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Recovery within grasp?

A report on a preliminary study investigating the short and medium term effects of the SaeboFlex (Functional Tone Management System) on chronic post stroke patients with residual upper limb deficit

The SaeboFlex (FTM Arm Training Programme) is a dynamic hand orthosis which assists subjects with upper limb deficit to grasp and release. Developed in the United States, it has recently been introduced into the United Kingdom and used primarily with chronic post stroke subjects. This paper aims to present a report based on the preliminary findings from pilot research being conducted in this country.

INTRODUCTION

Upper Limb Recovery

Literature on recovery post stroke supports clinical experience of many patients not achieving good outcomes in upper limb function (Wade et al 1983, Nakayama et al 1994, Broeks et al 1999). What treatment should be offered and at what intensity is still not clear. Evidence suggests that more treatment may be beneficial in the short term (Sunderland et al 1992, Feys et al 1998, Kwakkel et al 1999) although this has not been universally found with Lincoln et al (1999) suggesting that the type/severity of patient, the type of treatment offered and the amount of enhanced therapy may all potentially influence outcome.

Both Feys et al (1998) and Parry et al (1999), analysing a sub-group from the study by Lincoln et al (1999), commented on repetition of task as a feature of their enhanced input. Outcome being influenced by repetition of a simple functional task has been reported previously (Butefisch et al 1995), although similar results were not found for complex tasks (Woldag et al 2003). If treatment is to include repetition it is important to identify what activities need to be repeated.

Evidence suggests that the central nervous system is task dependent in its organisation (Flament et al 1993, Tinazzi et al 2003) and that movement patterns vary depending on the context and type of task being completed (Wu et al 2000). For upper limb rehabilitation to be functional and task orientated it is necessary to consider what role the upper limb plays. One of the main functions of the upper limb is to place the hand to achieve complex movements giving interaction with the environment (Carr and Shepherd 2003). This action of prehension consists of two temporally linked movement components: reach and grasp (Jeannerod 1984). Without activity in the hand, the rest of the upper limb has reduced functional use.

The SaeboFlex

The SaeboFlex orthosis is sprung loaded on the extensor aspect, allowing subjects to use active flexion to grasp objects and, if able to release flexion, the springs return the hand towards a position of extension. By adjusting the springs, subjects can either be assisted maximally or can be required to recruit active extension. The aim is for subjects to generate their own activity with less reliance on therapist facilitation, to reach, grasp and release objects, with multiple repetitions over a treatment period.

From anecdotal evidence and one published abstract (Farrell et al 2003), results have indicated increased range of movement (ROM), reduced tone and increased function from using the SaeboFlex orthosis. These results were achieved in subjects who followed a treatment paradigm similar to that used in constraint induced movement therapy (CIMT) (described in a review by Taub and Wolf 1997). In this review, minimum motor criteria was suggested as important in determining success of CIMT with success reported in subjects who had a minimum of 20° wrist extension and 10° finger extension (first quartile). The evidence for subjects in lower quartiles benefiting from CIMT was felt to be less clear, with a case of treatment failure reported. Bonifer and Anderson (2003) also described a case of a subject in the third quartile (without the active range above but able to pick up a rag from a table and release it) who did not progress the functional use of their upper limb following a CIMT programme. Increased severity of impairment resulting in poorer outcome has been reported by others (Parry et al 1999, Shelton et al 2001, Hendricks et al 2002). To use the SaeboFlex to grasp and release, subjects require only small range active shoulder and elbow movement, to initiate a quarter range of active finger flexion and to have passive wrist extension to 15° with passive digit extension. Therefore, for patients who may benefit less

from current therapies, such as those in the third/forth quartile, the Saeboflex may offer them an alternative method of treatment.

Within the UK, research on the SaeboFlex has been ongoing since the end of 2003. The aim has been to investigate the short and medium term effects of the orthosis on chronic stroke subjects with severe (third/fourth quartile) upper limb deficit. Pilot data has been gathered from ten subjects pre- and post- intervention and at three months (full six months data is still work in progress).

