Meniscal Substitutes: Polyurethane Meniscus Implant – Technique and Results

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Contents

Introduction

While the detrimental effects of total meniscectomy may have found a clinical solution in meniscal allograft transplantation, painful partial meniscectomy in the young active adult still remains an issue [5]. In case of proper alignment and an inherently normal ligament status, partial meniscal replacement is an emerging possibility. Using a polyurethane cut-to-size implant with documented cellular ingrowth potential could turn out to be a valid alternative [3, 4, 6].

Indications

The Actifit meniscal implant is designed to reduce pain from a damaged or torn meniscus in a well-aligned and stable knee joint. Recent findings suggest that the cartilage damage should be limited to grade two or three of the International Cartilage Repair Society (ICRS) classification. It is essential for the meniscal remnant to have an intact meniscal rim. Systemic disease or infection sequelae are contraindications to the use of the Actifit meniscal implant. The body mass index must be lower than 35 kg/m². It is still unclear whether the implant is indicated in patients who have undergone recent partial meniscectomy but do not yet experience chronic disability.

Surgical Technique

Introduction

The Actifit meniscal implant is made of polyurethane, which is credited with the potential to induce tissue ingrowth and reduce pain. The implant is available in a medial and lateral shape for medial and lateral meniscal defects, respectively (Fig. 1). Implantation of the Actifit meniscal implant is

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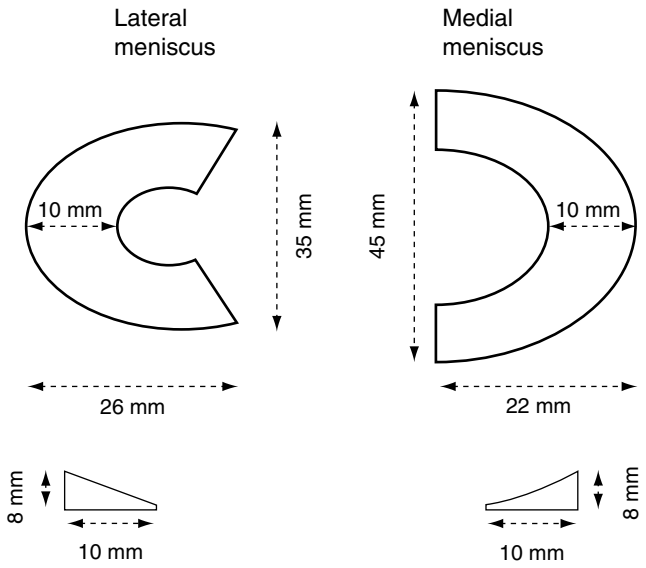

Fig. 1 The Actifit meniscal implant is available in a medial and lateral shape

performed arthroscopically using routine arthroscopic knee surgery equipment. A tourniquet is usually applied and either spinal or general anaesthesia is used at the discretion of the orthopaedic surgeon.

Two to three small incisions are made for the placement of anteromedial and anterolateral portals, with an optional central transpatellar tendon portal. A larger incision may be required to insert the device, as well as a posteromedial or posterolateral incision when an inside-out meniscal fixation technique is used. The cartilage status and the integrity of the medial and lateral meniscal wall remnant need to be assessed.

Implantation of the Actifit Medial Meniscal Implant

Following the induction of anaesthesia, preferably using a tourniquet, routine arthroscopic preparation and draping are performed. Depending on the surgeon's preference, the leg is placed in a thigh holder to allow the application of proper valgus stress. To obtain a better view of the femoral and tibial cartilage, the medial collateral ligament (MCL) can be distended using the outside-in puncture method of Paessler (personal communication) or the inside-out pie-crusting technique as described by Steadman (personal communication). This allows the surgeon to properly assess the femoral and tibial cartilage status and to decide whether he can proceed with the implantation of the Actifit device.

