

# PROCHONDRIX® CR: EARLY PROSPECTIVE CLINICAL OUTCOMES FOR THE REPAIR OF FOCAL ARTICULAR CARTILAGE DEFECTS IN THE KNEE

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# ProChondrix<sup>®</sup> CR: Early Prospective Clinical Outcomes for the Repair of Focal Articular Cartilage Defects in the Knee

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## INTRODUCTION

The current standard in cartilage replacement for full thickness chondral lesions is fresh osteochondral allograft (OCA) transplantation due to its extensive clinical history and acceptable long-term success rates.<sup>1,2</sup> However, due to the limited number of donors that meet the criteria for fresh cartilage donation and required size matching, these grafts are in short supply, limiting accessibility to clinicians and patients. Furthermore, availability of fresh OCA grafts are also limited by a short shelf life; for instance, OCA grafts stored at 4 °C have a shelf life of no more than 28 days.<sup>2,3</sup>

ProChondrix CR (PROCR) is a readily available thin, laser – etched cryopreserved osteochondral allograft used to treat surface cartilage lesions. It was developed as a cost– effective single–stage alternative cartilage treatment that retains the necessary components for articular cartilage restoration. PROCR is a full thickness intact living cellular articular cartilage graft that stimulates hyaline cartilage regeneration by retaining viable, functional chondrocytes and other biological components necessary for the repair and replacement of damaged cartilage tissues.<sup>4</sup> The allograft's extracellular matrix provides structural support for cell migration and proliferation along the graft–native tissue line, thus promoting integration while providing retained signaling proteins known to aid in cartilage repair by retaining signaling proteins that help promote chondrogenesis. While PROCR has demonstrated promising data in the laboratory, data evaluating the clinical outcomes is essential.

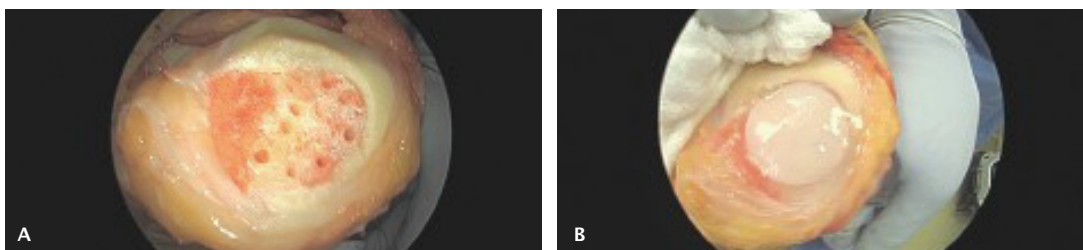
## OBJECTIVE

The purpose of this study is to evaluate short-term prospective clinical outcomes of PROCR, a cryopreserved, thin, laser–etched, osteochondral allograft in focal cartilage lesions of the patella and femoral condyle in the knee.

## METHODS

Thirty-one patients with full thickness cartilage lesions of the knee (Grade II–III) were treated with implantation of PROCR (**Figure 1**, **Table 1** and **Table 2**). Pre– and post– operative International Knee Documentation Committee (IKDC) and Knee Injury and Osteoarthritis Outcome Score (KOOS) were recorded, and data was analyzed post operatively at 6–, 12–, 24– and 36–months.

Mean follow–up period was 15.1 months (3–36 months). There were 12 males and 19 females with a mean age of 28 years (**Table 2**). This study was approved by the Central Institutional Review Board (IRB ID#20183423).



**Figure 1.** Image demonstrating a full thickness cartilage lesion on the patellar articular surface (A) treated with PROCR allograft placed in the defect with fibrin glue fixation (B).

