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Nitinol Medical Devices and Implants

Stoeckel

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Summary



Superelastic Nitinol is now a common and well-known engineering material in the medical industry. While the greater flexibility of the alloy drives many of its applications, there are also a large number of lesser-known advantages of Nitinol in medical devices. This paper reviews 7 of these less-obvious but very important reasons for Nitinol's success, both past and future. Several new medical applications will be used to exemplify these points, including the quickly-growing and technologically-demanding stent applications. Stents are particularly interesting because they take advantage of the thermoelastic hysteresis of Nitinol.

Keywords



Nitinol, shape memory, superelasticity, dynamic interference, biased stiffness

Introduction

Nickel-titanium (Nitinol) alloys are rapidly becoming the materials of choice for self-expanding stents, graft support systems, filters, baskets and various other devices for minimally-invasive interventional and endoscopic procedures. Most medical device companies now offer products the performance of which is based on the highly unusual properties of these materials.

Nitinol alloys are most commonly known for their superelasticity and thermal shape memory [1]. The term 'shape-memory' is used to describe the phenomenon of restoring to a predetermined shape on heating, after having been 'plastically' deformed; 'superelasticity' refers to the enormous elasticity of these alloys. It can be 10 times more than the elasticity of the best stainless steels (SS) used in medicine today and follows a non-linear path, characterised by a pronounced hysteresis (Figure 1).

Although both effects are clearly spectacular, they are by no means the only important properties of the material. In this paper some important device characteristics, not commonly known to the device designers, will be discussed, all of which can be attributed to the specific properties of Nitinol. They allow interesting solutions for superior medical devices [2]:

- Elastic deployment
- Thermal deployment
- Kink resistance
- Constant stress
- Dynamic interference
- Stress hysteresis (biased stiffness)
- Temperature dependence of stress

Other, equally important properties, such as MRI compatibility, biocompatibility and corrosion are discussed elsewhere in this publication.

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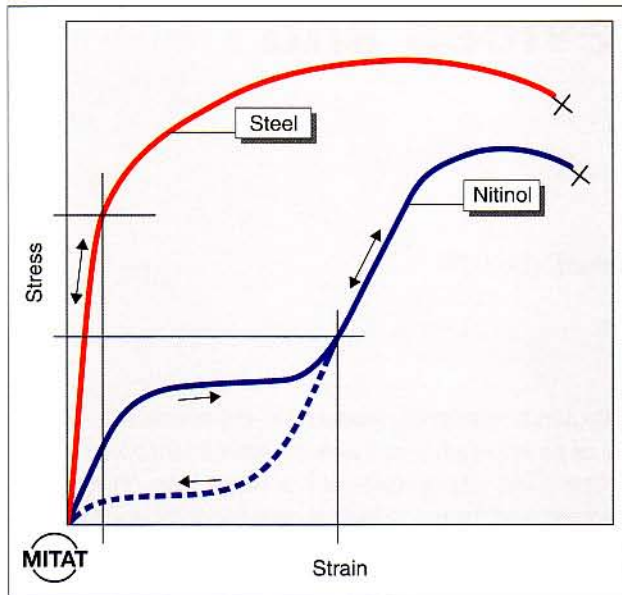


Figure 1. Tensile behaviour of stainless steel and Nitinol (schematic).

Elastic deployment

The enormous elasticity of Nitinol allows devices to be brought into the body through catheters or other delivery systems with a small profile. Once inside the body, the devices can be released from constraining means and unfold or expand to a much larger size. Probably the first such product to be marketed was the Homer Mammalok, which radiologists use to 'mark' the location of a breast tumour. It consists of a Nitinol wire hook and a SS cannulated needle (Figure 2) [3]. The wire hook is withdrawn into the needle



Figure 2. The Homer Mammalok needle/wire localiser [2].

cannula, which is inserted into the breast and adjusted until its tip is verified to be at the site of the tumour. The hook is then advanced, reforming a tight hook configuration. If necessary, the device can be withdrawn into the needle, repositioned and re-deployed until the position is verified to be marked correctly for the surgeon.

