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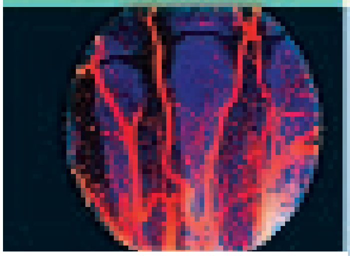

Metallurgical principles of Nitinol and its use in interventional devices

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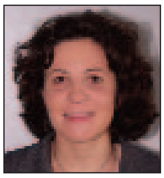


Sylvie Lombardi holds a master's degree in biomedical engineering from the Ecole Polytechnique of Montreal, Canada. In the scope of various research grants, she evaluated the corrosion resistance and biocompatibility of Nitinol and performed research to modify the surface of Nitinol to improve these qualities. During the past ten years, she has developed a variety of Nitinol stents and stent graft devices used in vascular and non-vascular applications. She is currently managing an R&D stent programme at the medical device company C. R. BARD angiomed.

Abstract

Nickel-titanium shape-memory alloys, commonly known as Nitinol, are used increasingly in a variety of medical devices for minimally invasive and interventional procedures. The success of Nitinol is attributable to two unique properties – shape-memory effect and superelasticity – based on the ability of Nitinol to exist in two reversible phases. Thermal shape-memory enables Nitinol implants to be compressed for insertion into delivery systems and deployment, but then restored to their original shape following release. Superelasticity is highly advantageous in applications where crush and kink resistance, flexibility, constancy of applied stress and large expansion or deformation ratios are a necessity. Nitinol is stable, biocompatible, MRI compatible and has good corrosion resistance. The unique combination of properties of Nitinol offers exciting possibilities for the design of new devices and instrumentation.

Introduction

Since the late 1980s, the nickel-titanium shape-memory alloys, commonly known as Nitinol, have been increasingly utilised in a variety of medical devices used in minimally invasive and interventional procedures. Nitinol derives its name from Nickel Titanium Naval Ordnance Laboratory. In the early 1960s, Buehler and his associates from the US Naval Ordnance Laboratory discovered the shape-memory property of Nitinol.[1]

Nitinol exhibits two unique properties:

- **Shape-memory effect**, which refers to the ability of the material to recover its original shape upon heating
- **Superelasticity**, which describes the ability of the material to undergo large elastic deformations.

Nitinol is able to overcome a wide range of design challenges related to the miniaturisation of medical devices for less invasive procedures. The aim of this article is to briefly describe the metallurgical principles behind the unique properties of Nitinol, as well as comment upon some of the applications in today's interventional devices.

Structure of Nitinol

The main properties of Nitinol are based on its ability to exist in two reversible crystalline phases. Phase transitions between liquid and solid states are commonly known phenomena, such as water freezing to ice. However, what makes Nitinol unique is its ability to exist in two distinct reversible crystal phases – in its solid state – known as martensite and austenite. The solid phase change in Nitinol, known as the reversible martensitic transformation, can be induced by two parameters: temperature and mechanical stress.

Shape-memory effect and applications

The basic mechanism governing the shape-memory effect consists of martensite formation upon cooling from the austenite phase. The soft martensite can be easily deformed (up to 8% strain) and will recover its original shape upon heating to the much stronger austenite (see Figure 1).

