Reference

Tina P Torabi [1], Kristian Mortensen [1], Josephine S Michelsen [1], Christian Wong [1,2]

Exploratory Evaluation for Functional Changes of Six-Month Systematic Non-Invasive Electrical Stimulation in a Whole-Body Suit on Children with Cerebral Palsy GMFCS III-V

Neurology International, 17(7), 102. DOI: 10.3390/neurolint17070102, Open Access

Products

EXOPULSE Mollii Suit

Major Findings

With the EXOPULSE Mollii Suit after 24 weeks of stimulation:

→ Reduced Spasticity

- Significant mean decrease in overall spasticity according to the Modified Ashworth Scale (MAS) for the 11 muscles tested ($p = 0.005$).
- Significant mean decrease in overall spasticity according to the MAS for lower extremity muscles ($p = 0.001$) and upper extremity muscles ($p = 0.013$) respectively.
- Significant decrease in spasticity according to the MAS in the hamstrings bilaterally, as well as the left quadriceps (Figure 1). For the Modified Tardieu Scale (MTS), there were no significant improvements after 24 weeks except in the hamstring muscles.

→ Significant improvement in the Goal Attainment Scale (GAS) as demonstrated by an overall improvement in the T-score after 24 weeks (Δ = 10.3 ± 8.8 points, $p = 0.001$).

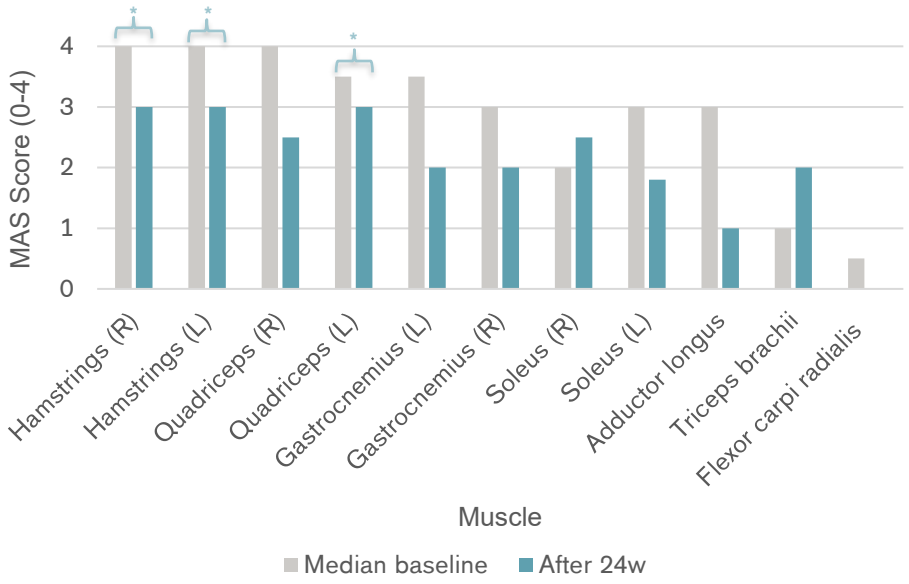


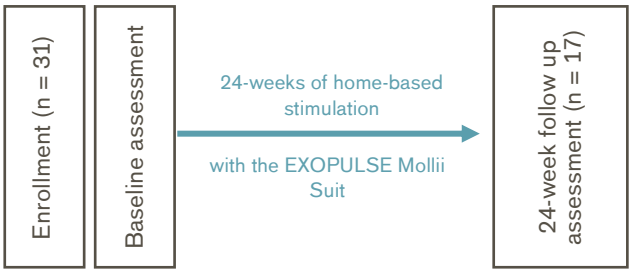
Figure 1. Spasticity according to the MAS for each muscle tested between baseline and 24-weeks follow-up. *$p < 0.05$.

Population

Subjects:	Enrolled: n=31 Completed: n=17 (7 females)
Etiology:	Spastic tetraplegic CP (n=9) Spastic hemiplegic CP (n=1) Mixed dystonic/spastic tetraplegic CP (n=5) Mixed ataxic/spastic tetraplegic CP (n=1) Metachromatic leukodystrophy with predominant spasticity (n=1)
Median age:	11.0 years with a range between 7-17
GMFCS:	III: (n=4), IV: (n = 1), V: (n = 12)

Study Design

Exploratory single arm study:



Participants received 60-minutes of stimulation every other day during a 24-week intervention period. Outcome measures were assessed at baseline and after 24 weeks of home-based stimulation. Some of the endpoints were assessed again at 4- and/or 12-weeks follow-up (FU). However, in the statistical analysis, all outcome measures were evaluated between baseline and 24-weeks follow-up.

