Acta Biomed 2024; Vol. 95, N. 2: e2024032 DOI: 10.23750/abm.v95i2.15425

Original article

Meniscal scaffold implantation in post meniscectomy syndrome results in clinical and radiological outcomes comparable to primary subtotal meniscectomy in patients without post meniscectomy syndrome

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Abstract. *Background and aim:* The aim of the study was to assess clinical and radiological outcomes among patients who underwent scaffold implantation after post meniscectomy syndrome (scaffold group) comparing them with patients undergoing primary subtotal meniscectomy (primary subtotal meniscectomy group) without post meniscectomy syndrome at a minimum of 3 years of follow-up. Moreover, the morphology of the meniscal implant was verified by MRI at the last follow-up. *Methods:* 24 patients were enrolled (age, 37 ± 12.2 years) and two groups of 12 patients were created (scaffold and primary subtotal meniscectomy). Data were collected before surgery, at 12 months and at the last follow-up (min 3 years - max 13 years). Clinical and radiological outcomes (Subjective IKDC score, VAS, Tegner scale, physical examination, Kellgren-Lawrence classification) were collected. MRI images were analyzed according to the Genovese classification. *Results:* Both groups showed an improvement in knee function at the last follow-up. No differences were recorded in terms of pain reduction at 1 year, while subtotal meniscectomy showed a significantly lower VAS score at the last follow-up. Both groups showed a significant progression of knee osteoarthritis at the last follow-up. No patient showed a completely reabsorbed scaffold. *Conclusions:* The ActifitTM polyurethane implant demonstrated good clinical and radiological results in patients with symptomatic post meniscectomy syndrome at final follow-up. However IKDC score and VAS showed inferior clinical results compared to those of primary subtotal meniscectomy. (www.actabiomedica.it)

Key words: knee, meniscal scaffold, meniscectomy, arthroscopy, post meniscectomy syndrome

Introduction

The meniscus has different functions: load distribution, shock absorber, cartilage nutrition, stability and the capacity of lower friction increasing the congruency of the joint (1-3). However, meniscectomy remains the most commonly performed procedure in Europe and the United States (4). It is well known that complete or partial meniscectomy leads to higher stress on the articular surface and early osteoarthritis of the knee (5). Hence, lately an effort has been made to preserve injured meniscal tissue by repair, reconstruction or replacement (6-7).

In case of the onset of post meniscectomy syndrome after partial resection, scaffold implants can offer an option for reconstructive surgery if the peripheral

meniscal rim and anterior and posterior insertions are intact, in a neutral-aligned knee with minimal cartilage damage (8-9). Nowadays, the two most used scaffolds available for inducing vascular in-growth and meniscal tissue regeneration are the Collagen Meniscus Implant (ReGen Biologics, USA) and the Actifit™ (Orteq Ltd) (10). The Actifit, a biodegradable highly porous scaffold made of aliphatic polyurethane, was developed to treat symptomatic irreparable segmental meniscal defects with promising short-term clinical results as reported in the literature (11).

From our knowledge there is a lack of clinical evidence in the current literature regarding studies comparing meniscal scaffold implantation and subtotal meniscectomy. Hence, the aim of the present study was to demonstrate that Actifit™ meniscal scaffold would be clinically effective in improving symptoms and knee function in post meniscectomy syndrome.

The hypothesis was that clinical outcomes, in terms of IKDC score improvement, of the implantation of a polyurethane meniscal scaffold in patients suffering from post-meniscectomy syndrome demonstrated results comparable to patients who underwent primary arthroscopic subtotal meniscectomy without post meniscectomy syndrome, at minimum 3 years of follow-up. The secondary outcomes included the evaluation of knee function, pain reduction and activity level at 1 year and last follow-up; furthermore, the development or progression of knee osteoarthritis (OA) at mid-term follow-up in both groups was assessed. Moreover, the morphology of the meniscal implant was verified by MRI at the last follow-up.

Materials and methods

The present study was carried out according to a spontaneous, retrospective, non-randomized, observational design, following the ethical standards of 1964 Declaration of Helsinki and approved by the regional ethical committee (ID number 335_2022bis). Informed consent was obtained from each patient enrolled in the study.

