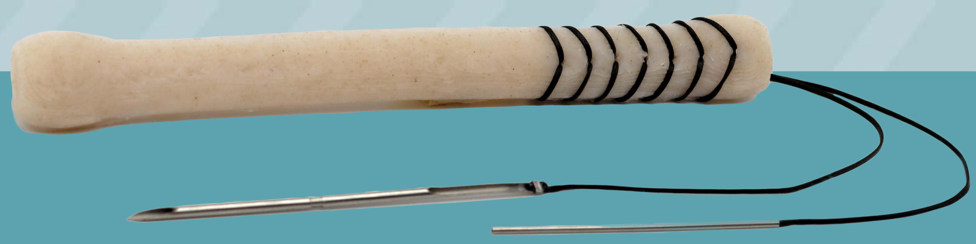
SUMMARY OF EASYWHIP™ PRE-CLINICAL TESTING
WINTER INNOVATIONS R&D | DATA ON FILE

EASYWHIP™ SUTURING PROVIDES BIOMECHANICALLY EQUIVALENT TENDON CONSTRUCT STRENGTH WITH IMPROVED EASE OF USE AND TIME

Summary of pre-clinical bench testing performed on *ex vivo* porcine tissue, data on file. Clinical results in humans are unknown.



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EASYWHIP™ SUTURING PROVIDES BIOMECHANICALLY EQUIVALENT TENDON CONSTRUCT STRENGTH WITH IMPROVED EASE OF USE AND TIME

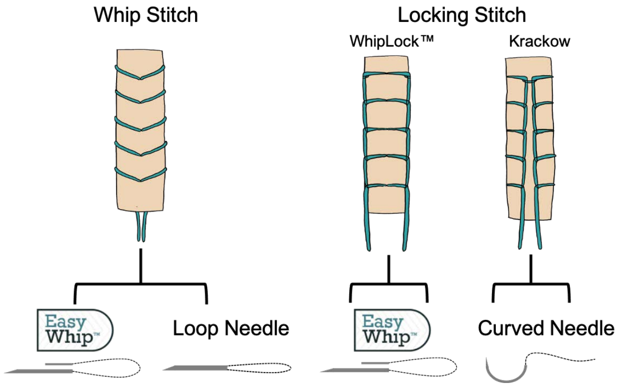
ABSTRACT

OBJECTIVES

This pre-clinical study aimed to evaluate EasyWhip™ in a simulated use setting by orthopedic specialists on animal tissue and compare performance to currently marketed needle products. Both whip stitch and locking stitch patterns were evaluated.

METHODS

Test groups are outlined in **Figure 1**. Four groups were compared with two main categories of (a) locking stitches and (b) whip stitches. Within each category, both EasyWhip™ and an existing needle product were used to create the same stitch method. All sutures were #2 Ultra High Molecular Weight Polyethylene (UHMWPE).



Stitch Technique	Product	Sample Size
Locking Stitch (WhipLock™)	EasyWhip™ w/ UHMWPE Suture	12
Locking Stitch (Krackow)	Curved Needle w/ UHMWPE Suture	12
Whip Stitch	EasyWhip™ w/ UHMWPE Suture	12
Whip Stitch	Loop Needle w/ UHMWPE Suture Loop	12
		48

Figure 1: Test groups

Three orthopedic specialists (one surgeon, one resident, and one physician assistant) prepared porcine deep digital flexor tendon grafts in a simulated use setting. Each user prepared 4 grafts from each group, with a total of 16 grafts prepared per user and 48 grafts prepared in total. One-way ANOVA analyses were performed to compare results between groups.

Procedure Duration Testing

Time to complete one 5-stitch series was recorded and compared between groups.

Biomechanics Testing

Stitched grafts were then subjected to biomechanics testing on a materials testing machine. The test method began with three cycles from 25 N to 100 N and a one-minute hold at 50 N to remove slack in the system. Cyclic loading was then competed by subjecting the samples to 200 cycles between 50 N to 175 N at a rate if 200 mm/min to simulate a walking cadence. Following cyclic loading, the samples were pulled at a rate of 100 mm/min until failure occurred. Load and elongation data were collected every 0.1 seconds for the duration of the test method, and results were compared between groups.

