NITINOL MEDICAL DEVICE DESIGN CONSIDERATIONS

Philippe P. Poncet

MEMRY Corporation, 4065 Campbell Avenue - Menlo Park, CA 94025 – USA
(Tel) 650-463 3416 - (Fax) 650-463 3456 - Email: philippe_poncet@memry.com

ABSTRACT

Since the late 1980's, Nitinol has been increasingly utilized in a variety of medical devices and, in some cases, has become one of the materials of choice for many designers and engineers. From surgical devices to endoluminal stents and other prosthesis, the material's thermo-mechanical characteristics and its biocompatibility has allowed its use across many medical and surgical specialties both on the diagnostics and therapeutics sides.

Nitinol's non-linear behavior and thermal dependency are presenting a variety of design challenges that are further enhanced by the material processing complexity. Clear definitions and understanding of the final medical product performance requirements will assist the designers in selecting the right material condition for the application but also in defining the right testing and validation protocols. This paper lists a few design and processing guidelines when it comes to evaluating nitinol as a material candidate for a medical device application.

INTRODUCTION

Nitinol has become a material of strategic importance as it allows to overcome a wide range of technical and design issues relating to the miniaturization of medical devices and the increasing trend for less invasive and therefore less traumatic procedures across medical specialties.

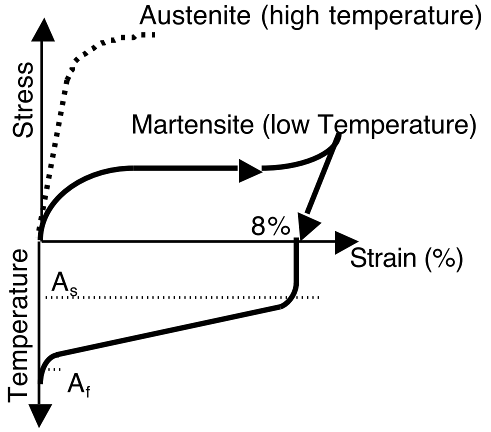
From a design perspective, it is essential that very early on in the development process, designers and engineers assimilate and focus on the end product specification e.g. the medical device's technical and performance requirements. From there, they need to identify a subset that would be applicable in defining the key characteristics that the nitinol component needs to fulfill. In all cases, and not only from a regulatory perspective, one shall demonstrate the safety and efficacy of the medical device and select its components accordingly. In the Unites States for example, the Food and Drug Administration (FDA) regulates medical devices and not materials.

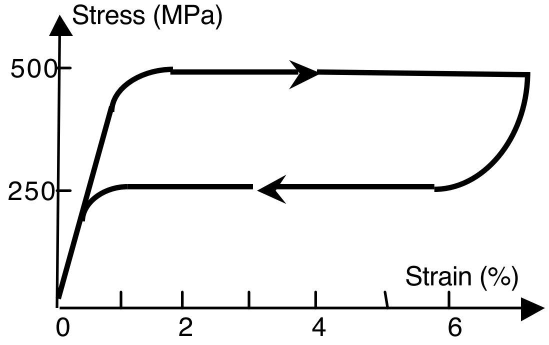
As materials demand has increased over the last 10 years, such has the number of nitinol processors and suppliers. A wider variety of semi-finished product formats and conditions are available adding to the material selection flexibility. It is also essential that design and development engineers also understand and identify the appropriate material condition as it may alleviate a number of headaches at the manufacturing stage and when devices need to be produced in large volumes.

SHAPE MEMORY EFFECT AND THERMAL DEPENDENCY

It is well documented that the shape memory effect results from a reversible crystalline phase change known as martensitic transformation. Two types of events are associated with this phenomenon. In either case, the material always attempts to recover to its austenitic original shape. The two-way shape memory effect characterizing a material's ability to transition from one pre-defined shape to another remains a laboratory curiosity and has had very few successful commercial applications to date.

<u>Thermal event</u> (referred to as thermal shape memory effect): the reversible phase transformation between austenite and martensite is thermally induced. Martensite forms upon cooling from the austenitic phase. The soft martensite can be easily deformed and will recover its original shape upon heating to a much stronger austenite. Upon cooling, the martensite will reform and the shape retained. Very importantly, one should be aware that there is a thermal hysteresis or difference between the forward and reverse transformation paths.





<u>Mechanical event</u> (referred to as non-linear superelasticity): the reversible phase transformation is stress induced. Contrarily to the thermal event described above, superelasticity does not rely on temperature change. The martensitic transformation results from the application of a stress and, in that case, the martensite is referred to as stress-induced martensite. The martensite reverts to austenite once the stress is removed, as the austenite is thermodynamically stable at this temperature

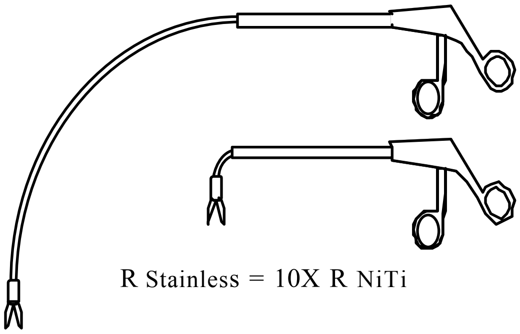
The alloys that exhibit these effects have been either cold-worked and heat treated, solution treated and aged or neutron irradiated, the later being more of an academic exercise than an efficient and cost effective manufacturing technique.

