

Patient-Reported Outcomes and Factors Associated with Achieving the Minimal Clinically Important Difference After ACL Reconstruction

Results at a Mean 7.7-Year Follow-up

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Background: Analyzing outcomes and the minimal clinically important difference (MCID) after anterior cruciate ligament reconstruction (ACLR) is of increased interest in the orthopaedic literature. The purposes of this study were to report outcomes after ACLR at medium to long-term follow-up, identify the threshold preoperative outcome values that would be predictive of achieving the MCID postoperatively, and analyze outcome maintenance at medium to long-term follow-up after ACLR.

Methods: Active athletes who underwent ACLR were identified in an institutional ACL registry. Patient-reported outcome measures (PROMs) were administered preoperatively and at the 2-year and >5-year postoperative follow-up; measures included the International Knee Documentation Committee (IKDC) form, the 12-item Short Form Health Survey (SF-12) Physical Component Summary (PCS) and Mental Component Summary (MCS), and Lysholm scale. We calculated the MCID from baseline to each of the 2 follow-up periods (2-year and mean 7.7-year). Logistic regression was performed to investigate factors associated with achievement of the MCID.

Results: A total of 142 patients (mean follow-up, 7.7 years [range, 6.6 to 9.1 years]) underwent ACLR. The mean age and body mass index at the time of surgery were 27.2 ± 13.0 years and 23.2 ± 3.0 kg/m², respectively. Final postoperative outcome scores improved significantly from baseline for the IKDC (50.9 ± 14.7 to 87.9 ± 11.2), SF-12 PCS (41.6 ± 8.9 to 55.6 ± 3.2), and Lysholm scale (62.2 ± 17.6 to 90.5 ± 10.3) (p < 0.0001), while the SF-12 MCS did not improve significantly (54.2 ± 8.0 to 54.4 ± 6.0) (p = 0.763). Between 2- and >5-year follow-up, the SF-12 PCS showed significant improvement (54.6 ± 4.5 to 55.6 ± 3.2 ; p = 0.036), while no change was noted in the IKDC (87.6 ± 11.1 to 87.9 ± 11.2), SF-12 MCS (55.5 ± 5.3 to 54.4 ± 6.0), and Lysholm scale (89.8 ± 10.6 to 90.5 ± 10.3) (p ≥ 0.09). At the time of final follow-up, the MCID was achieved by 94.7% of patients for the IKDC, 80.8% for the Lysholm, 79.0% for the SF-12 PCS, and 28.2% for the SF-12 MCS. At 2-year follow-up, 95.3% of patients were either "very" or "somewhat" satisfied with their surgery, compared with 88.6\% at the time of final follow-up.

Conclusions: We found a high level of maintained function following ACLR. The IKDC, SF-12 PCS, and Lysholm scores improved significantly after ACLR at the time of final follow-up and were not significantly different between follow-up periods. Approximately 95% and 89% of patients reported being satisfied with the outcome of surgery at the 2-year and final follow-up, respectively.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

A nterior cruciate ligament reconstruction (ACLR) is commonly performed to restore knee stability, improve function, relieve pain, and return recreational and competitive athletes to sports^{1,2}. Patients and surgeons are increasingly looking to preoperative metrics to predict the likelihood of achieving a satisfactory outcome after ACLR³⁻⁶. To accomplish this, patient-

*A list of the HSS ACL Registry Group members is provided in a Note at the end of the article.

Disclosure: The Disclosure of Potential Conflicts of Interest forms are provided with the online version of the article (http://links.lww.com/JBJSOA/A337).

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reported outcome measures (PROMs), such as the International Knee Documentation Committee (IKDC) Subjective Knee Evaluation, the 12-item Short Form Health Survey (SF-12), and the Lysholm scale, have become widely used as benchmarks to measure postoperative improvement⁷. These questionnaires are readily administered to patients in the preoperative setting and can be followed longitudinally at prescribed intervals during the postoperative period.

The minimal clinically important difference (MCID) is most often defined as the smallest change in outcome that a patient is able to perceive and appreciate⁸⁻¹⁰. Often, for setting guidelines and flagging ineffective treatments, the MCID is a useful tool for determining the efficacy of a treatment, shifting focus from statistical significance to clinical value¹⁰. While others have used PROMs to predict which patients will achieve the MCID at early follow-up, there is currently a paucity of literature predicting achievement of the MCID in ACLR patients at later follow-up^{4.5}.