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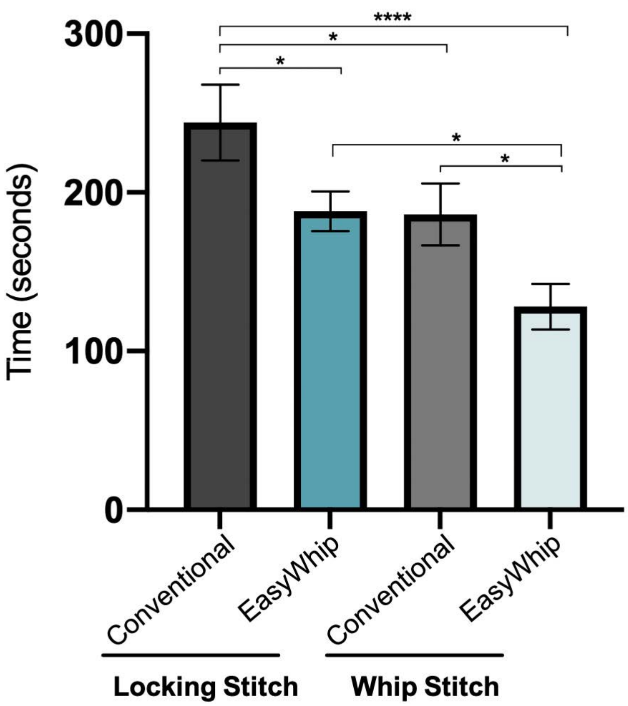
RESULTS

Procedure Duration Testing

Creating a locking stitch (WhipLock™) with EasyWhip™ took 3:08 on average, whereas creating a locking stitch (Krackow) with a curved needle and suture took 4:05. Creating a whip stitch with EasyWhip™ took 2:08 on average, whereas creating the same stitch with a loop needle took 3:06. Results are summarized in **Figure 2**. Time savings were statistically significant at a 0.1 confidence level. Using EasyWhip™ to create a whip stitch or a locking stitch can save up to 2 minutes per 5-stitch series, and it is common that 2-4 stitch series must be created to prepare a soft tissue graft during surgery. Standard deviation values for time required to complete a stitch series were lower for stitching performed with EasyWhip™. All three users felt that it was easy to learn how to use EasyWhip™ and preferred it over conventional suturing needle products.



[P<0.1 *, P<0.01 **, P<0.001 ***, P<0.0001 ****]

		Mean (min:sec)				Mean (sec)	Std. Deviation	
		User 1 Resident	User 2 PA	User 3 Surgeon	Overall	Overall	Overall	n
Locking Stitch	Conventional	4:37	4:55	2:40	4:04	244	82.84	12
	EasyWhip	3:01	3:48	2:35	3:08	188	43.44	12
Whip Stitch	Conventional	3:18	2:57	3:04	3:06	186	67.46	12
	EasyWhip	2:32	2:11	1:41	2:08	128	49.83	12

Figure 2: Stitch timing results

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RESULTS (CONTINUED)

Biomechanics Testing

Cyclic Loading

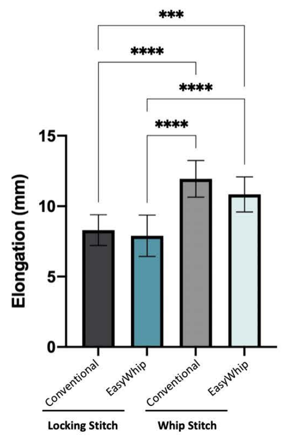
Total cyclic elongation is defined as the elongation of the sample from the end of the first cyclic cycle to the end of 200th cyclic cycle. Results are summarized in **Figure 3**. In general, locking stitches experienced lower total cyclic elongation than whip stitches.

Load to Failure

Total elongation at failure is defined as the elongation of the sample from the end of the first cyclic cycle to the point of failure. Results are summarized in **Figure 4**. Less variability was observed in the EasyWhip™ groups. In general, locking stitches experienced lower total elongation at failure than whip stitching.

