Long-term clinical and radiological outcomes of meniscal allograft transplantation: A minimum 15-year follow-up.

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Conflict of interest

Each author certifies that neither he/she or any member of his/her immediate family receives funding from or has any commercial associations (consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article. Each author certifies that his/her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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Author contributions

1. **Raúl Torres-Claramount MD, PhD:** Conception of the research question, acquisition and analysis of the data, writing of a part of the manuscript and approval of its definitive version.

2. **Rodolfo Morales-Avalos MD, MSc**: Conception of the research idea, protocol design and drafting, obtaining, analyzing and interpreting the data, drafting the manuscript and approval of its definitive version as well as agreement with the other authors that all doubts or aspects of the manuscript were meticulously reviewed before being sent to publication.

3. **Simone Perelli MD:** Design and conception of the study, realization of the translation, realization of the statistical analysis, writing of part of the manuscript, search of literature, analysis and interpretation of the data, support of the definitive version of the manuscript.

4. **José Ramón Padilla Medina MD:** Acquisition and analysis of data, intellectual advisor in the area of human anatomy, wrote part of the manuscript and gave approval of its definitive version**.**

5. **Joan Carlos Monllau MD, PhD:** One of the two main investigators of the study, editing of the manuscript before its definitive version, orthopedic adviser, proposal of the idea, proposal of the clinical relevance of the study, implementation of the protocol methodology, interpretation of results, approval of the definitive version, writing of part of the manuscript.

Abstract

Purpose. The aim of this study was to evaluate graft survivorship and report the functional and radiographic results throughout a minimum 15-year follow-up of meniscal allograft transplantation (MAT).

Methods. Fifty-one patients that had undergone MAT during the period studied in isolation. The results were assessed with the Lysholm, Tegner scores and the VAS. Magnetic resonance imaging and a complete radiographic protocol were carried out to determine the degree of meniscal extrusion and joint-space narrowing. A comparison was made between the radiological findings of the last follow-up, mid-term follow-up of 5-years and those from the preoperative period. A specific criterion for surgical, clinical failure was also established.

Results. Finally, 38 patients were available for the final follow-up. The mean follow-up was 17.45 years. Twenty-three (60.53%) menisci transplantation were realized of the medial meniscus and 15 of the lateral meniscus (39.47%). Meniscal extrusion increased from the 29.69% ± 14.89 obtained at the 5-year follow-up to the 72.54% ± 22.52 seen at the end of the follow-up (p= 0.0001). Joint-space narrowing stayed almost same from the initial evaluation (3.35 ±1.5 mm) to the 5-year follow-up measurement (3.1±1.7mm, n.s.), and decreased at the last follow-up (1.9±1.5 mm, $p<0.05$). Functional outcomes improved from the preoperative period to the mid-term follow-up and later worsened at final follow-up. The mean preoperative Lysholm score at the initial follow-up was 61.48 ± 9.67, 86.90 ± 10.9 for the 5-year evaluation and it was 77.42 ± 11.48 (p= 0.0001) at the final follow up. Regarding the Tegner score, pre-operative scores were compared to those at the last follow up (2.65 ±1.33 vs. 5.23±1.74, respectively; p=0.0001). The VAS went down from 6.6 ±1.75 at the initial evaluation to 2.54±1.98 at the final follow-up (p=0.0001).

Five patients (13.16%) presented a failure at 5 years of the MAT, which was followed by extirpation of the meniscal graft. At the final follow-up, a total of 16 patients (42.11%) presented a failure. At that time, there were 4 more MAT removals and seven patients that required a total knee replacement. The mean years until failure was 16.14 ±2.19.

Conclusions. Meniscal allograft transplantation has shown good functional results at a minimum 15-year follow-up. However, degenerative arthritis in the affected compartment progressed during that period of time.

Key Words. Meniscal transplantation; Medial meniscus; Lateral meniscus; Meniscal extrusion.

Introduction

Meniscal allograft transplant (MAT) is a safe and effective procedure to treat post-meniscectomy syndrome [5, 9]. The short-term and midterm follow-up findings of MAT have been widely described and a high survival rate (89% to 95%) and good clinical results have been seen [3, 8].

