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Use of the NESS Handmaster to restore handfunction in tetraplegia: clinical experiences in ten patients

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Objective: To explore possible functional effects of the Handmaster in tetraplegia and to determine suitable patients for the system.
Patients: Patients with a cervical spinal cord injury between C4 and C6, motor group 0–3. Important selection criteria were a stable clinical situation and the absence of other medical problems and complications.
Design: Ten patients were consecutively selected from the in- and outpatient department of a large rehabilitation hospital in The Netherlands. Each patient was fitted with a Handmaster by a qualified therapist and underwent muscle strength and functional training for at least 2 months.
Methods: Functional evaluation comprised the performance of a defined set of tasks and at least one additional task as selected by patients themselves. Tasks were performed both with and without the Handmaster. Finally, patients were asked for their opinion on Handmaster use as well as their willingness to future use.
Results: In six patients a stimulated grasp and release with either one or both grasp modes (key- and palmar pinch) of the Handmaster was possible. Four patients could perform the set of tasks using the Handmaster, while they were not able to do so without the Handmaster. Eventually, one patient continued using the Handmaster during ADL at home.
Conclusion: The Handmaster has a functional benefit in a limited group of patients with a C5 SCI motor group 0 and 1. Suitable patients should have sufficient shoulder and biceps function combined with absent or weak wrist extensors. Though functional use was the main reason for using the Handmaster, this case series showed that therapeutic use can also be considered.
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Introduction

Patients with a spinal cord injury at level T1 and above suffer from sensori-motor deficits of their upper extremities, which affects their level of independence. The initial therapy of the upper extremities in tetraplegia combines intensive functional training with use of orthoses. The therapy aims at preservation of joint mobility, optimal function of the innervated muscles and learning of compensatory movements. Orthoses, eg writing splints and adapted aids are used to obtain an increased level of independence given the impairment status of the patient.

When no more progression can be expected continuing this approach, augmentative therapeutic options can be considered. Much experience has been gained during the last few decades with reconstructive arm-hand surgery.[1–4] In patients with C6 lesions and motor group 3 and higher, according to the international classification of the upper limb in tetraplegia,[5] there are usually 'motors' available for tendon transfer in order to create active grasp function as well as elbow extension.

Unfortunately, surgical reconstruction of grasp function in patients with motor group 2 and 1 is more complicated and less options are possible. In cases of absent active muscle function below the elbow, a satisfying surgical reconstruction of grasp function is not possible.

An interesting method in these patients may be the use of functional electrical stimulation (FES). In the last decades several research groups have been working on the development of FES systems for the upper extremities.[6–8] At present, four FES systems for the restoration of grasp function of tetraplegic patients

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can be mentioned: the Bionic Glove,[9] the Fesmate,[10] the Freehand system[10] and the Handmaster.[11]

The Bionic Glove (marketed as Tetron Glove by Neuromotion, Edmonton, Canada) is a surface FES system in which self adhesive surface electrodes placed over motor points of the muscles to be stimulated are connected with a fingerless glove on which a stimulator is mounted. Active wrist movements are detected by a wrist position sensor and result in stimulation of finger and thumb flexors and extensors. The system is developed to be used in patients with a C6–C7 spinal cord injury. The first multi centre trial, which concerned nine patients with SCI, with the bionic glove showed improvement of hand-grasp force in all nine patients and improvement in the performance of standardised handfunction tests in four patients.[9]

The Fesmate (NEC Medical Systems, Tokyo, Japan) uses percutaneous indwelling electrodes in selected muscles connected to an external stimulator. Depending on the level of the spinal cord injury the stimulation is controlled by various types of switches activated by hand- mouth- or head-activity. Some case reports are published about the successful use in tetraplegic patients.[12]

A hybrid approach, reconstructive surgery combined with FES, is used in the Freehand system (NeuroControl, Cleveland, USA). FES is applied via implanted epimysial electrodes on selected muscles whereas the electrode leads are connected to a subcutaneous receiver/stimulator.[13] A range of surgical procedures may be undertaken to enhance the effects of FES in the Freehand system. Over 80 systems are implanted world wide and several clinical reports indicate good results with the system on the level of impairment-disability- and handicap reduction.[14–17]

A different, but also hybrid, approach (ie splint and FES) is used in the Handmaster (NESS Ltd., Ra'anana, Israel). The device is designed to be used in C5 tetraplegic patients as well as in hemiplegic (stroke) patients. So far, only three small conference contributions have been published on preliminary results of the Handmaster in tetraplegia.[18–20] The Handmaster was introduced in our rehabilitation hospital at the end of 1995 and in this paper we aim to describe the clinical findings in the first ten SCI patients treated with the Handmaster. Description of the results is focused at the actual functional benefit and at determination of potentially suitable patients for the system.

