



The magnetic resonance aspect of a polyurethane meniscal scaffold is worse in advanced cartilage defects without deterioration of clinical outcomes after a minimum two-year follow-up



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ABSTRACT

Background: Meniscal scaffolding is thought to provide functional improvement and to prevent cartilage degeneration. Advanced chondral injuries might damage the scaffold structural properties.

Objective: To evaluate the influence of different degrees of articular chondral injuries on the imaging aspect of a polyurethane meniscal scaffold (Actifit®).

Methods: Fifty-four patients operated on with an Actifit® were studied. The status of the articular cartilage in the involved compartment was classified according to ICRS. The characteristics of the implant were evaluated in MRI with the Genovese score. Functional scores included WOMET, IKDC and Kujala scores. The Genovese score was correlated with the degree of chondral injury and functional results.

Results: The mean follow-up was 39 months (range 25–63). Additional procedures were performed in 69.5%. There were 19 patients without chondral injuries and 14 with grade 1, 10 with grade 3 and eight with grade 4 chondral lesions. The morphology and size of the implant on MRI scanning were worse with a higher degree of chondral injury ($p = 0.023$). WOMET, IKDC and Kujala improved from $36.2 \text{ SD} \pm 7.6$, $32.3 \text{ SD} \pm 13.5$ and $39.2 \text{ SD} \pm 8.1$ to $75.8 \text{ SD} \pm 12.9$ ($p = 0.02$), $75.5 \text{ SD} \pm 15.4$ ($p = 0.03$) and $85.6 \text{ SD} \pm 13.4$ (0.042), respectively. There was no relationship between the severity of chondral injury and functional scores.

Conclusions: Patients without chondral injuries showed a better MRI aspect of the polyurethane scaffold in terms of size and morphology. By optimizing biomechanics, in particular the implantation of a meniscal substitute, significant pain relief and functional improvement were observed after a minimum two-year follow-up.

Level of evidence: Therapeutic case series; level 4.

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1. Introduction

The meniscus is crucial in sharing the force load by increasing the contact surface area and providing uniform distribution of weight bearing across the articular surfaces of the knee [1,2]. Arthroscopic meniscal resection is one of the most common surgical procedures performed in the world [3]. Although the extent of meniscectomy leading to clinically significant outcomes is unknown, it has been seen that the larger the meniscectomy, the larger the decrease in the contact area and the larger the increase of the mean and peak contact stresses [1]. However, not all damaged menisci can be treated with minimum resection or repair. The advent of tissue engineering has led to the use of scaffolding materials to fill defects so as to help regenerate host tissue. The Actifit® meniscal

implant (Orteq Sports Medicine, London, UK) is one of the promising implants. It has been shown to restore the contact pressures to those of the intact knee and improve peak contact pressures and the mean contact area relative to the partially meniscectomized knee [4]. It has also demonstrated its safety and its efficacy at improving the functional status of previously meniscectomized patients in short-term clinical investigations [5–8].

Advanced articular cartilage injuries corresponding to the International Cartilage Repair Society (ICRS) score [9] >2 is considered a contraindication for meniscal substitution with the Actifit® polyurethane meniscal scaffold [6–8]. However, no study has clinically evaluated the real effect of advanced cartilage injuries on the polyurethane meniscal structure. This structure can be assessed with a validated score [10] that includes different criteria to evaluate the status of meniscal scaffolds in magnetic resonance images (MRI).

Thus, the principal aim of this study was to evaluate the influence of different degrees of articular chondral injuries on the MRI aspect of the implanted polyurethane meniscal scaffold. Secondly, the relationship

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between the MRI aspect of the scaffold and the functional scores was studied. It was first hypothesized that more advanced chondral lesions would lead to a worse MRI aspect of the implanted Actifit®s. The second hypothesis was that higher ICRS scores of the corresponding compartment of the knee would lead to poorer clinical outcomes.

2. Materials and methods

All the patients operated on with an Actifit® implant between 2008 and 2011 were studied. The procedure was only performed on patients with either persistent medial or lateral compartmental joint line pain due to a previous sizable meniscus resection or a large irreparable meniscal tear at arthroscopy. The presence of anterior and posterior meniscus remnants as well as an intact outer rim of the meniscus was a necessary condition for the procedure. An ACL 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 concomitantly with the meniscal substitution. Other inclusion criterion was an MRI of the operated knee performed at least two years after the index surgery. Exclusion criteria were the complete loss of the corresponding meniscus, a diffuse kissing chondral lesion (bipolar), untreated instability, untreated axial deviation greater than five degrees, inflammatory arthritis, polyurethane allergies, autoimmune disease and pregnancy.

