Effects of the SaeboFlex® Orthosis and Therapy Compared to Therapy Alone on Upper Extremity Recovery in Patients with Chronic Moderate to Severe Hemiparesis

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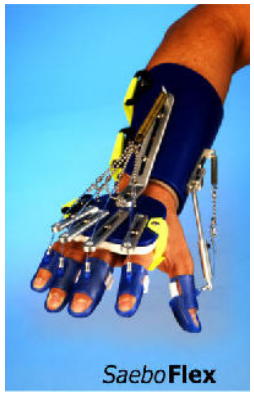
Introduction/Background



- Six months following a stroke 55-75% of people still have impaired arm use[1]
- Upper extremity (UE) research for individuals with hemiparesis has focused on interventions such as Constraint Induced Therapy targeting those with active wrist/finger extension[2,3,4]
- Research on interventions for individuals with moderately to severely impaired UE function is lacking[5,6]
- The SaeboFlex® is a device that assists finger extension to allow individuals without active finger extension successful practice of grasp and release

The specific aim of this pilot study was to determine the effect of rehabilitation using the SaeboFlex® versus rehabilitation alone on upper extremity function, strength and quality of life in individuals with chronic moderate to severe hemiparesis.

Methods

Participants: 19 participants (10 males, mean age = 52 years +/- 29, mean time since onset = 5.3 years +/- 9.7).
Study criteria: ≥18 years age; ≥6 months post onset; ≥15º passive wrist extension with finger extension; ≥25º active shoulder, elbow and finger flexion; No history of fragile skin; Unable to grasp and release a ball (4 inch diameter)

Outcome Measures: Administered by blinded testers prior to intervention, post 6 weeks of therapy and again 4 weeks later
Box and Blocks Test (B&BT) – number of blocks moved across a partition with the involved hand in one minute
Action Research Arm Test (ARAT) – Arm function test, 19 items scored on an ordinal scale where 0=unable to do, 1=partial, 2=done with difficulty and 3=normal
Stroke Impact Scale (SIS) – Questionnaire answered by participants about perception of their recovery in 9 domains; Strength & Arm Function domains were analyzed

Intervention: Participants were randomly assigned to a group; **Group S** (n=10) participants were fitted with a SaeboFlex® which was used during therapy and the home exercise program (HEP); **Group T** (n=9) received therapy alone; Intervention for both groups consisted of one hour of therapy per week for 6 weeks and a HEP performed twice daily 4 days/week for 10 weeks; Intervention focused on reaching tasks while grasping & releasing balls

Data Analysis: Nonparametric statistical tests were used on the data. A Friedman's Analysis of Variance (ANOVA) was used to assess differences over time with each dependent measure. Next the Kruskal-Wallis Test was used for multiple comparisons between paired time frames.
Participants were categorized as moderately or severely involved using the following definition: severe= 0 on B&BT and ≤ 5 on ARAT. The level of significance was set at p<0.05. Statistics were calculated on SPSS v. 16.0

Results

Of the 19 participants who completed the intervention and first post test, 2 were lost to follow-up prior to the final day of measurements; Group S had 6 moderately and 4 severely involved participants; Group T had 4 moderately and 5 severely involved participants.

The Friedman ANOVA when used to compare scores across treatment days on subjects regardless of group showed significant differences between days for the Action Research Arm Test (p<0.021), Box and Blocks (p<0.035) and Arm Use on the SIS (p<.002).

