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# How the fixation method stiffness and initial tension affect anterior load-displacement of the knee and tension in anterior cruciate ligament grafts: a study in cadaveric knees using a double-loop hamstrings graft

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#### Abstract

There were two objectives to this study. The first was to investigate the relationship of graft fixation stiffness and graft initial tension on the anterior load-displacement behavior of knees reconstructed with a double-loop hamstrings tendon graft. The second was to determine the corresponding graft tensions at 225 N of anterior force applied to the knee. To satisfy these objectives, the anterior-load displacement curves were measured for seven cadaveric knees with the ACL intact at flexion angles ranging from 0° to 90°. The ACL was reconstructed in the same knees using a double-loop hamstrings graft. A/P load-displacement curves of the knee and graft tension were measured as the fixation method stiffness and the initial tension applied at full extension were varied (25-326 N/mm and 25–300 N). The 0 N posterior limit (unloaded position of tibia) and the anterior laxity (difference between the 0 N posterior limit and 225 N anterior limit) were computed to characterize the A/P load-displacement of the intact and reconstructed knees. The key results were that the 0 N posterior limit of the tibia was insensitive to changes in stiffness (p > 0.6503) but that increasing initial tension caused increasing posterior subluxation of the tibia with respect to the femur (p = 0.0001). The tibia was subluxed posteriorly by 5-6 mm on average at high levels of initial tension. Both initial tension and stiffness significantly affected the anterior laxity (p = 0.0001 for both factors). Anterior laxity was restored closely to normal (i.e. <1 mm difference) by relatively high initial tension of 200 N in combination with low stiffness of 25 N/mm and by low initial tension of 25 N in combination with higher stiffness ranging between 94 and 326 N/mm. When anterior laxity is restored to normal using a high initial tension-low stiffness combination however, the tibia undergoes a large posterior subluxation with respect to the femur in the unloaded state (approximately 5 mm) and a relatively high graft tension of 275 N is developed at 225 N of anterior force. Both the tibial subluxation and graft tension are reduced substantially with low initial tension-higher stiffness combinations because the amount of initial tension required to restore anterior laxity to normal is reduced by about 200 N.

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## Introduction

Surgeons are confronted with a number of clinical considerations that affect how well an ACL reconstruction achieves the goal of restoring normal load-displacement behavior of the knee. The selection of the graft construct [1,25,26,34], placement of the femoral and tibial tunnels [9,16,17,21,43], choice of the fixa-

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tion devices [8,18,33,38,41], flexion angle at which the initial tension is set and the amount of initial tension [2,7,9,13,30,45] are all factors which affect the outcome of an ACL reconstruction. Although preferences have emerged for both graft construct [1,6,26] and tunnel placement [9,17,21,44], the fixation method and initial tension are less established and were the focus of this study.

One important structural property of the fixation method, which can affect the anterior-posterior (A/P) load-displacement behavior of the knee, is the stiffness. It has been demonstrated that the stiffness of the graft influences the A/P load-displacement behavior of the

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knee [7]. However, during the early healing phase before the graft is incorporated in the bone tunnels, the stiffness of the graft-fixation complex is determined primarily by the fixation method because the fixation method is in series with the graft and is typically less stiff than the graft [24,40]. Depending on the stiffness of the fixation method, the stiffness of a double loop tendon graftfixation complex can be varied 10-fold at implantation (i.e. 24–259 N/mm) [24,40]. Therefore, the stiffness of fixation will profoundly influence the A/P load–displacement behavior of the knee for a given amount of initial tension. However, the influence of stiffness of fixation on the A/P load–displacement behavior of the knee and the graft tension developed under the application of an anterior force applied to the tibia are unknown.

The graft initial tension also affects both the A/P loaddisplacement behavior of the knee and graft tension. The lack of tension on a graft will leave a reconstructed knee unstable or lax, rendering the reconstruction ineffective. Although increasing the initial tension will stabilize the knee, the tension in the graft-fixation complex under an applied anterior force will also increase [9,13]. If the initial tension is excessive, then the corresponding increase in graft tension could reach the failure load of the graft-fixation complex [27]. Posterior tibial subluxation, also caused by excessive initial tension, will alter the A/P load–displacement behavior of the knee [30].

Although both initial tension and graft complex stiffness affect A/P load-displacement behavior of the knee individually, interaction between these two variables is also possible. A previous study showed that the initial tension required to restore laxity was graft construct specific [7]. Because the geometry and the material properties of a graft contribute to its stiffness, the study concluded that the initial tension required to restore laxity was inversely related to the stiffness of the graft construct. Similar reasoning applies to the stiffness of fixation but how initial tension and stiffness of fixation interact to affect both the A/P load-displacement behavior and graft tension is unknown.

There were two objectives to this study. The first was to investigate the relationship of graft fixation stiffness and graft initial tension on the A/P load-displacement behavior of knees reconstructed with a double-loop hamstrings graft through a range of motion from  $0^{\circ}$  to  $90^{\circ}$ . The second was to determine the corresponding graft tension under the application of a 225 N anterior force.

### Methods and materials

#### Experiments

Seven fresh frozen cadaveric knees (average age = 75 years, range = 70-79 years) were selected for this study. The knee joints were

inspected roentgenographically and visually at the time of anterior cruciate ligament reconstruction. In all of the specimens, there was no evidence of degenerative arthritis or gross deterioration of the articular cartilage and the cruciate ligaments were intact.

