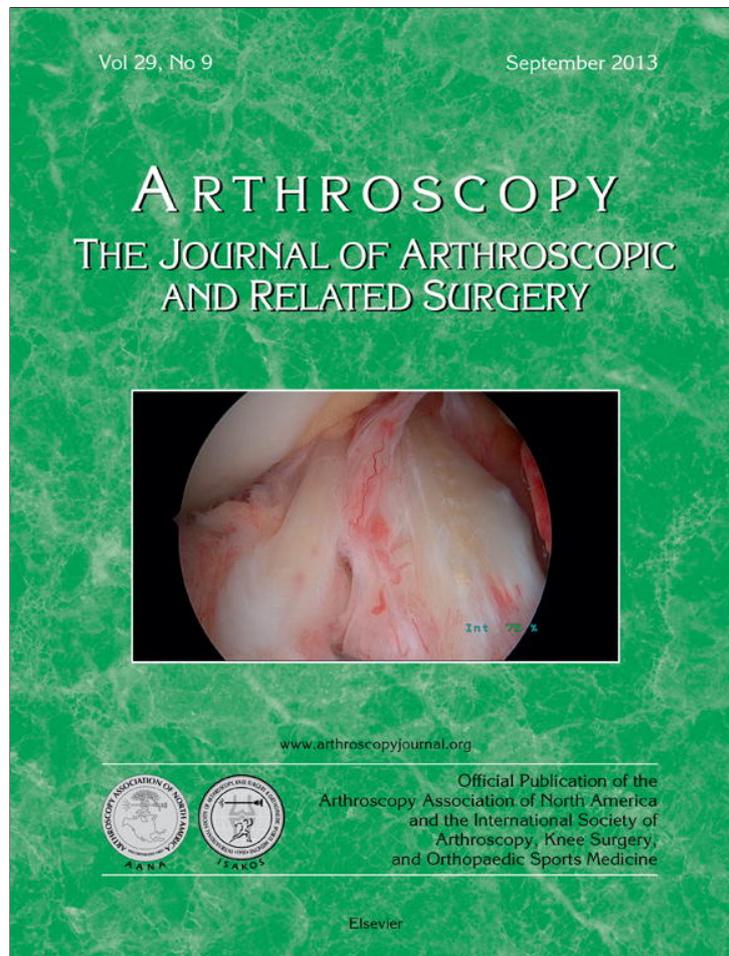


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Systematic Review

Long-Term Failure of Anterior Cruciate Ligament Reconstruction

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Purpose: The aim of this study was to review and describe the cumulative incidence of anterior cruciate ligament (ACL) graft rupture and/or clinical objective failures at greater than 10 years after ACL reconstruction. **Methods:** A PubMed search was performed to identify and systematically evaluate all studies performed between 1980 and 2012 with clinical outcomes after intra-articular, non-artificial ACL reconstruction and minimum 10-year follow-up. Studies reporting standardized surgical technique, ACL graft rupture, and objective International Knee Documentation Committee (IKDC) grade or ligament stability examination were included for analysis. After we first identified patients with graft rupture, clinical failure was further identified as 1 or more of the following: overall IKDC objective score of C or D, IKDC grade C or D pivot shift (i.e., >2+ or pivot shift), IKDC grade C or D Lachman examination, and/or abnormal KT arthrometer (MEDmetric, San Diego, CA) measurement (i.e., >5 mm). For this study, cumulative ACL failure rates were defined as the sum of both clinical failures and ACL graft ruptures. **Results:** After review and exclusion of 625 references, 14 studies were identified for subsequent review. At longer than 10 years' clinical follow-up, the reported ACL graft rupture rate was 6.2% (173 of 2,782) (range, 0% to 13.4%) and clinical failure occurred in approximately 10.3% (158 of 1,532) (range, 1.9% to 25.6%). The overall cumulative ACL failure rate was 11.9% (range, 3.2% to 27%). **Conclusions:** At least 1 in 9 patients undergoing ACL reconstruction will have rerupture or clinical failure at long-term follow-up. **Level of Evidence:** Level IV, systematic review of Level II and IV studies.

Anterior cruciate ligament (ACL) reconstruction is 1 of the most commonly performed surgeries in orthopaedics.¹ Despite its prevalence and impact on patients' quality of life, the long-term outcomes of ACL reconstruction are poorly understood and have been inconsistently reported in the literature.² These studies vary widely in terms of quality, patient population, primary and secondary outcome measures, surgical techniques, and graft selection. Given this heterogeneity, it is difficult to extrapolate surgical outcomes of ACL

reconstruction at a minimum of 10 years' clinical follow-up. Similarly, failure after ACL reconstruction lacks precision and requires more explicit definition. Although traumatic ACL rerupture can be easily identified, atraumatic or clinical failure can be attributed to a host of surgical and patient-specific factors, including nonanatomic tunnel placement, graft compromise, or inadequate rehabilitation.

