Attempting to Improve Function and Quality of Life Using the FTM Protocol: Case Report

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ABSTRACT

Background and Purpose: The Functional Tone Management (FTM) arm training program® uses repetitive task practice, stretching, and electrical stimulation as patients with moderate upper extremity hemiparesis wear a dynamic hand orthosis to retrain grasp and release of objects. The case study quantitatively evaluates the extent to which FTM training improved function and quality of life in a patient who met criteria for which the device was intended. **Case Description:** The participant, a 44-year-old male in the chronic stage of stroke recovery with moderate right upper extremity motor impairment, was trained for 10 days over a 2-week period by a licensed clinician with extensive experience in FTM training methods. Measurements were taken over 3 baseline visits, then immediately preintervention, postintervention, and at a 3-month follow-up. The outcome measures, following the *International Classification of Functioning, Disability, and Health* (ICF) Model, included the: Fugl-Meyer assessment (FMA) (upper extremity portion), UE range of motion (ROM), Modified Ashworth scale, Wolf Motor Function Test (WMFT), and the Motor Activity Log (MAL). Health related quality of life was measured using the Stroke Impact Scale (SIS). **Outcomes:** The participant showed limited gains in upper extremity function immediately postintervention. Increases in AROM occurred in forearm supination and wrist flexion and extension, but no improvements were noted in finger ROM. A slight decrease in tone was found in forearm pronators (1 to 0) and wrist flexors (1+ to 1). WMFT values for the more affected upper extremity did not change immediately after training, but a 17% reduction in time occurred at follow-up, with improvements, most notably in the tasks of lifting a pencil and lifting a paper clip. No changes occurred in UE-FMA scores immediately following the intervention, however, a 17% improvement was measured at follow-up. A slight improvement in MAL scores was noted but not to a level of independent functional use of the impaired upper extremity. SIS scores improved in the domains of strength, communication, mobility, social participation, hand recovery, and overall physical component, while decreases were seen in the ADL/IADL, hand function, emotion, and cognitive domains. **Discussion:** The case study indicates that for this patient with chronic, moderate upper extremity impairment following stroke, a 2-week FTM training regimen resulted in modest changes occurring as a decrease in impairment, with functional improvement and improved quality of life. Further investigation of the innovative training program should be undertaken before the efficacy of its use can be ascertained amongst patients with limitations comparable to the participant.

Key Words: brain, rehabilitation, evaluation, cerebrovascular accident, motor activity, physical therapy, International Classification of Functioning, Disability, and Health

INTRODUCTION

Considerable effort has been directed toward the development and testing of innovative approaches to reduce impairments and improve functional ability in patients with stroke.[1-3] Although evidence continues to mount regarding the effectiveness of intensive repetitive practice,[4,5], techniques such as constraint-induced therapy (CIT) may not benefit all individuals with Upper Extremity (UE) hemiparesis. To date, only one case study[6] has specifically examined intensive task-oriented training for an individual with greater impairment than typically seen in patients receiving CIT (ie, 10° of wrist extension, at least 10° of metacarpophalangeal (MP) and interphalangeal (IP) extension of 2 digits and the thumb.[7,8] The intensive protocol failed to show improvement in functional use of the more affected limb.

Few treatment options are available for stroke survivors whose hand cannot be effectively incorporated into a rehabilitation regimen. The Functional Tone Management (FTM) arm training program (Saebo, Inc, Charlotte, NC http://www.saebo.com/home.html) promises a treatment alternative for such patients with moderate to severe upper extremity (UE) impairment. The program combines the use of a dynamic hand orthosis, called the SaeboFlex™ (Figure.1) with a high repetition, task specific training program for the hand and arm (www.saebo.com). The SaeboFlex™ is specifically designed to position a nonfunctional hand at optimal biomechanical advantage so that grasp and release activities are possible. Positioning is accomplished by means of a fixed wrist extension angle and a variable strength finger and thumb spring system that maintains digit extension. In a process called 'agonist retraining,' the wearer uses the resistance of the finger and thumb spring system to voluntarily activate and relax the finger flexors, resulting in an assisted, functional grasp and release. Many repetitions of grasp and release are then performed in an effort to improve the volitional motor control of the finger flexors.[9]

