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No difference in the KOOS Quality of Life, 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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Abstract:

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

Study design: Randomized controlled clinical trial.

Hypothesis: Anatomic double-bundle ACL reconstruction would be superior to anatomic single-bundle reconstruction regarding the change in the KOOS QoL subscore from baseline to two-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 anatomic double-bundle or anatomic single-bundle reconstructions. Patients with PCL, PLC or LCL injuries or with established osteoarthritis were excluded. Patients with residual laxity from a coexistent MCL-injury were excluded. Data were registered at baseline, one- and two years. In 24 patients, postoperative 3D computer tomographic scanning was performed to verify positioning of the bundles. The outcome measurements were: The change in KOOS and IKDC 2000 subjective score, pivot shift test, Lachman´s test and KT 1000 measurements, activity level, return to sports rate and osteoarthritic changes on radiographic imaging. A linear mixed model was used for the analysis of all the PRO´s, including the primary outcome.

Results: The change in KOOS QoL from baseline to two-year follow-up was not different between the two groups (double-bundle: mean change 29.2 points versus single-bundle: mean change 28.7 points, -0.5 points difference, 95% CI -8.4 to 7.5 points, p=0.91). Neither were there any differences between the two groups in the remaining patient-reported outcomes, knee laxity measurements or the activity level of the patients. Radiological signs of osteoarthritis were found in two patients. Eleven patients had a graft rupture; 8 in the single-bundle and 3 in the double-bundle group (p=0.16). The 3D computer tomographic imaging of the knees verified the positioning of the AM-, PL- and single-bundle grafts to be within acceptable limits.

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

What is known about the subject: Multiple studies have compared the double- and single-bundle reconstruction technique. Most of those studies focus on knee laxity measures and physical examination. Studies have also compared the non-anatomic to the anatomic reconstructions, and very few verify their tunnel positioning by imaging. There has been questioned whether the double-bundle technique would benefit the patients, and there has been a request for high-quality studies with patient-reported outcome measures as the primary outcome.

What this study adds to existing knowledge: This study compared the difference in the KOOS QoL between anatomic double-bundle reconstructions compared to anatomic single-bundle technique. Additionally 3D-CT imaging to verify the tunnel positioning was performed. The study found that the change in KOOS QoL from baseline to two-year follow up did not differ between the two techniques. Neither was there any difference in any other outcome measures including knee laxity measures, activity level and return to sports. This is one of few studies that can verify the positioning of the bundles on 3D computer tomographic imaging.

Key terms: ACL, double-bundle, anatomic, single-bundle, KOOS, Pivot shift, Lachman, patient-reported outcome, PRO´s, return to sports, 3D CT, computer tomography, positioning.

INTRODUCTION

The double-bundle ACL reconstruction technique was developed to improve the ACL reconstruction, due to the anatomical restoration of both the anteromedial (AM) and the posterolateral (PL) bundle.[59] The different insertion sites and tension pattern of the two bundles during knee motion are supposed to resemble the native ACL more closely than the conventional single-bundle reconstruction. However, double-bundle reconstructions are considered to be technically more difficult and more cost demanding compared to single-bundle reconstructions.

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 focus on patient subjective outcomes, have been asked for.[2, 24, 25, 31, 44, 50, 53]

More than 30 clinical studies have compared the double-bundle to 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] But the question is whether the reported differences are of any clinical benefit to the patients.[21, 31, 53, 56] Patient-reported outcome scores (PRO´s) has been reported only as secondary outcomes although superior subjective scores in the double-bundle group have been reported.[2, 10, 31, 48]

Parallel to development of the anatomic double-bundle reconstruction, the 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 use transtibial drilling and "o´clock" positioning of the grafts.[2, 37, 44] Only a few studies describe a transportal, anatomic positioning of the tunnels both in the single- and double-bundle group.[3, 17, 24, 35] As rotational laxity measurements were the main outcome of those studies, the PRO´s were less focused on.

The current study was designed to compare single-bundle versus the double-bundle techniques for ACL reconstruction with a patient-reported outcome as primary endpoint. The hypothesis was that anatomic double-bundle ACL reconstruction would be superior to anatomic single-bundle reconstruction, regarding the change in the KOOS QoL subscore from baseline to two-year follow-up. Secondary objectives were to compare additional PROs, knee laxity measurements, range of motion, functional tests and radiographic imaging between the two ACL reconstruction techniques at two-year follow-up.

MATERIALS AND METHODS

Study design:

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

The study included 120 patients with symptoms from a primary ACL injury. They were 18-40 years old and referred from the outpatient clinics of the two recruiting hospitals, one university hospital and one hospital specialized in orthopaedic surgery. The patients that fulfilled the inclusion criteria were asked to carry out two months of knee-specific rehabilitation supervised by a physiotherapist 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 contralateral or subtotal ACL injury, injury to the posterior cruciate ligament (PCL), posterolateral corner (PLC), lateral collateral ligament (LCL) or medial collateral ligament (MCL) injury with a residual medial instability of the knee, were excluded (Table 1). Knees with osteoarthritic changes (Kellgren-Lawrence classification grade 3 or 4), were also excluded. Before inclusion, the participants signed a written informed consent. The randomization was then only carried out if the ACL rupture was verified by arthroscopy if more than 50 % of both menisci remained intact, and if the hamstring tendons had sufficient length and thicknesses for a two-bundle-reconstruction to be realized. The reasons for exclusion of eligible patients were reported (Table 2).

TABLE 1

Inclusion criteria
Age 18 to 40 years
Symptoms from the knee due to a primary ACL injury; verified by history, clinical assessments (Lachman´s test >1+ or positive pivot shift test) and identified at surgery.
Successfully completed 2 months of knee-specific rehabilitation supervised by a physiotherapist
Exclusion criteria
Previous ACL reconstruction in the involved or uninvolved knee.
Partially ruptured ACL.
Patients with a PCL, LCL or PLC injury.
MCL injury with increased medial ligament laxity at operation (>1+), compared with the uninvolved leg.
Established osteoarthritis (Kellgren-Lawrence classification grade 3 or 4) identified on standing front radiographs of the knee.
Hamstring tendons with insufficient graft thickness after preparation. (Defined as less than of 5.0 mm in diameter for the PL, and 6.0 mm for the AM bundle.)
Less than 50% of the medial or lateral meniscus preserved after treatment.
Patients living outside recruitment area.
Patients not understanding the norwegian written language.

