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CLINICAL OUTCOME AT A MINIMUM OF FIVE YEARS AFTER RECONSTRUCTION OF THE ANTERIOR CRUCIATE LIGAMENT

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Background: We are not aware of any previous studies in which independent measurements of function with validated outcome questionnaires such as the Knee Injury and Osteoarthritis Outcome Score and the International Knee Documentation Committee score were evaluated five years after reconstruction of the anterior cruciate ligament. We hypothesized that patient demographics, mechanism of injury, and intra-articular injuries and their treatment are factors associated with function five years after reconstruction of the anterior cruciate ligament.

Methods: A consecutive series of unilateral, arthroscopically assisted primary reconstructions of the anterior cruciate ligament performed by one surgeon using a patellar tendon graft was evaluated. Data on patient demographics, injury variables, and intra-articular lesions noted at the time of surgery were collected prospectively. Multivariable regression analysis was used to identify independent predictors of outcomes as measured with five questionnaires.

Results: Sixty-nine percent (217) of 314 knees with a reconstruction of the anterior cruciate ligament were followed for an average of 5.4 years. The average age at the time of the operation was twenty-seven years. Independent predictors of a worse outcome, which was measured with the overall Knee Injury and Osteoarthritis Outcome Score, the International Knee Documentation Committee score, the Lysholm score, and the Western Ontario and McMaster Universities Osteoarthritis Index score, included the patient's recollection of hearing or feeling a pop at the time of the injury, a weight gain of >15 lb (6.8 kg), and no change in educational level since the surgery. There was a lack of association between the outcome and either the occurrence or the form of treatment of a meniscal tear or chondromalacia of the articular cartilage.

Conclusions: To our knowledge, we performed the first prospective cohort study to evaluate the prognosis following reconstruction of the anterior cruciate ligament by identifying significant associations between multiple variables and clinical outcomes as measured with validated questionnaires. The clinician can counsel patients about the intermediate-term functional outcomes of reconstructions of the anterior cruciate ligament on the basis of these findings. Suggestions regarding weight control and future education may improve intermediate-term outcomes.

Level of Evidence: Prognostic Level II. See Instructions to Authors for a complete description of levels of evidence.

Intra-articular techniques with a variety of grafts have resulted in the modern era of reconstruction of the anterior cruciate ligament. Randomized, controlled trials have previously demonstrated the superiority of reconstruction compared with primary repair¹⁻³. Additional randomized, controlled trials have shown no clinical differences in outcome between the use of patellar tendon autograft and the use of hamstring tendon graft⁴⁻¹¹ or between one and two-incision arthroscopic operative techniques^{10,12-14}. Thus, reconstructions of the anterior cruciate ligament have been performed to al-

low patients to resume activities, especially in sports requiring cutting and pivoting, and studies have shown overall good short-term function^{15,16}. Fewer investigators have evaluated intermediate (five-year) results.

Traditionally, the clinical outcomes of reconstructions of the anterior cruciate ligament have been judged by measuring anterior-posterior knee stability combined with the limited use of sport-specific validated outcome questionnaires. Two recently developed and validated sport-specific knee outcome questionnaires are the International Knee Documenta-

TABLE I Potential Predictors Evaluated in the Study

Potential Predictor	Scale
Patient demographics	
Age	Years
Weight change	Lost, gain 0-15 lb (0-6.8 kg), gain >15 lb
Gender	Male or female
Change in educational level	Yes or no
Injury variables	
Sport	Type at injury
Pop	Yes or no
Contact	Yes or no
Jumping	Yes or no
Onset of swelling after injury	None, <1 hr, 1-8 hr, >8 hr
Reinjury before surgery	Number
Time from injury to surgery	Years
Intra-articular injuries	
Medial meniscal tear	None, partial, complete
Medial meniscal treatment	None, excision, repair
Lateral meniscal tear	None, partial, complete
Lateral meniscal treatment	None, excision, repair
Patellofemoral compartment	Normal or Grade I, Grade II or III, Grade IV*
Medial compartment	Normal or Grade I, Grade II or III, Grade IV*
Lateral compartment	Normal or Grade I, Grade II or III, Grade IV*
Duration of follow-up	Years
*Grade of chondromalacia, according to the modified Outerbridge scale ²⁰ .	

tion Committee (IKDC) Subjective Knee Form¹⁷ and the Knee Injury and Osteoarthritis Outcome Score (KOOS)¹⁸. Since these outcome questionnaires both measure function and evaluate arthritis, the results provide complementary information not found in smaller studies of stability after anterior cruciate ligament surgery.