The clinical research ethics committee of our institution approved the study. All the patients signed informed consent to participate in the study as well as for the evaluation and publication of the results. They were all informed that the device would be implanted even in cases with advanced chondral injury, which was out of the indications range for the product.

2.1. Surgical technique

The surgical technique was completely arthroscopic. Four surgeons experienced in meniscal substitution performed all the operations using the same technique. A complete diagnostic arthroscopy was first done through a standard anterolateral portal to evaluate the meniscus, cartilage and/or any other lesions of the knee. The status of the articular cartilage in the involved femorotibial compartment was classified according to the ICRS score [9] during the arthroscopic procedure. Concomitant surgical procedures were recorded. A convenient anteromedial portal was then established and any irreparable medial meniscal tear or any previous meniscal tissue loss was regularized until a healthy tissue bed was reached.

2.1.1. Actifit® implantation

The host bed for the scaffold had to be of healthy meniscal tissue, in all cases. Radiofrequency trephination was performed on the peripheral rim. Radiofrequency creates an area of synovial necrosis that is promptly substituted by a newly formed and more vascular synovial layer, which has proven beneficial in meniscal repair [11].

The location of the lesion was in the posterior and central zone of the meniscus in all cases. Sizing of the defect was then performed with a specially designed flexible rod that was introduced into a rigid cannula (Fig. 1a). The polyurethane meniscus implant was then trimmed with an extra of some five to 10 mm of the measured defect to compensate for the effect of the horizontal sutures, which partially shrinks the Actifit® device.

When the meniscal scaffold was implanted in the medial compartment, a release of the medial collateral ligament was usually performed by piercing the ligament percutaneously with a spinal needle while applying valgus stress in order to have easier access to the medial femorotibial compartment. The corresponding portal was generously enlarged to facilitate the easy introduction of the implant. The Actifit® implant was then introduced into the knee with the help of a vascular

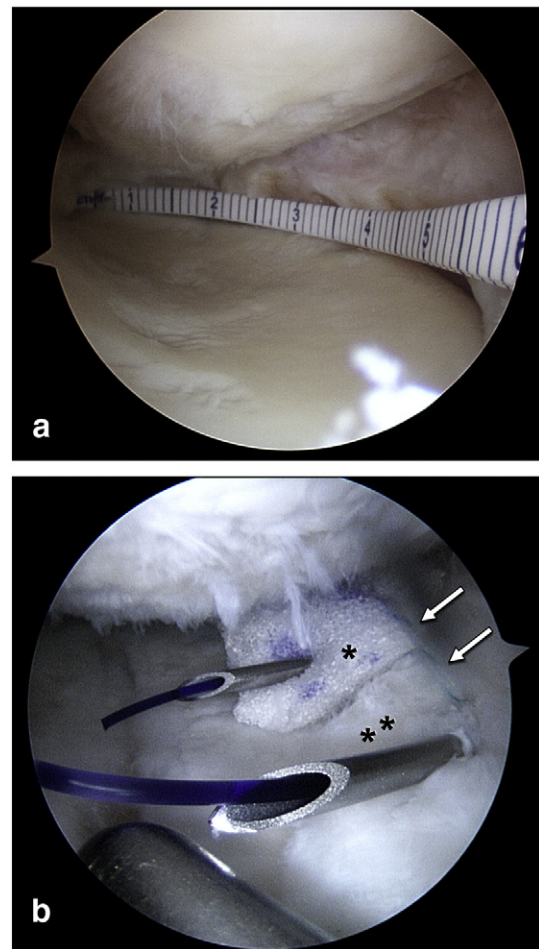


Fig. 1. Arthroscopic view of a medial Actifit® implantation in a right knee. (a) Once the meniscal defect was regularized, its sizing was performed with a specially designed flexible rod. (b) A horizontal outside–inside suture is being added to a previously horizontally placed all-inside suture (arrows) to fix the anterior end of the implant (*) to the host meniscal tissue (**).

clamp. The implant was subsequently fixed to the host meniscus with the FasT-Fix all-inside device (Smith and Nephew, Andover, MA, USA). In those cases in which the zone chosen to place the suture was too anterior, it was fixed with an outside-in repair technique. In most cases, two horizontal sutures were used to fix the anterior and posterior ends of the implant to the host meniscal tissue (Fig. 1b). Additional sutures, preferably in a horizontal pattern as recommended [12], were placed every 10 mm within the central body of the scaffold. Upon completion of suturing, the stability of the implant was tested with a probe.

