In Vitro Pull-Out Strength of MedShape DynaClip™ Bone Fixation System

MedShape, Inc. Research & Development

Study Objectives
To compare the pull-out strength of the DynaClip™ Bone Fixation System with a competitor staple.

Materials and Methods
Synthetic Sawbone® (Pacific Research Laboratories) of 20 PCF was used to model healthy, dense bone such as in the cuneiform or navicular bone. Holes were drilled into the Sawbone blocks using the manufacturer’s instructions and instrumentation as applicable. The following staple devices were tested:

1. DynaClip Bone Fixation System, 8x8x8 mm, n=8 (MedShape, Inc)
2. DynaClip Bone Fixation System, 26x20x20 mm, n=8 (MedShape, Inc)
3. FuseFORCE™ Fixation System, 8x8x8 mm, n=5 (Wright Medical)
4. FuseFORCE Fixation System, 25x22x22 mm, n=5 (Wright Medical)

Monotonic testing was conducted in general compliance with ASTM F564.¹ Samples were loaded into the fixtures of the universal test machine (Instron 5567) and secured using a U-Line polystrap (Figure 1). For each test, a 5N pre-load was applied before the strap was pulled at a rate of 1mm/sec until one of the following occurred: a significant drop (>50%) in tensile load after peak, visible tearing or rupture of the strap, fracture of the bone block, or loosening of the staple. The maximum force on the load-displacement curve (i.e. pull-out strength) was recorded for each test. Average +/- standard deviation was calculated for all test data, and a two-sample t-test was performed with a significance level of α=0.05.

Results
The 8x8 mm DynaClip Bone Fixation System exhibited 2X the pull-out strength compared to the 8x8 mm FuseFORCE. Likewise, the pull-out strength for the 26x20x20 mm DynaClip was almost 3.5 times greater than that of the 25x22x22 mm FuseFORCE (Figure 2). This difference was statistically significant for both staple sizes (p-value <0.05).

Conclusions
Pull-out strength testing aims to assess the axial holding strength of bone staples, and is useful in comparing staple materials, design, and performance.¹ Staples with higher pull-out strength are also potentially at lower risk of backing out post-surgery. In this paper, it was demonstrated that the pull-out strength of the DynaClip Bone Fixation System was superior to that of the similarly sized FuseForce Fixation System. The DynaClip’s demonstrated ability to generate greater compression² with a profile of variable length teeth in the legs could contribute to its superior fixation in bone.

Figure 1: Test Setup

Figure 2: Average pull-out strength +/- standard deviation for each staple test group

¹ ASTM F564, Standard Specification and Test Methods for Metallic Bone Staples