Acute Anterior Cruciate Ligament Rupture

Repair or Reconstruction? Five-Year Results of a Randomized Controlled Clinical Trial

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Background: High-level evidence for short-term outcomes of contemporary anterior cruciate ligament (ACL) suture repair (ACLSR) in comparison with those of ACL reconstruction (ACLR) is scarce. High-level evidence for mid- and long-term results is lacking, whereas outcomes of ACLSR in several historical studies were shown to deteriorate at midterm follow-up after initial good short-term outcomes.

Hypothesis: Contemporary ACLSR is noninferior to ACLR in the treatment of acute ACL rupture in terms of patient self-reported outcomes at 5 years postoperatively.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: A total of 48 patients were enrolled in the study and, after stratification and randomization, underwent either dynamic augmented (DA) ACLSR or anatomic single-bundle ACLR. The primary outcome measure was the International Knee Documentation Committee 2000 (IKDC) subjective score (IKDCs). Furthermore, the Knee injury and Osteoarthritis Outcome Score (KOOS), Tegner Activity Scale score (TAS), visual analog scale score for satisfaction (VASs), IKDC physical examination score (IKDCpe), limb symmetry index for quadriceps (LSIq) and hamstrings (LSIh) strength and jump test battery (LSIj), Kellgren-Lawrence grade of osteoarthritis (OA), and rate of adverse events were recorded. Analyses were based on an intention-to-treat principle.

Results: The lower limit of the 2-sided 95% CI for the median IKDCs of the DA ACLSR group (n = 23; 75.9) was lower than the prespecified noninferiority margin (n = 21; 86.6). Therefore, the null hypothesis was rejected. However, the upper limit of the 2-sided 95% CI of the DA ACLSR group (100.0) was higher than the median IKDCs of the ACLR group (96.6), rendering the result for noninferiority inconclusive. No statistical difference was found between groups for median IKDCs (repair, 90.2; reconstruction, 96.6). Furthermore, no statistically significant differences were found for any of the secondary outcome measures for the DA ACLSR compared with the ACLR group: KOOS Symptoms, 92.9 versus 96.4; KOOS Pain, 100 versus 97.2; KOOS Activities of Daily Living, 100 versus 100; KOOS Sport and Recreation, 85.0 versus 100; TAS score, 7.0 versus 6.5; VASs, 9.2 versus 8.7; IKDCpe, 81.8% versus 100%; LSIq, $\geq$91.6 versus $\geq$88.2; LSIh, $\geq$95.1 versus $\geq$90.7; LSIj, $\geq$94.2 versus $\geq$97.6; OA grade 0, 90.9% versus 77.8%; clinical ACL failure rate, 20.8% versus 27.2%; and repeat surgery rate, 37.5% versus 20.0%, respectively.

Conclusion: It remains inconclusive whether the effectiveness of DA ACLSR is noninferior to that of ACLR in terms of subjective patient-reported outcomes as measured using the IKDCs. Although DA ACLSR may be a viable treatment option for patients with acute ACL rupture, caution must be exercised when considering this treatment for young, active patients, corresponding to the present study population.

Keywords: anterior cruciate ligament; biologic healing enhancement; biology of ligament; anterior cruciate ligament reconstruction; anterior cruciate ligament suture repair; dynamic intraligamentary stabilization

There has been renewed interest in the concept of contemporary anterior cruciate ligament (ACL) suture repair (ACLSR) rather than ACL reconstruction (ACLR) using a tendon graft for surgical treatment of the ruptured ACL. The amount of literature on ACLSR has rapidly increased in the past decade, and good to excellent short-term outcomes have been reported.[24,53] However, high-level evidence for short-term outcomes of contemporary ACLSR in comparison with those of ACLR is scarce, and such evidence for mid- to long-term outcomes is lacking.[10,23,24,34,41] While the few randomized controlled trials (RCTs) on contemporary ACL suture techniques have reported good to excellent short-term outcomes, there is fear of history repeating itself, as initial satisfactory

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short-term results of several historical studies on ACLSR were reported to deteriorate at midterm follow-up.[10,23,34,41,46] It was reported that this deterioration might have been dependent on ACL rupture location, the quality of the ruptured ACL tissue, and the lack of augmentation of the suture-repaired ACL.[25,48,50] Therefore, there is a need for more randomized controlled studies with an adequate follow-up period, investigating patient-reported outcome measures and clinical stability testing to compare contemporary ACLSR techniques with ACLR.[10,24,46,53]

In 2019, Hoogeslag et al[23] reported that contemporary dynamic augmented (DA) ACLSR was noninferior to single-bundle ACLR with a hamstrings autograft in terms of subjective patient-reported outcome as measured using the International Knee Documentation Committee 2000 (IKDC) subjective score (IKDCs) and that there were no statistically significant differences in other patient-related, clinical, and radiological outcomes at short-term (2-year) follow-up. This study presents the 5-year outcomes for patients included in this RCT.

METHODS

The materials and methods have been extensively described by Hoogeslag et al.[23] An institutional review board (No. NL50116.044.14; P14-26)–approved RCT was conducted at the Centre for Orthopaedic Surgery OCON, the Netherlands. In the study period between January 2015 and March 2016, we enrolled patients who were 18 to 30 years of age; visited the outpatient clinic; had a proven primary ACL rupture confirmed by means of history, physical examination, and magnetic resonance imaging; had an indication for ACLR surgery; could be treated with surgery within 21 days after injury; and had a score of 5 to 10 on the Tegner Activity Scale (TAS) (Table 1).[49] Inclusion in the study was independent of ACL rupture location. Exclusion criteria were concomitant ligamentous lesions, a history of contra- or ipsilateral knee surgery, meniscal lesions needing surgical repair and full-thickness cartilage lesions, and osteoarthritis seen on the preoperative (weightbearing) radiographs.

The details of the inclusion, stratification (preinjury TAS score [moderate TAS score, 5-7; high TAS score, 8-10]), and randomization (blocks of varying sizes [sealed envelope, computer-generated schedule; block size n = 2 and n = 4]) to undergo either DA ACLSR or ACLR with a tendon graft have been previously reported.[23] Patients were not blinded to treatment.

