Nitinol Staple Fixation of Clavicle Fractures Results in a More Flexible Construct than Plating

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Introduction

Midshaft clavicle fractures are often reconstructed with plates and screws, but these implants

cause poor cosmesis and irritation, which may result in a second surgery for hardware removal.[1] This has driven the need for innovation in clavicle fixation, including the use of smaller 2.7 mm plates.[2,3] However, these techniques have not definitively shown improvements in hardware related complication rates.[4] Thus, areas of possible improvement remain in the operative management of these fractures. Continuous compression implants (CCIs) fabricated with shape memory alloys, such as Nitinol, provide an attractive alternative to plate and screw fixation, due to their low profile and ability to provide compression at the fracture site. The use of CCIs gained traction in foot and ankle reconstructions[5], but the technology has not yet been tested in the milieu of clavicular fixation. We hypothesized that CCI-based reconstructions would decrease resistance to external loads compared to plate and screw fixation.

Methods

This study was performed with 36 synthetic and 12 matched pairs of fresh-frozen, osteopenia-confirmed cadaveric clavicles (8F, 4M, 80 ± 8 years old). The synthetic study consisted of four reconstruction techniques: a single superiorly-placed staple (SS; n = 6), a single anteroinferiorly-placed staple (AS; n = 6), a 3.5 mm reconstruction plate (PLT; n = 12), and two Nitinol staples placed orthogonally to each other (2S; n = 12) (Fig 1). The cadaveric study examined three reconstruction techniques: PLT (n = 8), 2S (n=8), and a new group with a 2.7 mm reconstruction plate placed combined with a Nitinol staple (PLT+SS; n = 8) (Fig 1). All specimens underwent non-destructive 4-point bending (loading in superior-inferior direction, 2 mm deflections) and axial torsion tests (+/−10°) for 10 cycles each. Half of each group was then subjected to either a 3-point cantilever bend to failure (0.5mm/s), or cyclic failure under increasing torsion (+0.1 Nm/cycle) until implant breakage or bending exceeding 30 mm. Groups were evaluated for normality and equal variance and compared using one-way ANOVAs ($p < 0.05$).

