

Cyclic Displacement Data on the ToggleLoc™ Device with ZipLoop™ Technology

Biomet Sports Medicine Research & Development

Objective

The ToggleLoc™ Fixation Device with ZipLoop™ Technology is a suspensory fixation device made of #7 polyethylene suture and a 13mm titanium button that is used to secure an ACL graft. Suspensory fixation devices typically provide excellent strength, but are sometimes questioned relative to slippage and stiffness. Previous testing conducted by Biomet Sports Medicine on the ToggleLoc™ device with ZipLoop™ Technology has demonstrated excellent slippage characteristics,¹ but further testing was required to determine how this correlates to the overall cyclic displacement of the implant. The purpose of this testing was to validate that low slippage would yield low cyclic displacement.

Methods and Materials

The loops on the ToggleLoc™ device with ZipLoop™ Technology were pre-tensioned to stimulate the act of implantation and set at 40mm determined by calipers. The ToggleLoc™ device's titanium button was passed through a 4.5mm hole in a steel plate attached to the base of test machine "Sandman" (GPP-1257-5, Serial # 184549A). The loops of the ZipLoop™ suture were loaded over a pin which was attached to the upper half of the test machine. The test was run for 2000 cycles at 50 to 450 N. The complete set up is as seen in Figure 1 below.

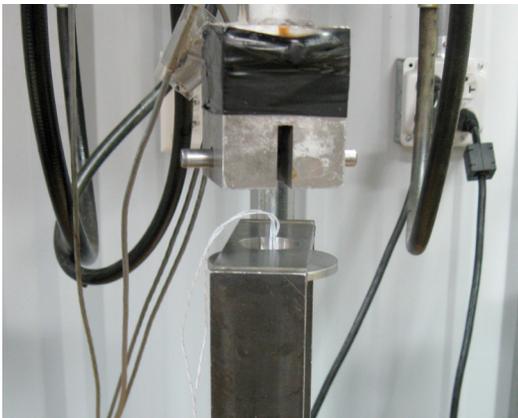


Figure 1: Test Set Up

Average Cyclic Displacement (mm)
Biomet Sports Medicine ToggleLoc™ with ZipLoop™ Technology⁵

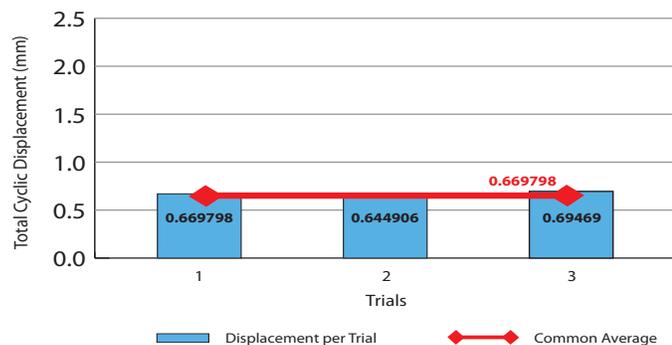


Figure 2: Cyclic Displacement Results

Summary

This result verifies the conclusion that the previously recorded slippage corresponds to low cyclic displacement (Figure 2). The ToggleLoc™ device proves that its low cyclic displacement is far less than the 5mm commonly accepted as clinical failure.^{2,3,4}

¹ Biomet Sports Medicine: *Max Load and Cyclic Load Physical Testing of the ToggleLoc™ Fixation Device with ZipLoop™ Technology*. Bench testing is not necessarily indicative of clinical performance. BSM0026.2.

² Kamelger FS, Onder U, Schmoelz W, et al. Suspensory Fixation of Grafts in Anterior Cruciate Ligament Reconstruction: A Biomechanical Comparison of 3 Implants. *Arthroscopy*, 25:767-776, 2009.

³ Ahmad CS, Gardner TR, Groh M, Arnouk J, Levine VN. Mechanical properties of soft tissue femoral fixation devices for anterior cruciate ligament reconstruction. *Am J Sports Med*, 32:635-640, 2004.

⁴ Fu FH, & Cohen SB. *Current Concepts in ACL Reconstruction* (p. 151). Thorofare, NJ: Slack Incorporated, 2008.

⁵ Data on file at Biomet Sports Medicine. Bench testing is not necessarily indicative of clinical performance.

BIOMET[®]
SPORTS MEDICINE
One Surgeon. One Patient.™

P.O. Box 587, Warsaw, IN 46581-0587 • 800.348.9500 ext. 1501

©2009 Biomet Orthopedics • www.biomet.com

Form No. BSM0204.0 • REV093009

This material is intended for the sole use and benefit of the Biomet sales force and physicians. It is not to be redistributed, duplicated or disclosed without the express written consent of Biomet.

All trademarks herein are property of Biomet, Inc. or its subsidiaries unless otherwise indicated.