Meniscal Substitutes: Polyurethane Meniscus Implant: Technique and Results

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Abstract

Pain and other short- and long-term sequelae of irreparable meniscal tears remain a challenge for the orthopedic community, and there is a genuine need for an approach which will offer patients and surgeons new acceptable treatment options (Gilbert and Ashwood, Trauma 9:189–194, 2007).

Orteq Ltd. (London, UK) has developed a polyurethane scaffold, Actifit® (Welsing et al., Am J Sports Med 36:1978-1989, 2008), for blood vessel ingrowth and meniscal tissue regeneration (Tienen et al., Am J Sports Med 34:64-71, 2006) intended for the treatment of irreparable, painful meniscus tears and meniscal tissue defects. It is available in the medial and lateral configurations (Fig. 1). Criteria for use include an intact meniscal rim and sufficient tissue in the anterior and posterior horns to permit fixation of the scaffold. Other requirements include a well-aligned and stable knee joint, an ICRS classification grade ≤ 3, a body mass index <35 kg/m^2, and the non-presence of systemic disease or infection sequelae (Arnosky andWarren, Am J Sports Med 10:90–95, 1982).

Introduction

Pain and other short- and long-term sequelae of irreparable meniscal tears remain a challenge for the orthopedic community, and there is a genuine

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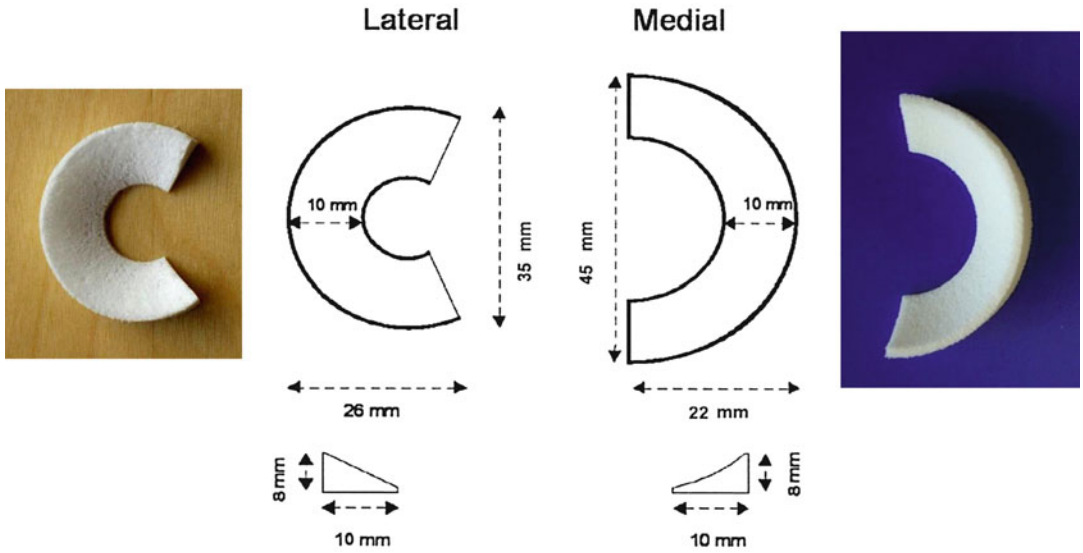

Fig. 1 The Actifit® meniscal scaffold comes in medial and lateral configurations

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Implantation Procedure, Postoperative Care, and Rehabilitation

Implantation Procedure

Implantation of the Actifit® meniscal scaffold is performed arthroscopically using standard surgical arthroscopic knee procedures and equipment. Detailed instructions and related warnings and precautions are set out in the Instructions for Use accompanying the device.

Using spinal or general anesthesia, at the discretion of the orthopedic surgeon, the implantation of the Actifit® meniscal scaffold is usually performed under tourniquet conditions. Thigh fixation may be used for appropriate valgus stress positioning.

