Reference

Hahn, Andreas[1]; Moeller, Susan[2]; Schlausch, Arne[3]; Ekmann, Matilda[4]; de Chelle, Gautier[5]; Westerlund, Marie[4]; Braatz, Frank[6]; Mayr, Winfried[7]

Effects of a full-body electrostimulation garment application in a cohort of subjects with cerebral palsy, multiple sclerosis, and stroke on upper motor neuron syndrome symptoms

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Products

EXOPULSE Mollii Suit

Major Findings

With EXOPULSE Mollii Suit:

→ **Positive effects on static and dynamic balance, fall risk, mobility, health utility, upper extremity function** (for subjects with Berg Balance Score < 45 at baseline)

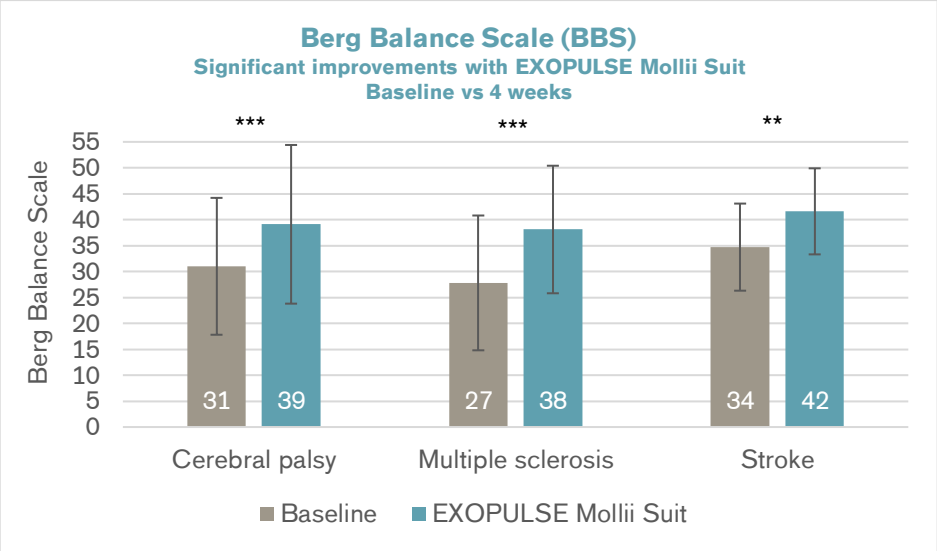
→ **Overall reduction in spasticity-related pain after 4 weeks** (for subjects reporting pain at Baseline)
Cerebral Palsy (CP): -35.8% | Multiple Sclerosis (MS): -26.5% | Stroke: -29.1%

→ **High increase in absolute Health Related Quality of Life (Health Utility)**
Cerebral Palsy (CP): -0.11 | Multiple Sclerosis (MS): -0.18 | Stroke: -0.21

→ **Functional and clinical improvements (effect size, Cohen´s d)*:**

	CP	MS	Stroke
Berg Balance Scale (BBS)	1.64	1.83	1.28
Functional Gait Assessment	1.59	1.28	0.89
10m walk test	0.76	1.07	0.92
Wolf Motor Function Test	1.00	0.93	0.71
Timed Up and Go	0.29	0.83	0.78
EQ 5D 5L	0.50	1.11	1.26
Pain (Subscale of EQ 5D 5L)	1.28	0.78	0.78

** Small effect size < 0.3; medium effect size = 0.3 - 0.8; large effect size > 0.8*



*Significant change: **: p<0.01, ***: p<0.001*

Population

	All subjects	BBS < 45 at baseline
Subjects:	72 (44 female, 28 male)	44 (24 female, 20 male)
Etiology:	CP (n = 29)	CP (n = 16)
	MS (n = 23)	MS (n = 16)
	Stroke (n = 20)	Stroke (n = 12)
Mean age:	36.64 ± 19.8 years	39.16 ± 19.9 years
GMFCS:	1-3	1-3

Study Design

Observational study:

[a]The suit (without stimulation); In case any aid (primarily orthotics) was used by participants during daily living, they were worn also during all assessments.

