Cyclic Testing of Flexible All-Inside Meniscus Suture Anchors

Biomechanical Analysis

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Background: Flexible meniscus repair devices are designed to combine the benefits of rigid all-inside meniscus anchors with the biomechanical properties of sutures.

Hypothesis: Stiffness and pull-out strength of flexible all-inside suture anchors and conventional sutures under cyclic loading conditions will be comparable.

Study Design: Controlled laboratory study.

Methods: In 50 fresh frozen bovine menisci, artificial meniscus lesions were repaired with different meniscus fixation techniques: horizontal and vertical FasT-Fix, RapidLoc, and horizontal and vertical 2-0 Ethibond sutures. The specimens were cycled 1000 times between 5 and 20 N and then loaded to failure.

Results: All devices survived the cyclic loading protocol. There was no significant difference in the displacement between all repair techniques tested (horizontal FasT-Fix, 6.23 mm; vertical FasT-Fix, 5.34 mm; RapidLoc, 6.84 mm; horizontal 2-0 Ethibond, 6.03 mm; vertical 2-0 Ethibond, 5.61 mm ($P > .05$). Vertical and horizontal FasT-Fix suture anchors had a significantly higher stiffness and pull-out strength (94.1 N and 80.8 N, respectively) than did horizontal sutures (50.2 N) and RapidLoc devices (30.3 N) ($P > .05$).

Conclusions: In this study, flexible all-inside meniscus anchors (FasT-Fix) had higher pull-out strength than did conventional vertical suture techniques. Biomechanical characteristics of the flexible RapidLoc are comparable to those of horizontal sutures.

Clinical Relevance: Flexible all-inside meniscus repair devices are an alternative to conventional suture techniques.

Keywords: meniscus fixation techniques; meniscus anchors; biodegradable implants; cyclic loading; anterior cruciate ligament (ACL)

Arthroscopic inside-out and outside-in meniscus repair techniques are technically demanding. The need for additional incisions with the risk of iatrogenic neurovascular damage can lead to prolonged intraoperative and tourniquet time and can thereby increase morbidity and anesthesia costs.[1,3]

To overcome these disadvantages, all-inside repair devices were developed.[2] Simple insertion of these rigid all-inside devices through standard arthroscopic portals makes them easy to use and is a reason for the increasing numbers of surgeons who repair tears rather than resect them. Clinical studies have reported good to excellent results after the use of rigid meniscus repair devices.[1,16,29] However, several biomechanical studies have shown that rigid meniscus anchors provide a significantly lower load to failure in comparison to conventional suture techniques.[‖] Therefore, many authors have recommended a nonaggressive rehabilitation protocol after all-inside meniscus repair with a rigid anchor.[15,19,20,47] Another dis-

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advantage of these techniques is that the head or bar of the rigid implant might be responsible for induction of articular cartilage damage due to improper implantation.[4,25,42,43] Other complications of rigid meniscus anchors include migration of the implant into the subcutaneous tissue with the risk of neurovascular damage.

The latest (third) generation of meniscus repair devices has been designed to incorporate the advantages of all-inside techniques, such as easy intra-articular handling and short operating time, with the superior biomechanical properties of conventional suture techniques (FasT-Fix, Smith & Nephew, Andover, Mass; RapidLoc, Ethicon, Mitek Division, Norderstedt, Germany).

In a previous study, the initial failure load of the FasT-Fix technique was shown to be comparable to that of vertical suture techniques, and the initial failure load of the RapidLoc technique was shown to be comparable to that of the rigid anchors and horizontal suture techniques.[48] However, the pull-out strength provides a measurement of the upper limit of the fixation technique only. This is useful information because it indicates the potential for the repair to withstand trauma after surgery. During early rehabilitation, the repair is repetitively loaded during exercise or daily living activities.[¶] Therefore, cyclic loading seems to be a suitable test to reproduce the physiological loading conditions.[¶]

