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Comparison of Anatomic Double- and Single-Bundle Techniques for Anterior Cruciate Ligament Reconstruction Using Hamstring Tendon Autografts

A Prospective Randomized Study With 5-Year Clinical and Radiographic Follow-up

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Background: The aim of this prospective randomized study was to compare the outcomes of the anatomic double-bundle (DB) and anatomic single-bundle (SB) techniques 5 years after anterior cruciate ligament (ACL) reconstruction. Since more effective restoration of rotational laxity is considered the main advantage of the DB technique, the pivot-shift test was the primary outcome variable of the study.

Hypothesis: Double-bundle ACL reconstruction will result in a better outcome in terms of the pivot-shift test.

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

Methods: A total of 105 patients (33 women, 72 men; median age, 27 years; range, 18-52 years) were randomized and underwent ACL reconstruction (DB group, n = 53; SB group, n = 52). All reconstructions were performed anatomically by identifying the ACL footprints, using the anteromedial portal for the femoral tunnel drilling, and utilizing interference screw for tibial and femoral fixation. A single blinded observer examined the patients preoperatively and at follow-up (median, 64 months; range, 55-75 months). Multiple subjective and objective clinical evaluation tests and radiographic assessments of osteoarthritis (OA) were performed using the Ahlbäck, Kellgren-Lawrence, and Fairbank grading systems at 6 weeks postoperatively and at the final follow-up evaluation.

Results: Preoperatively, no differences were found between the study groups, apart from the preinjury Tegner activity level, which was lower in the DB group (SB: mean, 7.8 [range, 3-9]; DB: mean, 7.3 [range, 0-9]; $P = .02$). Eighty-seven patients (83%) were available for examination at the 5-year follow-up. Statistical differences could not be found between the groups in terms of the pivot-shift test, KT-1000 arthrometer laxity measurements, manual Lachman test, single-legged-hop test, square-hop test, range of motion, Lysholm knee scoring scale, Tegner activity scale, or Knee injury and Osteoarthritis Outcome Score. Correspondingly, no differences were found between the groups regarding the presence of OA at follow-up. However, a significant increase of OA was found within the DB group at the 5-year follow-up. Both groups improved at follow-up compared with the preoperative assessment in terms of the laxity tests, hop tests, and scoring scales.

Conclusion: At the 5-year follow-up of an unselected group of patients, anatomic DB reconstruction was not superior to anatomic SB reconstruction in terms of the pivot-shift test.

Keywords: anterior cruciate ligament; reconstruction; anatomic; double-bundle; single-bundle; randomized controlled trial

The past decade has seen a shift in interest toward using anatomic anterior cruciate ligament (ACL) reconstruction techniques, with an emphasis on graft placement within the native femoral ACL footprint. Efforts have also been made to develop techniques to reconstruct the anteromedial (AM) and posterolateral (PL) bundles separately, the so-called double-bundle (DB) technique.[44,48] The theoretical advantage is that the 2 bundles can be tensioned separately, thereby mimicking more of the native tension

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patterns of the ACL bundles. As a result, in addition to restoring anterior-posterior laxity by reconstructing the AM bundle, it has been believed that DB ACL reconstruction more effectively restores rotational laxity to which the PL bundle primarily contributes.[5] Recent biomechanical and clinical trials have shown superior results in support of this technique, suggesting that a DB anatomic ACL reconstruction can result in the more effective restoration of rotational stability than single-bundle (SB) reconstruction.[14,19,22,39] In contrast, several clinical studies with a short- to midterm follow-up report few potential benefits of DB reconstruction over SB reconstruction in terms of laxity restoration or subjective patient-reported outcome measures (PROMs).[29,42]

ACL injuries have been believed to predispose the knee to the development of osteoarthritis (OA) as a possible consequence of changes in knee joint kinematics.[4] It does not appear that current methods of ACL reconstruction prevent the development of radiographic OA, and there is varying evidence with regard to the effect of ACL reconstruction on the development of OA.[4] However, the high frequency of radiographic evidence of OA development as early as 4 to 5 years postoperatively, although possibly not statistically significant, is still a striking observation,[11,38,40,45] lending importance to even midterm follow-up studies on new or adjusted operative techniques in ACL reconstruction.

The aim of this prospective randomized study was to compare the outcomes of the anatomic DB technique and anatomic SB technique 5 years after reconstruction. The primary hypothesis was that at the midterm follow-up, the anatomic DB technique would yield fewer positive pivot-shift test results when compared with the anatomic SB technique and that, in addition, there would be no statistically significant differences in terms of PROMs.

METHODS

Patients

The present study is a midterm follow-up of a previously reported cohort.[2] Participants were recruited from 2 hospitals (n = 31 and n = 74). The original cohort was an unselected group of patients without regard to age (if >18 years), sex, or activity level. Only patients >18 years old with a unilateral ACL injury were included. The exclusion criteria were a concomitant posterior cruciate ligament injury, medial or lateral collateral ligament laxity greater than 1+, previous major knee surgery, or a contralateral ACL injury. Patients fulfilling the inclusion criteria were consecutively asked to participate in the study. The indication for surgery was failed nonsurgical treatment or participation in pivoting sports in which nonsurgical treatment was regarded as an inferior treatment option. The participants were then randomized to undergo surgery through either the anatomic SB or anatomic DB technique. Randomization was by closed envelopes administered by the study coordinator, who drew them from a box with equal amounts of envelopes for both study groups (Figure 1). Moreover, all the envelopes were sealed and opened just before the operation when the patients were anaesthetized. The human ethics committee at the medical faculty at the University of Gothenburg approved this study. The participants received oral and written information about the study, after which written consent was obtained.

