

Initial Fixation Strength of Flexible All-Inside Meniscus Suture Anchors in Comparison to Conventional Suture Technique and Rigid Anchors

Biomechanical Evaluation of New Meniscus Refixation Systems

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Background: The newest generation of meniscus repair devices is designed to combine the benefits of the all-inside technique with the biomechanical properties of sutures.

Hypothesis: New flexible all-inside suture anchors have better fixation strength than rigid anchors, but there is no difference when compared to conventional horizontal and vertical mattress sutures.

Study Design: Controlled laboratory study.

Methods: In fresh-frozen bovine menisci, initial fixation strength, stiffness, and failure mode of different meniscus fixation techniques (FastT-Fix, RapidLoc, Meniscus Arrow, horizontal and vertical 2.0 Ethibond sutures) were evaluated in a computer-based materials testing machine at a rate of 12.5 mm/sec.

Results: The vertical and horizontal FastT-Fix suture anchors were the strongest devices with regard to pullout strength, with no significant difference compared to the vertical 2-0 Ethibond sutures. Horizontal sutures, Meniscus Arrow, and RapidLoc had significantly lower pullout strength. Vertical and horizontal FastT-Fix suture anchors showed significantly higher stiffness than the other devices.

Conclusions: Biomechanical properties of flexible all-inside meniscus anchors (FastT-Fix) are comparable to conventional vertical suture techniques. Characteristics of the flexible RapidLoc are comparable to rigid anchors (Meniscus Arrow).

Clinical Relevance: From the biomechanical point of view, flexible all-inside meniscus refixation devices are an alternative to conventional suture techniques and rigid meniscus anchors.

Keywords: meniscus fixation techniques; meniscus anchors; biodegradable implants; biomechanics; bucket-handle tear

The menisci are mobile joint surfaces, and they cover approximately 70% of the tibial plateau.²⁰ They play an

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important role in the load transmission, shock absorption, lubrication, passive stabilization, and load transmission of the knee.^{20,21,34,36} Several clinical long-term studies have shown that total or partial meniscectomy may lead to cartilage degeneration and osteoarthritis.^{18,22,45} When faced with these detrimental effects of meniscectomy, the desire to preserve the menisci is easy to understand.

Repair should be considered depending on the type and the location of the meniscal tear. Tears in the peripheral part of the menisci have a better healing potential than

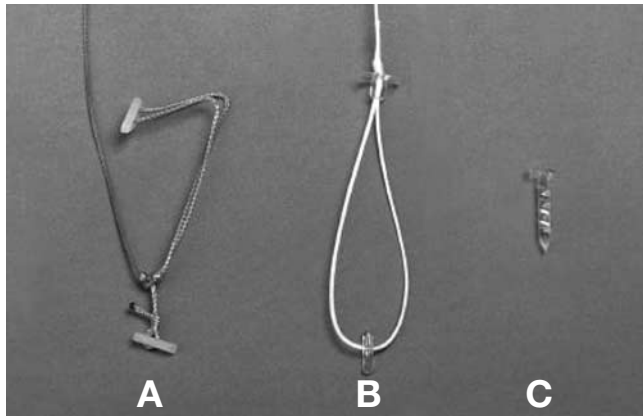


Figure 1. Implants used in the present study. A, FastT-Fix; B, RapidLoc; and C, Meniscus Arrow.

tears in the central part because the central two thirds of the menisci are avascular.^{6-8,32,40} Excellent results have been obtained in the repair of peripheral meniscal tears in the vascularized zone (red-red-zone).^{2,16,45} Arthroscopic meniscus repairs have been successfully performed with vertical and horizontal suture techniques. However, arthroscopic inside-out and outside-in surgical techniques are technically demanding, and they require incisions, which adds the risk of iatrogenic neurovascular damage.² Prolonged intraoperative and tourniquet time can increase morbidity and anesthesia costs.

