

Effects of Compliance With Procedure-Specific Postoperative Rehabilitation Protocols on Initial Outcomes After Osteochondral and Meniscal Allograft Transplantation in the Knee

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Background: Osteochondral and meniscal allograft transplantation have been performed in the knee for more than 40 years, with the number of patients treated each year growing as allograft quantity and quality increase. To date, the effects of postoperative management on outcomes after these procedures have received relatively little focus in the peer-reviewed literature.

Hypothesis: Compliance with the recommended postoperative management protocol will be associated with significantly higher initial success and significantly lower revision and failure rates for patients undergoing osteochondral and/or meniscal allograft transplantation in the knee.

Study Design: Cohort study; Level of evidence, 3.

Methods: Patients were prospectively enrolled into a dedicated registry designed to follow outcomes after osteochondral and/or meniscal allograft transplantation. Patients were included when at least 1 year of follow-up data were available, including data on complications and reoperations, patient-reported outcome measures, compliance with rehabilitation, revisions, or failures, based on the electronic medical record and communication logs with patients' outpatient physical therapists.

Results: For patients meeting the inclusion criteria (N = 162), compliance with the prescribed procedure-specific postoperative management protocol was associated with significantly higher 1- to 3-year success and significantly lower revision and failure rates. Specifically, patients who were compliant were 6.3 times less likely to need allograft revision or total knee arthroplasty and 7.5 times more likely to have a successful outcome at 1 to 3 years after osteochondral and/or meniscal allograft transplantation. In addition to noncompliance, older patient age and higher body mass index were associated with inferior short-term outcomes in this cohort.

Conclusion: These data suggest that compliance with procedure-specific postoperative rehabilitation protocols is associated with higher success, lower revision, and lower failure rates for patients undergoing osteochondral and meniscal allograft transplantation. Given these results showing the importance of these modifiable risk factors, our center has devoted resources to preoperative patient assessment and communication to provide education, set appropriate expectations, identify and address modifiable risk factors, impediments, and noncompliance, and monitor and adjust postoperative care as indicated.

Keywords: osteochondral allograft; meniscal transplant; compliance; postoperative rehabilitation; bipolar allografts

Osteochondral and meniscal allograft transplantation surgery has been performed in the knee for more than 40 years,^{6,8,15,23} with the number of patients treated each year growing as allograft quantity and quality increase.³ To date, the effects of postoperative management on outcomes

after such surgery have received relatively little focus in the peer-reviewed literature. For distal femoral osteochondral allograft (OCA) transplantation, Kane et al¹³ reported that 52% of physicians recommended nonweightbearing immediately after surgery, with movement to full weightbearing between 6 and 12 weeks after surgery. Less than half (45%) of physicians recommended the immediate postoperative use of continuous passive motion machines. Only 5% of the physicians allowed weightbearing as tolerated

The Orthopaedic Journal of Sports Medicine, 7(11), 2325967119884291
DOI: 10.1177/2325967119884291
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immediately after surgery, and interestingly, these physicians tended to be the most experienced. The majority (55%) of physicians surveyed allowed “unrestricted” activity at 26 weeks after surgery, with another 27% allowing unrestricted activity much earlier—at 16 weeks postoperatively. Importantly, this survey targeted only distal femoral OCA transplant surgery, without delineating exact graft location, number of grafts, or implantation technique.

Stone and Schaal²⁸ suggest that type of surgery and location of the defect must be considered, and they recommended weightbearing as tolerated immediately after OCA transplantation in the trochlea but suggested waiting at least 6 weeks to progress to weightbearing for femoral condyle OCA transplants. These authors also recommended that soft tissue adhesions, hip and quadriceps strengthening, and knee range of motion be considered during recovery, and that patients should not return to vigorous walking or biking until at least 12 weeks, with no jogging until at least 6 months after surgery.

