

Assessment of Outcomes After Multisurface Osteochondral Allograft Transplantations in the Knee

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Background: Treatment of multisurface articular cartilage lesions of the knee is a challenging problem.

Hypothesis: Large multisurface cartilage defects in the knee can be successfully managed with transplantation of high chondrocyte viability osteochondral allografts (OCAs) to result in statistically significant improvements in patient-reported outcome measures of pain and function.

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

Methods: Patients were prospectively enrolled into a registry to follow outcomes after OCA transplantation. The study included patients who received OCA transplantation for multisurface unipolar defects in 1 knee and had minimum 2-year follow-up data, including patient-reported outcome measures, failures, reoperations, and complications. The OCA transplants had been stored using 2 methods: standard preservation (SP) or Missouri Osteochondral Preservation System (MOPS). Preoperative data were compared with outcomes at 1 year and final follow-up, and risk factors for revision surgery or failure (total knee arthroplasty) were analyzed.

Results: The sample included 25 patients with a mean age of 37.2 years (range, 13-51 years), body mass index of 27.7 (range, 18-38), and follow-up of 45.1 months (median, 49 months; range, 24-68 months). OCAs stored using SP were transplanted into 6 patients, and those stored using MOPS were transplanted into 19 patients. The initial success rate was significantly higher for MOPS OCAs (94.7%) than SP OCAs (33.3%). There were statistically significant improvements in all patient-reported outcomes at 1 year and final follow-up in the MOPS cohort ($P < .0001$ for all). Revision surgery/failure was significantly associated with patients who were nonadherent to the prescribed postoperative restrictions and rehabilitation protocols ($P = .038$; odds ratio = 13.5) and with OCAs that had a viable chondrocyte density $<70\%$ of the established reference range mean at transplantation ($P = .0037$; odds ratio = 76).

Conclusion: OCA transplantation for treatment of large multisurface cartilage defects in the knee resulted in a 94.7% initial success rate when grafts with high viable chondrocyte density ($\geq 70\%$) were used and when patients strictly adhered to prescribed postoperative rehabilitation protocols. Successful outcomes were associated with statistically significant improvements in patient-reported outcome measures of pain and function.

Keywords: cartilage; knee; osteochondral allograft; transplantation; bone marrow aspirate concentrate

Chondral and osteochondral lesions in the knee are common, such that they are encountered in 36% to 66% of patients undergoing knee arthroscopy.^{3,13} These articular defects can cause significant pain and dysfunction that often progress to whole-joint osteoarthritis unless effectively treated.³⁴ While partial arthroplasty and total knee arthroplasty (TKA) can result in consistently successful outcomes when indicated, arthroplasty options are often

undesirable for patients aged <55 years, especially those who are highly active.^{1,2,6,15,22,32,38-40} In these younger, more active patients, cartilage restoration using osteochondral allograft (OCA) transplantation can be an effective treatment option.^{8,23,35}

Fresh OCA transplantation is well-established as a safe and effective treatment option for large symptomatic chondral and osteochondral lesions of the knee.[§] Yet, the majority of the peer-reviewed literature for OCA transplants has focused on single-surface focal lesions of the femoral condyles

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or trochlea using a dowel-graft technique.¹⁶ Cotter et al¹¹ reported excellent clinical outcomes and graft survival for patients undergoing multisurface OCA transplantation in the knee; however, just 13 patients were included, and assessment was limited to combinations of patellar, trochlear, and femoral condylar lesions treated using a single-dowel technique. As such, there is a remaining gap in knowledge regarding the great number of patients who are indicated for treatment of large multisurface lesions in the knee.^{3,16,21}

The present study was designed to analyze prospectively collected data from a dedicated registry that contribute to filling this knowledge gap and to compare results for OCA transplants stored using 2 different methods: standard preservation (SP) or Missouri Osteochondral Preservation System (MOPS). The data were analyzed to test the hypothesis that large multisurface cartilage defects in the knee can be successfully managed with transplantation of high chondrocyte viability OCAs to result in statistically significant improvements in patient-reported outcome measures of pain and function.

