Biomechanical Evaluation of an All-Inside Suture-Based Device for Repairing Longitudinal Meniscal Tears

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Purpose: A device for all-inside suture-based meniscal repairs has been introduced (NovoStitch; Ceterix, Menlo Park, CA) that passes the suture vertically through the meniscus, thereby encircling the tear, and does not require an additional incision or extra-capsular anchors. Our aim was to compare this all-inside suture-based repair with an inside-out suture repair and an all-inside anchor-based repair (FasT-Fix 360°; Smith & Nephew, Andover, MA). **Methods:** Longitudinal tears were created in 36 fresh-frozen porcine menisci. Repairs were performed using an all-inside suture-based meniscal repair device, an all-inside anchor-based repair, and an inside-out suture repair. They were tested with cyclic loading and load-to-failure testing. The displacement, response to cyclic loading (100, 300, and 500 cycles), and mode of failure were recorded. The stiffness of the constructs was calculated as well. **Results:** The all-inside suture-based repairs and the inside-out repairs showed significantly higher loads to failure than the all-inside anchor-based repairs. The stiffness values for the 3 repairs were not different. There were no differences in initial displacement. After 100, 300, and 500 cycles, the inside-out repair had higher gap formation (displacement) than the other 2 groups. Suture failure was the predominant mode of failure across all repair techniques. **Conclusions:** The all-inside suture-based repairs and inside-out repairs did not exhibit different load-to-failure values. In addition, the all-inside suture-based repairs and the all-inside anchor-based repairs did not exhibit different displacement values during cyclic loading. **Clinical Relevance:** When addressing a longitudinal meniscal tear, surgeons should consider biomechanical data of various repair devices and techniques in their decision-making process to maximize the mechanical strength and healing probability of the repair.

Longitudinal tears of the meniscus occur frequently at the periphery of the meniscus, where the blood supply is rich, making these tears amenable to repair.[1] An analysis by Kim et al.[2] identified a 25% increase in medial and lateral meniscal repairs between 1996 and 2006, and Abrams et al.[3] showed that between 2005 and 2011, more isolated meniscal repairs had been performed in the United States without an increase in the number of meniscectomies. Because the loss of meniscal tissue can lead to progressive arthrosis, considerable emphasis has been placed on repairing meniscal tears in the hope of preserving its force dissipation.[4,5]

Historically, the gold standard for meniscal repair has been the inside-out technique, which has been used in this study as the reference to compare with other methods. This method uses long flexible needles to pass suture through the tissue under arthroscopic guidance. The sutures are retrieved using a separate incision and are tied over the joint capsule.[6] This process can place the neurovascular structures at risk and requires an additional incision.[7]

To limit this risk and eliminate the extra incision, various devices have been developed by which the repair is performed arthroscopically using an "all-inside" technique. The most popular of these designs deploy nonabsorbable anchors that are passed through the torn meniscus and sit on the joint capsule. A study

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The authors report that they have no conflicts of interest in the authorship and publication of this article.

Received December 21, 2013; accepted August 27, 2014.

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0749-8063/13900/$36.00

http://dx.doi.org/10.1016/j.arthro.2014.08.027

on pig menisci has shown that the repair strength of the inside-out technique is significantly stronger than that of current all-inside repair devices,[8] whereas another study on fresh-frozen human menisci has shown no difference.[9] Though less invasive than the inside-out technique, all-inside repairs can result in neurovascular injury, irritation from the anchors, and implant failure.[10]

A device for all-inside suture-based meniscal repair has been introduced by Ceterix (Menlo Park, CA) that passes the suture vertically through the meniscus, thereby encircling the tear, and does not require an additional incision or extra-capsular anchors.[11] This study aims to compare an all-inside suture-based repair with a standard inside-out suture-based repair and an all-inside anchor-based repair (FasT-Fix 360°; Smith & Nephew, Andover, MA) using pig menisci. We hypothesized that the tears repaired with the all-inside devices would show higher loads to failure and less displacement in response to cyclic loading than the inside-out suture repair.