Outcome studies enable sports medicine clinicians to identify potential predictors of function after reconstructions of the anterior cruciate ligament and to counsel patients about expected outcomes of the surgery and ways to potentially improve function by identifying behavior changes that can be adopted. The deficiencies in the literature on anterior cruciate reconstruction include a lack of prospective risk-factor analyses at the time of intermediate (five-year) follow-up, insufficient sample size (underpowered studies), and a lack of use of sport-specific and knee-specific outcome questionnaires. In 1991, we established a database to prospectively collect information on patients undergoing reconstruction of the anterior cruciate ligament. To our knowledge, we are the first to use a series of validated outcome questionnaires to evaluate a group of patients at a minimum of five years following reconstruction of the anterior cruciate ligament. Our hypothesis¹⁹ was

that patient demographics, injury variables, and intra-articular injuries and their treatment are significantly associated with function (outcomes) at a minimum of five years following reconstructions of the anterior cruciate ligament.

Materials and Methods

Beginning in 1991, data on all reconstructions of the anterior cruciate ligament were entered prospectively into a database designed to record patient demographics, injury variables, time to surgery, classification and treatment of intra-articular injuries (articular cartilage and meniscal), reconstruction technique, and the major components of rehabilitation. The recorded demographic and injury variables are shown in Table I. The intraoperative factors included non-instrumented laxity measurements made with the patient under anesthesia and intra-articular injuries and their treatment as recorded on a scaled diagram and converted to a numeric classification as previously described¹⁹. Each of the six articular cartilage surfaces (medial tibial plateau, medial femoral condyle, lateral tibial plateau, lateral femoral condyle, patella, and trochlear groove) were analyzed separately to record the size of the area of chondromalacia on each surface and to grade the chondromalacia on each surface with use of a modified Outerbridge scale²⁰ (Grade I = softening, Grade II = superficial changes, Grade III = deep changes, and Grade IV = exposed bone). Injuries and treatment of the meniscus were considered separately. Variables regarding the ligament reconstruction included whether the procedure was primary or a revision, the type of graft, the operative technique, and the major rehabilitation milestones.

After approval had been obtained from our institutional review board, the records of the first 340 patients treated, between September 13, 1991, and June 30, 1997, with two-incision arthroscopically assisted reconstruction of the anterior cruciate ligament with a patellar tendon autograft by the senior one of us (K.P.S.) were reviewed. All patients had been followed for a minimum of five years following the surgery. We believe that this group represented >80% of the patients who presented for clinical evaluation of a deficient anterior cruciate ligament by that surgeon during that time period. Meniscal repairs were performed with use of inside-out suture techniques until June 1996. Then, all were done as inside repairs with bio-absorbable arrows (Bionix, Toledo, Ohio) for the next year. Chondral injuries were treated with simple débridement.

Only primary unilateral reconstructions of the anterior cruciate ligament were included in the study; revision reconstructions were excluded. Patients with deficiency or a reconstruction of the anterior cruciate ligament in the contralateral knee were also excluded, so that the measured outcomes would be related only to the reconstructed knees included in the study. Patients with associated injuries of the posterior cruciate ligament and the posterolateral corner were excluded as well. Also, at the time of follow-up, three patients who were known to have died, one patient with a total knee replacement, and nine patients in whom the primary reconstruction had been revised less than five years following the initial sur-

gery were excluded. We recognize that the ten patients who underwent knee replacement or reconstruction of the revision had a failure of the original reconstruction, but it would not have been appropriate to compare the data derived with the validated outcome instruments for these patients with those derived for the rest of our cohort. A review of the intra-articular pathological findings and demographics of the ten patients with a failure did not reveal apparent differences from the rest of our cohort.

Following the above exclusions, 314 patients remained in the study.

