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Comparison of All-Inside Meniscal Repair Devices With Matched Inside-Out Suture Repair

Claudio Rosso,*† MD, MSc, Konstantin Kovtun,* BSc, William Dow,* BSc, Brett McKenzie,* BSc, Ara Nazarian,* DSc, Joseph P. DeAngelis,* MD, and Arun J. Ramappa,*‡ MD
Investigation performed at the Center for Advanced Orthopaedic Studies, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts

Background: All-inside meniscal repairs are performed with increasing frequency because of the availability of newly developed devices. A comparison of their biomechanical characteristics may aid physicians in selecting a method of meniscal repair.

Hypothesis: All-inside meniscal repairs will be superior to their inside-out controls in response to cyclic loading and load-to-failure testing.

Study Design: Controlled laboratory study.

Methods: Sixty-six bucket-handle tears in matched porcine menisci were repaired using the Ultra FasT-Fix, Meniscal Cinch, Ultrabraid No. 0, and FiberWire 2-0 sutures. Initial displacement, cyclic loading (100, 300, and 500 cycles), and load-to-failure testing were performed. The displacement, response to cyclic loading, and mode of failure were recorded. The stiffness was calculated.

Results: The Meniscal Cinch demonstrated a significantly higher initial displacement than the other methods tested (P = .04). No significant difference was found among the methods in response to cyclic loading. The inside-out FiberWire repair demonstrated the highest load to failure (120.8 ± 23.5 N) and was significantly higher than both the Meniscal Cinch (64.8 ± 24.1 N, $P < .001$) and the Ultra FasT-Fix (88.3 ± 14.3 N, P = .002). It was not significantly higher than the inside-out Ultrabraid suture repair (98.8 ± 29.2 N). The inside-out FiberWire repair had the highest stiffness (28.7 ± 7.8 N/mm). It was significantly higher than the Meniscal Cinch (18.0 ± 8.8 N/mm, P = .01). The most common mode of failure in all methods was suture failure.

Conclusion: An inside-out suture repair affords surgeons the best overall biomechanical characteristics of the devices tested (initial displacement, response to cyclic loading, and load to failure). For an all-inside repair, the Ultra FasT-Fix reproduces the characteristics of its matched inside-out suture repair more closely than the Meniscal Cinch.

Clinical Relevance: Inside-out sutures and all-inside devices have similar responses to cyclic loading.

Keywords: meniscus repair; all-inside; initial displacement; biomechanics

Meniscectomy may result in premature knee osteoarthritis, and for this reason, torn meniscal tissue is repaired whenever possible.[16] An inside-out suture repair is the gold standard for meniscal repair.[19,21] However, this suture-based method has an increased risk of injury to neurovascular structures and is associated with increased perioperative morbidity. To address these limitations, all-inside meniscal repair devices have been developed and are used widely.[6,17,24] 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 can produce good outcomes, but reports of high failure rates have led to the support of flexible, suture-based techniques.[1-4,8,11,26] Many all-inside, suture-based devices are currently available including the Meniscal Cinch (Arthrex, Naples, Florida), FasT-Fix (Smith & Nephew, Andover, Massachusetts), Ultra FasT-Fix (Smith & Nephew), RapidLoc (Mitek, Westwood, Massachusetts), MaxFire (Biomet, Warsaw, Indiana), and CrossFix System (Cayenne Medical, Scottsdale, Arizona).

These different devices have been compared in various configurations. Zantop et al[25] compared the RapidLoc and FasT-Fix with a conventional suture repair (Ethibond 2-0, Ethicon, Johnson & Johnson, Somerville, New Jersey) in human menisci. In this trial, the FasT-Fix demonstrated higher pull-out strength than conventional suture repair

‡Address correspondence to Arun J. Ramappa, MD, BIDMC Department of Orthopaedics, 330 Brookline Avenue, ST-10, Boston, MA 02215 (e-mail: aramappa@bidmc.harvard.edu).

*Center for Advanced Orthopaedic Studies, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts.

