Foam-Reinforced Elderly Human Tibia Approximates Young Human Tibia Better Than Porcine Tibia

A Study of the Structural Properties of Three Soft Tissue Fixation Devices

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Background: Because there is an insufficient supply of young human knees, an alternative is needed for evaluating anterior cruciate ligament reconstructions. The authors determined whether an elderly human tibia reinforced with foam is a better substitute for a young human tibia than a porcine tibia in this study of the tibial fixation of a soft tissue anterior cruciate ligament graft using 3 devices.

Hypothesis: A foam-reinforced elderly human tibia more closely approximates the performance of a young human tibia than a porcine tibia.

Study Design: Biomechanical study.

Methods: Failure mode, stiffness, yield, and slippage were determined for a double-looped tendon graft fixed with either an interference screw, WasherLoc, or tandem washers in young human tibiae, foam-reinforced tibiae from elderly humans, and porcine tibiae.

Results: The stiffness and yield of interference screw and WasherLoc fixation in foam-reinforced tibiae more closely approximate those in young human tibiae than in porcine tibiae. Slippage of all combinations of tibiae and fixation devices was similar.

Conclusions: A foam-reinforced human tibia more closely approximates the performance of a young human tibia than that of a porcine tibia in this study.

Clinical Relevance: Fixation devices should be tested in foam-reinforced tibiae from elderly humans rather than tibiae from large farm animals when the supply of young human knees is insufficient.

Keywords: hamstring; anterior cruciate ligament (ACL); reconstruction; fixation; tibia

There is an insufficient supply of young human knees for evaluating ACL reconstructions, which has researchers investigating other alternatives. An alternative is to use a knee from a large farm animal (eg, porcine, bovine, ovine, and caprine).[†] The disadvantages of using a knee from a large farm animal as a substitute are that the stiffness and yield of 1 type of fixation device (ie, interference screw) are overestimated,[19] and the geometry and kinematics of a knee from a large farm animal differ from those of a human knee.[3,12,16] Therefore, the challenge is to devise a substitute that both approximates the fixation properties of young human bone and has the geometry and kinematics of a human knee.

A technique that has not been reported and that might circumvent the insufficient supply of young human knees is the use of foam to reinforce the osteopenic cancellous bone in an elderly human knee. A block of polyurethane foam has been used to test fixation devices.[8,11,29,34] A 2-part kit of liquid polyurethane foam, which when mixed and

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[†] References 1, 5, 13, 15, 16, 18, 19, 22, 24, 28, 30, 33.

One author has a commercial affiliation with a product named in this study

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cured to a solid has mechanical properties similar to human cancellous bone, is commercially available.[2,31] Aging reduces the density of cancellous bone[9,23,35] but not cortical bone.[4,27] Therefore, removing osteopenic cancellous bone in an elderly human knee and filling the cavity with foam of the correct density might provide results that approximate young human bone and have clinical relevance.

We evaluated the use of foam to reinforce an elderly human tibia as a substitute for a young human tibia. One purpose of our study was to describe a simple and inexpensive technique for reinforcing an elderly human tibia with foam. A second purpose was to quantify the density and distribution of foam in the tibia. The final purpose was to evaluate the tibial fixation of a double-looped tendon graft using 1 of 3 fixation devices (ie, interference screw, WasherLoc, and tandem washers) in young human tibiae, foam-reinforced elderly human tibiae, and porcine tibiae and to compare the stiffness, yield load, and slippage between types of tibia. We tested the hypothesis that the fixation properties in foam-reinforced elderly human tibiae more closely approximate those in young human tibiae than those in porcine tibiae when evaluating 3 soft tissue fixation devices.

MATERIALS AND METHODS

Materials

Knees from young humans (N = 14; average age 35; range, 18-48 years), elderly humans (N = 14; average age 75; range, 65-90 years), and porcine (N = 14; skeletally mature) were harvested and stored at –20°C. Three fixation devices were tested: a metal soft tissue interference screw (Standard Interference Screw, 9 × 25 mm, Smith & Nephew DonJoy, Carlsbad, Calif), WasherLoc (Arthrotek Inc, Warsaw, Ind), and tandem metal soft tissue washers (18-mm-diameter Soft Tissue Anchor Washers, Arthrotek Inc). A bovine extensor tendon (Holstein forelimb, Los Banos Abattoir Co, Los Banos, Calif) was used to make a double-looped bovine tendon (DLBT) graft. A kit of liquid polyurethane foam with a solid density of 0.19 g/cm^3 and consisting of two parts named Part A and Part B was obtained from the manufacturer (Last-A-Foam FRL-6712, General Plastics Manufacturing Co, Tacoma, Wash).

Preparation of the DLBT Graft

A bovine extensor tendon was used as the ACL graft because it is less expensive than a human double-looped semitendinosus and gracilis graft and because the structural properties are similar when the cross-sectional area and length are matched.[10] The ACL graft was prepared by cutting the extensor tendon to a length of 27 cm and dividing the tendon along the bifurcation into 2 strands. Placing the 2 strands side by side and folding the strands into a loop formed the DLBT graft. The cross-sectional area of the graft was determined by averaging measurements made with an area micrometer 15, 45, and 75 mm from the loop.[10,19] The cross-sectional area of the DLBT graft used with the interference screw was 46.6 ± 6.4 mm^2, with the WasherLoc was 42.7 ± 8.4 mm^2, and with the tandem washers was 42.6 ± 6.2 mm^2. Four centimeters of the end of each strand were whipstitched using a number 1, braided, nonabsorbable suture (Ethibond, Ethicon Inc, Somerville, NJ). An additional suture was applied to the grafts assigned for use with the interference screw, according to the manufacturer's recommendation. The 4 strands were sewn together using a baseball stitch (number 5, braided, nonabsorbable suture, Ethibond), which began 50 mm from the looped end and spanned 40 mm in length toward the free end of the graft.

