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Prospective Clinical Comparisons of Anatomic Double-Bundle Versus Single-Bundle Anterior Cruciate Ligament Reconstruction Procedures in 328 Consecutive Patients

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Background: Several trials have been conducted to compare the clinical results between anatomic double-bundle and single-bundle anterior cruciate ligament (ACL) reconstruction procedures. In these studies, however, the number of patients was insufficient to compare the clinical results of the 2 procedures.

Hypothesis: The anatomic double-bundle procedure may be significantly better concerning the anterior laxity and the pivot-shift test than the single-bundle procedure, while there may be no significant differences in the other clinical evaluations and the intra-operative and postoperative complications between the 2 procedures.

Study Design: Cohort study; Level of evidence, 2.

Methods: Three hundred and twenty-eight patients with unilateral ACL reconstruction using hamstring autografts were divided into 2 groups. The first 157 consecutive patients underwent single-bundle reconstruction and the remaining 171 patients underwent anatomic double-bundle reconstruction. Concerning all background factors, there were no statistical differences between the 2 groups. Each patient was examined 2 years after surgery.

Results: No serious complications were experienced in either group. The anterior laxity was significantly less in the double-bundle reconstruction (mean, 1.2 mm) than in the single-bundle reconstruction (mean, 2.5 mm). In the pivot-shift test, the double bundle (+ indication, 16%; ++, 3%) was significantly better than the single bundle (+ result, 37%; ++, 12%). The mean Lysholm score averaged 96.5 points and 97.3 points in single-bundle and double-bundle reconstructions, respectively, while the International Knee Documentation Committee evaluation showed that 90 and 110 patients, respectively, were evaluated as rank A (no significant difference between groups). There were no significant differences in the other clinical evaluations and the complications between the 2 procedures.

Conclusions: The postoperative anterior and rotational stability after the anatomic double-bundle ACL reconstruction was significantly better than that after the single-bundle reconstruction, although there were no significant differences between the 2 procedures concerning the complications and the clinical evaluations.

Keywords: anterior cruciate ligament; anatomic double-bundle reconstruction; hamstring tendon autograft; posterolateral bundle; clinical outcome

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Single-bundle anterior cruciate ligament (ACL) reconstruction has been a standard option to treat symptomatic ACL-deficient knees. Recently, however, Woo et al³⁷ reported that the single-bundle reconstruction cannot completely restore the normal anterior laxity, and that it is not effective for the rotatory instability. According to recent kinetic studies,^{9,12,13,32,33,36} the single-bundle reconstruction with the bone–patellar tendon–bone (BTB) or hamstring tendon graft did not show any significant effects on the

rotatory instability during walking or more active activities. The normal ACL consists of the anteromedial (AM) and posterolateral (PL) bundles, each having different functions.^{5,6,11,23,35,49} The concept of double-bundle ACL reconstruction was initially described in the 1980s.^{28,50} Recently, authors reported the first clinical procedure for "anatomic" double-bundle ACL reconstruction with 2-year follow-up results, in which they defined this procedure as involving transplantation of the 2 tendon grafts at the center of the anatomic attachment of the AM and PL bundles, respectively, in both the tibia and the femur.^{43,44} More recently, several prospective clinical trials have been conducted to compare the clinical results between anatomic double-bundle and single-bundle procedures.^{3,19,38,46} These studies reported that the anatomic double-bundle procedures were significantly better than the single-bundle procedures concerning the pivot-shift test and/or anterior laxity. In these studies, however, the number of patients (20 to 35) was insufficient to compare the overall clinical results, including the complications.

We have conducted a prospective, comparative cohort study of >300 patients to compare our anatomic double-bundle and single-bundle procedures. On the basis of our previous studies,^{21,22,42,46} we hypothesized that the anatomic double-bundle procedure may be significantly better concerning the anterior laxity and the pivot-shift test than the single-bundle procedure, while there may be no significant differences in the range of knee motion, the muscle strength, the Lysholm knee score, the International Knee Documentation Committee (IKDC) evaluation, and the intraoperative and postoperative complications between the 2 procedures. The purpose of this study was to test this hypothesis.

MATERIALS AND METHODS

Study Design

A prospective, comparative cohort study was conducted in patients who underwent ACL reconstruction with the hamstring tendon autograft, performed by a sufficiently trained surgeon (K.Y.) between 1999 and 2004. In 1999, we planned to perform single-bundle reconstruction using a 6-strand hamstring tendon autograft in 1999 and 2000 (group S) and double-bundle reconstruction using 4-strand and 2-strand hamstring tendon autografts in 2001 and 2002 (group D) for all patients who would agree to participate in this study under informed consent. Each patient showed chronic ACL deficiency in the unilateral knee at the time of surgery. The diagnosis of injured ligaments was made based on a detailed history of the knee injury, physical examination on pathologic status and abnormal laxity, routinely performed plain radiographs and MRI scans, and the findings at surgery. Patients with a combined ligament injury in the posterior cruciate ligament, the lateral collateral ligament, the posterolateral corner structures of the knee, and medial collateral ligament (grade 3) were excluded from this study. In addition, patients with any previous operations for ligament injuries, a concurrent fracture, or osteoarthritis were excluded. The time from onset of injury to surgery was 2 months or more.

Between 1999 and 2000, 178 patients were enrolled in this study; and 157 patients (89%, which excludes the 21 patients who were lost to follow-up) were evaluated as group S in this study. Between 2001 and 2002, 189 patients were enrolled in this study, and 171 patients (90%, excluding 18 patients lost to follow-up) were evaluated as group D. This clinical study design had been accepted by the institutional review board clearance in our hospital before commencement, based on the described study design and informed consent. All patients were informed that if they did not want to be in this study, they could choose another reconstruction procedure that was available at the moment. Other surgical options in this hospital included single-bundle reconstruction with the BTB graft and double-bundle reconstruction with the hamstring graft described by Rosenberg et al³⁴ in the first 2 years,⁴⁶ while they involved single-bundle reconstruction with BTB or hamstring graft in the second 2 years. The patients who did not want to take part in this prospective study were not enrolled in this study. In addition, we informed the patients that the anatomic double-bundle procedure was continuously being developed at Hokkaido University in parallel with this clinical trial.

Two years after surgery, each patient was examined with the standard clinical evaluation methods. In group S, there were 85 men and 72 women with a mean age of 25 years at the time of surgery. Group D included 101 men and 70 women with a mean age of 27 years. We identified no statistical differences between the 2 groups with regard to age, gender, height, weight, or time to surgery (Table 1). The follow-up period ranged from 24 to 60 months.

