The Need for Sustained Compression in Ankle Fixation Devices

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Introduction
Tibio-talo-calcaneal (TTC) arthrodesis is a salvage procedure for patients with severe malfunction of the ankle and subtalar joints. Serious ankle disease stems from post-traumatic arthritis, idiopathic osteo-arthritis, rheumatoid arthritis, Charcot arthropathy, talar osteonecrosis, or failed arthroplasty, which can lead to severe pain and deformity.

Patients with severe ankle disease may face limited salvage options including fusion and at times, amputation. Diabetic patients who undergo amputation experience a significantly shorter life expectancy. Consequently, ankle arthrodesis is preferred by patients and specialists.

Non-union rates reported for TTC fusion have ranged from 11% to 65% in the published literature. While many factors affect bone union, there is a general agreement that secure fixation and compression is desirable and directly relates to bone fusion.

The purpose of this study was to characterize the delivery and sustainability of the compressive forces of internal and external fixation devices in response to simulated bone resorption.

Methods
Two compression IM nails and two external fixateurs were tested: the PantaNail (Newdeal/Integra) and the VersaNail (DePuy), an Ace-Fischer external fixator (DePuy), denoted as “ExFix”, with a medium foot frame (8180-04-11), medium connecting rods (FA-10000-2), and 2 sets of medium 1/3 and 2/3 rings (FC-10031/32) was tested with 1.8 mm olive wires. A True/Lok (Encore) external fixator was also tested with the same model olive wires. Finally, a prototype dynamic IM nail was manufactured using a nickel-titanium (Ni-Ti) wire to further sustain compression.

Testing was performed initially using synthetic bone blocks and then verified using three cadaveric specimens. Figure 1 illustrates the test setup in the cadaveric model. A screw-driven parallel plate mechanism was used to simulate resorption while a donut load cell was used to monitor the forces.

Results
A summary of the forces during hardware/-implant installation and hardware removal can be seen in Figure 2. For the IM nails, the PantaNail instrumentation was able to apply 1898 N of compression in the sawbone model compared to 219 N of compression by the VersaNail. Therefore, the PantaNail was selected for testing in the cadaveric ankle; however, it only generated 1050 N of compression due to relaxation (viscoplasticity) and yielding of the real bone. All IM nail testing showed a decrease in load when the instrumentation was removed. The PantaNail was able to retain 735 and 920 N of compression in synthetic and cadaveric constructs, respectively.

The compressive forces of the devices as a function of resorption can be seen in Figure 3. The commercial IM nails tested showed over a 90% drop in compression force with 1 mm of resorption, whereas the external fixateurs maintained over 50% of their compression forces with 5 mm of resorption. Lastly, the prototype NiTi-Nail was able to sustain nearly 50% of its compression force with 4 mm of resorption.

Discussion
Compression is important for the stabilization of a fracture or fusion site and provides a driving force for local bone healing. Compression is also one of two key elements necessary to prevent non-union of a bone in healing according to AO/ASIF principles. Compression, either through external or internal fixation, provides stability between the bone ends, which has been shown to promote "direct" or "primary bone healing".1-3

Fig. 1: Test setup for IM nail and external fixateur testing. The parallel resorption plate and load cell are shown at the distal portion of the tibia.

Fig. 2: Loads during hardware and device installation.

Fig. 3: Compressive loads as a function of resorption.

All methods of TTC arthrodesis strive to achieve a functional, stable, pain-free fusion. The ability to generate and sustain compressive force across controlled osteotomy bone union and bone fracture sites is key to successful orthopedic fusion. Unfortunately, the majority of current internal ankle fusion devices, which are manufactured from static materials (stainless steel or titanium), are incapable of generating sustained compression in the presence of normal bone resorption during acute healing phases. The external fixateurs tested show highly sustained loads of compression and can be readjusted externally over time; however, are associated with high complexity and complications.

The prototype NiTi Nail may be an ideal solution for ankle arthrodesis. It would be a completely internal device that can provide sustained compression to drive joint stability and fusion. It would also provide rigidity in the event that the compression is incapable of driving successful fusion.

This study has several limitations. The amount of compression applied by each device was applied in an effort to maximize the capabilities of the device without causing plastic deformation to the device, instrument set, or bone. The optimal amount of compression required is currently debatable and may vary from patient to patient. This study did not investigate the effect of resorption with different initial loads in cadaveric bone.

The optimal amount of compression to promote fusion, or the amount of bone resorption experienced in a TTC fusion, has not yet been established. This study was intended to help identify the behavior of TTC fusion devices during installation and fusion.

References