Determination of Stiffness of the DLBT Graft

The stiffness of each DLBT graft was computed from a load-displacement test administered by a computer-controlled materials testing machine (Teststar IIs, v2.2 [software], Model 858, MTS Systems Corp, Minneapolis, Minn) with a 5-kN load cell (1010AF-1K-B, Interface, Scottsdale, Ariz). The DLBT graft was looped over a 6.3-mm-diameter steel bar attached to the base of the materials testing machine. A liquid nitrogen freeze clamp bolted to the shaft of the actuator was used to grip the free ends of the graft. Before gripping the graft, each strand was equally tensioned. The suture sewn to each strand was tied to a 0.5-kg weight and passed over a pulley.[10,14] While the strands were weighted, the freeze clamp was applied. The grip-to-grip length of the DLBT graft was 50 mm for the interference screw, 65 mm for the WasherLoc, and 67 mm for the tandem washer. Tension was applied to the graft with the actuator of the materials testing machine by cyclically loading the graft 11 times between 20 and 1000 N at a loading rate of 400 N/s.[10] The first 10 cycles preconditioned the graft. Stiffness was computed from the load-displacement curve obtained during the 11th cycle.

Technique for Reinforcing an Elderly Tibia With Foam

The elderly human knee was thawed overnight. The tibia was disarticulated from the femur and fibula, and all soft tissue was removed. The shaft of the tibia was cut 20 cm distal from the proximal articulating surface. The diaphysis of the tibia was cemented in an aluminum cylinder with a 6.4-cm diameter and 10-cm length using polymethylmethacrylate. A closed-end tibial tunnel was drilled in the tibia. The tibial tunnel was positioned with a drill guide (Howell Tibial Guide, Arthrotek, Inc) set at a length of 40 mm. The tip of the guide was centered between the medial and lateral tibial eminence, and the drill sleeve was positioned on the medial tibia midway between the anterior and posterior cortex. A 2.4-mm-diameter K-wire was drilled using the guide. A 7-mm-diameter cannulated reamer was used to drill the tibial tunnel from the distal to the proximal end. Drilling was stopped when the reamer reached subchondral bone. Cancellous bone was removed

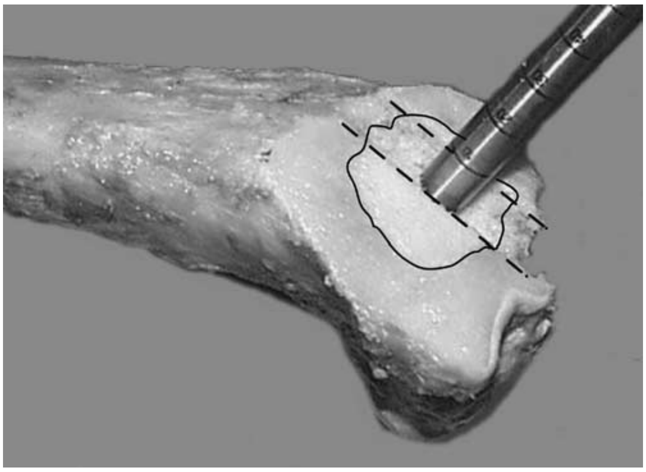

Figure 1. A nonorthogonal section of the tibia indicates the distribution of foam (bounded by solid line) surrounding the tibial tunnel (dashed lines). The foam replaced the osteopenic cancellous bone in the elderly tibia. Foam density was measured from a 9-mm-diameter, 10-mm-length cylinder of solid foam harvested with a coring reamer.

from the tibia through the distal end of the tibial tunnel using a series of tools (power rotary tool, #191 tip, #395 Variable-Speed Multipro Tool, Dremel, Racine, Wis; curettes; and a test tube brush). The reach and maneuverability of the tools inside the tibial tunnel determined the extent of the removal of cancellous bone and the size of the cavity. The cavity was cleaned and dried using isopropyl alcohol, pressurized air, and gauze. The liquid foam was prepared by pouring 30 mL of part A and 30 mL of part B into a 250-mL cup and manually stirring for 1 minute ($2 cost per tibia). The liquid foam was poured into the tibial tunnel until the cavity was filled (Figure 1). The foam expanded freely out of the distal end of the tibial tunnel during curing. The knee was stored for 2 hours at room temperature and 22 hours at 7°C, which completed the curing process. Foam that expanded out of the distal end of the tibial tunnel was removed. The foam-reinforced tibia was frozen at –20°C.

Insertion of the Fixation Devices

The young human knee, porcine knee, and foam-reinforced tibia were thawed overnight at room temperature. The tibiae were dissected from the young human knee and porcine knee, and each were mounted in an aluminum cylinder identical to that used for the foam-reinforced elderly human tibia. Each tibia was assigned a fixation device using a randomization protocol. In the tibiae assigned the WasherLoc, only 1 fixation device was tested. The randomization protocol assigned seven tibiae to the WasherLoc and seven tibiae to the interference screw for each type of tibia. In the tibiae assigned the WasherLoc, only the WasherLoc was tested. In the tibiae assigned the interference screw, the interference screw was tested first, the tandem washers next.

