Chapter 4

Shape Memory Actuators for Medical Rehabilitation and Neuroscience

Simone Pittaccio and Stefano Viscuso

Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/50201

1. Introduction

Actuators based on shape memory alloys (SMA) proved to be particularly advantageous with respect to other actuation technologies when they are embedded in applications requiring strict compliance to a set of compatibility (e.g. mechanical, biological, weight, …) and environmental constraints. Most noteworthy are the uses in miniaturised components, lightweight systems, sensing-actuating systems (e.g. actuators interacting with changing environmental variables), low-noise or low-impact appliances (e.g. actuators with reduced interaction with the environment) and self-sensing controllable devices. With particular regard to these preferred applications, SMA can also play a role in solving specific actuation problems in the fields of Medical Rehabilitation and Neuroscience. The main characteristics expected of SMA actuators for these fields are light weight and portability; self-adjustment to evolving needs; applicability of actuation in shielded environments (with bioimaging and diagnostic devices: magnetic resonance imaging (MRI, fMRI), magnetoencephalography (MEG), and the like).

Taking the move from these key ideas, this Chapter will discuss some innovative uses and some implemented examples of biomedical devices based on the Shape Memory Effect (SME), explaining their advantages and limitations. In particular, it will address the following main topics: analysis of the relevant literature and background; the derivation of technical constraints and required material properties given the expected biomechanical and or clinical cases; the mathematical design of sample actuators and their implementations; ideas for their clinical application and control. It is important to notice that these same concepts can be easily transferred to other important industrial engineering fields.

1.1. Biomedical background

Neuromuscular Rehabilitation is the science and practice of supporting the recovery of lost or impaired motor function, particularly due to damage of the Central Nervous System

(CNS). The established approach to treatment is physiotherapeutic, pharmacological and surgical, the choice of a specific line of action depending on the exact diagnosis, the general state of the patient, the severity of the damage, the time distance from the acute event, the evolution of sequelae, the presence of co-morbidities, etc.

In the general case, a patient undergoing neuromuscular rehabilitation was struck by a primary event (e.g. a stroke, a traumatic brain injury, an infection, hypoxia, a tumour,…) producing severe neuronal loss. According to the affected area of the CNS different scenarios may result, including a state of paresis (essentially, tetra- or hemi-plegia), and possibly other types of impairment, such as cognitive, sensory and so on. The recovery process from these initial insults often does not proceed independently of a series of interconnected secondary phenomena, which, if left uncontrolled, can undermine all hopes of an optimal final outcome. These phenomena include muscular contracture, spasticity, CNS remodelling and learned non-use.

With no ambition to be exhaustive, it can be pointed out here that the main mechanisms by which the human body, and in particular the neuromuscular system, react to the primary event are mediated by two functional disruptions of the physiological status, namely, *immobility* and *disuse*. Immobility is the absence of movement, especially of a limb or body joint; disuse is the lack of muscular activation and consequent mechanical loading of the skeleto-muscular structure. It is evident that both conditions are tightly connected to and often caused by the state of paresis. *Contracture* (shortening of the muscles) can occur due to prolonged (days or weeks) permanence of the body segment in a given position. This can be the case e.g. for a flexed elbow when patients sitting on wheelchairs keep their hands in their laps; or for an ankle joint that is maintained in an overly extended posture by gravity during continuous rest in bed. Muscular contracture produces, as a major consequence, a forceful and rigid ill-positioning of the adjacent joint, reduction of the available articular range of motion, and malformation. It can lead, in time, through reduced mobility, to structured calcifications of joints and retraction. Alongside contractures, the development of s*pasticity* is one of the most common and severe secondary events in the sub-acute phase of paresis. Spasticity is an abnormal and speed-dependent stiffening of the muscles due to hyperactive stretch reflex. This exaggerated response to muscle lengthening exacerbates the impossibility of movement and subjects the patient to discomfort and pain as soon as the limb is mobilised. In turn, contrasting immobility becomes an even harder challenge. The picture resulting from the instauration of contracture and spasticity is given the name of *spastic paresis*, which is a painful, disfiguring and severely disabling condition, and constitutes a serious obstacle to patients' recovery [1-2]. In fact, the increased rigidity of muscles and joints further hinders any voluntary or involuntary motion or use of the limb, thus creating a vicious circle towards greater disruption of neuromuscular functionality.

Besides producing peripheral modifications, the prolonged immobility and disuse of the limb appears to affect negatively the plastic reorganisation and remapping of brain structures, by which live neurons take over the role of lost ones. The manner of such remapping is bound to have a paramount influence on ultimate functional healing, and this

is one more motivation for trying and avoiding those conditions in the first place. Their removal could shun the worsening of muscle stiffness and hypertone, while a sustained proprioceptive (sensorial) stimulation through movement may support appropriate cortical reorganisation. However, a complete picture of brain remodelling after a CNS insult and the effect of rehabilitation in modulating such a reorganisation is still not available. Studies of Neuroscience investigating in particular rehabilitation processes are certainly of great interest for physicians, neurologists, researchers and physiotherapists, as they can shed some light on those phenomena.

Recent trends in neuromuscular rehabilitation rely on pharmacological treatments against mild and severe spasticity, such as denervating neurotoxins (BOTOX) or myorelaxation agents (Baclofen) [3]; in most severe cases of contracture the approach can resort to surgical interventions such as tendon lengthening or transfer. The most widely used technique for all severities and types of spastic paresis is however physical therapy, which consists in static repositioning by means of splints and casting, controlled and gradual mobilisation of the limbs, muscular stretching and active exercising. It has been widely acknowledged that active work-out is a particularly important part of the rehabilitation program [4-5]. However, if autonomous control by the patient is absent or insufficient, passive mobilisation is utilised to try and maintain the viscoelastic properties of muscles and periarticular tissues. Furthermore, it is reasonable to think that minimising immobility and disuse, even by means of passive motion, can be advantageous for the prevention of the other adverse sequelae of CNS damage or to contrast their worsening.

Robotic tools are becoming very popular, as they make it possible to extend the duration of therapeutic sessions without the need for an individual involvement of human therapists, and reduce costs. In fact, though time-extensive physiotherapy is known to influence positively the rehabilitation outcome, organisational issues may limit the practical application of this principle, especially for passive mobilisation, in which case the physiotherapist has to move each affected joint one by one. In most situations, robotic tools provide repetitive and repeatable passive mobilisation of the whole limb [6], or joint by joint [7]. Moreover, several rehabilitation robots can assist active work-out, by completing patient's efforts to move [8] with the aim of improving muscle recruitment, by perturbing limb trajectories to enhance active control, or by contrasting movement [9] to strengthen muscles. Some drawbacks can be identified concerning the current use of robots in rehabilitation. First, as many of these machines are large, massive and costly, in a typical clinical environment the number of robots is limited and their use at home is ruled out. Second, most part of them require minimal skills by the patients, e.g. trunk control, equilibrium or cognitive abilities: that excludes very early or severe subjects, although they could benefit from extended sessions of passive mobilisation as well.

Robotic devices have been used for the mobilisation of body parts also in the field of Neuroscience [10-15]. Machines to manage the motion of the effectors (muscles) can in fact be used to support the measurement and visualisation of the interconnections between the activities of peripheral segments and the brain structures involved in their control. In this

type of applications tight compatibility with Bioimaging and Biosignal technologies is mandatory [13].

1.2. Overview of shape memory alloys

Robotic devices for Rehabilitation, like all robotic devices, are based on one or more actuators to transfer motion and displace a load. The load, in the case of Rehabilitation, will often consist of body limbs and joints, comprehensive of their mechanical properties, inertia and gravity. As was reported in Section 1.1, there is still a want of appropriate robots, meeting the needs of frailer patients and organisational requirements of the clinical structure. Much investigation in this respect is devoted to the manufacture of light-weight, portable and/or wearable devices. To the ears of the materials scientist or technologist these properties and the capability for actuation are typical features of a special class of metallic alloys, namely Shape Memory Alloys (SMA).

SMA are a compositionally heterogeneous class of materials, comprising a number of intermetallic compounds made up of transition and post-transition metals of different groups. It is beyond the scope of this Chapter to relate about all the different available compositions and their properties, which can be found in reference texts and scientific literature [16-19]. The most relevant compound of this class, employed in most technological applications to date is nearly-equiatomic NiTi, which is also supplied commercially in many semi-finished forms. The general name of NiTi (or TiNi) or Nitinol refers to several grades of the alloy found in the quasi-stoichiometric range from 49%at Ni to 51%at Ni. There are also some important ternary compositions based on NiTi, such as NiTiCu, NiTiHf, NiTiPt, NiTiNb, NiTiCr, with optimised characteristics for dedicated uses.

The Shape Memory Effect (SME) is an athermal reversible martensitic transformation producing macroscopic strain recovery upon heating above a certain characteristic temperature, generally referred to as A_f in the specialised literature. In the case of binary NiTi, the stable low-temperature phase (below the M_f temperature) is a B19′ martensite, while the high-temperature structure is a B2 parent phase. M_f and A_f are separated by a temperature difference of around 20°C in the solution-treated state. The effect of cold working is to strengthen and embrittle the material, and suppress the transformation. A controlled work-hardening however produces beneficial effects on the mechanical properties. In this state the material forward and backward transformations occur across spread-out temperature ranges and the hysteresis is also increased. Ageing treatments are necessary to optimise mechanical and functional properties and to adjust the characteristic temperatures. Typically, NiTi is aged at 350-650°C and water quenched, and this process also shape-sets the material in the shape "to be remembered". Treatment temperature and duration have to be honed to the application and size of the specimen. The mechanical properties, as described by a stress-strain tensile loading curve, may vary but, in the most representative cases, show an initial linear-elastic range, followed by a long flat plateau and a final increase. Most of the macroscopic shape change happens along the plateau region (up to 6% long) and corresponds to the microstructural phenomenon of martensite detwinning.

There are two phenomenological varieties of the unloading curve, according to the temperature of the test. If the test is carried out below M_f , unloading occurs along a line and strain decreases only minimally, so no macroscopic shape recovery is often observable. Full recovery is obtained by successive heating above the A_f temperature. This is called the SME proper. However, if the test is carried out above A_f the unloading curve is different and shows a long recovery plateau, at lower stresses than the loading one, and a final linear decrease towards zero-strains. The curve, in this case, is hysteretic and the shape recovery is attained without any need to heat the material. When the test is at room temperature T_r ,and A_f lies below T_r , SME is given the special name of Pseudoelastic Effect (PE). In all cases where the test temperature falls between M_f and A_f the behaviour is intermediate. Cold-work, ageing and precipitation of second phases can have very significant effects on all aspects of the mechanical curves, and in particular, on the height and separation of the plateaux, and cycling stability. So has the precise test temperature: first of all, in the case of SME loading occurs through the deformation of preformed martensite, resulting in lower stress values of the plateau and lower linear elastic modulus than in the case of PE, where austenite is initially loaded until stress starts inducing the formation of detwinned martensite; furthermore, through the Clausius-Clapeyron effect, stress is proportional to temperature and thus plateau stress levels are increased by an increase in test temperature, in particular in the case of PE. Finally, the compositions in the range 49%at-50.5%at Ni (Ti-rich) tend to show SME proper, while the Ni-rich ones (50.6%at-51%at Ni) have a pseudoelastic behaviour at room temperature. As a general trend, the higher the Ni content, the lower are the transformation temperatures.

1.3. State of the art of SMA in rehabilitation and neuroscience

Many efforts were made in the last 20 years for developing SMA-rehabilitation tools. Figure 1 shows the evolution of the number of papers, patents and conference contributions over this period. It is evident that in the last five years several groups focused on studying the matter, issuing some two thirds of the overall production. All papers dealing with implanted devices were not included in the search, for a number of reasons: because the typical fields of use of implantable devices are hardly connected to Neuromuscular Rehabilitation; because the design of parts to be utilised inside the human body is based on assumptions and limitations rather different from those distinctive of external actuators; because the domain of implantable devices in NiTi is well covered by extensive and comprehensive reviews and is now an established application. A choice was made to include only papers addressing directly the issue of Neuromuscular Rehabilitation or, indirectly, suggesting manners of applying static or dynamic external forces to reposition or move body parts. Particular attention was paid to applications including SMA *actuators*, i.e. devices exploiting the SME to transform heat into mechanical work.

