Polyurethane Meniscal Scaffold for the Treatment of Partial Meniscal Deficiency: 5-Year Follow-up Outcomes

A European Multicentric Study

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Background: A biodegradable polyurethane scaffold was developed to treat patients with the challenging clinical condition of painful partial meniscal defects.

Hypothesis: The use of an acellular polyurethane scaffold in patients with symptomatic partial meniscal defects would result in both midterm pain relief and improved function.

Study Design: Case series; Level of evidence, 4.

Methods: A total of 155 patients with symptomatic partial meniscal defects (101 medial and 54 lateral) were implanted with a polyurethane scaffold in a prospective, single-arm, multicentric study with a minimum 5-year follow-up. Clinical outcomes were measured with the visual analog scale for pain, International Knee Documentation Committee subjective knee evaluation form, Lysholm knee scale, and Knee injury and Osteoarthritis Outcome Score at baseline and at 2- and 5-year follow-ups. Magnetic resonance imaging (MRI) was used to evaluate the knee joint, meniscal implant, and meniscal extrusion. Kaplan-Meier survival analysis was also performed. Removal of the scaffold, conversion to a meniscal transplant, and unicompartmental/total knee arthroplasty were used as endpoints.

Results: Eighteen patients were lost to follow-up (11.6%). The patients who were included in this study showed significant clinical improvement after surgery as indicated by the different outcome measures (P = .01). However, the clinical improvement tended to stabilize between 2 and 5 years of follow-up. MRI scans of the scaffolds in 56 patients showed a smaller-sized implant in the majority of the cases when compared with the native meniscus with an irregular surface at the 5-year follow-up. During the follow-up period, 87.6% of the implants survived in this study. At 5 years of follow-up, 87.9% of the medial scaffolds were still functioning versus 86.9% of the lateral scaffolds. In total, 23 treatments had failed: 10 removed scaffolds because of breakage, 7 conversions to meniscal allograft transplantation, 4 conversions to unicompartmental knee arthroplasty, and 2 conversions to total knee arthroplasty.

Conclusion: The polyurethane meniscal implant was able to improve knee joint function and reduce pain in patients with segmental meniscal deficiency over 5 years after implantation. The MRI appearance of this scaffold was different from the original meniscal tissue at the midterm follow-up. The treatment survival rates of 87.9% of the medial scaffolds and 86.9% of the lateral scaffolds in the present study compared favorably with those published concerning meniscal allograft transplantation after total meniscectomy.

Keywords: knee; meniscus; scaffold; polyurethane; partial meniscectomy; meniscal reconstruction

Meniscal tears are a frequent injury and a common reason for proceeding to a knee arthroscopy. At the present time, the treatment of a meniscal lesion is the most common orthopaedic surgical procedure. More than 1 million meniscal interventions are annually performed in the United States and approximately 400,000 in Europe.[39]

The menisci are semilunar, fibrocartilaginous structures. They preserve a well-functioning, pain-free knee by playing a pivotal biomechanical function, including load bearing, load and force distribution between the femoral condyles and tibial plateau, lubrication, proprioception, and joint stabilization.[9,27]

Damage to the meniscus or loss of meniscal tissue increases contact stress to the underlying chondral

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surface.[21,24] Loss of meniscal function increases the risk of premature degeneration of the articular cartilage and is a common cause of secondary osteoarthritis.[7,8,14]

Over the past few decades, there has been a shift from meniscal resection to meniscal preservation.[25,30] Meniscal repair is now the preferred treatment.[24,34,44] However, this is often not feasible, especially for those tears located in the avascular portion of the meniscus. Partial meniscectomy is the current standard of care for such irreparable symptomatic lesions. Partial meniscectomy results in a favorable outcome in the short term. However, the risk of developing osteoarthritis over the long term remains.[7,8]

As a result, the concept of meniscal regeneration has become very appealing. This concept requires the physical presence of a scaffold to allow successful migration and colonization with precursor cells and vessels, and finally, this all could result in the formation of organized meniscal tissue.[26,28,36,37,41]

Recently, there has been an increasing interest in the application of artificial meniscal scaffolds for the treatment of segmental meniscal deficiency because of promising clinical and radiological outcomes.[10] A biodegradable, synthetic acellular scaffold composed of aliphatic polyurethane (Actifit; Orteq Ltd) was developed to treat patients with symptomatic, irreparable, partial meniscal lesions. The goal of the scaffold is to provide symptom relief and restore lost meniscal function. Two configurations of this meniscal implant are available: 1 for the medial meniscus and 1 for the lateral meniscus. The structure is highly porous to allow tissue ingrowth. In theory, this approach could reduce the risk of future osteoarthritis.

