

# Effect of Saebo™ Orthosis Along with Functional Electrical Stimulation on Hand Function in Patients with Subacute Stroke: A Randomized Controlled Trial

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**How to cite this article:** Neha Kumari, Narkeesh Arumugam, Divya Midha. Effect of Saebo™ Orthosis Along with Functional Electrical Stimulation on Hand Function in Patients with Subacute Stroke: A Randomized Controlled Trial. Indian Journal of Physiotherapy and Occupational Therapy 2022;16(3):61-66.

## Abstract

**Background:** In stroke, there is loss of basic hand function like straightening of the fingers, grip strength and grasping of the item which make dependent for their basic activity of daily living. The Saebo-Flex™ orthotic is a mechanical device, which enables an individual to open hand, pick up the objects and release during task-oriented exercises. It facilitates thumb and finger extension movements by recruiting voluntary thumb and finger flexor movement.

**Objectives:** To determine the effect of FES along with Saebo-Flex™ device on Fugl Meyer assessment score for upper extremity, on Grip Strength, on Pinch Strength and on Hand Dexterity.

**Methodology:** 20 participants were randomly divided into experimental (Saebo-Flex™ hand orthosis + FES + Conventional physiotherapy) and control (FES + conventional physiotherapy) group. Intervention was given for 45min/session, 5 session/ week for 6 weeks. Assessment was done using Fugl Meyer assessment-upper extremity, Chedock hand inventory programme, Nine-hole peg test, Hand dynamometer and Pinch gauge on Day 0, Day 12 and Day 42 of the intervention period.

**Results:** The results were found to be non-significant ( $p > 0.05$ ) for all outcome measures. Statistically significant results were obtained for FMA-UE ( $p = 0.018$ ) on comparison of mean difference scores at Day 0, and Day 42, CAHAI scores ( $p = 0.011$ ) on comparison of mean difference scores at Day 0 and Day 42.

**Conclusion:** According to finding, the integrated intervention of Saebo-Flex™ device along with Functional Electrical Stimulation can be used effectively to improve the upper extremity motor functions in sub acute stroke survivors.

**Keywords:** Sub acute stroke; Saebo™ Orthosis; Functional Electrical Stimulation; Hand Function.

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## Background

Stroke is the cerebrovascular event in which sudden loss of neurological function caused by an interruption of blood flow to the brain, leads to cerebral infarct or a haemorrhage.<sup>1</sup> The World Health Organization defined stroke, as rapidly developed clinical sign of focal or global disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than of vascular origin. The post stroke disabilities occur primarily due to loss of locomotion, difficulty in Activity of Daily Living (ADL), cognitive impairment as a consequence of stroke.<sup>3</sup> Out of all motor impairments, approximately 85% of stroke patients have upper limb impairments.<sup>4</sup> Major disability following upper extremity impairment is loss of arm and hand function. After the onset of stroke there is disruption in the connection between the hand muscles and brain which leads to spasticity. Loss of all the hand function and difficulty in accomplishment of basic activities like straightening of the fingers, grip strength and grasping of the item makes them dependent for their basic activity of daily living. Thus, regaining optimum recovery of upper extremity and hand function is the prime goal of rehabilitation professionals.<sup>5</sup>

Traditional modes of intervention exist and are regularly practiced by the trained therapists in the form of constraint-induced movement therapy, task-oriented exercise, Proprioceptive neuromuscular training etc.

In order to overcome the constraints of existing rehabilitation models, there is exponential rise in the clinical utility of novel intervention therapies like Functional Electrical stimulation and mechanical devices like Saebo Flex with the aim to speed up the upper limb recovery following stroke.<sup>6</sup> Saeboflex provides low-load, long-duration stretches in the direction of the desired range of movement, while at the same time supporting the functional use of hand. The Saebo-Flex™ orthotic is a mechanical device, which enables an individual to open hand, pick up the objects and release during various task-oriented exercises. The device facilitating thumb and finger extension movements by recruiting voluntary thumb and finger flexor movement.<sup>7</sup> Training with

Saebo Flex grasp and release activities, participants require only small range of active shoulder and elbow movement, with passive wrist extension to 15° with passive digit extension.<sup>8</sup> Functional electrical stimulation (FES) is the electrical stimulation of motor neurons through transcutaneous electrode which cause the muscle contraction and movement at the joint. Rehabilitation with Functional electrical stimulation consists of preprogrammed electrical stimulation of peripheral sensory and motor nerves with functional movement of the upper extremity, which enable the stroke survivors to regain functional arm motion. FES helps in cortical excitability in the lesion sensory motor cortex following stroke.<sup>2</sup> Present study conducted to explore the therapeutics effect of novel Intervention methods like FES and Saebo Flex on upper extremity recovery following stroke.

