Nitinol Medical Devices

Shape memory and superelasticity properties of Nitinol have enabled the development of many novel medical devices. The intent of this article is to approach the shape memory effect from the perspective of the attributes of the Homer Mammalok needle localizer. Thermal deployment, elastic deployment, and the effects of stress and temperature dependence of the device are briefly reviewed.

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Application of shape-memory materials for medical devices has exploded during the past two decades, and the literature is richly illustrated with many novel devices. Although the science behind the shape memory properties has been known for decades, questions remain about the practical use of NiTi (or Nitinol) in the medical community.

The lack of complete understanding is certainly not surprising, since the underlying principles of mechanical behavior and temperature effects are dramatically different from those of stainless steel or titanium alloys. In this article, we will follow the approach of Duerig *et al.* and describe the shape memory effect in terms of functional attributes of the medical device. The following is a short list of important functions of Nitinol medical devices:

- Biomechanical compatibility
- Thermal deployment
- Elastic deployment
- Hysteresis/Biased stiffness
- Kink resistance
- Constancy of stress/Temperature dependency
- Fatigue resistance
- Dynamic interference
- MR compatibility
- Biocompatibility

This article explains the concepts of *Thermal Deployment*, *Elastic Deployment*, and *Constancy of Stress / Temperature Dependency* as they relate to product design and performance. To illustrate these effects, we describe a simple yet elegant Nitinol medical device, the Homer Mammalok, shown in **Fig. 1**. This device is a 0.4 mm diameter Nitinol wire that has a "J" hook radius of 19 mm. It is a minimally invasive aid for radiologists to locate breast tumors and nodules, and therefore is a prototype for other Nitinol-based medical components.

Thermal deployment

Thermal deployment of a Nitinol medical device refers to the function of its primary attribute: *Shape Memory*, defined as the ability to change shape because of a change in temperature.

The fundamental driving force is a solid-state phase transformation commonly designated a *martensitic transformation*. In the case of Nitinol, the atoms are arranged in an ordered simple cubic (B2 or CsCl) configuration at high temperature; this is known as the *Austenite* phase.

When the temperature is lowered, the nickel and titanium atoms move slightly to another arrangement called the *Martensite* phase, which has an or-

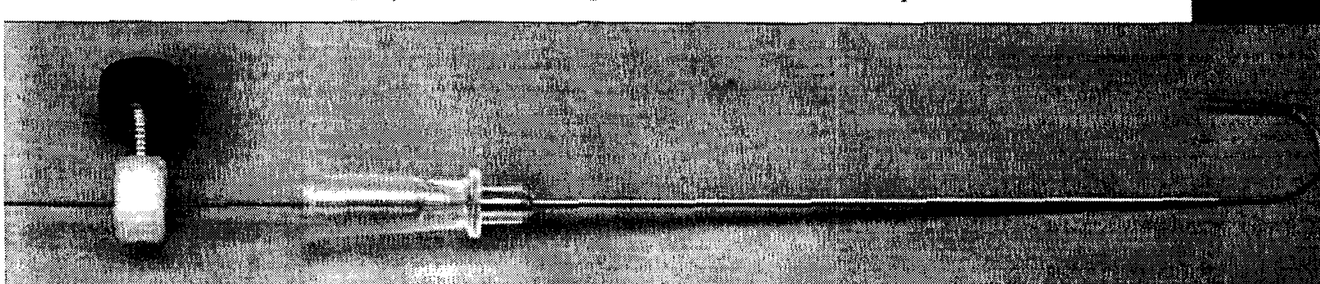

Fig. 1 — The Homer Mammalok Nitinol wire needle localizer.

dered monoclinic (B19') configuration.

- *Martensite start*: The temperature at which the transformation begins upon cooling is called the *Martensite Start* (M_s) temperature.
- *Martensite finish*: The temperature at which the sample has completely transformed to martensite is called the *Martensite Finish* (M_f) temperature. This transformation can be reversed by re-heating the sample to higher temperatures.
- *Austenite start*: The temperatures at which the martensite begins the transformation to austenite is *Austenite Start* (A_s).
- *Austenite finish*: The temperature at which the martensite has completed the transformation of Austenite is called the *Austenite Finish* (A_f), temperature.

The propensity of the material to be martensite at low temperatures and austenite at high temperatures is the driving force for the shape memory effect.

Mammalok device

For the purpose of illustration, we assume that the Mammalok wire has the following transformation temperatures: $M_f = -60°C$, $M_s \approx -40°C$, $A_s = 15°C$, and $A_f = 25°C$. To achieve the shape memory effect in this device, the austenitic wire is cooled to –60°C (*martensite*) and pulled through the cannula to induce a deformation strain of approximately 4% (*deformed martensite*).

