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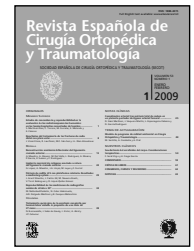

ORIGINAL PAPERS

Collagen meniscal implants with an associated tear of the anterior cruciate ligament

G. López [a,*], A. Maestro [b], J.A. Llopis [a], M. Leyes [a] and F. Forriol [a]

[a] *FREMAP Hospital, Majadahonda, Madrid, Spain*
[b] *FREMAP, Gijón, Asturias, Spain*

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KEYWORDS
Knee;
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Abstract
Purpose: To analyze the clinical results of collagen meniscal implants (CMIs) combined with tears of the anterior cruciate ligament (ACL).
Materials and methods: 37 males and 1 female were followed up, with ages ranging between 22 and 50, who were subjected to an arthroscopic implantation of a CMI in the medial compartment of the knee associated with repair of the anterior cruciate ligament and the semitendinosus and gracilis tendons in 35 cases; in 3 cases an allograft was used. Ten of the patients presented with an injury in the lateral meniscus of the same knee. Time elapsed between injury to the ACL and surgery ranged between three weeks and six months. All patients were evaluated on the IKDC scale, as well as weight-bearing X-rays and NMRi. Follow-up was between 24 and 84 months.
Results: The IKDC score was normal in 19 patients (A), almost normal in 14 (B), abnormal in 4 (C) and severely abnormal in one (D). Range of motion was normal in 26 patients and near-to-normal in 12. KT-1000 was normal in 30 patients, near-to-normal in 5, abnormal in 1 and severely abnormal in 2. The weight-bearing X-ray study was normal in 24 patients, near-to-normal in 7 and abnormal in 7. As regards complications, 8 implants had reabsorbed at 6 months; there were 7 dysesthesias in the area of the saphenous nerve, one failed repair, one loss of a CMI and two instances of stiffness that required mobilization under anesthesia.
Conclusions: CMI is a functional alternative for young patients with severe meniscal lesions who also have an ACL tear. However, further study is necessary before it can be considered a generalized technique.

* Corresponding author.
E-mail: gloria_lopez_hernandez@fremap.es (G. López).

PALABRAS CLAVE
Rodilla;
Menisco;
Implante meniscal;
Ligamento cruzado anterior

Implante meniscal de colágeno asociado a rotura del ligamento cruzado anterior

Resumen
Objetivo: analizar el resultado clínico de los implantes meniscales de colágeno (CMI) combinados con roturas del ligamento cruzado anterior (LCA).
Pacientes y método: se realizó el seguimiento de 37 varones y 1 mujer, con edades entre 22 y 50 años, a los que se implantó artroscópicamente un CMI en el compartimento medial de la rodilla asociado a plastia de ligamento cruzado anterior, semitendinoso y recto interno en 35 casos y con aloinjerto en 3. De los pacientes, 10 presentaban una lesión del menisco lateral en la misma rodilla. El intervalo de tiempo entre la lesión del LCA y la cirugía varió entre 3 semanas y 6 meses. Se evaluó a todos los paciente con la escala IKDC, radiografías en carga y resonancia magnética. La evolución fue entre 24 y 84 meses.
Resultados: el IKDC, en 19 de los pacientes fue normal (A), en 14 casi normal (B), en 4 anormal (C) y en uno severamente anormal (D). El rango de movilidad fue normal en 26 pacientes y cercano al normal en 12. El KT-1000 fue normal en 30 pacientes, casi normal en 5, anormal en 1 y severamente anormal en 2. El estudio radiográfico en carga fue normal en 24 pacientes, casi normal en 7 y anormal en 7. Como complicaciones encontramos 8 implantes reabsorbidos a los 6 meses; 7 disestesias en territorio del nervio safeno, una rotura de plastia, una pérdida del CMI y 2 rigideces que precisaron movilización bajo anestesia.
Conclusiones: el CMI es una alternativa funcional en pacientes jóvenes con lesiones meniscales graves que asocian roturas del LCA, pero requiere futuros estudios y desarrollos técnicos antes de ser generalizada.

