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Biodegradable Screw Versus a Press-Fit Bone Plug Fixation for Hamstring Anterior Cruciate Ligament Reconstruction

A Prospective Randomized Study

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Background: Press-fit fixation of a tendon graft has been advocated to achieve tendon-to-bone healing.

Hypothesis: Fixation of hamstring tendon grafts with a porous bone scaffold limits bone tunnel enlargement compared with a biodegradable interference screw fixation.

Study Design: Randomized controlled trial; Level of evidence, 1.

Methods: Between 2005 and 2006, 20 patients (17 men, 3 women) with a primary reconstruction of the anterior cruciate ligament (ACL) were enrolled in this study. Patients were randomized to obtain graft fixation in the tibial tunnel either by means of an interference screw (I) or a press-fit fixation with a porous bone cylinder (P). At 3 months after surgery, a computed tomography (CT) scan of the knee was performed, and tunnel enlargement was analyzed in the coronal and sagittal planes for the proximal, middle, and distal thirds of the tunnel. After 6 months and 1 and 2 years, radiographs of the knee in the sagittal and coronal plane were analyzed for bone tunnel widening. The International Knee Documentation Committee (IKDC), Tegner, and Lysholm scores of both groups were compared after 1 and 2 years.

Results: The bone tunnel enlargement determined by CT was 106.9% ± 10.9% for group P and 121.9% ± 9.0% for group I ($P <$ .02) in the anteroposterior (AP) plane and 102.8% ± 15.2% versus 121.5% ± 10.1% in the coronal plane ($P < .01$). The IKDC, Tegner, and Lysholm scores improved in both groups from preoperatively to postoperatively without significant differences between the 2 groups. There was a trend to higher knee stability in group P after 3 months (0.6 ± 1.4 mm vs 1.8 ± 1.5 mm; $P = .08$).

Conclusion: Both interference screw and a press-fit fixation lead to a high number of good or very good outcomes after ACL reconstruction. Tibial press-fit fixation decreases the amount of proximal bone tunnel enlargement.

Keywords: ACL reconstruction; hamstring tendons; press-fit

Numerous studies have investigated the outcome of anterior cruciate ligament (ACL) reconstruction. These studies have been summarized in 2 meta-analyses as follows[8,10]: Patellar tendon autografts have a significantly lower rate of graft failure and result in better static knee stability and increased patient satisfaction compared with hamstring tendon autografts. However, patellar tendon autograft reconstructions are associated with an increased rate of anterior knee pain. Reasons for the decreased stability of hamstring reconstructions[8] are differences in the biomechanical properties of the graft, fixation of the graft, and inferior healing inside the bone tunnel. Improved healing inside the bone tunnel may be fostered by initial pressure between the graft and the bone tunnel wall.[32]

Bone tunnel enlargement is a problem that has been observed after reconstruction of the ACL.[7,20,21] The occurrence of bone tunnel enlargement is more frequent, and the magnitude is greater when hamstring tendon grafts are

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used.[7,21] Migration of the graft within the tunnel has been suspected of causing this phenomenon.[13] Press-fit fixation of the patellar tendon with bone blocks has been demonstrated to show a good functional outcome in a study with a follow-up of 10 years.[12] In a previous study from our laboratory, 3 techniques of press fitting hamstring tendons in the femoral tunnel were investigated.[16] Two of the 3 techniques were mechanically equivalent compared with the patellar tendon press-fit technique if the grafts were preconditioned adequately.

We therefore conducted the present study to investigate the possibility of using press-fit fixation on the opposite end of the graft, namely in the tibial tunnel. The investigated techniques were also developed using a bone block that presses the graft against the tibial tunnel in close proximity to the joint space. Based on previous experience, such a technique could foster tendon to bone healing. Tendon-to-bone healing is compromised by many graft fixation techniques that are currently used.[5,22,25]

Hence, the purpose of this study was to analyze bone tunnel enlargement and clinical outcome of patients who were treated with a press-fit fixation (group P) of a hamstring tendon graft compared with interference screw fixation (group I) for ACL insufficiency.

