SMA - Smart Materials for Medical Applications

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Abstract

The paper presents Nitinol, a Nickel-Titanium shape memory alloy, as a smart material for medical implants and devices. The atomistic nature of shape memory and superelasticity of Nitinol and the associated unique changes in mechanical properties are described. The smartness of the material is exemplified by its use for self-expanding stents. Caused by the stress hysteresis of superelastic Nitinol, these devices exhibit a biased stiffness behavior, i.e. they exert a low chronic outward force on the vessel wall, but resist external deformation with much higher forces. Some recent developments of thin film Nitinol stents and filters are also discussed.

Introduction

Per one definition, smart materials respond to external stimuli with a change in a key material property [1], per another, smart materials generally exhibit properties which are, in some way, unexpected or novel [2]. Together with piezoelectric ceramics, magnetostrictive materials, and electro-rheological fluids, shape memory materials have long been classified as smart materials or components of smart systems. This is to be attributed to their ability to change shape upon heating and cooling, which appears to make them ideally suited for advanced actuator applications. However, although this is known for some forty years and many applications have been suggested, only a limited number of industrial products incorporating smart shape memory actuators have appeared in the market. At the same time Nitinol, the most popular metallic shape memory material (SMA — shape memory alloy), has established itself as the material of choice for many applications in the medical device industry [3, 4]. While few of those applications are presented as smart systems , they nevertheless qualify as such based on the definitions cited above.

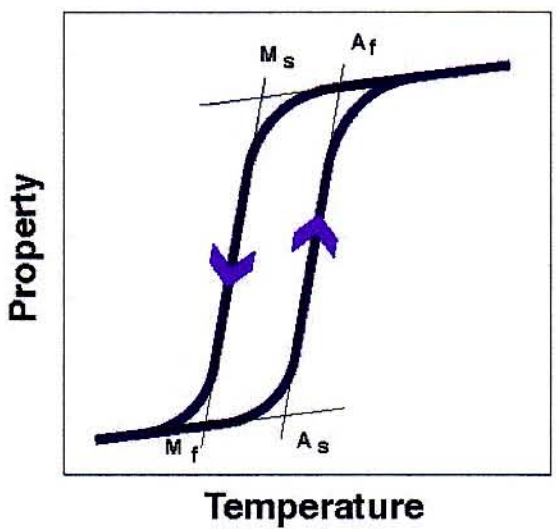
Nitinol is an equiatomic or near-equiatomic intermetallic compound of Nickel and Titanium which undergoes a solid state transformation in the temperature range of —100¡C to +100¡C, depending on the composition and/or processing history. Associated with this phase change is a significant change in the properties of the material. The most dramatic manifestation thereof is the ability of the material to return to its original shape upon heating after an apparent plastic deformation (thermal memory). Another related

effect is the so-called superelasticity, the ability of the material to return to its original shape upon unloading after being strained significantly (elastic memory). Besides these spectacular effects, shape memory alloys, and particularly Nitinol, exhibit some unusual yet useful properties that make this material truly smart .

In this paper, we will briefly describe the nature of the shape memory effect and the associated changes in mechanical properties. We will then discuss the most successful medical application of Nitinol, the self-expanding stent, an impressive example of the smart behavior of Nitinol in a medical device. Finally, we will take a look at some recent developments of thin film Nitinol stents and filters.

The shape memory effect in Nitinol

Shape memory as well as superelasticity are the results of a thermo-elastic martensitic transformation. Above the transformation temperature, Nitinol, a Nickel-Titanium alloy with approximately 50 at.% Titanium, is austenitc. The crystalline structure of the austenite is a cubic B2 or Caesiumchloride structure. Cooling below the transformation temperature transforms the B2 structure into a twinned monoclinic structure, called martensite. No macroscopic shape change occurs with this transformation. However, the twinned martensite can be easily deformed up to approximately 8% strain by an unconventional de-twinning mechanism. This deformation can be recovered by heating the material to temperatures above the transformation temperature, completing the shape memory cycle. As mentioned above, significant changes of material properties accompany this phase transformation. A typical plot of property changes with temperature is shown in Figure 1, depicting the characteristic hysteresis curve with the associated defining temperatures As (Austenite Start), Af (Austenie Finish), Ms (Martensite Start) and Mf (Martensite Finish).



