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Title

Can an expansion device be used in anterior cruciate ligament reconstruction? An in-vitro study of soft tissue graft tibial fixation

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Abstract

Background:

The purpose of this study was to compare the mechanical properties of an interference screw and an expansion device in anterior cruciate ligament (ACL) reconstruction.

Methods:

52 porcine tibia and 20 polyurethane foam blocks (0.16 g/cm3) have been used. 40 pull-out tests were carried out combining the two types of bones, surrogate and porcine, with the two fixation systems: interference screw and expansion device (n=10 per group). 32 cyclic tests (n=8 per group) were carried out with both fixation devices in porcine bone at two different force amplitudes (100 and 200 N)

Results:

Stiffness and load values at 6 mm of displacement were 74 ± 33 N/mm, 318 ± 135 N and 52 ± 28 N/mm, 205 ± 70 N, for the expansion device and the interference screw, respectively, showing difference in stiffness ($p = 0.016$) and in load at 6mm of displacement ($p = 0.001$). No correlation between insertion torque and the ultimate failure load was found, for both fixation devices tested. In cyclic tests, significantly higher number of cycles ($p < 0.001$) were reached with the expansion device (81,014 ± 30,291 at 100 N; 13,462 ± 11,351 at 200 N) than with the interference screw (15,100 ± 8,623 at 100 N; 343 ± 113 at 200 N) at 6 mm of displacement.

Conclusion:

The use of the expansion device for ACL reconstructions seems to be a promising alternative to an interference screw. Insertion torque alone is not a useful predictor of graft fixation strength in ACL reconstructions.

Keywords

Anterior cruciate ligament, biomechanical testing, ACL reconstruction, interference screw, expansion device

1. Introduction

In anterior cruciate ligament (ACL) reconstructions, the fixation of the graft to the bone tunnels, especially on the tibial side, is the weakest link of the reconstructions, at least during the initial period of rehabilitation [1,2].Thus several fixation devices have been developed and tested. One of the most commonly used devices in ACL reconstruction is the interference screw, either metallic or bioabsorbable [3-5]. However, some researchers have reported problems using this device due to graft laceration with the screw threads during introduction [6], or the lack of parallelism, named divergence, between the bone tunnel and the screw axis [7-9]. This divergence means that, even when the surgeon applies a high insertion torque whilst introducing the device, the quality of the fixation is very poor. To maintain the advantages of the interference screw and overcome its drawbacks, many researchers have designed fixation devices based on the concept of radial expansion, sometimes using a sheath device [10-12]. The divergence is caused because of the lack of available space when inserting the screw in the bone tunnel, already occupied by the graft. Therefore, the screw thread makes its own hole in the bone. When using an expansion device, because the device is gently tapped into the tunnel, no divergence is expected.

In essence, radial expansion devices are placed in the bone tunnel without an insertion torque or with a very low one, avoiding graft laceration and screw divergence. Once inside the bone tunnel, the surgeon expands the device generating compression forces that produce enough friction to resists the pull-out force. As indicated by Smith el al. [13] the greater this radial force, the higher the pullout strength of the ACL reconstruction. Therefore, the aim of this study was to compare the behaviour of one of these expansion devices [14-15] with the interference screw. The main advantage of the studied expansion device is that allows a final cylindrical shape, so the compression force along the graft is expected to be more uniform. Our hypothesis was that the behaviour of the two fixation systems was not statistically significant difference.

2. Materials and Methods

Fifty-two porcine tibiae and twenty artificial bone blocks were used. These were solid rigid polyurethane foam blocks (Sawbones, Pacific Research Laboratories, Inc.) of 10 lb/ft^3 (0.16 g/cm^3) laminated with a 3 mm solid rigid foam sheet of 40 lb/ft^3 (0.64 g/cm^3), simulating a cortical shell. Foam blocks were cut into a block of 42x40x40 mm which was considered sufficient to avoid edge effects. Bovine forelimbs extensor digitorum tendons were obtained from a local slaughterhouse and were wrapped in gauze soaked in normal saline just after the killing of the animals and stored at –20 °C until tested. Bovine tendons were used as a graft because they match the biomechanical properties of a human double looped semitendinosus and gracilis graft [16]. The porcine tibiae, after removing all muscles and soft tissues, followed the same handling and storage protocol.