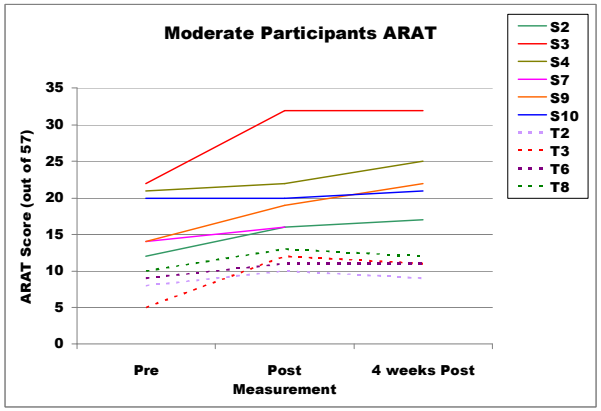
The Kruskal-Wallis Test showed no difference between the change in pretest to posttest scores when comparing dependent measures in Group S to Group T. Examining subjects grouped by severity demonstrated no difference for the severe group. However, in the moderate group a significant pre to posttest difference was found for the ARAT (p<0.05).

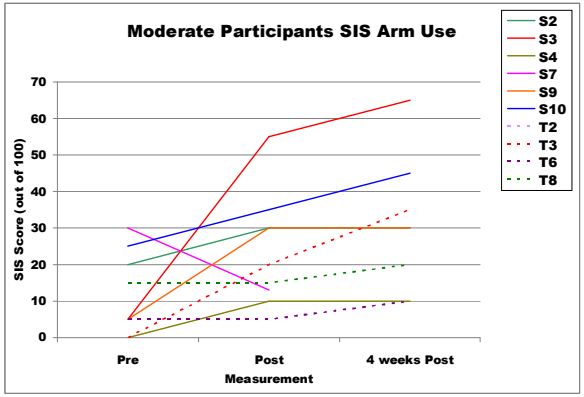
Table 1 below shows the median scores and ranges for the ARAT, SIS Arm Use domain and the B&BT with the participants divided into the treatment groups as well as by severity.

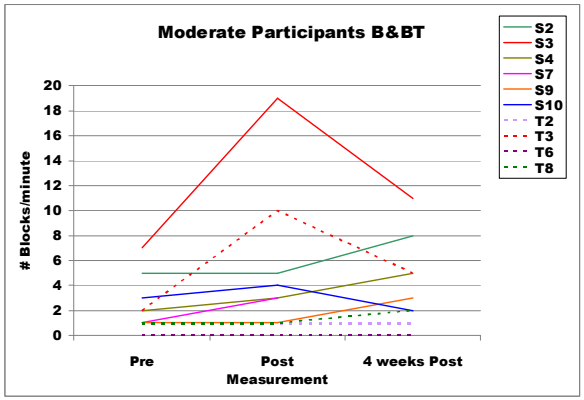
	ARAT		SIS Arm Use		B&BT	
Table 1	Pre	Post 1	Pre	Post 1	Pre	Post 1
Group S Median (range)	13 (3-22)	16 (3-32)	5 (0-30)	11.5 (0-55)	1 (0-1)	2 (0-19)
Group T Median (range)	5 (3-10)	4 (3-13)	5 (0-30	5 (0-40)	0 (0-2)	0 (0-10)
Moderate Median (range)	**13 (5-32)**	**16* (10-32)**	5 (0-30)	18 (5-55)	1.5 (0-7)	3 (0-19)
Severe Median (range)	3.5 (3-5)	3.5 (3-4)	0 (0-30)	0 (0-45)	0 (0)	0 (0-1)

* = statistically significant change (p<0.05)

The individual results for the moderately involved participants from Groups S & T are displayed in the following graphs for the ARAT, Arm Use domain on the SIS and the B&BT in order to show the trends that appeared in the data.







Conclusion

This pilot study showed that individuals with chronic moderate to severe hemiparesis receiving one hour of therapy per week and a HEP can make functional changes with their involved UE and have an improved perception of arm use. The model of delivery studied fits the current health care system.

The data show trends towards more improvement for individuals with moderate versus severe involvement as well as more improvement when training with the SaeboFlex®. However, these results were not statistically significant in this pilot study, possibly due to the small N.

Further studies are warranted with larger numbers, with a focus on the population with moderate involvement and looking at different intensity or dosages of the intervention provided.

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References available on request