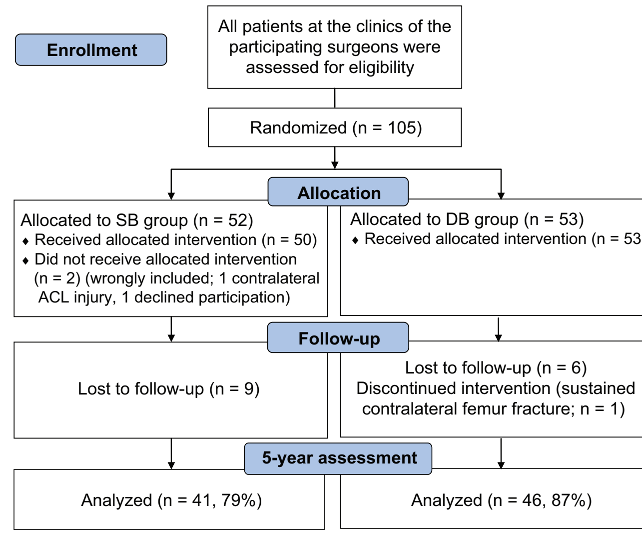

Figure 1. Flowchart of included patients. ACL, anterior cruciate ligament; DB, double-bundle; SB, single-bundle.

Surgical Techniques

Four senior surgeons performed all the reconstructions. One senior surgeon demonstrated to 3 others how the operations were to be performed. Three of the 4 surgeons were then allowed a surgical learning curve of about 30 cases before the start of the study. In hospital 1 (n = 74), the 2 surgeons operated separately; specifically, surgeon 1 operated on 43 cases (20 DB and 23 SB) and surgeon 2 on 31 cases (19 DB and 12 SB). In hospital 2 (n = 31), surgeons

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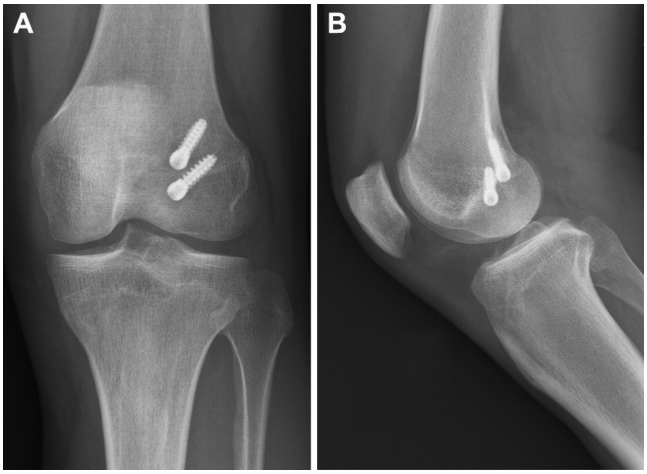

Figure 2. (A) Anteroposterior and (B) lateral radiographs of the left knee in the early postoperative period of a male patient in the double-bundle group demonstrating the tunnel positions in the femur and tibia.

3 and 4 performed all the procedures together, totaling 31 cases (14 DB and 17 SB).

Standard anterolateral and AM portals were established perioperatively. Associated intra-articular injuries, such as meniscal ruptures and chondral lesions, were addressed at the time of the index operation. Femoral and tibial ACL footprints were identified, in addition to the lateral intercondylar and bifurcate ridges. ACL remnants were resected. The semitendinosus and gracilis tendons were harvested with an open tendon stripper. Femoral drilling was performed through the AM portal. The tibial tunnels were drilled with a tibial elbow aimer and a fluted reamer.

Anatomic DB Technique

For the DB technique, both the femoral and tibial remnants of AM and PL bundles were identified with the knee at 90° of flexion. The femoral tunnels were addressed first. The femoral insertion sites of the AM and PL bundles were identified and marked with an awl. The AM tunnel was drilled first just deep to the bifurcate ridge, followed by the PL tunnel just shallow to the bifurcate ridge in 39 of the patients with a free-hand technique and in 14 patients with a DB femoral guide (Acufex Anatomic ACL Guide System; Smith & Nephew). The tibial tunnels were drilled in the center of the footprint of the AM and PL bundles; the AM tunnel was placed in line with the anterior horn of the lateral meniscus and the PL tunnel in front of the posterior cruciate ligament. All the drill holes had a diameter 0.5 mm larger than the graft diameters. On the femoral and tibial sides, the drill holes were between 6.5 and 7 mm for the AM bundle and 6 mm for the PL bundle. Metal interference screws, 6 × 20 mm (RCI; Smith & Nephew), were used on the femoral side in both tunnels, and bioresorbable screws, either 7.3 × 20 mm or 7.3 × 25 mm (Matryx; ConMed Linvatec), were used on the tibial side (Figure 2). The AM graft consisted of a doubled semitendinosus tendon, and the PL graft consisted of a doubled or tripled gracilis tendon. Tibial fixation was performed at 5° to 10° of knee flexion for the PL bundle and at 40° to 60° of knee flexion for the AM bundle.[2]

