5-Year Outcomes After Cryopreserved Osteochondral Allograft: Interim Analysis of IKDC and KOOS Scores in Knee Cartilage Repair

Elizabeth Esterl, DNP, MS, RN; Carolyn Rorick, MBA, BS; Ross Wilkins, MD, MS
AlloSource®, Centennial, CO

As Presented at the 2025 International Cartilage Regeneration & Joint Preservation Society World Congress

ProChondrix® CR
CRYOPRESERVED OSTEOCHONDRAL ALLOGRAFT

DO MORE WITH LIFE

AlloSource® LIFE SCIENCES

PURPOSE

The purpose of this clinical study is to evaluate the use of ProChondrix® CR Cryopreserved Osteochondral Allograft (OCA) to obtain evidence of effectiveness, defined as an improvement in physical function and pain, when used on a symptomatic cartilage defect on the femoral condyle or patella in a mechanically stable knee.

Rigorous evaluation of long-term patient-reported outcomes is critical to substantiate such biologic implants' durability and clinical efficacy. This interim analysis reports outcomes through 60 months in an ongoing prospective, multi-center clinical study.

Image of ProChondrix CR allograft with a laser-etched deep side for cellular outgrowth and a smooth articulating surface

MATERIAL

ProChondrix® CR: Viable, Hyaline Cartilage Allograft For The Repair And Replacement Of Articular Cartilage

- ProChondrix CR is an off-the-shelf, cryopreserved osteochondral allograft used to treat surface cartilage lesions
- 94.97% chondrocyte viability after two years of storage at -80C[1]
- Trimmable and flexible allograft that allows for easy manipulation during implantation
- Ergonomically designed disposable instruments created specifically for ProChondrix CR
- Contains Bone-Forming Cells[2]

ViaTrue® Cryopreservation Process

ProChondrix CR is created using AlloSource's innovative, proprietary cryopreservation technology, ViaTrue. The unique process includes a controlled rate freezing of fresh cartilage within 72 hours of donor death, when the chondrocytes are still highly viable. ViaTrue processed cartilage products are then preserved for up to two years, maintaining high chondrocyte viability.

METHODS

Patients receiving ProChondrix® CR cryopreserved OCAs for focal cartilage lesions of the knee were enrolled and longitudinally followed in a prospective, multi-center protocol.

Outcome measures included:

- International Knee Documentation Committee (IKDC) Subjective Knee Form
- Knee Injury and Osteoarthritis Outcome Score (KOOS) Pain Subscale
- Assessment of repair cartilage structure, using Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART) scores, as measured by magnetic resonance imaging (MRI)
- Short Form 12 Score (SF-12)
- Revision surgery

Assessments were performed preoperatively and at 6, 12, 24, 36, 48, and 60 months postoperatively.[3] Statistical analysis included descriptive statistics, paired t-tests comparing postoperative to baseline scores, and computation of 95% confidence intervals for mean differences.

RESULTS

Analysis includes longitudinal IKDC outcomes following surgical intervention for articular cartilage defects. Results indicate a consistent improvement from baseline (preoperative mean score of 41.83) through 12 months (75.24), with sustained functional gains through 60 months (74.83).

Similarly, KOOS Pain scores improved from a baseline mean of 59.72 ± 20.08 to 87.22 ± 9.37 at 60 months (mean difference: +27.50; 95% CI: 16.81-38.19; $p < 0.001$). Improvements across all time points were both statistically and clinically significant.