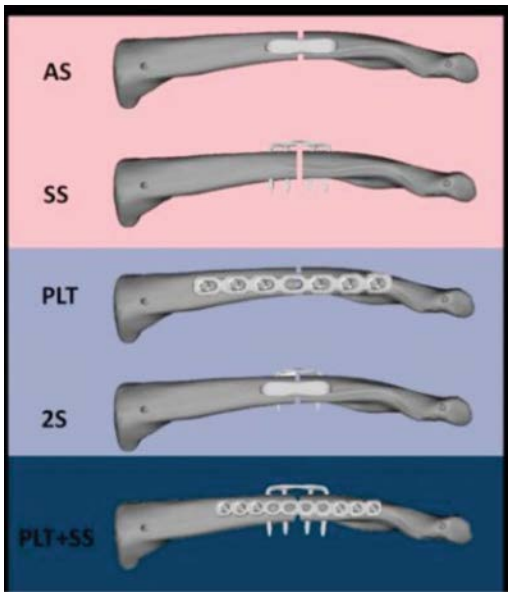


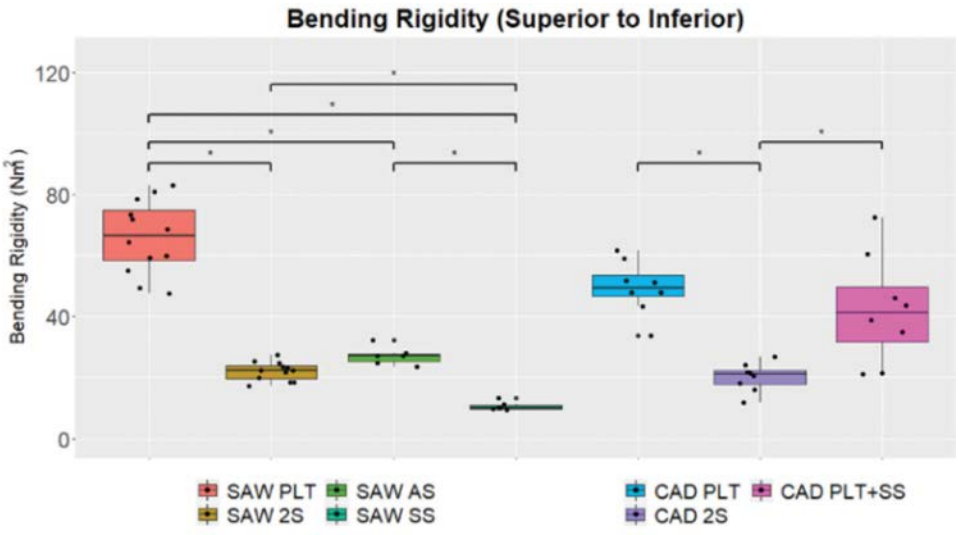
Figure 1. Clavicle fixation techniques examined in this study. Groups highlighted in pink were tested with synthetic bones, groups highlighted in blue were tested in cadaveric specimens. Purple represents overlap of synthetic and cadaveric test groups.

Results

In comparison to plated groups, the single-staple and double-staple groups demonstrated significantly decreased resistance to bending and torsion. For example, the synthetic and cadaveric PLT group exhibited significantly higher bending rigidity than all other groups in superior-inferior 4-pt bending ($p < 0.001$), except for the cadaveric PLT+SS group (Fig 2). In cantilever failure tests, the failure mode for PLT and AS groups was bending > 30mm, while all other groups exhibited catastrophic bone fractures primarily at the medial-most components of the implants. In destructive torsional testing, failure modes for cadaveric specimens were primarily due to implant tear-out (75%). (Fig 3A,C). Synthetic bone specimens primarily failed via implant breakage (67%) (Fig 3B, D).

Discussion

In accordance with our hypothesis, the use of Nitinol staples resulted in reconstructions that were significantly less stiff than those created with plates and screws. Single staples provided inadequate construct stiffness in non-destructive and destructive tests and are not currently indicated for stand-alone use in



p-values			
PLT vs 2S	<0.001	PLT vs 2S	<0.001
PLT vs AS	<0.001	PLT vs PLT+SS	0.241
PLT vs SS	<0.001	2S vs PLT+SS	0.002
2S vs AS	0.181		
2S vs SS	0.008		
AS vs SS	0.002		

Figure 2. Results from non-destructive 4pt bend tests on Sawbones (SAW) and cadaveric (CAD) specimens.

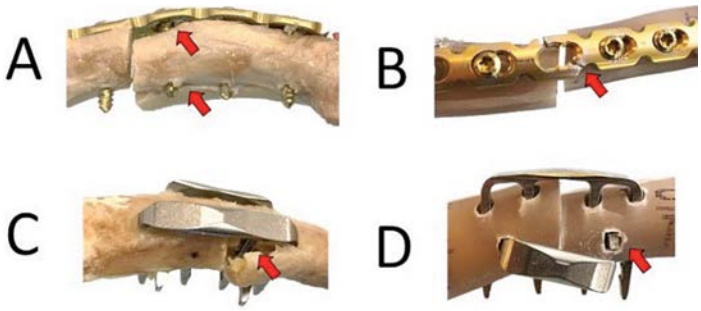


Figure 3. Differences in failure modes for cadaveric and synthetic specimens for the PLT and 2S groups.

the clavicle or in osteoporotic bone. However, the lack of permanent deformation of constructs during non-destructive cadaveric testing suggests that CCI fixation—particularly for configurations reinforced by an additional staple or plate—may provide adequate relative stability while the patients is in rehabilitation and protected from large ranges of motion and high external loads. Strikingly, the synthetic models produced failure mechanisms that were completely different from the cadaveric specimens, suggesting that plastic models are poor surrogates in these mechanical tests.

Significant/Clinical Relevance

Clavicle fracture fixation continues to be a challenging clinical problem, and improving fixation while minimizing cosmesis and irritation is a worthwhile clinical endeavor. This study also highlights the need for better synthetic bone analogs, especially for osteoporotic bone.

Acknowledgements

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