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An Overview of Nitinol Medical Applications

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Materials Science and Engineering A273-275
pp.149-160

1999

An overview of nitinol medical applications

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Abstract

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 the applications, there are actually a large number of lesser-known advantages of nitinol in medical devices. This paper reviews 10 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 in that they involve new and complex manufacturing techniques, present a demanding and interesting fatigue environment, and most interestingly, take advantage of the thermoelastic hysteresis of nitinol. © 1999 Elsevier Science S.A. All rights reserved.

Keywords: Nitinol; Mechanical applications; Superplasticity; Shape memory behavior; Stents

1. Introduction

The commercialization of shape memory alloys, and specifically nitinol, is a truly unique success story. The discovery of shape memory in Au–Cd and Cu–Zn occurred with little fanfare in somewhat obscure technical papers with little, if any, follow-on work. However, when the shape memory effect was rediscovered in equiatomic Ni–Ti in 1962, there was suddenly a great deal of commercial interest. Early commercialization activities, fueled by applications such as rivets, heat engines, couplings, circuit breakers and automobile actuators, were intense and often highly secretive. Metallurgists were quick to solve the microstructural mysteries of shape memory, and by the early 1970's could explain even the minutes details of the shape memory process. Unfortunately, industry's understanding of engineering lagged well behind: non-linear tensile properties, hysteresis, fatigue, and adiabatic heating and cooling effects were just a few of the new problems baffling product designers during these years [1]. Moreover, alloy melting and processing remained expensive and unreliable, with relatively few product forms available. By the early 1980's it became clear that shape memory was not a financial panacea. When the picture

had not improved much by the early 1990's, many companies threw in the towel and returned to core technologies.

As we approach the end of the century the picture looks very different. Nitinol has become a 'household' word in the medical engineering world. Nitinol producers have experienced explosive growth. In general, it has not been the original large companies that have survived, but a core of entrepreneurs whose belief in the technology was so strong that they started small companies when the efforts of larger companies began to flag. Attention turned towards superelasticity instead of the more complicated shape memory effect and towards medical applications, particularly implants. The human body offered an isothermal environment that seemingly solved many of the design complexities. Indeed body temperature turns out to be perfectly tuned to the superelastic 'sweet spot' of the basic binary Nitinol alloys, and does not require the cryogenic alloys of couplings and fasteners or the very high- M_s alloys of actuators.

What really triggered the sudden change in fortune? Superelasticity was certainly well known since the early 1970's. Material costs have come down, but not enough to drive the market and, in fact, material costs make up only a small fraction of the total cost of a medical device and costs seldom enable or disable an application. There appear to be three primary reasons for the

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sudden success. Perhaps most importantly, the medical industry itself has been driven towards less and less invasive medical procedures. This, in turn has created a demand for new medical devices, that really can not be made with conventional materials. Other factors were the availability of microtubing and the ability to laser cut tubing with very high precision. Finally, we should not underestimate the importance of the 'release' of technology from materials science technologists and companies to product designers and doctors.

Probably the best illustration of all these points is also the most celebrated superelastic medical device: the self-expanding stent. The word stent derives from a dentist, Dr C.T. Stent, who in the late 1800's developed a dental device to assist in forming an impression of teeth. Nowadays, the term stent is reserved for devices used to scaffold or brace the inside circumference of tubular passages or lumens, such as the esophagus, biliary duct, and most importantly, a host of blood vessels including coronary, carotid, iliac, aorta and femoral arteries (Fig. 1). Stenting in the cardiovascular system is most often used as a follow-up to balloon angioplasty, a procedure in which a balloon is placed in the diseased vessel and expanded in order to reopen a clogged lumen (called a stenosis). These balloons are introduced percutaneously (non-surgically), most often through the femoral artery. Ballooning provides immediate improvement in blood flow, but 30% of the patients have restenosed within a year and need further treatment. The placement of a stent immediately after angioplasty has been shown to significantly decrease the propensity for restenosis [2].

Stents are also used to support grafts, e.g. in the treatment of aneurysms (Fig. 2). An aneurysm is caused by the weakening of an arterial wall, that then balloons out and presents a risk of rupture. Surgical repairs are often difficult. With the endovascular approach, a graft is placed through the aneurysm and anchored in the

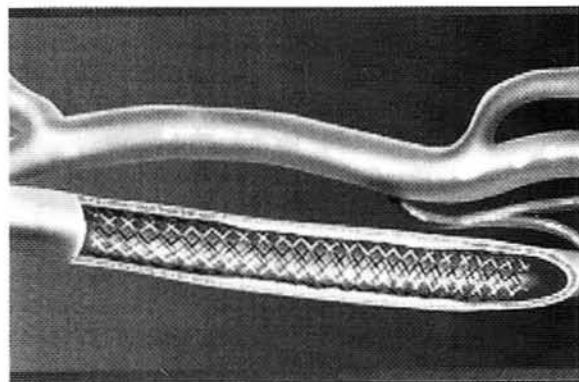


Fig. 1. A stent is portrayed in a cut-away view of the internal carotid artery, maintaining vessel patency and blood flow to the brain. The stent is also pinning loose debris against the vessel wall, reducing risk of embolization and stroke.

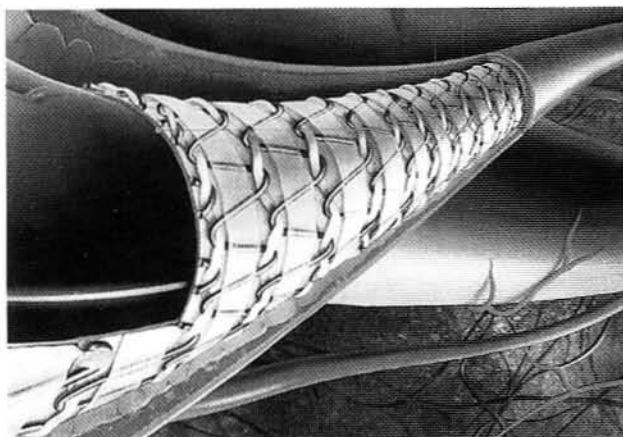


Fig. 2. The Hemobahn product incorporates a superelastic Nitinol wire into a PTFE. Stent-grafts such as these are used to exclude aneurysms, to provide an artificial replacement for injured vessels, or to prevent restenosis after angioplasty.

healthy part of the artery at least at the proximal neck of the aneurysm. Thus, blood is excluded from the aneurysm sack. The grafts are typically supported and anchored by self-expanding stent structures.