†Orthopaedic Department, University Hospital Basel, University of Basel, Basel, Switzerland.

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with no difference in displacement after cyclic loading. Barber et al[6] found comparable load to failure in the all-inside repair devices and conventional repairs when tested in porcine menisci. Mehta and Terry[17] compared 3 different all-inside repair devices in a horizontal technique. They found that the Ultra FasT-Fix and the Meniscal Cinch were superior to the MaxFire in both cyclic displacement (100 cycles) and construct stiffness.

To our knowledge, the Ultra FasT-Fix and the Meniscal Cinch have never been compared with their matched suture controls (Ultrabraid No. 0 [Smith & Nephew Endoscopy, Andover, Massachusetts] and FiberWire 2-0 [Arthrex, Naples, Florida], respectively). Comparison with the inside-out gold standard repair is important to determine the quality of the all-inside construct. We hypothesize that all-inside meniscal repairs will be superior to their inside-out controls in response to cyclic loading and load-to-failure testing. Therefore, the purpose of this study was to compare the initial displacement, response to cyclic loading, ultimate load to failure, and construct stiffness of the Ultra FasT-Fix, Meniscal Cinch, Ultrabraid, and FiberWire in a vertically oriented meniscal repair.

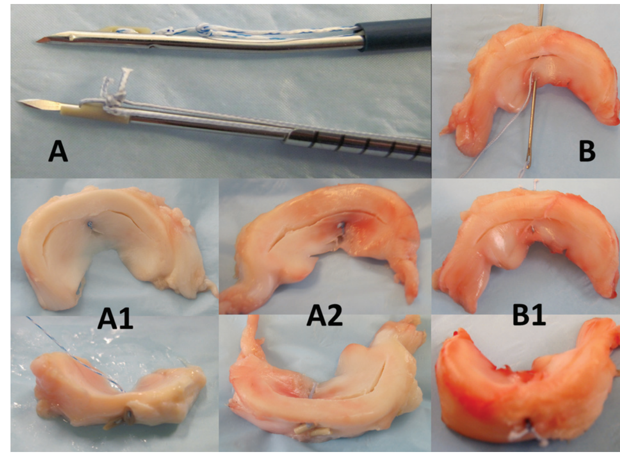

Figure 1. Devices and sutures tested. (A) Top: Ultra FasT-Fix (Ultrabraid No. 0 suture and two 5-mm PEEK-OPTIMA by Invibio implants used). Bottom: Meniscal Cinch (FiberWire 2-0 suture and 2 PEEK-OPTIMA by Invibio implants used). (A1) A sutured meniscus using the Ultra FasT-Fix. (A2) A meniscus where the Meniscal Cinch has been used. (B) View of an inside-out repair as a control, (B1) with a repaired meniscus.

MATERIALS AND METHODS

Preparation and Repair

Paired (medial and lateral), fresh-frozen porcine menisci were randomly assigned to 1 of 4 groups: Ultra FasT-Fix, Meniscal Cinch, Ultrabraid No. 0, or FiberWire 2-0 (Figure 1). The all-inside groups (Ultra FasT-Fix and Meniscal Cinch) each contained 20 menisci, while the matched suture repair groups (Ultrabraid No. 0 and FiberWire 2-0) contained 13 menisci. Each group contained an equal distribution of medial and lateral menisci (Figure 2).

The menisci were thawed 5 hours before testing. A vertical bucket-handle tear was created with a No. 11 surgical blade approximately 3 mm from the peripheral rim starting at the midpoint of the pars intermedia and extending to the anterior and the posterior horns.[6,17,25] The meniscal repair was performed in the body at the midpoint of the pars intermedia of the meniscus by one surgeon in accordance with the manufacturer's instructions. A single vertical repair was performed to limit elongation after cyclic loading and maximize ultimate load to failure.[5,15,19] Inside-out suture repairs were secured with 2 square knots (5 throws) on the capsular side of the meniscus. Once repaired, the bucket-handle tear was completed with a No. 11 blade through the anterior and posterior horns. During testing, the menisci were moistened with 0.9% saline.

