AJSM PreView, published on May 14, 2015 as doi:10.1177/0363546515584041

Proportion of Patients Reporting Acceptable Symptoms or Treatment Failure and Their Associated KOOS Values at 6 to 24 Months After Anterior Cruciate Ligament Reconstruction

A Study From the Norwegian Knee Ligament Registry

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Background: The proportion of patients perceiving their symptoms as either acceptable or as a failure of treatment after anterior cruciate ligament reconstruction (ACLR) is unknown. Commonly used outcome scores such as the Knee injury and Osteoarthritis Outcome Score (KOOS) suffer from poor interpretability, and little is known about which scores represent an acceptable or failed postoperative outcome.

Purpose: To determine the proportion of patients reporting acceptable symptoms or treatment failure at 6 to 24 months after ACLR and to define KOOS values corresponding to the patients' perceptions of treatment outcome.

Study Design: Cross-sectional study; Level of evidence, 3.

Methods: In 2012, a total of 1197 patients were randomly extracted from the Norwegian Knee Ligament Registry at 3 postoperative time points: 397 at 6 months, 400 at 12 months, and 400 at 24 months. The inclusion criterion was unilateral primary ACLR. Questions about acceptable symptoms and treatment failure and the KOOS questionnaire were sent to the patients, and those who answered ''yes'' to the acceptable symptoms question were considered to have acceptable symptoms. Patients who answered ''no'' to the same question and ''yes'' to the treatment failure question were considered to have treatment failure. Mean KOOS values and 95% CIs were calculated for each category.

Results: A complete data set was obtained from 598 (50%) responders. Fifty-five percent of the patients perceived their symptoms as acceptable at 6-month follow-up versus 66% at 12- to 24-month follow-up. Similarly, 7% at 6-month follow-up perceived their treatment to have failed versus 12% at 12- to 24-month follow-up. Postoperative mean KOOS subscale values ranged from 72 (95% CI, 70-74) to 95 (95% CI, 94-96) for patients with acceptable symptoms and from 28 (95% CI, 22-34) to 71 (95% CI, 65-76) for patients with treatment failure. For both categories, the worst subscale values were seen in the sport and recreation and quality of life subscales and the best in the activities of daily living subscale.

Conclusion: Only half of the patients at 6 months and about two-thirds at 1 to 2 years perceived their symptoms as acceptable after ACLR. For these patients, KOOS values reflected no problems to mild problems on average, while for patients reporting treatment failure, KOOS values reflected moderate to severe problems.

Keywords: anterior cruciate ligament reconstruction; patient acceptable symptom state; treatment failure; Knee injury and Osteoarthritis Outcome Score

Patient-reported outcome (PRO) measures are advocated to investigate treatment outcomes from the patient's point of view after anterior cruciate ligament reconstruction (ACLR).[10,15] Recently, Lynch et al,[10] in a consensus report, suggested PRO threshold scores between 85 and 90 on a 0-to-100 (worst to best) scale as a cutoff for a successful outcome. Another approach was taken by Barenius et al,[3] who investigated the rates of functional recovery and treatment failure in patients included in the Swedish National Knee

The American Journal of Sports Medicine, Vol. XX, No. X
DOI: 10.1177/0363546515584041

Ligament Register who had undergone ACLR. They defined functional recovery as scores ranging from 81 to 91, corresponding to the lower 95% CI of the general population for a commonly used PRO, the Knee injury and Osteoarthritis Outcome Score (KOOS).[12] Treatment failure was defined as a KOOS quality of life (QOL) subscale value of <44 points.[3] Using these cutoffs, about 20% perceived their postoperative outcome to be a treatment success and 30% a treatment failure at 2 years, indicating a far from optimal outcome after ACLR.[3] However, it is not known if these KOOS cutoffs correspond to the patients' own perception of acceptable symptoms and treatment failure after ACLR. Asking the patients themselves would clarify the patients' own perception of the overall treatment outcome after ACLR.