Most stents today are 316L stainless steel, and are expanded against the vessel wall by plastic deformation caused by the inflation of a balloon placed inside the stent. Nitinol stents, on the other hand, are self-expanding — they are shape-set to the open configuration, compressed into a catheter, then pushed out of the catheter and allowed to expand against the vessel wall. Typically, the manufactured stent OD is about 10% greater than the vessel in order to assure the stent anchors firmly in place. Nitinol stents are now available in both Europe and in the USA. They are made from knitted or welded wire, laser cut or photoetched sheet, and laser cut tubing. Clearly the preferred devices are laser cut from tubing, thus avoiding overlaps and welds (Fig. 3).

Why use nitinol for making stents and other devices? The most apparent feature of superelastic (SE) nitinol is

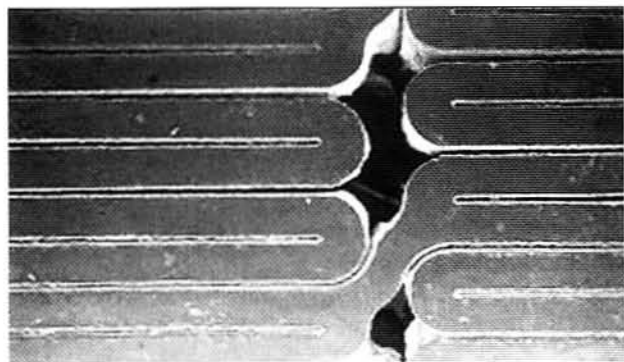


Fig. 3. Stents are often made from laser cut tubing. In this case, the laser beam cuts a kerf of less than 25 μm , through a thickness of over 200 μm .

that its flexibility is 10–20 times greater than stainless steel; that is to say, one can observe devices to 'spring-back' with strains as high as 11%. This in situ flexibility plays a role in some superficial stent applications such as the carotid and femoral arteries, where the vessels may be subject to outside pressures that would cause conventional stents to crush. Such deformations have been observed in stainless steel stents, and can lead to serious consequences. Although superficial applications requiring in situ flexibility are rare, there are many subtle aspects of superelasticity that actually drive the selection of nitinol for all stent applications, even those not subjected to deformations. The purpose of this paper is to explore some of these more subtle aspects of nitinol performance, and to discuss them with respect to specific medical applications. More specifically, 11 will be introduced:

- Elastic deployment
- Thermal deployment
- Kink resistance
- Biocompatibility
- Constant unloading stresses
- Biomechanical compatibility
- Dynamic interference
- Hysteresis
- MR compatibility
- Fatigue resistance
- Uniform plastic deformation

2. Elastic deployment

One of the most common reasons to use nitinol is to allow the efficient deployment of a medical device. Modern medicine has been steadily driving towards less and less invasive procedures. Entire operations of increasing complexity are performed through small, leak-tight portals into the body called trocars; vascular diseases are repaired by passing wires and instruments percutaneously through needles into the femoral artery and on to the heart, brain, etc. These procedures require instruments and devices that can pass through very small openings and then elastically spring back into the desired shapes. Many of these devices could be made with any flexible material, but clearly nitinol allows the greatest freedom in design.

Probably the first such product to be marketed was the Homer Mammalok, which radiologists use to 'mark' the location of a breast tumor. It consists of a nitinol wire hook and a stainless steel cannulated needle [3]. The wire hook is withdrawn into the needle cannula, and then the cannula is inserted into the breast and adjusted until its tip is verified to be at the site of the tumor. The hook is then advanced, reforming a tight hook configuration. If necessary, the device can be withdrawn into the needle, repositioned, and re-de-

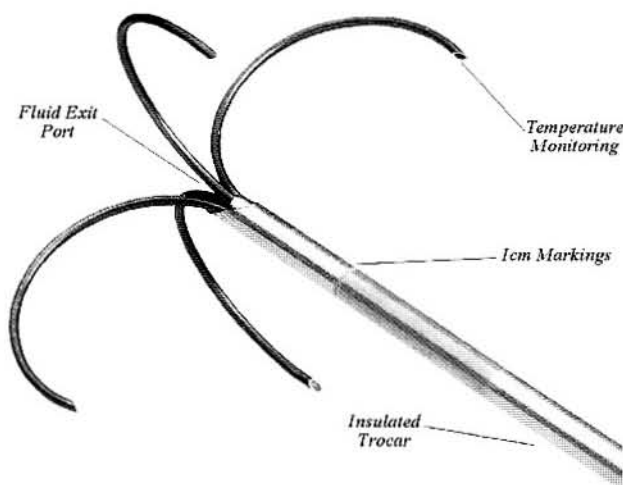


Fig. 4. The RITA tissue ablation device uses four sharply curved tubular needles which are deployed from a straight needle after insertion through a trocar.

ployed until the position is verified to be marked correctly for the surgeon. A stainless steel device would require the wire diameter to be much smaller, assuming the hook geometry is to remain fixed. Such a fine wire would be too flimsy to anchor the hook effectively. It would also allow inadvertent transection, leaving bits of wire behind in the breast.

The concept of elastically deploying a curved device through a straight needle or cannula is probably the most common use of nitinol for medical instrumentation. Among the newer devices are the TUNA prostrate ablation device, the Daum deflectable puncture needle, and the RITA tissue ablation device (Fig. 4). While the latter two devices deliver curved needles, other devices such as suture passers, retractors, deflectable graspers and scissors have been in use since the early 1990's in endoscopic surgery.

The atrial septal defect occlusion system (ASDOS) is a more complex device [4]. This system allows non-surgical occlusion of holes in the atrial wall of the heart, ranging from 20 to 35 mm in diameter. The entire procedure is conducted through two low profile catheters. The actual device is comprised of two small umbrellas consisting of five nitinol wire loops supporting webs of microporous polyurethane (Fig. 5). The two devices are passed into the body while folded one each in two catheters, and then positioned on either side of the defect area. A guide wire passing directly through the hole is used to ensure that the two catheters and umbrella devices are aligned correctly. Once positioned, the umbrellas are advanced from their catheters, and screwed together using a special torquing catheter. The resulting 'sandwich' forms a patch, occluding the atrial defect. Although it is too early to

convincingly evaluate the success of this particular product, it well illustrates the concept of elastic deployment. Several companies are now marketing similar devices.

