

Shape Memory Alloys in Biomedical Applications: A Review of Clinical and Biomedical Engineering Advances

Dr. Hiroshi Sato^{1*}, Dr. Yuki Tanaka¹

¹University of Tokyo Hospital, Department of Biomedical Engineering and Regenerative Medicine, Tokyo, Japan

ABSTRACT

Shape memory alloys (SMA) have the ability to return to a former shape when subjected to heating. Shape memory properties gives a very attractive insight into materials science, opening unexplored horizons and giving access to unconventional functions in every material class. Shape memory alloys (SMAs) use new insights in biomedical engineering with the unique properties they exhibit, in applications such as cardiovascular stents, guide wires and organ frame retractors. The biomedical field, forever in search of materials that display unconventional properties able to satisfy the severe specifications required by their implantation, is now showing great interest in shape memory materials. Biocompatibility, particularly for long-term and permanent applications, has not yet been fully recognized and is therefore the object of controversy. This paper a detailed reviews of 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 and 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: shape memory, biocompatibility, and biomedical applications.

I. INTRODUCTION

Shape memory alloys (SMA) have the ability to return to a former shape when subjected to heating. Shape memory materialis a lightweight, solid-state alternative to conventional actuators such as hydraulic, pneumatic, and motor-based systems in robotics and automotive, aerospace and biomedical industries.

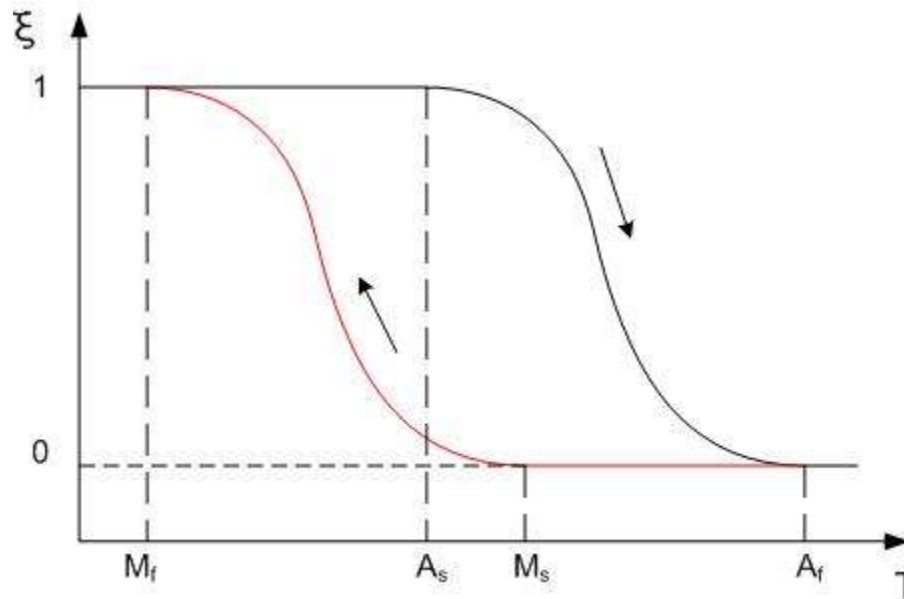
The two main types of shape-memory alloys are copper-aluminium-nickel, and nickel-titanium (NiTi) alloys but SMAs can also be created by alloying zinc, copper, gold and iron. Although iron-based and copper-based SMAs, such as Fe-Mn-Si, Cu-Zn-Al and Cu-Al-Ni, are commercially available and cheaper than NiTi, NiTi based SMAs are preferable for most applications due to their stability, practicability and superior thermo-mechanic performance. e two most prevalent shape-memory alloys are copper-aluminium-nickel, and nickel-titanium (NiTi) alloys but SMAs can also be created by alloying zinc, copper, gold and iron. Although iron-based and copper-based SMAs, such as Fe-Mn-Si, Cu-Zn-Al and Cu-Al-Ni, are commercially available and cheaper than NiTi, NiTi based SMAs are preferable for most applications due to their stability, practicability^{[1][2][3]} and superior thermo-mechanic performance.^[4] SMAs can exist in two different phases, with three different crystal structures (i.e. twinned martensite, detwinned martensite and austenite) and six possible transformations.

