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

Abstract: Background. The optimal fixation method for the first tarsometatarsal arthrodesis remains controversial. This study aimed to develop a reproducible first tarsometatarsal testing model to evaluate the biomechanical performance of different reconstruction techniques. Methods. Crossed screws or a claw plate were compared with a single or double shape memory alloy staple configuration in 20 Sawbones models. Constructs were mechanically tested in 4-point bending to 1, 2, and 3 mm of plantar displacement. The joint contact force and area were measured at time zero, and following 1 and 2 mm of bending. Peak load, stiffness, and plantar gapping were determined. Results. Both staple configurations induced a significantly greater contact force and area across the arthrodesis than the crossed screw and claw plate constructs at all measurements. The staple constructs completely recovered their plantar gapping following each test. The claw plate generated the least contact force and area at the joint interface and had significantly greater plantar gapping than all other constructs. The crossed screw constructs were significantly stiffer and had significantly less plantar gapping than the other constructs, but this gapping was not recoverable. Conclusions. Crossed screw fixation provides a rigid arthrodesis with limited compression whereas staples provide an alternate method of fixation as well as material for stabilization of the osteotomy site.

DOI: 10.1177/1938640015620655. From the Institute for Foot and Ankle, Mercy Medical Centre, Baltimore, Maryland (AA, MM); and Surgical and Orthopaedic Research Laboratories, University of New South Wales, Randwick, New South Wales, Australia (NAR, MHP, WRW). Address correspondence to William R. Walsh, PhD, Surgical and Orthopaedic Research Laboratories, University of New South Wales, Level 1 Clinical Sciences Building, Prince of Wales Hospital, Avoca Street, Randwick, New South Wales 2031. Australia; e-mail: w.walsh@unsw.edu.au.

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and contact footprint across the joint. Shape memory alloy staples afford dynamic fixation with sustained compression across the arthrodesis. A rigid polyurethane foam model provides an anatomically relevant comparison for evaluating the interface between different fixation techniques. Clinical Relevance. The dynamic nature of shape memory alloy staples offers the potential to permit early weight bearing and could be a useful adjunctive device to impart compression across an arthrodesis of the first tarsometatarsal joint.

Level of Evidence: Therapeutic, Level V: Bench testing

Keywords: biomechanical; Lapidus; nitinol; sawbone; staple

The Lapidus procedure and its modifications include an arthrodesis of the first metatarsal cuneiform joint introduced in 1934. The original description by Lapidus included stabilization of the first to the second metatarsal, and while this procedure remains necessary for certain deformities, more commonly a modified Lapidus procedure is performed that includes only the arthrodesis at the base of the first tarsometatarsal (TMT) joint.

Although the Lapidus procedure was originally described for the treatment of patients with metatarsus primus varus, the indications for this first metatarsocuneiform (first TMT) arthrodesis have evolved. This procedure has been used with clinical success for addressing hallux valgus deformities, arthritis, for adolescent bunions, hypermobility of the first ray, and in the revision setting. Myerson et al retropsectively evaluated 63 patients who underwent a Lapidus procedure and reported that 77% of patients were totally relieved with regard to pain, comfort, foot appearance, and shoe wear postoperatively. A more recent prospective study evaluated the clinical outcome of the Lapidus procedures, noting significant improvements in pain scores and American Orthopaedic Foot and Ankle Society forefoot scores. The choice of optimal mechanical fixation constructs for the Lapidus procedure remains controversial.

This study investigated the effects of different reconstruction techniques for first TMT arthrodesis in an anatomically relevant testing model. Traditional fixation methods using screws and plates were compared to different SMA staple configurations. The null hypothesis was that all reconstruction techniques would perform the same. The primary aim of the study was to develop a reproducible biomechanical testing model for evaluating mechanical rigidity and joint coaptation following first TMT arthrodesis with different fixation. Biomechanical testing in 4-point bending was performed to characterize the mechanical properties of the repaired constructs and to evaluate the plantar gapping, pressure distribution at the interface, and the ability to recover from loading.

Materials and Methods

Sawbones full foot models (#1131, Pacific Research Laboratories, Inc, Vashon Island WA) were used. These solid polyurethane foam models have a compressive modulus of 250.3 ± 41.6MPa and provide an anatomically relevant comparison. Twenty identical models were randomly assigned to 1 of 4 treatment groups (n = 5 per group; Table 1). A sample size of n = 5 per group was based on a pre hoc power calculation to detect a 25% difference with α at .05 and β at .75. A bandsaw was used to isolate the first TMT and allow for consistent placement during testing. Implant alignment in the sagittal, coronal, and transverse planes was controlled by marking a line down the midaxis of the cuneiform and the first metatarsal, 2 dots just below the line on the cuneiform and the metatarsal, and 2 dots on the nail plate (Figure 1).

