It has been reported that 10% of all ankle fractures, the most common type of fracture in patients between 20 and 65 years, are associated with syndesmotic injuries.7,8,18-20 Currently, the standard treatment of syndesmotic injury is fixation with a metallic screw.7,10,24,29 When 3-4 cortices are secured, screw fixation can create a rigid construct that is prone to failure by loosening and subsequent revision.5,24,26,27

Even in the case of a positive clinical outcome with satisfactory healing, there are reports of screw fracture; therefore, secondary operations are frequently performed to remove the screw preemptively.12,24 One literature review of 7 clinical studies concluded that no significant difference exists between the outcomes of patients who had the screw removed or not removed.21 However, other studies have reported that patients with screws that broke after fixation, allowing for more motion in the ankle joint, had a significantly better outcome than patients with intact screws.11,16

Recently, suture-button constructs have been developed to have stability similar to screws but allow for more ankle motion. The potential advantages of suture-button devices are reduced risk of tibiofibular synostosis, reduced risk of device failure, and potentially improved functional healing.5,10,28 Several clinical studies have reported the outcomes of patients with the TightRope Syndesmosis

Abstract
Background: There is growing interest in suture-button devices for syndesmotic injury, which are intended to offer less rigid fixation than screw fixation.

Methods: The fixation strength with 2 different suture-button devices, ZipTight and TightRope, were compared using 5 cadaveric leg pairs (n = 10). In an additional 5 pairs (n = 10), ZipTight was compared to 3.5 mm quadricortical screw fixation. Ankle motion was measured intact, then following simulated syndesmosis injury and fixation. Cyclic loads (peak 750 N, 7.5 Nm) were applied. Finally, external rotation to failure was measured and failure mode was documented.

Results: Range of motion increased after simulated injury and fixation with all devices (max 14.5 degrees). In all groups, diastasis remained below 1.0 mm intact and below 2.0 mm during cyclic loading. Compared to intact, under load to failure, diastasis with ZipTight devices increased by 4.7 ± 1.3 mm and 7.6 ± 4.3 mm, with TightRope, 6.3 mm, and screw construct, 1.3 mm. ZipTight specimens rotated approximately 80 ± 22 degrees before failure, TightRope, 67 ± 13 degrees, screw constructs, 76 ± 27 degrees. Mean failure torque was between 22.2 ± 6.9 Nm and 28.1 ± 12.7 Nm for ZipTight, compared to 32.9 ± 8.0 Nm for TightRope (P = .07), and 30.1 ± 9.6 Nm for screw constructs (P = .03). The majority of suture-button constructs failed by fibular fracture (ZipTight = 6, TightRope = 4), the remaining by device pull-through (ZipTight = 3, TightRope = 1) and loosening (ZipTight = 1). Conversely, 3 of screw-fixed specimens failed by device failure, 2 from bone fracture.

Conclusion: Suture-button devices provided torsional strength below that of screw fixation. However, all devices may provide failure torques well above 20 Nm, exceeding likely torques applied in casts during healing.1,2,4

Clinical Relevance: Suture-button devices appear to have provided adequate fixation strength for syndesmotic injuries.

Keywords: syndesmotic injury, ankle fixation, suture-button, screw fixation

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Fixation suture-button device compared with patients with metallic screw fixation with a 1- to 2-year follow-up. Overall, patients with the TightRope device fixation had shorter time to full weight bearing, higher AOFAS score, and a lower incidence of hardware removal. Another study reported 48% of patients with screw fixation required hardware removal due to loosening or breakage, while no TightRope device required hardware removal. In addition, a CT-based study found that 21.7% of patients with screw fixation had syndesmotic malreduction, which was noted as an independent predictor of clinical outcomes, whereas none of the patients in the TightRope group showed malreduction.

Several other clinical studies evaluating the outcome of patients with traumatic syndesmotic ankle injuries fixed with the TightRope suture-button over a 2-year period also found a short time to full weight bearing, ranging from 4.5 to 7.7 weeks, and an average AOFAS score above 85. However, they all had patients who needed hardware removal due to local discomfort caused by the knot on the lateral side. Specifically, 1 study found that 1 in 4 patients required device removal due to prominence, local skin irritation, and pain with activity.

More recently, the ZipTight Fixation Device, also a suture-button, has been introduced. This device differs from the traditional TightRope in that a self-tightening mechanism is employed as opposed to the multiple-knots required to secure the TightRope. The purpose behind this innovation was to address the documented problem of soft tissue irritation.

