Original Research

Prospective Assessment of Outcomes After Femoral Condyle Osteochondral Allograft Transplantation With Concurrent Meniscus Allograft Transplantation

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Background: Osteochondral allograft transplantation (OCAT) and meniscus allograft transplantation (MAT) have each become more commonly implemented for the treatment of young to middle-aged patients with complex knee pathology. Evidence regarding tibiofemoral OCAT in the setting of concurrent MAT is limited.

Purpose/Hypothesis: The purpose of this study was to characterize outcomes for femoral condyle OCAT with concurrent MAT (OCAT + MAT) in the ipsilateral compartment of patients after evidence-based shifts in practice. It was hypothesized that OCAT + MAT would be associated with successful outcomes characterized by statistically significant and clinically meaningful improvements in patient-reported outcome measures (PROMs) of knee pain and function in >80% of patients for at least 2 years after transplantation.

Study Design: Case series; Level of evidence, 4.

Methods: With institutional review board approval and documented informed consent, patients who underwent primary OCAT + MAT between 2016 and 2020 and enrolled in a lifelong registry for prospective collection of outcomes after OCAT were included. Patients with minimum 2-year follow-up data regarding complications, failures, adherence, and PROMs were analyzed. Patients who required OCAT and/or MAT revision or conversion to arthroplasty were defined as experiencing treatment failures.

Results: A total of 23 consecutive patients (mean age, 37.1 years; mean body mass index, 28 kg/m^2; 14 men) met the inclusion criteria, with a mean follow-up of 51 months (range, 24-86 months). The initial treatment success rate was 78% based on 5 initial treatment failures, and the overall success rate was 83% based on a successful revision OCAT. All failures occurred in the medial compartment. Older patient age (42.2 vs 32.1 years; P = .046) and nonadherence to postoperative restriction and rehabilitation protocols (P = .033; odds ratio, 14) were significant risk factors for treatment failure. All measured PROMs achieved significant improvements ($P < .001$) and minimum clinically important differences at a minimum of 2 years postoperatively.

Conclusion: OCAT + MAT was associated with successful short- to mid-term outcomes in 83% of cases. Evidence-based shifts in practice were implemented before the enrollment of this patient cohort. Older patients and those who were not adherent to postoperative restriction and rehabilitation protocols had a significantly higher risk for treatment failure and subsequent conversion to arthroplasty.

Keywords: arthroplasty; arthroscopy; joint preservation; knee, knee replacement; meniscus; meniscus allograft transplantation; osteochondral allograft

Osteochondral allograft (OCA) transplantation (OCAT) and meniscus allograft transplantation (MAT) have each become more commonly implemented for treating young to middle-aged patients with complex knee pathology.[7,8,11,12,16,24] Patients indicated for OCAT and/or MAT typically present with symptomatic articular cartilage lesions $\geq$2 cm^2 and/or meniscal deficiency, which have not sufficiently improved after previous nonsurgical and surgical treatments. While indications and outcomes for independent treatment of these articular cartilage or meniscus disorders are well established, evidence

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regarding tibiofemoral OCAT in the setting of concurrent MAT is limited.[3,15,32] The available evidence indicates that concomitant OCAT and MAT can be associated with early success (ie, no revision at 2 years) in 77% to 90% of patients.[7,8,11] As such, OCAT with MAT warrants further consideration as a bridging joint preservation technique to potentially restore knee function and delay arthroplasty in eligible patients.

Recent advances in allograft preservation methods, transplantation techniques, and patient management strategies have improved OCAT and MAT outcomes.[4,8,11,16,25,27,30,34] These advances suggest that more complex allograft transplant surgeries—including femoral condyle OCAT with concomitant MAT—may consistently achieve the goals for a bridging joint preservation strategy. Therefore, this study aimed to characterize outcomes for OCAT to the femoral condyle with concomitant MAT in the ipsilateral compartment of patients at our institution after evidence-based shifts in practice that include the use of high-chondrocyte-viability OCAs, preimplantation allograft bone irrigation and bone mineral content saturation, and double bone plug fixation and meniscotibial ligament reconstruction for fresh (viable) MAT; in addition, patient management strategies—including assessment, education, and support for adherence to prescribed postoperative restriction and rehabilitation protocols—were implemented.[7,8,24,25,34] The study was designed to test the hypothesis that femoral condyle OCAT with concurrent MAT would be associated with successful outcomes characterized by statistically significant and clinically meaningful improvements in patient-reported outcome measures (PROMs) of knee pain and function in >80% of patients for at least 2 years after transplantation.