The target population included a group of patients (scaffold group) who were treated with the polyurethane meniscal scaffold Actifit™ between 2009 and 2017, following the diagnosis of persisting knee pain after subtotal arthroscopic meniscectomy; another group of patients with a diagnosis of not repairable meniscal injury treated with subtotal meniscectomy with a loss of more than 60% of tissue (primary subtotal meniscectomy) in the same period was evaluated. Every patient was treated at our Institution by the same senior orthopedic surgeon.

The two groups, homogeneous for sex and age, were then compared, evaluating the clinical and radiographic differences in terms of knee function and development or progression of osteoarthritis.

All the patients selected were then included or excluded from the study based on inclusion and exclusion criteria (Table 1, Figure 1).

For both groups of patients, data were collected before surgery, at 12 months of follow-up (FU) and at the last follow-up (min 3 years - max 13 years).

The evaluation included subjective clinical outcomes assessed by Subjective IKDC score, VAS for pain and Tegner activity level scale (12,13). The objective clinical outcome was acquired through a physical examination of the treated knee at the last follow-up, conducted by the same investigator for all patients and included the limb axis (neutral-varus-valgus), the knee swelling and range of motion (ROM), muscle tone (poor-good-excellent), pain at palpation on every compartment, anterior and posterior laxity tests, McMurray test (intra- and extra-rotation), varus and valgus stress at 0° and 30°.

The Kellgren and Lawrence classification was used to assess the degree of osteoarthritis on weight-bearing radiographs (anteroposterior and lateral views), performed before surgery and at last follow-up in both groups (14,15). MRI images were evaluated by a radiologist with experience in the musculoskeletal field at the last follow-up only for patients undergoing meniscal scaffold implantation, to assess the meniscal morphology and the residual polyurethane scaffold, according to the Genovese classification (16). The magnetic resonance examination was performed at our Institution by a 1.5 Tesla scanner; all the radiographs and MRI images were evaluated by the same radiologist specialized in musculoskeletal and joint diseases. On MRI, the following parameters were acquired: meniscal morphology on the sagittal plane

Table 1. Inclusion and exclusion criteria applied in patients' enrollment.

Inclusion criteria
• Patients aged between 19 and 60 at the time of surgery • Patients diagnosed with chronic knee pain after meniscectomy with indication to meniscal scaffold implantation (Scaffold group) or patients diagnosed with a not repairable medial or lateral meniscal tear with indication to partial or subtotal arthroscopic meniscectomy with a loss of more than 60% (primary subtotal meniscectomy). • Integrity of meniscal roots and meniscal rim • Pre-operative osteoarthritis grade <II according to Kellgren-Lawrence or cartilage lesions grade <2 according to ICRS scale • Ligaments' integrity (ACL, PCL, LCL, MCL) • Minimum follow-up: 3 years
Exclusion criteria
• Lower limb coronal axis in varus/valgus (clinical evaluation) • Patients undergoing an associated major surgery on the same knee (ex. osteotomy or Kinespring^{TM} implantation) • Associated ligamentous instability • Lack of meniscal roots or meniscal wall • Patients with underlying rheumatic or metabolic diseases • Subsequent major surgery related to the operated knee within 3 years of follow-up

Abbreviations: ACL: anterior cruciate ligament, PCL: posterior cruciate ligament, LCL: lateral collateral ligament, MCL: medial collateral ligament.