The concept of elastically deploying a curved device through a straight needle or cannula is probably the most common use of Nitinol in medical instrumentation. Among the newer devices are the SmartGuide deflectable puncture needle (Daum Medical, Figure 3), and the radiofrequency interstitial tissue ablation device (RITA Medical Systems, Inc., Figure 4). Both devices deliver curved tubular needles. Other devices, such as suture-passers, retractors, deflectable graspers and scissors, have been in use since the early 1990s in endoscopic surgery [4,5].

Significantly more complex devices can also be superelastically deployed. Interesting examples are occlusion devices for repairing defects in the septal wall, or the patent ductus of the heart. The Amplatzer Septal occlusion device is a Nitinol wire mesh shaped into a 'double mushroom' configuration (Figure 5). It can be delivered through a 6–9 F catheter [6]. Other Nitinol occlusion devices are the ASDOS (Osypka, Figure 6), the AngelWings (MicroVena) and the CardioSeal (Nitinol Medical Technologies). These devices use an umbrella type design, while the PFM Duct-Occlude device (Figure 7) uses a Nitinol double helix configuration.

Thermal deployment

Most self-expanding implants, such as stents and filters, make use of the thermal shape-memory of Nitinol. A device with a transition temperature (A_f) of 30°C can be compressed at room or lower temperature. It will stay compressed until the temperature is raised to >30°C. It will then expand to

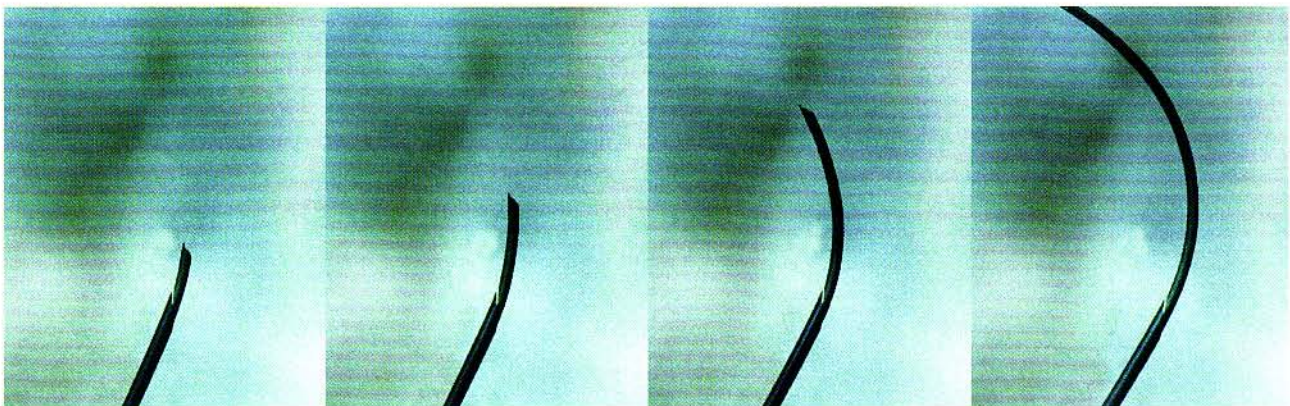


Figure 3. SmartGuide deflectable puncture needle (Daum Medical).

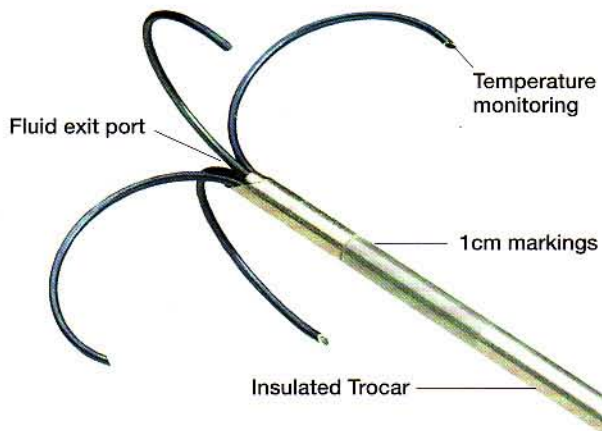


Figure 4. Radiofrequency interstitial tissue ablation device (RITA Medical Systems, Inc.).

