Initial Fixation Strength of Two Bioabsorbable Pins for the Fixation of Hamstring Grafts Compared to Interference Screw Fixation

Single Cycle and Cyclic Loading

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Background: During the early postoperative period, the fixation of a hamstring graft to the bone tunnel is the primary factor in limiting rehabilitation.

Hypothesis: The initial fixation strength of a double cross pin fixation technique is comparable with the biodegradable interference screw fixation technique.

Study Design: Experimental laboratory study.

Methods: The authors examined the initial fixation strength of two 3.3-mm bioabsorbable pins compared to interference screws for hamstring grafts in bovine knees.

Results: Analysis of yield load, maximum load, and stiffness in the single-cycle loading test showed no statistically significant differences for cross pin and interference fixation ($P < .05$). For cross pins and interference screws, the mean displacement under 1000 cycles to 250 N was 5.07 (±1.9) mm and 4.81 (± 2.5) mm, stiffness 252 (±78) N/mm and 289 (±148) N/mm. Only grafts fixed with cross pins survived 1000 cycles to 450 N.

Conclusion: The initial fixation strength of the double cross pin technique is comparable to that of interference screw fixation with a stiffness comparable to that of the native ACL.

Clinical Relevance: Hamstring graft fixation using two cross pins provides an alternative to bioabsorbable interference screw fixation.

Keywords: hamstring graft fixation; biomechanics; maximal load; tensile stress; failure mode; cyclic testing

Reconstruction of the ACL with autologous tendon grafts is a well-accepted operative technique and aims to reestablish normal knee function.[12,14,15]

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The patellar tendon is the most commonly used graft in ACL reconstruction.[12,14,15] Although bone-patellar tendon-bone graft provides excellent stability, several complications have been associated with this procedure, such as extensor mechanism dysfunction with consecutive anterior knee pain or limitations in the range of motion.[2] In recent years, the use of four stranded hamstring tendons (semitendinosus and gracilis) has been a topic of increasing interest because their harvest causes less donor site morbidity and functional deficit.[7]

A free tendon graft loses its initial strength during the remodeling process.[6,18,49] However, during the early postoperative period, the fixation of the graft to the bone tunnel is the primary factor in limiting early rehabilitation. Current rehabilitation protocols after knee ligament surgery emphasize immediate full range of motion, return to neuromuscular function, and early weightbearing.[42,43] During rehabilitation, the graft is loaded between approximately 30 and 450 N depending on the activity.[21,29,30,31,32,38] The gold standard for the fixation of bone-patellar tendon-bone grafts is the interference screw technique introduced by Lambert in 1983.[27] Hamstring tendon grafts usually do not have bone blocks attached. Tendon-to-bone healing of hamstring grafts requires an extended time for graft incorporation.[6,18,37,49]

Many techniques have been used for the fixation of hamstring grafts to the bone.[7,9,14,15,20,24,26] Extra-articular graft fixation with soft-tissue washers is the technique that provides the highest fixation strength,[7] even higher than that of bone-patellar tendon-bone grafts fixed with interference screws.[25,28,48] However, the stiffness of extra-articular fixation techniques is far below the stiffness of bone-patellar tendon-bone grafts.[3,4,6,7,22,23,44,51] Micromotion of the graft within the tunnel might distort tendon-to-bone healing.[20,34,37,49] Anatomic fixation techniques with interference screws at the original ACL insertion site have been developed because of the disadvantages of extra-articular hamstring graft fixation.[17,24,26,36,51] Despite the good fixation strength of metallic interference screws, these implants have various disadvantages such as distortion of MRI, risk of graft laceration, or the need for hardware removal.[7] Bioabsorbable screws with softer threads may be advantageous.[7] Especially at the tibial fixation site, a large screw may damage the holding tape by which the graft is tensioned. Statements in the literature regarding the pullout strength of interference screw fixation of soft-tissue grafts are contradictory, but in most studies both screws—metallic and bioabsorbable—have provided comparable initial fixation strength in biomechanical tests.[‡] However, biodegradable implants in contact with the intra-articular cavity may cause inflammatory reactions of the synovium during the degradation process.[46,47,50]

A new strategy of anatomic hamstring graft fixation is to fix the graft with two biodegradable pins (length, 42 mm; diameter, 3.3 mm; Rigid Fix, Ethicon, Mitek Division, Norderstedt, Germany), piercing the strands of the graft perpendicular. To our knowledge, biomechanical data such as initial fixation strength of this technique have not been published (for review, see reference 6).

