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Prospective Long-Term Outcomes of the Medial Collagen Meniscus Implant Versus Partial Medial Meniscectomy

A Minimum 10-Year Follow-Up Study

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Background: Loss of meniscal tissue can be responsible for increased pain and decreased function.

Hypothesis: At a minimum 10-year follow-up, patients receiving a medial collagen meniscus implant (MCMI) would show better clinical, radiological, and magnetic resonance imaging (MRI) outcomes than patients treated with partial medial meniscectomy (PMM).

Study Design: Cohort study; Level of evidence 2.

Methods: Thirty-three nonconsecutive patients (men; mean age, 40 years) with meniscal injuries were enrolled in the study to receive MCMI or to serve as a control patient treated with PMM. The choice of treatment was decided by the patient. All patients were clinically evaluated at time 0 and at 5 years and a minimum of 10 years after surgery (mean follow-up, 133 months) by Lysholm, visual analog scale (VAS) for pain, objective International Knee Documentation Committee (IKDC) knee form, and Tegner activity level scores. The SF-36 score was performed preoperatively and at final follow-up. Bilateral weightbearing radiographs were completed before the index surgery and at final follow-up. Minimum 10-year follow-up MRI images were compared with preoperative MRI images by means of the Yulish score. The Genovese score was also used to evaluate MCMI MRI survivorship.

Results: The MCMI group, compared with the PMM one, showed significantly lower VAS for pain (1.2 ± 0.9 vs 3.3 ± 1.8 ; $P = .004$) and higher objective IKDC (7A and 10B for MCMI, 4B and 12C for PMM; $P = .0001$), Tegner index (75 ± 27.5 vs 50 ± 11.67 ; $P = .026$), and SF-36 (53.9 ± 4.0 vs 44.1 ± 9.2 ; $P = .026$ for Physical Health Index; 54.7 ± 3.8 vs 43.8 ± 6.5 ; $P = .004$ for Mental Health Index) scores. Radiographic evaluation showed significantly less medial joint space narrowing in the MCMI group than in the PMM group (0.48 ± 0.63 mm vs 2.13 ± 0.79 mm; $P = .0003$). No significant differences between groups were reported regarding Lysholm ($P = .062$) and Yulish ($P = .122$) scores. Genovese score remained constant between 5 and 10 years after surgery ($P = .5$). The MRI evaluation of the MCMI patients revealed 11 cases of myxoid degeneration signal: 4 had a normal signal with reduced size, and 2 had no recognizable implant.

Conclusion: Pain, activity level, and radiological outcomes are significantly improved with use of the MCMI at a minimum 10-year follow-up compared with PMM alone. Randomized controlled trials on a larger population are necessary to confirm MCMI benefits at long term.

Keywords: knee; arthroscopy; meniscal scaffold; collagen meniscus implant

Well-known studies have revealed that preserving the meniscus as much as possible could be the key factor to

avoid degenerative joint progression.^{6,14,15} Arthroscopic partial meniscectomies demonstrated better clinical results than complete meniscus removal, but at long-term follow-up, a substantial number of patients suffered the effect of a lost meniscus cartilage.^{4,7,10,12,20} Meniscus allografts are indicated when it is necessary to restore all or nearly all of the injured natural meniscus, with good success reported at long-term follow-up.^{21,33,34,37}

The Collagen Meniscus Implant (CMI, now called Menaflex; ReGen Biologics, Hackensack, New Jersey) has successfully replaced partial loss of meniscal tissue in humans. The CMI, made of collagen type I fibers (purified from bovine Achilles tendon), is suitable to fill meniscus defects after a partial/subtotal meniscectomy because it

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requires a meniscal rim for attachment. Several studies have shown the safety and early to mid-term good clinical results in using this scaffold.^{22,23,25,27-29}

Recently, Rodkey et al²² published a large multicenter randomized controlled trial (RCT) comparing medial CMI with partial medial meniscectomy, demonstrating that the CMI supports the formation of a new biomechanically competent meniscus-like tissue just 1 year after implantation and “the utility of this device to replace irreparable or lost meniscal tissue in patients with a chronic meniscal injury” at medium-term follow-up. Bulgheroni et al³ have investigated the medial CMI with radiological and magnetic resonance imaging (MRI) results at 5 years, but the efficacy of this device in reducing the risk of degenerative disease long term has not been reported.

The purpose of this prospective controlled trial was to evaluate the efficacy of the medial CMI (MCMI) compared with a control group of partial medial meniscectomies (PMM). The hypothesis of the present study was that the MCMI group would show superior clinical, radiographic, and MRI outcomes compared with their preoperative condition and with the PMM group at a minimum 10-year follow-up.

MATERIALS AND METHODS

We performed this prospective controlled study enrolling 36 nonconsecutive patients with acute or chronic meniscal injuries. Patients with acute injuries had no prior surgery to the involved meniscus, whereas patients with chronic injuries reported 1, 2, or 3 prior meniscal surgical procedures.

More specifically, inclusion criteria were identified as (1) irreparable acute meniscal tears requiring partial meniscectomy or chronic prior loss of meniscal tissue (traumatic or degenerative) greater than 25%, (2) intact anterior and posterior attachments of the meniscus, (3) intact rim (1 mm or greater) over the entire circumference of the involved meniscus, (4) anterior cruciate ligament (ACL) deficiencies stabilized at the time of the index surgery, (5) participant between 15 and 60 years of age, and (6) contralateral healthy knee. Exclusion criteria included (1) concomitant posterior cruciate ligament (PCL) insufficiency of the involved knee; (2) diagnosis of Outerbridge¹⁹ grade IV degenerative cartilage disease in the affected joint; (3) uncorrected malformations or axial malalignment in the lower extremity; (4) documented allergy to collagen or chondroitin-sulfate of animal origin; (5) systemic or local infection; (6) history of anaphylactoid reaction; (7) systemic administration of any type of corticosteroid or immunosuppressive agents within 30 days of surgery; (8) evidence of osteonecrosis in the involved knee; (9) history of rheumatoid arthritis, inflammatory arthritis, or autoimmune diseases; (10) neurological abnormalities or conditions that would preclude the patient's requirements for the rehabilitation program; and (11) pregnancy.

