

## Introduction

- Stroke is the primary cause of adult neurological disability.
- Ability to walk is the goal most often requested by stroke patients.
- Robotic exoskeletons have shown to be able to provide more intensive patient training, better quantitative feedback and improve functional outcomes.
- Soft wearable robots, which are lightweight and comfortable, allow active participation of the patient while enabling faster and efficient gait.

## Methods

- Design**
  - Randomized controlled trial conducted from April 2022 to September 2022
  - 30 patients randomly assigned to Myosuit® group or control group
- Inclusion criteria**
  - Hemiparetic patients over 19 years old
  - Functional ambulatory category scale between 2 and 4

- Exclusion criteria**
  - Patients who are not fit to the device in terms of height, weight, and excessive spasticity
  - Patients who are not able to ambulate due to medical or musculoskeletal condition

- Myosuit®**
  - Soft wearable exoskeleton robot developed to actively assist hip and knee extension (Figure 1)



Fig1. Myosuit®, a wearable exoskeleton robot developed by MyoSwiss AG

- Training session**
  - 10 training sessions within 5 weeks
  - 5 minutes warmup, 40 minutes of main training and 5 minutes of cooldown exercise
  - Main training comprised of 3 sets of either walking or balance protocol

- Outcomes**
  - 10-meter walking test (10MW), Motricity index of the lower extremities (MI), Berg balance scale (BBS), Timed Up and Go (TUG), 6-minute walking test (6mWT)
  - Gait analysis training system to evaluate kinematic and kinetic gait parameters

## Results

Table 1. Baseline characteristics

Characteristics	Myosuit®	Control	P-value
Patient number	15	15	0.157
Age (years)	63.7±6.5	66.7±4.9	0.157
Weight (kg)	65.2 (10.4)	65.7 (13.2)	0.903
Height (cm)	164.5 (8.7)	163.3 (9.4)	0.733
Stroke etiology			0.71
Hemorrhagic	7	5	
Infarction	8	10	
Years from onset	19.9 (7.5)	17.0 (6.7)	0.274
Baseline FAC			0.763
2	1	2	
3	4	5	
4	10	8	

\*Values are presented as mean±SD

Table 2. Changes in gait function, balance ability and gait parameters from baseline and after training

	Myosuit® (n=15)			Control (n=15)			P-value for group difference
	Pre-training	Post-training	P-value	Pre-training	Post-training	P-value	
10MW <sup>a</sup> (m/s)	0.72 (0.31)	0.85 (0.38)	0.018*	0.70 (0.30)	0.81 (0.28)	0.046*	0.813
MI <sup>a</sup>	62.2 (11.9)	64.1 (11.4)	0.062	59.1 (10.6)	60.9 (10.8)	0.020*	1.000
BBS <sup>a</sup>	44.9 (6.4)	48.0 (7.2)	0.001*	45.2 (7.6)	49.4 (3.6)	0.021*	0.529
TUG <sup>a</sup> (sec)	19.6 (11.9)	16.5 (6.2)	0.119	19.8 (6.9)	17.4 (6.0)	0.054	0.745
6mWT <sup>a</sup> (m)	263.7 (105.3)	275.1 (103.7)	0.126	252.2 (93.2)	279.6 (96.3)	0.015*	0.199
V <sub>intact</sub> <sup>a,c</sup> (m/s)	0.65 (0.27)	0.82 (0.27)	0.006*	0.76 (0.31)	0.88 (0.21)	0.061	0.644
V <sub>affected</sub> <sup>a,c</sup> (m/s)	0.64 (0.31)	0.70 (0.32)	0.354	0.67 (0.50)	0.53 (0.36)	0.298	0.178
SLSP <sup>intact</sup> <sup>b,d</sup> (%)	40.0 (37.4)	41.5 (37.3)	0.561	38.3 (34.2)	40.8 (35.6)	0.847	0.787
SLSP <sup>affected</sup> <sup>b,d</sup> (%)	49.2 (37.5)	44.0 (34.4)	0.229	40.8 (31.9)	44.0 (33.3)	1.000	0.633
	38.2	37.2		37.0	36.7		

<sup>a</sup> Values are presented as mean±SD

<sup>b</sup> Values are presented as median [IQR]

<sup>c</sup> Velocity of intact/affected limb

<sup>d</sup> Single limb support phase of intact/affected limb

Table 3. Training effects on patients with better ambulation ability (FAC 4)

	Myosuit® (n=15)			Control (n=15)			P-value for group difference
	Pre-training	Post-training	P-value	Pre-training	Post-training	P-value	
10MW <sup>a</sup> (m/s)	0.82 (0.33)	0.96 (0.41)	0.0433*	0.88 (0.31)	0.96 (0.23)	0.245	0.605
MI <sup>a</sup>	65.4 (10.6)	67.1 (10.3)	0.2061	59.6 (8.3)	62.4 (8.2)	0.0342*	0.542
BBS <sup>a</sup>	47.9 (4.9)	50.7 (4.4)	0.0002*	49.6 (3.2)	50.9 (3.3)	0.2857	0.176
TUG <sup>a</sup> (sec)	18.1 (14.5)	14.3 (6.1)	0.2134	16.2 (6.6)	13.2 (2.8)	0.1932	0.841
6mWT <sup>a</sup> (m)	294.8 (114.9)	312.1 (105.6)	0.0993	312.5 (77.5)	335.5 (76.2)	0.1167	0.719
V <sub>intact</sub> <sup>a,c</sup> (m/s)	0.66 (0.29)	0.87 (0.30)	0.0153*	0.90 (0.34)	1.00 (0.15)	0.3885	0.424
V <sub>affected</sub> <sup>a,c</sup> (m/s)	0.72 (0.34)	0.81 (0.34)	0.2099	0.93 (0.58)	0.65 (0.43)	0.2511	0.098
SLSP <sup>intact</sup> <sup>b,d</sup> (%)	48.7 (40.1)	42.2 (39.6)	0.4922	39.5 (34.9)	37.2 (34.8)	0.3125	0.859
SLSP <sup>affected</sup> <sup>b,d</sup> (%)	50.7 (38.1)	48.4 (35.3)	0.625	44.6 (33.6)	43.1 (34.4)	0.5469	0.722
	38.2	38.7		36.6	35.9		

<sup>a</sup> Values are presented as mean±SD

<sup>b</sup> Values are presented as median [IQR]

<sup>c</sup> Velocity of intact/affected limb

<sup>d</sup> Single limb support phase of intact/affected limb

- Myosuit® group and the control group patients all showed some progress in outcome measures, but the gait parameters before and after the training was not significantly different (Table 2).
- Subgroup analysis of FAC 4 patients showed significant improvements in 10-meter walking test, Berg balance scale, and gait velocity of the intact limb (Table 3).

## Discussion

- All groups benefited from training regardless of Myosuit® use.
- Patients with relatively spared ambulation function showed better response to Myosuit® training.
- Myosuit® training is feasible and safe to utilize.
- Future directions
  - Study on more patients
  - Evaluate Myosuit® training in acute and subacute patients

## Conclusion

- This study showed that gait training using Myosuit®, a soft exoskeleton type robot, was effective in improving gait function in patients with relatively spared gait function.