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Medical Uses of Nitinol

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ABSTRACT

The growth of Nitinol in the medical industries has exploded in the past ten years. Patients and care providers have encouraged the transition from traditional open-surgical procedures, which require long hospital stays, to less-invasive techniques, which are often performed in out-patient clinics. This demand for minimally invasive procedures has allowed novel instrumentation and implants to be designed. An increasing number of these devices use Nitinol as the critical component. Examples of medical applications range from orthodontic archwires and endoscopic instruments to endovascular stents. This paper will focus on key performance attributes of Nitinol that make it an ideal material for medical applications. Specific applications will be introduced through their use of the enabling features.

INTRODUCTION

Shape memory alloys, and in particular NiTi-based materials, have enjoyed a long-standing interest with academicians and inventors. For many of its nearly forty year history, however, the allure of perpetual motion or "magic" prevented Nitinol from being seriously considered for commercial applications. Furthermore, even when a potential application seemed feasible, the non-linear stress-train-temperature response was a barrier for even the most diligent stress analyst or design engineer. The result was that few companies were able to harness the potentials of the shape-memory effects for commercially successful products. This situation led Schetky [1] to remark in 1979 that, "...shape memory is a solution looking for problems." In the twenty years since Schetky's review article was written, the fortunes of the shape-memory industry have improved dramatically. This positive turn in fate can be attributed to a few important changes in business and technology:

- focus on a few, rather than many "boutique" compositions of Ni-Ti,
- the advent of seamless hypotubing,
- more complete analytical design tools,
- refinement of thermo-mechanical processing,
- acceptance of Nitinol as a biomaterial.

It is now apparent that shape memory and superelasticity are viable solutions for problems in the medical device industry. If we use shape memory conferences as a barometer of Nitinol medical device growth, we note that in 1988 **Engineering Aspects of Shape Memory Alloys** [2] devotes six chapters to such uses as orthopedics, orthodontics, radiology, and guidewires. Subsequent conference proceedings, including ICOMAT-92 [3], SMM'94 [4], SMST'94 [5], ICOMAT-95 [6], C-J SMA'97 [7], SMST'97 [8], ICOMAT-98 [9], and SMM'99 [10], all describe advances in the shape-memory medical technology. It is also interesting to observe that with the proliferation of use of Nitinol in medicine, the performance of the material and devices are now measured with novel characteristics [11]. The purpose of this article therefore is to describe a few of these attributes with specific examples of current medical applications.

ELASTIC DEPLOYMENT

The trend in modern medicine is to treat patients with minimally invasive surgery (MIS); the prospect of one or two small incisions is certainly more appealing to the patient undergoing surgery than the long scars and other complications that result from traditional open surgery [12]. One of the enabling technologies to advance MIS are instruments and devices which can be inserted through these small openings and then expand elastically to the desired size and function. Clearly, the superelastic properties of Nitinol allows medical device engineers more creative design option than are available with more conventional materials.

The concept of elastic deployment is beautifully illustrated with the Homer Mammalok, as described in reference [13]. Other, more recent applications, include two devices for radio frequency tissue ablation: the TUNA prostrate ablation device (Figure 1) and the RITA tissue ablation device (Figure 2). In the TUNA instrument, straight Nitinol needles are elastically deployed through a curved tip; whereas, the RITA Nitinol tubes are shape set into a curved configuration and deployed through a straight trocar. The Nitinol components can deployed for the procedure, withdrawn into the cannula, moved to another location and the process repeated as many times as required.

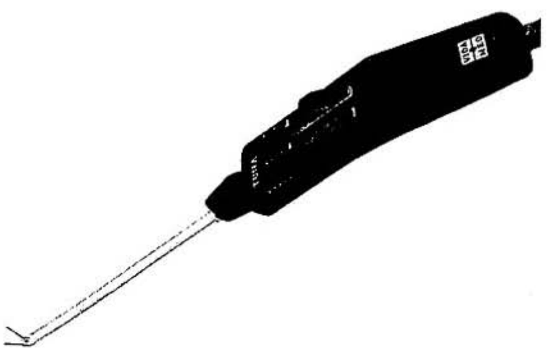

Figure 1: Vidamed TUNA catheter, which is used to treat tumors in the urethra with RF energy. Nitinol wires are elastically deployed through the catheter to the specific site.

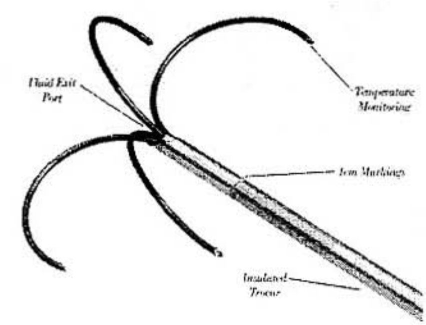

Figure 2: RITA tissue ablation device uses Nitinol tubing which are shape set into a curve and are deployed through a catheter.