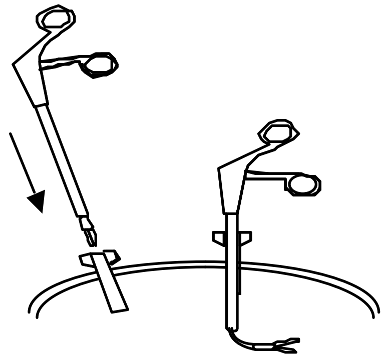
DESIGNING WITH NITINOL

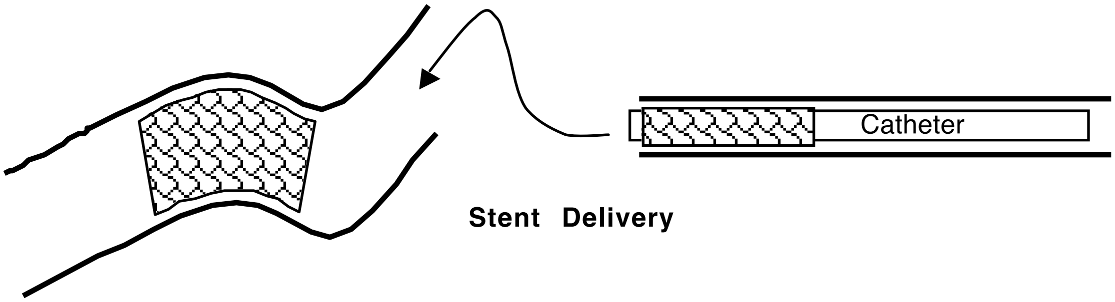
Before getting into some of the difficulties and challenges of designing with nitinol, one must have a sound understanding of some of its tremendous potential from an engineering and application perspective.

1- Ability to recover large deformation

Mechanical strain reaching up to 8% can be recovered either via thermal shape memory or superelasticity. This characteristics is extensively valuable as it allows compact designs, small delivery systems, larger installation or insertion clearances. It also allows a confined entry through narrow cannulas, trocar ports, catheters and other percutaneous access devices. Once recovered inside the patient's body cavity, the nitinol component can be used to steer, bend, twist, deploy, and/or expand.

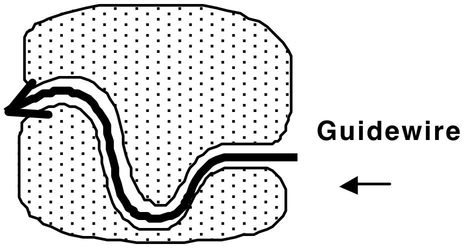


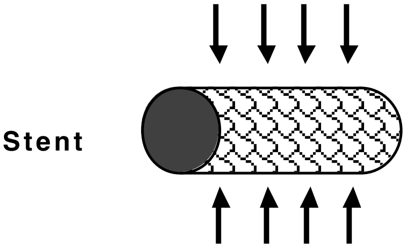




2- Kink and crush resistance

Both refer to as the ability to resist a permanent deformation under a certain amount of strain. Superelastic nitinol's superiority to other alloys systems typically used in the medical device industry like stainless steels and titanium alloys is indisputable and makes it a material of choice for a large number of surgical, guidewire or stent applications where kink or crush resistance are essential.





Kink and crush resistance are directly proportional to superelasticity therefore one must ensure that the application or design fit well within the superelastic temperature range. This range is highly sensitive to heat treatment conditions. Both superelastic range and fatigue properties beneficiate from a high UTS to loading plateau stress ratio. Once again and because of temperature dependencies, design and manufacturing must focus on the device operating conditions.

3- Flexibility, torqueability and pushability

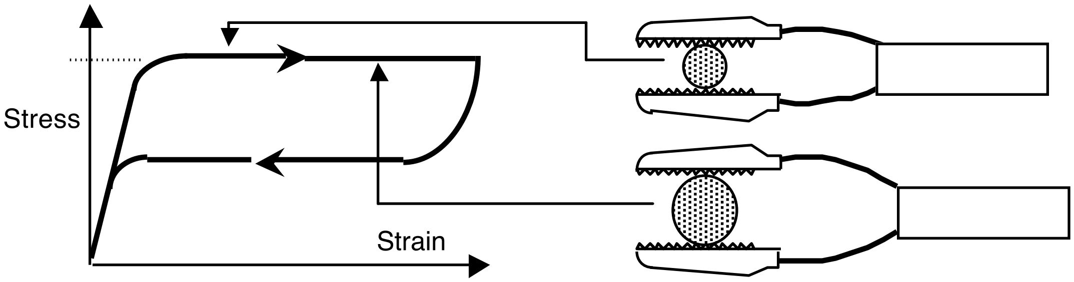
Flexibility is the ability of a material to deflect elastically under very low stresses. Inversely proportional to stiffness, flexibility (often referred to as floppiness for a guidewire) can be enhanced by proper thermo-mechanical processing (increase the amount of cold work to decrease modulus for example or aging treatment) and/or geometric variations.