NiTi alloys change from austenite to martensite upon cooling; M_f is the temperature at which the transition to martensite completes upon cooling. Accordingly, during heating A_s and A_f are the temperatures at which the transformation from martensite to austenite starts and finishes. Repeated use of the shape-memory effect may lead to a shift of the characteristic transformation temperatures (this effect is known as functional fatigue, as it is closely related with a change of microstructural and functional properties of the material). The maximum temperature at which SMAs can no longer be stress induced is called M_d , where the SMAs are permanently deformed.

The transition from the martensite phase to the austenite phase is only dependent on temperature and stress, not time, as most phase changes are, as there is no diffusion involved. Similarly, the austenite structure receives its name from steel alloys of a similar structure. It is the reversible diffusion less transition between these two phases that results in special properties. While martensite can be formed from austenite by rapidly cooling carbon-steel, this process is not reversible, so steel does not have shape-memory properties.

II. SHAPE MEMORY EFFECT

The shape memory effect reflects the unique properties of the austenite and martensite phases and their capability for reversible transformation. Initial shape memorization occurs in the parent phase, in which the predetermined structure is fixed in the atomically ordered austenite state. Transformation to the martensite phase, when the crystalline structure permits a high degree of strain with minimal stress, allows for deformation of the material. With heating and reverse transformation, the material returns to the atomically ordered structure of the parent phase, with recovery of the predetermined shape. Therefore, the overall shape memory effect is attributable to the material's ability to easily deform in the secondary phase and then recover a "memorized" shape upon reversal to the parent phase.



SMA is also a well-established technology with numerous applications in several markets since the discovery of SMA effect in NiTi alloys in the Naval Ordnance Laboratory. Most remarkable applications can be found in the field of actuators for deployable structures and in aerospace mechanisms. Other extended applications of SMA make use of their superelastic properties (also in combination with their biocompatibility). Herein a selection of applications is offered:

Temperature control systems: as it changes shape, it can open or close a valve, activate a switch or a variable resistor to control the temperature.

Demonstration model heat engines have been built which use SMA to produce mechanical energy from hot and cold heat sources.

Aeronautical market: design of adaptive structures to control flaps or the chevron shape during taking off and landing phases.

Actuators for automotive industry, such as latch mechanisms for doors and appendices, air valves, adaptive structures, etc.

Actuators for autofocus mechanisms in cameras.

Triggering actuators for aerospace applications, especially in hold-down and release mechanisms in charge of deploying structures and appendices in satellites.

Healthcare: active implants, valves, catheters.

III. SUPERELASTICITY

SMAs also display super elasticity, which is characterized by the recovery of relatively large strains with some , however, dissipation. In addition to temperature-induced phase transformations, martensite and austenite phases can be induced in response to mechanical stress. When SMAs are loaded in the austenite phase (i.e. above a certain temperature), the material will begin to transform into the (twinned) martensite phase when a critical stress is reached. Upon continued loading and assuming isothermal conditions, the (twinned) martensite will begin to detwin, allowing the material to undergo plastic deformation. If the unloading happens before plasticity, the martensite transforms back to austenite, and the material recovers its original shape by developing a hysteresis. For example,

these materials can reversibly deform to very high strains – up to 7 percent. A more thorough discussion of the pseudoelastic behavior is presented by the experimental work of Shaw & Kyriakides, and more recently by Ma et al.

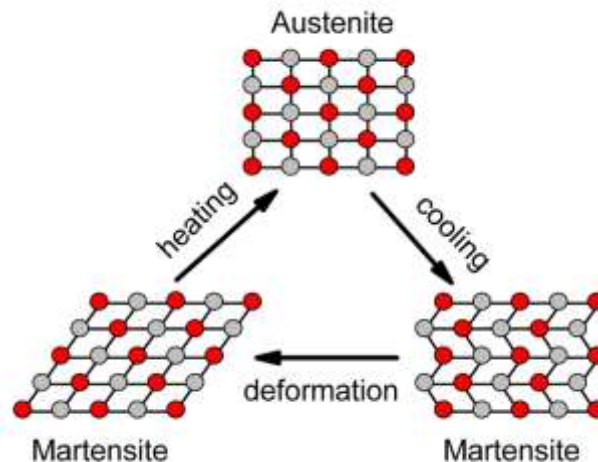
IV. HISTORY OF SMA DEVELOPMENT

In the 1990's, the term shape memory technology (SMT) was introduced into the SMM community. SMA application design has changed in many ways since then and has found commercial application in a broad range of industries including automotive, aerospace, robotics and biomedical. Currently, SMA actuators have been successfully applied in low frequency vibration and actuation applications. Therefore, much systematic and intensive research work is still needed to enhance the performance of SMAs, especially to increase their bandwidth, fatigue life and stability.

