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InternalBrace has biomechanical properties comparable to suture button but less rigid than screw in ligamentous lisfranc model

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ABSTRACT

Purpose: The aim of this study was to investigate the biomechanical properties of the InternalBrace for lisfranc injuries.
Methods: A Sawbone model was developed comparing screw, suture button and InternalBrace.
Results: When loaded in axial tension at 0.5 mm/s, the screw was stiffest (2,240 N/mm), while the InternalBrace (200 N/mm) was stiffer than the suture button (133 N/mm). Cyclic loading with 10,000 cycles of 69 N, 138 N, and 207 N showed the InternalBrace maintained stiffness, but fatigued earlier than the suture button.
Conclusion: The mechanical properties of the InternalBrace support clinical use, but further studies are needed regarding early weight bearing.

1. Introduction

Lisfranc injuries treated with open reduction and screw fixation are still associated with post traumatic osteoarthritis 24% of the time and 12.5% even go on to require arthrodesis.[1] Despite anatomic reduction, purely ligamentous injuries show a trend toward poorer outcome. Lisfranc injuries are characterized by a disruption of the ligaments between the medial cuneiform and the base of the 2nd metatarsal.[2] Unlike the other metatarsals, there is no intermetarsal ligament between the first and second metatarsals, thus the integrity of the Lisfranc ligament is important for maintaining foot stability of the medial aspect of midfoot. The Lisfranc ligamentous complex consists of one dorsal ligament, two plantar ligaments, and one interosseous ligament. The dorsal ligament is the weakest of the ligaments with a load to failure of 170 N, as compared to the interosseous ligament which has a load to failure 449 N.[2]

Current methods of treatment include screw and suture button fixation [3,4] While both interfragmentary screws and suture button fixation have been shown to decrease diastasis, screw fixation decreases natural physiological movement compared to the suture button. This may be particularly undesirable in athlete.[5] Furthermore, screw related complications were found in 16.1% of patients and post traumatic arthritis reported in as high as 49.6% of patients.[6]

The InternalBrace (Arthrex, Inc., Naples, FL, USA) is a flexible fixation technique that may decrease iatogenic cartilage damage that occurs during fixation.[5] The InternalBrace uses a 2 mm k-wire across the cartilaginous area of the Lisfranc joint. This is smaller than the drill required for a 3.5 mm cortical screw, 3.0 mm cannulated screw or mini TightRope (Arthrex, Inc., Naples, FL, USA). Other benefits include the potential for physiologic motion and collagen ingrowth.[5] Although these benefits may be seen with other suture button techniques, the InternalBrace also avoids a button on the medial cuneiform. Theoretically this may prevent bony erosion and soft tissue irritation on the tibialis anterior tendon, potentially decreasing the need for hardware removal. Given these benefits, the InternalBrace may be an appropriate option for Nunley Stage 2 and 3 injuries and may allow for weight bearing before complete healing and earlier return to sport.[5,7]

In general, biomechanical and clinical studies regarding the InternalBrace are extremely limited and to our knowledge, there are no studies that fit the fixation strategy used at the Lisfranc joint. We aimed to determine if the mechanical properties of the InternalBrace support its continued clinical use for Lisfranc injuries. We hypothesized that there would be no significant difference between the mechanical behavior of the screw, suture button and InternalBace in load to failure

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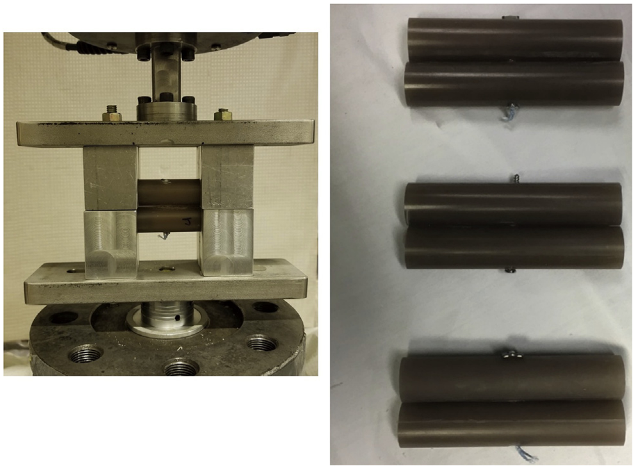

Fig. 1. Completed suture button, screw and InternalBrace (right, top to bottom) Sawbone constructs. Sawbone placed for analysis (left).

and with cyclic loading.