Torqueability is the ability of a material to transfer a twisting or rotating action from one end to the other under some level of constraint (bends, etc). It is a function of both geometrical (straightness and roundness) and microstructural integrity of the material and the constraint strain. In the case of nitinol, processing parameters such as time, temperature and tension in the production of a straight product for example, play a key role in achieving a torqueable component. In most cases and size for size, nitinol is far less torqueable than stainless steel for example.

Pushability is the ability of a material to transfer a longitudinal motion throughout its length without significant lateral deflection or buckling. It is important to understand that this quality is defined by the stiffness or elastic modulus of the material and not the superelastic loading plateau stress although it may be perceived as such because of a subjective 'feel' in the hands of an interventionist. This characteristics is sensitive to processing parameters such as amount of cold-work and annealing conditions as well as operating temperature. Geometrical parameters, such as straightness, are also important.

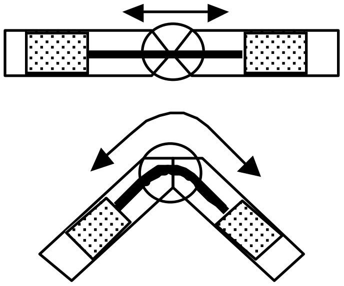
3- Generation of constant or low forces over a wide range of deformation

The very typical plateau stresses exhibited by superelastic nitinol can be used advantageously to limit forces and pressures against structures or to minimize their variations over a large range of deformation or deflection, acting as a safety



4- Transmission of forces, motions, work generation

It is often very difficult to transmit forces and/or motions with requiring complex mechanisms such as multiple linkages. The difficulty of the task is heightened when these transmissions needs to occur through articulations, curves and sharp angles, etc.

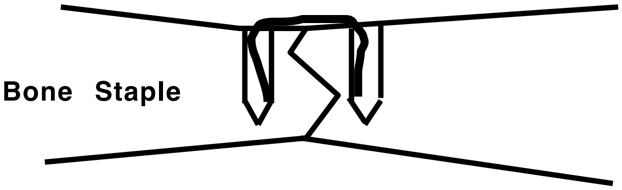


5- Constrained or free recovery

Considered the simplest application of the shape memory effect, thermal free recovery is seldomly used in medical devices, especially if they are designed to be recovered via temperature means inside a patient's body cavity as the effect usually dictates temperatures that would easily necrose and destroy vital tissues.

Nevertheless, a component manufactured from a martensitic nitinol can be easily deformed and set to a specific shape by surgeons or interventionists in the operating theater and then used to adapt to a patient's specific anatomy. After use, these types of devices can be autoclaved or heated to their austenitic phase and recover an original storing shape until the next use.

Constrained recovery is used in applications where force generation or precise positioning are required. This is accomplished by a rigidly constrained recovery prohibiting the material to fully recover to its original austenitic shape. This type of recovery has been typically used for locking-type or expandable medical devices in order to locate and/or anchor the device at a specific location.



6- Energy storage and delivery

One of the most famous and oldest application of superelasticity relating to energy storage and delivery is orthodontic archwires. In typical energy storage and restoration designs, the material is usually deformed initially to high strain levels against an opposing substrate. As the substrate starts to yield and the deformation strain diminishes, the plateau stress exerted by the nitinol component remains fairly constant (plateau stress) and accommodates a wide range of motion.

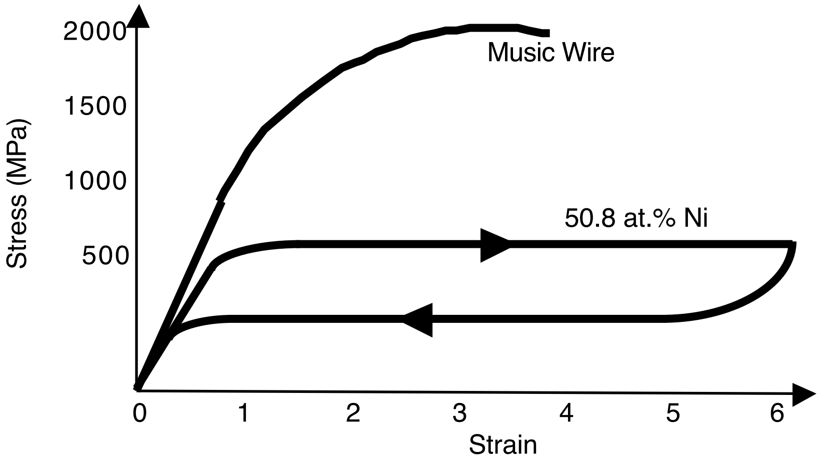
DESIGN AND MANUFACTURING CHALLENGES AND DIFFICULTIES

The engineering community faces great challenges when it comes to designing with nitinol and manufacturing components therefrom, the later often being a strong limitation to the creative minds. The following points encompass some of the key issues at hand and focus on the more widely used superelastic properties, as witnessed in the majority of medical device applications to date.