Two ACL fixation systems were tested, an interference screw (Propel, 9 × 30 mm, Linvatec, Largo, FL, USA) and a new fixation system based on radial expansion [14-15]. We used a 9-mm interference screw because it was found to have a significantly higher failure load than a 7-mm diameter screw [17]. The main dimensions of the radial expansion device are 31.8 mm length and an unexpanded 9 mm diameter. Final diameter is 11.5 mm achieved after inserting the 3.8 mm diameter interior screw (Figure 1).

Twenty-four hours before pull-out testing, bones and tendons were thawed to room temperature. Throughout the handling and test period the specimens were kept damp using a nebulizer with normal saline and preparation and tests were carried out at room temperature. In the porcine bones, tunnels were created following a 45° angle with its longitudinal axis, entering at the lateral side of the tibial tuberosity and exiting from the upper part of the tibia, approximately at the natural insertion point of the ACL. In the artificial bone blocks, tunnels were made perpendicular to the laminated cortical shell, exiting from the opposite face. The tunnel diameter depended on the fixation system, 9 mm (C-Reamer, Conmed Linvatec, Largo, FL, USA) was used for the interference screw, as usually used, whereas 10.5 mm (Badger, Conmed Linvatec, Largo, FL, USA) was employed for the radial expansion device, because in previous tests it was found that this tunnel diameter gives the best performance. Tendons were classified by diameter (measured with a custom made tendon caliper), using the 6.5 mm tendon for the interference screw reconstructions and the 6.0 mm for the radial expansion device reconstructions. Tendons that were damaged due to cuts or lacerations were discarded.

For each test, a tendon was taken and its ends sutured to make a double-looped graft that was inserted into the tunnel with the assistance of the sutures. Approximately 4 cm of the tendon was left extending out from the upper part of the tibia or of the artificial bone block. The loop at this end of the tendon was used to hold the graft to a hook in the upper grip of the testing machine. The radial expansion device or interference screw was then inserted. The expansion device was gently tapped into the tunnel and the inner screw, which allows expansion, was inserted. The interference screw was inserted using a 3.5 mm Allen key. Maximum insertion torque during both fixation system insertion was recorded using a digital torque meter (DR-2453, Lorenz Messtechnik GmbH, Alfdorf, Germany) mounted on the Allen key.

Twenty pullout tests were carried out for each fixation method and two types of bone model (artificial and porcine) were used, resulting in n=10 for each subgroup. Each bone model-fixation system-graft complex was subjected to a pull-out test until failure at a rate of 30 mm/min on a materials testing machine (EFH/5/FR, Microtest S.A., Madrid, Spain). The artificial bone blocks were placed directly in the lower machine jaw, whereas for the tibia a custom made jaw was used to hold the tibiae at an angle of 45º to the vertical axis of the testing machine (Figure 2). In both cases the force was along the tunnel axis, representing the “worst-case” scenario for analyzing a fixation technique [18]. A small tension of 5N was applied to all constructs for 3 seconds to establish the zero value for displacement [19]. The test ended when the graft was pulled out of the bone (either artificial or porcine) and could not take any more loading. The load was recorded using the 5kN testing machine load cell (error ± 5N) and displacement was recorded using the testing machine LVDT (error ± 0.05 mm), so the cross-head displacement was obtained. Maximum load and displacement were recorded. A force versus displacement graph was created for each test and stiffness was calculated as the slope of the regression line for displacements of 0 mm to 6 mm.

