

Nitinol for Medical Applications: A Brief Introduction to the Properties and Processing of Nickel Titanium Shape Memory Alloys and their Use in Stents

Considerations for the manufacture of Nitinol parts for stents and some other medical applications

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Shape memory alloys are remarkable materials that open up a wide range of uses. Nitinol, an alloy of nickel and titanium, is one of the most important of these materials. Some of its major applications are in medical devices where its unique properties allow minimally invasive surgery and implants to improve quality of life for millions of people. With the growing global population and increasing numbers of people able to access quality healthcare, the availability of advanced materials such as Nitinol is essential to allow continued progress in improving lives across the world. This article will review the discovery, material properties, processing methods and medical applications of Nitinol, with a special focus on stents for the treatment of arterial diseases, which constitute one of Nitinol's major uses.

Introduction

Per the United Nations Department of Economic and Social Affairs, the world population is expected to

increase to 8.5 billion by 2030 and 9.7 billion by 2050. Globally, life expectancy at birth is projected to rise to 77 years in 2045–2050 (1). While this increase is projected based on a reduction of the spread of human immunodeficiency virus (HIV) and other infections as well as non-communicable diseases, advances in medicine and better access to healthcare certainly contribute to increased life expectancy. Globalisation has increased living standards in many countries where populations historically may not have had access to good healthcare. A combination of increased living standards and the choices people make has also increased the incidence of lifestyle related illness such as cardiovascular diseases (2). As companies race to develop medical devices to cure challenging physical conditions and diseases, they rely on novel materials for solutions. A variety of metals like stainless steel, titanium and its alloys, platinum and associated platinum group metals (pgms) and cobalt-based alloys are used in medical devices (3, 4). One material that has seen increased use and acceptance within the medical device community is Nitinol (NiTi), a shape memory alloy made of nickel and titanium in almost equal concentrations.

A shape memory alloy has the ability to restore its original shape after deformation. Used in a variety of applications in industries ranging from consumer

appliances to automotive to aerospace and medical, shape memory alloys have gained a strong foothold because they offer designers incredible flexibility compared to conventional materials or systems. In medical devices, Nitinol is popular due to its biocompatibility, superelasticity and fatigue and kink resistance (5). Nitinol is used to manufacture catheter tubes, guidewires, stone retrieval baskets, filters, needles, dental files and archwires and other surgical instruments (6).

A particularly important use of Nitinol is in stents. **Figure 1** shows an illustration of stent application: normal blood flow in an artery (**Figure 1(a)**), decreased blood flow due to plaque (**Figure 1(b)**), and a stent placed to open the artery and restore blood flow (**Figure 1(c)**) (7). Global Data (8) valued the global market for peripheral vascular stents for lower extremities at approximately US\$2.2 billion in 2012 and forecast it to reach US\$3.6 billion by 2019. The growth is driven by the availability of improved technologies like drug eluting and bio-absorbable stents, patient awareness, physician training and the growing number of cases of peripheral artery disease (PAD) due to diabetes, hypertension, obesity and tobacco use (9). Transparency Market Research (10) predict an US\$11 billion market by 2019 for all forms of Nitinol stent devices.

Nitinol was a serendipitous discovery by William Buehler from the US Government Naval Ordnance

Laboratory in the 1960s. Buehler and his team were developing fatigue, wear and impact resistant materials for missile cones of US Navy missiles. One such formulation was similar to the Nitinol we know today, an equiatomic alloy of nickel and titanium. Buehler would fold the material into an accordion shape and pry it open multiple times to demonstrate its flexibility and that it would not break. At a meeting one day, a team member lit a pipe lighter under the accordion shape and to everyone's amazement, the sheet of nitinol regained its original flat shape. Buehler named the material 'NITINOL' which stood for Nickel Titanium Naval Ordnance Laboratory (11). Frederick Wang, also from the Naval Ordnance Laboratory, was an expert in crystal physics. He discovered the reason behind the behaviour of the material. It was due to atomic rearrangement or phase changes at different temperatures while the material was still a solid.

Nitinol was used in orthodontic archwires around 1976 and the first military application of Nitinol was hydraulic couplings for the Grumman F-14 Tomcat fighter aircraft in 1978. By the late 1980s, the first commercial Nitinol medical device, the Homer Mammalok[®], a breast tumour localisation device, and the first Nitinol based implant, the Mitek[®] bone anchor, became commercially available (12).

This article will review the properties, processing methods and applications of Nitinol with a focus on stents, their most important current use.

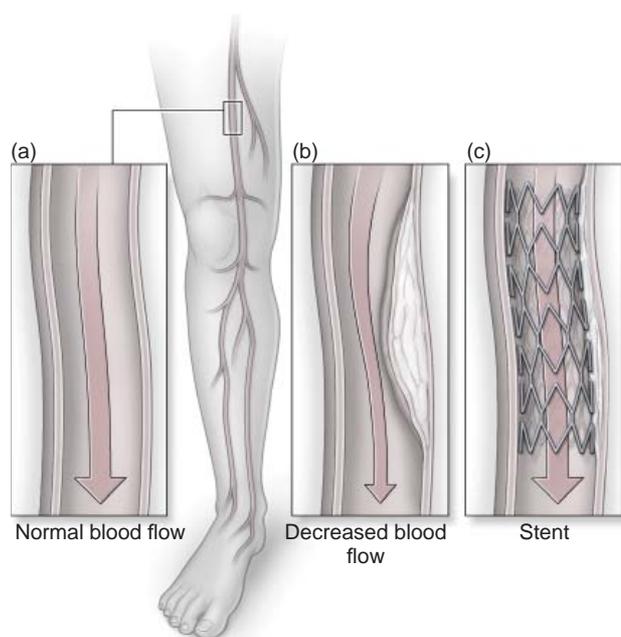


Fig. 1. Schematic of stent used to treat a peripheral artery (7). Art by Scott Leighton, Medicus Media, USA

