Pilot Evaluation of the TissueStat—A Novel Device for Minimally Invasive Spine Surgery Fascial Closure

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Study Design: Pilot Evaluation Study.

Objective: To assess the ease-of-use and performance of TissueStat, a novel minimally invasive spine surgery (MIS) fascial closure device, compared with conventional suturing techniques.

Summary of Background Data: Wound issues in spine surgery can be a major source of morbidity and decreased patient satisfaction. A robust, multilayered closure can lead to decreased complications and need for revision surgery. However, the development of technology to assist in MIS fascial closures has lagged.

Methods: Participants completed a fascial suturing trial using a benchtop model with both conventional suture and TissueStat. Time to completion and accuracy of each suture pass with were compared using the Student *t* test. After the trial, participants filled out a survey to quantify the ease of use and accuracy of conventional suture versus TissueStat. Survey responses were compared using descriptive statistics.

Results: Eight participants were recruited (5 orthopaedic surgery residents and 3 orthopaedic spine surgery fellows). This group performed 16 attempts with the conventional suturing technique and 16 attempts with TissueStat. The average time to knot completion of the conventional suturing technique was slower than TissueStat [3 min and 22 s (range: 1:27–5:19) vs. 2 min and 1 s (range: 1:22–3:15), $P = 0.001$]. The average distance from the suture location to the target dot was larger for the conventional suturing compared with TissueStat (1.25 vs. 0.22 mm, $P = 0.007$). Participants reported a higher average ease of use score for TissueStat compared with conventional suture (9.4 vs. 3.9). Participants reported a higher average accuracy rating for TissueStat compared with the conventional suture (9.3 vs. 6.1). All participants answered that TissueStat offered the higher quality closure and allowed better suture targeting.

Conclusion: TissueStat may be a useful tool to decrease operative time, improve closure accuracy/quality, and assist with meticulous fascial soft-tissue handling.

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Wound issues in spine surgery can be a major source of morbidity and decreased patient satisfaction, with surgical site infection rates reported in the literature ranging as high as nearly 20%.[1–3] In addition to their impact on surgical outcomes, suboptimal wound closure and delayed healing have also been identified as drivers of excess health care resource utilization and cost.[4] Unfortunately, there is minimal consensus regarding best practices for wound closure techniques.[3] Consequently, closure practices, instrumentation, and postoperative wound care are largely determined per surgeon preference and thus vary widely.

Despite this heterogeneity, one aspect of wound closure that has broad agreement among spine surgery providers is the importance of a multilayered closure, especially the necessity for a robust closure of the fascial layer. In one of the few works on this topic, Ward et al[5] demonstrated that multilayered closure technique resulted in a lower wound complication rate compared with a nonstandardized closure technique among patients undergoing spine surgery. Similarly, improper fascial closure technique has been associated with incisional hernia, pain, and even bowel incarceration.[6] Finally, a robust fascial closure is important in the setting of incidental durotomy and subsequent cerebrospinal fluid leak (CSF)—a watertight, multilayered closure can help prevent CSF fistula and potentially the need for revision surgery.[7,8] Unfortunately, minimally invasive spine surgery (MIS) techniques can make proper fascial closure challenging due to narrow tissue/retractor windows with a small working area for manipulation of the fascia. Although the evolution of MIS has seen expansive introductions of new technology for many procedural objectives, tissue closure innovation has largely lagged behind.

This study is particularly relevant in light of growing industry initiatives on long-term outcomes, coordinated services, and accountable care relationships such as the Centers for Medicare & Medicaid Services' (CMS) Transforming Episode Accountability Model (TEAM).[9]

Within this model, early complications such as wound issues, would be bundled within the first 30-day episode of care and thus hospitals would incur responsibility for associated cost after the beneficiary leaves the hospital.[9] Consequently, developments aimed at improving efficiency and viability of wound closure are essential to improving postoperative outcomes and maximizing value. For these reasons, the goal of the current work was to perform a small pilot study evaluating the efficacy and usability of a novel fascial closure device (TissueStat), which was specifically designed for use in a MIS context.

METHODS

Participants

All participants were either current orthopedic surgery residents or orthopedic spine surgery fellows at a single, large urban academic institution. Participants were recruited by an institution-wide invitation e-mail. Inclusion criteria were current orthopedic surgery residents at the postgraduate year-2 (PGY-2) level or higher, including several current orthopedic spine surgery fellows. All participants had extensive experience with suturing wounds using conventional suturing techniques. Participants were excluded if they had any prior experience with the novel fascial closure device (TissueStat). All participants received a brief instructional lecture regarding how to use the TissueStat device before any suturing trials taking place. Participants were not allowed to ask questions or otherwise interact verbally with staff during suturing trials.