The Atrial Septal Defect Occlusion devices, such as those manufactured by Osypka and AGA Medical, (Figure 3) both use Nitinol components that are elastically deployed into the heart to "patch" holes in the atrial wall.

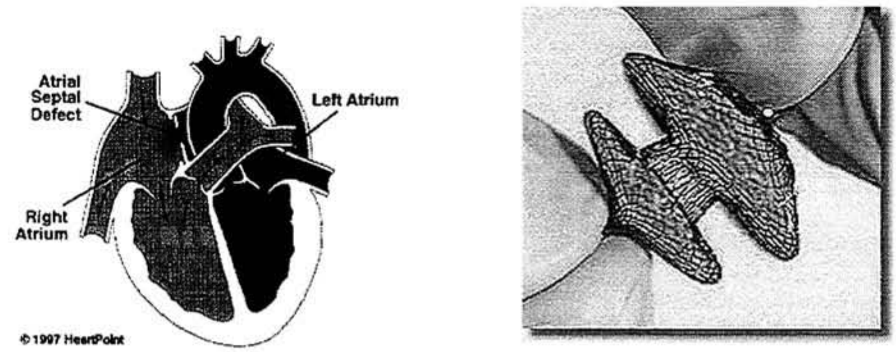

Figure 3: Left is a diagram of the heart that illustrates the atrial septal defect between the left and right atria. The AGA ASD device can be elastically deployed to the defect site and manipulated into position to seal the hole.

THERMAL DEPLOYMENT

Some of the early uses of Nitinol medical devices employed thermal shape memory characteristics. For example, osteosynthesis plates and staples, with transformation temperatures above body temperature, can be shaped, inserted into the body, and heated to promote closure of bone fractures [14]. Another important example is the Simon vena cava filter (Figure 4). The device is preloaded into the delivery system in the martensitic state, flushed with chilled saline, positioned, and released. The flowing blood triggers the shape memory motion to return to its pre-set shape so that it can lodge in the *vena cava* and trap potentially life-threatening blood emboli.

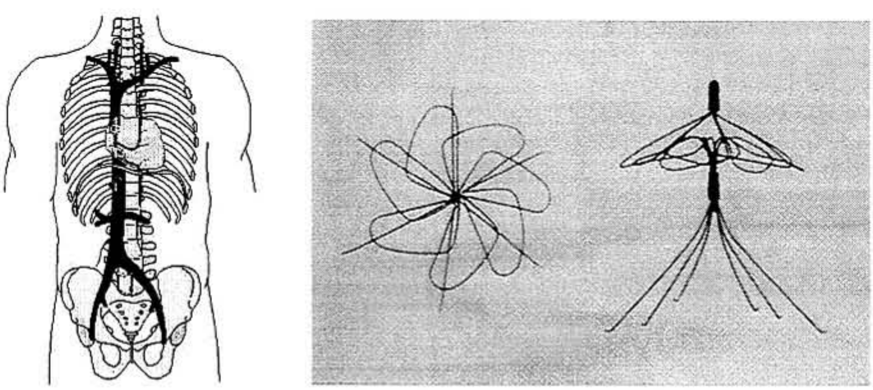

Figure 4: Left is an illustration of the venous system of a human body. During surgical procedures emboli can be dislodged and flow towards the heart, which can potentially block blood flow and cause serious problems. Nitinol filters, such as the Simon Nitinol filter, are placed in the *vena cava* to trap and break up the emboli.

Self-expanding Nitinol stents also have Af temperatures slightly above room temperature, and therefore are technically shape memory devices. One advantage of this process is that it allows the stents to be loaded into their delivery systems and deployed with lower (martensitic) forces. However, once the stents are in place, they react to stresses and strains (e.g., pulsating blood, external forces) superelastically. Interestingly enough, the first metallic stents were made from Nitinol coils in 1983 [15], as shown in Figure 5. Examples of stents approved by the FDA or in clinical trials include the Cordis S.M.A.R.T. for biliary indications (Figure 6), the SciMED Radius for coronary applications, and the Medtronic AneuRx stent graft for abdominal aortic aneurysms (AAA). All three of these stents are laser machined from Nitinol tubing and shape set into their expanded sizes.

