Present and Future Applications of Shape Memory and Superelastic Materials

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PRESENT AND FUTURE APPLICATIONS OF SHAPE MEMORY AND SUPERELASTIC MATERIALS

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ABSTRACT

The utility of superelastic Ni-Ti alloys in the medical industry has been rather dramatically demonstrated in recent years. A great number of devices are now in production, and still others are staged to enter production during the next few years. This surge in interest from the medical community stems from an increased acceptance of Ni-Ti because of its biocompatibility, advances in micromachining techniques and trends towards less-invasive surgical techniques. In addition, there are a variety of new developmental concepts that will have a major influence on this and other markets during the next 5 years of commercialization. This review will highlight many of the properties of Ni-Ti by illustration in a variety of recent medical applications, and then discuss some of the newer developmental concepts. Medical applications that will be presented here include guidewires, laparoscopic surgical instruments, implants, stents, retrieval baskets, and bone anchors. Some of the new concepts and capabilities that are reviewed include microvalves made from thin films, high temperature alloys, fatigue resistant composites, and robotic actuators with tactile feedback.

INTRODUCTION

Thermoelastic materials are able to adjust their properties and shape according to changes in their environment: specifically, changes in applied stress and temperature. This capability to sense and react to change has often caused these materials to be dubbed a *smart material*. Ni-Ti, or Nitinol, alloys are the most important of the thermoelastic smart materials, able to change shape by strains greater than 8% and to adjust constraining forces by a factor of 5 times. The scientific foundations for these "smart" effects have been well-known for over 20 years. The ability to engineer successful devices using these effects, however, has been quite another story. The early product development history of Ni-Ti has been full of failures and disappointments. It seems that the materials were so smart, they out-smarted the designers. The infamous reference to shape memory as "*a solution looking for a problem*"[1] has finally been shaken. Though success has not come from the directions originally expected, few can doubt that the technology has now come of age. Success has largely come about by focusing on medical applications of Ni-Ti taking advantage of its superelastic properties.

Below, some of the more recent applications of Ni-Ti alloys are reviewed. Many older applications, such as pipe couplings, fasteners, and many actuator applications have been often reviewed elsewhere[1-5] and are not included in this review. Here we will concentrate first on the medical field that has recently had such a profound effect on the Ni-Ti engineering field. It will be evident to the reader that these devices are almost entirely superelastic in nature. After this, we will review some of the newer concepts and capabilities, and thus provide more of a look forward rather than over our shoulders.

MEDICAL DEVICES

As already stated, most successful medical devices take advantage of the superelastic properties of Ni-Ti. Some use shape memory for deployment, but in nearly all cases the choice of material is primarily dictated by the alloy's superelasticity attributes once at body temperature. Superelasticity refers to the ability of a material to reversibly transform from austenite to martensite when a stress is applied. The resulting stress-strain behavior is

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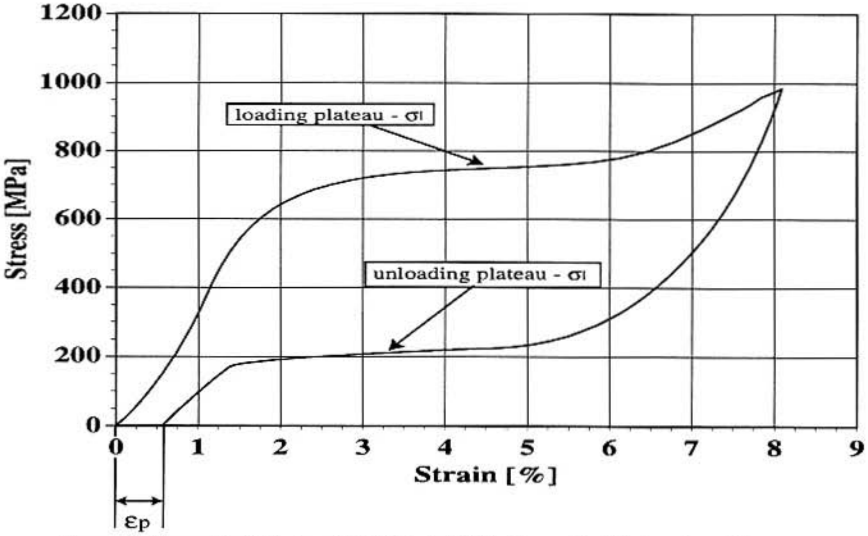