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The FTM arm training program, developed in 2001 evolved from research documenting that insufficient agonist recruitment (ie, those muscles primarily responsible for movement about a joint) contributes significantly to movement limitations in the neurologically impaired arm[10,11] as well as evidence that UE function can be improved through numerous repetitions, task training programs for motor relearning.[4,12] The SaeboFlex™ incorporates functional use of the hand into the FTM training approach, thus providing an alternative to therapies based on a proximal to distal recovery paradigm.[13] The FTM arm training program includes (1) highly repetitive SaeboFlex -assisted grasp and release combined with target driven arm movement patterns designed to address the patient's movement impairments, (2) SaeboGlide™ that facilitates active and active-assisted range of motion exercises for unilateral shoulder and elbow movement, and (3) functional electrical stimulation (FES) to improve movement in wrist and finger extensors. According to the company, these elements are presumed to incorporate specific aspects of evidence based practice in neurological rehabilitation. Specifically, intensive, high repetition arm training has been shown to increase cortical activation in areas of the somatosensory and pre-motor cortex.[14] The activation has been correlated with improved UE motor function.[15,16] Also, repetitive, passive-active movement training has been shown to improve upper limb motor function and ability in patients with chronic stroke with all degrees of UE paresis.[17] Finally, the use of electrical stimulation has also been shown to improve voluntary motor control of the hemiplegic wrist and forearm.[18,19] The expectation of Saebo Inc. is that the orthosis will allow patients to immediately begin using their hand to perform functional exercises; thus allowing unilateral intensive arm training to occur.

According to the Saebo Company website, the FTM arm training program is currently being used by over 450 therapists across the United States and in 4 countries, yet there is little evidence supporting the effectiveness. In a preliminary study[20] involving 10 patients with severe chronic stroke, small gains were seen in reaching and grasping, although these improvements were "minimally reflected in the outcome measures chosen" (pg. 14). One published abstract,[21] evaluating 13 chronic stroke survivors, indicated that increased range of motion, reduced tone and increased function occurred using the SaeboFlex™ orthosis. Neither of these studies used blind evaluators, or disability and health-related quality of life (HRQOL) outcome measures in their assessment of the technique. Consequently, there is a need to objectively assess the value of the FTM program in assisting patients with upper extremity impairment following stroke.

We describe a 2-week FTM UE training program comprised of repetitive task practice using the Saebo customized dynamic wrist orthosis, functional electrical stimulation (FES), and stretching with anticipation that the program may lead to increased UE range of motion, improved function, and improved quality of life in a patient with moderate UE impairment following stroke. Unique to the case study, we use an unbiased evaluator naive to the intervention to administer an array of outcome measures that follow the *International Classification of Functioning, Disability and Health* [22](ICF) Model of Functioning and Disability.

CASE DESCRIPTION

History

The participant was a 44-year-old right handed male diagnosed with a left middle cerebral artery (MCA) infarct one year earlier with consequent moderate right hemiparesis (UE impairment greater than lower extremity) and expressive aphasia. His magnetic resonance (MR) images revealed a large (>5.0 cm) ischemic infarct involving predominantly the left insula, extending slightly into the external capsule, caudate, and external medullary lamina of globus pallidus. Although his past medical history included a myocardial infarction and coronary bypass surgery 10 years prior to his stroke he had no hospitalization or major medical treatment until the initial post-stroke hospitalization. He underwent 7 weeks of inpatient rehabilitation, followed by intensive outpatient treatment for aphasia and outpatient occupational and physical therapy. At the conclusion of his therapy (3 months prior to entering the study), he was independent in all activities of daily living and community ambulation without an assistive device. He was taking the following medications: Coumadin®, Prinivil® and Zocor®, but was not receiving any pharmacologic treatment for spasticity. He had no other recent cardiac related complications or complaints and presented with adequate endurance to ambulate community distances and drive independently.