Surgical Procedure

A simulated benchtop tissue model was utilized to compare conventional fascial suturing to a novel fascial closure device (TissueStat). The TissueStat is a fascial closure device that deploys a needle and suture with a curved, upward trajectory, eliminating the wrist rotation required by traditional needle drivers and simplifying needle passage in tight spaces. A tubular retractor (*P*/N 9560708; Medtronic) was attached to a secured METRx arm (*P*/N 9560524; Medtronic) to simulate MIS positioning and visualization. A finger cot was placed over the distal end of the tubular retractor to simulate a fascial layer. Using a disposable scalpel, a standardized defect was made in the finger cot similar to the size of a fascial wound for MIS procedures. Two ~1 mm dots were marked near the apex of the simulated fascial opening. The participants were instructed to target the dots with their needle (either conventional suturing needle or TissueStat). Working through the retractor, each participant placed 1 interrupted suture using size 0 TissueStat Suture through the finger cot material, then tied 3 knots for each simulated repair. The distance between the participant's suture placement and the dot target was measured.

One repair was completed using a UR6 needle and suture (*P*/N J603; Ethicon). Following conventional methods, the surgeon loaded a Castroviejo needle driver with the needle, drove the needle through the simulated fascial layer, and retrieved the needle using bayoneted forceps before tying the knots and securing them with a knot pusher. The model was then reset, and a second repair was performed. The second repair was completed using TissueStat (*P*/N TIS-004; DuraStat LLC, Austin, TX). The needle was retrieved and tied using the same forceps and knot pusher as the conventional repair. For each repair, the distance from the knots to the target dots was measured (mm) and the time for each repair was recorded. The timer started when the surgeon picked up the first instrument and ended when the third and final knot was secure. All materials and methods were identical between the 2 suturing trials other than the suturing device and the interfacing needle. The knot pusher was the device included in the TissueStat kit and was used for both repairs.

Statistical Analysis

Data collection sheets were filled out for each participant by an observer. Two trials were performed by each participant (each trial had a conventional suture attempt and a TissueStat device attempt). Recorded information included time to first suture completed, number of times instruments were picked up and placed down for each pass, and the distance from the target dots to the suture (mm). Data collection sheets also included a participant survey questionnaire to assess participants' comparative reactions to the 2 sutures. Questions with binary answers included "which device offered the higher quality closure," and "which device allowed you to best target a specific location?" (answers: "conventional" vs. "TissueStat"), and "if available in your hospital, would you use TissueStat for fascial closure?" (answers: "Y" vs. "N"). All remaining questions were answered on a Likert scale from 1 to 10, with 10 being the most positive answer.[10] Likert scale questions included "was the conventional suture easy to use?" "was TissueStat easy to use?" "how accurate was the conventional suture?" and "how accurate was TissueStat?". Finally, to approximate the "soft tissue handling" of conventional suture versus TissueStat, images of finger cots after both conventional suture placement and TissueStat trials were taken for each participant. Those images were then blinded to 2 independent reviewers, who rated the appearance of the finger cots on a scale of 1–10, with 1 denoting "Very Poor" soft tissue handling and 10 representing "Immaculate" handling. These grades were then averaged between the 2 reviewers for each suture type.

For continuous data, 2-tailed Student *t* test was used for parametric data and Mann-Whitney *U* test was used for nonparametric data (XLSTAT 2024.3.0.1423). Alpha was set at 0.05. Questionnaire results were compared with descriptive statistics.

RESULTS

Eight participants were recruited (5 orthopedic surgery residents and 3 orthopedic spine surgery fellows). In total, this group performed 16 attempts with the conventional suture and 16 attempts with the novel TissueStat

device. The average time to knot completion of the conventional suturing technique was slower than the TissueStat device [3 min and 22 s (range: 1:27–5:19) vs. 2 min and 1 second (range: 1:22–3:15), $P = 0.001$] (Fig. 1).

The average distance from the suture location to the target dot was larger for the conventional suturing technique compared with the TissueStat device (1.25 vs. 0.22 mm, $P = 0.007$) (Fig. 2). The results of the participant questionnaire largely matched the quantitative data regarding the performance of the conventional suture versus the TissueStat.