1.3.1. Repositioning

Repositioning is the set of procedures aiming at contrasting ill-postures and malformations caused by contractures and spasticity. Static orthoses are often used to impart these

treatments and may be as rigid as castings or partially compliant. Many authors imagined the use of SMA in orthotics as passive components that apply static corrective forces [20-30]. In these applications SMA are mostly employed for their pseudoelastic properties, even though some designs are also based on SME. A series of papers [20-25] showed applications of pseudoelastic NiTi for spastic limb repositioning (elbow, ankle). The authors suggest that pseudoelasticity can be an interesting solution to the disuse and immobility problems during the orthotic repositioning therapies, in that it safeguards residual motor capabilities (voluntary or reflex) and decreases contact pressure by yielding under muscular jerks. They also showed possible advantages of this type of devices for correcting equinus gait [25]. In [26], pseudoelastic NiTi was utilised to remodel deformed auricles. Though not strictly correlated to the main subject of Neuromuscular Rehabilitation, this paper presents an approach in which the anatomic and biomechanical constraints are integrated in the design procedure. In [27], PE is employed to try and correct flat foot malformation and provide increased stability.

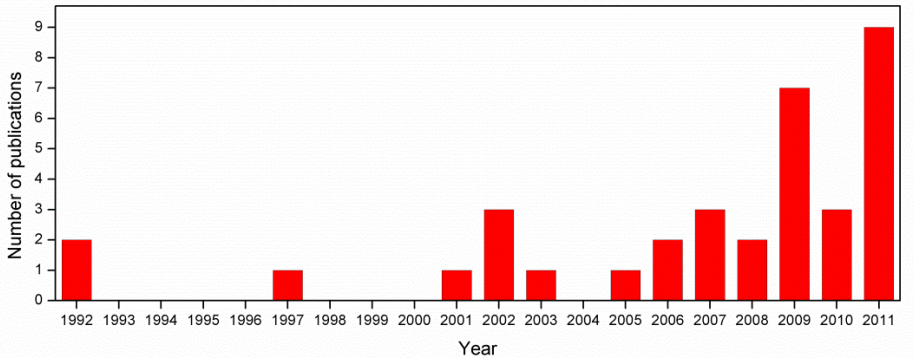

Figure 1. Histogram of the number of publications about SMA-based rehabilitation devices in the last 20 years.

On the other hand, [28] used the Shape Memory Effect to stretch gradually spastic wrist and fingers of paretic patients. The authors of this particular report also carried out measurements of joint resistance to movement, and designed the NiTi elements on the basis of these results. Thanks to the biomechanical design, the joints could be positioned at the neutral angle when the SMA was activated. The main characteristic of SMA exploited for this application was its ability to change shape, which eased putting on the device on malformed limbs. In an international patent [29], SMA are cited as a possible means to produce adjustable degrees of knee joint distraction and assuage contact overload between femur and tibia in unicompartmental osteoarthritis. Another international patent [30] discloses the use of SMA elements as possible actuators in a dynamically adjustable shoe to adapt to congenital or acquired deformities of the foot.

1.3.2. Functional exercise

Passive physiotherapy consists in repetitions of movements, muscular stretching and proprioceptive stimulation imparted by the hands of a therapist or by robots. Some authors

[31-41] investigated the possibility of employing SMA to make portable or wearable devices to act as functional exercising robots.

Some papers focused on finger movement, in particular the review [31] reported an example of rehabilitation glove fully actuated by SMA wires showing the two-way Shape Memory Effect. Another attempt to move fingers is reported in [32,33]. This paper describes the characterisation of bending wire actuators on a dummy finger and a temperature-controlled switch, and clearly evidences the issue of the force-speed trade-off. In [34] another device for passive mobilisation of the flaccid fingers is presented. This paper dealt with biomechanical constraints and design issues connected to the use of SMA springs as actuators, also proposing several modelling equations. Interestingly, both [33,34] employed the composition NiTiCu, which is known to have a narrower thermal hysteresis and lower detwinning stress than binary NiTi.

Other papers [35-41] concentrated on the lower limb. In [35], a concept for a paediatric boot is described. In the intention of the authors, a control system would activate two NiTi wires producing slow movement of the ankle and provide the possibility for home passive mobilisation. Two different implementations of a wearable ankle mobiliser were published by another group [36-41]. In the first paper [36] a description of the design procedure is presented, including mechanical and power dimensioning of SMA linear actuators based upon biomechanical considerations. Pre-clinical trials are also reported in the text. The following publications [40-41] dealt with an amagnetic rotary actuator and its use for the construction of a biosignal-controlled ankle exerciser that could be used in two different modes: fully passive and haptic-assistive, according to the evolving state of the patient during recovery. Trials on healthy subjects are described in [41].

A different use of SMA is proposed in [42], where a NiTi-wire was utilised to produce fingertip tactile stimulation with the purpose of providing a means for sensory feedback in haptic rehabilitation. Several implementations are presented and also qualitative tests on healthy volunteers are reported.

1.3.3. Muscle toning

Some robotic tools provide resisting forces that contrast active exercising by the patients. This could help increase muscle strength and control abilities. A few publications propose SMA-based devices for manifestly therapeutic uses and for generic muscle strength training. In the international patent [43], a set of wearable pseudoelastic garments are proposed to favour muscle toning during daily life activities. Though this application was not described as a therapeutic tool, it shows similarities with techniques that are used in Neuromuscular Rehabilitiation. Two papers by another group [32,33] suggest the use of SMA actuators for applying resisting forces to active movement. Unfortunately, the authors did not discuss either the level of force required or the consequent dimensioning of the actuator.

1.3.4. Assistive robotics

Other proposed applications of SMA in Rehabilitation comprise a number of studies that present active tools to support [44-47] or take over [48-51] impaired motor functions.

An M.Sc. thesis and a following paper by the same authors [44,45] report about the design and control of a downscaled bio-inspired mechanical model of an ankle joint wearing a SMA-actuated orthosis to support the walking capabilities of plegic subjects. The thesis discusses the biomechanical constraints and both publications clearly explain the dimensioning of the device. The authors also discuss the relationship between the size and number of SMA elements and the actuation properties. Another group issued a paper [46] and a patent [47] describing the use of SMA actuators to manufacture soft wearable orthoses for the knee joint. The garments were intended to provide sufficient torque to support the impaired gait of neurological patients, but the authors eventually found that the cycling speed was somewhat slower than appropriate.

An international patent [48] describes an orthotic device for restoring the grasping function in paretic subjects. The SMA actuation is intended to substitute entirely the lost function by allowing index and middle finger tips to reach jointly the tip of the thumb. A more complex multi-joint device with the same general purpose was developed in a Ph.D. thesis [49], where motors (possibly SMA-based ones) are however not mounted on the patient's arm, but lie at a distance, being connected to the limb by Bowden cables. This manuscript also includes biomechanical measurements and a control system. Another patent [50] imagines orthotic devices activated by SMA elements aiming at accurately simulating the mobile capabilities of human limbs. An unusual application is provided by [51], where SMA wires are employed as actuators to regain lost facial mobility and the ability to smile. The activation of the wires, aligned along the main affected muscle groups, is triggered by bioelectric signals acquired on the contralateral healthy side of the face.

1.3.5. Neuroscience

The scope of limb-moving actuators in the field of Neuroscience is mainly to provide proprioceptive, kinaesthetic or tactile stimulation in order to investigate neural responses to those stimuli. Increasing interest has being expressed during the last few years [10-15] to the effect of finding specialised tools that can be compatible with the instrumentation used to conduct Neuroscience experiments, e.g. magnetic resonance imaging (MRI, fMRI), magnetoencephalography (MEG), electroencephalography (EEG), near-infrared spettroscopy (NIRS).

SMA actuators have found little application in this field as yet: only two examples of SMA-based devices for use in Neuroscience were identified in the literature [37-41]. These publications describe a linear and a rotary actuator designed to comply with electromagnetic noise constraints, and be compatible in particular with MEG and fMRI. Most other devices were implemented using alternative technologies such as pneumatic and piezoelectric. The main reported advantage of SMA actuators is again portability and wearability.

1.3.6. Final remarks

Most authors recognised as a major advantage of using SMA in orthotics the light weight and compactness of the actuators. These factors, in fact, suggest that these materials can be used to build portable and/or wearable devices, and oriented the concepts of many designs towards compact robots, light static or dynamic splints, or even soft wearable garments, often for use in the home environment. Going from concept to actual implementation of the devices, the most challenging issue in this field appears to be the dimensioning of the actuators to address at the same time long-strokes and fairly-high-force requirements. In particular, human joints, bones and muscles move or deform across broad ranges of angular motion and several centimetres in length, and possess non-negligible masses. Understanding this is a first fundamental step of an engineering approach to the problem of actuation for Rehabilitation. Some papers did not find an optimal solution to the design question, because there is a serious trade-off between size and power variables to be overcome. In particular, high forces require large cross-sections of SMA: big diameters or many units working in parallel, or both. Any one of these choices, however, brings along some drawbacks: large diameters generally imply larger currents (for Joule's heating) and longer heating and especially cooling times; thin actuators are faster, but building large bundles or arrays of those require cross-insulation of the parallel fibres, larger volumes or surfaces to store them on board and the right strategy of electric connection (in series to minimise the current but requiring high voltages, or *vice versa* for the parallel configuration). It must be kept in mind, as an extra constraint, that patient's safety issues would tend to favour solutions with both low currents and voltages. Furthermore, when precise timing of the movements, matching some physiological rhythm (such as gait), or speed control are parts of the desired functionality of the device, actuation frequency is also an important factor, imposing tighter limitations on the acceptable surface-volume ratio and thermal exchange properties (viz. heating and cooling times) of the SMA actuators. The most successful approaches appeared to be characterised by a precise preliminary analysis of the biomechanics of the joint to be moved, and an optimal and simultaneous modelling solution of the overall functioning and sizing of the SMA actuator: this method made it possible to balance advantages and drawbacks against all standing trade-offs.

In terms of control systems, some designs implemented fine closed-loop architectures to set, maintain or change speed and position of the effector. These systems attracted the attention mostly of designers of dynamic tools, such as those to support the gait or the motion of the fingers. Simpler approaches were used to obtain automatic switching on and off of the actuators, based on some measurable variable (position, temperature, time,…). A few papers employed biosignals (particularly muscular bioelectric activity measured from the skin surface) to trigger actuation. We find this idea particularly interesting, dealing with Neuromuscular Rehabilitation, because it may bring the residual abilities of the patients into the design picture.

Actuators for Neuroscience share a number of characteristics with those described for the field of Rehabilitation. Besides the constraints depending on biomechanics and SMA

properties, special requirements must be fulfilled in order for these devices to be able to be used in electromagnetically shielded environments. In particular, if the Joule's Effect is chosen as a means to heat SMA elements and produce phase transformation, care will have to be taken in controlling any unwanted stray magnetic fields generated by the current flow.

2. Uses of SMA actuators in medical rehabilitation

This section will provide guidelines for designing SMA actuators aiming at moving human joints. General statements and suggestions will be accompanied by the discussion of a case study taken from the authors' experience, i.e. an ankle mobiliser conceived as a lightweight and portable tool for providing neurologic patients (stroke, traumatic brain injury, paresis) with motor support and sensorial stimulation not only during the very early phase of rehabilitation when they are still unable to exercise, but also during the subsequent phase of motor relearning, thanks to a specially-designed biofeedback-based control system.

2.1. Biomechanical, bioengineering and clinical specifications

The initial step of a biomechanical design is identifying the anatomical compartment, the pathology of interest and aim of the medical device. This is however just the basic set of information to tackle the problem and provides a very rough description of the actual boundary conditions affecting the following steps. Further human-related design constraints that ought to be considered in developing rehabilitation devices span from the mechanical properties of the joint, to the typical characteristics of target patients, and as far as considering the psychological impact.

2.1.1. Tissues and joints

Any biomedical device, either implantable or external, should take into account the peculiar characteristics of living tissues. Focusing on the musculoskeletal system, a great variety of tissues can be described: cortical bone, cancellous bone, muscular fibres, tendon, ligament, cartilage, synovial fluid, fibrous tissues… All these tissues show non-linear, viscoelastic and hysteretic properties. Some of them, such as the muscular tissues, also display active mechanical behaviour. Moreover, tissue characteristics may vary significantly with age, sex, ethnicity, fitness, pathology or malformation. The properties of biological tissues work together to produce the observed features of joints and limbs, which therefore also display non-linear, viscoelastic and patient-dependent behaviour.

Human joints may differ significantly from one another in terms of dimensions, degrees of freedom, neutral position, range of motion, associated muscular power and weight of the adjacent limb segments, neighbouring structures, etc. A "general purpose" actuator is hard to imagine, but dedicated devices can be tailored to target specific joints and pathologies. Furthermore, once the application has been selected, a statistical analysis of the target population could be carried out and possibly *ad-hoc* assessment of joint characteristics, biometric parameters, classic associated malformations or impairments and comorbidities, so that an appropriate average set of biomechanical parameters is acquired for a "typical user".