One senior orthopaedic surgeon (K.Y.), who was sufficiently trained concerning each procedure, performed all operations using the same procedure for each group. At the time of reconstruction, the medial or lateral meniscus was partially resected in 93 patients (51 in group S and 42 in group D), and repaired in 13 patients (5 in group S and 8 in group D). No treatment was administered for softening or fissuring of the articular cartilage. In each group, an approximately 4-cm-long incision was made in the AM portion of the proximal tibia, and the semitendinosus and gracilis tendons were harvested using a tendon stripper. Each reconstruction procedure was performed using the arthroscopically assisted 1-incision (transtibial tunnel) technique. Each graft was secured with EndoButtons (Smith & Nephew Endoscopy, Andover, Massachusetts) on the femur and with 2 staples (Meira, Nagoya, Japan) on the tibia. All patients underwent postoperative management with the same rehabilitation protocol (Table 2).⁴⁴

Single-Bundle Reconstruction Procedure

The single-bundle reconstruction procedure was performed using precisely described techniques.⁴⁴ Briefly, the semitendinosus tendon was quadrupled and the thickest portion of the gracilis tendon was doubled. Both the free ends were firmly sutured side by side at 3 different sections, using the circumferential ligation technique with 2-0 polyester threads.^{46,47} A commercially available polyester tape (Leeds-Keio artificial ligament, Neoligament, Leeds, England,

TABLE 1
Comparison of Background Factors of Patients Between Groups S and D^a

Background Factors	Group S (N = 157)	Group D (N = 171)
Mean age in years (range)	25 (13-52)	27 (14-57)
Male:female ratio	85:72	101:70
Mean interval between injury and operation (months)	12	16
Meniscal injury (partial meniscectomy/repair)	51/5	42/8
Mean height in cm (standard deviation)	166 (8)	168 (9)
Mean mass in kg (standard deviation)	65 (12)	67 (14)

^aThere were no significant differences between the 2 groups. Group S, single-bundle procedure group; group D, anatomic double-bundle procedure group

TABLE 2
Postoperative Rehabilitation Protocol^a

Time Period (Postoperative)	Activities
Immediately	Walking (half weightbearing) with an immobilization brace ROM exercise (0°-30°) Simultaneous quadriceps and hamstrings (at 30° of knee flexion) Leg raising Reversed leg raising Hip abduction
2 Weeks	Walking (full weightbearing) with a functional brace ROM exercise (0°-120°) Separate isometric quadriceps (at 70° of knee flexion) Squatting (at 90° of knee flexion) Leg curl
4 Weeks	Walking Half squat exercise (range, 70°-90°)
8 Weeks	ROM exercise (0°-140°) Half squat exercise (range, 30°-90°) Fast walking Bicycling Calf raise Stairs exercise (walking)
12 Weeks	ROM exercise (full range)
16 Weeks	Isokinetic exercise (range, 30°-90°) Squat exercise (full range) Swimming (flutter kick)
20 Weeks	Jogging Isokinetic contraction (full range)
9 Months	Running, hopping, jumping rope Backwards running, carioca (lateral crossover)
12 Months	Competitive sports

^aROM, range of motion.

United Kingdom) was then mechanically connected in series with the sutured end, using the original "hybrid" technique.^{47,48} We then passed another polyester tape through 2 holes of an EndoButton. We passed both ends of the tape through the looped end portion of the tendon graft, and the tape ends were sutured side by side using the circumferential ligation technique (Figure 1). Notchplasty was performed with a curved chisel and curette because the single-bundle graft was relatively thicker than the normal bundle of the ACL. To create a tibial tunnel, we used a

hole-in-1 guide system (Wire-navigator, Meira, Nagoya, Japan), which was precisely explained in an earlier article (Figure 2A).⁴⁴ The Wire-navigator is composed of a Navi-tip and a Wire-sleeve. The Navi-tip consists of sharp tibial and femoral indicators. The axis of the Wire-sleeve passes through the tip of the tibial indicator. The Navi-tip was introduced into the joint cavity through the medial infrapatellar portal. Then, keeping the tibial indicator at the center of the most posterior aspect of the normal ACL insertion between the medial and lateral tibial eminences, we aimed

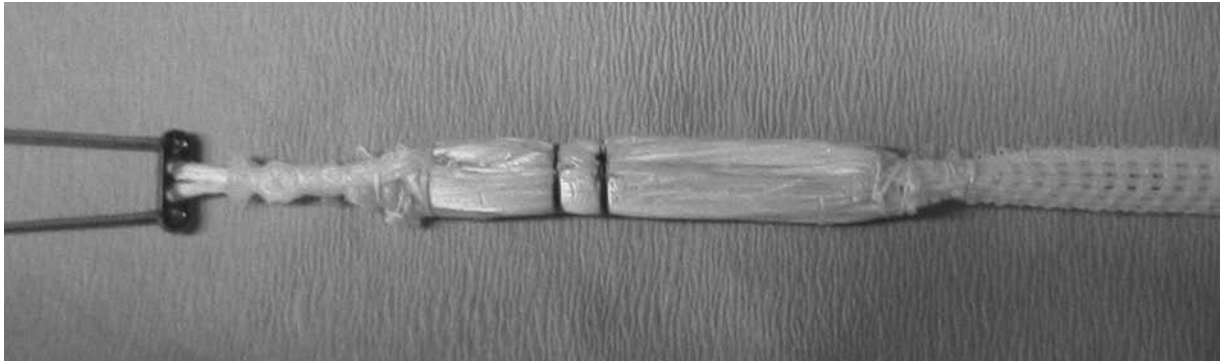


Figure 1. The hamstring tendon autografts were connected in series with polyester tapes and an EndoButton for the single-bundle procedure. The diameter of the tendon portion was 8 to 11 mm and the length was approximately 55 to 60 mm.