All participants responded to the postprocedure questionnaire. All participants answered that the TissueStat offered the higher quality closure and allowed better targeting to a specific location. Participants reported a higher average ease of use score for the TissueStat compared with conventional suture (9.4 vs. 3.9). Participants reported a higher average accuracy rating for the TissueStat compared with the conventional suture (9.3 vs. 6.1).

Images of the finger cots after conventional suture and TissueStat closure were graded by 2 independent reviewers after blinding to suture type used. The reviewers noted that TissueStat performed better with regard to soft tissue handling, with an average score of 7.88, when compared with conventional suture closure, which received a score of 5.63. Example images of tissue cots postclosure are included in Figure 3.

DISCUSSION

The present investigation was a small pilot study that used a benchtop simulation model to replicate a MIS tubular retractor and fascial wound to assess the efficacy and usability of the TissueStat, a novel MIS fascial closure device. In the present study, the average time to knot completion using the conventional suturing technique was significantly slower than with the TissueStat device. Furthermore, the accuracy of suture placement using the conventional technique was significantly worse than with the TissueStat device. There was more variability in both time to knot completion and accuracy with the conventional technique when compared with the TissueStat device. In assessing participants' subjective experience using the device, all participants answered that TissueStat offered a higher quality, more accurate closure.

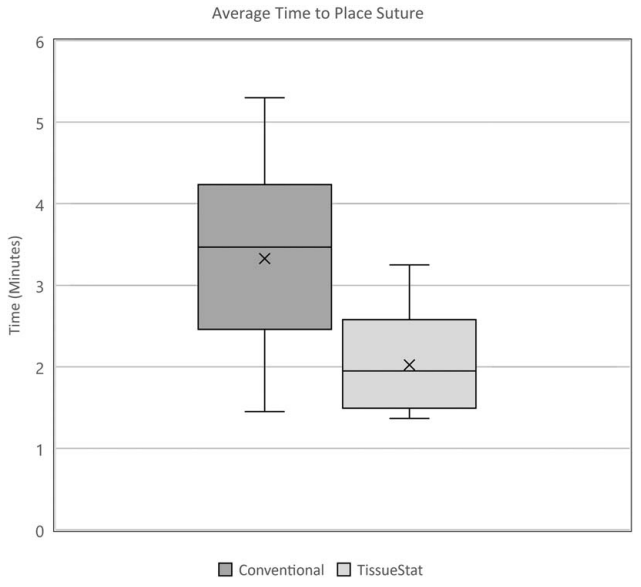

FIGURE 1. Average time to place suture.

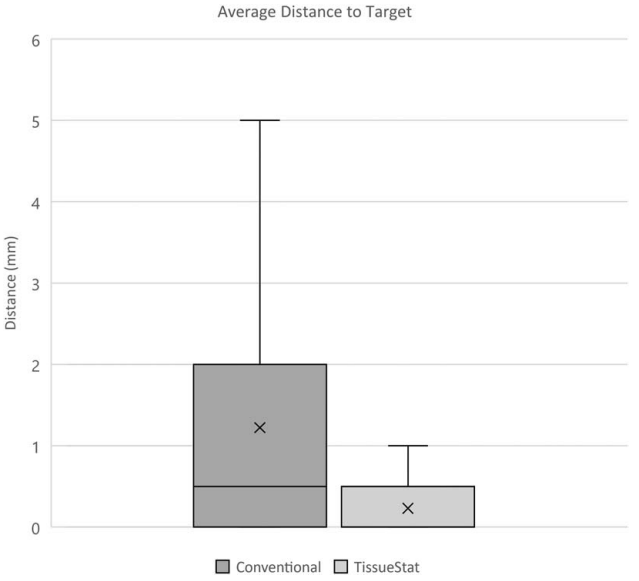

FIGURE 2. Average distance to target.