MATERIALS AND METHODS

Sample Size Assessment

The following parameters were chosen for the assessment of sample size: 2-sided test, significance level of .05, difference of means in tunnel enlargement of 14% (standard deviation [SD], 10%),[7,20,21] difference in maximum manual knee laxity of greater than 2 mm (SD, 2 mm),[8] and difference in Lysholm score of 4 points (SD, 2 points). For all of these parameters, a sample size of 10 per group was sufficient to obtain a power of >80% (Table 1).

TABLE 1
Sample Size Was Determined Using the Following Parameters for the Variables: Expected Lysholm Scores, Arthrometric Side-to-Side Difference (Lachman Test), and Tunnel Enlargement

	Lysholm Score	Arthrometric Side-to-Side Difference (mm)	Tunnel Enlargement (%)
Test significance level, α	0.050	0.050	0.050
1- or 2-sided test?	2	2	2
Difference in means, $\mu_1 - \mu_2$	4.000	3.000	13.249
Common standard deviation, σ	2.000	2.000	10.000
Effect size, $\delta = \lvert\mu_1 - \mu_2\rvert / \sigma$	2.000	1.500	1.325
Power (%)	98	88	80
N per group	10	10	10

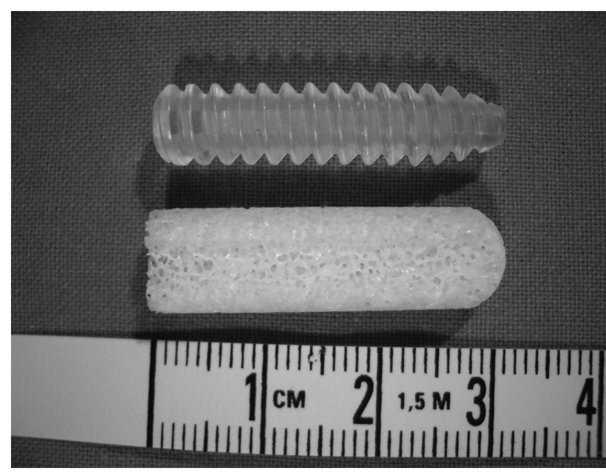

Figure 1. Implants used in this study for tibial fixation of the graft: biodegradable interference screw (Absolute, DePuy Mitek, Johnson & Johnson Medical GmbH, Norderstedt, Germany) (top) and a xenogenic spongiosa cylinder (Tubobone, Tutogen Medical GmbH, Neunkirchen, Germany) (bottom). The length of both implants was 30 mm. The diameter matched the diameter of the tibial tunnel.

Study Population

Between January 2005 and December 2006, a total of 20 patients (17 men, 3 women; age, 27.8 ± 8.8 years) with primary ACL insufficiency were enrolled in the study. Patients with a loss of more than one third of either medial or lateral meniscus or a chondral damage of grades III or IV according to the International Cartilage Repair Society (ICRS[30]) were excluded. Informed consent was given to participate. The study was approved by the Institutional Ethics Committee and by the Federal Office for Radiation Protection (BfS). The mean time interval between injury and surgical intervention was 55.3 ± 57.9 days in group P and 51.6 ± 31.9 days in group I. There were 2 partial meniscectomies carried out in group P and 1 in group I (more than two thirds of the meniscus was preserved in all of these cases). Patients were selected after evaluation of magnetic resonance imaging (MRI), and inclusion criteria were re-evaluated during arthroscopic examination of the knee joint. Patients were randomized using a computer-generated random list. Patients of group I received tibial fixation by means of a biodegradable interference screw (Absolute, DePuy Mitek, Johnson & Johnson Medical GmbH, Norderstedt, Germany). Grafts of group P were pressed against the tibial tunnel by a xenogenic spongiosa cylinder (Tubobone, Tutogen Medical GmbH, Neunkirchen, Germany) (Figure 1). Both groups additionally received fixation via a post over a bone bridge (Figure 2) using 2 FiberWire 2 sutures (Arthrex, Naples, Florida).[19] The study population is described in Table 2.