1- Non linear behavior

The non-linear elastic or thermo-elastic behaviors of nitinol hamper accurate theoretical modelization and analysis. They also make the more subjective ‘feel’ so critical to doctors and interventionists, manipulating a device which is an extension of their hand, a very foreign experience. Familiar hookean elasticity and plastic yield concepts do not apply any longer.

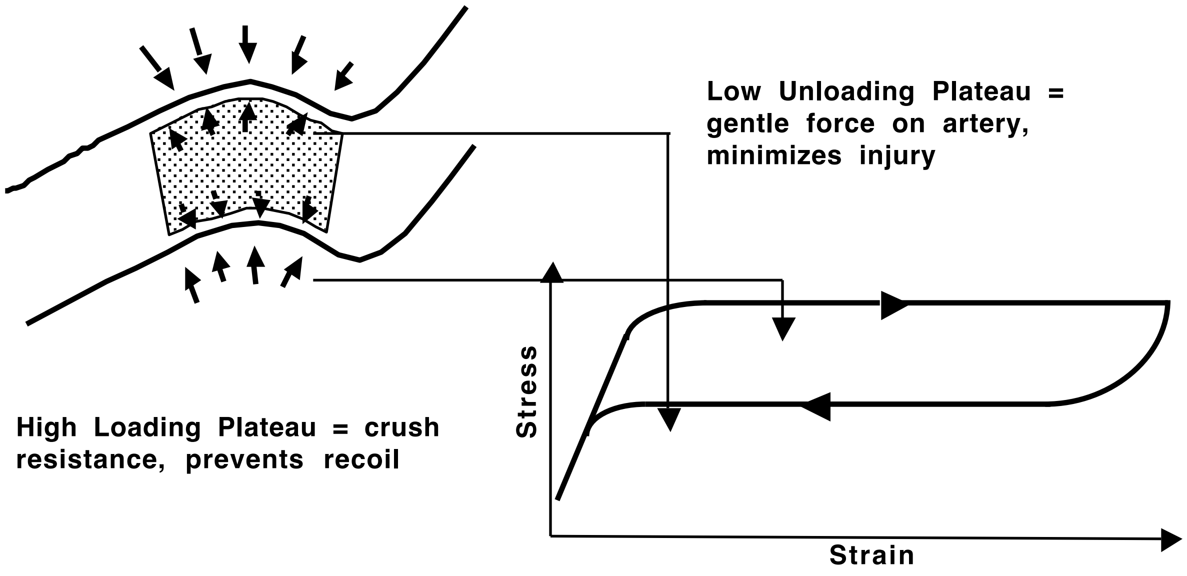
Because of this non-linear elastic behavior, the material can accumulate and restore a tremendous amount of potential energy that could be extremely deceiving and lead to premature failure or malfunction of the device. One could for example imagine a surgical guidewire prevented to rotate by a very tortuous vascular pathway or a kink and the energy that the interventionist could potentially store in the wire while continuing to torque it. The wire could either break within a patient’s arteries or unwind brutally creating serious damages.



2- Stress hysteresis

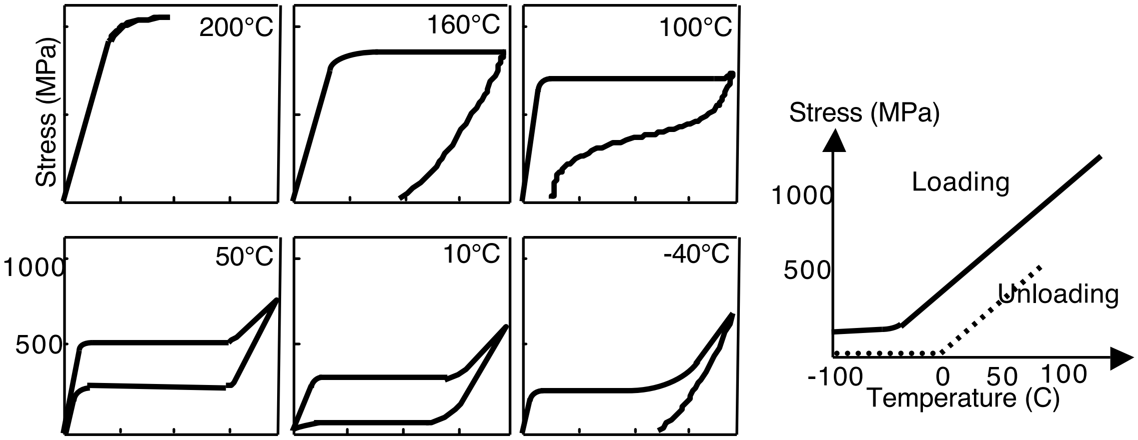
The stress hysteresis between loading and unloading plateau stresses of superelastic nitinol can be used advantageously. In an endoluminal stent application for example, the high loading plateau stress increases the crush resistance of a stent placed in superficial arteries (carotid, etc) and in articulated areas when stents are under a lot of external loading configurations. Manufacturing wise, the high plateau stress has to be overcome for compression and insertion in a delivery or constraining system leading potentially to frictional resistance and other assembly issues.

The usually much lower unloading plateau stress assists in maintaining a gentle external pressure against the wall of the artery and minimize the vessel’s recoil.