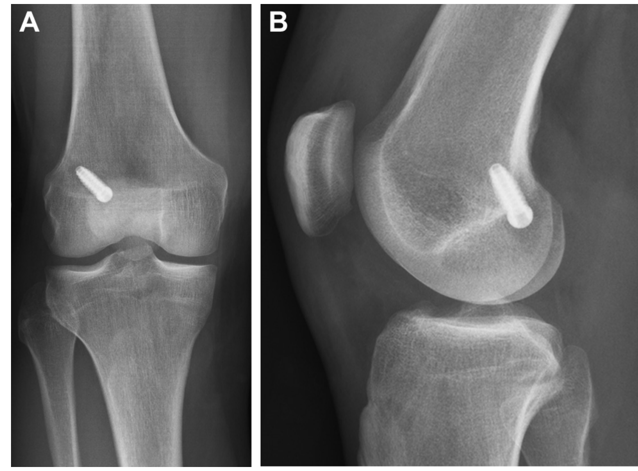

Figure 3. (A) Anteroposterior and (B) lateral radiographs of the right knee in the early postoperative period of a male patient in the single-bundle group demonstrating the tunnel positions in the femur and tibia.

Anatomic SB Technique

The femoral tunnel was addressed first. The femoral ACL insertion site was marked with an awl in the shallow aspect of the AM bundle insertion site, near the center of the ACL footprint to place the center of the tunnel just deep to the bifurcate ridge about 8 to 10 mm from the posterior cartilage at the 3- or 9-o'clock position in the notch orientation, with the knee at 90° of flexion. The femoral tunnel was predrilled with a 4.0-mm sharp noncannulated drill or a guide wire before the final tunnel, determined by the size of the graft, was drilled. On the tibial side, the center of the tunnel was placed in line with the anterior horn of the lateral meniscus. All the bone tunnels were drilled 0.5 mm larger that the diameter of the respective grafts, which were between 7.5 and 8.5 mm. Metal interference screws, 7 × 25 mm (RCI), were used on the femoral side, and bioresorbable screws, 9 × 25 mm (Matryx), were used on the tibial side (Figure 3). The ACL graft consisted of 4- or 5-stranded semitendinosus and gracilis tendons. Tibial fixation was performed at 10° to 20° of knee flexion.[2]

In both techniques, all tunnels were placed anatomically in accordance with the knowledge on anatomic ACL reconstruction available in 2008-2009, when the surgeries were performed.

Rehabilitation

All patients underwent rehabilitation in accordance with the same guidelines and under the supervision of their local physical therapists, permitting immediate full weightbearing and full range of motion (ROM), including full hyperextension and without the use of a brace. Closed kinetic chain exercises were started immediately postoperatively. Running was permitted at 3 months and contact sports at 6 months postoperatively at the earliest, provided that the patient had regained full functional stability in terms of strength, coordination, and balance as compared with the contralateral leg.[2] Moreover, all patients had a 6-month clinical follow-up evaluation by their respective surgeon to determine the progress of the rehabilitation.

Clinical Assessments

A single independent physical therapist performed all the pre- and postoperative follow-up examinations used in the study, including the laxity measurements. The physical therapist was blinded to the surgical technique to which the patient had been randomized but not to the aim of the study at the time of the examination.

At the preoperative examination and the 5-year follow-up, both groups underwent multiple subjective and objective evaluation tests, including ROM, single-legged hop test, square-hop test (only at follow-up),[33] Lysholm knee scoring scale, Knee injury and Osteoarthritis Outcome Score (KOOS),[36] and Tegner activity scale. Knee laxity measurements were assessed with a KT-1000 arthrometer (MEDmetric Corp), the manual Lachman test, and the pivot-shift test. All these tests are commonly used to evaluate the results after ACL surgery. Regarding ROM, the flexion or extension deficit was calculated by subtracting the respective degrees of the index knee from those of the contralateral knee.

The manual Lachman test was estimated by the examiner as the amount of anterior drawer movement with the knee at 15° to 20° of flexion. It was graded as 0, + (<5 mm), ++ (5-10 mm), or +++ (>10 mm) compared with the uninjured contralateral knee. The pivot-shift test was graded clinically with grades 0 to 3 according to International Knee Documentation Committee guidelines.[13]

The instrumented KT-1000 arthrometer was used to test the anterior displacement of the tibia in relation to the femur and was registered at 134 N and as the maximum manual test. At least 3 measurements were made on each knee, and the average value was registered.

The single-legged hop test was performed by jumping and landing on the same foot holding the hands behind the back. The noninjured leg was always tested first. Three attempts were allowed for each leg, and the longest hop was registered for each leg separately. A quotient (%) between the index and noninjured legs was calculated.

The square-hop test was performed by standing on the leg to be tested outside a 40 × 40–cm square marked with tape on the floor. For the right leg, the patients were instructed to jump clockwise in and out of the square as many times as possible during a period of 30 seconds. For the left leg, the patient performed the test in a counterclockwise direction. The test was video recorded and assessed by the same blinded physical therapist, and both the total number of jumps and the number of successful jumps (ie, without touching the taped square) were counted. A quotient (%) between the index and noninjured leg was calculated. This test was modified from the one previously described by Ostenberg et al.[33]

Patients who sustained a contralateral ACL injury were excluded from side-to-side clinical assessments at the 5-year follow-up.