Modelling of the joint behaviour is often an essential step in the design process. The desired application can direct modelling choices as to whether a detailed or simplified description of the joint should be included. For example, it may be a purpose of the new device to activate only one degree of freedom (d.o.f.) of a di- or tri-axial joint; in this case, the extra d.o.f's can be excluded from the joint model, but it must be realised that the neglected mobility can produce unwanted stresses or sliding, or pain when the actuator is in use, and it is up to the designer to decide if not controlling those events is acceptable, or else they ought to be controlled by some other means (e.g by fixing and preventing movements along the extra d.o.f.'s). Joint characteristics cannot be considered as unchangeable data, but have to be connected to the current design case: for instance, in judging what a suitable range of motion (ROM) for the actuator should be, the designer must consider the joint type, but also the application (what is the required movement for the rehabilitation exercise?), the pathology (is it likely to change the ROM? Does the actuator have to work to restore the physiological ROM?), the relationships with posture (e.g. certain positions of adjacent joints can affect the available ROM of the target one), the influence of other d.o.f.'s, etc. In relation to this, it can also be decided if joint mechanical properties can be linearised within the ROM of interest.

2.1.2. Expected loads

Considering the force or torque generated by the actuator, it is important to keep in mind that joints have passive and active torque-angle characteristics that can be activated by the patient voluntarily or unconsciously.

A passive response is elicited from the muscles and periarticular structures when the joint is moved from its neutral angle, i.e. a resting position where forces producing joint flexion are balanced by those producing joint extension (including or not including gravity, according to limb position in space). As mentioned above, this response is generally nonlinear, viscoelastic and hysteretic, even in physiologic conditions. It can be evaluated by means of a motor-dynamometer-encoder system, in such a manner that the joint can be mobilised passively at controlled speed across a set range of motion, and resisting torque and position can be acquired simultaneously throughout the movement. By changing movement speed the viscoelastic characteristics can be evidenced, while conducting tests both in the flexion and extension direction (or inversion and eversion; or adduction and abduction; etc.) can reveal the hysteresis. The obtained torque-angle curves can be used as load curves in the design of the actuator. The absolute values of passive joint torques strongly depend not only on pathology (viz. contracture, retraction, fibrosis, etc.), but also on age, sex and muscular trophism, and of course change from joint to joint in the body. For this reason we can only give here some examples to clarify the order of magnitude of these torques. Maximum physiological passive torques can be as low as 50-60Ncm for finger joints [52], 100-300Ncm for the elbow [53] and up to 500-1000Ncm for the ankle joint [53-54], also depending on the angle of the knee. In healthy conditions, joint passive stiffness is not prevalently affected by movement speed. The same may not be true in some pathological cases. Muscle contracture and joint retraction can cause the reported values of joint passive stiffness to increase several times and can even make joints completely rigid to any practical purpose.

Apart from a passive response, joints can resist imposed movement also through the activation of the associated muscle groups. Muscular power can be delivered voluntarily (active motion) or by reflex activation. Involuntary active motion can also be produced by neurological conditions such as cloni, dystonia, chorea, etc. During limb and joint passive mobilisation muscle stretching can occur: a dedicated physiologic reflex produces instantaneous muscular contraction when the muscle fibres are elongated over a certain limit. This so called *stretch reflex* is much exasperated in spastic syndromes and may produce an involuntary, uncontrolled increase of resisting loads. Spasticity strongly depends on the speed of stretching; preconditioning the limb by a few cycles of slow manual stretching can help reduce momentarily the intensity of stretch reflex. Very severe spasticity, however, may correspond to the absolute impossibility of mobilising a joint.

Furthermore it must be remembered that the limbs adjacent to a joint possess a mass, and are therefore subjected to gravity and inertial forces connected to accelerations produced even in different parts of the body. One important case is gait. Where and when any or all of these components of the resisting or facilitating loads for the actuation must be taken into account has to be decided for each new application separately, in particular considering the typical position held by the target patient while the actuator is functioning, whether the patient will be prone to uncontrollable movements (jerks, dystonia, convulsions, etc.), or, on the contrary, whether some physiological movements will be typically impeded or suppressed (paresis, coma, castings, etc).

2.1.3. Interfaces

The forces and strokes generated by the actuator must be suitably transmitted to the patient's limb, so connective or fastening elements have to be carefully considered in relation to local anatomical constraints, such as the size of the limbs or body parts and the available surrounding space. In particular, when designing a wearable device, additional dimensional and weight constraints must be taken into account. Generally, the device should be attached to the limb segments that articulate at the target joint, in order to promote their reciprocal movement. Designing such connections should take into account the dimensions of limb segments (that strongly depend on age, sex and pathology) and the available space (determined primarily by joint position and orientation relative to the rest of the body, sex and malformation, etc.). For example, a device to move the shoulder should be designed taking into account the sex of the patient, especially if a frontal strap is required; in the case of a knee device, on the other hand, the lateral aspect of the joint could provide more free space for attachment than the medial one, so that interference with the other leg can be avoided. Another important factor linked to the transmission of forces and movement is the device-skin interface. This must be carefully designed so that no excessive pressure, friction or relative motion occurs during activation of the actuator. Some of these problem can arise due to misalignment of the actuator rotation axis with respect to the corresponding anatomic joint axis. In case of wearable applications, also the weight and stability of the device on the limb should be taken into account.

2.1.4. Other issues

Safety is a mandatory constraint when designing medical devices in general. For the particular case of rehabilitation actuators based on SMA, most risks could arise from electric, mechanical or thermal hazards. IEC 60601-1 is a widely accepted standard for medical electric equipment, and many countries tend to require compliance with IEC 60601-1 before commercialization of an electrical medical device is permitted [55]. Even if the medical device is intended for use only in the scientific laboratory, reference to this set of prescriptions may suggest precautions and guide designers and engineers in the development of safe devices. In connection with this latter standard, international standard ISO 14971 specifies a process for identifying the hazards associated with the use of medical devices and carrying out a suitable risk analysis [56]. Consequently, good practice requires to try and minimise all the identified risks. Moreover, when the medical device is approaching clinical validation, another norm to be considered is ISO 14155, which addresses the issues of designing, conducting, recording and reporting of clinical investigations carried out on human subjects [57]. All of these guidelines are valid also for SMA-based devices and may help consider further implications of new designs for the human body.

Dealing with patients, there are still other questions to be considered. Even if the device is functional and efficient and the actuator fulfils all the technical requirements, they will not be employed in the clinical setting if they are not acceptable to the patient. At the basis of *acceptability* there is a set of physical and psychological factors. Of course, the medical device should not produce nuisance or pain during short or prolonged use. Those problems, in the particular case of rehabilitation appliances and actuators, may depend on badly-designed interfaces with the skin or on movements imparted too fast. In fact, as already stated, contracted and spastic muscles are very responsive to stretch, especially when it is applied rapidly. During mobilisation, the increased muscle tone due to spastic reflexes may result in much discomfort for the patient. The use of SMA actuators in general has the advantage of providing low movement rates; however, severe spasticity may be hard to treat even with slow active devices. Other acceptability issues are often connected to psychological aspects. In particular, wearable devices should not embarrass the patient with noisy, bulky or cumbersome structures. For children, shape and colour can also be important features. SMA actuators are likely to be silent and miniaturised, and thus suitable in this respect, but all other components may not (i.e. power supply). Other impediments for patients employing rehabilitation devices actively or for assistive therapies may arise from their possible co-existing cognitive impairment: this consideration supports the use of very clear instructions and user interfaces, especially using non-verbal pictorial communication, lights, vibrations or sounds.

2.2. Actuator design

2.2.1. Strokes and loads

Rehabilitation devices in most cases are intended to generate a mutual rotation of limb segments around an anatomical joint. By employing rotary actuators, it is possible to

provide directly angular strokes and torques. On the other hand, linear actuators can be coupled with suitable lever arms and achieve the same results indirectly. The first step in designing an SMA-based rehabilitation actuator is to define, by careful analysis of the biomechanical constraints and clinical requirements, the appropriate neutral position, range of motion and resisting loads. The neutral position and range of motion will help determine a correct linear or angular stroke for the actuator; the resisting loads will set the linear force (and lever arm) or torque requisites. Of course, the two quantities will influence each other, for example different choices of lever arm may affect the linear stroke.

Once the required stroke and load have been determined, the geometrical parameters of SMA element can be worked out. Different types of actuators need different formulas for determining the parameters: for example, wire actuators have only two parameters, length and cross-section that directly depend on stroke and load respectively, while springs (helical, torsion or flat) parameters comprise coil dimensions, wire diameter and number of turns, which all depend on both stroke and load. Moreover material properties influence actuator parameters, especially in springs where anisotropy may play an important role [34]. Attention should be paid in particular to the critical stresses needed to detwin martensite both in the heated (above A_f) and cooled (below M_f) states. This consideration can guide the choices about material composition and thermomechanical treatment, because those factor have great impact on the height of the plateaux and the mechanical hysteresis. In most actuation applications, in fact, it must be guaranteed that the load to be displaced is low enough that stress in the material is lower than the critical stress for the heated state; on the other hand, sufficient loading should be provided to detwin martensite and ensure actuator deformation and position reset during cooling for most cyclic applications. Whatever the SMA geometry, it can be stated in general terms that cross-section depends mainly on the maximum desired work output, through the mean level of stress acting on it. The question of choosing the level of stress is quite complex, and also involves the expected fatigue life of the actuator and the strains recovered upon activation. For example, it is reported that commercial NiTi-wire actuators can remain stable for more than 10^5 cycles at 200MPa and 4% of strain in traction [58], but other optimal compromises can be found, provided that stress does not exceeds 400MPa and strains 5%. The use of parallel actuators can help reduce required work from each actuator, i.e. given a stress level, cross-section can be reduced. Dimensioning cross-section should also take into account cooling rates, as will be discussed in the next section.

2.2.2. Power

Heating and cooling are key points concerning SMA actuation. The general equation that drives these processes is

$$P_{in}(t) = c_p m \frac{dT}{dt} + m\Delta H \left|\frac{d\xi(T)}{dt}\right| + \frac{dW(\theta(t),t)}{dt} + P_{diss}(t). \quad (1)$$

Considering the heating (actuation) phase, $P_{in}(t)$ is the heating power, $c_p m \frac{dT}{dt}$ is the power needed to increase SMA element temperature (c_p is the constant-pressure specific heat and m

is the mass), $m\Delta H\left|\frac{d\xi(T)}{dt}\right|$ is the power involved in phase transformation (ξ is the fraction of austenite and increases in time as transformation goes on, ΔH is the transformation enthalpy), $W(\theta(t),t)$ is the mechanical output (useful work, inertia and frictional losses) which varies along the movement trajectory $\theta(t)$, and $P_{diss}(t)$ is the power dissipated by thermal convection, thermal conduction and (less important in this case) thermal irradiation. Considering the cooling phase, and imagining that a bias force acts to restore the starting actuator configuration (by deforming the SMA element), $P_{in}(t)$ is again a heating power that could be used to help control the cooling rate, $c_p m\frac{dT}{dt}$ is the power to be dissipated in order to decrease SMA element temperature, $m\Delta H\left|\frac{d\xi(T)}{dt}\right|$ is the power involved in phase transformation (enthalpy in this case is negative), $W(\theta(t),t)$ accounts for the mechanical energy stored in detwinned martensite plus inertial and loss terms, and $P_{diss}(t)$ is the power dissipated. The contribution of $P_{diss}(t)$ is present both during the heating and cooling phases of an actuation cycle, but it may differ significantly if any active cooling system is included. Equation 1 gives a simplified description of the process, but permits to focus on some key points. First, SMA mass is an important factor when designing power consumption. Second, as all the diverse forms of dispersed energy depend on the amount of exposed surface, surface/mass ratio is the driving contribution to determine cooling time. Therefore, thin actuators (maximising the surface/mass ratio) should be preferred to bulky ones if cyclic, especially high-frequency actuation is desired. Having in mind which use is intended for the device provides a guidance for the choice of heating source and consequently gives some hints for the actuator design. The best strategy for providing controllable, cyclic actuation is heating by Joule's effect, but, especially for non-cyclic and one-shot activation, also direct thermal transfer may be suitable. Focusing on Joule's effect, the energy provided depends on the injected current and the electric resistance of the SMA element according to Equation 2:

$$P_{in}(t) = P_{Joule}(t) = I(t)^2 \cdot R_{SMA}(\xi) \tag{2}$$

where the electric resistance $R_{SMA}(\xi)$ can be expressed as

$$R_{SMA}(\xi) = \rho(\xi) \cdot \frac{L(t)}{S} \tag{3}$$

with $\rho(\xi)$ representing the SMA resistivity, S the cross-sectional area of the SMA element, L(t) the length over which the current flows, that obviously changes as actuation goes on. Given a length of SMA wire (which depends directly on the stroke required from the actuator), the thinner the wire, the higher is the electrical resistance. Moreover, mass-dependent contributions to Equation 1 are also minimised, and heating efficiency increased.

