

Influence of the Crosshead Rate on the Mechanical Properties of Fixation Systems of ACL Tendon Grafts

Oscar Martel,¹ Juan F. Cárdenes,¹ Gerardo Garcés,² and José A. Carta¹

¹Las Palmas University, Campus de Tafira Baja; ²Las Palmas University, Campus de San Cristóbal

Anterior cruciate ligament (ACL) reconstruction is one of the most important aspects of knee surgery. For this purpose, several fixation devices have been developed, although the interference screw is the most frequently used. The most typical biomechanical test of these devices consists of placing them in a testing machine and subjecting them to a pull-out test. However, insufficient attention has been paid to the influence of the displacement test rate on the mechanical properties of the fixation system. The aim of this study is to compare the influence of the crosshead rate in the biomechanical test of two different devices for the fixation of ACL tendon grafts. One hundred in vitro tests were performed using porcine tibiae and bovine tendons. The fixation devices used were (1) an interference screw and (2) a new expansion device. All ACL reconstructions were subjected to pull-out test to failure. Five crosshead rates were employed in a range from 30 mm/min to 4000 mm/min. Statistical analyses of the results show that, for the two devices, the rate has a significant effect on both maximum force and stiffness. Moreover, the new expansion device showed lesser dependency on the crosshead rate than the interference screw.

Keywords: anterior cruciate ligament, in vitro test, clinical biomechanics

Acute knee ligament injuries with pathologic motion are found at a rate of 0.6 per 1000 in the general population (Miyasaka et al., 1991), and of these, injury to the anterior cruciate ligament (ACL), is the most common. The normal method of ACL repair comprises reconstruction using a graft from the patient's own body, given its biocompatibility and lack of immunogenicity. The graft normally used is the bone-patellar tendon-bone or the hamstring tendon. ACL reconstruction basically involves drilling a tunnel into the tibia and femur and pushing the graft through in such a way that it reproduces the behavior of an intact ACL. Obviously, the graft has to be secured to the femoral and tibial tunnel for this reconstruction to carry out its function properly. For this purpose, several fixation devices have been developed, which have given rise to numerous studies designed to determine their mechanical properties. Basically, these biomechanical tests are performed in the following manner: the reconstruction is performed in the mode the researchers consider appropriate, and then the resulting fixation is placed in a testing machine and subjected to a pull-out test.

Direct comparison of the various fixation systems through the data obtained from the studies is normally very difficult (Camillieri et al., 2004). This is because each researcher uses different types of grafts and bones, from different sources (young human, old human, or different animals). Likewise, each researcher usually performs the fixation test following their own particular protocol. Thus, each author establishes the test speed, the diameter of the bone tunnel, the angle of traction with respect to the bone tunnel axis, the graft pretension, and the number of tests. Most of these parameters have been the subject of studies. However, after an analysis of the extensive bibliography available, the authors have concluded that insufficient attention has been paid to the influence of the test rate on the mechanical properties of the ACL reconstruction.

It has been stated that single cycle tests to failure relate to traumatic incidents, and therefore it is best to use a high rate of elongation (Beynon & Amis, 1998). However, an analysis of the references consulted reveals a wide range of rates used in the pull-out tests, although

Martel is with the Department of Mechanical Engineering, Las Palmas University, Campus de Tafira Baja, Las Palmas de Gran Canaria, Spain. Cárdenes is with the Department of Mechanical Engineering, Las Palmas University, Campus de Tafira Baja, Las Palmas de Gran Canaria, Spain. Garcés is with the Department of Medical and Surgical Science, Las Palmas University, Campus de San Cristóbal, Las Palmas de Gran Canaria, Spain. Carta is with the Department of Mechanical Engineering, Las Palmas University, Campus de Tafira Baja, Las Palmas de Gran Canaria, Spain.

