

## Assessment of Selection Criteria for Anterior Cruciate Ligament Reconstruction

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### Abstract

**Aim:** To assess the need and advisability of anterior cruciate ligament reconstruction (ACLR).

**Methods:** We assessed 85 subjects with a mean age of 28 years (SD 10, range 15-57) who had been assigned to ACLR at the Regional Orthopedic Center in Lodz, Poland. All subjects completed a questionnaire covering sport activity, injury mechanism, experience of knee stability, a way they were assigned for ACLR and expectations of surgery. Preoperative assessment of the knee was made with the Knee injury and Osteoarthritis Outcome Score (KOOS). Satisfactory preoperative clinical knee outcome was defined as the lower threshold for the 95% CI of 18–34-year-old males and corresponded to the KOOS score above 90 for Pain, 84 for Symptoms, 91 for ADL, 80 for Sports/Recreation, and 81 for QOL. The activity level was determined with the Tegner activity scale. We considered subjects to be eligible for the operation if they fulfilled the newly established criteria: 1) pre-injury activity level  $\geq 7$  according to Tegner, depending on sport discipline performed, and a will to return to professional sport activity following ACLR and/or 2) residual knee instability regardless of six-weeks structured exercise program and 3) pre-injury activity level  $\geq 4$  according to Tegner and/or knee instability regardless of structured exercise program in adolescents.

**Results:** New criteria for ACLR were fulfilled by 44% of the study group. Part of the subjects had satisfactory preoperative clinical knee outcome in the KOOS subscales for Pain, Symptoms and ADL. Subjects scored significantly higher in the KOOS subscales Pain, and KOOS ADL (mean 73 and 79 points respectively) than in the KOOS subscales Sports/Recreation and Quality of Life (mean 47 and 38 points, respectively ( $P \leq 0.001$ )).

**Conclusions:** Our findings indicate that more than a half of subjects who are eligible for ACLR according to our inclusion's criteria could be operated on in vain. Patient's education, adequate assessment of clinical symptoms, ability to perform activities of daily living and a proper rehabilitation program could decrease the number of subjects assigned to ACLR.

**Keywords:** Anterior cruciate ligament reconstruction; Clinical outcome; Selection criteria

### Introduction

Rupture of the anterior cruciate ligament (ACL) is the most common and one of the most serious ligament injuries in the knee joint. It affects mainly young and active people [1]. The injury causes knee joint instability which in turn leads to decreased knee function. ACL injury is often associated with concomitant damage of other joint structures, including meniscus tears and chondral lesions [2,3]. Since it has been documented that ACL injury places the patient at risk for early osteoarthritis, ACL reconstruction (ACLR) has been widely advocated as a treatment method of choice [4,5].

It has been assumed that restoring stability through ACLR enables the patients to go back to a high functional level in a relatively short time [6]. However, the study of Frobell et al. showed that ACLR must not be recommended to all patients [7]. Up to date, there has been no evidence from high-quality randomized, controlled trials comparing ACL reconstruction with other treatments. Since knee stability can be improved not only by surgery but also by neuromuscular rehabilitation [8-10], the subjects who are not professional sportsmen achieve clinical results good enough to perform daily activities and recreation if appropriate structured physiotherapy is provided.

Thus, an easy-to-implement algorithm for selection of subjects assigned for ACLR should be constituted. The purpose of our study was to assess the need and advisability of surgical intervention in individuals who were eligible to receive ACLR treatment, taking into account

subjects' activity level, expectations following surgery and results of pre habilitation. We hypothesized that establishing of selection criteria could remarkably affect the choice of treatment strategy in subjects with torn ACL.

### Methods and Materials

#### Study group

All subjects who had undergone ACLR at the Department of Reconstructive Surgery and Arthroscopy of the Knee Joint, Medical University, between June and December 2012 were enrolled in the study group. The only exclusion criterion was a previous surgery of the knee joint.

We also distinguished a group of subjects who at the time of surgery were younger than 18 years.

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ACL rupture was assessed in clinical examination, accompanied, in case of doubt, by magnetic resonance imaging (MRI).

The study protocol was approved by the local ethics committee (approval no. RNN/580/12/KB). An informed written consent was obtained from all subjects who participated in the study.

### General assessment

All subjects were evaluated prior to ACLR. The study-specific questionnaire included information about body mass index, occupation, the type of subjects' activity before ACL injury. In addition, the subjects answered to multiple choice questions how they describe their knee stability (full stability, moderate instability, pronounced instability), how they were assigned for a surgical intervention and what expectations of ACLR they had.

