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Pseudoelastic Nitinol-Based Device for Relaxation of Spastic Elbow in Stroke Patients

S. Viscuso, S. Pittaccio, M. Caimmi, G. Gasperini, S. Pirovano, E. Villa, S. Besseghini, and F. Molteni

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A compliant brace (EDGES) promoting spastic elbow relaxation was designed to investigate the potentialities of pseudoelastic NiTi in orthotics. By exploiting its peculiar characteristics, EDGES could improve elbow posture without constraining movements and thus avoiding any pain to the patient. A commercial $Ni_{50.7}$-$Ti_{49.3}$ alloy heat treated at 400 °C 1 h + WQ was selected for this application. A prototype of EDGES was assembled with two thermoplastic shells connected by polycentric hinges. Four 2-mm-diameter NiTi bars were encastred in the upper-arm shell and let slide along tubular fixtures on the forearm. Specially designed bending tests demonstrated suitable moment-angle characteristics. Two post-stroke subjects (aged 62 and 64, mild elbow flexors spasticity) wore EDGES for 1 week, at least 10 h a day. No additional treatment was applied during this period or the following week. A great improvement (20° ± 5°) of the resting position was observed in both patients as early as 3 h after starting the treatment. Acceptability was very good. A slight decrease in spasticity was also observed in both subjects. All the effects disappeared 1 week after discontinuation. EDGES appears to be a good alternative to traditional orthoses in terms of acceptability and effectiveness in improving posture, especially whenever short-term splinting is planned.

Keywords orthosis, pseudoelastic alloy, rehabilitation, shape memory alloy

1. Introduction

Elbow rehabilitation techniques are very widespread in the clinical practice, as they are strongly indicated in treating spasticity and contrasting its insurgence. The upper extremities are very often affected by stroke events, which, on the whole, now have a social impact of 15 million people worldwide suffering a stroke every year and 5 million of these left permanently disabled (Ref 1). Between 17 and 28% of post-stroke patients develop spastic contractures within the first 6 months after stroke (Ref 2, 3): it is therefore easy to appreciate the importance of developing new strategies in this field.

Considering the elbow, stroke often causes a flexor spastic syndrome that results in muscle contractures and chronic ill-positioning of the limb. The reason for this appears to be linked to inappropriate posture habits held during the first few weeks after the event (Ref 4). In the clinically relevant case of long-stabilized contractures and spasticity, the rigidly flexed position of the elbow is generally improved by physical therapy, pharmacological treatment, and the application of repositioning braces. These are either rigid casts that constrain the joint at a certain, more extended angle, or else adjustable hinged shells that are fixed on the arm and forearm at step-wise increasingly wide angles. Both types of orthoses are not very well accepted because they cause high instantaneous strains on the muscles, ensuing in much discomfort and pain for the patients, particularly on the occurrence of dystonic jerks or myocloni. Hence, their use is restricted to only certain phases of the treatment, produces limited effects, and is not appropriate to decrease spasticity. Furthermore, by keeping the joint at fixed angles for long periods of time, they hinder or totally prevent limb motion, thus eliminating one extremely important factor to maintain tissue suppleness and avoid paresis (Ref 5).

Compliant splints, providing suitable stretch without keeping the joint in a locked position, could be so well tolerated as to be worn continuously for many hours a day: they would thus help improve position, decrease spasticity, and prevent excessive strain, pain, and the unwanted sequelae of paresis. Such devices can be designed utilizing pseudoelastic alloys, which are inherently compliant, among others, with the limited weight and compactness requirements of wearable orthoses. The deformation characteristics of these materials, in fact, provide sufficient range of motion coupled with a stable force output even at low deflection angles: this can ensure a reasonable push for relaxing muscles through a creep action and, at the same time, a yielding constraint to possible involuntary jerks.

A dynamic brace (named EDGES), compliant with patient's movements and promoting spastic elbow relaxation, was designed for clinical use and helped investigate the potentialities of pseudoelastic NiTi in orthotics. The objective of this work is ultimately evaluating the possibility of using braces mounting pseudoelastic inserts in clinical settings.

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S. Viscuso, S. Pittaccio, E. Villa, and **S. Besseghini**, CNR Institute for Energetics and Interphases at Lecco, Lecco, Italy; and **M. Caimmi, G. Gasperini, S. Pirovano,** and **F. Molteni**, Ospedale Valduce Centro di Riabilitazione Villa Beretta, Costamasnaga, Italy. Contact e-mail: s.viscuso@ieni.cnr.it.

2. Materials and Characterization

2.1 Materials

A Ni-rich grade of commercial NiTi ($Ni_{50.7}$-$Ti_{49.3}$) 2-mm-diameter wire, work-hardened above 30% in the as-received state, was selected to undergo thermal treatment and be ultimately used to construct EDGES. The choice of using commercial rather than home-cast material was made in order to provide results directly exploitable in future larger scale applications requiring off-the-shelf basic materials.

The EDGES orthosis is made up of two thermoplastic shells modeled on a prototype human arm of average size. These are connected by a polycentric hinge at each side of the elbow joint. A variable number of NiTi wires can be laid into two tubular elements connected in parallel to the hinges. For the current trials, two wires were used on each side. On putting on the brace, the shells are securely but comfortably strapped on the upper arm and forearm by Velcro® bands (Fig. 1).

