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Biofix resorbable meniscus arrow for meniscal ruptures: results of a 1-year follow-up

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Abstract Modern individuals with a long and healthy life expectancy perform more and more physical activities both in daily life and in sport. This demanding life-style forces the surgeon to perform less radical surgery for meniscal ruptures, thus avoiding the early degenerative changes which frequently occur in totally or partially meniscectomized knees. When repair is possible, meniscal suture must be considered. Various arthroscopic techniques of meniscus suturing have been reported. "Inside-out," "outside-in," and more recently "all-inside" techniques can be used. Complications include saphenous and peroneal nerve damage and vascular lesions. The Biofix arrow fixation technique, which is an all-inside procedure, is easier and in our hands less time-consuming than other arthroscopic suturing techniques. Postoperatively, partial weight bearing is prescribed for 3 weeks. Progressive return to sport activity is allowed after 3 months. Twenty-five patients (26 meniscal repairs) with a mean age of 31.6 years (13–57) were reviewed. Follow-up averaged 16.7 months (12–22). The evaluation was based on the modified Marshall knee score. Three patients had an extra-articular reconstruction for anterior cruciate ligament deficiency, and five had an arthroscopic ACL reconstruction with a ligament allograft. The results were excellent or good in 22 patients (88% "satisfactory" outcome). Three patients had poor results. One patient with a new trauma presented a lateral meniscal lesion associated with an ACL rupture. The Biofix arrow fixation technique allows safe fixation of meniscal ruptures, specifically of posterior horn lesions where injury of neurovascular structures is not uncommon.

Key words Meniscal ruptures · Biofix resorbable arrow

Introduction

Since the historical reports of King [19] and Fairbank [16] it has been known that total meniscectomy leads to degenerative changes in the long term. Later studies have documented the functional value of the menisci in load transmission, shock absorption, and joint lubrication, and their contribution to joint congruity and stability [23, 29]. Several other studies have also demonstrated that partial meniscectomy may lead to cartilage degeneration [9]. Despite the pioneering publication of Annandale [4] over 100 years ago, it was not until the classic publications of Heathley [17], Cabaud et al. [9] and Arnoczky and Warren [5], who showed the healing potential of peripheral meniscal tears, that meniscal repair gained widespread support.

Preservation rather than excision and repair of the meniscal tear came to be performed in the 1970s and early 1980s following the successful results of open meniscal repair. Various arthroscopic techniques for meniscus repair, such as the inside-out or the outside-in methods, can be used [18, 30]. De Meulemeester et al. [13] report that the menis-

cal repair can allow a functionally competent knee and an anatomical restoration in 90% of cases. However, several complications including saphenous and common peroneal nerve injuries have been reported [12, 26]. To overcome these problems an all-inside technique has been described more recently, especially for posterocentral lesions [21]. In 1993 in an attempt to avoid neurovascular injuries and to shorten operating time, Albrecht-Olsen and Kristensen developed a new all-inside meniscal repair technique using absorbable tacks [1].

In this study we review a consecutive series of arthroscopic meniscal repairs using an all-inside Biofix technique, with a 12- to 22-month follow-up. Surgical technique, clinical outcomes, and complications are reported.

Material and methods

Between October 1995 and August 1996, 36 patients underwent arthroscopic all-inside meniscus repair in our Department using the Biofix arrow fixation technique. Twenty-six patients having minimum 1-year follow-up, were reevaluated. One patient reruptured his initial meniscal tear when playing soccer 6 months after meniscal and ACL repair and was not included for the evaluation. Preoperatively nine patients had anteroposterior knee instability. Three of these had previously undergone a Lemaire extra-articular reconstruction and in six patients ACL reconstruction was performed using a ligament allograft, four at the time of meniscus repair and in two 5 months after repair. All repaired tears were located in the vascularized (red-on-red and red-on-white area) zone of the meniscus, except one erroneously white-on-white area repair.

The 25 patients included 16 men and 9 women. One patient had a medial and lateral rupture in the same knee, making a total of 26 meniscal repairs in 25 knees. The mean age was 31.6 years (range 13–57). Follow-up averaged 16.7 months (12–22). Fourteen repairs were in the right knee and 11 in the left. Only one lateral meniscus was repaired in each group. Six patients were operated on in the acute phase (injury-to-repair interval < 2 weeks). Sports injuries were the main cause of meniscal tears (15 cases). Other causes included: accidents at work (3 cases), accidents at home (3 cases), degenerative process (3 cases), and motor vehicle accidents (2 cases). Because of our limited experience with this new technique and the high cost of the implant in the first five patients we combined the inside-out technique (Double-Barrel Meniscal Repair System; Acufex Microsurgical, Norwood, Mass., USA) with the Biofix arrow as a second fixation method. We placed an average of 2.8 tacks per meniscal tear.