Borden et al[13] showed in human menisci that there was no statistically significant difference in gap formation between conventional suture techniques and the flexible FasT-Fix repair after 500 cycles of load between 5 and 50 N. Because meniscus repair is often performed in combination with a reconstruction of the ACL, it seems relevant to evaluate the behavior of meniscus repair techniques using a loading protocol as it has been used for the evaluation of fixation of an ACL graft. Most biomechanical studies that evaluate ACL graft fixation techniques use a higher number of cycles, ranging between 1000 and 1500 cycles.[26-28,32,40] This cycle number is considered representative of the loading cycles to which a graft is subjected within 1 week of postoperative rehabilitation.[26-28,32,40]

The objective of the present study was, therefore, to evaluate the biomechanical properties of flexible meniscus anchors (FasT-Fix technique, RapidLoc technique) under cyclic loading conditions (1000 cycles of load). The hypothesis was that the new flexible all-inside suture anchors would provide similar biomechanical properties to those of horizontal and vertical mattress sutures.

MATERIALS AND METHODS

Biomechanical Model

In this study, 50 fresh frozen lateral bovine menisci were used. This model was previously described by Rankin et al,[39] Boenisch et al,[12] and Arnoczky et al,[5,6] and it has been used in a previous study by our group.[48] The mean age of the animals was 28 ± 2 weeks. The menisci were harvested from the bovine knees. Care was taken to ensure the integrity of the adhering capsule. The menisci were stored at –20°C until 5 hours before testing. With a No. 15 scalpel, an artificial vertical lesion of 30 mm was created 3 mm from the peripheral rim in the middle third of the meniscus.

The menisci were then repaired in a standardized fashion using 1 of the following 5 techniques: vertical loop sutures (2-0 Ethibond, Ethicon), horizontal loop sutures (2-0 Ethibond, Ethicon), vertical FasT-Fix sutures (Smith & Nephew), horizontal FasT-Fix sutures (Smith & Nephew), and the RapidLoc device (Ethicon). Each meniscus was tested once, and 1 device was used to repair 1 lesion. In each group, 10 artificial bucket-handle tears were repaired with 1 of the 5 different implant techniques.

The vertical and horizontal loop sutures were performed in accordance with the outside-in technique using 2-0 Ethibond. The sutures were placed 3 mm inside the incision and tied by hand on the joint capsule. The spacing between each limb was 6 mm.

The FasT-Fix device contains two 5-mm nonbiodegradable polymer suture bar anchors, with a pretied, self-gliding knot composed of a nonbiodegradable USP#0 braided polyester suture. The insertion instrument (FasT-Fix Meniscal Delivery Needle, Smith & Nephew) was placed 3 mm from the artificial lesion, and the inner meniscal fragment was pierced with the needle (Figure 1). Then, the needle was advanced into the outer meniscal fragment to the end of the depth limiter. After the needle was oscillated approximately 5°, the needle was pulled out of the meniscus, and the implant was released behind the meniscus. Next, the trigger was forwarded to advance the second implant into the ready position at the end of the needle. Then, the delivery needle was inserted 5 mm from the first implant on either a vertical or a horizontal plane. The delivery needle was removed from the meniscus, leaving the free end of the suture. The free end was then pulled to advance the sliding knot and reduce the meniscus tear. While the suture was held taut, a knot pusher was gently advanced to the meniscus until the desired tension was achieved.

The RapidLoc device (Ethicon) consists of 3 components: (1) a soft tissue anchor called a "Backstop," (2) a connecting suture (biodegradable 2-0 Panacryl suture or 2-0 nonbiodegradable Ethibond suture), and (3) a second soft tissue anchor called "TopHat" that compresses the meniscus against the Backstop (Figure 1). In the present study, only the biodegradable 2-0 Panacryl sutures were used. The Backstop was inserted into a specially designed curved needle provided by Mitek, and the needle was mounted on an application instrument (Ethicon, Mitek Division). The needle was placed 3 mm from the artificial lesion, and the inner meniscal fragment was pierced with the needle. Then, the needle was advanced into the outer meniscal fragment to the end of the depth limiter. By depressing the trigger on the applier, the Backstop was deployed and the needle was removed from the meniscus. The limb of the suture was pulled to ensure capture and fixation of the Backstop. The end of the suture was then threaded through the tip of a knot pusher, and the pusher was gently advanced down the length of the suture while tension was

¶References 8, 9, 11, 13, 15, 23, 30, 44, 45, 48.