Recently, many researchers have taken an experimental approach to enhance the attributes of SMAs, by improving the material compositions (quantifying the SMA phase transition temperature) to achieve a wider operating temperature range, and better material stability, as well as to improve the material response and stroke with better mechanical design (or approach), controller systems and fabrication processes. Research into alternative SMMs, forms or shapes, such as MSMA, HTSMA, SMP, shape memory ceramic, SMM thin film or a combination of them (i.e. hybrid or composite SMMs), are also intensively being conducted, and the number of commercial applications is growing each year. More details of recent applications and development of SMA are described in the subsequent sections.

V. CRYSTAL STRUCTURES

Many metals have several different crystal structures at the same composition, but most metals do not show this shape-memory effect. The special property that allows shape-memory alloys to revert to their original shape after heating is that their crystal transformation is fully reversible. In most crystal transformations, the atoms in the structure will travel through the metal by diffusion, changing the composition locally, even though the metal as a whole is made of the same atoms. A reversible transformation does not involve this diffusion of atoms, instead all the atoms shift at the same time to form a new structure, much in the way a parallelogram can be made out of a square by pushing on two opposing sides. At different temperatures, different structures are preferred and when the structure is cooled through the transition temperature, the martensitic structure forms from the austenitic phase.



VI. BIO MEDICAL APPLICATIONS OF SHAPE MEMORY ALLOY

After the discovery of the SME in nitinol by Buehler et al. in 1962, they proposed to use this material for implants in dentistry, and a few years later, the first superelastic braces made from a NiTi alloy were introduced by Andreassen in 1971. SMA made a significant breakthrough into biomedical domain after its introduction in minimally invasive surgery (MIS), and more biomedical applications are developed and introduced into the market after the approval of the Mitek surgical product (i.e. Mitek Anchor) for orthopaedic surgery by US Food and Drug Administration (FDA)

in September 1989. Although NiTi alloys are significantly more expensive than stainless steels, SMAs have exhibited excellent behaviour for biomedical applications such as high corrosion resistance, bio-compatible, non-magnetic, the unique physical properties, which replicate those of human tissues and bones, and can be manufactured to respond and change at the temperature of the human body.

Orthopedic applications

Shape memory alloys are a group of metallic materials with some unusual properties such as one-way and two-way shape memory effects, super elastic effect, high damping property and rubber-like effect. These characteristics make the material suitable for different orthopedic applications such as load-bearings, plates for bone fracture repair, internal fixators for long bone shafts, spinal correctors, vertebral spacers and bone distraction devices. Some of these applications are explained in the following subsections.

A) Spinal vertebral spacer

The spinal vertebral spacer is one of the applications of this material in orthopedics. The insertion of the spacer (disc) between two vertebrae provides the local reinforcement of the spinal column, avoiding any traumatic motion during the healing process. The employ of a shape memory spacer enables the use of a constant load regardless of the patient position with some degree of motion. This device is used to treat scoliosis. Figure represents spinal vertebrae spacer in the in the original shape (right) and martensitic state (left).



Figure . Spinal vertebrae spacer (Duerig, Melton et al. 1990)

B) Plates for fractured bone

Shape memory plates also have been used to heal and recover the fractured bones, in the injured area where it is not possible to apply cast such as facial areas, nose, jaw, and eye socket. They are inserted to the fracture and fixed with intermediate screws. This maintains the original alignment of the bone and enables cellular regeneration. When these plates are heated, they tend to recover their previous shape (because of the shape memory effect) and exert a constant and uniform force on the two broken sections, which causes to join separated parts of fractures and helps in the healing process.