METHODS

After institutional review board approval and documented informed consent were received, patients were prospectively enrolled into a dedicated registry designed to follow OCA transplantation outcomes. All OCAs were obtained from American Association of Tissue Banks–accredited sources and used in conformance to the US Food and Drug Administration’s classification of a human cell and tissue product under section 361 of the Public Health Services Act. We initially used SP grafts from 1 of 3 tissue banks, which were stored in refrigeration in proprietary solutions for up to 21 days after graft recovery. After MOPS grafts became commercially available, we implemented a shift in practice to use only MOPS-preserved OCAs stored at room temperature for up to 56 days after the graft was recovered.^{36,37}

Study Patients

Patients were identified from those enrolled in the registry between July 1, 2015, and September 30, 2019, who underwent primary OCA transplantation for large grade 3 or 4 focal articular cartilage defects (>2.5 cm²) involving >1 articular surface (eg, lateral femoral condyle, medial femoral condyle, trochlea, patella, lateral tibial plateau, or medial tibial plateau), none of which were opposing

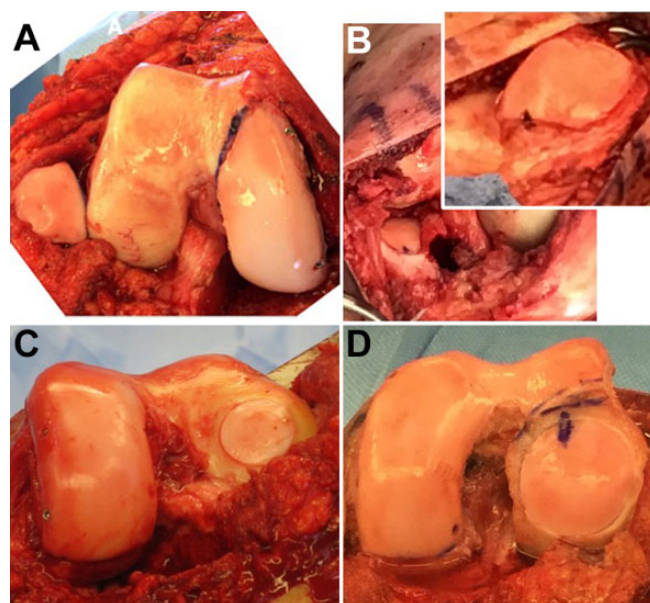


Figure 1. Representative intraoperative images for osteochondral allograft transplantations for large multisurface articular cartilage defects (>2.5 cm²) involving the (A) lateral femoral condyle and patella; (B) lateral tibial plateau and patella (inset); (C) lateral and medial femoral condyles; or (D) trochlea, medial femoral condyle, and lateral femoral condyle.

(bipolar) (Figure 1). All study patients had minimum 2-year follow-up data available, such as demographics, operative data, complications, reoperations, revisions, failures, and patient-reported outcomes.

Patients chose OCA transplantation over nonsurgical or other surgical alternatives and were approved for coverage by their insurance providers. Each patient spent considerable time (45-60 minutes) in preoperative consultation with the attending surgeon and joint restoration health care team to discuss risks, benefits, expectations, and limitations associated with the planned OCA transplant surgery and recovery prior to consenting to surgery and consenting and enrolling in the registry.

Surgical Procedure

All surgical procedures were performed by 1 author (J.P.S.) using press-fit cylindrical grafts or custom-cut patient-specific shell grafts (~7 mm thick) to resurface large grade

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3 or 4 focal articular cartilage defects diagnosed via arthroscopy.³⁵ Subchondral drill holes (3.2-mm diameter) were created, and the donor bone was thoroughly irrigated to remove marrow elements.^{5,24} Allograft bone was saturated with autogenous bone marrow aspirate concentrate (Angel System; Arthrex) immediately before implantation.²⁸ Shell OCAs were stabilized with 2.0 mm stainless steel screws (Synthes), bioabsorbable pins (Arthrex) or bioabsorbable nails (ConMed) based on the discretion of the operating surgeon. If relevant comorbidities were noted in the affected knee, such as lower extremity malalignment or ligament-related instability, these were addressed using standard-of-care procedures (eg, anterior cruciate ligament [ACL] reconstruction or high tibial osteotomy) with health care insurance preauthorization.

The viable chondrocyte density (VCD) of OCAs at the time of transplantation was determined when tissues were available—specifically, when sufficient femoral condyle OCA tissue remained after transplantation and the patient provided informed consent for the research use of otherwise-discarded donor tissue, as previously described.³⁶

Rehabilitation Protocol

Throughout the study period, each patient received procedure-specific postoperative rehabilitation instructions verbally and as a written prescription.^{12,30} These instructions were also communicated at multiple time points to outpatient physical therapists who were involved in the patients' postoperative rehabilitation. Physical therapists at our institution were present at pre- and postoperative clinic visits, provided inpatient therapy, and coordinated outpatient therapy. Patient adherence with the postoperative rehabilitation protocol was monitored and documented per 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.²¹

Outcome Measures

Patients completed the Patient-Reported Outcomes Measurement Information System (PROMIS)—Physical Function subscale and PROMIS—Mobility subscale, International Knee Documentation Committee (IKDC) questionnaire, Single Assessment Numeric Evaluation (range, 0-100), and 10-point visual analog scale for pain preoperatively and at 3 months, 6 months, and yearly after surgery.^{7,14,26,27,33} Patient electronic medical records were used to determine demographic information, operative data, postoperative complications, and reoperations.