Major concomitant procedures included treatment of cartilage injuries and ACL reconstruction or revision. In the case of localized ICRS 3 and 4 cartilage injuries, microfractures were made on the bone to promote a healing response (Fig. 2). When necessary, an arthroscopic cruciate ligament reconstruction or a varus/valgus knee osteotomy was performed as a final step.

2.2. Postoperative protocol

Passive as well as active range of motion exercises were started immediately after surgery. Knee flexion was limited to 60° during the first three weeks and up to 90° between weeks 4 and 6. Then, unrestricted ROM was encouraged. Between the ROM exercises, a locked brace was worn until muscle control was reasonably restored. Weight bearing was not allowed during the first three weeks. Between three and six weeks postoperatively, plantar contact and partial weightbearing were allowed as tolerated on toward full weight bearing not later than eight

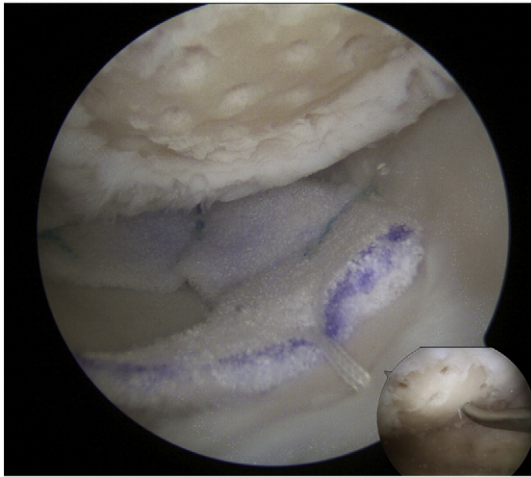


Fig. 2. Arthroscopic view of a medial Actifit® implantation in a right knee where a microfracture technique was concomitantly performed due to a focal ICRS grade 4 defect.

weeks postoperatively. Patients returned to a normal workload by the fourth month after surgery. Running and unrestricted physical activity was allowed by the sixth month, depending on patient tolerance and concomitant surgically treated lesions.

2.3. Functional evaluation

Functional evaluation included the Western Ontario Meniscal Evaluation Tool (WOMET) [13], the subjective IKDC knee form score [14] and the Kujala score [15]. A 10-point visual analog scale (VAS) for pain was also used. Patient satisfaction was evaluated with a subjective score and graded as very satisfied (four points), satisfied (three points), neutral (two points), somewhat dissatisfied (one point) and not satisfied at all (0 points). The scores were filled in at the consultation preoperatively and at the last follow-up upon the instruction of a single sports medicine surgeon who was independent of the study.

2.4. MRI evaluation

All the patients underwent an MRI examination on the operated knee joint in the supine position with full knee extension. The MRIs considered for the study's assessment were those performed at least two years after the index procedure. In cases in which a patient had no available MRI with the stated follow-up time, a new MRI was taken. The MRI had to be performed at our institution in all cases. They were performed with a 1.9-T superconducting magnet (Prestige 2 T; Elscint, Haifa, Israel) using a knee specific circular coil. A positioning device for the ankle was used to ensure uniformity. The standard knee protocol for each subject consists of the following sequence: Axial fast-spin-echo T2-weighted with fat saturation (TR: 2300 ms; TE: 30 ms; FA: 90°; ST: three millimeters; FOV: 20 cm), coronal fast spin-echo intermediate-weighted (TR: 2500 ms; TE: 30 ms; FA: 90°; ST: four millimeters; FOV: 18 cm), sagittal spin-echo intermediate-weighted (TR: 700 ms; TE: 14 ms; FA: 90°; ST: four millimeters; FOV: 18 cm) and sagittal fast spin-echo T2-weighted with fat saturation (TR: 2500 ms; TE: 85 ms; FA: 90°; ST: four millimeters; FOV: 18 cm).

