Usability and Performance Evaluation of a Novel Surgical Suture Needle in a Cadaveric Tendon Model

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Background

- In practice, the use of a whip stitch versus a locking stitch in anterior cruciate ligament (ACL) graft preparation is based on surgeon preference.
- Preference for efficiency and shorter stitch time typically choose a Whip Stitch.
- Those who require improved biomechanical properties select a locking stitch

Objective

- Evaluate a novel suture needle design that can be used to perform two commonly used stitch methods, a whip stitch, and a locking stitch
- Compare graft preparation time and biomechanical properties of stitched graft constructs

Stitch Methods & Product

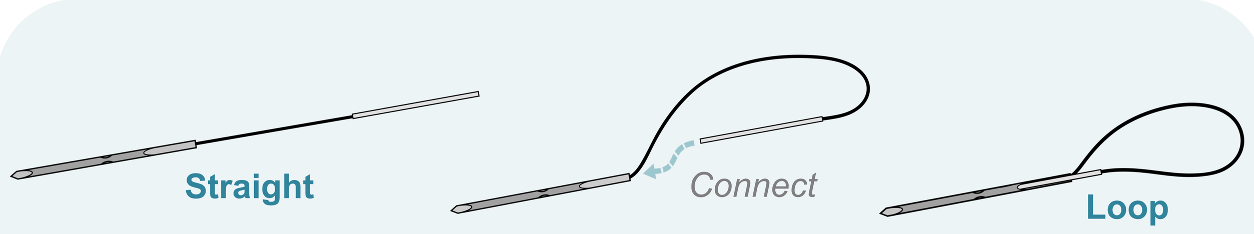

Figure 1. Illustration of novel two-part needle product in straight and loop positions used to create both stitch patterns

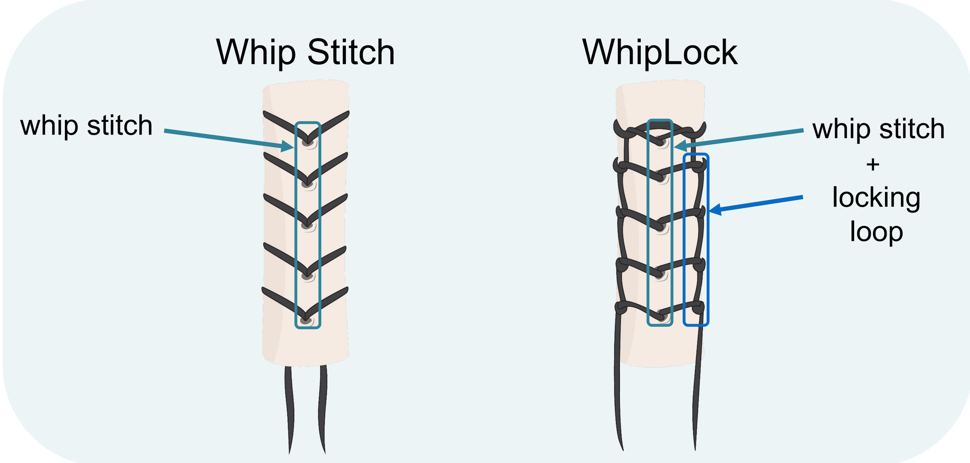

Figure 2. Illustration of Whip Stitch and locking whip stitch (WhipLock) patterns

- Whip Stitch = single needle pass stitches both sides of tendon
- WhipLock = sutures looped around to create locking mechanism

Grouping

Table 1. Experimental test groupings

Group	Sample Size	Users	User ID	Method
1	12	2	1A, 3F	Whip Stitch
2	12	2	1A, 3F	WhipLock
3	12	2	2A, 4F	Whip Stitch
4	12	2	2A, 4F	WhipLock
Total	**48**	User Training Level = A: Attending; F: Fellow		

Table 2. Pooled experimental test groupings

Group	Sample Size
Whip Stitch (WS)	24
WhipLock (WL)	24
Total	**48**

- Users completed stitching under simulated surgical conditions in a randomized order. Five evenly spaced points were marked 0.5 cm apart as a guide to create a 5-stitch series.

Methods

Graft Preparation Time
- Time for graft preparation was recorded for each sample

Biomechanical Testing
- A standardized length of tendon, 10 cm, was coupled to the MTS actuator by passing it through a cryoclamp cooled by dry ice to a temperature of -5°C.