Technique

We have been using the Biofix meniscal fixation technique in our Department since October 1995. The implant provides a horizontal fixation and has been designed to create optimal fixation of the meniscus. It consists of a T-shaped tack with barbs on the stem, resembling a fishing hook, and is made totally absorbable self-reinforced polylactic acid (Biofix; Bioscience, Tampere, Finland), which is a highly biocompatible and totally biodegradable substance in the human body (Fig. 1). The present implants have a stem diameter of 1.1 mm and are available in three lengths (10, 13, and 16 mm) for different localizations of meniscal lesions (Fig. 2).

The T-head of the arrow locks the central part of the ruptured meniscus while the scaled stem is fixed in the circular fibers of the peripheral part of the meniscus (Fig. 3). The implants gradually lose their strength by degradation over several months and stresses are

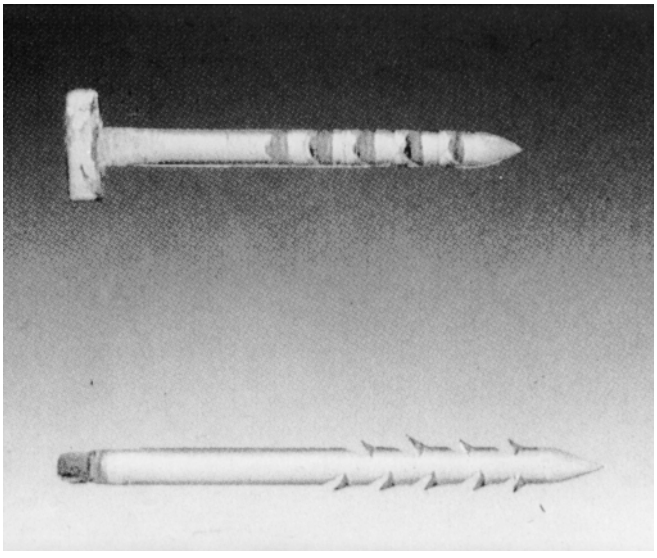

Fig. 1 The Biofix meniscus arrow

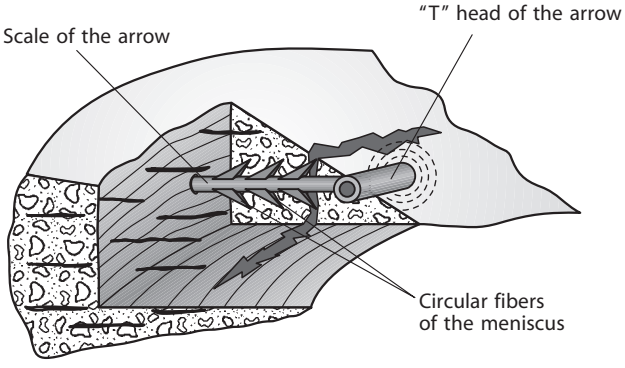

Fig. 2 Principle of fixation: the scaled stem is fixed in the semicircular fibers of the peripheral meniscus while the T-head of the arrow locks the ruptured part of the meniscus