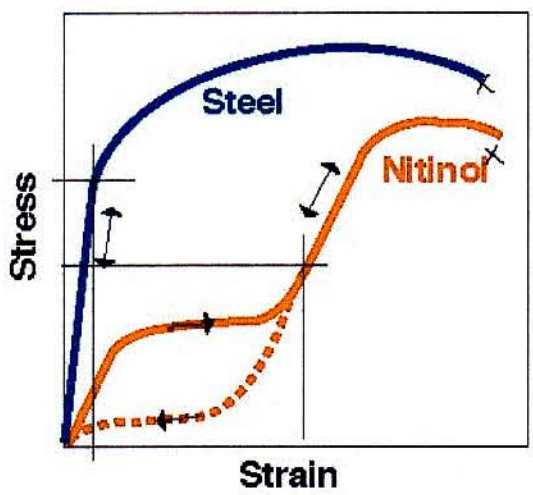


Fig. 1 (left) Temperature Hysteresis of Nitinol (schematic)
Fig. 2 (right) Stress/Strain Characteristic and Stress Hysteresis of Nitinol (schematic)

At temperatures above Af, martensite can be stress induced, i.e. subjecting the material to a deforming stress yields recoverable strains of up 8% with little stress increase by transforming the austenite into martensite and immediately deforming it by detwinning. . As austenite is the stable phase at this temperature under no-load conditions, the material springs back into its original shape when the stress is no longer applied This is an isothermal event called superelasticity or elastic memory. Because the underlying mechanisms are the same as with thermal memory, a distinct hysteresis can be found when plotting stress versus strain. Figure 2 schematically shows the stress-strain curve for a Nitinol wire at a temperature approximately 30 degrees above Af. Upon loading, stress first increases linearly with strain up to approx. 1% strain. After a first yield point , several percent strain can be accumulated with only a little stress increase. The end of this plateau (loading plateau) is reached at about 8% strain. After that, there is another linear increase of stress with strain. Unloading from the end of the plateau region, causes the stress to decrease rapidly until a lower plateau (unloading plateau) is reached. Strain is recovered in this region with only little decrease of stress. The last portion of the deforming strain is finally recovered in a linear fashion again. The unloading stress can be as low as 25% of the loading stress.Based on the stress hysteresis, a device can exhibit so-called biased stiffness, i.e. high stiffness during loading and low stiffness during unloading. As will be shown later, this is a major aspect of the performance of self-expanding stents for the treatment of diseased vessels.