Many longitudinal studies fail to account for failures related to poor subjective and/or objective patient outcomes, which could lead to an artificially low graft failure rate. This underscores the importance of sensitive, objective measures of graft laxity and ACL function, particularly instrumented or manual laxity measures and validated outcome measures such as the International Knee Documentation Committee (IKDC) score.³

Because of the rarity of long-term data on ACL reconstruction, systematic review may provide the best available evidence to guide contemporary treatment and prognosis. The aim of this study was to review and describe the cumulative incidence of ACL graft rupture and objective failures at greater than 10 years after ACL reconstruction. Our hypothesis was that ACL long-term clinical outcome data underestimate the true failure rate of ACL reconstruction.

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Methods

A PubMed/Medline database search was performed in September 2011 and updated in December 2012 by use of the terms “anterior cruciate year follow” to evaluate failure rates of ACL reconstruction at greater than 10 years’ follow-up. All citations were then screened by 2 investigators. Inclusion criteria required English-language publication, intra-articular allograft or autograft ACL reconstruction, consistent surgical technique, minimum 10-year follow-up, reported rerupture rate, and objective IKDC scoring and/or stability examination at final follow-up. Exclusion criteria included studies with extra-articular or tenodesis reconstructions, artificial graft sources, primary ACL repair, less than 10 years’ follow-up, and/or systemic reviews or meta-analyses. If inclusion criteria were met or the abstract was not sufficient to determine inclusion, full review was performed.

Full review was performed to determine several parameters. Demographic characteristics, methodologic quality, timing of reconstruction, graft choice, surgical technique, coexisting pathology, subjective (e.g., Lysholm, Tegner) and objective outcome measures (e.g., Lachman test, instrumented laxity measures), and contralateral ACL rupture were identified. Furthermore, reported ACL rerupture were identified, objective clinical failure, and cumulative failure rates were extrapolated. For the purposes of this study, the clinical failure rate was defined, in cases exclusive of graft rupture, as one of the following: an overall IKDC objective score of C or D, IKDC grade C or D pivot shift (i.e., >2+ or pivot shift), IKDC grade C or D Lachman examination or KT arthrometer (MEDmetric, San Diego, CA) measurement (i.e., >5 mm), and/or identified grossly abnormal stability examination without IKDC scoring available. Finally, the redefined cumulative failure rate includes the sum of ACL rerupture plus clinical failure rates (adjusted for cohort size, as noted in the paragraph below).

The articles in this review excluded ACL graft ruptures, contralateral ACL injury, and incomplete outcome data in their reporting of subsequent objective clinical outcomes. As a result, clinical failure is identified among a smaller subset of patients who have achieved complete final follow-up with required objective clinical assessments. Conversely, rerupture rates were reported among the full patient cohort, thus accounting for differences in the denominator.

Results

After screening 625 results, we selected 26 studies for full review. Twelve of these were excluded because of surgical technique,⁴⁻⁶ insufficient clinical follow-up,^{7,8} absent or inadequate stability testing,⁹⁻¹² no reported rerupture rate,¹³ non-English-language publication,¹⁴ and inconsistent surgical technique.¹⁵

Data Extraction

A total of 14 studies were isolated for evaluation, including 8 retrospective series, 4 prospective series, 1 prospective comparative study, and 1 randomized controlled trial.¹⁶⁻²⁹ A total of 2,782 initial patients were evaluated for inclusion in this study, and 1,532 patients were isolated for full review at greater than 10 years’ follow-up. Table 1 details the characteristics and study design of the included studies. Studies were analyzed for patient demographics, follow-up period, graft choice, allograft processing, femoral and tibial fixation, femoral tunnel drilling technique, contralateral ACL rupture, rerupture rate, return to previous sport/activity, 1-legged hop test, instrumented laxity measurement, range of motion, Lachman examination, pivot-shift testing, donor-site morbidity, period from injury to surgery, surgical complications, coexisting knee pathology (including chondral and meniscal lesions), concomitant knee procedures, and outcome measures (i.e., IKDC, Tegner, Lysholm, and visual analog scale scoring systems).