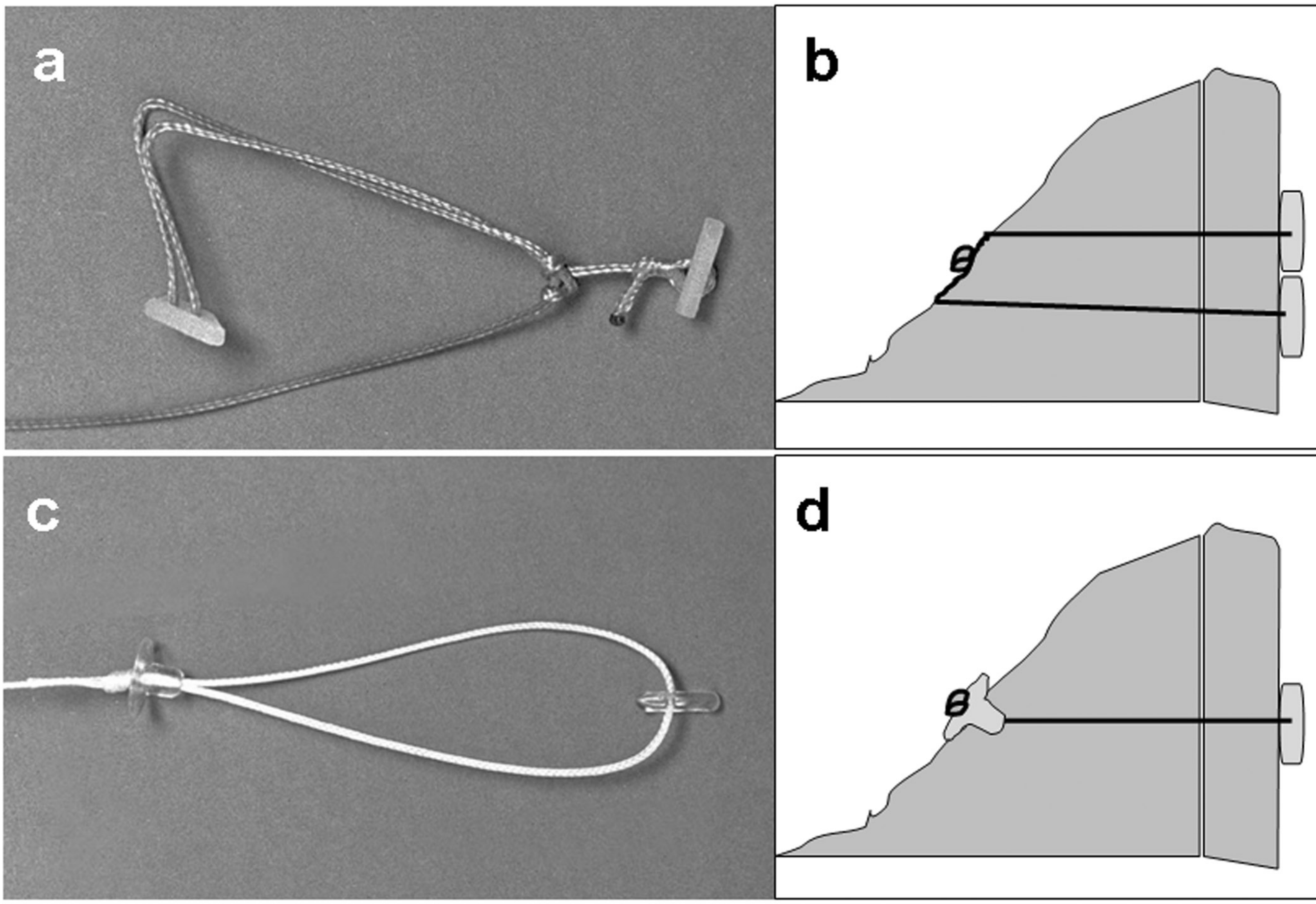

Figure 1. Close-up of the FasT-Fix (a) and the RapidLoc (c) devices. Schematic drawing of the 2 suture anchor implants in place: vertical FasT-Fix (b) and RapidLoc (d).