The two main purposes of meniscal transplantation are the reduction of pain related to postmeniscectomy syndrome and the delay of partial or total knee replacement [7]. The latter would take place thanks to the chondroprotective power that the meniscal transplant is thought to have [11-14]. To understand whether this procedure can play a chondroprotective role and to better conduct a cost-effectiveness analysis, long-term data is needed [14]. Few series have been published with a minimum of 10 years of follow up [7, 10].

In some of those studies, the population was often composed of patients with wide-ranging follow-up periods (from 1 to 2 years to more than 10 years) [10]. Furthermore, a variety of surgical techniques (including the open approach) and different meniscal grafts for transplantation (including lyophilized grafts) were included in some of those series, increasing the heterogeneity of the results [4, 12]. With that being the case, little data from homogeneous sources is available about the long-term results after MAT.

The purpose of the present study is to evaluate the clinical and radiological outcomes as well as the failures at a minimum 15-year follow-up of fresh-frozen MAT performed arthroscopically in a homogenous series. The hypothesis of this study was that a graft survival rate greater than 60% would be found at that time.

Material and Methods

This was a ~~retrospective study~~ prospective series that included all MATs performed in our institution from January 2001 to July 2006. All the patients were operated by a single experimented surgeon (XXX) and gave consent to participate in the study. The clinical research ethics committee of our institution approved the study (XXX). The MAT procedure was indicated in cases of persistent compartmental joint pain due to a previous meniscectomy in a well-aligned knee. Normal alignment was considered up to 5° varus and 7° valgus alignment. If misalignment was corrected during the procedure, patient was also included in the study. Having an anterior cruciate ligament (ACL)-deficient knee was not considered a contraindication if the ligament was reconstructed at the same time. Patients that had severe degenerative joint disease diagnosed with a complete collapsed compartment on the Rosenberg view were excluded. Fifty-one MATs were performed. Of those 51 patients, 38 (74.5%) completed the minimum 15-year follow-up and 13 (25.5%) dropped out.

Surgical procedure

Fresh-frozen (80°C), non-irradiated, non–antigen matched meniscal allografts were used in all the patients. The allografts were supplied by local authorized tissue bank. Allograft sizing was done based on the radiological measures, in accordance with Polland´s method. The morphometric dimensions were also taken (weight and size) and provided to the Tissue bank for further matching (15).

First, debridement of the meniscal remnant was done. Then, two 6mm bone tunnels were drilled at the anatomic site of meniscal insertion (the anterior and posterior horns). The allograft was thawed in a saline solution. High-strength sutures (FiberWire; Arthrex, Naples, FL) with Krackow mattres configuration were put in place on both horns. One additional vertical suture was placed approximately at ~~1.5cm~~ 2cm from the posterior horn to facilitate the correct positioning of the allograft. The meniscal graft was then fixed to the rim with inside-out sutures (Sharp Shooter; ConMed Linvatec, Largo, FL) for the body and posterior horn and with outside-in sutures for the anterior horn. In those cases in which bone plugs were used, the plug and the meniscal horn were sutured and then introduced into a 8mm tibial tunnel with the bone plug. In the case of localized Outerbridge grade IV cartilage injuries, microfractures were performed. ACL reconstruction was performed as a last step in cases of a concomitant ACL rupture. However, the tibial bone tunnel for the ACL graft was previously done, and a dilator left inside, to prevent wall breakage or collapse among the different tibial tunnels. In a case in which a high tibial osteotomy was called for, it was performed before the MAT.

After the surgery, immediate quadriceps and hamstring muscle exercises were initiated. Passive range-of-motion from 0° to 60° was also initiated. Knee flexion progressed gradually to 90° by the end of the 4th postoperative week. At 3 weeks postoperatively, partial weight bearing with a knee immobilizer was allowed and progressed to full weight bearing at about 8 weeks. Running was allowed by the sixth month.