The safety and feasibility of this meniscal scaffold have already been demonstrated.[6,39] Early results have proven the beneficial effects of the implant with regard to knee function, pain reduction, and restoration of activity levels.[1,20,30-32,39]

The goal of this European multicenter study was to report the midterm clinical and survival outcomes in patients treated with a polyurethane scaffold for meniscal deficiency with a minimum 5-year follow-up. We hypothesized that applying an acellular polyurethane scaffold in patients with symptomatic partial meniscal defects would result in both midterm pain relief and improved function.

METHODS

Study Population

Patients with partial meniscal defects or irreparable meniscal tears (tears not suitable for suturing) of either the lateral or medial meniscus were enrolled in the study. Patients who smoked or had workers' compensation cases were also included. All patients had meniscal symptoms (pain and tenderness at the joint line) and had undergone adequate debridement of the meniscal defect in a standard arthroscopic procedure, followed by implantation of the scaffold during the same procedure. Clinical experimentation was approved by the ethics committee of the 6 involved centers, and informed consent to participate in the study and to comply with the postoperative regimen was obtained from all patients.

The key study inclusion criteria were (1) an irreparable medial or lateral meniscal tear (tear not suitable for suturing) or partial meniscal loss with an intact rim, (2) skeletally mature male or female patients, (3) age from 18 to 55 years, (4) stable knee joint or a joint that was stabilized within 12 weeks before surgery, (5) International Cartilage Repair Society (ICRS) classification $\leq$3, (6) willingness and ability to give consent to participate in the clinical study and follow the rehabilitation protocol, and (7) no more than 3 surgeries on the involved meniscus. The key exclusion criteria were (1) total meniscal loss or an unstable segmental rim defect, (2) a meniscus root tear, (3) multiple areas of unilateral partial meniscal loss that could not be treated by a single scaffold, (4) ICRS classification $>$3, (5) body mass index $>$35 kg/m^2, and (6) untreated tibiofemoral malalignment. If the varus/valgus angle exceeded 5°, osteotomy was performed.

In total, 164 patients were treated consecutively in 6 centers. The minimum follow-up time was 5 years. Nine patients were excluded for analysis. Four of them were $>$55 years at the time of surgery, and 5 had a too short of a follow-up period at the time of this analysis. Thus, 155 patients (109 men, 46 women) were included.

Of the treated meniscal defects, 101 were located on the medial side and 54 on the lateral side. The peripheral edge of the lesion defect had a mean size of 39.4 $\pm$ 10.5 mm. The mean age of the patients was 33.7 $\pm$ 10.4 years.

In 141 of the 155 patients, previous partial meniscectomy was performed, and the patients had postmeniscectomy pain. In these 141 patients, the scaffold was implanted during subsequent arthroscopic surgery. In 14 of the 155 patients, the scaffold was used because of an irreparable meniscal tear (tear not suitable for suturing) and implanted during the index arthroscopic procedure. Associated procedures were performed in 68 patients (44.0%): 43 (28.0%) high tibial osteotomies (HTOs), 29 (19.0%) anterior cruciate ligament (ACL) reconstructions, and 6 (4.0%) microfracture procedures. Preoperatively, all patients underwent a full-length weightbearing radiograph. If the varus/valgus angle exceeded 5°, osteotomy was performed.