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	Sig*
Spasticity	Modified Tardieu Scale (MTS)	No significant change in the MTS after 24 weeks of stimulation, except in the hamstring muscles, where the angle for the first registered catch/resistance (V3)[a] improved from 92.5° to 100° ($p = 0.002$).	0
	Modified Ashworth Scale (MAS)	Significant mean decrease in the overall spasticity of the 11 muscles tested from 2.26 to 1.83 ($\Delta = 0.43$; $p = 0.005$[b]).	++
		Significant mean decrease in the overall spasticity of the lower extremity muscles from 2.47 to 1.9 ($\Delta = 0.57$; $p = 0.006$[b])	++
		Significant mean decrease in the overall spasticity of the upper extremity muscles from 1.73 to 1.48 ($\Delta = 0.25$; $p = 0.016$[b]).	++
		Reduction of the MAS was most pronounced in the Lower Extremity of the hamstrings and the quadriceps muscles.	++
Physiological function	Passive Range of Motion (pROM)	No significant improvements were found in the passive Range of Motion (V1)[a].	0

Category	Outcomes	Results for EXOPULSE Mollii Suit	Sig*
		The passive dorsal flexion in the hand changed from 72.5° to 70° ($p = 0.054$).	0
		In the quadriceps muscles during knee flexion, there was a change from 55° to 80° ($p = 0.066$), and in the hamstring muscles during the straight leg test, there was a change from 92.5 to 100° ($p = 0.074$).	0
Activity	Goal Attainment Scale (GAS)	Significant improvement in the GAS as demonstrated by an overall significant change in the T-score from 38.5 ± 1.0 at baseline to 48.8 ± 8.6 after 24 weeks (Δ = 10.3 ± 8.8 points, $p = 0.004$[b]).	++
		Change in the T-score (Δ) from baseline to 24 weeks for goals related to: • Walking improved by 15.1 points • Body control improved by 15.2 points • Hand and Arm use improved by 27.4 points • Transferring/ position changes improved by 10.2 points • Eating/ mouth control improved by 1.6 points • Standing/weight bearing positions improved by 11.9 points	n.a.
Mobility & Safety	Gross Motor Function Measure (GMFM-66)	In the GMFM-66, a mean increase from 27.87 points at baseline to 32.02 points after 24 weeks was detected (Δ = +4.15 points, $p = 0.122$).	0
		As for specific domains, the mean change (Baseline to 24 weeks) in: • Subcategory A: Lying and Rolling increased from 8.17 points to 8.33 points ($p = 0.586$) • Subcategory B: Sitting from 13.92 to 14.50 ($p = 0.443$). Subcategory C, D and E were not included in the analysis.	0
	Postural and Postural Ability Scale (PPAS)	After 24 weeks no significant changes were found for the PPAS.	0
		A slight mean increase in the PPAS in the quantitative measures for overall standing up, sitting, as well as back and front lying down from 13.7 points to 14.5 points (Δ = 0.8 points) was detected.	n.a.
		In the qualitative evaluation of overall standing up, sitting, as well as back and front lying down the PPAS decreased from 68.3 to 56.6 points (Δ =-11.8 points), indicating a deterioration.	n.a.

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
[a] Velocity of stretch; V1= As slow as possible (minimizing stretch reflex); V3= As fast as possible (faster than the rate of the natural drop of the limb segment under gravity)
[b] Bonferroni correction applied to adjust for multiple comparisons

Author's Conclusion

"Although there were statistically significant but underpowered changes in the MAS after 24 weeks, there were no clinically relevant effects. Exploratorily, we found observer-reliant motor-related functional improvements, which, however, we were unable to detect when trying to quantify them. Donning the suit led to dropout throughout the study. Caregivers need to allocate time, mental capacity and have the physical skill set for donning the suit for long-term use." (Torabi et al., 2025)

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