Cyclic test were carried out in porcine bone for both the interference screw and the expansion device. The bones were placed in the same testing machine and in the same way as in the pull-out tests. Two different force amplitudes (100N and 200N) were used, resulting in four test groups (n=8 per group) from the combination of the two amplitudes with the two fixation systems. For each test an initial static load equal to half of the force amplitude was applied. Thereafter a cyclic load ranging from 5 N to the force amplitude value at a frequency of 1Hz was applied. In order to prevent tendon drying during cyclic tests, a drip with normal saline was used. Each test was considered complete when the graft exited more than 6 mm from the bone tunnel. Displacement versus time graphs were recorded at a 50 Hz sampling rate, and cycles reached at every mm of displacement were obtained.

We initially planned to study 20 samples for each type of fixation in pullout tests. Power calculations determined that, to detect a 20 N/mm difference in stiffness with a power of 0.8 and a significance level of P = .05, 18 samples were required for each group. The same number of samples was needed to detect a 75 N difference in load at 6 mm of displacement. By oversampling by an additional 2 samples in each group, we were accounting for the potential of 2 lost samples. A two-way ANOVA was used to compare the stiffness and load at 6 mm of displacement between the two fixation methods, including the tested specimen (porcine bone or artificial bone) as a factor.
In cyclic tests at 100 N, a power analysis for number of cycles reached at 6 mm of displacement showed that 7 samples per group would show a difference of 40,000 cycles with an 80% power. So we decided to perform 8 cyclic test per group, both for 100 and 200 N force levels. Comparisons between cycles achieved by each fixation method were made with an ANOVA, using displacement level as a covariate, both for the 100 N and 200 N force amplitude levels. Statistical significance was set at P = .05. The relationship between the insertion torque and maximum load was studied by linear regression obtaining the coefficient of determination (R^2). All statistical analyses were performed using IBM SPSS® Statistics v. 17.0.

3. Results

3.1 Pull-out tests

In all cases the failure mode was the tendon coming out of the bone tunnel. No instance of breakage of the tendon was observed. The coefficient of determination R^2 between insertion torque and the ultimate failure load showed no correlation between these two variables, both for the interference screw and the new expansion device (Table 1).The mean ultimate failure load ranged from 240 ± 58 N to 428 ± 199 N, but in all cases the mean displacement at ultimate failure load exceeded the 6 mm limit.

The stiffness obtained with the expansion device was 74 ± 33 N/mm (considering the two types of bone). This was significantly higher ($p = 0.016$) than that achieved with the interference screw (52 ± 28 N/mm). Similarly, 318 ± 135 N was the mean load at 6 mm of displacement with the expansion device, higher ($p = 0.001$) than the one achieved with the interference screw (205 ± 70 N). Two-way ANOVA analysis showed that no influence ($p = 0.057$) of the test specimen was found in the load at 6 mm of displacement. However, stiffness was higher ($p = 0.004$) in artificial bone than in porcine bone. Statistical interaction between test specimen and fixation system was not significant neither for stiffness ($p = 0.456$) nor for load at 6 mm of displacement ($p = 0.336$)

3.2 Cyclic tests

In the 100 N force amplitude tests (Figure 3), the expansion device reached 81,014 ± 30,291 cycles whilst the interference screw only reached 15,100 ± 8,623 before reaching the maximum slippage level (6 mm) showing a significant difference ($p <0.001$) between the two fixation methods. Similar results were obtained when using 200 N force amplitude, showing a significant difference ($p <0.001$) (Figure 4). At 6 mm slippage the expansion device reached 13,462 ± 11,351 cycles, whilst the interference screw reached only 343 ± 113 cycles.

4. Discussion

The main finding of the present in vitro study was that the expansion device showed higher biomechanical performance than the interference screw, both in pullout and cyclic tests. In a previous study [10], no difference in fixation properties between the interference screws and the combination screw and sheath devices was found. The combination screw and sheath devices analyzed in that study were the AperFix II, BIOSURE SYNC, ExoShape, GraftBolt and INTRAFIX. In all these combinations, the sheaths get deformed during screw insertion and that deformation allows the compression of the graft to the bony tunnel walls. In the expansion device studied in this paper no significant deformation of the parts of the device occurs. It's the parallel movement of the wings during the inner screw insertion what causes the graft compression. This parallel movement of the wings allows exertion of the same compression along all the graft-fixation device interface. On the contrary, the five combination screw and sheath devices previously studied gives a final conical shape of the sheath after insertion of the screw, so the graft does not have the same compression force all along the graft-fixation device interface. This is the main difference between the expansion device presented in this paper and the five systems previously studied, and we believe that this difference causes the improved performance.

