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Technical note

Expansion anchors for use in anterior cruciate ligament (ACL) reconstruction: establishing proof of concept in a benchtop analysis

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Abstract

The current method for graft fixation in bone tendon-bone anterior cruciate ligament (ACL) reconstruction is the interference screw. Although this method of fixation provides for adequate graft fixation with respect to strength, intraoperative placement is difficult and the failure rate is high. To address these concerns, we have designed and fabricated prototype expansion anchors that could be expanded to anchor the graft in the bone tunnel. As a first step in assessing the validity of this concept, in the current work, we demonstrate that these systems are of comparable fixation strength (biomechanical pullout testing) to the standard interference screw, are smaller at the time of insertion and thus provide for increased visibility and ease of placement. The increased visibility should result in better placement and reduced failure rates. The increased ease of placement should result in significant savings in decreased OR time.

Keywords: Anterior cruciate ligament reconstruction; Expansion anchors; Implant design; Prototype development; Mechanical testing

1. Introduction

The "weak link" in the immediate post op phase following ACL reconstruction has been shown to be at the fixation site of the graft in the femoral and tibial tunnels [1,9,17,18]. As early range of motion and "accelerated rehabilitation" have become the standard of care following surgery, the importance of secure graft fixation is paramount. The failure rate of ACL reconstructive surgery, as measured by a >3 mm side-to-side difference in knee laxity, is approximately 15%. We view this as unacceptably high and indicative of the need for an improved surgical technique.

The utilization of interference fit screws for bone-patella tendon-bone graft fixation became popular after Kurosaka et al. [9] demonstrated their superiority relative to other fixation techniques for securing a bone-tendon–bone patella tendon graft in a tunnel. Since then, modifications of the original design have been tested, and utilized clinically if appropriate. These include changes in screw length, width, thread design, and materials [1–3,5,7,8,14,16,17]. The basic principle underlying this type of fixation device lies in its ability to compress a bone plug in a tunnel. At the time of surgery, a trapezoidal shaped bone plug from the tibial tubercle and patella, with a maximum width of 10 mm, is contoured to fit snugly into a 10 mm bone tunnel. Fixation of the bone plug in the tunnel is then achieved by inserting a screw that is typically 7 or 9 mm in diameter and approximately 20–25 mm in length, compressing the bone plug against the wall of the tunnel (Fig. 1). Over time, the bone plug incorporates with the wall of the tunnel [18]. Although there have been some concerns with screw divergence (relative to the angle of the tunnel) resulting in suboptimal fixation [6,10], multiple biomechanical studies have consistently demonstrated acceptable graft fixation [4,11–13,15]. There are, however, concerns that exist intraoperativley, particularly for graft fix-

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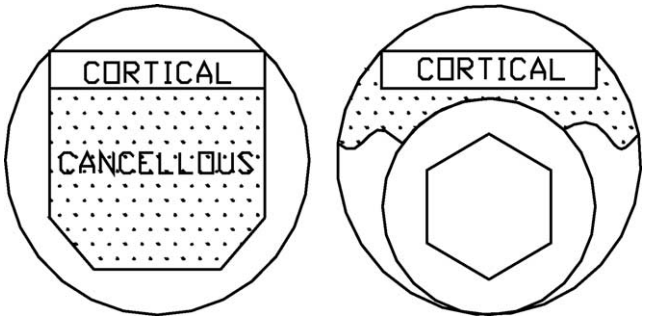

Fig. 1. Planform sketch illustrating typical graft size before and after screw fixation within the bone tunnel.

ation to the femur, that are not addressed in cadaveric studies. Chief among these is the pure technical act of insertion of a screw endoscopically. In addition, due to the diameter of the screw relative to the length and width of the intercondylar notch of the knee, potential exists for graft damage at the time of screw insertion. Finally, as the angle at which the screw is inserted is not the angle at which the tunnel is drilled, the screw can be inserted divergently, resulting in inadequate fixation.

Ideally, fixation should be achieved with a device that does not obscure visualization, can be inserted easily, and provides secure fixation. Our approach to addressing this problem has been to develop an expandable anchoring device. Intraoperative experience has demonstrated to surgeons that a 7 mm diameter screw is easier to insert than a 9 mm screw, and biomechanical studies have demonstrated that graft fixation is not compromised [4,7]. Here, we have developed a fixation device that is even smaller at the time of insertion, making it more "user friendly" technically, but can be subsequently expanded to provide comparable fixation of the graft.

2. Methods

2.1. Overview

The goal of the current study was to evaluate the concept of an expandable anchoring system for use in ACL reconstruction surgery. To this end, we developed four prototype designs from Alloy 260 brass (260 brass) (conforming to ASTM B36), as well as fabricating 260 brass interference fit screws for comparison. The brass was used to expedite machining and minimize cost of the prototypes and brass screws were fabricated (with the use of a comparator) to eliminate material variability. Anchor systems were compared to interference fit screw design performance in a variety of synthetic and porcine bone block models. Standard protocols for anchor insertion and pullout were developed and followed to minimize human error. Stiffnesses, pullout loads and displacements to failure of the brass anchors were determined and compared to the brass interference fit screws. The aim was to develop an expansion anchor system capable of mechanically performing as well as the interference fit screw while providing for increased ease of placement (ideally one-handed placement for arthroscopic use) and increased visibility.

2.2. Anchor designs

For establishing 'proof of concept', four expansion anchor systems were designed and machined. As shown in Fig. 2, the four designs compared were:

(i) 13.5 mm long × 6.6 mm wide, unconstrained expansion system (anchor 1);
(ii) 25.0 mm long × 6.3 mm wide, unconstrained expansion system (anchor 2);
(iii) 25.0 mm long × 6.3 mm wide, constrained expansion system with wedge insert (anchor 3);

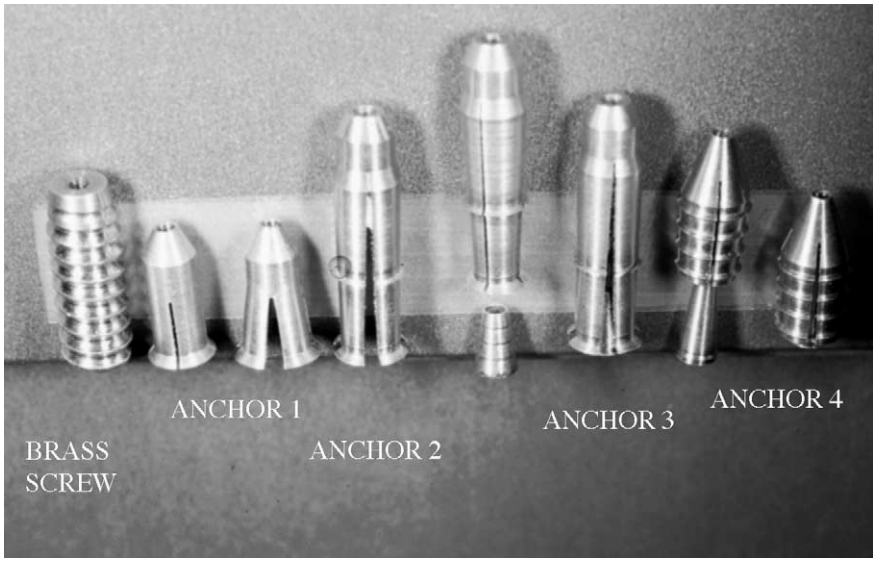

Fig. 2. Photograph of the four brass expansion devices evaluated in this study. Anchors are shown from left to right as anchor 1; anchor 2; anchor 3; anchor 4.