If the initial meniscus lesion cannot be sutured or repaired by any other means, a partial meniscectomy will have to be performed. After debridement and preparation, the defect site should extend into the red-red or red-white zone, i.e. 1–2 mm

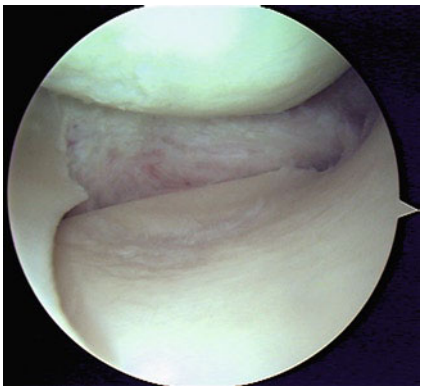

Fig. 2 The damaged meniscus is debrided to a stable and potentially bleeding rim

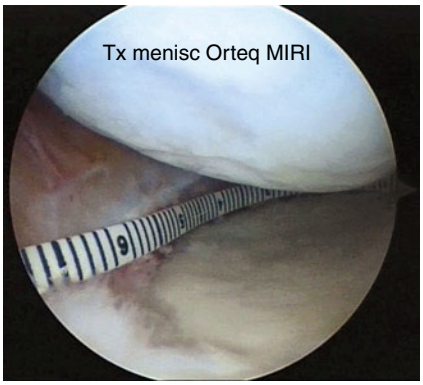

Fig. 3 The resulting meniscus defect is measured with the measuring device and assessed using the appropriate evaluation tools

from the synovial border [1, 2]. Lesions situated further away from the synovial border have only very limited healing potential and are not suitable for this type of meniscoplasty. To enhance healing and in association with the pie-crusting technique for MCL tightness, the meniscal rim can be punctured in order to create vascular access channels. Gentle rasping of the synovial lining is of added benefit to stimulate meniscal healing (Fig. 2). The resulting meniscal defect is then measured with a specially designed measuring tool and assessed using the appropriate evaluation tools (Fig. 3). The Actifit meniscal implant is tailored on the back table using a scalpel for a perfect fit into the meniscus defect. Scissors are not to be used at this time. Care is taken not to oversize or undersize the implant. The scaffold device should be manipulated using a pair of anatomical tweezers. Although the implant material is strong, it needs to be handled with care (Fig. 4a, b).

The tailored Actifit meniscal implant is delivered into the knee joint through a (potentially enlarged) anteromedial portal using curved clamps or any clamp device at the surgeon's discretion.

Other options are to first place a vertical holding suture in the defect and then insert the implant through the eye of this suture. This may ensure a good initial position of the implant and facilitate fixation of the device. The upper and lower

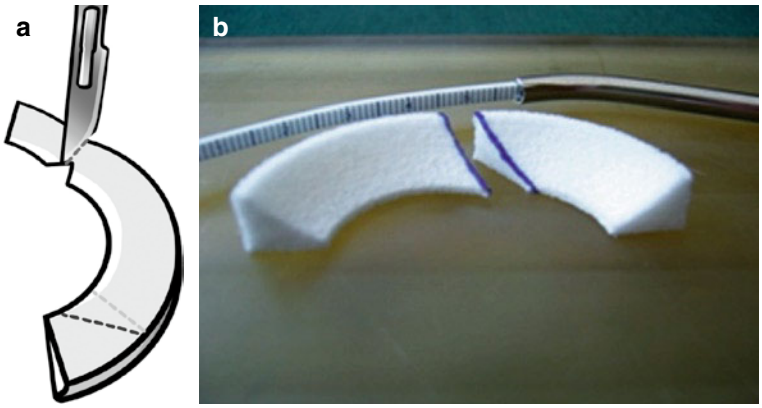

Fig. 4 (**a**) The Actifit meniscal implant is tailored on the back table using a scalpel for a perfect fit into the meniscus defect. (**b**) Care is taken not to oversize or undersize the device. Although the implant material is strong, it needs to be handled with care

meniscal implant surfaces are marked to avoid positioning problems (Fig. 5). Further stabilization of the implant is obtained by suturing it to the meniscal remnant and rim.

