Journal of Clinical Orthopaedics and Trauma 15 (2021) 16–21

Contents lists available at ScienceDirect

Journal of Clinical Orthopaedics and Trauma

journal homepage: www.elsevier.com/locate/jcot

Meniscal polyurethane scaffold plus cartilage repair in post meniscectomy syndrome patients without malalignment improves clinical outcomes at mid-term follow-up

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ARTICLE INFO

Article history:
Received 10 October 2020
Received in revised form
3 November 2020
Accepted 10 November 2020
Available online 14 November 2020

Keywords:
Actifit
Meniscal
Implant
Scaffold
Polyurethane

ABSTRACT

Background: The aim of this study is to report the mid-term follow-up results of a prospective cohort of patients who underwent a polyurethane (PU) meniscal scaffold implantation for post meniscectomy syndrome (PMS), without limb realignment procedures.

Methods: Prospective study in patients with PU meniscal scaffolds implanted during 2014–2016. Limb realignment procedures excluded. Clinical outcomes were prospectively evaluated pre-operatively and every year post-operatively using patient-reported outcome scores (KOOS, VAS, Lysholm and IKDC). Post-operative radiologic evaluation was done using 3.0 T magnetic resonance imaging (MRI). Meniscal scaffold extrusion, signal intensity, tibio-femoral cartilage degeneration progression and complications were analyzed.

Results: Fourteen patients with an average age of 25.8 years (range: 17–47) received a PU scaffold (8 lateral and 6 medial). Associated procedures were done in all patients, with an osteochondral allograft transplantation (OAT) being the most common. Mean follow up was 51.6 (range: 39–66) months. Post-operative mean clinical outcomes scores showed significantly improved results compared to the pre-operative scores. Lysholm scores increased from 62.4 to 80.2 ($P = 0.0023$), KOOS from 68.9 to 80 ($P = 0.0083$) and VAS for pain decreased from 5.3 to 3.1 ($P = 0.0024$). Average post-operative IKDC score was 67.7. There were 8 cases of complete extrusion (>3 mm). The mean extrusion value was 4.0 mm (range: 3–6 mm). Three patients showed signs of a ruptured meniscal scaffold. One patient showed progression of the cartilage degenerative process.

Conclusion: The use of a PU scaffold, associated with other surgical procedures in the knee, especially chondral repair, had a significant improvement in clinical outcomes compared to the baseline status, at an average of 51.6 months follow-up in patients suffering from PMS. Although imaging results show a high proportion of implant extrusion, this does not appear to imply a worsening in clinical outcomes in the short term.

Level of evidence: IV. Case series.

1. Introduction

Higher levels of participation in sports in young patients have led to an increase in the incidence of acute meniscal tears in this population. An important number of these patients are treated with a partial meniscectomy because of irreparable tears.[1] Even though this procedure leads to rapid symptomatic relief and early return to sports, there is evidence that this causes higher peak stresses on the articular surface and early osteoarthritis (OA) in the knee.[2–4] In addition, a small group of patients can eventually develop uni-compartmental pain after surgery, with or without associated cartilage lesions, a pathology known as post-meniscectomy

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https://doi.org/10.1016/j.jcot.2020.11.006
0976-5662/

syndrome (PMS). Currently, thousands of arthroscopic meniscectomies are performed each year in the young and active population in the United States alone,[5–7] which means that we can expect the number of patients with PMS to increase in the next few years.

Due to all the consequences that a partial meniscectomy can provoke,[8] in the last decade there has been a great interest in meniscal procedures pursuing to restore the native meniscus function and delay early OA. Current available treatment options include allograft meniscal transplantation (MAT), and the use of meniscal scaffolds (MS). MAT has become an accepted option for selected patients with total or sub-total meniscectomy to treat unicompartmental pain and eventually prevent OA.[9] However, several drawbacks exist concerning this alternative, such as its limited availability, high cost, potential infectious disease transmission and lack of evidence whether it can definitely prevent OA in the long term.