Pre-Conditioning
- 25-100 N for three cycles
- 89 N hold for 15 minutes

Cyclic Loading
- 50-200 N for 500 cycles at 1 Hz

Failure Loading
- 20 mm/min ramp to failure

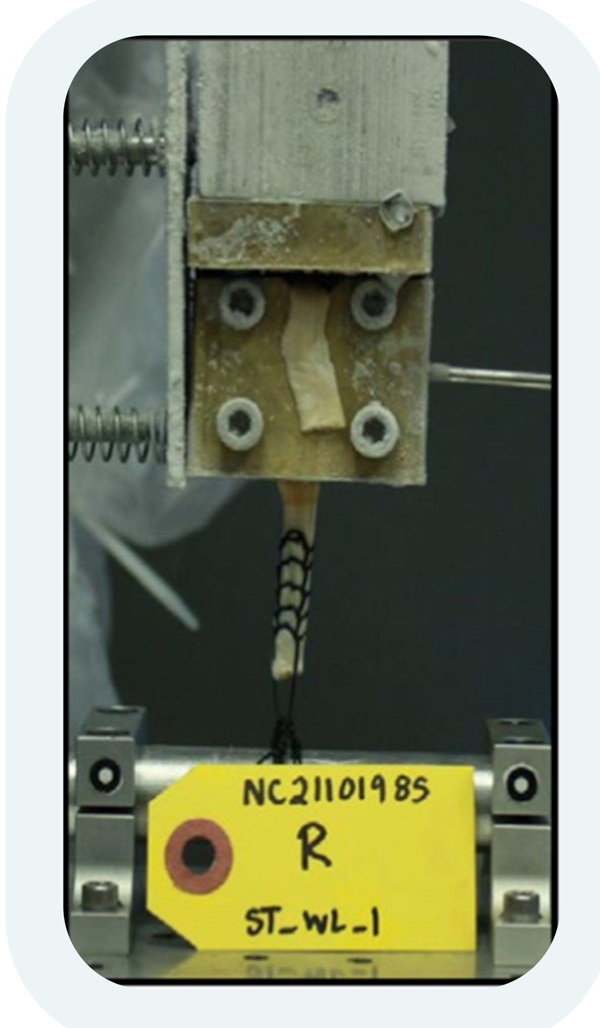

Figure 3. Biomechanical test setup

Metrics of Interest
- Peak-to-peak displacement (mm)
- Stiffness (N/mm)
- Ultimate failure load (N)
- Failure mode

Statistical Analysis
- Data are presented as averages and standard deviations. A Wilcoxon signed-rank test was used to evaluate the groups for time to complete stitch and biomechanical performance. Statistical significance was set at P = .05.

Results

Graft Preparation Time

Table 3. Graft preparation time results

Grouping		total time (min:sec)	p Value
Whip Stitch	User 1A	1:13	0.66
	User 3F	1:12	
Whip Stitch	User 2A	1:48	0.033
	User 4F	1:25	
WhipLock	User 1A	1:59	0.068
	User 3F	1:40	
WhipLock	User 2A	3:44	0.0023
	User 4F	2:03	

Group	total time (min:sec)
Whip Stitch	1:25
WhipLock	2:20

Overall, the Whip Stitch (WS) was 40% faster than the WhipLock™ (WL) stitch (WS, 1 min 25 sec; WL, 2 min 20 sec: p<0.001) (Table 3)

Biomechanical Testing

Within groups, no significant differences were found between Users and all stitches were biomechanically equivalent. Secondary analysis was performed to pool the stitch data according to Table 2.

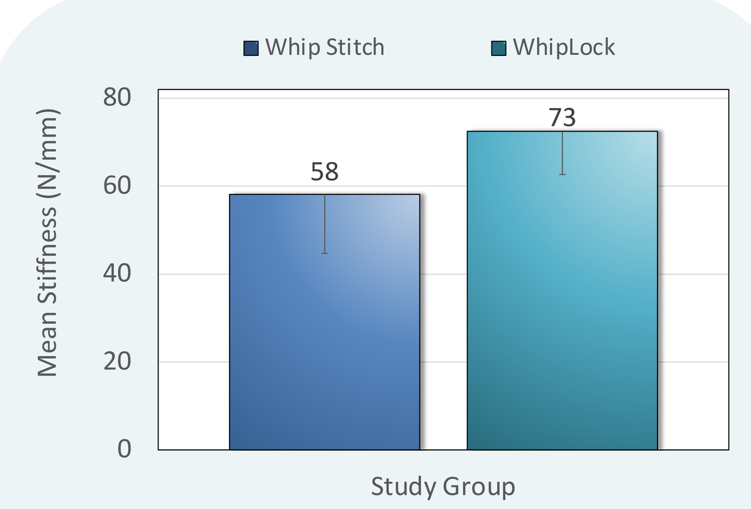

Figure 4. Stiffness results

Results (Continued)

Averages for peak-to-peak displacement (mm), stiffness (N/mm), and ultimate failure load (N) are presented in Figure 4-6.