SMA actuators are subjected also to the Clausius-Clapeyron relation, that can be expressed as:

$$\theta^* = \theta + \frac{\sigma}{C} \tag{4}$$

where $\boldsymbol{\theta}$ is one of the transformation temperatures, which is effectively increased to $\boldsymbol{\theta}^*$ when a stress σ is applied to the material. This is a very important issue when purchasing shape memory materials or dimensioning SMA actuators powering: the transformation

temperatures as provided by DSC analysis will be shifted when the material is loaded. Typical values of C for NiTi range from 5 to 9 MPa/°C, i.e. an actuator designed to bear 200MPa would have transformation temperatures increased by as much as 40°C. However, actuation temperatures cannot be increased indefinitely: in fact, above a certain temperature (M_d), part of the deformation cannot be recovered and material undergoes plastic slip.

2.2.3. Choice of the SMA element

SMA actuators can be provided in a number of shapes, which may differ significantly from one another in terms of available stroke and force. The first distinction is based on the deformation mode imposed onto the material. Wires are subjected mainly to traction, which produces a uniform loading of the material cross-section: this fact makes it possible to produce high force actuators, but, on the other hand, the available stroke is limited by the fact that linear deformation can be as high as 8% only, 4% in most cyclic operating modes. Other simple SMA actuators are linear springs (tension or compression springs), whose principal mode of deformation is torsion. Springs of this kind are helical coils of SMA wire arranged around a central axis: this allows for large elongations along the central axis depending on spring ratio and the number of turns. On the contrary, force is limited by the fact that torsional loading is not uniform in the material cross-section. Some authors proposed also bending actuators, made of SMA ribbons [27] or SMA wires [33]. For the same purpose, also torsion springs and flat springs can be employed, which share the same principal mode of deformation, i.e. flexion. The advantage of this actuation is that angular stroke is directly available, but the non-uniform cross-section loading limits the available torque.

The problem of moving human joints generally involves large angular strokes coupled with fairly high levels of force or torque. The simple configurations just described most of the time provide solutions only for very long wires or thick cross-section springs, ribbons or bars, which are often deemed impractical for a number of reasons. Long wires have to be housed in a suitable manner, to limit length into a compact three-dimensional structure. A way to do so is coiling the SMA wire along a series of pulleys, whose diameter should be sufficiently large with respect to the wire diameter, to avoid strain concentrations. On the other hand, large cross-section actuators are impractical because they need high electric power to reach the transformation temperature. Moreover, cooling down bulky wires or ribbons may require too long a time for most cyclic applications. A possible solution for increasing force output in springs and ribbons is arranging many actuators in parallel or in bundles. Provided space around the joint is sufficient, attention should be posed to electrical insulation and electrical connections, in order to provide suitable solution to tension-current requirements for actuation, keeping in mind also the safety issues.

2.3. Actuator control

The problem of controlling actuation is very important for many applications in Rehabilitation, as patient's needs and responses may vary during the evolution of therapy or even during the same session of exercise. Control strategies apply mainly to assistive robots,

but may also be employed in passive mobilisation devices. As the focus of this Chapter is not on control systems, only a brief overview of possible applications to SMA rehabilitation devices will be discussed.

2.3.1. Control of passive mobilisation cycles

Two major strategies exist to control cyclic heating and cooling of SMA actuators: in *open-loop control* parameters are predetermined by a set routine, whereas *closed-loop control* employs a feedback signal of any nature to adjust heating and cooling parameters (timing, current or voltage, active cooling systems, etc). The main drawback of open-loop control is that any perturbation to the trajectory would not be compensated, as the current profile is predetermined. This could happen, for example, if patient exerts any unexpected active contraction or in the case of unpredicted changes in environmental conditions. However, there are applications in which open-loop control is still feasible, for example repetitive passive motion of flaccid limbs. Closed-loop controls need monitoring of a feedback variable, which could be the SMA temperature, the joint angle, actuation speed, SMA force or any other measurable physical quantity. Apart from rare examples of feedback loops based on monitoring of SMA resistance [59], closed-loop controls rely on dedicated sensors that are better included from the initial steps of the device design.

Another distinction can be made on different types of control of movement trajectory. In many applications an ON/OFF actuation is suitable: the focus is only on the initial and final positions, while the detailed trajectory is controlled only mechanically and the speed only in average terms. In this case, open-loop control may be practical, and heating can be achieved with a very simple current profile, e.g. a step or a ramp. Experimental tests are a viable solution to adjust the heating and cooling parameters. In particular, attention should be paid to the experimental conditions, including the orientation of the actuator in the gravitational field, as thermal convection is strongly dependent on that.

On the other hand, when a precise trajectory of movement over time is required for the application, alternatively open-loop or closed-loop control strategies can be applied. In the open-loop approach, Equation 1 should be solved by imposing the desired mechanical output $W(\theta(t),t)$ and by calculating the time-varying current profile to be injected. However, the most reliable way to provide trajectory control is closed-loop control, in which the current input is continuously adjusted to match the prescribed position, thus counterbalancing perturbations.

2.3.2. Assistive control

As rehabilitation implies that patient's capabilities evolve during therapy, the characteristics of therapeutic tools could be devised to change accordingly. A way to implement this is to trigger SMA actuators only when the patient makes some effort to move the paretic limb: thus, a measure of the "effort" should be chosen to implement such a biofeedback-based closed-loop control. In some cases, mechanical variables could be employed: for example, the SMA actuator completes movement only if the patient generates at least a certain level of

voluntary muscular force or flexes the joint over a minimal extent. On the other hand, possible biosignals for closed-loop control can be the surface electromyographic signals from the muscles that control the movement to be rehabilitated. The level of the biofeedback variable above which actuators are switched on may depend on the patient, pathology and progression of therapy, and therefore should be adjusted to match patient's capabilities with rehabilitation goals.

Besides the biofeedback signal, another key point for assistive rehabilitation is how to encourage the patient to participate actively in the rehabilitative session. Visual or verbal or acoustic feedback are the most common way to prompt, instruct and reward the patients during the exercise, but when selecting the communication format attention should be paid to their possible co-existing cognitive impairment.

2.3.3. Gait triggering

A very peculiar example of precise trajectory control is gait, during which any wearable active device should be able to activate according to the walking rhythm of the patient. A closed-loop control is desirable, and can be implemented with mechanical sensors (which detect angles at different joints or contact forces when the foot contacts the ground) and/or electromyographic monitoring of the leg muscles. Gait is a quite demanding application for SMA in terms of frequency of activation, as even slow walk takes place at over 1Hz. This influences dramatically actuator design, i.e. diameter and number of SMA elements. For gait applications, movement trajectory must be controlled fully within the step and from step to step: in other words, both heating and cooling phases should have adjustable parameters so that actuation can adapt to changing stride or external perturbations. The possibility of modulating input current profiles has already been discussed and may be sufficient for the control of heating; cooling, on the other hand, shall not be left to natural convection in this case, but an active system for accelerating and tuning heat transfer will often have to be adopted.

2.4. Case study: Passive/assistive SMA device for ankle dorsiflexion

2.4.1. Design aims and clinical constraints

Ankle is one of the body joints that often suffer from the sequelae of stroke, i.e. immobility, disuse, contracture and spasticity. After stroke, a rehabilitation program should be carried out as soon as the patient's conditions are sufficiently good, but in the acute phase the patient is unable to exercise actively. In these circumstances, moving the limb passively can help maintaining joint flexibility and normal muscle tone, while also contrasting contracture, spasticity and sensory deprivation. A rehabilitation device for promoting repetitive dorsiflexion of the ankle in the first few weeks after the acute event could help improve clinical outcomes. The fact of limiting mobilisation to just one degree of freedom (sagittal plane of the joint) is appropriate because dorsi-plantarflexion is the principal motion involved in gait. It is regarded as a matter of importance that the device be able to manage patient's changing conditions during recovery. As needs evolve during patient's improvements, this therapeutic

device should be able to guide and sustain gradual recovery by providing commensurate aid. This includes exploiting even initial attempts at voluntary motion and turn those into effective workout. To this end appropriate control will have to be included.

The device is intended for patients in the first weeks after a stroke, i.e. we should expect adult subjects having a flaccid ankle (no active control of the muscles, mild or no hypertone) and possibly increased ankle stiffness. Figure 2 shows the passive viscoelastic ankle characteristic of a healthy subject at rest (no spasticity, no contracture, no voluntary movement) and a typical chronic flaccid patient with mild contracture. The ankle joint can move in the sagittal plane in the approximate range -30°/+20° (negative being towards plantarflexion) even though the range of -15° to +10° is the functional range of utmost interest in gait. These ranges become reduced with evolving contracture and spasticity, and in particular the positive degrees are progressively lost. In the range of interest (-15°/+10°) the characteristics of the presented healthy and paretic joints differ mostly for dorsiflexed angles (greater than around +2°, in this case), where increased stiffness in the paretic ankle can be observed. The typical acute flaccid patient will have intermediate characteristics between the healthy one and the chronic.

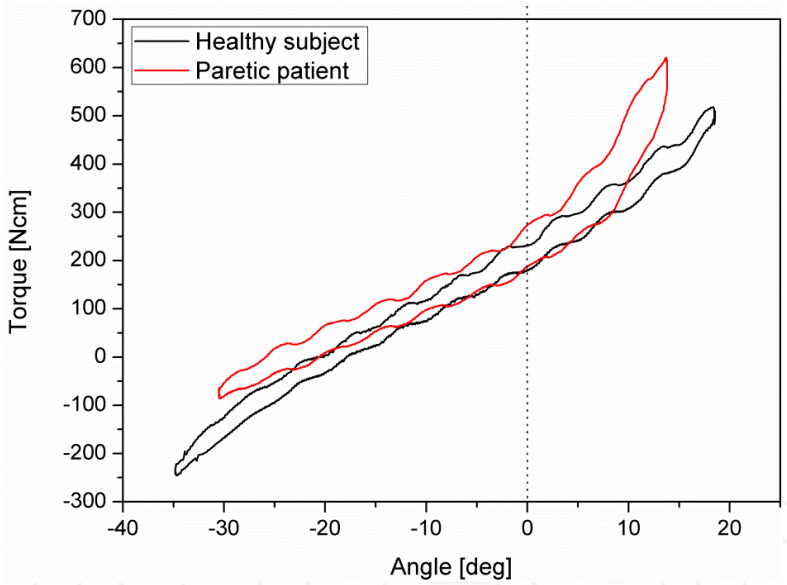

Figure 2. Measured passive characteristic of the ankle in a healthy subject vs. a paretic patient with mild contracture and ROM limitation. The main difference appears for positive dorsiflexion angles

Given this information, the biomechanical constraints on the design can be summarised as follows:

1. the resisting forces which have to be considered in actuator dimensioning are the viscoelastic passive characteristic of the joint and the foot weight. No active contribution from the muscles are expected.

2. Choosing a reduced range for the device, biased towards dorsiflexion, has the advantage that the calf muscles are kept under a relative stretch (physiological neutral angle is around -25°); furthermore it is appropriate to avoid forcing the joint excessively towards the extreme dorsiflexion position (conservative approach to limit insurgence of spastic reflexes). A target ROM for mobilisation was therefore was chosen as -5°/+10°. Of course, the actual working range will depend on the passive characteristic of the specific ankle, but is not expected to be much different from the target one.
3. For a target population represented by this type of subjects it is reasonable to assume that passive resisting torque does not exceed 400Ncm in the range of interest.

Considering the general conditions of the patients in the first weeks after a stroke, it would be wise to design a device that can be employed in the bed. However, the knee joint should be sustained in a flexed position, so that the bi-articular *gastrocnemius* muscle is not pre-stretched and full ankle range of motion is available. As a way of compromise, an angle of 10° for the leg rest can be assumed, with the foot positioned lower than the knee. It should be taken into account that, in such a configuration, the contribution of foot weight to the resisting force is limited. Figure 3 shows the total resisting torque, comprising different foot weights, and the same viscoelastic resistance from a typical patient. The expected maximal resisting torque can be approximately calculated in 400Ncm. As the curve hysteresis is not large for this joint (cf. Figure 2), the same values used for dorsiflexion can be also utilised when considering the movement towards plantarflexion and the loading level associated to martensite detwinning.

