Meniscus Allograft Survival in Patients with Moderate to Severe Unicompartmental Arthritis: A 2- to 7-Year Follow-up

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Purpose: We present meniscus allograft survival data at least 2 years from surgery for 45 patients (47 allografts) with significant arthrosis to determine if the meniscus can survive in an arthritic joint. **Type of Study:** Prospective, longitudinal survival study. **Methods:** Data were collected for 31 men and 14 women, mean age 48 years (range, 14 to 69 years), with preoperative evidence of significant arthrosis and an Outerbridge classification greater than II. Failure is established by previous studies as allograft removal. No patient was lost to follow-up. **Results:** The success rate was 42 of 47 allografts (89.4%) with a mean failure time of 4.4 years as assessed by Kaplan-Meier survival analysis. Statistical power is greater than 0.9, with $\alpha = 0.05$ and N = 47. There was significant mean improvement in preoperative versus postoperative self-reported measures of pain, activity, and functioning, with $P = .001$, $P = .004$, and $P = .001$, respectively, as assessed by a Wilcoxon rank-sum test with $P = .05$. **Conclusions:** Meniscus allografts can survive in a joint with arthrosis, challenging the contraindications of age and arthrosis severity. These results compare favorably with those in previous reports of meniscus allograft survival in patients without arthrosis. **Level of Evidence:** Level IV. **Key Words:** Meniscus allograft—Meniscus—Meniscectomy—Transplantation—Survival—Arthrosis.

Meniscal transplantation has previously been indicated for patients who have mild or early osteoarthritis, are younger than 50 years of age, and present with an Outerbridge (OB) II classification or lower.[1-5] This classification describes patients with superficial fibrillation or fragmentation less than 1.3 cm^2 of the subchondral bone (Table 1).[1] This indication is based on early observations of a few failures that occurred in patients with advanced arthrosis.[6-8] However, few studies include a statistical survival analysis to assess long-term viability of the meniscus allograft.[9] It has yet to be determined if a meniscus allograft can survive in a severely arthritic knee.

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The indications for meniscus replacement are yet to be established; however, it is well documented that removal of meniscus tissue can lead to degenerative changes and arthrosis.[5] Meniscus replacement in the arthritic knee may delay progression of arthrosis and may provide pain relief, but this has not yet been studied. Common treatment for severe arthrosis is unicompartmental or total knee replacement. Patients appropriately desire to delay total knee replacement because implant lifespan is relatively short and activity recommendations are far too restrictive for patients with moderate to vigorous lifestyles.

Few treatment options are available for patients who have had a meniscectomy who present with pain in the same compartment. Treatment of arthritic changes in the meniscectomized knee by joint debridement without replacement of the meniscus has led to variable outcomes.[10] The addition of an allograft meniscus could improve the outcome and possibly delay joint replacement.

To assess survival of meniscus allografts in knees with documented arthrosis, the following Institutional

Table 1. *Outerbridge Grading System for Cartilaginous Degeneration*

Stage I	Soft discolored superficial fibrillation
Stage II	Fragmentation <1.3 cm^2
Stage III	Fragmentation >1.3 cm^2
Stage IV	Erosion to subchondral bone (eburnation)

Review Board (IRB)–approved prospectively designed outcome study was initiated in 1997. Of special note is that this is a unique collection of patients who are in general very motivated and present with severe preoperative osteochondral degenerative changes after failed attempts at joint debridement types of procedures. Every effort was made during meniscal allograft transplantation in this patient population to smooth the rough articular cartilage surfaces, including mechanical debridement, microfracture, and an articular cartilage paste grafting procedure. Because the individual contribution of articular cartilage treatment, alignment correction, or meniscus replacement is extremely difficult to parse, this study focused on the survival of the implant in a severely arthritic knee. Secondary benefits of pain relief and function improvement are reported and can be attributed to the combination of meniscal allografting, concomitant procedures, a defined rehabilitation program, and a high level of attention from the surgical team.

METHODS

Forty-five patients, 31 men (69%) and 14 women (31%), were longitudinally followed for a minimum of 2 years and an average of 5.8 years (range, 2 to 7.25 years). All patients underwent surgery between March 1997 and December 1999. The mean age at the time of surgery was 48 years (range, 14 to 69 years), with 25% over the age of 55. The surgical site was the right knee in 23 cases (49%) and the left knee in 24 (51%). The operative compartment was medial in 37 (79%) and lateral in 10 (21%). The severity of arthrosis was determined both preoperatively by radiographic changes and at surgery (Table 2) using the OB classification (Table 1).[1] Because the OB classification is based on cartilage surface roughness, which is speculated to be a major factor in meniscus allograft failure, it is the most appropriate grading scale to apply to the survival data. Of 47 meniscal allograft transplantations, 9 compartments presented with OB III (19%) and 38 with OB IV (81%) degenerative changes.