A quality, multilayered closure is paramount in spine surgery. Despite this, TissueStat is the among the first devices specifically designed to assist with fascial closure in MIS spine surgeries. In evaluating the efficacy of a particular fascial closure device, the authors deemed three factors to be of particular importance: efficiency, accuracy, and soft tissue handling. To that end, the present study compared the time to knot completion for conventional suturing with that using the TissueStat device. TissueStat was significantly faster than conventional suturing. TissueStat saved, on average, 1 minute and 20 seconds compared with the conventional suture technique, which is particularly impressive considering that all of the study participants had never used the TissueStat device before. A previous study examining fascial closure within spine surgery associated a faster closure time with decreased operating room costs per case, despite the increased cost of the suture examined within the study.[11] Given the average cost per minute of OR time has been estimated at nearly $50, the use of a specialized MIS fascial closing device such as TissueStat could potentially reduce health care expenditure and improve OR efficiency.[12] In addition to enabling faster closure, the closure times were much more consistent using TissueStat, as opposed to the conventional technique, where there was considerably higher variability in closure time. This improved consistency and ease of use of the TissueStat could improve predictability of closure times and allow less advanced trainees or nonsurgeons to potentially help with

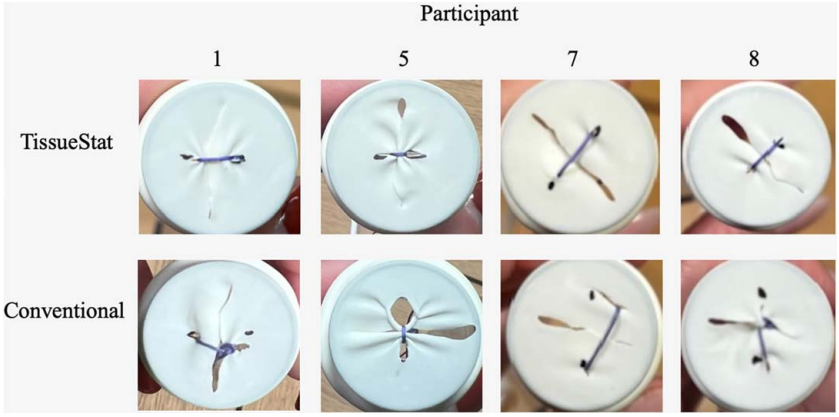

FIGURE 3. Representative images after suture placement. full color online

closure, helping ORs and spine surgeons to perform more efficiently. These factors may also contribute to a more ergonomic closure process due to TissueStat being designed specifically for use in MIS closure. A recent systematic review by Alostaz et al[13] mentioned that nearly 75% of spine surgeons reported musculoskeletal discomfort, including hand/wrist pain. The authors also mentioned that ergonomic concerns are linked to mental and emotional well-being and stress/burnout—factors which can be impactful on patient care.[13] These issues of ergonomics and time may be compounded in the setting of patients with elevated BMI. Prior literature has reported that MIS procedures in the setting of obesity can increase operative time.[14] Because the TissueStat has a long working length and allows for easier localization of tissue for suturing, it may translate well to specific clinical scenarios that place extra demand on MIS procedures, such as patients with obesity or other sources of poor visualization and surgeon positioning. Thus, TissueStat, which was universally described as easier to use than conventional suture by the current study's participants, may be a simple means of addressing these common issues.

In addition to enabling a faster and more reproducible closure, the present study demonstrated that closure using TissueStat may be more accurate as well. The average distance from the suture location to the target dot was over 1 mm larger for the conventional suturing technique compared with the TissueStat device. These quantitative results were substantiated by the results of the qualitative survey, wherein participants consistently noted that the TissueStat device was more accurate than conventional suture. The accuracy and integrity of fascial closure is of upmost importance within spine surgery to limit wound dehiscence, readmissions, and reoperations.[15–17] In addition to enabling decreased closure time and increased accuracy, TissueStat also performed better than conventional suture with regard to soft tissue handling during closure. Proper handling of soft tissues is essential for optimal wound healing.[18] When working in a confined space during MIS spine surgery, it can be difficult to cleanly puncture soft tissue with conventional curved suture. This can necessitate rougher handling of soft tissues to obtain closure. In contrast, the TissueStat system is specifically designed to facilitate ease of needle insertion and retrieval.

Although the current study indicates that TissueStat has a number of advantages in terms of both performance and surgeon preference compared with conventional suturing, this study is not without limitations. Foremost, the small sample size limits the statistical power of the current study. The goal of the current work was to perform a small pilot study evaluating the TissueStat compared with conventional suturing in both a quantitative and qualitative manner. However, future work will include more participants and will utilize a live surgical design with more suturing repetitions. Furthermore, this study was susceptible to selection and volunteer bias, by which participants may have certain interests and predeveloped skillsets that could affect suture performance in the study that may not be generalizable to other populations. This was hopefully ameliorated by only using orthopedic trainees at a single institution. Thus, training technique exposure was somewhat uniform among participants. Lastly, although the simulation model was relatively robust, it does not exactly mimic the consistency of human tissue. As such, further studies should examine how the TissueStat device may affect closure timing and accuracy on a cadaveric model or in a live intraoperative setting. Finally, although designed with MIS challenges and principles in mind, the TissueStat is a relatively simple platform that is adaptable to broader applications. Due to the complexity of neighboring anatomy and the challenges with approaching the spine from different orientations and at different levels, there are numerous opportunities for application of the TissueStat. Future work will focus on these potential outlets to evaluate the impact of this novel device on the demands of specific clinical procedures.

