


Primary Fixation and Cyclic Performance of Single-Stitch All-Inside and Inside-Out Meniscal Devices for Repairing Vertical Longitudinal Meniscal Tears

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Background: Primary device fixation and the resistance against gap formation during repetitive loading influence the quality of meniscal repair. There are limited biomechanical data comparing primary tensioning and cyclic behavior of all-inside versus inside-out repair.

Hypothesis: All-inside devices provide higher initial load on the meniscal repair than inside-out fixation, and stiffer constructs show higher resistance against gap formation during cyclic loading.

Study Design: Controlled laboratory study.

Methods: In total, 60 longitudinal bucket-handle tears in human cadaveric menisci were created and repaired with a single stitch and randomly assigned to 4 all-inside groups (TrueSpan, FastFix 360, Stryker AIR, FiberStich) and 2 inside-out groups (suture repair [IO-S], suture tape [IO-ST]). Residual load after repair tensioning (50 N) and relief displacement were measured. Constructs underwent cyclic loading between 2 and 20 N over 500 cycles (0.75 Hz) with cyclic stiffness, gap formation, and final peak elongation measured. Ultimate load and stiffness were analyzed during pull to failure (3.15 mm/s).

Results: All-inside repair demonstrated significantly higher primary fixation strength than inside-out repair. The significantly highest load (mean \pm SD; 20.1 ± 0.9 N; $P < .037$) and relief displacement (-2.40 ± 0.32 mm; $P < .03$) were for the knotless soft anchoring FiberStich group. The lowest initial load (9.0 ± 1.5 N; $P < .001$) and relief displacement (-1.39 ± 0.26 mm; $P < .045$) were for the IO-S repair group. The final gap formation (500th cycle) of FiberStich (0.75 ± 0.37 mm; $P < .02$) was significantly smaller than others and that of the IO-S (1.47 ± 0.33 mm; $P < .045$) significantly larger. The construct stiffness of the FiberStich and IO-ST groups was significantly greater at the end of cyclic testing (16.7 ± 0.80 and 15.5 ± 1.42 N/mm; $P < .042$, respectively) and ultimate failure testing (23.4 ± 3.6 and 20.6 ± 2.3 N/mm; $P < .005$). The FastFix 360 (86.4 ± 4.8 N) and Stryker AIR (84.4 ± 4.6 N) groups failed at a significantly lower load than the IO-S group ($P < .02$) with loss of anchor support. The FiberStich (146.8 ± 23.4 N), TrueSpan (142.0 ± 17.8 N), and IO-ST (139.4 ± 7.3 N) groups failed at significantly higher loads ($P < .02$) due to suture tearing.

Conclusion: Overall, primary fixation strength of inside-out meniscal repair was significantly lower than all-inside repair in this cadaveric tissue model. Although absolute differences among groups were small, meniscal repairs with higher construct stiffness (IO-ST, FiberStich) demonstrated increased resistance against gap formation and failure load.

Clinical Relevance: Knotless single-stitch all-inside meniscal repair with a soft anchor resulted in less gapping, but the overall clinical significance on healing rates remains unclear.

Keywords: meniscal repair; all-inside; inside-out; primary fixation; biomechanics

Knee injuries in younger patients are often accompanied with longitudinal tears at the periphery of the meniscus.^{14,18,19} Primary repair is intended to preserve the meniscal tissue and reduce the risk of osteoarthritic changes over time.^{20,29,32,41} Historically, the inside-out

technique has long been considered the gold standard for meniscal repair, with overall reduced clinical complications and extra-articular knot fixation, but it requires additional dissection of soft tissue with protection of neurovascular structures using arthroscopic assistance.^{8,23} The all-inside repair was introduced to address these problems by reducing the risk of neurovascular injury, operative time, and assistance without compromising meniscal healing or functional results.^{12,15,36} Equivalent clinical success rates and outcome scores to inside-out repair

contributed to the widespread use of all-inside suture devices for adjustable compression at the tear site of longitudinal vertical meniscal tears.^{13,35} Clinical implant-related complications with all-inside devices are associated with improper suture tensioning,³⁷ rigid anchor breakage or migration,^{2,9} and soft tissue irritation or swelling,¹⁶ as well as retears through the larger holes with all-inside devices.³⁵ The latest generation of all-inside meniscal repair devices offers knotless all-suture loop fixation for tissue preservation and better control of tissue compression at the time of surgery.

