Nitinol Implant Fixation: Effect of Cortical Bone Troughing on Construct Compression and Stability

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Introduction

One challenge with Nitinol staple fixation is the prominence of the device on the bone in certain applications. This may cause soft tissue irritation and impingement as well as intra-articular prominence such as between the radius and lunate in a midcarpal partial wrist fusion. To overcome this, staples sometimes require a small trough in order to recess the implant, a practice more commonly performed in the hand and wrist. However, since two important factors in achieving bone fusions are compression and construct stability, it is important to understand the effects of troughing.

The purpose of this study was to determine the effects of troughing on compression construct stiffness and construct strength. Our hypothesis was that there would be no difference between troughing and no troughing with regard to the biomechanical integrity of the construct.

Methods

Three different sizes of Nitinol bone implants (SPEED™ Continuous Compression Implant, BME, San Antonio, TX) were used in this study. The bridge and leg lengths for each of these implants are provided in Table 1.

Table 1: Implant dimensions.

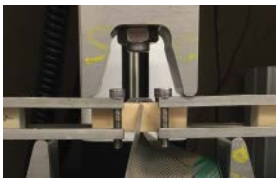
Implant	Bridge Length	Leg Length
11 mm x 10 mm	11 mm	10 mm
13 mm x 15 mm x 13 mm	13 mm	13 mm and 15 mm
15 mm x 12 mm	15 mm	12 mm

The constructs were prepared from custom 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 15 mm wide with various heights that matched the implant leg length to simulate bicortical implant insertion (Table 1).

The bone blocks were aligned and placed against each other. The appropriate sized drill guides were used to drill holes for the implant legs. For the No Trough group, the implants were inserted into the drill holes so that the bottom of the implant bridge was against the bone surface.

Figure 1: No Trough (top) and Trough (bottom) constructs.

Figure 2: Four-point bending with installed pressure maps.



For the Trough samples, prior to inserting the implants, a rongeur was used to create a trough in each construct approximately 2 mm deep. The trough allowed the implant bridge to sit flush with the top surface of the bone block (Fig. 1).

To obtain the compression force for each construct, pressure sensors (Tekscan®) were placed between the bone blocks.

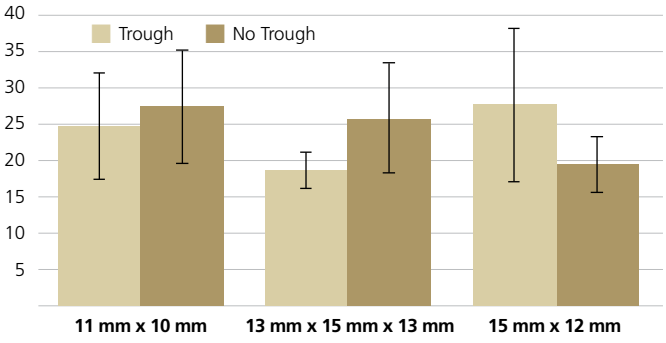
The stiffness and ultimate bend strength of the constructs were tested using a 4-point bend apparatus (Fig. 2).

Results

After averaging each sample group, the results showed that the differences in compression between the Trough and No Trough groups for 11 mm x 10 mm and 13 mm x 15 mm x 13 mm implants was not statistically significant ($p>0.05$). The 11 mm x 10 mm Trough group averaged 24.8N ± 7.4N and the No Trough group averaged 27.5N ± 7.7N. The 13 mm x 15 mm x 13 mm Trough Group averaged 18.7N ± 2.5N and the No Trough group averaged 25.9N ± 7.6N.

For the 15 mm x 12 mm group, the No Trough group showed higher compressive forces (27.6N ± 10.7N) than the Trough group (19.5N ± 3.9N) ($p>0.05$). (Fig. 3).

Figure 3: Compression (N).



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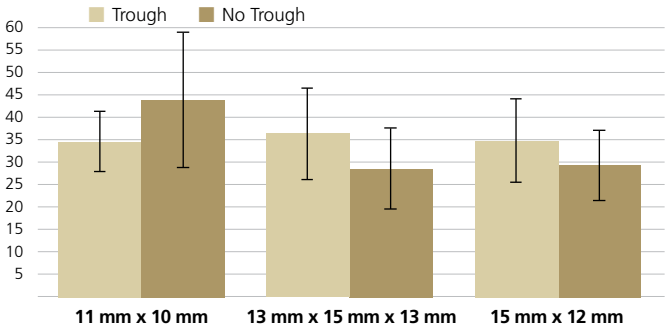
Testing materials and facilities provided by BioMedical Enterprises, Inc. (San Antonio, TX).

Results (continued)

The stability of the construct was determined by testing in 4-point bend. The differences in bending stiffness between the Trough and No Trough groups were not statistically significant (p>0.05) (Fig. 4).

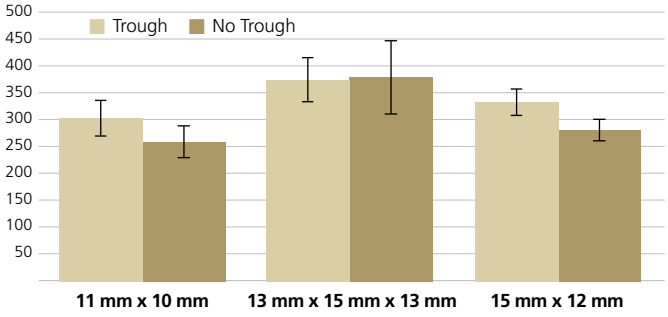
Figure 4: Bending stiffness (N/mm).



The results showed the Trough 11 mm x 10 mm and 15 mm x 12 mm implant groups to have higher bending strength compared to the respective No Trough 11 mm x 10 mm and 15 mm x 12 mm implant groups (p<0.05).

The differences in bending strength between the Trough and No Trough 13 mm x 15 mm x 13 mm groups were not statistically significant (p>0.05) (Fig. 5).

Figure 5: Bending strength (N/mm).



Conclusion

The creation of a trough in the cortical layer does not affect the compressive force, bending stiffness, and ultimate bend strength of a Nitinol implant. In addition, the creation of a trough results in constructs with similar or better bend stiffness and ultimate bend strength than constructs without troughs.

Mechanical testing supports the creation of a trough when needed to recess the implants, potentially lowering the risk of hardware prominence in hand and wrist surgery. Through the creation of a trough, surgeons can safely minimize implant profile without compromising biomechanical integrity.

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

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