Screening and Rationale for Participant Selection

The participant was selected with the intent to gain knowledge about the utility of the device in a comprehensively documented manner while using the protocol established by the company. There was no expectation regarding the resulting magnitude of improvement. The local ethics committee approved the experimental procedures. Information concerning the participant's hospitalization, inpatient rehabilitation, and outpatient therapy was obtained in compliance with the Health Information Portability and Accountability Act (HIPPA). Prior to receiving the intervention, details of the study were explained and signed informed consent was obtained. General criteria for use of the SaeboFlex™ orthosis included: (1) at least 10° of active range of motion (AROM) of shoulder flexion/abduction, 10° of elbow flexion/extension and at least 20° of volitional finger flexion when the hand was positioned with wrist and fingers extended. He scored 24 or greater on the Folstein Mini-Mental State Examination;[23] communicated accurately for training and evaluation procedures; was independent in transfers, self-care needs, and standing for 2 minutes without an assistive device and; was not receiving other rehabilitation therapy. He exhibited a predominant flexor synergy in his right UE through approximately 120° of range against gravity at the shoulder and elbow, 20° against gravity at the wrist, and no finger extension. Light touch and proprioception were intact.

The FTM orthosis was designed for patients without volitional wrist/finger extension, so we specifically did not choose a participant with full AROM of the wrist and finger extensors. The participant was also chosen for this case study because he was extremely motivated, had reliable family support, no recent medical complications, and had UE active range of motion that fit within the typical characteristics of patients who are considered appropriate for the FTM protocol (ie, a patient whose movement

characteristics did not qualify for CIT). It was felt that his available active movement in the shoulder, elbow, and wrist were good indicators of his potential ability to incorporate his arm in a task-oriented intensive repetitive practice protocol, but his limited finger active range of motion prevented independent use of the hand in functional tasks. Prior to the intervention, he expressed specific functional goals of being able to eat, write, and play drums with his more affected limb. Unexpectedly, 2 months following the intervention, he underwent cardiac pacemaker implant surgery. The potential effect of the surgery is addressed further in the discussion.

Examination

All examinations were conducted by the same clinician, not associated with Saebo Inc. at a site independent from the Saebo training site. The study design was intended to reduce the likelihood of inherent bias or potential conflict of interest between evaluator and interventionalist.

Tests and measures

The collection of outcome measures was assembled to evaluate potential full-spectrum (body structure/function, activities, and participation) effects of the FTM UE intervention, following the *International Classification of Functioning, Disability and Health* [22](ICF) Model of Functioning and Disability. Consequently, we believed that the collection would address not only the functionally-based goals of the manufacturer to improve hand grasp and release, but also would consider the broader effect of the intervention on disability and social participation.

Structure/Function: UE impairment and function were measured using the Fugl-Meyer UE assessment evaluation (FMA),[24,25] physical assessment evaluations of UE active/passive range of motion, the modified Ashworth scale for muscle tone,[26] and the Wolf Motor Function Test (WMFT).[27,28] Excellent intra-rater, inter-rater reliability[25,29] and construct validity[30,31] have been demonstrated for the FMA. The WMFT has been shown to have good clinometric properties in the stroke population[27,28] and correlates well with the FMA. The inter-rater and intra-rater reliability of the modified Ashworth scale in assessing spasticity remains uncertain.[32] Bakheit et al[33] suggest that the scale does not reliably distinguish between the multiple components of hypertonia (spasticity, thixotropy, and changes in the viscoelastic properties of muscles). Important to note, the scale measures passive resistance to movement and does not give information about movement restrictions during active functional use of the limb.

Activities and Participation: The Motor Activity Log (MAL)[34,35] a self-report interview, was used to measure UE disability in 30 activities of daily living. High construct validity and reliability has been demonstrated using a 14-item version of the instrument in chronic stroke patients[35] and a 28-item version in subacute stroke patients.[35]

HRQOL was measured using the Stroke Impact Scale (SIS) Version 3.0 (Version 3.0; Rehabilitation Outcomes Center, Gainesville, Fla).[36] Reliability and validity have been established in the stroke population, and the SIS is sensitive to change in function across domains.[36]

The FTM arm training protocol is an intense intervention; consequently, self-report pain and fatigue levels were monitored daily throughout the course of training by therapists at the training facility. Pain and fatigue levels were evaluated at the end of each afternoon session using a Likert scale of 0-10 (0 = no pain/not at all fatigued to 10 = unbearable pain/absolutely exhausted).