The specimens were prepared for experimentation by completely removing the skin. The semitendinosus and gracilis muscles were removed at their tibial insertions and saved in saline to be prepared as the graft. All tissue 50 mm above and 50 mm below the joint line was removed down to the bone. The bone was scraped to remove the periosteum. The fibula was fixed in its relative position by placing a screw through the fibula that anchored in the tibia. The fibula was then sawn off approximately 70 mm below the joint line. After reaming the intramedullary canals of the tibia and femur until only cortical bone remained, steel rods of either 10, 11, or 12 mm in diameter were fixed in the canals with PMMA. The knee was wrapped in saline soaked gauze to prevent desiccation of the remaining tissues.

The graft was prepared by scraping the muscle tissue from both the semitendinosus and gracilis tendons. The tendons were trimmed to taper slightly at the ends. Each end was sutured with 5 or 6 self-tightening whip stitches with no. 1 Ethibond suture. After folding the tendons in half about the mid-section to make a four-bundle graft, the graft was passed through cylinders with progressively smaller inside diameters (Sizing Sleeves, Arthrotek, Warsaw, IN) to determine its diameter [22]. The double loop semitendinosus and gracilis (DLSTG) graft was then placed in saline and refrigerated until use.

A load application system was used to produce load-displacement curves for each specimen [3]. The load application system is a six degree-of-freedom apparatus that can apply loads to the knee in either any or all degrees of freedom and measure the corresponding displacements according to a joint coordinate system [20]. Flexion/ extension is adjustable over the full physiologic range. For this study, only anterior/posterior force was applied and only anterior/posterior position was measured (resolution  $\pm 0.1$  mm). Using the steel rods to interface the specimen to the load application system, each specimen was aligned using the functional axes method which aligns the natural axes of joint motion with those of the load application system [4]. Once aligned the shafts of the tibia and femur were potted in aluminum tubes filled with PMMA which were clamped rigidly to their respective units of the load application system.

The intact knee was preconditioned in 50 N increments, increasing the anterior force from 0 to 250 N, decreasing the anterior force to 0 N, increasing the posterior force from 0 to 250 N, and decreasing the posterior force to 0 N. This complete loading and unloading sequence was considered one preconditioning cycle. Five complete preconditioning cycles were applied at 0° and 90° of flexion which produced a repeatable load displacement cycle [3]. Following preconditioning, a 2.5 N m extension moment was applied to define a 0° (i.e. full extension) knee extension reference.

Following preconditioning, each specimen was subjected to an anterior-posterior-anterior load cycle to determine two limits of motion at  $0^{\circ}$ ,  $30^{\circ}$ ,  $60^{\circ}$ , and  $90^{\circ}$  of flexion selected at random [12]. An anterior 45 N load was applied to the tibia and then removed. A posterior 45 N load was then applied to the tibia and removed; the position of the tibia at this point was the 0 N posterior limit (Fig. 1). Next, an anterior 225 N load was applied to the tibia; the position of the tibia at 225 N was the 225 N anterior limit.

Four springs (25, 94, 202, and 326 N/mm) were selected to represent the distribution of the stiffness of different combinations of femoral and tibial fixation methods. The calculation of the overall stiffness of different combinations of femoral and tibial fixation methods was performed using available values for the stiffness of each femoral and tibial fixation method [24,40]. The overall stiffness of 18 combinations of femoral and tibial fixation methods ( $K_{Overall}$ ) was calculated from the stiffness of the femoral fixation ( $K_{Femoral}$ ) and the stiffness of the tibial fixation ( $K_{Tibial}$ ) with the equation  $K_{Overall} = 1/(1/K_{Femoral} + 1/K_{Tibial})$ using a spring-in-series analysis [24]. The overall stiffness for these fixation combinations ranged from 18 to 269 N/mm (Table 1).

The knee was removed from the load application system and the joint was exposed. Both medial and lateral parapatellar incisions allowed the patella and patella tendon to be reflected distally as one unit. The joint was inspected and the anterior cruciate ligament was excised.

The anterior cruciate ligament was reconstructed using a technique that provides acceptable clinical outcome [22] and reciprocal tension behavior in the DLSTG graft similar to that of the intact ACL [43].



Fig. 1. Example A/P load-displacement response of the intact knee showing definitions of the 0 N posterior limit, the 225 N anterior limit, and the anterior laxity.

| Table I   |  |
|---|--|
| Overall stiffness of 18 different combinations of femoral and tibial fixation methods |  |

| Stiffness of   | Stiffness of tibial fixation                       |   |                                       |  |  |                                    |  |  |
|--|--|---|---------------------------------------|--|--|------------------------------------|--|--|
| femoral fixation   | #5 sutures<br>tied to Post<br>70 N/mm <sup>a</sup> | Double staples<br>174 N/mm <sup>a</sup> | 20 mm washer<br>192 N/mm <sup>a</sup> | Tandem wash-<br>ers—Typical 318<br>N/mm <sup>b</sup> | Metal interference<br>screw 340<br>N/mm <sup>b</sup> | WasherLoc<br>506 N/mm <sup>b</sup> |  |  |
| Endo Button 24<br>N/mm <sup>b</sup>                                  | 18 N/mm  | 21 N/mm                                 | 21 N/mm                               | 22 N/mm  | 22 N/mm  | 23 N/mm                            |  |  |
| Mitek Anchor<br>26 N/mm <sup>b</sup>                                 | 19 N/mm  | 23 N/mm                                 | 23 N/mm                               | 24 N/mm  | 24 N/mm  | 25 N/mm                            |  |  |
| Bone Mulch<br>screw with bone<br>compaction 575<br>N/mm <sup>b</sup> | 62 N/mm  | 134 N/mm                                | 144 N/mm                              | 205 N/mm   | 214 N/mm   | 269 N/mm                           |  |  |

<sup>a</sup> Stiffness of fixation determined using porcine tibia [24].