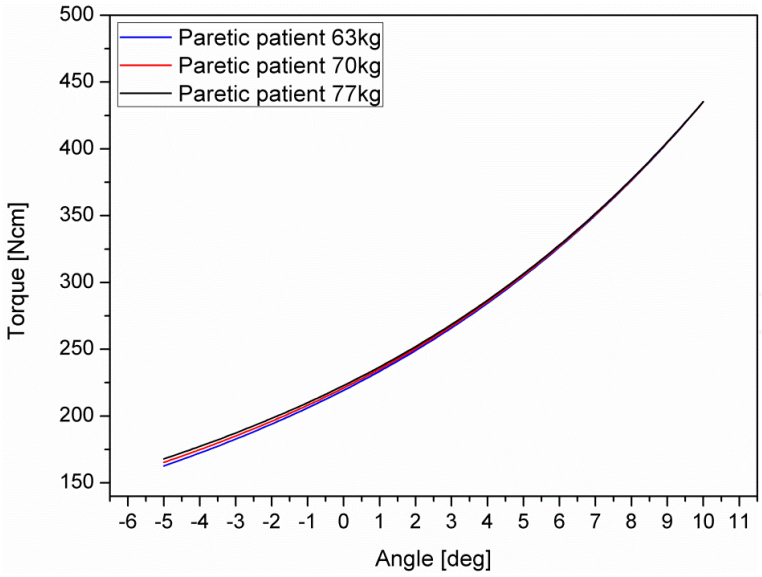

Figure 3. Influence of foot weight on the total resisting torque at the ankle. Differences in foot weight (proportional to the body weight) account for little change due to the lying position of the limb.

As the device is not intended for walking, there are no direct constraints on cycle duration, provided that a suitable number of cycles can be delivered to the patient's ankle in a therapeutic session (at least 100 cycles/hour), and movement speed is not too elevated, lest spastic responses are aroused. The actuator should provide repeatable movement and maintain the same characteristics for a number of sessions, as it may be impractical to adjust or change the SMA actuator too often. For this reason, maximal strain should be limited to 3% and stress to 300MPa.

2.4.2. General concept of the device

Figure 4 shows a simple embodiment of the concept. Two thermoplastic shells lined with soft foam are modelled on a prototype human lower limb of average size. These shells are hinged together and strapped by Velcro® bands respectively on the frontal aspect of the shin and the foot, in such a manner that the ankle and the hinge are perfectly aligned along the same axis (this minimises unwanted friction and sliding between the orthosis and the skin). The choice of planar hinges was also made to control (fixate) ad/abduction and in/eversion, although this solution makes the device unsuitable for patients that have already developed severe malformations out of the sagittal plane (unusual in the acute phase). With this structural configuration, two linear actuators are fixed on the front of the leg shell and transfer actuation pull to the foot shell through inextensible threads.

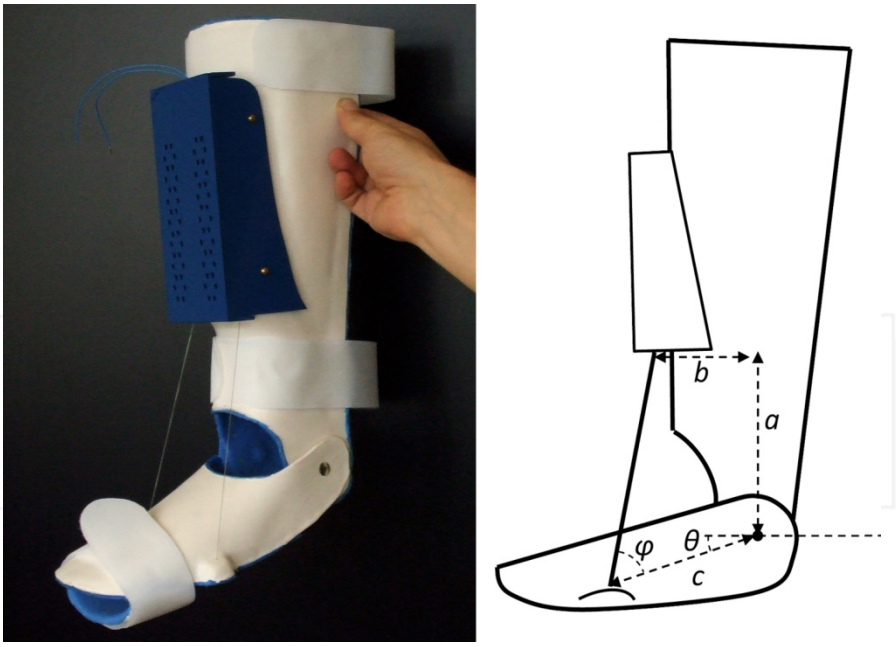

Figure 4. Implementation of an exerciser for the ankle joint with linear SMA actuators. The device is designed to provide cyclic joint flexion in the rehabilitation of neurological patients in the acute phase. On the left, schematic representation of the main design dimensions to calculate the lever arm.

The linear stroke and force output required of the SMA actuators depend, through the lever arm, on the fixation points for the actuators (on the shin), and the distal ends of the inextensible threads (foot shell). Actuators produce dorsiflexion, while plantarflexion and actuators position reset is left to gravity and viscoelastic resistances.

Power supply is to be provided by a dc-generator, which is not on board the wearable device, as the intended use is not for walking. This choice helps limiting weight and keep the device stable on the patient's leg during use.

An open-loop control strategy is adopted for the use as passive exercise device, whereas a simple closed-loop control for assistive rehabilitation employs the electromyographic activity from *tibialis anterior* as control signal, picked up by surface electrodes. As for the power supply, it was decided that all the components needed for control are not mounted on board the wearable device, even though integration would be possible by developing *ad-hoc* electronics.

2.4.3. Actuator design and characterisation

With the selected set of geometrical parameters (Figure 4: a=16cm, b=8.5cm, c=15cm), a linear stroke of 2.5cm is required to produce an angular movement across the range -5°/+10°. Considering a linear deformation of 3%, the required amount of wire for linear actuation would be 83cm. However, in our case it would be impractical to have a free-standing wire of such a length as a linear actuator. For this reason, the NiTi wire should be confined into a more compact actuator. In dimensioning the length of wire now we must take into account also the local deformations that inevitably will be imposed on the SMA wire when coiling it. The actuator was designed as an insulated cartridge wherein the necessary reference length of NiTi wire is led back-and-forth between two arrays of ten pulleys. An end of the wire is connected to an inextensible thread that transmits the force to the foot, while the other one is fixed to the housing. A pseudoelastic spring is connected to the moving end of the NiTi wire in order to keep it just taut, and its pull is negligible during actuation.

Considering the force requirement, each actuator should bear half of the resisting torque T_r showed in Figure 3, and the amount of force varies at varying ankle angles θ (defined between the foot direction and the horizontal, Figure 4):

$$F(\theta) = \frac{T_r(\theta)}{c \cdot \sin\varphi} \tag{5}$$

where φ is the angle between the inextensible thread and the foot and depends on θ according to:

$$\varphi(\theta) = \frac{\pi}{2} - \theta - \arccos\left[\frac{c \cdot \sin\theta + a}{\sqrt{(c \cdot cos\theta - b)^2 + (c \cdot sin\theta + a)^2}}\right] \tag{6}$$

With a maximum torque of 200Ncm, Equations 5 and 6 give a maximum load of 13N on each actuator. By selecting a 250μm-diameter commercial NiTi wire, stabilised for actuation, the maximum stress on the wire cross-section is 266MPa. In order to complete

plantarflexion, full martensite detwinning should be achieved. It is certainly possible to find stabilised wires for which martensite detwinning occurs with less than 100MPa, corresponding to around 5N pulling on a 250μm-diameter wire. With the expected resisting torque in Figure 3 and the geometrical parameters, force requirement for martensite detwinning is always satisfied in the range -5°/+10° and thus cyclic actuation will take place in that range. Considering a diameter of the pulleys of 12mm, the maximum amount of localised strain is 2%. In order to respect the 3% limit for the maximal deformation, only 1% of strain is available for actuation and can be employed for calculating the length of wire to be coiled within each actuator, that is to say, 250cm.

Having limited strains to 3% and stress to 300MPa, a cycling life of 30k-100k cycles is expected [58].

2.4.4. Power dimensioning

In order to evaluate the parameters for Joule's effect heating, various experimental tests were carried out on samples of NiTi wire. First, the transformation temperatures were investigated by means of differential scanning calorimetry (on DSC 220 SSC/5200 - Seiko Instruments, Tokyo, Japan), showing A_f = 351K and M_f = 274K. However, calorimetry gives information about the material with no loads applied, whereas Equation 4 suggests that transformation temperature depends on the load applied. For this reasons, tensile tests on the material at different temperatures were conducted using an MTS 2/M thermo-mechanical test machine (MTS Systems, Eden Prairie, MN, USA) equipped with a 2kN load cell. The material was deformed up to an engineering strain of 5%, at 365K, 380K, 390K and 400K. The pseudoelastic plateau values varied as a function of temperature with a ratio of 8.402 MPa/K, which is exactly the constant C in Equation 4. With the estimated stress level of 266MPa, full transformation and strain recovery can be achieved at 383K.

Activation tests on the wire were conducted injecting different currents (0.65A, 0.7A, 0.75A, 0.8A) in the wire at a constant strain of 3% for a set period of 13s, in order to evaluate what current value is most appropriate to provide the working load of 13N, minimizing current expenditure and heating time. As expected, the higher the current the faster is actuation. Patient safety considerations should be taken into account, as well. A compromise solution can be accepted with 0.7A, which allows for reaching 13N within 6s. With the selected current, voltage is limited to 35V, considering an average resistance of 49.5 Ω (45-54Ω during transformation from fully austenitic to fully martensitic). Notice that the rehabilitation device mounts two actuators, which need a 0.7A current each. The electrical configuration of the two actuators could be a series or a parallel circuit: in the first case, the dc-generator should be able to provide 0.7A at 70V, in the latter case 1.4A at 35V. According to IEC 60601-1 specifications, dc tension preferably does not exceed 60V, i.e. in our case the two linear actuators are better connected in parallel.

Heating parameters can be extracted by testing a free-standing NiTi wire, and by applying 35V to the ends of the cartridge actuator suspending a 13N weight. It was demonstrated that nominal linear stroke is reached in around 6s (mean dorsiflexion speed 2.5°/s). On the other hand, cooling times depend strictly on the geometrical arrangement of the wire in space. A

compact actuator may have a considerably slower cooling and position reset time, as tests on the actuator confirms. Basically, if the vertical free-standing wire cools down in approximately 10s, cooling and actuator position reset takes place in 30s. The full cycle thus lasts 36s, which makes it possible to deliver 100 cycles/hour to the patient's ankle, as required by the design specifications.

2.4.5. Control strategy

An open-loop control is adopted for using the device as a passive exerciser. A computer routine was written in LabView (National Instruments, Austin, TX, USA) to control an electronic relay (NI9481 - National Instruments, Austin, TX, USA) that closes the electric circuit between the dc-generator and the actuators.

For the assistive therapy, a closed-loop architecture is preferred, with surface electromyographic signal (sEMG) from *tibialis anterior* as control variable representing the patient's attempt to move his ankle. Three Ag/AgCl electrodes (positive, negative and reference) were used to pick up the signal. Analogical waveforms were acquired, pre-amplified and band-pass filtered (18-478Hz) before being digitalised (sampling at 1000Hz) using an NI9205 (National Instruments, Austin TX, USA) connected to an ordinary laptop computer running a LabView routine. Pre-amplifying and filtering stages were assembled using conventional 8-pin PDIP components, and included also a feed-back loop towards the body (akin to the driven right leg stage used in electrocardiographers). Further signal manipulation is built into the control software, including rectification and low-pass filtering (3Hz), so that the obtained waveform is sufficiently smooth that it can be employed as a measure of instantaneous muscular activation.

Through the user interface of the control routine two patient-specific sEMG threshold values can be selected. The lower one is set to the minimal required level of exercise (which can lie even lower than the muscular motor threshold, in some cases); the upper one is set to an appropriate activation representing the ultimate (or a higher) therapeutic goal, i.e. an effective motion.

At the start of the assistive exercise session, a visual cue is presented to the patient to dorsiflex the ankle. Then the system is set on hold waiting for the sEMG from *tibialis anterior* to cross one of the threshold values. If the lower threshold is reached, then the system waits a few milliseconds for the upper threshold also to be reached. If this latter event does not occur before the time-out, then power is supplied to the actuators and the motor task is completed for the patient. If, on the contrary, the upper threshold is reached, then a visual feedback is provided to the patient that the higher goal was hit, while the device does not intervene to support the movement.