The aim of this study was to compare the initial fixation strength of the cross pin fixation technique (Rigid Fix) with the biodegradable interference screw fixation technique in the hamstring reconstruction of the ACL using both single-cycle and cyclic-loading tests. To elucidate the biomechanical behavior of the cross pin fixation in different rehabilitation programs, the cyclic-loading protocol existed out of two groups. Ten pairs of cross pin and interference screw fixations underwent 1000 cycles between 50 and 250 N, and 10 pairs were subjected to cycles up to 450 N.

[‡] References 1, 15, 17, 19, 22, 23, 24, 25, 28, 33, 35, 36, 38, 40, 41, 44, 48.

MATERIALS AND METHODS

Biomechanical Model

In this study, tibias from 30 pairs of fresh bovine knees were used, as described by Weiler et al[48] and Giurea et al[17] In this model, the screw insertion site represents a trabecular bone density of 0.8 g/cm^3 similar to what is expected in young human femora.[13,16,17,20,22]

The mean age of the animals was 28 weeks ± 2 weeks. The material was obtained from a local butcher, fresh frozen at –20° 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 drill hole was drilled centrally into the tibia.

The hamstring grafts were obtained from fresh human cadavers (mean age, 55.6 years; range, 23-78 years). 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 dissication.

All tendons were folded to four-strand tendon grafts, and a whip stitch was used to sew the strands to each other. Slippage of the graft was monitored via the material testing machine's digital readout.

Study Groups

The tibia specimens were divided into two study groups so that of each pair, both sides went into different groups. In the first group (biodegradable cross pin fixation), the 30

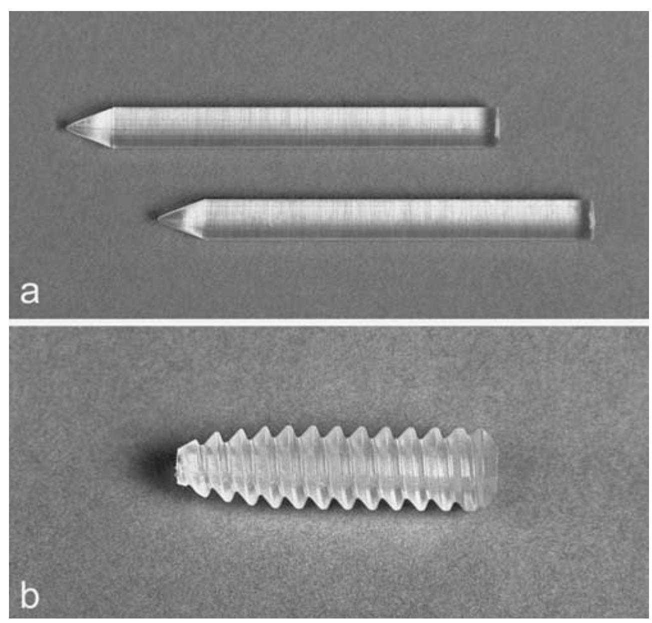

Figure 1. Implants used in the present study. a, Biodegradable (PLLA) cross pins (diameter, 3.3 mm; length, 42 mm; Rigid Fix, Ethicon, Mitek Division, Norderstedt, Germany). b, Conventional biodegradable interference screw (diameter, 9 mm; length, 23 mm; Innovasive Devices, Inc., Marlborough, Mass).

hamstring grafts were fixated to the bone tunnel with two gamma-sterilized bioabsorbable L-lactide/D-lactide (PLA) copolymer pins with a diameter of 3.3 mm and a length of 42 mm (Rigid Fix; Figure 1). In the second group, a biodegradable standard interference screw with a diameter of 9 mm and a length of 23 mm (Absolute Absorbable Interference Screw, Innovasive Devices, Inc., Marlborough, Mass) was used. This screw is a tapered, threaded fastener for use in interference fixation of soft-tissue or bone-tendon grafts.

Fixation Technique

Hamstring grafts (mean age, 55.6 years; range, 23-78 years) were harvested from fresh human cadavers. 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 semitendinosis and gracilis were separated and harvested using a tendon stripper.

