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Acute Anterior Cruciate Ligament Rupture: Repair or Reconstruction?

Two-Year Results of a Randomized Controlled Clinical Trial

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Background: Contemporary anterior cruciate ligament (ACL) suture repair techniques have been subject to renewed interest in recent years. Although several clinical studies have yielded good short-term results, high-quality evidence is lacking in regard to the effectiveness of this treatment compared with ACL reconstruction.

Hypothesis: Dynamic augmented ACL suture repair is at least as effective as anatomic single-bundle ACL reconstruction for the treatment of acute ACL rupture in terms of patient self-reported outcomes at 2 years postoperatively.

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

Methods: After stratification and randomization, 48 patients underwent either dynamic augmented ACL suture repair or ACL reconstruction with a single-bundle, all-inside, semitendinosus technique. The International Knee Documentation Committee (IKDC) subjective score at 2 years postoperatively was the primary outcome measure. Patient-reported outcomes (IKDC subjective score, Knee injury and Osteoarthritis Outcome Score, Tegner score, visual analog scale for satisfaction), clinical outcomes (IKDC physical examination score, leg symmetry index for the quadriceps, hamstrings strength, and jump test battery), and radiological outcomes as well as adverse events including reruptures were recorded. Analyses were based on an intention-to-treat principle.

Results: The lower limit for the median IKDC subjective score of the repair group (86.2) fell within the prespecified noninferiority margin, confirming noninferiority of dynamic augmented ACL suture repair compared with ACL reconstruction. No statistical difference was found between groups for median IKDC subjective score (repair, 95.4; reconstruction, 94.3). Overall, 2 reruptures (8.7%) occurred in the dynamic ACL suture repair group and 4 reruptures (19.0%) in the ACL reconstruction group; further, 5 repeat surgeries—other than for revision ACL surgery—took place in 4 patients from the dynamic ACL suture repair group (20.8%) and in 3 patients from the ACL reconstruction group (14.3%).

Conclusion: Dynamic augmented ACL suture repair is not inferior to ACL reconstruction in terms of subjective patient-reported outcomes as measured with the IKDC subjective score 2 years postoperatively. However, for reasons other than revision ACL surgery due to rerupture, a higher number of related adverse events leading to repeat surgery were seen in the dynamic augmented ACL suture repair group within 2 years postoperatively.

Clinical Relevance: Dynamic augmented ACL suture repair might be a viable treatment option for patients with an acute ACL rupture.

Registration: NCT02310854 (ClinicalTrials.gov identifier).

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

Suture repair of the ruptured anterior cruciate ligament (ACL) has been subject to renewed interest in recent years with the advent of contemporary arthroscopic techniques using static or dynamic augmentation or no augmentation.[28,39,53,54] In static augmentation, a tape or braid is fixed to both the tibial and the femoral bones directly, whereas in dynamic augmentation, a braid is fixed to the femoral cortex and to an additional elastic link (spring-in-screw mechanism) on the tibial side.

Although biomechanical studies have shown that only ACL suture repair with dynamic augmentation restored anterior tibial translation, preclinical porcine and ovine

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animal model studies have shown that both static and dynamic augmented ACL suture repair techniques led to good results.[24,29,41,47,54,56] Moreover, promising short-term to midterm results have been reported in retrospective and prospective series using nonaugmented, static augmented, or mostly dynamic augmented ACL suture repair techniques.[§] Some authors have even questioned whether these promising clinical results would lead to a paradigm shift in treatment of acute ruptures of the ACL, away from the current gold standard of autograft ACL reconstruction and back to ACL suture repair.[23,51,56]

However, the body of evidence for clinical studies using contemporary ACL suture techniques is rather small, and high-quality evidence is lacking.[54] Therefore, the purpose of this study was to examine patient-reported, clinical, and radiological outcomes of augmented ACL repair compared with ACL reconstruction in patients with an acute rupture of the ACL. The aim was to examine the following null hypothesis: Dynamic augmented ACL suture repair is at least as effective as anatomic single-bundle ACL reconstruction in the treatment of acute ACL rupture in terms of patient self-reported outcomes at 2 years postoperatively.

METHODS

A prospective, stratified, block randomized controlled trial (RCT) was conducted at the Centre for Orthopaedic Surgery OCON, Hengelo, the Netherlands. The institutional review board approved this study. Patients 18 to 30 years of age visiting the outpatient clinic were screened for eligibility for this study. Eligible patients had a proven primary ACL rupture confirmed by means of history, physical examination, and magnetic resonance imaging; had an indication for ACL reconstruction surgery; could undergo surgery within 21 days after injury; and had a score of 5 to 10 on the Tegner Activity Scale.[5,50] Inclusion was independent of ACL rupture localization. Exclusion criteria were concomitant ligamentous lesions, meniscal lesions needing surgical repair, and full-thickness cartilage lesions, as these injuries require a change in the postoperative rehabilitation regimen. Further exclusion criteria were a history of knee surgery of the contralateral and/or ipsilateral knee; hypersensitivity to cobalt, chromium, or nickel; muscular, neurological, or vascular abnormalities; osteoarthritis seen on the weightbearing preoperative radiograph; and a tendency to form excessive scar tissue.

Randomization and Intervention

After written informed consent was obtained, patient characteristics were recorded and a baseline measurement was performed. Subsequently, patients were stratified according to their preinjury Tegner score (moderate, Tegner 5-7; high, Tegner 8-10) to distribute the risk of reinjury based on physical activity level equally between groups, after which patients were randomized by the sports physical therapist in blocks with varying sizes (sealed envelope, computer-generated schedule; block sizes n = 2 and n = 4) to undergo either dynamic augmented ACL suture repair or single-bundle ACL reconstruction with a semitendinosus graft.[5,50,57]

Surgical Procedure

Augmented ACL suture repair was performed within 3 weeks after injury. ACL reconstruction was performed within 2 weeks after patients met the preoperative criteria.[55] If these criteria were not met at baseline measurement, the patients undergoing ACL reconstruction underwent preoperative rehabilitation by a sports physical therapist and were reassessed for the presence of preoperative criteria at a later stage. After administration of prophylactic antibiotics and anesthesia, the surgical procedures started with manual examination and standard arthroscopy with the patient in a supine position, the leg in an electric leg holder, and a tourniquet inflated to 300 mm Hg, to assess all compartments for concomitant injury. One surgeon (R.A.G.H.), who has considerable experience in ACL reconstruction surgery, performed all surgical procedures.

