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The Use of Superelasticity in Medicine

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The Use of Superelasticity in Medicine

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Superelastic Ni-Ti (Nitinol) alloys are becoming integral to the design of a variety of new medical products. The enormous elasticity of these alloys is the most dramatic advantage afforded by this material, but by no means the only or most important. Also discussed in this paper are features such as biocompatibility, kink resistance, constancy of stress, physiological compatibility, shape memory deployment, dynamic interference and fatigue resistance. Each of these properties is discussed and highlighted through example. Products presented include stents, filters, retrieval baskets and surgical tools.

Superelastizität in der Medizintechnik

Superelastische Ni-Ti (Nitinol) Legierungen haben sich auf breiter Basis als Konstruktionswerkstoffe in der Medizintechnik durchgesetzt. Die enorme elastische Dehnbarkeit des Materials ist dabei nur eine der für den Einsatz bestimmenden Eigenschaften. In der vorliegenden Arbeit werden außerdem Biokompatibilität, Knickfestigkeit, Spannungs Konstanz, physiologische Kompatibilität, thermisches Formgedächtnis, dynamische Anpassungsfähigkeit und Ermüdungsfestigkeit behandelt. Jede dieser speziellen Eigenschaften wird anhand von Einsatzbeispielen besprochen. Aus der Vielzahl von Anwendungen werden Stents, Filter, Körbchen und chirurgische Instrumente vorgestellt.

Superelasticity refers to the unusual ability of certain metals to undergo large elastic deformation. Although used synonymously with pseudoelasticity we adhere to the definition that pseudoelastic alloys need only show non-linear unloading behaviors, while superelastic alloys must exhibit an inflection point. An inflection point in the unloading behavior indicates the presence of an unloading plateau, or a strain range with approximately constant stress. As we will see, this is an important distinguishing feature in medical applications. While many metals exhibit superelastic effects, only NiTi based alloys appear to be chemically and biologically compatible with the human body. Although a large number of Ni-Ti ternary alloys have been introduced, none have been objectively shown to be superior to simple binary Ni-Ti with between 50.6 and 51.0 atomic percent nickel.

The stress-strain behavior of superelastic Nitinol is exemplified in Figure 1. The detailed mechanistic origins of superelasticity have been extensively discussed elsewhere (1, 2). The most superficial advantage of superelastic alloys is that up to 11 % springback or elasticity is realized, as compared to 0.5 % available in the most commonly used medical material, stainless steel. Of course superelasticity only occurs over a relatively narrow temperature range just above the A_f temperature – optimum performance is found at the A_f temperature, and steadily deteriorates until the M_d temperature, at which all indications of superelasticity have vanished. It should be noted that many designs have complex geometries and strain distributions, and that A_f increases with strain. For example, an 8 % strain will increase A_f by approximately 10 °C. Thus, optimum superelasticity requires that one completely understands the strain to which the part is to be subjected.

Strengthening the alloy, through a combination of cold work, ageing, and annealing steps, provides the alloy with optimum performance over approximately a 40° window, starting at the A_f temperature. Still, the functional temperature range is too narrow for most industrial and consu-

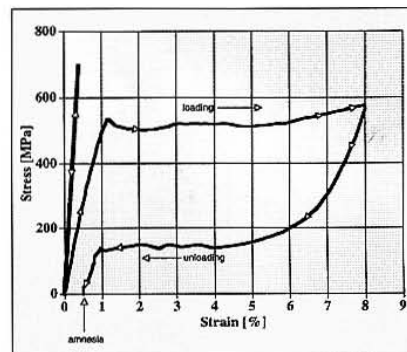


Figure 1: Stress strain curve for a Ti-50.8 at. % Ni alloy tested 10 °C above its A_f temperature. A typical elastic loading-unloading curve for stainless steel is shown in light gray.

mer applications – automobile springs, for example generally require elasticity from -30° to +200°. Moreover the stiffness of a superelastic device changes with temperature according to the Clausius-Clapeyron equation, at a rate of about 4–8 MPa/°C. The variability of superelasticity with temperature is, by far, the factor most limiting to its general use. Fortunately mammalian bodies have a relatively constant temperature, ideally suited to the use of superelasticity. Further, the 37 °C temperature of humans is, by chance, easily achieved in NiTi without having to go to brittle Ni-rich alloys, or very soft Ti-rich alloys. Thus the vast majority of successful superelastic applications are of a medical nature.