2. Methods

2.1. Fixation of Sawbone models

The Sawbone models consisted of two 4th generation Sawbone cylinders clamped together. The cylinders had 20 mm outer diameter, with a three mm cortical wall and were filled with 15 pound per cubic foot open cell rigid foam. These Sawbones were fixed with either InternalBrace, suture button, or screw (Fig. 1).

For InternalBrace fixation, a 2.0 mm hole was drilled through four cortices, The proximal cortex was then drilled with a 4.0 mm cannulated drill over a k-wire. Next, a 4.75 mm tap was used. The collagen coated fiber tape was passed and secured on the distal cortex with a curved button. While holding tension, a 4.75 mm biotenodesis screw was used to secure the internal brace on the proximal cortex (Fig. 1).

With suture button fixation (Mini TightRope, Arthrex, Inc., Naples FL, USA) a 2.7 mm drill was passed across all four cortices. The TightRope was passed and tensioned proximally over its suture button. This was followed by 6 half hitches. For conventional screw fixation, a 2.5 mm drill was placed through all four cortices. A 3.5 mm × 46 mm cortical screw was then placed in standard fashion (Fig. 1).

2.2. Monotonic load to failure

Thirty Sawbones (n = 10 per fixation method) were held in a mechanical testing system [Model 809, MTS Systems Corp, Minneapolis MN] using custom aluminum fixtures that held the two rods precisely parallel to each other (Fig. 1). Each group was loaded in axial tension at 0.5 mm/s until failure. Load-displacement data was plotted for each test. Failure was defined as loss of force less than 50% peak force. Yield was determined by detecting a deviation from linearity with a running least squares mean regression line and 0.1% displacement offset criteria. Stiffness prior to yield was calculated as the slope of the middle third of the data between the start of loading curve and construct yield. Ultimate strength was defined as the maximum load that occurred prior to failure.

2.3. Cyclic testing

Twenty-four Sawbones (n = 8 per fixation method) were loaded at cyclical physiologic loads until failure, defined as a 1.5 mm increase in displacement. Constructs were loaded at 10,000 cycles at 69 N, 138 N, and at 207 N. The cyclic loading parameters described are meant to represent protected weight bearing, normal walk, and jog. Because exact physiologic tension or force at the Lisfranc ligament due to weight bearing is unknown, it was estimated as follows. Prior literature has shown isolated Lisfranc stiffness of 189 N/mm[8] and Lisfranc joint stiffness to be 89 N/mm[2], which average to approximately 139 N/mm. An intact Lisfranc joint displaces 0.5 mm when a force is applied,[9] so assuming linear elastic stiffness, we calculate a tension of ~69 N for an intact Lisfranc ligament. Furthermore, weight bearing is defined as 50% body weight or the weight on one leg during standing.[10] Similarly, 50% body weight is also the load during push off phase of gait when walking assisted with a crutch.[11] We therefore use ligament force of 69 N as an estimate for protected weight bearing, 138 N to estimate full weight bearing, and 207 to estimate a jog. In this manner an attempt is made to correlate our findings to weight bearing.

Furthermore, our cyclic loading was meant to estimate the number of cycles over a 10 day course. An average adult walks 5,000 cycles per day, so if a repair is limited to 1,000 steps per day over the course of 10 days, there would be 10,000 cycles.[12] Constructs were therefore loaded for 10,000 cycles at 69 N to simulate protected weight bearing. After completion of 10,000 cycles, displacement was noted at 69 N (loaded displacement) and 5 N (unloaded displacement). The constructs that survived were subsequently loaded at 138 N to simulate full weight bearing, and the displacements were again noted at 138 N and 5 N. Finally, surviving constructs were loaded at 207 N to simulate load during jogging for an additional 10,000 cycles and displacement were again recorded at 207 N and 5 N.

2.4. Statistical analysis

Normality was assessed using a Shapiro-Wilks Test. Differences in continuous variables between fixation type were compared using a Kruskal-Wallis Test. Where statistical differences were detected using the Kruskal-Wallis test, a post-hoc Steel-Dwass test was used to determine which groups were significantly different from one another. Where only data for two types of repair types were available, a Wilcoxon Rank Sums nonparametric *t*-test was used. The median and interquartile range were reported for continuous variables. Computations were performed using statistical software [JMP Pro, 13.0, http://www.jmp.com] Significance was set at $p < 0.05$.