Failure was defined as conversion to TKA, and revision was defined as reoperation to revise any of the previously implanted OCAs at any time during follow-up. Decisions to pursue revision surgery or arthroplasty were based on the surgeon's discussion of failure mechanism, treatment options, and prognosis in conjunction with the patient's expectations and preferences. Treatment was categorized

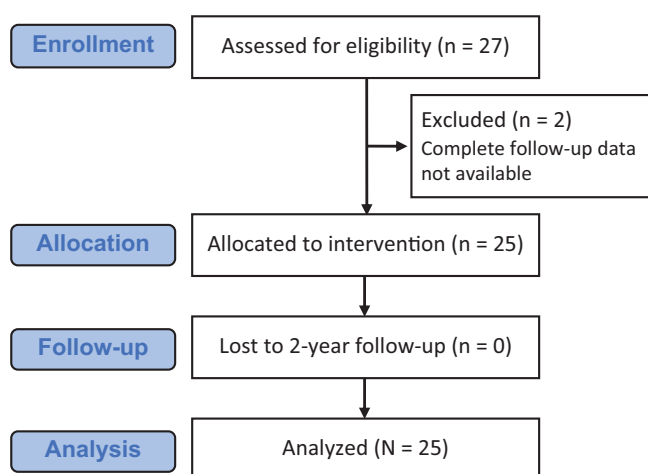


Figure 2. Flow diagram of patient enrollment.

as successful when patients returned to functional activities without need for revision or TKA. The initial success rate was calculated using the following formula: % success = 100% – (% revision + % failure).

Statistical Analysis

Descriptive statistics were calculated to report means, ranges, and percentages. Outcomes were compared by differences in graft preservation methodology, defined as SP vs MOPS. Chi-square or Fisher exact tests were used to assess for significant differences in proportions. When significant differences in proportions were noted, odds ratios (ORs) were calculated for comparisons of variables such as patient age, sex, body mass index (BMI), VCD (<70% vs ≥70% of the mean of established reference range³⁶), number of surfaces transplanted, and adherence to rehabilitation protocols. Normality tests were performed, and *t* tests, rank sum tests, 1-way analysis of variance (ANOVA), or 1-way ANOVA by ranks was used to assess for significant differences between cohorts at respective time points. Repeated-measures ANOVA was used to assess for significant differences within each cohort over time. Significance was set at $P < .05$.

RESULTS

Twenty-seven eligible patients were screened based on registry data, and 25 ($n = 14$ male [56%]) met inclusion criteria (Figure 2). The mean patient age was 37.2 years (range, 13-51 years), and the mean BMI was 27.7 kg/m² (range, 18-38 kg/m²). The final follow-up occurred at a mean 45.1 months (median, 49 months; range, 24-68 months). Data are shown in Table 1. Regarding storage method, 6 OCAs (24%) were SP and 19 (76%) were MOPS. There were no statistically significant differences between preservation cohorts in patient demographics or number of surfaces treated. VCD data were obtained for 15 cases (5 SP, 10 MOPS). Average VCD in the MOPS cohort

TABLE 1
Patient, Graft, and Surgical Characteristics for Patients Who Underwent Multisurface Unipolar OCA Transplantation in the Knee^a

Variable	All Patients (N = 25)	OCA Preservation Method		P Value
		SP (n = 6)	MOPS (n = 19)	
Age, y, mean (range)	37.2 (13-51)	41.5 (22-51)	35.8 (13-50)	.31
BMI, kg/m ² , mean (range)	27.7 (18-38)	26.7 (21-32)	28.1 (18-38)	.57
Sex, n				.55
Male	14	3	11	
Female	11	3	8	
OCA graft characteristics				
Days in storage, mean (range)	—	19.7 (18-21)	42.2 (29-55)	<.0001
VCD at transplantation, % ^b	90	27	105	<.0001
No. of surfaces treated, n				>.43
2	20	4	16	
3	4	2	2	
4	1	0	1	
Initial success rate, %	80	33.3	94.7	.006

^aBMI, body mass index; MOPS, Missouri Osteochondral Preservation System; OCA, osteochondral allograft; SP, standard preservation; VCD, viable chondrocyte density. Bold *P* values denote statistically significant differences between the SP and MOPS groups (*P* < .05).