Proximal tibiae were cut 5.5 cm distally to the intercondylar spine, as stated by Weiler et al.[48] The bone tunnel was drilled in centrally into the cancellous bone of the tibia (distance from tibial tuberosity approximately 4 cm; distance from medial cortex approximately 4 cm). For both fixation devices, tunnels were drilled to the smallest possible graft diameter and a depth of 30 mm. The tunnel was cleared of debris to ensure that the graft was not damaged. All tendons were folded to four-strand tendon grafts over a No. 5 Ti-Cron suture, and a whipstitch was used to connect the strands to each other at 30 mm at each end. Care was taken to measure the exact length of the graft to compare the stiffness of the grafts. The length included 30 mm of sutured tendon for grasping by the testing machine, 30 mm of intra-articular tissue, and 30 mm of sutured tendon for the femoral fixation device.

For cross pin insertion, the Mitek Rigid Fix cross pin guide has been used (Figure 2). Figure 3 shows the cross pin insertion technique as it is performed by a surgeon in the operating room. In our biomechanical model, the same instruments and technique were used. An appropriately sized rod is attached to the guide body and then placed into the bone tunnel. A sleeve is assembled over an interlocking trocar and drilled through the bottom hole of the guide into the lateral side of femur or tibia until the sleeve hub meets the guide (Figure 3A). The trocar is removed by pulling it from the sleeve, leaving the sleeve in the guide. The trocar must not be drilled when removing it from the sleeve. After drilling the second sleeve trocar assembly through the top hole of the guide, the guide plate is detached and the guide body is removed from the bone, leaving only the two sleeves in the bone (Figure 3B). Next, a long guide pin is placed through the bone tunnel and out through the cortex. The stay suture of the bone bloc is placed through the eyelet of the guide pin, and the graft is pulled into the bone tunnel. During surgery, this step is performed under arthroscopic visualization. After the hamstring graft is in place, a longer trocar is drilled through the sleeves and the graft. A biodegradable cross pin (diameter, 3.3 mm; Rigid Fix) is

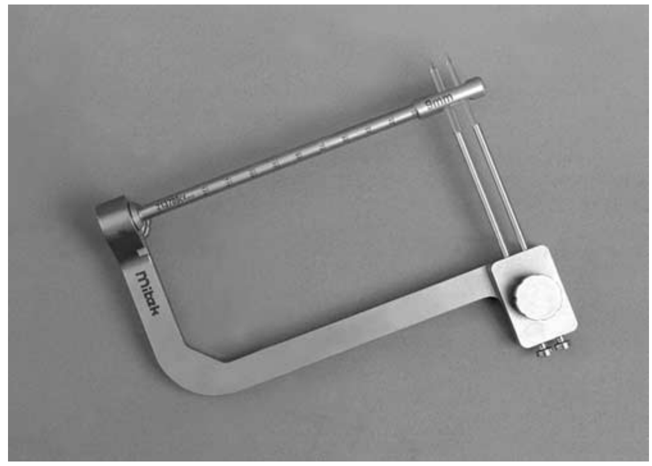

Figure 2. The Rigid Fix (Mitek, Ethicon, Nordestedt, Germany) cross pin guide was used for the insertion of two biodegradable cross pins.

inserted into the sleeve. With a stepped pin insertion rod and a mallet, the pin is advanced until the step portion of the rod meets the sleeve hub. This procedure is repeated in the other sleeve, and the fixation is completed with a second biodegradable cross pin (Figure 3C). The sleeves are released using a sleeve removal tool.

Bone Mineral Density Measurement

The bone density of all bovine knees was determined using a dual photon absorptiometry (DXA, Hologic QDR-4500 A, whole body x-ray Bone Densitometer; Hologic, Inc., Bedford, Mass) scan after thawing the knees. Bones were submerged in saline solution. The machine was used in a fan beam mode using the subregion array spine.

Tensile Testing

Before testing, the specimens were removed from the freezer, thawed for 12 hours at room temperature, and moistened with saline solution buffer during area measurement, 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 Instuments, Great Britain). 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 (Figure 4).