Participant Enrollment/Withdrawal					
Total Enrolled	Total Withdrawn	Reasons for Subject Withdrawal			
31	8	Protocol Deviation	Lost to Follow-Up	No PROCR	Revision Surgery
		3	1	2	2

**Table 1**

Patient Characteristics - Patients (n=31)	
Characteristic	
Age: years, mean (range)	28 (18-52)
Sex: (male:female)	12:19
Lesion Location: (condyle:patella:both)	11:18:01

**Table 2**

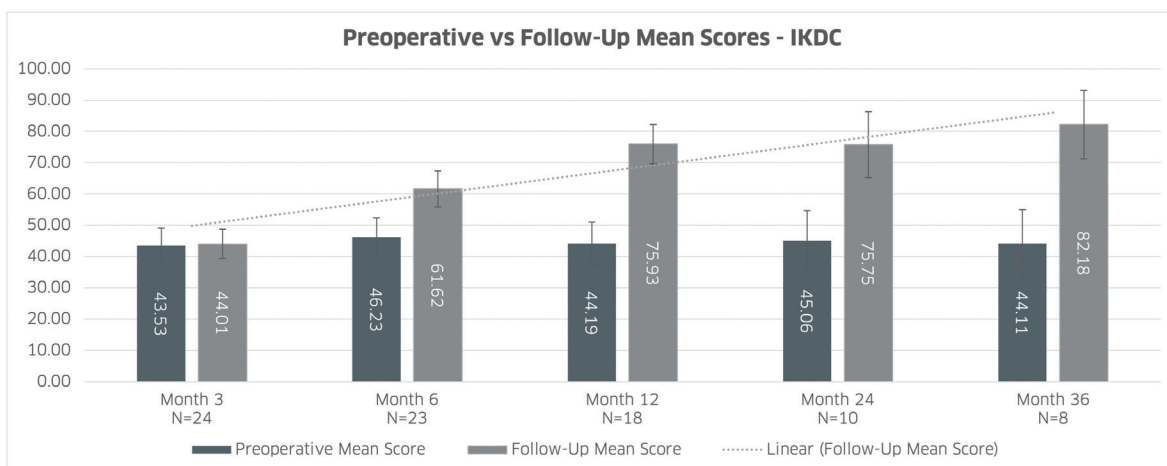
## RESULTS

The IKDC evaluation was the study's primary outcome score and is a commonly used patient reported outcome survey that assesses a variety of knee disorders. The survey contains three sections: knee symptoms, function and sports activities. Scores range from 0 to 100, with lower scores indicating lower function and higher severity of symptoms and higher scores indicating higher function and lower severity of symptoms.<sup>5</sup>

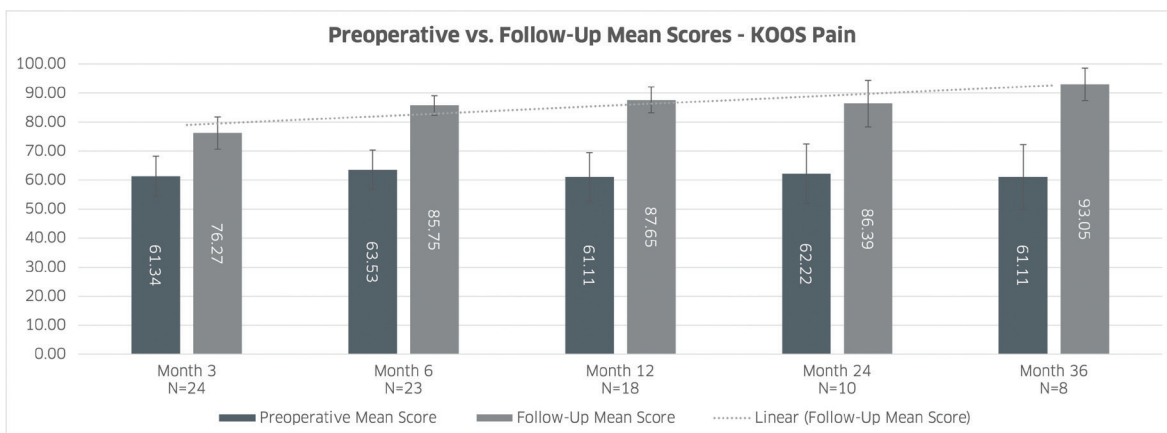
Patients in this study showed improvements from preoperative scores at months 6 through 36 (**Figure 1**). With total IKDC score improvements of 31.74 ( $p<.001$ ) at 12-months ( $n=18$ ), 30.69 ( $P=.001$ ) at 24 months ( $n=10$ ) and 38.07 ( $p<.001$ ) at 36 months ( $n=8$ ), these scores met the protocol's defined measure of success with an improvement of 27.3 or greater.

