The NESS Handmaster orthosis: restoration of hand function in C5 and stroke patients by means of electrical stimulation


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Introduction

Loss of hand function due to cervical spinal cord injury is one of the more severe disabilities one can sustain. Patients with paralysis of the upper extremity have to depend on the help of their attendant. Restoration of lost hand function in these individuals is one of the most important rehabilitation goals. By means of conservative as well as multiple surgical procedures one can restore simple grasps which allow patients to perform daily tasks.1,2 A relative new technique is the application of either surface, percutaneous or implanted Functional Neuromuscular Stimulation (FNS) to improve or restore grasps.3 The Cleveland free-hand implant system is one of the possibilities to provide simple grasps to tetraplegic patients by using a combination of reconstructive surgery as well as implanted FNS.4,5

Another commercially available system using FNS is the NESS Handmaster, which is a combination of a splint with built-in surface electrodes.5,6-10 Advantages of the surface FNS system with respect to implanted or percutaneous systems is ease of application, reversibility of the results and the price.

Besides application of the handmaster in tetraplegic patients, several authors have outlined the benefits of surface electrical stimulation in stroke patients, traumatic brain injury and even cerebral palsy.9,11 It has been suggested that the Handmaster would be beneficial regarding reduction of spasticity. Furthermore, it is hypothesized that patients can regain some voluntary movement after using the Handmaster.8

Abstract

The NESS Handmaster is a new non-invasive hybrid (orthosis combined with functional neuromuscular stimulation) neuroprosthesis which has been developed for therapy and restoration of hand function to the paralized upper limb in C5 tetraplegia, CVA and brain injuries. The system comprises a spiral wrist-extension splint housing the electrode array which is connected to the control unit by a thin flexible cable. It has been designed for independent use for both stroke and tetraplegic patients. Two exercise modes and three functional modes (grasp, key-grip and hand open) can be generated with the Handmaster. During the last year, several rehabilitation centres in Europe were provided with trial versions of the Handmaster in order to transfer the device to the market. Suitable tetraplegic candidates are those with C5 lesions with a loss of wrist extension activity. We concluded from literature and our own findings that these patients can benefit from the Handmaster with respect to performance of tasks in daily living. Examples of tasks which can be performed by means of the Handmaster are replacing a tape in a videorecorder, use of an electric razor for shaving, and drinking coffee. Reduction of spasticity seems to be the main therapeutic outcome in stroke patients. However, this reduction might be achieved by the stimulation as well as the orthosis. Further analysis of both components is required in order to determine treatment interaction.

Keywords: Functional Neuromuscular Stimulation; Hand function; Tetraplegia; Stroke.
Laboratory prototypes of FNS systems for therapy and for restoration of hand function have been developed since the early 1960s. In order to achieve clinical acceptance of the system by patients a careful ergonomic design of the system was carried out. Special attention was given to donning and doffing of the splint and control of the stimulation. The Handmaster is now undergoing the process of technology transfer to the market. Several institutes have been provided with some trial versions of the device in order to gain experience with the application of the device in both tetraplegic and stroke patients.

This technical note comprises a description of the NESS Handmaster and a summary of preliminary results achieved with the device in different rehabilitation centres. The results in the literature and our own experiences will be discussed separately.

**The Handmaster**

The NESS Handmaster is a commercially available device using surface electrical stimulation to restore simple grasps. The device comprises a carbon fibre reinforced splint with built-in surface electrodes and a control unit (figure 1). The system is easy to don and doff for stroke as well as tetraplegic patients.

![Image of NESS Handmaster](image1.png)

**Figure 1. The NESS Handmaster comprising the control unit and a left-handed splint.**

**Splint**

The splint consists of a dorsal wing and a wrist bridge, made of a carbon fibre reinforced plastic body, and a distal spiral section around the hand. A single size (medium) is available at the moment with different closure sizes. The wrist bridge can also be adapted by means of wrist inserts of different thicknesses. Five electrodes are attached to the main body of the splint and the thenar pad in order to stimulate the flexor digitorum (FDS), extensor digitorum communis (EDC), flexor pollicis longus (FPL), extensor pollicis brevis (EPB) and the thenar muscle group.

**Control Unit**

The splint is attached to the control unit by means of a thin flexible cable. The control unit houses an electronic circuit board, including a preprogrammed microchip. The control unit is responsible for relaying commands from push button activation to the electrodes. The trigger button, on the control unit as well as on the ulnar side of the splint, starts the stimulation program.

The "mode" button allows the user to select one of the preprogrammed patterns of muscle activation. The modes will be discussed later in this section. The stimulation intensity can be adjusted by means of an increase/decrease button. The unit uses a 18 Hz or a 36 Hz stimulation frequency during functional and exercise modes. The stimulation adjustment button allows the user to adjust the duration of the pulse burst. The clinical panel on the control unit contains three potentiometers for the initial adjustment by the clinician of relative stimulation intensity (amplitude) levels for the extensors and flexors, as well as duration of the phases of stimulation between opening of the hand and either grasp or key grip. The thumb adjustment slider can be used to adjust the position of the thumb during gripping. When the slider is in the up position, the main part of the intensity is directed to the Flexor Pollicis Longus electrode, causing increased flexion at the interphalangeal joint of the thumb. When the slider is in the down position, more stimulation is directed to the thenar electrode, causing opposition of the thumb to the other fingers. An intermediate position of the slider combines both motions.