none of the authors explains the reasons for choosing a particular test rate. The following figures corroborate the above assertion: 3000 mm/min (Ferretti et al., 2003), 1800 mm/min (Aune et al., 1998; Shapiro et al., 1995; Stadelmaier et al., 1999), 1524 mm/min (Shino & Pflaster, 2000), 600 mm/min (Dargel et al., 2006), 500 mm/min (Giurea et al., 1999; Rowden et al., 1997; Stapleton et al., 1999), 360 mm/min (Paschal et al., 1994), 250 mm/min (Harvey et al., 2003), 200 mm/min (Ahmad et al., 2004; Fabbriani et al., 2005), 150 mm/min (Lee et al., 2005), 120 mm/min (Espejo-Baena et al., 2006; Nagarkatti et al., 2001; Scheffler et al., 2002), 60 mm/min (Behfar et al., 2005; Brown et al., 2004; Camillieri et al., 2004; Honl et al., 2002; Steiner et al., 1994; Weiler et al., 2000), 50 mm/min (Hayes et al., 2005; Kousa et al., 2001; Kudo et al., 2005; Lee et al., 2003; Pena et al., 1996; Rupp et al., 1999), and 20 mm/min (Caborn et al., 1997; Caborn et al., 1998; Kocabey et al., 2004; Martel et al., 2007).

In the study presented in this article, two types of ACL reconstruction devices were tested at five different rates. The purpose was to determine, for both types of device, the influence of the crosshead rate on the mechanical properties of the ACL reconstruction. Using the variation graph of applied force versus displacement graph, the force for different displacement values was determined together with the stiffness of the ACL reconstruction.

The rate used in the tests is that known as the *cross-head rate*, which is usually expressed in mm/min or mm/s, and refers to the displacement speed of the testing machine crosshead. However, it should be pointed out

that some of the authors who have performed tensile tests to analyze the mechanical characteristics of tendons and ligaments have expressed the test rate as a percentage of the initial length of these tissues. This rate is known as the *strain rate* and the unit in which it is usually expressed is %/s. This way of expressing the test rate makes sense when tendon or ligament deformation is being measured in the test. However, its use is less justified when displacement that occurs during the test is due to deformation of the tissue and its slippage in the bone tunnel.

Methods

One hundred porcine tibiae were used together with an equal number of tendons from the extensor digitorum muscle of bovine front legs. The tissues were obtained from a local slaughterhouse. Bones and tendons were wrapped in gauze soaked in normal saline just before the killing of the animals and stored at -20°C until testing. The specimens to be tested were randomly divided into two groups of 50. The interference screw was used in one of the groups (Propel, 9 mm \times 30 mm, titanium alloy Ti-6Al-4V ELI, Linvatec, Largo, FL, USA) as the fixation system, while for the other group a new fixation system prototype was used based on radial expansion (Martel et al., 2007). This new prototype has been slightly modified with respect to that analyzed by Martel et al. (2007). The modification involves the generation of grooves on the wings (Figure 1), to increase the friction of the system.

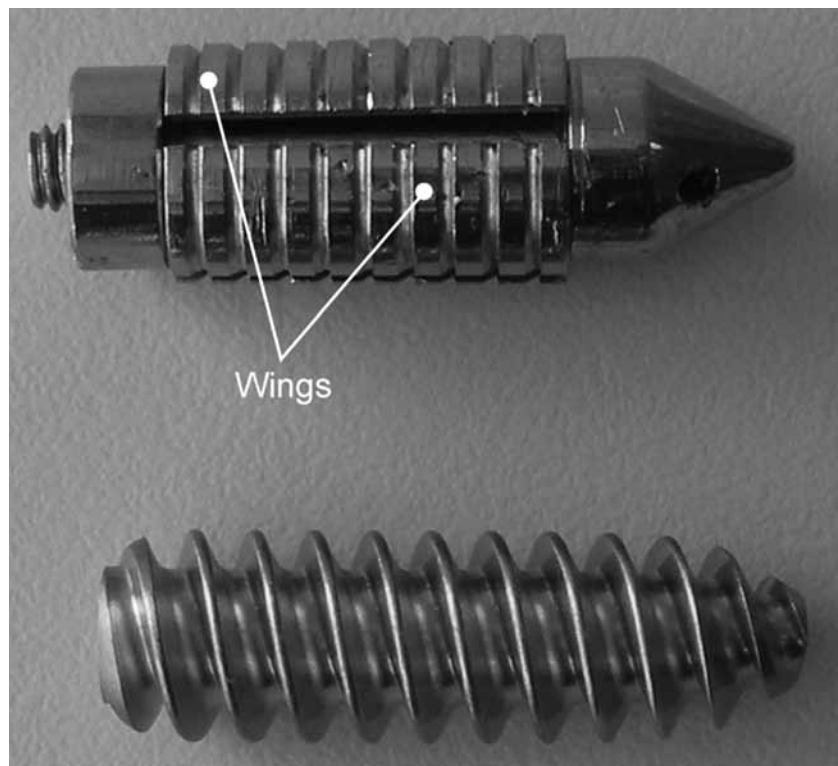


Figure 1 — Photograph of the two devices used in this study. Above: new device, Below: interference screw.

