Efficacy of Armeo®Spring during the chronic phase of stroke. Study in mild to moderate cases of hemiparesis

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Abstract

Objective: To evaluate the efficacy of a gravity-supported, computer-enhanced device (Armeo®Spring) for upper limb rehabilitation in chronic stroke patients.

Materials and methods: We included 23 chronic hemiparetic patients (chronicity: 328±90.8 days; distribution: 17 men and 6 women) aged 54.6±9.5 years, who had sustained ischaemic stroke (n=12) or haemorrhagic stroke (n=11). All patients completed 36 one-hour sessions using the Armeo®Spring system. Arm movement was assessed at the beginning and end of the treatment programme and once more 4 months later. Main outcome measurements covered structure, activity, and function, as per the International Classification of Functioning, Disability and Health: Modified Ashworth Scale, Motricity Index (MI), Fugl-Meyer Assessment Scale (FM), Motor Assessment Scale (MAS), Manual Function Test (MFT), and Wolf Motor Function Test (WMFT).

Results: Repeated measures ANOVA showed significant improvement (time effect) for all function scales (P<0.01 for FM and MI) and activity scales (P<0.01 for MAS, MFT and WMFT-ability, and P<0.05 WMFT-time) without significant changes in muscle tone. The post hoc analysis (Bonferroni) showed different evolutionary patterns for function and activity measurements, and clear benefits related to Armeo®Spring training, especially on activity scales.

Conclusions: Armeo®Spring is an effective tool for rehabilitating the affected arm in patients with hemiparesis secondary to ictus, even in the chronic stage.

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PALABRAS CLAVE
Armeo; Clasificación Internacional del Funcionamiento; Discapacidad y Salud; Ictus; Miembro superior; Sistemas robóticos; Rehabilitación

Eficacia del sistema Armeo® Spring en la fase crónica del ictus. Estudio en hemiparesias leves-moderadas

Resumen
Objetivo: Valorar la eficacia del sistema Armeo® Spring para la rehabilitación del miembro superior en pacientes crónicos que han presentado un ictus.

Material y métodos: Veintitrés pacientes (17 varones y 6 mujeres), con una edad media ± desviación estándar de 54,6 ± 9,5 años, que presentaban una hemiparesia crónica (cronicidad de 328 ± 90,8 días) secundaria a ictus isquémico (n = 12) o hemorrágico (n = 11), se incluyeron en este estudio. Todos los pacientes completaron 36 sesiones de una hora de duración con el sistema Armeo® Spring y fueron valorados al inicio, al fin y 4 meses después de completar el tratamiento con escalas dirigidas a los dominios de estructura, función y actividad de la Clasificación Internacional del Funcionamiento, de la Discapacidad y de la Salud (ICF) incluyendo: Ashworth Modified Scale, Motricity Index (MI), Fugl-Meyer Assessment Scale (FM), Motor Assessment Scale (MAS), Manual Function Test (MFT) y Wolf Motor Function (WMFT).

Resultados: Un ANOVA de medidas repetidas mostró una mejora significativa (efecto tiempo) en todas las escalas de función (p < 0,01 en FM y MI) y actividad (p < 0,01 en MAS, MFT, WMFT-Habilidad y p < 0,05 en WMFT-tiempo), sin que se apreciaran cambios significativos en el tono muscular. El estudio post hoc (Bonferroni) mostró un patrón de evolución diferente entre las escalas de función y las de actividad, con un beneficio directamente ligado al entrenamiento, especialmente en las escalas de actividad.

Conclusiones: El Armeo® Spring constituye una herramienta eficaz para la rehabilitación del miembro superior afectado en pacientes con una hemiparesia debida a un ictus, incluso en estádios crónicos.

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Introduction

Stroke is the main cause of disability in Spanish adults. Multiple studies report that 86% of stroke patients will suffer sensorimotor problems and up to 65% will have only limited use of the hemiparetic arm for activities of daily living. In addition, although many of these patients will recover the ability to walk, a large percentage will continue to experience difficulty moving the upper limb. Treatment of these deficits is especially relevant given that their severity is closely related to the patient’s overall functional level on a medium to long-term basis.