3- Thermal sensitivity of stresses

The design engineer must evaluate and anticipate an increase of the plateau stresses as the temperature of the material rises, typically this increase ranges from 3 to 25 MPA/°C. Therefore, appropriate testing at body temperature for an implant for example is critical. Advantageously, this characteristics can be very helpful on a manufacturing standpoint: the nitinol component can also be cooled to facilitate its insertion in a delivery system or constraining sheath.

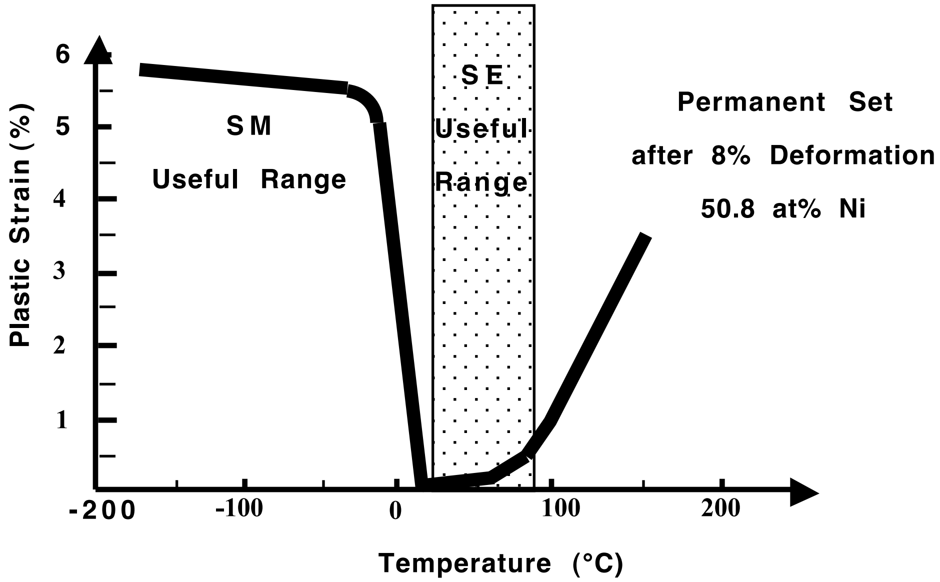


50.8 at% Ni - 35%CW + 500C HT

4-Thermal sensitivity of permanent deformation

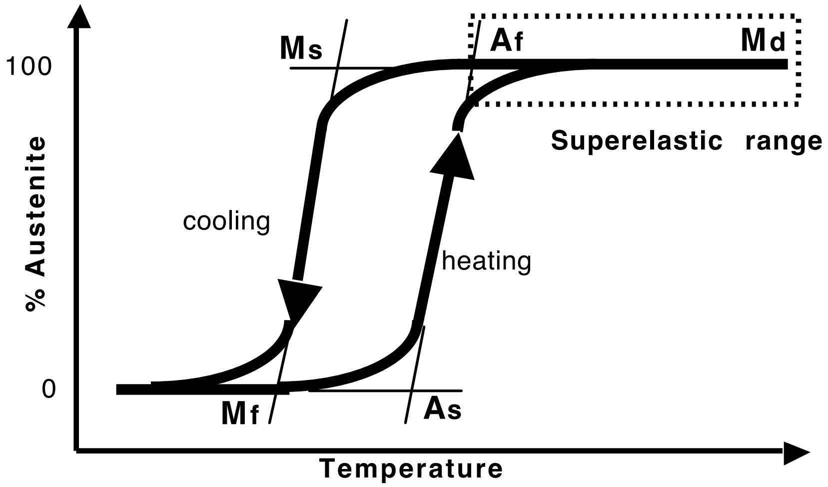
Superelasticity occurs only within a narrow temperature range, typically 50 to 60°C wide for binary nitinol alloys. An increasing post loading deformation subsides on either side of this range, some of which may be thermally recoverable when the material reverts to its martensite structure. Above Md, temperature at which it is no longer possible to stress induce martensite and achieve superelasticity, the deformation is permanent and unrecoverable.

Once again, from a manufacturing or assembly perspective, it may be advantageous in some cases to cool down and deform the nitinol component in its martensite condition to facilitate a fixturing or constraining operation.



5- Thermal hysteresis

The difference between the martensitic transformation paths (cooling and heating) needs to be accounted for when designing with nitinol. The constant 37°C body temperature allows using the thermal hysteresis effectively not only in a variety of device applications but also during manufacturing or assembly.

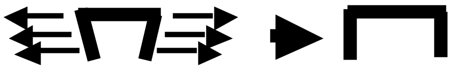


This hysteresis can be used advantageously from a design or manufacturing perspective by ensuring its position in relation to body temperature by either selecting the right material chemical composition or thermo-mechanical processing. The following examples describe 2 situations in which body temperature is either within the material's hysteresis cycle or slightly above it (BT>Af).

