

# IDEAS AND INNOVATIONS Hand

# Learning Curve of Wrist-level Tendon Repairs Using a Novel Tendon Stapler versus Traditional Suture Methods

Russell J. Hendrycks, MD\* Evelyn R. Reed, MD\* Emily M. Graham, MD\* Niki K. Patel, MD, MSc† Megan Rosales, MS, MStat‡ Shaun D. Mendenhall, MD†

**Summary:** Numerous effective techniques for primary tendon coaptations exist. However, these techniques are complex and require a substantial amount of training to become proficient. Recently, a novel tendon stapler device (TSD) was developed that could potentially diminish the discrepancies among surgeons of varying levels of training. We hypothesized that the TSD would be easier to learn and would demonstrate improved learning curve efficiencies across participants of differing tendon repair experience compared with traditional suture methods. Participants included a novice, intermediate, and expert in tendon repairs. Comparisons were performed on wrist-level flexors and extensors from human donor arms. The suture repairs were performed with a modified Kessler with a horizontal mattress and were performed in one session on two donor arms by each participant. In a second session, each participant performed the TSD repairs on the matched, contralateral donor arms. Scatterplots fitted with Loess curves, one-way analysis of variance, Tukey pairwise comparisons, two-sided independent samples t test, and Fisher exact test were used to analyze findings. Results of our study showed that TSD repair times did not vary significantly by experience level. Suture repairs reached a stable "learned" level around repair #30, whereas the TSD repairs showed a more efficient curve that stabilized around repair #23. The TSD required less educational time, demonstrated a more efficient learning curve, and showed less variability across participants and repair order. Overall, the TSD is easy to adopt and may carry positive implications for surgeons and patients. (Plast Reconstr Surg Glob Open 2023; 11:e5167; doi: 10.1097/GOX.00000000005167; Published online 11 August 2023.)

#### **INTRODUCTION**

Executing strong, efficient tendon coaptations requires deliberate practice. However, it can be

From the \*Division of Plastic Surgery, Department of Surgery, University of Utah School of Medicine, Salt Lake City, Utah; †Division of Plastic, Reconstructive, and Oral Surgery, Division of Orthopaedic Surgery, Children's Hospital of Philadelphia, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pa.; and ‡Division of Epidemiology, Department of Internal Medicine, University of Utah School of Medicine, Salt Lake City, Utah.

Received for publication May 14, 2023; accepted June 23, 2023.

Presented at the 10th Annual Winter Meeting of the American Council of Academic Plastic Surgeons, New Orleans, La., February 23–February 26, 2023.

Copyright © 2023 The Authors. Published by Wolters Kluwer Health, Inc. on behalf of The American Society of Plastic Surgeons. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. DOI: 10.1097/GOX.00000000005167 challenging for trainees to gain proficiency performing tendon coaptations because no single, gold standard approach exists. Trainees must instead become familiar with a multitude of techniques and materials. Additionally, exposure to cases varies by individual training programs and can be limited by work-hour restrictions.<sup>1,2</sup> Due to limited tendon repair practice in residency and fellowship, extra time and resources are often dedicated for trainees to learn these complex techniques.<sup>3</sup> Thus, innovative approaches that are easy to learn should be explored to facilitate trainee proficiency.

A newly developed 510(k) Food and Drug Administration–cleared tendon stapler device (TSD) (CoNextions Medical Inc., Salt Lake City, Utah) (510(k) number: K203855) may mitigate many of the challenges trainees encounter. A recent randomized controlled trial comparing a four-strand locking cruciate suture repair technique with the TSD on zone 2 flexor tendons indicates that this new device is at least as safe and effective as traditional suture coaptations.<sup>4</sup>

Disclosure statements are at the end of this article, following the correspondence information.

In this study, we compared the learning curves of a standard, four-strand core suture technique with the TSD across individuals of differing tendon repair experience. We hypothesized that the TSD coaptations would require less educational time and would demonstrate less variability across study participants.

### **METHODS AND MATERIALS**

#### **Participants**

Participants included three individuals (novice, intermediate, and expert). The novice participant was a second-year medical student. The intermediate participant was a second-year plastic surgery resident. The expert was a board-certified, hand-fellowship-trained plastic surgeon.

#### Materials and Repair Techniques

Comparisons between the TSD and suture repairs were performed on six left and six right matched fresh frozen human donor arms. Each matched pair of arms came from one human donor; so one arm could be randomized into the suture group, and the contralateral arm could be randomized into the TSD group. Each participant performed repairs on two sets of matched arms.

A standard, four-strand Kessler with an additional horizontal mattress was used for the suture repairs. The expert participant trained the intermediate and novice participants to perform this technique. All suture repairs were performed with 3-0 Ethibond (Ethicon, Somerville, N.J.). The TSD repairs used a single, handsewn 5-0 polypropylene (Serag-Wiessner, GmbH & Co. KG, Naila, Germany) approximation suture to align the tendon ends followed by deployment of the staple. The TSD developers trained each participant to use the device (Fig. 1).