In this study, a cadaveric model was used to compare 3 different implants for fixation of syndesmotic injuries. Specifically, ankle range of motion, motion between the tibia and fibula under cyclic loading, and strength of fixation under external torque to failure were measured and compared using cadaveric specimens fixed using 1 of 2 suture-button devices or quadricortical screw fixation.

Methods

Cadaveric specimens were obtained through Science Care (Phoenix, AZ) after approval of the protocol and disclosure of the institutional facilities to dispose of the remains. Ten pairs of fresh-frozen cadaveric lower legs, disarticulated at the knee, were used. Bone mineral density (BMD) was obtained using DEXA and anteroposterior and lateral radiographs were taken before biomechanical testing, to screen for previous surgeries, fractures, or any bony abnormalities. Using BMD values obtained from DEXA, specimen pairs were assigned at random into 1 of 2 groups, the ZipTight versus TightRope group (group 1) or the ZipTight versus Screw group (group 2), such that each group contained 5 pairs and that the average BMD values for the 2 groups were similar. In each group, the pairs were separated at random such that 1 leg of each pair received the ZipTight fixation device and the contralateral received either the TightRope device or the screw, depending on the group assignment. Given the wide variability between cadaveric specimens, using matched pairs reduced the effects of variation in mechanical properties among cadaver specimens (Figure 1).

Figure 1. The experimental design is shown, explaining how matched pairs were used to minimize the effects of variation among cadavers in quality of bone and soft tissues. In group 1, one of each pair (at random) was assigned to fixation with ZipTight and the contralateral to TightRope. Likewise, in group 2, one of each pair was assigned to ZipTight and the other to screw fixation. By using paired specimens, the only comparisons that were made were between the right and left legs of the same cadaver.

Specimen Preparation

Once each specimen was thawed to room temperature, 2 rectangular sections of soft tissue, each 1 x 2 cm, and both 1 cm above the ankle joint, were removed, 1 on the medial aspect of the leg to expose the tibia, the other on the lateral aspect to expose the fibula. The remainder of the soft tissue was left intact, specifically the syndesmosis.

The specimens were mounted in a custom apparatus in a biaxial MTS 858 MiniBionix servohydraulic load frame (MTS Systems, Minneapolis, MN) such that the long axis of the tibia was aligned with the load actuator of the MTS machine (Figure 2). The proximal end of each tibia was rigidly secured in a custom aluminum ring using pointed screws, leaving the fibula free of any constraint. The ring was then rigidly attached to the MTS actuator. The foot was secured in an aluminum ring with pointed screws through the calcaneus. The foot ring was then attached to an aluminum plate at the
motion throughout experimentation using an Optotrak 3020 Motion Capture System (Northern Digital Inc, Waterloo, Ontario, Canada), with an accuracy of 0.1 mm and a resolution of 0.01 mm. This motion tracking system has been used extensively in biomechanics, with reported accuracies as low as 0.03 mm. Motion tracking flags were rigidly attached, using cortical bone screws, 1 cm to the tibia and another to the fibula, each 5 cm above the malleoli (Figure 2). Therefore each flag could be used to measure the 3-D position of the bone it was attached to. Points were digitized, relative to the tibia and fibula flags, directly on the tibia and fibula bone surfaces. The digitizing probe consisted of a motion tracking flag rigidly attached to the end of a Kirschner wire (k-wire; Figure 2). Points were located 10 mm proximal to fixation device, and at the level of the malleoli. Therefore, the Motion Capture System provided direct measurement of the relative motion of the tibia to the fibula, treating both as rigid bodies.

Intact Loading

Range of motion (ROM) was tested on all specimens both before intact loading and before postfixation loading to determine if any changes occurred after loading. Dorsiflexion, plantarflexion, inversion, and eversion measurements were performed by manually flexing the specimen 5 times in each direction, with the foot held stationary, while the angle between the long axis of the leg and the table was measured using the motion tracking system. Next, with both the foot and proximal tibia secured to the MTS machine, each specimen underwent initial intact physiological loading, consisting of 10 cycles of axial loading with a peak of 750 N, followed by 10 cycles of external torsional loading with a peak of 7.5 Nm, and finally 10 cycles of combined axial and external torsional loading with a peak of 750 N and 7.5 Nm, at 0.05 Hz.

