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A Biomechanical Evaluation of All-Inside 2-Stitch Meniscal Repair Devices With Matched Inside-Out Suture Repair

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Background: Many all-inside suture-based devices are currently available, including the Meniscal Cinch, FasT-Fix, Ultra FasT-Fix, RapidLoc, MaxFire, and CrossFix System. These different devices have been compared in various configurations, but to our knowledge, the Sequent meniscal repair device, which applies running sutures, has not been compared with the Ultra FasT-Fix, nor has it been compared with its suture, No. 0 Hi-Fi, using an inside-out repair technique.

Purpose: To assess the quality of the meniscal repair, all new devices should be compared with the gold standard: the inside-out repair. To that end, this study aims to compare the biomechanical characteristics of running sutures delivered by the Sequent meniscal repair device with 2 vertical mattress sutures applied using the Ultra FasT-Fix device and with 2 vertical mattress sutures using an inside-out repair technique with No. 0 Hi-Fi suture.

Study Design: Controlled laboratory study.

Methods: Paired (medial and lateral), fresh-frozen porcine menisci were randomly assigned to 1 of 3 groups: Sequent (n = 17), Ultra FasT-Fix (n = 19), and No. 0 Hi-Fi inside-out repair (n = 20). Bucket-handle tears were created in all menisci and were subjected to repair according to their grouping. Once repaired, the specimens were subjected to cyclic loading (100, 300, and 500 cycles), followed by loading to failure.

Results: The Sequent and Ultra FasT-Fix device repairs and the suture repair exhibited low initial displacements. The Sequent meniscal repair device demonstrated the lowest displacement in response to cyclic loading. No. 0 Hi-Fi suture yielded the highest load to failure.

Conclusion: With the development of the next generation of all-inside meniscal repair devices, surgeons may use these findings to select the method best suited for their patients.

Clinical Relevance: The Sequent meniscal repair device displays the least amount of displacement during cyclic loading but has a similar failure load to other devices.

Keywords: meniscal repair; all inside; inside out; initial displacement; biomechanics; 2-stitch repair

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Meniscal tears are a significant source of knee pain and disability, and their treatment may result in premature osteoarthritis.[10] As a result, a concerted effort is made to preserve meniscal tissue whenever possible. Given its historical success and favorable mechanical profile (high load to failure), the inside-out suture repair is the gold standard of meniscal repair techniques.[5,15] Because this technique depends on sutures passed from inside the knee to the outside, there is an increased risk of injury to neurovascular structures when the suture limbs are tied. Moreover, this procedure is associated with increased perioperative morbidity.[12,16] To minimize this risk, "all-inside" devices have been developed to repair the meniscus arthroscopically without passing needles or sutures through the skin.[3,5,12,16] All-inside repair devices can be divided into 2 types: resorbable rigid arrows (staples), which provide rigid fixation, and flexible suture-based repair devices, which deploy anchors for stability. Rigid all-inside devices have demonstrated good outcomes, but their high failure rate has led to the more frequent use of flexible suture-based techniques.[1,2] While previous all-inside devices such as the Ultra FasT-Fix (Smith & Nephew, Andover, Massachusetts) achieve a simple suture repair (a single vertical or horizontal stitch), newer devices, such as the Sequent meniscal repair device (Conmed Linvatec, Largo, Florida), allow for the application of multiple sutures

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with a single device. As an "all-inside" device, this implant is designed to deploy multiple polyether ether ketone (PEEK) anchors arthroscopically without leaving the knee. Using a continuous strand of No. 0 Hi-Fi suture (Conmed Linvatec) to create a knotless meniscal repair, this system can be used to treat meniscal tears of varying sizes and configurations.

Many all-inside suture-based devices are currently available including the Meniscal Cinch (Arthrex, Naples, Florida), FasT-Fix (Smith & Nephew), Ultra FasT-Fix, RapidLoc (Mitek, Westwood, Massachusetts), MaxFire (Biomet, Warsaw, Indiana), and CrossFix System (Cayenne Medical, Scottsdale, Arizona). These different devices have been compared in various configurations,[5,12,21] but to our knowledge, the Sequent meniscal repair device, which applies running sutures, has not been compared with its own suture, No. 0 Hi-Fi, nor to the Ultra FasT-Fix device.