Methods

Preparation and Repair

Paired (medial and lateral), fresh-frozen porcine menisci, from 1-year-old female pigs, were randomly assigned to 1 of 3 groups: all-inside suture-based repair (NovoStitch [No. 2-0 ultrahigh—molecular weight polyethylene Force Fiber; Teleflex Medical, Research Triangle Park, NC]) (n = 18); all-inside anchor-based repair (FasT-Fix 360° [PEEK (polyether ether ketone), No. 2-0 UltraBraid; Smith & Nephew]) (n = 18); and inside-out repair (No. 2-0 Force Fiber) (n = 18).

The menisci were harvested intact by resecting the tissue at the meniscocapsular junction. They were allowed to thaw 8 hours before testing. After harvesting, each sample was put in a bag and the bag was numbered (2 digits). Each repair group was numbered (1 digit). A random-number generator was used to generate 2 random-number order lists, 1 digit and 2 digits. The order for 1 digit was 2-1-3. Each sample was allocated to a repair group in 2-1-3 repeating order per the 2-digit random order list. The repairs and testing were performed per the 2-digit random list order.

The all-inside suture-based NovoStitch system delivers an all-inside suture-based repair and has 2 (upper and lower) jaws that facilitate a needle to pass suture from the lower jaw to the upper jaw (Fig 1).[11] Various types of sutures and suture configurations can be used. Arthroscopic suture-tying techniques are required to complete the repair. In this study we used No. 2-0 ultrahigh—molecular weight polyethylene (Force Fiber) for our suture material and the Revo knot with 2 extra half-hitches for the knot technique.[12,13] We placed a vertical loop suture for our repair. The FasT-Fix 360° meniscal repair system was used for all-inside anchor-based repairs. The system deploys two 5-mm PEEK polymer implants (PEEK-OPTIMA; Invibio, West Conshohocken, PA) (Fig 1). The anchors are joined by a continuous strand of No. 2-0 high-strength polyethylene suture (UltraBraid) that, when triggered, advances a pretied sliding knot secured to best reproduce the vertical mattress suture.

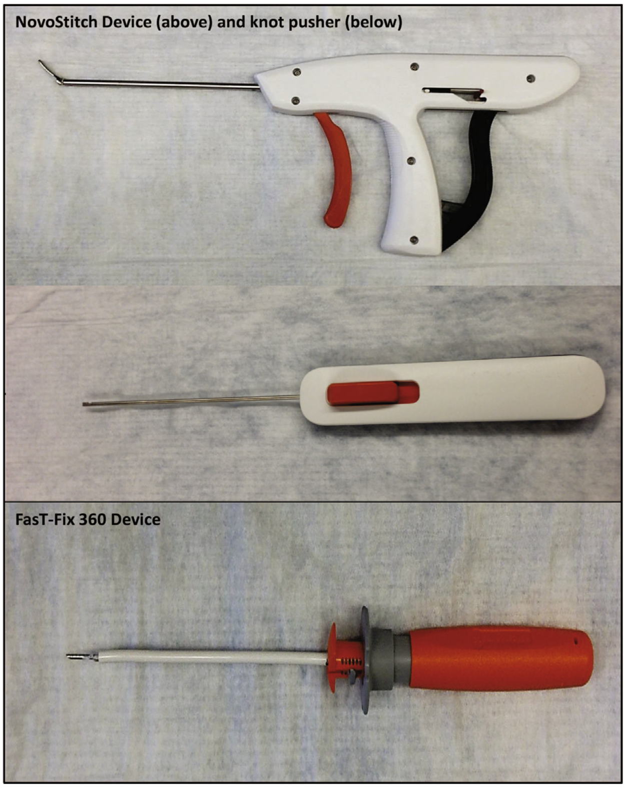

Fig 1. NovoStitch disposable suture passer/knot pusher and FasT-Fix 360° device.

To simulate a longitudinal tear, a No. 11 surgical blade was used to make a vertical cut in each meniscus 3 mm from the peripheral rim, beginning at the midpoint of the central two-thirds of the meniscus (pars intermedia) and extending into the anterior and posterior horns. The 3-mm mark and midpoint were measured by a digital caliper.