Introduction

The menisci in the knee joint are difficult to replace because of their role as stabilizers and shock absorbers and because of their no less important proprioceptive function. Meniscal disruption and meniscal loss can lead to a kind of articular degeneration that can sometimos be hard to evaluate. Nonetheless, meniscectomy alters the knee joint mechanics and leads to articular cartilage degeneration, which reduces elastic modulus by 20–25% by lowering the concentration of glycosaminoglycans, which promotes the breakage of the collagen fiber network[1–4].

Obtaining meniscal substitutes is no easy task since congruence of the menisci with the joint surfaces is achieved in the course of embryonic development and growth, and meniscal morphology is not easy to replicate since fibrocartilages have a greater radius of curvature at their extremes[1,2].

From a biomechanical perspective, the human meniscus is characterized by having significant tension-relaxation capabilities since, depending on the position of the joint, it may be trapped between the femoral and tibial surfaces without pressing the cartilage[5]. With flexion/extension, the menisci adapt to the different radii of curvature of the articular surfaces, both on the sagittal and the coronal plane[6].

In an attempt to find an alternative way to address complex and extensive meniscal lesions in an active individual, meniscal substitutes made of synthetic substances like Teflon®, Dacron® or carbon fiber[7–9] have been used, until Steadman and his group[10–15] developed and marketed a type I collagen meniscal implant (CMI) derived from young bovine Achilles tendon that was 8 mm thick and 7.5 cm long to which hyaluronic acid and chondroitin sulphate.

The main indication for a meniscal replacement is in patients with an extensive meniscectomy and a painful medial tibiofemoral compartment; the knee is either stable or amenable to stabilization by means of previous or simultaneous reconstruction of the anterior cruciate ligament and with adequate tibiofemoral alignment. If there is malalignment, it should be corrected either previously or simultaneously by means of an osteotomy. Lastly, it should be said that meniscal replacement should not be carried out in knees with degenerated articular cartilage (rheumatoid arthritis or Outerbridge grade III or IV chondral lesions). Some authors claim that candidates for this surgery must not be older than 40 or 50 years of age.

In young patients with an anterior cruciate ligament (ACL) tear subjected to a meniscectomy, collagen meniscal implants (CMIs) may help achieve a normal daily and occupational life and prevent articular cartilage degeneration.

The purpose of our study was to analyze the clinical result of collagen meniscal implants associated with ACL tears.

Material and methods

The study, carried out between 2001 and 2005, comprised a total of 38 patients, 37 males and 1 female, with ages

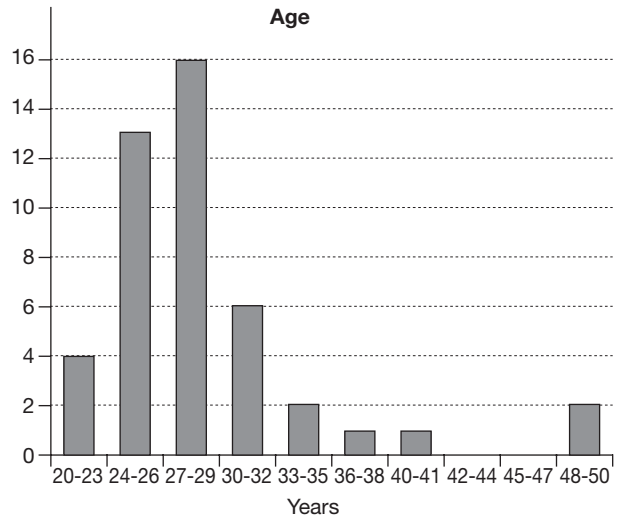

Figure 1 Implant distribution according to age.

