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SHADE: A Shape-Memory-Activated Device Promoting Ankle Dorsiflexion

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Acute post-stroke rehabilitation protocols include passive mobilization as a means to prevent contractures. A device (SHADE) that provides repetitive passive motion to a flaccid ankle by using shape memory alloy actuators could be of great help in providing this treatment. A suitable actuator was designed as a cartridge of approximately 150 × 20 × 15 mm, containing 2.5 m of 0.25 mm diameter NiTi wire. This actuator was activated by Joule's effect employing a 7 s current input at 0.7 A, which provided 10 N through 76 mm displacement. Cooling and reset by natural convection took 30 s. A prototype of SHADE was assembled with two thermoplastic shells hinged together at the ankle and strapped on the shin and foot. Two actuators were fixed on the upper shell while an inextensible thread connected each NiTi wire to the foot shell. The passive ankle motion (passive range of motion, PROM) generated by SHADE was evaluated optoelectronically on three flaccid patients (58 ± 5 years old); acceptability was assessed by a questionnaire presented to further three flaccid patients (44 ± 11.5 years old) who used SHADE for 5 days, 30 min a day. SHADE was well accepted by all patients, produced good PROM, and caused no pain. The results prove that suitable limb mobilization can be produced by SMA actuators.

Keywords actuator, orthosis, rehabilitation, shape memory alloys

1. Introduction

Ankle rehabilitation techniques are very commonly present in the clinical practice, as they are strongly indicated in the treatment of several different neuromuscular diseases. For instance, the distal lower extremities are very often affected by stroke events. Considering the social impact of stroke alone (annually, 15 million people worldwide suffer a stroke and 5 million of these are left permanently disabled) (Ref 1), it is easy to appreciate the importance of developing new strategies in this field. After stroke, a rehabilitation program should be performed as soon as the patient's conditions are sufficiently good. Moving the limbs passively can improve circulation, maintain joint flexibility and normal muscle tone, while the patient is unable to exercise actively (Ref 2, 3). Contracture prevention due to passive stretching in the acute phase after CNS injury is also reported (Ref 4). The motor impairment due to paresis after stroke is greatly aggravated by the muscle and joint contracture and the changes in muscle contractile properties caused by immobilization (Ref 5). AHA/ASA endorsed guidelines for 2005 (Ref 6), besides stressing the need for a multidisciplinary approach in post-stroke care, also indicate that a strong difference in the final treatment outcomes derives from the sheer time spent on physical rehabilitation. Favorable effects on activities of daily living are particularly evident if therapy input is augmented by at least 16 h within the first 6 months relative to standard practice (Ref 7).

Passive mobilization (Ref 8-10) may also contrast deafferentation and learned non-use, i.e. directly address impairment of the cortical pathways involved in active limb control. The way this happens is not clear. There is evidence, however, that functional recovery occurs while changes in sensorimotor activation take place in the cerebral cortex.

A simple, user-friendly and safe device for use in the first few weeks after the acute event, during or following manual treatment by a therapist, could lead to great benefits for the patient by preventing the insurgence of severe sequelae and would help limit health service costs. In order to be a reliable device for rehabilitation purposes, this orthosis should comply with a number of clinical and functional requirements, i.e. it should be capable of promoting cyclic mobilization of the ankle joint across at least a range of −5 to 10° (negative being toward plantarflexion), have suitable repetition times in a physiological range, be thermally and electrically safe for the patient, lightweight and compact to wear.

Such a device was designed as a prototype named SHADE. It mounts shape memory alloy (SMA) actuators, which are inherently compliant, among others, with the limited-weight and compactness requirements of wearable orthoses. To try and build such a device was an invaluable opportunity to study the possible applications of SMAs in rehabilitation medicine.

