Patient-Reported and Quantitative Outcomes of Anatomic Anterior Cruciate Ligament Reconstruction With Hamstring Tendon Autografts

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Background: The pivot-shift test has become more consistent and reliable and is a meaningful outcome measurement after anterior cruciate ligament reconstruction (ACLR).

Purpose/Hypothesis: The purpose of this investigation was to assess patient-reported outcomes (PROs) and the quantitative pivot shift (QPS) preoperatively, at time zero immediately after anatomic ACLR, and after 24 months as well as the relationship between PROs and the QPS. It was hypothesized that anatomic ACLR would restore rotatory stability measured by the pivot-shift test and that QPS measurements would be positively correlated with PROs.

Study Design: Cohort study; Level of evidence, 2.

Methods: The ACL-injured and contralateral uninjured knees from 89 of 107 (83.2%) enrolled patients at 4 international centers were evaluated using a standardized pivot-shift test. Tibial acceleration was assessed with an inertial sensor, and lateral compartment translation was measured using an image analysis system preoperatively, at time zero immediately postoperatively, and at follow-up after 2 years. PROs were assessed at 12 and 24 months postoperatively with the International Knee Documentation Committee (IKDC) subjective knee form, Cincinnati Knee Rating System (CKRS), Marx activity rating scale, and activity of daily living score (ADLS).

Results: The mean patient age at surgery was 27 years (range, 15-45 years). A positive pivot shift preoperatively (side-to-side difference in tibial acceleration, 2.6 ± 4.0 m/s²; side-to-side difference in anterior tibial translation, 2.0 ± 2.0 mm) was reduced at time zero postoperatively (side-to-side difference in tibial acceleration, –0.5 ± 1.3 m/s²; side-to-side difference in anterior tibial translation, –0.1 ± 1.0 mm). All PROs improved from preoperatively to final follow-up at 24 months: from 56.5 to 85.5 points for the IKDC (P = .0001), from 28.8 to 32.4 points for the CKRS (P = .04), from 11.2 to 7.9 points for the Marx (P < .0001), and from 75.7 to 91.6 points for the ADLS (P < .0001). Neither preoperative nor time zero postoperative rotatory laxity assessed by the pivot-shift test correlated with PROs at 24-month follow-up. A graft retear was observed in 4 patients (4.5%) within 2 years of follow-up.

Conclusion: Anatomic ACLR resulted in significantly improved and acceptable PROs at 2-year follow-up and a low failure rate. Anatomic ACLR restored QPS measurements of anterior tibial translation and tibial acceleration to those of the contralateral knee immediately after surgery while still under anesthesia, but there was no correlation between the QPS preoperatively or at time zero after ACLR and PROs at 2-year follow-up.

Keywords: ACL; anterior cruciate ligament; pivot shift; image analysis; translation; inertial sensor; acceleration; rotatory knee instability

An anterior cruciate ligament (ACL) injury results in increased anterior tibial translation and rotatory knee laxity.40 Whereas the Lachman test7 and anterior drawer test15 are 2 well-established clinical tools for the evaluation of anterior laxity, rotational laxity can be assessed using the pivot-shift test.6 By standardizing the maneuver, as well as the use of video-based image analysis and inertial sensor technology, the pivot shift has become more consistent, reliable, and objective.10,11 The quantitative pivot shift (QPS) has been validated by an international outcome network.10,23,26 Additional soft tissue injuries involving the meniscus or anterolateral complex, in association with ACL
injuries, may be detected by the pivot-shift test or the presence of static subluxation on magnetic resonance imaging (MRI).\textsuperscript{19,25,27} The pivot-shift test has been used both preoperatively and immediately postoperatively with the patient under anesthesia to assess rotatory knee laxity.\textsuperscript{20,28}

Although many factors, such as bony morphology and soft tissue injuries,\textsuperscript{16,28,29,31,32} influence rotatory stability, anatomic single-bundle ACL reconstruction (ACLR) is effective in restoring rotational stability as measured by the pivot-shift test.\textsuperscript{39} A persistent increased pivot shift after ACLR may be associated with an increased risk of cartilage and meniscal lesions.\textsuperscript{15} Moreover, a correlation between the pivot shift after ACLR and patient-reported instability has been demonstrated.\textsuperscript{17,18} A systematic review has demonstrated that the pivot shift is a meaningful functional outcome measurement with good correlation to functional outcome scores.\textsuperscript{3} Additionally, there is a significant correlation between high-grade preoperative instability and increased rates of ACL graft revision.\textsuperscript{21}