Other than the biologic healing environment, the success of meniscal healing mainly depends on the primary fixation strength at the time of insertion and the resistance against gap formation during repetitive loading in the rehabilitation phase. Biomechanical performances of various meniscal repair systems have been reported, mainly focusing on gap formation and ultimate failure data.^{5,23,30,33} Increased construct stiffness is normally associated with higher stability and resistance against deformation but could also have an influence on the mode of failure under cyclic loading conditions.³⁶ Currently, there is a paucity of biomechanical data available on the primary fixation strength of commercially available all-inside and inside-out devices for meniscal repair. A direct measurement of the tensioning during meniscal repair fixation is required for stability evaluation at the time of reapproximation at the tear site.^{24,30,33,38} Additional knowledge about the construct stiffness and load-bearing behavior during cyclic loading may help to better understand device-induced damage effects on the meniscal tissue.⁷

The purpose of this study was to evaluate the initial repair load and relief displacement after primary fixation, gap formation, and stiffness behavior during cyclic loading, as well as ultimate load and stiffness during failure testing of 6 devices for repairing longitudinal meniscal tears using human menisci. We hypothesized that adjustable tensioning for primary all-inside meniscal repair fixation would lead to higher initial repair load and that stiffer constructs would show higher resistance against gap formation during cyclic loading conditions.

METHODS

Meniscal Preparation and Repair

Overall, 60 adult human cadaveric menisci (medial and lateral side) obtained from 30 knees (15 male and 15 female; mean \pm SD age, 61.3 \pm 7.2 years) were isolated by releasing the meniscocapsular tissue and dissecting the roots at the tibial attachments. All specimens were provided by the Science Care donor bank and were visually inspected after harvesting to ensure structural integrity without tears or obvious degenerative changes. An artificial longitudinal vertical tear was created using a No. 11 scalpel 3 mm from the peripheral rim starting from the midpoint of the meniscus and separating the central third portion of the meniscal body along the circumferential fiber orientation toward the anterior and posterior horns. Paired specimens were randomly assigned to 1 of 6 groups but evenly distributed by sex and age (Figure 1). A single vertical mattress repair was performed at the midpoint of the meniscus with the first pass 3 mm internally from the tear. The second suture pass was also made 3 mm from the tear toward the capsule. Once the repair was in place, the meniscal tear was completed by vertical resection through the anterior and posterior horns.

Single-stitch repairs were performed on all tears. The following were used for all-inside meniscal repair testing: 3 PEEK anchor-based fixation devices (each group, n = 10) consisting of the Stryker AIR (Stryker Corporation), Fast Fix 360 (Smith & Nephew), and the TrueSpan (DePuy Mitek Inc), as well as an adjustable tensioning soft anchor-based fixation device (FiberStitch [FS]; Arthrex Inc). The knotless FS device required stepwise tensioning of individual loops, whereas both suture loops of the PEEK anchor devices were shortened at the same time with final advancement of a pretied sliding knot. The anchor size and shape as well as the location of the sliding knot varied among PEEK anchor devices with either outside position on the capsular side of the meniscus (TrueSpan) or inside the joint (FastFix 360, Stryker AIR) (Figure 1). Two inside-out groups using preloaded repair needles with either No. 2-0 suture (2-0 FiberWire Meniscus Repair

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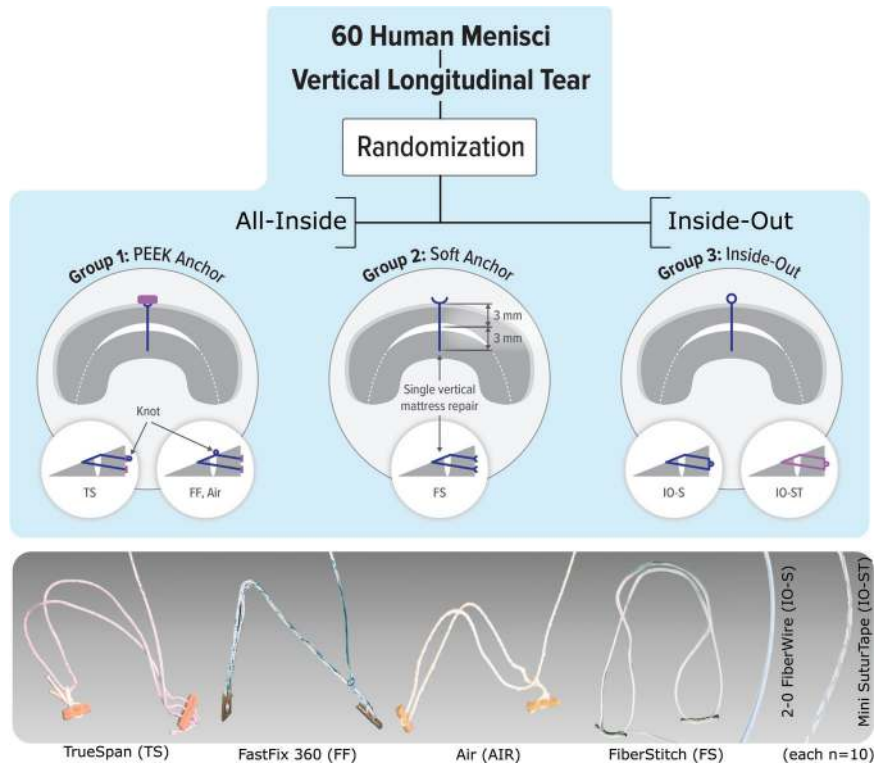


