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JewelACL™

Mechanical properties and fixation performance testing of the JewelACL

Introduction

The JewelACL is a *tissue graft sparing* device for Anterior Cruciate Ligament reconstruction that overcomes the need to take any tissue from the semitendinosus and gracilis hamstrings. If however a tissue graft is still desired, in order to promote cell ingrowth, the JewelACL may also be used in a *partial tissue graft sparing* approach, whereby a tissue graft can be passed through the tubular, open weave structure via purposefully designed openings.

These two approaches not only reduce operative time but also avoid donor site morbidity and the deficiency created in the strength of the hamstring muscle group. The immediate strength of the JewelACL and its fixation also allows for rapid weight bearing and rehabilitation in comparison to tissue grafts, which lose much of their strength after implantation.

In addition it is specifically designed to be implanted with approaches familiar to most surgeons so it is compatible with almost any of the standard instrumentation in current use and may also be secured with a range of common fixation devices for both femoral and tibial attachment.

Objective

The purpose of this investigation was firstly to examine the mechanical properties of the JewelACL, in terms of its strength and stiffness, and compare them to those of the semitendinosus graft, for which it is a substitute. The second aim of this study was to determine the pullout strength of the device with a range of fixation devices, both with and without tissue grafts. The femoral fixation devices tested were the 15 mm ENDOBUTTON CL ULTRA (ECLU) [Smith and Nephew] and a TransFix Pin [Arthrex]. The tibial fixation devices tested were the 7 x 25 mm RCI screw [Smith and Nephew], 7 x 30 mm Interference Screw [Medgal] and 8 mm Fastlok [Neoligaments].

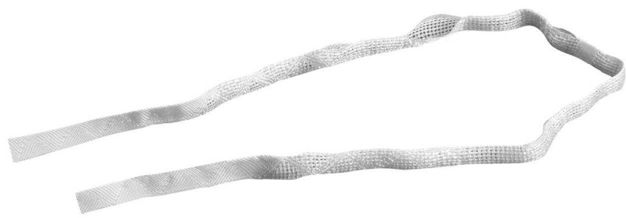

Figure 1 The JewelACL

Methods

The tests were performed using an Instron 8031 materials testing machine and a physiologically representative strain rate of 20 mm/s was used in all test groups, each of which consisted of at least six replicates for statistical relevance.

JewelACL Mechanical Properties

The mechanical properties of the JewelACL were determined by securing a single strand of the device between two rubber lined clamps, with a 40 mm gauge length, and applying a uniaxial load until the device failed.

Femoral Fixation Devices

The JewelACL was looped over either the ECLU or TransFix Pin, which were fixed directly to the test machine. The free ends of the ligament were then secured in rubber lined clamps and a uniaxial load applied until failure occurred. A gauge length of 75 mm was used to represent the typical length of the intra-articular space and bone tunnels.

Tibial Fixation Devices

Tibial fixation devices were tested by looping the ligament over a 10 mm mandrel and securing the free ends into a synthetic bone material with either the Fastlok, RCI screw or Interference screw, which was also tested with a tissue graft incorporated. The bone substitute material was chosen to be weaker than normal bone to show the minimum performance characteristics. A 75 mm gauge length was used again and a uniaxial load applied until failure.

Fatigue Testing

As the RCI and Interference screws are the most likely cause of damage to the device, fixation strengths for these were also determined after fatigue cycling. This was achieved by applying a uniaxial sinusoidal tensile load between 50 N and 450 N at a frequency of 25 Hz for 500,000 cycles, which represents approximately six months of highly active, healthy use. After this point there should be sufficient tissue ingrowth to form a protective layer around the device, preventing any further abrasion.

Results

JewelACL Mechanical Properties

Figure 2 shows the Ultimate Tensile Strength (UTS) for both the JewelACL and semitendinosus hamstring and it may be seen that the properties are generally equivalent. The stiffness is well matched to the maximum of the natural ACL, which is 320 N/mm[1].

