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Pretensioning of anterior tibialis tendons and fan-folded iliotibial bands

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Abstract

Introduction and Background: **There are an estimated 200,000 anterior cruciate ligament (ACL) ruptures yearly in the USA. Pretensioning allografts prior to anterior cruciate ligament reconstruction in order to minimize graft laxity is a common, but controversial practice.**

The goal of this study is to determine if pretensioning anterior tibialis (ATs) and fan-folded iliotibial bands (FITBs) alters their creep and stress relaxation properties.

Materials and Methods: **One of each matched pair of allografts was pretensioned under a load of 67 N (15 lbs) for 15 minutes. Each group (pretensioned and non-pretensioned) was then mounted in the tensile grips of the MTS machine. Creep was performed by loading in load control to 67 N for 30 seconds to mimic the load applied by the surgeon at the time of graft fixation onto the patient's tibia. Stress relaxation testing was then performed to mimic the behavior of the graft early post-implantation. The grafts were cyclically extended (+1.5 mm) for 10 minutes at 1 Hz.**

Results: **We observed that pretensioned FITBs crept more than their non-pretensioned counterparts (3.5 mm additional creep, p =0.02). The increase in creep observed after pretensioning was not significant for the ATs. Pretensioned and non-pretensioned allografts, either ATs or FITBs, did not exhibit any significant difference during the stress relaxation test, which was designed to mimic the post-implantation graft behavior.**

Discussion and Conclusions: **Under these study parameters, pretensioning of ATs and FITBs appeared to have no obvious mechanical advantage, thereby questioning the utility of the clinical practice. Additional research will be needed to refine these findings as well as to understand the molecular basis for the observed graft behavior after pretensioning.**

Keywords: Anterior tibialis tendon, Iliotibial band, Allograft, Biomechanical testing, ACL repair, Sport medicine.

Introduction

There are an estimated 200,000 anterior cruciate ligament (ACL) ruptures yearly in the USA[1]. Bone-patellar-tendon bone (BPTB) and hamstring autografts have become the dominant graft choices for ACL reconstruction, while anterior tibialis tendons (ATs) are also being increasingly used. Despite their favorable biomechanical properties[2,3], iliotibial band (ITB) allografts have been infrequently used since the early 1990s[4]. A recent study found no clinical difference between BPTB and ITB groups at 15 year follow-up for primary ACL reconstruction, which supports the use of ITBs[4]. Our group also previously demonstrated that fan-folded iliotibial band (FITB) constitutes an allograft of choice for ACL reconstruction due to its biomechanical properties similar to those of other commonly used allografts such as tibialis and peroneus longus tendons[3]. Furthermore, we later found no significant difference in the viscoelastic properties of FITB and anterior tibialis (AT) allografts, while FITB allografts also demonstrated a higher propensity for *in vitro* cell attachment and repopulation over time[2].

The tensile properties of ligaments and tendons are viscoelastic, showing time-dependent and history-dependent behavior reflecting complex interactions of collagen, elastin, surrounding proteins and ground substances[5]. The viscoelasticity decreases the tension imposed during surgery until final equilibrium is reached, which may result in subsequent knee instability and implant failure[6]. Creep occurs when a constant load is applied to a viscoelastic material, causing an increase in material length over time. Stress relaxation occurs where a viscoelastic material is stretched and held at a constant length during which time the force required to hold the material at the set length decreases. As allograft tension has been shown to decrease over time due to its viscoelastic properties, pretensioning and preconditioning the graft have become common practices among surgeons to decrease the amount of postoperative creep and stress relaxation, therefore maintaining the initial tension necessary for clinical success[5,7-11]. Pretensioning usually refers to any loading of the graft before the graft is pulled into the femoral and tibial bone tunnels while preconditioning refers to the loading of the graft once it has been pulled to its proper place within the bone tunnels and one end of the graft has already been fixed. The tension applied to the graft at the time of fixation indeed plays an important role in joint kinematics; too little tension results in excessive laxity and joint instability, while excessive tension may restrain the joint motion and compromise graft integrity, eventually leading to permanent deformation, myxoid degeneration and poor vascularity[8,12-15]. While it has been demonstrated that graft tension at the time of fixation influences knee stability, the benefit of pretensioning allografts prior to ACL reconstruction remains a controversial issue with poorly understood mechanisms[15,16].