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2. Material and Characterization

2.1 Orthosis Design

A prototype of SHADE (Fig. 1) was assembled with two thermoplastic shells modeled on a prototype human lower limb of average size. These are hinged together at the ankle and strapped by Velcro® bands on the frontal aspect of the shin and on the foot. Two cartridge actuators are fixed on the front of the upper shell with inextensible threads connecting each NiTi wire to the foot shell. The fixation points for the actuators (on the shin) and the distal ends (foot ends) of the inextensible threads were optimized by a factorial experiment and principal component analysis scheme. This yielded the triplet of distances $a = 11.5$ cm, $b = 5.5$ cm, $c = 9.5$ cm for the fixtures with respect to the orthosis joint (Fig. 1). This configuration provides a theoretical maximum angular displacement of 28.67° with maximum force per actuator of around 10 N with a foot weighing 12-17 N. A dedicated software home-written in LabView (National Instruments, Austin, TX) controls an array of electronic relays (NI9481—National Instruments, Austin, TX) that switch on and off a dc-generator providing sufficient power to get shape recovery. All the electric connections and the thermal shielding are suitable to guarantee patients' safety.

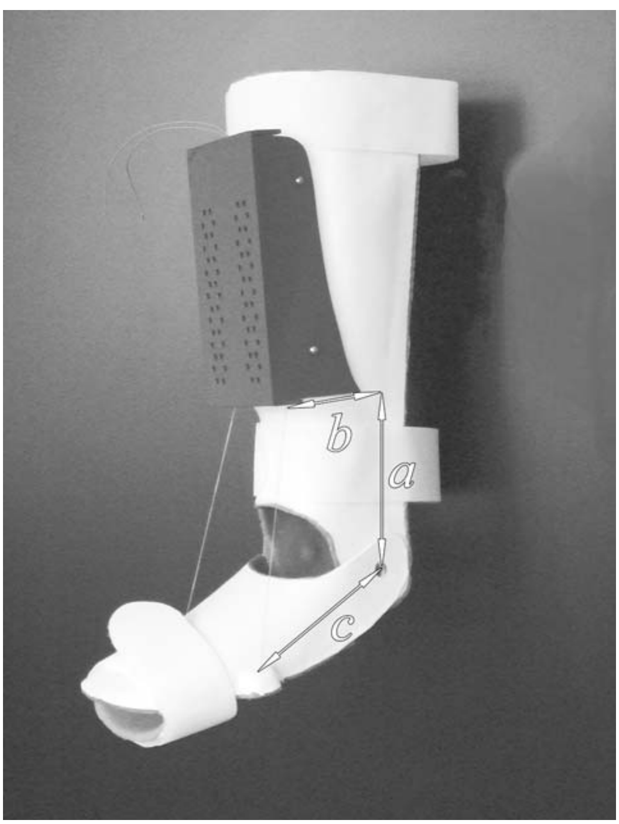

Fig. 1 Prototype of SHADE showing the two thermoplastic shells hinged at the ankle joint. The Velcro® straps around the calf and foot are visible; the cartridge actuators are enclosed in the vented box; the power wires (from the top) and the inextensible threads (from the bottom) are clearly exposed. Label a shows the distance of the thread exit from the ankle along the tibial shell, b shows the same distance along the orthogonal direction; and c shows the radial distance of the foot insertion of the thread from the ankle

2.2 Actuator Design

Choosing a lever arm of around 9.5 cm, to produce an angular movement of say 25°, the NiTi wire was taken 250 cm long (with a maximum expected deformation well beneath 4%, to guarantee cycling stability). The actuator was designed as a $150 \times 20 \times 15$ mm insulated aluminium cartridge wherein the necessary reference length of NiTi wire is led back-and-forth between two arrays of ten mini-pulleys. This makes it possible to confine a long wire within a limited space (Fig. 2). An end of the wire is connected to the electric contact and to an inextensible thread that transmits the force to the foot, while the other one is fixed to the housing and makes the second electric contact. A pseudoelastic spring (40 turns, 2 mm inner coil diameter, 300 μm wire) is connected to the moving end of the NiTi wire in order to keep it taut. Heating is provided by Joule's effect, while cooling is left to natural convection.

2.3 Shape Memory Material

A shape memory NiTi 250 μm diameter commercial wire stabilized for actuation was mounted in the two cartridges to ensure lasting performance for SHADE and industrial reproducibility.

Differential scanning calorimetry (on DSC 220 SSC/5200—Seiko Instruments, Tokyo, Japan) was carried out on a sample of wire, showing $A_f = 351$ K and $M_f = 274$ K (Fig. 3).

Tensile tests were conducted using an MTS 2/M thermo-mechanical test machine (MTS Systems, Eden Prairie, MN) equipped with a 2 kN load cell. The material was deformed up to an engineering strain of 5%, at 365, 380, and 390 K. The pseudoelastic plateau values varied as a function of temperature with a $\Delta\sigma/\Delta T$ ratio of 8.402 MPa/K (Fig. 3).