The wire retains this new shape only as long as it is below A_s. As the wire is inserted into the body and is warmed above A_f, the original shape (*austenite*) is recovered. This process is schematically shown in Fig. 2, with approximate shapes at intermediate recovery temperatures from A_s to A_f (Fig. 2c).

Many self-expanding Nitinol stents are based on thermal deployment as the mechanism for insertion into the body. These stents are cooled, crimped to a smaller diameter, and then inserted into a delivery system in the deformed martensite configuration. The stents then recover their shape at body temperature by the shape memory process.

Elastic deployment

Elastic deployment refers to the phenomenon of *Superelasticity*. The superelastic process also involves the transformation from austenite to martensite, but at a constant temperature at or above A_f. At these temperatures, the transformation is induced by an applied stress.

As illustrated in Fig. 3, when the Homer Mammalok wire is pulled through the cannula at 25°C, the austenitic wire accommodates the applied stress by transforming directly to (deformed) martensite. This stress-induced martensite is stable only while the stress is applied. When the wire is pushed back through the cannula, it reverses transformation from martensite to austenite, and the shape is thereby recovered fully.

Elastic Deployment is a common method of inserting medical devices directly into the human body; the Homer Mammalok is actually used in this mode. Other examples include endoscopic instruments, such as graspers and retrieval baskets.

Designing with Nitinol

The above descriptions of shape memory and superelasticity (Thermal and Elastic Deployment, respectively) demonstrate that these effects can be observed in the same device under different application conditions. Therefore, a *continuum* of shape memory-to-superelastic responses is possible for a given composition and thermomechanical processing.

Understanding the temperature dependence of mechanical properties is essential when designing medical devices with Nitinol. Uniaxial tensile tests are a common method to monitor the effects of test temperature on attributes such as effective modulus, loading and unloading stress, residual strain, and ductility.

For example, Fig. 4 shows the tensile properties of $Ni_{50.8}Ti_{49.2}$ with the Mammalok wire transformation temperatures. For each test temperature, the curves illustrate the stress required to elongate the wire to 6% strain and then to unload.

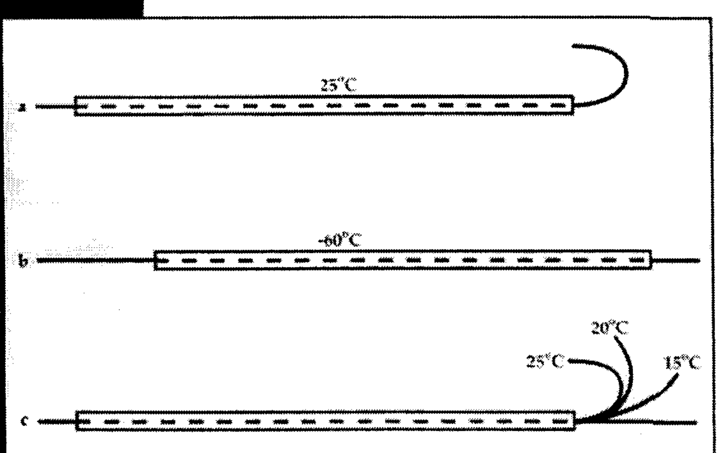

Fig. 2 — The shape memory process illustrated with the Homer Mammalok wire.

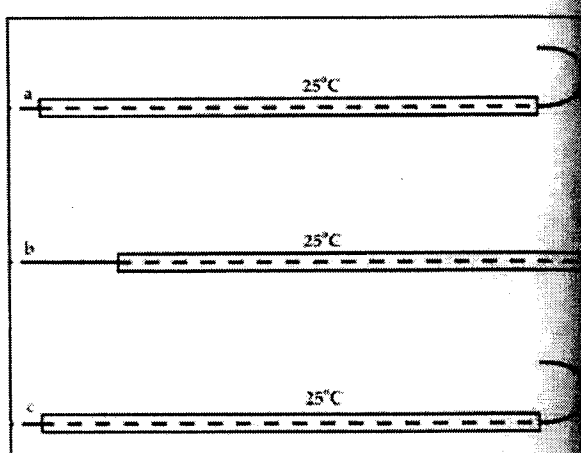

Fig. 3 — The superelastic process illustrated with the Homer Mammalok wire.