Construct Preparation

Nitinol Shape Memory Alloy Staples. In groups 1 and 2, the dorsal SMA staples were placed approximately 5 mm from
the intercuneiform/intermetatarsal joints. Given the dorsal staples were 20 mm in length, a calibrated caliper was used to ensure that the legs of the staple were 10 mm from the joint surface. A drill guide and 2.65 mm drill was used for the staples. The osteotomy was created using a bandsaw to detach the first metatarsal from the cuneiform. Sandpaper (120 grit) was used to smooth the edges of the cut. Using the alignment markings, the metatarsal was held in a reduced position against the cuneiform. The staple was inserted and disengaged from the deployment device. In group 2, the drill guide was offset 5 mm proximally to prevent interference with the legs of the first staple and accommodate the second medial staple (Figure 2).

**Crossed Screws.** Using the alignment markings, the metatarsal was held in a reduced position against the cuneiform. A point was measured 5 mm from the intermediate cuneiform joint and 15 mm from first TMT joint (in line with the midaxis of the first MT in the coronal plane). A second point was measured on the first MT 15 mm from first TMT (in line with the midaxis of first MT), then marked 3 mm medial to this point. Kirschner wires were placed across the joint. The wire from the cuneiform ran from dorsoproximal/medial to plantar-distal/medial. The wire from the metatarsal ran from dorsodistal/medial to plantar-proximal/lateral. A 2.7 mm screw was used to secure the alignment, and the osteotomy was closed with a 3-0 absorbable suture (Figure 2).

<table>
<thead>
<tr>
<th>Test Group</th>
<th>Sample Size</th>
<th>Implants</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>Single BME SPEED staple (SE-2020TI, BioMedical Enterprises, San Antonio, TX)</td>
<td>Dorsal</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>Two BME SPEED staples (SE-2020 and SE-1518, BioMedical Enterprises, San Antonio, TX)</td>
<td>One dorsal, one medial and slightly plantar</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>Crossed cannulated lag screw (4.0 × 40 and 4.0 × 32 mm, Synthes, West Chester, PA)</td>
<td>Crossed configuration from proximal dorsal to distal plantar</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>Compression plate (Claw II 2-hole, 20 mm with 2.7 × 20 mm screws, Wright Medical Technology, Memphis, TN)</td>
<td>Dorsal</td>
</tr>
</tbody>
</table>
A cannulated drill bit was used to create a path for the screw. Cannulated, partially threaded screws were then placed over the guide wires. A 40 mm screw was placed form the metatarsal into the cuneiform and a 34 mm screw was placed from the cuneiform into the metatarsal (Figure 2).

**Claw Plate.** Similar to group 3, the metatarsal was held in a reduced position against the cuneiform using 1 mm diameter stainless steel Kirschner wires. The claw plate was applied to the dorsomedial aspect of the joint, 5 mm from the intercuneiform and intermetatarsal joints. The center of the plate was positioned over the joint. A 2.0 mm drill bit was used to create paths for the locking screws placed within the plate. After the locking screws (2.7 × 20 mm) were placed, the compression device was applied to the center of the plate based on the manufacturer’s technique guide (Figure 2).

**Testing Protocol**

A summary of the testing protocol utilized in this study is outlined in Table 2.

**Contact Force and Area.** Prior to mechanical testing, a calibrated pressure sensor (model 4000, TekScan, South Boston, MA) was placed between the joint surfaces of each construct. Each sensor was calibrated as per the manufacturer’s specifications by incrementally loading the sensor using a calibrated servo hydraulic testing machine. Samples were then equilibrated at 37°C in a temperature-controlled incubator with austenitic phase transformation noted by an increase in contact force as temperature increased. Crossed screw constructs required an alternative sensor setup as the screws would otherwise penetrate the sensor. Two sensors were used, one inserted medially and one laterally with a 4 mm gap to accommodate the screws. A time zero reading was taken for calculation of the initial contact force and area. The pressure film was subsequently kept in between the joint interface for a 1 and 2 mm mechanical test, with measurements taken following each test to assess the ability of the reconstruction technique to restore the contact footprint.