Figure1
Flow chart

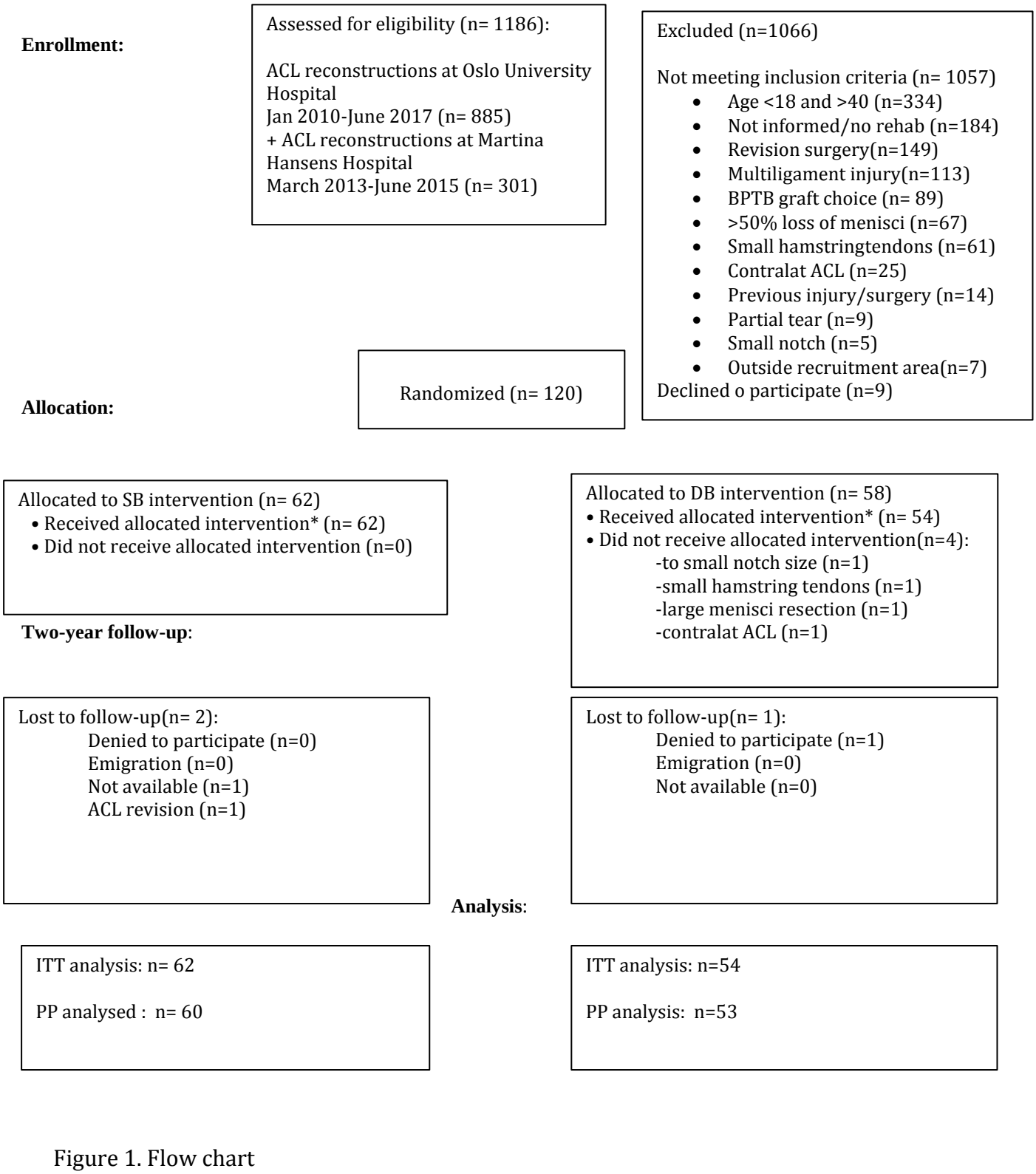


Figure 1. Flow chart
DB, double-bundle; SB, single-bundle; BPTB, bone patellar-tendon bone graft; ITT, intention to treat; PP, per protocol.
*All 120 patients received the allocated treatment group from sealed envelopes, but in 32 patients, the treatment proposed by the envelopes were inconsistent with the treatment suggested by the randomisation list.

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 five to two-year follow-up because of the difficulties recruiting patients. The minimum graft size of the PL-bundle was decreased from 5.5 to 5.0 mm due to the same reason. The patients with randomisation number 62 to 120 were blinded for the intervention. A subgroup of the patients was asked to perform a postoperative 3D computer tomographic imaging 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 1st, 2013 the site of intervention was changed to Martina Hansens Hospital. Both hospitals performed more than 100 ACL reconstructions yearly. One surgeon performed the surgical procedure in all but two patients. The surgeon was experienced and had also participated in anatomy studies describing the ACL and its two bundles.[61]

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

Single-bundle technique:

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

Double-bundle technique:

Through the accessory anteromedial portal, the central position 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, London, United Kingdom) was then used to drill PL tunnel. On the tibial side, the centre of the AM footprint was marked using an external tibia guide. First, the AM tunnel was drilled, the Anatomic ACLR PL Tibial Aimer® (Smith & Nephew, London, United Kingdom) was placed in the AM tunnel and the PL guide pin placed into the centre of the footprint. Then the PL tunnel was drilled. The grafts were passed through the tibial and then the femoral tunnels, and cycled through 20 flexion-extension movements. Fixation was then performed under manual tension and with the knee at 60 degrees flexion for the AM bundle, and at full extension for the PL bundle. Graft fixation on the femoral side was carried out with two suspension devices (Endobutton CL®, Smith & Nephew, London, United Kingdom), and on the tibial side with two eccentric placed, PEEK interference screws (Biosure PK ®, Smith & Nephew, London, United Kingdom). The wounds were closed and bandaged before the tourniquet was loosened.

A 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 two tunnels. Mobilization on crutches was achieved from the first postoperative day without brace support or the use of a CPM. Patients were allowed to bear weight as possible, but if the menisci were sutured, partial weight-bearing was recommended for six weeks followed by an adjusted ACL rehabilitation. The patients were advised to performed strength and neuromuscular training guided by a physiotherapist in 9 months after surgery, and to avoid pivoting sports during the same period.

Three-dimensional computed tomographic (3D-CT) imaging:

From March 2012 until March 2013 all the randomly assigned patients were asked to perform a 3D-CT scan the first postoperative day. Twenty-four of 33 patients (twelve double-bundle and twelve single-bundle patients) agreed to perform the additional imaging. The pictures were anonymized and sent to the Steadman Philippon Research Institute. Further, they were transferred into an image processing software (Mimics v 16.0®, Materialise, Leuven, Belgium). Within the software, the best-fit circle was created at the tunnel apertures on the tibial and femoral side, and the centres of the circles were identified.[12] For the femoral tunnel centres, 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 centre of the femoral tunnels were detected in the "deep-shallow" and "high-low" direction within a grid adapted to the lateral condyle.[9] The positioning was reported as the mean percentage ± the standard deviation(SD) in each direction. On the tibial side, the 3D-CT model of the tibial plateau was positioned in the axial view. The tunnel positions were recorded as the mean percentage ± SD of the total anteroposterior distance as described by Tsukada et al..[55]

Outcomes:

The primary outcome of the study was the Knee Osteoarthritis Outcome Score (KOOS) Quality of Life (QoL) subscore with two-year follow-up as the primary endpoint. The two groups were also

compared by the other subscores of the KOOS: Symptoms, Pain, Activity of Daily living (ADL) and Sports/Recreation, and by the IKDC 2000 subjective knee evaluation form.[22] Furthermore, the differences in knee laxity between the two groups at two-year follow-up were evaluated. Rotational laxity was recorded by the Slocum´s test for pivot shift and graded from 0 to 3+.[46] Anteroposterior laxity was detected by the Lachman´s test, compared to the uninvolved knee.[54] The Lachman´s test was graded: 0(0-3 mm), 1+ (3-5 mm), 2+ (5-10 mm) and 3+ (>10 mm).[22] The anterior laxity was also measured by the KT 1000 (Knee Laxity Testing Device®, MEDmetric, San Diego, CA, US). The difference in translation compared to the uninvolved knee was measured at 134 Newton (134N) and maximum, manual load (MM).[13] Range of motion (ROM) was measured by the use of a goniometer to detect flexion or extension deficits. The deficits were reported in degrees compared to the uninvolved knee. Functional capacity of the knee was measured by the one-leg hop test, comparing the hop-distance of the involved leg to the uninvolved leg.[32] Level of activity at two-year follow-up was reported by the Tegner activity scale and by the four levels of the Sports Activity scale.[6, 52] The four levels of the Sports Activity Scale were: 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 the baseline examination and two-year follow-up. Return to sports was defined as attending to the same main sport at two-year follow-up as preinjury. Finally, standing anteroposterior radiographic images of the knees were taken, using a Synaflexer® (Synarc, California, US) frame to achieve a fixed flexion positioning of the knees. The images were evaluated and classified by the Kellgren-Lawrence system for classification of osteoarthritis.[27] At the one-, and two-year follow-up, all patients were questioned if they had experienced any knee-specific adverse events or reoperations after the reconstruction. Details from these events were obtained from the patient´s medical journal. Patients with KOOS QoL subscore less than 44 points at the two-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 (MPCI) was set to be 8 points.[40] With equal allocation to both treatment arms and with a standard deviation of 15 points, power of 80% and a two-sided significance level of 0.05, 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]

Randomisation and blinding:

A nurse not involved in the research project performed a computer-generated block randomization, consisting of ten 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 theatre and opened at the request of the surgeon.