3. Thermal deployment

An additional unique attribute of nitinol devices is that they can be deployed using the shape memory effect. One example is the Simon vena cave filter (Fig. 6). The device is intended to filter rather large embolized blood clots in the vena cave vein [5], as blood returns to the heart from the lower body. The clots are trapped by the legs of the filter and by the filter's 'flower', then dissolved over time. Such clots are common in bed-ridden patients and pose a serious hazard if they reach the heart or lungs. The device itself is preloaded into a catheter while in the martensitic state. Flushing chilled saline solution through the catheter keeps the filter in the martensitic phase while positioning to the deployment site. When released from the catheter and the flow of chilled saline stopped, the device is warmed by the surrounding blood, and recovers its 'pre-programmed' shape.

Like the vena cave filter, stents also have an A_f temperature only slightly above room temperature.

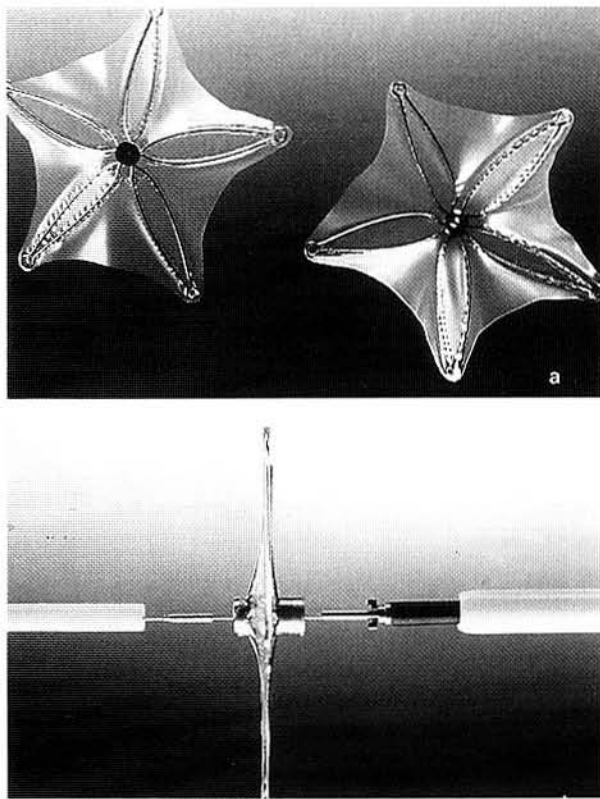


Fig. 5. The atrial septal occlusion device incorporates nitinol wires in a polyurethane film in order to repair defects in the wall of the heart.

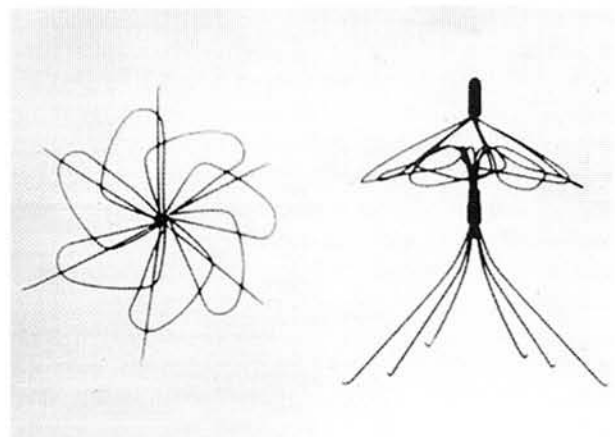


Fig. 6. The Simon vena cave filter expands once in the vena cava, and is left permanently in place to prevent embolized thrombus from reaching the heart and lungs.

Thus they are superelastic in the body yet martensitic when constrained into the sheath. When deployed at room temperature, the stents will not adopt their expanded shape; that occurs only when body temperature is reached. Stents typically expand to 3–8 times the catheter diameter.

4. 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 strain, 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 localization, is prevented by creating a more uniform strain than could be realized with a conventional material.

The first applications to take advantage of this feature were angioplasty guidewires, which must be passed through tortuous paths without kinking [6]. The wires, once in place, form a guide over which other devices are advanced, including angioplasty balloons, stents, filters, etc. The wires must be very long when accessing places in the more distal parts of the body, such as the brain from a femoral access point. Paths can also be very tortuous and full of side branches, making it very important that the wires are steerable and torquable. Even very small permanent deformations will cause the wire to whip and destroy the ability to steer the wire through side branches or around sharp bends. In order to improve lubricity, the wires are generally coated with Teflon or a hydrophilic coating, and often employ a helical wrap of fine Pt to improve radiopacity at the distal tip. There can be little doubt that nitinol guidewires have played an important role in the success of angioplastic medicine.

Another early application is retrieval baskets with nitinol kink-resistant shafts, as well as a superelastic basket to retrieve stones from kidneys, bladders, bile ducts, etc. Still another example, with an ingenious twist, is a line of laparoscopic instruments made by Surgical Innovations (Fig. 7). The shaft of the instruments is composed of a series of hollow knuckles strung on a stainless steel cable. When the cable is relaxed, the knuckles are loose and shapeless; when the actuator is tensioned, the knuckles are pulled together, and the shaft is forced into specific, predetermined shapes. The object of the innovation is to provide a means to pass a shaft through a trocar, then reform a rigid complex shape once the instrument end is through the trocar and into the body. The actuator was originally braided stainless steel so that it would not kink when the knuckles locked into their formed shape. The problem with braided cable was that the device became so flaccid when the tension was released that it was difficult to advance through the trocar. The solution was to replace the actuator cables with a nitinol rod, which provides some rigidity to the relaxed state yet can be bent with the knuckles without plastic deformation.

Since superelastic tubing became available in the early to mid 1990's, a variety of catheter products and

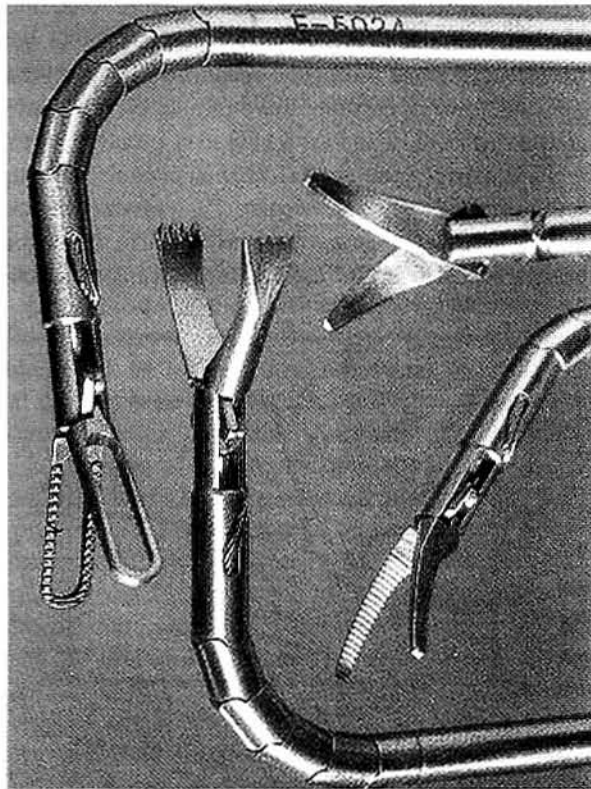


Fig. 7. Surgical Innovations endoscopic instruments use nitinol rods to actuate scissors, graspers, etc. A braided stainless steel cable (visible in the center grasper) is used to tension the articulating joints, locking the instrument in a predetermined shape once past the trocar.