More peer-reviewed information is available regarding rehabilitation after meniscal allograft transplantation than after OCA transplantation.^{10,33} When bone plugs or blocks are used for fixation, most physicians allow weightbearing as tolerated or partial weightbearing immediately after surgery, with full weightbearing initiated between 4 and 6 weeks after meniscal allograft transplantation. Closed chain exercises are then instituted between 4 and 9 weeks after surgery, strengthening activities at 4 months, and return to full activities after 6 months. However, some surgeons have suggested that meniscal allograft transplantation recipients avoid high-impact activities for the rest of their lives.⁸ Despite these relatively consistent management recommendations, studies comparing meniscal allograft transplantation outcomes based on protocol differences and/or patient compliance were not found in the current peer-reviewed literature.

Importantly, to our knowledge, there are no peer-reviewed studies that assess the effects of postoperative rehabilitation protocols and/or compliance on outcomes for patients undergoing bipolar osteochondral and/or meniscal allograft transplantation surgery. This patient cohort is of great importance for assessing the effects of postoperative management based on the historically inferior outcomes reported for these complex cases.^{7,17} While some major risk factors for poor outcomes in this cohort have been examined—including age, tobacco use, body mass index

(BMI), chondrocyte viability at time of transplantation, allograft bone pretreatment, and surgical techniques—postoperative management recommendations and patient compliance have been largely overlooked.^{3,18,31}

Given these critical gaps in the literature, in conjunction with the growing use of osteochondral and meniscal allografts for treatment of symptomatic articular pathology in the knee, our institution developed and implemented procedure-specific postoperative rehabilitation management protocols for patients undergoing allograft transplantation. The objective of the present study was to assess the effects of these rehabilitation protocols and patient compliance with the prescribed protocol on outcomes for patients undergoing osteochondral and/or meniscal allograft transplantation. We hypothesized that compliance with the recommended postoperative management protocol would be associated with significantly higher initial success and significantly lower revision and failure rates for patients undergoing osteochondral and/or meniscal allograft transplantation in the knee.

METHODS

With institutional review board approval and documented informed consent, patients were prospectively enrolled into a dedicated registry designed to follow outcomes after OCA and meniscal allograft transplantation surgery. Data were collected preoperatively and at 3 months, 6 months, and yearly after surgery. Demographic and operative data were collected from the electronic medical records. Visual analog scale pain scores and patient-reported outcomes were collected and entered into the registry database at each time point (data not provided in the present study). All reported complications and reoperations were recorded in the electronic medical record. Revision was defined as a second operation to revise the osteochondral and/or meniscal allograft in at least 1 part of the patient’s knee, and failure was defined as conversion to total or unicompartmental knee arthroplasty (TKA or UKA). The decision to pursue revision surgery, TKA, or UKA was based on the attending surgeon’s discussion of joint pathology, treatment options, and related prognosis in conjunction with patient preference. Successful outcomes were defined as patients reporting return to activities of daily living and intended work and meeting minimum clinically important improvements for International Knee Documentation Committee and Single

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One or more of the authors has declared the following potential conflict of interest or source of funding: The Musculoskeletal Transplant Foundation has licensing related to Missouri Osteochondral Preservation System technology. J.L.C. receives royalties and grants from and is on the medical board of trustees for the Musculoskeletal Transplant Foundation and has received research support from the Coulter Foundation, US Department of Defense, National Institutes of Health, Arthrex, ConforMIS, DePuy Synthes, Eli Lilly, Merial, the Musculoskeletal Transplant Foundation, and Zimmer-Biomet; consulting fees from Arton, Arthrex, Eli Lilly, and Schwartz Biomedical; royalties from Arthrex; and speaking fees from Arthrex. J.P.S. has received research support from Smith & Nephew and Arthrex; consulting fees from Acelity, DePuy Synthes, Arthrex, Orthopedic Designs North America, Smith & Nephew, and Nuvasive Specialized Orthopedics; speaking fees from Arthrex and Synthes; publishing royalties from Thieme; and hospitality payments from Organogenesis. AOSSM checks author disclosures against the Open Payments Database (OPD). AOSSM has not conducted an independent investigation on the OPD and disclaims any liability or responsibility relating thereto.