The study participants were not blinded initially (from participants 1 to 61) because it was considered challenging to keep the treatment concealed for the patients. Because the blinding was considered important in a study with patient reported outcome, those concerns were reconsidered. As the skin incisions were similar in both treatment groups the blinding could be performed after information was given to both patients and the hospital staff. The participants with randomisation number 62 to120 were consequently blinded for the intervention. Unblinding was completed for all participants after the two-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 the radiographic imaging. The statistical advisor was presented a dataset that was blinded for the intervention.

After the randomisation key was broken, the allocation of treatment was inconsistent with the randomisation-list from the computer-generated randomisation in thirty-two of the one hundred twenty patients, resulting in sixty-two patients receiving single-bundle and fifty-eight patients receiving double-bundle reconstructions. All included patients were operated after opening the envelopes in the

operation theatre, but the envelope-allocations were not consistent with the randomisation-list. Additional unplanned sensitivity analysis to control for a potential selection bias of the two treatment groups was therefore considered necessary.

Statistical analysis

The planned statistical analysis was presented to the co-authors and published online as a Statistical Analysis Plan https://www.ostrc.no prior to data analysis. The PRO´s and the one-leg hop test was analyzed with a linear mixed model which included fixed effects for treatment, time point (baseline, one year, and two years treatment) x time point interaction and a random intercept. From the fitted model, estimated mean values and 95% confidence intervals (CI) were reported for each time point, and the difference in changes from baseline to two-year follow-up, as well as a P-value for the null hypothesis of no treatment difference. The two-sample T-test and its associated CI were used to analyze the remaining continuous variables at two-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 a 95% Newcombe hybrid score CI, and the null hypotheses of equal probabilities were analyzed with the Fisher mid-P test.[16] All analyses were done with the intention to treat (ITT), analysis set. Per protocol analyses were only performed for the KOOS subscores. Stata 14 (StataCorp®, Texas, US) was used to perform the statistical analyses.

A planned subgroup analysis of the primary outcome in the blinded versus not-blinded 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 three scenarios to assess the impact of the missing values. See online Statistical analysis plan for further details (https://www.ostrc.no). An unplanned subgroup analysis was performed in the cohort of patients with intact grafts at two-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 impact on the primary outcome. The latter analysis considered any

possible difference in treatment effect over time, including – but not limited to – changes from baseline to two-year follow-up.

Ethical consideration:

The study was approved by, the Regional Committees for Medical and Health Research Ethics, South East Norway.

RESULTS:

Out of 1186 patients assessed for eligibility, 120 patients were randomized to either single-bundle intervention or double-bundle intervention (Figure 1). Three patients were excluded after being randomized, because of menisci resections >(n=1), small notch size (n=1) and insufficient size of the hamstring tendons(n=1), and one was excluded at the one-year follow-up because of an unrecognized contralateral ACL injury prior to inclusion (n=1). Finally, 116 patients were available for analysis of the primary outcome. Baseline demographics and surgical characteristics showed a difference in the gender distribution between the two groups (Table 3). In the double-bundle group, there were 87% patients of male sex (47 of 54 patients), whereas the single-bundle group only contained 66% males (41 of 62 patients) (Table 2).

Table 2
Baseline demographics, and patient characteristics

Demographics, patient characteristics	Double bundle	Single bundle
No. of patients	n=54	n=62
Age, (years), mean ± SD	27.4 ± 6.3	27.1 ± 5.5
Sex, n(% male)	47 (87.0)	41 (66.1)
Side, n(% right)	28 (51.9)	29 (46.8)
Contralateral injury, n	2	4
Previous injury, n	2	3
BMI, (kg/cm^2)±SD	25.1 ± 2.9	24.5 ± 3.1
Tegner activity scale score, preinjury, mean ± SD	7.9 ± 1.2	7.7 ± 1.5
Tegner activity scale score, baseline, mean ± SD	3.9 ± 1.1	3.7 ± 0.9
Total number of days sports/week preinjury, mean ± SD	3.8 ± 1.3	4.2 ± 1.4
Total number of days sports/week baseline. mean ± SD	3.0 ± 1.4	3.1 ± 1.5
Pivoting sports as main sports n(%)	38 (70.4)	36 (58.1)
Cause of injury		
Traffic, n(%)	0 (0.0)	1(1.6)
ADL, n(%)	3 (5.6)	4 (6.5)
Work, n(%)	0 (0.0)	0 (0.0)
Sports, n(%)	51 (94.4)	57 (91.9)
Preop rehab period , months Mean± SD	6.8 ± 5.6	6.6 ± 4.9
Time from injury to operation, months Mean ±SD	15.5 ± 18.2	15.7 ± 20.3
Time from test to operation, months Mean ± SD	1.5 ± 1.3	1.5 ± 1.6
Follow-up period, 1-year, months Mean ± SD	12.5 ± 1.0	12.5 ± 0.9
Follow-up period mean 2-years, months Mean ± SD	24.5 ± 0.9	25.2 ± 2.3
Patients with combined injuries (menisci and/or cartilage injury), n (%):	31 (57.4)	39 (62.9)
Patients with menisci injuries, n (%):	26 (48.1)	33 (53.2)
Medial, n	13	14
Lateral, n	9	14
Both menisci, n	4	5
Treatment:		
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	1	1
ICRS 2	9	8
ICRS 3	0	3
ICRS 4	0	1

BMI,body mass index; SD, standard deviation; ICRS, international cartilage rating system.

Patient-reported outcomes (PROs):

The KOOS QoL subscore at two-year follow-up was 72.9 points, 95% CI (67.6 to 78.2) in the double-bundle group and 66.6 points, 95% CI (61.8 to 71.4) in the single-bundle group. The change in KOOS QoL from baseline to two-year follow-up was not different between the two groups, (29.2 points change in the double-bundle group, versus 28.7 points change in the single-bundle group; -0.5 points difference; 95% CI (-8.4 to 7.5); p=0.91) (Table 3) (Figure 2). Furthermore, there was no difference between the groups for the remaining PRO´s (Table 3) (Figure 3a and 3b). The per protocol analysis for the primary outcome KOOS QoL detected no further difference between the two groups (29.2 points change in the double-bundle group and 29.7 points in the single-bundle group, difference between groups: 0.50; 95% CI (-7.5 to 8.5); p=0.90). Neither were there any differences 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 two-year follow-up ($p<0.001$).

