Collagen Meniscus Implant: Technique and Results

11.2

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Introduction

The early degeneration of knee joint articular surfaces following meniscectomy was well described in the literature of the last century [4]. This detrimental effect, caused by the higher compressive loads in the involved compartment, has recently been introduced in the concept of meniscal replacement [5]. Although allografts used for meniscal substitution have shown good early results, information about the long-term effects of this procedure and particularly its protective effect on cartilage is scarce [12]. Furthermore, the limited availability of meniscal allografts along with potential infectious disease transmission has motivated some authors to explore the possibilities of scaffold-guided meniscal tissue regeneration.

The Menaflex™, former collagen meniscus implant (CMI), was developed from bovine collagen in the early nineties in order to promote meniscal regeneration in segmental defects of meniscal tissue [10, 11]. Experimental and clinical experiences with the medial CMI, to date, have shown promising results [8, 9, 13], and a lateral CMI has recently been developed.

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The purpose of this chapter is to describe the CMI surgical technique along with some tips and gems gleaned from experience that might provide the most successful outcome. The mid-term results of a medial CMI series are also presented.

Surgical Procedure

Implantation of the CMI is performed using an arthroscopic surgical procedure with specially designed instruments and requires skill in meniscal repair techniques. Basically, the damaged meniscus is debrided until healthy tissue is reached. After the size of the defect created in the meniscus has been measured, the implant is trimmed to fit the lesion. The prepared implant is then inserted into the knee joint, placed into the defect and fixed using either an inside–out or an all-inside suturing technique. The final goal is an implant that fits perfectly into the meniscus defect and is stable along the entire length. No drains should be used after surgery, especially if an isolated meniscus procedure has been performed. In case of poor bleeding, some microfracture holes should be made in the intercondylar notch to obtain an extra blood supply as well as some bone marrow stimulation.

Technical Points Specific to the Medial CMI

Patient Positioning

The patient is positioned supine on the surgical table. The affected limb is placed with the knee flexed to 90°

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and the thigh well beyond the table hinge. This provides access to the posteromedial corner of the knee, which can be useful in the subsequent suturing procedure. If a limb holder is used, it should be placed high enough on the thigh to allow access to the aforementioned area of the knee. The authors simply use a lateral post placed some 5 cm proximal to the patella and apply a valgus load to open up the medial compartment. The use of a tourniquet is optional although recommended if an inside–out suture technique is used.

Establishing Portals

The surgery starts with a standard anterolateral portal placed adjacent to the patella and a thumb's breadth above the joint line. Careful arthroscopic inspection is then performed. If the medial meniscus satisfies the criteria for CMI (irreparable meniscus tear or loss of meniscus tissue), an anteromedial portal is placed slightly more distally so that the surgeon can easily reach the posterior horn. The use of an 18-gauge spinal needle might help localize the most appropriate place. Accessory portals might be needed in order to obtain the desired view or access.

Preparing the Implant Bed

Proper preparation of the implant site requires the removal of any degenerative or unstable meniscal tissue in order to obtain a full-thickness defect and a stable meniscus rim over the entire length. For that purpose, a combination of straight and angled basket punches as well as a 4.0 mm motorized shaver is useful. Since the objective is to obtain a press-fit meniscus implant, the anterior and posterior horns should be squared off to accept the CMI with maximum congruence. The prepared site should extend into the vascular zone of the meniscus to guarantee an adequate blood supply. This can be accomplished by making puncture holes in the meniscal rim with either an 18-gauge spinal needle (from the outside of the joint) or a microfracture awl (from the inside). Because the potential channels obtained with a needle tend to close after needle withdrawal [14], the authors currently use either formal trephination with a more aggressive trephine or radiofrequency trephination (Fig. 11.2.1). The latter creates an area of synovial necrosis adjacent to the implant that is promptly substituted by a newly formed and more vascular synovial layer, which invades the scaffold implant like a wave [3].

If the medial compartment space is too tight for proper visualization, an arthroscopic partial release of the medial collateral ligament permits good access and facilitates manoeuvrability. The medial release can easily be done with multiple outside–in needle punctures while applying a valgus stress to the leg until a crack is heard. As we have not noted any residual valgus instability following this procedure, there is no need for a knee brace or a knee immobilizer.

