Primary Stability of Bone–Patellar Tendon–Bone Graft Fixation With Biodegradable Pins

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Purpose: We evaluated the initial bone–patellar tendon–bone (BPTB) graft fixation strength of biodegradable pins compared with interference screws in anterior cruciate ligament reconstruction using bovine knees. **Type of Study:** Biomechanical in vitro study. **Methods:** Ten BPTB grafts from human donors fixed with 2 biodegradable 2.7-mm pins (Rigid Fix; Ethicon, Mitek Division, Norderstedt, Germany) crossing the bone block perpendicular and 10 BPTB grafts fixed with conventional biodegradable interference screws (Absolute Absorbable Interference Screw; Innovasive Devices, Marlborough, MA) underwent ultimate single-cycle failure loading at a rate of 200 mm/min. The grafts were fixed to bovine tibia to simulate young human femoral bone density. Failure mode, displacement before failure, and ultimate failure load were tested with a testing machine. The pullout force was in line with the bone tunnel to simulate a worst case scenario. **Results:** The failure mode for cross pins was either fracture of the bone block (5 specimens) or fracture of the articular pin (5 specimens). The failure mode for interference screws was slippage past the screw in all specimens. In the single cycle loading test, the mean yield load for the biodegradable pins was 400.2 ($\pm$ 122.4) N, maximum load, 524.6 ($\pm$ 136.6) N, with a mean stiffness of 155.2 ($\pm$ 32.4) N/mm. The yield load at failure for the interference screw was 402.7 ($\pm$ 143.9) N, maximum load 515.7 ($\pm$ 168.5) N with a mean stiffness of 168 ($\pm$ 42) N/mm. **Conclusions:** Fixation of a BPTB graft with 2 biodegradable 2.7-mm pins (Rigid Fix) leads to primary stability that is comparable to fixation with biodegradable interference screws. **Key Words:** ACL—BPTB graft fixation—Biomechanics—Maximal load—Tensile stress—Failure mode.

The bone–patellar tendon–bone (BPTB) graft is the most commonly used graft in anterior cruciate ligament (ACL) reconstruction.[1,2] An aggressive rehabilitation protocol may help to prevent typical complications of BPTB grafts such as extensor mechanism dysfunction with consecutive anterior knee pain or limitations in the range of motion.[3,4] A BPTB graft loses its initial strength during the remodeling process.[5,6] However, during the early postoperative period, the fixation of the graft to the bone tunnel is the primary factor in limiting early aggressive rehabilitation.

Many techniques have been used for fixation of BPTB grafts to bone. The gold standard is the interference screw technique introduced by Lambert.[7] Various studies have shown that the initial fixation strength of BPTB grafts fixed with metallic interference screws is better than that of any other technique.[8-10] Despite the good fixation strength of metallic interference screws, these implants have various disadvantages, such as distortion of magnetic resonance imaging (MRI), risk of graft laceration, and need for hardware removal.[11] Biodegradable screws with softer threads may be advantageous.[11]

Both screws, metallic and biodegradable, have provided comparable initial fixation strength in biomechanical tests.[12-17] However, biodegradable implants

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that are in contact with the intra-articular cavity may cause inflammatory reactions of the synovium during the degradation process.[18,19] A general disadvantage of the interference technique is that insertion of the screw may cause fracture of the posterior wall of the femoral bone tunnel.

To overcome these disadvantages, a new fixation technique using 2 biodegradable pins (length, 42 mm; diameter, 2.7 mm; Rigid Fix, Ethicon, Mitek Division, Norderstedt, Germany) crossing the bone perpendicularly has been developed. Primary stability as achieved with this fixation technique has not been investigated to date.[20] The goal of this study was to compare the initial fixation strength of the cross pin fixation technique (Rigid Fix) with that of the biodegradable interference screw fixation technique in the BPTB reconstruction of the ACL using load to failure tests.

