

Doucet B, Mettler, J. Pilot Study Combining Electrical Stimulation and a Dynamic Hand Orthosis for Functional Recovery in Chronic Stroke. American Journal of Occupational Therapy, March/April, Vol 72, Num 2, 2018.

Objective: To investigate the effect of a combined neuromuscular electrical stimulation and dynamic hand orthosis regimen with a group of people with chronic stroke to improve performance on specific daily tasks.

Subjects: Four people with chronic stroke.

Intervention: Consisted of combination treatment (NMES/*SaeboFlex*) using the affected upper extremity 5x/wk for 6 weeks.

Outcome Measures: Grip strength, range of motion (ROM), and analysis of muscles activation-deactivation during release of grasp through electromyography. Ability to perform specific daily living tasks was assessed using the Assessment of Motor and Process Skills (AMPS).

Results: Improvements in strength, ROM, and grasp deactivation are possible with the combined NMES/*SaeboFlex* regimen. All participants' AMPS motor scores improved.

Conclusion: The findings of this study suggest that *SaeboFlex* treatment combined with NMES can improve motor skills needed for functional task performance in people with chronic stroke.

Franck J, Johannes R, Smeets E, Alexander H, Seelen M. Evaluation of a Functional Hand Orthosis Combined with Electrical Stimulation Adjunct to Arm-Hand Rehabilitation in Sub-Acute Stroke Patients with a Severely to Moderately Affected Hand Function. Disability and Rehabilitation, January 10, 2018.

Objective: To investigate the usability and effectiveness of a functional hand orthosis (*SaeboGlove*), combined with electrical stimulation adjunct to therapy-as-usual, on functional use of the moderately/severely impaired hand in sub-acute stroke patients.

Subjects: 8 sub-acute, first-time stroke patients. All patients were clinically diagnosed with moderately to severely impaired arm-hand.

Method: Single case experiment (A-B-A design). The functional hand orthosis and electrical stimulation were used for six weeks, four days per week, 45 minutes per day.

Outcome Measures: ARAT, Intrinsic Motivation Inventory.

Results: At group level, ARAT test scores showed statistically significant improvement. At individual level, six of the eight patients improved as to arm-hand skill performance at follow-up.

Conclusion: Sub-acute stroke patients who display moderate to severe arm-hand impairments, seem to benefit from training with the *SaeboGlove* in combination with electrical stimulation. Patients' perceived intrinsic motivation and sense of self-regulation was high.

Soros P, Teasell R, Hanley D, Spence J. Motor Recovery Beginning 23 Years After Ischemic Stroke. Journal of Neurophysiol, May 17, 2017.

Objective: Case report describing remarkable recovery beginning 23 years after severe stroke due to embolization from the innominate artery and subclavian artery.

Subject: Patient exhibited large right fronto-parietal infarction with severe left hemiparesis and totally non-functional spastic left hand.

Intervention: More than 2 decades after the injury, patient received intensive physiotherapy using the *SaeboFlex*, a spring-loaded mechanical orthosis that provides resistance to the finger flexors and assists finger extensors with extension.

Outcome Measures: fMRI, The Chedoke McMaster Stroke Assessment, Modified Ashworth Scale and Box and Block Test.

Results: fMRI studies document widespread distribution of the recovery in both hemispheres. Patient's hand function improved as evidenced by picking up coins with previously useless affected hand. Patient was also able to transfer 10 blocks in 60 seconds using the Box and Block Test.

Conclusion: The findings of this report suggest that further recovery should not be abandoned after the chronic stage of stroke begins. In addition, the generally accepted window of recovery beyond which further therapy is not indicated should be entirely reconsidered.

Rickards N, Sharma A, Prosser M. Feasibility Audit of SaeboFlex in Stroke Patients: Impact on Recovery Across the Patient Pathway. Journal of the Association of Chartered Physiotherapists in Neurology, 2015, Spring/Summer.

Objective: To audit and assess the feasibility of the introduction and implementation of the use of Saebo throughout the acute to community pathway in Southend-on-sea.

Subjects: 14 acute stroke patients

Intervention: Patients received daily *SaeboFlex* training for a minimum of 45 minutes per day using repetitive reach and grasp activities appropriate for the patients ability prescribed and reviewed by a Saebo trained therapist.

Outcome Measures: Fugl-Meyer Assessment - Upper Limb portion and video analysis.

Results: thirteen out of fourteen patients demonstrated improvements on the Fugl-Meyer and achieved functional goals across the treatment pathway. Six patients had achieved near to full functional use of their arm.

Conclusion: The findings of this study suggest that the use of the *SaeboFlex* can enhance the recovery of the upper limb post stroke.

Runnells K, Anson G, Byblow W. Partial Weight Support of the Arm Affects Corticomotor Selectivity of Biceps Brachii. Journal of NeuroEngineering and Rehabilitation: 12:94, 2015.

Objective: To explore the neurophysiological effect of weight support on the selectivity of biceps brachii activation in healthy adults.