Given that the pivot-shift test is indicative of outcomes, the question arose as to whether there is a relationship between preoperative rotatory laxity, laxity at time zero immediately after ACLR, and laxity at 2 years’ follow-up and patient-reported outcomes (PROs). Therefore, the purpose of this study was to evaluate the effect of anatomic single-bundle ACLR with hamstring tendon autografts on PROs, QPS measurements, and the correlation between these measurements. It was hypothesized that anatomic ACLR would result in acceptable PROs and restored rotatory knee stability, as measured by the pivot-shift test, with a positive correlation between the measurements at 2-year follow-up.

METHODS

This study was part of a multicenter, prospective, observational cohort study, the Prospective International Validation of Outcome Technology (PIVOT) trial, at 4 international centers using a published study protocol.\textsuperscript{20,26} Patients between 14 and 50 years of age who presented with a primary ACL injury and underwent surgery between December 2012 and February 2015 were included. Further inclusion criteria were at least 1 injured ACL bundle (evaluated on MRI) with surgery performed within 1 year of injury. Exclusion criteria included (1) prior ligament surgery of the injured knee, (2) severe cartilage lesions (grade ≥3), (3) comitant injuries of the posterior cruciate ligament, (4) inflammatory arthritis, (5) prior surgery or ligament injuries to the healthy knee, and (6) refusal to participate. Institutional review board approval was obtained from all 4 international centers, and all recruited patients gave written informed consent, and all recruited patients gave written informed consent.

There were 107 patients prospectively enrolled in the PIVOT trial, and 89 patients (83.2\%) with an ACL injury and who underwent primary single-bundle ACLR had data available on preoperative and immediately postoperative lateral tibial translation and tibial acceleration. PROs were assessed at 12 and 24 months postoperatively by the use of the International Knee Documentation Committee (IKDC) subjective knee form (range, 0-100, with higher scores representing fewer symptoms and higher function and sports activity),\textsuperscript{8} Cincinnati Knee Rating System (CKRS; assessing knee function after ACLR, with 100 representing the best knee function and 0 representing the worst),\textsuperscript{2} Marx activity rating scale (assessing the level of activity based on 4 activity points: running, deceleration, cutting, and pivoting),\textsuperscript{22} and ability of daily living score (ADLS; assessing daily living, independence, and self-care with 100 representing no restrictions). Patient satisfaction was classified with the IKDC form based on the threshold for the patient acceptable symptom state (PASS).\textsuperscript{24,33}

Surgical Technique

All patients underwent anatomic single-bundle ACLR\textsuperscript{34} with a hamstring tendon autograft (Figure 1). The same surgical technique was used at all 4 clinical centers; consistency was ensured via a careful review of the critical steps by all participating surgeons. Both semitendinosus and gracilis tendons were harvested and looped over a suture button device, creating a quadruple hamstring tendon autograft. The tibial and femoral ACL footprints were identified. At the femoral footprint, the center of the anatomic position was marked posterior to the lateral intercondylar ridge and centered between the anteromedial and posterolateral bundles.\textsuperscript{3,4} The femoral tunnel was reamed through the anteromedial portal. The tibial tunnel was created in the central position of the anatomic footprint. The graft was fixed at the femoral side with a suture button and at the tibial side with an interference screw at 20° of flexion.\textsuperscript{30}

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Ethical approval for this study was obtained from the University of Pittsburgh Institutional Review Board (study No. PRO09030172).
Pivot-Shift Test