To simulate a clinically relevant repair in the all-inside suture-based repair group, the NovoStitch device (Figs 1 and 2 A and B) was used to pass a No. 2-0 Force Fiber suture through the midpoint of the pars intermedia on either side of the tear approximately 1 cm apart. The suture was then tied, using the Ceterix NovoStitch Disposable Knot Pusher (Fig 1) and an arthroscopic Revo knot with 2 extra half-hitches.[12,13]

By use of the FasT-Fix 360° device in the all-inside anchor-based repair group, a single vertical mattress suture was created by deploying the 2 anchors at the midpoint of the pars intermedia approximately 1 cm apart (Figs 1 and 2 C and D). For the inside-out repair, 1

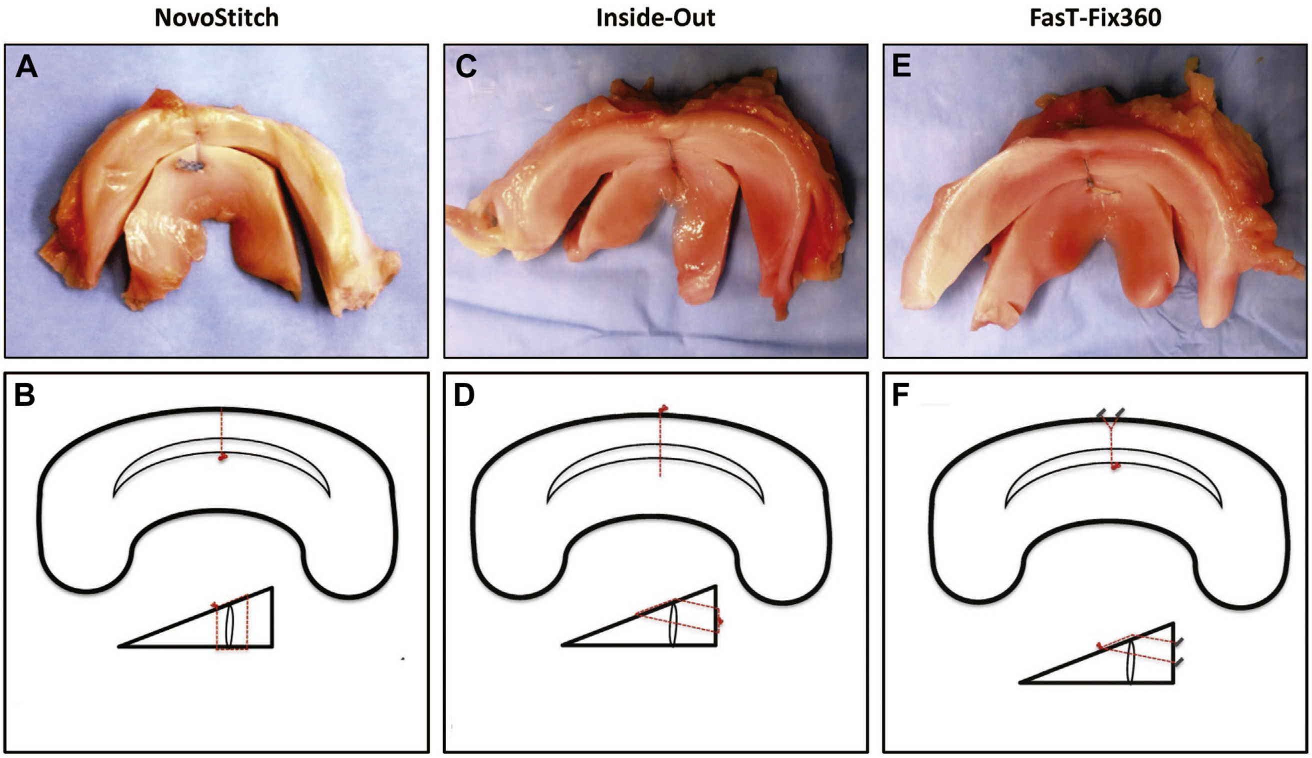

Fig 2. Meniscal repairs with (A) NovoStitch meniscal repair technique, (C) inside-out suture technique, and (E) FasT-Fix 360° device and surgical repairs using (B) NovoStitch disposable suture passer, (D) inside-out suture technique, and (F) FasT-Fix 360° device.