<sup>b</sup> Stiffness of fixation determined using human tibia [24] or femur [40] from donors with an average age 35 years.

The tibial tunnel was placed using the One Step Tibial Guide System (Arthrotek, Ontario. CA) [17,21]. The tibial drill guide placed a 2.4 mm guide wire 4-5 mm posterior and parallel to the slope of the intercondylar roof with the knee in maximum manual extension. In the coronal view, the guide wire was 0-2 mm from the lateral edge of the PCL. A cannulated reamer 1 mm in diameter larger than the graft size was used to drill the tibial tunnel. Bone was removed from the intercondylar notch and wall until an impingement rod, the same diameter of the tibial tunnel, passed freely indicating that the roof would not impinge upon the graft.

An endoscopic style blind femoral tunnel was placed using the Femoral Aimer Guide System (Arthrotek, Ontario, CA). A femoral aimer for the specific graft size was positioned through the tibial tunnel while the knee was placed at  $40-50^{\circ}$  of flexion. The top flat of the femoral aimer was oriented to 11 o'clock for a right knee and to 1 o'clock for a left knee. Once the aimer was locked in this position, a 2.4 mm guide wire was drilled into the femura. An endoscopic cannulated cutting reamer was used to drill a femoral tunnel 25–30 mm deep.

To allow the spring attached to the free end of the DLSTG graft to simulate the combined stiffness of a femoral and tibial fixation method, the femoral fixation used in the specimen had to be much stiffer than the stiffest fixation spring (326 N/mm). Accordingly a special procedure was developed to create an ultra-high stiffness femoral fixation. A 10 mm lateral-medial tunnel was positioned 25 mm inside the femoral tunnel using the U-Shaped Drill Guide (Arthrotek, Ontario, CA). A 4 mm in diameter steel rod was centered in the tunnel with a plug inserted in the femoral tunnel. The lateral-medial tunnel was then packed with PMMA and forced into the cavities of the trabecular bone using threaded end caps [29]. Once the PMMA hardened the 4 mm in diameter rod was removed so that the femoral tunnel plug could be extracted. The femoral tunnel was cleared of PMMA 'flashing' with a curette. The rod was reinserted in the cement mantle to form the femoral fixation post.

A Teflon sleeve was placed in the tibial tunnel to reduce friction between the graft and the tunnel [17]. Since the tibial tunnel was drilled 1 mm in diameter greater than the graft size, a sleeve of Teflon with a 0.5 mm wall thickness fit perfectly.

The graft was passed through the tibial and femoral tunnels so that each tendon was looped around the 4 mm in diameter steel rod mid way along the tendon's length. Care was taken to make sure that the two tendons did not cross in the tunnels. The sutures were marked so that each limb of the graft could be identified (e.g. anterior limb of the gracilis tendon) as they exited the tibial tunnel. A custom fixture was added to the tibial unit of the load application system that measured the graft tension, allowed the graft initial tension to be varied, and allowed the effective stiffness of the fixation method to be varied (Fig. 2). Upon exiting the tibial tunnel, the four limbs of the graft were gripped with a freeze clamp that was chilled with liquid nitrogen [35]. A load cell (Futek Advanced Sensor Technology, Inc., Irvine, CA), attached to the freeze clamp measured the graft tension. A coil spring was sandwiched between the steel plate and the end cap that threaded onto a shaft allowed so that the spring was compressed when the graft initial tension. Turning the knurled end cap adjusted of the graft initial tension. Note that as the initial tension was adjusted the tibia was free to translate relative to the femur. When the end cap was removed from the shaft, a coil spring of a different stiffness could be installed.

Once the graft was frozen in the freeze clamp, an arbitrary initial tension greater than 250 N was applied to the graft with the knee at  $0^{\circ}$  of flexion and with the stiffest spring installed. The knee was subjected to the same preconditioning protocol that was used for the intact case.

After the graft was preconditioned, the experimental protocol varied graft initial tension, spring stiffness, and flexion angle. All combinations of four springs (25, 94, 202, 326 N/mm), four initial tensions (25, 100, 200, 300 N), and four flexion angles ( $0^{\circ}$ ,  $30^{\circ}$ ,  $60^{\circ}$ ,  $90^{\circ}$ ) were tested. Spring values were selected randomly, followed by random selection of initial tension, followed by random selection of flexion angle. For each spring, the initial tension was set at  $0^{\circ}$  of flexion after which the flexion angle was adjusted to the required value and the knee was subjected to the same anterior–posterior–anterior load cycle used for the intact case. When a load cycle was completed, the knee was



