Can the Shape Memory Properties of Nitinol Implants be Used in Interbody Containment Spinal Applications?

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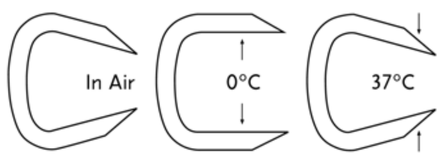
Introduction: Direct lateral interbody fusion (DLIF) procedures use anterior support (e.g. a structural interbody spacer) in the lumbar spine implanted from the side of the patient and typically use additional posterior fixation (e.g. pedicle screws and rods). As with any interbody procedure, intervertebral disc must be removed to create a pathway to place the structural spacer. Some physicians may choose to use an anti-backout device because there is potential for the spacer to expulse through its insertion location. A Nitinol staple is currently on the market with a spinal indication as supplemental fixation for anteriorly placed bone screws because it provides additional pullout resistance. This pullout resistance could be useful in interbody containment. The staple's pullout resistance is due to the material properties of Nitinol, a shape memory alloy. The staple is first cooled to bring the Nitinol to its martensitic phase. Next the staple tines are manually spread open (Figure 1, center).

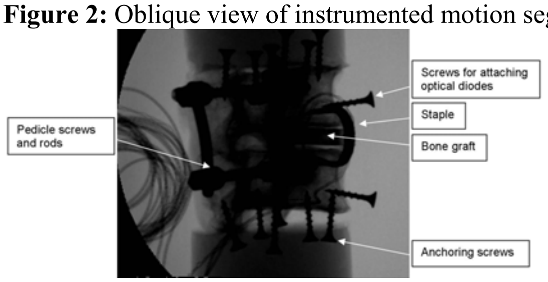
Figure 1: Nitinol staple at various temperatures.



Then the staple is impacted into bone over the void where the structural spacer was inserted. As the staple warms to body temperature, the Nitinol transitions to its austenitic phase and the staple tines attempt to return to their original shape (Figure 1, right) inside the bone, which creates pullout resistance. One concern with using the device in this manner is the amount of load shared by the device during anatomical motions. The hypothesis for this study was that the staple would share a minimal amount (< 10%) of the load in flexion-extension (FE), lateral bending (LB), and axial torsion (AT).

Materials and Methods: Six potted lumbar cadaveric motion segments (L1-L2, L2-L3, or L3-L4) were implanted laterally with a bone graft and either an 8mm or 14mm Nitinol staple, and posteriorly with 5.5 mm diameter Ti alloy pedicle screws and rods (Figure 2).

Figure 2: Oblique view of instrumented motion segment.



Strain gauges were affixed to four sides of the staple and were configured in three signal channels to capture strain under FE, LB and AT. Each motion segment was tested in pure moment in FE, LB, and AT to 7.5 Nm. Three test states were evaluated: intact; fully-instrumented (graft, staple, and pedicle screws/rods), and stand-alone (no graft or pedicle screws/rods). The amount of load shared by the staple was calculated by taking the ratio of the strain seen on the staple during the stand-alone state to the strain measured during the fully-instrumented state. A major challenge during this testing was how to heat the staple to body temperature and maintain it for the duration of the test. For a number of reasons, it was concluded that the best way to achieve uniform heating on the construct was to close off the lab and heat the entire room to 37°C.

Results: In all of the fully-instrumented tests, the staple maintained its position in the vertebral bodies. Four tests (three 8mm staple specimens and one 14mm specimen) produced conclusive strain results (Table 1).

Table 1: Unadjusted Load Share Percentages.

	8mm Staple	14mm Staple
Flexion-Extension (FE)	15±14%	20%
Lateral Bending (LB)	13±8%	23%
Axial Torsion (AT)	11±9%	6%

However, the ratio of strain shared by the staple was much higher than expected. It was discerned after testing was completed that the stand-alone specimens were evaluated with both the anterior and posterior longitudinal ligaments intact. Other posterior element structures, such as facet capsules, facet joints, ligamentum flavum, supraspinous and interspinous ligaments, were also kept intact during testing of the stand-alone state. Studies have shown that these structures have substantial contributions to the overall loading of the functional spine unit. FE data from Doehring et al. show that the posterior elements share 66% of the load. Adams et al. showed that in AT posterior structures share 63% of the load. Adjusting the original FE and AT load share values accordingly, these load share values fall well below 10% (Table 2).

Table 2: Estimated True Load Share Percentages.
*Unadjusted Percentages.

	8mm Staple	14mm Staple
Flexion-Extension (FE)	5.2±4.8%	6.8%
Lateral Bending (LB)	13±8%*	23%*
Axial Torsion (AT)	4.1±3.3%	2.2%

To the authors' knowledge, no study has been performed examining posterior contribution in LB, but the posterior elements would be expected to share a portion of the load in LB as well.

Conclusions: A staple made of the shape memory alloy Nitinol was able to maintain its position during biomechanical testing when placed as a graft containment device. Furthermore, when the contributions of the posterior elements were considered (when possible), the amount of load shared by the staple was minimal. In conclusion, the shape memory properties of the staple were deemed useful to the containment of interbody devices.

References:

[1] Doehring et al. Poster, 47th Annual Meeting of ORS.
[2] Adams, et al. Spine 6(3): 241-248, 1981.