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Arthroscopic meniscal repair with an absorbable screw: results and surgical technique

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Abstract The results of a new method for arthroscopic all-inside meniscus repair using a biodegradable cannulated screw (Clearfix meniscal screw) were assessed in a medium-term follow-up prospective study. The Clearfix meniscal screw system consists of delivery cannulae, screw driver, and screw implants. After tear debridement, a screw is located on the driver and passed through the cannula to the insertion site, holding the two sides of the tear together under linear compression. Forty-eight patients (48 repairs) with a mean age of 32.7 years were included in the study. Ligament stabilizing procedures were done in 39 patients (81%) who had anterior cruciate ligament deficient knees. Only longitudinal lesions in the red/red or red/white zone were repaired. Follow-up averaged 19 months, with a range from 12 to 48 months. Patients were evaluated using clinical examination, the "Orthopaedische Arbeitsgemeinschaft Knie (OAK)" knee evaluation scheme and magnetic resonance imaging (MRI). Criteria for clinical success included absence of joint-line tenderness, absence of swelling and a negative McMurray test. Postoperatively, there were no complications directly associated with the device. Twelve of 48 repaired menisci (25%) were considered failures according to the above-mentioned criteria. According to the OAK knee evaluation scheme, 38 patients (79%) had an excellent or good result. MRI, however, showed persisting grade III or IV lesions in 35 patients (73%). Analysis showed that age, length of tear, and simultaneous anterior cruciate ligament reconstruction did not affect the clinical outcome. In contrast, risk factors for failure of meniscus repair are chronicity of injury, location of tear more than 3 mm from the meniscosynovial junction and meniscus side (medial).

Keywords Meniscus repair · Absorbable screw · Clearfix

Introduction

Today, the role of the menisci in joint stability [25, 37] load transmission [24, 38, 41] shock absorption and lubrication of articular cartilage [14, 31] has been well defined, owing to laboratory and clinical investigations during the last two decades. Therefore, meniscal repair became an attractive method to preserve meniscal tissue, especially in young patients with longitudinal meniscal tears [27, 35].

The development of arthroscopic techniques and instrumentation has led to three arthroscopic repair techniques which are known today: inside-out, outside-in and all-inside. Arthroscopic repair, as with open repair, carries risks for serious complications such as saphenous neuropathy, peroneal nerve palsy and deep

vein thrombosis [8]. Recent advances have been made in meniscal repair, and products such as biodegradable meniscal arrows (made of polylactid acid) have been developed that allow for all-inside meniscal repair. These new meniscal-repair devices offer two main advantages: reduction of both the risk of serious neurovascular complications and of operative time [1, 2].

More recently, a new technique using biodegradable cannulated screws—the Clearfix meniscal screw— (Innovasive Devices, Marlborough, MA, USA) has been introduced which is designed for all-inside arthroscopic meniscal repair of longitudinal tears in vascularized red/red and red/white meniscus tissue. The Clearfix meniscal screw compresses the tear as the screw is delivered. The screw retains 100% strength during the healing process and is gradually absorbed by the body during the subsequent 12–18 months period. The purpose of this prospective study was to evaluate repaired meniscal longitudinal tears with this new system, in patients with a medium-term follow-up, and to compare the clinical outcome with the magnetic resonance imaging (MRI) results.

Material and methods

From November 1998 through June 2001, 50 arthroscopic meniscal repairs in 50 consecutive patients were performed by the senior author (H.H.P) with the Clearfix meniscal screw system, using the arthroscopic technique detailed below. Inclusion criteria were: (a) vertical full thickness tear greater than 10 mm in length, (b) location of the tear less than 6 mm from the meniscocapsular junction, (c) no former meniscus surgery, (d) no evidence of arthritis during arthroscopy, and (e) fixation of the meniscus only with Clearfix screws. Anterior cruciate ligament (ACL) deficient knees were reconstructed, using patella tendon or semitendinosus autograft, at the time of the meniscal repair.

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 such as the McMurray and Apley tests. Knee laxity was measured with the KT 1000 Arthrometer (MED metric, San Diego, CA, USA). In addition, all patients underwent MRI evaluation preoperatively.