Biomechanical Testing

With use of custom-built aluminum/steel clamps (Figure 3), the menisci were tested using an Instron 8511 (Instron Inc, Norwood, Massachusetts) mechanical testing system with a 20-kN load cell (Instron). The menisci were aligned in a way that the repair would be perpendicular to the metal clamps. Cyclic loading was performed between 5 and 20 N at a frequency of 1 Hz.[17,23,25] 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 (PixeLINK PL-B681C, PixeLINK, Ottawa, Ontario, Canada) and Labview 8.51 (National Instruments, Austin, Texas) 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[12,14] (Figure 4).

Load to failure was performed at 3.15 mm/s. Failure was defined as a sudden loss of fixation (suture failure), suture pull-through (tissue failure), anchor pull-through, or knot slippage. If the repair had failed during cyclic testing, the number of cycles and the mode of failure were recorded. The load at failure and mechanism were recorded.

Stiffness was defined as the slope of the load-displacement curve, where load was plotted versus displacement. A linear regression was performed to define the best-fit line for the linear portion of the curve. Because some of the specimens underwent stress relaxation before they reached their ultimate failure, the linear region, for consistency, was taken to be from the beginning of elongation until 60% of each specimen's full failure stress.

Statistical Analysis

Data analysis was performed with JMP 8.0 (SAS Institute, Cary, North Carolina). A 1-way analysis of variance (ANOVA) with a Bonferroni post hoc analysis was used to compare displacement, load to failure, and stiffness among the 4 groups.

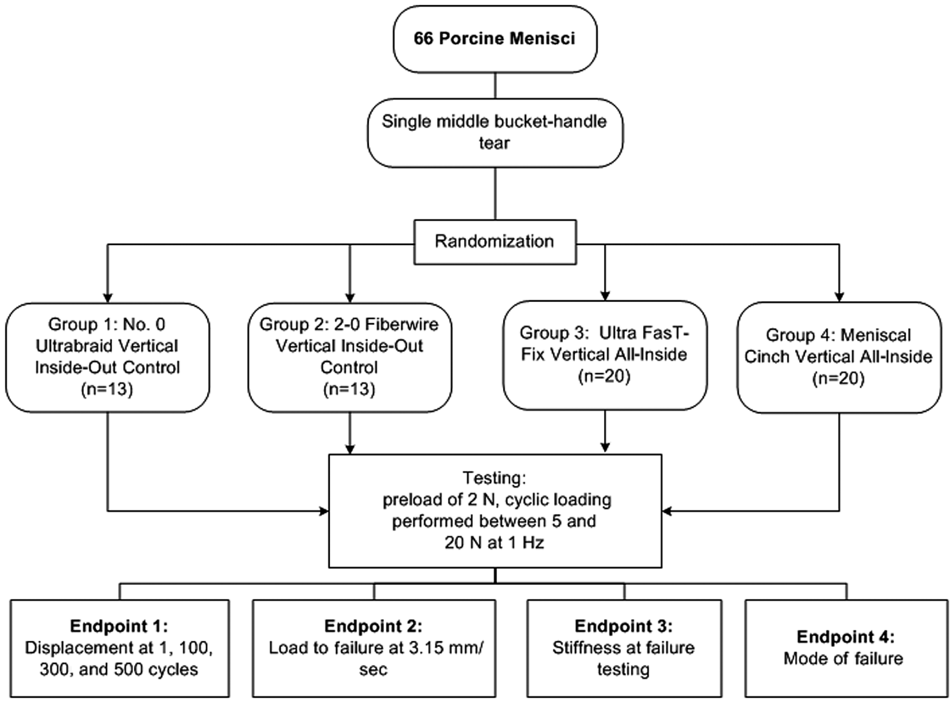

Figure 2. Groups and end points.

