

Original article

# Patient satisfaction needs as related to knee stability and objective findings after ACL reconstruction using the LARS artificial ligament

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## Abstract

The purposes of this study are to compare patient satisfaction with the objective measurement of knee stability and assess early complications following ACL reconstruction using a LARS artificial ligament. Forty-seven patients were reviewed 8–45 months after surgery. Assessment was made by the Knee and Osteoarthritis Outcome Score for patient satisfaction, a modified International Knee Documentation Committee form for clinical knee stability, and a Telos stress radiography for PA stability. Complications were assessed at interview and were double-checked with charts. The LARS artificial ligament may be a safe device to reconstruct an ACL tear. Documenting mechanical stability of the knee is inadequate when reporting follow-up studies and a questionnaire assessing patient satisfaction should be added to provide a better picture of the outcome and results. © 2000 Elsevier Science B.V. All rights reserved.

**Keywords:** Anterior cruciate ligament; ACL; Artificial ligament; LARS; Patient satisfaction; Surgical complications

## 1. Introduction

In the young and active population with an ACL tear, reconstruction is often the best therapeutic option. Several researchers have developed different ACL substitutes to meet clinical needs. The patellar bone–tendon–bone autograft is widely reported in the literature as one of the best solutions for ACL replacement [1–5]. When this graft is successful, the implant undergoes ‘ligamentization’, being slowly revascularized after approximately 6 weeks and pre-

senting most histological and functional properties of the ACL after 30 weeks [2]. Some pain, loss of motion, knee instability and other problems, however, may be associated with this technique [6–9]. This situation stimulated interest in the use of artificial ligaments to replace the ACL.

After a preliminary period of enthusiasm and intensive clinical use of artificial ligaments for intra-articular ACL reconstruction in the 1980s, most surgeons gave up prosthetic ligaments due to the high device failure rate. Our research group provided evidence that under certain conditions an artificial ACL reconstruction can be successful [10–16]. The ligament must be made of polyester, the intra-articular part must be a multifilament strand and the surgical technique must minimize 3D stress on the ligament. The

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similarity between these concepts and the design of the LARS® artificial ligament (Ligament Advanced Reinforcement System — surgical implants and devices, Arc-sur-Tille, France) prompted our interest in this implant.

The purposes of this study are to compare patient satisfaction with the objective measurement of knee stability and to assess early complications following ACL reconstruction using a LARS artificial ligament.

## 2. Material and methods

### 2.1. Study design and population

Two research assistants assessed 47 patients between May 1997 and November 1997 for knee stability and early complications following ACL reconstruction with the LARS artificial ligament. One orthopedic surgeon performed the surgery between November 1993 and November 1996 in an affiliated University teaching hospital. The surgical technique was identical to that described by Laboureau [17,18] using the arthroscope.

All patients included in the study had an ACL rupture with different associated pathologies of the knee. Thirty-eight patients had chronic ruptures (delay between rupture and surgery was greater than 6 months) and nine had acute or subacute ruptures (delay between rupture and surgery was shorter than 6 months). Six patients had already had surgery for the ACL tear but the surgery failed to relieve the symptoms.

### 2.2. Data collection and measurement

Prior to the interview with the patient, data were collected from the chart. These included demographics (age, gender), diagnosis of the injured knee, date of injury, type of surgery, associated procedures in addition to the ACL repair, findings at the time of surgery, and post-operative complications. These data were double-checked for accuracy when the patients were interviewed.

Each patient was interviewed by one of the two research assistants. Data collected were status of the opposite knee, follow-up period, Tegner scores before injury, between the injury and surgery and after surgery. Assessment was made by the Knee Osteoarthritis Outcome Score (KOOS) for patient satisfaction, a modified International Knee Documentation Committee (IKDC) scoring system for clinical knee stability, and a Telos stress system for radiographic PA translation (Telos, Marburg, Germany).

