Gender-based Differences In Outcome After Anatomic Double-Bundle Anterior Cruciate Ligament Reconstruction With Hamstring Tendon Autografts

Harukazu Tohyama, MD, PhD, Eiji Kondo, MD, PhD, Riku Hayashi, MD, PhD, Nobuto Kitamura, MD, PhD, and Kazunori Yasuda, MD, PhD

From the Department of Sports Medicine and Joint Surgery, Hokkaido University School of Medicine, Sapporo, Hokkaido, Japan

Address correspondence to Harukazu Tohyama, MD, PhD, Department of Sports Medicine, Hokkaido University School of Medicine, Kita-15 Nishi-7, Kita-ku, Sapporo, Hokkaido, 060-8638, Japan (e-mail: tohyama@med.hokudai.ac.jp).

Abstract

Background: Although previous studies suggested that female patients are predisposed to increase graft laxity compared with male patients after single-bundle anterior cruciate ligament (ACL) reconstruction using autogenous hamstring tendons, there have been no studies specifically examining gender-based differences in outcome after anatomical double-bundle ACL reconstruction with hamstring tendon autografts.

Hypotheses: 1) Female patients would have significantly smaller hamstring graft diameters than did men for anatomical double-bundle ACL reconstruction surgery; 2) Female patients would have increased graft laxity compared with male patients after anatomical double-bundle ACL reconstruction using autogenous hamstring tendons.

Study Design: Cohort study

Methods: The consecutive 174 patients who underwent anatomical double-bundle ACL reconstruction using autogenous hamstring tendons were enrolled. Of these subjects, 49 women and 73 men were prospectively evaluated 2 years after surgery.

Results: The diameters for anteromedial and posterolateral grafts in the female group were significantly smaller than those in the male group. On Lachman testing, 98% of the female group and 97% of the male group were rated as negative. Regarding the pivot-shift test, 80% of the female group and 85% of the male group were rated as negative. No significant differences were found between the female and male groups in these tests. The average side-to-side differences in the KT-2000 knee ligament arthrometer values were 1.3 mm in the female group and 1.4 mm in the male group; this difference between females and males was not statistically significant. The average Lysholm scores were 96.7 points in the female group and 97.2 points in the male group. 73% of the female group and 74% of the male group were graded as normal on the IKDC evaluation. There were no significant differences in Lysholm score or IKDC evaluation between the female and male groups.

Conclusion: The results of assessment for ligament laxity at the 2-year postoperative evaluation in the female group were approximately identical to those of the male group after anatomical double-bundle ACL reconstruction using autogenous hamstring tendons. Therefore, the present study suggests that anatomical double-bundle ACL reconstruction using autogenous hamstring tendons provides satisfactory knee stability to female patients as well as male patients.

Introduction

Single-bundle anterior cruciate ligament (ACL) reconstruction has been a standard option to treat symptomatic ACL deficient knees. However, Woo *et al*. [28] reported that the single-bundle reconstruction cannot completely restore the normal anterior laxity and that it is not effective for treating the rotational instability. According to recent kinetic studies [6], the single-bundle reconstruction with the bone-patellar tendon-bone or hamstring tendon graft restored antero-posterior stability but not rotational stability during pivoting after stair descending and jumping. Recently, "anatomic" double-bundle ACL reconstruction, which is defined as involving transplantation of the 2 tendon grafts at the center of the anatomic attachment of the anteromedial (AM) and posterolateral (PL) bundles, respectively, in both the tibia and the femur, has attracted great notice, since <u>Yasuda et al [33] reported the first clinical procedure with two-year follow-up results at the Fourth Biennial Congress of the International Society of Arthroscopy, Knee surgery, and Orthopaedic Sports Medicine, Auckland, New Zealand, March, 2003.</u> Recently, clinical trials have shown that their anatomic double-bundle reconstruction procedures are significantly superior to their single-bundle procedures concerning the knee stability, although no investigators found a significant difference in subjective benefits or the impact on the quality of life

[2,3,11,12,14,18,24,30,35]. A few studies reported that there were no significant differences between the two procedures [17, 25]. However, no studies to examine gender-based differences in clinical outcome after anatomic double-bundle ACL reconstruction have been conducted to date, while it has been known that gender-based differences exist in clinical outcome after single-bundle ACL reconstruction.

For example, Corry *et al*. [7] first reported a difference in laxity between men and women after single-bundle ACL reconstruction with a hamstring tendon autograft. They compared 180 patients 2 years after ACL reconstruction with either a patellar tendon or hamstring tendon autograft and found that female patients with hamstring tendon grafts had greater laxity on arthrometer testing than did female patients with patellar tendon grafts and male patients with either hamstring tendon or patellar tendon grafts. Noojin *et al*. [19] examined 39 male and 26 female patients after single-bundle ACL reconstruction with an autogenous hamstring tendon and EndoButton fixation. When compared with the male subjects, female subjects had greater laxity, higher failure rates, and greater pain frequency and intensity. Gobbi *et al.* [8] also examined gender-based differences after single-bundle ACL reconstruction with a hamstring tendon and EndoButton fixation and found greater laxity in the female patients, but no significant differences in graft rupture rates, self-reported outcome, or functional assessments. Salmon *et al*. [22] compared 100 men and 100 women 7 years after single-bundle ACL reconstruction with a quadrupled hamstring tendon graft and interference screw fixation and reported that laxity on physical evaluation was significantly greater in women than in men on Lachman, pivot-shift, and instrumented testing. Tuman et al. [27] reported that women had significantly smaller hamstring graft diameters than did men for ACL reconstruction surgery. Hamstring graft with a small diameter can also induce residual anterior laxity even after anatomical double-bundle ACL reconstruction. These studies suggested that female patients are predisposed to increased graft laxity compared with male patients after single-bundle ACL reconstruction using an autogenous hamstring tendon.