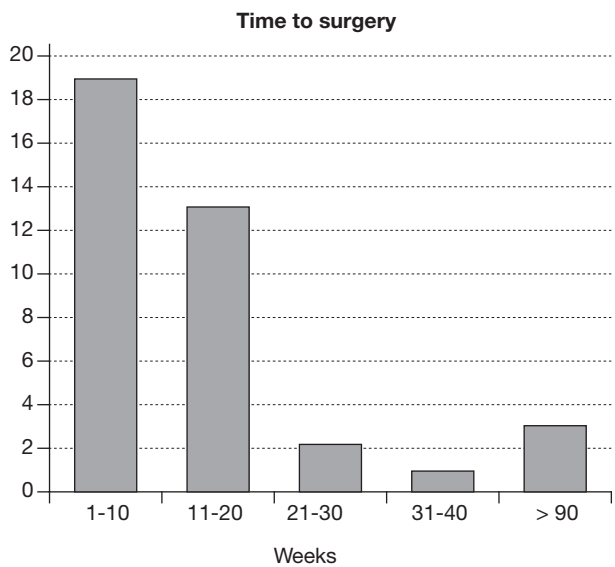

Figure 2 Implant distribution according to time to surgery.

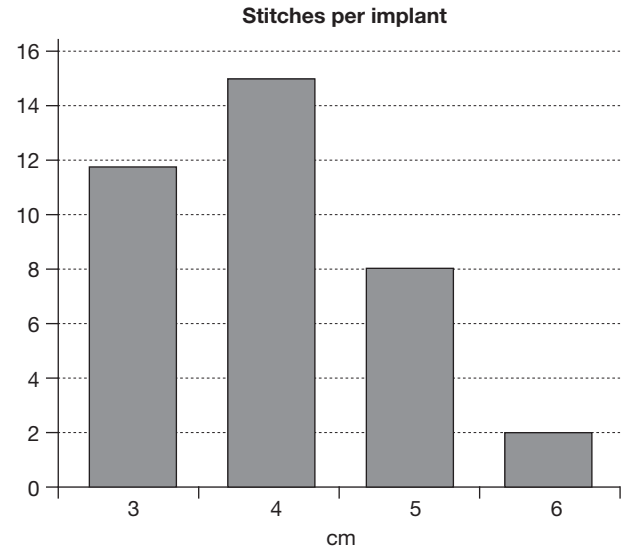

Figure 3 Implant distribution according to size.

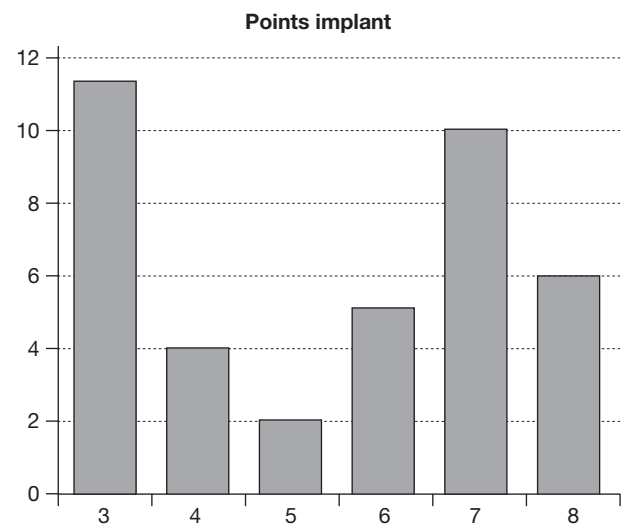

Figure 4 Implant distribution according to number of sutures.

ranging between 20 and 50 years (fig. 1), without predominance of either side (20 were on the right side and 18 on the left side). There were 6 cases of acute irreparable meniscal injuries. The mean time elapsed from the appearance of the first symptoms to surgery was 11 weeks (fig. 2). Patients included in our series were young, with an chronic irreparable medial meniscal injury or a painful previous meniscectomy, with a tear or re-tear of the ACL without severe signs of osteoarthritis. Patient follow-up ranged between 2 months and 6 years.

In all but 3 cases, ACL reconstruction with semitendinous and gracilis grafts was performed concomittantly with the meniscal replacement. All 3 patients had sustained ACL re-tears, which were addressed with freeze-dried grafts. In 10 casos, they were related to a partial lateral meniscectomy (6 on the right and 4 on the left side). Semitendinous and gracilis grafts were fixated on 5 occasions with Richards staples and in the other cases with a Rigid-Fix® system. The length of the implant ranged between 3 and 6.5 cm (fig. 3) and the number of stitches applied was 3 to 8 (fig. 4).