Once a stable and bleeding implant site has been prepared and there is sufficient manoeuvring space, the meniscus defect is measured using a specially designed measuring device (Fig. 11.2.2). The obtained measure should be oversized by 10% in order to obtain a good press-fit. The tailored implant can then be rehydrated and inserted into the delivery cannula (standard method) or just mounted on a curved atraumatic vascular clamp and directly inserted into the joint without previous rehydration (dry insertion) (Fig. 11.2.3). The latter is the authors' preferred method because of its simplicity and the swiftness of the procedure. Regardless of the method used, the anteromedial portal should be previously enlarged using a vertical cut to accommodate the surgeon's fifth finger in order to facilitate the manoeuvre. The implant tends to be stable within the compartment once it has been placed in the joint. However, a loop suture can optionally be used to temporally hold it in place until the first stitch is placed.

Suturing

Inside–Out Technique

According to Cannon [1], a 4-cm long posteromedial skin incision centred slightly below the joint line is made when an inside–out suture technique is used. The incision runs parallel to the posterior margin of the medial collateral ligament. The infrapatellar branch of the saphenous nerve should be identified after blunt dissection (Fig. 11.2.4). Subsequently, a spoon retractor is placed as deeply as possible between the posterior capsule and the medial head of the gastrocnemius

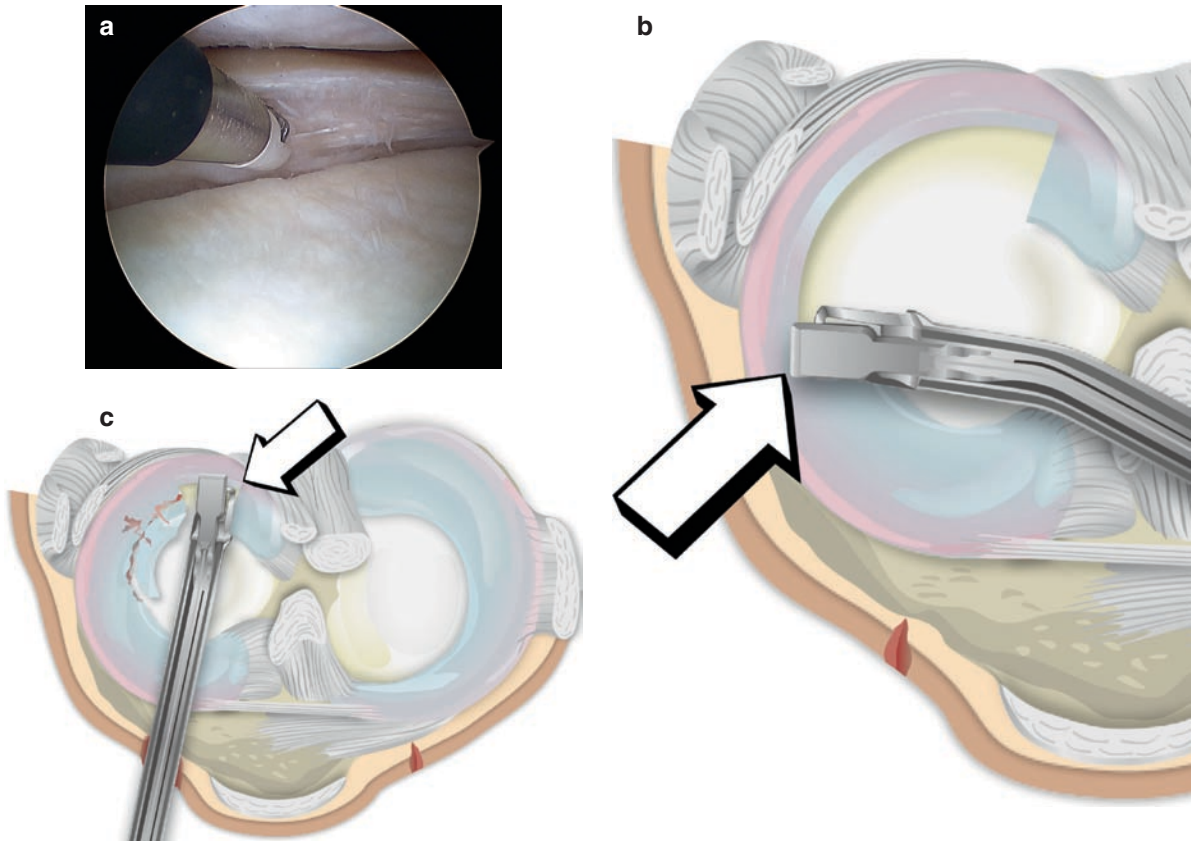


Fig. 11.2.1 (**a**) Arthroscopic view of a right knee medial meniscus after partial meniscectomy, showing the application of radiofrequency in the adjacent synovial tissue. (**b–c**) The prepared site should extend into the vascular zone of the meniscus. A combination of straight and angled basket punches is useful