Injury Creation and Fixation

After intact loading was completed, a deltoid ligament and syndesmosis injury was created for each specimen. First, the ankle joint was exposed by removing the skin around the medial and lateral malleolus. The syndesmosis was then predrilled using the necessary drill bit (ZipTight (Biomet, Inc), 3.2 mm solid; TightRope (Arthrex, Inc), 3.5 mm cannulated; screw, 2.5 mm solid), depending on which device the specimen was to receive, from lateral to medial. The ankle joint was localized with a k-wire through the anterior medial portal and the devices were placed 2 cm proximal to this. Starting at the lateral side, 2 cm above the ankle joint, the drill bit was passed through the tibia and fibula at a 30 degree angle, relative to the frontal plane, with the foot dorsiflexed to neutral. The syndesmotic injury was then created by sectioning the syndesmosis from the lateral malleolus to a point 10 cm proximal to the distal tip of the fibula. All components of the deltoid ligament were completely divided, as well as the anterior and posterior tibiofibular ligaments and the interosseous membrane, to ensure an unstable injury. Each fixation device was then inserted according to the manufacturer’s instructions, with the foot dorsiflexed to neutral. Injury creation and fixation were performed by the same surgeon to reduce variability.

Postfixation Loading

Postfixation cyclic loading consisted of 1000 cycles of combined axial and external torsional loading, with a peak of 750 N and 7.5 Nm, at a rate of 0.1 Hz. After postfixation loading, each specimen underwent failure loading by external rotation at 0.25 degrees/second. Failure was defined as a sudden drop in the torque-rotation curve.

Data Reduction

ROM data was normalized by using the initial position, with the specimen held in the neutral position, as the reference value. Peaks in the data, indicating maximum plantarflexion,
dorsiflexion, inversion, or eversion, were then measured for each cycle and then averaged. Diastasis between the tibia and the fibula at the level of the fixation was measured during intact and postfixation loading, and determined by calculating the distance between each set of digitized points. In the present study, diastasis was defined as the difference in the size of the gap between the tibia and fibula as a result of applied loading, and not the absolute value of the gap. Torque and rotation were recorded during the external rotation to failure testing. The levels of interest were at the fixation device, and at the malleoli. Following all biomechanical testing, radiographs were taken and specimens were dissected, if necessary, to determine mode of failure.

Statistical Analysis

A power analysis was conducted to determine the appropriate sample size for the study. Although there were several outcome variables of interest (ROM, diastasis, failure torque, and mode of failure), the power analysis was based on diastasis, as previous studies had reported diastasis values for similar constructs. The analysis was based on a paired Student's t test. The minimum clinically important difference was selected to be 2.5 mm based on previous studies. A standard deviation of 1.5 mm was assumed in each group. For a power of 80%, and an alpha (significance level) of .05, 5 pairs in each group were required.

SPSS statistical software (IBM, Armonk, NY) was used to determine P values associated with differences between groups. A paired samples Student’s t test was used to compare (1) change in ROM between intact and postfixation testing, as well as between fixation groups, (2) change in diastasis during each loading step and between each fixation group, and, (3) failure torque and rotation between each fixation group. Failure mode was determined by the senior surgeon using radiographs, examining each specimen, and removing and measuring the angle of the screw. The failure modes were broken down by general mode, (1) fibula fracture, (2) pull-through, and (3) device, and by specific mode and compared by frequency of occurrence.

In addition, BMD of the specimens in each of the failure mode groups was compared overall and in each fixation device group, using an independent samples Student’s t test. BMD of the specimens that failed by fibula fracture was compared between each fixation device group using an independent samples Student's t test. A power analysis was conducted to determine the appropriate sample size for the study. Although there were several outcome variables of interest (ROM, diastasis, failure torque, and mode of failure), the power analysis was based on diastasis, as previous studies had reported diastasis values for similar constructs. The analysis was based on a paired Student’s t test. The minimum clinically important difference was selected to be 2.5 mm based on previous studies. A standard deviation of 1.5 mm was assumed in each group. For a power of 80%, and an alpha (significance level) of .05, 5 pairs in each group were required.

Ebramzadeh et al

Diastasis During Cyclic Loading

During intact loading, the diastasis between the tibia and fibula for all specimens remained below 1.5 mm, with medians below 1.0 mm (Figure 3). Following fixation, regardless of fixation method, under cyclic loading, compared to intact measurements, diastasis between the tibia and fibula increased, although the increases were smaller for the screw construct group, compared to the suture-button devices (Figure 3).

External Rotation to Failure

One pair of specimens in group 1 failed before the end of the postfixation combined cyclic loading test. The remaining 8 specimens in that group, and all specimens in group 2 completed the 1,000 cycles of combined loading and were subsequently tested to failure (n = 18). As compared to diastasis measurements under the intact combined loading, during load to failure, the diastasis increased at the fixation level for all methods of fixation (Table 2), and was associated with statistical significance for all comparisons (P < .05). During load to failure testing, specimens with the ZipTight fixation device had a greater maximum rotation at failure and lower maximum torque than either of the other fixation devices (Table 3).