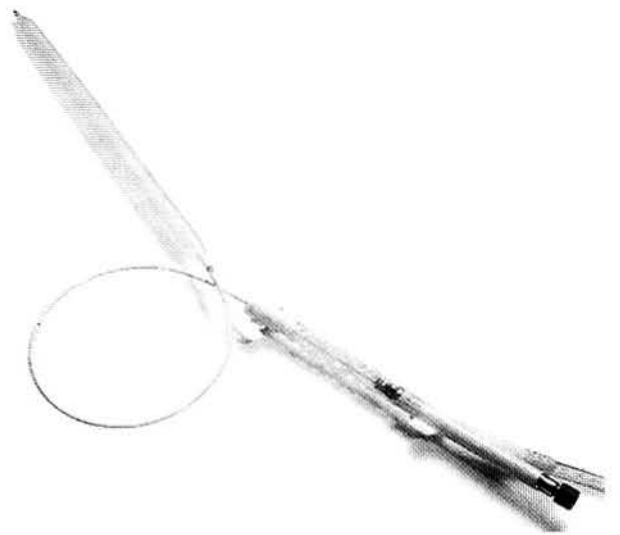


Fig. 8. The arrow intraaortic balloon pump uses a nitinol tube to pressurize the balloon. Stainless steel would not be flexible enough, and a polymer tube would have to be a much larger diameter.

other endovascular devices using nitinol as the inner lumen appeared on the market. An interesting example is the intraaortic balloon pump (IABP) used in cardiac assist procedures (Fig. 8). The use of nitinol allowed a reduction in the size of the device compared with polymer tube based designs, and increased the flexibility and kink resistance compared with stainless steel tube designs.

Kinking of thin-wall steel tubing limits the use of many interventional devices. Biopsy forceps made from stainless steel, for example, are very delicate instruments, which can be destroyed by even very slight mishandling. Nitinol instruments on the other hand can handle serious bending without buckling, kinking or permanent deformation. Fig. 9 shows a 1.5 mm biopsy forceps that consists of a thin wall nitinol tubing with a nitinol actuator wire inside. Together they are able to

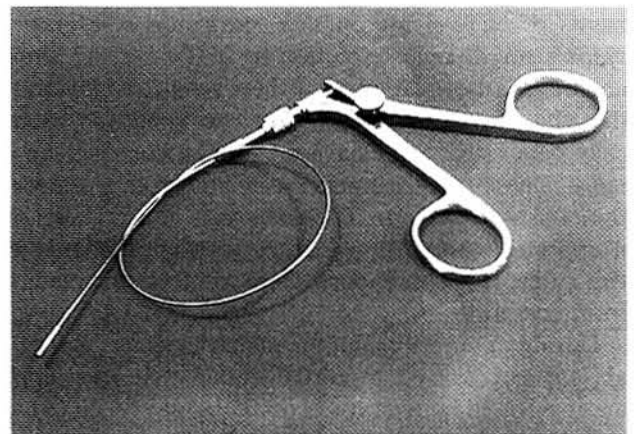


Fig. 9. Nitinol tubing with an internal actuation wire allows this 0.8mm diameter grasper to operate while tied in a knot.

be bent around radii of less than 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 stressed in bending should be at least 10% of the outer diameter to withstand buckling [8].

5. Biocompatibility

The term 'biocompatibility' may be simply defined as the ability of a material to be accepted by the body. Since all materials generate a 'foreign body reaction' when implanted in the body, the degree of biocompatibility is related to the extent of this reaction. Therefore, biocompatibility is directly related to the corrosion behavior of the material in a specified solution and the tendency for the alloy to release potential toxic ions. Literature reviews generally indicate that nitinol has extremely good biocompatibility, due to the formation of a passive titanium-oxide layer (TiO_2) [9–12] similar to that found on Ti alloys [13]. This finding corroborates basic thermodynamics data that specify that the free energy of formation of TiO_2 is favored over other nickel or titanium oxides [12]. This oxide layer serves two purposes:

- Increases the stability of the surface layers by protecting the bulk material from corrosion.
- Creates a physical and chemical barrier against Ni oxidation and modifies the oxidation pathways of Ni [14].

Several comparative studies have shown that in simulated physiological solutions NiTi is more resistant to chemical breakdown than 316L stainless steel, but less so than Ti-6Al-4V. Fig. 10 compares typical anodic polarization curves for the three materials (from Ref. [9]). More recently, Trepanier et al. [10] investigated the effects of electropolishing and subsequent heat treatments of NiTi stents on their corrosion resistance in Hank's physiological solution at 37°C. Fig. 11 shows anodic polarization curves of these stents and illustrates that the electropolished or electropolished and chemically passivated stents have the highest corrosion resistance. These two treatments were shown to promote a thin and very uniform Ti-based oxide layer. Therefore, it appears that uniformity of, rather than thickness of, the oxide is most important to protect the material from corrosion.