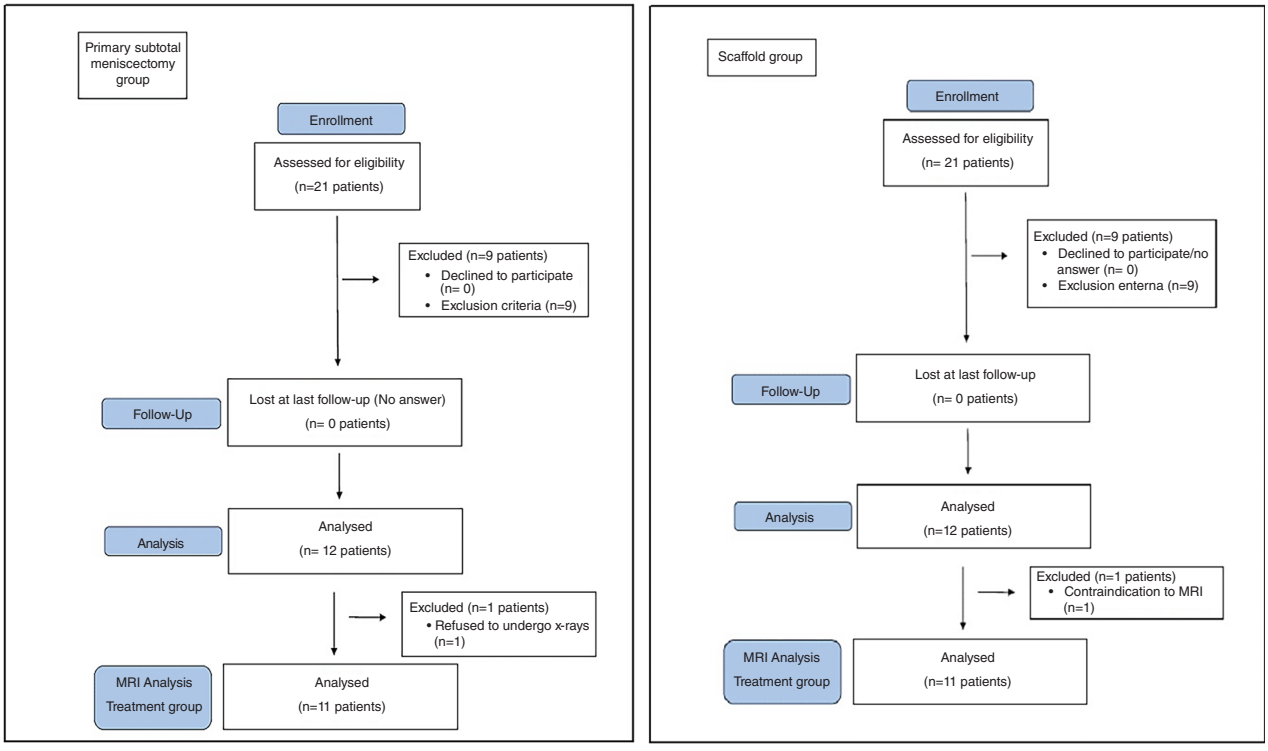

Figure 1. Flow diagram of patients' selection and drop out (on the left the primary meniscectomy group, on the right the scaffold group.

(fragmented, linear or triangular), signal intensity on T1 and TSE-FS sequences, presence of edema and osteochondral femoral and/or tibial defects, presence and degree of any cartilage lesions, extrusion of the scaffold (17,18).

Statistical analysis

All the analyses were performed using SPSS Statistics for Windows, Version 20.0 (IBM Corporation, Armonk, NY, USA). The Shapiro-Wilk test was used to verify the normal distribution of the following continuous variables which were expressed as mean ± SD and median + interquartile range [Q1–Q3]. Categorical variables were expressed as counts and percentages. A paired sample t-test was used to compare preoperative and postoperative IKDC score, Tegner activity level, VAS and Kellgren-Lawrence grade of osteoarthritis, while an independent sample t-test was used to compare differences between groups of improvement in every clinical score at 1 year and at last follow-up respect to baseline. The difference in OA incidence between the two groups was assessed by employing the chi-square test.

Mc Nemar test was used to compare Genovese classification parameters at the last follow-up in the treatment group.

All data were expressed as means ± standard deviation (SD). Statistical significance was achieved if $p < 0.05$.

Results

Twenty-four patients (8 females and 16 males), twelve per group, with a mean age of 37 ± 12.2 at the time of surgery, were available for a clinical and radiological follow-up. One patient was not allowed to undergo MRI because of some contraindications to magnetic field exposure. Mean follow-up was 7.7 ± 2.9 years overall (min 4 - max 13 years), 7 ± 2.7 in the scaffold group and 8.4 ± 3 in the primary subtotal meniscectomy group, with no statistically significant difference. In the first group, a mean of 6.3 ± 3.1 years passed from the time of meniscectomy to the scaffold implantation. The two groups resulted homogenous for demographic features (Table 2).

