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No Difference in the KOOS Quality of Life Subscore Between Anatomic Double-Bundle and Anatomic Single-Bundle Anterior Cruciate Ligament Reconstruction of the Knee

A Prospective Randomized Controlled Trial With 2 Years' Follow-up

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Background: The double-bundle reconstruction technique was developed to resemble the properties of the native anterior cruciate ligament (ACL) more closely than the conventional single-bundle technique. The clinical benefit of the operative procedure is controversial, and there is a need for studies with a focus on patient-reported outcomes (PROs).

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

Hypothesis: Anatomic double-bundle ACL reconstruction would be superior to anatomic single-bundle reconstruction regarding the change in the Knee injury and Osteoarthritis Outcome Score (KOOS) Quality of Life (QoL) subscore from baseline to 2-year follow-up.

Methods: According to sample size calculations, 120 patients aged 18 to 40 years with a primary ACL injury of their knee were randomized to the anatomic double-bundle or anatomic single-bundle reconstruction groups. Patients with posterior cruciate ligament, posterolateral corner, or lateral collateral ligament injuries or with established osteoarthritis were excluded. Patients with residual laxity from a coexistent medial collateral ligament injury were excluded. Data were registered at baseline, 1 year, and 2 years. In 24 patients, postoperative 3-dimensional computed tomography was performed to verify the positioning of the bundles. The outcome measures were the change in KOOS subscores and the International Knee Documentation Committee 2000 subjective score, pivot-shift test result, Lachman test finding, KT-1000 arthrometer measurement, activity level, return-to-sports rate, and osteoarthritic changes on radiographs. A linear mixed model was used for the analysis of all the PROs, including the primary outcome.

Results: The change in the KOOS QoL subscore from baseline to 2-year follow-up was not different between the double- and single-bundle groups (mean change, 29.2 points vs 28.7 points, respectively; –0.5-point difference; 95% CI, –8.4 to 7.4 points; P = .91). Neither were there any differences between the 2 groups in the remaining PROs, knee laxity measurements, or activity levels of the patients. Radiological signs of osteoarthritis were found in 2 patients. Eleven patients had a graft rupture: 8 in the single-bundle group and 3 in the double-bundle group (P = .16). Three-dimensional computed tomography of the knees verified the positioning of the anteromedial bundle, posterolateral bundle, and single-bundle grafts to be within acceptable limits.

Conclusion: There was no difference in the KOOS QoL subscore, the remaining PROs, knee laxity measurements, or activity levels comparing the double- and single-bundle ACL reconstruction techniques. The number of bundles does not seem to influence clinical and subjective outcomes, as long as the tunnels are adequately positioned.

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The double-bundle anterior cruciate ligament (ACL) reconstruction technique was developed to improve the ACL reconstruction procedure with anatomic restoration of both the anteromedial (AM) and posterolateral (PL) bundles.[59] The different insertion sites and tension patterns of the 2 bundles during knee motion are supposed to resemble the native ACL more closely than conventional single-bundle reconstruction. However, double-bundle reconstruction is considered to be technically more difficult and more costly compared with single-bundle reconstruction.

Several biomechanical laboratory studies support the advantage of double-bundle reconstruction; clinical studies are less convincing.[11,50] Thus, more extensive, high-quality studies, with a focus on patient subjective outcomes, are desired.[2,24,25,31,44,50,53]

More than 30 clinical studies have compared the double-bundle technique with the single-bundle technique.[34] The results of those studies have been inconsistent. Three systematic reviews all concluded that the double-bundle technique would improve rotational stability and anteroposterior translation.[31,53,56] Yet, the question is whether the reported differences are of any clinical benefit to the patients.[21,31,53,56] Patient-reported outcome (PRO) scores have been reported only as secondary outcomes, although superior subjective scores in the double-bundle group have been reported.[2,10,31,48]

Parallel to the development of anatomic double-bundle reconstruction, anatomic single-bundle reconstruction was introduced. As the positioning of the bundles has been shown to be crucial for the biomechanical properties of the grafts, the focus on anatomic placement has increased. Despite this knowledge, most of the literature comparing single- and double-bundle reconstruction has reported on transtibial drilling and “o’clock” positioning of the grafts.[2,37,44] Only a few studies have described transportal anatomic positioning of the tunnels both in the single- and double-bundle groups.[3,17,24,35] As rotational laxity measurements were the main outcome of those studies, the PROs were given less focus.

The current study was designed to compare the single- versus double-bundle techniques for ACL reconstruction, with PROs as the primary endpoint. The hypothesis was that anatomic double-bundle ACL reconstruction would be superior to anatomic single-bundle reconstruction regarding the change in the Knee injury and Osteoarthritis Outcome Score (KOOS) Quality of Life (QoL) subscore from baseline to 2-year follow-up. The secondary objectives were to compare additional PROs, knee laxity measurements, range of motion measurements, functional test results, and radiographic findings between the 2 ACL reconstruction techniques at 2-year follow-up.

METHODS

Study Design

The study was designed as a prospective randomized controlled trial following 2 parallel groups. The intervention group was anatomic double-bundle ACL reconstruction, and the control group was anatomic single-bundle ACL reconstruction (ClinicalTrials.gov identifier: NCT01033188). The patients were included from January 1, 2010, to June 18, 2015. Follow-up was performed at 12 and 24 months after index surgery. The study sites were Oslo University Hospital and Martina Hansens Hospital.

The study included 120 patients with symptoms from a primary ACL injury. They were 18 to 40 years old and referred from the outpatient clinics of the 2 recruiting hospitals: one university hospital and one hospital specialized in orthopaedic surgery. The patients who fulfilled the inclusion criteria were asked to carry out 2 months of knee-specific rehabilitation supervised by a physical therapist before inclusion. If the patients still had symptoms from their ACL injury that required reconstructive surgery, they were asked to participate in the study. Patients with a contralateral or subtotal ACL injury; injury to the posterior cruciate ligament, PL corner, or lateral collateral ligament; and medial collateral ligament injury with residual medial instability of the knee were excluded (Table 1).

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TABLE 1
Inclusion and Exclusion Criteria[a]

Inclusion Criteria
Age 18-40 years
Symptoms of the knee due to a primary ACL injury, verified by history and clinical assessments (Lachman test result >1+ or positive pivot-shift test finding) and identified at surgery
Successful completion of 2 months of knee-specific rehabilitation supervised by a physical therapist
Exclusion Criteria
Previous ACL reconstruction in the involved or uninvolved knee
Partially ruptured ACL
Posterior cruciate ligament, lateral collateral ligament, or posterolateral corner injury
Medial collateral ligament injury with increased medial ligament laxity at surgery (>1+) compared with the uninvolved leg
Established osteoarthritis (Kellgren-Lawrence grade 3 or 4) identified on standing front radiographs of the knee
Hamstring tendons with insufficient graft thickness after preparation (defined as <5.0 mm in diameter for the posterolateral bundle and <6.0 mm for the anteromedial bundle)
<50% of the medial or lateral meniscus preserved after treatment
Living outside the recruitment area
Not understanding the Norwegian written language

[a]ACL, anterior cruciate ligament.

