

Benefits of Nitinol for Bone Fixation

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Introduction

Nitinol (also called NiTi) is an alloy of Nickel and Titanium that has unique "superelastic" mechanical properties. The mechanical properties of Nitinol make it ideal for use in many orthopedic medical devices as well as other fields of medicine. Superelasticity results from a crystal structure transformation (Austenitic to Martensitic) due to stress. This transformation permits large recoverable strains allowing the material to be only temporarily deformed before returning to its initial state. With proper design, orthopedic implants can take advantage of this superelasticity to achieve four key goals:

1. Uniform compressive stress distribution across mating bone surfaces
2. Dynamic, continuous compression despite bone resorption
3. Implant stiffness more analogous to bone
4. Good fatigue life with large mean and cyclic strains

The next generation of foot and ankle fixation devices will utilize implant designs that more predictably take advantage of these Nitinol properties.

Nitinol is categorized as either thermal shape memory or superelastic. The thermal shape memory effect requires a temperature change either via body temperature or an external heat source. These are typically more complex systems. Superelastic Nitinol performs in the stronger phase of the material (austenite) for all service temperatures and is malleable only when cooled. Implant systems utilizing superelastic Nitinol do not require special storage conditions or surgical techniques to achieve desired results. Table 1 summarizes the mechanical characteristics of Nitinol as compared to conventional materials as well as how they relate to bone. It is well known in the scientific literature that overly stiff implant constructs may not be ideal for bone healing (Roderer et al, Samiezadeh et al).

Table 1: Comparison of Mechanical Properties

	Elastic Modulus	Yield Stress	UTS
Nitinol (SE 508)	60 Gpa	380 MPa**	1070 MPa
316L Stainless Steel (ASTM F138)	193 Gpa	880 MPa	1200 MPa
Ti-6Al-4V (ASTM F136)	110 GPa	760 MPa	825 MPa
Poly-ether-ether-ketone (PEEK)	4 GPa*	100 MPa	
Cortical Bone (longitudinal)	11-21 GPa	60-70 MPa	
Cortical Bone (transverse)	5-13 GPa	~50 MPa	

*Tensile Modulus
**Plateau Stress

Nitinol Characteristics & Behavior

Discussion

Table 1 demonstrates that titanium alloy has approximately twice the stiffness of Nitinol and stainless steel has over three times the stiffness of Nitinol. However, those materials are well beyond the stiffness of native bone. Nitinol has a stiffness that is much closer to native bone which may result in improved healing characteristics. This may explain the success of Nitinol staples as reported by Chang et al and Malal et al.

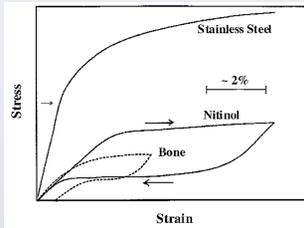


Figure 1

Nitinol has the ability to recover from strains 30-50 times greater than linear materials such as stainless steel and titanium alloys. This gives the material the ability to store energy. This energy storage, when properly incorporated into a design, can provide continuous, dynamic compression to a fracture or fusion site. Proper implant design utilizing Nitinol material requires the design to operate at the upper plateau stress zone (Figure 1).

As shown in Figure 1, Nitinol's response to stress is an initial linear response, followed by a plateau. Implants should be designed to perform in Nitinol's optimal strain range of 4-5% as represented by the plateau portion of the stress-strain curve (Figure 1). It is this response that allows Nitinol to respond to clinical loading events and resorption. CrossRoads Extremity Systems has developed a dynamic compression clip based on the design and material principles presented here. One key aspect of the design process is Finite Element Analysis (FEA) to predict device performance, Figure 2. CrossRoads Extremity Systems is engaged in ongoing development to further explore the science of continuous compression.



Figure 2

Summary

Nitinol has great benefits and significance for the foot and ankle clinical setting. Implants, such as the CrossRoads Extremity Systems' MotoCLIP Superelastic Fixation System, maintain dynamic compression even after unloading events. Future implant designs should take advantage of the benefits of Nitinol to enhance clinical success.

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