Both groups showed an improvement in every clinical score at 1 year and at the last follow-up, which was statistically significant for all the variables, except for the Tegner activity scale in the primary subtotal meniscectomy group. The comparative analysis between the two groups demonstrated a significative better trend in the subtotal meniscectomy group for IKDC score. No differences were recorded in terms of pain reduction between the two groups at 1 year after surgery ($p = 0.1362$), but at last follow-up a statistically significant difference was reported between the groups ($p = 0.0239$); indeed subtotal meniscectomy group showed a significantly lower VAS score at the last FU (1.6 ± 2.1 vs 4.3 ± 2.7, $p<0.05$). The level of physical activity or sport reported by patients remained stable in the primary subtotal meniscectomy group during follow-up, while a significant improvement was achieved by patients who underwent the scaffold implantation at the last FU compared to the baseline (Table 3).

A further analysis was conducted comparing the results depending on the treated compartment (medial or lateral) despite the number of patients for each group was quite small. At the last follow-up, patients treated with lateral subtotal meniscectomy or lateral scaffold implantation reported a worsening in terms of pain compared to 1 year after surgery (VAS up to 3.5 ± 2.8 from 2.7 ± 3.4 and up to 5.6 ± 3.1 from 3.4 ± 2.7 in subtotal meniscectomy and scaffold groups, respectively), though not significant and still significantly lower than the baseline (Table 4).

On the other hand, results remained stable in case the medial meniscus was addressed. Knee function, investigated through IKDC score, showed the same trend: indeed, patients who underwent medial subtotal meniscectomy or received a medial scaffold reached higher scores at the last follow-up, whilst lateral cases reported a slight deterioration of outcome compared to one year FU (Table 5).

The physical examination showed no differences between the meniscectomy and meniscal scaffold groups, neither in ROM, nor pain at palpation or stability tests.

Concerning the development of knee osteoarthritis on the radiographs acquired at the last follow-up,

Table 2. Demographics. Data are expressed as mean ± SD, median [Q1–Q3] or number of patients (percentage).

	Overall	Subtotal meniscectomy group	Meniscal scaffold group
No. of patients	24	12	12
Mean follow-up (years)	7.7 ± 2.9 7 [5-10.2]	8.4 ± 3 9 [5-9.5]	7 ± 2.7 6 [5-7.5]
Age at last follow-up (years)	45.5 ± 13 46.5 [35.2-54.7]	45.7 ± 12.9 48.5 [36-52.5]	45.4 ± 13.6 44.5 [35.2-55]
Age at surgery (years)	37 ± 12.2 38 [28.5-46.5]	37.08 ± 11.64 38 [31.25-45.00]	37.8 ± 13.3 36 [26.7-46.5]
Time from meniscectomy to scaffold implantation	-	-	6.3 ± 3.16 6 [5-7]
Gender			
female	8 (33.3)	3 (25)	5 (41.6)
male	16 (66.6)	9 (75)	7 (58.3)
Treated knee			
left	11 (45.8)	6 (50)	5 (41.6)
right	13 (54.1)	6 (50)	7 (58.3)
Treated meniscus			
medial	15 (62.5)	8 (66.6)	7 (58.3)
lateral	9 (37.5)	4 (33.3)	5 (41.6)
Associated procedures			
Microfractures	3 (12.5)	0 (0.00)	3 (25)
ACL reconstruction	6 (25)	5 (41.6)	1 (8.3)

Abbreviations: SD: standard deviation, Q1: first quartile, Q3: third quartile, No: number, Control group: subtotal meniscectomy, Treatment group: meniscal scaffold implantation, ACL reconstruction: Anterior cruciate ligament reconstruction with autologous hamstrings graft.

both groups showed a significant progression from a median Kellgren-Lawrence grade 1 [1-1.4] at baseline to 2 [1-2] in case of subtotal meniscectomy and from 1 [1-1.4] to 2 [1.2-2] in patients treated with the meniscal scaffold ($p<0.05$). However, no difference was detected between the two groups (Table 6).

In terms of morphology on MRI, the scaffold was classified as grade II (reduced in size) with irregular morphology in 4 cases (36.36%) and grade 3 (similar to normal meniscus) in 7 cases (63.64%). In none of the patients it was completely reabsorbed, and in 5 cases (45.45%) it appeared isointense as the native meniscus. Moreover, extrusion of the meniscal scaffold was registered in 4 patients (36.36%) (Table 7).