maintained on the suture. With this maneuver, the sliding knot and the TopHat were advanced down to the surface of the meniscus. Tension on the suture was continued until the knot was seated into the TopHat, locking it in place. Tension was applied manually to allow the TopHat to just dimple the meniscus, and the suture was cut with an arthroscopic cutter, leaving approximately 2-mm suture length.

After the reconstruction using only 1 device or suture of the 5 different techniques, the remaining meniscus tissue bridging the sides of the artificially created bucket-handle tear was dissected. The complete load transfer via the meniscus repair complex was thereby guaranteed. The length of the meniscus lesion (30 mm) was consistent for all biomechanical tests.

Tensile Testing

The test setup has been described in previous studies.[5,6,12,48] Before testing, the specimens were removed from the freezer, thawed, and moistened. The tests were performed at room temperature, and the menisci were kept moist with saline solution during mounting and testing to prevent desiccation. Tensile testing was performed using a uniaxial testing frame (LR5k-Plus, Lloyd Instruments, Fareham, England). The peripheral section of the repaired meniscus was clamped using a custom-made tissue clamp. A clamp designed as published by Arnoczky and Lavagnino[5,6,12] was used to fix the central part of the meniscus. A universal joint attached the meniscus clamp to the crosshead of a materials testing machine equipped with a 500-N load cell (Lloyd Instruments) while the grip was fixed to a stationary post. The loads were applied parallel to the axis of the implants to simulate a worst-case scenario. In each group, 10 meniscus implant/suture constructs were tested. After a preload of 2 N was applied, each meniscus implant/suture construct was subjected to 1000 cycles of a load between 5 and 20 N at a crosshead speed of 12.5 mm/s (Figure 2). The displacement rate of 12.5 mm/s is thought to be reflective of in vivo loading forces and has been used previously.[3,5,6,12,48] The number of loading cycles has been adopted from studies investigating the primary stability of techniques for the fixation of autologous ACL grafts.[26-28,32,40] The load (20 N) was chosen according to statements by Seil et al.[44,45] Displacement was defined as the displacement between the 2 clamps and was measured after 1, 100, and 1000 cycles of load. After cyclic loading, the fixations were

TABLE 1
Displacement During Cyclic Loading[a]

Fixation Technique	Displacement, mm		
	1 Cycle	100 Cycles	1000 Cycles
Vertical 2-0 Ethibond suture	0.68 ± 0.2	4.32 ± 0.5	5.61 ± 1.8
Horizontal 2-0 Ethibond suture	1.73 ± 0.8	4.30 ± 0.6	6.03 ± 2.3
Vertical FasT-Fix	1.04 ± 0.3	4.31 ± 0.4	5.34 ± 1.2
Horizontal FasT-Fix	2.03 ± 0.3	4.80 ± 0.5	6.23 ± 1.8
RapidLoc	1.87 ± 0.8	4.21 ± 1.5	6.84 ± 2.8

[a]In the displacement, no significant difference between all fixation techniques tested was found. All values are means ± SDs.

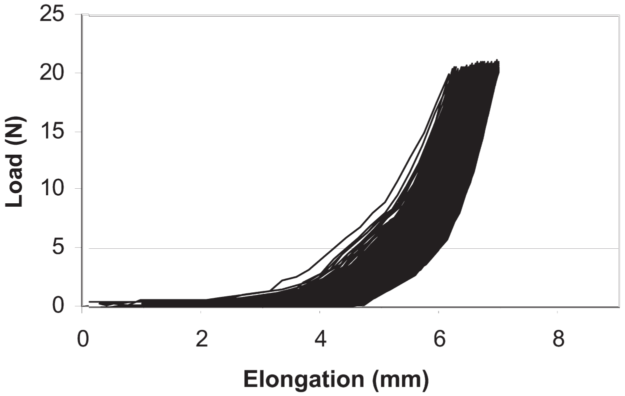

Figure 2. Cyclic loading protocol.