During in vitro dissolution studies in saliva, Barret et al. [15] and Bishara et al. [16] found that NiTi appliances released an average of $13.05 \mu\text{g day}^{-1}$ Ni, which is significantly below the estimated average dietary intake of $200\text{--}300 \mu\text{g day}^{-1}$. In addition, orthodontic patients with NiTi appliances had the Ni-concentration

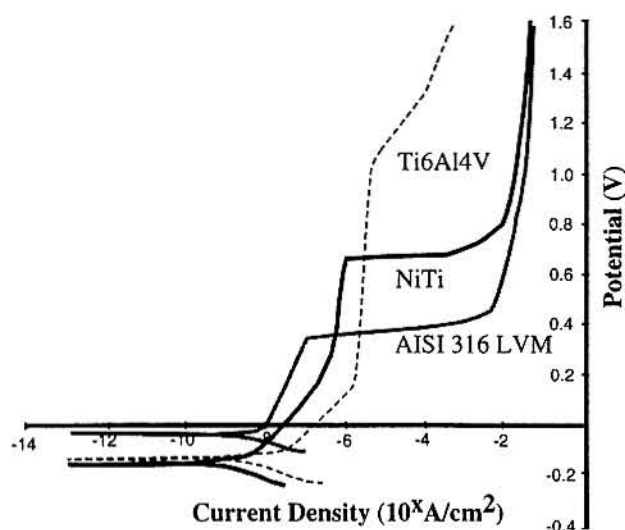


Fig. 10. Potentiodynamic results are compared for three common medical materials in 37°C Hanks solution, showing NiTi to be roughly between Ti-6-4 and 316L. These results have been confirmed by many independent researchers.

in their blood measured during a period of 5 months [16]. The results show no significant increase in the nickel blood level throughout this study. Furthermore, Trepanier et al. [17] performed an in vivo study on passivated NiTi stents. Implantation of the material in rabbit paravertebral muscles and study of the inflammatory reaction for periods ranging from 3 to 12 weeks demonstrated good biological response to NiTi. Analysis of the fibrous capsule surrounding NiTi stents revealed a decrease of the thickness as a function of time. Fig. 12 illustrates the typical fibrous capsule surrounding the implants after 12 weeks.

These laboratory investigations confirm the clinical reports from Japan, Germany, China and Russia dating

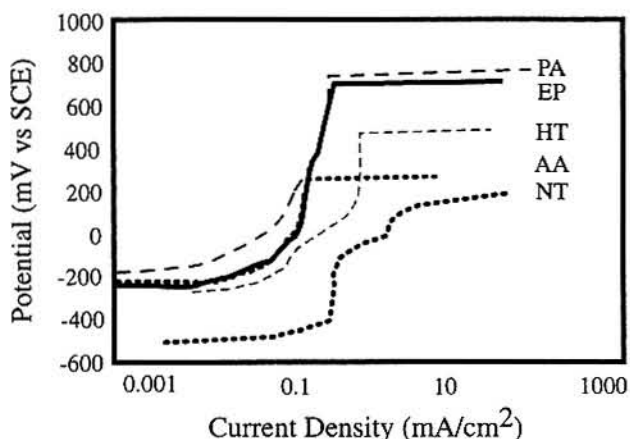


Fig. 11. Anodic polarization testing in 37°C Hank's solution compares several different surface treatments of nitinol: NT, natural processing oxide; EP, electropolished; AA, electropolished and aged in air to return light blue oxide; and PA, electropolished and passivated.

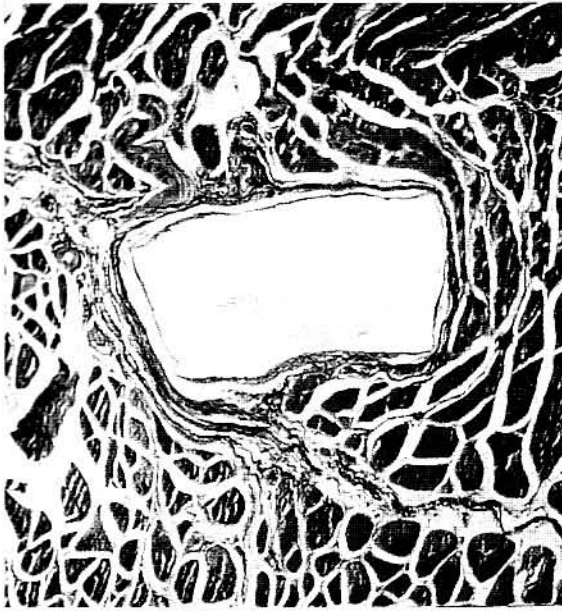


Fig. 12. A nitinol stent strut is shown in cross section 12 weeks after implantation.

back to the early 1980's. Perhaps the longest and most extensive history pertains to the dental implant, in use in Japan since the early 1980's [18]. In the USA, the FDA has approved several nitinol class III implants, among them the Simon vena cava filter and the SMART, radius and symphony stents. The FDA has also approved the Mitek bone anchor system, another permanently implanted nitinol device [19].

6. Constant stress

Another important feature of superelastic materials is that they exhibit constant unloading stresses over large strains. Thus, the force applied by a superelastic device is determined by temperature, not strain as in conventional materials. Since body temperature is substantially constant, one can design a device that applies a constant stress over a wide range of shapes.

The orthodontic archwire was the first product to use this property [20]. Stainless steel and other conventional appliances require adjustment by the attending orthodontist, often to the point of causing pain. As treatment continues, the teeth move and the forces applied by the appliances quickly relax, which retards the correction process. Re-tightening by the orthodontist recycles the process, with only a narrow optimum-treatment period. In contrast, Nitinol wires are able to move with the teeth, applying a constant force over a very broad treatment time and tooth position. Different grades of wire stiffness are available allowing the orthodontist to 'program' the treatment stress and be sure treatment will continue properly with fewer visits and

less pain. Nitinol archwires were introduced in the late 1970's. We estimate that over 30% of the archwires used today are nitinol.

Superelastic eyeglass frames provide another example of this property [21]. These are now available at nearly every optician, and are the most popular of all frames sold in the USA and Europe, despite the fact that they are priced in the top 5%. These frames can be twisted a full 180° without permanent deformation, but more importantly the frames press against the head with a constant and comfortable stress. Not only is 'fit' less important, but small bends and twists that may develop do not cause discomfort to the wearer. It should be noted that this particular product is a very demanding product in terms of manufacturing technology, requiring dissimilar material welding or brazing, and sophisticated plating technologies. These technologies did not exist prior to the need of the eyeglass frame application, and were all developed by the frame industry.