Based on these studies, we hypothesized, first, that there are significant gender-based differences in graft dimension as well as body height and weight, and, second, that in clinical outcome after anatomical double-bundle ACL reconstruction using autogenous hamstring tendons, knee stability is significantly worse in female patients than in male patients. The purpose of the present prospective comparative study is to test these hypotheses.

Subjects and Methods

Study Design

A prospective comparative study was conducted in patients who underwent anatomical double-bundle ACL reconstruction using autogenous hamstring tendons, performed by a single senior surgeon (K.Y.) between 2002 and 2004. Each patient underwent the following ACL reconstruction surgery more than two months or later after the ACL injury and showed ACL deficiency 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 magnetic resonance imaging 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 2002 and 2004, 174 patients were enrolled in this study; 52 patients were lost to 2-year follow-up, resulting in 122 patients (70%) that were evaluated in this study. 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. Patients were prospectively evaluated. All knees were examined before surgery and at 24 months after the operation. Preoperatively, we took medical history and performed standard physical examination including range of knee motion, Lachman test, pivot shift, and Cybex II isokinetic muscle strength measurements. The clinical outcomes were IKDC, Lysholm score, range of motion, Lachman test, Pivot shift sign test, KT-2000 arthrometer measurements, and Cybex II isokinetic muscle strength measurements 24 months after the operation. We then compared the clinical outcomes of 49 female subjects with those of 73 male subjects. We identified no statistical differences between two groups with regard to the age at the time of surgery, the time from the injury to the surgery, or the follow-up period, although the average time from the injury to the surgery in the female group was 10 months longer than that in the male group (Table 1). In the female group of the present study, one subject underwent ACL surgery after more than 20 years from her initial injury. If we exclude this case, the average difference in the time from the initial injury between female and male groups was 1.8 months. Considering standard deviations of the time from the initial injury in both groups, we think that this difference of 1.8 months is not large. In addition, median values of the time from the initial injury were similar in both groups.

Surgical Procedure

The details of the anatomic double-bundle procedure were previously described in the literature (Fig. 1)[33,34,35]. Briefly, the harvested semitendinosus tendon was cut in half. The gracilis tendon was 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 two polyester tapes (Neoligament) and an EndoButton (Smith & Nephew Endoscopy) 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 the PL bundle graft. After the preparation of the grafts, the diameter of each graft was measured using cylindrical sizers (Smith & Nephew Endoscopy) in 0.5-mm increments and recorded in the patient's surgical record. First, a tibial tunnel for the PL bundle was created. To insert a guide-wire, a wire navigator (Smith & Nephew Endoscopy) was used. The navigational tip 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 navigational 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, the femoral indicator was aimed at the center of the PL bundle footprint on the femur (Fig. 2-a). Subsequently, the direction of the extra-articular wire sleeve was 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 guide-wire of 2 mm in diameter was drilled through the sleeve into the tibia (Fig. 2-b).

To create two femoral tunnels for the AM and PL bundles in the lateral condyle, first a guide-wire was placed at the center of the femoral footprint of the AM bundle through a 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 (Fig. 2-c). 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 guide-wire and aimed it at the center of the PL bundle attachment on the femur through the tibial tunnel (Fig. 2-d). 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, two sockets were created for the AM and PL bundles with cannulated drills for the EndoButton fixation system (Smith & Nephew Endoscopy), the diameter of which were matched to the two grafts prepared.

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 same manner. Thus, the two bundles are intra-articular with different directions. 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 allowed the knee to be flexed to 10° with the unsecured leg. A spring tensiometer (Meira) was 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. The surgeon simultaneously secured the two tape portions onto the AM aspect of the tibia using two spiked staples (Meira) in the turn-buckle fashion (Fig. 1).

The medial meniscus was torn in 6 knees (12%) in the females and 10 knees (14%) in the males. The lateral meniscus was torn in 12 knees (25%) in the female group and in 18 knees (25%) in the male group. Two and 4 medial meniscal lesions were sutured in the female and male groups, respectively. A stable longitudinal lesion (<1 cm) of the medial or lateral meniscus was left untreated in 2 knees (4%) in the female group and in 4 knees (6%) in the male group. A limited partial meniscectomy was performed in all other cases. For all medial meniscal lesions, the posterior horn was preserved. No treatment was administered for mild softening or fissuring of the articular cartilage, which was observed in 6 knees (12%) and 9 knees (12%) in female and male groups, respectively. One male subject underwent microfracture management for the full-thickness cartilage defect less than 2 cm^2 at the medial femoral condyle.

Postoperative Regimen

The rehabilitation protocol was identical for both groups. The same postoperative regimen was applied postoperatively for the patients who underwent the combined surgical treatments, i.e. menisectomy, meniscal repair, and microfracture management. Postoperative management was performed according to our original rehabilitation protocol [32]. Based on the results of our previous biomechanical studies, we encouraged quadriceps and hamstring muscle training immediately after surgery [31]. The static squat exercise was started 1 week postoperatively [20]. A post-operative immobilizer was applied for two weeks after the operation. Full weight-bearing walking was then allowed with a hinged brace two weeks after surgery. Various kinds of athletic training were gradually allowed after 6 weeks, although no running was allowed until nine months after surgery. Return to full sports activity was generally permitted at 12 months. The same rehabilitation was applied postoperatively for the patients who underwent the combined surgical treatments for torn menisci and chondral lesions.