Six evaluations occurred over 7 months, with the evaluator naive to the specific date and time of intervention delivery. Three baseline (BSL) measurements were taken, BSL1, BSL2 (2 weeks after BSL1), and BSL3 (1 month after BSL1). Approximately 1 month later, the participant underwent an additional set of evaluations, immediately prior to intervention (PreT), immediately after the 2-week intervention (PostT), and 3 months later, (Post 3T). The final evaluation, Post 3T, occurred 7 months after initial assessment, BSL1 (Table 1). Due to the time-frame of the questions, the SIS questionnaire was given only at the following evaluation times: BSL 1, BSL3, PreT, and Post3T. The evaluator had been previously standardized on the WMFT and MAL testing procedures through her involvement in the EXCITE national clinical trial. [38]

Intervention

The FTM arm training program applied by occupational therapists at the Saebo, Inc. training facility occurred 6 hours a day, 5 days a week for 2 consecutive weeks. The intensive protocol was based on the CI therapy protocol standards.[37,38] The duration of arm training sessions with the SaeboFlex™ was based on recommended wearing limits for the SaeboFlex™ orthosis to prevent possible skin or soft tissue irritation and clinical experience suggesting that most patients are fatigued to the point of decreased performance beyond that duration. The 10 day intervention consisted of the following daily schedule: (1) four 45 minute sessions of intensive repetitive practice using a dynamic wrist orthosis to assist in wrist and finger extension during functional tasks; (2) two 20 minute sessions of FES focusing on wrist and finger extensor musculature and (3) two 25 minute sessions of UE stretching.

Specific procedural intervention

The dynamic orthosis consists of a wrap around forearm support attached to a dorsal hand platform that supports 2 spring attachments (Figure 1). Individual finger sleeves are attached to springs by high tensile polymer line to provide assistance with finger extension. Spring tensile strength was adjusted for the appropriate amount of finger extension assistance needed to initiate opening of the hand. Each 45 minute repetitive practice session included one or more of the 4 following components: (1) individual muscle group strengthening (ie, biceps during task of bringing hand to mouth); (2) multiple muscle group strengthening (ie, pectoralis major/triceps during a complex reach and retrieve task); and (3) hand exercises with the orthosis and (4) hand exercises without orthosis. The first of these daily four 45 minute repetitive practice sessions focused on unidirectional reaching tasks, while the remaining 3 sessions were primarily multidirectional in nature. A unidirectional task refers simply to reaching and grasping a ball in a container, then transport and release of the ball into an adjacent container. A multidirectional task increased the demand of the reach and/or transport phase of the activity by directing the patient to reach through strategically placed hoops before and after grasping the ball to increase the complexity

Figure 1. The Saeboflex® dynamic UE orthosis worn by the patient during training. The photograph is reprinted with permission from SAEBO, Inc.

of shoulder movements. Typically the patient stood during these repetitive practice sessions using the orthosis.

Each functional task involved progressively challenging grasp and release activities, modified to elicit increased movement at certain joints; with consideration for movement limitations of the participant. Frequent feedback regarding knowledge of performance was given throughout each activity, including verbal instruction to facilitate grasp and release. Active problem solving was facilitated through alteration of the practice environment to increase task complexity.

Unilateral SaeboGlide™ exercises for the shoulder and elbow (a gliding sleeve/pole mechanism that facilitates glenohumeral proximal activity) were included to provide assisted AROM exercises and stretching to maximize the intensity of arm training exercise.[3,39] Between intervals of arm training with the SaeboFlex, FES was applied to the wrist and finger extensors. The wrist was positioned in flexion[40] to allow for decreased resistance from the finger flexors and then wrist and finger extension was elicited using the BMR NeuroTech♦ electrical stimulation unit (BMR NeuroTech, Inc. Phoenix, Ariz). Parameters were set for single channel bi-phasic current delivered at intensity sufficient to produce muscle tetany. Current frequency was 35Hz, pulse width 275 μs and duration set at 8 seconds on 16 seconds off.