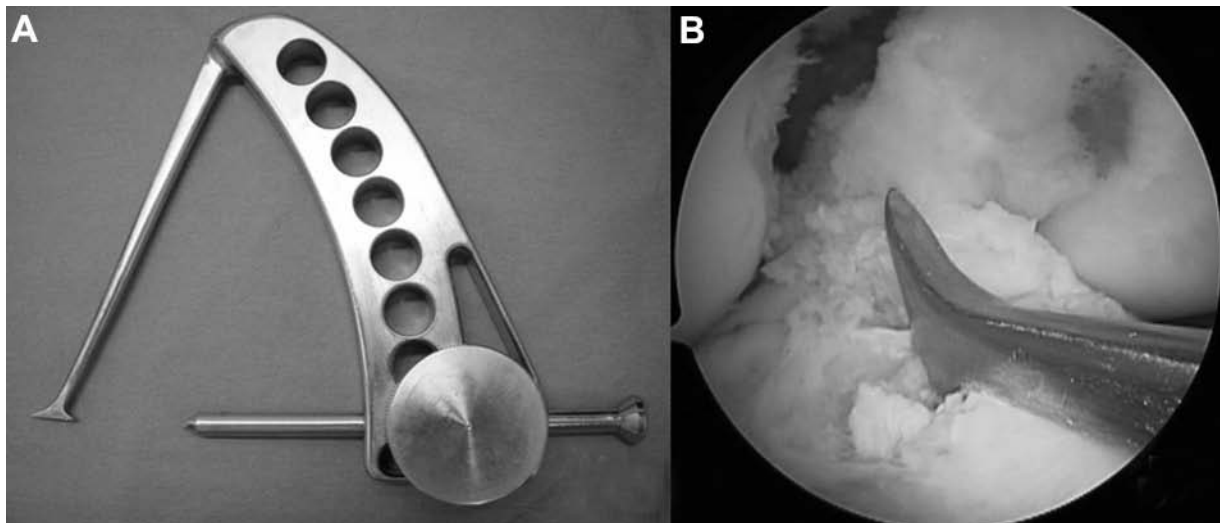


Figure 2. A, the Wire-navigator is composed of a Navi-tip and a Wire-sleeve. The Navi-tip consists of sharp tibial and femoral indicators. The axis of the Wire-sleeve passes through the tip of the tibial indicator. B, the Wire-navigator for the tibial tunnels in arthroscopic surgery. The axis of the Wire-sleeve is passed through the tip of the tibial indicator. Keeping the tibial indicator at this point, we aimed the femoral indicator at a targeted point on the femur.

the femoral indicator at the center of the AM bundle footprint on the femur (Figure 2B). A guide wire was inserted into the tibia through the Wire-sleeve. A tibial tunnel was created with a cannulated drill with a diameter matched to the width of the prepared graft (Figure 3A). A Kirschner wire (K-wire) was then drilled into the lateral femoral condyle at the 1:30 o'clock (or 10:30) position for the knee, using the transtibial tunnel technique. This location is in the standard position reported in most literature on single-bundle reconstruction.¹⁷ To decide the most appropriate point on the femur, we used a 5-mm or 6-mm offset guide system (transtibial femoral ACL drill guide, Arthrex, Naples, Florida). Then the drill system for EndoButton fixation was used to create a femoral tunnel. First, a tunnel was made with a 4.5-mm-diameter cannulated drill using the wire as a guide. The length of the femoral tunnel was measured with a scaled probe. Finally, a socket for the tendon

autograft was created with cannulated drills for the EndoButton system, the diameter of which were matched to the prepared grafts (Figure 3B). The graft diameter in the single-bundle procedure ranged from 8 to 11 mm (mean, 9.3 ± 0.8 mm). After the graft was placed in the tibial and femoral tunnels (Figure 3C), the femoral side was secured with an EndoButton and the tibial side was fixed onto the tibia with 2 spiked staples (Meira), using the turn-buckle stapling technique (Figure 3D).^{47,48} Before the fixation, an initial tension of 80 N was applied to the graft with a spring-type tensiometer (Meira) at 30° of knee flexion.⁴⁴

Anatomic Double-Bundle Procedure

The details of the anatomic procedure were previously described in the literature.⁴⁴⁻⁴⁶ Briefly, the harvested semitendinosus tendon was cut in half. The gracilis tendon was

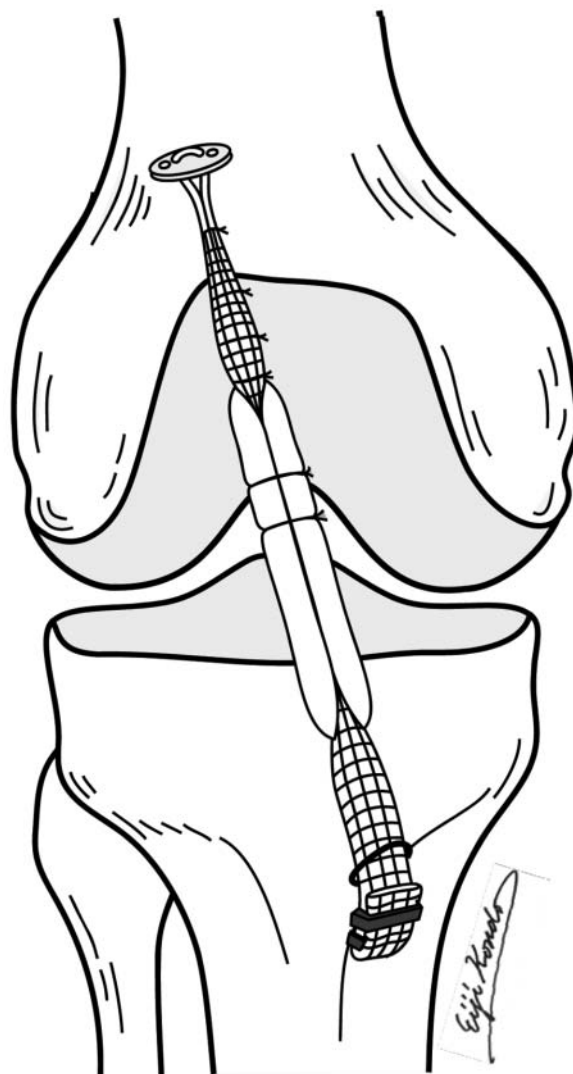
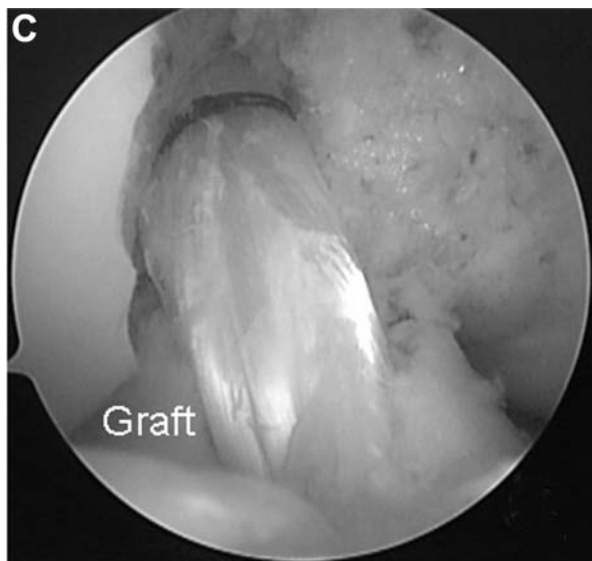
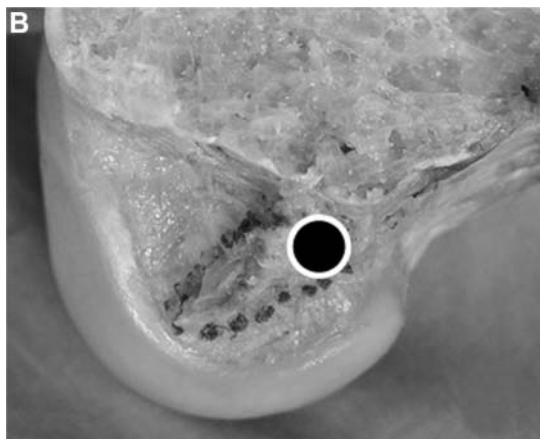
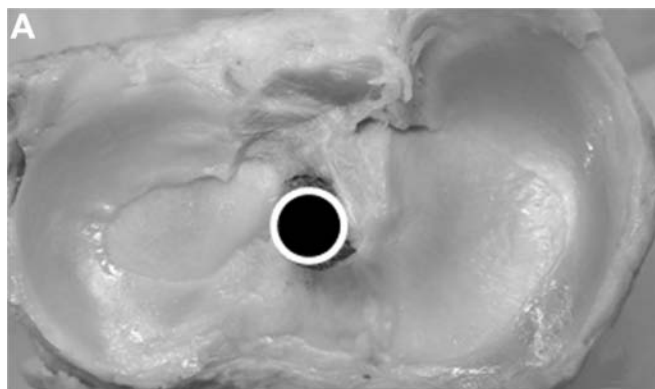