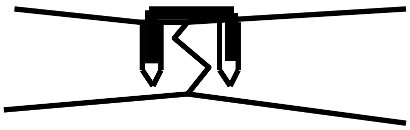
A- Bone staple

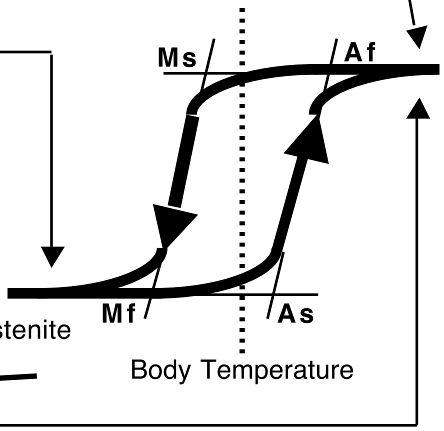
1. Staple is formed by heat treatment (austenitic shape)

2. Staple is cooled down and stretched (martensitic shape) and will remain stable (opened) slightly above BT

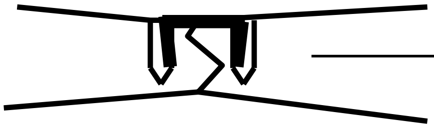


3. Staple is inserted into bone (Zero Insertion Force)



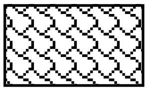


4. Staple is heated, recovers shape and remains in austenite (constrained recovery)

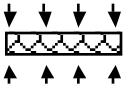


B- Stent

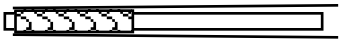
1. Expanded Stent (austenitic shape)

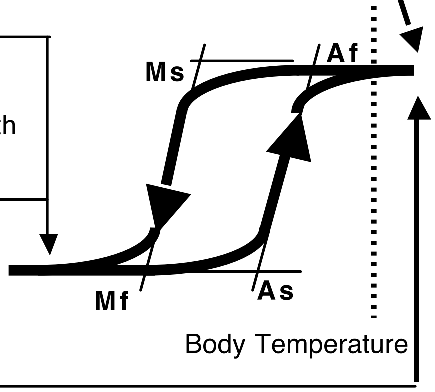


2. Stent is cooled down and mechanically crushed into a smaller diameter (martensitic)

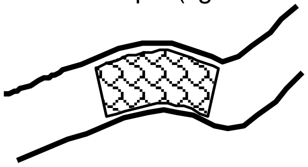


3. Cold stent is inserted into delivery system sheath (reduced drag), warms up but is constrained





4. During delivery, sheath is removed and the stent self expand to austenitic shape (light constrained recovery)



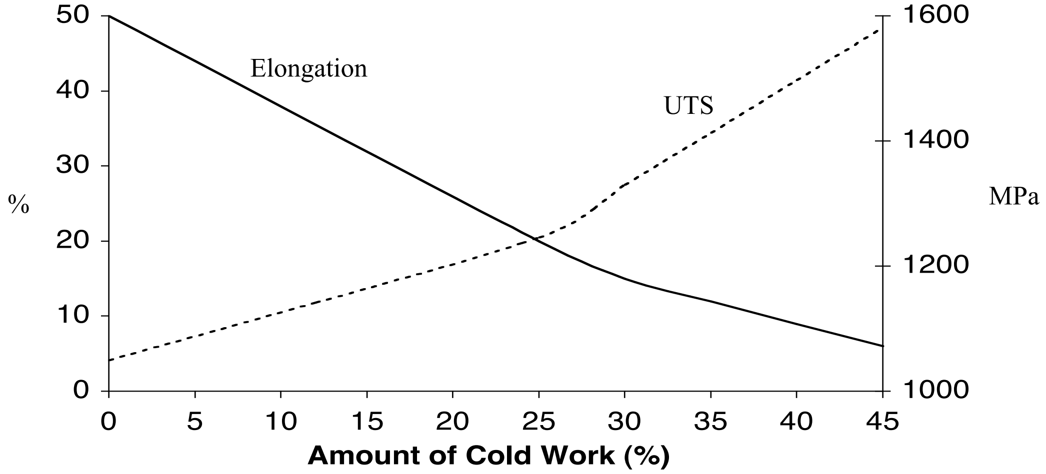
6- Stress dependency of transformation temperatures

The transformation temperatures Mf, Ms, As and Af are stress sensitive and increase with the level of stress applied to the material. One shall remember to test the material in actual or simulated operating conditions.

7- Cold work influence on UTS and elongation, cold forming and ductility issues

The ductility of nitinol drastically decreases with the amount of area reduction or cold-work. Additionally, the ductility decreases when the nickel content increases making it sometimes impossible to cold work (nitinol's transformation temperatures also decrease very rapidly as the nickel content increases). Contrarily, the ultimate tensile strength (UTS) increases

Ductility issues of heavily cold worked material can lead into cold forming issues. For example, it might be very difficult to wrap a cold worked as-drawn wire around fixturing pins for a shape-set heat treatment or flatten the distal end of a wire in a paddle shape for some guidewire applications.

