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ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION: BONE-PATELLAR TENDON-BONE COMPARED WITH DOUBLE SEMITENDINOSUS AND GRACILIS TENDON GRAFTS

A PROSPECTIVE, RANDOMIZED CLINICAL TRIAL

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Background: The choice of graft for anterior cruciate ligament reconstruction is a matter of debate, with patellar and hamstring tendons being the two most popular autologous graft options. The objective of this study was to determine in a prospective, randomized clinical trial whether two grafts (bone-patellar tendon-bone or doubled hamstring tendons) fixed with modern devices affect the two-year minimum clinical and radiographic outcomes of anterior cruciate ligament reconstruction.

Methods: One hundred and twenty patients with a chronic unilateral rupture of the anterior cruciate ligament underwent arthroscopically assisted reconstruction with use of either autologous bone-patellar tendon-bone or doubled hamstring tendon grafts, in a strictly alternating manner. Both groups were comparable with regard to demographic data, preoperative activity level, mechanism of injury, interval between the injury and the operation, and the amount of knee laxity present preoperatively. The same well-proven surgical technique and aggressive controlled rehabilitation was used. An independent observer, who was blinded with regard to the involved leg and the type of graft, performed the outcome assessment with use of a visual analog scale, the new International Knee Documentation Committee form, the Knee Injury and Osteoarthritis Outcome Score, the Functional Knee Score for Anterior Knee Pain, and an arthrometric and an isokinetic dynamometric evaluation. Radiographs were also made.

Results: At the two-year follow-up evaluation, no differences were found in terms of the visual analog score, the Knee Injury and Osteoarthritis Outcome Score, the new International Knee Documentation Committee subjective and objective evaluation scores, the KT-1000 side-to-side laxity measurements, the Functional Knee Score for Anterior Knee Pain, muscle strength recovery, or return to sports activities. In the bone-patellar tendon-bone group, we found a higher prevalence of postoperative kneeling discomfort ($p < 0.01$) and an increased area of decreased skin sensitivity ($p < 0.001$). In the hamstring tendon group, we recorded a higher prevalence of femoral tunnel widening ($p < 0.01$). In this group, a correlation was also found between medial meniscectomy and an increased prevalence of pivot-shift glide ($p = 0.035$).

Conclusions: We believe that, with use of accurate and proven surgical and rehabilitation techniques, both grafts are an equivalent option for anterior cruciate ligament reconstruction.

Level of Evidence: Therapeutic study, Level I-1b (randomized controlled trial [no significant difference but narrow confidence intervals]). See Instructions to Authors for a complete description of levels of evidence.

In 1994, we published a randomized clinical trial comparing two autologous grafts, the middle third of the patellar tendon (bone-patellar tendon-bone) and the double-looped semitendinosus and gracilis tendons, for anterior cru-

ciate ligament reconstruction¹. The study showed that the same functional results could be obtained with a higher rate of minor extension deficits and a trend toward less anterior knee laxity in the bone-patellar tendon-bone group. The patients

were reviewed again at a minimum follow-up period of five years and, while the extension deficits were diminished, the trend toward better stability in the bone-patellar tendon-bone group became substantial². The higher rate of knee laxity in the double-looped semitendinosus and gracilis tendon group was attributed to inadequate graft fixation when the graft was fixed distally with sutures only. The patients in whom the graft was fixed with a spiked washer and a cortical screw had stability comparable with that of the bone-patellar tendon-bone group.

Numerous studies, including other randomized clinical trials³⁻⁸, have failed to show significant differences between the two graft techniques, although a trend toward an increased number of failures and increased laxity has been noted with the use of hamstring tendon grafts^{2,4,5,9,10}, particularly with the two-stranded technique¹¹⁻¹³. Extension deficits or motion problems can be more frequent in patients managed with the bone-patellar tendon-bone technique^{11,10}, and patients treated with the bone-patellar tendon-bone technique have more patellar symptoms^{9,10,14-16}. Some authors have found persistent muscular deficits in flexion^{4,17} and internal rotation, particularly in women^{18,19}, after treatment with the double-looped semitendinosus and gracilis tendon technique.

The goal of this study was to conduct a prospective, randomized clinical and radiographic comparison of bone-patellar tendon-bone and double-looped semitendinosus and gracilis tendon grafts to reconstruct a chronic tear of the anterior cruciate ligament, with use of modern techniques and principles, in particular a better fixation method for the hamstring tendons²⁰⁻²³.

Materials and Methods

Patients and Entry Criteria

From January 2000 to June 2001, 120 consecutive patients undergoing primary anterior cruciate ligament reconstruction were randomized in a strictly alternating manner to treatment with use of autogenous bone-patellar tendon-bone or doubled hamstring tendon autografts. Patients were excluded if they were adolescents with open physes or were more than forty years old; if they had an acute lesion of the anterior cruciate ligament (i.e., the interval between the injury and the operation was less than thirty days); if they had other ligament tears or had undergone a previous operation in the same knee (with the exception of a previous meniscectomy); if they had injured the contralateral knee; if they had degenerative changes of the articular cartilage (grade-III or IV changes according to the Outerbridge classification system²⁴) at arthroscopy; if they complained of patellofemoral symptoms; and, if after being informed about the purpose of the study before the operation, they refused to reliably take part in the study up to the two-year follow-up. Ethical approval was obtained from the internal review board. All subjects were informed of the study procedure, the purpose of the study, and any known risks, and all gave informed consent.

