

The Use of Superelasticity in Modern Medicine

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Abstract

The value of Nitinol (Ni-Ti) in the field of medicine has proven to be far greater than just as the simple "springy metal" it was once considered to be. In particular, its use in vascular implants highlights many valuable yet subtle behaviors, including a "biased stiffness," enhanced fatigue resistance, low magnetic susceptibility, and good biocompatibility. Nitinol today is nearly as well known to medical-device designers and physicians as are stainless steel and titanium, and it is the enabling ingredient in a growing number of successful and profitable life-saving devices.

Keywords: alloys, biomedical materials, intermetallic, shape memory, superelasticity.

Introduction

It has long been understood that "mechanical memory" and "thermal memory" are simply different manifestations of the same thermoelastic behavior, but the commercial potential of the former (later called "superelasticity," or "pseudoelasticity") was not considered in its own right until the mid-1970s. Until then, the use of Nitinol (Ni-Ti) as simply a more efficient spring was not considered interesting, due to the very narrow temperature range over which the shape-memory effect could be observed and because one could just add more mass to a conventional spring, achieving the same result at a lower cost. In 1976, it was recognized that the constant temperature of the human body was ideally suited to the superelastic temperature range of Nitinol.¹ Not only did this resolve the temperature limitations of its use, but the drive toward minimally invasive instruments, devices, and surgical techniques also provided a perfect response to the second concern: the enormous value placed on compact, simple designs made the use of a larger spring highly undesirable.

The medical field, however, does not quickly adopt new materials, and the 50% nickel content of Nitinol (nickel being a known carcinogen²) raised concerns about biocompatibility. Two major breakthroughs occurred in this same time period: Castleman et al.² wrote the first overview of Nitinol's biocompatibility, concluding

that while more work should be done, the alloy appeared to be biologically compatible; and Nonnenmann³ completed his thesis under Andreasson, in which the use of Nitinol as an orthodontic archwire was explored (this was soon to become the first commercial "medical" application of Nitinol).

Many concepts using Nitinol were conceived during the next decade, but it was several years before guidewires⁴ and a surgical anchor⁵ known as Mammalok[®] joined the ranks of commercially successful products that used superelasticity as an enabling technology. Meanwhile, other nonmedical superelastic products began to emerge in high volumes, such as eyeglass frames and brassieres, then later, fishing lures and cellular telephone antennae. The success of these products created the much-needed production volume and acceptance of the material, and by the early 1990s, Nitinol began to appear in a host of new medical devices. Nitinol is now nearly as well known to medical-device designers and physicians as are stainless steel and titanium. Product designers choose Nitinol for a variety of reasons, which we will review and exemplify in this article.

Enhanced Elastic Recoil

We first consider the most apparent asset of Nitinol, its enhanced elastic recoil, often

over 10% or even 11%, as compared with 0.3% in annealed stainless steel, 1% in piano wire, and perhaps 1.5% in hardened titanium alloys. While this can be of value *in vivo*, the greatest benefit appears to be in deploying devices. As an example, Figure 1 shows a distal protection filter made from Nitinol wire covered with a very thin polyurethane cone with small (100 μ m) holes laser-drilled into the film (inset in Figure 1). Deployment is accomplished by pulling back a constraining sheath, thus allowing the Nitinol wire basket to elastically expand to its manufactured size and shape. The device is deployed in the carotid artery downstream of the diseased site prior to performing angioplasty (the dilation of an artery through the inflation of a balloon). Debris broken free from the artery wall during angioplasty is intercepted by the filter and thus prevented from embolizing to the brain and causing stroke. After the procedure is complete, the Nitinol umbrella is withdrawn into the catheter and the embolized debris is thus removed from the body. Several such Nitinol protection filters are being developed or are already in clinical trials.

The filter described is one of the many examples of expanding devices that are either on the market or in development. A second class of devices that is gathering attention are those that redirect the insertion direction of a needle or catheter, as shown in Figure 2. Needles can be ad-

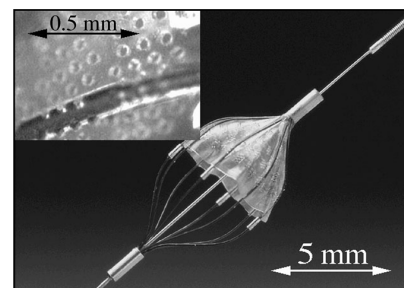


Figure 1. Many physicians are concerned with stenting certain blood vessels where there is a likelihood of displacing small particles that may migrate into the neurovascular system, causing stroke. The Angioguard[®] filter shown here is intended to be deployed downstream of the site to be stented and opened into the shape shown, thus forcing the blood through small holes in a polyurethane film (inset). After the procedure is complete, the protective filter is collapsed, capturing the potential emboli. The device must be exceedingly small and flexible, yet be clearly visible by x-ray, thus Ta markers are included in the design.



