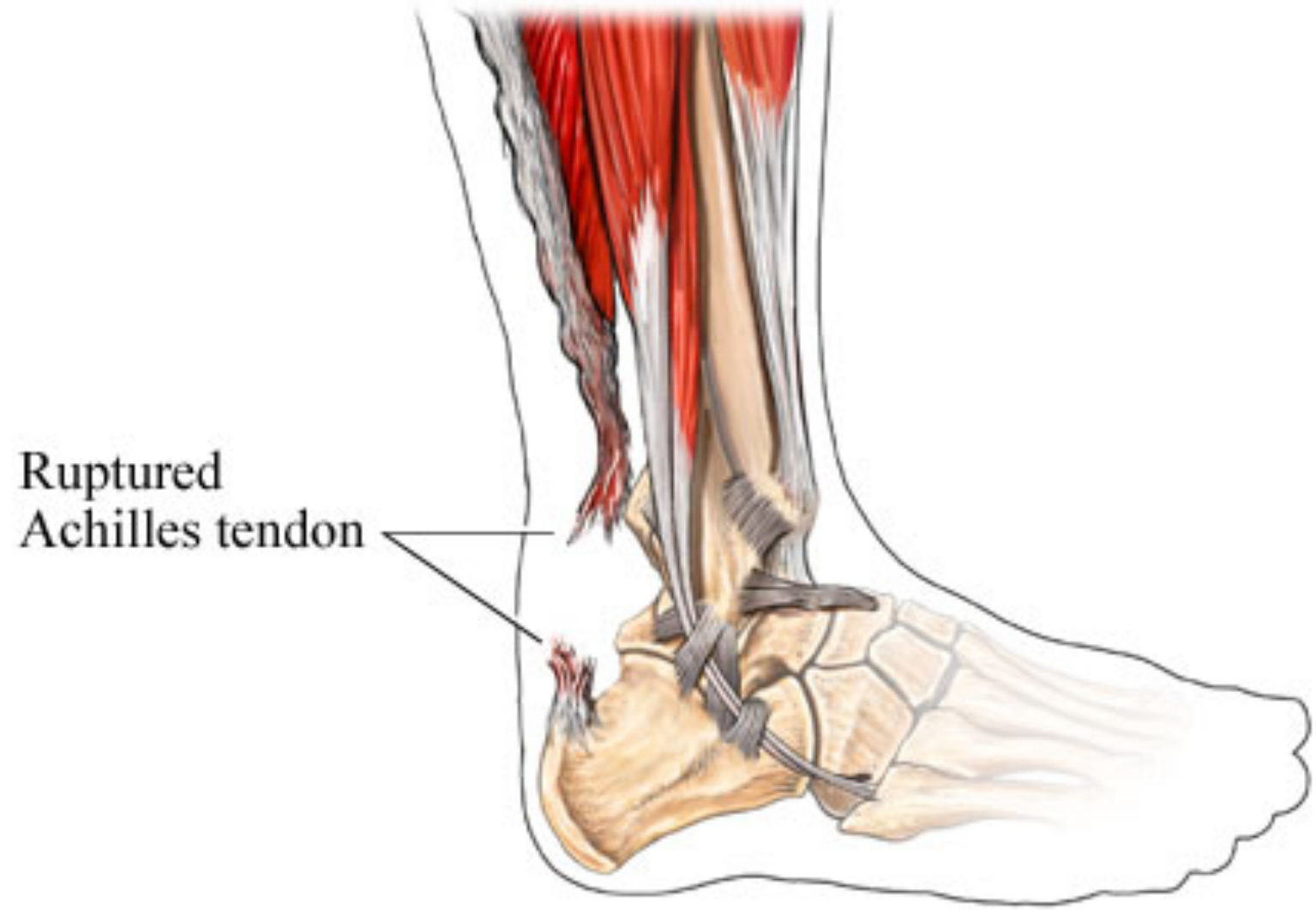
- Aim 2 is to characterize the biologic healing of the tendon-bone interface in surgically-repaired rabbit Achilles tendons
  - 2a: characterize with H&E staining (1/2 animals)
  - 2b: characterize healing tendon with MRI
  - 2c: perform biomechanical testing of healed tendon