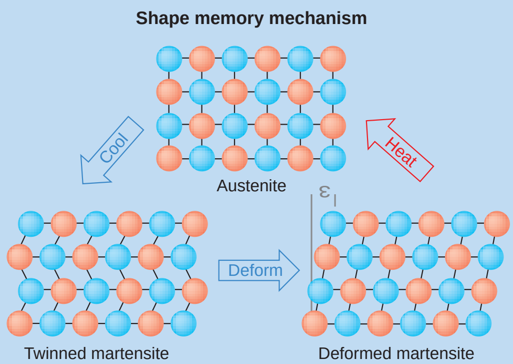
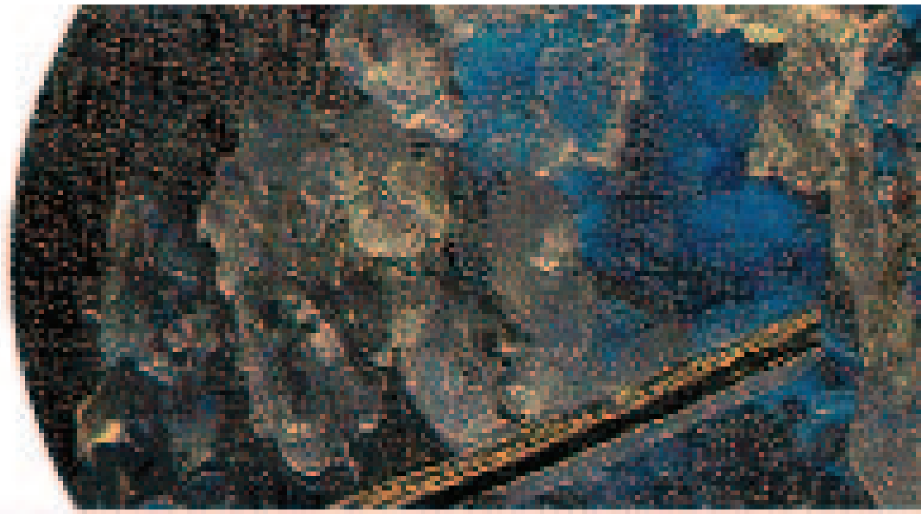


Figure 1. An atomic model depicting the shape-memory mechanism. (Diagram courtesy of Memry Corporation)



Today, most self-expanding implants such as stents and filters use the thermal shape-memory of Nitinol to enable deployment into the body.[2]

- The implant is usually compressed at low temperature to fit into a delivery catheter.
- It is not necessary to keep the implant cold during introduction into the body since the implant remains constrained inside the delivery catheter to prevent any premature release.
- The original shape of the implant is restored when it is released and reaches body temperature (see Figures 2a–2d).

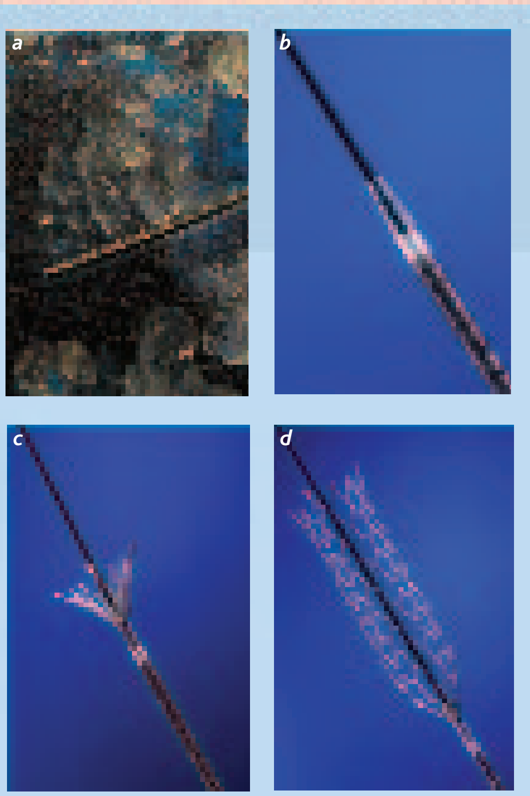


Figure 2. Thermal deployment of Bard® LuminexxTM stent. (a) Stent compression at low temperature; (b) Stent loading into delivery system; (c) and (d) Stent deployment at body temperature.

Superelasticity and applications

The superelasticity phenomenon is caused by a stress-induced transformation. By deforming the austenite, stress-induced martensite is formed. The martensite reverts to austenite once the stress is removed (see Figure 3).

