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REVIEW ARTICLE

Introduction to Shape Memory Material: Biomedical, Prosthetic and Orthotic Application

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ABSTRACT

The need for prosthetic and orthotic devices is increasing significantly all over the world. Due to the increasing incidence of sports injuries and road accidents, the rising number of diabetes-related amputations, and the growing prevalence of osteosarcoma around the world are poised to drive the global market. Sports-induced injury is anticipated to drive demand, aiding market growth during the forecast period. The global prosthetics and orthotics market was valued at USD 6.39 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 4.3% from 2022 to 2030. Materials like polymers (Polypropylene, Silicon, etc.), metals (Aluminium, Iron, etc.), alloys (stainless steel, bronze etc.), and carbon fibers are now used for making prosthetic and orthotic devices. Shape memory polymers (SMP) and shape memory alloys (SMA) are having ability to change and regain their original shape after changes in external stimuli like temperature, PH, heat, etc. This review has discussed shape memory materials' mechanical, chemical, and general properties, including their classification, advantages, disadvantages, FDA regulations, and applications in prosthetics and orthotics. This review will help prosthetists, orthotist, and biomedical engineers better understand these materials and how they increase the medical devices' quality, durability and functionality.

Keywords: Prosthetics, Orthotics, Shape memory polymers, Shape memory alloys.

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INTRODUCTION

Shape memory materials (SMM) are novel and smart materials that have the ability to regain their shape after a change in temperature or stress on them.[1] Properties like super-elasticity and shape memory make it different from the other materials. Due to their unique properties, these materials are very popular in many fields now. Due to the smart nature of this material, shape-memory alloys and polymers are very popular now. Apart from the aerospace, engineering, and civil fields, shape memory materials are getting popular in the biomedical field.[2] Some of the materials in this family also meet the demand for bio-inertness and biocompatibility, indicating an application in implants. Because of its dynamic nature, it is also beneficial in the fields of prosthetics and orthotics. SMA has unique thermo-mechanical properties known as martensitic transformation. SMA has a super elasticity or pseudo elasticity feature in which there is recovery after the application of significant strain only mechanically while loading and unloading. Without any externally imposed change in temperature, super elasticity arises. This process occurs if loading and unloading occur at a specific temperature.

The chart given below shows the process of the material transformation from austenitic to the detwinning phase after the application of the force. It regains its original shape after the withdrawal of the applied force. These changes will happen at a constant temperature.

This chart shows the full process of the material from its austenitic phase to the detwinning phase on loading, and immediately after unloading, the martensite begins to transform back to austenite. This process happens while the temperature remains constant. SMAs have been used in a wide range of applications where large amounts of deformation are required. Some of these applications are frames of eyeglasses, CV stents, cell phone antennae, and dental arches. The hardness of the SMA depends on the elastic modulus of each transformation (EA for the austenite phase and EM for the martensitic phase) and the total martensitic volume fraction (z) that represents the hysteresis curve.

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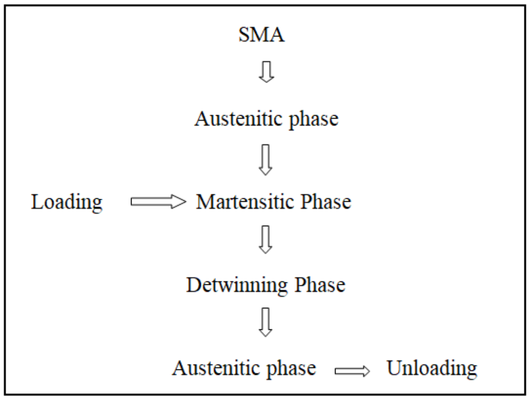

Figure 1: Phase transformation of SMM

The crystalline shape of the shape memory materials

The properties of any material totally depend on its crystalline structure. The atomic arrangement of any crystal determines its behavior and properties. Each metal or polymer substance has a unique lattice structure; in the case of the shape-memory alloy and the polymers, the crystalline structures are always different, which makes them novel and smart.[3] Shape memory material has two different phases. Austenitic and Martensitic have two different structures, so there are six possible formations of the same substance with different properties. The structural difference in shape-memory material changes the strength and elastic properties of the material.[4,5] The transverse rate of the material also varies from material to material.