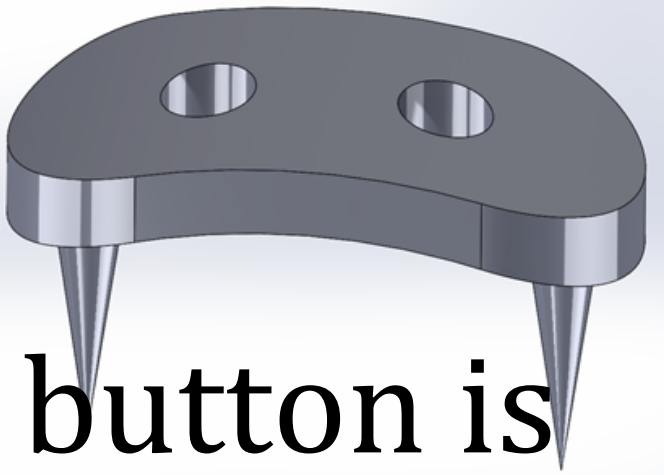
Funding

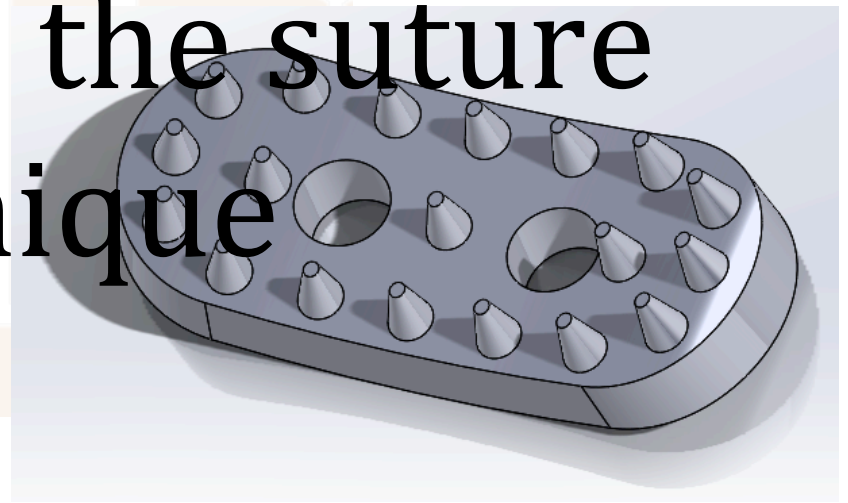
- Study Funded by the Wallace H. Coulter Foundation Translational Research Award ($100,000)

- http://whcf.org/the-wallace-h-coulter-foundation/#

Problem: Imperfect Tendon Repair







Goal

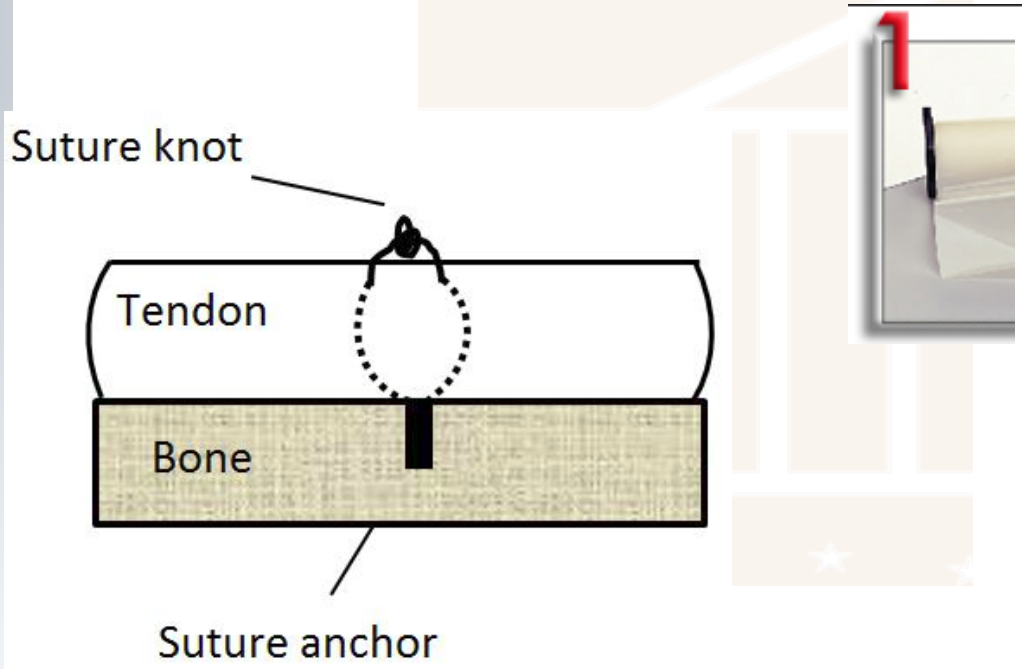
Show that the suture button is an improvement to the suture anchor technique