Standard Radiographs

Early in the postoperative period (at approximately 6 weeks) and in conjunction with the 5-year follow-up, the enrolled patients underwent unilateral standard radiographs with weightbearing anteroposterior and lateral views of the index knee. An independent musculoskeletal radiologist interpreted the radiographs and assessed them according to the grading systems of Ahlbäck[1] and Kellgren-Lawrence,[18] which are often used to classify OA in the literature, and the Fairbank system, originally designed to detect minor changes after meniscectomy.[10] For the Fairbank system, the cumulative number of positive findings, from 0 to 6, was calculated for each patient, as previously described by Lidén et al.[26] Patellofemoral OA was classified as *none, minor, moderate*, or *severe* and the presence of patellofemoral osteophytes as *none, minor, moderate*, or *large*. The radiologist in the present study has previously been analyzed for reproducibility for OA classifications of the knee, with kappa values between 0.55 and 1.00.[26]

Statistical Analysis

The primary variable in the study was the pivot-shift test. The study was powered to reveal a difference of 1 grade on the pivot-shift test between the study groups, with a power >80%.[2] It was assumed that a difference of 1 grade in the pivot test was clinically important; the standard deviation of the pivot-shift test was estimated to be 1.5 grades. To reach a power of 80%, 36 patients were thus needed in each group. To increase the power of the study and to allow for dropouts, 105 patients were initially randomized.

Mean ± SD and median (range) values are presented when applicable. For comparisons of dichotomous variables between the groups, the chi-square test was used. When comparisons of continuous and noncontinuous variables were required, the Mann-Whitney *U* test was used. The Wilcoxon signed-rank test was used for comparisons of the pre- and postoperative data and for comparisons between 6-week and 5-year radiographic assessments within the study groups. The Spearman test was used for correlation analysis between the cumulative Fairbank score and body mass index (BMI). Statistical significance was set at $P < .05$.

RESULTS

Between March 2008 and September 2009, a total of 105 patients were randomized, and they underwent surgery in either the SB group (n = 52; 2 patients wrongly randomized) or the DB group (n = 53). Two patients did not receive the allocated intervention, because they were incorrectly

TABLE 1
Patient Demographics[a]

	SB Group (n = 50)	DB Group (n = 53)	P Value
Age, y			.20
Median (range)	25 (18-52)	29 (18-52)	
Mean ± SD	28 ± 8.5	30 ± 9.2	
<25 y, n	22	20	.77
Sex, male:female, n	35:15	35:18	.67
Injured side, right:left, n	28:22	32:21	.65
Preinjury Tegner activity level			.02[b]
Median (range)	8 (3-9)	8 (0-9)	
Mean ± SD	7.8 ± 1.3	7.3 ± 1.5	
Missing values		1	
Time between the injury and index operation, mo			.49
Median (range)	10 (3-240)	9 (2-240)	
Mean ± SD	23 ± 37	24 ± 42	
Follow-up period, mo			.31
Median (range)	64 (59-75)	64 (55-73)	
Mean ± SD	65 ± 3.8	63 ± 4.3	
Missing values	9	7	
Associated injuries (meniscal and/or chondral lesions), yes:no, n (%)	38 (76):12 (24)	35 (66):18 (34)	.68
Cause of additional surgery until the 5-year follow-up (n = 87 patients), n	41	46	.08
Meniscal	4	1	
Meniscal and chondral	1	—	
Chondral	—	2	
Notchplasty	2	1	
Loose bodies	1	—	
Tibial interference screw removal	1	—	
BMI preoperative (n = 103), n	50	53	.82
Median (range)	24.9 (20.7-37.2)	25.1 (19.9-33.8)	
Mean ± SD	25.5 ± 3.6	24.9 ± 2.5	
Missing values	14	11	
BMI postoperative (n = 87), n	41	46	.87
Median (range)	25.1 (19.5-33.6)	25.2 (20.3-35.7)	
Mean ± SD	25.4 ± 2.9	25.3 ± 2.8	
Missing values	0	2	

[a]BMI, body mass index; DB, double-bundle; SB, single-bundle.
[b]Statistically significant between-group difference ($P < .05$) was found for preinjury Tegner activity score.

included in the study; 1 patient discontinued the intervention during the follow-up because of a contralateral femoral fracture; and 15 patients were lost to follow-up. The 5-year follow-up examinations were performed on 87 patients (83%; SB: n = 41; DB: n = 46) (Figure 1).

The demographics of the study groups are presented in Table 1. The preinjury Tegner activity level was significantly lower in the DB group (SB: median, 8 [range, 3-9]; DB: median, 8 [range, 0-9]; *P* = .02) (Table 1).

Preoperatively, we were unable to demonstrate significant differences between the study groups in terms of Tegner activity level, Lysholm knee score, single-legged hop test, extension or flexion deficit of the knee, KOOS, side-to-side laxity tests, or pivot-shift test (Tables 2-4).

During the follow-up period, no patient sustained septic arthritis or underwent revision ACL reconstruction. Thirteen patients, 9 in the SB group and 4 in the DB group, underwent second-look arthroscopic surgery (*P* = .08) (Table 1). A further 6 patients—5 in the SB group (median age, 24 years; range, 18-29 years) and 1 in the DB group (age, 21 years)—sustained a contralateral ACL injury (*P* = .07).

At the 5-year follow-up, significant differences could not be demonstrated between the groups in terms of Tegner activity level, Lysholm knee score, or KOOS (Tables 2 and 3). Similar findings were observed in terms of the hop tests and the extension and flexion deficits of the knee (Table 2).