All 120 patients returned for four-month, one-year, and two-year follow-up visits. The two groups were comparable

with respect to age, sex, body weight, height, generalized laxity, involved side, interval between the injury and the surgery, preoperative activity level, and mechanism of injury. In both groups, there were forty-six men and fourteen women, and there was an equal number (thirty) of right and left knees. The mean age at the time of surgery was twenty-five years (range, sixteen to thirty-nine years in the bone-patellar tendon-bone group and fifteen to thirty-nine years in the hamstring group). The average body weight and height were 74 kg (range, 49 to 102 kg) and 175 cm (range, 155 to 201 cm), respectively, in the bone-patellar tendon-bone group and 70 kg (range, 45 to 95 kg) and 174 cm (range, 156 to 195 cm), respectively, in the hamstring group. On the basis of the Carter and Wilkinson method²⁵, generalized joint laxity was recorded in thirteen patients in the bone-patellar tendon-bone group and in eleven patients in the hamstring group.

The majority of injuries were noncontact-type injuries that occurred during sports activities, such as soccer (thirty-four in the bone-patellar tendon-bone group and thirty-five in the hamstring group) and skiing (five in the bone-patellar tendon-bone group and six in the hamstring group), or during a motor-vehicle accident (ten in the bone-patellar tendon-bone group and seven in the hamstring group).

The mean interval between the injury and the operation was twenty-four months (range, one to ninety-six months) in the bone-patellar tendon-bone group and twenty-seven months (range, one to 123 months) in the hamstring group. In the bone-patellar tendon-bone group, seven patients had surgery one to three months after the injury, twelve patients had surgery three to six months after the injury, and forty-one patients had surgery more than six months after the injury. In the hamstring group, eight patients had surgery one to three months after the injury, eight patients had surgery three to six months after the injury, and forty-four patients had surgery more than six months after the injury. There were nine competitive athletes in the bone-patellar tendon-bone group and eleven in the hamstring group. The remaining patients were recreational athletes. All but eight patients in the bone-patellar tendon-bone group and seven patients in the hamstring group played pivoting sports before the injury. Previous surgery included six arthroscopic medial meniscectomies (10%) in each group.

Preoperatively, all knees had positive Lachman and pivot-shift tests. In the bone-patellar tendon-bone group, the Lachman test was graded 1+ (3 to 5 mm) in nine knees (15%), 2+ (6 to 10 mm) in forty-seven knees (78%), and 3+ (>10 mm) in four knees (7%). The pivot shift was 1+ (glide) in eight knees (13%), 2+ (clunk) in forty-eight knees (80%), and 3+ (gross) in four knees (7%). In the hamstring group, the Lachman test was graded 1+ in seven knees (12%), 2+ in forty-nine knees (82%), and 3+ in three knees (5%). The pivot shift was 1+ in seven knees (12%), 2+ in fifty knees (83%), and 3+ in three knees (5%). Anterior tibial translation was evaluated preoperatively with use of the KT-1000 arthrometer, and the side-to-side difference at 30 lb (13.6 kg) was an average of 7 mm (range, 4 to 12 mm) in both groups. Asymptomatic pa-

tellofemoral crepitation was present preoperatively in nine knees in the bone-patellar tendon-bone group and in eight knees in the hamstring group. No significant differences were detected between the two groups with respect to any of the above-mentioned categories.

Surgical Technique and Postoperative Rehabilitation Program

To standardize the surgical technique, we adopted the technique described by Mariani et al.²⁶ for the bone-patellar tendon-bone graft and by Howell and Gottlieb²⁷ for the double-looped semitendinosus and gracilis tendon graft. The grafts and the fixation devices used represent the only variations between the two techniques. A one-year learning curve was considered to be sufficient to become skilled in both methods and thus avoid any bias. All anterior cruciate ligament reconstructions were performed by the senior author (P.A.) under arthroscopic control and with the use of a tourniquet. The operation began with evaluation of the intra-articular abnormality and treatment of the meniscal lesions.

The bone-patellar tendon-bone graft was harvested through an 8-cm longitudinal skin incision centered over the medial aspect of the patellar tendon. After undermining the subcutaneous tissue, the paratenon was dissected in order to define the tendon margins and was preserved for closure. The central third of the patellar tendon, 9 to 11 mm in width, was removed with a rectangular bone plug (20 to 25 mm in length) at each end. The tendon portion of the graft was freed from fat, whereas the bone blocks were trimmed in order to fit a 9, 10, or 11-mm-diameter bone tunnel. Five knees (8%) were treated with a 9-mm graft; fifty-two (87%), with a 10-mm graft; and three (5%), with an 11-mm graft. At the end of surgery, the paratenon was sutured to close the defect while the bone defects were filled with autologous bone chips collected during graft preparation and tunnel drilling.

The hamstring tendons were harvested through a 3 to 4-cm vertical skin incision placed 2 cm medial to the tibial tubercle across the top of the pes anserinus. Both tendons were delivered out of the wound with a curved clamp, their distal expansion to the crural fascia was severed^{28,29}, and the tendons were stripped to the proximal musculotendinous junction with a smooth tendon stripper (Linvatec, Largo, Florida). The distal ends of the tendons were left attached to bone and fascia. Retained muscle and fat tissue were removed by blunt dissection with a periosteal elevator, and number-1 Vicryl absorbable sutures (polyglactin; Ethicon, Somerville, New Jersey) were sewn to the tendon ends. In order to taper the tendons when tension was applied to the sutures, one-quarter of the circumference of each tendon was encircled with each throw of the suture to achieve a crisscrossing Chinese finger-trap pattern. The midpoint of both tendons was then looped over a single suture. This suture was used to pull the four-bundle graft through a series of calibrated cylinders (Arthrotek, Warsaw, Indiana). The diameter of the snuggest-fitting cylinder defined the diameter of the four-bundle graft and the size of the cannulated reamer used to drill a snug bone tunnel.

Seven knees (12%) were treated with a 7-mm graft; forty-five knees (75%), with an 8-mm graft; and eight knees (13%), with a 9-mm graft. Once prepared, the graft was rolled up and placed under the sartorius fascia to avoid contamination before insertion.

