Butler AJ, Blanton S, Rowe VT, Wolf SL. Attempting to Improve Function and Quality of Life Using the FTM Protocol. Journal of Neurologic Physical Therapy: 30(3): 148-156, 2006.

Objective: To evaluate the extent to which FTM training improved function and quality of life in a patient who met criteria for which the device was intended.

Subject: 4-year-old male in the chronic stage of stroke recovery with moderate right upper extremity motor impairment.

Intervention: Intensive training with the SaeboFlex consisting of 6 hours a day, 5 days a week for 2 consecutive weeks. The intensive protocol was based on the CI therapy protocol standards.

Outcome Measures: Fugl-Meyer UE assessment evaluation (FMA), physical assessment evaluations of UE active/passive range of motion, the modified Ashworth scale for muscle tone, and the Wolf Motor Function Test (WMFT) were performed.

Results: Increases in AROM occurred in forearm supination and wrist flexion and extension. 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 showed a 17% reduction in time at follow-up, with improvements, most notably in the tasks of lifting a pencil and lifting a paper clip. UE-FMA showed a 17% improvement at follow- up. A slight improvement in MAL scores were also noted. SIS scores improved in the domains of strength, communication, mobility, social participation, hand recovery, and overall physical component.

Conclusion: The case study indicates that for this patient with chronic, moderate upper extremity impairment following stroke, a 2-week FTM training regimen resulted in decrease in impairment, with functional improvement and improved quality of life.

Farrell JF, Hoffman HB, Snyder, JL, Giuliani CA, Bohannon RW. Orthotic aided training of the paretic upper limb in chronic stroke: results of a phase 1 trial. NeuroRehabilitation: 22: 99-103, 2007.

Objective: To determine whether orthotic aided training (SaeboFlex) to assist with hand opening would provide participants with enhanced opportunities for goal directed upper limb tasks and thus improve limb movement and function.

Subject: 13 chronic stroke survivors

Intervention: Intensive training with the SaeboFlex consisting of 6 hours a day, 5 days a week for 1 week. Training included repetitive, task-oriented activities with the SaeboFlex and functional electrical stimulation.

Outcome Measures: Active range of motion of the shoulder, elbow, and wrist, Fugl-Meyer Upper Extremity Assessment, Motor Status Score, and the Modified Ashworth Scale were performed.

Results: Active movement increased significantly for all shoulder and elbow movements. At the wrist, extension increased significantly. The Fugl-Meyer and Motor Status Assessment improved significantly over the course of the intervention. Muscle tone decreased and no patient reported any pain in the upper limb, either before or after the intervention.

Conclusion: This investigation demonstrates that a program using the SaeboFlex orthosis to assist with highly repetitive, task-oriented training can promote increased upper limb mobility and function.

McCombe Waller S, Whitall J. The Sequential Combination of Bilateral and Unilateral Arm Training to Promote Arm and Hand Function in Patients with More Severe Paresis. University of Maryland, School of Medicine, Department of Physical Therapy and Rehabilitation Science, Baltimore, Maryland, USA, 2008.

Objective: To determine whether the combination of bilateral training sequentially with unilateral training (assisted by use of the Saeboflex orthosis) will improve arm and hand function in subjects with moderate severity paresis.

Subjects: 10 patients with unilateral stroke with moderate severity paresis.

Intervention: The subjects received bilateral arm training using the BACTRAC for 3 times per week for 6 weeks followed by unilateral arm training using the SaeboFlex for 3 times per week for 6 weeks.

Outcome Measures: Fugl-Meyer, Box and Blocks, Modified Wolf Motor Function Test, Grip Strength, and the University of Maryland Arm Questionnaire for Stroke were performed.

Results: Clinically meaningful gains in function are seen after combination training compared to baseline.

Conclusion: Combining bilateral and unilateral training shows promise in promoting recovery of meaningful function of the arm and hand in patients with moderate severity paresis. Gains in hand use were seen in some patients after unilateral training with the Saeboflex device.