### Disease-specific outcome measure

The Knee injury and Osteoarthritis Outcome Score (KOOS) was used in the study. KOOS is 42-item self-administered knee-specific questionnaire that evaluates knee-related problems in five subscales: Pain, other Symptoms, Activities of Daily Living (ADL), Sports and Recreation and Quality of Life (QOL) [11,12]. A separate score ranging from 0 to 100 (where 100 represent the best result) is calculated for each subscale [13]. The score had already been validated for ACLR, and culturally adapted for Polish ACL-reconstructed patients [14]. The measurement was done prior to ACLR.

**Evaluation of activity level:** The assessment of the activity level was made with the 10-points Tegner activity scale where 10 represented the highest professional performance represented by an elite soccer player [15,16]. Subjects assessed their pre-injury activity.

### ACLR recruitment criteria

Subjects' eligibility for ACLR was assessed by an orthopedic surgeon, in most cases the same who later performed the surgery. No general algorithms for qualification were used. The only recruitment criteria were the rupture of ACL, active lifestyle and a subject's request to be operated on. We critically verified these criteria and, based on contemporary proposals, re-qualified all subjects qualified for ACLR [17].

We considered subjects to be eligible for the operation if they fulfilled the following criteria: 1) pre-injury activity level  $\geq 7$  according to Tegner, depending on sport discipline performed, and a will to return to professional sport activity following ACLR and/or 2) residual knee instability regardless of six-weeks structured exercise program [18]. Since the surgical treatment in young subjects, especially physically active, appears to provide the best outcome due to meniscus-salvage opportunities, the selection criteria for adolescents included pre-injury activity level  $\geq 4$  according to Tegner scale and/or knee instability regardless of structured exercise program [19,20].

### Symptomatic and functional assessment

The subjects were stratified into two groups according to their activity level. Group A included those who were professional elite athletes (4 subjects) or those who represented a high level of sport activity (who scored  $\geq 6$  in the Tegner activity scale, 37 subjects). Group B included the recreationally active subjects and those who were active on a basic level ( $\leq 5$  in the Tegner activity scale, 44 subjects).

Based on the published Swedish reference population, the satisfactory clinical outcome (corresponding to previously described functional recovery [21]) was defined as the lower threshold for the 95%

CI of 18–34-year-old males [22] representing the group corresponding best to the subjects examined. Subsequently, to be classified as a satisfactory clinical outcome, the KOOS subclasses had to be scored above 90 points for Pain, 84 for Symptoms, 91 for ADL, 80 for Sports/Recreation and 81 for QOL.

### Statistical analysis

No prior sample size determination was made due to the observational character of the present study. Continuous outcomes are given as mean (standard deviation, SD) values. Binary data in 2 x 2 tables were evaluated by Fisher's exact test. The Wilcoxon signed ranks test was used for assessment of comparisons between groups. All tests were 2-tailed and P-value of  $< 0.05$  was considered statistically significant. All analyses were performed with SPSS for Windows 15.0 software package (SPSS Inc., Chicago, IL, USA).

## Results

### Study group

The study sample consisted of 85 subjects (59 men and 26 women) with a mean age of 28 years (SD 10, range 15-57 years). Mean age of assessed adolescents ( $n = 19$ ) was 16 years (SD 1, range 15-18 years). The characteristics of subjects in activity groups are given in Table 1.

**ACL injury by sport discipline:** ACL rupture in subjects examined occurred most commonly in soccer (43 subjects, 51%), volleyball (6 cases, 7%), alpine skiing (5 cases, 6%), track and field (4 cases, 5%) and basketball (4 cases, 5%). In 23 (27%) individuals the injury occurred either during other activities or the subjects could not indicate its reason.

**Knee stability:** Out of 85 subjects assessed prior to ACLR, 37 experienced pronounced instability and 27 moderate instability of the knee joint. Twenty-one subjects experienced full stability of the knee.

No differences between groups concerning subjective assessment of knee stability were observed.

### ACLR recruitment criteria

Subjects participating in the study were assessed for ACLR eligibility by an orthopaedic surgeon or a specialist in sports medicine. In five cases there were subjects themselves or their families that desired the surgical treatment. In all individuals, qualification for surgery was undertaken based on a subjective examination. No patient-related outcome measurements were used for qualification.

Most of the subjects examined (70 out of 85, 82%) had undergone rehabilitation prior to surgery (pre habilitation). However, the exercise program was usually very limited except for elite athletes who trained with physical therapists individually. All subjects had reached the full range of motion prior to ACLR.