Clinical Evaluations

Each patient underwent clinical examinations two years after surgery. One well-trained orthopaedic surgeon (E.K.) performed the Lachman test and the pivot-shift test, the results of which were subjectively evaluated by the examiner. The Lachman test was graded as – (less than 3 mm), + (3–5 mm), or ++ (more than 5 mm). In the 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 of 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. By a well-trained physical therapist who was not an author of this study, the side-to-side anterior laxity was measured using a KT-2000 knee ligament arthrometer (MEDmetric, San Diego, CA, USA) at 30° of knee flexion under an anterior draw force of 133 N. Peak isokinetic torque of the quadriceps and the hamstrings was measured at 60°/s of angular velocity using the Cybex II extremity system (Lumex, Ronkonkoma, NY, USA) in both knees before and after surgery. Muscle torque in the operated knee was represented as a percentage of the muscle torque in the uninvolved knee. Regarding the overall evaluation, the Lysholm score (maximum score, 100 points) and the International Knee Documentation Committee (IKDC) form were used. The activity levels before injury and at the follow-up period were also evaluated using the Tegner score [26].

Statistical Analysis

Statistical comparison for all but Tegner activity level between the male and female groups was performed using the $\chi 2$ test and unpaired Student t-test. For differences in Tegner activity level between female and male groups, we used the non-parametric Mann–Whitney test. We also compared Tegner activity level at the follow-up with that before the ACL injury using Wilcoxon signed-rank test. A commercially available software program (StatView, SAS Institute, Cary, NC, USA) was used for statistical calculation. The significance level was set at $P \leq 0.05$.

Results

At the time of surgery, the height and the body weight of female patients were significantly smaller than those of male patients (both $p<0.0001$; Table 1). Also, the body mass index (BMI) at the time of surgery was significantly lower in the female group than in the male group ($p=0.0095$). Regarding the graft diameters of the AM and PL grafts for ACL reconstruction, the graft diameters in the female group were significantly smaller than those in the male group (AM: $p<0.0001$, PL: $p=0.0002$) (Table 2).

In eight cases (two for the AM graft and six for the PL graft), EndoButton migration away from the external surface of the femoral cortex was noticed by radiographs taken immediately after ACL reconstruction. These EndoButtons were normally positioned on the external surface of the femoral cortex via an additional 2-cm skin incision at the lateral thigh. One and two knees had postoperative 5° flexion contractures in the female and male groups, respectively. These patients had arthroscopic debridement of scar tissue and ultimately regained full extension. There were no graft failures and no reoperations for instability. No patient tore his or her ACL graft after the procedure. There were no knee infections.

Ligament laxity was assessed with the Lachman, pivot-shift, and KT-2000 knee ligament arthrometer instrumented testing at the 2-year postoperative evaluation. On Lachman testing, 48 cases in the female group (98.0%) and 71 cases in the male group (97.3%) were rated as negative. Regarding the pivot-shift test, 39 cases in the female group (79.6%) and 61 cases in the male group (84.6%) were rated as negative. There were no patients with a ++ Lachman-test in spite of two cases with with a ++ pivot-shift in each group. The χ^2 test did not show a significant difference in these manual tests between the female and male groups (Lachman test, p=0.8250; pivot shift test, p=0.8012; Table 3). The average side-to-side differences of the KT-2000 arthrometer values were 1.3 mm in the female group and 1.4 mm in the male group. We could not show a significant difference in side-to-side differences of the KT-2000 arthrometer values between the female and male groups (p=0.7314, power (1-β)=0.063, Table 3). At the 24-month follow-up, 39 cases (79.6%) of the female group and 53 cases (72.6%) of the male group had <3 mm of side-to-side difference. Although one

(2.0%) of the female group and two (2.7%) of the male group had >5 mm of difference, there were no revision cases after the index surgery in the present clinical series. The diameters of the AM grafts were 7.1 ± 0.6 mm, 6.8 ± 0.7 mm, and 7.3 ±0.6 mm in the cases with <3 mm, 3-5 mm, and >5 mm of the KT side-to-side difference, respectively. The diameters of the PL graft were 6.0 ± 0.3 mm, 6.0 ± 0.4 mm, and 6.3 ± 0.6 mm, respectively. There were no significant differences in the diameter of the AM or PL graft among the three groups with <3 mm, 3-5 mm, and >5 mm of the side-to-side difference (AM graft: p=0.0933, power (1-β)=0.467; PL graft: p=0.1187, power (1-β)=0.423).

Concerning the passive range of motion, there were no significant differences in knee extension or flexion between the female and male groups [extension: p=0.1736, power (1-β)=0.242; flexion: p=0.2765, power (1-□β)=0.181] (Table 4). We failed to detect the significance difference in knee extension between the involved and the uninvolved knees in the femomale or male group [female: p=0.1333, power (1-β)=0.306; male: p=0.1719, power (1-□β)=0.260], while the knee flexion of the involved knees were significantly smaller than that of the uninvolved knees in both groups [female: p=0.0126; male: p=0.0009]. For the preoperative muscular strength of knee extension, the average isokinetic peak torques of the involved legs were 85% and