**Fig. 1.** This photograph depicts the tendon staple after deployment. The edges of the device are made of stainless steel, and the middle section that overlies the approximated tendons is made of ultra-high-molecular-weight polyethylene. The material, size, and design of the tendon staple are theorized to produce a flexible and secure tendon coaptation.

#### **Takeaways**

**Question:** Gaining competency in suture tendon repair techniques may be challenging without repeated practice. Does a novel tendon stapler device (TSD) produce a more efficient learning curve across participants of various experience levels when compared with a traditional suture technique?

**Findings:** Participants of varying levels of surgical experience performed tendon repairs via suture method or TSD. When compared with the suture technique, the TSD required less time to learn, demonstrated a more efficient learning curve, and showed less variability across participants and repair order.

**Meaning:** The TSD is easy to learn, simple to use, and requires less practice to become proficient.

Both training sessions included video demonstration, observation, and hands-on practice. Each participant demonstrated competency on a minimum of five tendon repairs per technique before data collection; however, the expert participant did not practice the suture technique. Educational times were recorded for each participant and repair technique.

#### **Statistical Analyses**

Statistical analyses used one-way analysis of variance, Tukey pairwise comparisons, two-sided independent samples *t* test, and Fisher exact test. Learning curves were compared across repair types and participants, using scatterplots fitted with Loess curves. Significance was determined with  $\alpha$  less than 0.05.

#### **RESULTS**

#### **Donor Arm Demographics**

Each participant repaired 76 tendons across four donor arms. There were no significant differences in age, weight, sex, or tendon width between donor arms (Table 1).

#### **Training Time and Learning Curves**

The suture technique required significantly more training time to learn than the TSD (suture repairs = 53.5 and 106 minutes for the intermediate and novice, respectively) (TSD repairs = 40.8 minutes, 37.5 minutes, 59.8 minutes for the expert, intermediate, and novice respectively) (P < 0.001). The average TSD coaptation time was 1.31 minutes versus 3.93 minutes for the average suture coaptation (P < 0.001). Experience level did not influence TSD repair times (P > 0.05).

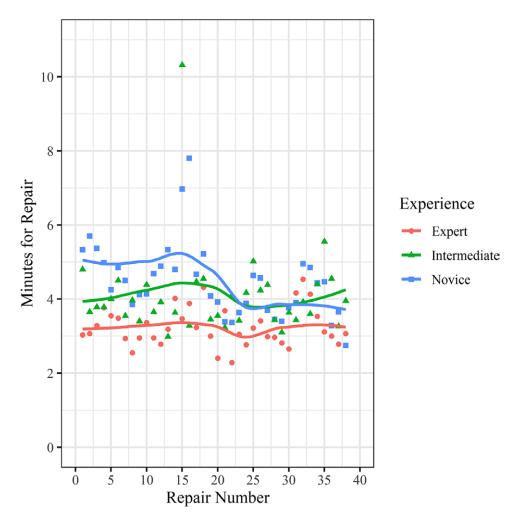
The plateau segment of the learning curve is the point where repair times stabilize and demonstrate decreased variability. The suture repair time decreased to a stable "learned" level around repair #30, and increased again toward the end of the session (Fig. 2). The TSD repair times for all participants stabilized around repair #23 and remained constant throughout the session (Fig. 3).

## Hendrycks et al • Learning Curve of Novel Tendon Stapler Device

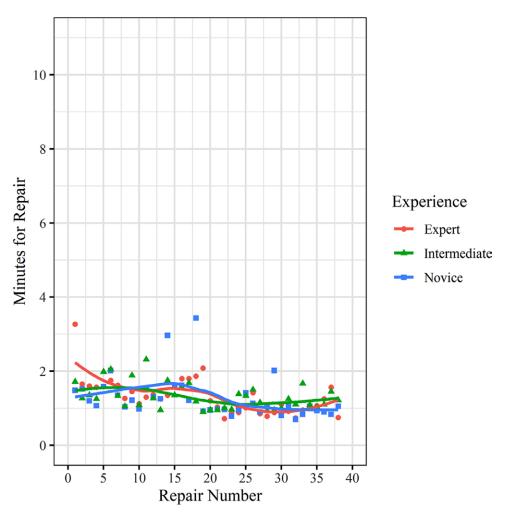
	Entire Cohort	Expert versus Intermediate P	Expert versus Novice P	Intermediate versus Novice P	TSD versus Suture Repair <i>P</i>
Gender		0.50	0.25	0.25	0.55
Masculine	4				
Feminine	2				
Age (y)		0.30	0.06	0.50	0.99
Average	63				
SD	1				
Range	61-64				
Weight (lbs.)		0.57	0.67	0.43	0.99
Average	155.7				
SD	14.3				
Range	132-175				
Tendon thickness (cm)					
Average	2.1	0.47	*0.02	*0.003	*0.009
SD	0.58				
Range	0.9-3.8				
Tendon width (cm)		0.23	0.59	0.10	0.99
Average	4.9				
SD	1.4				
Range	1.9-8.8				

#### **Table 1. Donor Arm Demographics**

\*Statistically significant value.