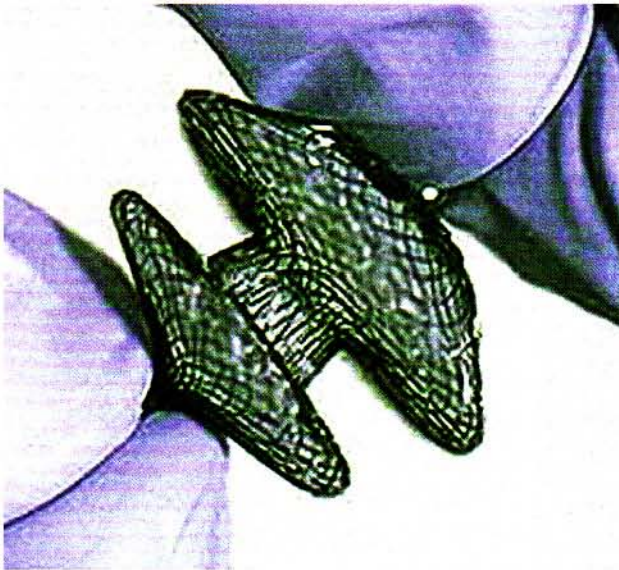


Figure 5. Amplatzer septal occlusion device (AGA Medical Corporation).

its preset shape. If this device could be kept cold during introduction into the body, it would not expand until at the desired location where body heat would warm it up. This is, of course, rather difficult to accomplish. All self-expanding devices, therefore, are constrained in the delivery systems to prevent premature deployment. Figure 8 shows the deployment of the TrapEase (Cordis) vena cava filter from a 6 F delivery system at 37°C. Devices could, theoretically, be built with transition temperatures of 40°C or higher. These devices would have to be heated after delivery to the site to make them expand.

The Simon vena cava filter (Nitinol Medical Technologies) was the first shape-memory vascular

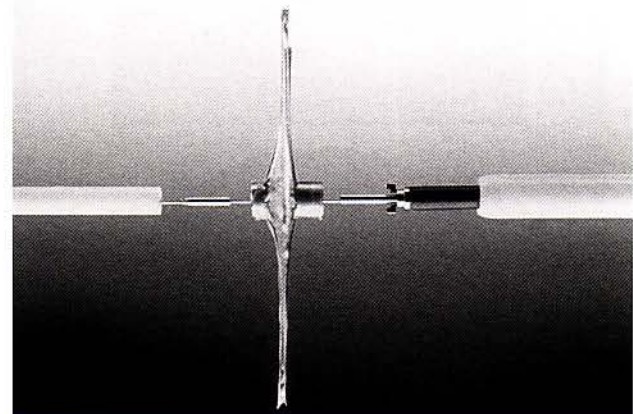
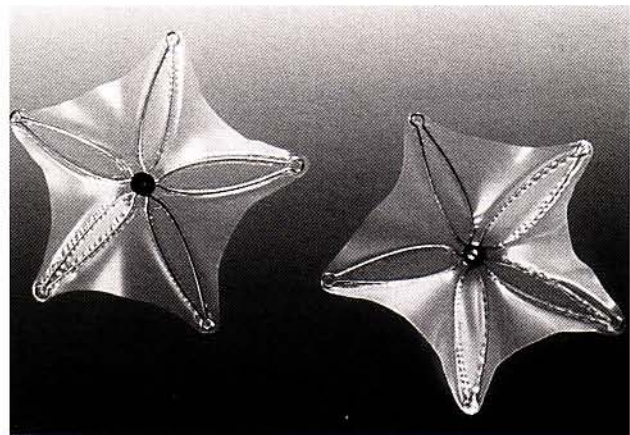


Figure 6. Atrial septal defect occlusion system ASDOS (Osypka Medizintechnik).

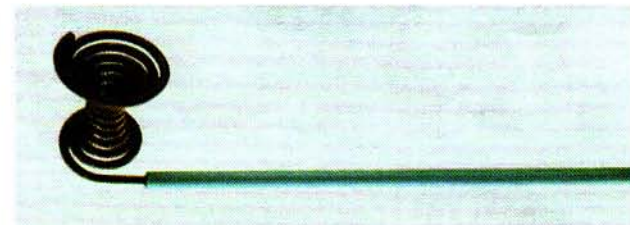


Figure 7. Duct-occlude occlusion device (PFM Produkte für die Medizin AG).

implant developed for thermal deployment. The device has a transition temperature around or below room temperature, it is preloaded in a catheter in its low-temperature state. Flushing the catheter with chilled saline solution keeps the device in this state while positioning it at the deployment site. When released from the catheter, the device is warmed by body heat and recovers its 'pre-programmed' shape [7].

