Outcome After Partial Medial Meniscus Substitution With the Collagen Meniscal Implant at a Minimum of 10 Years' Follow-up

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Purpose: The aim of the study was to evaluate the clinical outcome of a collagen meniscus graft implanted in an injured medial meniscus after a minimum of 10 years' follow-up. **Methods:** Twenty-five patients underwent arthroscopic implantation of the collagen meniscus device. They had either persistent compartmental joint line pain due to a previous medial meniscus resection (5 cases) or a large irreparable meniscus tear at arthroscopy (20 cases). Implant failure was defined as infection due to the implant or mechanical failure of the device. Twenty-two patients returned for clinical, functional, and radiographic evaluation. Magnetic resonance imaging was also performed and was analyzed with the criteria of Genovese et al. (where type 3 indicates normal and type 1 indicates completely abnormal). All the aforementioned evaluations were carried out at a minimum of 10 years (range, 10.1 to 12.5 years) after the procedure. **Results:** The mean Lysholm score improved from 59.9 preoperatively to 89.6 at 1 year ($P < .001$), and it was 87.5 at final follow-up ($P < .001$). The results were good or excellent in 83% of the population. No differences were observed when we compared the Lysholm score at 1 year of follow-up with the score at final follow-up ($P > .05$). The mean pain score on a visual analog scale improved by 3.5 points at final follow-up. Patient satisfaction with the procedure was 3.4 of 4 points. Radiographic evaluation showed either minimal or no narrowing of the joint line. Magnetic resonance imaging showed type 2 in 64% of cases and type 3 in 21%. All cases showed less volume than expected (size type 2 in 89%). The failure rate in the patient population was 8% (2 of 25). There were no complications related to the device. **Conclusions:** Although there were several different types of patients and acute and chronic tears were treated in a limited number of patients, meniscal substitution with the collagen meniscal implant provides significant pain relief and functional improvement after a minimum of 10 years' follow-up. The implant generally diminished in size, but the procedure proved to be safe and had a low rate of implant failure on a long-term basis. No development or progression of degenerative knee joint disease was observed in most cases. **Level of Evidence:** Level IV, therapeutic case series.

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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. The subsequent loss of some degree of meniscal tissue alters this protective function by modifying the pattern of load distribution.[1,3] This condition has frequently been shown to lead to a painful knee, chondral lesions, joint space narrowing, and osteophyte formation.[3-5]

The extent of meniscectomy leading to clinically significant outcomes is unknown. However, it has been

shown that the larger the meniscectomy, the larger the decrease in the contact area and the larger the increase in the mean and peak contact stresses.[2] However, not all damaged menisci can be treated with minimum resection or repair. This fact makes some large resections inevitable. In these cases and in an effort to keep the knee functional and pain free, an interest in meniscal preservation techniques has increased over the last few decades. Meniscal tissue–engineering implants were developed as a promising option for regeneration of partial native tissue loss.[6] Collagen meniscal implant (CMI; ReGen Biologics, Franklin Lakes, NJ) is a first-generation collagen-based meniscus substitute. This resorbable scaffold was designed to support ingrowths of new tissue that eventually regenerate the lost meniscus.[6-8] It can only be implanted after partial loss of the meniscus because it requires the meniscal rim and horn remnants to be properly fixed. Since its development, it has been used in patients with partial medial meniscectomy and has shown promising midterm results.[8-13] However, no long-term outcomes of the CMI procedure have been published yet.

For objective evaluation of the CMI implantation, Genovese et al.[10] recently described different criteria to evaluate the status of the CMI on magnetic resonance imaging (MRI). They observed a progressive worsening of the appearance of the CMI and a reduction of its height on the MRI scans throughout the 2-year study period.

The aim of this study was to evaluate, at a minimum of 10 years of follow-up, the outcome of the CMI device implanted in an injured medial meniscus. The indications suggested by the European Multicenter Prospective Study were followed. That study was originally designed to evaluate the safety and effectiveness of the device. However, this work focused on subjective and objective clinical outcomes as well as standard radiography and MRI. The main hypothesis was that the patients would show that pain decreases and functionality is improved after implantation of the CMI and that this situation could be maintained after 10 years. The second hypothesis was that the device would demonstrate its safety all along the studied period. Finally, we hypothesized that there would not be any progression or new development of degenerative knee joint disease.

METHODS

Between September 1997 and January 2000, a total of 25 patients underwent CMI implantation. All the patients were included in the European Multicenter Prospective Study. The procedure was performed in patients with either persistent medial compartmental joint line pain due to a previous sizable meniscus resection or a large irreparable meniscus 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 anterior cruciate ligament (ACL)–deficient knee was not considered a contraindication if the ligament was reconstructed at the same time as the CMI implantation. Patients who had an Ahlbäck grade[14] greater than grade II on the radiographs of the medial tibiofemoral compartment were excluded. Other exclusion criteria were complete loss of the medial meniscus, lateral meniscus injuries, untreated instability, grade IV chondral lesions, axial deviation greater than 5°, inflammatory arthritis, collagen allergies, autoimmune disease, and pregnancy.[9,15]

All 25 patients gave their informed consent before intervention. The study received the approval of our local clinical investigation ethics committee. At the time of CMI implantation, the mean age of the 25 patients was 29.2 years (range, 18.3 to 48.2 years) and the body mass index averaged 25.1 (range, 18 to 44.1). The study group yielded 20 male and 5 female patients (11 left and 14 right knees).