Evaluation methods

Postoperatively, each patient was assessed clinically at 3 and 6 weeks, at 3, 6, 9 and 12 months, and yearly thereafter. Using Barrett's criteria [11] a repaired meniscus was considered healed if there was no joint-line tenderness, no 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. In addition, a clinical evaluation designed to score knee symptoms and function—the Orthopaedische Arbeitsgemeinschaft Knie (OAK) knee evaluation sheet—was completed [30].

Because MRI in a fat-suppression sequence seems to be more sensitive in evaluating the status of repaired menisci [40] all patients received MRI (ARTOSCAN-ESAOTE 0.2T, Genova, Italy) at the latest follow-up. MRI images were evaluated by the senior author according to the classification of Reicher et al. [34]. Grade I is a homogenously black meniscus (no tear), grade II shows increased signal within the meniscus (tear unlikely), grade III shows linear regions of increased density within the meniscus reaching cartilage surface (definitive tear) and grade IV gross distortion of normal meniscal shape.

The clinical and not the MRI result was used to determine the success rate of our study.

Surgical technique

The Clearfix meniscal screw system consists of three components: delivery cannulae (Fig. 1), screw driver and screw implant (Fig. 2). Bent positioning cannulae give access to medial and lateral posterior meniscus horns, and optimize screw placement. Screws are 2.0 mm in diameter and 10 mm long. Screw threading extends 7 mm from the proximal end toward the distal tip.

General anaesthesia 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. Tear debridement with a rasp, and trephination of the rim to stimulate healing response were carried out. After the appropriate

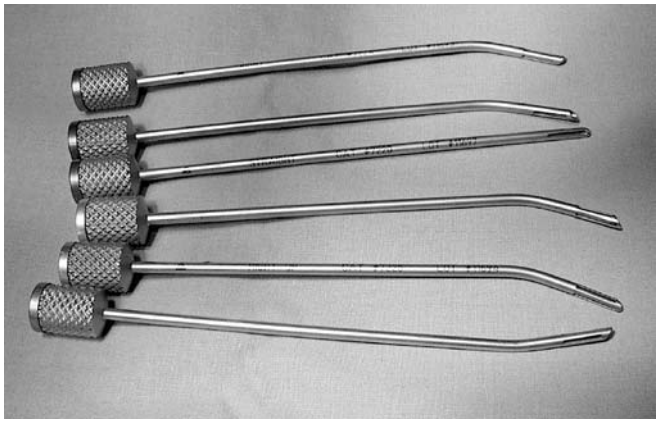

Fig. 1 Set of straight and curved cannulae

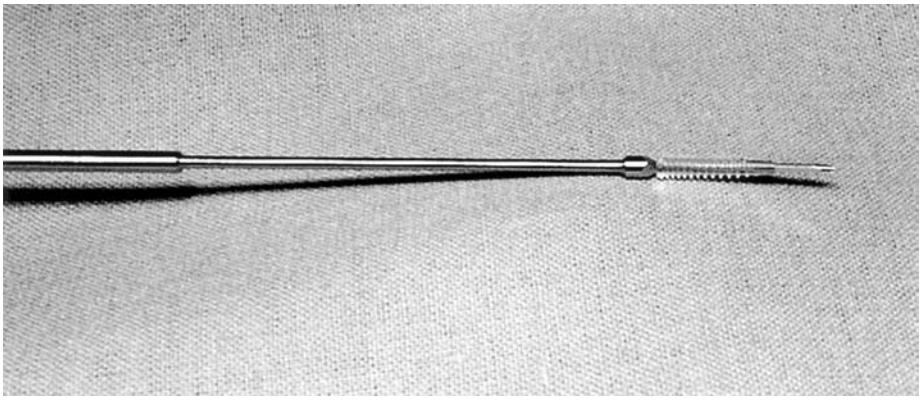

Fig. 2 Clearfix meniscal screw and driver

cannula is positioned on the meniscus, a cannulated Clearfix screw is located on the driver and passed through the cannula to the insertion site (Fig. 3). Because the needle tip is longer than the screw, the distal portion of the needle can be used to manipulate tissue before inserting a screw. As the screw is rotated, its variably-pitched threads draw the two sides of the tear together under linear compression. If screw position is sub-optimal, it can be reversed and re-inserted into a new location. When screw placement is satisfactory, the driver is removed and the screw is left to bridge the tear (Fig. 4). Approximately every 8 mm a new screw is inserted until the meniscus is stable.