## Methodology

The present study was randomized control trial in nature and Computer-generated random sampling method was used to allocate the participants into two groups i.e. Group A (Experimental Group) and Group B (Control Group). Participants of (Group A) received Saebo-Flex™ hand training, FES at extensor compartment of the forearm and conventional physiotherapy treatment, while participants of (Group B) received FES electrode placing at the extensor compartment of the forearm skin and conventional physiotherapy treatment. Treatment was given for 45 minutes/sessions x 5 sessions/week for 6 weeks.

Saeboflex assisted Task oriented Training is explained in appendix A.

## Functional Electrical stimulation

Functional electrical stimulation was given with the programmable device designed to give electrical stimulation. Functional electrical stimulation included wrist and finger extensors/flexors transcutaneously by self adhesive surface electrode, during voluntary movement in order to elicit the extension of the wrist and fingers. FES parameters ranged 20-50 Hz frequency, with pulse width of 0-300 ms, peak current < 70 mA and duration of stimulation was 10 minutes.<sup>2</sup>

## Conventional Physiotherapy Treatment

The standard Physiotherapy Treatment was given to the individual participants, the repetition and intensity of the exercises were guided by Research therapist based on the strength of the paretic limb of the participant. Modification in the progression of the Exercise was done the research therapist based on the performance of participant, with the aim to improve motor functions of paretic arm muscle.<sup>6</sup>

## Control Group Intervention

Participants of the Control Group were receiving the Functional Electrical Stimulation with Conventional Physiotherapy intervention for 45 minutes, 5 sessions per week for 6 weeks similar to as given the Experimental Group participants. Before the commencement of the study, an ethical approval was taken from the Institutional Ethical Committee (IEC), Punjabi University, Patiala. Written consent was taken from all the selected individuals before the start of study. Baseline assessment was done using various outcome measures (Fugl Meyer assessment-upper extremity, Chedock arm and hand inventory programme, Nine-hole peg test, Grip strength and Pinch strength). Post Intervention assessment was done Day 12 and Day 42 using outcome measures. Data was collected and statistical analysis was done using SPSS 22 version.

## Result

### FMA-UE

The mean scores of FMA-UE for Group A and B were detailed in table 1 on Day 0, Day 12 and Day 42 respectively with  $p \leq 0.05$  which depicts statistically significant results of Group A as compare to Group B.

### CAHAI

It was observed that after 6 weeks of intervention

there was increase seen in the mean scores of CAHAI for both the groups, their scores were explained in table 1 which indicates the significant difference between two groups.

### Nine-hole peg test

The NHPT is used to measure the dexterity in individuals after the onset of stroke. It is found that the mean scores of NHPT for Group A and Group B were statistically non-significant results as shown in table 1.

### Power Grip Strength

The mean scores of Power Grip Strength for Group A and Group B were statistically non-significant results in both groups.

### Lateral Pinch strength

The mean scores of Lateral Pinch strength for Group A and Group B were statistically non-significant results in both groups.

### Chuck Pinch strength

The mean scores of Chuck Pinch strength for Group A and Group B were statistically non-significant results. Here the  $p \leq 0.05$  level of significance as their values shown in table 1.

### Tip to Tip Pinch strength

The mean scores of Tip-to-Tip Pinch strength for Group A and Group B were statistically non-significant results. Here the  $p \leq 0.05$  level of significance as their values given in table 1.

### Pulp Pinch strength

The mean scores of Pulp Pinch strength for Group A and Group B were statistically non-significant results. Here the  $p \leq 0.05$  level of significance as their values shown in Table 1.