Graft Preparation and Fixation

Preparation and fixation of the grafts were done according to published protocols.[18,19] Briefly, both semitendinosus and gracilis tendons were harvested by a horizontal skin

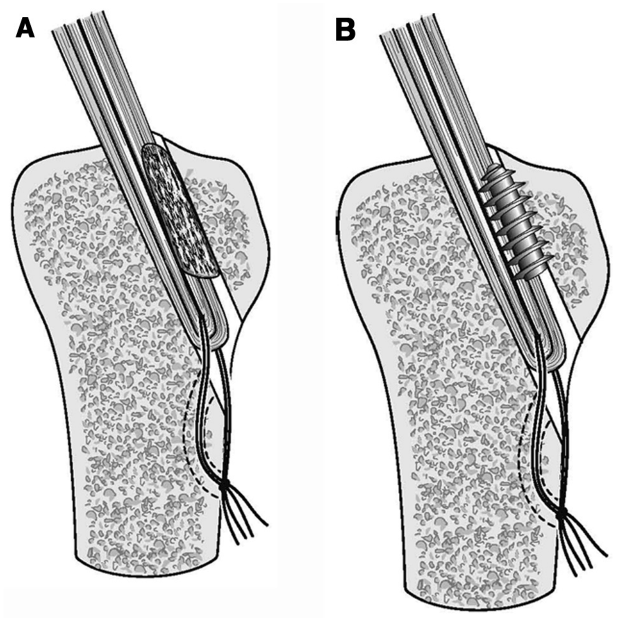

Figure 2. The implants were inserted from the distal end of the tibial tunnel and advanced as close as possible to the proximal end of the drill hole under arthroscopic control. In both groups, a post fixation over a 10-mm bone bridge was achieved using a 4.5-mm AO drill bit. A, Porous bone cylinder. B, Interference screw. Both figures demonstrate the situation in a 4-stranded graft, where a loop could be created at the distal end of the graft.

incision and dissection of the sartorius tendon. Graft harvest was performed using closed tendon strippers. The tendons were measured and, depending on the size, a 3- or 4-bundle graft was prepared. In both groups, there were 4 patients receiving a 3-strand graft and 6 receiving a 4-strand graft. The femoral side of the graft was secured using No. 2 polyester sutures (Ethibond, Johnson & Johnson Medical GmbH), the tibial side using FiberWire 2 (Arthrex). The grafts were kept moist during preparation with a buffered physiological saline solution.

All tibial bone tunnels were drilled using a Howell 65° tibial guide (Biomet Sports Medicine Inc, Warsaw, Indiana[15]) with the knee in full passive extension. The diameter of the drill bit was chosen according to the thickness of the femoral side of the graft. Then, the cortical bone was overdrilled distally with a diameter matching the distal end of the graft. Dilatators were used to enlarge the tunnel diameter to the size of the distal end of the graft. This method was used to make the entrance of the bone tunnel to the joint as tight as possible to enhance tendon to bone contact and minimize bone tunnel enlargement.[13] Femoral tunnel drilling was achieved with a drill guide that left a 1-mm bridge to the posterior wall of the femur. The tunnel was drilled in a 10- or 14-o'clock position through the anteromedial portal. Fixation was performed by 2 cross-pins (Rigidfix, DePuy Mitek, Johnson & Johnson Medical GmbH). The graft was then preconditioned by taking the

TABLE 2
Descriptive Data of Study Population[a]

	Fixation Type		
	P	I	Significance
No. of patients	10	10	
Age, y	27.7 ± 10.1	27.9 ± 7.8	NS
Gender (male/female)	9/1	8/2	NS
Diameter of tibial tunnel	9.3 ± 0.9	8.3 ± 0.9	NS
No. of strands	3.5 ± 0.5	3.6 ± 0.5	NS

[a]NS, not significant.

knee through the full passive range of motion 20 times. Adjacent to the distal outlet of the tibial tunnel, a 10-mm-wide bone bridge was created using a 4.5-mm AO drill bit. The distal end of the graft was advanced into the tibial tunnel (Figure 2). Two of 4 strands of a FiberWire 2 suture (Arthrex) were passed through the bone bridge and were tightened with the knee in 30° of flexion until the maximum manual Lachman test (determined by a Rolimeter, DJO Inc, San Diego, California) matched the value of the opposite side.[26] All strands of the graft were tightened at the same time. The right amount of tension was implemented using 3 half-hitches, locking the last hitch before the measurement. If necessary, the half-hitch was loosened and tightened again. After the right amount of displacement was obtained, the sutures were locked using another 2 half-hitches in opposite directions.