**Exercise Modes and Functional Modes**

The control unit has been preprogrammed for two exercise modes and three functional modes. The exercise modes (cyclic hand open + relax or cyclic hand open + grasp) are used for muscle strengthening as well as for reduction of spasticity in CVA patients.

The functional modes are hand open, hand grasp and key-grip (figures 2 and 3). Both grasp and key-grip are preceded by stimulation of hand open in order to pick up objects. The delay time between initiation of hand open and subsequent grasp or key-grip can be adjusted.

![Image of tetraplegic patient](image2.png)

**Figure 2. A tetraplegic patient picking up a glass of water by means of the grasp grip.**
Fitting and Training

Fitting of the device requires the use of a clinical unit in order to find the motor points of the muscles. This clinical unit is the basic frame of the Handmaster splint itself (figure 4). The thenar electrode and flexor pollicis longus electrode remain permanently in place. The wing and tail of the clinical unit splint consist of a frame forming the shapes of the wing and tail, and leaving 'window-like' spaces to allow visualization of the optimal stimulation points.

The three detachable electrodes (EDC, EPB and FDS) are each connected by a wire to designated sockets. The electrodes are each fixed onto a flexible broad band of plastic designed to be maneuvered under the frame of the wing and tail. The place of the electrode with respect to the splint can be marked if the muscle contraction is satisfactory. This definitive electrode position can be transferred from the clinical unit to the Handmaster splint.

Training of tetraplegic patients with the device comprises exercise (muscle strengthening) followed by functional training. The exercise protocol gradually increases from 20 minutes of exercise twice a day, to 50 minutes of exercise twice a day using the exercise mode. It is recommended to use the exercise protocol for at least 2 weeks. The stimulation intensity should be specified. Initially, there may be a low tolerance for electrical stimulation which generally improves with use. Fatigue and spasticity of electrically stimulated muscles may cause problems, but these can be reduced by conditioning the muscles with built-in therapeutic FES programs prior to using the system to perform activities of daily living. Functional training under supervision of either an occupational or physical therapist may start after two weeks of exercise training.

Preliminary results

Tetraplegic patients

Only three small reports have been published on results achieved in tetraplegic patients. Aito et al. included 14 patients in a follow-up study and evaluated the outcome by means of an Activities of Daily Living (ADL) scale and the Frenchay Hand Function test. They concluded that the device has given interesting results and is very well accepted by patients. Florence concluded that of all C5 tetraplegics approximately 20% is suitable for the Handmaster and that another 40% may achieve good results after correction of contractures. The Handmaster is a cost-effective way of providing cylindrical and key pinch grasp to suitable candidates. Up to now, five C5 tetraplegic patients were fitted in our centre with the Handmaster. All patients were able to don and doff the device independently. Two patients found the Handmaster helpful while performing ADL, such as drinking coffee, brushing teeth and other simple ADL tasks using cylindrical and key pinch grasps. Additional evaluation of the Handmaster in tetraplegic patients is ongoing.

Stroke patients

Over 100 hemiplegic patients have been supplied with a Handmaster by the manufacturer in Israel. Only a few case reports have been presented. The device is only supplied to patients with a neurologically stable level. Thus far, it could not be shown that patients with acute lesions benefit from the device compared to a control group without Handmaster treatment.

In chronic stroke patients, an immediate release of spasticity generally occurs in the upper extremity during the treatment period and for several hours post-treatment. Other effects have been reported, including improved range of voluntary motion and improved control of voluntary motion.

Three stroke patients were fitted with a Handmaster at our rehabilitation centre. All patients noticed a decrease in spasticity immediately after stimulation. This reduction was present for at least two hours after training, but most patients also noticed a reduction of spasticity over a longer period of time.

Discussion

Although only a limited number of case studies is avail-
able in order to determine treatment efficacy, we conclude that the Handmaster may be a promising aid for carefully selected tetraplegic patients. The results achieved in two of our patients were promising and the patients were satisfied with the results. Selection criteria, mentioned by the manufacturer are C5 tetraplegia, dorsal flexion of wrist less than force 3, sufficient control of shoulder movements and excitability of muscles in the forearm. We expect that most benefits may be achieved if patients are provided with a Handmaster shortly after their injury, since the use of the device may enhance their rehabilitation process. Tetraplegics who have been discharged from the rehabilitation centre have developed specific tricks in their home situation which prevents a suitable evaluation of the Handmaster.

Reduction of spasticity in chronic stroke patients by means of electrical stimulation has been reported previously. The efficacy of electrical stimulation to reduce spasticity has been recently shown in a meta-analysis. Moreover, a properly designed wrist orthosis may reduce spasticity as well. Since the Handmaster was designed as a tone reducing orthosis, the possibility of a treatment interaction does exist. Further evaluation of the Handmaster orthosis with and without stimulation is required.

Information regarding the NESS Handmaster can also be obtained from Roessingh Research and Development, distributor of the NESS Handmaster for the Dutch market.

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References