Figure 1. Schematic illustration of different groups with single vertical repair utilizing PEEK and soft anchor-based all-inside as well as inside-out devices.

Needles; Arthrex Inc) or suture tape (Mini SutureTape Meniscus Repair Needles; Arthrex Inc) served as references for baseline comparison. Device fixation of inside-out samples was performed by manual knot tying of 4 alternating counteractive half-hitch knots using an arthroscopic knot pusher on the capsular side of the meniscus.

Fixation and Tensioning

The peripheral and central meniscal portions were secured using custom clamps with ruffled surfaces with the midpoint of the meniscus in the central position (Figure 2). Both meniscal clamps were attached with the vertical repair aligned to the actuator axis over a bottom and top mount to the baseplate and test machine actuator (ElectroPuls E10000; Instron), respectively. The actuator was moved to achieve an initial distance between meniscal parts of 5 mm measured along the repair with a caliper.

Tensioning of all-inside meniscal repair devices for meniscal reapproximation at the tear site was performed according to the device manufacturer guidelines, with a final manual 50-N pull on the tightening suture over 5 seconds using a spring-loaded tensiometer and knot pusher to simulate intraoperative single-hand tensioning. The level of applied traction for primary fixation of available all-inside repair devices was evaluated during pre-tests and was chosen to achieve a residual load after traction release in the range of the cyclic peak load (20 N).

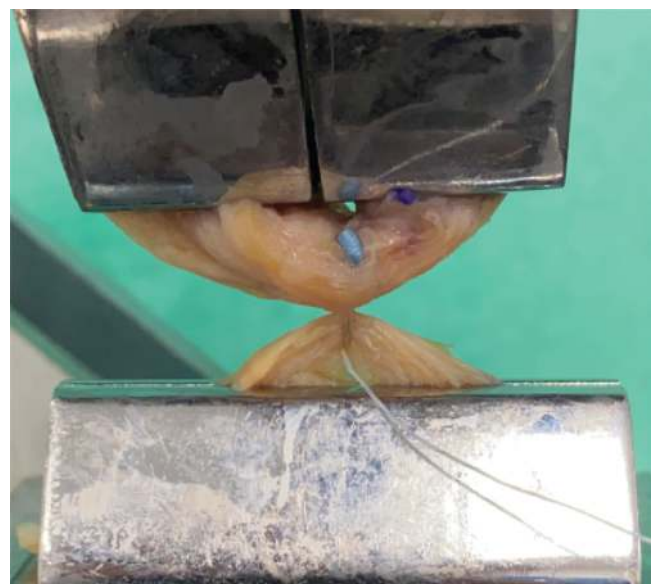


Figure 2. Experimental test setup with separated meniscal portions secured with ruffled metal clamps and the single vertical repair in line with the test machine actuator axis.

Suture fixation of inside-out samples was performed similarly but with 50-N traction on every locking half-hitch knot. Reproducible meniscal repair suture tensioning with