To avoid graft impingement, a Kirschner wire was inserted into the tibia with use of the One Step tibial guide (Arthrotek). With the knee in extension, the intra-articular arm and the bullet tip of the guide were centered within the intercondylar notch being constrained between the posterior cruciate ligament, the lateral femoral condyle, and the roof of the notch. This three-point fixation customized the orientation of the guide and allowed the insertion of the guidewire without notch impingement. The extra-articular arm of the guide has a hole for the insertion of a reference pin. Keeping this pin parallel to the joint line (perpendicular to the tibial crest), the guidewire was inserted in the frontal plane at an angle of 70° to the medial tibial plateau³⁰. The tibial tunnel was then drilled with use of a cannulated reamer of the specific graft size. During reaming, a cylindrical sleeve was pushed against the tibia to collect bone debris, which later was used for grafting bone defects in the bone-patellar tendon-bone group and bone tunnels in the hamstring group.

The need for a notchplasty was evaluated with use of an impingement rod of the same diameter as the graft passed through the tibial tunnel into the notch with the knee in full extension. If passage of the rod was obstructed, we expanded the anterior notch using a motorized shaver until there was 2 to 3 mm of clearance between the rod and the roof and the lateral wall of the notch, allowing the rod to pass freely in and out of the notch.

The femoral guidewire was inserted with use of size-specific femoral aimers through a transtibial approach, keeping the knee at about 80° of flexion. The femoral guidewire was placed 5 mm anterior to the posterior cortex to allow a 1 to 2-mm posterior cortical wall after reaming at about eleven o'clock (right) or one o'clock (left). With use of a femoral aimer through a transtibial approach, the entry site of the guidewire is constrained and there is a consistent risk of being too vertical (the twelve o'clock position). To avoid this, we aimed to the most inferior position on the wall of the notch; varus, internal tibial rotation, and external rotation of the femoral aimer helped in this step. The femoral socket was then reamed to the graft size with use of a cannulated atraumatic reamer.

Fixation on the femoral side was transcondylar with use of a Tunneloc screw (Arthrotek) in the bone-patellar tendon-bone group and a Bone Mulch screw (Arthrotek) in the hamstring group. After proximal fixation of the graft, the pistoning pattern of both types of graft was checked by applying tension to the free ends for ten cycles of knee motion from full extension to full flexion. In the hamstring group, traction on the two free graft ends also had a further stabilizing effect on the joint. In fact, they acted as a cord looped around a pulley (the nose of the Bone Mulch screw) so the pretensioning forces were directly transmitted to the tibia through the other



Fig. 1-A

Figs. 1-A and 1-B Right knee of a patient who had anterior cruciate ligament reconstruction with a bone-patellar tendon-bone graft. **Fig. 1-A** Postoperative anteroposterior radiograph.

two graft ends attached to the tibia compressing the tibia toward the femur. Tibial fixation was achieved in extension with use of a soft threaded interference screw (Soft Silck Cannulated Screw; Smith and Nephew Acufex, Mansfield, Massachusetts) for the bone-patellar tendon-bone group and a WasherLoc device (Arthrotek) for the hamstring group. A low manual tension of approximately 20 N was applied to both grafts, to minimize the risk of a dangerous increase in graft tension during full active knee extension.

In the hamstring group, at the end of surgery, the bone debris collected during tunnel reaming was grafted in the femoral and tibial tunnels. With use of specific compactors, the bone graft was compacted in the femur through the body of the cannulated screw, whereas in the tibia it was placed directly from the extra-articular end of the tunnel.

Postoperative anteroposterior and lateral radiographs (Figs. 1-A through 1-D) were made at the end of each reconstruction to assess the correct placement and fixation of the graft.

A brace-free, aggressive controlled rehabilitation protocol was adopted in both groups. Passive range-of-motion exercises were instituted immediately. The rehabilitation protocol was deemed to be aggressive (but not accelerated) in order to try to restore full range of motion within the first month. A written rehabilitation protocol with clear drawings and pictures of each single exercise was also given to all of

the patients in an attempt to achieve maximum compliance. Knee swelling was managed with rest, ice, nonsteroidal anti-inflammatory drugs, and partial weight-bearing. Muscle-strengthening exercises were started on the first postoperative day with isometric quadriceps contractions and progressed to active closed-chain exercises by four to six weeks postoperatively. Patients were allowed full weight-bearing three to five weeks postoperatively and returned to running at three months. Return to sports-specific training was allowed at four months, and return to competition was allowed at six months.

Follow-up Evaluations

All patients were evaluated before surgery, every two weeks up to the second postoperative month, monthly up to four months after surgery, and then at one and two years thereafter by an independent and blinded observer (F.G.). At each evaluation, both knees of the patient were covered with a stockinette in order to hide the involved side and the skin incision.

All patients were evaluated with use of a visual analog scale³¹, the Knee Injury and Osteoarthritis Outcome Score³², the new International Knee Documentation Committee (IKDC) evaluation form³³, and the functional knee score for anterior knee pain³⁴.

At each follow-up visit, the range of motion of the involved knee in relationship to that of the contralateral, normal knee was measured with use of a long-arm goniometer. Extension deficit was determined with the subject lying in the prone



Fig. 1-B

Postoperative lateral radiograph.

position and was measured as the difference in the heel height of the involved limb in comparison with the passively fully extended posture of the contralateral, uninjured limb.

A side-to-side difference in anterior tibial translation was assessed with the knee flexed 30° with use of the KT-1000 arthrometer (MEDmetric, San Diego, California) at 133 N and maximum manual forces³⁵.