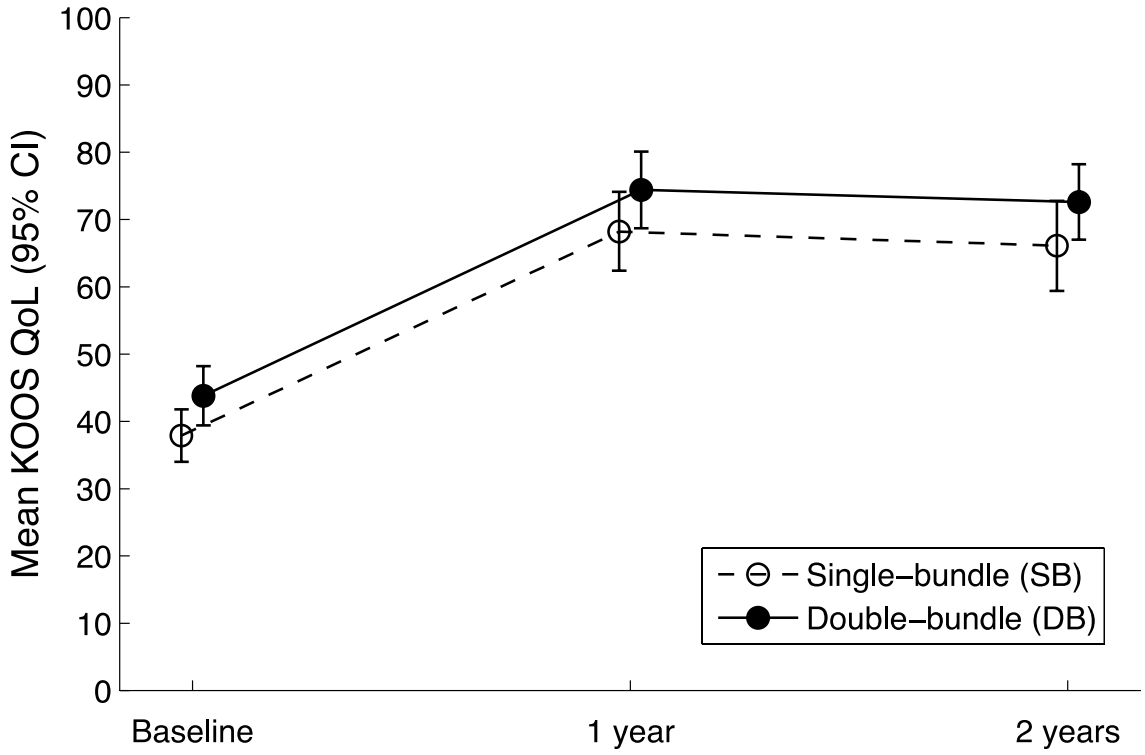
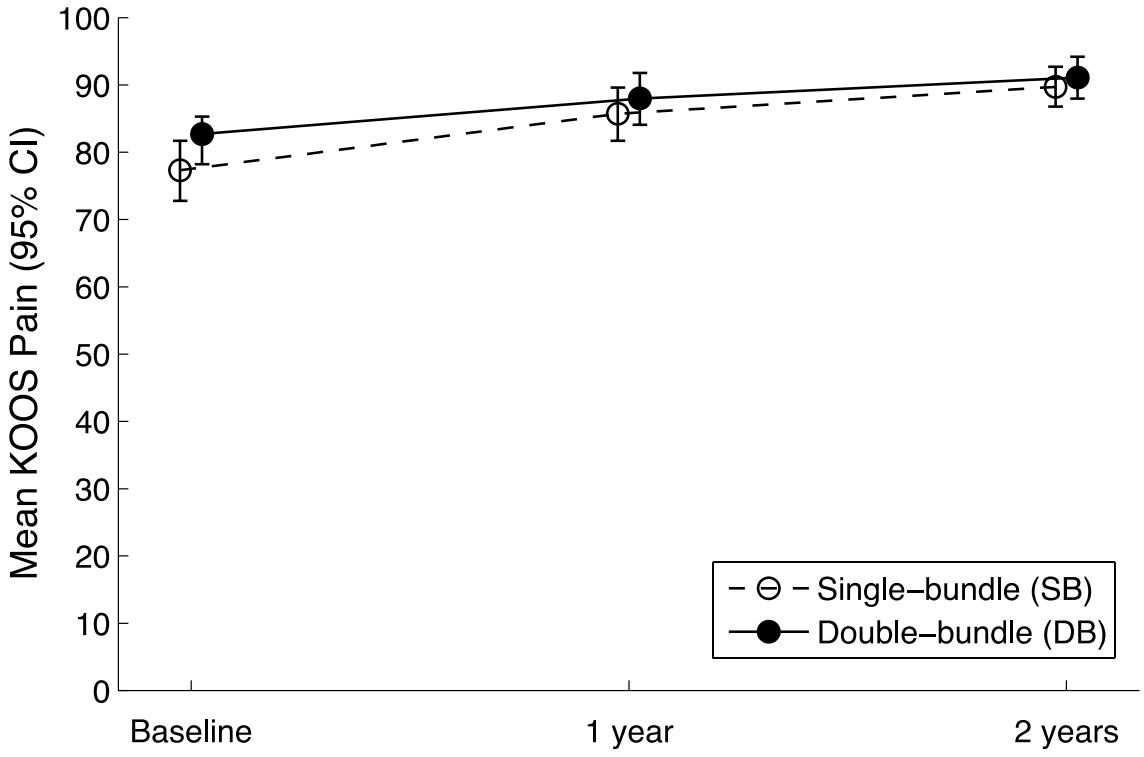
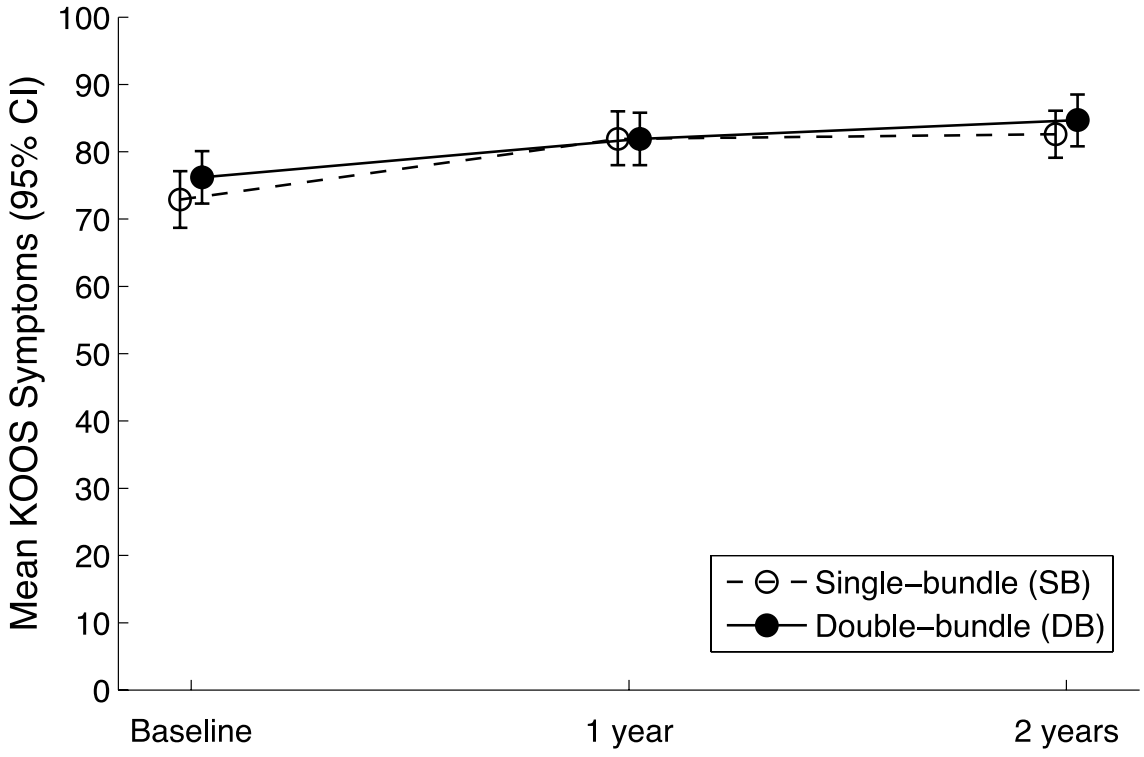
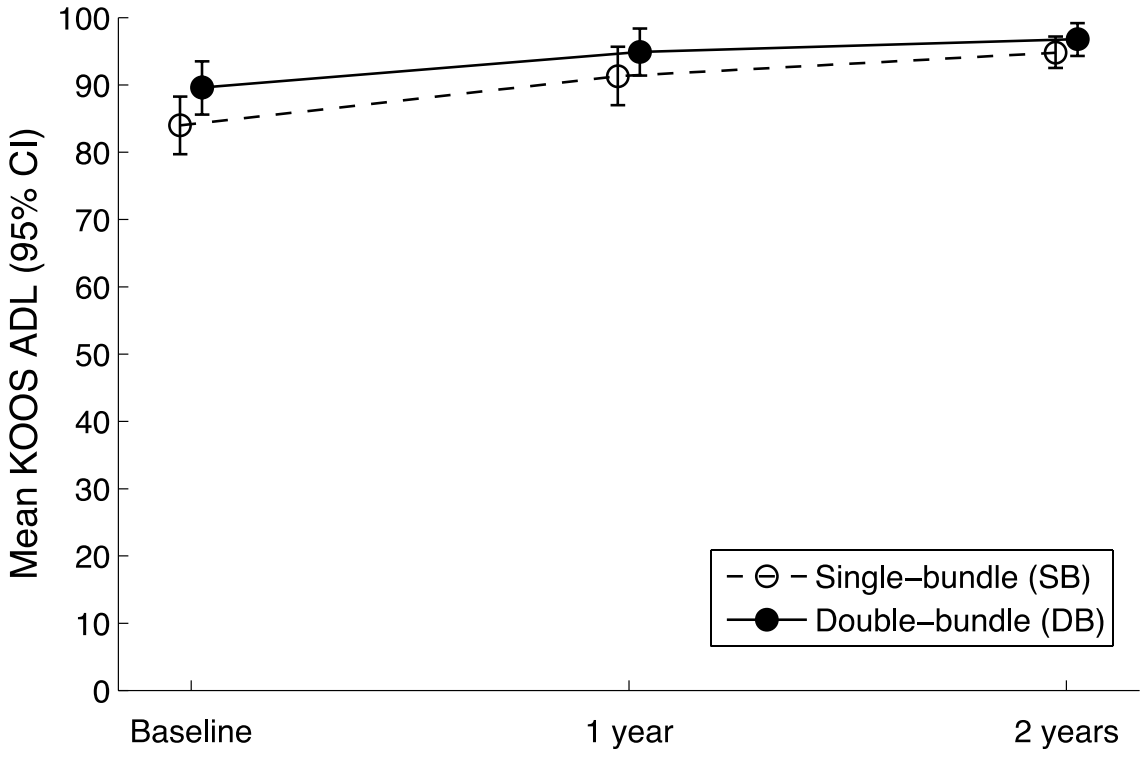