Radiographic assessments included standing anteroposterior (AP), posteroanterior (PA) flexion, lateral, skyline, and long-leg alignment views to determine joint space narrowing and alignment. Eleven of 45 had no joint space narrowing (24%), 18 had moderate narrowing (40%), and 16 had severe narrowing (36%). Twenty-six presented with no malalignment (58%), 17 with moderate ($\leq 7°$) malalignment (38%), and 2 with severe ($>7°$) malalignment (4%). Of 19 patients with alignment issues, 18 were varus (95%), and 1 patient was valgus (5%). Fourteen patients (73.7%) underwent a medial opening wedge corrective osteotomy.

Forty-five knees had chronic injuries (96%), defined as more than 12 months elapsed from the date of injury to the date of surgery. The time from injury to surgery averaged 14.4 years (range, 0.6 to 34 years). The mean number of preallograft surgeries averaged 2.1 (range, 1 to 7). Sixty-six percent of the patients had at least 1 other knee procedure performed at the time of allograft surgery, with an average of 2.9 concomitant procedures (range, 1 to 8).

The surgeon made efforts to smooth rough articular surfaces (chondroplasty) and debride impinging scar tissue in all patients. Major concomitant procedures included any combination of a meniscal allograft transplantation, an articular cartilage paste graft procedure,[11] microfracture, medial opening wedge tibial osteotomy, or anterior cruciate ligament reconstruction and/or revision. Seven patients underwent 1 concomitant procedure (16%), 13 underwent 2 (29%), 24 underwent 3 (53%), and 1 underwent 4 (2%). Statistical analysis stratified each of these groups, with no significance found in failures between different groups, nor was there a statistically significant difference in validated subjective outcome scores between these groups. Patient profiles are summarized in Table 2. Figures 1 and 2 illustrate the severity of arthrosis and represent both concomitant procedures and postoperative results representative of this patient population.

Inclusion Criteria

Patients entered the study serially and were followed-up longitudinally from 1997 to 2004. The indication for meniscus allograft transplantation included pain at the joint line of a previous meniscectomized patient (as determined by validated subjective questionnaires) that failed conservative care (including various combinations of unloader braces, heel wedges, and courses of physical therapy over a period of years) or previous surgical debridement. Inclusion criteria included (1) loss of the me-

