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Prospective comparative study between two different fixation techniques in meniscal allograft transplantation

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Abstract
Purpose To compare the functional and radiographic results between two different horn fixation techniques for meniscal allograft transplant.
Methods This is a prospective study of 88 meniscal allograft transplants with a mean 5-year follow-up. Forty transplants were performed on the medial compartment and 48 on the lateral compartment. The same surgeon performed all surgeries. Thirty-three grafts were fixed only with sutures (Group A) and 55 only with bony fixation (Group B). Both groups were comparable in terms of age, laterality, time since meniscectomy and preoperative functional and radiographic status. Functional assessment was done with Lysholm and Tegner scores and the Visual Analogical Scale for pain. Joint space narrowing was evaluated in the Rosenberg view.
Results There was a significant improvement in Lysholm, Tegner and VAS scores without differences between Group A and Group B (n.s.). Radiographic evaluation did not show any joint space narrowing (n.s.). No differences in the comparison of all the variables of the two compartments were found. There were complications in 33.3 % of patients in Group A that including 7 graft tears (21.4 %) and in which there was an allograft failure rate of 9 %. Group B showed complications in 16.4 % of the patients and included 4 graft tears (7.3 %, n.s.) with an allograft failure rate of 3.6 %.
Conclusions Meniscal allograft transplantation with either technique provided good functional and radiographic results at mid-term follow-up. Both graft fixation methods showed no differences relative to functional and radiographic results. There was a considerably higher rate of complications in transplantations performed with the only-suture technique than those with bony fixation, although the difference was not statistically significant with the numbers available. The results suggest that similar functional results should be expected whether the meniscal graft includes bone plugs or not. However, graft tears seem to happen more frequently if the MAT is performed without bony fixation.
Level of evidence Prospective comparative study, Level II.

Keywords Meniscectomy · Meniscal transplantation · Meniscal allograft · Suture fixation · Bony fixation

Introduction

Total meniscectomy was the treatment of choice for a meniscal rupture for a long period of time. Since Fairbank described arthritic changes occurring in a meniscectomized knee, which was later confirmed by others investigators [9], more conservative techniques such as partial meniscectomy and meniscal repair have increasingly been used. More recently, in an attempt to replace the lost tissue and to possibly prevent progressive deterioration of the joint, meniscal allograft transplantation (MAT) was introduced in clinical practice by Milachowsky et al. [23]. Since then, good mid- and long-term results have been reported after

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MAT as a treatment for pain in the previously meniscectomized compartment of the knee [11, 20, 24, 33, 36, 37]. Although MAT might offer a certain chondroprotective effect in some cases, it is still a matter of controversy [7, 18, 19, 28, 30, 36].

Controversy regarding the best fixation method for the graft still exists. Although it may be easier to secure the graft with soft tissue alone (only-suture technique), cadaver model research indicates that superior transmission of load occurs when fixing the meniscal horns of the graft with bone plugs (bony-fixation technique) [2, 6]. However, the superiority of one fixation technique over another has not been clinically demonstrated. McDermott et al. [22], in one of the few clinical studies that compares different meniscal graft fixation methods, reported similar results in the reduction in articular stress using only sutures and bony fixation in lateral meniscal transplantations. In the Verdonk [35] or van der Wal et al. [33] clinical studies, good results were reported on MAT without bone plugs. On the other hand, authors like Stollsteimer et al. [29] and Hommen et al. [16] reported good results with bony fixation.

The aim of this study was to compare the functional and radiographic results as well as the complications observed in MAT performed with 2 distinct allograft fixation techniques (bony and only-suture fixation) in a short-term prospective clinical study.

The first hypothesis of the work was that MAT would give similar results with both techniques. The second hypothesis was that both techniques would show a similar complications rate.

Materials and methods

A prospective study of 88 consecutive patients was carried out between 2001 and 2008. The senior surgeon (JCM) performed all the surgical procedures. The average follow-up period was 5 years (range, 2.5–10). The inclusion criterion was joint line pain due to a previous total or subtotal meniscectomy (postmeniscectomy syndrome). Malalignement was considered an exclusion criterion. Normal alignment was considered up to 5° varus alignment and 7° valgus alignment. Those patients who presented with an Ahlbäck greater than grade II in the Rosenberg view were also excluded. An ACL-deficient knee was not considered a contraindication if the ligament was reconstructed at the same time as the transplant.

