The Handmaster NMS1 surface FES neuroprosthesis in hemiplegic patients

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ABSRACT

The Handmaster NMS1 is a surface FES system comprising a hand/forearm orthosis and portable control box. It activates the plegic hand, and is intended for use in the home or clinic. It is designed to be simple and fast to don and to operate. The device is programmed to provide three phased-patterned, therapy protocols, a functional hand "open" mode, and two hand prehension - release patterns for functional grasp/ release of objects. Clinical trials are ongoing in Israel, Europe and the USA on chronic hemiplegic patients. These are being conducted with similar protocols on neurologically stable patients in CVA, TBI, MS, and CP. Results to date of the multicenter "metastudy" have demonstrated a significant average reduction in spasticity (Ashworth scale), improvements in limb posture, improvements in both passive and active ROM, and functional gains in some cases (Franchay, Jebson-Taylor, Fugl-Meyer). Correlation is made between the pretreatment condition of the patient and the expected outcomes and benefits. Compliance in long-term device use is very high. In addition trials are ongoing in Israel on orthopedic patients suffering hand trauma and surgery, and in the USA on restoration of upper limb function in SCI. The device is commercially available in Israel and in several European countries.

INTRODUCTION

Surface electrical stimulation has been shown to have multiple beneficial effects in the treatment of hemiplegic patients suffering from neuromotor dysfunction, including decreasing spasticity, providing a supplementary means for range of motion exercises, increasing muscle strength, and improving local blood flow. Studies have also shown functional gains in the hemiplegic upper extremity.

Electrical stimulation therapy has proved to be an effective therapeutic modality, and with a low ratio of man-hours to treatment time, has proved potentially cost-effective. In addition to the usual effort directed towards avoidance of secondary complications, and on the use of one handed adaptive techniques, electrical stimulation offers treatment directed to the involved extremity which includes sensory stimulation, and the possibility to isolate movements out of the synergy patterns. Once initially set up, a session of TES can be carried out unsupervised, and allows for frequent repetitions of the desired movements.

Its use can by no means considered widespread though. In medical centers TES is not a commonplace treatment, and in the home even less so. Even when TES is initiated, patient compliance has in the past been low. The modality merits a more extensive use.

The Handmaster NMS1 is an upper limb FES device designed to be used at home for therapy and/or functional restoration. It was developed to address the possibility of advancing the ergonomic design of the TES system. Speed and simplicity in donning and user-friendly operation of the device has resulted in high patient compliance in its use. Portability of the device and freedom of movement of the FES-activated limb allows treatment duration to reach several hours per day without interfering with the daily routine of the patient.

Clinical trials have been conducted over the last two years in a number of medical centers internationally using the Handmaster NMS1 with similar experimental and treatment protocols at each site, to assess the efficacy of the device and of the treatment protocols. The results of some of these studies have been published in the medical literature. Here we present an initial review of the results and findings as a multicenter "metastudy". On completion of the studies in all the collaborating centers, an in-depth paper with full results and statistical analysis will be published.

METHODOLOGY

Neurologically stable (at least 10 months post event) hemiplegics were included in the trials. Eligibility criteria included informed consent to partake in the program, hand/forearm size appropriate for the Handmaster orthosis, and adequate response from electrical activation of the muscles. 86 CVA patients, 13 TBI patients, 6 CP patients, and 3 MS patients have to date completed the protocol: a total of 108 hemiplegic patients. Measurements quantifying shoulder, elbow, wrist, finger and thumb spasticity, elbow, wrist, and hand posture at rest and after stress (rise from a chair, walk 5 m, return and sit down), and active Range Of Motion (ROM), were made prior to beginning and after approximately two months of an intensive home therapy protocol using the device.

The electronic orthosis is placed on the forearm/hand and holds the wrist at a functional angle of extension. Five electrodes on the inside surface of the orthosis activate the following muscles: two extensor muscles - the extensor digitorum and the extensor pollicis brevis, and three flexor muscles - the flexor digitorum superficialis, the flexor pollicis longus, and the thenar group. The electrodes are positioned in the first session by the clinician. Thereafter the patient places the orthosis on his own limb, and the electrode array relocates precisely over the hand/forearm surface. Disposable cloth pads overlying the electrodes are dampened with tapwater prior to each session with the device.

The Treatment Protocol: Was selected by the clinician from the Handmaster treatment modes available. Cyclic extension / flexion movements, cyclic extension - relaxation, or fast extension waves were three modes used. The spastic flexors were, in most cases activated. Choice and duration of treatment protocol, cycle time, and stimulation intensity and electrode location were set by the clinician. Hand grasp - release was in addition used by some patients for training, providing, or enhancing functional grasp, and the ability to release objects. The daily treatment was increased from twenty minutes up to four hours over the period of intervention.