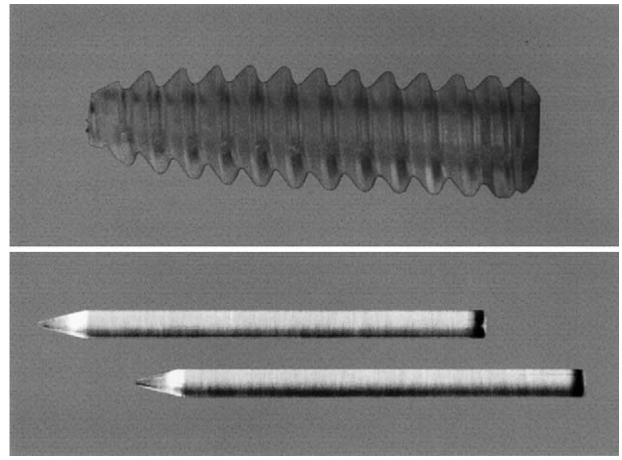

FIGURE 1. Implants used in the present study. (Top) biodegradable cross pins (PLA, Rigid Fix). (Bottom) Biodegradable interference screw (Absolute Interference screw).

METHODS

Biomechanical Model

In this study, 10 pairs of fresh bovine knees were used to simulate young human femoral density as described by Weiler et al.[17,18] In this model, the screw insertion site represents a trabecular bone density of 0.8 g/cm^3,[17,18] similar to what is expected in young human femora.[21,22]

The mean age of the animals was 28 weeks $\pm$ 2 weeks. The material was obtained from a local abattoir, 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.

The BPTB graft was obtained from fresh human cadavers (mean age, 55.6 years; range, 23 to 78 years). The BPTB graft was prepared by obtaining a rectangular tibial bone block. The blocks were trimmed to a size of 20 $\times$ 9 mm. To control for specimen uniformity, free tendon length, bone plug length, and bone plug width were recorded.

Study Groups

The tibia specimens were divided into 2 study groups so that of each pair, both sides went into different groups. In the first group (biodegradable cross pin fixation), the 10 BPTB grafts were fixated to the bone tunnel with 2 gamma sterilized biodegradable poly-L-lactide-D-lactide (PLA) copolymer pins (Rigid Fix) (Fig 1). Pin insertion was performed using specially designed instruments provided by Ethicon, Mitek Division (Fig 2). In the second group, a biodegradable standard 8 $\times$ 20 interference screw (Absolute Absorbable Interference Screw; Innovasive Devices, Marlborough, MA) was used. This screw is a tapered, threaded fastener for use in interference fixation of soft tissue or bone–tendon grafts. For screw insertion, a guidewire was used to prevent screw graft divergence, and the screw was placed between the graft and the tunnel wall.

The Cross Pin Fixation Technique

For cross pin insertion, the Mitek Rigid Fix Cross Pin guide has been used (Fig 2). Figure 3 shows the cross pin insertion technique as it is performed by the surgeons 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. 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 2 sleeves in the bone. Next, a long guide pin is placed through both the bone tunnel and out through the cortex. The stay suture of the bone block is placed through the eyelet of the guide pin and the graft is pulled into the bone tunnel. During surgery, this step

