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New Developments in Superelastic Instrumentation for Minimally-Invasive Surgery

Stoeckel

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New Developments in Superelastic Instrumentation for Minimally Invasive Surgery

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Introduction

The term "superelasticity" is used to describe the property of certain alloys to return to their original shape upon unloading after a substantial deformation. Superelastic alloys can be strained ten times more than ordinary spring materials without being plastically deformed. This unusually large elasticity is also called pseudoelasticity, because the mechanism is non conventional in nature, or transformational superelasticity because it is caused by a stress induced phase transformation. Alloys that show superelasticity undergo a thermoelastic martensitic transformation which is also the prerequisite for the shape memory effect. While superelastic components recover elastically into their prestressed shape after being released from a constraining means, shape memory components recover a previous shape upon heating above a certain temperature (Fig. 1). Superelasticity and shape memory effect are therefore closely related [1].

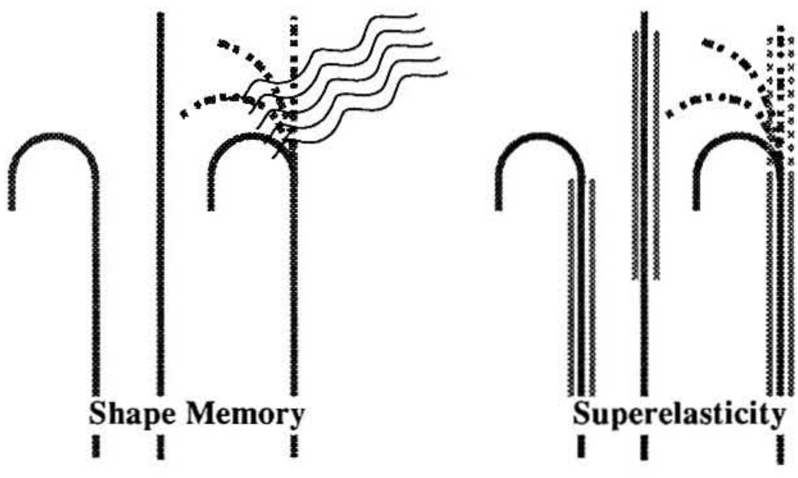

Fig. 1: Thermal and mechanical memory

Nickel-Titanium alloys show a very pronounced superelastic and shape memory effect. They are commonly known as NITINOL alloys. Some manufacturers use brand names like Flexinol, Elastenite, Tinel, Memorite etc. Nitinol alloys are very corrosion resistant and are considered biocompatible. Although known for over 30 years, these materials have found widespread use for biomedical applications only during the last few years. Medical device manufacturers are increasingly using Nitinol in instruments and devices for minimally invasive procedures. Most of these new devices make use of the superelasticity of Nitinol. Therefore, in the following, focus will be on this aspect.

Designing with Superelastic Nitinol Alloys

Superelasticity as well as shape memory of Nitinol alloys are transformational effects, i.e. the material exists in two different crystalline structures. While shape memory is a thermally induced transformation, superelasticity is mechanically stress-) induced. In-depth explanations of the effects are given in [1,2]. While high elasticity in conventional materials is typically the result of a high yield strength combined with a low modulus, and is therefore limited to approx. 2% elastic strain, superelasticity is caused by a phase change in the material which allows it be strained to almost 10% without significant permanent deformation. Unlike in conventional materials, these high elastic deformations don't require very high deforming stresses. Superelastic alloys "yield" at rather low stresses due to the onset of the phase transformation and are then deformed with only little stress increase while the material continues to transform. Up to strains of about 8%, the deformation is reversible due to the reverse transformation, although with a stress hysteresis. Figure 2 schematically shows stress/strain curves of conventional materials and a superelastic material.

