REVIEW

Properties and medical applications of shape memory alloys

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Abstract

One of the most known intelligent material is nitinol, which offers many functional advantages over conventional implantable alloys. Applications of SMA to the biomedical field have been successful because of their functional qualities, enhancing both the possibility and the execution of less invasive surgeries. The biocompatibility of these alloys is one of their most important features. Different applications exploit the shape memory effect (one-way or two-way) and the super elasticity, so that they can be employed in orthopedic and cardiovascular applications, as well as in the manufacture of new surgical tools. Therefore, one can say that smart materials, especially SMA, are becoming noticeable in the biomedical field. Super elastic NiTi has become a material of strategic importance as it allows to overcome a wide range of technical and design issues relating to the miniaturization of medical devices and the increasing trend for less invasive and therefore less traumatic procedures. This paper will consider just why the main properties of shape memory alloys hold so many opportunities for medical devices and will review a selection of current applications.

Keywords: nitinol, medical applications, biocompatibility, implants.

Introduction

Shape memory alloys (SMA) constitute a group of metallic materials with the ability to recover a previously defined length or shape when subjected to an appropriate thermo-mechanical load [1]. When there is a limitation of shape recovery, these alloys promote high restitution forces. Because of these properties, there is a great technological interest in the use of SMA for different applications. Although a relatively wide variety of alloys present the shape memory effect, only those that can recover from a large amount of strain or generate an expressive restitution force are of commercial interest.

Super elastic NiTi has become a material of strategic importance as it allows to overcome a wide range of technical and design issues relating to the miniaturization of medical devices and the increasing trend for less invasive and therefore less traumatic procedures. Essentially nitinol is an alloy containing approximately 50 at.% nickel and 50 at.% titanium.

Properties of super-elastic nitinol

SMA based on Ni-Ti are the alloys most frequently used in commercial applications because they combine good mechanical properties with shape memory. Basically, SMA presents two well-defined crystallographic phases, i.e., austenite and martensite [2]. Martensite is a phase that, in the absence of stress, is stable only at low temperatures; in addition, it can be induced by either stress or temperature. Martensite can be easily deformed, reaching large strains (~8%) [1].

Martensitic transformation explains the shape recovery in SMA. Four characteristic transformation temperatures can be defined: M_s and M_f (the temperatures at which the formation of martensite starts and ends), and A_s and A_f (the temperatures at which the formation of austenite starts and ends) (Figure 1).

When the loading-unloading process is finished, the SMA sample presents a residual strain, which can be recovered by sample heating, which induces the reverse phase transformation. This is the shape memory effect, also known as one-way shape memory effect. In the case of two-way shape memory effect, the sample has a shape in the austenitic state and another in the martensitic state. In order to obtain the two-way effect, it is necessary that the SMA sample be trained.

Recoverable strains of approximately 8% are possible if appropriate processing of the nitinol is carried out.

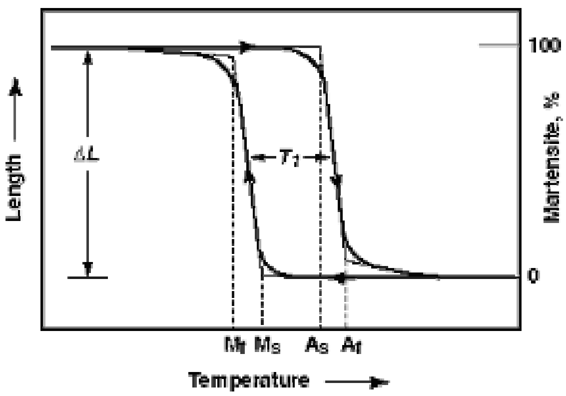

Figure 1 – ***The typical temperature-transformation curve of a NiTi alloy [3]: Ms: martensite start temperature upon cooling; Mf: martensite finish temperature upon cooling; As: reverse transformation start temperature upon heating; Af: reverse transformation finish temperature upon heating; T1: the transformation hysteresis.***

The hysteresis associated with the superelastic stress/strain behavior of nitinol can be exploited in the application and deployment of different medical devices. Figure 2 shows how the stress/strain behavior of bone and Steel fits with the hysteresis of nitinol. High elasticity, low deformation forces and constant force over wide ranges of strain are characteristic of human tissue and bone as well as nitinol [4].