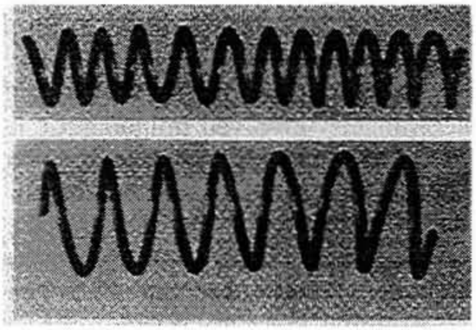

Figure 5: Image of the Nitinol coil stents used by Charles Dotter, pioneer in the field of metallic stents [15]. He noted that the open structure allowed endothelialization.

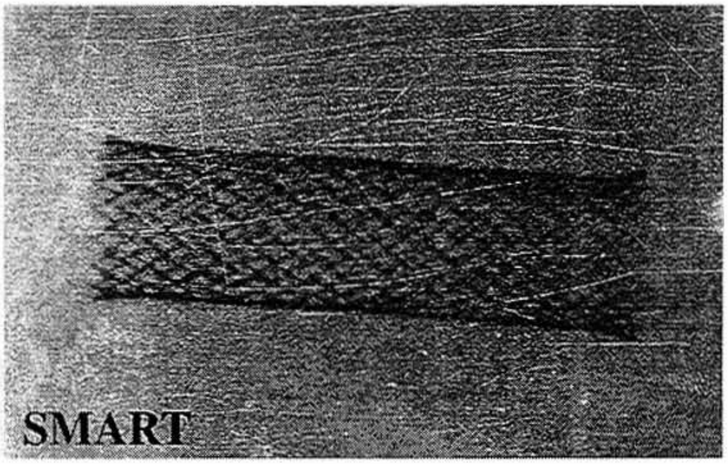

Figure 6: Fluoroscopic image of the Cordis Nitinol SMART stent, which was approved for biliary use in the US in late 1998. It is laser machined from tubing and expanded to final configuration. It is thermally deployed into the body by proper control of the A_f temperature. The fine features allows optimal flexibility and gentle chronic outward force.

KINK RESISTANCE

Angioplasty guidewires are a prime example of the benefits of employing the kink-resistant properties of Nitinol [16]. This characteristic derives from the shape of the superelastic stress-strain curve: long strain plateaus (up to 8% strain) followed by rapidly increasing stresses. These features allow bending through tortuous paths while preventing strain localization and plastic deformation. Recent examples of kink resistant Nitinol devices include retrieval baskets (Figure 6), the endovascular radiation probe and the intra-aortic balloon pump (Figure 7). The baskets are made from Nitinol wire and the distal end are shape set into the basket configuration. The later two devices showcase the benefits of superelastic Nitinol tubing, as described, for example in references [17-19]. The radiation probe consists of a Nitinol tube and guidewire, which are used to place radioactive material in precise locations near tumors in the body. The balloon pump is used to assist heart beating in patients waiting for heart surgery. Nitinol permits smaller profiles for the devices without concern of tube kinking or buckling upon insertion through vessels in the body.

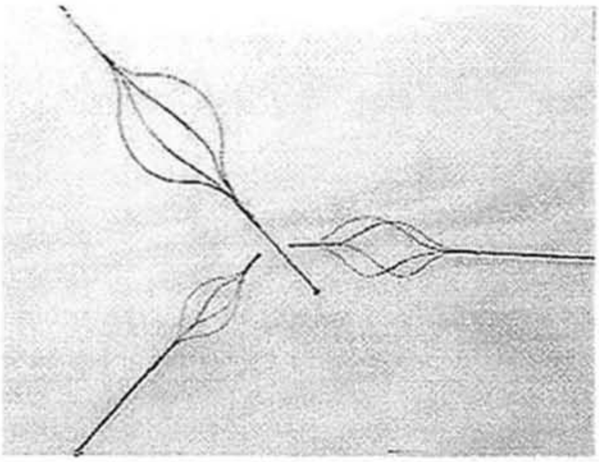

Figure 6: Examples of Nitinol baskets with distal ends shape set into the final configuration.

Figure 7: Arrow Intra Aortic Balloon catheter which uses kink resistant Nitinol tubing to allow movement through tortuous paths into the heart chamber. The device is used to provide back pressure to assist heart beating.

GENTLE, CONSTANT PRESSURE

Nitinol orthodontic archwires have been used since the late 1970's [20]. There are three different types of wires available: linear elastic, shape memory and superelastic, although the latter is used most often. The obvious advantage of superelastic archwires is that they can provide a constant, gentle pressure to move teeth compared with stainless steel. This constant pressure is due to the unloading plateau, which is a function of temperature, not strain. Since the body has a constant temperature, these devices can deliver a predictable force. There are other medical products that rely on the forces exerted by the unloading curve, such as Nitinol stents. For these devices, the unloading plateau provides a measure of the Chronic Outward Force (force against the vessel), which is an important design feature. An additional benefit of superelastic stents is the high stress hysteresis (difference between loading and unloading plateau stresses). For stents, the loading plateau indicates the Hoop Stress (resistance to crushing).