Of the patients, 14 (56%) had undergone previous knee surgeries. Partial arthroscopic meniscectomy had been performed in 10 of those cases (40%). ACL reconstruction and partial meniscectomy had been the index procedures in the remaining 4 cases (16%).

The CMI was implanted because of compartmental knee pain due to a prior meniscectomy (post-meniscectomy syndrome) in 5 cases (20%). In those cases the mean time from meniscectomy to CMI implantation was 6.2 years (range, 4.7 to 7.1 years). The CMI was implanted at the time of arthroscopy in the acute setting when a medial meniscectomy for irreparable meniscal lesions had to be performed in the remaining 20 cases (80%). The injury patterns of the menisci were classified as complex in 5 cases, horizontal tear in 2, bucket-handle tear in 2, and radial tear in 2. A primary ACL reconstruction was also performed with a bone–patellar tendon–bone autograft in 13 of the 20 cases (52%). A 1.5 × 2–cm grade III chondral lesion on the medial femoral condyle was observed in 1 of these knees, and it was microfractured. In another patient a failed ACL graft was reconstructed. In 2 additional patients a grade II chondral lesion was also detected in the medial femoral condyle. They were both left untreated. An irreparable meniscal tear was the only finding observed in the remaining 6 cases (24%). Of these 20 cases operated on in an acute

FIGURE 1. Intraoperative view. The implant was introduced into the knee with a specially designed metallic delivery cannula. It contained the CMI enveloped in a plastic sheath (inset) to prevent damaging it and to facilitate expelling it from the metallic cannula when pushing the implant into the knee.

setting, the elapsed mean time from injury to surgery was 3.5 years (range, 0.25 to 10.5 years).

CMI failure was defined as infection due to the implant or mechanical failure of the implant.

Surgical Technique

The surgical technique was completely arthroscopic, and all the surgeries were performed by the senior surgeon (J.C.M.). A complete diagnostic arthroscopy was first done through a standard anterolateral portal to evaluate the meniscus and/or any other lesion of the knee. A convenient medial 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. Puncture holes were then made through the meniscal bed rim, extending into the vascular zone of the meniscus, with either a microfracture awl (from the inside of the joint) or an 18-gauge spinal needle (from the outside of the joint) so as to guarantee an adequate blood supply. The location of the lesion was the posterior and central zone of the medial meniscus in all cases. Sizing of the defect was then performed with a specially designed flexible rod that was introduced into a rigid cannula. The CMI was then measured and trimmed to fit the defect. The mean length of the implant was 48.2 mm (range, 32 to 67 mm).

To have easy access to the medial femorotibial compartment, the surgeon performed a release of the medial collateral ligament by piercing the ligament percutaneously with a spinal needle in most cases while applying valgus stress. The anteromedial portal was generously enlarged to facilitate the easy introduction of the implant. The CMI was soaked for a few seconds in saline solution before implantation. The implant was then introduced into the knee with a specially designed delivery cannula to avoid damaging it (Fig 1). The implant was sutured to the host meniscus with an in-out technique by use of the SharpShooter device (ConMed Linvatec, Largo, FL). The sutures were placed in a vertical pattern (Fig 2) every 4 to 5 mm along the meniscus rim and in a horizontal pattern at the anterior and posterior ends of the implant (Fig 3). A longitudinal posteromedial 3- to 4-cm incision was also made to safely retrieve the suture devices that were securing the most posterior aspect of the implant to the meniscus remnant and knee capsule. Upon completion of suturing, the stability of the implant was tested with a probe.

Postoperative Protocol

Immediate quadriceps and hamstring muscle exercises as well as 0° to 60° passive range of motion were initiated. Range of motion progressed gradually to 90° after 3 weeks, and unlimited passive motion was allowed after 6 weeks. The patients were non–weight bearing for the first 2 weeks after surgery. Progressive

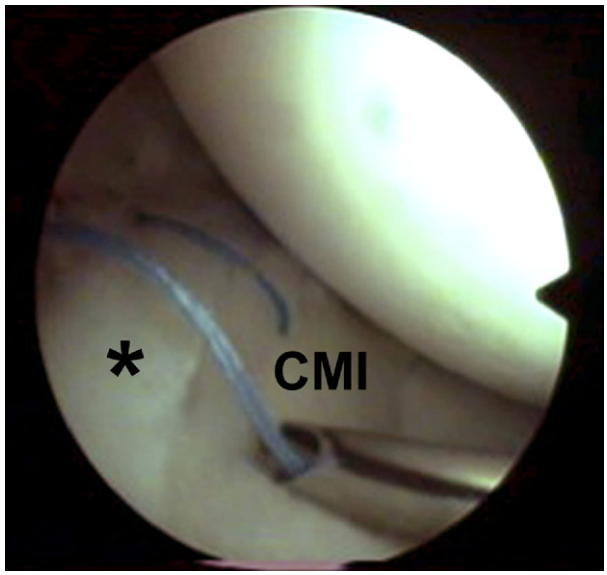

FIGURE 2. Arthroscopic view. The central zone of the CMI was sutured to the meniscus remnant (asterisk) with vertical in-out mattress sutures.

