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REVIEW PAPER

# The applications and research progresses of nickel–titanium shape memory alloy in reconstructive surgery

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**Abstract** In spite of some good successes and excellent researches of Nickel–titanium shape memory alloy (NiTi-SMA) in reconstructive surgery, there are still serious limitations to the clinical applications of NiTi alloy today. The potential leakage of elements and ions could be toxic to cells, tissues and organs. This review discussed the properties, clinical applications, corrosion performance, biocompatibility, the possible preventive measures to improve corrosion resistance by surface/structure modifications and the long-term challenges of using SMAs.

**Keywords** Nickel–titanium shape memory alloy (NiTi-SMA) · Corrosion · Biocompatibility · Modifications · Reconstruction

## Introduction

Shape memory alloys (SMA) possess certain original properties, particularly their ability to return to their memorized shape by a simple change of temperature. Over the past 20 years, Ni–Ti alloys have revolutionized the field of metallic biomaterials. Applications in the biomedical area are multiple and these materials improve significantly the quality of the diagnostics, treatments and surgeries [1–3]. One of the most exciting areas is the applications in reconstructive surgery. It is well known that NiTi SMA are generally characterised by good corrosion properties, in most cases superior to those of conventional stainless steel or Co–Cr–Mo-based biomedical materials. The majority of biocompatibility studies suggest that these alloys have low cytotoxicity as well as low tissue-toxicity. However, Due to the presence of high amounts of Ni, the toxicity of such alloy is under scrutiny. The release of Ni ions depends on the surface state and the surface chemistry [4]. In this review paper the work on the properties, clinical applications, corrosion performance, biocompatibility, the possible preventive measures to improve corrosion resistance by surface/structure modifications and long-term challenges of using NiTi-SMA are analyzed.

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## NiTi-SMA alloy and its properties

NiTi-SMA alloy was invented in the late 1960s, which contains an almost equal mixture of nickel and titanium. For many years, it has become a key component of several revolutionary medical devices including vascular stents, tools, and grafts. Which makes NiTi-SMA 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.

### Three-dimensional structure and shape-memory effect

The SMAs are mostly known for their ability to revert to their initial shape upon heating until they enter their high temperature phase after having been deformed in the low temperature phase. The atomic structure of NiTi-SMA is a three-dimensional symmetric grid, with each atom of nickel surrounded by four atoms of titanium. The macroscopic characteristics of stress–strain and electrical resistivity depend on the microscopic crystalline structure. The atomic forces that bind these atoms create a unique crystal structure that can exhibit a transition between two phases. The first phase is known as the austenite phase and the second phase, the martensite phase. The phase transformation from martensite to austenite starts upon heating the SMA above austenite start temperature, while the phase transformation is complete at austenite finish temperature, resulting in recovering to the initial shape. This is called the shape memory effect (SME) [5]. The transformation between the two phases gives NiTi-SMA its unique physical properties. When cooled below the transformation temperature, a product made of NiTi-SMA transforms to its martensitic phase, with mechanical properties enabling easy deformation of the product [6] (Fig. 1). The one-way SME allows a material to return to its original shape by simply increasing the temperature. As long as the deformation does not exceed about 8–10% [7, 8], the product will resume its memorized austenitic shape and mechanical characteristics when reheated above the transformation temperature. This process is fully reversible. As in the one-way shape memory, the two-way SME allows the material to return to its original shape by simply increasing the temperature. In addition, it also permits the return of a second shape by cooling. The phase transformation of a nickel–titanium alloy is characterized by the hysteretic behavior [9] (Fig. 2). The temperatures of transformation from martensite to austenite are indicated as *As* and *Af*, respectively, at the beginning and end of the transformation, while the temperatures for the austenite to martensite transformation are indicated as *Ms* and *Mf*, respectively, at the beginning and end of the transformation.