Advantages of Superelasticity in Medicine

Material selection is seldom based on a single attribute, but a combination of several. Similarly, the tremendous elasticity of Nitinol is only one of many unique factors favoring its use. To highlight the value of superelastic Nitinol to the medical industry, ten specific device characteristics will be discussed and illustrated in the design of a superior medical device.

- Elastic Deployment
- Biocompatibility
- Kink Resistance

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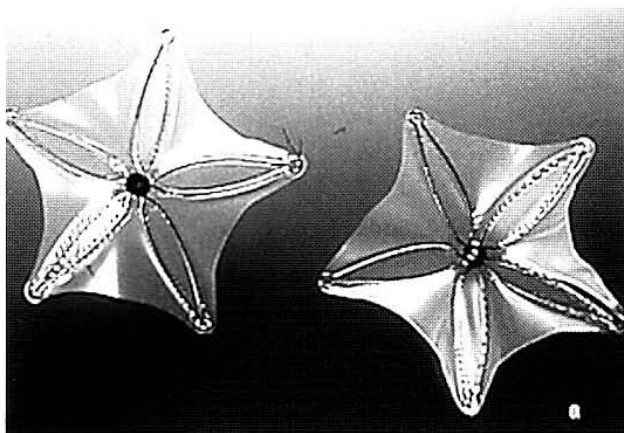
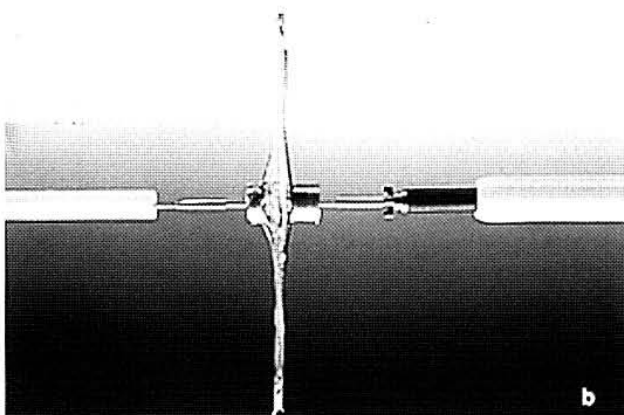


Figure 2: The Atrial Septal Defect Occlusion device, is used to seal holes in the heart wall: (a) shows the two umbrella-shaped patches that will be positioned on either side of the defect and (b) shows the installed halves after releasing from the two catheters, positioned by a guide-wire, and then screwed together. The entire operation is conducted through a 10 French catheter without surgery.



- Constancy of Stress
- Physiological Compatibility
- Thermal Deployment
- Dynamic Interference
- Fatigue Resistance
- Hysteresis
- MRI Compatibility

some of these, such as elastic deployment, are obvious to designers; others, such as dynamic interference and hysteresis, are not. Still, all provide potentially important grounds for the application of Nitinol.

Elastic Deployment: Atrial Septal Defect Occlusion (ASD) system, Endoscopic Instruments