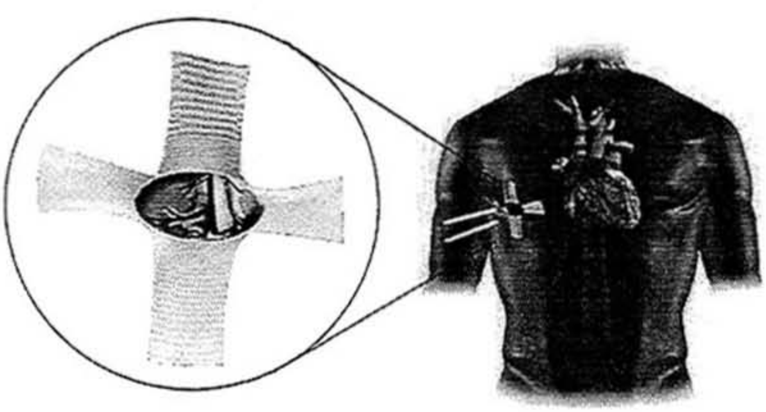

Figure 8: Schematic illustration of the Heartport PortAccess™ which is made from Nitinol strip and is used to apply gentle outward pressure to the small incision to access the heart.

Figure 8 is another example of a medical product made from a superelastic Nitinol strip, Port-Access™ minimally invasive coronary artery bypass grafting (CABG). This device enables MIS techniques for heart surgery by providing constant force against tissue around the relatively small incisions ("port").

FATIGUE RESISTANCE

Most research studies of the fatigue properties of Nitinol have focussed on either stress-controlled or strain-controlled conditions [21]. Nitinol performs exceptionally well at high strains in strain-controlled environments, such as exemplified with dental drills for root canal procedures (Figure 9). The advantage of these Nitinol drills is that they can be bent to rather large strains and still accommodate the high cyclic rotations. The US FDA requires Class 3 implants to be able to survive at least 400, 000, 000 cycles in the human body, which is high number of cycles in a complicated environment. The fatigue conditions of a stent, for example, consist of the cyclic pulsating blood rate (on the order of 1 Hz) and the cyclic amplitude in a vessel is the systolic-diastolic pressure (as high as 100 mm Hg). These conditions are further complicated with an unknown compliance of the diseased vessel. Figure 10 illustrates the strain-cycle fatigue data of stent structures [22] compared with rotary-bending data of wires by Kim and Miyazaki [23].

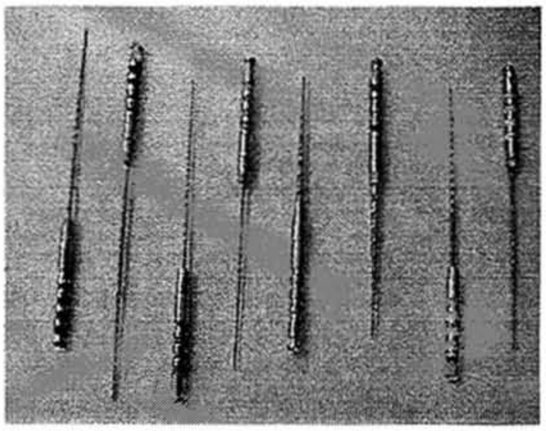

Figure 9: Ormco Nitinol dental drills have good fatigue resistance along with high elasticity to prevent premature failure during root canal procedures.

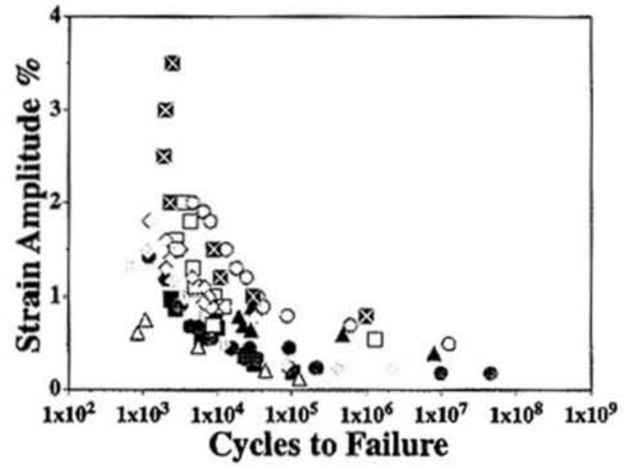

Figure 10: Strain amplitude-cycles fatigue data for Nitinol devices which simulate the complicated stress-strain environment of the human body [22]. Rotary-bending fatigue data of wire from Kim and Miyazaki [23] are also included.