Functional and radiological assessment

The patients were assessed along a 5 to 10-year follow-up period and some of these results were published in previous studies [1, 2, 6]. The final follow-up was performed at a minimum 15 years, postoperatively. Functional assessment included different scores like the 100-point Lysholm score and the KOOS (Knee injury and Osteoarthritis Outcome Score). The EuroQol Quality of Life Scale (EQ-5D) was also used. It consists of two parts, a descriptive system and a visual analogue scale (VAS). The descriptive system of the scale consists of 5 single-item dimensions that include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (16-18). Patient satisfaction was evaluated with a subjective score and graded as follows: very satisfied (4 points), satisfied (3 points), neutral (2 points), dissatisfied (1 point), and very dissatisfied (0 points). Preoperatively and at the mid-term follow-up, patients only filled out the Lysholm and Tegner score as well as the VAS.

Radiographic assessment included a weight bearing long-standing radiograph as well as the posteroanterior Rosenberg view at 45° of flexion. Because one of the potential effects of MAT might be preservation of the cartilage, we focused on joint-space narrowing in the involved compartment, which was measured preoperatively and at final follow-up. The shortest distance between the femoral condyle and tibial plateau of the involved compartment on a posteroanterior Rosenberg view at 45° of flexion was taken as a measure of joint-space narrowing. A Magnetic resonance imaging (MRI) evaluation was also done to assess allograft evolution. Extrusion was defined as the greatest distance from the most peripheral aspect of the meniscus to the border of the tibia divided by the total width of the meniscus on the same magnetic resonance coronal image (19). Preoperative and postoperative radiological measures were analyzed by means of the ePACS viewer (version 5.0.0.0; Real Time Image, San Bruno, CA) for clinical imaging. Medial allografts were also compared with lateral allografts at final follow-up. The radiographic evaluation was carried out by 2 independent observers that were not involved in the study. The intraclass correlation was calculated ranging from 0 to 1. The entire functional evaluation was performed by 1 observer that was not the surgeon (20).

Definition of Failure Criteria

Surgical failure was defined as a requirement for a revision procedure related to the initial MAT. The requirements included total knee arthroplasty, unicompartmental knee arthroplasty, retransplantation or complete or partial removal of the allograft. Those patients that needed a new surgery in which the graft was maintained or reattached were not considered failures. The clinical scores of those patients that experienced surgical failure were not included in the final analysis. However, the time to failure of those patients was used for the survival analysis (2, 6).

Statistical analysis

For the statistical analysis, the categorical variables are presented as percentages and frequencies and the continuous variables are presented as mean and standard deviations. After evaluating the normal distribution of the differences between the preoperative and postoperative scores with the Kolmogorov-Smirnov method, the differences were analyzed with the paired Student's t-test. The statistical analysis was performed with the SPSS software package (version 13.0; SPSS, Chicago, IL). Statistical significance was set at 0.05.

IRB approval??? Utilizar alguno de los previos

Results (*algún comentario sobre las causas de pérdida de seguimiento*)

Thirty-eight out of 51 patients were located and came to the hospital for the assessment. The study group consisted of 25 men and 13 women (65.79%/34.21%) with a mean age of 36.92 years ±8.54 at the time of transplantation. The mean follow-up of the patients was 17.4 years ± 2. Nineteen (50%) meniscus transplants were performed on right knees and 19 (50%) on left knees. Twenty-three (60.53%) were medial meniscus transplantations and 15 (39.47%) were lateral meniscus transplantations. An Anterior ACL reconstruction was associated in eleven patients (28.9%), a microfracture procedure was carried out on 5 patients at the time of the surgery (13.1%) and 4 patients needed a high tibial osteotomy (10.5%). For 12 (21.5%) patients, the bone plug technique was used.