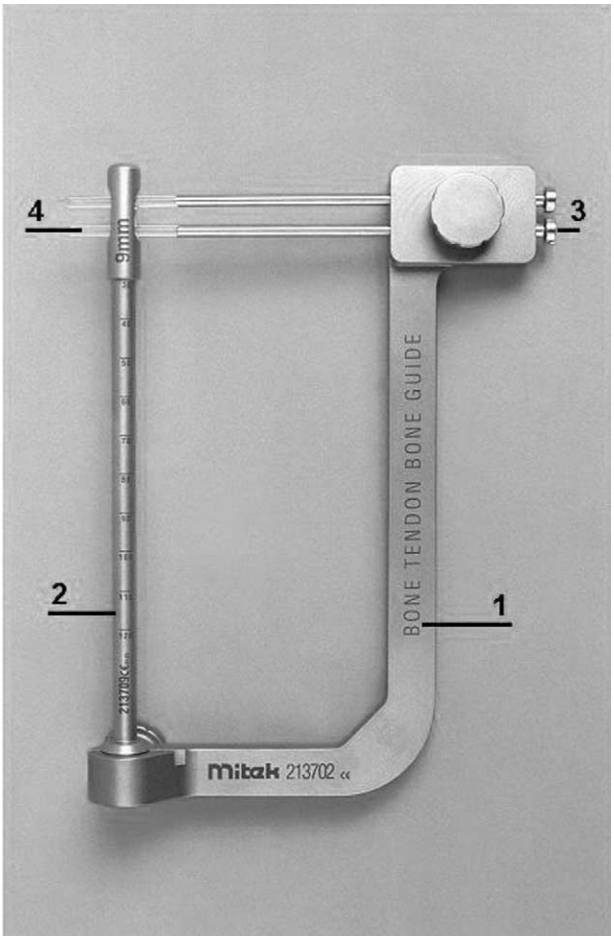

FIGURE 2. The Rigid fix cross pin guide was used for the insertion of 2 biodegradable cross pins. 1, guide; 2, rod; 3, sleeve; 4, cross pin.

is performed under arthroscopic visualization. After the bone block is in place, a longer trocar is drilled through both of the sleeves and a biodegradable cross pin (diameter 2.7-mm Rigid fix) is inserted into the sleeve. With a stepped pin insertion rod and 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. The sleeves are released using a sleeve removal tool.

Tensile Testing

Before testing, the specimens were removed from the freezer, thawed, and moistened with phosphate-buffered saline 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 Instruments, Fareham, Hampshire, England, Fig 4). BPTB specimens were mounted between 2 custom-made tissue patch clamps. The loads were applied parallel to the long axis of the bone tunnel. A preload of 25 N was applied to the tendon specimen, after which it was cyclically preconditioned between 0 and 2 mm of deformation 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 recorded simultaneously until the graft failed. Stiffness was determined as the linear region of the load elongation curve. Maximal load at failure as well as yield load was determined by the load–elongation curve. The paired Student *t* test was used for the statistical analysis of the results.

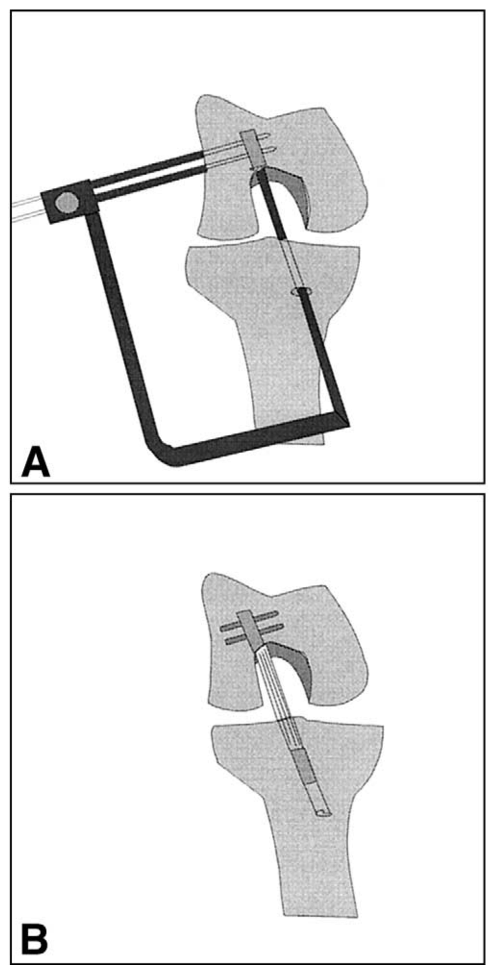

FIGURE 3. Surgical technique for BPTB fixation using the cross pins (2.7-mm diameter Rigid Fix). (A) Femoral fixation. (B) Cross pins in situ.

