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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.

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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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E-mail address: tduerig@mail.nitinol.com (T. Duerig) 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 as placed in the diseased vessel and expanded in order 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 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.

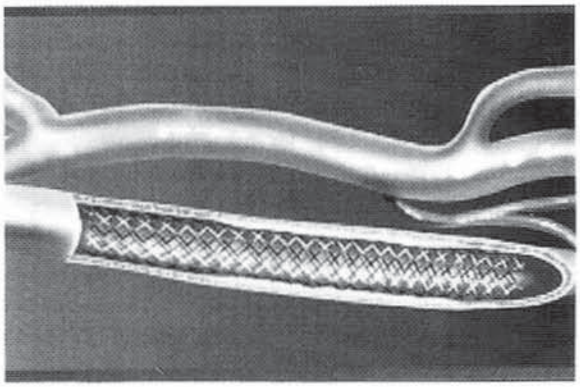

Fig. 1. A stent is portrayed in a cut-away view of the internal carotid artery, maintaining vessel patency and blood flow to the brain. The stent is also pinning loose debris against the vessel wall, reducing risk of embolization and stroke.

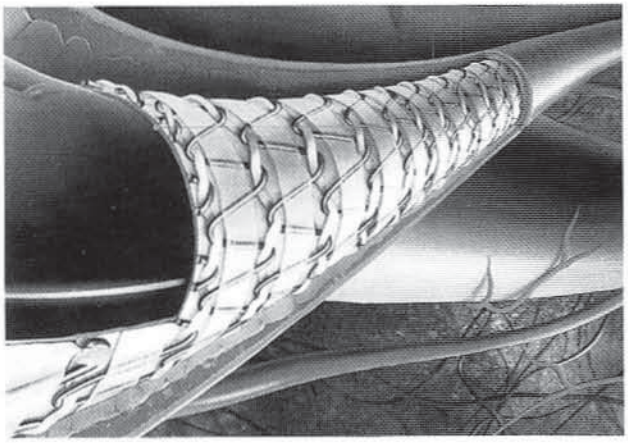

Fig. 2. The Hemobahn product incorporates a superelastic Nitinol wire into a PTFE. Stent-grafts such as these are used to exclude aneurisms, to provide an artificial replacement for injured vessels, or to prevent restenosis after angioplasty.

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

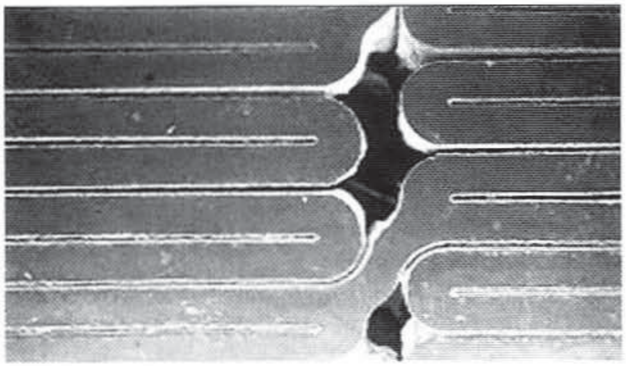

Fig. 3. Stents are often made from laser cut tubing. In this case, the laser beam cuts a kerf of less than 25 μm, through a thickness of over 200 μm.

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-deployed 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 transsection, leaving bits of wire behind in the breast.

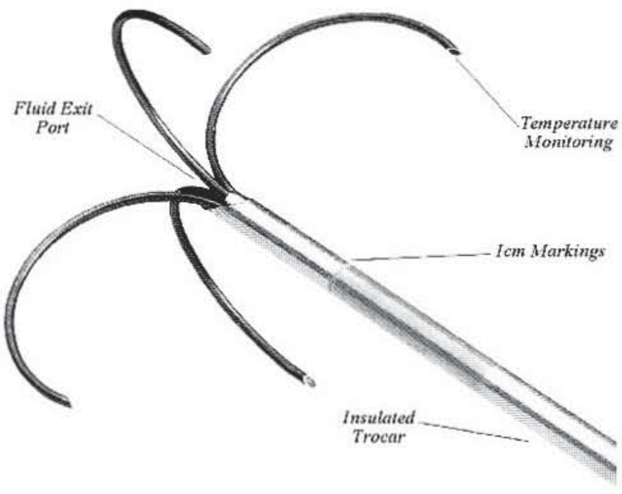

Fig. 4. The RITA tissue ablation device uses four sharply curved tubular needles which are deployed from a straight needle after insertion through a trocar.

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. 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.

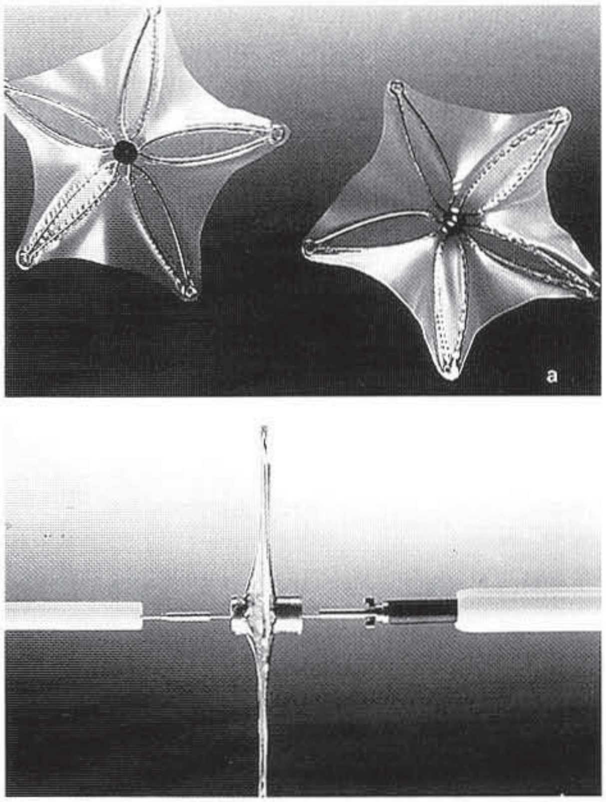

Fig. 5. The atrial septal occlusion device incorporates nitinol wires in a polyurethane film in order to repair defects in the wall of the heart.

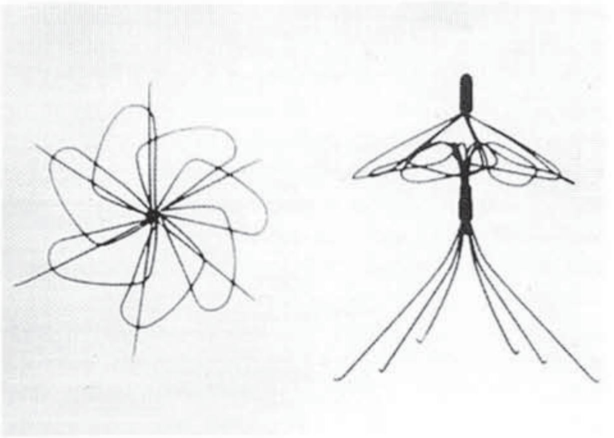

Fig. 6. The Simon vena cava filter expands once in the vena cava, and is left permanently in place to prevent emoblized thrombus from reaching the heart and lungs.

4. Kink resistance

To some extent this design property stents 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.

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