Original article

Actifit® synthetic meniscal substitute: Experience with 18 patients in Brest, France

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ABSTRACT

Background: The management of post-meniscectomy pain is poorly standardised. Allogeneic transplantation may be appropriate in some patients after total meniscectomy. After partial meniscectomy, the synthetic meniscal substitute Actifit® may constitute a valid option if the knee is stable or stabilised and aligned or re-aligned. The interconnected pore structure of Actifit® promotes tissue regeneration from the meniscal wall. Arthroscopy is used to position the implant, which is then sutured to the remaining native meniscus using horizontal stitches and to the meniscal wall using vertical stitches. However, a burdensome programme of rigorous rehabilitation is required after Actifit® implantation.

Hypothesis: We hypothesised that implantation of a meniscal substitute effectively alleviated pain without adversely affecting the knee.

Objectives: To assess the intra-articular behaviour of Actifit® and the outcomes of Actifit® implantation in a prospective case-series of patients monitored using arthroscopy, pathology, and imaging studies, as well as the Lysholm score to assess clinical benefits on daily activities.

Materials and methods: Between October 2009 and April 2012, 18 patients underwent Actifit® implantation at the military hospital in Brest, France. All procedures were performed by the same surgeon, who had extensive experience with meniscal suturing. There were 13 males and 5 females aged 20 to 46 years. The medial meniscus was involved in 13 patients and the lateral meniscus in 5 patients. Actifit® implantation was used alone in 6 patients and in combination with anterior cruciate ligament reconstruction and/or realignment osteotomy in 12 patients. All patients were followed-up for at least 2 years.

Results: The mean Lysholm score after 1 year was 92%, indicating excellent outcomes. Magnetic resonance imaging showed no damage to the implant or degeneration of the neighbouring cartilage. Histological examination of meniscal substitute biopsies taken 1 year after implantation showed polymer ingrowth by normal chondrocytes and fibrochondrocytes. The clinical and radiographic outcomes compared favourably with those seen after isolated procedures on bone or ligaments.

Discussion: Actifit® has no deleterious effects on patients. The implant induces and promotes meniscal regeneration. Actifit® constitutes a major addition to our therapeutic armamentarium. We provide convincing evidence that meniscal reconstruction can be highly beneficial in decreasing the risk of progression to knee osteoarthritis.

Level of evidence: IV.

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1. Introduction

As military surgeons, we provide care to many young athletic individuals who engage in activities that cause trauma to the joints. This young population is at high risk for knee disorders, most notably damage to the menisci [1]. We encounter difficult challenges raised by individuals younger than 40 years of age with knee pain and meniscal lesions that inevitably result in knee osteoarthritis if left untreated [2]. Several treatment options are available for these patients. Meniscal repair by suturing is feasible in some cases [3]. Another option consists of replacing the meniscus with either allogeneic

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transplants or synthetic substitutes [4]. Finally, a scaffold impregnated with growth factors can be implanted to induce meniscal tissue regeneration [5].

Until now, we had no effective treatment options for young patients with knee pain after partial meniscectomy. Our team at the Brest military hospital therefore decided to use the meniscal substitute Actifit® in this situation [6].

The objective of this study was to assess the intra-articular behaviour of Actifit® and the clinical benefits of Actifit® implantation on the everyday life of these patients with chronic knee pain. To this end, we performed a prospective cohort study.

2. Material and methods

2.1. Material

Actifit® [6] is a synthetic polymer composed of poly-ε-caprolactone acid and polyurethane. The matrix (Fig. 1) is characterized by a highly interconnected pore structure that encourages tissue regeneration from the meniscal wall [7]. The primary stability of the substitute facilitates implantation and produces favourable mechanical sensations.

From the meniscal wall, whose preservation is mandatory [8] (Fig. 2), blood vessels develop and grow into the honeycomb structure of the implant (Fig. 3). The result is regeneration of the meniscal tissue. Over the years, once regeneration is complete, breakdown of the replacement matrix occurs.

Although some degree of dexterity is required, meniscal transplantation is within the reach of any surgeon who is experienced in arthroscopic procedures. Different kits are available for the medial and lateral menisci. A special ruler is always provided to allow measurement of the defect produced by the meniscectomy. A meniscal suture kit is required to stitch the implant to the meniscal wall and residual meniscus, and the all-inside technique is the most appropriate.

The technique itself involves the following steps:

- preparation of the meniscectomy region and abrasion of the meniscal wall (Fig. 4);
- measurement of the meniscal defect (Fig. 5);
- cutting of the implant to match the size of the defect (Fig. 6);
- positioning of the implant in the knee;
- suturing of the implant to the meniscal wall and residual meniscus (Fig. 7).

2.2. Methods

Replacement of part of a damaged meniscus can be considered only if the criteria below are met:

- knee pain with a visual analogue scale (VAS) score >6/10 every day for more than 6 months;
- stable knee or knee scheduled for stabilisation;
- normally aligned knee or knee scheduled for realignment;
- intact meniscal wall;
- intact meniscal anchors.

In addition, the cartilage damage in the involved tibio-femoral compartment should not exceed grade II in the Kellgren–Lawrence radiological classification.
This set of criteria served as inclusion criteria for our study. All procedures were performed at the Clermont-Tonnerre Military Teaching Hospital by a single surgeon who had extensive experience with arthroscopic surgery and meniscal suturing.