The KOOS is commonly used to evaluate outcomes after ACLR. KOOS data from more than 60,000 patients are available from ACL registries in Sweden, Norway, Denmark, the United States, the United Kingdom, and Australia (E. Roos, unpublished data). Data from these registries show postoperative mean KOOS values corresponding approximately to mild pain (mean range, 84-89), moderate to mild symptoms (mean range, 60-86), no problems with activities of daily living (ADL) (mean range, 90-97), moderate to mild problems with sport and recreation (Sport/Rec) (mean range, 63-78), and moderate to mild reductions in knee-related QOL (mean range, 60-69) at 1 to 2 years after reconstructive surgery.[5,9] Establishing postoperative KOOS values corresponding to the patients' own perception of treatment outcome would improve the interpretability of KOOS values and allow for a more accurate comparison of outcomes across ACL studies.

The purpose of this study was to determine the proportion of patients perceiving their symptoms as acceptable versus the treatment having failed at 6 to 24 months after ACLR. The second purpose was to define KOOS values that correspond to the patients' perception of their treatment outcome as either having achieved an acceptable level of symptoms or as treatment failure.

METHODS

Design and Setting

The study used a cross-sectional approach. Postoperative data were obtained from patients included in the Norwegian Knee Ligament Registry (NKLR).[7] This register includes nationwide data, with high data completeness for surgical data (90%) but only moderate completeness for patient-reported data at 2 years (65%).[17] The NKLR has received approval from the Norwegian Data Inspectorate as an expansion of the Norwegian Arthroplasty Register concession.[7] Person-sensitive information obtained in this study was handled in accordance with applicable rules and regulations.

Patients

Data were collected in 2012 by randomly extracting 1197 patients from the NKLR at 3 postoperative time points: 397 at 6 months (range, 5-7 months), 400 at 12 months (range, 10-14 months), and 400 at 24 months (range, 20-28 months). The inclusion criterion was patients who had undergone unilateral primary ACLR. Sample size calculation was based on the COSMIN (Consensus-based Standards for the selection of health Measurement Instruments) guidelines, which state that at least 100 patients are recommended for investigating measurement properties.[11] A response rate of 60% was expected.[8] To enable subgroup analyses, the inclusion of at least 250 patients from each time point was considered necessary.

Questionnaires

The patients were sent a postal questionnaire including an explanatory letter, 2 single-item questions, the Norwegian version of the KOOS, and a prepaid envelope. Patients who had not responded after 2 months were sent a reminder. No further action was taken to include nonresponders.

The first single-item question asked about the "patient acceptable symptom state" and was an adaptation of the original question used for rheumatology patients.[16] This question was reworded and adapted for patients having undergone ACLR: "Considering your knee function, do you feel that your current state is satisfactory? With *knee function*, you should take into account all activities during your daily life, sport and recreational activities, your level of pain and other symptoms, and also your knee-related quality of life." The question was answered by selecting either the "yes" or "no" box. Patients who answered "no" were asked to complete the second single-item question, relating to treatment failure: "Would you consider your current state as being so unsatisfactory that you think the treatment has failed?" This question was also answered by selecting either the "yes" or "no" box. Finally, the patients filled out the KOOS questionnaire, a 42-item PRO in which the 5 subscales are scored separately on a 0-to-100 (worst to best) scale: pain, symptoms, ADL, Sport/Rec, and QOL.[14] By definition, a mean KOOS subscale value of 0 corresponds to extreme problems, a value of 25 to

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One or more of the authors has declared the following potential conflict of interest or source of funding: This research was funded by the Danish Rheumatism Association and the Region of Southern Denmark.

severe problems, a value of 50 to moderate problems, a value of 75 to mild problems, and a value of 100 to no problems.

Statistical Analysis

The patients were categorized into 3 groups based on their responses to the 2 single-item questions regarding the patient acceptable symptom state and treatment failure, respectively. The patients who answered "yes" to the acceptable symptoms question were considered to have acceptable symptoms. The subgroup of patients who answered "no" to the same question and "yes" to the treatment failure question was considered to have treatment failure. The remaining patients constituted an undecided intermediate group, defined as having neither an acceptable outcome nor treatment failure. The KOOS subscale values for these 3 groups are presented with their means and 95% CIs. Patient characteristics are given as the mean and standard deviation for continuous variables and frequency and percentage distribution for categorical variables. Because data were not normally distributed, we analyzed between-group comparisons by using the Mann-Whitney test for continuous variables and the χ^2 test for dichotomous variables. Missing items in any KOOS subscale were treated according to the rule for handling missing items as described in the 2012 KOOS guidelines.[13] Missing items in the acceptable symptoms question resulted in exclusion from further analysis. All analyses were performed with SPSS (v 19; SPSS Inc).

