Biomechanical Comparison of 3 Syndesmosis Repair Techniques With Suture Button Implants

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Background: Suture button fixation of syndesmotic injury is growing in popularity, as it has been shown to provide adequate stability in a more cost-effective manner than screw fixation while allowing more physiologic distal tibiofibular joint motion. However, the optimal repair technique and implant orientation have yet to be determined.

Purpose/Hypothesis: The purpose of this study was to biomechanically compare 3 suture button construct configurations/ orientations for syndesmosis fixation: single, parallel, and divergent. The authors hypothesized that all 3 methods would provide adequate stabilization but that the divergent technique would be the most stable.

Study Design: Controlled laboratory study.

Methods: The fixation strengths of 3 stabilization techniques with suture button devices were compared with 10 cadaveric legs each (N = 30). Ankle motion under cyclic loading was measured in multiple planes: first in the intact state, then following simulated syndesmosis injury, and then following fixation with 1 of 3 randomly assigned constructs—1 suture button, 2 suture buttons in parallel, and 2 divergent suture buttons. Finally, axial loading with external rotation was applied to failure.

Results: All syndesmotic fixation methods provided stability to the torn state. There was no statistically significant difference among the 3 fixation techniques in biomechanical stability. Failure most commonly occurred through fibular fracture at supraphysiologic loads.

Conclusion: Suture button implant fixation for syndesmotic injury appears to provide stability to the torn syndesmosis, and the configuration of the fixation does not appear to affect the strength or security of the stabilization.

Clinical Relevance: This study provides further insight into the biomechanics and optimal configuration of suture button fixation of the torn syndesmosis. Based on these results, the addition of a second suture button may not significantly contribute to immediate postoperative stability.

Keywords: syndesmosis; repair; single; parallel; divergent; biomechanics

Syndesmotic sprains account for a significant number of ankle injuries.⁸ The current standard practice achieves stabilization of the disrupted syndesmosis via transosseous fixation methods, most commonly cortical screws or suture button constructs.^{1,13,15,20,29} The goal of fixation is to provide an anatomic reduction with sufficient stability of the joint.

Suture button constructs continue to grow in popularity as their advantages become more apparent.⁸ Screw fixation has been shown to result in an increased frequency of syndesmotic malreduction.^{4,7,14,16,28} In addition, the frequency of screw removal required after this technique indicates that suture button implants may be a more cost-effective fixation method.¹⁸ It is also thought that suture button constructs allow a more physiologic articulation of the syndesmosis after fixation in comparison with the rigidity of screw fixation.^{9,26} The biomechanics of suture button implant fixation have already been studied in some detail, although the optimal configuration of the devices has yet to be definitively determined. Many prior studies have focused on proving the noninferiority of the implants to the standard of screw fixation and have not emphasized the comparison of varying techniques of suture button placement.^{2,6,9-12,16,22-25,27}

The purpose of this study was to biomechanically compare 3 suture button constructs for syndesmosis fixation, with detailed motion analysis. Constructs were varied per the number of suture button implants (1 vs 2) as well as the orientation of the implants (parallel vs divergent). It was

The Orthopaedic Journal of Sports Medicine, 6(10), 2325967118804204 DOI: 10.1177/2325967118804204 © The Author(s) 2018

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METHODS

Specimen Preparation and Operative Technique

Thirty fresh-frozen cadaveric specimens (midfemur to toe tip; MedCure) with a mean age of 45 years (range, 29-52 years) and no prior lower extremity injury were procured by the sponsor. Once each specimen was thawed to room temperature, superficial dissections were performed medially and laterally to identify all ligamentous and tendinous structures about the ankle. The knee was disarticulated, leaving the proximal tibiofibular joint unaffected. Drill holes were made in the center of the medial and lateral malleoli approximately 1 cm from the distal tips to allow for placement of two 1.8-mm electromagnetic microsensors to be used for motion tracking.