The KOOS score collects data on five knee-specific patient-centered outcomes: pain and other symptoms such as swelling, restricted range of motion and mechanical symptoms; disability on the level of daily activities; disability on a level physically more demanding than activities of daily living; and mental and social aspects, such as awareness and lifestyle changes. The score is a percentage score from 0 to 100 with 0% representing extreme problems and 100% representing no problems.<sup>6</sup>

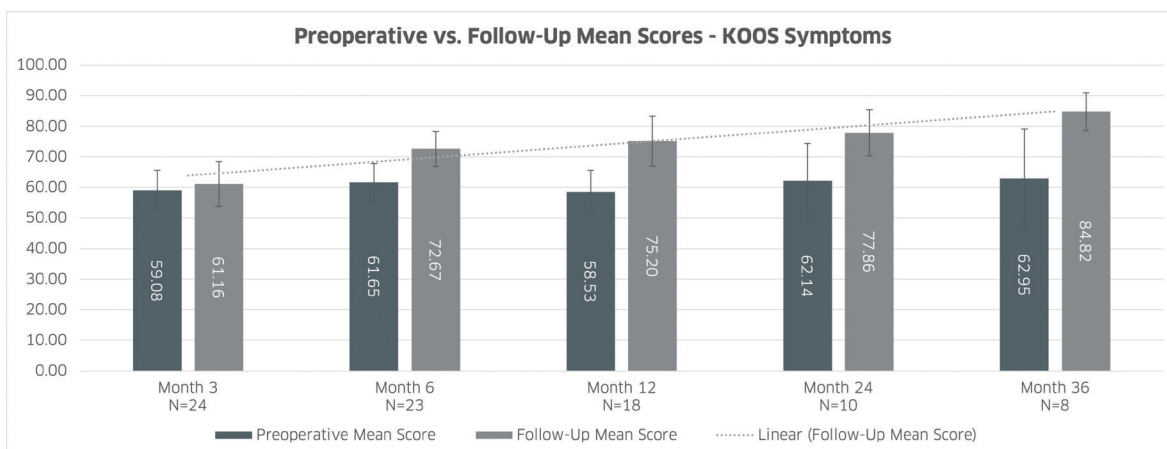
At the 12 month time point, statistically significant increases were also seen in KOOS Pain (+26.54,  $p<.001$ ), KOOS Symptom (+16.67,  $p=.001$ ), KOOS Ability in Daily Living (+19.85,  $p=<.001$ ), KOOS Sports and Recreation (+35.28,  $p<.001$ ), KOOS Quality of Life (+35.07,  $p<.001$ ) and KOOS WOMAC (+20.08,  $p<.001$ ) (**See Figure 2, Figure 3, Figure 4, Figure 5, Figure 6, and Figure 7**). While the sample size is notably different at months 24 and 36, improvements in scores continued to be seen, with the largest increase at 36 months.



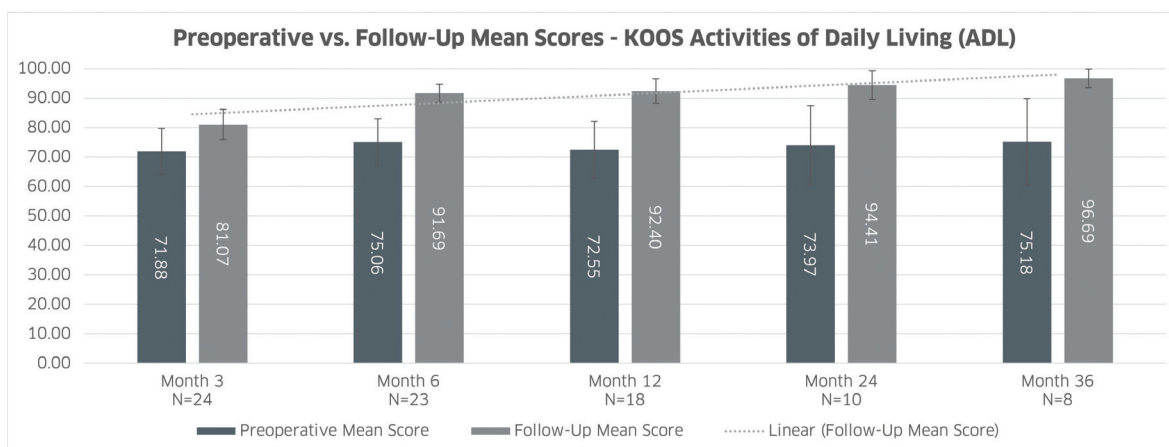
**Figure 1.** Displays comparisons in mean scores from each preoperative and corresponding follow-up timepoints. Mean scores improved from preoperative scores to follow-up scores, except for the month 3 follow-up. There is also a trend of follow-up scores generally improving at each subsequent timepoint which includes an 86.3% increase from preoperative scores at 36 months follow-up.