Press-Fit Fixation (P)

A conical bone cylinder (length: 30 mm) (Tubobone, Tutogen Medical GmbH) (Figure 1) was inserted into the tibial tunnel, and a pusher was used to advance the cylinder to the proximal end of the tibial tunnel (Figure 2A).

Interference Screw Fixation (I)

A poly-D/L lactide degradable interference screw (Absolute, Mitek Johnson & Johnson Medical GmbH) with a screw length of 30 mm and a diameter that matched the tunnel was inserted over a guide wire using the instruments and guidelines provided by the manufacturer. The screw was advanced to the proximal outlet of the tunnel.

Rehabilitation

Patients were braced in 0° of extension for the first 24 hours. Then, they were allowed 0° to 90° of knee flexion, and continuous passive motion was administered. Partial weightbearing was conducted for 3 weeks followed by weightbearing as tolerated. Closed kinetic chain exercises were recommended for the first 6 weeks. Return to cutting sports was allowed only after 6 months if knee function was normal or nearly normal on clinical examination.

Figure 3. Representative examples of measuring the amount of bone tunnel enlargement. Volume datasets were transferred to a multimodality workstation (GE Advantage Workstation 4.2, GE Healthcare, Chalfont St Giles, United Kingdom). Planes perpendicular to the tibial tunnel were created, and measurements were made in the sagittal and coronal planes. The examples show measurements of the proximal third of the tunnel. A, Porous bone cylinder. B, Interference screw.

Clinical Follow-up

All patients were assessed by an independent examiner before surgery and at 3, 6, 12, and 24 months after surgery using the International Knee Documentation Committee (IKDC) evaluation form,[1,28] the Lysholm, and the Tegner activity score.[2] Side-to-side knee laxity was measured using the KT-1000 arthrometer (MEDmetric Corp, San Diego, California) on manual maximum testing. Range of motion was measured using a long arm goniometer.

Radiological Follow-up

Before surgery and 6 and 12 months after surgery, weight-bearing anteroposterior (AP) and lateral view radiographs were taken. Three months after surgery, an Iso-C scan of the proximal tibia was performed (Siremobil Iso-C 3d, Siemens AG Medical Solutions, Erlangen, Germany); 62 kV and 3.4 mA were applied, and a slice thickness of 0.46 mm was used. One hundred images were obtained performing a 190° scan. The DICOM datasets were transferred to a multimodality workstation (GE Advantage Workstation 4.2, GE Healthcare, Chalfont St Giles, United Kingdom), and image data were analyzed as follows: Double-oblique multiplanar reformations (MPRs) perpendicular to the length axis of the tibial channel were generated, and the maximum diameter at the proximal and distal end of the channel was measured. Likewise, the cross-sectional area was determined at these levels. All measurements were performed by an independent radiologist (C.vF.) 3 times. The mean values were recorded. Representative examples of the planes used are displayed in Figure 3. The values for tunnel enlargement are reported in percentages, with 100% representing the baseline (no tunnel widening). Likewise, radiographs were analyzed using a multimodality workstation (GE Advantage Workstation 4.2, GE Healthcare). Values were transferred into cross-sectional area and reported in percentages, with 100% representing the baseline (no tunnel widening).

Statistical Analysis

For the determination of sample size, n-query Advisor 7.0 for Windows (Statcon, Witzenhausen, Germany) was used (Table 1). All mean values are reported with standard deviations. The 2 groups were compared using a 2-tailed Student t test. Comparisons of the 3 tunnel locations (proximal, middle, distal) were conducted using ANOVA with a post hoc Tukey test. For comparison of the IKDC distribution, the χ^2 test was used. All operations were performed using SigmaStat 3.0 (SPSS, Chicago, Illinois). A significance level of .05 was used.