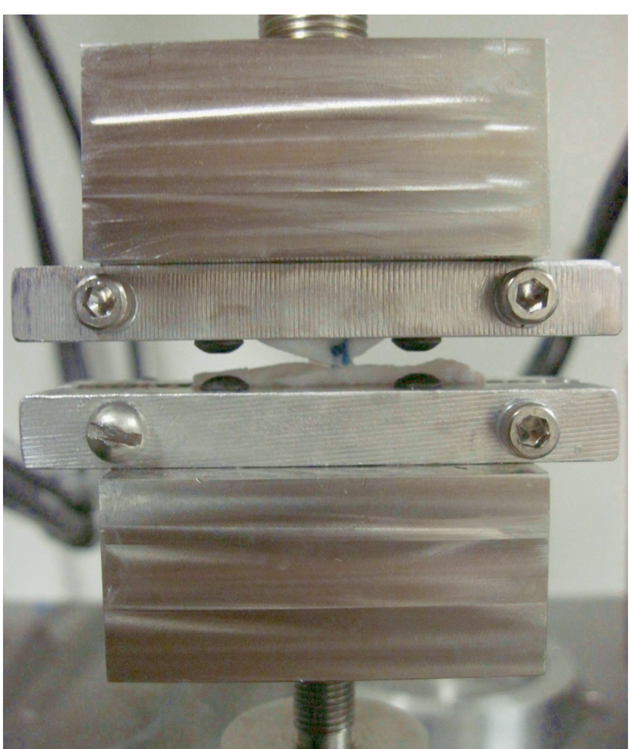

Figure 3. Custom-made gripping device with x-shaped serrated gripping surface (facing the meniscus). The gripping devices have a high-contact area, thus reducing stress concentration.

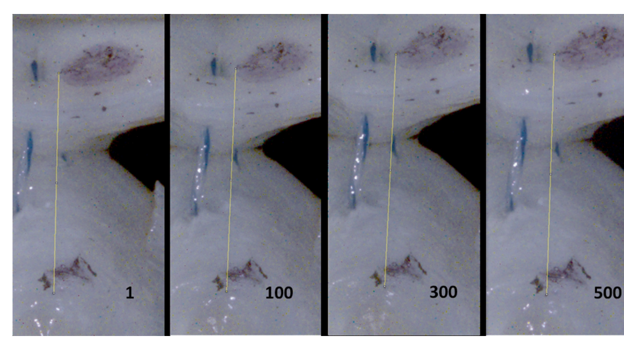

Figure 4. Camera displacement measurements using ImageJ. An Ultrabraid repair measured after 1, 100, 300, and 500 cycles (left to right) as an example.

Two-sided 95% confidence intervals were reported, and a *P* value less than .05 was considered significant.

RESULTS

The allocation of the 66 menisci tested is presented in Figure 2.

Initial Displacement and Response to Cyclic Loading (Gap Formation)

The Meniscal Cinch (7.26 ± 2.51 mm) demonstrated a significantly higher initial displacement than the Ultra FasT-Fix (5.45 ± 1.60 mm, $P < .05$). No other difference was found when the other groups were compared. In response to cyclic

TABLE 1
Initial Displacement and Increase in Elongation During Cyclic Loading[a]

Outcome Measurement	FiberWire 2-0	Meniscal Cinch	Ultra FasT-Fix	Ultrabraid No. 0	*P* Value ANOVA
Initial displacement	5.87 ± 1.01	7.26 ± 2.51[b]	5.45 ± 1.60[b]	5.72 ± 1.45	.03
Increase in elongation					
1 to 100	0.32 ± 0.20	0.36 ± 0.16	0.30 ± 0.16	0.31 ± 0.14	.81
1 to 300	0.39 ± 0.14	0.56 ± 0.33	0.45 ± 0.21	0.36 ± 0.14	.12
1 to 500	0.45 ± 0.14	0.54 ± 0.22	0.57 ± 0.24	0.61 ± 0.42	.52

[a]Mean ± standard deviation measured in millimeters.
[b]Representing $P = .04$ after Bonferroni correction between the Meniscal Cinch and Ultra FasT-Fix.