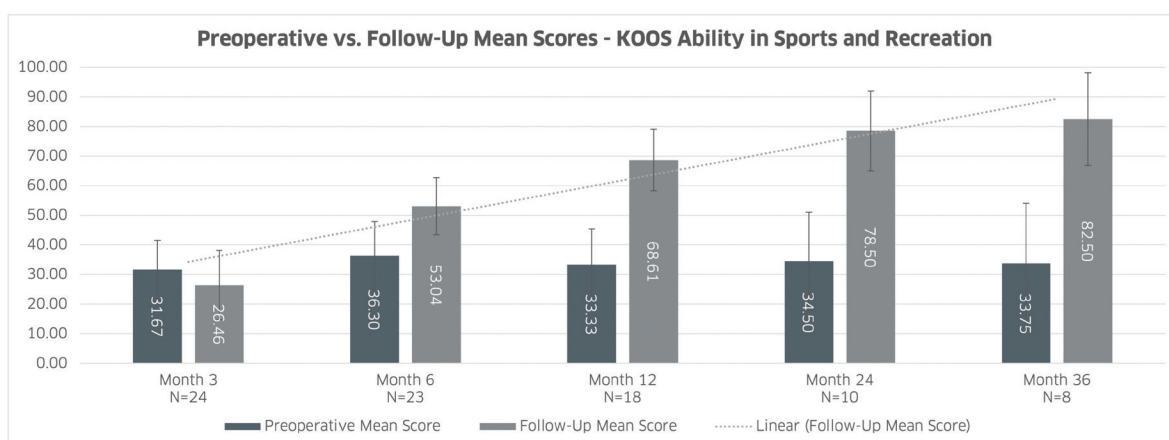
**Figure 2.** A 52.2% increase was seen at 36 months follow-up from preoperative scores for KOOS Pain scores.



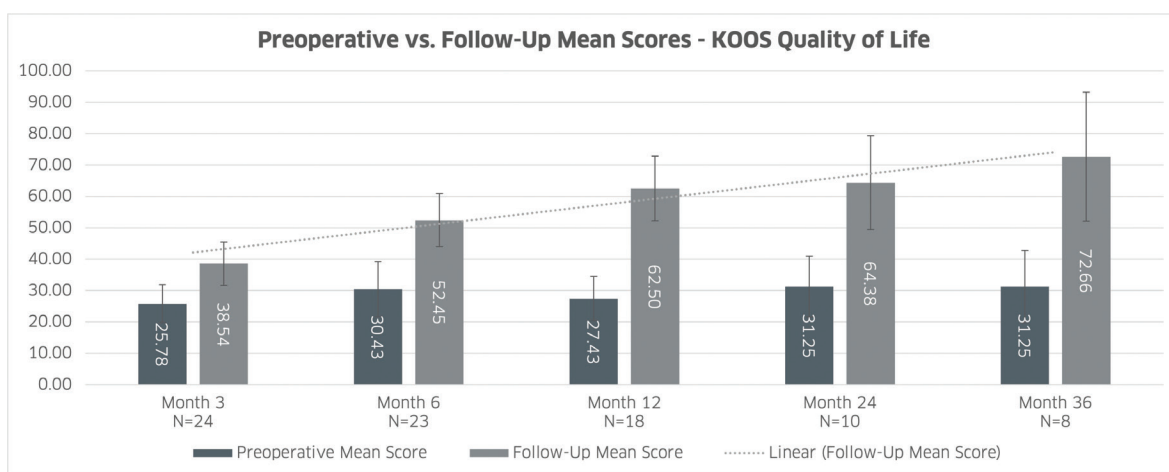
**Figure 3.** A 37.7% increase was seen at 36 months follow-up from preoperative scores for KOOS Symptom scores.



