Systematic Review

# Synthetic Devices for Reconstructive Surgery of the Cruciate Ligaments: A Systematic Review

Lachlan M. Batty, M.B.B.S., Cameron J. Norsworthy, F.R.A.C.S., Nicholas J. Lash, F.R.A.C.S., Jason Wasiak, M.P.H., Anneka K. Richmond, B.Sc., and Julian A. Feller, F.R.A.C.S.

**Purpose:** The role of synthetic devices in the management of the cruciate ligament–injured knee remains controversial. The aim of this systematic review was to assess the safety and efficacy of synthetic devices in cruciate ligament surgery. **Methods:** A systematic review of the electronic databases Medline, Embase, and The Cochrane Library (issue 1, 2014) on January 13, 2014, was performed to identify controlled and uncontrolled trials. Trials that assessed the safety and efficacy of synthetic devices for cruciate ligament surgery were included. The main variables assessed included rates of failure, revision, and noninfective effusion and synovitis. Patient-reported outcome assessments and complications were also assessed where reported. **Results:** From 511 records screened, we included 85 articles published between 1985 and 2013 reporting on 6 synthetic devices (ligament augmentation and reconstruction system [Ligament Augmentation and Reconstruction System (LARS; Surgical Implants and Devices, Arc-sur-Tille, France)]; Leeds-Keio [Xiros (formerly Neoligaments), Leeds, England]; Kennedy ligament augmentation device [3M, St Paul, MN]; Dacron [Stryker, Kalamazoo, MI]; Gore-Tex [W.L. Gore and Associates, Flagstaff, AZ]; and Trevira [Telos (limited liability company), Marburg, Germany]). The heterogeneity of the included studies precluded meta-analysis. The results were analyzed by device and then type of reconstruction (anterior cruciate ligament [ACL]/posterior cruciate ligament [PCL]/combined ACL and PCL). The lowest cumulative rates of failure were seen with the LARS device (2.6% for ACL and 1% for PCL surgery). The highest failure rate was seen in the Dacron ACL group (cumulative rate, 33.6%). Rates of noninfective synovitis and effusion ranged from 0.2% in the LARS ACL group to 27.6% in the Gore-Tex ACL group. Revision rates ranged from 2.6% (LARS) to 11.8% (Trevira-Hochfest; Telos). Recent designs, specifically the LARS, showed good improvement in the outcome scores. The mean preoperative and postoperative Lysholm knee scores were 54 and 88, respectively; the mean preoperative and postoperative Tegner activity scale scores were 3.3 and 6, respectively. **Conclusions:** Preliminary results for newer-generation devices, specifically the LARS, show lower reported rates of failure, revision, and sterile effusion/synovitis when compared with older devices. **Level of Evidence:** Level IV, systematic review of Level II through IV studies.

Although synthetic implants and devices are used widely within many fields of medical practice, their role in the treatment of the knee with cruciate ligament injury continues to be defined. Both currently and historically, the use of autogenous graft tissue has been a widely accepted method of restoring the function of knees affected by cruciate ligament deficiency.[1,2] Arguably, autograft cruciate reconstruction is the gold standard, providing reliable long-term results. However, donor-site morbidity remains a drawback.[3,4]

Allograft tissue is also an option for cruciate reconstruction, with the benefit of no harvest morbidity, but availability and sanctions mean that allograft tissue is not used in many countries. Some authors have reported higher-than-anticipated rates of failure with various preparations of allograft for cruciate ligament reconstruction especially in younger patient populations.[5-8] In addition, allograft tissue carries the potential risk of disease transmission and graft rejection.

Since the 1970s, synthetic devices have been available for use in the management of the cruciate-injured knee. These devices have the intended benefits of avoiding donor-site morbidity, providing a strong stabilizing construct, and allowing aggressive rehabilitation and a

*From the OrthoSport Victoria Research Unit, Deakin University and Epworth Healthcare, Melbourne, Australia.*

*The authors report the following potential conflict of interest or source of funding: J.A.F. receives support from Stryker, Tornier, and Smith & Nephew.*

*Received July 15, 2014; accepted November 18, 2014.*

*Address correspondence to Anneka K. Richmond, B.Sc., OrthoSport Victoria, Level 5, 89 Bridge Road, Richmond, VIC 3121, Australia. E-mail: anneka@osv.com.au*



*0749-8063/14611/$36.00*

*http://dx.doi.org/10.1016/j.arthro.2014.11.032*

relatively rapid return to sporting activity without the risks of disease transmission and rejection.

A full historical account of the use of synthetic devices in cruciate ligament surgery is not within the scope of this review; however, the article by Mascarenhas and MacDonald[9] provides an excellent overview. In brief, early carbon fiber devices were modified to include polylactic acid and polycaprolactone coating in an attempt to reduce problems with carbon wear particles. The Gore-Tex device (W.L. Gore and Associates, Flagstaff, AZ) made from expanded polytetrafluoroethylene was used between the mid 1980s and mid 1990s. In the early 1980s Kennedy[10] proposed the use of a polypropylene braid as a ligament augmentation device (LAD; 3M, St Paul, MN) to protect patellar tendon autogenous grafts in the early postoperative period.

A number of devices have been developed from polyester composites, such as polyester mesh in the case of the Leeds-Keio device (Xiros [formerly Neoligaments], Leeds, England) and polyester strips in the case of the Dacron device (Stryker, Kalamazoo, MI). A second-generation Leeds-Keio device was made available in 2003 with the addition of radiofrequency-generated glow discharge treatment.[11] A number of polyethylene terephthalate devices released include the Trevira-Hochfest device (Telos [SARL], Marburg, Germany), Proflex device (Protek, Bern, Switzerland), Pro-Pivot device (Istituto Ortopedico Gaetano Pini, Milan, Italy), and Ligament Augmentation and Reconstruction System (LARS; Surgical Implants and Devices, Arc-sur-Tille, France).

Initial enthusiasm for these devices was later tempered by reports of complications specific to their use: device creep and failure, noninfectious knee effusion and synovitis,[12] accumulation of synthetic material within the knee,[13] and premature development of osteoarthritis.[14] Because of reports of complications, a number of devices were subsequently withdrawn from the market by the early 1990s, but there has recently been renewed interest in later generations of synthetic devices, including the LARS.[15]

The aim of this systematic review was to assess the safety and efficacy of synthetic devices in cruciate ligament surgery, with particular attention paid to rates of failure, revision, and noninfective effusion or synovitis. Patient-reported outcome measures and rates of complications were also compared among devices where available. Included in this study were the LARS, Kennedy LAD, Leeds-Keio device, Dacron device, Gore-Tex device, and Trevira device (Telos).

## Methods

### Data Sources and Search Strategy

A structured literature search was performed in Medline from 1946, Embase from 1980, and The Cochrane Library (issue 1, 2014) using the following key words: "knee injuries," "knee joint," "anterior cruciate ligament," "posterior cruciate ligament," "ligament augmentation and reconstruction systems," "LARS," "Leeds-Keio," "Kennedy ligament augmentation device," "LAD," "polyethylene terephthalate," "Goretex," and "Dacron." The predefined search strategy was designed for maximal retrieval using Medical Subject Headings and free text searching. The thesaurus vocabulary of each database was used to adapt the search terms. The selected time frame was chosen to take into account the development and clinical availability of the synthetic devices. In addition to the automated search strategies, reference lists of related journal articles, key journals, and existing reviews were hand searched for additional trials. No attempt was made to locate unpublished material or to contact authors of unpublished studies.