To the authors' knowledge, the effect of pretensioning on AT and FITB allografts has never been previously reported. We designed the present *ex vivo* study to mimic clinical practice and answer 2 questions: does pretensioning of anterior tibialis (ATs) and fan-folded iliotibial bands (FITBs) have an effect on 1) their creep and 2) stress relaxation properties?

Materials and Methods

Preparation of FITB and AT Allografts. All human tissues were recovered within the University of Miami Tissue Bank. Tissues were recovered from human cadaveric male and female donors with an average age of 42±19 years old. We purposely chose not to further restrict the donor age as we wanted our study to be representative of the age of donors commonly available at tissue banks in the USA. Matched pairs of allografts (2 ATs and 2 FITBs) were recovered from each donor in order to test pretensioned and non-pretensioned grafts originating from the same donor. Allografts were prepared as previously described[2,3] and a tendon sizer was used to select FITB and AT allografts with a diameter (in a single-loop configuration) of 9.5±0.5 mm. The grafts were recovered aseptically and no terminal sterilization was used in order to preserve the native properties of the tissues. A total number of 10 ATs and 10 FITBs were used in this study.

Experimental parameters. To define the test parameters, we performed a survey in the Miami area among four orthopaedic surgeons routinely performing ACL reconstruction. On average, we found that they pretension their grafts at 67 N (15 lbs) for approximately 15 minutes (step 1), during which they set up the arthroscopic instruments and prepare the patient's knee. Once they have anchored the graft in the femur, they manually pull on the graft while they range the knee for about 30 seconds before anchoring the tibial side (step 2). In order to estimate how much force is placed on the graft with this manual tensioning technique, we placed a simulated graft in a Sawbones® knee simulator (Sawbones, Vashon, WA, USA) and had each surgeon pull on the graft while ranging the knee for 30 seconds. The femoral side of the graft was held with a force transducer, which measured the tension on the graft during this maneuver. The average tension among the four surgeons tested was approximately 67 N as well.

Biomechanical testing. One of each matched pair graft was mounted in a graft pretensioning workstation (workstation base: AR-1950, soft tissue clamps: AR-1967F and tensioning device AR-4002 and AR-4003A, all from Arthrex, Naples, FL, USA). Pretensioning was performed by loading to 67 N for 15 minutes in order to simulate the time the graft is pretensioned in the operating room. Grafts were maintained wet by coverage with gauze soaked in saline solution. Matched grafts (pretensioned and non-pretensioned) were then prepared for testing on the MTS® MiniBionix II 858 appara-