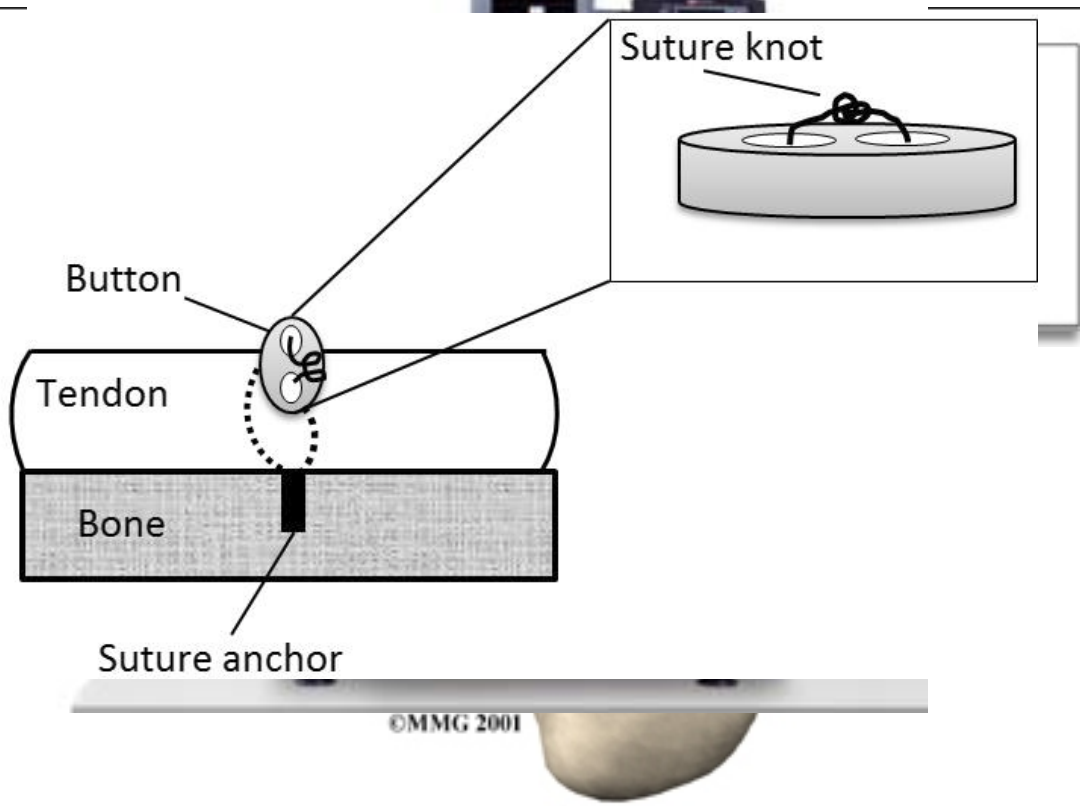
Methods

- Validation of Hypothesis
  1. Increased contact area
  2. Stronger tendon-bone interface