Augmented ACL Repair. Augmented ACL suture repair was performed with the dynamic intraligamentary stabilization technique (Ligamys; Mathys Medical) as described by Eggli et al.[10] Using a suturing forceps, the surgeon tied the tibial stump of the ruptured ACL with 3 or 4 retaining threads (PDS No. 2-0; Ethicon). An aiming device was positioned from the anteromedial aspect of the tibial metaphysis to the center of the tibial ACL attachment, and a 2.4 mm–diameter drill tip guide pin was used to create a tibial tunnel of at least 50 mm in length. An outside-in tibial socket of 30-mm length and 10-mm diameter was reamed over the tibial guide pin with a cannulated drill, leaving a 20-mm bone bridge between the top of the tibial socket and the joint line. A Ligamys Monobloc fixation device was screwed inside the tibial tunnel over the guide pin, until it lined up precisely with the tibial cortex. A shuttle thread replaced the tibial guide pin. A femoral tunnel was created with a 2.4 mm–diameter drill tip guide pin with eyelet, in the direction of an accessory anteromedial portal, just superior to the tibial plateau and medial meniscus and just anterior to the medial femoral condyle, with the knee in 120° of flexion, to the anteromedial part of the femoral ACL attachment. An incision was made from the skin to the lateral femoral cortex in the trajectory of the guide pin to allow cortical fixation of the button and retaining threads. The

[§]References 1, 3, 6, 9, 11, 13, 23, 30, 31, 35, 36, 40, 46, 52.

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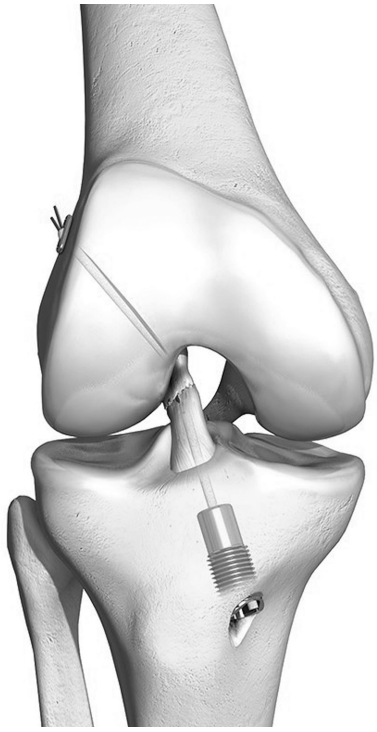

Figure 1. Dynamic augmentation of the ruptured anterior cruciate ligament (ACL). ACL suture repair was augmented with an intraligamentary braid with cortical button fixation on the femoral side and an additional elastic link (a spring-in-screw mechanism) on the tibial side. Reprinted with permission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

shuttle thread in the tibial tunnel and the retaining threads in the ACL stump were led through the femoral tunnel with the femoral drill tip guide pin with eyelet. The knee was placed in 0° of flexion.[24] After the retaining threads in the ACL stump were tensioned individually and the tibial stump of the ruptured ACL was repositioned to its femoral origin, a Ligamys braid was pulled distally through the femoral and tibial tunnels with the shuttle wire. It was verified that the braid's proximal fixation button abutted the lateral femoral cortex, thereby also fixing the tensioned retaining threads to the femoral cortex. With a tensioning device, the braid was tensioned to maximal manual load and released, after which it was tensioned again to 80 N.[24,47] A clamping cone was fixed into the Monobloc with a torque screwdriver (Figure 1). The procedure was completed with microfracturing of the notch in and near the femoral attachment. If patients requested removal of the tibial implant, this was performed after the 2-year follow-up in order to prevent interference with the primary outcome measure.

ACL Reconstruction. ACL reconstruction was performed with an all-inside technique (Arthrex).[34] The semitendinosus tendon from the ipsilateral leg was harvested with a mini-incision technique at the posterior side of the knee and quadrupled.[44] The remnants of the ruptured ACL were removed, leaving approximately 3 mm of remnant on the tibial and femoral ACL attachment sites. Independent tibial and femoral sockets were prepared with a retrograde drill (FlipCutter; Arthrex), with the tibial socket in the center of the tibial ACL attachment and the femoral socket with a bias from the center toward the femoral anteromedial bundle attachment.[34] After advancement and fixation of the graft in the femoral socket, the graft was advanced and fixed in the tibial socket with the knee in 0° of flexion while anterior translation of the tibia in relation to the femur was reduced manually. Position and tension of the graft were verified under arthroscopic view, and the graft tension was adjusted if necessary.

Postoperative Rehabilitation. Both groups received a near-identical, structured, criteria-based rehabilitation protocol and were guided by their own sports physical therapist accordingly.[55] Patients treated with augmented ACL repair received a long-leg splint locked in extension during the first 5 days postoperatively, whereas patients treated with ACL reconstruction were allowed full range of motion as tolerated directly postoperatively.