Methods

The Handmaster[21]

The splint and control box The Handmaster (Figure 1) contains an external control unit connected by a cable to a below elbow splint. The splint contains a body

Figure 1 The Handmaster system

with a front spiral end and a wing which pivots about the body and can be opened by lifting a release handle. Five surface electrodes are attached in the splint and correspond with the motorpoints of the flexor digitorum superficialis (FDS), extensor pollicis brevis (EPB), flexor pollicis longus (FPL), extensor digitorum communis (EDC) and thenar muscles. The stimulus parameters are pulse-width range of 0.01–0.5 ms which can be adjusted in ten intervals by the patient, and frequency 18 Hz for functional modes and 36 Hz for muscle restrengthening mode. The maximum output of the stimulation unit is 60 mA and can be adjusted by the therapist.

Three exercise modes and two grasp modes can be selected on the control unit. The exercise modes provide repetitive stimulation of the muscles in order to improve strength and muscle condition. The functional modes provide a key- and palmar grasp stimulation pattern. After activation of the selected grasp via trigger button on the control unit, a stimulation sequence is started in which the hand is opened via stimulation of the extensors. After a preset and adjustable delay, the flexors are subsequently stimulated in order to obtain the selected grasp. The stimulation of the flexors is maintained until a push on the trigger button activates the extensors in order to release the object. The stimulation of the extensors is stopped after a preset duration. The palmar grasp mode requires stimulation of the EDC and EPB for hand opening, followed by stimulation of the FDS, FPL and thenar muscles. The key mode requires stimulation of the EPB and FDS for acquisition, followed by stimulation of FDS, FPL and thenar

muscles. The stimulation amplitude can be adjusted by the therapist while fitting the Handmaster.

The patient can increase or decrease the stimulation intensity by adjusting the pulse width on the control unit.

Fitting procedure Excitability of the relevant muscles is confirmed prior to preparing a splint for the patient. Three splint sizes are available in which interchangeable wrist inserts with different sizes can be used in order to individually fit the splint. A so-called clinical unit, which is an open version of the basic frame of the splint, is used to determine the motor points of the relevant muscles (FDS, EDC and EPB). One year ago NESS introduced a new fitting technique using different panels containing standard electrode configuration. The thenar electrode and the FPL electrode remain permanently in place. After determination of the localisation of the motorpoints the exact position of the electrodes can be copied in the Handmaster splint. Star springs are put into prepared holes of the splint in order to connect the electrodes with the stimulation circuit of the splint.

Assessment

Patients Patients admitted to the in- and outpatient department of the spinal unit of the rehabilitation centre Het Roessingh with a stable spinal cord injury level C4–C6 and motor group 0 to 3 according to the International Classification of the Upper Limb in Tetraplegia were selected for treatment with the NESS Handmaster.

Patients were excluded if they had severe spasticity of the upper extremities, contractures of the elbow and shoulder that prevented positioning of the arm, skin defects and infection of the upper extremities, pacemaker implant or other implants which could be disturbed by the electrical field of the Handmaster, pregnancy, haemorragic diathesis, received handsurgery on the side to be fitted with the Handmaster, malignancy or other interfering medical problems. An informed consent was obtained from all patients and the project was approved by the local medical ethics committee.

Training Following the fitting procedure the patient was instructed to use the exercise modes in order to improve strength and condition of the stimulated muscles. After an exercise period of 2 weeks the patients continued with a training period. The training period lasted from 6 –12 weeks depending on functional progress being made. The training was stopped if patient and therapist did not expect any additional functional gain.

Functional assessment Functional performance was assessed using four tasks as selected by the rehabilitation staff to test the key and palmar grasp modes. Patients were free to use either the key or the palmar grasp mode to fulfil the tasks. These tasks were: pouring water from a can, opening a jar, opening a bottle, taking a video tape out and putting it into a video player. In addition the patients were asked to select at least one other task. Criteria for these tasks were the inability or great difficulty to perform the tasks independently and the expectation to improve the performance with the Handmaster.