The Shape Memory Effect

The most common demonstration of the shape memory effect is that a piece of the alloy can be deformed – for example, by winding a piece of straight wire into a tight coil – and then the deformation can be completely removed by heating the metal a small amount, as by dipping it into hot water. As it is heated, the metal instantly 'remembers' its original shape and returns to the form of a straight wire.

The shape memory effect is caused when a material undergoes a change in crystal form as it is cooled or heated through a range of characteristic transformation temperatures. In Nitinol, the change is from an ordered cubic crystal structure (austenite) to a monoclinic crystal phase (martensite) (13). This behaviour is known as the martensitic transformation. The temperatures at which the formation of martensite starts and ends are called M_s and M_f . Austenite formation starts and ends at A_s and A_f , respectively (14, 15).

The majority of commercial applications of Nitinol utilise a useful property which is the exceptional elasticity, commonly referred to as ‘superelasticity’ (more accurately called pseudoelasticity) when one deforms the alloy at a temperature above the active austenite finish temperature, A_f . Above this temperature, the material is in the high-temperature or austenitic phase. When stress is applied, the deformation causes a stress-induced phase transformation from austenite to deformed martensite. When the applied stress is removed, the material returns to its original shape, and the crystal form returns to the austenite phase (13). The thermomechanical behaviour of materials in the martensitic and austenitic states is well explained in the literature (14, 15).

Conventional materials like stainless steels exhibit different elastic deformation behaviour than structural biological materials in the human body. Elastic deformation of such materials is limited to about 1% and strain is proportional to applied load (16). Hair, tendon and bone can be elastically deformed up to 10% strain in a non-linear way. Superelastic (austenitic) Nitinol behaves in a similar way to those biological materials; when loaded, it accommodates a large strain without increase in stress, and when unloaded, the strain reduces at a lower but constant stress. Nitinol stress-strain behaviour has been shown to be very similar to that of structures in the human body (16, 17).

Superelastic Nitinol alloys take advantage of a stress-induced martensitic transformation to achieve incredible amounts of flexibility and kink resistance. For example, alloys which are intended to be superelastic at room temperature are generally produced with their active A_f temperatures just below room temperature, say in the range of 0–20°C (18). Such a material will also exhibit good superelastic properties at body temperature (37°C). Superelastic alloys comprise the largest volume of Nitinol material manufactured today.

Shape memory Nitinol alloys exploit the ability of the materials to recover a trained shape upon heating above their active A_f temperature. Therefore, this is the most critical property to specify (18). The active A_f represents the finish of the transformation from martensite to austenite upon heating, and therefore the temperature at which the shape recovery is complete.

A representation of the shape memory and superelastic effect (19) with specific reference to Nitinol is seen in **Figure 2**. Since the material is equiatomic, one sphere in the crystal structure represents nickel and the other represents titanium. The structure at the top

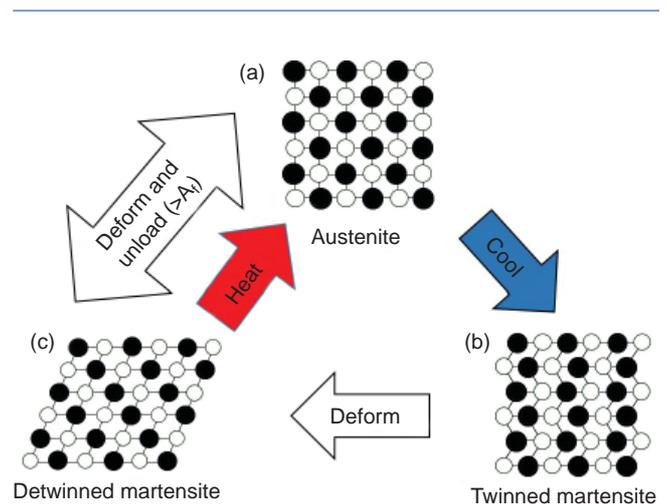


Fig. 2. Schematic illustration of shape memory effect

(**Figure 2(a)**) represents the crystal structure of the material in the stable or austenitic state. This is when the material is above the A_f . When the material is cooled below the martensite start temperature, M_s , it starts transformation into twinned martensite (like a herringbone) shown in the lower right structure, **Figure 2(b)**. Below the martensitic finish (M_f) temperature, the material is completely martensitic. This martensitic transformation is called thermally induced or twinned martensite. When twinned martensite is subject to stress, it transforms into deformed or detwinned martensite, **Figure 2(c)**. The induced strain does not recover upon unloading. Upon heating the material above the A_f , the material returns to austenite exhibiting the shape memory effect. If the material in the austenitic state is deformed, the austenite transforms into stress induced martensite and upon removal of the load, the material returns to austenite as it is the more stable form (19). This phenomenon is the basis for superelasticity.

Material Characterisation

Knowledge of the transformation temperatures (A_s , A_f , M_s and M_f) of the alloy is a key requirement for using Nitinol. There are two commonly used methods of performing transformation temperature testing: differential scanning calorimetry (DSC) and bend and free recovery (BFR).