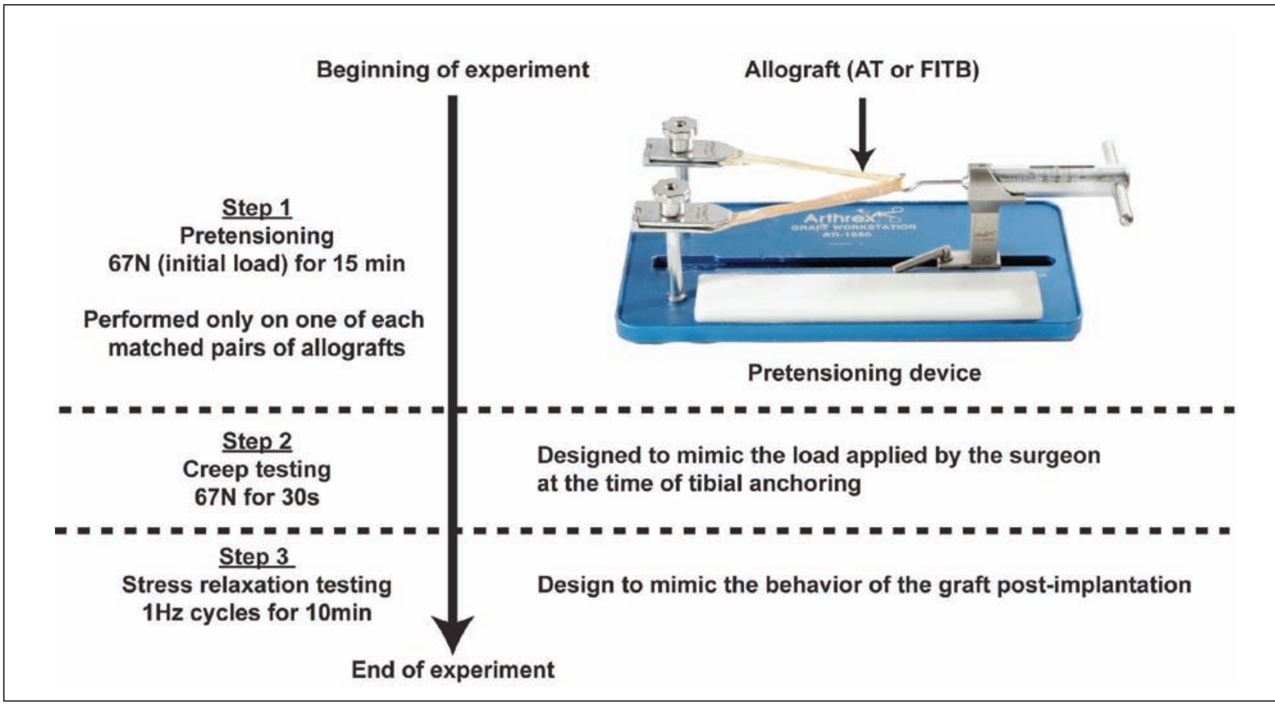

Figure 1. Experimental design. Step 1: one of each graft pair was mounted in an Arthrex® graft pretensioning workstation constituted of a graft workstation base (AR-1950), soft tissue clamps (AR-1967F) and tensioning device (AR-4002, all from Arthrex, Naples, FL). Pretensioning was performed by loading to 67 N for 15 minutes in order to simulate the time the graft is pretensioned in the operating room. Step 2: the pretensioned and non-pretensioned grafts were then submitted to a 67N load for 30s to mimic the load applied by the surgeon at the time of tibial anchoring. Step 3: the grafts were finally submitted to a stress relaxation testing for 10 minutes at a 1Hz frequency to mimic the behavior of the graft post-implantation. Abbreviations: ATs: anterior tibialis tendons; FITBs: fan-folded iliotibial bands.

tus (MTS, Eden Prairie, MN, USA). Grafts were positioned in a single-loop fashion and held in place with 2 soft tissue grips. Grips were not frozen due to the low forces applied. An active length of 6 cm was chosen to correspond to the distance from the femoral to tibial anchoring point immediately post-surgery. A creep test at constant distance was first conducted by loading the graft from 0N to 67N over 5 seconds, and holding that load for 30 seconds, to simulate the manual load placed on the graft by the surgeons prior to tibial fixation (step 2). Next, the MTS machine was shifted to stroke control, and the ram was placed at its position from the end of the creep test, Y_0. The MTS was programmed to cycle from Y_0 to a maximum peak of $Y_0 + 1.5$ mm at a frequency of 1 Hz for 10 min to simulate the behavior of the graft post-implantation (step 3). An elongation of 1.5mm was chosen since a 4.4% strain on the ACL is observed at the first physical therapy post-operative visit[17,18]. Since the ACL is 3.5 cm long on average, 4.4% of that length would be 1.5 mm of elongation. The experimental design and its 3 main steps are summarized in Figure 1.

Statistical analysis. Creep and stress relaxation data are presented as average values ± standard deviation. A total number of 10 ATs and 10 FITBs were used in this study. Significant differences between matched pairs of non-pretensioned and pretensioned allografts were calculated by use of a paired *t*-test on the end values obtained during creep and stress relaxation testing. Statistical significance was ascribed to a threshold *p* value of 0.05.

Results

The results of the creep testing (step 2), which was designed to mimic the load applied by the surgeon onto the graft at the time of tibial anchoring, demonstrated a tendency for the pretensioned grafts to creep more than their non-pretensioned counterparts (Figure 2). However, statistical analysis performed on the final value of the creep testing demonstrated that this increase in creep was significant only in the case of the pre-tensioned FITBs (p =0.02, Table 1), with an average creep increase from 5.0±2.9 mm to 8.5±4.0 mm, when comparing the non-pretensioned and pretensioned FITBs (Figure 2B).