Subjects: 13 participants completed counterbalanced movement tasks in a repeated measures design. Three levels (0, 45, 90% of full support) of weight support were provided to the arm using the *SaeboMAS*.

Intervention: At each level of weight support, participants maintained a flexed shoulder posture while performing rhythmic isometric elbow flexion or forearm pronation. Single-pulse transcranial magnetic stimulation of the primary cortex was used to elicit motor-evoked potentials (MEP).

Outcome Measures: Baseline muscle activity and MEP amplitude were the primary dependent measures.

Results: With increased support, tonic activity was reduced across all muscles. This effect was greatest in the anti-gravity muscle anterior deltoid, and evident in biceps brachia and pronator teres as well.

Conclusion: Weight support of the arm influences neuromechanical control for the limb. These findings may inform the application of weight support in upper limb stroke rehabilitation.

McCombe Waller S, Whittall J, Jenkins T. et al. Sequencing Bilateral and Unilateral Task-Oriented Training Versus Task-Oriented Training Alone to Improve Arm Function in Individuals with Chronic Stroke. BMC Neurology. 14:236, 2014.

Subjects: 26 chronic patients with moderate severity hemiparesis.

Intervention: Participants received either 6-weeks of bilateral proximal training followed sequentially by 6-weeks unilateral task-oriented training (COMBO) or 12-weeks of unilateral task-oriented training alone (Saebo).

Outcome Measures: Motor cortex activation (fMRI), Fugl-Meyer Upper Extremity Scale, Modified Wolf Motor Function test and the University of Maryland Arm Questionnaire for Stroke.

Results: The COMBO group demonstrated significantly greater gains between baseline and 12-weeks over all outcome measures and specifically in the Modified Wolf Motor Function test. Both groups demonstrated within-group gains on the Fugl-Meyer Upper Extremity test and the University of Maryland Arm Questionnaire for Stroke. fMRI subset analyses showed motor cortex (primary and premotor) activation during hand movement was significantly increased by sequential combination training.

Conclusion: Sequentially combining a proximal bilateral before a unilateral task-oriented training may be an effective way to facilitate gains in arm and hand function in those with moderate to severe paresis post-stroke compared to unilateral task-oriented training alone.

Pooyania S, Semenko, B. Botulinum toxin type-A (BoNTA) and dynamic wrist-hand orthoses versus orthoses alone for the treatment of spastic-paretic upper extremity in chronic stroke patients. Open Journal of Therapy and Rehabilitation: 2, 12-18, 2014.

Objective: To investigate the potential functional improvement of the spastic-paretic upper extremity of individuals with chronic hemiparesis when using a dynamic wrist- hand orthosis (*SaeboFlex*) with and without concurrent botulinum toxin type-A (BoNTA) injections into the spastic upper extremity muscles.

Methods: A three-year retrospective chart review was conducted on all stroke patients referred to out-patient occupational therapy for an upper extremity rehabilitation program, which included use of the *SaeboFlex*.

Pre- and post-intervention outcome measure scores were compared between the two groups.

Outcome Measures: Grip strength and lateral pinch strength, Modified Ashworth Scale, Fugl Meyer-Upper Extremity and the Canadian Occupational Performance Measure were recorded.

Results: Significant difference was found between the pre- and post-intervention scores irrespective of treatment group. Although improvement approached significance when comparing the *SaeboFlex* + BoNTA and *SaeboFlex* only, no significant changes were found.

Conclusion: The findings of this study indicate that for some patients with chronic upper extremity hemiparesis post stroke, there is the potential for further functional improvement using the *SaeboFlex*, however the use of concurrent BoNTA injections for those with moderate-severe spasticity, in facilitating.

Runnells, K, Anson G, Wolf S, Byblow W. Partial Weight Support Differentially Affects Corticomotor Excitability Across Muscles of the Upper Limb. Physiological Reports Vol. 2, Iss. 12, 2014.

Objective: Explore the neurophysiological effects of upper limb weight support in 13 healthy young adults.

Subjects: Thirteen right-handed healthy young adults (six females) without history of upper limb injury or neurological illness. Motor-evoked potentials (MEPs) from transcranial magnetic stimulation (TMS) of primary motor cortex and EMG from anterior deltoid (AD), biceps brachii (BB), extensor carpi radialis (ECR), and first dorsal interosseous (FDI) were assessed.

Intervention: Five levels of weight support, varying from none to full, were provided to the arm using the *SaeboMAS*. For each level of support, stimulus-response (SR) curves were derived from the MEPs across a range of TMS intensities.

Results: Weight support affected background EMG activity in each of the four muscles examined. Tonic background activity was primarily reduced in the AD. The SR plateau for ECR increased at the lowest support level. For FDI, the SR plateau increased at the highest support level.

Conclusion: The findings indicate that weight support of the proximal upper limb modulates corticomotor excitability across the forearm and hand.

