UTendoSleeve – A tendon-to-muscle Fixation Device

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Description of the Problem

Artificial tendon-muscle connections have traditionally relied on sutures. The technique typically used is known as a lock-in-loop stitch. While effective initially, it presents several drawbacks. Sutures can induce scarring in the muscle tissue, leading to disruptions in muscle function and blood flow. Moreover, they are prone to snapping due to uneven force distribution across the muscle.

To address these issues, our UTendoSleeve endeavors to distribute muscle force evenly across various points within the sleeve. Furthermore, we prioritize biocompatibility, flexibility, and the ability to withstand walking loads on the gastrocnemius muscle.

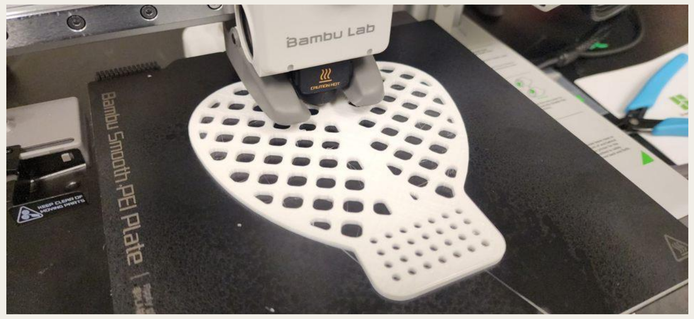
Design Specifications

Functionality

- Does not split tendon fibers
- Does not detach from artificial tendon nor muscle
- Allows room for 10-20 locking loop sutures
- Withstands 5330 Newtons of force
- Encourages muscle regrowth and rehabilitation
- Flexible to stretch and bend with muscle movements

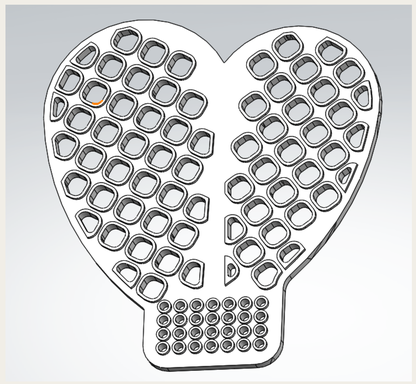
Material

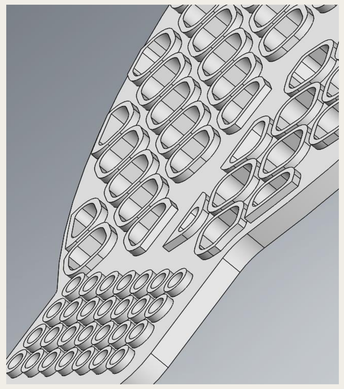
- Biocompatible
- Machinable
- 3-D printable
- Elongates between 18-52% of muscle length



Design Methodology

- Started with a general idea of a fixation point to be a sleeve to distribute forces
- Heart shape was decided on to match the gastrocnemius muscle heads
- Holes placed at bottom paddle so that the needle won't cause damage to print
- Windows along top were placed at angles to match the pennation angle of each head of the muscle
- Grommets were placed around holes to reinforce prototype integrity to ensure sutures did not tear through





Final Design

- Made from 3D printed TPU
- "Heart" shape to match the anatomy of the gastrocnemius muscle
- One side grommeted for extra strength, one side smooth to reduce muscle irritation
- Paddle of sleeve as an attachment point for an artificial tendon
- "Squoval" shaped muscle windows oriented along pennation angles to best accommodate necessary flexibility of the sleeve

Testing

Test 1: Tensile Loading until Failure

- Secure the suture sleeve within an Instron machine and increase the tensile load (Newtons) until failure
  - Acceptance Criteria: Withstand up to 5330 N without breaking or plastically deforming

Test 2: Cyclical Loading Testing

- Place the goat leg and suture sleeve attachment in a cyclical loading machine and run; 100-1000 cycles will be conducted
  - Acceptance Criteria: Shows no evidence of tearing or plastic deformation

Results

Tensile Test:

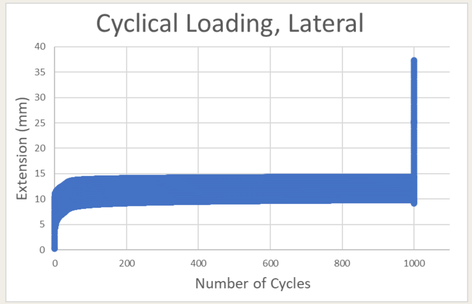
	Averages (N)
Lateral	128.31
Medial	142.82
Corners	133.74
Flats	137.39

Part of Sleeve	Flat or Corner	Edge or Midline	Load at Break (N)	Failure Point
Lateral	Flat	Midline	136.87	Knot
Lateral	Flat	Edge	127.75	Knot
Lateral	Corner	Midline	110.2	Knot
Lateral	Corner	Edge	138.41	Knot
Medial	Flat	Midline	147.52	Knot
Medial	Flat	Edge	137.41	Knot
Medial	Corner	Midline	141.64	Knot
Medial	Corner	Edge	144.7	Knot
Paddle	N/A	Midline	141.64	Knot
Paddle	N/A	Edge	146.1	Knot

Cyclical Load Testing:

- 4.5mm/s rate

Part of Sleeve	Preset Max Load	Number of Cycles	Load at Break	Failure Point
Medial	60N	1000	135N	Suture knot
Lateral	60N	1000	155N	Suture knot
Paddle	230N	<1	130N	Suture knot
Paddle	115N	342	115N	Suture knot



Key Takeaways:

- In all tests, the main failure point was the knot of the suture
- For surgical settings, a stronger suture would need to be used
- Potential future research would include optimizing material choice and testing with multiple types of sutures

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