Superelastic Nitinol can be strained 20 times more than stainless steel without being plastically deformed, and has tremendous advantages in applications requiring:

- Kink resistance
- Flexibility
- Crush resistance
- Constancy of applied stress, and
- Large expansion or deformation ratios.

Therefore, most Nitinol stents are:

- Superelastic at body temperature, and
- Can be crushed fully flat and still recover their original shape.

Superelasticity is a very important feature in the treatment of superficial vessels such as carotid and femoral arteries subjected to external crushing.

To date, the most successful medical applications of Nitinol using the superelasticity property are:

- Guidewires
- Baskets
- Snares
- Needles
- Coils
- Soft tissue anchors
- Intramedullary canal reamers
- Anastomotic devices
- Self-expanding stents and stent-grafts
- Filters and occlusive distal protection devices
- Various catheters used for
  - radiofrequency ablation
  - brachytherapy
  - atherectomy
  - thrombectomy
  - laser therapy

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Metallurgical principles of Nitinol and its use in interventional devices *continued*

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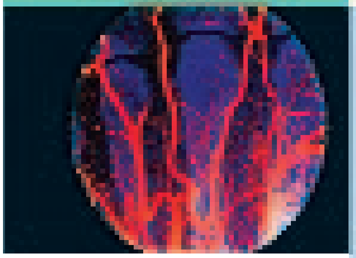

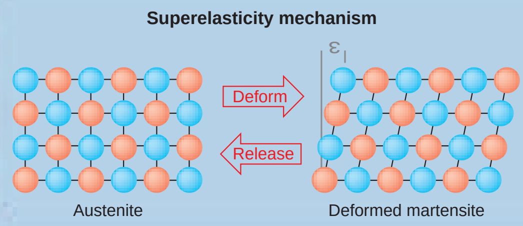

Figure 3. An atomic model depicting the mechanism of superelasticity. (Diagram courtesy of Memry Corporation)

Biocompatibility and corrosion resistance

Experimental and clinical data strongly support Nitinol as a safe biomaterial:[1,3]

- The tissue response to Nitinol is similar to pure titanium and stainless steel[1,3]
- It has been proven that Nitinol is more biocompatible than stainless steel[4]
- Nitinol is chemically more stable and less corrosive than stainless steel[5]

The good corrosion resistance of Nitinol is caused by the formation of a protective titanium oxide layer on its surface. When combining Nitinol with other metals or alloys, the metal type should be carefully selected in order to minimise any potential galvanic corrosion. The electrochemical potential of Nitinol, tantalum, titanium and stainless steel are very similar, making their combination with Nitinol safe, in general. However, combining Nitinol with noble metals such as gold or platinum should be avoided.[5,6]

Magnetic Resonance Imaging (MRI) compatibility

Nitinol is non-ferromagnetic with a lower magnetic susceptibility than stainless steel. Nitinol implants and devices are less likely to produce artefacts in MRI as compared to stainless steel, and are usually considered to be MRI safe.[7]

Conclusion

Nitinol provides a unique combination of properties not found in other conventional metals traditionally used in medical devices. It offers unique possibilities for designing implantable devices and instrumentation for minimally invasive and interventional procedures.

Key Learning

- Nitinol can exist in two reversible crystalline solid phases (martensite and austenite). A phase change can be induced by temperature or mechanical stress
- Due to this feature, Nitinol has two unique properties – shape-memory effect and superelasticity – that can be utilised in medical devices
- The thermal shape-memory of Nitinol enables implants such as stents to be compressed for delivery into the body, and then restored to original shape following release and warming to body temperature
- The superelasticity of Nitinol provides flexibility, kink resistance, constancy of applied stress and recovery of original shape after crushing, leading to extensive use in medical applications
- Nitinol is a safe biomaterial, offering biocompatibility, corrosion resistance and MRI compatibility

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