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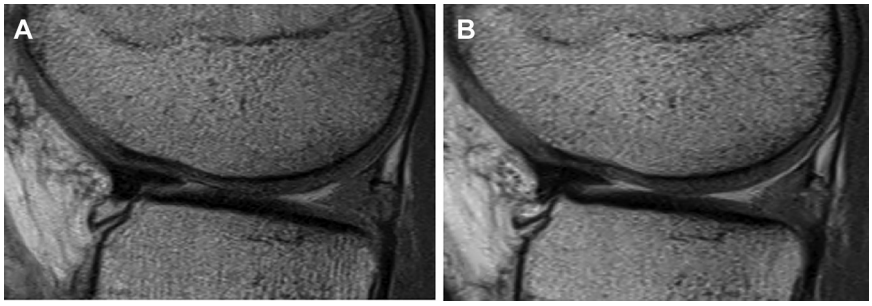

Figure 1. Sagittal proton density– and T2-weighted turbo spin echo image on a 3.0-T magnetic resonance unit at (A) 2 years and (B) 5 years of follow-up. Both pictures show the presence of the scaffold in the posterior horn of the lateral meniscus and the maintenance of the intact surrounding cartilage surface. The Genovese score was type IIb for morphology and type II for signal intensity.

Surgical Procedure

The surgical procedure and rehabilitation protocol were identical to those published previously.[38,41] Briefly, all patients underwent arthroscopic partial meniscectomy with surgical debridement back to the vascularized zone of the damaged portion of the meniscus. The resulting defect was measured for sizing of the implant along the peripheral edge using a commercially available ruler guide and ruler supplied with the implant. The scaffold was cut to fit with an oversizing of 10%. Then it was introduced into the knee joint through the anteromedial or anterolateral portal using a blunt-nosed grasper and sutured to the native meniscus. Depending on the area to be sutured and the surgeon's preference, all-inside, inside-out, or outside-in sutures were used. In most of the cases, 2 all-inside sutures were placed to fix the posterior part of the scaffold (FasT-Fix; Smith & Nephew), and 2 inside-out sutures were used for the anterior part (Orthocord; DePuy). To provide optimum conditions during the tissue healing and maturation process after implantation, all patients were required to follow a standardized rehabilitation protocol for 16 to 24 weeks. The rehabilitation protocol allowed no weightbearing until week 4, after which patients were allowed to begin partial weightbearing, which was gradually increased to full weightbearing at week 9. A gradual return to sports was allowed beginning 6 months after the index surgery. Patients were assessed preoperatively and at 2 and 5 years after the index surgery.

Clinical Evaluation

Patients were clinically and prospectively evaluated with use of the Knee injury and Osteoarthritis Outcome Score (KOOS), the Lysholm knee scale, the International Knee Documentation Committee (IKDC) subjective knee evaluation form, and the visual analog scale (VAS) for pain preoperatively and at 2- and 5- year follow-ups.[3,11,16,19,29] Eighteen patients (11.6%) were lost to follow-up: 5 (3.2%) at 2 years and 13 (8.4%) at 5 years. Outcome data of 137 patients (88.4%) were available for analysis.

MRI Evaluation

Magnetic resonance imaging (MRI) examinations were performed at the 5-year follow-up. MRI data of 56 patients (49.1%) were available for analysis. The imaging parameters of the sequences were similar to those published previously[39,42] (Figure 1). The scaffold was described according to Genovese et al,[12] evaluating the morphology and size of the scaffold (type I: totally resorbed scaffold; type II: small scaffold with regular and/or irregular shape; type III: scaffold with identical size and shape to the normal meniscus) as well as the signal intensity of the scaffold (type I: markedly hyperintense; type II: slightly hyperintense; type III: isointense relative to the normal meniscus). Extrusion (mm) of the meniscal scaffold was also evaluated using MRI 5 years postoperatively. We used the same method as described previously.[4] MRI was also carried out to monitor any adverse changes to the articular cartilage, in particular in the index compartment. The articular cartilage was assessed using the ICRS cartilage scoring system, which provides a measure of the cartilage status and lesion depth at each MRI follow-up.[2,18]

Statistical Analysis

All data are expressed as means ± SDs. The paired t test was used to measure the differences between the preoperative and postoperative findings. The unpaired t test was used to analyze the differences between subgroups. $P < .05$ was considered statistically significant. A Kaplan-Meier survival analysis was also performed. We used removal of the scaffold, conversion to a meniscal transplant, and unicompartmental/total knee arthroplasty as endpoints. Those lost to follow-up were excluded from the survival analysis. The log-rank test and the Breslow test were used to compare survival analysis of the medial