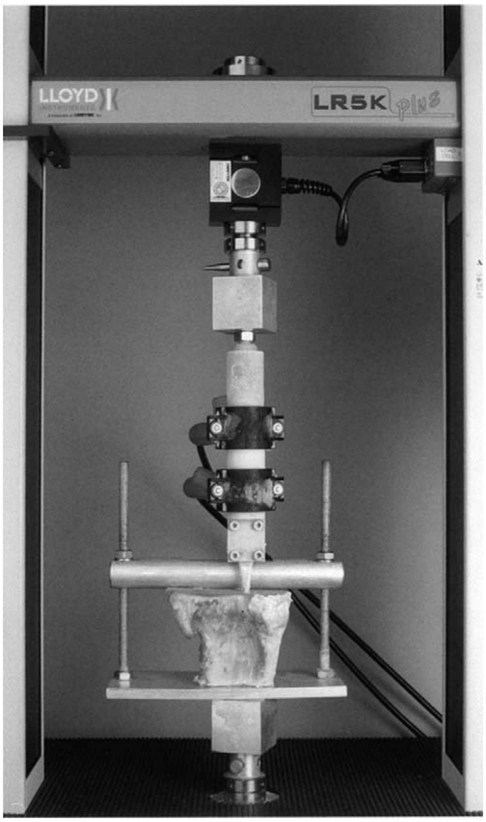

FIGURE 4. Tensile testing was performed in a uniaxial testing frame (LR5K-plus). BPTB grafts were friction-locked in a custom made cryofixation clamp. All loads were applied parallel to the longitudinal axis of the bone tunnel to simulate a worst case scenario.

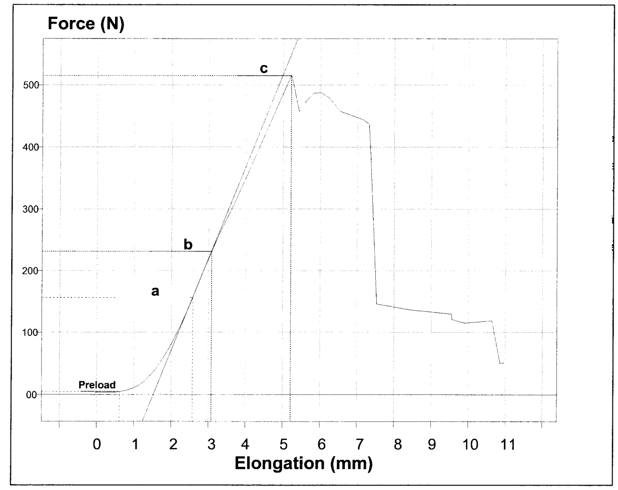

FIGURE 5. Typical load-elongation curve of a BPTB graft fixed with cross pins. Specimens were loaded to failure at a range of 200 mm/min. (a) stiffness, (b) yield load, (c) maximum load, and displacement were recorded.

RESULTS

A typical load–elongation curve is shown in Fig 5. The mean yield load in the cross pin group (Rigid Fix) was 400.2 (± 122.4) N and 402.7 (± 143.7) N in the biodegradable interference screw group. The maximum load at failure was 524.6 (± 136.6) N in the cross pin group and 515.7 N (± 168.5 N) in the interference screw group. Cross pin fixation resulted in a linear stiffness of 155 (± 32) N/mm and interference fixation in 168 (± 42) N/mm. All these measurements were not significantly different ($P > .05$).

All grafts of the interference screw group failed by bone block pullout. Two different failure modes were seen in the cross pin group: transverse fracture of the bone block at the level of the proximal pin (5 specimens) and fracture of the biodegradable pins (5 specimens, Table 1).