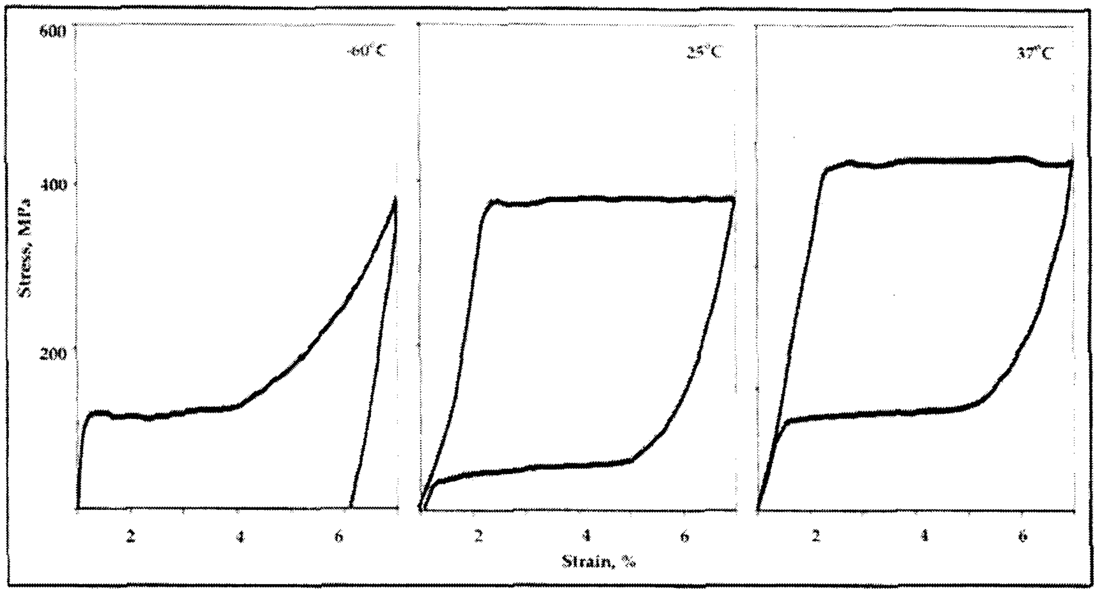

Fig. 4 — Tensile stress-strain curves of Nitinol ($Ni_{50.5}Ti_{49.5}$) wire tested at M_f (–60°C), A_f (25°C) and at body temperature (37°C).

• At M_f, the structure is fully martensitic. At this point, the graph represents the equivalent behavior of the hook pulled through the cannula (slender tube) that is shown in Fig. 2b.

• Note that at –60°C, an initial linear elastic region is followed by a nearly constant loading stress (115 MPa) up to approximately 3% strain, and then an additional increase in stress to 6% strain.

• Upon release of the strain, the wire unloads to about 5.1%; full shape memory strain recovery requires heating to above A_f.

• At 25°C, the wire has an elastic region with a loading stress of 378 MPa, and an unloading stress of 50 MPa. It returns to nearly zero strain at zero load. This condition represents the superelastic behavior shown schematically for the hook in Fig. 3. Because of the differences in the atomic structure of martensite and austenite, the values of plateau stress in the two conditions are different. Consequently, it is substantially easier to pull a hook through the cannula at –60°C than at 25°C.

• For comparison, the tensile curve for the wire is also shown for a test temperature of 37°C, which has a loading stress of 430 MPa and an unloading stress of 120 MPa.

The loading stress value increases systematically at test temperatures between A_f and approximately 150°C for thermomechanically processed NiTi. The stress increase with respect to test temperature is called the stress rate and has a value of about 6 MPa/°C. The origin of this effect is based on the thermodynamic Clausius-Clapeyron relationship.

Stress levels

A key element that must be considered when designing a Nitinol-based medical device is the level of force (stress) that the device must exert when implanted. For example, orthodontic archwires deliver a low, constant stress against the teeth, exemplified by the unloading stresses in Fig. 4 at 25°C and 37°C. At both temperatures, the Nitinol archwire will apply a constant force over a long treatment time and tooth position.

Note the decrease in stress with the decrease in temperature. This is why many orthodontists suggest that the patients drink ice water to "loosen" the archwires temporarily if there is any pain after treatment.

The selection of the proper A_f temperature and its effect on the "restoring stress" of Nitinol medical devices must also be considered. For example, the tensile curves shown in Fig. 4 are for a device with an A_f of 25°C.

However, if stresses greater than 120 MPa are required at body temperature, it is possible to process the device to a lower A_f temperature. The larger difference between A_f and 37°C will result in higher unloading stress for the same geometry. For example, suppose that the A_f is lowered to 10°C. This device would generate approximately 270 MPa; this change in unloading stress with temperature also follows the Clausius-Clapeyron relationship.

It should be noted that there are drawbacks to this approach, such as the possibility of higher residual strains after deformation. Nevertheless, the A_f temperature is a powerful device optimization parameter. **MPMD**

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