For this paper the results are presented from two subjects in whom six month data is complete. They are not necessarily representative of the whole.

METHOD

Subjects attended a week-long clinic in response to an advertisement published in a self-help group magazine. Ethical approval was gained from the University of Hertfordshire Radiography and Physiotherapy Ethics Committee.

Intervention

Treatment consisted of subjects undertaking multiple repetitions of object grasp and release using the SaeboFlex in up to six daily sessions of 45 minutes over five days. Sessions involved subjects completing task-orientated activities of picking up and placing soft balls into or on to objects. More functionally related tasks were introduced as the subjects were able to manage with the substitution of balls with real-life objects such as fruit and water bottles. Each day, spread between the 'rest periods', subjects had one neuromuscular electrical stimulation session for 20 minutes (electrodes placed to achieve wrist and finger extension, 30Hz, five seconds on/five off) and 1-2 SaeboGlideTM sessions (a gliding sleeve/pole mechanism that facilitates glenohumeral/proximal activity).

Following completion of the weeks treatment, it was suggested to the subjects that they worked actively in the orthosis for one to two hours per day, until the three/six month follow-up.

Outcomes

Prior to treatment, screening for sensory (light touch and pin prick) and perceptual (line bisection and star cancellation) deficits were conducted. Outcome measures (upper limb range of movement (ROM), hand dynamometer, upper limb section of Motor Assessment Scale (MAS), patient set goals scored on a likert and VAS scale, grasp and release of different objects, ten metre walk) were conducted at the start and end of the week and at three and six months.

RESULTS

Mike was a 33 year old male who attended the clinic following his stroke which had occurred twelve months earlier. He presented with residual right sided weakness, increased tone (primarily distally) and associated soft tissue changes. He was independently mobile, indoor and outdoors, with a stick and lived alone. Prior to his stroke, he was right handed. His main presenting problems in his right upper limb were reduced ROM proximally, especially into glenohumeral flexion (active ROM 15°) and increased tone distally into flexion and pronation (hand held in fist posture). He had full active flexion/extension of his elbow. His main goal was to be able to open his right hand sufficiently to allow him to shake hands when greeting someone.

At three months, minimal change was recorded in the objective outcome measures, however, perceived change in subject set goals, as recorded on both the likert and VAS, had increased. In the period following the clinic week, active use of the orthosis was limited with a focus being given to both returning to work and driving.

Discussions with Mike relating to neuroplasticity increased his understanding of activity driven change. It was stressed that active work in the orthosis, rather than the orthosis alone, may result in change in function. At the six month follow-up use had increased to, on average, one hour per day. Although tonal changes remained into flexion, with associated soft tissue changes and altered joint alignment, without the splint on Mike was able to recruit active extension through thumb and fingers to allow hand opening to shake hands. Subjectively Mike rated an increase in his perceived ability to achieve his goals, however, there remained minimal change on the objective outcome measures.

The second subject, Susan, was a 52 year old female who had also had her stroke twelve months prior to the study. She presented with weakness in both the flexor and extensor components of her right wrist/hand resulting in flickers of activity in her index finger only (no other selective movement in other fingers or thumb). Proximally there was also weakness through both her shoulder girdle and elbow with reduced ROM. She was independently mobile indoor and outdoors with no aids. Her main goal was to hold an object, for example a saucepan, in her hand.

As with Mike, at the three month follow-up, other factors in Susan's life had resulted in use of the orthosis being limited. Between three and six months, however, she reported that she worked actively in the orthosis for 30 minutes, every other day. Objectively there was selective movement to allow finger/thumb opposition to each finger. Functionally, this allowed her to hold a pen and start to write. She remained with reduced range of

finger extension, if combined with wrist extension, that limited functional use of the hand for some activities and reduced glenohumeral flexion/abduction. Her MAS score had changed from 0 to 8 with increase particularly in the hand movement section.