Mode of Failure

The majority of specimens failed by fibular fracture (12 out of 20). The remaining failures occurred by device pull-through or device failure, that is, screw bending or device loosening. Specifically, in 3 cases, the screw bent an average of 6 degrees, and in 1 case, the ZipTight device became loose, providing more slack and allowing for more movement between the tibia and fibula. The majority of suture-button failures were due to fibular fracture (ZipTight = 6, TightRope = 4), followed by device pull-through (ZipTight = 3, TightRope = 1) and device loosening (ZipTight = 1). In contrast, 3 of screw-fixed specimens failed by device failure, and 2 from bone fracture.

Overall, specimens that failed by fibula fracture (mean BMD 1.204 ± 0.137 g/cm²) had higher BMD than those that failed by the device pull-through (1.089 ± 0.162 g/cm²) or device failure (1.183 ± 0.105 g/cm²). Within the ZipTight fixation group, specimens that failed by fibular fracture (1.191 ± 0.075 g/cm²) had a significantly higher BMD than specimens that failed by device pull-through.
Foot & Ankle International 34(12)

(1.16 ± 0.187 g/cm²), \( P = .05 \). In the screw fixation group, specimens that failed by fibula fracture (1.276 ± 0.353 g/cm²), had a significantly higher BMD than specimens that failed by the device bending (1.178 ± 0.128 g/cm²), \( P = .04 \).

Discussion

The present study sought to determine differences in the ROM, diastasis, and failure torque among 2 types of suture-button fixation devices and a quadricortical screw construct. Overall, we found a general similarity among all 3 fixation devices in terms of ROM as well as how the diastasis between the tibia and fibula changed during both intact and postfixation cyclic loading. The differences between the 2 different suture-button devices, such as the torque at failure (ZipTight, 28.1 Nm; TightRope, 32.9 Nm), were not significant (\( P = .07 \)). The screw construct provided the highest torsional fixation strength, and the ZipTight device provided the lowest (ZipTight = 22.2 Nm; screw = 30.1 Nm; \( P = .03 \)). Nevertheless, all 3 devices provided torsional fixation strength exceeding the range of physiological loads that would likely be experienced during the healing process. Specifically, external torsional moments about the ankle joint in the ankle and the knee during level walking are well below 2 Nm and, during various other activities are still well below 20 Nm.\(^{1,2,4}\)

As indicated, 7 ZipTight specimens and 4 TightRope specimens experienced increase in diastasis of 5 mm or more during failure loading by external rotation, whereas none of the screw construct specimens experienced an increase in diastasis of 5 mm or more. This indicates that fixation of syndesmosis injuries using screws provided an assurance of solid fixation during the healing period.

Table 1. Average Change in Range of Motion (postfixation range of motion minus intact range of motion).

<table>
<thead>
<tr>
<th>Group</th>
<th>Motion</th>
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<th>TightRope</th>
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<td>SD</td>
<td>( P ) Value</td>
<td>Mean (deg)</td>
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<table>
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<th>Screw</th>
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<td>SD</td>
<td>( P ) Value</td>
<td>Mean (deg)</td>
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<td>&lt;.01</td>
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</table>

Figure 3. Boxplots of the diastasis at the level of fixation during loading are presented for intact, the first 50 cycles, the last 50 cycles, and at failure. The thick horizontal lines in the boxes represents the median (50th percentile), the top and bottom of the boxes represent the 75th and 25th percentiles, respectively, and the top and bottom error bars (“whiskers”) represent the maximum and minimum values.

As indicated, 7 ZipTight specimens and 4 TightRope specimens experienced increase in diastasis of 5 mm or more during failure loading by external rotation, whereas none of the screw construct specimens experienced an increase in diastasis of 5 mm or more. This indicates that fixation of syndesmosis injuries using screws provided an assurance of solid fixation during the healing period.

However, similar to previous studies,\(^{2,4}\) no hardware failure occurred in specimens with the TightRope or ZipTight fixation devices, while 3 out of the 5 screws bent. In only 1 of
the 10 specimens where failure of the ZipTight fixation device was suspected, the senior surgeon found loosening of the implant rather than breakage of the device.

With the pairs divided as they were, we were unable to provide a direct comparison between the TightRope device and screw fixation. Furthermore, since it is difficult to avoid while using cadaveric specimens, many of the specimens used in this study exhibited poor bone quality, which led to early fracture in both legs of 1 of the specimen pairs.

