

## A Prospective Randomized Investigation Comparing Functional Outcomes of Syndesmotic Suture-Button Fixation to Screws

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Source of funding: Arthrex Inc.

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Received: April 1, 2020

Revised: June 6, 2020

Accepted: June 10 2020

Published online: September 7, 2020

### ABSTRACT

**AIM:** To compare functional outcomes and adverse events of surgically treated syndesmotic injuries with either screw(s) or suture-button(s). It was hypothesized that suture-button fixation would provide equal clinical results with fewer adverse events.

**MATERIALS AND METHODS:** Multi-center, randomized clinical study. Sixty-five subjects with confirmed acute syndesmotic injury requiring surgical intervention were enrolled. Subjects were randomized and treated with either suture-button or screw fixation. Foot and Function Index pain, disability, and activity scores, American Orthopaedic Foot and Ankle Society scores, and the Visual Analogue Scale for pain were reported up to 12-months. The adverse events were also collected. The forty subjects with complete data up to one year ( $n = 40$ ; suture-button = 18 and screw = 22) were included in analysis. Single or multiple screws or suture-button implants were based on surgeon preference and patients' characteristics.

**RESULTS:** There was statistically significant improvement in Foot and Function Index and American Orthopaedic Foot and Ankle Society scores with both techniques ( $p < 0.05$ ). Visual Analog Scale scores improved significantly with the screw technique ( $p < 0.05$ ) but not with the suture button technique.

**CONCLUSION:** One-year clinical data suggests that acute syndesmotic injuries can be effectively treated with either technique. A possible benefit of suture button fixation may be a lower occurrence of adverse clinical events.

**Key words:** Syndesmosis, syndesmotic, screw, suture button

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Giza E, Oliver T, Barousse P, Allen T, Shelton T, Sarcon A, Sathy A, Maroto MR, Garras DN, Faerber W, Lin J, Stannard JP, Crist BD, Rocca GJD, Fiala K, Summerhays B, Volgas DA, Ronan J, Vogt M, Jones V, Fech J, Briggs E, Kreulen C. A Prospective Randomized Investigation Comparing Functional Outcomes of Syndesmotic Suture-Button Fixation to Screws. *International Journal of Orthopaedics* 2020; 7(4): 1322-1328 Available from: URL: <http://www.ghmet.org/index.php/ijo/article/view/2784>

## INTRODUCTION

The syndesmosis is a ligamentous articulation between the distal tibia and fibula; it is comprised of the anterior inferior tibiofibular ligament, interosseous ligament, and posterior inferior tibiofibular ligament. Reportedly, 1 to 18% of ankle sprains involve the syndesmotic ligaments<sup>[1]</sup>. The mechanism may involve either a pronation-external rotation or an excessive external rotation injury.

Compared to the more commonly sprained lateral ankle ligaments, syndesmotic injuries require a greater recovery time<sup>[2,3]</sup>. Failure to properly treat syndesmosis instability can cause lateral displacement of the talus with a 40% decrease in tibiotalar surface contact area.<sup>[4]</sup> Operative syndesmotic fixation can stabilize the ankle and prevent degenerative changes to the ankle<sup>[5,6]</sup>.

The ideal surgical technique to address syndesmotic injuries has been debated. One option involves rigid, screw fixation across the syndesmosis articulation. One or multiple screw(s) are used to stabilize the ankle and facilitate ligamentous healing. Depending on the surgeon's preference and patient's symptoms, screws may require subsequent removal. As the syndesmosis has an amplified rotational and translational motion during the gait cycle<sup>[7]</sup>, some electively remove screws to preserve motion and to prevent symptoms. However, this exposes the patient to another operation, and elective screw removal remains controversial. One study found that 65% of surgeons routinely remove screws<sup>[8]</sup>. The ideal timing of removal is also unknown, and premature removal can result in syndesmotic diastasis<sup>[6,9]</sup>.

Since the introduction of the suture-button (SB) device in the early 2000s, several studies have demonstrated its advantages over screw(s). These include fewer malreductions<sup>[10]</sup>, reduced implant failure<sup>[5,6,11,12]</sup>, and a quicker recovery time<sup>[6,11,12]</sup>. The SB construct also provides a more anatomic and physiologic method of syndesmotic fixation<sup>[13]</sup>.

