The Impact of Nitinol Staples on the Compressive Forces, Contact Area and Mechanical Properties in Comparison to a Claw Plate for the Lapidus Arthrodesis

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Introduction: Adequate compression across an arthrodesis interface in the foot and ankle leads to primary bone healing. Fixation constructs that minimize micromotion and maintain contact may limit the risk of fibrous nonunion. Stainless steel and Ti alloys are established materials but have a limited elastic zone, whereas Nitinol exhibits a unique super-elastic property. Nitinol staples can provide dynamic compression across the interface compared to the static nature of plates. This study develop a reproducible 1st tarsometatarsal (TMT) arthrodesis (Lapidus) model to characterize the biomechanical and interface properties of constructs using Nitinol staples compared to a compression plate.

Methods: Fifteen sawbone models of the left foot were divided into three groups (5 per group). Each model was cut at the level of the first TMT to simulate removal of the articular surface. The TMT was provisionally fixed using K-wires, before the arthrodesis was performed. In group 1, the models were implanted with one dorsally placed Nitinol staple (Speed Titan (SE-2020-Ti), BME, San Antonio, TX). In group 2, the models were implanted with one dorsally placed Nitinol staple (Speed (SE-2020) and one dorsomedially placed Nitinol staple (Speed (SE-1518). In group 3, the models were implanted with a dorsomedially placed claw plate (Wright Medical Technology, Arlington, TN). A calibrated pressure sensor (model 4000, TekScan, Boston, MA) was placed between the joint surfaces and the constructs equilibrated to 37oC. A time zero reading was taken for calculation of the initial contact force and area. The constructs were tested using a custom four-point bending jig at 1mm/minute to 1mm, 2mm and 3mm displacements. The peak load, stiffness and energy were evaluated. Pressure film measurements were taken following each of the 1mm and 2mm tests to assess the ability of the reconstruction technique to restore the contact footprint. For the 3mm test, digital photographs were taken every 6 seconds for evaluation of plantar gapping. Gapping was evaluated using an in-house Matlab subroutine. Data was analyzed using a one way ANOVA with Games-Howell post-hoc test.

Results: The mechanical results showed no statistical difference between groups in terms of peak load, stiffness and energy at 1 and 2mm of displacement. At 3mm, there was a significant increase in the peak load (p=0.002) and energy (p=0.017) of the two staple constructs compared to the single staple group. No statistical difference was observed between the claw plate and the two Nitinol staple constructs. The pressure sensor results showed a significantly greater (p<0.05) contact force and contact area in both staple groups compared to the claw plate group at time zero, following 1mm and following 2mm of displacement (figure 1). The addition of the second dorsomedial staple increased both the contact force and area compared to the single staple construct for all measurements; though statistical significance
was only reached for contact force (p=0.05) following 1mm of displacement. Both the one and two Nitinol staple constructs maintained joint contact after 2mm displacement, with statistically insignificant reductions in contact force and contact area compared to their time zero values of 1.5% and 17% for the single staple group, and 4% and 12% for the two staple group, respectively.

There was significantly (p<0.005) less plantar gapping in the staple groups compared the claw plate group at 1mm, 2mm and 3mm of displacement (figure 3). Importantly, the staple groups completely recovered their plantar gap following unloading while there was a significant 5.3mm gap remaining in the claw plate group (p<0.001). The addition of a dorsomedial staple reduced plantar gapping in group 2 compared to group1 at all displacements, but only reached statistical significance at 3mm (p=0.036).

**Discussion:** The biomechanical properties, contact area, contact force, footprint, gapping and recovery from loading all play an important role in the success of any arthrodesis. Other factors of equal importance include surgical technique, rehabilitation, patient related parameters as well as cost. While biomechanical properties (load, stiffness and energy) of the three groups examined were similar, significant findings were revealed in terms of contact area, contact force and gapping. The contact footprints (force and area) were superior for the Nitinol staple groups compared to the Claw Plate. The additional of a dorsomedial staple did not alter the contact area but increased the contact force distribution (figure 1). Both one and two Nitinol staple constructs had significantly less plantar gapping compared to the Claw Plate (p<0.05) and fully recovered after unloading (figure 2) reestablishing the joint contact (figure 1).

The use of Nitinol staples as an inter-fragmentary compressive adjunct could ultimately enable more rapid weight bearing, without compromising mechanical stability or biological viability of the arthrodesis.

**Significance:** The use of Nitinol staples for Lapidus arthrodesis significantly reduces plantar gaping compared to the Claw plate and fully recovers the joint contact footprint after unloading.
Figure 1. Pressure sensor output showing a representative contact footprint for each group at time zero, and following the 1 and 2mm tests.
Figure 2. Digital photographs showing the plantar gapping of each group following the 2mm test, at 3mm displacement and following unloading.

Figure 3. A comparison of the plantar gapping in each group at different axial displacements; * denotes statistical significance compared to the 1 and 2 staple groups at p<0.05; † denotes statistical significance compared to the 2 staple group at p<0.05; & denotes a zero value.

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