The series was composed of 56 men (64 %) and 32 women (36 %) with a mean age of 37.3 years (range, 15–51 years). Forty transplantations (45 %) were performed to replace the medial meniscus and 48 (55 %) to replace the lateral meniscus. Fifty-four (61 %) were performed on right knees and 34 (39 %) on left knees. It was a consecutive series in which the first 33 of the grafts (37.5 %) were fixed with an only-suture technique (Group A) and the following 55 cases (62.5 %) with associated bony-fixation technique (Group B).

Both groups were comparable in terms of gender, age, previous functional status, radiographic evaluation, time since meniscectomy and number of previous surgeries (n.s.) (Table 1).

Additional procedures were performed on 13 patients (39 %) in Group A: ACL reconstruction in 8, microfracture in 8 and chondral shaving in 9. On the other hand, 24 patients (43 %) in Group B had concomitant surgical procedures: ACL reconstruction in 10, microfracture in 7, hardware removal in 3 (Puddu osteotomy plate) and arthroscopic cartilage repair with TruFit plugs (Smith and Nephew, Andover, MA, USA) in 2.

The clinical research ethics committee of our institution approved the study (10/090/1129). All the patients signed an informed consent to participate in the study as well as for the evaluation and publication of their results.

Type of graft

Fresh-frozen (−80 °C), non-irradiated, non-antigen-matched meniscal allografts [10] were used in this series.

Table 1 Description of both groups

Variables	Group A	Group B	Sig. (*p*)
Sex (male/female)	27 %/73 %	40 %/60 %	n.s.
Age (years)	38.8 ± 6.3	35.7 ± 7.9	n.s.
Knee (R/L)	67 %/33 %	61 %/39 %	n.s.
Compartment (med/lat)	42 %/58 %	46 %/54 %	n.s.
Number of previous surgeries	1.5 ± 0.6	1.8 ± 0.7	n.s.
Time since meniscectomy (years)	11.2 ± 2.2	15.5 ± 3.8	n.s.
Rosenberg pre-surgery (mm)	3.2 ± 0.8	3.05 ± 1.1	n.s.
Lysholm pre-surgery	65.4 ± 11.6	62.3 ± 9	n.s.
Tegner pre-surgery	3 (1–6)	3 (1–7)	n.s.
VAS pre-surgery	6.4 ± 2.2	6.7 ± 2.2	n.s.

Values are presented as percentages, mean ± SD or median (range)

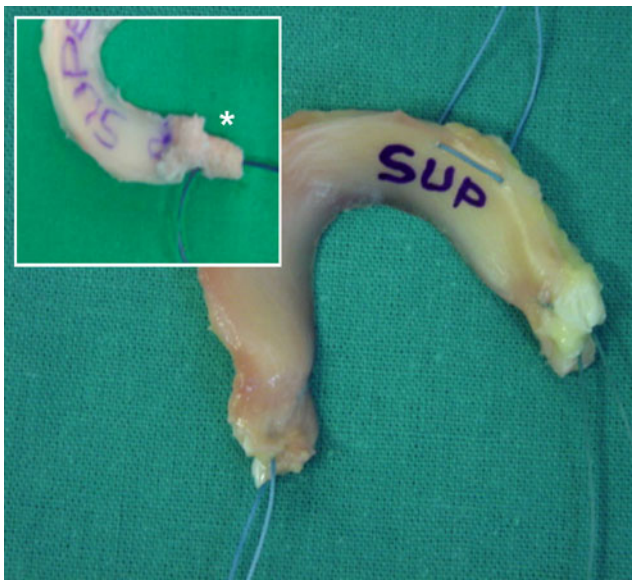

Fig. 1 Medial meniscus allograft of a left knee. The sutures in both horns pierced directly in the meniscal tissue (Group A). *Inset* Meniscus corresponding to Group B; the suture is passed through a 1.5-mm transversal hole in the bone plug (*asterisks*) attached to the posterior horn of the allograft

Local authorized tissue banks supplied the allografts. Allograft sizing was done according to the morphometric dimensions (weight and size) as well as the radiographic measures of the donor and recipient's knee as described by Pollard et al. [25].