Meniscal scaffolds were developed in the last decade as another treatment alternative in patients with partial meniscal defects. Verdonk et al. described a biodegradable polyurethane (PU) meniscal scaffold (Actifit, Orteq Sports Medicine, London, UK).[10] Its objective is to restore the meniscal tissue by providing a structural matrix for cellular ingrowth, therefore avoiding the increase of surface contact pressures in the cartilage and thus preventing early OA in the knee. Initial studies analyzing tissue ingrowth into the scaffold showed vital cells on histological examination and complete integration on second look arthroscopy in 97.7% of the cases at 12 months follow-up.[10] Recent studies with long-term follow-up[11,12] had demonstrated that 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 with high survival rates that are comparable to meniscal allograft transplantation after total meniscectomy.

Despite these favorable results, concerns still exist regarding the biologic response needed to achieve the goal of establishing a biomechanically functioning meniscus or provide an equivalent meniscus substitute. Also, a reasonable doubt has arisen regarding the role of associated procedures (especially limb realignment procedures) in the high survivorship rates reported.[13]

The aim of this study is to report the mid-term follow-up results of a prospective cohort of patients who underwent a PU meniscal scaffold for PMS, without limb realignment procedures. Our hypothesis is that using a meniscal scaffold in this group of patients improves clinical outcomes compared to the preoperative status.

2. Methods

Patients that underwent a PU meniscal scaffold (Actifit®) during the years 2014–2016 were prospectively enrolled in the study if they fulfilled the inclusion and exclusion criteria. The ethics committee of our institution approved this study.

The inclusion criteria were: 1) Skeletally mature male or female patients younger than 50 years old. 2) Symptomatic unicompartmental pain. 3) Partial meniscal loss with intact posterior and anterior horns and an intact peripheral rim. 4) No diffuse chondral damage in the diseased compartment or presence of a focal chondral lesion (smaller than 4.0 cm^2) grade 3 to 4 in the International Cartilage Repair Society (ICRS) classification amenable for surgical repair. 5) Absence of ICRS grade 4 chondral lesions in non-symptomatic compartments. 6) Minimum follow-up of 2 years.

The exclusion criteria were: 1) Limb mechanical axis greater than 2° of varus or valgus as measured in long-length standing x-rays 2) Complete meniscus loss or unstable peripheral rim 3) Meniscal root tear 4) Chondral lesions ICRS grade 3–4 larger than 4.0 cm^2 in the symptomatic compartment. 5) Any chondral lesion ICRS grade 4 in non-symptomatic compartments. 6) Inflammatory diseases 7) Associated multiple ligament injuries.

Implantation of the meniscal scaffold (Fig. 1) was done arthroscopically using a standard arthroscopic technique with an anterolateral and anteromedial portals. Three knee surgeons, who work as a team at our hospital, participated in the surgical procedures in all of the cases. All patients had at least one other associated procedure done concomitantly prior to definitive meniscal scaffold implantation. These included: anterior cruciate ligament (ACL) reconstruction, osteochondral autograft transplantation (OAT) and microfractures (Table 1). After these procedures were done, the native affected meniscus was trimmed to the vascularized zone on the peripheral rim. The defect was measured intraarticularly with a measuring device provided with the scaffold. The implant was cut and shaped to the measured size plus an extra 10% (Fig. 2). After that, it was placed intraarticularly through either the anterolateral or the anteromedial portal and it was sutured to the native meniscus using all inside (Fast-Fix; Smith &Nephew, Andover) and outside-in sutures (Fig. 3). An average of 6 sutures were used on each patient. At the end of the procedure, 6 cc of platelet-rich plasma (GPS III, Biomet-Zimmer, Warsaw Indiana, USA) was injected as a single shot intraarticularly in all patients.

