The Use of NiTi Alloys for Surgical Instruments

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THE USE OF Ni-Ti ALLOYS FOR SURGICAL INSTRUMENTS

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Shape memory and superelasticity of Nickel-Titanium alloys allow the design of a new class of surgical, particularly endoscopic instruments. Articulation and actuation of scissors, graspers and other instruments can be achieved with a minimum number of parts at reduced cost. Hingeless instruments with superelastic jaws meet the stringent requirements for cleanability of reusable and hybrid tools. The non-linear elasticity of superelastic Ni-Ti provides a "physiologic" feel and built-in overload protection.

1. INTRODUCTION

Nickel-Titanium alloys, commonly known as NITINOL alloys, show a very pronounced superelastic and shape memory effect[1] . They are very corrosion resistant and are considered biocompatible. Their mechanical properties are characterized by the appearance of the so-called martensite plateau, a region of large strains with no or insignificant stress increase. Fig. 1 schematically shows the stress/strain curves for a superelastic and a shape memory Nitinol alloy as well as that of stainless steel for comparison. The shape memory material can be deformed up to eight percent strain. It will stay in the deformed shape until heated to above the transformation temperature of

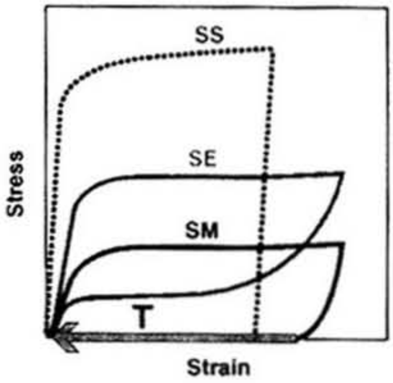

FIGURE 1
Schematic stress/strain curves of superelastic and shape memory Ni-Ti as well as steel

the specific alloy. It will then return into its predeformed shape. The superelastic material, on the other hand, can also be deformed to eight percent strain. However, it will immediately return to its original shape upon unloading. Stainless steel, or any other "conventional" material, will be permanently deformed, if deformed to eight percent strain.

2. THE USE OF NITINOL FOR MEDICAL INSTRUMENTS AND DEVICES

Although known for over 30 years, Nitinol alloys have found widespread use for biomedical applications only during the last few years. The first application of superelastic Nitinol was as orthodontic archwire during the1970s. The advantages that Nitinol provides over conventional materials, obviously are the increased elastic range and a nearly constant stress during unloading[2].

Superelastic Nitinol guidewires are increasingly used because of their extreme flexibility and kink resistance. They also show enhanced torquability (the ability to translate a twist at one end of the guidewire into a turn of nearly identical degree at the other end)[3], thus significantly improving steerability. The low force required for bending the wire is considered to cause less trauma than stainless steel guidewires. Kink resistance and steerability are also the main reasons for using Nitinol in stone retrieval and fragmentation baskets. The shaft as well as the basketwires can be made from superelastic Nitinol.

More recently, shape memory and superelastic Nitinol alloys have been used very effectively for self-expanding stents. The small profile of the compressed stent facilitates safe, atraumatic placement of the stent. After being released from the delivery system, the stent self-expands either elastically or thermally and exerts a constant, gentle radial force on the vessel wall.

2.1. "Deployable" devices

Medical device manufacturers are increasingly using Nitinol in instruments and devices for minimally invasive procedures[4]. The concept is to enter the body with a minimum profile through small incisions with or without a portal, and then changing shape inside the body cavity. This can be accomplished with Nitinol alloys either thermally or elastically. A hook, for example, can be preformed using an alloy with Af between room temperature and body temperature. The hook is then deformed at room temperature into a straight configuration and introduced into the body. Through body heat the device will recover its original hooked shape (Fig. 2). The same function can be achieved using a superelastic hook, and constraining it inside a straight cannula during insertion into the body. Once inside the body, the superelastic component is deployed from the constraining cannula and returns into its curved shape. Most medical applications use the superelasticity of Nitinol rather than its shape memory effect.

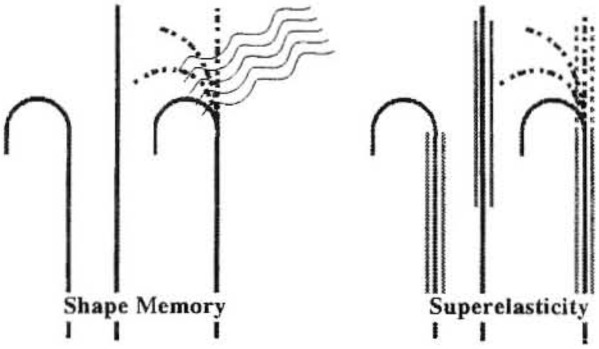

FIGURE 2
Shape memory and superelasticity (thermal and mechanical recovery)

One of the first instruments to use superelastic Nitinol was the Mitek (USA) Mammalok® needle wire localizer (Figure 3), used to locate and mark breast tumors so that subsequent surgery can be more exact and less invasive[5]. A hook shaped Ni-Ti wire straightens when it is pulled into a hollow needle. The needle is then inserted into the breast using a mammogram as a guide to the location of the lesion. At the right location the wire is pushed out of the needle, thereby deploying itself around the lesion. If the mammogram after placement shows that the needle was improperly positioned, the superelastic hook can be pulled back into the needle and repositioned. This done in radiology. The patient is then taken to the operating room for surgery.