Radiographic evaluation

Table 1 shows how the joint-space width remained almost unchanged from the initial evaluation (3.35 ±1.5 mm) up to the 5-year follow-up measurement (3.1±1.7mm, n.s.). However, this joint-space decreased at the last follow-up last evaluation (1.9±1.4 mm, $p<0.05$). Moreover, there was a non-statistical difference in the frontal mechanical axis between the preoperative value and the first and second follow-ups ($p = 0.621$). Meniscal extrusion increased from the 29.7% ± 14.89 obtained at the 5-year follow-up to 72.5% ± 22.5 at the last follow-up ($p= 0.0001$).

Functional and satisfaction scores

A significant improvement in all scores was reported at the last follow-up. The mean preoperative Lysholm score was 61.48 ± 9.67. It increased to 86.90 ± 10.9 at the 5-year evaluation and dropped to 77.42 ± 11.48 at the final follow up ($p= 0.0001$), still showing significant difference from the preoperative values ($p= 0.002$).

A significant difference was also found upon comparing the pre-operative Tegner scores with those at the last follow up (2.65 ±1.33 vs. 5.23±1.74, respectively; $p=0.0001$).

The VAS score decreased from 6.6 ± 1.75 at the initial evaluation to 2.54 ± 1.98 at the end of the follow-up ($p=0.0001$).

The mean KSS at the last follow-up reported excellent for pain assessment (80.49 ± 13.44) and good for symptoms (78.41 ±10.70), normal life activities (79.46 ± 13.53), functional (61.05 ± 25.23) and life quality (68.71 ± 24.77). The EQ-5D reported good results at the final follow-up (71.90 ±15.20). A complete description of the results is shown in Table 2.

Failure

Sixteen patients (42.11%) presented with a failure. Seven patients underwent a knee replacement. Another 9 had an extirpation, with 5 (13.6%) of them before five years. The mean time to failure of the meniscal graft was 206.17 months ± 13.38 (18.01 years) (see Fig. 1). There was no difference between the medial or lateral MAT, with a mean of 199.3 and 208.33 months, respectively (p=0.794) (see Fig. 2).

The intra- and interobserver agreements were evaluated with the Intraclass correlation coefficient (ICC) value, with ICC = 1 representing perfect agreement. In this study, the ICC values were analyzed for all measured values. Interobserver agreement ranged from .84 to .90, and intraobserver agreement ranged from 0.88 to 0.96.

DISCUSSION

The main finding of this study is that patients that underwent MAT due to a post-meniscectomy syndrome showed survivorship rate of 58% at a mean 18-year follow up. Those patients had good functional outcomes at that time. Nevertheless, the chondroprotective effect of the MAT cannot be demonstrated.

Different series have studied the long-term MAT survivorship rate. It is difficult to establish the rate of failure as various authors considered failure differently (7, 10, 21). While Noyes et al. (21) estimated a survivorship probability of 19% at 15 years, Vundelinckx et al (22) had a view that 59.1% of patients were free of reinterventions 15 years after a MAT. In fact, most patients that are considered as experiencing a failure underwent a transplant extirpation in the early years or had a TKA many years later. Most of the MAT patients had some degree of chondral lesions at the moment of the surgery and most of them had undergone several surgeries on the knee prior to the MAT surgery. Therefore, it is possible to assume that the MAT can delay the need for TKA surgery in young people. Sometimes, one does not have many alternatives to offer patients. Although it is known the degenerative process cannot be stopped with this procedure, painful symptoms can be improved on in the meniscectomized compartment. With that, a survivorship rate of 58% at 18 years of follow-up can be considered a success even though the radiological studies performed showed significant of osteoarthritic changes in some of those patients. Recently, Winkler et al. (23) described a 34% MAT failure rate at 7.6 years of the surgery. They observed that preoperative osteoarthritic changes in the index compartment was the main predictor of MAT failure. If we want to demonstrate a chondroprotective effect of MAT, surgeries should be done only in non-degenerated knees. Wang et al. (24) observed that MAT had a moderate chondroprotective effect along with less joint-space narrowing in the long-term follow-up (more than 11 years) when compared to the meniscectomy. In our series, there were 2 patients considered as a failure with a MAT extirpation as the 15-year follow-up approached. In one of those cases, the patient was re-implanted with a new MAT. The second patient presented a