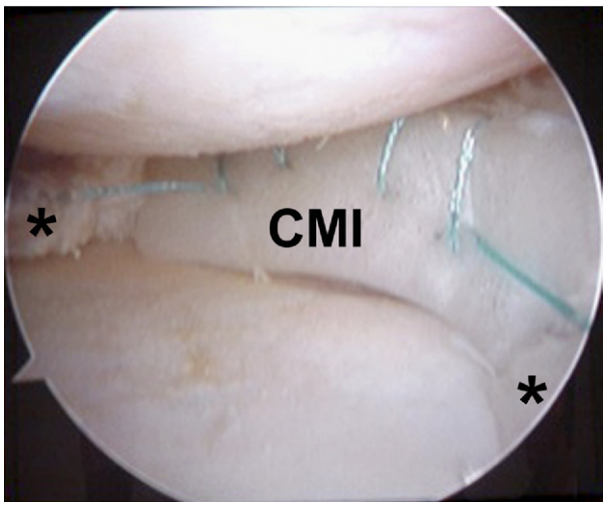

FIGURE 3. Arthroscopic view of a CMI inserted in a defect surrounded by the remnant meniscal tissue (asterisks). One should note the vertical sutures in the middle of the CMI and the horizontal sutures at the anterior and posterior ends of the device.

partial weight bearing up to full weight bearing was achieved from week 3 through week 8. Patients returned to a normal workload by the fourth month after surgery. Running and unrestricted physical activity were allowed by the sixth month, depending on patient compliance.

Functional and Imaging Evaluation

Functional follow-up included the 100-point Lysholm score. The Lysholm score was interpreted as excellent when greater than 94 points, good from 84 to 94 points, fair from 65 to 83 points, and poor when less than 65 points.[16] 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 (4 points), satisfied (3 points), neutral (2 points), dissatisfied (1 point), or very dissatisfied (0 points). Thigh diameter was bilaterally measured at 5 cm above the patella.

All patients' radiographic assessments included a non–weight-bearing lateral radiograph with 30° of flexion and a weight-bearing long-standing anteroposterior view of both inferior extremities to assess lower-limb alignment. Six patients had knees with 5° valgus, and one patient had a knee with 5° varus. We also obtained a weight-bearing posteroanterior view with 45° of flexion (Rosenberg view) of both knees to assess any early joint line collapse following the criteria of Ahlbäck and Rydberg.[14] In 7 patients Ahlbäck grade I was observed in the medial femorotibial compartment.

The functional evaluation and the radiographic assessment were performed at final follow-up by the same independent observer.

Preoperatively, MRI was done to confirm the loss of meniscal tissue and the status of the cartilage, as well as any associated condition. The standard knee protocol for each subject consisted of the following sequence: axial fast spin-echo T2 weighted with fat saturation, coronal fast spin T1 weighted, sagittal spin T1 weighted, and sagittal fast spin-echo T2 weighted with fat saturation. The MRI scans were analyzed to assess the 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 3 types. Type 3 corresponds to the MRI characteristics of a normal meniscus and type 1 to a hyperintense and reabsorbed implant. The criteria of Genovese et al. are detailed in Table 1. The interface between the residual and prosthetic meniscus was also assessed. The MRI scans were analyzed and classified by an independent and trained radiologist.

The functional and radiographic evaluations were performed at final follow-up by the same independent observer and compared with the original preoperative data and the 1-year results by use of the same criteria.

Follow-Up

All patients prospectively underwent functional and radiographic assessment preoperatively and at the

TABLE 1. *MRI Criteria**

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

NOTE. MRI scans were used to categorize the evolution of the MRI aspect of the CMI.
*Based on data from Genovese et al.[10]

6-month, 1-year, and final follow-up. For this study, data from our records were used to analyze all 25 patients at preoperatively and at 6 months and at 1 year after implantation of the collagen meniscus device. Of the patients, 22 returned for the final evaluation at a mean of 11.1 years (range, 10.1 to 12.5 years). In 2 of the patients, final evaluation was not required because of allograft meniscal transplantation (AMT) that had to be performed for different complications. The remaining patient was unavailable for a cause unrelated to the procedure. MRI was performed in 10 patients at 1 year after the implantation and at final follow-up in 19 of the 22 patients who returned for this last evaluation.