Following completion of the 2 weeks of treatment, the participant was instructed to work actively in the orthosis for 45 minutes per day, stretch with the Unilateral SaeboGlide™ daily for 20 minutes and use FES daily for 20 minutes. The patients self report home diary indicated that he was compliant with these guidelines 5 days a week for approximately 9 weeks, at which time he entered the hospital for cardiac pacemaker implant surgery. After the hospitalization, he reported that he did not use the FTM or perform other aspects of the home exercise program for the remainder of the follow-up period.

Outcomes

Values for changes in physical measures are represented in Table 1 across baseline visits and from PreT to Post 3T.

FMA motor and coordination score improved a total of 17% from BSL 1 to Post 3T, with 9.5% of the change occurring across the baseline period, no change occurring from PreT to PostT and 6.5% of the change occurring from PreT to Post 3T. Range of motion values were variable across evaluations, without clear patterns of improvement. With the exception of the active forearm supination and wrist extension, none of the PROM or AROM gains after intervention were greater than the peak values observed for the same motions measured during baseline visits. Shoulder flexion and abduction were maintained at full range during the intervention, but decreased by over 30% at follow-up. Wrist flexion and forearm supination showed increases immediately after training and at follow-up. Reduced tone was seen immediately after training in forearm pronator muscles (eg, scores went from 1 to 0), but the decrease was not evident at the 3-month follow-up. The slight tone decrease observed in wrist flexors (score of 1+ to 1) was maintained at follow-up. No change in the Modified Ashworth score was noted in elbow flexor musculature.

The mean scores for the WMFT timed items (15 of 17 tasks) were calculated for each visit (Figure 2). Tasks that could not be completed within 120 seconds were coded as 121 and calculated as such in the overall mean score. Little change occurred for the more affected UE over baseline evaluations (Bsl 1= 52.43s; Bsl 2=53.16s and Bsl 3 = 48.71s). There were no changes observed immediately following training (PreT = 47.55s; PostT=47.65s), but there was a decrease in average movement time at the 3 month follow-up after training (Post 3T = 39.34s). Over the entire 7 month evaluation period, a 25% decrease occurred from Bsl 1 to Post 3T, with 17% of that change occurring from post 1T to 3T. A detailed examination of individual tasks within the WMFT showed large improvements (ie, decreased movement times) in 'lift pencil' and 'lift paper clip' tasks that persisted to the 3-month follow-up. The participant never successfully completed the following fine motor tasks: lift a can, stack 3 checkers, flip 3 cards, or turn a key in a lock.

The amount of use scores (AS) on the MAL were constant across baseline visits and increased slightly after training (Figure 3). AS

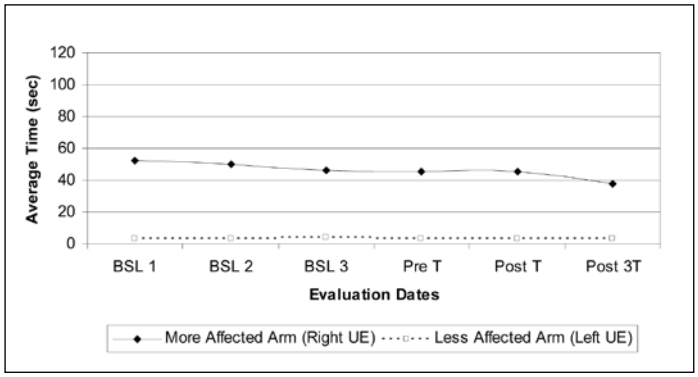

Figure 2. Changes in mean WMFT times (ordinate) across visits (abscissa). The less affected UE corresponds to the stippled line, while the more affected arm corresponds to solid line. Refer to narrative for a complete description of visits.

Table 1. Physical Measures Pre- and Post- FTM arm training intervention. Presented are active and passive range of motion measurements, modified Ashworth scores, Fugl-Meyer UE motor assessment scores, and Stroke Impact Scale scores across visits. Scores in parentheses indicate either maximum attainable score for each part of the FMA or minimum and maximum scores for the SIS.