Femoral and Tibial Fixation

Figures 3 and 4 show the pullout strength for a range of fixation devices. The pullout force in all cases is at least 950 N, which is far more than the device should ever normally receive. Furthermore, these tests omit any strengthening effect of bone tissue ingrowth, meaning normal pullout strengths are likely to be much higher still.

Tibial Fixation after Fatiguing

Figure 5 shows the pullout strengths of the RCI screw and Interference Screw after fatiguing. When used with or without a tissue graft, the pullout strength remained well above that likely to be seen in normal use. These maintained pullout strengths indicate that the screw causes minimal wear to the JewelACL prior to the point at which it would become protected by tissue ingrowth.

Conclusions

- The JewelACL has mechanical properties that are equivalent, if not slightly superior, to those of the semitendinosus hamstring graft.
- The fixation devices provide a greater pullout strength than the JewelACL should receive in normal use, even after significant fatigue cycling.

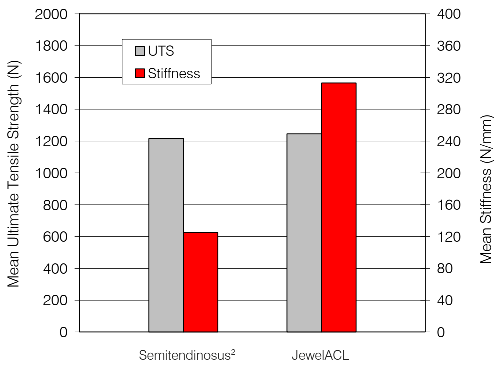

Figure 2 JewelACL mechanical test results

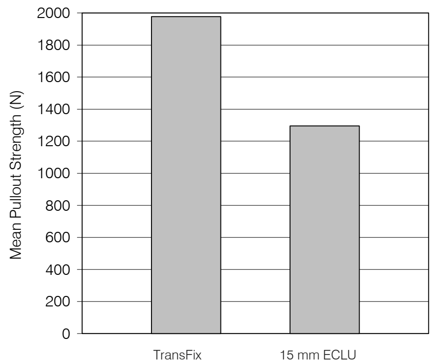

Figure 3 Femoral fixation test results

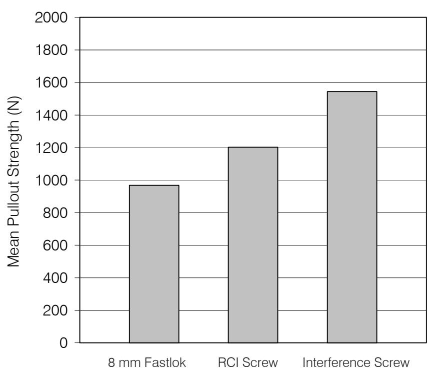

Figure 4 Tibial fixation test results

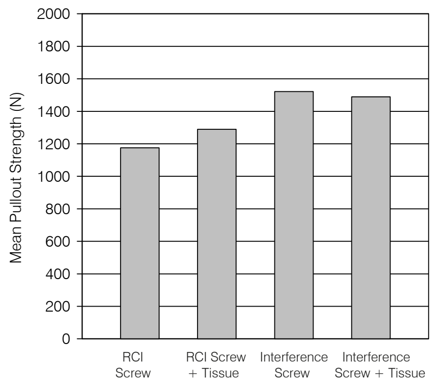

Figure 5 Post fatigue tibial fixation test results

1. Woo SLY, Adams DJ. The Tensile Properties of Human Anterior Cruciate Ligament (ACL) and ACL Graft Tissues. *Knee Ligaments: Structure, Function, Injury, and Repair.* Raven Press Ltd., 1990, 279-289.
2. Noyes FR *et al*. Biomechanical Analysis of Human Ligament Grafts used in Knee-Ligament Repairs and Reconstructions. *The Journal of Bone and Joint Surgery*. 1984;66:344-352.

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