Several suturing techniques are available, among which vertical suturing techniques are preferably used. Horizontal sutures can also be used and provide the same stability. Because all-inside suturing material has proven to be most effective, these techniques are commonly used, although a combination of outside-in techniques, depending on the exact location of the defect and the experience of the surgeon, is also an option.

Most often, outside-in suturing techniques are recommended for the anterior and middle parts of the medial meniscus, and all-inside techniques for the stabilization of the mid-posterior and posterior Actifit meniscal implants. The sutures have to be placed approximately 0.5 cm apart, each suture at 1/3 to 1/2 of the implant height measured from its lower surface, in order to allow for proper fixation of the suture in the implant. Once the implant has been securely fixed, the stability of the fixation is tested with the probe while carefully moving the knee through a range of motion (0–90°) (Fig. 6a, b). The surgical field should be visualized and the skin sutures properly placed for correct skin closure.

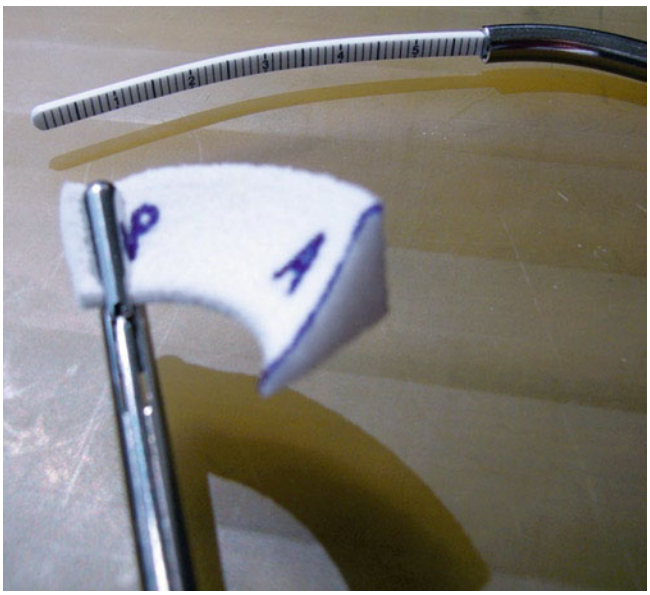

Fig. 5 The scaffold device should be manipulated using a pair of anatomical tweezers. The upper and lower meniscal implant surfaces are marked

Implantation of the Actifit Lateral Meniscal Implant

The Actifit lateral meniscal implant is placed in accordance with the medial meniscal technique.

Surgery is performed arthroscopically, using routine arthroscopic knee surgery equipment. Either spinal or general anaesthesia is used at the discretion of the orthopaedic surgeon. A tourniquet and thigh fixation is routinely used so that proper varus stress can be applied. Although lateral compartment narrowing is rare, progressive pie-crusting release techniques as used in the medial compartment cannot be applied because of anatomical considerations. The surgeon needs to confirm whether the lesion is amenable to meniscal reconstruction with the Actifit lateral meniscal implant, and to assess the cartilage and ligament status. The integrity of the lateral meniscal wall across the popliteal space is of mechanical importance. As in medial meniscal implantation, the lateral meniscus needs to be debrided and prepared to extend into the red-red or red-white zone. Meniscal healing can be enhanced by puncturing the meniscal wall in order to create vascular access channels. Additional gentle rasping may be performed to stimulate healing. The resulting meniscal defect is then measured with a special measuring device, and assessed using the appropriate evaluation tools. The Actifit lateral meniscal implant is tailored to size using a scalpel, taking care not to undersize or oversize the device, and is then manipulated into the correct position through an enlarged anterolateral portal. The upper and undersurface are marked to avoid confusion. Usually, clamps are most effective while inserting the device. Again, a vertical