The first of the newly proposed criteria for ACLR, professional sport practising at the elite level, was fulfilled by four persons, three soccer players and one volleyball player. All these subjects experienced

Characteristics	Group A	Group B
N (% women)	44 (41)	41 (20)
Age at surgery, mean (SD), years	28.6 (10.8)	27.6 (9.1)
Time from injury, mean (SD), years	2.9 (3.5)	2.7 (4.2)
Tegner activity score (SD), points	4.1 (0.9)	6.4 (1.0)
Body mass index (BMI), mean, (SD), kg/m <sup>2</sup>	26.6 (4.0)	25.3 (3.0)

Table 1: Characteristics of subjects.

pronounced instability, thus they also fulfilled the second criterion. One of the soccer players was operated on after three weeks from the injury; the other professional athletes underwent ACLR in an elective manner.

The second criterion, residual instability of the knee joint regardless of structured rehabilitation, was fulfilled totally by 19 subjects (46%) with pronounced instability from group A and 18 (41%) individuals from group B. Moreover, moderate instability was reported by 11 (27%) subjects from group A and 16 (36%) from group B. Since any subjects with moderate instability completed structured pre habilitation process they did not fulfil the second criterion for ACLR.

Consequently, 11 subjects from group A and 10 subjects from group B reported full stability of the knee joint.

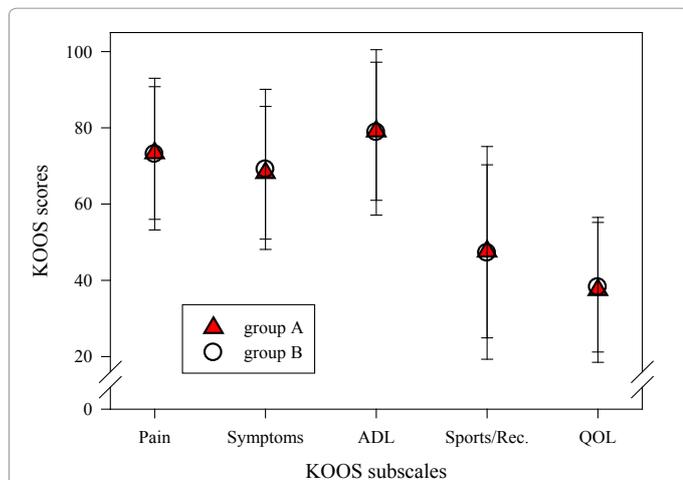
Among adolescents, the criteria were fulfilled by 17 out of 19 subjects. One individual, a 15 year-old boy with BMI 29.3 and activity level 3 had no instability of the knee joint, while another person, a 15 year-old girl with BMI 26.7 and activity score 2 had only moderate instability but had not completed her exercise program. Qualification to ACLR was also doubtful in the case of a 16-year old boy with BMI 35.5. This patient was, however, physically active (Tegner activity level 5).

### Symptomatic and functional assessment

**Group level:** Subjects scored significantly higher in the KOOS subscales Pain (mean 73 points, SD17 for subjects from group A and SD 20 for group B), KOOS Symptoms (mean 68, SD 17 for group A and mean 69, SD 21 for group B) and KOOS ADL (mean 79, SD 18 for group A and SD 22 for group B) than in the KOOS subscales Sports/Recreation (mean 48, SD 23 for group A and mean 47, SD 28 for group B) and Quality of Life (mean 38, SD 19 for group A and 17 for group B) ( $P \leq 0.001$ ) (Figure 1).

No significant differences in outcomes between group A and B were observed.

**Individual level:** Scores corresponding with satisfactory preoperative clinical outcome together in three of five KOOS subscales (Pain, Symptoms, ADL) were observed in five out of 41 (12%) individuals from group A and in seven out of 44 (16%) subjects from group B.



**Figure 1:** Mean scores in KOOS subscales for subjects practicing sport at professional or advanced level (group A, N = 41) and those who are recreationally active or active on a basic level (group B, N = 44). Vertical segments represent standard deviation.

Satisfactory preoperative clinical outcome was observed in significantly more subjects in the KOOS subscale ADL than in the KOOS subscales Sports/Recreation and QOL in both, group A ( $P = 0.02$  and  $P=0.0007$  respectively) and group B ( $P=0.04$  and  $P=0.0001$  respectively) and in the KOOS subscales Pain and Symptoms than in the KOOS subscale QOL in group B ( $P=0.0002$ ) (Table 2, Figures 2 and 3). No differences were observed in the number of subjects with satisfactory preoperative clinical outcome in the KOOS subscales Pain and Symptoms when compared to the subscale Sports/Recreation both in group A ( $P=0.55$ ) and B ( $P=0.3$ ) and in the KOOS subscales Pain and Symptoms compared to subscale QOL in group A ( $P=0.09$ ).