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 increase of range of motion between 0 and 90°, and progression to full weight-bearing by the 6th postoperative week. Jogging was permitted after 3 months, and full activity at 5 months.

Statistics

Comparisons between subgroups of patients were performed using the chi-square or Fisher's exact test as appropriate. Significance was set at $p < 0.05$.

Results

Two of 50 patients (4%) were lost to follow-up and were excluded from the study. Thus, 48 patients (48 menisci) with a minimum follow-up of 12 months constitute the subjects of this report.

Thirty men (62.5%) and 18 women (37.5%), were included in the study population. The average age at the time of meniscal repair was 32.7 years (range,

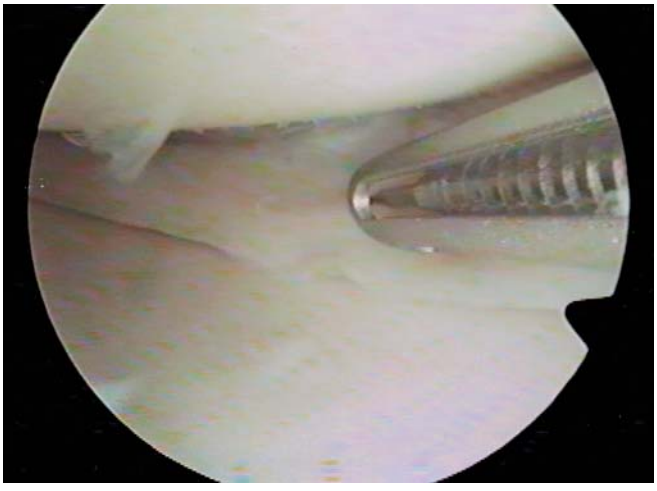

Fig. 3 Intraarticular placement of a cannula with driver and screw in the medial compartment

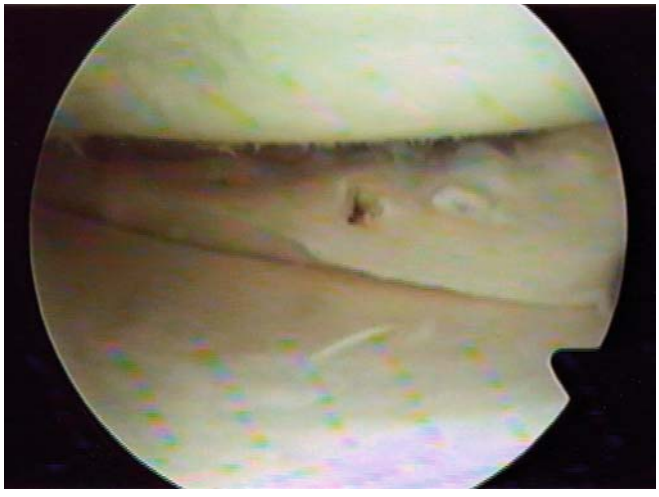

Fig. 4 Repair of a medial meniscus tear with screws in place

16–53 years). The average period from injury to meniscal repair was 89 days (range, 4–270 days). Sixteen meniscal tears (33%) were rated acute (injury-to-repair interval ≤ 3 weeks), and 36 tears (77%) were rated chronic (injury-to-repair interval > 3 weeks). The mean follow-up period was 19 months (range, 12–48 months). Five patients (15%) suffered from isolated meniscal tear and underwent only meniscal repair, whereas 39 patients (81%) underwent both meniscal repair and arthroscopic ACL reconstruction. Two patients (4%) suffered from meniscal tear and ACL rupture, but refused ACL reconstruction although they were offered it, and underwent only meniscal repair.

There were 30 right knees (62.5%) and 18 left knees (37.5%). The medial meniscus was affected in 31 cases (65%) and the lateral meniscus in 17 cases (35%). Eleven meniscal tears (23%) were located within a rim width of < 3 mm (red/red zone), whereas 37 (77%) were within a rim width of 3–6 mm. The meniscal tears' morphology included 48 longitudinal tears (100%). The average length of the tears was 25.2 mm (range 13–50 mm). The number of meniscal screws used averaged 2.8 (range 1–7 screws).