Figure 2. Primary outcome KOOS QoL subscore, observed mean values at baseline and at one- and two-year follow-up, with 95% confidence interval (CI); SB, single-bundle(white dots); DB, double-bundle(black dots)


Mean KOOS Pain (95% CI)
100
90
80
70
60
50
40
30
20
10
0
Baseline
1 year
2 years
Single–bundle (SB)
Double–bundle (DB)


Mean KOOS Symptoms (95% CI)
100
90
80
70
60
50
40
30
20
10
0
Baseline
1 year
2 years
Single–bundle (SB)
Double–bundle (DB)


Mean KOOS ADL (95% CI)
100
90
80
70
60
50
40
30
20
10
0
Baseline
1 year
2 years
Single–bundle (SB)
Double–bundle (DB)

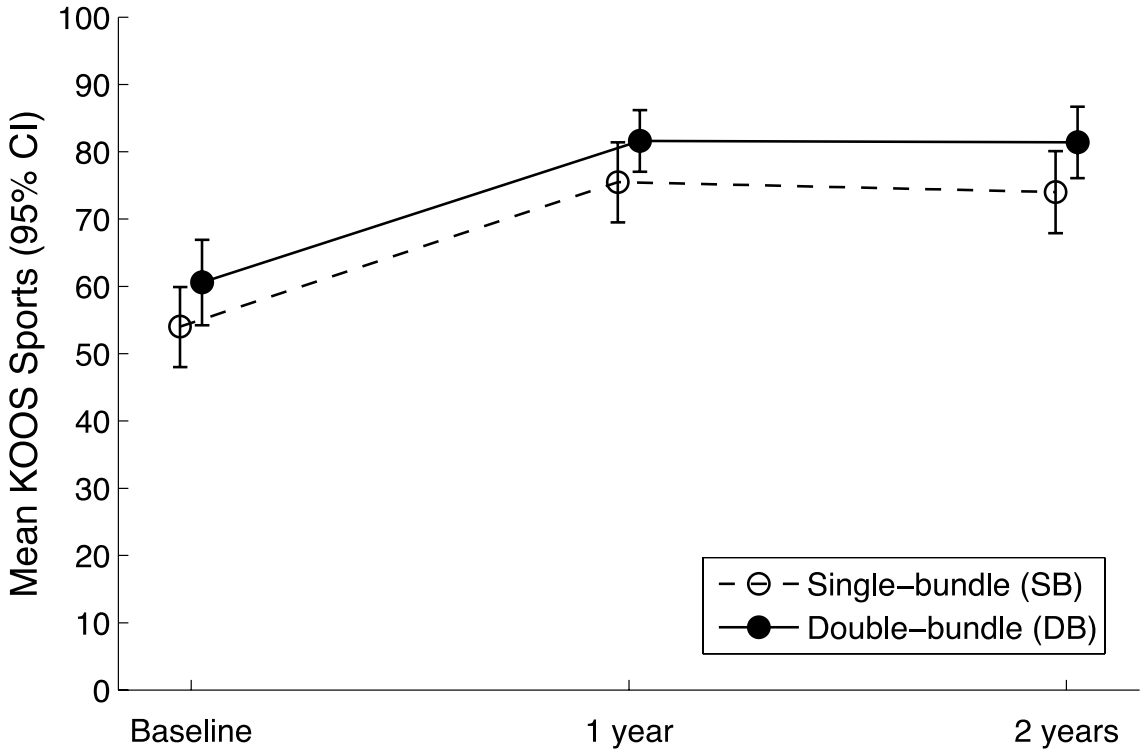

Mean KOOS Sports (95% CI)
100
90
80
70
60
50
40
30
20
10
0
Baseline
1 year
2 years
Single–bundle (SB)
Double–bundle (DB)

Figure 3. a)KOOS Pain, b)KOOS Symptoms , c)KOOS ADL and d)KOOS Sports subscores observed mean values at baseline and at one- and two-year follow-up, with 95% confidence interval (CI); SB, single-bundle(white dots); DB, double-bundle(black dots) . ADL, Activity of Daily Living; Sports, Sports and Recreation.

TABLE 3
Subjective outcome measurements (KOOS,IKDC subjective score)

Outcome variable	Baseline Mean (95%CI)	1-year follow-up Mean (95%CI)	2-years follow-up Mean (95%CI)	Changes from baseline to 2-years, Mean (95%CI)	Between group diff. Mean (95%CI)	p-value*
PRIMARY OUTCOME						
KOOS, Quality of Life						
DB (n=54)	**43.8 (38.3, 49.2)**	**74.5 (68.8, 80.3)**	**72.9 (67.6,78.2)**	**29.2 (23.3, 35.0)**	**-0.5 (-8.4, 7.4)**	**0.91**
SB (n=62)	**37.9 (32.8, 43.0)**	**68.6 (63.4, 73.9)**	**66.6 (61.8,71.4)**	**28.7 (23.3, 34.0)**		
SECONDARY OUTCOMES						
KOOS, Pain						
DB (n=54)	81.7 (78.0, 85.4)	88.0 (84.1, 91.9	90.9 (87.3, 94.5)	9.1 (5.1, 13.2)	3.0 (-2.6, 8.5)	0.29