STRUCTURE/FUNCTION						
Range of Motion Tasks-for the more affected arm	**BSL1**	**BSL2**	**BSL3**	**PreT**	**PostT**	**Post3T**
PROM (degrees)						
Shoulder Int. Rot.	20	70	70	40	70	50
Wrist Extension	70	70	70	45	50	70
AROM (degrees)						
Hand MCP Extension 5th	0	0	0	0	0	10
Wrist Flexion	0	0	90	30	45	50
Wrist Extension	38	35	25	40	40	45
Forearm Supination	0	30	0	10	20	40
Shoulder Flexion	115	120	180	180	180	115
Shoulder Abduction	90	85	180	180	180	95
Modified Ashworth Scale of Muscle Tone (0-4)						
Elbow Flexors	1+	1+	1+	1+	1+	1+
Forearm Pronators	1+	1+	1	1	0	1
Wrist Flexors	1+	1+	1	1+	1	1
Fugl-Meyer						
Motor and Coordination (0-66)	42	41	46	46	46	49
ACTIVITIES/PARTICIPATION						
Stroke Impact Scale (0-100)						
Subscale 1: Strength	31.25	**	31.25	43.75	**	62.5
a. Arm strength "How would your rate strength of your arm?" (0-5)	2	**	2	3	**	3
b. Grip strength "How would your rate strength of your grip?" (0-5)	2	**	2	3	**	4
Subscale 2: Memory and Thinking	75	**	78.57	75	**	67.86
Subscale 3: Emotion	41.67	**	61.11	52.78	**	44.44
Subscale 4: Communication	32.14	**	42.86	50	**	64.29
Subscale 5: ADL/IADL	50	**	52.50	77.50	**	67.50
Subscale 6: Mobility	55.56	**	61.11	63.89	**	66.67
Subscale 7: Hand function	5	**	5	10	**	5
Subscale 8: Social Participation	12.5	**	21.88	28.16	**	37.5
Overall physical component score (subscales 1, 5, 6, 7 combined)	35.45		37.47	48.78		50.42
Hand recovery from stroke (percentage of recovery 0-100)	30	**	30	15	**	40

** SIS data were not recorded at all evaluation sessions due to the time dependence of the interview.

scores did not go above one, demonstrating the person used their more affected UE only occasionally or very rarely. A slight increase was noted in the How Well (HW) scores, from a 0.98 (note: score of 1 = the arm was used during the activity but was not helpful or very poorly) at Pre1T to a 1.11 at PostT and continued to an average of slightly above 2 at follow-up; indicating the more affected arm was of some use during activities but needed some help from the stronger arm or was moved very slowly or with difficulty.

The largest increases after FTM training in HRQOL (from PreT to Post 3T) were seen in the domains of strength (combined upper and lower extremity 43% change), communication (29% change), social participation (33% change), and hand recovery from stroke (33% change) (SIS, Table 1). The highest score in the hand function domain was still very minimal (10 out of 100), and decreased after training (5 out of 100). Emotion, memory and thinking, and ADL/IADL scores all decreased after training.

Self-report pain and fatigue level scores ranged from 3.5 to 9 (10 representing "absolutely exhausted") across the 2-week intervention, with an average fatigue level of 7. The first 2 intervention days fatigue levels were rated at less than moderate, but from day 3 through day 10 the patients fatigue level ranged from 7 to 9. There was no mention of arm pain at any time point during the training. Our volunteer did complain of back pain, especially during the first 4 days of the intervention (average 6.5 – moderate pain), but during the second week of the intervention he had no complaints of pain.

DISCUSSION

To our knowledge this case is the first evaluation of the FTM arm training program utilizing the Saeboflex® with a spectrum of outcomes measures that span structure/function to participation in activities of daily living. The results indicate that for a patient with chronic, moderate upper extremity impairment following stroke, 2 weeks of FTM training regimen resulted in modest changes occurring as a decrease in impairment, with functional improvement and improved HRQOL. Changes in impairment in this individual appear to be somewhat greater than those seen in a previous report[20] showing minimal improvement and limited functional use of the hand in 2 chronic stroke survivors at 3 months. One must consider that changes in the current study may have become evident only because of the application of an array of measures across multiple domains. The potential for change is particularly relevant for this participant because the extent of his UE impairment was such that no other evidence-based treatment options were available.