Single Cycle Load

A preload of 5 N was applied to the tendon specimen after which it was cyclically preconditioned between 0 and 20 N at a rate of 200 mm/min. After 20 cycles, the specimen was loaded to failure at a rate of 200 mm/min. Load and elongation were recorded continuously using a strip chart recorder. The resulting load–elongation curve was documented as well as the ultimate failure load, elongation at

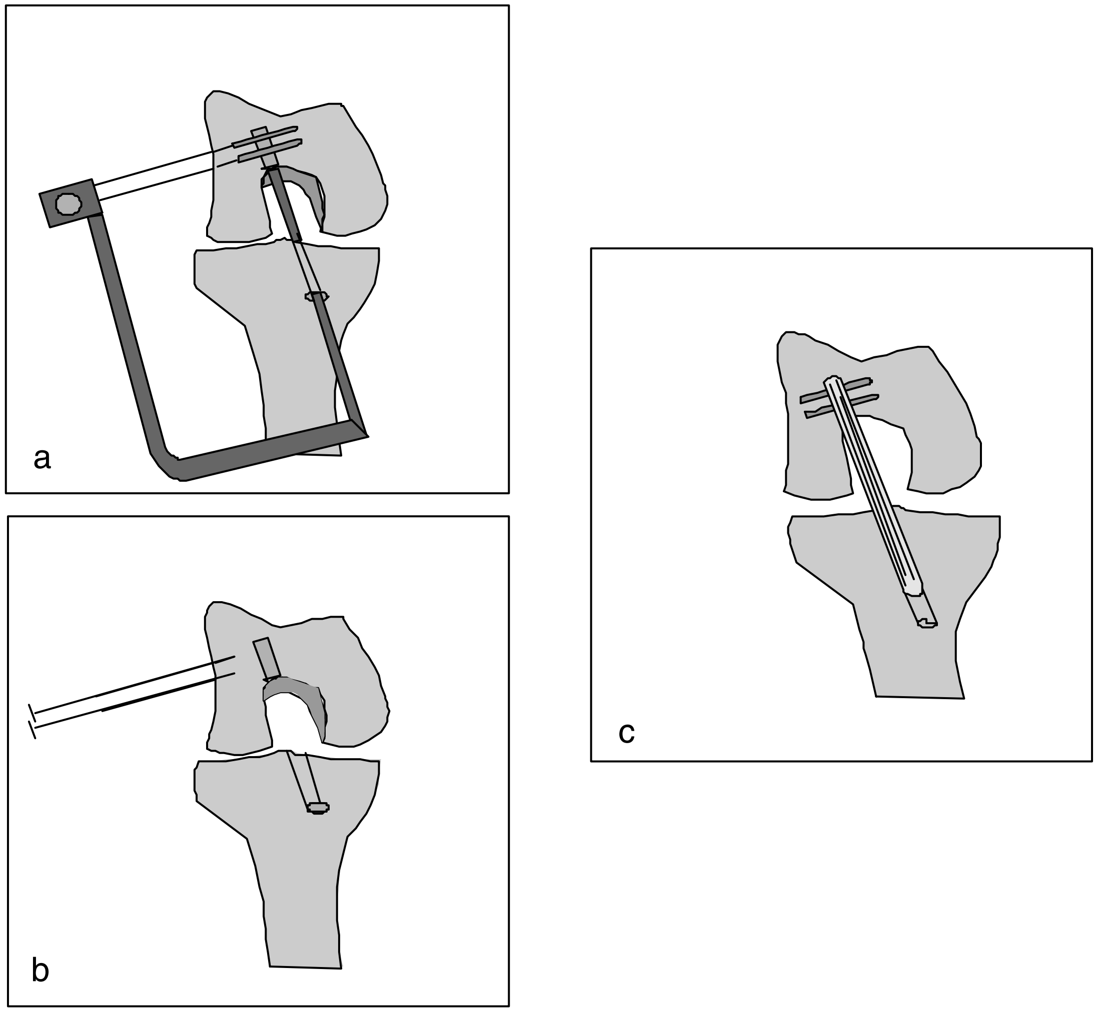

Figure 3. Surgical technique for femoral hamstring graft fixation using cross pins (diameter, 3.3 mm; Rigid Fix, Ethicon, Mitek Division, Norderstedt, Germany). a, The Rigid Fix cross pin guide is placed into the bone tunnel with an appropriately sized rod attached. The sleeve is assembled over a trocar and drilled through the holes of the guide into the cortex until the sleeve hub meets the guide. b, After the second sleeve trocar assembly is placed, the guide plate is detached and the guide body is removed from the bone, leaving only the two sleeves in the bone. c, After pushing the hamstring graft into the tunnel, a longer trocar is drilled through the sleeves and the graft. Cross pins are inserted into the sleeves and advanced using a stepped pin insertion rod and a mallet until the step portion of the rod meets the sleeve hub.

failure, yield load, and the mode of failure. Stiffness was determined as the linear region of the load elongation curve (Figure 5).