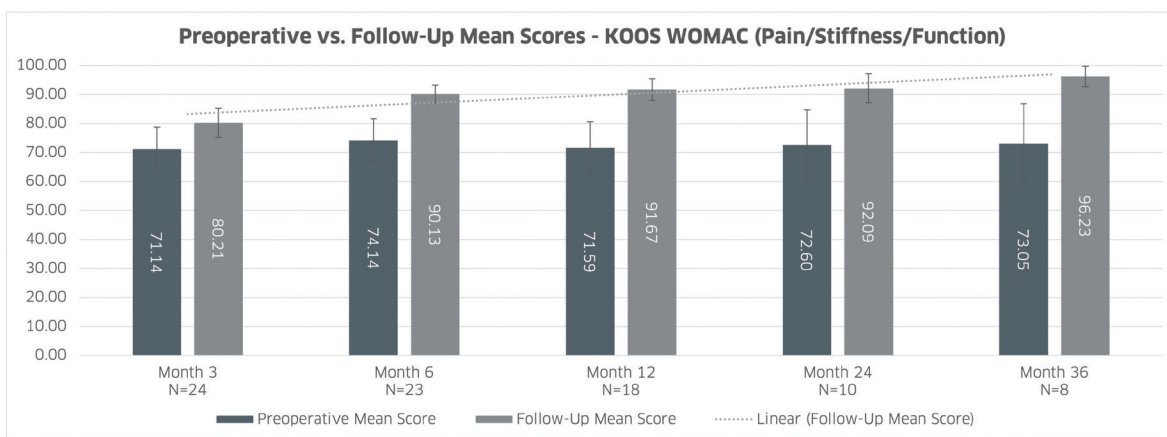
**Figure 4.** A 28.6% increase was seen at 36 months follow-up from preoperative scores for KOOS ADL scores.



**Figure 5.** A 144.4% increase was seen at 36 months follow-up from preoperative scores for KOOS Ability in Sports and Recreation scores.



**Figure 6.** A 132.5% increase was seen at 36 months follow-up from preoperative scores for KOOS Quality of Life scores.



**Figure 7.** A 31.7% increase was seen at 36 months follow-up from preoperative scores for KOOS WOMAC scores.

## DISCUSSION

Patients showed sustained positive results for IKDC and KOOS scores when PROCR grafts were implanted with statistical significance achieved at the 6-, 12-, 24- and 36- months postoperatively. Most notably at 36 months, IKDC scores improved by 86.3% and KOOS Quality of life scores improved by 132.5% from preoperative scores.

There are many options for cartilage repair or replacement and osteochondral allografts remain the only technique that restores the natural biology and architecture of the articular cartilage in the joint with living mature hyaline cartilage.<sup>1</sup> Osteochondral allografting is the transplantation of healthy living cartilage. Cells must be kept viable and functional with cold storage post recovery until transplantation occurs for this procedure to be successful. PROCR has demonstrated its ability to maintain chondrocyte viability, functionality and its ability to maintain the collagen extracellular matrix after 2 years of cryopreserved storage in basic science testing.<sup>4</sup>

While cryopreserved osteochondral allografts, such as PROCR, have limited clinical data, this study suggests that they could be a suitable treatment option of focal cartilage lesions in the patella and femoral condyle joints. PROCR provides advantages over other treatment options including eliminating the need for donor site morbidity as seen with autografts, ensuring single-stage surgical procedure and allowing the storage of grafts for up to 2 years. These advantages make it a more accessible OCA graft for patients needing cartilage defect repair.

## CONCLUSION

In conclusion, PROCR demonstrated positive, short-term, prospective, clinically reported patient outcomes in focal cartilage lesions of the patella and femoral condyle in the knee. However, this is still an ongoing study which will require more time and data to be collected for confirmation of the longer-term results.

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