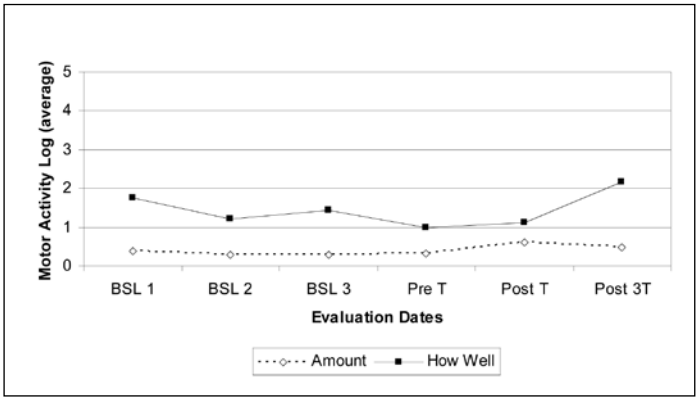

Figure 3. Changes in MAL scores (ordinate) for the more affected arm for each visit (abscissa). The amount score (Amount) corresponds to the stippled line, while the how well (How Well) corresponds to the solid line.

Current recommendations from the Heart and Stroke Foundation of Ontario 2001 Consensus Panel [4] for clients with mild to moderate UE motor impairments (who demonstrate high motivation and potential for functional gains) include the use of repetitive and intense practice of novel tasks. These tasks should be designed to challenge the stroke survivor, facilitating the progression of motor skills acquisition to use the more-involved upper limb during functional activities. Our patient exhibited potential for functional gains, as he was a highly motivated, cognitively alert, middle-aged man, living and driving independently in the community. The FTM arm training paradigm, composed of a combination of evidence-based therapeutic approaches including repetitive and intense use of novel tasks with elements of motor learning, may have resulted in only modest improvements in impairments, function, and QOL in our stroke survivor because of initial level of UE impairment.

Improving limb function among stroke survivors with moderately to severely impaired upper extremities continues to be a challenge to clinicians. In a study by Kwakkel and colleagues,[41] 62% of individuals with a MCA stroke failed to achieve some dexterity at 6 months, indicating that the prognosis for functional outcome in this patient group is poor. Other studies have also reported poorer outcomes associated with increased severity of impairment.[42-44] Although the participant in this case study could be described as moderately impaired at baseline based upon his initial Fugl-Meyer Assessment score, he did not have active finger extension and would not have met the minimal motor criteria for a CI therapy intervention. The impaired ability of the individual to initiate finger extension may lend support for a key factor in the prognosis of functional hand recovery. For example, Fritz, et al showed that finger extension was the only significant predictor of outcomes using the WMFT (mean score from timed tasks only) in patients receiving CI therapy.[45] Indeed, the initial level of UE impairment after stroke appears to be a *moderating variable*[46] in recovery and the ability to initiate distal active movement of the UE is emerging as a potent indicator for potential reacquisition of meaningful function. The minimal movement criteria (the ability to initiate wrist extension and finger extension of at least 2 digits) for CI therapy was developed from a series of electromyography (EMG) biofeedback studies in stroke patients performed by Wolf and Binder-Macleod[8] that indicated voluntary movements of finger and wrist extension were a better predictor of future acquisition of independent limb use than was the ability to reduce the hyperactive responses from stretching UE flexor muscle groups.[47] The number of patients that actually achieve this level of functional recovery in the upper limb is estimated to be approximately 28% to 32% of the stroke population.[48]

While lack of finger and wrist extension may rightly be considered an important prognostic indicator in stroke recovery, it is important to recognize that traditional therapeutic approaches designed to promote recovery have struggled to develop methods that allow

patients with moderate to severely impaired UEs to successfully practice highly repetitive grasp and release activities. Importantly, one of the signature elements of the FTM treatment paradigm is the dynamic orthosis that is used to assist finger extension. The device allows the impaired hand to engage in functional activities during training and is expected to facilitate use of the limb during functional tasks in an effort to carry-over into 'real world' activities of daily living. Unfortunately, the patient did not report subjective improvements in his goals of eating, writing, or playing the drums. Despite an increase in functional activities reported by MAL scores immediately after training and at follow-up, the actual changes in movement were not manifest as independent use of the limb in functional tasks. These outcomes are similar to the minimal MAL changes that occurred in a patient with comparable motor deficits who received 3 weeks of CI therapy.[6] The only other brief mention of a patient without active finger extension receiving a similar intensive therapy was Taub and colleagues (1999) who describe a client that had 'almost no ability to move his fingers' (pg. 245) as a 'treatment failure.'[49]