Cyclic Loading

A preload of 5 N was first applied to the specimens. The grafts were cyclically preconditioned between 0 and 20 N at a rate of 200 mm/min. To elucidate the biomechanical behavior of the cross pin fixation in different rehabilitation programs, cyclic-loading protocol existed out of two groups. Ten pairs of cross pin and interference screw fixation underwent 1000 cycles between 50 and 250 N, and 10 pairs were subjected to cycles up to 450 N. Cyclic loading was performed at a displacement rate of 200 mm/min 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 paired Student's t test was used for the statistical analysis of the results.

RESULTS

Bone Mineral Density (BMD)

The mean density of all bovine tibiae using dual photon absorptiometry (DXA, Hologic QDR-4500 A, whole body x-ray Bone Densitometer; Hologic, Inc.) scan running in a

Figure 4. Tensile testing was performed in a uniaxial testing frame (LR5K-plus, Lloyd Instruments, Great Britain). The hamstring grafts were friction locked in a custom-made cryofixation clamp. All loads were applied parallel to the longitudinal axis of the bone tunnel to simulate a worst-case scenario.

fan beam mode using the subregion array spine was 0.84 g/cm^3 (± 0.07).

Single-Cycle Load-to-Failure Test

The mean yield load in the cross pin group (Rigid Fix) was 486.5 (± 103.7) N and 541.3 (± 91.3) N in the bioabsorbable interference screw group (see Table 1). The maximum load at failure was 639.3 (± 156.4) N in the cross pin group and 702.1 (± 168.5) N in the interference screw group. The cross pin group (Rigid Fix) resulted in a linear stiffness of 226 (± 63) N/mm and the interference screw group a linear stiffness of 190 (± 78) N/mm. All these measurements were not significantly different ($P > .05$).

Cyclic Loading Test

The displacement under cyclic loading between 50 and 250 N was 5.07 (± 1.9) mm in the cross pin group and 4.81 (± 2.5) mm in the interference screw group. Under cyclic loading, none of the interference screw or cross pin fixation failed. In the pullout test, after 1000 cycles the mean ultimate failure load was 813.6 (± 152.8) N and 830.6 (± 103.9) N for the cross pin and interference group, respectively (see

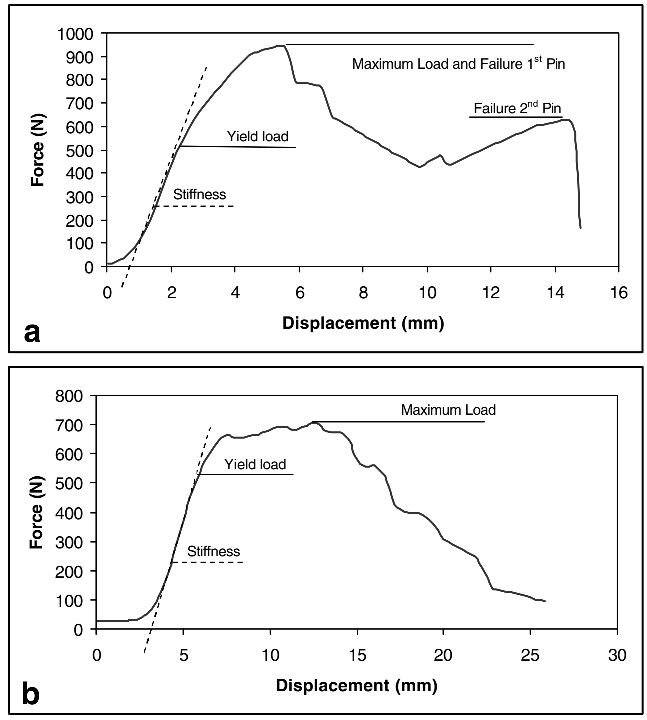

Figure 5. Typical load-elongation curve of a hamstring graft fixed with (a) cross pins and with (b) a bioabsorbable interference screw. Specimens were loaded to failure at a range of 200 mm/min. Stiffness (linear region of the load elongation curve), yield load, maximum load, and displacement were recorded.