The KOOS is a validated instrument [19,20] developed by a research team at the University of Lund,

Sweden, to assess the patients' opinion about their knee and associated problems. It is used for knee injuries that may result in post-traumatic osteoarthritis; e.g. ACL, meniscal and chondral injuries. This instrument consists of five subscales: function in ADL; pain; knee-related quality of life; function in sport and recreation; and other symptoms including stiffness, swelling, grinding, audible clicking or other noise, catch or hang up. The questionnaire is patient-administered, self-explanatory and takes approximately 10 minutes to fill out.

Standardized answer options are provided in five Likert boxes and each question is scored from 0 to 4. A normalized score, 100 for no symptoms to 0 for extreme symptoms, is calculated for each subscale. English and Swedish versions only were available at the beginning of this study. The questionnaire was translated into French and back translated into English and then into French again by an epidemiologist and one orthopedic surgeon. This is the usual epidemiological procedure to insure proper translation.

The IKDC scoring system was designed in 1991 and modified 2 years later by 11 members of the AOSSM and 10 members of the European Society for Knee Surgery and Arthroscopy (ESKSA). There are eight categories of assessment, each of which has four grades: normal, nearly normal, abnormal and severely abnormal. Each category assesses different clinical information including subjective self-assessment of preinjury and current activity level, symptoms, range of motion, ligament stability, compartmental findings, the graft harvest site, radiographic findings, and overall perception of knee function. The algorithm for scoring uses the lowest grade within a category to determine that category's grade. The worst grade determines the final evaluation. Only the first four categories' grades for subjective assessment count toward the final evaluation in patients with chronic ACL rupture.

We found no references in the French or English literature with regard to validation of the IKDC scoring system. We used this system because it is widely employed to report data in the current orthopedic literature. Among the eight categories, we removed the first and second because they were more detailed in the KOOS. The level of activity was assessed by Tegner's score pre-injury, pre-surgery and post-surgery. We retained the range of motion and the ligament examination as described in the knee ligament standard evaluation form using 'Telos stress radiograph instrumented Lachman'. We did not use the fifth, sixth and seventh groups of the IKDC because it was difficult to measure these parameters accurately and their clinical significance related to ACL problems is not clear. Because of the numerous changes, we could not use the IKDC scoring system

Table 1  
Descriptive statistics for demographic data

| Variable                         | Mean | Median | Range     | S.D.  | Frequency (%)   |
|----------------------------------|------|--------|-----------|-------|---|
| Age (years)                      | 31.6 | 31.0   | 18.0–50.0 | 10.39 |   |
| Gender                           |      |        |           |       | 15 (32%) Female<br>32 (68%) Male  |
| Injured knee                     |      |        |           |       | 22 (47%) Right<br>25 (53%) Left   |
| Diagnosis                        |      |        |           |       | 36 (77%) ACL rupture<br>4 (9%) ACL and MCL rupture<br>3 (6%) Failure of ACL reconstruction (PBTB)<br>1 (2%) Failure of ACL reconstruction (fascia lata)<br>1 (2%) Failure of ACL reconstruction (semi-tendinosis)<br>1 (2%) Failure of ACL repair |
| Opposite knee                    |      |        |           |       | 8 (17%) Abnormal<br>38 (83%) Normal   |
| Associated procedures            |      |        |           |       | 33 (70%) None<br>12 (26%) Meniscectomy<br>1 (2%) Meniscal repair<br>1 (2%) Debridement of lateral femoral condyle   |
| Follow-up after surgery (months) | 21.9 | 19.0   | 8.0–45.0  | 9.65  |   |

for the final evaluation. Two other points made us reluctant to use this scoring system. Firstly, a scoring system where raw scores from different categories are combined into an overall numerical score was of great concern to us because of potential distortion and the loss of some information. Secondly, the lowest score in any of the groups will determine the final score and may not reflect knee function accurately.

The Telos radiographic stress system was used to assess anterior knee displacement. Measurements of displacement of the tibia in relation to the femur were obtained on both knees, flexed at 30°, with an applied anterior force of 15 Kp. The lateral stress radiograph allowed measurement of compartmental displacements. The differential displacement in millimeters between the two knees was then calculated.