Subjects with subjectively stable knee joints ( $N=21$ ) had more often satisfactory preoperative clinical result than those with moderate instability and pronounced instability in the KOOS subscales Pain ( $P=0.01$  and  $P=0.002$  respectively), Symptoms ( $P=0.04$  and  $P=0.0003$ ), ADL ( $P=0.004$  and  $P=0.0004$ ), and Sports/Recreation ( $P=0.03$  for both groups).

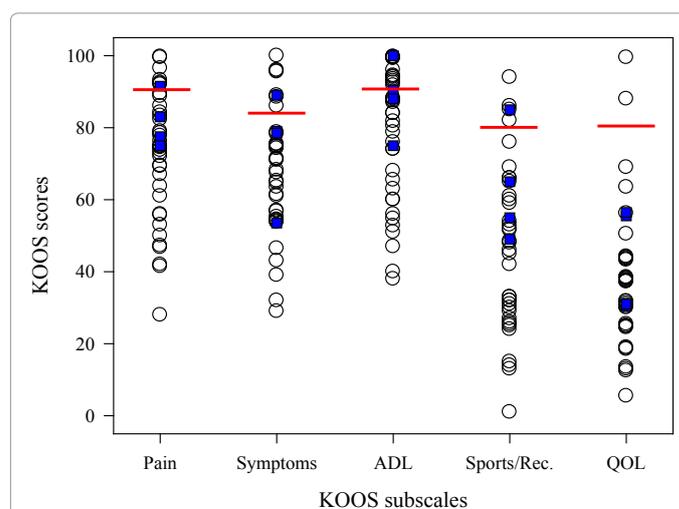
Satisfactory clinical outcome was observed in the KOOS subscale QOL in one person with a stable knee joint and in one with pronounced instability.

### Discussion

In our study we took up the challenge to verify critically if the subjects who were eligible to ACLR treatment fulfilled the criteria of

Group assessed	KOOS subscales				
	Number of subjects (%)				
	Pain	Symptoms	ADL	Sports/Rec	QOL
Sportsmen (group A, N=41)	8 (20)	8 (20)	15 (37)	5 (12)	2 (5)
Non-sportsmen (group B, N=44)	12 (27)	12 (27)	20 (46)	7 (16)	0

**Table 2:** The number of subjects with satisfactory preoperative clinical outcome in separate KOOS subscales in those subjects with high level performance (Sportsmen, group A) and in those who practice sport recreationally (Non-sportsmen, group B).



**Figure 2:** The KOOS scores for subjects from group A. The results within this group are presented separately for elite sportsmen (■) and those who practise sport on high recreational level (○). The red parallel segments correspond with minimal score values representing the satisfactory clinical outcome for the KOOS subscales (lower threshold for the 95% CI of 18–34-year-old males as reference group).

selection for surgery basing on patient-related KOOS outcome and subjective assessment of knee stability.

We found that over one fourth of the subjects assessed were qualified for ACLR despite they experienced full stability of the knee joint and had satisfactory preoperative clinical outcome in the KOOS subscales. The criteria for ACLR surgery were fulfilled by only 44% of subjects evaluated. Moreover, additional 29% of the study group had a moderate instability of knee joint but they should have completed a structured rehabilitation program first to be assessed if they needed a surgical intervention. Our study shows that subjects with good stability and satisfactory preoperative clinical outcome measured with patient-related outcome may have been qualified for surgical reconstruction in vain. Frobell et al. in their randomized controlled study observed that early ACLR with structured rehabilitation was not superior to a strategy of rehabilitation with the option of delayed reconstruction when needed in two-year follow-up [7]. The authors reported that in a rehabilitation group, ACLR was necessary only in 39% of subjects who scored low in the KOOS subscales mostly because of residual instability of the knee joint, which is consistent with our results. In our study, the subjective assessment with the KOOS scale was not performed to qualify subjects for surgery. The analyses we present were made a posteriori in order to verify the ACLR selection criteria. We observed that, over 41% of subjects had satisfactory clinical outcome with over 91 points in the KOOS subscale ADL. It has been, however, suggested that ACLR does not affect the outcome in this subscale. On the contrary, we found that the subjects had low scores in the KOOS subscale Sports/Recreation irrespectively of the activity level and in the subscale QOL irrespectively of the experience of knee stability. These results should be, however, interpreted with caution and always in relation to the properties of the measurement tool. The KOOS subscale Sports/Recreation refers to the activities as squatting, kneeling, jumping, turning/twisting and running. These activities demand higher physical ability than those described in the KOOS subscale ADL. Consequently, the results in the KOOS Sports/Recreation subscale are very important when deciding about a knee surgery. Satisfactory preoperative clinical outcome was achieved by seven subjects who are active on a recreational level and five subjects who practice sport activity an advanced level. We assume that satisfactory clinical outcome with over 80 points in the KOOS

