Magnetic Resonance Imaging and Functional Outcomes After a Polyurethane Meniscal Scaffold Implantation: Minimum 5-Year Follow-up

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Purpose: To report the magnetic resonance imaging (MRI) and clinical outcomes at a minimum 5-year follow-up in a series of patients with postmeniscectomy syndrome and treated with a polyurethane scaffold. **Methods:** All consecutive patients operated on from September 2008 to February 2011 for either persistent medial or lateral joint line compartmental pain receiving a polyurethane scaffold due to a previous partial meniscus resection with a minimum 5-year follow-up were included. Functional scores (Knee Injury and Osteoarthritis Outcomes Score, International Knee Documentation Committee, Lysholm, and Tegner) were assessed preoperatively and at the last follow-up. The state of the scaffold as well as postoperative scaffold extrusion and the total remaining meniscal volume was also evaluated in MRI. **Results:** Thirty-two patients were included. The mean follow-up was 70.8 ± 7.5 months. The functionality of the knees improved in all the scores used ($P < .001$) except for the Tegner score that stayed steady. Most of meniscal implants showed extrusion of 2.4 mm (95% confidence interval [CI], 1.1-3.7) were smaller and a hyperintensity signal was seen in the MRI. Three scaffolds were resorbed at the last follow-up. The meniscal volume, determined by MRI, was 1.14 cm^3 (95% CI, 0.96-1.31) preoperatively and 1.61 cm^3 (95% CI, 1.43-1.7) at the last follow-up. No differences were presented. **Conclusions:** The use of a polyurethane meniscal scaffold in patients with a symptomatic meniscus deficit had a good functional outcome at 5 years after surgery. However, the implanted scaffolds did not present normal meniscal tissue with MRI, and the implant volume was considerably less than expected. The fact that most of patients included received different concomitant procedures during scaffold implantation introduces a degree of performance bias into the results. **Level of Evidence:** Level IV, case series.

Postmeniscectomy syndrome is defined as pain occurring in a previously meniscectomized knee compartment. It is believed that the pain is the result of overload due to meniscal tissue loss.[1-7] Although several treatments can be considered, the etiologic approach seems to be the restitution of the lost meniscal tissue. This can be accomplished with either meniscal allograft transplantation or a meniscal scaffold, depending on whether the meniscus defect is complete or partial.

In the last decade, meniscal scaffolds have been shown to successfully treat symptomatic partial meniscal defects, providing pain relief and restoring the function of the knee. Two scaffolds have been marketed until now. The Collagen Meniscal Implant (CMI, ReGen Biologics, Franklin Lakes, NJ), a bovine collagen scaffold, was the first to market with good results in series that has more than 10 years of follow-up.[8,9] More recently, a biodegradable and synthetic acellular scaffold composed of aliphatic polyurethane has been introduced

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(Actifit; Orteq Ltd., London, UK). This new scaffold aims to improve some of the limitations of the bovine scaffold. These limitations were its rapid degradation, being of bovine origin, and difficulty in its handling.[10] The ultrastructure of this scaffold is characterized by its 80% porosity and 20% low reabsorption rate polymer. Within the polymer, there are softer polycaprolactone segments that constitute 80% of the polymer and the remaining 20% is a more rigid urethane. Degradation starts with hydrolysis of the polycaprolactone segments that lasts up to 5 years. The polyurethane segments are removed by macrophages and giant cells, whereas the scaffold is replaced by cells coming from the surrounding tissues.[10-12] Dhollander et al.[13] have recently published the first polyurethane scaffold implantation series with a minimum 5-year follow-up. They reported improved knee joint function and pain relief. However, they questioned its theoretical chondroprotective effect and observed that almost 40% of the implants failed. These data agree with those reported by Schüttler et al.[14] with a 4-year follow-up. Although these 2 studies reported good functional outcomes at mid-term follow-up, they do not confirm the good imaging aspect and low failure rate reported in the short follow-up studies.[15-18] To date, only these 2 series on a polyurethane meniscal scaffold with mid-term results have been published. It is important that more clinical and radiological data with at least a 5-year follow-up be published to better understand the true effect of the scaffold as a meniscal substitute.

The aim of this study was to report the magnetic resonance imaging (MRI) and clinical outcomes at a minimum 5-year follow-up in a series of patients with postmeniscectomy syndrome and treated with a polyurethane scaffold. Total meniscal volume (TMV), measured in MRI, was considered the primary variable. It was hypothesized that the scaffold would be able to improve on pain relief and knee function as well as be replaced by new meniscus-like tissue according to MRI.