Figure 1: Superelasticity in a Ti-50.8 at. % Ni alloy pulled in tension. Shown are the design parameters: loading plateau-σ_l, unloading plateau-σ_u, permanent set-ε_p.

characterized by plateaus during both loading and unloading (Figure 1). In cases, the plateau may be somewhat ill-defined, but should in all cases exhibit at least an inflection point during unloading. As shown on Figure 1, the effect is parameterized by its loading stress, unloading stress, hysteresis (by implication), and permanent set. Strains of 10% can be nearly fully recovered, with the stress induced martensite responsible for approximately 8% and conventional elasticity for the balance. Superelastic properties can be observed at temperatures above A_f and below M_d. In fact full superelastic effects are found over an even narrower range—typically only 20-40°C in width. Further information concerning the origin and characteristics of the effect has been presented elsewhere[6,7].

At first it may not be clear why superelastic properties are an indication of a "smart" material, and in fact the term may be poorly applied—after all, any material dumbly obeys the laws of nature as programmed by its hopefully smart human designers. Still, two important features should be considered. First, the material reversibly alters its crystal structure and shape in order to relieve applied stresses. Secondly, and often neglected, is that the stress applied by a constrained superelastic device will rise and fall with temperature in a linear fashion, thus acting as a temperature sensor and actuator.

A superelastic spring does not follow Hook's Law, but in fact delivers a constant stress when deformed between 1.5% and 7%. This can be very important in the field of medicine since one can engineer a device to deliver a certain, physiologically ideal stress and rely on the fact that the stress will be held constant. Prototypical of this type of application are orthodontic archwires, which also happen to be one of the first medical applications[8,9]. Here the archwire is constrained while being installed into brackets mounted on the mal-aligned teeth. During treatment, the arch struggles to restore the teeth to their proper location, but always applies forces according to the unloading plateau of the arch's stress-strain curve. This maintains a therapeutically ideal force while eliminating adjustments, causing the patient less discomfort and accelerating treatment. Superelastic archwires were researched in the mid-1970's, and have been in widespread use since the early 1980's. They are now an appliance used by virtually all orthodontists.

A second key property of Ni-Ti alloys is their biocompatibility. In 1975, Simon proposed

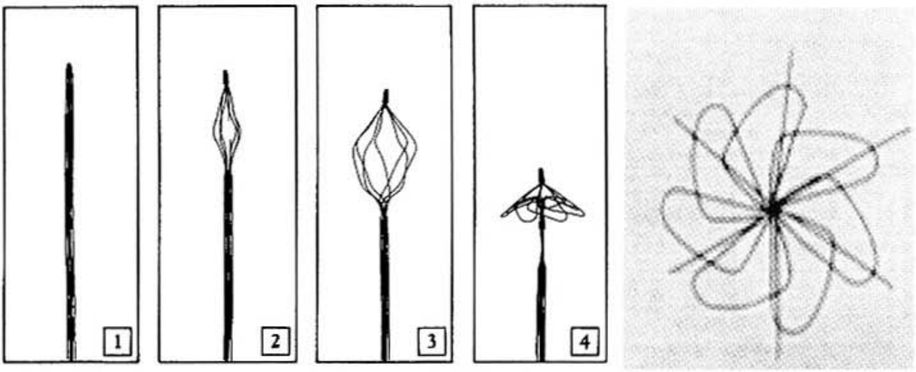

Figure 2: The Simon filter is inserted through a 2.3mm catheter (Frame 1), then thermally expands to form a filter used to prevent recurrent pulmonary embolism. Frame 6 (far right) shows the fully deployed filter from an end view.

using Ni-Ti for a *vena cava* filter (Figure 2), to break-up blood clots (thrombus) in the *vena cava*[10] which can lead to life threatening pulmonary embolism. This application has now been approved by the FDA; very significant considering this is a permanent, critical, Class III implant. To date, nearly 10,000 installations have been completed. The filter is installed by sliding it forward through a 7 French (2.3 mm) ID catheter to the intended deployment location, then de-constraining it, allowing it to expand into place. This is an example of a device that utilizes both the shape memory and superelastic properties of the alloy. The A_f temperature is chosen so that the filter is martensitic at room temperature but superelastic once installed in the *vena cava*. Cool saline solution is flushed through the catheter during the installation procedure to keep the filter martensitic until release. This reduces the force of the filter against the catheter wall and reduces the force needed to slide the filter within the catheter. One installed, its superelastic properties keep a constant stress against the vessel walls despite cyclical "breathing" of the vessel. During a two year clinical trial period involving 273 patients, there was and 91% success rate, which is considered excellent.