In our study ultimate failure load was recorded, but the comparison between fixation methods was made using the load at 6 mm of displacement. This is because ultimate failure load can be reached at such a high slippage level that in a real clinical ACL reconstruction it would be considered as having failed. In this study we have obtained mean displacements at ultimate failure load that range from 7.6 mm to 17.3 mm. With these values is considered that reconstruction has already failed and therefore, these maximum values should be interpreted with caution, as they represent values that are not relevant to clinical cases. It should be noted that mean stiffness and ultimate load values of intact ACL in porcine knee are 441.5 N/mm and 1266 N, respectively [20] resulting in a mean maximum elongation of approximately 3 mm. Other authors have also limited the slippage values to 3 or 5 mm [21,22]. We chose the 6 mm limitation because we believe that the graft would completely lose its function with a greater slippage. The load obtained at 6 mm of displacement was significantly higher ($p = 0.001$) in the expansion device than in the interference screw, which indicates that the ACL reconstruction performed with the expansion device has the ability to withstand a traumatic insult better than the interference screw, because pullout tests determine the strength of the fixation to this kind of load [23].

The other parameter used to compare fixation methods was the stiffness. It must be pointed out that the goal of ACL reconstruction is to restore normal knee biomechanics and to achieve this it is more important to recreate the natural stiffness of the intact ACL than to reach a very high ultimate load [24,25]. In this study we have chosen a 6 mm slippage limit in stiffness determination because it was observed that this was the most linear part of the test graph and to be consistent with the considered failure load. The new expansion device reached a significantly ($p = 0.016$) higher stiffness (74 ± 33 N/mm) than the interference screw (52 ± 28 N/mm). These results were similar to others stiffness values published [21,26], but much lower than other stiffness values obtained by other authors [1,27]. We believe that this difference could be due to the way of measuring the displacement of the graft. In this study we measured the displacement of the cross-head, while other researchers measured the change of graft length directly using a digital image correlation system [28] or an inductive displacement sensor between the attachment points [27]. Using the cross-head displacement is considered the whole deformation (graft+fixation device, bone and connections), so the stiffness is lower. Despite this we consider that, as far that this is a comparative study and the test conditions are the same for both fixation methods, conclusions are valid.

Insertion torque has been proposed as a useful predictor of graft fixation strength with an interference screw [29] and some surgeons use insertion torque as a direct predictor of fixation strength [30]. However, other authors have stated that insertion torque does not provide a sufficiently accurate prediction of the fixation strength of an individual ACL graft [31]. In our study we found no correlation between insertion torque and maximum load, so our results support the thesis that the insertion torque is not a good indicator of fixation quality. We believe this may be due to the divergence of the screw, cuts of the grafts during screw insertion and/or the graft position around the screw when it is inserted. So we believe that insertion torque alone is not a reliable predictor of the ACL reconstruction quality.

Initially, it is obvious to suppose that human bone is the best material for the tests; however the use of human cadaveric specimens causes problems in availability, handling, preparation and preservation. Furthermore, the variability of cadaveric specimens is an additional problem, requiring large sample sizes to obtain a satisfactory significance and power of statistical comparisons [32]. Finally, the ACL reconstruction is normally carried out in young patients and the cadaveric specimens usually are of older donors, with poor bone quality. To avoid these issues, porcine knees have been used, however porcine bone still presents the problem of the inherent variability of living origin tissues. The solution to this may be the use of artificial bone, which possesses more uniform mechanical properties than animal or human bones, so we can concentrate on the influence of the fixation type. In addition, the artificial bone also means an uncontaminated and clean test environment that is not possible in cadaver testing. Thus, there is currently a pronounced trend towards the use of artificial bones when assessing the performance of fixation devices [13,33,34]. In this study, polyurethane foam blocks of 0.16 g/cm^3 laminated with a 3 mm solid rigid foam sheet of 0.64 g/cm^3, simulating a cortical shell, were used. This was because in previous tests we observed that this density mimics the porcine tibia mechanical behaviour better than the 0.32 g/cm^3 and 0.48 g/cm^3 polyurethane foam blocks. Our results showed that the artificial bone tested is an adequate substitute to porcine bone when evaluating the fixation method strength, because there was no significant difference ($p = 0.057$) in load at 6 mm of displacement between the test specimens. However, stiffness is overestimated ($p = 0.004$) in the artificial bone in comparison to porcine bone. So, we suggested not to use 0.16 g/cm^3 polyurethane foam blocks for ACL in vitro reconstruction tests.