Baseline Characteristics

Patient baseline and preoperative characteristics included in the study were sex, age, injured side, body mass index, smoking status, time from injury to surgery, presence and treatment of concomitant cartilage and meniscal injuries, operating time, ACL rupture location (proximal, midsubstance, or distal tear), type of reconstruction (1 bundle, 2 bundles, $\geq$3 bundles), and integrity of the synovial sheath (completely intact, $\geq$50% intact, <50% intact).[23]

Outcome Measures

The primary outcome measure was the International Knee Documentation Committee 2000 (IKDC) subjective score 2 years postoperatively. The IKDC subjective score measures symptoms and functional limitations for a variety of knee disorders, including ligamentous injuries, and is validated in Dutch.[20,25,26]

Patients were evaluated at baseline and at 3, 6, 9, 12, and 24 months postoperatively with patient-reported outcome measures (PROMs) and physical examination. The PROMs were IKDC subjective score (range, 0 [worst] to 100 [best]) and Knee injury and Osteoarthritis Outcome Score (KOOS) (range, 0 [worst] to 100 [best]) to assess perceived level of functional recovery; Tegner score (range, 0 [low physical activity] to 10 [high physical activity]) to assess level of physical activity; and a visual analog scale (VAS) (range, 0 [unsatisfied] to 10 [very satisfied]) to assess level of satisfaction with the outcome of surgery. The physical examination entailed IKDC physical examination score (range, A [best] to D [worst]) and instrumented Lachman testing with a Rolimeter (Aircast).[4,8,15,20,25,38,50]

Leg symmetry index (LSI) for isokinetic quadriceps and hamstrings strength (Isoforce dynamometer; TUR) (peak torque at 60, 180, and 300 deg/s) and for jump tests

(single-legged hop and hold, side hop and triple hop for distance) were evaluated at 6, 9, 12, and 24 months postoperatively.[18,42] LSI for isokinetic quadriceps and hamstrings strength was also evaluated at baseline.[42] Signs of osteoarthritis were scored on the anteroposterior weightbearing and lateral radiographs 1 year and 2 years postoperatively by use of the Kellgren-Lawrence score.[27] Rerupture and repeat surgery, as well as other complications or adverse events, were recorded and extracted from the patients' records. The clinimetric assessments were performed by 2 independent, experienced sports physical therapists in the orthopaedic department's outpatient clinic; for practical reasons, assessors were not blinded to the patients' treatment allocation.

Statistical Analysis

Sample size was calculated based on 1-sided noninferiority of ACL suture repair compared with ACL reconstruction in terms of patient-reported functional outcomes measured by the IKDC subjective score. SD was set at 9, and with a reported minimal clinically relevant difference of 8.8 to 15.6 points of the IKDC subjective score, the clinically relevant difference was set at 10.[7,26,33] To achieve a statistical power of 90% and an alpha of 5%, a sample size of 20 patients in each study group was required. To allow for a 20% rate of loss to follow-up, 24 patients per group were included, 48 patients in total.

Descriptive results are presented as frequency, percentage, or median (interquartile range). Since data were not normally distributed (Shapiro-Wilk test), the Mann-Whitney-Wilcoxon test was used to investigate differences between groups. Chi-square tests were applied for categorical variables.

To assess whether dynamic augmented ACL suture repair was noninferior to ACL reconstruction in terms of the IKDC subjective score at 2 years postoperatively, an intention-to-treat (ITT) analysis was performed.[43] The ITT cohort consisted of patients who completed the IKDC subjective questionnaire at 2-year follow-up.

Dynamic augmented ACL suture repair was considered noninferior to ACL reconstruction if the lower boundary of the 2-sided 95% CI of the IKDC subjective score of the ACL suture repair group at 2-year follow-up lay within the noninferiority margin ($\Delta = -10$ points) of the median IKDC subjective score of the ACL reconstruction group at 2-year follow-up. For nonparametric data, 95% CIs for the median IKDC subjective score at 2-year follow-up were calculated per group by means of the Gardner and Altman formula (http://web1.sph.emory.edu/users/cdckms/median-final.html). The level of significance was set to $<.05$. Statistical analyses were performed with SPSS 22.0 (SPSS Inc), and a P value of $\leq.05$ was considered statistically significant. For secondary outcome measures, in case of multiple testing, the Bonferroni-Holm correction was used to adjust the level of significance.

RESULTS

During the study period of January 2015 to March 2016, 323 of the 375 patients who underwent primary ACL reconstruction did not meet the inclusion criteria preoperatively and 3 patients declined to participate. Of the remaining 49 patients, 1 patient was excluded preoperatively because of the need for a meniscal suture repair, leaving 48 patients who were included for analysis in this study (Figure 2). During the 2-year follow-up, 1 patient in the ACL reconstruction group was lost to follow-up because of pregnancy and 3 patients were lost to follow-up despite multiple attempts to contact them. In the repair group, 1 patient was lost to follow-up.

Baseline and Preoperative Characteristics

Baseline characteristics are presented in Table 1. No differences were found in baseline characteristics between groups, except for a significantly shorter time from injury to surgery ($P < .0001$) and a significantly longer operating time for dynamic augmented ACL suture repair compared with ACL reconstruction ($P = .000$). The variation in KOOS and IKDC subjective score between patients within both groups was high but was not statistically different between groups. In patients requiring partial meniscectomy, no more than 20% of the surface area was resected. For the dynamic augmented ACL suture repair group, rupture in the proximal third (83.3%), with more than 1 bundle (87.5%), was most prevalent.

Primary Outcome Measure: IKDC Subjective Score

The lower limit of the 2-sided 95% CI for the median IKDC subjective score of the dynamic augmented ACL suture repair group (86.2) fell within the prespecified noninferiority margin, confirming the null hypothesis of noninferiority of dynamic augmented ACL suture repair compared with ACL reconstruction (Figure 3).

No statistically significant difference was found between groups for the median IKDC subjective score at 2-year follow-up: 95.4 in the dynamic augmented ACL suture repair group and 94.3 in the ACL reconstruction group ($P = .902$) (Tables 2 and 3).

Furthermore, no statistically significant differences were found between groups regarding changes in IKDC subjective scores at 3, 6, 9, 12, and 24 months postoperatively (Table 2).

Secondary Outcome Measures

After Bonferroni-Holm correction for multiple testing, no statistically significant between-group differences were found at 3, 6, 9, 12, and 24 months postoperatively for any of the secondary outcome measures except for the KOOS Other Symptoms score at 3 months postoperatively and the delta instrumented Lachman at 6 months postoperatively, with a median delta instrumented Lachman of $\leq$2 mm in both groups (Table 2). Furthermore, no radiological signs of osteoarthritis were present at 1-year and 2-year follow-up.