DISCUSSION

In ACL reconstruction with BPTB grafts, bone block healing occurs between 4 and 12 weeks after surgery.[5] In a study by Clancy et al.,[6] the bone blocks were histologically incorporated at 8 weeks after surgery in a Rhesus monkey. Until biological fixation has occurred, a stable fixation of the graft is necessary if the patient underwent an aggressive rehabilitation protocol.[3] Therefore, fixation strength is integral to the success of ACL reconstruction.[20]

The initial fixation strength required for ACL grafts in bone tunnels was investigated by several authors. During rehabilitation, the graft is loaded between approximately 30 and 400 N, depending on the activity.[23-27] According to these data, an initial fixation strength of more than 400 N is needed to withstand the force of rehabilitation. In contrast, one study achieved

TABLE 1. *Load, Stiffness, and Mode of Failure*

	Rigid Fix Cross Pin	Absolute Interference Screw
Maximum failure load (N)	524.6 (±136.6)	515.7 (±168.5)
Yield load (N)	400.2 (±122.4)	402.7 (±143.9)
Stiffness (N/mm)	155 (±32)	168 (±42)
Failure mode		
Pullout	0	10
Midsubstance rupture	0	0
Bone bloc fracture	5	0
Implant failure	5	0

excellent clinical results with an astonishingly weak fixation system.[28] Shelbourne and Gray[28] reported use of a button for both tibial and femoral fixation of a patellar tendon reconstruction, with a failure strength of 248 N.[20] Excellent knee stability was maintained with an accelerated rehabilitation program.[28]

Today the interference technique is considered to be the gold standard for the fixation of BPTB grafts with an acceptable clinical success rate.[1] Biomechanical studies have shown that interference screw fixation with biodegradable implants provides a fixation strength of BPTB grafts between 215 and 850 N.[8-13,15,29,30] A possible disadvantage of this technique is that the biodegradable implants are in contact with the synovial cavity. Foreign body reactions as complication of biodegradable implants have been described with the possible complication of a synovitic reaction during the degradation process.[18,19] Other complications of this technique are graft laceration or fractures of the bone block or fracture of the posterior tunnel wall with consecutive instability of the graft.

To our knowledge, clinical or biomechanical data of this method have not been published.[20] 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.,[16,17] with known bone mineral density of 0.8 g/cm^3 to quantify free tendon graft fixation. This bone mineral density is comparable to that of young human proximal femora.[21,22] The present study could not show a difference between fixation strength as achieved with cross pins versus biodegradable interference screws.

As stated by Beynnon and Amis,[31] the pullout test provides a measurement of the upper limit of the graft fixation construct strength. This information may be useful in describing the failure mode of the graft during unusual loading events such as a fall. Further studies are needed to study the biomechanical behavior of the Rigid Fix system under cyclic loading conditions, because under intense rehabilitation of a surgically treated knee, the graft fixation is subjected to repetitive submaximal loading.[31]

Stiffness—the slope of the linear region of the load–elongation curve—is an important feature of tendon graft fixations. The majority of tendon fixations are less stiff than the interference screw technique because they are placed in a distance from the joint surface (staple screw, suture soft tissue washer).[20] If strain is in line with the linkage between implant and graft, micromotion between graft and tunnel occur (bungee cord effect).[2] The Rigid Fix implants are placed close to the joint line, and the present study could not show a difference between the stiffness of the cross pin technique versus biodegradable interference screws. If implants for tendon graft fixation are placed close to the articular cavity, knee stability increased and graft isometry also improved.[2]

A few limitations apply to this study because we tested a worst case scenario. Additionally, when discussing the clinical implications of results of biomechanical studies, caution should be used. This is because we can still only speculate about in vivo forces an intact ACL or a graft must withstand. Another limitation could be the age of the human BPTB grafts used in this study. The grafts had a mean age of 55.6 years and a range of 23 to 78 years. Although 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. However, the lower bone mineral density of older donors might adversely affect the performance of the cross pin fixation, because in the Rigid Fix group, 5 grafts failed by bone block fracture at the articular pin. In contrast, in the interference group, the predominant failure mode was bone block pullout.

In conclusion, our biomechanical data suggest that fixation of a BPTB graft using 2 biodegradable 2.7-mm pins (Rigid Fix) leads to primary stability comparable to fixation with biodegradable interference screws.

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