Tendon graft fixation in ACL reconstruction

In vitro evaluation of bioabsorbable tenodesis screw

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Background Conventional ACL reconstruction requires sufficient tibial bone quality for secure graft fixation. We evaluated the mechanical characteristics of a supplemental tenodesis screw in cadaveric specimens.

Material and methods One group of 7 specimens from 7-paired tibiae was randomly assigned to undergo tibialis anterior tendon graft-bone tunnel fixation with a bioabsorbable interference screw, using conventional ACL reconstruction techniques. The other group of 7 specimens underwent the same procedure supplemented with a bioabsorbable tenodesis screw. All specimens were subjected to pullout testing on a servo hydraulic device.

Results Specimens in the supplemental fixation group had double the load to failure (tenodesis = 467 (SD 184) N, control group = 223 (SD 66) N, p = 0.02) and were also one-third stiffer (tenodesis = 31 (SD 13) N/mm, control group = 21 (SD 6) N/mm, p = 0.03) than the specimens in the conventional fixation group.

Interpretation Supplemental bioabsorbable tenodesis screw fixation may be advantageous for primary reconstruction in patients with low tibial bone mineral density or during revision procedures. By providing secure soft tissue graft-tibia fixation during the early phase after ACL reconstruction, supplemental tenodesis fixation may enable patients to participate safely in more intense, early rehabilitation.

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Concern over tibia side fixation during ACL reconstruction among patients with low bone mineral density has led to the development of innumerable surgical alternatives. Patients between 20 and 30 years of age who possess relatively high bone mineral density in the tibia have traditionally constituted the primary ACL reconstruction group. Recently, however, many patients who are over 40 years of age are undergoing this procedure with good results (Kuechle et al. 2002). A matter off concern regarding this older patient group is their greater predisposition to sub-optimal tibial bone mineral density (Vuori et al. 1994). Moreover, bone density in the tibia may decrease considerably during the first year after an ACL injury and reconstruction, particularly when weight bearing has been restricted (Leppala et al. 1999). Both intra-bone tunnel fixation, using metal or bioabsorbable interference screws, and supplemental fixation methods, using screws, staples, buttons, or screw-washer combinations, are now available (Noyes and Barber 1991, Aglietti et al. 1992, Draganich et al. 1995, Novak et al. 1996, McGuire et al. 1999, Zysk et al. 2000). They have been developed, at least partly, to augment reconstructive tendon fixation in tibiae with reduced bone quality, such as that commonly observed among females, middle-aged persons, patients who smoke, and other groups (Howell et al. 1999, Brand et al. 2000). Despite the number of surgical alternatives developed, a reproducibly consistent method of providing stable fixation in tibiae with low bone mineral density is lacking. One promising method to deal with this problem is to combine intra-bone tunnel and supplemental fixation.

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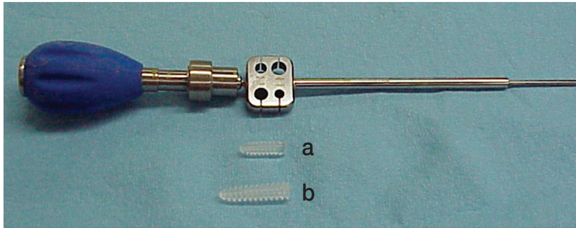

Figure 1. Bio-Tenodesis System with bioabsorbable tenodesis screw (a) and interference screw (b)

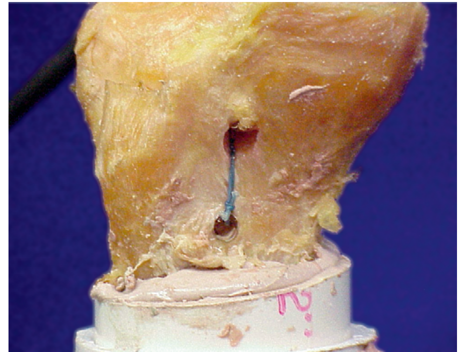

Figure 2. Supplemental biotenodesis screw fixation.

Combined or "hybrid" tibia fixation may be particularly advantageous when soft tissue tendon grafts are selected as the graft of choice. Ideally, soft tissue tendon graft-tibia tunnel fixation should incorporate the load to failure characteristics provided by supplemental, graft tenodesis techniques with the intimate graft-tibia tunnel contact area and the compression provided by interference screw fixation. The increase in surface contact area provided by an appropriately-sized interference screw placed in a suitably positioned tibial tunnel in close proximity to the knee joint line reportedly improves bone deposition and the development of calcified fibrocartilage at the soft tissue tendon graft-tibia tunnel junction (osteointegration), and prevents the windshield wiper effect (Arnoczky et al. 1988, Rodeo et al. 1993, Scranton et al. 1998).