Still other applications take advantage only of the large springback strain afforded by superelastic Ni-Ti. One of the best examples of these is the bone anchor shown in Figure 3, used to re-attach torn ligaments to bone in the shoulders and knees[11]. The device consists of a suture, a titanium tip, and superelastic Nitinol wires curved into a tight "C"-shape in its equilibrium state. The operative site is exposed, a small hole is drilled into the soft marrow of the bone, and the anchor is "injected" through the hole. The hard surface of the bone causes the anchor to temporarily straighten during passage, but it is again allowed to spring back to its equilibrium shape once entering the softer marrow of the bone. After springback, the anchor has locked itself underneath the hard bone surface much like a normal household moly bolt. The sutures are then used to tie the ligaments in place, and bone then grows over the operative site. The implant is again permanent. This product has dramatically shortened recovery periods with respect to traditional procedures involving large stainless steel screws.

The quickly growing field of laparoscopy involves performing operations though very small ports into the body called trocars and cannulae. Obviously the advantages are that the operation can be far less invasive than open procedures. The field requires, however, highly specialized and complex instruments in order to pass through a narrow cannula yet be able to perform tasks such as gripping, cutting, retracting, viewing, etc. The utility of superelasticity in the design of such instruments was recognized as early as 1981[12]. In what seems to be the first such device, an endoscope was proposed that used a superelastic member to bend the tip of an optic fiber to right angles with respect to the cannula itself. Now, there are a great variety of instruments using superelasticity to articulate grasping ends[13], to grasp sutures[14], steer endoscopes[12], and to

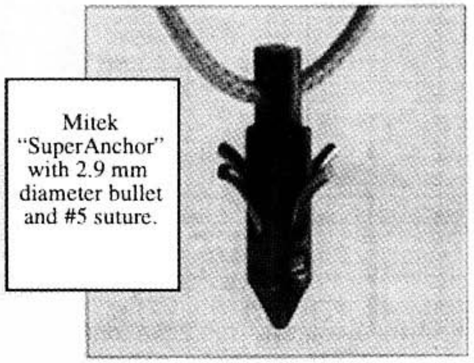

Figure 3: The bone anchor uses tightly curved superelastic Ni-Ti wires to lock itself beneath the hard mantle of the bond, anchoring a suture used to tie down torn ligaments.

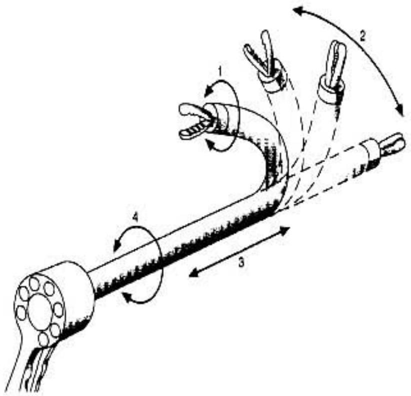

Figure 4: Surgical graspers use Ni-Ti tube and wires pre-shaped into a curved configuration to articulate away from the axis of the laparoscopic cannula.

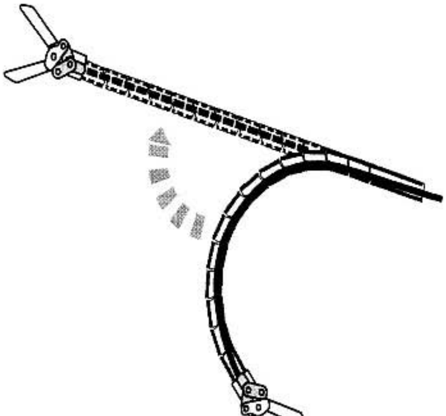

Figure 5: Retractor uses programmed stainless steel segments to accomplish articulation after passing through the cannula, but employs a stainless steel wire to maintain the normally-straight configuration of the instrument.