Methods

This is a retrospective study that included all consecutive patients who were operated on from September 2008 to February 2011 for either persistent medial or lateral joint line compartmental pain receiving a polyurethane meniscal scaffold due to a previous partial meniscus resection. Those patients with a complete loss of the corresponding meniscus, symptomatic grade III or IV chondral injury in whatever knee compartment, untreated instability, untreated varus or valgus malalignment greater than 5°, inflammatory arthritis, polyurethane allergies, autoimmune disease, and pregnancy were excluded. All the patients who were finally included in the study were called up for clinical and MRI evaluation. The presence of anterior and posterior meniscus remnants as well as an intact outer rim of the meniscus was the necessary condition for the procedure. An anterior cruciate ligament–deficient knee was not considered a contraindication if the ligament was reconstructed at the same time as the polyurethane scaffold implantation. Similarly, varus knees were not a contraindication if the malalignment was addressed previously or concomitantly with meniscal substitution.

The study was approved by the clinical research ethics committee of our institution (Dex-Actifit). All the patients signed informed consent to participate in the study as well as for the evaluation and publication of the results.

Surgical Technique

The implantation of the meniscal scaffold was performed with a fully arthroscopic technique through standard anterolateral and anteromedial portals. The remaining meniscus was trimmed and trephinated by using an intramuscular needle from inside-out to the joint capsule to create multiple bleeding areas. Radiofrequency was also used at the synovial junction to promote a healing response.[19] The meniscal defect was measured with a ruler and the scaffold was oversized by 10% to better fit in the defect, as recommended. The implant was fixed with nonabsorbable sutures, either with an all-inside suture in the posterior horn or with an outside-in suture at the body and anterior horn, when necessary. Data on scaffold length and the number of all-inside and outside-in stitches needed were collected.

Subsequently, concomitant surgical procedures were performed when called for (Table 1).

Postoperative Protocol

Passive and active range of motion were started on the first postoperative day. Flexion was limited to 60° the first 3 weeks and progressed to 90° until the sixth postoperative week. From that moment on, unrestricted range of motion was allowed. A locked brace was used in all cases until correct muscle control had been acquired. Partial weight bearing was allowed from the fourth postoperative week and full weight bearing

Table 1. Concomitant Surgical Procedures

Surgical Technique	n
Isolated polyurethane scaffold implantation	7
Microfractures	3
ACL-R	6
ACL-R + microfractures	2
HTO	3
HTO + microfractures	9
PCL-R	1
ACL-R + HTO	1

ACL-R, anterior cruciate ligament reconstruction; HTO, high tibial osteotomy; PCL-R, posterior cruciate ligament reconstruction.

the eighth week after the surgery. Unrestricted physical activity and sports were allowed after the sixth postoperative month. This protocol was modified and adapted in case of concomitant surgical procedures.

Functional Evaluation

The patients included in the study were evaluated preoperatively and at the last follow-up. For this, the patients included in the study were called up for a clinical evaluation. This evaluation was performed with patient-reported outcome scores: the Knee Injury and Osteoarthritis Outcomes Score (KOOS), the International Knee Documentation Committee (IKDC), the Lysholm score, and the Tegner score.[20-22] Patient satisfaction was evaluated with a subjective score and graded as very satisfied (4 points), satisfied (3 points), neutral (2 points), somewhat dissatisfied (1 point), and not satisfied at all (0 points).

MRI Evaluation

A T2 mapping MRI was performed preoperatively and at the 5-year follow-up with a 1.9-Tesla MRI device using gradient-echo T2-weighted, spin-echo T1-weighted, fat saturation fast spin-echo, and T2-weighted sequences in coronal, sagittal, and transverse slice orientations. Scaffold morphology was evaluated based on the method described by Genovese et al.[23] This score evaluates the morphology and size of the scaffold. A type I means totally resorbed scaffold, a type II is a small scaffold with regular (a) and/or irregular (b) morphology, and a type III scaffold with the same size and shape as the normal meniscus. The method also assesses the signal intensity of the scaffold. Type I is markedly hyperintense, type II is slightly hyperintense, and type III is isointense when compared with the normal meniscus. Meniscus extrusion was measured on the coronal view as described by De Coninck et al.[24] Further assessment of remnant meniscal regrowth was performed by calculating the TMV. This was accomplished with the "ROI segmentation" feature integrated into the OsiriX v7.0.4 Lite software. The overall volume of each meniscus was calculated by using all the coronal MRI slices of the meniscus (Fig 1A). Initially, the appropriate range of image signal intensities based on the gray-level index values of the pixels within each meniscus was selected. After that, a colored marker image was used to demarcate the boundaries of the meniscus. The overall volume (cm^3) of the menisci was calculated using the total surface areas by obtaining a 3D image for each meniscus (Fig 1B). This method was previously used by Narvy et al.[25]