CONCLUSIONS

The current work was a small pilot study utilizing a benchtop model to show that the novel MIS fascial closure device, TissueStat, outperformed conventional suturing in terms of accuracy, speed and disruption to soft tissues among a small group of orthopedic residents and orthopedic spine surgery fellows. In addition, a survey of participants after

trialing the 2 suture techniques demonstrated overwhelming preference for the TissueStat compared with conventional suturing. Given the particular challenges and importance of fascial closure in MIS spine surgery and the lack of specialized equipment to address these needs, the present study addresses a substantial paucity in the literature. However, further work is needed to confirm these results with more participants and repetitions and ideally in the intraoperative setting.

REFERENCES

1. Silber JS, Anderson DG, Vaccaro AR, et al. Management of postprocedural discitis. *Spine J Off J North Am Spine Soc*. 2002;2:279–287.
2. Rechtine GR, Bono PL, Cahill D, et al. Postoperative wound infection after instrumentation of thoracic and lumbar fractures. *J Orthop Trauma*. 2001;15:566–569.
3. Yilmaz E, Blecher R, Moisi M, et al. Is there an optimal wound closure technique for major posterior spine surgery? A systematic review. *Glob Spine J*. 2018;8:535–544.
4. Whitmore RG, Stephen J, Stein SC, et al. Patient comorbidities and complications after spinal surgery: a societal-based cost analysis. *Spine*. 2012;37:1065–1071.
5. Ward JP, Feldman DS, Paul J, et al. Wound closure in nonidiopathic scoliosis: does closure matter? *J Pediatr Orthop*. 2017;37:166–170.
6. Januszewski J, Vivas AC, Uribe JS. Limitations and complications of minimally invasive spinal surgery in adult deformity. *Ann Transl Med*. 2018;6:109.
7. Suter A, Spirig JM, Fornaciari P, et al. Watertightness of wound closure in lumbar spine—a comparison of different techniques. *J Spine Surg*. 2019;5:358–364.
8. Tosun B, Ilbay K, Kim MSM, et al. Management of persistent cerebrospinal fluid leakage following thoraco-lumbar surgery. *Asian Spine J*. 2012;6:157–162.
9. CMS. Transforming Episode Accountability Model (TEAM). Accessed December 28, 2024. https://www.cms.gov/priorities/innovation/innovation-models/team-model
10. Sullivan GM, Artino AR. Analyzing and interpreting data from Likert-type scales. *J Grad Med Educ*. 2013;5:541–542.
11. Aiman U, Shahzad UB. Revolutionising spinal surgery: the impact of STRATAFIX^{TM} symmetric barbed sutures on closure time and costs. *Neurosurg Rev*. 2024;47:457.
12. Smith T, Evans J, Moriel K, et al. The cost of OR time is $46.04 per minute. *J Orthop Bus*. 2022;2:10–13.
13. Alostaz M, Bansal A, Gyawali P, et al. Ergonomics in spine surgery: a systematic review. *Spine*. 2024;49:E250–E261.
14. Abbasi H, Grant A. Effect of body mass index on perioperative outcomes in minimally invasive oblique lateral lumbar interbody fusion versus open fusions: a multivariant analysis. *Cureus*. 2018;10:e2288.
15. Akins PT, Harris J, Alvarez JL, et al. Risk factors associated with 30-day readmissions after instrumented spine surgery in 14,939 patients: 30-day readmissions after instrumented spine surgery. *Spine*. 2015;40:1022–1032.
16. McCormack RA, Hunter T, Ramos N, et al. An analysis of causes of readmission after spine surgery. *Spine*. 2012;37:1260–1266.
17. Goz V, Weinreb JH, McCarthy I, et al. Perioperative complications and mortality after spinal fusions: analysis of trends and risk factors. *Spine*. 2013;38:1970–1976.
18. Khansa I, Harrison B, Janis JE. Evidence-based scar management: how to improve results with technique and technology. *Plast Reconstr Surg*. 2016;138(suppl):165S–178S.