post-meniscectomy syndrome without significant chondral lesions after the extirpation but declined the surgery. In those 2 cases, which had completely stable and non-degenerated knees, the chondroprotective effect of the MAT was present. Lee et al. (12) reviewed 222 patients that received a MAT. They compared those patients operated on with low-grade chondral lesions (ICRS<2 in both tibial and femoral side) to those operated on with high degree of chondral degeneration (ICRS 3 or 4 on either femoral or tibial side) and the cases with indication for salvage (ICRS 3-4 on both sides). They concluded that MAT acts as a good symptomatic treatment in all cases. However, graft survival was clearly related to the degree of cartilage degeneration. Smith et al. (25), in a literature review, studied the hypothetical chondroprotective effect of the MAT. They studied all series published to date and concluded that it is too much to ask that it function like a native meniscus even though MAT may reduce the progression of the osteoarthritis.

Functional outcomes have been studied in depth in various series. Wirth CJ et al. (26, 27) has published various articles on a long-term MAT series at the 14- and 20-year follow-up of medial MAT associated with ACL reconstruction. They documented good functional scores with a Lysholm score of 75 ± 23 at the 14-year follow-up. This score also was reasonably maintained at 20 years. However, only a few patients were analyzed at the last follow-up. Van der Wal et al. (28) reported on a series of 63 MATs operated on with an open approach with a survival rate of 71% at the 14-year follow-up. They reported poorer outcomes, with a Lysholm score of 61, than those observed in this study (SD, 20). Novaretti et al. (29) reviewed all the functional outcomes of all series published until 2019 with more than 10 years of follow-up. The Lysholm score ranged from 61 to 75 and the Tegner from 2.5 to 4.6. Our series showed mean Tegner score values of around 5 and 77 for Lysholm at the last follow-up. These results can be considered good when compared to those seen by Novaretti et al.

The limitation of this study is the differing extents of chondral lesions in each patient at the time of the surgery and the variety of previous procedures before MAT. A second limitation was the impossibility to bring in all the patients at the last follow-up. The third limitation is not having a series of postmeniscectomized patients with other type of treatment for comparison.

Conclusions

This is one of the largest series of MAT performed by a single surgeon with a long follow-up. It can be concluded that MAT is a procedure that improves knee symptoms over an extended period and has a high survival rate after 15 years. However, its chondroprotective effect cannot yet be demonstrated.

TABLES

Variable	***Pre-operative***	***5-years***	***Last FU***	***P-value Preoperative vs. last FU***	***P-value 5 years vs. last FU***
Lysholm, mean ± SD	61.48 ± 9.67	86.90 ± 10.09	77.42 ± 11.48	<.0001	.002
Tegner activity score (range)	2.66 (0–6) Median 3	5.93 (3-9) Median 6	5.23 (3–8) Median 5.5	<.0001	n.s.
Visual analog scale (0-10) score, mean ± SD	6.60 ±1.75 Median 7 (2-9)		2.54± 1.98 Median 2 (0-8)	<.0001	
Graft extrusion percentage (%)	N/A	29.7 ±14.89	72.54 ±22.52	<.0001	
Failure		5 (13.6%)	13 (42.11%)		
Joint-space width (mm)	3.35±1.5	3.1 ±1.7	1.9 ± 1.5	n.s.	<0.05
Mechanical axis deviation, (°)	0.33± 1.86 (varus)	0.60 ± 2.93	0.79 ± 4.61	n.s.	n.s.

Table 1. Comparison of the results obtained in the long-term follow-up with respect to the preoperative state and at the 5-year follow-up in the different variables analyzed in the present study. FU=follow-up

Variable	***Mean***	***SD***	***Confidence interval***
Kellgren & Lawrence osteoarthritis stage	3.86	0.58	3.64 - 4.08
Satisfaction	2.56	0.97	2.17 - 2.94
EQ movement	1.57	0.81	1.20 - 1.94
EQ care	1.48	0.98	1.03 - 1.92
EQ daily life	1.38	0.67	1.08 - 1.69
EQ pain	1.52	0.68	1.21 - 1.83
EQ anxiety	1.33	0.66	1.03 - 1.63
EQ total	71.90	15.20	64.98 - 78.83
KSS symptoms	78.41	10.70	73.54 - 83.28
KSS pain	80.49	13.44	74.37 - 86.60
KSS daily life	79.46	13.53	73.30 - 85.62
KSS function	61.05	25.23	49.56 - 72.53
KSS life quality	68.71	24.77	57.44 - 79.99

Table 2. Functional scores at the final follow up.