In cyclic tests, the number of cycles achieved by the expansion device was significantly higher than for the interference screw in the two force amplitudes tested (100 N and 200 N). That suggests that the expansion device is better than the interference screw for the rehabilitation process as long as cyclic tests represent the repetitive application of low forces expected in the normal postoperative rehabilitation. However, it is important to consider that all these results represents device performance in an in vitro animal model and are not directly transferable to an in vivo clinical situation [10].

This study has another limitation, besides the displacement measurement as mentioned above. The complete comparison (pull-out and cyclic) between the two types of fixation has been performed on porcine bone because it is the standard used by many researchers [10,7,1]. But the use of porcine bone in mechanical tests of ACL graft fixation systems is another limitation of this study, since in comparison to young human cadaver tibia, porcine tibia underestimate graft slippage and overestimate the failure load of the soft tissue graft in ACL reconstructions [35]. Other authors [1] state that the structural properties of a fixation method may not be the same in animal and human tissue, and found that an interference screw fixation performed significantly worse in human tissue compared to animal tissue. However, since our purpose was to compare the two fixation systems, we believe like other authors [27], that the relative differences between them obtained here would be maintained for human specimens and therefore that the conclusions of this study are valid.

5. Conclusions

The use of the expansion device for ACL reconstructions seems to be a promising alternative to an interference screw, since stiffness and number of cycles is higher with the new expansion device than with the interference screw.

Insertion torque alone is not a useful predictor of graft fixation strength in ACL reconstructions.

Figure Captions

Figure 1. The two devices used in this study. Above: new radial expansion device. Below: interference screw**.**

Figure 2. Tibia specimen prepared for the test. The loop of tendon placed on the upper part is observed.

Figure 3. Slippage (mm) vs. number of cycles (logarithmic scale) in both interference screw and expansion device at 100 N force amplitude.

Figure 4. Slippage (mm) vs. number of cycles (logarithmic scale) in both interference screw and expansion device at 200N force amplitude

Tables

Table 1. Data recorded in pull-out tests.

Fixation system	**Test Specimen**	**Insertion torque (N-m)**	**Ultimate Failure Load (UTL)**	**R^2 (Insertion torque vs. UTL)**	**Displacement at UTL (mm)**	**Load at 6mm of displacemen**	**Stiffness (N/mm)**

			(N)			**t (N)**	
Interference	10/40	2.61 ± 0.34	240 ± 58	0.03	11.7 ± 10.9	189 ± 49	69 ± 28
Interference	Bone	2.39 ± 0.26	358 ± 151	0.24	17.3 ± 9.6	221 ± 86	35 ± 14
Interference	Both					205 ± 70	52 ± 28
Expansion	10/40	0.42 ± 0.13	304 ± 91	0.07	7.6 ± 4.9	270 ± 82	84 ± 33
Expansion	Bone	0.43 ± 0.24	428 ± 199	0.71	9.1 ± 6.3	367 ± 164	64 ± 32
Expansion	Both					318 ± 135	74 ± 33