^bPercentage of published reference mean.36 VCD data were obtained for 15 patients (5 SP, 10 MOPS).

TABLE 2
Multisurface Unipolar Osteochondral Allografts in the Knee: Patient-Reported Outcome Scores by Preservation Method^a

	SP			MOPS ^b		
	Preoperative	1-y Follow-up	Final Follow-up	Preoperative	1-y Follow-up	Final Follow-up
VAS pain	4.7 ± 1.8	4.7 ± 2.4	2.9 ± 2.1	5.7 ± 1.6	1.4 ± 1.1	1.1 ± 1
IKDC	30.9 ± 6.4	39.5 ± 14.4	54.2 ± 14.3	38.5 ± 8.8	61.9 ± 13.5	71.1 ± 10.6
SANE	30.7 ± 8.5	41 ± 17.1	52.3 ± 11.7	39.4 ± 6.5	71 ± 13	73.2 ± 9.8
PROMIS						
Physical function	37 ± 3.9	39.6 ± 8	43.6 ± 7.4	39.2 ± 5.7	47.3 ± 7.6	48.3 ± 7
Mobility	35.5 ± 6	38.8 ± 13.1	43.3 ± 8.2	38.8 ± 6.5	46.2 ± 3.1	49.8 ± 7.1

^aValues are presented as mean ± SD. IKDC, International Knee Documentation Committee; MOPS, Missouri Osteochondral Preservation System; PROMIS, Patient-Reported Outcomes Measurement Information System; SANE, Single Assessment Numeric Evaluation; SP, standard preservation; VAS, visual analog scale.

^bDifferences over time in outcome scores in the MOPS cohort: *P* < .0001 for every variable listed (repeated-measures analysis of variance).

was 105% of the published reference mean,³⁶ which was significantly higher than that in the SP cohort (27% of the published reference mean; *P* < .0001).

For the 6 patients in the SP cohort, 1 underwent concurrent ACL reconstruction, and another underwent a staged high tibial osteotomy to address comorbidities in the operated lower extremity. For the 19 patients in the MOPS cohort, 3 had concurrent ligament reconstructions (ACL, ACL/posterolateral corner, or ACL/medial patellofemoral ligament), and 2 underwent osteotomy (staged or concurrent distal femoral osteotomy) to address comorbidities in the operated lower extremity.

Outcome Measures

There were statistically significant improvements in all patient-reported outcomes at 1 year and final follow-up in the MOPS cohort (*P* < .0001 for all). Significant

improvements were not noted for the SP cohort at either time point (*P* > .1 for all) (Table 2).

Treatment Success/Failure

Based on the *a priori* definitions for success and failure described in the Methods, the initial 2-year success rate within the SP cohort was 33%, with 2 patients undergoing OCA revision and 2 undergoing conversion to TKA. The 2 revisions were performed for patients whose primary OCA transplantations involved 2 surfaces (medial and lateral femoral condyles or medial femoral condyle and patella). The 2 failures occurred in patients whose primary OCA transplantations involved 3 surfaces (medial and lateral femoral condyles and patella or medial and lateral femoral condyles and trochlea). Neither of the patients with ligament reconstruction or osteotomy required revision surgery or TKA during the study period. Of the 4 patients, 3 (75%)

who required revision or TKA were nonadherent to rehabilitation protocols during the first year after multisurface OCA transplantation.

The initial success rate within the MOPS cohort was 94.7%, which was significantly higher than that within the SP cohort ($P = .006$). The single instance of failure occurred in a patient in which the primary OCA transplantations involved 2 surfaces (lateral tibial plateau and trochlea). This patient did not undergo concurrent or staged ligament reconstruction or osteotomy and was not documented to be nonadherent.

Risk Factors for Treatment Failure

Patients requiring revision or TKA were significantly more likely to be nonadherent to rehabilitation protocols, not only within the SP cohort ($P = .016$; OR = 28.5) but among all patients ($P = .038$; OR = 13.5). VCD <70% of the mean of the established reference range³⁶ was also significantly associated with need for revision or failure ($P = .0037$; OR = 76). None of the other variables assessed (ie, age, sex, BMI, and number of surfaces transplanted) were significantly associated with need for revision or failure.

No other OCA transplantation–related complications or reoperations were noted during the study period.