SB (n=62)	77.3 (73.8, 80.7)	85.7 (82.1, 89.3)	89.4 (86.1, 92.6)	12.1 (8.4, 15.8)		
KOOS, Symptoms						
DB (n=54)	76.2 (72.3, 80.2)	81.8 (77.7, 85.9)	84.7 (80.8, 88.5)	8.5 (4.3, 12.6)		
					1.2 (-4.4, 6.9)	0.67
SB (n=62)	72.9 (69.2, 76.5)	82.1 (78.3, 85.8)	82.6 (79.1, 86.0)	9.7 (5.9, 13.5)		
KOOS, Activity of daily Living						
DB (n=54)	89.6 (86.0, 93.2)	95.0 (91.2, 98.8)	96.8 (93.3, 100.3)	7.3 (3.5, 11.0)		
					3.2 (-1.8, 8.3)	0.21
SB (n=62)	83.9 (80.6, 87.3)	91.5 (88.0, 94.9)	94.4 (91.2, 97.6)	10.5 (7.1,13.9)		
KOOS, Sports and Recreation						
DB (n=54)	60.5 (54.8, 66.3)	81.4 (75.4, 87.5)	81.5 (75.9, 87.1)	21.0 (14.9, 27.1)		
					-0.6 (-8.8, 7.7)	0.89
SB (n=62)	53.9 (48.5, 59.3)	75.7 (70.2, 81.3)	74.3 (69.2, 79.4)	20.4 (14.9, 25.9)		
IKDC, subjective						
DB (n=54)	55.4 (51.9, 58.8)	69.5 (66.0, 73.1)	72.2 (68.8, 75.6)	16.8 (13.5, 20.2)		
					-0.3 (-4.8, 4.2)	0.90
SB (n=62)	51.6 (48.4, 54.8)	64.3 (61.0, 67.6)	68.1 (65.1, 71.2)	16.5 (13.5, 19.6)		

Variable outcome reported as estimated mean values obtained from linear mixed models, with the primary outcome KOOS QoL in bold letters.
DB, double-bundle; SB, single-bundle; CI, confidence interval.
*p.value of the between group difference, from baseline to 2-years follow-up.

Knee laxity evaluations

There were no differences between the two groups for the pivot shift test, Lachman´s test or in the KT 1000 measurements at two-year follow-up (Table 4). In the double-bundle group, 86% (45 of 52 patients) had 0 or +1 in the Lachman´s test at two years, the respective numbers in the single-bundle group was 84 % (51 of 61 patients). Eighty-eight % of the patients in the double-bundle group and 85% in the single-bundle group had a pivot shift 0 or 1+ at two-year follow-up (46 of 52 patients in the double-bundle group, and 53 of 61 in the single-bundle group)(Table 4).

TABLE 4
Knee laxity measurements and ROM

Test	Baseline (n=116)		1-year FU (n=111)		2-years FU (n=113)		DB vs SB 2-years FU	
	DB (n=54)	SB (n=62)	DB (n=50)	SB (n=61)	DB (n=52)	SB (n=61)	Between group diff. (CI)	p-value
Lachman test, n (%)								0.20
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, n (%)								0.53
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		
KT 1000 side-to side diff, mean ± SD, (mm)								
Anterior 134 N	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(-0.3,1.5)	0.19
Anterior MMT	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(-0.4,1.6)	0.27
ROM mean ± SD, (deg)								
Extension deficit					1.9±3.1	2.0±3.2	0.1(-1.3,1.1)	0.89
Flexion deficit					1.9±3.5	2.6±3.8	0.7(-2.1,0.7)	0.31

FU, follow-up; DB, double-bundle; SB, single-bundle; MMT, manual maximum test; CI,confidence intervall; ROM, range of motion

Range of motion and functional tests

There was no difference in range of motion between the two groups (Table 4). Compared to the uninvolved knee, 31% in the double-bundle group had an extension deficit (16 out of 52 patients), versus 34% in the single-bundle group (18 out of 59) at two-year follow-up. The mean deficit in knee extension was 1.9 degrees for the double-bundle group and 2.0 degrees for the single-bundle group (0.08 degrees difference; 95% CI (-1.3 to 0.10); p=0.90). Knee flexion deficits, compared to uninvolved leg, were 27% (14 of 52 patients) for the double-bundle group and 37% (22 out of 59) for the single-bundle group. Mean flexion deficit was 1.9 degrees for the double-bundle group and 2.6 degrees for the single-bundle group (0.70 degrees difference; 95% CI (-0.66 to 2.07); p=0.31) (Table4). The functional performance of the knee was measured by the one-leg hop test. The test reported a significant change in difference from baseline to two years measures in the single-bundle group compared to the double bundle group (23.6 % change in the single-bundle group and 14.6% change in the double-bundle group, 9.1 % difference between the two groups, 95% CI from 0.5 to 17.6, p= 0.04). Both legs achieved more than 97 % of the capacity of the uninvolved leg at the two-year follow-up.

Activity level:

The Tegner activity level and the Sports activity scale level at two-year follow-up were not different between the two groups (Table 5). The rate of the patients that returned to their pre-injury main sport was also not different between the single- and double-bundle group. In the double-bundle group 53% (26 of 53 patients), and in the single-bundle group 44% (27 of 44), returned to sports at two-year follow-up (8.8%, 95% CI, (-9.7% to 26.5%), p=0.39) (Table 5).

TABLE 5
Activity level of the patients

	Baseline		2-years FU		DB vs SB, 2-years FU p-value
	DB (n=54)	SB (n=62)	DB	SB	
Tegner activity scale					
Median (range)	4.0 (1 to 7)	3.5 (1 to 6)	5.0 (1 to 9)	5.0 (2 to 9)	0.77
Missing values	0	0	1	1	
Sports Activity scale					
Median (range)	2 (1 to 4)	2 (1 to 4)	2 (1 to 3)	2 (1 to 4)	0.73
Missing values	1	2	1	1	
Return to sports					
n (%)			26 (53)	27 (44)	0.39
Missing values			5	1	

FU, follow-up; DB, double-bundle; SB, single-bundle; SD, standard deviation.

Radiographic imaging:

Degenerative changes detected by radiographic imaging of the knees revealed that 13 patients had Kellgren-Lawrence grade one and two patients (one in the single-bundle and one in the double-bundle group) had a Kellgren-Lawrence classification grade two at the two-year follow-up.

Adverse events:

Eight graft-ruptures were detected in the single-bundle group, and three in the double-bundle group at two-year follow-up (p=0.16) (Table 6). The graft-ruptures were detected by clinical examination and confirmed by MRI in 9 of the eleven patients. Only one of the patients had a revision ACL before the two-year follow-up. Four patients had a postoperative infection, two in the double-bundle group and two in the single-bundle group. Sixteen patients were hospitalized because of a new surgical procedure within the first two years after the reconstruction. The main reasons for having a reoperation were: infection (n=5), new menisci injury (n=4) or because of cyclops and extension deficit of the knee (n=3) (Table 6).

TABLE 6
Adverse events and reoperations

	DB (n)	SB (n)
Adverse events*	18	25
Graft rupture	3	8
Infection	1	3
Hematoma	8	8
Menisci injury	3	1
Cyclops/ext.def.	1	3
Donor site pain	2	2
Reoperations*	5	11
Revision	0	1
Menisci surgery	3	1
Lavage	2	3
Cyclops/ext.def.	0	3
Others	0	5

DB, double-bundle; SB, single-bundle; ext.def., extension deficit;
*More than one event per patient possible.

Subgroup analysis:

Planned subgroup analysis of the blinded subgroup revealed no further difference in the KOOS QoL subscore compared to the no blinded group (p= 0.98). The number of subjective treatment failures was also not different between the two groups. From 54 patients 3 were treatment failures (5.6%) in the double-bundle group and 10 out of 62 patients (16.1%) in the single-bundle group (10.6% difference, 95% CI (-1.3% to 22.2%), p=0.06) were defined as treatment failures.

A sensitivity analysis comparing the KOOS scores and the knee laxity measurements in patients with only intact grafts at the two-year follow-up did not detect any further differences between the two 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 two groups (p=0.08). The primary outcome in the correctly randomized patients (n=84) gave p=0.96 for the difference between the two treatment arms.