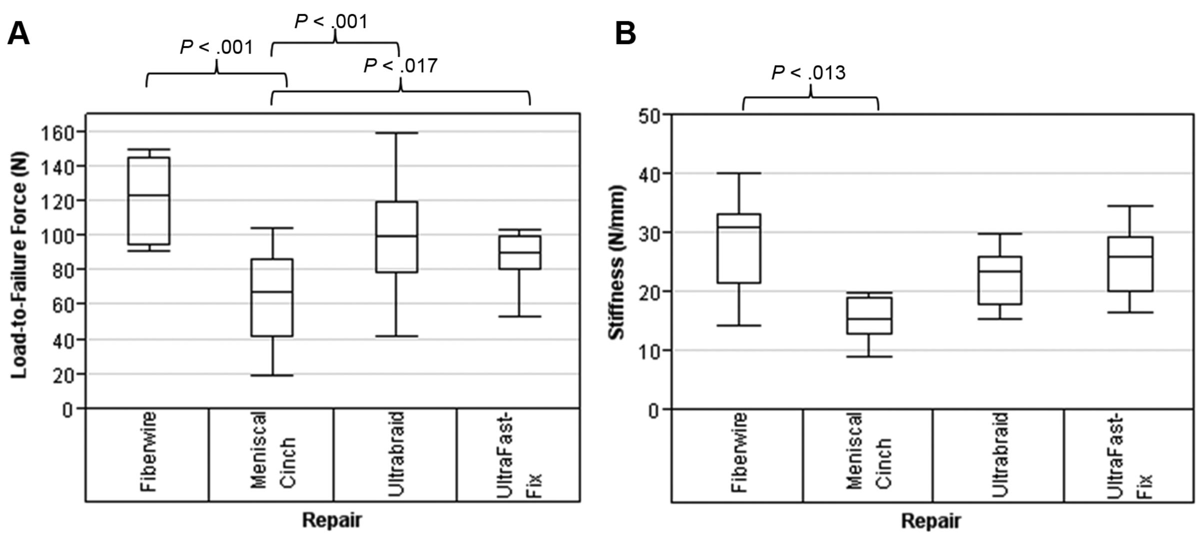

Figure 5. (A) Load to failure and (B) stiffness. Box-and-whisker plots indicate interquartile ranges, maximums, minimums, and medians.

loading, no significant differences were found after 100, 300, or 500 cycles (Table 1).

Load-to-Failure Testing and Construct Stiffness

The FiberWire suture repair had the highest load to failure (120.8 ± 23.5 N) and was significantly higher than the Meniscal Cinch (68.8 ± 24.1 N, $P < .01$) and the Ultra FasT-Fix (88.3 ± 14.3 N, $P < .01$). No difference was found when the FiberWire repair was compared with the Ultrabraid suture repair (98.8 ± 29.2 N). For the Ultrabraid and Ultra FasT-Fix, the load to failure was significantly higher than the Meniscal Cinch, but no difference was identified when they were compared with one another (Figure 5A). When the construct stiffness was calculated, the FiberWire suture repair (mean, 28.7 ± 7.8 N/mm) was significantly higher than the Meniscal Cinch (mean, 18.0 ± 8.8 N/mm, $P < .05$), but no other comparison was significantly different (Figure 5B).

Mode of Failure

Suture failure was the most common mode of failure (FiberWire 85%, Meniscal Cinch 55%, Ultra FasT-Fix 60%) for all groups except Ultrabraid, whose construct was most likely to fail when the suture pulled through the meniscal tissue (62%) (Figure 6). Three Ultra FasT-Fix repairs failed at cycle 1. None of the remaining repairs failed during cyclic loading in any of the groups. No statistical analysis was performed comparing groups by the mode of failure.