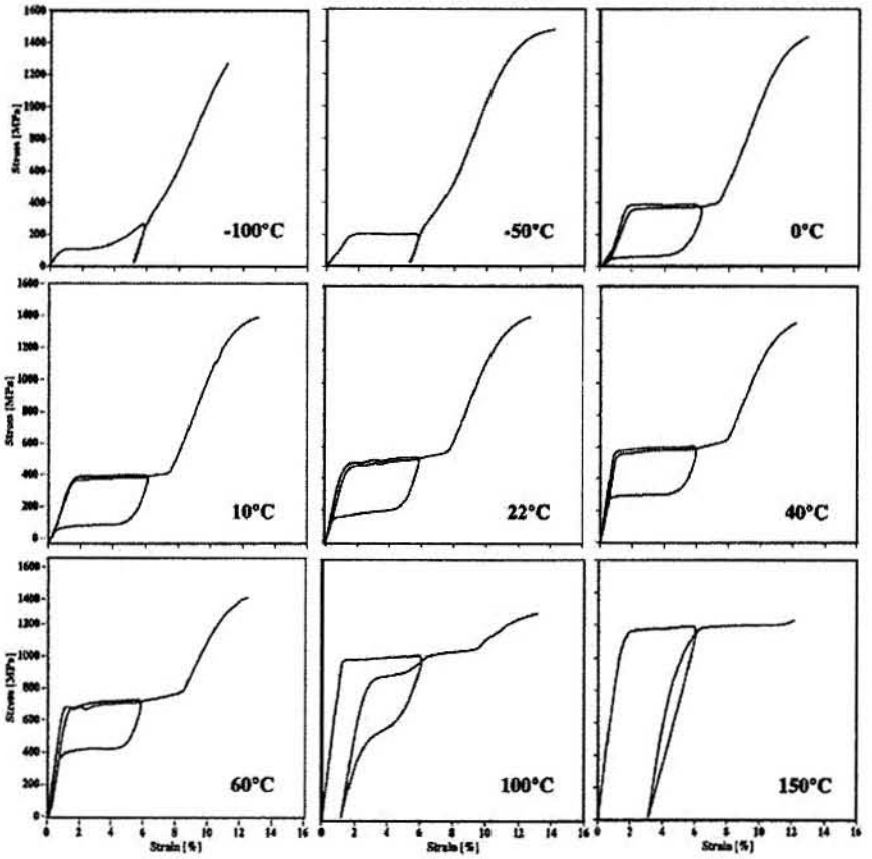


Fig. 3 Tensile curves of a superelastic Nitinol wire at various temperatures

The stress-strain behavior of Nitinol alloys is strongly temperature dependent. The hysteresis shifts up with increasing difference between Af and operating temperature, i.e. a device with a given Af becomes stiffer with increasing temperature. Lowering the temperature, on the other hand, will shift the hysteresis down. When the operating temperature is below Af, and more specifically below Mf, the deformation will no longer be elastically recovered. However, it can be recovered thermally (thermal memory). Figure 3 shows tensile curves of a superelastic alloy with Af -10¡C for various temperatures [5].

Smart Self-Expanding Inplants and Devices

Undoubtedly, the most celebrated application of Nitinol in a medical device is its use for self-expanding stents [6]. Stents are scaffolding tubular structures that prevent vessels from re-closing after balloon dilatation, ingrowth of tumors or other obstructive influences. While most stents for coronary applications are still balloon expandable, the majority of stents for non-vascular or peripheral vascular applications are self-expanding. Self-expanding stents are manufactured with a diameter larger than that of the target vessel, crimped and restrained in a catheter based delivery system. They are inserted into the body through small incisions or through natural body openings typically under fluoroscopic or endoscopic guidance. At the target site the stent is released from the delivery system and elastically expands until it hits the vessel wall (Figure 4). The performance of a self-expanding stent is therefore dependent on the ability of the material to store elastic energy while constrained in the delivery system, making Nitinol the ideal choice.

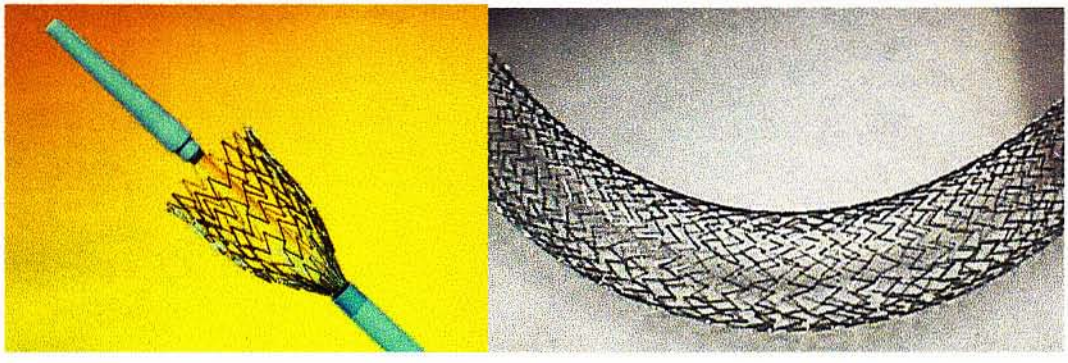


Fig. 4 Self-expanding Nitinol stent (left: half deployed from the delivery system)