TABLE 2. *Summary of 45 Patient Profiles*

Patient (Sex)	Age	Operative Compartment*	Months to Failure	Allograft Material†	Outerbridge Grade‡	Injury Type	Previous Surgeries	Operative Procedures§	Joint Space Narrowing‖	Alignment‖	Varus/ Valgus‖
1 (F)	55	RMed	29	Cryo	IV	Chronic	3	ALL, ARC	1	0	0
2 (M)	46	LMed		Cryo	IV	Chronic	1	ALL, ACL, ARC	2	0	0
3 (F)	37	LMed		Cryo	IV	Chronic	3	ALL, ARC, MFX	1	0	0
4 (M)	55	L Lat		Cryo	IV	Chronic	2	ALL, ARC	1	0	0
5 (M)	49	R Lat		Cryo	IV	Chronic	2	ALL, MFX	0	0	0
6 (F)	42	RMed		Cryo	III	Chronic	5	ALL, MFX	1	0	0
7 (M)	37	RMed		FF	IV	Chronic	1	ALL, ARC	2	0	0
8 (M)	46	LMed		FF	IV	Chronic	2	ALL, ARC, MFX	2	1	1
9 (F)	47	L Lat	57	FF	IV	Chronic	7	ALL, ARC, MFX	2	0	0
10 (M)	65	LMed		FF	IV	Chronic	1	ALL, ARC	2	0	0
11 (F)	57	RMed		FF	IV	Chronic	3	ALL, ARC, OST	2	1	1
12 (M)	39	LMed		Cryo	IV	Chronic	2	ALL, ARC, OST	0	1	1
13 (M)	14	L Lat		Cryo	IV	Acute	3	ALL	0	0	0
14 (M)	36	RMed		Cryo	IV	Chronic	2	ALL, MFX	0	0	0
15 (M)	53	RMed		Cryo	III	Chronic	3	ALL, ARC, MFX, OST	2	1	1
16 (M)	35	RMed	7	Cryo	IV	Chronic	1	ALL, ACL	0	1	2
17 (F)	51	L Lat		Cryo	III	Chronic	2	ALL	0	0	0
18 (F)	31	RMed		Cryo	IV	Chronic	0	ALL, ACL, MFX	1	0	0
19 (M)	64	RMed		Cryo	III	Chronic	3	ALL	1	0	0
20 (M)	40	LMed		Cryo	IV	Chronic	3	ALL, ARC, OST	2	1	1
21 (F)	52	RMed		Cryo	IV	Chronic	0	ALL, MFX, OST	2	1	1
22 (M)	63	R Lat		Cryo	IV	Chronic	0	ALL, ARC, MFX	1	0	0
23 (F)	49	LMed		Cryo	III	Chronic	1	ALL	0	0	0
24 (M)	55	LMed	18	Cryo	IV	Chronic	2	ALL, ARC, MFX	2	0	0
25 (F)	41	LMed		Cryo	III	Chronic	1	ALL, ACL	1	0	0
26 (M)	55	LMed	15	Cryo	IV	Chronic	0	ALL, ARC, MFX	1	1	1
27 (M)	52	RMed		Cryo	III	Chronic	6	ALL, ARC, OST	1	1	1
28 (M)	54	RMed		Cryo	IV	Chronic	1	ALL, ARC, OST	2	1	1
29 (M)	39	L Lat		Cryo	IV	Chronic	2	ALL	1	0	0
30 (M)	35	RMed		Cryo	III	Chronic	5	ALL	0	0	0
31 (M)	42	LMed+Lat		Cryo	IV	Chronic	2	ALL	0	0	0
32 (M)	47	RMed+Lat		Cryo	IV	Chronic	2	ALL, ARC	1	0	0
33 (M)	64	RMed		FF	IV	Chronic	0	ALL, MFX, OST	2	2	1
34 (M)	54	LMed		FF	IV	Chronic	4	ALL, ARC, MFX	1	1	1
35 (M)	51	RMed		FF	IV	Chronic	1	ALL, MFX, OST	2	2	1
36 (M)	38	RMed		FF	IV	Chronic	6	ALL, ACL, MFX	1	1	1
37 (M)	53	LMed		FF	IV	Chronic	2	ALL, ARC, OST	2	0	0
38 (F)	59	LMed		FF	IV	Chronic	1	ALL, ARC	1	0	0
39 (M)	41	RMed		FF	IV	Acute	1	ALL, ARC, OST	1	1	1
40 (M)	57	LMed		FF	IV	Chronic	1	ALL, ARC, OST	1	1	1
41 (F)	39	RMed		FF	IV	Chronic	2	ALL, MFX	0	0	0
42 (M)	69	LMed		FF	IV	Chronic	0	ALL, ARC, MFX	2	1	1
43 (F)	37	L Lat		FF	IV	Chronic	2	ALL, ACL, MFX	1	0	0
44 (F)	58	RMed		FF	IV	Chronic	1	ALL, OST	2	1	1
45 (M)	51	LMed		FF	III	Chronic	2	ALL, MFX, OST	0	1	1

*Operative compartments separated by left (L) or right (R) knee and medial (Med) or lateral (Lat) compartments. Two patients had bilateral allografts performed within the same knee.

†Cryopreserved (Cryo) versus fresh-frozen (FF) allograft material.

‡Outerbridge RE.[1]

§Concomitant procedures included any combination of meniscal allograft (ALL), osteochondral paste graft resurfacing (ARC),[14] ACL repair or reconstruction (ACL), microfracture (MFX), or a medial opening wedge corrective osteotomy (OST).

‖Joint space narrowing and alignment were measured as normal (0), moderate (1), or severe (2). Normal (0). Varus (1) and Valgus (2) values were also determined for each patient.

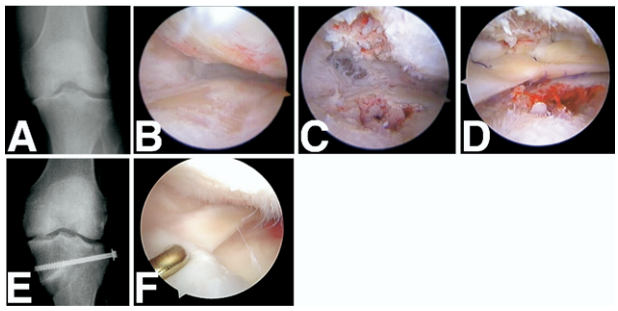

FIGURE 1. Preoperative, interoperative, and postoperative images of patient 37. Patient 37 was classified as OB IV, and underwent a meniscal allograft, articular cartilage paste graft resurfacing technique, and a high tibial wedge osteotomy. (A) Preoperative radiograph shows medial joint space narrowing and varus alignment. (B) Bipolar chondral lesions of the medial femoral condyle and tibial plateau with an absent meniscus. (C) Fracture and morselization of the OB IV chondral lesions until bleeding occurs. (D) Placement of the meniscus and osteochondral paste graft of the chondral lesions. (E) Six-month postoperative standing anteroposterior radiograph showing healing of high tibial wedge osteotomy with restored medial joint space. (F) Second-look arthroscopy 3 years postoperatively shows healthy integration of the medial meniscus and re-establishment of cartilage on both tibial and condylar lesions.

niscus with pain in the respective compartment, (2) a range of motion of at least 90° or correctable at surgery to 90°, (3) articular cartilage damage identified by radiograph, magnetic resonance imaging (MRI), and at surgery, and (4) degenerative changes classified as OB III or OB IV.