The purposes of the current study were to (1) report outcomes after ACLR at medium to long-term follow-up, (2) identify threshold preoperative PROMs predictive of achieving the MCID after ACLR, and (3) analyze outcome maintenance from early to medium and long-term follow-up after ACLR. We hypothesized that (1) patient satisfaction would be high and there would be significant improvement in PROMs, (2) threshold preoperative outcome scores that are predictive of postoperative outcome could be defined, and (3) there would be maintenance of achievement of the MCID from early to medium/long-term follow-up.

Materials and Methods

Patients who underwent primary ACLR were prospectively enrolled in an institutional ACL registry from 2009 to 2013. Institutional review board approval was obtained for database querying and to contact patients for follow-up.

Key demographic and clinical variables as well as PROMs were recorded preoperatively and at the 6-month, 1-year, 2-year, and >5-year postoperative follow-ups. Demographic and clinical variables recorded in the registry include age, sex, race/ethnicity, sports participation, mechanism of injury, laterality, graft type, and presence of meniscal tears. PROMs recorded in the registry include the IKDC Subjective Knee Evaluation, the SF-12 Physical Component Summary (PCS) and Mental Component Summary (MCS), the Lysholm scale, and the Marx Activity Scale. Similar to use of the Single Assessment Numeric Evaluation (SANE), patients were also asked to score their knee function on a scale of 0 to 100, with 0 being the worst it has been and 100 being the best it has been ("knee grade").

There were 2,324 ACLRs performed during the study period by 24 fellowship-trained sports medicine surgeons. The registry was queried for active athletes, defined as patients with a maximum score on the Marx Activity Scale. Patients achieving a maximum Marx Activity Scale score are those who participated in sports ≥4 times per week prior to their injured state. A total of 294 patients from 19 surgeons were identified as being eligible for the study. Because of the methods for registry

TABLE I Demographic Cha	racteri	stics*			
	No.	%	Mean	SD	Range
Total	142	100.0			
Age (yr)	142	100.0	27.2	13.0	13-63
BMI (kg/m^2)	135	95.1	23.2	3.0	15.7-31.3
Laterality					
Left	78	54.9			
Right	64	45.1			
Sex					
Female	71	50.0			
Male	71	50.0			
Race/ethnicity					
White	123	86.6			
Black or African American	5	3.5			
Asian or Pacific Islander	6	4.2			
Hispanic	6	4.2			
Other	1	0.7			
Missing	1	0.7			
Sport					
Soccer	43	30.3			
Skiing	40	28.2			
Basketball	25	17.6			
Lacrosse	13	9.2			
Football	9	6.3			
Tennis	7	4.9			
Badminton	2	1.4			
Missing	3	2.1			
Injury mechanism					
Non-contact	102	71.8			
Contact	37	26.1			
Missing	3	2.1			
Meniscal pathology					
Lateral	32	22.5			
Medial	26	18.3			
Both	18	12.7			
None	54	38.0			
Missing	12	8.5			
Another knee surgery					
No	111	78.2			
Yes	31	21.8			
Treatment					
No	2	1.4			
Yes, same knee	16	11.3			
Yes, contralateral knee	13	9.2			
Graft					
BTB autograft	74	52.1			
HT autograft	33	23.2			
Allograft	25	17.6			
Missing	10	7.0			

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*SD = standard deviation, BMI = body mass index, BTB = bone-tendonbone, and HT = hamstring tendon.