The pivot-shift test revealed no significant differences between the study groups at follow-up. Significant differences could not be found regarding the other side-to-side laxity tests (Table 4). Furthermore, 89% of patients in the SB group and 84% in the DB group had a negative (grade 0) pivot-shift test at follow-up (not significant, *P* = .56) (Table 4).

Both groups improved significantly between the preoperative and 5-year follow-up assessments in terms of all variables, except for the range of extension (extension deficit) in the SB group (*P* = .11) and the range of flexion (flexion deficit) in the DB group (*P* = .5). Moreover, the range of flexion (flexion deficit) was significantly poorer at the follow-up than preoperatively in the SB group (*P* = .03) (Tables 2-4). Additionally, 7 patients in the SB group (17%) and 11 (24%) in the DB group (*P* = .43) returned to

TABLE 2
Functional, Objective, and Subjective Results Preoperatively and at 5-Year Follow-up[a]

	Preoperative (n = 103)		5-Year Follow-up (n = 87)[b]		P Value[c]	
	SB (n = 50)	DB (n = 53)	SB (n = 41)	DB (n = 46)	Preoperative	5-Year Follow-up
Tegner activity level, points						
Median (range)	4 (1-7)	4 (0-6)	6 (2-9)***	6 (3-8)***	.41	.99
Mean ± SD	3.9 ± 1.1	3.8 ± 1.2	5.7 ± 1.5	5.7 ± 1.3		
Missing values		1				
Lysholm knee score, points						
Median (range)	62 (9-85)	64 (19-100)	90 (8-100)***	91 (64-100)***	.63	.53
Mean ± SD	60.0 ± 16.7	61.7 ± 18.8	84.3 ± 21.2	90.1 ± 9.1		
Missing values		3		2		
Square-hop test total, %[d]						
Median (range)	—	—	94 (42-143)	98 (72-130)	NA	.30
Mean ± SD			93 ± 18	98 ± 12		
Missing values			3	8		
Square-hop test correct, %[d]						
Median (range)	—	—	91 (29-142)	97 (61-179)	NA	.41
Mean ± SD			89 ± 25	98 ± 23		
Missing values			8	14		
Single-legged hop test, %[d]						
Median (range)	79 (0-120)	73 (0-116)	96 (0-134)**	90 (0-120)**	.08	.38
Mean ± SD	72.4 ± 26.7	62.7 ± 30.5	87 ± 28	79 ± 37		
Missing values		1				
Extension[d]						
Deficit, yes:no, n (% yes)	29:20 (59)	33:19 (64)	14:22 (39)	18:25 (42)*		
Median (range), deg	5 (–5 to 15)	5 (–5 to 20)	0 (–5 to 15)	0 (–5 to 10)	.21	.50
Mean ± SD, deg	3 ± 4	5 ± 5	2 ± 4	2 ± 4		
Missing values	1	1		2		
Flexion[d]						
Deficit, yes:no, n (% yes)	22:27 (45)	32:20 (62)	24:12 (67)*	28:15 (65)		
Median (range), deg	0 (–10 to 15)	5 (–5 to 45)	5 (–5 to 20)	5 (–15 to 20)	.11	.84
Mean ± SD, deg	4 ± 6	7 ± 10	5 ± 6	5 ± 6		
Missing values	1	1		2		

[a]DB, double-bundle; NA, not applicable; SB, single-bundle.
[b]Significant within-group difference between preoperative and follow-up values: *$P < .05$, **$P < .01$, ***$P < .001$.
[c]Statistically significant differences could not be found between the DB and SB groups.
[d]Side-to-side difference at 5-year follow-up: SB, n = 36; DB, n = 45. Patients with reconstructed/injured contralateral-side anterior cruciate ligament were excluded when the side-to-side difference-based variables were analyzed.

the same or higher Tegner activity level when compared with the preinjury level at the 5-year follow-up.

Owing to technical problems, there were a total of 15 patients with missing radiographs in the early postoperative period. The mean time to the early postoperative radiographs was 53 ± 29.0 days (median, 47 [range, 30-209]) in the SB group and 49 ± 26.8 days (median, 43 [range, 10-202]) in the DB group (P = .29). The early postoperative Ahlbäck classification of the lateral knee compartment was significantly poorer in the SB group (P = .01) (Table 5). In the DB group, there was a significant increase in the development of OA between the early postoperative and 5-year postoperative radiographic assessments according to the Ahlbäck classification concerning the lateral compartment, the cumulative Fairbank changes, and the Kellgren-Lawrence classification (Table 5). Correspondingly, in the SB group, a significant increase in the presence of patellofemoral osteophytes was seen (Table 5). Apart from this, significant differences could not be shown between the study groups in the presence of OA early in the postoperative period or at the 5-year follow-up (Table 5). The cumulative Fairbank score was significantly worse at the 5-year follow-up for the patients with concomitant injuries in the whole cohort (with concomitant injuries: mean, 1.35 [range, 0-6]; without: mean, 0.35 [range, 0-2]; P = .01) and in the SB group (with concomitant injuries: mean, 1.32 [range, 0-6]; without: mean, 0.11 [range, 0-1]; P = .046) but not in the DB group (with concomitant injuries: mean, 1.38 [range, 0-5]; without: mean, 0.47 [range, 0-2]; P = .08). No correlation was found between the cumulative Fairbank score at the 5-year follow-up and BMI (DB: ρ = 0.16; SB: ρ = 0.06) in the DB or SB group.