RESULTS

Included Patients

At the time of data extraction from the NKLR, data from 2298 patients were available for random extraction. Data from 1197 patients were randomly extracted, and 744 patients (62.2% response rate; 51.3% women; mean age, 29.5 years) responded: 246 (62%) on average at 6 months postoperatively, 261 (65.3%) on average at 12 months postoperatively, and 237 (59.3%) on average at 24 months postoperatively. One hundred thirty-nine patients (49 at 6 months, 47 at 12 months, and 43 at 24 months) were excluded from further analyses for not answering the acceptable symptoms question, and a further 7 patients (5 at 12 months and 2 at 24 months) were excluded for not answering the treatment failure question when answering "no" to the acceptable symptoms question. Details are given in Figure 1.

Responders Versus Nonresponders

To allow for a comparison between those responding and those not responding in our study, we compared their preoperative data from the NKLR. Preoperative characteristics of responders with a complete data set, responders without a complete data set, and nonresponders are presented in Table 1. Responders with a complete data set (included in the analysis) compared with responders without a complete data set and nonresponders combined were, on average, 2 years older, and more were women. There were, however, no significant differences in KOOS baseline values between the groups (Table 1).

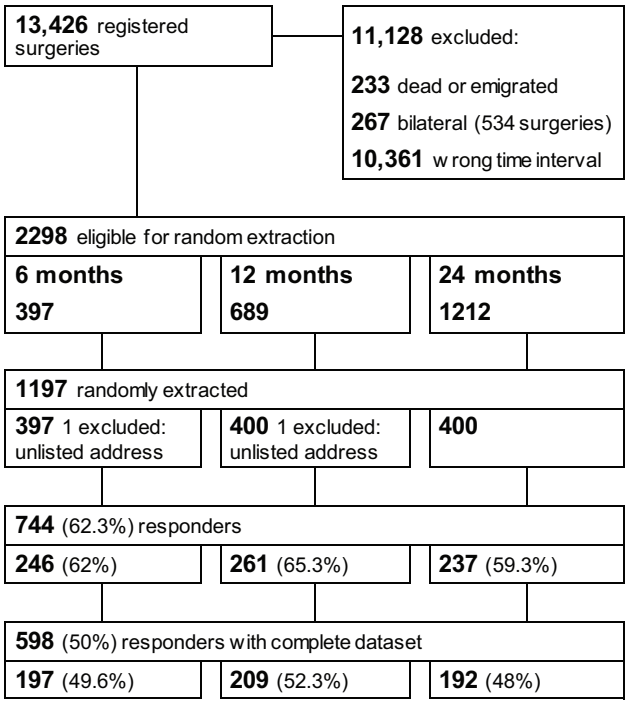

Figure 1. Study flow diagram.

Acceptable Symptoms and Treatment Failure

Patients were categorized into 3 groups: (1) those perceiving their symptoms as being acceptable, (2) those perceiving their treatment had failed, and (3) the undecided intermediate group reporting neither acceptable symptoms nor treatment failure. Fifty-five percent of the patients with a follow-up of 6 months perceived their symptoms as acceptable and 66% with a follow-up of 12 to 24 months. Similarly, 7% of the patients with a follow-up of 6 months perceived their treatment to have failed and 12% with a follow-up of 12 to 24 months. The percentages for the 3 outcome groups at 6, 12, and 24 months postoperatively are given in Figure 2.