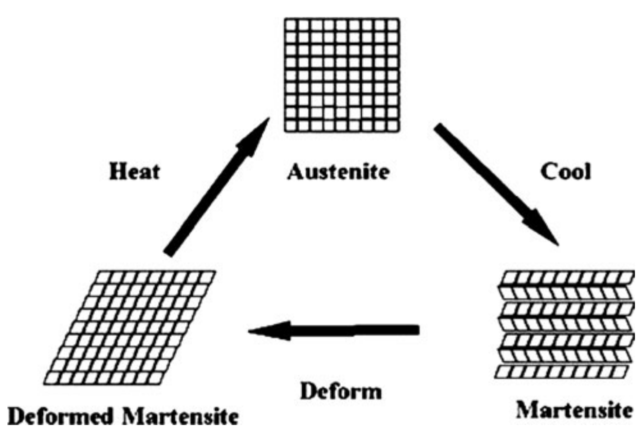


**Fig. 1** The shape-memory effect of NiTi SMA

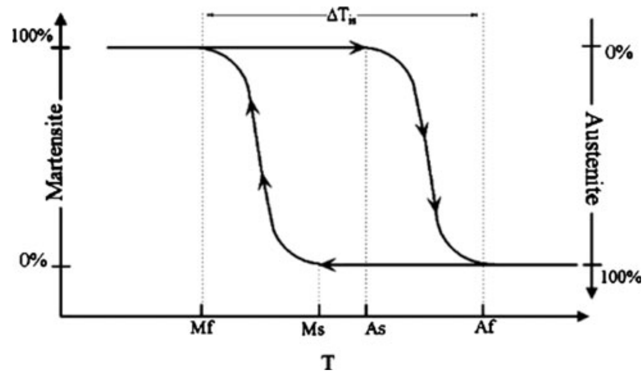


**Fig. 2** Hysteretic behavior of Ni–Ti SMA

Superelasticity

NiTi-SMA demonstrate superelasticity (also referred to as pseudoelasticity) in which the phase transformation from austenite to martensite occurs just by increasing the external stress and without changing the temperature [10]. In other words, the phase transformation from austenite to martensite also can be achieved by applying force (strain) to the product. When the force is removed, the product will resume its memorized austenitic shape and characteristics. NiTi-SMA demonstrates unique mechanical stress–strain behavior when loaded and unloaded.

High-damping effect

The high-damping effect is the ability of a material to transform mechanical energy (provided by an applied force, for example) into thermal energy (in the form of heat dissipation). This irreversible energy transformation allows the material to resist shocks and absorb vibrations. The internal friction in the form of heat disperses the energy between the different phases or varieties of the same phase.

## The clinical applications of NiTi-SMA

The unique properties of SMA allow the possibility of multiple applications in implantology. In those situations where a tissue or organ has suffered from some diseases or conditions that have resulted in pain, malfunction or structural degeneration, and which can only be alleviated by the replacement or augmentation of the affected part, the SMA alloy is often used. But with an atherosclerotic artery, the objective may be more easily achieved with a by-pass rather than a replacement. The important thing is that the function is restored. It is, with a few exceptions, not necessary to make the prosthetic component look like or otherwise physically resemble the tissue that it is replacing, as long as it carries out the appropriate function.

The use of Nickel–Titanium (NiTi or nitinol) SMAs in the medical industry has shown a remarkable breakthrough during the past years [11]. NiTi alloy combines the characteristics of SME and pseudoelasticity with excellent corrosion resistance, wear characteristics, mechanical properties and good biocompatibility. These properties make it an ideal biological engineering material, especially in orthopaedic surgery [12, 13] and orthodontics [14, 15]. Neurosurgery [16], minimal access surgery [17], in vivo skin closure [18].

In orthopedic applications, bone plates are used in the surgical treatment of broken bones. The plates based on the SME have been developed to allow a constant and uniform constraint on the two sections of the broken bone. The continuous pressure between the two parts of the bone encourages rapid healing as well as a quick recovery of mobility compared to traditional surgical techniques. Like synthetic bone plates, compression staples are used to set broken bones and promote healing. They are implanted directly into the area of the break to compress the two parts of the bone. Nails for marrow cavity stimulate the osteosynthesis where long bones, such as the femur, are broken. The current surgical procedure to treat the break consists of hollowing out the bone marrow cavity of the two bone sections followed by the reconnection and insertion of a nail to allow the healing of the break. The nail is made of an SMA stem with soft polymer ends that completely fill the cavity and prevent relative movement of the bone. SMA have been considered for the manufacture of hip prostheses. The total replacement of the acetabulum cavity of the hip joint by a double half-sphere, SMA prothesis represents a compromise between the friction resistance and mechanical resistance of the prosthetic joint. The insertion of a spacing disc between two vertebrae assures the local reinforcement of the spinal column and prevents all traumatic movement during the healing process. SMA is of great interest for treating arthrodesis of the vertebrae. Concerning the resistance to rupture and the maximum elastic deformation, the nickel–titanium SMA also used as anterior cruciate ligament (ACL) prosthesis.