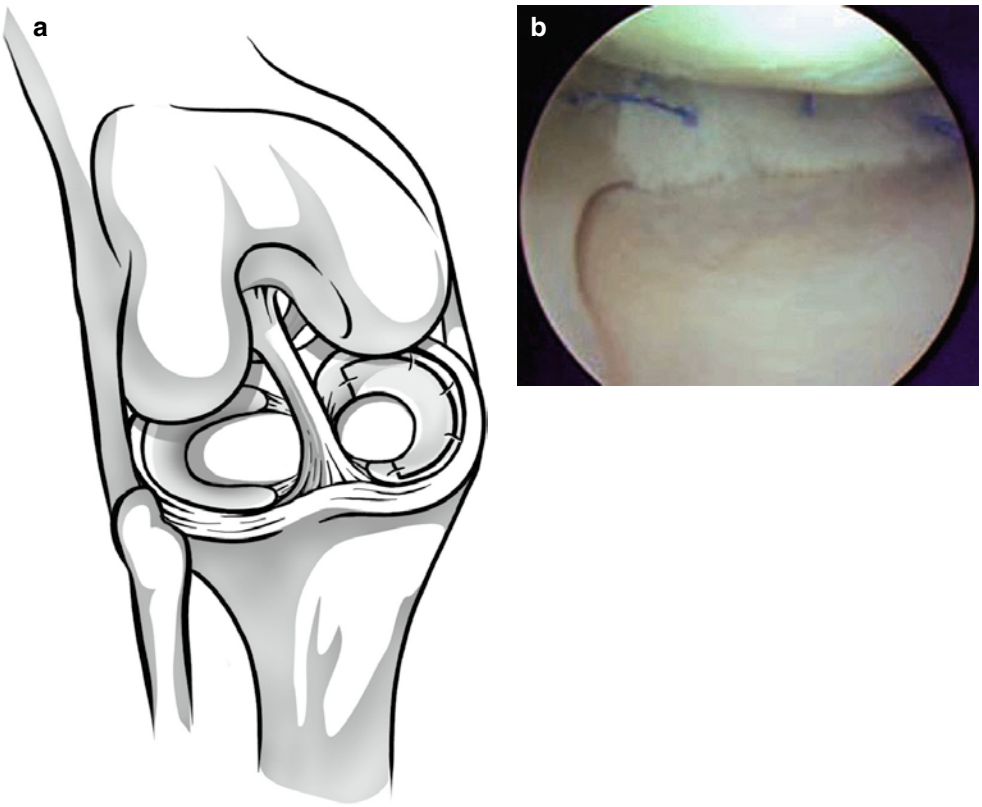

Fig. 6 (**a**) The sutures have to be placed approximately 0.5 cm apart. (**b**) Each suture should be placed at 1/3 to 1/2 of the implant height measured from the lower surface of the implant in order to allow for proper fixation

holding suture can be helpful to pull the implant into place and to ensure a good initial implant position, making further fixation simple and easy. Posterior and mid-posterior meniscal fixation requires the use of an all-inside fixation technique. Additional fixation into the popliteus tendon is of added benefit. Inside-out or outside-in suturing techniques are appropriate for the anterior and middle parts of the lateral meniscus. A posterolateral skin incision may be necessary to avoid lateral structure damage, as has been described for standard meniscal suturing techniques. Once the implant has been securely fixed, the stability is tested by carefully moving the knee through a range of motion (0–90°) and using the arthroscopic hook.

Postoperative Care

Venous thromboembolism prophylaxis is prescribed at the surgeon's discretion and is comparable to that administered after routine meniscal suturing. A rigid removable brace can be applied over a compression bandage in the first postoperative week depending on meniscal implant stability, as evaluated at the end of the procedure.

Rehabilitation

The surgeon should be familiar with the rehabilitation protocol after meniscus suturing techniques, and make sure that it is strictly followed, particularly with regard to the timing and intensity of weightbearing. Weightbearing is prohibited until 6 weeks postsurgery. The rigid brace fixation can be discontinued as tolerated. At 6 weeks, progressive weightbearing can be initiated, with weekly increments of 10 kg for patients weighing up to 60 kg, or 15 kg for patients weighing up to 90 kg or more. At 9 weeks, the patients should be able to bear full weight on the knee with the help of crutches.

