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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.

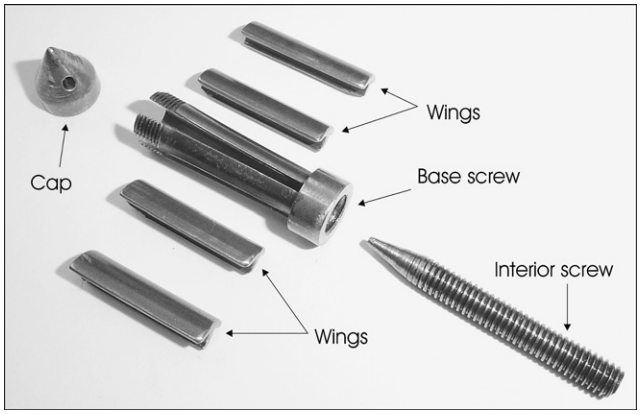

Fig. 1. Individual components of the new device presented in this paper.

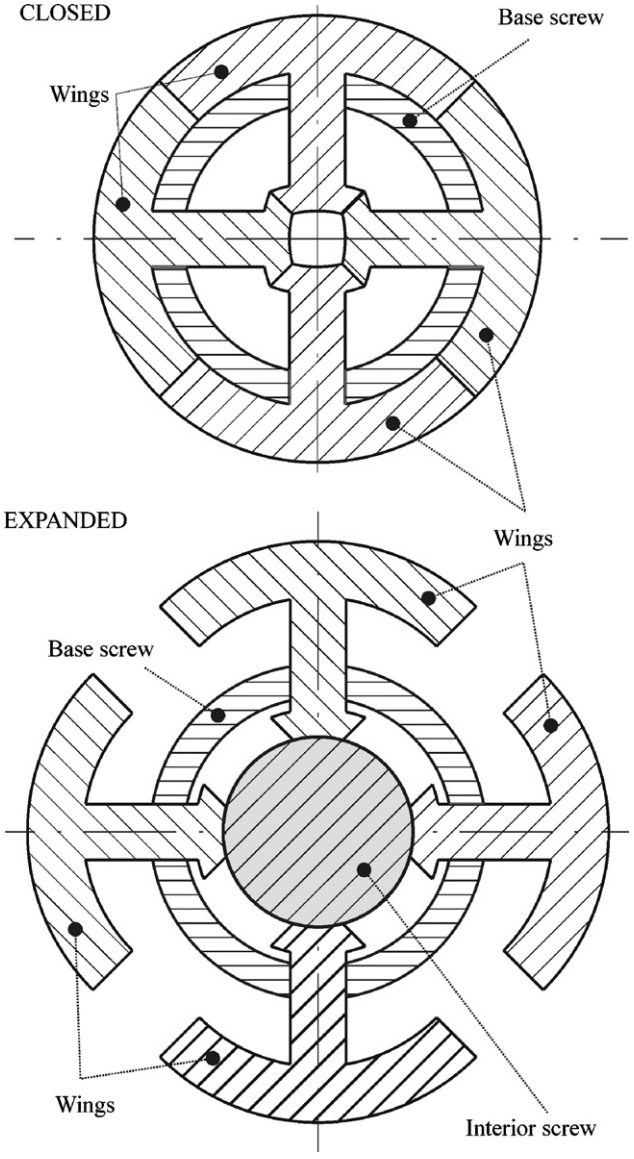

Fig. 2. Cross-sectional plan of the new device. Closed (above) and open (below) on introducing the interior screw.

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