Activation tests were conducted on the same test machine, maintaining the crosshead fixed and injecting different currents (0.65, 0.7, 0.75, and 0.8 A) in the wire at a constant strain of 4% for a set period of 13 s. Results are shown in Fig. 4.

2.4 Power Dimensioning

The choice and the settings of a dc-generator to activate SHADE depend on both the application and the material properties. Actuators mount a 250 cm long 250 μm diameter wire, which implies an electric resistance ranging 45-54 Ω during transformation from fully austenitic to fully martensitic. Activation tests on the wire were analyzed to decide what current value is more appropriate to provide a maximal force of at least twice an estimated working load of 10 N per wire, minimizing current expenditure and heating time to reach 10 N (Fig. 4). The current selected was 0.7 A, corresponding to a voltage of 35 V, considering an average resistance of 49.5 Ω.

The temperature to achieve full transformation depends on the load applied. With the estimated working load of 10 N, the calculated $\Delta\sigma/\Delta T$ ratio and a DSC A_f of 351 K, this means 375 K. By applying 35 V to the ends of the cartridge actuator suspending a 10 N weight, it was demonstrated that this temperature is reached in around 7 s.

2.5 Technical Characterization

The cartridge was tested by applying to it increasing loads of 0.8, 0.9, 1.0, 1.1, and 1.2 kg (respectively 7.85, 8.83, 9.81, 10.79, and 11.76 N) and measuring the displacement achieved with a current injection of 0.7 A for 7 s. Cooling and reset by natural convection took around 30 s.

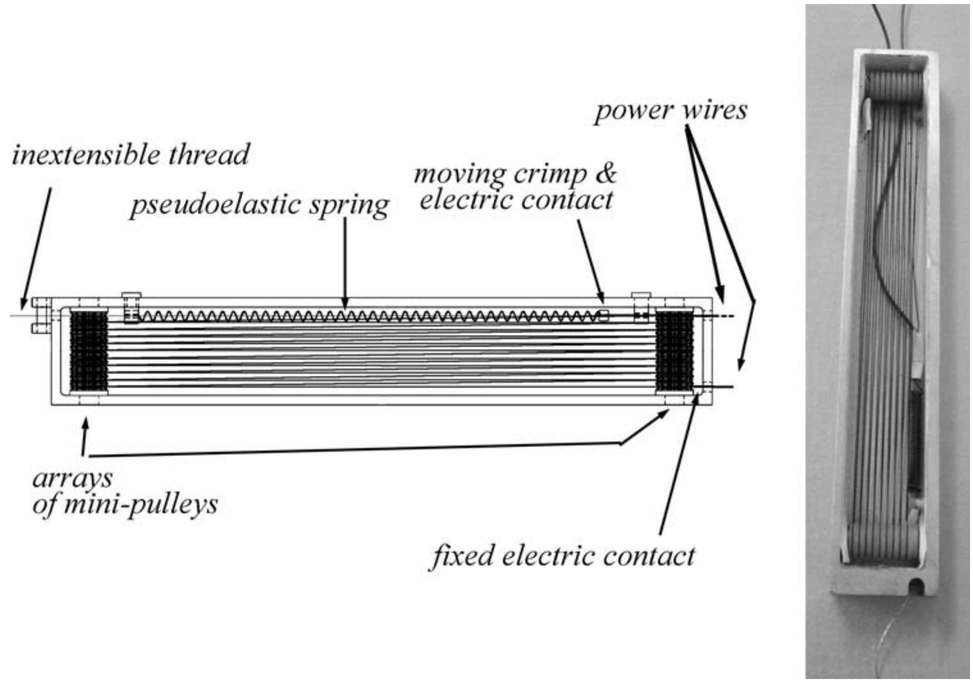

Fig. 2 Drawing and photograph of the cartridge actuator. SMA wire is pulled back-and-forth between two arrays of mini-pulleys. A pseudoelastic spring keeps the wire taut. Electric connections are made to both ends of the wire, so that the actuator can be worked by Joule's effect. While one end is fixed, the other end is connected to an inextensible thread that transfers force and displacement outside the cartridge