The aluminum cylinder containing a tibia was clamped in a jig that facilitated drilling of the tibial tunnel, tensioning the DLBT graft, and inserting each fixation device. A tibial tunnel 40 mm in length was aligned using the previously described technique and drilled through the subchondral bone. The diameter of the tibial tunnel was chosen to match the diameter of the DLBT graft. The diameter of the graft was determined by pulling the graft through a series of sizing sleeves that differed in diameter by 1 mm (ie, 7, 8, or 9 mm) (Arthrotek, Inc). The diameter of the tibial tunnel was the diameter of the smallest sizing sleeve through which the graft freely passed.

In the tibiae assigned the interference screw, the DLBT graft was looped around a steel bar attached to the jig, and the strands were passed through the tibial tunnel. The strands of the DLBT graft were tensioned equally by tying a 0.5-kg weight to each strand and hanging the weights over pulleys. The jig was adjusted until the intra-articular length of the graft was 35 mm. A guide wire was placed between the posterior wall of the tibial tunnel and the DLBT graft. The interference screw was inserted until the distal end of the screw entered the tibial tunnel.

In the tibiae assigned the WasherLoc, a 17-mm-diameter counter bore was drilled into the distal end of the tibial tunnel to recess the fixation device. The DLBT graft was inserted, and the intra-articular length of the graft was set to 35 mm. The strands of the DLBT graft were tensioned equally, as previously described. The WasherLoc was threaded on an awl. The awl was positioned in the hole created by the counter bore, and 1 strand from each tendon was placed on opposite sides of the awl. Striking the awl with a mallet drove the WasherLoc into bone within the counter bore. A 4.5-mm-diameter self-tapping cortical screw was inserted through the WasherLoc and tightened to compress the DLBT graft.

In the tibiae assigned the tandem washers, the interference screw and DLBT graft were removed. A new DLBT graft was inserted, and the intra-articular length of the graft was set to 25 mm. The intra-articular length of the graft was shortened to 25 mm from the 35 mm length used with the other 2 types of fixation devices to lengthen the section of the graft exiting the tibial tunnel. Lengthening the graft exiting the tibial tunnel allowed the graft to be securely gripped by the distal washer. Because the intra-articular length of the graft was the same for the tandem washer in all 3 types of tibia, the length of the graft did not affect the comparisons of the fixation properties. A 3.2-mm-diameter bicortical drill hole was made 11 mm distal to the distal exit of the tibial tunnel on the medial cortex. A second drill hole was made 19 mm distal and parallel to the first. The holes were threaded using a 4.5-mm tap. The washers were inserted to within 10 mm of the cortex by advancing the two 4.5-mm diameter cortical screws. One strand from each tendon was wrapped in an "S-shaped" configuration around both screws, and the other strands were wrapped in the opposite direction.[19] The strands of the DLBT graft were tensioned equally. The proximal and distal screws were tightened to compress the graft. The torque used to seat the screw was applied by hand and not

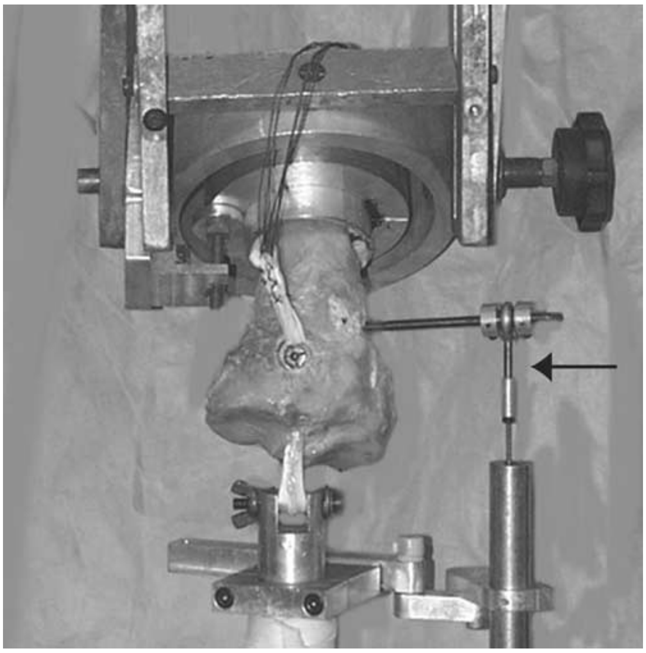

Figure 2. The testing apparatus for determining stiffness, yield, and slippage using the 6 degree of freedom fixture is shown with a foam-reinforced elderly tibia. The actuator applies a tensile load to the graft in line with the long axis of the tibial tunnel. Local displacement of the graft-tibia-fixation complex was measured by a linear variable displacement transformer (arrow) placed on the side of the tibia at the level of the fixation device and at the looped end of the double-looped bovine tendon graft.

with a torque screwdriver. The screwdriver was gripped with the thumb, index, and long finger, and a maximum torque tolerated by the bone was applied. The same researcher seated all fixation devices.