Surgical technique

The surgical technique was completely arthroscopic. In all the cases, the previous meniscal resection was almost complete. Two 6-mm bone tunnels were drilled at the anatomic sites of meniscal insertion: one at the anterior horn and the other at the posterior horn. In those allografts corresponding to Group A, either No. 2 high-strength sutures (FiberWire; Arthrex, Naples, FL) or No. 2 polyester sutures (Ethibond; Ethicon, Somerville, NJ) with a Krackow mattress were placed at both horns. In those patients corresponding to Group B, a 6-mm-diameter and 10-mm-long bone plug was left on each horn. Then, a transversal 1.5-mm tunnel was drilled in each bone plug, and a No. 2 FiberWire suture was passed through it (Fig. 1). One additional vertical mattress suture was placed in each allograft of both groups at the junction between the posterior horn and the body of the meniscus. The posterior horn suture was used to pull the meniscal allograft in place. The additional vertical suture aids in situating the graft because it is first retrieved from the posterolateral or posteromedial corner with an outside-in technique and pulled when the graft is being introduced into the joint. The allograft was then well fixed to the rim using either an inside-out technique with mattress sutures (SharpShooter; ConMed Linvatec, Largo, FL) or an all-inside technique (FasT-Fix; Smith and Nephew, Andover, MA). Both kinds of sutures were oriented vertically whenever possible. Finally, the sutures placed in the anterior and posterior horns or through the bone plugs of each horn were tied together over the tibia cortical surface.

Major concomitant procedures included treatment for cartilage injuries and ACL reconstruction or revision. In the case of localized Outerbridge grade IV cartilage injuries, microfractures were made on the bone that had undergone eburnation to promote a healing response. Debridement and shaving were used in cartilage lesions graded as III or less to obtain smooth articular surfaces. When necessary, a standard arthroscopic ACL reconstruction was performed as a final step. This allowed for maximum joint line distraction, especially in stiff joints, at the time of the transplant. The tibial bone tunnel for the ACL graft was previously established to avoid wall breakage between the different bone tunnels.

Rehabilitation protocol

Both groups followed the same rehabilitation protocol. Partial weight bearing with a knee immobilizer was allowed at 3 weeks and progressed to full weight bearing at about 6 weeks. Patients returned to a normal workload by the fourth month after surgery.

Functional and radiologic evaluation

Functional follow-up included the 100-point Lysholm score as well as Tegner score. A ten-point Visual Analogical 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), somewhat dissatisfied (1 point) and not satisfied at all (0 points).

Radiographic assessment included long-standing X-ray as well as the posteroanterior 45° flexion Rosenberg view. Because one of the potential effects of MAT might be the preservation of the cartilage, joint space narrowing in the involved compartment measured at the beginning and at final follow-up was focused on. The shortest distance between the femoral condyle and the tibial plateau of the involved compartment was measured preoperatively and at latest follow-up in the Rosenberg view as a measure of joint space narrowing. Measurements were carried out with the ePACS viewer software (5.0; Real Time Image, San Bruno, CA), which might improve the accuracy of the measurement of the joint space width. However, it still depended on the influence of radio-anatomical plane of

measurement, degree of knee flexion, magnification and angulation of the X-ray beam [5].

Functional as well as radiographic evaluation was carried out by two independent observers who were blinded for the type of allograft fixation used. It was done so because, although the series are consecutive, the evaluations of the radiographies and functional scores corresponding to a similar a follow-up period were done at the same time. Medial allografts were also compared with lateral allografts at final follow-up. The intraclass correlation coefficient for the radiographic evaluation was calculated. Values ranged between 0 (poor) and 1 (excellent) [13].

Statistical analysis

Categorical variables are presented as percentages and frequencies. Continuous variables are presented as average ± standard deviation, maximum and minimum values. Categorical variables are presented as a median (range). Interobserver agreement was analysed using the intraclass correlation coefficient (ICC). In those relevant cases, a 95 % confidence interval was calculated. The Pearson correlation coefficient was also calculated. A Kolmogorov–Smirnov analysis was performed to test for the normal distribution of the difference between the preoperative and postoperative scores. The inferential statistic applied was the *t* test from a sample in order to compare the results with a previous study. In the case of studying two situations (e.g. medial vs. lateral compartment), a *t* test for independent data was employed. Likewise, the comparisons between previous and posterior values were made with a "*t*" test but with paired data in this case. The level of significance was set at 5 % ($\alpha = 0.05$, $p < 0.05$). Statistical analysis was performed using SPSS version 19.0 (SPSS Inc, Chicago, Illinois).

Results

At a mean of 5 years (range, 2.5–10 years), all the 88 patients were available for follow-up.

Functional and radiographic results

An overall improvement was obtained in terms of Lysholm, Tegner and VAS scores. The Lysholm score improved from 65.4 ± 11.6 to 88.6 ± 7 in Group A and from 62.3 ± 9 to 91.2 ± 6.9 in Group B, respectively ($p = 0.04$). The median follow-up Tegner score significantly improved from 3 (range, 1–6) to 6 (range, 3–8) in Group A and from 3 (range, 1–7) to 6 (range, 2–9) in Group B (n.s.). The average VAS score dropped 4.9 and 5.8 points in Groups A and B, respectively. The satisfaction of the patients with regard to the procedure had a mean overall degree of 3.7 ± 0.3 points out of a maximum of 4. No differences were observed when the two groups under study were compared in any of the analysed variables (Table 2). The radiographic evaluation with the Rosenberg projection did not show any joint space narrowing (n.s.). The intraclass correlation coefficient (0.89) as well as the Pearson correlation coefficient (0.91) for the interobserver agreement relative to the radiographic assessment qualified both as excellent.