Recently, several all-inside repair devices have been developed to overcome the disadvantages of conventional suture techniques.¹ These rigid devices can be placed quickly via standard arthroscopic portals into the meniscal tissue to stabilize the tear. The first of these implants was the Meniscus Arrow (Bionx Implants, Tampere, Finland), introduced by Albrecht-Olsen et al in 1993.¹ The Meniscus Arrow consists of a T-shaped stem with perpendicular barbs. During the years following, many similar devices have been developed and provided by the industry. The ease of insertion of these rigid all-inside devices might have prompted surgeons to repair tears that otherwise would have been resected. A prospective randomized clinical study with the Meniscus Arrow reported similar healing rates as achieved with conventional suture techniques.² Several other studies also reported good to excellent clinical results after the use of rigid meniscus repair anchors.^{17,28} Of concern is the significantly lower load-to-failure strength for these devices when compared to conventional vertical sutures.^{5,9,11-14,19,29,35,37,44} Complications from these devices include migration into the subcutaneous tissue²⁸ with the risk of neurological injury, loosening,²⁸ and articular cartilage damage.^{4,41}

To overcome these disadvantages, new all-inside fixation techniques using anchors connected to suture material have been developed (FastT-Fix, Smith & Nephew, Andover, Mass; RapidLoc, Ethicon, Mitek Division, Norderstedt, Germany). The FastT-Fix is a modification of a previously introduced device, the T-Fix. This latest generation of meniscal repair devices should incorporate the

advantages of all-inside techniques, such as easy intra-articular handling and short operating time, with the superior biomechanical properties of the inside-out technique.

The hypothesis of the present study was that new flexible all-inside suture anchors would have better fixation strength than rigid anchors but that there would be no difference when compared to conventional horizontal and vertical mattress sutures. Therefore, we analyzed the ultimate strength and stiffness of meniscal repairs performed on a bovine model with different techniques: vertical loop sutures, horizontal loop sutures, Meniscus Arrow, vertical FastT-Fix, horizontal FastT-Fix, and RapidLoc.

MATERIALS AND METHODS

Biomechanical Model

In this study, 60 fresh-frozen lateral bovine menisci were used as described by Rankin et al,³⁷ Boenisch et al,¹⁴ and Arnoczky et al.^{5,8} The mean age of the animals was 28 weeks \pm 2 weeks. Material properties of bovine menisci have been described by Proctor et al.³⁶ The menisci were dissected free, leaving the adhering capsule intact, and stored at -20°C until 5 hours before testing. With a number 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 by using 1 of the 6 techniques: vertical loop sutures (2-0 Ethibond, Ethicon), horizontal loop sutures (2-0 Ethibond, Ethicon), 10-mm Meniscus Arrow (Bionx Implants), vertical FastT-Fix sutures (Smith & Nephew), horizontal FastT-Fix sutures (Smith & Nephew), and the RapidLoc device (Ethicon, Mitek Division, Norderstedt, Germany) (Figure 1). Each device was used to repair 1 lesion.

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. Finally, the remaining meniscus tissue bridging each side of the artificially created bucket-handle tear finally was dissected (see Figure 2). By doing this, the anterior and posterior horn of the meniscus was resected, guaranteeing the complete load transfer via the meniscus repair complex. The length of the meniscus lesion (30 mm) was consistent for all biomechanical tests.

The 10-mm Meniscus Arrow is an all-inside rigid implant. It is T-shaped with perpendicular barbs. It is made of biodegradable polylactid acid and consists of a T-head (4 mm) and a stem of 1.1-mm diameter. For insertion of the 10-mm Meniscus Arrow, a special cannula (CrossBow, Bionx Implants) was placed 3 mm from the tear on the meniscus, and the implant was inserted in the meniscus.

The FastT-Fix device contains two 5-mm nonbiodegradable polymer suture bar anchors, with a pre-tied self gliding knot composed of a nonbiodegradable compound num-



Figure 2. The test setup with the test specimen in place.

ber 0 USP braided polyester suture. The insertion instrument (FastT-Fix Meniscal Delivery Needle, Smith & Nephew) 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. After oscillating the needle 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, and the free end was pulled to advance the sliding knot and reduce the meniscal tear. While holding the suture taut, a knot pusher was gently slid to the meniscus until the desired tension was achieved.

The RapidLoc device consists of three components: (1) a soft tissue anchor called a “Backstop,” (2) a connecting suture (biodegradable 2-0 Panacryl suture or 2-0 non-biodegradable Ethibond suture), and (3) a second soft tissue anchor called a “TopHat,” which compresses the meniscus against the Backstop. In the present study, only the biodegradable 2-0 Panacryl sutures have been used.

The Backstop was inserted into a specially designed curved needle provided by Mitek, then 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 applicator, 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 slid down the length of the suture while maintaining tension 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 of suture length.