3. Results

3.1. Monotonic load to failure

Yield force showed no significant difference between the InternalBrace (183 N) and the suture button (177 N). Yield displacement was significantly smaller for the InternalBrace (0.64 mm) than the suture button (1.56 mm) (Table 1).[13] Stiffness was significantly greater in the screw group compared to the InternalBrace and suture button groups. The InternalBrace, however, was significantly stiffer than the suture button (200 N/mm vs. 133 N/mm) (Fig. 2). During monotonic loading, screw constructs failed when the Sawbone broke, so yield was not determined. Eight of ten suture button constructs had a yield point, whereas the other 2 constructs directly failed.

Screw constructs also exhibited greater ultimate force, displacement at ultimate force, and failure displacement than InternalBrace and suture button constructs. Ultimate force and displacement at ultimate force were significantly less for the InternalBrace compared to the suture button. On the other hand, failure displacement was significantly greater for the Internal Brace than the suture button (Table 1).[13]

Qualitatively, the InternalBrace failed by having the suture tape slide past the biotenodesis screw. The suture button construct failed by either having the knot unravel, break or having one of the sutures break. Screw constructs failed by fracturing the Sawbone on the side of the screw head. These failure patterns remained the same during cyclic loading failure.

Table 1
Load to failure analysis showing statistical comparisons. Numbers presented as median and interquartile range. The screw did not show yield.

	InternalBrace (n = 10)	Screw (n = 10)	Suture Button (n = 10)	P – Values
Yield Displacement (mm)	0.64 [0.34, 0.97] (n = 10)	–	1.56 [1.43, 1.74] (n = 8)	0.0004
Yield Force (N)	183 [142, 224] (n = 10)	–	177 [132, 239] (n = 8)	0.8940
Energy to Yield (N*mm)	80 [42, 126] (n = 10)	–	173 [100, 201] (n = 8)	0.0235
Post-Yield Energy (N*mm)	315 [129, 421] (n = 10)	–	539 [357, 774] (n = 8)	0.0295
Stiffness (N/mm)	200 [177, 273]^{A}	2240 [1995, 2407]^{B}	133 [108, 183]^{C}	< 0.0001
Displacement at Ultimate Force (mm)	2.06 [1.16, 2.38]^{A}	0.87 [0.83, 0.94]^{B}	3.47 [2.42, 4.06]^{C}	< 0.0001
Ultimate Force (N)	238 [176, 322]^{A}	1690 [1570, 1775]4^{B}	393 [307, 465]^{C}	< 0.0001
Energy at Ultimate Force (N*mm)	418 [166, 555]^{A}	682 [593, 754]^{B}	644 [526, 885]^{B}	0.0039
Failure Displacement (mm)	13.34 [12.46, 16.16]^{A}	0.89 [0.86, 0.98]^{B}	5.39 [4.25, 5.82]^{C}	< 0.0001

P-Values reported using Kruskal-Wallis test. Superscript letters (A, B) indicate where statistical differences exist between groups using a post-hoc Steel-Dwass test. *Where only two repair types are compared, *P*-Values are reported using a Wilcoxon Rank Sums *t*-test.

3.2. Cyclic testing

After 10,000 cycles of cyclic loading at 69 N, there was no difference in displacement between the InternalBrace and suture button at either peak load or at 5 N load (Figs. 3 and 4, Table 2). Displacement of the screw construct was significantly less than the InternalBrace and suture button constructs, except at 5 N load the displacement with the InternalBrace was not significantly different than with the screw. After 10,000 cycles of cyclical loading at 138 N, three InternalBrace and one suture button had failed. In the remaining constructs, there was no difference in displacement between the InternalBrace and suture button at either peak load or at 5 N load. Again, the screw constructs had less displacement than the other fixation methods. With cyclic loading at 207 N, all InternalBrace constructs had failed. Only two suture button constructs remained, but all screws lasted 30,000 cycles.

4. Discussion

Injuries to the Lisfranc joint span from low energy to high energy crush injuries, and from solely ligamentous to those associated with fractures. They are often missed injuries and in trauma patients and may be better evaluated with CT.[6,14] The two most common mechanisms of injury are falls from heights which cause low energy injury and motor vehicle accidents, which cause high energy injuries.[6,14] Pure ligamentous sprains and tears occur as well in athletes.[7] Treatment with reduction and anatomic stabilization of the joint is thought to be required for improved outcomes.[1,6,7,15,16] Furthermore, low energy Lisfranc injuries treated with percutaneous fixation may be able to return to low energy sport at a sooner timeframe.[16]