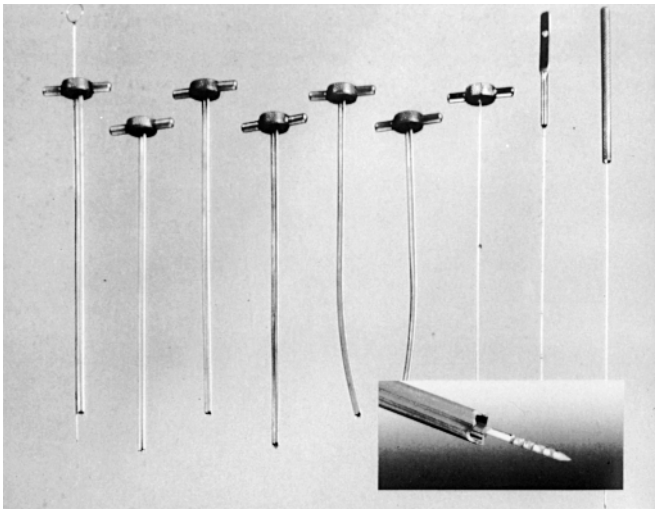

Fig. 3 Instrumentation set for the application of the Biofix arrow

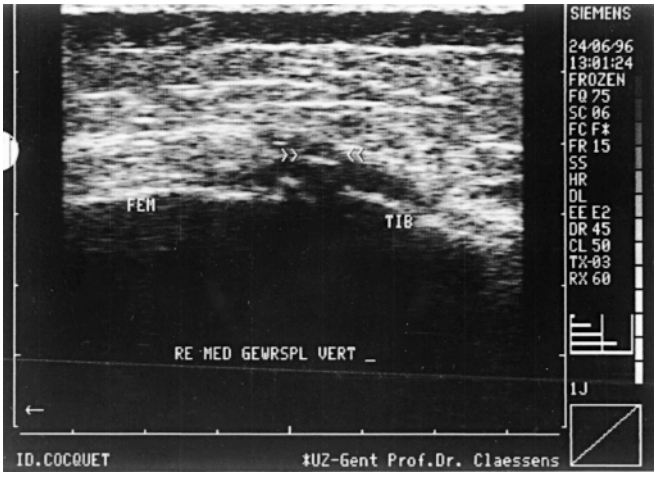

Fig. 4 Sonography shows a localized edematous zone in the MCL following Biofix arrow application for the meniscal rupture in the middle one-third

transferred more and more from the implant to the healing meniscus tissue. Experimental studies have shown that implant (poly-L-lactide) degradation time is up to the 4 years in bone [7].

A specially designed instrument set allows repair through standard arthroscopy portals, and consists of six cannulas with various curves, an obturator, a needle, perforator, pusher, and hammer (Fig. 4). The cannulas are designed for easy access to all lesion sites and have the same lumen geometry as the implant. Their tips are oblique and have sharp teeth for a firm hold on the meniscus.

After the rupture has been freshened and reduced, the chosen cannula with the blunt obturator inside is inserted through the portals. After withdrawal of the obturator the cannula is fixed at 3–4 mm from the lesion, and the meniscus is kept reduced. With a special perforator a hole for the arrow is made through the meniscus into the joint capsule. The irrigation fluid is turned off, and the perforator is retracted. A tack is pushed into the cannula with the pusher and hammered into the meniscus. A special reciprocating instrument can be used for this procedure. Every 5–10 mm a new tack is inserted until the rupture is stable. In our experience, each application of the arrow takes a few minutes.

Postoperative treatment

Although opinions differ, we recommend 3 weeks of partial weight bearing without the use of a brace for small ruptures (1.5–2 cm). In the case of larger lesions (> 2 cm) 3 weeks of non-weight-bearing) is advised. Progressive sports activity is allowed after 3 months depending on the patient's progress. Generally return to competitive sports is allowed after 6–7 months.

Evaluation

The evaluation was based on a modification [27] of the Marshall et al. [22] knee rating system (Table 1). This score originally included the evaluation of ligament stability, but this was beyond the scope of our study. We did not use the "patient's own evaluation" section of the modified Marshall score in our evaluation questionnaire. Our modified knee rating system included the evaluation of pain, swelling, symptoms of giving-way, and – in an attempt to establish a functional level – the ability to return to sports or work. The patients were examined or questioned for knee effusion, soft tissue swelling, joint line tenderness, intra-articular crepitus and ability to squat. Muscle power, thigh circumference and knee range of movement were also measured and compared to the findings obtained in the contralateral extremity. Depending on the results, the patient's condition was categorized as excellent, good, fair, or poor. A score of 26–30 points represented an excellent result, 21–25 points a good result, 16–20 points a fair result, and fewer than 16 points a poor result.

Table 1 Modified Marshall knee scoring scale, total maximum points = 30 (*ADL* activities of daily living)