subscale Sports/Recreation should be interpreted as contraindication to ACLR in subjects who are not elite athletes. Since a level of 8-10 points of score change was suggested as a cut-off representing a clinically significant difference [23], a detectable improvement would be difficult to reach. One might expect that after successful surgery outcomes would be located higher on the scale, approaching the maximal score of 100 points (*ceiling effect*).

Unlike the KOOS subscale Sports/Recreation, the outcomes of KOOS QOL reflects rather psychological and social aspects, as apprehension to perform some activity or to change a lifestyle [13]. It seems to be clear that subjects with torn ACL can be limited in sports activity; however they could improve their quality of life, e.g. by changing the sport activity in order to avoid exercises in which the knee is exposed to cutting, pivoting and shear forces. We suppose that subjects' desire to return to their pre-injury activity without changing their habits determines low scores in the KOOS subscale QOL on both the individual and group level.

It has been reported that subjects with high pre-injury activity levels are prone to choose surgical intervention rather than conservative treatment [24]. However, when qualifying for surgery, one should take into account that ACLR does not give satisfactory results in all individuals. Clinical outcomes are often far from optimal with one third of subjects experiencing residual knee laxity and over 60% with disturbances in knee function [25]. It is reported that only 65-70% of subjects undergoing reconstruction return to their pre-injury activity level [25,26].

In the adolescent group, it was questionable to qualify for surgery overweight and obese subject, including one 16-year-old boy with BMI > 35. However, most of these subjects were physically active and according to our criteria could undergo ACLR in order to minimize the risk of secondary knee injuries, including meniscus tears and chondral injuries [18,27].

Our study had some limitations. We assessed only the subjects who had already been qualified for surgical intervention. We do not know how many subjects with ACL injury denied surgery when they were consulted by an orthopaedic surgeon. Moreover, the study was based on only one assessment performed prior to ACLR. Although we assume that surgery is not beneficial in subjects who scored well in the KOOS subscales, we need a further study with continued follow-up and assessment of longer term outcomes to verify this statement.

## Conclusion

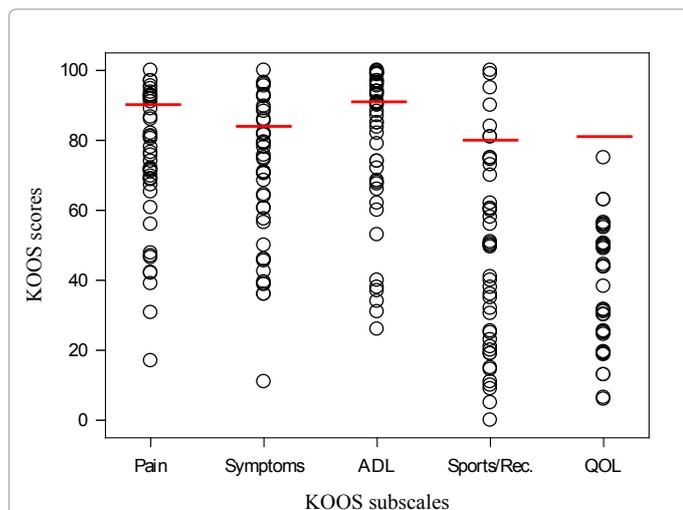
Our findings indicate that more than a half of subjects who are eligible for ACLR according to our inclusion's criteria could be operated on in vain. All subjects with ACL injury who desire ligament reconstruction need structured rehabilitation supervised by a physical therapist. Subjects should be qualified for surgical intervention more carefully, based on clinical assessment and results from a validated subjective knee-specific measurement tool.

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**Figure 3:** The KOOS scores for subjects from group B. The red parallel segments correspond with minimal score values representing the satisfactory clinical outcome for the KOOS subscales (lower threshold for the 95% CI of 18–34-year-old males as reference group).

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