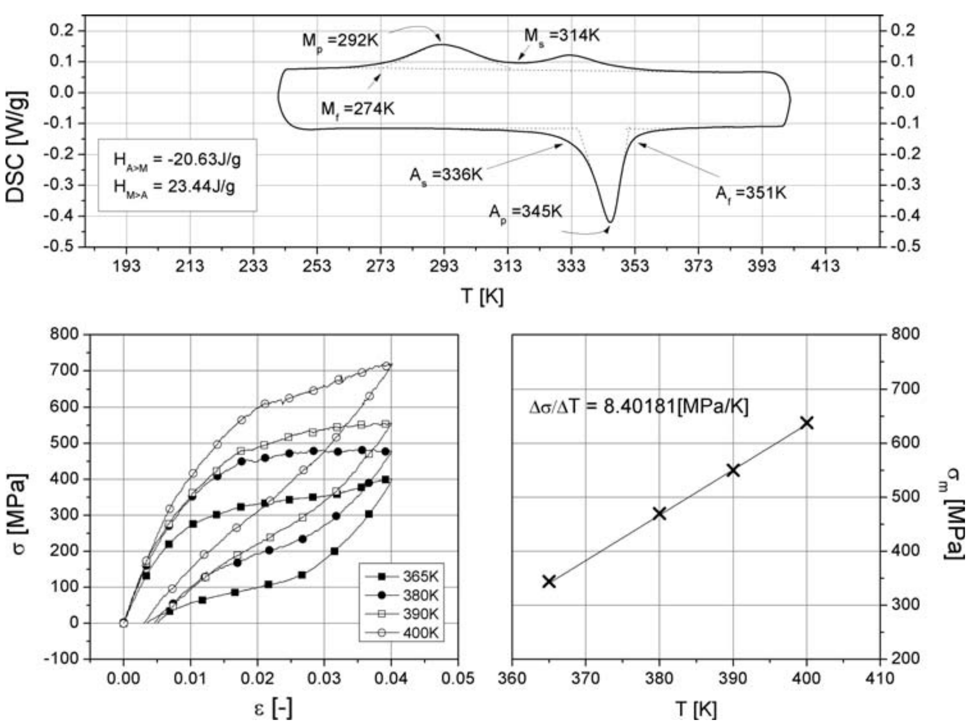

Fig. 3 SMA wire static characteristics. The top graph shows the results of DSC analysis on a sample of commercial wire, as received. The bottom left graph displays stress-strain curves for different working temperatures. The bottom right graph shows linear fitting of the plateau values (as measured near 2.5% strain) vs. working temperature. Clausius-Clapeyron constant is derived from the fit

Similarly the assembled SHADE orthosis was tested with a sequence of increasing loads (7.85, 8.83, 9.81, and 10.79 N) fixed on the foot shell at a distance of 15 cm from the ankle, while measuring the angular displacement by means of electrogoniometer SIM-HES-E.G 042 (Signo Motus, Messina, Italy). The current pattern was the same as that of the cartridge tests, with a 7 s step of 1.4 A (0.7 A per cartridge) and 30 s allowed for cooling.

3. Subjects and Clinical Methods

3.1 Patient Selection

A first group of 3 patients (A1, A2, A3) was enrolled to assess the efficacy of SHADE in producing ankle dorsiflexion in accordance with the clinical requirements and to prove short-term tolerability. Later on, acceptability of passive mobilization was evaluated on a second group of 3 inpatients (B1, B2, B3) who were treated with SHADE 30 min a day for 5 consecutive days, alongside standard physical therapy. The selection criteria for both groups were flaccid or slightly spastic (≤1 on the Ashworth Scale) hemiparesis involving the ankle as a consequence of first stroke, no major skin or articular pathologies, no severe cognitive impairment, able to answer questions. The patients' characteristics are presented in Table 1.

Patients were treated according to ethical principles, as approved by the hospital ethical committee, and gave informed consent.

