Evidence for

KMI
Active Repetitive Motion Therapy

for increasing the Function and
Independence of
Stroke Patients

Preface

This report highlights the rapidly advancing research involving *Neuroplasticity* and the first clinical study of Active Repetitive Motion (ARM)™ therapy that is based on this research. The scientific community's emerging understanding of brain plasticity, i.e., the brain's ability to be rewired, is providing opportunities for new therapeutic approaches that restore lost function resulting from many neurological diseases. The KMI study demonstrates the feasibility that the innovative technology involved in ARM therapy increases functional independence of stroke patients and provides cost-effective treatment.

Introduction

Neuroplasticity refers to the ability of neurons to make new connections within the brain. Research and clinical evidence of neuroplasticity in the developing brain of children and adolescents is well accepted by the research community. Although experiments throughout the 1900's showed the adult brain to be plastic (1-4), the concept that the mature brain does not have the ability to change was the tenet of neuroscience (5). However, a growing number of research reports in the later half of the 20th century by numerous investigators have shown that the mature brain is a dynamic structure that has the ability to rewire itself (6-10). A requirement of this remodeling is attention by the patient. "Plastic changes in brain representations are generated only when behaviors are specifically attended"(11). These research results are beginning to be translated into clinical applications. Treatments for focal hand dystonia, dyslexia, and stroke have emerged.

Stroke is the leading cause of adult disability in the United States. Each year 590,000 people in the United States survive a stroke. There are 4.5 million living stroke survivors (12). The annual cost of stroke related care is $51 billion; $17 billion of this is in direct medical costs. Restoration of function for the stroke patient leads to significant reduction in the cost of care (13). Constraint-Induced (CI) Movement Therapy is a treatment born out of research on brain plasticity. Numerous studies have validated the effectiveness of this approach that improves upper extremity function of stroke patients (14). Although CI therapy is effective for many stroke patients, insurers or Medicare does not cover it because of the expense of this labor-intensive method (15,16). In addition, a questionnaire to patients and therapists indicated a majority were concerned about the restrictive intense treatment schedule (17).

Following a stroke, the initial treatment is to stabilize the patient. This usually occurs in an emergency room and critical care unit. Following stabilization, the patient is typically transferred to a hospital rehab unit. The time in a rehab unit has been significantly reduced in recent years by the pressures of health care reimbursement. Currently the stay is 14 days. Because of the reduced time, very little therapy is aimed at restoring function of affected limbs. Patient activities involve learning toileting, transfers and how to perform compensatory functions with the unaffected limb. This reinforces **learned non-use** and further hinders restoration of function of the affected limb.

The degree of motor disability existing in many neurological disorders exceeds the underlying organic pathology. This has been attributed to "learned non-use" (18,19). Spontaneous recovery of *potential* function often occurs after a significant neurological injury. This occurs over a period of months. However, the suppression of use learned in the acute phase remains. Overcoming learned non-use and obtaining full motion potential is one of the main goals of repetitive task practice therapy.

Transcranial Magnetic Stimulation (TMS), neuroelectric source imaging (EEG) and magnetic source imaging (MEG) studies in humans and intracortical microstimulation (ICMS) studies in animals have shown cortical reorganization associated with massed-practice therapy (20-28). Focal TMS was used to map the areas of the brain that control arm movement in chronic upper limb hemiparesis patients before and after repetitive task practice therapy (29). These measurements demonstrate that repetitive task practice therapy result in a use-dependent increase in cortical reorganization. Thus, there are two goals of repetitive task practice therapy, [1] to realize the full potential for movement by negating learned non-use, and [2] to increase the potential for motion by forming new neurological pathways.

The KMI Mentor device provides performance reinforcement, goal setting, clinician reports, and patient feedback. Thus it is an essential part of Active Repetitive Motion (ARM) therapy that provides clinicians with an effective, cost reimbursable, patient-friendly therapy that increases repetitions and encourages patient participation.

Clinical Study

A pilot clinical study was performed that addressed three main questions:

- Does the Mentor work in a clinical setting?
- Is ARM therapy effective in restoring function to stroke patients?
- Is the use of the Mentor with its associated ARM therapy cost effective?

In addition this pilot study provided perspectives on treatment protocol strategies.