To assess the quality of the meniscal repair, these new devices should be compared with the gold standard: the inside-out repair. To that end, we hypothesized that 2 vertical mattress sutures using the No. 0 Hi-Fi inside-out technique would have a higher load to failure and less displacement in response to cyclic loading when compared with running vertical mattress sutures performed with the Sequent meniscal repair device and 2 vertical mattress sutures placed using the Ultra FasT-Fix (all-inside) system. Therefore, we aimed to compare the biomechanical characteristics of the 2 running sutures applied using the Sequent meniscal repair device with the 2 vertical mattress sutures applied using the Ultra FasT-Fix device or using an inside-out repair technique with No. 0 Hi-Fi suture.

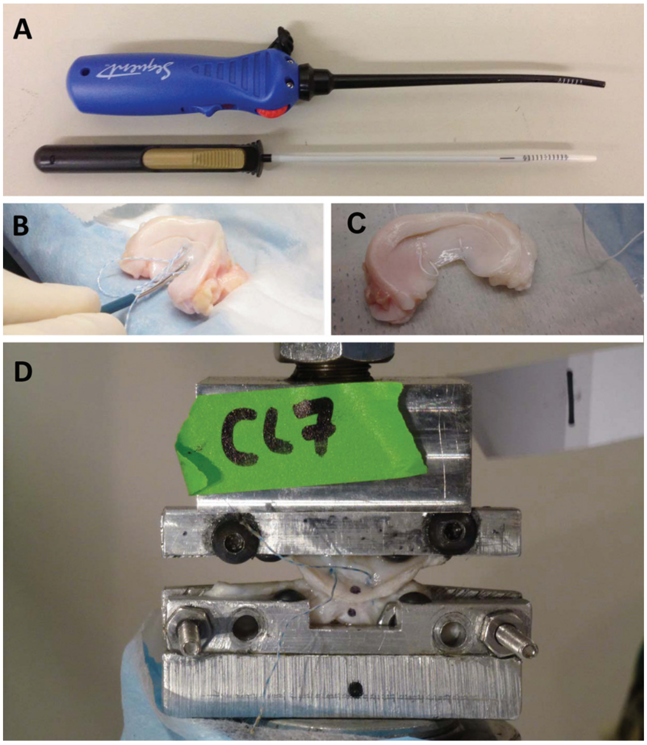

Figure 1. (A) Sequent (top) and Ultra FasT-Fix (bottom) meniscal repair devices used in the study, (B) meniscal repair with the Ultra FasT-Fix device, (C) meniscal repair with the No. 0 Hi-Fi inside-out suture technique, and (D) mechanical testing setup used in the study.

MATERIALS AND METHODS

Preparation and Repair

The Sequent meniscal repair device is an "all-inside" device that can deploy multiple PEEK anchors arthroscopically without leaving the knee. Between the anchors is a continuous strand of No. 0 Hi-Fi suture that is secured without tying a knot. The Ultra FasT-Fix system is designed to introduce and deploy 2 PEEK-OPTIMA implants (Invibio Biomaterial Solutions, West Conshohocken, Pennsylvania) arthroscopically without leaving the knee. Between the anchors is a continuous strand of No. 0 Ultrabraid suture (Smith & Nephew) that is secured without tying a knot.

Paired (medial and lateral), fresh-frozen porcine menisci were randomly assigned to 1 of 3 groups: Sequent (PEEK, No. 0 Hi-Fi) (n = 17), Ultra FasT-Fix (PEEK, No. 0 Ultrabraid) (n = 19), and No. 0 Hi-Fi inside-out repair (n = 20). The menisci were harvested intact by resecting the tissue at the meniscocapsular junction. The menisci were thawed 8 hours before testing, and a No. 11 surgical blade was used to create a bucket-handle tear by making a vertical incision 3 mm from the peripheral rim, starting at the midpoint of the pars intermedia and extending to the anterior and posterior horns. To achieve a clinically relevant repair, the Sequent meniscal repair device (Figures 1A and 2C) was used to deploy 2 vertically oriented running stitches across the midpoint of the pars intermedia by performing 4 passes, 1 cm apart, in accordance with the manufacturer's instructions. To perform a 2-suture repair using the Ultra FasT-Fix, 2 vertical mattress sutures were placed using 2 Ultra FasT-Fix devices