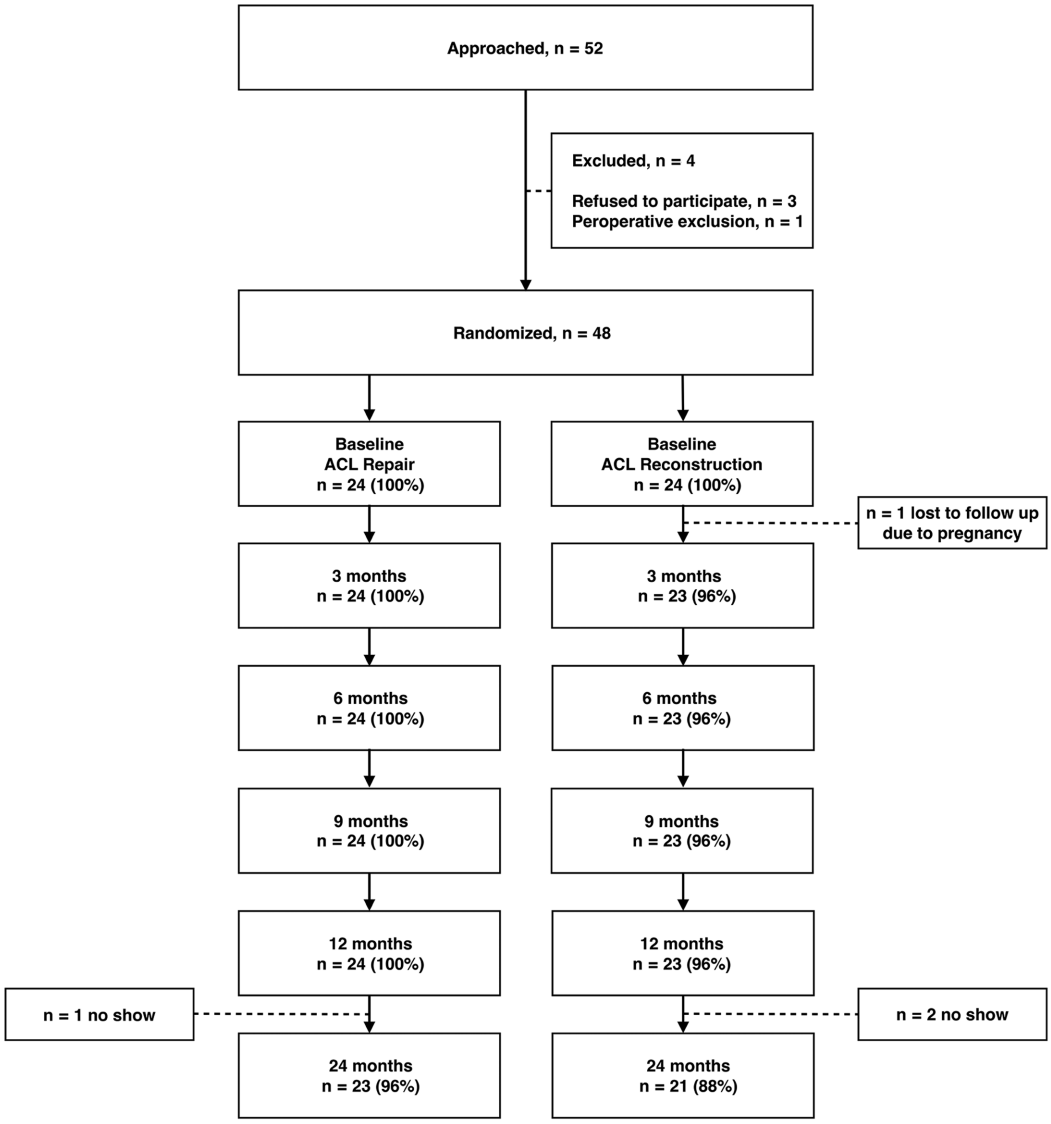

Figure 2. Flowchart of inclusion and randomization of patients. ACL, anterior cruciate ligament.

Adverse Events

Adverse events are presented in Table 4.

Results showed 2 ipsilateral reruptures (8.7%) in the dynamic augmented ACL suture repair group and 4 ipsilateral reruptures (19.0%) in the ACL reconstruction group; 2 contralateral ACL ruptures (8.7%) occurred in the dynamic augmented ACL suture repair group versus none in the ACL reconstruction group. All patients with an ACL rerupture underwent revision ACL surgery with autologous ipsilateral patellar tendon without complications, using the prior tunnels. Overall, 5 repeat surgeries other than for revision ACL surgery took place in 4 patients from the dynamic ACL suture repair group (20.8%; 2 cyclops lesions, 2 cases of residual synovitis with suspected bacterial infection but negative intraoperative cultures, treated with adjuvant antibiotics, and 1 extension deficit) and in 3 patients from the ACL reconstruction group (14.3%; cyclops lesions). In 2 of these patients, the Ligamys implant was removed (5 months after the index surgery). In another 5 patients (20.8%) in the dynamic augmented ACL suture repair group and 4 patients (19.0%) in the ACL reconstruction group, symptoms of extension deficits, pain, and swelling occurred between 0 and 10 months postoperatively but disappeared spontaneously. In the dynamic ACL suture repair group, "other" adverse events entailed 1 patient who developed a traumatic tuberculum majus fracture during skiing and 1 patient with traumatic cervical spine fracture; no patients were awaiting hardware removal at 2-year follow-up.