Tensile Testing

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. Tensile testing was performed using a uniaxial testing frame (LR5k-plus, Lloyd Instruments, UK). The peripheral section of the repaired meniscus was mounted in a custom-made tissue clamp while the central part of the meniscus was held in a grip (Figure 2). The clamp was designed as published by Arnoczky and Lavagnino.^{5,8} A universal joint attached the meniscus clamp to the crosshead of a material 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. Each meniscus-implant/suture construct was cyclically preconditioned between 0 and 5 N at a crosshead speed of 12.5 mm/sec.

Load-to-failure testing was performed at a constant displacement rate of 12.5 mm/sec. This displacement rate was consistent with that used in prior studies evaluating the ultimate pullout strength of sutures and suture anchors and is reflective of rapid loading forces.^{5,8,14} Load and elongation were recorded continuously using a strip chart recorder. The resulting load/elongation curve was documented, as well as the ultimate failure load and the mode of failure. The failure mode was documented by a digital camera. Stiffness was determined as the linear region of the load/elongation curve.

Statistics

Data were analyzed for equal distribution using the Kolmogorov-Smirnov test. In all groups, nonparametric distribution of the data was found. Parameters of interest

TABLE 1
Ultimate Pullout Strength of Meniscal Repair Devices

	Mean Pullout Strength, N	Range, N
Vertical 2-0 Ethibond suture	85.3 ± 6.6 ^a	62.3 to 98.9
Horizontal 2-0 Ethibond suture	63.2 ± 6.7 ^b	58.3 to 78.9
Vertical FastT-Fix	106.0 ± 21.8 ^c	84.9 to 128.5
Horizontal FastT-Fix	87.4 ± 4.9 ^d	80.5 to 102.1
RapidLoc	45.2 ± 1.4	40.7 to 48.2
10-mm Meniscus Arrow	48.8 ± 1.1	34.2 to 67.4

^aSignificantly different from horizontal 2-0 Ethibond suture ($P < .05$), Meniscus Arrow ($P < .05$), and RapidLoc ($P < .05$).

^bSignificantly different from vertical 2-0 Ethibond suture ($P < .05$), vertical FastT-Fix ($P < .05$), Meniscus Arrow ($P < .05$), and RapidLoc ($P < .05$).

^cSignificantly different from horizontal 2-0 Ethibond suture ($P < .05$), Meniscus Arrow ($P < .05$), and RapidLoc ($P < .05$).

^dSignificantly different from horizontal 2-0 Ethibond suture, Meniscus Arrow, and RapidLoc.

were statistically compared between groups using the Mann-Whitney test. The level of significance was set at $P < .05$.

RESULTS

Pullout Strength

Typical load/elongation curves of the devices tested are shown in Figure 3. The vertical FastT-Fix suture was the strongest device, with a mean pullout strength of 106 ± 21.8 N (range, 84.9-128.5 N), followed by the horizontal FastT-Fix suture, with 87.4 ± 4.9 N (range, 80.5-102.1 N) (see Table 1). The pullout strength of horizontal and vertical FastT-Fix sutures was not significantly different from the slightly inferior pullout strength of vertical 2-0 Ethibond sutures (85.3 ± 6.6 N; range, 62.3-98.9 N).

Horizontal 2-0 Ethibond sutures had a significantly lower pullout strength, with 63.2 ± 6.7 N (range, 58.3-78.9 N) than vertical FastT-Fix, vertical 2-0 Ethibond, and horizontal FastT-Fix sutures.

The next 2 groups, with a significantly lower pullout strength than the vertical and horizontal FastT-Fix and vertical 2-0 Ethibond sutures, were the Meniscus Arrow with 48.8 ± 1.1 N (range, 34.2-67.4 N) and the RapidLoc with 45.2 ± 1.4 N (range, 40.7-48.2 N).

Stiffness

Linear stiffness was calculated from the linear region of the load/elongation curve. Vertical FastT-Fix fixation showed the highest stiffness of 32.8 ± 13.4 N/mm (range, 19.4-46.3 N/mm), followed by horizontal FastT-Fix fixation with 27.0 ± 8.9 N/mm (range, 15.9-37.8 N/mm). Vertical 2-0 Ethibond sutures had a significantly lower stiffness than vertical and horizontal FastT-Fix sutures with 16.5 ± 1.2