After the patients gave informed consent, they were asked to complete an eleven-page questionnaire, which they returned by mail. The questionnaire included four validated outcome instruments, a review of systems, questions regarding additional surgery, and questions regarding any changes in social or demographic information. The four validated outcome assessment tools included two sport-specific forms (the KOOS¹⁸ and IKDC¹⁷), a well-documented scale for assessing lower-extremity osteoarthritis (the Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC])²¹, and a general health assessment measure (Short Form-36 [SF-36])^{22,23}. Finally, the questionnaire-based Lysholm scale²⁴ was included so that we could compare this study with previous studies and measures of anterior cruciate instability.

Descriptive statistics are presented as means and standard deviations or as medians and interquartile ranges for the continuous variables, as appropriate. Frequencies and percentages are used to summarize the categorical variables. The overall KOOS¹⁸ and its five subscales (quality of life, functional-sports-recreation, activities of daily living, pain, and symptoms), the overall WOMAC²¹ and its three subscales (stiffness, pain, and physical function), the subjective IKDC questionnaire¹⁷, the Lysholm²⁴ scale, and both the mental and physical components of the SF-36^{22,23} were scored as described in the original references. Table I lists the potential predictors of outcome that were assessed.

Univariable regression modeling was completed separately for each outcome with use of linear or logistic regression analysis, as appropriate. When markedly non-normally distributed data were identified, transformations were used prior to analysis and then back-transformations were used for interpretations. Multivariable modeling was used to adjust for the covariates and to identify a set of independent predictors for each outcome. Furthermore, the statistical modeling involved assessment of both multicollinearity and possible inter-

actions among the predictor variables. Independent predictors for each outcome were identified and interpretations of the results were summarized with the details of the models as well as with an interpretation of the relationships between each predictor and outcome. During the model-building process, variables were allowed to enter the model if the p value was <0.15 (trend toward significance), and they were allowed to stay in the model if the p value was ≤0.05. Results were considered significant when the p value was ≤0.05. SAS software (version 8.2; SAS Institute, Cary, North Carolina) was used for the statistical analysis.

Results

Of the 340 patients who underwent unilateral reconstruction of the anterior cruciate ligament, thirteen were excluded at the follow-up evaluation: three had died, one had had a total knee arthroplasty, and nine had had failure of the graft and subsequent revision. Of the 327 patients who remained, 230 (70%) completed the questionnaire at a minimum of five years postoperatively. However, for thirteen patients, the procedure had been entered into the database as a revision reconstruction of the anterior cruciate ligament, so they were excluded. Thus, 217 patients (69.1%) with a unilateral primary reconstruction of the anterior cruciate ligament were evaluated at the time of final follow-up. Of the 30% who were lost to follow-up, 10% could not be located and 20% were contacted but did not complete the questionnaire. In addition, intra-articular data on three (1.4%) of the 217 patients were lost.

The average age of the 217 patients at the time of follow-up was 27 ± 9.5 years. One hundred and nineteen patients (55%) were male. The average duration of follow-up was 5.4 ± 1.7 years. The majority of the patients (167 [77%] of the 217) were injured in sports activities, and 154 (71%) recalled hearing or feeling a pop at the time of injury. One hundred and sixty-nine injuries (78%) were noncontact injuries, and 161 injuries (74%) did not involve jumping. In the half-decade since the surgery, 130 (60%) of the patients had increased their educational level.

Eighty-six percent (184) of the patients had a normal medial collateral ligament, 2% (five) had a Grade-I injury of the medial collateral ligament (with ≤5mm of laxity), 9% (nineteen) had a Grade-II injury (with 6 to 10 mm of laxity), and 3% (six) had a Grade-III injury (with >10 mm of laxity). Ninety-nine percent of the patients had a normal lateral collateral ligament, and only three had a Grade-II injury.

TABLE II Meniscal Tears and Treatment at the Time of the Anterior Cruciate Reconstruction

Meniscus	Tears (no. [%] of knees)			Treatment (no. [%] of knees)			
	None	Partial	Complete	NA*	None	Excision	Repair
Medial	122 (57%)	19 (9%)	73 (34%)	122 (57%)	22 (11%)	22 (11%)	48 (22%)
Lateral	104 (49%)	37 (17%)	73 (34%)	104 (49%)	45 (21%)	64 (30%)	1 (0.5%)

*NA = not appropriate as the meniscus was normal.