The MRIs were analyzed in order to assess implant evolution following the direct criteria suggested by Genovese et al. [10]. Morphology, size and signal intensity characteristics were the direct criteria studied. They were classified into three types. Type 3 corresponds to the MRI characteristics of a normal meniscus and type 1 to a hyperintense and reabsorbed implant. The Genovese et al. [10] criteria are detailed in Table 1. The interface between the residual and prosthetic menisci was also assessed, which was classified as present or absent. The MRIs were analyzed and classified by an independent trained radiologist.

2.5. Statistical analysis

Statistical analyses were performed using SPSS 19 (SPSS, Chicago, IL, U.S.A.). Categorical variables are expressed as percentages and frequencies. 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 a Student t-test for parametric data and contrasted using a Wilcoxon rank test. The correlation between the degree of chondral injury with the Genovese score and with the functional results was assessed with the Kruskal–Wallis and Mann–Whitney tests. The level of significance was set at $p < 0.05$.

3. Results

From a total 64 Actifit implantation procedures during the studied period, seven patients were excluded because no MRI was performed at our institution within a minimum of 24 months from the surgical treatment was available and because it was not possible for them to come for a new MRI and functional evaluation due to logistics and geographic reasons. Another three patients were lost during the follow-up. Thus, 54 patients were included in the study. There were 42 males and 12 females with a median follow-up of 39 months (range 25–63). The patients had a median age of 40.2 years (range 17–58 years) and a mean body mass index of $25.7 \text{ SD} \pm 4.4 \text{ kg/m}^2$ at the time of the surgical procedure. In 23 patients, the lesion was located in the right knee and in the left in the remaining 31 cases.

3.1. Surgical data

The surgical time was a mean $56 \text{ SD} \pm 6.5$ min. There were 40 medial and 14 lateral implanted Actifit®s. The average length of the implant was 42.7 mm (range 25 to 55). Fixation of the Actifit® implant required a mean of $3.9 \text{ SD} \pm 1.3$ Fast-fix devices and $0.9 \text{ SD} \pm 0.6$ out-in sutures. There were no complications due to the Actifit® implantation in any patient. Following the ICRS criteria, 19 patients had no chondral injuries (grade 0) whereas 16 patients had grade 2, 10 grade 3 and nine had grade 4 chondral lesions.

Additional procedures were performed in 41 patients (69.5%). The anterior cruciate ligament reconstruction was the most frequently performed concomitant technique (Table 2). The postoperative mechanical axis in the 14 patients who underwent concomitant high tibial osteotomy realignment averaged $1.9 \pm 1.2^\circ$ of valgus. Five out of these 14 patients underwent hardware removal due to local tenderness that subsided postoperatively in all cases. Stability was normal or nearly normal in all the 20 cases that had undergone ACL reconstruction. The KT-1000 evaluation showed a <3 mm difference between the operated and unoperated knee in 18 patients. In the remaining patient, a five millimeters difference between both knees was observed.

3.2. Functional results

An overall improvement was obtained in terms of the WOMET, IKDC, Kujala and VAS scores. The WOMET score improved 41.3 points ($p = 0.02$). The mean follow-up IKDC score significantly improved by 45.7 points ($p = 0.02$). The Kujala score rose 44 points and the mean VAS score dropped 5.2 points. The satisfaction of the patients with regard to the procedure showed a mean overall of $3.5 \text{ SD} \pm 0.7$ points out of a maximum of four. The functional results are summarized in Table 3. Analysis with the Kruskal–Wallis test showed no relationship between the severity of the chondral injury and any of the evaluated functional scores (Table 4).

Table 1
MRIs of Genovese et al. [12] criteria.

Characteristics	Type 1	Type 2	Type 3
Morphology and size	Totally resorbed	Small implant with regular and/or irregular morphology	Identical shape and size to the normal meniscus
Signal intensity	Markedly hyperintense	Slightly hyperintense	Isointense relative to the normal meniscus (no signal)

Table 2
Concomitant surgical procedures.