Statistical Analysis

Categorical variables are presented as percentages and frequencies. Continuous variables are presented as means and ranges. The Lysholm score and VAS pain score at the most recent follow-up evaluation were compared with the preoperative scores by use of the paired Student *t* test. Statistical analysis was performed with SPSS software (version 13.0; SPSS, Chicago, IL). Statistical significance was set at .05.

RESULTS

The 22 patients who returned for final follow-up evaluation had a mean age of 42.3 years (range, 23.1 to 58.2 years). At the time of final follow-up, no patient was observed to have any meniscal symptoms. No complications related to the implant were reported in these 22 patients either.

Functional Results

The Lysholm score improved from 59.9 (range, 30 to 90) to 89.6 (range, 78 to 100; $P < .001$) at 1 year and 87.56 (range, 59 to 100; $P < .001$) at final follow-up. Considering that 2 of the patients underwent AMT in the meantime, good and excellent results were obtained for 83% of the population after a minimum of 10 years from the implantation of the CMI. No differences were observed when we compared the Lysholm score at 1 year of follow-up with the score at final follow-up ($P = .74$). There were no differences when we compared the patients with a concomitant ACL reconstruction with isolated CMI implantation either ($P = .43$). The mean VAS pain score improved by 3.5 points at final follow-up. It decreased from a mean of 5.5 preoperatively (range, 2 to 8) to 2 (range, 0 to 6) at final follow-up ($P = .005$). No differences were observed between the VAS score at 1 year of follow-up and final follow-up ($P = .18$). The satisfaction of the patients with regard to the procedure was 3.4 points (of a maximum of 4 points).

The functional results are summarized in Table 2.

Imaging Findings

The result of the radiographic evaluation with the Rosenberg view did not show any further narrowing at final follow-up when we analyzed the joint space in those 7 cases that had Ahlbäck grade I before the CMI procedure. At final follow-up, another 4 patients progressed from Ahlbäck grade 0 preoperatively to Ahlbäck grade I at final follow-up. None of those patients showed any narrowing of the joint line 1 year after the index surgery. One 48-year-old patient who had undergone ACL reconstruction and collagen meniscal implantation 11.4 years ago progressed from Ahlbäck grade 0 to Ahlbäck grade II joint space narrowing on the radiographic evaluation at final follow-up (Fig 4). In the remaining 11 patients available at final follow-up, radiographic evaluation of the Rosenberg view did not show any narrowing of the medial joint line compartment (Ahlbäck grade 0).

Evaluation at 1 year of follow-up on the 10 available MRI scans, following the criteria of Genovese et al.,[10] showed that the signal intensity was type 1 in 3

TABLE 2. *Functional Results*

	Preoperative	1-yr Follow-up	All Cases at Final Follow-up	Isolated CMI at Final Follow-up	CMI + ACL Reconstruction at Final Follow-up
Lysholm score	59.9 (30-90) (excellent, 0%; good, 4%)	89.6 (78-100); $P <$ .001 (excellent, 32%; good, 60%)	87.56 (59-100); $P <$ .001 (excellent, 29%; good, 54%)	90.1 (59-100) (excellent, 40%; good, 40%)	86.2 (68-100) (excellent, 21%; good, 64%)
VAS	5.5 (2-8)	1.5 (1-6); $P = .003$	2 (0-6); $P = .005$	2.1 (0-6)	1.8 (0-4)

NOTE. All data are expressed as mean (range). Statistical significance (*P* value) was set at .05. The mean Lysholm score as well as the mean VAS score for knee pain improved from preoperatively to the 1-year evaluation, and this improvement was retained at final follow-up. There was no difference when we compared the patients with concomitant ACL reconstruction with those with an isolated CMI procedure.

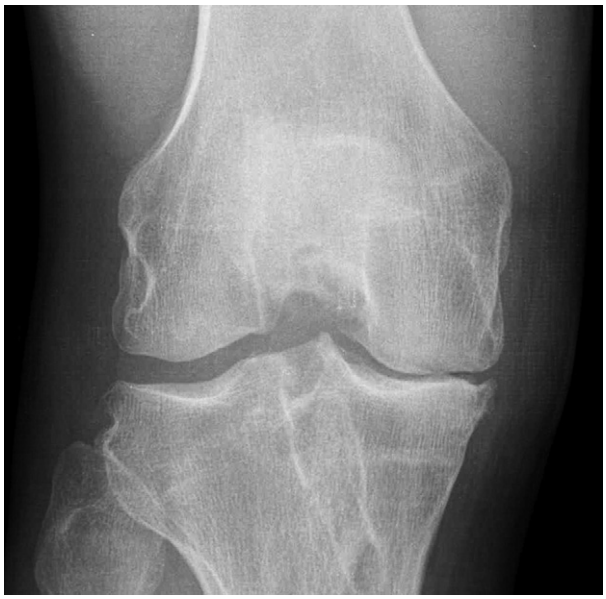

FIGURE 4. Rosenberg-view radiograph. This Ahlbäck grade II medial tibiofemoral joint space narrowing at final follow-up progressed from Ahlbäck grade 0 in a 48-year-old patient who had undergone ACL reconstruction and CMI implantation 11.4 years ago.