Every patient followed the same standardized rehabilitation protocol. On the first post-operative day physical therapy (PT) was begun and early passive range of motion (ROM) was encouraged using a continuous passive motion device. After hospital discharge, PT was done with the same therapist 3 times a week. Patients were allowed toe-touch weight bearing with two crutches for the first 4 weeks and then gradually progressed to full weight bearing at 8 weeks. A knee brace was applied and locked in 0° extension and 60° flexion for the first 3 weeks and then to 90° of flexion for 3 more weeks. Progressive full ROM was permitted after 6 weeks. Patients were allowed to do swimming, biking, pilates, and other non-impact sports after 12 weeks. Return to high-impact sports such as jogging, field hockey, rugby, football or others was not encouraged.

Functional evaluation was prospectively done by asking patients to fill pre-operatively and after every year post-operatively the following functional score questionnaire's: Knee Injury and Osteoarthritis Outcome Score (KOOS),[14] Lysholm knee scoring scale[15] and visual analog scale (VAS) asked as an average level of pain when they had episodes of pain.[16] International Knee Documentation Committee (IKDC) form was the only questionnaire done

Fig. 1. Polyurethane meniscal scaffold (Actifit, Orteq Sports Medicine, London, UK).

Table 1
Patient population demographics and concomitant surgical procedures done at the time of surgery.

Patient	Age	Sex	Body mass index	Affected compartment (Lateral/Medial)	Concomitant Procedures
1	38	M	28.2	Lateral	OAT, ACL reconstruction
2	22	F	19.0	Lateral	OAT
3	21	F	20.3	Lateral	OAT
4	21	M	27.4	Lateral	OAT, microfracture
5	17	M	22.1	Medial	OAT
6	47	M	23.9	Medial	Microfracture
7	37	M	30.0	Lateral	ACL reconstruction
8	23	M	24.1	Medial	OAT, ACL reconstruction
9	17	F	19.3	Medial	OAT
10	25	M	23.8	Lateral	OAT
11	18	F	22.4	Lateral	OAT
12	29	M	26.5	Medial	OAT
13	20	M	25.8	Medial	ACL reconstruction
14	27	M	28.2	Lateral	OAT

OAT: Osteochondral autograft transplantation.

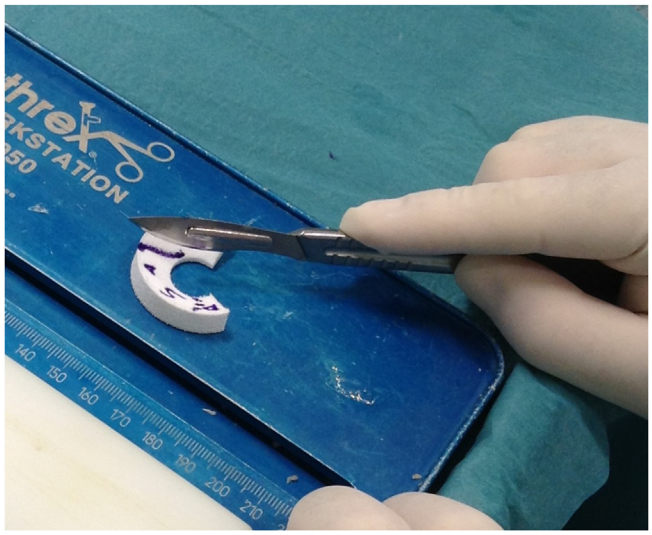

Fig. 2. Trimming of the meniscal scaffold.