With the patient under general anesthesia, a standardized pivot-shift test was performed at all centers preoperatively in the operating room (Figure 2).20 The pivot-shift test was repeated with nonsterile devices immediately after surgery with the patient still in the operating room and under general anesthesia. Both times, the pivot-shift test was performed on the injured and contralateral healthy sides by an experienced orthopaedic surgeon to determine the side-to-side difference. The test was performed according to Galway and MacIntosh6 and Jakob et al.14 For standardization of the maneuver, a study group meeting was held for the training of all involved study personnel. An instructional video was also available.9 During the pivot-shift test, tibial acceleration was measured using the KiRA device (Orthokey),37,38 an inertial sensor with a sampling rate of 120 Hz, which was fixed on the knee at the Gerdy tubercle (Figure 2). The signal of the sensor was analyzed and plotted with a specifically developed application on a tablet computer (iPad; Apple) (Figure 2). For measuring lateral compartment translation, 3 yellow 0.75-inch adhesive surface markers (Color Coding Labels; Avery Dennison) were placed on the skin at the lateral epicondyle, the Gerdy tubercle, and 3 cm posterior to the Gerdy tubercle along the joint line. Anterior tibial translation relative to the femur was assessed using an image analysis system.10,11 With the digital camera of the tablet computer, the test was recorded and automatically processed in another specifically developed application to determine lateral compartment translation (Figure 2). Excellent repeatability and accuracy greater than 92% have been shown for the image analysis software.23

Statistical Analysis

The change in tibial acceleration and anterior tibial translation from before to immediately after surgery while still under anesthesia was evaluated using a paired t test. The difference in PROs from before surgery to 24-months follow-up was also evaluated using a paired t test. Correlations between QPS measurements and PROs were assessed by the Pearson correlation coefficient. Statistical significance was set at $P < .05$.

RESULTS

A total of 89 patients with a mean age of 27 years (range, 15-45 years) and 2-year follow-up were included (Table 1). A concomitant medial meniscal lesion was treated in 34 patients (38.2%) and a lateral meniscal lesion in 25 patients (28.1%) (Table 2).

At a mean follow-up of 64.9 ± 7.5 months, 26 patients (29.2%) underwent a second surgical procedure: 24 patients (27.0% of entire cohort) underwent secondary meniscal surgery, 18 patients (20.2%) underwent hardware removal, and 3 patients (3.4%) underwent arthroscopic lysis of adhesions and debridement. There was 1 intraoperative adverse event in which femoral hardware failure was detected by persistent elevated QPS measurements at time zero after ACLR and was confirmed by fluoroscopy to be caused by a defective suspensory button. The graft was removed, repassed into the tunnels, and fixed securely on the femoral side. The QPS was subsequently restored to that of the
Overall, 6 patients (6.7%) sustained a traumatic injury and graft tear, of which 4 (4.5%) occurred within 2 years after surgery.

The QPS measurements of tibial acceleration (5.5 ± 4.1 m/s² preoperatively to 2.4 ± 0.9 m/s² postoperatively; \( P < .0001 \)) and anterior tibial translation (3.1 ± 2.2 mm preoperatively to 1.0 ± 0.9 mm postoperatively; \( P < .0001 \)) were significantly reduced at time zero after ACLR as compared to preoperatively. At 24-month follow-up, tibial acceleration was reduced to 3.6 ± 1.7 m/s² (\( P < .0001 \)) and anterior tibial translation to 1.9 ± 1.9 mm (\( P < .0001 \)). In addition, the side-to-side difference for tibial acceleration (2.6 ± 4.0 m/s² preoperatively and –0.5 ± 1.3 m/s² postoperatively; \( P < .0001 \)) and anterior tibial translation (2.0 ± 2.0 mm preoperatively and –0.1 ± 1.0 mm postoperatively; \( P < .0001 \)) was also significantly reduced at time zero postoperatively.

All PROs were significantly improved at final follow-up as compared to preoperative values (Table 3). At 12 months, 76% of patients achieved the PASS as defined by the IKDC threshold of 75.9.24 At 24 months, 80% achieved the PASS.

Preoperative anterior tibial translation and tibial acceleration were not correlated with PROs at 24-month follow-up (Table 4). Similarly, anterior tibial translation and tibial acceleration at time zero postoperatively were not correlated with PROs at 24-month follow-up (Table 4). The side-to-side difference for anterior tibial translation and tibial acceleration at time zero postoperatively also demonstrated no significant correlation to PROs at 24-month follow-up (Table 5).