2.4.6. Experimental tests on the device

The assembled device was tested with a static load of 40N fixed on the foot shell at a distance of 10cm from the hinge axis, while measuring the angular displacement by means

of electrogoniometer SIM-HES-EG 042 (Signo Motus, Messina, Italy). The device was tested for 4000 cycles, with the actuators powered with a 6s step of 1.4A (0.7A per cartridge) and 30s allowed for cooling. The results of these tests (Figure 5) demonstrated that stroke is quite stable across cycling. Plantarflexion occurs more rapidly after cycling because of the instauration of two-way shape memory. Following this result, by employing cycled wire or wire stabilised for two-way shape memory, cycle duration could be reduced from 36s to 30s without changing the stroke, if desired (reaching 120 cicles/hour).

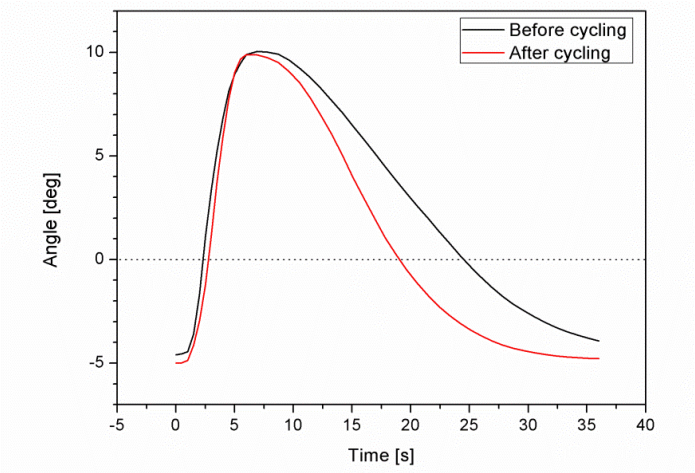

Figure 5. Angular stroke of the SMA-based device for ankle dorsiflexion: first activation and after 4000 cycles against a resisting torque of 400Ncm.

The closed loop control strategy was tested on three healthy volunteers (28.17±6.08 years old). Ag/AgCl electrodes were placed on the belly of the *tibialis anterior* muscle of the dominant side, the corresponding distal muscle-tendon junction, and the internal malleolus (driven electrode). Subjects were asked to perform a maximal isometric contraction at the ankle neutral position, then to sustain the minimum voluntary activation they could manage. Subsequently, values were set for the lower (110% of minimum individual contraction) and upper (60% of individual maximum isometric contraction) thresholds. Then, the control routine was launched and subjects were asked to follow on-screen instructions (graphic and written) trying to respond with just a supra-minimal contraction when cued to dorsiflex the ankle.

The measured joint angle and sEMG time courses for a representative subject are shown in Figure 6. When the lower threshold was crossed, the system triggered the powering of the orthosis, which completed the movement of dorsiflexion (assisted active session). It can be appreciated how passive mobilisation can be triggered by a very subtle muscular contraction, which may correspond only to a very slight movement (~1°). The movement produced by the orthosis as a consequence of a minimal contraction brings along some degree of reflex sEMG activity: this may also be thought of as an interesting result to the effect of rehabilitative exercise.

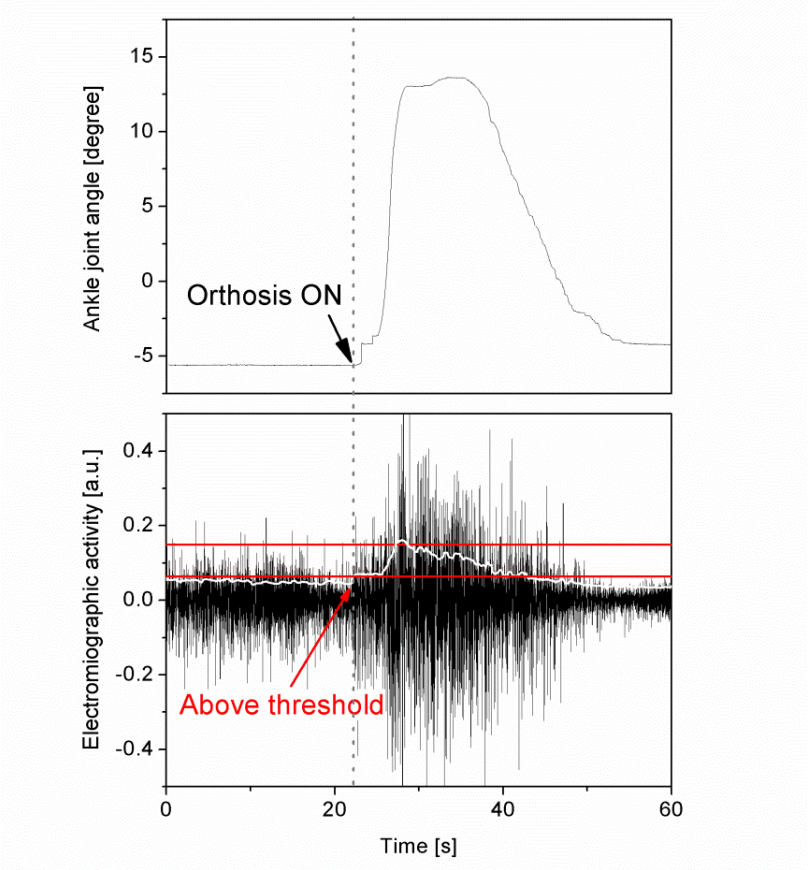

Figure 6. Top: angle timecourse measured during an EMG-triggered activation of the device for a healthy volunteer. Bottom: EMG recording during the trial. When the subject's muscular activity crosses the lower threshold, actuators are triggered to complete the movement of dorsiflexion.

3. SMA actuators for neuroscience

The development of SMA devices for use in Neuroscience is a very challenging task as diagnostic equipment utilised in this field of research is generally very sensitive to electromagnetic noise. Whereas some techniques (e.g. electroencephalography or near-infrared spectroscopy) are less affected by environmental conditions, magnetic resonance imaging (MRI, fMRI) and magnetoencephalography (MEG) acquisitions can be carried out only in highly shielded Faraday cages, to abate electromagnetic noise. Therefore, materials and devices must comply with a number of requirements, in order to be allowed into the acquisition room. In the next paragraph, these two diagnostic techniques will be discussed separately, as their peculiar characteristics demand different compatibility constraints.

3.1. Electromagnetic constraints

3.1.1. Functional magnetic resonance imaging (fMRI)

fMRI is a magnetic resonance procedure utilised in Neuroscience for measuring brain activity by detecting associated haemodynamic responses. MRI equipment uses a strong static magnetic field to polarise the nuclear spins of atoms in living tissues: the higher the magnetic field, the higher the polarisation of the spins, thus, the higher signal-to-noise ratio. Commercial scanners can generate polarisation fields up to 3T, but efforts are being made to increase the available magnetic field far beyond [13]. In addition to this static magnetic field, the MR scanner uses rapidly-varying magnetic field gradients for spatial encoding during the imaging sequence. The use of strong polarisation magnetic fields entails safety precautions, as high forces can be exerted especially on objects made of ferromagnetic materials, which may become dangerous projectiles for the patient, medical personnel, and the instruments. Besides safety issues, ferromagnetic materials generally affect image quality, as they alter the homogeneity of the static magnetic field. Another potential source of artefacts is the presence of objects made of conductive materials inside the acquisition room. In fact, the magnetic field gradients can induce electrical fields and currents flowing through the conductive materials (eddy-currents): these currents, in turn, induce magnetic fields which inevitably interact with the MR fields and affect the quality of the images. In much the same way as eddy-currents, it can be inferred that any current flowing inside conductive materials could generate image artefacts.

Given these strict constraints, a possible solution for moving the limbs of a patient during fMRI investigations by an actuator is to keep the actuator and control system outside the scanning room and transfer the mechanical energy to the subject via pneumatic, hydraulic, or mechanical (pulleys, ropes, etc.) means. These systems are usually complex and suffer from long transmission lines accompanied by dissipative and delay effects. It would be desirable to place actuators directly inside the acquisition room, but this limits the possibilities of using many categories of actuators. Of course, electromagnetic actuators are, in general, not compatible with the MRI environment, but also pneumatic or hydraulic motors could hardly get into the acquisition room, because of their bulky metallic components. Generally speaking, in order to be utilised in an MRI acquisition room, actuators should not include ferromagnetic and conductive materials. However, it is reported that small parts made of MR-incompatible materials do not compromise safety or generate image artefacts as long as they are sufficiently small and appropriately positioned relative to the imaged area [13]. This clears the way to the use of SMA actuators in this field, provided that some specific design rules are respected and that they are applied to body segments sufficiently distant from the head, which is the area of principal interest in Neuroscience.

3.1.2. Magnetoencephalography (MEG)

MEG is a technique for investigating neuronal activity in the living human brain by recording magnetic fields produced by the electrical currents flowing in cortical neurons. These weak magnetic fields (ranging 10^{-14}T-10^{-12}T), can be detected by employing arrays of

SQUID (Superconducting Quantum Interference Device) gradiometers, which convert the magnetic flux threading a pick-up coil into voltage. Since the magnetic fields to be measured are extremely small as compared to the Earth's magnetic field (10^{-5}-10^{-4}T), MEG measures are carried out in a shielded room that minimises interference. Of course, any electromagnetic noise should be avoided inside the acquisition room: there is no safety issue for the patient connected with this constraint, but if not respected the measure would be impossible because SQUID channels would saturate rapidly and would remain unusable as long as the pick-up coils are in the superconductive state. Unlike the case of MRI, theoretically any material could enter an MEG acquisition room. In practice, objects made of conductive materials should remain still inside the shielded room, as any movement would generate an artefact. These constraints are very demanding for most actuation technologies, but design solutions are possible for SMA actuators.

3.2. Compatible design guidelines

Some design indications could be useful for devices intended for either fMRI or MEG studies. In particular, the SMA element should have a shape or should be arranged in a way that limits to a great extent the magnetic fields induced by eddy-currents and by the current used for Joule's heating. For example, the coil of a spring is not particularly indicated, as the intensity of the magnetic field is proportional to the number of turns. Moreover, the SMA actuator should be supplied with a dc-current rather than other types of time-varying currents (pulse-width modulation, sinusoidal current…). In fact, this could help reduce the magnetic field induced by currents flowing into the SMA elements. Power generators and control systems should be positioned outside the acquisition room and wires passed through. As these cables could act as antennas that radiate electromagnetic noise, some countermeasures should be adopted: shielded or twisted cables can limit pick-up of stray frequencies, while using proper filters when connecting the wires inside and outside the acquisition room can help rejecting the time-varying components of the power signal. Coming to the control strategy, an open-loop may be preferred (for its simplicity), as both fMRI and MEG data analysis generally need a precise windowing of signals that matches different phases of movement, in order to extract features of interest with statistical significance. So, closed-loop architectures could be used e.g. to control precise abidance to set movement speed evolution, but might not be strictly necessary if the experimental protocol only requires repeatable ranges of motion in a given time. In fact, within the very protected environments of the shielded rooms, often no major disturbances are expected to intervene and perturb the movement.

Additional recommendations apply only to devices for use in the MRI acquisition room: in particular, ferromagnetic materials should be avoided for safety reasons, even if small parts could be tolerated in some cases. On the other hand, as we said before, during MEG acquisition conductive materials should not move inside the shielded room. Translating this information into design specifications, a first recommendation would be that the moving parts should not mount conductive materials, including the SMA actuators. However, the principle of SMA actuation is that metal moves! The geometry of the SMA element should

be conceived so that macroscopic changes of space occupancy are avoided, thus limiting the amount of movement. For example, in SMA helical springs the linear length can vary considerably during actuation, spanning in many cases more than 300% the unloaded length. On the other hand, traction wires, having a limited elongation, change their space occupancy less dramatically. Interestingly, it should be noticed that the slow actuation rates typical of SMA could be an advantage for limiting artefacts influencing MEG measurements. In fact, it is reasonable that artefacts have mostly the same time frequency components as the movement that generated them, i.e. typically less than 1Hz for SMA actuation. Cortical oscillations range 1-100Hz, but when investigating sensorimotor representation (as expected in the case of Neuroscience for Neuromuscular Rehabilitation), the range of interest reduces to 8-100Hz, giving the possibility to devise suitable signal filtering stages.

