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Technical note

A new device for the fixation of anterior cruciate ligament tendon grafts Design and experimental study

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Abstract

In this paper the design and experimental analysis is presented of a new fixation device of anterior cruciate ligament (ACL) grafts of the knee. This device is inserted into the bone tunnel, after the graft, in the same way as an interference screw. However, the fixation device described in this paper has been designed in such a way that, after the insertion of a threaded element in its interior, some of its components expand in a radial direction, pressing against the walls of the bone tunnel and thereby increasing the fixation of the graft. This expansion device can be used in both the femur and the tibia.

The device proposed in this paper was compared with an interference screw for load failure and fixation stiffness in experiments performed using porcine bones. The failure load was significantly higher in the new expansion device group (633 ± 202 N) than in the interference screw group (471 ± 179 N). The stiffness obtained when the new device was used (59 ± 20 N/mm) was also significantly higher than that obtained using the interference screw (37 ± 19 N/mm) (t-test, $P < 0.05$). According to these results, this new device could be considered a good alternative to improve fixation of anterior cruciate ligament grafts.

Keywords: Anterior cruciate ligament reconstruction; Interference screw; Implant design; Mechanical testing

1. Introduction

Anterior cruciate ligament (ACL) reconstruction is one of the most important aspects of knee surgery as the ACL is the most frequently torn ligament in this joint [1]. However, graft-bone fixation continues to be a major cause of concern, as shown by the large number of researchers involved in its study [2–15]. A number of devices have been designed with this end in mind, as the method of surgical fixation is the major factor influencing the graft's mechanical properties in the immediate postoperative period [2]. There are basically two types of fixation, anatomical and non-anatomical. The former are fully embedded in the bone tunnel made for the graft, while the latter extend out of the tunnel. However, there are problems associated with each of these two types, or the techniques associated with them. Non-anatomical fixations can result in pain and irritation, may require the removal of the hardware [3,4], and can produce bone tunnel enlargement with a consequent weakening of the fixation [16,17].

Among anatomical methods of fixation, the interference screw is the most popular. However, during insertion into the bone tunnel screw divergence may occur [5,6], resulting in a fixation of poor quality. The screw threads can also lacerate the graft [6,18]. In addition, the results for initial grip strength obtained by some researchers [7–9] have been lower than 450 N, impeding intensive rehabilitation of the knee [19,20]. For these reasons, Magen et al. [4] suggest that the ability of the interference screw to provide adequate fixation during intensive rehabilitation should be questioned. The cross pin, another important type of anatomical fixation, requires an

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additional transversal incision and can only be used for the femur.

This paper presents the design and experimental study of a new fixation device for anterior cruciate ligament (ACL) grafts of the knee. The device has been designed for tendon hamstring type grafts without bone insertions, due to the complications after harvesting the patellar tendon [7,8,12,18]. The device can be used for both tibial and femoral fixation and, like an interference screw, is introduced via the bone tunnels. The operating principle is the radial expansion of some of its components, resulting in greater compression between the graft and the bone tunnel. This compression generates frictional force which improves the bone-graft fixation, a property which has been used in ACL fixation devices proposed by other researchers [5,10,13].

2. Materials and methods

2.1. Description of the new fixation device

The new device designed for ACL graft fixation consists of various components (Fig. 1) which enable the expansion effect to take place. The central piece, the *base screw*, has longitudinal grooves which serve as a support for four *mobile wings*. These wings have a semi-circular exterior part which enters into contact with the bone and graft, and a circular interior part (attachment blade) which serves to ensure that the wings do not escape in a radial direction from the base screw. The *cap* is inserted into the upper end of the base screw, which facilitates the insertion of the device and prevents the wings from escaping in an axial direction. The cap has a hole to pass a suture through which helps to insert the device in the bone tunnel. The expansion of the wings (Fig. 2) takes place on inserting the *interior screw*, which only screws onto the lower part of the base screw. The new device can be seen during its expansion stage in Fig. 3, alongside an interference screw. When closed, and before insertion of the interior screw, the expansion device is 31 mm long by 7 mm in diameter. The device was manufactured in $TiAl_6V_4$ ELI with three different interior diameters of 2.5, 3 and 3.5 mm, with expanded diameters of 9.5, 10 and 10.5 mm, respectively.