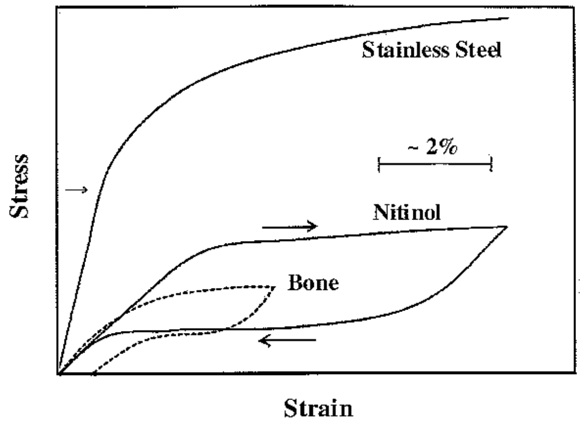

Figure 2 – ***Diagrams* stress-*strain for different materials [4].***

Nitinol is much more compliant to bends in the vessel and contours in the lumen. The upper plateau represents the force required to deform the stent or the force that resists crushing (radial resistive force) and the lower plateau represents the force exerted on the vessel tissue during self-expansion. The plateau of the chronic outward force also means that the stent continues to exert constant force over a considerable strain recovery range.

Magnetic resonance imaging is a diagnostic technique that yields high quality cross-sectional images of the body. Nitinol is very much less sensitive to magnetic resonance and therefore yields a much cleaner image than stainless steel.

In comparison to other alloys, nitinol shows excellent fatigue properties at high strain levels. One of the complications of using laboratory test data for assessing the fatigue life of real applications is that the actual loading conditions *in vivo* are likely to be complicated combinations of varying mean strain, mean stress and the compliance of the surrounding tissue [3]. Surface condition, inclusions and plastic deformation do appear to influence the crack growth [4]. Analysis of fracture surfaces and microstructure implies that the unusual aspects of nitinol fatigue behavior are associated with domains of high dislocation densities, internal stresses, stabilized martensite and micro-fissures [4–6].

The kink resistance of nitinol is very closely related to its high elasticity although more specifically it is due to the plateau in the stress/strain curve of the alloy. The increased stress is accommodated by surrounding areas of lower strain, so the localized peak strain is distributed more uniformly and kinking is prevented.

Figure 3 – ***The arrow interaortic balloon pump [3].***

The steerability and torquability are dependent upon the ability of nitinol guide wire to pass through tortuous paths during angiographic procedures without permanently deforming or kinking and the ability of the guidewire to translate twist and motion from the proximal end to the distal end (Figure 3).

Biocompatibility is the ability of a material to remain biologically innocuous during its functional period inside a living creature [7]. This is a crucial factor for the use of SMA devices in the human body [8]. A biocompatible material does not produce allergic reactions inside the host, and also does not release ions into the bloodstream. Several aspects can contribute to the allergic reactions such as patient's characteristics (age, health, immunological state), and material characteristics (porosity of the surface and toxic effects of the elements present in the material) [8]. Titanium is not toxic when used in the human body; however, nickel is extremely toxic. Nitinol forms a passive titanium oxide layer (TiO_2) that acts as both a physical barrier to nickel oxidation and protects the bulk material from corrosion. This layer is responsible for the high resistance to corrosion of titanium alloys, and the fact that they are harmless to the human body. Its corrosion resistance is greater than that of stainless steel [7]. It has been shown that the cytotoxicity of nitinol is comparable with other implantable alloys [9]. These findings are supported by another study that showed no cytotoxic, allergic or genotoxic response to the nitinol during short term *in vitro* testing [10]. Surface processing has been shown to have a significant effect on cytotoxicity [11, 12]. Some studies have shown that nitinol has no toxic effects on tissue [13], or that it is at least comparable to stainless steel and Ti_6Al_4V titanium alloy [14].

Medical applications of shape memory alloys

The use of shape memory alloys in medicine is now widely recognized and accepted. The super elasticity is the property that is utilized in the vast majority of medical applications. The biocompatibility of these alloys is one of the most important points related to their biomedical applications as orthopedic implants [15], cardiovascular devices [16], and surgical instruments [17], as well as orthodontic devices [15, 18].

Biomedical applications of SMA have been extremely successful because of the functional properties of these alloys, increasing both the possibility and the performance of minimally invasive surgeries [16, 19, 20].

