Comparing the anatomic single-bundle versus the anatomic double-bundle for anterior cruciate ligament reconstruction: A prospective, randomized, single blind, clinical study

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ORIGINAL ARTICLE

Comparing the anatomic single-bundle versus the anatomic double-bundle for anterior cruciate ligament reconstruction: a prospective, randomized, single blind, clinical study

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Abstract
Purpose The aim of this study was to compare the early results of anatomic single bundle versus double-bundle anterior cruciate ligament (ACL) reconstruction.
Methods We conducted a prospective randomized study of anatomic single-bundle versus double-bundle ACL reconstruction using the hamstring tendons of 67 patients with unilateral ACL deficiency. The subjects were randomized into two groups. The single-bundle group consisted of 37 patients and the double-bundle group 30 patients. We used the following evaluations: clinical examination, KT-1000 arthrometry, Tegner knee score, modified Cincinnati score, Knee Injury and Osteoarthritis Outcome Scale (KOOS), International Knee Documentation Committee (IKDC) score. Two surgeons performed all operations, and a blinded independent author conducted the clinical follow-up assessments.
Results The mean follow-up period was 25.8 months. The differences between the preoperative and postoperative clinical examinations and the KT-1000 measurements were statistically different in both groups ($p<0.05$). There were no statistically significant differences between the groups. Tegner knee scores, modified Cincinnati scores, and KOOS and IKDC scores showed statistically significant improvement in both groups ($p<0.05$). There were no statistically significant differences between the groups.
Conclusions This prospective study found no difference between the outcomes of the anatomic single-bundle and the anatomic double-bundle ACL reconstructions.
Level of evidence II.

Keywords ACL reconstruction · Double bundle · Single bundle · Anatomic

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Introduction

Traditional transtibial single-bundle anterior cruciate ligament (ACL) reconstruction is considered the gold standard for ACL surgery. Clinical studies, however, have demonstrated that transtibial ACL reconstruction often produces vertical grafts that result in loss of motion and residual laxity [1]. That is, the transtibial technique fails to restore normal knee function and does not prevent osteoarthritis in a high percentage of patients [2–4]. At the same time, a cadaveric study showed the inability of single-bundle reconstruction produced by conventional transtibial drilling to restore normal laxity [5]. Opponents of transtibial single-bundle ACL reconstruction suggest that this approach does not restore the native anatomy and may therefore not provide normal knee kinematics, which they hypothesized could lead to early osteoarthritic changes over time [4]. It has been shown that the ACL consists of two functional bundles: an anteromedial (AM) bundle and a posteromedial bundle. Anatomic reconstruction has been developed to prevent early degeneration. In this context, "anatomic" means that the tunnels are placed in the native ACL insertion site regardless of how many bundle are used [6]. The purpose of this prospective, randomized clinical study was to evaluate the clinical outcomes of arthroscopic anatomic single-bundle ACL reconstruction versus arthroscopic anatomic double-bundle ACL reconstruction.

Patients and methods

The local ethics committee approved this study (ID number: 08087). We obtained written informed consent from all of the patients in the study.

A total of 67 patients with ACL deficiency were included in our study (from June 2006 to January 2011). The actual number of ACL operations was nearly 300 during the same time interval. Patients with partial ACL rupture, meniscal pathology, chondral lesions, misalignment of the lower extremity, and/or previous surgery to the same knee were excluded from the study to obtain homogeneous group. Patients were also excluded from the study if they did not give their consent, complete the rehabilitation program fully, or attend regular checkups. Randomization was performed according to the patients' date of birth. Patients whose date of birth ended with an odd number comprised group 1 and patients whose date of birth ended with an even number comprised group 2. Arthroscopic reconstruction with the anatomic single bundle was performed in the group 1 patients, and arthroscopic reconstruction with the double bundles was done in the group 2 patients. Group 1 consisted of 37 patients and group 2 of 30 patients. If we did not perform the double-bundle reconstruction for any reason in a group 2 patient, that patient was not included in the study.

There were 65 male and two female patients, with an average age of 27.6 years (range 16–56 years). In all, two patients were injured in a work accident and 65 had sports injuries. The latter were related to volleyball in two patients (2.9 %) and soccer in 63 patients (94.0 %). The affected extremity was the right knee in 64 % of the patients and the left knee in 36 %. The average interval between the injury and the operation was 7 weeks (range 3–24 weeks). The mean follow-up was 25.8 (range 18–72) months.

Two independent examiners performed the clinical and functional evaluations, including the Lachman test, pivot-shift test, anterior drawer test, and KT-1000 arthrometry (MEDmetric, San Diego, CA, USA). Each patient was evaluated with non-weight-bearing lateral and anteroposterior (AP) radiography and magnetic resonance imaging to rule out evidence of osteoarthritis or misalignment at the time of surgery. The functional evaluation was performed using the Tegner, modified Cincinnati, and Knee Injury and Osteoarthritis Outcome (KOOS) scores prior to the operation in both groups of patients.