The DSC method (20) yields a plot such as **Figure 3** by measuring the amount of heat given off or absorbed by a tiny sample of the alloy (<50 mg) as it is cooled and heated through its phase transformations

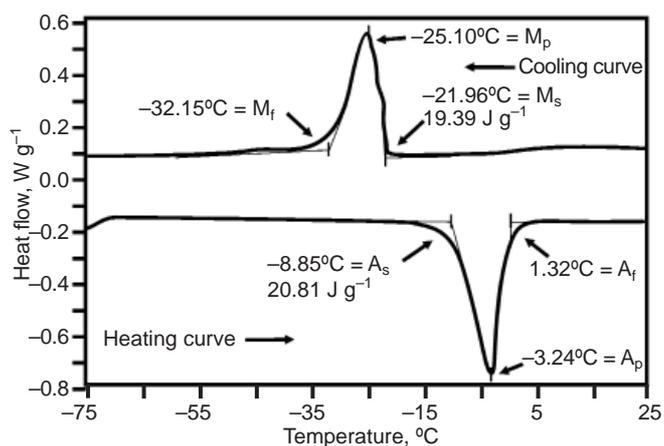


Fig.3. Characteristic curve produced from a differential scanning calorimetry (DSC) test (13)

(21). DSC results obtained in the fully annealed condition, annealed at temperatures of 800–850°C for 15–60 minutes (20), are often used as the basis for Nitinol raw material selection (ingot) since they effectively characterise the baseline properties of the material prior to cold working and heat treatment. The DSC yields excellent, repeatable results on fully annealed samples. One important drawback to the DSC method is that tests on partially cold worked materials, such as those used to optimise superelasticity, can yield poor, inconclusive results. Active A_f tests are recommended for materials in these conditions (21).

While DSC is used for characterising raw materials, the temperature most frequently specified for the finished product (whether wire, sheet or tube) is the active A_f temperature which is generally determined by a BFR test (22). In this test, one deforms a sample of the material after cooling it into the martensitic region and then records the amount of shape recovery that occurs as it is warmed. A graph, **Figure 4**, of temperature *versus* sample displacement is plotted and used to determine the active A_f temperature where the shape recovery is complete. BFR is a very good functional test that shows distinct shape recovery.

Tensile testing is performed to characterise the strength and ductility of the material (23). In a typical tensile test (23), the sample is pulled to 6% strain, then unloaded and subsequently pulled to failure. In addition to the ultimate tensile strength and elongation that are common to other materials, there are other critical parameters that are measured when testing Nitinol. When the test is conducted above the active A_f of the sample, upper plateau strength, lower plateau

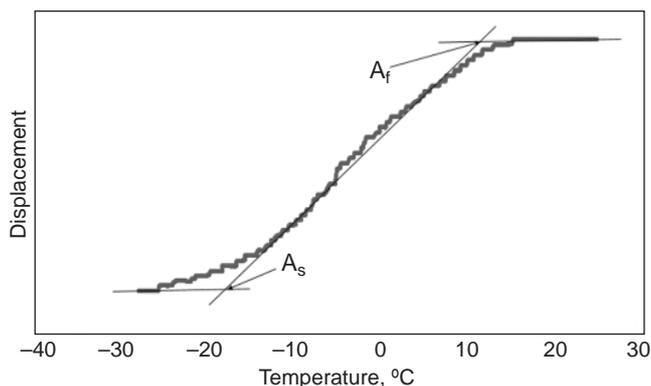


Fig 4. Bend and free recovery (BFR) determination of austenite transformation temperatures A_s and A_f

strength and the residual elongation (or permanent set) are also recorded. As the material is being loaded, the material transforms from austenite into stress induced martensite, and as the sample is unloaded, the material reverses into austenite. During loading, the material strains at a constant stress (where upper plateau is recorded) and when the material is unloaded, the strain is reduced but at a lower stress level (where lower plateau is recorded). Per the ASTM F2516 standard, the upper plateau is the stress at 3% strain recorded during tensile loading and lower plateau is the stress at 2.5% strain recorded as the sample is unloaded. This stress hysteresis is the basis of stent design and performance (24). Residual elongation is the strain after the load to 6% strain and unload is completed. **Figure 5** depicts these points.

Processing

Nitinol ingots are melted using combinations of vacuum induction melting (VIM) and vacuum arc remelting (VAR) (25). Most Nitinol materials are a simple alloy of nickel and titanium with the ratio of the two constituents at about 50 atomic percent each (about 55 percent by weight of nickel). However, subtle adjustments in the ratio of the two elements can make a large difference in the properties of the NiTi alloy, particularly its transformation temperatures. If there is any excess nickel over the 50:50 ratio, one sees a dramatic decrease in the transformation temperatures and an increase in the austenite yield strength. Increasing the nickel-to-titanium ratio to 51:49 causes the active A_f to drop by over 100°C (**Figure 6**) (26). This sensitivity of the properties to very small