Prior to implantation of either the medial or the lateral scaffold, cartilage status and meniscal wall remnant status and integrity should be assessed. In the case of the lateral meniscus, meniscal wall integrity across the hiatus popliteus is essential for secure fixation and optimal tissue regeneration. All pathological cartilage and ligamentous findings should be carefully recorded.

In the case of a tight medial compartment, the medial collateral ligament (MCL) can be distended using the outside-in puncture method. Under valgus stress, and directed by the inside arthroscopic light, the surgeon is able to place a needle in the posteromedial side of the knee joint into the joint. The MCL is sensed and allows for progressive pie-crusting of the ligament until the appropriate opening is obtained.

The inside-out pie-crusting release technique as described by Steadman can also be used. Under

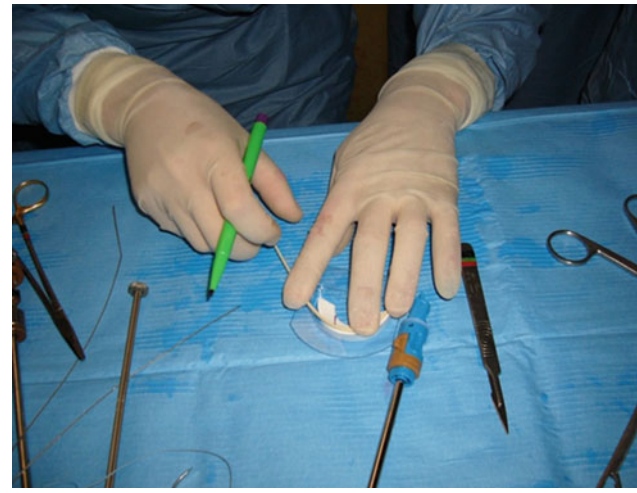

Fig. 2 The Actifit meniscal scaffold is tailored using a scalpel for a snug fit to the meniscus defect

arthroscopic control, the posteromedial corner of the knee joint is visualized. Using the Steadman pick or a spinal needle, the MCL can be reached and progressively disrupted in order to open the knee joint appropriately until visualization is obtained.

In the lateral compartment progressive pie-crusting release techniques as described above and used in the medial compartment are not possible because of anatomical considerations; however, lateral compartment narrowing is rare.

To facilitate healing, the meniscal rim can be punctured for vascular access channels and gentle rasping of the synovial lining is recommended. After debridement and preparation, the defect should reach into the red-red or red-white zone, approximately 1–2 mm from the synovial border. The defect should thereafter be measured along its inner margin using the meniscal ruler and meniscal ruler guide which accompany the Actifit® device.

The Actifit® meniscal scaffold should be measured and cut using a scalpel (Fig. 2). Sterility should be continually maintained. Care should be taken not to undersize the device. For the purpose of achieving a snug fit into the defect, the length of the scaffold should be oversized by approximately 10 %, i.e., 3 mm for small defects (<3 cm) and approximately 5 mm for large defects (≥3 cm). It is recommended that the

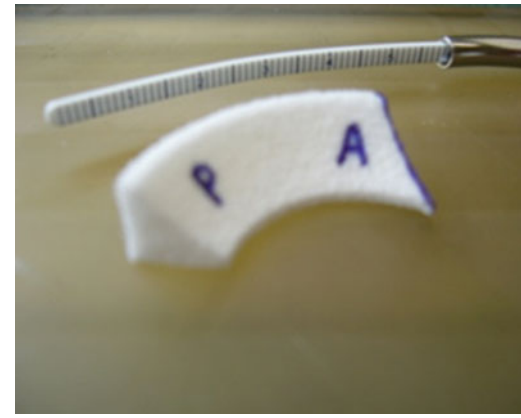

Fig. 3 The anterior side should cut at an angle of 30–45° for easier suturing

anterior side be cut at an angle of 30–45° for easier suturing (Fig. 3).