Exclusion Criteria

Exclusion criteria included (1) uncorrected axis deformity greater than 10°, (2) tricompartment arthrosis, (3) multiple compartmental pain, (4) history of inflammatory arthrosis, (5) diabetes mellitus, (6) immune disorders, and (7) degenerative changes classified as OB I or II.

Surgical Procedure

The surgical procedure used for transplantation of meniscal allografts is known as the 3-tunnel technique.[12] Briefly, it involves the arthroscopic transplantation of meniscal allografts using cadaver allografts without bone block or bone plugs. The arthroscopic surgical implant procedure implements a 3-tunnel technique to secure the anterior and posterior meniscal horns and posterior corner of the allograft. Additional stabilization of the implant is achieved through an inside-out suture technique. No posterior medial or lateral incisions were made except for skin punctures for percutaneous suturing.

Articular Cartilage Paste Grafting

The articular cartilage paste grafting technique[10] is an arthroscopic procedure using historical methods of lavage, debridement, and subchondral fracture to stimulate autologous mesenchymal stem cell proliferation, differentiation, and growth factor release, and is described as follows:

Damaged cartilage was shaved removing fibrillated tissue. The lesion was then penetrated at multiple sites in the bed of the lesion with an arthroscopic awl until bleeding occurred (Figs 1C and 2C). Unlike microfracture, the arthritic bed is completely morselized. Tissue for graft preparation was harvested from the margin of the intercondylar notch using an 8-mm trephine impacted into the margin of the articular cartilage and from the underlying cancellous bone to a depth of 1.5 cm. The trephine was removed and the graft morselized manually in a graft impactor (DePuy, Warsaw, IN). The paste created from the cancellous bone and articular cartilage was then impacted into the fractured bed of the traumatic and/or arthritic defects (Fig 1D). The impacting step was performed multiple times. The paste graft material formed a grout of chondrocytes, matrix, and bone marrow in the interstices of the exposed bone. The paste graft was held in place for 1 to 2 minutes and then the instruments were

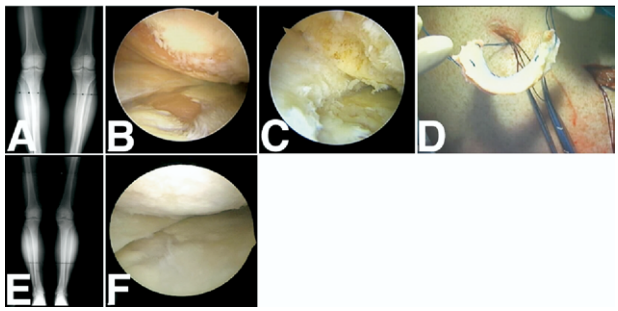

FIGURE 2. Preoperative, interoperative, and postoperative images of patient 40. Patient 40 was classified as OB IV, and underwent a meniscal allograft, articular cartilage paste graft resurfacing technique, and a tibial wedge osteotomy. (A) Preoperative radiograph revealing joint space narrowing and varus alignment. (B) Bipolar chondral lesions of the medial femoral condyle and tibial plateau with a severely damaged meniscus. (C) Debridement and morselization of chondral lesions. (D) Arthroscopic insertion of the allograft meniscus. (E) Radiograph 42 months postoperatively shows healed tibial wedge osteotomy with restored medial joint space. (F) Second-look arthroscopy 3.5 years postoperatively showing healthy integration of the medial meniscus and re-establishment of cartilage on both tibial and condylar lesions.

removed. If other arthroscopic procedures were to be performed, the impaction of the paste was the last step.

Rehabilitation Program

The primary objective of the meniscus allograft rehabilitation protocol is to protect and preserve the allograft, with a secondary goal of restoring range of motion. General considerations include a partial weight-bearing status for 4 weeks postoperatively, 10% to 20% toe-touch for 1 to 2 weeks, a hinged rehabilitation brace locked in full extension for 4 weeks postoperatively unless otherwise indicated, regular assessment of gait to avoid compensatory patterns, regular manual mobilizations to surgical wounds and associated soft tissue to decrease the incidence of fibrosis, no resisted leg extension machines, no high-impact, cutting, or twisting activities for at least 4 months postoperatively, and to stretch 5 times daily by bending the knee back as far as tolerated for 10 seconds.