After the procedure, all patients were managed at our rehabilitation department, where they followed the 24-week stepwise rehabilitation programme recommended by the manufacturer of Actifit®. Weight bearing on the operated lower limb was completely eliminated for 1 month then, resumed gradually until full weight bearing was reached after 9 weeks.

The patients were re-evaluated by the surgeon after 3, 6, and 12 months, then once a year. Follow-up was at least 2 years in all study patients. The Lysholm score was determined at each visit. Magnetic resonance imaging (MRI) was performed after 1 year and whenever a further surgical procedure was required, most notably in the event of material removal, in which case arthroscopy with a biopsy of the implant was performed.

3. Results

Between October 2009 and April 2012, 18 patients were prospectively included into the study, 13 males and 5 females aged
20 to 46 years. Among them, 13 had damage to the medial meniscus and 5 to the lateral meniscus. Actifit® implantation was performed alone in 6 patients (Fig. 8). The remaining 12 patients also underwent anterior cruciate ligament reconstruction and/or realignment osteotomy.

The intra- and postoperative complications consisted of residual knee pain due to median saphenous nerve injury in 1 patient and quadriceps weakness due to a femoral nerve conduction block related to the regional anaesthesia in another.

Follow-up was at least 2 years in all 18 patients. No patients were lost to follow-up. The Lysholm score changes showed a marked clinical improvement as early as 6 months after the procedure. After 1 year, the mean Lysholm score was 92%, indicating an excellent result (Fig. 9). After 2 years, all 18 patients had returned to their usual everyday activities and 9 had resumed their sporting activities at the same level as before the procedure.

MRI was performed 1 year after surgery in all 18 patients. The implant was seen as a structure of intermediate signal intensity that had the shape of the meniscal triangle (Fig. 10). No cases of implant separation or meniscal degeneration were recorded. Meniscal extrusion was visualised in 1 patient but had no clinical impact.

An arthroscopic biopsy of the implant was performed 1 year after surgery in 3 patients. The histological study (Fig. 11) showed that the polymer was colonised by normal chondrocytes and fibrochondrocytes.
4. Discussion

As military surgeons, we provide care to young athletic individuals in whom one goal is to maintain operational ability for as long as possible. These specific characteristics raise challenges in the management of post-meniscectomy knee pain. To meet the expectations of the members of the armed services, we investigated the potential benefits of meniscal substitute therapy. The support of our hospital pharmacy was crucial in allowing this endeavour, as the cost of each Actifit® implant is about 2000 €. Our primary objective was to demonstrate that Actifit® implantation had no deleterious effects on the patients. The clinical and radiological data collected after 4 years of experience with Actifit® are extremely encouraging and compare favourably with the outcomes obtained after bone or ligament surgery alone.

The first meniscal substitute was the collagen meniscal implant (CMI) composed of bovine collagen. In 98 patients who underwent medial meniscus reconstruction with the CMI, Beaufils et al. showed that 87% of patients had normal knees after 1 year, with a mean Lysholm score of 97% [9]. MRI was performed after 1 year in all 98 patients and showed no adverse effects on the neighbouring cartilage or evidence of early degeneration. In April 2009, Makrides et al. reported the outcomes of 6 patients managed with the CMI to reconstruct the lateral (n = 4) or medial (n = 2) meniscus [10]. After 6 months, all 6 patients were free of pain and the mean Lysholm score was 96%.

Despite these promising results, the same teams, who by then had acquired considerable experience with meniscal transplantation, were drawn to evaluate the synthetic polymer substitute Actifit®. In a study involving routine arthroscopy and implant biopsy after 1 year, Verdonk and Forsyth [11] showed ingrowth of native meniscal tissue into the implant, which consistently produced viable tissue with no evidence of necrosis. In April 2011, the same Belgian team reported 3-month data on tissue ingrowth into Actifit® implants in 52 patients evaluated using dynamic contrast-enhanced MRI [12]. Tissue ingrowth was documented in 81.4% of patients.

Our prospective study has an obvious source of bias in that 12 of the 18 patients underwent another procedure in addition to Actifit® implantation. Thus, although clinical benefits were recorded, we cannot determine with certainty that they were directly related to Actifit® implantation. Nevertheless, our optimism regarding the beneficial effects of Actifit® is supported by the results of earlier studies. The Actifit® Study Group reported a multicenter case-series study of 52 patients managed using Actifit® implantation alone [13]. Significant improvements were recorded for pain and function (IKDC score, KOOS, and Lysholm score). In addition, the condition of the cartilage (ICRS grade) remained unchanged or improved in 92.5% of patients.

5. Conclusion

Actifit® induces and supports meniscal regeneration. This implant constitutes a major addition to our therapeutic armamentarium. We are confident that meniscal reconstruction can prove beneficial in decreasing the risk of progression to osteoarthritis.

Unfortunately, the French National Authority for Health (HAS) recently ruled [14] that the benefits from Actifit® were not sufficient to warrant reimbursement of the implant by the French statutory healthcare system. Nevertheless, we will continue to use this synthetic implant while striving to diversify our practice by also using meniscal substitutes derived from native meniscal tissue, such as the T-menisces®, with the goal of providing optimal care to our young patients with symptomatic meniscal lesions.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References