Sensory changes possibly related to the surgical dissection of the infrapatellar branch of the saphenous nerve were evaluated by asking the patients to delineate the boundaries of the area using a dermatographic pen. The two major axes were measured, and the overall area was calculated in square centimeters.

Concentric muscle strength recovery of extensors and flexors was measured with use of an isokinetic dynamometer (Cybex NORM; Lumex, Ronkonkoma, New York). Before testing bilateral seated knee extension and flexion, a ten-minute warm-up was done on a stationary bicycle. Formal testing consisted of ten maximal repetitions at 180°/sec, five maximal repetitions at 120°/sec, and five maximal repetitions at 60°/sec, testing the uninvolved extremity first and the involved limb second. The arc of motion recorded by the machine during the test ranged from full extension to 90° of flexion. We also evaluated the muscle strength of the tibial rotators. In this case, the patient was positioned as described by Hester and Falkel³⁶ and was fitted with an appropriately sized



Fig. 1-C

Figs. 1-C and 1-D Right knee of a patient who had anterior cruciate ligament reconstruction with a double-looped semitendinosus and gracilis tendon graft. **Fig. 1-C** Postoperative anteroposterior radiograph.



Fig. 1-D

Postoperative lateral radiograph.

Air-Stirrup ankle brace (Aircast, Summit, New Jersey) to restrict ankle inversion and eversion. The foot was then affixed to a foot-plate at 30° of dorsiflexion with use of two crossing Velcro straps and a heel post to restrict foot motion. Five warm-up repetitions were performed before each measurement. Formal testing consisted of ten maximal repetitions at 90°/sec, five maximal repetitions at 60°/sec, and five maximal repetitions at 30°/sec, testing the uninvolved extremity first and the involved limb second. Mean peak torque (measured in Nm) was established by averaging the five maximal effort repetitions for each tested velocity. The strength deficits of the involved limb were calculated by subtracting the mean peak torque of the involved knee from that of the normal knee. The result was then divided by the mean peak torque of the normal knee and was expressed as a percentage.

An anteroposterior weight-bearing radiograph, lateral radiograph with the knee in full passive extension, and posteroanterior tunnel radiograph were made at four months, one year, and two years postoperatively. All images were centered with an image amplifier. In the sagittal plane, we measured the position of the anterior aspects of the femoral and the tibial tunnel using a previously described method³⁷. Radiographic evidence of graft impingement was investigated with use of the method described by Howell and Clark³⁸. On the tunnel radiograph, we measured the angle between the central axis of the tibial tunnel and a line tangent to the tibial plateau (Fig. 2). On the basis of the studies by Howell et al.³⁰, it has been demonstrated that the correct tibial tunnel position has an angle of <70°^{39,40}.

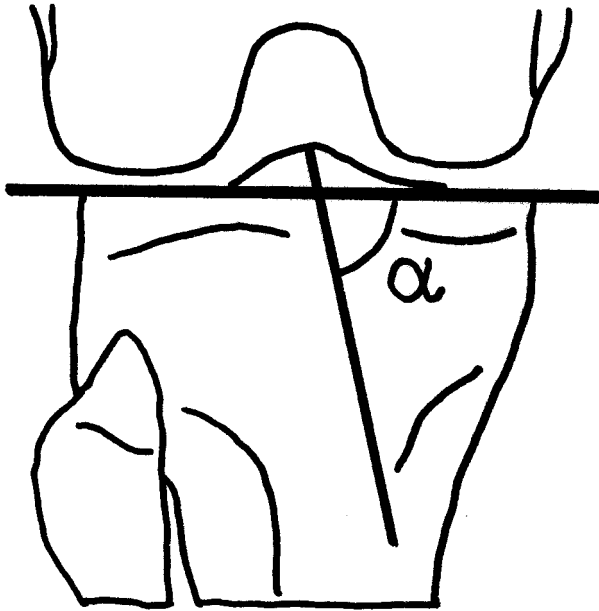


Fig. 2
Drawing showing the method of measurement of the tibial tunnel angulation in the coronal radiographic view. α = the angle between the central axis of the tibial tunnel and a line tangent to the medial tibial plateau.

Tunnel enlargement was measured, according to the method described by L'Insalata et al.⁴¹, by two independent observers (F.B. and F.S.) on the anteroposterior and lateral radiographs. With use of a caliper, the distance between the sclerotic margins of each tunnel was measured at its widest dimension, together with the diameter of the femoral fixation device. (The size of the drill-bit used for tunnel reaming was recorded at the time of surgery, and the diameter of the femoral fixation device was known and constant.) All measurements were corrected for magnification, and change in the tunnel size was calculated as a percentage of the diameter of the drill-bit. On the lateral radiograph, the prevalence of

femoral tunnel widening was not assessed because of the superimposition of the fixation device on the femoral tunnel margins.

Statistical Methods

Before the investigation was initiated, the sample size was estimated on the basis of the hypothesis that there was no difference in anterior-posterior knee laxity between the treatment groups. A clinically relevant difference between the groups was considered to be a 1-mm increase in anterior knee laxity compared with the contralateral side. The standard deviation, as has been seen in a previous trial⁴², was set at 1.5 mm. A power calculation was performed with a confidence level of 95% ($\alpha = 0.05$) and a power ($1 - \beta$) of 90%. This yielded an estimated sample size of forty-eight patients per group, and, when combined with an expected rate of patients lost to follow-up of 20% at two years, a sample size of sixty patients per group, or a total of 120 patients, was required. All statistical analyses were conducted on Statistica for Windows (5.1 edition; StatSoft, Tulsa, Oklahoma). A comparison of the differences between the groups was made with the Student t test for continuous variables and with the chi-square test and Fisher exact test for categorical variables. In all tests, an alpha level of 0.05 was considered significant.