2.2 Thermal Treatment and Characterization

NiTi wire samples were thermally treated in different conditions: 1023 K 10 min, 773 K 20 min, 723 K 30 min, 673 K 60 min and 648 K 60 min, and water quenched. During treatment they were formed straight. Those samples were used for the subsequent physical and chemical characterizations, the mechanical tests and the applications. Differential scanning calorimetry (on DSC 220 SSC/5200—Seiko Instruments, Tokyo, Japan) was carried out for their thermal characterization. The top of Fig. 2 shows the DSC curves for the different thermal treatments. The treatment of choice was 673 K for 1 h followed by quenching in water. M_f and M_s cannot be appreciated. The R-phase start and finish temperatures during cooling are 320 and 290 K, respectively. The martensite-to-R-phase transformation ends at 303 K (A'_f). Finally, A_f (end of R-phase-to-austenite transformation) is 328 K.

Fig. 1 An EDGES orthosis prototype made up of two thermoplastic shells connected by a polycentric hinge at each side of the elbow joint. A variable number of NiTi wires can be laid into two tubular elements connected in parallel to the hinges. On putting on the brace, the shells are strapped on the upper arm and forearm by Velcro® bands

2.3 Basic Characteristics of NiTi Wire

Tensile tests were conducted using an MTS 2/M thermo-mechanical test machine (MTS Systems, Eden Prairie, MN, USA) equipped with a 2 kN load cell on a sample of NiTi wire treated at 673 K for 1 h and water quenched. That sample was deformed up to an engineering strain of 4%, at room temperature (T_r = 298 K) and a tensile stress-strain curve was recorded. Since T_r was slightly below A'_f partial loss of shape memory (0.18%, as in Fig. 2, bottom) was observed. In fact, at A'_f most part of shape recovery is complete, but the small amount of deformation associated with the presence of the R-phase is left unresolved and could only be recovered above A_f. To counterbalance the negative effect of residual strains, the chosen treatment provided quite high plateau values given the measured transition temperatures (σ_m = 550 MPa and σ_r = 240 MPa). This aspect was felt to be very important to minimize the number of wires in the orthosis.

Cyclic deformation up to 4% for 20 times (at T_r, without any intermingled heating above A_f) was also applied on the sample, in order to evaluate its stabilization characteristics (Fig. 2, bottom) in relation to the expected accumulation of residual strains.

2.4 Bending Tests on NiTi Wire

Nonconventional application-oriented bending tests were carried out changing the set-up of the test machine by adding special home-made quasi-frictionless fixtures to grip the wire (Fig. 3). These fixtures are based on commercial stainless steel ball-bearings (SKF, Göteborg, Sweden), which have declared friction coefficients of 0.001-0.002: thus the present measure is affected by no more than 0.3%, which can be considered negligible for the purpose of this study. This equipment allowed testing of the wire one-way across the range 30-220° (0° referring to the straight condition). A 21 cm long sample of wire (grip-to-grip) underwent two recorded deformation cycles across that range. The same sample was then manually preconditioned to bending between −180 and 180°, 50 times in the same bending plane of the test. Subsequently, recorded continuous cyclic deformation was applied 10 times across the 30-220° range.

2.5 Bending Characterization of EDGES

A prototype of EDGES was used for technical tests directed to the assessment of its quantitative static working capabilities. A test bench was designed and constructed as follows (Fig. 4). An aluminum platform sliding in a finely controllable way along two horizontal guides holds the orthosis arm shell blocked by four screws. A crosshead is mounted horizontally between two vertical poles attached to the sides of the platform, so that it lies above the orthosis at a selectable distance from it. Two 0.03 N/mm harmonic steel linear tension springs are pinned onto the crosshead at a suitable distance from the midline and attached to the sides of the orthosis forearm shell,

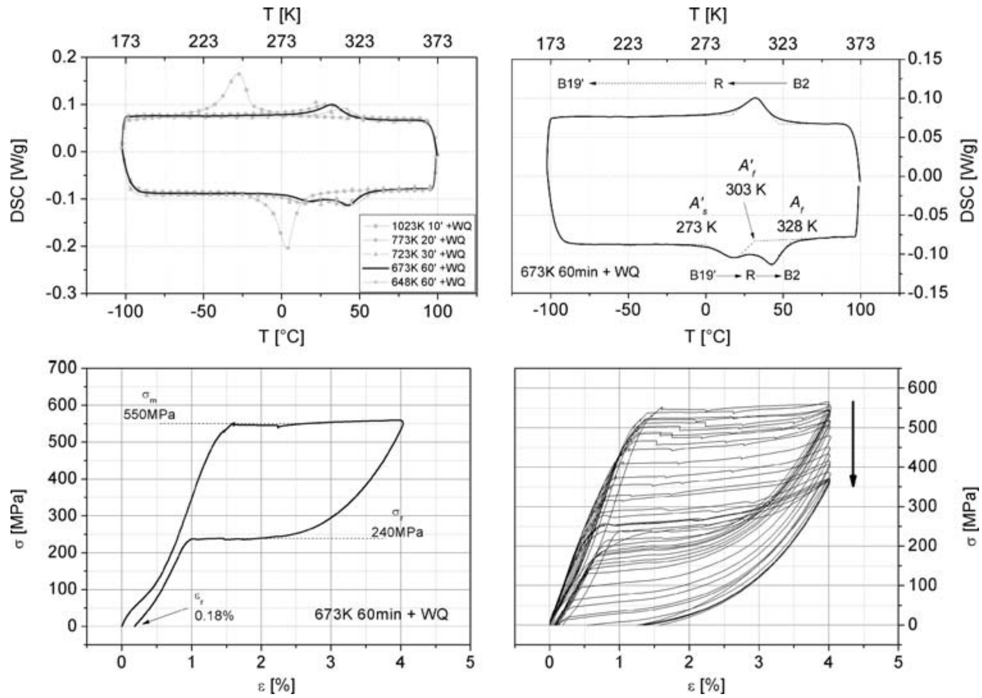

Fig. 2 Top left: measured DSC curves for different treatments on the chosen commercial Ni-Ti alloy. Top right: graph shows the calorimetric behavior corresponding to the selected thermal treatment (673 K 1 h + WQ). Bottom left: as-treated stress-strain characteristic at 298 K. Bottom right: the effect of tensile cycling at 298 K, for constant nominal end-strain of 4%, without intermingled heating above A_f