For the implantation two to three small incisions for anteromedial and anterolateral portals are needed. An arthroscopic central transpatellar tendon portal is optional. For easy insertion of the scaffold, it is recommended that the relevant portal is sized sufficiently to approximately the size of the little finger. In addition, a posteromedial or posterolateral incision may be required if an inside-out meniscal suture fixation technique is used.

Although the Actifit® material is easy to manipulate and is strong and flexible, it should

be handled with care. The tailored Actifit® scaffold can be introduced into the knee joint through the anteromedial or anterolateral portal using a non-cannulated tissue tension grasper such as the Acufex Grasper Tissue Tensioner™ (Smith & Nephew) (Fig. 4). Marking the cranial and caudal scaffold surface helps to avoid problems in positioning. The Actifit® scaffold should be clamped at the posterior part of the scaffold and placed into the knee joint through the anteromedial or anterolateral portal. To ensure a good initial position of the scaffold and facilitate fixation, a vertical holding suture may be placed in the native meniscus tissue to bring the scaffold through the eye of this holding suture.

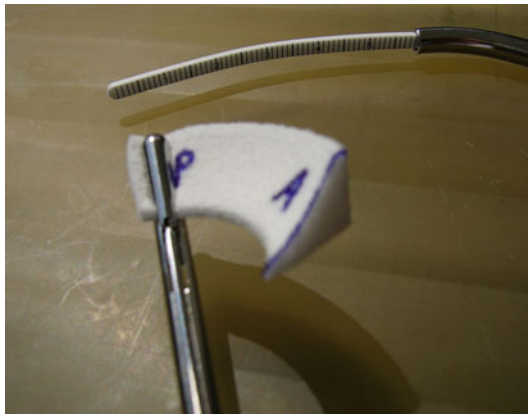

Fig. 4 The scaffold device should be manipulated using a blunt nose grasper. It is useful to mark the cranial and caudal meniscal scaffold surface

Fixation of Actifit® is accomplished by suturing the scaffold to the native meniscus tissue. Standard commercially available size 2.0 non-resorbable sutures, such as polyester or polypropylene and braided or monofilament sutures, are recommended. Which suturing techniques are used depends on the location of the defect and the surgeon's experience and preference (Hardeman et al. 2013). All-inside suturing is commonly used for the posterior horn and posterior part of the rim. All-inside, inside-out, and outside-in techniques may be used for the middle and anterior part of the rim. Horizontal sutures with an outside-in technique are commonly used for the anterior horn.

Fixation should start with a horizontal all-inside suture from the posterior edge of the scaffold to the native meniscus. Suturing should be secure; however, sutures must not be overtightened because they may alter and indent the surface of the scaffold. The distances between the sutures should be kept to approximately 0.5 cm (Fig. 5a). Each suture should be placed at one-third to one-half of the scaffold's height, as determined from the lower surface of the scaffold (Fig. 5b). Suturing through the popliteus tendon is not detrimental to later function (De Coninck et al. 2013a).

Once sutured in place if required, the scaffold may be further trimmed and fine-tuned intra-articularly using a basket punch. Stability of the fixation is tested using a probe and carefully moving the knee through a range of motion (0–90°).