Surgical technique	n
Isolated Actifit implantation	14
ACL reconstruction	15
Microfractures	8
HTO + microfractures	6
HTO	5
ACL reconstruction + microfractures	2
ACL reconstruction + HTO	2
PCL reconstruction	1
ACL reconstruction + HTO + microfractures	1

Abbreviations: n, number of cases; ACL, anterior cruciate ligament; HTO, high tibial osteotomy; PCL, posterior cruciate ligament.

3.3. MRI assessment

Thirty-two out of the 48 patients had an MRI performed two years after surgery. In the remaining 16 patients, the MRI was done at the last follow-up (median 47 months; range 34–63 months). When the MRI was assessed with the Genovese score [10], evaluation with the Kruskal–Wallis test showed a tendency to a worse result in terms of the morphology and size aspect when the chondral injury had been classified with a higher ICRS score ($p = 0.023$) (Figs. 3–4). A post-hoc analysis with the Mann–Whitney test showed that this observed correlation was only due to the difference between patients without chondral injuries versus any of the groups of patients with chondral injuries (Table 5). No relationship was observed between the ICRS cartilage score and the functional outcomes with the signal intensity characteristics of the polyurethane scaffolds, as they were all classified as type 2 in this item of the Genovese score. An interface between the implant and the native meniscus could be identified in only seven patients.

4. Discussion

The results showed a tendency to obtain a poorer aspect of the polyurethane scaffolds assessed in MRI images with higher degrees of ICRS cartilage lesions. That finding is in agreement with the main hypothesis of the study. More specifically, knees without chondral injuries were shown to better preserve the size and morphology of the implant in comparison to knees with any ICRS chondral injuries ≥ 2 . In addition, substituting the loss of meniscal tissue with the Actifit® implant provided significant pain relief and functional improvement regardless the presence of advanced cartilage injuries after a minimum two-year follow-up, which refuted the second hypothesis of the study.

At present, two meniscal scaffolds are available clinically to replace the loss of meniscal tissue in patients with chronic pain due to a previous partial meniscectomy. One of them, the collagen meniscus implant (CMI®; Ivy Sports Medicine, Gräfelfing, Germany), has shown good long-term clinical results [23]. In July 2008, a biodegradable polyurethane acellular meniscal implant was approved for clinical use in Europe (Actifit®; Orteq Sports Medicine, London, UK) [4].

In the MRI evaluation of the CMI® device, the most common finding was its reduction in size and its partial alteration of the morphology (Genovese type 2). Conversely, the size and morphology of the polyurethane meniscal scaffold were better preserved (Genovese 3) in the current as well as in a previous study [6]. However, the composition of the Actifit® and thus its degradation rate are completely different from the CMI® [17,18]. Thus, a two-years follow-up might still be too short to conclude any advantage. In addition, no correlation was observed

Table 3
Functional results.

Variable	Preoperative	Last follow-up	Sig. (p)*
WOMET	36.1 ± 7.5	77.4 ± 10.9	0.02
IKDC	32.5 ± 11.1	78.2 ± 14.8	0.02
Kujala	39.6 ± 7.8	83.6 ± 12.7	0.03
VAS	7.5 ± 1.2	2.3 ± 1.5	0.04
Satisfaction	3.5 ± 0.7		

All data are expressed in the mean score ± SD.

* The level of significance was set at $p < 0.05$.

Table 4
Statistical significance when the relationship between the postoperative functional scores with the morphology and size aspect of the Genovese score was calculated with the Kruskal–Wallis test.

ICRS score	p
WOMET	0.13
IKDC	0.22
Kujala	0.20
Tegner	0.07
VAS	0.16

between the clinical outcomes with the MRI appearance in this study as well as in studies with collagen meniscus implantation [10,19].