keeping it aloft and tied. The springs are designed to balance the action of the orthosis NiTi wires (the orthosis weight being negligible in comparison). The test is conducted in the following manner: after 50 two-way manual bending cycles between -180 and $180°$ for preconditioning of the wires, those are mounted into the orthosis, which is then fixed to the test bench horizontally and almost completely extended. The platform and the crosshead are moved relatively to one another until the springs are at square angles to the orthosis connection bars; at this point a photograph is taken of the orthosis and springs from a sufficiently far distance that the parallaxis has neglectable influence on relative measures. Then, the platform and crosshead are moved again so that the springs, still at square angles to the orthosis bar, balance the force of the NiTi wires with the orthosis slightly more flexed; a new photograph is taken. The same thing is then repeated for increasingly flexed orthosis angles and then back toward extension. On post-processing the photographs, a point-wise hysteretic characteristic of orthosis corrective torque versus orthosis angle can be obtained: the spring length (force) and the lever arm (spring distance from the instantaneous centre of rotation) can be measured from the pictures taken at different flexion angles. Trigonometric corrections can be made, in case the springs are not exactly at 90° to the orthosis bars. Tests were conducted with the orthosis mounting 1 and 2 wires per side.

3. Subjects and Clinical Methods

3.1 Patient Selection

Inclusion criteria for the study were single ischemic stroke earlier than 6 months before the study; stable general conditions, spasticity (at least 2 on the Ashworth's Scale) of the elbow flexors, no joint or skin pathologies, no severe cognitive impairments, able to understand and answer questions. Patients were chosen among the inpatients of the ward that were not under any other treatment to the elbow. Two patients (A and B) were enrolled. They were both chronically affected by contracture and spasticity of the elbow following ischemic stroke. Their characteristics are presented in Table 1.

Patients were treated according to the ethical principles as approved by the Hospital Ethical Committee (Ospedale Valduce Villa Beretta, Costamasnaga, Italy) and gave oral informed consent to undergo a period of treatment with EDGES. The consent was put in writing by a close relative.

3.2 Clinical Protocol

Patients underwent general clinical assessment prior to the start of the treatment. The actual treatment duration was 1 week and consisted in wearing EDGES continuously for the first 24 h, after which the patients were instructed to keep the orthosis on as many hours a day as individually tolerated. A nurse, physiotherapist, or a trained relative would help the patient to put on EDGES and check its correct positioning and fastening.

The testing protocol was made up of a manual assessment and an instrumental one, which were both repeated at T_0, 3 h, and 24 h after the initiation of therapy, at discontinuation of it (1 week), and 1 week thereafter.

The manual measurements by a trained physiatrist were carried out without the orthosis and included evaluation of active and passive range of motion by a protractor, spasticity on the Ashworth's Scale and resting elbow position, in a set of body attitudes, i.e. (1) sitting with the plegic arm hanging down along the body side; (2) just after standing up; (3) standing, just

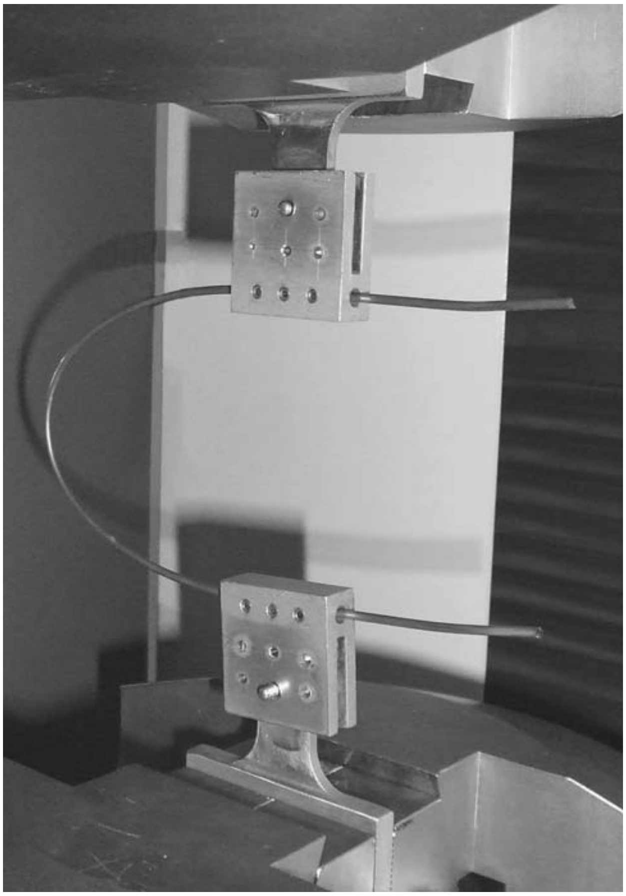

Fig. 3 Experimental set-up for wire bending tests. Each fixture is made up of two parts: one can be held by MTS machine grips, while the other, connected by a roller bearing hinge to the first, is used to hold the wire end fixed. In this way each wire end can rotate freely and in an almost frictionless manner while the MTS machine crosshead moves up and down

after a 2 min walk about the room; (4) standing after the walking task and after trying to relax for 1 min. Motion tasks (2) and (3) were chosen because they may elicit, in spastic patients, synergetic flexion of the elbow. The walking and standing actions were carried out by the patients with some support by a physiotherapist, so they were safe. This set of measurements were taken just after the patients took off the orthosis.