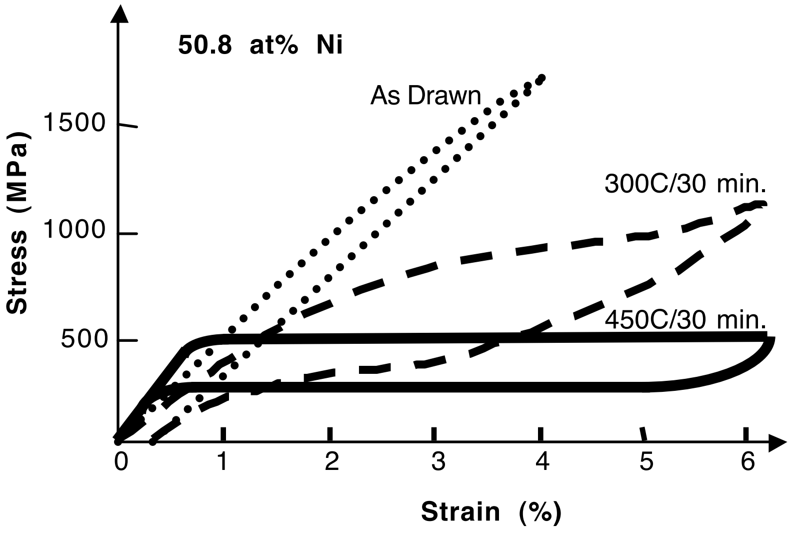


8- Thermo-mechanical processing influence on properties

Depending upon the selection of heat treatment parameters (time and temperature), one can achieve a variety of mechanical responses. Depending upon the final application, it is essential to understand and select the appropriate material condition to achieve a good compromise of optimum performance and manufacturing friendliness. To achieve intricate formed shapes without long straight portions, it is recommended to start from an as-drawn or as-rolled material as it offers more flexibility and options from a shaping heat treatment perspective. Nevertheless one could encounter ductility issues when trying to fixture an as-drawn wire for example around a small radius pin for a shape setting heat treatment

On the other hand, it is a lot easier to start from a straight as-drawn and heat treated wire when forming a J hook at the end of a nitinol guidewire because the main body of the wire is straight.

Be aware that nitinol tubing is currently only available in the straight heat treated condition and in discrete pieces.



9- Fatigue

S-N curves for nitinol shows the same logarithmic decrease of life cycle as the number of cycles increase. The material can fracture in stress or strain cycling conditions at constant temperature while the material is either martensitic, austenitic or if martensite is stress-induced during cycling. Other types of fatigue failures include the deterioration of physical, mechanical and shape memory properties due to thermal cycling through the transformation temperature range with or without applied stress. As for corrosion, the surface characteristics and conditions of the material play an important role.

10- Radiopacity

Nitinol is slightly more radiopaque that stainless steels but far less that platinum, gold, tantalum or tungsten. When the mass of the nitinol component cannot be increased to address radiopacity concerns, it can be plated to enhance radiopacity but the process is delicate and costly.

11- Available test data

Unfortunately, the vast majority of mechanical test data available relates to tensile testing. Although a few designs dictates (high recovery stress and small motion) and uses nitinol components in a tensile load configuration, most use bending or even torsion load configurations. As design complexity increases, combined loading modes are often encountered.

For superelastic nitinol, plateau stresses in pure bending are different from their equivalent in tension. One must carefully test and characterize the material in the condition the closest to the one to be used in a design. Test methods are also critical and for example, 4-point pure bending test is encouraged over the typical 3-point test. Because of temperature dependencies stated in previous paragraphs, the test temperature is also critical.

MANUFACTURING CHALLENGES

It is well known that nitinol is not an easy material to work with and in many cases, manufacturing issues or difficulties minimize a number of design options usually available to the medical device engineering community when they work with other materials like stainless steels for example.

1- Joining and assembly

Nitinol is very difficult to join with dissimilar materials and the most reliable methods are usually of a mechanical nature. Crimping, swaging, staking or similar techniques have been used very successfully for several years. In other cases where adhesive bonding, welding, brazing or soldering is considered, one must be particularly thorough with the removal of the very tenacious TiO_2 oxide layer. Welding and brazing is difficult due to solidification cracking issues. Laser welding or microplasma welding can be effective on smaller components but a stress relieving heat treatment should be considered. In any case, these techniques should be used with extreme caution and limited to low stress/strain joints. Combined with an aggressive flux and sound process controls, soldering with Sn-Ag alloys is possible and effective. Ni or Ni-Au platings can be helpful to enhance solderability. Because of the temperature sensitivity of the material characteristics, long exposure at high temperatures will alter detrimendously its mechanical and thermal performance.

Although one shall first be completely understand installation clearance, tolerance stack-ups, substrate compliance and amount of unresolved (constrained) recovery required, the shape memory effect and its relating recoverable motion available (up to 8%) can be used effectively and very reliably to assemble or mate parts together. It becomes obviously very difficult as the size of parts to assemble decreases.

2- *Platings and coatings*

Electroplating remains a challenging operation due to the presence of the TiO_2 oxide layer. Its effective removal by mechanical testing like sand or beadblasting or via chemically etching means is necessary. The One must be assured that the actual plating layer itself can withstand the very high level of recoverable strain that the nitinol component can be subject to. In addition, hydrogen embrittlement shall be a concern depending upon the plating process used. Process temperatures can also adversely affect material properties.