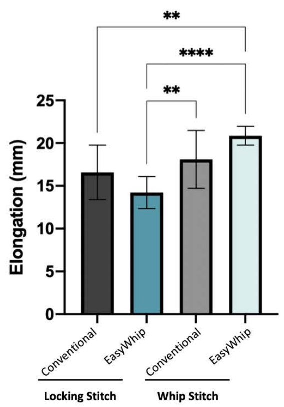
Tension load at failure is defined as the tension force on the sample at the time of failure. Results are summarized in **Figure 5**. In the testing environment EasyWhip™ whip stitches experienced 90N higher tension loads at failure than whip stitches made with a conventional needle (P=0.001).

[P<0.05 *, P<0.01 **, P<0.001 ***, P<0.0001 ****]



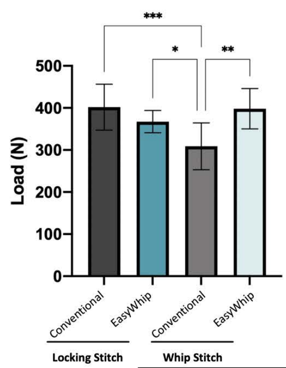
		Total Cyclic Elongation		
	Group	Average (mm)	Standard Deviation (mm)	n
Locking Stitch Conventional	D	8.30	1.09	12
Locking Stitch EasyWhip	B	7.90	1.47	12
Whip Stitch Conventional	C	11.95	1.30	8
Whip Stitch EasyWhip	A	10.84	1.25	11

Figure 3: Cyclic elongation



		Total Elongation at Failure		
	Group	Average (mm)	Standard Deviation (mm)	n
Locking Stitch Conventional	D	16.57	3.19	12
Locking Stitch EasyWhip	B	14.23	1.87	12
Whip Stitch Conventional	C	18.10	3.38	8
Whip Stitch EasyWhip	A	20.87	1.11	11

Figure 4: Total elongation at failure



		Tension Load at Failure (excluding cycling failures)		
	Group	Average (N)	Standard Deviation (N)	n
Locking Stitch Conventional	D	401.85	54.44	12
Locking Stitch EasyWhip	B	367.43	26.52	12
Whip Stitch Conventional	C	308.86	55.67	8
Whip Stitch EasyWhip	A	398.29	47.94	11

Figure 5: Tension load at failure

There were no statistically significant differences in any biomechanics metrics for locking stitches made with EasyWhip™ (WhipLock™) compared to locking stitches made with a conventional needle (Krackow), suggesting that novel WhipLock™ stitches are biomechanically equivalent to locking Krackow stitches made with conventional needle products. Thus, the WhipLock™ stitch is clinically viable for ligament and tendon repair.

Similarly, there were no significant differences in biomechanics metrics for whip stitches made with EasyWhip™ compared to whip stitches made with a conventional needle, so EasyWhip™ is capable of creating clinically viable whip stitches.

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RESULTS (CONTINUED)

			Mode of Failure (count)		
		Group	Premature Failure During Cyclic Loading	Suture Breakage (post cyclic loading)	Suture Pullout from Tendon (post cyclic loading)
Locking Stitch	Conventional	D	0	12	0
	EasyWhip	B	0	12	0
Whip Stitch	Conventional	C	4	1	7
	EasyWhip	A	1	4	7
	Total		**5**	**29**	**14**

Figure 6: Mode of failure results

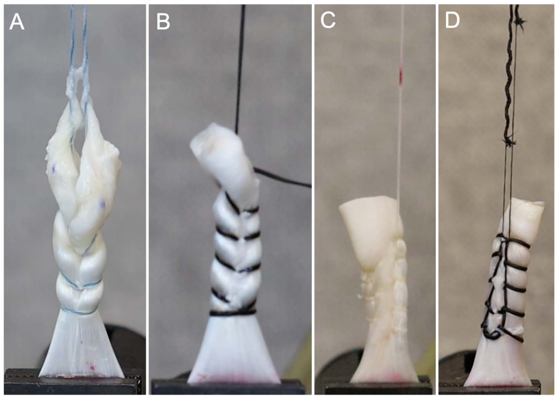

Figure 7: Mode of failure representative images
(A) whip stitch suture pullout from tendon (B) whip stitch suture break
(C) Krackow stitch suture break (D) WhipLock™ stitch suture break

Failure Mode
For each test sample the mode of failure was recorded. Results are shown in **Figure 6**. Suture breakage was the most common mode of failure for the locking stitches. Suture pullout from the tendon was most common with whip stitches. Representative images of failure modes for each stitch method are shown in **Figure 7**. Several whip stitch samples experienced premature failure during cyclic loading. These samples were not included in analysis for biomechanics endpoints.