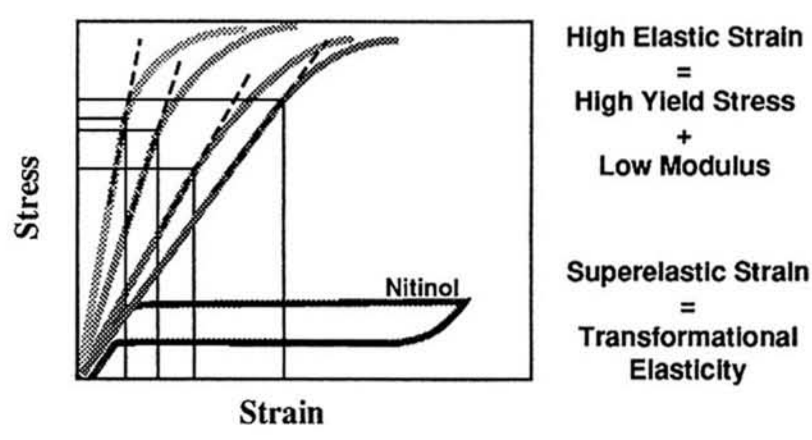

Fig. 2: Schematic stress/strain comparison of elastic and superelastic materials

As mentioned above, conventional metals and alloys exhibit a linear elasticity, i.e. stress and strain increase proportionally. In the fully superelastic condition Nitinol alloys show the characteristic, non-linear ("flag-shaped") loading/unloading curve, i.e. large strains are accumulated with no or only little stress increase. Depending on the processing, however, a more linear elastic behavior can be achieved, which does not reach the extreme values of the true superelasticity, but exceeds the elastic limits of all other conventional elastic materials [2]. This is called martensite elasticity. Figure 3 compares the elastic strain limits of superelastic Nitinol (SE) and martensitically elastic Nitinol (ME) with those of conventional materials.

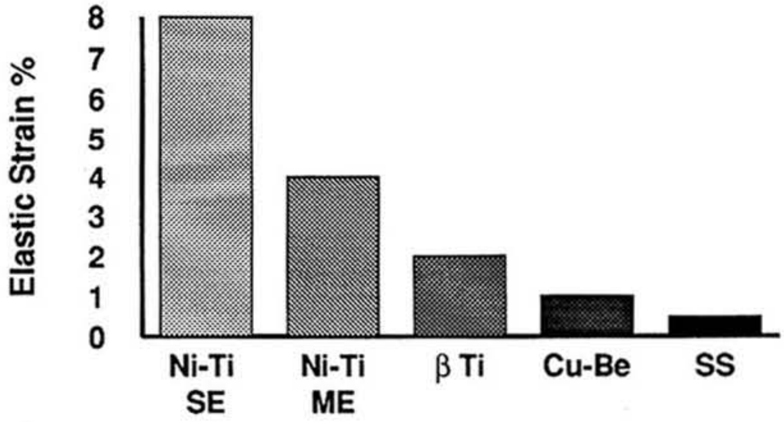

Fig. 3: Elastic strain limits of different materials

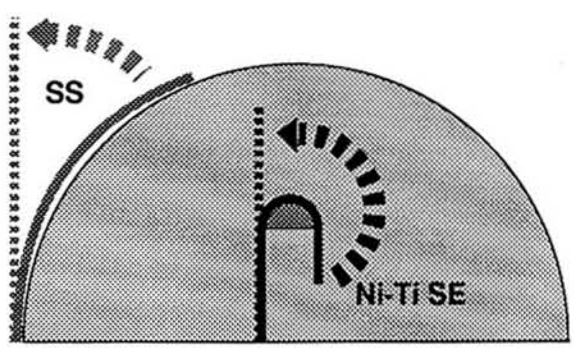

Fig. 4: Elastic bending performance of stainless steel and superelastic Nitinol

The increased elasticity of Nitinol alloys allows the design of instruments with fewer parts, simpler configurations and smaller size. In Figure 4 the elastic bending performance of stainless steel and superelastic Nitinol is compared schematically . A superelastic component can be bent around a radius 10 times smaller and still recovers to its original shape. Instruments made from Nitinol are therefore much more kinkresistant than stainless steel instruments, an interesting feature in guidewires, needles, microsurgical instruments etc.. For hingeless instruments, like grasping forceps etc., increased elasticity means reduced stroke to achieve the same opening gap (Figure 5).