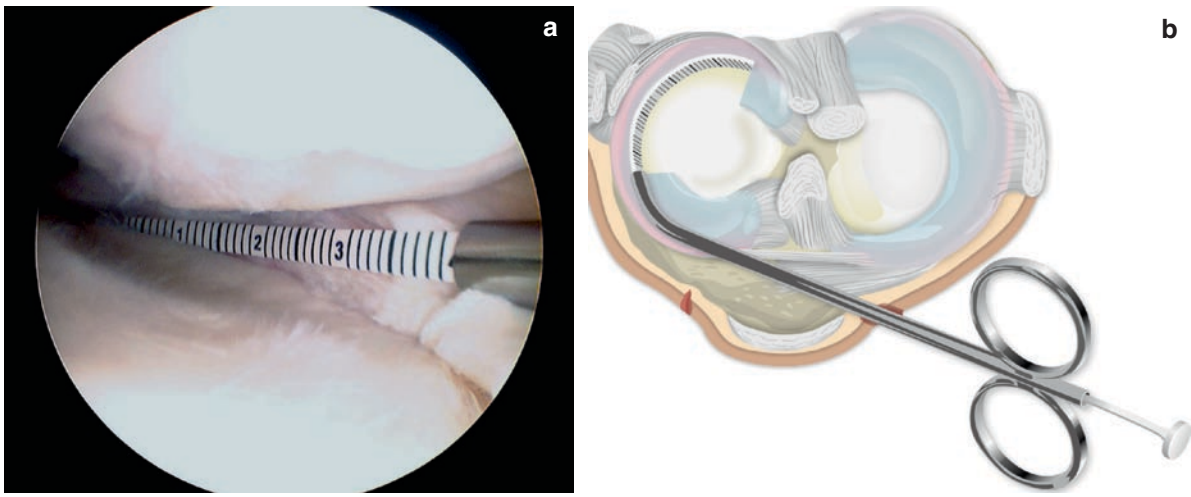


Fig. 11.2.2 (**a**, **b**) Arthroscopic view showing the measuring rod placed along the meniscus defect

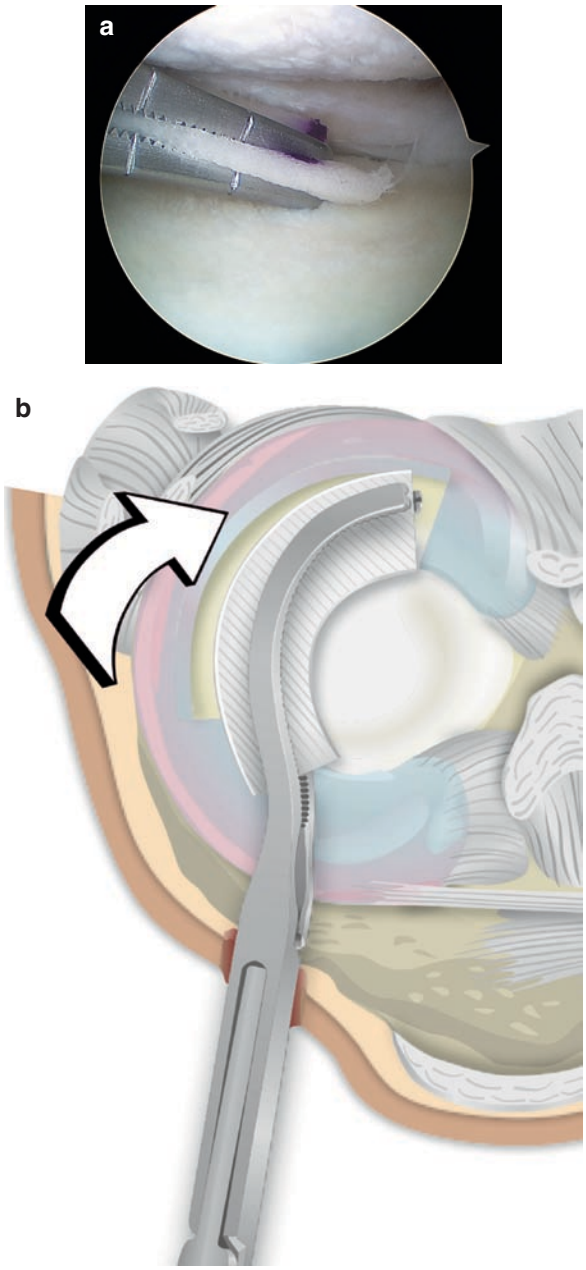


Fig. 11.2.3 (**a**, **b**) Dry insertion of a medial CMI. The vascular clamp leaving the scaffold in front of the already prepared defect site