TABLE III Modified Outerbridge Classification of Chondromalacia at the Time of the Anterior Cruciate Reconstruction

Articular Surface	No. (%) of Knees		
	Normal or Grade I	Grade II or III	Grade IV
Lateral femoral condyle	168 (78%)	42 (20%)	4 (2%)
Lateral tibial plateau	183 (86%)	29 (14%)	2 (1%)
Medial femoral condyle	166 (78%)	46 (22%)	2 (1%)
Medial tibial plateau	207 (97%)	5 (2%)	2 (1%)
Patella	189 (88%)	25 (12%)	0 (0%)
Trochlea	205 (96%)	9 (4%)	0 (0%)

The meniscal injuries and their treatment are shown in Table II, and the locations of the articular cartilage lesions are presented in Table III. There were more lateral meniscal tears than medial meniscal tears, and partial tears were seen primarily in the lateral meniscus. Medial meniscal repair was performed in 22% (forty-eight) of the patients. The percentage of knees that were normal or had Grade-I chondromalacia ranged from 78% to 97% across the six articular surfaces. Only ten surfaces had Grade-IV chondromalacia. In summary, the cohort in this study comprised primarily young patients with a variety of meniscal tears and treatment who only rarely had Grade-II or greater chondromalacia observed at surgery.

The independent predictors of outcome, as measured with the overall KOOS, the IKDC questionnaire, and the Lysholm questionnaire, are shown in Table IV. A lack of further education ($p = 0.009$) and a pop heard or felt at the time of injury ($p = 0.03$) were associated with a significantly worse KOOS. A lack of further education ($p = 0.01$) and weight gain of >15 lb (6.8 kg) were associated with a significantly worse WOMAC score ($p = 0.04$). Weight gain of >15 lb had the largest impact on outcome, with a maximum of a 7-point difference in the IKDC score compared with the score associated with weight loss. Both the sound or feeling of a pop at the time of injury and the change in the educational level

were associated with smaller average differences in the outcome measures. A lack of further education was identified as a significant predictor of the SF-36 score ($p = 0.02$).

A summary of analysis of the KOOS and WOMAC subscales demonstrated several variables that were not significant predictors of overall scores. Chondromalacia of the medial tibial plateau was a significant predictor of the KOOS pain subscale score ($p = 0.01$), and more than eight years between the injury and the surgery was significantly associated with both a lower KOOS pain score ($p = 0.04$) and a lower WOMAC pain score ($p = 0.02$).

More importantly, several variables commonly believed to be important predictors of function and outcome were not found to be significant. These included the presence of a meniscal tear and its treatment as well as chondromalacia of the patellofemoral, femoral, and/or tibial articular cartilage. In addition, gender, age, sports activity, contact injury, a jumping mechanism, and the onset of swelling within hours after the injury were not predictors of function or outcome five years after reconstruction of the anterior cruciate ligament.

Discussion

We used new validated outcome questionnaires to evaluate a prospectively collected series of two-incision patellar tendon reconstructions of the anterior cruciate ligament

TABLE IV Multivariable Regression Modeling of Independent Predictors of Function at a Minimum of Five Years

	Knee Injury and Osteoarthritis Outcome Score (KOOS)*	International Knee Documentation Committee (IKDC) Score*	Lysholm Score*
Weight change	No significant association	$P = 0.01$	No significant association
Loss		83 ± 16	
Gain 0-15 lb (0-6.8 kg)		81 ± 15	
>15 lb		76 ± 17	
Pop	$P = 0.03$	$P = 0.01$	$P = 0.046$
Yes	88 ± 13	79 ± 17	84 ± 15
No	90 ± 10	83 ± 11	88 ± 11
Educational level	$P = 0.009$	$P = 0.02$	No significant association
Continued to advance	91 ± 9	83 ± 15	
No advance	87 ± 14	78 ± 16	

*The scores are given as the mean and standard deviation, in points.

performed by one surgeon. After a minimum of five years of follow-up, several independent predictors of outcome were identified. Surprisingly, meniscal injury and its treatment and the status of the articular cartilage did not significantly influence the intermediate outcome. The present study had two unique attributes: (1) we were, to our knowledge, the first to use the KOOS and IKDC outcome questionnaires for functional evaluation to identify independent predictors, and (2) we performed one of the largest prospective five-year studies of arthroscopically assisted reconstructions of the anterior cruciate ligament with a patellar tendon autograft.