TABLE 2
Ultimate Pull-out Strength and Stiffness of Meniscus Repair Devices After 1000 Cycles Between 5 and 20 N[a]

After 1000 Cycles Between 5 and 20 N	Failure Load, N	Stiffness, N/mm
Vertical 2-0 Ethibond suture	71.3 ± 12.4	7.7 ± 1.9[b]
Horizontal 2-0 Ethibond suture	50.2 ± 9.8[c]	6.9 ± 2.0[b]
Vertical FasT-Fix	94.1 ± 13.1	21.4 ± 14.7
Horizontal FasT-Fix	80.8 ± 11.1	18.6 ± 10.2
RapidLoc	30.3 ± 6.5[c]	8.5 ± 2.2[b]

[a]All values are means ± SDs.
[b]Significantly lower stiffness than vertical and horizontal FasT-Fix sutures ($P < .05$).
[c]Significantly lower failure load than vertical FasT-Fix, vertical 2-0 Ethibond, and horizontal FasT-Fix sutures ($P < .05$).

loaded to failure immediately. This displacement rate has been used in previous studies to evaluate the primary stability of sutures and suture anchors and is thought to be reflective of rapid loading forces.[3,5,6,12,48] Load and elongation were recorded continuously using a strip chart recorder. To determine the biomechanical properties of the meniscus/implant constructs, stiffness as the linear region of the load elongation curve, ultimate failure load, and the mode of failure were documented.

Statistics

The Mann-Whitney *U* test was used for the statistical analysis of the results. Significance was set at $P < .05$.

RESULTS

Displacement During 1000 Cycles of Load

All repairs survived the cyclic loading protocol. Immediately after starting the testing protocol, a gap between the meniscal margins could be seen. Figure 2 shows the typical course of displacement of the meniscus repair complex using a FasT-Fix during 1000 cycles of load. Approximately 50% of the displacement appeared during the first 100 cycles of load, and within the first cycles, the suture of the FasT-Fix or the TopHat of the RapidLoc device tended to disappear from the meniscal surface. After 100 and 1000 cycles of load, there was no significant difference in the displacement between all fixation techniques tested ($P > .05$) (Table 1).

Stiffness After 1000 Cycles of Load

Vertical and horizontal 2-0 Ethibond sutures and RapidLoc showed a stiffness of 7.7 ± 1.9 N/mm, 6.9 ± 2.0 N/mm, and 8.5 ± 2.2 N/mm, respectively. There was no statistically significant difference between the vertical 2-0 Ethibond sutures, the RapidLoc technique, and horizontal 2-0 Ethibond sutures ($P > .05$) (Table 2). Vertical and horizontal FasT-Fix sutures showed a significantly higher stiffness than did vertical and horizontal Ethibond sutures and the RapidLoc technique ($P < .05$).

Failure Load After 1000 Cycles of Load

Repair using the vertical FasT-Fix was the strongest reconstruction, followed by the horizontal FasT-Fix suture and the vertical 2-0 Ethibond suture, with maximum loads of 94.1 ± 13.1 N, 80.8 ± 11.1 N, and 71.3 ± 12.4 N, respectively (Table 2). There was no significant difference in the failure load between vertical and horizontal FasT-Fix sutures and vertical 2-0 Ethibond sutures (Table 2). Horizontal 2-0 Ethibond sutures and the RapidLoc technique had a significantly lower failure load than did vertical FasT-Fix, vertical 2-0 Ethibond, and horizontal FasT-Fix sutures ($P < .05$), but there was no significant differ-