A number of clinical trials have shown significant advances in upper limb recovery with the use of different sensorimotor techniques, including intensive repetitive movement, constraint-induced movement therapy, functional electrical stimulation treatment, the use of virtual reality, and robot-assisted therapy. This last approach has been used in neurorehabilitation for more than 15 years for the purpose of recreating conditions favourable to motor learning by facilitating the active and intensive performance of manoeuvres involved in important tasks. Robots are frequently used in association with interactive settings in order to provide functional meaning to training tasks. Researchers use virtual reality with avatars to represent the movements of the limb or the objects with which the subjects has to interact.

The function of the upper limb, especially the hand, is versatile and complex. Therefore, designing robotic systems for the arm rehabilitation must take multiple factors into account. These peculiarities have favoured the appearance of different types of robots that may vary with respect to their technical specifications, the part of the arm being trained, the different rehabilitation models on which the system is based, etc. Therefore, different clinical trials using robots have been published to study proximal tasks in the upper limb, distal tasks, global tasks, or for bilateral training, etc. On a technical level, depending on the movement being practised and how the movement is directed, we may distinguish between exoskeleton systems, which completely surround and direct the upper limb, and end-effector devices, which control movement distally and leave the overall structure of the arm free. Lastly, researchers have designed robot-assisted therapies that involve either passive or active mobilisation depending on the type of movement assistance they provide. To date, there are no solid results to show which robotic system is the most effective since outcome depends on the patient’s clinical state. However, it is advisable to employ systems favouring the subject’s active participation in movement, if the subject’s motor conditions so permit. In fact, functional recovery is achieved through use-dependent cortical reorganisation, and active participation favours increased levels of physiological reorganisation and provides more clinical benefits.

Robotic systems for upper limb rehabilitation have been shown to be effective in patients following different types of neurological lesions. However, there is a marked lack of studies of chronic patients who have been assessed using the International Classification of Functioning, Disability, and Health (ICF). The aim of our study is to evaluate efficacy
of a rehabilitation programme employing Armeo®Spring in a group of patients with chronic hemiparesis following stroke who were assessed using the ICF.

Methods

Patients

The study included a total of 142 patients with hemiparesis secondary to ischaemic or haemorrhagic stroke (confirmed by neuroimaging tests) who were monitored consecutively in a specialised neurorehabilitation department between January 2009 and January 2011. We excluded patients with cognitive decline (Mini-Mental State Examination \( < 23 \) points) or comprehension difficulties (cut-off point of the comprehension subtest of Mississippi Aphasia Screening Test \( < 40 \)). Due to the requirements of the robotic system, we also excluded patients with abnormal movements, poorly controlled painful shoulder syndrome or articular rigidity in any segment of the upper limb, and a spasticity score \( \geq 2 \) according to the Modified Ashworth Scale.\(^{31}\) Using the resulting sample, we included subjects as soon as they reached the minimum level of active movement required to use the system (overall activity of the upper limb \( \geq 2 \) according to the Medical Research Council Scale).\(^{34}\) The final sample included 23 subjects (17 males and 6 females) with chronic hemiparesis secondary to ischaemic stroke \((n = 12)\) or haemorrhagic stroke \((n = 11)\), mean age \( \pm \) standard deviation of 54.6 \( \pm \) 9.5, and a post-stroke time of 328 \( \pm \) 90.8 days.

Armeo®Spring system

The Armeo®Spring includes an adjustable suspension system for the upper limb which connects to virtual reality settings with varying degrees of complexity. The suspension system is an exoskeleton that supports the subject’s arm from the proximal to the distal region and magnifies any residual active movement of the hemiparetic arm in three-dimensional space. In its distal region it includes a system that detects grasp pressure. System sensitivity may be adjusted depending on the patient’s condition. Virtual reality settings are designed to provide different levels of difficulty (direction of movement, velocity, moving area) and a functional approach to the task. The system allows researchers to calibrate the working space according to the patient’s active mobility. It provides information about specific movement parameters (resistance, strength, range of motion, and coordination), to permit proper adjustment of the level of difficulty for each patient during the entire recovery process.