In dental applications, braces used for adjust the teeth. During an orthodontic treatment the bone is remodeled by the force exerted by the braces. Nickel–titanium braces are more comfortable for patients during the installation and throughout the treatment. The apparatus allows autonomous adjustment of the transmitted constraint, avoiding visits to the orthodontist to retighten it. Furthermore, SMA is a better fixation of the implant in the jaw due to shape memory.

Other clinical applications involve cardiovascular stents, endoprosthesis, cava filters, intracranial staples, supports for heart valves, bridges of blood vessels, inner ear bone replacements, intraocular lenses for the treatment of cataracts and so on [19].

## Corrosion properties and biocompatibility of NiTi-SMA

All materials used to make industrial products for implantation in the human body for short-, medium-, or long-term must be tested to prove their "biocompatibility." The main disadvantages of medical alloy are that it has no bioactivity and difficult to attach to body when embedded [20]. A Ni–Ti superelastic alloy is susceptible to environmental embrittlement in a corrosive atmosphere [21].

Nickel–titanium (NiTi) has been used for implants in many fields due to the unique properties discussed in part 1. However, NiTi alloys are eroded in a given circumstance, e.g. in the oral cavity because they are immersed by saliva with enzymolysis. Nickel and titanium release when placed in an artificial saliva medium at 37°C is an important parameter to study. The reactions lead corrosion and nickel release into the body. The higher concentrations of Ni ion release may generate harmful reactions. Ni ion release causes allergenic, toxic and carcinogenic reactions. The factors affecting corrosion are manifold and may be grouped into two classes: (1) the medium surrounding the metal, characterised by its pH, temperature and chemical composition (presence of $Cl^-$, $F^{2+}$, $O^{2-}$, etc.) and (2) the metal's surface state (roughness, due to product processing or wear use; geometry factors such as sharp-angled, edged faces). What makes the application of NiTi controversial is not the intermetallic compound itself but the corrosion products, in particular, the amount of leached $Ni^{2+}$ in organic fluids. Although $Ni^{2+}$ is one of essential microelement for cells, it can influence the cell proliferation at a high concentration. 1% NaCl is enough to make corrosive action to medical alloy which can influence the stabilization of the alloy [22]. Meanwhile, the corrosion has some toxic and side effects to human body. Studies [23] have shown that the pitting potential for NiTi in artificial saliva decreased at low and high pH; at 25°C, the pitting potential was the lowest compared to those at 10, 37 and 50°C; When the $Cl^-$ concentration was not less than 0.05 mol/L the pitting potential decreased with increasing $Cl^-$ concentration. Numerous attempts have been undertaken to characterize the corrosion behaviour of NiTi-SMA used in medical devices. However, using comparable testing strategies, the results differ considerably. The study conducted by Wang et al. [24] obtained the conclusion that the significance of dominating factors in free corrosion potential is in the order of temperature, pH and $Cl^-$; At pH6, NiTi was more stable than in acidic or alkaline saliva.

Apart from corrosion, fatigue is an issue when long time operation is intended. When looking at fatigue behavior of SMAs we need to distinguish between structural fatigue (also referred to as classical mechanical fatigue) and functional fatigue (also referred to as shape memory fatigue) [25, 26]. Structural fatigue is the accumulation of microstructural defects as well as formation and growth of surface cracks until the material finally ruptures. Functional fatigue is the gradual degradation of either SME or damping capacity by microstructural changes. The latter is associated with modification of the stress–strain-curve under cyclic loading.

Biocompatibility is the primary requirement for biomaterials. Since the human body does not normally contain foreign objects, such as large pieces of metal or plastic, and since evolution has determined that the body has exquisitely refined capabilities to defend itself against invasion, for example by bacteria, we should expect there to be a strong inherent capacity to respond aggressively to implanted medical devices. Actually, the initial tendency of many physicians, surgeons, dentists and orthodontists is to reject NiTi alloys due to the assumption that the high nickel content suggests a high risk of triggering Ni sensitivity/allergy. The currently accepted definition of biocompatibility is 'the ability of a material to perform with an appropriate host response in a given situation' [27]. This definition emphasizes the positive nature of the interactions.