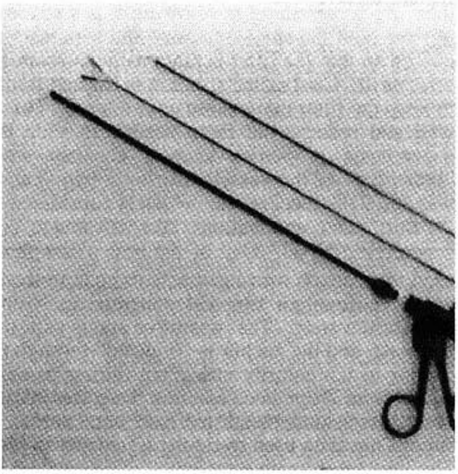

Figure 6: The great flexibility of Ni-Ti allows this grasper to open and close without employing hinges or other complex moving parts. The instrument can be easily dismantled and cleaned.

articulate staplers away from the cannula axis[13]. Figures 4 and 5 show typical examples of such articulated instruments. It is interesting to note that these two examples show similar functions achieved in opposite ways. The instrument in Figure 4 is articulated when the superelastic member is allowed to springback to its austenitic structure and shape. Figure 5 shows an instrument with a normally straight wire used to return the device to a straight configuration to allow insertion and withdrawal through the cannula—it is therefore articulated in its martensitic state.

Superelasticity also allows one to improve upon "hingeless" instruments, allowing convenient and thorough cleaning and paving the way for instrument re-use.[15] Figure 6 shows such an example. Here a set of Ni-Ti graspers is closed by advancing a tube around the outside, thus constraining the normally-open jaws. Stainless steel instruments such as this have been on the market for many years, but Ni-Ti offers a substantially increased jaw opening. The instrument shown in Figure 6 can be very quickly disassembled into components each one of which has no moving parts or narrow nooks and crannies which would make the instrument difficult to clean. The graspers shown in Figure 6 also highlights another advantage of Ni-Ti. The grasping jaws in Figure 6 close with a fixed force. This force can be adjusted to prevent severe damage to tissue, and allowing a more "physiologically correct" squeeze. Though somewhat difficult to quantify, many surgeons have confirmed the value of this physiological feel.

Another feature of superelasticity is its extreme resistance to kinking.[16] This has been the key attribute making Ni-Ti guidewires successful since the mid-1980's. Now, they would have to be considered the standard of the industry. Their advantage over conventional stainless steel is derived from the fact that they can be passed along very tortuous vessels without kinking, without undue frictional effects and damage to the vessel, and can thus be steered more easily by the surgeon. Several new angioplasty devices are now appearing which combine kink resistance with large elasticity. For example, wire baskets are being used to capture and retrieve kidney stones (Figure 7).

Still another use of Ni-Ti's kink resistance brings us back to surgical instruments. Kinking has long been the bane of traditional very long and small diameter instruments. Figure 8, however shows a small grasper with a diameter of only 1 mm. The entire instrument can be passed through tortuous passages without difficulty. This particular instrument uses a superelastic actuation wire within a superelastic tube. Of course the outer sleeve could be made from helical winding of stainless steel, much as a bicycle brake cable, but such an approach would lead to an instrument that is very difficult to clean and hermetically seal to a cannula.

Superelastic microtubing[17-19] has just become available withing the last 2 years, and is the recipient of great interest by the field of angioplasty. Until now, a guidewire has been used to lead the way for a subsequently inserted catheter. Now that superelastic tubing is available,

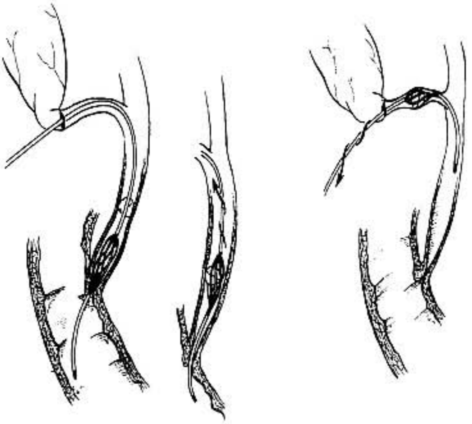

Figure 7: Ni-Ti superelastic wire is used to make a kink-resistant basket, passed through a 4 French catheter, then expanding to capture kidney stones.

