Torsional Comparison of Two Nitinol Implants, Two Crossing Screws and a Four-Hole Compression Plate With a Lag Screw

Don Petersen, PhD*; Lisa Actis, PhD**; Diana Castillo, BS***

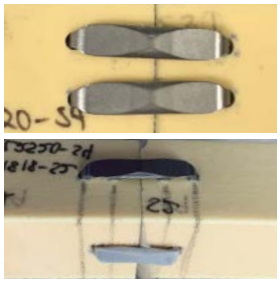
Introduction

A lag screw with a compression plate is a common fixation method used for midfoot fusion application. Alternatively, crossing screws are also used. The latest Nitinol implant designs are now offering options due, in part, to their improved rigidity along with continuous active compression and ease of use (Fig. 1). A comparable fixation method to a 4-hole compression plate with lag screw, as well as crossing screws, is the use of 2 Nitinol implants placed in parallel or perpendicular to each other.

The purpose of this study was to compare the torsional stability of constructs utilizing 2 Nitinol implants in parallel and perpendicular configurations, 1 leading 4-hole titanium locking compression plate with a headed lag screw, and 2 crossing screws. Our hypothesis was that there would be no significant difference between these 3 fixation methods with regard to torsion.

Figure 1: 2- and 4-leg Nitinol implants.

Figure 2: BME ELITE Implants in parallel (top) and perpendicular (bottom).

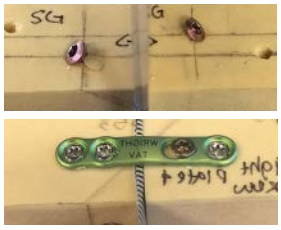


Methods

In this study, 4 constructs were tested. The Nitinol implant constructs featured two 4-leg straight Nitinol implants placed parallel to each other (BME ELITE® Continuous Compression Implant EL-2520S4 with 25 mm bridge and 20 mm legs; BME, San Antonio, TX) and one 4-leg straight Nitinol implant (EL-2420S4) placed perpendicular to a 2-leg Nitinol implant BME ELITE EL-1818S2 with 18 mm bridge and 18 mm legs) (Fig. 2).

The crossing screws construct featured 2 dorsally-placed screws (4.0 mm x 30 mm Darco® Headed Compression Screw; Wright Medical Technology, Inc., Memphis, TN). The locking plate with lag screw construct featured a 4-hole compression plate (Ortholoc® 3Di Straight Plate; Technology, Inc., Memphis, TN) augmented by a lag screw (4.0 mm x 30 mm Darco® Headed Compression Screw; Wright Medical Technology, Inc., Memphis, TN) (Fig. 3).

Figure 3: Crossing screws (top) and locking titanium midfoot compression plate with lag screw (bottom).



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. The hardware for each construct was placed using the pertinent manufacturer's technique. For the Nitinol implant construct groups, the implants were inserted into predrilled holes for unicortical fixation. For the crossing screws group, the 4.0 mm x 30 mm lag screws were placed dorsally on the block at opposing 45-degree angles to achieve bicortical purchase. 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 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.

Constructs were subjected to torsion repetitively 100 times to 15° at 3°/second using a Mark-10 device. Torque readings were obtained during the 1st and 100th cycle.

* Dr. Petersen is the Director of Research and Testing for BioMedical Enterprises, Inc. (BME), San Antonio, TX.

** Dr. Actis is a Research & Development Engineer for BME.

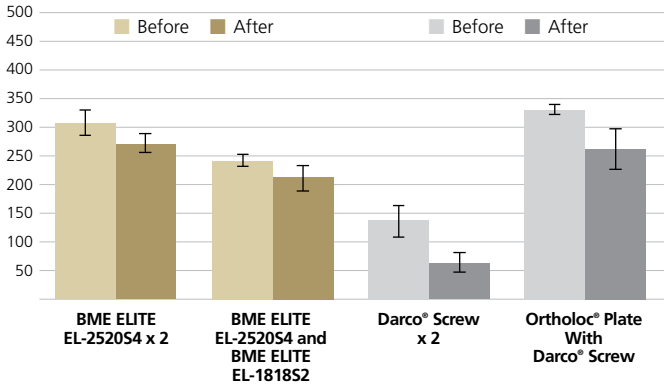
*** Ms. Castillo is a Research & Development Engineering Intern for BME.

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

Results

After averaging each sample group, the differences in torque between the 2 BME ELITE Implants perpendicular group and locking plate with lag screw group before and after cycling were not statistically significant ($p>0.05$). The same was seen between 2 BME ELITE Implants parallel group and locking plate with lag screw group. Mean torque for the BME ELITE Implants in parallel group was 307N·cm ± 22N·cm before cycling and 271N·cm ± 16N·cm after cycling. Mean torque for the crossing screws group was 139N·cm ± 30N·cm before cycling and 64N·cm ± 18N·cm after cycling. Mean torque for the BME ELITE Implants in perpendicular group was 241N·cm ± 12N·cm before cycling and 211N·cm ± 23N·cm after cycling. The locking plate with lag screw group achieved 331N·cm ± 9N·cm before cycling and diminished to 261N·cm ± 38N·cm after cycling (Fig. 4).

Figure 4: Torque stability (torsion) at 1st and 100th cycle (N·cm) (100 cycles at 15° displacement).



Conclusion

With respect to torsion, we believe that the use of 2 BME ELITE Nitinol Implants is a viable alternative to the use of a 4-hole midfoot locking compression plate with lag screw as well as crossing screws.

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

DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Manufactured or distributed by:
Synthes USA Products, LLC
1302 Wrights Lane East
West Chester, PA 19380

Synthes USA, LLC
1101 Synthes Avenue
Monument, CO 80132

To order (USA): 800-523-0322
To order (Canada): 855-946-8999

Note: For recognized manufacturer, refer to the product label.

www.depuysynthes.com

DSUS/TRM/0916/1072 5/17 DV