Twenty-four hours before pull-out testing, bones and tendons were thawed to room temperature. Bone tunnels were created following a 45° angle with its longitudinal axis, entering at one side of the tibial tuberosity and exiting at the upper part of the tibia, approximately at the natural insertion of the ACL. Tunnel diameter was chosen depending on the type of fixation system employed. For the interference screw, a 9-mm diameter was used, whereas a 10.5-mm diameter was employed for the radial expansion device. For each test, a tendon was taken and its ends sutured to make a bifascicular graft that was inserted into the bone tunnel with the

assistance of the sutures hanging from it. An interference screw or the new prototype was then inserted. The standard technique was used for the interference screw, and the procedure described in Martel et al., 2007, was used for the new prototype. A loop of tendon approximately 4 cm long was thus left extending out from the upper part of the tibia (Figure 2). This loop was used to hold the graft to a hook in the upper grip of the testing machine.

The grafts for each type of fixation system were divided into five groups ($n = 10$ per group) and subjected to a pull-out test until failure. The criterion for

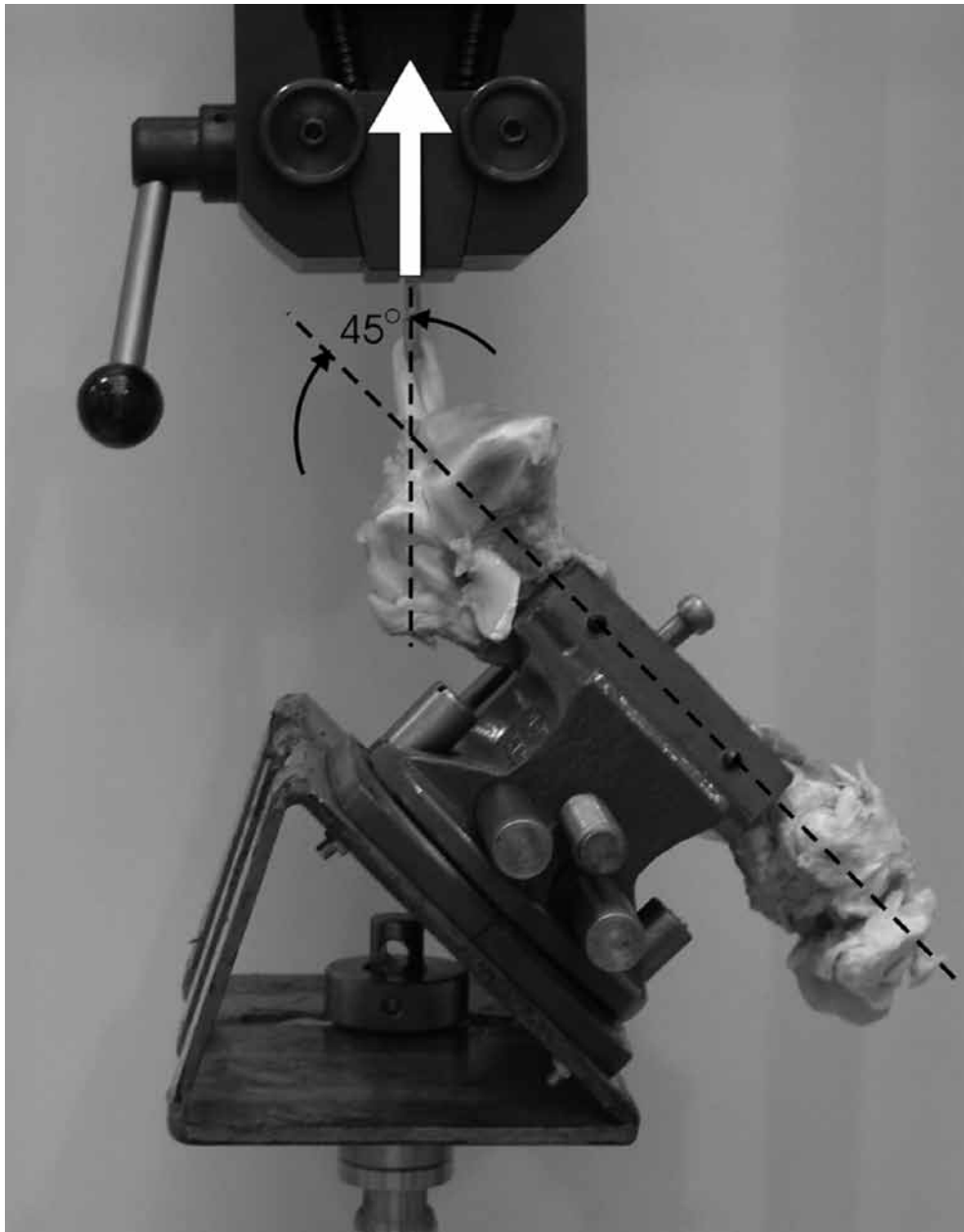


Figure 2 — Photograph of the tibia placed in the testing machine, where the loop of tendon can be seen in the upper part of the machine.

fixation failure was established as occurring when one or both tendon sections was fully extracted from the bone tunnel. Each group was tested at a different crosshead rate (30, 300, 600, 1200, and 4000 mm/min) in a materials testing machine (EFH/5/FR, Microtest S.A., Madrid, Spain). The bone was placed in the lower part of the machine and the graft in the upper part (Figure 2). A custom-made jaw was used to hold the tibia at an angle of 45° (Figure 2) to the vertical axis of the testing machine. This enabled pulling along the tunnel axis and represented a worst-case scenario for analyzing a fixation technique (Caborn et al., 1998). A small tension of 5 N was then applied to all constructs for 3 s to establish the zero value for displacements (Espejo-Baena et al., 2006).