Figure 1 compared typical stress strain curves for stainless steel and Nitinol. The most apparent difference is that elasticity, or „springback“, is some 20 times greater in Nitinol than in stainless steel. There are a large variety of products now on the market which use this particular design feature, but perhaps the newest and most interesting (3) is the atrial septal defect occlusion system (ASDOS). The device is the first to allow non-surgical repairs of

occlusions, or holes, in the atrial wall of the heart. At the time of writing, at least five procedures are published, treating defects ranging in diameter from 20 to 35 mm. The method used is a transcatheter method: the entire procedure is conducted through two catheters, in this case 10 Fr (approx. 3.5 mm) in diameter. The actual device consists of two small umbrellas consisting of five Nitinol wire loops supporting webs of microporous polyurethane (Figure 2a). The two devices are passed into the body while folded, one each in two catheters, and are positioned one on either side of the defect area. A guidewire passing directly through the hole is used to assure that the two catheters and umbrella devices are positioned correctly. Once positioned, the umbrellas are pushed forward from their catheters, and screwed together using a special torquing catheter. The resulting sandwich forms a patch, occluding the atrial defect. Available umbrella diameters range from 20 to 65 mm. Although it is too early to convincingly evaluate the success of this particular product, it well illustrates the concept of elastic deployment – no other known metal would survive the deployment.

The compliance, or elasticity, of an engineered component depends of course upon design as well as the inherent elasticity of the material used. For example, one can increase the compliance of a coil spring by adding coils, but this would increase weight and size. Material properties dictate the total elastic energy stored in the device, while design can only change how one partitions the total stored elastic energy of given amount of material (favoring either force or motion). The use of Nitinol allows one to design more compact, stiffer and more elastic devices by increasing the elastic energy storage by a factor of nearly ten. To highlight this, we consider the Homer Mammalok, which radiologists use to “mark” the location of a breast tumor. It consists of a 0.4 mm diameter Nitinol wire hook and a stainless steel cannulated needle (4). The wire hook is withdrawn into the needle cannula, the cannula is inserted into the breast and adjusted until its distal end is verified to be at the site of the tumor. The hook is then pushed out, reforming a tight hook configuration of 9 mm radius. The device can be withdrawn, repositioned, and redeployed as required until the position has been correctly marked for the surgeon. When inside the cannula, the strain in the hook is estimated to be in excess of 8 % – far more than can be obtained with stainless steel. A Mammalok made from stainless steel would require one to reduce the wire diameter from 0.4 to 0.05 mm, assuming the hook geometry is to remain fixed – such a fine wire would be far too flimsy to anchor the hook effectively and could allow inadvertent and undetected transection. Alternatively, a stainless steel wire of the same 0.4 mm diameter could only form a hook of 50 mm radius, in contrast to the 9 mm radius of Nitinol. In either case, the hook would again fail to firmly hold position.

Endoscopy is another field that has taken advantage of elastic deployment (5). As the range of endoscopic operations increases, so does the need for increasing complex tooling, all of which must pass through a narrow trocar. Superelasticity allows one to pass a rather complex instrument through a straight trocar, and the instrument to elastically return to the deployed configuration once through. Instruments include suture passers, retractors, graspers that operate at right angles to the trocar, and retrieval bags. Similarly surgical graspers and scissors can be designed which do not required hinges and other complex parts that make cleaning and sterilization difficult or impossible (an example will be introduced in Figure 10).

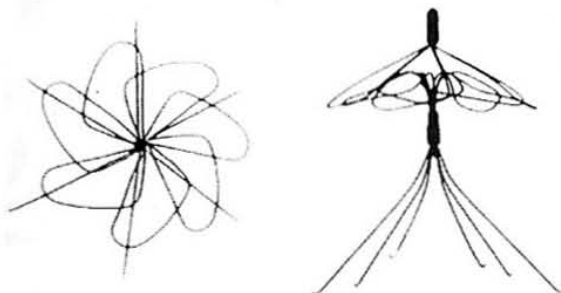


Figure 3: Simon Filter, shown in longitudinal and transverse views of the deployed state, is the first class III Nitinol implant approved by the FDA (the function of the device is described later).