Surgical Procedure

The surgical procedures have been extensively described by Hoogeslag et al.[23] DA ACLSR was performed within 3 weeks after injury, and ACLR was performed within 2 weeks after patients met the preoperative criteria for functional recovery of the knee and leg.[52] If patients who were planned to undergo ACLR did not meet these preoperative criteria at baseline, they were reassessed at a later stage and meanwhile continued preoperative rehabilitation with a sports physical therapist. One experienced ACL surgeon (R.A.G.H.) performed all surgeries.

Anterior Cruciate Ligament Suture Repair. ACLSR was performed using the dynamic intraligamentary stabilization technique (Ligamys; Mathys Medical) as described by Eggli et al[8] (Figure 1). The Ligamys braid was tensioned to 80 N at 0° of knee flexion (Figure 1), and microfracturing of the notch was performed in and near the femoral ACL attachment.[25]

Anterior Cruciate Ligament Reconstruction. Anatomic ACLR was performed using a single-bundle all-inside ipsilateral semitendinosus technique (Arthrex).[37] A mini-incision technique at the posterior side of the knee was used to harvest the tendon, which was then quadrupled.[44] Using a retrograde drill, we prepared independent tibial and femoral sockets (Flipcutter; Arthrex).[37] The graft was tensioned with the knee at 0° of knee flexion. Graft tension was adjusted under arthroscopic view if necessary.

Postoperative Rehabilitation. Postoperatively, patients who underwent DA ACLSR received a long leg splint locked in extension for the first 5 days, and patients who underwent ACLR were allowed full range of motion as tolerated directly. Both groups received an otherwise identical, structured, criterion-based rehabilitation protocol and were guided by their own sports physical therapist accordingly.[52]

Outcome Measures

Patients were evaluated at the 5-year follow-up using patient-reported outcome measures and physical and radiological examination. Similar to our previous study, the primary outcome measure was the IKDCs at the 5-year follow-up.[23] The IKDCs is validated in Dutch and measures symptoms and functional limitations for a variety of knee disorders, including ligamentous injuries (range, 0-100; worst to best).[20,29,30]

Secondary outcome measures included patient-reported, clinical, and radiological outcome measures as

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TABLE 1
Summary of Baseline Characteristics and ACL Rupture Characteristics[a]

	Repair, n = 24	Reconstruction, n = 24	*P* Value
Sex			.731
Male	19 (79.2)	18 (75)	
Female	5 (20.8)	6 (25)	
Age, y	21.0 (10.0–27.0)	22.0 (19.3–25.0)	.693
Injured side			.247
Left	9 (37.5)	13 (54.2)	
Right	15 (62.5)	11 (45.8)	
BMI	23.0 (21.0–24.5)	23.3 (22.1–24.4)	.445
IKDC subjective score	72.4 (49.1–95.2)	59.8 (39.0–100.0)	.438
KOOS			
Symptoms	96.0 (41.8–100.0)	54.0 (64.0–94.6)	.261
Pain	100 (62.5–100.0)	62.5 (50.8–100.0)	.095
ADL	99.5 (66.8–100.0)	73.5 (57.0–100.0)	.245
Sport and Recreation	97.5 (17.5–100.0)	27.5 (6.3–100.0)	.194
QoL	97 (44.0–100.0)	53.5 (20.5–100.0)	.208
Tegner Activity Scale score	8.0 (7.0–9.0)	8.5 (7.0–9.0)	.893
Tegner Activity Scale score stratification			.771
Intermediate	11 (45.8)	10 (41.7)	
High	13 (54.2)	14 (58.3)	
ACL rupture location			
Proximal third	20 (83.3)	—	
Central third	3 (12.5)	—	
Distal third	1 (4.2)	—	
ACL rupture bundle			
1 strand	3 (12.5)	—	
2 bundles	10 (41.7)	—	
≥3 strands	11 (45.8)	—	
ACL rupture sheath			
Completely intact	3 (12.5)	—	
≥50% intact	16 (66.7)	—	
<50% intact	5 (20.8)	—	

[a]Since data were not normally distributed, they are expressed as median (interquartile range) or frequency (%). ACL, anterior cruciate ligament; ADL, Activities of Daily Living; BMI, body mass index; IKDC, International Knee Documentation Committee 2000; KOOS, Knee injury and Osteoarthritis Outcome Score; QoL, Quality of Life; —, not applicable.

well as clinical ACL failure (a combination of subjective instability, findings at physical examination, and/or graft rupture) and repeat surgery rates and rates of other complications and non–knee related adverse events at the 5-year follow-up: TAS (range, 0-10; low physical activity to high physical activity), visual analog scale (VAS) for satisfaction (range, 0-10; unsatisfied to very satisfied), Knee injury and Osteoarthritis Outcome Score (KOOS; range, 0-100; worst to best), IKDC physical examination score (range, A-D; best to worst) including instrumented Lachman test (Rolimeter), limb symmetry index (LSI) for jump tests (single-leg hop and hold, side hop, and triple hop for distance) and for isokinetic quadriceps and hamstrings strength (peak torque at 60 deg/s, 180 deg/s, and 300 deg/s; isoforce dynamometer; TUR), and signs of osteoarthritis scored on the anteroposterior weightbearing and lateral radiographs using the Kellgren-Lawrence score (0-4; no osteoarthritis to severe osteoarthritis).[3,5,18,29,32] Two independent experienced sports physical therapists performed the assessments in the orthopaedic department's outpatient clinic. Assessors were not blinded for the patients' treatment allocation for practical reasons.

Statistical Analysis

A detailed description of the statistical analysis has been previously reported.[23] Sample size was calculated based on 1-sided noninferiority of ACLSR to ACLR for the IKDCs, standard deviation was set at 9, and the clinically relevant difference was set at 10.[4,30] A sample size of 20 patients in each study group was required to achieve a statistical power of 90% and an alpha of 5%. Twenty-four patients per group were included (48 total) to allow for a lost-to-follow-up rate of 20%. Noninferiority of DA ACLSR to ACLR regarding the primary outcome was assessed using an intention-to-treat analysis (ie, by including patients who completed the IKDCs questionnaire at the 5-year follow-up).[43]

DA ACLSR was considered noninferior to ACLR if the lower limit of the 2-sided 95% CI of the IKDCs of the DA ACLSR group was within the margins of clinically significant difference (of 10 points) of the median IKDCs of the ACLR group. As data were not normally distributed, the 95% CI around the median IKDCs at the 5-year follow-up was calculated per group using the Gardner and Altman formula (https://www.openepi.com/CIMedian.htm).