Ethical approval for this study was obtained from the University of Missouri–Columbia Institutional Review Board (No. 2003053 HS).

Assessment Numerical Evaluation scores, as well as Patient-Reported Outcomes Measurement Information System scores within the range for the healthy adult population, with no need for conversion to TKA or UKA at last recorded follow-up.

Based on preclinical and clinical evidence^{1,3,4,19,21,24-27,29} as well as our training and experience, procedure-specific postoperative management protocols were developed for the first full year after surgery for each major variation of osteochondral and/or meniscal allograft transplantation surgery in the knee performed at our institution (Appendices 1-5, available as supplemental material). Once these protocols were implemented, they were prescribed to each patient undergoing allograft transplantation in the knee. All patients received verbal and written instructions regarding postoperative rehabilitation, as outlined in the Appendices, available as supplemental material. These instructions were also directly communicated to the outpatient physical therapist identified by the patient to be involved in his or her postoperative care.

Dedicated physical therapists at our center attended all pre- and postoperative outpatient physician visits, provided all inpatient therapy, and either provided outpatient physical therapy or personally communicated with each patient's outpatient physical therapist throughout the rehabilitation process.

Patient compliance with the prescribed protocol was monitored and documented throughout the postoperative period based on outpatient physical therapy reports and through patient communication regarding therapist-monitored and at-home activities. Patients were considered noncompliant if there was documented evidence from these communications or reports, as reviewed in detail by the center's physical therapists, of definitive breaks in the prescribed protocol (see Appendices 1-5, available as supplemental material) during the first year after surgery, such as intentionally initiating activities before the allowed time frame, intentionally performing disallowed activities, and/or completely discontinuing recommended physical therapy.

Data were included for statistical analyses when applicable registry data were available for at least 1 year following surgery, and compliance status was documented for at least 1 year following surgery. Descriptive statistics were calculated to report means, ranges, and percentages. Chi-square or Fisher exact tests were used to assess significant differences in proportions. When significant differences in proportions were noted, odds ratios were calculated. One-way analysis of variance tests were used to assess significant differences in variables with continuous data. Significance was set at $P < .05$.

RESULTS

For patients meeting inclusion criteria with at least 1 year of follow-up data (mean, 21 months; range, 12-37 months; $n = 162$), the mean age was 38.7 years, and the mean BMI was 28.9 (Table 1). Of the total, 88 patients (54.3%) were male. No patient was lost to follow-up for the outcome measures and time frame reported in this study. In this cohort,

TABLE 1
Mean Age, BMI, and Documented Noncompliance Percentage for Each Outcome Category Assessed^a

Category	Age, y	BMI	Noncompliance, %
All	38.7	28.9	19.8
Successful	37.6*	28.3 [‡]	11.3
Revision	36.8*	29.6	44.4 [¶]
Failure	44.8 [†]	31.2 [§]	40.7 [¶]

^aDifferent symbols per column denote statistically significant differences ($P < .05$). BMI, body mass index.

105 patients (64.8%) received bipolar transplants, with 73 of those involving >2 articular surfaces. Bipolar grafts were defined as those involving 2 apposing articulating surfaces, including patellofemoral, femorotibial, and/or femoromeniscal. Meniscal allograft transplants were performed via a bone plug technique with suspensory fixation or included as part of the tibial OCA transplant (Table 2). All grafts were obtained from tissue banks accredited by the American Association of Tissue Banks, with 41 (25.3%) being stored in refrigeration in proprietary solutions for ≤ 21 days after recovery and 121 (74.7%) being stored at room temperature with Missouri Osteochondral Preservation System (MOPS) methods for <57 days after recovery. Sixty-five patients (40.1%) underwent concurrent or staged procedures to address comorbidities in the same knee, including anterior cruciate ligament (ACL) reconstruction ($n = 18$), tibial tuberosity osteotomy ($n = 9$), high tibial osteotomy ($n = 30$), and distal femoral osteotomy ($n = 10$). None of these procedures were noted to be significantly associated with differences in compliance or outcomes in the present study.