Orthopedic applications

The application of nitinol in orthopedics and a lot of research has gone into various correction rods, compression staples and fracture fixators. Orthopedic applications tend to be concerned with shape memory thermal recovery and the associated forces generated during recovery. SMA has a large number of orthopedic applications. The spinal vertebra spacer is one of them. The insertion of this spacer between two vertebrae assures the local reinforcement of the spinal vertebrae, preventing any traumatic motion during the healing process. The use of a shape memory spacer allows the application of a constant load regardless of the position of the patient, who preserves some degree of motion. This device is used in the treatment of scoliosis [15, 22, 23].

Figure 4 shows spinal vertebrae and a shape memory spacer. On the left side, the spacer is in the martensitic state, and on the right side, the spacer is in its original shape, recovered by the pseudoelastic phenomenon.

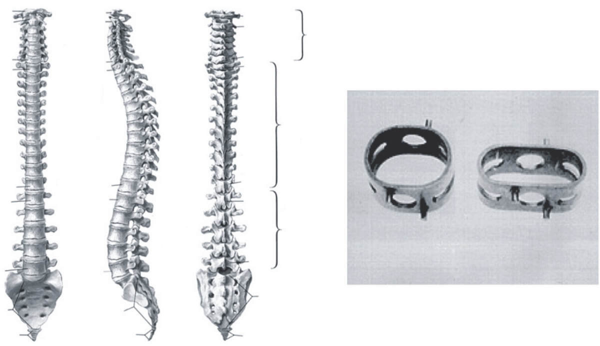

Figure 4 – ***Spinal vertebrae and shape memory spacers [24].***

Another application in the orthopedic area is related to the healing process of broken and fractured bones [3], [22, 23]. Several types of shape memory orthopedic staples are used to accelerate the healing process of bone fractures, exploiting the shape memory effect. The shape memory staple, in its opened shape, is placed at the site where one desires to rebuild the fractured bone. Through heating, this staple tends to close, compressing the separated part of bones. It should be pointed out that an external device performs this heating, and not the temperature of the body. The force generated by this process accelerates healing, reducing the time of recovery. Figure 5 [24] presents an application of these staples during the healing process of a patient's foot fracture. With respect to the healing of fractured bones, it can be used shape memory plates for the recovery of bones. These plates are primarily used in situations where a cast cannot be applied to the injured area, i.e., facial areas, nose, jaw and eye socket. They are placed on the fracture and fixed with screws, maintaining the original alignment of the bone, and allowing cellular regeneration. Because of the shape memory effect, when heated, these plates tend to recover their former shape, exerting a constant force that tends to join parts separated by fractures, helping with the healing process. Figure 6 illustrates this device [25].

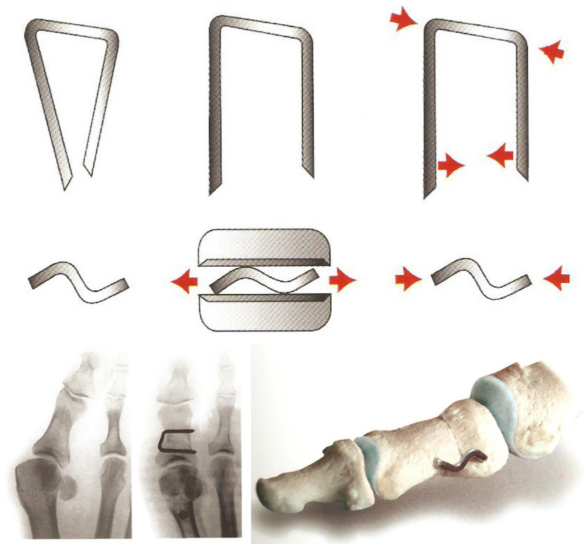

Figure 5 – ***Orthopedic staple [24].***

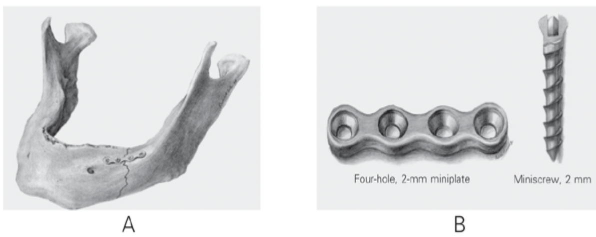

Figure 6 – ***Shape memory bone plates: (A) plates fixed upon a human jaw; (B) detail of the plate and the screw [25].***

Porous SMA [26, 27], have a great potential application in orthopedic implants since their porosity enables the transport of body fluids from outside to inside the bone, which is in the healing process

(Figure 7). This fact optimizes the treatment and also helps the fixation of the implant. Porous NiTi SMA has a high compressive strength (208 MPa) and a low Young's modulus (2.26 GPa), which is similar to natural bones and can meet the mechanical property demands of hard tissue implants for heavy load-bearing applications.