84% of the non-operated side in the female and male groups, respectively. Regarding knee flexion, the average peak torques of preoperative involved legs were 93% and 89% of the uninvolved legs in the female and male groups, respectively. There were no significant differences in the isokinetic peak torque of knee extension or flexion between the female and male groups [extension: $p=0.7200$, power $(1-\beta)=0.064$; flexion: $p=0.1928$, power $(1-\beta)=0.240$] (Table 1). At the follow-up, the average extension peak torques of the operated leg were 91% of the non-operated side in the female group and 90% in the male group. Regarding the isokinetic peak torque of knee flexion, the average values of the operated side were 93% of the non-operated side in the female group and 96% in the male group. There were no significant differences in the isokinetic peak torque of knee extension or flexion between the female and male groups [extension: $p=0.5564$, power (1-□β)=0.088; flexion: $p=0.3791$, power (1-□β)=0.135] (Table 4). As compared with the muscle strength of the uninvolved legs, the peak torques of knee extension of both groups were significantly lower in the involved legs then in the uninvolved legs [female: $p=0.0004$; male: $p=0.0001$]. The peak torque of knee flexion of the female group was significantly lower in the involved legs then in the uninvolved legs [$p=0.0011$], while we failed to find a statistical difference in the peak torque of knee flexion between the involved and the uninvolved legs in the male group [p=0.0626, power (1-β)=0.449].

The average values of Lysholm score were 96.7 ± 3.7 points in the female group and 97.2 ± 3.5 points in the male group. In the female group, 35 cases (73%) were graded as normal, 12 cases (24%) were graded as nearly normal, and 2 cases (4%) were graded as abnormal on the IKDC knee examination form (no knees ranked D). In the male group, 54 cases (74%) were graded as normal, 17 (23%) as nearly normal, and two (3%) as abnormal (no knees ranked D). There were no significant differences in Lysholm score or IKDC evaluation between the female and male groups (Lysholm score: p=0.4957, power (1- β)=0.101; the IKDC evaluation: p=0.4616). Concerning Tegner activity scale, pre-injury average values were 6.5 points and 6.9 points in female and male groups, respectively (Table 1). At the follow-up, the average activity scores were 6.1 points and 6.3 points in female and male groups (Table 4). There was no significant difference in the activity level before the injury or at the follow-up between female and male groups (pre-injury: p=0.404, follow-up: p=0.707), while the activity level at the follow-up was still significantly lower than that at before the ACL injury (p=0.003).

Discussion

The present study demonstrated that the height, body weight, BMI, and graft diameter of each bundle were significantly less in the female patients than in the male patients at the time of surgery. However, the results of assessment for ligament laxity in the female group were almost identical to those of the male group at the 2-year postoperative evaluation after anatomical double-bundle ACL reconstruction using autogenous hamstring tendons. According to these results, the first hypothesis was approved, but the second hypothesis was denied.

The present study approved the first hypothesis that there are significant gender-based differences in graft dimension as well as body height and weight. The graft diameter of each bundle was smaller in the female group than in the male group. During the operation of anatomical double-bundle ACL reconstruction, the authors adjusted the graft diameter for each bundle to avoid overlapping the AM and the PL bundle tunnels. We also reduced the graft size and the diameter of bone tunnels for the patients with small knees to make whole areas of bone tunnels within the footprint of the ACL. As a reference, we calculated a normalized graft size, which was the graft diameter divided by the BMI, and found no substantial differences in the normalized values between female and male cases. The normalized graft sizes of the AM graft were 0.306 ± 0.038 mm/(kg/m^2) and 0.308 ± 0.043 mm/(kg/m^2) in the female and male groups and those of the PL graft were 0.266 ± 0.030 mm/(kg/m^2) and 0.257 ± 0.038 (kg/m^2) in the female and male groups, respectively. Therefore, the graft diameter difference between the female and male groups supposedly reflects the size of the knee joint. We also found no significant differences in the diameter of the AM or PL graft among the three groups with <3 mm, 3-5 mm, and >5 mm of the side-to-side difference. Our findings suggest that the diameter of the grafts does not affect the side-to-side difference of the anterior knee laxity after the anatomical double-bundle ACL reconstruction using hamstring tendons.

The present study denied the second hypothesis that knee stability is significantly worse in female patients than in male patients in clinical outcome after anatomical double-bundle ACL reconstruction using autogenous hamstring tendons. For example, the present study showed that the average knee ligament arthrometer side-to-side difference within the female patients after double-bundle ACL reconstruction using hamstring autografts, 1.3 mm, was approximately identical to that within the male patients, 1.4 mm. The present study also found no substantial difference in the ratio of cases with >5 mm of side-to-side difference, i.e. 2.0% in the female and 2.7% in the male groups. On the other hand, previous studies show significant gender-based differences in the side-to-side difference in the arthrometer values after single-bundle ACL reconstruction using hamstring tendons [7, 19].

Biomechanical studies showed that the contribution of the ACL graft to anterior knee stability is greater in the double-bundle ACL reconstruction than in the single-bundle procedure with hamstring graft [15,21,29]. The lower contribution of the ACL graft to anterior knee stability means the higher contribution of the soft tissues around the knee joint. Huston and Wojtys [10] reported that female subjects have greater anterior laxity than male subjects. Their finding suggests that stiffness of soft tissues around the knee joint is less in females than in males. Therefore, the lower contribution of the ACL graft to anterior knee stability in the female patients likely induces greater anterior laxity after single-bundle ACL reconstruction with hamstring graft. On the other hand, the greater contribution of the ACL graft to anterior knee stability may diminish the gender-based difference in anterior laxity in the subjects who undergo double-bundle ACL reconstruction.