Patient assignment to the MCMI or PMM group was not randomized, and the choice was made by the patients themselves. The patients received information concerning each technique according to the available literature at the time of recruitment²⁷⁻²⁹ at least 1 week before surgery. They expressed their decision the day before surgery. No

patient refused to participate during the recruitment period. Between October 1997 and March 2000, the enrolled patients underwent arthroscopic treatment (18 MCMI and 18 PMM); all surgeries were performed by the same experienced senior surgeon. Among the selected patients, 33 were available for the last follow-up (>90% follow-up of the enrolled patients), 17 of the MCMI group and 16 of the PMM group; 3 patients were excluded because 1 MCMI patient sustained a tibial plateau fracture during the follow-up period, and 2 PMM group patients did not complete the entire planned follow-up evaluations. By chance, all patients enrolled in the study were men. The average age of the patients at index surgery was 40 years (range, 24-60 years).

The technique for arthroscopic CMI implantation is well described in literature.^{23,41} Specifically, after the implant site preparation (creating a full-thickness meniscus defect without degenerative tissue), we provided extra blood supply by making puncture holes in the peripheral rim with a Steadman awl; we also trimmed square the anterior and the posterior meniscal attachment points to accept the scaffold. Once the implant site was prepared, we measured the meniscus defect using a specifically designed instrument. The dehydrated CMI was removed from the sterile packaging, measured, and trimmed to fill the defect. After the implant was inserted into the defect, it was sutured to the host meniscus remnant with a standard in-out suturing technique, using a 2-0 nonabsorbable suture. We placed vertical stitches every 5 mm (with a zone-specific meniscal repair cannulae; Linvatec Corp, Largo, Florida), using horizontal stitches only in the posterior and anterior junctions.

For arthroscopic PMM, we used a standard approach. We used the same measuring instruments described above to measure the length of the removed meniscus in the PMM group.

Patients requiring an ACL reconstruction procedure were treated after the PMM or MCMI procedure by means of a “single bundle plus lateral extra-articular plasty hamstrings” technique (Table 1).¹⁷ Grade III Outerbridge¹⁹ chondropathy of femoral condyles was treated with the microfracture technique according to Steadman et al.²⁶

Physical therapy started from the first postoperative day and was different for each group. The control patients (PMM group) underwent a standard physical therapy program, including full weightbearing, unrestricted range of motion, quadriceps and hamstring strengthening, and resumption of activity as tolerated. In the MCMI group, a knee brace was applied and locked in full extension immediately after the surgery, and it was worn by the patient for 6 weeks; it was removed 4 times per day to allow continuous passive motion (CPM). When a CPM range from 0° to 60° was achieved, the CPM was increased to 90° of flexion after 2 weeks, and after 2 more weeks, complete passive motion was allowed. During the first 2 weeks, weightbearing was not allowed; ambulation was permitted only using crutches. After 2 weeks, progressive weightbearing was started, and patients usually used 1 crutch for the first period (on the basis of evidence derived from basic science and preclinical studies).^{16,27,28} Muscle strengthening started on the second postoperative day with isokinetic exercises. Cycling was

TABLE 1
Demographic and Anthropometric Data^a

	MCMI (n = 17)		PMM (n = 16)	
	Acute	Chronic	Acute	Chronic
Patients enrolled	8	10	10	8
Patients evaluated	7	10	10	6
Follow-up time, mo				
Range	120-152		122-145	
Mean	135		130	
Age, y				
Range	24-60		28-60	
Mean	38		44	
Sex	All men		All men	
Body mass index				
Mean (SD) at surgery	25.24 (1.65)		26.03 (1.88)	
Mean (SD) at last follow-up	26.15 (3.23)		27.28 (3.30)	
ACL reconstructions at time of index surgery	2		2	

^aThere were no statistically significant differences between groups. MCMI, medial collagen meniscus implant; PMM, partial medial meniscectomy.

allowed the second postoperative week. Elastic resistance and isotonic strengthening programs were started the fourth postoperative week. All patients followed a rehabilitation protocol for 6 months until they returned to full unrestricted activity as tolerated.

The PMM group patients who underwent a microfracture procedure followed the same MCMI group rehabilitation program.

All patients underwent preoperative and then postoperative clinical evaluation at 3, 6, 12, and 24 months after surgery. The medium-term and long-term follow-up evaluations were completed at 5 and 10 years.

Clinical evaluations included the following:

- Clinical evaluation at times noted above:

Visual analog scale (VAS) for knee pain (assessed during rest and activity; 0 indicates no pain and 10 the worst possible pain, measured on a 10 cm scale)¹³

The objective International Knee Documentation Committee (IKDC) form¹¹

Lysholm knee score and Tegner activity level questionnaires²

- Self-administered SF-36 health-related quality questionnaire¹ (preoperative and 10-year follow-up controls):

Physical Health Index (PHI) normalized for age and gender¹

Mental Health Index (MHI) normalized for age and gender¹

- Radiographic and MRI evaluation (preoperative and 10-year follow-up visits):

Preoperatively, every patient underwent a bilateral longstanding anteroposterior (AP) weightbearing radiograph and a lateral view in 30° of flexion of the involved knee. A bilateral double-leg posteroanterior (PA) weightbearing roentgenogram at 35° to

45° of flexion (tunnel view) and a lateral view in 30° of flexion were taken at the 10-year follow-up evaluation. Radiographs were evaluated by a single experienced musculoskeletal radiologist, blinded to patient identification and surgical status, to maximize the reliability of the knee assessment. The radiologist measured, using an electronic digital system (PACS; Kodak, Rochester, New York), the medial joint line heights of the involved and contralateral healthy knees on the tunnel view radiographs obtained (with the same XRay machine: Omni Diagnost; Philips Medical Systems Nederland, Best, Netherlands) at the 10-year follow-up.

