Results of All-Inside Meniscal Repair With the FasT-Fix Meniscal Repair System

Elias S. Kotsovolos, M.D., Michael E. Hantes, M.D., Dimitrios S. Mastrokalos, M.D., Olaf Lorbach, M.D., and Hans H. Paessler, M.D.

Purpose: The goal of this prospective study was to evaluate the results of arthroscopic meniscal repair using the FasT-Fix repair system. **Type of Study:** Prospective case series. **Methods:** Sixty-one meniscal repairs with the FasT-Fix meniscal repair system in 58 patients with a mean age of 32.6 years were performed between 2001 and 2002. Concurrent anterior cruciate ligament reconstruction was performed in 36 patients (62%). All tears were longitudinal and located in the red/red or red/white zone. Criteria for clinical success included absence of joint-line tenderness, locking, swelling, and a negative McMurray test. Clinical evaluation also included the Tegner and Lysholm knee scores, and KT-1000 arthrometry. In addition, all patients were evaluated preoperatively with magnetic resonance imaging. **Results:** The average follow-up was 18 months (range, 14 to 28 months). Six of 61 repaired menisci (9.8%) were considered failures according to our criteria. Therefore, the success rate was 90.2%. Time required for meniscal repair averaged 11 minutes. Postoperatively, the majority of the patients had no restrictions in sports activities. The mean Lysholm significantly improved from 43.6 preoperatively to 87.5 postoperatively ($P < .001$). Fifty-one patients (88%) had an excellent or good result according to the Lysholm knee score. Four patients had a restriction of knee joint motion postoperatively, and an arthroscopic arthrolysis was performed in 1 of them. Analysis showed that age, length of tear, simultaneous anterior cruciate ligament reconstruction, chronicity of injury, and location of tear did not affect the clinical outcome. **Conclusions:** Our results show that arthroscopic meniscal repair with the FasT-Fix repair system provided a high rate of meniscus healing and appeared to be safe and effective in this group of patients. **Level of Evidence:** Level IV, therapeutic study, case series (no control group). **Key Words:** Meniscus repair—All-inside technique—Clinical results.

Although meniscal repair was first reported more than 100 years ago by Annandale,[1] it did not gain appreciation until the last 2 decades. This is because the importance of the meniscus for the knee has been well established owing to laboratory and clinical investigations during the last 2 decades.[2-4] In addition, improvements in arthroscopic techniques and instrumentation in recent years permit a large number of surgeons to easily perform this procedure.

Among the 3 arthroscopic techniques that are known today (inside-out, outside-in, and all-inside), the all-inside fixation with biodegradable products has increased in popularity because of its fast application and reduction of the risk of serious neurovascular complications.[5,6] However, there are several reports in the literature of complications directly associated with these devices such as chondral injuries and synovitis.[7-9] Another concern is the inferior strength of these devices in comparison with vertical sutures, which could be a critical factor contributing to meniscal healing according to some biomechanical studies.[10-12]

There is today a plethora of devices for all-inside meniscal repair. Most of these have been tested in vitro but clinical results are not available for the

From the Center for Knee, Foot Surgery and Sports Trauma, ATOS Clinic, Heidelberg, Germany.

Address correspondence and reprint requests to Elias S. Kotsovolos, M.D., 2 Parodos Platias G. Stavrou str., 45444 Ioannina, Greece. E-mail: lias14@hotmail.com

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majority of them. One of these devices that has been recently introduced is the FasT-Fix meniscal repair system (Smith & Nephew). It combines the advantages of all-inside technique while providing high biomechanical properties.[13,14]

Therefore, we designed a study to evaluate the clinical results and complications of arthroscopic meniscal repairs in a consecutive series using the FasT-Fix meniscal repair system, and to evaluate factors that could affect the healing rate. Our hypothesis was that the FasT-Fix meniscal repair system will provide clinical results equal to other similar meniscal repair systems.