METHODS

Patient Selection

Institutional review board approval (No. 265688) and documented informed consent from each patient were obtained before the initiation of this study. Patients who underwent primary femoral condyle OCAT and concomitant MAT (OCAT + MAT) to resurface large (>2 cm^2) grade 3 or 4 focal articular cartilage defects and treat symptomatic meniscus deficiency between 2016 and 2020 were enrolled in our institution's registry for prospective collection of outcomes. Patients chose OCAT + MAT over nonsurgical or surgical alternatives and were approved for coverage by their insurance providers. Before consenting to surgery and consenting and enrolling in the registry, each patient spent 45 to 60 minutes in preoperative consultation with the attending surgeon (J.P.S.) and joint preservation health care team to discuss risks, benefits, expectations, and limitations associated with the planned surgery and recovery.

All OCAs and meniscus allografts were obtained from 1 American Association of Tissue Banks–accredited source (MTF Biologics) and used in conformance with the United States Food and Drug Administration classification of a human cell and tissue product under section 361 of the Public Health Services Act after recovery from the tissue donor and preservation for up to 56 days using the Missouri Osteochondral Preservation System (MOPS). The following criteria were required preoperatively for surgery and subsequently inclusion in this consecutive patient series:

- Failed prior nonsurgical and/or surgical treatments for the primary problem
- Absence of tricompartmental osteoarthritis
- Absence of infectious, inflammatory, or immune-mediated arthritis
- Willingness and ability to adhere to postoperative restrictions and rehabilitation protocols
- Minimum 2-year follow-up data regarding complications, failures, adherence, and PROMs

The initial treatment success was defined as patients not requiring revision surgery. The final treatment success was defined as patients not requiring conversion to arthroplasty. PROMs—including the visual analog scale (VAS) for pain, the International Knee Documentation Committee (IKDC) subjective knee form, the Single Assessment Numeric Evaluation (SANE), and the Patient-Reported Outcomes Measurement Information System (PROMIS) Mobility and Physical Function—were collected at 3 months, 6 months, and then annually after transplantation.[1,2,5,14]

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Ethical approval for this study was obtained from the University of Missouri-Columbia (ref No. 2003053).

Surgical Technique

All surgical procedures were performed by 1 of 2 surgeons (J.P.S., C.W.N.) using a press-fit femoral cylindrical dowel or custom-cut patient-specific shell OCAs (~6-7 mm thick) and double bone plug MATs[3,30,32,34] (Figure 1). Subchondral drill holes were created, and the donor bone was thoroughly irrigated with 1 to 1.5 L of isotonic saline to remove donor marrow elements.[34] The allograft bone was saturated with autogenous bone marrow aspirate concentrate (Angel System; Arthrex) immediately before implantation.[23] Shell OCAs were stabilized with 2- or 2.4-mm cortical screws (Mini Fragment LCP System; DePuy Synthes), bioabsorbable pins (Trim-It Pins; Arthrex), or bioabsorbable nails (SmartNail; CONMED) at the margin of the shell allograft using a subchondral technique based on the discretion of the operating surgeon. All MATs were performed with fresh (viable) MOPS-preserved meniscus allografts using a double bone plug technique with cortical suspensory fixation and meniscotibial ligament reconstruction.[29,30,34]

If relevant comorbidities—such as additional focal cartilage defects, lower extremity malalignment, or ligament instability—were noted in preoperative assessments of the affected knee, they were addressed in either a staged fashion before or concurrently with the OCAT + MAT procedure. The following were performed as deemed necessary by the treating surgeon: additional OCAT, autograft or allograft ligament reconstruction, distal femoral osteotomy, high tibial osteotomy, and/or tibial tuberosity osteotomy.