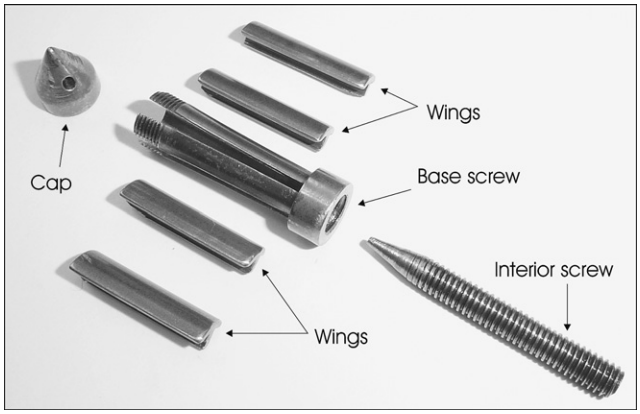

Fig. 1. Individual components of the new device presented in this paper.

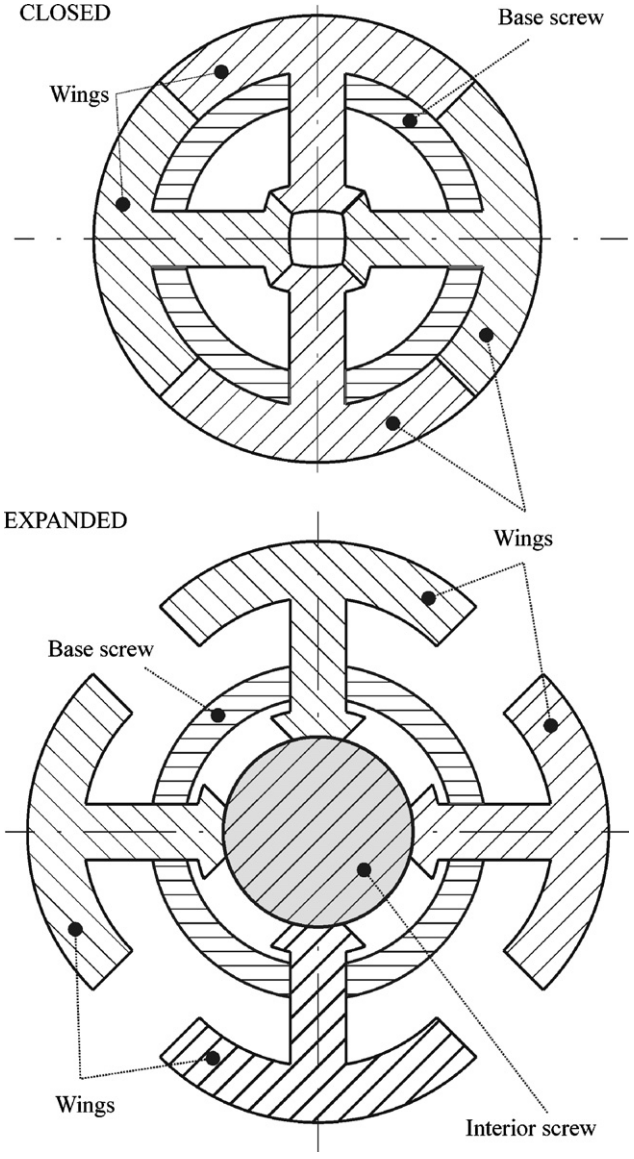

Fig. 2. Cross-sectional plan of the new device. Closed (above) and open (below) on introducing the interior screw.