### Study Selection Criteria and Procedures

All published peer-reviewed studies including randomized controlled trials (RCTs), nonrandomized comparative studies, cohort studies, and case series with more than 10 patients that examined the safety and efficacy of synthetic devices in surgery of the anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL) were considered for inclusion. We included studies that made reference to skeletally mature patients with 1 or more cruciate ligament deficiencies requiring surgery as an isolated or combined procedure. In vivo studies, animal studies, non–English-language studies, non–peer-reviewed studies, studies not available in full text, unpublished manuscripts, narrative or systematic reviews, guidelines, commentaries, case series of fewer than 10 patients, and studies looking at cruciate reconstruction in conjunction with high tibial or distal femoral osteotomy were excluded. Records retrieved by the initial search were scanned by 2 review authors (L.M.B., J.W.) to exclude obviously irrelevant studies, and 2 authors (L.M.B., N.J.L.) then screened titles and abstracts against the inclusion criteria. Full-text articles were retrieved and reviewed independently by 2 authors for the purpose of applying inclusion criteria. In all instances, differences of opinion were resolved by discussion among the authors. In the case of multiple reports on the same patient cohort with an increasing duration of follow-up, only the latest publication was included.

### Data Extraction

Extracted data included details on study designs; patient demographic characteristics; and clinical variables including follow-up time, time to surgery, complications, patient-reported outcome knee scores (Lysholm, Internal Knee Documentation Committee [IKDC], Tegner, Knee Injury and Osteoarthritis Outcome Score [KOOS]), stability assessments (KT-1000 [MEDmetric, San Diego, CA], KT-2000 [MEDmetric], Telos, Lachman

grade, pivot-shift grade), and functional outcomes (return to sport, return to work). For comparative studies in which data for the synthetic device subgroup were available, these data were extracted and included in cumulative totals for each device. All reconstructive procedures were considered to be primary unless specifically stated to be revision procedures. Knees with a previous extra-articular reconstructive procedure were included in the primary group. If a study did not specifically state whether it was retrospective or prospective in nature, it was assumed to be retrospective. Failure was defined either as complete or partial rupture of the ligament or as a documented "failure" as defined by each included study. Revision was defined as subsequent reconstruction or device removal without replacement for any indication including arthrodesis or total knee arthroplasty. The event rate for a study was only counted as zero if a study specifically reported that outcome as zero. If the study made no specific reference to an outcome, it was deemed not to report on that outcome, as opposed to acceptance of this as a zero event rate.

### Assessment of Methodologic Quality

We assessed the methodologic quality of the articles using the Methodological Index for Non-Randomized Studies (MINORS) along with additional criteria for comparative studies.[16] Eight criteria were used to assess noncomparative studies and case series, and 12 criteria were used for comparative studies. The criteria were not weighted, but each criterion was scored using a 3-point scale from 0 to 2, with 0 representing not reported, 1 being reported but inadequate, and 2 being reported and adequate. The ideal score was 16 points for noncomparative studies and case series and 24 points for comparative studies.

### Statistical Analysis

Summative data were presented for categorical variables, with means and standard deviations for continuous variables. Meta-analysis was not possible because of the heterogeneity of the included studies, low numbers of randomized trials, and inconsistent outcome reporting.

## Results

### Search Results

An overview of the selection process to identify studies for inclusion is provided in Figure 1. Our database search retrieved 500 records that were screened to identify 162 potentially relevant articles obtained in full text. An additional 11 articles were found after reference checks. After applying our selection criteria, we included 85 articles reporting on 6 different synthetic devices (Fig 1, Table 1). A total of 77 articles were excluded for the following reasons: article not relevant on full-text review (n = 56), article in a foreign language (n = 8), no full text available/abstract only (n = 6), previous report on a patient cohort already included (n = 5), and reconstruction in combination with a high tibial osteotomy (n = 2).

### Assessment of Methodologic Quality

The MINORS score was used to assess the methodologic quality of included studies. The mean MINORS score for the included comparative and noncomparative studies stratified by ligament type is as follows: LARS comparative, 17.3 points (SD, 1.5 points); LARS noncomparative, 7.6 points (SD, 1.2 points); Kennedy LAD comparative, 16.3 points (SD, 3.5 points); Kennedy LAD noncomparative, 7.9 points (SD, 2.3 points); Leeds-Keio comparative, 20.5 points (SD, 1.5 points); Leeds-Keio noncomparative, 11.3 points (SD, 2.1 points); Dacron comparative, 16.5 points (SD, 0.5 points); Dacron noncomparative, 9.4 points (SD, 1.2 points); Gore-Tex noncomparative, 9.1 points (SD, 2.9 points); Trivera comparative, 16 (single study); and Trivera noncomparative, 10 points (SD, 0.8 points).

### Demographic Characteristics

For all included studies (N = 85), there were 5,725 patients. Of these, 585 (10.2%) were lost to follow-up, leaving 5,140 patients with 5,168 synthetic ligament devices implanted. Not all studies described the gender spread, but when analyzed, 3,085 of 4,690 patients (65.8%) were male patients. The mean age of recruited patients was 29.3 years, with a mean time to reconstruction of 47.6 months (range, 3.5 to 119 months; median, 46.9 months). The mean follow-up period was 50 months (range, 36.7 to 70.2 months; median, 49.2 months).

### Ligament Augmentation and Reconstruction System

Twenty studies, published between 1995[17] and 2013,[18,19] reported on the use of the LARS device to address deficiency of the ACL (n = 13), PCL (n = 4), or combined ACL and PCL (n = 5). The article by Huang et al.[20] reported on patients undergoing ACL, PCL, and combined ACL-PCL surgery. Therefore data for each of these 3 groups were extracted individually, providing a total of 22 patient groups available for analysis from the 20 studies.

The included studies comprised 1 RCT,[21] 2 nonrandomized comparative studies,[22,23] and 16 retrospective case series[17-20,24-35] reporting on a combined total of 1,102 knees. Of these knees, 843 underwent ACL surgery, 120 underwent PCL surgery, and 139 underwent combined ACL-PCL surgery. Of the ACL operations, 50 were revisions of a previous reconstruction.[17,27] There were no revision PCL or combined ACL-PCL operations. The LARS device was used as an augmentation to autograft reconstruction in 1 ACL series and 1 combined ACL-PCL series. When stratified by