The patient **inclusion criteria** were: the patients had to be medically stable, over 18 years of age, have intact cognition, and have at least minimal hand movement. Six of the eight patients had less motion than the minimum requirements necessary to be eligible for CI therapy which are 20° of wrist extension and at least 10° of extension at two digits in addition to the first digit of the affected hand.

The **study protocol** consisted of the patient coming to the clinic five days a week for three weeks for 3 hours a day. The Mentor was used for 1.5 hours each day and 1.5 hours were spent on repetitive task practice with a clinician. One Physical Therapist and one assistant treated the patients in groups of four, one group in the morning and one group in the afternoon. Extensive pre and post therapy testing was performed on each patient. The Wolf Motor Function Test (WMFT) was used to quantify upper extremity movement ability through timed single- or multiple-joint motions and functional tasks (30). The upper extremity portion of the Fugl-Meyer Motor Assessment (FMA) was used to measure upper extremity function (31). The Motor Activity Log (MAL) was administered to assess the patients' subjective impression of how well and how often movement is observed in the affected arm during basic activities of daily living (ADL) (14). The Finger Tapping test was used to measure finger control. Patients were also asked to fill out a questionnaire at the completion of the study regarding their personal assessment of the therapy.

Twenty-eight prospective patients were screened and 8 patients were selected based on their meeting the inclusion criteria and being able to be present for the time scheduled for the study. There were seven stroke patients and one closed head trauma patient. The demographics of the patients are shown in Table I.

Table I Patient Demographics

Age	Sex	Diagnosis*	Years Post Event
57	M	CVA	1.5
62	M	CVA	4.5
63	M	CVA	7
58	M	CVA	23.5
26	M	TBI	1.6
74	M	CVA	0.5
78	F	CVA	1.3
63	F	CVA	9

*CVA = Cerebrovascular Accident = Stroke; TBI = Traumatic Brain Injury

Results

Figure 1 shows the results of the WMFT and the Finger Tapping test using measurements taken before and immediately following the three weeks of treatment. The WMFT percentage is the amount of time to do all of the tasks by the affected side before therapy minus the total time to do the tasks after therapy divided by the difference between the total time of the affected side before therapy and the total time of the unaffected side. Thus if the affected side is able to do the tasks in the same time that the unaffected side can, the improvement would be 100%. The Finger Tapping test results for the affected hand are expressed as the difference in the number of taps before and after treatment divided by the number of taps before treatment. All patients showed significant improvement in their finger dexterity as measured by the Finger Tapping test. All but two of the patients showed significant improvement in the total of all WMFT results.

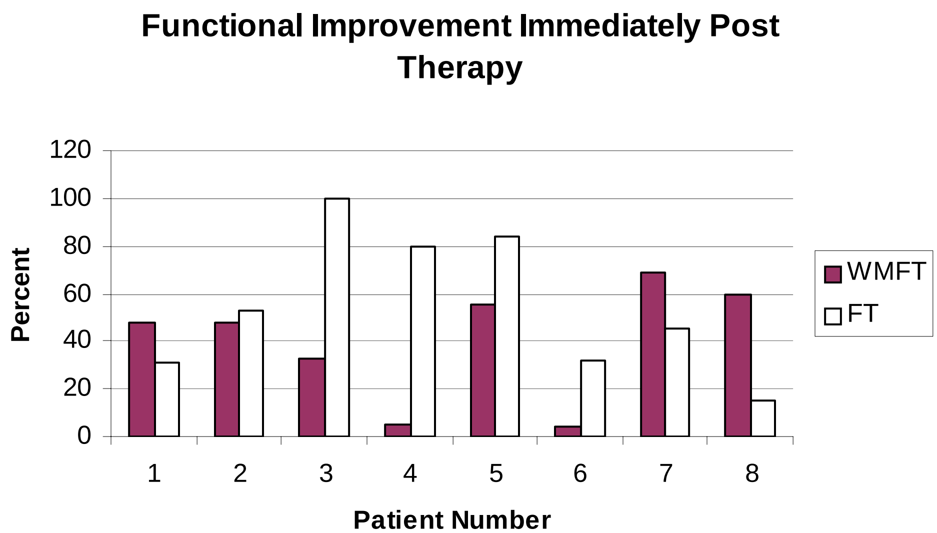

Figure 1 Percent Improvement in WMFT and Finger Tapping Test Immediately Post Treatment

The results for the WMFT and Finger Tapping test at 8 weeks post the end of treatment are shown in Figure 2. At eight weeks post treatment, four of the patients had slight increases in WMFT performance compared to the immediate post treatment measurements and four had slight decreases in the WMFT test results. The 8-week post treatment results for the Finger Tapping tests showed 3 of the patients had increases and 5 had decreases in their scores compared to immediate post treatment results, but all were better than pre-test results.