General properties of shape memory material

Shape memory effect[6]

It is the main and most important property of shape-memory material. Shape-memory materials are smart materials that undergo deformation when external stimuli are applied, like a change in stress, temperature, PH, etc., but this type of material has the characteristic that it doesn't undergo any permanent deformation and has the ability to regain its shape after the removal or change in the external stimuli.[7]

Super elasticity or pseudo plasticity

It is characteristic of materials related to strain and stress of the material under a constant temperature. The proper super elasticity of the material is demonstrated under constant temperature (Isothermal) or constant pressure (Isobaric) conditions. There is applied stress on the material, which leads to deformation. The form of the material changes from martensitic to austenitic, which are the different phases of the shape-memory material.[8] Shape-memory material shows the hysteresis loop of the transformation and the recovery in the strain and stress profile.

Damping of material

It is the property of every material that converts mechanical energy into heat energy. After performing a large function, every material produces heat. This material property is important in the case of phase transformation from martensitic to austenitic and vice versa.[9]

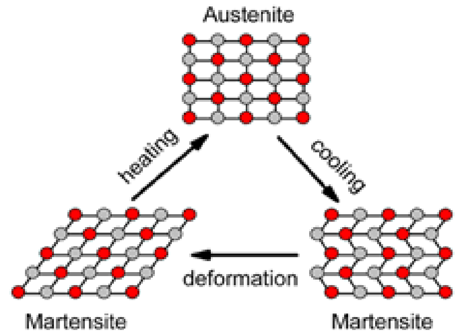

Figure 2: The crystalline structure of shape memory Materials

Mechanical Properties of Shape Memory Material

Young's Modulus

Any material's mechanical characteristic gives it strength, elasticity, and toughness. This is a very important property in terms of shape-memory material. While using this material for any application, its properties are tested and it needs to be compatible with standards, which is needed for any application.[10] Each variant of the SMM has a different Young's Modulus. Alloys with shape memory show more Young's modulus than polymers with shape memory.

Flexural Modulus of the SMM

Flexural modulus determines material bending. This bending test is performed by the three-point bending test.[11] This is an important characteristic in terms of metals and alloys.

Fracture Toughness

It is the maximum pressure at which any material will break. This type of character of the material defines its toughness. In the case of alloys, toughness is very important. Metals and alloys are tougher than non-metals or polymers.[12]

Plasticity and Elasticity

Plastic and elastic behavior are important in the case of polymers. In the case of prosthetics and orthotics, plasticity plays an important role. Shape-memory alloys are also used in prosthetic hands and actuators for the hands.[13]

Fatigue Strength

Fatigue strength is an important property of any material that determines its application. It is the maximum strength that any material can withstand after a number of medical cycles.[14]

Advantages of SMM

- Due to their best response to external stimuli like temperature, PH, and an electrical field, these are the best materials to be used in the medical field and a better alternative to conventional materials.[15]
- These are smart materials, and hence they are significantly used in composite as well as piezoelectric materials.
- SMMs have the ability to act in 3D, allowing them to easily extend, bend, and twist, making them useful.
- These dynamic materials are very flexible to use for various

Table 1: Properties comparison of SMA & SMP

Sl. No.	*Properties*	*SMP*	*SMA*
1.	Density	0.9 to 1.25	6 to 8
2.	Phase transformation	Glass type transformation	Martensitic transformation
3.	Strain Percent	400 to 800	Up to 10%
4.	Recovery stress (MPa)	1 to 5	100 to 300
5.	Recovery time	10 sec. to 1 min.	Less than 10 sec.
6.	Deformation stress (MPa)	1 to 5	50 to 200

applications.

- The specificity of the material is identical to that used in various biomedical applications.

Disadvantages of SMM

- This material needs very specific external stimuli to change its shape.
- The cost of this type of alloy is high compared to normal material.
- Control of the characteristics of these materials is very difficult.

Problems associated with SMM

Sterilization

In the field of medical devices, sterilization is a very important part. Various methods, like heating or cold sterilization, do sterilization. Due to a change in heat, the shape or function might change. That is why it is very difficult to sterilize the devices using heat. Medical devices are also sterilized using gamma or other kinds of radiation. If we sterilize using such radiation, there may be the chance of the generation of free radicals; these free radicals might be carcinogenic.[16]

Toxicity and Biocompatibility

Cell toxicity or cell lysis may happen when any material comes into direct contact with cells. Genotoxicity is a toxicity in which the polymers of DNA are damaged. These polymers are responsible for DNA replication and cell division. Some of the plastic-like material or polymers are responsible for cell lysis; therefore, the selection of a proper SMP is very important. The cell death or cell lysis could be determined by MTT (3, 4-dimethylthiazol-2-yl) and 2, 5-diphenyltetrazolium bromide), gel electrophoresis, or ELISA (enzyme-linked immunosorbent assay). When selecting the Shape Memory Polymers (SMP) or Shape Memory Alloy (SMA) for implants or insertion in the body, biocompatibility is a key aspect of material selection.[17]