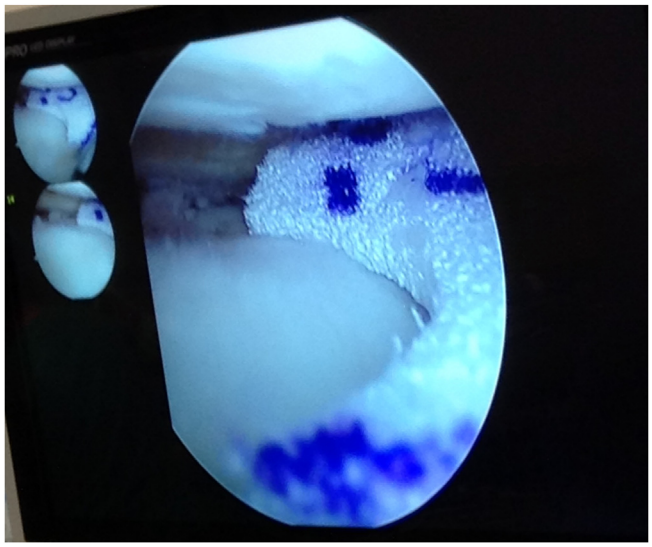

Fig. 3. Arthroscopic view of the meniscal scaffold after implantation.

post-operatively (and not pre-operatively) as it was decided to be included after the first cases were already performed.[17] In every patient we decided to consider only the questionnaire with the longest follow-up to be compared with the pre-operative state.

Magnetic resonance imaging (MRI) was indicated at 6, 12 and 24 months post-operatively in all patients using a 1.5- or a 3.0-T magnetic resonance machine. The images were analyzed with the hospital's imaging software (IMPAX Results Viewer, AGFA Healthcare). Implant integration and extrusion were evaluated. Radial extrusion was assessed on the coronal MRI image in the middle of the anteroposterior distance of the tibial plateau measured on the sagittal MRI image. The distance measured in millimeters was between a line perpendicular to the edge of the articular surface of the tibial plateau and the most peripheral aspect of the meniscal implant. A distance of more than 3 mm was considered a complete extrusion of the meniscal implant.

A senior radiologist blind to the study and two of the authors analyzed overall status of the tibio-femoral cartilage and its degenerative process using the ICRS classification on all available MRIs.

Statistical analysis was performed using the paired Student *t*-test to analyze the mean difference between preoperative and post-operative functional outcome scores. Descriptive statistics were calculated for the rest of the parameters analyzed. The significance level was set at a p value of less than 0.05.

3. Results

Fourteen patients with partial subtotal meniscal defects of either the lateral or the medial meniscus that were surgically treated with a PU scaffold between the years 2014 and 2016 fulfilled the inclusion criteria. There were ten men and four female patients, with a mean age of 25.8 years old (range 17–47). Among them, eight were placed in the lateral compartment and six in the medial compartment. Every patient studied underwent an associated procedure being an OAT the most common accounting for eleven cases. All of them were used to treat an isolated chondral lesion in the same compartment where the meniscal scaffold was placed. There were also four cases of ACL reconstruction, and two microfractures (Table 1).

3.1. Clinical outcomes

Post-operative mean clinical outcome scores showed significantly improved results an average of 51.6 (range: 39–66) months

Table 2
Average post-operative clinical outcome scores obtained pre-operatively and at follow-up.

Functional Scores	Pre − op	3 years	P value
VAS	5.3	3.1	0.0024
Lysholm	62.4	80.2	0.0023
KOOS	68.9	80	0.0083
IKDC	-	67.7	-

follow-up compared to pre-operative scores. Average Lysholm scores increased from 62.4 to 80.2 points (P = 0.0023), KOOS from 68.9 to 80 points (P = 0.0083) and VAS decreased from an average of 5.3 to 3.1 points (P = 0.0024). The mean post-operative IKDC score was 67.7 points. No patient was lost to follow up (Table 2).

3.2. Return to sports

All the patients returned to sports, six of them returned to their previous sports activities despite medical recommendation. Three returned to rugby and three to soccer, all to an amateur level of competition. Of these patients, one had an ACL reconstruction and five had an OAT procedure. None reported any symptoms or issues during activity. The other nine patients remained practicing non-impact sports such as cycling, mountain biking or elliptical machine, and most referred not wanting to return to previous activity because they were aware that the surgery was done as a salvage procedure.