Biocompatibility: The Simon Filter, Mitek Bone Anchor, Dental Implants

Nitinol alloys contain more nickel than do their primary competitor, stainless steel (grade 316L). This rather obvious statement has little meaning to metallurgists, but unfortunately entirely too much meaning to non-specialists, who recognize that nickel itself is considered toxic. As Nitinol oxidizes, it forms a TiO_2 layer, with small islands of pure nickel on the surface, or, depending upon the treatment, with no nickel present at the surface (6). Polarization testing in Hank's solution has repeatedly shown that Nitinol is chemically more stable and less corrosive than stainless steel, and less stable than pure titanium (7). Extensive *in vivo* testing and experience indicates that Nitinol is highly biocompatible – more so than stainless steel. Implants exist in dentistry orthopaedics, and in many other branches of medicine, with large numbers of permanent implantations reported in Japan, Germany, China and Russia dating 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 (8). Most significantly, the FDA has approved the first Class III implant for use in the USA, specifically the Simon *vena cava* filter, developed by Nitinol Medical Technologies (Figure 3). The FDA has also approved the Mitek Bone Anchor system, another permanently implanted Nitinol device.

A detailed discussion of biocompatibility and all its nuances is certainly beyond the scope of this article, and readers are referred to several reviews of the field (8–10). One should be cautioned, however to carefully observe testing and material con-

ditions before relying on published information; a great deal of the literature is inadequate in defining starting chemistries, thermomechanical treatments, and most importantly, surface treatments. More work on Nitinol biocompatibility must be performed before one can firmly establish just how biocompatible the material is, and how one can optimize performance. Still, it is already clear that it will outperform stainless steel in most environments.

Kink Resistance: Guidewires, Retrieval Baskets, and Instruments

Within reasonable limits, Nitinol wires cannot be kinked. To some extent this design property stems from the increased elasticity cited above, but even more, it is a result of the shape of the stress strain curve. When strains are locally increased beyond the plateau strain, stresses increase suddenly. This causes the incremental 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 would be realized in a conventional elastic-plastic material.

The first applications to take advantage of this feature were angioplasty guidewires, which must be passed through tortuous paths without kinking. Even very small permanent bends in the wire cause "whipping" and destroy the ability to steer the wire. The ASDOS procedure described above, for example, employs Nitinol guidewires to place the catheters correctly. There can be little doubt that Nitinol has played a key role in the success of angioplasty medicine.

More recently, retrieval baskets have used Nitinol kink-resistant shafts, as well as a

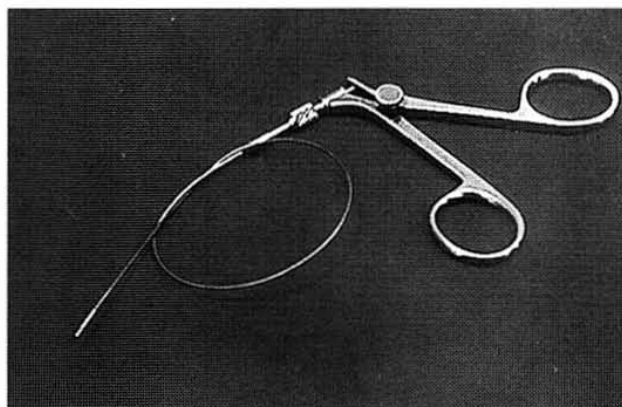


Figure 4: A 1 mm diameter urological grasper demonstrates kink resistance. The shaft consists of a Nitinol wire concentrically placed in a Nitinol tube; the distal end is a stainless steel, hinged "grasper", opening to about a 90° included angle.

superelastic basket to retrieve stones from kidneys, bladders, bile ducts, etc. Perhaps the newest and most interesting application is in extremely small diameter instruments (Figure 4). The 1 mm diameter grasper is composed of a very thin walled Nitinol tube with a Nitinol wire inside. Together they are able to 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. Stainless steel, or other metallic instruments would kink and be destroyed by even very slight mishandling, whereas the Nitinol instrument continues to operate smoothly even while bent around tortuous paths.