**Mechanical Testing.** The constructs were tested in 4-point bending using a calibrated servo hydraulic testing machine (MTS 858 Bionix, Eden Prairie, MN) with adjustable loading platens to ensure uniform loading. Each construct was placed on the jig with the osteotomy centered between the central loading platens and loaded dorsally to 1, 2, and 3 mm of actuator displacement at a rate of 1 mm/min. These displacements were chosen to simulate different levels of loading and induce plantar gapping to ≈3 mm, which has been used previously as a failure criteria.\(^{15,17,18}\) Peak load and stiffness were calculated from the load-displacement output. A hair dryer provided a constant heat source to ensure the SMA staples remained activated during each test to 37°C. Temperature was confirmed using an infrared thermal imaging camera (thermoIMAGER TIM 160, Micro-Epsilon, Germany).

**Plantar Gapping.** For the 3 mm mechanical test, the pressure sensors were removed from the joint interface and digital photographs of the osteotomy were taken every 6 seconds for the duration of the test. Plantar gapping was evaluated by measuring the distance between the distal edges of the joint interface using an in-house Matlab subroutine (Matlab R2014a, Natick, MA). Gapping values were determined prior to loading, at 1 mm, 2 mm, and 3 mm of actuator displacement, and following unloading to determine the recovery of each construct. Additionally, gapping results were correlated with the load output to a give load versus gapping plot.

**Statistical Analysis.** Statistical analyses were performed using SPSS for Windows (IBM SPSS Statistics 22, New York, NY). An analysis of variance with post hoc Tukey test was used to compare the mechanical testing outcomes, pressure
sensor readings, and plantar gapping results between groups. Similarly, changes in the time zero contact force and contact area following the 1 and 2 mm displacements were compared within groups. Any difference with the $P$ value < .05 was considered to be significant.

**Results**

**Contact Force and Area**

The different reconstruction techniques used in this study resulted in substantially different contact footprints at the joint interface. There was a significantly greater ($P < .05$) contact force and contact area in both SMA staple groups compared to the claw plate and crossed screw groups at time zero, following 1 mm and 2 mm of displacement (Figures 3 and 4). The time zero contact force of the double staple constructs was 4.5 times greater than the crossed screws and 10.5 times greater than the claw plates. Following the 2 mm test, these disparities increased to 8.2 times and 18.6 times, respectively. Similarly large differences were also observed for contact area.

The addition of the second dorsomedial SMA staple significantly ($P < .01$) increased the interfragmentary contact force compared to the single SMA staple alone at all measurements. Interfragmentary contact area also increased between the SMA staple groups, though this was not statistically significant.

Both the single and double SMA staple constructs maintained joint contact after 2 mm 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 double staple group, respectively. Correspondingly, the contact force and contact area of the crossed screw constructs both decreased by 48%, though this did not reach statistical significance. There was a significant ($P = .049$) 57% reduction in contact area in the claw plate group following 2 mm displacement.

![Figure 3.](image1.png)

Interfragmentary contact force in each construct at time zero, post 1 mm displacement, and post 2 mm displacement. *Denotes statistical significance compared to the double staple group at $P < .01$; *Denotes statistical significance compared to both staple groups at $P < .05$.

![Figure 4.](image2.png)

Interfragmentary contact area in each construct at time zero, post 1 mm displacement, and post 2 mm displacement. *Denotes statistical significance compared to both staple groups at $P < .01$. 
No device pullout (staple or screw) was noted during mechanical testing. The 4-point bending results showed that the crossed screw configuration was the most rigid construct with a significantly ($P < .001$) greater peak load and stiffness at all displacements compared to both SMA staple groups and the claw plate group (Table 3). At 1 and 2 mm of displacement there was no significant difference in either peak load or stiffness between the SMA staple groups and the claw plate group, or between the single and double staple groups. (Table 4).

### Table 3.

Four-Point Bending Results for Peak Load and Stiffness at 1 mm, 2 mm, and 3 mm of Actuator Displacement.

<table>
<thead>
<tr>
<th>Group</th>
<th>Test Displacement (mm)</th>
<th>Peak Force (N)</th>
<th></th>
<th>Stiffness (N/mm)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>176.60</td>
<td>34.42</td>
<td>206.78</td>
<td>50.87</td>
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<tr>
<td></td>
<td>2</td>
<td>337.82</td>
<td>54.98</td>
<td>220.20</td>
<td>46.66</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>501.78</td>
<td>36.28</td>
<td>214.20</td>
<td>35.45</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>203.83</td>
<td>36.39</td>
<td>226.24</td>
<td>21.70</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>415.66</td>
<td>44.19</td>
<td>260.87</td>
<td>45.70</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>610.64</td>
<td>27.89</td>
<td>262.79</td>
<td>26.34</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>334.89*</td>
<td>34.35</td>
<td>347.85*</td>
<td>52.37</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>703.76*</td>
<td>105.89</td>
<td>434.59*</td>
<td>80.95</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>1030.94*</td>
<td>378.15</td>
<td>439.73*</td>
<td>81.57</td>
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<tr>
<td>4</td>
<td>1</td>
<td>176.74</td>
<td>41.69</td>
<td>184.47</td>
<td>31.68</td>
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<tr>
<td></td>
<td>2</td>
<td>392.77</td>
<td>53.12</td>
<td>223.02</td>
<td>43.58</td>
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<tr>
<td></td>
<td>3</td>
<td>531.85</td>
<td>70.79</td>
<td>233.08</td>
<td>27.53</td>
</tr>
</tbody>
</table>