RESULTS

Bone Tunnel Enlargement

Values are reported for computed tomography (CT) measurements 3 months after surgery for the proximal, middle, and distal portions of the tibial tunnel, respectively. The enlargement in the AP plane was 106.9% ± 10.9% (range, 90.6%-126.0%), 114.4% ± 19.7% (range, 76.7%-144.5%), and 112.2% ± 25.0% (range, 85.0%-156.7%) in group P but averaged 121.9% ± 9.0% (range, 108.9%-138.8%), 113.6% ± 12.3% (range, 96.7%-140.0%), and 104.4% ± 18.7% (range, 76.7%-133.3%) in group I, respectively. In the sagittal plane, the observed tunnel diameter was

102.8% ± 15.2% (range, 86.4%-135.6%), 114.2% ± 14.2% (range, 87.8%-134.4%), and 93.7% ± 17.5% (range, 66.7%-121.1%) in group P but was observed with 121.5% ± 10.1% (range, 106.3%-138.6%), 111.7% ± 25.5% (range, 84.4%-147.8%), and 99.3% ± 14.2% (range, 80.0%-120.0%) in group I, respectively. The cross-sectional diameter was enlarged 110.4% ± 23.2% (range, 87.3%-150.6%), 132.5% ± 34.3% (range, 67.3%-180.8%), and 107.4% ± 40.4% (range, 57.0%-189.7%) in group P but averaged 148.1% ± 16.6% (range, 127.0%-174.2%), 127.5% ± 36.6% (range, 92.4%-206.9%), and 108.1% ± 32.4% (range, 61.4%-155.6%) in group I, respectively. There was a significant difference between the 2 groups for the proximal tunnel enlargement in both planes (AP: $P = .04$; SAG: $P < .01$; cross-sectional diameter: $P < .01$). For group I, there was less tunnel enlargement at the distal third of the tunnel ($P = .01$) compared with the proximal and middle third. The data are represented by the graphs in Figure 4.

The radiological measurements, after 6 months, determined that the cross-sectional diameter changed 97.6% ± 17.0% (range, 69.1%-127.2%), 53.7% ± 35.0% (range, 11.7%-108.4%), and 98.5% ± 38.7% (range, 51.9%-179.3%) in group P but averaged 123.4% ± 32.8% (range, 54.0%-178.4%), 124.5% ± 28.1% (range, 56.2%-158.6%), and 103.5% ± 18.0% (range, 57.7%-118.0%) in group I, respectively.

After 1 year, the cross-sectional diameter was 97.6% ± 22.0% (range, 66.9%-140.4%), 82.7% ± 32.2% (range, 39.7%-124.4%), and 101.4% ± 22.9% (range, 66.9%-140.0%) in group P and 133.6% ± 38.3% (range, 81.0%-200.9%), 126.6% ± 37.0% (range, 84.4%-205.3%), and 96.0% ± 20.9% (range, 78.6%-145.1%) in group I, respectively.

After 2 years, the diameter was determined to be 92.8% ± 17.9% (range, 68.0%-120.0%), 83.4% ± 30.8% (range, 39.7%-120.4%), and 99.6% ± 22.8% (range, 78.0%-130.5%) in group P and 130.7% ± 36.2% (range, 80%-160.5%), 124.5% ± 37.4% (range, 89.3%-190.5%), and 98.5% ± 19.7% (range, 78.6%-135.5%) in group I, respectively. There was a highly significant difference between techniques regarding the proximal ($P < .001$) and midportion ($P < .008$) of tunnel enlargement (Figure 5). There was a difference between the 3 tunnel locations in both groups ($P < .02$).

IKDC and KT-1000 Evaluation

Before index surgery, only 2 patients in group P and 4 patients in group I were rated category B; no patient was in category A. Three months after ACL reconstruction, 8 patients in groups P and I were rated category A or B. There was 1 graft rupture in group P after 5 months with an adequate trauma (knee rotation injury when playing soccer). After 1 and 2 years, all patients in both groups were rated A or B. There was a time-dependent increase in both groups (χ^2 test, $P = .02$). However, no difference was seen between groups. The entire data for the analysis are shown in Table 3.

The arthrometric measurement of the maximum manual side-to-side displacement revealed a difference of 6.7 ± 1.8 mm in group P and of 6.6 ± 3.1 mm in group I before surgery. Postoperatively, the amount of maximum manual displacement improved in group P (3 months: 0.6 ± 1.4 mm; 1 year: 0.9 ± 1.4 mm; 2 years: 1.1 ± 1.5 mm) and in group I (3 months: 1.8 ± 1.5 mm; 1 year: 2.0 ± 1.6 mm; 2 years: 2.2 ± 1.8 mm). This improvement was highly significant for both groups (t test, $P < .001$). There was a trend toward less laxity in group P after 3 months ($P = .08$).