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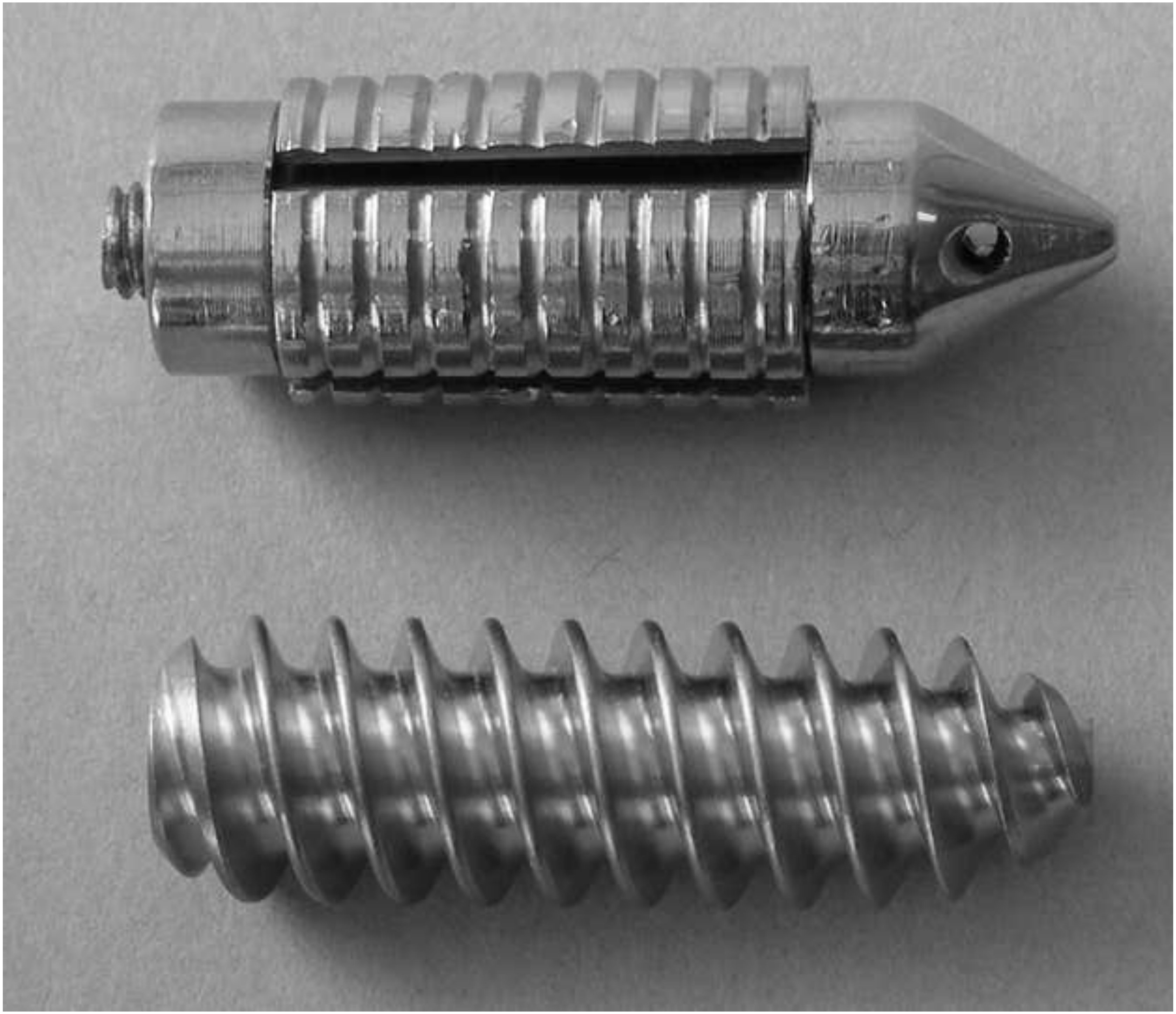