After intact cyclic motion testing was complete (detailed later) but prior to any sectioning of ligaments, the joint line was identified through a 1-cm anterolateral capsulotomy. A mark was made across the skin to show the orientation of the joint line. A 3.7-mm bit was then used to drill a hole parallel to and 2 cm above the joint line in an anatomic orientation (from the lateral malleolar ridge of the fibula to the center of the anterior-posterior width of the tibia), as previously described.²⁰ This ensured that an anatomic reduction would be achieved once fixation was performed. The syndesmosis was then sectioned-including the anterior inferior tibiofibular ligament, interosseous tibiofibular ligament, superficial and deep posterior inferior tibiofibular ligament, and interosseous membrane to at least 10 cm proximal from the joint line-taking care to leave the anterior talofibular ligament, calcaneofibular ligament, and peroneal tendons intact. The deltoid ligament was then cut medially, leaving the posterior tibialis and flexor hallucis tendons intact. The torn-state ankles were then tested in a manner similar to the intact testing.

Following cyclic testing in the torn condition, the syndesmosis was then stabilized with 1 of 3 suture button implant orientations (Arthrex Knotless Syndesmosis TightRope; Arthrex): a single suture button, 2 suture buttons in parallel orientation in the axial plane, and 2 suture buttons with approximately 20° of divergence in the axial plane (Figure 1). For the parallel and divergent

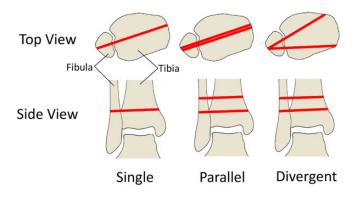


Figure 1. Orientation of the fixation for the single, parallel, and divergent configurations shown from the top and the side.

configurations, the proximal hole was drilled approximately 12 to 15 mm from the initial distal hole. A divergence of 20° was chosen as the maximal angle at which quad-cortical fixation remains possible, and it was determined with trigonometric calculations based on digital caliper measurements of the medial-lateral width of the tibia/ fibula and the anterior-posterior depth of the medial tibia. Assignment to the 3 groups was randomized. Each fixation device was inserted according to the manufacturer's instructions. Once the syndesmosis had been stabilized with the predetermined number and orientation of the fixation device, each specimen was then subjected to a final round of cyclic testing. Upon completion of cyclic testing, each specimen subsequently underwent torque to failure in external rotation. After all biomechanical testing had been completed, specimens were dissected to determine mode of failure.

Biomechanical Testing

Specimens were mounted into an MTS 858 MiniBionix servohydraulic mechanical test frame (MTS Systems) with axial and torsional capabilities. Test methods were created according to previous research in this area.^{6,24} Briefly, the tibia was secured with its longitudinal axis aligned with the MTS actuator via a custom jig with sharpened set screws at several locations around the tibia, while leaving the fibula free-floating. The ankle was fixed into a nylon base that included sharpened set screws to fix the calcaneus, as well as a clamp to prevent motion of the forefoot (Figure 2). The

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Ethical approval was not sought for the present study.

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One or more of the authors has declared the following potential conflict of interest or source of funding: This study was supported by Arthrex, which provided direct funding as well as in-kind donations of surgical implants. A.S.P. has received educational support from Stryker, Zimmer/Biomet, and Smith & Nephew. J.B.S. has received hospitality payments from Wright Medical Group. N.E.W. is a consultant for Arthrex, is a paid speaker/presenter for Arthrex and Procedural Orthopedics, has received educational support from Arthrex, has received research support from RTI Surgical, has received royalties from CrossRoads Extremity Systems and Wright Medical. AOSSM checks author disclosures against the Open Payments Database (OPD). AOSSM has not conducted an independent investigation on the OPD and disclaims any liability or responsibility relating thereto.



Figure 2. Overall test setup showing motion-tracking source, tibial sensor, and test fixture. The upper fixture applied torsion and compression to the proximal tibia, while the lower fixture held the foot stationary.

talar joint itself was not fixed in any way. Based on preliminary testing, a nonmetallic base fixture with 18-8 stainless steel screws was used to prevent artifact in the electromagnetic motion capture data.