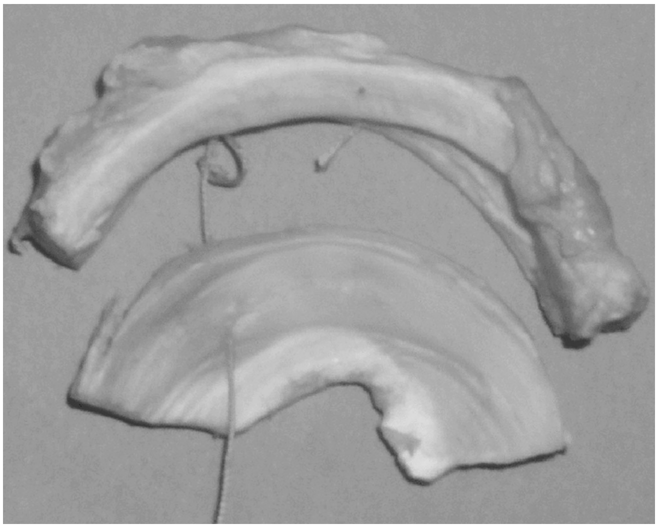

Figure 3. In the vertical FasT-Fix group, the implant/meniscus constructs predominately failed at the knot of the suture. This meniscus loaded to failure after being subjected to 1000 cycles of loading.

ence between horizontal 2-0 Ethibond sutures and the RapidLoc technique (Table 2).

Failure Mode

In the vertical suture group and in the vertical FasT-Fix group, all implants failed at the knot of the suture (Figure 3). In the horizontal FasT-Fix group, 6 of the specimens failed by tissue failure, and 4 of the specimens failed at the knot. The majority of horizontal 2-0 Ethibond sutures failed by tissue failure (7 specimens). In the RapidLoc group, most of the devices failed by a rupture of the suture to the Backstop (7 implants), and the TopHat was pulled through the central part of the meniscus 3 times.

DISCUSSION

The present study showed that new flexible meniscus repair devices such as the FasT-Fix or the RapidLoc provide displacement values that are comparable to those seen with conventional suture techniques. For meniscus repair, accelerated rehabilitation protocols have increasing popularity.[8] Most in vitro studies on meniscus repairs only report the ultimate failure load. Cyclic loading protocols are considered to more closely mimic the in vivo loads to which the repair is subjected.[11,13,17,30,39,44,45] Seil et al[44,45] examined different suture types and materials in a porcine model and showed that during cyclic loading (100 cycles, 5-20 N), a gap appears between the meniscal margins irrespective of the suture type used. Becker et al[11] compared different rigid meniscus anchors with conventional horizontal and vertical 2-0 Ethibond sutures in menisci of human origin. This study revealed different displacements for different repair techniques. Both studies concluded that the displacement of the meniscus repair complex was caused mainly by gapping at the repair site, which was also visible during testing.

Borden et al[13] examined the displacement of the FasT-Fix technique in a human model and found that all FasT-Fix sutures and conventional sutures survived a cyclic loading protocol, whereas a rigid anchor (meniscus arrow) failed. Borden et al used a cyclic loading protocol with 500 cycles between 5 and 50 N and a crosshead speed of 5 mm/min. Albrecht-Olsen et al[3] stated that a crosshead speed of 5 mm/min used in their own and various other studies was probably far below the speed of meniscus movements in the knee during normal conditions.[#] In this study, a displacement rate of 12.5 mm/s was used, which is thought to be reflective of in vivo loading forces and has been used previously to investigate the meniscus arrow.[3,5,6,12,48] In the present study, a loading protocol of 1000 cycles with a load between 5 and 20 N was used. The cycle number has been adopted from studies investigating the primary stability of techniques for the fixation of autologous ACL grafts. The load has been chosen according to statements by Seil et al.[44,45] It is not known how much fixation strength is needed to ensure a satisfactory repair, and the necessary fixation strength for meniscal healing is still in question.[23] Proctor et al[38] investigated the mechanical properties of bovine menisci and reported a mean Young modulus of only 2.8 MPa for radial samples and a modulus of 198.4 MPa for circumferentially orientated samples. Because the tissue is functionally adapted to its strain, this could be a hint that in vivo, possibly only low forces occur in the radial direction.[18] Kirsch et al investigated the forces occurring in meniscus sutures in a cadaveric model and found low forces that were never higher than 10 N.[23]