Testing the Graft-Tibia-Fixation Complex

The aluminum cylinder containing a tibia was clamped in a 6 degree of freedom fixture bolted to the actuator of the materials testing machine (Figure 2). The axis of the tibial tunnel was aligned with the shaft of the actuator by adjusting the fixture. The graft was looped around a steel bar bolted to the base of the materials testing machine. A linear variable displacement transformer (LVDT) was placed on either the left or right side of the tibia to measure local displacement of the graft-tibia-fixation complex. One end of the LVDT was fixed in the cortex of the tibia through a 4.7-mm-diameter drill bit placed at the level of the fixation device, and the other was bolted to the base of the materials-testing machine. The gauge length was established by applying a 10-N load. A tensile load was applied to the graft-tibia-fixation complex at a rate of 400 N/s in increasing increments of 50 N until failure. Between each increment, the load was reduced to 10 N for 90 seconds.

During pilot testing, we observed bending of the tibia and testing fixture under tensile load. Bending either compressed or distracted the LVDT depending on whether the LVDT was mounted on the medial or lateral side of the tibia. Compression or distraction of the LVDT introduced an error in the displacement of the graft-tibia-fixation complex, which affected the determination of stiffness. The error in displacement of the graft-tibia-fixation complex due to bending might have been prevented by the simultaneous use of 2 LVDTs placed on opposite sides of the tibia at equal distances. However, because only 1 LVDT was available, the error in displacement was corrected using the following technique.

After testing each graft-tibia-fixation complex, the graft was replaced with a loop of steel cable (1.7-mm diameter). Distal to the tibial tunnel, the 2 ends of the cable were passed through a washer (7-mm inner diameter, 35-mm outer diameter, 2-mm thickness). The grip-to-grip length of the loop was set to 136 mm, and the ends of the cable were clamped with a U-bolt. The function of the washer was to stabilize proximal migration of the U-bolt against the distal end of the tibial tunnel during tensile loading. A tensile load was applied to the cable-tibia complex at a rate of 400 N/s in increasing increments of 50 N to a maximum load of 350 N. The tensile load was repeated until the proximal migration of the washer stabilized. The displacement of the LVDT was recorded, the LVDT was then symmetrically repositioned on the opposite side of the tibia, and the entire testing protocol was repeated.

The 2 LVDT measurements from the steel cable–tibia complex were averaged at each load within the 350-N load increment as a first step in the determination of a corrected load-displacement curve. The displacement of the LVDT in the steel cable–tibia complex that was placed on the same side of the tibia as the graft-tibia-fixation complex was subtracted from the average displacement of the 2 LVDT measurements from the steel cable–tibia complex. This displacement error was subtracted from the displacement of the graft-tibia-fixation complex to provide a corrected displacement of the graft-tibia-fixation complex. The original displacement was replaced by the corrected displacement of the graft-tibia-fixation complex at each load level to obtain a corrected load-displacement curve. The stiffness was computed from the linear region of the corrected load-displacement curve with use of a previously described technique.[19]

Determination of Mode of Failure

Three modes of failure were observed. The graft slipping from under the fixation device without a change in the position of the fixation device was graft pullout. The graft tearing from under the fixation device without a change in the position of the fixation device was graft rupture. A change in the position of the fixation device without slippage or tearing of the graft was bone fracture.

Distribution of Foam

The evaluation of the distribution of foam in the proximal tibia required an anteroposterior osteotomy in a nonorthogonal plane along the axis of the tibial tunnel (Figure

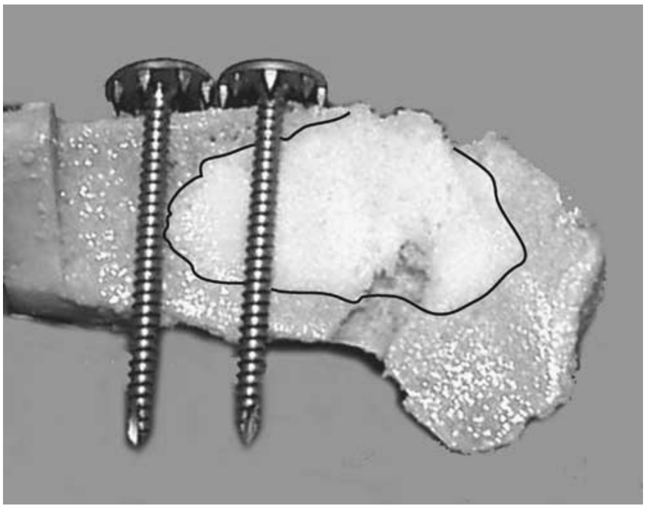

Figure 3. A section of tibia indicates the distal distribution of foam in the diaphysis (bounded by solid line). Foam extended distal to the proximal screw in 7 of 7 tibiae and distal to the distal screw in 1 of 7 tibiae.

1) and an anteroposterior osteotomy in the sagittal plane along the axis of the tibial shaft (Figure 3). The distribution of foam was characterized by measuring the distance between the proximal edge of the foam and the joint line, determining whether the foam circumferentially covered the tibial tunnel and the length of coverage, and determining whether the foam extended distally past the proximal and distal screws in the tandem washers.

Determination of Foam Density

Foam density was determined from a cylinder of foam that was harvested 20 to 25 mm distal to the joint line (Figure 1). A solid core of foam was harvested using a coring reamer with an inside diameter of 9 mm (Coring Reamer, Arthrex Inc, Naples, Fla). The length of the core was trimmed to 10 mm. The foam cylinder was degreased and dried,[9] and the density was calculated by dividing the dry weight by the volume.