Procedure

All patients were being treated by our department before starting the programme. The treatment protocol for Armeo®Spring consisted of 36 intensive therapy sessions. During the first session, the device was adjusted for the patient’s arm size and the required angle of suspension (45° shoulder flexion and 25° elbow flexion, approximately).

Once the upper limb had been fitted to the system, researchers measured the working space and selected the exercises the patient was able to perform from a large variety of tasks. From that moment on, all patients completed 3 one-hour sessions per week for a total of 36 sessions. The working sessions were supervised by a physiotherapist who modified the exercise programmes according to each patient’s progress. Every 9 sessions, patients were asked to perform specific evaluation exercises making use of virtual reality software. Doctors then recalibrated the working space and the angle of suspension.

While patients were undergoing treatment with a multidisciplinary approach, they also took part in other types of rehabilitation therapy according to their deficits, provided that those therapies did not target the arm. Once the intervention protocol had been completed, all patients continued conventional physiotherapy, including specific techniques for upper limb rehabilitation without the use of robotic systems.

Evaluation

All patients included in the Armeo®Spring training programme were prospectively assessed by 2 specialised physiotherapists at onset (T1) and end (T2) of treatment, and once more 4 months later (T3) using different scales measuring distinct domains of the ICF.

Body structures domain

For the body structures domain, researchers assessed muscle tone in both proximal and distal regions of the arm using the Modified Ashworth Scale.

Body functions domain

This section includes the following upper limb evaluation subtests: the Motricity Index (MI)\(^{35}\) and the Fugl-Meyer Assessment Scale (FM).\(^{36}\)

The upper extremity section of the MI evaluates muscle strength in 3 muscle groups and includes pinch grip, elbow flexion, and shoulder abduction. Each movement is scored separately (0 if there is no movement, 9 if there is a palpable flicker, 14 if movement is visible, 19 if movement is against gravity, 25 if movement is against resistance, and 33 if movement is normal). The total score for the upper limb ranges from 0 (severely affected) to 100 (normal).

The FM scale assesses the mobility of the hemiparetic arm, including reflexes, the appearance of synergies, and each of the isolated movements of the upper limb, including grip. This scale also includes 3 items that evaluate patient’s dysmetria, coordination, and velocity. Patients score 1 if they are unable to perform the task, 2 if they perform partially, and 3 if they perform fully. The maximum score is 66 points.

Activities domain

We evaluated this domain using the Motor Assessment Scale (MAS),\(^{27}\) the Manual Function Test (MFT),\(^{38}\) and the Wolf Motor Function (WMF).\(^{39}\)

The MAS includes 9 items ranging from 0 (severely affected) to 6 (normal). Our study included only the 3 items
describing the upper limb: (a) upper arm function; (b) hand movements, and (c) advanced hand activities. Scores range from 0 to 18.

The MFT includes 32 items which assess arm motion, manipulative activities, and both categories combined. A patient is awarded 1 point when he/she successfully performs an item on the test by meeting the required criteria. The maximum score is 32 points.

Lastly, the WMFT contains 17 items, with 15 being timed activities and 2 being strength tasks (the latter were not included as per instructions given for the original scale). The subject’s ability to perform each of the tasks was scored according to the original scale (range, 0–5) which scores inability to perform the task as 1 point and normal function as 5 points. All the activities on this scale should be performed as quickly as possible. Therefore, subjects who are unable to perform a task are penalised with a maximum time of 120 seconds. The WMFT total score includes an overall ability score (WMFT-Ability), as well as a final time score resulting from the total time needed to perform all the tasks (WMFT-Time).