Additional operation time required for meniscal repair averaged 12 min per operation. Physical examination at the last follow-up revealed no symptoms of meniscal tears in 36 patients (75%). Three patients (6%) had a positive McMurray sign, and tenderness on joint line palpation, four patients (8%) had tenderness on joint line palpation, four patients (8%) reported frequent pain in their knee and frequent swelling, and one patient (2%) reported swelling that occurred only after sports activity. No patient had locking episodes. These 12 patients (12 menisci) were considered as failures. Therefore the overall failure rate was 25% (12 out of 48 repairs).

According to the results obtained from the OAK knee evaluation sheet, 26 patients (54%) had an excellent result, 12 patients (25%) a good result, nine patients (19%) had a fair result and one patient (2%) had a poor result. All patients had returned to full-time work. Twenty-four patients (50%) returned to the same activity level postoperatively, with no restrictions in sports activities, 19 patients (40%) were limited in their sports activities, and five patients (10%) gave up sports due to their knee problems.

Preoperatively as well as at the last follow-up, two patients (4%) had side-to-side differences of more than 5 mm on KT-1000 arthrometer testing (6 and 8 mm). These knee joints showed a positive Lachman test and pivot shift test and were considered unstable. Both patients refused ACL reconstruction in the first operation for personal reasons. However, one of them had no symptoms of meniscal tear. The remaining knees were considered stable, with an average side-to-side difference of 1.8 mm in maximum-manual KT-1000 arthrometer testing.

Complications occurred in two of 48 patients. One developed an excessive hematoma in the calf after combined meniscal refixation and ACL reconstruction. He underwent open removal of the hematoma to prevent imminent compartment syndrome. One patient developed painful hemarthrosis and underwent aspiration. There were no 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 to those with 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), and ACL reconstruction at the time of meniscal repair (Table 1).

Statistical analysis showed that age and length of tear did not affect the clinical outcome. Patients with simultaneous ACL reconstruction performed better than patients with isolated meniscal repair, but this difference was not statistically significant ($p = 0.235$). Significantly-higher failure rates were seen in patients in the chronic group (more than 3 weeks from injury) than patients in the acute group. Similarly, patients with medial meniscus tear had a statistically-significant higher failure in comparison with patients with lateral meniscus tear. Only one out of 17 (5%) lateral meniscus repairs failed, whereas 11 out of 31 (36%) medial meniscus repairs failed. Finally, the width of the rim played a significant role in meniscus healing. All tears located in the red/red zone (within 3 mm from the meniscosynovial junction)

Table 1 Effect of six factors on outcome of meniscus repair. *NS* not significant

Factor	Asymptomatic number of patients (%)	Symptomatic number of patients (%)	Total	*p*
Chronicity				
> 3 weeks	22(69)	10(31)	32	0.04
< 3 weeks	14(88)	2(12)	16	
Age				
> 30 years	23(74)	8(26)	31	NS
< 30 years	13(76)	4(24)	17	
Meniscus side				
Medial	20(64)	11(36)	31	0.025
Lateral	16(95)	1(5)	17	
Length of tear				
> 25 mm	14(78)	4(22)	18	NS
< 25 mm	22(73)	8(27)	30	
Location of tear				
Red/red	11(100)	0(0)	11	0.01
Red/white	25(67)	12(33)	37	
ACL reconstruction				
No	30(77)	9(23)	39	NS
Yes	6(66)	3(33)	9	

healed, whereas all of our failures were in the red/white zone.

In MRI evaluation, eight repaired menisci (16.5%) were rated grade I, five (10.5%) grade II, 19 (39.5%) grade III, and 16 (33.3%) grade IV according to Reicher's classification described above. All clinical failures showed grade III or IV lesions in MRI (Fig. 5).