- 3 Tests
  1. Pressure Film
  2. Cyclic Loading
  3. Tensile Load-to-Failure

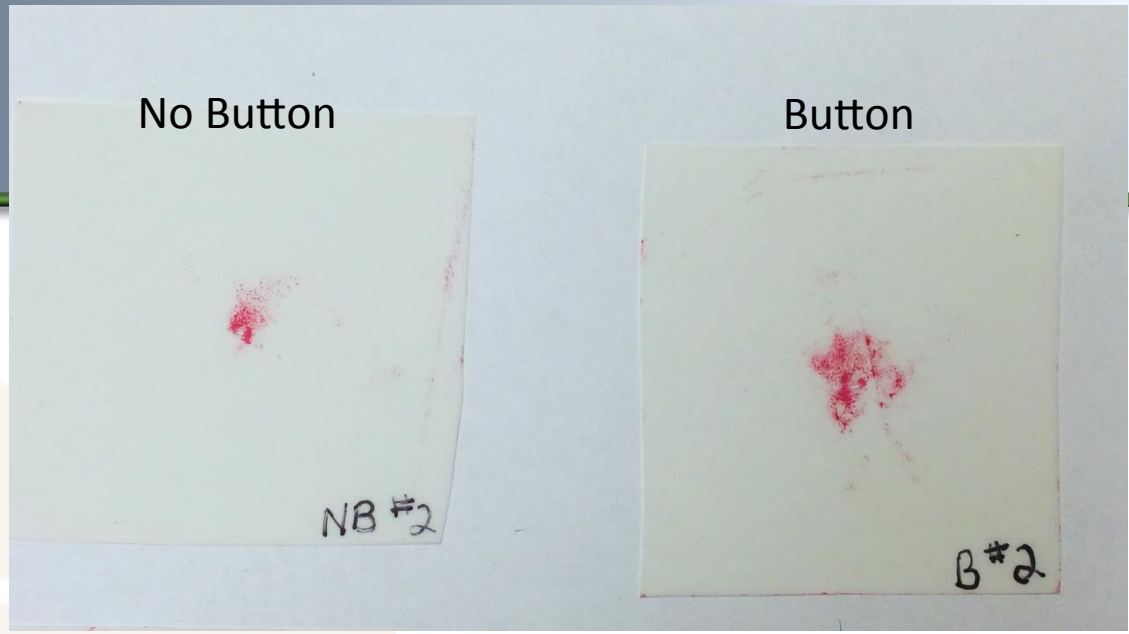
2 Conditions:
Control
Device

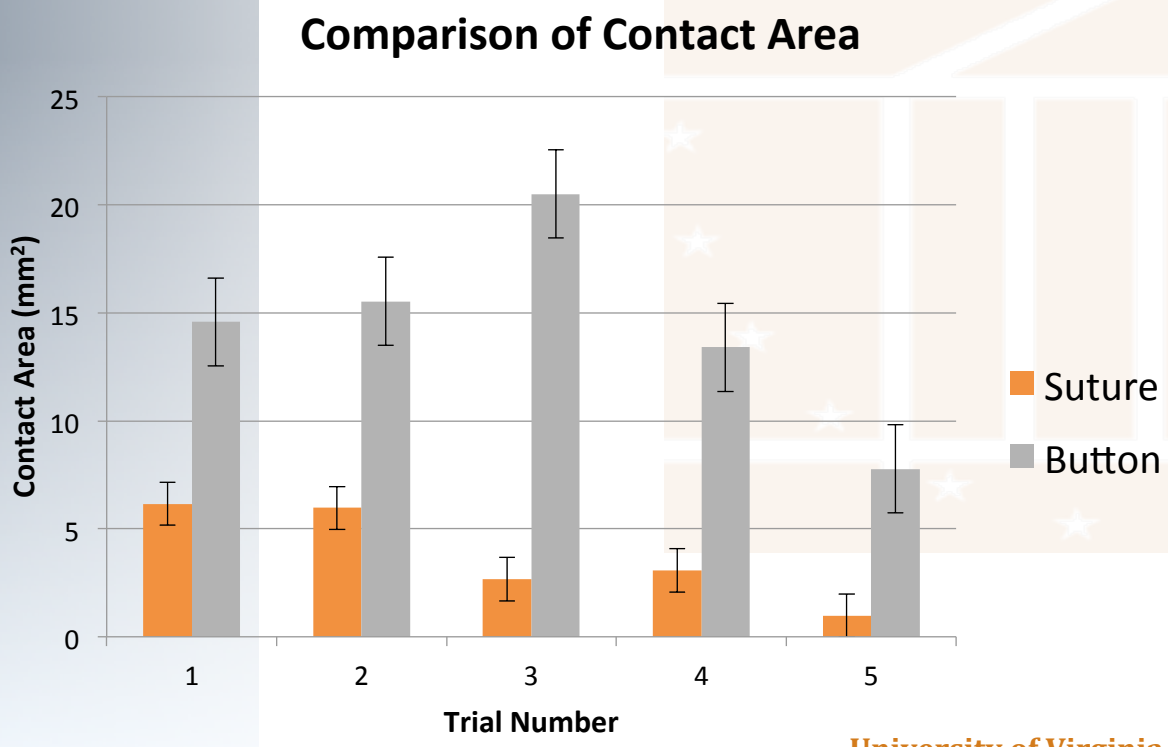


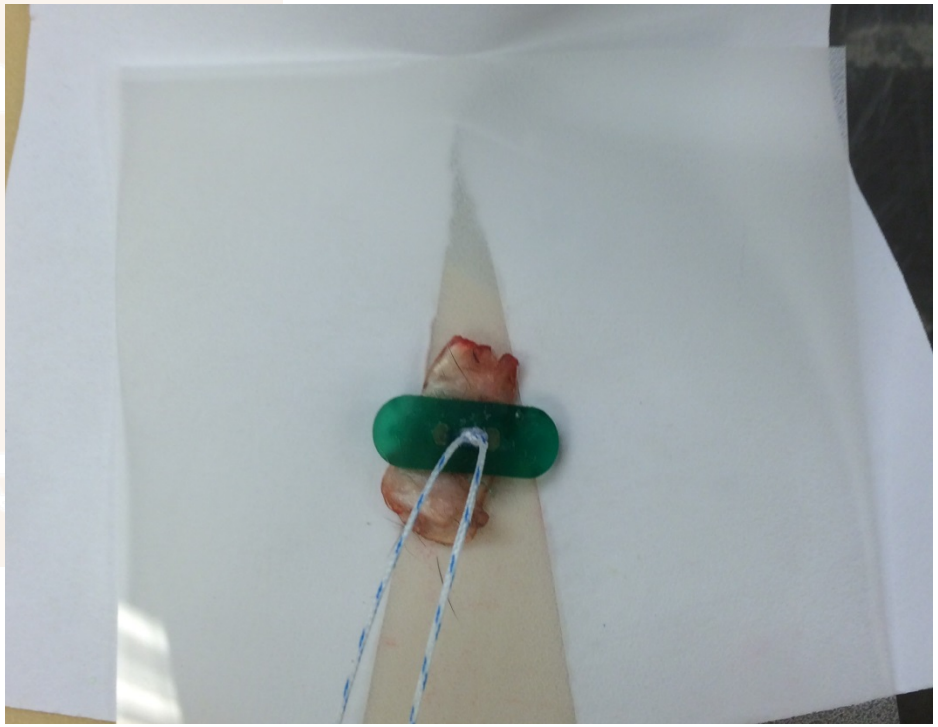


Contact Area

- Use Fuji Pressure Film to characterize compressive force applied.
- Button → 3.8 x increase area of compression (P <0.002).







Cyclical Loading

- New Zealand White rabbit achilles tendons were attached to bone block substitute (Sawbones.com) via Biomet Juggerknot anchors
- 25 N of force were applied for 50 cycles (0.5 Hz)
- Control: 2.24 mm liftoff
- Device: 0.19 mm liftoff (0.99 mm at 500 cycles)

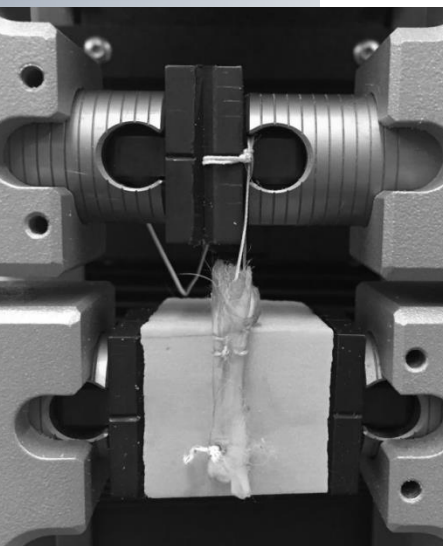
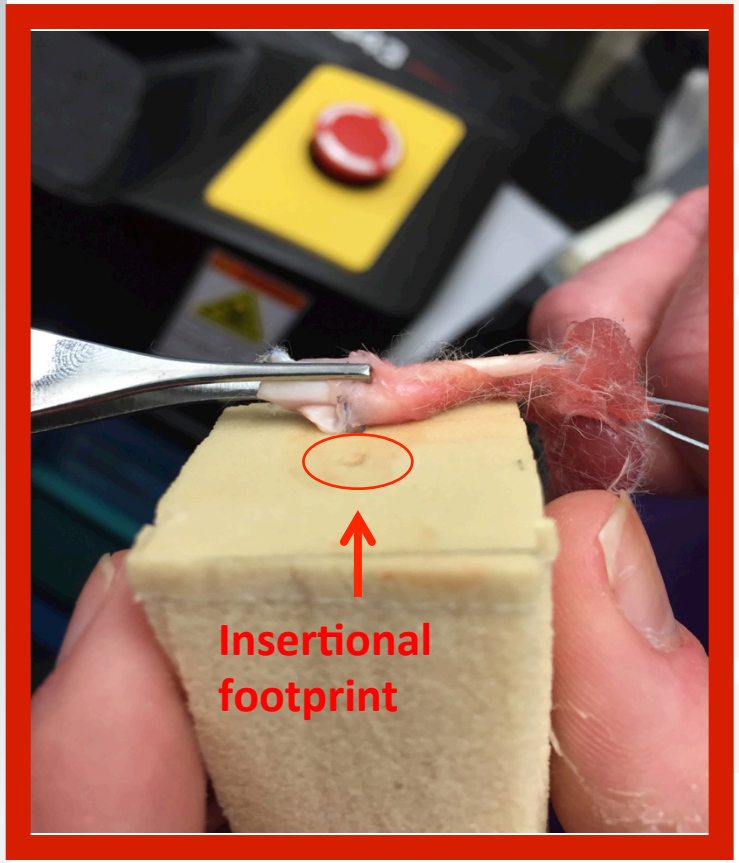