BIOCOMPATIBILITY

Ni-Ti alloys have extremely good corrosion resistance based on formation of a tenacious titanium oxide surface. Recent technical articles show conclusively that the pitting resistance of Nitinol is significantly higher than stainless steel (E_{pit} >800mV compared with <250mV) with a corrosion current density on the order of 10 nA/cm^2 [24, 25]. Furthermore, Trépanier, et al. [26] have shown that optimal corrosion resistance is obtained through passivation treatments, such as electropolishing the surface. Cell culture and implant studies were conducted to assess the cytotoxicity response of Nitinol compared with stainless steel and titanium alloys. Trépanier, et al. [27] and Ryhänen, et al. [28] have shown that although the initial Ni ion release was slightly higher in Nitinol, the overall Ni release rate is similar to stainless steel. Furthermore, it was shown that NiTi induced no toxic effects, decrease in cell proliferation or inhibition in the growth of cells in contact with Nitinol. Figure 11 shows fibro-cellular tissue surrounding a Nitinol stent after twelve weeks implantation in rabbit para-vertebral muscle [29]. Note that there is excellent acceptance of the Nitinol device in the muscle tissue. Based on early indications of exceptional biocompatibility of Nitinol, products such as the Mitek suture anchor (Figure 12) and the Simon vena cava filter (Figure 4) have been routinely implanted in the human body for over ten years with no reports of toxic behavior.

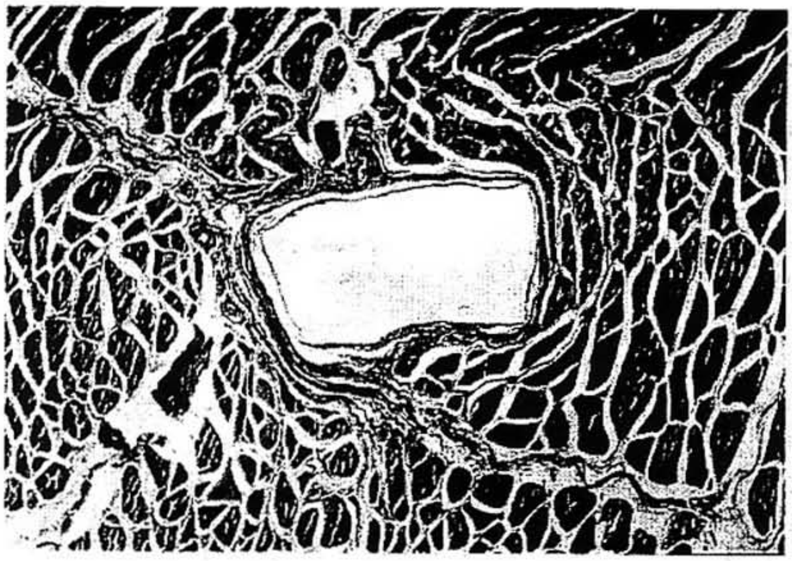

Figure 11: Image of an ex-planted Nitinol stent in rabbit muscle tissue after 12 weeks. Note the uniformity of cell growth near the stent [29].

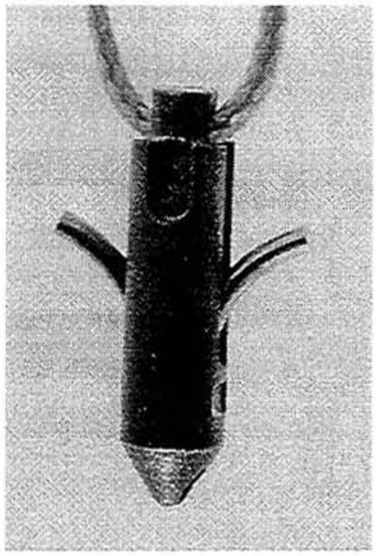

Figure 12: Mitek suture anchors have been implanted into bones for over 15 years with no reports of rejection.

SUMMARY

During the past decade, Nitinol has become the material of choice for minimally invasive surgical techniques. Devices and instruments, such as orthodontic archwires, guidewires, stents, dental drills, catheter tubes, ASD patches, among others, make use of the unique properties provided by Nitinol. Indeed, shape memory is no longer looking for problems; Nitinol has found a comfortable home in the medical industry.

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