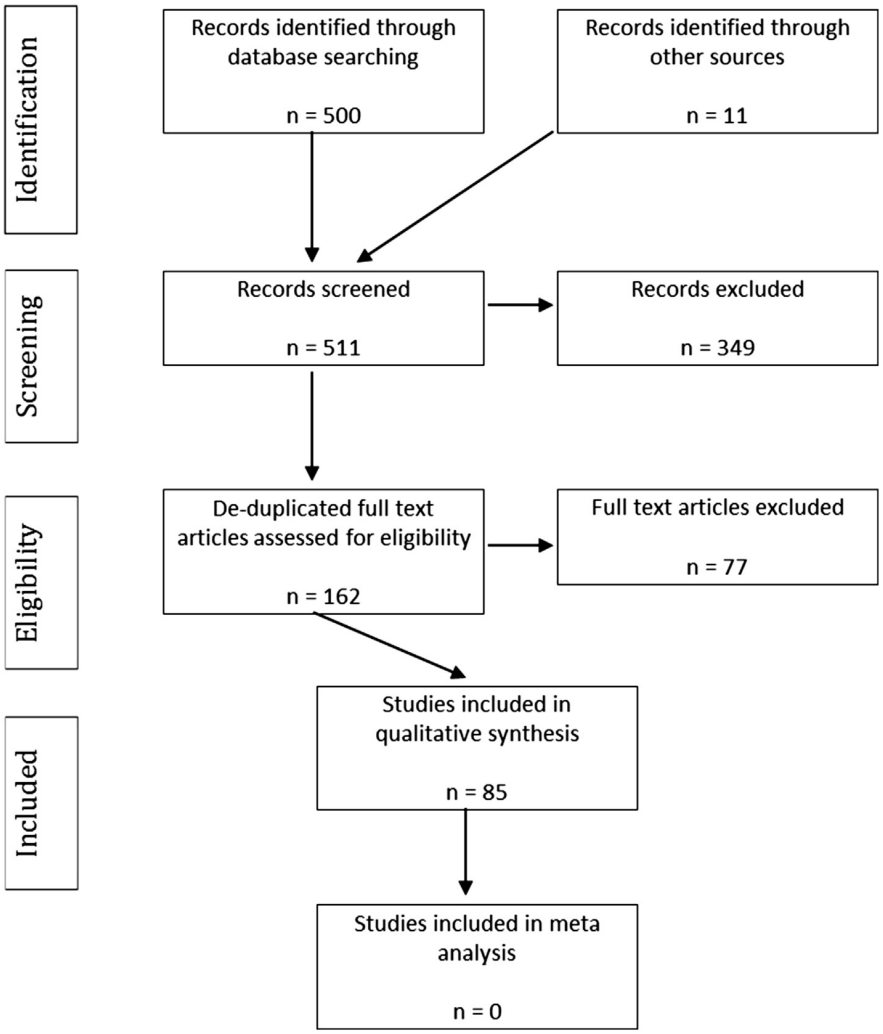


**Fig 1.** PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) inclusion flowchart.

time to surgery, 10 studies reported on 497 knees, with a mean time to surgery of 3.5 months. Of the remaining 10 studies, 5 reported a mean time to surgery of 11 to 14 days (n = 212) and 5 had a longer time to surgery, ranging from 3 to 12 months (n = 285). For the ACL group, the mean follow-up ranged from 21.9 to 95.3 months and the absolute minimum and maximum follow-up ranged from 4 to 110 months. The mean follow-up period ranged from 26.4 to 44 months for the PCL group and from 27.4 to 44 months for the combined ACL-PCL group.

The advent of the LARS device, being a more recently designed device, had coincided with a time in which patient-specific knee outcome scores were more widely used. Of the 20 studies reporting on the LARS device, 11 reported preoperative Lysholm scores (mean, 54) and 17 reported postoperative Lysholm scores (mean, 88). Scores on the Tegner activity scale were less commonly reported, with 5 studies reporting preoperative scores (mean, 3.3) and 8 studies reporting postoperative scores (mean, 6).

Knee stability assessment was performed using 3 methods. Postoperative anterior laxity was assessed by clinical examination using the Lachman test in 5 studies in 517 knees, of which 65 (12.6%) had grade 2 laxity (translation >5 mm) or higher. The KT-1000 arthrometer side-to-side difference was measured in 7 studies in 394 knees. A mean side-to-side difference of 2.2 mm (range, 1.2 to 4.2 mm) was found. Rotary laxity was measured by pivot-shift clinical examination in 4 studies. Of the 497 knees, 32 (6.4%) had a grade 2 pivot, with a clear shift and visible reduction.

Ten of the 13 ACL patient cohorts reported on failure rates, with 18 documented failures in 736 patients. One further patient had gross instability requiring revision despite the LARS device being intact.[28] The overall failure rate was 2.6% during the follow-up period. Three of the 4 PCL studies reported failure rates, with 1

**Table 1.** Summary of Included Studies and Patient Demographic Data

| Device | Ligament | Total No. of Cohorts* | No. of Case Series | No. of Nonrandomized Comparative Studies | No. of RCTs | Year of Publication (Minimum-Maximum) | Total No. of Knees | No. of Revision Reconstructions | Male/Female† | Range in Mean Follow-up, mo |
|---|---|---|---|---|---|---|---|---|---|---|
| LARS | ACL | 13 | 10 | 2 | 1 | 1995-2013 | 843 | 50 | 539/192 | 21.9-95.3 |
| | PCL | 4 | 3 | 1 | 0 | 2009-2012 | 120 | 0 | 81/39 | 26.4-44 |
| | ACL and PCL | 5 | 5 | 0 | 0 | 2004-2013 | 139 | 0 | 115/23 | 27.4-44 |
| Kennedy LAD | ACL | 26 | 12 | 5 | 9 | 1985-2006 | 1,905 | 12 | 983/694 | 18-192 |
| | PCL | 2 | 1 | 1 | 0 | 1993-1994 | 27 | 1 | 19/8 | 29-36 |
| Leeds-Keio I | ACL | 12 | 10 | 0 | 2 | 1992-2010 | 806 | 12 | 479/265 | 14.2-59.6 |
| Leeds-Keio II | ACL | 1 | 1 | 0 | 0 | 2006 | 13 | 0 | 9/4 | 14.2 |
| Dacron | ACL | 10 | 10 | 0 | 0 | 1989-1997 | 560 | 150 | 350/147 | 21-108 |
| Gore-Tex | ACL | 11 | 10 | 0 | 1 | 1987-2005 | 482 | 63 | 271/143 | 11-108 |
| | PCL | 1 | 1 | 0 | 0 | 2000 | 13 | NR | NR | 108 |
| Trevira-Hochfest | ACL | 3 | 3 | 0 | 0 | 1994-2010 | 265 | 0 | NR | 40.2-225 |
| | PCL | 1 | 0 | 1 | 0 | 1995 | 12 | 0 | NR | 12 |

ACL, anterior cruciate ligament; LAD, ligament augmentation device; LARS, ligament augmentation and reconstruction system; NR, not reported; PCL, posterior cruciate ligament; RCTs, randomized controlled trials.
*Some studies reported on more than 1 cohort, meaning that 89 cohorts of patients were reported on from the included 85 studies.
†Not all studies provided total numbers of male and female participants.

documented failure in 99 patients (1%). In the ACL cohort, 8 patients (0.9%) had loss of fixation.[17,19,24,28] In the 5 articles describing the treatment of patients with combined ACL and PCL deficiency, 2 patients required revision of the LARS ACL device.[31] There were 2 reported cases of noninfective effusion or synovitis: 1 ACL patient[24] and 1 PCL patient.[34]

In terms of comparative studies, the 1 RCT compared 26 LARS devices with 27 patellar tendon autografts for reconstruction of the ACL.[21] Patients were followed up for 24 months, with no significant difference between the groups in terms of IKDC score or KOOS at final review. Anterior laxity was significantly greater in the LARS group at 6 months. However, at 12 and 24 months, the difference was not significant. One retrospective study compared 30 patellar tendon autografts with 32 LARS reconstructions of the ACL with a minimum follow-up of 4 years.[23] There was no difference between the groups in terms of Lysholm, Tegner, IKDC, and KT-1000 assessments. Another comparative study, by Liu et al.,[22] retrospectively compared 32 four-strand hamstring ACL reconstructions with 28 LARS ACL reconstructions with a minimum follow-up of 4 years. There was no difference in Lysholm, IKDC, or Tegner scores; however, the LARS group had significantly less anterior displacement as measured by KT-1000 testing.

For the ACL cohort, rehabilitation protocols varied. Return to unrestricted sporting or pivoting activities was allowed at 2 months in 1 study,[29] 3 months in 3 studies,[18,22,28] 4 months in 4 studies,[19,20,25,26] and 6 months in 2 studies.[23,24] Two studies did not report on a specific time when these activities could begin,[21,27] although Nau et al.[21] found that the LARS group had better results in terms of early return to sports and recreational activities based on KOOS and Tegner scores. Dericks[17] did not comment on the rehabilitation protocol but stated that 61% of patients returned to heavy work or full sports within 4 months and 83% by 6 months.

## Kennedy LAD

Twenty-six studies reported on the use of the Kennedy LAD as an augmentation for reconstruction (n = 22) or repair (n = 4)[36-39] of the ACL. Two studies reported on this device as an augmentation in PCL reconstruction.[40,41] The dates of publication ranged from 1980[42] to 2006.[43] A wide variety of autografts and allografts were used across studies. Among the ACL studies, there were 9 RCTs,[36,38,43-49] 7 nonrandomized trials,[50-56] and 10 case series.[37,39,57-64] One RCT[41] and 1 case series[40] reported on augmentation in PCL reconstruction. In total 1,905 Kennedy LADs were used to augment ACL repair or reconstruction in 1,896 patients, including 12 revision reconstructions. There were 27 patients who underwent a unilateral augmented PCL reconstruction; in 5 of these, the procedures were revisions. The mean follow-up period for the ACL group ranged from 18 to 192

months,[43,57] and for the PCL group, the mean follow-up for the 2 studies was 29 months[40] and 36 months.[41] Three ACL studies did not present the mean follow-up time.[44,46,62] Where reported, the mean time to reconstruction ranged from 2 weeks to 11 months after injury.