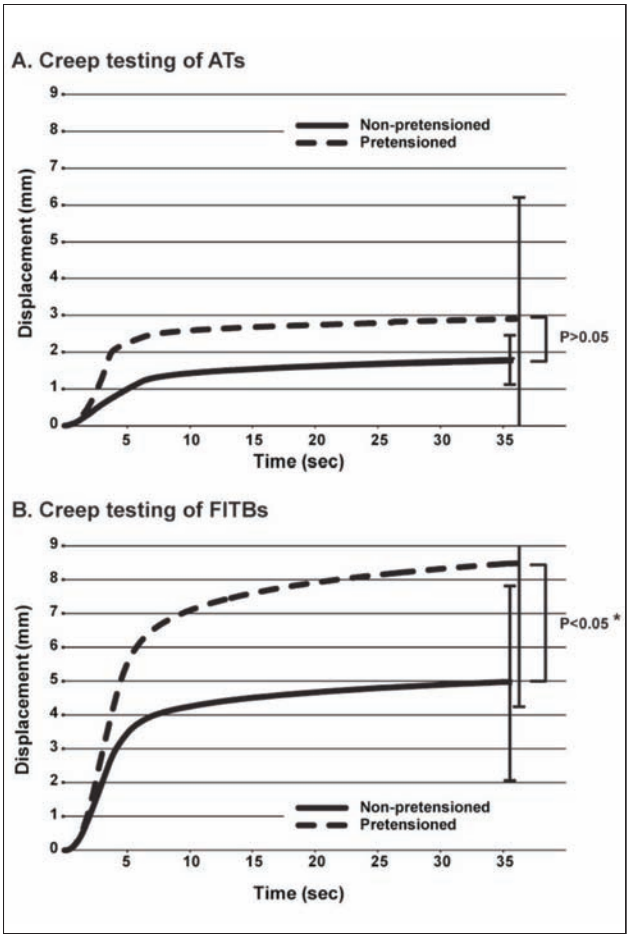

Figure 2. Pre-tensioning effects on creep testing. A creep testing was performed by applying a constant load of 67N to the grafts for 30s in order to mimic the load applied by the surgeon at the time of tibial anchoring. Pre-tensioning led to an increased creep of the allograft, which was significant only in the case of the FITBs: AT (A), FITB (B). The curves represent the average creep obtained from all the grafts tested, and only the standard deviation of the endpoint was depicted for the sake of clarity (please refer to Table 1 for the numerical values). Abbreviations: ATs: anterior tibialis tendons; FITBs: fan-folded iliotibial bands.

Indeed, ATs only slightly increased from 1.8±0.7 mm to 2.9±3.3 mm upon pretensioning (Table 1), which was not a statistically significant difference (p =0.61) (Figure 2A). We also noticed more variability in the creep behavior of pre-tensioned ATs compared to non-pretensioned (Figure 2A and Table 1).

The stress relaxation testing was designed to mimic the behavior of the graft early post-implantation. Pretensioned and non-pretensioned allografts, either ATs or FITBs, did not exhibit any significant difference during the stress relaxation test (Figure 3A and 3B). In the AT stress relaxation test, the mean force following relaxation was not significantly modified (p =0.55) with final values of 71.8±41.0N and 77.1±26.6N for the non-pretensioned and pretensioned ATs, respectively (Table 2). In the FITB stress relaxation test, we observed a non-significant (p =0.06) decrease in the mean force following relaxation, from 57.7±18.2N to 41.9±8.8N for the non-pretensioned and pretensioned FITBs, respectively (Table 2).

An important finding observed is that there was no significant difference in the creep (p =0.07) and stress relaxation (p =0.47) behavior of non-pre-tensioned ATs and FITBs, confirming our previously published findings[2].

Discussion

Pretensioning grafts prior to fixation remains a controversial issue in ACL reconstruction, and no consensus has been reached regarding its utility or the proper amount of pretension to apply. Our investigation sought to determine the effect of pretensioning on AT and FITB allografts creep and stress relaxation, which to our knowledge has never been investigated before.