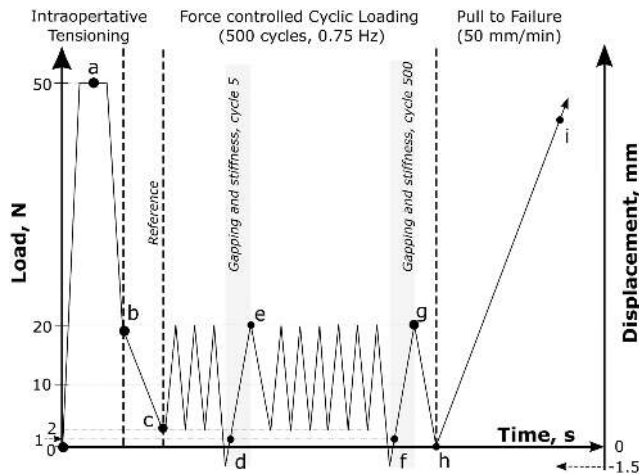


Figure 3. Testing protocol with simulation of intraoperative tensioning for meniscal repair fixation, cyclic loading, and pull to failure. Points of data analysis included initial repair tension (F_0 , b) and dependent relief displacement to reach the time-zero valley position with 2-N load on the repair (s_0 , Δbc), peak elongation (s_p , Δcg), and initial (g_5 , d) and final (g_{500} , f) gap formation, as well as ultimate load and stiffness during pull to failure (Δhi).

the actuator locked in position ensured proper time-zero fixation for comparative analysis of the initial tension and simultaneously reduced settling effects before cyclic testing. As the primary tension varied after tensioning, the test machine actuator moved to reach a defined time-zero preload position of 2 N, which served as a common reference for later elongation analysis and guaranteed similar and reproducible initial testing conditions for all groups. The initial load on the repair (F_0) after tensioning with corresponding actuator relief displacement to reach the time-zero valley position for cyclic testing with 2-N load on the repair (s_0) was acquired by the test machine (Figure 3). The actuator relief displacement from the tensioned state after fixation toward repair unloading represents a direct indicator for gap initiation. An absolute greater relief displacement of a device at the time of insertion is equivalent to a higher degree of security against gap initiation. All tests were performed at room temperature, and soft tissue was kept moist with physiological saline solution during preparation and testing.

Cyclic and Failure Testing

Cyclic loading was applied perpendicular to the tear, with the meniscal repair aligned with the actuator axis at a test frequency of 0.75 Hz over 500 cycles between 2 and 20 N to simulate stress loading on the repair. Utilized test parameters are in line with numerous other studies evaluating the biomechanical performance of meniscal repair systems.^{3,5-7,23,33} Actuator translation relative to the time-zero preload position (-1.5 mm) at the beginning of testing (cycle 5) and end (cycle 500) served for complete unloading-

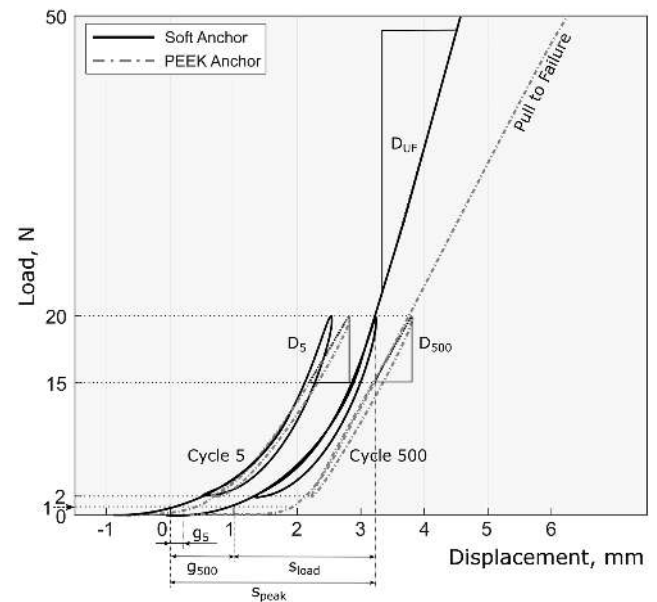


Figure 4. Schematic illustration of representative load-displacement progression for outcome analysis of meniscal repair devices based on soft (black line) and PEEK (dotted gray line) anchors. Outcome parameters included gap formation (g_5 and g_{500}) and dynamic stiffness at cycles 5 and 500 (D_5 and D_{500}), final peak elongation (s_{peak}), and elastic displacement range with load on the repair (s_{load}), as well as ultimate stiffness (D_{UF}) and load (F_{max} , not shown).

loading simulation of the repair, which was used for gap formation analysis (Figure 3).¹ Mechanical data were recorded continuously with a sampling rate of 500 Hz. Final load-to-failure testing was performed at a rate of 3.15 mm/s.

Outcome Data

Metrics for comparisons included data of meniscal repair fixation, cycling, and pull to failure. After primary fixation, the initial repair load (F_0) with corresponding actuator relief displacement (s_0) to reach the time-zero preload position of 2 N was assessed. Cyclic loading outcome data included gap formation (g_5 and g_{500}) and dynamic stiffness at cycles 5 and 500 (D_5 and D_{500}), as well as final peak elongation (s_{peak}) with ultimate load (F_{max}) and stiffness (D_{UF}) determined during pull to failure (Figure 4).