DISCUSSION

The most important finding of this study is that dynamic augmented ACL suture repair was not inferior to ACL reconstruction in terms of subjective patient-reported

TABLE 1
Baseline Characteristics and Preoperative Findings[a]

	Repair (n = 24)	Reconstruction (n = 24)	*P* Value
Sex			.731
Men	19 (79.2)	18 (75)	
Women	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)	
Body mass index	23.0 (21.0-24.5)	23.3 (22.1-24.4)	.445
Smoking			.753
Yes	7 (29.2)	7 (29.2)	
No, never	14 (58.3)	14 (58.3)	
No, quit <6 mo ago	0 (0.0)	1 (4.2)	
No, quit ≥6 mo ago	3 (12.5)	2 (8.3)	
IKDC subjective score	72.4 (49.1-95.2)	59.8 (39.0-100.0)	.438
KOOS subscales			
Other 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 & recreation	97.5 (17.5-100.0)	27.5 (6.3-100.0)	.194
Knee-related QoL	97 (44.0-100.0)	53.5 (20.5-100.0)	.208
Tegner score	8.0 (7.0-9.0)	8.5 (7.0-9.0)	.893
Tegner stratification			.771
Intermediate	11 (45.8)	10 (41.7)	
High	13 (54.2)	14 (58.3)	
IKDC physical examination score			.671
A	0 (0)	0 (0)	
B	3 (12.5)	4 (16.7)	
C	11 (45.8)	8 (33.3)	
D	10 (41.7)	12 (50.0)	
LSI force ratio injured/uninjured	(n = 17)[b]	(n = 18)[b]	
Quadriceps 60 deg/s	62.6 (51.9-81.0)	58.1 (40.9-88.1)	.446
Quadriceps 180 deg/s	79.2 (60.3-84.7)	60.9 (47.3-85.5)	.199
Quadriceps 300 deg/s	74.7 (65.0-83.8)	66.7 (58.2-85.2)	.318
Hamstrings 60 deg/s	70.0 (51.7-79.6)	66.9 (30.7-72.3)	.202
Hamstrings 180 deg/s	75.4 (59.1-95.2)	63.7 (27.9-88.6)	.141
Hamstrings 300 deg/s	84.4 (58.5-104.0)	73.7 (48.6-90.1)	.222
Time from injury to surgery, d	13 (12-16)	47 (42-71)	.000
Accompanying injury noted preoperatively			
Partial medial meniscectomy	3 (12.5)	4 (16.7)	.683
Partial lateral meniscectomy	2 (8.3)	7 (29.2)	.064
Lateral femoral chondral lesion	1 (4.2)	0 (0)	.312
Medial femoral chondral lesion	0 (0)	1 (4.2)	.312
Lateral tibial chondral lesion	0 (0)	1 (4.2)	.312
Medial tibial chondral lesion	0 (0)	0 (0)	
Patellar chondral lesion	0 (0)	1 (4.2)	.312
Operating time, min	61.5 (55.3-68.0)	44.0 (39.0-49.0)	<.0001
ACL rupture location			
Proximal third	20 (83.3)	—	
Central third	3 (12.5)	—	
Distal third	1 (4.2)	—	
ACL rupture bundle			
1 bundle	3 (12.5)	—	
2 bundles	10 (41.7)	—	
≥3 bundles	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 (percentage). ACL, anterior cruciate ligament; ADL, activities of daily living; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; LSI, leg symmetry index; QoL, quality of life; —, not applicable.

[b]Baseline data for LSI were missing because of pain and/or inability to perform LSI tests.

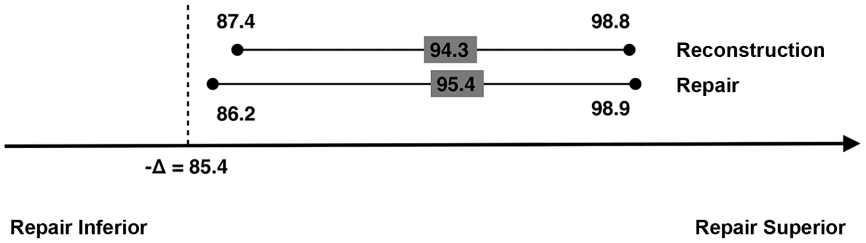

Figure 3. Noninferiority International Knee Documentation Committee (IKDC) subjective score results at 2-year follow-up. Data are expressed as median with interquartile range. Dotted line indicates the median IKDC subjective score of the anterior cruciate ligament reconstruction group; clinically relevant difference (Δ) of 10 points = 85.4.

TABLE 2
Differences Between Dynamic Augmented ACL Suture Repair and ACL Reconstruction Over Time[a]