METHODS

From June 2001 through December 2002, 64 arthroscopic meniscal repairs in 61 consecutive patients were performed by the senior author (H.H.P) with the FasT-Fix Meniscal Repair Suture System (Smith & Nephew) using the arthroscopic technique detailed below. During this period only this system was used for meniscal repair in our institution. Ten meniscal repairs using a hybrid fixation of sutures and the FasT-Fix System were performed but these cases were not part of this study. Inclusion criteria were (1) vertical full-thickness tear greater than 10 mm in length, (2) location of the tear less than 6 mm from the meniscocapsular junction, (3) no former meniscus surgery, (4) no evidence of arthritis during arthroscopy, and (5) fixation of the meniscus only with FasT-Fix. Anterior cruciate ligament (ACL)-deficient knees were reconstructed using hamstrings autograft at the time of the meniscal repair. Institutional Review Board approval was obtained before initiating the study. All patients gave their informed consent to participate.

Preoperatively, diagnosis of meniscal tear was based on clinical examination; special attention was paid to signs of meniscal tear, such as locking, tenderness on palpation of the joint line, presence or absence of effusion, and meniscal tests like McMurray and Appley test. Knee laxity was measured with the KT-1000 Arthrometer (MEDmetric, San Diego, CA). The Lysholm knee score[15] and Tegner activity score[16] were obtained to evaluate knee function. In addition, all patients underwent preoperative evaluation with magnetic resonance imaging.

Surgical Technique

Each device of FasT-Fix contains two 5-mm polymer suture bar anchors with a pre-tied self-sliding knot of No. 0 nonabsorbable USP braided polyester suture material. Also, there is a split cannula for easier introduction of the device into the knee joint, a depth penetration limiter, and a knot pusher–suture cutter (Fig 1).

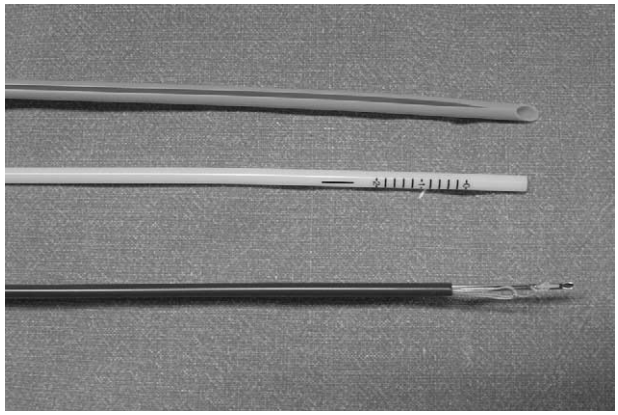

FIGURE 1. Components of the FasT-Fix meniscal repair system: delivery needle with the implant, depth penetration limiter, and split cannula.

General anesthesia was used in all patients. After diagnostic arthroscopy, the morphology of the meniscus tear was determined. The tear length and the rim width were recorded at the time of surgery. In case of a dislocated bucket-handle tear, reduction was performed. Tear edges were freshened with a meniscus rasp and shaver. Multiple perforations were made with microfracture awls in the meniscus rim to produce vascular channels and encourage bleeding in order to stimulate healing response. Using a meniscal depth probe the desired length of penetration is determined and then the depth limiter is trimmed accordingly, followed by the introduction of the Fast-Fix delivery needle through the split cannula. It was positioned so that it perpendicularly pierced the surface of the inner meniscal fragment and then was advanced into the peripheral meniscal fragment to the end of the depth penetration limiter (Fig 2). The needle was then withdrawn from the meniscus with a gentle oscillating motion, releasing the first anchor. Then the gold trigger was slid forward to advance the second implant. For a horizontal suture, the delivery needle was transferred 5 mm sideways and for a vertical one we placed it perpendicular to the tear (Fig 3). As soon as the second implant was inserted, the delivery needle was removed from the knee joint, leaving the free end of the sutures (Fig 4). Finally, the pre-tied self sliding knot was tensioned with the aid of the knot pusher–suture cutter. The sutures could be cut with the knot