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TABLE II Cha Pos	ange i stoper	n PROM ative Fo	s from llow-up	Preope *	eratively	to Final	I
	No.	%	Mean	SD	Min.	Max.	P Value
Follow-up duration (mo)	142	100.0	92.9	8.7	79.0	109.0	
IKDC							
Preop.	141	99.3	50.9	14.7	13.8	88.5	
Postop.	132	93.0	87.9	11.2	42.5	100.0	
Net change	131	92.3	36.9	17.4	-33.4	73.6	<0.0001
SF-12 MCS							
Preop.	136	95.8	54.2	8.0	27.3	69.1	
Postop.	130	91.5	54.4	6.0	29.8	62.8	
Net change	124	87.3	0.4	9.3	-28.3	23.8	0.763
SF-12 PCS							
Preop.	136	95.8	41.6	8.9	25.3	60.2	
Postop.	130	91.5	55.6	3.2	36.8	61.5	
Net change	124	87.3	13.7	9.6	-10.1	31.2	<0.0001
Lysholm scale							
Preop.	141	99.3	62.2	17.6	21.0	100.0	
Postop.	121	85.2	90.5	10.3	55.0	100.0	
Net change	120	84.5	27.9	20.2	-32.0	74.0	<0.0001
*PROMs = p	atient	-reported	d outco	me me	easures,	SD = s	standard

deviation, IKDC = International Knee Documentation Committee, SF-12 = 12-item Short Form Health Survey, PCS = Physical Component Summary, and MCS = Mental Component Summary.

tracking and data recording, we are unable to provide details regarding the patients who did not meet the inclusion criteria. Patients were contacted by mail and/or telephone by 1 of the authors who had no involvement in the data analysis. Patients were asked to report subsequent knee surgery on the operative or contralateral extremity and to rate their satisfaction with the outcome of their ACLR on an ordinal satisfaction scale: very satisfied, somewhat satisfied, neither satisfied nor dissatisfied, somewhat dissatisfied, or very dissatisfied. Use of this satisfaction scale has been previously reported in the sports medicine literature^{5,11}. There were 142 patients who reported preoperative PROMs in their injured state (completed in the time period between injury and surgery) as well as had a minimum of 2-year and >5-year follow-up (final follow-up).

Statistical Analysis

Data analysis was performed using SAS software, version 9.4 (SAS Institute). The threshold for statistical significance indicating clinical importance was p < 0.05. The Wilcoxon matchedpair signed-rank test was used for statistical comparison of continuous variables, including preoperative versus postoperative and 2-year versus >5-year PROMs. The chi-square test was used for statistical comparison of categorical variables, including patient satisfaction between 2-year and final follow-ups.

The MCID is calculated using either a distribution, anchor, or consensus method $^{\!\!\!^{8-10}}$. For this study, the distribution method

was selected, and the MCID was calculated using half the standard deviation of the difference in outcome scores for each PROM instrument^{3,12-15}. For each PROM instrument, we calculated the MCID from baseline to 2-year and final follow-ups. In addition, to evaluate whether there are preoperative patient-reported outcome scores that could be predictive of achieving the MCID, threshold analyses were performed. Receiver operating characteristic (ROC) curve calculations with area under the curve (AUC) analysis were performed to determine whether threshold preoperative scores could be identified that significantly differentiated patients who did and did not achieve the MCID. Once threshold values were identified, an AUC of \geq 0.7 was used to determine whether these threshold values were significantly predictive.

Univariate and multivariate logistical regression analysis was performed to investigate demographic and clinical factors associated with increased or decreased odds of achieving the MCID. Demographic factors, including age and body mass index (BMI), were assessed as continuous variables, while race/ ethnicity (White versus non-White), sport (cutting sports, including soccer, lacrosse, football, and basketball, versus skiing and racket sports), and sex were assessed as categorical variables. Clinical factors including duration of follow-up and preoperative PROMs were assessed as continuous variables, while mechanism of injury (contact versus non-contact), laterality, graft type, meniscus pathology, and subsequent knee surgery were assessed as categorical variables. Multivariate logistical regression analysis was performed on variables that achieved a p value of <0.15 during univariate analysis. Odds ratios (ORs) were calculated only for significant predictors in multivariate logistical regression analysis.

Source of Funding

No external funding was received in support of this study.

Results

Demographics of Included Patients

O ne hundred and forty-two patients completed final followup, at a mean of 7.7 years postoperatively (range, 6.6 to 9.1 years). The mean age at the time of surgery (and standard deviation) was 27.2 ± 13.0 years (range, 13 to 63 years). Fifty percent of the patients were female, the mean BMI was 23.2 ± 3.0 kg/m² (range, 15.7 to 31.3 kg/m²), and 86.6% of the patients were White. Participation in soccer was most common (30.3%), followed by skiing (28.2%) and basketball (17.6%). The majority of injuries (71.8%) resulted from a non-contact mechanism. Meniscal tears were identified in 76 (53.5%) of the patients, involving the lateral meniscus only (n = 32, 22.5%), medial meniscus only (n = 26, 18.3%), and both menisci (n = 18, 12.7%) (Table I).