	3 Months			6 Months			9 Months			12 months			24 Months		
	Repair	Reconstruction	*P*	Repair	Reconstruction	*P*	Repair	Reconstruction	*P*	Repair	Reconstruction	*P*	Repair	Reconstruction	*P*
IKDC subjective	69.5 (62.6-80.2)[b]	73.6 (62.1-85.1)[b]	.406	87.9 (70.7-93.1)[c]	86.2 (79.0-95.1)[c]	.409	95.4 (80.5-98.6)[d]	90.8 (82.5-97.4)[d]	.480	95.4 (87.1-97.7)[c]	96.6 (89.9-98.9)[c]	.663	95.4 (80.5-100.0)[e]	94.3 (86.5-98.9)[e]	.902
KOOS subscales															
Other symptoms	71.0 (64.0-86.0)[b]	86.0 (75.0-93.0)[b]	.011	86.0 (72.0-96.0)[c]	89.0 (82.0-93.0)[c]	.514	91.0 (82.0-100.0)[f]	89.0 (86.0-96.0)[f]	.854	93.0 (79.8-99.0)[c]	96.0 (78.5-100.0)[c]	.653	89.3 (85.7-96.4)[g]	92.3 (78.6-100.0)[g]	.934
Pain	86.0 (78.8-92.0)[b]	92.0 (81.0-97.0)[b]	.215	97.0 (83.0-100.0)[c]	94.0 (90.5-100.0)[c]	.981	97.0 (88.3-100.0)[f]	97.0 (94.0-100.0)[f]	.657	100.0 (93.3-100.0)[c]	100.0 (95.5-100.0)[c]	.869	100.0 (88.9-100.0)[e]	100.0 (95.1-100.0)[e]	.471
ADL	96.0 (87.3-99.0)[b]	99.0 (94.0-100.0)[b]	.174	100.0 (99.0-100.0)[c]	100.0 (97.0-100.0)[c]	.796	100.0 (98.5-100.0)[f]	100.0 (98.0-100.0)[f]	.808	100.0 (100.0-100.0)[c]	100.0 (100.0-100.0)[c]	.847	100.0 (100.0-100.0)[g]	100.0 (99.3-100.0)[g]	≤.999
Sport & recreation	62.5 (40.0-83.4)[b]	60.0 (40.0-85.0)[b]	.966	85.0 (70.0-95.0)[c]	85.0 (70.0-95.0)[c]	.954	97.5 (81.3-100.0)[f]	90.0 (83.0-100.0)[f]	.365	100.0 (86.3-100)[c]	95.0 (85.0-100.0)[c]	.668	75.0 (68.8-93.8)[g]	75.0 (68.8-90.6)[g]	.292
QoL	63.0 (50.0-67.5)[b]	63.0 (50.0-69.0)[b]	.331	69.0 (63.0-81.0)[c]	75.0 (69.0-81.0)[c]	.475	75.0 (63.0-81.0)[f]	81.0 (69.0-94.0)[f]	.342	78.0 (63.0-94.0)[c]	81.0 (69.0-91.0)[c]	.705	95.0 (85.0-100.0)[g]	100.0 (90.0-100.0)[g]	.972
Tegner	4.0 (3.0-5.0)[b]	4.0 (3.0-5.0)[b]	.903	5.0 (5.0-6.0)[c]	5.0 (4.0-6.0)[c]	.771	7.0 (5.0-9.0)[f]	7.0 (5.0-9.0)[f]	.509	7.0 (6.3-9.0)[c]	9.0 (6.5-9.0)[c]	.682	7.0 (5.0-9.0)[g]	7.0 (5.0-9.0)[g]	.981
Active at preinjury Tegner level										14 (58.3)[c]	9 (42.9)[c]	.172	12 (52.2)[e]	11 (55.0)[e]	.989
VAS satisfaction	8.2 (6.9-9.5)[b]	8.5 (7.5-9.3)[b]	.594	9.3 (7.1-9.6)[c]	8.5 (7.9-9.9)[c]	.682	9.1 (8.3-9.8)[f]	8.8 (6.9-9.4)[f]	.215	9.3 (8.1-9.8)[g]	8.9 (8.4-9.5)[g]	.814	9.1 (7.7-10.0)[e]	9.3 (7.7-9.8)[e]	.883
IKDC physical examination, n (%)			.073			.333			.157			.141			.438
A	5 (20.8)[b]	12 (52.2)[b]		14 (63.6)[f]	16 (76.2)[f]		19 (86.4)[f]	13 (61.9)[f]		19 (82.6)[g]	14 (66.7)[g]		20 (87.0)[h]	14 (77.8)[h]	
B	14 (58.5)[b]	9 (39.1)[b]		6 (27.3)[f]	5 (23.8)[f]		3 (13.6)[f]	7 (33.3)[f]		2 (8.7)[g]	7 (33.3)[g]		3 (13.0)[h]	4 (22.2)[h]	
C	5 (20.8)[b]	2 (8.7)[b]		2 (9.1)[f]	0 (0)[f]		0 (0)[f]	1 (4.8)[f]		1 (4.3)[g]	0 (0)[g]		0 (0)	0 (0)[h]	
D	0 (0)[b]	0 (0)[b]		0 (0)[f]	0 (0)[f]		0 (0)[f]	0 (0)[f]		0 (0)[g]	0 (0)[g]		0 (0)[h]	0 (0)[h]	
Lachman delta, mm	2.0 (1.0-2.0)[f]	1.0 (0.0-2.0)[f]	.149	2.0 (2.0-2.0)[e]	1.0 (1.0-2.0)[e]	.012	2.0 (1.0-2.0)[f]	1.0 (1.0-3.0)[f]	.568	1.0 (0.0-2.0)[h]	2.0 (1.0-2.0)[h]	.098	1.0 (0.8-2.0)[h]	1.0 (0.0-2.0)[h]	.777
LSI force ratio injured/uninjured															
Quadriceps 60 deg/s	—	—	—	77.2 (67.0-84.6)[e]	86.0 (77.3-97.5)[e]	.209	90.0 (81.8-100.3)[i]	99.5 (87.3-104.7)[i]	.191	100.0 (80.0-106.0)[j]	100.0 (92.4-109.0)[j]	.385	93.2 (82.4-104.5)[h]	88.2 (79.8-116.2)	.854
Quadriceps 180 deg/s	—	—	—	78.5 (66.2-86.2)[e]	92.1 (79.8-105.4)[e]	.072	90.5 (82.4-97.7)[i]	95.5 (84.8-103.3)[i]	.333	92.1 (85.4-103.4)[j]	101.5 (89.8-107.1)[j]	.222	89.9 (84.3-102.5)[h]	92.9 (84.3-112.2)[h]	.462
Quadriceps 300 deg/s	—	—	—	79.5 (69.9-91.0)[e]	90.7 (81.3-107.7)[e]	.226	93.4 (75.9-99.4)[i]	95.6 (81.5-105.8)[i]	.433	97.1 (81.6-106.1)[j]	97.0 (84.4-113.3)[j]	.308	91.0 (83.1-100.0)[h]	98.9 (84.7-110.0)[h]	.198
Hamstrings 60 deg/s	—	—	—	96.3 (82.5-105.9)[e]	81.5 (70.7-92.1)[e]	.724	99.9 (87.3-116.6)[i]	82.8 (75.6-103.9)	.026[k]	100.3 (88.0-116.8)[j]	88.1 (78.0-106.7)[j]	.026[k]	99.9 (88.1-109.8)[h]	88.7 (73.5-98.9)[h]	.080
Hamstrings 180 deg/s	—	—	—	97.9 (85.1-105.9)[e]	89.9 (78.2-102.1)[e]	.282	104.2 (92.4-114.1)	87.9 (75.0-109.0)[i]	.036[k]	107.9 (91.0-118.0)[j]	93.8 (75.2-113.3)[j]	.054	99.4 (87.5-119.5)[h]	86.4 (78.4-99.6)[h]	.190
Hamstrings 300 deg/s	—	—	—	99.1 (85.6-109.1)[e]	87.2 (78.6-102.6)[e]	.565	102.6 (89.6-122.6)[i]	104.4 (82.8-110.7)[i]	.480	106.8 (91.1-118.0)[j]	91.0 (71.0-116.3)[j]	.085	103.9 (87.6-112.8)[h]	97.0 (83.0-121.1)[h]	.741
LSI hop injured/uninjured	—	—	—												
Single hop	—	—	—	94.9 (91.1-99.1)[d]	97.4 (83.0-102.1)[d]	.838	100.0 (94.6-100.8)[l]	100.0 (96.6-102.9)[l]	.678	97.1 (95.0-99.3)[m]	100.0 (97.4-103.0)[m]	.027[k]	99.6 (92.9-100.5)[i]	100.9 (96.9-104.1)[i]	.170
Triple hop	—	—	—	95.9 (90.0-100.6)[d]	95.7 (86.8-99.6)[d]	.673	99.5 (95.8-100.0)[l]	99.3 (95.5-100.0)[l]	.755	98.0 (89.7-100.1)[d]	99.4 (95.2-102.9)[d]	.137	96.0 (93.5-103.7)[n]	100.4 (96.7-109.6)[n]	.103
Side hop	—	—	—	96.3 (82.1-102.6)[d]	95.0 (80.8-100.0)[d]	.546	100.0 (94.9-102.8)[l]	100.0 (92.7-103.8)[l]	.690	96.9 (74.5-101.7)[j]	101.7 (92.2-105.5)[j]	.084	96.01 (91.9-100.0)[n]	100.0 (92.8-103.5)[n]	.256