The overall ACL failure rate was 13.2% (180 failures in 1,364 reconstructions) in the 16 studies reporting on this outcome.[37,38,43,45-47,51,53,54,57,60-63,65,66] Fifteen studies reported on rates of noninfective effusion and noninfective synovitis, with an overall incidence of 4.7% (38 cases in 813 patients). There was inconsistent reporting of fixation failure (6 cases), tunnel osteolysis (no reported cases), revision reconstruction (13 cases), and infection (8 cases) across the studies.

Of the 9 RCTs, 5 compared ACL repair or reconstruction with either patellar tendon autograft or Kennedy LAD augmentation.[45-49] Muren et al.[48] followed up 40 patients with acute ACL rupture who were randomized to patellar tendon autograft ACL reconstruction (n = 20) or patellar/quadriceps tendon reconstruction with Kennedy LAD augmentation (n = 20). At a mean of 7 years postoperatively, there was no statistical difference in stability testing, Lysholm scores, or Tegner scores. Similar findings were observed in another RCT by Muren et al.,[47] in which 40 patients with chronic ACL-deficient knees were randomized to reconstruction with bone–patellar tendon–bone (BPTB) graft (n = 20) or half-thickness patellar tendon autograft augmented with the Kennedy LAD. There was no difference in terms of Lysholm score, KT-1000 testing, or clinical stability testing at a mean 4-year follow-up. In 2002 Drogset and Grøntvedt[45] randomized 100 patients to ACL reconstruction with patellar tendon grafts with (n = 49) or without (n = 51) the use of a Kennedy LAD. At 8 years' follow-up, 68 patients were available for review, and there was no difference between groups in terms of rerupture rate, Lysholm score, Lachman score, or KT-1000 measurement. Grøntvedt et al.[46] randomized 100 patients with chronic ACL-deficient knees to BPTB reconstruction (n = 51) or BPTB reconstruction with Kennedy LAD augmentation (n = 49). There was no difference between groups in terms of Lysholm score or KT-1000 testing. Thuresson et al.[49] showed no difference in median Lysholm scores in patients randomized to patellar tendon autograft ACL reconstruction with or without LAD augmentation at 2-year follow-up.

One RCT compared the Gore-Tex device with the Kennedy LAD for ACL reconstruction in 41 patients and found significantly higher Lysholm scores in the Kennedy LAD group at 5-year follow-up.[44] The remaining RCTs compared ACL repair. Moyen et al.[38] randomized 64 patients to ACL repair with or without Kennedy LAD augmentation. There was no difference between groups at 2 years in terms of Lysholm score, sporting activities, or KT-1000 stability testing. Grøntvendt and Engebretsen[67] randomized 48 patients with acute ACL rupture to repair with the Kennedy LAD (n = 22) or BPTB augmentation (n = 26) and found no difference in activity or functional scores between groups. There was a high incidence of rupture in the LAD group, and the authors recommended against its use. Drogset et al.[43] randomized 150 patients with ACL-deficient knees to acute primary repair, acute repair plus Kennedy LAD augmentation, or acute repair augmented with BPTB autograft. One hundred twenty-nine patients were available for long-term follow-up at 16 years. The rate of revision was 10 times higher in the primary repair group than in the group that underwent repair with BPTB graft ($P = .003$), and the BPTB group had significantly more stable knees compared with the Kennedy LAD group, as measured by the Lachman test.

### Leeds-Keio Device

Twelve studies, published between 1992[66] and 2010,[68] reported on the use of the first-generation Leeds-Keio device for ACL surgery. There were 10 case series[66,69-77] and 2 RCTs,[68,78] reporting on a total of 793 ACL reconstructions. Of these, 12 were revision procedures. The mean follow-up period ranged from 23 months[70] to 159 months,[73] with absolute minimum and maximum follow-up among the studies ranging from 6 months[68] to 192 months.[73] Where reported, the mean time from injury to reconstruction ranged from 15 months[76] to 48.3 months.[69]

Seven studies reported on failure, with an overall rate of 16.8% (60 failures in 356 grafts).[66,69,71,73,75-77] There were 19 documented revisions in the 3 studies reporting on this outcome.[69,71,73] Three studies reported postoperative Lysholm scores; these ranged from 77.2 to 91.2.[66,69,73]

The 2 RCTs by Engström et al.[78] and Ghalayini et al.[68] both compared the Leeds-Keio device with BPTB autograft in ACL-deficient knees. Engström et al. followed up 55 patients for a mean period of 28 months. There was no difference between the 26 patellar tendon autograft patients and the 29 Leeds-Keio patients in terms of Lysholm or IKDC scores; however, pivot-shift testing and anterior laxity were both significantly greater in the Leeds-Keio group. Ghalayini et al. randomized 26 patients to BPTB autograft and 24 to the Leeds-Keio device and performed follow-up for 5 years. There was no difference in Lysholm or IKDC scores between groups at final follow-up or at any stage prior.

One study reported on results for the second-generation Leeds-Keio device (i.e., Leeds-Keio II).[11] This case series of 13 patients had a mean follow-up period of 14.2 months. There was 1 failure due to impingement requiring revision and no cases of noninfective effusion or synovitis.

### Dacron Device

Ten case series, published between 1989[79] and 1997,[14] reported on the use of the Dacron ligament for ACL reconstruction.[12,14,79-86] Cumulatively, these studies reported on a total of 525 knees. Five studies reported on a total of 150 revision reconstructions.[14,79,81,83,84] One study exclusively looked at revision procedures.[79] Follow-up ranged from 21 months[83] to 108 months.[14] The mean time to surgery, where reported, ranged from 30 months[86] to 5.4 years.[81] Ten studies reported on failure rates, with an overall rate of 33.6% (168 of 499 reconstructions). Five studies reported on the rates of noninfective effusion or synovitis, with an overall rate of 6.3% (23 of 366).[12,80,81,83,85] Mean postoperative Lysholm scores ranged from 82[12,79] to 89[81] in 6 studies.[12,14,79,81,83,84] Two studies reported on mean postoperative Lysholm scores in revision reconstructions, which were both lower than those for primary reconstructions: 75[81] and 82.[79]

### Gore-Tex Device

Eleven studies, published between 1987[87] and 2005,[66] reported outcomes for a cumulative total of 482 ACL reconstructions using the Gore-Tex synthetic device. One of these studies also reported on the results of 13 patients who underwent Gore-Tex PCL reconstruction.[88] Ten studies were case series using 6 prospective[87-92] and 4 retrospective[65,93-95] designs. There was 1 RCT comparing the Gore-Tex device with the Kennedy LAD.[44] One study reported results of a cohort of 20 patients (21 knees) who underwent a second-look arthroscopy,[94] and 1 study focused on bone tunnel widening, with clinical and arthrometric data also presented.[65] Among the 482 ACL reconstructions, there were a total of 63 revisions included in 4 studies.[87,88,90,93] The mean follow-up period ranged from 11 months[94] to 108 months,[88] with absolute minimum and maximum follow-up between 2 months[94] and 180 months.[65] One study did not report the mean follow-up period but stated that follow-up was between 13 and 15 years.[65]

Nine studies reported on ligament failure, with an overall rate of 12.9% (59 failures in 475 ligaments).[44,65,87,89,91-95] Seven studies reported on the rate of noninfective effusion or synovitis, with an overall rate of 26.6% (103 cases in 387 knees).[44,65,91-95] Five studies reported mean Lysholm scores for their ACL cohorts,[44,65,88,89,91] ranging from 83.9 at follow-up between 13 and 15 years[66] to 92 at a mean follow-up of 2 years.[91] The mean Lysholm score in the PCL group was 79 at 5 years' follow-up.