7. Biomechanical compatibility

Stainless steel, titanium and other metals are very stiff relative to biological materials, yielding little if at all in response to pressure from the surrounding tissue. The extraordinary compliance of nitinol clearly makes it the metal most mechanically similar to biological materials (Fig. 13). In fact, even the stress-strain hysteresis that is so foreign to metallurgy is commonplace with biological materials [22]. Though nitinol is the exception with respect to the world of metallurgy, stainless steel is the misfit in the world of biology. This improved physiological similarity promotes bone in-

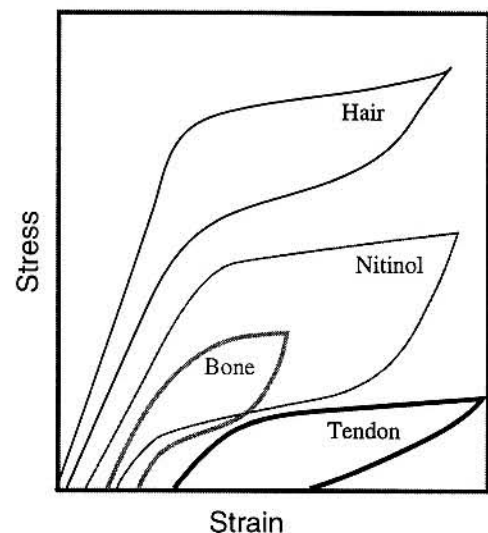


Fig. 13. The stress-strain curves of several natural biological materials are superimposed on those of stainless steel and nitinol. The close similarity of nitinol to natural materials leads to more rapid healing times and less trauma to surrounding tissue.

growth and proper healing by sharing loads with the surrounding tissue. A large number of orthopedic devices take vantage of this property, including hip implants, bone spacers, bone staples, skull plates and the like.

This latter application is particularly interesting in that it utilizes porous nitinol [23], which further leverages the above advantages, particularly bone in-growth. Combustion synthesis, or using the heat of fusion to 'ignite' the formation of the NiTi compound from nickel and titanium, has been shown to be an effective way to produce a porous 'sponge' of nitinol, with densities from 40–90%. The sponge maintains superelastic and shape memory properties, has a reduced modulus of elasticity, accelerates bone in-growth and has improved adhesion to surrounding tissue. The application of these particular devices was pioneered in Russia, and warrants a good deal more attention than it has thus far received in the USA.

The concept of physiological compatibility also plays an important role in stents. Vessels are generally rather tortuous; angioplasty balloons, on the other hand, are hard, noncompliant and straight when fully inflated, often to pressures in excess of 15 atmospheres. Stainless steel stents are thus invariably deployed in a straight configuration, forcing the vessel to be straight. This leads to high bending stresses, and potential restenosis problems. Nitinol stents, on the other hand, are much more compliant and will contour themselves to the vessel wall while minimizing these bending stresses. To be thorough, we should say that this stent property, called 'contourability' is largely design related, but still, materials do play an important role.

8. Dynamic interference

Dynamic interference refers to the long-range nature of nitinol stresses. To illustrate this, we compare a self-expanding nitinol stent with a balloon expanded stainless steel stent. Following balloon expansion, the balloon is deflated, causing the stent to 'spring back' towards its smaller, undeformed shape. This spring-back, or loosening, is called acute recoil and is a highly undesirable feature. In order to fill a 5 mm lumen, a stainless steel stent might have to be expanded to 6.0 mm so that it is certain it will spring back to at least the 5 mm lumen diameter. This over-expansion may damage the vessel and cause restenosis. Moreover, if the vessel diameter relaxes with time, or undergoes a temporary spasm, a stainless steel stent will not follow the vessel wall. The interference stresses will be reduced and the stent could even embolize.

In contrast, the expansion forces in a nitinol stent are of a long-range nature. The stent is oversized in the vessel and continues to apply an outward force until it

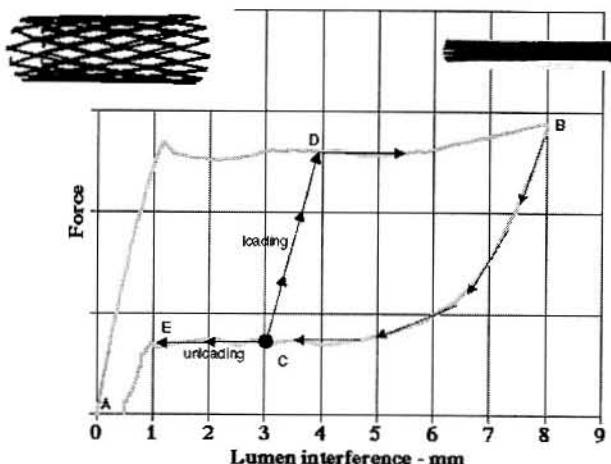


Fig. 14. The product performance cycle of a stent is portrayed on a typical superelastic stress-strain curve. The x-axis represents the interference of the stent diameter with the vessel (e.g. the unconstrained state, to the left, represents the shape set diameter of 10 mm, 1 mm of interference a diameter of 9 mm, and so on). The stent is constrained in a catheter, following the curve from A to B, then unloaded until a stress equilibrium is achieved at point C. Loading and unloading (D and E) exhibit dramatically different compliances.

fully reaches its preprogrammed diameter. The nitinol will also try to fill an oblong or irregularly shaped cross section, and dynamically apply force during changes in cross sectional shape.

9. Hysteresis

The superelastic hysteresis of nitinol has long been considered a drawback because it reduces the energy storage efficiency: a device requiring 5 J for deformation, may only return 2 J of mechanical energy upon unloading. This hysteresis is a desirable feature in stent design. A superelastic stent should provide only a very light chronic outward force (COF) against a vessel wall, and at the same time be highly resistant to crushing — compliant in one direction, and stiff in the other. This is a very important feature in stent design. Nitinol offers both a very low, dynamic outward force, yet a very high radial resistive force (RRF).

This is exemplified in Fig. 14. The stent is manufactured in the expanded diameter (A), then compressed into a catheter (B). Note this is simplified in that it is unlikely that the actual compression would be done at body temperature; the actual path from A to B would follow a different curve, possibly a martensitic deformation. Once in the body, the stent would be deployed, following the unloading path from B to C, at which point the stent makes contact with the vessel wall. Most interesting is that point C exhibits a biased stiffness: while the COFs follow the unloading plateau (C to D), the resistance of the stent to further compression is

much higher (following C to E). Also note that if the stent is later re-expanded to a larger diameter, the filled circle (B) in Fig. 14 will be displaced to the left, but the stiffness will remain the same.

The desire to have a high RRF yet a low COF leads device designers to use high A_f temperatures. Lowering A_f reduces COF and RRF by the same amount. Altering the stent design to reduce COF by the same amount (e.g. reducing strut width) would cause a proportional reduction in RRF. This leads designers to choose as high an A_f temperature as possible, while still being absolutely certain that A_f remains below body temperature.

10. MR compatibility

Nitinol is non-ferromagnetic with a lower magnetic susceptibility than stainless steel. MRI compatibility is directly related to the susceptibility of a material relative to human tissue. Therefore, nitinol provides a clear, crisp image, with much less artifacts than stainless steel, similar to pure titanium. Fig. 15 shows an MRI image of a grasper used in gall bladder surgery, with a matching light photograph of the same instrument end. The same grasper made from stainless steel would be completely unrecognizable. Similarly, Fig. 16 shows MR images of a nitinol stent being deployed from a catheter — even delicate features of the stents are visible with only very minor artifacts. With the increased use of open-MRI procedures, MR compatibility will become an important requirement for the design of instruments and implants.