Statistical Analysis

For each fixation device, the data concerning the effect of the type of tibia on the individual fixation properties were modeled with a Mann-Whitney *U* test with the independent variable being the type of tibia with 2 contrasts (young versus foam-reinforced and young versus porcine) and the dependent variables being stiffness, yield, and slippage at 250 N. A value of 0.0 N/mm was assigned for stiffness when the specimen yielded below the 350-N load increment. A value of 1000 mm was assigned for slippage when the specimen yielded at or below the 250-N load increment. These assigned values were used only in the nonparametric analysis and were not used in the calculation of the descriptive statistics. The level of significance was set at $P < .05$. Statistical analyses were performed with software (SAS, release 8.0, SAS Institute, Cary, NC).

For each fixation device, the average values of stiffness and yield were normalized to provide a unitless value that allowed a graphic comparison of the effect of the type of tibia on fixation properties (Figures 4, 5, and 6). Normalization was performed by dividing the average value of a fixation property in the foam-reinforced and

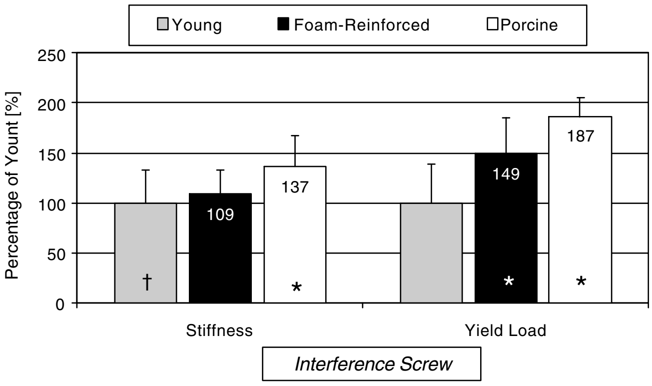

Figure 4. The normalized stiffness and yield of fixation with the interference screw in young human, foam-reinforced, and porcine tibiae. The asterisk (*) indicates that the fixation property in that type of bone was greater than that in young human tibiae ($P < .05$). For fixation with the interference screw, stiffness and yield in foam-reinforced tibiae were more similar to those in young human tibiae than those in the porcine tibiae. The stiffness of the fixation with the interference screw in young human tibiae may have been less than 298 N/mm (†) because 2 of 7 specimens failed below the 350-N load increment, and these 2 specimens were excluded from the calculation of the average stiffness. Error bars indicate 1 standard deviation.

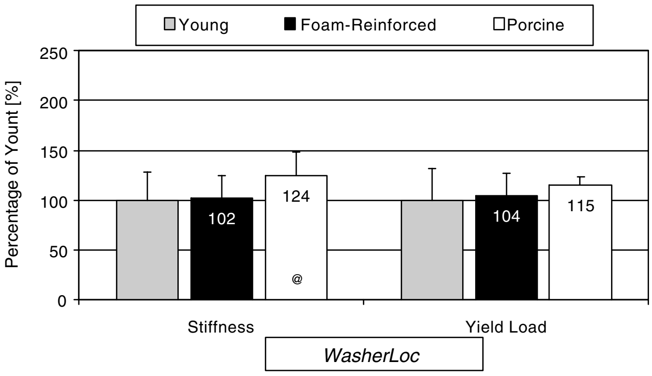

Figure 5. The normalized stiffness and yield of fixation with the WasherLoc in young human, foam-reinforced, and porcine tibiae. The "@" indicates that there was a trend that the stiffness in porcine tibiae was greater than that in young human tibiae ($P < .06$). For fixation with the WasherLoc, stiffness in foam-reinforced tibiae was more similar to that in young human tibiae than that in porcine tibiae. Error bars indicate 1 standard deviation.

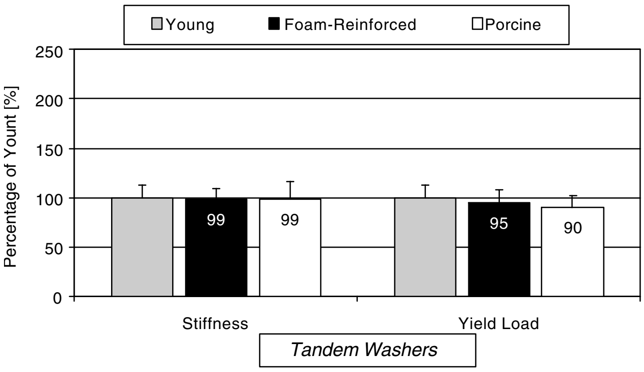

Figure 6. The normalized stiffness and yield of fixation with the tandem washers in young human, foam-reinforced, and porcine tibiae. For fixation with the tandem washers, stiffness and yield in foam-reinforced tibiae and porcine tibiae were similar to those in the young human tibiae. Error bars indicate 1 standard deviation.

porcine tibiae by the average value of that fixation property in young human tibiae.

RESULTS

Failure Mode

Failure of interference screw fixation was by graft pullout in the young human tibiae, foam-reinforced tibiae, and porcine tibiae. Failure of WasherLoc fixation was by bone fracture in the young human tibiae, foam-reinforced tibiae, and porcine tibiae. Failure of tandem washer fixation was by graft rupture (6/7) and bone fracture (1/7) in the young tibiae, by graft rupture (5/7) and bone fracture (2/7) in the foam-reinforced tibiae, and by graft rupture (7/7) in the porcine tibiae.