Tests were performed at room temperature, and throughout the handling and test period the specimens were kept damp using a nebulizer with normal saline. For each test, a force versus displacement graph was generated with the software of the testing machine. The load at different displacement values, the maximum load, and the displacement at maximum load were obtained directly from the graph. Stiffness was calculated as the slope of the regression line for each test. This regression line was limited to displacement values from 0 mm to 6 mm because it was observed that this was the most linear part of the test graph. A different data acquisition frequency was used for each test rate, so that the graph for each test would have the same number of points. Thus, acquisition frequencies were used that varied linearly from 20 Hz for the test at 30 mm/min to 2660 Hz for the test at 4000 mm/min. Data were analyzed using statistical software (SPSS 14.0.1; SPSS Inc., Chicago, IL, USA). ANOVA tests were carried out for the mean comparison, and post hoc analysis was made with the Bonferroni test. Significance was accepted at $p < .05$.

Results

Tables 1 and 2 show the results obtained for each type of fixation system. From left to right, they indicate the crosshead rate values, maximum load, displacement for maximum force, force at 3 mm and at 6 mm of displacement, and stiffness. These values are tabulated for the five rates tested.

When a statistical comparison is made, it is observed that the crosshead rate significantly affects the value of almost all the parameters shown in Tables 1 and 2. The mean stiffness and standard deviation obtained with the tests that were carried out with the interference screw were 37.5 ± 15.6 N/mm and 111.9 ± 39.7 N/mm, when using the lowest rate (30 mm/min) and the highest rate (4000 mm/min), respectively. It can be concluded from the analysis of these results that the crosshead rate statistically affects the mean stiffness ($p < .001$). Furthermore, the rate of 30 mm/min is significantly different with respect to the mean stiffnesses of 600, 1200, and 4000 mm/min ($p = .016$, $p = .015$, and $p < .001$). Also as a result of the statistical analysis, it can be seen that the rate of 300 mm/min represents a significant difference in mean stiffness with respect to the rate of 4000 mm/min ($p < .001$).

In terms of the mean value of the maximum force, it is observed that the only significant difference is that between the rate of 30 mm/min and that of 4000 mm/min ($p = .042$). With the results for force at 3 mm of displacement, it is observed that the differences in means of 30 mm/min are significant with respect to 600, 1200, and 4000 mm/min ($p = .028$, $p < .001$, and $p < .001$); of 300 mm/min with respect to 1200 and 4000 mm/min ($p = .003$ and $p < .001$); and of 600 mm/min with respect to 4000 mm/min ($p = .002$). With the results of force at 6 mm of displacement, less statistical signifi-