3.2 Clinical Protocol

Patients underwent general clinical assessment prior to the start of the treatment. The first group used SHADE in single trials to measure the instantaneous range of motion by means of eight optoelectronic cameras sampling at 100 Hz (Elite Gait Eliclinic—BTS, Garbagnate Milanese, Italy). Six IR reflective markers were positioned on the *condyli tibiales*, the *malleoli*, *metatarsi I* and *V*, identifying the ankle angle as the one extending between the central axes of shin and foot. The additional measurement *D* and segment length *L* allowed adjusting the angle baseline (Fig. 5). The patients, wearing SHADE, were asked to try and lift the tip of the foot without any cues about to what extent or at what speed the task had to be carried out; irrespective of the results of this active trial, SHADE was then used to elicit passive dorsiflexion twice.

The second group of patients used SHADE 30 min for 5 days, subsequently to the usual physiotherapeutic manoeuvres. Acceptability of SHADE was investigated by observation and interviewing the patients.

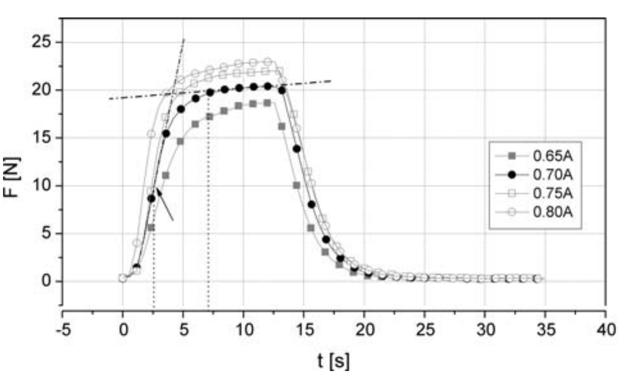

Fig. 4 SMA wire dynamic characteristics. This graph shows the wire force response to a 13 s square current pulse. The wire was kept at a constant strain of 4% while current was injected. The black line with filled circles relates to the current value selected for the application (0.7 A): rise time to 10 N approximates the one for 0.75 A (2.5 s) although current expenditure is less; transformation offset occurs near 4 s; power is sufficient to reach a force of 20 N in around 7 s

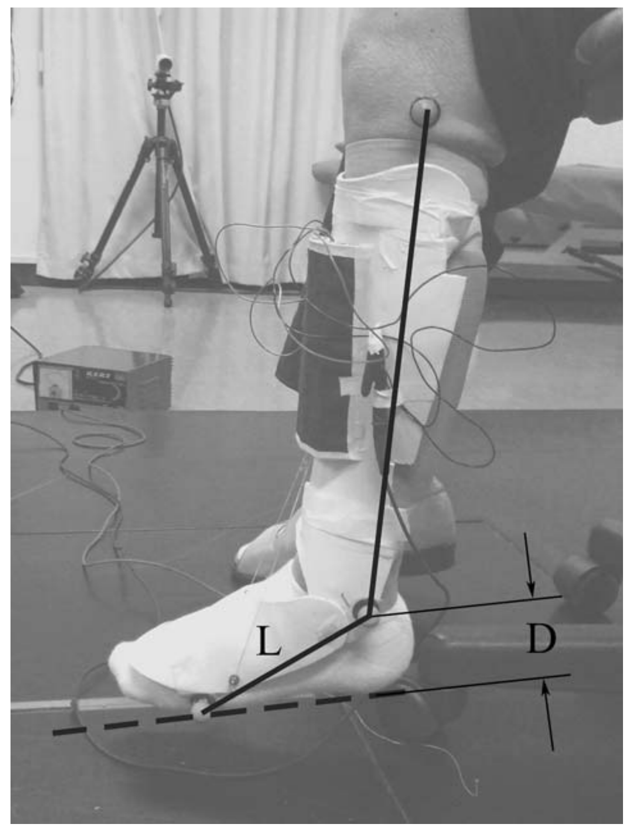

Fig. 5 IR-reflective markers for optoelectronic movement tracking were positioned on the *condyli tibiales*, the *malleoli*, *metatarsi I* and *V*, identifying the ankle angle as the one extending between the central axes of shin and foot. The additional manual measurement *D* and the segment lengths *L* acquired during tracking allowed adjusting of the angle baseline

Table 1 Patients' characteristics (PROM = passive range of motion; AROM = active range of motion)