Fixation Properties

For the interference screw, the stiffness in foam-reinforced tibiae was similar to that in the young human tibiae (P = .1896), the yield load was 49% greater than that in young human tibiae (P = .0180), and the slippage was similar to that in young human tibiae (P = .3215) (Figure 4, Table 1). In contrast, the stiffness of the interference screw in the porcine tibiae was 37% greater than that in the young human tibiae (P = .0416), the yield load was 87% greater than that in the young human tibiae (P < .0001), and the slippage was similar to that in the young human tibiae (P = .9511). Therefore, for the interference screw, 2 of 3 fixation properties in the foam-reinforced tibiae closely approximated those in the young human tibiae, whereas only 1 of 3 fixation properties in the porcine tibiae closely approximated the young human tibiae.

For the WasherLoc, the stiffness in the foam-reinforced tibiae was similar to that in the young human tibiae (P = .9521), the yield in the foam-reinforced tibiae was similar to that in the young human tibiae (P = .8568), and the slippage at 250 N in the foam-reinforced tibiae was similar to that in the young human tibiae (P = .2591) (Figure 5, Table 2). In contrast, the stiffness of the WasherLoc in the porcine tibiae was 24% greater than that in the young human tibiae (trend, P = .0602), the yield load in the porcine tibiae was similar to that in the young human tibiae (P = .5043), and the slippage in the porcine tibiae was similar to that in the young human tibiae (P = .7594). Therefore, for the WasherLoc, 3 of 3 fixation properties in the foam-reinforced tibiae closely approximated those in the young human tibiae, whereas only 2 of 3 fixation properties in the porcine tibiae closely approximated those in the young human tibiae.

For the tandem washers, the stiffness in the foam-reinforced tibiae was similar to that in the young human tibiae (P = .9521), the yield load in the foam-reinforced tibiae was similar to that in the young human tibiae (P = .5441), and the slippage in the foam-reinforced tibiae was similar to that in the young human tibiae (P = .1042) (Figure 6, Table 3). Similarly, the stiffness of the tandem washers in the porcine tibiae was similar to that in the young human tibiae (P = .7633), the yield load in the porcine tibiae was similar to that in the young human tibiae (P = .1902), and the slippage in the porcine tibiae was similar to that in the young human tibiae (P = .3087). Therefore, for the tandem washers, all 3 fixation properties in the foam-reinforced tibiae and porcine tibiae closely approximated those in the young human tibiae.

Foam Density

The average foam density within the metaphysis of the proximal tibiae was 0.29 ± 0.07 g/cm^3 (range, 0.18-0.41 g/cm^3).

Distribution of Foam

The distance between the proximal edge of the foam and the joint line along the long axis of the tibial tunnel was 9 ± 3 mm (range, 4-15 mm). The foam circumferentially covered 9 of 14 tunnels, with the length of coverage being 12 ± 7 mm (range, 4-24 mm). The foam extended distal to the proximal cortical screw in 7 of 7 tibiae and distal to the distal cortical screw in 1 of 7 tibiae.

DISCUSSION

The overall objective of the study was to determine whether the properties of foam-reinforced elderly human tibiae more closely approximate those of young human tibiae than those of porcine tibiae when evaluating tibial fixation of a soft tissue ACL graft. One important finding of our study is that replacement of cancellous bone in the proximal tibia from elderly humans with polyurethane foam is easy to perform, the foam distribution is consistent, and the technique is inexpensive. Another finding is that the fixation properties of the interference screw and

TABLE 1
Stiffness, Yield Load, and Slippage of the Interference Screw in Young Human, Foam-Reinforced, and Porcine Tibiae (mean ± 1 SD)

	Interference Screw		
Type of Tibia	Stiffness (N/mm)	Yield Load (N)	Slippage (mm)
Young human	298 ± 99[a]	353 ± 134	0.5 ± 0.3[a]
Foam-reinforced	324 ± 72	523 ± 126[b]	0.9 ± 0.2
Porcine	407 ± 92[b]	654 ± 65[b]	0.7 ± 0.2

[a] Two of 7 specimens failed at or below the 250-N load increment, and these 2 specimens were excluded from the calculation of the average stiffness and slippage.

[b] The fixation property in that type of bone was greater than that in the young human tibia ($P < .05$).

TABLE 2
Stiffness, Yield Load, and Slippage of the WasherLoc in Young Human, Foam-Reinforced, and Porcine Tibiae (mean ± 1 SD)

	WasherLoc		
Type of Tibia	Stiffness (N/mm)	Yield Load (N)	Slippage (mm)
Young human	371 ± 105	905 ± 291	0.5 ± 0.4
Foam-reinforced	379 ± 84	939 ± 213	0.8 ± 0.3
Porcine	461 ± 89[a]	1038 ± 77	0.5 ± 0.2

[a] There was a trend that the stiffness in the porcine tibia was greater than that in the young human tibia ($P < .06$).

TABLE 3
Stiffness, Yield Load, and Slippage of the Tandem Washers in Young Human, Foam-Reinforced, and Porcine Tibiae (mean ± 1 SD)

	Tandem Washers		
Type of Tibia	Stiffness (N/mm)	Yield Load (N)	Slippage (mm)
Young human	306 ± 40	1129 ± 141	0.7 ± 0.2
Foam-reinforced	302 ± 33	1070 ± 154	0.9 ± 0.2
Porcine	302 ± 56	1010 ± 136	0.9 ± 0.2

WasherLoc in foam-reinforced elderly tibiae more closely approximate those of young human tibiae than porcine tibiae. The final finding is that the fixation properties of the tandem washers in foam-reinforced tibiae and porcine tibiae closely approximate those of young human tibiae. Before discussing the clinical implications of these observations, several methods issues and limitations of the study should be reviewed.

