Primary Stability of Hamstring Graft Fixation With Biodegradable Suspension Versus Interference Screws

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Purpose: During the early postoperative period, the stability of the fixation of a hamstring graft to the bone tunnel is the primary factor in limiting rehabilitation. The aim of this study was to evaluate if the initial fixation strength of a new suspension screw is comparable to that of the biodegradable interference screw fixation technique in the hamstring reconstruction of the anterior cruciate ligament (ACL). Type of Study: Experimental laboratory study. Methods: We evaluated the initial fixation strength of a biodegradable poly-L-lactide/tri-calcium phosphate (PLLA/TCP) screw that suspended the graft in the bone tunnel and compared it with the strength of an interference screw for fixation of hamstring grafts in ACL reconstruction using bovine knees. Single-cycle and cyclic loading tests were performed using a materials testing machine. Results: The suspension screw provided a significantly higher yield load and ultimate failure load than the interference screw. There was no significant difference in the stiffness of both techniques. The typical failure mode for the suspension screw was fracture of the screw and for the interference screw it was slippage of the graft past the screw. In cyclic testing, both methods of fixation ran out to 1,000 cycles up to 250 N with a mean displacement of 2.6 mm (range, 1.8 to 3.3 mm) for the suspension screw and 4.1 mm (range, 2.3 to 6.0 mm) for the interference screw. Only the grafts fixed with the suspension screw survived a protocol with 1,000 cycles up to 400 N. Conclusions: Our biomechanical data suggest that hamstring graft fixation using a biodegradable PLLA/TCP suspension screw provides an alternative to interference screw fixation. Clinical Relevance: Hamstring graft fixation using a suspension screw provides a reasonable alternative to interference screw fixation. Key Words: Hamstring graft fixation—Biomechanics—Maximal load—Tensile stress—Failure mode—Cyclic testing.

Reconstruction of the anterior cruciate ligament (ACL) with autologous tendon grafts is a well-accepted surgical technique that aims to re-establish normal knee function.1,2 Although there is still a controversial debate about the most appropriate graft for ACL reconstruction, the use of 4-strand hamstring tendons (semitendinosus and gracilis) is a topic of increasing interest because their harvest causes less donor-site morbidity and functional deficit than the bone–patellar tendon–bone graft.3,4 A disadvantage is that the tendon-to-bone healing of hamstring grafts requires a longer time for graft incorporation than the bone-to-bone healing of bone–patellar tendon–bone grafts.3,5,9

Many techniques have been used for the fixation of hamstring grafts to the bone tunnel (for a review, see Brand et al.3). Extra-articular graft fixation with the EndoButton (Smith & Nephew, Andover, MA) is the technique that provides the highest fixation strength,10 even higher than that of bone–patellar tendon–bone grafts fixated with interference screws.11-13 However, the stiffness of extra-articular fixation techniques is far below the stiffness of bone–patellar tendon–bone grafts.14-16 Because the low stiffness of extra-articular techniques is predominantly caused by the linkage material, micromotion of the graft within the bone tunnel might distort...
tendon-to-bone healing. Anatomic fixation techniques with interference screws at the original ACL insertion site have been developed to overcome the disadvantages of extra-articular hamstring graft fixation. Despite the good fixation strength of metallic interference screws, these implants have various disadvantages, such as distortion of magnetic resonance imaging, risk of graft laceration, or the need for hardware removal. Bioabsorbable screws with softer threads may be advantageous. Especially at the tibial fixation site a large screw may damage the holding tape by which the graft is tensioned. Reports in the literature regarding the pullout strength of interference screw fixation of soft-tissue grafts are contradictory, but in most studies both screws, both metallic and bioabsorbable, have provided comparable initial fixation strength. However, biodegradable implants in contact with the intra-articular cavity may cause inflammatory reactions of the synovium during the degradation process.

Another potential disadvantage of interference screw fixation of soft-tissue grafts has been shown by Singhatat et al. These investigators studied the effect of 4 weeks of implantation on the strength and stiffness of a tendon in a bone tunnel using an interference screw and a soft-tissue washer in a bovine model. While the strength and stiffness for the interference screw deteriorated significantly, the strength for the washer remained similar and the stiffness even improved. One possible explanation for this finding was that the high pressure of the interference screw might impair the blood supply of the graft in the bone tunnel.