Surgical technique

The patient was placed in the supine position, with ischemia on the ipsilateral side. Either medial or lateral approaches were used. After performing the semitendinous and gracilis reconstruction, the meniscectomy was carried out, sparing the meniscal wall and the anterior and posterior meniscal attachments. The size of the resection was measured and the implant was adapted and hydrated in saline solution.

After refreshing the meniscal wall, the size of the lesion was measured and the implant was introduced. We

subsequently performed a medial retroligamentous approach so that the needle could be extracted and the posterior area of the implant sutured; a guard was used to avoid damaging the posterior anatomic structures. Anatomical structures were not dissected and the retractor was kept in close contact with the bone to separate the soft tissues.

Initially, the CMI was sutured to the meniscal wall with inside-out sutures by means of the ReGen system, and in 3 patients with the Fastfeed system® (Stryker). Once the CMI hsd veen sutured, the semitendinous ligament repair was performed with a single tunnel, with proximal fixation achieved by Rigidfix® (Mitek), and distal fixation by a staple or an interference screw with hydroxyapatite (Milagro®, Mitek).

In the postoperative, a plaster splint was applied on the extended leg for 2 weeks. Subsequently, physical therapy began. Patients had to wear an orthosis to perform their activities of daily living for 6 weeks. Partial weight bearing

Table 1 Data of the patients operated

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	Ñ	O	P	Q	R	S	T
1	3	25	1	1	2	16	0	0	1	1	5	4	17	0	0	0	0	0	3	0	0
2	2	28	2	1	1	250	0	0	1	1	5	8	16	0	0	0	0	0	4	0	0
3	4	35	2	1	1	12	0	0	1	2	3,5	3	20	0	0	0	0	0	5	1	—
4	3	29	1	1	2	3	0	0	1	1	3	3	21	0	0	0	0	0	7	0	0
5	3	37	2	1	1	16	0	0	1	1	4	5	14	0	0	0	0	0	3	0	0
6	3	28	2	1	1	8	1	0	1	1	5	7	14	1	0	0	1	1	6	0	0
7	3	25	2	1	1	6	0	0	1	1	3	7	16	0	0	0	0	0	6	1	—
8	2	30	1	1	2	8	0	1	1	1	4	3	23	0	0	0	0	0	8	0	0
9	2	20	2	1	2	100	0	0	1	1	6.5	8	2	0	0	0	0	1	5	0	0
10	2	21	3	1	2	20	0	0	1	1	4	6	18	0	0	0	0	0	3	0	0
11	2	24	2	1	1	6	0	0	0	1	6.5	8	18	1	1	1	1	1	6	0	—
12	2	27	2	1	1	6	0	0	1	1	4	7	15	0	0	0	0	0	3	0	0
13	2	27	2	1	1	12	0	0	1	1	4	7	18	0	0	0	0	0	3	0	0
14	3	24	2	1	1	12	0	0	1	1	4,5	7	16	0	0	0	0	0	3	0	0
15	3	29	2	1	2	8	0	0	1	1	5.5	7	20	0	0	0	0	0	4	0	0
16	4	26	1	1	1	24	0	0	1	1	4	3	21	0	0	0	0	0	9	0	0
17	3	27	2	1	1	200	0	1	1	1	5	6	18	1	1	1	2	1	IPT	1	—
18	4	26	1	1	1	24	0	0	1	1	4	3	21	0	0	0	0	0	9	0	0
19	4	29	2	1	2	20	1	0	1	2	3	4	15	0	0	0	0	0	5	0	0
20	4	32	3	1	2	8	0	0	0	2	4	4	21	1	1	1	2	1	IPT	0	0
21	3	30	1	1	2	12	0	0	1	1	3	3	21	0	0	0	0	0	7	1	—
22	4	50	2	1	2	20	0	1	0	2	3	5	21	0	1	1	1	1	6	1	—
23	3	39	2	1	1	10	0	0	0	1	5	8	18	0	0	0	0	0	3	0	0
24	3	27	2	1	1	6	0	0	1	1	3	3	21	1	0	0	1	0	12	0	0
25	4	33	2	1	1	20	1	0	1	2	3.5	4	21	0	0	0	0	0	5	0	0
26	3	21	1	1	2	8	0	0	1	1	4	8	16	0	0	0	0	0	4	0	0
27	3	29	1	1	2	16	1	0	1	1	5	6	16	1	1	0	0	0	4	0	0
28	4	26	2	1	1	8	0	0	1	1	3	2	21	0	0	0	0	0	8	1	—
29	2	30	4	1	2	36	0	0	1	1	4	6	20	1	0	0	0	0	6	0	0
30	3	32	1	1	2	16	0	1	1	1	3	3	21	0	0	0	0	0	12	0	0
31	2	27	2	2	2	8	0	0	1	1	5	8	18	0	0	0	1	0	4	0	0
32	3	49	1	1	1	6	0	1	0	1	4	3	56	1	0	0	1	0	12	0	0
33	3	29	2	1	1	6	0	1	1	1	3	3	21	0	0	0	1	0	9	0	0
34	2	26	2	1	1	4	0	1	1	1	3	3	18	0	0	0	0	0	8	1	—
35	3	25	2	1	2	8	0	0	1	1	4.5	7	18	0	0	0	0	0	3	0	0
36	3	27	2	1	2	8	1	0	1	1	4.5	6	18	0	0	0	0	0	5	0	0
37	4	24	2	1	2	4	0	0	1	1	4.5	7	14	0	0	0	0	0	3	0	0
38	3	30	2	1	1	12	0	1	0	1	4.5	7	21	1	1	1	1	1	IPP	1	—