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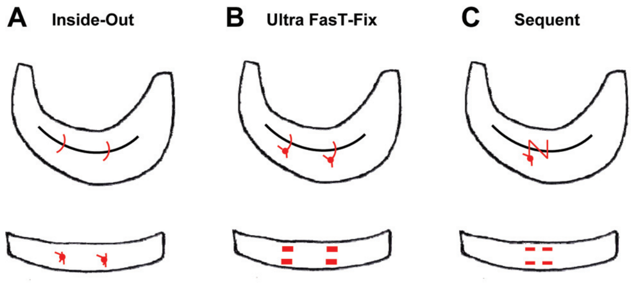

Figure 2. Illustration of surgical repairs using the (A) inside-out, (B) Ultra FasT-Fix, and (C) Sequent devices and techniques.

(Figures 1A and 1B and 2B) 1 cm apart. Similarly, 2 strands of No. 0 Hi-Fi suture (Figures 1C and 2A) were passed 1 cm apart using a straight Keith needle to complete an inside-out suture repair. Four square knots were used to tie each suture. Once the devices and sutures were secured, the bucket-handle tear was created by extending the vertical incision through the anterior and posterior horns. Tissue moisture was maintained during testing by consistent spraying of physiological saline (0.9% by volume) on the specimens.

Biomechanical Testing

The menisci were fixed in custom-made clamps aligned perpendicular to the tear and mounted in an Instron 8511 (Instron Inc, Norwood, Massachusetts) mechanical testing system (Figure 1D). Cyclic loading was performed between 5 and 20 N at a frequency of 1 Hz and recorded continuously using LabView 2011 (National Instruments, Austin, Texas). Displacement (gap formation) was recorded at a load of 5 N after cycles 1, 100, 300, and 500 using a calibrated, high-resolution digital camera (PL-B681C, PixeLINK, Ottawa, Ontario, Canada) and LabView 8.51 (National Instruments) at a sample rate of 50 Hz. Measurements to determine the gap formation were made from points adjacent to the suture repair so that possible slippage from the clamp would not affect the measurement. Displacement measurements were made using ImageJ (National Institutes of Health, Bethesda, Maryland) and were recorded as the vertical component of the measured distance. This software has previously been validated.[12] Load-to-failure testing was then performed at a rate of 3.15 mm/s, and stiffness was calculated as the slope of the linear segment (between 20% and 60% of yield load) for each load-displacement curve. Finally, the mode of failure was recorded for each specimen. The modes of failure were defined as a sudden loss of fixation (suture failure), suture pull-through (tissue failure), anchor pull-through, or knot slippage.

Statistical Analysis

A previous study indicated mean load-to-failure results of 187 ± 42 N and 140 ± 30 N for the Ultra FasT-Fix and FiberWire (Arthrex) suture repair techniques, respectively.[16] Employing these values as a guide, a sample size of n = 18 would result in 80% power to detect a 20% change in the failure load based on analysis of variance (nQuery Advisor version 7.0, Statistical Solutions, Saugus, Massachusetts). The Shapiro-Wilk test for normality was used to evaluate the distribution of the data. A 1-way analysis of variance (ANOVA) with Bonferroni post hoc analysis was performed to assess changes in the failure load and stiffness between the groups. A 2-way ANOVA was performed at a set number of cycles (1, 100, 300, and 500) using an estimated margin mean analysis to assess the differences between groups and differences between cycles across the groups. Data analysis was performed using SPSS software (version 19.0, SPSS Inc, Chicago, Illinois). All comparisons were 2-tailed, and a P value <.05 was considered statistically significant.

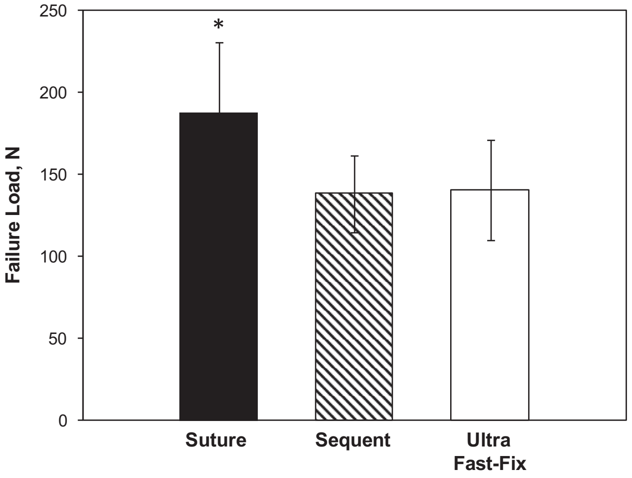

Figure 3. Failure load depicted across the 3 repair groups.