The rehabilitation protocol can be described by 2 phases: a maximal protective phase and a moderate protective phase. The maximal protective phase is from weeks 1 to 4 and includes daily icing and elevation 5 times a day for 15 minutes, straight leg exercises, passive and active range of motion exercises, manually resisted hip, foot, and ankle exercises (PNF patterns), pool workouts, soft-tissue treatments, a trunk stabilization program, and non–weight bearing aerobic exercises.

The moderate protective phase is from weeks 4 to 12 and includes stretching, manual treatments to restore range of motion, the introduction of functional exercises (i.e., partial squats, calf raises, and proprioception exercises), road cycling as tolerated, slow walking on a low-impact treadmill, and lateral training. Exercises increasingly focus on single-leg exercises, strength training, and sport-specific training for a gradual return to activities.

Follow-up Schedule

Preoperative data collection included a range of motion (ROM) assessment, a pain-activity questionnaire, AP, PA flexion, and long-leg radiographs, and MRI. A clinical examination was conducted postoperatively at days 1 and 10, months 1 and 3, and years 1, 2, 5, and 7. A ROM assessment was conducted postoperatively at month 3, and years 1, 2, 5, and 7. Validated Western Ontario and McMaster's Universities Osteoarthritis Index (WOMAC), International Knee Documentation Committee (IKDC), and Tegner activity scores, and a pain and functioning questionnaire were collected postoperatively at years 1, 2, 5, and 7. Anteroposterior and posteroanterior flexion radiographs were taken postoperatively at years 2, 5, and 7.

Failure Criteria

The presence of healthy meniscus tissue is proven to provide shock absorption and stabilization to the knee joint. Insertion of a new meniscus into an arthritic knee should provide at least a soft tissue interpositional pad and may function as a normal meniscus. Therefore, our primary outcome measure was failure of maintenance of the meniscus transplant. As such, failure was defined as removal of the allograft transplant alone and/or progression to partial or total knee arthroplasty. We believe this is the primary and objective measure of meniscus transplant failure in the arthritic knee. New trauma resulting in a new tear or injury to the allograft that required a repair or partial resection was not deemed as a failure because many of these patients returned to athletic endeavors and continued to have pain relief. Furthermore, the definition of failure in this study is consistent with that of other meniscus allograft outcomes studies.[3,4,13-17]

Statistical Methods

Primary analysis evaluated the long-term survival of meniscal allografting with Kaplan-Meier (KM) product-limit survival analysis, and life tables.[17] Secondary analysis was a comparison of preoperative and last follow-up postoperative self-reported measures taken from IKDC, Tegner, and WOMAC pain, activity, and functioning questionnaires, and are reported on a scale of 1 to 5, where 1 equals the highest degree of pain and difficulty. Assessments are reported in mean scores $\pm$ standard deviation. Analysis of self-reported measures was performed by nonparametric analysis (Wilcoxon rank-sum test). All statistical tests were 2-sided, and the threshold of significance was set at $\alpha = 0.05$.

RESULTS

Forty-two of 47 meniscus allografts (89.4%) survived 2 to 7 years in arthritic knees, many of which also underwent concomitant arthroscopic debridement, cartilage treatment, or stabilization as necessary. Successful outcomes as assessed by survival of the implant were noted, as was postoperative versus

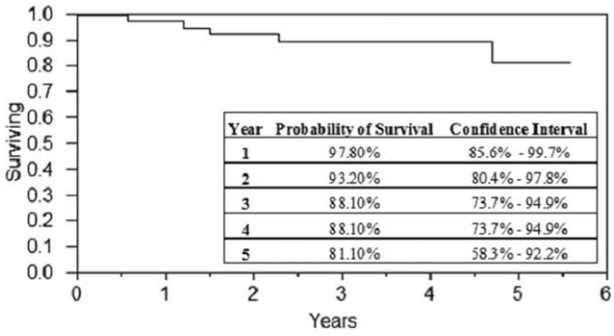

FIGURE 3. Product-limit survival fit survival plot and Survival Probabilities based on 5 failures.

preoperative improvement in the secondary outcomes of pain, activity, and functioning scores during the course of this study.

Meniscus Allograft Survival

KM product analysis (censored data) mean time-to-failure was 52.3 months, or 4.4 years (standard deviation, 1.83). Using KM censoring (uncensored data) mean time-to-failure is 25.3 months, or 2.12 years (standard deviation, 19.3). The shortest time-to-failure was 6.9 months, and the longest was 56.7 months. Figure 3 presents survival probabilities from 1 to 5 years. Because the failure probabilities were derived with only 5 patients, the results represent exploratory trends.