### Trevira-Hochfest Device

Three studies, published between 1994[96] and 2010,[97] reported on ACL reconstruction with the Trevira-Hochfest device.[96-98] One study also reported on 2 other polyethylene terephthalate devices, namely the Proflex and Pro-Pivot,[97] which were included in the analyses. All studies were prospective cases series and included a total of 265 reconstructions.[96-98] Ventura et al.[97] examined patient subjectivity, level of activity, and clinical assessment tools using various instrument such as the KOOS, IKDC questionnaire, and Tegner activity scale, whereas the remaining studies reported use of a single instrument on isolated outcomes. The mean follow-up time ranged from 40.2 months[96] to 225 months.[97] Across the studies, the failure rate was 9.4% (25 failures in 265 reconstructions). In terms of PCL surgery, 1 nonrandomized study, by Jung et al.,[99] reported on outcomes for patellar tendon autograft reconstruction (n = 12) compared with patellar tendon autograft reconstruction augmented with the Trevira ligament (n = 20) in PCL-deficient knees. Patients were followed up for more than 12 months, with higher Muller knee scores in the augmented group.

## Discussion

This systematic review examined the safety and efficacy of synthetic ligament devices used in cruciate ligament reconstruction. Specifically, it examined the rate of synthetic ligament rupture/failure, as well as complications surrounding these events, such as effusion and synovitis (Table 2). In addition, this review reports on the knee outcome scores of more recently used devices.

Regarding the earlier devices used, a total of 64 studies described the use of the Kennedy LAD, Dacron device, Gore-Tex device, first-generation Leeds-Keio device, and Trevira device. The highest overall failure rate was 33.6%, for the Dacron device, and the lowest overall failure rate was 9.8%, for the Trevira-Hochfest device. However, the Trevira-Hochfest group comprised only 3 studies. The highest rates of sterile effusion/synovitis were seen with the Gore-Tex device (27.6%), first-generation Leeds-Keio device (7.2%), Dacron device (6.3%), and Kennedy LAD (4.7%). Reporting of these complications was variable and inconsistent among studies. These high rates of effusion and device failure are the reasons that these devices are no longer used in reconstruction.

A postulated reason for the deterioration over time is the mechanical failure of the device through creep, fatigue, or abrasion (especially at the tunnel margins), with the generation and accumulation of synthetic debris material within the knee.[100] Previous studies have examined the deleterious effects of synthetic wear particles on intra-articular structures.[100] This, in combination with cruciate ligament failure and instability, is a plausible explanation for the high rates of radiologic osteoarthritis reported in some of the included studies at long-term follow-up.[73,97]

**Table 2.** Complications

| Device | Ligament | Failure* (n) | Revision* (n) | Noninfective Effusion/Synovitis* (n) |
|---|---|---|---|---|
| LARS | ACL | 2.6% (19 of 736) | 2.6% (19 of 728) | 0.2% (1 of 483) |
| | PCL | 1% (1 of 99) | 0% (0 of 120) | 1.2% (1 of 79) |
| | ACL and PCL | 0% (0 of 27) | 2.2% (2 of 89) | NR |
| Kennedy LAD | ACL | 13.9% (180 of 1,364) | 3.5% (13 of 368) | 4.7% (38 of 813) |
| | PCL | NR | NR | NR |
| Leeds-Keio I | ACL | 16.8% (60 of 356) | 8.8% (19 of 215) | 7.2% (13 of 179) |
| Leeds-Keio II | ACL | 7.7% (1 of 13) | 7.7% (1 of 13) | 0% (0 of 13) |
| Dacron | ACL | 33.6% (168 of 499) | 11.7% (48 of 409) | 6.3% (23 of 366) |
| Gore-Tex | ACL | 12.9% (59 of 475) | 10.7% (46 of 428) | 27.6% (103 of 387) |
| | PCL | NR | NR | NR |
| Trevira-Hochfest | ACL | 9.8% (26 of 265) | 11.8% (25 of 211) | 2.3% (5 of 214) |
| | PCL | 16.7% (2 of 12) | 0% (0 of 12) | NR |

NOTE. Not all studies reported on each complication.

ACL, anterior cruciate ligament; LAD, ligament augmentation device; LARS, ligament augmentation and reconstruction system; NR, not reported; PCL, posterior cruciate ligament.

*Percentages represent the cumulative incidence among studies reporting on each particular outcome.

More recent designs of synthetic ligament devices include the LARS and Leeds-Keio II device. Twenty-one studies in this review reported outcomes for these designs: LARS (n = 20) and Leeds-Keio II device (n = 1). Regarding the LARS, the 20 included studies reported acceptably low rates of failure (2.6% for ACL and 1% for PCL), revision (2.6% for ACL, 0% for PCL, and 2.2% for ACL-PCL), and complications during follow-up periods that ranged from 22 to 95 months.

The single article reporting on the Leeds-Keio II device had the shortest mean follow-up time when compared with the earlier generation of the Leeds-Keio device, and meaningful interpretation of the results is difficult because only 13 patients were included. With these limitations, we believe that it is speculative to claim that the Leeds-Keio II device can be considered a viable device for ACL reconstruction at this stage.

In terms of the LARS device, only 10 studies commented on the incidence of synovitis or sterile effusion. The overall incidence was 0.2% (1 reported case in 483 knees) in the ACL group and 1.3% (1 reported case in 79 knees) in the PCL group. Although these rates are lower than those reported for earlier synthetic devices, the reporting of synovitis and effusion after the use of the LARS was inconsistent, with half of the studies making no mention of these outcomes. The apparently lower incidence should therefore be interpreted with caution.

The results of this systematic review suggest that the current synthetic designs do achieve a number of their intended goals, allowing restoration of knee stability and potentially a faster progression through postoperative rehabilitation. In the LARS ACL group, return to unrestricted sports was allowed between 2 and 6 months postoperatively. If a synthetic device that mimics the anatomy of an injured cruciate ligament is well positioned within the knee and adequately fixed in place, then it is likely to immediately replicate the function of the deficient ligament and render the knee stable. If no graft tissue is harvested from the limb, and therefore no donor-site morbidity is encountered, the patient will be able to rehabilitate the knee rapidly, with only the trauma of the synthetic device implantation to overcome.

### Limitations

A limitation of this review is the paucity of well-conducted clinical trials included. In relation to the LARS device, there was only 1 RCT[21] and the longest mean follow-up period was 8 years.[19] Another limitation of this review was the exclusion of non–English-language studies (n = 8). Moreover, variability and heterogeneity in outcome reporting made comparisons across studies difficult. For example, we accepted each study's definition as to what constituted a failure; however, this was variable. Some studies maintained, "The only way to document a ruptured LARS ligament is by diagnostic arthroscopy,"[27] whereas others had more liberal definitions, including "a positive pivot shift, anterior drawer or Lachman test graded 2+ or higher, instrumented laxity test demonstrating greater than 3mm of side to side translation at 89N, or an arthroscopic examination demonstrating rupture of the graft."[84]

Standardized definitions and outcome measurements would facilitate comparison of outcomes across future studies. Reporting standards have been developed by other disciplines to address this problem.[101] Such standards may be a potential solution to allow unbiased comparison, systematic review, and meta-analysis of future studies reporting on the use of synthetic devices for reconstructive surgery.

## Conclusions

There was a broad range of reported failure rates for synthetic ligament devices, between 2.6% and 33.6% for ACL reconstruction. There was a low rate of

reported failures (1%) for synthetic ligament devices when used for PCL reconstruction. Outcome data are more readily available for recent designs, with good outcomes at a mean follow-up of 50 months. Knee instability is better documented in studies of more recent designs. Objective knee instability occurs at a rate of between 6% and 12% for the LARS. Earlier synthetic ligament device designs have higher rates of failure and rates of synovitis/sterile effusion. Results for newer-generation devices, specifically the LARS, appear to show lower reported rates of failure, revision, and sterile effusion/synovitis when compared with older devices. These findings should be interpreted within the context of this systematic review, including predominantly studies with low levels of evidence, and additional work is still required to validate the initial and early systematic review findings for the newer synthetic devices.