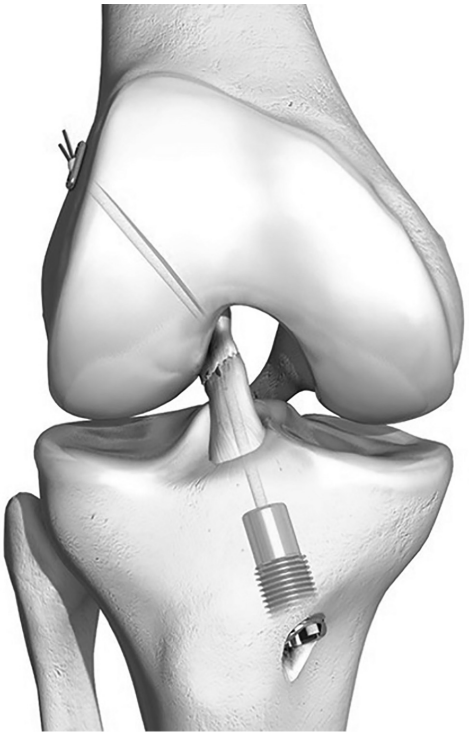

Figure 1. Dynamic augmentation of the ruptured anterior cruciate ligament (ACL). ACL suture repair augmented with intraligamentary braid with cortical button fixation on the femoral side and additional elastic link (a spring-in-screw mechanism) on the tibial side. (Reprinted with permission of Hoogeslag et al.[24])

Descriptive results are presented as median (interquartile range [IQR]) or frequency (percentage) for continuous and categorical variables, respectively. The Mann-Whitney-Wilcoxon test was used to investigate the difference between groups for continuous variables. The chi-square test was used to test for significant differences between groups for categorical variables. The related-samples Wilcoxon signed rank test was used to investigate the difference within groups between the 2-year and 5-year follow-ups. The change of IKDC scores within groups between the 2-year and 5-year follow-ups was calculated, and an independent *t* test was used to investigate if this was different between groups.

Statistical analyses were performed using SPSS Version 22.0 (IBM Corp), and the level of significance was set to $<.05$.

RESULTS

Of the 375 patients who underwent primary ACLR, 323 patients did not meet the inclusion criteria, 3 declined to participate, and 1 was excluded preoperatively because of the need for a meniscal suture repair, leaving 48 patients who were included in the study.[24] During the 5-year follow-up, 1 patient in the ACLSR group and 3 patients in the ACLR group were lost to follow-up (Figure 2).

Primary Outcome Measure: IKDCs

The lower limit of the 2-sided 95% CI for the median IKDCs of the DA ACLSR group at the 5-year follow-up (75.9) was lower than the prespecified noninferiority margin (86.6). Therefore, the null hypothesis of noninferiority of the DA ACLSR was rejected (Table 2, Figure 2). However, the upper limit of the 2-sided 95% CI of the DA ACLSR group at the 5-year follow-up (100.0) was higher than the median IKDCs of the ACLR group (96.6). Therefore, the results were inconclusive, and DA ACLSR was not considered inferior to ACLR (Table 2, Figure 3). No statistically significant difference in the median IKDCs at the 5-year follow-up was found between groups (ACLSR, 90.2; ACLR, 96.6; $P = .571$) (Tables 2 and 3). The difference in IKDCs between the 2-year and 5-year follow-ups was 1.2 $\pm$ 11.0 for the ACLSR group and 0.8 $\pm$ 8.3 for the ACLR group, and this was not statistically significant between groups ($t(39) = 0.629$; $P = .533$).

Secondary Outcome Measures

No statistically significant differences were found between groups at the 5-year follow-up in any of the secondary outcome measures (Table 3).

Adverse Events

Several adverse events were reported between the 2- and 5-year follow-ups, in addition to those reported between index surgery and the 2-year follow-up (Table 4).[24] Three ipsilateral clinical failures occurred in the DA ACLSR group versus 2 in the ACLR group. All patients with clinical failure underwent single-stage revision ACL surgery using autologous ipsilateral patellar tendon without complications, using the previous tunnels. One contralateral ACL rupture occurred in the DA ACLSR group and none in the ACLR group.

Furthermore, repeat surgeries other than for revision ACL surgery took place in 4 patients from the DA ACLSR group (cyclops lesion, ACL rerupture stump impingement, medial meniscal tear, and recurrent pain) and 1 patient in the ACLR group (snapping lateral meniscus). No patients were awaiting hardware removal at the 5-year follow-up.

Last, 4 non–knee related adverse events were reported in the DA ACLSR group (1 renal insufficiency and subsequent kidney transplant; 1 concern of pain at the tibial button after contralateral ACLR; 1 contralateral combined posterior cruciate ligament and posterolateral corner injury; and 1 hernia nucleus pulposus, which was symptomatic at the time of the 5-year follow-up) and 1 in the ACLR group (symptomatic shoulder instability).