With the apparent clinical and scientific acceptance of reconstructions of the anterior cruciate ligament as a means of enabling athletes to regain function, as assessed at two years postoperatively, the next critical question is: which variables determine intermediate (five-year) and long-term function? Identifying significant variables, some of which are potentially modifiable, can direct resources to additional research, and the education of patients, about these variables. Clearly, longitudinal data on this cohort after ten years of follow-up are required to further evaluate the role of intra-articular injuries with regard to treatment outcomes and function.

Outcome measures have gained importance in sports medicine, and they have increasingly become dependent on patient satisfaction. In a review of outcome measurement for anterior cruciate-deficient knees, Johnson and Smith²⁵ recommended the use of validated instruments, including the Lysholm, IKDC, and KOOS scores. They thought that the KOOS was attractive but cumbersome and that the IKDC score will remain popular because of the international influence of the committee that formulated it. They believed that the original IKDC 1991 scale and the Cincinnati rating scale have not been adequately validated and may lack reliability. In a subsequent study, Marx et al. demonstrated high validity, reliability, and responsiveness for the Cincinnati rating scale when used to assess athletes²⁶.

There has been a paucity of studies evaluating arthroscopically assisted reconstructions of the anterior cruciate ligament with patellar tendon autograft at five years. Four such studies²⁷⁻³⁰ had several deficiencies. First, they were retrospective reviews. Second, they did not employ validated outcome measures. Third, they lacked sufficient power or sample size to evaluate a minimum of eight major intra-articular injury variables (six articular cartilage surfaces and two menisci) as potential predictors of function or outcome. Also, although they documented meniscal tears at surgery, neither chondromalacia nor treatment of intra-articular injuries was factored into the analysis, in which the primary outcome variable was instrumented measurement of laxity.

In two additional studies, reconstructions of the anterior cruciate ligament were evaluated at eight to ten years postoperatively. The most relevant review, by Wu et al.³¹, was a prospective ten-year follow-up study of sixty-three (of 103) reconstructions with patellar tendon autograft. The IKDC, Tegner, and Lysholm scales as well as instrumented laxity measurements and single-leg hop tests were used for evaluation. The IKDC and Lysholm scores were lower for patients

who had undergone any type of meniscal resection than they were for those with intact menisci. The authors did not control for multiple confounding variables as they did not utilize multivariable regression modeling. When they controlled for the degree of arthritis or chondromalacia associated with a meniscal injury, the meniscal effect was no longer significant. They concluded that meniscal tears should be repaired, if possible, to improve outcome.

In a follow-up study of subjective outcomes, Shelbourne and Gray³² utilized a modified Noyes questionnaire and the 1994 IKDC evaluation form at an average of 8.6 years after reconstructions of the anterior cruciate ligament. They did not use the current IKDC outcome form or the KOOS, WOMAC, or SF-36 instrument. In their review, 928 (75%) of their original group of 1231 patients were available for subjective evaluation and 482 (39%) were available for objective evaluation at the time of follow-up. This study demonstrates the near impossibility of achieving a 70% rate of long-term in-person follow-up in this population of young, mobile individuals. The objective evaluation included measurement with a KT-1000 arthrometer, assessment of quadriceps strength with a Cybex dynamometer, the single-leg hop test, range-of-motion measurements, and radiographs, including 45° flexion posterior-anterior weight-bearing views. The authors concluded that partial or total medial or lateral meniscectomy and damaged articular cartilage lowered the quality of the subjective results, as assessed with the Noyes questionnaire.

Järvelä et al.³³ retrospectively reviewed the results of primary reconstruction of the anterior cruciate ligament in seventy-two patients (from an original group of 102) who returned for follow-up five to nine years (average, seven years) postoperatively. The patients were divided into two groups: Group A (thirty-four patients) had an isolated injury of the anterior cruciate ligament, and Group B (thirty-eight patients) had associated injuries, including ten medial and twelve lateral meniscal tears treated with a partial or subtotal meniscectomy as well as nineteen ruptures of the medial collateral ligament, two ruptures of the lateral collateral ligament, and one rupture of the posterior cruciate ligament. All ligament ruptures, except for one of the medial collateral ligament, were treated with primary repair. The two groups were evaluated with use of the Lysholm, Marshall, and IKDC scores. There were no differences in outcome between the two groups, except that Group B required more repeat surgery, including manipulation (two knees), lysis of adhesions (eight), and partial meniscectomy (six). There was no mention of chondral injury in this study.