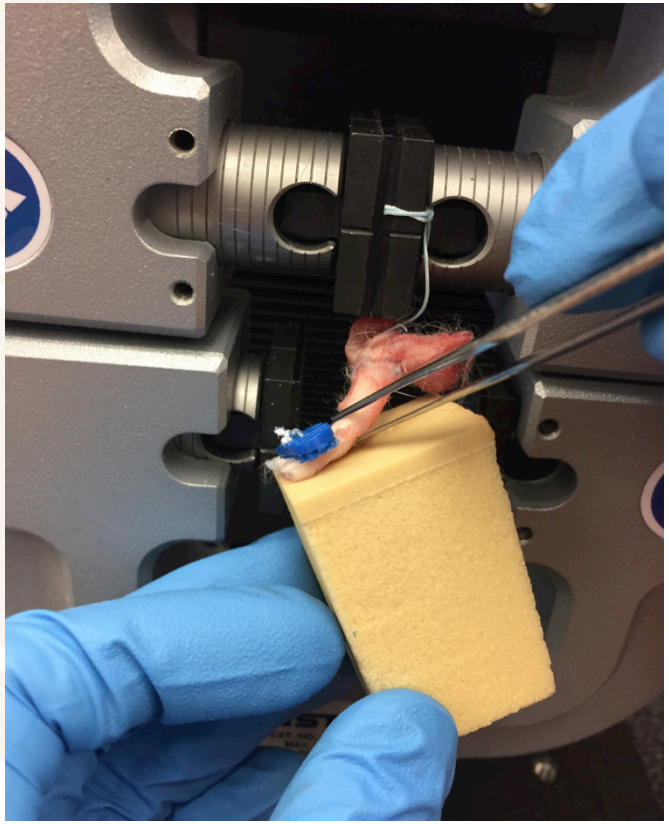
TABLE 2	
Measurement of Liftoff After 50 Cycles	
	Distance From Underside of Tendon to Bone Block, mm
Device condition specimens	
1	2.11
2	2.31
3	2.31
Average	2.24
SD	0.12
Control condition specimens	
1	0.20
2	0.10
3	0.27
Average	0.19
SD	0.09