An interesting twist of the thermal deployment feature is 'thermal retrieval' of temporary devices, such as prostatic stents. Coil stents made by Engineers & Doctors, or by EndoCare, for example, can be retrieved from the prostate by chilling the device with cool solution causing the Nitinol to lose

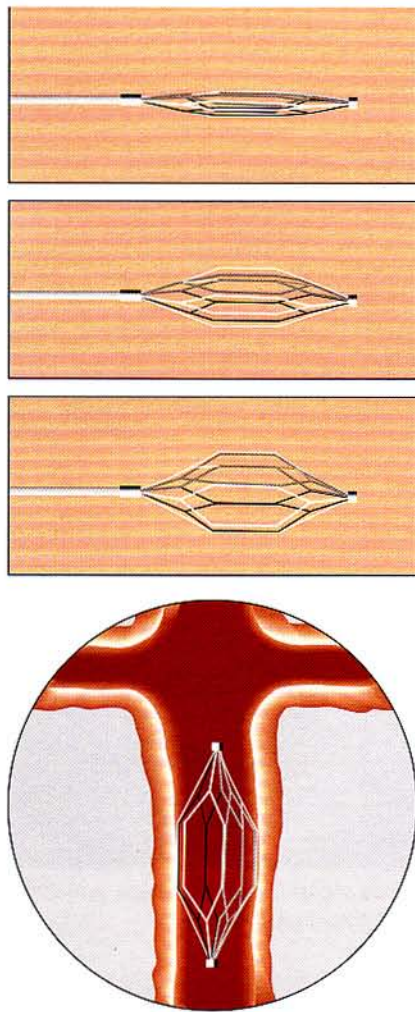


Figure 8. Deployment of the TrapEase vena cava filter (Cordis).

its stiffness. The stent becomes soft and pliable and can be retrieved with a grasping forceps (Figure 9) [8].

A multitude of vascular implants have been approved by the FDA in recent years, or are being investigated or marketed in Europe. Among these are stents and filters by Bard/Angiomed (Memotherm stent, Simon vena cava filter), Boston Scientific (Radius, Symphony stents), Medtronic (AneuRx and Talent AAA devices) and Cordis (SMART stent, TrapEase vena cava filter, AngioGuard distal protection device)

Kink resistance

To some extent this design property stems from the increased elasticity of superelastic Nitinol, but it is also a result of the shape of the stress-strain curve. When strains are locally increased beyond the plateau level, stresses increase markedly. This causes strain to partition to the areas of lower strain, instead of increasing the peak strain itself. Thus kinking, or strain localisation, is prevented by creating a more uniform strain than could be realised with a conventional material. The first applications to take advantage of this feature were guide-wires, which must be passed through tortuous paths without kinking [9]. Steerability and torquability (the ability to translate a twist at one end of the guide-wire into a turn of nearly identical degree at the other end) of a guide-wire are directly affected by the straightness of the wire. Even very small permanent deformations will cause the wire to whip and destroy the ability to steer it through side branches or around sharp bends in the vasculature. Kink-resistant Nitinol wires play an important role in interventional cardiology and radiology. Another early application was in retrieval baskets with Nitinol kink-resistant shafts, as well as a superelastic baskets used to retrieve stones from