Heise K, Liuzzi G, Zimerman M, Gerloff C, Hummel F. Intensive orthosis-based home training of the upper limb leads to pronounced improvements in patients in the chronic stage after brain lesions, 2010.
(Submitted for Publication)

Objective: The purpose of this study was to test whether self-administered training with a dynamic training orthosis (SaeboFlex), supporting hand and finger extension, is feasible to actively improve the hand function in patients after brain lesion.

Subjects: 13 patients with upper limb (UL) hemiparesis in the chronic stage with initial severe impairment of UL function (i.e. inability to actively extend fingers and wrist.)

Intervention: The subjects were trained over five consecutive days to don and use a dynamic training orthosis followed by daily self-administered training at home for 6 months.

Outcome Measures: Upper limb active range of motion, Fugl-Meyer assessment (UEFMA), grip/pinch force, Action Research Arm Test (ARAT), and Stroke Impact Scale (SIS) were performed.

Results: Significant gains noted in the upper extremity Fugl-Meyer Test, grip force, pinch force (key grip), and the Action Research Arm Test. Significant improvements were also noted on the "physical domain" portion (strength, hand function, mobility, and ADL) of the Stroke Impact Scale. There was a non-significant trend for improved social participation.

Conclusion: Patients with stable moderate to severe impairment of UL function after receiving common neurorehabilitative therapy can substantially further improve their hand function with intensive self-initiated and regularly supervised DTO-based home training.

Deering J, Terry K, Silver N, Amling L , Araniecke C, Barry J: Will Upper Extremity Performance Change Following Use of a Dynamic Orthosis Exercise Session in Individuals with Chronic Stroke?: A Pilot Study Maryville University, St. Louis, Missouri: 2009

Objective: The purpose of this pilot study was to evaluate the short-term effectiveness of a 60-minute SaeboFlex training protocol in individuals with chronic stroke.

Subjects: 9 individuals; Ages 41-73 (mean 56.1, SD 11.7). Time since stroke 1-12 years (mean 3.8, SD 3.8).

Intervention: Each participant completed a 60 minute functional training program focusing on grasp and release activities.

Outcome Measures: Box and Block for functional grasp, Modified Tardieu Scale for wrist flexors, PROM (wrist extension), Muscle Catch Angle for wrist flexor tone (goniometric), and Handheld Dynamometry for grip strength were performed.

Results: This study showed significant increases in functional grasp, PROM and muscle catch angle. The increases noted with PROM remained into the Post 3 measurement.

Conclusion: This study showed that one hour of SaeboFlex training yielded significant improvements in grasp, PROM and tone in individuals with chronic stroke.

Krug G, Ebert A, Schmittgens J, Stanley H. The Effectiveness of Bilateral vs. Unilateral Task Retraining Using the SaeboFlex Orthosis in Individuals with Sub-Acute or Chronic Sroke. Department of Occupational Therapy and Occupational Science, University of Missouri, 2010

Objective: To examine the effectiveness of the SaeboFlex orthosis, comparing unilateral versus bilateral training with individuals in the sub-acute and chronic phases of stroke recovery.

Subjects: 6 patients

Intervention: The subjects were divided into 2 groups (bilateral and unilateral) and received two 90-minute clinic visits per week for program monitoring and modification. A home program twice per day for 1 hour each was also performed.

Outcome Measures: Wolf Motor Function Test, Motor Activity Log, Modified Ashworth Scale, Canadian Occupation Performance Measure, and AROM assessment was performed.

Results: All participants demonstrated increased motor performance in their affected arm on both rote and functional tasks. The unilateral group demonstrated greater increases when compared to bilateral group. Both the unilateral and bilateral groups gained active range of motion. Overall, the unilateral group showed more increase in movement. Tone decreased in all 12 movements measured in both the unilateral and bilateral groups. The unilateral group demonstrated a greater decrease in tone when compared to the bilateral group. An increase in task performance and satisfaction was identified in both groups. The unilateral group showed a greater increase in task performance and satisfaction. Both groups reported increases in task performance and satisfaction with the unilateral group reporting a greater rate of improvement.

Conclusion: Performing unilateral training with the SaeboFlex may be considered to be more effective than bilateral training in increasing motor performance, AROM, and satisfaction as well as reducing tone.