Surg Endosc (2006) 20: 1493–1496
DOI: 10.1007/s00464-005-0867-1

© Springer Science+Business Media, Inc. 2006

SURGICAL ENDOSCOPY
and Other Interventional Techniques

Nitinol: shape-memory and super-elastic materials in surgery

A. Szold

Endoscopic Surgery Service, Tel Aviv Sourasky Medical Center, 6 Weizman street, Tel Aviv 64239, Israel

Received: 27 December 2005/Accepted: 29 March 2006/Online publication: 20 July 2006

Nitinol (Nickel Titanium Naval Ordinance Laboratory), an alloy containing an almost equal mixture of nickel and titanium, was invented in the late 1960s. For many years, it was considered a "solution in search of a problem." It has generated interest in the medical device world only in the past decade, when it became a key component of several revolutionary medical devices including vascular stents, tools, and grafts.

Nitinol belongs to a group of materials referred to as "smart materials" because of their unique physical properties and the fact they behave in ways surprisingly different from closely related materials. The two physical properties that make nitinol so remarkable are shape-memory and superelasticity. These properties enable new types of medical devices to be designed and produced in diverse fields of medicine.

Structure and qualities

The atomic structure of nitinol is a three-dimensional symmetric grid, with each atom of nickel surrounded by four atoms of titanium (Fig. 1). The atomic forces that bind these atoms create a unique crystal structure that can exhibit a transition between two phases. The first phase, known as the austenite phase, is a high-temperature, stronger state. The second phase, the martensite phase, is a low-temperature, unstable, weak phase. The transformation between the two phases gives nitinol its unique physical properties.

Shape-memory

Two features can be "memorized" in a product made of nitinol: transformation temperature and memorized austenitic shape. When cooled below the transformation temperature, a product made of nitinol transforms to its martensitic phase, with mechanical properties enabling easy deformation of the product. As long as the deformation does not exceed about 6%—a very high value for metals—the product will resume its memorized austenitic shape and mechanical characteristics when reheated above the transformation temperature. This process is fully reversible.

After being plastically manufactured in a certain form and at a given temperature, nitinol will stay in that form as long as it is kept at or above this temperature. When cooled below the stable temperature, it will transform into the weak, unstable phase, and may be deformed easily into other shapes. Once warmed back to the stable temperature, it will regain the original form exactly.

Superelasticity

Some nitinols demonstrate superelasticity. With products of this type of nitinol, the phase transformation from austenite to martensite also can be achieved by applying force (strain) to the product. When the force it removed, the product will resume its memorized austenitic shape and characteristics.

Mechanical properties

Nitinol demonstrates unique mechanical stress-strain behavior when loaded and unloaded. This unique behavior is characterized by atypical loading and unloading plateaus usually not associated with metals. Most body tissues also demonstrate similar mechanical behavior, which makes nitinol biocompatible when used as an implant in either bones or soft tissue (Fig. 2).

At room temperature, nitinol typically is in the stable, strong phase. When subjected to strain, it goes into the unstable, weak phase that exhibits low stress forces and allows deformation, with a resulting small change in stress or yield. In similar conditions, other metals either resist the deformation or break. When the strain is no longer exerted, the metal goes back to the more stable, strong phase and regains its original form with very little distortion.

Correspondence to: A. Szold

NEURENT 1061

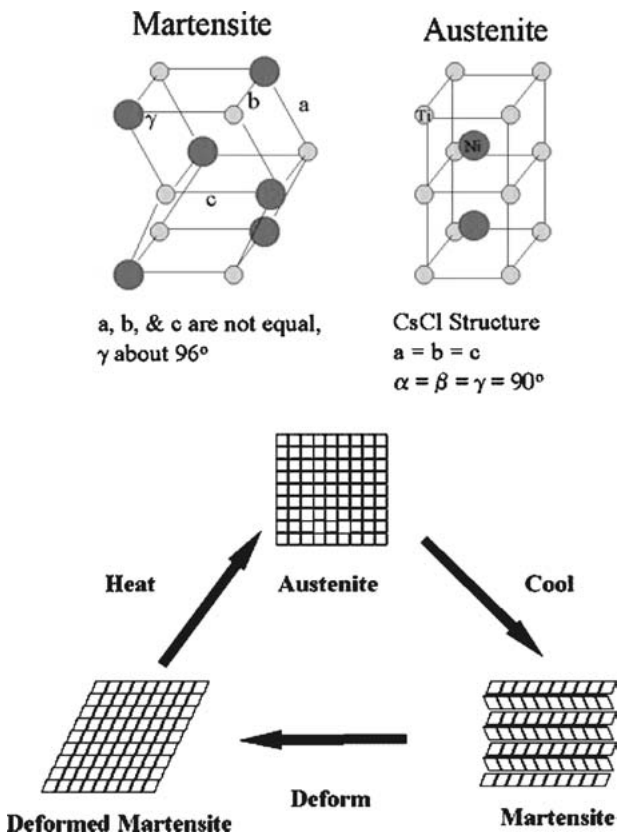

Fig. 1. The atomic structure of the nitinol alloy.