DISCUSSION

This randomized trial compared anatomic DB and SB ACL reconstruction in an unselected group of patients in terms of

TABLE 3
KOOS Outcomes Preoperatively and at 5-Year Follow-up[a]

	Preoperative (n = 103)		5-Year Follow-up (n = 87)[b]		*P* Value[c]	
	SB (n = 50)	DB (n = 53)	SB (n = 41)	DB (n = 46)	Preoperative	5-Year Follow-up
KOOS pain						
Median (range)	75 (14-100)	76 (28-100)	94 (28-100)***	97 (58-100)***	.69	.13
Mean ± SD	73 ± 16	72 ± 16	87 ± 19	94 ± 9		
Missing values		1		1		
KOOS symptoms						
Median (range)	64 (32-100)	64 (29-100)	90 (11-100)***	93 (61-100)***	.58	.60
Mean ± SD	66 ± 17	64 ± 18	83 ± 22	88 ± 12		
Missing values		1		1		
KOOS ADL						
Median (range)	88 (21-100)	89 (38-100)	100 (26-100)***	100 (75-100)***	.99	.68
Mean ± SD	83 ± 16)	81 ± 18	93 ± 18	97 ± 6		
Missing values		1		1		
KOOS sports/recreation						
Median (range)	40 (0-80)	35 (0-100)	90 (0-100)***	90 (20-100)***	.43	.73
Mean ± SD	40 ± 24	38 ± 25	75 ± 33	83 ± 19		
Missing values		1		1		
KOOS QoL						
Median (range)	25 (0-56)	31 (0-75)	75 (13-100)***	81 (19-100)***	.06	.07
Mean ± SD	28 ± 13	34 ± 18	69 ± 25	79 ± 19		
Missing values		1		1		

[a]ADL, activities of daily living; DB, double-bundle; KOOS, Knee injury and Osteoarthritis Outcome Score; QoL, quality of life; SB, single-bundle.
[b]Significant within-group difference between preoperative and follow-up values: ***$P < .001$.
[c]Statistically significant differences could not be found between the DB and SB groups.

anterior and rotational laxity, functional and patient-reported outcomes, as well as radiographic evidence of OA. The midterm results indicated no significant differences between the study groups. Specifically, no significant difference was found in the number of patients with a positive pivot-shift test at the midterm follow-up.

These results are in opposition to our hypothesis, as fewer positive pivot-shift tests were not present in the DB group. Kinematics and rotational laxity in particular are important postoperative outcome measurements in the short term.[21] As opposed to subjective outcome scores, laxity measurements provide a more accurate means of objectively evaluating differences in outcome between anatomic SB and DB ACL reconstruction. In the present study, a majority in both study groups had a negative pivot-shift test at the 5-year follow-up, with no significant difference between the groups. These results are in agreement with the results of recent randomized trials comparing SB and DB ACL reconstruction.[17,38,47]

There are, however, several randomized trials showing that DB ACL reconstruction is superior to SB in terms of the restoration of rotational laxity measured by the pivot-shift test.[14,15,22,37,39] A recent meta-analysis comprising 19 randomized controlled trials comparing SB and DB reconstruction revealed that DB ACL reconstruction results in significantly better anterior-posterior and rotational stability when compared with SB reconstruction.[46] It is, however, important to note that the comparability of many of these studies can be questioned, as they display large-scale heterogeneity in their surgical technique with regard to transtibial/transportal drilling and nonanatomic/anatomic tunnel placements.[8] The present trial adhered strictly to transportal tunnel drilling and anatomic tunnel placement on the femoral and tibial ACL footprints in both the SB and DB groups. Several recent studies specifically comparing anatomic SB and DB techniques have yielded results favoring anatomic DB reconstruction over anatomic and nonanatomic SB in terms of the restoration of laxity measured with manual laxity tests, such as the pivot-shift test and KT-1000 arthrometry.[9,43]

The diagnostic threshold for minimal clinically meaningful detectable change is regarded as 1 grade for the Lachman test and 1 grade for the pivot-shift test.[13] The diagnostic threshold for minimal clinically meaningful detectable change for KT-1000 is 3 mm.[35] The significance of the often small improvements in anterior and rotational laxity between SB- and DB-reconstructed knees is, however, questionable. Despite a possible lack of clinical significance, these residual laxities may alter the biomechanical and kinematic environment, contributing ultimately to the development of OA.[30,41] Evidence to support the fact that injury to the ACL is associated with the increased development of OA is well established in the literature.[4] One of the proposed theoretical benefits of DB reconstruction is that it more closely reestablishes the native ACL anatomy as compared with SB reconstruction, thereby restoring closer-to-normal knee kinematics and subsequently possibly delaying OA development more effectively than SB

TABLE 4
Knee Laxity Assessments According to the KT-1000 Arthrometer, Manual Lachman, and Pivot-Shift Tests Preoperatively and at 5-Year Follow-up[a]