Load to Failure

Control

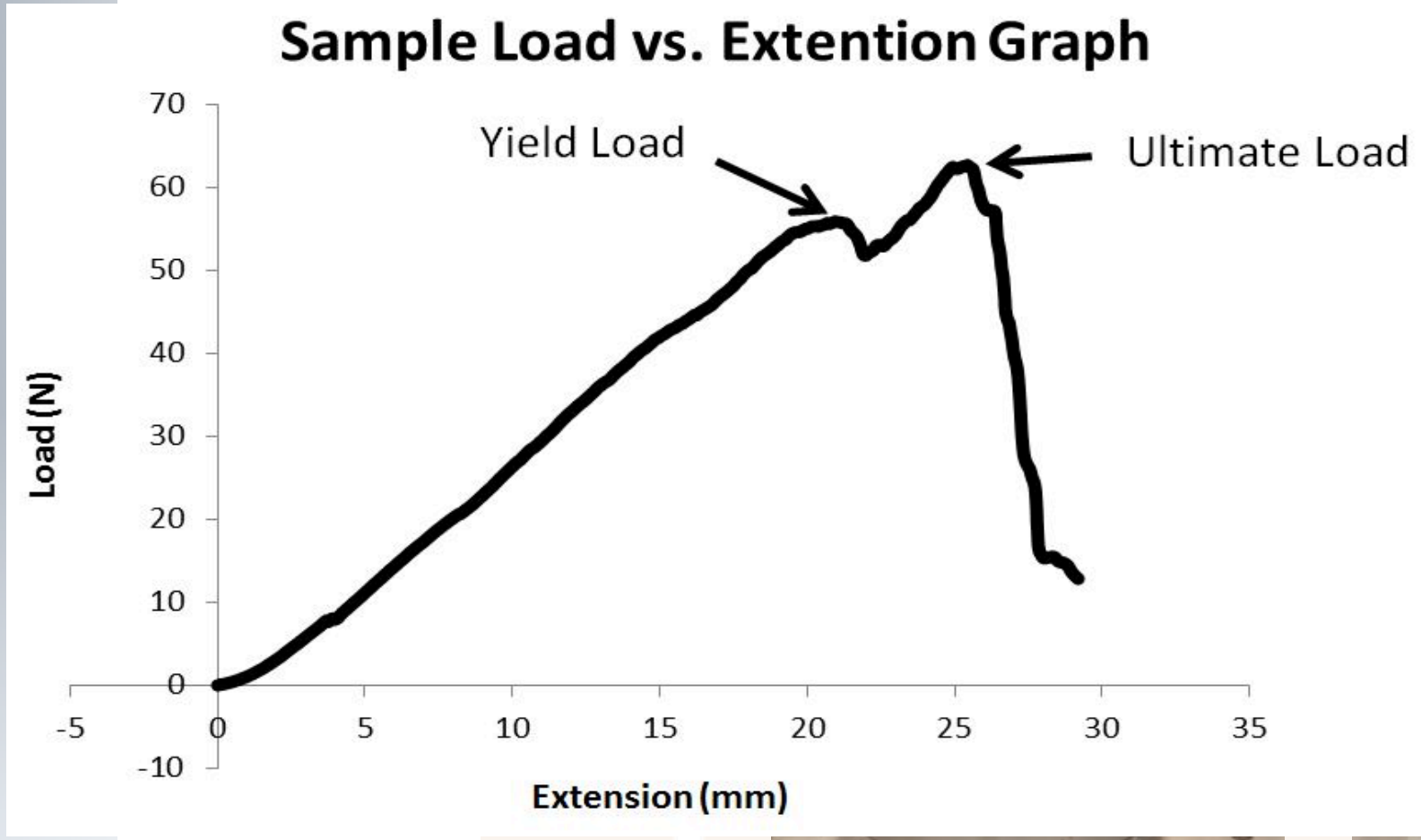


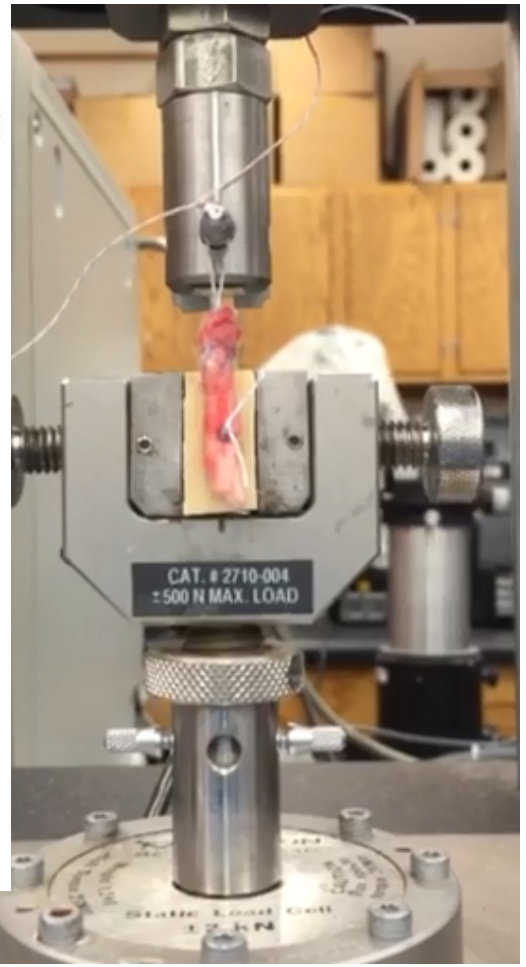
Device



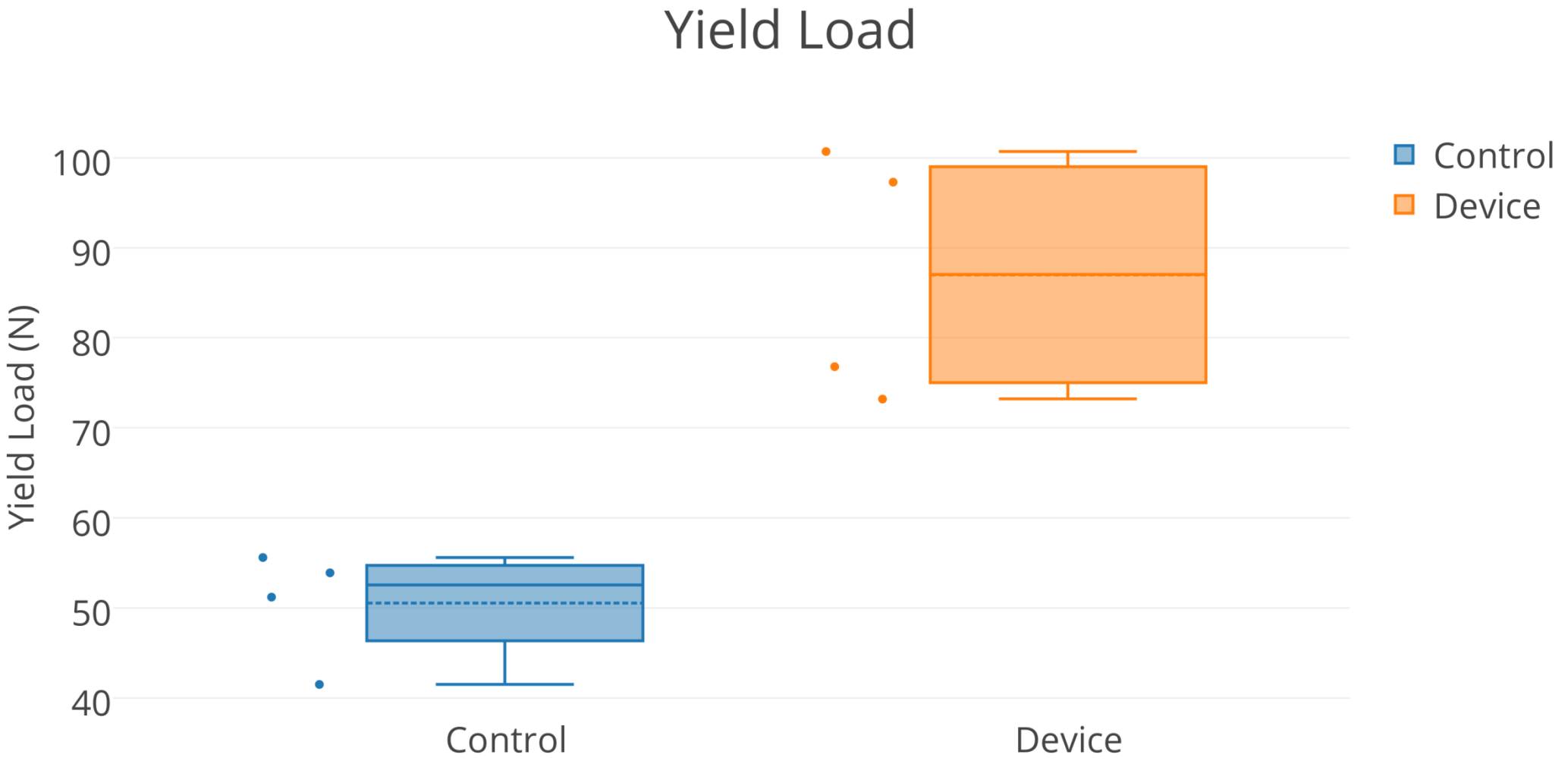
Tensile Failure Testing

- Pull to failure tests
- Looked at yield load and ultimate load
  - Yield load : begins to tear
  - Ultimate load: complete failure


Sample Load vs. Extention Graph
Yield Load
Ultimate Load
Load (N)
70
60
50
40
30
20
10
0
-10
-5
0
5
10
15
20
25
30
35
Extension (mm)


CAT. # 2710-004
±500 N MAX. LOAD