When the results were analysed by compartment (medial vs. lateral), there were no differences found in any of the studied variables (Table 3).

Complications

There were complications in 11 patients (33.3 %) in Group A. Two patients developed arthrofibrosis who required arthroscopic arthrolysis. There were also 2 cases of septic arthritis that needed arthroscopic lavage plus specific antibiotic therapy over a period of 6 weeks. In all the aforementioned 4 cases, the transplanted menisci looked viable and were kept in place. Due to graft tears, a second surgery was necessary for the remaining 7 patients (21.4 %). Four of them had later loss of allograft fixation requiring new fixation. In the other 3 cases of graft tears, the allograft had to be completely removed. This represents an allograft failure rate in this group of 9 % (3 out of 33).

In Group B, there were complications in 9 patients (16.4 %). They included 3 arthrofibrosis and 2 infections. In these 5 cases, the transplanted grafts were also viable

Table 2 Comparison of functional and radiographic outcomes

Variables	Group A	Group B	Sig. (*p*)
Lysholm (pre–post)	65.4 ± 11.6–88.6 ± 7	62.3 ± 9–91.2 ± 6.9	n.s.
Tegner (pre–post)	3 (1–6)–6 (3–8)	3 (1–7)–6 (2–9)	n.s.
VAS (pre–post)	6.4 ± 2–1.5 ± 1.2	6.7 ± 2–0.9 ± 1.3	n.s.
Radiographic joint space narrowing (mm; pre–postoperative)	3.2 ± 1.2–3.2 ± 1.9	3.1 ± 1.5–3.5 ± 1.5	n.s.
Satisfaction	3.6 ± 0.2	3.8 ± 0.2	n.s.

Tegner scores are shown as median (range). The remaining variables are shown as mean ± SD

Table 3 Postoperative functional outcomes comparing medial versus lateral meniscal transplantation

	Group A		Group B		*p* value
	Medial	Lateral	Medial	Lateral	
Lysholm	88.4 ± 7.5	89 ± 9.2	89.2 ± 7.4	93.2 ± 6.2	n.s.
Tegner	6 (3–8)	6 (3–8)	6 (3–9)	7 (1–9)	n.s.
VAS	1.4 ± 1.5	1.8 ± 1.3	0.9 ± 1.1	0.9 ± 1.4	n.s.
Satisfaction	3.6 ± 0.31	3.5 ± 0.5	3.8 ± 0.4	3.7 ± 0.5	n.s.

Tegner scores are shown as median (range). The remaining variables are shown as mean ± SD

and kept in place after arthroscopic arthrolysis or arthroscopic lavage plus specific antibiotic therapy for 6 weeks. There were graft tears in 4 patients (7.3 %). Two of these graft tears could be saved after re-fixation. The remaining 2 meniscal allograft that developed tears had to be completely removed. They represent an allograft failure rate in Group B of 3.6 % (2 out of 55). However, the difference in graft failures between Group A (9 %) and Group B (3.6 %) was not statistically significant with the numbers available (n.s.). This was also true with the graft fixation failure, which included not only the grafts that had to be finally removed but also those graft that had to be refixed (n.s.).

Discussion

The most important finding of the current study was that no differences were observed in terms of pain, functionality and joint space narrowing between the two different methods of graft fixation investigated. This confirms our initial hypothesis. However, the second hypothesis was refuted because a considerably higher complication rate, although without statistical significance, was observed in the group in which the allografts were fixed only with sutures.

The main difference between the two performed techniques was found in the percentage of complications observed between groups. MAT fixed with an only-suture technique showed a complications rate that was 3 times greater than MAT performed with a bony-fixation method. The literature reports a complication rate of 0–45 % [14]. This high variation depends on what is considered a complication. However, the most frequent complication reported in MAT is tearing of the allograft. In a review of 15 series evaluating the clinical outcome of meniscal transplantation, Matava et al. [21] found a tear rate of 8.2 %. Our series has shown an overall tear rate of 12.5 %. However, a clearly lower tear rate was observed in those implants fixed with bony plugs (7.2 %) in comparison with those fixed with sutures (21.2 %). This difference might be due to the greater stability of the implant when bone fixation was used [29]. In the case of infections, while some series have not reported any cases, some others reached a rate of 4.5 % [23], which coincides with the infection rate observed in the present study. The fact that the graft could be finally kept viable in place in all the patients who developed septic arthritis showed the concordance with a reported study, which suggested that early aggressive arthroscopic debridement and repeated irrigation with graft retention can be an effective treatment regimen in these cases [4].