patients, type 2 in 6 patients, and type 3 in 1 patient. The morphology and size were type 2 in 5 patients and type 3 in the remaining 5. The interface between the implant and meniscal tissue was distinguishable in all (Fig 5) but 1 case. At final follow-up, the 19 patients who underwent MRI showed the following distribution: 4 type 3 (21%), 12 type 2 (64%) (Fig 6), and 3 type 1 (15%). All the cases showed less volume than expected at final follow-up. Whereas 17 cases were classified as size type 2, the remaining 2 cases were classified as type 1. Furthermore, as in the case shown in Fig 5, the interface between the new tissue and the native meniscal tissue could no longer be resolved. The MRI findings following the criteria of Genovese et al. are summarized in Table 3.

Physical Assessment and Complications

No serious complications occurred in the immediate postoperative period. Moderate knee effusion was observed in 3 patients 1 week after surgery. They required arthrocentesis for pain relief. At 6 months' follow-up, 3 patients showed slight effusions and 4 moderate effusions. Two patients had slight effusions at 1 year after implantation. Whereas exploration of 1 of them had shown moderate effusions at 6 months of follow-up, the other patient had been effusion free in the same evaluation period. Repetitive knee effusion subsequently developed in the latter patient; this required second-look arthroscopy 4 years after the CMI procedure (Lysholm score of 63 at final follow-up). Joint space narrowing did not progress from the assessed Ahlbäck grade 0 before the CMI procedure. During the revision surgery, it was observed that the CMI had degenerated and was unviable (Fig 7). For that reason, AMT was performed. No patient showed knee effusion at final follow-up examination. However, 7 patients complained of some degree of knee swelling after high-level sporting activities. Thigh-girth measurement showed slight differences ($<$1.5 cm) between the 2 sides in 3 cases at final follow-up.

One of the patients who had had a CMI implantation as well as an ACL reconstruction required a second surgery at 14 months after the first operation because of a cyclops lesion complication. The patient showed Genovese type 1 on the MRI scan performed at 1 year of follow-up. During the arthroscopic evaluation, the implant was almost completely reabsorbed. This fact showed no clinical consequences at final follow-up except for mild effusion after high-level sporting activities. Another patient who complained of

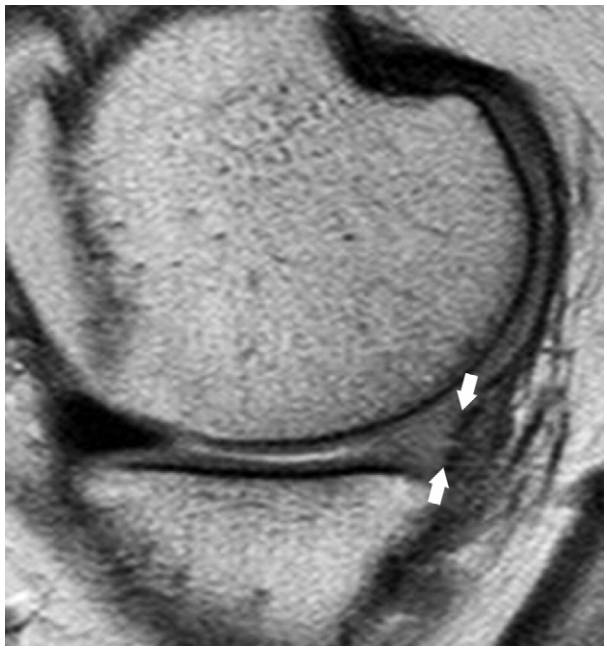

FIGURE 5. MRI examination at 1 year. The sagittal image obtained with spin T1-weighted MRI shows that the CMI size was in this case identical to that of the normal meniscus (type 3) and that the signal intensity had increased in an inhomogeneous manner, reaching type 1. The interface between the implant and meniscal tissue is clearly distinguishable (arrows).

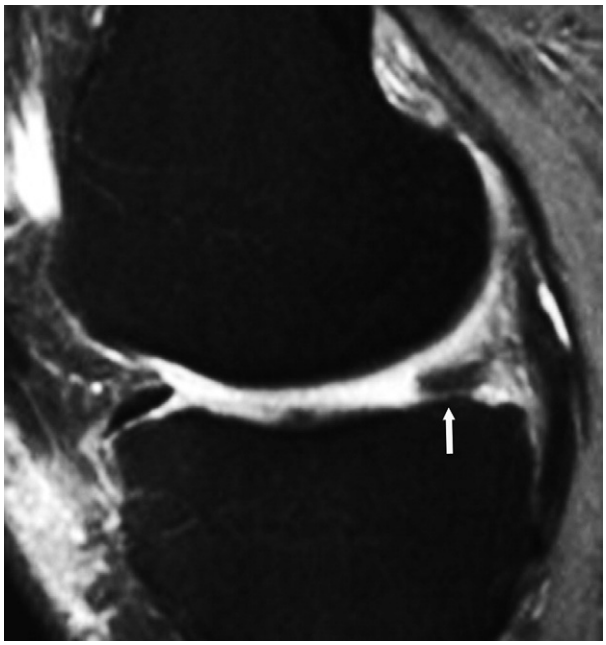

FIGURE 6. MRI examination at 11.3 years of follow-up. The T2-weighted sagittal image with fat suppression shows that the size of the collagen implant (arrow) has moderately decreased over the years (type 2). Signal intensity is reduced and homogeneous (type 3). The interface between the prosthetic meniscus and the native meniscal tissue can no longer be observed.