Interfacial phenomena, host response and stability of alloy are major aspects of the biocompatibility of NiTi-SMA. Similar to other biomaterials, once NiTi-SMA is placed in contact with tissues, certain molecules dissolved in the fluid phase of that tissue are adsorbed onto the alloy's surface. An adsorbed protein layer is established within minutes, and a dynamic process of adsorption, desorption and exchange takes place within this region. There are several important consequences of these interfacial reactions. First, the adsorption of a protein or similar molecule may cause a profound change to its properties, which can under some circumstances lead to major physiological events. The change to the shape of certain plasma protein molecules after adsorption can be the initiating event in the formation of a blood clot or the development of a profound response from the immune system, for example. Secondly, the layer of protein may be only of monomolecular dimensions, its presence means that the rest of the body does not come into contact with the native biomaterial surface again. The interactions between cells and materials, which really control biocompatibility actually takes place via a layer of proteins.

NiTi-SMA has been selected on the basis of its inertness, which implies a resistance to degradation. This again is a very complex matter since there are so many active substances and components of the physiological environment that have the potential to interact with and ultimately degrade material surfaces. Material degradation can have two consequences for medical devices. First, degradation of a material can result in loss of structural integrity of a device, possibly with its ultimate dissolution or removal. This may be undesirable in the case of a device designed to be inert, but could be desirable in those devices which are intentionally biodegradable. Secondly, the release of products of the degradation process may affect the tissues, either locally or systemically. With a metal, it may involve the release of soluble metal ions or particulate corrosion products. The release of Ni ion from alloy may take many different forms. These Ni ion released into the tissue can have an effect on that tissue, and clearly this can take place over a prolonged period of time. The majority of biocompatibility studies suggest that these alloys have low cytotoxicity (both in vitro and in vivo) as well as low genotoxicity. The release of Ni ions depends on the surface state and the surface chemistry [28]. The high biocompatibility of NiTi appears to be a direct consequence of the low Ni ion release rate due to the build-up of a protective $TiO_2$ layer. Smooth surfaces with well-controlled structures and chemistries of the outermost protective $TiO_2$ layer lead to negligible release of Ni ions, with concentrations below the normal human daily intake. Although tissues are often thought of as saline solutions as far as reactivity with synthetic materials is concerned, they are far more complex than that, and it is the precise nature of the tissue environment that controls the degradation process. In particular, the key feature of the tissue in the response to a degrading material is inflammation [29]. Inflammatory cells tend to produce a variety of active species, such as free radicals, peroxides and superoxides and enzymes, all of which are able to influence or even initiate material degradation.

Cytotoxicity is a toxic effect due to various elements at cellular level that causes the death/alteration of the cellular membrane or that inhibits enzymatic metabolic processes. The genetic toxicity (genotoxicity) may cause mutagenic effects that damage or change the genes or chromosomes.

The study conducted by Liu et al. [30] developed a new artificial anal sphincter using SMAs in order to improve the quality of life of such patients and evaluated the influence of this sphincter on blood serum chemistry in animal experiments. The artificial anal sphincter was driven by two Ti–Ni SMA actuators sandwiching the intestine and was implanted in three female goats. Their study indicates that the artificial sphincter SMA demonstrated no adverse influence on blood serum chemistry and exhibited an effective system performance. Chu et al. [31] investigated the microstructure of the titanium film and its influence on the biocompatibility of NiTi SMA by scanning electron microscopy (SEM), X-ray photoelectron spectroscopy (XPS), inductively coupled plasma mass spectrometry (ICPMS), hemolysis analysis, and platelet adhesion test. The results indicate that the titania film has a Ni-free zone near the surface and can effectively block the release of harmful Ni ions from the NiTi substrate in simulated body fluids.

### Surface and structure modification of NiTi-SMA

From a biological point of view, it is the state of the material's surface (the amount it hinders ion leaching processes) that influences the biocompatibility of these materials. Consequently, the stability of the outermost surface layer against chemical attack and wear corrosion which ultimately affects the performance of implant device appears to be of crucial importance for biocompatible materials. Biocompatibility is concerned with the interactions that take place between biomaterial and the tissue of the body. In order to prevent nickel diffusion, various surface modifications have been proposed. Coatings with nitrides, oxides and carbides seem to be an attractive way to create a barrier, which sufficiently reduces corrosion resistance of NiTi alloys.

