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## Polyurethane scaffold in lateral meniscus segmental defects: Clinical outcomes at 24 months follow-up



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### ABSTRACT

*Background:* Segmental tissue loss in the lateral meniscus is associated with pain and increased risk of osteoarthritis even when indications have been carefully considered.

*Hypothesis*: Repairing the defect using a novel biodegradable scaffold will reduce pain and restore the knee function.

*Methods:* In this prospective multicenter study, a total of 54 patients (37 males/17 females; mean age: 28 years [16–50]) were enrolled. All patients presented with postmeniscectomy syndrome and segmental lateral meniscus loss, and were treated with a polyurethane biodegradable scaffold (Actifit<sup>®</sup>, Orteq) implanted arthroscopically. Clinical outcomes were assessed at 6, 12 and 24 months using Visual Analogue Scale (VAS), International Knee Documentation Committee Score (IKDC) and Knee Injury and Osteoarthritis Outcome Score (KOOS).

*Results:* VAS decreased from 5.5 at baseline to 3.6 at 6 months, 3.4 at 12 months and 2.9 at 24 months. IKDC improved from 47.0 at baseline to 60.2, 67.0 and 67.0 at 6, 12 and 24 months. All KOOS subscores improved between baseline and 24 months.

*Discussion:* Clinical results of this study demonstrate clinically and statistically significant improvements of pain and function scores (VAS, IKDC, and all KOOS subscales except sport), at the 6 months follow-up and on all clinical outcomes at the 2-year follow-up. The Actifit<sup>®</sup> scaffold is safe and effective in treating lateral meniscus defects.

*Level of evidence:* IV: continuous prospective multicenter study.

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#### 1. Introduction

The menisci play an important biomechanical role in the knee including load bearing, load and force distribution between the femoral condyles and tibial plateau, joint stabilization, lubrication and proprioception [1]. This is especially important in the lateral compartment which is considered to be more biomechanically challenging, as the lateral meniscus has a smaller contact area combined with higher peak stresses when compared to the medial meniscus under various loads, degrees of flexion and meniscectomy

Corresponding author. Tel.: +33 01 39 63 89 51. E-mail address: pbeaufils@ch-versailles.fr (P. Beaufils). conditions. Furthermore, the lateral compartment is more mobile than the medial as the antero-posterior translation is greater [2,3].

The standard of care for irreparable meniscal tears, partial lateral meniscectomy, is well known to predispose patients to long-term degenerative changes and osteoarthritis [4,5]. Furthermore, worse outcomes have been reported following lateral rather than medial meniscectomy [6,7]. In a 30-year longitudinal study, McNicholas et al. [8] found that after medial meniscectomy 80% of patients had good or excellent results at long-term follow-up, compared to only 47% after lateral meniscectomy, thus there are even greater negative consequences following meniscal tissue loss in the lateral compartment. Chatain [6] when comparing results of 109 lateral and 362 medial partial meniscectomies with more than 10 years follow-up concludes that subjective and clinical results are quite

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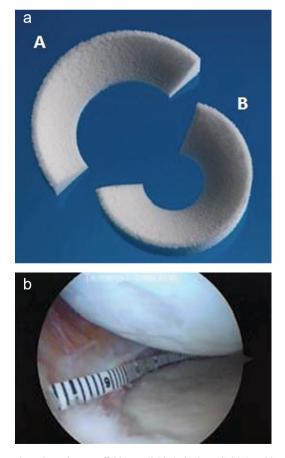
similar but radiographic results, in particular, joint space narrowing are significantly worse in the lateral compartment.

The unacceptably low rate of success following lateral partial meniscectomy, common to all current standard procedures, has led to a genuine need for an approach which will offer patients better and more reliable treatment. Meniscal reconstruction would be the solution to this problem; by allograft in the case of total meniscectomy or scaffold in the case of a partial defect with the aim of closely mimicking the shape and biomechanical properties of the native meniscus [9,10]. The novel porous biodegradable polyurethane scaffold (Actifit<sup>®</sup>) is intended to meet this unmet need, by providing a scaffold for vessel ingrowth and meniscal tissue regeneration. Studies have shown that treatment of irreparable meniscal tissue loss with the polyurethane scaffold is both safe and efficacious in mixed populations of medial and lateral patients [11,12]. However, no data are currently available that focus on the more biomechanically challenging lateral indication.

The objective of this study was to clinically evaluate the lateral polyurethane scaffold for the treatment of patients with lateral segmental tissue loss with postmeniscectomy syndrome. We hypothesize that the lateral polyurethane meniscal scaffold, indicated in case of partial defect, is able to reduce pain and restore knee function.

#### 2. Materials and methods

This study was a prospective, single-arm, multicentre study designed to assess the safety and efficacy of the lateral polyurethane meniscal scaffold (Actifit<sup>®</sup>, Orteq Ltd, London, UK) for the treatment of postmeniscectomy syndrome (Fig. 1a). A total of



**Fig. 1.** a: the polyurethane scaffold is available in both medial (A) and lateral (B) configurations; b: measurement of defect length.

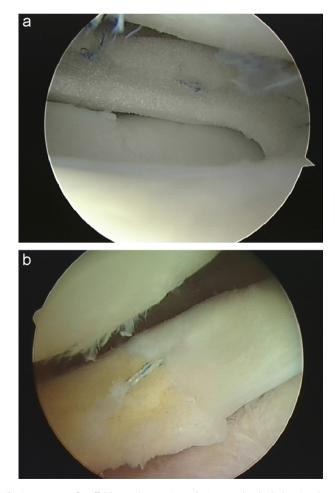
54 patients from six European centres were enrolled between 2007 and 2011 who were treated with the polyurethane scaffold for postmeniscectomy syndrome. Inclusion criteria were the same as used by Verdonk et al. [11], but in brief comprised; (1) irreparable painful lateral meniscal tear or partial meniscus loss, with intact rim; (2) skeletally mature male or female patients; (3) age 16 to 50 years; (4) stable knee joint or knee joint stabilization procedure within 12 weeks of index procedure; (5) International Cartilage Repair Society (ICRS) classification  $\leq$  3 and (6) body mass index  $\leq$  35.

#### 2.1. Surgical technique

Following exploration of all compartments and verification of cartilage status, debridement and preparation were performed: the defects extended into the vascularized red-on-red or red-on-white zone of the damaged portion of the meniscus. The meniscal defect was measured along the curvature of its inner edge using a special meniscal ruler (Fig. 1b), then the scaffold was cut to size; with the scaffold oversized by 10% to allow for shortening caused by suturing. The implant was introduced into the joint by the anterolateral portal and then fixed to the native meniscus by sutures (using all inside devices, and/or outside-in techniques) (Fig. 2).

#### 2.2. Rehabilitation

Following the implantation of Actifit<sup>®</sup> scaffold, rehabilitation was provided as per the procedure described by Verdonk et al. [13].



**Fig. 2.** a: suture of scaffold to native meniscus; b: 24-month relook showing tissue ingrowth into the scaffold at the interface with the native meniscus. *Courtesy S. Roberts.* 

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