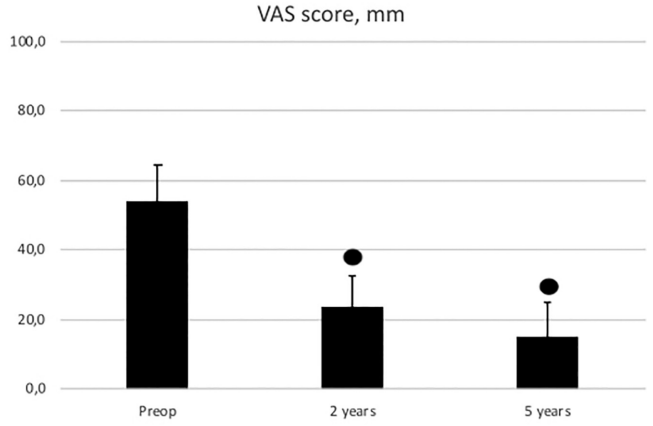

Figure 2. Mean values (in mm) of the visual analog scale (VAS) for pain preoperatively (Preop) and at 2 and 5 years postoperatively (n = 114). Error bars represent SDs. The black dots indicate statistically significant differences ($P < .05$) between the preoperative and postoperative values.

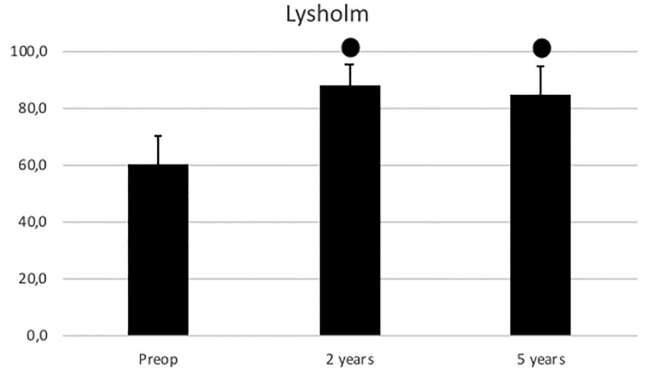

Figure 3. Mean values of the Lysholm knee scale preoperatively (Preop) and at 2 and 5 years postoperatively (n = 114). Error bars represent SDs. The black dots indicate statistically significant differences ($P < .05$) between the preoperative and postoperative values.

and lateral scaffolds. Statistical analyses were performed using IBM SPSS Statistics version 21 (IBM Corp).

RESULTS

Clinical Outcomes

During the follow-up period, the VAS scores for pain and Lysholm knee scale scores indicated by the patients improved significantly (Figures 2 and 3). The differences between the preoperative and postoperative (2 and 5 years) values were statistically significant ($P < .05$). In general, all KOOS subscale scores improved statistically significantly in the postoperative period (Figure 4). According to the IKDC subjective scores, a significant improvement

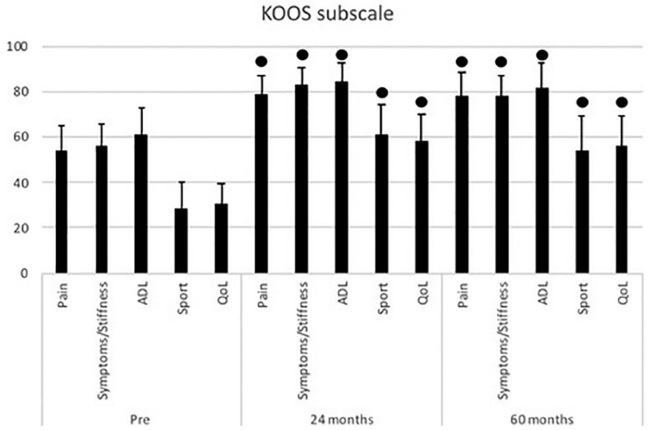

Figure 4. Mean values of the Knee injury and Osteoarthritis Outcome Score (KOOS) subscales preoperatively and at 2 and 5 years postoperatively (n = 114). Error bars represent SDs. The black dots indicate statistically significant differences ($P < .05$) between the preoperative and postoperative values. ADL, Activities of Daily Living; QoL, Quality of Life.