PROMs

Compared with baseline measures, the mean postoperative IKDC, SF-12 PCS, and Lysholm scale scores improved significantly (p < 0.0001), while the SF-12 MCS did not improve significantly (p = 0.763) at the time of final follow-up (Table II). The mean postoperative knee grade score was 85.4 ± 14.2 (range,

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Fig. 1

Change in mean IKDC, Lysholm scale, SF-12 MCS, and SF-12 PCS scores over time. Error bars represent 1 standard deviation. Asterisks indicate significance as follows: *baseline to 2-year (p < 0.001) and baseline to final follow-up (p < 0.0001); **baseline to 2-year (p < 0.001), baseline to final follow-up (p < 0.0001), and 2-year to final follow-up (p < 0.05). The Wilcoxon matched-pair signed-rank test was used for comparison between the follow-up periods.

20 to 100), but no comparison to the preoperative state was performed because the score was not collected preoperatively in the registry. Comparing scores between 2-year and final follow-up, no significant changes were observed in the mean IKDC, SF-12 MCS, or Lysholm scores (p > 0.05) (Fig. 1). By contrast, the SF-12 PCS improved significantly (p = 0.036), while knee grade (p = 0.001) scores were significantly worse between 2-year and final follow-up (Table III).

Patient Satisfaction

Among patients who responded to the satisfaction question, 95.3% reported being "very satisfied" or "somewhat satisfied" with the outcome of surgery at the 2-year follow-up compared with 88.7% of patients at the >5-year follow-up. There was a significant decrease in the number of patients reporting that they were "very satisfied" between 2- and >5-year follow-up (p < 0.0001) (Table IV).

MCID

The MCIDs calculated using the distribution method at 2-year and final follow-up are reported in Table V. The postoperative MCID decreased for all PROMs between 2-year and final follow-up. ROC curve analysis for preoperative PROMs revealed that scoring below the following values was predictive of achieving the MCID: IKDC, 62.1 (AUC, 0.952), SF-12 PCS, 50.3 (AUC, 0.988), SF-12 MCS, 53.2 (AUC, 0.949), and Lysholm, 74.0 (AUC, 0.933). At mean 7.7-year follow-up, threshold postoperative scores for the MCID were achieved by 94.7% of patients for the IKDC,

80.8% for the Lysholm, 79.0% for the SF-12 PCS, and 28.2% for the SF-12 MCS scores.

Univariate and Multivariate Logistical Regression Analyses

Logistical regression analyses were used to identify patient and surgical variables associated with achieving the MCID at the time of final follow-up. In the univariate analysis, the presence of any meniscal tear was associated with significantly decreased odds of achieving the MCID for the IKDC score (p = 0.022); however, this association was not significant in the multivariate analysis. On multivariate analysis, higher preoperative IKDC, SF-12 MCS, SF-12 PCS, and Lysholm scores were associated with significantly decreased odds of achieving the MCID for the IKDC (OR = 0.83, 95% confidence interval [CI] = 0.72 to 0.96; p = 0.01), SF-12 MCS (OR = 0.62, 95% CI = 0.50 to 0.76; p < 0.0001), SF-12 PCS (OR = 0.49, 95% CI = 0.33 to 0.74; p = 0.001), and Lysholm (OR = 0.82, 95% CI = 0.75 to 0.89; p < 0.0001) scores, respectively. Additionally, patients with skiing as their primary sport had significantly increased odds of achieving the MCID for the Lysholm score compared with those participating primarily in cutting sports including soccer, lacrosse, football, and basketball (OR = 43.4, 95% CI = 2.0 to 927.8).