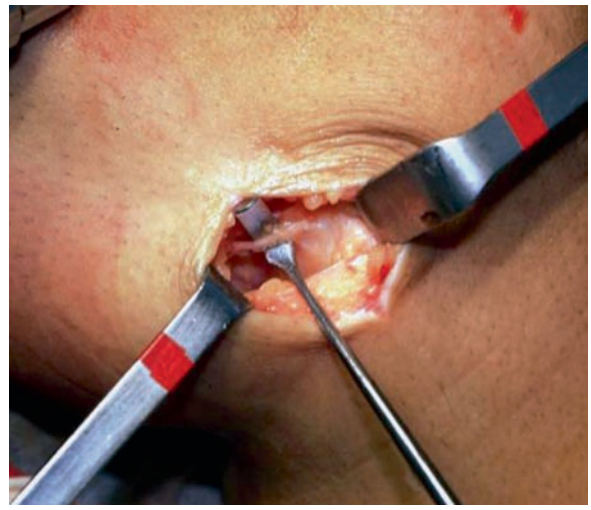


Fig. 11.2.4 Intraoperative photograph of the posteromedial approach to a left knee. The infrapatellar branch of the saphenous nerve (protected with a small retractor) should be identified to avoid iatrogenic injuries

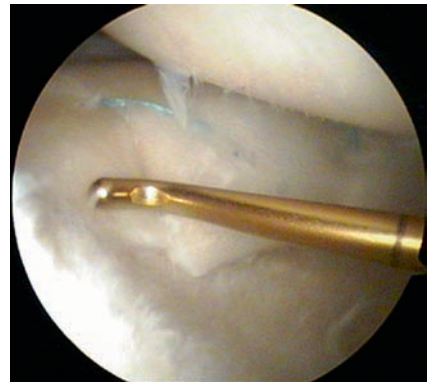


Fig. 11.2.5 Arthroscopic view of the most posterior part of a medial CMI. Note the horizontal suture placed to fix the implant to the posterior horn

to facilitate the capture of the needles during the suturing procedure. When a large defect (4–5 cm) is to be repaired, dissection superficial to the medial collateral ligament might be required. Alternatively, the needles can be retrieved directly by making small skin nicks (about 1 cm) and dissecting the soft tissues, because the risk of neurovascular damage is low in this particular area.

Suturing can be done by using a conventional inside–out zone-specific instrumentation set (ConMed Linvatec, Largo, FL) or the more sophisticated SharpShooter® Tissue Repair System (ReGen Biologics, 545 Penobscot Drive, Redwood City, CA). The CMI is sutured to the remaining meniscus rim with vertical mattress sutures of 2–0 braided polyester placed approximately 5 mm apart. The anterior and posterior ends of the implant are secured with horizontal sutures (Fig. 11.2.5). Each part

of the CMI is approached from the most appropriate portal using the most adequate cannula. In order to fix the stitches, knotting outside the joint capsule is necessary. The suturing process can be done either from the posterior to the anterior end of the implant or vice versa, depending on the surgeon's preferences.

All-Inside Technique

The use of the all-inside FasT-Fix™ Suture System (Smith & Nephew, Inc., Andover, MA) has recently been introduced as an alternative suturing technique. This new-generation meniscus repair device is designed to take advantage of the benefits of both the all-inside technique and the biomechanical properties of sutures. It is particularly useful for the posterior third of the meniscus, because it obviates the need for any additional approach to retrieve sutures. Although clinical experience with this procedure is limited, the authors have been using it over the last 2 years without complications. Again, vertical mattress sutures should be used to minimize the risk of damage to the implant (Fig. 11.2.6). It appears that fewer sutures, approximately one every 10–15 mm, are needed with this suturing technique.