Gap formation represents plastic deformation (laxity) with no load (<1 N) on the repair measured in the loading phase after complete unloading. Dynamic stiffness represents the linear inclination of hysteresis data in the loading phase in the range between 15 and 20 N. The peak elongation (s_{peak}) was used to provide additional group-specific information about the load-bearing elongation range (s_{load}) at the end of testing (500th cycle). Ultimate failure load (F_{max}) and stiffness (D_{UF}) were determined during pull to failure. Stiffness was calculated within the linear portion of the load elongation curve.

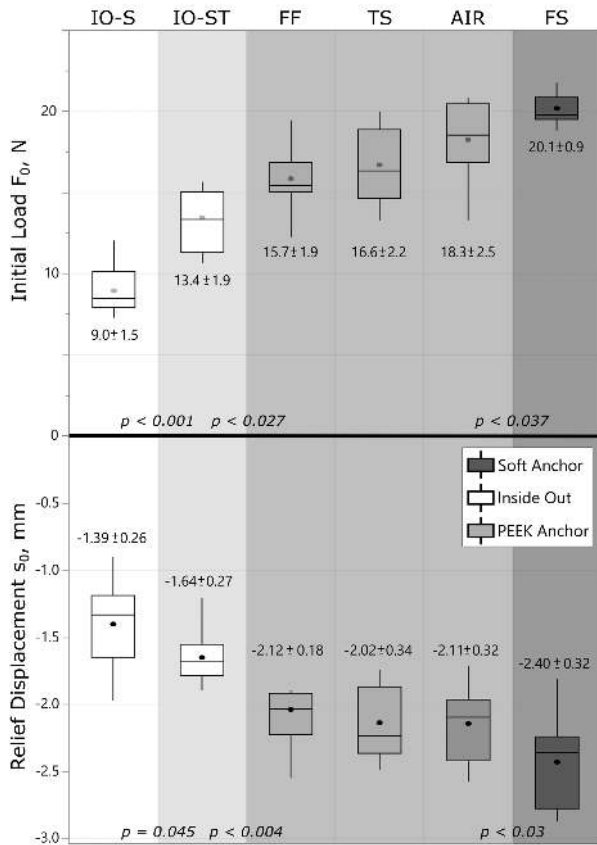


Figure 5. Box plot with mean \pm SD of initial repair load after tension release (50 N) with corresponding relief displacements to reach the time-zero valley position with 2-N load on the repair. Different background shadings indicate statistical significance levels. For abbreviations, see Figure 1. Circle, mean; line, median; box, interquartile range; error bars, 95% CI.

Statistical Analysis

In this study, repair techniques and devices were independent variables. All metrics for comparison were dependent variables. Initial repair tension (F_0) with relief displacement (s_0), gap formation (g_5, g_{500}), dynamic stiffness (D_5, D_{500}), and ultimate failure load (F_{max}) and stiffness (D_{UF}) were defined as primary outcome variables.

Statistical analysis was performed using Sigma Plot Statistics for Windows Version 13.0 (Systat Software). The statistical analysis included a 1-way analysis of variance with Holm-Sidak post hoc test performed for significant pairwise analysis of primary outcome variables. Significance was defined as $P \leq .05$, and the desired power level was set at 0.8. The Shapiro-Wilks test was used to confirm that each data set followed a normal distribution. A nonparametric test (Kruskal-Wallis) was used for data sets that failed this test. For Kruskal-Wallis tests that found significance, a post hoc test according to the Dunn method was conducted to analyze the differences. The observed post hoc average power values of all 1-way