DISCUSSION

To draw definite conclusions at this stage is not possible or appropriate although several features did become apparent through this preliminary study that will inform further work. In the group of ten subjects, many were a year plus post stroke and all had severe upper limb deficit (third/fourth quartile). They presented with many of the secondary changes seen post neurological insult, for example weakness, soft tissue shortening and learnt non-use. Although some subjects changed in their ability to grasp and release objects within the week-long clinic, these results were maintained but generally not improved at three months. On follow-up, it became apparent that time spent using the orthosis was limited for most subjects. Explanation of activity driven change given at this stage (now introduced from the start) may have impacted on subsequent outcome and, at six months, for those subjects who engaged in a programme of use of the SaeboFlex, small objective and perceived changes were recorded.

The variance in intensity of use and lack of therapist guidance were two of the main differences between the clinic week and follow-up, and therefore may be important factors influencing outcomes seen at follow-up. It is important to consider the impact of integrating an 'exercise programme' using the SaeboFlex into an already established daily routine. Upper limb impairment has been shown to be less closely related to handicap than lower limb impairment (Desrosiers et al 2003). Broeks et al (1999) showed that at four year follow-up despite subjects reporting and demonstrating continuing upper limb dysfunction, 96% scored greater than 60/100 on the Barthel Index, indicating minimal disability and adaptive recovery. The sensitivity of the Barthel Index in assessing upper limb disability has, however, been questioned (Lai et al 2002).

Many of the findings from this subject population were ascertained in discussion and in the subjective markers rather than through the impairment/disability outcome measures chosen. For further research with chronic stroke subjects changes to the outcome measures used would be made. It would be of benefit to investigate both compliance and overall quality of life. This was highlighted by some subjects returning to work and/or driving again following the intervention which were not officially assessed by the measures chosen. With still relatively few subjects having used the SaeboFlex and research being so exploratory, it remains difficult to predict what changes may occur in the populations chosen and thus what outcomes measures would most accurately reflect changes made. For this reason the measures chosen for future research will be continually reassessed.

Future research is being planned to look at the use of the orthosis with acute stroke patients with the aim of increasing the use/repetition of early hand and upper limb movement before secondary complications become established.

SUMMARY

The SaeboFlex is a dynamic hand orthosis that assists subjects with upper limb deficit to grasp and release objects. Following a week of use of, on average, four 45 minute sessions per day it was possible for subjects with severe chronic stroke to make small gains in reaching and grasping, although this was minimally reflected in the outcome measures chosen. To continue to change and overcome the secondary changes seen in the subjects, it appears that a level of use greater than that adopted by many at follow-up would be needed. Subjects in this study had all adapted their lifestyles to being one handed and although by attending the clinic showed intention to regain more activity, the guidance at the end of the clinic of use per day was achieved by few. Thus far, the subject who made the greatest functional change was the one with weakness as the primary problem. The sample, however, remains small and very diverse and thus this paper is a preliminary report.

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REFERENCES:

Bonifer N, Anderson KM (2003) *Application of constraint-induced movement therapy for an individual with severe chronic upper-extremity hemiplegia* Physical Therapy 83, 4 pp384-398.

Broeks JG, Lankhorst GL, Rumping K, Prevo AJH (1999) *The long-term outcome of arm function after stroke: results of a follow-up study* Disability and Rehabilitation 21, 8, pp357-364.

Butefisch C, Hummelshiem H, Denzler P, Mauritz KH (1995) *Repetitive training of isolated movements improves the outcome of motor rehabilitation of the centrally paretic hand* Journal of Neurological Science 130, pp59-68.

Carr J, Shepherd R (2003) *Stroke Rehabilitation* Butterworth Heinemann, Elsevier Science Ltd.

Desrosiers J, Malouin F, Bourbonnais D, Richards CL, Rochette A, Bravo G (2003) *Arm and leg impairments and disabilities after stroke rehabilitation: relation to handicap* Clinical Rehabilitation 17, pp666-673.