Statistical Analysis

Statistical analyses were performed using STATA/SE 12.1 (Stata, College Station, TX). Categorical variables are expressed as percentages and frequencies. Mean and standard deviations as well as medians, minimums, and maximums were used for each item of descriptive data. Mean and 95% confidence intervals (CIs) were used for each continuous variable. Mean and standard deviations as well as medians, minimums, and maximums were calculated for each continuous variable. The results were statistically analyzed and compared using the Student *t*-test for parametric data with normal distribution. The level of significance was set at $<.05$.

Results

No patient was lost to follow-up. There were 25 males and 7 females with a mean age of 41.3 ± 11.1 (range 23-60) years at the time of index surgery. The mean follow-up was of 70.2 ± 7.5 (range 63-93) months. Considering the TMV as the main variable, a post hoc power analysis was performed. With an alpha error probability of .05 and with an effect size of 0.8, a power of 100% was obtained.

There were 18 left and 14 right knees. Of those, 21 were medial and 11 lateral. The average length of the

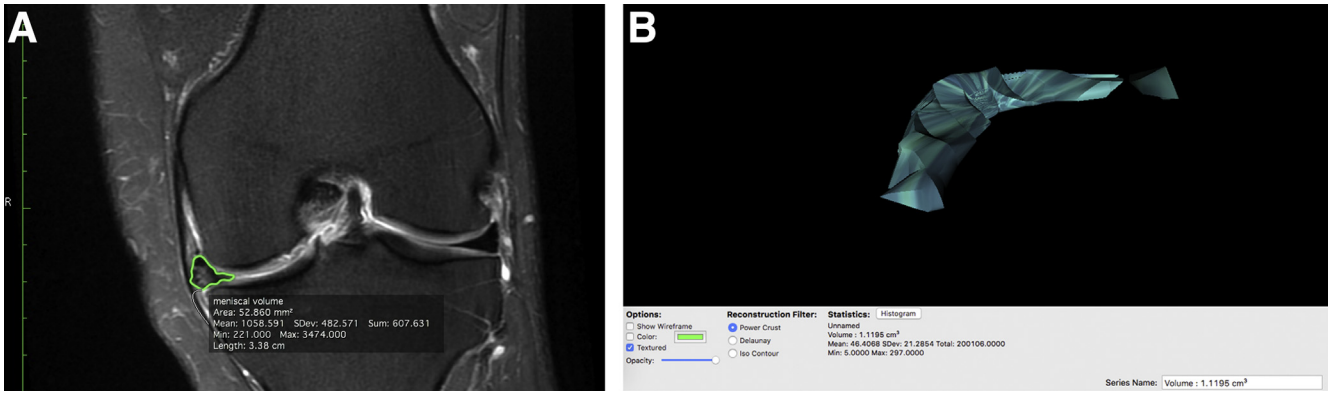

Fig 1. An example of a left knee medial meniscus supplemented with a polyurethane scaffold. (A) Total meniscal volume was calculated using coronal magnetic resonance imaging slices. The meniscus tissue was marked in green. (B) The 3D image obtained in one of the menisci studied.