## References

1. Salmon LJ, Russell VJ, Refshauge K, et al. Long-term outcome of endoscopic anterior cruciate ligament reconstruction with patellar tendon autograft: Minimum 13-year review. *Am J Sports Med* 2006;34:721-732.
2. Hui C, Salmon LJ, Kok A, Maeno S, Linklater J, Pinczewski LA. Fifteen-year outcome of endoscopic anterior cruciate ligament reconstruction with patellar tendon autograft for "isolated" anterior cruciate ligament tear. *Am J Sports Med* 2011;39:89-98.
3. Kartus J, Movin T, Karlsson J. Donor-site morbidity and anterior knee problems after anterior cruciate ligament reconstruction using autografts. *Arthroscopy* 2001;17:971-980.
4. Feller JA, Webster KE, Gavin B. Early post-operative morbidity following anterior cruciate ligament reconstruction: Patellar tendon versus hamstring graft. *Knee Surg Sports Traumatol Arthrosc* 2001;9:260-266.
5. Sterling JC, Meyers MC, Calvo RD. Allograft failure in cruciate ligament reconstruction. Follow-up evaluation of eighteen patients. *Am J Sports Med* 1995;23:173-178.
6. Kaeding CC, Aros B, Pedroza A, et al. Allograft versus autograft anterior cruciate ligament reconstruction: Predictors of failure from a MOON prospective longitudinal cohort. *Sports Health* 2011;3:73-81.
7. Van Eck CF, Schkrohowsky JG, Ramirez C, Irrgang JJ, Fu FH, Working Z. Failure rate and predictors of failure after anatomic ACL reconstruction with allograft (SS-61). *Arthroscopy* 2011;27:e62-e63 (abstr).
8. Pallis M, Svoboda SJ, Cameron KL. Survival comparison of allograft and autograft anterior cruciate ligament reconstruction at the United States Military Academy. *Am J Sports Med* 2012;40:1242-1246.
9. Mascarenhas R, MacDonald PB. Anterior cruciate ligament reconstruction: A look at prosthetics—Past, present and possible future. *Mcgill J Med* 2008;11:29-37.
10. Kennedy JC. Application of prosthetics to anterior cruciate ligament reconstruction and repair. *Clin Orthop Relat Res* 1983;172:125-128.
11. Sugihara A, Fujikawa K, Watanabe H, et al. Anterior cruciate reconstruction with bioactive Leeds-Keio ligament (LKII): Preliminary report. *J Long Term Eff Med Implants* 2006;16:41-49.
12. Klein W, Jensen K-U. Synovitis and artificial ligaments. *Arthroscopy* 1992;8:116-124.
13. Prescott RJ, Ryan WG, Bisset DL. Histopathological features of failed prosthetic Leeds-Keio anterior cruciate ligaments. *J Clin Pathol* 1994;47:375-376.
14. Maletius W, Gillquist J. Long-term results of anterior cruciate ligament reconstruction with a Dacron prosthesis: The frequency of osteoarthritis after seven to eleven years. *Am J Sports Med* 1997;25:288-293.
15. Legnani C, Ventura A, Terzaghi C, Borgo E, Albisetti W. Anterior cruciate ligament reconstruction with synthetic grafts. A review of literature. *Int Orthop* 2010;34:465-471.
16. Slim K, Nini E, Forestier D, Kwiatkowski F, Panis Y, Chipponi J. Methodological Index for Non-Randomized Studies (MINORS): Development and validation of a new instrument. *ANZ J Surg* 2003;73:712-716.
17. Dericks G. Ligament advanced reinforcement system anterior cruciate ligament reconstruction. *Oper Tech Sports Med* 1995;3:187-205.
18. Ye JX, Shen GS, Zhou HB, et al. Arthroscopic reconstruction of the anterior cruciate ligament with the LARS artificial ligament: Thirty-six to fifty-two months follow-up study. *Eur Rev Med Pharmacol Sci* 2013;17:1438-1446.
19. Parchi P, Gianluca C, Dolfi L, et al. Anterior cruciate ligament reconstruction with LARS artificial ligament results at a mean follow-up of eight years. *Int Orthop* 2013;37:1567-1574.
20. Huang JM, Wang Q, Shen F, Wang ZM, Kang YF. Cruciate ligament reconstruction using LARS artificial ligament under arthroscopy: 81 cases report. *Chin Med J (Engl)* 2010;123:160-164.
21. Nau T, Lavoie P, Duval N. A new generation of artificial ligaments in reconstruction of the anterior cruciate ligament. Two-year follow-up of a randomised trial. *J Bone Joint Surg Br* 2002;84:356-360.
22. Liu Z-T, Zhang X-L, Jiang Y, Zeng B-F. Four-strand hamstring tendon autograft versus LARS artificial ligament for anterior cruciate ligament reconstruction. *Int Orthop* 2010;34:45-49.
23. Pan X, Wen H, Wang L, Ge T. Bone-patellar tendon-bone autograft versus LARS artificial ligament for anterior cruciate ligament reconstruction. *Eur J Orthop Surg Traumatol* 2013;23:819-823.
24. Gao K, Chen S, Wang L, et al. Anterior cruciate ligament reconstruction with LARS artificial ligament: A multicenter study with 3- to 5-year follow-up. *Arthroscopy* 2010;26:515-523.
25. Huang JM, Liu HY, Chen FR, et al. Characteristics of bone tunnel changes after anterior cruciate ligament reconstruction using Ligament Advanced Reinforcement System artificial ligament. *Chin Med J* 2012;125:3961-3965.
26. Hamido F, Misfer AK, Harran Al H, et al. The use of the LARS artificial ligament to augment a short or undersized ACL hamstrings tendon graft. *Knee* 2011;18:373-378.
27. Lavoie P, Fletcher J, Duval N. Patient satisfaction needs as related to knee stability and objective findings after