The instrumental evaluation of elbow angles was obtained by a physiatrist and a bioengineer via optoelectronic measurements, which allowed a dynamic evaluation of the patient-orthosis interaction. The optoelectronic protocol was based on 100 Hz acquisition of the position of three IR reflecting markers (fixed on the shoulder, elbow, and forearm to track the elbow angle) by eight IR cameras (Elite Gait Eliclinic—BTS, Garbagnate Milanese, Italy). During this trial the patient (initially sitting with the affected limb resting on his/her lap) was cued to relax the arm down along the side of the body, then stand up, relax the arm down again and finally start walking along the gangway. These actions were quite similar to the ones chosen for the manual tests, but were analyzed dynamically with the patients both wearing and not wearing the orthosis. Sketches of the motion sequence are shown at the bottom of Fig. 7.

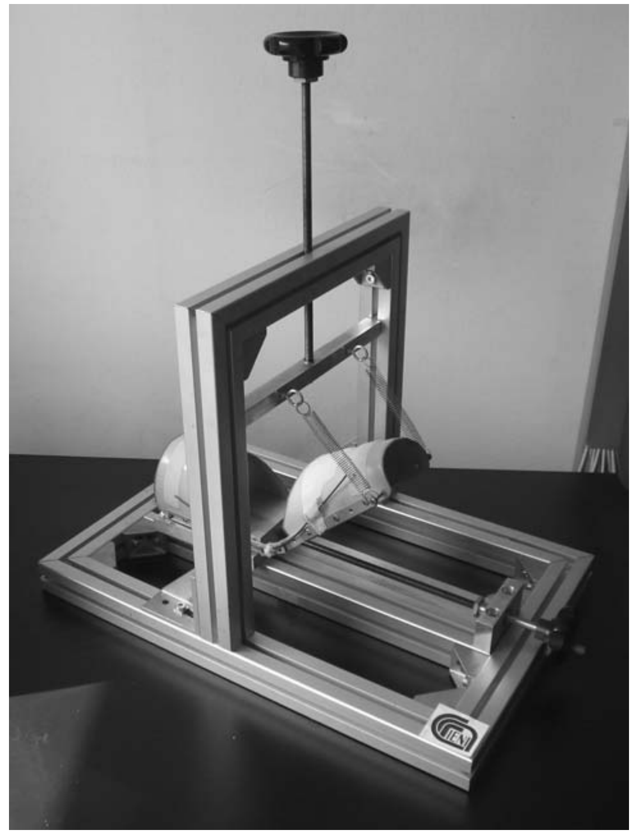

Fig. 4 Experimental set-up for bending tests on the EDGES orthosis. See text for explanations

Acceptability of EDGES was also investigated by means of a visual scoring questionnaire proposed by Gracies et al. (Ref 6). The questionnaire was submitted to the patients every day visually, but the manual filling-in was done by a nurse or a relative following oral instructions by the patients.

4. Results

4.1 Bending Characterization of NiTi Wires

The results of the bending tests are shown in Fig. 5. Since the test is not a standard one, a few remarks are essential for understanding the recorded curves. These curves show a quasi-linear increase of force until the bent wire forms a pseudoplastic hinge where stress concentration induces detwinned martensite. This happens when the external wire fibers reach the yield strain of around 1.5% (wire curvature radius ca. 6.5 cm). At that point material resistance quickly drops toward a plateau value that is conserved at larger deformations. This plateau is not directly associated with the tensile test one, but it is rather dependent on the material characteristics coupled with a changing bending lever arm. The backward path shows hysteresis but the general shape of the tracing is akin to the forward one. In particular, the peak value is reached when all the allowed martensite-to-rhombohedral phase conversion is complete (i.e. for a lower deformation value than the forward yield point, as in the tensile curves). The material is not stabilized at the first cycles but significant stiffening occurs (Fig. 5, left). After manual preconditioning, however, the

Table 1 Patients' characteristics

Patient	Age	Sex	Time since event, years	Paresis	Spasticity score Flexors (extensors)	ROM
A	62	M	6	Left sensory-motor hemisyndrome	Ashworth 3 (3)	Full passive No active
B	64	F	9	Left sensory-motor hemisyndrome	Ashworth 2 (0)	Full passive No active