*Denotes a statistically significant increase compared to groups 1, 2, and 4 at $P < .001$. 

### Table 4.

Plantar Gapping Results for Each Group Following the 2 mm Test, at 1, 2, and 3 mm of Displacement, and the Recovery Following Unloading.

<table>
<thead>
<tr>
<th>Displacement</th>
<th>Single Staple</th>
<th>Double Staple</th>
<th>Crossed Screw</th>
<th>Claw Plate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>1 mm</td>
<td>0.95</td>
<td>0.18</td>
<td>0.69</td>
<td>0.33</td>
</tr>
<tr>
<td>2 mm</td>
<td>2.58^</td>
<td>0.32</td>
<td>1.91</td>
<td>0.79</td>
</tr>
<tr>
<td>3 mm</td>
<td>4.62^</td>
<td>0.54</td>
<td>3.29^</td>
<td>0.93</td>
</tr>
<tr>
<td>Recovery</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

*Denotes a significant increase in plantar gapping compared to all other groups at $P < .01$. ^Denotes a significant increase in plantar gapping compared to the crossed screw group at $P < .05$. 

### Mechanical Testing

Crossed screw configuration was the most rigid construct with a significantly ($P < .001$) greater peak load and stiffness at all displacements compared to both SMA staple groups and the claw plate group (Table 3). At 1 and 2 mm of displacement there was no significant difference in either peak load or stiffness between the SMA staple groups and the claw plate group, or between the single and double staple groups.
SMA staple configurations. At 3 mm of displacement, there was a 21% and 22% increase in the peak load and stiffness of the double staple group compared to the single staple, respectively, though these changes did not reach statistical significance ($P = .07$ and $P = .09$).

**Plantar Gapping and Recovery**

The dynamic nature of the SMA staples was evident in the complete recovery of the plantar gap in both the single and double staple groups following the 2 mm mechanical test (Table 4).

Correspondingly, there was a nonrecoverable plantar gap of 0.11 mm in the crossed screw group and 0.96 mm in the claw plate group, which was statistically significant ($P < .01$). Following the 3 mm test a similar trend was observed, with both SMA staple groups completely recovering their plantar gap following unloading (Figure 5). Conversely, there was a permanent plantar gap in the crossed screw group and claw plate group, which increased to 0.72 mm and 5.3 mm ($P < .001$), respectively. The nonrecoverable gapping in the crossed screw and claw plate groups was a result of plastic deformation of the fixation hardware rather than fixation failure with the Sawbones models.

Comparison of the screw and staple groups showed that the crossed screw constructs had the least plantar gapping on loading compared to both SMA staple groups at all displacements (Figure 6). This difference was greatest at 3 mm of displacement, with a significantly smaller plantar gap of 1.7 mm in the crossed screw group compared to 4.6 mm ($P < .001$) and 3.2 mm ($P = .015$) in the single and double staple groups, respectively. The addition of the dorsomedial staple reduced plantar gapping in the double staple group compared to the single staple group at all displacements, but only reached statistical significance at 3 mm ($P = .027$).

**Discussion**

Biomechanical studies of the first TMT arthrodesis report a wide range of techniques and devices. The optimal biomechanical construct remains controversial, reflected in the wide range of techniques and hardware options. Our in vitro study evaluated the biomechanical characteristics of different fixation techniques using SMA staples, cross screw cancellous fixation, and a claw plate. The ability of each construct to maintain the joint contact footprint and to resist and recover from plantar gapping was assessed. A standardized anatomical model was chosen to control variables related to anatomical variations (size, bone quality, density) and implant sizes. Variations in bone density and size as well as hardware between samples would only serve to increase the scatter of the data and result in larger samples sizes to obtain a statistically meaningful result. The polyurethane model is not meant to replicate the properties of human bone but does provide a uniform model to control variables. The osteotomy represents an ideal interface to evaluate the contact area and force. The nondestructive testing and lack of any hardware pull-out or cut through supports the use of this type of anatomical model for comparison.