For the intact and torn conditions, each specimen underwent 3 sets of 10 cycles as previously developed⁶: compressive loading to 750 N, torsional loading in external rotation to 7.5 N·m, and combined loading to each of the previous 2 regimens. Testing in the intact and torn conditions was conducted at 0.05 Hz.⁶

For the repaired condition, specimens were subjected to 1000 cycles of combined loading as described but at 0.1 Hz.⁶ Immediately after the fatigue testing, specimens were tested to failure in external rotation at 0.25 deg/s while maintaining the 750-N compressive load.

Data Collection and Processing

Two electromagnetic microsensors (Patriot; Polhemus Corporation) were inserted into the malleoli drill holes previously described. During biomechanical testing, 6–degree of freedom motion data (3-dimensional positions and orientations) for the 2 sensors were collected at 60 Hz with an electromagnetic motion-tracking device (Patriot; Polhemus Corporation). Time series data of the movement of the fibula relative to the tibia in the plane normal to the longitudinal axis of the tibia were then calculated. The superior-inferior (z) axis of the reporting reference frame was aligned with the compressive loading axis of the MTS machine (as well as the longitudinal axis of the tibia). The

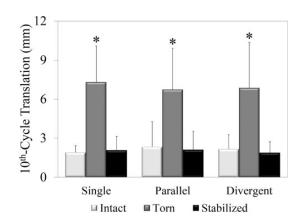


Figure 3. Syndesmotic disruption resulted in a significant increase in anterior-posterior translation of the fibula relative to the tibia at the 10th cycle, followed by a general return to intact levels with fixation. There was no overall effect of fixation type. Values are presented as mean \pm SD * $P \leq .05$ vs intact.

anterior-posterior (y) axis was defined as the cross-product of the superior-inferior axis and the vector connecting the 2 malleoli sensor locations while in the intact unloaded condition. Finally, the medial-lateral (x) axis was defined as the cross-product of the anterior-posterior axis and the superior-inferior axis. The reporting reference frame was fixed to the tibia while in the intact unloaded condition. From the time series data, minimum and maximum values within predefined testing cycles were calculated.

Parameters measured with the Polhemus system included rotation of the fibula relative to the tibia, medial-lateral diastasis, and anterior-posterior translation relative to the 10th-cycle minimum values. Parameters measured by the MTS system included maximum torque, torsional stiffness (defined as the slope of the linear region of the torque-rotation failure curve), and overall joint angle at maximum torque.

Statistical Analysis

Differences among single, parallel, and divergent fixation at 100, 500, and 1000 cycles, as well as failure properties, were compared with analysis of variance and Tukey honest significant difference post hoc for intergroup comparisons. For comparisons of the intact, torn, and repaired (at the 10th cycle of loading) conditions among the 3 repair groups, 2-way analysis of variance with repeated measures was employed with similar pairwise comparison methods. Statistical significance for all tests was set at $P \leq .05$.

RESULTS

When intact, torn, and repaired conditions at the 10th cycle of combined loading were compared, specimens showed a general significant increase in fibular translation (P < .0001), diastasis (P = .001), and rotation (P < .0001) in the torn state, following by a significant decrease (P < .0001 for

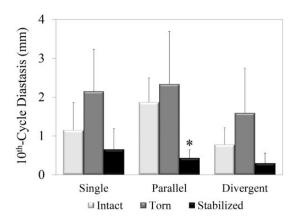


Figure 4. Syndesmotic disruption resulted in a significant increase in diastasis of the fibula relative to the tibia at the 10th cycle, followed by a general decrease to below intact levels with fixation. Values are presented as mean \pm SD. **P* \leq .05 vs intact.

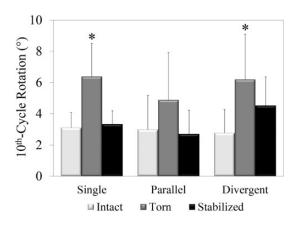


Figure 5. Syndesmotic disruption resulted in a significant increase in rotation of the fibula about the tibia at the 10th cycle, followed by a general decrease with fixation. Values are presented as mean \pm SD. * $P \leq .05$ vs intact.

all measurements) following fixation (Figures 3-5). There was an overall significant effect of fixation for diastasis (P = .03), with the divergent group having significantly less (P = .03) separation than that of the parallel group; there was no effect for rotation (P = .4) or anterior-posterior translation ($P \ge .999$). The interaction term of the statistical analysis was not significant for any measurement. For diastasis, specimens were shown to actually have significantly less (P = .0006) separation following fixation than in the intact case, indicating that the tibiofibular distance was reduced in the early stages of the suture button fixation (Figure 4).