Table 1 Relevant subject information and general results

	Gender/age	*Fitted hand*	*Level of injury*	*Time since onset SCI*	*Classification*	*Actual hand status*	*Functional training*	*Overall result*
1	Male 21	right	C6	1 year	3-Cu	1	Yes	Disliked rigid splint, received handsurgery
2	Male 29	right	C6	6 years	3-Cu	1,3	Yes	Disliked rigid splint, received Freehand
3	Male 32	right	C4 (Z.P.P. C5) L:C6	1 year	1-O	5,7	Yes	Improved shoulder function
4	Female 65	left	C5 (Z.P.P. C6) R:C6	½ year	1-O	1,2,4,6	–	Therapeutic use to reduce finger contractures
5	Male 33	right	C6	2 years	3-Cu	1	–	Fitting not possible
6	Male 41	right	C6	1 year	2-O	1,3	–	Muscles not excitable
7	Male 23	left	C5	1 year	1-O	2,3,4,6	Yes	Actual daily use combined with conventional splint
8	Female 20	left	C4 (Z.P.P. C5) R:C5	1 year	1-O	2,3,4,7	–	Withdrawn during training period; improved shoulder function
9	Male 22	left	C5	2 years	1-O	2,3,4	–	Not motivated after fitting
10	Male 43	right	C4 (Z.P.P. C5) L:C5	3 years	0-O	2,4,6	–	Muscles not excitable

Table includes information regarding the hand which was fitted with the Handmaster, the level of spinal cord injury (Z.P.P. = zone of partial preservation), time since injury and the international classification for surgery of the upper limb in tetraplegia. Actual hand status refers to the actual grasp function which patients had prior to fitting and the way it was acheived: 1 = tenodesis grasp; 2 = eating splint; 3 = writing splint; 4 = typing splint; 5 = cock up splint; 6 = adapted cutlery or tools; 7 = O.B. apparatus

Performance was recorded on video tape, and was judged by an experienced panel of a physiotherapist, an occupational therapist and a rehabilitation physician. The necessary objects for the tasks were put on a table in front of the patient. The patients sat in their wheelchairs in front of the table with the arm fitted with the Handmaster, switched off, placed on the arm rest of the wheelchair. The performance was considered successful if the apprehension of the object (starting the stimulation, proper positioning of the upper extremity and acquisition of the object with the selected grasp), the functional task itself (if required lifting of the object and carrying out the necessary manipulations to fulfil the task) and the release of the object (after placing it back on the table in the starting position) could be done independently. If one of these aspects could not be done without assistance the performance was considered unsuccessful.

Finally, subjective user information was collected by asking patients' opinion on actual Handmaster use as well as their willingness to future use.

Results

Fitting

Ten patients with a SCI level C4–C6 volunteered to participate in the pilot study. The relevant clinical data and the general results are listed in Table 1.

In three patients the split could not be fitted, either due to inability to stimulate the key muscles or to anthropometric (splint size was too small) problems. In the other seven patients the splint could be fitted properly.

Training

Two patients could obtain a proper palmar grasp and four patients a palmar as well as a key grasp. In one patient serious finger flexion contractures prevented opening of the hand. For this patient, the Handmaster was used as a therapeutic device to treat these contractures. At the end of the training period the contractures of the meta carpo phalangeal joints were reduced from 50 to 10 degrees, measured with a hand held goniometer. Prolonged use of the Handmaster as a training device appeared in possible due to the discharge of this particular patient and the practical problems of continuing in the trial on an out patient basis.

Compliance

One patient was not motivated to continue with the Handmaster training after the fitting procedure and another patient stopped the training period after 4 weeks and was not motivated to undergo the evaluation. The other four patients completed the training period.

Side effects

No medical or technical problems were encountered during the study.

Functional results

The functional results are summarised in Table 2. All four patients who completed the training period were able to perform several tasks with the Handmaster, while they were unable to do so without the

Table 2 Functional task performance in four subjects

	Performance											
	Subject 1			*Subject 2*			*Subject 3*			*Subject 7*		
Task	*w/o*	*splint*	*handm.*	*w/o*	*splint*	*handm.*	*w/o*	*splint*	*handm.*	*w/o*	*splint*	*handm.*
1. Pouring water from a can	–	–	+	–	–	+	–	–	–	–	–	+
2. Opening a jar	–	–	+	–	–	+	–	–	–	–	–	–
3. Opening a bottle	–	–	+	–	–	+	–	–	+	–	–	–
4. Putting a tape in a VCR	–	–	–	–	–	+	–	–	+	–	–	–
5. Cutting meat	–	–	+	–	–	+						
6. Handling a hammer	–	–	–	–	–	+						
7. Putting on socks				–	–	+						
8. Writing				–	+	+				–	+	+
9. Handling a credit card				–	–	–						
10. Handling a zipper from a coat				–	+	–						
11. Handling a CD							–	–	–			
12. Brushing teeth							–	+	–	–	+	+
13. Drinking coffee without a straw							–	–	–			
14. Dry shaving										–	–	+
15. Pouring coffee										–	–	+

Functional training was conducted in four patients. Tasks 1--4 were selected by professionals. Tasks 5--15 were selected by patients. W/O refers to performance of the task without any device; splint refers to performance with an orthosis; handm. refers to performance with the Handmaster. A minus sign (–) indicates unsuccessful completion of the task, a plus sign (+) successful completion. No sign after tasks 5–15 indicates that the particular task was not selected by the patient and was not evaluated

Handmaster. A few of the selected tasks by the patients could be performed with other splints as well but the selection of these tasks by the patients indicated that they were not satisfied by or had difficulty with the performance. Two patients were able to use the key- as well as the palmar grasp mode for functional tasks, while two patients were only able to use the palmar grasp because of inability to obtain a proper stimulated key grasp in one patient and pain during the key grip stimulation sequence in the other patient.