All MRI examinations were performed with a 1.5-T unit using gradient-echo (GE) T2-weighted, spin-echo (SE) T1-weighted, FatSat fast spin-echo (FSE) DP, and T2-weighted sequences, with different orientations. Preoperative MRIs were collected from patients. All postoperative examinations were done at our institute with the same machine (Twin Speed; GE Medical Systems, Milwaukee, Wisconsin). All MRIs were examined by a single independent radiologist, blinded to patient identification and surgical status, evaluating CMI implant signal and articular cartilage alterations using the Genovese et al⁹ system and the Yulish score.³⁹ Not all patients of the PMM group completed the 5-year follow-up MRI, so these data were not taken into account for the final Yulish score³⁹ evaluation.

Tegner activity scores were obtained preinjury (retrospectively, on the basis of patient recall), preoperatively, and postoperatively; thus, we could calculate the Tegner index, the percentage of the loss of activity level that was regained as a result of the treatment.²² The Tegner index is calculated by subtracting the preoperative Tegner score from the latest score and then dividing the difference by the difference of the preinjury minus the preoperative

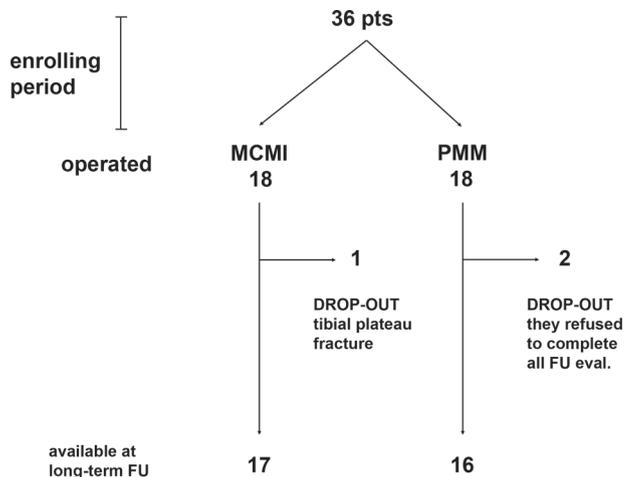


Figure 1. Flow diagram showing the patient recruitment and dropout. FU, follow-up; MCMC, medial collagen meniscus implant; PMM, partial medial meniscectomy.

score. The quotient multiplied by 100% yields the percentage of lost activity due to the original inciting injury regained from the treatment intervention.

Every complication and/or revision surgery during the follow-up period was assessed.

Statistical Methods

The statistical analysis was performed with SPSS (Analyse-it Software, Ltd, Leeds, UK). A priori sample size definition was prospectively estimated for unpaired Student *t* test with a power >80%, starting from the hypothesis of 2.00 mm of difference between groups (MCMC vs PMM) for joint space height and the same variance in measurements (1.00 mm). Considering an expected high dropout rate for the long-term follow-up planned, we decided to enroll at least 16 patients for each group (Figure 1).

Differences between the 2 groups (MCMC and PMM) were compared using the nonparametric Mann-Whitney test for nonparametric variables (Lysholm, Tegner activity, 10-year follow-up Tegner index, and Yulish scores) and the independent Student *t* test for parametric ones (demographic and anthropometric data reported in Table 1; arthroscopic measurements, VAS for pain and SF-36 scores, medial joint line height, and side-to-side difference).

The nonparametric Wilcoxon and the paired Student *t* test were used to prospectively assess outcomes changes in the MCMC group respectively for nonparametric (Lysholm, Tegner activity, and Genovese scores) and parametric (VAS for pain and SF-36 scores) variables.

The objective IKDC grading results were compared between the 2 groups using the Pearson χ^2 test. The medial joint line height differences between the operated and the healthy knee were compared between groups by means of the paired Student *t* test. The level of significance was set at $P < .05$.

Results are expressed using mean values \pm standard deviation (SD) for parametric values and median \pm interquartile range (IQR) for nonparametric ones.

Ethics

Approval of the study was obtained from the Institutional Review Board. Informed consent complied with European Union laws and was signed by the patient before the operation.

RESULTS

Demographic and anthropometric data are summarized in Table 1. Differences between the 2 groups were not statistically significant.

The average length of the implanted MCMC was 36 ± 9 mm, and this length was similar to the size of defect measured in the PMM group (35 ± 8 mm). All the MCMCs and the PMMs were performed in the red/red (14 in the MCMC group and 14 in the PMM group) or the red/white (3 in the MCMC group and 2 in the PMM group) zone. Four patients (2 in each group) required an ACL reconstruction procedure at the time of meniscus surgery. During arthroscopy, grade III Outerbridge¹⁹ medial femoral condyle chondropathy was diagnosed in 4 patients (2 in each group) and treated by the microfracture technique.²⁶ None of these differences was significant.