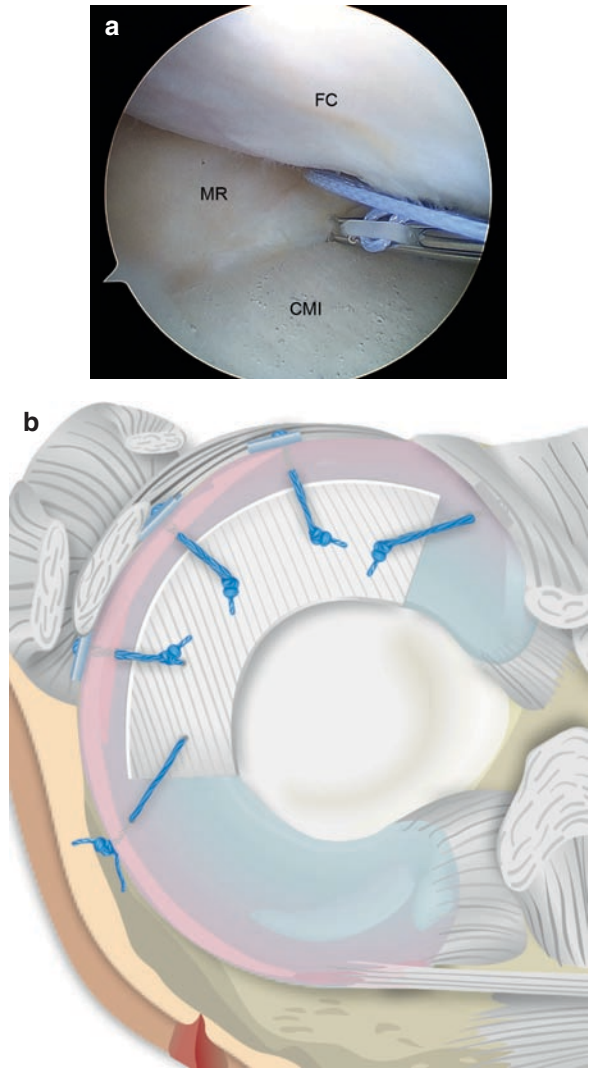


Fig. 11.2.6 (**a**, **b**) Operative view of a medial CMI fixed with an all-inside suturing device

Technical Points Specific to the Lateral CMI

The lateral CMI has been the subject of a post-marketing study in Europe since receiving the CE mark in 2006. Its specific surgical technique has recently been developed with the help of several experienced European surgeons (unpublished data). The basic sequence of steps for repairing the lateral CMI is similar to that for the medial one. The suitability of the procedure should be carefully considered if there is complete disruption of the meniscal rim at the popliteal hiatus. When no rim is present, the newly formed meniscus tends to extrude under loading conditions. Furthermore, it seems that a suture placed across the popliteal tendon does not cause any symptoms in a conventional meniscal repair procedure [1, 7]. However, the use of sutures across the popliteus tendon cannot be recommended in case of CMI substitution, because the physiological micromotion of this tendon might damage the still immature scaffold. An implant oversized by 20%, not fixed at the hiatus, seems to be the most prudent recommendation if the surgeon decides to use a CMI in this particular situation.

Patient Positioning

The patient is positioned supine on the operating table. The affected leg is positioned with the knee hanging free and flexed to 90° with the contralateral leg fully extended on the surgical table. This allows the leg to be flexed over the contralateral knee in a figure-four

position. This position places a varus force across the knee, opens up the lateral compartment, and provides easier access to the posterolateral corner during an inside–out suturing procedure.

Arthroscopic Portals

The anterolateral portal is placed in the standard position 1 cm superior to the joint line, although slightly more lateral and approximately a thumb's breadth lateral to the patella. The anteromedial portal is placed in a position that allows good access to the lateral compartment, particularly to its most anterior aspect. This is usually a thumb's breadth medial to the patella and slightly higher over the joint line than that for the medial CMI.

Preparation and Delivery

The preparation of the implant site is largely the same as for the medial CMI. The O-shape of the lateral meniscus might make a square cut more difficult, particularly at the anterior horn. Therefore, special care should be taken to tailor the CMI in such a way that the implant matches the shape of the meniscus defect (Fig. 11.2.7). Dry insertion is the rule because of the almost circular shape of the lateral CMI. An enlarged lateral portal is mandatory. When enlarging this portal (Fig. 11.2.8), it is extremely useful to lower it to the level of the joint line with an 11-blade scalpel. This simple manoeuvre will facilitate the insertion of the loaded vascular clamp. The surgeon must be careful not to injure the cartilage with the clamp jaws after the CMI has been inserted into the lateral compartment, especially when opening the jaws. A probe or blunt trocar can be used to manoeuvre the implant into the correct position and an optional loop suture can again be used to hold it in place. If the lateral compartment is too tight, it may not be possible to place the CMI into the defect, which precludes CMI implantation.