Knees with osteoarthritic changes (Kellgren-Lawrence grade 3 or 4) were also excluded. Before inclusion, the participants signed a written informed consent form. Randomization was then only carried out if the ACL rupture was verified by arthroscopic surgery, if more than 50% of both menisci remained intact, and if the hamstring tendons had sufficient lengths and thicknesses for 2-bundle reconstruction to be achieved.

Deviations From Trial Registration Protocol

During the inclusion period, Martina Hansens Hospital was added as a recruiting hospital, and the main endpoint was changed from 5- to 2-year follow-up because of the difficulties in recruiting patients. The minimum graft size of the PL bundle was decreased from 5.5 to 5.0 mm for the same reason. The patients with randomization numbers 62 to 120 were blinded for the intervention. A subgroup of the patients was asked to undergo postoperative 3-dimensional computed tomography (3D-CT) of the reconstructed knee to verify the exact positioning of the drilled tunnels.

Interventions

The interventions were initially performed at Oslo University Hospital, but from March 1, 2013, the site of the intervention was changed to Martina Hansens Hospital. Both hospitals perform more than 100 ACL reconstruction procedures yearly. One surgeon performed the surgical procedure in all but 2 patients. The surgeon was experienced and had also participated in anatomy studies describing the ACL and its 2 bundles.[61]

The surgical technique consisted of placing the patient in a supine position, with the knee at 90° of flexion and with a tourniquet placed around the upper thigh. The regular anterior arthroscopic portals and an accessory AM portal were established. The ACL lesion was confirmed by visualization and by probing the ACL remnants. The femoral and tibial insertion sites were visualized, and surrounding soft tissue and bony landmarks were used to identify the center of the proximal and distal ACL footprints.[30,61] A 3- to 5-cm skin incision was made at the pes anserinus insertion site. The semitendinosus and gracilis tendons were identified. A tendon harvester was used to free the tendons, and both tendons were doubled or tripled according to their lengths and thicknesses. For the double-bundle technique, a minimum graft size of 5.0 mm in diameter for the PL bundle and 6.0 mm for the AM bundle was desirable. Both ends of each of the grafts were whipstitched with a nonabsorbable suture.

Single-Bundle Technique

An accessory AM portal was used for establishment of the femoral tunnel. A Steadman awl was positioned at the center of the femoral footprint. With the knee in hyperflexion, the femoral tunnel was drilled according to the measured graft size. Then, the center of the tibial footprint was identified.[30,61] With an external tibial guide, the tibial tunnel was drilled. The graft was passed through the tibial tunnel and then the femoral tunnel and cycled through 20 flexion-extension movements. Finally, fixation was performed with the knee at 20° of flexion and under manual tensioning of the graft. Graft fixation on the femoral side was performed with a suspension device (Endobutton CL; Smith & Nephew) and on the tibial side with an eccentrically placed PEEK interference screw (Biosure PK; Smith & Nephew).

Double-Bundle Technique

Through the accessory AM portal, the center of the AM bundle footprint was marked with a Steadman awl. With the knee in hyperflexion, the femoral AM tunnel was drilled. A double-bundle femoral drill guide (Anatomic ACLR PL Femoral Aimer; Smith & Nephew) was then used to drill the PL tunnel. On the tibial side, the center of the AM bundle footprint was marked using an external tibial guide. First, the AM tunnel was drilled, the Anatomic ACLR PL Tibial Aimer was placed in the AM tunnel, and the PL guide pin was placed in the center of the footprint. Then, the PL tunnel was drilled. The grafts were passed through the tibial tunnel and then the femoral tunnel and cycled through 20 flexion-extension movements. Fixation was then performed under manual tension and with the knee at 60° of flexion for the AM bundle and at full extension for the PL bundle. Graft fixation on the femoral side was carried out with 2 suspension devices and on the tibial side with 2 eccentrically placed PEEK interference screws. The wounds were closed and bandaged before the tourniquet was loosened.

Notchplasty was only carried out if graft impingement was detected after graft insertion. Measurements of the insertion sites were performed if the surgeon was in doubt of having sufficient space for the 2 tunnels. Mobilization on crutches was achieved from the first postoperative day without brace support or the use of continuous passive motion. Patients were allowed to bear weight as possible, but if the menisci were sutured, partial weightbearing was recommended for 6 weeks, followed by an adjusted ACL rehabilitation program. The patients were advised to undergo strength and neuromuscular training guided by a physical therapist in the first 9 months after surgery and to avoid pivoting sports during the same period.

3D-CT Imaging

From March 2012 to March 2013, all the randomly assigned patients were asked to undergo 3D-CT on the first postoperative day. Twenty-four of 33 patients (12 in the double-bundle group and 12 in the single-bundle group) agreed to undergo additional imaging. The images were anonymized and sent to the Steadman Philippon Research Institute. Further, they were transferred to image processing software (Mimics v 16.0; Materialise). Within the software, the best-fit circle was created at the tunnel apertures on the tibial and femoral sides, and the centers of the circles were identified.[12] For the femoral tunnel centers, a 3D-CT model was positioned in the sagittal view, and the medial femoral condyle was cropped. The positioning of the tunnels was defined by using the quadrant method described by Bernard et al.[9] With this method, the center of the femoral tunnel was detected in the "deep-shallow" and "high-low" directions within a grid adapted to the lateral condyle.[9] The positioning was reported as the mean (±SD) percentage in each direction. On the tibial side, the 3D-CT model of the tibial plateau was positioned in the axial view. The tunnel position was recorded as the mean percentage of the total anteroposterior distance as described by Tsukada et al.[55]

Outcomes

The primary outcome of the study was the KOOS QoL subscore with 2-year follow-up as the primary endpoint. The 2 groups were also compared by the other subscores of the KOOS (Symptoms, Pain, Activities of Daily Living, and Sports/Recreation) and by the International Knee Documentation Committee (IKDC) 2000 subjective knee evaluation form.[22] Furthermore, the differences in knee laxity between the 2 groups at 2-year follow-up were evaluated. Rotational laxity was recorded by the Slocum test for pivot shift and graded from 0 to 3+.[46] Anteroposterior laxity was detected by the Lachman test compared with the uninvolved knee.[54] The Lachman test was graded as follows: 0 (0-2 mm), 1+ (3-5 mm), 2+ (6-10 mm), and 3+ (>10 mm).[22] Anterior laxity was also measured by the KT-1000 arthrometer (MEDmetric). The difference in translation compared with the uninvolved knee was measured at 134 N and anterior manual maximum displacement.[13] Range of motion was measured by the use of a goniometer to detect flexion or extension deficits. The deficits were reported in degrees compared with the uninvolved knee. Functional capacity of the knee was measured by the single-legged hop test comparing the hop distance of the involved leg with that of the uninvolved leg.[32] Activity level at 2-year follow-up was reported by the Tegner activity scale and by the 4 levels of the sports activity scale.[6,52] The 4 levels of the sports activity scale are as follows: level 1 (sports 4-7 days per week), level 2 (sports 1-3 days per week), level 3 (sports 1-3 times per month), and level 4 (no sports). Preinjury main sport was recorded at baseline and 2-year follow-up. Return to sports was defined as returning to the same main sport at 2-year follow-up as before the injury. Finally, standing anteroposterior radiographs of the knees were taken using a Synaflexer (Synarc) frame to achieve fixed flexion positioning of the knees. The images were evaluated and classified by the Kellgren-Lawrence system for the classification of osteoarthritis.[27] At 1- and 2-year follow-up, all patients were questioned as to whether they had experienced any knee-specific adverse events or reoperations after reconstruction. Details from these events were obtained from the patient's medical journal.