At the 10-year minimum follow-up, all the MCMC group clinical, general health, and activity level outcomes showed a statistically significant improvement compared with the preoperative status (VAS $P < .0001$; Lysholm $P = .001$; SF-36 PHI $P < .0001$, SF-36 MHI $P = .016$; objective IKDC $P = .003$; Tegner activity level $P = .001$) (Figures 2 and 4). In the MCMC group, there was no significant medial joint line narrowing of the operated knee compared with the contralateral healthy one, as noted for the PMM group ($P = .0002$) (Figure 5a). The MRI evaluation of the MCMC patients revealed in 11 cases a myxoid degeneration signal; 4 had a normal signal with reduced size, and 2 patients had no recognizable implant. The median Genovese score value, both for signal intensity and morphologic evaluation, was 2 (CMI with reduced size and irregular shape). Nevertheless, differences between the 5-year and the 10-year follow-up MRI evaluations were not statistically significant ($P = .5$) (Figure 6b). The MCMC group showed significantly lower VAS for pain ($P = .004$) (Figure 2a), higher objective IKDC ($P = .0001$) (Figure 3), and higher Tegner index ($P = .026$) (Figure 4b) scores compared with the PMM group at minimum 10-year follow-up, starting from comparable preoperative values. The SF-36 results showed a similar trend ($P = .026$ for PHI and $P = .004$ for MHI) (Figure 2c). No statistically significant differences between groups were reported regarding Lysholm scores ($P = .062$). Radiographic evaluation showed significantly less medial joint space narrowing side-to-side difference ($P = .0003$) in the MCMC group compared with the PMM group at final follow-up (Figure 5b). Starting from comparable preoperative levels (2 ± 1.5 for MCMC, 2 ± 1 for PMM), Yulish score results for the MCMC group at 10-year follow-up were encouraging compared with those of controls; however, these differences were not significant ($P = .122$) (Figure 6a).

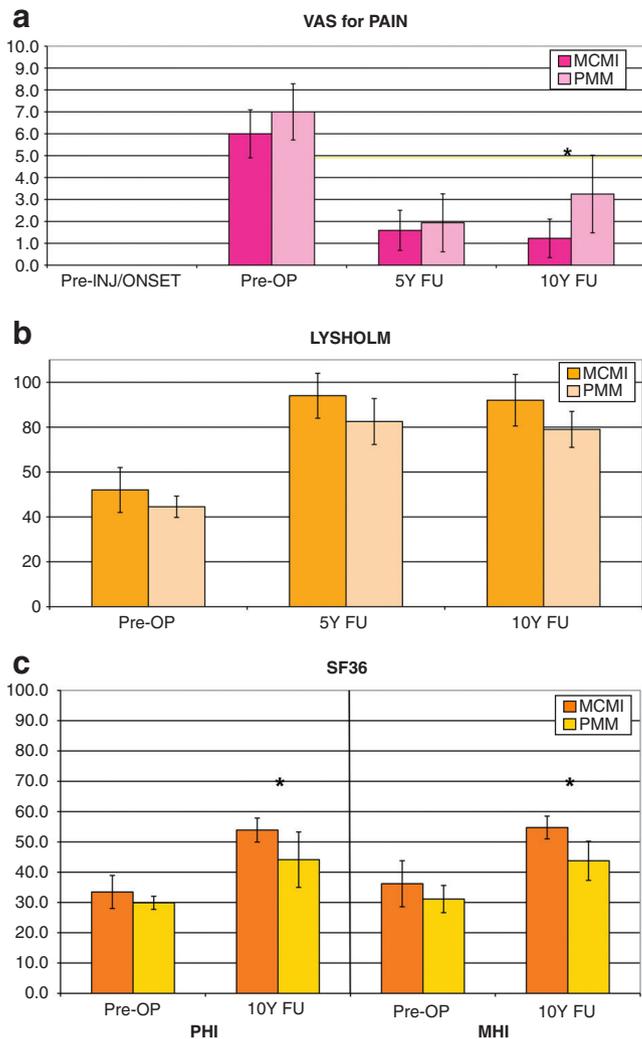


Figure 2. Prospective clinical and general health evaluation. a, Visual analog scale (VAS) for pain score; b, Lysholm score; c, SF-36 score normalized for age and gender. FU, follow-up; MCMI, medial collagen meniscus implant; MHI, Mental Health Index; PHI, Physical Health Index; PMM, partial medial meniscectomy. *Statistically significant differences between the MCMI and control groups.

Reoperation was necessary in 4 cases, 2 for each group. The reason was swelling in 2 cases (1 for each group) and pain and swelling in 2 cases (1 for each group). These symptoms developed and were treated during the last 3 years of follow-up. The procedures performed were arthroscopic debridement in the case of swelling, associated with a high tibial osteotomy (HTO) in the others, yielding successful symptom relief in all cases. No other complications were reported.

DISCUSSION

Current concepts in meniscus surgery advocate to preserve, suture, or replace (when necessary) this important

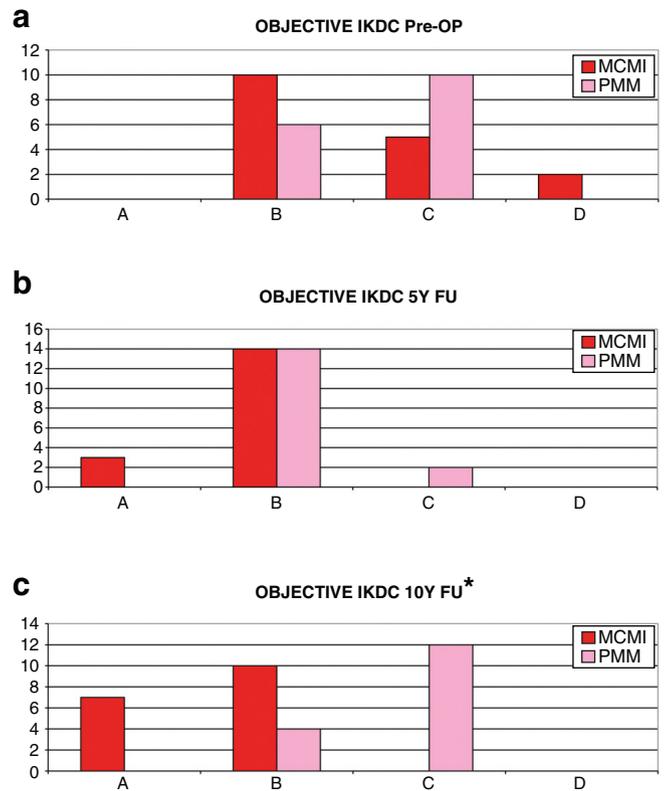


Figure 3. Prospective objective International Knee Documentation Committee (IKDC) evaluation (a) preoperatively and at the (b) 5-year and (c) 10-year follow-up. FU, follow-up; MCMI, medial collagen meniscus implant; PMM, partial medial meniscectomy. *Statistically significant differences between the MCMI and control groups.

articular structure.²⁴ The best-known meniscal substitute is meniscus allograft transplantation, but it is indicated when all or nearly all of the native meniscus is destroyed or removed. It requires a certified and available tissue bank to decrease as much as possible infectious disease transmission. The sizing procedure is another critical issue of this technique, even though recently, van Thiel et al³¹ described a new reliable algorithm to better predict the allograft size by easily collected parameters (height, weight, and gender).