Suturing

Inside–Out Technique

An additional posterior approach as described by Cannon [1] is required when an inside–out suture technique is used. With the knee flexed to 90°, a 4-cm longitudinal incision is made just posterior to the lateral collateral ligament. Surgical dissection proceeds between the posterior edge of the iliotibial band anteriorly and the anterior border of the biceps cruris posteriorly. The peroneal nerve is identified behind the biceps tendon. The interval between the posterior capsule and the lateral head of the gastrocnemius is defined and a spoon retractor is placed as deeply as possible.

When using zone-specific cannulas, the sutures are placed either from the anteromedial portal (anterior horn and middle third) or from the anterolateral portal (posterior horn) in order to approach the implant with maximum perpendicularity.

All-Inside Technique

Again, the main advantage of this technique is that the time-consuming posterior approach can be avoided. However, it is difficult to properly fix the most anterior part due to the curvature of the lateral CMI. Therefore,

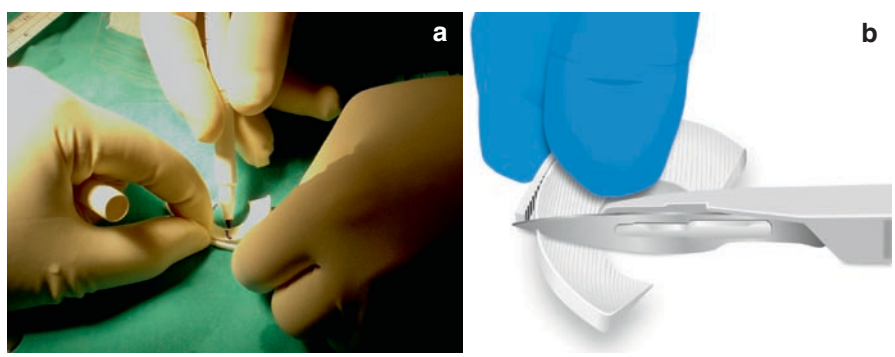
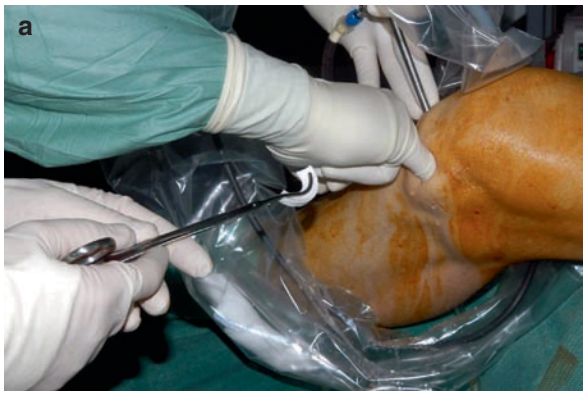


Fig. 11.2.7 (**a**, **b**) Tailoring a lateral CMI



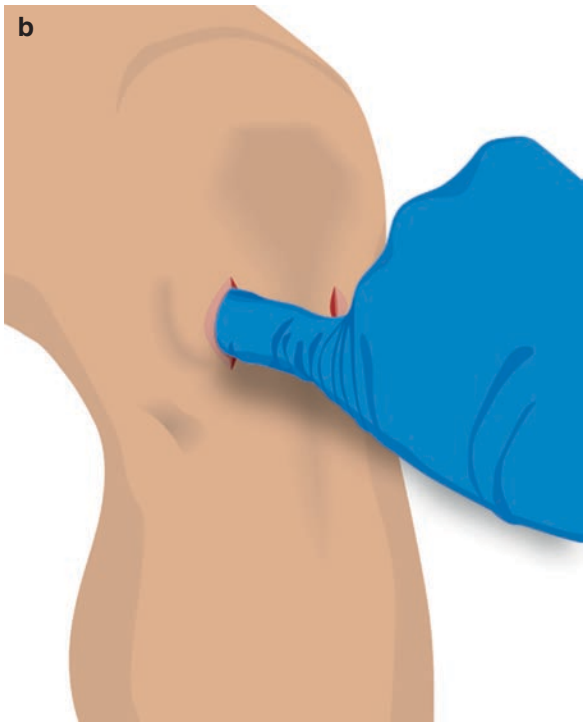


Fig. 11.2.8 (**a**, **b**) Enlarging the lateral portal with the surgeon's fifth finger previous to CMI insertion