11. Fatigue resistance

Much work has been done to characterize the fatigue performance of nitinol and these laboratory investigations are usually in tension–tension or rotary bending of wire. Fatigue environments can be divided into two groups: strain-controlled and stress-controlled. The for-

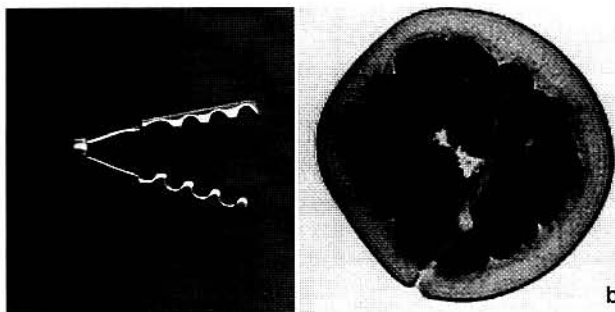


Fig. 15. A nitinol hinged grasper (a) is shown in MRI while inserted in a grapefruit (b).

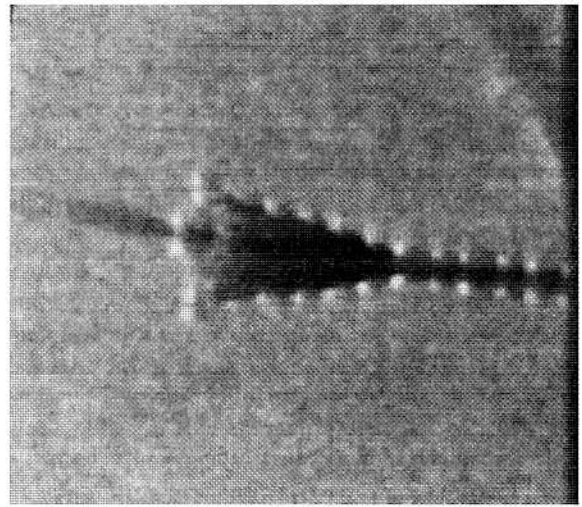


Fig. 16. MR image of a stent being deployed from a catheter.

mer describes environments in which a device is alternately deformed between two set shapes, while the latter describes the influences of cyclic loading. It is well known that nitinol offers exceptional fatigue resistance in high strain, strain-controlled environments, while it may well fatigue rapidly in stress-controlled environments. A recent and very quickly growing application that utilizes nitinol's excellent strain controlled fatigue properties is dental drills for root canal procedures (Fig. 17). In the past, conventional drills would veer off course to follow the soft nerve of the tooth, leading to large bending strains and frequent breakage inside the tooth. The nitinol drills are able to tolerate such severe fatigue environments.

Practically speaking, most fatigue environments in the body involve irregular cyclic motion against highly compliant tissue, and thus are a combination of stress-

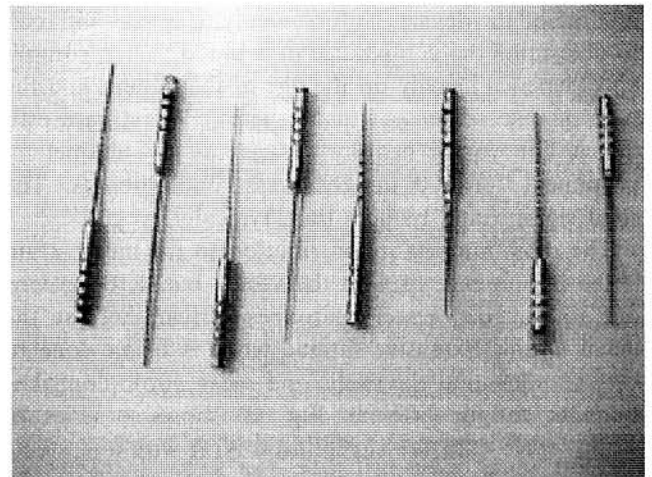


Fig. 17. Nitinol drills used for root canal procedures are far more resistant to failure when the drill veers off course following the soft nerve of the tooth.

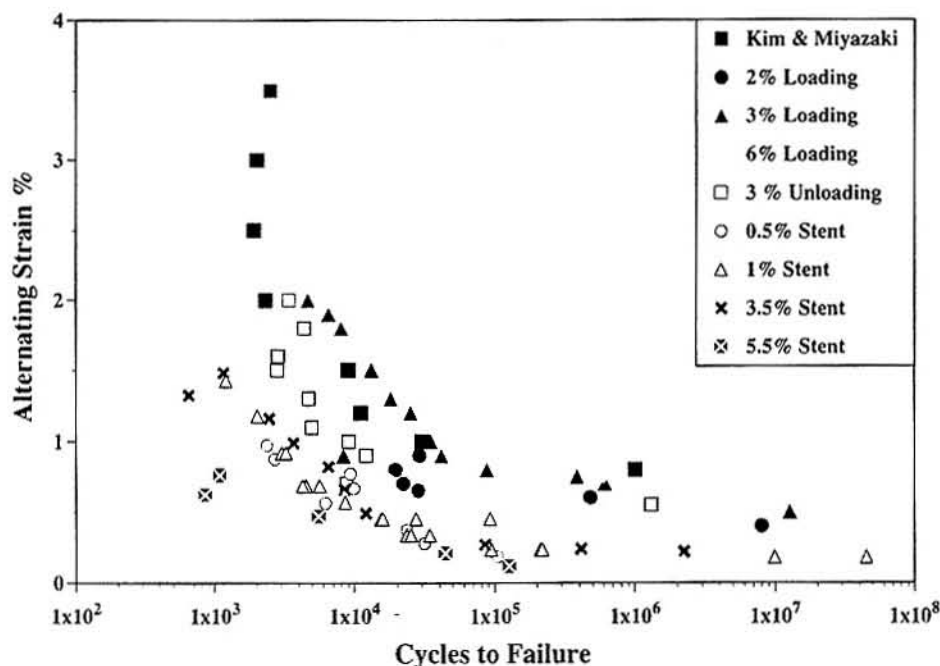


Fig. 18. The results of several fatigue tests are superimposed, including tests on wire (first five legends) and tests on stents laser cut from tubing (last four legends). The legend describes the mean strains used in the individual tests. Stent data was determined after unloading to the mean strain, wire tests are as marked (either loading to, or unloading to the mean strain). The reference Kim and Miyazaki [24] data was tested with no mean strain.