3.3. MRI results

Meniscal scaffold extrusion was seen in all patients on the first MRI. There were eight cases of complete extrusion (>3 mm) and six with partial extrusion (≤3 mm). The mean extrusion value was 4 mm (range: 3–6 mm), with the lateral and medial extrusions averaging 3.8 mm (range 3–5) and 4.3 mm (range: 3–6) respectively (Table 3). All the scaffolds showed a hyperintense signal that clearly distinguished it from the intact meniscus. In the second and third MRIs we noted no change in signal intensity during follow-up.

Three patients showed signs of a ruptured meniscal scaffold during follow-up. All occurred in lateral meniscal scaffolds. The locations of the ruptures were the following: 2 radial ruptures in the corporal zone of the lateral meniscus (Fig. 4) and a partial rupture in the posterior horn of the meniscus. This latter case had non-improvement in clinical outcome scores at final follow-up. The rest were asymptomatic in the affected compartment.

The patient with a partial rupture of the free edge of the posterior horn of the meniscus was the only case in our series that showed progression of the chondral degenerative process, which presented as an increase in size and depth of a tibial plateau chondral lesion seen in previous MRI studies. There were no cases of OAT complications or failures.

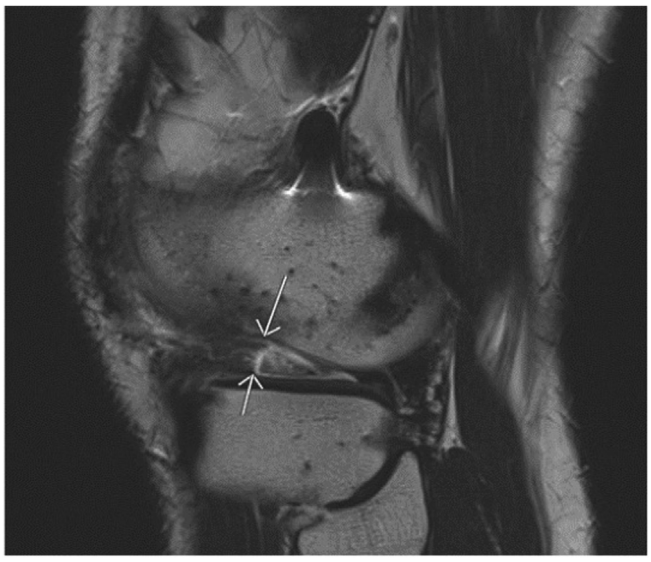

Fig. 4. MRI evaluation. A meniscal implant rupture can be seen on the sagittal view (white arrows).

4. Discussion

The PU scaffold had appeared as a treatment strategy to address PMS in patients with specific indications (presence of anterior and posterior roots, 1 mm rim remaining in the middle portion of the meniscus),[10] and had been used with the objective of obtaining symptomatic relief and a theoretical chondro-protective effect in this subgroup of patients. Recent studies with long-term follow-up[11,12,18] had demonstrated that the PU meniscal scaffold was able to improve knee joint function and reduce pain in patients with segmental meniscal deficiency over 5 years after implantation with high survival rates that are comparable to meniscal allograft transplantation after total meniscectomy. Despite these favorable results, concerns still exist regarding the biologic response needed to achieve the goal of establishing a biomechanically functioning meniscus or provide an equivalent meniscus substitute. Also, a

Table 3
Imaging results and complications at final follow-up.

Patient	Meniscal implant extrusion (mm)	Meniscal implant rupture (Yes/No)	Progression of cartilage degeneration (Yes/No)	Other Complications	Improvement of clinical outcome scores (Yes/No)	Return to previous sports (Yes/No)
1	4	No	No	-	Yes	No
2	3	No	No	-	Yes	Yes
3	5	Yes	Yes	-	No	No
4	4	Yes	No	-	Yes	Yes
5	4	No	No	-	Yes	Yes
6	6	No	No	-	No	No
7	3	Yes	No	-	Yes	Yes
8	3	No	No	-	Yes	No
9	3	No	No	-	Yes	No
10	5	No	No	-	Yes	No
11	3	No	No	-	Yes	Yes
12	6	No	No	-	Yes	Yes
13	4	No	No	-	Yes	No
14	3	No	No	-	Yes	No

reasonable doubt has arisen regarding the role of associated procedures (especially limb realignment procedures)[19] in the high survivorship rates reported.[13] Considering this, we decided to exclude patients with limb realignment procedures from our cohort, to be able to eliminate this confounding factor from the results.