Biodegradability

This is a phenomenon in which the material will degrade in the body of any organism. In the case of implants or scaffolds, tissue formation occurs. The material must degrade simultaneously as it forms tissue. But in some conditions, the materials are unable to degrade, and there may be problems with toxicity associated with them. Its characteristics must be determined while selecting the material for such an application. Some of the shape-memory materials meet the requirements for materials used in tissue engineering.[18]

Types of memory materials

High heat shape memory material

Nowadays, the need for high-heat shape memory materials (HHSMMs) is increasing enormously in the field of engineering as well as medical applications. To fulfill this type of requirement HHSMMs are used. High-temperature sensitivity of the material will help with deformation after the huge change in heat. This type of material is processed at temperatures above 100°C[19] but its limitations include low ductility, poor fatigue, and high cost. To reduce the cost of these materials, researchers are finding an alternative option. The use of copper in making the shape memory alloy will help reduce the cost and increase its heat sensitivity. Ex. TiNiPd, TiNiPt, NiTiHf, NiTiZr, and CuAlMnNi.

Magnetic shape memory alloys

Because the actuation energy is conveyed by magnetic fields rather than the comparatively sluggish heat transfer mechanism, magnetic alloys shape memory (MSMAs), also referred to as ferromagnetic shape memory alloys (FSMAs), may show an actuation process at higher force (up to 1 kHz). At stresses as large as SMAs, the FSMA tensile stress is remarkably comparable to that of magnetostrictive and piezoelectric active components. The same particular power as SMAs can also be delivered by FSMA,[20] albeit at higher frequencies. The massive magnetostrictive Terfenol-D (TbDyFe2) has a maximum strain that is 32 times greater than that of FSMA, and FSMA trades off greater strain for 46 times less elastic modulus (stiffness). In light of this, FSMAs are well suited to bridge the technical barriers in smart materials and magnetostrictive materials and would serve a specific need in motors and valve applications that need much higher displacement at a lower force.

Shape Memory Materials thin film

This type of shape-memory material is modified for the improvements of the fabrication process. SMM are directly coated on the micro-machines or components. The field of microelectromechanical systems is increasing rapidly due to the fact that these materials are finding applications. Ni-Ti is a very versatile material that shows various properties like multiple degrees of freedom, a compact structure, and the potential to expand.[21,22]

Shape Memory Polymers

Shape memory polymers are the best alternative to shape memory alloy in terms of cost and use. Its primary application is as tailor-maid material. SMPs show good mechanical properties and biodegradability, making them useful for implant and scaffold applications.[23,24]

Table 2: Shape memory material application

Material	*Examples*	*Application*
Metals/ Alloys	NiTi, CuZn, FePt, AuCd, etc.	- Actuators is prosthetic and orthotic devices. - Cardiac stent and valves - Dental Implants - Sutures and surgical staples
Polymers	Nitrile Rubber, PU, PMMA, PET- PEG.	- Artificial Heart - Contact Lenses - Prosthetic sockets - Soft Orthotic Devices
Ceramics	ZrO_2, MgO.	- Hip Implant Sockets - Eyewear Glasses.

FDA regulations for SMM-made devices

The Food and Drug Administration does not have any regulations on the shape of memory material as such. But the medical devices that are made out of shape-memory material come under regulation. The devices made by SMM are mostly used in implants like cardiac stents and dental implants, so they fall under Class III of medical devices.[25]

Different Applications of Shape Memory Material

Cardiovascular Applications of SMM

In the cardiovascular system, SMMs are used in cases of thromboembolism and angina. The Simons filter was used in embolism to prevent blood clots from passing through it. Cardiovascular stents are also used to prevent heart attacks. These devices are inserted into the circulatory system via catheters containing a saline solution and take shape after being exposed to the blood environment.[26]

Orthopaedic Application of SMM

The SMM material is mainly used as vertebral spacers in the case of patients with scoliosis. The SMM spacer plays an important role in avoiding the jerk moment after spinal surgery.[27]

Neurosurgical Application of SMM

Coils or wires made of the memory, mainly the NiTi (Nitinol) alloy, is used mainly to treat the aneurysm of the vessels. Aneurism is a bulginess in one part of the vessels that may lead to hemorrhage. To avoid this, the ball of the shape-memory alloy is being used.[28]

SMM in Pharmaceuticals

4D printing is getting popular nowadays. 3D-printed pharmaceutical dosage forms are also a broad field of research. For this type of prototyping, smart materials are required. Smart materials" are the materials.[29]

Surgical Sutures and Staples

Surgical sutures and staples are used in medical procedures to close wounds. These types of sutures or staples are very important for tightening the tissues. Sutures or staples are used internally or externally for the fixation of the wound; if sutures fail or tightening does not occur, then it leads to internal bleeding and other complications. To overcome this problem, shape memory material SMM is being used. At the body's temperature or blood PH level, it takes proper shape.[30]

SMM in Tissue Engineering

Tissue engineering is also an important field of biomedicine. This method generates new tissues and organs. For the proliferation and growth of cells, scaffolds play a very important role. The scaffolds are externally made devices that provide medium to the cells for their growth. Scaffolds are mainly made of polymeric material; shape-memory polymeric materials are widely used for such an application.