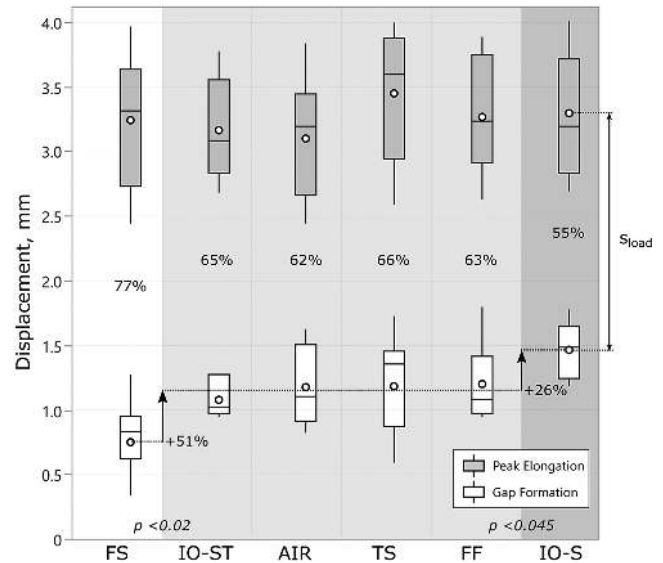


Figure 6. Box plot with mean (circle) and median (line) gap formation, peak elongation, and percentage load-bearing share of the peak elongation at the end of cycling (500th cycle). Different shaded backgrounds indicate significance between gap formation levels. For abbreviations, see Figure 1. Box, interquartile range; error bars, 95% CI.

analysis of variance tests were much higher than the desired power level of 0.8, leading us to conclude that our sample size was sufficient. Data analysis was performed with MATLAB Version R2019a (MathWorks).

RESULTS

Primary Fixation

Overall, all-inside repair demonstrated significantly higher primary fixation strength than inside-out devices. The knotless soft anchoring device (FS) achieved the highest initial load as well as the lowest relief displacement (Figure 5). In contrast, the inside-out suture repair (IO-S) group had the lowest initial load as well as the highest displacement. Knot tying of a suture tape for inside-out repair fixation (IO-ST) led to significantly increased initial repair load and decreased relief displacement as compared with suture-based repair (IO-S).

Cyclic Testing

The mean and standard deviation results of gap formation, dynamic stiffness, and load-bearing share of the final peak elongation (500th cycle) are shown in Table 1. The gap formation was significantly smaller for FS and larger for the IO-S group as compared with all other groups throughout testing. All groups demonstrated construct stiffening during cycling (D_5 to D_{500}). The FS and IO-ST constructs resulted in significantly higher stiffness at the end of testing compared with the other groups ($P < .042$).

TABLE 1
Statistical Analysis of Dynamic Outcome Parameters for All Test Groups^a

Group: Device	Gap Formation		Stiffness		Loading Range
	g_5 , mm	g_{500} , mm	D_5 , N/mm	D_{500} , N/mm	S_{load} , %
All-inside					
Soft anchor: FiberStich	$0.07 \pm 0.07^-$	$0.75 \pm 0.37^-$	$14.1 \pm 1.93^+$	$16.7 \pm 0.80^+$	77
PEEK anchor					
AIR	0.16 ± 0.14	1.18 ± 0.29	12.2 ± 0.64	13.8 ± 1.42	62
TrueSpan	$0.26 \pm 0.13^+$	1.19 ± 0.37	12.3 ± 1.30	13.7 ± 1.31	66
FastFix 360	0.13 ± 0.11	1.20 ± 0.30	11.5 ± 0.60	13.3 ± 1.60	63
Inside-out					
Mini SutureTape	0.13 ± 0.10	1.10 ± 0.14	$13.6 \pm 1.60^+$	$15.5 \pm 1.42^+$	65
2.0 FiberWire	0.15 ± 0.10	$1.47 \pm 0.21^+$	11.9 ± 1.16	13.9 ± 1.15	55
Significance, <i>P</i> value					
+	<.037	<.044	<.023	<.042	
-	<.025	<.018	—	—	
Test power	0.72	0.93	0.98	0.98	

^aValues are presented as mean \pm SD. +/- indicates significantly higher/lower value vs others. For abbreviations, see Figure 4.

No significant difference was found for peak elongation at the end of testing (500th cycle) between groups ($P > .13$). The mean and standard deviation were 3.26 ± 0.45 mm (Figure 6). The FS and IO-S groups provided the highest and lowest load-bearing elongation share (S_{load}), respectively.

Pull to Failure

All constructs reached the regular test end and were pulled to failure. Ultimate stiffness data were in line with cyclic data, with significantly higher construct stiffness for the FS and IO-ST groups as compared with IO-S and PEEK anchor devices (Figure 7). The ultimate loads of the Fast-Fix 360 and Stryker AIR were significantly lower than other devices and failed because of loss of anchor fixation (breakage and meniscal pull-through). Suture tearing was the common mode of failure for the IO groups with significantly increased failure load in the IO-ST group, which demonstrated similar failure strength as compared with the TrueSpan and FS groups. Both the TrueSpan and FS group failed owing to the rupture of the anchor-connecting suture.