DISCUSSION

The most important finding of this study was that, because of the wide CI around the median IKDCs of the DA ACLSR group, the results were inconclusive regarding whether DA ACLSR is noninferior to ACLR in terms of the IKDCs 5

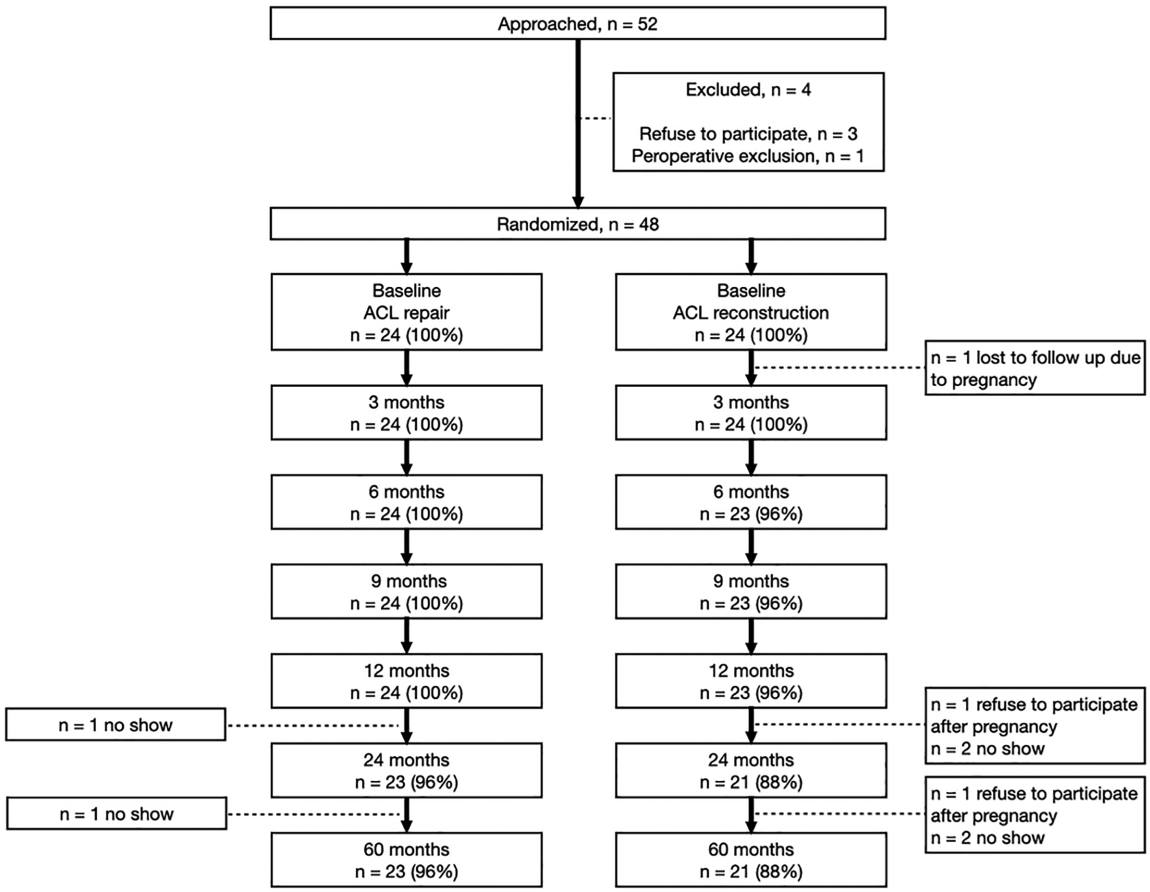

Figure 2. Flowchart of inclusion and randomization of participants. ACL, anterior cruciate ligament.

TABLE 2
Results of Noninferiority for International Knee Documentation Committee 2000 Subjective Scores at 5-Year Follow-up After Anterior Cruciate Ligament Surgery[a]

ITT Analysis	n	Median (IQR)	95% CI	*P* Value
Repair	23	90.2 (75.9–100.0)	75.9–100.0	.571
Reconstruction	21	96.6 (86.8–98.9)	88.5–98.9	(Z .567)

[a]IQR, interquartile range; ITT, intention-to-treat.

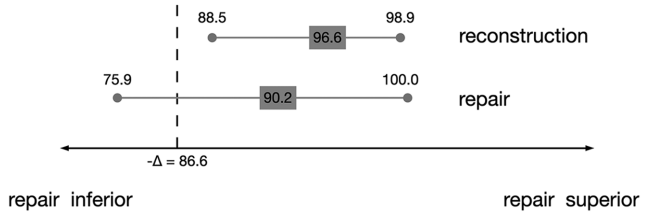

Figure 3. Noninferiority as per International Knee Documentation Committee 2000 (IKDC) subjective scores at the 5-year follow-up. Data are expressed as median with 95% CI. The dotted line indicates the median IKDC subjective score of the anterior cruciate ligament reconstruction group minus the clinically relevant difference (Δ) of 10 points (86.6).

years postoperatively. Nevertheless, no statistically significant difference for the IKDCs or for any of the secondary outcomes between groups was found.

To the best of our knowledge, this is the first RCT reporting outcomes of contemporary ACLSR in comparison with those of ACLR at a midterm (5-year) follow-up. Only a few case series on this topic with a 5-year follow-up (or longer) have been published. Some retrospective case series on nonaugmented and static augmented ACLSR have reported outcomes comparable with those reported in the present study.[7,22,27] Furthermore, in a prospective pilot study of 10 patients after DA ACLSR, Eggli et al[9] reported a median IKDCs of 98.9 with a range of 79.3 to 100 at the 5-year follow-up. In a prospective case series of 57 patients after DA ACLSR, Ahmad et al[1] reported

TABLE 3
Primary and Secondary Outcome Measures in the Dynamic Augmented Anterior Cruciate Ligament Suture Repair and Anterior Cruciate Ligament Reconstruction Groups at 5-Year Follow-up[a]