Item	Points
Subjective	0–11
Pain (no, yes)	0, 1
Swelling (no, yes)	0, 1
Stair difficulty (no, yes)	0, 1
Clicking, numbness (no, yes)	0, 1
Giving way	0–4
Normal	4
With athletic activity only	3
With stress upon ADL	2
Regularly upon ADL	0
Return to sports or work	0–3
Return, no limitation	3
Return, some limitation	2
Change in occupation	1
Cannot work	0
Objective	
Functional tests	1–7
Duck walk	0–2
Performance without discomfort	2
Performance with discomfort	1
Cannot perform	0
Run in place	0, 1
Jump on leg	0–2
Performance without discomfort	2
Performance with discomfort	1
Cannot perform	0
Half squat	0, 1
Full squat	0, 1
Specific knee examination (12 points)	
Tenderness	0, 1
Joint effusion	0, 1
Swelling (soft tissue)	0, 1
Crepitation	0, 1
Muscle power	0–3
Normal	3
Mild weakness	2
Moderate weakness	1
Severe weakness	0
Thigh size	0–2
Equal	2
1–2 cm difference	1
≥ 2 cm difference	0
Range of motion	0–3
Normal	3
5° ext. loss and/or 10° flex. loss	2
10° ext. loss and/or 20° flex. loss	1
≥ 10° ext. loss and/or > 20° flex. loss	0

Stability testing was excluded from the scoring because of the small number of ACL reconstructions ($n = 6$)

Results

Complications

One patient developed a deep postoperative infection and was treated with antibiotics. Another patient showed persistent hemarthrosis during the first postoperative month which regressed spontaneously. Irritation from the Biofix implant was observed in two cases. In the first patient the meniscal lesion was localized in the white-on-white area of the middle one-third of the medial meniscus and three 13-mm arrows were used to repair the rupture The patient developed focal pain around the medial collateral ligament (MCL), and sonography showed a clear focal edematous zone in this ligament. In this erroneously performed meniscal repair a control arthroscopy revealed an unhealed meniscus rupture, and a partial meniscectomy was performed for intractable pain and functional disability. Physiotherapy successfully resolved the MCL inflammation. The second patient whose one-third posteromedial meniscal rupture was repaired using two 13-mm and one 16-mm absorbable arrows, developed focal and more superficial posteromedial knee pain in the postoperative period. Sonography (Fig. 5) and magnetic resonance imaging (Fig. 6) revealed inflamed tissue at the posteromedial capsular insertion of the semimembranosus tendon and a subcutaneous "foreign body." Symptomatic treatment was instituted and at 14 months postoperatively the patient retained only minor symptoms at this site. Four patients developed persistent effusion during the first postoperative weeks. This effusion spontaneously regressed in the following weeks. We observed no neurovascular damage.

Functional results

Based on a modified Marshall knee evaluation system, 13 patients had an excellent result (52%) and 9 a good result; thus 22 patients (88%) experienced satisfactory postoperative outcomes. Three patients underwent partial meniscectomy 5, 8, and 12 months after meniscal repair. Their score was retrospectively categorized as poor. One of these failures was due to an improper indication (white-on-white zone). The other patient had associated, untreated partial ACL deficiency. The third patient had no associated lesions and reruptured her meniscus 1 year after the initial trauma during daily activities. The patient who was not included in this study, after an excellent postoperative rehabilitation period, reruptured both his meniscus at the same location and ACL when playing competitive soccer 6 months after meniscal repair and ACL reconstruction. We excluded this case because of his remarkably violent trauma which can damage any healthy meniscus. He underwent a partial meniscectomy to resolve his complaints. This patient did not return to our clinic but followed further rehabilitation programs at the sports medicine center. All of the reconstructed ACL injured knees had satisfactory results.

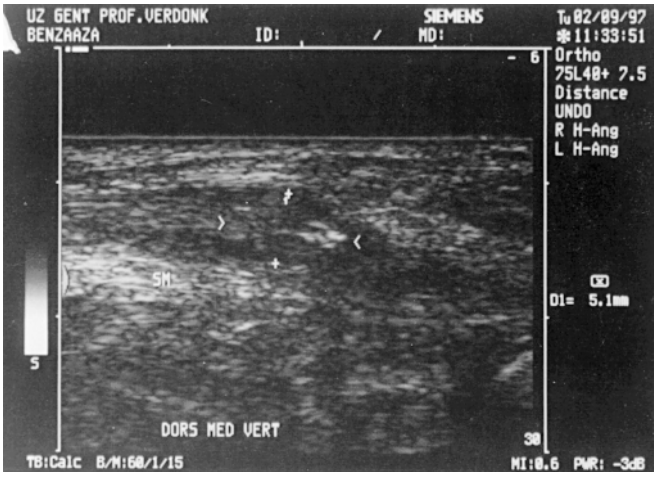

Fig. 5 Sonographic image showing a subcutaneous foreign body at the posteromedial corner of the knee, probably representing a small part of the implant that has migrated into the soft tissue