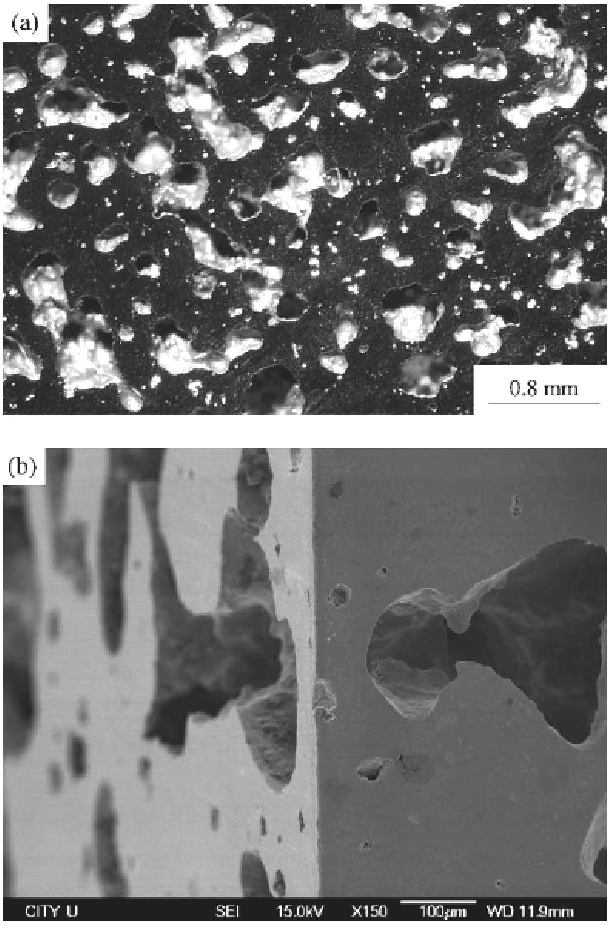

Figure 7 – ***Pore characteristics of porous NiTi SMA: (a) optical micrograph; (b) SEM micrograph [27].***

Cardiovascular applications

In last years, the passing of catheters into arteries and veins has developed into a form of minimally invasive therapy known as interventional radiology. This therapy employs X-ray imaging techniques and magnetic resonance imaging (MRI) to guide different instruments and carry out advanced medical procedures. The atrial septal occlusion device (Figure 8) is an alternative to the traditional surgery that is extremely invasive and dangerous because the thorax of the patient is opened and the atrial hole is sewn. This device is composed of SMA wires and a waterproof film of polyurethane [3, 23]. First, one half of the device is inserted through a catheter by the vena cava up to the heart, in its closed form. Then, it is placed on the atrial hole and opened, recovering its original shape. Next, the second half of the device is placed by the same route as the first one, and then both halves are connected. This procedure seals the hole, avoiding blood flow from one atrium to the other. The scheme of the heart with the device in place is presented in Figure 9 [8].