Table 2). In ultimate failure load, no statistically significant difference between cross pin and interference screw fixation was found ($P > .05$). The mean yield load after cyclic loading was 476.2 (± 143.9) N for the cross pins and 525.3 (± 104.8) N for the interference screws. The linear stiffness resulted in 252 (± 78) for the cross pins and 289 (± 148) for the interference screw fixation. In ultimate failure load, mean yield load, displacement, and stiffness, no statistically significant difference between cross pin and interference screw was found ($P > .05$). Subjecting the fixation devices to 1000 cycles to 450 N, only the cross pin fixation could be tensile tested. All specimens fixed with bioabsorbable screws failed prior to 1000 cycles by slippage of the graft. In the cross pin group, none of the specimens failed prior to 1000 cycles between 50 and 450 N, and the displacement after 1000 cycles was 8.6 (±2.1) mm. Mean yield load after 1000 cycles was 445.4 (±112.6) N, and mean ultimate failure load was 772.5 (±183.9) N. The linear stiffness was 234 (±109). Subjecting the specimens to 1000 cycles between 50 and 450 N, the cross pin fixation showed a secure fixation.

Failure Mode

All tested specimens failed at the attachment site. In the failure mode analysis, all specimens in the cross pin group failed by fracture of the pins. All grafts in the interference

TABLE 1
Primary Stability of the Tested Devices

Single Cycle	Cross Pin (Rigid Fix)	Interference Screw (Absolute)
Maximum failure load (N)	639.3 (± 156.4)	702.1 (± 168.5)
Yield load (N)	486.5 (± 103.7)	541.3 (± 91.3)
Stiffness (N/mm)	226 (± 63)	190 (± 78)
Failure mode		
Pullout	0	10
Midsubstance rupture	0	0
Implant failure	10	0

TABLE 2
Biomechanical Characteristics After 1000 Cycles Between 50 and 250 N

Load to Failure After 1000 Cycles 50-250 N	Cross Pin (Rigid Fix)	Interference Screw (Absolute)
Maximum failure load (N)	813.6 (± 152.8)	830.6 (± 103.9)
Yield load (N)	476.2 (± 143.9)	525.3 (± 104.8)
Stiffness (N/mm)	252 (± 78)	289 (± 148)
Failure mode		
Pullout	0	10
Midsubstance rupture	0	0
Implant failure	10	0

group failed by slippage of the graft past the screw, leaving the screw in position.

Under submaximal cyclic-loading conditions between 50 and 250 N, all biodegradable interference screws and all double cross pins provided a secure fixation. Using the machine's digital readout, none of the grafts exhibited any slippage. However, under cyclic loading up to 450 N, all specimens fixed with interference screws failed rapidly while the screw remained in position. All specimens fixed with a double cross pin fixation survived 1000 cycles up to a 450 N peak and showed a secure fixation.

DISCUSSION

Animal studies have shown that tendon-to-bone healing occurs between 6 to 12 weeks after surgery.[6,10,18,37,49] During this period, a stable fixation of the graft is necessary if the patient underwent an aggressive rehabilitation protocol.[7,42,43] The benefit of early unrestricted motion, early full weightbearing, and intensive rehabilitation minimizes postoperative problems such as anterior knee pain due to quadriceps atrophy and restrictions in the range of motion.[2,42,43] Therefore, initial fixation strength is integral to the success of ACL reconstruction.[7,8,14,15,25]

The initial fixation strength required for ACL grafts in bone tunnels has been studied widely.[§] However, the exact in vivo forces the graft is subjected to are still not known. According to data of various biomechanical studies, the in situ forces of the graft are estimated between 30 and 450 N depending on the activity.[7,13,21,29,31,32,38,51] Forces up to 150 N might occur during daily living activities such as walking, and forces up to 450 N might occur during moderate or strenuous activities such as descending stairs or jogging.[7,13,21,29,31,32,38,51] According to these data, an initial fixation strength of more than 450 N is needed to withstand the force of rehabilitation. In contrast, Shelbourne and Gray reported use of a button for both tibial and femoral fixation of a patellar tendon reconstruction with a failure strength of only 248 N. Excellent knee stability was maintained with an accelerated rehabilitation program.[42,43] An explanation for this controversy might be that most studies evaluating biomechanical properties of fixation devices are worst-case scenarios in which the applied force is in line with the bone tunnel. Under in vivo conditions, the angle between tunnel and graft serves as a pulley and minimizes the forces the fixation device is subjected to in most joint positions.

