SUPERSCAFFOLD™ - A NOVEL NITINOL BONE CONDUCTING SCAFFOLD AND INTERDIGITAL FUSION DEVICE

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Since the late 1980's, when the US Food and Drug Administration (FDA) cleared the first Nitinol implantable device to market, Nitinol has become an essential material in the medical device industry. Innovative medical device companies, partnered with Memry Corporation, are harnessing the unique shape memory behavior of Nitinol to revolutionize surgical treatments, improving patient health and ultimately the standard of living. The orthopedic industry was one of the first to embrace Nitinol technologies, driving continuous advancement in the standard for musculoskeletal repair. In this article, the Nitinol science and manufacturing technologies behind Metric Medical Devices, Inc.'s *SuperScaffold™*, designed for inter-digital fusion in fingers and toes, is presented. Metric's *SuperScaffold™* was cleared to market by the FDA in 2016 and its unique performance enabled by the novel Nitinol design is changing the way surgeons approach interdigital fusion [1].

Interdigital Fusion

The most common indications for interdigital fusion includes toe deformities, such as hammertoes, claw toes and mallet toes, caused by degradation of the joint and an imbalance of forces in the muscles, tendons and ligaments. In severe cases, surgical intervention is required to correct the deformity thereby relieving pain and discomfort through arthrodesis (i.e. fusion) of the interphalangeal joints. Traditionally, this procedure is performed through the use of stainless steel Kirschner wires (or K-wires) that run longitudinally through the toe's bony structures. These K-wires are temporarily implanted and left for weeks protruding through the skin. Common complications include K-wire tract infection from bacteria migration and loss of fixation between the phalanges. These complications often lead to delayed unions or even failed arthrodesis altogether. Moreover, the patient's mobility is limited for weeks as a result of K-wires protruding from the toe(s).

The Nitinol Solution

Metric's *SuperScaffold™* is a permanent tubular scaffold type implantable device that utilizes the superelastic and biocompatible properties of the Nitinol shape memory alloy. The device was designed by Dr. Fox to instantaneously apply constant compressive force to the phalanges immediately following implantation and simultaneously allow for bone ingrowth through the implant during healing, promoting quick and more effective arthrodesis of the interphalangeal joints. In most cases, the patient can apply pressure to the foot earlier following surgery and complications due to infection and return of the deformity are drastically reduced [1].

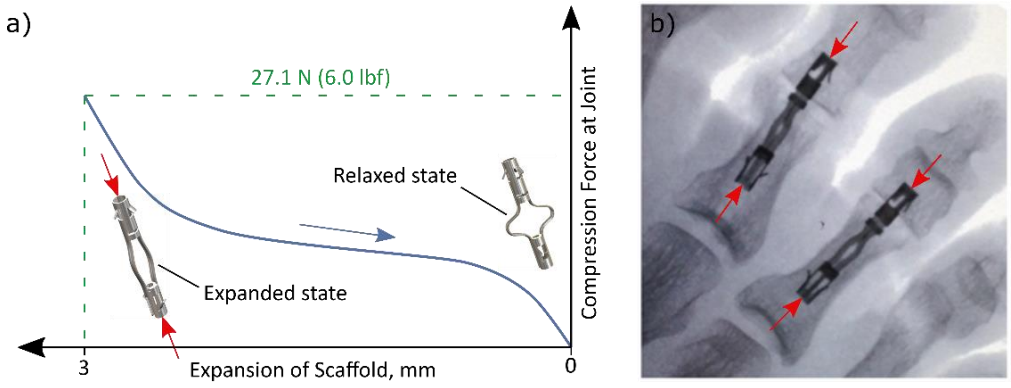

Figure 1: a) Schematic of compression force at the joint versus expansion of scaffold. b) X-ray of two implanted SuperScaffold™ devices.