Successful outcomes without need for revision were documented in 115 (71.0%) patients, all of whom reported return to functional activities and a visual analog scale pain score ≤ 2 at least 1 year after surgery. Revisions of the osteochondral and/or meniscal allografts were performed in 18 patients (11.1%). Ten revisions were performed for refrigerated grafts (24.4%), while 8 revisions were performed for MOPS grafts (6.6%), which was a significantly lower proportion of patients ($P = .004$). For revised cases, 5 patients eventually went on to undergo TKA for failure, making the overall success rate 83.3% at final follow-up. Documented failures occurred in 27 patients (16.7%), with all undergoing TKA to treat the failed grafts. For refrigerated grafts, 9 failures (22.0%) were documented. For MOPS grafts, 18 failures (14.9%) were documented, which included 5 revision cases such that the failure rate for primary (nonrevision) MOPS grafts was 10.7%. Failures were determined at a mean 13.4 months (range, 3-29 months) after transplantation, with 11% occurring before 6 months and 48.1% occurring between 6 and 12 months after surgery. Failure mechanisms included meniscal tear and/or extrusion (40.7%); allograft bone necrosis and/or collapse (18.5%); cartilage erosion or delamination (18.5%); damage to new, nontransplanted areas in the knee (18.5%); or unknown (3.8%). Patients requiring TKA were significantly older ($P = .016$) than patients requiring allograft revisions and

TABLE 2
Breakdown of Unipolar and Bipolar Surfaces Transplanted and Their Corresponding Failure Mechanisms^a

Surgery Type	Procedure, n	Revision, n	Failure (TKA), n	Failure Mechanism
Unipolar (n = 57)				
Femoral condyle	14	0	1	Damage to new, nontransplanted areas in the knee
Patella	9	0	0	—
Meniscus (bone plugs)	15	3	0	—
Meniscus on tibial plateau	1	0	1	Meniscal tear and/or extrusion
Multiple surfaces	18	1	2	Damage to new, nontransplanted areas in the knee; cartilage erosion or delamination
Bipolar (n = 105)				
Femoromeniscotibial	24	4	4	Meniscal tear and/or extrusion; allograft bone necrosis and/or collapse; cartilage erosion or delamination
Femoromeniscal	3	0	1	Damage to new, nontransplanted areas in the knee
Patellofemoral	5	0	0	—
Multiple	73	10	18	Meniscal tear and/or extrusion; allograft bone necrosis and/or collapse; cartilage erosion or delamination; damage to new, nontransplanted areas in the knee; unknown

^aTKA, total knee arthroplasty.

than successful cases. Patients requiring TKA also had significantly higher BMI ($P = .033$) than successful cases (Table 1).

Overall, 80.2% of patients included in the present study were compliant per the study criteria. For the patients requiring allograft revisions, 8 (44.4%) were documented to be noncompliant during the initial postoperative period. For patients requiring TKA, 11 (40.7%) were noncompliant. In contrast, 13 patients (11.3%) with successful outcomes were noncompliant during the postoperative period, making noncompliance to be significantly ($P = .002$) and 6.3 times more likely associated with need for allograft revision and significantly ($P = .0002$) and 6.3 times more likely to be associated with failure in patients undergoing osteochondral and/or meniscal allograft transplantation. Taken together, compliance with prescribed procedure-specific rehabilitation management protocols for the first full year postoperatively was significantly ($P < .0001$) and 7.5 times more likely to be associated with a successful outcome at 1 to 3 years after OCA and/or meniscal allograft transplantation for patients in this study.