Today, the interference technique introduced by Lambert[27] 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 the fixation of bone-patellar tendon-bone grafts, no consensus has been found for the fixation of hamstring grafts.[7] Hamstring reconstruction methods vary by their fixation devices and the fixation level (anatomic versus extra-articular). Most extra-articular fixation techniques are indirect. They rely on linkage material to connect the tendon to the fixation device. These fixation techniques provide a high ultimate fixation strength between 520 and 905 N,[7] but the stiffness of extra-articular fixation techniques is far below of that of bone-patellar tendon-bone grafts.[3,4,7,15,23,44,51] Stiffness—the slope of the linear region of the load-elongation curve—is an important feature of tendon graft fixations.

Höher et al[20] have shown that the low stiffness of extracortical fixation using endobuttons or washer primarily resulted from the mechanical behavior of the suture or tape material and not from the graft itself. Shearing forces that occur due to 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.[7,15,29,34,37,44]

Anatomic fixation techniques with interference screws at the original ACL insertion site have been developed because of the disadvantages of extra-articular indirect graft fixation. When implants for tendon graft fixation are placed close to the articular cavity, knee stability at a variety of flexion angles is increasing, and graft isometry improves.[7,14,15] In most studies about hamstring graft fixation, interference screws—metallic and bioabsorbable—

[§]References 3-7, 9, 15, 17, 19, 22, 25-28, 35, 38, 39-41, 44, 45, 48.
[‖]References 7, 8, 10, 14, 19, 20, 22, 23, 35.

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 reports have demonstrated inflammatory reactions after intra-articular use of biodegradable implants.[46,47,50]

Clark et al reported a new fixation technique using stainless steel cross pins of 35 and 70 mm lengths.[11] With this technique, the hamstring loops are suspended by one pin inserted at the proximal end of the femoral tunnel. Biomechanical tests showed a mean initial load to failure of 1003.3 N and 1604.3 N for the 35 mm and 70 mm steel cross pins, respectively.[11] Another anatomic graft-fixation technique is the double cross pin technique (Rigid Fix). With this technique, the grafts are fixed by two biodegradable pins (diameter, 3.3 mm; length, 42 mm) piercing the tendon strands perpendicularly. The articular pin is inserted close to the anatomic origin of the ACL, but none of the pins is in contact with the articular cavity. To our knowledge, no clinical or biomechanical data of a technique using two biodegradable pins crossing the graft perpendicular have been published.

Previous studies have shown that the bone mineral density has much influence on the initial fixation strength of tendon graft fixation.[8,10,16,17,36] We used a bovine model as described by Weiler et al[48] with known bone mineral density of 0.8 g/cm^3 to quantify free tendon graft fixation. In this study, a mean bone mineral density of 0.84 g/cm^3 has been measured. This bone mineral density is comparable to that of young human proximal tibiae.[16,17] This model has also been used by Giurea et al.[17]

The present study demonstrates that the cross pin method provides similar fixation strength compared to a biodegradable interference screw in the single-cycle failure test. The results for biodegradable interference screws have similarities with previous work on other anatomic hamstring graft-fixation techniques using the same model (bovine tibial bone). Weiler et al[48] found a mean fixation strength between 332 and 647 N for various biodegradable interference screws, and Giurea et al[17] found a fixation strength of 445 N for the biodegradable RCI screw. 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 Rigid Fix group, all grafts failed by a fracture of both pins. In contrast, in the interference group the predominant failure mode was slippage of the graft past the screw leaving the screw relatively undamaged in position.

The ultimate failure load of the Rigid Fix device is lower than that of the cross pin technique stated by Clark et al.[11] In their study, the initial fixation strengths ranged from 1003.3 N to 1600.3 N for animal tissues fixed with 35-mm or 70-mm cross pins. Clark et al[11] used a cross pin made of stainless steel; the 3.3-mm biodegradable pins used in this study were made of L-lactide/D-lactide (PLA). The different material properties of the devices might be one cause for the differences in the ultimate pullout failure strength. Another reason could be the different testing model. Clark et al[11] used an ovine leg tendon as graft and fixed it in a porcine femur. In the current study, a human hamstring graft and a bovine model were used. This model has been described by Weiler et al[48] and Giurea et al[17] previously. In this model, the screw insertion site represents a trabecular bone density of 0.8 g/cm^3,[13,20,22] which is similar to what is expected in young human femora.[16,17] The different graft tissue (ovine versus human) and different material properties of the bone might be additional reasons for the diverse results. In contrast to the technique described by Clark et al,[11] the Rigid Fix implants pierce the hamstring graft and are not placed between the looped strands of the graft as the stainless steel pins are. This could be another cause for the lower ultimate pullout force of the Rigid Fix technique.