A new strategy of hamstring graft fixation is to suspend the graft in the bone tunnel using a pin or a screw. The Bilok ST screw (Biocomposites Ltd, Etruria, UK) is manufactured from a composite material of resorbable poly-L-lactide/tri-calcium phosphate (PLLA/TCP). To our knowledge biomechanical data such as the initial fixation strength of this technique have not been published (for a review see Corsetti and Jackson). The aim of this study was to compare the initial fixation strength and the cyclic loading performance of a biodegradable suspension screw (Bilok ST) with an interference screw (Bilok TS; Biocomposites Ltd) of the same material.

METHODS

Biomechanical Model

In this study, 30 pairs of fresh bovine knees were used as described by Weiler et al. and Guirea et al.

In this model, the screw insertion site represents a trabecular bone density of 0.8 g/cm³, which is similar to what is expected in young human femora.

The mean age of the animals was 27 weeks ± 2 weeks. The material was obtained from a local butcher, fresh frozen at −20°C, and thawed for 12 hours at room temperature before testing. The muscles and soft tissues were removed, leaving the proximal tibia intact; a 9-mm hole was drilled.

The hamstring grafts were obtained from fresh human cadavers (mean age, 48.2 years; range, 26 to 66 years). A 4-cm long oblique incision was made approximately 2 cm medial to the tibial tubercle. Dissection was taken down to the sartorius fascia and the sartorius tendon was incised along its fibers. The attachments of semitendinosus and gracilis were separated and harvested using a tendon stripper. The grafts were harvested and immediately stored at −20°C. All tendons were thawed at room temperature 12 hours before use and kept moist with saline irrigation during preparation and mechanical testing to prevent drying. The tendons were folded to 4-stranded tendon grafts with a diameter of 9 mm.

The tibia specimens were divided into 2 study groups so that of each pair, both sides went into different groups. In the first group, the hamstring grafts were fixated by a gamma-sterilized biodegradable PLLA/TCP suspension screw (diameter, 9 mm; length, 35 mm) as a transverse suspension device (Bilok ST screw; Fig 1). In the second group a biodegradable PLLA/TCP interference screw with a diameter of 9 mm and a length of 30 mm (Bilok TS; Fig 1) was used. This screw is a tapered, threaded fastener for use in interference fixation of soft tissue or bone-tendon grafts. Insertion torque has
been measured by a specially designed torque screw driver.

**Specimen Preparation and Graft Fixation Technique**

Proximal tibiae were cut 55 mm distally to the intercondylar spine. For both fixation devices, tunnels were drilled with a diameter of 9 mm and a depth of 30 mm. The tunnel was cleared of debris to assure the graft was not damaged. All tendons were folded to 4-stranded tendon grafts over a No. 5 Ticron suture (Tyco, Waltham, MA). Care was taken to measure the exact length of the graft to compare the stiffness of the grafts. The length included 25 mm of sutured tendon for the fixation in the bone tunnel, 25 to 30 mm of sutured tendon was required for fixation to the testing machine, and 25 mm was left in between. This is similar in length to the intra-articular portion of an ACL graft.

Figure 2 shows the suspension screw insertion technique as it is performed by the surgeons in the operating room. In our biomechanical model, the same instruments and technique were used.

For positioning of the Bilok ST screw, a specific drill guide has been used. An appropriately sized locator was attached to the guide body and then placed into the bone tunnel. A 2.4-mm guidewire was drilled from the cortex until it touched the locator in the bone tunnel. Then the guide was removed, leaving the guidewire in position. The guidewire was advanced to penetrate the bone on the opposite wall of the bone tunnel by approximately 1 cm. The guidewire was overdrilled with an 8-mm drill. The arthroscope has been used to assess penetration of the drill into the bone tunnel. The drill should not penetrate the opposite wall of the socket. After removal of the drill, a 9-mm Bilok tap was inserted and a threaded transverse tunnel was created. The tap was advanced and withdrawn 3 times to create an adequate thread. The graft was then pulled into the bone tunnel under control of an arthroscope that has been placed in the lateral tunnel. A 1-mm guidewire was placed under arthroscopic control through the middle of the double loop. The graft was pulled in both directions to ensure that the guidewire was in the middle of the inner loop. A cannulated tunnel expander was then advanced over the guidewire to open up the graft bundles in order to facilitate the passage of the screw beneath the loop. Finally, the Bilok ST screw was inserted over the guidewire until the screw established an engagement with the contralateral wall.

**Testing Protocol**

Before testing, the specimens were removed from the freezer, thawed for 12 hours at room temperature, and moistened with saline solution during mounting and testing. All tests were performed at room temperature. Tensile testing was performed using a custom-made apparatus mounted in a uniaxial testing frame (LR5K-plus; Lloyd Instruments, Fareham, UK). Hamstring specimens were friction-locked in a custom made cryofixation clamp. All loads were applied parallel to the longitudinal axis of the bone tunnel to imitate a “worst-case” scenario.