ROM, range of motion

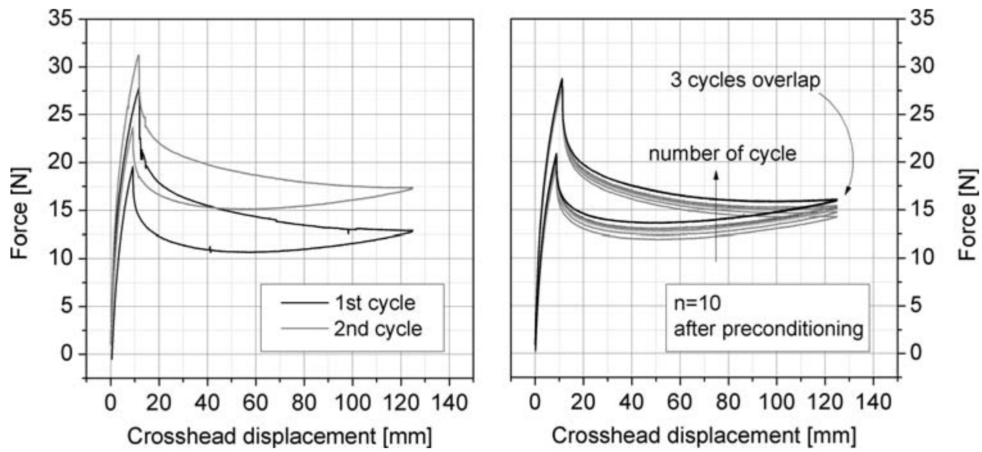

Fig. 5 Wire bending results. Left: first two deformation cycles on the as-thermally treated sample; right: deformation cycling on the same sample (after manual preconditioning cycles)

sample appears to be more stable; in fact, even if slight further stiffening occurs it can be noticed that the 8th, 9th and 10th cycles are completely overlapping (Fig. 5, right).

4.2 Mechanical Characterization of EDGES

Figure 6 reports the results of the bending tests conducted on the assembled orthosis. The corrective torque versus angle characteristic of EDGES was nonlinear and hysteretic in both trials. Sufficient corrective push is ensured also at lower angles. The orthosis produces a moment increasing with angle in the 20-80° range, after which it appears to reach a plateau at around 0.95 and 1.9 Nm when equipped with 2 and 4 wires, respectively.

4.3 Pre-Clinical Assessment

Variations of clinical conditions during the follow-up period were recorded and results are as in Table 2. It can be noticed that the general trend, even in these very chronic patients, is definitely toward an improvement of elbow posture, which is already present at 24 h and becomes more evident after 1 week. The decrease in spasticity obtained after 1 week of EDGES application is indeed a very interesting datum. All improvements appear to regress within 1 week of discontinuation. Minor skin rash was the only observed complication.

4.4 Optoelectronic Measurements

Optoelectronic measurements show very nicely the time course of elbow angle during the proposed clinical trials

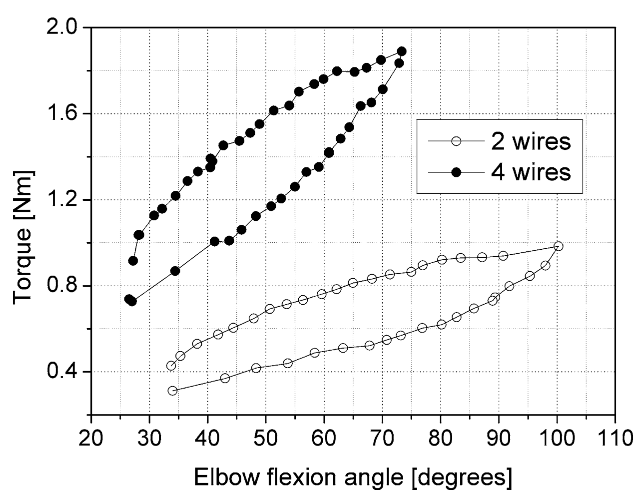

Fig. 6 EDGES bending results. Data are shown by the dots. Lines are guides for the eye. Both tests confirm that the orthosis has a non-linear hysteretic torque-angle behavior

(Fig. 7). The quantitative analysis of movement confirms the general trend toward an increased elbow extension during therapy. Furthermore, it is very interesting to observe that, while EDGES allows for wide movement of the elbow and does not impede flexing synergies during standing-up and walking, it is capable of reducing the amplitude of this pathological movement.

Table 2 Clinical status as from manual assessment during therapy follow-up: resting elbow angle during different motion tasks and Ashworth spasticity score (without EDGES)

Patient	Time	Sitting, °	Standing, °	After walking, °	After relaxing, °	Ashworth
A	T_0	60	50	65	50	3
	3 h	45	45	60	50	3
	24 h	45	50	60	50	3
	1 week	35	40	55	40	2
	1 week after	50	60	65	60	3
B	T_0	70	110	100	60	2
	3 h	30	60	70	50	1+
	24 h	30	30	40	30	1
	1 week	25	30	40	20	1
	1 week after	65	80	95	60	2

