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ABOUT SOME ISSUES CONCERNING SHAPE MEMORY ALLOYS APPLICATIONS IN NEURO-REHABILITATION

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Shape memory alloys (SMAs) are a very promising class of metallic materials showing promising nonlinear properties, such as pseudo-elasticity behavior, shape memory effect and damping capacity, due to high mechanical hysteresis and internal friction. SMA have been recently applied in the field of neuromuscular rehabilitation, designing some new devices based on the above properties. The paper discusses possible uses of these materials in the treatment of movement disorders, such as dystonia or hyperkinesia, where their dynamic characteristics can be the key issue.

Key words: shape memory alloys, phase transformation, properties, pseudo-elasticity, neurology

INTRODUCTION

Shape memory alloys (SMAs) are unique materials since they can retain their original form, after being deformed by the application of heat above a certain temperature. Shape memory alloys are characterized by two stable crystallographic phases: austenite and martensite. Austenite is the high temperature phase and martensite is the low temperature one. During heating, the alloy changes from the martensite phase to the austenite phase. Vice-versa on cooling. This feature of it and its superelasticity is what is used for all the application purposes.

The use of SMAs has increasingly expanded in recent decades [1-4]. Many researchers have intensively been involved in activities aimed at exploring innovative devices and applications, making use of these smart materials. Indeed, the number of commercial applications is growing each year, with the largest application segment of the market represented by actuators and motors. The global market for smart materials was approximately \$ 19,6 x 10^9 in 2010; it is estimated to \$ 80 x 10^9 by the end of 2019, with an average annual growth rate of 7,8 % between 2010 and 2019 [5].

The shape memory alloy's market is not characterized by few active players in the world. The market players are mainly from Europe, Asia and the US. Growth driver for the shape memory alloy market is the advantage that it gives with respect to conventional systems that are setup in automotive and aerospace: due to its temperature sensitiveness, it does not need a whole system to behave like an actuator. It is resilient, wear resistant, temperature activated, bio-compatible, flexible and non-corrosive. Its replacement in place of the conventional actuators is advantageous as it reduces the weight of the body and it is cost effective. Since it is temperature activated, it also does not require any kind of secondary working system for the actuation.

SMAs show physical and mechanical features that made them successful candidates for use in structural engineering applications [6-9] and for nuclear applications [10]. Up to know, SMAs played a key role in the development and implementation of smart materials/devices, which can be integrated into structures to provide functions such as sensing, energy dissipation, actuation, monitoring, self-adapting, and healing of structures. In recent decades, intensive research efforts have been concentrated in the field of structural engineering, aiming at employing smart engineered systems in civil engineering applications, with emphasis to seismic response control of structures also in partial substitution of most commonly used steel materials [11-15]. Just as an example, several innovative systems and devices, mainly using NiTi and Cu-based SMAs, have been developed aimed to absorb a part of the seismic energy and reduce the earthquake forces acting on a structure, for damping control, structural retrofit, etc. SMAs have been integrated within these devices in many possible shapes and configurations, such as single and stranded wires, ribbons, strips, tubing, and bars.

Another major growth driver for the shape memory alloy has also been the boom in the medical sector and in general in the health sector, using shape memory alloy in dental, orthopedics, neural, vascular and surgical fields. This is mainly due to its good bio-compatibility, excellent magnetic resonance and Computer Tomography (CT) compatibility. This was also favored by an increasing use of Additive Manufacturing (3D printing) processes applied to metallic materials [16-17] with consequent customization of the component.