Rehabilitation Protocol

Each patient received oral and written procedure-specific postoperative rehabilitation instructions.[10,27,34] In-patient physical therapy was completed with a dedicated rehabilitation coordinator who then communicated postoperative rehabilitation protocols and expectations to each patient's chosen outpatient physical therapist. Patient adherence to the postoperative rehabilitation protocol was monitored and documented through patient communication and outpatient physical therapy reports. Patients were categorized as nonadherent when definitive deviations from the prescribed protocol were documented to occur during the first year after surgery.[24] The dedicated rehabilitation coordinator independently classified patients as adherent or nonadherent based on the review of their medical records. Examples of nonadherence included not following weightbearing restrictions, returning to high-impact activities before being cleared by the attending physician, or not completing home exercises or attending outpatient physical therapy. Follow-up appointments were scheduled for 2 weeks, 6 weeks, 3 months, 6 months, 1 year, and then annually, with standardized radiographic imaging ordered for each appointment other than at 2 weeks after transplant surgery.

Statistical Analyses

Statistical analyses were performed using XLSTAT (Lumivero). Descriptive statistics were calculated to report means, ranges, and percentages. Fisher exact test was used to compare proportions. As data were determined to follow a normal distribution, unpaired t test was used to compare variables based on treatment success versus failure, and repeated-measures analysis of variance was used to compare longitudinal PROMs data. Significance was set at .05. Odds ratios (ORs) were calculated when significant proportion differences were noted. The mean clinically important differences were derived from reported values in the relevant peer-reviewed literature.[17,21,22,35,36,38]

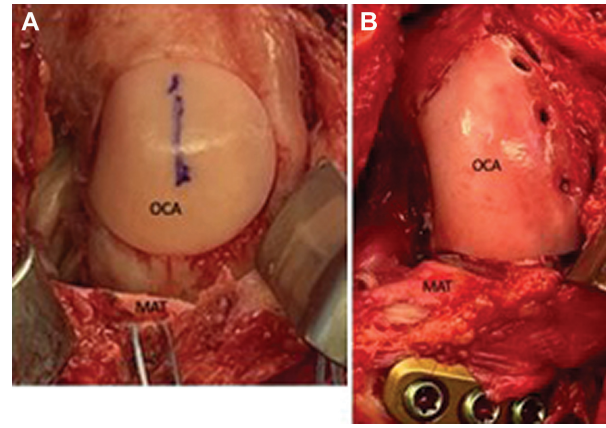

Figure 1. (A) An intraoperative image of a press-fit medial femoral condyle cylindrical dowel fresh OCA and double bone plug fresh medial MAT for the treatment of combined full-thickness articular cartilage defect and meniscus deficiency; (B) an intraoperative image of a custom-cut medial femoral condyle shell fresh OCA stabilized with bioabsorbable nails and double bone plug fresh medial MAT with concurrent high tibial osteotomy for the treatment of combined full-thickness articular cartilage defect and meniscus deficiency. MAT, meniscus allograft transplant; OCA, osteochondral allograft.

RESULTS

Eligible patients, totaling 23, were screened, and all 23 consecutive patients (n = 14 men; 61%) met the inclusion criteria, with 2 years of complete follow-up data available (mean, 51 months; range, 24-86 months) (Table 1).

The mean age of patients was 37.1 years (range, 15-54 years), and the mean body mass index (BMI) was 28 kg/m^2 (range, 19-35 kg/m^2). Femoral OCATs were performed using custom-cut shell grafts in 15 patients and single cylindrical dowel grafts in 8 patients. Medial compartment femoral OCAT + MAT was performed in 18 patients, whereas 5 patients underwent the procedure in the lateral compartment. Additional OCATs for the patella, trochlea, tibial plateau, or femoral condyle were performed in 5 knees. Tibial plateau single cylindrical dowel OCATs were performed in 2 knees, 1 medial and 1 lateral, such that 2 bipolar OCATs were included. Realignment osteotomies were performed in

TABLE 1
Characteristics of Patients Undergoing OCAT + MAT[a]

		Age, y		BMI, kg/m^2		Final Follow-up, mo	Compartment, n		Nonadherence	
	n	Mean (Range)	P^b	Mean (Range)	P^b	Mean (Range)	Medial	Lateral	%	P^b
All	23	37.1 (15-54)	-	28 (19-35)	-	51 (24-86)	18	5	35	-
Success	18	32.1 (15-54)	**.046**	27.5 (19-35)	.578	45 (24-86)	13	5	22	**.033**
Failure	5	42.2 (24-49)		28.8 (24-34)		31 (24-72)	5	0	80	

[a]Failure was defined as revision osteochondral allograft, revision meniscus allograft transplantation, or conversion to arthroplasty. BMI, body mass index; OCAT + MAT, femoral condyle osteochondral allograft transplantation with concurrent meniscus allograft transplantation. Dash signifies no p value calculated.