Fig. 2. Diagram of the mechanism used to connect the free ends of the DLSTG graft exiting the tibial tunnel to the tibial unit of the load application system and allow the interchange of springs that represented the overall stiffness of different combinations of femoral and tibial fixation methods. The DLSTG graft was rigidly gripped with a freeze clamp. The freeze clamp was bolted to a tension load cell (LC) connected to a threaded shaft that passed through a spherical alignment bearing in a steel plate bolted to the load application system. A knurled end cap, attached to the threaded shaft, was turned to compress the spring until the initial tension in the graft was set at the desired level with the knee in full extension. Because the steel plate was connected to the tibial unit of the load application system, the method of setting initial tension created a corresponding reaction load on the tibia, which caused compression between the tibia and femur and posterior translation of the tibia. Both the tibia and the femur were connected rigidly to their respective units of the load application system by clamping the PMMA-filled aluminum tubes. The tibia was also rigidly clamped to the steel plate. The steel intramedullary rods, which were cemented into both the tibia and femur along the diaphysis, are not illustrated for clarity. Also large gussets, which reinforced the steel plate, are not illustrated for clarity.

returned to  $0^{\circ}$ , the initial tension adjusted if required, the next flexion angle set, and the load cycle applied once again. When all initial tension and angle combinations had been tested for each spring, the knee was again loaded at the first initial tension/flexion angle combination as a repeatability check. Excluding the repeatability checks, 64 combinations (4 springs × 4 initial tensions × 4 flexion angles) were tested on each specimen.

#### Data analysis

The A/P load-displacement data of the knee were analyzed to compute two dependent variables. The two variables were the 0 N posterior limit and the anterior laxity defined as the difference between the 225 N anterior limit and the 0 N posterior limit. To illuminate the changes caused by varying both initial tension and stiffness, each of the dependent variables of the intact knee was subtracted from the respective dependent variable of the reconstructed knee for each initial tension and stiffness combination. Positive differences indicated anterior laxity.

Several statistical analyses were performed on the data. At each flexion angle, two two-factor repeated measures ANOVAs were performed where stiffness and initial tension were the independent variables and the 0 N posterior limit and the anterior laxity were the dependent variables. Each ANOVA was followed by a polynomial decomposition to identify any significant trends for the main effects (i.e. graft initial tension and fixation stiffness). Additional analyses were performed to verify the main effect trends for each initial tension x stiffness interaction that was significant and important. A polynomial decomposition was performed at each level of initial tension over all levels of stiffness and at each level of stiffness over all levels of initial tension.

To determine the dependence of graft tension upon initial tension and stiffness, a two-factor repeated measures ANOVA was performed for each flexion angle where initial tension and stiffness were the independent variables and the graft tension at 225 N anterior force was the dependent variable. The level of significance for all tests was 0.05.

## Results

The difference in the 0 N posterior limit was affected differently by the initial tension and the fixation stiffness. The difference in the 0 N posterior limit was affected significantly by variations in the initial tension (p =0.0001) at all flexion angles. The 0 N posterior limit of the reconstructed knee moved posterior relative to the 0 N posterior limit of the intact knee for all values of initial tension (Table 2, Fig. 3). As initial tension increased, posterior movement increased (significant quadratic trend). However the difference in the 0 N posterior limit was not significantly affected by variations in fixation stiffness (p > 0.6503) at all flexion angles except 30°. Thus the smallest posterior movement always corresponded to the initial tension-stiffness combination with the lowest initial tension value of 25 N. Because the difference in the 0 N posterior limit was unaffected by stiffness, the difference in the 0 N posterior limit from that of the intact knee when averaged over the four flexion angles was comparable for each fixation stiffness and ranged from -1.6 to -1.8 mm.

The difference in anterior laxity was affected significantly by variations in both initial tension (p = 0.0001) at all flexion angles and by variations in stiffness (p = 0.0001) at all flexion angles. The initial tension x Table 2

Average and standard deviation<sup>a</sup> of the difference between the 0 N posterior limit in millimeters for the reconstructed knee and that of the intact knee over all specimens at each of four flexion angles

| Flexion angle (deg) | Initial tension (N) | Spring stiffness (N/mm) |            |            |            |  |
|---------------------|---------------------|-------------------------|------------|------------|------------|--|
|                     |                     | 25                      | 94         | 202        | 326        |  |
| 0                   | 25                  | -0.8 (1.6)              | -0.7 (1.4) | -1.0 (1.9) | -1.2 (1.6) |  |
|                     | 100                 | -2.6 (1.8)              | -2.4 (1.7) | -2.2 (1.9) | -2.5 (1.6) |  |
|                     | 200                 | -3.2(1.5)               | -3.2 (1,5) | -3.6 (1.9) | -3.4 (1.9) |  |
|                     | 300                 | -4.3 (1.8)              | -4.2 (1.7) | -4.3 (2.2) | -4.1 (1.8) |  |
| 30                  | 25                  | -1.2 (2.4)              | -1.1 (2.4) | -1.0 (2.8) | -1.3 (2.6) |  |
|                     | 100                 | -3.0 (2.3)              | -2.8 (2.4) | -2.5 (2.4) | -2.5 (2.3) |  |
|                     | 200                 | -4.0(1.8)               | -3.7 (2.1) | -3.8 (2.2) | -3.6 (2.4) |  |
|                     | 300                 | -4.8 (2.1)              | -4.6 (2.0) | -4.6 (2.2) | -4.3 (2.2) |  |
| 60                  | 25                  | -2.3 (0.8)              | -2.0 (1.1) | -2.1 (1.4) | -2.2 (1.3) |  |
|                     | 100                 | -3.4 (1.1)              | -3.5 (1.0) | -3.4 (1.2) | -3.6(1.1)  |  |
|                     | 200                 | -4.3 (0.7)              | -4.2 (1.0) | -4.4 (1.2) | -4.3 (1.2) |  |
|                     | 300                 | -5.2 (1.0)              | -5.2 (1.1) | -5.1 (1.3) | -5.0 (1.1) |  |
| 90                  | 25                  | -2.1 (1.4)              | -2.4 (0.8) | -2.2 (1.4) | -2.4 (1.3) |  |
|                     | 100                 | -3.7 (0.8)              | -3.7 (1.4) | -3.6 (1.4) | -3.8 (1.5) |  |
|                     | 200                 | -4.8 (0.8)              | -4.7 (1.3) | -4.8 (1.4) | -4.7 (1.3) |  |
|                     | 300                 | -5.9 (0.8)              | -5.9 (1.1) | -5.7 (1.6) | -5.4 (1.5) |  |

<sup>a</sup> Standard deviation in parentheses.