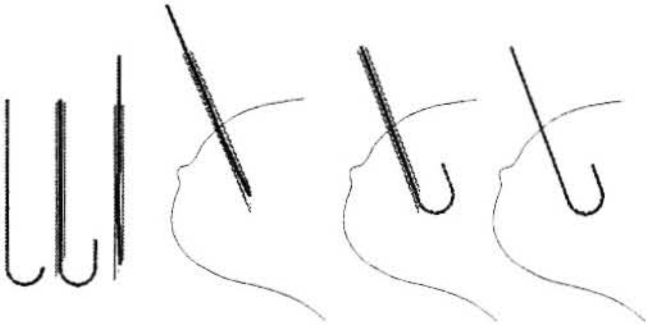

FIGURE 3
The Mammalock needle-wire localizer (MITEK)

The concept of constraining a curved superelastic component inside a cannula during insertion into the body is used in a variety of instruments for minimally invasise surgery. Figure 4 shows a dissecting spatula, the curvature of which is increased by progressive extrusion of the superelastic blade[6]. Different blade configurations are used for variable curvature suture and sling passers.

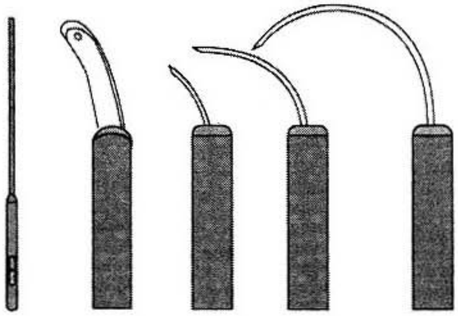

FIGURE 4
Variable curvature dissecting spatula (Cushieri)

A problem with laparoscopic surgery vs. open surgery is the reduced number of degrees of freedom for manipulation. Most laparoscopic instruments have two to three degrees of freedom[7]: translation (the movement of the instruments in the direction of their longitudinal axis), axial rotation (rotation of the instrument around its longitudinal axis) and relative rotation around the entry point. Steerable or at least deflectable instruments provide additional degrees of freedom. A system developed by the Center for Nuclear Research in Karlsruhe together with the University Hospital in Tübingen (Germany) adapts remote handling concepts used in robotics. The movements of the distal tip, which can be equipped with different functional heads, is achieved by superelastic Nitinol wires/rods controlled by a multifunctional handle[8].

A similar concept is used in the "Endoflex" devices developped and marketed by Surgical Innovations (UK). For steering and/or actuation, Nitinol rods are used instead of bowden cables or twisted cables, providing an inherent structural strength and stiffness when unstressed. They go around tight bends transmitting motion and/or force without being permanently deformed (Fig. 5).

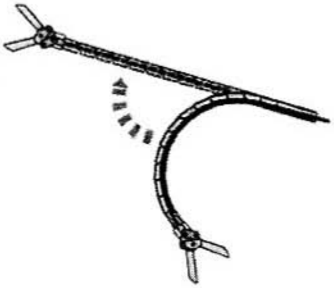

FIGURE 5
The Endoflex deflectable scissors (Surgical Innovations)

Instruments with deflectable distal ends use curved superelastic components which are constrained in a cannula during insertion into the body and deployed once inside the body. Graspers, needle holders and scissors, manufactured by US Surgical (USA) can be inserted through straight trocar cannulae. Once inside the peritoneal cavity, they can change into their curved configuration, thus increasing the degrees of freedom for manipulation (Fig 6).

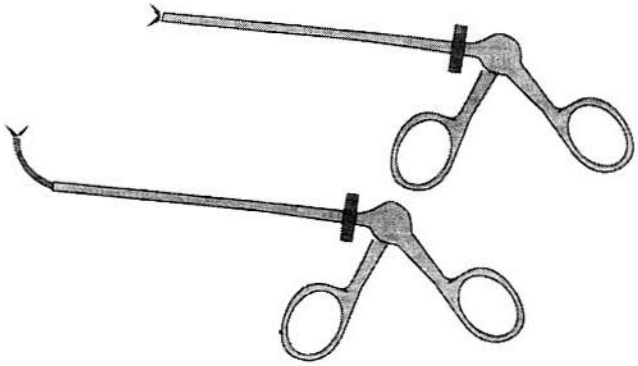

FIGURE 6
Instrument with deployable curved functional tip (USSC)