According to the final evaluation of the IKDC examination form, the success rate for patients in the present study, determined by grades of "normal" or "nearly normal", were 96% for females and 97% for males. Success rates for single-bundle ACL reconstruction using autogenous hamstring tendons have ranged from 82% to 90% [1,4,7,9,13,16,23,36]. The criteria for failure in the study of Noojin *et al*. [19]

included a 2+ Lachman result, a 1+ or greater pivot shift test result, a greater than 5-mm side-to-side difference with KT-1000 knee ligament arthrometer testing, or revision surgery. Aglietti *et al*. [1] also used arthrometer differences of greater than 5 mm and a positive pivot shift test as criteria for determining graft failure. Likewise, Siegel and Barber-Westin [23] defined graft failure with KT-1000 knee ligament arthrometer differences of greater than 5.5 mm or a 2+ pivot shift result. Our criteria for failure includes not only postoperative results of the ligament examination with arthrometer differences of greater than 5.0 mm but also effusion, passive motion deficit, compartment findings, harvest site pathology, x-ray findings, and a functional test. In spite of our strict criteria, the success rate of double-bundle ACL reconstruction using autogenous hamstring tendons in female patients is considered to be comparable to previously reported success rate in the single-bundle ACL reconstruction for male patients.

There are some limitations to this study. The first limitation is that the minimum follow-up was only two years. Beynnon *et al.* [5] reported that anterior laxity and the pivot shift grades in the knee were within the limits of normal one year after single-bundle ACL reconstruction using two-strand hamstring tendons and then increased at three years. Therefore, we need longer follow-up to clarify gender-based differences in the outcome of the patients after double-bundle ACL reconstruction using hamstring tendons. The second limitation is that the follow-up rate of the present study, 70%, was insufficient. There is a possibility that the outcomes of female cases who were lost at the follow-up might be significantly worse than those of male cases. Briefly, a transfer bias might affect our results in the present study. The third limitation is that the results of the Lachman test and the pivot-shift test might be affected by the examiner's subjectivity. In all subjects, the side-to-side difference of the KT-2000 arthrometer values in the cases with negative Lachman results was 1.2 ± 1.5 mm, while the differences in the cases with 1+ Lachman results was 5.8 ± 0.3 mm. Regarding pivot shift testing, the differences in the cases with negative, 1+, and 2+ pivot shift test results were 0.6 ± 1.5 mm, 2.4 ± 1.1 mm, and 5.0 ± 0.6 mm, respectively. These findings suggested that the results of the Lachman test and the pivot-shift test performed by one of us were considered to be reliable. In addition, we did not compare gender-based differences in the outcomes of the patients after ACL reconstruction using hamstring tendons between the double-bundle and the single-bundle procedures. In spite of these limitations, the present study implies that anatomical double-bundle ACL reconstruction using hamstring tendons provides satisfactory knee stability to female patients as well as male patients.

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Figure Legends

Figure 1: Anatomical double-bundle ACL reconstruction procedure.

Figure 2:Positioning of tibial and femoral tunnels (a. the tibial indicator of the navigational tip is placed at the center of the PL bundle footprint on the tibia and the femoral indicator aims at the center of the PL bundle footprint on the femur, b. a guide-wire drilled through the AM bundle footprint of the tibia, c. a femoral tunnel placed at the center of the femoral footprint of the AM bundle, d. the guide-wire aimed at the center of the PL bundle attachment on the femur through the tibial tunnel).

Table 1. Patient demographics of the subjects (49 females and 73 males)

	Mean (SD)	Median (range)	P-value	Power
Age at surgery, yr				
Female	27.8 (12.8)	25 (13-62)	0.585	0.083
Male	25.7 (9.9)	22 (15-59)		
Time to surgery from injury, mo				
Female	19.5 (59.4)	3 (2-362)	0.2065	0.229
Male	9.5 (15.9)	3 (2-84)		
Follow-up period, mo				
Female	36.8 (16.3)	24 (24-60)	0.1878	0.245
Male	31.8 (13.5)	24 (24-60)		
Height, cm				
Female	159.3 (5.0)	160 (146-173)	<0.0001	1.000
Male	172.5 (5.9)	172 (159-188)		
Body weight, kg				
Female	56.6 (7.4)	57 (43-76)	<0.0001	1.000
Male	71.5 (11.1)	69 (54-107)		
Body mass index (BMI, kg/m^2)				
Female	22.2 (2.6)	21 (18-28)	0.0095	0.753
Male	24.0 (3.7)	23 (17-35)		
Preoperative isokinetic peak torque (the involved leg / the uninvolved leg)				
Knee extension				
Female	85.1% (13.4%)	86.8% (57.3-99.2)	0.7200	0.064
Male	83.7% (20.7%)	84.5% (40.0-126.7)		
Knee flexion				
Female	93.1% (11.8%)	96.6% (58.5-124.7)	0.1928	0.240
Male	89.0% (15.8%)	92.9% (39.9-119.8)		
Pre-injury activity level (Tegner)				
Female	6.5 (2.0)	6 (3-9)	0.4038	
Male	6.9 (2.1)	7 (2-10)		

Table 2. Graft diameters of anteromedial and posterolateral bundles for anterior cruciate ligament reconstruction

	Female (n=49) Mean (SD), mm	Male (n=73)	P-value	Power
Anteromedial bundle	6.7 (0.4)	7.2 (0.5)	<0.0001	1.0000
Posterolateral bundle	5.8 (0.2)	6.0 (0.2)	0.0002	0.981