Fig. 3. Contour plot illustrating how variations in graft initial tension and stiffness affected the difference between the 0 N posterior limit in the reconstructed knee from the 0 N posterior limit in the intact knee at 30° of flexion.

stiffness interaction was significant (p < 0.008) at all flexion angles except 90°. For all flexion angles, the difference in anterior laxity decreased (significant linear or quadratic trend) as stiffness increased (Table 3, Fig. 4). The difference in anterior laxity also decreased (significant linear or quadratic trend) as initial tension increased. Smallest differences in anterior laxity depended on the initial tension-stiffness combination. For stiffness of 94 N/mm or greater, the smallest absolute difference in anterior laxity when averaged over the four flexion angles was  $\leq 1$  mm and occurred for the lowest initial tension of 25 N. For the lowest stiffness of 25 N/mm however, the smallest difference in anterior laxity was 0.2 mm when averaged over the four flexion angles and occurred for an initial tension of 200 N.

The average graft tension at 225 N of anterior force increased significantly as initial tension increased (p = 0.0001) and as stiffness increased ( $p \le 0.0039$ ) at all flexion angles (Table 4, Fig. 5). The graft tension averaged over the four flexion angles varied from a minimum of

Table 3

Average and standard deviation<sup>a</sup> of the difference between the anterior laxity in millimeters for the reconstructed knee and that of the intact knee over all specimens and each of four flexion angles

| Flexion angle (deg) | Initial tension (N) | Spring stiffness (N/mm) |            |            |            |
|---------------------|---------------------|-------------------------|------------|------------|------------|
|                     |                     | 25                      | 94         | 202        | 326        |
| 0                   | 25                  | 2.5 (1.6)               | 1.3 (1.5)  | 0.8 (1.7)  | 0.5 (1.6)  |
|                     | 100                 | 2.0 (1.3)               | 1.0 (1.5)  | 0.3 (1.9)  | -0.4 (1.8) |
|                     | 200                 | 1.6 (1.8)               | 0.5 (1.7)  | -0.3 (1.9) | -0.7 (1.9) |
|                     | 300                 | 0.5 (1.7)               | -0.3 (1.8) | -0.8 (1.9) | -1.1 (1.5) |
| 30                  | 25                  | 2.9 (1.5)               | 0.7 (1.7)  | -0.7 (2.0) | -0.7 (2.0) |
|                     | 100                 | 2.7 (1.3)               | 0.3 (1.7)  | -0.9(2.0)  | -2.4(1.7)  |
|                     | 200                 | 1.2 (0.9)               | -0.6 (1.8) | -2.2 (2.2) | -2.9 (2.7) |
|                     | 300                 | -0.8 (1.5)              | -2.1 (2.8) | -3.3 (2.6) | -3.9 (2.2) |
| 60                  | 25                  | 1.4 (1.8)               | -0.4 (2.0) | -1.3 (2.2) | -1.7 (2.2) |
|                     | 100                 | 0.4 (1.7)               | -1.1(2.3)  | -2.3(2.9)  | -2.9(2.6)  |
|                     | 200                 | -0.8(2.1)               | -2.4 (2.7) | -3.5(2.8)  | -3.7(2.8)  |
|                     | 300                 | -2.8 (2.4)              | -3.3 (3.0) | -3.7 (3.0) | -4.1 (2.7) |
| 90                  | 25                  | 0.0 (2.1)               | -1.1 (2.1) | -1.7 (2.4) | -2.1 (2.3) |
|                     | 100                 | -0.4(2.1)               | -1.6(2.4)  | -2.3(2.7)  | -3.0 (2.6) |
|                     | 200                 | -1.2(2.2)               | -2.3(3.1)  | -3.1(2.9)  | -3.6 (2.8) |
|                     | 300                 | -2.6 (2.8)              | -3.2 (3.0) | -3.2 (3.2) | -3.6 (2.7) |

<sup>a</sup> Standard deviation in parentheses.



Fig. 4. Contour plot illustrating how variations in initial tension and stiffness affected the difference between the anterior laxity in the reconstructed knee from the anterior laxity in the intact knee at 30° of flexion.