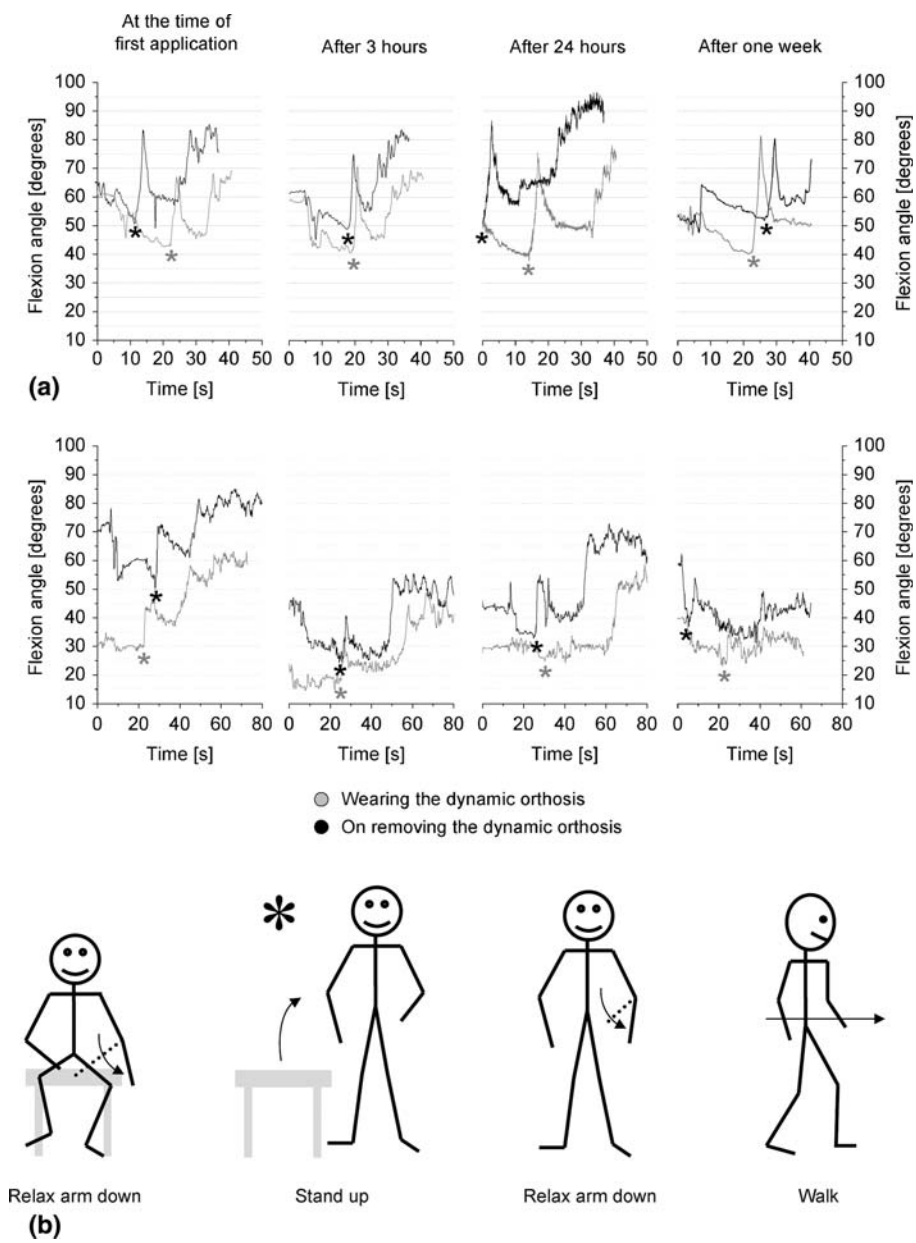

Fig. 7 Clinical tests on EDGES. Optoelectronic acquisition of patients' arm movement during the motion sequence sit – relax down the arm – stand up – relax down the arm – start walking. Stars mark the "stand up" command and are followed by a sudden and pronounced flexion of the elbow (flexor synergies)

Table 3 Outcomes of Gracies' questionnaire for orthosis acceptability

Question	A (24 h)	B (24 h)	A (1 week)	B (1 week)
How long did you wear EDGES today?	24 h	24 h	12 h	18 h
How did your arm feel while wearing EDGES?	8/10	8/10	7/10	8/10
Did you notice any changes when wearing EDGES?				
When walking	Better	Better	Better	Better
When toileting	No change	No change	No change	No change
When eating	No change	No change	No change	No change
When dressing	No change	No change	No change	No change
In ease of movement (muscle tone)	No change	No change	Better	No change
In the confidence in your arm	Better	Better	Better	Better
Would you wear EDGES for a few weeks if recommended?	Yes	Yes	Yes	Yes
Comments…	N/A	N/A	Cannot put on brace by myself. Some skin rash	Cannot sit putting the arm on the lap

4.5 Acceptability

The results of the acceptability questionnaires taken on the first and last days of therapy are presented in Table 3.

Patients' acceptation of EDGES was generally good after both 24 h and 1 week of therapy. Willingness to continue wearing it is preserved and only minor problems were observed, among which some light skin rash in the regions covered by the shells (far from the NiTi elements), which required no particular medication and that could possibly be avoided by a better lining than the present one. A particularly good result is in terms of improved ease of movement and confidence for the patient. It is interesting to note that both patients reported walking better when they are wearing this elbow splint, possibly suggesting that improved confidence and decreased flexor synergies bring about greater stability and equilibrium. Further comments related to the patients' inability to put on the brace by themselves or to rest the elbow on their laps when wearing EDGES.

5. Discussion

5.1 Choice of Material and Thermo-Mechanical History

This study aimed at demonstrating the possibility of using off-the-shelf basic pseudoelastic NiTi in orthotics. For this reason a commercial wire with an easily available formulation was utilized. The thermo-mechanical treatment was selected according to well-known principles of NiTi technology such as: first, good mechanical characteristics, working stability and fatigue life at higher loads can be obtained by an appropriate combination of cold working and annealing below re-crystallization temperature (Ref 7, 8); second, mechanical preconditioning can be employed to stabilize the material behavior for a specific application (Ref 8). According to literature (Ref 7, 9, 10) suitably fine and homogeneously dispersed Ti_3Ni_4 precipitates can be obtained by ageing at temperatures around 673 K for 1 h. That precipitation was obtained with this treatment and was confirmed by DSC analysis, which shows two-stage transformation to parent phase (Fig. 2, top left).

Although the above-mentioned technological criteria were applied, the present batch of material responded only partially well: in particular, static mechanical properties were actually very good, but the cycling behavior appeared rather poor, especially in the (rather severe) tensile tests.