Several studies described the positive effects of pretensioning allografts for ACL reconstruction. For example, Yasuda et al[19] compared the efficacy of

Table 1. Statistical analysis of creep behavior between non-pretensioned and pretensioned ATs and FITBs. This table depicts the endpoint numerical values of the average creeps presented in Figure 1. Pretensioned grafts tended to creep more than non-pretensioned graft, but this was significant only in the case of the FITBs. Abbreviations: ATs: anterior tibialis tendons; FITBs: fan-folded iliotibial bands.

	Creep testing (End of step 2)			
	ATs		FITBs	
	Non-pretensioned	Pretensioned	Non-pretensioned	Pretensioned
Average creep (mm)	1.8	2.9	5.0	8.5
Standard deviation	0.7	3.3	2.9	4.1
***p*-value**	0.61		*0.02	

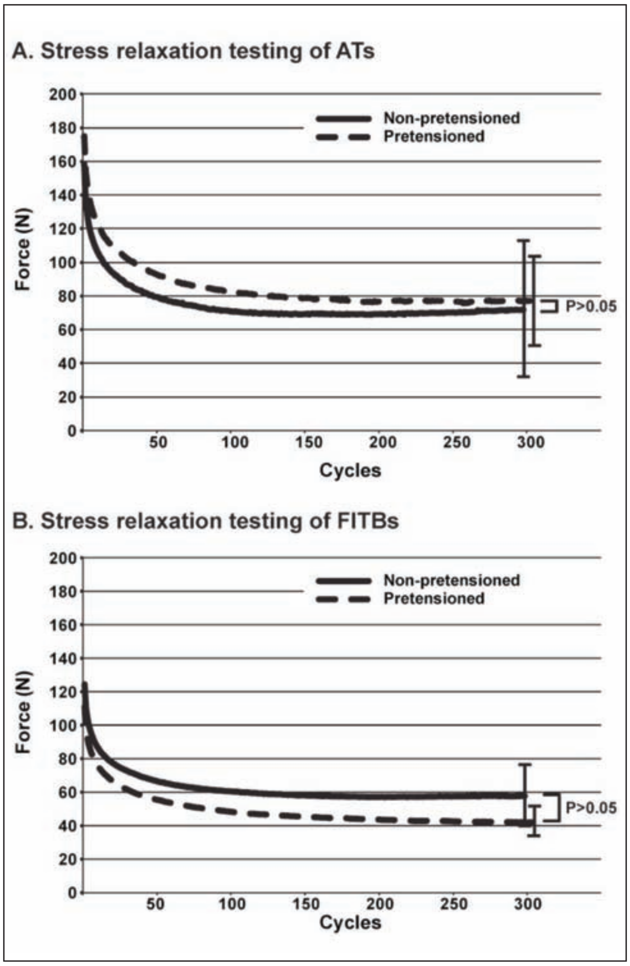

Figure 3. Pre-tensioning did not significantly affect stress relaxation behavior. A stress relaxation testing was performed following the creep testing in order to mimic the behavior of the graft post-implantation. Pre-tensioning had no significant effects on the stress relaxation behavior of neither the ATs (A) nor FITBs (B). The curves represent the average stress relaxation obtained from all the grafts tested, and only the standard deviation of the endpoint was depicted for the sake of clarity (please refer to Table 2 for the numerical values). Abbreviations: ATs: anterior tibialis tendons; FITBs: fan-folded iliotibial bands.

pretensioning grafts with 20 N, 40 N or 80 N of force, leading to the observation that a high pretensioning force (80 N) was beneficial and showed significantly less laxity post-fixation than those grafts that were subjected to 20 N of force. Nicholas et al[20] performed a similar investigation, comparing patients undergoing ACL reconstruction that were randomized to either high tension (90 N) or low tension (45 N) groups, with follow-up at 1 week and 20 months following surgery. They concluded that patients from the high tension group had significantly less anterior tibial displacement, whereas all occurrences of abnormal displacement were observed in the low tension group. Finally, Elias et al[21] demonstrated that grafts subjected to 160 N of force, as opposed to 80 N, were able to maintain significantly greater stiffness and tension after both 5 minutes and 3 hours of relaxation time.