No complications related to surgery were recorded during the follow-up. One patient was diagnosed with rheumatoid arthritis after a pregnancy 3 years after the scaffold implantation. At the last follow-up (10 years), she reported a deterioration in all clinical scores (VAS 7, IKDC 26, Tegner 1) compared to baseline (VAS 3, IKDC 62, Tegner 3), confirmed as well by an arthroscopic finding of subtotal scaffold reabsorption and severe diffuse cartilage wear. Two patients in the scaffold group at 6 years FU were indicated for medial unicompartmental knee arthroplasty and distal femoral osteotomy due to OA progression and persistent pain respectively, though in the last case symptoms were located in the opposite compartment than the implanted scaffold.

Discussion

The most important finding of this study was the good functional results achieved by both the groups

Table 3. Subjective clinical outcome: comparison of clinical scores at baseline, 1 year and last follow-up in the two treatment groups.

		Follow-up (years)			p-value[a]		p-value[b]	
	Group	**Baseline**	**1 year FU**	**Last FU**	**1 year FU**	**last FU**	**1 year FU**	**last FU**
VAS (0-10 points)	Subtotal meniscectomy	7.3 ± 2.2 8.00 [7-8]	2.00 ± 2.00 2.00 [0.7-2.2]	1.6 ± 2.10 1.00 [0-2.2]	*<0.001**	*<0.001**	*0.1362*	*0.0239**
	Scaffold Group	6.5 ± 2.3 7 [5.5-8.2]	3.1 ± 2.5 2.5 [1.7-3.8]	4.3 ± 2.7 4 [1.7-7]	*<0.001**	*0.002**		
IKDC (0-100 points)	Subtotal meniscectomy	31.9 ± 21.9 34 [15 - 45]	68.4 ± 9.4 69.5 [62.5-71.5]	72 ± 9.3 74 [66.7-78.2]	*<0.001**	*<0.001**	*0.0281**	*0.0433**
	Scaffold Group	34.3 ± 13.8 32 [23.7-40]	55.5 ± 13.7 57 [47.7-65.7]	57.1 ± 16.5 62 [53.7-66.5]	*<0.001**	*<0.001**		
TEGNER (0-10 points)	Subtotal meniscectomy	4.4 ± 2.5 4.5 [2 - 7]	4.5 ± 1.6 4.5 [3 - 6]	4.5 ± 1.7 4 [3-6]	*0.363*	*0.363*	*0.3441*	*0.4270*
	Scaffold Group	2.2 ± 1.8 2 [1-2.4]	2.8 ± 1 3 [2-3.2]	2.7 ± 0.9 3 [2.7-3]	*0.026**	*0.032**		

Data are expressed as mean ± SD, median [Q1–Q3] or number of patients (percentage). Abbreviations: SD: standard deviation, Q1: first quartile, Q3: third quartile, Control group: subtotal meniscectomy, Treatment group: meniscal scaffold implantation, FU: follow-up, VAS: visual analogue scale; IKDC: International Knee Documentation Committee Subjective score; Tegner: Tegner Activity Score. [a] Significance of the within-group changes from baseline to 1 and last year FU (paired sample t-test). [b] Significance of the between-group difference at to 1 and last year FU (independent sample t-test). *: statistically significant.

Table 4. VAS comparison at baseline, 1 year and last follow-up among lateral and medial compartment in the two treatment groups.

		Follow-up (years)			p-value [a]	
	Group	**Baseline**	**1 year FU**	**Last FU**	**1 year FU**	**last FU**
VAS LAT (0-10 points)	Subtotal meniscectomy (4)	9 ± 1.1 9 [8-10]	2.7 ± 3.4 2 [0-4.7]	3.5 ± 2.8 3.5 [2.2-4.7]	*<0.001**	*<0.001**
	Scaffold Group (5)	5.4 ± 2.8 4 [3-8]	3.4 ± 2.7 3 [2-3]	5.6 ± 3.1 7 [4-7]	*<0.040**	*<0.040**
VAS MED (0-10 points)	Subtotal meniscectomy (8)	6.5 ± 2.2 7 [6-8]	1.6 ± 0.9 2 [1-2]	0.7 ± 0.7 1 [0-1]	*<0.001**	*<0.001**
	Scaffold Group (7)	7.2 ± 1.6 7 [6-8.5]	4.2 ± 4.2 2 [1.5-6.5]	3.4 ± 2.2 4 [1.5-4.5]	*0.032*	*0.032*