A preload of 5 N was first applied to the tendon specimens after which it was cyclically preconditioned between 0 and 50 N at a rate of 100 mm/minute. After 20 cycles, the specimen was loaded to failure at a rate of 100 mm/minute. Load and elongation were recorded continuously using a strip chart recorder. The resulting load-elongation curve was documented as well as theultimate failure load, elongation at failure, yield load, and the mode of failure. Stiffness was determined as the linear region of the load elongation curve (Fig 3). All these data have been calculated by the computer software.

A preload of 5 N was first applied to the specimens. The grafts were cyclically preconditioned.
between 0 and 50 N at a rate of 100 mm/minute. Ten suspension screw and interference screw fixations underwent 1,000 cycles between 50 and 250 N and another 10 equal ones were tested with 1,000 cycles between 50 and 400 N. Cyclic loading was performed at a displacement rate of 200 mm/minute and a loading frequency of 80 cycles per minute. The loading frequency was similar to that of other studies and appears to be within a physiological range of loading.21,31,32
Statistics

The results are reported as mean values and standard deviation of the mean. A rank-sum test (U test according to Mann, Whitney, and Wilcoxon) was used for the statistical analysis of the results. Significance was set at \( P < .05 \).

RESULTS

Single-Cycle Load to Failure Test

A typical load elongation curve is shown in Fig 3. The mean yield load in the suspension screw group (Bilok ST) was 998.5 ± 122.5 N and in the interference screw group (Bilok TS) was 537.8 ± 86.7 N. The maximum load at failure was 1,475.8 ± 315.3 N in the suspension screw group and 651.1 ± 155.4 N in the interference screw group (Table 1). These differences in yield load and maximum load were statistically significant \( (P < .05) \).

The suspension screw group (Bilok ST) resulted in a linear stiffness of 248.1 ± 76.1 N/mm and the interference screw group of 199.5 ± 82.9 N/mm (Table 1). The difference in stiffness measurements was not significantly different \( (P > .05) \).

All tested specimens failed at the tendon-to-bone fixation site. In the failure mode analysis, 7 specimens in the suspension screw group failed by fracture of the screw (Fig 4). In 3 specimens, we noted a midsubstance rupture of the graft. All grafts in the interference group failed by slippage of the graft along the screw leaving the screw in position (Table 2). The insertion torque for the interference screw was 1.67 ± 0.4 N/m.

Cyclic Loading Test

The displacement after 1,000 cycles loading between 50 and 250 N was of 2.6 ± 0.5 mm (range, 1.8 to 3.3 mm) in the suspension screw group, and 4.1 ± 1.1 mm (range, 2.3 to 6.0 mm) in the interference screw group. This difference was statistically significant. Under cyclic loading up to 250 N, none of the fixations of either group failed. In the pullout test after 1,000 cycles up to 250 N, the mean ultimate failure load was 1,523.3 ± 366.8 N in the suspension screw group and 688.5 ± 177.2 N for the interference screw group. In ultimate failure load, there was a statistically significant difference between suspension and interference screw fixation \( (P < .05) \). The mean yield load after cyclic loading was 1,046.1 ± 201.3 N for the suspension screw and 579.9 ± 122.8 N for the interference screws. The linear stiffness resulted in 211.2 ± 89.4 Nm for the suspension screw and 178.3 ± 74.9 Nm for the interference screws. Under cyclic loading up to 400 N, all the interference screw group failed after a mean of 572 ± 178 cycles by pullout of the graft, but all grafts fixated with the suspension screw survived.

DISCUSSION

Animal studies have shown that tendon-to-bone healing within a bone tunnel occurs between 6 to 12 weeks after surgery.\(^5\)\(^,\)\(^7\)\(^,\)\(^9\)\(^,\)\(^27\) During this period, a stable fixation of the graft is necessary if the patient under-

### Table 1. Yield Load, Maximum Load, and Stiffness of the Single-Cycle Loading Tests

<table>
<thead>
<tr>
<th>Single Cycle</th>
<th>Suspension Screw (Bilok ST)</th>
<th>Interference Screw (Bilok TS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum failure load (N)</td>
<td>1,475.8 (± 315.3)*</td>
<td>651.1 (± 155.4)*</td>
</tr>
<tr>
<td>Yield load (N)</td>
<td>998.5 (± 122.56)†</td>
<td>537.8 (± 86.7)†</td>
</tr>
<tr>
<td>Stiffness (N/mm)</td>
<td>248.1 (± 76.1)‡</td>
<td>199.5 (± 82.9)‡</td>
</tr>
</tbody>
</table>

*Statistically significant, \( P < .05 \).
†Statistically significant, \( P < .05 \).
‡Statistically not significant, \( P > .05 \).