ACL reconstruction using the LARS artificial ligament. *Knee* 2000;7:157-163.
28. Gäbler C, Schmidt R, Schurz M. The introduction of an artificial ligament for reconstruction of the anterior cruciate ligament: A department's critical review of complications and problems. *Osteo Trauma Care* 2006;14:51-53.
29. Fu P-L, Wu Y-L, Wu H-S, et al. Anterior cruciate ligament reconstruction using ligament advanced reinforcement system artificial ligament in 28 cases. *J Clin Rehabil Tissue Eng Res* 2008;12:5393-5396.
30. Ibrahim SAR, Ghafar S, Salah M, et al. Surgical management of traumatic knee dislocation with posterolateral corner injury. *Arthroscopy* 2013;29:733-741.
31. Ranger P, Renaud A, Phan P, Dahan P, Oliveira E, Delisle J. Evaluation of reconstructive surgery using artificial ligaments in 71 acute knee dislocations. *Int Orthop* 2011;35:1477-1482.
32. Talbot M, Berry G, Fernandes J, Ranger P. Knee dislocations: Experience at the Hôpital du Sacré-Coeur de Montréal. *Can J Surg* 2004;47:20-24.
33. Tao J, Li X, Zhou Z, Zhu Z. Acute single-stage reconstruction of multiligament knee injuries using the ligament advanced reinforcement system. *Med Princ Pract* 2013;22:373-378.
34. Chen CP, Lin YM, Chiu YC, et al. Outcomes of arthroscopic double-bundle PCL reconstruction using the LARS artificial ligament. *Orthopedics* 2012;35:e800-e806.
35. Shen G, Xu Y, Dong Q, Zhou H, Yu C. Arthroscopic posterior cruciate ligament reconstruction using LARS artificial ligament: A retrospective study. *J Surg Res* 2012;173:75-82.
36. Grøntvedt T, Engebretsen L, Rossvoll I, Smevik O, Nilsen G. Comparison between magnetic resonance imaging findings and knee stability: Measurements after anterior cruciate ligament repair with and without augmentation. A five- to seven-year followup of 52 patients. *Am J Sports Med* 1995;23:729-735.
37. Kdolsky R, Kwasny O, Schabus R. Synthetic augmented repair of proximal ruptures of the anterior cruciate ligament. Long-term results of 66 patients. *Clin Orthop Relat Res* 1993;295:183-189.
38. Moyen BJ, Jenny JY, Mandrino AH, Lerat JL. Comparison of reconstruction of the anterior cruciate ligament with and without a Kennedy ligament-augmentation device. A randomized, prospective study. *J Bone Joint Surg Am* 1992;74:1313-1319.
39. Paessler HH, Deneke JJ, Dahners LEL. Augmented repair and early mobilization of acute anterior cruciate ligament injuries. *Am J Sports Med* 1992;20:667-674.
40. Fujii K, Yamagishi T, Sai S, et al. Reconstruction of the posterior cruciate ligament with LAD-augmented semitendinosus and gracilis tendons: A preliminary report. *Knee Surg Sports Traumatol Arthrosc* 1993;1:148-151.
41. Noyes FR, Barber-Westin SD. Posterior cruciate ligament allograft reconstruction with and without a ligament augmentation device. *Arthroscopy* 1994;10:371-382.
42. Kennedy JC, Roth JH, Mendenhall HV, Sanford JB. Presidential address. Intraarticular replacement in the anterior cruciate ligament-deficient knee. *Am J Sports Med* 1980;8:1-8.
43. Drogset JO, Grøntvedt T, Robak OR, Mølster A, Viset AT, Engebretsen L. A sixteen-year follow-up of three operative techniques for the treatment of acute ruptures of the anterior cruciate ligament. *J Bone Joint Surg Am* 2006;88:944-952.
44. Dahlstedt L, Dalén N, Jonsson U, Adolphson P. Cruciate ligament prosthesis vs. augmentation. A randomized, prospective 5-year follow-up of 41 cases. *Acta Orthop Scand* 1993;64:431-433.
45. Drogset JO, Grøntvedt T. Anterior cruciate ligament reconstruction with and without a ligament augmentation device: Results at 8-year follow-up. *Am J Sports Med* 2002;30:851-856.
46. Grøntvedt T, Engebretsen L, Benum P, Fasting O, Mølster A, Strand T. A prospective, randomized study of three operations for acute rupture of the anterior cruciate ligament. Five-year follow-up of one hundred and thirty-one patients. *J Bone Joint Surg Am* 1996;78:159-168.
47. Muren O, Dahlstedt L, Dalén N. Reconstruction of old anterior cruciate ligament injuries. No difference between the Kennedy LAD-method and traditional patellar tendon graft in a prospective randomized study of 40 patients with 4-year follow-up. *Acta Orthop Scand* 1995;66:118-122.
48. Muren O, Dahlstedt L, Dalén N. Reconstruction of acute anterior cruciate ligament injuries: A prospective, randomised study of 40 patients with 7-year follow-up. No advantage of synthetic augmentation compared to a traditional patellar tendon graft. *Arch Orthop Trauma Surg* 2003;123:144-147.
49. Thuresson P, Sandberg R, Johansson O, Balkfors B, Westlin N. Anterior cruciate ligament reconstruction with the patellar tendon—Augmentation or not? A 2-year follow-up of 82 patients. *Scand J Med Sci Sports* 1996;6:247-254.
50. Roth JH, Kennedy JC, Lockstadt H, McCallum CL, Cunning LA. Polypropylene braid augmented and non-augmented intraarticular anterior cruciate ligament reconstruction. *Am J Sports Med* 1985;13:321-336.
51. Barrett GR, Field LD. Comparison of patella tendon versus patella tendon/Kennedy ligament augmentation device for anterior cruciate ligament reconstruction: Study of results, morbidity, and complications. *Arthroscopy* 1993;9:624-632.
52. Jonsson H, Elmqvist LG, Kärrholm J, Fugl-Meyer A. Lengthening of anterior cruciate ligament graft. Roentgen stereophotogrammetry of 32 cases 2 years after repair. *Acta Orthop Scand* 1992;63:587-592.
53. Noyes FR, Barber SD. The effect of a ligament-augmentation device on allograft reconstructions for chronic ruptures of the anterior cruciate ligament. *J Bone Joint Surg Am* 1992;74:960-973.
54. Santi MD, Richardson AB. The ligament augmentation device in hamstring grafts for reconstruction of the anterior cruciate ligament. *Am J Sports Med* 1994;22:524-530.
55. Sgaglione NA, Del Pizzo W, Fox JM, Friedman MJ, Snyder SJ, Ferkel RD. Arthroscopic-assisted anterior cruciate ligament reconstruction with the semitendinosus tendon: Comparison of results with and