Statistical analysis

We used repeated measure ANOVA for a single group for purposes of statistical analysis. Time effect was analysed by including the initial assessment (T1), assessment at the end of the Armeo®Spring treatment programme (T2), and an additional assessment 4 months after that (T3). We used the Bonferroni correction as a post hoc analysis for detecting differences between the 3 times included in the study. The level of statistical significance was set at P < .05 for all comparisons. We used SPSS software version 15 for Mac (Chicago, United States).

Results

All patients finished the treatment programme without the appearance of any usability problems or training-related clinical complications. The statistical analysis (repeated measure ANOVA) showed a significant improvement (time effect) on all function scales (P < .01 for FM and MI) and activity scales (P < .01 for MAS, MFT, WMFT-Ability and P < .05 for WMFT-Time) without significant changes in muscle tone (Ashworth scale). The post hoc analysis (Bonferroni) showed that the progression pattern differed between the function and activity scales, and demonstrated benefits directly related to training, especially regarding the activity scales. Researchers observed that all patients improved at the end of treatment (T1 versus T2) upon analysing results from the MFT (P < .01), MAS (P < .01), and WMFT-Ability scales (P < .05). These improvements remained stable 4 months after the end of treatment, with no significant changes (T2 versus T3). Regarding function scales, analysis of the FM assessment showed that all patients had improved by the end of the Armeo®Spring training programme (T1 versus T2, P < .01). Researchers also found a small but significant improvement between T2 and T3 (P < .01). Significant improvements on MI and WMFT-Time were only detected between treatment onset and 4 months after the end of treatment (T1 versus T3, P < .05). Table 1 shows results from clinical assessments throughout the study period.

Discussion

Changes in the scores obtained on the scales used in the current study suggest that training with the Armeo®Spring system effectively promotes functional recovery of the upper limb in subjects with mild to moderate chronic hemiparesis following a stroke. Our patients displayed improvements on both function and activity scales for the upper limb without there being any significant changes in muscle tone. These improvements typically remained stable while the patients continued with traditional rehabilitation techniques. Our results may be explained in part by the psychometric properties of the function scales used here and the specificity of the training programme. Regarding the FM, the improvement of more than 5 points on average at the end of robot-assisted therapy is clearly greater than any improvements observed after that therapy. This change, which is linked to the treatment period, falls within the range of minimum detectable change described in chronic stroke patients, compared to changes observed after treatment has concluded. This demonstrates the clinical relevance of the Armeo®Spring programme for patients of this type. MI provides discrete measurements, which may explain those changes which are only observed at the end of the study. Our patients presented no significant changes in

<table>
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<th>Table 1</th>
<th>Results from the assessment scales for each of the 3 time periods.</th>
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<tr>
<td></td>
<td>Onset (T1)</td>
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<tr>
<td>Fugl-Meyer Assessment Scale</td>
<td>45.7 ± 14.3</td>
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<tr>
<td>Ashworth Proximal</td>
<td>0.6 ± 0.6</td>
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<tr>
<td>Ashworth Distal</td>
<td>1 ± 0.8</td>
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<tr>
<td>Motricity Index</td>
<td>69 ± 14.6</td>
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<tr>
<td>Manual Function Test</td>
<td>16.9 ± 6.3</td>
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<tr>
<td>Motor Assessment Scale</td>
<td>10 ± 5.5</td>
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<tr>
<td>Wolf Motor Function Test-Ability</td>
<td>44 ± 15.5</td>
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<tr>
<td>Wolf Motor Function Test-Time</td>
<td>459.2 ± 486</td>
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</table>

Repeated measure ANOVA using the Bonferroni correction as a post hoc analysis.

a onset versus end; b: end versus end + 4 months; c: onset versus end + 4 months; p: significant; NS: not significant.