DISCUSSION

The results of this study support the hypothesis that large multisurface cartilage defects in the knee can be successfully managed with transplantation of high chondrocyte viability OCAs to result in statistically significant improvements in patient-reported outcome measures of pain and function. Importantly, successful outcomes for these complex cases were significantly more likely to be realized when OCAs with high VCD at time of transplantation were used. A 94.7% initial success rate was achieved after multisurface OCA transplantation using MOPS-preserved grafts. Patient nonadherence with the prescribed postoperative rehabilitation protocol was also a significant risk factor associated with revision and failure in this patient population. When these 2 risk factors were combined, nonadherent patients who received low-viability OCA transplants were nearly 30 times more likely to require revision or TKA. Interestingly, age, sex, BMI, and number of surfaces transplanted were not significantly associated with need for revision or TKA in the patient cohort studied.

The findings from the present study regarding the impact of VCD and patient adherence on OCA transplantation outcomes correspond well with previous studies.^{9,10,17,25,30,36,37} OCAs transplanted with VCD $\geq 70\%$ of the mean of the established reference range for day 0 VCD (ie, at time of graft recovery from the donor) have been associated with consistently superior results, such that MOPS-preserved grafts have had significantly better clinical outcomes when compared with grafts preserved using standard tissue bank methods.^{8-10,30,35-37} Patient adherence to the prescribed postoperative rehabilitation protocol during the first year after transplantation

has also been documented as a consistent risk factor for revision OCA or conversion to TKA. In 2019, Rucinski et al³⁰ first reported the impact of nonadherence after OCA transplantation, finding that patients who did not adhere to the full 1-year postoperative rehabilitation protocol were 6.3 times more likely to require revision or TKA. Three subsequent studies cited similar odds ratios for patient nonadherence after OCA transplantation in the knee, ranging from 6.7 to 15.5 times the risk for treatment failure.^{8,31,35} Based on best current evidence, these two factors likely have heightened impact in more complex cases in terms of high-demand patients and the size and extent of OCA transplants. In our experience, health care teams must provide clear preoperative expectations, including details on restrictions and length of physical therapy required, and should utilize a health psychologist to help identify and resolve barriers to adherence to most effectively mitigate risk for nonadherence.

To our knowledge, only 1 previously published study targeted multisurface unipolar OCA transplantation in the knee.¹¹ Cotter et al¹¹ reported a 93.3% success rate with significant improvements in patient-reported outcomes at a minimum 2-year follow-up in their cohort of 13 patients. In a systematic review, Familiari et al¹⁶ focused on isolated defects of the femoral condyles, patella, or trochlea, and the combined 5- and 10-year OCA functional survival rates were 86.7% and 78.7%, respectively. IKDC scores were combined to result in a mean preoperative score of 39.6 and a mean postoperative score of 69.7. In a systematic review, Assenmacher et al⁴ calculated a mean success rate of 75% at 12.3 years and noted significant improvements in patient-reported outcome scores at final follow-up after OCA transplantation for isolated defects in the knee, with least favorable outcomes associated with transplants involving the patellofemoral joint. The present study provides a larger series of outcomes after multisurface unipolar OCA transplantation in the knee for which initial outcomes (2-5 years) compare favorably with previous single- and multisurface OCA transplantation cohorts. Taken together, these data suggest that the size, extent, and volume of OCA transplanted, or “bioburden,” may not be defining risk factors for initial outcomes when VCD at the time of transplantation and postoperative patient adherence are ensured.

There are several limitations to this study that should be considered when applying this information. First is the lack of long-term follow-up data. While most failures occur within the first 2 years after OCA transplantation, longer-term follow-up data are lacking for multisurface OCA transplantation in the knee. Similarly, while improvements in patient-reported outcome measures and functional OCA survival rates in the present study are on par with those for treatment of isolated defects of the knee, extrapolation to long-term results is cautioned. Another limitation of the study is the lack of randomization for use of SP vs MOPS-preserved OCAs, with graft choice instead determined by an evidence-based shift in practice. As such, confounding variables such as comorbidities, distribution of lesions, and surgical learning curve may influence the results. Still, it is valid to compare preservation cohorts

based on all other variables remaining consistent, including patient demographics, surgeon, surgical techniques, and postoperative management protocols. Last, while this is, to our knowledge, the largest case series focused on multisurface unipolar OCA transplantation in the knee to date, it comprises a relatively small cohort of patients treated by a single surgeon at 1 institution, such that the results are not broadly generalizable.

CONCLUSION

OCA transplantation for treatment of large multisurface cartilage defects in the knee resulted in a 94.7% initial success rate when grafts with high VCD ($\geq 70\%$) were used and patients strictly adhered to prescribed postoperative rehabilitation protocols. Successful outcomes were associated with statistically significant improvements in patient-reported outcome measures of pain and function.

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