RESULTS

All data (failure load, stiffness, and displacement) were distributed normally ($P > .05$ for all cases). The No. 0 Hi-Fi inside-out repair resulted in the highest load to failure ($P < .001$) (Figure 3 and Table 1). No difference in the load to failure was observed between the Sequent and Ultra FasT-Fix repair techniques ($P = .98$). No differences in stiffness were observed among the 3 repair groups ($P = .64$) (Figure 4 and Table 1).

The Ultra FasT-Fix repair demonstrated the highest initial displacement ($P < .001$), while no difference in initial displacement was observed between the No. 0 Hi-Fi inside-out and the Sequent repair techniques ($P = .82$) (Figure 5). However, for cycles 100, 300, and 500, the Sequent repair method resulted in the lowest displacement value among the 3 repair groups ($P < .001$ for all 3 cycles) (Figure 5). Comparing these values, the No. 0 Hi-Fi inside-out and the Ultra FasT-Fix repair techniques were not statistically different (P = .19, .15, and .13, respectively).

TABLE 1

Load, Stiffness, and Displacement Results for the 3 Repair Techniques[a]

	Suture	Sequent	Ultra FasT-Fix
Load to failure, N	187.750[b] ± 42.427	138.298 ± 23.326	140.436 ± 30.282
Stiffness, N/mm	22.984 ± 9.350	24.704 ± 8.184	21.735 ± 10.458
Cyclic loading displacement, mm			
1 cycle	0.299 ± 0.107	0.310 ± 0.104	0.460[b] ± 0.084
100 cycles	1.046 ± 0.113	0.847[b] ± 0.119	1.105 ± 0.105
300 cycles	1.503 ± 0.144	1.257[b] ± 0.155	1.567 ± 0.131
500 cycles	1.753 ± 0.173	1.477[b] ± 0.125	1.865 ± 0.229

[a] Values are expressed as mean ± standard deviation.

[b] Significantly different from the other 2 techniques.

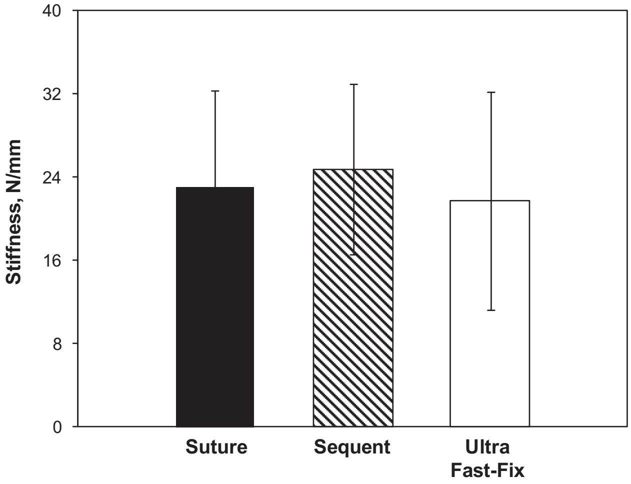

Figure 4. Stiffness depicted across the 3 repair groups.

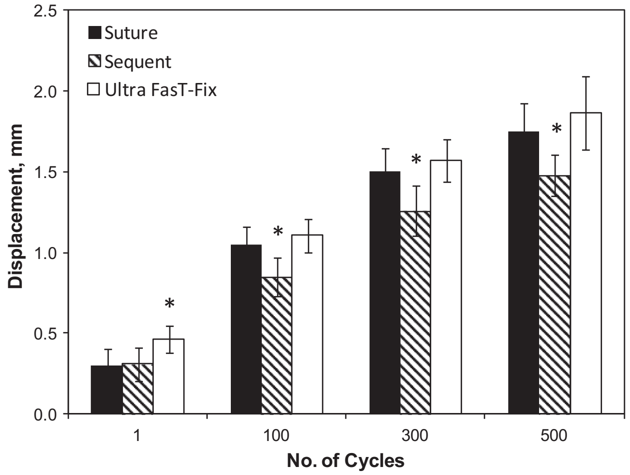

Figure 5. Displacement values after 1, 100, 300, and 500 cycles across the 3 repair groups.