5.2 Results of Tensile Tests on the NiTi Wire

The plateau stresses measured during tensile tests, although apparently high given the presented T_r and A_f, are consistent with the chosen ageing process and the underlying working history. The comprehensive 2005 review by Otsuka and Ren (Ref 7) duly shows specific evidence of how the combined effects of cold-working and precipitation ageing can powerfully increase strength in Ni-rich NiTi, even to the extent of allowing for large recovery stresses strictly below A_f. Even elsewhere it is reported (e.g. Ref 11) that in the intermediate temperature range (673-773 K) for ageing of cold-worked high-Ni NiTi, the main effect of residual work-hardening (and Ni-rich precipitates) on DSC-measured transformation temperatures is a strong decrease in M_s and M_f, while A_s and A_f tend to remain stable. On the other hand, lower-end intermediate treatment temperatures (e.g. 673 K rather than 773 K, the latter inducing too much softening) are typically employed to provide improved shape recovery forces (Ref 12). These concepts put together mean that the heights of the plateaux cannot be straightforwardly linked to the position of A_f alone. In other terms, dynamic explanations considering nonlinear interactions among the solid phases must be sought, as the calorimetric (viz. a Clausius-Clapeyron approach) cannot take into account microstructural rearrangements due to applied mechanical strains. This deviation from basic assumptions is also observable in the data presented within the cited review by Otsuka and Ren, and comes even more expected with our Ni-richer alloy ($Ti\text{-}Ni_{50.7}$ rather than their $Ti\text{-}Ni_{50.6}$). It is also likely that these effects might occur even more strikingly with a fine-grained and inclusion-rich matrix (as in the present case, see Fig. 8), where dislocation disentanglement and movement is further impeded. The phenomenology of pseudoelasticity in the present instance is probably more appropriately analyzed by observing that, from a thermodynamic perspective, a certain amount of work hardening and precipitation causes M_s to shift toward lower values and peaks to spread, thus increasing the energy requirement for inducing detwinned martensite from austenite. At the same time, the same factors have direct mechanical effects in the form of hardening, through defect formation and hindrance to material undergoing phase transitions. The large difference in transformation enthalpies between

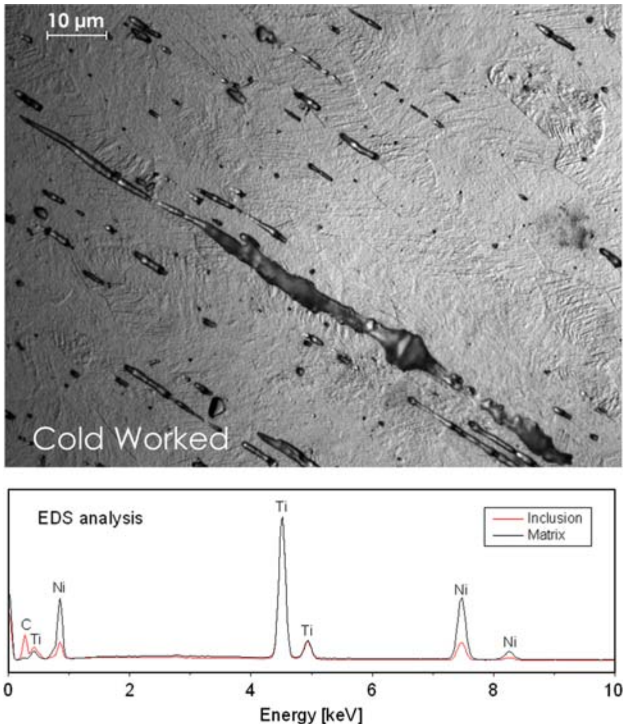

Fig. 8 Longitudinal 1000× micrographs for the cold worked (as-received) NiTi wire. The sample was polished and etched in a 10% HNO_3, 5% HF water solution for 20 s. Large defects are visible (mainly TiC, from EDS analysis, see bottom graphs). Grain size is in the order of 20 μm

the solution treated and aged samples (approximately 14 and 8 J/g, respectively) demonstrates that in the aged specimen some material either does not transform at all by sheer temperature changes or transforms so gradually that its DSC signal lies outside the main peaks but cannot be appreciated. Gradual transformation is also evidenced by the characteristic curved pattern of early shape recovery in tensile tests, signaling an important contribution of mechano-elastic terms in transformational energy.

5.3 Tensile Cycling and Microstructural Issues

In the light of the mechanical characterization results, it appears that cycling stability, particularly in tensile tests, is worse than generally expected, even considering that the chosen cycling protocol is rather heavy. Indeed, the fact of not heating the sample over A_f after every cycle produces an accumulation of strains within the matrix, so that finally nominal end-strains of 4% do not correspond to real strains of that amount. Thence a certain stress-hardening and structural rearrangements with slanting and lowering of the plateaux would be normal, probably not to the observed extent in "good" material. The excessively detrimental effect of cycling in the present test suggested that some investigation of the microstructural and chemical characteristics should be undertaken: light and scanning electron microscopy and the use of EDS elemental analysis demonstrated that the as-received material was fine grained (~20 μm), definitely textured along the drawing direction, and affected by abundant and large TiC inclusions across the whole sample, as clearly visible in Fig. 8. This was felt to explain the below-average cycling attributes and called for the choice of more refined materials for this type of applications in the future.