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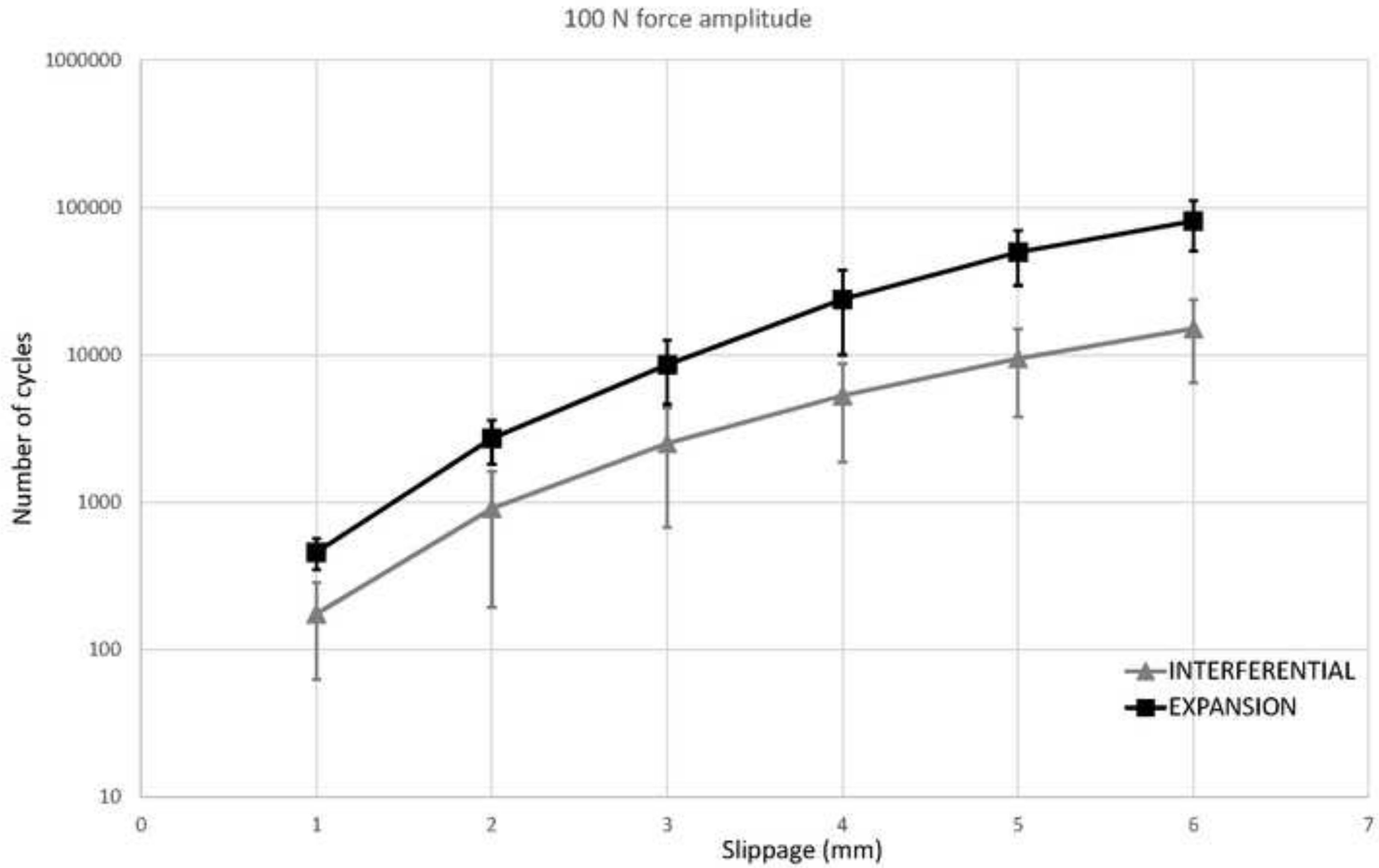