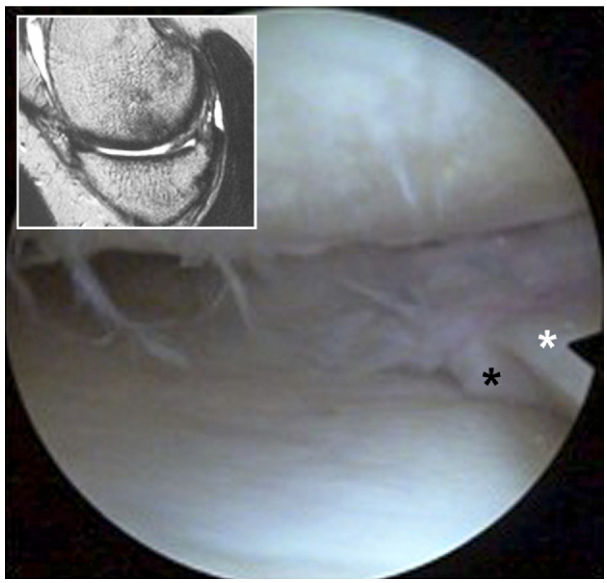

FIGURE 7. Repetitive knee effusion developed in 1 patient and required second-look arthroscopy. The host meniscus was still present (white asterisk), and the CMI was observed to be degenerated and unviable (black asterisk). A sagittal MRI scan obtained with spin T1-weighted MRI (inset) showed that the implant had reduced in size (Genovese type 2) and signal characteristics were type 2.

persistent pain in the affected femorotibial compartment (Lysholm score of 58 and VAS score of 6 at final follow-up) also underwent a 2-stage open-wedge high tibial osteotomy and AMT 7 years after the CMI procedure (Fig 8). Joint space narrowing had progressed from Ahlbäck grade 0 to Ahlbäck grade I.

Stability was normal or nearly normal in all 14 cases that had undergone ACL reconstruction. The KT-1000 evaluation showed a difference of less than 3 mm between the operative and nonoperative knees in 13 patients. In the remaining patient, a 5-mm difference between knees was observed.

The failure rate in the patient population was 8% (2 of 25).

DISCUSSION

This study evaluated the functional and radiographic results of CMI implantation with a minimum of 10 years of follow-up after surgery and showed the effectiveness of the procedure. This technique im-

TABLE 3. *Distribution According to MRI Criteria**

	Signal Intensity	Morphology/Size	CMI/Meniscus Interface
1-yr follow-up			90% distinguishable (9)
Type 1	30% (1)	0%	
Type 2	60% (6)	50% (5)	
Type 3	10% (3)	50% (5)	
Final follow-up			100% non-distinguishable (19)
Type 1	15% (3)	11% (2)	
Type 2	64% (12)	89% (17)	
Type 3	21% (4)	0%	

NOTE. MRI evaluation was possible in 10 patients at 1 year of follow-up and in 19 patients at final follow-up. Data are expressed as percentage (number of cases).

*Based on data from Genovese et al.[10]

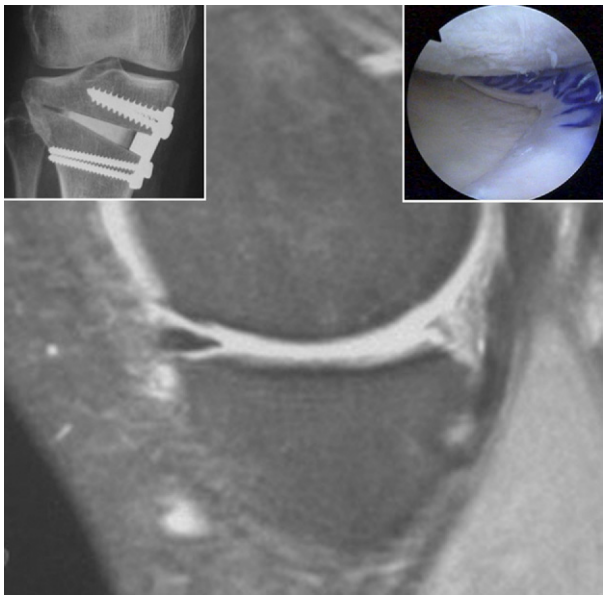

Figure 8. The second failure occurred in a patient who complained of persistent pain. This sagittal MRI scan obtained with T2-weighted MRI with fat suppression shows that the CMI considerably reduced in size (type 1) and had signal characteristics that were certainly abnormal (type 3). The patient underwent a 2-stage open-wedge high tibial osteotomy (left inset) and AMT (right inset) 7 years after the CMI procedure.

proved knee function and symptoms in this group of patients. The Lysholm and VAS pain scores significantly improved for at least 10 years when compared with preoperative values. This confirms our first hypothesis. The procedure also was safe, because no complications were noted as a result of the device. Surgical revision because of implant failure in the period studied was necessary in only 2 patients. They required AMT. The aforementioned finding confirms our second hypothesis.