Constant Stress: Orthodontic Archwire, Eyeglass Frames

Still another important feature of superelastic materials is that their unloading curves are flat over large strains. Thus the force applied by a superelastic device is determined by the temperature, not strain as in conventional Hookean materials. Since body temperatures are 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. Stainless steel and other conventional wires are tightened by the orthodontist – often to the point of causing pain. As treatment continues, the teeth move and the forces applied by stainless steel quickly relax. This causes treatment to slow, retarding tooth movement. 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, apply-

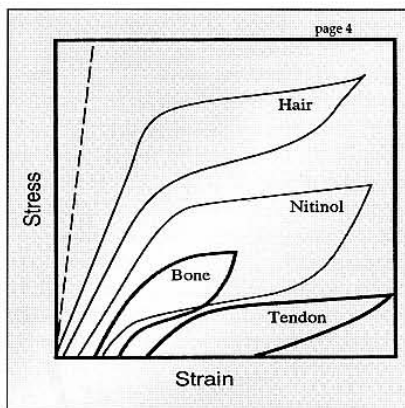


Figure 6: Stress strain curves comparing with biomaterials. Clearly the exception in terms of physiological compatibility is stainless steel (dashed line), not Nitinol.

ing 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 (Figure 5). These are now available at nearly every optician, and are among the most popular of all frames sold in the United States and Europe, despite the fact that they are priced at the top 5 %. Because they are so common, and always within grasp, they are often used to demonstrate superelasticity. Opticians will often twist these frames a full 180° and amaze prospective buyers with the durability and elasticity of the frames, but this is not really the point. Much more important is that 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. In fact, most wearers are unaware that the frames are superelastic, and favor them only for their remarkable comfort. We estimate that approximately one million superelastic frames were sold in 1995, with demand steadily increasing. It should be noted that this particular product may have been most responsible for the recent acceptance of this technology: it was the first successful consumer product, advertised extensively on television and in print media, and required manufacturers to develop welding, brazing, and plating technologies.

Physiological Compatibility: Spinal Vertebrae Spacer

Stainless steel, titanium and other metals are very stiff relative to biological materials, yielding little if at all in response to pressures from surrounding tissue. The extraordinary compliance of Nitinol clearly makes it the metal most mechanically similar to biological materials Figure 6. 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 boney ingrowth and proper healing by sharing loads with the surrounding tissue and has led to applications such as hip implants, bone spacers (Figure 7), bone staples, and skull plates and the like. This later application is particularly interesting in that it utilizes porous Nitinol (13), which further leverages the above advantages, particularly boney ingrowth. Combustion synthesis, or using the heat of fusion to "ignite" the formation of NiTi 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 mechanically reduced modulus of elasticity, and accelerate boney ingrowth 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.

It should be noted, however that the physiological compatibility discussed here comes at a price: calculational complexity. Conventional metals are linearly elastic, and readily lend themselves to both analytical and Finite Element Analysis (FEA) methods. Nitinol, like biological materials, are much more difficult to model: not only is their behavior nonlinear but there is a hysteresis, a strong temperature dependency and a permanent set. To make matters worse, the latter two properties are strain dependent. A great deal of work is currently underway to improve the applicability of modeling methods to these types of material, but a much more is needed - as yet the authors are unaware of a single FEA package that is able to deal with all of the above characteristics. FEA is becoming an important tool to designers and a required element in FDA submissions, thus we feel this is an area warranting, but not currently receiving, substantial R&D funding.

Thermal Deployment: Vena Cava Filter, Stents

An additional unique attribute of superelastic devices is that they can be deployed using the shape memory effect. One example is the *vena cava* filter discussed earlier. The device is received by the physician preloaded in a catheter and in its

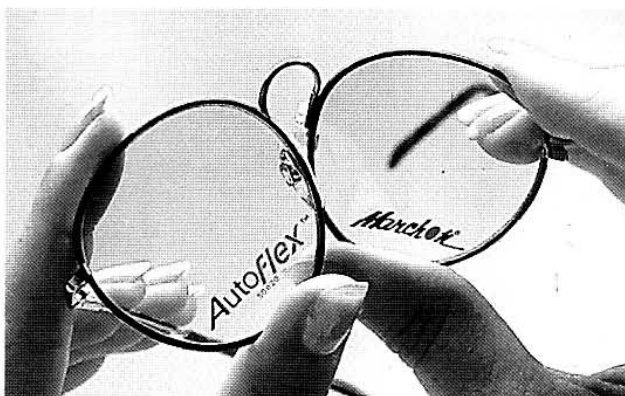


Figure 5: Superelastic eyeglass frames are constructed of superelastic temples, nose bridge, and often a brow piece. Components are brazed and welded to Monel or German Silver, then often polished and gold plated.