Patients with a KOOS QoL subscore less than 44 points at 2-year follow-up were defined as "subjective treatment failures."[7] The number of patients within this subgroup was detected for both groups.

Sample Size Calculation

The sample size was calculated based on the primary outcome: KOOS QoL subscore. The minimal perceptible clinical improvement was set to be 8 points.[40] With equal allocation to both treatment arms and with an SD of 15 points, power of 80%, and 2-sided significance level of .05, the sample size was calculated to be 56 patients in each treatment group. A total of 120 patients were planned to be included in the study.[40]

Randomization and Blinding

A nurse not involved in the research project performed computer-generated block randomization consisting of 10 patients in each block (https://randomization.com; ID: 9412). Allocation concealment was ensured by sequentially numbered, opaque, sealed envelopes containing the name of the procedure in a randomized order. The envelopes were placed in the operating theater and opened at the request of the surgeon.

The study participants were not blinded initially (participants 1-61) because it was considered challenging to keep the treatment concealed from the patients. Because blinding was seen as important in a study with PROs, those concerns were reconsidered. As the skin incisions were similar in both treatment groups, blinding could be performed after information was given to both patients and the hospital staff. The participants with randomization numbers 62 to 120 were consequently blinded for the intervention. Unblinding was completed for all participants after 2-year follow-up. The outcome assessor for the PROs and functional tests was blinded for the intervention. The assisting surgeon, who enrolled the patients and performed the clinical examination, was not blinded. The radiologist was not blinded as the intervention was visible at radiographic imaging. The statistical advisor was presented a dataset that was blinded for the intervention.

After the randomization key was broken, allocation of the treatment was inconsistent with the randomization list from computer-generated randomization in 32 of the 120 patients, resulting in 62 patients undergoing single-bundle reconstruction and 58 patients undergoing double-bundle reconstruction. All included patients were operated on after opening of the envelopes in the operating theater, but the envelope allocations were not consistent with the randomization list. An additional unplanned sensitivity analysis to control for a potential selection bias of the 2 treatment groups was therefore considered necessary.

Statistical Analysis

The planned statistical analysis was presented to the coauthors and published online as the Statistical Analysis Plan (https://www.ostrc.no) before the data analysis. The PROs and single-legged hop test results were analyzed with a linear mixed model, which included fixed effects for treatment, time point (baseline, 1 year, and 2 years), and treatment × time point interaction as well as a random intercept. From the fitted model, estimated mean values and 95% CIs were reported for each time point, the difference in changes from baseline to 2-year follow-up, and P values for the null hypothesis of no treatment difference. The 2-samples t test was used to analyze the remaining continuous variables at 2-year follow-up. The Wilcoxon-Mann-Whitney test was used to analyze ordered categorical variables. Differences between probabilities of return to sports and subjective treatment failures were estimated with Newcombe hybrid score 95% CIs, and the null hypotheses of equal probabilities were analyzed with the Fisher mid-P test.[16] All analyses were conducted with the intention-to-treat analysis set. Per-protocol analyses were only performed for the KOOS subscores. Stata 14 (StataCorp) was used to perform the statistical analyses.

A planned subgroup analysis of the primary outcome in the blinded versus nonblinded patients was performed by adding an interaction term. For variables with more than 5% missing values, a sensitivity analysis was performed, consisting of inputting the missing values according to 3 scenarios to assess the effect of the missing values. See the Statistical Analysis Plan online for further details. An unplanned subgroup analysis was performed in the cohort of patients with intact grafts at 2-year follow-up. Because of potential bias, an additional sensitivity analysis was carried out to assess whether the inconsistencies between the randomization list and the treatment received had any effect on the primary outcome. The latter analysis considered any possible difference in treatment effects over time including, but not limited to, changes from baseline to 2-year follow-up.

The study was approved by the Regional Committee for Medical and Health Research Ethics, South-Eastern Norway.

RESULTS

Of 1186 patients assessed for eligibility, 120 patients were randomized to either the single-bundle intervention or double-bundle intervention (Figure 1). Three patients were excluded after being randomized because of meniscal resection (n = 1), a small notch size (n = 1), and insufficient size of the hamstring tendons (n = 1), and 1 patient was excluded at 1-year follow-up because of a previously unrecognized contralateral ACL injury. Finally, 116 patients were available for an analysis of the primary outcome. Baseline demographics and surgical characteristics showed a difference in the sex distribution between the 2 groups (Table 2). In the double-bundle group, there were 87% male patients (47/54 patients), whereas the single-bundle group only contained 66% male patients (41/62 patients).

Patient-Reported Outcomes

The KOOS QoL subscore at 2-year follow-up was 72.9 points (95% CI, 67.6-78.2) in the double-bundle group and 66.6 points (95% CI, 61.8-71.4) in the single-bundle group. The change in the KOOS QoL subscore from baseline to 2-year follow-up was not different between the double- and single-bundle groups (29.2-point change vs 28.7-point change, respectively; –0.5-point difference; 95% CI, –8.4 to 7.4; P = .91) (Table 3 and Figure 2). Furthermore, there was no difference between the groups for the remaining PROs (Table 3 and Figure 3). The per-protocol analysis for the primary outcome, KOOS QoL subscore, detected no further difference between the double- and single-bundle groups (29.2-point change vs 29.7-point change, respectively; –0.5-point difference; 95% CI, –7.5 to 8.5; P = .90). Neither was there any difference detected for the other 4 KOOS subscores in the per-protocol analysis set. All KOOS subscores and the IKDC 2000 score revealed a significant change from baseline to 2-year follow-up ($P < .001$).

Knee Laxity Evaluation

There were no differences between the 2 groups for the pivot-shift test, Lachman test, or KT-1000 arthrometer results at 2-year follow-up (Table 4). In the double-bundle group, 86% (45/52 patients) had 0 or 1+ on the Lachman test at 2 years; the respective percentage in the single-bundle group was 84% (51/61 patients). Eighty-eight percent of the patients in the double-bundle group and 86% in the single-bundle group had a pivot shift of 0 or 1+ at 2-year follow-up (46/52 patients in the double-bundle group and 53/61 patients in the single-bundle group).