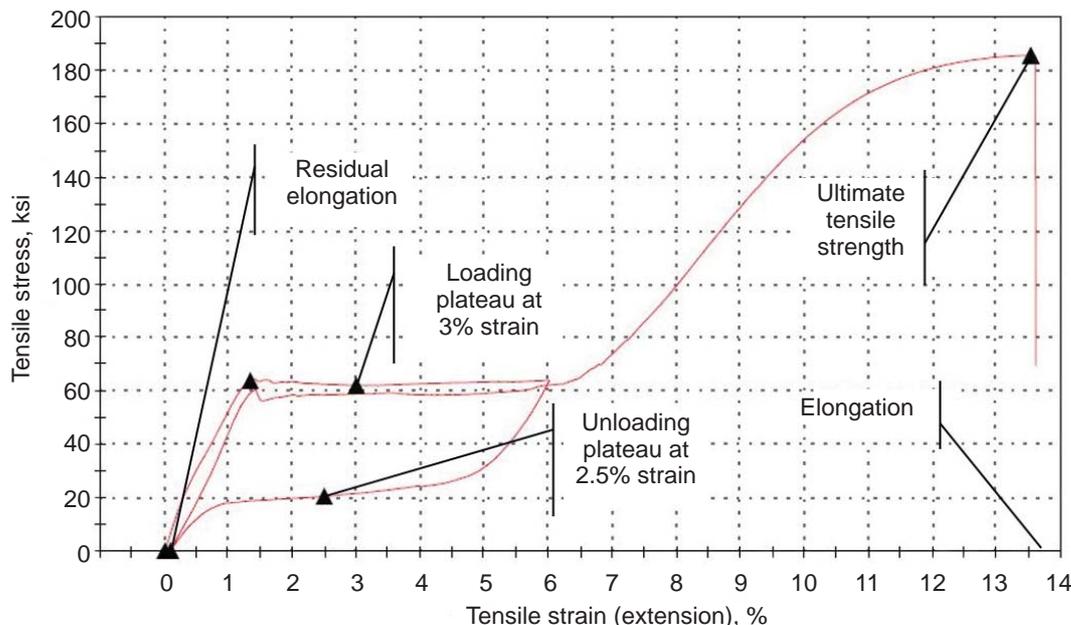


Fig. 5. Typical stress-strain plot of superelastic Nitinol showing measured properties

increases in the percentage of nickel makes it difficult to manufacture Nitinol of uniform and repeatable properties, but at the same time gives manufacturers a powerful method to control properties and to make ingots of the desired transformation temperature. The shaded rectangle in **Figure 6** represents the Ni content of typical binary superelastic alloys (26). The sensitivity of the A_f temperature to alloy composition is so great that chemistry is not recommended as a way to specify the alloy of interest. The transformation temperature, instead, is a much more accurate means to specify the alloy.

The raw material ingot or wrought microstructure is not refined to provide superelastic or shape memory properties and tends to have a low fracture resistance (26). In order to refine the microstructure of the material to make it useful, hot working at 600–800°C through forging, swaging and hot rolling operations is required (26). The output from this process is intermediate forms like bars, rods and plates, according to specified chemical and metallurgical requirements (27).

Melting methods, type of raw materials and processing techniques result in impurities which lead to the formation of non-metallic inclusions in the ingot (28). It is critical to control the oxygen, nitrogen and carbon content in the melt because of the formation of titanium oxides, nitrides and carbides. These hard

inclusions act as discontinuities in the matrix. These have been the subject of numerous studies on device failure and fatigue strength. Studies have shown that both inclusion size and total number of inclusions are important factors in determining fatigue resistance (29). It has been shown that material with smaller

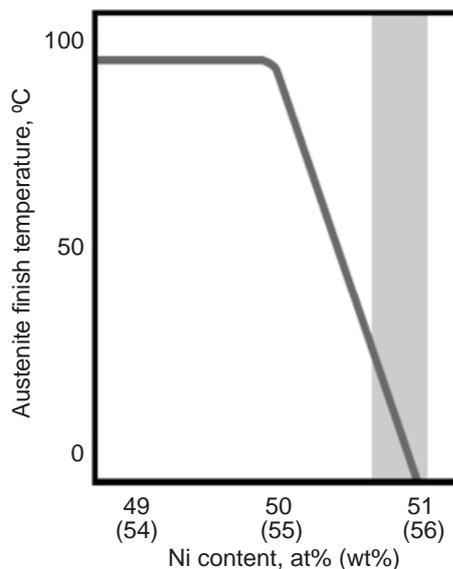


Fig. 6. Schematic of the effect of the Ni content of Nitinol on the active austenite finish temperature, A_f (26)

inclusion sizes overall shows much improved fatigue life when compared to material with larger inclusions (28, 29). Over the past few years, advances in process optimisation and input raw material purity have led to the successful development of Nitinol ingots with fewer or smaller inclusions (29), while Steegmüller *et al.* (30) observed that inclusion size, rather than number of inclusions, plays a dominant role in influencing fatigue life.

The intermediate forms are then further processed through cold working operations to make the final products that possess appropriate tensile strength, transformation temperatures and size. Rods can be drawn through dies to make smaller diameter wires. Plates are rolled down to make thinner sheet. Nitinol sheet is popular because it offers design flexibility not available with other forms, designing products flat and then forming it to make devices.

To make a tube, one starts with bars that are gun-drilled to create a 'tube hollow'. Gun-drilling is a necessary evil; it immediately reduces the effective yield of the process as it removes a considerable amount of material to create a hollow core. The tube hollows are subject to step-by-step cross-sectional area reduction using successively smaller dies to size the outer diameter and successively smaller mandrels to size and support the inner diameter during tube drawing.