and strain-control. Fatigue is also complicated by the superposition of a mean stress or strain on top of the cyclic component. Consider the stent as an example. In most locations only the heartbeat contributes to the cyclic stress. The cycling frequency is the pulse rate (slightly over 1 Hz), and the cyclic amplitude in a vessel is the systolic–diastolic pressure (as high as 100 mmHg). The cyclic pressure is not applied to the stent, however, but to the blood vessel. If we know the compliance of the stented blood vessel, we can estimate the cyclic strain amplitude and determine the fatigue lifetime of the device. Unfortunately, it is very difficult to determine the compliance of a blood vessel; compliance depends heavily on the age of the patient and the type of disease present in the vessel. Worst case estimates, for young healthy vessels are 5% diametral movement for 100 mmHg pressure differences. The stent significantly reduces that, typically, to 2%.

The most important contribution to the mean strain is the interference fit with the vessel, but deformations due to tortuous vessel anatomies further increase the mean strain. Extensive fatigue work is being done to better understand the cyclic and mean strain contributions to fatigue lifetime. Fig. 18 shows a series of strain–cycle data for superelastic NiTi wire and stents in strain control as a function of mean strain. In general, the data follow the data from Kim and Miyazaki [24] in rotary bending. It is interesting that the agreement is so good between rotary bending of

wire and stents made by laser cut tubing and tested in the circumferential direction.

In order to analyze the lifetime of a device subjected to both a cyclic and static strain, a modified Goodman diagram may be used (Fig. 19) [25]. First a strain approach is used in constructing the axes. But then, as one might expect based on the shape of the stress–strain curves, the line itself is non-linear, departing from the endurance limit along a tangent to the first

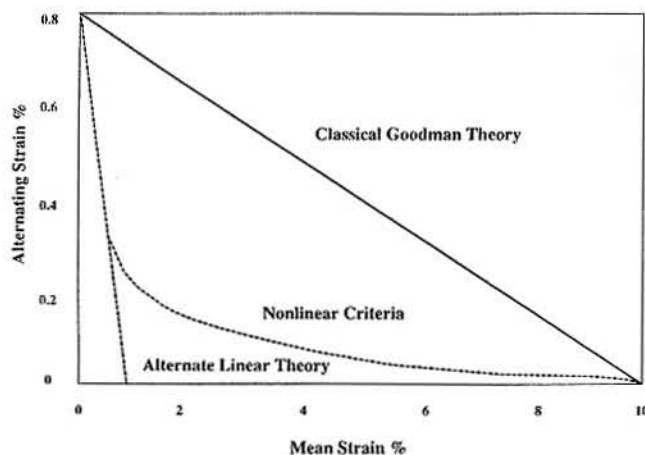


Fig. 19. A modified Goodman diagram may be used to analyze the effects of mean strains on fatigue lifetime. Classical Goodman theory connects the endurance limit to the elastic limit, but which elastic limit, classical elasticity or superelasticity? Evidence suggests that the real curve is non-linear, departing along the classical elastic limit, and ending up at the limit of superelasticity.

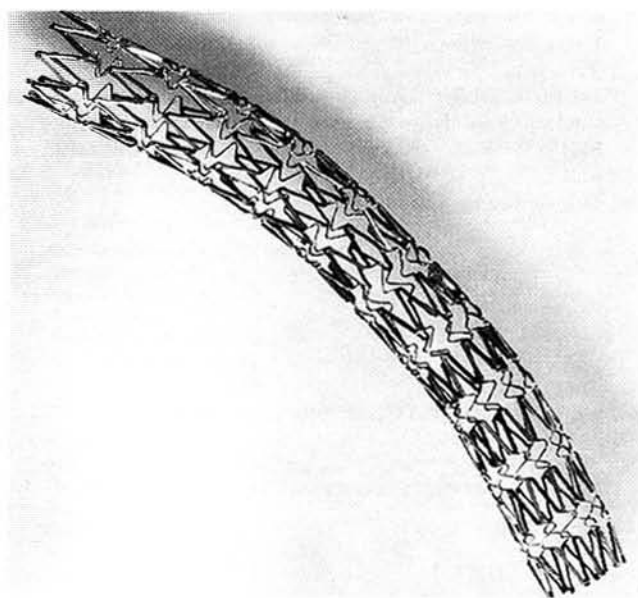


Fig. 20. The Paragon stent is unique in that it is made of martensitic nitinol, and uses neither shape memory nor superelastic properties.

yield (associated with stress-inducing martensite), then finishing at a second yield (associated with true plastic deformation). While these rudimentary diagrams are helpful, a great deal of work is still needed to fully understand the complicated fatigue environment of a stent and of other medical devices.

12. Uniform plastic deformation

Up to this point we have focussed on the advantages of self-expanding nitinol stents, but it would be incorrect to think that they are always better than balloon expandable stents. Balloon expansion provides extremely accurate placement and very high radial strengths for the most calcified lesions. This does not mean, however, that nitinol has no role to play. The Paragon stent (Fig. 20) is a balloon expandable, nitinol stent. The stent has an A_f temperature well above body temperature, and is thus always martensitic. It is manufactured in the closed configuration, crimped onto a balloon, then expanded just like conventional stainless steel stents. It has some advantages over stainless steel (e.g. MR compatibility) and some disadvantages (lower strength especially after smaller expansions). One advantage, however, is worth particular note. Balloons are folded in order to get them into the stent, and thus they do not generally produce uniform forces. The unusually high work hardening rate of martensitic nitinol causes the deformation to be more uniform, and thus leads to lower peak stresses and strains.

13. Conclusions

We can only expect the use of nitinol in medicine to increase: processing capabilities (plating, joining, laser machining, etc.) are improving, the trend towards less-invasive techniques will continue, and perhaps most importantly, nitinol has earned a prominent position in the toolbox of all medical design engineers. The advent of newer open MR procedures in particular is likely to make obsolete stainless steel in many procedures, and open new doors for nitinol. Still there are opportunities to further improve the technology. Radiopacity remains an issue for many devices, providing a need for new alloys richer in elements with large X-ray cross sections. Although the eyeglass frame industry has enriched our understanding of welding and plating, more work needs to be done in order to make reliable medical devices using these two technologies. Finally, it is likely that future medical devices will incorporate a variety of coating designed to improve lubricity, biocompatibility, or to deliver drugs.

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