Clinical Rehabilitation 2001; **15**: 217–220

Functional electrical stimulation by means of the 'Ness Handmaster Orthosis' in chronic stroke patients: an exploratory study

HT Hendricks St. Maartenskliniek, Nijmegen, Universitair Medisch Centrum St. Radboud, Nijmegen, **MJ IJzerman** Roessingh Research and Development, **JR de Kroon, FACG in 't Groen** and **G Zilvold** Rehabilitation Centre Het Roessingh, Enschede, The Netherlands

Received 11th October 1999; returned for revisions 8th December 1999; revised manuscript accepted 18th March 2000.

Objective: To gain experience with 'Ness Handmaster Orthosis' treatment in chronic stroke patients, to identify suitable patients, and to study the effects of treatment.
Design: Exploratory, uncontrolled trial with measurement of motor functions and muscle tone of the upper extremity prior to, during, upon completion, and six weeks after a treatment period.
Setting: A rehabilitation centre in the Netherlands.
Subjects: Eighteen chronic stroke patients (more than six months post stroke), who exhibited upper extremity dysfunction due to spastic paresis.
Intervention: A 10-week therapy programme of functional electrical stimulation by means of the 'Ness Handmaster Orthosis'.
Results: The results of 15 patients were available for analysis. The differences in motor score and muscle tone before and at the end of treatment were statistically significant ($p = 0.008$ and 0.021, respectively). The follow-up measurements showed that the effects on motor functions and muscle tone decreased after therapy completion. Stratification of the patients in two subgroups indicated that patients with initial high motor scores benefited most during the intervention period.
Conclusion: The present study suggests that Handmaster treatment possesses therapeutic opportunities in chronic stroke patients with spastic paresis of the upper extremity.

Introduction

Motor impairments of the upper extremity contribute substantially to functional disability after stroke.[1–3] A variety of neurofacilitatory techniques are used nowadays to improve motor control.[4] As soon as the motor impairments are stable, therapy is aimed at the development of adaptive control strategies. The results of these therapeutic regimens appear to be disappointing in many cases, especially at the level of functional abilities of the paretic upper extremity.[2,3]

In recent decades, functional electrical stimulation (FES) has been applied in the management

Address for correspondence: Maarten J IJzerman, Roessingh Research and Development, PO Box 310, 7500 AH Enschede, The Netherlands. e-mail: m.ijzerman@rrd.nl

© Arnold 2001

0269–2155(01)CR405OA

Downloaded from cre.sagepub.com at UNIV OF NORTH DAKOTA on May 23, 2015

of upper extremity dysfunction after stroke. A meta-analysis of four reported randomized controlled trials of FES in chronic stroke patients showed statistically significant favourable recovery of muscle strength in the FES group compared with no FES.[5] Evidence of efficacy of FES in acute stroke patients is evolving.[6–8]

Several commercially available systems providing FES have been developed. The Ness Handmaster is such a system (NESS Ltd, Raanana, Israel). The special construction of this hybrid orthosis and electrical stimulation device provides an instrument for both treatment at the level of impairments (neuromuscular and articular properties) and disabilities (functional handgrip with stabilized wrist).[9,10] The device is user friendly in terms of side-effects, application and operation. The continuous support of a therapist is not necessary and patients can perform the therapy at home, even during other activities. However, clinical reports concerning the Ness Handmaster are limited,[9–11] and it is not clear which chronic stroke patients benefit most from this therapy. From this perspective, we conducted an uncontrolled trial to gain experience with Ness Handmaster treatment, to identify suitable patients, and to study the effect of the treatment on spastic paresis of the upper extremity.

Methods

Patient selection

All patients were recruited from an outpatient population. Many were referred by general practitioners and rehabilitation physicians. Several patients visited our outpatient clinic on their own initiative. About 35 patients were screened for entry. Patients were included if they had had a stroke more than six months ago, and if they exhibited upper extremity dysfunction due to spastic paresis, with muscle tone of 1 and higher at the elbow as measured by the modified Ashworth Scale.[12] Patients were included if they had no hemineglect, no other severe cognitive impairments, no severe sensory impairments, no frozen shoulder, no contractures at the elbow and wrist, and no shoulder–hand syndrome. Informed consent was obtained from all participants.

Assessment

Motor functions and muscle tone were assessed before treatment onset (t0), 4–6 weeks after treatment onset (t1), upon completion of treatment (t2), and six weeks after the treatment (t3). Assessments were taken at regular controls at the rehabilitation centre. Motor control was evaluated by the Fugl-Meyer Motor Assessment (FMA).[13] Muscle tone at the elbow was assessed by the modified Ashworth Scale. Additionally, patients were asked to report any change in functional abilities, muscle tone and changes otherwise. Patients were also asked if they experienced any negative treatment aspects. The therapy compliance was assessed by a timer, which was integrated in the control unit of the Handmaster.