Graft Selection

Eleven studies used bone–patellar tendon–bone autografts,^{17-20,22,23,25-29} including 2 prospective studies concomitantly evaluating hamstring autograft.^{23,26} One retrospective study exclusively evaluated hamstring autograft.²¹ Two additional studies used soft-tissue allograft (anterior tibialis, posterior tibialis, and/or Achilles tendon grafts). Nakata et al.²⁴ used non-irradiated allograft tissue with antibiotic treatment, whereas the sterilization methods were indeterminate for Almquist et al.¹⁶

Surgical Technique

The surgical techniques, particularly femoral tunnel drilling and graft fixation, were variable among the included studies (Table 1). Of the studies, 9 involved tibial independent femoral tunnel drilling (7 transportal and 2 outside in), 3 used a transtibial technique, and 2 used unspecified techniques. Aperture interference screw fixation was the most common technique, but an implant-free press-fit technique, cross-pin fixation, suture anchor, screw post, and/or washer technique were also used.

ACL Failure

The ACL failure rates for the included studies are summarized in Table 2. The total ACL rerupture rate was 6.2% (173 of 2,782) (range, 0% to 13.4%). After application of our failure criteria, the clinical failure rate was 10.3% (158 of 1,532) (range, 1.9% to 25.6%). When taken in sum, the cumulative ACL failure rate at long-term follow-up increased to 11.9% (331 of 2,782) (range, 3.2% to 29.9%).

Discussion

This cumulative failure rate of primary ACL reconstruction may be higher than previously documented.

Table 1. Study Characteristics in Selected Studies

| Study | Almqvist et al. ¹⁶ | Cohen et al. ¹⁷ | Felmet ¹⁸ | Hertel et al. ¹⁹ | Hui et al. ²⁰ | Inderhaug et al. ²¹ | Lebel et al. ²² |
|--|--|---------------------------------------|----------------------------------|--|---|---|-------------------------------|
| Year | 1995-1997 | 1986-1991 | 1998-1999 | 1987-1991 | 1993-1994 | 1999-2001 | 1993-1994 |
| Mean follow-up (yr) | 10.5 | 11.2 | 10.3 | 10.7 | 15.3 | 10.2 | 11.6 |
| No. of patients (final follow-up/total consecutive patients) | 50/60 | 62/126 | 148/189 | 95/159 | 72/333 | 80/96 | 101/272 |
| Age (range) (yr) | 25 (17-50) | 27 (15-46) | 38 (15-58) | 42 (22-66) | 26 (15-50) | 25 (15-42) | 29 (14-66) |
| Sex (% male) | 72% | 75.8% | 61.5% | 59.0% | 51.1% | 57.5% | 76.5% |
| Methodology | Retrospective | Retrospective | Prospective | Retrospective | Retrospective | Retrospective | Prospective |
| Graft | Allograft PTT/ATT | Autograft BPTB | Autograft BPTB | Autograft BPTB | Autograft BPTB | Autograft 4HS | Autograft BPTB |
| Surgical technique | NP Suture anchors (F), IFS staple (T) | NP Screw washer (F/T) | TP Press fit (F/T) | TP Press fit (F/T) with or without cross-pin fixation (T) | TP IFS (F/T) | TT IFS (F) spiked washer screw (T) | TP IFS (F/T) |
| Reported outcomes | ROM, hop test, Biodex (Biodex Medical Systems, Shirley, NY), KT, Tegner, Lysholm, IKDC, XR | Lysholm, pivot, Lachman, KT, IKDC, XR | Lachman, pivot, Tegner, IKDC, XR | Tegner, Lysholm, IKDC, XR | Hop test, Lachman, pivot, KT, Lysholm, IKDC, XR | Lysholm, Lachman, pivot, KT, IKDC, Tegner, XR | IKDC, KT, XR, tunnel position |
| Level of evidence | IV | IV | IV | IV | IV | IV | IV |

BPTB, bone–patella tendon–bone; F, femur; IFS, interference screw fixation; KT, instrumented knee laxity measures; NP, not provided; OI, outside-in; PTT/ATT, posterior tibialis and anterior tibialis tendon; ROM, range of motion; T, tibia; TP, transportal or independent femoral tunnel technique; TT, transtibial femoral tunnel technique; VAS, visual analog scale; XR, plain film radiographs; 4HS, quadruple-looped hamstring tendon.

Previous studies have focused on a limited description of failure after primary ACL reconstruction, reporting only on rates of ipsilateral ACL rerupture.³⁰ However, a more inclusive definition of ACL failure should encompass patients with poor clinical outcomes as indicated by established objective clinical measures. In this systematic review of 14 studies, ACL rerupture occurred in an average of 6.2% of patients at greater than 10 years' follow-up. Furthermore, when we considered additional objective failure criteria, the long-term, cumulative ACL failure rate nearly doubled to a rate of 11.9%.