Figure 2. The SmartGuide™ is a deflectable, multipurpose 2.0-mm-diameter needle produced by Daum. It can be deflected at a 90° angle by advancing a curved Nitinol tube from stiffer, straight tubing. Such redirection applications become a commonplace use of superelasticity due to the abruptness with which the redirection can be affected.



Figure 3. This grasper (cut from 0.3-mm-diameter Nitinol tubing) is designed to percutaneously retrieve embolized occlusion coils from the neurovascular system. Reaching the arterial system of the brain from the groin requires a shaft that is exceedingly small, flexible, and kink-resistant.

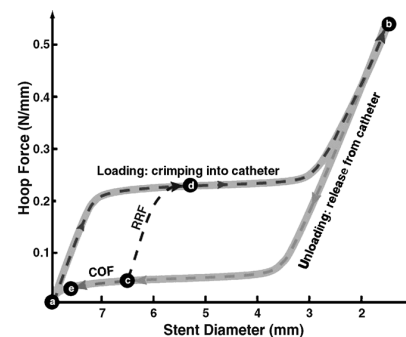


Figure 4. A typical superelastic stress-strain curve is represented as it applies to the life cycle of a stent. The stent is crimped into a catheter (path a-b), then later deployed, reaching a stress equilibrium with the vessel at point c. The force or pressure against the vessel is controlled by the unloading curve (chronic outward force, COF), and the force resisting deformation is controlled by the loading curve (radial resistive force, RRF). Hoop force is the force around the circumference of an object.

vanced at right angles to the primary axial direction and pushing direction of a device, allowing physicians to work in more compact surroundings, such as in a magnetic resonance imaging field. Still other devices use Nitinol for no other reason than that it allows long metal tubes to be tightly coiled and thus efficiently packaged.

Work Hardening and Kink Resistance

The unusual nonlinear loading curve of superelastic Nitinol complements the alloy's high elastic range in providing the alloy with an exceptional resistance to buckling or kinking. Deformation proceeds easily along the strain plateau until the second elastic increase. Thus, the device will strive to uniformly distribute deformation strains, bringing all regions to the end of the strain plateau before any single region plastically yields. Wires and tubes thus roll smoothly around tortuous bends.

Several devices take advantage of Nitinol's extraordinary kink resistance, including the guidewires already mentioned. More recently, however, designers have chosen Nitinol as the shaft material for complex microinstruments, such as the grasper shown in Figure 3. While still in the design phase, this instrument highlights both modern micromachining capabilities and the expanding opportunities in neurovascular medicine. This particular grasper can be used to retrieve embolized coils (coils for sealing the defect in an aneurysm that escape and float freely in the bloodstream) or even clots from the brain. The vascular approach to the brain is extraordinarily tortuous,

making the use of conventional metals nearly impossible.

The Unloading Plateau and Uniform Recovery Stresses

During unloading, the nonlinearity of the stress-strain curve of superelastic Nitinol again provides some unique and useful properties. By loading to beyond the plateau, then unloading so that the device strains are on the plateau, one can preprogram a device to apply a constant and desirable stress against surrounding tissue. This is best illustrated by the pioneering orthodontic archwire application commonplace in orthodontics today. After attaching the wire to the brackets, the wire is allowed to unload as the teeth straighten. Very quickly after attachment, the wire is on the unloading curve and is thus applying a gentle, constant, and long-range force against the teeth.

Deformation Hysteresis and Biased Stiffness

The next unusual aspect of the stress-strain curve is its hysteresis (Figure 4). One might think of this as an undesirable aspect of superelasticity since devices require a great deal more energy to cause deformation than they return when they are released. In fact, Nitinol is a very inefficient spring—it is resilient in terms of strain, but not in terms of energy. Still, the hysteresis is of value in many medical devices. During unloading, the modulus of elasticity is biased, substantially more in the loading direction than in the unloading direction. The result is that superelastic devices resist deformation with much greater force than the force they apply passively to surrounding tissue. This is essential, in fact, to the performance of the

single most successful Nitinol product, the stent.