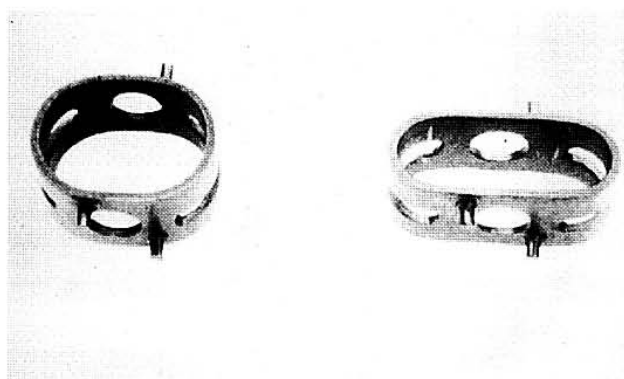


Figure 7: Spinal vertebrae spacer shown in the martensitic state (left) and deployed superelastic state (right). The properties of Nitinol promote more rapid recovery due to the similarity of mechanical properties between the implant and the surrounding tissue.

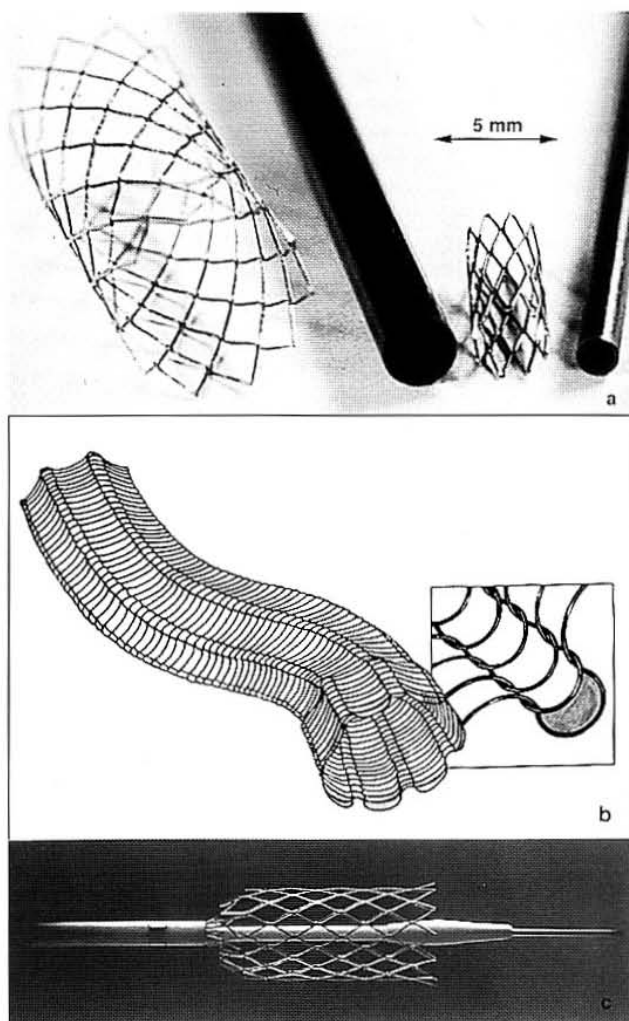


Figure 8: Stents made from Nitinol tubing appear to be of the greatest interest (a), though wire stents, such as the Microvase device shown in (b) are already in use in the United States. Deployment of an Angiomed stent (from tubing) is shown in (c).