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Following SMAs promising properties in terms of non-linear behavior, in the last years they have been applied in the field of neuromuscular rehabilitation, designing some new devices based on the above recalled SMA properties [18-19]. As a matter of fact, the use of conventional materials strongly limits in terms of versatility because material properties are fixed and do not adapt to the dynamic changes in patient's clinical needs or disorder evolutions. Materials with unusual and non-linear properties, on the other hand, can offer possible alternatives to standard ones [20-21]. A satisfactory balance between deformability, strength, weight and reliability gives the SMA materials the right characteristics to be employed in the physical rehabilitation field. Among the several properties of SMA, pseudo-elasticity and the shape memory effect are the most useful in neurology and neuromuscular rehabilitation applications: in particular, stable (quasi-constant stress levels) and long (large deformability ranges) *plateaux* and also the possibility to modify those parameters with thermomechanical treatments can be exploited in designing a variety of devices and solutions for rehabilitation; also the internal friction and mechanical hysteresis characteristics show allows such materials to be used for such applications.

SMAs PHENOMENOLOGY

SMAs are a heterogeneous class of metal alloys. The main groups are ferromagnetic and non-ferromagnetic alloys, but only the non-ferromagnetic ones have practical applications. Among the non-ferromagnetic SMAs, two classes of compositions have been employed practically: Cu-based and NiTi-based, but the NiTi-based ones are the most widespread due to their superior characteristics in most applications. Ni-Ti is a quasi-stoichiometric intermetallic compound with the predominant feature of undergoing an a-thermic reversible martensitic transformation between a cubic (B2) parent phase (austenite) and a monoclinic (B19') one (martensite). This phase transformation in the metallic lattice is at the base of interesting macroscopic effects, such as the Shape Memory Effect (SME) and Pseudo-Elasticity (PE). The direct B2–B19' transformation can be obtained by either cooling or introducing mechanical strains. Cooling the alloy in the B2 structure to a temperature lower than a characteristic point (M_s) induces exothermal formation of B19' in twinned ordering, without any macroscopic change in shape; on the other hand, subjecting B2 to strains in excess of approximately 1 % – 1,5 % leads to a reversible movement of atomic layers and the formation of an un-twinned (or de-twinned) version of B19'. Conversely, starting with a martensitic structure, ~~the~~ heating up the alloy above a characteristic temperature (A_s) sets an endothermal transformation from B19' to B2; straining a twinned B19' structure produces a de-twinned B19'. For thermally-driven processes, transformations can be considered complete below M_f (direct transition B2–B19') and above A_f (reverse transition B19'–B2). In the mechanically-driven formation of de-twinned martensite, stresses for initiating the process are proportional to the alloy temperature (Clausius–Clapeyron's law). The precise values of characteristic temperatures M_s, M_f, A_s and A_f are functions of Ni content and depend, more subtly, on thermomechanical processing. Increases of one part in the thousands in Ni atomic concentration can produce drops by tens of degrees Kelvin in characteristic temperatures. Coming to the practical exploitation of these effects, because the de-twinning stress of initially twinned martensite is low compared to the de-twinning stress for the B2 phase (the latter is stable at higher temperature), NiTi is more deformable in martensitic state. By de-twinning B19', it is possible to obtain recoverable strains of up to 10 %; recovery is achieved through heating above A_f and the consequent reverse transformation to B2. This is called the SME. Thanks to SME, a weight heavy enough to induce B19' de-twinning at a temperature lower than M_f can be lifted during heating-induced strain recovery at a temperature appropriately higher than A_f. SME is indeed a means of making solid-state actuators. PE is a different aspect of the same phenomenon. For alloys having an A_f lower than room temperature, the initial state before straining is B2. With a proper level of stress, de-twinned martensite can be formed by deformation. Strains up to 10 % are readily recoverable upon removing the loading stress; being the working environment at a temperature higher than A_f, B2 is re-formed immediately. In this case, both the direct (loading) and inverse (unloading) transformations occur at constant stresses. The two *plateaux* are separated by mechanical hysteresis, and the area of the hysteresis loop corresponds to energy lost by structural viscosity in the process of loading and unloading. Fatigue life in SMA depends strongly on the levels of stress and maximal strains. Strains of 10 % are incompatible with cyclic applications, for which 4 % can be considered an upper limit, unless a high number of cycles is required, in which case, strains as low as maximum 1 % or less would be appropriate, depending on stress.