A: evolution (years); B: age (years); C: mechanism of injury (1=sport; 2=torsion; 3=direct trauma; 4=traffic); D: sex (1=male; 2=female); E: side (1=right; 2=left); F: time to surgery (weeks); G: lateral meniscus lesion (0=no; 1=partial); H: chondral lesion (0=no; 1=medial femoral condyle); I: prior rehabilitation (1=yes; 0=no); J: fixation ACL reconstruction (1=RigidFix®; 2=staples); K: implant length (cm); L: stitches implant; M: immobilization (weeks); N: effusion (0=no; 1=yes); Ñ: fever (0=no; 1=yes); O: gastroc pain (0=no; 1=yes); P: reoperation (0=no; 1=mobilization under anesthesia; 2=lavage); Q: involvement of saphenous nerve (0=no; 1=yes); R: discharge (months) (IPT=temporary disability; IPP=partial disability); S: MRI 6 months (0=persists CMI; 1=resorbed); T: MRI 1 year (0=persists CMI; 1=resorbed).

Table 2 IKDC score

	Subjective	ROM	Symptoms	Stability	Medial x-ray	Lateral x-ray
1	B	A	A	A	A	A
2	B	A	A	A	A	A
3	C	B	B	A	B	B
4	A	A	A	A	A	A
5	B	A	B	A	A	A
6	A	A	A	A	A	A
7	A	B	B	B	A	A
8	A	A	B	A	C	B
9	A	A	B	A	A	A
10	A	B	B	A	A	A
11	B	A	A	A	A	A
12	B	B	A	B	B	B
13	B	A	A	A	A	A
14	B	B	B	A	A	A
15	A	B	B	B	A	A
16	B	B	C	C	C	A
17	C	A	B	D	C	A
18	B	A	A	A	A	A
19	B	A	A	A	A	A
20	C	B	B	D	C	B
21	A	A	A	A	A	A
22	A	A	A	A	A	A
23	A	A	A	A	A	A
24	A	B	A	A	A	A
25	A	B	B	A	B	B
26	B	A	A	B	A	A
27	B	A	A	A	A	A
28	A	A	A	A	A	A
29	A	B	B	A	A	A
30	A	A	A	A	C	A
31	A	A	A	A	B	B
32	A	A	A	A	C	A
33	B	A	B	A	B	A
34	C	A	B	A	B	A
35	A	A	A	A	B	B
36	B	A	B	A	A	B
37	A	A	B	A	A	A
38	D	B	D	B	C	C

A: normal; B: nearly normal; C: abnormal; D: severely abnormal.

was allowed at 6 weeks and total weight bearing at 8 weeks.