### TABLE 2

QPS Measurements for Patients With a Simultaneously Treated Meniscal Lesion During ACLR

|                  | Anterior Tibial Translation, mm | Tibial Acceleration, m/s² |
|------------------|---------------------------------|---------------------------|
|                  | Preoperative | Postoperative   | Preoperative | Postoperative   |
| MM resection (n = 10) | 4.7 ± 3.8 | 1.4 ± 1.2 | 5.3 ± 1.6 | 2.8 ± 0.8 |
| MM repair (n = 24) | 2.9 ± 1.9 | 1.2 ± 1.2 | 6.2 ± 3.7 | 2.4 ± 0.7 |
| LM resection (n = 10) | 3.0 ± 1.7 | 1.0 ± 0.6 | 4.6 ± 1.3 | 2.4 ± 0.7 |
| LM repair (n = 15) | 2.7 ± 1.9 | 0.8 ± 0.5 | 5.2 ± 4.1 | 2.6 ± 0.8 |

### TABLE 3

Patient-Reported Outcome Scores

|                  | Preoperative | 12 mo | 24 mo | P Value |
|------------------|--------------|-------|-------|---------|
| IKDC             | 56.5 ± 16.6 (n = 87) | 84.5 ± 16.1 (n = 71) | 85.5 ± 18.5 (n = 65) | <.0001 |
| CKRS             | 28.8 ± 15.1 (n = 87) | 32.9 ± 15.2 (n = 71) | 32.4 ± 13.7 (n = 66) | .04 |
| Marx             | 11.2 ± 5.1 (n = 87) | 9.3 ± 5.5 (n = 71) | 7.9 ± 5.3 (n = 66) | <.0001 |
| ADLS             | 75.7 ± 19.1 (n = 87) | 92.2 ± 11.4 (n = 71) | 91.6 ± 15.0 (n = 66) | <.0001 |

### TABLE 4

Correlation Between Preoperative and Postoperative Anterior Tibial Translation and Tibial Acceleration and PROs at 24-Month Follow-up

|                  | Preoperative | Postoperative |
|------------------|--------------|---------------|
|                  | r            | P Value       | r            | P Value       |
| IKDC             | 0.13         | .30           | 0.13         | .31           |
| CKRS             | –0.01        | .93           | 0.07         | .57           |
| Marx             | 0.03         | .81           | 0.09         | .46           |
| ADLS             | 0.11         | .37           | 0.15         | .20           | –0.01 | .95 |

### TABLE 5

Data are reported as mean ± SD. ACLR, anterior cruciate ligament reconstruction; LM, lateral meniscus; MM, medial meniscus; QPS, quantitative pivot shift.
TABLE 5
Correlation Between Postoperative Side-to-Side Difference for Anterior Tibial Translation and Tibial Acceleration and PROs at 24-Month Follow-up*°

|                     | Anterior Tibial Translation | Tibial Acceleration |
|---------------------|-----------------------------|---------------------|
|                     | r Value | P Value | r Value | P Value |
| IKDC                | 0.07    | .56     | –0.12   | .33     |
| CKRS                | –0.11   | .39     | 0.22    | .08     |
| Marx                | –0.01   | .94     | 0.01    | .96     |
| ADLS                | 0.01    | .96     | –0.01   | .93     |

*°ADLS, activity of daily living score; CKRS, Cincinnati Knee Rating System; IKDC, International Knee Documentation Committee; PRO, patient-reported outcome.

DISCUSSION

The most important finding of the present study was that anatomic ACLR resulted in acceptable PROs at 24-month follow-up, with 80% achieving the PASS and a 4.5% failure rate from traumatic graft tears. As demonstrated previously, QPS measurements of anterior tibial translation and tibial acceleration were significantly reduced at time zero postoperatively with minimal side-to-side difference with regard to the contralateral healthy knee.39 The QPS measurements preoperatively and at time zero after ACLR did not correlate with PROs at 24-month follow-up.

In recent years, interest in rotatory knee laxity assessed by the pivot-shift test has increased.25,27,32 Whereas anterior tibial translation has been shown to be significantly higher in ACL injuries with medial or lateral meniscal tears (3.7 vs 2.7 mm, respectively),27 tibial acceleration was influenced by only lateral meniscal tears (2.1 ± 1.1 vs 1.2 ± 0.7 m/s², respectively).12 The present study demonstrated that anatomic ACLR with appropriate meniscal repair resulted in excellent restoration of rotatory laxity as measured by the pivot-shift test, as well as acceptable PROs, at 24-month follow-up.

