

## Reference

Perpetuini, D.<sup>1</sup>, Russo, E. F.<sup>2</sup>, Cardone, D.<sup>1</sup>, Palmieri, R.<sup>3</sup>, De Giacomo, A.<sup>3</sup>, Intiso, D.<sup>4</sup>, Pellicano, F.<sup>2</sup>, Pellegrino, R.<sup>5</sup>, Merla, A.<sup>1</sup>, Calabrò, R. S.<sup>6</sup>, & Filoni, S.<sup>4</sup>

# Assessing the Impact of Electrosuit Therapy on Cerebral Palsy: A Study on the Users' Satisfaction and Potential Efficacy

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## Products

### EXOPULSE Mollii Suit

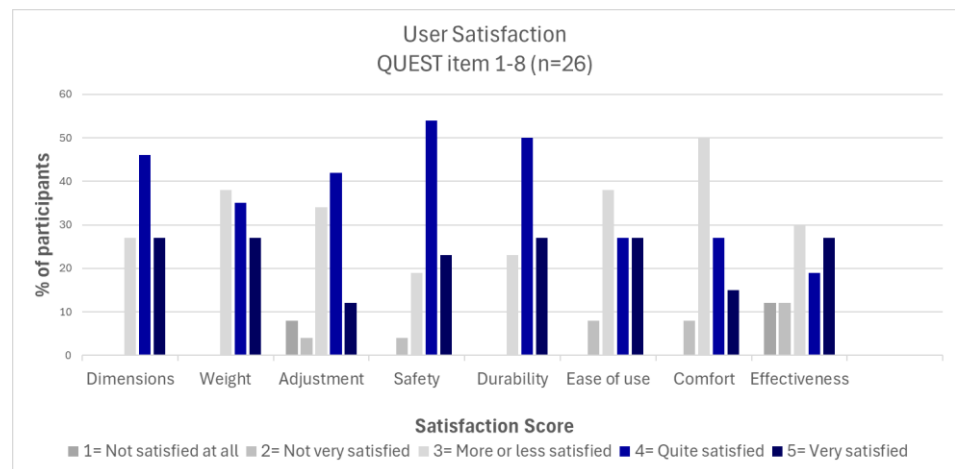
## Major Findings

With the EXOPULSE Mollii Suit after 60 minutes of stimulation:

→ **100% user satisfaction in terms of dimension, weight and durability according to Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)**

→ **User satisfaction of > 80% in terms of safety, ease of use, comfort and adjustment (QUEST)**

→ **76% user satisfaction with the overall effectiveness after 60 minutes of stimulation (QUEST)**



*Distribution of participant satisfaction (1-5) for the first 8 questions of the QUEST regarding the features of the device. The chart is based on information from the original publication.*

→ **Significant increase in trunk control as seen in Level of Sitting Scale (LSS)**

With the EXOPULSE Mollii Suit after 4 weeks of stimulation:

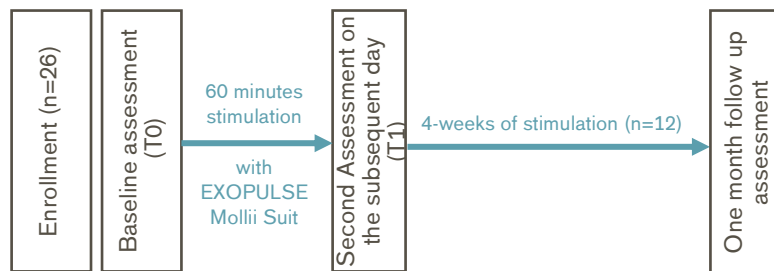
→ **User satisfaction of >90% regarding the professionalism service, service delivery, repair & servicing and follow up**

→ **Improvements in adaptability, competence and self-esteem as seen in the Psychosocial Impact of Assistive Devices (PIADS) questionnaire**