We determined the mechanical efficacy of supplementing conventional intra-bone tunnel interference screw fixation of a soft tissue tendon graft with supplemental fixation provided by a bioabsorbable tenodesis screw (Bio-Tenodesis Screw, Arthrex, Naples, FL) (Figure 1). Cadaveric specimens were used to simulate a patient population with low bone mineral density in the tibia. Our hypothesis was that soft tissue tendon graft-tibial tunnel fixation supplemented with secondary fixation from a bioabsorbable tenodesis screw would have superior mechanical testing characteristics.

Material and methods

7 paired, fresh frozen male cadaveric tibiae (mean age 74.4 (56–89) years) were harvested from the University of Louisville Fresh Tissue Laboratory. All cadaveric specimens had been "lightly embalmed", using 7.6 L of a formaldehyde-based arterial conditioner, Metasyn (Cambridge, MA), the better to maintain normal tissue color, moisture content, and "life-like" mechanical properties. This is in contrast to the about 40 L of embalming fluid commonly used to prepare cadaveric specimens for gross anatomy dissection laboratories. All tibiae were harvested within 2 weeks post-mortem. After harvesting, each tibia was placed in a sealed plastic bag for immediate freezing. Before using, all tibiae were thawed at room temperature (24 °C) for 24 hours and tested within 2 weeks. Specimens were stripped of all soft tissue attachments and embedded in a fiberglass reinforced filler compound (Bondo Corporation, Atlanta, GA) with the longitudinal axis of the bone aligned vertically. Doubled grafts of the tibialis anterior tendon (CryoLife, Marietta, GA) were prepared, using 2 braided polyblend sutures (AR-7200, FiberWire, Arthrex, Naples, FL) and standard techniques (Charlick and Caborn 2000). Tunnels were drilled at 50 degrees retrograde to the anterior tibial surface, with an initial diameter of 2 mm less than that of the grafts (Goble et al. 1995, Howell et al. 1999). The tunnels were then dilated to have the same diameters as the graft. The graft were measured using a grooved sizing block (AR-1889, Arthrex, Naples, FL) and they were all 9 mm in diameter. Tibialis anterior grafts were secured by a single 34.5 mm long, 10 mm diameter bioabsorbable interference screw (Arthrex, Naples, FL) (conventional group). One specimen from each pair was randomly assigned to receive supplemental fixation with a bioabsorbable tenodesis screw (Bio-Tenodesis Screw System, Arthrex, Naples, FL) (biotenodesis group) (Figure 1).

Estimates of bone mineral density (g/cm²)

	N	Mean	SD	Range	Percentile 25th	50th	75th
Group 1 (conventional)	7	0.95	0.18	0.77–1.3	0.80	0.91	1.0
Group 2 (biotenodesis)	7	0.84	0.13	0.68–1.0	0.75	0.81	0.99

During bioabsorbable tenodesis screw fixation, we drilled a second tibial tunnel, measuring 6.0 mm in diameter and 25 mm in depth, perpendicular to the anterior tibial surface at 20 mm distal to the ACL tunnel. The two ends of excess graft preparation suture material were passed through a double-braided polyblend suture loop via a cannulated bioabsorbable tenodesis screwdriver. The suture loop was tightened around the graft "delivery" sutures before being inserted into the tenodesis tunnel with a 7.0 mm diameter, 23 mm long bioabsorbable tenodesis screw. The ends of the graft "delivery" sutures were then secured around the bioabsorbable tenodesis screw rim with a Mulberry knot, thereby completing the secondary fixation (Figure 2).

During mechanical testing, each tibia specimen was mounted on an anchoring base with the proximal portion of the doubled tibialis anterior tendon graft looped over a 4.3 mm diameter stainless steel pin and secured to the load actuator of a servohydraulic testing device (Model #858, MTS, Minneapolis, MN). The loading axis was aligned directly with the tibial tunnel to provide a direct, tensile load ("worst case scenario"). Each specimen was then cycled 10 times from 10–50 N before pull to failure at a rate of 20 mm/minute. We recorded the mechanical characteristics (load to failure, stiffness and displacement) and mode of construct failure for each specimen and the data were analyzed, using Wilcoxon signed rank tests ($p < 0.05$).

