DynaNite™ Nitinol Staple Exhibits 51% More Compressive Force Compared to DePuy SPEED™* Compression Implant in a Lapidus Sawbones Model

Arthrex Research and Development

Objective

The purpose of this study is to compare the compressive forces and the contact area generated by Nitinol staples in a repeatable 1st tarsometatarsal arthrodesis Lapidus procedure. This study compares the DynaNite Nitinol staple 20 mm x 20 mm and the DePuy SPEED compression implant 20 mm x 20 mm using pressure-mapping sensors.

Methods and Materials

Twelve (12) Sawbones forefoot models (#1122; Pacific Research Laboratories Inc) of the left foot were used in this study. These solid polyurethane foam models are identical in shape, have a uniform density and compressive modulus, and provide an anatomically relevant comparison. The models were randomly assigned to one of the two groups (n = 6 per group). Each model was marked with a line down the midaxis of the cuneiform and first metatarsal; models were also marked with 2 dots just above and 2 dots just below the midaxis line. These markings were made in order to establish appropriate alignment of the cuneiform and 1st metatarsal in the sagittal, coronal, and transverse planes (Figure 1). A band saw was then used to cut the models across the 1st metatarsocuneiform joint in order to simulate a Lapidus procedure. Surfaces on either side of the 1st metatarsocuneiform joint were lightly sanded with sandpaper (150 grit) to ensure direct contact between the joint surfaces and the pressure-mapping sensor. All additional metatarsals in the sawbones model were removed to prevent interference with the pressure-mapping sensor inserted between the 1st metatarsocuneiform joint.

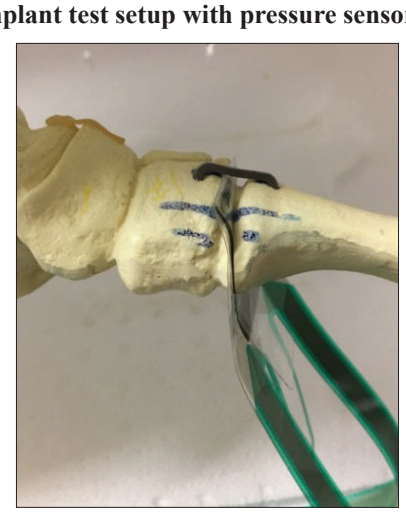
A pressure-mapping system (I-Scan™, Evolution™ DAQ Handle IE1, Pressure Mapping Sensor 5033; Tekscan, Inc) was calibrated with a tensile testing frame (MTS Systems Corp) prior to testing. In order to simulate body temperature conditions, the solid polyurethane foam forefoot models were placed in a chamber heated to 37°C prior to, during, and postinsertion of staples into the models. The pressure sensor was zeroed prior to testing and inserted between the cuneiform and the first metatarsal in the metatarsocuneiform joint. The metatarsal was then held in a reduced position against the cuneiform. A second operator delivered the implants into the anatomical models according to the DynaNite staple and SPEED implant directions for use, respectively (Figure 2). Drilling and insertion of the implants into the models was carried out using the respective instrumentation provided by each manufacturer; instrumentation for both manufacturers included: drill guide, drill bit, alignment pins, implant preloaded on inserter, and tamp (Arthrex: AR-8719DS-2020; DePuy: SE-2020).

In both groups, implants were aligned in a repeatable manner by orienting the center of the drill guide with the joint plane, and were aligned with the 2 markings above the midaxis line. Implants that were not set flush to the surface were pressed flush to the cortical surface of the sawbones model manually or with the provided tamp.

Figure 1. **Preparation of composite bone anatomical model**

Sawbones forefoot model cut along 1st metatarsocuneiform joint to replicate a Lapidus procedure. Cuneiform and 1st metatarsal were marked prior to cutting for alignment purposes.

Figure 2. **Implant test setup with pressure sensor**



Forefoot bone stimulation model showing placement of pressure sensor to measure compressive force of implant. Note: Excess metatarsals removed from models.

*SPEED is a trademark of DePuy Synthes.