Therapy

FES was administered by the Ness Handmaster. It is a portable open-loop neuroprosthesis, consisting of a microprocessor-based electrical stimulation unit, incorporated in a spiral forearm–wrist–hand splint, containing radial, dorsal and volar surface electrodes. The stimulator delivered constant voltage biphasic symmetrical pulses (stimulation frequency 36 Hz, duty cycle 40%) in an interrupted mode of contraction and relaxation, which generated movements at the wrist, hand and fingers. Both amplitude and pulse duration (0.1–0.5 ms) were adjusted to optimal contraction and patients' comfort. For further technical notes, the reader is referred to the study by IJzerman *et al*.[10] Patients were scheduled in a 10-week stimulation programme. The first two weeks were used for instruction and optimal fitting and fine-tuning of the neuroprosthesis. In the following eight weeks, patients worked out an intensive stimulation programme at home, with regular controls at the rehabilitation centre. Stimulation started with three sessions of 20 minutes per day, gradually increasing to 60 minutes. Any other, concurrent therapy was continued.

Data analysis

Statistical analysis of differences in motor scores and muscle tone between baseline (t0) and the end of the stimulation period (t2) and between t2 and the scores at six weeks follow-up without FES (t3) was carried out using the Wilcoxon's matched pair rank test.

Downloaded from cre.sagepub.com at UNIV OF NORTH DAKOTA on May 23, 2015

Results

Eighteen patients were initially included in the study: 10 males and 8 females. The mean age was 52.8 years (range 20–70), the mean time post stroke was 4.9 years (range 0.75–18 years). Two patients experienced no changes during the first fitting and fine-tuning sessions and they left the programme before treatment onset. Follow-up measurements were not completed in another patient due to a breakdown in communication between researcher and therapist. Thus, the results of 15 patients were available for analysis. At t2 13 patients showed improved motor functions, four of them even exhibited considerable improvement. The median scores for motor functions and muscle tone and their ranges at all assessments are shown in Table 1. The differences in motor scores and muscle tone between t(0) and t(2) were statistically significant (p = 0.008 and 0.021, respectively). After completion, motor functions decreased and muscle tone increased, the p-values for the differences between t(2) and t(3) were 0.038 and 0.74, respectively.

Therapy efficacy seemed to be dependent on initial motor scores. We therefore stratified our patients into two subgroups, eight patients with initial FMA scores below 35 and seven patients with higher scores (Table 1). The subgroup of patients with initial high motor scores benefited clearly more from Handmaster treatment.

As for the subjective assessment, functional improvement was experienced by 10 patients, of which four patients (all in the subgroup FMA above 35) even noticed a remarkable improvement of fine motor control. All patients reported muscle tone reduction during the training period. Furthermore, increased awareness of the affected side, relief of shoulder pain and trophic changes were experienced in several cases. Technical problems (splint breakdown, loose contact), considerable time investment and seldomly painful stimulation were reported as negative aspects. Therapy compliance, as measured by a timer in the control box, indicated that all patients were stimulated in accordance with prescription.

Discussion

The present study suggests that FES administered by means of the Ness Handmaster possesses therapeutic opportunities in chronic stroke patients with spastic paresis of the upper extremity. Increased motor function and reduction of muscle tone were the observed effects during the treatment period, especially in the subgroup of

Table 1 Median motor scores and median muscle tone with minimal and maximal values at all assessments

	t0	t1	t2	t3
FMA median (min–max)	27 (8–54)	23 (6–58)	25 (10–64)	26 (6–63)
Ashworth median (min–max)	3 (1–4)	2 (0–4)	2 (0–4)	2 (0–4)
Subgroup 1				
FMA median (min–max)	20 (8–27)	21 (6–23)	23.5 (10–25)	22 (6–26)
Ashworth median (min–max)	3 (2–4)	2 (2–4)	2.5 (1–4)	2 (0–4)
Subgroup 2				
FMA median (min–max)	40 (36–54)	54.5 (36–58)	56 (35–64)	45 (39–63)
Ashworth median (min–max)	2 (1–4)	2 (0–3)	1 (0–3)	2 (1–3)

FMA, Fugl-Meyer Motor Assessment.
Subgroup 1: initial Fugl-Meyer motor scores below 35 (8 patients).
Subgroup 2: initial Fugl-Meyer motor scores higher than 35 (7 patients).