In total, five whip stitch patterns failed prematurely during cyclic loading. Four were stitched with the conventional suture product and one was stitched with EasyWhip™. The premature failure rate for the whip stitch with a conventional needle was 33%, whereas the premature failure rate for the whip stitch with EasyWhip™ was only 8%. None of the locking stitch patterns failed prematurely during cyclic loading.

When preparing a graft with a conventional loop needle, one end of the graft must remain free from the prep stand to pass the loop from the bottom back to the top of the graft and place subsequent whip stitches. This makes it difficult for the user to adequately tension the sutures to remove slack. With EasyWhip™, both ends of the graft are secured on the prep stand and the user can tension the suture tails with greater leverage. It is thought that the excess slack in the whip stitched graft constructs prepared with conventional needles is a contributing factor to premature failure.

CONCLUSION

The data presented herein show that EasyWhip™ can create whip stitches and locking stitches that are biomechanically equivalent to the same stitch methods created using conventional stitching needle products, and EasyWhip™ provides several benefits over existing stitching needle products:

Speed
- Whip Stitching with EasyWhip™ is 30% faster than a conventional loop stitching needle (P=0.071)
- Using EasyWhip™ to create a locking stitch (WhipLock™) is 25% faster than a conventional curved stitching needle (Krackow stitch) (P=0.0864)

Usability
- 3/3 users preferred EasyWhip™ compared to the conventional stitching needles

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CONCLUSION (CONTINUED)

Biomechanics

- Whip stitches made with EasyWhip™ had a 90N higher load at failure (398 N vs. 309 N) and comparable elongation versus whip stitches made with a conventional needle.
- Locking Stitches made with EasyWhip™ had comparable load at failure and elongation versus a locking stitches made with a conventional needle.
- Statistically significant differences were observed between biomechanics endpoints for a whip stitch versus a locking stitch. When choosing between a whip stitch and a locking stitch, elongation and load requirements should be considered for each case.

Variation

- A smaller standard deviation was observed in the EasyWhip™ groups for time, total elongation at failure, and tension load at failure. This suggests that EasyWhip™ creates a more consistent graft and stitching with EasyWhip™ is less variable than conventional needles.

Failure

- Whip stitches failed from shredding/pulling through the tendon, and locking stitches failed from suture breakage.
- 33% (4/12) of whip stitches prepared with a conventional needle failed prematurely during cyclic loading, whereas only 8% (1/12) of whip stitches prepared with EasyWhip™ failed prematurely.

COMPARISON TO LITERATURE

Figure 10 compares results of this study to existing literature that performed similar testing. The values for elongation and tension load at failure that were obtained for EasyWhip™ whip stitches and locking stitches are comparable to those reported in existing literature.

mean ± SD	EasyWhip	Reference 1 Barber, et. al.	Reference 2 Deramo, et al.	Reference 3 Hahn, et al.	Reference 9 Michel, et al.	Reference 13 Su, et al.	Reference 14 White, et al.
Whip Stitch Elongation, mm	20.87 ± 1.11	19.5 ± 7.1	23.5 ± 8.7	16±.1 ± 3.0	18.65 ± 5.9	35.3 ± 5.1	17 ± 2.66
Whip Stitch Tension Load at Failure, N	367.43 ± 26.52	413 ± 95	337.3 ± 103.8	332.8 ± 26.2	392 ± 107	396.5 ± 26.6	344 ± 23.1
Locking Stitch (Krackow) Elongation, mm	14.23 ± 1.87	14.9 ± 4.4	11 ± 4.5	15.2 ± 5.3	10.59 ± 2.63	27.6 ± 4.6	15.6 ± 5.7
Locking Stitch (Krackow) Tension Load at Failure, N	398.29 ± 47.94	364 ± 24	376.2 ± 39.8	319.4 ± 21.7	553 ± 82	381.0 ± 25.2	301.3 ± 24.4

Figure 8: Comparison of results to existing literature

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