Shape Memory Alloy in Prosthetics and Orthotics

Orthotics

The role of orthosis for gait-related deformities with several disorders (such as foot drop, spasticity, etc.) includes applying various braces for muscles or several joints. This brace's main role is to improve balance, gait, and muscle strength. The passive mechanical braces help to correct the deformity and prevent it from returning at no specific time or day. The recovery of the patient depends on the use of the device and exercise. Patients with stroke, for example, typically have foot drop deformity due to muscle weakness. In these cases, a posterior leaf spring (PLS) AFO helps to constrain the ankle to a specific position with limited flexion. The ROM determined this limitation of ankle ground clearance and improved gait naturally. The PLS AFO allows mobility, but it should not be more flexible; neither will there be a chance of breaking, nor should it be too stiff, which can limit the ankle's motion. The flexibility and rigidity of the PLS AFO should be decided according to the patient's satisfaction. All these AFOs need external power from the respective subject, and the application is limited. A portable powered ankle-foot orthosis (PPAFO) was developed at the University of Illinois[31] using a pneumatic actuator, a CO2 power source, and an onboard controller.

Shape-memory alloy An AFO promotes sufficient ankle motion and stability in terms of safety. Two generations of designs based on the thermo-mechanical properties of SMAs were developed at the University of Toledo 32-34. First, an SMA-based AFO must satisfy the required motion. Second, it increases the limitations of superelastic elements' ability to store and release energy. The first generation can do this by using an actuator, but it has been observed that the response time of the actuator is not good enough for normal walking.

Orthotics of SMM

Subjects suffering a muscular stroke cannot move due to the absence of sensations in them. For improving activity, proper blood supply and muscular activity are necessary to improve. Ankle-foot orthoses (AFO) are orthotic devices prescribed by the physician for improving conditions. A shape-memory alloy, i.e., Ni-Ti (Nitinol 250), is preferably used in such types of muscular problems. Two actuators made of SMA are fixed on either position of the AFO[35], which allows the free movement of the leg. It preferably promotes the dorsiflexion of the ankle joint. The problem of stroke arises in the patient, especially in the arm, and when it gets severe, it leads to muscle spasms. This type of deformity needs exercise.

Gait Cycle

Gait can be defined as an alternating movement of the lower limb in a systematic manner that leads to the forward movement of the body with minimal energy requirement. The gait cycle is divided into two phases: the stance phase and the swing phase.[36]

Stance Phase

This phase starts when the foot hits the floor and ends when the same foot got lifted from the ground. This phase consists of approximately 60% of the gait cycle.

Swing Phase

This phase starts when the foot got lifted from the floor and ends when the same foot lands on the ground. This phase covers approximately 40% of the gait cycle.

In a normal gait, during the loading response phase, the foot goes into plantarflexion, which drives the feet toward the floor. During mid-stance, motion of the ankle provides propulsion to the limb. In the stance phase, dorsiflexion will be provided by body movement over the leg. At heel-off, the GRF shifts to the anterior part of the body, and the pressure comes on the forefoot area of the foot. Push-off, or plantar flexion at the conclusion of the stance, results from the calf muscle's contraction. Pretibial fibers play a significant role in the commencement of the swing phase by generating foot dorsiflexion. Midway through the swing, the dorsiflexion moment diminishes. At the conclusion of the swing, pretibial muscles will once more govern ankle position in order to produce the required force for the subsequent initial contact. Patients with foot drop have weak pretibial muscles, which makes it difficult to control the foot from the heel strike to the toe off throughout the stance phase and prevents dorsiflexion throughout the swing.