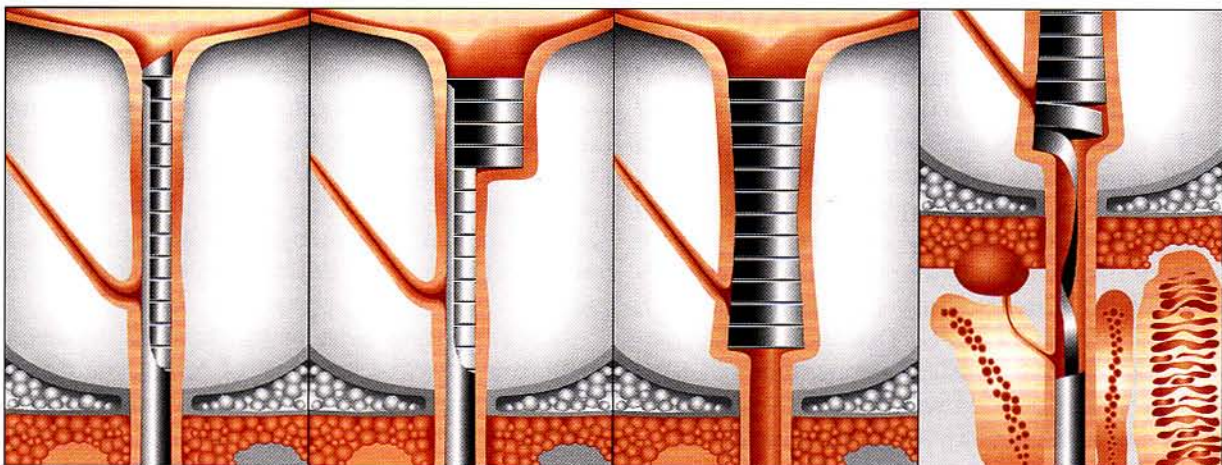


Figure 9. Deployment and retrieval of the horizon stent (Endocare) [7].

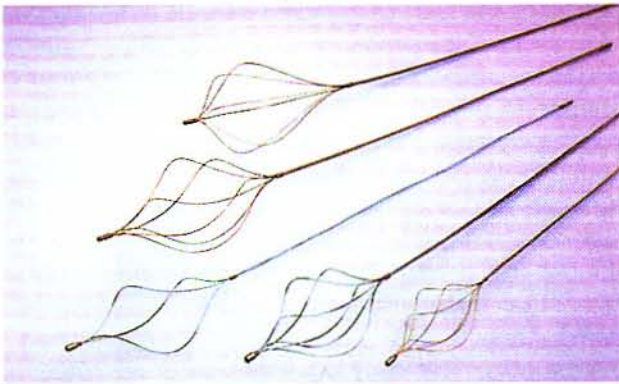


Figure 10. Superelastic Nitinol baskets (Epflex GmbH).

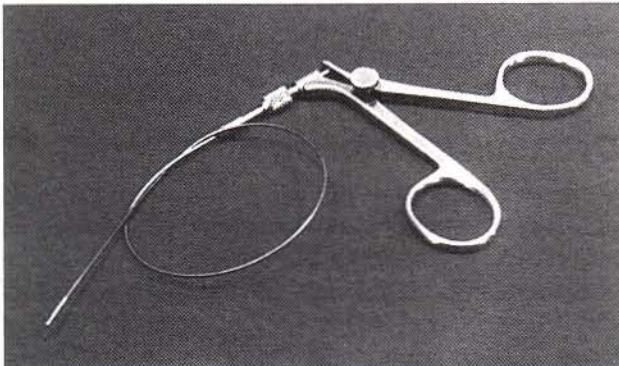


Figure 12. Biopsy forceps (Bacher).

kidneys, bladders, bile ducts, etc. (Figure 10).

Since superelastic tubing became available in the early to mid 1990s, a variety of catheter products and other endovascular devices which use Nitinol as the inner lumen have appeared on the market. An interesting example is the intra-aortic balloon pump (IABP, Figure 11), used in cardiac assist procedures. The use of Nitinol allowed the reduction of the size of the device, compared with polymer-tube based designs, and increased the flexibility and kink resistance, compared with SS tube designs.