FIGURE 1. IKDC SCORE PROGRESSION OVER TIME

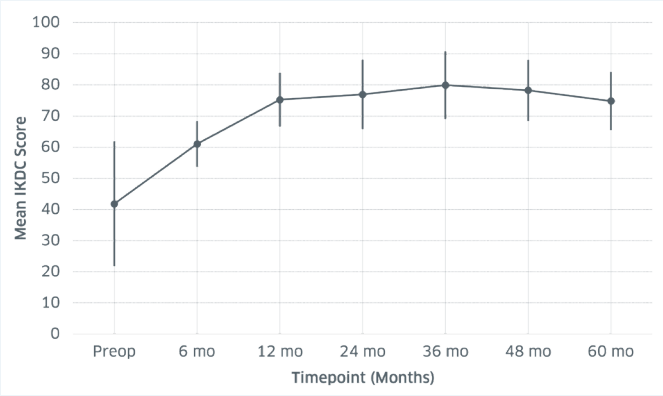

Figure 1. Line graph displaying mean IKDC scores over time, from preoperative through 60 months. Error bars represent standard deviation at each timepoint. Substantial gains were observed by 12 months, with mean scores sustained across all follow-up periods.

FIGURE 2. KOOS PAIN SCORE PROGRESSION

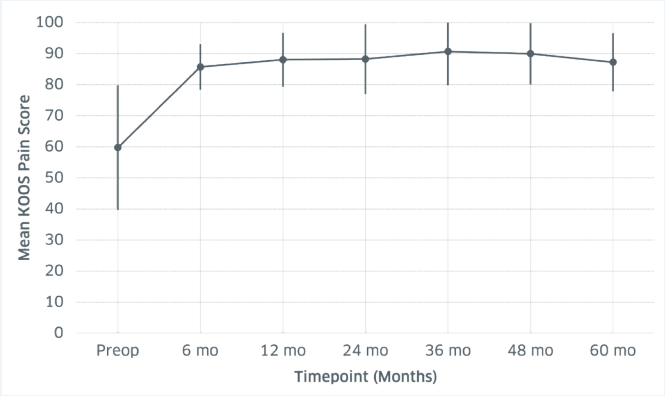

Figure 2. Line graph displaying the progression of KOOS Pain scores from preoperative baseline through 60 months, postoperatively. Mean scores at each follow-up timepoint are plotted with standard deviation error bars. Scores show a substantial increase from baseline (mean: 59.72) to 12 months (88.03) and remain elevated through 60 months, indicating sustained improvement in patient-reported knee pain outcomes.

TABLE 1. DESCRIPTIVE SUMMARY OF IKDC SCORES

Timepoint	N	Missing (%)	Unique	Min	Max	Mean	St Dev	Sum	P5	P10	P25	Median (P50)	P75	P90	P95
Preop	33	1 (2.9%)	25	4.6	78.16	41.83	16.37	1380.5	14.02	25.52	31.03	42.53	51.72	61.61	65.06
6 mo	28	5 (15.2%)	23	36.78	97.7	61.04	12.39	1709.2	43.74	46.78	53.45	61.49	67.82	73.91	77.7
12 mo	26	7 (21.2%)	19	37.93	95.4	75.24	14.31	1956.3	52.01	60.34	64.37	76.44	84.77	91.38	93.68
24 mo	17	15 (46.9%)	14	41.38	98.85	76.94	16.19	1308.1	45.06	57.7	72.41	77.01	89.66	96.09	98.85
36 mo	17	15 (46.9%)	14	45.98	100.0	79.92	15.82	1358.6	57.93	61.61	67.82	83.91	91.95	98.62	100.0
48 mo	12	20 (62.5%)	10	50.57	100.0	78.26	19.75	939.08	50.57	51.49	61.49	80.46	96.84	99.77	100.0
60 mo	10	22 (68.8%)	9	51.72	100.0	74.83	16.17	748.28	53.79	55.86	63.51	76.44	79.89	98.97	99.48

Table 1. Summary statistics for IKDC scores at each follow-up timepoint. Metrics include the number of observations, missing values, distribution percentiles, and measures of central tendency and dispersion.