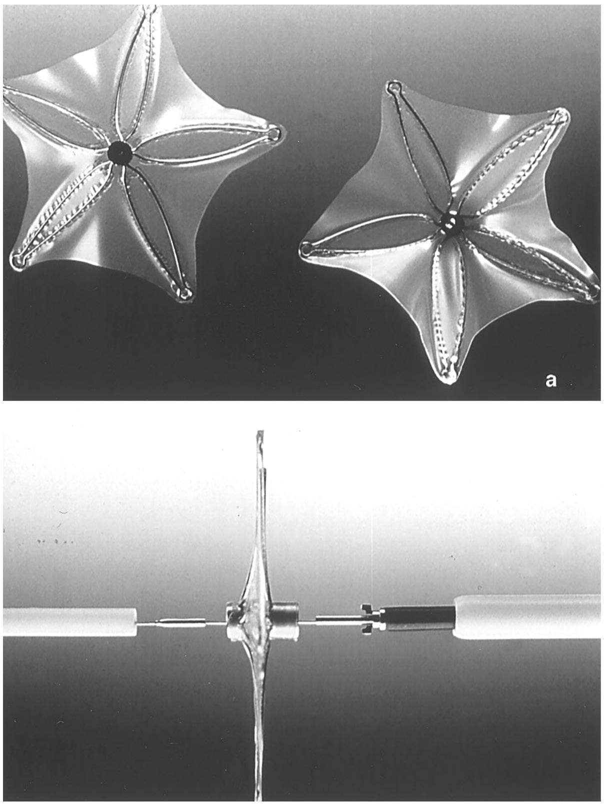

Figure 8 – ***Atrial septal occlusion device [33].***

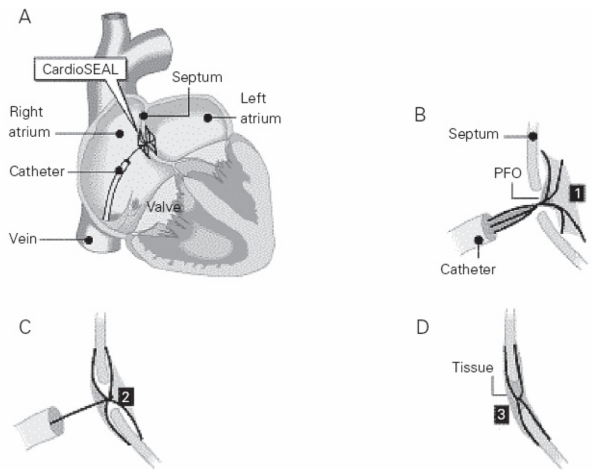

Figure 9 – ***Atrial septal occlusion device: (A) scheme of the heart with the device in place; (B) the first half of the device is placed in the left atrium; (C) the second half of the device is placed in the right atrium; (D) the catheter is withdrawn and the tissue begins its recovery. PFO – patent foramen oval [8] (http://www.nmtmedical.com).***

Angioplasty is a technique for treating occlusion of a blood vessel or heart valve. It is used extensively for the treatment of peripheral vascular disease to restore correct blood flow and for the treatment of coronary heart disease. The procedure involves guiding a thin guide wire through the femoral artery until it is just past the blockage. Permanently implantable metal cylinders named stents are often used to support the walls of the vessel and maintain arterial lumen. The stent is shape set into the open condition, then compressed, and inserted into the delivery catheter. The deployed stent is prevented to completely recover its original shape and exerts a very gentle outside pressure against the vessel wall to keep it open and minimize its recoil (Figure 10).

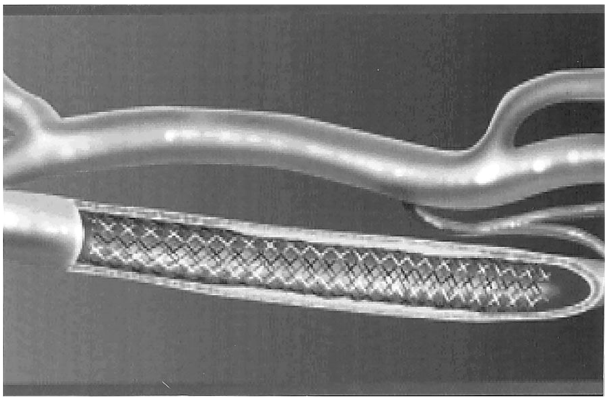

Figure 10 – ***Stent introduced in internal carotid artery [8].***

The graft stents are also used in the repair of abdominal aortic aneurysms, which may occur when the pressure from blood flow causes the wall of a weakened artery to swell and extend. Traditional invasive repair of abdominal aortic aneurysms is a traumatic surgery and carries with it high risk, high morbidity and high patient recovery time. Endovascular repair involves delivering the graft through a catheter via the femoral artery and carries with it average recovery periods of just 11 days. A pulmonary embolism can occur when one or more emboli break off from a blood clot in a vein and are carried to the lung where they lodge causing shortness of breath, pain and where they may ultimately lead to heart failure and death. Traditionally treatment usually involves anticoagulant drugs to reduce the clotting ability of the blood. If the embolus is very large, then an emergency surgery is necessary to remove it.

The first cardiovascular device developed with shape memory was the Simon filter (Figure 11) [8], which represents a new generation of devices that are used for blood vessel interruption in order to prevent pulmonary embolism.