87 N for the 25 N×25 N/mm combination to 432 N for the 300 N×326 N/mm combination.

## Discussion

Both initial tension and stiffness of fixation are among the independent variables that have the potential to affect the A/P load-displacement behavior of the knee and graft tension but the stiffness of fixation has not been studied heretofore to the knowledge of the authors. Accordingly, the objectives of the present study were (1) to investigate the relationship of graft fixation stiffness and graft initial tension on the A/P load-displacement behavior of knees reconstructed with a double-loop hamstrings graft, and (2) to determine the corresponding graft tensions. The key findings were that (1) relatively high amounts of initial tension caused corresponding large posterior subluxation of the tibia on the femur in the unloaded state but subluxation was not influenced by the stiffness of fixation, (2) low initial tension of 25 N combined with high stiffness of at least

Table 4

Average and standard deviation<sup>a</sup> of the graft tension in Newtons for the reconstructed knee under the application of a 225 N anterior force over all specimens and each of four flexion angles

| Flexion angle (deg) | Initial tension (N) | Spring stiffness (N/mm) |          |          |           |  |
|---------------------|---------------------|-------------------------|----------|----------|-----------|--|
|                     |                     | 25                      | 94       | 202      | 326       |  |
| 0                   | 25                  | 79 (21)                 | 142 (24) | 172 (47) | 188 (32)  |  |
|                     | 100                 | 171 (21)                | 228 (21) | 270 (36) | 284 (35)  |  |
|                     | 200                 | 275 (17)                | 311 (14) | 360 (21) | 375 (26)  |  |
|                     | 300                 | 372 (27)                | 406 (20) | 438 (21) | 443 (16)  |  |
| 30                  | 25                  | 91 (27)                 | 166 (51) | 200 (48) | 215 (46)  |  |
|                     | 100                 | 192 (23)                | 271 (35) | 304 (62) | 307 (75)  |  |
|                     | 200                 | 291 (21)                | 345 (38) | 395 (44) | 396 (52)  |  |
|                     | 300                 | 367 (24)                | 417 (37) | 453 (55) | 447 (63)  |  |
| 60                  | 25                  | 96 (27)                 | 156 (50) | 154 (65) | 169 (65)  |  |
|                     | 100                 | 180 (28)                | 253 (45) | 282 (64) | 292 (75)  |  |
|                     | 200                 | 277 (28)                | 322 (51) | 371 (67) | 377 (82)  |  |
|                     | 300                 | 364 (35)                | 395 (58) | 433 (78) | 437 (87)  |  |
| 90                  | 25                  | 81 (26)                 | 144 (50) | 147 (49) | 147 (59)  |  |
|                     | 100                 | 166 (33)                | 220 (54) | 259 (68) | 251 (82)  |  |
|                     | 200                 | 259 (32)                | 299 (57) | 328 (83) | 343 (97)  |  |
|                     | 300                 | 337 (44)                | 365 (83) | 397 (97) | 400 (109) |  |

<sup>a</sup> Standard deviation in parentheses.



Fig. 5. Contour plot illustrating how variations in initial tension and stiffness affected the graft tension at 225 N of anterior force and 30° of flexion.

94 N/mm best restored the A/P load-displacement behavior of the reconstructed knee to that of the intact knee, and (3) the graft tension at 225 N of anterior force increased with both increasing initial tension and increasing stiffness. The importance and interpretation of each of these findings will be discussed in turn.

# Importance and interpretation

The large posterior subluxation of the tibia with respect to the femur (i.e. 5 mm, Table 2) caused by the high initial tensions when the knee was not otherwise loaded externally is undesirable. Posterior subluxation abnormally loads the posterior structures of the knee (e.g. PCL) and decreases the moment arm of the patellar tendon hence increasing the force that must be developed by the quadriceps to produce knee extension [9]. Increasing the force developed by the quadriceps in turn increases the compression across the joint and could promote more rapid degeneration of the articular cartilage.

Posterior subluxation in the unloaded knee was minimized but not eliminated with the lowest initial tension of 25 N used in these experiments. The presence of posterior subluxation in the unloaded knee with 25 N of initial tension applied at 0° of flexion was an unexpected finding. In the intact ACL, the pattern of tension exhibits a sharp rise as the joint is moved passively from 10° of flexion into full extension so that the ligament tension is 67 N on average for specimens at 0° of flexion [28]. Based on this finding in conjunction with the finding that double-loop hamstring tendon grafts reconstructed using the surgical procedures described herein exhibit a similar tension pattern to that of the intact ACL as the knee is passively extended [43] it was expected that 25 N of initial tension at full extension would result in no subluxation. While the 0 N posterior limit was overconstrained by less than 1 mm on average at 0°, the 0 N posterior limit became increasingly overconstrained as the flexion angle increased. This occurred because the graft tension decreased only to about 15 N on average as the knee was passively flexed from 0° to 30° and this tension increased slightly thereafter. However the tension in the intact ACL nearly vanishes at 30° and increases only to about 10 N on average at 60° and 90° [28]. The higher tension in the graft than that in the intact ACL at flexion angles other than 0° would explain the posterior subluxation observed in the present study when the difference in the 0 N posterior limit was averaged over all flexion angles (Table 2). Considering that this posterior subluxation was caused by a small amount of initial tension, which decreased further as the knee was flexed, this subluxation probably would not be detrimental to the function of the knee.

The insensitivity of the 0 N posterior limit to stiffness was expected based on the definition of this limit. The 0 N posterior limit was determined by applying a 45 N posterior force and then unloading the specimen until a 0 N force was registered. With this procedure the resistance to the posterior force was provided by the PCL rather than either the ACL or graft so that the structural properties of the ligament or graft should not have affected the 0 N posterior limit of motion. Thus the procedure used to determine the 0 N posterior limit provided a useful reference position that was unaffected by the structural properties of the graft-fixation complex.