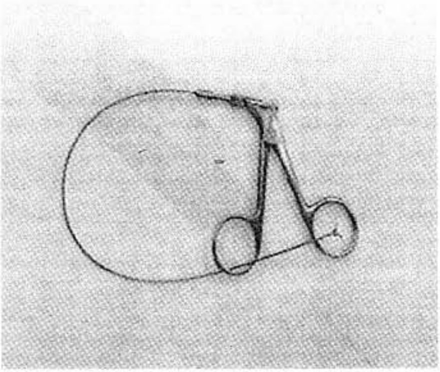

Figure 8: A superelastic wire inside a superelastic microtube is used to actuate a 1 mm diameter grasper. Normal materials could be used as well, but the instrument would be highly prone to kinking, which would disable its function.

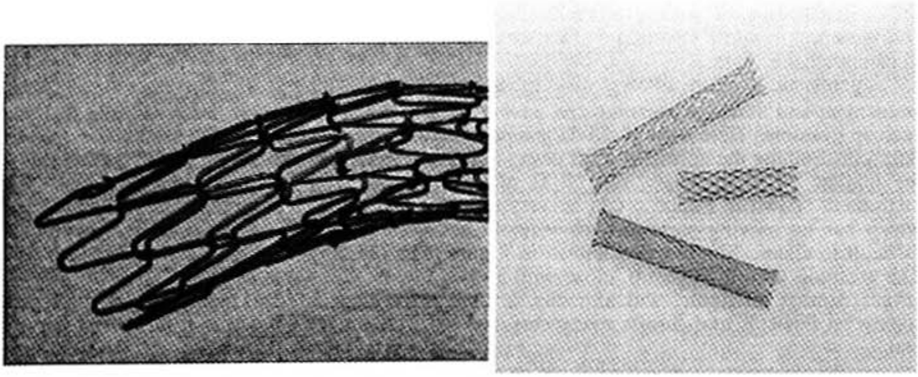

Figure 9: Stents of various configuration are used in a variety of procedures to open and maintain lumens. Some stents are made from wire (left), others are cut from sheet or tubing.

there is a great deal of activity focused on devising catheter products capable of being pushed directly into tortuous blood vessels. At the time of writing, no products are currently on the market using such concepts. Still confidence remains very high in the industry that this process simplification will take place.

Certainly one of the most interesting new applications of Ni-Ti is as stents. A stent can be defined as an object used to hold open a lumen. The lumen may be a blood vessel, a bile duct, the esophocus, etc. For example a cardiovascular stent can be used to maintain the lumen of a cardiac artery subsequent to angioplasy (reopening of astenosis). Two such devices are shown in Figure 9. Superelasticity in this case allows the stent to "breath" with the artery, and apply a physiologically correct force against the vessel wall. It also allows a large stent to be delivered through a small catheter. Again deployment can take place via superelasticity or via the shape memory effect. Currently available stents have an A_f temperature between room temperature

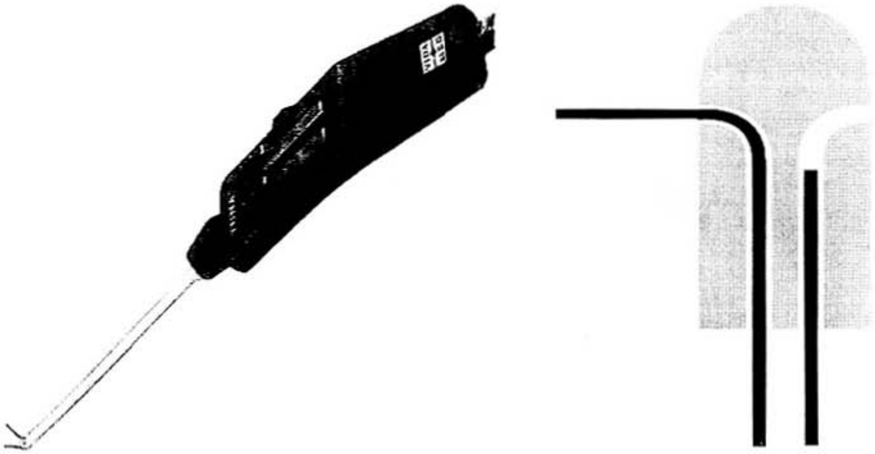

Figure 10: An instrument used to electrocauterize the prostate gland deploys two superelastic wires perpendicular to the axis of the instrument through tightly curved channels. The full instrument is shown on the left and a schematic representation of the bullet tip is shown on the right, with one wire deployed and the other withdrawn.

and body temperature and are expanded using body temperature. Af is generally controlled to provide a physiologically correct force against the lumen wall.