Over the years, there has been a growing interest in comparing the two modes of fixation. A recent meta-analysis of five major studies comparing SB to screws revealed significantly lower reoperation rate with SB fixation<sup>[14]</sup>. Although the authors found clinically better American Orthopedic Foot and Ankle Society (AOFAS) scores and malreduction rates, the pooled analysis ultimately did not reveal any statistically significant difference in these outcomes due to study heterogeneity<sup>[14]</sup>. Thus, continued research on the topic is warranted.

Several randomized controlled trials (RCT) have compared the two techniques<sup>[13,15-19]</sup>. However, only one RCT was performed in the U.S.A with a sample size of 24 patients<sup>[15]</sup>. To the best of our knowledge, there are no larger level I studies from the U.S.A. The purpose of this multicenter RCT was to compare functional outcomes and adverse events of surgically treated syndesmotic injuries with either screw(s) or SB device(s). It was hypothesized that SB fixation would provide equal clinical results with fewer adverse events.

## METHODS

### Design

This was a prospective, multi-institutional, (5 study centers, U.S.A) RCT comparing treatment of acute syndesmotic injury with either

screw or SB (Tightrope, Arthrex, Inc, Naples, FL) fixation. The follow-up period was up to one year. Institutional Review Board approval was obtained from all participating study centers. Informed consent was obtained from all study subjects. Randomized allocations were kept in sealed envelopes which were revealed to the study surgeon intraoperatively. Operations were performed prospectively by specialty trained orthopaedic foot and ankle and/or trauma surgeons. Subjects were treated by 9 surgeons from 2011 to 2014.

The study's procedures are graphically illustrated (Figure 1). Patients with acute ankle trauma and suspected syndesmosis instability on exam or radiography were initially screened (Table 1). Voluntary informed consent was obtained from potential subjects. Preoperative functional outcome scores were evaluated. Intraoperatively, syndesmotic injuries were confirmed via fluoroscopy, and with ankle arthroscopy at the discretion of the surgeon. Only subjects with intraoperatively confirmed unstable syndesmosis injuries were included. Subjects were randomized intraoperatively into either treatment with

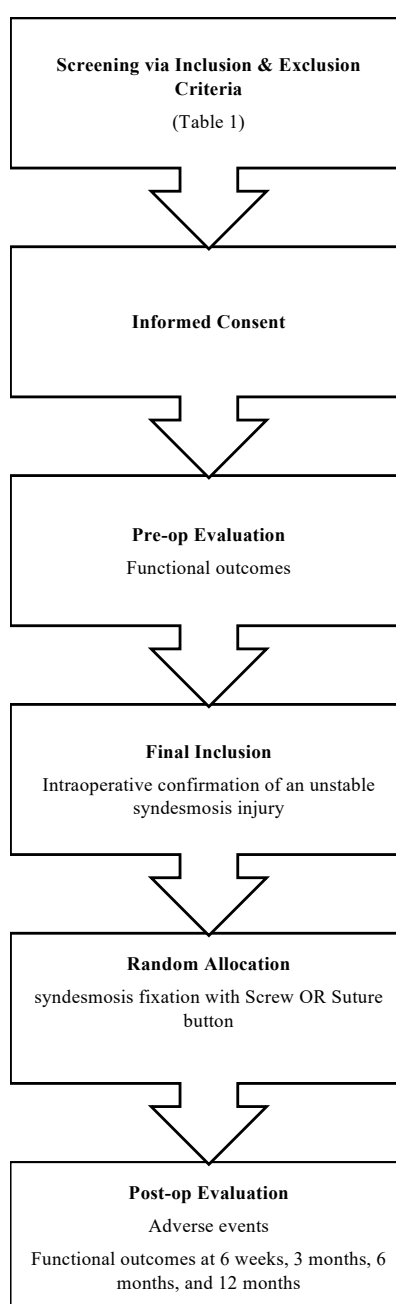


Figure 1 Flow chart of the study's procedures.

syndesmotic screw(s) or SB(s). Single or multiple screws or SBs were based on the study surgeon’s preference, intraoperative findings, and the patient’s characteristics (i.e. patient body mass index, amount of displacement and the potential stability of the construct). Tourniquet time was evaluated. The postoperative functional outcome scores and adverse events were evaluated.