NEURO-REHABILITATION APPLICATIONS: SOME RESULTS

Some applications of SMAs in the field of neuromuscular rehabilitation ~~is~~ are reported and described, aimed to show the feasibility and relevant outcomes, and showing how the different functionalities of this class of materials can be applied.

Portable Devices for Passive and Aided Exercise

The physical rehabilitation of patients that suffer from paresis because of a neurological insult generally includes active exercise, which is often segmental at an initial stage and becomes increasingly functional as motor recovery proceeds. Although it is recognized that active exercise is extremely important for the re-acquisition of motor skills, passive mobilization of the limbs is also a standard part of physical treatment, because it can help safeguard the viscoelastic properties of tissues in otherwise disused muscles and joints. This approach is particularly important in the sub-acute period after the neural trauma, because in that phase, paresis itself precludes the active work-out of the patient. In addition to this, it can be imagined that a repetitive mobilization of the affected segments could help maintain viable a network of neuronal circuitry that is involved in movement planning and execution, at least by continually providing proprioceptive information and avoiding deafferentation. In this framework a portable mobiliser for the ankle joint was developed [22]. Portability was the fundamental requirement in order to make this device truly available to patients in the acute phase, because they are often bedridden and sometimes cannot even sit upright. The system is suitable to be utilized by patients sitting on or lying in bed. This characteristic differentiates the present device from other ones able to produce passive movements of the tibiotarsal joint. The concept was implemented using SMA actuation, because it allows compactness and low weight. For reasons related to the possibility of assessing the central effects of the therapy administered through this device, it was also of interest that the actuator should emit limited electromagnetic noise, in order not to affect electroencephalographic (EEG) measurements. This is also possible using SMA-based technology.

Compliant orthoses for limb repositioning

Spastic syndromes, are characterized by paresis, stiffness, involuntary phasic contractions and jerks of the limbs and, depending on the affected joint, unnatural flexion or extension. Immobility and disuse of the affected joints tend to have adverse consequences, in that holding a static position for a long time can determine a shortening of the muscles and a worsening of contractures and spastic reflexes [22]. Orthotic devices can be used to stretch muscles affected by this malformation to restore a more physiological neutral posture and increase usable joint range of motion. In the practice of standard orthotics, devices are used to hold the affected joint in a fixed position that is closer to the desired one, and muscles are expected to regain in time a more physiological length. The target position can also be changed in a stepwise manner by modifying the orthosis in order to proceed with the treatment. "Dynamic" orthoses are different because they aim at producing muscular remodeling by imposing forces or torques that pull in the desired direction. The target position is not fixed *a priori*, but it is the result of a dynamic balance between the pulling force of the muscles affected by contracture and the force offered by the orthosis. This behavior is much more physiological, because residual movements of the limbs are potentially preserved, and involuntary postural changes are allowed by the device compliance, thus increasing the general comfort. What is truly important is that, thanks to orthosis compliance, immobility and disuse are avoided and so is a major cause of the known negative chronic sequelae of paresis. Under the action of the corrective torque, the muscular lengthening process generally occurs in a slow and gradual manner: in this respect, therefore, the term "dynamic" must be interpreted just to mean the opposite of "fixed" or "static". In order to implement these concepts, a set of hinges has been recently reported [23] that can be used to create compliant orthoses. Inside the hinges two springs made of NiTi are placed, shaped as a capital letter omega (Ω). This specific shape allows the material to be loaded along its entire length, prevents localized stress concentrations and, ultimately, failures. The spring action is based on pseudo-elasticity. The nonlinearity and hysteretic behavior of NiTi-based alloys indeed endow these orthoses with convenient characteristics for this application and solve some inherent problems of dynamic splints with purely elastic elements. In fact, in classic elastic tension or torque elements, the spring-back forces change with elongation; assuming that those elements are preloaded in such a manner as to guide repositioning towards a desired posture, the corrective force applied to the limb will be high at the beginning of the process and ~~will~~ gradually decrease the closer the joint angle gets to the target. Clockwork springs could be used to counter this effect, but they tend to be either weak or bulky. On the contrary, the nonlinear behavior of pseudo-elastic SMA, due to the presence of long *plateaux* at quasi-constant stress, makes it possible to administer a continual therapeutic action even in proximity of the goal and in general for much wider deformation/elongation ranges.