A combination of cold working (defined as the percentage reduction in cross-sectional area) and heat treatment (thermomechanical processing) is critical to attaining the desired properties in the material. During cold working fabrication operations such as drawing or rolling, Nitinol alloys work harden very rapidly. If the material is not annealed after a certain amount of cold work, the strength rises to the point where the fracture strength is reached on further deformation and failure occurs.

Heat treatment is used to set the final shape in the Nitinol component. If the Nitinol has a reasonable amount of cold work (of the order of 30–50%), temperatures of 450–550°C (26) with appropriate dwell times will create a straight, flat or shaped part. The term 'shape setting' is a general term that refers to setting a shape in cold-drawn material. In addition to straight wires and tubes or flat sheet, shaped parts can be created using bespoke fixtures. **Figure 7** shows a simple example of a part shape set from a straight tube. The end of the tube is constrained in hook shape in a fixture. The fixture with the tube is placed in a furnace

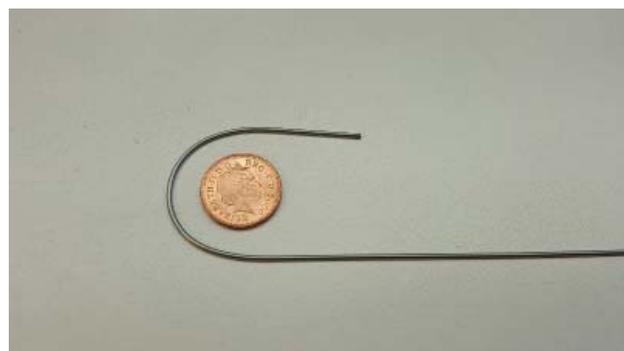


Fig 7. Example of a shape set part

and heated to approximately 500°C for a few minutes. Upon removal from the furnace, the fixture with the part is quenched in water. The nitinol tube is removed from the fixture and it exhibits the hook shape. In this specific example the tube is superelastic at room temperature. When the legs of the hook are pried apart and the load is released, the legs return to their original hook shape.

Another objective of heat treatment is to establish the final mechanical properties and transformation temperatures in the Nitinol component (31). After the material has been cold worked, the proper heat treatment will establish the best possible shape memory or superelastic properties in the material while retaining enough of the residual cold work effect to resist permanent deformation during cycling. It also helps to set the active A_f of the parts.

Properties that Suit Medical Applications

Numerous references discuss Nitinol properties that make it attractive for use in medical devices (5, 6, 32). The major use for Nitinol is in stents, however there are a number of other applications which will be briefly introduced here. Due to the shape memory effect, Nitinol is quite versatile in applications that use elevated temperature to activate a device (called thermal deployment) like the Simon Nitinol[®] vena cava filter (6). Superelastic Nitinol also elastically attains a free shape after being released from a constraining device like a cannula (called elastic deployment) in devices like stone retrieval baskets. Nitinol guidewires are used to guide catheters into difficult to reach places of the body. They are favourable because they are kink resistant, unlike stainless steel. The wire is elastic and it can follow a tortuous path in the body without damage. Nitinol will rotate smoothly and impart torque (33). Due to its kink resistance and torquability, Nitinol

tubes are used as catheter shafts or delivery devices for stents, drugs, guidewires or as biopsy needles (34). The superelastic hysteresis of Nitinol, sometimes referred to as the 'flag' of a stress-strain diagram, is beneficial for stent performance.

Nitinol is biocompatible. When Nitinol implants receive appropriate surface treatment through electropolishing and passivation, they develop a passive titanium oxide layer, which forms a barrier that prevents corrosion and release of toxic Ni ions into the bloodstream (35, 36). Nitinol orthodontic archwires rely on the ability of the Nitinol to accommodate a wide strain when loaded, hence enabling the archwire to exert a constant stress as the teeth move (5, 37). This results in less trips to the dentist to change archwires or undergo painful retightening if using conventional materials. The compliance of Nitinol with bone and other structural elements of the body, in contrast with the stiffness of titanium or stainless steel, makes it a good choice for orthopaedic implants like bone staples and plates (5). Superelasticity and high strain accommodation have also been utilised in endoscopic applications. In order to reach difficult access locations in the body, the concept of articulating laser-cut Nitinol shafts for endoscopy has been discussed by Dewaele *et al.* (38) and Michaels (39).

Stents

Stents are 'scaffold' like structures that support or hold open circulatory vessels (see [Figure 1](#)). One of the best known applications of Nitinol is to make self-expanding stents, especially for peripheral vascular applications. Peripheral arteries in the lower extremity include the iliac, femoral popliteal and infrapopliteal arteries (8). Stents implanted in the peripheral arteries are exposed to high mechanical stress from the surrounding environment, for example bending of the knee, walking or running. Nitinol is able to handle these external forces better than other materials due to its characteristic properties of superelasticity and stress hysteresis. Due to kink resistance, these stents are well suited for the tortuous vessel pathways of peripheral arteries. Bare metal stents, drug eluting stents, covered stents and bioabsorbable stents are the four types of peripheral vascular stents available (8). In the Global Data study (8) 63% of the peripheral stents profiled were made using Nitinol, and in their Nitinol Medical Devices market study, Transparency Market Research (10) estimates that over 50% of the peripheral and

coronary stents currently available in the market are made from Nitinol.