An association has been found between positive pivot-shift test results at 2-year follow-up and reduced PRO scores.15 In addition, an association between the pivot shift at 2-year follow-up and functional instability has been shown.17 Interestingly, such an association was not evident for the Lachman test.17 A recent systematic review concluded that the literature supports an association between the pivot shift at least 1 year after ACLR and clinical and functional outcomes.1 Although a correlation between residual rotatory laxity immediately postoperatively and reduced PRO scores at 12 and 24 months' follow-up is logical, the present study did not find this association. This could potentially be because anatomic ACLR provided relatively high PRO scores without much variability in this cohort. Although a correlation between increased preoperative rotatory laxity and the risk of ACL revision surgery has been found, no correlation to postoperative IKDC scores at 2-year follow-up was evident.21 Because no correlation between the preoperative pivot shift and PROs was evident, questions arose as to whether rotatory stability immediately after ACLR could predict PROs at 2-year follow-up. In the present study, the hypothesis that rotatory stability at time zero as measured by the pivot-shift test correlates with short-term PROs was not confirmed. However, the present study showed that anatomic ACLR restored symmetrical rotatory laxity and resulted in acceptable PROs.

PRO measures assess activity, pain, satisfaction, and limitations in daily living,13 which are indirectly connected to stability of the knee but are also dependent on postoperative rehabilitation, range of motion, muscle strength, and individual sports level.5,36 These factors may provide some explanation for the lack of correlation between PROs and rotatory stability at time zero. Additionally, in this study, anterior tibial translation and tibial acceleration at time zero postoperatively were reduced to those of the contralateral normal knee. Therefore, the lack of residual rotatory laxity during the pivot-shift test and uniformly high PROs may limit the ability to show a relationship between rotational knee laxity and PROs. However, at 1- to 2-year follow-up, rotatory stability has been associated with functional PROs.1 Therefore, although no direct correlation is evident, an indirect correlation between rotatory stability at time zero and PROs at longer term follow-up could be suspected.

In this study, anatomic single-bundle ACLR with a hamstring tendon autograft was effective in restoring rotatory knee stability in cases of ACL deficiency, similar to the literature.39 When discussing rotatory knee stability, a patient-specific individualized treatment strategy based on the injured structures and degree of instability must be considered.12,27 An individualized anatomic approach may be the key to optimize long-term PROs. In the literature, a broad variety of soft tissue injury patterns and bony morphologies has been described to influence rotatory instability.16,28,29,31,52 But a threshold for high-grade rotatory instability for which additional procedures are required is still lacking.25 Individualized treatment for patients with ACL injuries is important, and the QPS may help direct attention to additional soft tissue injuries, ensuring complete restoration of rotatory knee stability, as shown in this study.12,25,27 Moreover, in 1 case, the pivot-shift test was helpful in confirming intraoperative knee stability. In this patient, the QPS was equal at time zero postoperatively compared to preoperative measurements, which led to an investigation into femoral fixation with fluoroscopy. It was detected that the dispansory button had failed to flip, an easily correctable situation, and this failure was remedied.

A limitation of this study is its small cohort and lack of variability in the QPS at time zero postoperatively, limiting the predictive value of the QPS. Additionally, the present study is limited by the lack of blinding of the examiners to the data that were collected in real time and the potential for differences in performing the pivot-shift test, even in the face of a standardized technique.

CONCLUSION

Anatomic ACLR with hamstring tendon autografts resulted in acceptable PROs and objective rotatory laxity
with a low reported failure rate at short-term follow-up. The QPS, as demonstrated by anterior tibial translation and tibial acceleration, was restored to that of the contralateral normal knee by this technique. Rotatory knee laxity assessed by the pivot-shift test preoperatively or immediately after ACLR had no correlation with PROs at 2-year follow-up. Given the evidence in the literature that rotatory knee laxity at 1- to 2-year follow-up correlates with the development of posttraumatic osteoarthritis, as well as clinical outcomes, ACLR should focus on the restoration of rotatory knee laxity in patients.

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