3.3. Case study: amagnetic rotary actuator for ankle dorsiflexion during MEG and fMRI acquisitions

3.3.1. Concept

A possible device for ankle dorsiflexion could be devised as a leg part and a foot part connected by planar hinges parallel to the ankle joint, in a similar way to the device presented in section 2.4.2. Two SMA rotary actuators mounted externally with respect to the hinges promote the dorsiflexion of the foot part with respect to the leg part, while plantarflexion and position reset is left to viscoelastic resistance and foot weight (Figure 7). It should be noticed that the requirements for the ranges of movement are different in this application, as the purpose is to produce a clearly detectable movement without muscular stretching. This can be done maintaining joint angle negative or slightly positive (i.e. extended). The objective of the study was to test healthy subject, so it can be estimated that maximum resisting torque will be in the range 200-250Ncm (see Figure 2).

A rotary SMA actuator can be generally described as a structure in which the SMA wire connects parts that can rotate relative to one another about a central axis: when the elongated SMA wire is heated above A_f and recovers its deformation, the linear stroke ΔL is converted into a rotation $\Delta\theta$ of the moving parts. However, it is likely that a conspicuous length of wire is needed to produce a suitable amount of rotary stroke $\Delta\theta$ for ankle dorsiflexion. As we already said, in such cases coiling the wire could improve conveniently overall compactness of the actuator. Unfortunately, this design decision contrasts with the aim of fabricating an amagnetic actuator, as the electric current flowing in coils of wire produces, according to Ampère's Law, an overall magnetic field along the central axis of the solenoid, which is proportional to the number of turns. A very simple solution can be found exploiting the same physical laws of electromagnetic fields. In fact, the magnetic field vector is directed according to the right hand rule with respect to the direction in which the current flows that induced it. Thus, theoretically, given two identical and concentric solenoids traversed by the same electric current in opposite directions, the magnetic fields generated by the coils will mutually annihilate. Moreover, no ferromagnetic materials should be employed in the implementation of all other components of such actuator, as well as the assembled device.

Figure 7. Implementation of an amagnetic device for ankle dorsiflexion with rotary actuators

3.3.2. Actuator implementation and mechanical characterisation

An implementation of the invented amagnetic actuator is shown in Figure 8. Two discs of approximately 10cm in diameter are connected through a central shaft allowing reciprocal rotation, leaving a clearance of 2cm between the two discs. One of the two discs mounts, along its circumference, 6 pins bearing 3 pulleys each, to create a spiralling sequence, along which the SMA wire can be coiled suitably. These pulleys have a double triangular groove, which makes the double coiling as compact as possible. The two ends of the SMA wire are fixed to one disc, while the mid-point of the wire connects to the other disc. The two halves of the wire are would along the pulleys thus creating two concentric coils very close to one another. By providing sufficient current flowing between the two ends of the SMA wire, shape recovery occurs generating a linear stroke ΔL that is converted into a reciprocal rotation $\Delta\theta$ of the two discs. Notice that the torque generated is given by twice the cross-section of the wire, while the induced magnetic field is self-compensated to a large extent, as the two coils are traversed by the same electric current in opposite directions [40].

As already described for the linear actuator in paragraph 2.4.3, wire length depends on the expected angular stroke and the working strain level, while torque output is connected to the wire diameter and mean stress on the cross-section. Moreover, the geometrical parameters of the assembled actuator affect both wire length and torque output. The rotary actuator was designed to provide an angular stroke up to 40° against resisting torques in the

range 120Ncm-250Ncm. By limiting the linear strain to 3.8%, the required length of NiTi wire can be calculated in 219cm. The selected NiTi wire is 250μm in diameter, corresponding to stresses of 130-270MPa in the above-mentioned range of torques. Taking into account the localized strain on the wire resting on the pulleys, the total maximal strain reaches 4.42%, which in combination with the chosen stress level should guarantee suitable fatigue life (several thousands of cycles). Commercial stabilised NiTi wire was utilised, displaying large deformability (4.5%) at room temperature for stress levels as low as 150MPa [58]. The power dimensioning procedure was similar to the one described in paragraph 2.4.3 and led to utilizing 0.7A at 30V for each actuator. Control is achieved with an open-loop strategy, by which acquisition windows can be synchronised to the ankle movement. Power supply and control appliances are left outside the acquisition room, and shielded cables are let into the shielded room through suitable access vents.

Figure 8. Amagnetic SMA rotary actuator, consisting of two coils of wire traversed by the same current in opposite directions. This arrangement produces self-annihilation of induced magnetic fields.

In the present implementation, ferromagnetic materials were avoided. However, it was not possible to exclude completely metallic components, such as the bearing balls, the shafts and the pins. After careful consideration, it was decided that the rotating discs and the frame of the device could be made of an aluminium alloy, in order to minimise structural sections. This choice did not affect the acquisition of biosignals, as will be discussed in the next paragraphs.

Technical tests were carried out on the assembled device, to assess its characteristics. Increasing loads were attached to the foot part of the orthosis 13cm from the axis of rotation,

while the device was held aloft by a static support. The weights used in this test produced resisting torques in the range 28-250Ncm. A direct current injection at 30V for 7s was applied to the actuators, connected in parallel; then 30s were allowed for position reset through natural cooling and the action of the weights. The resulting angular upward and downward strokes were measured by means of electrogoniometer SIM-HES-EG 042 (Signo Motus, Messina, Italy). Figures 9 shows the results. At lower values of resisting torques (i.e. in the range 28Ncm-120Ncm), angular stroke is not stabilised and steadily increases from 24° to 36°. For torques above 120Ncm, angular stroke is quite stable at 36°. Curves steadily shift towards negative angles (zero being the horizontal position, and negative in the direction of plantarflexion) with increasing torques. This increase in stroke is caused by the incomplete detwinning of martensite at lower torques: it is worth noticing that anyway, even at the lower values of measured angular stroke, suitable angular strokes are obtained.

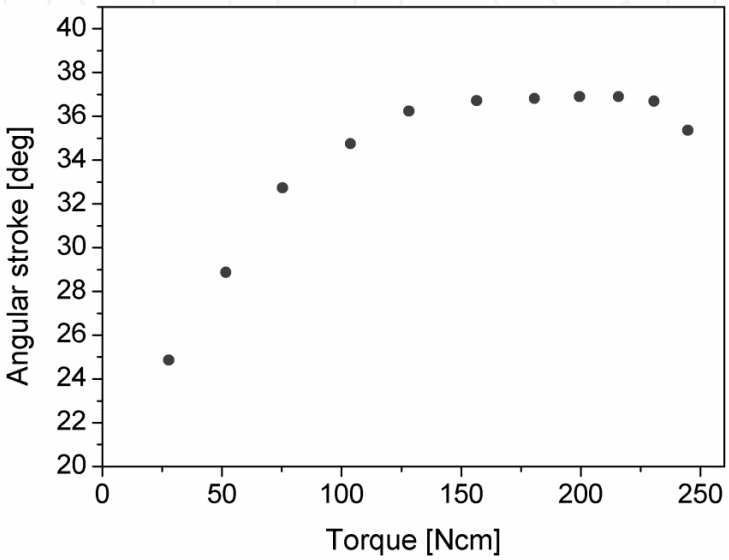

Figure 9. Angular stroke of the SMA-based exerciser for different resisting static torques. The dotted line is just a guide for the eye.

3.3.3. Tests in a MEG shielded room

In order to assess compatibility with the MEG technology, neural activity from a healthy subject's brain during repeated passive mobilisation of the ankle by the device was carried out with an MEG system composed of 153 SQUID channels covering the whole surface of the scalp. The electric power generator and the programming computer were kept out of the shielded room, and cables were passed through suitable vents in the shims. The NiTi wire was activated by a current pulse (ramp to 0.7A in 1s, then flat for 9s).

These tests revealed no significant noise on SQUID channels. Figure 10 (left) shows the signal recorded by one representative channel during MEG testing of the healthy volunteer.

At t=0s, the actuators on board the orthosis were switched on. There is no artefact at that moment, indicating that the level of noise in the acquisition room has not changed. Furthermore, the right graph in the same Figure demonstrates that the frequency components in the actuator-OFF and actuator-ON states are the same. The variation in intensity of the signal power spectral density (PSD) can be totally accounted for by a change in the cortical reactivity of the subject under testing: this variation is an important part of the measured quantities of interest.

Incidentally, the use of conductive materials in the construction of the device did not affect the acquisition. This is probably due to the slow movement provided by the actuators, which generates low-frequency artefacts that can be suitably eliminated during routine filtering and windowing of the MEG data.

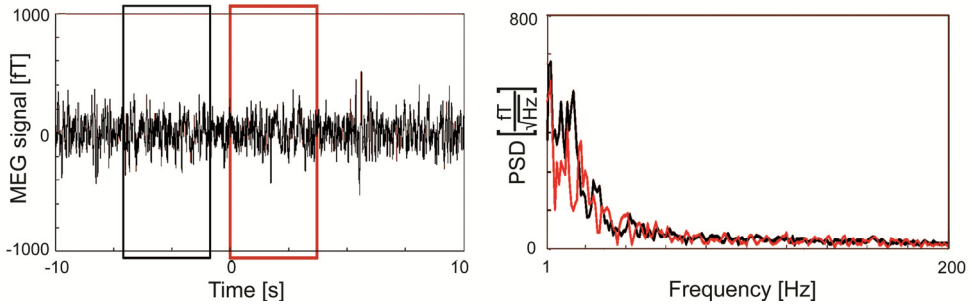

Figure 10. Left: MEG signal recorded by a representative SQUID channel from a healthy subject during passive mobilisation of the ankle by the amagnetic exerciser. Right: spectral components of the recorded MEG signal, before and after switching on the actuators at t=0s (black and red line, respectively).

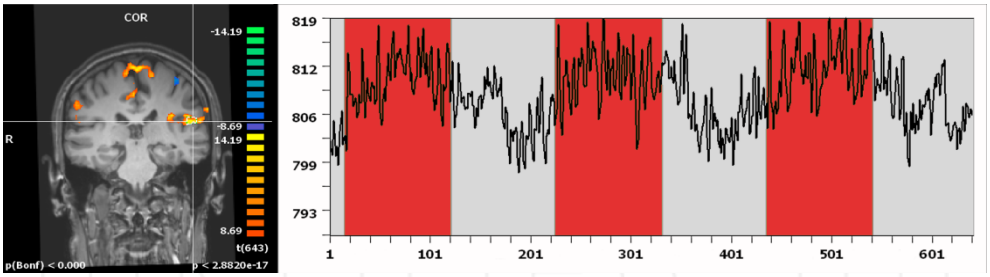

Figure 11. Left: fMRI image of metabolic activity in a healthy brain during passive mobilisation of the ankle. Right: time-course of the BOLD signal (arbitrary units) in the area of the brain highlighted in the left figure.

3.3.4. Tests in a MRI acquisition room

Magnetic resonance images were collected in a Philips 3T Achieva X-Series Magnetic Resonance scanner. fMRI signals were treated to extract the Blood Oxygen Level Dependent (BOLD) image, which depicts changes in neural metabolism related to neural activity. fMRI images (Figure 11) were not affected by any artefact. The BOLD signal was clearly collected

from all parts of the brain and in some areas seemed to be temporally dependent on the movements of the ankle. The use of conductive materials in the implementation of the device did not affect the acquisition. The distance between the gantry (or head coil) and the ankle probably helped limit any influence on image encoding.

4. Conclusions

This Chapter showed some innovative applications of Shape Memory Alloys requiring deep understanding of the interaction of the material characteristics with the complex constraints imposed by the human body. In particular, it was explained how the design plan should be laid considering the many aspects connected to the state of the target patient, and the technical requirements should be chosen to meet very well identified needs. The field of Medical Rehabilitation is an interesting domain for exploiting the functional properties of NiTi-based alloys in making new lightweight and portable actuators. The Neuroscience applications introduced in this Chapter, on the other hand, albeit representing a niche sector *per se*, both make the most of the typical design techniques employed for rehabilitation devices, and provide a development ground for interesting industrial actuators with amagnetic characteristics. It is hoped that the SMA-based design strategies presented here will be of inspiration to engineers interested in utilising shape memory actuation for biomedical, robotic, aerospace or automotive applications with tight and mandatory external constraints where compactness, light weight or wearability are desired features of the device.

Author details

Simone Pittaccio* and Stefano Viscuso
National Research Council of Italy, Institute for Energetics and Interphases, Lecco, Italy

Acknowledgement

The authors would like to thank the staff of ITAB, University of Chieti, where the tests employing MEG and fMRI were conducted: in particular Gian Luca Romani, Filippo Zappasodi, Vittorio Pizzella and Gabriella Tamburro for the MEG measurements, Cosimo Del Gratta, Antonio Ferretti and Mauro Gianni Perrucci for the fMRI trials. The financial support from Regione Lombardia (Mind in Italy Project) is most gratefully acknowledged.