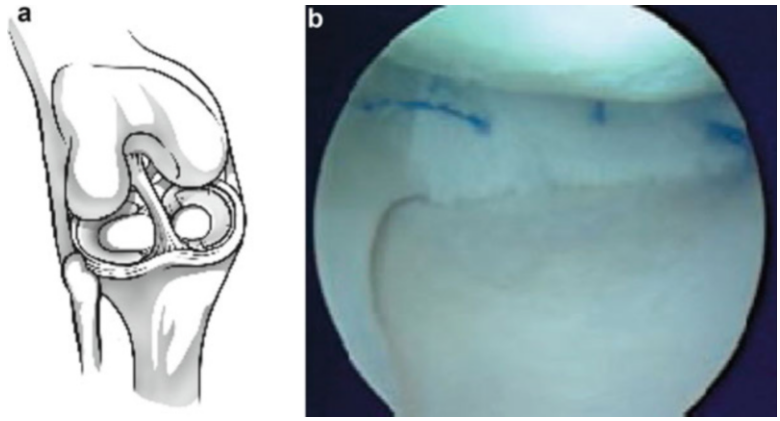

Fig. 5 (**a**) The distances between the sutures should approximately 0.5 cm. (**b**) Each suture should be placed at one-third to one-half of the scaffold height determined from the lower surface of the scaffold in order to allow proper fixation

Postoperative Care

Following implantation of the Actifit® scaffold, pain and thromboprophylactic medications are administered at the surgeon's discretion and would be those typically administered following classic meniscal suturing.

Dependent upon the meniscal scaffold stability as determined at the end of the surgical procedure, a rigid removable brace may be used over a compression bandage in the first week postimplantation.

Postoperative Rehabilitation

Following implantation of the Actifit® scaffold, the recommended postoperative rehabilitation protocol should be strictly followed to ensure optimum conditions for healing and to protect the newly formed fragile tissue from potentially harmful stresses while tissue remodeling and maturation processes are ongoing during the first 3 months postsurgery. It is important that the rehabilitation protocol is reviewed and approved to be suitable for the patient in question by the responsible orthopedic surgeon and carried out under the supervision of a professional physiotherapist.

Non-weight-bearing is recommended until 4 weeks postsurgery. Partial weight-bearing is permitted from 4 weeks onward with a gradual increase in loading up to 100 % load at 9 weeks postimplantation, at a rate of 10 kg per week for patients weighing $\leq$60 kg and 15 kg per week for patients weighing $\leq$90 kg, and without the use of the unloader brace from week 14 onward.

Under the rehabilitation protocol, motion is initiated immediately after implantation, with bending up to 30° with full extension permitted in weeks 1 and 2. Flexion is increased to 60° in week 3, and to 90° in weeks 4 and 5. From week 6 onward, flexion is further increased until a full range of motion is achieved; however, forceful movements should be avoided. Light exercise, including isometric quadriceps exercises, mobilization of the patella, heel slides, quad sets, anti-equinus foot exercises, and Achilles tendon stretching, is advised from week 1. After 9 weeks, additional exercises, including increased closed hamstring exercises, lunges between 0 and 90°, proprioception exercises, dynamic quadriceps exercises, and use of a home trainer, are indicated. Increased open and closed exercises, jogging on level ground, plyometrics, and sports-related exercises without pivoting are recommended from week 14 onward. Hydrotherapy and swimming (crawl stroke and headstroke) can commence 24 weeks postimplantation. Gradual resumption of other sports is generally commenced as of 6 months at the discretion of the responsible orthopedic surgeon; however, contact sports should be resumed only after 9 months.

Clinical Results

Safety, performance, and efficacy results to support use of the Actifit® scaffold in the treatment of painful irreparable meniscal defects were obtained from a prospective, nonrandomized, single-arm, clinical investigation conducted at nine orthopedic centers of excellence located throughout Europe. Patients recruited ($N = 52$) had an irreparable medial or lateral meniscus tear or partial meniscus loss, intact rim, both horns, and a stable well-aligned knee.

Thirty-four patients were treated with a medial meniscal scaffold and 18 patients were treated with a lateral meniscal scaffold. Demographics and baseline characteristics were representative of the population for which Actifit® is intended. The mean patient age was 30.8 $\pm$ 9.4 years and 75 % were male. The mean longitudinal defect length was 47.1 $\pm$ 10.0 mm.

The study follow-up period was 24 months and the study has been reported in the American Journal of Sports Medicine (Verdonk et al. 2012; De Coninck et al. 2013b).