2.2. Description of the tests carried out

The purpose of the tests was to compare the device proposed in this paper with a commercial interference screw for load failure and fixation stiffness.

Thirty-six fresh-frozen porcine tibiae were used together with an equal number of tendons from the extensor digitorum muscle of bovine front legs. Tendons were classified by diameters (6, 6.5 and 7 mm) using a tendons calliper. All the specimens, bones and tendons, were wrapped in gauze soaked in normal saline and stored at −20 °C until testing. Twenty-four hours prior to pull-out testing, bones and tendons were thawed to room temperature. Throughout the handling and

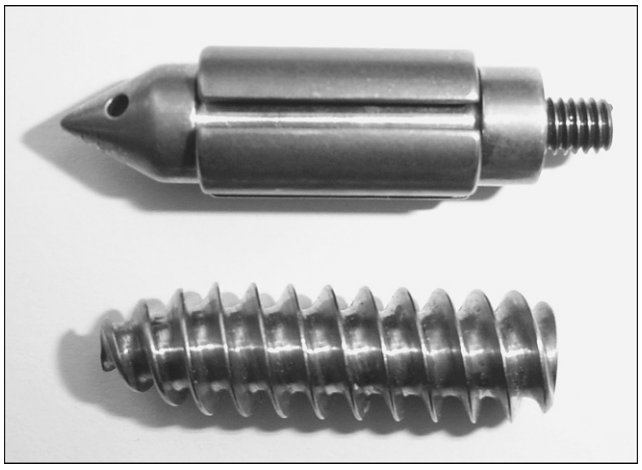

Fig. 3. Photograph of the new device in expanded layout, together with an interference screw.

test period the specimens were kept damp using a nebulizer with normal saline. 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. For each test a tendon was taken and its ends sutured to make a bifascicular graft which was inserted into the bone tunnel with the assistance of the sutures hanging from it. A loop of tendon approximately 4 cm long was thus left extending out from the upper part of the tibia. As can be seen in Fig. 4, this loop was used to hold the graft to a hook in the upper grip of the testing machine. The fixation system was then inserted. In 17 tibiae an interference screw was used (Propel®, 9 mm × 25 mm, ASTM F-136, Linvatec, FL, USA), while the new device was employed in the other 19.

The standard technique was employed during the insertion process of the interference screw. The new device was placed in the mouth of the bone tunnel and was inserted with the help of a suture thread, sliding it between the tendon and the bone until it was in a position similar to that of the interference screw. When the device was inside the bone tunnel, the interior screw was inserted to expand the wings in a radial direction. All the devices proposed in this paper which were tested had the same diameter before expansion $\phi_{be} = 7$ mm. However, three different types were manufactured, each of which would allow the insertion of an interior screw of different diameter ϕ_{is} (2.5, 3 or 3.5 mm). The screw size used, shown in Table 2, was selected to achieve the best possible fit in the bone tunnel between the fixation system and the graft. Preliminary tests were performed (not shown in this paper) to determine the appropriate diameter of the interior screw in relation to the diameter ϕ_t of the tendon used and the diameter ϕ_{bh} of the bone drill hole made. A relatively new parameter, called interference I, was defined to interrelate these three variables. This parameter is similar to that introduced by Pena et al. [11], and shows the degree of tendon grip against the walls of the bone tunnel. We define interference as the cross-sectional area occupied by the fixation system FS_{area}, less the