Our stiffness data regarding anatomic interference screw fixation resemble the results of Stadelmaier et al[44] and Nagarkatti et al[33] 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.[23] 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 an intra-articular length of 30 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) as described by Woo et al.[51]

As stated by Beynnon and Amis,[5] the single-cycle load failure test provides a measurement of the upper limit of the graft fixation construct, which is useful information since 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.[43] Cyclic loading seems to duplicate the physiological loading conditions more closely than single-cycle failure tests. Therefore, we tested the Rigid Fix-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 stated by Seil et al[41] and Giurea et al[17] These authors used a testing protocol in which the grafts were subjected to two different cyclic-loading levels. Cyclic loading between 60 and 250 N should simulate low- to moderate-level activity such as walking.[31,32] During rehabilitation, a stable fixation of the graft is necessary to allow early weightbearing and full range of motion and to minimize postoperative problems.

Investigations have shown that full extension of the knee by a quadriceps muscle contraction can produce resultant forces in the ACL or the graft of up to 200 N.[13,21] Using this load, there was no difference between the elongation of the interference and the cross pin group. Other investigations showed much higher forces the ACL or the graft has to withstand. Morrison[31] and Brand et al[7] report-

¶References 1, 15, 17, 19, 22, 23, 24, 25, 26, 28, 33, 35, 36, 38, 40, 41, 44, 48.

ed forces of up to 450 N during activities and rehabilitation such as descending stairs or jogging. Therefore, we additionally used a second protocol similar to that of Giurea et al.[17] The graft-fixation device bone complex was subjected to 1000 cycles between 50 and 450 N. All specimens with an interference screw device failed rapidly by slippage of the graft past the screw and could not be tensile tested. These findings are similar to that of Giurea et al.[17] All specimens fixed with a double cross pin device survived 1000 cycles and had a mean yield load of 445.4 (± 112.6) N and a maximum load of 772.5 (±183.9) N. The linear stiffness resulted in 234 (± 109) N/mm.

During rehabilitation, the hamstring graft is subjected to thousands of loading cycles. Therefore, ultimate failure loads without cyclic loading might not reflect the possible changes in the graft-fixation device-bone construct during rehabilitation exercises. To determine possible changes in the strength of the graft-fixation device-bone construct after cyclic loading, we performed the pullout test alone 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 both techniques.

A few limitations apply to this study since we tested a worst-case scenario with the force of pull in the line to the bone tunnel. This might not reflect the forces the graft is subjected to in vivo. Under in vivo conditions, the angle between tunnel and graft serves as a pulley and minimizes the forces the fixation device is subjected to in most joint positions. In addition, when discussing the clinical implications of results of biomechanical studies, care should be taken because we still can only speculate about the in vivo forces an intact ACL or a graft has to withstand. Another limitation could be the age of the human hamstring grafts used in this study. The grafts had a mean age of 55.6 years and a range of 23 to 78 years. Even though this may not reflect the most typical age for patients suffering from ACL ruptures, it is comparable to the mean age of human grafts used in other studies. Future studies concerning cross pin fixations under cyclic-loading conditions could include the use of a hamstring graft with a bone block attached.[48] The authors expect an increase in mean stiffness, yield load, maximum load, and displacement after cyclic loading of a bone block hamstring graft versus a conventional hamstring graft. In this study, a standardized 9-mm drill hole was used for all specimens. Since human hamstrings vary in size and could possibly fit in an 8-mm hole, there could be some variation in how tightly the tendons fit in the hole. But this could affect the interference fit more than the cross pin technique.

In conclusion, our biomechanical data suggest that hamstring graft fixation using two bioabsorbable 3.3 mm pins (Rigid Fix) provides a reasonable alternative to bioabsorbable interference screw fixation, and the clinical application is therefore justified.

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