Estimated margin mean analysis indicated that displacement values were significantly different between the different testing intervals for each repair technique ($P < .001$ for all cases) (Figure 5), with a higher number of cycles corresponding to greater displacement. All displacement results are outlined in Table 1.

There were differences in the modes of failure observed in the 3 repair groups. The No. 0 Hi-Fi inside-out repairs predominantly failed by suture breakage (n = 14, 70%), with suture pulling through the tissue (n = 4, 20%) and knot slippage (n = 2, 10%) occurring less frequently. In the Sequent group, the most common mode of failure was loss of anchor fixation (n = 15, 88.2%), followed by the anchor pulling through the specimens (n = 2, 11.8%). Likewise, the Ultra FasT-Fix repairs mainly failed through loss of anchor fixation (n = 12, 63.2%), with suture breakage (n = 6, 31.6%) and tissue pull-through (n = 1, 5.3%) occurring less commonly.

DISCUSSION

Over the past decade, meniscal repair techniques have improved significantly because of an enhanced understanding of the biomechanical properties of menisci, applied in conjunction with improvements in surgical techniques, materials, and methods. The literature suggests that failure rates of meniscal repair range from 0% to 23%.[13] These failures are most commonly caused by an inadequate or suboptimal technique. While an "inside-out" meniscal repair is the standard, this technique is associated with increased neurovascular injuries and perioperative morbidity.[12,16] Consequently, these risks have led to an increased use of "all-inside" repair devices.[5,12,16,17] All-inside meniscal repair techniques are less invasive, are quicker to perform, and are associated with lower rates of morbidity and complications.[12,16,17] In the setting of simultaneous anterior cruciate ligament reconstructions, meniscal repairs have been found to have higher rates of healing.[19] The process of wound healing after meniscal repair depends on many factors including tear size, blood supply, location of the tear, duration from injury, rehabilitation protocol, and surgical technique. Surgical technique plays a significant role in patient outcomes. For this reason, selection of the optimal repair technique should be considered carefully. Based on the pattern of meniscal injury, the biomechanical characteristics of the different repair devices and their application may facilitate decision making in a clinical setting.[8,20] Repetitive stress during rehabilitation can lead to failure of a meniscal repair. However, failures may also occur suddenly in response to a single load beyond the repair's load to failure. An ideal meniscal repair technique should provide stability of fixation. It should withstand the repetitive stresses associated with joint motion during rehabilitation as well as large sudden stresses that can occur incidentally. Therefore, our biomechanical testing protocol aimed to address these issues by assessing both displacement with cyclic loading and load to failure. To the best of our knowledge, this study is the first of its kind to evaluate the strength of a 2-suture repair.

In the load-to-failure analysis, the specimens in the No. 0 Hi-Fi inside-out repair group had significantly higher loads to failure than those in the Sequent and Ultra FasT-Fix repair groups, whereas these 2 techniques were not different from one another. Given the 47- to 50-N difference in the load-to-failure results and the standard deviation range of 23 to 42, the effect size for this difference is in the order of 1 to 2, suggesting that a 40-N difference is clinically relevant. In contrast, Barber et al[4] reported that the Sequent meniscal repair device displayed a load to failure of 66 N, while their suture controls had a load to failure of 73 N, with all experimental groups ranging between 54 and 88 N. The differences in our study were larger than those reported by Barber et al,[4] further reinforcing the clinical relevance of this technique. The differences in the load-to-failure results between the current study and the work by Barber et al[4] can be attributed to the differences in meniscus type (human vs porcine) and the gripping and failure mechanisms associated with the testing methods employed by the respective laboratories. A number of studies have shown that the vertical FasT-Fix suture has superior biomechanical characteristics for meniscal fixation during cyclic and load-to-failure testing compared with other devices.[9,16] Another recent study has shown that the all-inside Sequent device provided radial meniscal tear fixation that was comparable, but not superior, to conventional inside-out suturing.[11]