**Operative technique**

The operative technique is described by Anand et al<sup>[5]</sup>. Patients were positioned supine on the operating table and a tourniquet was applied to the lower extremity. Any associated fibular and/or tibial fractures were fixed with standard techniques. Syndesmotic fixation in the neutral position was achieved using a reduction clamp. Mandatory clamping was included in the operative protocol in order to standardize the reduction between surgeons. Reduction was evaluated via fluoroscopy under direct visualization of the syndesmosis when possible.

**Postoperative Rehabilitation**

Postoperatively, all patients were non-weight bearing for six weeks. During the initial 2 weeks, patients were in a short leg plaster splint until the sutures were removed. From weeks 2 to 6, patients were transitioned to a controlled ankle motion (CAM) boot. From weeks 3 to 6, patients were permitted gentle active and passive range of motion of the ankle to prevent stiffness. During weeks 6 to 8, patients were advanced to weight bearing in the CAM boot with increased



CONSORT 2010 Flow Diagram

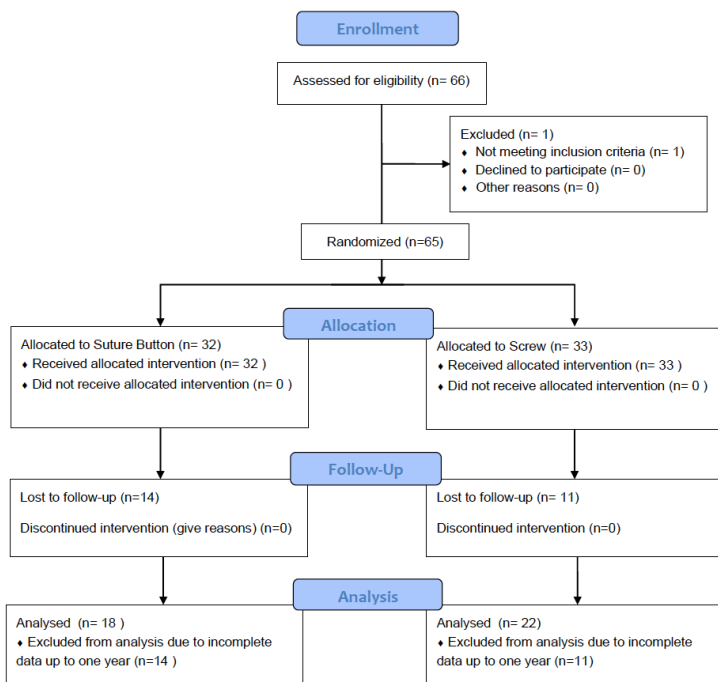


Figure 2 CONSORT Flow chart.

Table 1 Inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria	Intraoperative Exclusion Criteria
<ul style="list-style-type: none"> <li>• 18 to 65 years old</li> <li>• Complete history and physical exam</li> <li>• Isolated acute syndesmosis injury requiring operative treatment</li> <li>• Clinical &amp; radiographic confirmation of an acute syndesmosis injury</li> <li>• Voluntary informed consent</li> </ul>	<ul style="list-style-type: none"> <li>• Prior surgery</li> <li>• Chronic syndesmosis injury</li> <li>• Ankle fracture malunion</li> <li>• History of septic ankle arthritis</li> <li>• Multi-system or multi-limb trauma</li> <li>• Associated pilon fracture</li> </ul>	<ul style="list-style-type: none"> <li>• Stable syndesmosis injury at the time of surgical intervention</li> </ul>

