

Cyclic Fatigue and Creep Resistance Testing of the PUMA System™

Background

The PUMA System (Panther Orthopedics, Sunnyvale, CA) is a superelastic, nitinol based fixation device for the ankle syndesmosis which provides stabilization without over-compression or loosening due to creep from cyclic loading.

Objective

The objective of this study was to test resistance to lengthening (creep) of the PUMA System in cyclic fatigue testing.

Methods and Materials

Five PUMA System devices, each having a nitinol Body consisting of six layers, were cycle-tested between 20/40 pounds per cubic foot (lb/ft³) polyurethane foam Bone Blocks (Figure 1).¹

Test Fixture for Cyclic Displacement

The PUMA System devices were set up with an initial device Active Length of approximately 66 millimeters (mm) between their polyether ether ketone (PEEK) Anchor

buttons. All devices were tightened to a minimum of 11.1 Newtons (2.5 pounds force) and cycled at 5 cycles per second (5 Hz) for 4500 cycles to 2.4 mm displacement. Device Active Length was recorded pre- and post-testing. Devices were visually inspected for any break in the 30 nitinol layers.

Results

None of the 30 layers incorporated in the 5 PUMA System device Bodies failed due to cyclic fatigue. Also, there was little-to-no difference between pre- and post-testing Active Length (Figure 2). More specifically, an average increase of only 0.2% in length with a with a Standard Deviation of 0.16% evidences no significant creep (Table 1).

Conclusion

The PUMA System allows for ankle syndesmosis repair with an implant that experiences no significant creep as demonstrated in cyclic-fatigue testing under challenging displacement cycle testing.

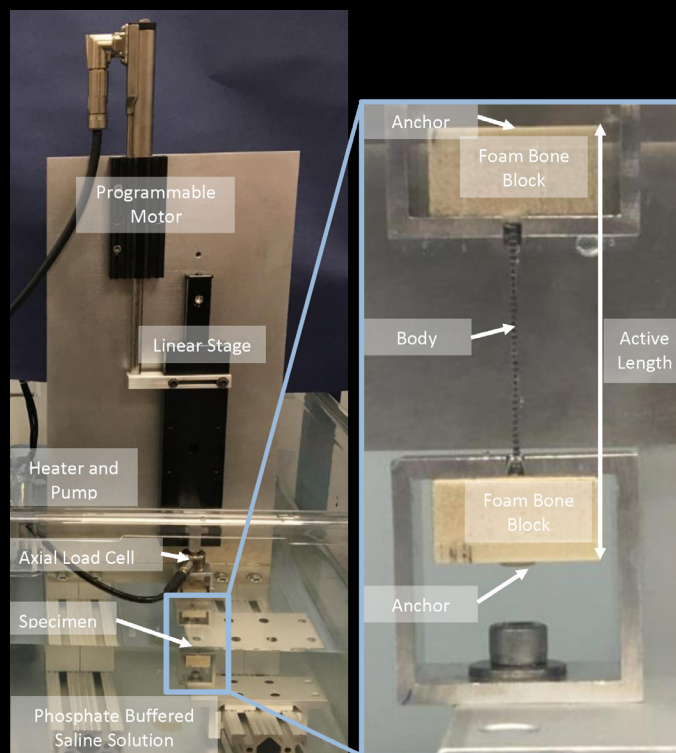


Figure 1

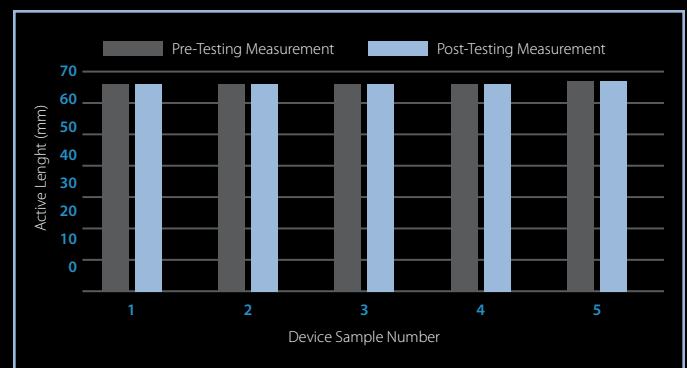


Figure 2

Sample	Intact Layers	Pre-testing Length (mm)	Post-testing Length (mm)	Length Change (mm)	Percent Creep
1	6/6	65.80	65.80	0.00	0%
2	6/6	65.57	65.62	0.05	0.07%
3	6/6	65.25	65.40	0.15	0.23%
4	6/6	65.80	66.03	0.23	0.35%
5	6/6	66.40	66.63	0.23	0.35%

Table 1

452 Oakmead Parkway • Sunnyvale, CA 94085 • United States

1.650.407.5062 • info@pantherortho.com • pantherorthopedics.com

¹ ASTM F1839: Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopedic Devices and Instruments.

© 2020 Copyright Panther Orthopedics, Inc. All rights reserved. APM004 Rev A (DCO-0004) 11/2020