DISCUSSION

Most clinicians favor an all-inside, arthroscopic meniscal repair technique because of their lower complication rate and decreased morbidity.[6,17,24] However, a vertical inside-out repair is considered the standard.[15,19] Rigid fixation devices (darts and staples) have been cited as a cause of chondral injury, and for this reason, suture-based, flexible repair techniques are now the preferred method for meniscal repair.[8,17,25]

The stability of a meniscal repair at the time of insertion (initial displacement) has been evaluated by Mehta and Terry and Zantop et al.[17,25] However, traditional biomechanical investigations have focused on the construct's response to motion (gap formation following cyclic loading) and the ultimate strength of the repair (load to failure).

In this investigation, cyclic loading resulted in no significant differences among the different repair techniques when

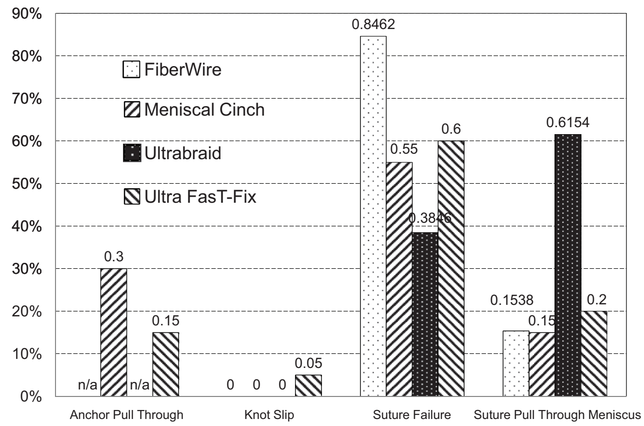

Figure 6. Mode of failure during testing. Suture failure was the predominant mode of failure for all groups except Ultrabraid. Note that the y-axis shows the percentage failure rate.

gap formation was calculated as the difference between the initial displacement and the displacement after cycles 100, 300, and 500 (Table 1). In contrast to these findings, Barber et al[6] showed that Ultrabraid had a significant increase in gap formation when compared with Mersilene, Orthocord, FiberWire, Ultra FasT-Fix, RapidLoc, MaxFire, and CrossFix. The average increase in displacement (gap formation) reported in this study is smaller than previously reported (0.54 mm, 4.55 mm,[6] and 3.21 mm[17]) and may be the result of the difference in load applied, the orientation of the repair, or a difference in methodology. Barber et al[6] loaded their specimens to 50 N, while this investigation employed a 20-N force like Mehta and Terry and Zantop et al.[17,25] The magnitude of the force applied to each specimen and number of cycles tested were chosen because they approximate the established in vivo loading forces associated with early rehabilitation after meniscal repair.[2,4,9,15,18,22] Additionally, vertically oriented repairs were performed, while Mehta and Terry[17] used a horizontal technique.

In this investigation, the Meniscal Cinch demonstrated a significantly higher initial displacement than the other repair methods but did not show a significant difference in gap formation. Among the other repair methods, no significant difference in initial displacements was identified. After finding the significant difference in initial displacements between the Meniscal Cinch and the Ultra FasT-Fix, we looked for differences in the repair mechanism of these constructs. One possible reason for the difference in initial displacement between the all-inside constructs could be that the sliding knot of the Meniscal Cinch did not always slide to the maximum range; rather, it tightened earlier.

Barber et al[6] did not measure the initial displacement. Mehta and Terry[17] found no difference in the initial displacement among the Meniscal Cinch, Ultra FasT-Fix, and MaxFire.

We agree with Mehta and Terry[17] and Zantop et al[25] to test and report initial displacements because we hypothesize that initial displacement is important in meniscal repairs, as it might affect healing rates. Initial displacement might be masked in an arthroscopic technique, as the tear is mostly seen from the front of the repair and not from the top. If not tested with a hook, the repair might seem tight, but when gap testing is performed, the level of contact can be determined. Hence, there is a need for biomechanical evaluation to determine the level of initial contact.