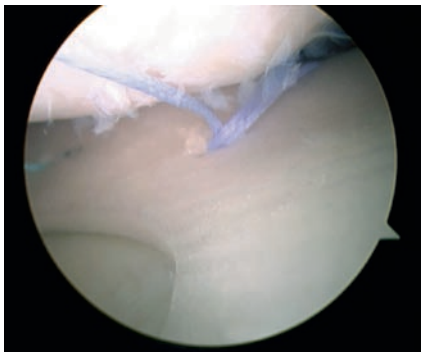


Fig. 11.2.9 Suturing a lateral CMI with zone-specific cannulae in the "safe zone". Arthroscopic view

the combined use of FasTFix™ (posterior and middle thirds) and SharpShooter® (anterior third) (Figs. 11.2.9 and 11.2.10) is not uncommon on this side. In some instances, the addition of an outside-in stitch to fix the anterior horn might even be useful. This can easily be done with the help of an 18-gauge spinal needle and a monofilament suture.

The early results obtained with the lateral CMI in a limited series of cases have been promising and the behaviour of the implant in terms of meniscal regrowth seems to be quite similar to that of the medial one (Fig. 11.2.11).

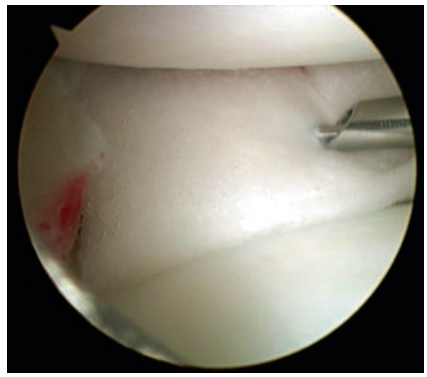


Fig. 11.2.10 The nitinol needles are retrieved through small skin nicks

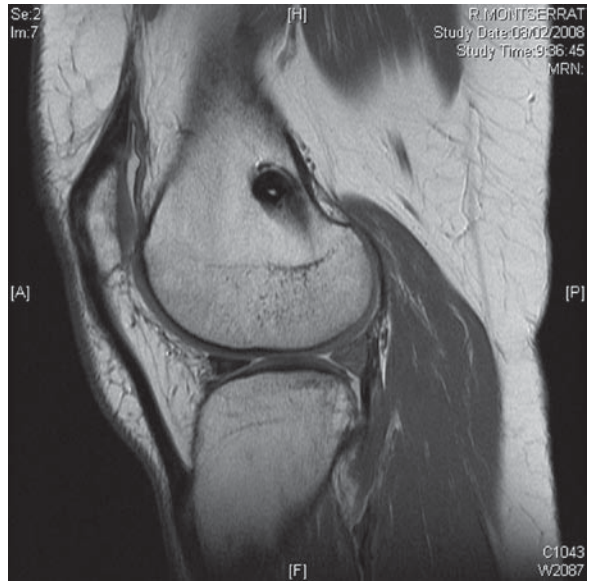


Fig. 11.2.11 One-year follow-up MRI result of the case shown in Figs. 11.2.9 and 11.2.10. Complete regrowth of a newly formed meniscus can be observed at the posterior horn

Combined Surgeries

ACL Deficiency

Combined ACL reconstruction and meniscus repair has been reported to create a more favourable environment for meniscus healing [7]. Since medial meniscectomy in an ACL-deficient knee may lead to a significant increase in laxity, combined reconstruction of both structures is especially recommended. If the procedures are to be staged, CMI implantation should be performed first and ACL reconstruction should be completed within 12 weeks, because knee instability might be detrimental to the implant. In case of concurrent procedures, the CMI must be implanted first because, with the reconstructed ACL resulting in a tighter knee, it may be more difficult or even impossible to work inside the compartments. When applying a valgus load to an ACL-deficient knee to open up the medial compartment, the tendency of the tibial plateau to slide forward has to be taken into account. In some instances, it makes it difficult to work on the posterior horn of the medial meniscus. No drain is used after surgery, since as mentioned before, postoperative hemarthrosis might create an appropriate biological environment to start the healing process of the CMI. However, if the surgeon prefers to use a drain, it should be without suction.

Axial Malalignment

Any angular deformity of the involved knee should be corrected before or concurrently with CMI implantation. The science and surgical procedure of osteotomies around the knee are beyond the scope of this chapter. However, according to the general guidelines, varus malalignment should be corrected by a high tibial osteotomy (HTO). Both an opening-wedge and a closing-wedge HTO can be used. When using the former technique, special care should be taken not to increase the tibial slope [6]. On the other hand, proper release of the medial collateral ligament is necessary so as not to overload the medial CMI.