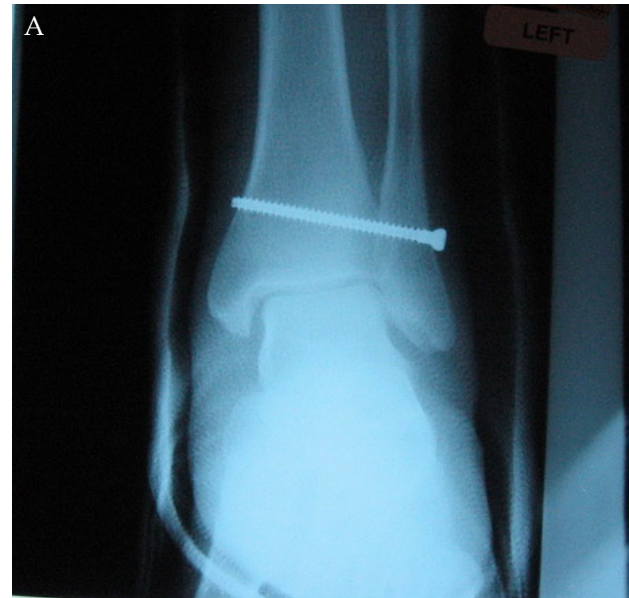


Figure 3 A: X-ray of the ankle demonstrating syndesmosis screw fixation; B: X-ray of the ankle demonstrating syndesmosis suture-button fixation.

range of motion, and weaned from the CAM boot to the air cast. Lastly, during weeks 10 to 12, patients could return to normal activities.

### Outcomes

The primary outcomes were functional scores and postoperative adverse events. The outcomes reported were the Foot and Function Index (FFI) pain, disability, and activity scores, American Orthopaedic Foot and Ankle Society (AOFAS) scores, and the Visual Analogue Scale (VAS) score for measurement of pain. A lower VAS or FFI score, or a higher AOFAS score indicates a better outcome. The FFI and VAS scores are reported preoperatively, as well as postoperatively at 6 weeks, 3 months, 6 months, and 12 months. The AOFAS scores are reported postoperatively at 6 weeks, 3 months, 6 months and 12 months. The percentage and type of postoperative adverse events were evaluated. The potential adverse events included, but were not limited to: infection, symptomatic hardware, hardware loosening, hardware breakage, loss of reduction, and reoperation.

### Statistical Analysis

Computations were performed using JMP® Pro statistical software (version 14.0, <http://www.jmp.com>). Statistical significance was determined at alpha of less than or equal to 0.05. Normality was assessed for continuous variables using a Shapiro-Wilks Test. Continuous variables between groups were compared with a Wilcoxon Rank Sums Test while categorical variables were compared with a Fisher's exact test. The Kruskal-Wallis test was used to compare the outcome scores for differences at each timepoint. The median and interquartile ranges were reported for the outcome scores. If a difference was detected, a post-hoc Wilcoxon test was used to determine statistical differences between timepoints as denoted by superscripts A, B, C, and D (i.e. a statistical difference does not exist between groups if there is a repeating letter). The patient characteristics were reported with the mean value, +/- standard deviation (SD), and range (Microsoft® Excel, version 16.27).

## RESULTS

Sixty-six subjects were initially assessed for eligibility, and 65 subjects were enrolled (Figure 2). However, only subjects with near complete clinical outcomes up to one-year were included in the final analysis ( $n = 40$ ). Twenty-two of the 40 (55%) received screw fixation, and 18 (45%) received SB (Figure 3). The patient characteristics are listed in Table 2. The most frequent mechanism of injury in either group was slip and fall, and a majority sustained a concomitant Weber B or C fibula fracture.

Most subjects with screw fixation had either one or two screws placed ( $n = 21$ ; one screw = 11, two screws = 8, three screws = 1 and four screws = 1). One subject had screws placed, but the number of screws was not reported. A majority of subjects in the SB group had only one SB placed ( $n = 18$ , one SB = 14, and two SB = 4). For 17 subjects, the type of SB was recorded: nine had the knotless type, and 8 had a SB that required tying a minimum of five knots after placement. Tourniquet time was available for 31 subjects. The average tourniquet time for the screw fixation was  $64.3 \pm 30.9$  minutes ( $n = 20$ ; range, 15 to 121 minutes). The average tourniquet time for SB was  $65.7 \pm 29.0$  minutes ( $n = 15$ ; range, 24 to 120 minutes).