Conceived in 1983 by Dotter,⁶ a stent is a device that scaffolds or holds open a biological lumen (a cylindrical channel). Though stents can be used in a wide variety of biological systems, the majority are used to prevent restenosis (lumen constriction) after angioplasty performed on coronary arteries, which feed blood to the heart muscles, and "peripheral" arteries (most frequently the iliacs, carotids, and renals). Typically, a physician gains access to the vascular system through a needle placed into the femoral artery in the groin, then snakes a thin, flexible guidewire (often made of Nitinol) through the arterial system until it reaches and crosses the diseased site. Once access is established, a noncompliant balloon is usually advanced over the guidewire, then inflated to open the vessel to the desired diameter (angioplasty). After deflation and removal of the balloon, a stent is advanced and deployed against the vessel wall to prevent vessel recoil. Stents can either be deployed by inflating a balloon to plastically deform and open the device, or they can "self-expand," meaning that they expand simply upon their release from a constraining sheath (Figure 5). Expanded stent diameters can range from under 3 mm to more than 25 mm, with lengths from under 20 mm to more than 160 mm; marketed designs include devices laser-cut from tubing, woven wire, welded wire, and sheets.

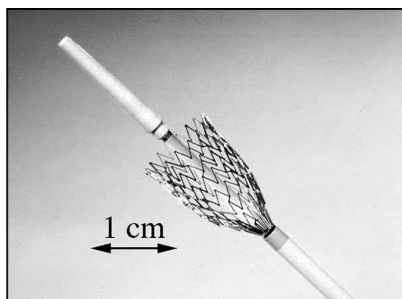


Figure 5. A Nitinol SMART® stent is shown as it is released, expanding from <2 mm to 8 mm in diameter. This particular stent is intended for use in the biliary tract, but is commonly used “off-label” in a variety of other ducts. Several other Nitinol-based stents and stent grafts are in common use in hospitals throughout the world.

While expandable stents (generally of stainless steel) comprise the majority of those used, particularly for coronary applications, both types have advantages. The preferred material for self-expanding stents is clearly Nitinol.

Nitinol was initially favored only in superficial vessel locations, such as the carotid artery, where there was a risk of externally crushing stainless-steel stents, but now several more subtle yet very important advantages have been discovered, including the value of the deformation hysteresis. Here, “biased stiffness” causes the stent to passively press against the vessel in a very compliant fashion (the unloading direction), yet the stent resists constriction with a comparatively high stiffness (the loading direction). This feature turns out to be essential to the performance of the device and has led to a new way of considering vessel-implant interactions.⁷ Physicians can “oversize” the stent to the vessel, and feel confident that while the stent is stiff enough to scaffold the vessel, the passive forces will not be so great as to perforate the vessel wall. Furthermore, the biased stiffness allows the physician to “ratchet up” the diameter of the stent: balloon expansion subsequent to stent deployment unloads the stent, yet when the balloon is again deflated, the stent retains the new shape rather than simply recoiling with the vessel to the original diameter, as it would in a conventional elastic system.

Strain-Controlled Fatigue Resistance

While Nitinol exhibits only poor to fair stress-controlled fatigue resistance, its

strain-controlled fatigue properties (especially at strains above 1%) far exceed those of any other known metal. In fact, many biological deformations are displacement-controlled rather than load-controlled. Perhaps the best example is the dental file used for root-canal work. The file tends to follow the soft nerve of the tooth, routinely bending as it turns at a high speed. The older steel files would often fail in fatigue in the more tortuous root systems. Today, however, most files are made from Nitinol, thus preventing fatigue damage. Other Nitinol devices, such as orthopedic reamer shafts, provide similar benefits to the patient.

Another example is the vena cava filter (Figure 6). The intent of the filter is to prevent pulmonary embolisms caused by blood clots migrating up from the lower extremities through the vena cava and into the lungs. The filter is deployed from a catheter into the inferior vena cava, where sharp anchors hold the device fast. Clots traveling through the vena cava are intercepted on the struts of the filter and remain there until safely dissolved in the blood flow. Unlike arteries, the vena cava itself is a very dynamic environment, flattening due to breathing and especially from chest-muscle contractions (coughing). A filter must be able to flatten with such contractions, yet must be strong enough to anchor firmly in place. The older stainless-steel filters are designed to survive such distortions, but by necessity they are thin and flimsy, often migrating downstream,