Kinking of thin-wall steel tubing limits the use of many interventional devices. Biopsy forceps made from SS, for example, are very delicate instruments that can be destroyed by even very slight mishandling. Nitinol instruments, on the other hand, can handle serious bending without buckling, kinking or permanent deformation. Figure 12 shows 1.5 mm biopsy forceps that consist of a thin wall Nitinol tubing with a Nitinol actuator wire inside. Together they are able to be bent around radii of <3 cm without kinking and still allow opening and closing of the distal grasper jaws without increased resistance. This instrument continues to operate smoothly even while bent around tortuous paths. It should be pointed out however, that the wall thickness of a Nitinol tube

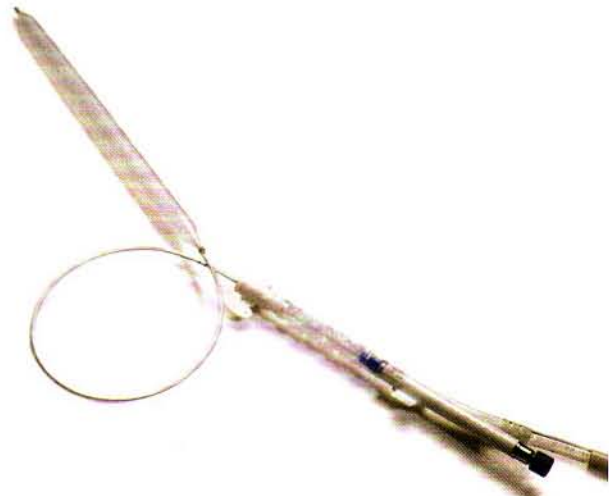


Figure 11. Intraaortic balloon pump with superelastic central lumen.

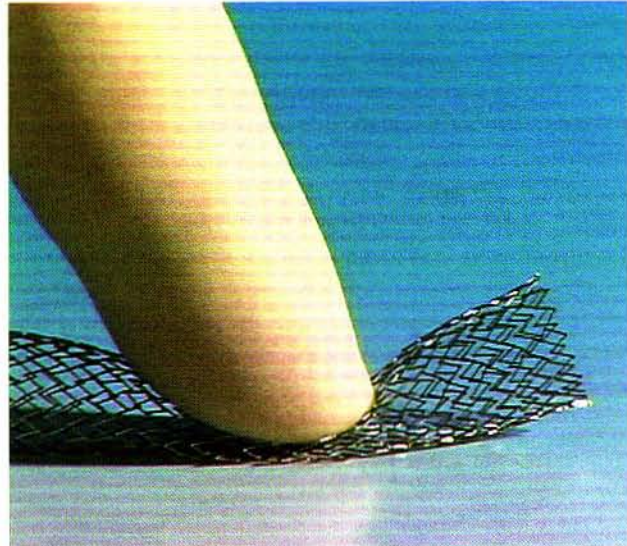


Figure 13. Crush-recoverable Nitinol stent.

stressed in bending should be at least 10% of the outer diameter, to withstand buckling [10].

Kink resistance or, more appropriately, crush recoverability, is an important feature of Nitinol for stents in superficial vessels that could be deformed through outside forces. The carotid artery is a prime example. There is a perceived risk for balloon-expandable stents in carotid arteries to be permanently deformed through outside pressure, resulting in a partially or completely blocked vessel once the buckling strength of the stent is exceeded. Although Nitinol stents typically don't have the buckling strength of SS stents, they cannot be

permanently deformed through outside forces. Nitinol stents can be completely compressed (crushed) flat and will return to their original diameter when the deforming force is removed (Figure 13).

The resistance of Nitinol to kinking and deformation is used in the Vidamed TUNA (trans-urethral needle ablation) catheter to deploy a straight needle through a curved guiding channel with a small radius of curvature. This allows the advancement of the ablation needle out of the catheter perpendicular to the catheter axis.

Constant stress

An important feature of superelastic Nitinol alloys is that their loading and unloading curves are substantially flat over large strains. This allows the design of devices that apply a constant stress over a wide range of shapes. The orthodontic archwire was the first product to make use of this property – more specifically the constant unloading stresses. SS and other conventional wires are tightened by the orthodontist regularly. As treatment continues, the teeth move and the force applied by SS wires quickly relaxes, according to Hook's law. This causes treatment to slow, retarding tooth movement. Nitinol wires, on the other hand, are able to 'move with the teeth', applying a constant force over a very broad treatment time and tooth position.