The smart nature of a Nitinol stent becomes particularly apparent, when the balance of forces in a stented vessel is examined. As mentioned above, the stress hysteresis or path dependence of Nitinol results in a feature termed biased stiffness. This concept is illustrated in Figure 5, which shows a typical schematic superelastic stress-strain curve for Nitinol, illustrating both non-linear response and hysteresis. Using this graph, we will follow the cycle of crimping a stent into a delivery system, deploying it and have it expand and interact with the vessel. For this purpose, the axes have been changed from stress - strain to hoop force - stent diameter. A stent of a given size larger than the vessel (point a in Figure 5) is crimped into a delivery system (point b), then packaged,

sterilized and shipped. After insertion to the target site, the stent is released into a vessel, expanding from "b" until movement is stopped by impingement with the vessel (point c). At this point, further expansion of the stent is prevented. Because the stent did not expand to its pre-set shape, it continues to exert a low outward force, termed chronic outward force or COF. However, it will resist recoil pressures or any other external compression forces with forces dictated by the loading curve from point c to d , which is substantially steeper (stiffer) than the unloading line (towards e). These forces are called radial resistive forces or RRF.

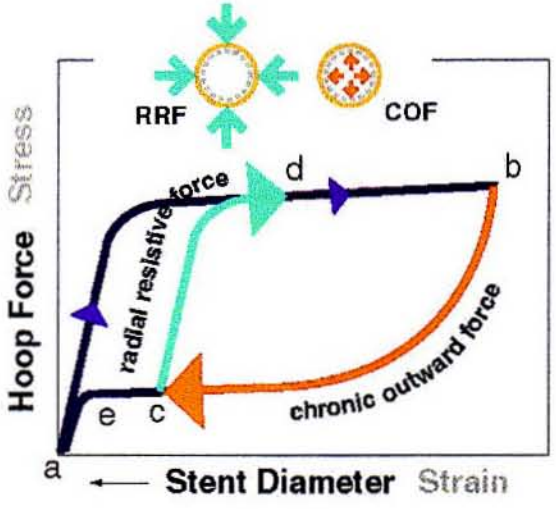


Fig. 5 Concept of biased stiffness as path dependence of force along hysteresis

Is the stent smart? It certainly meets the requirements of the definition. The unusual elastic hysteresis of Nitinol allows the continuing opening force of the stent acting on the vessel wall, the *Chronic Outward Force* (COF), to remain very low even through large deflections and oversizing of the stent. Meanwhile the forces generated by the stent to resist compression, the *Radial Resistive Force* (RRF), increase rapidly with deflection until the plateau stress is reached. In general, stent designers strive for as high an RRF with as low a COF as possible.

Figure 6 shows actual measurements of hoop force versus diameter for a commercially available 10mm Nitinol stent (nominal diameter. The device is crimped to 2mm and is deployed into an emulated 8.5 mm vessel diameter (data at diameters less than 4 mm is not recorded). At 8.5 mm, the RRF is recorded by crimping the stent back to 7.5 mm, then the stent is unloaded entirely to its original diameter. One can see that the COF is quite constant at 0.035 N/mm throughout the indicated diameter range (8 to 9 mm). The RRF increases sharply as the stent is deformed from the equilibrium diameter, reaching 0.22 N/mm after a one mm deflection. Continued deformation would indicate a plateau at approximately 0.24 N/mm.