	5-y Follow-up		
	Repair	Reconstruction	*P* Value
IKDC subjective score	90.2 (75.9–100.0)[b]	96.6 (86.8–98.9)[b]	.571
KOOS			
Symptoms	92.9 (85.7–96.4)[b]	96.4 (89.3–100.0)[b]	.172
Pain	100.0 (94.4–100.0)[b]	97.2 (94.4–100.0)[b]	.722
ADL	100.0 (97.1–100.0)[b]	100.0 (100.0–100.0)[b]	.279
Sport and Recreation	85.0 (75.0–100)[b]	100.0 (86.3–100.0)[b]	.138
QoL	75.0 (50.0–100.0)[b]	81.3 (71.9–100.0)[b]	.125
TAS score	7.0 (4.0–9.0)[c]	6.5 (4.0–8.8)[c]	.891
Active at preinjury TAS level	7 (35.0)[c]	9 (39.1)[c]	.780
VAS satisfaction score	9.2 (6.9–9.8)[b]	8.7 (7.1–9.7)[b]	.645
IKDC physical examination score			.134
A	18 (81.8)[d]	20 (100.0)[d]	
B	3 (13.6)[d]	0 (0.0)[d]	
C	1 (4.5)[d]	0 (0.0)[d]	
D	0 (0.0)[d]	0 (0.0)[d]	
Lachman delta, mm	1.0 (0.0–2.0)[e]	1.0 (0.0–1.0)[e]	.491
LSI force ratio, i/u			
Quadriceps 60 deg/s	91.6 (82.2–107.5)[f]	91.1 (84.7–101.2)[f]	.648
Quadriceps 180 deg/s	95.1 (85.3–107.2)[f]	93.2 (81.8–102.0)[f]	.259
Quadriceps 300 deg/s	93.4 (83.7–102.3)[f]	88.2 (82.1–97.2)[f]	.377
Hamstrings 60 deg/s	95.1 (83.7–104.5)[f]	94.7 (86.6–106.8)[f]	.692
Hamstrings 180 deg/s	96.3 (84.7–102.7)[f]	90.7 (83.9–98.4)[f]	.428
Hamstrings 300 deg/s	97.5 (90.8–108.5)[f]	100.7 (84.5–109.3)[f]	.493
LSI hop, i/u			
Single hop	97.9 (91.8–103.8)[g]	98.3 (95.0–103.1)[g]	.656
Triple hop	94.2 (90.0–103.9)[g]	98.5 (92.9–102.1)[g]	.265
Side hop	97.2 (90.3–105.4)[h]	97.6 (88.6–106.4)[h]	.778
KL			.247
0	20 (90.9)[i]	14 (77.8)[i]	
1	2 (9.1)[i]	4 (22.2)[i]	
2	0 (0.0)[i]	0 (0.0)[i]	
3	0 (0.0)[i]	0 (0.0)[i]	
4	0 (0.0)[i]	0 (0.0)[i]	

[a]Since data were not normally distributed, they are expressed as median (interquartile range) or frequency (%). ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee 2000; i/u, injured/uninjured; KL, Kellgren-Lawrence osteoarthritis score; KOOS, Knee injury and Osteoarthritis Outcome Score; LSI, limb symmetry index; QoL, Quality of Life; TAS, Tegner Activity Scale; VAS, visual analog scale.
[b]Analysis based on 23 patients with repair and 21 patients with reconstruction.
[c]Analysis based on 23 patients with repair and 20 patients with reconstruction.
[d]Analysis based on 22 patients with repair and 20 patients with reconstruction.
[e]Analysis based on 22 patients with repair and 19 patients with reconstruction.
[f]Analysis based on 20 patients with repair and 17 patients with reconstruction.
[g]Analysis based on 20 patients with repair and 16 patients with reconstruction.
[h]Analysis based on 19 patients with repair and 16 patients with reconstruction.
[i]Analysis based on 22 patients with repair and 18 patients with reconstruction.

a median IKDCs of 94.0 with a range of 63.2 to 100.0 at the 6-year mean follow-up. Last, in a prospective case series of 65 patients after DA ACLSR, Kosters et al[33] reported a mean IKDCs of 90.0 at the 5-year follow-up; however, they reported neither standard deviation nor range. Moreover, the median IKDCs in the present study at the 5-year follow-up is comparable with that reported in other studies on ACLSR with shorter follow-up periods as well as with that reported for ACLR in comparative studies.[24,34,41] No comparative study between contemporary ACLSR and ACLR with midterm outcome is available to compare any of the outcome measures reported in the present study.[24] Thus, overall, the median outcome for the IKDCs for the ACLSR group in the present study seems to be on par with those reported in the literature for both ACLSR and ACLR at short- and midterm follow-ups.

Although the reported failure, complication, and repeat surgery rates after contemporary DA ACLSR vary widely

TABLE 4
Adverse Events ≤5 Years After ACL Surgery[a]

	2-y Follow-up[23]			5-y Follow-up		
	Repair	Reconstruction	*P* Value	Repair	Reconstruction	*P* Value
Adverse events			.238			.330
Ipsilateral clinical ACL failure	2 (8.7)[b]	4 (19.0)[b]	.663	5 (20.8)[d]	6 (27.2)[d]	.731
Contralateral ACL rupture	2 (8.7)[b]	0 (0.0)[b]	.470	3 (13.0)[e]	0 (0.0)[e]	.094
Repeat surgery	5 (20.8)[c]	3 (14.3)[c]	.669	9 (37.5)[f]	4 (20.0)[f]	.205
Abnormal symptoms: pain, swelling, extension deficits, donor-site morbidity	5 (20.8)[c]	4 (19.0)[c]	>.999	6 (26.1)[b]	7 (33.3)[b]	.599
Other non–knee related adverse events	3 (12.5)[d]	1 (4.2)[d]	.602	7 (29.2)[f]	1 (5.0)[f]	.038

[a]Data are expressed as frequency (%). Data on adverse events are based on different numbers of patients in each group, for instance, if a patient had a contralateral clinical ACL failure within 2 or 3 years postoperatively but was lost to follow-up at 5 years. ACL, anterior cruciate ligament.
[b]Analysis based on 23 patients with repair and 21 patients with reconstruction.
[c]Analysis based on 24 patients with repair and 21 patients with reconstruction.
[d]Analysis based on 24 patients with repair and 22 patients with reconstruction.
[e]Analysis based on 23 patients with repair and 20 patients with reconstruction.
[f]Analysis based on 24 patients with repair and 20 patients with reconstruction.

and some authors report these to be unacceptably high, the results in the present study fell well within the limits of those reported in the literature for contemporary ACLSR.[24,28,39,42]

Furthermore, the reported clinical failure rates for both groups (DA ACLSR, 20.8%; ACLR, 27.2%) were consistent with those reported in the literature for ACLR in young and active patients, reflecting the population of the present study.[19] For ACLR, Getgood et al[15] and Mohtadi et al[40] reported clinical failure rates of 40% and 26% in their RCTs, respectively, and Wiggins et al[55] reported ACL graft rupture rates between 6.3% and 34.2% in a systematic review. Moreover, Rousseau et al[47] reported a 39% overall complication rate and 28% repeat surgery rate within a 2-year follow-up period after ACLR in a population of 811 patients, which are also similar to the results for both groups in the present study. Last, consistent with our results, several other comparative studies between contemporary ACLSR and ACLR with shorter follow-up periods reported no differences in adverse events between groups.[24,34,41] Therefore, the clinical failure, complication, and repeat surgery rates reported in the present study seem to be on par with those reported in the literature.