Table 2. Functional Outcomes and Satisfaction

	Preoperative	Final Follow-up	*P* Value
KOOS	48.6 (95% CI, 44.3-53)	79.4 (95% CI, 76.9-82)	$P < .001$
IKDC	41.7 (95% CI, 38.1-45.4)	68.7 (95% CI, 65.4-72.1)	$P < .001$
Lysholm	40.7 (95% CI, 36.8-44.7)	78.1 (95% CI, 74.7-81.6)	$P < .001$
Tegner	5.1 (95% CI, 4.6-5.6)	5.7 (95% CI, 5.3-6.2)	$P = .23$

CI, confidence interval; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcomes Score.

implant was 45 mm ± 7.6 mm. Fixation of the polyurethane scaffold implant required a mean of 3.5 ± 0.7 all-inside sutures and 0.8 ± 0.7 outside-in sutures. No patients suffered any complication during and/or after scaffold implantation. There were no complications related to scaffold implantation in any patient. Additional or combined procedures were performed in all but 7 patients (Table 1), high tibial valgus osteotomy (HTO) being the most frequent. The preoperative mechanical axis in those patients who underwent HTO realignment averaged 6° ± 5° of varus. After the surgery, the mechanical axis in the 12 patients who required the HTO was 0.5° ± 2° of varus. Eight patients were operated during the follow-up period. Five patients who had been previously operated with an HTO underwent a plate removal procedure in the follow-up period. Three patients needed a new surgery to remove the scaffold. Those 3 scaffolds presented no signs of meniscal tissue in-growth.

Functional scores are summarized in Table 2. The KOOS, IKDC, and Lysholm scores significantly improved at the last follow-up. However, the Tegner score showed no differences at that time. Patient satisfaction with the procedure scored a mean of 3.3 (95% CI, 3.13-3.47) (range 2-4).

MRI at baseline and at the last of follow-up was performed on 19 of the 32 patients (60%) included in the study. The remaining patients either rejected or did not consent to having an MRI at that moment. Sixteen of the 19 postoperative MRIs showed a mean 2.4 mm (95% CI, 1.12-3.68) of scaffold extrusion after 5 years of follow-up. Complete reabsorption of the meniscal scaffold was observed in the other 3 cases. With regard to the MRI scaffold shape and morphology, these 3 cases were classified as Genovese type I. The other 16 cases were classified as type IIb. Relative to MRI signal intensity, 4 patients showed isointensity (Genovese type III), 2 cases markedly hyperintensity (type I), and the remaining 10 patients presented a slight hyperintensity (type II) of the scaffold.

The TMV estimate was 1.14 cm^3 (95% CI, 0.96-1.31) before surgery (meniscal remnant), whereas it was 1.61 cm^3 (95% CI, 1.43-1.79) at the last follow-up (n.s.). Figure 2 shows an arthroscopic image of the meniscal tissue observed 4 years after scaffold implantation. It is possible to observe the incomplete in-growth of new meniscus-like tissue in the polyurethane scaffold.

Discussion

The main finding of this study was the degree polyurethane meniscal scaffold resorption observed at a minimum 5-year follow-up. The small, statistically nonsignificant increase in meniscal tissue (in terms of volume) and the incomplete in-growth of new meniscus-like tissue promoted by the scaffold (as measured by the Genovese score) affirmed that finding. Therefore, these data do not support our main hypothesis. Secondarily, good functional outcomes were observed after implantation of a polyurethane scaffold at a minimum of 5 years of follow-up. That finding confirms the second hypothesis of the study.

Dhollander et al.[13] investigated a large series of patients who had a polyurethane scaffold implanted due to a symptomatic partial meniscus defect at a minimum 5-year follow-up. Similar to our results, the clinical outcomes were rated as good. In that series, the greatest improvement was achieved during the first 2 years postoperatively[24] and most of the scores stayed at the same level afterward. Schüttler et al.[14] also reported the results of a series of 18 medial polyurethane scaffolds with a minimum of 2 years of follow-up. They found improvements in functional outcomes, compared with baseline, in all but 1 patient. Similarly, the activity level did not improve beyond 2 years after the index surgery. Some other authors have also reported great clinical improvement with this scaffold in the short-term follow-up,[16,18,26] even in cases of advanced cartilage injuries.[17]

Interestingly enough, these results were comparable to those reported for the CMI scaffold at similar follow-up periods.[27-29] Although the polyurethane implant has been available for a shorter period of time, there are already long-term follow-up studies reporting favorable outcomes with the use of the CMI.[8,9,30]

Scaffold morphology and the MRI aspect were assessed with the Genovese score.[23] In all but 3 cases, the shape of the new meniscal tissue showed decreased volume and an irregular shape at the 5-year follow-up. In the remaining 3 cases, the scaffold was completely reabsorbed. These results are similar to those found in the Dhollander et al. study, in the Leroy et al. polyurethane scaffold studies,[13,31] as well as in those observed in a systematic review of the CMI scaffold at 5- and 10-year follow-ups.[32] In all these series, most of the scaffolds were classified as Genovese type IIb, which