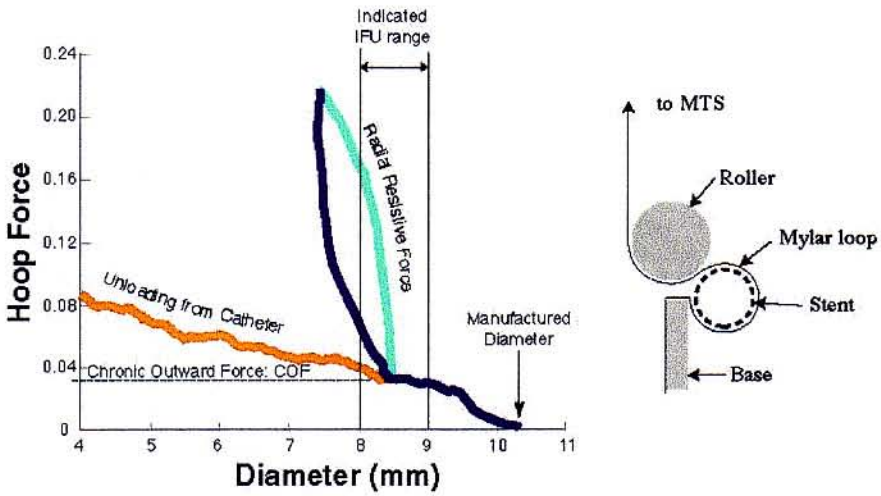


Fig. 6 Radial force test and illustration of biased stiffness

Another dramatic and demonstrable attribute of Nitinol stents is their *Crush Recoverability*. Most, if not all, Nitinol stents can be crushed fully flat and still elastically recover their original shape without clinically relevant loss of lumen diameter. This attribute is important in superficial indications subject to external crushing such as the carotid artery (Figure 7).

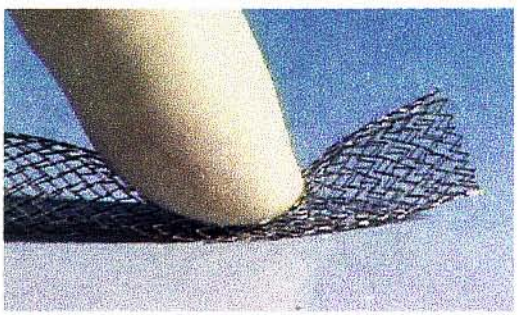


Fig. 7 Demonstration of the crush recoverability of Nitinol stents

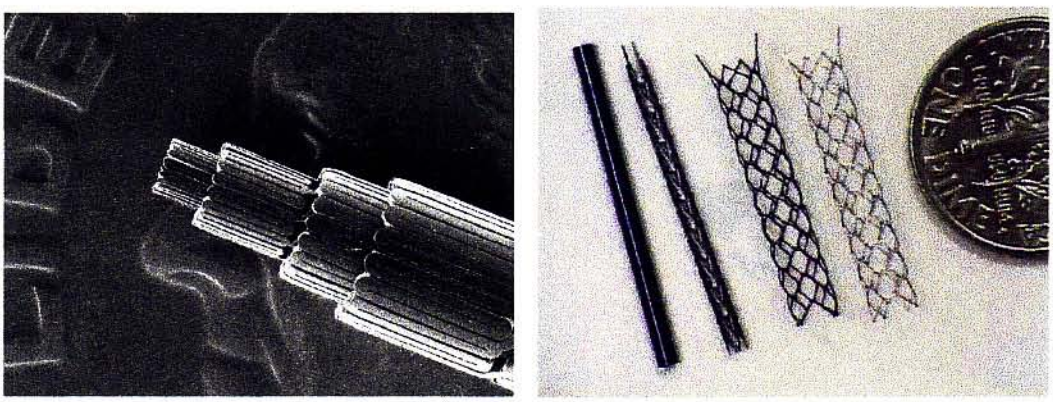
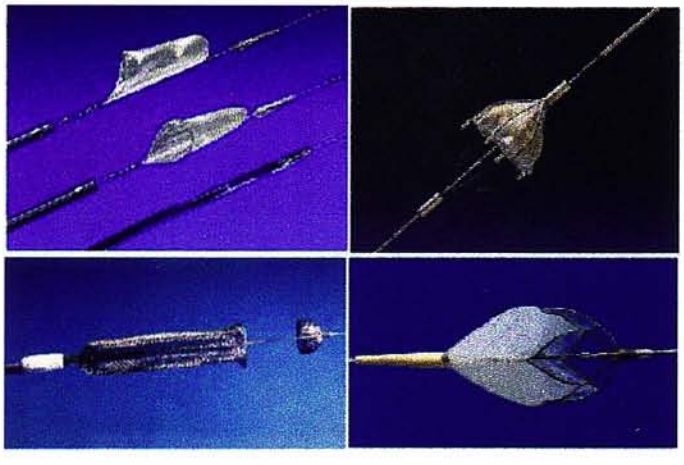


Fig. 8 Laser cutting of stents from Nitinol tubing. The largest tube in the picture on the left has an O.D. of 2 mm, the smallest 0.4 5 mm