<b>Population</b>	Subjects:	n=26 (8 females)	
	Etiology:	<b>All subjects (n=26):</b> CP Quadriplegia (n=22) CP Diplegia (n=2) CP Hemiplegia (n=2)	<b>Subset (n=12):</b> CP Quadriplegia (n=10) CP Diplegia (n=2) CP Hemiplegia (n=0)
	Mean age: GMFCS:	11±7.00 years I (n=2) II (n=3) III (n=4) IV (n=9) V (n=8)	10±5.69 years I (n=0) II (n=2) III (n=1) IV (n=6) V (n=3)

### Study Design

Interventional, open label pre- to post-test design. All participants received a 60-minute session of stimulation, and a subset of n=12 participants received another 4 weeks of stimulation. Because of local regulations due to the Global health crisis at the time, no clinical measurements were gathered at the 4-week 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 Ashworth Scale (MAS)	No significant change in spasticity after 60 minutes of stimulation	0
Activity	Trunk function Level of Sitting Scale (LSS)	Significant increase after 60 minutes of stimulation (pre=3.84±1.52, post=4.64±1.47; p<0.001) **	++

Category	Outcomes	Results for EXOPULSE Mollii Suit	Sig.*
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Preference, Satisfaction, QoL

Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST)

**Result distribution in % of the total number of participants per score for item 1-8 (n=26)**

n.a.

Score (1-5)**	1	2	3	4	5
Dimensions	0%	0%	27%	46%	27%
Weight	0%	0%	38%	35%	27%
Adjustment	8%	4%	34%	42%	32%
Safety	0%	4%	19%	54%	23%
Durability	0%	0%	23%	50%	27%
Ease of use	0%	8%	38%	27%	27%
Comfort	0%	8%	50%	27%	15%
Effectiveness	12%	12%	30%	19%	27%

**Result distribution in % of the total number of participants per score for item 9-12 (n=12)**

Score (1-5) **	1	2	3	4	5
Service delivery	0%	7%	20%	40%	33%
Repairs and servicing	0%	13%	33%	27%	27%
Professionalism services	0%	0%	34%	33%	33%
Follow up	0%	6%	40%	27%	27%

Psychosocial Impact of Assistive Devices (PIADS)

**Result distribution for the different subscales per user (n=12)**

n.a.

Score (-3 to +3)***	Competence Subscale	Adaptability Subscale	Self-esteem Subscale
Patient 1	1.00	2.33	0.88
Patient 2	2.17	1.83	1.50
Patient 3	0.33	0.33	0.25
Patient 4	0.00	0.00	0.00
Patient 5	1.25	1.17	1.38
Patient 6	1.17	0.00	0.00
Patient 7	0.00	0.00	0.00
Patient 8	1.25	1.83	1.50
Patient 9	0.00	0.00	0.00
Patient 10	0.17	0.67	0.00
Patient 11	0.67	0.50	0.75
Patient 12	0.08	0.17	0.25
<b>Mean</b>	<b>0.67</b>	<b>0.74</b>	<b>0.59</b>
<b>Standard deviation</b>	<b>0.70</b>	<b>0.85</b>	<b>0.60</b>

Category	Outcomes	Results for EXOPULSE Mollii Suit	Sig.*
<p>* no difference (0), positive trend (+), negative trend (-), significant (++/--), not applicable (n.a.)</p> <p>**not satisfied at all (1); not very satisfied (2); more or less satisfied (3); quite satisfied (4); very satisfied (5)</p> <p>***maximum negative impact (-3); somewhat negative impact (-2, -1); no impact (0); somewhat positive impact (+1, +2); maximum positive impact (+3)</p>			

### Author's Conclusion

"This study investigates the impact of the employment of the EMS on CP children's ability to maintain trunk control. Specifically, after undergoing a single EMS session, LSS showed a discernible improvement in children's trunk control. In addition, the QUEST and the PIADS questionnaires demonstrated a good acceptability and satisfaction of the garment by the patients and the caregivers. However, it is important to consider these findings as an initial stage in the progression toward more extensive, varied, and long term investigations in subsequent research endeavors. In fact, future investigations can offer more definitive proof regarding the usefulness and efficacy of the EMS for pediatric individuals affected by CP."

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