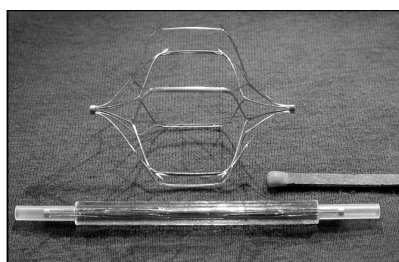


Figure 6. At least two vena cava filters made from Nitinol are approved for use by the U.S. Food and Drug Administration, including this TrapEASE® device, which expands to 28 mm as it is deployed from a 2-mm sheath. Once deployed, 12 sharp barbs firmly anchor the device into the wall of the vein, and the blood is forced through diamond-shaped filters. Large blood clots that break loose in the leg are caught by the Nitinol struts and over time will harmlessly dissolve rather than be carried into the lungs where they can lead to sudden death.

eventually even lodging in the heart itself. Nitinol provides a much stronger and more stable device that still survives the fatigue strains.

Stents, too, utilize the enhanced fatigue resistance of Nitinol. Stainless-steel stents must be designed to be very stiff in order to resist the fatigue damage that may result from the systolic blood-pressure pulsation. These stiff designs, however, prevent the natural systolic vessel motion, resulting in high stent-tissue interface stresses. Nitinol vascular implants are able to elastically “breathe” with the natural systolic vessel diameter changes, yet they resist fatigue damage, thus applying lower interface stresses. The criticality of fatigue in stent design has led to extensive research into the effects of mean strain on cyclic fatigue lifetime, with the unusual finding that increasing the mean strain can increase fatigue resistance.⁸ Once fully documented, this may have a dramatic influence on design methodology and application.

Thermal Deployment

Superelastic Nitinol devices can also be thermally deployed. For example, physicians using the pioneering Simon vena cava filter⁹ flush chilled saline down the catheter until ready to deploy, then stop the flow to affect expansion. Other examples exist, such as Harrington rods (used in spinal fixation) and spinal spacers, but for the most part, thermal deployment has proven impractical due to the difficulties in keeping a device reliably cool until it is properly positioned. In fact, it is doubtful that the Simon filter actually remains martensitic until released from the insertion catheter, but the chilled saline can act to reduce the frictional forces in the catheter.

Biocompatibility

A great deal of work has been done on the corrosion, biocompatibility, and thrombogenicity (tendency to promote the formation of blood clots) of Nitinol since the original work of Castleman et al.² We know today that Nitinol, when its surface is properly treated, has a Ni-free, TiO₂ surface¹⁰ and has excellent corrosion resistance compared with stainless steel. We also know that properly treated Nitinol causes no abnormal cell reactions. Endothelialization (first-layer cell formation) occurs rapidly, and thrombogenicity is minimal.¹¹ Conversely, we know that poorly treated surfaces can readily pit and that contact with noble metals can quickly break down the passive TiO₂ surface. Perhaps the most important feature, however, is that after 18 years of use in the human body, few if any adverse reactions have been reported.

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Summary

The commercial success of shape-memory alloys has arrived much later and in a very different form than that envisioned by early researchers, but it has arrived: engineers now consider Nitinol a staple of their design toolbox. Physicians are also routinely familiar with both Nitinol and superelasticity, and its once-mysterious properties are routinely discussed at medical conferences. Superelastic alloys such as Nitinol have brought far more to the medical field than the simple highly elastic characteristics for which they were originally recognized. Many of these advantages have been discussed here, yet there are many others, such as Nitinol's low magnetic susceptibility; this in particular is becoming increasingly important as magnetic resonance imaging becomes more commonplace.

Micromachining capabilities continue to grow, and devices will become smaller and procedures less invasive (Figure 7)—these are trends that will continue to provide fuel for Nitinol's continued development. An improved understanding of fatigue, greater radiopacity, and better

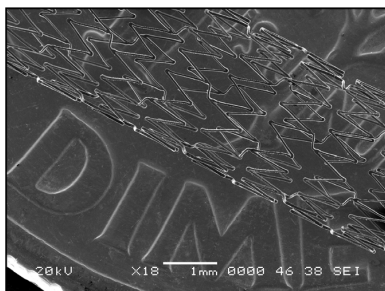


Figure 7. Prototype of a neurovascular stent, laser-machined from 0.45-mm-diameter superelastic tubing, illustrating the direction of product development for biomaterials during the next few years: smaller, more flexible, and less invasive.

joining methods are areas of particular developmental need.

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