Discussion

In this paper our experience of 48 repaired menisci with this new fixation system is presented. We chose this method for the following advantages: (a) it is an all-inside arthroscopic method of meniscus repair, (b) the instrumentation-set components are easy to use; this simplicity reduces operation time and the operator's learning curve, and minimizes pitfalls, and (c) articular damage is avoided because of the headless design of the screw. The special instrumentation design (screw driver with long needle tip in combination with a cannulated screw) offers two additional important advantages: (d) the possibility of accurate reduction of the tear, since the free tear flap or bucket-handle can be "hooked", reduced, and stabilized by pushing the needle tip through the tear up to the rim of the meniscus, and (e) the possibility of re-inserting a screw if its position is not optimal. One disadvantage of this method is the high cost of the screw. The cost of the Clearfix screw could be balanced by reduced operation time, and by the possibility of re-insertion if not correctly positioned.

According to Morgan et al. [28] 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. However, other authors found that some clinically-successful cases had incomplete healing at the repair site [22]. In our study, a repaired meniscus was considered healed if there was neither joint-line tenderness, nor effusion, nor a negative McMurray test, according to the criteria of Barrett et al. [11] . We had 12 clinical failures in 48 patients (25%), considered as unhealed meniscal tears. This is a high failure rate compared with the clinical results of other study groups, varying from a 5 to 10% failure rate [2, 7, 19, 22, 23, 26, 29, 33]. However, comparison is not always possible, because several study groups use a different evaluation system. The need for repeat surgery (partial meniscectomy) was defined as failure in some studies [19, 23, 33]. We believe that our criteria are more strict and probably this factor plays a significant role for this difference. For example, patients who had occasional soreness or minor symptoms in our study population were classified as failures, although their symptoms were not so intensive as to cause them to undergo revision surgery.

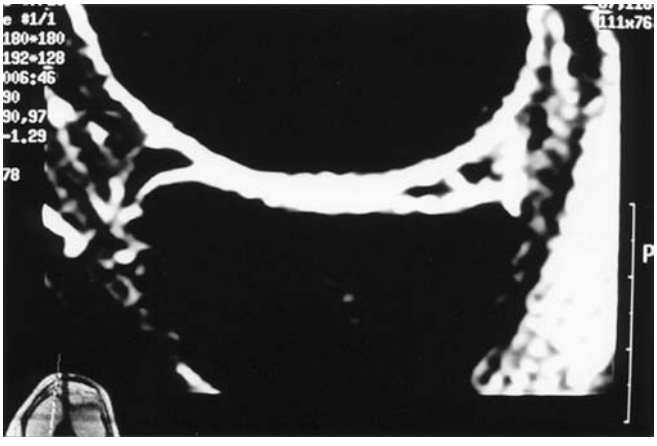

Fig. 5 Magnetic resonance imaging 16 months postoperatively in a symptomatic patient: increased signal of the repaired meniscus (grade IV lesion)

Our results are in accordance with Eggli et al. [18] and Perdue et al. [32], who reported a failure rate of 27 and 28% respectively, using the same criteria for clinical failure. Eggli et al. [18] showed that the vast majority of failures occurred during the 1st year after repair and very rarely thereafter. Therefore, since all of our patients examined at least 1 year postoperatively, and our average follow-up is 19 months, we do not expect a significant increase in our failure rate.

Considering the time from injury to operation, we found an almost-90% success rate in patients operated acutely (within 3 weeks after injury) and only 70% in patients operated after the first 3 weeks (88%). This difference was statistically sufficiently significant to be asymptomatic. Therefore, we believe that acute tears have a better chance for healing, as most study groups have shown [12, 32, 39]. On the other hand, other authors have stated that patients chronicity does not have a significant effect on meniscal healing [18, 22].

We found that there is a significantly-higher incidence of lateral meniscus healing than medial meniscus in our study population. We had a 95% healing rate for lateral meniscal tears vs 64% for medial meniscus. Buseck and Noyes [12] had similar results, with a 100% healing rate in lateral menisci. Barrett et al. [11] reported that tears of the medial meniscus had a higher tendency of failure than those of the lateral meniscus, because of the higher biomechanical demands placed on the medial meniscus. Some authors find no difference between healing rates in medial and lateral menisci [32]. Some found higher rates of failure after lateral meniscus repair [21], possibly due to an avascular area adjacent to the area of the popliteus tendon [26].