Methods Issues and Limitations

One methods issue is whether testing the interference screw before the tandem washers in the same tibia caused a carryover effect that underestimated stiffness and yield and overestimated slippage of fixation with the tandem washers. Fixation with the interference screw failed by

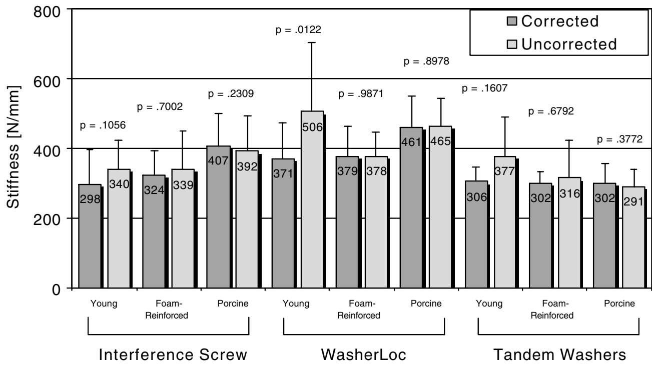

Figure 7. The corrected and uncorrected stiffness for the 3 tibial fixation devices tested in the 3 types of bone (mean ± 1 SD).

TABLE 4
Data From a Pilot Study Showing that Foam Density (0.13, 0.19, and 0.24 g/cm^3) Had a Strong Effect on the Stiffness, Yield Load, and Slippage for the Interference Screw and WasherLoc in a Foam-Reinforced Elderly Human Tibia (mean ± 1 SD)[a]

	Stiffness (N/mm)		Yield Load (N)		Slippage (mm)	
Foam Density (g/cm^3)	Interference Screw	WasherLoc	Interference Screw	WasherLoc	Interference Screw	WasherLoc
0.13 (N = 3)	200 ± 66	208 ± 11	311 ± 88	610 ± 296	2.1 ± 0.5	1.3 ± 0.3
0.19 (N = 7)	324 ± 72	379 ± 84	523 ± 126	939 ± 213	0.9 ± 0.2	0.8 ± 0.3
0.24 (N = 3)	491 ± 146	408 ± 93	672 ± 75	1005 ± 83	0.6 ± 0.0	0.5 ± 0.1

[a] A foam density of 0.19 g/cm^3 was used in the present study because it gave fixation properties for all 3 fixation devices that closely approximated a young human tibia.

graft pullout (21/21) and not by bone fracture. Fixation with the tandem washers failed predominately by graft rupture (18/21) and rarely by bone fracture (3/21). Because the interference screw did not fracture the bone and because the predominant failure mode of the tandem washers was graft rupture, it is unlikely that testing the fixation with the interference screw before the tandem washers weakened the cortical bone and caused a carryover effect that affected the fixation properties of the tandem washers fixation.

A second methods issue was whether correcting stiffness affected the conclusions of the study (Figure 7). The stiffness was corrected because bending of the tibia and load apparatus introduced an error in the measurement of displacement. Correcting stiffness provided a more conservative estimate of stiffness with less variability than the stiffness without correction. The correction reduced the stiffness in 6 of 9 comparisons, did not change the stiffness in 1 of 9 comparisons, and slightly increased the stiffness in 2 of 9 comparisons. The conclusions of the study were not affected by correcting stiffness.

A third methods issue was that the selection of foam density was not straightforward. One reason for this is that the effect of foam density on the performance of a fixation device in a foam-reinforced elderly human tibia was unknown. The manufacturer makes a variety of foams with different densities. A series of pilot studies was performed to determine whether foam with densities of 0.13, 0.19, and 0.24 g/cm^3 affected stiffness, yield load, and slippage of the interference screw and WasherLoc in foam-reinforced elderly human tibiae (Table 4). The foam density of 0.13 g/cm^3 underestimated the fixation properties, and the foam density of 0.24 g/cm^3 overestimated the fixation properties. The foam density of 0.19 g/cm^3 matched the fixation properties of young human tibiae the closest and was used in the present study.

A second reason the selection of foam density was not straightforward is that the foam density in the elderly tibiae (0.29 g/cm^3) was substantially greater (52%) than the foam density reported by the manufacturer (0.19 g/cm^3). We investigated the cause of the difference in foam density by examining 2 steps in the curing process that differed between our study and the manufacturer's recommendations. The manufacturer recommends baking the foam between 49°C and 71°C for 1 hour. Baking was omitted in our study because the temperature range of 49°C and 71ºC is greater than body temperature (37°C) and might have damaged the tibia. Omission of the baking step was not the cause of the difference in foam density because the foam density without baking (which was prepared in a cup to allow the foam to rise or expand freely) (0.19 g/cm^3) is the same as the foam density reported by the manufacturer (0.19 g/cm^3). The manufacturer recommends allowing the foam to rise freely during curing because it is general knowledge that restricting the rise increases foam density (General Plastics Manufacturing Company). The small opening of the 7-mm-diameter tibial tunnel does not allow the foam to rise freely from inside the tibial metaphysis. The restriction in rise imposed by the tibial tunnel was the most likely cause of the foam density inside the tibia being greater than that stated by the manufacturer. If this explanation is correct, then the insertion of foam through a small tunnel to reinforce a cavity inside any type of bone should result in a foam density that is greater than a technique that allows the foam to freely rise.