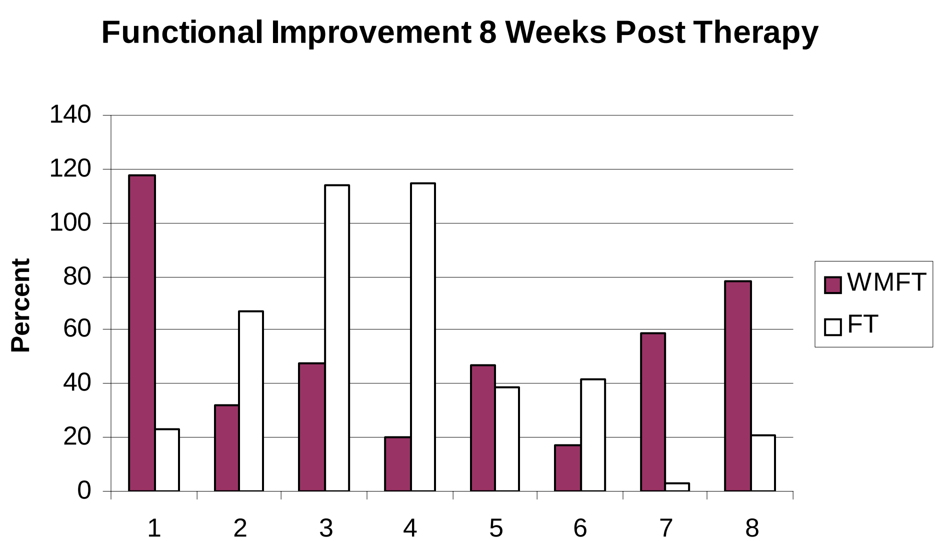

Figure 2 Percent Improvement in WMFT and Finger Taping Test 8 Weeks Post Treatment

The Fugl-Meyer Motor Assessment test assesses voluntary movement, reflex activity, grasp, and coordination. Performance is measured on 33 tasks with a 3-point ordinal scale (0-2) with zero being no function and 2 being full function. The maximum score for all tasks is 66. All patients showed slight improvement in the FM test comparing pre and immediate post therapy test results. The average increase in total score for all patients was 5.9.

In the Motor Activity Log results, all patients showed an increase in the amount of time they used their affected hand in the results obtained immediately post treatment. On the 0 to 5 scale, they showed an average increase of 0.9 with a range of 0.4 to 2.4 increase.

Patient exit interviews indicated that the patients thought the Mentor was safe and user-friendly. Sample comments were:

- "I can cut steak!"
- "I would like more 'device time' "
- "I can put deodorant on myself"
- "I am doing more ADL myself"
- "My hand movement is better"
- "I'm trying more things now" [with my affected hand]

Discussion

Patients 4 and 6 showed little improvement in the total WMFT results. Patient 4 was 23 years post stroke and had an improvement of 70 percent on the total of the six simple WMFT tasks but could not do some of the complex coordinated tasks that involve elbow and shoulder function. Patient 6 was the one participant that consistently did not concentrate on the tasks. All patients maintained most of the function they had gained. However, most of the patients showed little or no improvement over the post treatment 8 weeks that had no therapy. Rewiring of the adult brain is a process requiring extended time periods. Concentrated therapy can jump start the process of functional improvement. One of the premises of repetitive task practice is that with more function, a patient will use the affected side more and recovery will continue. The lack of increases in function during non-therapy time for some patients in this study of highly affected patients suggest for this degree of disability, cost efficient means of extending treatment times should be explored.

Conclusions

The answers to the pilot study questions were all affirmative. The Mentor was well accepted by patients. The therapy works in a clinical setting. ARM therapy is effective in restoring function to stroke patients. By using therapist time more efficiently, the therapy is cost-effective compared to conventional CI therapy.

Home treatment with the Mentor, interspersed with clinic visits that extend treatment over longer periods of time but with minimal increase in therapy cost is a promising extension of the clinic-based therapy in this study. The patient monitoring and reporting capabilities of the Mentor will aid the clinician in evaluating and adjusting home treatment protocols.

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