Constant stress upon loading is used as 'overload protection' in hingeless graspers (or forceps) made from Nitinol. Hingeless instruments use the elasticity of spring materials, instead of pivoting joints, to open

and close the jaws of grasping forceps or the blades of scissors. Their simple design, without moving parts and hidden crevices, makes them easier to clean and sterilise. A new generation of hingeless instruments use superelastic Nitinol for the actuating component, resulting in an increased opening span and/or reduced displacement of the constraining tube for ergonomic handling [11]. In many cases the functional tip can be a monolithic superelastic component, rather than the multiple intricate, precision-machined components and linkages of conventional instruments. This allows the design of instruments with very small profiles. The substantially constant loading stress of Nitinol provides constant force gripping of large and small objects and built-in overload protection. This reduces the risk of tissue damage (Figure 14).

Dynamic interference

Dynamic interference refers to the long-range nature of Nitinol stresses and can be clearly illustrated using self-expanding stents as an example. Unlike balloon-expandable SS stents, self-expanding Nitinol stents will always expand to their pre-set diameters without recoil. Balloon-expandable stents, on the other hand, have to be over-expanded to achieve a certain diameter as a result of elastic spring-back after deflation. This spring-back, or loosening, is called acute recoil and is a highly undesirable feature. The over-expansion may damage the vessel and cause restenosis. Moreover, if the vessel diameter relaxes with time, or undergoes a temporary spasm, a SS stent will not follow the vessel wall. The interference stresses will be reduced and the stent could embolise. The Nitinol stent will continue to gently push outward against the vessel wall after deployment and follows vessel movements. Typically, the pre-set diameter of a Nitinol stent is $\approx 1\text{--}2$ mm greater than the target vessel diameter. It will therefore try to reach this diameter. Should the vessel increase in diameter, the Nitinol stent will also expand until it reaches its final diameter. A more complete description of this feature can be found elsewhere in this publication.

Biased stiffness (stress hysteresis)

The most unusual feature of Nitinol alloys is stress hysteresis (see Figure 1). While in most engineering materials stress increases with strain upon loading in a linear way and decreases along the same path upon unloading, Nitinol exhibits a distinctly different behaviour. Upon loading, stress first increases linearly with strain, up to $\approx 1\%$ strain. After a first 'yield point', several percentage points of strain can be accumulated with only a little stress increase. The end

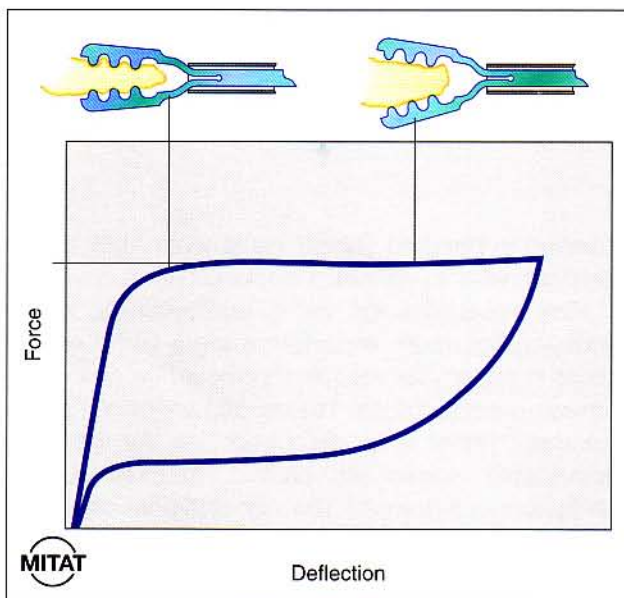


Figure 14. Constant gripping force of a hingeless Nitinol grasper (schematic).