**Fig. 2.** Learning curves for the suture repair group. The suture repair time stabilized near repair #30 and increased again during later repairs toward the end of the session.



**Fig. 3.** Learning curves for the TSD repair group. The TSD repair times for all participants stabilized around repair #23 and did not demonstrate a subsequent increase for repairs that occurred later in the session.

TSD repair times also demonstrated less variability across participants and repair order.

#### **DISCUSSION**

In this study, we compared the learning curves of a four-strand core suture technique to a novel tendon stapler across individuals of differing surgical experience. The TSD required significantly less training time compared with sutures. This was expected because handsewn repairs are more technically demanding and complex than firing the device.

Our study is also the first to evaluate a novel tendon repair device between participants of varying experience levels.<sup>5</sup> This study showed that the TSD learning curves, compared with the suture counterparts, showed superior consistency among participants. This suggests that this device was equally easy to learn among participants. The degree of consistency reached at the end of each participant's curve also suggests that it is easier to master across educational levels (Figs. 2 and 3). These findings have implications for trainees learning to perform tendon repairs using multiple techniques, especially with work-hour and program-dependent case number limitations.<sup>6</sup> Although strategies to optimize training are being explored, improving existing techniques and investing in straightforward surgical devices should contribute to the solution.<sup>7,8</sup>

Access to specialty-trained hand surgeons can be challenging. Rural communities and low-income and middleincome countries often rely on general surgeons with minimal to no formal hand surgery training to repair hand injuries.<sup>9,10</sup> A device like the TSD may thus benefit surgeons across all of these settings because the device is easy to adopt and creates reliable repairs.

Study limitations include the use of a laboratory setting for the experiments, which does not capture the experience of an operating room. Further study is also warranted using a larger number of participants with varying levels of experience to enhance generalizability. Although our number of data points were similar to other studies examining tendon fixation techniques, additional research would allow increased power to examine any more nuanced differences between groups as well.

Ultimately, the TSD's technical accessibility and optimal learning curve may carry positive implications for patients around the world, as it improves consistency among surgeons of varying levels of experience.

#### Shaun D. Mendenhall, MD

Division of Plastic, Reconstructive, and Oral Surgery Division of Orthopaedic Surgery Children's Hospital of Philadelphia Perelman School of Medicine at the University of Pennsylvania Philadelphia, PA

E-mail: shaunmend@gmail.com

#### DISCLOSURES

Author Shaun D. Mendenhall is an educational consultant for PolyNovo, which is unrelated to this study. The other authors have no financial interest to declare in relation to the content of this article.

#### ACKNOWLEDGMENTS

This was an investigator-initiated and investigator-led study funded by CoNextions Medical Inc., Salt Lake City, USA. The statistical portion of this study was supported by the University of Utah Study Design and Biostatistics Center, with funding in part from the National Center for Research Resources and the National Center for Advancing Translational Sciences, and National Institutes of Health, through Grant 8UL1TR000105 (formerly UL1RR025764).

#### REFERENCES

- Levidy MF, Dobitsch A, Luis J, et al. A review of orthopaedic resident case logs to identify fluctuations in exposure to adult orthopaedic procedures. *JB JS Open Access*. 2021;6:e21.00023.
- 2. Antiel RM, Van Arendonk KJ, Reed DA, et al. Surgical training, duty-hour restrictions, and implications for meeting the accreditation council for graduate medical education core competencies: views of surgical interns compared with program directors. *Arch Surg.* 2012;147:536–541.
- 3. Bari AS, Woon CY, Pridgen B, et al. Overcoming the learning curve: a curriculum-based model for teaching zone II flexor tendon repairs. *Plast Reconstr Surg*, 2012;130:381–388.
- ClincalTrails.gov. Pivotal, randomized controlled trial to evaluate the safety and effectiveness of the CoNextions TR Implant System for zone 2 flexor tendon repair. Available at https://clinicaltrials.gov/study/NCT03622372. Published August 09, 2018– November 3, 2020.
- Irwin CS, Parks BG, Means KR. Biomechanical analysis of zone 2 flexor tendon repair with a coupler device versus locking cruciate core suture. *J Hand Surg Am.* 2020;45:878.e1–878.e6.
- Enani G, Watanabe Y, McKendy KM, et al. What are the training gaps for acquiring laparoscopic suturing skills? J Surg Educ. 2017;74:656–662.
- Schimpke SW, Larson BM, Veenstra BR, et al. Do one, do one, teach one: altering the dogma using simulation-based training to maximize efficiency of surgical resident education. *J Am Coll Surg.* 2020;231:140–148.
- 8. Tulipan J, Miller A, Park AG, et al. Touch surgery: analysis and assessment of validity of a hand surgery simulation "app." *Hand* (*N Y*). 2019;14:311–316.
- 9. Rios-Diaz AJ, Metcalfe D, Singh M, et al. Inequalities in specialist hand surgeon distribution across the United States. *Plast Reconstr Surg.* 2016;137:1516–1522.
- Elzinga K, Chung KC. Treating hand trauma in low-resource setting: a challenge for low- and middle-income countries. *Hand Clin.* 2019;35:479–486.