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FasT-Fix Versus Inside-Out Suture Meniscal Repair in the Goat Model

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Background: Recent all-inside meniscal repair devices are available, but in vivo studies with these devices are sparse.

Hypothesis: The FasT-Fix has inferior meniscal healing compared with the inside-out suture technique in the goat model.

Study Design: Controlled laboratory study.

Methods: After Institutional Review Board approval, 73 male castrated goats (*Capra hircus*) underwent a 2-cm meniscal incision and subsequent repair with the FasT-Fix device on one knee and inside-out meniscal repair on the contralateral knee. Both repairs used a vertical mattress suture technique. Access to the menisci was via an open technique with an extra-articular osteotomy of the medial collateral ligament origin on the femur. The animals were then allowed to ambulate unrestricted in a pasture after a 7-day stay in cages. Necropsy was carried out 6 months postoperatively, and the menisci and articular cartilage were studied with gross and microscopic inspection.

Results: Nine of the 73 animals were excluded before necropsy. A total of 64 animals underwent necropsy, gross measurement of residual lesions, gross evaluation for chondral damage, histologic evaluation of meniscal repair, histologic evaluation of any adjacent inflammatory reaction to implants, and data analysis. Compared with the inside-out group, the FasT-Fix group had longer residual full-thickness defects (1.2 ± 2.9 mm vs 0.2 ± 1.1 mm; $P = .011$) and longer residual partial-thickness defects (8.4 ± 6.3 mm vs 3.6 ± 5.5 mm; $P < .001$). A total of 148 FasT-Fix devices were placed for 73 knees. Two devices were replaced for improper deployment. The device deployed and attached correctly 146 of 148 times for a success rate of 98.6%. There was no gross chondral damage and no histologic findings of inflammatory reaction to the implants with either technique.

Conclusions: The FasT-Fix meniscal repair had inferior meniscal healing results in this animal model. Previous studies using this animal model have paralleled clinical outcomes. Implantation of the FasT-Fix device does not damage adjacent femoral or tibial cartilage. The deployment of the FasT-Fix implant was simple and reproducible. There was no inflammatory reaction to the FasT-Fix implant.

Clinical Relevance: The FasT-Fix meniscal repair has inferior meniscal healing results compared with the inside-out meniscal repair technique in the goat model. The clinical significance of this finding is not known. Further clinical study of the FasT-Fix implant is warranted.

Keywords: meniscus; animal study; meniscal fixation techniques; repair; all-inside; FasT-Fix

The long-term effects of meniscal injury and meniscectomy are well known and place patients at increased risk for early knee arthritis. The menisci have multiple functions in the

knee such as joint stability, shock absorption, load bearing, and joint lubrication.^{6,7,10,12,14,15,23} At present, there are multiple meniscal repair devices and techniques. However, not all devices have been studied in vivo for efficacy of meniscal repair or for intra-articular damage from device placement. The goat model has been used in prior meniscal studies.^{19,20,24} In these studies, the majority (85%-93%) of surgically created tears in the goat model healed with a modified inside-out technique. Eight to fourteen percent of untreated tears completely healed, and 23% partially healed. Meniscal healing in these studies was graded according to Henning's criteria: healed (<10% cleft), partially healed (<50% cleft), and not healed (>50% cleft).¹⁰ Furthermore, some meniscal

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repair devices caused chondral injury, and no repair device was superior to the inside-out suture repair.^{19,20}

The FasT-Fix (Smith & Nephew Endoscopy, Andover, Massachusetts) is a commonly used all-inside meniscal repair device in humans, and the in vivo results have not been completely evaluated. It is a new-generation meniscal repair device that allows tensioning of the repair after implant placement. Laboratory studies have shown that it is biomechanically comparable with traditional inside-out suture placement.^{2,3,5,13,18,26,27} Because the FasT-Fix is an all-inside device, it avoids the need for a separate incision and therefore diminishes the potential risk for postoperative complication (infection, nerve damage, etc). The reported dangers for all-inside meniscal repair devices include the risk of inadequate repair, poor healing of meniscal repair, reaction to the implant, cartilage damage from device, and device failure.^{1,4,9,11,16,17,21,25} The FasT-Fix has been studied clinically for improvement in knee scores after meniscal repair; however, we are unaware of any human or animal study showing the healing of the meniscal tear.⁸ The purpose of this study was to compare the efficacy of the FasT-Fix meniscal repair device versus conventional inside-out meniscal repair on meniscal healing in a goat model.