[b]Use of the suit for 60 minutes daily or every other day during the entire trial period and no change of lifestyle, routine or other applied medical interventions, e.g., physical therapy, should be made during their participation in the study.

For six outcome measures the recorded data were stratified by etiology (CP, MS, Stroke) and a Berg Balance Score <45 at baseline. The results of the pain subscale of EQ 5D 5L were stratified by etiology (CP, MS, Stroke) and subjects reporting pain at baseline. The effect sizes (Cohen´s d) were classified as “large” if d ≥ 0.8.

Results

Body Functions & Structure					Activity			Participation	Environment
Pain	**Spasticity**	**Physiological function**	**Psychological function**	**General Health**	**Activity**	**Mobility & Safety**	**ADLs**	**Preference, Satisfaction, QoL**	**Health Economics**

Category	**Outcomes**		**Results for EXOPULSE Mollii Suit vs. Baseline**				**Sig.***
			Baseline (T0)	60 min (T1)	4 weeks (T2)	**Effect size (T2 vs. T0)**	**T2 vs. T0**
Pain	Pain (Subscale of EQ 5D 5L)	CP	2.79	2.22	1.79	**1.28**	***
		MS	3.06	2.00	2.25	**0.78**	**
		Stroke	2.58	1.83	1.83	**0.78**	*
Activity	Wolf Motor Function Test	CP	53.1	56.1	59.1	**1.00**	***
		MS	64.2	71.7	71.7	**0.93**	*
		Stroke	28.6	30.6	38.3	**0.71**	+

Category	Outcomes	Results for EXOPULSE Mollii Suit vs. Baseline					Sig.*
			Baseline (T0)	60 min (T1)	4 weeks (T2)	**Effect size (T2 vs. T0)**	**T2 vs. T0**
Mobility & Safety	Functional Gait Assessment	CP	11.0	15.5	16.6	**1.59**	***
		MS	11.3	16.7	18.3	**1.28**	**
		Stroke	14.17	16.5	19.0	**0.89**	+
	10m walk test [m/s]	CP	0.96	1.0	1.1	**0.76**	+
		MS	0.66	0.76	0.8	**1.07**	***
		Stroke	0.57	0.67	0.76	**0.92**	**
	Berg Balance Scale	CP	31.0	36.3	39.1	**1.64**	***
		MS	27.8	34.1	38.1	**1.83**	***
		Stroke	34.7	40.8	41.6	**1.28**	**
	Timed Up and Go [s]	CP	26.4	22.0	23.2	**0.29**	*
		MS	29.7	23.3	21.3	**0.83**	***
		Stroke	36.0	25.7	22.3	**0.78**	**
Participation, QoL	EQ 5D 5L (Health Utility)	CP	0.76	0.87	0.87	**0.5**	*
		MS	0.55	0.77	0.73	**1.11**	**
		Stroke	0.54	0.66	0.75	**1.26**	*

* no difference (0), positive trend (+), negative trend (–), significant (*: p<0.5, **: p<0.01, ***: p<0.001), not applicable (n.a.)

Effect size Cohen´s d: ***Small effect size < 0.3; medium effect size = 0.3-0.8; large effect size > 0.8***

Author's Conclusion

"Individualized multi-site transcutaneous electrical stimulation seems to increase ambulation-related skills in subjects with upper motor neuron syndrome stemming from infantile cerebral palsy, multiple sclerosis and stroke. These results obtained with an improved full-body electrostimulation garment show encouraging effects on static and dynamic balance, fall risk and mobility. Upper extremity improvement may be observed as well as an overall increase in health utility and a reduction in spasticity-related pain. Effects are immediate (after one hour of stimulation) as well as sustained (1 month of application) with stimulation applied for 60 minutes daily or every other day. Outcomes being sensitive to such improvements could be identified. The results may improve the quality of individual trial fittings as well as inform controlled trials that are most clearly warranted in this context." (Hahn et al. 2023)

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