In load-to-failure testing, the FiberWire suture repair represented the strongest construct, being significantly stronger than the Meniscal Cinch and the Ultra FasT-Fix. The Meniscal Cinch repairs failed at a significantly lower force than the other 3 methods (Figure 5). Mehta and Terry reported an average load to failure of 85.3 N for the Meniscal Cinch and 86.1 N for the Ultra FasT-Fix.[17] Barber et al[6] published a much higher load to failure for the Ultrabraid, FiberWire, and Ultra FasT-Fix, with values ranging from 109 N to 120.9 N. While the results of this investigation are within the previously reported range, a reason for the discrepancy with Barber et al's study could not be identified.[10,15,25] Currently, there is no evidence that higher failure loads translate into better clinical results.

The mean stiffness for the FiberWire was 28.7 ± 7.8 N/mm. The stiffness for the Meniscal Cinch repair (18.0 ± 8.8 N/mm) was significantly lower than the FiberWire repair ($P = .01$), while the other constructs did not significantly differ (Ultra FasT-Fix, 25.8 ± 5.4 N/mm; and Ultrabraid, 26.1 ± 14.9 N/mm). Barber et al[6] reported remarkably lower construct stiffness, while other investigators reported comparable values for similar constructs. Barber et al[6] reported a mean stiffness of 4.31 for the FiberWire, 4.0 for the Ultra FasT-Fix, and 6.83 for the Ultrabraid. Their article did not state a unit for the stiffness. Mehta and Terry[17] reported a mean stiffness of 25.3 N/mm for the Ultra FasT-Fix and 25.5 N/mm for the Meniscal Cinch. Zantop et al[25] tested the FasT-Fix construct, which was the preceding product before the Ultra FasT-Fix and not loaded with a No. 0 Ultrabraid but with a USP No. 0 braided polyester suture. They reported a mean stiffness of 21.4 N/mm for the vertically oriented FasT-Fix repair and 18.6 N/mm for the horizontally oriented FasT-Fix repair.

One of the strengths of this investigation was that the actual displacement was measured at the level of the suture (Figure 4). Previously, calipers or actuator measurements have been used to measure the displacement between the clamps or gripping devices.[6,17] These methods may introduce error by compressing the tissue (caliper), measuring the displacement level of the clamp site (meniscal attachment), and failing to account for changes in the position of the meniscus within its holder (slippage) or the clamp on the testing machine. For increased accuracy, a high-resolution digital camera was used to capture images of the meniscal repairs during testing, and the digital images were then used to precisely measure the displacement adjacent to the repair site.[12,14] Additionally, this setup used metal clamps directly attached to the machine on one side and the meniscus on the other side. In this way, the forces were directly applied to the meniscus and the suture repair. Other studies have used sutures or clamps to hold the meniscus during testing.[6,17] These methods of fixation introduce error due to elongation of the holding suture or relative motion of the clamp on the machine.

As with all biomechanical investigations, certain limitations are inherent to the study design. The donor species significantly affects the biomechanical testing.[13] In selecting the tissue origin, sheep menisci are similar to human menisci in both permeability and aggregate modulus.[13] However, their small size presents a technical challenge when testing devices designed for use on human tissue. In contrast, porcine menisci demonstrate properties that are comparable with human tissue with the added benefit of more representative dimensions.[13]

Similarly, because the displacement, strength, and stiffness of each meniscal repair construct were determined in the laboratory, this testing protocol re-creates the worst-case scenario of placing the axis of force perpendicular to the tear. However, this method of testing does not correspond directly to the physiological loads found inside the human knee. In vivo, the maximum force on a meniscal repair is estimated to be 5 N, but this value does not account for the rotational and shear forces that may result in construct failure.[7,20] A different testing apparatus that re-creates shear forces would be a great advancement in evaluating the properties of meniscal repair techniques.

In conclusion, this study compared 2 all-inside meniscal repair devices with their matched inside-out suture repairs (Ultra FasT-Fix and Ultrabraid, and Meniscal Cinch and FiberWire). The Meniscal Cinch had a significantly higher initial displacement than the other repair constructs, but no difference was found between the repair constructs in gap formation following cyclic loading. Vertical-oriented FiberWire was the strongest repair in load-to-failure testing.

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