MATERIALS AND METHODS

Institutional Review Board approval was obtained for this in vivo controlled study. Following this approval, 73 male castrated goats (*Capra hircus*) underwent open meniscal repair with the FasT-Fix device on one knee and inside-out meniscal repair on the contralateral knee. After preanesthesia administration and intubation, the goats were anesthetized with an inhalational anesthetic. An intravenous antibiotic (ceftriaxone, 1 g) was infused at least 30 minutes before the procedure. Both hind limbs underwent sterile preparation and drape. A 5-cm medial-longitudinal incision was used to access the sartorial fascia of the hindlimbs. The fascia was carefully reflected using electrocautery to expose the medial collateral ligament (MCL).

A wedge-shaped femoral bone block (2 cm wide, 3 cm long, and 1.5 cm deep), centered on the MCL and bordered inferiorly by the femoral condyle, was created with an oscillating saw and osteotome. Before the bone block was cut and elevated, it was predrilled and tapped for later reattachment with a 3.5-mm cortical screw. The bone block and MCL were carefully elevated to expose the medial meniscus. A No. 15 scalpel was used to incise a 2-cm longitudinal tear in the peripheral 3 mm of the medial meniscus. An elevator was inserted to ensure that the tear was complete and was of the appropriate length.

In the inside-out group, 2 No. 0 Ethibond (Ethicon Inc, Piscataway, New Jersey) vertical mattress sutures were used to join the incised meniscal edges using a modified inside-out technique under direct visualization. The vertical mattress suture technique has previously been reported superior to the horizontal suture technique.^{13,22,26} The sutures were tied outside of the capsule with a surgeon's knot. In the FasT-Fix group, the same vertical mattress repair was performed using 2 implants following the manufacturer's described

repair technique under direct visualization. Each FasT-Fix implant contains a pretied, self-sliding knot composed of No. 0, nonabsorbable, USP-braided, polyester suture.

After reduction and fixation of the meniscal tear, the bone block was secured with a 3.5-mm cortical screw with the lag technique. The miniarthrotomy, the fascia of the sartorius, and the subcutaneous tissues were closed with nonabsorbable sutures. The skin was closed with running, buried subcuticular Prolene (Ethicon Inc). Postoperatively, the animals were transferred to short runs and allowed to immediately bear weight. They remained in the runs for 1 week for pain control and were subsequently released to pasture.

Six months after the index operation, each animal was sacrificed. At the time of necropsy, the entire knee was visualized, and any gross chondral damage or other defects were noted. The menisci were harvested and evaluated by an independent, blinded veterinary pathologist. The menisci were evaluated for residual length of meniscal tear (in millimeters) and categorized as full or partial thickness. For this procedure, the residual length of the tear was the measured endpoint, and the criteria for meniscal healing according to Henning et al were not used.¹⁰ Microscopic specimens of each meniscus and the extracapsular areas adjacent to the implants were also taken for histologic inspection of repair tissue and possible inflammatory reaction.

A priori power analysis was performed to design the experiment. The power of *t* tests was 99.8%, assuming a sample size of 64, a type I error rate of 5%, and a large effect size (Cohen *d* = 0.8). The power of *t* tests was 87.8%, assuming a sample size of 64, a type I error rate of 5%, and a medium effect size (Cohen *d* = 0.5).

Data Analysis

Statistical analysis was performed in SPSS 14.0 (SPSS Inc, Chicago, Illinois) with paired *t* tests, Wilcoxon signed-rank tests, χ^2 tests, relative risks analysis, and number needed to treat analysis. An α value (type I error rate) of .05 was considered significant. A β value (type II error rate) of .80 was used as a minimum cutoff for power analysis.