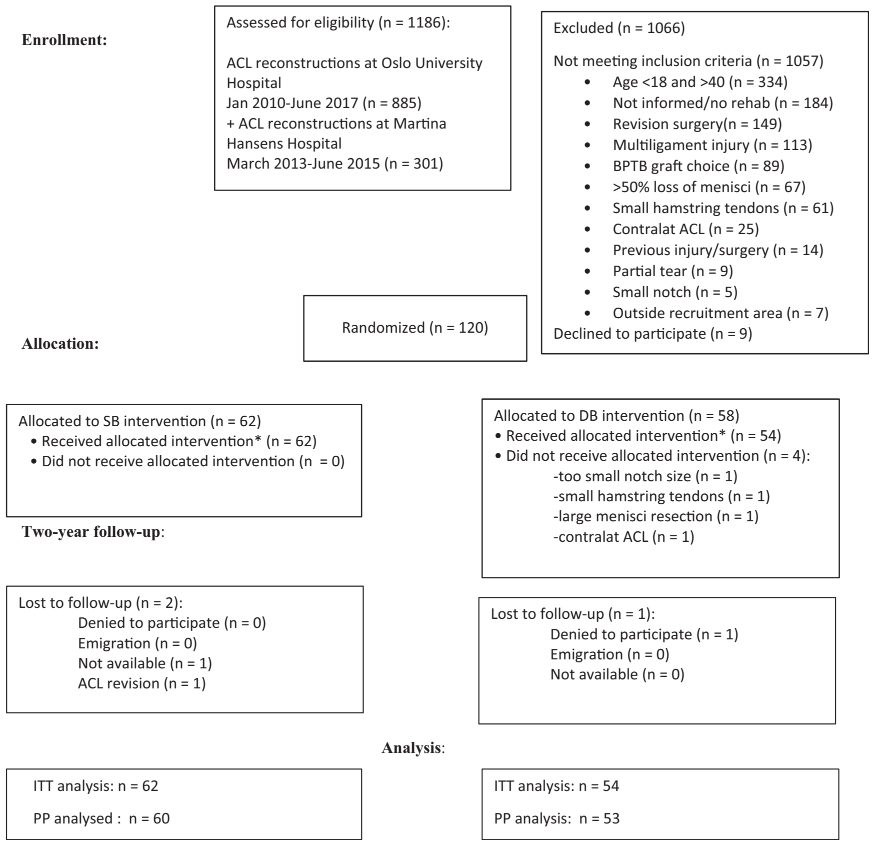

Figure 1. Flowchart. All 120 patients received the allocated treatment from sealed envelopes, but in 32 patients, the treatment proposed by the envelopes was inconsistent with the treatment suggested by the randomization list. ACL, anterior cruciate ligament; BPTB, bone–patellar tendon–bone; DB, double bundle; ITT, intention to treat; PP, per protocol; SB, single bundle.

Range of Motion and Functional Tests

There was no difference in range of motion between the 2 groups (Table 4). Compared with the uninvolved knee, 31% in the double-bundle group had an extension deficit (16/52 patients) versus 31% in the single-bundle group (18/59 patients) at 2-year follow-up. The mean deficit in knee extension was 1.9° for the double-bundle group and 2.0° for the single-bundle group (0.1° difference; 95% CI, –1.3 to 1.1; P = .89). Knee flexion deficits, compared with uninvolved leg, were present in 27% (14/52 patients) of the double-bundle group and 37% (22/59 patients) of the single-bundle group. The mean flexion deficit was 1.9° for the double-bundle group and 2.6° for the single-bundle group (0.7° difference; 95% CI, –2.07 to 0.66; P = .31). The functional performance of the knee was measured by the single-legged hop test. The test reported a significant change in the difference of results from baseline to 2 years in the single-bundle group compared with the double-bundle group (23.6% change vs 14.6% change, respectively; 9.1% difference; 95% CI, 0.5-17.6; P = .04). Both legs achieved more than 97% of the capacity of the uninvolved leg at 2-year follow-up.

Activity Level

The Tegner activity scale and sports activity scale scores at 2-year follow-up were not different between the 2 groups (Table 5). The rate of patients who returned to their preinjury main sport was also not different between the single- and double-bundle groups. In the double-bundle group, 53% (26/49 patients), and in the single-bundle group, 44% (27/61 patients), returned to sports at 2-year follow-up (8.8% difference; 95% CI −9.7% to 26.5%; P = .39).

Radiographic Imaging

Degenerative changes detected by radiographs of the knees revealed that 13 patients had Kellgren-Lawrence grade 1, and 2 patients (1 in the single-bundle group and 1 in the double-bundle group) had Kellgren-Lawrence grade 2 at 2-year follow-up.

Adverse Events

Eight graft ruptures were detected in the single-bundle group and 3 in the double-bundle group at 2-year follow-

TABLE 2
Baseline Patient Characteristics[a]

	Double Bundle (n = 54)	Single Bundle (n = 62)
Age, y	27.4 ± 6.3	27.1 ± 5.5
Male sex, n (%)	47 (87.0)	41 (66.1)
Right side, n (%)	28 (51.9)	29 (46.8)
Contralateral injury, n	2	4
Previous injury, n	2	3
Body mass index, kg/cm^2	25.1 ± 2.9	24.5 ± 3.1
Tegner activity scale score		
Preinjury	7.9 ± 1.2	7.7 ± 1.5
Baseline	3.9 ± 1.1	3.7 ± 0.9
Total No. of days playing sports per week		
Preinjury	3.8 ± 1.3	4.2 ± 1.4
Baseline	3.0 ± 1.4	3.1 ± 1.5
Pivoting sport as main sport, n (%)	38 (70.4)	36 (58.1)
Cause of injury, n (%)		
Traffic	0 (0.0)	1 (1.6)
Activities of daily living	3 (5.6)	4 (6.5)
Work	0 (0.0)	0 (0.0)
Sports	51 (94.4)	57 (91.9)
Preoperative rehabilitation period, mo	6.8 ± 5.6	6.6 ± 4.9
Time from injury to surgery, mo	15.5 ± 18.2	15.7 ± 20.3
Time from testing to surgery, mo	1.5 ± 1.3	1.5 ± 1.6
Follow-up period, mo		
1 year	12.5 ± 1.0	12.5 ± 0.9
2 years	24.5 ± 0.9	25.2 ± 2.3
Combined injuries (meniscal and/or chondral injuries), n (%)	31 (57.4)	39 (62.9)
Meniscal injuries, n (%)	26 (48.1)	33 (53.2)
Medial meniscus, n	13	14
Lateral meniscus, n	9	14
Both menisci, n	4	5
Treatment, n		
Medial resection	4	4
Medial suture	12	12
Lateral resection	4	12
Lateral suture	7	7
Chondral injuries, n (%)	10 (18.5)	13 (20.0)
ICRS 1, n	1	1
ICRS 2, n	9	8
ICRS 3, n	0	3
ICRS 4, n	0	1

[a]Data are shown as mean ± SD unless otherwise indicated. ICRS, International Cartilage Repair Society.

up (P = .16) (Table 6). The graft ruptures were detected by a clinical examination and confirmed by magnetic resonance imaging in 9 of the 11 patients. Only 1 of the patients underwent revision ACL reconstruction before 2-year follow-up. Four patients had a postoperative infection: 2 in the double-bundle group and 2 in the single-bundle group. Sixteen patients were hospitalized because of a new surgical procedure within the first 2 years after reconstruction. The main reasons for undergoing a reoperation were an infection (n = 4), new meniscal injury (n = 4), or cyclops and extension deficit of the knee (n = 4) (Table 6).

Subgroup Analysis

A planned subgroup analysis of the blinded subgroup revealed no further difference in the KOOS QoL subscore compared with the nonblinded group (P = .98). The number of subjective treatment failures was also not different between the 2 groups. Of 54 patients, 3 were treatment failures (5.6%) in the double-bundle group, and 10 of 62 patients (16.1%) in the single-bundle group (10.6% difference; 95% CI, –1.3% to 22.2%; P = .06) were defined as treatment failures.