The primary objective of this study was to determine if the mechanical integrity of InternalBrace supports its continued use, and to compare its mechanical properties to that of the screw and suture button fixations. We also aimed to determine if the InternalBrace properties could support early weight bearing by tolerating a full-weightbearing load. In our load to failure analysis the screw was shown to be stiffer and stronger than the InternalBrace and suture button. The Lisfranc joint does have physiologic motion and an intact Lisfranc stiffness has been shown to be between 89 and 189 N/mm[1,2]. The suture button device lies within this range, and the InternalBrace is slightly more stiff. Clinically, this flexibility is desirable, especially for athletes,[5] though the literature has yet to determine the appropriate amount of motion.[4]

A variety of techniques have been described for use of the InternalBrace including flatfoot reconstruction, lateral ligament stabilization and medial collateral ligament augmentation.[17–22] However, the literature has few studies evaluating the biomechanical outcomes after these techniques are employed. One cadaveric study showed similar failure between allograft medial colateral ligament reconstruction and InternalBrace repair. Both allograft and InternalBrace repair were significantly weaker than the native MCL however.[21] Another cadaveric study showed similar failure between native anterotalofibular ligament and Broström repair with InternalBrace augmentation.[22] A third study showed that cadaveric spring ligament repair did not return of the spring ligament did not reduce displacement compared to native tissue, unless augmented by an InternalBrace.[20]

In our study, when assessing yield properties, the InternalBrace showed a lower displacement, but a similar yield force (Table 1).[13] This means that the suture button had stretched more than the InternalBrace at yield. The yield energy is larger in the suture button due to the stretching that occurs. This excess displacement is not desirable for an effective repair since too much motion may alter the physiologic environment at the joint. However, the exact stiffness desired during

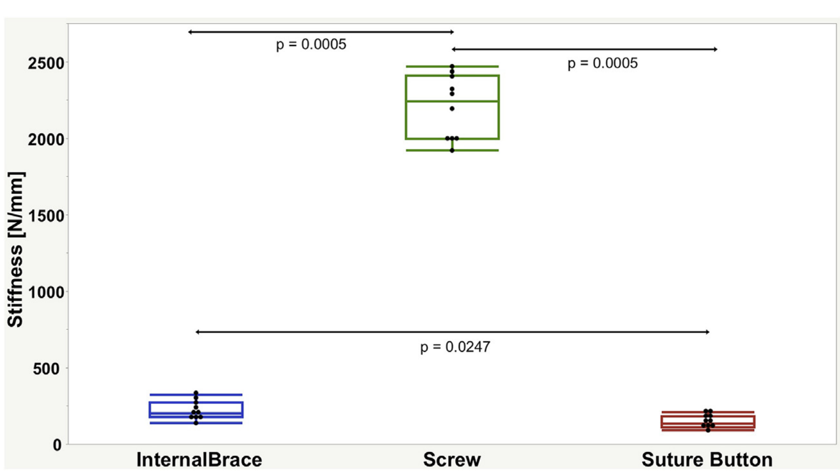

Fig. 2. Screw Stiffness was highest, though InternalBrace was significantly stiffer than the suture button. Intact lisfranc Stiffness is 89–189 N/mm.[8,24]

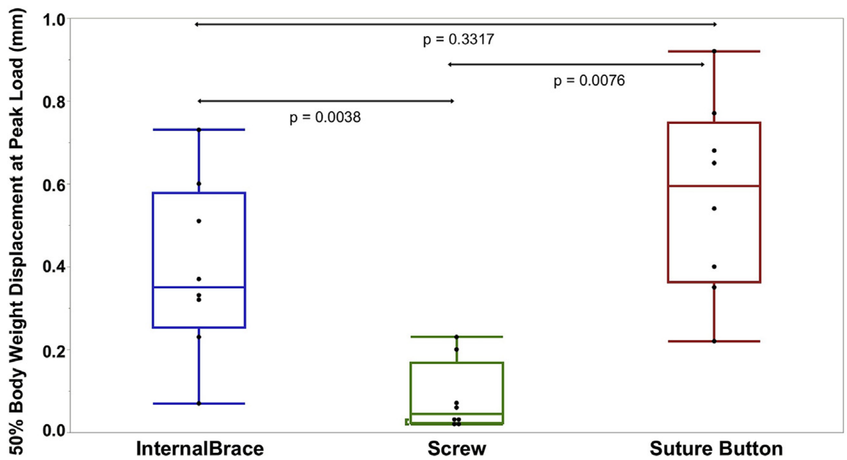

Fig. 3. Cyclic loading with 69 N for 10,000 cycles showed no difference in displacement between the InternalBrace and Suture button at peak load. The screw had significantly less displacement at peak load.