Compared with allograft replacement, the scaffold meniscal replacement was appealing because of restoring the lost meniscal tissue after partial meniscectomy, with the aim to avoid the progression of joint degeneration and no need for tissue bank allografts or complex sizing procedures. Many different scaffolds have been evaluated in recent years for replacement of the meniscus. After past unsatisfying experimental experiences with nonbiologic materials,^{18,30,35,38} only the CMI was proved to be safe and useful as a meniscus allograft in the medium-term follow-up, protecting the knee from the likely degenerative effects of a partial meniscectomy.²² Recently, an in vivo research study in dogs proposed a new synthetic

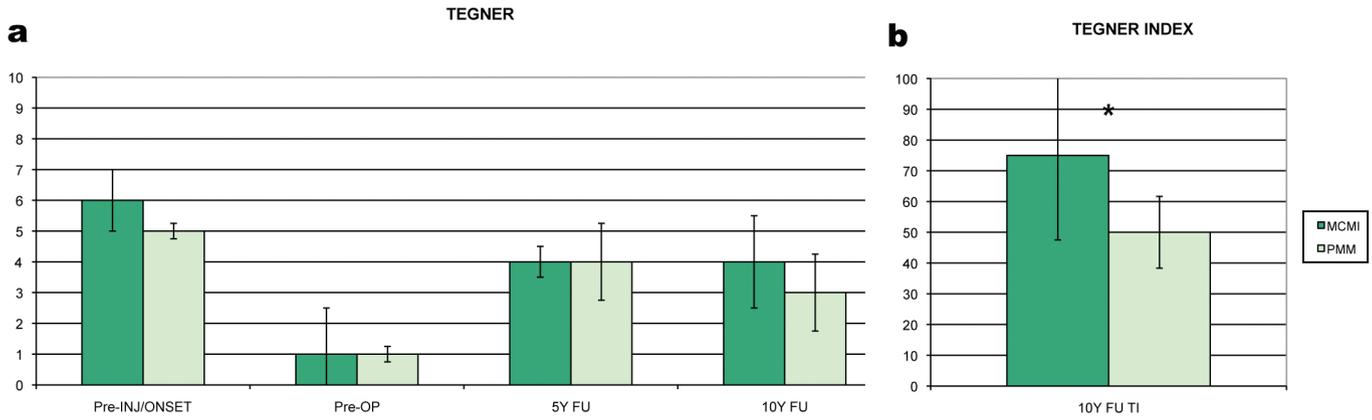


Figure 4. Tegner evaluation. Prospective Tegner activity level scores (a), and 10-year follow-up Tegner index (b). FU, follow-up; MCMI, medial collagen meniscus implant; PMM, partial medial meniscectomy. *Statistically significant differences between the MCMI and control groups.

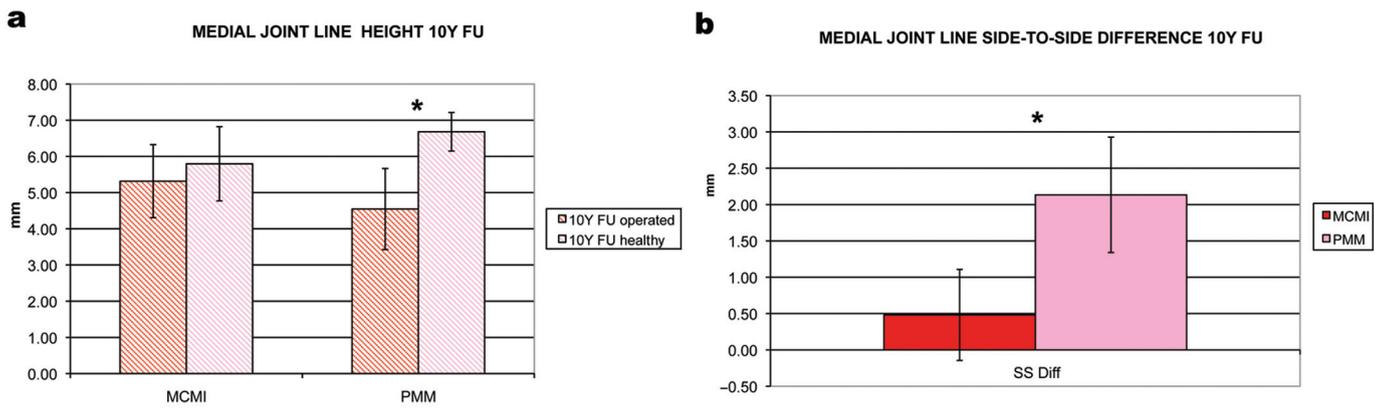


Figure 5. Radiographic measurements at 10-year follow-up. a, Medial joint line height comparison between the operated and contralateral healthy knee for each group. b, Medial joint line height side-to-side difference between the MCMI and the PMM groups. FU, follow-up; MCMI, medial collagen meniscus implant; PMM, partial medial meniscectomy. *Statistically significant differences between groups.