DISCUSSION

The most important finding of this study was that all-inside devices provided significantly higher initial load and relief displacement than inside-out repair, with the all-suture knotless tensioning FS device achieving significantly lower gap formation and higher ultimate strength after repetitive loading than the all-inside PEEK anchoring devices in human menisci. The quality of meniscal repair is determined by the primary device fixation but also by the resistance against gap formation during repetitive loading. It is unclear from the literature whether a gap matters or if there is a critical gap size that compromises meniscal

healing. Reduced time-zero meniscal tissue compression at the repair site combined with evolving meniscal repair loosening during cyclic loading should result in a lower likelihood of a healing response.^{24,33,38} Currently, there is a lack of biomechanical data on the tensioning behavior of meniscal repair devices for primary fixation. Results of this study demonstrated significant differences between some of the commercially available meniscal repair devices in terms of primary fixation and the construct behavior during cyclic and ultimate failure testing.

Reproducible application of traction (50 N) was used in this study to simulate intraoperative tensioning of the meniscal repair. The initial load parameter quantified the amount of residual load on the repair after traction release. An absolute greater relief displacement to reach the time-zero valley position after fixation is equivalent to a higher degree of security against gap initiation. Previous biomechanical studies utilized initial displacement during the first load cycle as an indirect indicator for the fixation strength of a device at the time of insertion.^{24,30,33,38} Inside-out repair with suture tape demonstrated improved fixation as compared with suture repair, but all-inside meniscal repair in general resulted in significantly greater initial load and relief displacement, with the highest fixation strength for the knotless soft anchoring FS device. The ability to convert traction force applied on the loop-shortening strand into meniscal tissue compression is a measure of quality for primary fixation of all-inside devices. Suture transfer through rigid anchors and advancement of the pretied sliding knot in PEEK anchoring devices produces higher friction losses, reducing the efficiency of converting traction force into meniscal tissue compression. Surgical technique-based differences in the tensioning process among all-inside devices may have also had an influence on the primary fixation. PEEK anchoring devices were fixed by pulling on the tensioning suture and reducing both anchor-connecting suture loops at the same time. The soft anchoring FS device required

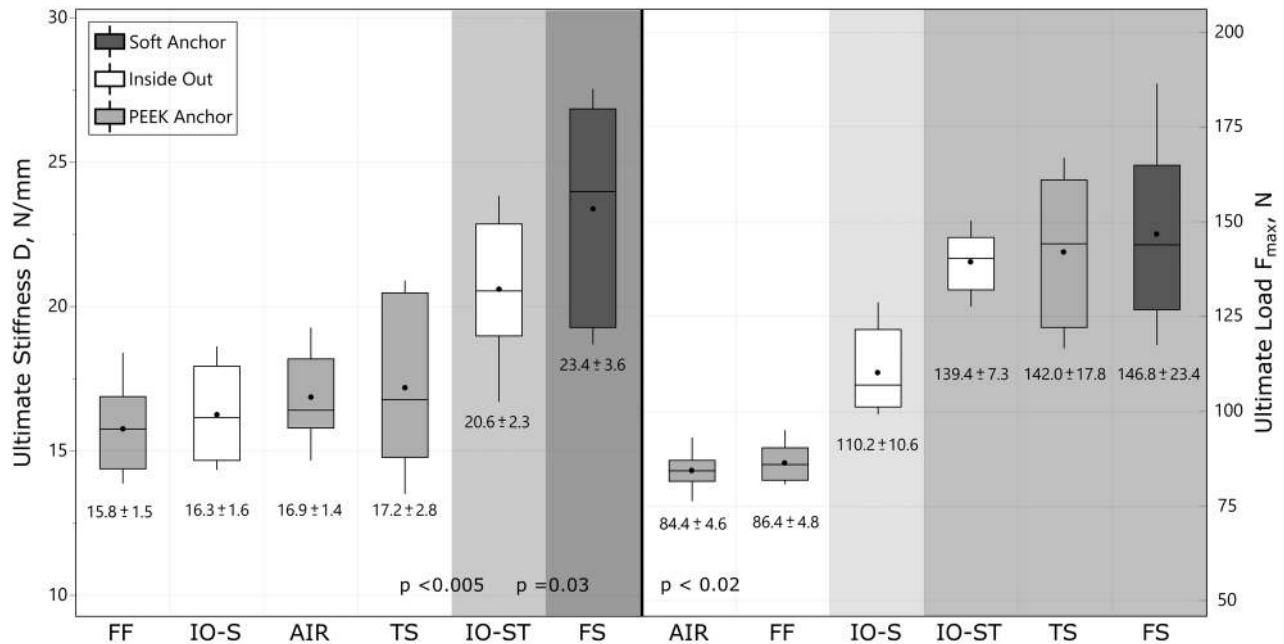


Figure 7. Box plot with mean ± SD values of the stiffness (left) and ultimate load during pull to failure (right). Different shaded backgrounds indicate significant differences. For abbreviations, see Figure 1. Circle, mean; line, median; box, interquartile range; error bars, 95% CI.