Figure 3. Single-bundle ACL reconstruction procedure. These images were obtained in our previous anatomic study by use of a cadaver.⁴⁴ A, a single tibial tunnel outlet was created at the center of the most posterior aspect of the normal ACL insertion between the medial and lateral tibial eminences in the single-bundle procedure (group S). B, the single femoral tunnel outlet was located at the 1:30 o'clock (or 10:30) position for the knee. C, 1 graft transplanted across the knee joint at the time of surgery at 90° of knee flexion in arthroscopic view by use of the lateral infrapatellar portal. D, schematic illustration.

resected so that the length was matched to one-half of the semitendinosus tendon. Using one-half of the semitendinosus tendon and the resected gracilis tendon, a “hybrid” graft for AM bundle reconstruction was fashioned with 2 polyester tapes (Neoligament) and an EndoButton in the

same manner as the single-bundle procedure. The remaining half of the semitendinosus tendon was also doubled, and the same type of fashioning was performed for a PL bundle graft (Figure 4). The additional cost using this added construct is only an Endobutton (Smith & Nephew

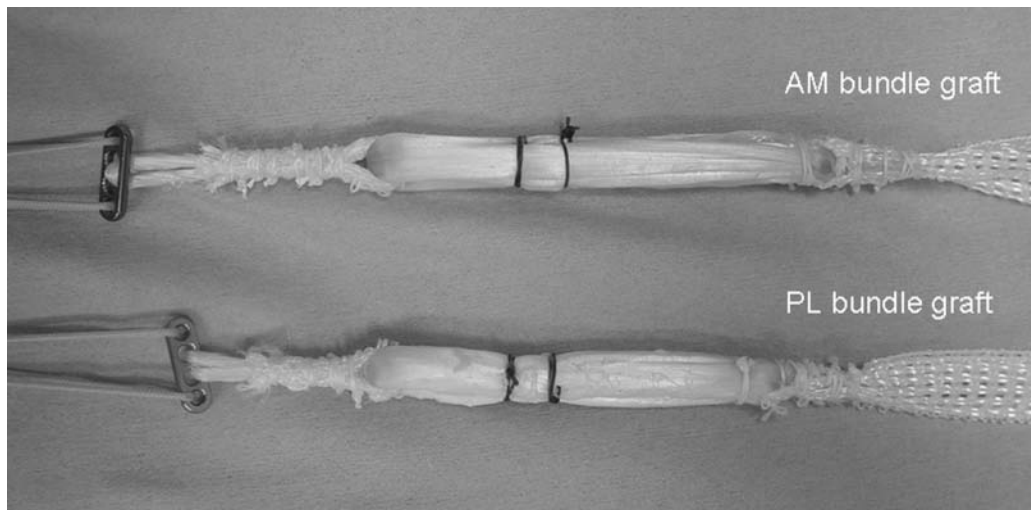


Figure 4. The hamstring tendon autografts were connected in series with polyester tapes and EndoButtons for the double-bundle reconstruction. The anteromedial (AM) bundle graft was 6 to 9 mm in diameter and 55 to 60 mm in length. A posterolateral (PL) bundle graft was 5.4 to 7 mm in diameter and 45 to 50 mm in length.

Endoscopy). We inserted an arthroscope through the lateral infrapatellar portal. The ACL remnant was resected, leaving a 1-mm-long ligament tissue at the femoral and tibial insertions to obtain landmarks for inserting guide wires. When an osteophyte was formed at the notch in chronic cases, notchplasty was performed. First, a tibial tunnel for the PL bundle was created. To insert a K-wire as a guide wire, we used a Wire-navigator. The Navi-tip portion of this device was introduced into the joint cavity through the medial infrapatellar portal. The surgeon held the tibia at 90° of knee flexion, keeping the femur horizontal. The tibial indicator of the Navi-tip was placed at the center of the PL bundle footprint on the tibia, which was located at the most posterior aspect of the area between the tibial eminences and 5 mm anterior to the posterior cruciate ligament. Then, keeping the tibial indicator at this point, we aimed the femoral indicator at the center of the PL bundle footprint on the femur. Subsequently, the direction of the extra-articular Wire-sleeve was automatically decided. The proximal end of the sleeve was fixed on the AM aspect of the tibia through the skin incision made for the graft harvest. A K-wire of 2 mm in diameter was drilled through the sleeve in the tibia.

We then drilled a tibial tunnel for the AM bundle. The same Wire-navigator was used to insert a K-wire. The tibial indicator of the Navi-tip was placed at the center of the tibial footprint of the AM bundle. The center was located at a point approximately 7 mm anterior to the K-wire for the PL bundle. Keeping the tibial indicator at this point, we then aimed the femoral indicator at the center of the femoral footprint of the AM bundle, which was located 5 mm anterior to the most posterior aspect of the notch at the junction of the intercondylar roof and the medial wall of the lateral femoral condyle. This point is positioned at the 1:30 o'clock (or 10:30) position. The wire sleeve is fixed on the AM cortex. At this point, the knee was extended to

ensure the tip of the second wire was located at the point 5 mm posterior to the anterior edge of the roof in the intercondylar notch. A K-wire was drilled through the sleeve in the tibia. The 2 tibial tunnels were made with a cannulated drill corresponding to the measured diameter of the prepared substitute (Figure 5A).