TABLE 7
Subgroup analysis,
Patients without graft-rupture at 2-years follow-up

Subgroup	DB Baseline (n=51)	SB Baseline (n=54)	DB 2-years follow-up	SB 2-years follow-up	Between group differences * Mean difference (CI)	p-value
KOOS, Mean(CI)						
Pain	81.6 (77.9, 85.3)	77.2 (73.6, 80.8)	91.6 (87.9, 95.2)	90.6 (87.2, 94.0)	3.4 (-2.3, 9.2)*	0.24*
Symptoms	75.9 (71.8, 80.0)	73.1 (69.1, 77.0)	85.0 (81.0, 88.9)	83.2 (79.5, 87.0)	1.1 (-4.8, 7.1)*	0.71*
ADL	89.5 (85.8, 93.2)	83.9 (80.2, 87.5)	97.2 (93.5, 100.8)	94.8 (91.4, 98.2)	3.3 (-2.1, 8.6)*	0.23*
QoL	43.6 (38.5, 48.7)	38.3 (33.4, 43.3)	74.7 (69.8, 79.7)	70.0 (65.4, 74.7)	0.6 (-7.4, 8.7)*	0.88*
Sports	61.3 (55.7, 66.8)	54.5 (49.2, 59.9)	82.5 (77.1, 87.9)	77.2 (72.2, 82.3)	1.5 (-6.8, 9.7)*	0.72*
Pivot shift						0.63

Lachman´s test				0.24
KT 1000, Mean±SD				
134 N	1.6 ± 2.1	2.0 ± 2.1	0.4 (-0.4, 1.2)	0.35
MMT	1.9 ± 2.4	2.3 ± 2.3	0.4 (-0.5, 1.3)	0.39

All KOOS values are presented as estimated means from a linear mixed model analysis based on baseline, 1- and 2-years follow-up. DB, double-bundle; SB, single-bundle; MMT, manual maximum test; CI, confidence intervall; SD,standard deviation.
*Between group differences in change of KOOS subscore from baseline til 2-years follow-up

The 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% (mean ± SD) of the total lateral condyle distance (Figure 4a). For the AM bundles the centre 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 27.7 ± 4.3%, the AM tunnels at 24.2 ± 7.0% and the PL tunnels at 45.9 ± 6.6% of the distance from the Blumensaat´s line (Figure 4a).

The mean centre of the tibial tunnels was positioned at 37.7 ± 6.4% of the total anteroposterior distance for the single-bundles, and at 34.2 ± 4.9% for the AM bundles and 49.9 ± 6.4% for the PL bundles (Figure 4b).

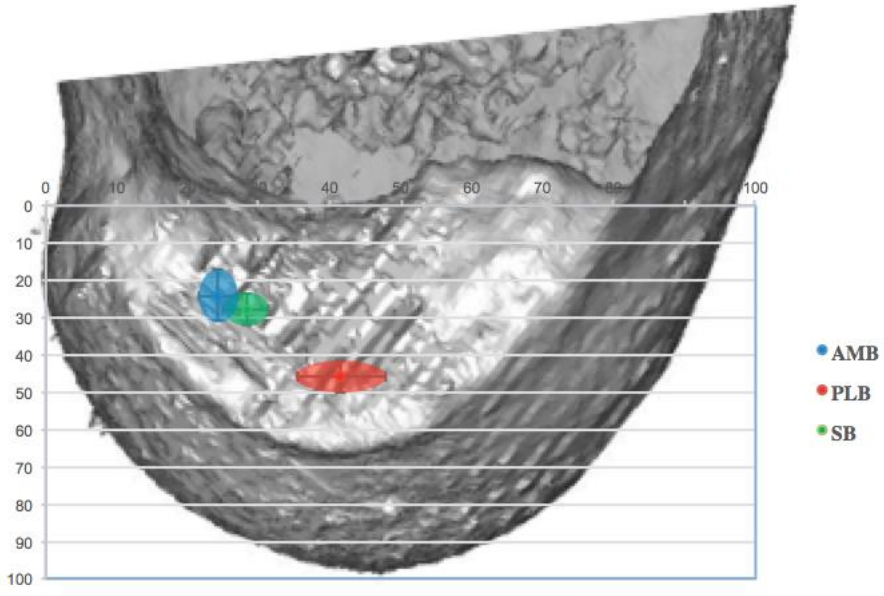
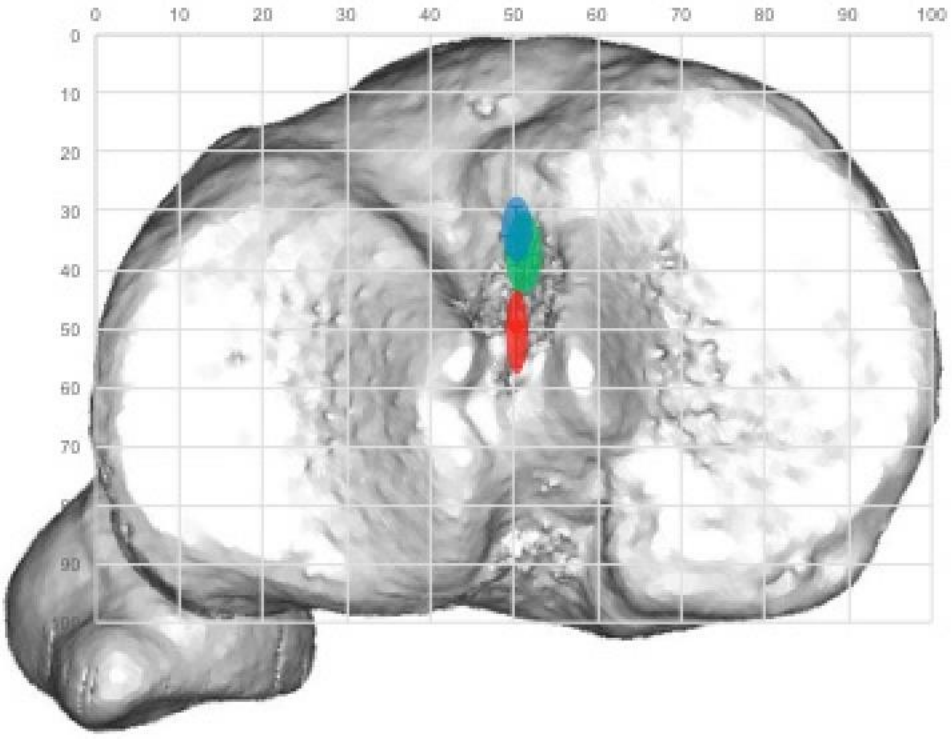


Figure 4a. Femoral tunnel positioning (center ± SD); AM, anteromedial bundle(blue); PL, posterolateral bundle(red); SB, single-bundle(green).

Figure 4b. Tibial tunnel positioning (center ± SD); AM, anteromedial bundle(blue); PL, posterolateral bundle(red); SB, single-bundle(green).