martensitic state. Flushing chilled saline solution through the catheter keeps the device in the martensitic phase while positioning to the deployment site. When released from the catheter, the device is warmed by its warmer surroundings, recovers its "pre-programmed" shape and becomes a superelastic device. In fact, it is neither clear nor important, just when the device becomes superelastic – very likely this occurs before being fully released from the catheter. Chilled saline only acts to reduce the forces applied by the filter against the catheter wall, making deployment easier. It is proper to consider the device to have completed the shape memory effect when heating above A_f , even in the case where the filter is still fully constrained in the catheter: the equilibrium shape of the device has been recovered, even though it is temporarily restrained by the catheter. The most celebrated superelastic medical devices are self-expanding stents, used to brace the inside circumference of a tubu-

lar passage, such as an esophagus, bile duct, or blood vessel (Figure 8). Probably the most interesting area of application is in the cardiovascular system, as a follow-up to balloon angioplasty. The placement of a stent has been shown to significantly decrease the propensity for restenosis. Like the *vena cava* filter, these devices are generally permanent implants, deployed through a catheter using the shape memory effect. Even in the case where no chilling is done to assist deployment, one should consider them to be thermally deployed since their equilibrium shape is restored by warming to body temperature. Cardiovascular stents currently available in the United States are made of 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 – instead of being deformed to the vessel diameter, they expand by simply returning to their equilibrium, non-

deformed, shape. Self-expanding stents are now available in Europe, and for certain applications in the USA. Nitinol stents can be made from wire, laser cut sheet, or tubing. Because overlaps and irregularities can lead to thrombicity the most promising devices appear to be those cut from tubing. Of course one might cut the expanded or the contracted shape depending upon the specific design and needs. Stents are also made from sheet, by either welding of mechanically linking into a cylinder after cutting. Typically the diametral ratio of the two states is between 300 % and 600 %. Surface finish is very important to both thrombicity and biocompatibility, and plays a key role in device production.

Anticipated advantages over current balloon expandable stents include a greater resistance to crushing in exposed vessels (such as the femoral or carotid arteries) lower bending stresses when situated in tortuous paths, more flexible delivery systems, the ability to scaffold cross sections other than circles, and the elimination of acute recoil. (Several of these points will be highlighted in sections below.) It is certain that Nitinol will become the preferred material for many devices, but only time will tell if self-expanding stent technology will indeed become the next generation of interventional treatment as many physicians and device manufacturers believe.

Dynamic Interference: Stents

Stents take advantage of a second important feature of superelasticity: dynamic interference. 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 springback, or loosening, is called acute springback and is clearly an undesirable feature. In order to fill a 5 mm lumen, the stent might have to be expanded to 6 mm so that it springs back to 5 mm. This potentially damages the vessel and leads to restenosis. In contrast, the Nitinol stent expands directly to its pre-programmed diameter with no recoil. After deployment, the Nitinol continues to gently push outwards against the vessel wall, helping to prevent undesirable changes in position despite movements in the vessel. Moreover the Nitinol will try to fill an oblong or irregularly shaped cross section, whereas a balloon expanded stent will always adopt the round shape of the balloon.

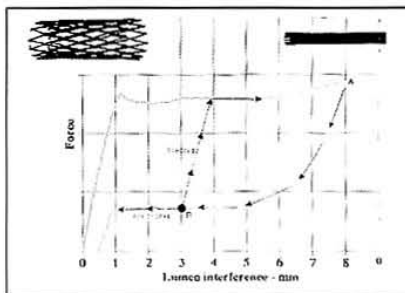


Figure 9: Biased stiffness illustrated in a stent. A stent is manufactured in the open configuration (left), and deformed to a closed position (A). After deformation is complete, it is deployed by releasing from a catheter, following the light gray unloading arrows, until the lumen is filled and expansion stopped (shown by the dark circle marked 'B'). The gentle pressure against the vessel wall is controlled by the unloading arrows, but effort to re-close the vessel are resisted by the stiffness indicated by the unloading arrows. Note that a re-expansion of the stent to a larger diameter moves the circle to the left, but the same biased stiffness is maintained.