Results

Despite randomized assignment, slight bone mineral density differences existed between test group tibiae (conventional group = 0.95 (SD 0.18) g/cm^2, biotenodesis group = 0.84 (SD 0.13) g/cm^2 (Table). The bone mineral density of the cadaveric tibiae used in this study was slightly lower than that reported for unimpaired, 21-year-old females (Vuori et al. 1994). Specimens that received supplemental bioabsorbable tenodesis screw fixation showed twice the load to failure (tenodesis = 467 (SD 184) N, control group = 223 (SD 66) N, Wilcoxon signed rank test $Z = -2.4$, $p = 0.02$), as compared to the conventional fixation group. Specimens that received supplemental bioabsorbable tenodesis screw fixation were also 34% stiffer (tenodesis = 31(SD 13) N/mm, control group = 21 (SD 6) N/mm, Wilcoxon signed rank test $Z = -2.2$, $p = 0.03$) than those in the conventional fixation group. Displacement at failure were similar in the groups (tenodesis = 11 (SD 3) mm, control group = 10 (SD 4) mm, Wilcoxon signed rank test $Z = -0.68$, $p = 0.5$). The failure of all control group constructs was due to graft slippage. The failure of all biotenodesis group constructs was due to a combination of graft slippage and elongation at the graft-suture interface. We found no breakage of the suture material or bioabsorbable interference screws. Furthermore, no displacement of the bioabsorbable tenodesis screw occurred.

Discussion

We believe that a combination of standard bioabsorbable interference screw soft tissue tendon graft-tibia tunnel fixation with supplemental bioabsorbable tenodesis screw fixation may prove clinically useful by providing secure soft tissue graft-tibia fixation during the early reconstruction phase after ACL in patients with low bone mineral density in the tibia.

With long-term biomechanical strength characteristics comparable to quadruple strand hamstring autografts and surpassing BPTB allografts, double-strand tibialis anterior tendon allografts provide an effective construct for ACL reconstruction, while avoiding the tissue morbidity com-

monly associated with autograft harvest (Shino et al. 1986, 1990, Haut Donohue et al. 2002). However, there are several disadvantages in using soft tissue allografts. Specifically, soft tissue tendon allografts take a longer time (8–12 weeks) for successful graft-tunnel osteo-integration and greater attention must be paid to fixation of the tibiae side, particularly in tibiae with low bone mineral density (Jackson et al. 1993, Rodeo et al. 1993, Pinczewski et al. 1997, Scranton et al. 1998).

With supplemental biotenodesis fixation, the load to failure results we found for tibialis anterior tendon graft fixation in tibiae with poor mineral density exceeded the loading requirements reported for safe activities of daily living and exercises for rehabiliation shortly after surgery (Morrison 1969, 1970, Noyes et al. 1983, 1984). The load to failure values we obtained with conventional fixation did not reach the 445-450 N threshold (Morrison 1969, Noyes et al. 1983, 1984) that is required for safe early postoperative function and rehabilitation. The 100% increase in load to failure and 34% increase in stiffness shown by the biotenodesis group more closely replicated the characteristics of the native ACL.

Our experiment yielded encouraging preliminary data supporting the use of a bioabsorbable tenodesis screw for secondary fixation when ACL reconstruction is performed in a tibia with low bone mineral density. By its placement in a separate bone tunnel, through the same skin incision, and with countersunk screw placement below the extracortical tibial surface, a bioabsorbable tenodesis screw would be less likely to produce perceptible skin irritation and adjacent tissue morbidity than permanent supplemental fixation methods such as staples or buttons, that require placement along the extracortical surface of the tibia. After tibia side graft-tunnel fixation during rehabilitation, the bioabsorbable tenodesis screw will be gradually replaced by living tissue. In contrast, washers and staples may have to be removed in a second operation. The intra-bone tunnel fixation provided by a bioabsorbable interference screw and the supplemental fixation given by the bioabsorbable tenodesis screw combine the positive mechanical strength characteristics of extra-articular fixation with the graft-tunnel compression afforded by intra-bone tunnel fixation. Since the manner of failure in the tenodesis group consisted of a combination of graft slippage and elongation at the graft-suture interface, conceivably even greater load to failure results may be expected with continued advancements in soft tissue tendon graft suturing techniques. Further study is needed to evaluate the effects of this procedure on patient functional outcomes and disability levels during and after rehabilitation.

The findings we report are limited to the use of a double-bundled tibialis anterior allograft. We would expect similar superior mechanical characteristics with supplemental biotenodesis fixation of tripled or quadrupled autogenous semitendinosus-gracilis soft tissue grafts, as compared to intra-tunnel fixation alone with a bioabsorbable interference screw. However, given the differences in graft diameter and mechanical characteristics, further studies are recommended. Of equal or potentially greater value to the knee surgeon would be further study on the development of a safe, accurate and clinically efficient method of quantifying bone mineral density in the proximal tibia in the tunnel region. Improved measurements of tibia bone mineral density and content, trabecular orientation, and cancellous-cortical bone distributions in the tunnel region will permit better planning of fixation before surgery and selection of patients who would benefit most from supplemental fixation.

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