Extension of Compression Beyond the Tips of the Legs of Nitinol Bone Fixation Implants

R. Glenn Gaston, MD* and Steve K. Lee, MD**

Introduction

Some common forms of small bone fixation, such as cortical screws, achieve fixation of fragments through bicortical purchase. These products are generally offered in a variety of lengths, often in 2 mm increments, in order to capture the far cortex. Nitinol implant manufacturers, in contrast, generally offer a select number of leg lengths in their inventory with the idea that bicortical fixation may not be necessary in order to achieve far cortex compression.

The purpose of this study was to determine if compression occurs beyond the tips of the legs of Nitinol implants, and if so, to establish the effective leg length (leg length plus extension of compression beyond the tips of the legs) of the implants tested in order to provide more accurate recommendations pertaining to implant selection. Our hypothesis was that there would be compression extending beyond the tips of the legs of Nitinol implants.

Methods

Three different sizes of Nitinol bone implants (BME SPEED™ Implants SE-1110, SE-131513, SE-1512; 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

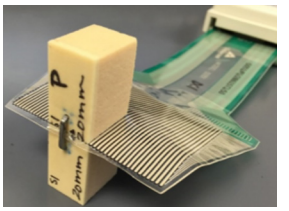
Four constructs for each size implant were prepared from unicortical Sawbones® blocks that were 15 mm wide x 20 mm long x 20 mm deep with each matching surface milled flat and sanded with 600 grit abrasive paper in order to obtain flat, smooth surfaces.

The bone blocks were aligned and placed against each other. The appropriate sized drill guides were used to drill holes for the implant legs on the cortical end of the blocks. The implants were then inserted into the drill holes.

For the purpose of this study, troughs were not created between the drill holes.

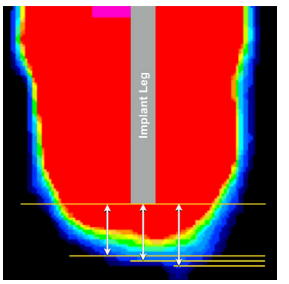
To obtain the pressure map for each construct, pressure sensors (Tekscan®) were placed between the bone blocks (Fig. 1).

Figure 1: Testing construct.



A scaled representation of the implant leg was then superimposed over the pressure map image. An image analysis program (ImageJ) was used with the test samples to identify the compression distance at three different points between the tip of the implant leg to the end of the compression force reading (Fig. 2).

Figure 2: Pressure map analysis.



These readings were averaged to establish the extension of compression beyond the tip of the leg for each sample. The addition of this extension to the implant leg length established the effective leg length of the implant.

Results

After averaging each sample group, the results showed that the 11 mm x 10 mm implant group achieved an average extension of 2.5 mm ± 0.9 mm and the 15 mm x 12 mm implant group had an average of 3.8 mm ± 1.0 mm extension. The 13 mm x 15 mm x 13 mm implant group had an average extension of 2.4 mm ± 1.0 mm when the shorter 13 mm leg was taken into account. Percent extension for each implant group was determined using the following formula: (extension/leg length) x 100, where extension is the average compression measured beyond the tip of the leg. The average percent extension was then determined by averaging the percent extensions for each implant group (Table 2).

Table 2: Extension beyond tips of legs (mm).

Implant	Compression Beyond Tip	Percent Extension	Standard Deviation
11 mm x 10 mm	2.5 mm	25%	0.4
13 mm x 15 mm x 13 mm†	2.4 mm	19%	1.0
15 mm x 12 mm	3.8 mm	32%	1.1
Average	**2.9 mm**	**25%**	

†Shortest leg.

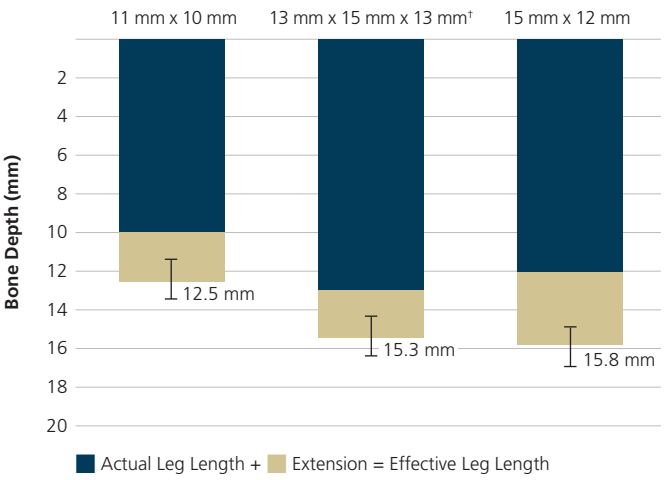
*OrthoCarolina, Charlotte, NC.

**Hospital for Special Surgery (HSS), NY, NY; Weill Medical College of Cornell University. Testing materials and facilities provided by BioMedical Enterprises, Inc. (San Antonio, TX).

Results (continued)

By adding the actual leg length to the average extension, the effective leg length of each implant was determined. The 11 mm x 10 mm implant group had an average effective leg length of 12.5 mm while the 13 mm x 15 mm x 13 mm and 15 mm x 12 mm implant groups had effective leg lengths of 15.3 mm and 15.8 mm, respectively (Fig. 3).

Figure 3: Effective Leg Length (mm).



†Shortest leg.

Conclusion

For the 11 mm x 10 mm and 15 mm x 12 mm implants, it was determined that compression extended beyond the tips of both legs. On average, each of these implants provided compression to 12.5 mm ± 0.9 mm and 15.8 mm ± 1.0 mm of depth, respectively.

For the 13 mm x 15 mm x 13 mm implant, compression extended beyond the tip of the shorter of the two legs. This implant provided compression to an average of 15.4 mm ± 1.0 mm of depth, which corresponds to the approximate length of the longer leg. Clinically, this implant is appropriate for the fusion of two bones of different depths where the depth of the shortest bone does not exceed 15 mm. Table 3 describes the recommended bone depths for each implant tested.

Table 3: Recommended bone depths for each implant tested.

Implant Dimensions	Effective Leg Length	Approximate Appropriate Bone Depths
11 mm x 10 mm	12.5 mm	10 mm-12 mm
13 mm x 15 mm x 13 mm	15.4 mm	13 mm-15 mm
15 mm x 12 mm	15.8 mm	12 mm-16 mm

Based on this study on Sawbones constructs, we recommend using the Nitinol implant with legs that most closely match the depth of the bones being fused. However, if the legs are within 2.4 mm from the far cortex, bicortical fixation may not be necessary to achieve far cortex compression. Finally, this study does not take into account the effects of creating a trough to recess the implants on the depth of compression.

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 GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland

To order (USA): 800-523-0322
To order (Canada): 844-243-4321

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

www.depuysynthes.com

173653-210413 DSUS

Please also refer to the package insert(s) or other labeling associated with the devices identified in this white paper for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this white paper may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.