KOOS Values

Postoperative mean KOOS values (95% CI) for those perceiving their symptoms as being acceptable, those perceiving their treatment to have failed, and those in the undecided intermediate group perceiving to have neither acceptable symptoms nor treatment failure are given in Table 2. Taken together and for the 3 time points separately, the 95% CIs for the postoperative mean KOOS values did not overlap between the 3 groups reporting acceptable symptoms, treatment failure, or neither (the undecided intermediate group), with 3 exceptions: (1) the ADL subscale, where the 95% CI overlapped between the

TABLE 1
Preoperative Characteristics[a]

	Responders With Complete Data Set (n = 598)	Responders Without Complete Data Set (n = 146)	Nonresponders (n = 453)	*P* Value[b]
Female sex, n (%)	315 (52.7)	67 (45.9)	158 (34.9)	.000[c]
Age, y	29.74 ± 11.50	28.48 ± 12.23	27.42 ± 9.93	.005[d]
Height, cm	174.06 ± 8.91	172.80 ± 8.26	175.35 ± 8.95	.170[d]
Weight, kg	76.61 ± 15.18	74.11 ± 13.82	78.90 ± 16.60	.235[d]
KOOS subscale				
Pain	72.53 ± 19.25	73.51 ± 20.95	71.65 ± 20.35	.993[d]
Symptoms	71.04 ± 18.29	73.82 ± 18.09	71.37 ± 18.60	.325[d]
ADL	81.83 ± 19.32	80.87 ± 20.91	80.23 ± 19.98	.199[d]
Sport/Rec	40.41 ± 27.22	44.19 ± 30.03	42.64 ± 26.59	.151[d]
QOL	33.98 ± 18.07	34.72 ± 21.19	35.16 ± 18.01	.349[d]
Graft type,[e] n (%)				
BPTB	141 (23.9)	37 (25.5)	100 (22.3)	.747[c]
Hamstring	445 (75.4)	105 (72.4)	345 (77.0)	.853[c]
Allograft	2 (0.3)	1 (0.7)	1 (0.2)	
Other	2 (0.3)	1 (0.7)	1 (0.2)	
Unknown	0 (0)	1 (0.7)	1 (0.2)	

[a]Data are reported as mean ± SD unless otherwise indicated. ADL, activities of daily living; BPTB, bone–patellar tendon–bone; KOOS, Knee injury and Osteoarthritis Outcome Score; QOL, quality of life; Sport/Rec, sport and recreation.
[b]Responders with a complete data set versus responders without a complete data set and nonresponders.
[c]χ^2 test.
[d]Mann-Whitney test.
[e]Some patients had missing values for graft choice: 8 in the responders with complete dataset group, 1 in the responders without complete dataset group, and 5 in the nonresponder group.

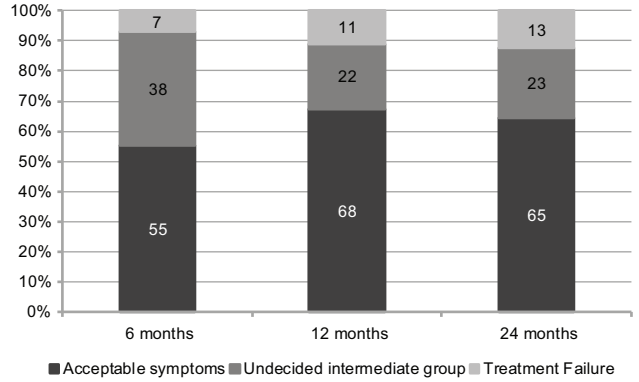

Figure 2. The percentage of patients with acceptable symptoms, those with perceived treatment failure, and those belonging to the undecided intermediate group at 6 to 24 months after anterior cruciate ligament reconstruction.

acceptable symptoms and undecided intermediate groups at 6 months, (2) the undecided intermediate group and treatment failure group at 24 months, and (3) the Sport/Rec subscale, where the 95% CI overlapped between the treatment failure and undecided intermediate groups at 24 months (Table 2).

For patients with acceptable symptoms, the mean KOOS subscale values were some 10 to 20 points higher (ie, better) than for those in the undecided intermediate group not perceiving their symptoms as acceptable. For this group, the mean KOOS subscale values corresponded to, on average, mild to moderate problems. Those patients perceiving their ACLR to have failed had mean KOOS subscale values reflecting moderate to severe problems, with the exception of ADL in which they reported mild problems. For those in the treatment failure group, the mean KOOS values were approximately 10 to 25 points lower (ie, worse) than for patients in the undecided intermediate group not perceiving their symptoms as acceptable (Table 2).