Bioactive titanium metals can be prepared by alkaline treatment with NaOH solution or oxidizing treatment with hydrogen peroxide ($H_2O_2$) solution. The former treatment produces a sodium titanate layer on titanium surface, while the latter forms a titania gel layer. Both sodium titanate layer and titania gel layer have the ability to induce deposition of bone-like apatite in vitro and in vivo and thus are considered bioactive [32]. Chrzanowski's research also confirmed that alkali treatment and spark oxidation can resulted in some bioactivity [33]. Barrabes et al. [34] examined NiTi foams that have been treated using a new oxidation treatment for obtaining Ni-free surfaces that could allow the ingrowth of living tissue, thereby increasing the mechanical anchorage of implants. The result shows titanium oxide on the surface significantly improves corrosion resistance and decreases nickel ion release, while barely affecting transformation temperatures. Diamond-like carbon (DLC) films have excellent properties, such as extreme hardness, low friction coefficients, high wear resistance. Owing to its superior mechanical properties with corrosion resistance, biocompatibility, and hemocompatibility, DLC has emerged as a promising material for biomedical applications [35–37]. In addition, DLC film has many other superior properties as a protective coating for biomedical applications such as biocompatibility and chemical inertness. Therefore, DLC film has received enormous attention as a biocompatible coating [38]. Studies have shown that the oxide significantly decreases Ni ion release into exterior medium compared with untreated surfaces [39–41]. Tantalum metal has successfully been used for implants for half a century. Since the galvanic potentials of tantalum and nitinol are very similar, the galvanic corrosion effect is almost immeasurable and complete failure of the implants is impossible. Tantalum and tantalum oxide particles are often used to improve radiopacity of other materials. No problems have been reported concerning its biocompatibility [42]. Another study also shows that tantalum is an excellent candidate for NiTi alloys as coatings to improve its anti-corrosion property and radiopacity [43]. In the research of Boccaccini et al. [44], Polyetheretherketone (PEEK) and PEEK/Bioglass coatings were produced on SMA (NiTi) wires using electrophoretic deposition (EPD). The results have demonstrated for the first time that EPD is a very convenient method to obtain homogeneous and uniform bioactive PEEK and PEEK/Bioglass coatings on nitinol wires for biomedical applications. Li's study [45] shows bone-like apatite coating NiTi alloy is bioactive material, which is chemically bond with bone tissue. Some researchers [46] have already lucubrated on this issue. In the research of Alves-Claro et al. [47], wear resistance was determined in vitro by using an equipment for the application of horizontal movements on previously prepared notched plates made of resin. The results found led to the conclusion that the surface treatment significantly increased the nitinol files wear resistance. Different surface modifying temperature also influences the biocompatibility and behavior of NiTi-SMA. In the study of Samaroo [48], we synthesized various NiTi substrates with different micron to nanometer surface roughness by using dissimilar dimensions of constituent NiTi powder that NiTi with sub-micron to nanometer surface features can play in promoting a natural anti-thrombogenic and anti-inflammatory surface (the endothelium) on a vascular stent. Liu et al. [49], Yeung et al. [21] and Li et al. [50] modified the surface of NiTi alloy by nitrogen plasma immersion ion implantation (N-PIII) at various voltages. Results show that N-PIII conducted using the proper conditions improves the biocompatibility and mechanical properties of the NiTi alloy significantly. Yanga et al. [51] prepared three types of surface-treated NiTi samples, M-1 (700°C/0.5 h), M-2 (650°C/1 h) and M-3 (400°C/50 h) by ceramic conversion treatment under different conditions. The result show that low temperature treated NiTi samples M-3 showed the best fretting wear resistance in all samples tested. With the ever-expanding use of coatings in the biomedical industry, the need for methods to study how a coating interacts with the substrate becomes increasingly important. Coating imperfections can result in poor biocompatibility and an increased risk of restenosis. These imperfections may be uneven coating thickness, non-uniform roughness, or delamination.