P < .01.
muscle tone according to the MAS scale, as has been shown by a number of other studies.17 Of the prior studies we reviewed, only the article by Posteraro et al.18 describes a decrease in muscle tone, and the decrease was limited to the proximal region. Furthermore, that study included patients with strokes and traumatic injury, and the treatment period was shorter than the one we describe. Lastly, the scores for specific activity scales (WMFT, MAS, and MFT) suggest that task-directed training may be involved in the improvement we observe.42,43 According to the results from the WMFT, ability seems to depend on specific training for the task, while the task’s completion time seems to improve regardless of the training method. Based on the above, results from studies comparing robot-assisted with non robot-assisted therapies, given the same type and intensity of exercises, are inconclusive.15,17,19 According to some authors, benefits from robot-assisted therapy are at least as effective as those from conventional therapy regimens. Other authors affirm that certain robotic systems deliver better results than conventional therapy. For example, Lum et al.44 compared a control group treated with conventional therapy to a group treated with robot-assisted therapy. They concluded that the latter presented better clinical results and biomechanical measurements. Other authors believe that robot-assisted therapy combined with conventional therapy is probably better than either regimen by itself, for both kinematic and function.12 The preference for robotic systems over conventional therapies is probably based on the uniformity, velocity, and intensity of the robot-assisted exercises.15

The effectiveness of robot-assisted therapy, such as the Armeo®Spring system, stems from the fact that many of its characteristics facilitate completion of rehabilitation programmes based on key factors in motor learning. Robotic systems, such as Armeo®Spring, promote the active, systematic, and intensive repetition of specific movements and may provide a setting of sensorimotor integration with a variable degree of attentional demand and complexity. In the Armeo®Spring system, the association with different virtual realities provides the tasks with functional significance and increased visual feedback. The system allows researchers to adjust the level of difficulty to match the patient’s condition, which is also a relevant concern in motor learning strategies. On the other hand, it is interesting to note that the most frequently repeated tasks with the Armeo®Spring system are reaching/grasping tasks. These movements are commonly used in activities of daily life, and the interarticular coordination needed to complete this task is often impaired in hemiparetic patients.45

We should point out that our sample includes patients with long post-stroke times. However the common belief is that most of the neurological recovery following a stroke occurs during the first 6 months.46 These results are consistent with those from prior studies with different robotic systems, such as MIT-MANUS,77 ReGo®,47 or InMotion2®,48 designed to train the proximal segment of the upper limb in long-term patients. Our results should be interpreted in the context of the limitations of both the study sample and the robotic system. The Armeo®Spring system lacks a mechanical robot-assisted device that mobilises the limb and directs its movements. Unlike manual or passive robot-assisted therapies, the Armeo Spring system cannot be used by severely impaired patients lacking the ability to actively mobilise the proximal limb segment at will or by patients with abnormal movements or severe hypertonia. Additionally, this system requires a minimum level of voluntary motor activity in order to start treatment, as shown by our sample’s inclusion and exclusion criteria. Given the rapid progress of technology, new therapies are likely to be available in the near future in order to treat the increasing number of patients with neurological sensorimotor disabilities. In fact, the Armeo®Spring system has recently been updated by the addition of a robotic arm which allows patients with no motor activity to use it.

One of our study’s limitations is that we did not include a control group. However, the post-stroke times in our sample and the inclusion of a clinical assessment 4 months after the end of treatment allow researchers to associate benefits observed with the therapy measures applied. Lastly, our study does not include the measurements of participation proposed by the ICF model. With the above in mind, most study groups have not been able to consistently show that changes in the specific function scales of the upper limb in training give rise to better performance of the activities of daily life.13 Similarly, the most recent Cochrane review49 confirms that electromechanical rehabilitation systems are effective for improving the strength and function of the paretic upper limb, but not for improving performance of activities of daily life. These results have been related to the capacity of robots to promote dexterity motor learning, but not compensation mechanisms,10–30 which are frequently involved in the activities of daily life.13,20,48

In conclusion, our results show that robotic systems are effective for upper limb rehabilitation in cases of mild to moderate paresis, even at long post-stroke times. Although the physiological basis explaining the efficacy of these systems seems obvious, one challenge for today’s and tomorrow’s professionals is to identify methods and settings that effectively foster motor learning according to each patient’s clinical characteristics and time elapsed since the stroke.

Conflicts of interest

The authors have no conflicts of interest to declare.

References