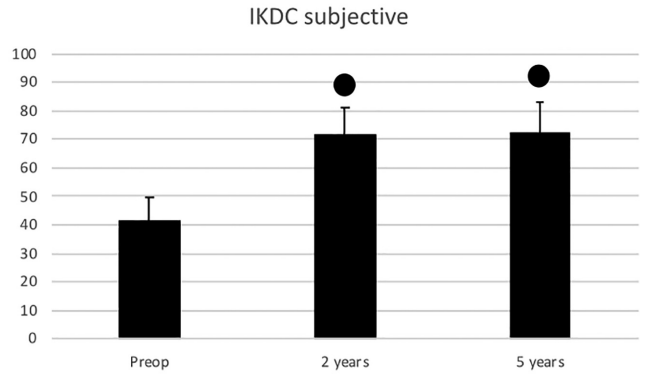

Figure 5. Mean values of the International Knee Documentation Committee (IKDC) subjective knee form preoperatively and at 2 and 5 years postoperatively (n = 114). Error bars represent SDs. The black dots indicate statistically significant differences ($P < .05$) between the preoperative and postoperative values.

became apparent during the follow-up period ($P < .05$) (Figure 5).

Clinical outcomes were stable between 2 and 5 years of follow-up. Clinical outcome data of 114 patients were available for analysis. All clinical outcome scores, as well as P values of the comparison between preoperative and postoperative scores, are given in Table 1.

Subgroup Analysis

Clinical outcomes at 2 and 5 years of follow-up were compared between patients who received a medial implant

TABLE 1
Clinical Scores Preoperatively and at 2- and 5-Year Follow-ups (n = 114)[a]

	Preoperative	2-Year	5-Year
VAS for pain	54.0 ± 20.7	23.7 ± 17.2	15.2 ± 19.2
Lysholm	60.5 ± 19.6	88.1 ± 14.3	84.5 ± 20.1
IKDC subjective	41.8 ± 16.3	71.5 ± 19.0	72.3 ± 21.4
KOOS subdomains			
Pain	54.2 ± 22.0	78.8 ± 17.4	78.4 ± 21.3
Symptoms	56.0 ± 19.7	83.0 ± 15.6	78.2 ± 19.5
ADL	61.2 ± 24.0	84.7 ± 16.3	82.1 ± 21.0
Sports	28.5 ± 24.0	61.3 ± 26.6	53.9 ± 31.4
QoL	30.9 ± 16.7	58.6 ± 23.2	56.2 ± 26.4

[a]Data are presented as mean ± SD. All scores were statistically significantly different compared with preoperatively (P = .01 for all). ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; QoL, Quality of Life; VAS, visual analog scale.

TABLE 2
Different Clinical Outcome Scores 5 Years Postoperatively Comparing Medial Versus Lateral Meniscal Scaffolds[a]

	Medial (n = 73)	Lateral (n = 41)	P Values
VAS for pain	15.7 ± 19.9	14.1 ± 18.2	.39
Lysholm	86.6 ± 19.8	78.4 ± 10.1	.14
IKDC subjective	72.3 ± 20.7	72.4 ± 19.4	.49
KOOS subdomains			
Symptoms	80.9 ± 16.5	72.5 ± 13.7	**.04**
Pain	76.3 ± 19.6	81.5 ± 12.5	.20
ADL	79.5 ± 19.1	85.9 ± 10.3	.14
Sports	50.7 ± 28.2	58.8 ± 19.8	.18
QoL	53.4 ± 22.2	60.6 ± 23.0	.17

[a]Data are presented as mean ± SD. Boldface type indicates statistical significance. ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; QoL, Quality of Life; VAS, visual analog scale.

versus those who received a lateral implant. No statistically significant differences in clinical outcomes were observed between the 2 groups at each time point, except for KOOS Symptoms at 5 years of follow-up (Table 2).

The same was done for patients who underwent an HTO versus those without an HTO. Again, no statistically significant differences in clinical outcomes were observed between the 2 groups at each time point (Table 3).

Finally, the same was done between patients who underwent an ACL reconstruction versus those without an ACL reconstruction. Interestingly, at 2 years of follow-up, there was no significant difference between groups, but at 5 years, significant differences were noticed in favor of an ACL reconstruction (Table 4). More specifically, the VAS, Lysholm, and KOOS Symptoms scores were significantly better in the ACL reconstruction group.