Results

Meniscal Lesions and Treatment

The medial meniscus was torn in twenty-nine knees (48%) in the bone-patellar tendon-bone group and in twenty-six (43%) in the double-looped semitendinosus and gracilis tendon group. The lateral meniscus was torn in eight knees (13%) in the bone-patellar tendon-bone group and in seven (12%) in the hamstring group. Two meniscal lesions (medial and lateral) were recorded in eight (7%; five in the bone-patellar tendon-bone group and three in the hamstring group) of the 120 knees. A partial medial meniscectomy was performed in thirty-seven knees (31%; nineteen in the bone-patellar tendon-bone group and eighteen in the hamstring group). A partial

TABLE I Subjective Assessment*

	Preop.		4 Mo Postop.		1 Yr Postop.		2 Yr Postop.	
	BPTB	DSTG	BPTB	DSTG	BPTB	DSTG	BPTB	DSTG
Mean visual analog scale score† (points)	5	6	8	8	8	9	8	9
Mean Knee Injury and Osteoarthritis Outcome Score (points)								
Pain	75	81	89	91	90	94	92	95
Symptoms	73	77	85	87	88	89	88	90
Activities of daily living	87	90	95	96	96	97	97	97
Sports activities	57	53	72	79	81	87	84	87
Quality of life	41	39	66	67	75	83	79	83
Mean IKDC score‡ (points)	45	52	73	72	80	83	82	85

*BPTB = bone-patellar tendon-bone graft, and DSTG = double-looped semitendinosus and gracilis tendon graft. †A 10-point scale, with 10 points indicating a normal result. ‡IKDC score = International Knee Documentation Committee subjective score.

TABLE II Flexor-Extensor Muscle Strength Deficit

	Bone-Patellar Tendon-Bone Group			Double-Looped Semitendinosus and Gracilis Tendon Group		
	4 Mo	1 Yr	2 Yr	4 Mo	1 Yr	2 Yr
Strength deficit (%)						
Quadriceps						
60°/sec	24	11*	0.5*	18	5*	1
120°/sec	23	10*	1*	19	4*	0
180°/sec	21	9*	-1*	19	1*	-1
Hamstrings						
60°/sec	8	3†	-2	9	4	-3
120°/sec	4	-3	-2	4	4	-1
180°/sec	4	-2	-3	6	6	0

*Compared with findings at previous follow-up evaluation, the improvement in extensor strength was significant ($p < 0.005$ for the bone-patellar tendon-bone group, and $p < 0.04$ for the hamstring group). †Compared with findings at previous follow-up evaluation, the improvement in flexor strength was significant ($p = 0.02$).

lateral meniscectomy was performed in fifteen knees (12.5%; eight in the bone-patellar tendon-bone group and seven in the hamstring group). Nine knees (7.5%; four in the bone-patellar tendon-bone group and five in the hamstring group) with a reparable (longitudinal in the red-red zone of the posterior horn) medial meniscal tear were repaired with an inside-out technique⁴³. Meniscal repair sutures were tied after the anterior cruciate ligament reconstruction was completed. A stable longitudinal lesion (<1 cm) of the medial meniscus was left untreated in six knees (10%) in the bone-patellar tendon-bone group and in three knees (5%) in the hamstring group.

Complications and Additional Surgery

No intraoperative or postoperative complications occurred in this series. No patient underwent additional surgery of the knee.

Subjective Functional Assessment

The mean visual analog scale score, Knee Injury and Osteoarthritis Outcome Score, and IKDC score showed a progressive and substantial increase during the review period compared with the preoperative condition (Table I). All patients were satisfied with the postoperative result of the reconstruction. No significant differences were found between the two groups with respect to the subjective assessments at each follow-up evaluation. Furthermore, no correlation was found between subjective assessment and the postoperative knee stability, range of motion, muscle strength recovery, sports activity level, or radiographic evaluations.

Range of Motion

Extension deficit was assessed with the patient lying in the prone position and was measured as the difference in the heel height of the involved limb in comparison with that of the contralateral, uninjured limb in full passive extension. At the

four-month follow-up evaluation, only three knees in the bone-patellar tendon-bone group showed a 3° to 5° extension loss. No patient in the hamstring group showed an extension deficit. At the two-year follow-up examination, there was a progressive recovery of knee extension and only one knee in the bone-patellar tendon-bone group had a persistent 3° extension loss.

Full flexion, or a loss of <6° of flexion in comparison with the contralateral knee, according to the IKDC definition, was found in all knees in the bone-patellar tendon-bone group and in fifty-nine knees in the hamstring group at two years. One knee in the hamstring group had a 10° loss of flexion. There were no changes with respect to the recovery of knee flexion between four months and two years. No significant differences were found between the two groups. No correlation was found between postoperative recovery of the range of motion and knee stability, patellofemoral crepitus, sports activity level, muscle strength recovery, or radiographic evaluation.

Clinical Ligament Evaluation

Anterior tibial translation as demonstrated by the Lachman test was restored to within 5 mm (1+), and with a firm end point, in all patients for all follow-up visits for up to two years after surgery. At the two-year follow-up examination, a pivot-shift glide (1+) was recorded in ten knees (17%) in the bone-patellar tendon-bone group and in eleven knees (18%) in the hamstring group. No patient reported symptoms of giving-way or showed a pivot-shift clunk (2+). In the hamstring group, a correlation was found between medial meniscectomy and an increased prevalence of a pivot-shift glide at the time of follow-up. Eight of the twenty-four patients who had undergone a medial meniscectomy previously or at the time of the anterior cruciate ligament reconstruction showed a pivot-shift glide, whereas only four of the thirty-six patients who had not had a medial meniscectomy showed a pivot-shift glide ($p =$

TABLE III Internal-External Rotation Muscle Strength Deficit

	Bone-Patellar Tendon-Bone Group			Double-Looped Semitendinosus and Gracilis Tendon Group		
	4 Mo	1 Yr	2 Yr	4 Mo	1 Yr	2 Yr
Strength deficit (%)						
Internal rotation						
30°/sec	15	7	1	15	12	6
60°/sec	17	3	1	14	8	6
90°/sec	13	1	2	10	8	7
External rotation						
30°/sec	3	3	2	4	2	2
60°/sec	2	4	3	2	3	2
90°/sec	3	1	3	0	2	3

0.035). An analogous correlation was not found in the bone-patellar tendon-bone group. No correlation was found between the postoperative knee ligament evaluation and the range of motion, muscle strength recovery, sports activity level, patellofemoral crepitus, or radiographic evaluation.

