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Fastlok™

Performance testing of the 6 and 8mm titanium Fastlok

Introduction

The Fastlok device consists of a staple and buckle and is intended for the attachment of sutures, tapes or ligaments to bone. It is also used for soft tissue and connective tissue repairs, tendon transfers, or autogenous and/or prosthetic ligament reconstruction, repair or replacement.

This recent version of the Fastlok, which is manufactured in titanium alloy, comes in two sizes; a 6mm and an 8mm. It has been developed in response to requests from users for a design that requires only one set of instruments to implant both sizes. In this white paper we demonstrate that the performances of both sizes of the new device are at least comparable with, if not slightly superior to, the previous versions.

Figure 1 The new design of titanium Fastlok

Objective

The purpose of this investigation was to compare the performance characteristics for tensile and fatigue tests of the new design for the 6 and 8mm Fastlok (part numbers 102-1380 and 102-1381) with those achieved with the previous versions (part numbers 102-1338 and 102-1372).

Methods

Tensile and fatigue tests were performed on sutures, tapes and ligaments that were anchored to wooden blocks with Fastlok devices. The tests were performed using an Instron 8031 materials testing machine. This is the same protocol that has been previously used with the original versions of the Fastlok.

Tensile Test

Three groups each comprising a minimum of three 6mm Fastlok specimens were used. One group was used with Ethibond sutures USP No 2 (5 metric), another with Ethibond sutures USP No 5 (7 metric) and the third group was used with Neoligaments' 3mm orthopaedic tape (part number 102-1338). The Fastlok test specimens were impacted into wood, using the impactor (part number 202-1137). The sutures were configured to create 4 loops (8 strands), but just one loop in the case of the 3mm orthopaedic tape (2 strands). A mandrel was passed through the loops such that the specimen could be mounted on the test machine. A uni-axial tensile load was applied at a constant strain rate until failure.

Fatigue Test

Two groups of three of the 6mm Fastlok specimens were used for this test; one group with Ethibond No 5 the other with No 7 sutures. A minimum of four specimens of the 8mm Fastlok were tested with the

Leeds-Keio HPA ligament (part number 102-6007). The Fastlok specimens, whether tested with sutures, tapes or with ligaments, were tested in the same configuration as for the tensile test described above. The HPA ligament was clamped in rubber-lined jaws at its free end. Each specimen was fatigued by applying a cyclic uni-axial sinusoidal tensile load along the sutures, tapes or ligaments. The load varied between 50N and 500N for the HPA, 50N and 250N for the No. 2 sutures and 50N and 400N for the No. 5 sutures. All the tests were performed at a frequency of 25Hz, for 540,000 cycles. On completing the application of these, the residual strength and stiffness of the fatigued implant and construct was determined by applying a single tensile test to failure load cycle on the implant at a constant strain rate of 50% (20mm/second).

Results

Tensile Tests with 6mm Fastlok

The ultimate tensile strength (UTS) and stiffness for the three groups with the 6mm Fastlok are shown in Figure 2 and Figure 3. Results show the superior performance of the new Fastlok in each case.

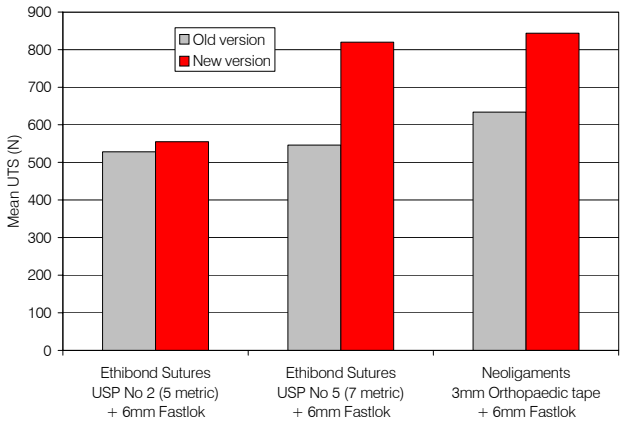

Figure 2 6mm Fastlok tensile test results - UTS

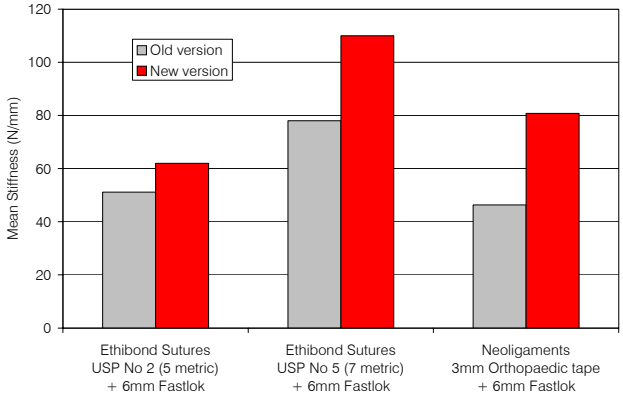

Figure 3 6mm Fastlok tensile test results - stiffness

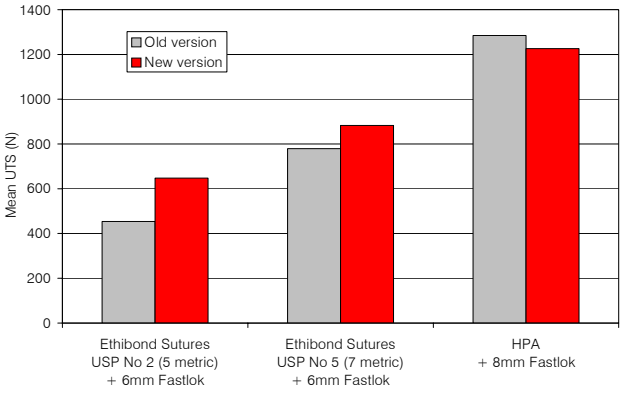

Figure 4 Residual tensile test results - UTS

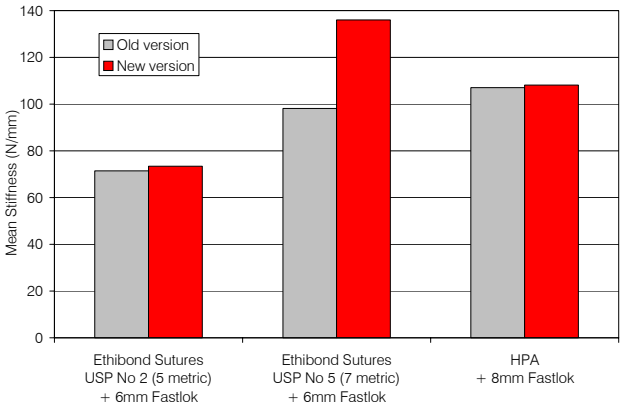

Figure 5 Residual tensile test results - stiffness

Fatigue Tests with 6mm Fastlok

The residual UTS and stiffness for the two groups with the 6mm Fastlok are shown in Figure 4 and Figure 5. Results again show the superior performance of the new Fastlok.

Fatigue Tests with 8mm Fastlok

Comment: Only fatigue tests (residual UTS and stiffness) are reported for the 8mm Fastlok as they are the most representative of the clinical situation.

The residual UTS and stiffness for the HPA ligament with the 8mm Fastlok are shown in Figure 4 and Figure 5. These results indicate that the performance of the new 8mm Fastlok is equivalent to the previous version of the device.

Conclusions

- The new 6mm Fastlok has superior mechanical performance compared with the previous version of the device.
- The new 8mm Fastlok has residual tensile properties comparable with those of the previous version.

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