The Tegner activity scale quantifies the subject's activity level but does not incorporate the frequency of participation. Ideally, the KOOS should have been used prior to injury, between injury and surgery and after surgery to compare the results among the five subscales. The KOOS, however, was not available prior to surgery. Tegner's scores represented a good alternative because they are the most reliable way to assess the patient's activity level prior to trauma and between trauma and surgery.

### 2.3. Statistical analysis

Statgraphics Plus version 2.1 (Manugistics Inc., Rockville, MD, USA) was used for the statistical analysis. We determined the descriptive statistics of the study population and data collected at the time of the interview, physical examination and radiological testing. Complications were listed and grouped into categories.

We used paired *t*-tests (two-sided test and  $\alpha = 0.05$ ) to compare the difference in the level of activity before injury, between injury and surgery and after surgery ( $H_0$ : mean difference = 0 and  $H_A$ : mean difference  $\neq 0$ ,  $\alpha$  level = 0.05).

Analysis was directed to examining the association between the predictor's variables and the dependant variable, KOOS. Thus we could determine whether signs usually reported by physicians would be predictive of the patients' satisfaction with their knee. All the above variables were entered into multiple regression analysis. A backward elimination strategy for variable selection was used ( $\alpha = 0.05$ ). The result of this analysis provided a parameter estimate that described how much the dependant variable, KOOS, changed for every unit of change in the predictor variables.

Table 2  
Descriptive statistics of modified IKDC scoring system —  
physical exam data

| Variable                                 | Frequency (%) |
|--|---------------|
| <i>Lachman</i>                           |               |
| 0–2 mm                                   | 4 (9%)        |
| 3–5 mm                                   | 10 (22%)      |
| 6–10 mm                                  | 22 (49%)      |
| > 10 mm                                  | 9 (20%)       |
| <i>Lateral joint opening</i>             |               |
| 0–2 mm                                   | 39 (87%)      |
| 3–5 mm                                   | 6 (13%)       |
| 6–10 mm                                  | 0             |
| > 10 mm                                  | 0             |
| <i>Medial joint opening</i>              |               |
| 0–2 mm                                   | 36 (80%)      |
| 3–5 mm                                   | 7 (16%)       |
| 6–10 mm                                  | 2 (4%)        |
| > 10 mm                                  | 0             |
| <i>Limitation of flexion</i>             |               |
| 0–5°                                     | 30 (67%)      |
| 6–15°                                    | 14 (31%)      |
| 16–25°                                   | 1 (2%)        |
| > 25°                                    | 0             |
| <i>Limitation of extension (from 0°)</i> |               |
| 0–2°                                     | 41 (91%)      |
| 3–5°                                     | 3 (7%)        |
| 6–10°                                    | 1 (2%)        |
| > 10°                                    | 0             |
| <i>Pivotshift</i>                        |               |
| Normal                                   | 26 (58%)      |
| +  | 16 (36%)      |
| ++                                       | 3 (7%)        |
| +++                                      | 0             |

### 3. Results

#### 3.1. Study population / descriptive statistics

Forty-seven patients completed the KOOS questionnaire and 45 were interviewed, examined and had the Telos stress radiograph. Descriptive statistics for selected predictor variables and the dependent vari-

able (KOOS) are shown in Tables 1–4. The delay between injury and surgery varied from 1 to 435 months and the length of follow-up ranged from 8 to 45 months.

#### 3.2. Difference in the level of activity

Results of the paired *t*-test for differences in Tegner's scores are shown in Table 5. The difference in Tegner's scores after injury and post-surgery was significant and shows that Tegner's scores improved after the surgery. The difference in Tegner's scores pre-injury and post-surgery was also significant, showing that even if improvement was seen after surgery, the level of activity did not return to the pre-injury level (Fig. 1).