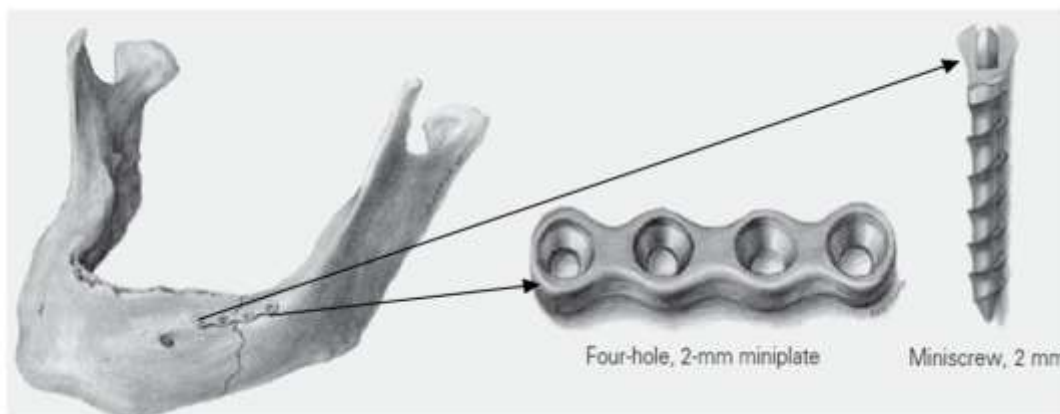


Figure. SMA plate for fractured human jaw bone and details of the plate and the screw (Machado and Savi 2003)

Dentistry and orthodontics applications

An artificial tooth root can, after application in a deformed shape, return to its required shape after reaching body temperature and, so, will be tightened in the mandible. Figure shows the single wing-type shapememory implant; part of the apex opens Bucco-lingually after insertion into the jaw bone. The advantages of the shape memory implants are that they have a good initial fixation in the jaw bone, are easily installed in a simple operation and have a good stress distribution to the surrounding bone compared with the ordinary non-opening blade-type implant



Fig. Shape memory oral implant design

Applications to surgical instruments

In recent years, medicine and the medical industry have focused on the concept of less invasive surgical procedures. Following this tendency, shape memory surgical instruments have been created and are becoming noticeable. Among the advantages of these tools, one can emphasize their flexibility as well as their possibility to recover their former shape when heated. The SMA basket is used to remove kidney, bladder and bile duct stones. This basket is inserted into the human body in the same way as the Simon filter. presents a sequence of pictures related to the basket opening as it is heated. The intra-aortic balloon pump is used to unblock blood vessels during angioplasty. The device has an SMA tube whose diameter is reduced compared to polymer materials due to its pseudoelastic effect. Moreover, it also allows greater flexibility and torsion resistance when compared to the same tube made of stainless steel. Laparoscopy is another procedure where SMA have been employed. Figure shows some surgical tools where the actions of grippers, scissors, tongs and other mechanisms are performed by SMA. These devices allow smooth movements tending to mimic the continuous movement of muscles. Moreover, these devices facilitate access to intricate regions.



Figure. Intra-aortic balloon pump

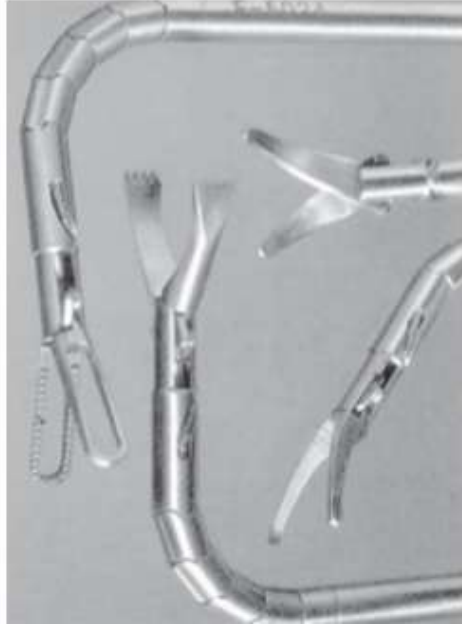


Figure. Laparoscopy tools. The actions of graspers, scissors, tongs and other mechanisms are performed by SMA.