The overall complication rate was 22.7 % (20 of 88). This percentage is not worse than the complication rate observed after standard arthroscopic meniscal repair [31]. More in detail, the complication rate of Group A was considerably worse (33.3 %) in comparison with the complication rate observed in Group B (16.4 %). However, following the criteria of Van Arkel and de Boer [32], which considers not only meniscal retention but also good knee function, our global allograft survival rate was 92.4 % at a mean 5 years postoperatively.

Allograft fixation techniques continue to be the subject of debate. Although it may be easier to secure the graft by soft tissue alone, cadaver model research indicates that superior transmission of load occurs when fixing the meniscal horns of the graft with bone plugs [2, 5]. However, other experimental studies have shown good healing of the transplanted allograft when both horns are sutured without bone plug fixation [8, 26]. Some authors have otherwise suggested introducing the graft through the patellar tendon [39] or to plicate the capsule arthroscopically [17] in order to improve the biomechanical characteristics of the graft. Hunt et al. [16], in an experimental investigation comparing grafts fixed with and without bone plugs, showed no differences in terms of the mean pullout strength in a cadaveric model. There are also clinical studies in which satisfactory results have been obtained with the only-suture technique [11, 20, 33–35, 37] as well as with bony fixation [12, 18, 29, 38]. Interestingly enough, although a different degree of reproducibility of the meniscal belt might be expected, similar functional outcomes were also observed when the only-suture technique was performed with simple peripheral sutures without any horn fixation [33–35, 37] or including horn fixation through

tibial tunnels [14, 20], as was performed in the present study. One of the few clinical studies comparing both fixation techniques did not find any functional differences [15]. This was in agreement with the similar functional results obtained in the current study with the use of both the soft-tissue and bony-fixation techniques.

It has also been reported that lateral allografts yielded better functional scores than medial allografts [30]. However, this was in contrast to the results observed in the present investigation and in agreement with other studies [1, 11, 14, 36], where lateral and medial MAT scored similarly in all the analysed variables.

Most of the authors have found pain relief and functional improvement to be the main benefits of MAT. This has been demonstrated not only during the first years after the procedure [1, 11, 20, 29, 36, 40], but also in a long-term follow-up [7, 15, 33, 35, 37]. Similarly, a significant improvement in the functional evaluation as well as in pain measured with a VAS in the two studied groups was found.

One limitation of this work is that, although prospective, the study was not randomized as the first 33 patients were assigned to Group A and the following cases to Group B. Thus, the learning curve may have had a certain relationship to the obtained results. However, all cases were followed longitudinally through all the clinical and radiologic aspects and both groups were also comparable in terms of age, gender and radiographic and functional preoperative state. In addition, although the series were consecutive, the evaluations were done at the same time by two independent observers who were blinded for the type of allograft fixation used.

Another important limitation is that the studied groups included patients undergoing isolated MAT 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 transplantation 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 [3], 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 MAT. Nevertheless, the added morbidity of these concurrent surgical procedures may diminish the likelihood of a successful outcome or presents a higher rate of complications [27, 28]. In addition, ACL reconstruction was performed in similar percentages of patients in both groups. Future investigation comparing isolated MAT versus a MAT procedure with concomitant ACL reconstruction or other concomitant procedures should be addressed. Finally, there was no postoperative magnetic resonance imaging evaluation. It could have permitted the assessment of the healing process and also the degree of graft extrusion in the two fixation techniques.

Regardless of the aforementioned limitations, our study provides one of the first comparisons between a group of MAT fixed only with sutures versus another group of MAT fixed with bone plugs in which all the surgeries were performed in comparable groups of patients by the same surgeon.

Conclusion

Meniscal allograft transplantation performed with either of the evaluated fixation methods provided good functional and radiographic results at mid-term follow-up. Both graft fixation techniques showed no differences relative to functional and radiographic results. There was a considerably higher rate of complications in transplantations performed with the only-suture technique than those that included bony fixation, although the difference was not statistically significant with the numbers available.

The results suggest that similar functional results should be expected if the meniscal graft includes bone plugs or if it does not. However, graft tears seem to happen more frequently if the MAT is performed without bony fixation.

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