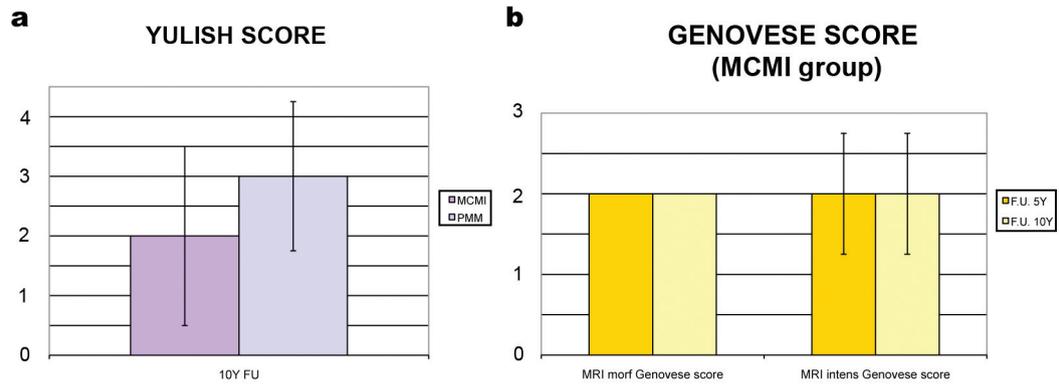


Figure 6. Outcomes of magnetic resonance imaging (MRI) evaluation. a, Yulish score comparison between the MCMI and the PMM groups at 10-year follow-up. b, MRI signal morphologic and intensity comparison between the 5-year and the 10-year follow-up in the MCMI group based on the Genovese score. There were no statistically significant differences between the groups. FU, follow-up; MCMI, medial collagen meniscus implant; PMM, partial medial meniscectomy.

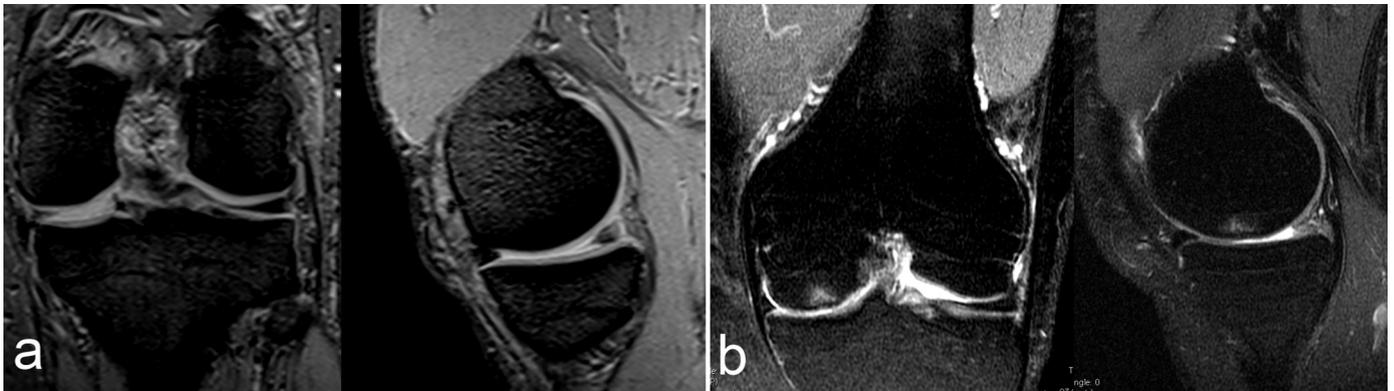


Figure 7. Examples of magnetic resonance imaging (MRI) studies. a, MRI of a left knee (40-year-old man) 10 years after the implantation of a medial collagen meniscus implant. b, MRI of a left knee (38-year-old man) 10 years after a partial medial meniscectomy.

material³⁶ to be used to restore physically and functionally a deficient meniscus, but it is still under investigation.

In our work, inclusion and exclusion criteria for CMI implantation were the same as used by Steadman and Rodkey,²⁵ Rodkey et al,²² and Bulgheroni et al.³ The clinical evaluation showed significant improvement of all measured scores at the 5-year follow-up in the MCMI group compared with the preoperative status, and this level was maintained up to the final 10-year follow-up evaluation. Pain and Lysholm scores were somewhat reduced, and Tegner activity level did not change during the last 5 years. These results were different from those previously published at medium-term follow-up,^{3,22,25,40} suggesting that stabilization of the pain allowed activity to remain level after the 5-year follow-up.

In this study, we observed that MCMI provides statistically significantly improved clinical and radiological outcomes compared with PMM at long-term follow-up (minimum 10 years to maximum 12.5 years). The VAS for pain, objective IKDC, Tegner index, and SF-36 scores confirmed this difference. The Lysholm score may not be sensitive enough to detect differences in a study of this type, or differences may not have been great enough to matter clinically.

The most distinctive feature of this work compared with other previously published studies was the quantitative radiological assessment of CMI function in preserving the radiographic medial joint space. These data represent an indirect demonstration of the biomechanical effectiveness of the new meniscus-like fibrochondrocytic tissue (whose formation was previously demonstrated in a large population by Rodkey et al²²) at long-term follow-up.

The evolution of the MCMI over the time was estimated with MRI. The FatSat FSE T2-weighted sequence signals were hyperintense compared with normal meniscus (Figure 7a). Our results are consistent with those of Zaffagnini et al⁴⁰ and Bulgheroni et al³ in medium-term findings, but they differ from the “progressive CMI signal maturation” found by Steadman and Rodkey.²⁵ In fact, in this study, the MCMI patients’ signal in more than 50% of

cases was compatible with a myxoid degeneration. This variation could be related to different MRI protocols. However, Genovese scores⁹ remained constant between the medium-term and the long-term follow-up in our population. This finding and the good clinical and radiographical results support our hypothesis of scaffold stabilization over time, although we could not verify it directly by means of second-look arthroscopies and biopsies.

The chondral surface was evaluated in both study groups by means of MRI (Figure 7) using the Yulish score.³⁹ This system was developed for chondromalacia patellae, but recently, Verdonk et al³³ used it to classify femoral and tibial cartilage degeneration after meniscus allograft transplantation. From comparable preoperative values, an apparent chondroprotective effect of the MCMI compared with controls was detected, but this observation was only a trend without reaching statistical significance. This finding could be related to the avoidance of intra-articular contrast material injections in our protocol, or more likely it is because of the low MRI sensitivity for knee chondral lesions rather than second-look arthroscopy.⁸ Moreover, this score is very reader dependent; therefore, the results must be considered with caution.