Comparison among the 3 fixation groups at higher cycles (ie, 100, 500, and 1000) revealed significantly less (P = .03) relative rotation in parallel fixation versus divergent fixation at 100 cycles of combined loading (Table 1). No other differences were found at 500 or 1000 cycles or in translation or diastasis (data not shown).

 TABLE 1

 Rotation Results of Fatigue Testing for Single,

 Parallel, and Divergent Groups^a

	Rotation, deg			
	10th Cycle	100th Cycle	500th Cycle	Final Cycle
Single Parallel Divergent <i>P</i> value	$\begin{array}{c} 3.33 \pm 0.86 \\ 2.70 \pm 1.51^b \\ 4.52 \pm 1.84^b \\ .04 \end{array}$	$\begin{array}{c} 4.36 \pm 1.52 \\ 3.35 \pm 1.77^b \\ 5.64 \pm 2.03^b \\ .03 \end{array}$	$5.17 \pm 2.13 \\ 4.26 \pm 2.05 \\ 6.75 \pm 2.40 \\ .06$	$5.50 \pm 2.54 \\ 4.63 \pm 2.23 \\ 7.21 \pm 2.93 \\ .1$

^{*a*}Rotation was significantly increased in the divergent group versus the parallel group at 10 and 100 cycles. Data are presented as mean \pm SD. One-way analysis of variance *P* values are noted.

 $^b \rm Post$ hoc analysis revealed increased rotation in divergent fixation versus parallel fixation at 10 and 100 cycles.

TABLE 2				
Results of Torque-to-Failure Test for Single,				
Parallel, and Divergent Groups ^a				

	Joint Rotation at Failure, deg	Torsional Stiffness, N∙m/deg	Failure Torque, N·m
Single Parallel Divergent P value	$70.8 \pm 22.3 \\ 87.6 \pm 25.4 \\ 83.2 \pm 12.9 \\ .2$	$\begin{array}{c} 1.23 \pm 0.21 \\ 1.29 \pm 0.41 \\ 1.29 \pm 0.28 \\ .9 \end{array}$	$28.7 \pm 9.16 \\ 35.3 \pm 10.4 \\ 32.4 \pm 11.7 \\ .4$

"No statistical differences were found among the 3 groups. Data are presented as mean \pm SD. One-way analysis of variance P values are noted.

Regarding torque-to-failure properties, no differences were found among the single, parallel, and divergent groups for overall joint rotation at failure, torsional stiffness, or torque at failure (Table 2).

Two specimens (a pair from a 42-year-old, 25-kg female donor) failed through spiral fibular fracture during the early cycles of the torn condition and were excluded from the study, leaving 28 total specimens. Of those, 22 failed via fibular fracture (mean \pm SD, 32.7 ± 10.9 N·m). The majority of fibular fractures were through 1 or both implant drill holes; however, 2 specimens failed via spiral fibular fracture proximal to the device(s). The remaining 6 specimens did not fracture but experienced severe tibiotalar joint dislocation accompanied by profound device loosening. No notable differences were seen in failure mode among fixation groups.

DISCUSSION

As previously shown in the literature, all suture button fixation techniques tested in this study provided stability when compared with the injured syndesmosis.^{2,6,9,21,24,25,27} There was no clear superiority or definitive stability advantage among the suture button implant configurations tested in our study.

The divergent method returned a weaker control of fibular rotation than the parallel technique, which was a surprising and counterintuitive result, as we expected this to produce the greatest stability given that the fixation was in multiple planes. However, we found that by 500 cycles, the statistical significance of this difference in rotational control had disappeared. In addition, we expected 2 suture button implants to have a greater effect on stability when compared with a single implant; however, in keeping with the findings of the recent study by Clanton et al,² no biomechanical benefit was generated by the extra fixation. There may still be a benefit to 2 implants by providing a backup should one of the devices loosen or fail, but if only 1 implant can be placed in a favorable position because of comminution or the height of the fibular fracture, the syndesmotic stability should provide stability comparable with that of a 2-implant fixation.