While the patient simply may not have had the residual neural substrate to improve despite a baseline FMA score of 42, other possible factors affecting these results should be considered. Active assistance with grasp and release (ie, finger extension) using the dynamic orthosis may not be an effective means of fostering engagement of the forearm and wrist musculature in the functional training activities that do not use or require an orthosis. Additionally, the activities associated with the repetitive task practice involved manipulation of various sized foam balls (versus functional-used based objects such as eating or writing utensils), which may not have offered an adequate functional task practice environment to enhance motor learning.

The patient's greatest improvements in HRQOL were manifest in the domains of strength, communication, mobility, social participation, and perceived percentage hand recovery of the SIS. Although percentage of hand recovery improved, in contrast the highest score in the hand function domain was still very minimal (10 out of 100), and decreased after training (5 out of 100). This apparent improvement may be a reflection of the context of the questions in each section. Although the participant felt his hand had recovered 40% since he had his stroke, this percentage of recovery was still not adequate to perform the primarily fine motor activities described in the hand function domain.

Emotion, memory and thinking, and ADL/IADL scores all decreased by the 3 month follow-up, domains that perhaps were more sensitive to conditions associated with his cardiac surgery at 2 months post training. A comprehensive instrument such as the SIS is therefore helpful in illuminating the complexity of the participant's stroke recovery process.

Strengths and Limitation of the Case

A major strength of the case study was the use of multiple outcome measures across domains of the ICF model to detect change in a broad array of areas. These measurements were applied by a standardized evaluator naive to the participant's interventional status and not associated with the individuals performing the intervention, therefore reducing the likelihood of inherent bias or potential conflicts of interest. Multiple baseline evaluations allowed a comparison of the magnitude of change occurring over time without intervention to change occurring as a result of the intervention. The comparison of change values across measurements showed the inherent variability of performance over time in a moderately impaired stroke survivor while clarifying the actual improvements that resulted from the intervention.

An important potential modifier that may have limited the individual's long term improvement was the fact that he underwent cardiac pacemaker implant surgery 2 months following the 2-week intensive training. While the surgery did not impair the patient's ability to move his arms (ie, pacemaker was implanted subcutaneously inferior to the right clavicle), he was limited in his more affected arm use for several weeks postsurgery. Although the break in his home exercise program may have impaired his progress, the patient stated that he continued to use his more affected limb as much as possible. One must also consider the overall affect of the participant's co-morbidities on the outcomes. His history of heart disease with a recent pacemaker implant indicates that he may not have had the cardiovascular endurance to achieve maximal gains offered by the intensive 2 week training paradigm. Indeed, lower HRQOL scores in the physical domain of the SIS are correlated with more co-morbidities in stroke survivors.[50] Considering the potentially profound effect of these confounding factors, the participant nonetheless continued a trend toward improvement in the subjective reports of strength, mobility, and overall physical domains of the SIS and in the "How well" portion of the MAL at the 3 month follow-up.

The results from the study raise many questions. For instance, in those domains in which functional improvement occurred; what aspect of the training paradigm was responsible for the functional improvement? What are the distinct effects of the stretching, FES, dynamic orthosis, and goal directed task practice? Who is appropriate for FTM training? Would a patient with more distal movement or less flexor tone gain greater benefit from the intervention? Can patients with flaccid paresis and increased flexor tone show improvements? What are the minimum neural substrates required to achieve clinically meaningful improvements in UE function through intense therapeutic intervention? Only well-designed studies with a large and diverse number of patients can address each of these questions adequately.

CONCLUSION

The case is one of the first to describe the use of the FTM arm training paradigm in a patient with chronic stroke. These outcomes suggest modest improvements in impairment, function, and HRQOL are possible with the FTM arm training program. In light of the intensity, cost and time demands of the intervention, the further clinical use of the paradigm would require clinical support from additional investigations. Our results demonstrate the need for a systematic series of studies to objectively assess the value of the FTM arm training program in assisting patients with moderate to severe UE impairment following stroke to improve both their impairment status and functional potential.

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