To create 2 femoral tunnels for the AM and PL bundles in the lateral condyle, first a K-wire was drilled at the center of the femoral footprint of the AM bundle through the second tibial tunnel, by use of the previously described 5-mm or 6-mm offset guide system (Arthrex). With the use of this wire as a guide, a tunnel was made with a 4.5-mm cannulated drill. The length of the tunnel was measured with a scaled probe. The portal for an arthroscope was then changed to the medial infrapatellar portal because it was difficult to precisely identify the attachment of the PL bundle through the lateral infrapatellar portal. The surgeon again held the tibia at 90° of knee flexion, keeping the femur horizontal. The surgeon manually held the K-wire and aimed it at the center of the PL bundle attachment on the femur through the tibial tunnel. The surgeon first hammered the wire into the femur and then drilled it. A 4.5-mm-diameter tunnel was drilled, and its length was measured in the same manner. Finally, 2 sockets were created for the AM and PL bundles, respectively, with cannulated drills for the EndoButton fixation system (Smith & Nephew Endoscopy), the diameter of which were matched to the 2 grafts prepared with the technique described below (Figure 5B). In the double-bundle procedure, the AM graft diameter ranged from 6 to 9 mm (mean, 7.1 ± 0.7 mm), and the PL graft diameter ranged from 5.4 to 7 mm (mean, 5.8 ± 0.4 mm).

The graft for the PL bundle was introduced through the tibial tunnel to the femoral tunnel by use of a passing pin. The EndoButton was flipped on the femoral cortical surface. The graft for the AM bundle was then placed in the

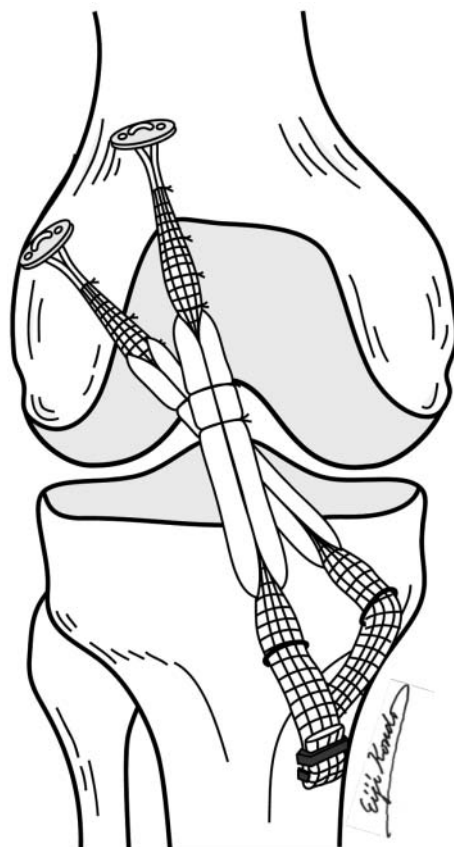
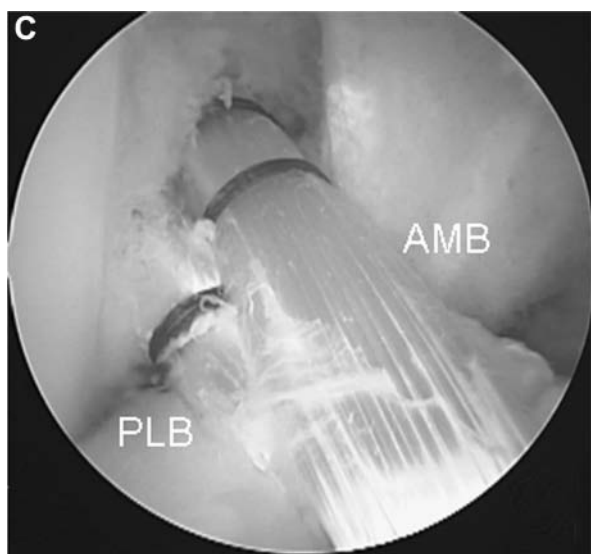
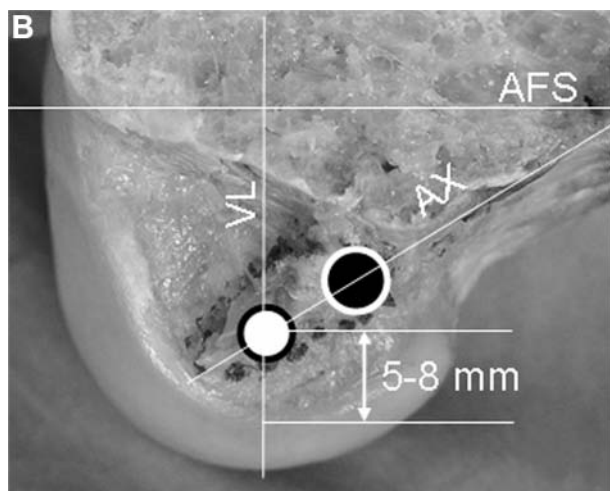
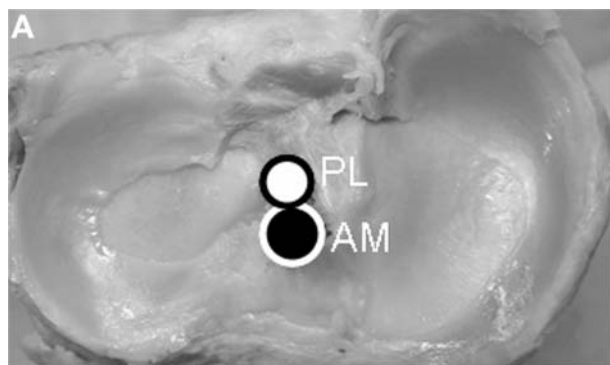


Figure 5. Anatomic double-bundle reconstruction procedure. These images were obtained in our previous anatomic study by use of a cadaver.⁴⁴ A, bone tunnel position in attachment of the ACL on the tibia. AM, tunnel outlet of anteromedial bundle; PL, tunnel outlet of posterolateral bundle. B, bone tunnel position in attachment of the ACL on the femur. A picture of the lateral condyle was taken with a precise medial view (AFS, parallel line of axis of femoral shaft). When we drew a vertical line (VL) through the contact point between the femoral condyle and the tibial plateau on a picture taken at 90° of flexion, this line and the long axis of the ACL attachment (AX) crossed at the PL point on the vertical line 5 to 8 mm anterior to the edge of the joint cartilage. The center of the attachment of the PL bundle was located approximately at this crossing point. The center of the attachment of the AM bundle was located at the point 5 to 6 mm distal from the back of the femur in measurements using the offset guide. C, 2 grafts transplanted across the knee joint at the time of surgery at 90° of knee flexion in arthroscopic view by use of the lateral infrapatellar portal. AMB, anteromedial bundle graft; PLB, posterolateral bundle graft. D, schematic illustration.

same manner. Thus, the 2 bundles are intra-articular with different directions (Figure 5C). For graft fixation, the thigh was manually fixed on a sterilized hard pillow placed

on the operating table, keeping the heel in contact with the operating table. This allows the knee to be flexed to 10° with the unsecured leg. A spring tensiometer (Meira) was

TABLE 3
Comparisons of the Anterior Stability of the Knee^a

	Group S (N = 157)	Group D (N = 171)	P Value (Group S vs D)
Mean side-to-side anterior laxity in mm (standard deviation)	2.5 (2.5)	1.2 (1.9)	$P < .0001$
Pivot-shift test			$P < .0001$
-	80	139	
+	58	27	
++	19	5	

^aGroup S, single-bundle procedure group; group D, anatomic double-bundle procedure group.