Table 3. Ligament laxity assessment at 2-year postoperative evaluation

	Female (n=49)	Male (n=73)	P-value	Power
Lachman test				
-	48 cases (98.0%)	71 cases (97.3%)		
+	1 case (2.0%)	2 cases (2.7%)		
++	none (0%)	none (0%)	0.8250	
Pivot shift test				
-	39 cases (79.6%)	61 cases (84.6%)		
+	8 case (16.3%)	10 cases (13.7%)		
++	2 cases (4.1%)	2 cases (2.7%)	0.8012	
KT-2000 side-to-side difference (mm)				
mean (SD)	1.3 (1.7)	1.4 (1.7)	0.7314	0.063

Table 4. Passive range of knee motion, muscular strength of the knee and Tegner activity score at 2-year postoperative evaluation

	Female (n=49)	Male (n=73)	P-value	Power
	Mean (SD)			
Passive range of motion, degrees				
Knee extension	-1.0 (2.5)	-0.4 (1.9)	0.1904	0.242
Knee flexion	147.3 (8.7)	148.6 (3.6)	0.2765	0.181
Isokinetic peak torque (the operated leg / the unaffected leg)				
Knee extension	91.6% (17.3%)	89.7% (13.3%)	0.5564	0.088
Knee flexion	92.7%(12.9%)	95.7% (17.1%)	0.3791	0.135
Tegner activity score	6.1 (2.4)	6.3 (2.3)	0.707	

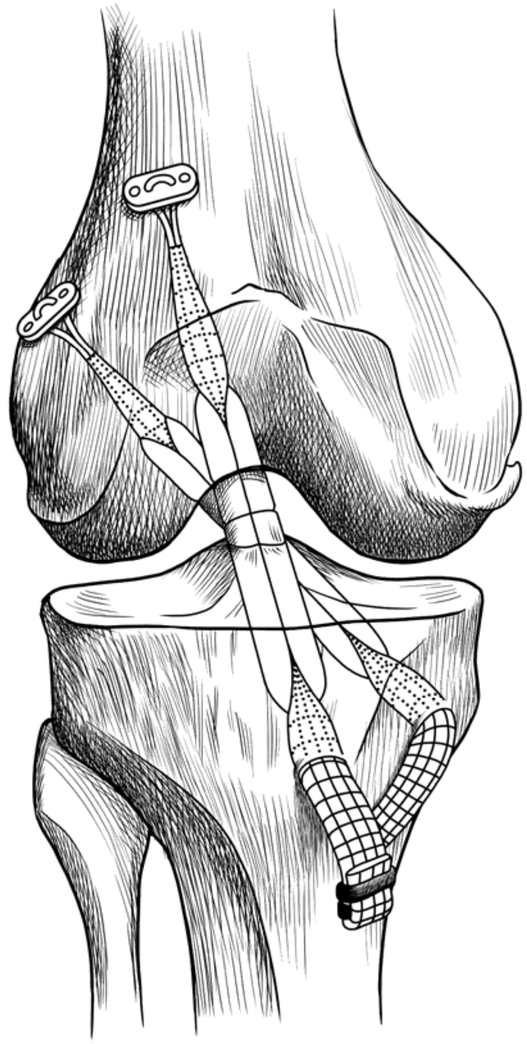

Figure 1: Anatomical double-bundle ACL reconstruction procedure.