Franck J, Timmermans A, Seelen H. Effects of a Dynamic Hand Orthosis for Functional Use of the Impaired Upper Limb in Sub-Acute Stroke Patients: A Multiple Single Case Experimental Design Study. Technology and Disability 25: 177-187, 2013.

Objective: To investigate the usability and the effects of a dynamic spring-loaded orthosis, adjunct to therapy-as-usual, on functional use of the impaired hand in moderately/severely impaired sub-acute stroke patients.

Subjects: 8 patients

Intervention: The *SaeboFlex* was used for six weeks, five days/week, 45 min./day, and adjunct to therapy-as-usual.

Outcome Measures: Action Research Arm Test, ABILHAND, Intrinsic Motivation Inventory.

Results: Participants improved on the Action Research Arm Test and ABILHAND.

Conclusion: Patients in the early sub-acute phase of stroke that display little to modest improvement on their capacity to perform activities or their perceived level of daily performance, benefit most from the *SaeboFlex* training.

Woo Y, Jeon H, Hwang S, Choi B, Lee J. Kinematics Variations After Spring-Assisted Orthosis Training in Persons with Stroke. *Prosthetics and Orthotics International*, 2012.

Objective: To evaluate the efficacy of training using kinematic parameters after a *SaeboFlex* orthosis training on chronic stroke patients.

Subjects: 5 patients

Intervention: Five patients participated in four weeks of training using the *SaeboFlex* orthosis for 1 hour per day, 5 times per week.

Outcome Measures: Fugl-Meyer Assessment, Box and Block Test, Action Research Arm Test, and 3D motion analysis system for smoothness of movement.

Results: The upper extremity score of the Fugl-Meyer Assessment and the Box and Block Test increased significantly after the intervention. The jerkiness score of the shoulder and elbow joints at the sagittal plane decreased significantly during the reach-to-grasp task. The jerkiness scores of the wrist joint during the reach-to-grasp task decreased significantly at both elbow and acromion heights.

Conclusion: The results of this study indicate that *SaeboFlex* training is effective in recovering the movement of the hemiparetic upper extremity of patients after stroke.

Gollega A. Innovative Technique to Improve Arm Function Following Acquired Brain Injury. Poster Presentation, 2012.

Subjects: 6 chronic patients

Intervention: All patients participated in 1 hour *SaeboFlex* sessions, 3-4 times per week.

Outcome Measures: Modified Ashworth Scale, Action Research Arm Test, Chedoke McMaster Stroke Assessment Inventory (Arm/Hand portion), Canadian Occupational Performance Measure, Manual Function Test, Grip Strength, and Range of Motion.

Results: Active shoulder flexion and abduction improved 10-25% in all participants. Muscle tone decreased during the treatment sessions. Motor recovery of the arm and hand increased an average of 10-15%. Four participants demonstrated increased grip strength. All participants achieved 80% of their personal functional goals within 5 months.

Conclusion: The results of this study indicate that the *SaeboFlex* training program can be an effective technique used to improve upper limb recovery following a neurological injury.

Stuck R, Marshall, L, Sivakumar R. *SaeboFlex* Upper Limb Training in Acute Stroke Rehabilitation. *International Journal of Stroke* 7(2): 20-1, 2012.

Objective: To explore the feasibility and patient experience of *SaeboFlex* training in acute stroke.

Subjects: 8 patients

Intervention: Patients with moderate to severe upper limb weakness participated in *SaeboFlex* sessions for 12 weeks in addition to conventional rehabilitation.

Outcome Measures: Primary measures included the Action Research Arm Test and UL Motricity Index. Secondary measures included Motor Assessment Scale, Modified Barthel Index, Berg Balance Scale, Visual Analogue Scale, and Stroke Impact Scale.

Results: Clinically significant improvements were noted in the Action Research Arm Test in five out of the seven participants while six out of seven participants showed significant gains in the UL Motricity Index. Clinically significant improvements were also noted in secondary outcomes.

Conclusion: *SaeboFlex* training facilitated clinically significant improvements in UL function. It has the potential to improve participation and independence in ADLs, reduce carer burden and associated costs.

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.

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.

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 Stroke. 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.

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 *SaebFlex* 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 *SaebFlex* training yielded significant improvements in grasp, PROM and tone in individuals with chronic stroke.

McCombe Waller S, Whittall 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 *SaebFlex* 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 *SaebFlex* 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 *SaebFlex* device.

Farrell J, Hoffman H, Snyder, J, Giuliani C, Bohannon R. 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 (*SaebFlex*) to assist with hand opening would provide participants with enhanced opportunities for goal directed upper limb tasks and thus improve limb movement and function.

Subjects: 13 chronic stroke survivors

Intervention: Intensive training with the *SaebFlex* consisting of 6 hours a day, 5 days a week for 1 week. Training included repetitive, task-oriented activities with the *SaebFlex* 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 *SaebFlex* orthosis to assist with highly repetitive, task-oriented training can promote increased upper limb mobility and function.

Butler A, Blanton S, Rowe V, Wolf S. 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.

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

Intervention: Intensive training with the *SaebotFlex* 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.