TABLE 4
Comparisons in the Clinical Outcome between Groups S and D

	Group S (N = 157)	Group D (N = 171)
Loss of knee motion		
Loss of extension (>5°)	3 patients	7 patients
Loss of flexion (>15°)	9 patients	2 patients
Mean Lysholm knee score (standard deviation)	96.5 (5.8) points	97.3 (3.3) points
International Knee Documentation Committee evaluation		
A (normal)	90 patients	110 patients
B (nearly normal)	48 patients	53 patients
C (nearly abnormal)	16 patients	8 patients
D (abnormal)	3 patients	0 patients
Mean isokinetic peak torque ^a		
Quadriceps muscle	88.9 (16.7)	89.4 (14.4)
Hamstring muscles	90.9 (20.4)	94.3 (19.5)

^aRatio of the treated knee to the uninjured knee, expressed as a percentage (standard deviation).

attached at each end of the polyester tape portion of the graft. An assistant surgeon simultaneously applied tension of 40 N to each graft for 2 minutes using the tensiometer. A surgeon simultaneously secured the 2 tape portions onto the AM aspect of the tibia using 2 spiked staples (Meira) in the turn-buckle fashion (Figure 5D).

Clinical Evaluations

Each patient underwent clinical examinations 2 years after surgery. The side-to-side anterior laxity was measured with a KT-2000 arthrometer (MEDmetric, San Diego, California) at 30° of knee flexion under an anterior drawer force of 133 N. A well-trained physical therapist who was not a coauthor of this study and was blinded to the procedure collected the KT-2000 arthrometer results postoperatively. One well-trained orthopaedic surgeon (E.K.), who was blinded to the procedure, performed the pivot-shift test, the results of which were subjectively evaluated by the examiner. In evaluation of the pivot-shift test, the indication of ++ was defined when the examiner felt a sudden rotational slip movement between the tibia and femur, a so-called jog, during the test for the injured knee. The ++ pivot-shift test result showed an obvious failure of the ACL function. The

indication of + was defined when the examiner felt some difference in the rotational movement during the test between the injured and uninjured knees but did not obviously feel the sudden rotational slip movement. This condition showed some insufficiency of the ACL function but did not show a complete failure of the ACL. As to overall evaluation, the Lysholm knee score (maximum score, 100 points) and the IKDC form were used. Peak isokinetic torque of the quadriceps and the hamstrings was measured at 60 deg/s of angular velocity using Cybex II (Lumex, Ronkonkoma, New York) in both knees before and after surgery. Muscle torque as measured postoperatively in the uninvolved knee was represented as a ratio (percentage) to the uninvolved value.

Statistical Analysis

A priori power analysis was performed. A sample size of 300 was calculated to have >90% power to test the hypothesis. Statistical comparison between the 2 groups was performed using the χ^2 test and unpaired Student *t* test. A commercially available software program (StatView, SAS Institute, Cary, North Carolina) was used for statistical calculation. The significance level was set at $P = .05$.

RESULTS

Clinical Evaluations

The postoperative side-to-side anterior laxity measured with the KT-2000 arthrometer averaged 2.5 mm and 1.2 mm in groups S and D, respectively (Table 3). The anterior laxity was significantly less in group D than in group S ($P < .0001$). Eighteen knees (12%) and 5 knees (3%) showed laxity >5 mm in groups S and D, respectively. The χ^2 test showed a significant difference between groups S and D ($P = .0025$).

Regarding the pivot-shift test, 58 and 19 patients were rated as + and ++, respectively, in group S, while 27 and 5 patients were rated as + and ++, respectively, in group D (Table 3). The χ^2 test showed a significant difference between groups S and D ($P < .0001$).

As for the postoperative loss of terminal knee motion, the Lysholm knee score, the IKDC evaluation, and the peak muscle torque, there were no significant differences between the 2 groups (Table 4). However, 16 and 3 knees were ranked C and D, respectively, in group S, while only 8 knees were ranked as C in group D (no knees ranked D).

Intraoperative and Postoperative Complications

The total operation time between the skin incision and the skin closure averaged 81 ± 25 minutes in group S and 84 ± 30 minutes in group D. There was no significant difference between the 2 groups. In the cases with only the ACL reconstruction, the total operation time averaged 68 ± 16 minutes in group S and 78 ± 25 minutes in group D. The operation time for the double-bundle procedure was significantly longer than that of the single-bundle procedure ($P = .0336$).

During surgery, there were no serious complications such as iatrogenic cartilage injuries, serious malposition of the tunnels, graft fixation failure, etc. As for minor intraoperative problems, an EndoButton was flipped within the lateral vastus muscle in 5 and 9 knees of groups S and D, respectively. In the 9 buttons in group D, 7 and 2 buttons were used to fix the PL and AM bundles, respectively. The malposition of an EndoButton was clinically suspected immediately after flipping the button, confirmed by taking radiographs during surgery, and reduced to an appropriate position during surgery by palpating the button with a surgeon's fingertip inserted along with the intermuscular septum through an approximately 2-cm-long incision on the anterolateral skin of the distal thigh. Thus, there were no patients who showed malposition of the EndoButton in the postoperative radiographs. Concerning minor intraoperative problems, there were no significant differences between the 2 groups.

There were no serious postoperative complications including fractures, deep vein thrombosis, and infections in either group. Between 10 months and 2 years after surgery, 8 and 5 patients complained of moderate knee pain in the involved knee in groups S and D, respectively. These knees underwent arthroscopic examinations, and partial meniscectomies were performed in 10 knees (6 and 4 in groups S and D, respectively) and the microfracture technique in 3 knees (2 and 1 in groups S and D, respectively).

Two patients (1 from each group) who showed recurrence of knee instability were diagnosed as complete disruption of the graft by using second-look arthroscopy. One patient with a failed semitendinosus and gracilis graft subsequently underwent reconstruction with a contralateral hamstring autograft. The other patient declined further surgery. Concerning the postoperative complications, there were no significant differences between the 2 groups.

DISCUSSION

The present study demonstrated that the clinical results of both the anterior laxity and the pivot-shift tests were significantly better after the anatomic double-bundle reconstruction than after the single-bundle reconstruction in our procedures. On the other hand, there were no significant differences in the range of knee motion, the muscle torque, and rate of return to sports activities between the 2 procedures. Also concerning the IKDC evaluation, we could not find any statistical significance between the 2 procedures, although the anatomic double-bundle reconstruction revealed some tendency of superiority to the single-bundle reconstruction. The present study also showed that there are no significant differences concerning the intraoperative and postoperative complications between the 2 procedures. Specifically, there were no serious complications such as fractures and infections, which surgeons had been afraid might occur after the anatomic double-bundle reconstruction,¹⁵ in either group.