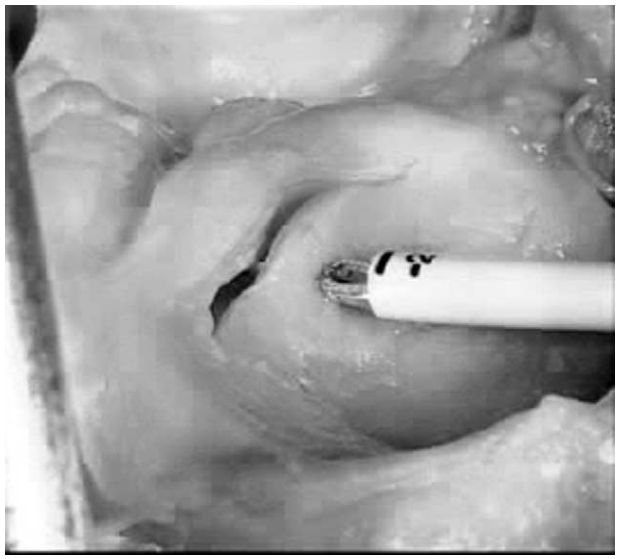

FIGURE 2. Placement of the first suture bar anchor in a medial meniscus tear (demonstration in a cadaver knee).

pusher–suture cutter or arthroscopic scissors. Sutures were applied to the femoral and the tibial site of the lesion.

Postoperatively, all patients (isolated meniscal repair and meniscal repair with an ACL reconstruction) used a hinged brace and motion was restricted between 0° and 60° for the first 3 weeks with partial weight bearing, followed by another 3 weeks with an increase of range of motion between 0° and 90°, and progression to full weight bearing by postoperative week 6. Jogging was permitted after week 10, and full activity at 5 months for all patients.

Evaluation Methods

An experienced sports medicine fellow (D.S.M) performed all the postoperative examinations. Using

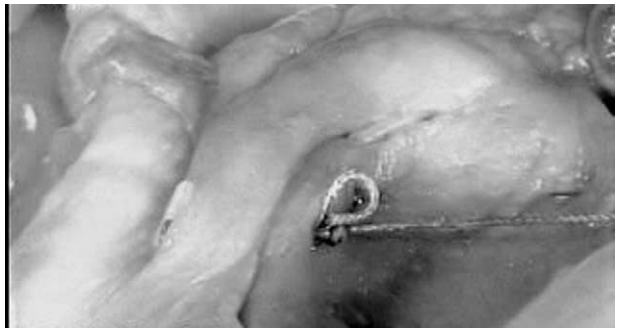

FIGURE 4. Both suture bar anchors have been placed and the free end of the sutures is used to tighten the knot (demonstration in a cadaver knee).

Barrett's criteria,[17] a repaired meniscus was considered healed if there was no joint-line tenderness or effusion, and a negative McMurray's test at the latest follow-up. If one or more of these parameters was present, the result was classified as a failure. Knee laxity was measured with the KT-1000 Arthrometer postoperatively and knee function in activities of daily living and in recreational and competitive sports was assessed using the Lysholm and Tegner activity scores.

Statistics

The paired t test was used for comparison of the preoperative and postoperative Lysholm and Tegner scores. Comparisons between subgroups of patients were performed using the Fisher Exact test as appropriate. Significance was set at $P < .05$.

RESULTS

Two of 61 patients were lost to follow-up (they are living abroad) and 1 patient had a new severe trau-

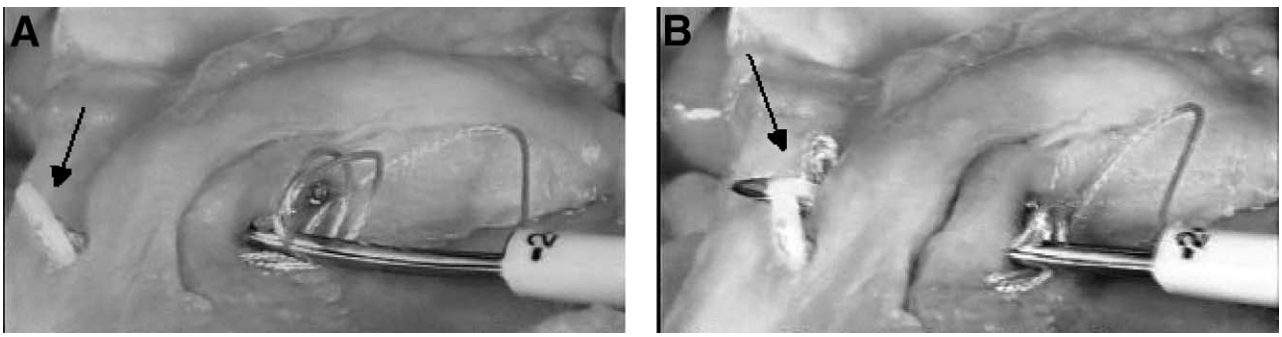

FIGURE 3. (A) After deployment of the first implant (arrow), the delivery needle is ready to pierce the meniscus again in order to release the second implant. (B) The second implant (arrow) is in place 4 to 5 mm from the first implant (demonstration in a cadaver knee).