TABLE 3
Different Clinical Outcome Scores 5 Years Postoperatively Comparing Patients Who Underwent an HTO Versus Those Without an HTO[a]

	HTO (n = 22)	No HTO (n = 92)	P Values
VAS for pain	15.9 ± 17.2	15.2 ± 19.9	.44
Lysholm	83.5 ± 19.3	85.6 ± 21.5	.37
IKDC subjective	75.2 ± 19.5	71.3 ± 22.3	.24
KOOS subdomains			
Symptoms	78.8 ± 18.6	78.0 ± 20.1	.44
Pain	75.9 ± 18.1	79.0 ± 22.2	.34
ADL	78.8 ± 16.8	82.9 ± 22.1	.29
Sports	58.0 ± 24.4	52.9 ± 33.1	.32
QoL	54.5 ± 22.0	56.7 ± 12.1	.41

[a]Data are presented as mean ± SD. ADL, Activities of Daily Living; HTO, high tibial osteotomy; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; QoL, Quality of Life; VAS, visual analog scale.

TABLE 4
Different Clinical Outcome Scores 5 Years Postoperatively Comparing Patients Who Underwent an ACL Reconstruction Versus Those Without an ACL Reconstruction[a]

	ACL (n = 27)	No ACL (n = 87)	P Values
VAS for pain	6.7 ± 14.8	17.9 ± 19.8	**.03**
Lysholm	96.3 ± 5.7	81.7 ± 21.7	**.03**
IKDC subjective	79.3 ± 15.0	70.6 ± 22.7	.07
KOOS subdomains			
Symptoms	90.7 ± 14.8	75.2 ± 19.5	**.01**
Pain	86.5 ± 14.0	77.3 ± 22.0	.16
ADL	90.7 ± 12.4	80.9 ± 21.8	.14
Sports	59.2 ± 39.3	53.2 ± 30.6	.33
QoL	64.5 ± 30.8	55.1 ± 25.9	.21

[a]Data are presented as mean ± SD. Boldface type indicates statistical significance. ACL, anterior cruciate ligament; ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; QoL, Quality of Life; VAS, visual analog scale.

MRI Evaluation

The Genovese score showed a type II scaffold in the majority (80.3%) of the patients, representing a smaller-sized scaffold compared with the native meniscus with an irregular surface at 5 years of follow-up. At the same time point, the signal intensity of the implants was significantly different from that of the residual meniscal tissue in all of the patients, representing a Genovese type I (markedly hyperintense) score in 26.8% of the patients and a Genovese type II (slightly hyperintense) score in 73.2% of the patients (Table 5). The mean radial displacement (extrusion) of the meniscal scaffolds evaluated using MRI 5 years postoperatively was 3.0 ± 1.2 mm.

TABLE 5
Percentage of Patients With Type of Genovese Score at 5 Years Postoperatively (n = 56)

	Signal	Morphotype
Type 1	26.8	10.7
Type 2	73.2	80.3
Type 3	0.0	9.0

A stable cartilage status of the index compartment at the 5-year follow-up was demonstrated in 62.1% of the patients compared with the baseline status.

Survival Analysis

Data from all 137 patients were available for the Kaplan-Meier survival analysis. This analysis revealed a mean overall survival of the meniscal scaffold of 92.1% ± 2.2% at 2 years and 87.6% ± 2.7% at 5 years of follow-up (Figure 6).

The medial implants had a mean survival of 88.9% ± 3.1% at 2 years and 87.9% ± 3.2% at 5 years of follow-up. The lateral scaffold had a mean survival of 96.1% ± 2.7% at 2 years and 86.9% ± 4.8% at 5 years of follow-up (Figure 6).

In total, 23 treatments failed: 10 removed scaffolds because of breakage, 7 conversions to meniscal allograft transplantation, 4 conversions to unicompartmental knee arthroplasty, and 2 conversions to total knee arthroplasty.

DISCUSSION

The most important finding of this large multicentric study was the good midterm clinical outcomes of the polyurethane meniscal implant. Our hypothesis was confirmed. Moreover, functional outcomes were stable over time. One has to consider that this implant was developed to treat patients with partial meniscal loss in an otherwise stable and normally aligned knee with an intact cartilage surface.