Table 1: Improvement in FMA-UE, CAHAI, NHPT, PG, LP, CP, TP and PP strength within Group A and Group B

Outcome Measures	Group A			Group B			F Value		p Value	
	Day 0	Day 12	Day 42	Day 0	Day 12	Day 42	Group A	Group B	Group A	Group B
FMA-UE	93.60± 9.89	105.50± 8.02	111.00± 7.72	92.10± 15.12	96.70± 14.90	100.50± 15.81	10.76	0.758	0.000	0.478
CAHAI	29.00 ± 6.38	35.00± 6.15	40.10± 5.57	23.00± 10.58	25.90± 11.74	28.50± 11.78	8.463	0.584	0.001	0.564
NHPT	273.20± 236.62	232.50 ±182.15	145.00 ±102.67	321.60± 283.55	187.10 ±128.55	215.00 ±179.77	1.291	1.170	0.291	0.326
PG	11.50 ± 9.32	14.00± 8.47	16.90± 7.92	6.70± 5.64	9.30± 6.17	11.40± 6.17	0.989	1.542	0.385	0.232
LP	3.00± 1.70	3.35± 1.97	3.80± 1.81	2.20± 1.40	2.50± 1.51	2.90± 1.29	0.479	0.628	0.624	0.541
CP	3.00± 1.49	3.80± 1.55	4.10± 1.29	2.30± 1.42	2.60± 1.51	3.00± 1.41	1.545	0.589	0.232	0.562
TP	1.95± 1.46	2.35± 1.63	2.90± 1.37	1.13± 0.96	1.55± 1.21	1.80± 1.23	1.021	0.881	0.079	0.531
PP	2.30± 0.95	2.80± 1.23	3.40± 0.97	2.00± 1.41	2.20± 1.55	2.50± 1.51	2.721	0.285	0.084	0.755

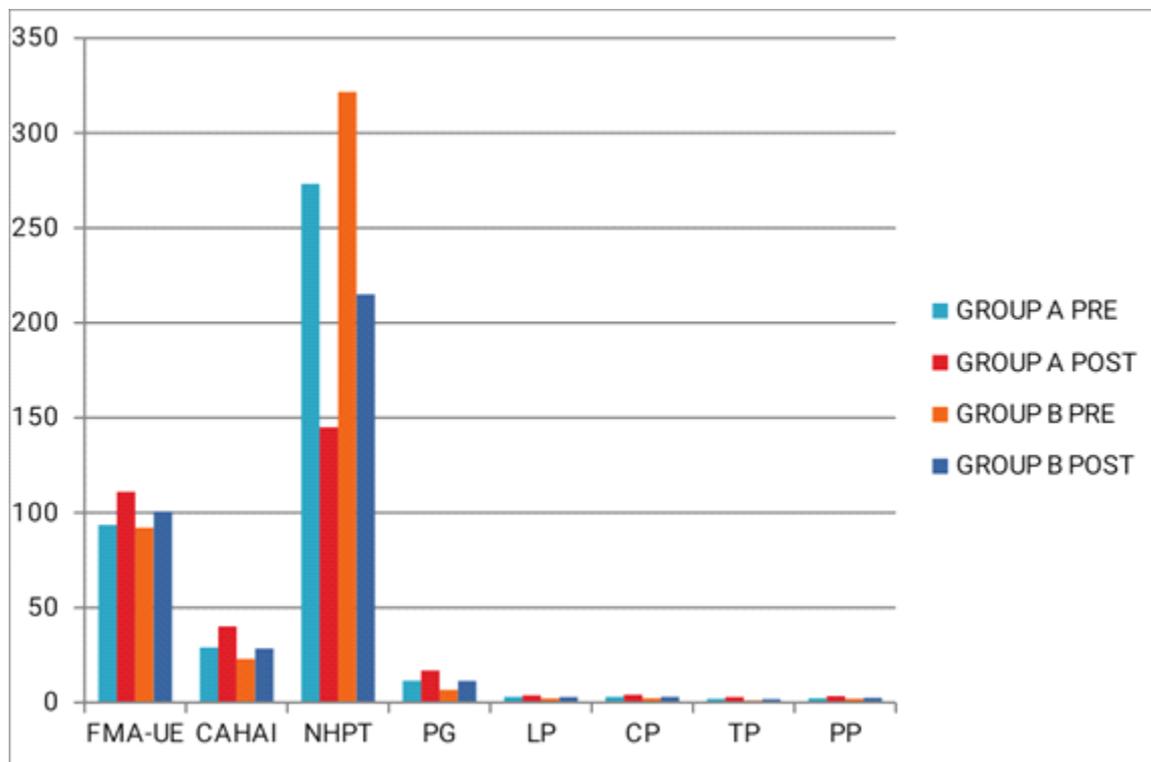


Figure 1: Improvement in FMA-UE, CAHAI, NHPT, PG, LP, CP, TP and PP strength within Group A and Group B

