A Pseudoelastic Approach to Sustain Compression in Bone Fractures and Fusions in Response to Bone Resorption

Christopher M. Yakacki PhD[1,2], Ken Gall PhD[1-3], Ravi Patel[1,3], Douglas Dirschl MD[4], Douglas Pacaccio DPM[1,5].
[1]Research and Development, MedShape Solutions Inc, Atlanta, GA 30318
[2]School of Materials Science and Engineering, The Georgia Institute of Technology, Atlanta, GA 30332
[3]George Woodruff School of Mechanical Engineering, The Georgia Institute of Technology, Atlanta, GA 30332
[4]Department of Orthopaedics, University of North Carolina, Chapel Hill, NC 27599
[5]Advanced Foot and Ankle Surgeons Inc, Yorkville, IL 60560

Statement of Purpose: Stability is created when two bone surfaces are brought into contact with each other and is generally required for bone healing to occur in many fractures and fusions. Medical devices such as intramedullary (IM) nails, screws, and external fixators provide stability to bone surfaces by applying compression across the site of repair. Bone loss mechanisms, such as several cell layers of resorption, can be detrimental to the bone-device interface by experiencing a rapid and severe loss of compression and subsequently stability.(*1*) Previous studies have suggested that current compressive IM nails and screws are inherently incapable of sustaining compression in response to bone loss mechanisms. (*2, 3*) External fixators are capable of adjustments over the course of healing to sustain compression but are marked with a high degree of surgical complexity, pin tract infections, and poor patient compliance.(*4*) Pseudoelastic materials, such as Nickel Titanium (NiTi) are a class of smart materials that are able to exhibit and recover large-strain deformations and may offer the solution to sustain compression. Therefore, the purpose of this study was to investigate and compare the compressive capabilities of IM nails and external fixators to a new approach of using pseudoelastic materials to sustain compression.

Methods: Two compressive IM nails (PantaNail, Integra, Plainsboro, NJ and VersaNail, DePuy, Warsaw, IN), two external fixators (Ace-Fischer external fixator, DePuy and True/Lok, Encore, Austin, TX) were tested against a prototype IM utilizing a stretched element of NiTi to connect the screws to the body of the nail. The devices were initially tested in a synthetic bone construct. A load cell and adjustable parallel plate mechanism to simulate resorption were placed within the construct to measure the compressive forces of the devices as a function of installation and bone resorption. Tests were repeated in cadaveric bone to represent an ankle fusion for the PantaNail, True/Lok, and prototype pseudoelastic device.

Results: The pseudoelastic IM nail generated 893N of compressive force during the stretching and releasing of the NiTi element in synthetic bone. These forces were within the ranges of the IM nails (301 – 775N) and external fixators (1,170 – 1,248N) upon installation. In cadaveric bone, the pseudoelastic nail generated 806N of compression compared to the PantaNail (897N) and True/Lok (1,188N). The response of the devices tested can be seen in Figure 1, which shows compressive load as a function of bone resorption. The compressive loads for all the commercially available IM nails tested in both synthetic and cadaveric bone reduced dramatically when resorption was applied to the construct. Over 90% of the starting compressive loads were lost in less than 1 mm of resorption. On average, the external fixators could maintain 90% of their load for ~15mm. The pseudoelastic NiTi-based nail showed a dramatic difference from the standard Titanium-based nails. The compressive load was maintained for ~6.5 mm of bone resorption. During resorption, the compressive load of the pseudoelastic nail reached a plateau after the first 1 mm of resorption.

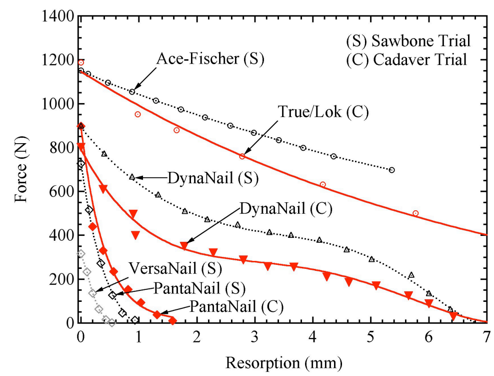

Figure 1. Compressive force as a function of simulated bone resorption for 2 IM nails, 2 external fixators, and 1 pseudoelastic prototype nail utilizing a NiTi.

It should be noted that external fixators typically would be adjusted to account for loss of compression due to bone resorption; however, the purpose of this testing illustrated their capacity to sustain compression over large displacements.

Conclusions: A prototype device demonstrated *in vitro* that pseudoelastic materials could be utilized in high force orthopedic applications to treat fusions and fractures. The pseudoelasticity of NiTi was shown to be capable of sustaining compressive loads across a joint for over 6 mm of bone resorption. The addition of NiTi allowed the prototype IM nail to more efficiently store and recover large strain deformations, which better enabled sustained compression. Future studies should investigate the amount of resorption experienced *in vivo* as a function of dynamic, and pseudoelastic fixation mechanisms.

References:

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