Surgical procedure

Two consultant surgeons performed all of the surgical procedures. The patients underwent general anesthesia or spinal anesthesia and a tourniquet. The Lachman test, pivot-shift test, and anterior drawer test were performed in all patients under anesthesia.

Generally, the operation began by harvesting the graft. If we were unsure if the ACL had ruptured, diagnostic arthroscopy was first applied. An accessory anteromedial port was used with a standard anteromedial port plus an anterolateral port if necessary. The femoral side was prepared via an anteromedial or auxiliary anteromedial port (not transtibially) with a free-hand technique without guidance. We created the femoral and tibial bone tunnels at the original position of the AM bundle footprint for the single and double-bundle reconstructions. We added a bone tunnel at the posterolateral bundle (PL) footprint in the double-bundle group and at the central position between these two bundles in the single-bundle group. The tibial tunnel guide angle was 55° in the single-bundle group. Both tibial tunnel guide angles were 45° in the double-bundle group.

Autogenous hamstring grafts were used for all single- and double-bundle reconstructions. Graft fixation in all cases was performed using the Loop Endobutton CL® (Smith & Nephew, Mansfied, MA, USA) for the femoral fixation. Tibial fixation was performed with an oversized bioabsorbable screw (Bio-RCI HA®; Smith & Nephew) and a U-pin. In 20 patients, the fixation was reinforced with a staple. In the single-bundle group, the tibial fixations were performed at 30° flexion of the knee. During tibial fixation in the double-bundle group, the knee flexion angles were 45° for the AM bundle and 15° for the PL bundle (Figs. 1 and 2).

Rehabilitation

The same rehabilitation program was applied to both groups. Quadriceps strengthening movements began on the first day after the operation. Passive exercises were performed twice a day during the patients' hospitalization using a continuous passive motion (CPM) device. The patients continued active exercises on the edge of the bed throughout the day by adjusting the flexion and extension values to the last value available on the CPM device. Walking with crutches and partial weight bearing were allowed without a brace or splint for the first 3 weeks. Six weeks after surgery, the patients returned to performing activities of daily living. Noncontact sports were permitted after 3 months and contact sports at 1 year after surgery.

Statistical analysis

SPSS version 20.0 for Windows software (SPSS, Chicago, IL, USA) was used for statistical analysis. The quantitative

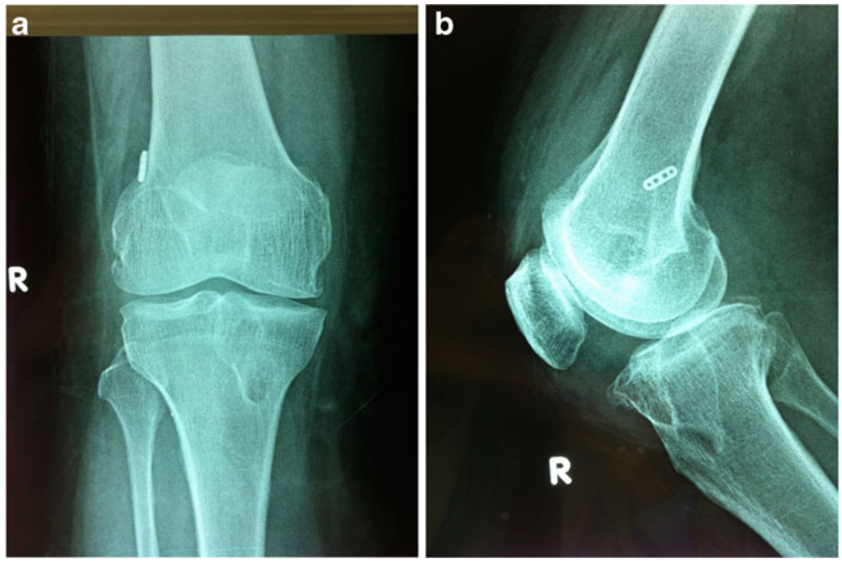

Fig. 1 **a** A 26-year-old male patient that underwent single bundle ACL reconstruction anterior–posterior view. **b** Lateral view