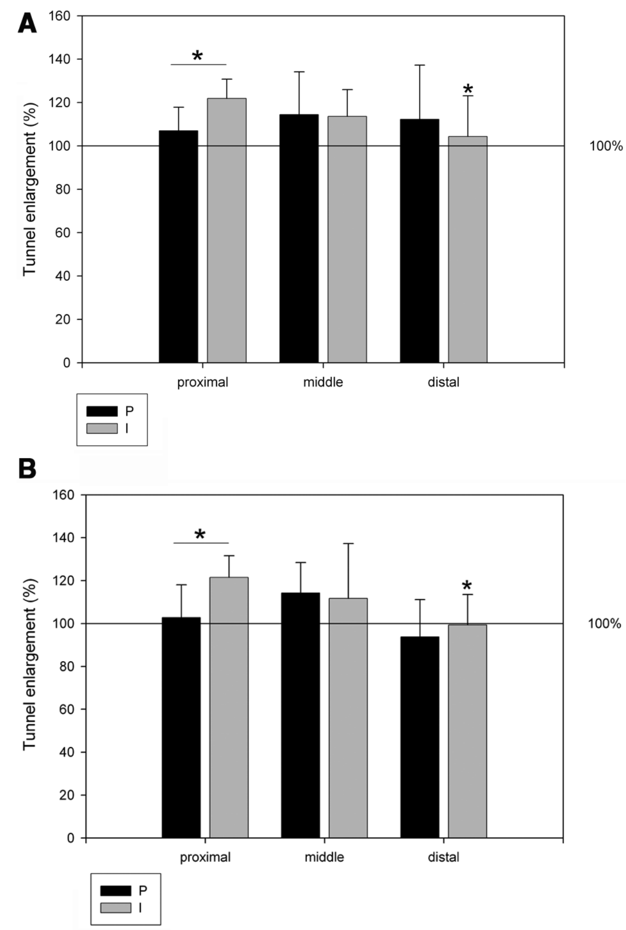

Figure 4. Percentage of bone tunnel enlargement in the sagittal (A) and coronal (B) planes. One hundred percent represents the baseline. There was a significant difference between the 2 groups for the proximal tunnel enlargement in both planes (t test, AP: $P = .04$, SAG: $P < .01$). For group I, there was less tunnel enlargement at the distal third of the tunnel (ANOVA, $P = .01$) compared with the proximal and middle thirds.

Tegner Scores

Activity levels of the patients were 3.2 ± 1.8 in group P and 3.3 ± 1.5 in group I preoperatively. Tegner scores increased (6.7 ± 1.3 and 5.8 ± 1.0) after the first and second year (6.5 ± 1.1 and 5.6 ± 1.2, respectively). There was a significant increase in activity level from preoperatively to postoperatively in both groups (t test, $P < .001$). The entire data are represented in Table 3.