To validate the data gained by cyclic loading, Seil et al[44,45] tested suture repairs (2-0 Ethibond sutures) to failure and found that cyclic testing did not change the failure strength of the repair. In the present study, the repair complexes were tested to failure after 1000 cycles. The results showed that different flexible all-inside meniscus refixation devices such as the FasT-Fix and the RapidLoc provided significantly different ultimate failure strength. There was no statistically significant difference in the pull-out strength between vertical and horizontal FasT-Fix sutures and vertical 2-0 Ethibond sutures. Horizontal 2-0 Ethibond sutures and the RapidLoc technique had a significantly lower failure load than did vertical FasT-Fix, vertical 2-0 Ethibond, and horizontal FasT-Fix sutures. There was no significant difference between horizontal 2-0 Ethibond sutures and the RapidLoc technique. These results are in accordance with results of a previous in vitro study using the same bovine model[48] and with results of a study in a human model.[13]

The suture disappearance on the meniscus surface resulting from partial tissue failures, which were more pronounced in horizontal sutures than in vertical sutures, confirmed the superior resistance of vertical sutures.**

[#]References 1, 3, 8, 10, 11, 17, 30, 37, 46, 48.

**References 5, 7, 9-12, 14, 17, 24, 28, 33, 34, 36, 39, 45.

Superior strength of the vertical loop suture can be explained by its perpendicular orientation to the circumferential collagen bundles of the meniscus.[24,35,41] Horizontal sutures provide inferior stability because fewer collagen fibers are caught by the suture.[24] This finding might also explain why tissue failures could only be observed with horizontal sutures and why vertical sutures provide a higher stiffness than do horizontal sutures.

Stiffness is an important feature of a repair technique because it describes the ability of the repair to withstand deformation. A high stiffness is required to provide stability at the meniscus repair complex, which is essential for tissue healing.[11,12] In the current study, the highest stiffness was found for the vertical FasT-Fix suture, followed by the horizontal FasT-Fix suture. The RapidLoc device provided a stiffness that is comparable to that of a 2-0 horizontal Ethibond suture. Recent biomechanical data published by Borden et al[13] reported a stiffness of 7.7 N/mm and 7.7 N/mm for FasT-Fix and vertical suture techniques, respectively. An explanation of the differences in stiffness between the study of Borden et al and this study could be the different models and test setup used in the 2 studies. Borden et al used a Mersilene tape as a linkage material to connect the meniscus to the clamp of a materials testing machine. This material could be responsible for the different stiffness values between the study of Borden et al and the current study. In the current study, a custom-made tissue clamp was used, designed after the description by Arnoczky et al.[5,6,12,48] The stiffness data of the horizontal and vertical suture techniques are in accordance with the values reported in other studies using the same bovine model and tissue clamp.[5,6,12,48] Stiffness values for the FasT-Fix technique reported in the present study are in accordance with our previous biomechanical data of flexible meniscus anchors without prior cyclic testing.[48]

Limitations of this study include the use of bovine material. The use of bovine menisci, however, eliminates the highly variable degenerative components of human cadaveric menisci obtained from aged donors, and many studies have shown that the bovine meniscus is an ideal model to study biomechanical characteristics of meniscus repair techniques.[5,6,21,38] Another limitation of this study is that we tested the worst-case scenario, whereby the load is applied parallel to the axis of the fixation device. Although the exact forces across a meniscus repair in vivo are unknown, the in vivo forces might be more complex than in a unidirectional test setup.

In conclusion, the present study shows that the displacement, pull-out strength, and stiffness after cyclic loading of the FasT-Fix anchor were comparable to those of vertical suture techniques, whereas the biomechanical characteristics of the RapidLoc device were comparable to those of horizontal sutures. Because biomechanical properties evaluated in a controlled laboratory study are not the only factors influencing the result of a meniscus repair technique, caution should be used with the uncritical use of new surgical techniques.[31] In the future, the different devices will need to be tested in a healing model in conjunction with growth factors.

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