#### 3.3. Complications

None of the patients presented symptoms or signs of synovitis (Table 6). One patient had superficial wound infection that resolved after oral administration of antibiotics. Three patients had failure of implant fixation and required another operation to secure anchorage in bone. One of these failures occurred in a traumatic accident 3 months after surgical reconstruction of the ACL. One other patient required removal of the tibial screw because it was painful.

#### 3.4. Multivariate analysis

All variables were entered as a full model into a multiple regression equation. No parameter estimate was statistically significant in its association with the five subscales of the KOOS. When a backward elimination strategy for variable selection was used, none was significant.

### 4. Discussion

Data were collected on 47 patients who had an ACL reconstruction with the LARS artificial ligament in the designated hospital. According to the scores

Table 3  
Descriptive statistics for modified IKDC — Tegner's scores and Telos stress radiography

| Variable   | Mean | Median | Range    | S.D. |
|--|------|--------|----------|------|
| Tegner's score prior to injury   | 7.2  | 7.0    | 6.0–9.0  | 0.97 |
| Tegner's score after injury but prior to surgery   | 4.1  | 4.0    | 1.0–9.0  | 2.15 |
| Tegner's score after surgery   | 6.2  | 7.0    | 2.0–9.0  | 1.68 |
| Difference in PA translation between the injured knee and the opposite one (Telos Stress radiography) (mm) | 7.30 | 7.0    | 0.0–17.0 | 4.22 |

Table 4  
Results of the KOOS

| Subscale                           | Mean | Median | Range      | S.D.  |
|------------------------------------|------|--------|------------|-------|
| Activity of daily living score     | 93.0 | 98.5   | 50.0–100.0 | 11.97 |
| Pain score                         | 87.6 | 91.7   | 36.0–100.0 | 14.03 |
| Quality of life score              | 73.5 | 81.3   | 18.0–100.0 | 24.11 |
| Sport and recreational score       | 76.7 | 85.0   | 10.0–100.0 | 25.01 |
| Stiffness and other symptoms score | 84.3 | 85.7   | 25.0–100.0 | 15.65 |

obtained by the KOOS, patients showed a high degree of satisfaction for the activities of daily living, pain, knee-related quality of life, sport and recreation function, and stiffness and other symptoms following reconstruction of the ACL. Tegner's scores are decreased following injury to the ACL (statistically significant) but increased following ACL repair (statistically significant). Despite improvement of the level of activity following surgery, patients did not return to pre-injury levels (statistically significant).

PA displacement of the knee was still present after surgery as documented by the Lachman test and the Telos stress radiography. KT-1000 is often used to assess anterior laxity of the knee but we chose the Telos stress radiography because the KT-1000 presents problems with inter-observer reproducibility [2,12,14,18,21–25] and in this particular study, two observers were assessing the patients. Gougeon et al. [21] showed that interobserver reproducibility of KT-1000 measurements was low, but improved for intraobserver agreement. However, even for a unique KT-1000 experienced examiner, reliability of KT-1000 was poor when comparing Telos and KT-1000 and they recommend Telos instead of KT-1000 to assess laxity after ACL repair. Jardin et al. [22] are making the same recommendations. Tyler et al. [23] suggested as well that side-to-side KT-1000 measurements obtained with an anterior translation force of 89 N should not be used in isolation to determine ACL reconstruction success or failure. Berry et al. [24] showed that experience in using the KT-1000 is related to the interrater error of measurements and that training is an important consideration when using the KT-1000 arthrometer. Ballantyne et al. [25] also recommend that repeated measurements should be taken by the same examiners whenever possible to insure reliability.

From that data set, no variable can predict the degree of satisfaction of the knee following surgery. The population studied is rather heterogeneous; chronic, acute and subacute ruptures of the ACL are included, different associated lesions of the knee are present and some patients already had previous surgical treatment for ACL repair that failed. It is thus more difficult to draw conclusions for the satisfaction and clinical results of surgery.