The Nitinol stent market size for peripheral applications is estimated to be near $ 500 Million and is rapidly growing with the introduction and acceptance of new procedures. An area of particular interest are new devices for intracranial implantation, where small delivery sizes are required. Most stents currently available are fabricated by laser cutting form Nitinol tubing. However, tubes with wall thickness of <0.05 mm, as required for neurovascular applications, are very difficult to produce (Figure 8). An alternative method to produce stents with very thin struts is vapor deposition, particularly sputter deposition of Nitinol [7]. To create 3D shapes like tubular thin films, Nitinol is sputter deposited on highly polished substrates, heat treated to crystallize the material and then removed from the substrates. The process can be controlled to create films of 1 to 5 microns thickness that exhibit either shape memory or superelasticity essentially equivalent to bulk Nitinol. Stent patterns are then created by photochemical etching methods. These devices can potentially be delivered into the brain through microcatheters.



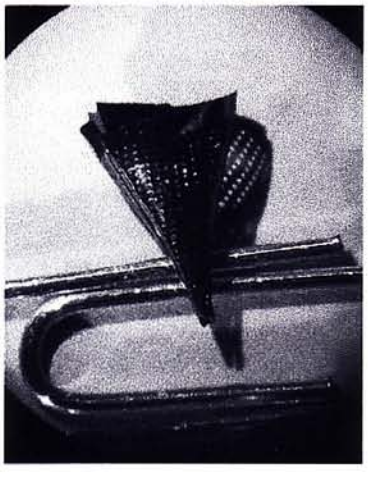


Fig. 9 (left) Different designs of distal protection filters (from top left clockwise: BSC, Cordis, Guidant, MicroVena)
Fig. 10 (right) Prototype of thin film Nitinol cone shaped filter [7]

To capture clots that could cause strokes during neurovascular interventions, self-expanding filters can be placed distal to the treatment site. These filters prevent debris from reaching the brain and allow the clots and particles to be removed after the procedure. Several variations of Nitinol filters are already in the market (Figure 9). Filters made from thin film Nitinol could vastly improve the procedures by allowing smaller delivery systems and to potentially reach more distal locations. First prototypes have been produced by sputtering a 4 micron thick Nitinol film onto a cone-shaped substrate, fenestrating the film by photochemical etching and removing the patterned film cone from the substrate (Figure 10 [7]).

Other Applications of SMA for Smart Medical Devices

The medical device industry has adopted Nitinol as the material of choice for a multitude of devices. Extensive product reviews can be found in [3,4] as well as in previous

proceedings of the International Conference on Shape Memory and Superelastic Technologies. The major benefit of using Nitinol in medical devices is the simplicity of designs possible, supporting the general trend toward minimally invasive therapies in medicine [8]. The unique response of Nitinol to thermal or mechanical stimuli allows devices to be built with fewer parts and smaller dimensions at potentially reduced costs and with performance features otherwise unobtainable. An early example are hingeless instruments, consisting of only one as opposed to multiple intricate, precision-machined components and linkages of conventional devices [9]. Additionally, the non-linear stress/strain characteristics of Nitinol provide constant force gripping of large and small objects and built-in overload protection. The strongly temperature dependent stiffness of Nitinol can be used to make guidewires and catheters more steerable by changing the stiffness of the component locally during the procedure. This can be achieved by either electrically heating the section, or, as suggested recently, by sliding an optical fiber inside a Nitinol microtube and heating the material with laser light [10].

The emerging thin film technology will further expand the use of Nitinol for medical devices. Besides stents and filters, all-metal grafts have been suggested to be produced by vapor deposition and photochemical etching to replace conventional polymeric grafts [11]. MEMS incorporating thin film Nitinol actuators could be used in implantable drug pumps and valves.

Conclusions

The trend toward minimally invasive procedures in medicine has allowed novel implants and instrumentation to be designed using smart shape memory alloys for the critical components. Fueled by this demand, Nitinol has seen explosive growth during the past ten years. The unique material characteristics of Nitinol, specifically thermal memory, non-linear stress/strain behavior, stress hysteresis and the temperature dependent stiffness, make this material a truly smart material and the devices incorporating Nitinol components truly smart systems.

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