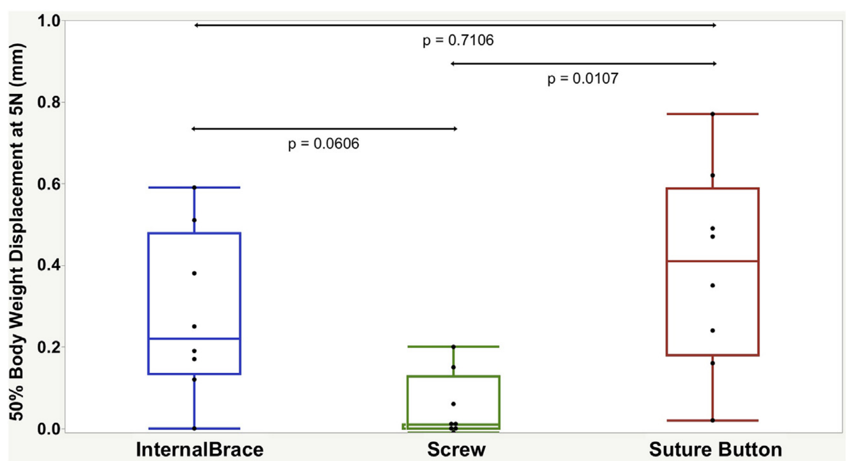

Fig. 4. Cyclic loading with 69 N for 10,000 cycles showed no difference in displacement between the InternalBrace and Suture button at 5 N load. The screw had significantly less displacement than the suture button at 5 N load, but was not significantly different than the InternalBrace.

Table 2
Cyclic loading analysis showing differences in displacement at peak load and at 5 N for 50%, 100%, and 150% body weight. Numbers presented as median and interquartile range. The fatigue life of the InternalBrace was shorter than the suture button or screw.

	InternalBrace (n = 8)	Screw (n = 8)	Suture Button (n = 8)	P – Values
50% Body Weight at Peak Load (mm)	0.35 [0.25, 0.58]^{A}	0.05 [0.02, 0.17]^{B}	0.60 [0.36, 0.75]^{A}	0.0007
50% Body Weight at 5 N (mm)	0.22 [0.13, 0.48]^{A,B}	0.01 [0.00, 0.13]^{B}	0.41 [0.18, 0.59]^{A}	0.0067
100% Body Weight at Peak Load (mm)	0.96 [0.69, 1.10]^{A} (n = 5)	0.10 [0.05, 0.22]^{B} (n = 8)	1.19 [0.97, 1.41]^{A} (n = 7)	0.0006
100% Body Weight at 5 N (mm)	0.76 [0.48, 0.89]^{A} (n = 5)	0.02 [0.00, 0.13]^{B} (n = 8)	0.87 [0.67, 1.10]^{A} (n = 7)	0.0008
150% Body Weight at Peak Load (mm)	–	0.16 [0.09, 0.24] (n = 8)	1.82 [1.28, 2.36] (n = 2)	0.0502*
150% Body Weight at 5 N (mm)	–	0.05 [0.02, 0.14] (n = 8)	1.37 [0.84, 1.90] (n = 2)	0.0488*

P-Values reported using Kruskal-Wallis test. Superscript letters (A, B) indicate where statistical differences exist between groups using a post-hoc Steel-Dwass test. *Where only two repair types are compared, *P*-Values are reported using a Wilcoxon Rank Sums *t*-test.

anatomic reduction has not been borne out in the literature. Ultimate Force and Energy are superior in the suture button compared to the InternalBrace, however the InternalBrace continues to hold load more consistently and for a larger displacement compared to the suture button. This is exemplified in load-displacement curves where the suture button has more drastic decrease in load and this loss occurs with less displacement (Fig. 5). Although the InternalBrace shows a propensity to keep the sawbones together longer and with less displacement for a given load, the displacements noted here are likely outside clinically relevant measurements. For example, in a cadaveric model the difference in displacement between a cut Lisfranc and fixed Lisfranc were between 1 and 1.2 mm.[3] In our study failure displacement of the InternalBrace and suture button were 5–13 mm, and therefore far outside this range. We therefore cannot necessarily infer these InternalBrace benefits in vivo.