5.4 Results of Bending Tests on the NiTi Wire

Considering the wire bending tests, it can be noted that the major effect in the first cycles is a relative increase in measured stress values. This depends on the typical stiffening (very palpably perceived on manual deformation) correlated with the progressive increase in Young's modulus brought about by the strain-induced straightening of the R-phase notch. As a result of this, the whole curve is rotated counter-clockwise and the measured stresses tend to be higher. After the 50-cycle manual conditioning, the material shows a decrease in strength which can be associated with the decline in stress values produced by repeated deformation. Of course, the intensity of such decline is not comparable with the results of the tensile tests, as the severity of strain cycling is much reduced in the bending set-up. The final cycles are affected by another stiffening phase occurring in the transition between a manual two-way bending regime and a machine-controlled one-way one, probably implying, among other things, a slight shift of the principal inflection point and a variation of the loading path and speed. These minor adjustments should nonetheless be accompanied by a tuning of the characteristics of the newly involved material grains. After that, stabilization does occur as the test is conducted at fixed displacements, which means that wire curvature and fiber *real* strains remain close to constant. The use of EDGES on patients is more similar to the bending (rather than the tensile) testing procedure, so the presented results suggest fair working stability in spite of the tensile cycling curves.

5.5 Working Principles of the EDGES Orthosis

The purpose of including pseudoelastic elements in a positioning brace is to provide a corrective torque across an angle as wide as possible such that it is not negligible even when the arm is almost fully extended. This principle is very innovative with respect to traditional orthotics, which is based on fixing the position of the limb and await tissue remodeling by relaxation. In the present work, a stable corrective force (and not a stable position) drives muscle stretching. This force ought to be sufficiently strong to produce tissue lengthening by *viscoelastoplastic creep* and not as strong as to impede arm movements.

The values of corrective torque produced by EDGES, as measured from the bending tests (0.95 and 1.9 Nm), are considerably lower than maximal muscular flexor torques of around 50-75 Nm (Ref 13, 14), and somewhat less than the maximal passive-reflex torques, which are reported to be in the range 0.5-6 Nm (Ref 15, 16). These measurements confirm that EDGES can stretch muscles while not constraining elbow position during voluntary movements or involuntary jerks.

5.6 Pre-Clinical Considerations

The present study is far from a conclusive clinical validation of this EDGES orthosis. However, it yielded some interesting pre-clinical considerations worth taking into account in view of future developments. The clinical procedures carried out to assess the dynamic characteristics of EDGES when worn by spastic subjects showed that even in this unoptimized version it can produce corrective loads in a stable manner for at least a week and that it does not constrain the elbow in a fixed position. This is clearly visible from the strong oscillations in arm position detected and shown in Fig. 7. Flexor synergies, which are a very common feature of post-stroke syndromes, cause involuntary arm flexion during some types of body movements (standing up, walking…), as can be evinced also from the manual measures presented in Table 2. Constraining devices can therefore be ill-tolerated in these circumstances. Acceptability of EDGES was, on the other hand, very good, suggesting that longer orthotic treatments with this orthosis can be attempted. The ratings reported in the questionnaire of Table 3 were high and the daily application long, demonstrating that the patients felt no pain or discomfort during the therapy. Decrease in spasticity could be a wonderful result but it needs strong further evidence to be confirmed, as spasticity attenuation has never been conclusively proved in connection with orthotic treatments (Ref 17). Relapse of ill-posture and spasticity after treatment discontinuation was absolutely expected, as 1 week is not a sufficiently long time to obtain plastic remodeling of human muscular and nervous tissues. Stabilized benefits could only be attended, should treatment be prolonged by several weeks. Reversibility of patients' conditions in the present clinical experiment suggests that EDGES is not harmful or produces any permanent damage in a week's application.

The only observed complication was some light skin rash in patient A, which was considered a minor problem as it disappeared in a matter of hours without any need for medications. To fix this, a softer lining will be added to the next generation of EDGES.

Concerning the additional remarks in the questionnaires: first, it is believed that the willingness to be able to put on the orthosis without assistance, although suggesting that the patient was at ease with EDGES and confident with its working principles, actually points out a generalized problem with wearable aids, i.e. that they may be difficult to handle for impaired subjects. In the case of EDGES, there is still some marginal opportunity to improve on this, e.g. by implementing customized shells and connection bars, so that increased surface coherence between the orthosis and the body may guide easier fitting. Second, the question of whether allowing patients to rest the arm in their laps is moot, as this very attitude is reported to be among the leading causes for early development of ill-postures in paretic subjects (Ref 4). Most surely, a device provoking a certain degree of arm extension can make sitting positions less comfortable, but this question could probably be re-addressed by suggesting that the arm be rested at a more extended, rather than flexed angle, for instance on a table or portable tray.

6. Conclusions

A pseudoelastic positioning brace was designed and built based on commercial NiTi wires. A thermal treatment at 673 K 1 h + WQ to produce abundant precipitation and only limited material softening provided the wires with sufficient strength for the application. Orthosis characterization showed that it can generate corrective torques of 0.95 and 1.9 Nm when equipped with 2 and 4 wires, respectively. Clinical outcomes show very fast improvement of patients' posture within 24 h and further progress at 1 week. Spasticity appears to be decreasing during the first week, but this observation needs strong additional evidence to be confirmed. Patients' satisfaction was very high, as was acceptability at both 24 h and 1 week of treatment. This suggests that pseudoelastic NiTi is a suitable material for constructing elbow positioning braces that work on the principle of tissue lengthening by *viscoelastoplastic creep*. Other types of orthoses could be significantly enhanced with the use of pseudoelastic NiTi elements, whose quality must be controlled particularly in order to ensure good performance stability. As a conclusive consideration, however, it must be stressed that, in spite of the great informative value of our experience so far, true clinical validation of this type of pseudoelastic treatment will have to be sought in the future by longer application trials and randomized comparison studies with larger patient populations.

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