In considering outcomes after ACL reconstruction, multiple primary and secondary endpoints may be considered. Foremost, rates of secondary ACL rupture are readily accessible from previous studies because this represents a discreet, yet variable measure of failure. In the included studies, the long-term rerupture rate varied between 0% and 13.4%, although short-term rerupture rates have been reported in up to 24.4% of

high-demand, active patients receiving allograft reconstruction.³¹ The risk of ACL graft failure may be highest in the first 2 years postoperatively, in part because of delayed biological incorporation associated with soft-tissue or allograft use. Bourke et al.³² reported a 2.45% annual graft rupture rate within 2 years of surgery, but annual rates subsequently declined to 0.42% thereafter at up to 15 years' follow-up. Similarly, other studies have documented an annual rupture rate of 0.3% to 1.3%.³²

In addition, a variety of objective knee outcome measures are currently in use, although they are not standardized across the literature. Among these, the IKDC scoring system remains 1 of the most commonly reported and is a comprehensive validated measure that includes objective assessments of range of motion, ligament stability, and radiographic findings. In their series of 133 patients, Irrgang et al.³ showed the usefulness of the IKDC scoring system in describing

Table 1. Continued

| Leys et al. ²³ | Nakata et al. ²⁴ | Oiestad et al. ²⁵ | Sajovic et al. ²⁶ | Salmon et al. ²⁷ | Shelbourne and Gray ²⁸ | van der Hart et al. ²⁹ |
|---|--------------------------------------|---|---|---|---|-----------------------------------|
| 1993-1994 | 1986-1990 | 1990-1997 | 1999-2000 | 1989 | 1982-1994 | 1993-1994 |
| 15 | 11.5 | 12.4 | 11 | 13 | 14.1 | 10.3 |
| 94/180 | 61/125 | 181/221 | 64/75 | 49/97 | 502/1,545 | 28/53 |
| 25 (15-42) | 20.9 (NP) | 39.5 (NP) | 38 (27-58) | 27 (25-28) | 23.1 (11-53) | 30.5 (16-42) |
| 24 (13-52) | | | 36 (25-54) | | | |
| 50.0% | 42.6% | 58.0% | 56.9% | 70.2% | 72.0% | 60.7% |
| Prospective comparative | Retrospective | Prospective | Randomized trial | Retrospective | Prospective | Retrospective |
| Autograft 4HS v BPTB | Non-irradiated soft tissue allograft | Autograft BPTB | Autograft BPTB v 4HS | Autograft BPTB | Autograft BPTB | Autograft BPTB |
| TP | 2-incision OI Post/button (F/T) | TT NP | TP IFS (F/T) | TP Screw (F/T) | 2-incision OI IFS (F/T) | TT IFS (F/T) |
| ROM, hop test, donor-site morbidity, Lachman, anterior drawer, pivot, KT, IKDC, Lysholm, VAS, XR, tunnel position | Strength, KT, XR | Strength, hop test, Lachman, pivot, KT, Cincinnati, VAS, Tegner, XR | Hop test, Lachman, pivot, KT, Lysholm, IKDC, XR | Hop test, Lachman, pivot, KT, IKDC, Lysholm, XR | Strength, ROM, hop test, pivot, KT, IKDC, Noyes, KT | VAS, Tegner, Lysholm, IKDC, XR |
| II | IV | II | II | IV | II | IV |

outcomes after ACL reconstruction. After outcome analysis, 62% of the variability of the final IKDC rating was determined by the symptoms and laxity subgroup ratings,³ underscoring the importance of long-term ACL stability. In our study, patients with an overall IKDC grade of C and D accounted for 10.3%, with rates ranging from 2% to 25.6%. However, this measure may represent a more stringent assessment of knee function compared with other instruments because the overall IKDC rating is defined by the lowest rating within each subgroup. As a result, this tool may be complemented by functional assessment scales in future studies to better evaluate return to sports or other routine daily activities.