Prosthetic

In amputation cases, patients use a prosthetic arm and leg to replace the original anatomical limb. The artificial limb should be lightweight, compact, and dexterous while maintaining a high lifting capacity.[37] The prosthetic robotic hand should be actuated by artificial muscles, in which the patient can control multiple degrees of freedom and activity. The prosthetic arm works with electromyography (EMG) signals. These signals

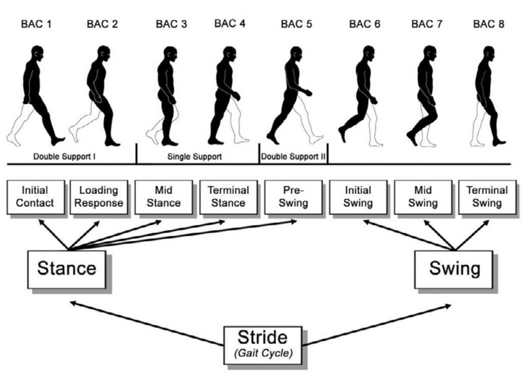

Figure 3: Normal gait cycle

were obtained from the remaining cutting part of the hand by placing an electrode on the muscles with the highest function. The main application of shape memory alloys are their minor size, more weight-to-force ratio, volume and weight, lower cost, and humanoid behavior.

Before upper extremity amputation, hand prostheses use an end device (hand or hook) controlled by the shoulder bone movements transmitted via a body-powered cable. Then the next version comes the myoelectric hand[38], which works with motors triggered by the contraction of muscles in the residual limb. The myoelectric prosthesis has a major problem: it increases the weight of the prosthesis due to the electronic components. The functionality of the myoelectric hand is very limited, i.e., only opening and closing. These closing and opening are between the two or three fingers of the hand: the thumb, index, and middle. It provides a limited ability to hold and manipulate objects. The gripping ability is often less because of the lack of sensory response. The improved control of holding and degree of freedom with sensory feedback would improve the function of an upper prosthesis. The prosthetic robotic hands have more griping patterns and a greater capability of weightlifting and finger joint movements.

The limitations are:

1. The voluminous, heavy, weak actuator that cannot be compatible with the human anatomical hand.
2. The use of very traditional approaches
3. There is less sensory feeling between human and artificial members.
4. There is a communication gap between the robot and the human.

The Anatomy of Arm

The shoulder joint is one of the most complex joints, but this is the most freely movable area in the human body because of the articulation at the glenohumeral joint. The shoulder joint contains the shoulder bone, which connects the upper limb to the axial frame via the sternoclavicular joint. The shoulder joint contains four joints: the sternoclavicular (SC), acromioclavicular (AC), scapulothoracic, and glenohumeral joints.[39] The glenohumeral joint, also known as a ball and socket joint, is joined together by muscle and ligaments. It has three degrees of freedom to mimic exact human motion. A draught pin holds the hinge joint together. The lower part of the elbow is connected to the radius and ulna of the forearm by the elbow joint. These two bones, the radius and ulna, allow forearm rotation.

Application of SMM in the actuator of a prosthetic

Prosthetic or robotic hands are very popular now. The prosthetic hand is to be manufactured in a way that it will show gripping movement with different grip patterns. Shape Memory Materials were used to create actuators. In the gripping pattern, a wire or bundle of wires is induced in the prosthetic.[40]

This type of actuator is also used in prosthetic legs and knee joints. Knee joints have different degrees of freedom. For proper load bearing, stability, and movement of the leg, shape memory alloy wires are being used.[41]

Robotic hand finger with SMA

One finger for a robotic hand has been developed recently with shape-memory alloy. The finger is made of three degrees of freedom controlled by a set of wires and artificial wires. The cables work like tendons, are connected one-fourth inch from the axis distal to each joint (forward of the axis) and run along the length of the bottom of the finger.[42] The cable usually crimps to six-inch SMA muscle wire, placed parallel to each other three inches from the finger like in a human hand. For smooth function, each finger joint is attached with a small spring to provide the recovery force needed to reposition the finger to its original configuration.[43-47] The placement of artificial tendons and muscle wires in relation to fingers, palm, and forearm for direct application to a prosthetic device.

CONCLUSION

This review concluded that shape memory material has some unique features like pseudo-elasticity and shape memory effect. Due to its crystallographic arrangement, these materials have good thermal and mechanical properties. Here we discussed the crystallographic arrangement, types of these materials, mechanical properties, advantages and disadvantages of material, problems associated with these materials, and its application in biomedical devices and prosthetics and orthotics. In this article, we briefly described the prosthetics and orthotic devices and use of the shape memory material in this field, and how this material will help to increase functionality, durability and strength. We also discussed the regulatory requirements of shape memory materials. Along with prosthetics and orthotics application of this material in the fields like implant, tissue engineering, neuromuscular surgeries, orthopedics, and pharmaceuticals is mentioned shortly. This literature about the given material will help engineers, medical practitioners, prosthetists and orthotist manufacture various devices. Presently these materials are getting popular in prosthetics and orthotics. This need also will increase in the future.

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