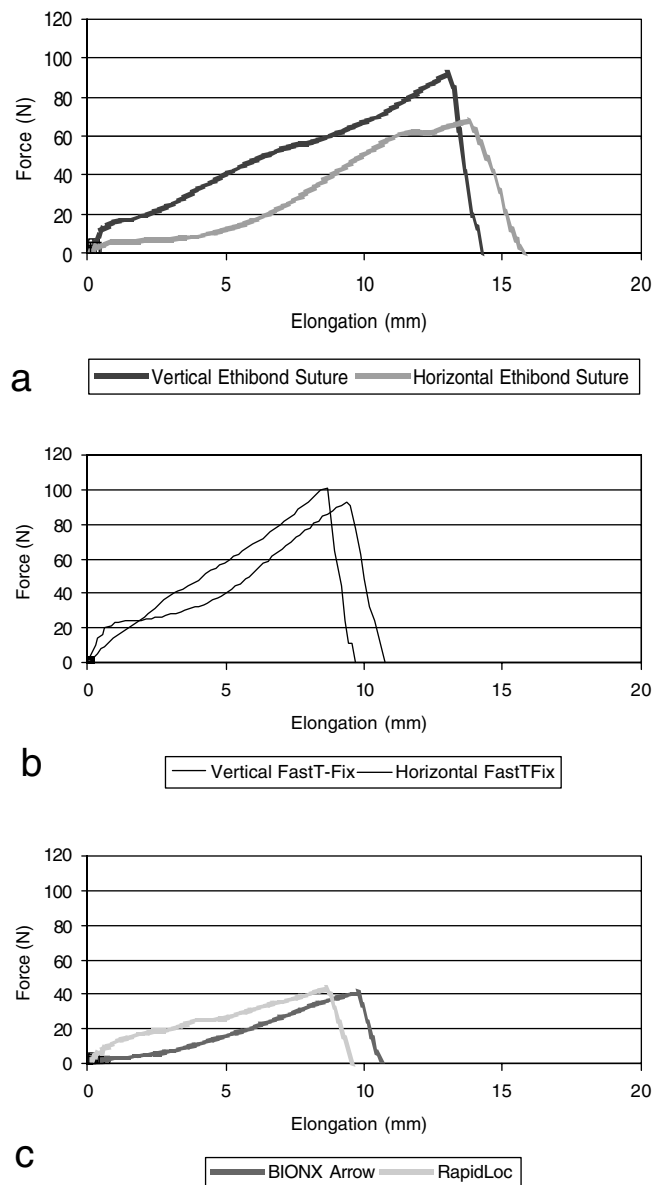


Figure 3. Typical load elongation curves of all devices tested in this study. A, vertical and horizontal Ethibond suture; B, vertical and horizontal FastT-Fix suture; and C, Bionx Meniscus Arrow and RapidLoc.

N/mm (range, 12.4-18.5 N/mm), followed by the RapidLoc device with 13.3 ± 3.4 N/mm (range, 9.0-17.2 N/mm), the horizontal 2-0 Ethibond sutures with 12.2 ± 1.2 N/mm (range, 10.0-16.2 N/mm), and the Meniscus Arrow with 10.5 ± 3.2 N/mm (range, 6.2-12.9 N/mm). The difference between the vertical 2-0 Ethibond sutures, the RapidLoc, Meniscus Arrow, and horizontal 2-0 Ethibond sutures was not statistically significant ($P > .05$) (see Table 2).

Failure Mode

In the vertical and horizontal Ethibond suture group and in the FastT-Fix groups, all repairs failed at the knot of the

TABLE 2
Stiffness of Meniscal Repair Devices

	Stiffness, N/mm	Range, N/mm
Vertical 2-0 Ethibond suture	16.5 ± 1.2 ^a	12.4 to 18.5
Horizontal 2-0 Ethibond suture	12.2 ± 1.2	10.0 to 16.2
Vertical FastT-Fix	32.8 ± 13.4 ^b	19.4 to 46.3
Horizontal FastT-Fix	27.0 ± 8.9 ^c	15.9 to 37.8
RapidLoc	13.3 ± 3.4	9.0 to 17.2
10-mm Meniscus Arrow	10.5 ± 3.2	6.2 to 12.9

^aSignificantly different from horizontal 2-0 Ethibond suture, vertical FastT-Fix, horizontal FastT-Fix, Meniscus Arrow, and RapidLoc.

^bSignificantly different from vertical and horizontal 2-0 Ethibond sutures ($P < .05$), Meniscus Arrow ($P < .05$), and RapidLoc ($P < .05$).