Limitations

When ACL reruptures and objective clinical failures are collectively considered, the cumulative failure rate of primary ACL reconstruction after greater than 10 years' follow-up is nearly double that reported in the literature. However, as with any systematic review, we do acknowledge certain limitations within

our study. Although strict inclusion criteria were used, our cumulative ACL failure rate did not account for functional or subjective outcome measures, such as the IKDC subjective form, Tegner score, and Lysholm score. These measures were inconsistently available, and subjective grading may be influenced on long-term follow-up by other pathologic processes both in and outside of the knee joint. As a result, our cumulative ACL failure rate may underestimate actual rates of long-term failure after ACL reconstruction. In addition, instrumented and manual laxity testing was not uniformly performed by a blinded examiner, which may introduce detection bias. Heterogeneity in patient demographics, surgical technique, tissue graft, and other study variables may also be considered. Lastly, differential losses to follow-up may contribute to selection bias, particularly when one considers the clinical outcomes in studies such as that of Shelbourne and Gray.²⁸ In this series of 1,545 patients, only 502 individuals completed final objective follow-up among 1,276 patients without postoperative ACL rupture. Further

Table 2. Long-Term Objective Clinical Outcomes in Selected Studies

| | Stated Rerupture Rate | Abnormal Lachman | Abnormal Pivot Shift | Abnormal Instrumented Measures | IKDC Overall Grade C or D | Clinical Failure Rate | Redefined Cumulative Graft Failure Rate |
|-----------------------------------|-----------------------|------------------|----------------------|--------------------------------|---------------------------|-----------------------|---|
| Almqvist et al. ¹⁶ | 4/55 (7.3%) | — | — | — | 11/50 (22%) | 11/50 (22%) | 15/55 (27.3%) |
| Cohen et al. ¹⁷ | 0/62 (0%) | 7/62 (11.3%) | 6/62 (9.7%) | 5/62 (8.1%) | — | 7/62 (11.3%) | 7/62 (11.3%) |
| Felmet ¹⁸ | 6/154 (3.9%) | — | 4/148 (2.7%) | — | 9/148 (6.1%) | 9/148 (6.1%) | 15/154 (9.7%) |
| Hertel et al. ¹⁹ | 0/95 (0%) | — | 3/95 (3.2%) | — | — | 3/95 (3.2%) | 3/95 (3.2%) |
| Hui et al. ²⁰ | 7/90 (7.2%) | 7/72 (9.7%) | 7/72 (9.7%) | — | 10/72 (13.9%) | 10/72 (13.9%) | 17/90 (18.9%) |
| Inderhaug et al. ²¹ | 3/83 (3.6%) | 11/80 (14%) | 16/80 (20%) | 6/80 (8%) | — | 16/80 (20%) | 19/83 (22.9%) |
| Lebel et al. ²² | 9/110 (8.2%) | 9/101 (8.9%) | 7/101 (6.9%) | 2/101 (2.0%) | 10/101 (9.9%) | 10/101 (9.9%) | 19/110 (17.3%) |
| Lays et al. ²³ | 22/180 (12.2%) | 0/94 (0%) | 0/94 (0%) | 1/94 (2%) | 1/94 (2%) | 1/94 (2%) | 23/180 (12.8%) |
| Nakata et al. ²⁴ | 3/68 (4.4%) | 2/61 (3.3%) | 4/61 (6.6%) | 0/61 (0%) | — | 4/61 (6.6%) | 7/68 (10.3%) |
| Oiestad et al. ²⁵ | 15/181 (8.3%) | 23/144 (16.0%) | 17/144 (11.8%) | — | — | 23/144 (16.0%) | 38/181 (21.0%) |
| Sajovic et al. ²⁶ | 5/64 (7.8%) | 1/52 (1.9%) | 1/52 (1.9%) | 1/52 (1.9%) | — | 1/52 (1.9%) | 6/64 (9.4%) |
| Salmon et al. ²⁷ | 9/67 (13.4%) | 3/43 (7.0%) | 0/43 (0%) | 3/35 (8.6%) | 11/43 (25.6%) | 11/43 (25.6%) | 20/67 (29.9%) |
| Shelbourne and Gray ²⁸ | 90/1,545 (5.8%) | — | 5/502 (1.0%) | 15/502 (3.0%) | 48/502 (9.6%) | 48/502 (9.6%) | 138/1,545 (8.9%) |
| van der Hart et al. ²⁹ | 0/28 (0%) | — | — | 4/28 (14.3%) | 4/28 (14.3%) | 4/28 (14.3%) | 4/28 (14.3%) |
| Total | 173/2,782 (6.2%) | — | — | 4/28 (14.3%) | 158/1,532 (10.3%) | 158/1,532 (10.3%) | 331/2,782 (11.9%) |

emphasis on standardized study design and comprehensive patient follow-up may obviate these issues in future studies.

Conclusions

At least 1 in 9 patients undergoing ACL reconstruction will have rerupture or clinical failure at long-term follow-up.

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