In the present study, although there was no statistically significant difference between groups at the 5-year follow-up and within groups between the 2-year and 5-year follow-ups, the lower limits of the IQR and 95% CI for the median IKDCs in the DA ACLSR group decreased more than those in the ACLR group over time; this caused the null hypothesis to be rejected.[23] This finding brings to mind several historical ACLSR studies that had good short-term outcomes but deteriorating midterm outcomes. In 1976, Feagin and Curl[13] reported initial good to excellent outcomes at the 2-year follow-up of nonaugmented ACLSR of mainly proximally ruptured ACLs in a young and athletically active population, but a clinical failure rate >50% at the 5-year follow-up. These results were echoed in several other studies, and although it was subsequently proposed that proximal ACL rupture location with good tissue quality would yield better results, the discussion about patient selection criteria came too late, which ultimately led to the abandonment of ACLSR in favor of ACLR in the late previous century.[11,14,31,38,48,50] Recently, patient selection criteria for contemporary ACLSR have been proposed, and younger age (which may be a proxy for activities that are strenuous on the knee), (pursuit of) higher activity level, midsubstance ACL rupture location, lack of integrity of the ruptured ACL tissue and synovial sheath, and prolonged time from injury to surgery have been reported to negatively influence the outcomes of contemporary ACLSR techniques.[2,12,21,27,35,51,54] Except for timely operative treatment, none of the above factors were considered when including patients in the present study; included patients were young and athletically active, their inclusion was independent of ACL rupture location (although most patients had a proximal ACL rupture with <50% retraction of the synovial sheath), and the majority had a multilacerated tibial ACL remnant.[23] Thus, this might have negatively influenced the results for DA ACLSR in the present study. Nevertheless, no statistically significant differences were found for any of the reported outcome measures between groups. Moreover, patient satisfaction was high, and side-to-side differences assessed with the instrumented Lachman test were <3 mm in both groups.

The addition of a collagen bioscaffold to DA ACLSR in midsubstance ACL ruptures was reported to decrease complication rates drastically (from 79% to 9% at the 2-year follow-up).[12] Recently, an RCT by Murray et al[41] reported that the outcomes of ACLSR with the addition of a proprietary bioscaffold were noninferior to those of ACLR at the 2-year follow-up; the patients in the ACLSR group predominantly had nonproximal ACL ruptures. Furthermore, a recent RCT reported that the addition of anterolateral corner reconstruction could protect the reconstructed ACL, with a significant and clinically relevant reduction

in failure rate.[15] It has now been proposed that the addition of anterolateral corner reconstruction in ACLSR may add rotational stability and reduce complication rates in high-risk patients as well.[6,26] However, further research is necessary to investigate these possibilities.

To our knowledge, this is the first independent RCT comparing contemporary DA ACLSR with ACLR reporting the outcomes at the 5-year follow-up. Although by itself this is not sufficient to evaluate the utility of DA ACLSR as a treatment modality for acute ACL ruptures, our results could provide direction to future research. Nevertheless, this study had several limitations, and these have been extensively described by Hoogeslag et al.[23] Some of these limitations are worth revisiting explicitly. First, most importantly, the sample size was large enough to reject the null hypothesis, but it had insufficient power to enable us to draw conclusions on potential differences in secondary outcomes between groups. Second, there was no standard criterion to determine an appropriate noninferiority margin.[17] In treatment outcome studies, a noninferiority margin is commonly set based on what is considered clinically relevant.[16,45] Therefore, with a reported minimal clinically relevant difference of 8.8 to 15.6 points for the IKDCs, the clinically relevant difference was set at 10, and the standard deviation was set at 9.[4,30,36] Third, although no differences between groups were found, the variation in IKDCs and KOOS within both groups at baseline was high. This was probably caused by the nature of the questionnaires, which ask for symptoms in the past 4 weeks, versus the nature of the study, in which baseline characteristics were measured well within 3 weeks after the knee injury. Therefore, since the questionnaires overlap the preinjury and injured state of the knee, it is probable that patients interpreted the questionnaires in a different manner. The (very) high IQR for the KOOS Sport and Recreation subgroup substantiates this assumption. In future studies on acute ACL injuries, it might be better to ask for symptoms in the 4 weeks before the injury explicitly.

CONCLUSION

The results of the present study were inconclusive regarding the noninferiority of DA ACLSR to ACLR in terms of subjective patient-reported outcomes as measured using the IKDCs.

CLINICAL RELEVANCE

Although DA ACLSR may be a viable treatment option for patients with acute ACL rupture, caution must be exercised when considering this treatment for young, active patients, corresponding to the present study population.