Less invasive surgery - Guidewires

In the interventional radiology the different imaging techniques, including X-ray fluoroscopy and magnetic resonance imaging (MRI), are employed to guide the instruments and carry out advanced medical procedures. Such are, for example, re-establishing blood flow in blocked arteries or implantation of filters to prevent pulmonary emboli (blood clots) reaching the lungs. With Ni-Ti guide wires the catheters for a radiopaque contrast medium can be inserted through an artery into the required position and this medium reveals the possible blockages of the blood circulation in x-ray imaging. The route from the insertion point to the target (for example the heart or brain) can involve very small and wavy vessels and the strains required may result in permanent deformation and kinking of the guidewire. The localized strain peaks can be distributed uniformly and kinking can be prevented due to the recoverable strains of approximately 8 % in the Ni-Ti-wires. As the Ni-Ti wires do not deform or kink to large extent, their steerability and torque ability is good which in practice means that the problems associated with the accurate positioning disappear.

Artificial Muscles – case: function as the sphincter muscles

Shape memory alloys can also be applied as actuating muscles. In addition to the heart valve there are some other possible applications, too. One of them is a solution to a common old age problem, incontinence. This artificial urethra valve consists of four nitinol plates and is able to control the opening and closing of the urethra artificially, i.e. it substitutes the function of the sphincter muscles around the urethra.

VII. LITERATURE REVIEW

Mr F J Gil et al. (1998) reviews shape memory alloys for medical applications and describe that the most important alloy used in biomedical applications is NiTi and also reviewed the different properties of shape memory, super elasticity, two-way shape memory, rubber-like behaviour and a high damping capacity. He describe some applications proposed in recent years and classified according to different medical fields.

Mr Diego Mantovani (2000) present a review on Shape Memory Alloys: Properties and Biomedical Applications and describes the applications of shape memory alloys such as Orthopedic Applications, dental applications, cardiovascular applications, Other applications like gynecological and surgical instruments etc.

Mr Fatiha El Feninat et al. (2002) presented a review on Shape Memory Materials for Biomedical Applications and this paper will first review the most common biomedical applications of shape memory alloys and SMPs and address their critical biocompatibility.

Mr L.G. Machado et al. (2003) present a review on Medical applications of shape memory alloys . The purpose of this review article is to present a brief discussion of the thermomechanical behaviour of SMA and to describe their most promising applications in the biomedical area. These include cardiovascular and orthopaedic uses, and surgical instruments.

Takashi Maeshima et al. (2004) present a review Shape Memory Properties of Biomedical Ti-Mo-Ag and Ti-Mo-Sn Alloys and in this Ti-Mo-Ag and Ti-Mo-Sn alloys for biomedical applications are developed and their shape memory properties are investigated.

Mr S.-P. Hannula et al. (2006) present a review paper on Shape Memory Alloys for Biomedical Applications and reviews the biomedical applications of shape memory alloys consist of quite a broad field starting from the dental and less-invasive surgery where they are mostly used today. The orthopaedic applications were previously expected to become more numerous, but the development of the new materials such as polymers resembling the human bone has narrowed their field of use.

Mr Daniela Tarnița et al. (2009) presented a review on Properties and medical applications of shape memory alloys and in this paper a detailed reviews of 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 and 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.

Mr C. E. Wen et al. (2010) presented a review on Porous shape memory alloy scaffolds for biomedical applications and this paper reviews current state-of-the art on the processing, porous characteristics and mechanical properties of porous SMAs for biomedical applications, with special focus on the most widely used SMA nickel–titanium (NiTi), including (a) microstructural features, mechanical and functional properties of NiTi SMAs; (b) main processing methods for the fabrication of porous NiTi SMAs and their mechanical properties and (c) new-generation Ni-free, biocompatible porous SMA scaffolds.

Mrs Lorenza Petriniand et al. (2011) presented a review article on Biomedical Applications of Shape Memory Alloys and in this paper a detailed review of the main applications of NiTi alloys in dental, orthopaedics, vascular, neurological, and surgical fields is presented. In particular for each device the main characteristics and the advantages of using SMA are discussed. Moreover, the paper underlines the opportunities and the room for new ideas able to enlarge the range of SMA applications.

Mr Maria C. Serrano et al. (2012) presented a review on recent Insights into the Biomedical Applications of Shape-memory Polymers and discussed advances in the design of shape memory alloy with emphasis on materials investigated for medical applications. Future directions necessary to bring SMP closer to their clinical application are also highlighted.

