The Evolgate: A Method to Improve the Pullout Strength of Interference Screws in Tibial Fixation of Anterior Cruciate Ligament Reconstruction With Doubled Gracilis and Semitendinosus Tendons

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Purpose: The goal of the study was to investigate the biomechanical properties of a new device for tibial fixation in arthroscopic anterior cruciate ligament reconstruction using doubled semitendinosus and gracilis tendons. **Type of Study:** Biomechanical study. **Methods:** This study compares the initial pullout strength, stiffness, and failure modes of 7 pairs of 4-strand human semitendinosus and gracilis grafts fixed to porcine tibias using either the Evolgate (Citieffe, Bologna, Italy) or 1 round threaded titanium interference screw. Structural tests of the graft fixation method tibia complexes were performed using a materials testing machine (MTS Bionix 855, Minneapolis, MN) at a strain rate of 50 mm/second. **Results:** The mean failure load was 1,237 $\pm$ 191 N for the Evolgate and 537 $\pm$ 65 N for the interference screw ($P < .05$) and the mean stiffness was 168 $\pm$ 37 N/m for the Evolgate and 105 $\pm$ 17 N/m for the interference screws ($P \leq .05$). Although in all the cases fixed with the Evolgate failure occurred because of tendon rupture inside the tibial tunnel close to the fixation device, in 4 of the 7 cases fixed with interference screws, failure occurred because of tendon slippage at the fixation site. **Conclusions:** These results indicate that initial pullout strength of hamstring tendon graft interference screw fixation can be significantly increased using the Evolgate. In fact, because the screws purchase only in the cancellous bone, the Evolgate reinforces the walls of the tibial tunnel with a titanium involute, avoiding the loss of fixation strength related to the low density of the cancellous bone of the proximal metaphysis of the tibia. **Key Words:** ACL—Biomechanics—Knee—Semitendinosus—Tendons.

To the best of our knowledge, it was Galeazzi[1] in 1934 who was the first to describe a technique of anterior cruciate ligament (ACL) reconstruction using the semitendinosus tendon. He proposed detachment of the semitendinosus tendon from its muscolotendinous junction and intra-articular ACL reconstruction without bone tunnels with fixation to the fascia lata in an over-the-top position, leaving the distal insertion of the tendon on the pes anserinus intact. Since that first description,[1] ACL reconstruction with semitendinosus and gracilis tendons has became very popular in the past decade, because laboratory studies have shown that a combined 4-strand hamstring graft, tensioned and correctly secured, is stronger and stiffer than a 10-mm patellar tendon graft. However, at the time of reconstruction, the weakest points in an ACL construct are its points of fixation, especially on the tibial side. Methods for hamstring graft fixation to bone should be strong enough to avoid failure, stiff enough to restore load-displacement response, and secure enough to resist slippage under cyclic loading during

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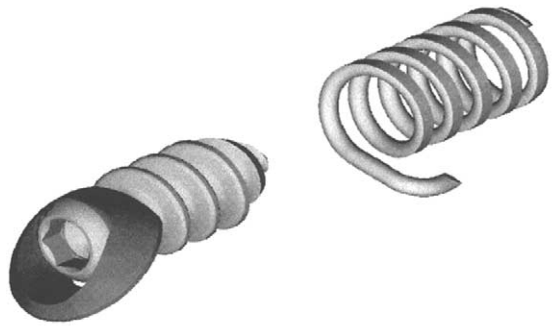

FIGURE 1. The 3 components of the Evolgate.

the first 1 to 2 months, before the conversion from mechanical to biologic fixation.

The purpose of this article is to describe a new method for tibial fixation of doubled gracilis and semitendinosus tendon (DGST) graft that can be used with any femoral fixation device. Another goal is to present the results of a biomechanical test conducted on human tendons and porcine tibias, in comparison with the interference screws, a commonly used method for tibial fixation of DGST.