Data are expressed as mean ± SD, median [Q1–Q3] or number of patients (percentage). Abbreviations: SD: standard deviation, Q1: first quartile, Q3: third quartile, Control group: subtotal meniscectomy, Treatment group: meniscal scaffold implantation, FU: follow-up, VAS: visual analogue scale; LAT: lateral, MED: medial. [a] Significance of the within-group changes from baseline to 1 and last year FU (paired sample t-test). *: statistically significant.

of patients who received the polyurethane meniscal scaffold following a post meniscectomy syndrome and patients treated with subtotal meniscectomy at a follow-up of at least 4 years.

Meniscal scaffolds emerged as meniscal substitutes in those patients who have developed a post meniscectomy syndrome. Two-year follow-up studies report a significant short-term improvement of all clinical parameters (VAS, IKDC, KOOS and Lysholm scores), as reported in our series (19-21).

In the present study, a significant improvement in IKDC score was achieved by both groups, mostly during the first year of follow-up in the group of patients who underwent primary subtotal meniscectomy.

Table 5. IKDC score comparison at baseline, 1 year and last follow-up among lateral and medial compartment in the two treatment groups.

		Follow-up (years)			p-value [a]	
	Group	**Baseline**	**1 year FU**	**Last FU**	**1 year FU**	**last FU**
IKDC LAT (0-100 points)	Subtotal meniscectomy (4)	16.5 ± 19.3 11.5[1.7-26.2]	66.7 ± 13.1 70.5 [63-74.2]	65 ± 2.8 64 [58.5-70.5]	*<0.001**	*<0.001**
	Scaffold Group (5)	40.8 ± 15.9 36 [31-52]	58.8 ± 12.8 58 [49-68]	46 ± 20 47 [26-61]	*<0.001**	*0.258*
IKDC MED (0-100 points)	Subtotal meniscectomy (8)	39.6 ± 19.8 42 [24.7-49.5]	69.2 ± 7.9 69.5 [62.5-72.5]	75.6 ± 7 77 [72-8]	*<0.001**	*<0.001**
	Scaffold Group (7)	29.7 ± 11.2 29 [22.5-32]	53.1 ± 14.8 55 [46-65]	65.1 ± 7.4 66 [60.5-67]	*<0.01**	*<0.001**

Data are expressed as mean ± SD, median [Q1–Q3] or number of patients (percentage). Abbreviations: SD: standard deviation, Q1: first quartile, Q3: third quartile, Control group: subtotal meniscectomy, Treatment group: meniscal scaffold implantation, FU: follow-up, IKDC: International Knee Documentation Committee Subjective score; LAT: lateral, MED: medial. [a] Significance of the within-group changes from baseline to 1 and last year FU (paired sample t-test). *:statistically significant.

Table 6. Osteoarthritis progression on X-rays from baseline to the last follow-up in both Control and Treatment groups.

		Follow-up (years)		p-value [a]
	Group	**Baseline**	**Last FU**	**Last FU**
Osteoarthritis (KL: 0-4 points)	Subtotal meniscectomy	1.1 ± 0.3 1.00 [1.00-1.04]	1.6 ± 0.5 2 [1-2]	*0.0008**
	Scaffold Group	1.2 ± 0.4 1.00 [1.00-1.4]	1.7 ± 0.4 2.00 [1.2-2.00]	*0.0016**

Data are expressed as mean ± SD and median [Q1–Q3]. Abbreviations: SD: standard deviation, Q1: first quartile, Q3: third quartile, KL: Kellgren-Lawrence classification, Control group: subtotal meniscectomy, Treatment group: meniscal scaffold implantation, FU: follow-up. [a] Significance of the within-group changes from baseline to 1 and last year FU (paired sample t-test). *:statistically significant.

Table 7. Imaging evaluation of meniscal scaffold on MRI at last follow-up.