Mr Gupta, Parbin K et al. (2012) present a review article on studies on shape memory alloys and this paper on “shape memory alloys” carries out simplified study of the crystallographic structures/ transformation of SMAs, general characteristics, working principles, commonly used alloys, and applications and describe many uses and applications of shape memory alloys have ensured a bright future for these metals. Main advantages of shape memory alloys may be summarised as - Bio-compatibility, Diverse Fields of Application, and Good Mechanical Properties (strong, corrosion resistant).

Marjan Bahraminasab et.al (2013) presented a review on NiTi Shape Memory Alloys, Promising Materials in Orthopedic Applications and describes Shape memory alloys (SMA) have provided new insights into biomedical area for cardiovascular, orthopedic and dental applications, and for making advanced surgical instruments. Among many SMAs, NiTi alloy is considered to be the best because of its superb characteristics. NiTi alloy possesses most of the necessities for orthopedic implantation and is used in a large number of applications.

Mr JaronieMohd Jani et al. (2014) presenta review of shape memory alloy research, applications and opportunities and This work provides a timely review of recent SMA research and commercial applications, with over 100 state-of-the-art patents; which are categorised against relevant commercial domains and rated according to design objectives of relevance to these domains (biomedical and other).

Mr Ferdinando Auricchio et al. (2015) presented a review on shape memory alloy biomedical applications and describe Shape memory alloys (SMAs) are a group of metallic materials that exhibit unique properties. The most used SMA in the biomedical field is Nitinol (NiTi), which is discussed.

Mr Benjamin Qi Yu Chan et al. (2016) presented a review on Recent Advances in Shape Memory Soft Materials for Biomedical Applications and discuss the design considerations critical to the successful integration of SMPs for use in vivo, also highlight recent work on three classes of SMPs: shape memory polymers and blends, shape memory polymer composites, and shape memory hydrogels.

Mr Aniket Kolekar et al. (2017) studied recent Advancement in Shape Memory Alloy and describes the attributes of SMAs that make them ideally suited to actuators in various applications such as biomedical and addresses their associated limitations to clarify the design challenges faced by SMA developer. This work presents an extensive review of SMAs, other categories of SMMs are also discussed; including a historical overview, summary of recent advances and new application opportunities.

Mr Chunsheng Wen et al. (2018) presented a review on Mechanical behaviours and biomedical applications of shape memory materials and in this review, he provides an overview of mechanisms and biomedical applications of some common SMAs and SMOS, experimental evidences on their mechanical biocompatibility and some aspects of computational modelling., also challenges and progress in developing new shape memory materials for biomedical applications are also presented.

Mr VybhaviShivakumaret al.(2018)) presented a review on studies on biocompatibility of shape memory alloys and the paper is a review of biocompatibility of shape memory alloys. Based on the literature review, research objectives were defined and also the future frame work for the synthesis and evaluation of biocompatibility of Cu-Al-Mn shape memory alloy for bio-medical applications

VIII. SUMMARY OF LITERATURE SURVEY

From the literature review, it was observed that the biomedical applications of shape memory alloys consist of quite a broad field starting from the dental and less-invasive surgery where they are mostly used today. The orthopaedic applications were previously expected to become more numerous, but the development of the new materials such as polymers resembling the human bone has narrowed their field of use. The most applied biomedical shape memory alloy is Ni-Ti (nitinol) and some of the possible problems connected to its use can be overcome with different types of surface modifications and coatings. 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. Also studied properties and biomedical applications. The biomedical applications of shape memory alloys are Orthopaedic applications, dental applications, cardiovascular applications, Other applications like gynaecological and surgical instruments etc

IX. FUTURE SCOPE

In the coming years, a true revolution will occur in some medical specialties. The revolutionary advancements in endovascular surgery have already injected new challenges in the traditional vascular surgery. New horizons have been opened, and clinicians, scientists, and industrialists are starting to work together to master the complexity of a problem through a multidisciplinary approach. In the near future, more medical devices will be engineered with smart materials because of their inherent sensing and actuating capabilities, which allow for sophisticated functionality over otherwise passive conventional materials. Development of new or improved SMAs, combination of the functional properties of SMAs with the structural properties of other materials (e.g. hybrid or composite SMMs) search for new markets. SMP present significant advantages when compared to traditional shape-memory alloys, including lower density, lightweight, lower cost of raw materials, lower cost of fabrication and processing, and easy tailoring. Furthermore, the resulting materials have higher versatility in shapes, higher recovery strains (>300%) and lower recovery stresses (1–10 MPa).