The functional outcomes at the select time-points for those treated with syndesmotic screws are shown in Table 3. Subjects had statistically improved AOFAS scores from 6-weeks postoperative until the 12-month visit. There was a statistical pre- to postoperative improvement in VAS scores between 6-months and 12-months. There was a statistical pre- to postoperative improvement in FFI pain scores

**Table 2** Patient characteristics (mean +/-SD; range)

	Screw	Suture Button
Age	$n = 15$	$n = 15$
	$31 \pm 9$	$38 \pm 15$
	(Range, 19 to 48)	(Range, 18 to 61)
BMI	$n=5$	$n=7$
	$31 \pm 4$	$30 \pm 4$
	(Range, 26 to 36)	(Range, 24 to 35)
L:R	11:11	8:10
MOI	$n = 21$	$n = 18$
Slip/fall	13	15
Sports	7	1
ADL	1	2
M:F	$n = 16$	$n = 15$
	9:07	8:07
Smoking	$n = 12$	$n = 13$
No	10	11
Yes	2	2
Preoperative Medial clear space(mm)	$n = 19$	$n = 16$
	$4.7 \pm 2.9$	$6.7 \pm 3.9$
	(Range, 2 to 14)	(Range, 0 to 16)
Preoperative tib-fib overlap(mm)	$n=19$	$n=15$
	$2.1 \pm 4.3$	$1.2 \pm 1.7$
	(Range, -11 to 10)	(Range, -2 to 4)
Concomitant fracture	$n=22$	$n=18$
Fibula shaft	2	1
Lateral malleolus	1	0
Medial malleolus	0	3
Posterior malleolus	0	1
Weber A	0	1
Weber B	6	4
Weber C	13	8

Abbreviation: BMI, Body Mass index; MOI, mechanism of injury; ADL, activities of daily living.

at 3, 6, and 12-month visits; there was also continued improvement between the 6-weeks and 3, 6, and 12-month visits. There were also improved disability scores from preoperative scores to 3, 6, and 12-months postoperative visits. The patients' activity limitations also significantly improved from preoperative at the 3, 6, and 12-months postoperative visits.

Table 4 describes the functional outcomes scores for patients treated with SB technique. Similar to the screw fixation group, there were statistically significant improvements in the postoperative AOFAS scores between 6 weeks until the 12-month visit and maintained scores between 6-month and 12-month visits. Unlike syndesmotic screws, there were no differences in VAS scores. Patients with SB initially had increased FFI pain scores which significantly decreased at the 6- and or 12-month visit; this was also maintained without symptom deterioration between the 6- and 12-month visit. Although there was a significant increase in the FFI disability scores at the 6-week visit compared to preoperative, symptoms significantly improved during the subsequent visits. A similar trend was observed with the FFI activity scores, which ultimately resulted in similar scores between preoperative and the final 12-month visit.

With the exception of significantly higher VAS scores at postoperative 6-weeks in patients treated with syndesmotic screws, there were no statistical differences between the two fixation methods (Table 5). With respect to postoperative adverse events, 7 out of the 22 (32%)

**Table 3** Clinical outcome scores for patients with Screw Fixation (number of subjects reported in each visit).

Outcome Score	Preoperative	6 Week Postoperative	3 Month Postoperative	6 Month Postoperative	1 Year Postoperative	P-Values
AOFAS	-	58 [49, 75] <sup>A</sup> (N = 22)	83 [75, 89] <sup>B</sup> (N = 20)	92 [85, 99] <sup>C</sup> (N = 18)	90 [84, 100] <sup>C</sup> (N = 20)	< 0.001
VAS	5 [0, 8] <sup>A</sup> (N = 22)	3 [2, 5] <sup>A,B</sup> (N = 22)	2 [1, 3] <sup>A,C</sup> (N = 21)	1 [0, 3] <sup>C</sup> (N = 21)	1 [0, 3] <sup>C</sup> (N = 22)	0.01
FFI Pain	9 [0, 10] <sup>A</sup> (N = 21)	7 [2, 8] <sup>A</sup> (N = 18)	2 [1, 4] <sup>B</sup> (N = 21)	1 [0, 4] <sup>B,C</sup> (N = 21)	0 [0, 1] <sup>C</sup> (N = 22)	< 0.001
FFI Disability	8 [0, 10] <sup>A</sup> (N = 22)	6 [4, 8] <sup>A</sup> (N = 22)	3 [1, 7] <sup>B</sup> (N = 21)	2 [0, 5] <sup>B,C</sup> (N = 21)	1 [0, 3] <sup>C</sup> (N = 22)	< 0.001
FFI Activity Limit	9 [0, 10] <sup>A</sup> (N = 22)	8 [4, 9] <sup>A</sup> (N = 22)	1 [0, 6] <sup>B</sup> (N = 21)	0 [0, 3] <sup>B,C</sup> (N = 21)	0 [0, 1] <sup>C</sup> (N = 22)	< 0.001