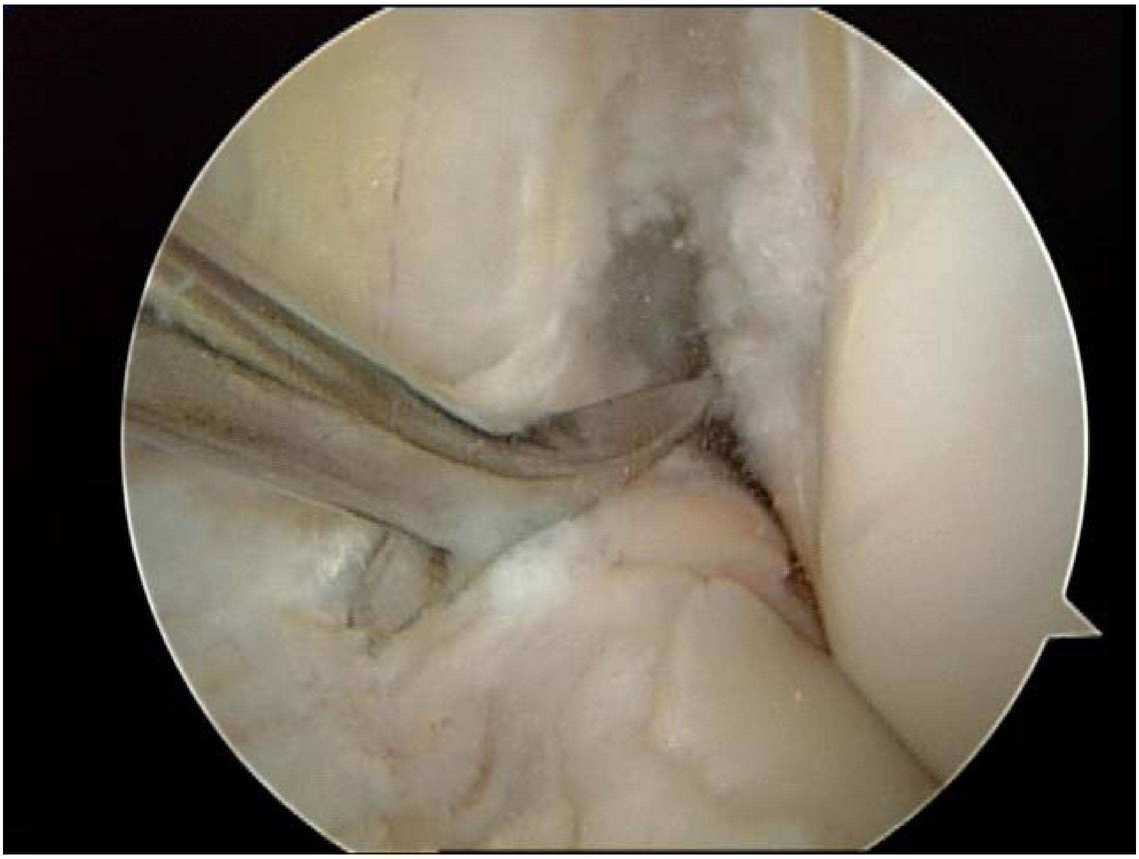

Figure 2-a Positioning of tibial and femoral tunnels (a. the tibial indicator of the navigational tip is placed at the center of the PL bundle footprint on the tibia and the femoral indicator aims at the center of the PL bundle footprint on the femur).

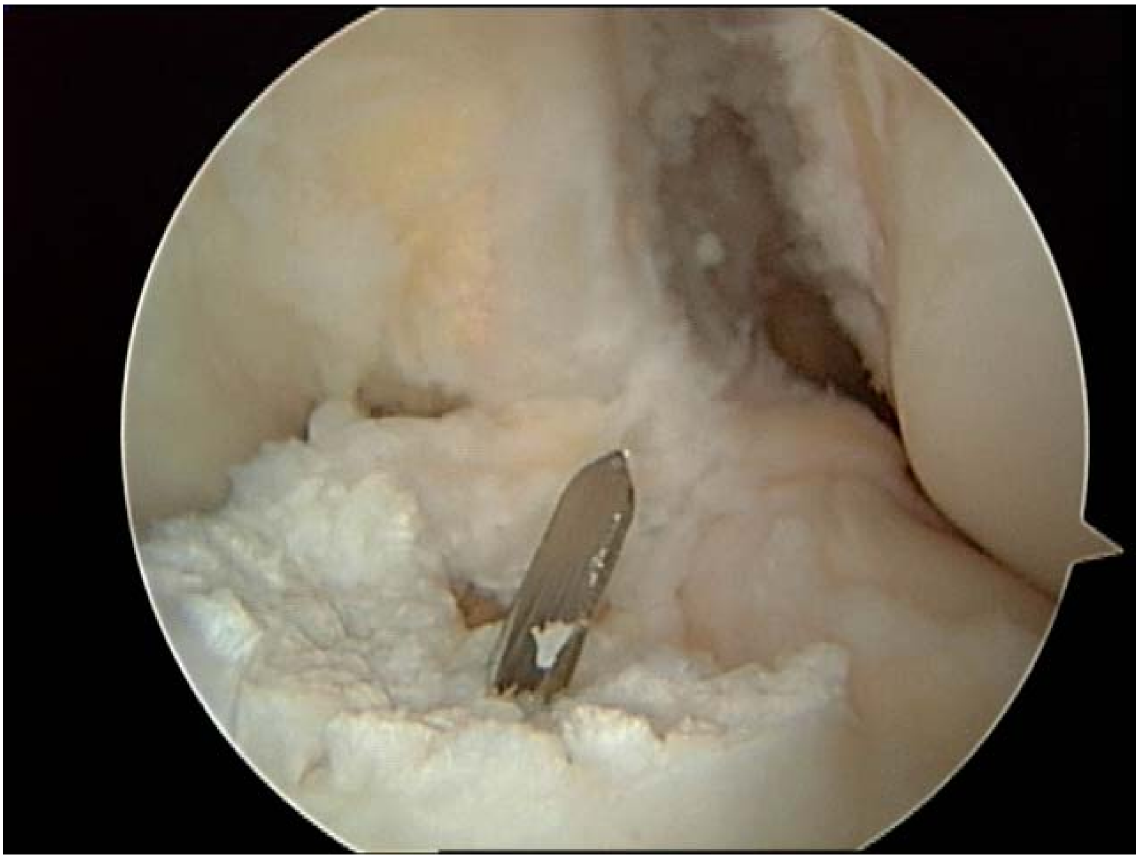

Figure 2-b　Positioning of tibial and femoral tunnels (b. a guide-wire drilled through the AM bundle footprint of the tibia).