matic incidence 4 months postoperatively, resulting in ACL and medial meniscus rerupture plus a malleolar fracture. Consequently, all 3 of them (5%) were excluded from the study. Thus, 58 patients (61 menisci) constitute the subjects of this report. The mean follow-up period was 18 months (range, 14 to 28 months).

Thirty-seven men (64%) and 21 women (36%) were included in the study population. The average age at the time of meniscal repair was 32.6 years (range, 16 to 54 years). The period from injury to meniscal repair ranged from 2 to 196 days (median, 76 days). Thirty (48%) meniscal tears were rated acute (injury-to-repair interval $\leq$3 weeks), and 31 (52%) tears were rated chronic (injury-to-repair interval $>$3 weeks). There were 22 (36%) isolated meniscal tears, and 39 (64%) were combined with arthroscopic ACL reconstruction. Three patients who underwent ACL reconstruction had medial and lateral meniscus tear.

There were 25 right knees (43%) and 33 left knees (57%). The medial meniscus was affected in 34 cases (56%) and the lateral meniscus in 27 cases (44%). Twenty-two (36%) meniscal tears were located within a rim width of less than 3 mm (red-red zone), whereas 39 (64%) were within a rim width of 3 to 6 mm. The meniscal tears' morphology included 61 (100%) longitudinal tears. The average length of the tears was 31.6 mm (range, 13 to 45 mm). There were 22 bucket-handle tears (36%) and 10 of them were displaced at the time of operation. The number of FasT-Fix anchors used averaged 4.4 (range, 1 to 8). Additional operation time required for meniscal repair averaged 11 minutes per procedure.

At the last follow-up, we found no symptoms of meniscal tears in 55 (90.2%) cases. One patient (1.6%) had a positive McMurray test and tenderness on joint-line palpation, 3 patients (5%) had tenderness on joint-line palpation, and 2 patients (3.2%) had tenderness on joint-line palpation plus effusion. No patient had locking episodes. These 6 cases (9.8%) were considered as failures. However, revision arthroscopy and a partial meniscectomy was necessary only in 2 cases, 1 and 9 months postoperatively.

Overall, the Lysholm score increased to a mean value of 87.5 (range, 57-100), which was statistically significant compared with the preoperative mean value of 43.6 (range, 18-61) ($P < .001$, paired t test). Fifty-one patients (88%) had an excellent or good outcome, 6 patients (10.3%) had a fair result, and 1 patient (1.7%) had a poor result. For patients with concurrent ACL reconstruction, the Lysholm score improved significantly ($P < .001$) from an average of 49.3 (range, 25-61) preoperatively to 88.2 (range, 57-100) postoperatively. For patients with isolated meniscal repair, the Lysholm score improved significantly ($P < .001$) from an average of 41.2 (range, 18-60) preoperatively to 86.8 (range, 61-100) postoperatively. Overall, the mean preinjury Tegner activity score was 6.42 (range, 5-9). Preoperatively the mean preinjury Tegner activity score was 3.21 (range, 2-5) whereas the postoperative mean value was 5.7 (range, 5-8) and this difference was statistically significant ($P < .001$, paired t test). For patients with concurrent ACL reconstruction, the Tegner activity score improved significantly ($P < .01$) from an average of 2.9 (range, 2-5) preoperatively to 5.7 (range, 5-8) postoperatively. For patients with isolated meniscal repair, the Tegner activity score improved significantly ($P < .01$) from an average of 3.5 (range, 2-5) preoperatively to 5.9 (range, 5-7) postoperatively. All patients had returned to full-time work. Also, at the last follow-up, all the knees were considered stable with negative Lachman and pivot-shift test and an average side-to-side difference of 1.9 mm (range, 0-5 mm) on maximum-manual KT-1000 arthrometer testing.