No. 2-0 Force Fiber suture was passed using 2 straight Keith needles 1 cm apart at the midpoint of the pars intermedia (Fig 2 E and F). The suture was tied by hand without a knot pusher on the peripheral side using 2 half-hitches, followed by 5 alternating half-hitches, to complete 3 square knots. A single repair construct was used for each specimen.

Before testing, the longitudinal tear was completed by extending the incision through the anterior and posterior horns. Tissue moisture was continuously maintained using physiological saline solution (0.9% by volume).

Biomechanical Testing

The repaired menisci were placed in custom-made clamps aligned perpendicular to the tear and mounted onto a mechanical testing system (Instron 8511; Instron, Norwood, MA) (Fig 3). After application of a 2-N preload, cyclic loading was performed between 5 and 20 N at a frequency of 1 Hz. Data were recorded continuously.[8,14-16] These loads were chosen after pilot testing showed that some knots failed around 30 N of force and therefore 20 N would allow all specimens to survive the cyclic loading stage of the experiment. Furthermore, these loads are in keeping with prior studies on meniscal repair by our group and others.[8,17-19] On each specimen, 3 sets of paired markings were placed on either side of the repair using India ink (Fig 3). Gap formation (displacement) was recorded by measuring the distance between the paired markings at a load of 5 N after cycles 0, 1, 100, 300, and 500 with a calibrated, high-resolution digital camera (PixeLINK PL-B681C; PixeLINK, Ottawa, Ontario, Canada). Displacement measurements were calculated as the vertical component of the measured distance between each paired marker and then averaging of the 3 paired markers (MATLAB; The MathWorks, Natick, MA). This method and software have

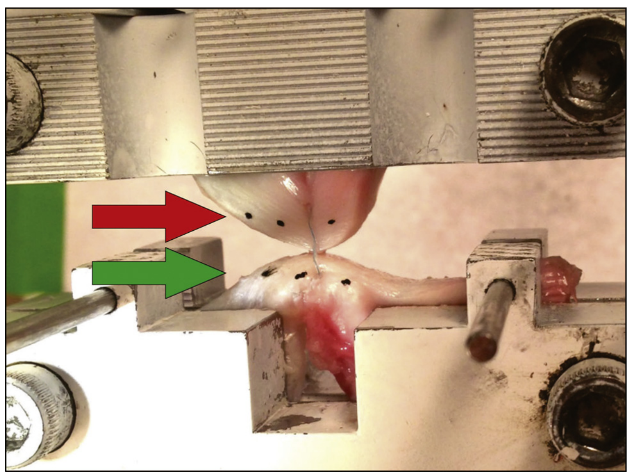

Fig 3. Representative specimen mounted in testing jig with India ink markers visible on specimen above and below repair site (arrows).