During cyclic loading, the InternalBrace was able to maintain its stiffness as well or better than the suture button with 69 and 138 N loads. The loading parameters described were developed to represent protected weight bearing, normal walk, and jog. Those calculations allow some degree of clinical correlation to our cyclic loading results. This correlation is especially important since it has been proposed that early weight bearing is an advantage of the InternalBrace[5] and percutaneous techniques.[16] Although the stiffness of the InternalBrace was better, the average fatigue life of the InternalBrace, was shorter than

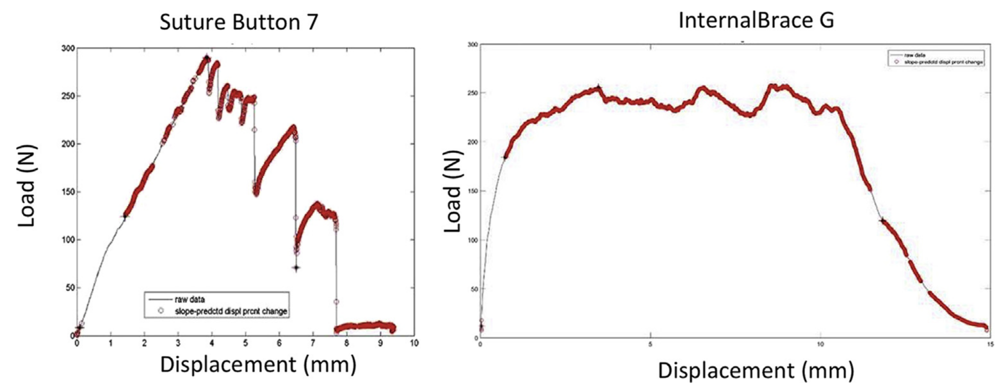

Fig. 5. Comparison of load displacement curves between a suture button and InternalBrace. The suture button has more drastic decrease in load at a smaller displacement.

that of the suture button. Even with 138 N, two InternalBrace constructs failed. This would be concerning and could potentially cause a loss of reduction in the early stages of healing. The screw had the greatest resistance to fatigue with significantly less displacement for all parameters. We can infer that the InternalBrace is adequate to prevent displacement with protected weight bearing, but may not allow for early weight bearing.

Although our results do not necessarily support early weight bearing from an InternalBrace construct, one unique difference is present. In the previously described medial collateral ligament and anterior talofibular ligament techniques, the InternalBrace is used as an augmentation to repair.[21,22] In the Lisfranc technique, no such repair occurs and this may be a major difference in the current technique.

Although our study adds the InternalBrace comparison, results are similar to those in the literature regarding the screw and suture button. Ahmed (2010) found the screw to have less displacement than mini TightRope in their cadaveric model.[4] They conclude that screw fixation should remain the accepted treatment over mini TightRope until further studies are performed. In contrast, Panchbhavi (2009) found no difference in displacement between screw and suture button in their cadaveric model.[3] No other studies compare to the InternalBrace technique however.

The main limitation of our study is that it is a Sawbone model. Furthermore, in vivo, bone quality and size are not reproducible. We used a 4.0 mm drill and tap when placing the interference screw in this study, but this is larger than described by [5,13] Clinically, a smaller drill size may even be warranted and further cadaveric and clinical studies will likely be needed to determine the appropriate interference fit in different bone.

Finally, our study also used a straight tension vector to assess the strength of our constructs. This may not be the exact mechanism of a Lisfranc injury. However, one study demonstrated that the magnitude of motion at the Lisfranc joint with axial loads was significantly less than seen with abduction testing.[23] For that reason an abduction vector may actually be more important when assessing the strength of fixation. Although this may not be the natural occurring injury mechanism, our study demonstrates strength at the most reliable and potentially the most dramatic displacement vector.

5. Conclusions

The InternalBrace shows properties that appear comparable to the suture button, while being less rigid than the screw in load to failure. During cyclical loading, the InternalBrace shows properties appropriate for anatomic fixation with protected weight bearing, though it has increased failure rates with increased load. This study provides valuable biomechanical information to guide surgeons in continued use and rehabilitation.

Declaration of interest

J.H. has nothing to disclose.
K.N. has nothing to disclose.
N.H. has nothing to disclose.
T.S. has nothing to disclose'.
C.K reports the following disclosures: Consultant: Arthrex, Inc., Zimmer, Inc.
T.G. has nothing to disclose.
B.C. has nothing to disclose.
E.G. reports the following disclosures: Consultant for Arthrex, Inc., Zimmer, Inc.; Fellowship and Grant Funding: Arthrex, Inc., Zimmer, Inc.

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