A sensitivity analysis comparing the KOOS subscores and knee laxity measurements in only patients with intact grafts at 2-year follow-up did not detect any further differences between the 2 groups (Table 7). A sensitivity analysis between the groups of correctly and incorrectly randomized patients did not reveal any difference in the treatment effect between the 2 groups (P = .08). The primary outcome in the correctly randomized patients (n = 84) provided a P value of .96 for the difference between the 2 treatment arms.

TABLE 3
Subjective Outcomes[a]

	Baseline	1-Year Follow-up	2-Year Follow-up	Change From Baseline to 2 Years	Between-Group Difference	P Value[b]
Primary outcome						
KOOS Quality of Life						
DB (n = 54)	43.8 (38.3 to 49.2)	74.5 (68.8 to 80.3)	72.9 (67.6 to 78.2)	29.2 (23.3 to 35.0)	–0.5 (–8.4 to 7.4)	.91
SB (n = 62)	37.9 (32.8 to 43.0)	68.6 (63.4 to 73.9)	66.6 (61.8 to 71.4)	28.7 (23.3 to 34.0)		
Secondary outcomes						
KOOS Pain						
DB (n = 54)	81.7 (78.0 to 85.4)	88.0 (84.1 to 91.9)	90.9 (87.3 to 94.5)	9.1 (5.1 to 13.2)	3.0 (–2.6 to 8.5)	.29
SB (n = 62)	77.3 (73.8 to 80.7)	85.7 (82.1 to 89.3)	89.4 (86.1 to 92.6)	12.1 (8.4 to 15.8)		
KOOS Symptoms						
DB (n = 54)	76.2 (72.3 to 80.2)	81.8 (77.7 to 85.9)	84.7 (80.8 to 88.5)	8.5 (4.3 to 12.6)	1.2 (–4.4 to 6.9)	.67
SB (n = 62)	72.9 (69.2 to 76.5)	82.1 (78.3 to 85.8)	82.6 (79.1 to 86.0)	9.7 (5.9 to 13.5)		
KOOS Activities of Daily Living						
DB (n = 54)	89.6 (86.0 to 93.2)	95.0 (91.2 to 98.8)	96.8 (93.3 to 100.3)	7.3 (3.5 to 11.0)	3.2 (–1.8 to 8.3)	.21
SB (n = 62)	83.9 (80.6 to 87.3)	91.5 (88.0 to 94.9)	94.4 (91.2 to 97.6)	10.5 (7.1 to 13.9)		
KOOS Sports/Recreation						
DB (n = 54)	60.5 (54.8 to 66.3)	81.4 (75.4 to 87.5)	81.5 (75.9 to 87.1)	21.0 (14.9 to 27.1)	–0.6 (–8.8 to 7.7)	.89
SB (n = 62)	53.9 (48.5 to 59.3)	75.7 (70.2 to 81.3)	74.3 (69.2 to 79.4)	20.4 (14.9 to 25.9)		
IKDC subjective						
DB (n = 54)	55.4 (51.9 to 58.8)	69.5 (66.0 to 73.1)	72.2 (68.8 to 75.6)	16.8 (13.5 to 20.2)	–0.3 (–4.8 to 4.2)	.90
SB (n = 62)	51.6 (48.4 to 54.8)	64.3 (61.0 to 67.6)	68.1 (65.1 to 71.2)	16.5 (13.5 to 19.6)		

[a]Data are shown as mean (95% CI). DB, double bundle; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; SB, single bundle.
[b]P value of the between-group difference from baseline to 2-year follow-up.

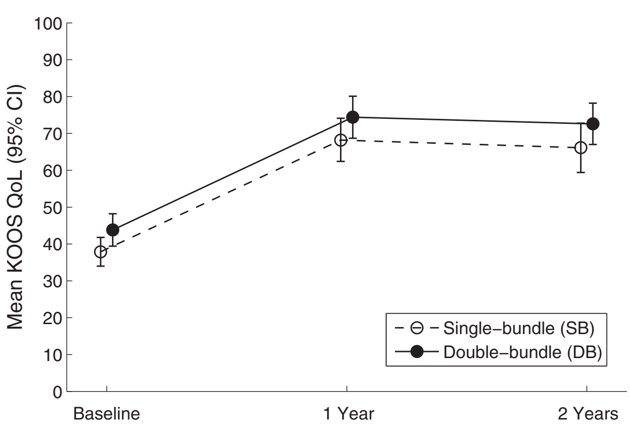

Figure 2. Mean Knee injury and Osteoarthritis Outcome Score (KOOS) Quality of Life (QoL) subscores at baseline and 1- and 2-year follow-up, with 95% CIs. Double bundle (black dots); single bundle (white dots).

Positioning of the Femoral and Tibial Tunnels

The mean positioning of the single-bundle femoral tunnels in the "deep-shallow" direction was at 28.2% ± 3.2% of the total lateral condyle distance (Figure 4A). For the AM bundles, the mean center was at 24.4% ± 2.8% and for the PL bundles at 41.6% ± 6.2% of the total depth. In the "high-low" direction, the single-bundle tunnels were placed at a mean 27.7% ± 4.3%, the AM tunnels at a mean 24.2% ± 7.0%, and the PL tunnels at a mean 45.9% ± 6.6% of the distance from the Blumensaat line (Figure 4A). The mean center of the tibial tunnels was positioned at 37.7% ± 6.4% of the total anteroposterior distance for the single bundles, 34.2% ± 4.9% for the AM bundles, and 49.9% ± 6.4% for the PL bundles (Figure 4B).

DISCUSSION

The main finding of the current study was that there was no difference between double- and single-bundle ACL reconstruction at 2-year follow-up evaluated by the KOOS QoL subscore or any of the other subjective outcome measures used. Studies with more focus on PROs after ACL reconstruction have been requested as there have been a considerable number of published studies comparing objective outcomes between the double- and single-bundle techniques.[34] In most of those studies, rotational and anteroposterior knee laxity has been the outcome of interest.[3,23,35,56] The KOOS has been proven as a reliable, valid, and responsive PRO measure for patients undergoing ACL reconstruction.[40] The KOOS QoL is considered the most sensitive and responsive among the 5 subscores for ACL-injured patients.[40,41] Ahlden et al[3] compared the KOOS subscores of anatomic single-bundle reconstruction with anatomic double-bundle reconstruction and found a significant improvement in both groups but no difference between the 2 groups for any of the 5 KOOS subscores 2 years after surgery. Similarly, Sasaki et al[43] used the KOOS for the evaluation of single-bundle rectangular