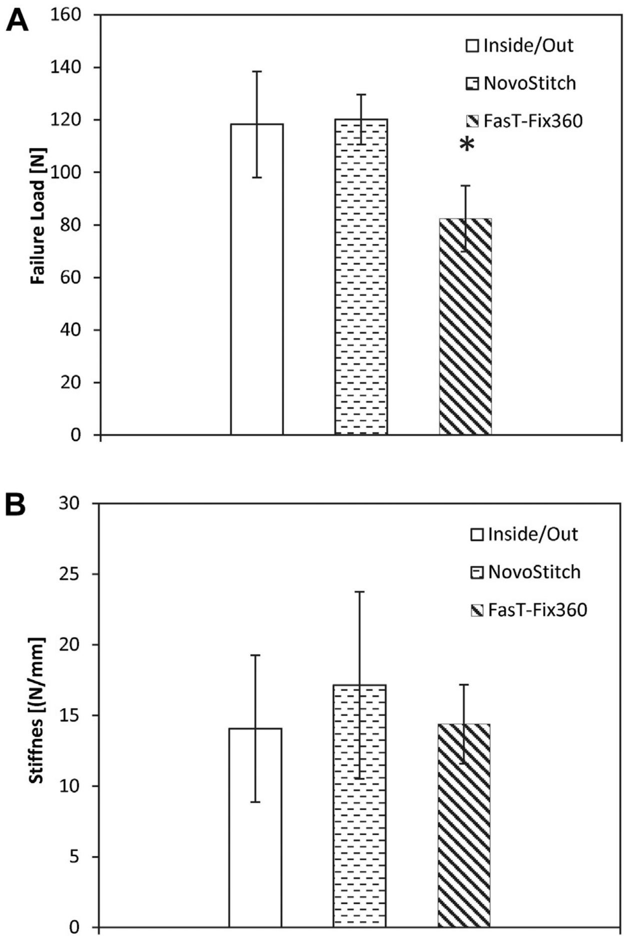

Fig 4. (A) Failure load and (B) stiffness in 3 repair groups. The asterisk indicates a statistically significant difference.

previously been validated.[7,8,20] Cycle 0 served as the reference value for reporting the displacements for subsequent cycles of 1, 100, 300, and 500.

Load-to-failure testing was performed at a rate of 3.15 mm/s.[8] Stiffness was calculated as the slope of the load-displacement curve between 20% and 60% of the yield load. The mode of failure was recorded for each specimen and was defined as suture breakage (suture failure), suture pull-through (tissue failure), or knot slippage (knot failure).

Statistical Analysis

On the basis of 2 previous investigations and an a priori sample size calculation analysis (failure loads of 120 ± 23 N and 98 ± 29 N), we determined that 18 specimens per group were adequate to detect a 20% change in load to failure at 80% power (nQuery Advisor, version 7.0; Statistical Solutions, Saugus, MA).[8,22] The distribution of data was assessed for skewedness using the Shapiro-Wilk test. A paired Student *t* test was used to compare load to failure and stiffness. A repeated-measures 2-way analysis of variance with mixed modeling was used to compare the response to cyclic loading (cycles 1, 100, 300, and 500) between the groups. The Fisher-Freeman-Halton exact test for contingency tables larger than 2 × 2 was used to assess differences in failure mode (suture failure, tissue failure, or knot slippage) between groups (SPSS software, version 21.0; SPSS, Chicago, IL). All comparisons were 2 tailed, and $P < .05$ was considered statistically significant. All data were reported as mean ± standard deviation.

Results

All data (load to failure, stiffness, and displacement) were distributed normally ($P > .05$ for all cases). The NovoStitch and inside-out repairs exhibited significantly higher loads to failure than the FasT-Fix 360° repairs (Fig 4A, Table 1). The stiffness values of the 3 repair groups were not different (Fig 4B, Table 1).

The 3 groups showed no differences on testing of the first cycle of displacement (Table 1). However, after 100, 300, and 500 cycles, the inside-out repair showed

Table 1. Load, Stiffness, and Displacement Results for 3 Repair Techniques

			Displacement, mm			
	Load to Failure, N	Stiffness, N/mm	1 Cycle	100 Cycles	300 Cycles	500 Cycles
I/O repair						
Mean	118.3	14.0	0.26	1.06*	1.48*	1.70*
SD	20.2	5.2	0.12	0.52	0.57	0.53
NovoStitch repair						
Mean	111.4	18.0	0.27	0.78	1.17	1.37
SD	14.9	5.2	0.13	0.18	0.26	0.28
FasT-Fix 360° repair						
Mean	82.4*	13.8	0.20	0.70	0.94	1.10
SD	12.5	1.6	0.15	0.57	0.65	0.50
P value						
I/O *v* NovoStitch	.99	.12	.89	.04	.005	.002
I/O *v* FasT-Fix	.001	.99	.93	.02	.002	.001
NovoStitch *v* FasT-Fix	.001	.10	.98	.65	.18	.12

I/O, inside-out.
*Significantly different from the other 2 techniques.