METHODS

The Evolgate

The Evolgate (Citieffe, Bologna, Italy) is composed of 3 components, all made from a titanium alloy: an involute (a spiral 21 mm in length and 10 mm in diameter) with a spike positioned at one extremity, a screw 9 × 20 mm, and a washer (Fig 1). Before the tendons are pulled through the tibial tunnel, the spiral is inserted into the tibial tunnel with a special impactor (also acting as extractor should a revision be necessary) that also provides penetration of the spike in the predrilled tibial cortex. After the tendons are pulled through the bone tunnels and secured at the femoral side, the 4 ends of the tendons coming from the tibial side are properly tensioned. The screw and the washer are then inserted interfering with the tendons and the spiral, until the washer leans against the tibial cortex. The spike prevents rotation of the spiral as the screw tightens (Fig 2).

Biomechanical Tests

The Evolgate was tested to failure using fresh frozen human tendons obtained from cadavers (mean age at death, 58 years; range, 30 to 74 years). Failure was defined as the peak reached by the force-displacement curve as shown by the testing machine.

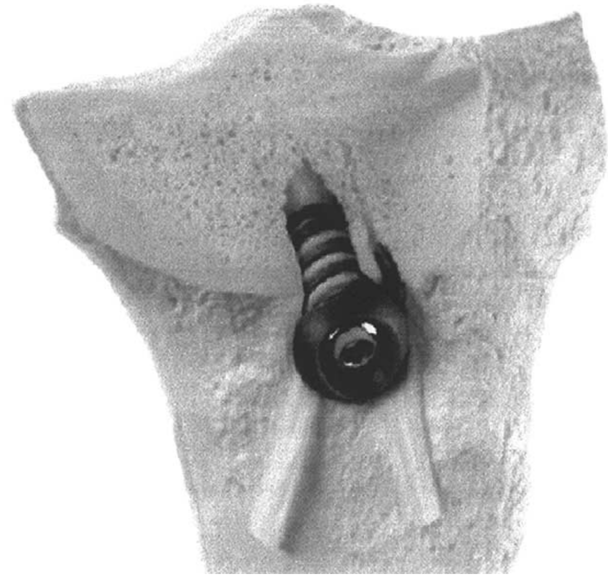

FIGURE 2. The Evolgate as it appears when assembled.

Semitendinosus and gracilis tendon grafts were harvested in an open fashion from each cadaver knee and prepared following a standard surgical protocol until the graft passed through a 9-mm diameter cylinder. A No. 1 suture was used to sew 4 cm of both ends of each tendon using a criss-cross stitch. Porcine tibias were used in this study because they are readily available, inexpensive, and have been used in previous similar studies (Fig 3).[2-4]

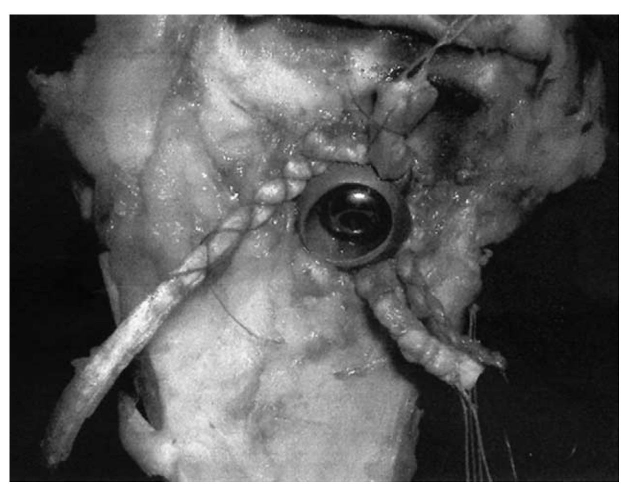

FIGURE 3. The tendons and the cortical grip of the Evolgate.

TABLE 1. *Pullout Strength and Stiffness of Paired Human Tendons*

			Pullout Strength (N) and Mode of Failure		Stiffness (N/mm)	
Specimen	Sex	Age (yr)	Evolgate	Int Screw	Evolgate	Int Screw
1	F	65	1,205R	458 S	227	106
2	M	30	1,504R	596 S	155	76
3	F	50	1,245R	580R	125	132
4	F	35	875R	611R	131	108
5	M	47	1,200R	560 S	160	106
6	M	70	1,287R	462R	180	110
7	F	65	1,343R	491 S	200	98
		Mean, 58	Mean, 1,237; SD, 191	Mean, 537; SD, 65	Mean, 168; SD, 37	Mean, 105; SD, 17

Abbreviations: R, rupture of the tendons; S, slippage of the tendons; Int, interference.