[a]Since data were not normally distributed, they are expressed as median (interquartile range) unless otherwise indicated. ADL, activities of daily living; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; LSI, leg symmetry index; QoL, quality of life; VAS, visual analog scale; —, not applicable.

[b]Analysis based on 24 repair and 23 reconstruction patients.

[c]Analysis based on 24 repair and 21 reconstruction patients.

[d]Analysis based on 21 repair and 20 reconstruction patients.

[e]Analysis based on 23 repair and 20 reconstruction patients.

[f]Analysis based on 22 repair and 21 reconstruction patients.

[g]Analysis based on 23 repair and 21 reconstruction patients.

[h]Analysis based on 23 repair and 18 reconstruction patients.

[i]Analysis based on 22 repair and 19 reconstruction patients.

[j]Analysis based on 21 repair and 21 reconstruction patients.

[k]Nonsignificant after Bonferroni-Holm correction for multiple testing.

[l]Analysis based on 24 repair and 24 reconstruction patients.

[m]Analysis based on 20 repair and 22 reconstruction patients.

[n]Analysis based on 22 repair and 20 reconstruction patients.

TABLE 3
Results of Noninferiority Test for International Knee Documentation Committee Subjective Score at 2-Year Follow-up After Anterior Cruciate Ligament Surgery With Intention to Treat Analysis[a]

	n	2-Year Median (IQR)	95% CI	*P*
Repair	23	95.4 (80.5-100.0)	86.2-98.9	.902
Reconstruction	21	94.3 (86.5-98.9)	87.4-98.8	(Z = –0.123)

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

TABLE 4
Adverse Events ≤2 Years After Anterior Cruciate Ligament (ACL) Surgery[a]

	Repair (n = 23)	Reconstruction (n = 21)	*P* Value
Adverse events			.238
Ipsilateral ACL rerupture	2 (8.7)	4 (19.0)	.663
Contralateral ACL rupture	2 (8.7)	0 (0.0)	.470
Repeat surgery	5 (20.8)	3 (14.3)	.669
Abnormal symptoms: pain, swelling, extension deficits	5 (20.8)	4 (19.0)	≤.999
Other adverse events	3 (12.5)	1 (4.2)	.602

[a]Data are expressed as frequency (percentage).

outcomes as measured with the IKDC subjective score 2 years postoperatively; no statistically significant differences in IKDC subjective scores were found between groups. However, for reasons other than revision ACL surgery for rerupture, a higher yet nonsignificant number of related adverse events leading to repeat surgery were seen in the dynamic augmented ACL suture repair group within 2 years postoperatively.

As far as we are aware, the study by Schliemann et al[46] is the only other RCT comparing contemporary (dynamic augmented) ACL suture repair with ACL reconstruction. In line with the findings of our study, Schliemann et al[46] reported no differences between groups, which was consistent with earlier findings of those authors in a prospective cohort of patients treated with dynamic augmented ACL suture repair.[31] At 1-year follow-up, Schliemann et al[46] found an IKDC subjective score of 85.7, which was slightly lower than the IKDC subjective scores in our study at 1-year and 2-year follow-up (95.4 at both points).[46] Several prospective case series, authored by the developers of the dynamic augmentation technique, reported IKDC subjective scores of 94 to 100 obtained after dynamic augmented ACL suture repair at 1-year, 2-year, and (in one pilot study with 10 patients) 5-year follow-up.[6,11,22,23,30,36] The median VAS scores for patient satisfaction in the current study, 9.3 at 1-year follow-up and 9.1 at 2-year follow-up, were comparable with those reported in the literature, and no statistical difference was found between groups.[11,23,30,36,46] Furthermore, no statistical difference was found between groups in return to preinjury activity level at 1 year and 2 years postoperatively; 58.3% in the ACL repair group and 42.9% in the ACL reconstruction group had returned to their previous Tegner level at 1 year, and 52.2% and 55.0%, respectively, had returned to their previous Tegner level at 2 years. As previously reported by other authors, the results for return to preinjury activity level in the ACL reconstruction group improved over time, with half of the patients returning to preinjury activity level at 2-year follow-up in both groups.[2] Thus, the IKDC subjective scores found in this study are consistent with those found in literature.