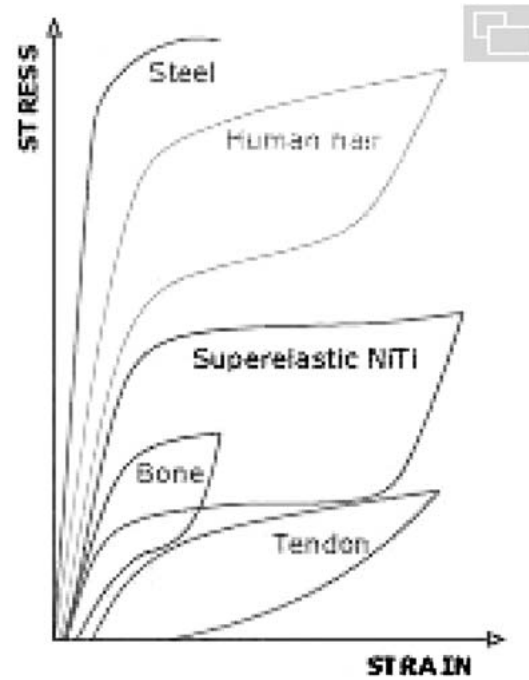

Fig. 2. Stress/strain plot of live tissues, steel, and nitinol. Nitinol behaves much like tissues when subjected to stress.

Fig. 3. The use of self-expanding disc spacers made of nitinol. On the right, the spacer is deformed for insertion. On the left, the spacer is in the permanent configuration.

Biocompatibility

During production, nitinol surfaces may be finished in a way that leaves mostly titanium oxide atoms and a small proportion of nickel atoms strongly bound to the crystal structure. Thus, although nitinol contains much higher concentrations of nickel than stainless steel, it releases much smaller amounts of free nickel atoms into adjacent tissues and the blood stream than commonly used stainless steel medical devices. Along with titanium and special grades of stainless steel, nitinol is one of the three metals commonly used for permanent implants.

Physiologic compatibility

Metals used in medical devices are poorly compliant relative to biologic materials, yielding little, if at all, in response to pressure. The compliance of nitinol makes this alloy the most similar mechanically to biologic materials. This improved physiologic similarity promotes bony ingrowth by sharing loads with the surrounding tissue, and has led to applications such as hip implants, bone spacers (Fig. 3), bone staples, and skull plates. For some of these applications, porous nitinol is used, which possesses the advantageous characteristic of promoting bony ingrowth.

Combustion synthesis, in which the heat of fusion is used to "ignite" the formation of Nitinol from nickel and titanium, is shown to be an effective way of producing a porous "sponge" of nitinol with densities of 40% to 90%. The sponge maintains superelastic and shape-memory properties, has a mechanically reduced modulus of elasticity, accelerates bony ingrowth, and offers improved adhesion to surrounding tissue.

MRI compatibility

Nitinol is completely magnetic resonance imaging (MRI) compatible (Fig. 4), allowing MR scanning even with large implants such as gastrointestinal and major vessel stents.

Potential uses

The properties of nitinol make it an ideal material for the production of stents. When delivered, the stent may

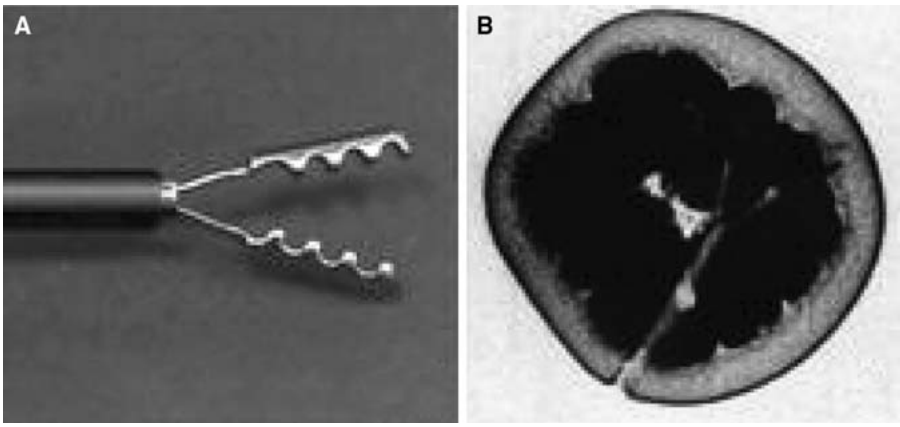

Fig. 4. The nitinol grasper is shown in the picture (**A**) and in a magnetic resonance (MR) image inside an orange (**B**). Note the lack of any artifacts around the grasper.