Data presented in median [interquartile range]. P-Values reported using Kruskal-Wallis test. Superscript letters (A, B) indicate where statistical differences exist between groups using a post-hoc Wilcoxon Test. Abbreviations: American Orthopedic Foot and Ankle society score, AOFAS; Visual Analogue Scale score, VAS; Foot Function Index score; FFI

**Table 4** Clinical outcome scores for patients with Suture Button Fixation (number of subjects reported in each visit).

Outcome Score	Preoperative	6 Week Postoperative	3 Month Postoperative	6 Month Postoperative	1 Year Postoperative	P-Values
AOFAS	-	63 [58, 67] <sup>A</sup> (N = 16)	76 [71, 88] <sup>B</sup> (N = 17)	90 [83, 96] <sup>C</sup> (N = 17)	98 [88, 100] <sup>C</sup> (N = 17)	< 0.001
VAS	1 [0, 8] (N = 18)	1 [0, 3] (N = 17)	2 [1, 3] (N = 17)	1 [0, 2] (N = 18)	0 [0, 2] (N = 18)	0.136
FFI Pain	0 [0, 10] <sup>A,B,C</sup> (N = 18)	4 [1, 8] <sup>A</sup> (N = 9)	2 [0, 3] <sup>A</sup> (N = 16)	0 [0, 3] <sup>B</sup> (N = 17)	0 [0, 1] <sup>C</sup> (N = 18)	0.015
FFI Disability	0 [0, 9] <sup>A,C</sup> (N = 18)	8 [4, 10] <sup>B</sup> (N = 15)	3 [2, 5] <sup>A</sup> (N = 17)	1 [0, 4] <sup>A,C</sup> (N = 17)	0 [0, 1] <sup>C</sup> (N = 18)	< 0.001
FFI Activity Limit	0 [0, 10] <sup>A,B,C</sup> (N = 18)	8 [3, 9] <sup>A</sup> (N = 15)	2 [0, 5] <sup>B</sup> (N = 17)	0 [0, 1] <sup>C,D</sup> (N = 17)	0 [0, 0] <sup>D</sup> (N = 18)	< 0.001

Data presented in median [interquartile range]. P-Values reported using Kruskal-Wallis test. Superscript letters (A, B) indicate where statistical differences exist between groups using a post-hoc Wilcoxon Test. Abbreviations: American Orthopedic Foot and Ankle society score, AOFAS; Visual Analogue Scale score, VAS; Foot Function Index score; FFI

subjects treated with syndesmotic screws had complications; there were 5 broken screws, one symptomatic screw, and one loose screw; two of these patients had the screws removed. Conversely, only one of 18 (6%) with the SB technique had an adverse event which was a symptomatic knotted device requiring removal. However, the difference in rates of adverse events was not statistically significant ( $p = 0.054$ ).

## DISCUSSION

The authors report short term clinical outcomes after randomized treatment of acute syndesmosis injuries with either screw or SB. The one-year clinical outcomes of this investigation suggest that either method is effective in treating acute syndesmosis injuries as both techniques lead to a statistically significant improvement in FFI and AOFAS scores. Although we did not find a statistical difference in the number of adverse events, patients with SB fixation had a clinically lower complication rate (6% vs 32%).