Synovitis is a serious problem associated with artificial ligaments [26–31]. None of the patients reported here had clinically evident synovitis, but it is possible that some had a mild synovitis that was not diagnosed because they did not pay attention to it. Longer follow-up will be necessary to document tolerance of the knee to the LARS ligament because of the reported increasing effusion rates over time experienced with other artificial ligaments [32].

The complication rate was low and was mainly associated with failure of fixation of the ligament related to an early return to sports. We did not document any obvious ligament rupture, although some knees presented a significant PA translation on clinical examination. The only way to document a ruptured LARS ligament is by diagnostic arthroscopy. This was considered too invasive and was not performed on a routine basis. We are currently studying a new imaging technique combining magnetic resonance imaging with intra-articular Gadolinium for that purpose [33]. This technique will document whether residual knee laxity is the result of a rupture of the artificial ligament or loss of its bony fixation.

There were no major complications and no ligament required removal. Although we expect the failure rate to increase over time, this study suggests that the LARS artificial ligament should be included in a prospective, randomized clinical trial.

Table 5  
Paired *t*-test for Tegner's scores according to injury and surgery

| Difference in Tegner's scores:    | Mean difference | S.D. | 95% CI             | <i>t</i> -Statistic | <i>P</i> -Value |
|-----------------------------------|-----------------|------|--------------------|---------------------|-----------------|
| Prior to injury and post-injury   | -3.1            | 2.19 | [-3.7799; -2.4810] | -9.7085             | 1.3E-12         |
| Post-injury and after surgery     | 2.1             | 2.24 | [1.4015; 2.7290]   | 6.2668              | 0.00000049      |
| Prior to injury and after surgery | -1.1            | 1.37 | [-1.4729; -0.6575] | -5.2628             | 0.0000041       |

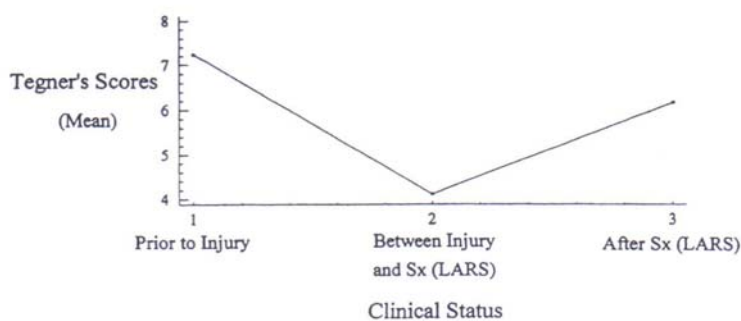


Fig. 1. Tegner's scores according to clinical status.

Table 6  
Complications following ACL reconstruction using LARS artificial ligament

| Complication                                    | Frequency | Treatment           |
|---|-----------|---------------------|
| Superficial infection (stitches)                | 1         | Antibiotics p.o.    |
| Failure of fixation                             | 3         | Anchor site revised |
| Fracture secondary to screw at site of fixation | 1         | Screw removed       |

**Conclusion**

The purposes of this study were to compare patient satisfaction with the objective measurement of knee stability and to assess early complications following ACL reconstruction using a LARS artificial ligament. Forty-seven patients were reviewed 8–45 months after surgery. The KOOS showed a mean score of 70.0 for activities of daily living, 87.6 for pain, 73.5 for knee-related quality of life, 76.7 for sport and recreation function, and 84.3 for stiffness and other symptoms. The average PA displacement was 7.3 mm. Pearson product moment correlation demonstrated a weak correlation between the KOOS, measurement by goniometry, radiography or clinical examination. These results therefore show little correlation between the objective findings at clinical examination and the patients' subjective perception of surgical outcome. We conclude that documenting only mechanical stability of the knee is inadequate when reporting follow-up studies and a questionnaire assessing patient satisfaction should be added to provide a more complete view of the outcome.

No clinical evidence of synovitis and minor complications are reported. We feel that the LARS artificial ligament may be a safe device to reconstruct an ACL tear. We are currently conducting a prospective, randomized clinical trial with a minimum 5-year follow-up.

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