Our study showed a significant improvement in clinical outcomes from baseline with a minimum 3 year follow-up in patients undergoing a PU meniscal scaffold implantation, without limb realignment procedures, most of them including chondral repair procedures. In the same direction, a small proportion of the cases presented progression of the cartilage degenerative process addressed by a two-year follow-up MRI. However, there were a high number of patients that presented imaging alterations, especially meniscal extrusion. In our series, meniscal extrusion occurred in 100% of the cases, with eight of the cases presenting complete extrusion. The mean average value of implant extrusion was similar to other reports in the literature.[20,21] This high rate of imaging alterations in our series is also in concordance to an observation done by Gelber et al.[22] The same authors[23] published inferior results in the most extruded meniscal scaffolds using the (Western Ontario Meniscal Evaluation Tool) WOMET score.[24] The small numbers in our study preclude a specific analysis regarding the results of meniscal extrusion, however, there were two patients that presented no improvement of the clinical outcomes at follow-up, both presenting high meniscal scaffold extrusion values in the follow-up MRI (5 mm and 6 mm).

When analyzing functional results, this study showed that postoperative mean clinical outcome scores improved significantly at a mean 51.6 months follow up compared to pre-operative scores in patients undergoing a PU meniscal scaffold implantation. Many published case series showed similar outcomes.[11,12,25–27] However, most of the patients included in our study required chondral repair procedures as an addition to the PU meniscal scaffold. Gelber et al.[22] described that substitution of the meniscal tissue with a PU scaffold significantly improved pain relief and function regardless of the presence of advanced cartilage injuries after a minimum two-year follow-up. Kon et al.[27] described in their series of 18 patients that those with combined surgery, including cartilage procedures for high-grade lesions, tended to present a slower recovery during the first year, but eventually reached good functional results comparable to the group of patients without combined procedures.

Regarding the chondroprotective effect of the PU scaffold, only one patient presented a progression of the chondral degenerative process in our series. However, a longer follow-up is needed to determine if these results are maintained over time, especially in those patients with significant scaffold extrusion. Shin et al.[28] in their meta-analysis of patients treated with a PU meniscal scaffold, found that articular cartilage status worsened between baseline and final follow-up (7 studies: 5 with follow-up longer than 2 years, 2 studies with follow-up less than 2 years). Nevertheless, in spite of those findings, patients showed significant functional improvement and pain relief when compared with baseline scores.

The main limitations of this study are the small sample size, and the lack of randomization and long-term follow-up. With the high tearing rate (21%) seen in meniscal PU implant in this small cohort, improvement in clinical scores cannot be solely attributed to this procedure. A long-term prospective study with a matching control group without meniscal scaffolds is required to establish clinical efficacy of Meniscal PU implants. On the other side, the main strength of this study is the exclusion of patients that had a combined meniscal scaffold and limb realignment procedures, eliminating the most mentioned confounding factor[19] that has created controversy over the results of meniscal implants.

5. Conclusions

The use of a PU scaffold, associated with other surgical procedures in the knee, especially chondral repair, had a significant improvement in clinical outcomes compared to the baseline status, at an average of 51.6 months follow-up in patients suffering from PMS. Although imaging results show a high proportion of implant extrusion, this does not appear to imply a worsening in clinical outcomes in the short term.

Contributions

DF: design and reviewing of the study
FF: writing of the study
RC: conducting data
CG: writing of the study
AV: conducting data

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