Complications occurred in 7 of 58 patients. One patient, after combined meniscal repair and ACL reconstruction, had a painful hemarthrosis and underwent aspiration. Four patients, also after combined meniscal refixation and ACL reconstruction, had difficulties in regaining full flexion of the knee. In only 1 of them was an arthroscopic arthrolysis considered necessary, 3 months postoperatively; the rest of them had only 10° of flexion deficit after intensive physical therapy. Two patients with isolated meniscal repair complained of persistent knee joint swelling and erythema 1 month after the operation. They were treated with arthroscopic debridement, synovectomy, and antibiotic therapy. However, cultures obtained at debridement surgery were negative for bacteria. In both cases, diffuse synovitis was present but no chondral lesions were noted, the suture knot was barely visible, and the sides of the tear were maintained in good position. It is difficult to conclude if the menisci were healed because the time interval from the index operation was short. In addition, no chondral injuries were observed associated with the device. One of these patients had a persistent joint-line tenderness and underwent a revision arthroscopy and a partial meniscectomy. There were no neurovascular or other complications directly associated with the device.

In an effort to identify factors that affect the results of meniscus repair, we compared patients with clinically healed menisci with the patients with

Table 1. *Effect of 7 Factors on Outcome of Meniscus Repair*

Factor	Asymptomatic: No. of Repairs (%)	Symptomatic: No. of Repairs (%)	Total	*P* Value
Chronicity				
>3 weeks	26 (84)	5 (16)	31	.142
<3 weeks	29 (96.7)	1 (3.3)	30	
Age				
>30 years	30 (90.9)	3 (9.1)	33	.763
<30 years	25 (89.3)	3 (10.7)	28	
Meniscus side				.167
Medial	29 (85.3)	5 (14.7)	34	
Lateral	26 (96.3)	1 (3.7)	27	
Length of tear				.871
>25 mm	30 (90.9)	3 (9.1)	33	
<25 mm	25 (89.3)	3 (10.7)	28	
Location of tear				.256
Red/red	21 (95.5)	1 (4.5)	22	
Red/white	34 (87.2)	5 (12.8)	39	
ACL reconstruction				.823
No	20 (90.9)	2 (9.1)	22	
Yes	35 (89.8)	4 (10.2)	39	
Complications				.284
No	49 (90.8)	5 (9.2)	54	
Yes	6 (85.7)	1 (14.3)	7	

clinically failed repairs. Parameters that were examined for their influence in the clinical result were age, chronicity of tear (time from injury to repair), length of tear, repair side (medial or lateral), location of tear (distance from the meniscocapsular junction), presence of complications, and ACL reconstruction at the time of meniscal repair (Table 1). Statistical analysis showed that none of these factors significantly affected the clinical outcome.

DISCUSSION

After the introduction of the biodegradable Meniscus Arrow by Bionx Implants (Blue Bell, PA) in 1993,[6] a large number of all-inside arthroscopic meniscal repair devices have been introduced to the market. Perhaps the most popular device is the Meniscus Arrow, and therefore several reports with clinical results using this device are available.[5,18-21] However, very few clinical studies are available for some of the newer meniscal devices,[22-24] and for the majority of them no clinical data exist.

In this study, the clinical results of 61 repaired menisci with the FasT-Fix meniscal repair system with an average follow-up of 18 months are presented. The success rate in this series was 90% (55 clinically healed menisci out of 61) according to the criteria of Barrett et al.,[17] and 51 patients (88%) had an excellent or good result. Evaluation of meniscal healing after meniscal repair is performed using these or similar clinical criteria by the vast majority of the studies today.[18-24] Of course, we acknowledge that a meniscal repair without symptoms postoperatively does not always reflect the true status of the meniscus and that only second-look arthroscopy can verify healing of the meniscus or not, and this is a limitation of our study. According to Albrecht-Olsen et al.,[6] the healing rate of the repaired menisci after second-look arthroscopy is lower than the clinical estimation. However, we used strict criteria to consider a clinical result as a success. For example, patients who had occasional soreness or minor symptoms in our study population were classified as failures, although their symptoms were not so intense as to require revision surgery. On the other hand, Morgan et al.[25] showed that clinical examination seems to be a reliable method of evaluating the status of repaired menisci. In this study, it was proved that clinical examination accurately predicted all failures in second-look arthroscopy, with no false positives.