An ACL reconstruction procedure was carried out in 4 patients (2 for each group), but as previously reported by Rodkey et al,²² this procedure has no influence on the amount of new tissue growth.

Reoperations were necessary in 2 patients for each group (13%) during the follow-up time period: adverse events (swelling and pain) in the MCMI group were assumed related to the device (6%) and were successfully treated by means of arthroscopic debridement and HTO (to treat pain by properly redistributing the weight between knee compartments). Patients recovered without sequelae. The MCMI long-term survival rate in this trial (approximately 85%) is comparable with that reported after open meniscal repair⁵ and is superior to the 75% reported by Verdonk et al³² for an open meniscus allograft transplantation.

This study has several limitations. The more important weakness of this study is the lack of randomization. This fact probably led to the meniscectomy group being older than the MCMI one, even if this difference was not statistically significant. It seems that older and more sedentary patients, who were mainly interested in “getting it over with,” self-selected themselves into the PMM group, whereas younger, more active patients chose the MCMI. In addition, the study was not blinded, and a lack of blinding could lead to patient reporting bias. Patients were not divided into 2 study arms (acute and chronic) because of the low number of enrolled patients, but both MCMI and PMM groups were homogeneous regarding this variable and included a similar number of acute and chronic cases. Rodkey et al²² were not able to find clinical differences between treated patients and controls in the acute group at 5-year follow-up in their study, but we speculate that the follow-up time was not enough for significant changes to be observed.

The rehabilitation protocols were very different between groups, but we hypothesize that those differences would have minimal effects 10 years after surgery.

Another weakness is the possibility of recall bias in pre-injury Tegner activity levels, but as addressed by Rodkey et al,²² “if patients overestimated their pre-injury activity levels, in most instances this overestimation would have resulted in an underestimation of the Tegner index.” An additional weakness is the lack of preoperative medial joint line height measurements. We decided to not include these data in the evaluation because the radiographs were executed with different machines by different technicians at different sites. Consequently, we compared the operated knee to the contralateral healthy knee, and we also calculated the side-to-side difference between knees. To our knowledge, this is the best method to evaluate differences in degenerative knee progression because it takes into account each patient’s related physiological differences. Therefore, we used this method as primary radiographic outcomes to compare the MCMI group with the PMM group.

In conclusion, improvements in pain relief, activity level, general health, and radiological outcomes were documented with the use of MCMI at a minimum 10-year follow-up compared with PMM. On the basis of available results, 87% of the patients benefited from this scaffold implantation. The possibility to improve function while decreasing the risk of degenerative changes related to meniscectomy led us to believe that for irreparable meniscal lesions, the use of a scaffold to regrow meniscal tissue would help to maintain patient activity level for a longer time while protecting the joint against pain and degeneration. This study supports that belief; hence, we recommend use of scaffolds in such cases.

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REFERENCES

1. Apolone G, Mosconi P. The Italian SF-36 Health Survey: translation, validation and norming. *J Clin Epidemiol*. 1998;51(11):1025-1036.
2. Briggs KK, Kocher MS, Rodkey WG, Steadman JR. Reliability, validity, and responsiveness of the Lysholm knee score and Tegner activity scale for patients with meniscal injury of the knee. *J Bone Joint Surg Am*. 2006;88(4):698-705.
3. Bulgheroni P, Murena L, Ratti C, Bulgheroni E, Ronga M, Cherubino P. Follow-up of collagen meniscus implant patients: clinical, radiological, and magnetic resonance imaging results at 5 years. *Knee*. 2010;17(3):224-229.
4. Burks RT, Metcalf MH, Metcalf RW. Fifteen-year follow-up of arthroscopic partial meniscectomy. *Arthroscopy*. 1997;13(6):673-679.
5. DeHaven KE, Lohrer WA, Lovelock JE. Long-term results of open meniscal repair. *Am J Sports Med*. 1995;23(5):524-530.
6. Fairbank TJ. Knee joint changes after meniscectomy. *J Bone Joint Surg Br*. 1948;30(4):664-670.
7. Fauno P, Nielsen AB. Arthroscopic partial meniscectomy: a long-term follow-up. *Arthroscopy*. 1992;8(3):345-349.
8. Figueroa D, Calvo R, Vaisman A, Carrasco MA, Moraga C, Delgado I. Knee chondral lesions: incidence and correlation between arthroscopic and magnetic resonance findings. *Arthroscopy*. 2007;23(3):312-315.
9. Genovese E, Angeretti MG, Ronga M, et al. Follow-up of collagen meniscus implants by MRI. *Radiol Med*. 2007;112(7):1036-1048.
10. Hede A, Larsen E, Sandberg H. Partial versus total meniscectomy: a prospective, randomised study with long-term follow-up. *J Bone Joint Surg Br*. 1992;74(1):118-121.
11. Hefti F, Muller W, Jakob RP, Staubli HU. Evaluation of knee ligament injuries with the IKDC form. *Knee Surg Sports Traumatol Arthrosc*. 1993;1(3-4):226-234.
12. Higuchi H, Kimura M, Shirakura K, Terauchi M, Takagishi K. Factors affecting long-term results after arthroscopic partial meniscectomy. *Clin Orthop Relat Res*. 2000;377:161-168.
13. Hoher J, Munster A, Klein J, Eypasch E, Tiling T. Validation and application of a subjective knee questionnaire. *Knee Surg Sports Traumatol Arthrosc*. 1995;3(1):26-33.
14. Jackson JP. Degenerative changes in the knee after meniscectomy. *Br Med J*. 1968;2(5604):525-527.
15. Krause WR, Pope MH, Johnson RJ, Wilder DG. Mechanical changes in the knee after meniscectomy. *J Bone Joint Surg Am*. 1976;58(5):599-604.
16. Li ST, Rodkey WG, Yuen D, Hansen P, Steadman JR. Type I collagen-based template for meniscus regeneration. In: Lewandowski KU, Wise DL, Trantolo DJ, eds. *Tissue Engineering and Biodegradable Equivalents*. New York, NY: Marcel Dekker; 2002:237-266.
17. Marcacci M, Zaffagnini S, Giordano G, Iacono F, Presti ML. Anterior cruciate ligament reconstruction associated with extra-articular tenodesis: a prospective clinical and radiographic evaluation with 10- to 13-year follow-up. *Am J Sports Med*. 2009;37(4):707-714.
18. Messner K, Lohmander LS, Gillquist J. Cartilage mechanics and morphology, synovitis and proteoglycan fragments in rabbit joint fluid after prosthetic meniscal substitution. *Biomaterials*. 1993;14(3):163-168.
19. Outerbridge RE. The etiology of chondromalacia patellae. *J Bone Joint Surg Br*. 1961;43:752-757.
20. Rockborn P, Gillquist J. Outcome of arthroscopic meniscectomy: a 13-year physical and radiographic follow-up of 43 patients under 23 years of age. *Acta Orthop Scand*. 1995;66(2):113-117.
21. Rodeo SA. Meniscal allografts—where do we stand? *Am J Sports Med*. 2001;29(2):246-261.
22. Rodkey WG, DeHaven KE, Montgomery WH III, et al. Comparison of the collagen meniscus implant with partial meniscectomy: a prospective randomized trial. *J Bone Joint Surg Am*. 2008;90(7):1413-1426.