Although in this study only 2 implants were removed for medical reasons, the rate of repeat surgery for reasons other than rerupture was higher in the dynamic augmented ACL suture repair group compared with the ACL reconstruction group (20.8% vs 14.3%, respectively), mainly because of swelling or extension deficit due to a cyclops lesion. Some authors have reported even higher rates of repeat surgery (up to 42%) because of implant removal for medical reasons (and not patient request), partly because of motion deficits (up to 23%) within 1 year postoperatively.[3,6,11,19,23,29,31,36] This might be related to the necessity of scar formation for healing of the ruptured ACL, with this scar formation leading to the formation of a cyclops lesion and/or an extension deficit.[36] Furthermore, although young age and competitive sports activity, reflecting the population in this study, have been described as risk factors for both dynamic augmented ACL suture repair and ACL reconstruction, the rerupture rates found in this study are in line with or lower than those rates described in the literature (ranging from 7% to 15% and 8% to 28%, respectively).[‖]

Midsubstance location of the ACL rupture also has been described as a risk factor for failure of dynamic augmented ACL suture repair.[21,32] Interestingly, a difference was found between studies that used nonaugmented and static augmented suture repair techniques, which reported

[‖]References 3, 6, 11, 19, 21, 23, 29, 31, 32, 36, 37, 46, 57.

results of exclusively proximal ACL repairs, and studies that used dynamic augmented ACL suture repair, which reported results of proximal as well as central third repairs of the ruptured ACL. The results of some retrospective and prospective cohort studies of nonaugmented or static augmented ACL suture repair suggest that proximal ruptures of the ACL tend to have better clinical results compared with central or distal third ruptures.[9,35,53] However, in a prospective case-control study that compared nonaugmented ACL suture repair versus ACL reconstruction to treat proximal ACL ruptures, Achtnich et al[1] reported a statistically significant difference in rates of repeat surgery and failures, to the disadvantage of the ACL repair group. Analyzing dynamic augmented ACL suture repair in more detail, Evangelopoulos et al[13] reported that contemporary dynamic augmented ACL suture repair alone for central or distal third ruptures of the ACL resulted in a high complication and failure rate (79%) at 2-year follow-up and that the addition of an ACL bridging collagen bioscaffold reduced complication and failure rate dramatically (to 9%). Murray et al,[40] after extensive research in animal model studies, reported no short-term adverse events or differences compared with ACL reconstruction after application of a proprietary collagen bioscaffold for static augmented ACL suture repair in a prospective comparative clinical case series.[40]

Hence, adding a collagen bioscaffold to ACL suture repair procedures might improve results of ruptures not only in the central or distal third of the ACL but also in the proximal third of the ACL, even for patients with younger age and high level of activity, as were included in this study.[13,40] However, further research is necessary to investigate this possibility. Given that 16.7% of ruptures in this study were not located in the proximal third of the ACL and no bioscaffold was added to the procedure, this might have negatively affected the results of the dynamic augmented ACL suture repair group.

This study has limitations that have to be addressed. First, the sample size is too small to draw conclusions on potential differences in rerupture rate between groups. However, the sample size is large enough to sufficiently confirm the null hypothesis. Second, in contrast to the present study, historical ACL suture repair was performed nonaugmented or with static augmentation, patients were treated with arthrotomy and immobilized for several weeks postoperatively, and tear location seemed to play a role; studies of these historical techniques reported good to excellent short-term outcomes but deteriorating mid- to long-term outcomes.[12,14,48,49,53] The present study reports short-term outcomes, and by itself this is not sufficient to evaluate the utility of the dynamic augmented ACL suture repair technique as a treatment modality for acute ACL ruptures. More high-quality studies with longer follow-up are needed. Nevertheless, this is the first independent RCT examining contemporary (dynamic) augmented ACL suture repair compared with ACL reconstruction, and its short-term results might give direction to future research. Third, although 3 patients were treated with dynamic augmented ACL suture repair before the study, a longer learning curve for the ACL suture repair procedure has to be considered. Fourth, for practical reasons, neither the patients nor the assessors were blinded, which might have introduced some form of bias. Fifth, although no differences between groups were found, the variation in KOOS and IKDC subjective score between patients within both groups at baseline was high. The questionnaires ask for symptoms in the past 4 weeks, a period which in this study can overlap the preinjury and the injured state of the knee. It is probable that patients interpreted the questionnaires in a different manner, answering as to the state of the knee before or after the injury. In future research, to compare postoperative results with the preinjury state of the knee between patients within groups, it might be better to ask for symptoms in the 4 weeks before injury explicitly.[23] Sixth, no gold standard criterion is available for determining an appropriate noninferiority margin.[17] The most common approach in treatment outcome studies is to set a margin based on what is considered "clinically unimportant."[16,45] For noninferiority studies, some advocate an additional per-protocol analysis to compensate for protocol violation to demonstrate noninferiority from a more conservative perspective compared with an ITT analysis.[43] In the dynamic augmented ACL suture repair group, the surgical removal of the dynamic augmentation device in 2 patients could be considered a protocol violation. However, it has been reported that the braid of the dynamic augmentation device gradually loses tension, and therefore function, in the first months postoperatively.[3] Given that the 2 patients who were subject to protocol violations had their dynamic augmentation device removed 5 months postoperatively, it is unlikely that this affected their results at 2-year follow-up.

CONCLUSION

These results have shown that the effectiveness of dynamic augmented ACL suture repair is not inferior to that of ACL reconstruction in terms of subjective patient-reported outcomes as measured with the IKDC subjective score 2 years postoperatively. However, for reasons other than revision ACL surgery for rerupture, a higher number of related adverse events leading to repeat surgery were seen in the dynamic augmented ACL suture repair group within 2 years postoperatively.

Clinical Relevance

Although no high-level evidence with long-term follow-up exists, and the repeat surgery rate seems rather high, dynamic augmented ACL suture repair might be considered a viable treatment option for patients with an acute ACL rupture.

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