Instrumented Testing

At the two-year follow-up examination, the average KT-1000 arthrometer values for side-to-side differences were 1.95 mm (range, -1 to 5 mm) in the bone-patellar tendon-bone group and 2.2 mm (range, 0 to 5 mm) in the hamstring group when tested at 134 N. The 134-N and maximum manual side-to-side KT-1000 results were comparable, with ≤ 2 mm in thirty-nine patients (65%) in the bone-patellar tendon-bone group and thirty-four (57%) in the hamstring group and between 3 and 5 mm in twenty-one patients (35%) in the bone-patellar tendon-bone group and twenty-six patients (43%) in the hamstring group.

The KT-1000 side-to-side anterior tibial translation both at 134 N and at maximum manual force decreased significantly between the preoperative examination and the two-year follow-up examination for both groups ($p < 0.001$). No significant differences were found between the two groups in terms of the two-year postoperative arthrometric values. There were also no significant differences in the clinical data and instrumented testing with respect to gender, height, body weight, generalized laxity, or meniscectomy.

Patellofemoral Symptoms

At the two-year follow-up evaluation, moderate, but asymptomatic, patellofemoral crepitation was recorded in thirteen knees (22%) in the bone-patellar tendon-bone group and in fourteen knees (23%) in the hamstring group. The average functional knee score for anterior knee pain was 47 points (range, 35 to 50 points) in the bone-patellar tendon-bone group and 48 points (range, 34 to 50 points) in the hamstring group. No significant difference was found between the two groups with respect to preoperative and postoperative patellofemoral symptoms. No correlation was found between

postoperative extensor strength recovery and the presence of patellofemoral crepitus.

Harvest Site Abnormality

At the last follow-up examination, we found that a greater number of patients complained of kneeling discomfort in the bone-patellar tendon-bone group than in the hamstring group. Thirty-seven patients (62%) in the bone-patellar tendon-bone group had kneeling discomfort compared with nine (15%) in the hamstring group ($p < 0.01$). With regard to the infrapatellar branches of the saphenous nerve, forty-six (77%) of the sixty patients in the bone-patellar tendon-bone group and thirty (50%) of the sixty patients in the hamstring group complained of alteration in anterior knee sensitivity. The average area of the skin sensitivity disturbance was 40 cm² (range, 10 to 88 cm²) in the bone-patellar tendon-bone group and 25 cm² (range, 10 to 80 cm²) in the hamstring group; the difference was significant ($p < 0.001$).

Overall IKDC Score

At the two-year follow-up examination, thirty-eight knees (63%) in the bone-patellar tendon-bone group and thirty-four knees (57%) in the hamstring group were graded A. The remaining knees were graded B, and no knees were classified as C or D. No significant difference was found between the groups.

Muscle Strength Recovery

The extensor and flexor muscles showed progressive recovery with time, and the strength was comparable with the contralateral side in both groups at the time of the two-year follow-up examination (Table II).

Extensor muscle strength improved over time in both groups and became comparable with that on the normal side at two years. At all angular velocities in both groups, the improvement in strength between the four-month and the one-year tests was significant ($p < 0.005$ for the bone-patellar tendon-bone group, and $p < 0.04$ for the hamstring group). In the bone-patellar tendon-bone group, the strength im-

provement between the one-year and the two-year test was also significant ($p < 0.005$). With regard to flexor strength, a significant difference in terms of better performance was recorded only in the bone-patellar tendon-bone group between the four-month and one-year follow-up examinations ($p = 0.02$). However, no significant difference was found between the two groups of patients with respect to postoperative flexor and extensor muscle strength status at each follow-up evaluation.

Internal and external rotation strength recovery showed a similar progressive recovery with time and became comparable with that of the contralateral side in both groups by the two year follow-up evaluation (Table III). At the last follow-up evaluation, the internal rotation deficit at the three angular velocities ranged from 1% to 2% in the bone-patellar tendon-bone group and 6% to 7% in the hamstring group. However, no significant difference was found between the two groups of patients with respect to the postoperative rotator muscle strength.

Postoperatively, no correlation was found between residual muscle strength deficit and knee ligament stability, sports activity level, patellofemoral crepitation, or subjective functional assessment.

Activity

The IKDC form is used to grade the level of activity, with level I indicating strenuous activity (cutting, jumping, and twisting); level II, moderate activity (skiing, playing tennis, and performing heavy manual labor); level III, light activity; and level IV, sedentary activity. Before the rupture of the anterior cruciate ligament, fifty-two (87%) of the sixty patients in the bone-patellar tendon-bone group and fifty-three (88%) of the sixty patients in the hamstring group were involved in level-I or II activities. At the two-year follow-up evaluation, twenty-seven patients (45%) in the bone-patellar tendon-bone group were involved in level-I activities; seven (12%), in level-II activities; twenty-two (37%), in level-III activities; and four (7%), in level-IV activities. In the hamstring group at the time of the two-year follow-up, twenty-nine patients (48%) were involved in level-I activities; thirteen (22%), in level-II activities; eleven (18%), in level-III activities; and seven (12%), in level-IV activities. A significant difference was found with regard to the number of patients active in level-I or II sports before the anterior cruciate ligament tear and after the reconstruction. Postoperatively, significantly fewer subjects in both groups were able to return to higher-level sport activities ($p = 0.003$ for the bone-patellar tendon-bone group and $p < 0.001$ for the hamstring group). With respect to patient-specific changes in activity level from before the injury to after the surgery, thirty-four (65%) of fifty-two patients in the bone-patellar tendon-bone group and forty-two (79%) of fifty-three in the hamstring group returned to level-I or II sport activities. Only five patients (10%) in the bone-patellar tendon-bone group and six (11%) in the hamstring group reported that the decrease in sports activity level was related to knee symptoms. No patient in either