Stents can be classified into two types: self-expanding and balloon expandable stents, based on how the stent is deployed. A self-expanding stent is manufactured to a diameter larger than the vessel diameter. It is then crimped into a delivery catheter. When the stent is released from the catheter, it remembers its original shape and expands outward, thus the term self-expanding. Balloon expandable stents are manufactured in a crimped state and a balloon is inflated to expand the stent outwards to the vessel wall. In both cases, upon expansion, the stent contacts and supports the vessel wall (40). Morgan (33) and Stoeckel *et al.* (41) describe the practical use of Nitinol hysteresis and the stress-strain curve in stent assembly into a catheter, deployment during the surgical procedure and behaviour in the body vessel.

Stents can be produced by laser cutting tube or braiding wire. Stent manufacturing starts with laser cutting the tube into a strut pattern. The laser cut pattern is subject to deburring and slag removal using sand or bead blasting. The resulting frame is then expanded or shape-set in a multistep operation using progressively larger mandrels until the stent reaches the required size. The inner surface can be honed to smooth out the inner diameter and remove defects. The stent is then electropolished and passivated. Some stents are produced by laser cutting or photoetching sheet and then forming it into a cylindrical stent. Though use of sheet for stents is not as widespread as tubing, sheets can be rolled into thicknesses as low as 25.4 μm (0.001 inches). It would be considerably difficult to draw tubing to these thin wall thicknesses. Sheet also provides very good thickness tolerance control. It is more difficult to maintain tolerance and concentricity on drawn tubes.

Poncin *et al.* (42) review stent materials and tube requirements to produce a stent. Concentricity (sometimes specified as uniform wall thickness) control and surface finish of the tube inner diameter are critical to good yield when making stents. Uniform wall thickness is critical for laser processing, stent assembly and deployment. Laser cutting machines are programmed and set up to cut tube wall thicknesses defined for a specific job. Per Poncin, a thinner than nominally specified tube wall will result in a larger than required slot cut into the material and potential back-wall damage or burn. Conversely, a thicker than nominal tube wall could result in incomplete

cuts. Inconsistent tube wall thickness can result in non-uniform strut thickness and when the stent is crimped for assembly into a catheter, the stent wall can buckle or collapse due to this non-uniformity causing damage to the stent (43).

Tube manufacturers work on techniques to limit the damage to the inner diameter from defects like draw lines and scratches. Depending upon their depth, such inner diameter defects can continue to manifest in the stent even after deburring and electropolishing. These defects are like notches in the material and during cycling of the stent, these locations act as the points with maximum stress and can cause premature failure. These inner diameter defects can also cause stents to break during the expansion process described earlier. The outer diameter is less susceptible to defects as the outer diameters are shaped and sized by high quality dies creating uniform surfaces. Additionally, for laser cutting, tight tolerance tubes are manufactured by centreless grinding the tube outer diameter. This material removal operation removes defects present on the outer diameter.

A considerable amount of research has been published on the design, metallurgy, manufacture, fatigue and corrosion characterisation of stents. Bonsignore (44) provides a review of stent history, designs and properties. Stoeckel *et al.* (45) detail various stent designs, materials, types of raw material forms and stent geometries. Gong *et al.* (46) provide a comparison between finite element analysis and experimental evaluations of stent designs. Schuessler *et al.* (47) provide an overview of contemporary and future stent materials and manufacturing technologies. Stoeckel *et al.* (41) describe material and design requirements for self-expanding Nitinol stents. Robertson *et al.* (48) and Pelton *et al.* (49) discuss fatigue life and fracture of Nitinol implants. Mahtabi *et al.* (50) present the state-of-the-art on fatigue behaviour of Nitinol and also evaluate effects of material preparation and testing techniques. Corrosion of Nitinol and potential for Ni-ion release is of interest especially for permanent implants. Trépanier *et al.* (51) discuss the improvement in corrosion resistance with passivation and electropolishing. Trépanier *et al.* (52) present improvements in corrosion from processing material to develop a smooth and uniform oxide layer on the material. Sullivan *et al.* (53) discuss the effect of radial compression on Ni release from surfaces with thin and thick oxides.

One drawback of Nitinol is that it is not radiopaque, a requirement for proper placement of a stent or ability to

locate the device in the body. As stent designs become smaller or the geometry changes to create fine struts and meshes, the X-ray signature of the stent reduces. Markers are materials with higher radiopacity that are assembled onto stents to improve X-ray visibility (54). Tantalum markers are coined, riveted or welded onto stent ends. Various marking systems made out of precious metals like platinum-iridium or gold are also used to mark stents but due to differences in the galvanic potential between precious metals and Nitinol, design and processing needs careful consideration to prevent galvanic corrosion (41). Cowley *et al.* (55) discuss the use of platinum alloys in marking applications.

Summary

For over thirty years, Nitinol has been used in a wide range of medical devices. This article has focused on stents, but other applications include catheters, biopsy needles, surgical instruments and numerous more. As the use becomes more widespread, the industry is faced with challenging applications that test the capability of the material. Chemical composition is carefully controlled during melting and recent developments in melting have yielded materials with low inclusion sizes, a key to improving the fatigue life of the material. The performance of the product can be optimised by thermomechanical processing and one can tailor properties to meet functional requirements. Superior concentricity and surface uniformity of tube inner diameter help stent producers increase yields. Products with small form factors are being used for physiological conditions that cannot be tackled with conventional materials. The unique properties of the material make it a desirable choice for product designers whose design ambitions would probably be limited without the versatility of such a material.