Yield Load


Yield Load
Yield Load (N)
100
90
80
70
60
50
40
Control
Device
Control
Device

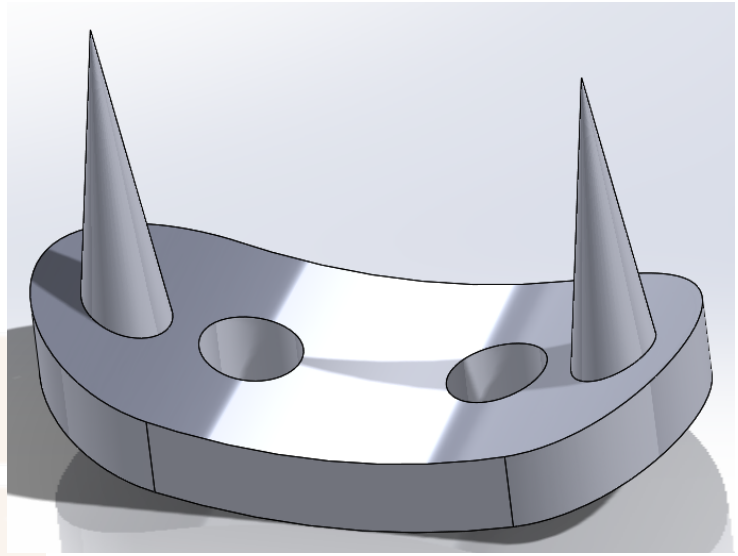
Yield Load

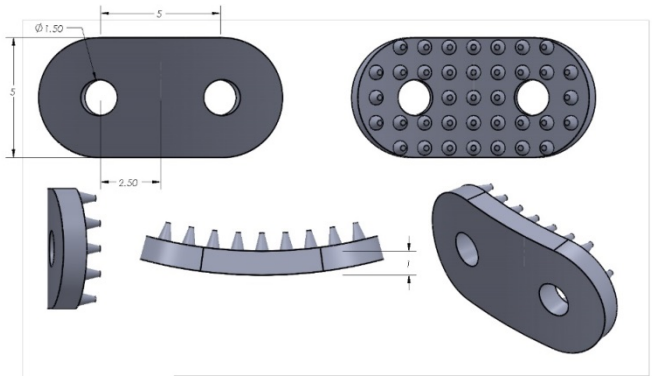
TABLE 3		
Results of Load-to-Failure Tensile Test		
	Yield Load, N	Ultimate Load, N
Device condition specimens		
1	73.2	73.2
2	100.7	104.1
3	76.8	76.8
4	97.3	124.9
Average	87.0	94.7
SD	14.0	24.3
Control condition specimens		
1	53.9	72.2
2	51.2	56.5
3	55.6	62.7
4	41.5	89.7
Average	50.6	70.3
SD	6.30	14.5