Table 1 Results for the interference screw

Crosshead Rate (mm/min)	F_{\max} (N)	D_{\max} (mm)	Forces (N)		Stiffness (N/mm)
			D = 3 mm	D = 6 mm	
30	370 ± 153	17.9 ± 9.9	143 ± 41	215 ± 60	37.5 ± 15.6
300	473 ± 235	19.9 ± 13.0	166 ± 76	281 ± 156	46.1 ± 28.6
600	561 ± 187	11.7 ± 8.6	260 ± 63	442 ± 160	78.7 ± 21.4
1200	504 ± 212	22.4 ± 42.3	311 ± 89	437 ± 165	79.1 ± 26.1
4000	642 ± 215	6.1 ± 1.7	412 ± 120	538 ± 283	111.9 ± 39.7

Table 2 Results for the new fixation device

Crosshead Rate (mm/min)	F_{\max} (N)	D_{\max} (mm)	Forces (N)		Stiffness (N/mm)
			D = 3 mm	D = 6 mm	
30	428 ± 199	9.1 ± 6.3	202 ± 62	367 ± 164	63.9 ± 31.5
300	484 ± 271	7.4 ± 5.7	266 ± 63	368 ± 230	70.3 ± 22.8
600	520 ± 210	13.1 ± 13.7	274 ± 75	412 ± 153	74.3 ± 33.7
1200	669 ± 300	16.8 ± 28.8	321 ± 143	553 ± 264	98.1 ± 38.6
4000	847 ± 293	10.9 ± 7.6	486 ± 151	626 ± 258	105.0 ± 49.4

cance is observed, as only the difference between the rate of 4000 mm/min with respect to 30 and 300 mm/min is significant ($p = 0.002$). Figure 3 shows the means of the force–displacement graphs corresponding to the interference screw.

For the new fixation device, stiffness is found to be 63.9 ± 31.5 N/mm for the lowest rate and 105.0 ± 49.4 N/mm for the highest. When making an isolated comparison between these two means, a significant difference is obtained ($p = 0.04$). However, it is observed that the difference is not significant between the mean stiffnesses when a comparison is made between any other two values of the rate.

In terms of the maximum force, a significant statistical difference is obtained between the rate of 4000 mm/min and those of 30 and 300 mm/min ($p = 0.007$ and $p = 0.029$). With the results for force at 3 mm of

displacement, it is observed that the differences in means of 4000 mm/min are significant with respect to 30, 300, 600, and 1200 mm/min ($p < .001$, $p < .001$, $p < .001$, and $p = 0.012$). With the results of force at 6 mm of displacement, the behavior is similar to that obtained for stiffness. In other words, a significant difference of means is obtained between the rate of 30 mm/min and that of 4000 mm/min ($p = .015$), with no significant difference being obtained when comparing any other two rate values. Figure 4 shows the means of the force–displacement graphs corresponding to the new expansion device.

In terms of displacement at maximum force, no statistical significance was observed between the values of that displacement and the values of the crosshead rate. This is true both for the interference screw and the new radial expansion device.

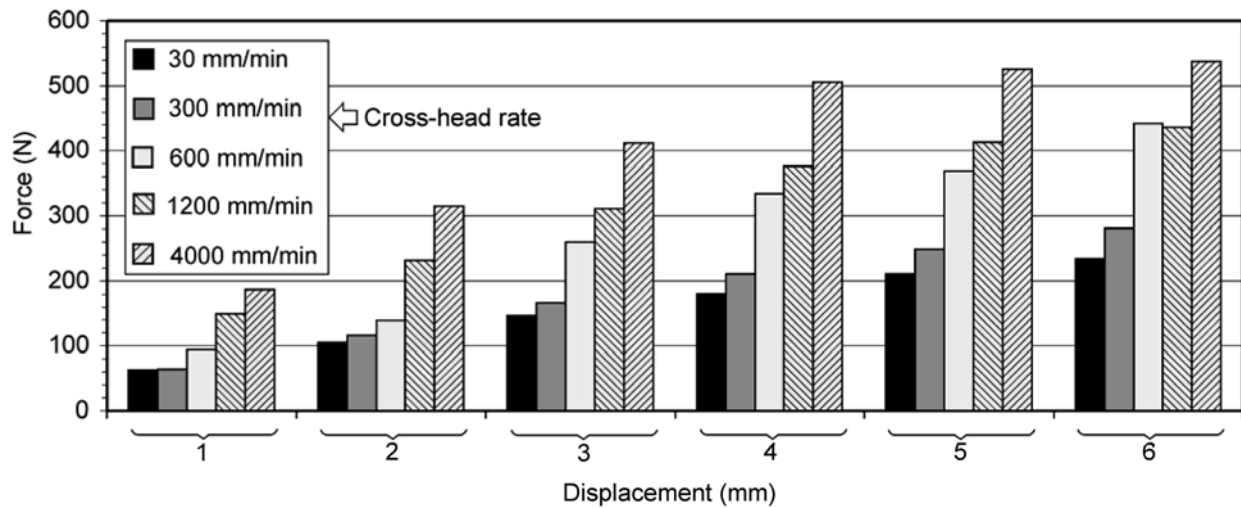


Figure 3 — Graphs of mean force versus displacement for the different test rates when using the interference screw.

