Two Parallel 4-Leg Nitinol Implants vs a 4-Hole Compression Plate With a Lag Screw

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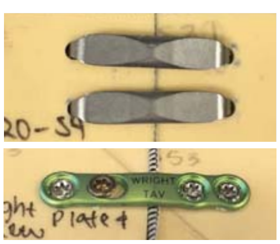
Introduction

A common fixation method, the use of a lag screw with a compression plate, is thought to increase the compression, contact area and rigidity of an arthrodesis site. A comparable fixation method using Nitinol implants is to place 2 implants parallel to each other. This is commonly seen in talonavicular (TN) joint arthrodeses, for example.

The purpose of this study was to compare the compression, contact area, and rigidity of constructs utilizing two 4-leg straight Nitinol implants in parallel (Figs. 1 and 2) and 1 leading 4-hole locking compression plate with a headed lag screw. Our hypothesis was that there would be no significant difference between these 2 fixation methods with regard to compression, contact area, and biomechanical integrity of the construct.

Figure 1: 4-leg Nitinol implant.

Figure 2: BME ELITE Implants (top) and WMT plate with lag screw (bottom).



Methods

In this study, 2 constructs were tested. The Nitinol implant construct featured two 4-leg Nitinol implants (BME ELITE® Continuous Compression Implants EL-2520S4 with 25 mm bridge and 20 mm legs; BME, San Antonio, TX) placed parallel to each other. The locking plate and lag screw construct featured a 4-hole compression plate (Ortholoc® 3Di Midfoot Fusion Straight Plate; Wright Medical Technology, Inc. (WMT), Memphis, TN) augmented by a lag screw (4.0 mm x 30 mm Darco® Headed Compression Screw; Wright Medical Technology, Inc., Memphis, TN).

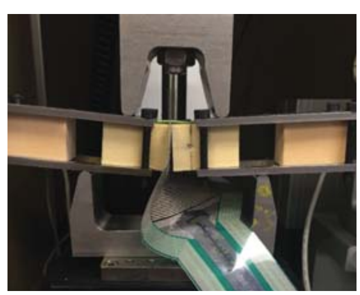
Six samples of each construct were prepared for testing from custom 25 mm x 25 mm bicortical Sawbones® blocks.

The constructs consisted of 2 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 implants, the implants were inserted into predrilled holes for unicortical fixation. For the locking plate with lag screw group, each plate was centered on the bone blocks. A 2.7 mm x 24 mm locking screw was placed on the 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 for free movement of the blocks. The lag screw was then placed bicortically across the bone blocks at an angle. The lag screw as well as the screw in the plate's compression slot was tightened to provide compression. The remaining matching locking screws were then placed on the plate.

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).

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



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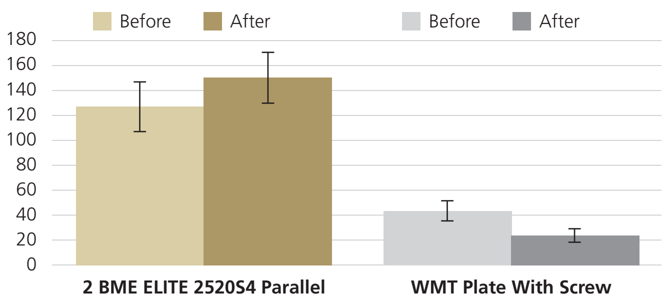
Results

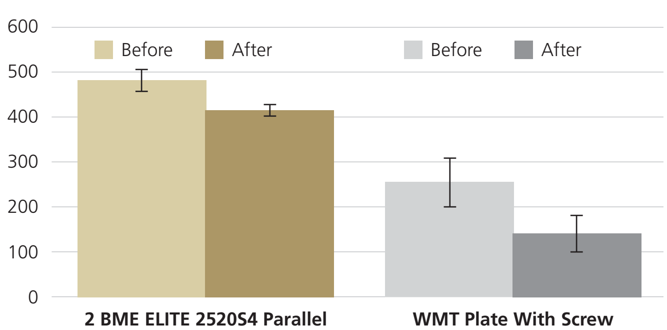
After averaging each sample group, the results showed that constructs using the 2 BME ELITE Implants in parallel achieved a significantly higher average compressive force than constructs fixed with the locking plate with lag screw ($p<0.05$) before and after repetitive loading. Mean compression for the BME ELITE Implant group was 127.5N ± 20.6N before cycling and increased to 150.5N ± 21.0N after cycling. The locking plate with lag screw group achieved 42.8N ± 8.3N before cycling and 24.1N ± 5.8N after cycling (Fig. 4).

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



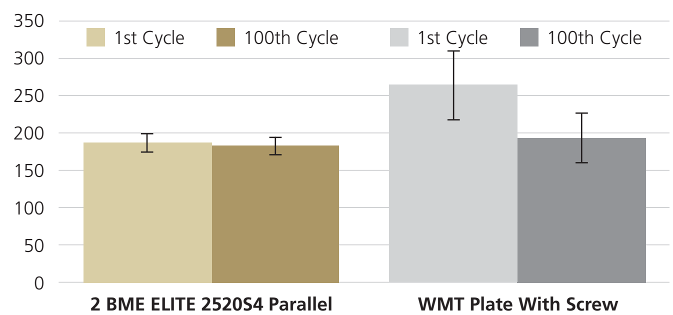
The contact area was determined by pressure map readings before and after repetitive loading. After averaging each sample group, the results showed that constructs using the BME ELITE Implant group achieved a significantly higher contact area than constructs fixed with the locking plate with lag screw ($p<0.05$) before and after repetitive loading. Mean contact area for the BME ELITE Implant group was 478 mm^2 ± 24 mm^2 before cycling and 412 mm^2 ± 12 mm^2 after cycling. The locking plate with lag screw group achieved 251 mm^2 ± 54 mm^2 before cycling and 139 mm^2 ± 40 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. After averaging each sample group, the results showed that the differences in construct rigidity between the 2 BME ELITE Implant group and the locking plate with lag screw group before and after cycling were not statistically significant ($p>0.05$). The locking plate with lag screw group had higher rigidity before cycling although this diminished with repetitive loading to a level similar to the Nitinol implant construct. Mean peak load for the BME ELITE Implant group was 190.3N ± 10.1N before cycling and 186.8N ± 9.0N after cycling. The locking plate with lag screw group achieved 264.8N ± 38.3N before cycling but decreased after cycling to 194.1N ± 28.7N (Fig. 6).

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



Conclusion

The 2 BME ELITE Implants placed parallel to each other provided significantly greater compression and contact area before and after repetitive loading, and similar rigidity to a leading 4-hole midfoot locking compression plate with lag screw after repetitive loading. The BME ELITE Implant constructs increased compression after cycling and maintained consistent rigidity throughout the loading cycles. In contrast, the plate with lag screw group achieved significantly lower initial compressive forces and contact area, which diminished further by cycling.

Based on this biomechanical study, we believe that the use of 2 BME ELITE Nitinol Implants in parallel is a viable alternative to the use of a 4-hole midfoot locking compression plate with a lag screw.

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

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