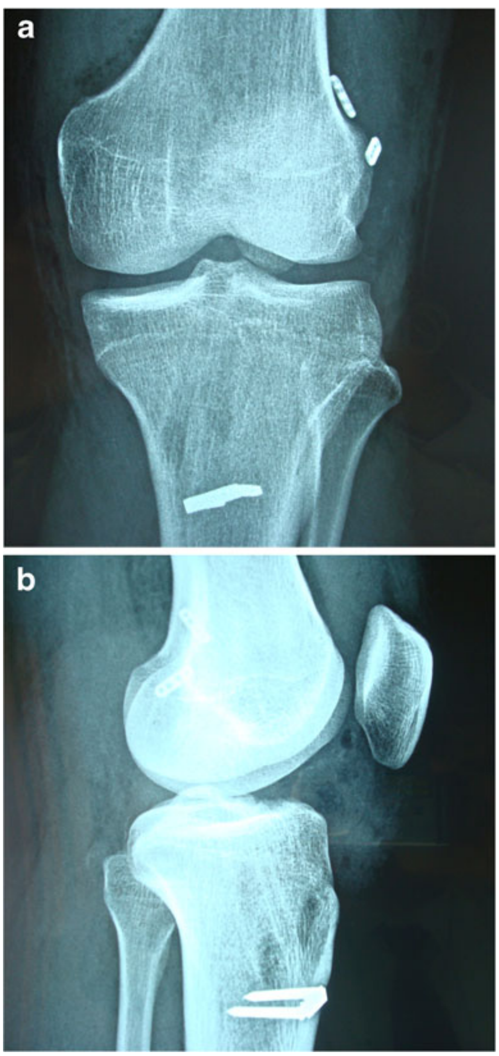

Fig. 2 **a** A 27-year-old male patient that underwent double-bundle ACL reconstruction. **b** Lateral view

variables were shown as the means, standard deviations, medians, numbers, and percentages. The differences between the preoperative and postoperative values were evaluated using a Wilcoxon test and paired *t* test, depending on the normal distribution. The Kolmogorov–Smirnov test was used for separation of parameters, and an independent *T* test was used for discrepancy analysis. The Mann–Whitney *U* test was used to determine the equality of variances and if the data were statistically accepted as meaningful. The significance level was set at $p<0.05$.

Results

The mean follow-up period was 25.8 (range 18–72) months. No patients experienced distress or loss of control. Swelling and minimal pain were detected after forced activity in eight patients (11.9 %). The Lachman test and pivot-shift test following the operation were negative in all patients (Table 1). Patients' preoperative AP instability was determined by KT-1000 arthrometry (Table 2), which revealed statistically significant differences between preoperative and postoperative measurements in the two groups, but there were no statistically significant differences between the groups.

In group 1, the mean preoperative Tegner knee score was 52.6 (range 31–65). At 6 months after surgery, it was 82.2 (range 51–100), and at 1 year, it was 84.1 (range 49–100). In group 2, the mean preoperative Tegner knee score was 55.3 (range 41–63). At 6 months after surgery, it was 80.8 (range 59–95), and at 1 year, it was 79.9 (range 62–96). There were statistically significant differences between the preoperative and postoperative measurements in both groups ($p<0.05$), but there were no statistically significant differences between the groups.

Table 1 Evaluation results for first and second groups at preoperation and postoperation

	Group 1 (single-bundle) preoperation	Group 1 (single-bundle) postoperation	Group 2 (double-bundle) preoperation	Group 2 (double-bundle) postoperation
Lachman test				
0	0	35	0	30
(+)	6	2	5	0
(++)	17	0	14	0
(+++)	14	0	11	0
Pivot-shift test				
Negative	11	37	6	30
Positive	26	0	24	0

In group 1, the mean preoperative modified Cincinnati score was 50.2 (range 33–68). At 6 months after surgery, it was 82.2 (range 50–100), and at 1 year, it was 83.2 (range 60–100). In group 2, the mean preoperative modified Cincinnati score was 49.0 (range 32–70). At 6 months after surgery, it was 80.4 (range 40–98), and at 1 year, it was 81.3 (range 50–100). There were statistically significant differences between the preoperative and postoperative measurements in both groups ($p<0.05$), but there were no statistically significant differences between the groups.

In group 1, the mean preoperative KOOS score was 52.0 (range 36.5–72.0). At 6 months after surgery, it was 79.4 (range 60.5–93.6), and at 1 year, it was 80.3 (range 60.7–95.0). In group 2, the mean preoperative KOOS score was 56.8 (range 37.4–73.2). At 6 months after surgery, it was 81.7 (range 50.9–95.5), and at 1 year, it was 83.5 (range 50.6–95.0). There were statistically significant differences between the preoperative and postoperative measurements in both groups ($p<0.05$). At 1 year after surgery, the KOOS scores of group 2 were better than those of group 1, a difference that was statistically significant ($p<0.05$).

Preoperative and postoperative International Knee Documentation Committee (IKDC) scores for both groups are shown in Table 3. There were statistically significant differences between the preoperative and postoperative measurements in both groups ($p<0.05$), but there were no statistically significant differences between the groups.