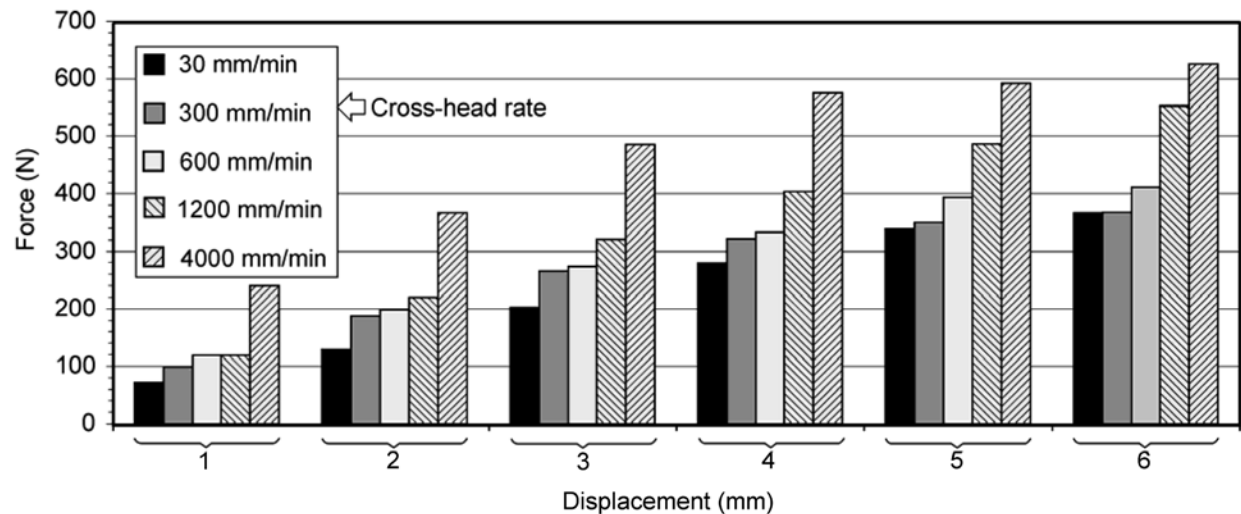


Figure 4 — Graphs of mean force versus displacement for the different test rates when using the new radial expansion device.

Discussion

From an analysis of the results of this article, it is concluded that the test rate significantly affects the stiffness and the maximum force obtained with the two ACL fixation systems analyzed. Therefore, when an ACL graft fixation system is tested, attention should be paid to this parameter. However, the stiffnesses of the fixations made with the interference screw are more affected by the test rate than those of the new radial expansion device. Interest in the study of stiffness in fixation systems lies in the fact that the objective pursued in ACL reconstruction is the functional recovery of the patient and, therefore, reduction of joint instability. With this in mind, the most important thing is to achieve adequate stiffness of the bone-fixation system-graft complex, more than a heightened maximum force (Ishibashi et al., 1997; To et al., 1999). In effect, the results for maximum force, in the view of the authors of this article, are not very significant because sometimes the displacements caused by such forces are relatively high, as shown in Tables 1 and 2. The magnitudes of these displacements can result in failure of the ACL reconstruction, when stabilization of the knee is not achieved. Therefore, so that knee joint laxity is not excessive, the stiffness calculation presented in this article has been limited to a maximum displacement of 6 mm. When analyzing the influence of the rate on the forces that generate displacement of 6 mm, the same behavior is obtained as with stiffness. In other words, the test rate has an influence on the magnitude of these forces. This influence was greater in the results obtained with the interference screw than in those obtained for the radial expansion device.