The most important factor in meniscal healing is probably rim width. Arnoczky and Warren [4] showed that the peripheral 30% of the meniscus has a rich blood supply, and therefore peripheral tears have a better

healing rate. This was confirmed from our study, since all tears (100%) located within 3 mm of the meniscus rim (red/red zone) were healed. In contrast, only 25 out of 37 tears (67%) located between 3 and 6 mm from the meniscus rim (red/white zone) were healed. Most of the studies have reported similar results, with a success rate more than 90% for meniscal tears with a rim width of less than 3 mm [11, 18, 36].

Neither tear length nor patients' age seem to have an effect on the outcome. Regarding the tear length, our results showed that the failure rate is almost equal in small tears (< 25 mm) and longer tears. Most authors found that although there is a higher tendency of failure in patients with longer tears, this parameter is not of great significance [11, 12, 32]. Groups of patients aged either below or over 30 years were equally asymptomatic (76 vs. 74%), probably because of the strict indication of meniscus repair in older patients. Our results are in coincidence with those of other authors, who show no significantly different results between younger and older age groups [12, 32, 39].

We did not find that ACL reconstruction at the time of meniscus repair had a significant influence in meniscal healing. Most authors agree that simultaneous meniscal repair and ACL reconstruction creates a more favorable environment for meniscal healing because of greater intraarticular bleeding and fibrin clot formation [10, 11, 15]. However, De Haven et al. [16] reported that they had only 4% failures in isolated meniscal repairs with rim width less than 3 mm, and according to their opinion rim width is the primary factor and not simultaneous ACL reconstruction.

According to some experimental biomechanical studies, the fixation strength of the Clearfix meniscal screw is lower in comparison with vertical suture and other common fixation devices like the Bionx Meniscus Arrow (Bionx, Blue Bell, PA, USA) or the Biostringer (Linvatec, Largo, FL, USA) [3, 6]. However, we do not know today how much fixation strength is required to maintain wound apposition during meniscal healing. It is probably more important for an absorbable fixation device to retain its holding power during the first 3 months, which is a critical period for meniscal healing [2, 22]. Arnoczky et al. [3] demonstrated that hydrolysis did not affect the ultimate holding power of the Clearfix meniscal screw 24 weeks after implantation. Furthermore, we have to keep in mind that the repair device is only one factor contributing to meniscal healing. Since we have no control group, direct comparison of the Clearfix meniscal screw to another alternative method cannot be made, and this is a limitation of our study.

In MRI examination, a fat-suppression sequence was used, as Van Trommel et al. [40] proved this method is more reliable in repaired menisci evaluation. Our MRI evaluation showed 35 out of 48 menisci (73%) to have a persisting grade III or IV lesion despite the 75% clinical success. It is of interest to note is that all of our failures had grade III or IV lesions. Because of these results we believe that MRI has a limited efficiency in showing and confirming meniscal healing, as has already been shown by several authors [5, 18, 29]. Eggli et al. [18] and Deutsch et al. [17] compared their results of MRI imaging after meniscal repair with those before meniscal repair, and found exactly the same tear extent as during surgery, although most of these tears are either totally or partially healed at second-look arthroscopy.

Reported complications in the literature concern arthrofibrosis [29, 39], especially in patients who had undergone meniscal refixation in combination with ACL-reconstruction, saphenous nerve neurapraxias [2, 9, 39], infection [2, 26, 39], and peroneal nerve palsy [26]. As rare complications, pain along patellar nerves [2, 42], a broken arrow causing pain [13], and a cystic hematoma formation [20] were reported. We had two complications out of 48 patients, concerning an excessive hematoma in the calf and a painful hemarthrosis. Since both patients underwent a meniscus refixation combined with an ACL-reconstruction, it seems unlikely that the cause of both complications was due to vessel penetration by the implants.

In conclusion, meniscal repair with the Clearfix meniscal screw offers three major advantages: optimized reduction of the tear, reduced risk of serious neurovascular complications, and decreased operation time. Our study demonstrated that acute tears, lateral meniscal tears, and tears within the red/red zone have a significantly-higher success rate. Perhaps these factors are more important than the fixation device. Further prospective comparative studies are needed to investigate whether this specific fixation device is superior or inferior, in clinical use, to other similar devices.

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