Morphology (size)					
Grade 1 (reabsorbed)		**Grade 2 (small)**		**Grade 3 (normal)**	
		2 A (regular)	**2 B (irregular)**		
0 (0.00)		0 (0.00)	4 (36.36)	7 (63.64)	
Signal intensity (T1)					
Markedly hyperintense		**Slightly hyperintense**		**Isointense**	
3 (27.27)		3 (27.27)		5 (45.45)	
Femoral edema		**Femoral osteochondral defect**		**Tibial edema**	
YES	**NO**	**YES**	**NO**	**YES**	**NO**
0 (0.00)	11 (100.00)	3 (27.28)	8 (72.72)	4 (36.36)	7 (63.64)

Data are expressed as number of patients (percentage), using the scale described by Genovese et al. for the evaluation of scaffold morphology in sagittal images and signal intensity, presence or absence of bone edema or osteochondral defects at the femoral or tibial side. Abbreviations: YES: present, NO: not present, T1:T1 weighted sequence. Morphology: Grade 1: Totally reabsorbed scaffold; Grade 2: Small scaffold with regular or irregular morphology; Grade 3: scaffold with size similar to normal meniscus. Signal intensity: Grade 1: Markedly hyperintense; Grade 2: Slightly hyperintense; Grade 3: Isointense relative to the normal meniscus (no signal).

This data is in line with the available literature and can be explained by a more rapid rehabilitation protocol which allows patients to recover in a short time a good physical activity level, similar to the pre-operative period (22,23).

It is important to underline that the IKDC score achieved at the last follow-up in patients treated with the meniscal scaffold is influenced by the clinical history preceding the implantation, such as progressive knee pain and drastic reduction in sports activity: in fact, these are patients reporting a lower knee function at baseline, and the scaffold implantation was indicated to overcome a persistent condition of post meniscectomy syndrome; moreover a longer period of time had passed from the first meniscectomy procedure.

In the present study, the VAS score improved at one year of follow-up for both groups but especially for patients treated only with meniscectomy. The patients with medial scaffold showed a greater pain relief at the last follow-up, better than the one reported at one year, whilst the VAS score actually increased at the last follow-up only for patients laterally treated. This data was confirmed by a recent meta-analysis in which the pain after the scaffold implantation improved within 6 months from surgery and then reached a stable value, 2.00 points lower than the pre-operative VAS score (9).

In the present paper the clinical improvement and pain relief with an average follow-up of 7 years (min 4 years, max 13), confirm the results reported in recent studies with longer follow-up, in which meniscal scaffolds have shown their role in improving joint function and reducing pain in patients with meniscal post meniscectomy syndrome, over 5 years after surgery, with a low failure rate (24-27). On the other hand, according to Sabater-Martos et al. (28) the use of Actifit^{TM} scaffold in patients undergone subtotal meniscectomy did not show a chondroprotective effect with no functional and radiological differences at a minimum follow-up of 5 years compared to isolated meniscectomy.

As demonstrated by several authors, such as Dhollander et al. and Schüttler et al., the use of polyurethane scaffold in patients with persistent pain after subtotal meniscectomy is effective in terms of knee function and pain relief (29,30). In particular, taking into account the patients treated medially or laterally, there is evidence of better outcomes in patients treated with the medial implant, as confirmed by our results. Toanen et al. reported a slightly lower survival rate for patients undergoing lateral scaffold (at final follow-up 86.9% of the lateral implants versus 87.9% of the medial scaffolds were still functioning) and this can be explained by the fact that lateral meniscus absorbs almost 70% of the load while the medial meniscus only 50% (3, 26, 30). On the other hand, a very recent article showed that there are no significant differences in clinical outcomes or survival rates between medial and lateral meniscal scaffold implants for irreparable partial meniscal defects at short- or mid-term follow up (31)

In our series, both groups revealed a progression in knee osteoarthritis at last follow-up, with no difference between the two treatments. That could be explained by the fact that patients suitable for meniscal scaffold had a previous subtotal meniscectomy but reported persistence of knee pain: therefore, it is important to take into account the period between the meniscectomy and the subsequent scaffold implantation, as it is well-known how meniscectomy speeds up OA progression. In this study, the average time between subtotal meniscectomy and meniscal scaffold was 6.3 ± 3.1 years (minimum of 1 year, maximum of 12 years). Hence it is necessary to consider that in the scaffold group, the pre-operative Kellgren-Lawrence grade (1.2 ± 0.4 at baseline) refers to a joint condition 6.3 years after meniscectomy.