Seven porcine tibias were prepared by removing all soft tissues and by drilling a tibial tunnel that was 9 mm in diameter and 45 mm in length, using a commercially available tibial guide for ACL reconstruction.

Structural test of the graft fixation method tibia complexes were administered using a materials testing machine (MTS Bionix 855, Minneapolis, MN) at a strain rate of 50 mm/second. The tibia, securely fixed in a metal cylinder, was attached to the base of the testing machine using a custom-designed fixture that allowed the tibial tunnel and graft to be loaded in alignment with the motion axis of the actuator. The tendons were wrapped around a rigid bar attached to the upper portion of the materials testing machine, pulled through the tibial tunnel, properly tensioned, and fixed to the tibia using a 9 × 25 mm round threaded interference screw (Arthrex, Naples, FL). The distance from the bar to the articular surface of the tibia was kept at 5 cm to replicate the length of the intra-articular portion of the graft (3 cm) and the section within the femoral tunnel. After the tendons were preloaded for 5 minutes at 100 N, a load to failure test was performed to determine the stiffness and the pullout strength of the graft fixation method tibia complex. Mode of failure was also recorded for each test.

The distal portion of the tibial tunnel (2 cm in length) was then enlarged to a diameter of 10 mm to perform the same test on the paired contralateral grafts fixed to the tibia using the Evolgate. The same tibia was used in each paired test to avoid having the comparison be invalidated by a difference in bone density between specimens. In each paired test, the interference screw was always tested first and the evolgate second. Results were statistically evaluated using a paired Student *t* test.

RESULTS

The mean failure load was 1,237 ± 191 N for the Evolgate and 537 ± 65 N for the interference screw ($P < .05$), and the mean stiffness was 168 ± 37 N/m for the Evolgate and 105 ± 17 N/m for the interference screws ($P \leq .05$). In all cases fixed with the Evolgate, failure occurred because of tendon rupture inside the tibial tunnel just proximal to the fixation device. In 4 of the 7 cases fixed with interference screws, failure occurred because of tendon slippage at the fixation site, and in the other 3 cases, failure occurred because of gross tendon damage followed by graft slippage. Results are shown in Table 1.

DISCUSSION

Secure graft fixation is important to the success of ACL reconstruction. The goal of graft fixation is to prevent stretching or failure at graft fixation sites, allowing early motion and weight bearing without loss of stability. Any fixation method with poor biomechanical properties has the potential to compromise the clinical outcome, especially if an accelerated rehabilitation protocol is used in the early postoperative period. Assuming that during daily activities and accelerated rehabilitation, the loads in the ACL should be about 20% of the failure capacity, assuming that a fixation method should be as stiff as the normal ACL and function to loads of at least 500 N, if a reconstructed knee is to be intensively rehabilitated, is reasonable.[5,6] Very few tibial fixation devices have been biomechanically proven to be stiff and strong enough to resist loads produced in the graft before definitive, biologic fixation.[7] The Evolgate discussed in this study was previously tested using bovine tendons with promising results for both strength and stiffness.[8]

In this study, the Evolgate was compared, using human tendons, with a very popular method for tibial fixation in ACL reconstruction with DGST, the interference screw, resulting in a significantly higher strength and stiffness. Moreover, none of the tests performed using the Evolgate resulted in a pullout strength of less than 500 N (minimum, 875 N). Conversely, in 3 of 7 tests performed with interference screws, the pullout strength was less than 500 N. The same bone and tunnel with paired tendons were used for each paired test to avoid any difference in bone tunnel positioning and length and in bone density between specimens. The interference screw was always tested first, and the evolgate was always tested second to avoid any disturbance in the test performed with the interference screw. Using a new bone and tunnel could eventually further increase the pullout strength of the Evolgate.

Researchers previously showed that increasing screw length[9] improves fixation strength more than oversizing the screw diameter. In our study, we used a screw of 25 mm in length and 9 mm in diameter to obtain an acceptable performance from the interference screw fixation method. That method was used as a control. Moreover, the 2 tested methods provide fixation of the tendons approximately at the same level inside the tibial tunnel.