Several authors have observed similar findings. In a previous study reporting on the first in vivo experience in 44 patients at a single center, Dhollander et al[5] concluded that the polyurethane meniscal implant can improve knee joint function and significantly reduce pain in patients with segmental medial meniscal deficiency up to 5 years after implantation. Monllau et al[23] stated that the use of a polyurethane meniscal scaffold in 32 patients with a symptomatic meniscal deficit had a good functional outcome at 5 years after surgery. Schüttler et al[30] showed that arthroscopic treatment for 18 patients with chronic segmental meniscal loss using a polyurethane meniscal implant can achieve sustainable midterm results regarding pain reduction and knee function. Leroy et al[22] observed stable functional scores at this time in 15 patients. In general, one can state that this type of meniscal implant results in favorable clinical outcomes at midterm follow-up. Longer-term data for this polyurethane scaffold are currently not available.

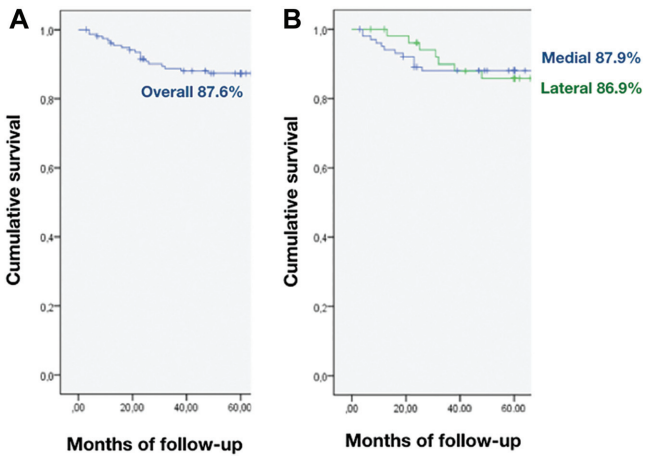

Figure 6. Kaplan-Meier cumulative survival plots. (A) Overall survival analysis. (B) Medial versus lateral implant survival analysis.

The Collagen Meniscus Implant (CMI; Ivy Sports Medicine) is another meniscal scaffold used for treating partial meniscal defects. It is a collagen implant and compares well to the polyurethane implant in terms of indications for use and surgical procedure of implantation. Clinical data of the collagen scaffold were summarized by Grassi et al[13] and are available for a follow-up period between 6 months and 10 years. They concluded that the CMI produced good and stable clinical results. Houck et al[17] published a systematic review evaluating the current literature concerning clinical outcomes after meniscal scaffold implantation using the 2 available scaffolds. They stated that patients undergoing meniscal scaffold implantation with either CMI or the Actifit scaffold can be expected to experience improvement in clinical outcomes. Therefore, one could state that the midterm clinical results of the polyurethane scaffold are similar to those of the CMI. A comparison of clinical outcomes between the medial and lateral polyurethane scaffolds was also made in this study. No significant differences were found. The same was seen with the CMI scaffold. No noticeable differences were present comparing short-term values of the Lysholm score between medial and lateral CMIs.[13]

An associated procedure was performed in 44.0% of the patients included in this study. The majority (28%) of those procedures were HTOs. Identical findings were seen in the published CMI outcome studies, whereas concomitant procedures were present in 48.8% of patients.[13] In the present study, we analyzed whether there was a difference in clinical outcomes in patients who also underwent an HTO or not at the time of the meniscal implant procedure. Again, no noticeable differences were observed at the midterm follow-up. This is somewhat contradictory to the report of Houck et al[17]; they stated that the presence of concomitant surgery, such as an HTO, may have a significant positive influence on the outcome of meniscal implants. Interestingly, this study found a significant difference in clinical outcome in favor of patients who underwent an ACL reconstruction

versus those without an ACL reconstruction at 5 years of follow-up. Houck et al did not notice a significant difference between these 2 groups.