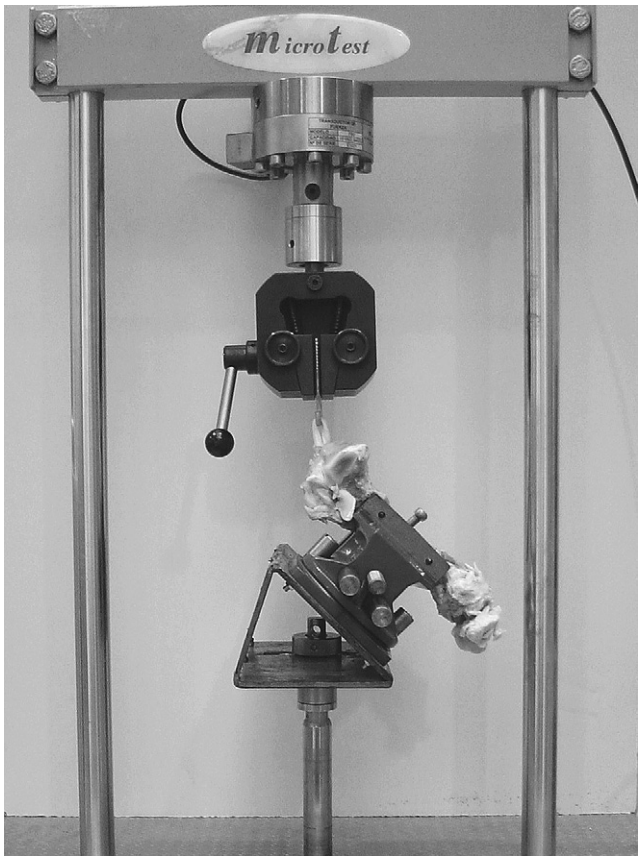

Fig. 4. Arrangement of the tibia-fixation system–graft complex in the testing machine.

area of free space which remains between the tendon and the bone tunnel. The magnitude of the interference was obtained mathematically using Eq. (1):

$$I = FS_{area} - \frac{\pi}{4}(\phi_{bh}^2 - \phi_t^2) \quad (1)$$

where FS_{area} depends on the fixation system used. Thus, as can be seen in Fig. 2, the area which the new device encompasses, once expanded, can be likened to a circle of diameter $(\phi_{be} + \phi_{is})$, with FS_{area} thus being as shown in Eq. (2). For the interference screw the area of the fixation system is defined using Eq. (3):

$$FS_{area} = \frac{\pi}{4}(\phi_{be} + \phi_{is})^2 = \frac{\pi}{4}(7 + \phi_{is})^2 \quad (2)$$

$$FS_{area} = \frac{\pi}{4}9^2 = 63.62\,\text{mm}^2 \quad (3)$$

Each tibia-fixation system-graft complex was subjected to a pull-out test until failure at a rate of 20 mm/min on 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 (Fig. 4). A custom made jaw was used to hold the tibia at an angle of 45° to the vertical axis of the testing machine, allowing to pull along the tunnel axis, representing a worst-case scenario for analyzing a fixation technique [6,14]. For each test, the maximum load

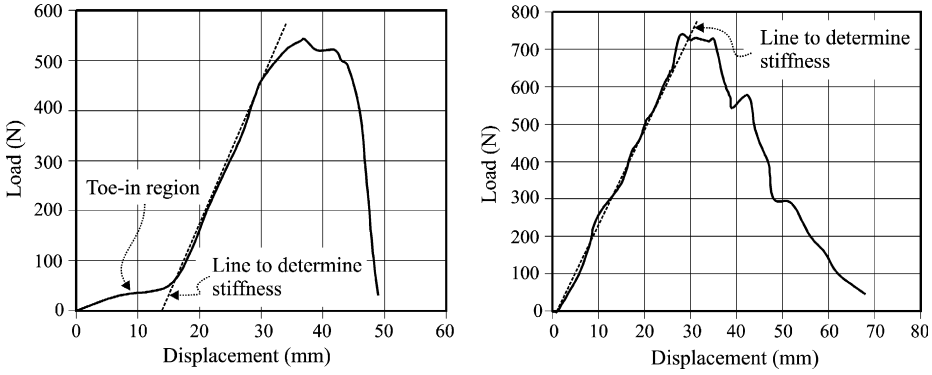

Fig. 5. Force vs. displacement graphs. The graph on the left shows one of the discarded tests with the toe-in region and on the right a valid test.

and slippage and failure mode were obtained and a force-versus-displacement graph (Fig. 5) created. Stiffness was calculated as the slope of the most linear part of the force-versus-displacement graph. In some of the tests, probably due to careless placement of the specimens in the machine, there was initial slippage at low load level (shown in Fig. 5 as the "toe-in" region). The results of these tests were discarded. Out of a total number of 31 valid tests, 14 correspond to the interference screw and 17 to the new device.