Unlike the 0 N posterior limit, the anterior laxity was affected by both initial tension and stiffness. Thus the initial tension needed to restore the anterior laxity to that of the intact knee depends on the stiffness of fixation. As evident from Table 3, an initial tension of 25 N restored the anterior laxity closest to normal for stiffness greater than or equal to 94 N/mm. In contrast, an increased initial tension of 200 N restored the anterior laxity closest to normal for a fixation stiffness of 25 N/mm.

Because the anterior laxity represents only the amount of movement of the tibia with respect to the femur between the 0 N posterior limit and the 225 N anterior limit, both the 0 N posterior limit and the anterior laxity must be considered together in evaluating how well a combination of initial tension and fixation stiffness restore the normal A/P load-displacement behavior of the knee. For example, while an initial tension of 200 N restored the anterior laxity closest to normal for a stiffness of 25 N/mm, this amount of initial tension caused a corresponding posterior subluxation of more than 4 mm when the knee was not loaded externally (Table 2). Thus while it may be possible to match the anterior laxity with a low stiffness fixation and properly adjusted amount of initial tension, the A/P load-displacement behavior of the knee was not restored to normal because of the posterior subluxation caused by the high initial tension.

Although increases in both initial tension and stiffness increased the graft tension (Table 4), the increase in graft tension was more sensitive to increases in initial tension than stiffness. Thus beyond causing a large posterior subluxation of the tibia with respect to the femur, an additional adverse effect of the relatively high initial tension necessary to restore normal anterior laxity for low fixation stiffness is increased graft tension. For example the graft tension for the 200 N–25 N/mm initial tension–stiffness combination was 107 N greater than the tension for the 25 N–202 N/mm combination.

Establishing the clinical relevance of our cadaveric study should be done with caution because of the many factors both intraoperatively and postoperatively that can affect both the maintenance of initial tension in the graft and the stiffness of fixation. Considering first the initial tension, intraoperative factors include the graft type, preconditioning of the graft [39], the method by which initial tension is applied (i.e. manual pull versus reaction load on the tibia) [42], and the type of fixation. Postoperative factors include the rehabilitation program [39] and remodeling of the graft in the in vivo environment [5].

As a consequence of these various factors being combined differently in previous in vivo studies in both humans and animals, it is not surprising that results from these studies have been conflicting. One group of studies has reported that the initial tension does not affect A–P laxity [10,37,42,46] and graft mechanical properties [10,37,46]. In contrast, another group of studies has reported that the initial tension does affect A–P laxity [45], and graft mechanical properties [23].

Considering the stiffness of fixation, the primary intraoperative factor affecting this stiffness is the fixation method (Table I) and the primary postoperative factor is healing of the graft in the bone tunnels. Once the graft has been biologically incorporated into the bone tunnels, the stiffness of fixation may either increase or decrease depending on the fixation device [36].

Because the final values of both the initial tension and fixation stiffness in the in vivo environment depend on the factors affecting these values, the potential clinical relevance of our cadaveric study should be discussed depending on whether the initial tension and fixation stiffness are either maintained or not maintained following anterior cruciate ligament reconstructive surgery. If the initial tension and the stiffness of fixation are maintained, then one clinical benefit of using lower initial tension in conjunction with high fixation stiffness might be that the kinematics of the knee are better restored and that remodeling of the graft is improved. High graft tension may cause both abnormal kinematics of the knee and also impaired remodeling of the graft. Abnormal knee kinematics include an overconstrained 225 N anterior limit of motion, posterior subluxation of the tibia [2,14,30], and inhibited knee extension [2]. Impairments to the graft include excessive graft wear at the femoral tunnel margin [19], and poor revavascularization, myxoid degeneration, and inferior mechanical properties [23,46].

If the initial tension and fixation stiffness are maintained, then another clinical benefit of using lower initial tension in conjunction with high fixation stiffness is that lengthening of the graft construct in the region of fixation might be reduced during the early healing phase. Lengthening in the region of the fixation increases as graft tension increases for a wide range of fixation devices [15,24,40], and may be greater when aggressive rehabilitation is used to recondition the knee. Therefore, the use of lower initial tension together with high fixation stiffness might limit graft lengthening in the region of the fixation, which would prevent increases in anterior laxity and hence better restore stability in the reconstructed knee following aggressive rehabilitation.

If the initial tension is not maintained but the fixation stiffness is maintained, then a clinical benefit of using high fixation stiffness might be that laxity is better restored to normal for low graft tension. For the lowest initial tension of 25 N applied in this study, the average anterior laxity was  $\pm 1.7$  mm for 25 N/mm, 0.1 mm for 94 N/mm, -0.8 mm for 202 N/mm, and -1.0 mm for 326 N/mm. Thus a substantial increase in laxity could be expected for the lowest stiffness fixation but either no increase in laxity or a slightly overconstrained knee could be expected for the higher stiffness fixations.

Note that the preceding paragraph does not imply that laxity cannot be restored to normal with the use of low stiffness fixation methods. For example, if the initial tension is not maintained but the stiffness achieved intraoperatively with a low stiffness fixation method (e. g. sutures tied to a post and Endo Button, Table 1) increases substantially postoperatively after the graft biologically incorporates in the bone tunnels, then it is still possible for laxity to be restored to normal.