Coatings have been used for years in a variety of medical devices, many to enhance lubricity, minimize infections, clotting, etc. Lubricious and other coatings like silicone, PTFE, parylene, polyurethanes, hydrophilcs, etc. can be applied. Curing temperatures, such as those required to cure sprayed PTFE films required, could alter the material characteristics and geometry and fixturing may be required to minimize their effects (for example, keep the wire in slight tension during spray coating of PFTE). Contrarily to electroplating, the oxide layer may promote a better adherence of some coating or thin wall extrusions. Vacuum, ion beam or chemically assisted deposition techniques have also been used successfully.

3- *Machining and stamping*

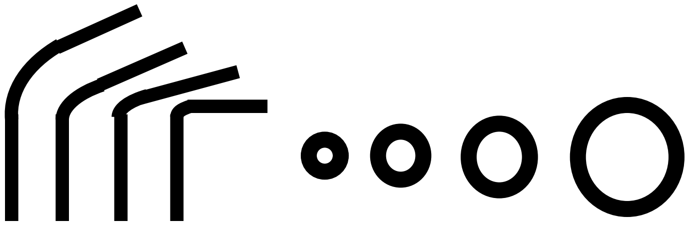
Nitinol can be machined using traditional techniques like milling, turning, grinding (example: profile grinding of guidewires), etc but rapid tool wear shall be anticipated. Plunge or wire EDM, laser machining can be used effectively for most intricate shapes and small parts. For example, laser cutting has become the industry standard to manufacture endoluminal stents from nitinol tubing. Except for etching, electropolishing and some cutting operations, chemical or electro-chemical material techniques are seldomly employed for material removal.

Stamping, coining operations have been used extensively on nitinol wire, strop, sheet and tubing products. The high amount of cold-work (low ductility) and poor high impact fracture toughness of the material can contribute to a low success rate. In addition the right combination of tool materials, design and clearances are critical. High tool wears or tool life and deburring difficulties shall be expected.

4- *Forming*

Cold forming operations are difficult because they are usually process intensive and can introduce an excessive amount of cold work that can lead to brittleness. Stress relieving heat treatment can alleviate or minimize the occurrence of some of these problems. Selective heat treatments can been used locally to enhance formability.

Hot forming operations are been used traditionally to shape set pieces and components. It is a fairly easy technique as it implies only fixturing to constrain the material and heat treat to shape. The tooling can be complex and heat treatment parameters can drastically alter the material properties like transformation temperatures, plateau stresses, etc. especially in case of staged heat treatments or when one starts from a already heat treated as-supplied condition, for example a straight superelastic wire or tube. For example, one could consider the following shapes in a staged heat treatment when trying to achieve a very tight radius or a stent. Another solution is to use a solution treatment followed by an aging low temperature treatment



COST AND AVAILABILITY

Nitinol is an expensive material due to extensive processing costs and a very limited amount of suppliers. Cost has often impeached the use of the material in highly competitive and/or cost driven applications. The rise of managed health care, including reimbursement policies by insurance companies in a lot of countries may dampen the use of nitinol in high added value designs.

Available in a number of alloy compositions, sizes and thermo-processing conditions, nitinol wires have become ‘commodity’ items. Ribbons, strip, sheet and especially tubing are less readily and far more costly.

The vast majority of nitinol components being used in current medical device applications (including some FDA-approved permanent implants or stents) are manufactured from the very typical 50.8 at% Ni alloy composition. This alloy has well documented superelastic characteristics at room and around body temperature making it an ideal candidate. When the thermal shape memory effect is required, a warmer binary composition (50.7 & 50.6 at% Ni) can also be used successfully.

PATENT SITUATION

A large and increasing number of fairly broad patents covering a variety of NiTi alloy compositions, processes, designs and applications (including medical devices) are contributing to design and manufacturing challenges and added cost in a lot of cases.

CONCLUSION

Mainly because of the material’s strong thermo-mechanical sensitivity and processing difficulties, designing with nitinol is not easy and has been a challenge for many years. The last 10 years have demonstrated that nitinol has found its place next to stainless steels and titanium alloys in a wide variety of medical device applications and across medical specialties.

Along with design and performance requirements, engineers must be able to anticipate the manufacturing steps necessary for the production of the finished device or component and make sure that they develop the appropriate test protocols or programs to validate the design input. It will start very early on in the design process when time comes to select the right starting material just like it would be the case for any other materials.

The end-product specification or requirements associated with a sound assessment of the manufacturing techniques to be used for its fabrication shall dictate the actual material requirements such as mechanical characteristics, transformation temperatures, sizes, formats, thermo-mechanical conditions, surface conditions or combinations therefrom. These material requirements shall then be compared with nitinol suppliers product specifications and a fit must be established or a compromise reached. The nitinol industry as a whole is investing a lot of time and effort to try to educate and assist the engineering, manufacturing and users communities and designers shall never hesitate to tap into that resource.

For example, a nitinol stent design and validation could look as follows:

- Design verification in the expanded and catheter-loaded condition: geometry, coverage, foreshortening, flexibility, ‘fish scaling’, axial integrity, workmanship, etc.
- Radial force testing, therno-cycling, shelf life (catheter loaded condition0, catheter insertion and deployment forces.
- Af testing (pre and post cycling)
- Stent removal, recovery or repositionning testing
- Biocompatibility and corrosion testing.
- Fatigue testing
- Abrasion resistance and permeability testing (stent-graft)