[b]Reported P values reflect comparisons of initial success versus failure cohorts, with bold P values indicating statistically significant ($P <$ .05) differences.

4 patients: 1 with a concurrent distal femoral osteotomy, 1 with a concurrent tibial tubercle osteotomy, 1 with a concurrent high tibial osteotomy (HTO), and 1 with a staged HTO. Concurrent anterior cruciate ligament reconstruction was performed in 4 patients. Previous ligament reconstructions were performed in 4 patients—3 anterior cruciate ligament reconstructions and 1 anterior cruciate ligament/posterolateral corner reconstruction.

The initial treatment success rate was 78% based on 5 initial treatment failures (Table 1). Revision OCAT consisting of converting a dowel graft to a shell graft to treat a new full-thickness cartilage defect on the medial femoral condyle occurred in 1 patient at 16 months postoperatively. The final success rate was 83% based on the successful revision OCAT that did not require conversion to arthroplasty at a final follow-up of 32 months. Conversion to arthroplasty was performed in 4 patients at a mean of 19 months postoperatively. All failures occurred in the medial compartment. Failure mechanisms were attributed to MAT tearing and/or extrusion (n = 3) or failure of OCA bone incorporation with fragmentation and subsidence (n = 1 shell OCA). Three treatment failures were documented to be associated with nonadherence based on not following weightbearing restrictions and returning to high-impact activities before allowed (n = 2) or not attending outpatient physical therapy (n = 1).

The initial treatment success was associated with a significantly younger patient age at the time of transplantation (32.1 vs 42.2 years; P = .046). The BMI did not differ significantly between initial treatment success and failure cohorts (27.5 vs 28.8 kg/m^2; P = .578). Nonadherence to postoperative restriction and rehabilitation protocols was a significant risk factor for initial treatment failure (P = .033; OR, 14). Age >40 years was a statistically significant risk factor for conversion to arthroplasty (P = .017; OR, 20).

All measured PROMs achieved significant improvements ($P <$ .001) at a minimum of 2 years postoperatively (Table 2).

Patient-reported VAS for pain scores improved from a mean of 5.8 preoperatively to a mean of 1.2 at the final follow-up ($P <$ .001). When comparing the preoperative to final follow-up time points, mean IKDC scores improved by over 28 points—from a mean of 40.9 to a mean of 69.7 ($P <$ .001); SANE scores improved by over 31 points—from a mean of 46.2 to a mean of 78.1 ($P <$ .001); PROMIS Physical Function scores improved from a mean of 38.7 to a mean of 47.7 ($P <$ .001); and PROMIS Mobility scores improved from a mean of 38.8 to a mean of 47.5 ($P <$ .001). Minimum clinically important differences were exceeded for all the assessed PROMs.[17,21,22,35,36,38] At the final follow-up of $\geq$2 years after OCAT + MAT, 83% of patients reported satisfaction with their outcome.

DISCUSSION

The results of this study allow for acceptance of the hypothesis in that OCAT + MAT was associated with an initial success rate of 78% and an overall success rate of 83% after a successful revision OCAT. Successful outcomes were characterized by statistically significant and clinically meaningful improvements in PROMs of knee pain and function—including VAS for pain, IKDC, SANE, and PROMIS Mobility and Physical Function—for at least 2 years after transplantation and a patient satisfaction rate of 83%. Older age and nonadherence to postoperative restriction and rehabilitation protocols were significant risk factors for treatment failure, while BMI, OCA type (cylindrical vs shell), and affected-knee comorbidities were not. Interestingly, all treatment failures occurred in patients undergoing OCAT + MAT in the medial compartment of the knee.