### Table 2. Failure Mode of the Single-Cycle Loading Tests

<table>
<thead>
<tr>
<th>Failure Mode</th>
<th>Suspension Screw (Bilok ST)</th>
<th>Interference Screw (Bilok TS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pullout</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Tendon graft failure</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Failure of the device</td>
<td>7</td>
<td>0</td>
</tr>
</tbody>
</table>
goes an aggressive rehabilitation protocol. Fixations must be rigid and stiff to allow current rehabilitation protocols after knee ligament surgery, which stress immediate full range of motion, return to neuromuscular function, and early weight-bearing exercises.

The exact in vivo forces the graft is subjected to are still not known. Noyes et al.,32 have estimated the strength required for activities of daily living to be 454 N based on the failure strength of the ACL. Morrison calculated in vivo forces in the ACL with 169 N for level walking and 445 N for descending stairs. Rupp et al. showed that quadriceps muscle pull against the gravity alone produces resultant forces up to 247 N in the ACL. According to these data, an initial fixation strength of more than 450 N is needed to withstand the force of rehabilitation.

Today the interference technique is considered to be the gold standard for the fixation of bone–patellar tendon–bone grafts with an acceptable clinical success rate. Although there is little controversy on interference screw fixation of bone–patellar tendon–bone grafts, no consensus has been found on the fixation of hamstring grafts. Hamstring reconstruction methods vary by their fixation devices and the fixation level (close to the joint [anatomic] v distant to the joint [nonanatomic, extracortical]). Most extra-articular fixation techniques rely on linkage material (textile bands) to connect the tendon to the fixation device. These fixation techniques provide a high, ultimate fixation strength, but the stiffness of extra-articular fixation techniques is far below of that of bone–patellar tendon–bone grafts. Stiffness is an important feature of tendon graft fixations.

Höher et al. have shown that the low stiffness of extracortical fixation using EndoButtons primarily resulted from the mechanical behavior of the suture or tape material and not from the graft itself. Shear forces that occur because of the large elongation of the extra-articular graft-fixation device complex may be responsible for expansion of the bone tunnels, also known as the bungee cord effect or the windshield wiper effect. In a study using the porcine knee model, the effect of tibial tunnel fixation was found to have a significant effect on the knee kinematics and in situ forces of the replacement graft. The reconstruction that resulted in the most stable knee occurred when the interference screw was positioned close to the articular surface followed by central and distal fixation.

In most studies about hamstring graft fixation, interference screws, metallic and bioabsorbable, have provided sufficient initial fixation strength in biomechanical tests. A possible disadvantage of biodegradable interference screws is their contact with the intra-articular cavity. Recent studies have reported inflammatory reactions after intra-articular use of biodegradable implants.

Clark et al. reported a new fixation technique using stainless steel cross-pins of 35 and 70 mm length. With this technique the hamstring loops are suspended by 1 pin inserted at the proximal end of the femoral tunnel. According to the classification of Ishibashi et al., this fixation level can be classified as central. Biomechanical tests showed a mean initial load to failure of 1,003.3 N and 1,604.3 N for the 35 mm and 70 mm steel cross pins, respectively. Another transverse fixation technique is the double cross-pin technique (Rigid Fix; Ethicon, Mitek Division, Nordrstedt, Germany). With this technique, the grafts are fixed by 2 biodegradable pins (diameter, 3.3 mm; length, 42 mm) piercing the tendon strands perpendicular. The device is designed to compress the graft to the tunnel wall and not to suspend the tendon loop (compression technique). An analysis of yield load, maximum load, and stiffness showed no statistically significant differences for double cross-pin technique and interference fixation. However, the ultimate failure load of the Rigid Fix device (compression technique) is lower than that found for both suspension devices (metal cross-pin and Bilok ST screw).

The Bilok ST screw is designed as a transverse suspension device but it is manufactured from a composite material of biodegradable PLLA and TCP. TCP is similar to ceramic hydroxyapatite in its ability to become directly bonded to bone. It is a fully resorbable porous bioceramic with the properties to allow resorption and subsequent replacement by bone. The polymer component of the composite device is a medical grade PLLA. The present study shows that the transverse PLLA/TCP screw (Biocomposites Ltd) provides an initial fixation strength that is comparable to that of the metal cross-pin reported by Clark et al. and superior to that of an interference screw made of the same material (PLLA/TCP).