Biomaterial structure and hardness can also influence the biocompatibility of NiTi-SMA. Porous NiTi SMA has been the subject of considerable interest as a promising biomaterial for use as hard tissue implants and medical instruments. For the reason of its cellular structures and mechanical characteristics are similar to those of some natural biomaterials. Up to now, many porous NiTi SMAs with different pore structures were developed by combustion synthesis or self-propagating high-temperature synthesis (SHS) [52]. A research [53] on porous nitinol interbody fusion device revealed that nitinol has perfect biocompatibility on the dura mater, spinal cord and nerve roots, lymph nodes (abdominal para-aortic), and organs (kidneys, spleen, pancreas, liver, and lungs). Liang et al. [54] prepared porous microstructures on Nickel–Titanium (NiTi) alloy surfaces by linearly polarized femtosecond lasers with moving focal point at a certain speed. This investigation provides a new approach to improve the biocompatibility of NiTi-based implant devices. Likibi's [55] study indicated that the porous nitinol obtained the better bone integration and apposition compared to titanium cage in intervertebral fusion implants sheep models. The osseo-integration of each implant seemed to be influenced by its structure and its hardness. In his another research [56], porous nitinol was evaluated in sheep and compared to a conventional Titanium intervertebral cage packed with autologous iliac crest bone. Both device types were implanted at two non-contiguous intervertebral lumbar sites. The osseointegration capacity and biocompatibility of both implants seemed comparable. Compared with the biomedical criteria for choice of implanting materials, porous NiTi alloy is satisfying to a great degree [57]. In the study of Nie [58], a very nice fractal structure, microdomains with identical nanometer sized grooves, was obtained on the surfaces of the orthodontic wires with an oxygen plasma and acid corrosion. The concave parts of the grooves were dominated by titanium and convex parts were the same as the bulk wires. The micro–nano fractal structure generated a hydrophobic surface with the largest contact angle to water being about 157°. The titanium dominated nanolayer and the hydrophobicity of the surface resulted in jointly the great improvement of the anti-corrosion ability of the orthodontic wires.

Some researchers combined other metals with SMA to enhance the performance of the alloy. The advancement in this field is to be worth follow with interest. Alternative to coatings is addition of a third alloying element, which substitutes nickel. Titanium alloys such as titanium–niobium (Ti–Nb), nickel–titanium–cobalt (Ni–Ti–Co) and nickel–titanium–copper (Ni–Ti–Cu) are commonly used. Addition of tungsten, platinum or tantalum, in proper amounts, also improves the radiopacity of the TiNi implants. The ternary alloy poses properties comparable to NiTi. The SME of each of these alloys makes them useful in various stages of clinical conditions [59]. Especial, attention was paid to copper addition. Other researches involve aluminum–nickel–titanium (Al–Ni–Ti) [60], aluminum–cobalt–nickel–titanium (Al–Co–Ni–Ti) [61], aluminum–ferrum–nickel–titanium (Al–Fe–Ni–Ti) [62], titanium–manganese–gallium (Ni–Mn–Ga) [63], nickel–ferrum–gallium (Ni–Fe–Ga) [64], ferrum–manganese–silicon–chromium–titanium (Fe–Mn–Si–Cr–Ni) [65] and so on. Liu et al. [66]. confirmed that the corrosion resistance of Fe–Mn–Si–Cr–Ni is superior to that of Ni–Ti alloy and 316L stainless steel in NaCl and NaOH solution. Gil [67] compared NiTiCu alloys with various copper concentrations with the conventional NiTi alloys. The addition of copper was effective to narrow the stress hysteresis and to stabilize the superelasticity characteristics. Moreover, it produced greater stability on both the transformation temperatures and the forces applied to the different tissues. However, the studies of cell cultured with human fibroblasts showed certain toxicity.

## Conclusions

This review was attempted to demonstrate the very significant progress that has been made in recent years on NiTi-SMA, one of most advanced biomaterials. From the different publications analysed, it can be concluded that a passivated surface of NiTi SMAs is highly recommended in reconstructive application. However, that the human body is a very complex place, it is not surprising that there is still a long way to go before we can readily, routinely and successfully use the material in human body. The interactions between materials and the human environment, degradation in vivo, the possible toxicity, must be better understood before the general use of NiTi-SMA. So it is advisable to avoid all Ni-containing materials for already Ni-sensitized people. New solutions must be found to solve the problems that arise. A surface and structure treatment would perhaps make NiTi-SMA more tempting for human implantation. In effect, the surface treatment opens up unsuspected possibilities. The biocompatibility of SMA must be studied in a rigorous, orderly way to validate the long-term effects of the implant and eliminate the apprehensions of potential users. The direction of studies of biocompatibility, biostability, and biofunctionality of SMA implants must follow from their specific functions.

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