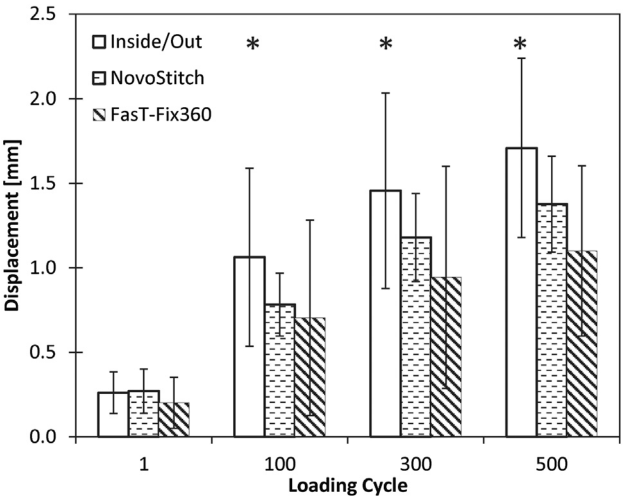

Fig 5. Displacement values after 1, 100, 300, and 500 cycles in 3 repair groups. The asterisks indicate statistically significant differences.

higher gap formation (displacement) than the other 2 groups (Fig 5, Table 1). When the NovoStitch and FasT-Fix 360° repairs were compared, they were not statistically different after 100, 300, and 500 cycles (Fig 5, Table 1).

There were no differences in the modes of failure among the groups. The inside-out repairs predominantly failed through suture failure (n = 14, 78%), followed by tissue failure (n = 3, 17%) and knot slippage (n = 1, 6%). The NovoStitch repairs predominantly failed through suture failure (n = 16, 89%), followed by knot slippage (n = 2, 11%). All FasT-Fix 360° repairs failed through suture failure (n = 18, 100%) ($P = .89$).

Discussion

We sought to biomechanically compare 3 different techniques of repairing longitudinal meniscal tears. The results showed that the NovoStitch and inside-out repairs had significantly higher loads to failure than the FasT-Fix 360° repairs and that the NovoStitch and FasT-Fix 360° repairs had significantly lower displacement values after 100, 300, and 500 cycles than the inside-out control repairs. The mode of failure did not differ among the groups because suture failure was the predominant mode of failure across the groups.

Longitudinal meniscal tears occur in young, active patients and may displace, causing locking of the joint in flexion or extension.[6] Because the injury often occurs at the periphery of the meniscus, these tears are often amenable to repair and have a high rate of healing, particularly when addressed concurrently with anterior cruciate ligament reconstruction.[21,22] Many surgeons favor all-inside repair techniques because of their ease and lower chance of neurovascular injury.[7,10] Two devices have been shown to compare favorably with inside-out repair, with the FasT-Fix 360° device showing the higher load to failure of the all-inside devices and similar stiffness to the inside-out control repairs.[8]

Failure of the suture material, instead of knot failure or pulling through the tissue, may be considered the preferred method of failure in this setting. This finding suggests that the suture's orientation may be the key to drawing on the meniscal architecture to achieve a stable repair. Aligning the suture perpendicular to the intact circumferential fibers may offer greater holding strength to maximize the load to failure and response to cyclic loading. The NovoStitch device is able to pass suture vertically through the tear fragments to create a compressive loop of suture, passing through the entire thickness of the meniscus. On the contrary, the superior limb of the vertical mattress repair for both the inside-out and FasT-Fix 360° constructs passes through less meniscal tissue because of the suture's orientation relative to the triangular cross section of the meniscus. If the circumferentially oriented fibers in the periphery are more effectively held, a vertical loop of suture may be stronger.[23,24] This mechanical effect has been demonstrated previously and may explain the difference in the mechanisms of failure.[24,25]

However, if the decreased displacement observed in the repairs in the NovoStitch and FasT-Fix 360° groups is compared with the inside-out technique, this disparity suggests that knot security and loop security of the tied suture are also important. For the NovoStitch and inside-out repairs, the process of tying and securing the suture requires careful consideration, and it follows that the use of a knot pusher may introduce variability into the process. We may translate the increased displacement into reduced healing rates in the in vivo setting. In a meta-analysis, the healing rate of meniscus has been reported as only 75%.[22] Although the FasT-Fix 360° system uses a knot pusher/cutter to secure the fixation, the knots come pretied on the suture that is strung between the anchors. This technique may offer greater standardization and limit suture management.