Patient	Age	Sex	Diagnosis	Range of motion	Treatment
A1	63	F	Left hemiplegia post stroke (2003)	Full PROM, full AROM	Single trial
A2	53	M	Left hemiplegia post stroke (2004)	Full PROM, no AROM	Single trial
A3	58	M	Left hemiplegia post stroke (2007)	Full PROM, no AROM	Single trial
B1	48	M	Right hemiplegia post stroke (2007)	Full PROM, no AROM	30 min for 5 days
B2	53	M	Right hemiplegia post stroke (2007)	Full PROM, no AROM	30 min for 5 days
B3	31	F	Right hemiplegia post stroke (2007)	Full PROM, limited AROM	30 min for 5 days

4. Results

4.1 Technical Characterization of the Cartridge Actuator

The results of the characterization of a single actuator are shown in Fig. 6. Displacement peaks for a static load of about 8.83 N, with the free end of the wire moving by around 8 cm (3.2% strain, not considering localized deformation around the pulleys). Note that between-weight differences are all below 10%. Work capability continues to rise for heavier loads but appears to come to a maximum at around 12 N. These data suggest that the actuator should be able to lift the estimated load of 10 N across sufficiently large displacements.

4.2 Technical Characterization of SHADE

The results of the tests on SHADE are shown in Fig. 7. Angular displacement is very stable with weight (26.25° ± 1.5°, mean ± SD), while curves tend to drift toward lower angles (decreasing dorsiflexion) on increasing weights.

4.3 Clinical Outcomes

Optoelectronic movement analysis of the patients in group A revealed that SHADE is capable of producing (and even exceeding) the minimum required angle span (Fig. 8). In particular, with patient A3 it elicited motion from −4.5 to +19°, adding up to a total angular displacement of 23.5°, not too far from the theoretical limit. Patient A1 is particularly interesting, as she was able to produce active movements of her own. As can be appreciated from the graphs of her acquisitions, the speed of passive dorsiflexion (SHADE activation) closely matches the one of natural spontaneous motion. The reset speeds and angles are not matched, however.

Acceptability every day and after 5 consecutive days of exercise with SHADE was very good, as no patients complained of any pain (patient B1 only reported slight friction nuisance), while all of them said they would be willing to continue therapy with SHADE if recommended to do so.

5. Discussion

5.1 Actuator Design

In the light of the a priori choice to employ and study the application of shape memory materials to this case, the functional and clinical requirements set out in the introduction could be rephrased in terms of material and technical characteristics. In particular, the SMA actuators, whatever their shape, ought to overcome collectively loads in excess of 150 Ncm, provide angular motion across over 15° and have relatively short cooling times. Those issues have tread-offs in terms of

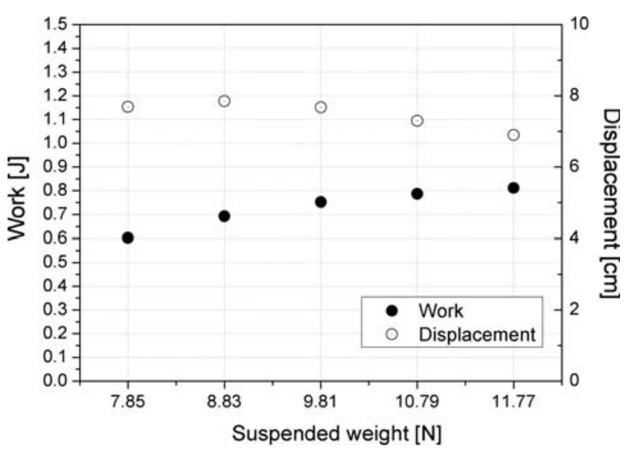

Fig. 6 Results of cartridge actuator characterization. Maximum displacement occurs for loading at around 0.9 kg (8.83 N). Maximum work output is achieved for loads above 1.2 kg (11.77 N)

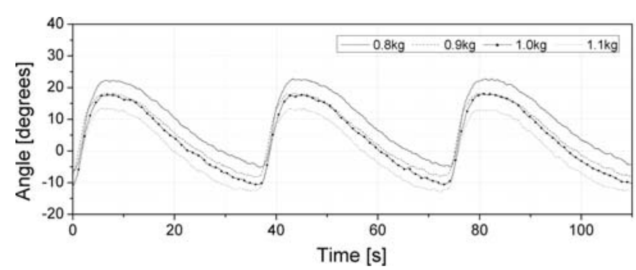

Fig. 7 Results of SHADE characterization. Angular range is stable with different loads, while maximum dorsiflexion angle decreases with load. Between-cycle repeatability is very good