DISCUSSION

To our knowledge, this is the first study to document the association between compliance with prescribed procedure-specific postoperative rehabilitation management protocols and patient outcomes after osteochondral and/or meniscal allograft transplantation. The results of the present study allow us to accept our hypothesis in that compliance with the recommended postoperative management protocol was associated with significantly higher 1- to 3-year success and significantly lower revision and failure rates for patients. Specifically, patients who complied with prescribed procedure-specific postoperative rehabilitation management protocols for the first full year postoperatively were 6.3 times less likely to need allograft revision or total knee

arthroplasty and were 7.5 times more likely to have a successful outcome at 1 to 3 years after osteochondral and/or meniscal allograft transplantation.

In subjectively assessing the associations between non-compliance and complications, patients' electronic medical record data revealed that 55.6% of patients who were non-compliant and went on to revision or failure reported visual analog scale pain scores ≤ 2 of 10 before reporting complications. When asked to justify their noncompliance, patients routinely reported that they performed activities outside the prescribed protocol because their operated knee "felt great" and the activities that they were performing did not feel painful at the time. Interestingly, 72.7% of failures in patients who were noncompliant occurred between 6 and 12 months postoperatively, when pain scores are typically markedly improving; in addition, recorded failure mechanisms in the noncompliant cohort involved tibial allograft bone necrosis/collapse and/or meniscal tear/extrusion (54.6%), cartilage erosion or delamination (27.3%), new damage to nontransplanted areas (9%), or unknown (9%). The majority of patients who were noncompliant and experienced complications reported rapidly increasing pain after noncompliant activities or accidents. For the present cohort, none of the patients who were noncompliant reported a lack of understanding of the activities allowed based on the prescribed protocol.

While few published studies discuss compliance with postoperative rehabilitation protocols and none have critically assessed the effects of patient compliance on outcomes after allograft transplantation in the knee, other areas in orthopaedic surgery (particularly ACL reconstruction) document the strong association between compliance with postoperative rehabilitation protocols and outcomes. Patients who undergo ACL reconstruction and comply with prescribed postoperative rehabilitation regimens are more likely to have higher function and return to sport than patients who are noncompliant.¹² In addition, patients who

do not meet defined strength and agility criteria during the rehabilitation period and do not wait at least 6 months after ACL reconstruction before returning to sport are at significantly higher risk for ACL graft failure.¹⁴ Based on the results of the present study, patient compliance is equally important after osteochondral and/or meniscal allograft transplantation. "Return to activity" and "minimum time after surgery" criteria may also be important to implement before patients who undergo allograft transplant return to activity.

In addition to compliance with postoperative rehabilitation protocols, patient age was associated with inferior outcomes in the present study. While patient age and BMI should be considered for use of osteochondral and/or meniscal allograft transplantation, neither previous studies nor the present study provides evidence for either as a strict contraindication for these procedures.^{7,18,23,32} Instead, a comprehensive approach to patient assessment and education regarding treatment options is recommended. This is especially important based on outcomes associated with other treatment options available to this cohort of patients.^{2,9,16,30}

It is clear that pre-, intra-, and postoperative management strategies are vital to continuing to improve outcomes after osteochondral and/or meniscal allograft transplantation surgery. After a shift in practice based on the validation and availability of MOPS grafts,^{3,4,25-27} pre-implantation treatment of OCA bone with autogenous bone marrow aspirate concentrate,^{1,19,24} and modifications to OCA cutting and fixation techniques,^{19,20} primary allograft transplantations performed at our center were associated with a 1- to 3-year combined revision and failure rate of 13.2% based on the data from the present study. In addition, revision allograft transplantation cases, which were all performed with these same graft preservation and implantation protocols, were associated with a 72% success rate. In conjunction with these shifts in operative practice, the results of the present study suggest that if patient compliance with prescribed procedure-specific postoperative rehabilitation management protocols could be ensured in all cases, combined short-term revision and failure rates for primary allograft transplants could drop to as low as 6%.