Subjective Pain, Activity, and Functioning

In conjunction with meniscus survival, we recognize that pain, activity, functioning, and satisfaction are important in assessing the absolute success or failure of any surgical procedure. Pain improved preoperatively to postoperatively (average, 5.8 years; range, 2 to 7.25 years) from 3.02 ± 0.99 to 4.06 ± 0.86. Activity refers to sports-like activities where the most strenuous activities are basketball or soccer and the least strenuous is recreational walking, and increased from 2.16 ± 0.90 preoperatively to 2.65 ± 0.92 postoperatively. Functioning refers to daily activities such as heavy or light work, ascending and descending stairs, and getting in and out of a car, and increased from 2.37 ± 0.82 preoperatively to 3.34 ± 0.81 postoperatively. Subjective score improvement is summarized in Table 3. There was a statistically significant mean improvement from preoperative to postoperative IKDC, WOMAC, and Tegner based self-reported pain, activity, and functioning, with corresponding values of $P = .001$, $P = .004$, and $P = .001$, respectively, as based on the nonparametric Wilcoxon rank-sum test. There was no significant difference between measures of pain ($P = .705$), activity ($P = .110$), or functioning ($P = .206$) in patients who had concomitant procedures, including osteotomy, and those who did not, suggesting that the meniscus allograft being the only common procedure played a primary role in subjective score improvement.

Effects of Multiple Procedures

Patients in this study had an average of 2.4 procedures at the time of allograft transplantation. No difference between the mean number of concomitant procedures of those who had failed allografts and those who did not have failed allografts could be shown (1.6 and 3.0, respectively, $P = .20$). Because the number of failed allografts was only 5, the nonsignificant result listed above is attributable to inadequate statistical power ($P = .24$).

Subgroup with Failed Allografts

There were 5 failures out of the 47 (10.6%), consisting of 3 men and 2 women with a mean age of 49.4 years (range, 35 to 55 years). Four of the 5 failures (80%) were in the medial compartment. No failures were observed in OB III patients. If only OB IV compartments are considered, 5 of 38 patients are considered failures (13.2%). All of the failures had unremitting pain in the affected compartment that led to examination, radiography, MRI, and either removal of the graft or joint arthroplasty. The average time from initial injury to the time of surgery was nearly 11 years (131.8 months). Mean follow-up time corre-

TABLE 3. *Descriptive Statistics for Self-Reported Pain, Activity, and Functioning: Preoperative and Postoperative*

Variable	Preop Score*	Postop Score*	*P* value	Improvement
Pain				
Mean	3.02	4.06	.001	20.8%
SD	0.99	0.86		
Activity				
Mean	2.16	2.65	.004	9.8%
SD	0.90	0.92		
Functioning				
Mean	2.37	3.34	.001	19.4%
SD	0.82	0.81		

*Pain, activity, and functioning scores are reported on a scale of 1 to 5, where 1 = a high degree of pain and difficulty, and 5 = the least degree of pain and difficulty.

sponding to mean of failure time unadjusted for censoring was 5.8 years (range, 0.3 to 7.25 years). Patients had an average of 2.1 surgeries (range, 0 to 7) in the affected knee before the allograft transplantation and a distribution of 2.6 (range, 1 to 5).

In this series, 29 allografts were cryopreserved (62%) and 18 were fresh-frozen allograft material (38%). Four of the 5 failures (80%) were of cryopreserved allograft material. A statistically significant failure rate based on allograft material could not be observed because of the low number of failures and larger number of cryopreserved versus fresh-frozen allografts.

The best predictor of failure based on a stepwise discriminant analysis was the number of past surgeries to the affected knee ($P = .012$). Neither the number nor type of concomitant procedures had a predictive association with the success or failure of the allograft ($P > .05$).

Ten of 47 knees (21.3%) developed torn meniscus allografts and were taken back to surgery for repair. Three tears occurred in the medial compartment allograft and 7 in the lateral. The repairs were successful and, therefore, were not considered failures, with both failure rates and tear rates comparable with those of other studies (Table 4). Eight of 10 (80%) underwent a partial meniscectomy, and the remaining 2 meniscal tears (20%) were repaired using Ethibond and PDS sutures (Johnson & Johnson, Piscataway, NJ).

Three patients (6.7%) had complications following allograft transplantation, including phlebitis, pulmonary embolus, and severe pain requiring removal of the allograft. The patient with phlebitis was treated as an outpatient with antibiotics and had resolution of his symptoms. The patient with pulmonary embolus, as confirmed by ventilation-perfusion (V-Q) scan, was treated as an inpatient with anticoagulants with full resolution. The patient with severe pain was atypical in that all assessments of his knee indicated that the allograft was in position and functioning well, but the patient wanted the allograft removed regardless.