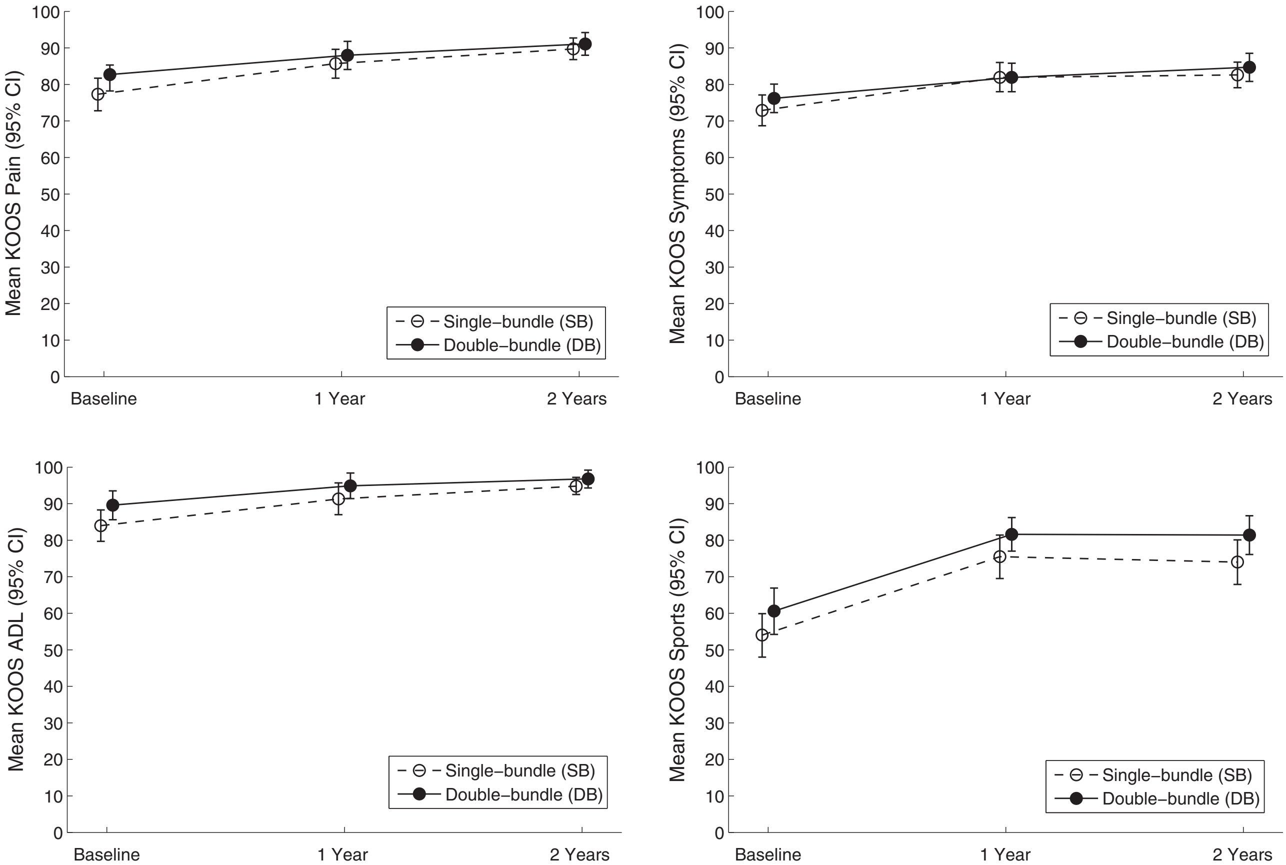

Figure 3. Mean Knee injury and Osteoarthritis Outcome Score (KOOS) (A) Pain, (B) Symptoms, (C) Activities of Daily Living (ADL), and (D) Sports/Recreation (Sports) subscores at baseline and 1- and 2-year follow-up, with 95% CIs. Double bundle (black dots); single bundle (white dots).

TABLE 4
Knee Laxity and Range of Motion Measurements[a]

	Baseline (n = 116)		1-Year Follow-up (n = 111)		2-Year Follow-up (n = 113)		DB vs SB at 2-Year Follow-up	
	DB (n = 54)	SB (n = 62)	DB (n = 50)	SB (n = 61)	DB (n = 52)	SB (n = 61)	Between-Group Difference, Mean (95% CI)	*P* Value
Lachman test, n (%)								.20
0	0	1	18	30	29 (55.7)	25 (40.9)		
1+	11	13	28	25	16 (30.7)	26 (42.6)		
2+	31	30	4	5	6 (11.5)	9 (14.8)		
3+	12	18	0	1	1 (1.9)	1 (1.6)		
Pivot-shift test, n (%)				(n = 60)				.53
0	5	7	32	42	34 (65.4)	36 (59.0)		
1+	11	19	17	12	12 (23.1)	17 (27.9)		
2+	24	16	1	6	5 (9.6)	8 (13.1)		
3+	14	20	0	0	1 (1.9)	0 (0.0)		
KT-1000 arthrometer side-to-side difference, mm								
Anterior 134 N displacement	3.2 ± 2.7	3.5 ± 2.2	2.2 ± 2.0	1.5 ± 1.9	1.8 ± 2.1	2.3 ± 2.6	0.6 (–0.3 to 1.5)	.19
Anterior manual maximum displacement	4.7 ± 3.2	4.8 ± 2.6	2.6 ± 2.5	1.8 ± 2.1	2.1 ± 2.6	2.7 ± 2.8	0.6 (–0.4 to 1.6)	.27
Range of motion, deg					(n = 52)	(n = 59)		
Extension deficit					1.9 ± 3.1	2.0 ± 3.2	0.1 (–1.3 to 1.1)	.89
Flexion deficit					1.9 ± 3.5	2.6 ± 3.8	0.7 (–2.1 to 0.7)	.31

[a]Data are shown as mean ± SD unless otherwise indicated. DB, double bundle; SB, single bundle.

TABLE 5
Activity Levels[a]

	Baseline		2-Year Follow-up		
	DB	SB	DB	SB	*P* Value[b]
Tegner activity scale					
Median (range)	4.0 (1-7)	3.5 (1-6)	5.0 (1-9)	5.0 (2-9)	.77
Missing, n	0	0	1	1	
Sports activity scale					
Median (range)	2 (1-4)	2 (1-4)	2 (1-3)	2 (1-4)	.73
Missing, n	1	2	1	1	
Return to sports					
n (%)			26 (53)	27 (44)	.39
Missing, n			5	1	

[a]DB, double bundle; SB, single bundle.
[b]*P* value of the difference in the activity level between the DB group versus SB group at 2-year follow-up.

TABLE 6
Adverse Events and Reoperations[a]

	Double Bundle, n	Single Bundle, n
Adverse events	18	25
Graft rupture	3	8
Infection	2	2
Hematoma	8	8
Meniscal injury	3	1
Cyclops/extension deficit	1	3
Donor site pain	2	2
Reoperations	5	11
Revision	0	1
Meniscal surgery	3	1
Lavage	2	3
Cyclops/extension deficit	0	3
Other	0	5

[a]More than 1 adverse event or reoperation per patient possible.

bone–patellar tendon–bone grafts versus double-bundle hamstring reconstruction. They found no difference in the KOOS QoL subscore between the 2 groups at 2-year follow-up. These results are in line with the findings reported from this study. However, knee laxity measurements do not necessarily correlate with the PROs. Objective testing of ligament instability is frequently emphasized, although the relation between knee laxity and subjective outcomes of the knee has been discussed. One study has found rotational knee laxity, as measured by the pivot-shift test, to correlate with patient satisfaction, sports participation, and the Lysholm score, but no significant relationship was observed between the Lachman test or KT-1000 arthrometer findings and subjective scores.[28]