group was unable to return to sports because of knee symptoms. Postoperatively, no significant difference was found between the two groups with respect to the number of patients active in sports or the level of participation.

Radiographic Assessment

The anterior margin of the intra-articular exit of the tibial tunnel in the sagittal plane was located, on the average, at 42% (range, 32% to 52%) of the width of the tibial plateau in the bone-patellar tendon-bone group and 40% (range, 24% to 50%) of the width of the tibial plateau in the hamstring group. On the basis of the radiographic measurement method of Howell and Clark³⁸, moderate graft impingement was present in seventeen knees in the bone-patellar tendon-bone group and in eighteen knees in the hamstring group. No case of severe graft impingement was noted. At the time of follow-up, no correlation was found between the presence of moderate impingement and increased anterior tibial translation. The anterior margin of the femoral tunnel was located, on the average, at 67% (range, 63% to 71%) of the femoral condyle width for the bone-patellar tendon-bone group and at 63% (range, 55% to 69%) for the hamstring group on the lateral projection radiograph. No correlation was found between the position of the femoral tunnel and knee stability.

Tibial tunnel angulation with respect to the medial tibial plateau in the frontal plane was an average of 66° (range, 60° to 78°) in the bone-patellar tendon-bone group and an average of 69° (range, 60° to 76°) in the hamstring group; the difference was not significant. No correlation was found between tibial tunnel angulation and increased knee laxity or loss of knee flexion.

The amount of tibial tunnel widening in the sagittal plane was 55% in the bone-patellar tendon-bone group and 60% in the hamstring group. In both groups, the average tibial tunnel widening was 25% (range, 20% to 50%). In the coronal plane, tibial tunnel widening was found in 32% of the knees in the bone-patellar tendon-bone group and in 39% of those in the hamstring group. The average widening of the tibial tunnel was 24% (range, 20% to 50%) in both groups. Femoral tunnel widening in the coronal plane was observed in 17% of the patients in the bone-patellar tendon-bone group and in 51% of the patients in the hamstring group. This rate of femoral widening was significantly greater in the hamstring group ($p < 0.01$). The average amount of tunnel widening in the coronal plane in the femur was 23% (range, 20% to 30%) in the bone-patellar tendon-bone group and 27% (range, 20% to 50%) in the hamstring group.

The frequency and the amount of tunnel widening showed no changes after the one-year follow-up evaluation. No correlation was found between tunnel widening and knee stability.

Discussion

The popularity of the use of hamstring tendons in anterior cruciate ligament reconstruction has increased in recent years. Compared with the bone-patellar tendon-bone graft,

however, the initial results, in terms of stability and clinical results, were inferior^{2,44,45}. Recent investigations have found superior material properties of the equally tensioned double-looped semitendinosus and gracilis tendons graft⁴⁶ compared with the bone-patellar tendon-bone graft. Furthermore, the mechanical properties of hamstring tendons seem to be preserved with increasing age, in contrast to the bone-patellar tendon-bone graft, which seems to weaken with age⁴⁷.

The initially inferior clinical results with the hamstring graft could be explained by inadequate graft fixation. Steiner et al.⁴⁸ were the first to demonstrate that a direct and strong fixation of the hamstring graft to bone was the key to success. New fixation devices have been introduced to improve fixation of the hamstring graft, and the clinical results have improved in terms of patient satisfaction, joint stability, and sports activity recovery^{49,50}.

The present prospective, randomized clinical trial was performed to compare double-looped semitendinosus and gracilis tendon and bone-patellar tendon-bone grafts with use of newer surgical techniques and fixation devices. The fixation devices for the hamstring graft were chosen on the basis of their excellent biomechanical properties²⁰⁻²³. The femoral fixation in the bone-patellar tendon-bone group was selected to resemble the transcondylar fixation used for the hamstring graft. At the two-year follow-up evaluation, no significant difference was found between the groups with respect to the IKDC scores. Kneeling discomfort was more frequent in the bone-patellar tendon-bone group ($p < 0.01$), and femoral tunnel widening was more frequent in the hamstring group ($p < 0.01$). All patients were satisfied with the outcome of the operation, and three different subjective scores failed to reveal any significant difference between the groups. The knee range of motion was recovered in 100% of the patients in both groups.

Knee stability was comparable in the two groups, with the exception of a correlation that was found between the presence of a pivot-shift glide and medial meniscectomy in the hamstring group ($p = 0.035$).

In contrast to our series that was reported in 1994¹, in which the recovery of the sports activity level was significantly higher in the bone-patellar tendon-bone group ($p = 0.01$), the present study showed an initial significant improvement over the preoperative condition, but the mean preinjury activity level was not achieved in either group at two years. While most of our patients were recreational athletes, 65% of the patients in the bone-patellar tendon-bone group and 79% of the patients in the hamstring group who were involved in vigorous (IKDC level-I or II) sports activities before the injury were able to return to the same level. In only 10% of the patients in both groups was the inability to return to the preinjury level of sports related to the knee.