In the current study, we did not detect a difference in outcomes, at a minimum of five years postoperatively, on the basis of the status of the meniscus or the articular cartilage, or their treatment, at the time of surgical reconstruction. This difference between our findings and those of Wu et al.³¹ and of Shelbourne and Gray³² may reflect the shorter average duration of follow-up in our study, the use of different validated outcome measures, or the control of multiple confounding variables. However, the planned longer-term follow-up of this cohort may reveal different results with regard to intra-articular injuries.

The observation that weight gain of >15 pounds and a failure to advance to a higher educational level resulted in worse intermediate outcomes suggests two behaviors that potentially could be modified to improve outcome. It is unknown whether weight gain leads to increased stress on the knee or is a secondary consequence of a lack of regular physical activity. However, postoperative counseling stressing that regular exercise can control weight gain and perhaps lead to an improved five-year outcome could potentially motivate patients. How a change in educational level alters outcome is less certain. Higher education may lead to jobs requiring less intensive physical labor or it may help individuals to develop better coping strategies. To our knowledge, these observations have not been reported, and the issues have not even been addressed, in previous studies of reconstructions of the anterior cruciate ligament. Functional demand on the knee is a critical issue that is potentially related to the findings regarding weight gain and educational level in this study. Unfortunately, no validated measure of activity level was available at the time that these patients were enrolled. We included this measure in our current studies.

This study had several limitations, including the evaluation of the results of only one fellowship-trained surgeon at one institution and the lack of objective physical examination data (measurement of anteroposterior laxity, imaging, and objective functional testing). The majority of the studies in the literature involve the results of a single surgeon at a single institution, which limits the generalizability of the findings to other orthopaedists, but we intend to address this concern in the future with the addition of patients treated by other surgeons and at other institutions into the database.

Previous studies have demonstrated a lack of correlation between objective knee laxity and subjective outcome. Snyder-Mackler et al.³⁴ performed a study of twenty patients with an anterior cruciate-deficient knee, ten of whom were classified as compensators (individuals who returned to all sports activities without operative treatment) and ten of whom were classified as noncompensators (patients who ultimately underwent reconstruction of the anterior cruciate ligament). Objective knee laxity, as evaluated with a KT-2000 arthrometer, was actually greater in the compensators. No significant differences in subjective outcomes, as measured with the Lysholm and Knee Outcome Scores, were noted between the two groups. In a study evaluating muscle timing and recruitment with anterior tibial translation, Wojtys and Huston³⁵ also obtained subjective data. They noted no relationship between the subjective outcome and the amount of anterior translation. Finally, in a recent review of the results of hamstring reconstructions of the anterior cruciate ligament, Williams et al.³⁶ concluded that the functional outcome did not correlate with measurements of laxity with a KT-1000 arthrometer.

The strengths of our study include the use of validated sport-specific questionnaires as well as historical “gold standard” outcome measures for lower-extremity osteoarthritis (the WOMAC and SF-36). These outcome measures were designed and validated to be the primary measure of function. In this setting, objective knee laxity becomes less relevant than patient-based outcome. The use of questionnaires enabled us to evaluate a large cohort of patients with a high rate of follow-up (nearly 70%). Currently, we are involved in what we believe will be the ideal, but practical, prospective study. The study includes the use of validated outcome and activity instruments prior to surgery and at two, five, and ten years postoperatively, with a goal of a >80% rate of follow-up.

In conclusion, we used sport-specific questionnaires to identify several independent predictors of outcome at a minimum of five years after reconstructions of the anterior cruciate ligament. The predictors include the patient’s recollection of hearing or feeling a pop at the time of injury, no change in educational level, and a weight gain of >15 lb. Meniscal tears and their treatment as well as the presence or absence and degree of chondral injury were not found to be significant predictors of future function. A prospective longitudinal analysis of these patients is ongoing. ■

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