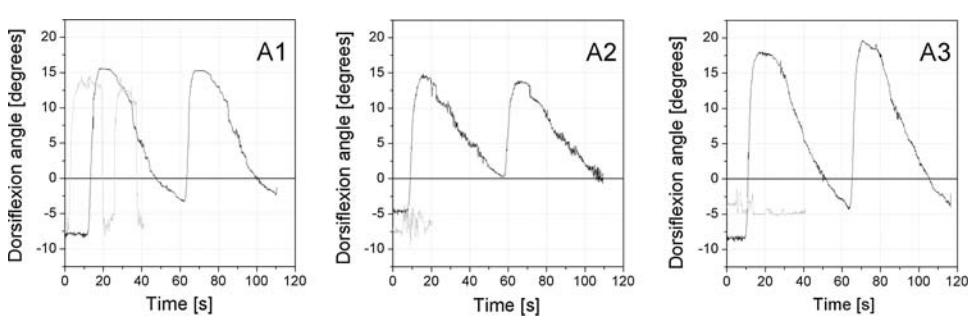

Fig. 8 Results of optoelectronic tracking of ankle motion during dorsiflexion mechanically produced by SHADE. Black lines represent passive exercise by SHADE; grey lines relate to the patients' attempts to carry out active ankle motion. The range of motion produced by SHADE is patient-dependent and adapts to the specific requirements. For patient A1 it is possible to appreciate that dorsiflexion speed (positive slope) is similar to the one spontaneously chosen by the patient during natural movement. Plantarflexion (negative slope) is limited to 30 s by the input current waveform. Natural convection allows resetting of the initial position to an extent dependent on the patient and on the selected plantarflexion time

actuator cross-dimensions (force versus cooling time) and actuator longitudinal dimensions (compactness versus maximal displacement, i.e. actuator recoverable strains times actuator length).

First, considering ankle biomechanics, it can be realized that, when using linear actuators, depending on what lever arm is utilized with respect to the joint pivot to convert linear motion into angular rotation, either fairly long displacements or large forces are needed to produce a sufficient foot movement. With a little lever arm it would be possible to achieve optimal compactness, but very large forces would then be required. Should these be obtained by significantly enlarging the diameter of the wire within the actuator, cooling time would rise dramatically; alternatively, if more actuators were employed, any advantage of compactness would be annuled. Therefore, a solution implying comparatively large lever arms was selected.

This posed the question of how to minimize overall actuator size while guaranteeing sufficient linear motion at reasonable strains. Although the actuator could theoretically mount either springs or wires, wires were ultimately selected. In fact, springs provide large displacements but are much less strong than the wire that is coiled to make them. Increasing the diameter of the spring wire to make the coiling stronger, on the other hand, is not practical, because it tends to increase both cooling times and material fragility due to excessive coiling strains. So the only solution with these constraints appeared to be an actuator mounting straight wires. The implementation with the use of mini-pulleys has several advantages but relies upon careful component design in order to minimize both friction and unwanted wire hardening, carrying along fragility and loss of shape memory properties. Due to the impossibility to eliminate these problems completely, it was paramount to allow for some safety ranges in the choice of construction elements both along the force and displacement dimensions. In particular, the choice of actuation force and electrical current was made considering a weight of 20 N per cartridge, which corresponded to twice the expected working load. This corrected for uncertainties in dimensioning and also took into account the possible abrupt failure of one actuator, so that the remaining one could temporarily take over.

5.2 Orthosis Performance

Technical tests were conceived so that the weights and lever arm produced plantarflexion moments in the range of those typical of foot weights (e.g. 15 N foot weight × 10 cm lever arm). These tests demonstrated that SHADE can produce a suitable range of motion (even exceeding the clinical requirements). Furthermore, the best match for the $-5°/+10°$ range was achieved in the 1.0 kg test, most closely corresponding to the estimated foot weight. It is important to notice that also with the other weights (producing moments 80-110% of the reference one) the clinical requirements are always met.