There are some limitations in this study. The first limitation is that the patients were not truly randomized because randomized studies are not well received by Japanese patients in the case of surgical treatment. Therefore, we conducted a prospective, comparative cohort study instead because it was one of the methods more readily accepted by our patients. In this study, the grouping was not affected by the physician's will. Although age, gender, and the time from injury to surgery are not completely the same between the 2 groups, there were no statistical differences. The second limitation is that because we only evaluated ACL reconstructions with hamstring tendon graft, we cannot refer to ACL reconstructions with the BTB graft. The third limitation is that the follow-up period was only 2 years. Therefore, at the present time, we cannot speculate whether there will be differences between the single-bundle and double-bundle procedures in terms of long-term outcome of knee function and return to sports. The fourth limitation is that we did not precisely evaluate the ability of sports performance because, in the short-term results, these parameters are commonly favorable, independent of reconstruction procedures. In the present study, in fact, all patients in each group were able to return to their chosen sport between 9 and 18 months after surgery. In the future, we should conduct a long-term follow-up study to compare the subjective evaluation and the ability of sports performance between the 2 groups.

In this study, we used a commercially available polyester tape (the Leeds-Keio artificial ligament) in our ACL reconstruction. However, we did not use this tape as an artificial

ligament or an augmentation device, but as one of the fixation devices for the hamstring tendon graft to the bone. Namely, the tape was connected in series with the doubled tendon using our original technique,^{47,48} and only the autogenous tendon portion was placed across the joint. It is well known that weak points of the hamstring tendon graft fixed with sutures to the bone are (1) low stiffness of the graft-suture-bone complex, (2) rapid relaxation of the graft tension after surgery, and (3) difficulty in tension control during graft fixation. The "hybrid graft" was used to improve upon these weak points. Namely, the femur-graft-tibia complex with the hybrid graft involves the following advantages according to many biomechanical properties with the tensile test and the cyclic loading test^{20,27,41}: (1) higher stiffness and stronger ultimate load than the complex with the suture method; (2) more resistance to the graft tension relaxation; and (3) clinically, an acceptably long and thick hybrid graft can be fashioned by surgeons with a relatively short or thin autogenous tendon, and the hybrid graft can be more easily fixed to the bone, applying a tension quantified by using a tensiometer to the graft. We understand that the hybrid graft technique is not common for ACL reconstruction at the present time. However, we believe that the technique will be useful for ACL reconstruction if such a polyester tape becomes commercially available in other countries.

In most patients with single-bundle reconstruction, we performed a minimal notchplasty, because the single-bundle graft was relatively thicker than the normal ACL and had no anatomic twist. This is a relatively common problem in single-bundle reconstruction. Many studies^{16,17} have reported that graft impingement to the notch reduces the clinical outcome of the ACL reconstruction because of mechanical causes. In the anatomic double-bundle reconstruction, most patients did not exhibit the graft impingement, because the placed AM and PL grafts were relatively thin and anatomically twisted in the intercondylar notch. Therefore, the notchplasty was performed only when an osteophyte was formed at the notch in chronic cases. Thus, there is the obvious difference concerning the frequency of notchplasty between the 2 groups. LaPrade et al²⁴ reported that an aggressive intercondylar notchplasty may cause articular cartilage histopathologic changes. There is a possibility that the difference in the frequency of notchplasty between the two groups may lead to increased laxity. However, our notchplasty was not aggressively performed but minimally carried out. No studies have reported that a small notchplasty provides any detrimental effects. Therefore, we consider that the relatively high frequency of minimal notchplasty in the single-bundle reconstruction may not be a primary cause of the increased laxity in the outcome.

Previous biomechanical studies^{4,8,25} reported that single-bundle ACL reconstruction frequently leaves a residual "mini-pivot." In earlier clinical studies to evaluate single-bundle reconstruction, however, sufficient attention has not been paid to the residual mini-pivot, although the anterior laxity has been highly focused. Recently, several clinical studies^{3,7,10,29} reported that 32% to 42% of the patients had a positive pivot shift as grade 1 or 2 at a few years after

single-bundle ACL reconstruction using a hamstring graft fixed with various devices. In addition, concerning side-to-side anterior laxity measured by the KT-1000 arthrometer after single-bundle ACL reconstruction using a hamstring graft, Beynon et al⁷ reported an average value of 4.4 mm and Aglietti et al² reported 2.2 mm with a wide range. These clinical studies implied that the results of the pivot-shift test and the anterior laxity after conventional single-bundle reconstruction procedures may be worse than the commonly expected value. These clinical results may be explained by above described biomechanical studies.^{4,8,25,37} In addition, many kinetic studies^{9,12,13,32,33,36} demonstrated that patients with nominally successful ACL reconstructions may have abnormally increased tibial rotation during walking or more active activities. In our clinical results, for the postoperative pivot-shift test after our single-bundle ACL reconstruction using hamstring graft with Endobutton and staples, 37% and 12% of patients were rated as + and ++, respectively. The postoperative side-to-side anterior laxity measured with the KT-2000 arthrometer averaged 2.5 mm in single-bundle reconstruction. Thus, the results of our single-bundle reconstruction were similar to the previously reported results after various single-bundle hamstring reconstruction procedures. Concerning the failure rate, there were a few definitions in the previous literature. It remains difficult to use the mini-pivot for definition of failure of ACL reconstruction because no studies have used it in the definition, and the evaluation of the pivot-shift test is subjective. Noyes et al³⁰ stated that the magnitude of anterior subluxation depended on the examiner's technique. In our considerations, anterior laxity >5 mm is a clear definition of failure of ACL reconstruction. According to this definition, 12% and 5% of the patients showed anterior laxity >5 mm in our single-bundle and double-bundle reconstruction, respectively. There was a statistical significance between the 2 procedures. However, we do not consider that the clinical outcome of our single-bundle procedure is representative of various single-bundle reconstruction procedures. The present study was conducted to compare the clinical results between 1 single-bundle procedure and 1 double-bundle procedure that were performed by 1 surgeon. Further clinical studies are needed concerning comparisons with other single-bundle procedures.