References

1. 'World Population Prospects: The 2015 Revision, Key Findings and Advance Tables', ESA/P/WP.241, United Nations, Department of Economic and Social Affairs, Population Division, New York, USA, 2015, pp. 2–6
2. M. Sharma and P. K. Majumdar, *Indian J. Occup. Environ. Med.*, 2009, **13**, (3), 109
3. T. Hall, 'Specialty Metals Make Sophisticated Medical Devices Possible', *Med. Design Briefs*, 1st September, 2013

4. 'Overview of Biomaterials and Their Use in Medical Devices', in "Handbook of Materials for Medical Devices", ASM International, Ohio, USA, 2003, pp. 1–11
5. T. Duerig, A. Pelton and D. Stöckel, *Mater. Sci. Eng. A*, 1999, **273–275**, 149
6. A. R. Pelton, D. Stöckel and T. W. Duerig, *Mater. Sci. Forum*, 2000, **327–328**, 63
7. 'Peripheral Artery Disease', Harvard Health Publications, Harvard Medical School, USA, April, 2012
8. GlobalData, 'MediPoint: Peripheral Vascular Stents for the Lower Extremity – Global Analysis and Market Forecasts', GlobalData Healthcare, London, UK, April, 2013
9. GlobalData, 'MediPoint: Peripheral Vascular Interventions – Global Analysis and Market Forecasts', GlobalData Healthcare, London, UK, March, 2016
10. Transparency Market Research, 'Nitinol Medical Devices Market - Semi-finished Raw Material (Nitinol Tubes, Wiring and Others) and Final Medical Components (Nitinol Stents, Guidewires and Others) – Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2013–2019', Transparency Market Research, Albany, New York, USA, May, 2014
11. G. B. Kauffman and I. Mayo, *Chem Matters*, October, 1993, 4
12. T. Duerig and K. Melton, 'The History of Our Industry', NDC Tech Note: The International Conference on Shape Memory and Superelastic Technologies (SMST), Oxfordshire, UK, 18th–22nd May, 2015
13. D. E. Hodgson and J. W. Brown, 'Using Nitinol Alloys', Shape Memory Applications, Inc., San Jose, California, USA, 2000
14. L. G. Machado and M. A. Savi, *Braz. J. Med. Biol. Res.*, 2003, **36**, (6), 683
15. D. E. Hodgson, M. H. Wu and R. J. Biermann, 'Shape Memory Alloys', in "ASM Handbook Volume 2: Properties and Selection: Nonferrous Alloys and Special-Purpose Materials", ASM International, Ohio, USA, 1990, pp. 897–902
16. D. Stöckel, 'Nitinol – A Material with Unusual Properties', *Endovascular Update*, 1998, (1), 1
17. S. A. Shabalovskaya, *Bio-Med. Mater. Eng.*, 1996, **6**, (4), 267
18. D. Kapoor, 'An Overview of Nitinol: Superelastic and Shape Memory', *Med. Design Briefs*, October, 2015
19. R. R. Adharapurapu, 'Phase Transformations in Nickel-Rich Nickel-Titanium Alloys: Influence of Strain-Rate, Temperature, Thermomechanical Treatment and Nickel Composition on the Shape Memory and Superelastic Characteristics', PhD Thesis, University of California, San Diego, USA, 2007
20. 'Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis', ASTM F2004-05(2010), ASTM International, West Conshohocken, Pennsylvania, USA
21. Johnson Matthey Medical Components, Measuring Transformation Temperatures in Nitinol Alloys: <http://jmmedical.com/resources/211/Measuring-Transformation-Temperatures-in-Nitinol-Alloys.html> (Accessed on 4th January 2017)
22. 'Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery', ASTM F2082 / F2082M-16, ASTM International, West Conshohocken, Pennsylvania, USA
23. 'Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials', ASTM F2516-14, ASTM International, West Conshohocken, Pennsylvania, USA
24. T. Duerig, D. Stoeckel and D. Johnson, 'SMA – Smart Materials for Medical Applications', European Workshop on Smart Structures in Engineering and Technology, Giens, France, 21st May, 2002, in Proceedings of SPIE, Vol. 4763, ed. Brian Culshaw, 2003, pp. 7–15
25. A. R. Pelton, S. M. Russell and J. DiCello, *J. Met.*, 2003, **55**, (5), 33
26. S. M. Russell, 'Nitinol Melting and Fabrication', in "SMST-2000 Proceedings of the International Conference on Shape Memory and Superelastic Technologies", Pacific Grove, California, USA, 30th April–4th May, 2000, eds. S. M. Russell and A. R. Pelton, ASM International, Ohio, USA, 2000
27. 'Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants', ASTM F2063-12, ASTM International, West Conshohocken, Pennsylvania, USA
28. P. K. Kumar and C. Lasley, *J. Mater. Eng. Perform.*, 2014, **23**, (7), 2457
29. S. W. Robertson, M. Launey, O. Shelley, I. Ong, L. Vien, K. Senthilnathan, P. Saffari, S. Schlegel and A. R. Pelton, *J. Mech. Behav. Biomed. Mater.*, 2015, **51**, 119
30. R. Steegmüller, J. Ulmer, M. Quellmalz, M. Wohlschlägel and A. Schüßler, *J. Mater. Eng. Perform.*,