Dynamic interference also means that there will be a permanent force acting in the radial direction, even if the vessel should increase in diameter over time. Though this may be beneficial in maintaining the location of the stent in the vessel, it remains unclear if there will be long-term side effects. It is possible that this continuous opening force may cause irritation, restenosis, or undesirable creep effects. Current designs try to maintain this force at very low levels.

Fatigue resistance: Pacemaker lead wires

Due to the unusual way that Nitinol deforms, it has a fatigue behavior that is quite atypical of metals in general. Fatigue environments can be divided into two groups: strain-controlled, and stress-controlled. The former describes environments in which a device is alternately de-

formed between two set shapes, while the latter describes the influences of cyclic loading. To illustrate the differences, compare the fatigue behaviors of a rubber band and a loop of steel wire. In a stress-controlled environment the steel survives far longer than the rubber band. In a strain-controlled environment (e.g. alternately stretching and releasing), the rubber band will certainly out-perform the steel. Nitinol is much the same: in strain-controlled environments it will dramatically outperform all conventional metals. In stress-controlled environments, however it may well fatigue rapidly. Practically speaking, most fatigue environments in the body are a combination of the two, making it difficult to make summary judgements concerning fatigue. In general, the very compliant nature of biological materials tends to push in the direction of strain-controlled fatigue, where Nitinol will excel.

One example of a clear strain-controlled application is in pace-maker leads, requiring a conductive metal that can survive very high numbers of flexing motions without breaking. Nitinol has been repeatedly shown to outperform other metals for this particular application, even though to date we are unaware of its commercial use. Certainly a great deal of fatigue testing of stents is being done as well; although no results have been published, it does appear that performance is at least as good as stainless steel.

Hysteresis: Stents

Stresses applied by superelastic components are path dependent: the stresses applied by a superelastic device are likely to be more dependent upon whether one is loading or unloading, than the position of the device itself. This "biased stiffness" is illustrated in Figure 9 by following expansion of a stent. A superelastic stent should provide only a very light outwards

force 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. As pointed out earlier, opening forces are "live", and will forever continue to act to open the lumen. These opening forces must be very low to avoid damage through creep of the vessel wall. On the other hand, it is important to have a device which resists the forces tending to close the lumen. Nitinol offers both. Also note that if the stent is later re-expanded to a larger diameter, the filled circle (B) in Figure 9 will be displaced to the left, but the stiffnesses will remain the same.

MRI Compatibility: Instruments, needles

Nitinol provides a very clear, crisp MRI image. Figure 10 shows an MRI image of a grasper used in a gall bladder surgery, with a matching light photograph of the same end. The same grasper made from stainless steel would be completely unrecognizable. Although there are no commercially available products which take advantage of this feature, it is of great potential importance, particularly with the advent of open-MRI procedures. Applications for needles and instruments are being explored.

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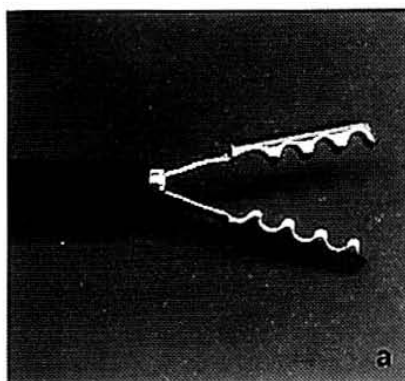
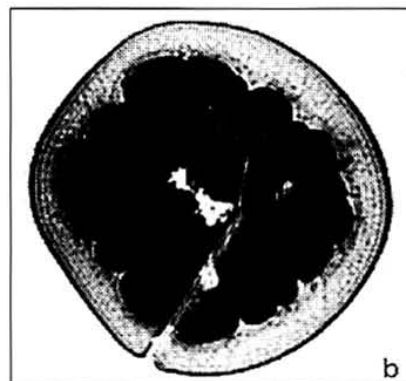


Figure 10: A Nitinol grasper, designed for endoscopic gall bladder surgery, is shown optically (a) and in an MRI image while testing in a grapefruit (b).