23. Rodkey WG, Steadman JR, Li ST. A clinical study of collagen meniscus implants to restore the injured meniscus. *Clin Orthop Relat Res.* 1999;367(suppl):S281-S292.
24. Sgaglione NA, Steadman JR, Shaffer B, Miller MD, Fu FH. Current concepts in meniscus surgery: resection to replacement. *Arthroscopy.* 2003;19(suppl 1):161-188.
25. Steadman JR, Rodkey WG. Tissue-engineered collagen meniscus implants: 5- to 6-year feasibility study results. *Arthroscopy.* 2005;21(5):515-525.
26. Steadman JR, Rodkey WG, Briggs KK, Rodrigo JJ. The microfracture technic in the management of complete cartilage defects in the knee joint. *Orthopade.* 1999;28(1):26-32.
27. Stone KR, Rodkey WG, Webber RJ, McKinney L, Steadman JR. Future directions: collagen-based prostheses for meniscal regeneration. *Clin Orthop Relat Res.* 1990;252:129-135.
28. Stone KR, Rodkey WG, Webber R, McKinney L, Steadman JR. Meniscal regeneration with copolymeric collagen scaffolds: in vitro and in vivo studies evaluated clinically, histologically, and biochemically. *Am J Sports Med.* 1992;20(2):104-111.
29. Stone KR, Steadman JR, Rodkey WG, Li ST. Regeneration of meniscal cartilage with use of a collagen scaffold: analysis of preliminary data. *J Bone Joint Surg Am.* 1997;79(12):1770-1777.
30. Toyonaga T, Uezaki N, Chikama H. Substitute meniscus of Teflonnet for the knee joint of dogs. *Clin Orthop Relat Res.* 1983;179:291-297.
31. van Thiel GS, Verma N, Yanke A, Basu S, Farr J, Cole B. Meniscal allograft size can be predicted by height, weight, and gender. *Arthroscopy.* 2009;25(7):722-727.
32. Verdonk PC, Demurie A, Almqvist KF, Veys EM, Verbruggen G, Verdonk R. Transplantation of viable meniscal allograft: survivorship analysis and clinical outcome of one hundred cases. *J Bone Joint Surg Am.* 2005;87(4):715-724.
33. Verdonk PC, Verstraete KL, Almqvist KF, et al. Meniscal allograft transplantation: long-term clinical results with radiological and magnetic resonance imaging correlations. *Knee Surg Sports Traumatol Arthrosc.* 2006;14(8):694-706.
34. Verdonk R, Van Daele P, Claus B, et al. Viable meniscus transplantation. *Orthopade.* 1994;23(2):153-159.
35. Veth RP, Jansen HW, Leenslag JW, Pennings AJ, Hartel RM, Nielsen HK. Experimental meniscal lesions reconstructed with a carbon fiber-polyurethane-poly(L-lactide) graft. *Clin Orthop Relat Res.* 1986;202:286-293.
36. Welsing RT, van Tienen TG, Ramrattan N, et al. Effect on tissue differentiation and articular cartilage degradation of a polymer meniscus implant: a 2-year follow-up study in dogs. *Am J Sports Med.* 2008;36(10):1978-1989.
37. Wirth CJ, Peters G, Milachowski KA, Weismeier KG, Kohn D. Long-term results of meniscal allograft transplantation. *Am J Sports Med.* 2002;30(2):174-181.
38. Wood DJ, Minns RJ, Strover A. Replacement of the rabbit medial meniscus with a polyester-carbon fibre bioprosthesis. *Biomaterials.* 1990;11(1):13-16.
39. Yulish BS, Montanez J, Goodfellow DB, Bryan PJ, Mulopulos GP, Modic MT. Chondromalacia patellae: assessment with MR imaging. *Radiology.* 1987;164(3):763-766.
40. Zaffagnini S, Giordano G, Vascellari A, et al. Arthroscopic collagen meniscus implant results at 6 to 8 years follow up. *Knee Surg Sports Traumatol Arthrosc.* 2007;15(2):175-183.
41. Zaffagnini S, Marcheggiani Muccioli GM, Giordano G, et al. Synthetic meniscal scaffolds. *Techniques Knee Surg.* 2009;8(4):251-256.

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