RESULTS

A total of 73 animals started the protocol. Nine animals met the exclusion criteria. Two were initial surgical pilot subjects and were not further analyzed; the other 7 were excluded for the following reasons: iatrogenic fracture of the medial femoral condyle (*n* = 1), knee instability from an incompetent medial collateral ligament (*n* = 1), peritonitis (*n* = 1), septic joint (*n* = 3), or death before necropsy (*n* = 1). The remaining 64 animals completed the protocol and underwent necropsy, gross measurement of residual lesions, gross evaluation for chondral damage, histologic evaluation of meniscal repair, histologic evaluation of any adjacent inflammatory reaction to implants, and data analysis. For the all-inside repairs, a total of 148 devices were placed for 73 knees. Two devices were replaced for improper deployment. The device deployed and attached correctly 146 of 148 times for a success rate of 98.6%.

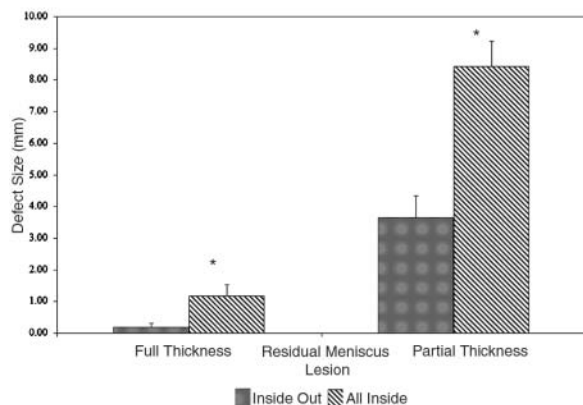


Figure 1. Comparison of full- and partial-thickness residual defects for inside-out and all-inside (FasT-Fix) repairs of goat menisci. The stippled bars indicate the inside-out repairs, and the striped bars indicate the all-inside (FasT-Fix) repairs. The error bars denote the standard error of the mean. Significant differences between inside-out and all-inside repairs are marked (*).

For the all-inside FasT-Fix repairs, the residual full-thickness defect was 1.2 ± 2.9 mm (mean \pm SD) in 10 of 64 (16%) meniscal repairs. For the inside-out repairs, the residual full-thickness defect was 0.2 ± 1.1 mm in 2 of 64 (3%) meniscal repairs. The difference in residual full-thickness defects was significant by a paired *t* test ($P = .011$) and by the Wilcoxon signed-rank test ($P = .014$). For the all-inside FasT-Fix repairs, the residual partial-thickness defect was 8.4 ± 6.3 mm in 52 of 64 (81%) meniscal repairs. For the inside-out repairs, the residual partial-thickness defect was 3.63 ± 5.5 mm in 27 of 64 (42%) meniscal repairs. The difference in residual partial-thickness defects was significant by a paired *t* test ($P < .001$) and by Wilcoxon signed-rank test ($P < .001$). This is illustrated in Figure 1.

The disparity in the number and the frequency of residual full-thickness, partial-thickness, and completely healed tears for the inside-out and all-inside (FasT-Fix) repairs is presented in Table 1. These differences are statistically significant by the χ^2 test ($P < .001$). The relative risk of performing a meniscal repair operation with either technique is outlined in Table 2 with 95% confidence intervals. The relative risk of obtaining a residual full-thickness defect by using the all-inside (FasT-Fix) technique was statistically significant ($P < .05$). In addition, the relative risk of any residual defect (full or partial thickness) was also significant ($P < .05$). Because the all-inside (FasT-Fix) technique yields a risk of residual tears greater than one, the number needed to treat is also noted.

The cartilage of the medial compartment and surrounding compartments was pristine without chondrolysis, grooving, thinning, dimpling, or other irregularity. The microscopic specimens taken of the menisci revealed meniscal healing with fibrovascular connective tissue and no evidence of increased inflammation. The capsular tissues did not show any increased inflammation adjacent to the sutures or the FasT-Fix anchor bars.