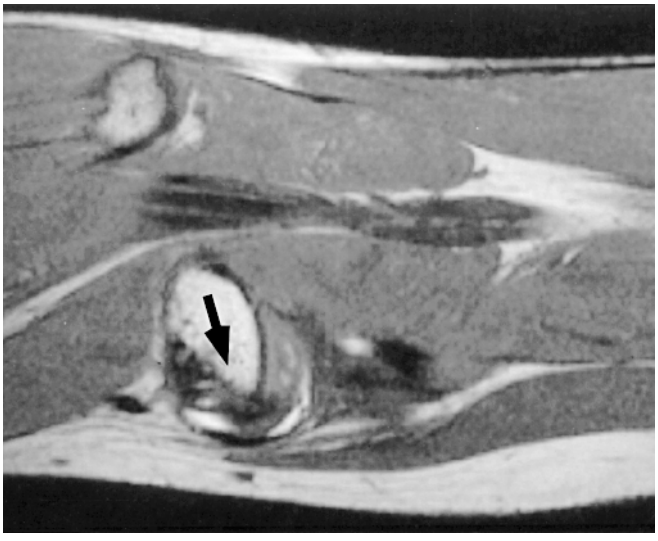

Fig. 6 Magnetic resonance image of inflamed tissue at the posteromedial capsular insertion of the semimembranosus tendon due to an inappropriate arrow length

Discussion

Preservation of the functional value of the menisci forces the surgeon to perform less radical surgery for the management of meniscal ruptures. Various meniscal repair techniques have been published, such as the inside-out, outside-in, and all-inside methods. However, these technically demanding procedures are encumbered with several complications, including popliteal artery injuries and saphenous and common peroneal nerve damage. In his review of the literature on arthroscopic meniscal repair Small [26] reports that the complication rate ranges from 1.2% to 2.5%.

To reduce the risk of neurovascular complications and simplify meniscal repair, an all-inside technique using resorbable implants (Biofix) has been proposed by Albrecht-Olsen et al. [2]. In their recent randomized prospective study comparing the inside-out meniscal repair technique to the Biofix method, these authors report that the operating time is half as long and the healing rate significantly better in the Biofix arrow group Although we did not collect data on operating times, we totally agree with the time-saving aspect of this technique.

Recently another design of absorbable staple – made of copolymer of polyglicolic and polylactic acid – for arthroscopic meniscal fixation has been proposed and evaluated in an in vivo canine study by Koukoubis et al. [20]. They also compared the tensile strength of the staple to the single 3-0 PDS suture. Although the tensile strength of the staple was greater than that of the suture for up to 4 months, no difference was found in the long term between the two groups. A risk of migration of the staple into the perimeniscal tissue has been reported, and theoretically it may carry the risk soft tissue irritation about the knee joint.

We did not include stability testing in the scoring system because of the small number of ACL reconstructions (six patients). It seemed to us that the evaluation of stability in this small group would not allow conclusions to be drawn on the effect of ACL reconstruction on the performance of the repaired meniscus.

We performed a second-look arthroscopy in only three failed meniscal repair. These patients underwent partial meniscectomy and were retrospectively categorized as poor. Obviously the 22 patients who achieved satisfactory clinical results should not be interpreted as anatomically healed cases. Theoretically it is possible that some of them have a clinically asymptomatic but unhealed meniscus [31]. An anatomically complete healing rate cannot be predicted from our study.

We confronted no neurovascular problems, but in two patients we did see soft tissue irritations problems from the arrow involving the MCL and the semimembranosus, respectively. A similar problem has also been reported by Whitman et al. [32]. Four of the 13 patients who were treated with the Biofix arrow system showed transient focal posterior knee pain, which resolved within 6 months and was unrelated to the length of implants. In our similar case of posteromedial knee pain, symptoms continued up to 14 months. We can agree, as Whitman et al. speculate, that the penetrated sharp tips of the arrows cause irritation of the overlying soft tissues.

Soft tissue and nerve irritation problems have also been observed by Albrecht-Olsen et al. [1, 2]. They had to remove tips of the Biofix arrow, compromising the infrapatellar branch of the saphenous nerve in three patients. Another case has also been reported of protrusion of a 16-mm arrow through the MCL under the skin [1].