It has been shown that the larger the meniscectomy, the larger the decrease in the contact area and the larger the increase in the mean and peak contact stresses.[2] Thus a prudent strategy is to preserve the greatest amount of meniscus possible. The possibility of trimming the CMI to fit an existing or created meniscus defect without compromising the entire meniscal structure made the implant a unique device to try to restore the important role of the meniscus.

The CMI is considered a first-generation meniscal substitute that was developed in the United States a couple of decades ago.[17] This device is a collagen-based meniscus substitute. It is fabricated from bovine Achilles tendons. It provides a scaffold of purified type I collagen fibers that is swollen in hyaluronic acid and chondroitin sulfate, homogenized, and supplemented with glycosaminoglycans.[7,18] The CMI provides a 3-dimensional scaffold that is suitable for colonization by precursor cells and vessels and leads to the formation of fully functional tissue.[10] Histologic studies showed that the lacunae of the implant are filled with connective tissue that contains newly formed vessels and fibroblast-like cells.[8,11] Since its development, the CMI has been used in patients with partial medial meniscectomy. Although the CMI is cleared for sale in Europe and several other countries around the world, it is not yet available in the United States. Recently, a polyurethane meniscal implant was approved for clinical use (Actifit; Orteq, Groningen, Holland). To date and because of the recent European Union regulatory clearance (approved for sale in July 2008), no studies providing clinical outcomes have been published. Because the CMI and the Actifit implant are not suitable for total meniscal replacement because they require a meniscal rim and horn remnants for the implant to be properly fixed, AMT is still the only approved method for total meniscal substitution.[19] However, meniscal allograft is not widely available, and it presents a potential infectious disease transmission risk.[20] In addition, in cases with partial loss of meniscal tissue, the AMT procedure requires re-sectioning of the entire native meniscal remnant. Furthermore, because the chondroprotective effect of the AMT is yet to be established,[19] it cannot be considered the end-all meniscal replacement procedure.

Rodkey et al.,[11] in a midterm follow-up study, have recently provided further evidence supporting CMI-promoted regrowth of meniscal-like tissue. They prospectively performed a randomized study where more than 300 patients with meniscal tears were divided into 2 arms, either acute or chronic. One group had patients with an irreparable acute medial meniscus injury with no previous surgery. The other group had patients with previous partial medial meniscectomy with up to 3 previous surgeries on the involved meniscus. The patients were randomized to undergo either CMI treatment or partial meniscectomy. Second-look arthroscopies and biopsies performed in the CMI patients 1 year postoperatively showed that the implant was able to produce new meniscus-like tissue. Furthermore, after a mean follow-up of 5 years, the patients in the chronic group significantly regained more of their lost activity than did the control patients and underwent significantly fewer operations. The authors concluded that the CMI is a useful tool for replacing irreparable or lost meniscal tissue and im-

proving quality of life in patients with a symptomatic chronic meniscal injury. Other CMI midterm studies have also shown promising results. Steadman and Rodkey[9] have shown that the CMI improved the preoperative status in 8 patients and that the implant maintained its structure and functioned without negative effects for more than 5 years. Zaffagnini et al.[12] have published the results of the CMI procedure in 8 patients at 6 to 8 years' follow-up. They also observed that although the implant generally diminished in size, the outcome for the 8 patients was highly satisfactory and the implant may have helped reduce deterioration of the knee joint. Similarly, in our study the outcome was good in the majority of the cases (22 of 25). Our functional results also showed an improvement in Lysholm score as well as pain relief reflected by means of VAS score at a minimum of 10 years' follow-up. Interestingly, no differences were observed when we compared the outcomes after 1 year versus 10 years of follow-up. This suggests that functional improvement was not only substantial but was also long-lasting. Although the Lysholm score showed low sensitivity to detect changes over time after ACL reconstruction,[21] it showed an acceptable psychometric performance as an outcome measure for patients with meniscal injuries of the knee.[22] Moreover, the procedure proved to be safe because no adverse effects on the knees were observed.