2.3. Statistical analysis

Mean values are reported with standard deviations. Differences between the groups were determined using t-tests. A value of $P < 0.05$ was considered statistically significant. The procedures were performed using SPSS (SPSS-company, Chicago, IL 60606, USA).

3. Results

The results obtained can be seen in Tables 1 and 2. The mean failure load was 633 ± 202 N in the new expansion device group and 471 ± 179 N in the interference screw group ($P < 0.05$). Stiffness was 59 ± 20 N/mm in the new expansion device group and 37 ± 19 N/mm in the interference screw group ($P < 0.05$).

In all the test samples of the interference screw group the failure mode was the tendon coming out of the bone tunnel, leaving the interference screw behind still inserted in the bone tunnel. In the new device group two types of failure were observed: (1) the tendon coming out of the bone tunnel, leaving behind the fixation device (t*endon alone*) and (2) the tendon coming out of the bone tunnel and taking with it the fixation device (t*endon + fix*). No instance of breakage of the tendon was observed.

4. Discussion

The fundamental purpose of this work has been the study of the in vitro performance of a new fixation system for ACL surgery tendon grafts, based on radial expansion of its wings. Its fundamental principle is the same as that of the interference screw, namely its insertion in the bone tunnel, pushing the tendon against the bone wall to achieve

Table 1
Results obtained with the interference screw

No.	Tendon diameter, ϕ_t (mm)	Bone hole diameter, ϕ_{bh} (mm)	Interference, I (mm^2)	Failure load (N)	Stiffness (N/mm)	Failure mode
1	7	10	23.56	196	25	Tendon alone
2	6	9	28.27	698	50	Tendon alone
3	7	10	23.56	446	43	Tendon alone
4	6	9	28.27	438	38	Tendon alone
5	7	10	23.56	451	38	Tendon alone
6	6	9	28.27	255	29	Tendon alone
7	7	10	23.56	608	25	Tendon alone
8	6.5	10	18.26	542	29	Tendon alone
9	7	10	23.56	769	15	Tendon alone
10	6.5	10	18.26	347	29	Tendon alone
11	6	9	28.27	558	77	Tendon alone
12	6	9	28.27	220	21	Tendon alone
13	6	9	28.27	661	78	Tendon alone
14	7	10	23.56	402	28	Tendon alone
Mean			24.82	471	37	
S.D.			3.58	179	19	

Table 2
Results obtained with the new device

No.	Tendon diameter ϕ_t, (mm)	Bone hole diameter, ϕ_{bh} (mm)	Interior screw diameter, ϕ_{is} (mm)	Interference (mm^2)	Failure load (N)	Stiffness (N/mm)	Failure mode
1	6	10	3.5	36.32	480	85	Tendon + fix
2	6	9	3	43.20	386	57	Tendon + fix
3	7	10	3	38.48	770	35	Tendon + fix
4	6.5	9	3	48.11	962	76	Tendon + fix
5	7	10	3	38.48	707	40	Tendon + fix
6	6.5	9	2.5	40.45	487	36	Tendon alone
7	6	9	3	43.20	475	47	Tendon alone
8	6	9	3	43.20	477	28	Tendon alone
9	6.5	9	3	48.11	965	68	Tendon + fix
10	6	9	3	43.20	554	42	Tendon alone
11	6.5	10	3.5	41.23	911	81	Tendon + fix
12	6	9	3	43.20	736	74	Tendon + fix
13	6.5	9	3	48.11	732	101	Tendon alone
14	6	10	3.5	36.32	510	70	Tendon alone
15	6.5	9	3	48.11	497	46	Tendon alone
16	6	9	2.5	35.54	325	65	Tendon + fix
17	6.5	9	3	48.11	782	60	Tendon + fix
Mean				42.55	633	59	
S.D.				4.49	202	20	