With this goal in mind, our center has enhanced our pre- and postoperative patient assessment, education, communication, and monitoring protocols carried out by a single team of health care professionals dedicated to the comprehensive treatment of these patients. Physical therapists attend all pre- and postoperative outpatient physician visits and provide all inpatient therapy. In addition, they either (1) provide outpatient physical therapy or (2) personally communicate with each patient's outpatient physical therapist to provide education, set appropriate expectations, monitor progress, and identify and address complications, impediments, and noncompliance. Finally, they communicate relevant details with the attending physician throughout the rehabilitation process. Led by a health behavior psychologist, the team also identifies patients at risk for noncompliance based on documented patient-related factors (eg, attitudes, motivation, sex, and understanding), socioeconomic barriers (eg, literacy, education

level, support system, employment, and insurance status), and condition- and treatment-related factors (eg, BMI, pain, coexistent conditions, length of postoperative rehabilitation, and lack of early symptom relief).²² The team works to overcome barriers to compliance before starting the process of insurance precertification and graft requests, and patients are asked to sign a "rehabilitation partnership contract" (Appendix 6, available as supplemental material) that documents their understanding of the prescribed protocol and timeline and their commitment to fully complying with it. In addition, postoperative rehabilitation protocols and patient management strategies are adjusted (eg, step count limits, educational videos, vitamin D supplementation, bone stimulators) on the basis of best current evidence from the peer-reviewed literature and the continuous real-time analysis of our registry data.

Limitations to the present study include the relatively short follow-up period, the reliance on patients and outpatient physical therapist to report compliance status in a timely and truthful manner, and the numerous patient, operative, and environmental factors that cannot be accounted for in analyzing the data. In addition, the results of the present study can be applied only with respect to compliance with the specific protocols prescribed by our institution, which may differ from those prescribed by other institutions. While longer-term follow-up is necessary before conclusions regarding true success and cost-effectiveness can be made, revision and failure data are highly relevant and applicable on the basis of consistent timing of complications after osteochondral and meniscal allograft transplantation surgery reported in the present study and the previous literature.^{5,7,11,18} While it is likely that compliance status data for the present study are not complete or fully accurate, incompleteness and inaccuracies are most likely related to lack of identifying or reporting noncompliance such that the data presented and the conclusions made are overconservative in nature. However, there may also be a relative bias in searching out and/or reporting noncompliance for unsuccessful cases. In addition, differences in insurance coverage for supervised physical therapy and a myriad of factors that may influence outcomes for patients undergoing osteochondral and meniscal allograft transplantation surgery can never be completely accounted for, and there may be confounding and/or dependent factors that multivariate analysis may help further elucidate in moving this work forward. Still, major risk factors that have the potential to be controlled for and/or mitigated in optimizing patient care were included in the initial analysis of the registry data. Given these results showing the importance of these modifiable risk factors, our center has devoted resources to preoperative patient assessment and communication to provide education, set appropriate expectations, and identify and address modifiable risk factors, impediments, and noncompliance and then to monitor and adjust postoperative care as indicated. Ongoing research at our center is focused on further determining and reporting the key components for optimal pre-, intra-, and postoperative treatment of patients undergoing osteochondral and/or meniscal

allograft transplantations that are associated with continued improvement in long-term outcomes.

CONCLUSION

Data from the present study suggest that compliance with prescribed procedure-specific postoperative management protocols was associated with significantly higher 1- to 3-year success and significantly lower revision and failure rates for patients. Specifically, patients who were compliant were 6.3 times less likely to need allograft revision or total knee arthroplasty and were 7.5 times more likely to have a successful outcome at 1 to 3 years after osteochondral and/or meniscal allograft transplantation. In addition to noncompliance, patient age and BMI were associated with inferior short-term outcomes in this cohort of patients.

SUPPLEMENTAL MATERIAL

Appendices 1-6 for this article are available at <http://journals.sagepub.com/doi/suppl/10.1177/232596711984291>

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