TABLE 2. KOOS SCORE SUMMARY TABLE

Timepoint	N	Missing (%)	Unique	Min	Max	Mean	St Dev	Sum	P5	P10	P25	Median (P50)	P75	P90	P95
Preop	32	2 (5.9%)	18	0.0	94.44	59.72	20.08	1911.1	28.61	39.17	44.44	63.89	72.22	80.56	81.81
KOOS 6 months	28	5 (15.2%)	10	72.22	100.0	85.71	7.36	2400.0	73.19	75.0	81.94	86.11	89.59	94.44	96.25
12 months	26	7 (21.2%)	10	69.44	100.0	88.03	8.67	2288.9	70.14	76.39	83.33	88.89	96.53	97.22	97.22
24 months	17	15 (46.9%)	8	66.67	100.0	88.23	11.22	1500.0	66.67	70.0	83.33	88.89	97.22	98.33	100.0
36 months	17	15 (46.9%)	8	58.33	100.0	90.69	10.93	1541.7	73.89	81.11	86.11	94.44	100.0	100.0	100.0
48 months	13	19 (59.4%)	8	72.22	100.0	89.96	9.86	1169.4	73.89	76.11	80.56	94.44	97.22	99.44	100.0
60 months	10	22 (68.8%)	5	77.78	100.0	87.22	9.37	872.23	77.78	77.78	78.48	84.73	94.44	100.0	100.0

Table 2. Summary statistics for KOOS Pain scores at each follow-up timepoint. This table includes the number of observations, percentage of missing values, distribution percentiles (5th–95th), and measures of central tendency and dispersion.

CONCLUSIONS

This prospective evaluation of functional outcomes, following surgical intervention for focal articular cartilage defects in the knee, demonstrates significant and sustained patient-reported improvements over time. Both the International Knee Documentation Committee (IKDC) and Knee injury and Osteoarthritis Outcome Score (KOOS) Pain Subscale exhibited marked increases from preoperative baseline to postoperative follow-up periods.

Mean IKDC scores improved from 41.83, preoperatively, to 75.24 at 12 months, maintaining elevated levels through 60 months. Similarly, KOOS Pain scores rose from 59.72 to 88.03 at 12 months and remained consistently high, reaching 90.69 at 36 months and 87.22 at 60 months. These findings reflect durable improvement in knee function and pain perception as reported by patients.

Future analyses incorporating individual longitudinal data will be essential for confirming the magnitude and statistical significance of these outcomes. Nevertheless, the current data supports the continued evaluation of this intervention as a viable approach to improving long-term quality of life and joint function in patients with focal cartilage damage.

LEARN MORE

ProChondrix® CR

CRYOPRESERVED OSTEOCHONDRAL ALLOGRAFT

ProChondrix CR is an off-the-shelf cryopreserved osteochondral allograft used to treat surface cartilage lesions.

Disclosures:

Authors are employees of AlloSource, Centennial, Colorado, USA

References:

1. Rorick C, et al. Cryopreserved, Thin, Laser-Etched Osteochondral Allograft maintains the functional components of articular cartilage after 2 years of storage. *J Orthop Surg and Res.* 2020;15:521.
2. Nelson A, Barrett C, Sakthive R. ProChondrix fresh osteochondral allograft maintains viable chondrocytes, osteoblasts and mineralized matrix necessary to support bone and cartilage formation. *AlloSource White Paper.* 2017; M8S0128.001.
3. Rorick C, Esterl E, Wilkins R. ProChondrix CR: early prospective clinical outcomes for the repair of focal articular cartilage defect in the knee. *AlloSource White Paper.* 2023; 01202-TECH [001].

AlloSource, one of the largest human tissue providers, honors tissue donors by creating innovative dermal, cartilage, tendon, fascia, bone, amniotic, and living cellular allografts to help heal patients. Since 1994, we have continued to advance our allografts to improve patient outcomes, serving as a trusted tissue partner to the medical community. Learn more at allosource.org.

ProChondrix® CR is regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). AlloSource® is registered with the FDA as a tissue establishment and accredited by the Association for Advancing Tissue and Biologics.

The ProChondrix® CR family of products are covered under one or more of the following US Patents: 9,168,140; 9,186,253; 9,603,710; 9,700,415; 10,335,281; 11,123,193

AlloSource® LIFE SCIENCES

6278 S Troy Cir
Centennial, CO 80111
USA

MAIN 720. 873. 0213

allosource.org

012010-TECH [001] - 05/2026