Also, the clinical tests showed that SHADE can produce dorsiflexion beyond the minimum requirements. The dorsiflexion speed, which was implicitly chosen when deciding on the actuation current value, resulted appropriate to generate a natural movement. The reset speed is, on the other hand, much lower than the spontaneous one. This depends on the cooling rate, which is rather low, as convection is strongly hindered by the actuator housing walls (albeit they are vented). It was decided that an adjustable reset time of 30 s would be allowed during cyclic clinical working. This time is long enough to reach plantarflexion almost completely by means of the sheer foot weight without any forced convection. The chosen reset time, even though it is unnatural, could be suitable for physical rehabilitation because it allows the ankle to remain stretched for as long as 70% of each cycle, which is hoped to avert the development of contractures.

It was noted that the generated range of motion self-adapted to every patient's characteristics, i.e. it never happened that patients felt any pain due to an excessive pulling of their feet beyond the maximal individual passive range of motion (PROM): this is thanks to the existence of a detwinning plateau limiting the peak available force in SMA.

6. Conclusions

The actuators passed the technical tests and were able to produce, with good stability, the expected forces and displacements. Once put on, the orthosis and used in a clinical setting, they provided sufficient propulsion to elicit dorsiflexion up to almost +20°. It is believed that the use of such a device could be beneficial particularly in the early phases of post-stroke care, when it is vital to stop the insurgence of contractures and spasticity.

The main problem with the use of SMA in this context appears to be dealing with lengthy and hardly controllable cooling rates. This problem could well be lived with, if it was proven that long reset periods could provide extra time for therapeutic stretch. An important future development will be in the direction of including electromyographic control on SHADE activation, so that this orthosis can be used also as an aid and movement booster during early active workouts.

References

1. J. Mackay and G. Mensah, eds., *Atlas of Heart Disease and Stroke*, World Health Organization, Geneva, 2004
2. L.M. Brass, Stroke, Chap. 18, *The Yale University School of Medicine Heart Book*, 1st ed., B.L. Zaret, M. Moser, and L.S. Cohen, Eds., William Morrow & Co, 1992, p 215–234
3. NINDS (National Institute of Neurological Disorders and Stroke), Post-Stroke Rehabilitation Fact-Sheet, NIH Publication number: 02-4846, Office of Communications and Public Liaison—National Institute of Neurological Disorders and Stroke—National Institutes of Health, Bethesda, MD, 2002
4. L. Harvey and R. Herbert, Muscle Stretching for Treatment and Prevention of Contractures in People with Spinal Cord Injury, *Spinal Cord*, 2002, **40**, p 1–9
5. J.-M. Gracies, Pathophysiology of Spastic Paresis I: Paresis and Soft Tissue Changes, *Muscle Nerve*, 2005, **31**, p 535–551
6. P.W. Duncan, R. Zorowitz, B. Bates, J.Y. Choi, J.J. Glasberg, G.D. Graham, R.C. Katz, K. Lamberty, and D. Reker, Management of Adult Stroke Rehabilitation Care. A Clinical Practice Guideline, *Stroke*, 2005, **36**, p e100–e143
7. G. Kwakkel, R. van Peppen, R.C. Wagenaar, S. Wood Dauphinee, C. Richards, A. Ashburn, K. Miller, N. Lincoln, C. Partridge, I. Wellwood, and P. Langhorne, Effects of Augmented Exercise Therapy Time After Stroke: A Meta-Analysis, *Stroke*, 2004, **35**, p 2529–2536
8. S. Masiero, A. Celia, G. Rosati, and M. Armani, Robotic-Assisted Rehabilitation of the Upper Limb After Acute Stroke, *Arch. Phys. Med. Rehabil.*, 2007, **88**, p 142–149
9. S. Pittaccio, S. Viscuso, M. Rossini, L. Magoni, S. Pirovano, S. Besseghini, and F. Molteni, SHADE: An Active Orthosis for

Safeguarding Ankle Motion Skills in Dropfoot Patients, *Proceedings of the 4th World Congress of the International Society Physical and Rehabilitation Medicine*, U.W. Rah, Ed., June 10–14, 2007 (Seoul), Organizing Committee of ISPRM, 2007, p 360

10. S. Pittaccio, F. Zappasodi, S. Viscuso, F. Mastrolilli, M. Ercolani, F. Passarelli, F. Molteni, P.M. Rossini, and F. Tecchio, Cortical Correlate of Passive Mobilisation of the Ankle Joint by means of the SHADE Orthosis, *Clin. Neurophysiol.*, 2008, **119**(Suppl 1), p S20