Many factors can be considered when determining the “best” fixation method.
Load versus plantar gapping for each group; values are the mean of the 5 samples in each group.

![Graph showing Load vs Plantar Gapping](image)

Repair stiffness and compression are perhaps the most important factors determining the success.\(^{20}\) This includes the ability to stabilize bony fragments, resist and recover plantar gapping, and provide adequate contact area and pressure at the interface to facilitate fusion. While the cross screw fixation provided the greatest rigidity in 4-point bending, the inability to recover from plantar gapping and minimal contact footprint and pressure distribution are limiting. SMA staples and claw plate fixation provided similar biomechanical properties. SMA staple groups offered the unique ability to provide a large contact area and contact force across the osteotomy site, as well as full recovery from plantar gapping. These constructs may have the ability to adapt to subtle changes that occur in vivo such as gapping and resorption. Finally, the double staple configuration imparts multiplanar resistance to gapping, providing improved stability to the arthrodesis which may facilitate earlier weight bearing postoperatively.

The results of the current study have important clinical implications. Although not as stiff as crossed screws, nitinol SMA staples create a larger contact footprint and generate more contact force in comparison to the other constructs in this study. More important, the contact area was maintained in the staple groups even after loading. Rethnam et al\(^{22}\) reported this dynamic ability when comparing the bending and torsional properties of SMA staples and regular compression staples. Shibuya et al\(^{23}\) took this a step further assessing the compression force generated across a simulated osteotomy by SMA staples and compression staples. The SMA staples consistently generated the greatest, most uniform compression, and maintained it for 12 hours.

Whether these results translate to improved clinical outcomes is yet to be determined. Mallette et al\(^{25}\) retrospectively evaluated the fusion rates of 36 Lapidus procedures performed using nitinol staples in a delta configuration. Strict non-weight bearing was prescribed for the first 6 weeks postoperatively. The incidence of nonunion was 8.3%, which is comparable to what has been reported in the literature for crossed screw procedures.\(^{3,6,10,24,25}\) Choudhary et al\(^{26}\) reported a fusion rate of 96.7% at 8.2 weeks in a prospective clinical evaluation of 30 first metatarsophalangeal joint arthrodeses using 2 nitinol staples. Patients were permitted to weight bear in a rigid shoe immediately following surgery. Taken together with the results of the present study, these findings are suggestive that SMA staples could be used to help start early weight bearing after a Lapidus arthrodesis. This is even more pertinent as the staples used in the present study were a more advanced design, allowing greater rigidity and compression than those reported in the Mallette\(^{23}\) and Choudhary\(^{24}\) studies. However, further clinical studies would be required in order to support this assertion.

Claw plates are designed to allow for a surgeon-mediated compression to be applied to the plate, which is intended to impart a compressive force across the joint and thereby improve the fusion rate compared to standard plates. The current study showed that interfragmentary forces induced by the claw plate were significantly lower than staple constructs. Plantar gapping was greater compared to all other constructs, with no recovery following unloading. These results compare favorably with a matched-pair cadaveric of Baxter et al\(^{16}\) where they compared the plantar gapping induced in crossed screw constructs and claw plate constructs after 1000 cycles of 4-point bending. They reported a significant (\(P = .006\)) 3-fold decrease in plantar gapping in the crossed screw constructs compared to the claw plate constructs. While not directly comparable, Cohen et al\(^{18}\) also reported a significant increase in stiffness in crossed screw constructs compared to H-locking plates. They suggested that the locking plate was inferior because it did not induce compression or friction across the arthrodesis site. These poor results...
reflect the inability of the claw plate to provide an initial compression and resist dorsal bending without the aid of adjunctive hardware.

This study aimed to develop a reproducible means to evaluate different reconstruction techniques for arthrodesis of the first TMT joint. Anatomically identical Sawbones models controlled anatomical variations and reduced sample sizes. These models are polyurethane not bone and lack the native soft tissues making direct clinical comparisons limited. The model is reflective of only one anatomy that does not take into consideration variations associated with anatomical size and change in bone density. Furthermore, the presence of the screw(s) required a slightly different sensor arrangement, resulting in a small area of the footprint that could not be assessed in the crossed screw group. However, despite these limitations, the Sawbones samples provide a reproducible model for direct comparison of different reconstruction techniques of the arthrodesis. Considering the biomechanical results obtained in the current study collectively provides a unique insight into the positive and negative aspects of different fixation constructs.

Authors’ Note

Sawbones models and implants were provided by Biomedical Enterprises (San Antonio, Texas).

References