Discussion

In this study, we analyzed outcomes at medium to long-term follow-up (mean, 7.7 years) in an active cohort of patients who underwent ACLR. We confirmed our hypotheses that there would be significant improvement in PROMs, high

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TABLE III Cha era	ange ir tive Fo	n PROM pllow-up	ls Betw)*	een 2-1	(ear an	d Final P	ostop-
	No.	%	Mean	SD	Min.	Max.	P Value
IKDC							
2-yr	141	99.3	87.6	11.1	47.1	100.0	
5-yr	132	93.0	87.9	11.2	42.5	100.0	
Net change	132	93.0	0.4	15.0	-2.9	2.2	0.972
SF-12 MCS							
2-yr	137	96.5	55.5	5.3	33.5	63.8	
5-yr	130	91.5	54.4	6.0	29.8	62.8	
Net change	126	88.7	-1.2	8.0	-0.2	2.6	0.090
SF-12 PCS							
2-yr	137	96.5	54.6	4.5	35.1	63.2	
5-yr	130	91.5	55.6	3.2	36.8	61.5	
Net change	126	88.7	1.0	5.0	-1.9	-0.1	0.036
Lysholm scale							
2-yr	139	97.9	89.8	10.6	55.0	100.0	
5-yr	121	85.2	90.5	10.3	55.0	100.0	
Net change	119	83.8	0.9	13.9	-3.5	1.6	0.672
Knee grade							
2-yr	141	99.3	89.1	12.8	5.0	100.0	
5-yr	141	99.3	85.4	14.2	20.0	100.0	
Net change	140	98.6	-3.8	14.2	1.4	6.1	0.001
*PROMs = pa deviation, IKD	atient-r C = In	eporteo ternatio	l outcor onal Kne	ne mea e Docu	asures, imenta	SD = s tion Com	tandard mittee,

SF-12 = 12-item Short Form Health Survey, PCS = Physical Component Summary, and MCS = Mental Component Summary.

patient satisfaction, and a high rate of achievement of the MCID as well as maintenance of the MCID out to medium/ long-term.

Patients improved from baseline to final follow-up with respect to IKDC, SF-12 PCS, and Lysholm scale scores. From the 2-year to the final follow-up, these scores did not differ significantly other than in the SF-12 PCS, which improved, and knee grade, which slightly worsened over that time period.

There is evidence that maximum improvement after ACLR occurs around 1 year postoperatively, and this study demonstrates that improvements are largely preserved at a mean follow-up of 7.7 years¹⁶. The MOON (Multicenter Orthopaedic Outcomes Network) group also noted that patient-reported outcome scores were improved at 2 years and preserved at 6 and 10 years postoperatively². The mean IKDC score for our cohort was similar to theirs (88 versus 86) at the time of final follow-up. Additionally, there is a paucity of literature examining the SF-12 MCS and PCS scores after ACLR. This includes defining the MCID for the SF-12 MCS and PCS as well as their results at midterm follow-up. This study adds to the literature by serving as a potential reference for further studies.

While the rate of patients who were "very satisfied" decreased from 2-year to final follow-up, from 74.6% to 65.5%, the vast majority of patients (88.6%) were either "very satis-

fied" or "somewhat satisfied" at the time of final follow-up. In a systematic review, Kahlenberg et al.¹¹ demonstrated that reporting on satisfaction after ACLR has declined in the past decade. As health care moves toward valuing care from the patient's perspective, it is increasingly important to demonstrate that a given procedure increases patient satisfaction^{17,18}. This study demonstrates that ACLR leads to high levels of patient satisfaction at a mean follow-up of 7.7 years. Despite high satisfaction, it is interesting to note that the proportion of patients who reported they were "very satisfied" with the surgery declined between the 2 follow-up periods. This may be related to the known sequelae of early posttraumatic osteoarthritis that has been shown to occur in patients who experience an ACL tear and reconstruction^{19,20}. Further research should be conducted to determine the variables that patients consider in terms of satisfaction following ACLR.

The threshold MCID value decreased for all outcome scores from 2-year to final follow-up. Prior studies have examined the MCID for the IKDC form for a mix of pathological conditions, but there is limited evidence examining the MCID after ACLR²¹. The MCIDs at final postoperative follow-up were similar to those of a previous study examining 231 patients with 2-year follow-up (8.7 versus 9.0 for the IKDC, 4.7 versus 4.3 for the SF-12 MCS, 4.8 versus 5.2 for the SF-12 PCS, and 10.1 versus 10.0 for the Lysholm scale, respectively)²². This is the first study, to our knowledge, to examine the MCID at longer-term follow-up after ACLR and demonstrates that a majority of patients achieved the MCID for the IKDC (94.7%), the Lysholm scale (80.8%), and the SF-12 PCS (79%), but only 28.2% achieved the MCID for the SF-12 MCS. The lack of MCID achievement for the SF-12 MCS is likely explained by the fact that the SF-12 MCS is a relatively stable construct that is intrinsic to the patient and less likely to change with surgical intervention.