Studies have shown greater improvement in clinical outcomes following fixation with the SB technique versus screws<sup>[13,16,20,21]</sup>. A randomized clinical study by Andersen *et al.* revealed significantly higher AOFAS scores and lower pain with SB fixation<sup>[16]</sup>. Unlike the SB group, there were 7 cases of symptomatic diastasis with syndesmotic screws<sup>[16]</sup>. Laflamme *et al.* also found statistically greater Olerud-Molander Ankle scores at one year and clinically higher AOFAS scores with the SB technique<sup>[13]</sup>. The screw fixation had a higher number of reoperations, and three patients experienced loss of reduction<sup>[13]</sup>. Stiene *et al.* also found higher AOFAS scores (score of 92,  $n = 271$ , mean follow up of 22 months) compared to screw fixation (score of 85,  $n = 494$ , mean follow up of 38 months)<sup>[21]</sup>. The average time to

weightbearing was also shorter with the SB technique compared to static fixation (6.0 versus 10.5 weeks)<sup>[21]</sup>. In our study, although subjects treated with SB fixation had higher AOFAS scores at 12-month postoperative visit, we were unable to achieve statistical significance, likely due to sample size.

The SB technique offers the advantage of lower adverse events. A systematic review by Zhang *et al.* revealed a 4% rate of SB removal compared to 40% with screws. Additionally, the reported screw removal rate may have been underestimated since screws routinely removed were excluded. Stiene *et al.* also found significantly higher screw removal rates (39% of 584 with screw versus 8% of 350 with SB)<sup>[21]</sup>. Recently, Sanders' *et al.* found that patients treated with screw fixation had both a statistically higher rate of malreduction (39% vs 15%) and reoperation rate (30% vs 4%) compared to SB<sup>[19]</sup>.

Fewer reoperations are cost effective and beneficial for patients. Neary *et al.* performed a cost analysis of SB to syndesmotic screw fixation<sup>[22]</sup>. Although the baseline cost of the SB device was greater than two cortical screws (\$880.00 vs \$65), SB was overall more cost effective. With a screw removal rate of 20%, and SB removal rate of 4%, the authors found that the total cost of two cortical screws was greater (\$20,836 versus \$19,354)<sup>[22]</sup>. The study found that for syndesmosis screws to be more cost effective, a removal rate of less than 10% is needed<sup>[22]</sup>. In another cost analysis study, Ramsey *et al.* found that SB fixation was the more cost effective technique if the screw removal rate was greater than 17.5%<sup>[23]</sup>. These findings can be extrapolated to the previously mentioned studies<sup>[11,21]</sup>; given an average screw removal rate of 40%, both of the aforementioned investigations suggest that SB fixation is the more cost-effective approach for the majority of United States hospitals and clinical practices.

In agreement with the literature, our data revealed a clinically

**Table 5** Clinical outcome scores comparing patients who received Suture Button to Screw Fixation (N represents the number of subjects reported in each visit).

Outcome Score	Screw Fixation	Tight Rope	P-Values
<b>Preoperative</b>			
VAS	5 [0, 8] (N = 22)	1 [0, 8] (N = 18)	0.234
FFI Pain	9 [0, 10] (N = 21)	0 [0, 10] (N = 18)	0.108
FFI Disability	8 [0, 10] (N = 22)	0 [0, 9] (N = 18)	0.152
FFI Activity Limit	9 [0, 10] (N = 22)	0 [0, 10] (N = 18)	0.165
<b>6 Week Postoperative</b>			
AOFAS	58 [49, 75] (N = 22)	63 [58, 67] (N = 16)	0.668
VAS	3 [2, 5] (N = 22)	1 [0, 3] (N = 17)	0.012
FFI Pain	7 [2, 8] (N = 18)	4 [1, 8] (N = 9)	0.468
FFI Disability	6 [4, 8] (N = 22)	8 [4, 10] (N = 15)	0.389
FFI Activity Limit	8 [4, 9] (N = 22)	8 [3, 9] (N = 15)	0.595
<b>3 Months Postoperative</b>			
AOFAS	83 [75, 89] (N = 20)	76 [71, 88] (N = 17)	0.492
VAS	2 [1, 3] (N = 21)	2 [1, 3] (N = 17)	0.717
FFI Pain	2 [1, 4] (N = 21)	2 [0, 3] (N = 16)	0.731
FFI Disability	3 [1, 7] (N = 21)	3 [2, 5] (N = 17)	0.79
FFI Activity Limit	1 [0, 6] (N = 21)	2 [0, 5] (N = 17)	0.976
<b>6 Months Postoperative</b>			
AOFAS	92 [85, 99] (N = 18)	90 [83, 96] (N = 17)	0.539
VAS	1 [0, 3] (N = 21)	1 [0, 2] (N = 18)	0.662
FFI Pain	1 [0, 4] (N = 21)	1 [0, 3] (N = 17)	0.975
FFI Disability	2 [0, 5] (N = 21)	1 [0, 4] (N = 17)	0.372
FFI Activity Limit	0 [0, 3] (N = 21)	0 [0, 1] (N = 17)	0.453
<b>1 Year Postoperative</b>			
AOFAS	90 [84, 100] (N = 20)	98 [88, 100] (N = 17)	0.353
VAS	1 [0, 3] (N = 22)	0 [0, 2] (N = 18)	0.201
FFI Pain	0 [0, 1] (N = 22)	0 [0, 1] (N = 18)	0.329
FFI Disability	1 [0, 3] (N = 22)	0 [0, 1] (N = 18)	0.173
FFI Activity Limit	0 [0, 1] (N = 22)	0 [0, 0] (N = 18)	0.114