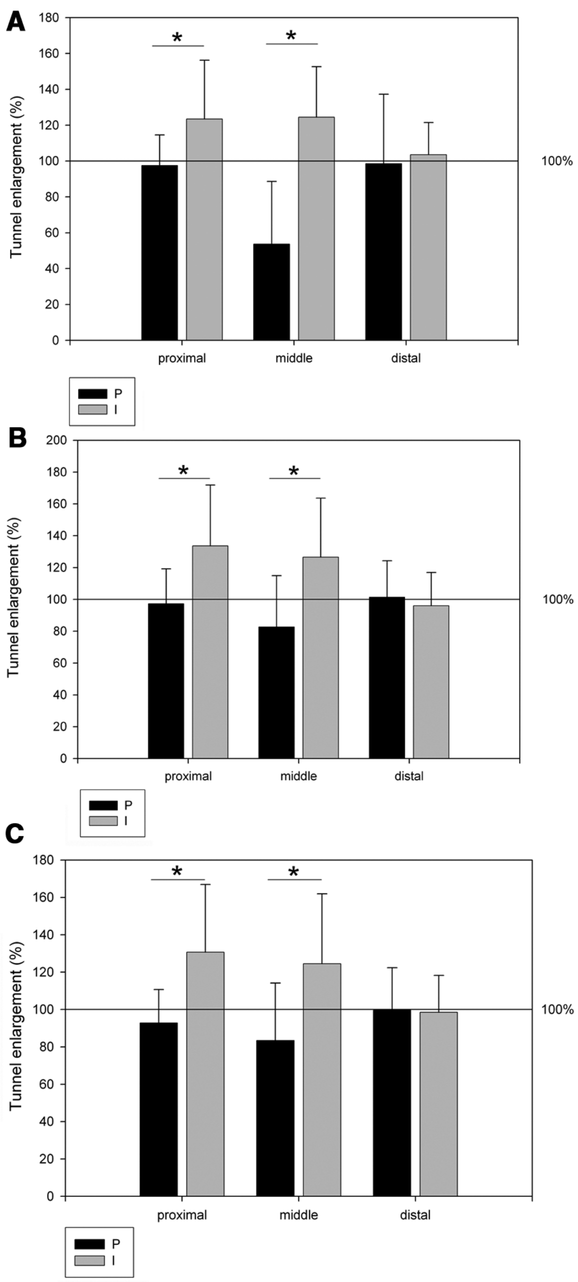

Figure 5. Percentage of bone tunnel widening determined by the change in cross-sectional diameter on plain radiographs in 2 planes at 6 months (A), 1 year (B), and 3 years (C) after surgery. There was a highly significant difference between techniques regarding the proximal (t test, $P < .001$) and midportion ($P < .008$) of the tibial tunnel (marked by asterisk). There was a difference between the 3 tunnel locations in both groups (ANOVA, $P < .02$).

Lysholm Scores

Preoperative Lysholm scores were 67.1 ± 22.0 in group P and 71.6 ± 18.6 in group I. Both groups improved postoperatively (group P: 1 year: 84 ± 15.9, 2 years: 94.3 ± 6.7, $P < .01$; group I: 1 year: 85.0 ± 13.4, 2 years: 92.3 ± 7.4, $P < .01$). There were no significant differences between the 2 groups ($\beta > 82\%$).

TABLE 3
International Knee Documentation Committee (IKDC) (No. of Patients in Group A/B/C/D) and Tegner Scores (Mean ± SD) of Groups P (Press-Fit) and I (Interference Screw Fixation)

Time	Fixation Type		Significance (P Value, χ^2 Test, and t Test)
	P	I	
Before index surgery			
	0/3/7/0	0/4/4/2	.98
	3.2 ± 1.8	3.3 ± 1.5	.89
3 months postoperatively			
	5/2/2/1	3/5/1/1	.84
	6.4 ± 1.5	5.5 ± 1.2	.13
1 year postoperatively			
	7/2/0/0	6/4/0/0	.98
	6.7 ± 1.3	5.8 ± 1.0	.11
2 years postoperatively			
	6/3/0/0	5/5/0/0	.99
	6.5 ± 1.1	5.6 ± 1.2	.13

DISCUSSION

The purpose of this study was to compare press-fit fixation of tendon autografts with biodegradable interference screw fixation in a prospective, randomized controlled trial. A main focus was the analysis of bone tunnel enlargement.

Similar encouraging results have been reported after reconstruction of the ACL using hamstring and patellar tendon grafts.[28,33] Only one investigation has focused on a press-fit fixation.[27] In a meta-analysis, hamstring tendon reconstructions have been associated with decreased joint stability and patient satisfaction.[8] With adequate preconditioning[27] and sufficient fixation[16,19] and a moderate aggressive rehabilitation protocol,[11] excellent joint stability and knee function can be restored.

The observed bone tunnel widening is consistent with theoretical[13,18] and practical[20,24,31] observations after ACL reconstructions with hamstring tendons. The extent of tunnel enlargement has been found to increase during the first 3 postoperative months[20] and then stays at a steady state or drops the following year. Therefore, the time point for the CT investigation was 3 months. Both implants were visible after 3 months and were excluded from the measurements of tunnel widening. Unlike other studies, we have conducted measurements of the bone tunnels on CT scans rather than MRI scans[9] because there is strong evidence in the literature that MRI images are less accurate in the determination of tunnel widening.[7] Tunnel enlargement in this study was less than the reported data for the hamstring tendons in the tibial tunnel: 20.9% to 31% in the coronal and 30.2% to 48% in the sagittal plane.[20,21] This could have 2 specific reasons. Fixation close to the tunnel entrance limits tunnel enlargement and fosters tendon-to-bone healing.[32] Both groups in this study received a rigid fixation close to the tunnel entrance. Tunnel widening has been attributed to extracortical fixation,[13,29] and the study by Fauno and Kaalund[6] provides level I evidence that close to tunnel fixation limits bone tunnel enlargement. A moderately aggressive rehabilitation protocol[11] has been demonstrated to limit tunnel widening. Such a protocol was used for both study arms of the current investigation.