Downloaded from cre.sagepub.com at UNIV OF NORTH DAKOTA on May 23, 2015

Clinical messages

- The Ness Handmaster Orthosis is a hybrid orthosis and electrical stimulation device. It demands no intensive support of a therapist.
- Patients with initial high motor scores seem to benefit more from Handmaster treatment than patients with initial low motor scores.
- Further research is needed to evaluate the real value of Handmaster treatment in patients with spastic paresis of the upper extremity.

patients with relatively moderate motor deficits.

Several methodological shortcomings impeded our study. It was uncontrolled and there was no blinding procedure; it cannot be concluded that the positive results emerge from FES, or from daily splint use, received attention from the therapists or subjective assessment. Therefore, the real value of therapeutic Handmaster use in relation to conventional therapy (including splint therapy) or electromyogram-triggered neuromuscular stimulation needs to be explored further in a randomized controlled trial. However, the first results were promising and in the present study chronic stroke patients could be identified, who benefit most from Handmaster treatment. Handmaster treatment is user friendly and can be performed at home. Besides initial fitting and fine-tuning, it demands no intensive support from a therapist. There are no serious side-effects.

Acknowledgements

The authors would like to thank Thecla Stoffers, José Paus and Martin Tenniglo for their participation in this project. Ten Kate-Huizinga and the Hulpfonds 'Het Roessingh' are gratefully acknowledged for their contributions. The Ness company provided the materials. There is no commercial relationship with the Ness company. Ness had no influence in preparing the manuscript.

References

1 Nakayama H, Jorgensen HS, Raaschou HO, Olsen TS. The recovery of the upper extremity function in stroke patients: the Copenhagen study. *Arch Phys Med Rehabil* 1994; **75**: 1–5.

2 Heller A, Wade DT, Wood VA, Sunderland A, Langton-Hewer R, Ward E. Arm function after stroke: measurement and recovery over the first three months. *J Neurol Neurosurg Psychiatry* 1987; **50**: 714–19.

3 Wade DT, Langton-Hewer R, Wood VA, Skilbeck CE, Ismail HM. The hemiplegic arm after stroke: measurement and recovery. *J Neurol Neurosurg Psychiatry* 1983; **46**: 521–24.

4 Caldwell CB, Wilson DJ, Braun RM. Evaluation and treatment of the upper extremity in the hemiplegic stroke patient. *Clin Orthop Rel Res* 1969; **63**: 69–92.

5 Glanz M, Klawansky S, Stason W, Berkey C, Chalmers T. Functional electrostimulation in poststroke rehabilitation: a meta-analysis of the randomized controlled trials. *Arch Phys Med Rehabil* 1996; **77**: 549–53.

6 Chae J, Bethoux F, Bohinc T, Dobos L, Davis T, Friedl A. Neuromuscular stimulation for upper extremity motor and functional recovery in acute hemiplegia. *Stroke* 1998; **29**: 975–79.

7 Faghri PD, Rodgers MM, Glaser RM, Bors JG, Ho C, Akuthota P. The effects of functional electrical stimulation on shoulder subluxation, arm function recovery, and shoulder pain in hemiplegic stroke patients. *Arch Phys Med Rehabil* 1994; **75**: 73–79.

8 Francisco G, Chae J, Chawla H *et al.* Electromyogram-triggered neuromuscular stimulation for improving the arm function of acute stroke survivors: a randomized pilot study. *Arch Phys Med Rehabil* 1989; **79**: 570–75.

9 Weingarden HP, Kizony R, Nathan R, Ohry A, Levy H. Upper limb functional electrical stimulation for walker ambulation in hemiplegia. A case report. *Arch Phys Med Rehabil* 1997; **76**: 63–67.

10 IJzerman M, Stoffers T, In 't Groen F *et al.* Experiences with the clinical application of the Ness Handmaster in C5 tetraplegic and stroke patients: a pilot study. *J Rehabil Sci* 1996; **9**: 86–89.

11 Weingarden HP, Zeilig G, Heruti R *et al.* A hybrid functional electrical stimulation orthosis system for the upper limb. *Am J Phys Med Rehabil* 1998; **77**: 276–81.

12 Bohannon RW, Smith MB. Interrater reliability of a modified Ashworth scale of muscle spasticity. *Phys Ther* 1987; **67**: 206–207.

13 Fugl-Meyer AR, Jaasko L, Leyman I, Olsson S, Steglind S. The poststroke hemiplegic patient. Part I. A method for evaluation of physical performance. *Scand J Rehabil Med* 1975; **7**: 13–31.

Downloaded from cre.sagepub.com at UNIV OF NORTH DAKOTA on May 23, 2015