	Preoperative (n = 103)		5-Year Follow-up (n = 81)[b]		*P* Value[c]	
	SB (n = 50)	DB (n = 53)	SB (n = 36)	DB (n = 45)	Preoperative	5-Year Follow-up
KT-1000 anterior MMT side-to-side difference, mm						
Median (range)	6.0 (0 to 11)	6.0 (–2 to 12)	2 (–4 to 8)***	2 (–7 to 8.5)***	.72	.72
Mean ± SD	5.6 ± 2.7	5.4 ± 3.0	2.3 ± 2.7	2.2 ± 2.7		
Missing values		1				
KT-1000 anterior 134-N side-to-side difference, mm						
Median (range)	5.0 (–1 to 11)	5.3 (–4 to 15)	2.3 (–4 to 11)***	2.5 (–3 to 10)***	.85	.68
Mean ± SD	5.2 ± 2.4	5.2 ± 3.2	2.8 ± 3.1	2.6 ± 3.0		
Missing values		1				
Manual Lachman test, n (%)					.63	.62
0			18 (50)	20 (44)		
1	1 (2)		18 (50)***	25 (56)***		
2	44 (88)	47 (89)				
3	5 (10)	6 (11)				
Pivot-shift test, n (%)					.68	.56
0			32 (89)	38 (84)		
1	1 (2)	1 (2)	4 (11)***	7 (16)***		
2	46 (92)	50 (94)				
3	3 (6)	2 (4)				
Age at index operation for patients with positive pivot-shift test at 5-year follow-up, y, median (range)	19.5 (18-45)	25 (19-46)				.25
Patients with positive pivot-shift test and age <25 y at index operation, n	22	20	3	2	NA	.75

[a]Patients with reconstructed/injured contralateral-side anterior cruciate ligament were excluded when the side-to-side differences were analyzed at the 5-year follow-up. DB, double-bundle; MMT, maximum manual test; NA, not applicable; SB, single-bundle.
[b]Significant within-group difference between preoperative and follow-up values: $^{***}P < .001$.
[c]There were no statistically significant differences between the DB and SB groups in terms of the pivot-shift test. Significant differences could not be found between the DB and SB groups in terms of the other laxity tests.

reconstruction.[38,40] The inadequate restoration of rotational laxity, resulting in a residual positive pivot shift after ACL reconstruction, for example, has destructive effects on meniscal and chondral structures in the knee and can be regarded as a predictor of future OA.[16,27] There are, however, few studies that have specifically investigated whether DB ACL reconstruction is superior to SB in this regard. The literature indicates that there is no significant difference between the 2 reconstruction techniques with regard to OA development, which is in line with the results of the present trial with a 5-year follow-up.[38,40] Moreover, it is noteworthy that the cause of OA after ACL injury and after ACL reconstruction is not solely influenced by the surgical technique that is used but also largely influenced by the presence of concomitant chondral and meniscal injuries and BMI.[3,32] In line with this, in the present study, significantly more OA was found at the 5-year follow-up in those patients who revealed concomitant injuries at index surgery. However, no correlation was found between OA and BMI, which might be due to the fact that both groups were rather homogeneous, with a BMI of about 25.

Objective clinical measurements, such as laxity, are essential in the assessment of outcome after ACL reconstruction. However, subjective PROMs are equally important to effectively gauge a patient's rehabilitation and essentially his or her recovery from the injury.[20] The results of the present study showed improvements in these subjective outcome scores between the preoperative and follow-up values within each group, but significant differences could not be shown between SB and DB groups at follow-up. The current evidence relating to subjective outcomes after ACL reconstruction is conflicting. One recent systematic review of 9 overlapping meta-analyses comparing SB and DB ACL reconstruction found higher International Knee Documentation Committee subjective scores favoring DB as compared with SB ACL reconstruction reported in 1 meta-analysis, whereas 4 meta-analyses found no difference between SB and DB groups.[28] None of the 9 included meta-analyses found significant differences in the Tegner or Lysholm scores between DB and SB groups.[28] The results of the present study indicate that despite significant improvements within each group at follow-up there was generally a low return to preinjury

TABLE 5

Radiographic Evaluation of OA in the Early Postoperative Period (6 Weeks) and at 5-Year Follow-up[a]

	6-Week Follow-up (n = 103)		5-Year Follow-up (n = 87)		*P* Value, SB vs DB		*P* Value, 6-Week vs 5-Year Follow-up	
	SB (n = 50)	DB (n = 53)	SB (n = 41)	DB (n = 46)	6-Week Follow-up	5-Year Follow-up	SB (n = 41)	DB (n = 46)
Ahlbäck classification–medial					.66	.70	.32	.08
0	37 (90)	41 (87)	35 (88)	39 (85)				
I	4 (10)	6 (13)	4 (10)	5 (11)				
II			1 (3)	2 (4)				
III								
IV								
V								
Missing values	9	6	1					
Ahlbäck classification–lateral					.01[b]	.90	.16	.01[b]
0	36 (88)	47 (100)	34 (85)	39 (85)				
I	4 (10)		3 (8)	7 (15)				
II	1 (2)		1 (3)					
III			2 (5)					
IV								
V								
Missing values	9	6	1					
Cumulative Fairbank changes					.39	.64	.08	.001[b]
0	32 (78)	40 (85)	25 (63)	25 (54)				
1	2 (5)	1 (2)	3 (8)	7 (15)				
2	4 (10)	4 (9)	5 (13)	5 (11)				
3	1 (2)	1 (2)	3 (8)	6 (13)				
4	1 (2)	1 (2)	1 (3)	2 (4)				
5	1 (2)		2 (5)	1 (2)				
6			1 (3)					
Missing values	9	6	1					
Kellgren-Lawrence classification					.25	.64	.053	.001[b]
0	31 (78)	41 (87)	23 (61)	24 (53)				
1	3 (8)	1 (2)	7 (18)	10 (22)				
2	5 (13)	5 (11)	5 (13)	10 (22)				
3			1 (3)	1 (2)				
4	1 (3)		2 (5)					
Missing values	10	6	3	1				
Patellofemoral osteophytes					.56	.20	.01[b]	.06
None	38 (93)	44 (96)	30 (75)	39 (87)				
Minor	3 (7)	2 (4)	9 (23)	4 (9)				
Moderate			1 (3)	2 (4)				
Large								
Missing values	9	7	1	1				
Patellofemoral OA					>.999	.35	>.999	.32
None	41 (100)	46 (100)	40 (100)	44 (98)				
Minor								
Moderate				1 (2)				
Severe								
Missing values	9	7	1	1				