RESULTS

Modification of Spasticity: The spasticity, estimated on the Ashworth scale, showed an average reduction at the fingers, wrist, elbow and shoulder joints of one point on the scale. This reduction was found to be of similar level at each of these joints. Similar results in spasticity reduction were obtained at each of the 15 participating centers. Similar one point reductions on the Ashworth scale were observed for patients suffering more severe and less severe spasticity.

Resting posture: A significant improvement ($> 15^0$) in the posture of the plegic upper limb was measured in 75% - 80% of the patients, both at rest and after physical stress.

Active Range of Motion (Voluntary): A significant improvement in active finger extension and flexion movements was found in 80% of patients who had at least trace movement, but less than full ROM at the initial assessment session. Additionally 80% of the patients having at least trace movement, but less than full ROM at the initial assessment session, benefited from significant ($>15^0$) improvement in wrist and elbow ROM.

Functional Gains: Where functional training was deemed appropriate by the local clinician, an improvement in test score (either Franchay, Jebson-Taylor, or Fugl-Meyer, depending on clinical center) was achieved by 35% of these patients. Also in 30% of the same patient group the ability to open up the hand voluntarily to release a grasped cylinder was restored.

DISCUSSION

Intensive and long- term home FES therapy has recently been made feasible by the development of the Handmaster system. The system is designed for very fast and simple set up, while allowing five forearm and intrinsic hand muscles to be exercised in functional patterns of activation. Use of the device may be integrated into the patient's overall therapeutic program. Massive sensory input generated by the stimulation, both through skin receptors, and proprioceptive muscle, tendon and joint receptors during the limb movements elicited by the stimulation are believed to contribute to the benefits obtained, as listed above. Various inhibitory neurological pathways are activated and reinforced by the repeated activation both of the antagonist muscles to the spastic limb, and also of the spastic muscles themselves. Normalization of fiber composition and restoration of Type II muscle fiber to the spastic muscle is suspected to be the cause of significant reduction of spasticity and long-term carry over when the spastic muscle is stimulated at high intensity and low duty cycle over a period of weeks. Reinforcement of the recurrent inhibition mechanism whereby activation of these type II fibers transmits inhibitory signals to the spastic type I fibers in the same muscle and in synergistic muscles may explain the spasticity reduction observed. The change in fiber composition resulting in the restoration of the natural recurrent inhibition reflex would explain a carry over effect whereby the benefits immediately post treatment were found to remain at least partially.

Benefit Prediction: Commercial sales of the Handmaster have necessitated our predicting the probable outcome benefits for candidate device purchasers. Most patients / families wish to know what will be the benefit in the long term if they invest the purchase price of the device and the treatment time. Due to different benefits for differing patient baseline conditions, we have divided patient initial condition into three groups:

Patient Group	**Group 1**	**Group 2**	**Group 3**
Initial Condition	Severe spasticity. Minimal active movement in shoulder & elbow. No active movement in wrist / fingers/ thumb.	Severe / moderate spasticity. Partial active movement in shoulder & elbow. Partial / minimal active movement in wrist. Partial active flexion movement, no active extension movement in fingers/ thumb.	Moderate / low spasticity. Good / partial active movement in shoulder / elbow. Partial active movement including extension in wrist / fingers.
Expected Benefits	Reduced spasticity. Improved limb posture. Improved active ROM in shoulder & elbow. Fingers / thumb / wrist: improved passive ROM.	Reduced spasticity. Improved limb posture. Improved active ROM in shoulder, elbow & wrist. Improvement in ability to relax fingers after grasp. Fingers / thumb: improved passive ROM.	Reduced spasticity Improved limb posture. Improved active and passive ROM in the shoulder / elbow / wrist / fingers.
Additional benefits	*Prevention of complications:* Skin problems, contractures, pain, edema		
	Improvements in: Limb blood flow, skin colour, muscle bulk, limb appearance, self image		

Functional Gains: Although functional gains are not emphasized in order to avoid possible disappointment at a later date, a significant number of hemiplegics have regained partial function of the paretic limb due to the improvements elicited, particularly in the unmasking enhancing and reinforcing of residual active voluntary movements. This improved ability combined with massive sensory input to the paretic limb, which draws attention of the patient to his limb has often reversed the "psychological amputation" phenomenon often seen in the hemiplegic patient and has resulted in a spontaneous initiation in the patient of the use of his paretic limb as a functional assist to the healthy limb.

Use of the device in its functional GRASP mode to restore grasp-release to the paretic hand in hemiplegia is less common, but in certain cases has been used: ambulation with a walking frame, holding a bag in the paretic hand while walking with a cane in the healthy hand, sweeping the floor with a broom, writing while holding a telephone in the paretic hand; these are some examples of functional restoration our hemiplegic patients carry out using the device itself as a neuroprosthesis to restore hand grasp-release.

CONCLUSIONS

Multiple benefits resulting from the long-term home use of the Handmaster neuroprosthesis has been demonstrated in multicenter clinical trials on over 100 hemiplegic patients, with functional gains achieved by a significant group.