The preoperative threshold values for achieving the MCID are useful for preoperative counseling of patients. It is increasingly recognized that more focus should be placed on achieving clinically important differences than just significant differences. It is encouraging for surgeons and patients to know that those with lower scores preoperatively are more likely to clinically benefit from ACLR. Similarly, Chen et al.⁴ demonstrated that lower PROMIS (Patient-Reported Outcomes Measurement Information

TABLE IV Postoperative Patient S	TABLE IV Postoperative Patient Satisfaction			
	2	-Yr	>!	5-Yr
	No.	%	No.	%
Very satisfied	106	74.6	93	65.5
Somewhat satisfied	16	11.3	32	22.5
Neither satisfied nor dissatisfied	1	0.7	2	1.4
Somewhat dissatisfied	5	3.5	11	7.7
Very dissatisfied	0	0.0	3	2.1
Missing	14	9.9	1	0.7

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TABLE V MCID Postoperative Threshold Values and Achievement*						
	2-Yr MCID Threshold	2-Yr % Achieved	>5-Yr MCID Threshold	>5 Yr % Achieved		
IKDC	9.5	92.9	8.7	94.7		
SF-12 MCS	5.1	31.3	4.7	28.2		
SF-12 PCS	5.2	76.3	4.8	79.0		
Lysholm	10.6	81.2	10.1	80.8		

*MCID = minimal clinically important difference, IKDC = International Knee Documentation Committee, SF-12 = 12-item Short Form Health Survey, PCS = Physical Component Summary, and MCS = Mental Component Summary.

System) physical function scores preoperatively were associated with an increased likelihood of achieving the MCID postoperatively. Conversely, it is also important for patients and surgeons to understand that higher preoperative scores correlate negatively with achieving the MCID. This finding may be subject to a ceiling effect, in that patients who start with higher scores have less room for improvement (and therefore for reaching the MCID).

An additional distinction of this study compared with others is the inclusion criterion of a maximum score on the Marx Activity Scale preoperatively, indicating that the patients are very active at baseline (preinjury state). By contrast, the MOON study with 10-year follow-up included patients with a preoperative Marx Activity Scale score ranging from 8 to 16². Furthermore, the type of sport has been shown to have an effect on outcomes after ACLR. On multivariate analysis, patients whose primary sport was skiing had increased odds of achieving the MCID for the Lysholm score compared with those who primarily participated in cutting sports. Skiing and snowboarding have previously been identified with a high rate of return to sport and previous performance levels²³. This information can also be utilized in preoperative counseling of patients based on their primary sport.

This study had several limitations. We used an institutional registry, which includes ACLRs performed by 24 surgeons; there is, therefore, heterogeneity in graft choice, surgical technique, treatment of meniscal tears, and postoperative rehabilitation. Additionally, the role of preoperative physical therapy was not accounted for in this cohort. Patients who participate in post-injury but presurgical physical therapy may have improved baseline PROMs, which could confound the results of predicting the MCID. Baseline PROMs were obtained at the patients' first visit with the orthopaedic surgeon, but there could be a subset of patients who were already participating in physical therapy prior to being evaluated. Given that our study was a retrospective review of prospectively collected data, the MCID was calculated using a distribution method. This precluded us from performing any sensitivity analysis around the MCID values as there was no opportunity to introduce an anchor question.

Conclusions

We found a high level of maintained function at >5 years following ACL reconstruction—specifically, the IKDC, SF-12 PCS, and Lysholm scores showed significant improvement after ACLR at >5-year follow-up, and overall outcomes did not differ significantly between 2- and >5-year follow-up. Approximately 95% of the patients reported being satisfied with the outcome of surgery at 2-year follow-up, and this had only diminished to 89% by final follow-up. The high percentage of patients achieving the MCID remained consistent from 2-year to final follow-up, indicating clinical outcome maintenance in the medium to long term.

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