This study did not compare the ease of use of the devices or the risk of intra-articular damage with the different techniques. Moreover, in the clinical setting, more than 1 suture is usually used to perform the repair. Our work addresses the biomechanical properties of 1 suture as a baseline. We suggest that further studies be conducted using the baseline data to compare different techniques with multiple sutures.

Limitations

As a laboratory investigation, this study may be limited in its applicability to human tissue. Porcine menisci, though similar in size and shape, are not a perfect surrogate for human menisci.[26] Being at the same age and being healthy are benefits of their use, whereas cadaveric menisci are usually old and damaged. They can be thicker and tougher than human tissue and do not compare as favorably as ovine menisci.[27,28] However, our findings support the work performed by Rimmer et al.,[25] who showed that a vertical loop of suture was the strongest orientation in human menisci, making the comparison of suture orientation and architecture more reasonable. In addition, this study stressed the repairs directly, using a custom design. This approach tests displacement in 1 plane but does not apply compression, tension, or shear as seen in the knee. As a biomechanical model, these results address the repair when it is most vulnerable and no healing has occurred. Because it has been shown that the repair integrity increases with time, it is unclear how the repairs may affect meniscal healing clinically.[29,30]

Conclusions

The all-inside suture-based repairs and inside-out repairs did not show differences in load to failure, and the all-inside suture-based repairs and the all-inside anchor-based repairs showed no difference in displacement during cyclic loading.