Further rehabilitation should be supervised by a physiotherapist following the guidelines of the orthopaedic surgeon. Passive motion is initiated immediately after implantation and is gently increased to 60° at 4 weeks. The range of motion is then further increased until week 9, when active motion until 120° of flexion can be achieved. Straight leg raising is recommended. Once 90° of flexion has been obtained, stationary cycling can be started. From week 10, progressive closed-chain exercises and hamstring reeducation can be initiated, as well as progressive proprioception exercises. From week 12, exercises focusing on single-leg strength, running, jogging and sport-specific drills are started.

Squatting is prohibited until 3 months postoperatively.

Clinical Outcome

The results of a safety and efficacy study performed at several orthopaedic centres of excellence throughout Europe are presented.

Material and Methods

From March 2007 until April 2008, 52 subjects (mean age : 30.8 ± 9.4 years) were enrolled in the study. Male patients accounted for 35% of the study population. Thirty-four medial implants and 18 lateral implants were used. The mean longitudinal defect length was 47.1 ± 10.0 mm.

At the time of preparation of this chapter, 45 patients had a 12-month follow-up.

Safety

The adverse effects were similar to those reported in the literature for meniscal surgery and meniscal implants. To date, no patients have reported serious adverse device-related effects. Seven patients experienced serious adverse events, five of which were considered to be related to the procedure but not to the device itself. Moreover, the majority of adverse events were mild to moderate in intensity. Of these, seven were probably or possibly related to the device; 22 were related to the meniscal procedure.

Efficacy

Statistically significant improvements from baseline were reported for the International Knee Documentation Committee (IKDC), Lysholm and Visual Analogue Scale (VAS) knee pain scores at 3, 6 and 12 months postimplantation ($p < 0.05$). For the five Knee Injury Osteoarthritis Outcome Score (KOOS) subcomponents, statistically significant improvements ($p < 0.05$) were found in pain, daily living and quality of life at 3, 6 and 12 months, and in sports/recreation and other symptoms at 6 and 12 months postimplantation.

Histology and Magnetic Resonance Imaging Findings

Tissue ingrowth into the scaffold was assessed at 12 months by gross examination of the knee joint and index compartment ($n = 45$) and histological examination of biopsies collected from the inner free edge of the implanted scaffold during relook arthroscopy ($n = 45$). Tissue ingrowth was also assessed at 3 months postimplantation by evidence of vascularization in the scaffold, shown by dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) using intravenous gadolinium contrast material ($n = 42$). All DCE-MRI scans were assessed for neovascularization in the peripheral half of the scaffold meniscus and for integration of the implanted device. Cartilage scores in the index compartment were assessed at 3 and 12 months postimplantation using anatomic MRI scans. At 3 months postimplantation, early evidence of tissue ingrowth in the peripheral half of the scaffold was observed on DCE-MRI in 36/42 (85.7%) subjects. MRI at 12 months showed stable or improved cartilage scores compared to baseline in the index compartment. In addition, tissue regeneration was observed in all subjects and complete defect refill in ten subjects. Presence of vital tissue with no necrosis or cell death, consistent with biocompatibility of the scaffold, was observed in all 45 biopsies at 12 months.

Successful tissue ingrowth with cells resembling meniscus cells was visible in distinct layers, each with its own histological characteristics, presence or absence of vessel structures, and composition of extracellular matrix. Histological data support an ongoing process of regeneration, remodelling and maturation towards tissue resembling the human meniscus.

Conclusion

No safety concerns other than those generally acknowledged with surgery, were identified. Importantly, no safety issues related to the device, including cartilage damage or inflammatory reaction to the device or its degradation products, were observed. Efficacy data demonstrated a statistically and clinically significant improvement compared to the preoperative status for the VAS, IKDC and Lysholm scores at 3 months and for all subjective clinical outcome scores at 6 and 12 months postimplantation. The 12-month clinical results are comparable to those of partial meniscectomy, with the scaffold implant having the considerable added benefit of promoting meniscal tissue regeneration.

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