The biocomposite material combining PLLA and TCP should offer improved biocompatibility, bioactivity (ability to form bone apatite like material or carbonate hydroxyapatite on their surfaces), and osteoconductivity (ability to provide the appropriate scaffold or template for bone formation). In addition, TCP biomaterials with appropriate 3-dimensional geometry are able to bind and concentrate endogenous bone morphogenetic proteins in circulation, and may become osteoinductive (capable of osteogen-
The potential benefits of this new implant material have been demonstrated in applications other than ACL surgery. Although the biomechanical data for PFFL/TCP implants at the time of implantation seem to be promising, more experimental and clinical research studies are needed to evaluate the effects of this material in ACL reconstruction.

Previous studies have shown that the bone mineral density has much influence on the initial fixation strength of tendon graft fixation. We used a bovine model as described by Weiler et al. with known bone mineral density of 0.8 g/cm³ to quantify free tendon graft fixation. This bone mineral density is comparable to that of young human proximal femora.

In this study, failure mode analysis showed an evident difference in the failure mode of both implants that can be attributed to the design of the devices. In the Bilok ST group, most fixations failed by a fracture of the implant. In contrast, in the interference group, the predominant failure mode was slippage of the graft along the screw leaving the screw relatively undamaged in position.

Our stiffness data regarding anatomic interference screw fixation resemble the results of Stadelmaier et al. and Nagarkati et al. They reported a stiffness of 144 N/mm and 214 to 639 N/mm. Ishibashi et al. reported that an increase in length of the graft will lead to a reduced stiffness. They stated that a matching of the stiffness of the graft with the native ACL could be a more important goal of graft selection for the purpose of achieving normal knee kinematics. In the present study, care was taken to measure the exact length of every graft to match the pairs as much as possible, thus resulting in a free tendon length of 25 mm. Reduced functional length maximized the stiffness of the hamstring grafts. The stiffness values of the graft–fixation device–bone constructs found in this study closely resemble the stiffness of the native tibia-ACL-femur complex (242 N/mm) as described by Woo et al.

As stated by Beynnon and Amis, the single-cycle load-to-failure test provides a measurement of the upper limit of the graft fixation construct, which is useful information as it indicates the potential for the reconstruction to withstand trauma after surgery. During early rehabilitation, the graft is repetitively loaded during exercise or daily living activities such as walking. Cyclic loading seems to duplicate the physiologic loading conditions more closely than single-cycle failure tests. Therefore, we tested the fixation device–graft construct under cyclic loading conditions. The literature provides a wide range of different cyclic loading protocols, which makes it difficult to compare results of various studies. We decided to use a protocol similar to that of Guirea et al. The graft–fixation device–bone complex was subjected to 1,000 cycles between 50 and 250 N. Both fixations ran out 1,000 cycles without a failure. To determine possible changes in the strength of the graft–fixation device–bone construct after cyclic loading we performed the pullout test before and after cyclic loading. The maximum loads after cyclic loading were slightly higher than the results for single-cycle, but there was no statistical difference between the 2 techniques. To simulate an aggressive rehabilitation protocol, the graft–fixation device–bone complex was subjected to 1,000 cycles between 50 and 400 N. Under this load, all specimens with an interference screw device failed by slippage of the graft past the screw but all specimens fixed with the suspension screw survived the 1,000 cycles.

A few limitations apply to this study because we tested a worst-case scenario with the force in the line to the bone tunnel. This might not reflect the forces that the graft is subjected to in vivo. Additionally, when discussing the clinical implications of results of biomechanical studies, caution should be used because we still can only speculate about the in vivo forces an intact ACL or a graft has to withstand. We always used bone tunnels with a diameter of 9 mm to standardize the testing protocol. In the operating room, semitendinosus/gracilis grafts often measure 8 mm. The use of a smaller tunnel might theoretically influence the stability of the interference screw technique. Another limitation could be the age of the human hamstring grafts used in this study. The grafts had a mean age of 48.2 years with a range of 26 to 66 years. Even though this may not reflect the most typical age for ACL ruptures, it is comparable to the mean age of human grafts used in other studies.

Variables that we are able to measure in the basic science laboratory at time zero of ligament reconstruction include data on ultimate failure load, yield load, and stiffness, but correlations of these results with clinical outcome has not been reported. In conclusion, our biomechanical data suggest that hamstring graft fixation using a biodegradable PLLA/TCP suspension screw (Bilok ST) provides an alternative to interference screw fixation.

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REFERENCES