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REFERENCES

1. Ahmad SS, Schurholz K, Liechti EF, Hirschmann MT, Kohl S, Klenke FM. Seventy percent long-term survival of the repaired ACL after dynamic intraligamentary stabilization. *Knee Surg Sports Traumatol Arthrosc*. 2020;28(2):594-598.
2. Ateschrang A, Schreiner AJ, Ahmad SS, et al. Improved results of ACL primary repair in one-part tears with intact synovial coverage. *Knee Surg Sports Traumatol Arthrosc*. 2019;27(1):37-43.
3. Balasch H, Schiller M, Friebel H, Hoffmann F. Evaluation of anterior knee joint instability with the Rolimeter. A test in comparison with manual assessment and measuring with the KT-1000 arthrometer. *Knee Surg Sports Traumatol Arthrosc*. 1999;7(4):204-208.
4. Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM. Measures of knee function: International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS). *Arthritis Care Res (Hoboken)*. 2011;63(suppl 11):S208-S228.
5. de Groot IB, Favejee MM, Reijman M, Verhaar JA, Terwee CB. The Dutch version of the Knee Injury and Osteoarthritis Outcome Score: a validation study. *Health Qual Life Outcomes*. 2008;6:16.
6. Delaloye JR, Murar J, Vieira TD, et al. Combined anterior cruciate ligament repair and anterolateral ligament reconstruction. *Arthrosc Tech*. 2019;8(1):e23-e29.
7. DiFelice GS, van der List JP. Clinical outcomes of arthroscopic primary repair of proximal anterior cruciate ligament tears are maintained at mid-term follow-up. *Arthroscopy*. 2018;34(4):1085-1093.
8. Eggli S, Kohlhof H, Zumstein M, et al. Dynamic intraligamentary stabilization: novel technique for preserving the ruptured ACL. *Knee Surg Sports Traumatol Arthrosc*. 2015;23(4):1215-1221.
9. Eggli S, Roder C, Perler G, Henle P. Five year results of the first ten ACL patients treated with dynamic intraligamentary stabilisation. *BMC Musculoskelet Disord*. 2016;17:105.
10. Engebretsen L. Editorial commentary: the anterior cruciate ligament cannot be reliably repaired. Studies with a control group are needed! *Arthroscopy*. 2020;36(2):613-614.
11. Engebretsen L, Benum P, Fasting O, Molster A, Strand T. A prospective, randomized study of three surgical techniques for treatment of acute ruptures of the anterior cruciate ligament. *Am J Sports Med*. 1990;18(6):585-590.
12. Evangelopoulos DS, Kohl S, Schwienbacher S, Gantenbein B, Exadaktylos A, Ahmad SS. Collagen application reduces complication rates of mid-substance ACL tears treated with dynamic intraligamentary stabilization. *Knee Surg Sports Traumatol Arthrosc*. 2017;25(8):2414-2419.
13. Feagin JA Jr, Curl WW. Isolated tear of the anterior cruciate ligament: 5-year follow-up study. *Am J Sports Med*. 1976;4(3):95-100.
14. Genelin F, Trost A, Primavesi C, Knoll P. Late results following proximal reinsertion of isolated ruptured ACL ligaments. *Knee Surg Sports Traumatol Arthrosc*. 1993;1(1):17-19.
15. Getgood AMJ, Bryant DM, Litchfield R, et al. Lateral extra-articular tenodesis reduces failure of hamstring tendon autograft anterior cruciate ligament reconstruction: 2-year outcomes from the STABILITY Study Randomized Clinical Trial. *Am J Sports Med*. 2020;48(2):285-297.
16. Greene CJ, Morland LA, Durkalski VL, Frueh BC. Noninferiority and equivalence designs: issues and implications for mental health research. *J Trauma Stress*. 2008;21(5):433-439.
17. Greene WL, Concato J, Feinstein AR. Claims of equivalence in medical research: are they supported by the evidence? *Ann Intern Med*. 2000;132(9):715-722.