stepwise tensioning of individual loops. Subsequent loop shortening of the knotless soft anchoring device may represent a more effective tensioning process with lower friction losses and a higher level of meniscal compression for reapproximation at the tear site. Reduced loads in the IO groups are in line with the reported upper tension limit (10 N) for primary fixation of suture (tape) repairs with manual knot tying.¹

Current test results suggest that stiffer constructs provide higher resistance against gap formation during repetitive loading (≤ 20 N) and that ultimate failure load mainly depends on weak links of the repair device if the quality of the meniscal tissue is sufficient. Increased construct stiffness is normally associated with higher stability and resistance against deformation but could also have an influence on the mode of failure under cyclic loading conditions. Stiffer meniscal repair constructs have been shown to more likely fail owing to suture cut-through (cheese wiring) than those with lower stiffness.²⁵ As the suture–meniscal tissue interface represents a weak point, the tissue quality is crucial for success of the repair. Similar peak elongation between groups confirmed comparable testing conditions in this study. Cheese wiring affects fatigue-induced tissue damage, leading to stress relaxation with gradual growing gap formation at the tear site and complete failure of the repair. Less gapping—equivalent to meniscal repair tension loss (< 1 N) attributed to anchor migration, knot slippage, or cheese wiring on the meniscus—could be associated with a higher potential for healing. Meniscal repair devices with higher fixation strength and reduced gap formation during simulated early rehabilitation loading should be considered best-choice devices for

clinical use. Previous test results of meniscal repair of longitudinal tears are in line with current results, except that failure modes differ among studies.^{3,4,7,23,24,30,33,39,40}

Meniscal repair with placement of a single vertical mattress suture within variable human menisci has an influence on the absolute stabilization potential and may explain the different failure modes of the same devices.^{11,23,26–28,31,34} A divergent gap formation calculation method, based on the change of the actuator position with minimum load on the repair (< 1 N) to the time-zero preload position, may refine recent calculation methods using average valley elongation⁵ or the change of distance between 2 optical markers adjacent to the suture repair.^{23,30,33} Suture- and anchor-related differences (size and shape) decisively codetermine the resistance against gap formation during repetitive loading and ultimate failure strength. Despite slight design- and biomechanical-specific differences of the suture material used for the repair devices, the ultimate failure strength of various devices was directly related to product-specific weak points: smaller-sized PEEK anchors broke (Stryker AIR, FastFix 360) at significantly lower ultimate loads than other all-inside devices (FS, TrueSpan) and inside-out devices with failure of the suture-anchor connection and suture tearing, respectively. A wider soft anchor support area on the capsular meniscal side reduced the risk of soft tissue damage and anchor subsidence into the tissue and may explain the overall higher load-bearing capability of the soft anchoring FS device. Superior inherent mechanical properties of the suture tape over similarly composed round suture with greater knot security, ultimate strength, and contact area to meniscal tissue may explain the better biomechanical performance of the IO-ST group.¹⁷

Limitations

We acknowledge some limitations to the current study. The mean age of human meniscal donors was older than patients undergoing a meniscal repair and therefore may not be representative of a clinical setting. Tensile load was applied along the repair to achieve worst-case testing conditions with the meniscus fixed in customized clamps, which differs from variable in vivo loading in the knee joint, including rotational and shear forces. Thus, the current test methodology is only a rough simulation of the in vivo loading environment; the obtained functional performance could differ from clinical device behavior for meniscal repair.^{10,22} Variable knot tying and tensioning of the repair depending on surgeon experience may influence the outcome in clinical practice. Although multiple stitches in different meniscal repair configurations are often used in clinic,²¹ this biomechanical work focused on the performance of a single repair stitch without clarifying the effects on the biology and the patient's clinical outcome. Slight differences in the stitching pattern in variable menisci (size and quality) may have had an influence on the mechanical behavior given the relative length of the repair construct.

CONCLUSION

Overall, primary fixation strength of inside-out meniscal repair was significantly lower than all-inside repair in this cadaveric tissue model. Although absolute differences among groups were small, meniscal repairs with higher construct stiffness (IO-ST, FS) demonstrated increased resistance against gap formation and failure load.

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