In opposition to the results mentioned above, and more specifically in the case of ATs and FITBs, our results demonstrated a significant difference only in the creep behavior of non-pretensioned and pretensioned FITB grafts (step 2), a difference that was absent when examining stress-relaxation in the FITB (step 3) and altogether in the AT tests (step 2 & 3). We observed that pre-tensioned FITBs crept significantly more than non-pretensioned FITB during the step 2 of our protocol which was designed to mimic the load applied by the surgeon onto the graft at the time of tibial anchoring (see Figure 1). Further investigations will be required to understand the underlying mechanisms of this behavior, as the role of collagen fibers, elastin and other extracellular matrix molecules following pretensioning/preconditioning remains poorly understood[16]. More importantly, no significant difference was observed between pretensioned and non-

Table 2. Statistical analysis of stress relaxation between non-pretensioned and pretensioned ATs and FITBs. This table depicts the endpoint numerical values of the average stress relaxations presented in Figure 2. There was no significant differences between pretensioned and non-pretensioned grafts. Abbreviations: ATs: anterior tibialis tendons; FITBs: fan-folded iliotibial bands.

	Stress Relaxation testing (End of step 3)			
	ATs		FITBs	
	Non-pretensioned	Pretensioned	Non-pretensioned	Pretensioned
Average force following relaxation (N)	71.8	77.1	57.7	41.9
Standard deviation	41.0	26.6	18.2	8.8
***p*-value**	0.55		0.06	

pretensioned allografts, either ATs or FITBs, during the stress relaxation testing which was designed to mimic the behavior of the graft early post-implantation (step 3, see Figure 1).

This result goes along the line of other reports that shows limited to no benefit of pretensioning various type of allografts for ACL reconstruction. For example, Yoshiya et al[22] showed that at 3 and 6 months post-operatively, there was no difference between patellar tendon grafts in patients subjected to 25 N or 50 N of force, as both demonstrated similar laxity. In a similar study, Kampen et al[23] separated patients undergoing patellar tendon ACL reconstruction into 20 N and 40 N pretensioned groups, with follow up at 1 year post-surgery, could not show a significant difference between the groups in terms of Lysholm scores, Lachman tests, IKDC level and tibial position versus the femur. Additionally, Ciccone et al[24] demonstrated that at 15 minutes following a pretensioning protocol of 65 N of force, the grafts lost 50% and 80% of their tension and stiffness, respectively. In a goat study, it was shown that pretensioning to low (5 N) versus high (35 N) tension provided a biomechanical advantage in terms of A-P translation at time zero following surgery, but demonstrated no advantage when evaluating A-P translation, *in situ* forces, stress relaxation, stiffness, ultimate load at failure, ultimate elongation at failure, and energy absorption 6 weeks post-operatively[25]. Ejerhed et al[26] showed that pretensioning BPTB autografts produced no difference in clinical outcomes in terms of joint laxity or functional outcome at two-year follow up examination. Finally, Nurmi et al[11] found that clinical pretensioning protocols failed to eliminate tendon viscoelasticity, where more than 60% of initial tension was lost post-operatively due to the remaining intrinsic tendon creep.

It is important to note that the *ex vivo* nature of our study limits its immediate clinical implications, and we also cannot rule out that different testing parameters may have different outcomes. We however chose the testing parameters which best reflect the practice of the surgeons we interviewed. Our results also exhibit large variability, which was expected as we purposely chose to not restrict the donor age so as to reflect the reality of the donor variability available from tissue banks. ACL repair using either ATs or FITBs is currently being performed by our surgeon collaborators, and the long term clinical data to be gathered will be a necessary complement to this *ex vivo* study. Studying the role of pretensioning in a long-term clinical setting will therefore be the next logical step to undertake.

Conclusions

To conclude, under these study parameters, pretensioning of ATs and FITBs appeared to have no obvious mechanical advantage, thereby questioning the utility of the clinical practice. Although we cannot make definitive claims regarding whether a surgeon should or should not pretension allografts because of the *ex vivo* nature of this study, our results do call into question the utility of pretensioning the AT and FITB allografts during ACL reconstruction. With the increasingly high volume of ACL reconstructions, further *ex vivo* as well as clinical studies are needed to better elucidate this complex issue of graft pretensioning.

Disclosure

The author reports no conflicts of interest in this work.

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