We followed the IKDC protocol to assess the results obtained and performed an Imaging study at 6 and 12 months. A magnetic resonance (MRi) test was performed before the procedure and at 6 and 12 months postoperatively.

Results

Tables 1 and 2 show the data on the evolution of our patients. Patient satisfaction was high in he majority of cases. All achieved full extension and flexion higher than 135 degrees.

Of the 38 patients subjected to surgery, 35 went back to their former occupation in 5 months on average (table 1). Of the 3 patients that were not included, one required 2 salvage procedures and is being followed up, another still complains of severe pain and the third was lost to follow up.

On the IKDC score, most cases were within normal or nearly normal ranges (table 2; fig. 5). The subjective IKDC score as normal or nearly normal in 33 patients; 38 cases presented with normal or nearly normal range of motion.

Comparing the KT-1000 arthrometer measurements of both knees, the results were normal or nearly normal, i.e. 3 mm or less, in 35 patients.

The MRi performed 6 months alter the procedure revealed 8 resorptions, which did not worsen at 12 months' follow-up

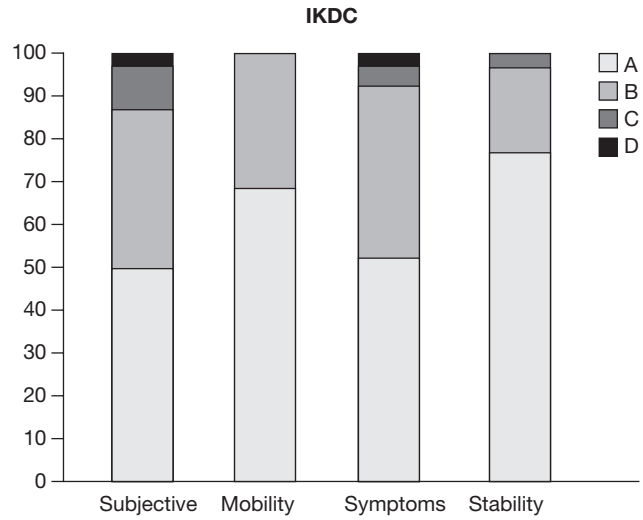

Figure 5 Distribution of scores on the the different categories of the IKDC form (subjective assessment, ROM, symptoms and ligament stability).

Figure 6 MRI of a meniscal implant one and a half years alter surgery.

Figure 7 Resorption of the implant at 6 months' follow-up.

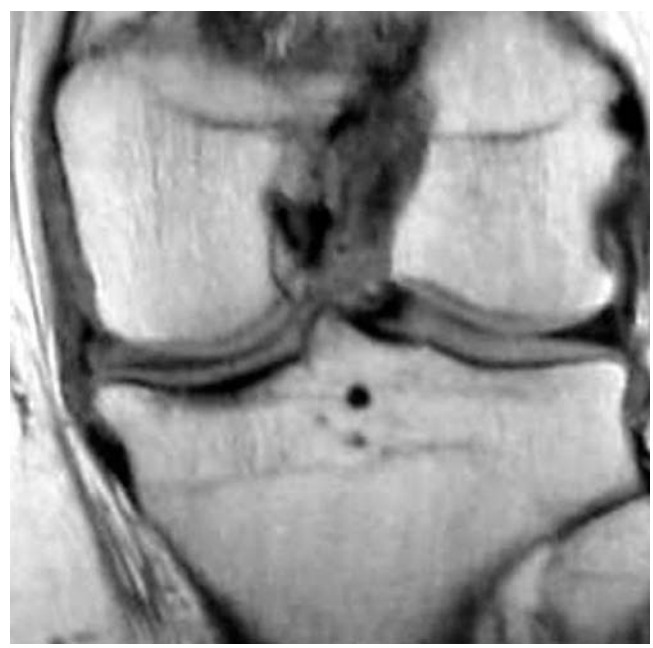

Figure 8 MRI where the implant has turned into a pseudomeniscus, one year alter the procedure.

(figs. 6-9). At one year, weightbearing x-rays showed 7 cases with degenerative signs in the medial compartment and only one in the lateral compartment. The remaining implants show a pseudomeniscal tissue of an appearance similar to that which ocuppies the joint space. Most instances of thinning occurred at the interface between the collagen implant and the host meniscus (fig. 10).