Relative to the chondral status, advanced articular cartilage injuries corresponding to International Cartilage Repair Society (ICRS) score >2 is considered a contraindication for meniscal substitution with the Actifit® device [6,8]. Then again, no study has clinically evaluated the real effect of advanced cartilage injuries on the polyurethane meniscal structure and its influence on the clinical outcomes. Interestingly, in the multicenter study performed by Verdonk et al. [8], stable or even improved cartilage status was observed in the MRI evaluation in 92.5% of the available patients at two years of follow-up. In addition, although the presence at arthroscopy of a ICRS score >2 was considered a contraindication for Actifit® implantation in the study performed by Efe et al. [6], they observed that six out of 10 patients showed an ICRS classification >2 at the six-months MRI. They remained stable in four and improved in two cases at the 12-months MRI. In this as well as in a previous study [7], ICRS chondral injuries >2 were not stated as a contraindication. However, no description of the chondral status was reported [7] in that previous investigation. Some degree of advanced cartilage lesions could be deduced as microfracture, chondral shaving and high tibial osteotomies were performed on some patients [7]. Thus, this is the first clinical study with the Actifit® device that has included patients with ICRS classified chondral injuries of any degree of severity. The inclusion of those patients allowed for the correlation of the chondral injuries with the clinical and MRI outcomes.

A poorer MRI aspect of the polyurethane scaffolds was observed with higher degrees of ICRS cartilage lesions. With the available data, the statistical analysis determined that patients without chondral injuries showed a better MRI aspect of the polyurethane scaffold in terms



Fig. 3. MRI examination of a medial compartment of the knee without chondral injury (ICRS grade 0) 24 months after a medial Actifit® implantation. The sagittal spin-echo intermediate-weighted images showed that the Actifit® implant (white arrow) size was in this case identical to that of the normal meniscus (type 3) and that the signal intensity was slightly hyperintense (type 2). The interface between the prosthetic meniscus and the native meniscal tissue can no longer be observed.



Fig. 4. MRI examination of a medial compartment of the knee with a grade 4 ICRS chondral injury 24 months after a medial meniscal polyurethane scaffold implantation. In this knee, a concomitant high tibial valgus osteotomy and a microfracture technique was concomitantly performed at the time of the index surgery. The sagittal images obtained with spin-echo intermediate-weighted showed the Actifit® with reduced size and irregular morphology (type 2). The signal intensity was slightly hyperintense (type 2) and the interface between the implant/meniscal tissue is clearly distinguishable (small white arrows).

of size and morphology. The long-term functional and radiographic effect of this MRI aspect remains uncertain. Unfortunately, most of the preoperative MRIs were performed in other medical institutions, which did not allow for comparison in terms of the MRI aspect of the chondral status with the postoperative MRIs. Similarly, the lack of postoperative MRI evaluation at different follow-up times did not allow for evaluation of the state of the articular cartilage or the polyurethane meniscal implant throughout the duration of the study. On the other hand, no relationship was observed between the chondral status at the time of the index surgery with the functional scores. However, an important limitation in this aspect is that the studied groups included patients undergoing isolated meniscal substitution as well as patients with concomitant procedures to address not only their meniscal problems but also concurrent ligamentous, cartilage or alignment deficiencies. This is an obvious limitation that makes a more accurate assessment of the meniscal substitution difficult because combined procedures introduce a degree of performance bias into the results. However, a recent investigation comparing isolated Actifit® implantation versus Actifit® implantation with other concomitant procedures achieved comparable results after two years of treatment [7].

Another limitation of this work is the short follow-up period. Considering that one potential effect of the meniscal substitution would be to act as a joint-preserving surgery that slows down the degenerative process of the corresponding compartment [16,20,21], evaluation at a much longer follow-up should be performed. Finally, due to the retrospective nature of the study, most of the postoperative MRIs were performed two years after the surgical procedure whereas the functional questionnaires were filled in at the last follow-up.

Table 5

Analysis of each ICRS grade with the morphology and size aspect of the Genovese score, performed with the Mann-Whitney test.

ICRS score	p
Grade 0 vs grade 2	0.014
Grade 0 vs grade 3	0.013
Grade 0 vs grade 4	0.01
Grade 2 vs grade 3	0.64
Grade 2 vs grade 4	0.43
Grade 3 vs grade 4	0.74

Regardless of the aforementioned limitations, our study provides one of the largest groups of patients operated on with the Actifit® implant and the first that evaluates the effect of different degrees of articular cartilage lesions of the knee in the MRI aspect of this meniscal polyurethane scaffold and in the functional scores.

5. Conclusion

Patients without chondral injuries showed a better MRI aspect of the polyurethane scaffold in terms of size and morphology. By optimizing biomechanics, in particular the implantation of a meniscal substitute, significant pain relief and functional improvement were observed after a minimum two-year follow-up.

Conflict on interest

We declare that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

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