The Nitinol stress-strain curve is critical for understanding how the *SuperScaffold*™ is able to instantaneously apply a constant force to the joint until arthroplasty is complete. A typical Nitinol cyclic superelastic stress-strain curve is provided in Figure 2 illustrating the relationship between the material properties, Nitinol crystal structure and strain-state of the device. The *SuperScaffold*™ is elongated below -76°C pre-implantation to lower the stresses required to expand the device and then constrained in Metric's implantation instrument for storage and use at room temperature. Upon heating to room temperature, following initial loading into Metric's implantation instrument, the constrained Nitinol material in the apexes of the bulge (*OmegaBow*™) feature remains in a detwinned monoclinic stress-retained Martensite phase at point B in Figure 2. This stress retained state leads to the isostress condition known as superelasticity where up to 6% recoverable strains can be realized in the Nitinol material once the device is deployed in the body. The resultant unloading isostress plateau (Figure 2, B → A) and the design of the *OmegaBow*™ leads to the constant compression force applied by the *SuperScaffold*™ on healing bone and hence a quicker and more effective arthrodesis compared to the traditional arthroplasty associated with most K-wire treatments. Note that the unloading portion of the Nitinol stress-strain curve closely resembles the trend in compressive load at the joint versus device contraction, illustrated in Figure 1 a).

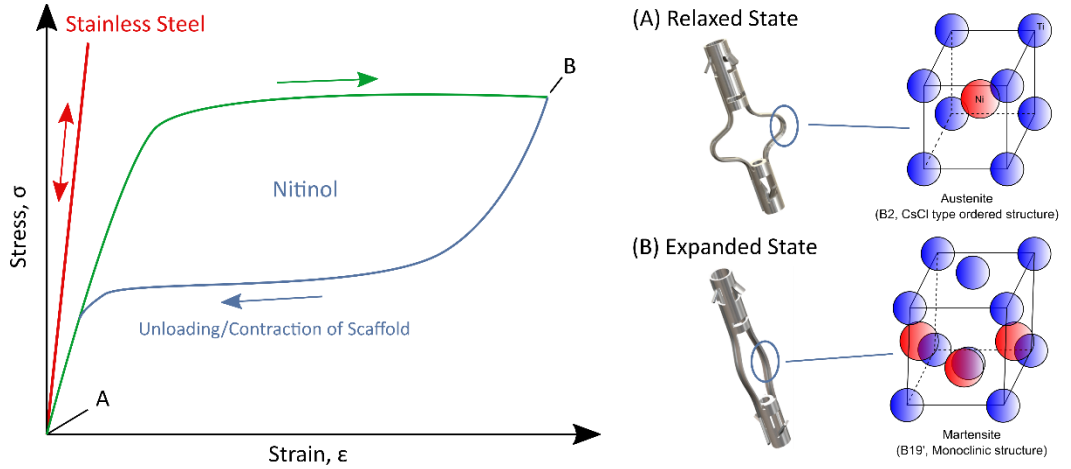

Figure 2: Typical Nitinol cyclic superelastic stress-strain curve & relation to Nitinol crystal structure and device state. A) Device in unstrained/relaxed state with the Nitinol material in the Austenite phase & B) Device constrained in an elongated/expanded state with Nitinol material in the Martensite phase.

In contrast to the constant stress applied by the superelastic Nitinol *SuperScaffold*™, the elastic stress in stainless steel under tensile loading is also included in Figure 2, which represents the behavior of the K-wire used in a traditional hammertoe treatment. A K-wire does not apply the necessary compressive forces on the joint due to the inability to strain the K-wire beyond ~ 1 % strain and its inability to fixate sufficiently to pull bone together.

In addition to compression at the bone healing interface, the expansion of the *OmegaBow*™ resist rotation of the phalanges and return of the deformity. Furthermore, the tubular design of the *SuperScaffold*™ allows it to act as a bone conducting scaffold so as to cause infiltration of bone into its lumen and more consistent fusion.

Manufacturing the *SuperScaffold*™

The development of a Nitinol device such as the *SuperScaffold*™, requires synergy between the device design and Nitinol material properties. This synergistic approach was achieved through strategic partnership between Metric and Memry Corporation, where several rounds of design iteration yielded the optimal design of the *SuperScaffold*™ device. As a leader in the Nitinol industry, Memry offers a unique "*melt to market®*" product where everything from the Nitinol ingot, raw semi-finished goods (rod, wire, tube and sheet), design/testing support, and final component manufacturing are vertically integrated. Vertical integration and Memry's extensive

expertise in Nitinol alloys allows for unparalleled process and quality control as well as highly competitive lead times.