DISCUSSION:

The main finding of the current study was no difference between double-bundle and single-bundle ACL reconstruction at two years follow-up evaluated by KOOS QoL subscore or any of the other subjective outcome measures used. Studies with more focus on PROs after ACL reconstructions have been requested as there has been published a considerable number of studies comparing the objective outcome between the double-bundle and the single-bundle technique.[34] In most of those studies rotational and anteroposterior knee laxity has been the outcome of interest.[3, 23, 35, 56] The KOOS is proven as a reliable, valid and responsive PRO for patients undergoing ACL reconstruction.[40] The KOOS QoL subscore is considered to be the most sensitive and responsive among the five dimensions for ACL injured patient.[40, 41] Ahlden et al. compared the KOOS score of anatomic single-bundle with anatomic double-bundle reconstructions and found a significant improvement in both groups, but no difference between the two groups for any of the five KOOS subscores two years after surgery.[3] Similarly, Sasaki et al. used the KOOS for evaluation of single-bundle rectangular bone-patellar tendon-bone grafts versus double-bundle hamstring reconstructions. They found no difference in KOOS QoL subscore between the two groups at the two-year follow-up.[43] These results are in line with the findings reported from this study. However, knee laxity measurements do not necessarily correlate with the PRO´s. Objective testing of ligament instability are frequently emphasised, although the relation between knee laxity and subjective outcome of the knee has been discussed. One study have found the rotational knee-laxity as measured by the pivot shift test, to correlate with patients satisfaction, sports participation and Lysholm score, but no significant relationship was observed between the Lachman´s test or KT1000 and the subjective scores.[28]

In vitro studies of the double-bundle reconstruction technique showed significantly improved anterior and rotatory knee laxity measures compared to single-bundle reconstructions when the technique was first introduced.[42, 59] More than 30 randomized or quasi-randomized, controlled, clinical trials have so far been published.[34] While some studies proclaim that the double-bundle improve the outcome of

ACL reconstructions, 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 due to the bias introduced by the anatomic single-bundle reconstruction as many of the publications compare non-anatomic single-bundles with anatomic or partly anatomic (only one bundle), reconstructed double-bundles. Studies have shown that drilling of the femoral tunnels through an accessory, anteromedial portal is important to achieve a femoral insertion cite similarly to the native ACL.[8, 14, 60] As anatomic reconstructions gradually was introduced for both single- and double-bundle placement, this could explain how many of the later publications strive to find a difference between the two techniques.[3, 49, 58] Only a few studies have consistently performed their reconstructions 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. found no difference in anterioposterior or rotational laxity, and they found similar IKDC subjective and objective score, Tegner activity score and Lysholm scores in both groups.[17] Ahlden et al. compared the single- and the double-bundle reconstruction technique and found similar results for knee laxity tests and the subjective outcome in both groups.[3] Mayr et al. evaluated the subjective and objective IKDC measurements between the two techniques and did also not find any difference between the two groups.[35] Xu et al. looked at 32 single-bundle and 34 double-bundle patients with clinical tests, PRO´s and 3D-CT measurements. [58] They found no difference in knee laxity measurements or PRO´s between the two groups at the two-year follow-up. The postoperative 3D-CT scans confirmed the anatomic placement of the bundles. Finally, Hussein et al. compared their double-bundle technique to two different single-bundle groups: Non-anatomic and anatomic single-bundle reconstructions.[24] In contrary to the other anatomic studies, they found that the anatomic double-bundle reconstructed knees were superior to both the non-anatomic and anatomic single-bundle reconstructions in rotational and anteroposterior laxity. Their difference in KT 1000 measures was 1.2 mm side-to-side difference in the anatomic double-bundle group and 1.6 mm in the anatomic single-bundle group. The amount of patients with a negative pivot shift test was 99.3% in the double-bundle and 66.7% in the anatomic single-bundle group. Like many other trials, they did not find any difference between the groups in the subjective outcome.[24] In summary, many of the listed studies are

in line with our study; revealing no significant differences between the two techniques for PROs or clinical tests.

In the current study, there was no difference in activity level between the two groups at the two-year follow-up, but the participants reported lower return-to-sport rates than in other studies.[3, 5] One reason could be that the period from injury to operation in the current study was longer (15 months) than reported from other studies.[3, 23] As the patients were advised by the surgeons to avoid pivoting sports for at least 9-12 months after the reconstruction, this could also have affected the return to sports rate. The only outcome variable with a difference between the two treatment options was the one-leg hop test. This test had a higher change from baseline to two-years follow-up in the single- than in the double-bundle group. It was however presumed that these results were prone to a ceiling effect as both DB and SB knees achieved more than 97% (97.8 and 99.8 % in the single- and double bundle group respectively) of the capacity of the non-involved leg at 2-years follow-up.

A 3D CT imaging was obtained in twenty-four patients the first postoperative day. This made it possible to verify the positioning of the femoral and tibial tunnels. Correct tunnel position could be dependent on other structures than distances to the different bone structures as suggested by Bernard et al. and Tsukada et al.[9, 55] And in this study the centre of the tunnels were 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 cadaver knees.[38] According to these studies, the positioning of the AM and PL bundles in this study were in agreement with the anatomic centres. The single-bundle tunnels were placed in the "deeper" and "higher" position compared to most of the anatomic studies.[38] Biomechanical studies have confirmed that the fibers with the highest restrain to the anteroposterior translation of the knee, originate from the proximal area of the femoral ACL attachment site.[26] Only two patients had radiographic signs of knee osteoarthritis at the two-year follow-up defined as Kellgren-Lawrence grade two or worse. However, to detect the posttraumatic cartilage degeneration radiographically, mid- and long-term follow-ups are preferable.

Minimal graft-sizes of the PL and AM bundle were introduced to prevent the double-bundle reconstructions to be 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 out of 120 patients (11.2%), were detected with a KOOS QoL less than 44 points (subjective treatment failures). This is lower than reported from the registers.[7] Thus, in this study the KOOS was answered by more than 95% of the patients. As the coverage of the subjective outcome measurements are generally low in the registers the reported KOOS scores could have been biased due to a high non-responder rate. There has also been stated that low KOOS QoL is correlated to the risk of later ACL revision.[7, 19] Of the 13 subjective treatment failures, only four were detected as having a graft-rupture. This suggests that other factors than the intact or non-intact graft play an important role for the low KOOS QoL scores. There were eight graft-ruptures in the single-bundle and three in the double-bundle group at the two-year follow-up. Two more single-bundle grafts had a partial rupture of the graft on MRI. The relatively high re-rupture rate in the single-bundle reconstructions 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 to transtibial drilling.[39, 51] Suomalainen et al. compared 75 double-bundles to 78 single-bundles. They concluded with significant fewer graft-ruptures in the double-bundle group. However, whereas the number of re-ruptures in the double-bundle group was one, the number of re-ruptures in the single-bundle group was seven.[49] The results should be interpreted with caution as the numbers of events was relatively few as also Suomalainen et al. suggested in their conclusion. In a more extensive register study comparing 52,000 single- and almost 1,000 double-bundle reconstructions in Scandinavia there was no difference in the risk of revision between the two 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 performing ACL reconstructions. 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, patients with revision surgery or multi-ligament surgery of the knee (Figure 1). Blinding of the patients can make an impact on the results of clinical studies.[57] Particularly when collecting subjective outcome blinding may prevent overestimation of the treatment effect.[57] A planned sensitivity analysis of a blinded subgroup of the patients was therefore carried out, and this analysis did not reveal any further difference between the two groups for the primary outcome.

Thirty-two patients did not achieve the correct treatment from the randomisation-list. The reason why the allocated procedure was not in line with the computer-generated list is unknown, but it could have been due to incorrect handling of the envelopes. The box of envelopes with block-randomised treatment options, were carried down in the operating room at the days of surgery. The assisting staff opened the envelopes at request of the surgeon. Even though the surgeon reported what treatment each included patient was randomized to in their journals, 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 two groups. The double-bundle group consisted of more males than the single-bundle group. In a Swedish register study, they found that the male sex was over-representative in the group of high KOOS scores (defined as functional recovery), but there was no gender difference in the group of low KOOS scores (KOOS QoL<44 points).[7] A higher proportion of males in the double-bundle group could potentially have overestimated the treatment effect in this group. The quality of the rehabilitation is of importance for the final results after ligament reconstructions.[20] It was assured that all participants went to a physiotherapist with

knee-injury expertise for rehabilitation. However, the compliance was not monitored. Neither were psychosocial aspects of the patients assessed, such as fear of re-injury and differences in the motivation to return to previous activity and activity level.[4, 5] To increase the reliability and the validity of the 3D-CT positioning of the tunnels, CT-measurements from a larger group of patients and inter- and intraclass correlation scores should have been performed.

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

Conclusion:

In the current randomized trial, there were no differences in KOOS QoL subscore, knee laxity measures or activity level comparing the double-bundle and the single-bundle ACL reconstruction techniques. Both the single- and double-bundle reconstructions 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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