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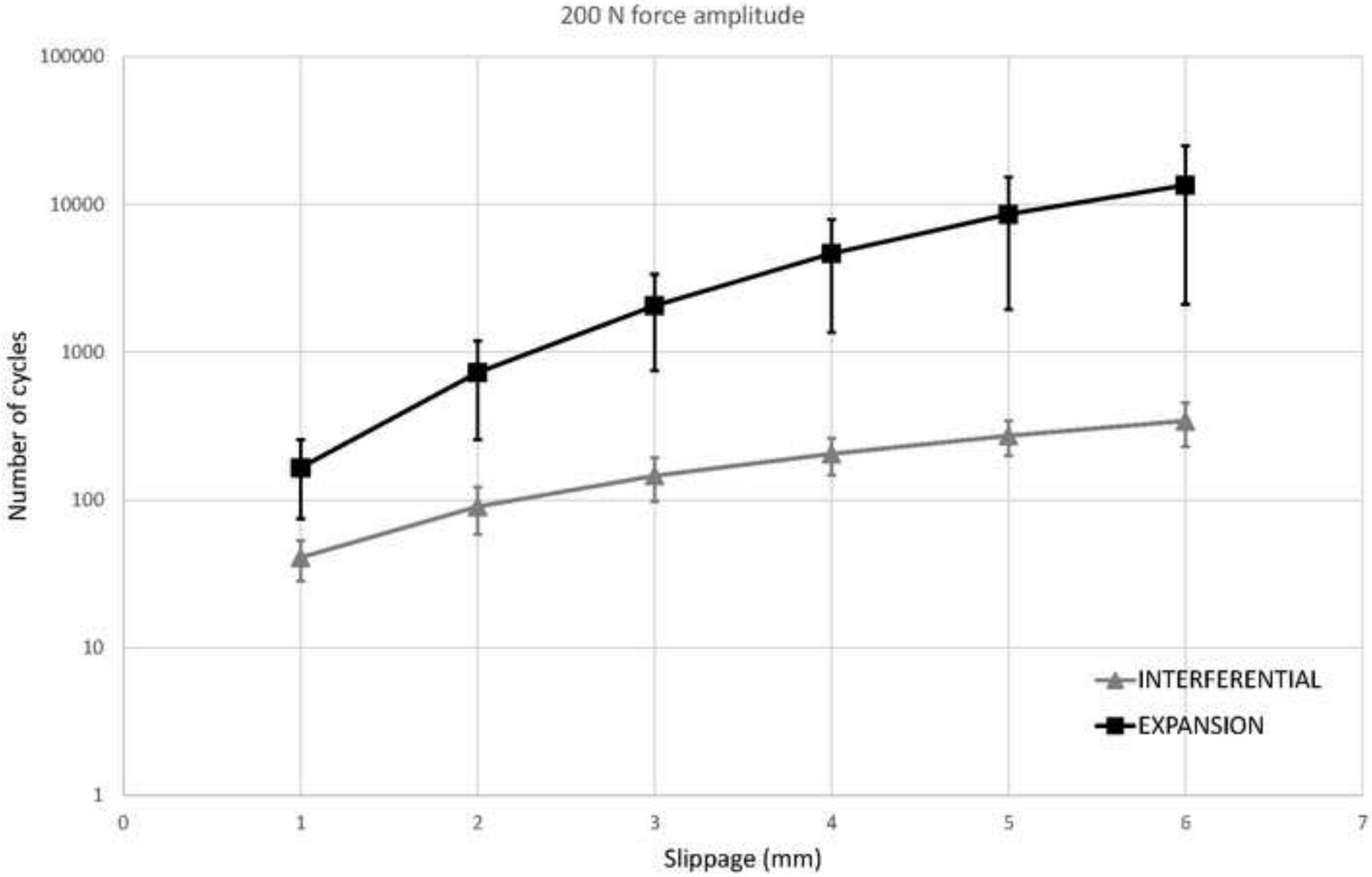

Figure Captions

Figure 1. The two devices used in this study.

Above: new radial expansion device. Below: interference screw.

Figure 2. Tibia specimen prepared for the test.

The loop of tendon placed on the upper part is observed.

Figure 3. Slippage (mm) vs. number of cycles (logarithmic scale) in both interference screw and expansion device at 100 N force amplitude.

Figure 4. Slippage (mm) vs. number of cycles (logarithmic scale) in both interference screw and expansion device at 200 N force amplitude.