DISCUSSION

Our primary purpose was to determine the proportion of patients who perceived their symptoms as acceptable and, on the contrary, the rate of patients who perceived their treatment to have failed after ACLR. Sixty-six percent of patients perceived their symptoms as acceptable at 12 and 24 months postoperatively, and thus, 34% perceived their symptoms as not being acceptable, including the 12% who perceived their treatment to have failed (Figure 2). The highest proportion of undecided patients was found in the group with 6 months' follow-up. The smaller and similar proportions of the undecided intermediate group (patients neither perceiving their symptoms as acceptable nor the treatment to have failed) at the 12- and 24-month follow-ups seem to indicate that at a group level, the patients' judgments stabilize at 1 year and do not change much from 1 to 2 years postoperatively. In support of this assumption, data from the Swedish National ACL Register showed that the KOOS values do not change much between 1- and 2-year follow-ups.[2] However, because

TABLE 2
Postoperative KOOS Subscale Values for the Acceptable Symptoms, Treatment Failure, and Undecided Groups[a]

	KOOS Subscale				
	Pain	Symptoms	ADL	Sport/Rec	QOL
Acceptable symptoms group					
6-24 mo (n = 362-372)	89 (88-90)	83 (82-85)	95 (94-96)	72 (70-74)	73 (71-75)
6 mo (n = 105-108)	88 (87-90)	83 (80-85)	94 (92-95)	69 (65-73)	72 (69-75)
12 mo (n = 137-141)	88 (86-90)	82 (79-84)	95 (93-96)	70 (66-73)	72 (69-75)
24 mo (n = 120-123)	91 (88-93)	85 (83-88)	96 (94-97)	77 (73-81)	76 (73-79)
Undecided intermediate group					
6-24 mo (n = 158-163)	76 (73-78)	70 (68-73)	86 (83-88)	48 (44-52)	48 (46-51)
6 mo (n = 72-74)	79 (76-83)	73 (69-76)	89 (85-92)	51 (46-57)	51 (47-55)
12 mo (n = 44-45)	77 (73-81)	71 (67-76)	88 (84-92)	51 (44-58)	49 (45-54)
24 mo (n = 42-44)	68 (63-74)	65 (60-71)	78 (73-83)	39 (31-47)	42 (38-47)
Treatment failure group					
6-24 mo (n = 56-61)	57 (52-63)	56 (51-61)	71 (65-76)	28 (22-34)	28 (23-32)
6 mo (n = 12-14)	58 (44-71)	55 (44-66)	69 (55-82)	26 (12-39)	27 (17-37)
12 mo (n = 21-23)	57 (48-66)	55 (48-63)	69 (59-80)	25 (15-35)	24 (17-32)
24 mo (n = 23-24)	58 (48-67)	57 (48-67)	73 (64-82)	33 (22-43)	31 (24-37)

[a]Data are reported as mean (95% CI). ADL, activities of daily living; KOOS, Knee injury and Osteoarthritis Outcome Score; QOL, quality of life; Sport/Rec, sport and recreation.

this is a cross-sectional study, it cannot be determined if a patient has changed his/her judgment over time. It is important to recognize that it was the patients who were asked to judge if they perceived their symptoms as acceptable. The wording of the question was deliberately used to obtain the largest possible group with postoperative symptoms that were perceived as acceptable by patients. Despite this conservative approach, we found that every third patient having undergone ACLR did not perceive their postoperative symptoms as acceptable, indicating either considerable room for improvement of the postoperative outcome or, possibly, that patients have unrealistically high expectations after reconstruction and rehabilitation. If we had asked about full recovery, back to normal, or return to sports activities, this would likely have reduced the proportion of patients achieving a positive outcome after ACLR even further.

