Compression Testing of the EasyFuse™ Staple vs BME® Staple

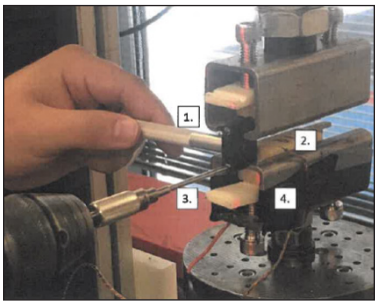
(Data on file)

Study Objectives

The objective of this study was to determine and compare the amount of compression force generated by the EasyFuse Nitinol Staple (Stryker) and the BME Elite (DePuy Synthes).

Materials and Methods

- Six 20 x 20mm EasyFuse Nitinol Staples and six 20 x 20mm BME Elite were inserted into the laminated foam bone blocks (Figure 1).
- Each staple was allowed to acclimate to the air until reaching 38°C, at which time the compression force and temperature were recorded.
- EasyFuse staples were manufactured as prototypes and characterized by an approved prototype and production supplier. BME Elite staples were all saleable goods, and therefore were subjected to all processes and inspections typical of saleable product.



1. Drill Guide
2. Foam Bone
3. Drill Bit
4. Compression Test Fixture

Figure 1. Typical Foam Bone Prep

Statistical Methods

- A two-sample t-test was used to determine whether any difference between staple performance characteristics were statistically significant, with the requirement for statistical significance set to $p < 0.05$.
- Minitab software (Minitab LLC, State College, PA) was used to perform all statistical analyses.

Results

- The average compression of the two staple groups is shown in Figure 2.
- The EasyFuse staple achieved statistically significantly higher compressive forces ($p < 0.001$) than BME Elite.

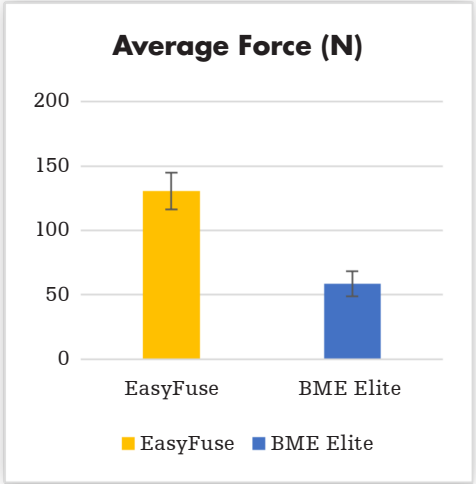


Figure 2. Comparison of Compressive Force Between EasyFuse and BME Elite

Discussion

- Maintaining compression has been shown to be a vital aspect of post-surgery care as it aids in stability and bone healing.[2]
- The average compression for the EasyFuse staples was over two times higher than that of the BME Elite staples.
- The present study also sought to replicate the study conducted by Safranski[1] as closely as possible allowing for a non-statistical comparison of the average value of the DynaClip staple (MedShape, Inc).
  - The Safranski study reported an average compressive force of 74 N for the DynaClip, which, while greater than the BME Elite staple, is almost 2 times less than EasyFuse (Figure 3).

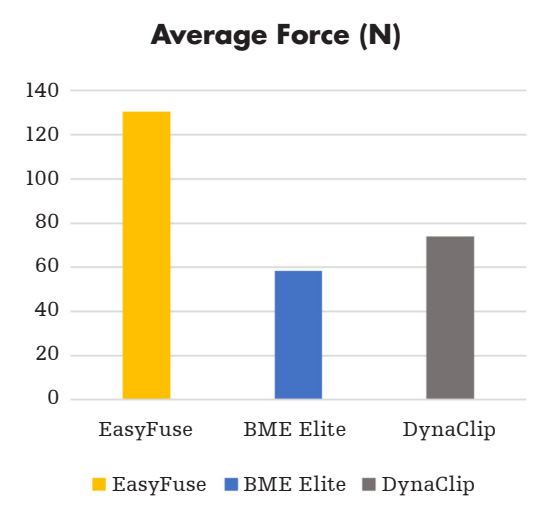


Figure 3. Comparison of Compressive Force for the EasyFuse, BME Elite and MEDSHAPE DynaClip

References:

1. Safranski, D. (2021). In Vitro Compressive Performance of MedShape DynaClip Bone Fixation System [White paper].
2. Shibuya et al. A Compression Force Comparison Study Among Three Staple Fixation Systems. American College of Foot and Ankle Surgeons, 2007; 46(1): 7-15.

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