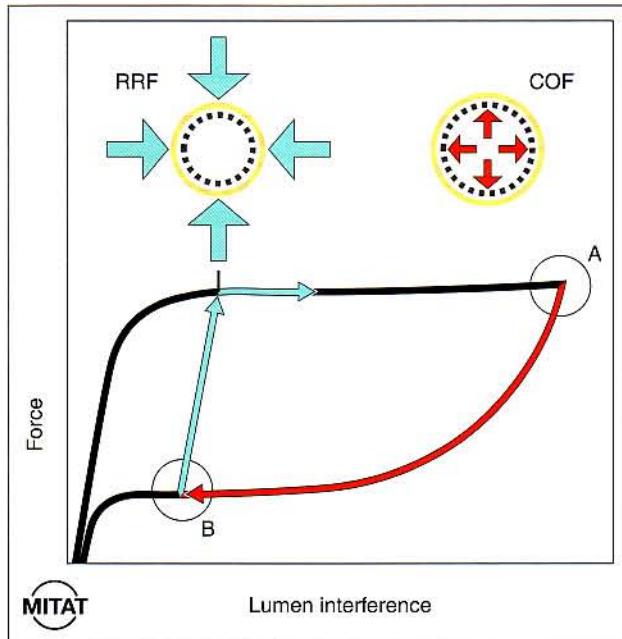


Figure 15. 'Biased stiffness' of a stent as a result of the stress hysteresis.

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 a small decrease in 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.

The pronounced stress hysteresis can be utilised advantageously for a variety of medical devices. Frank *et al.* [12] describe a detachable bowel clamp which uses a Nitinol spring. When the clamp is applied, it will be first opened to a size larger than the bowel diameter, following the loading curve. When released to occlude the bowel, the force decreases, following the unloading curve. Whenever bowel contents are propelled by peristalsis and increase the distraction force on the clamp, the force, again, follows the loading part of the stress-strain curve. Thus, the force required to open the clamp can be considerably larger than the force applied by the clamp under static conditions. Similarly, the holding force of hingeless forceps decreases when tissue is displaced, thus allowing atraumatic grasping.

In self-expanding Nitinol stents, the concept of 'biased stiffness' is most obvious. As illustrated in Figure 15, a stent is compressed into the delivery system following the loading curve to point A (for

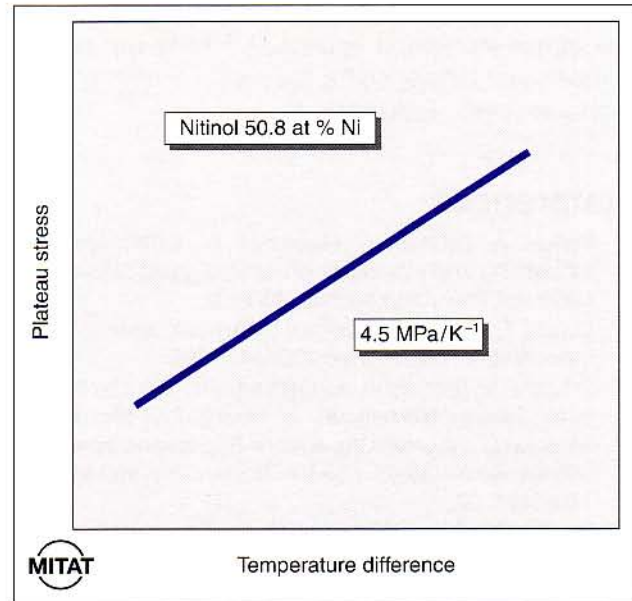


Figure 16. Influence of temperature on plateau stress (schematic).

simplicity isothermal conditions are assumed). Upon release from the delivery system inside the vessel, it expands following the unloading path of the stress-strain curve. At point B it reaches the diameter of the vessel lumen, appositioning itself against the vessel wall with a low outward force (chronic outward force, COF). As can be seen from the figure, this force remains nearly constant, even if the vessel would increase in diameter (dynamic interference). If the vessel contracts, through spasms for example, or is compressed from the outside, the stent resists deformation with a higher force (RRF, radial resistive force). The stress hysteresis of Nitinol allows the design of self-expanding stents with biased stiffness, meaning that the stents exert only low outward force, but resist deformation with a much higher force.

Temperature-dependent stiffness

The plateau stresses are strongly temperature dependent above the transition temperature of the alloy. As a result, superelastic devices become stiffer when temperature increases. The stiffness of a superelastic device of a given design at a specific temperature, body temperature for example, can be modified to some extent by adjusting the transition temperature of the Nitinol alloy used through a heat treatment [1]. Lowering the transition temperature makes the device stiffer at body temperature. Plotting the loading plateau stress (at a defined strain) versus ΔT (body temperature minus transition temperature)

yields a linear relationship as shown in Figure 16, with the stress increasing approx. 4.5 MPa per degree temperature difference for the most commonly used Nitinol alloy with Ti-50.8at% Ni.

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