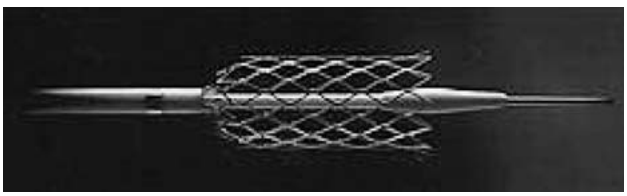

Fig. 5. Nitinol stent emerging from the deployment system.

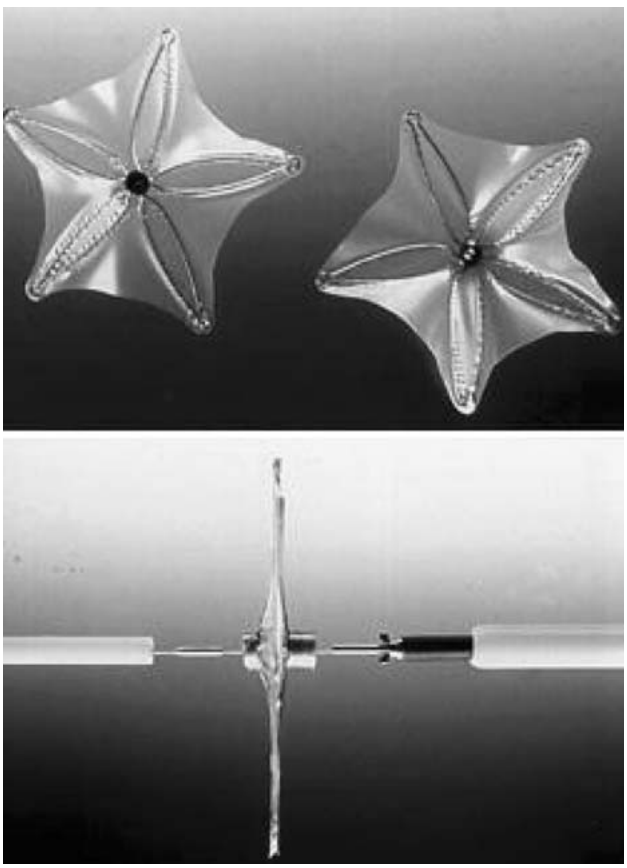

Fig. 6. Nitinol "double umbrella" used by interventional radiology for the treatmentof ASD (Atrial-Septal defect).

be deformed to fit into a low-caliber delivery system and delivered into a vessel or another tubular organ.

Fig. 7. Nitinol tool. The material allows deformability that is impossible with other materials.

When deployed, the stent regains its original diameter, exerting low, constant centrifugal force that keeps the vessel open (Figs. 5 and 6). However, because of its superelasticity, if an external force is used on the structure, the stent will deform, then regain its open configuration when the external force is no longer there. In addition, when used in a blood vessel, it will conform to the arterial wall and its movements during systole and diastole. Other nitinol medical devices in an early phase of adoption are bone and joint replacement devices, surgical tools, and bone clips and spacers (Fig. 7).

To date, only one medical device for use in general surgery takes advantage of nitinol's unique properties. The device is a bowel anastomosis compression clip made by NiTi Medical Technologies (Netanya, Israel). It is a double-loop clip (Fig. 8) that after being cooled, is deformed and inserted into two bowel loops through small incisions closed with a single suture. After it is heated to body temperature, the clip hardens and exerts a constant, low pressure on the bowel walls. During approximately 7 days, a simultaneous process of pressure necrosis and healing takes place. At the end of this time, the bowel loops are joined with a common lumen and the clip falls into the bowel, where it is excreted. The device has passed

Fig. 8. Nitinol anastomisis clip used for side-to-side bowel anastomosis.

human trials, and a second-generation device for end-to-end anastomosis currently is in development. The advantages of this device are that the anastomosis is continuous without gaps and staples, a feature that theoretically may reduce leaks, and that the device is eliminated after 7 days, allowing the anastomosis to dilate according to the physiologic needs of the specific site.

There are several additional potential developments that can use nitinol's special properties. For example, small tools can be built from thin nitinol tubes loaded with optic fibers. The fibers may be used to heat parts of the tool selectively using laser energy, thus using the nitinol as a mechanical actuator to move the arms of the instrument in a complex way. Another potential use may involve complex instruments or devices that can be introduced through very small incisions after being cooled and deformed.

It should be noted that the design and production of nitinol devices, pioneered in Russia, are not simple. Conventional metals are linearly elastic, readily lending themselves to both analytical and finite-element analysis methods. Nitinol, like biologic materials, is much more difficult to model. Not only is its behavior nonlinear, but there also is a hysteresis, a strong temperature dependency, and a permanent set. To make matters more complex, the latter two properties are strain dependent. A great deal of work currently is underway to improve the applicability of modeling methods to these types of materials, but much more investigation is needed.