TABLE 1
Number and Frequency of Residual Defects From All-Inside and Inside-Out Repairs^a

	Full-Thickness Defect	Partial-Thickness Defect	No Residual Defect
All-inside repair	10 (16%)	52 (81%)	2 (3%)
Inside-out repair	2 (3%)	27 (42%)	35 (55%)

^aThe differences are significant by the χ^2 test ($P < .001$).

TABLE 2
Relative Risk and Number Needed to Treat for Residual Tears With All-Inside Repair (Intervention) Versus Inside-Out Repair (Control)^a

	Relative Risk (95% CI)	Number Needed to Treat (95% CI)
Full-thickness defect	5.0 (1.3-19.8)	8 (5-37)
Any defect (full or partial)	2.1 (1.7-2.9)	2 (2-3)

^aCI, confidence interval. All values are statistically significant ($P < .05$).

DISCUSSION

Meniscal repair techniques have evolved over the past decade at a rapid pace. Some marketed devices have limited evaluation for successful meniscal repair, clinical improvement, or potential complications. Recently, all-inside meniscal repair implants (including the FasT-Fix) have gained favor because they do not require a second approach to the knee. They potentially decrease the chance of infection, nerve injury, and operative time.

The FasT-Fix has been previously studied with biomechanical testing and prospective case series. These studies showed the FasT-Fix implant has similar biomechanical properties of vertical inside-out meniscal repair, the knee scores improved in general after FasT-Fix meniscal repair, and the femoral and tibial cartilage was not injured by the implant.^{5,8} While these studies give an indirect conclusion that proper placement and use of the implant lead to successful outcomes, there has been no study to date that has evaluated the healing of the meniscus in vivo.

Some earlier studies have found difficulty with the use of the FasT-Fix device.¹⁹ The procedure was performed on 2 technique animals (4 knees) to assure surgeon facility with the implants before the start of the study. Among the study animals, only 2 device failures were noted. These failures were primarily because the implanted and deployed anchor bar could not obtain adequate capsular purchase and subsequently seated in the meniscal tear. Because the procedure was open, these devices were removed, and new implants were placed in an adjacent location without further problems or loss of reduction. In this series, the deployment of the FasT-Fix implant was simple and reproducible.

The visualization for the meniscal repair techniques used in this study was optimal. The meniscus was incised longitudinally in the red-red zone under direct visualization. The tears were subsequently repaired within minutes. The repairs were performed with adequate tension of the suture/device so that the repair was near anatomic.

It is unclear why the Fast-Fix implants had comparatively longer residual full- and partial-thickness defects in this animal model. Some uncontrolled variables within the study may prove to be important. The presence of full- and partial-thickness defects in both groups may be related to the medial dissection (medial femoral condyle bone block and MCL elevation), which may affect meniscal blood supply. Additionally, the animals had no weightbearing restrictions, which may have led to increased shear at the repair and could have decreased overall healing. Despite these uncontrolled variables, no meniscal repair for either group showed extension of the tear beyond the initial 2-cm tear.

Both techniques were relatively safe to perform. The cartilage of the medial compartment and surrounding compartments was pristine without chondrolysis, grooving, thinning, dimpling, or other irregularity at the time of necropsy. There was no microscopic evidence of inflammatory reaction with either technique.

The differences in residual full- and partial-thickness defects between the 2 techniques in this goat study are statistically significant, although the clinical significance remains an open question. A recent prospective case series study has reported overall clinical healing of meniscal repair with the Fast-Fix implant to be 86%.⁸ In our study, the difference in average residual full-thickness defects between the 2 techniques was 1 mm. The residual partial-thickness defects were larger on average, but it is unknown if these defects lead to clinical failure. It is conceivable that the residual and partial-thickness tears noted with either technique are small enough that they are clinically silent.

In conclusion, the Fast-Fix had inferior statistical results overall compared with the inside-out repair technique. There is no method to ascertain whether these differences in residual partial- or full-thickness defects affect the clinical outcome in human patients, although it can be hypothesized that a superior rate of healing leads to superior results. Implantation of the Fast-Fix device did not damage the adjacent femoral or tibial cartilage. There was no increased inflammatory reaction adjacent to either implant. The deployment of the Fast-Fix device was reproducible.

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