without braided polypropylene augmentation. *Arthroscopy* 1992;8:65-77.
56. Steenbrugge F, Verdonk R, Verstraete K. Allograft reconstructions for chronic ruptures of the anterior cruciate ligament: Augmentation versus non-augmentation. *Eur J Orthop Surg Traumatol* 2002;12:8-13.
57. Asahina S, Yamamoto H, Muneta T, Ishibashi T, Furuya K. Evaluation of anterior cruciate reconstruction reinforced by the Kennedy ligament augmentation device. *Int Orthop* 1995;19:229-233.
58. Asahina S, Muneta T, Ishibashi T, Yamamoto H. Effects of knee flexion angle at graft fixation on the outcome of anterior cruciate ligament reconstruction. *Arthroscopy* 1996;12:70-75.
59. Bernett P, Feldmeier C, Pieper B. Anterior cruciate ligament (ACL) repair by augmentation with the polypropylene braid (Kennedy LAD). Biocompatibility, technique, early clinical results. *Acta Orthop Belg* 1987;53:356-359.
60. Gómez-Castresana FB, Bastos MN, Sacristán CG. Semitendinosus Kennedy ligament augmentation device anterior cruciate ligament reconstruction. *Clin Orthop Relat Res* 1992;283:21-33.
61. Kdolsky RK, Gibbons DF, Kwasny O, Schabus R, Plenk H. Braided polypropylene augmentation device in reconstructive surgery of the anterior cruciate ligament: Long-term clinical performance of 594 patients and short-term arthroscopic results, failure analysis by scanning electron microscopy, and synovial histomorphology. *J Orthop Res* 1997;15:1-10.
62. MacDonald PB, Hedden D, Pacin O, Huebert D. Effects of an accelerated rehabilitation program after anterior cruciate ligament reconstruction with combined semitendinosus-gracilis autograft and a ligament augmentation device. *Am J Sports Med* 1994;23:588-592.
63. Saragaglia D, Leroy JM, De Sousa B, Tourne Y, Abu al Zahab M. Medium-term results of 173 ligamentoplasties of the anterior cruciate ligament using the MacIntosh technique reinforced by the Kennedy ligament augmentation device (LAD). *Knee Surg Sports Traumatol Arthrosc* 1995;3:68-74.
64. Yamamoto H, Ishibashi T, Muneta T, Furuya K, Mizuta T. Effusions after anterior cruciate ligament reconstruction using the ligament augmentation device. *Arthroscopy* 1992;8:305-310.
65. Muren O, Dahlstedt L, Brosjö E, Dahlborn M, Dalén N. Gross osteolytic tibia tunnel widening with the use of Gore-Tex anterior cruciate ligament prosthesis. *Acta Orthop* 2005;76:270-274.
66. McLoughlin SJ, Smith RB. The Leeds-Keio prosthesis in chronic anterior cruciate deficiency. *Clin Orthop Relat Res* 1992;283:215-222.
67. Grøntvedt T, Engebretsen L. Comparison between two techniques for surgical repair of the acutely torn anterior cruciate ligament. *Scand J Med Sci Sports* 1995;5:358-363.
68. Ghalayini S, Helm AT, Bonshahi AY, Lavender A, Johnson DS, Smith RB. Arthroscopic anterior cruciate ligament surgery: Results of autogenous patellar tendon graft versus the Leeds-Keio synthetic graft: Five year follow-up of a prospective randomised controlled trial. *Knee* 2010;17:334-339.
69. Dandy DJ. Some clinical aspects of reconstruction for chronic anterior cruciate ligament deficiency. *Ann R Coll Surg Engl* 1995;77:290-298.
70. Takeda T, Matsumoto H, Fujikawa K. Influence of secondary damage to menisci and articular cartilage on return to sports after anterior cruciate ligament reconstruction. *J Orthop Sci* 1997;2:215-221.
71. Schroven IT, Geens S, Beckers L, Lagrange W, Fabry G. Experience with the Leeds-Keio artificial ligament for anterior cruciate ligament reconstruction. *Knee Surg Sports Traumatol Arthrosc* 1994;2:214-218.
72. Ochi M, Yamanaka T, Sumen Y, Ikuta Y. Arthroscopic and histologic evaluation of anterior cruciate ligaments reconstructed with the Leeds-Keio ligament. *Arthroscopy* 1993;9:387-393.
73. Murray AW, Macnicol MF. 10-16 Year results of Leeds-Keio anterior cruciate ligament reconstruction. *Knee* 2004;11:9-14.
74. Matsumoto H, Toyoda T, Kawakubo M, Otani T, Suda Y, Fujikawa K. Anterior cruciate ligament reconstruction and physiological joint laxity: Earliest changes in joint stability and stiffness after reconstruction. *J Orthop Sci* 1999;4:191-196.
75. Marcacci M, Zaffagnini S, Visani A, Iacono F, Neri MP, Petitto A. Arthroscopic reconstruction of the anterior cruciate ligament with Leeds-Keio ligament in non-professional athletes. *Knee Surg Sports Traumatol Arthrosc* 1996;4:9-13.
76. Denti M, Bigoni M, Dodaro G, Monteleone M, Arosio A. Long-term results of the Leeds-Keio anterior cruciate ligament reconstruction. *Knee Surg Sports Traumatol Arthrosc* 1995;3:75-77.
77. Rading J, Peterson L. Clinical experience with the Leeds-Keio artificial ligament in anterior cruciate ligament reconstruction. A prospective two-year follow-up study. *Am J Sports Med* 1995;23:316-319.
78. Engström B, Wredmark T, Westblad P. Patellar tendon or Leeds-Keio graft in the surgical treatment of anterior cruciate ligament ruptures. Intermediate results. *Clin Orthop Relat Res* 1993;295:190-197.
79. Lukianov AV, Richmond JC, Barrett GR, Gillquist J. A multicenter study on the results of anterior cruciate ligament reconstruction using a Dacron ligament prosthesis in "salvage" cases. *Am J Sports Med* 1989;17:380-386.
80. Andersen HN, Bruun C, Sønergåro-Petersen PE. Reconstruction of chronic insufficient anterior cruciate ligament in the knee using a synthetic Dacron prosthesis A prospective study of 57 cases. *Am J Sports Med* 1992;20:20-23.
81. Barrett GR, Line LL, Shelton WR, Manning JO, Phelps R. The Dacron ligament prosthesis in anterior cruciate ligament reconstruction. A four-year review. *Am J Sports Med* 1993;21:367-373.
82. Wredmark T, Engström B. Five-year results of anterior cruciate ligament reconstruction with the Stryker Dacron high-strength ligament. *Knee Surg Sports Traumatol Arthrosc* 1993;1:71-75.
83. Wilk RM, Richmond JC. Dacron ligament reconstruction for chronic anterior cruciate ligament insufficiency. *Am J Sports Med* 1993;21:374-380.

84. Richmond JC, Manseau CJ, Patz R, McConville O. Anterior cruciate reconstruction using a Dacron ligament prosthesis. A long-term study. *Am J Sports Med* 1992;20:24-28.
85. Bartolozzi P, Salvi M, Velluti C. Long-term follow-up of 53 cases of chronic lesion of the anterior cruciate ligament treated with an artificial Dacron Stryker ligament. *Ital J Orthop Traumatol* 1990;16:467-480.
86. van Heerwaarden RJ, Stellinga D, Frudiger AJ. Effect of pretension in reconstructions of the anterior cruciate ligament with a Dacron prosthesis. A retrospective study. *Knee Surg Sports Traumatol Arthrosc* 1996;3: 202-208.
87. Ahlfeld SK, Larson RL, Collins HR. Anterior cruciate reconstruction in the chronically unstable knee using an expanded polytetrafluoroethylene (PTFE) prosthetic ligament. *Am J Sports Med* 1987;15:326-330.
88. Roolker W, Patt TW, van Dijk CN, Vegter M, Marti RK. The Gore-Tex prosthetic ligament as a salvage procedure in deficient knees. *Knee Surg Sports Traumatol Arthrosc* 2000;8:20-25.
89. Woods GA, Indelicato PA, Prevot TJ. The Gore-Tex anterior cruciate ligament prosthesis. Two versus three year results. *Am J Sports Med* 1991;19:48-55.
90. Markolf KL, Pattee GA, Strum GM, et al. Instrumented measurements of laxity in patients who have a Gore-Tex anterior cruciate-ligament substitute. *J Bone Joint Surg Am* 1989;71:887-893.
91. Indelicato PA, Pascale MS, Huegel MO. Early experience with the GORE-TEX polytetrafluoroethylene anterior cruciate ligament prosthesis. *Am J Sports Med* 1989;17: 55-62.
92. Glousman R, Shields C, Kerlan R, et al. Gore-Tex prosthetic ligament in anterior cruciate deficient knees. *Am J Sports Med* 1988;16:321-326.
93. Paulos LE, Rosenberg TD, Grewe SR, Tearse DS, Beck CL. The GORE-TEX anterior cruciate ligament prosthesis. A long-term followup. *Am J Sports Med* 1992;20:246-252.
94. Ferkel RD, Fox JM, Wood D, Del Pizzo W, Friedman MJ, Snyder SJ. Arthroscopic "second look" at the GORE-TEX ligament. *Am J Sports Med* 1989;17:147-152.
95. Bowyer GW, Matthews S. Anterior cruciate ligament reconstruction using the Gore-Tex ligament. *J R Army Med Corps* 1991;137:69-75.
96. Kock HJ, Stürmer KM, Letsch R, Schmit-Neuerburg KP. Interface and biocompatibility of polyethylene terephthalate knee ligament prostheses. A histological and ultrastructural device retrieval analysis in failed synthetic implants used for surgical repair of anterior cruciate ligaments. *Arch Orthop Trauma Surg* 1994;114:1-7.
97. Ventura A, Terzaghi C, Legnani C, Borgo E, Albisetti W. Synthetic grafts for anterior cruciate ligament rupture: 19-year outcome study. *Knee* 2010;17:108-113.
98. Krudwig WK. Anterior cruciate ligament reconstruction using an alloplastic ligament of polyethylene terephthalate (PET — Trevira — hochfest). Follow-up study. *Biomed Mater Eng* 2002;12:59-67.
99. Jung YB, Tae SK, Kim BS. Reconstruction of the posterior cruciate ligament: A clinical comparison between patellar tendon alone and patellar tendon plus artificial ligament. *J Orthop Surg* 1995;3:1-9.
100. Olson EJ, Kang JD, Fu FH, Georgescu HI, Mason GC, Evans CH. The biochemical and histological effects of artificial ligament wear particles: In vitro and in vivo studies. *Am J Sports Med* 1988;16:558-570.
101. Vena Caval Filter Consensus Conference. Recommended reporting standards for vena caval filter placement and patient follow-up. *J Vasc Interv Radiol* 2003;14(pt 2): S427-S432.