In the current study, we evaluated the scaffold morphology and intensity according to the Genovese system.[12] We observed a scaffold with a still increased signal intensity and a reduction in size compared with the normal meniscus in the majority of the cases. This is in line with the MRI outcomes presented by Leroy et al,[22] Schüttler et al,[30] and Monllau et al.[23] The latter authors observed that in 3 patients, the scaffolds were even completely resorbed at the last follow-up.[23] Therefore, one can state that this study confirms the fact that the MRI appearance of this scaffold is different from the original meniscal tissue at midterm follow-up and that we can somewhat concur with the findings of Houck et al.[17] They published that patients receiving CMI scaffolds had higher grades for Genovese morphology and signal intensity when compared with patients with Actifit scaffold. Extrusion of the polyurethane meniscal implant was also evaluated using MRI at 5 years postoperatively. We had a mean extrusion of 3.0 mm. Leroy et al[22] found a correlation between the amount of extrusion preoperatively and postoperatively. When more extrusion was present preoperatively, more extrusion was observed postoperatively. Therefore, one could assume that the existence of preoperative extrusion may be considered a contraindication for the implantation of a polyurethane meniscal scaffold.[22] Limited data are available concerning the amount of extrusion after CMI. In a study of 76 patients followed for 12 months postoperatively, the collagen implant was extruded by >3 mm (72%).[15] Extrusion of meniscal allograft transplant is a common MRI finding, with most studies reporting either a mean extrusion of >3 mm or the majority of allografts classified as "extruded" or "major extrusion."[35] At first sight, no obvious differences are seen between the 2 different meniscal implants and meniscal allograft transplants concerning extrusion using MRI. However, more studies are needed on this subject.

During the follow-up period, 87.6% of the implants survived in this study. At final follow-up, 87.9% of the medial scaffolds were still functioning versus 86.9% of the lateral scaffolds. A slightly higher failure rate for patients with a lateral scaffold was observed. Moreover, the survival rate of medial implants was stable over time, while those of the lateral implants decreased between 2 and 5 years of follow-up. However, this was not unexpected, as the lateral meniscus can be viewed as the more challenging application. Higher stresses are observed on the lateral plateau; the lateral meniscus has been shown to carry 70% of the load in the lateral compartment, whereas the medial meniscus carries only 50% of the load in the medial compartment.[33,43]

In this study, failure occurred in 16.8% (n = 23) of the 137 patients at the 5-year follow-up. Houck et al[17] found treatment failure in 9.9% of patients receiving the Actifit scaffold at a mean follow-up of 40 months and 6.7% of patients receiving CMI at a mean follow-up of 44 months. However, the rate of failure ranged from 0% to 31.8% among the included studies with a variable definition of failure. Therefore, it is impossible to conclude anything concerning the difference in survival between these 2 meniscal implants.

The 5-year treatment survival rates of 87.9% of the medial scaffolds and 86.9% of the lateral scaffolds in the present study are similar to those published concerning meniscal allograft transplantation.[38] Verdonk et al[40] published a survival rate of 86.2% for medial allografts at 5 years and 90.2% for lateral transplants. One can therefore conclude that the midterm survival rate of the polyurethane scaffold is similar with meniscal transplantation but for different indications.[38,40]

This study contains some limitations. First, it has a retrospective design, but the data were prospectively collected. Second, it is a multicenter study, but the indications and exclusion criteria were identical. Third, it must be emphasized that only the survival data in this study were complete (137 patients). One must take into account the loss of clinical and MRI data. Clinical data were available from 114 patients (73.5%) and MRI data from 56 (40.9%). Fourth, the follow-up period was limited to 5 years, no control group was used, and associated procedures were performed in 68 patients (44.0%). However, this study population corresponded to the daily practice of several expert centers. It consisted of a large cohort of patients and allowed a comparison between 2 and 5 years of follow-up.

CONCLUSION

The Actifit polyurethane meniscal implant was able to improve knee joint function and significantly reduce pain in patients with segmental medial meniscal deficiency up to 5 years after implantation. The MRI appearance of this scaffold was different from the original meniscal tissue at midterm follow-up, with a still increased signal intensity, a reduction in size, and an extrusion compared with the normal meniscus in the majority of the cases. The treatment survival rates of 87.9% of the medial scaffolds and 86.1% of the lateral scaffolds in the present study were comparable with those published concerning meniscal allograft transplantation after total meniscectomy.

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