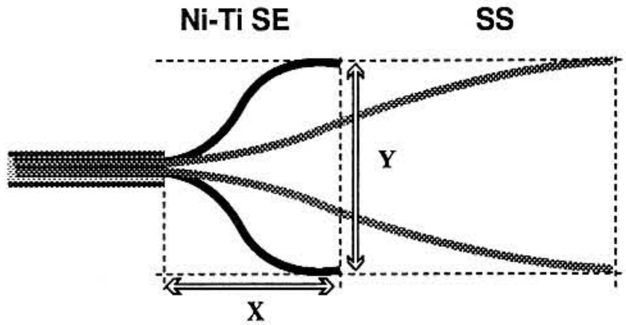

Fig. 5: Schematic performance comparison

Constraining a curved superelastic component in a straight cannula, allows the cannula to be introduced into the body through a small incision or endoscopic portal. Once inside the body, the superelastic component is deployed from the constraining cannula and returns into its curved shape. An instrument with a superelastic functional tip provides increased degrees of freedom for manipulation [3,4] without complicated mechanical systems.

For steering or actuation purposes, Nitinol wires can be used instead of bowden cables or twisted cables, providing an inherent structural strength or stiffness when unstressed. They will go around tight bends transmitting motion and/or force without being permanently deformed. This is also an interesting feature for needles, which have to go through curved cannulas.

The Use of Nitinol for Medical Applications

The first application of superelastic Nitinol was as orthodontic archwire in the early 1970s. The biggest advantages that Ni-Ti provides over conventional materials obviously are the increased elastic range and a nearly constant stress during unloading [5]. The first reduces the need to retighten and adjust the wire and provides the clinician with a greater working range. The second tends to decrease treatment time and increase patient comfort. Superelastic coil springs made from Ni-Ti wires have been introduced for treatment for either opening or closing of extraction spaces. The superelastic springs provide greater efficiency in tooth movement than coil springs made from stainless steel or Cr-Co-Ni alloys [5].

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) [6], 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.

Another application which utilizes the extreme elasticity of Nitinol materials very effectively is 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 to over twice its compressed diameter and exerts a constant, gentle radial force on the vessel wall. In one specific configuration, the compressed stent is encased in gelatin, which begins to dissolve immediately after release from the delivery system [7].

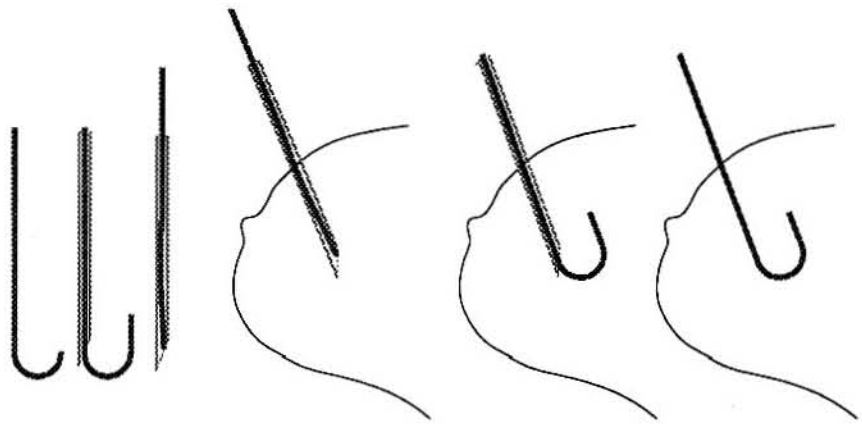

Fig.6: The Mammalock® needle wire localizer

One of the first instruments to use superelastic Nitinol was the Mammalok® needle wire localizer (Figure 6), used to locate and mark breast tumors so that subsequent surgery can be more exact and less invasive [8]. 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.

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 invasive surgery. Figure 7 shows a dissecting spatula, the curvature of which is increased by progressive extrusion of the superelastic blade [9]. Different blade configurations are used for variable curvature suture and sling passers.

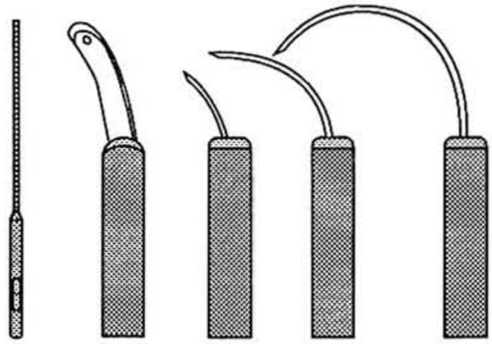

Fig. 7: Variable curvature dissecting spatula [9]

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 [10]: 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 (Figure 8). 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 [11].