At this time, some surgeons are sizing the bone tunnels in relationship to the graft diameter for interference screw fixation. We used a standardized protocol to better compare the 2 fixation devices. Screws of different diameters in relationship to the graft diameter could also be used for the Evolgate device, possibly increasing the pullout strength.

The level of the fixation inside the tunnel might influence the stiffness of the graft. In our study, although the point of fixation level was slightly more proximal in the interference screw group, the stiffness was significantly greater in the Evolgate group. As with the interference screw, the Evolgate provides a nearly anatomic graft fixation close to the original ACL insertion site (aperture fixation). This is preferable compared with devices that fix the tendons outside the tibial tunnel (suspended fixation). By fixing the tendons deeply in the tibial tunnel, a secure fixation can be obtained even in cases in which the tendons (especially the gracilis) are short or are accidentally cut during stripping.

However, although the Evolgate provides graft fixation as deeply in the tibial tunnel as interference screws, it is not completely recessed inside the tunnel because of the washer lying on the tibial cortex. Therefore, it should be considered a low prominent rather than a low profile fixation device.

The mean age of the specimen could be considered a limitation of this study, as could the use of porcine tibias. The mean age of the specimens was 58 years (range, 30 to 74 years). This is clearly not representative of the young, active population frequently treated for ACL injury. In particular, the strength of the tendons in the specimens used in the current study was probably lower than the tendon strength in patients undergoing ACL reconstruction. Because only 3 failures in the interference screw group were caused by tendon ruptures and 4 by tendon slippage, the age of specimens probably did not severely affect the prediction of failure strength in the interference screw group. However, because all the specimens in the Evolgate group failed because of a tendon rupture, tests in younger specimens would probably have yielded higher values for the strength of the Evolgate device. The device may prove to be even stronger when tested in samples more representative of the population undergoing ACL reconstruction (Table 1).

Although the mean failure of the tendons fixed with the Evolgate device in porcine bone is 1,237 N, this is slightly more than half the strength of the normal ACL measured in young specimens[10] and significantly less than the measured strength of a quadrupled hamstring tendon.[11] This result could suggest that the hamstring tendon graft has been weakened by the Evolgate, which may be an issue in the clinical situation. However, we should note that, as in the tests performed with interference screws, failure occurred because of rupture or slippage of the tendons at a low pullout strength. Similar damage or weakening also could be induced by the interference screw, resulting in a reduced strength of the tendons. Moreover, the failure of both devices, because of rupture or slippage of the tendons, occurred in all cases deeply inside the tibial tunnel, where the tendons enter the device. Therefore, the possible weak point is deeply recessed inside the tibial tunnel and should be incorporated by the bone ingrowth with no further stresses after conversion from mechanical to biologic fixation.

Porcine tibias were used because research has shown that the average density of porcine bone is similar to that of young human bone and significantly higher than that of elderly human cadaveric bone specimens.[4] However, caution should be used in extrapolating the results of our study to clinical estimates because we cannot assume that the structural properties of fixation devices determined in animal tissue and laboratory studies predict its performance in human knees. Interference screw fixation, for example, performed significantly worse in human tissue compared with animal tissue, probably because the interference screw purchases only in cancellous bone, which could vary in density between tissue sources.[2,12] A metal spiral inside the tibial tunnel should reinforce the walls of the tunnel, avoiding the loss of fixation strength related to the low density of the cancellous bone of the proximal epiphysis of the human tibia. The pullout strength of the Evolgate could be further increased by the washer, which provides a cortical support to the screw. During the period of planning of the Evolgate, several tests were performed with the coil only and with the coil and washer. Although the coil and screw provide about 75% of the total pullout strength of the Evolgate, the washer contributed further to about 25%. The washer alone without coil does not significantly improve the strength of the interference screw.

Although further studies are needed to investigate other mechanical properties of this new device, such as resistance to slippage and failure load under cyclic loading, the results of this preliminary test are encouraging. However, before clinical studies can be recommended, live animal studies should be performed evaluating the effect of the Evolgate on bone ingrowth into the tibial tunnel, because the initial fixation strength does not necessarily correlate with ultimate tissue ingrowth and pullout strength.

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