Farrell J, Hoffmann H, Snyder J, Giulian C (2003) *The effects of the functional tone management system (FTM) arm training program on upper extremity motor control on chronic post-stroke individuals* The Journal of Stroke and Cerebrovascular Diseases 12, 5, pp247.

Feys HM, De Weerdt WJ, Selz BE, Cox Steck GA, Spichiger R, Vereeck LE, Putman KD, Van Hoydonck GA (1998) *Effects of a therapeutic intervention for the hemiplegic upper limb in the acute phase after stroke. A single-blind, randomized, controlled multicenter trial* Stroke 29, pp785-792.

Flament D, Goldsmith P, Buckley CJ, Lemon RN (1993) *Task dependence of responses in first dorsal interosseous muscle to magnetic brain stimulation* Journal of Physiology 464, pp361-378.

Hendricks HT, van Limbeek J, Geurts AC, Zwarts MJ (2002) *Motor recovery after stroke: A systematic review of the literature* Archives of Physical Medicine and Rehabilitation 83, pp1629-1637.

Jeannerod M (1984) *The timing of natural prehension movements* Journal of Motor Behaviour 16, pp235-254.

Kwakkel G, Wagenaar RC, Twisk JWR, Lankhorst GL, Koetsier JC (1999) *Intensity of leg and arm training after primary middle cerebral artery stroke: A randomised trial* Lancet 354, pp191-196.

Lai S-M, Studenski S, Duncan PW, Perera S (2002) *Persisting consequences of stroke measured by the Stroke Impact Scale* Stroke 33, pp1840-1844.

Lincoln NB, Parry RH, Vass CD (1999) *Randomized, controlled trial to evaluate increased intensity of physiotherapy treatment of arm function after stroke* Stroke 30, pp573-579.

Nakayama H, Jorgensen HS, Raaschou HO, Olsen TS (1994) *Recovery of upper extremity function in stroke patients: The Copenhagen Stroke Study* Archives of Physical Medicine and Rehabilitation 75, pp394-398.

Parry RH, Lincoln NB, Vass CD (1999) *Effect of severity of arm impairment on response to additional physiotherapy early after stroke* Clinical Rehabilitation 13, pp187-198.

Shelton FD, Volpe BT, Reding M (2001) *Motor impairment as a predictor of functional recovery and guide to rehabilitation treatment after stroke* Neurorehabilitation and Neural Repair 15, pp229-237.

Sunderland A, Tinson DJ, Bradley EL, Hewer DF, Wade DT (1992) *Enhanced physical therapy improves recovery of arm function after stroke. A randomised controlled trial* Journal of Neurology, Neurosurgery and Psychiatry 55, pp530-535.

Taub E, Wolf SL (1997) *Constraint induced movement techniques to facilitate upper extremity use in stroke patients* Topics in Stroke Rehabilitation 3, pp38-61.

Tinazzi M, Farina S, Tamburin S, Facchini S, Fiaschi A, Restivo D, Berardelli A (2003) *Task-dependent modulation of excitatory and inhibitory functions within the human primary motor cortex* Experimental Brain Research 150, pp222-229.

Wade DT, Langton Hewer R, Wood VA, Skilbeck CE, Ismail HM (1983) *The hemiplegic arm after stroke: measurement and recovery* Journal of Neurology, Neurosurgery and Psychiatry 46, pp521-524.

Woldag H, Waldmann G, Heuschkel G, Hummelshiem H (2003) *Is the repetitive training of complex arm movements beneficial for motor recovery in stroke patients?* Clinical Rehabilitation 17, pp723-730.

Wu C, Trombly CA, Lin K, Tickle-Degen L (2000) *A kinematic study of contextual effects on reaching performance in persons with and without stroke: Influence of object availability* Archives of Physical Medicine and Rehabilitation 81, pp95-101.

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