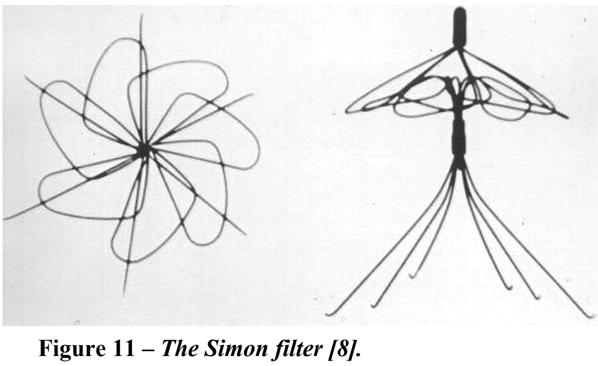

Figure 11 – ***The Simon filter [8].***

The insertion of the filter inside the human body is done by exploiting the shape memory effect. From its original shape, in the martensitic state the filter is deformed and placed on a catheter tip. Saline solution flowing through the catheter is used to keep a low temperature, while the filter is placed inside the body. When the catheter releases the filter, the flow of the saline solution is stopped. As a result, the bloodstream promotes the heating of the filter that returns to its former shape.

Clinical instruments

In recent years, medicine and the medical industry have focused on the concept of less invasive surgical procedures [21]. Following this tendency, shape memory surgical instruments have been created. In surgical endoscopic procedures, the very large amount of recoverable deformation is primarily the key characteristics sought in these types of applications. Instruments that are steer able, hinge less, kink resistant, highly flexible and that provide constant force have all been developed [28, 29].

The distal end of the device and the tube lumen can be used as the carrier for an internal actuation member, a guiding member for another device, a delivery port for a drug or other media. These include biopsy forceps [30] tissue ablators [3] hinge less graspers [30], arthroscopic guides, flexible protections for optical or laser-delivery fibers and retrieval baskets for laparoscopy [31].

These devices allow smooth movements tending to mimic the continuous movement of muscles. Moreover, these devices facilitate access to intricate regions. Usually shape-set super elastic nitinol components are constrained under a very high mechanical strain (up to 6–8%) pending insertion in the patient's body cavity though narrow cannulae, trocar ports or percutaneous needles where they are deployed and recover completely or in controlled fashion to their original shape.

In Figure 12, some surgical endoscopic instruments are presented [32], and in Figure 13, an endoscopic *Vessel-Harvesting System* is presented. Figure 14 shows several super elastic and martensitic dilatators for heart surgery in straight and other shapes. In Figure 15 is presented the *NGage Nitinol Stone Extractor*, manufactured by *Cook Medical* [35], which represents an entirely new category in the evolution of stone extraction. NGage allows easily engaging, releasing and extracting stones even in the most difficult anatomy while providing improved irrigation, visibility and enhanced efficiency.

Figure 12 – ***Surgical endoscopic instruments [32].***

Figure 13 – ***Endoscopic Vessel-Harvesting System [33].***

Figure 14 – ***Coronary dilatators [34].***

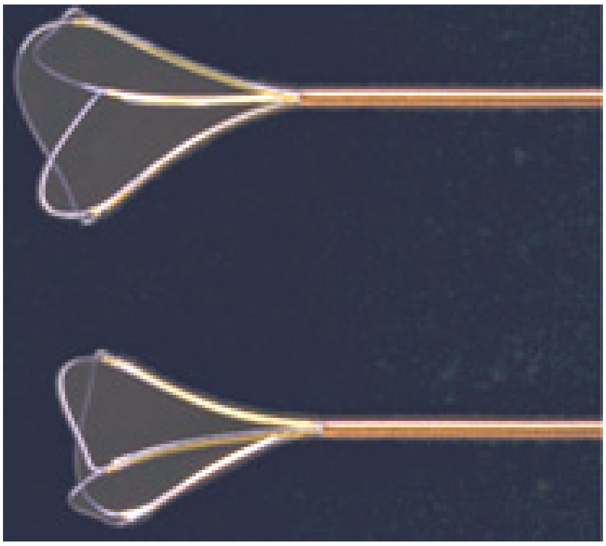

Figure 15 – ***The NGage Nitinol Stone Extractor [35].***

We can consider that nitinol offers many functional advantages over conventional implantable alloys. Applications of SMA to the biomedical field have been successful because of their functional qualities, enhancing both the possibility and the execution of less invasive surgeries. The biocompatibility of these alloys is one of their most important features. Different applications exploit the shape memory effect (one-way or two-way) and the pseudo elasticity, so that they can be employed in orthopedic and cardiovascular applications, as well as in the manufacture of new surgical tools. Therefore, one can say that smart materials, especially SMA, are becoming noticeable in the biomedical field.

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