By selecting appropriate thermo-mechanical treatments for the phase of shape setting, it is possible to obtain springs with different plateau stresses and lengths (deformability), and in this manner, alloy properties can be adjusted for different patients' needs. Hence, the following can be obtained simultaneously:

- providing a corrective push that is correlated to the biomechanical, biometric and clinical state of the patients, as well as to the likelihood that they will tolerate a given treatment intensity;
- maximizing acceptability and adherence to prescription times by making the corrective push mild enough and the orthosis sufficiently compliant to involuntary jerks that the pain induced by lengthening on spastic muscles is reduced;
- avoiding limb fixity, thus improving joint mobility and the chances of a residual use of the limb;
- avoiding the need to adjust spring preload as posture evolves and the associated burden for caregivers;
- self-regulating the strength of the orthotic action in relation to the direction of movement; thanks to SMA hysteresis, the stress during loading is higher than during unloading, so the perceived spring stiffness is higher for actions that are directed against the clinical goal.

Dynamic Applications and Movement Disorders

Some issues may arise with the use of wearable devices in the rehabilitation of neuromuscular diseases that have truly dynamic features. For instance, patients whose lower extremities are affected and have a residual capability of independent walking may perceive traditional orthoses as uncomfortable or quite rigid, because, while correcting for the exaggerated plantarflexion during swing, they do not preserve the ability to produce a physiological pattern of walking in all phases of the gait (e.g. plantarflexion is often hindered during propulsion). A pseudo-elastic orthosis for the ankle joint has been reported [15] and built with a valve on the frontal side of the leg and one on the dorsum of the foot. Straps hold the proximal valve in position, while the patient's shoe creates a suitable constraint for the other one. In this way, the calf and the sole remain free. The pseudo-elastic orthosis was equipped with two *ad hoc* omega-shaped NiTi springs able to support the patient's foot, leaving the plantarflexion/dorsiflexion motion free.

Tunability and Optimization of Characteristics

The properties of SMA are tuneable, *i.e.*, by changing alloy composition or applying suitable thermo-mechanical treatments, material characteristics, such as the transformation temperatures, the height and length of the stress *plateaux*, and to some extent, the hysteresis, the cycling stability, the internal friction, etc., can be adjusted to the final application. This opportunity offered by SMA can be exploited to modify material behavior and meet specific clinical requests, as well as the needs of the one patient for whom a certain therapeutic device is made. Some studies reported in the open literature took full advantage of that possibility, by customizing each single device to patients' characteristics, such as age, severity, affected joint, tolerance, pain, etc. Let us consider a wearable device application, like an orthosis: in practical terms, it can be imagined that a certain number of optimized processes can be utilized to produce SMA elements with as many different final properties, each of which may be suitable for a subgroup of patients with a set combination of the mentioned characteristics (age range, severity range, etc.). In this manner, *ad hoc* devices could be prescribed for each subgroup, thus improving tolerability and outcomes.

CONCLUSIONS

The non-linear and easily-adjustable characteristics of SMA make this class of materials a very interesting resource in the development of new devices and new therapies for neurologic conditions. This paper reported several applications, in which SMA provides added functionality, allows customization and improves tolerability and outcomes in clinical management of patients. The properties of SMA could help also in the design of alternative therapies for otherwise untreatable movement disorders.

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