The *SuperScaffold*™ device is manufactured from Nitinol tube and sheet produced at Memry, Menlo Park, CA and Saes Smart Materials in New Hartford, NY, respectively. The final device manufacturing occurs at Memry's headquarters in Bethel, CT. The manufacturing process flow for the Nitinol *SuperScaffold*™ device is provided in Figure 3 below. The two most important manufacturing considerations were the thermomechanical performance of the final Nitinol device and biocompatibility.

Due to the extreme sensitivity of Nitinol's material properties and surface chemistry to past processing history, great care must be taken when selecting and optimizing manufacturing processes. For example, pulsed laser processes are selected for cutting and joining operations as they provide precise, accurate and, most importantly, low heat input conditions. Additionally, shape setting operations are performed in a molten salt bath to achieve the most uniform heat treatment and oxide layer as well as the highest control of the Austenite finish (A_f) phase transformation temperature. This thermal phase transformation property is directly related to the superelastic loading and unloading plateau stresses and therefore critical in achieving the interphalangeal joint compression forces required in application (Figure 1). Finally, Memry uses a combination of chemical etching and chemical passivation processes to achieve optimal resistance to corrosion and biocompatibility. Through these final processing steps, a robust passive TiO_2 (Ti-oxide) layer is created as verified through industry standard cyclic potentiodynamic polarization corrosion testing performed in Memry's test lab.

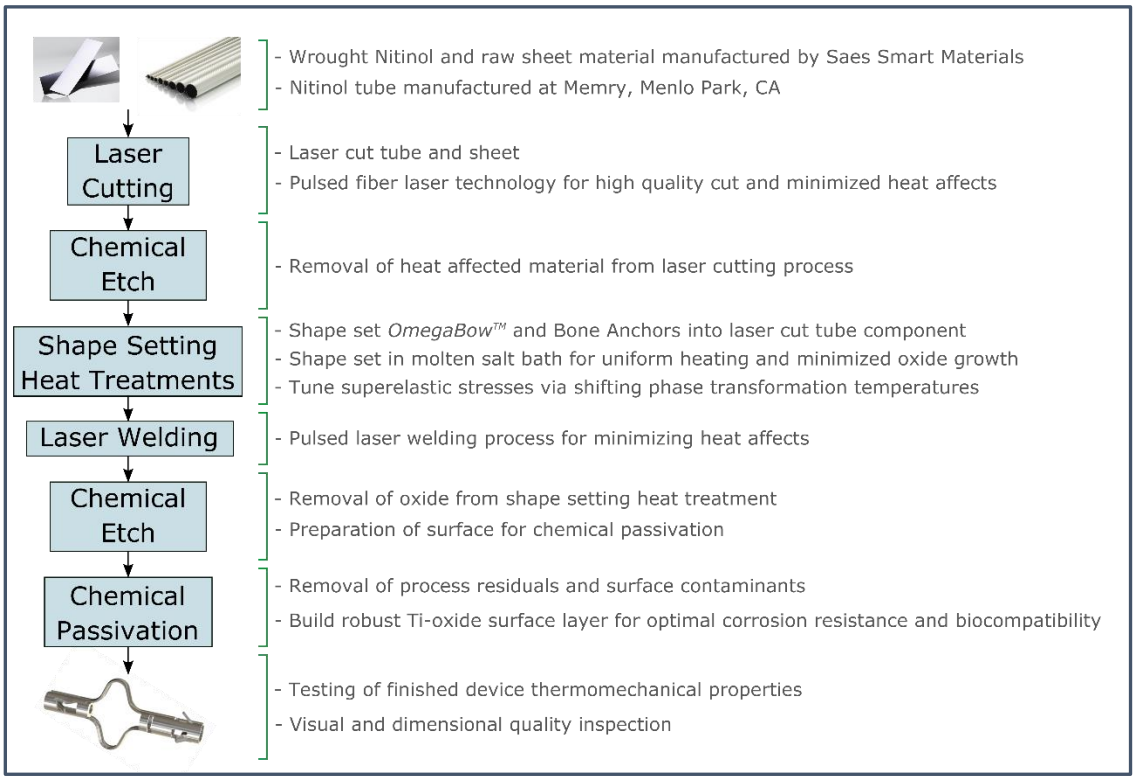

Figure 3: Memry's manufacturing process flow.

References

1. Garthwait R. Intramedullary Device May Facilitate Improved Bone Fusion. Podiatry Today. February 2017;30(2).
2. Metric U.S. Patent No.: 9,907,585