Table 2 Translation differences between the two knees of patients in groups 1 and 2 with KT-1000 device

	Group 1 preoperation	Group 1 postoperation	Group 2 preoperation	Group 2 postoperation
<3 mm	5	35	1	29
Between 3–5 mm	20	2	16	1
>5 mm	12	0	13	0

Table 3 IKDC scores

	Group 1 ($n=37$)	Group 2 ($n=30$)	Significance
IKDC score			
Preoperatively			
Normal	0	0	n.s.
Nearly normal	3	1	n.s.
Abnormal	27	25	n.s.
Severely abnormal	7	4	n.s.
1 year follow-up			
Normal	26	22	n.s.
Nearly normal	9	7	n.s.
Abnormal	2	1	n.s.
Severely abnormal	0	0	n.s.

Discussion

The most important finding of this study was that the outcomes of anatomic double-bundle ACL reconstruction were not superior to the outcomes of anatomic single-bundle ACL reconstruction.

Single-bundle reconstruction is the technique most commonly used for ACL injuries as it provides clinical results that are acceptable in most cases. There is, however, an appreciable failure rate that may necessitate revision surgery, and some cases are only partially successful including a group of patients who have residual "pivot–glide," which is reported to occur in 14–30 % of patients [7].

Several anatomic studies have shown that the ACL consists of two major bundles: the AM and PL bundles [8, 9]. When the knee flexes, the AM bundle is tight, and the PL bundle is loose. During knee extension, the AM bundle is loose, and the PL bundle is tight. The PL bundle contributes more to rotational stability [9, 10].

Previous research has shown that the native ACL footprint shows a large variation in size [11, 12]. The tibial and femoral insertions are most commonly 12–16 mm [13]. However, typical graft sizes for autograft single-bundle reconstruction are 7–9 mm for soft tissue grafts and 9–11 mm for bone–tendon grafts. The native footprint can therefore be filled only partially [14]. Hence, in theory, double-bundle ACL reconstruction is thought to yield better results than single-bundle reconstruction. Whether single-bundle or double-bundle reconstruction is better for treating ACL ruptures is thus controversial [9]. Some studies have shown no difference between these reconstruction techniques, whereas others have shown that double-bundle ACL reconstruction is better than single-bundle ACL reconstruction [9, 15–23]. For example, some retrospective studies have reported significantly better anterior stability in patients with the double-bundle ACL reconstruction along with more negative Lachman and pivot-shift tests. Recent publications emphasize the importance of rotational laxity after ACL surgery which double bundle reconstruction may be superior to single bundle [23–26]. On the other hand, instrumented manual devices and some robotic testing systems developed for rotational measurements are not available worldwide and are not used in this clinical trial. [25–28]. Three studies reported decreased pivot-shift after double-bundle ACL reconstruction, but these studies included nonanatomic positions for the femoral tunnel [29–31]. Another study reported that anterior stability is significantly better after double-bundle reconstruction based on the results of objective tests, but no difference was found based on subjective tests. Goldsmith et al. reported no significant differences were found between anatomic single bundle and double-bundle reconstructions for simulated pivot shift or anterior tibial loading [23, 32]. Suomalainen et al., in a prospective randomized study, reported that single-bundle ACL reconstruction is associated with more graft failures than double-bundle ACL reconstructions after 5 years. They also found no difference in the stability measurements between the two groups [33]. A meta-analysis performed by Meredick et al. failed to prove the superiority of the double-bundle method, but they lacked long-term follow-up times and needed a better study plan [34]. Xu et al. reported that a meta-analysis of randomized controlled trials revealed that double-bundle ACL reconstruction resulted in significantly better anterior and rotational stability and higher IKDC objective scores than single-bundle reconstruction [24].

Our study design was prospective, randomized, and blinded. The results of our study were similar in the two groups in regard to anterior and rotational stability. It is known that double-bundle ACL reconstruction provides good anterior and rotational stability, but we showed that anatomic single-bundle ACL reconstruction provides equal anterior and rotational stability.

The main limitation of this study was the short follow-up time and a low number of patients. We excluded from the study patients with associated meniscal pathologies, chondral lesions, collateral ligament injuries, misalignment of the lower extremity, and previous surgery on the same knee to lower bias in the statistical analysis. If a patient in the double-bundle group did not undergo double-bundle reconstruction for any reason (e.g., narrow notch, insufficient autograft) that patient was not included in the study. Patients were also excluded from the study if they did not give their consent, complete the rehabilitation program fully, or attend regular checkups. Also, patients on whom an allograft was used were not included.

Optimal ACL reconstruction is still an important clinical issue in orthopedic research. In particular, longer follow-up times are needed for assessment of osteoarthritis and to determine the optimal technique for ACL reconstruction.

Conclusion

This prospective study found no difference between the outcomes of anatomic single-bundle and anatomic double-bundle ACL reconstruction. Both reconstruction techniques were capable of restoring AP and rotational stability of the knee. Restoring normal anatomy via ACL reconstruction provides a good outcome, which is of utmost importance to the patient.

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