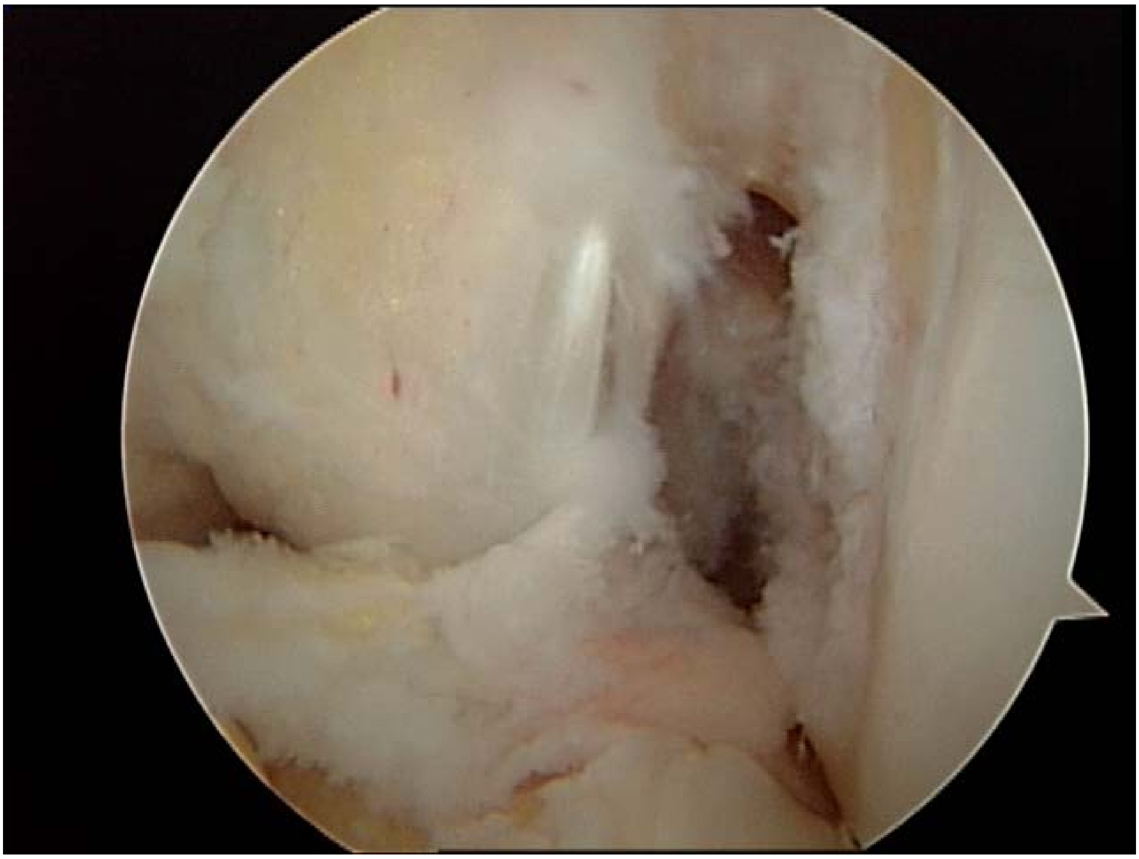

Figure 2-c Positioning of tibial and femoral tunnels (c. a femoral tunnel placed at the center of the femoral footprint of the AM bundle).

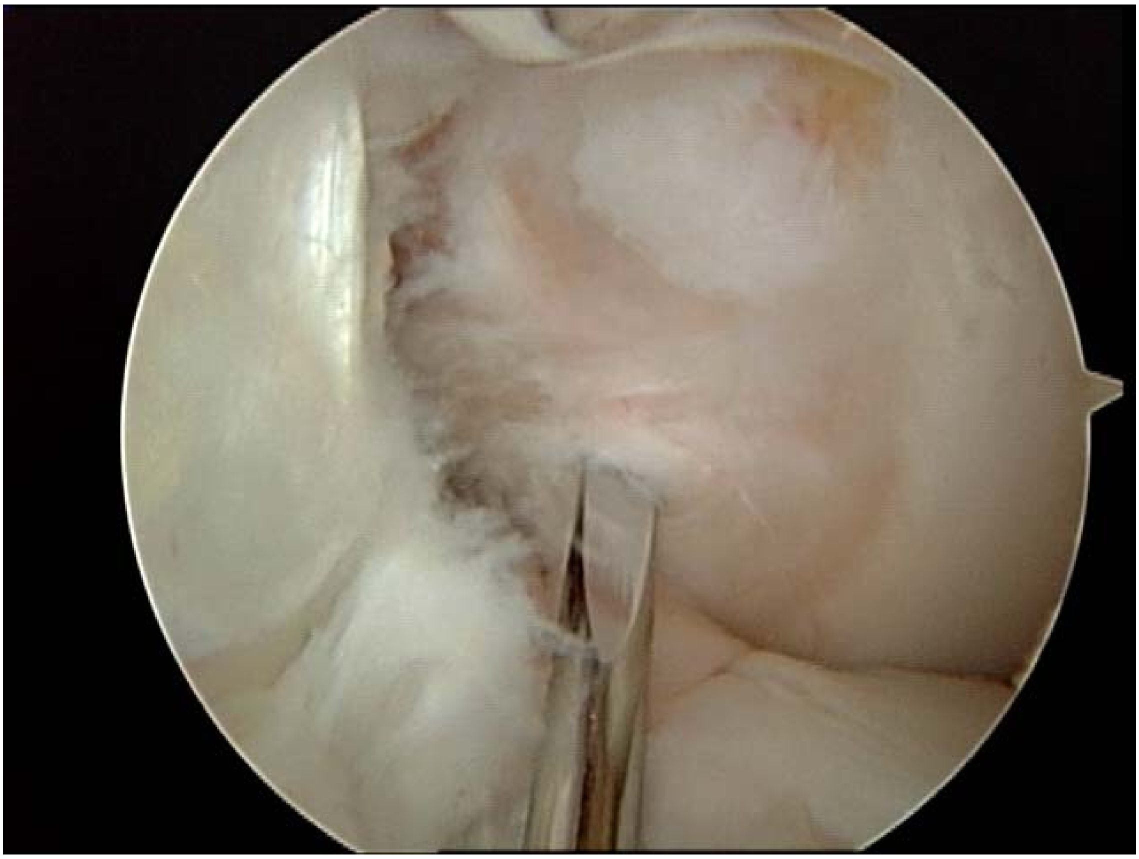

Figure 2-d　Positioning of tibial and femoral tunnels (d. the guide-wire aimed at the center of the PL bundle attachment on the femur through the tibial tunnel).