5. References

[1] Gracies J-M (2005) Pathophysiology of spastic paresis I: paresis and soft tissue changes, Muscle Nerve 31: 535–551.
[2] Gracies J-M (2005) Pathophysiology of spastic paresis II: emergence of muscle overactivity, Muscle Nerve 31: 552–571.

* Corresponding Author

[3] Simon O, Yelnik AP (2010) Managing spasticity with drugs. Eur J Phys Rehabil Med. 46: 401-410.
[4] European Stroke Organisation (ESO) Executive Committee, ESO Writing Committee (2008) Guidelines for management of ischaemic stroke and transient ischaemic attack, Cerebrovasc. Dis. 25: 457-507.
[5] Duncan PW, Zorowitz R, Bates B, Choi JY, Glasberg JJ, Graham GD, Katz RC, Lamberty K, Reker D (2005) Management of Adult Stroke Rehabilitation Care: a clinical practice guideline, Stroke. 36: e100-e143.
[6] Hesse S (2008) Treadmill training with partial body weight support after stroke: a review. NeuroRehabilitation. 23: 55-65.
[7] Krebs HI, Rossi S, Kim S, Artemiadis PK, Williams D, Castelli E, Cappa P. (2011) Pediatric anklebot. IEEE Int. Conf. Rehabil. Robot 1-5.
[8] Staubli P, Nef T, Klamroth-Marganska V, Riener R (2009) Effects of intensive arm training with the rehabilitation robot ARMin II in chronic stroke patients: four single-cases. J Neuroeng Rehabil. 17: 6:46.
[9] Fasoli SE, Krebs HI, Stein J, Frontera WR, Hogan N (2003) Effects of robotic therapy on motor impairment and recovery in chronic stroke. Arch. Phys. Med. Rehabil. 84: 477-482.
[10] Alary F, Simões C, Jousmäki V, Forss N, Hari R (2002) Cortical activation associated with passive movements of the human index finger: an MEG study. Neuroimage. 15: 691-696.
[11] Boonstra TW, Clairbois HE, Daffertshofer A, Verbunt J, van Dijk BW, Beek PJ (2005) MEG-compatible force sensor. J Neurosci Methods. 144: 193-196.
[12] Suminski AJ, Zimbelman JL, Scheidt RA (2007) Design and validation of a MR-compatible pneumatic manipulandum. J Neurosci Methods. 163: 255-266.
[13] Tsekos NV, Khanicheh A, Christoforou E, Mavroidis C (2007) Magnetic resonance-compatible robotic and mechatronics systems for image-guided interventions and rehabilitation: a review study. Annu Rev Biomed Eng. 9: 351-387.
[14] Onishi H, Oyama M, Soma T, Kubo M, Kirimoto H, Murakami H, Kameyama S (2010) Neuromagnetic activation of primary and secondary somatosensory cortex following tactile-on and tactile-off stimulation. Clin Neurophysiol. 121: 588-593.
[15] Hollnagel C, Brügger M, Vallery H, Wolf P, Dietz V, Kollias S, Riener R (2011) Brain activity during stepping: a novel MRI-compatible device. J Neurosci Methods. 201: 124-130.
[16] Funakubo H (1987) Shape memory alloys. New York: Gordon and Breach Science Publishers. 275p.
[17] Otsuka K, Wayman CM (1998) Shape Memory Materials, Cambridge: Cambridge University Press. 287 p.
[18] Otsuka K, Ren X (2005). Physical metallurgy of Ti–Ni-based shape memory alloys, Progr. in Mater. Science. 50: 511-678.
[19] Lagoudas DC (2008) Shape Memory Alloys: Modeling and Engineering Applications. Berlin: Springer. 435 p.

[20] Viscuso S, Pittaccio S, Caimmi M, Gasperini G, Pirovano S, Besseghini S, Molteni F (2009) Pseudoelastic alloy devices for spastic elbow relaxation. In: Lim CT, Goh JC, editors. ICBME 2008 – 13th International Conference on Biomedical Engineering, IFBME Proceedings 23. Berlin: Springer. pp. 1584–1587.

[21] Pittaccio S, Viscuso S (2009) The use of muscle "creep" as opposed to relaxation in stretching braces: a pseudoelastic device. In: Dössel O, Schlegel WC, editors. World Congress on Medical Physics and Biomedical Engineering 2009, IFMBE Proceedings 25/9. Berlin: Springer. pp. 178-181.

[22] Pittaccio S, Viscuso S (2009) Customizable neuro-mechanical model of a hemiplegic elbow interacting with a pseudoelastic dynamic orthosis. In: Dössel O, Schlegel WC, editors. World Congress on Medical Physics and Biomedical Engineering 2009, IFMBE Proceedings 25/9. Berlin: Springer. pp. 182-185.

[23] Viscuso S, Pittaccio S, Caimmi M, Gasperini G, Pirovano S, Villa E, Besseghini S, Molteni F (2009) Pseudoelastic Nitinol-Based Device for Relaxation of Spastic Elbow in Stroke Patients. J Mater Eng Perform 18: 805–813.

[24] Patent Number: WO/2011/137999. Joint For Articulations With Pseudo-Elastic Elements.

[25] Pittaccio S, Viscuso S, Beretta E, Turconi AC, Strazzer S (2010) Pilot studies suggesting new applications of NiTi in dynamic orthoses for the ankle joint. Prosthet Orthot Int 34: 305-318.

[26] Hanafusa A, Isomura T, Sekiguchi Y, Takahashi H, Dohi T (2002) Orthosis Design System for Malformed Ears Based on Spline Approximation. In: Dohi T, Kikinis R, editors. Medical Image Computing and Computer-Assisted Intervention — MICCAI 2002. Berlin: Springer. pp. 227-234.

[27] Shimizu Y, Kobayashi (2011) The Development of Foot Orthotics using Shape Memory Alloy for Preventing Falls. In: Werner B, editor. 2011 IEEE 11th International Conference on Bioinformatics and Bioengineering. Washington: Conference Publishing Services. pp. 117-120.

[28] Takami M, Fukui K, Saitou S, Sugiyama I, Terayama K (1992) Application of a shape memory alloy to hand splinting. Prosthet Orthot Int. 16: 57-63.

[29] Patent Number: US 2008/0294079 A1. Orthotic Apparatus And Method Of Operation.

[30] Patent Number: US 2011/0131838 A1. Dynamically Adjustable Orthotic Device.

[31] Machado LG, Savi MA (2003) Medical applications of shape memory alloys. Braz J Med Biol Res. 36: 683-691.

[32] Lai YJ, Yeh LJ, Chiu MC (2010) An Assessment of the Body Joint Bending Actuator using a Shape Memory Alloy. J Appl Sci, 10: 1973-1977.

[33] Lai YJ, Yeh LJ, Chiu MC (2012) An experimental investigation on shape memory alloy dynamic splint for a finger joint application. Sens Actuator A-Phys 173: 210–218.

[34] Torri M, Viscuso S, Pittaccio S, Nespoli A, Besseghini S (2006) Biomechanical design of a shape memory alloy spring for the activation of a flaccid hand rehabilitation device. In: Venugopalan R, Wu MH, editors. Medical Device Materials III: Proceedings of the Materials & Processes for Medical Devices Conference. Materials Park: ASM International. pp.237-242.

[35] Van Kuren MB, Gillette S, Mejia P, Stoever T, Walker A,(2005) Design considerations for a wearable pediatric rehabilitative boot. In: ICORR 2005, 9th International Conference on Rehabilitation Robotics. pp. 400- 403. Available: http://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=1501128. Accessed 2012 Mar 28.
[36] Pittaccio S, Viscuso S, Rossini M, Magoni L, Pirovano S, Villa E, Besseghini S, Molteni F (2009) SHADE: A shape-memory-activated device promoting ankle dorsiflexion. J Mater Eng Perform 18: 824–830.
[37] Viscuso S, Pittaccio S, Tecchio F, Zappasodi F, Rossini M, Magoni L, Pirovano S, Besseghini S, Molteni F (2009) Assessment of the peripheral performance and cortical effects of SHADE, an active device promoting ankle dorsiflexion. In: Lim CT, Goh JC, editors. ICBME 2008 – 13th International Conference on Biomedical Engineering, IFBME Proceedings 23. Berlin: Springer. pp. 961-965.
[38] Viscuso S, Pittaccio S, Zappasodi F, Tecchio F (2009) A magnetically quasi-transparent tool for ankle passive mobilization in investigations on cortical involvement using MEG. In: Dössel O, Schlegel WC, editors. World Congress on Medical Physics and Biomedical Engineering 2009, IFMBE Proceedings 25/7. Berlin: Springer. pp. 410-413.
[39] Pittaccio S, Zappasodi F, Viscuso S, Mastrolilli F, Ercolani M, Passarelli F, Molteni F, Besseghini S, Rossini PM, Tecchio F (2011) Primary sensory and motor cortex activities during voluntary and passive ankle mobilization by the SHADE orthosis. Hum Brain Mapp 32: 60-70.
[40] Patent Number: WO/2011/141183. Rotational Actuator.
[41] Pittaccio S, Viscuso S (2011) An EMG-Controlled SMA Device for the Rehabilitation of the Ankle Joint in Post-Acute Stroke. J Mater Eng Perform 20: 666-670.
[42] Merrett GV, Metcalf CD, Zheng D, Cunningham S, Barrow S, Demain SH (2011) Design and Qualitative Evaluation of Tactile Devices for Stroke Rehabilitation. Presented at IET Assisted Living 2011, London, UK. Available: http://eprints.soton.ac.uk/271802/. Accessed 2012 Mar 28.
[43] Patent Number: US 2001/0029224 A1. Exercise Kit And Method Of Using Same.
[44] Esfahani ET (2007) Developing an Active Ankle Foot Orthosis Based On Shape Memory Alloys. M.Sc. thesis. Available: http://etd.ohiolink.edu/send-pdf.cgi/Tarkesh%20 Esfahani%20Ehsan.pdf?toledo1197561946. Accessed 2012 Mar 28.
[45] Esfahani ET, Elahinia MH (2007) Stable Walking Pattern for an SMA-Actuated Biped IEEE/ASME Trans Mechatron 12: 534-541.
[46] Stirling L, Yu CH, Miller J, Hawkes E, Wood R, Goldfield E, Nagpal R (2011) Applicability of Shape Memory Alloy Wire for an Active, Soft Orthotic. J Mater Eng Perform 20: 658-662.
[47] Patent Number: WO 2011/008934 A2. Actively Controlled Orthotic Device.
[48] Patent Number: US 5103807. Shape Memory Alloy Orthotic Device.
[49] Abolfathi PP (2007) Development of an Instrumented and Powered Exoskeleton for the Rehabilitation of the Hand. Ph.D. thesis. Available: http://ses.library.usyd.edu.au/bitstream/2123/3690/1/01pp-abolfathi-2008-thesis.pdf. Accessed 2012 Mar 28.

[50] Patent Number: US 6379393 B1. Prosthetic, orthotic, and other rehabilitative robotic assistive devices actuated by smart materials.
[51] Jayatilake D, Gruebler A, Suzuki K (2010) Robot Assisted Smile Recovery. In: Kordic V, editor. Cutting Edge Robotics 2010. Rijeka: InTech. pp. 333-350.
[52] Esteki A, Mansour JM (1996) An experimentally based nonlinear viscoelastic model of joint passive moment. J Biomech. 29: 443-450.
[53] Given JD, Dewald JPA, Rymer WZ (1995) Joint dependent passive stiffness in paretic and contralateral limbs of spastic patients with hemiparetic stroke. J Neurol Neurosurg Psychiatry 59: 271-279.
[54] Lin CCK, Ju MS, Chen SM, Pan BW (2008) A Specialized Robot for Ankle Rehabilitation and Evaluation. J Med Biol Eng 28: 79-86.
[55] IEC 60601-1. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
[56] ISO 14971. Medical devices - Application of risk management to medical devices.
[57] ISO 14155. Clinical investigation of medical devices for human subjects - Good clinical practice.
[58] Fumagalli L, Butera F, Coda A (2009) SmartFlex® NiTi Wires for Shape Memory Actuators. J Mater Eng Perform 18: 691-695.
[59] Liu SH, Huang TS, Yen JY (2010) Tracking Control of Shape-Memory-Alloy Actuators Based on Self-Sensing Feedback and Inverse Hysteresis Compensation. Sensors 10: 112-127.