In vitro studies of the double-bundle reconstruction technique showed significantly improved anterior and rotatory knee laxity measurements compared with single-bundle reconstruction when the technique was first introduced.[42,59] More than 30 randomized or quasirandomized controlled trials have so far been published.[34] While some studies proclaimed that the double-bundle technique improves the outcomes of ACL reconstruction, other studies have found no advantage of using this new technique.[15,31,36,53,56] The discrepancy in the clinical outcomes between studies could be because of the bias introduced by anatomic single-bundle reconstruction as many of the publications compared nonanatomic single bundles with anatomic or partly anatomic (only 1 bundle) double bundles. Studies have shown that drilling of the femoral tunnels through an accessory AM portal is important to achieve a femoral insertion site similar to the native ACL.[8,14,60] As anatomic reconstruction was gradually introduced for both single- and double-bundle placement, this could explain how many of the later publications strove to find a difference between the 2 techniques.[3,49,58] Only a few studies have consistently performed their reconstruction procedures through an accessory AM portal and by the guidance of soft tissue and bony landmarks (not "o'clock" positioning). In their randomized study, Gobbi et al[17] found no difference in anteroposterior or rotational laxity, and they found similar IKDC subjective and objective scores, Tegner activity scores, and Lysholm scores in both groups. Ahlden et al[3] compared the single- and double-bundle reconstruction techniques and found similar knee laxity test results and subjective outcomes in both groups. Mayr et al[35] evaluated the subjective and objective IKDC scores between the 2 techniques and also did not find any difference between the 2 groups. Xu et al[58] looked at 32 patients with single bundles and 34 patients with double bundles with clinical tests, PROs, and 3D-CT. They found no difference in knee laxity measurements or PROs between the 2 groups at 2-year follow-up. Postoperative 3D-CT confirmed the anatomic placement of the bundles. Finally, Hussein et al[24] compared the double-bundle technique with 2 different single-bundle groups: nonanatomic and anatomic single-bundle reconstruction. Contrary to the other anatomic studies, they found that the knees that underwent anatomic double-bundle reconstruction were superior to those that underwent both nonanatomic and anatomic single-bundle reconstruction in rotational and anteroposterior laxity. Their KT-1000 arthrometer

TABLE 7
Subgroup Analysis of Patients Without a Graft Rupture at 2-Year Follow-up[a]

	Baseline		2-Year Follow-up		Between-Group Difference,	
	DB (n = 51)	SB (n = 54)	DB	SB	Mean (95% CI)	*P* Value
KOOS, mean (95% CI)						
Pain	81.6 (77.9 to 85.3)	77.2 (73.6 to 80.8)	91.6 (87.9 to 95.2)	90.6 (87.2 to 94.0)	3.4 (–2.3 to 9.2)[b]	.24[b]
Symptoms	75.9 (71.8 to 80.0)	73.1 (69.1 to 77.0)	85.0 (81.0 to 88.9)	83.2 (79.5 to 87.0)	1.1 (–4.8 to 7.1)[b]	.71[b]
Activities of Daily Living	89.5 (85.8 to 93.2)	83.9 (80.2 to 87.5)	97.2 (93.5 to 100.8)	94.8 (91.4 to 98.2)	3.3 (–2.1 to 8.6)[b]	.23[b]
Quality of Life	43.6 (38.5 to 48.7)	38.3 (33.4 to 43.3)	74.7 (69.8 to 79.7)	70.0 (65.4 to 74.7)	0.6 (–7.4 to 8.7)[b]	.88[b]
Sports/Recreation	61.3 (55.7 to 66.8)	54.5 (49.2 to 59.9)	82.5 (77.1 to 87.9)	77.2 (72.2 to 82.3)	1.5 (–6.8 to 9.7)[b]	.72[b]
Pivot-shift test						.63
Lachman test						.24
KT-1000 arthrometer, mean ± SD						
134 N displacement			1.6 ± 2.1	2.0 ± 2.1	0.4 (–0.4 to 1.2)	.35
Manual maximum displacement			1.9 ± 2.4	2.3 ± 2.3	0.4 (–0.5 to 1.3)	.39

[a]DB, double bundle; KOOS, Knee injury and Osteoarthritis Outcome Score; SB, single bundle.
[b]Between-group difference in the change in the KOOS subscore from baseline to 2-year follow-up.

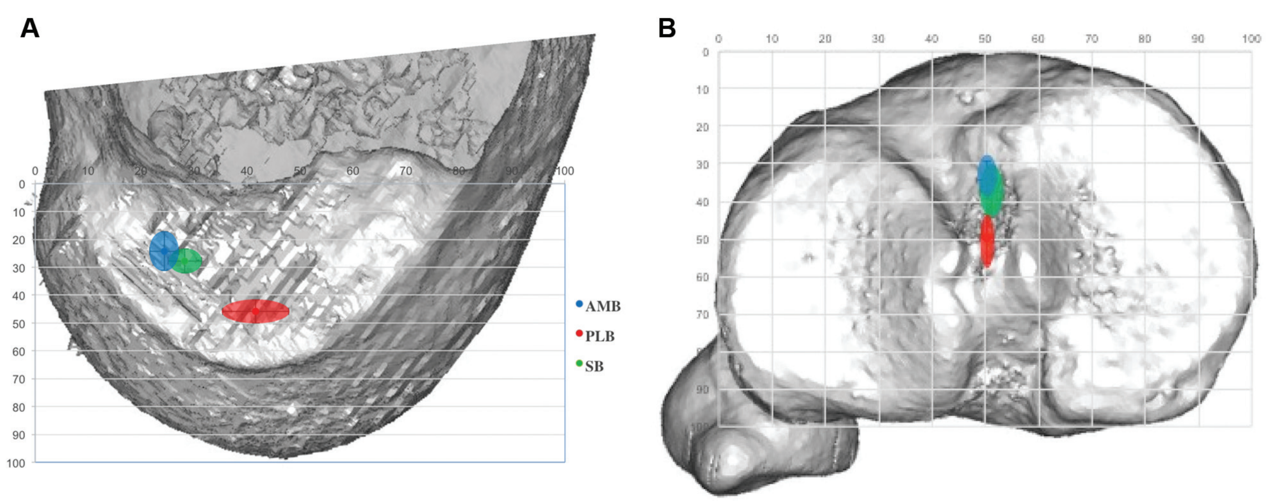

Figure 4. Mean values for (A) femoral tunnel positioning and (B) tibial tunnel positioning. AMB, anteromedial bundle (blue); PLB, posterolateral bundle (red); SB, single bundle (green).

side-to-side difference was 1.2 mm in the anatomic double-bundle group and 1.6 mm in the anatomic single-bundle group. The proportion of patients with a negative pivot-shift test result was 99.3% in the double-bundle group and 66.7% in the anatomic single-bundle group. As in many other trials, they did not find any difference between the groups in subjective outcomes.[24] In summary, many of the listed studies are in line with our study, revealing no significant differences between the 2 techniques for PROs or clinical tests.