In a new electrosurgical device for transurethral ablation of prostatic tissue, radiofrequency energy is delivered directly into the prostate via two side-deploying needles. These needles, made from superelastic Nitinol, are deflected from the axis of the catheter around a sharp bend to be deployed radially through the urethral wall into the prostate tissue. After passing the guiding channel, they protrude straight out of the catheter tip (Vidamed, USA)

2.2. Hingeless instruments

Minimally invasive endoscopic surgery is intended to reduce trauma and pain of access to the body without compromising exposure of the operating field for the surgeon. By working through an endoscope with small precision instruments, large painful access wounds are avoided, internal tissue trauma is reduced, hospital stays are shortened and recovery is accelerated. Conventional instrument development efforts have taken the form of miniaturization of mechanical linkages in hinged-type designs, resulting in highly complicated systems with many individual parts, which are difficult to assemble. Worldwide cost containement efforts favor the use of reusable or hybrid instruments, which have to be cleaned and sterilized after each use. Ease of assembly and disassembly, therefore, becomes an issue.

Hingeless instruments use the elasticity of spring materials instead of pivoting joints to open and close the jaws of grasping forceps or the blades of scissors. Because of their simple design without moving parts and hidden crevices, they are easier to clean and sterilize. The function of a hingeless instrument is illustrated in Figure 7. A new generation of hingeless instruments uses superelastic Nitinol for the actuating component of these instruments, which provides elasticity higher than stainless steel by at least a factor of 10. This results in an increased opening span and/or reduced displacement of the constraining tube for ergonomic handling (Fig. 8). In many cases the functional tip can be a monolithic superelastic component, vs. multiple intricate, precision machined components and linkages of conventional instruments. This allows the design of instruments with very small profiles.

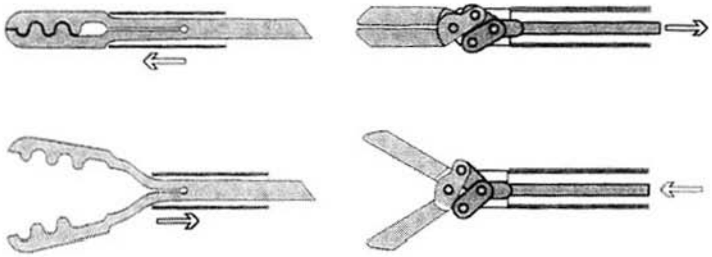

FIGURE 7
Hingeless vs. conventional instrument design

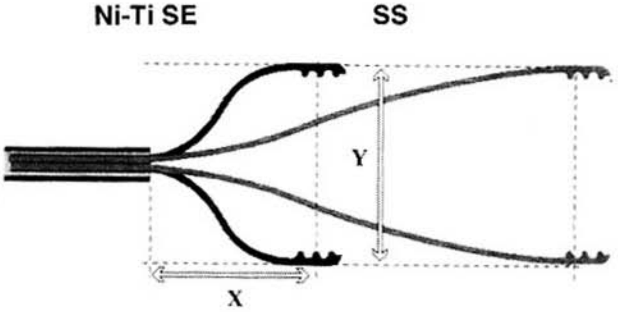

FIGURE 8
Schematic performance comparison Nitinol vs. steel

The non-linear stress/strain characteristics of Nitinol provides constant force gripping of large and small objects and built -in overload protection. This reduces the risk of tissue damage (Fig. 9).

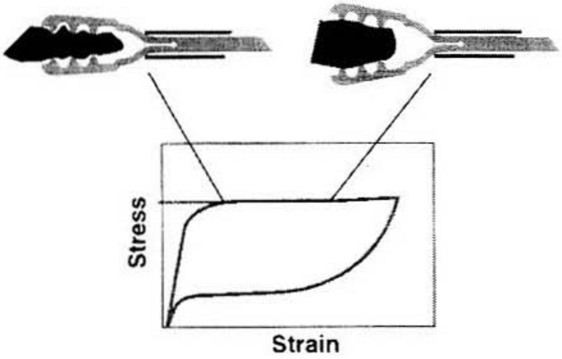

FIGURE 9
Constant force grasping and overload protection

2.3. Non-kinking instruments

Long and thin instruments, e.g. like forceps used in urology, tend to be very delicate and can kink easily, destroying an expensive tool. Using superelastic Nitinol for the outer tube and a superelastic actuation rod, makes the instrument very flexible and kink resistant. Superelastic tubes have only recently been made available by different suppliers. They are also used for biopsy needles, e.g. for interventional computer tomography or magnetic resonance imaging. In these techniques Nitinol instruments can be clearly detected without artifacts (glow)[9].

In arthroscopy, a major advantage of superelastic needles is their ability to be passed through curved cannulae or channels with out taking a permanent set.

3. CONCLUSIONS

Nitinol alloys provide a unique combination of properties, not found in any other material, which makes these alloys particularly interesting for medical applications:

- shape recovery (thermal or mechanical)
- extrem elasticity
- low deformation force/stress
- constant force over wide strain range
- high strength
- good ductility
- corrosion resistance
- biocompatibility
- excellent MRI visibility
- sufficient radioopacity

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