Clinical results similar to those in our study have been reported in other studies with meniscal repair devices. The success rate for the Meniscus Arrow ranged from 88% to 95% according to most recent studies.[6,18-21] The healing rate with the T-Fix system has been reported to be nearly 90%.[22] Laprell et al.[23] reported a success rate of 86% with the Mitek meniscal repair system. However, comparison is not always possible because several study groups used a different evaluation system. The need for repeat surgery (partial meniscectomy) was defined as failure in some studies.[20,26] When more strict criteria are used as in our study (joint-line tenderness, McMurray test, effusion), Barrett et al.,[27] using the T-Fix system, reported an 81% healing rate.

In our series, 4 patients had difficulty in regaining a full range of motion of their knee. All these patients underwent meniscal refixation in combination with ACL reconstruction. It is known from the literature that the risk of arthrofibrosis is increased in this type of surgery.[28] Because no patient with isolated meniscal repair developed such a problem, it seems unlikely that this restriction of knee motion was caused by the implants. We had 2 patients with knee joint swelling and erythema after meniscal refixation. Perhaps these 2 cases represent aseptic synovitis since no bacteria were identified. Aseptic synovitis after meniscal fixation with implants has been reported by others as a

foreign-body reaction,[29,30] although the mechanism of synovitis is not yet fully understood. We had no other complications directly associated with the device in our series, such as broken implants or migration of the implants, as has been reported with other devices.[7-9] We believe also, as Barber et al.[13] stated, that "since the implants of the FasT-Fix are embedded into the peripheral capsule" chondral injury is unlikely, although we had the chance to document it only in the 2 cases of second-look arthroscopy. However, we agree with Miller et al.[31] that to avoid penetration of superficial structures including the skin, premeasurement of the desired depth using meniscal depth probe is required followed by trimming of the depth-limitation device.

Although the strength of the repair device is only one factor contributing to meniscal healing, it is our opinion that our low failure rate is due to the fact that the FasT-Fix provides a high load at failure and stiffness at the repair site. Two biomechanical studies[13,14] found that the strength of the FasT-Fix meniscal repair system is comparable to that of vertical mattress sutures and superior to all the available meniscal devices in the market including the Meniscus Arrow. Even when the device is placed not vertically but horizontally as we did in most of the cases (which is technically much easier), the load to failure is not reduced.[13] Of course, we have no control group in our study to compare the FasT-Fix meniscal repair system to another alternative method, and this is another limitation of our study. It would be interesting if future studies compared this device with traditional suture techniques or other meniscal devices. However, our study has the advantage of a consecutive series of patients, operated by a single surgeon, using the same technique.

Many factors such as age, chronicity of tear, length of tear, location of tear, and ACL reconstruction at the time of meniscal repair influence the outcome of meniscal repair according to reports in the literature. However, disagreement exists regarding the effect of each of these factors on meniscal healing. Our analysis showed that none of these factors significantly affects the clinical outcome. Some studies reported a higher healing rate (with a success rate of more than 90%) for meniscal tears with a rim width of less than 3 mm,[17,32] acute tears,[33,34] and tears in the lateral meniscus.[17,32] However, other studies found that the tear site (medial or lateral) or chronicity of the tear does not influence meniscal healing. Our results are in concurrence with those of other investigators who found no significantly different results between younger and older age groups,[33,34] and that tear length[17] is not a significant factor in meniscal healing. Most authors agree that simultaneous meniscal repair and ACL reconstruction creates a more favorable environment for meniscal healing because of greater intra-articular bleeding and fibrin clot formation.[17,18] However, De Haven et al.[35] reported that they had only 4% failures in isolated meniscal repairs with rim widths less than 3 mm; in their opinion, rim width is the primary factor and not simultaneous ACL reconstruction.

CONCLUSIONS

Meniscal repair with the FasT-Fix meniscal repair system provides excellent clinical results in the vast majority of patients, with a success rate of 90%, which is comparable to those of traditional suture techniques in this short-term follow-up study. However, studies with a long-term follow-up are needed to determine if the repaired menisci will maintain structural and functional integrity over time. In addition, we found that the system has the advantage of avoiding neurovascular complications. An acceptable failure rate using this device can be expected, even in chronic tears, in tears that extent to the red/white zone, and in patients older than 30 years.

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