Previously, a few clinical studies reported that there were no significant differences in the quantified knee laxity between their single-bundle and double-bundle ACL reconstruction procedures.^{1,14} However, they described that the tunnel for PL bundle reconstruction was created at the 2 to 3 o'clock position. In addition, they created only 1 tunnel in the tibia. From the viewpoint based on the current anatomic knowledge, there is a strong possibility that these femoral tunnel positions were not on the attachment of the normal AM or PL bundles. Recently, 4 prospective clinical trials with Level 2 evidence are available to be compared with the present study.^{3,19,38,46} Yasuda et al⁴⁶ and Aglietti et al³ reported that their anatomic double-bundle reconstruction procedures were better in both the pivot-shift test and the quantified anterior laxity than their single-bundle reconstruction procedures. Yagi et al³⁸ reported that their anatomic double-bundle reconstruction procedures were better in the pivot-shift test measured with magnetic

sensors than their single-bundle reconstruction procedures, and Jarvela¹⁹ showed similar results with the conventional pivot-shift test. However, in these 4 studies the number of patients was not sufficient (20 to 30 patients in each compared group) to make a clinical conclusion. Therefore, the present study was conducted using over 150 patients in each compared group. The present study has supported the results reported by Yasuda et al⁴⁶ and Aglietti et al.³ We believe that our anatomic double-bundle reconstruction procedure can more frequently obtain better anterior and rotatory stability of the knee than our single-bundle reconstruction procedures, when sufficiently trained surgeons perform the operation. An essential goal of ACL reconstruction is to obtain stability near that of the normal, contralateral knee. The degree of improvement in knee stability is only a few millimeters, but we recognize that such improvement has advanced ACL reconstruction in these 20 years. However, because the present study is a short-term follow-up, we cannot estimate the clinical benefits for each patient in long-term follow-up evaluations, which may result from such short-term improvement in stability. Therefore, long-term follow-up studies are needed in the future.

Commonly in single-bundle reconstruction, the tibial tunnel is placed at a posterior location between the medial and posterior eminences to prevent impingement of a thick graft. Therefore, the intra-articular single graft was vertically located across the knee joint. This location may be one of the reasons why we found a relatively high rate of mini-pivot^{4,8,25} after our single-bundle reconstruction in the present study. Recently, the laterally placed femoral tunnel of the 2 to 3 o'clock orientation is recommended for single-bundle reconstruction. We should recognize that such single-bundle procedures may be similar in clinical stability to the anatomic double-bundle procedure. Recently, however, a biomechanical study⁴⁰ reported that the laterally placed single-bundle reconstruction is inferior in knee stability to the anatomic double-bundle procedure when the knee is flexed, and a clinical randomized study³⁸ found that the anatomic double-bundle procedure was significantly superior in the quantified pivot-shift test to the laterally placed single-bundle reconstruction.

In the present study, there were no significant differences in the other clinical measures (range of knee motion, muscle strength, Lysholm knee score, etc) between the 2 procedures. It has been the minimal requirement for ACL reconstruction procedures in these 10 years to obtain excellent short-term results in these clinical measures. We contend that because both our double-bundle and single-bundle procedures achieved this requirement, we could not detect any statistical difference between the 2 procedures. We also consider that because the IKDC evaluation scale included the evaluation on these clinical measures, it could not show any statistical difference between the 2 procedures. Therefore, the lack of significant difference between the 2 procedures in the other clinical measures does not imply disadvantages of the anatomic double-bundle reconstruction procedure. These clinical results show that the anatomic double-bundle reconstruction procedure is not a risky procedure concerning the fundamental clinical

measures (range of knee motion, muscle strength, and Lysholm knee score) compared with the single-bundle procedure.

In the cases with only the ACL reconstruction, this study showed that the operation time for the double-bundle procedure was slightly but significantly longer than that of the single-bundle procedure. However, the mean difference was only 10 minutes. We believe that the operation time for the double-bundle procedure is acceptable as compared with the operation time of various knee surgeries, if sufficiently trained surgeons perform this surgery. Technically, however, the anatomic double-bundle reconstruction procedure may be more difficult than single-bundle procedures. There has been considerable concern that the complication rate may be higher in the anatomic double-bundle reconstruction than for single-bundle procedures.¹⁵ However, the present study showed that there were no significant differences in the intraoperative and postoperative complication rate between the 2 procedures. This result suggested that the complication rate in the anatomic double-bundle reconstruction is the same as that in single-bundle procedures, if experienced surgeons perform this surgery. Concerning the surgeon's skill, one author (K.Y.) had experienced approximately 100 cases of nonanatomic double-bundle reconstruction and 20 cases of anatomic double-bundle reconstruction performed in another hospital before the commencement of operation for this study. However, beginners in ACL reconstruction should take much care to avoid intraoperative and postoperative complications, specifically in double-bundle ACL reconstructions.

We considered why the results of knee stability are superior in the anatomic double-bundle reconstruction in our clinical study compared with the single-bundle reconstruction. A few biomechanical studies using a robotic manipulator have shown that the anatomic double-bundle reconstruction produces a better outcome concerning both the anterior and rotatory stability of the knee, specifically in the extension positions of $<30^\circ$, compared with the single-bundle reconstruction.^{26,39,40} In addition, a recent study³¹ showed that the anatomic reconstruction with 2 tibial tunnels produced better biomechanical outcome at 0° and 30° of flexion than the anatomic reconstruction with 1 tibial tunnel. Although arthroscopic anatomic double-bundle procedures for human patients are technically more difficult than experimental procedures for cadaveric knees, currently in vivo biomechanical studies using position or force sensors showed that knee kinematics and graft functions similar to those obtained in the above-described cadaveric studies could be obtained in arthroscopic procedures for human patients.^{18,42} In addition, an arthroscopic second-look study showed that both the AM and PL bundles were successfully reconstructed in 96% of the 132 patients with the anatomic double-bundle ACL reconstruction.²¹ These in vitro and in vivo studies support the present results in the knee stability after the anatomic double-bundle ACL reconstruction in comparison with the single-bundle reconstruction. Namely, external forces loaded to the ACL are distributed to the 2 reconstructed bundles. Therefore, excessively overloading to 1 bundle can be avoided during the remodeling phase, resulting in good maturation of not only the PL graft but also the AM graft.

In addition, because each bundle in the double-bundle reconstruction is thinner than in the single-bundle reconstruction, the core portion of the former graft may be revascularized sooner than that of the latter graft. At the present time, however, we have to state that these theoretical advantages should be proved in future clinical studies.

Finally, although the present study showed promising results of the anatomic double-bundle ACL reconstruction procedure, further clinical studies, including quantitative evaluation of the effects on the rotatory stability, long-term survival of the graft functions, and comparisons with other procedures involving the reconstruction with the bone-patellar tendon-bone graft, are needed to establish the clinical utility of the anatomic double-bundle ACL reconstruction for the ACL-deficient knee.

CONCLUSION

The postoperative anterior and rotational stability after our anatomic double-bundle ACL reconstruction was significantly better than that after our single-bundle reconstruction with the hamstring tendon grafts, although there were no significant differences between the 2 procedures concerning the intraoperative and postoperative complications, range of knee motion, muscle strength, Lysholm knee score, and IKDC evaluation.

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