Performance Comparison Between 4-Leg Nitinol Implants and 4-Hole Compression Plates

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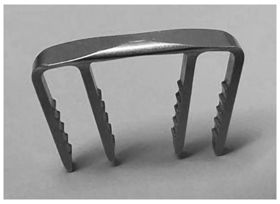
Introduction

Nitinol staple fixation has grown in popularity over the last several years. This is due, in part, to their ability to provide continuous active compression and dynamization along with their ease of use. The use of Nitinol staple fixation in high-load applications has been met with some resistance in the orthopaedic community. New designs, however, are trying to challenge the status quo.

Figure 1: 4-leg Nitinol implant.



A study was conducted to compare the compression, contact area, and rigidity of constructs utilizing a 4-leg straight Nitinol implant (Fig. 1) and one of the leading 4-hole compression plates. Our hypothesis was that there would be no significant difference between these two fixation methods with regard to the compression and biomechanical integrity of the construct.

Methods

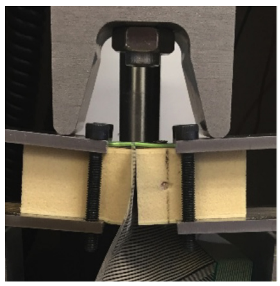
In this study, six 4-leg straight Nitinol implants (BME ELITE® Continuous Compression Implant EL-2520S4 with 25 mm bridge and 20 mm legs; BME, San Antonio, TX) and six 4-hole compression plates [Ortholoc® 3Di Midfoot Fusion Straight Plate; Wright Medical Technology, Inc. (WMT), Memphis, TN] were tested (Fig. 2).

Figure 2: BME Elite (top) and WMT plate (bottom).

The constructs were prepared from custom 25 mm x 25 mm bicortical Sawbones® blocks. The constructs consisted of two blocks of similar dimensions with each matching surface milled flat and sanded with 600 grit abrasive paper in order to obtain flat, smooth surfaces. The bone blocks were aligned and placed against each other in a vise with a pressure sensor (Tekscan®) placed between the bone blocks to obtain the compression force and contact area for each construct.

The hardware for each construct was placed using the pertinent manufacturer's technique. For the Nitinol implant group, each implant was inserted into predrilled holes for unicortical fixation. For the WMT plate group, each plate was centered on the bone blocks. A 2.7 mm x 24 mm locking screw was placed on the predrilled hole nearest the interface of the blocks on the side opposite the compression slot. A 2.7 mm x 24 mm nonlocking screw was then placed into the compression slot and compression was achieved after releasing the construct from the vise to allow free movement of the blocks. The remaining matching locking screws were then placed on the plate.

Figure 3: Construct with pressure film during 2 mm displacement of plate construct using 4-point bend apparatus.

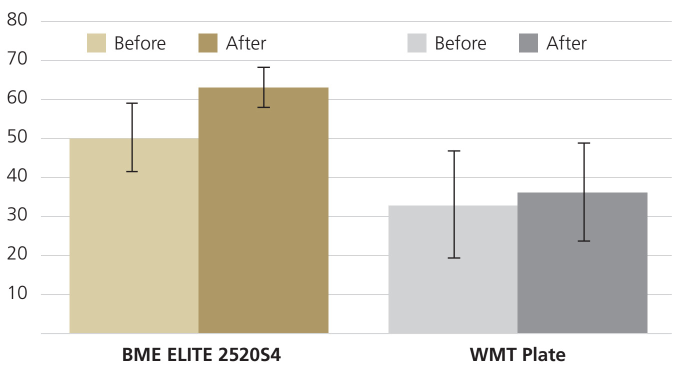


Pressure map readings were obtained on the constructs prior to and after cycling 100 times at 2 mm displacement using a 4-point bend apparatus (Fig. 3).

Results

After averaging each sample group, the results showed that the BME ELITE Implant group achieved a higher average compressive force than the 4-hole WMT plate group ($p<0.05$) before and after repetitive loading. Mean compression for the BME ELITE Implant group was 50.0N ± 8.8N before cycling and 62.7N ± 5.6N after cycling. The 4-hole WMT plate group achieved 32.6N ± 14.1N before cycling and 35.7N ± 12.8N after cycling. (Fig. 4).

Figure 4: Compression before and after repetitive loading (N) (100 cycles at 2 mm displacement).



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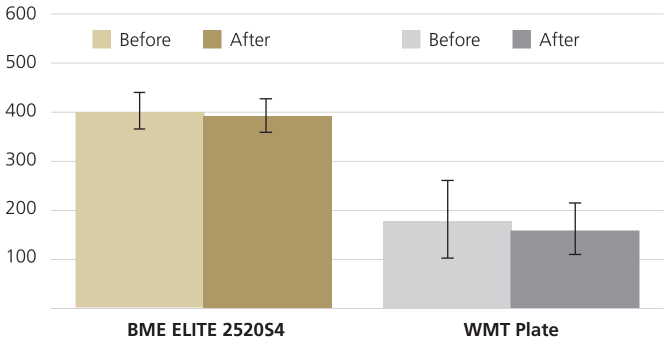
Testing materials and facilities provided by BioMedical Enterprises, Inc. (San Antonio, TX).

Results (continued)

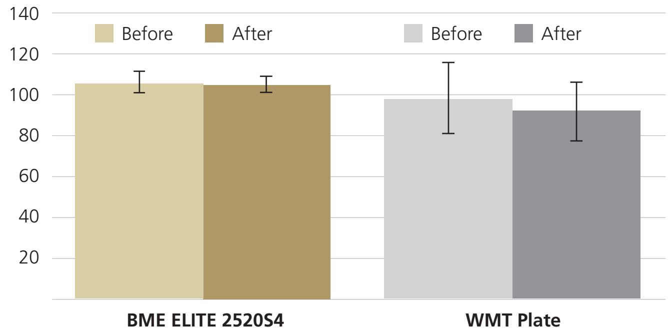
The contact area was determined by pressure map readings before and after repetitive loading. The results showed that the BME ELITE Implant group achieved a higher contact area than the 4-hole WMT plate group ($p<0.05$) before and after repetitive loading. Mean contact area for the BME ELITE Implant was 401 $mm^2 \pm 39.5$ mm^2 before cycling and 392 $mm^2 \pm 34.7$ mm^2 after cycling. The 4-hole WMT plates achieved 181 $mm^2 \pm 80.6$ mm^2 before cycling and 160 $mm^2 \pm 53.3$ mm^2 after cycling (Fig. 5).

Figure 5: Contact area before and after repetitive loading (mm^2) (100 cycles at 2 mm displacement).



The rigidity of the construct was determined by the peak load required to displace the construct 2 mm. Readings were taken during the 1st and 100th cycle. The results showed the differences in rigidity between the BME ELITE Implant and 4-hole WMT plate was not statistically significant at the 1st cycle ($p>0.05$) and was higher at the 100th cycle ($p<0.05$) (Fig. 6).

Figure 6: Construct rigidity at 1st and 100th cycles of repetitive loading (N) (2 mm displacement).



Conclusion

The BME ELITE Nitinol Implant provided significantly greater compression and contact area initially and after cycling, and higher rigidity to the leading 4-hole WMT plate after cycling.

Based on this biomechanical study, we believe that the BME ELITE Nitinol Implant is a viable alternative to the 4-hole WMT plate.

Note: Bench test results may not necessarily be indicative of clinical performance.

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