Complications included one instance of CMI breakage, a tear of the semitendinous-gracilis repair; 7 internal saphenous neuropathies with associated dysesthesias. We also found 7 cases of stiffness due to a flexion lag, which were resolved within 3 months with mobilization under anesthesia. In one case with effusion we performed joint lavage, which resulted in a clear improvement of the patient and we indicated 5 echo-Doppler studies in patients with calf pain. In 6 cases fever was present, which

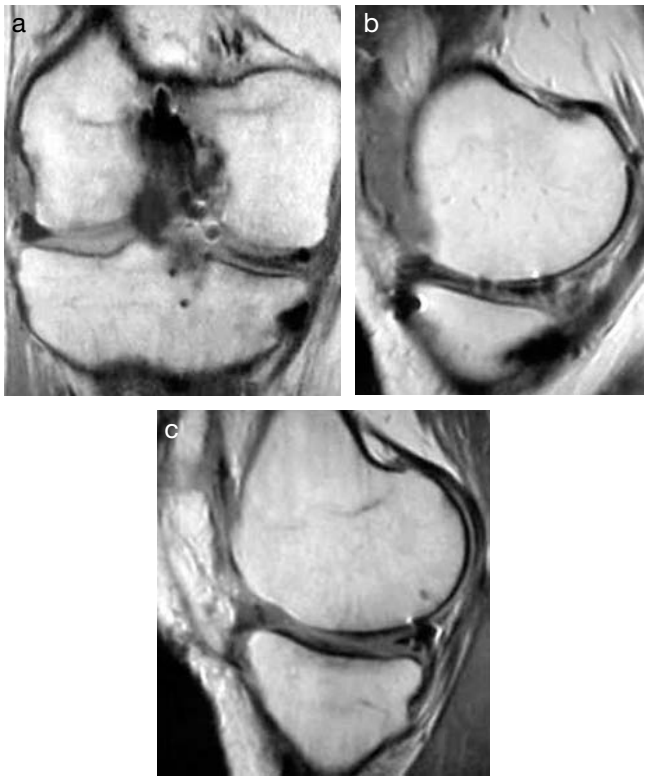

Figure 9 MRi of collagen meniscal implants. a y b: thinning can be seen in the sutured area. c: implant breakage.

Figure 10 Collagen meniscal implants (CMIs) showing a satisfactory clinical evolution at 2 years. a: weightbearing x-ray. b and c: MRi showing a CMI that preserves the joint space.

remitted alter a few days witout the need for antibiotics (table 1).

Discussion

Given that the meniscus must be considered a single functional unit, a meniscal implant will be effective provided that it permits adequate function andi t prevents joint deterioration without causing discomfort.

The assessment of the results of a meniscal transplant must be clinical and should evaluate relief or disappearance of pain, return to normal activity, including moderate sporting activity, the existence of stiffness or effusion, etc., by means of images like plain and weight-bearing films, MRi and a diagnostic arthroscopy some time after implantation. Moreover, mechanical instruments must be introduced that permit an objective assessment of the joint.

Total meniscectomy is currently indicated when the type of tissue or the type of injury preclude repair or when the special equipment or difficult techniques required make the surgeon opt for total meniscus resection[16]. Partial meniscectomy is reserved for symptomatic lesions in stable knees, in very active patients and when the injury is located in an area that cannot be repaired[17–19].

Meniscal implants seek to promote the regeneration of meniscal tissue from a scaffold that attracts fibrochondrocytes that produce basic cartilage substance[15]. In dogs, this collagen scaffold resorbs by around 90–95% alter 6 to 12 months. In a clinical study on 10 cases treated arthroscopically, Stone et al[11] saw that the implants were stable and did not present with vascular proliferation or a new chondroid matrix. CMI may be considered appropriate since they are made of a biocompatible bioresorbable material that can support the growth of new tissue inside it[10–15]. In the 4 biopsies studied at 6 months' from implantation, Reguzzoni et al[20] demonstrated that the tridimensional structure of the CMI is filled by non inflammatory cells and vessels that in due course put together a construct that is very similar to a natural meniscus. The new meniscal tissue is functionally acceptable and does not produce adverse effects. In turn, Steadman et al[10] carried out 3 biopsies that showed the formation of fibrocartílage.