## Discussion

The purpose of stroke rehabilitation training is to enhance arm-hand skill performance to make the best use of functional motor skill.<sup>11</sup> The current study find effect of Saebo- Flex™ device along with Functional Electrical Stimulation (FES) and conventional physiotherapy treatment on hand functions in sub acute stroke survivors was assessed using different scale as aforementioned as outcome measure at Day 0, Day 12 and Day 42 of the intervention. According to Frank who concluded that stroke survivors, who are in early sub-acute phase shows improvement in their performance of activity of daily living while doing rehabilitation training with the dynamic arm orthosis.<sup>11</sup> Although between group comparison of mean score value Day 0, 12, and Day 42 revealed statistical non-significant but clinically improvement was observed in the participant by increasing the mean scores value at Day 0, 12 and Day 42. The possible reason for statistical non significant result for the present study could be due to there were difference in terms of participant's age, gender and side of lesion (Lum et. al., 2002). The comparison of Mean difference in both the groups revealed that experimental group had more increase in FMA-UE scores than the control group.

The Chedock Arm and Hand Inventory programme was used to evaluate functional ability of affected upper extremity which indicated a significant improvement in CAHAI scores of experimental groups relative to that of control group. The NHPT in Group A and Group B were on comparisons of the mean scores were found to be non-significant ( $p>0.05$ ) for both the groups, present study concluded that training with Saebo-Flex™ device along with Functional Electrical Stimulation (FES) and conventional physiotherapy treatment shows clinical improvement in hand dexterity in sub acute stroke participants. Post-stroke rehabilitation with Saebo Flex facilitated clinically significant improvement in arm hand function. Saebo Flex help in regaining the function of upper extremity in stroke survivors with moderate and severe upper limb weakness, particularly those unable to do active finger extension. Saebo Flex helps in keep the wrist and finger in extension position and help in grasp and releases activities.<sup>12</sup>

In Power Grip Strength results of the study showed that there has been an increase in mean values of power grip strength from Day 0 to Day 42 in both groups. The comparison of Mean difference in both the groups revealed that experimental group had more in power grip strength value than the control group. It can be concluded that training with Saebo-Flex™ device along with Functional Electrical Stimulation (FES) shows clinical improvement in hand function in sub acute stroke. N.A. Lannin (2016) conducted the study on Saebo-Flex™ for rehabilitation showed the loss in baseline recorded hand grip measurement over the study period and stated that use of the Saebo-Flex™ is unable to help in regaining the strength of paretic muscles of hand early in post stroke and loss of strength may occurs during training protocol.

Improvement through Saebo-Flex™ in Pinch Strength (Lateral pinch, Tip to tip, Chuck pinch, and Pulp pinch) represent clinically significant reduction in the level of disability but improvement were not statistically significant.<sup>6</sup> This could be due to the limitation such as shorter duration of intervention. Saebo Flex only improves the gross motor function of the upper limb not show the much improvement in the fine activity of the hand. After the onset of stroke the survivors has a difficulty in voluntary opening of hand and loss of control of finger movements manifests as unable to move the single finger without moving other fingers of the hand at the same time. Post stroke there is neuronal hyperactivity and loss of reciprocal inhibition, which cause difficulty in independent movement of fingers face by the stroke survivors. Losing and difficulty in regaining individualization of fingers movements can also be explained by physiological basis of neural control of hand function. Motor cortex is able to controlling the individual finger movements as well as whole hand movements and in cortex there is no separate island of representation for each finger like other parts of body.<sup>13</sup>

## Conclusion

The integrated intervention of Saebo-Flex™ device along with Functional Electrical Stimulation can be used effectively to improve the upper extremity motor functions in sub acute strokesurvivors.

## Recommendations

Further research is needed for the use of Saebo Flex in acute stroke survivors' studies using larger samples size and follow up shall be done. In acute stroke survivors use of Saebo Flex the aim of increasing the use and repetition of early hand and upper limb movement before secondary complications become established.

**Ethical Clearance:** Taken from Institutional Ethical committee, Punjabi University, Patiala.

Source of funding: Self

Conflict of Interest: Nil.

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