References

1. Greis PE, Bardana DD, Holmstrom MC, Burks RT. Meniscal injury: I. Basic science and evaluation. *J Am Acad Orthop Surg* 2002;10:168-176.
2. Kim S, Bosque J, Meehan JP, Jamali A, Marder R. Increase in outpatient knee arthroscopy in the United States: A comparison of National Surveys of Ambulatory Surgery, 1996 and 2006. *J Bone Joint Surg Am* 2011;93:994-1000.
3. Abrams GD, Frank RM, Gupta AK, Harris JD, McCormick FM, Cole BJ. Trends in meniscus repair and meniscectomy in the United States, 2005-2011. *Am J Sports Med* 2013;41:2333-2339.
4. Seitz AM, Lubomierski A, Friemert B, Ignatius A, Durselen L. Effect of partial meniscectomy at the medial posterior horn on tibiofemoral contact mechanics and meniscal hoop strains in human knees. *J Orthop Res* 2012;30:934-942.
5. Fairbanks TJ. Knee joint changes after meniscectomy. *J Bone Joint Surg Br* 1948;30:664-670.
6. Johnson D, Weiss B. Meniscal repair using the inside-out suture technique. *Sports Med Arthrosc* 2012;20:68-76.
7. Baena AE, Castilla BM, Fernandez JS, de Rota Conde AF, Reina AE, Rubio FE. Inside-out medial meniscus suture: An analysis of the risk of injury to the popliteal neurovascular bundle. *Arthroscopy* 2011;27:516-521.
8. Rosso C, Kovtun K, Dow W, et al. Comparison of all-inside meniscal repair devices with matched inside-out suture repair. *Am J Sports Med* 2011;39:2634-2639.
9. Seitz A, Kasisari R, Claes L, Ignatius A, Durselen L. Forces acting on the anterior meniscotibial ligaments. *Knee Surg Sports Traumatol Arthrosc* 2012;20:1488-1495.
10. Grant JA, Wilde J, Miller BS, Bedi A. Comparison of inside-out and all-inside techniques for the repair of isolated meniscal tears: A systematic review. *Am J Sports Med* 2012;40:459-468.
11. Saliman JD. The circumferential compression stitch for meniscus repair. *Arthrosc Tech* 2013;2:e257-e264.
12. Baumgarten KM, Wright RW. Ease of tying arthroscopic knots. *J Shoulder Elbow Surg* 2007;16:438-442.
13. Nottage WM, Lieurance RK. Arthroscopic knot typing techniques. *Arthroscopy* 1999;15:515-521.
14. Szczesny SE, Lee CS, Soslowsky LJ. Remodeling and repair of orthopedic tissue: Role of mechanical loading and biologics. *Am J Orthop (Belle Mead NJ)* 2010;39:525-530.
15. Gobbi A, Mahajan V, Karnatzikos G. Tibial plateau fracture after primary anatomic double-bundle anterior cruciate ligament reconstruction: A case report. *Arthroscopy* 2011;27:735-740.
16. Stehling C, Souza RB, Hellio Le Graverand MP, et al. Loading of the knee during 3.0T MRI is associated with significantly increased medial meniscus extrusion in mild and moderate osteoarthritis. *Eur J Radiol* 2012;81:1839-1845.
17. Matsubara H, Okazaki K, Izawa T, et al. New suture method for radial tears of the meniscus: Biomechanical analysis of cross-suture and double horizontal suture techniques using cyclic load testing. *Am J Sports Med* 2012;40:414-418.
18. Barber FA, Herbert MA, Schroeder FA, Aziz-Jacobo J, Sutker MJ. Biomechanical testing of new meniscal repair techniques containing ultra high-molecular weight polyethylene suture. *Arthroscopy* 2009;25:959-967.
19. Chang HC, Nyland J, Caborn DN, Burden R. Biomechanical evaluation of meniscal repair systems: A comparison of the Meniscal Viper Repair System, the vertical mattress FasT-Fix Device, and vertical mattress Ethibond sutures. *Am J Sports Med* 2005;33:1846-1852.
20. Muriuki MG, Tuason DA, Tucker BG, Harner CD. Changes in tibiofemoral contact mechanics following radial split and vertical tears of the medial meniscus an in vitro investigation of the efficacy of arthroscopic repair. *J Bone Joint Surg Am* 2011;93:1089-1095.
21. Nepple JJ, Dunn WR, Wright RW. Meniscal repair outcomes at greater than five years: A systematic literature review and meta-analysis. *J Bone Joint Surg Am* 2012;94:2222-2227.
22. Ramappa AJ, Chen A, Hertz B, et al. A biomechanical evaluation of all-inside 2-stitch meniscal repair devices with matched inside-out suture repair. *Am J Sports Med* 2014;42:194-199.
23. Fithian DC, Kelly MA, Mow VC. Material properties and structure-function relationships in the menisci. *Clin Orthop Relat Res* 1990;252:19-31.
24. Asik M, Sener N, Akpinar S, Durmaz H, Goksan A. Strength of different meniscus suturing techniques. *Knee Surg Sports Traumatol Arthrosc* 1997;5:80-83.
25. Rimmer MG, Nawana NS, Keene GC, Pearcy MJ. Failure strengths of different meniscal suturing techniques. *Arthroscopy* 1995;11:146-150.

26. Haemer JM, Song Y, Carter DR, Giori NJ. Changes in articular cartilage mechanics with meniscectomy: A novel image-based modeling approach and comparison to patterns of OA. *J Biomech* 2011;44:2307-2312.
27. Joshi MD, Suh JK, Marui T, Woo SL. Interspecies variation of compressive biomechanical properties of the meniscus. *J Biomed Mater Res* 1995;29:823-828.
28. Nguyen AM, Levenston ME. Comparison of osmotic swelling influences on meniscal fibrocartilage and articular cartilage tissue mechanics in compression and shear. *J Orthop Res* 2012;30:95-102.
29. Kawai Y, Fukubayashi T, Nishino J. Meniscal suture. An experimental study in the dog. *Clin Orthop Relat Res* 1989;243:286-293.
30. Zhang Z, Arnold JA, Williams T, McCann B. Repairs by trephination and suturing of longitudinal injuries in the avascular area of the meniscus in goats. *Am J Sports Med* 1995;23:35-41.

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