Compressive force and contact area as measured by the sensor were recorded 10 minutes postinsertion to ensure temperature equilibration within the heating chamber. Contact area was defined as the amount of surface area at the metatarsocuneiform joint that received compressive force from the implant. Steps were taken to ensure that the pressure sensor window was not bent or distorted in any way, and that surfaces were minimized.

Compressive force tests were performed using this methodology on six (n = 6) 20 mm x 20 mm DynaNite Nitinol compression staples, and six (n = 6) 20 mm x 20 mm SPEED compression implants. Following data collection, a *t* test was performed to determine if the 2 sets of staples differed significantly in compressive force and contact area, respectively.

Table 1. **Average Compression Force and Contact Area[2]**

Implant	*Compressive Force [N] Avg. ± Std. Dev.*	*Contact Area [mm²] Avg. ± Std. Dev.*
DynaNite Nitinol Compression Staple, 20 mm x 20 mm	135.67 ± 27.91	144.50 ± 40.96
SPEED Compression Implant, 20 mm x 20 mm	89.93 ± 9.37	104.67 ± 20.68

Results

The average compressive force and average contact area for each of the 2 manufacturers' products are presented in Table 1, and also illustrated in Figures 3 and 4, respectively. The results of the *t* test indicated that the compressive force generated by the DynaNite Nitinol staple was significantly greater than that of the SPEED compression implant, with 95% confidence ($P = .0034$). A second *t* test indicated no significant difference in contact area between the 2 implants, with 95% confidence ($P = .0594$).

Figure 3. **Average compressive force[2]**

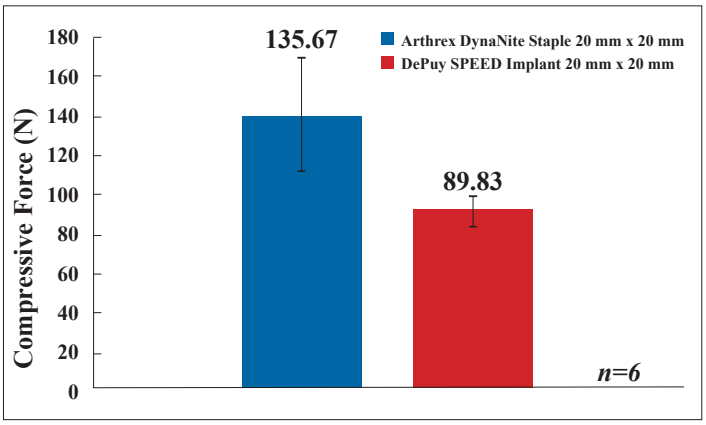
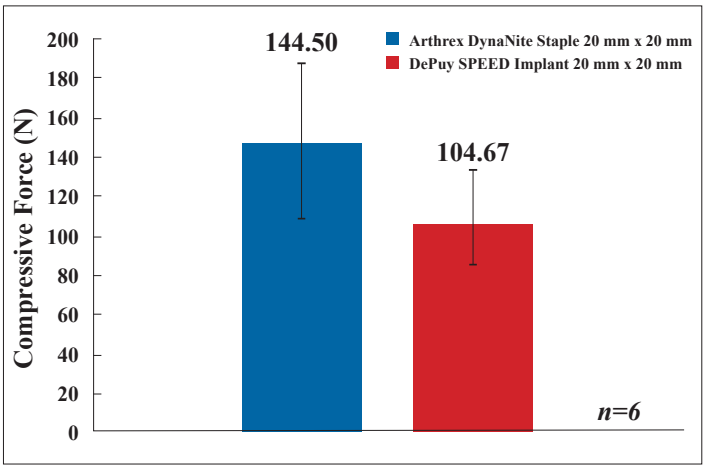


Figure 4. **Average contact area[2]**



Conclusion

The DynaNite Nitinol staple generates 51% more compressive force than the DePuy Synthes SPEED compression implant of a similar size when measured in a sawbones Lapidus procedure model.

References

1. Russell NA, Regazzola G, Aiyer A, et al. Evaluation of Nitinol staples for the Lapidus arthrodesis in a reproducible biomechanical model. *Front Surg*. 2015;2:65. doi:10.3389/fsurg.2015.00065.

2. Arthrex, Inc. Data on file (APT 3322). Naples, FL;2017