Data presented in median [interquartile range]. P-Values reported using a Wilcoxon Rank Sums Test Abbreviations: American Orthopedic Foot and Ankle society score, AOFAS; Visual Analogue Scale score, VAS; Foot Function Index score; FFI.

higher adverse events rate for syndesmotic screws compared to SB fixation (32% vs 6%). The knotted technique may influence the rate of SB removal. Forschner *et al.* found a relatively high SB removal rate of 26% (5/19) which was attributed to persistent skin irritation due to the suture knot prominence<sup>[20]</sup>. In the present study, only one subject with SB fixation had an adverse event which also required device removal, likely as a result of the knotted technique. The new knotless version of the SB has shown promise in reducing lateral skin irritation<sup>[17]</sup>.

There are limitations to the present study including the short duration of follow-up. A longer follow-up evaluating functional outcomes and adverse events can shed additional light onto the clinical differences between the two techniques. The study's small sample size was also a limitation. This may have affected the ability to detect differences and/or similarities between the two fixation techniques. Although the multi-institutional design of our study allowed for an increase in subject enrollment, there were multiple surgeons performing the procedures. However, all surgeons had experience with both techniques, and a standardized operative protocol was in place. The randomization design ensured there was no selection bias based on site or preference of fixation.

The randomized design of the study is a major strength which allowed for prospective comparison between two commonly performed surgical techniques. We also collected preoperative functional outcome scores, and thus minimized recall bias. The authors feel that this study contributes to the literature by reinforcing the prior studies that show that treatment using the SB technique leads to fewer post-operative complications.

#### Conflict-of-interest statement

E.G received a grant from Arthrex, Inc during the conduct of the study, and receives consulting fees from Arthrex, Inc.

C.K receives personal fees and research/fellowship support from Arthrex, Inc.

T.O received a grant from Arthrex, Inc during the conduct of the study, and receives consultant fees and royalties from Arthrex, Inc.

J.P.S receives consulting fees from Arthrex, DePuy Synthes, Orthopedic Designs North America, and Smith and Nephew company, he reports grants from Arthrex, Coulter foundation, U.S Dept of Defense, and the NIH; he reports publishing royalties from Thieme; he is part of the editorial board of the Journal of Knee Surgery, and is affiliated with and or received fees from AOA, AO north America, AO foundation, and Mid-America Orthopaedic association.

B.D.C received a grant from Arthrex, Inc during the conduct of the study. Outside of the submitted work, he receives personal fees from KCI and Globus, and receives stock fees from the Orthopaedic Implant Company.

G.J.D.R received a grant from Arthrex, Inc during the conduct of the study. Outside of the submitted work, he receives personal fees from Wright-Tornier and DePuy-Synthes, and stock fees from the Orthopaedic Implant Company and Mergenet Medical. He holds intellectual property in Intellectual Ventures.

D.A.V works for Synthes & AO faculty at national and international courses.

J.R is an employee of Arthrex, Inc.

All other authors have nothing to disclose.

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