This study's findings correspond well with previously reported success rates and risk factors for treatment failure.[7-9,11,16,24,26,34] In a matched cohort study comparing patients undergoing femoral condyle OCAT with or without concomitant MAT, Frank et al[11] reported identical 5-year success rates of 86% for both treatment cohorts. While the success rates and PROMs were very similar between studies, the patient population studied by Frank et al was notably younger with fewer affected-knee comorbidities, and significant risk factors for treatment failure were not reported. However, other studies have reported

TABLE 2
PROMs for Patients Undergoing OCAT + MAT[a]

		Preoperative	1 Year		2 Years		Final Follow-up	
		Mean (SD)	Mean (SD)	P^b	Mean (SD)	P^b	Mean (SD)	P^b
PROMs	VAS	5.8 (2.1)	2.1 (2.0)	**<.001**	1.5 (1.3)	**<.001**	1.2 (1.6)	**<.001**
	IKDC	40.9 (14.1)	56.9 (14.6)	**.044**	64.8 (12.1)	**<.001**	69.7 (13.5)	**<.001**
	SANE	46.2 (20.8)	67.7 (17.1)	**.011**	75.2 (20.2)	**<.001**	78.1 (16.8)	**<.001**
	Physical Function	38.7 (5.8)	44.8 (5.1)	**.003**	47.2 (4.9)	**<.001**	47.7 (4.5)	**<.001**
	Mobility	38.8 (5.9)	45.1 (5.5)	**<.001**	46.8 (4.9)	**<.001**	47.5 (5.5)	**<.001**

[a]All patients achieved a 2-year follow-up, with some achieving >2 years of follow-up (mean final follow-up, 51 months). IKDC, International Knee Documentation Committee scores; OCAT + MAT, osteochondral allograft transplantation with concurrent meniscus allograft transplantation; Mobility, Patient-Reported Outcomes Measurement Information System (PROMIS) Mobility score; PROMs, patient-reported outcome measuress; Physical Function, PROMIS Physical Function score; SANE, Single Assessment Numeric Evaluation; VAS, visual analog scale.

[b]Reported P values reflect repeated-measures comparisons between the preoperative and 1-year, 2-year, and final follow-up PROMs, with bold P values indicating statistically significant differences ($P < .05$).

significant risk factors for OCAT and/or MAT treatment failures that are very similar to those reported in the present study.[§] As noted in the present study, older patient age has been consistently associated with an increased risk for OCAT and/or MAT failure; however, this should be interpreted as a relative risk factor based on the inconsistent application of age cutoffs and a general lack of multivariate analyses that include age as a covariate. Patient nonadherence to prescribed postoperative restriction and rehabilitation protocols, as defined in the present study, has consistently been associated with OCAT and/or MAT treatment failures, ranging from 2.4 to 15.5 times increased risk.[7,8,24,27] For the patients included in our study, nonadherence was associated with a 14-fold increased risk of initial treatment failure. As nonadherence is a modifiable variable, a patient-centered approach—including a thorough patient assessment and education whereby an integrated care team identifies and addresses potential barriers and risk factors regarding postoperative adherence—should be implemented at centers performing these complex transplant surgeries based on the documented benefits for patients.[27] Other variables previously reported to be risk factors for treatment failure—including higher BMI, the extent of articular cartilage pathology, and affected knee comorbidities—were not significantly associated with treatment failure in this study population.

Limitations

The limitations of the present study include its relatively small number of patients, lack of control or treatment comparison cohorts, and single-center involvement. As such, the statistical analyses are underpowered to ensure type 2 errors did not occur, and multivariate analyses for risk factors were not feasible. The single-treatment design with only univariate subcohort comparisons measures valid but only allows for conclusions regarding short- to midterm outcomes for the specific treatments performed and the relative risk factors for treatment failures in the patient population studied. Furthermore, the involvement of a single institution and 2 surgeons with experience in OCAT and MAT stipulates that the results may not be generalizable to other patients, surgeons, or institutions. As such, further research is needed to further elucidate indications, shared decision-making algorithms, and generalizable long-term outcomes for OCAT + MAT in the knee.

CONCLUSION

OCAT + MAT was associated with successful short- to midterm outcomes (mean, 51 months; range, 24-86 months) in 83% of cases. Before the enrollment of this cohort, evidence-based shifts in practice were implemented that include the use of high-chondrocyte-viability fresh OCAs, preimplantation allograft bone irrigation and bone mineral content saturation, double bone plug fixation and meniscotibial ligament reconstruction for fresh (viable) MAT, and patient management strategies that include assessment, education, and support for adherence to prescribed postoperative restriction and rehabilitation protocols.[‡] Older patients and those who are not able to be adherent to postoperative restriction and rehabilitation protocols had a significantly (14-20 times) higher risk for treatment failure and subsequent conversion to arthroplasty.

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