Another recent superelastic instrument is used for the transurethral ablation of prostatic tissue using two Ni-Ti wires to deliver high frequency radiation directly into the prostate (electrocautery). The advantage of Ni-Ti is that the wires can be deployed perpendicular to a small diameter cannula through which the instrument passes (Figure 10). Normal metals would exit the tip with a distinct curvature, and fail to penetrate the prostate tissue.

A variety of orthopaedic implants exist which take advantage of still another attribute of superelasticity: physiological, or mechanical compatibility with natural tissue. Considerable work has been done in Russia on bone implants for maxiollofacial surgery, spinal, and orthopaedics[20]. One key to successful bone implantation is to achieve a high degree of bony ingrowth. It has been found that this does not readily occur when rigid implants are used which do not flex and stress the healing interface to natural tissue. Ni-Ti has been found to form a tissue-implant interface with much greater elastic continuity than other metals. The result is that the interface is stressed during heeling and superior boney in-growth is observed. Implants made from porous Ni-Ti have been found to further improve the mechanical compatibility of the interface. These implants are made by a combustion synthesis technique resulting in densities of approximately 50%. The porosity and high compliance appear to make this an ideal bone implant material.[21]

Any review would be remiss in leaving out superelastic eyeglass frames, which are not only a medical device, but without doubt the most commonly seen application for shape memory alloys. Advertised in the USA under the name Flexon® these frames have become the quality and performance standard of the industry in just 5 years. Well over one million superelastic frames have been sold in the USA alone. The frames are known for their near indestructibility, but are even more desirable because of their comfortable fit. Small fit problems with normal metal frames lead to discomfort, but with Ni-Ti, the forces are always in the comfortable range—even when the fit is poor, the pressure against the temple is consistent, firm and gentle. One should also note that Ni-Ti frames are welded, brazed, and plated—all operations once thought to be very difficult. In this sense too, eyeglass frames are truly a pioneering application.

Although the large majority of medical applications are superelastic in nature, there remain some classic shape memory applications. Perhaps the best known is the steerable catheter. Conventional catheters are inserted over a guidewire which is passively pushed through meandering vessels. Prototype devices exist, however, which allow active steering via a series of electrically activated shape memory actuators.[22] Many versions of this device have been proposed and prototyped, but despite a flurry of very recent activity, there are no devices marketed today. A second new shape memory device is a removable cardiovascular stent (Figure 12). This device is expanded by traditional balloon catherization, but unlike the superelastic stents, this device is fully martensitic during deployment and in use. Upon heating, the stent will shrink again, allowing easy removal.[23]

THE FUTURE

Certainly one of the most interesting new technologies to interface with shape memory has been that of thin films. Films can be made be sputtering, laser ablation[25], or by vapor deposition using targets of pre-alloyed Ni-Ti[24]. Such films are typically amorphous when deposited, but display bulk material shape memory properties after a short crystallization anneal[26]. Films have been "micromachined" to form actuators[27] typically 10 microns in thickness and a millimeter on each side. The first application for such an application is in microvalves (Figure 11). To date, such valves have diameters in the 5-10 mm range. This is certainly small compared to competitive technologies, but by no means represents the limit of the technology. Valves in the sub-millimeter range are certainly possible. Such valves are being studied in the construction of small medical robots, able to travel through and inspect gastrointestinal systems and ultimately even smaller passages[28]. Still another potential thin film application is for steerable catheters, using three or more thin film strips deposited along the length of microtubing. Actuation of

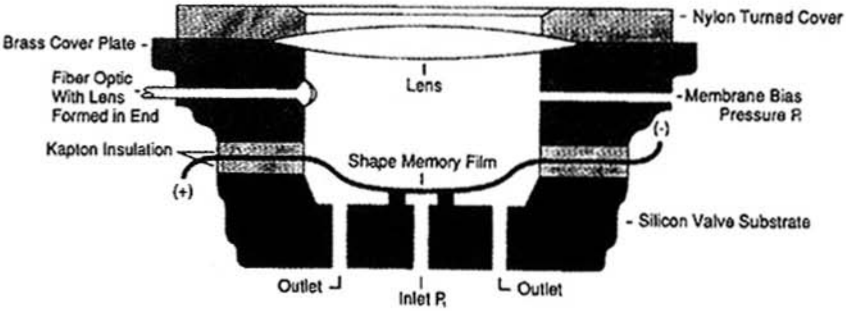

Figure 11: Thin films are used to construct microvalves used to control pneumatic devices on smaller scales than possible with other technologies. This particular device is shown in the closed state, and is actuated optically.

selected strips would cause the catheter to bend on command.