^cSignificantly different from vertical and horizontal 2-0 Ethibond sutures ($P < .05$), Meniscus Arrow ($P < .05$), and RapidLoc ($P < .05$).

suture. In the RapidLoc group, most of the devices failed by a rupture of the suture at the Backstop (9 implants) and in 1 specimen the TopHat was pulled through the central part of the meniscus. The 10-mm Meniscus Arrow failed by pullout of the barbs from the peripheral meniscal section in 8 specimens and pull-through of the T-head through the central meniscus segment in 2 specimens.

DISCUSSION

A meniscal repair technique should repair the torn meniscus tissue, and the repair must be protected from forces caused by rehabilitation during the healing process.¹¹ Primary stability of a fixation technique is an important determinant that should be considered when designing rehabilitation protocols. Barber¹⁰ used conventional suture techniques for meniscus repair and found no difference in the outcome of patients with a restricted or an accelerated rehabilitation protocol. Other authors, using new rigid anchor techniques with lower biomechanical fixation strengths, have suggested a more careful rehabilitation approach.^{2,17}

Kohn and Siebert²⁶ demonstrated that vertical suture techniques are superior to horizontal suture techniques. This finding could be confirmed in many other investigations. In all these studies, vertical sutures have consistently been shown to withstand greater tensile loads to failure than other available suture directions or meniscal repair devices.⁸ The human meniscus is made of collagen fibers embedded in a matrix. The majority of these fibers run circumferentially, with few radial tie fibers.^{15,33} The superior strength of the vertical loop suture can be explained by its perpendicular orientation to the circumferential collagen bundles of the meniscus.²⁶ The lower failure strength of the horizontal sutures may be attrib-

uted to less circumferential collagen fibers being encircled by the loop.²⁶

The present study shows that new-generation all-inside meniscus refixation devices such as the FastT-Fix provide comparable biomechanical characteristics to conventional 2-0 Ethibond sutures. The FastT-Fix suture system gives the surgeon the versatility of placing vertical or horizontal mattress sutures. Miller et al³⁰ stated that placing a vertical suture with the FastT-Fix is technically very demanding, and they therefore recommended use of the new FastT-Fix device for a horizontal suture. In the present study, there was no statistically significant difference in the pullout strength between vertical FastT-Fix and vertical 2-0 Ethibond sutures, and between horizontal FastT-Fix and horizontal 2-0 Ethibond sutures. In both fixation techniques, the mode of failure was suture failure at the knot. The higher pullout strength of vertical sutures found in this study is consistent with findings of various previous studies.^{5,9,11-14,19,29,35,37,44}

In accordance with other studies, the pullout strength of rigid meniscus anchors (10-mm Meniscus Arrow, 48.8 ± 1.1 N) was inferior to vertical and horizontal suture repair, but there was no significant difference from the flexible RapidLoc repair system (45.2 ± 1.4 N). Albrecht-Olsen et al³ reported a mean pullout strength of 53 N (range, 42-65 N) for the 13-mm Meniscus Arrow in a bovine model; Arnoczky and Lavagnino⁵ found a pullout strength of 57.7 ± 13.8 N in a bovine meniscus; and Becker et al¹³ reported a pullout strength of 32.7 N using a human model.

The stiffness of a repair technique allows us to draw conclusions regarding the stability of a fixation during normal loading. We define stability as the ability of a repair to resist deformation. This feature is described by the stiffness of a repair technique. Only a few studies have been published evaluating the linear stiffness of a meniscus repair.^{13,14} High stiffness and low displacement are required to provide stability, which is essential for tissue healing, at the meniscus repair complex.¹³

The finding that vertical sutures provide a higher stiffness than horizontal sutures is in accordance with other studies.^{13,14} The predominance in meniscal tissue of circular-oriented fibers, which are better captured in a vertical suture, may be an explanation for the higher stiffness of vertical sutures. The highest stiffness was found for the vertical FastT-Fix suture, followed by the horizontal FastT-Fix suture. The higher stiffness values of this device in comparison to 2-0 Ethibond sutures might be explained by the implant design or by the knot technique. The most important factor seems to be the suture material itself. In this study, a 2-0 Ethibond suture was used to repair the torn meniscus using a suture technique, whereas the FastT-Fix device consisted of two 5-mm nonbiodegradable polymer suture bar anchors and a nonbiodegradable number 0 USP braided polyester suture. The 2 different suture materials can be 1 explanation for the lower stiffness of the suture technique compared to the new FastT-Fix technique.