The protective function of the meniscus is directly related to its capacity to transfer and distribute loads. Only a meniscus with intact anterior and posterior anchorage can withstand the high stresses generated in the knee joint[21]. A meniscus, an implant or an allograft with lax or insufficient anchorage creates articular changes because they are loose and keep moving and because they are incapable of correct load transfer. As a result, they damage the cartilage and increase the amount of proteoglycans in the synovial fluid. This causes alterations that are similar to those found

following meniscectomy or radial meniscus tears[6]. In most of our cases we applied 3-8 fixation stitches.

In general, CMI results published in the literature obtain good results, even if problems are not infrequent Steadman et al[10] reviewed 8 cases with 5-6 years' evolution and found in all of them an improvement using the Lysholm score. The patients' subjective assessment and the pain score also improved. The MRI revealed that the articular cartilage was not altered. Nevertheless, in our study we found some problems that must be considered seriously, like neuritis and dysesthesia, Joint stiffness, calf pain and effusion and idiopathic fever.

The combination of ACL repair with a CMI must contribute greater mechanical stability to the joint than a meniscal smoothing procedure or meniscal resection. A stable knee permits a better incorporation of the repaired ligaments. However, more studies are needed to demonstrate and substantiate this hypothesis.

Zaffagnini et al[22] in a study of 8 cases, with a mean follow-up of 6-8 years, point out that all patients went back to work at 3 months from surgery. We prefer to lengthen this period to 4-6 months. When they reviewed their patients, these authors saw that 2 cases had poorer results than 2 years postoperatively and 4 cases experienced bearable pain. Image-based tests showed them that 6 cases presented with a preserved Joint space, with no changes, but the most striking finding are the MRI images where 5 cases showed myxoid degeneration; 2 cases showed a normal signal but with a smaller size and in one case the implant had resorbed. In our experience, we had 8 implant resorptions at 6 months. This 25% resorption rate remained unchanged at 12 months' follow-up, which might suggest that they may have been caused by rejection of the material or a deficient surgical technique, whereby the anchorage of the meniscus was either too lax or too tight. Perhaps the percentage is higher than those of other series because an additional ACL repair was performed.

In our study many patients showed a disruption of their sensitivity in the territory innervated by the internal saphenous nerve, probably caused by the posteromedial approach employed. This has been prevented in subsequent surgeries by using inside-out suturing. Dysesthesias could have been triggered by suture entrapment or by inadvertent severing of the ramus if the incision for the medial retroligamentous approach is not long enough. It should be said that saphenous nerve neuropathy is a clinical finding that goes unnoticed for patients until that specific area is clinically examined.

We also had frequent cases of postoperative fever that we attribute to an immune reaction to the implant that is unrelated to the result obtained and with the resorption of the implant. No transmission of infection diseases has been reported with CMI, nor did we have to explant any of our implants because of organ rejection.

Nevertheless, most of the clinical and functional results obtained, in spite of the high number of resorptions, are satisfactory. It could perhaps be said that results are better if a concomitant ACL repair is performed. Results would also improve if cases resolved by ligament stability are not differentiated from those resolved by meniscal stability. We do not exclude the possibility of improving the implant's structure by means of tissue engineering techniques which, like Martinek et al[23], obtain better experimental results because they contribute autologous fibrochondrocytes.

Implantation of a meniscal replacement requires a well trained and coordinated team, since the surgeon must work against the clock to prepare the meniscal bed and adapt the replacement. Moreover, it is not easy to calculate the exact length of the lesion and avoid implant displacement, without forgetting that approaching a medial compartment with a ruptured ACL is complex, because the tibial condyle is subluxed and the medial compartment is closed. In a nutshell, a CMI may represent an adequate functional solution, which has its drawbacks. Further studies and technological developments will be necessary before this technique can enjoy widespread use.

Conflict of interests

The authors have declared that they have no conflict of interests.

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