the biological integration of both components. The difference between the interference screw and the new device lies in the greater transversal compression obtained with the latter as it expands radially outward after its insertion in the bone tunnel. Furthermore, cuts to the graft may occur during the process of insertion of the interference screw. This is because of the protruding profile of the thread and its sharp configuration. This thread, when turning as the screw is inserted, may damage the graft. However, the new device has a non-cutting configuration as it is inserted into the bone tunnel with its wings in non-expanded position. Therefore the aggression affecting the graft on its insertion in the tunnel is less than that for threaded interference screws.

At the present time, accelerated rehabilitation methods are being employed after ACL reconstructive surgery to get patients back to their workplace as soon as possible [21,22]. It is therefore very important that the graft fixation method can support from the very beginning the loads to which the new ACL will be subjected to. The daily tensile loads of a normal ACL are believed to be, at most, 20% of its failure capacity, and the load that the ACL of a young adult can support is approximately 2500 N [23,24]. Therefore, it is reasonable to suppose a maximum daily load figure of 500 N, as well as 450 N in an intensive rehabilitation program [19,20]. The results observed in this study show that the new device achieved a mean maximum load of more than 600 N, significantly higher than the mean maximum load observed with the interference screw (more than 25% higher). Though it can be seen (Table 2) that some failure load values obtained with the new device are under 450 N, these only represent 12% of the cases, compared to 50% of those observed for the interference screw (Table 1). These results suggest that the fixation obtained with the new device would support the aggressive loads of an early rehabilitation program better than the interference screw.

The other variable analyzed in the tests was stiffness, a factor which affects the capacity of the replaced ligament to restore and maintain the stability of the knee reconstruction [4]. The stiffness of the intact ACL determined by Rowden et al. [7] was 306 ± 80 N/mm with knees from donors who were aged 42 years or less. The results of this study show that the mean stiffness obtained with the new device was 59 N/mm, 37% higher than that observed with the interference screw, though this is still a long way from the figure for a knee with an intact ACL.

The analysis of a relatively new parameter, interference, was also introduced into this study. To our knowledge, only Pena et al. [11] have studied interference, though the definition used in this paper is different. In our study, the results of the tests show a significantly clear difference between the interference screw and the new device (interference screw $24.82 \pm 3.58\ mm^2$; new device $42.55 \pm 4.49\ mm^2$). This difference is logical, given that the new device has been specially designed to obtain the effect of radial expansion.

The concept of radial expansion as a fixation method of ACL grafts is not a new one, and the present study supports the view that good results are obtained by applying this type of fixation. However, a few points need to be mentioned concerning the values obtained by other researchers. Though the expansive screw of Seitz et al. [5] obtained high values for maximum load and stiffness, grafts with bone insertions were used in their tests, namely the bone-patellar tendon-bone, and this may have given rise to the high values obtained. The expansive screw of Tuompo et al. [10] also uses grafts with bone insertions and the results obtained were strangely high; on making a comparison with the interference screw a value

of 2113 ± 407 N is obtained for it, a figure which far exceeds all the values obtained in other studies [8,9,11,12,15]. For this reason, the values given by these authors should be handled with caution. As for the results obtained by Black and Saunders [13], while they are encouraging they are unfortunately not comparable to those obtained in the present study, as they were only a test of the expansion concept and not an in-vitro test.

In conclusion, this study has shown the capacity of the device presented in this paper for fixation of ACL grafts. However, for these results to be applicable in clinical practice a long-term follow-up period of evaluation is required in a large patient population [5].

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