18. Gustavsson A, Neeter C, Thomeé P, et al. A test battery for evaluating hop performance in patients with an ACL injury and patients who have undergone ACL reconstruction. *Knee Surg Sports Traumatol Arthrosc*. 2006;14(8):778-788.
19. Haberli J, Jaberg L, Bieri K, Eggli S, Henle P. Reinterventions after dynamic intraligamentary stabilization in primary anterior cruciate ligament repair. *Knee*. 2018;25(2):271-278.
20. Haverkamp D, Sierevelt IN, Breugem SJ, Lohuis K, Blankevoort L, van Dijk CN. Translation and validation of the Dutch version of the International Knee Documentation Committee Subjective Knee Form. *Am J Sports Med*. 2006;34(10):1680-1684.
21. Henle P, Bieri KS, Brand M, et al. Patient and surgical characteristics that affect revision risk in dynamic intraligamentary stabilization of the anterior cruciate ligament. *Knee Surg Sports Traumatol Arthrosc*. 2018;26(4):1182-1189.
22. Hoffmann C, Friederichs J, von Ruden C, Schaller C, Buhren V, Moessmer C. Primary single suture anchor re-fixation of anterior cruciate ligament proximal avulsion tears leads to good functional midterm results: a preliminary study in 12 patients. *J Orthop Surg Res*. 2017;12(1):171.
23. Hoogeslag RAG, Brouwer RW, Boer BC, de Vries AJ, Huis In 't Veld R. Acute anterior cruciate ligament rupture: repair or reconstruction? Two-year results of a randomized controlled clinical trial. *Am J Sports Med*. 2019;47(3):567-577.
24. Hoogeslag RAG, Brouwer RW, de Vries AJ, Boer BC, Huis In 't Veld R. Efficacy of nonaugmented, static augmented, and dynamic augmented suture repair of the ruptured anterior cruciate ligament: a systematic review of the literature. *Am J Sports Med*. 2020;48(14):3626-3637.
25. Hoogeslag RAG, Brouwer RW, Huis In 't Veld R, Stephen JM, Amis AA. Dynamic augmentation restores anterior tibial translation in ACL suture repair: a biomechanical comparison of non-, static and dynamic augmentation techniques. *Knee Surg Sports Traumatol Arthrosc*. 2018;26(10):2986-2996.
26. Hopper GP, Aithie JMS, Jenkins JM, Wilson WT, Mackay GM. Combined anterior cruciate ligament repair and anterolateral ligament internal brace augmentation: minimum 2-year patient-reported outcome measures. *Orthop J Sports Med*. 2020;8(12):2325967120968557.
27. Hopper GP, Aithie JMS, Jenkins JM, Wilson WT, Mackay GM. Satisfactory patient-reported outcomes at 5 years following primary repair with suture tape augmentation for proximal anterior cruciate ligament tears. *Knee Surg Sports Traumatol Arthrosc*. 2022;30(1):253-259.
28. Hughes JD, Lawton CD, Nawabi DH, Pearle AD, Musahl V. Anterior cruciate ligament repair: the current status. *J Bone Joint Surg Am*. 2020;102(21):1900-1915.
29. Irrgang JJ, Anderson AF, Boland AL, et al. Development and validation of the International Knee Documentation Committee Subjective Knee Form. *Am J Sports Med*. 2001;29(5):600-613.
30. Irrgang JJ, Anderson AF, Boland AL, et al. Responsiveness of the International Knee Documentation Committee Subjective Knee Form. *Am J Sports Med*. 2006;34(10):1567-1573.
31. Kaplan N, Wickiewicz TL, Warren RF. Primary surgical treatment of anterior cruciate ligament ruptures: a long-term follow-up study. *Am J Sports Med*. 1990;18(4):354-358.
32. Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. *Ann Rheum Dis*. 1957;16(4):494-502.
33. Kosters C, Glasbrenner J, Raschke MJ, Lenschow S, Herbort M, Schliemann B. Clinical outcome 5 years after dynamic intraligamentary stabilization of acute ACL ruptures. *Orthop J Sports Med*. 2019;7(6)(suppl 4):2325967119S00239.
34. Kosters C, Glasbrenner J, Spickermann L, et al. Repair with dynamic intraligamentary stabilization versus primary reconstruction of acute anterior cruciate ligament tears: 2-year results from a prospective randomized study. *Am J Sports Med*. 2020;48(5):1108-1116.
35. Krismer AM, Gousopoulos L, Kohl S, Ateschrang A, Kohlhof H, Ahmad SS. Factors influencing the success of anterior cruciate ligament repair with dynamic intraligamentary stabilisation. *Knee Surg Sports Traumatol Arthrosc*. 2017;25(12):3923-3928.
36. Li YL, Ning GZ, Wu Q, et al. Single-bundle or double-bundle for anterior cruciate ligament reconstruction: a meta-analysis. *Knee*. 2014;21(1):28-37.
37. Lubowitz JH, Ahmad CS, Anderson K. All-inside anterior cruciate ligament graft-link technique: second-generation, no-incision anterior cruciate ligament reconstruction. *Arthroscopy*. 2011;27(5):717-727.
38. Marshall JL, Warren RF, Wickiewicz TL, Reider B. The anterior cruciate ligament: a technique of repair and reconstruction. *Clin Orthop Relat Res*. 1979;143:97-106.
39. Meister M, Koch J, Amsler F, Arnold MP, Hirschmann MT. ACL suturing using dynamic intraligamentary stabilisation showing good clinical outcome but a high reoperation rate: a retrospective independent study. *Knee Surg Sports Traumatol Arthrosc*. 2018;26(2):655-659.
40. Mohtadi N, Chan D, Barber R, Paolucci EO. Reruptures, reinjuries, and revisions at a minimum 2-year follow-up: a randomized clinical trial comparing 3 graft types for ACL reconstruction. *Clin J Sport Med*. 2016;26(2):96-107.
41. Murray MM, Fleming BC, Badger GJ, et al. Bridge-enhanced anterior cruciate ligament repair is not inferior to autograft anterior cruciate ligament reconstruction at 2 years: results of a prospective randomized clinical trial. *Am J Sports Med*. 2020;48(6):1305-1315.
42. Osti M, El Attal R, Doskar W, Hock P, Smekal V. High complication rate following dynamic intraligamentary stabilization for primary repair of the anterior cruciate ligament. *Knee Surg Sports Traumatol Arthrosc*. 2019;27(1):29-36.
43. Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJ; CONSORT Group. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. *JAMA*. 2006;295(10):1152-1160.
44. Prodromos CC, Han YS, Keller BL, Bolyard RJ. Posterior mini-incision technique for hamstring anterior cruciate ligament reconstruction graft harvest. *Arthroscopy*. 2005;21(2):130-137.
45. Rehal S, Morris TP, Fielding K, Carpenter JR, Phillips PP. Non-inferiority trials: are they inferior? A systematic review of reporting in major medical journals. *BMJ Open*. 2016;6(10):e012594.
46. Reider B. The quest continues. *Am J Sports Med*. 2019;47(6):1291-1293.
47. Rousseau R, Labruyere C, Kajetanek C, Deschamps O, Makridis KG, Djian P. Complications after anterior cruciate ligament reconstruction and their relation to the type of graft: a prospective study of 958 cases. *Am J Sports Med*. 2019;47(11):2543-2549.
48. Sherman MF, Lieber L, Bonamo JR, Podesta L, Reiter I. The long-term followup of primary anterior cruciate ligament repair: defining a rationale for augmentation. *Am J Sports Med*. 1991;19(3):243-255.
49. Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries. *Clin Orthop Relat Res*. 1985;198:43-49.
50. van der List JP, DiFelice GS. Role of tear location on outcomes of open primary repair of the anterior cruciate ligament: a systematic review of historical studies. *Knee*. 2017;24(5):898-908.
51. van der List JP, Jonkergouw A, van Noort A, Kerkhoffs G, DiFelice GS. Identifying candidates for arthroscopic primary repair of the anterior cruciate ligament: a case-control study. *Knee*. 2019;26(3):619-627.
52. van Melick N, van Cingel RE, Brooijmans F, et al. Evidence-based clinical practice update: practice guidelines for anterior cruciate ligament rehabilitation based on a systematic review and multidisciplinary consensus. *Br J Sports Med*. 2016;50(24):1506-1515.
53. Vermeijden HD, van der List JP, O'Brien RJ, DiFelice GS. Primary repair of anterior cruciate ligament injuries: current level of evidence of available techniques. *JBJS Rev*. 2021;9(5):e20.00174. doi: 10.2106/JBJS.RVW.20.00174
54. Webster KE. Editorial commentary: anterior cruciate ligament suture repair could have high failure rates in active athletes of all ages. *Arthroscopy*. 2021;37(4):1202-1203.
55. Wiggins AJ, Grandhi RK, Schneider DK, Stanfield D, Webster KE, Myer GD. Risk of secondary injury in younger athletes after anterior cruciate ligament reconstruction: a systematic review and meta-analysis. *Am J Sports Med*. 2016;44(7):1861-1876.