We chose to pose the question of acceptable symptoms or treatment failure directly to the patients, which yielded a more optimistic result than that in the Barenius et al[3] study from 2012. In their study from the Swedish National ACL Register, only 20% of the patients were considered to have achieved functional recovery compared with 66% reporting acceptable symptoms in our study. They used the lower 95% CI of population-based KOOS values for men aged 18 to 34 years as their cutoffs for functional recovery.[12] The lower 95% CI for KOOS subscale values corresponding to reporting acceptable symptoms in this study were similar to the cutoffs used by Barenius et al[3] for the KOOS subscales of pain (88 vs 90) symptoms (82 vs 84), and ADL (94 vs 91, respectively), and worse for Sport/Rec (70 vs 80, respectively) and QOL (71 vs 81, respectively). Thus, patients reporting acceptable symptoms after ACLR are within population norms with regard to pain, symptoms, and ADL but worse than population norms with regard to Sport/Rec and QOL. In the Barenius et al[3] study, 30% of patients perceived their postoperative outcomes as treatment failure. They used a KOOS QOL subscale value of <44 points as a cutoff for treatment failure. This cutoff originates from a randomized controlled trial on the treatment of ACL injuries in which it was used as a criterion for crossover from nonsurgical to surgical treatment.[6] In this study, a QOL score of 44 is better than the upper 95% CI for patients reporting treatment failure at any postoperative time point and worse than the lower 95% CI for the undecided intermediate group perceiving neither acceptable outcomes nor treatment failure at 2 of 3 postoperative time points. Thus, a QOL cutoff score of 44 included all those reporting treatment failure in response to the direct question but also a small proportion of those who at 2 years reported unacceptable symptoms but did not define their treatment as a failure.

In a recent consensus report, Lynch et al[10] proposed PRO threshold scores between 85 and 90 as a successful outcome after operative or nonoperative treatment for ACL injuries. In our study, patients reporting acceptable symptoms had mean KOOS subscale values that were in the range proposed by Lynch et al[10] for the pain, symptoms, and ADL subscales. For the Sport/Rec and QOL subscales, the corresponding mean scores were however substantially lower: 72 and 73, respectively. Mean KOOS subscale values better than 85 for Sport/Rec and QOL are rarely found after ACLR. The Scandinavian ACLR registries have reported mean scores of 63 to 70 for Sport/Rec and 60 to 69 for QOL at 1 to 2 years after ACLR,[9] while the United States MOON cohort reported median scores of 85 for Sport/Rec and 75 for QOL at 2 years after ACLR,[4] indicating Lynch et al's[10] suggestion as being far too optimistic for these specific outcomes after ACL treatment.

The strengths of our study include a large sample size in which the data are gathered from a whole country, which

implies that the results are highly generalizable across rural and urban areas and different hospital settings. Limitations include the low response rate (50%), which could limit the generalizability. Commonly, a response rate of 80% is required in longitudinal studies. There was an overrepresentation of younger men in the nonresponder group, possibly introducing a selection bias. Given that female patients seem to have poorer KOOS values before and after ACLR, it could be assumed that patients with poorer outcomes are overrepresented in the responder group in our study. At 1 year postoperatively, female patients in the Swedish ACLR registry reported worse scores than male patients in KOOS pain (mean difference, 1.4; 95% CI, 0.4-2.4) and KOOS Sport/Rec (mean difference, 2.7; 95% CI, 0.9-4.4) and at 2 years postoperatively in KOOS Sport/Rec (mean difference, 4.4; 95% CI, 2.1-6.7) and KOOS QOL (mean difference, 2.4; 95% CI, 0.4-4.4). Similarly, the preoperative sex differences in KOOS pain, symptoms, ADL, Sport/Rec, and QOL were 1.9, 1.4, 0.6, 4.7, and 2.1 points, respectively.[1] However, in the current study, there were no differences in any preoperative KOOS subscale values between the responders with a complete data set and nonresponders and responders without a complete data set combined (Table 1), which suggests that our results would not differ having included more men. However, a selection bias cannot be ruled out.

Two-thirds of patients at 1 to 2 years postoperatively perceive their symptoms to be acceptable after undergoing ACLR. About one-tenth of the patients perceive the treatment to have failed after ACLR. Patients reporting acceptable symptoms after ACLR had KOOS values reflecting, on average, no to mild problems, while those perceiving the treatment to have failed had KOOS values reflecting, on average, moderate to severe problems.

ACKNOWLEDGMENT

The authors acknowledge the help and support of the staff at the Norwegian Knee Ligament Registry.

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