WhipLock constructs significantly reduced peak-to-peak displacement by 55% (p=.001), increased stiffness by 25% (p <.001), and increased ultimate failure load by 35% (p<.001).

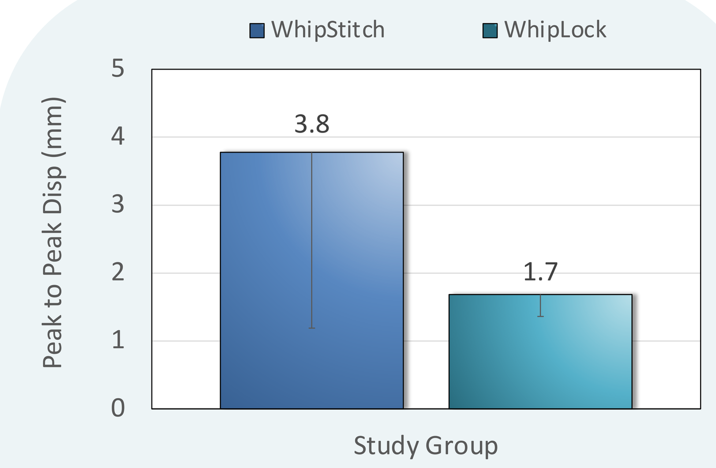

Figure 5. Peak to Peak Displacement Results

Failure Modes

Common mode of failure for Whip Stitch was by tendon damage whereas the WhipLock was by suture breakage.

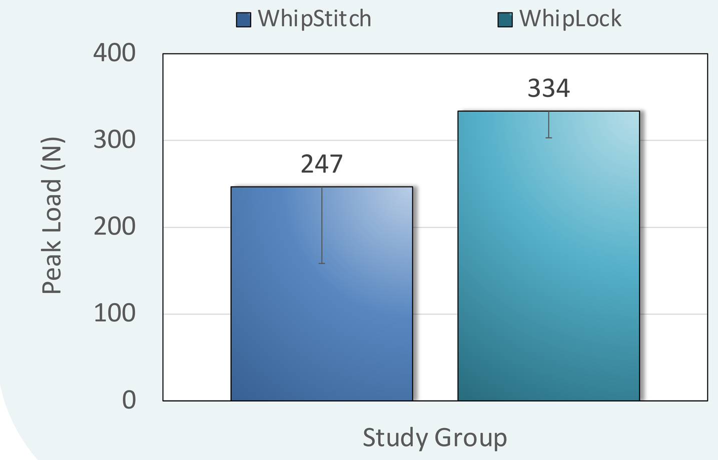

Figure 6. Ultimate load results

Table 4. Failure mode results

Group	Tendon Damage	Suture Breakage
Whip Stitch	75%	25%
WhipLock	8%	92%

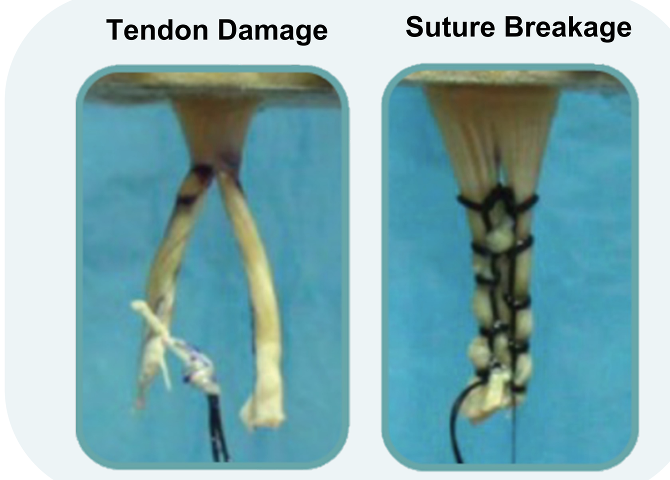

Figure 7. Representative common failure mode images for Whip Stitch (left) and WhipLock (right)

Conclusion

- Differences in **training level and graft preparation time** between Users **did not impact biomechanical performance** of stitched graft constructs.
- The **WhipLock stitch significantly improved biomechanical performance** compared to the Whip Stitch through reduced peak-to- peak displacement, increased ultimate failure load, and increased average construct stiffness.
- Added **strength benefits** of the **WhipLock stitch took**, on average 2min 20sec, only **55 seconds more** to complete than the **Whip Stitch**.
- Clinically, having a **suture needle device** available which can be used to **easily perform different constructs** including one with significant strength advantages **regardless of level of experience** is of benefit.

Future Work

- Understanding stitch method biomechanics in other tissue types and anatomical sites (Achilles, biceps, etc.)
- Expanding timing and biomechanics testing to overall procedure including preparation and fixation steps

References

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