The groups demonstrated similarly low rates of patellar symptoms, with asymptomatic patellofemoral crepitation found in 22% of the patients in the bone-patellar tendon-bone group and in 23% in the hamstring group. Nevertheless, kneeling discomfort was more frequent in the bone-patellar tendon-bone

group (62%) compared with the hamstring group (15%) ($p < 0.01$). No correlation was found between kneeling discomfort and the presence or the extent of skin hypoesthesias, even though the bone-patellar tendon-bone group had a larger mean area of decreased sensitivity ($p < 0.001$).

While some believe in the biological advantages of a multistranded hamstring graft compared with a bone-patellar tendon-bone graft^{51,52}, it is well accepted that healing of the tendon to bone is more difficult to achieve and requires more time (usually eight to twelve weeks) than does healing of bone to bone (usually four to six weeks)⁵³⁻⁵⁵. The attachment zone is said to be also more physiological with the bone-patellar tendon-bone graft with a regular chondral transition between tendon and bone⁵⁶, whereas in the hamstrings a fibrous insertion is usually obtained^{55,57}. The factors that may determine the strength and stiffness of the tendon-fixation device-bone complex after implantation are the tendon graft-tunnel interface and the fixation device itself. A recent study in dogs has demonstrated that pullout strength was enhanced by increasing the length and the press-fit of the tendon within the tunnel. With doubling the length of the tunnel, there was a 60% gain in terms of load to failure⁵⁸. Another study in sheep⁵⁹ has shown that the strength and stiffness of the tendon graft-fixation complex in the tibia was either maintained or improved with a low-profile distal fixation device such as the WasherLoc screw. Therefore, for our patients in the hamstring group, we increased the tendon-bone tunnel interface, adding bone graft inside the tunnel, and we fixed the graft with the WasherLoc screw.

We found the One Step tibial guide to be simple to use and reliable in achieving a satisfactory position of the tibial tunnel. This guide allows the surgeon to customize the tibial tunnel on the basis of the anatomy of the individual patient. No patient had severe impingement. A small anterior notchplasty is sometimes required. We avoided extending the notchplasty to the posterior part of the notch because doing so might change the insertion point of the graft and produce an abnormal graft tension pattern with knee flexion⁶⁰. The amount of notchplasty is not accurately shown on postoperative radiographs⁶¹—i.e., grafts that appeared to have impingement actually were free of impingement—which may explain why the moderate impingements found were of no consequence with regard to stability or motion. One advantage of the bone-patellar tendon-bone graft over the hamstring graft is the ability to rotate it to avoid impingement against the roof. In fact, the surgeon can adjust the rotation of the bone-patellar tendon-bone graft on the femoral side to position it more posteriorly and on the tibial side to reduce the impingement. This cannot be done with the hamstring graft.

The position of the femoral tunnel is another important influence upon graft tension during knee motion. In the sagittal plane, a posterior position along the notch is preferable, but recently several studies^{30,40} have emphasized the importance of the position of the femoral tunnel in the coronal plane as well. It has been shown that a position at about twelve

o'clock, resulting from drilling the femoral tunnel through a vertical tibial tunnel, can cause impingement of the graft and high graft tension in flexion. To minimize these problems, the angulation of the tibial tunnel in the coronal plane in this series averaged 66° in the bone-patellar tendon-bone group and 69° in the hamstring group. The resultant femoral tunnel was in the eleven o'clock position in the right knee and in the one o'clock position in the left knee⁶².

The fixation techniques for the hamstring graft that we adopted have been tested biomechanically^{20-23,27}. The Bone Mulch screw in the femur is a very strong and stiff fixation device²⁰. The four strands of tendon remain parallel and can be tensioned equally⁴⁶ after cycling. The femoral tunnel is grafted with autologous bone in order to increase stiffness and avoid the pulley effect around the nose of the screw. In the tibia, after grafting the tunnel, we used the WasherLoc system, which also has shown good strength, stiffness, and slippage characteristics^{21,60}.

In the bone-patellar tendon-bone group, transcondylar screw fixation in the femur was chosen to resemble the surgical technique used in the hamstring group. The effectiveness of this method was recently reported in a two-year anterior cruciate ligament reconstruction trial²⁶. Interference screw and Tunneloc screw fixation were compared. Substantially better knee stability and IKDC scores were found in those patients treated with the Tunneloc screw. Furthermore, transcondylar fixation offers other advantages, such as the absence of intra-articular hardware and greater bone-to-bone contact surface, and it allows graft fixation in the case of breakage of the posterior femoral wall.

The use of strong and stiff fixation allowed us also to achieve comparable clinical results in men and women. Several studies^{14,63,64} have described inferior results with the use of hamstring tendons in women, but the fixation devices used in those studies had inferior biomechanical properties. Moreover, in our series, the use of the One Step tibial guide, the Bone Mulch screw, and the WasherLoc fixation system al-

lowed us to accommodate for the generalized laxity and the decreased bone mineral density often found in women.

A certain amount of tunnel widening became apparent in a few months, most often in the hamstring group and particularly in the femur. While the cause of tunnel widening remains controversial and multifactorial^{41,65,66}, it did not correlate with increased laxity in this study.

In conclusion, we believe that with modern surgical and fixation techniques the same clinical results can be obtained with use of the two grafts. At the present time, it is not possible to clearly show that one graft is superior to the other. Specific indications for each of the two grafts have been presented in the past, depending on the level of activity, body habitus, gender, and the degree of joint laxity. From our results, the choice of the graft should not be made on the basis of these criteria but on the patient's preferences and on the surgical technique in which the surgeon is skilled. Surgeons who perform many anterior cruciate ligament reconstructions need to master both techniques. It is probable that the principles of surgical technique, graft fixation, and postoperative rehabilitation are more important than the graft choice in anterior cruciate ligament reconstruction. ■

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