FIGURE LEGENDS

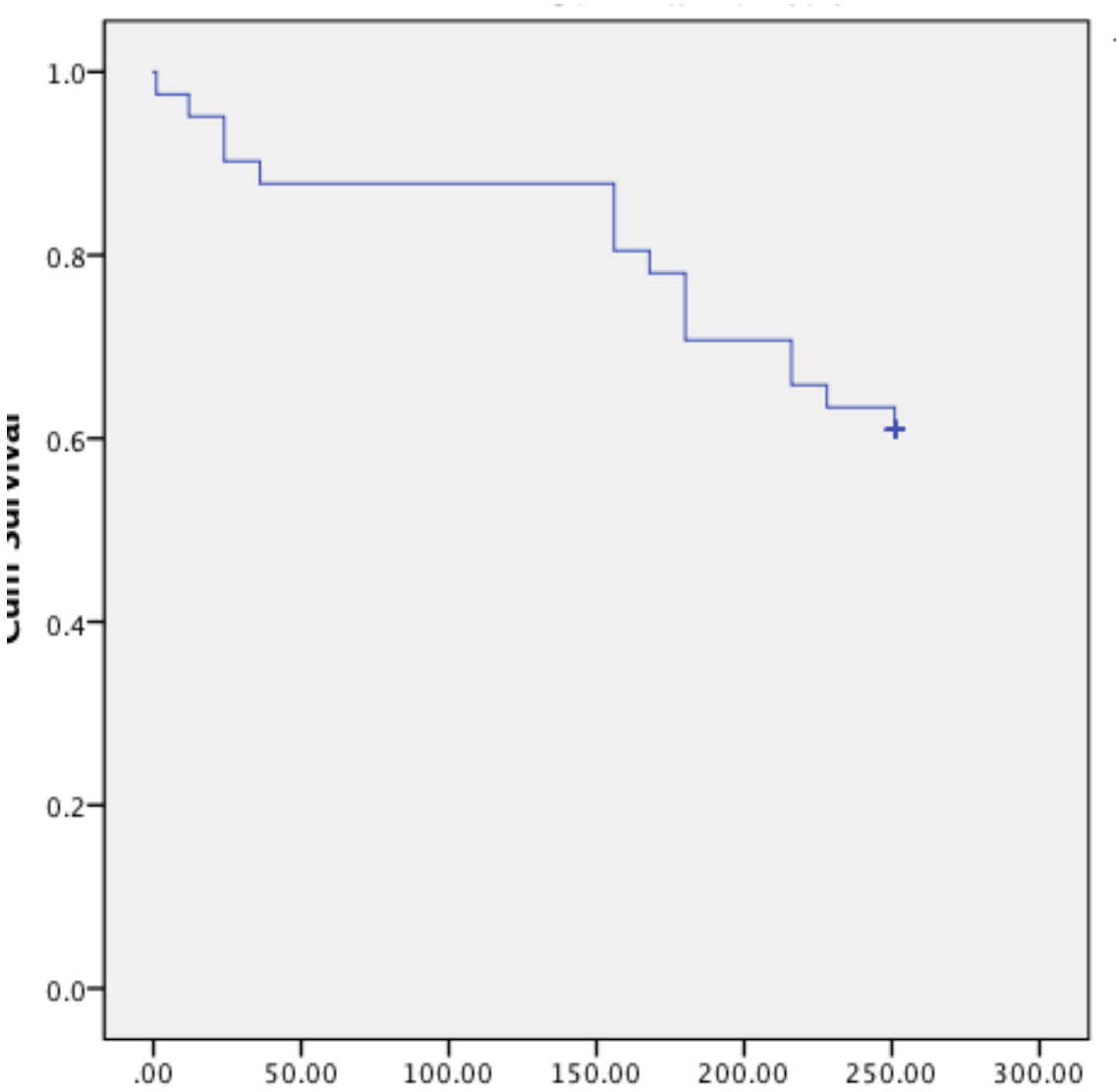

Figure 1. Meniscal graft survival time, in months.