Rapidly solidification techniques have also been used to produce "thin" Ni-Ti strips. Though a great deal of experimental work has been done during the past 10 years, it is notable that at least one "commercial" application has now been developed. 30 micron thick strips of Ni-Ti-Cu have been incorporated into an optical switch with a response time of 8 milliseconds. It is far too early to know if the application will be commercially acceptable, but nevertheless it represents a breakthrough.[29]

The resistance of Ni-Ti alloys exposed to strain controlled fatigue is known to be substantially greater than conventional alloys. This appears to be the case both in the superelastic temperature regime, and in the martensitic phase. This opens a rather large panorama of applications that really do not involve the shape memory effect *per se*. One example that is being seriously studied is again medical in nature: electrical leads for heart

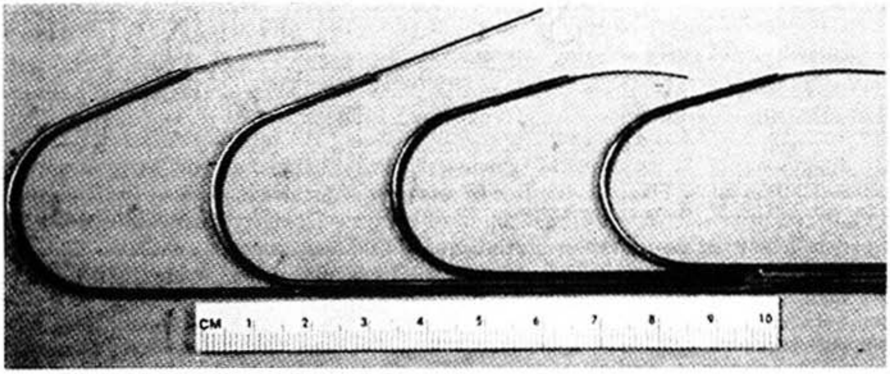

Figure 12: EDM electrodes made from various materials exiting a curved feed tube illustrate the advantages of Ni-Ti: from left to right are brass, Ni-Ti, copper and tungsten.

making it difficult to rely on an initial calibration for resistance and the volume fraction of martensite.

The maximum M_s temperature achieved in Ni-Ti binary alloys is 100°C. For many years, scientists have searched extensively for ways to increase this. Until just two years ago, the only alloys showing hope were extremely expensive: Ti-Pd-Ni and Ti-Pt-Ni alloys. Work on the Cu-Al-Ni and Ni-Al systems had been extensive, but both suffered from severe thermal stability and ductility problems. Recently, however, two new systems are showing a great deal of promise: Ni-Ti-Hf and Ni-Ti-Zr[33]. It appears that transformation temperatures of over 300°C are possible[34]. It is too early to know what the cost of the alloys will be, and if other properties will be as good as the binary alloys, but first indications are positive[35,36]. There are some early indications that work production and recovery forces may be much lower than one would hope, but still, these alloys may well open up new vistas for application, particularly for automotive applications. Until now, automotive electrical actuators have been extremely interesting on the surface, but for the most part impossible due to the possibility of self-actuation on a hot day.[37] Similarly, circuit breakers using shape memory elements have been impossible because the low actuation temperature cause actuation at lower current levels on warm days. In both cases, it is felt that M_s temperatures of at least 160°C, and preferably 200°C are necessary.

SUMMARY

A sampling of recent and future shape memory applications and capabilities have been presented. Many others could have equally well been mentioned. Tennis racket strings have been tested in China and the USA claiming performance superior to existing string materials. Plugs have been strategically inserted in other metals to act as crack stoppers. A non-explosive release bolt has now been used to release a satellite in space. A variety of damping applications are being examined including such ambitious projects as railroad wheel tires and damping mechanisms for suspension bridges. Prototype piping in nuclear reactors has been wound with pre-stretched Ni-Ti wire, which has then been thermally recovered, leaving very high compressive stresses in the pipe. Brassiers and telephone antennae remain two of the highest volume applications worldwide. Medical applications are leading the way at the present time, but as manufacturing methods are perfected and costs reduced, we should expect to see more and more products in these other markets.

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