A hybrid fixation technique was used for both study arms because it has been shown in biomechanical studies that extracortical fixation provides higher pullout forces than biodegradable screw fixation.[19] According to the data obtained from these studies, we believe a pure press-fit fixation on the tibial side alone does not provide adequate fixation strength for tendon grafts without bone blocks. However, close to the joint fixation is desirable to limit bone tunnel enlargement.[6] The chosen technique can provide higher primary stability with less tunnel widening.

The average diameter of the tibial tunnel was about 1 mm larger than it has been reported in previous investigations[24,28] but similar to the reported values for grafts with bone blocks.[26] The tunnel diameter had to be adjusted to introduce the implants in this study. Unlike most other studies,[11,28] the grafts of this study were 40% tripled and 60% quadrupled hamstring tendon grafts. This represents a limitation as a standardized graft can be expected to lead to more homogeneous results.

This study population had few female individuals (3 of 20), and therefore, the results must be interpreted with care regarding female patients. A higher number of female patients have knee hyperextension capacity and "unforgiving knees"[14] that require special attention.

The implants themselves are likely to influence changes within the tunnel.[3,5] The biodegradable screw used was a poly-D/L lactide screw. The implant was clearly detectable on the 3-month CT scans, and no signs of osteolysis were observed. There is evidence in the literature that poly-D/L lactide degrades slower in the human bone[3] than in animals.[32]

Tutobone is a bone substitute material that has been used for a number of animal trials and clinical studies with a focus on craniofacial surgery. It has been shown that the material supports cell proliferation and osteogenic cell differentiation.[17,23] No disintegration of the material or osteolysis was seen after 3 months in this study. The material was hard to detect on radiographs after 6 months. This may explain why there were significant differences in the tunnel widening for the center part of the drill hole only in the plain radiograph analysis. No signs of sclerosis around the graft or implant made it difficult to determine the extent of tunnel enlargement at the 6-month interval (Figure 5, B and C). The decreased tunnel widening at the tunnel entrance may be an effect of compressed spongiosa during the insertion of the bone plug rather than of the material itself. Costs of such allogeneic or xenogeneic bone substitute materials are comparable with biodegradable interference screws. Likewise, autologous bone cylinders can be harvested instead of drilling using diamond bone cutting systems (DBCS, Articomed Ltd, Schluechtern, Germany).

The clinical results observed for the study population are consistent with reported results of both hamstring tendon and bone patellar tendon reconstructions after 2 to 10 years. Like other studies,[28] this study focused on isolated ACL ruptures. Loss of more than one third of the meniscus or grade III or IV cartilage injuries were exclusion criteria. This has been demonstrated to influence clinical results.[33] Knee joint stability was better in both groups than that found in the meta-analysis by Freedman et al.[8] An explanation may be the emphasis of rigid close to tunnel fixation. This study reports 2-year results only.

The sample size of 10 per study arm is a limitation of this study. Most prospective studies have used a study population of at least 15 per group.[4,28] However, this study focused on the detection of tunnel enlargement that has been reported in the literature[7,20,21] and on differences of knee performance that are clinically relevant (eg, KT-1000 difference of more than 2 mm in the maximum manual test) (Table 1). The sample size was chosen a priori using a standard biostatistic software. Significant differences within the predetermined statistical range were found for tunnel enlargement, and a tendency was found for early knee stability. The power of the 2-year results of both groups being equal in terms of clinical knee performance was beyond 80%.

This study compares for the first time an innovative technique, press-fit fixation of the hamstring tendons, with a well-established fixation technique (biodegradable interference screw), in a level 1 clinical study. Excellent clinical results were found for both study arms. Press-fit fixation limits tunnel enlargement and thus may enhance tendon to bone healing. Limited bone tunnel enlargement and porous biomaterials have potential to improve the conditions for ACL revision surgery. Further clinical studies should be performed to compare press-fit fixation of hamstring tendons with other fixation techniques.

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