The final reason the selection of a foam density was not straightforward is that the foam density in the elderly tibiae (0.29 g/cm^3) was substantially lower (42%) than the density of cancellous bone in the young human tibiae (0.52 g/cm^3).[9] At the outset of the study, we predicted, as other investigators have,[6,23,34] that the foam density in the elderly human tibiae should match the density of cancellous bone in the young human tibiae. However, in contrast to the assertions of other investigators, we found this prediction was not true. Therefore, density is not the structural property to match to obtain approximately the same performance of the fixation devices in these 2 types of tibiae. The contribution of other structural properties such as modulus (elastic and shear), strength (yield, ultimate, and failure), strain (yield, ultimate, and failure), and microstructure might be of greater importance.

One limitation of our study is that the small sample size in our study may have prevented the detection of a significant difference in a fixation property between types of tibiae (ie, type II error). A significant difference was detected in 3 of 12 comparisons of stiffness and yield but not in the other 9. Of these 9 comparisons, 7 of 9 had a negligible difference between means (10% or less), 1 of 9 had a small difference between means (15%), and 1 of 9 had a moderate difference between means (24%). A difference was not detected in 6 of 6 comparisons of slippage with all 6 comparisons of slippage having a negligible difference between means of 0.4 mm or less. If a significant difference had been detected between the 2 comparisons with a greater than 10% difference between means, which were the fixations with the WasherLoc, then the 24% greater stiffness and the 15% greater yield load in the porcine tibiae compared to the young tibiae would have further supported the conclusion that a foam-reinforced elderly tibia is a better substitute for a young human tibia than a porcine tibia is.

Interpretation and Significance of Results

The technique of using foam to reinforce elderly tibiae is easy to perform, the foam distribution is consistent, and the technique is inexpensive. The time for preparing the elderly tibia and inserting the foam is 90 minutes. The tools are either readily available in the laboratory or can be purchased inexpensively at a hardware store. A kit of liquid foam (ie, 1 gallon of each part) reinforces 125 elderly tibiae at a cost of $2 per tibia. The technique widely distributes foam in the tibia within 10 mm of the joint line, circumferentially around the tibial tunnel, and distal to the proximal screw in the diaphysis. Any reasonably equipped laboratory with a limited budget should be able to reinforce elderly tibiae with foam.

Failure mode is a useful outcome measure when evaluating the performance of fixation devices.[20,23] In our study, the mode of failure of the interference screw and WasherLoc was the same for all 3 types of tibia. Bone fracture of tandem washer fixation was more likely to occur in foam-reinforced tibiae (2/7) than in young tibiae (1/7) or in porcine tibiae (0/7). Although we observed a trend of bone fracture with tandem washer fixation, the small sample size prevented the detection of a significant difference. Therefore, on the basis of failure mode, all 3 types of tibia perform similarly with these 3 fixation devices.

The fixation properties of stiffness, yield load, and slippage provide a comprehensive assessment of the in vitro and in vivo performance of fixation devices.[19,30,32] In our study, the fixation properties with the interference screw and WasherLoc in the foam-reinforced tibiae more closely approximated those in the young human tibiae than in the porcine tibiae. The fixation properties with the tandem washers in the foam-reinforced tibiae and porcine tibiae both closely approximated those in the young human tibiae. There-fore, on the basis of fixation properties, a foam-reinforced tibia is a better substitute than a porcine tibia if 1 type of tibia is selected to evaluate these 3 fixation devices.

The value of time zero, in vitro determination of the fixation properties of fixation devices, is to predict whether their use in vivo for humans undergoing ACL reconstruction will be safe and effective. Our results show that the prediction of safety and efficacy depends on the type of bone and the type of fixation device being evaluated. Our study clearly shows that the use of a porcine tibia overestimates the safety and efficacy of a fixation device that relies on cancellous bone (ie, interference screw). There is evidence to suggest that bone from other large farm animals might also overestimate the safety and efficacy of a cancellous fixation device because of substantial differences in density, elastic modulus, and compressive and tensile strength between the cancellous bone of large farm animals and young humans. The density of cancellous bone from bovine,[7,17] porcine,[28] and ovine[21]; the elastic modulus of cancellous bone from bovine[25]; and the compressive and tensile strength of cancellous bone from bovine[17,26] are all greater than the cancellous bone from young humans. These differences indicate that the results from tests of a cancellous fixation device in bone from a large farm animal should be confirmed in either young human bone or foam-reinforced elderly human bone before declaring that its use in humans is safe and effective.

In addition to evaluating fixation devices, another potential clinical application of the use of foam to reinforce elderly human bone is in the study of ligament reconstruction in the knee. The geometry, articulating surfaces, and range of motion of quadruped knees from large animals (ie, bovine, porcine) differ from human knees despite similarities in the cruciate ligaments.[2,12,16] Reinforcing the tibia and femur in an elderly human knee with foam might be a better substitute than animal knees for studying ligament reconstructions.

In summary, the use of foam to reinforce elderly human tibiae is a simple, inexpensive, and effective technique that provides a better substitute for evaluating the performance of fixation devices than the use of large farm animal knees. We suggest evaluating new fixation devices in foam-reinforced elderly knees instead of animal knees when young human knees are unavailable.

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