Safety Results

Nine index knee-related Serious Adverse Events (SAEs) were reported in the study (five in the medial and four in the lateral indication). Three of these in the medial indication and three in the lateral indication resulted in removal. Four of

the nine SAEs were reported as unrelated to the scaffold and to the procedure; four were reported as procedure related; none were reported as having a definite, probable, or possible relationship to the Actifit® scaffold.

One SAE was reported as having an unknown relationship to the Actifit® scaffold and to the procedure. This was the removal of an almost completely nonintegrated scaffold, which took place at the protocol-stipulated relook arthroscopy. The patient was asymptomatic, and importantly no signs of inflammatory reaction to the scaffold and no evidence of cartilage damage were observed during gross examination. A biopsy specimen taken from the meniscus rim post removal of the nonintegrated scaffold material showed cell-populated scaffold material integrated with tissue. No inflammatory reaction to the scaffold was observed in the biopsy. It was concluded that the integration failure was most likely due to the lack of biological response.

Cartilage scores in the index compartment were assessed at 3, 12, and 24 months postimplantation using anatomical MRI scans. Stable or improved cartilage status at 24 months was demonstrated in 92.5 % (37/40) of patients compared with baseline status.

Efficacy Results

Pain and functionality were assessed using validated clinical outcome scores. The Visual Analog Scale (VAS) was used for knee pain at 3, 6, 12, and 24 months postimplantation. The International Knee Documentation Committee (IKDC), the Lysholm score, as well as the Knee and Osteoarthritis Outcome Score (KOOS) were used to assess functionality.

For functionality on IKDC and Lysholm scores and for pain (VAS), statistically and clinically significant improvements from baseline to 24 months were reported at 3, 6, 12, and 24 months postimplantation ($p < 0.05$).

Statistically and clinically significant improvements ($p < 0.05$) were also reported for the five KOOS subcomponents: for pain, for activities of daily living and quality of life at 3, 6, 12, and 24 months, and for sports/recreation and symptoms at 6, 12, and 24 months postimplantation.

Evidence of New Tissue Formation

Tissue ingrowth into the Actifit® scaffold was assessed during the protocol-stipulated relook arthroscopy at 12 months ($n = 44$) by gross examination and histological examination of biopsies from the inner free edge of the implanted scaffold. The presence of vital tissue with no necrosis or cell death and hence consistent with biocompatibility of the scaffold was observed in all 44 biopsies at 12 months. Moreover, the histology data suggested an ongoing process of regeneration, remodeling, and maturation toward tissue resembling the human meniscus.

Tissue ingrowth was also assessed at 3 months postimplantation by evidence of vascularization in the scaffold using diagnostic contrast-enhanced MRI (DCE-MRI) ($n = 43$). All scans were assessed for neovascularization in the peripheral half of the scaffold meniscus.

At 3 months postimplantation, early evidence of tissue ingrowth was observed on DCE-MRI in the peripheral half of the scaffold, in 35 of 43(81.4 %) patients.

Conclusions

No safety concerns, other than those generally acknowledged with this type of surgery, were identified. Importantly, no safety issues related to the device, including cartilage damage or inflammatory reaction to the Actifit® scaffold or its degradation products, were observed. Efficacy data showed significant (statistical and clinical) improvement from preoperative status for the subjective clinical outcome scores as of 3 months to 24 months postimplantation. The 24-month clinical results provide strong evidence of the safety and efficacy of the Actifit® scaffold treatment option for a patient group for whom currently only restricted treatment options are available. In addition, compared to partial meniscectomy, treatment of irreparable meniscus defects with the

Actifit® scaffold has the benefit of promoting new tissue regeneration (Verdonk et al. 2008; Maher et al. 2009). The 5-year evaluation of the patients with Actifit meniscal implantation shows strong clinical evidence of good function and long-term pain relief in the indexed compartment. These findings are supported by well-positioned implant at MRI imaging at 5 years, however, still not comparable to the normal contrast of the physiological meniscus appearance.

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