**In Vitro Compressive Performance of MedShape DynaClip™ Bone Fixation System**

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**Study Objectives**
To compare the compressive performance of the DynaClip™ Bone Fixation System with a competitor staple and evaluate the effect of simulated bone resorption on the amount of compression applied by each staple.

**Materials and Methods**
Synthetic Sawbone® (Pacific Research Laboratories) of 20/40 PCF (3 mm 40 PCF cortical layer with 20 PCF underlying cancellous layer) was used to model healthy, dense bone such as in the cuneiform or navicular bone. A hole was drilled into the Sawbone blocks using the manufacturer’s instructions and instrumentation. The following staple devices were tested (Figure 1):
1. DynaClip™ Bone Fixation System, 20x22 mm (MedShape, Inc)
2. FuseForce™ Fixation System, 20x20 mm (Wright Medical Group)

**Interfacial Compression Mapping**
For each test, two 25x25x25 mm Sawbone blocks were finely sanded to provide a smooth flat surface. Each sensor was calibrated using a Tekscan® bladder calibrator prior to testing. A pressure sensor (Tekscan #4000) was placed in between the Sawbone blocks. Each staple was then inserted into the two holes across the Sawbone blocks and deployed according to manufacturer’s instructions and instrumentation (Figure 2). The data was analyzed using Tekscan ISCAN v 4.02 software to determine overall force and area of the applied force generated from the implanted staples.

**Simulated Resorption**
For each test (n=6), two 45x25x25 mm Sawbone blocks were mounted on a universal test machine (Instron 5567) using custom-designed fixtures that started 8 mm apart (Figure 3). Staples were deployed according to manufacturer’s instructions and instrumentation. The test set-up was heated to 37°C using a thermal chamber (Instron Environmental Chamber) before the initial load was recorded. The resorption gap between the fixtures was reduced by 2 mm and the compressive load was tracked via a load cell. Statistical significance between the compressive force of DynaClip versus the FuseForce was determined with a Student’s t-test (α=0.05).
Results
Compression maps were generated and are shown in Figure 4. The DynaClip Bone Fixation System generated a uniform compression force profile from the near cortex region underneath the bridge to the distal end around the legs. In contrast, the compression profile for a similarly sized FuseForce Fixation System showed only compression generated at the leg region.

As shown in Figure 5, the DynaClip staple generated almost twice the amount of compression upon initial deployment compared with the FuseForce. When subjected to 2 mm of simulated bone resorption, the DynaClip exhibited over 40% more compression than the FuseForce. This difference was statistically significant.

Conclusions
Maintaining compression post-surgery is important in providing stability and promoting bone healing.1 The results from this study show that the DynaClip Bone Fixation System more uniformly distributes compression and generates a higher overall compressive force across the fusion site compared with a competitor staple of the same size. In addition, the DynaClip can also maintain compression in response to bone resorption, an inherent part of the bone healing process. The DynaClip’s superior compressive performance could potentially be attributed to its broader, rounded bridge and more robust shoulders that provide a higher stiffness compared with that of the FuseForce.