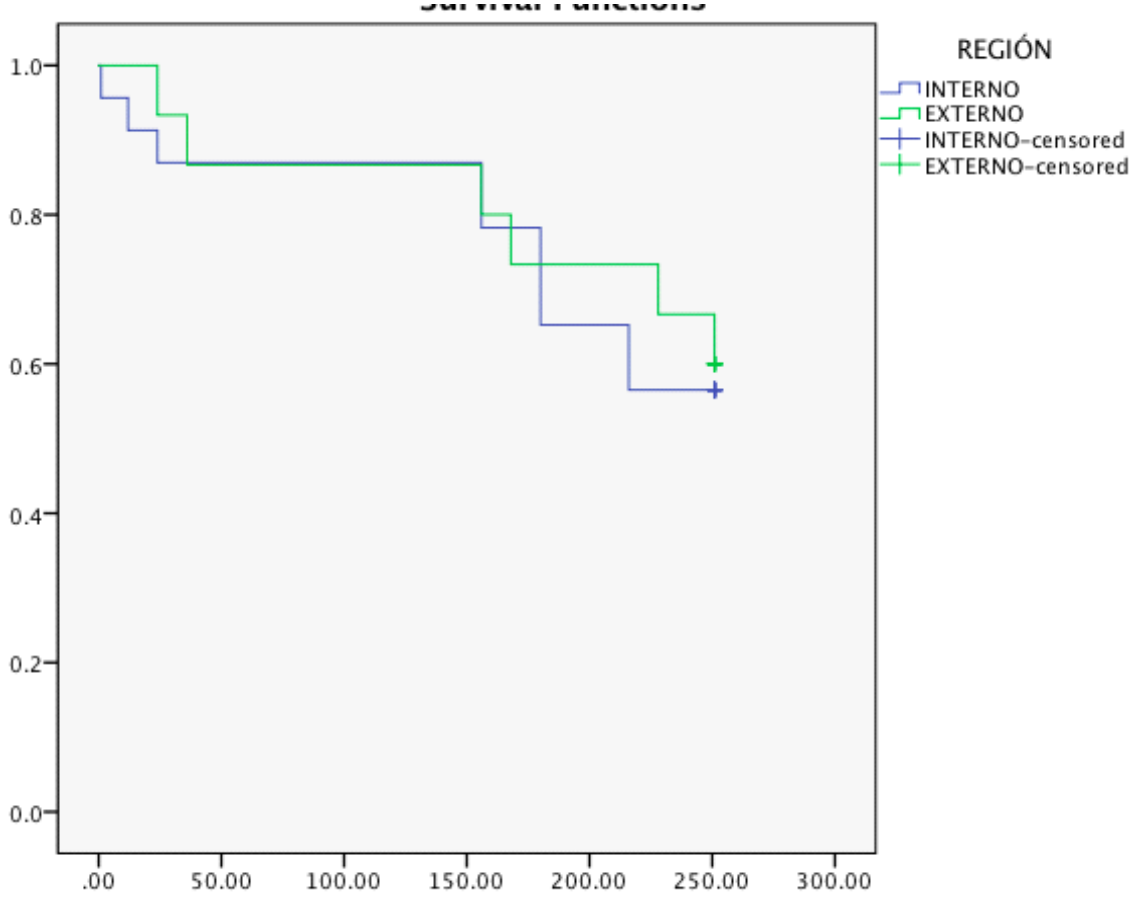

Figure 2. Meniscal graft survival time, in months, comparing the internal meniscus (blue line) and external meniscus (green line).

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