As a result of pull-out tests carried out previously (Martel et al., 2007) with both types of device at low rates (20 mm/min), the conclusion was reached of the superiority of the new radial expansion device in comparison with the interference screw. However, in the current study, no significant advantage is observed for either device when comparing the stiffness of one against the other. Though this might appear contradictory, in fact the two studies do coincide in that in the previous study a low rate was used (20 mm/min). Thus, if both devices are compared at the lowest rate used in this article (30 mm/min), a significantly better stiffness is obtained ($p = 0.029$) for the new device. It can therefore be concluded that, at a low rate, the stiffness of the new device is better than that of the interference screw, although the same conclusion cannot be made for the other rates tested.

In this article, the pull-out test has been used rather than the cyclic load test. The pull-out test measures the ability of the system to withstand sudden traumatic loads, but it does not represent the low repetitive loads that are expected in normal postoperative rehabilitation (Giurea et al., 1999). However, when a cyclic load test is used, it is not the test rate but rather the frequency (measured in Hz) that is indicated. As the cycles are given

between two load or displacement values, the testing machine adapts the rate to satisfy the requirements as indicated. This rate is variable due to the occurrence of slippage of the graft with respect to the bone. For this reason, in this study we have used the pull-out test, in which the rate is perfectly defined.

In the tests performed in this study, crosshead rates were used in the range between 30 and 4000 mm/min. This range comprises the rates used in tests of ACL fixation systems carried out by several authors. In terms of the real value of the strain rate in normal ACL activities, we have not found any information. As far as we know, the best approximation is one in which the strain is obtained for different commonly prescribed rehabilitation activities (Beynon & Fleming, 1998). In this study, strains are obtained that vary from 0.0% for some activities to 4.4% for isometric quads contraction at 15° (30 N·m of extension torque). However, no strain rate figures are given. If we suppose that the strain rate is constant during the performance of the exercise and that, for example, reaching the maximum strain takes 0.2 s, then the resulting strain rate will be 22%/s. As the anteromedial human ACL is approximately 33 mm long (Beynon & Amis, 1998), this strain rate will require a crosshead rate of 436 mm/min. In this way, it can be inferred that the rates tested in this study are within the range of strain rates of normal rehabilitation activities. However, if the aim is to study the strain rates that simulate what occurs during ligament injury, the rates must be much higher because Crowninshield and Pope (Crowninshield & Pope, 1976) estimate that these strain rates are between 50%/s and 150.000%/s (1000 m/min to $3e+6$ mm/min). Likewise, Woo and colleagues (Woo et al., 1990) stated that mechanical studies at high strain rates (more than 1.000%/s) were necessary to understand the mechanisms of high energy injuries such as those that occur during some sports activities and in automobile as well as industrial accidents.

In the bibliography related to ACL fixations analyzed by the authors of this article, no work has been found in which an analysis was carried out on the relation between the test rate and the mechanical properties of the reconstruction fixations of the ACL. In spite of this, results are available of studies that have analyzed the effects of test rates on the mechanical characteristics of tendons and ligaments. A high percentage of the authors who have performed such studies have concluded that there exists a clear relationship between the test rate and the mechanical properties of the tissues (Crowninshield & Pope, 1976; Woo et al., 1990; Noyes et al., 1974; Pioletti et al., 1999; Haut & Haut, 1997; France et al., 1987; Lydon et al., 1995; Danto & Woo, 1993; Haut, 1983; Neumann et al., 1994; Ng et al., 2004; Lynch et al., 2003; Peterson & Woo, 1986; Yamamoto & Hayashi, 1998). However, it should be pointed out that some researchers have reached conclusions that differ from those presented in the papers cited above. This group of authors does not detect significant differences in the mechanical properties of tendons and liga-

ments when subjected to tensile tests at different rates (Blevins et al., 1994; Kubo et al., 2002; Ker, 1981; Herrick et al., 1978; Wren et al., 2001).

From an analysis of the above-cited studies, it can be inferred that the load application rate does affect the mechanical properties of tendons and ligaments, but only when there is an appreciable difference between the high and low rate. Some studies appear to corroborate this. Wu (2006), testing the chicken flexor digitorum profundus, obtained that at low strain rates (<0.001%/s), no strain rate dependence was found and that at medium strain rates (0.003%/s to 0.1%/s), the elastic stiffness increased with increasing strain rate. Crisco and colleagues (Crisco et al., 2002) tested the medial collateral ligaments of rabbits at three rates (10.2, 38,400, and 150,000 mm/min) and observed a slight increase in stiffness and failure load between the low rate and high rates, although no significant differences could be appreciated between the high rates.

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