Concerning MRI evaluation, no cases of complete scaffold reabsorption were recorded at a mean follow-up of 7 years. According to Genovese classification, grade III morphology was mostly reported (7 out of 11 patients), corresponding to a size similar to the normal meniscus, showing a better scaffold shape preservation compared to data reported by Shüttler., Toanen and Monllau at a mean follow-up of 5 years (25, 26, 30). Although in a recent paper the Genovese's scale has been questioned since it may not be the most ideal radiological system for meniscal scaffold assessment in terms of size and signal intensity, its use is still common in clinical practice to compare the results of these devices (32).

Monllau et al. found good clinical outcomes at 5 years of follow-up but noticed a reduction in scaffold

volume (measured by MRI) at the end of the observation period (25). Despite resorption of the scaffold, pain reduction and clinical improvement have shown to remain stable, as confirmed by Filardo et al. that reported, in a meta-analysis on 613 Actifit™, a significant improvement of both VAS and Tegner scores for up to 72 months (33). These data suggest that stabilization of pain allows activity levels to remain unchanged over time.

In the literature, Actifit™ and CMI™ implants showed similar clinical and radiological outcomes, as highlighted in the systematic review by Houck et al (34). Comparative long-term follow-up papers (Actifit™ versus CMI™) showed positive and similar results for both devices, with an implant survival rate of approximately 80% at 10 years and no difference in terms of pain, knee function and activity level (36).

Zaffagnini et al. compared patients treated with medial CMI and patients who underwent medial partial meniscectomy in a prospective study with a minimum follow-up of 10 years and found in the scaffold group a significantly lower VAS (1.2 ± 0.9 vs 3.3 ± 1.8; P = 0.004) and higher objective IKDC Score and Tegner Activity Scale (36).

This study has several limitations that should be considered. First of all, the study is not a direct comparison between one group of patients (scaffold group) to another (primary meniscectomy group) because of the different indications. The authors strived to compare the two groups for evaluating the efficacy of meniscal scaffold implantation in terms of clinical and radiological outcomes, taking into consideration the different clinical conditions of the patients. In addition, another limitation is its retrospective design, with a consequent lack of randomization. Moreover, the relatively small pool of patients enrolled limited the analysis of the relationship between clinical and radiological outcomes and influencing factors, but that was due to the strict surgical indications; the small number of cases especially influenced the reliability of the subgroups statistical analysis, which should be considered only as data description and a hint for future studies. A further limitation is the absence of a second-look assessment and a lack of histological evaluation to observe meniscal tissue ingrowth after the implant procedure.

On the other hand, the main strength of this study is the presence of a group of patients undergoing primary subtotal meniscectomy, with homogeneous characteristics in terms of number of patients, age, sex, axial alignment and years of follow-up; to our knowledge, there are no studies in the literature evaluating clinical and radiological outcomes and osteoarthritis progression comparing patients treated with meniscal scaffold after post meniscectomy syndrome and patients who underwent primary subtotal meniscectomy.

Conclusions

The Actifit™ polyurethane meniscal implant demonstrated to improve knee function and significantly reduce pain in patients with symptomatic post meniscetomy syndrome at final follow-up. However IKDC score and VAS showed inferior clinical results compared to those of primary subtotal meniscectomy.

In most cases, meniscal tissue on MRI appeared similar to the original one. Further high-quality studies with a greater pool of patients and long-term follow-ups are needed to better understand the role of this implant in preventing knee osteoarthritis.

Funding: The authors report no involvement in the research by the sponsor that could have influenced the outcome of this work.

Ethic Committee: Comitato Etico Milano Area 2, ID number 335_2022bis (21/04/2022).

Conflicts of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

Authors' Contribution: AM, MR and SP conceived and designed the study and drafted the first version of the manuscript. Each author made substantial contributions to the design of the work as well as to the acquisition, analysis, and interpretation of data. All authors also substantively revised the work and approved the submitted version (and any substantially modified version that involves the author's contribution to the study), and agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any

part of the work, even those in which the author was not personally involved, are appropriately investigated and resolved, and the resolution documented in literature. All authors read and approved the final manuscript.

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Received: 16 November 2023
Accepted: 19 December 2023
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