Shape memory hydro gels, on the other hand, have weak mechanical properties that may pose challenges with regard to potential biomedical applications. Concentration of cross-links and the collective strength of various inter

chain interactions are important factors to be considered in the design shape memory hydro gel systems due to the interdependence between shape memory behaviour and mechanical properties. Apart from the types of stimuli mentioned above, shape memory hydro gels can also be triggered by stimuli such as pH, ion concentration, a redox reactions or ultra sound.

In recent years, medicine and the medical industry have focused on the concept of less invasive surgical procedures. Following this tendency, shape memory surgical instruments have been created and are becoming noticeable. Among the advantages of these tools, one can emphasize their flexibility as well as their possibility to recover their former shape when heated. The SMA basket is used to remove kidney, bladder and bile duct stones. This basket is inserted into the human body in the same way as the Simon filter.

The needs of biocompatibility represent a constraint that is not insurmountable but one that cannot be circumvented for the use of SMA in the field of medicine. Today, the advance of biomedical applications of SMA is important even though the level of knowledge in regard to its biocompatibility remains stagnant.

REFERENCES

1. Prof Mr. Aniket Kolekar, Mr. Akshay Natak, Mr. kiran Navratne, Prof. Mr. Amol Mali "Recent Advancement in Shape Memory Alloy" *International Research Journal of Engineering and Technology (IRJET)* Volume: 04 Issue: 04 Apr -2017.
2. Vybhavi Shivakumar, A.G. Shivasiddaramiah, C. Shashishekar, U.S. Mallikarjun "Studies on Biocompatibility of shape memory Alloys". *International Journal of Engineering Research in Mechanical and Civil Engineering (IJERMCE)* Vol 3, Issue 5, May 2018
3. Benjamin Qi Yu Chan, Zhi Wei Kenny Low, Sylvester Jun Wen Heng, Siew Yin Chan, Cally Owh, and Xian Jun Loh "Recent Advances in Shape Memory Soft Materials for Biomedical Applications" *Department of Materials Science and Engineering, National University of Singapore, 9 Engineering Drive 1, Singapore 117576, Singapore 2016*
4. Daniela Tarnita, D. N. Tarnita, N. Bizdoaca, I. Mindrila, Mirela Vasilescu "Properties and medical applications of shape memory alloys" *Romanian Journal of Morphology and Embryology* 2009.
5. F J Gil and J A Planell "Shape memory alloys for medical applications" *Journal of Engineering in Medicine* 1998.
6. S.-P. Hannula, O. Soderberg, T. Jamsa and V.K. Lindroos "Shape Memory Alloys for Biomedical Applications" *Advances in Science and Technology* Vol. 49 (2006).
7. Daniel J. Hoh, Brian L. Hoh, Arun P. Amar, Michael Y. Wang "shape memory alloys: metallurgy, biocompatibility, and biomechanics for neurosurgical applications" *Department of Neurological Surgery, Keck School of Medicine, University of Southern California, Los Angeles, California volume 64 | operative neurosurgery 2 | may 2009.*
8. L.G. Machado and M.A. Savi "Medical applications of shape memory alloys" *Brazilian Journal of Medical and Biological Research* (2003)
9. Takashi Maeshima and Minoru Nishida "Shape Memory Properties of Biomedical Ti-Mo-Ag and Ti-Mo-Sn Alloys" *Materials Transactions, Vol. 45, No. 4* (2004)
10. Lorenza Petrini and Francesco Migliavacca "Biomedical Applications of Shape Memory Alloys" *Hindawi Publishing Corporation Journal of Metallurgy Volume 2011.*
11. Debdatta Ratna J. Karger-Kocsis "Recent advances in shape memory polymers and composites" *J Mater Sci* (2008)
12. C E Wen, J Y Xiong, Y C Li and P D Hodgson "Porous shape memory alloy scaffolds for biomedical applications" *Institute for Technology Research and Innovation, Deakin University, Waurin Ponds, VIC 3217, Australia Phys. Scr. T139* (2010).