## Methodological issues

One issue concerning the design of our study was that the range of initial tension needed to be established. Ideally this range would have included lower and upper limits such that the values of initial tension necessary to restore anterior laxity to normal could be determined for the corresponding stiffness of fixation. While this ideal was satisfied for stiffness of fixation of 94 N/mm or less, the anterior laxity was overconstrained for higher stiffness of fixation. Nevertheless, the limits of the initial tension provided a match in anterior laxity to within 1 mm of that of the intact knee throughout the range of stiffness encompassing commercially available fixation methods (Table 1). A 1-mm match is within the 2–3 mm difference in anterior laxity between left and right pairs of intact knees [11,32].

Another issue concerning the design of our study was to simulate the stiffness of fixation using a coil spring rather than use an actual fixation method. In our study, using a coil spring to simulate the stiffness of fixation instead of using actual fixation methods allowed us to isolate the effects of the stiffness as an independent variable for study. In addition to providing stiffness, actual fixation methods also allow varying degrees of slippage [15,24,40]. Accordingly, using actual fixation methods would have confounded the design of our study because any change in the load-deflection behavior could have been caused by either slippage or the stiffness of fixation.

In connecting the graft to the coil spring used to simulate the stiffness of fixation, the graft was passed through a low-friction TEFLON bushing in the tibia (Fig. 2). A TEFLON bushing was used to minimize the difference between the extra-articular graft tension which was measured and the intraarticular graft tension [17]. When the graft exited the tibial tunnel so that the graft wrapped on the edge of the bushing, the worst case difference was 4% relative to the intraarticular graft tension. When the graft exited the tibial tunnel so that the graft did not wrap on the edge of the bushing, the difference was 0%. Thus the difference due to tunnel friction ranged from 0% to 4%.

The use of the low-friction bushing could have caused both the 0 N posterior limit and the 225 N anterior limit to be overestimated. Both limits could have been overestimated if the initial tension transmitted to the graft for the 0 N posterior limit and the tension transmitted to the spring for the 225 N anterior limit were both greater with the bushing than the tensions without the bushing. However a pilot study which compared the limits of motion both with and without the bushing for various stiffness values indicated no systematic differences. Accordingly the use of the bushing did not substantively affect the limits of motion measured herein. The method of femoral fixation was sufficiently rigid so that it did not affect the 225 N limit of motion and hence the anterior laxity. The femoral fixation had to be rigid relative to the combined stiffness of the graft (highest measured stiffness of 460 N/mm) and stiffest spring (326 N/mm) so that the fixation would not deflect under the application of the 225 N anterior force. We calculated a conservative bending and shear stiffness of the rod used as the femoral fixation of 87,000 N/mm. We also calculated a conservative estimate of the stiffness of the support of the rod by bone of 16,000 N/mm. With these two conservative estimates, the total deflection of the femoral fixation was less than 0.02 mm for the highest measured graft tension of 450 N, which is negligible.

Deflection of the tibia due to bending was not an important source of error in this study. Any deflection due to bending was minimal because the tibia was rigidly clamped to the steel plate and because the tibia was reinforced along the diaphysis by the steel intramedullary rod. Using a cantilever beam model in which the area moment of inertia of the tibia resisting A/P bending matched that previously reported [31], the deflection of the reinforced tibia under the 225 N load applied in this study was limited to 0.3 mm or 3% of the average anterior laxity. Moreover any deflection that may have occurred was largely systematic. Because as differences in displacements were of interest in this study, systematic deflection of the tibia was eliminated in the difference calculation and hence did not affect the laxity results.

The method used to set the initial tension developed a reaction load on the tibia which caused compression of the tibia against the femur and posterior translation of the tibia. Methods for setting initial tension can be considered in two different categories, those that produce a reaction on the tibia and those that do not produce a reaction on the tibia. For example pulling manually on the free ends of the graft while standing on the floor produces a reaction on the floor and not the tibia. In our experimental set up however, the method used to apply the initial tension developed a corresponding reaction on the tibia. If the initial tension was not reacted by the tibia, then the initial tension would affect the load–displacement behavior of the knee differently.

Methods of applying initial tension that develop reaction loads on the tibia similar to the method used herein are common in clinical practice. One example in clinical practice is the use of tibial fixations such as either the single screw and washer or double screw and washer which require that the tendon be wrapped around the screw 180°. Accordingly when initial tension is applied to the free ends of the graft, a reaction load on the tibia will develop. Another example in clinical practice is leaving the two tendons fixed to the tibia distally when harvesting hamstrings tendons as autografts. Accordingly when initial tension is applied to the two free ends, a pulley effect can take place around the femoral fixation device so that the initial tension carried by the two free ends is transmitted to the two ends that remain attached to the tibia. Final examples are the various devices manufactured and marketed commercially for the express purpose of creating a reaction load on the tibia from the application of initial tension. Devices include the Intrafix (Mitek, Norwood, MA), the Graft Tensioner (Arthrotek, Warsaw, IN), and the Tension Isometer (MEDmetric, San Diego, CA).

In summary, this investigation found that graft initial tension significantly affected the 0 N posterior limit, the anterior laxity, and the graft tension. In contrast, the fixation stiffness significantly affected only the anterior laxity and graft tension. The relatively high initial tension necessary to restore anterior laxity to normal with low fixation stiffness caused a substantial posterior subluxation of the tibia with respect to the femur in the unloaded state (4.1 mm) and relatively high graft tension in the loaded state (275 N). In contrast, both the posterior subluxation of the tibia and graft tension in the loaded state were reduced (to 1.6 mm and 168 N respectively for 202 N/mm) with high stiffness fixation because the initial tension required to restore anterior laxity to normal was reduced by about 200 N.

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