[a]Data are reported as n (%). Significant between-group difference was found for OA changes in the lateral femorotibial joint according to the Ahlbäck classification at the 6-week radiographic assessment. DB, double-bundle; OA, osteoarthritis; SB, single-bundle.

[b]Statistically significant difference ($P < .05$).

Tegner scores; however, the study was not able to demonstrate significant differences between groups at follow-up. The preinjury Tegner scores were therefore not better maintained by DB reconstruction. Individual patient expectations and motivation to participate in rehabilitation and compliance, in addition to the surgical technique used, are all factors that can affect the subjective postoperative results.[7]

A residual ROM deficit was seen in both SB and DB groups at follow-up. The current evidence on ROM, expressed as an extension or flexion deficit after SB or DB ACL reconstruction, is conflicting. Li et al[25] reported results in support of the findings in the present study in their comprehensive meta-analysis where extension deficits were less common in the DB groups. In contrast, Tiamklang et al,[42] as well as van Eck et al,[43] reported no differences between groups in terms of ROM. However, the loss of motion in both groups in the present study was small and, even though statistically significant, probably clinically not important.

In the current study, no patients required revision ACL reconstruction during the 5-year follow-up. Significant differences could not be seen between the SB and DB groups in this respect, and the results are in agreement with current evidence indicating comparable graft failure incidences between SB and DB reconstruction.[28] However, it is possible that the low failure rates observed in this study could be explained by the combination of implementation of anatomic ACL reconstruction techniques and the relatively low return to preinjury Tegner activity level. Graft integrity in our patients was, however, verified only by objective clinical tests. It is important to note, however, that the definition of failure in the literature varies, ranging from manifest, often traumatic graft rerupture to biological failure relating to graft incorporation and residual postoperative laxity with poor PROMs and septic complications resulting in revision, to name a few.[12]

The surgeon must still remember that the DB procedure is technically more challenging, entails a considerable learning curve, places increased demands on the surgeon's technical ability, requires the individualization of the procedure and potentially more invasive revision procedures, and involves higher costs.[31,34]

The short-term results of the 2-year follow-up of these patients was unable to reveal significant differences between the study groups with regard to laxity restoration, functional and patient-reported outcomes, and graft failure. Similar results are reported in the present study.[2] However, as previously discussed, the mid- to long-term results based on applicable and validated outcome measurements should form the basis for comparison between the 2 techniques. In addition, care should be taken to identify heterogeneity between the techniques when data are compared between SB and DB ACL reconstruction. Herein lies a strength of this present study. Including radiographic assessments of the patients at the 5-year follow-up is a further strength of this study.

There are a number of limitations to the present study. First, the primary outcome was the restoration of rotational laxity as perceived with the pivot-shift test. The pivot-shift test exhibits moderate levels of inter- and intraobserver reliability, this is a result of its subjective interpretation compounded by heterogeneity in execution, making it a somewhat blunt test of rotational laxity.[23] Second, information regarding exactly when the patients went back to activity was difficult to obtain, as the patients were rehabilitated by their local physiotherapist owing to the large geographic catchment area. Third, we evaluated the development of OA based on radiographic findings instead of magnetic resonance imaging. Furthermore, the integrity of the graft was not confirmed by any means other than clinical tests. Although studies have reported manifest OA after only 5 years,[11,40] the present 5-year follow-up may not have been long enough to detect potentially discrete differences in the prevalence and level of OA between the SB and DB groups; therefore, a long-term follow-up is recommended to evaluate OA development. In addition, meniscal injuries could affect functional outcomes, and they have been shown to lead to the development of OA.[6,24] However, this study was not designed to estimate the influence of meniscal and other associated injuries at the index surgery on the final outcomes. Moreover, the loss of some baseline radiographic assessments could influence the reliability of the OA development analysis. It could also be that the use of multiple OA evaluation systems is a weakness of the study and that the significant findings actually are statistical artifacts. One of the cornerstones of anatomic ACL reconstruction today is the concept of individualizing the procedure to suit the patient, based on activity levels, patient expectations, and knee anatomy. This process of individualization was not possible, as patients were randomized to either SB or DB, regardless of the aforementioned factors. In addition, it is always important to consider the possibility that the study is underpowered, in spite of power analyses performed before the initiation of the study.

On the basis of the results of the present study, in combination with the previously published results from the 2-year follow-up,[2] we have discontinued the use of the DB technique in unselected patients. Based on the fact that most surgeons in Sweden perform fewer than 10 to 20 ACL reconstructions annually, it seems appropriate to recommend a standardized and easy surgical procedure.

CONCLUSION

At the 5-year follow-up of an unselected group of patients, anatomic DB reconstruction was not superior to anatomic SB reconstruction in terms of the pivot-shift test, as seen in this prospective randomized study.

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