72% increase in Yield Load with Device Condition

Intellectual Property

- Provisional Patent Filed 9/23/14
- Pursuing partnership for manufacturing of surgical grade buttons (titanium/PEEK).
- Consideration for materials: titanium may allow for thinner implant for both cleated and spiked versions. (10x stronger versus flexion and 6x stronger versus compression)
- Button Optimization: due to fracture of button during initial Instron trials, made holes smaller, centered to increase strength of implant. 3D printed buttons made of Acrylonite Butadiene Styrene (ABS)



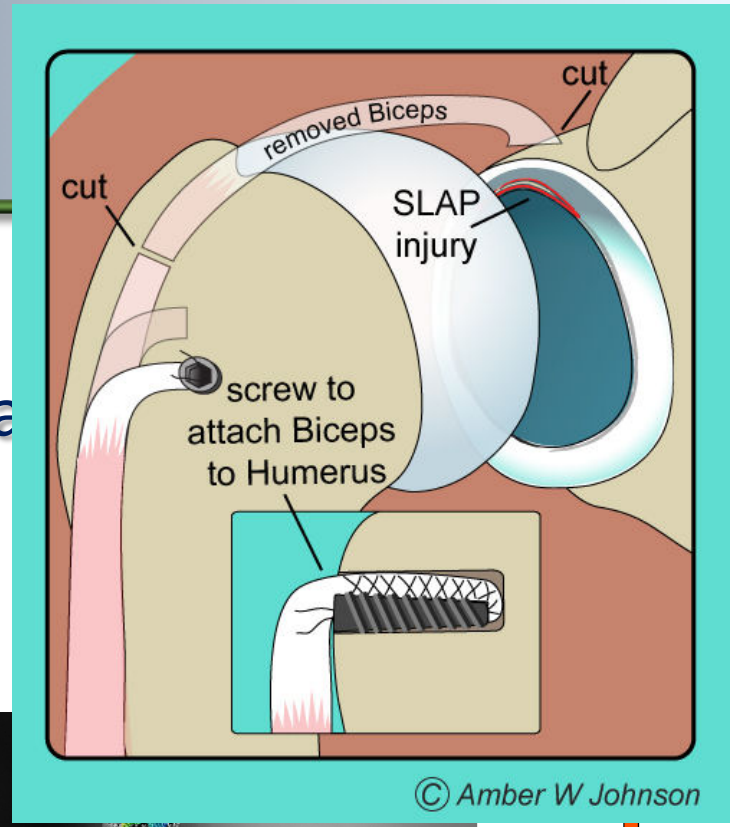


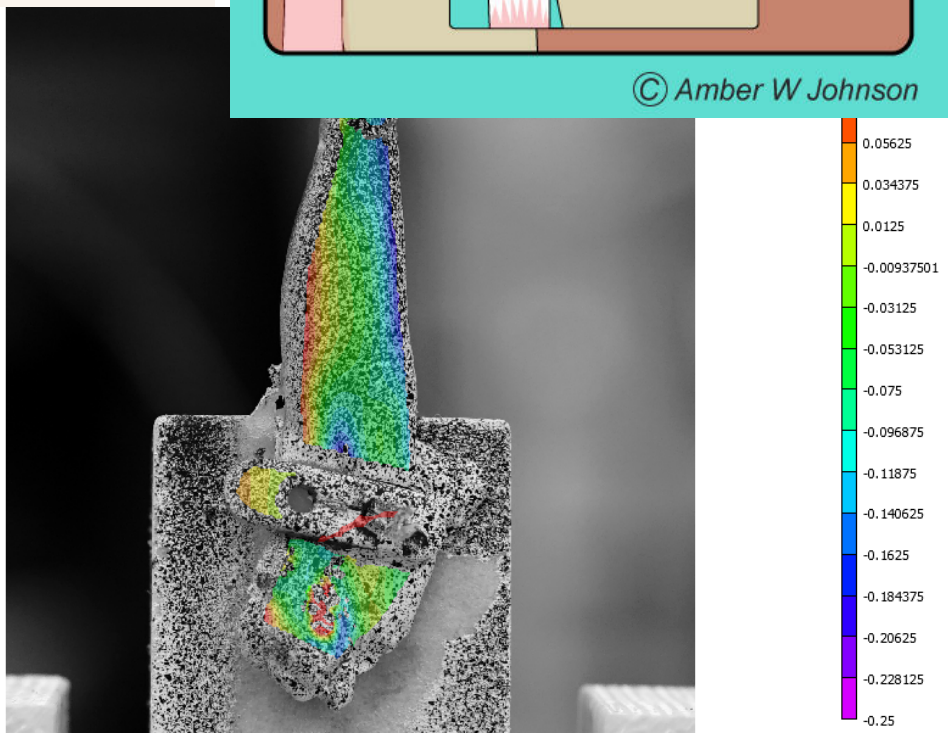
Intellectual Property-Future Directions

- ACUC Animal Protocol approved for rabbit in-vivo study
- IRB being written for MRI study for human subjects s/p tendon reattachment with/with-out suture button (Blemker/ Nacey/Miller)

Research Team

- Silvia Blemker PhD-Biomedical Engineering
- Capstone BME Team: Lauren Baetsen, Cate Ma
  McNulty, Audra Sawyer
- Chris Li, PhD-Mechanical Engineering
- Future Studies-
  - Master's Student?
  - Hilary Bart-Smith PhD?
  - Stephen Brockmeier MD?
  - Aim 2: In Vivo Rabbit Achilles Study
    - MRI evaluation
    - Histology
    - Mechanical Testing





Capstone Team

Thank You! jsp3x@virginia.edu