It is difficult to explain definitively why the load to failure is higher than that previously reported by Barber et al.[4] The use of porcine tissue in place of human menisci could contribute to this difference. Additionally, this novel testing apparatus with custom clamps may offer some explanation for the difference. Most importantly, in applying 2 points of fixation to the repair, this experiment was designed to re-create a clinically relevant method for meniscal repair. While other investigations have tested a single suture or repair device, the benefit of having 2 points of suture fixation (or multiple strands of suture) crossing the repair appears to have increased the load required for failure. While this study loaded the specimens to 20 N, Barber et al[4] loaded their specimens to 50 N. The choice of a 20-N load and 500 cycles is consistent with previous studies.[12,16,21] It approximates the in vivo loading forces associated with early rehabilitation after meniscal repair.[2,7,9,14,16]

The observed modes of failure varied among the 3 groups. The No. 0 Hi-Fi inside-out repairs failed by suture breakage, while the Sequent and Ultra FasT-Fix repairs experienced anchor failure. Chang et al[7] found that FasT-Fix repairs failed at the knot of suture near the first anchor, while the RapidLoc meniscal repairs failed because of suture ruptures.[6,7,11,21]

In this study, each of the repair techniques demonstrated very low initial displacements. The Ultra FasT-Fix repair demonstrated the highest initial displacement, while no difference in initial displacement was observed between the No. 0 Hi-Fi inside-out and the Sequent repairs. Subsequently, after 100, 300, and 500 cycles, the Sequent repair method demonstrated the lowest displacement among the 3 repair groups. There were no significant differences between the inside-out suture group and the Ultra FasT-Fix group at 100, 300, and 500 cycles. In contrast, Barber et al[4] found that after 100 cycles, the Sequent repair had a higher mean displacement (3.35 mm). As an arthroscopic technique, it is difficult to assign a clinical significance to a difference in displacement in the order of less than 0.3 mm. More formal biological evaluations of meniscal healing may be warranted.

Prior investigations have identified the importance of initial displacement in meniscal repair testing.[16] Both Mehta and Terry[12] and Zantop et al[21] have supported the assertion that initial displacement may be inversely proportional to the healing rate. Clinically, initial displacement is difficult to observe. Repeat magnetic resonance imaging provides a static evaluation of the unstressed repair. Second-look arthroscopic surgery is conducted infrequently to assess meniscal healing. In this study, each of the 3 groups demonstrated very low initial displacements. Specimens in the Ultra FasT-Fix group had the highest mean initial displacement: 0.460 mm versus 0.299 mm for the inside-out repair. However, the clinical significance of this difference is likely very small.

This investigation benefits from the testing techniques employed. Displacement was measured directly at the level of the sample using a high-resolution digital camera and markers adjacent to the tear. Previous studies have relied on calipers or actuator positions to measure displacement.[12,21] Unfortunately, these previously used methods cannot control for errors due to compression, stretching of the tissue, and slippage within the clamp. To further improve the testing configuration, customized metal clamps were designed to hold each specimen away from the sutures and the repair site. This modification was intended to improve the strength of the grip without affecting the load to failure or displacement. Previous biomechanical studies have employed a single implant or suture repair for longitudinal meniscal tears; our study employed 2 vertical mattress sutures to repair longitudinal meniscal tears. These repair configurations may more closely resemble what surgeons encounter clinically, as 1-implant/suture repairs are used less frequently than multiple-implant/suture repairs.

As with all biomechanical investigations, this study has some limitations. Ideally, fresh menisci from young human cadaveric donors would have been tested. However, given the scarcity and cost associated with this tissue, porcine menisci were used. The porcine meniscus has the size, shape, and structure that resemble those of the human meniscus. In testing their response to creep, porcine menisci demonstrate less deformation and equilibrium displacement when compared with bovine and human menisci.[18] This difference benefits the experimental design by minimizing specimen variability but raises a question regarding the direct applicability of the results to human tissue. Given that meniscal tears frequently occur in degenerated menisci that do not have the same mechanical strength as healthy tissue, the load to failure and response to cyclic loading may correlate directly. Additionally, in this investigation, a linear force was applied perpendicular to the tear. This approach does not re-create the complex multidirectional forces encountered in vivo.

In conclusion, the biomechanical characteristics of the 3 repair techniques were similar. No. 0 Hi-Fi suture yielded the highest load to failure. Both devices and the inside-out suture technique demonstrated low initial displacements. The 2 running sutures applied using the Sequent meniscal repair device demonstrated the lowest displacement in response to cyclic loading, but the difference may not be clinically relevant. With the development of the next generation of all-inside meniscal repair devices, surgeons may use these findings to select the method best suited for their patients.

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