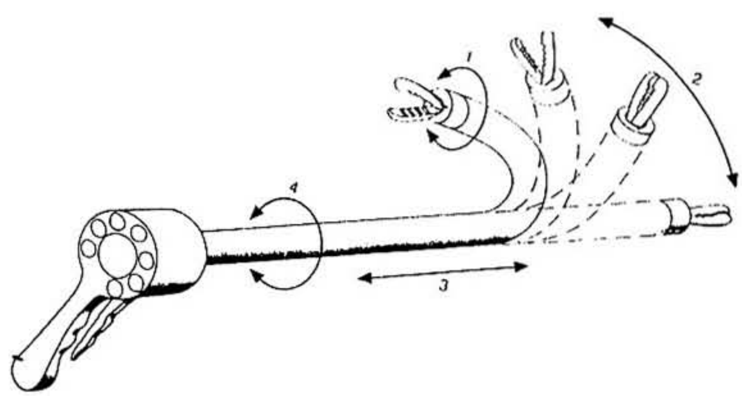

Fig. 8: Steerable instrument with Nitinol actuation rods [11]

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 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 (Figure 9) [3,4].

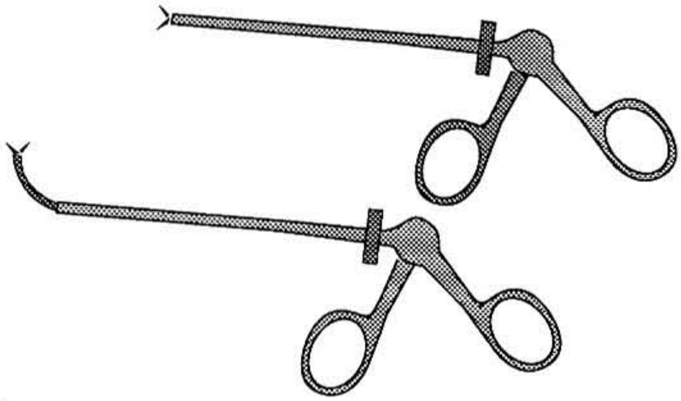

Fig. 9: Instrument with deployable curved functional tip [3,4]

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.

As mentioned earlier, a major advantage of superelastic needles is their ability to be passed through curved cannulae or channels with out taking a permanent set. 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 (Figure 10)[12].

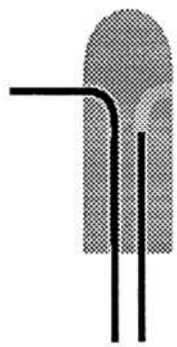

Fig. 10: Catheter tip with side-deploying needles [12]

The kink resistance and resistance to take a permanent set is also a major advantage of superelastic Ni-Ti suture needles for less invasive orthopedic surgery [6].

Another very successful application is the suture anchor (Figure 12): a small arc of Ni-Ti straightens when it is pushed through a hole drilled into the bone with a guiding device. When it reaches the softer core of the bone it springs back to its arc configuration and anchors itself into the bone. A suture tied to the anchor is then used to reattach ligaments to the bone. This sort of surgery has proven to be far less invasive than conventional methods using large stainless steel screws [13].

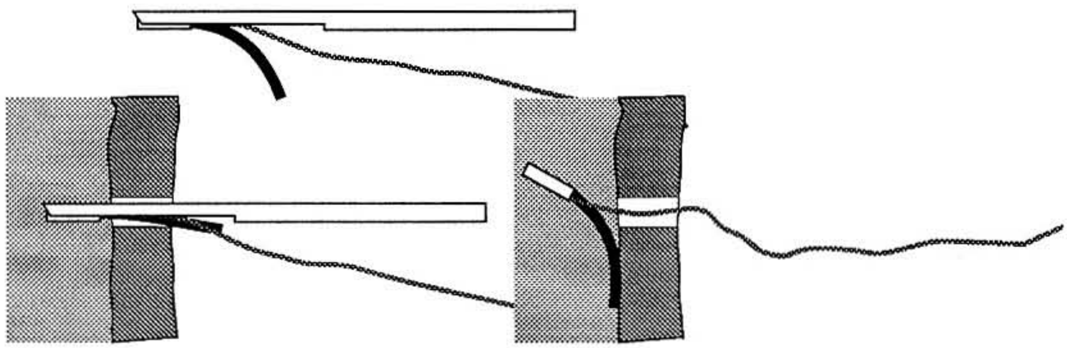

Fig. 12: Mitek Suture Anchor system [13]

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