It might be possible to reduce such complications by choosing the zone specific arrow length. The current arrows are made in three lengths: 10, 13, and 16 mm. The 13- and 16-mm arrows are used in the most posterior parts of the meniscus. For the anterior one-third 10-mm arrows are recommended, and for the middle one-third 13-mm arrows (Fig. 7). However, it seems to us that morphological variance of the human meniscus can interface with this recommendation. Schreiber [25] propose the use of 10-mm arrow in place of 13-mm one for the ruptures localized in middle one-third of the medial meniscus. The 13-mm arrow carries the risk of protrusion on the MCL. Using the meniscal perforator while creating the arrow hole may prove useful. If one can palpate the tip of the perforator under the skin, the 13-mm arrow is probably too long.

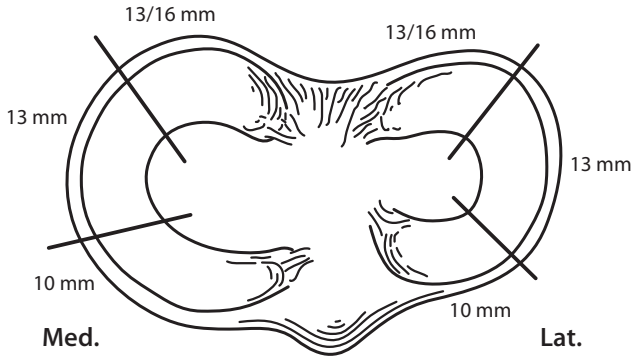

Fig. 7 Choice of appropriate arrow length for specific zones

It is also very important to hold the cannula firmly when hammering the tack into the meniscus. The arrows may slip over the surface of the central part of the meniscus and be embedded in the capsule. Accidental loss of the arrow in the joint is another potential problem but adverse reactions or cartilage lesions due to the implant have not been reported [1].

In a recent study Albrecht-Olsen et al. [3] report that repair with Biofix arrows has approximately the same failure strength as a horizontal (0-Maxon) suture loop. Pull-out strengths of vertical loop (2-0 Ethibond) suture technique and the Biofix arrow method have also been compared by Dervin et al. [14]. They found that the main failure load of the vertical loop technique is superior to the meniscal arrow, and they suggest modifications to the implant design to achieve better fixation.

Çetinkaya et al. [10] compare the failure strength of the meniscal arrow to (0-PDS) horizontal and vertical loop sutures. Although the meniscal arrow has a low failure load, they found no statistically significant difference between the primary stability of the techniques.

Postoperative hemarthrosis, which was present in one of our patients, spontaneously regressed after 1 month through consecutive knee aspirations. This favorable course obviated the need of further diagnostic investigations. Peroral antibiotic treatment successfully resolved deep postoperative infection in another patient. Persistent postoperative hydrops was found in four patients. This sterile effusion

subsided completely after repeated aspirations of the knee joint during the first postoperative mount.

This kind of sterile fluid secretion due to a nonspecific inflammatory reaction to the absorbable polyglicolide acid and only occasionally to the SR-poly-L-lactic acid (actual base of the implant) has already been reported in fracture osteosynthesis and considered as a foreign body reaction [8, 15]. A severe aseptic synovitis of the knee after the use of polyglicolide acid pins for the treatment of osteochondral lesions is also reported in the literature [28].

The postoperative treatment of meniscus repair remains controversial. Various postoperative protocols have been reported. Early immobilization, weight-bearing status, and return to pivoting sports are the main subjects of discussion. Recently Barber [6] and Shelbourn et al. [24] proposed an accelerated rehabilitation program permitting immediate, unlimited weight-bearing, full unbraced motion and return to pivoting sports activities as soon as tolerated. They found no significant difference between standard and accelerated postoperative rehabilitation programs. Even with these favorable results we still recommend 3 weeks of partial weight bearing without the use of a brace for ruptures smaller than 2 cm; in case of lesions larger than 2 cm 3 weeks of non-weight-bearing is advisable. Progressive sports activity is allowed after 3 months depending on the patient's progress. In the majority of cases return to competitive sports is allowed after 6–7 months. Our rehabilitation protocol is the same for routine meniscal sutures technique and for the Biofix arrow method.

Conclusion

We find this new technique promising. Our study shows that the Biofix arrow restores the stability of the ruptured meniscus with 88% satisfactory clinical results. The advantages include short operating time, superfluous capsular exposure, easier technique, and potentially lower risk of neurovascular lesions, especially when posterior horns are involved. The cost of the implant is much higher than that of previous methods, but the above advantages can justify its use. A longer follow-up and biocompatability studies are mandatory to evaluate the long-term benefits and drawbacks of this technique.

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