DISCUSSION

This study is the second largest among reported meniscus allograft clinical outcomes studies (Table 4). The mean age of the patients in this series was 48 years, with 13 (29%) patients 55 years or older and 5 (11%) patients over the age of 60, which is considerably older than in the other studies. No patient was lost to follow-up. Only 5 failures have occurred in this

TABLE 4. *Description of Related Studies*

Study	Patients (allografts)	Mean F/U (range)	Mean Age (range)	Allograft Material	Arthrosis Grade (n)	Failures (%)	Failure Criteria
Less than severe arthrosis (OB 0-III)							
Milachowski[13] (1989)	22 (22)	1.1 (0.33–2.5)	29.6 (21–45)	Deep-frozen (6) Lyophilized w/ γ-irradiation (16)	I (2) II (10) III (1) Normal (8) Unaccounted (1)	9.1	Undefined: self-assessment
Rath[3] (2001)	18 (22)	4.5 (2.0–8.1)	30 (19–41)	Deep frozen & cryopreserved w/ bone plugs	Severe arthrosis excluded.	9.1	Allograft removal
Noyes[2] (2003)	34 (35)	3.1 (1.9–5.8)	28 (14–46)	Cryopreserved	II III	8.6	Allograft removal
Total mean failure						8.9% (7/79)	
Includes arthrosis (OB IV)							
van Arkel[9] (1995)	23 (25)	3 (2–5)	41 (30–55)	Cryopreserved	II (1) III (23) IV (1)	12	Allograft removal
Potter[18] (1996)	24 (29)	1.1 (0.25–3.4)	33.2 (24–43)	Fresh-frozen *not* γ-irradiated	I-II (2) III-IV (22)	3.4	Allograft removal
Cameron[16] (1997)	63 (67)	2.6 (1.0–5.5)	41 (11pts >50)	Fresh-frozen γ-irradiated	II III IV	4.5	Allograft removal
Stollsteimer[4] (2000)	22 (23)	3.3 (1.1–5.8)	31 (20–42)	Cryopreserved w/ bone plugs	I II III IV	4.3	Postop infection & OB score
Current study (2005)	45 (47)	4.5 (2–7)	48 (14–69)	Cryopreserved & fresh-frozen	III (9) IV (38)	10.6	Allograft removal
Total mean failure						6.8% (13/191)	

2- to 7-year follow-up study of meniscus transplantation in arthritic knees.

Comparable Studies

Thirty-seven meniscus allograft studies are reported in the literature. Only 7 report allograft material, arthrosis grade and failure mechanisms (Table 4). Most published studies that excluded patients with severe arthrosis are more recent, with two thirds of them published after the year 2000, reflecting a change in criteria for meniscus allograft surgery. Studies that included patients with severe arthrosis were generally reported earlier; three fourths were published in the 1990s. There is an unexpected inversion of the failure rates; 7 of 79 patients (8.9%) had allografts removed in the composite group excluding those with severe arthrosis, whereas only 8 of 144 patients (5.5%) in the composite group including patients with severe arthrosis had allograft failures. The mean patient age in studies excluding patients with severe arthrosis is approximately 30 years compared with a significantly older average age of 40 for the group including severe arthrosis. Failure is defined as removal of the allograft in 5 of 7 studies.

Postoperative Tears

One common finding in many studies was postoperative tearing or fragmentation of the allograft, with an incidence rate ranging from 9% to 36%.[3,16] Our finding of 21% with postoperative tears is consistent with other studies despite the increased severity of arthrosis and, on average, older patients.

Postoperative Complications

We report 4 complications (8.5%), a rate comparable to other studies (range, 8.5% to 45.4%; average, 17.7%).[4] The wide range of rates likely has more to do with how complications are defined rather than poor surgical results. The rates of infection were less than 2%; pulmonary embolus, stroke, and death are reported but are very rare in these studies.

Survival Rates

The total mean time to failure for this study is 2.1 years (range, 0.6 to 4.7 years). The time to failure by compartment is 4.7 years for the only failure in the lateral allograft group, 1.5 years (range, 0.6 to 2.5 years) for the medial, and undefined for both compartments with zero failures. The arithmetic mean total survival time is 3.5 years (range, 0.3 to 5.6 years). The KM determined survival rate is 82% (confidence interval, 92.0-58.4) at 5 years. The life-table determined survival rate is 84% (confidence interval, 66-93) at 5 years for the medial allograft, and 100% at 3.8 years for both compartments.

van Arkel and de Boer[17] reported results of a study of survival analysis of meniscus allograft transplantation by compartment. This makes direct comparison difficult because survival statistics are dependent on the longest observation for a given subgroup. With only 12 failures in the van Arkel study, and only 5 failures in ours, the survival estimates may well be driven by the problem of small numbers for analysis.[17] Larger studies for longer periods will better resolve these issues; nevertheless, it is encouraging that we had only 5 failures, and we will continue monitoring these patients.