Several biomechanical studies have compared the TightRope fixation device to a metallic screw. They found that during or after external rotation loading, specimens with the TightRope device experienced a significant increase in the diastasis between the tibia and fibula, while specimens with the screw experienced a significant decrease.10,12,26 Similar to previous studies, the increase in diastasis during postfixation loading (cyclic combined loading and load to failure) compared to intact combined

| Table 2. Comparison of the Change in Diastasis Between the Tibia and Fibula During the Failure Loading and Intact Combined Loading. |
| Increase (+) or Decrease (−) in Diastasis at Failure Compared to Intact Combined Loading (diastasis at failure minus diastasis during intact combined loading) |
| Group 1 | ZipTight | TightRope |
| Mean (mm) | SD | P Value | Mean (mm) | SD | P Value |
| Malleolous | −2.3 | 1.4 | .05 | −1.3 | 1.3 | .15 |
| Fixation device | 7.6 | 4.3 | .04 | 6.3 | 2.8 | .02 |
| Group 2 | ZipTight | Screw |
| Mean (mm) | SD | P Value | Mean (mm) | SD | P Value |
| Malleolous | −1.1 | 1.8 | .24 | −1.6 | 0.9 | .02 |
| Fixation device | 4.7 | 1.3 | <.01 | 1.3 | 0.5 | .01 |

| Table 3. Comparison of Maximum Rotation and Torque at Failure Between Left and Right Pairs During Load to Failure. |
| Maximum Rotation (deg) | Maximum Torque (Nm) |
| Group 1 | ZipTight | TightRope |
| Mean | SD | P Value | Mean | SD | P Value |
| ZipTight | 78.9 | 22.5 | .27 | 28.1 | 12.7 | .07 |
| TightRope | 67.0 | 13.0 | .27 | 32.9 | 8.0 | .07 |
| Group 2 | ZipTight | Screw |
| Mean | SD | P Value | Mean | SD | P Value |
| ZipTight | 80.5 | 21.0 | .01 | 22.2 | 6.9 | .03 |
| Screw | 76.0 | 26.7 | .01 | 30.1 | 9.6 | .01 |

Overall, we found that ROM generally increased from intact testing to postfixation testing, an increase that was statistically significant in all specimens during eversion, and in specimens with the TightRope fixation device and the ZipTight fixation device (in the ZipTight vs screw group) during plantarflexion. Altered ROM can lead to a change in gait, which may result in subsequent musculoskeletal problems.3 However, although the kinematics of the bones in the foot, specifically the ankle complex, during ankle motion has been examined thoroughly in the literature,13-15 it is difficult to predict with certainty the precise outcome that would be observed in these patients without further clinical and in vivo investigation.

Several biomechanical studies have compared the TightRope fixation device to a metallic screw. They found that during or after external rotation loading, specimens with the TightRope device experienced a significant increase in the diastasis between the tibia and fibula, while specimens with the screw experienced a significant decrease.10,12,26 Similar to previous studies, the increase in diastasis during postfixation loading (cyclic combined loading and load to failure) compared to intact combined
loading was significant in specimens with the ZipTight and TightRope devices at the fixation device. However, in contrast to previous studies, we found that an increase in diastasis from intact combined loading to postfixation loading occurred in all specimens, including those with the screw. Furthermore, specimens with the screw construct experienced a significant increase during load to failure at the levels of the fixation device.

Only 3 previous biomechanical studies have compared failure torque under external rotation between specimens fixed with a metallic screw and specimens with the TightRope or suture-button device, and the results were contradictory. In particular, 1 study compared a 3.5 mm quadricortical screw to fixation with 2 suture-button devices. During failure loading by external rotation at 1 degree/second, they found that specimens with the screw failed at a significantly higher torque than specimens with the TightRope device (screw: median, 26.5 Nm; TightRope: median, 23.6Nm). Two other biomechanical studies compared a 4.5 mm quadricortical screw to the TightRope device or the Endobutton device. While 1 of these studies found that specimens with the TightRope device had a significantly higher failure torque than specimens with the screw (screw: median, 15 Nm; TightRope: median, 19 Nm), the other study found no significant difference in failure rate between groups. However, since only 3 specimens out of the 16 tested failed during loading (2 with a screw: 12.5Nm and 20Nm; and 1 with the Endobutton: 20Nm), the study may have lacked statistical power to draw a conclusion of no significant difference.

Conclusion
In the present study, suture-button devices provided torsional fixation strength below that of screw fixation. However, the fixation strength with both suture-button devices and screw fixation was above 20Nm, which exceeds torques that would be likely experienced during the healing period. Further studies and perhaps clinical observations may be required to assess the importance of the failure load measured in the study in the treatment of syndesmotic injuries.

Declaration of Conflicting Interests
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