The low rate of failures observed in this series is encouraging. In the first failure, no causes for the CMI resorption were identified. In the second failure, the patient had been operated on because of a post-meniscectomy syndrome. This case was considered a violation of the study protocol because he had a 14° varus knee that was not addressed because he was still involved in sports activity. However, the CMI procedure allowed him to be symptom free for a considerable period of 7 years. This is in agreement with the recent observations of Rodkey et al.,[11] in which the best results were observed in chronic cases or in cases after meniscectomy. A high tibial osteotomy performed at the time of the index surgery might have avoided the need for further surgeries. AMT was the final procedure in those 2 cases. Before CMI was developed, AMT used to be the procedure performed in cases with partial loss of meniscal tissue. Thus the CMI failures can be treated with a procedure that might have been an option initially.

This is the first report of any meniscal substitution with an artificial device on a long-term basis. The long follow-up period showed no deterioration in the joint line space at the end of the follow-up in almost all patients. However, the lack of a control group does not sufficiently allow for the demonstration of the chondroprotective effect of the device. Cicuttini et al.[23] have recently shown that the yearly ratio of cartilage loss after meniscectomy may be as high as 6.9%, whereas it is much less in normal knees. In only 1 patient, who had undergone ACL reconstruction and collagen meniscal implantation 11.4 years ago, a progression from Ahlbäck grade 0 to Ahlbäck grade II was observed. This might be explained by the higher initial knee injury necessary to cause an ACL tear. The 10-year period of follow-up in our study with no joint line derangement is an encouraging finding that suggests that some protection of the joint line cartilage might occur, which confirms our third hypothesis.

For an objective evaluation of the CMI implantation, we used standard radiography as well as MRI. We assessed the MRI scans following the direct criteria described recently by Genovese et al.[10] They concluded that the lack of interface between native and prosthetic meniscus on MRI scans did not have any correlation with their clinical outcomes. They also observed a reduction of 37.5% of the implant height at their final follow-up. In addition, they observed a progressive worsening of the CMI's appearance on the MRI scans throughout the 2-year period studied. At 2 years after surgery, most of the implants were type 2. In this study we observed similar results to those that they observed at 2 years after the procedure but with a much longer follow-up. The most common finding on MRI was an implant that had reduced in size, with a slightly hyperintense signal (Genovese type 2), with partial integration into the host meniscus, and with an unrecognizable interface between the residual and synthetic meniscus. This is also in agreement with the normal evolution of the CMI's appearance on MRI described by Genovese et al. Although we have not correlated the clinical outcome with the MRI appearance, previous studies have suggested a weak correlation between both instances.[10,24] The lack of association between the MRI appearance of the meniscus and the clinical outcome has also been described in AMT.[25]

With regard to the surgical technique, in recent years we have moved to an all-inside suturing technique using the FasT-Fix device (Smith & Nephew Endoscopy, Andover, MA). This device is particularly useful in avoiding the posteromedial incision and allows for a decrease in the operative time.[26]

The main limitation of this investigation is that it is not randomized and has no control group. Following the European Multicenter Trial protocol, there was no

randomization and no cohort of control patients because the original purpose of the study was to show the safety and efficacy of the CMI. However, all cases were followed longitudinally through all the clinical and radiologic aspects. The results show that the procedure is safe, because patients had no adverse effects and returned to physical activities without significant discomfort. Another weakness of the study is that data regarding functional outcome were limited to the Lysholm scale, VAS, and satisfaction of the patients with regard to the procedure. More information about activity level (i.e., Tegner score) or evaluation with the International Knee Documentation Committee score would have been tremendously helpful. Unfortunately, the European Multicenter Prospective Study protocol did not include this kind of information. In addition, the fact that only 5 of the patients were operated on because of a post-meniscectomy syndrome represents a particular challenge to drawing a more meaningful conclusion. An important limitation is that the study group included patients undergoing isolated CMI as well as patients with concomitant ACL reconstruction to address not only their meniscal problems but also concurrent ligamentous deficiencies. This is an obvious limitation that makes a more accurate assessment of the device's implantation difficult because combined procedures introduce a degree of performance bias into the results. On the basis of the interdependence of ACL reconstruction and meniscal surgery on knee function,[27] patients undergoing a combined procedure would be more likely to have an improved outcome compared with those with unaddressed knee instability who are undergoing isolated collagen meniscal implantation. However, the added morbidity of these concurrent surgical procedures may diminish the likelihood of a successful outcome. Future investigation comparing isolated CMI versus a CMI procedure with concomitant ACL reconstruction or other concomitant procedures should be addressed.

Our results suggest that this procedure is a safe and useful option in selected patients. Patients undergoing the implantation of the collagen scaffold device might expect functional improvement and pain relief that remain unchanged for at least 10 years. However, the device's potential chondroprotective effect is still to be shown in prospective randomized studies.

CONCLUSIONS

Although there were several different types of patients and acute and chronic tears were treated in a limited number of patients, meniscal substitution with the CMI provides significant pain relief and functional improvement after a minimum of 10 years' follow-up. The implant generally diminished in size, but the procedure proved to be safe and had a low rate of implant failure on a long-term basis. No development or progression of degenerative knee joint disease was observed in most cases.

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