In the current study, there was no difference in activity levels between the 2 groups at 2-year follow-up, but the participants reported lower return-to-sports rates than in other studies.[3,5] One reason could be that the period from injury to surgery in the current study was longer (~15 months) than that reported in other studies.[3,23] As the patients were advised by the surgeons to avoid pivoting sports for at least 9 to 12 months after reconstruction, this could also have affected the return-to-sports rate.

The only outcome variable with a difference between the 2 treatment options was the single-legged hop test. This test produced a higher change in results from baseline to 2-year follow-up in the single-bundle group than in the double-bundle group. It was, however, presumed that these results were prone to a ceiling effect as both double- and single-bundle knees achieved more than 97% (97.8% and 99.8% in the single- and double-bundle groups, respectively) of the capacity of the noninvolved leg at 2-year follow-up.

3D-CT was performed in 24 patients on the first postoperative day. This made it possible to verify the positioning of the femoral and tibial tunnels. A correct tunnel position could be dependent on other structures than distances to the different bone structures as suggested by Bernard et al[9] and Tsukada et al.[55] Also, in this study, the center of the tunnels was positioned dependent on bony landmarks and remnant soft tissue and hence specific for each patient. Nevertheless, anatomic studies have suggested the areas in which the footprints are detected on cadaveric knees.[38] According to these studies, the positioning of the AM and PL bundles in this study was in agreement with the anatomic centers. The single-bundle tunnels were placed in the "deeper" and "higher" position compared with most of the anatomic studies.[38] Biomechanical studies have confirmed that the fibers with the highest restraint to anteroposterior translation of the knee originate from the proximal area of the femoral ACL attachment site.[26] Only 2 patients had radiographic signs of knee osteoarthritis at 2-year follow-up, defined as Kellgren-Lawrence grade 2 or worse. However, to detect posttraumatic cartilage degeneration radiographically, midterm and long-term follow-ups are preferable.

Minimal graft sizes of the PL and AM bundles were introduced to prevent double-bundle reconstruction from being performed in knees with insufficient graft sizes.[45] Although a threshold for the minimum size of a bundle cannot be stated, many studies have shown an increased risk of revision with smaller grafts.[20,47,58]

In the current study, 13 of 116 patients (11.2%) were detected with a KOOS QoL subscore less than 44 points (subjective treatment failure). This is lower than reported from the Scandinavian registers.[7] However, in the current study, the KOOS was completed by more than 95% of the patients, whereas coverage of PROs is generally low in the population from the Scandinavian registers. Thus the reported KOOS subscores from register studies, could be biased because of a high nonresponder rate. It has also been stated that a low KOOS QoL subscore is correlated with the risk of later revision ACL reconstruction.[7,19] Of the 13 subjective treatment failures, only 4 were detected as having a graft rupture. This suggests that other factors than the intact or nonintact graft play an important role in the low KOOS QoL subscores. There were 8 graft ruptures in the single-bundle group and 3 in the double-bundle group at 2-year follow-up. Two more single-bundle grafts had a partial rupture of the graft on magnetic resonance imaging. The relatively high rerupture rate in the single-bundle group could be explained by the "higher" and "deeper" femoral single-bundle positioning, making the graft more exposed to anteroposterior forces.[26,58] Additionally, transportal drilling of the femoral tunnel has been shown to increase the risk of revision surgery compared with transtibial drilling.[39,51] Suomalainen et al[49] compared 75 double-bundle reconstruction procedures with 78 single-bundle reconstruction procedures. They concluded that there were significantly fewer graft ruptures in the double-bundle group. However, whereas the number of reruptures in the double-bundle group was 1, the number of reruptures in the single-bundle group was 7.[49] The results should be interpreted with caution because the number of events was relatively few, as Suomalainen et al[49] also suggested in their conclusion. In a more extensive register study comparing 52,000 single-bundle reconstruction procedures and almost 1000 double-bundle reconstruction procedures in Scandinavia, there was no difference in the risk of revision between the 2 groups.[1]

Limitations

There are several limitations to this study. First, the study was designed as an efficacy study, with an experienced surgeon in a high-volume hospital, making the results of this research not applicable for all hospitals and surgeons that perform ACL reconstruction procedures. The idea, however, was to see how this technique would perform under "ideal conditions." Therefore, results from other cohorts should be taken into consideration before any conclusions are to be made. The strict inclusion criteria also limited the external validity of the study. The main causes of exclusion from the study were too-young or too-old patients and patients with revision surgery or multiligament surgery of the knee (see Figure 1).

Blinding of the patients can affect the results of clinical studies.[57] Particularly when collecting subjective outcomes, blinding the patients may prevent overestimation of the treatment effect.[57] A planned sensitivity analysis of a blinded subgroup of patients was therefore carried out, and this analysis did not reveal any further difference between the 2 groups for the primary outcome.

Thirty-two patients did not receive the correct treatment from the randomization list. The reason why the allocated treatment was not in line with the computer-generated list is unknown, but it could have been caused by incorrect handling of the envelopes. The box of envelopes with block-randomized treatment options was carried down to the operating room on the days of surgery. The assisting staff opened the envelopes at the request of the surgeon. Even though the surgeon reported which treatment each included patient was randomized to in the patient's journal, the envelopes or inclusion numbers could have been incorrectly managed. A sensitivity analysis was performed, revealing no further difference in the results. The baseline demographics were different in the 2 groups. The double-bundle group consisted of more male patients than the single-bundle group. In a Swedish register study, the authors found that the male sex was overrepresentative in the group of high KOOS subscores (defined as functional recovery) but that there was no sex difference in the group of low KOOS subscores (KOOS QoL subscore <44 points).[7] A higher proportion of male patients in the double-bundle group could potentially have overestimated the treatment effect in this cohort. The quality of rehabilitation is of importance for the final results after ligament reconstruction.[20] It was ensured that all participants went to a physical therapist with knee injury expertise for rehabilitation. However, compliance was not monitored. Neither were psychosocial aspects of the patients assessed, such as the fear of reinjury and differences in the motivation to return to previous activities and activity levels.[4,5] To increase the reliability and validity of 3D-CT positioning of the tunnels, CT of a larger group of patients should have been performed and interclass and intraclass correlation coefficients been obtained.

The strengths of this study were its comprehensive design with a focus on PROs as well as knee laxity measurements and return-to-sports rates. A sample size was calculated according to the primary outcome, and the study group had few lost to follow-up at all time points. 3D-CT of the patients was performed to verify tunnel positioning. As the anatomic reconstruction technique is relying on tunnel placement, it is crucial to be able to verify this by imaging, as shown by the current study. Double-bundle reconstruction is a more complex procedure, takes a longer time, is harder to revise, and is more expensive.[33] Very few of the strictly anatomically placed reconstruction studies in vivo and in vitro could find any improved outcomes by the double-bundle technique.[3,17,18,29,35,58] The question is if there is a need for additional research on the short-term outcomes of this technique. Future research should concentrate on the long-term effects of double-bundle reconstruction and especially on the cartilage degeneration that it may or may not prevent.

CONCLUSION

In the current randomized trial, there were no differences in KOOS QoL subscores, knee laxity measurements, or activity levels comparing the double- and single-bundle ACL reconstruction techniques. Both single- and double-bundle reconstruction of the ACL resulted in improved patient-reported and clinical outcomes. However, the number of bundles does not seem to be important, as long as they are adequately positioned.

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