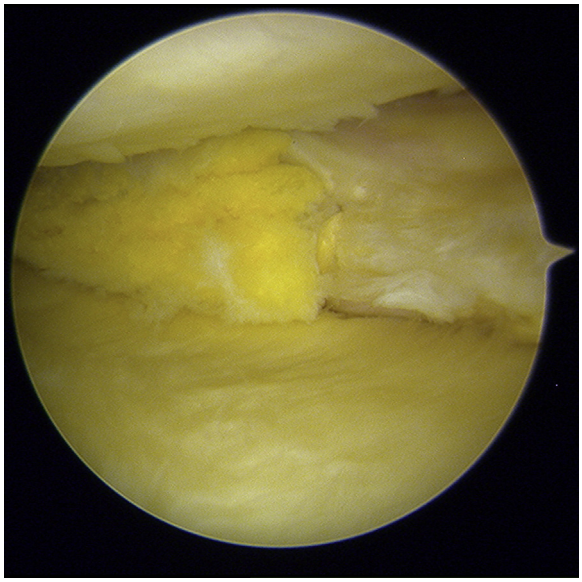

Fig 2. An arthroscopic image of a new meniscus tissue obtained 4 years after polyurethane scaffold implantation. The image corresponds to a medial meniscus of a left knee viewed from the anterolateral portal.

correspond to scaffolds with a decrease in size and with an irregular shape. However, this type of grading would include a wide range of meniscus-like tissue. In an effort to further refine these common findings, a volumetric assessment of the new meniscal tissue was also performed. This type of MRI measurement was first introduced by Narvy et al.[25] They aimed to categorize the meniscus size in noncadaveric knees. The TMV obtained (scaffold plus remnant meniscus) at the final follow-up was not significantly superior to the one observed before scaffold implantation. These data objectively define that the type IIb meniscus observed in the present series was closer to a situation of reabsorbed scaffold rather than a normal meniscus, which also questions the utility of the Genovese score to grade meniscal shape and size. This scale has also been questioned by a previous study of the CMI scaffold.[33]

The Genovese score was also used to assess the signal intensity of the new meniscal tissue. Dhollander et al.[13] observed that 60% of the cases showed a hyperintensity of the scaffold (type I). In our series, most of the scaffolds were rated as type II (slightly hyperintense) and only 2 cases showed marked signal hyperintensity. In the systematic review of the MRI evaluation of CMI series at 5 years after index surgery, Zaffagnini et al.[34] observed that 55.6% of the scaffolds were rated as type II, 11.1% as type I, and only 33.3% had a similar MRI intensity (type III) to a normal meniscus. However, at 10-year follow-up, the number of CMI scaffolds showing a normal Genovese type III (isointense) signal decreased to 11.1%. Although the collagen scaffold did not mature rapidly and the remodeling process was slow in the period up to the 5-year follow-up, the 10-year results showing a worse MRI aspect suggest a possible degenerative process of the scaffold at work. In the case of the polyurethane scaffold, the maturation process lasts around 5 years. It is due to the long policaprolactone resorption process.[12] Thus, the quality and amount of meniscal tissue observed at this moment should be definitive. To sum up, the MRI study of these scaffolds at the minimum 5-year follow-up showed a small increment in the amount of meniscal tissue. Furthermore, this scaffold is partially extruded and its radiological appearance is not as it initially seems.

Limitations

The present investigation had several limitations. There was no control group and the sample size was small even though it is comparable to previously published series. The fact that just 60% of patients consented to an MRI at the last follow-up is another limitation. An important limitation is that the series included patients who underwent concomitant procedures to address not only their meniscal problems but also concurrent deficiencies. This is an obvious and important limitation that makes a more accurate assessment of the scaffold implantation difficult because combined procedures introduce a degree of performance bias into the results. Finally, the fact of not studying cartilage status with the MRI and the fact of not including different observers to test inter-rater reliability in the MRI analysis can also be considered limitations.

Conclusions

The use of a polyurethane meniscal scaffold in patients with a symptomatic meniscus deficit leads to a good functional outcome at 5 years after surgery. However, implanted scaffolds do not show normal meniscal tissue with MRI and the implant volume is considerably less than expected. The fact that most of patients included received different concomitant procedures during scaffold implantation introduces a degree of performance bias into the results.

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