Literature Review

Reports of studies excluding patients with severe degenerative osteochondral changes and those with OB IV osteochondral lesions included those by Milachowski et al., [13] Rath et al.,[3] and Noyes and Barber-Westin.[2] Milachowski et al. studied 22 patients, all of whom had anterior cruciate ligament reconstruction at the time of meniscal allograft surgery. No OB IV patients were included, with only 1 of 22 presenting with OB III defects (4.5%). Failure was not specifically defined in the study; however, 2 allografts (9.1%) were found to have become so small as to be nonexistent on follow-up and were considered failures by our criteria. Rath et al.[3] used an arthroscopic procedure. Grade IV patients and those with greater than 3 mm of compartment narrowing on preoperative posteroanterior weight-bearing flexion radiograph were excluded. Two of 22 underwent total meniscectomy (9.1%), and were considered failures. Noyes and Barber-Westin[2] reported results of a series of 34 patients with 35 allografts, and included patients with only OB II or III osteochondral fragmentation. Three allografts (8.6%) were removed and considered failures.

Studies including patients with severe OB III and IV degenerative osteochondral changes are reported in articles by Cameron et al.,[16] Potter et al.,[18] Stollsteimer et al.,[4] and van Arkel and de Boer.[9] Stollsteimer et al.[4] presented a series of 23 allografts in 22 patients transplanted arthroscopically using cryopreserved allograft material with bone plugs. All OB classes were included, but a distribution is not reported. One patient's allograft (4.3%) was removed because of a postoperative infection and is considered a failure. van

Arkel and de Boer[9] reported 25 arthritic allografts transplantations in 23 patients. Concomitant procedures at the time of transplantation were not discussed. Twenty-three of 25 (92%) lesions were classified as OB III, with 1 OB II, and 1 OB IV. Three (12%) of the allografts were removed and were considered failures. Potter et al.[18] followed-up on 29 allografts in 24 patients inserted arthroscopically in 20 of the 24 patients.[18] An open procedure was used in 4 of the 24 patients who received both medial and lateral allografts placed in the same knee. Nonirradiated fresh-frozen allograft material was used in all patients. This study had a rather short follow-up period (mean, 1.1 years; range, 0.25 to 3.4 years), but they reported only 1 failure defined as removal (3.4%). Cameron and Saha[16] reported on one of the largest clinical follow-up studies reported to date that met our selection criteria, with a total of 67 allografts in 63 patients.[16] Eleven of 63 patients (17.5%) were over the age of 50 years and all had OB II, III, or IV degenerative changes (distribution was not specified). Three allografts (4.5%) were removed and were considered failures.

van Arkel and de Boer[17] published the first KM survival analysis of allograft transplantations. They followed-up 57 patients with 63 allografts for an average of 5 years (range, 0.33 to 10.5 years) between 1989 and 1999. They reported 13 of 63 failed allografts, defined as persistent pain or mechanical damage of the transplant. The mean age of patients in this study was 39 years (range, 26 to 55 years). The cryopreserved allografts were placed using an open procedure. The overall arithmetic survival rate (uncensored data) was over 11 years for 44 of 57 patients (77.2%). Survival rates calculated using the KM method (censored data) were not reported for the overall group, but were broken down by compartment of allograft placement. Lateral allografts were reported to have an average survival rate of 88% (range, 82% to 92%) at year 10 of follow-up, medial 63% at year 9 (range, 55% to 83%), and both in the same compartment of 67% at year 8 (58-94). Mean survival times were 9.1 years for lateral allografts, 5.8 years for medial, and 7.4 years for both medial and lateral.

CONCLUSIONS

Our study confirms that meniscus allograft can survive for 2 to 7 years in the presence of chondromalacia in the same compartment. Whether it functions as a normal meniscus or simply as an interpositional soft-tissue arthroplasty was not addressed by this study. The improvements noted in pain, activity, and functioning may be attributed to the transplant, the concomitant procedures, the rehabilitation program, or the attentive care of the medical team. The goal of the study was to determine if the graft could survive. A controlled study with and without the implant will help clarify the implant's contribution.

Compared with other outcome studies, patients in this study had successful meniscus allografts in spite of being older and having well-documented severe degenerative disease, both of which were previously believed to be contraindication for meniscal allograft transplantation. These results show that meniscal allograft transplantation can be used in higher-risk patients with reasonable expectations of allograft survival. This study reveals that the previous contraindications of age and severity of arthrosis are overstated, and that these results are comparable to those of other studies whose patients were younger and without arthrosis.

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