Three of these patients were able to don and doff the splint independently and one of them indicated that he would use the system at home. With some difficulty we managed to get the cost of the Handmaster reimbursed by his health insurance company. After discharge from clinical rehabilitation he continued to use the device at home for several ADL activities such as brushing teeth, shaving and pouring coffee. Both other patients who could handle the splint independently had good wrist extension and both indicated a strong interference of this function with the rigid Handmaster splint. Eventually these two patients were selected for other therapies (tendon transfer and a Freehand FES system respectively). Finally the patient who could not don and doff the Handmaster independently experienced no additional benefit of the Handmaster because of this inability and the unsuccessful completion of the tasks he found important to achieve.

In two patients, shoulder movement before Handmaster training was only possible when assisted by a therapist or with a supportive apparatus. In both patients, shoulder movement could be performed without assistance after the training period, resulting in a better use of the arm with conventional splints. We believe that this improvement is a secondary benefit related to the extended training possibilities with the arm and hand using the Handmaster.

Discussion

This study describes our first clinical experiences with one FES system, the Handmaster, in a group of ten SCI patients with level C4–C6 and motor group 0 to 3. The number of patients who had functional gain appeared to be limited due to the heterogeneous population. The Handmaster is primarily designed for patients with C5 lesions and we also included C6 patients. In six patients we achieved a stimulated grasp. Positive results concerning handling objects with the grasp function provided by the Handmaster were found in four patients. One C5 patient decided to use the system on a daily basis at home during ADL. Though the Handmaster is initially designed to improve hand function in tetraplegia, it was found that three patients gained therapeutic benefits (improved muscle strength and reduction of finger contractures) from training with the Handmaster.

Whereas functional gain was the main treatment goal, actual use of the device during ADL by the patient was the most important outcome in the evaluation of the system. In the clinical trials with the Handmaster reported by Florence *et al*,[20] 20% of the C5 tetraplegics showed good grasp and release with the Handmaster and an additional 40% were possible candidates after correction of contractures and other problems.[20] The C5 patients using the Handmaster in the study by Florence developed functional grasp and release, independence in the use of switches and independent ability to don and doff the device. Furthermore Florence *et al*[20] reported the use of the stimulated grasps in ADL and various activities. In our study six out of ten patients had a C5 level of SCI or partial innervation of C5. In four of these patients a stimulated grasp was possible, two of them showed improvement of functional handling of objects and one was able to don and doff the device independently and continued using it at home. Florence *et al*[20] did not report the actual number of patients using the Handmaster, neither did they report about the environment where it was used (in hospital or at home).

Aito[19] described 16 patients with a C5–C6 lesion in whom the Handmaster was tested. Only six patients completed this study. The device was well accepted by these patients and almost all the functions tested with ADL scales and the Frenchay hand function test improved. Though comparability of the study population (eg level of lesion) could not be confirmed, these results are comparable to our findings: four out of ten patients completed the study and showed improvement of hand function with the Handmaster.

Our preliminary conclusions are that the Handmaster has a functional benefit for a limited group of C5 patients, motor group 0 and 1. In our case series, half of the patients fitted with the Handmaster actually started functional training and four completed this with improved performance of several tasks in a test situation in the rehabilitation centre. Only one C5 patient decided to continue the use of the Handmaster at home after the training period. However, the functional gains provided by the Handmaster were important for this patient as they reduced his dependency. This demonstrates the importance of the evaluation of the actual use of FES devices.

In regard to our patients, successful functional use of the Handmaster seems to depend on a number of factors. Stimulation of the muscles as well as fitting of the orthosis must be possible. Arm function, especially shoulder and elbow function, must be sufficient to stabilise and position the arm. Active wrist extension however can interfere with Handmaster use. Independent donning and doffing is important for actual use at home and depends on the function of the opposite arm which is also important for bimanual activities with the Handmaster. Furthermore the motiviation of the patients is of paramount importance. This may reflect on the

tasks the patients hope to achieve with the system. It is remarkable that the patient in our series who continued using the Handmaster at home succeeded only in one of the tasks defined by the rehabilitation professionals and in all four tasks defined by himself. Besides functional use of the Handmaster therapeutic use in arm and hand function training programs can also be considered.

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