The less common valgus malalignment is usually corrected on the femoral side to avoid an oblique joint line, unless the deformity involves the tibial bone. Regardless of the technique used, the authors recommend to do the arthroscopy and implant the lateral CMI prior to performing the osteotomy. Although the rehabilitation programme does not differ greatly between the two procedures, the CMI-specific protocol is the most important and should be given full consideration.

Chondral Treatment

Historically, an Outerbridge grade IV chondral injury has been considered a formal contraindication to a CMI, because the gliding between the implant and an altered cartilage surface is thought to be detrimental to the new implant. This is also true when applying chondral treatments based on bone marrow stimulation, such as microfracture, when a rough surface is obtained at time zero. If this is the case, it is probably better not to stage the implant until 3 months later. However, it is the surgeon's choice whether to perform CMI implantation concurrently with chondral resurfacing procedures, such as osteochondral transplantation, using either a massive allograft or a mosaicplasty (Fig. 11.2.12), or autologous chondrocyte implantation, in which a smooth chondral surface can immediately be obtained.

Results

To date, more than 50 patients have been treated with a CMI at our institution. Twenty-five of them received a medial CMI from 1997 to 2000 as part of a EU multicentre clinical trial [2]. The series included 20 men and 5 women between the ages of 18 and 48. Five cases

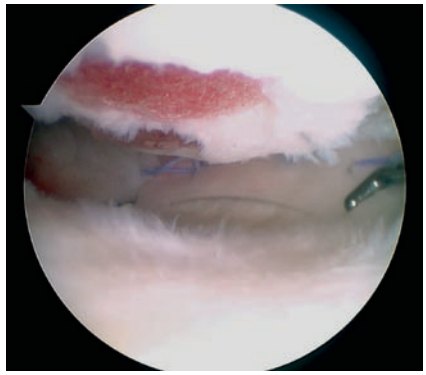


Fig. 11.2.12 Arthroscopic view of a medial CMI. Above the CMI, two chondral injuries treated with synthetic mosaicplasty plugs (TruFit® CB OsteoBiologics, Inc)

were operated on for a post-meniscectomy syndrome, 19 for degenerative meniscal ruptures and one for an acute rupture. The ACL was simultaneously reconstructed in 17 cases (68%). At the most recent follow-up, the Lysholm score was 89.6 ± 6.3 vs. 59.9 ± 15.8 preoperatively ($p < 0.003$). The visual analogue pain score decreased from a preoperative mean of 7.0 ± 1.8 to 2.0 ± 1.6 ($p < 0.001$). Conventional radiology showed no deterioration of the joint line. MRI showed some degree of meniscal regeneration in 68% of the cases. However, the implant tended to become smaller, and extrusion was commonly seen in some frontal sections.

Three patients had persistent pain on the medial side of the knee. We removed the CMI and performed an allograft meniscus transplantation (AMT) in one patient. The second patient was treated with an HTO and a staged AMT. The last patient was not treated at all.

We found no adverse effects on the knee after 4–7 years of follow-up. Clinically, the outcome was good in the majority of cases (22/25). Although the size of the newly formed meniscus was smaller than expected, regeneration appeared to occur in over two thirds of cases.

Further evidence supporting CMI-promoted regrowth of meniscal-like tissue has been provided in a very recently published paper [8]. This prospective randomized trial included more than 300 patients with an irreparable medial meniscus injury or previous partial medial meniscectomy. The patients were divided into two study arms: an acute group with no prior surgery to the medial meniscus and a chronic group with up to three previous surgeries to the involved meniscus. The patients were randomized either to undergo CMI treatment or partial medial meniscectomy (controls). 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 an average follow-up of 5 years, the patients in the chronic group regained significantly more of their lost activity than did the control patients, and underwent significantly fewer operations.

Summary

The CMI is a collagen scaffold designed to develop a tissue-engineered meniscus. The device is placed in the space where a damaged meniscus has been removed, and is anchored to the surrounding tissue. Following implantation, the matrix is invaded by cells and undergoes a process of remodelling. The CMI has already been applied clinically for partial meniscus replacement. Subsequently, the formation of a newly formed meniscus was observed in over two thirds of cases. Selecting the suitable candidate is one of the key factors in achieving a successful outcome. The knee must be stable and well-aligned. Technically, a secure intra-articular attachment is probably the most critical factor in achieving implant stability and function. Therefore, the potential surgeon should be familiar with current meniscus repair and reconstruction techniques and be skilled in performing them.

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