- 2014, **23**, (7), 2450
31. Johnson Matthey Medical Components, Nitinol Shape Setting: <http://jmmedical.com/resources/251/Nitinol-Shape-Setting.html> (Accessed on 4th January 2017)
 32. P. P. Poncet, 'Nitinol Medical Device Design Considerations', in "SMST-2000 Proceedings of the International Conference on Shape Memory and Superelastic Technologies", Pacific Grove, California, USA, 30th April–4th May, 2000, eds. S. M. Russell and A. R. Pelton, ASM International, Ohio, USA, 2000
 33. N. B. Morgan, *Mater. Sci. Eng. A*, 2004, **378**, (1–2), 16
 34. P. P. Poncet, 'Applications of Superelastic Nitinol Tubing', in "SMST-1994 Proceedings of the First International Conference on Shape Memory and Superelastic Technologies", Pacific Grove, California, USA, 7th–10th March, 1994, ASM International, Ohio, USA, 1994
 35. S. A. Shabalovskaya, J. Anderegg and J. Van Humbeeck, *Acta Biomater.*, 2008, **4**, (3), 447
 36. B. O'Brien, W. M. Carroll and M. J. Kelly, *Biomaterials*, 2002, **23**, (8), 1739
 37. D. Stoeckel, *Min. Invas. Therapy Allied Technol.*, 2000, **9**, (2), 81
 38. F. Dewaele, A. F. Kalmar, F. De Ryck, N. Lumen, L. Williams, E. Baert, H. Vereecke, J. P. K. Okito, C. Mabilde, B. Blanckaert, V. Keereman, L. Leybaert, Y. Van Nieuwenhove, J. Caemaert and D. Van Roost, *Surg. Innov.*, 2014, **21**, (3), 303
 39. B. Michaels, 'Using Nitinol and Lasers to Make Articulated Endoscopic Tool Tips', Medical Product Manufacturing News, Medtech Pulse, UBM Canon, Santa Monica, California, USA, 27th February, 2014
 40. T. Duerig and M. Wholey, *Min. Invas. Therapy Allied Technol.*, 2002, **11**, (4), 173
 41. D. Stoeckel, A. Pelton and T. Duerig, *Eur. Radiol.*, 2004, **14**, (2), 292
 42. P. Poncin and J. Proft, 'Stent Tubing: Understanding the Desired Attributes', in "Medical Device Materials: Proceedings of the Materials & Processes for Medical Devices Conference 2003", 8th–10th September, 2003, Anaheim, California, USA, ed. S. Shrivastava, ASM International, Ohio, USA, 2004, pp. 253–259
 43. Dave Mackiewicz, Process Engineer, Johnson Matthey, San Jose, California, USA, Private communication, January, 2016
 44. C. Bonsignore, 'A Decade of Evolution in Stent Design', in "SMST-2003: Proceedings of the International Conference on Shape Memory and Superelastic Technologies", Pacific Grove, California, USA, 5th–8th May, 2003, eds. A. R. Pelton and T. Duerig, ASM International, Ohio, USA, 2004, pp. 519–528
 45. D. Stoeckel, C. Bonsignore and S. Duda, *Min. Invas. Therapy Allied Technol.*, 2002, **11**, (4), 137
 46. X.-Y. Gong, A. R. Pelton, T. W. Duerig, N. Rebelo and K. Perry, 'Finite Element Analysis and Experimental Evaluation of Superelastic Nitinol Stent', in "SMST-2003: Proceedings of the International Conference on Shape Memory and Superelastic Technologies", Pacific Grove, California, USA, 5th–8th May, 2003, eds. A. R. Pelton and T. Duerig, ASM International, Ohio, USA, 2004, pp. 453–462
 47. A. Schuessler, U. Bayer, G. Siekmeyer, R. Steegmüller, M. Strobel and A. Schuessler, 'Manufacturing of Stents: Optimize the Stent with New Manufacturing Technologies', in 5th European Symposium of Vascular Biomaterials ESVB, Strasbourg, France, 27th April, 2007
 48. S. W. Robertson, A. R. Pelton and R. O. Ritchie, *Int. Mater. Rev.*, 2012, **57**, (1), 1
 49. A. R. Pelton, V. Schroeder, M. R. Mitchell, X.-Y. Gong, M. Barney and S. W. Robertson, *J. Mech. Behaviour. Biomed. Mater.*, 2008, **1**, (2), 153
 50. M. J. Mahtabi, N. Shamsaei and M. R. Mitchell, *J. Mech. Behaviour. Biomed. Mater.*, 2015, **50**, 228
 51. C. Trépanier, R. Venugopalan and A. R. Pelton 'Corrosion Resistance and Biocompatibility of Passivated NiTi', in "Shape Memory Implants", ed. L. Yahia, Springer-Verlag, Berlin, Heidelberg, Germany, 2000, pp. 35–45
 52. C. Trépanier, M. Tabrizian, L'H. Yahia, L. Bilodeau and D. L. Piron, *J. Biomed. Mater. Res.: A*, **43**, (4), 1998, 433
 53. S. J. L. Sullivan, M. L. Dreher, J. Zheng, L. Chen, D. Madamba, K. Miyashiro, C. Trépanier and S. Nagaraja, *Shape Memory Superelast.*, 2015, **1**, (3), 319
 54. R. Steegmüller, M. Strobel, E. Flaxmeier and A. Schüssler, 'Micro-Welding for Improved Radiopacity of Nitinol-Stents', in "SMST-2004: Proceedings of the International Conference on Shape Memory and Superelastic Technologies", Baden-Baden, Germany, 3rd–7th October, 2004, ASM International, Ohio, USA, 2004, pp. 591–595
 55. A. Cowley and B. Woodward, *Platinum Metals Rev.*, 2011, **55**, (2), 98

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