At 10 cycles in, regardless of configuration, the suture button implants overcompressed the syndesmosis in relation to the intact state in diastasis, as has previously been reported in the literature.^{10,22} There was no recovery back to a measurement closer to the intact state over the ensuing 990 cycles. With regard to rotation and translation, the elasticity and creep inherent to the suture in the implant¹⁹ caused those values to increase over the course of the 1000cycle experiment. Since there have been multiple long-term clinical studies of the suture button implant without a significant concern for loss of reduction or loosening of implant, ^{3,5,11,16,17,23} it is likely that the device finds its final tension over the initial few weeks of weightbearing and does not continue to loosen indefinitely, at least under physiologic loads. This property of elasticity may also be important for prevention of long-term malreduction of the syndesmosis and has been cited as a possible benefit of the implant over more rigid screw fixation.²⁸

Many studies highlight coronal plane diastasis as the main outcome measure of syndesmotic testing; however, significant fibular translation in the sagittal plane, as well as fibular rotation in the axial plane, has been shown.²⁴ The sagittal alignment of the fibula in relation to the tibia is one of the key components of a successful reduction and is frequently malreduced.⁷ LaMothe et al¹² showed that suture button fixation allowed greater fibular translation in the sagittal plane versus a screw and could not achieve stabilization equivalent to that of the intact ligaments; however, in our comparison, all implant configurations tested provided control of fibular sagittal translation roughly equal to that of the intact state.

The failure torque of each implant configuration in the current study was comparable with if not slightly higher than previously described values.^{6,24} The torque experienced before failure was almost certainly greater than what would be experienced under all but the most extreme loading conditions,⁶ which is in keeping with clinical studies showing very low rates of catastrophic failure of suture button implants.^{3,5,11,16,23}

Advantages to this study include the direct comparison of suture button implants in different configurations with a motion-tracking device that allowed for 6-degree of freedom measurements of fibular motion. This permitted calculation of the motion of the fibula relative to the tibia while allowing natural movement of each bone relative to the base fixture/foot. The soft tissue envelope of the ankle was preserved as much as possible to prevent exaggerated instability. Other than the skin and the syndesmotic and deltoid ligaments, the native anatomy was left intact.

The limitations of the study are largely those encountered in cadaveric biomechanical studies. Despite limiting our specimens to a younger age in an effort to avoid poor bone density, 2 specimens (a pair from a single small female) failed under minimal loading through fracture, and there were no quantitative measurements made of the bone mineral density of any specimen. The dynamic forces experienced by the leg in vivo through muscular stabilization are difficult to reproduce through in vitro testing, as are the benefits of healing tissue over time. Given the nature of this cadaveric study, the current results are applicable only for a time-zero postoperative scenario. The torque levels applied to the constructs are likely greater than what would be experienced in vivo,²⁴ which may challenge the fixation to an unnecessary extent. The data from our study were not directly comparable with prior studies comparing fixation techniques, as the type and location of the motiontracking sensors on the ankle were not directly comparable. Finally, our study may or may not be sufficiently powered for cases in which no difference was found.

The present study provides additional data that should be considered when treating a syndesmotic injury and that can be added to the growing volume of biomechanical and short-term clinical results regarding suture button fixation of this injury. Additional prospective clinical trials are needed to understand the long-term outcomes of syndesmotic fixation with suture button implants.

CONCLUSION

All suture button constructs tested in the study created stability to the tibiofibular joint over the torn state and nearly re-created the intact stability of the joint. There was no fixation construct that produced a significant stability advantage over the others. In situations where the surgeon feels that using only one device is appropriate (ie, because of comminution or the height of the fibular fracture), he or she should not feel obligated to place a second, and there are potential cost savings in using just 1 suture button; however, there are theoretical benefits in using 2-implant devices. First, should one of the devices loosen or fail, there would still be a backup device for stability. Second, if 2 devices are placed in a divergent orientation and are cinched down in an orderly, alternating fashion, this should allow the fibula to settle properly within the incisura, potentially aiding in preventing malreduction.

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