The failure mode analysis has shown that the knot itself is not the weak point. However, suture failure most frequently occurred close to the knot. The RapidLoc device

[§]References 5, 9, 11-14, 19, 29, 35, 37, 38, 42-44.

provided a stiffness of 13.3 ± 3.4 N/mm, which is comparable to that of a 2-0 horizontal Ethibond suture (12.2 ± 1.2 N/mm). Becker et al¹³ reported a stiffness of 10.1 ± 1.0 for the horizontal 2-0 Ethibond mattress suture using menisci of elderly humans; Boenisch et al¹⁴ reported a stiffness of 7.7 ± 0.8 for a 2-0 Ti-Cron horizontal stitch technique in a bovine model. The difference of this study from the findings of Becker et al may be caused by the different biomechanical characteristics of human menisci, whereas the difference of this study from the findings of Boenisch et al can be explained by the different suture material used in this study. Repair with the 10-mm Meniscus Arrow provided a stiffness of 10.5 ± 3.2 N/mm, which is consistent with findings of Boenisch et al, who reported a stiffness of 10.0 ± 2.8 N/mm.

A limitation of this study might be the use of bovine instead of human material. Nevertheless, bovine menisci have been used in many other laboratory studies investigating biomechanical properties of meniscus implants.^{3,5,14,24,29,37} The relative scarcity of human menisci from young donors makes it impractical to test new devices in the laboratory using human tissue, at least in the numbers necessary to obtain statistically meaningful results. The use of bovine menisci eliminates the highly variable degenerative components of cadaveric menisci obtained from elderly donors. The fine structure of the bovine meniscus, with predominantly circular-orientated collagen fibers, strongly resembles the structure of the human meniscus.^{15,33,36} Therefore, we believe that the bovine meniscus is a good model to study biomechanical characteristics of meniscus repair techniques. However, the interspecies variations found by Joshi et al²³ in the material properties of the knee joint meniscus indicate the need for caution in extrapolating data on the biomechanical behavior of the human meniscus from animal models. Therefore, the absolute values obtained in this study were less important than the comparative performance of each technique. To elucidate the biomechanical behavior of new meniscus fixation devices under repetitive loading conditions (such as found in postoperative care and rehabilitation after meniscus refixation), future research should include evaluation under cyclic-loading conditions.

Unfortunately, it is not known exactly how much fixation strength is needed to ensure a satisfactory repair, and the necessary fixation strength for meniscal healing is still in question.²⁵ Proctor et al³⁶ determined the material properties of the bovine meniscus and found a mean Young's modulus of 2.8 MPa for radially oriented samples and of 198.4 MPa for circumferentially oriented samples. Since the tissue is functionally adapted to its strain,³¹ it seems likely that under in vivo conditions only low forces occur in the radial direction. Kirsch et al²⁵ investigated the forces occurring in meniscus sutures in a cadaveric model and found low forces that were never higher than 10 N. Koukoubis et al²⁷ showed in a canine model that the repair tissue after meniscus suture failed at 46 N. In addition, as in this study, most biomechanical research studies test a worst-case scenario, in which the load is applied parallel to the axis of the tested fixation device. Although the exact

forces to which a meniscus repair is subjected in vivo are unknown, this setup may not reflect the in vivo situation. Therefore, caution should be used when conferring the absolute values to an in vivo condition. It is for this reason that we would like to stress the comparative performance of biomechanical research studies using this kind of test setup.

Clinical studies have shown that that meniscus repair with the bioabsorbable arrow leads to clinical results comparable to those of traditional suture techniques.^{2,10,17} The biomechanical characteristics of the new flexible meniscus suture anchors evaluated in this study were either comparable (RapidLoc) or superior (FastT-Fix) to the biomechanical characteristics of the 10-mm Meniscus Arrow. Therefore, the clinical use of the RapidLoc and the FastT-Fix can be justified from the biomechanical point of view. Since biomechanical properties evaluated in a controlled laboratory study are not the only factors influencing the result of a meniscal repair technique, caution should be used with the uncritical use of new surgical techniques. Miller et al³⁰ investigated the arthroscopic implantation technique of the FastT-Fix in a cadaveric model and identified several potential pitfalls of this technique, including suture tensioning issues, intra-articular deployment of the implants, premature deployment of both the first and second implants, and difficulty in placing vertical mattress sutures. All these complications, which are predominantly related to the arthroscopic technique, could adversely affect the biomechanical properties of the FastT-Fix in vivo as well as the clinical outcome.

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