Evaluating the Impact of the Cionic Neural Sleeve™ on Quality of Life in Multiple Sclerosis Patients: A Pilot Study

Bruce Wang[1], Doug Wajda[2], Jon Sakai[3], Jen Yee[3], Rebecca Webster[3]

[1]Value Genome, New York, NY, USA, [2]Cleveland State University, Cleveland, OH, USA, [3]Cionic, Scotts Valley, CA, USA

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Introduction

Background

- Medications alone provide limited improvements in mobility for patients with multiple sclerosis (MS).
- This study evaluated the Quality of Life (QoL) in MS patients using the Cionic Neural Sleeve™ (CNS), an advanced bionic garment that combines motion analysis with sequential stimulation of up to four muscle groups in the upper and lower leg.
- The EQ-5D, a widely recognized tool for assessing health-related QoL, was used to evaluate five key domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

Objective

- This study evaluated the Quality of Life (QoL) of MS patients using the Cionic Neural Sleeve™

Methods

Study Design

- A prospective, single-site pilot study was conducted, enrolling six ambulatory adults with relapsing-remitting or progressive multiple sclerosis (MS). Fig 1.
- Participants were randomly divided into two groups: Group A used the CNS for 6 weeks, followed by 6 weeks without it, while Group B started with 6 weeks without the CNS and then used it for 6 weeks.
- Both groups had a 1-week baseline period without the CNS and a 4-week follow-up phase.

Data and Analysis

- The EQ-5D-5L (EuroQol-5 Dimensions, 5-Level) questionnaire was administered before and after CNS use
- Analysis focused on the five dimensions of the EQ-5D, which were adjusted and weighted according to U.S. population norms.
- Data analysis included descriptive statistics.

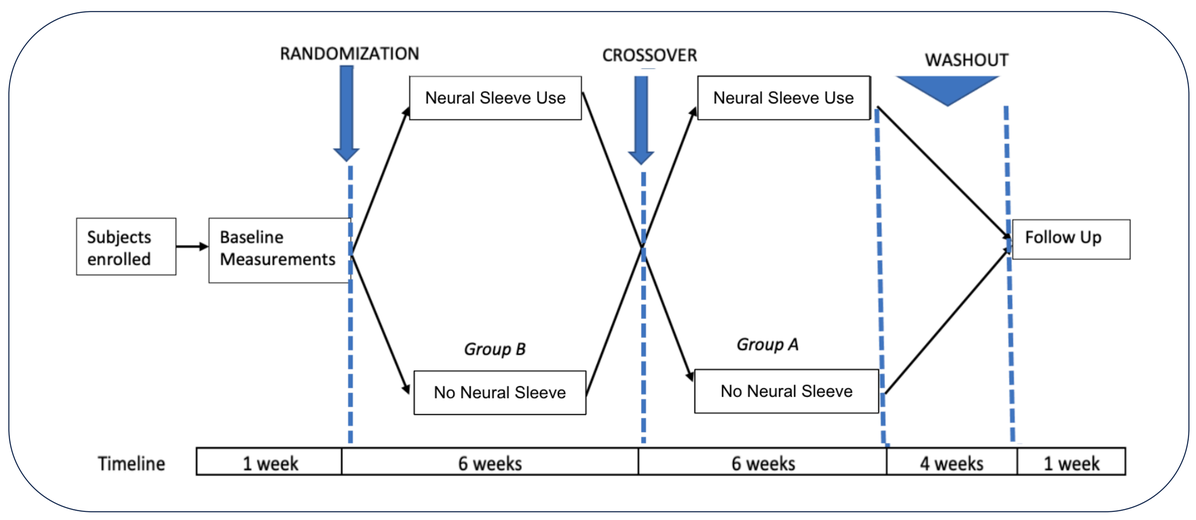

Figure 1 – Study Design

Results

- The average EQ-5D score increased from 0.63 before CNS to 0.78 after CNS, reflecting an absolute change of 0.16 or 24.9%, indicating an enhancement in quality of life (QoL). Fig. 2.
- All EQ-5D dimensions showed improvements following the use of CNS.
- Mobility and Self-Care experienced the greatest enhancements, with average scores increasing by 31.3% and 40.0%, respectively.
- Anxiety/Depression ratings improved by an average of 14.3%.
- Usual Activities and Pain improved by 14.3% and 10.0%, respectively.
- The overall improvement in the EQ-5D score was primarily driven by gains in Self Care, which contributed to 30.5% of the total score change, and Mobility, which contributed to 28.9% to the total score change. Fig. 3

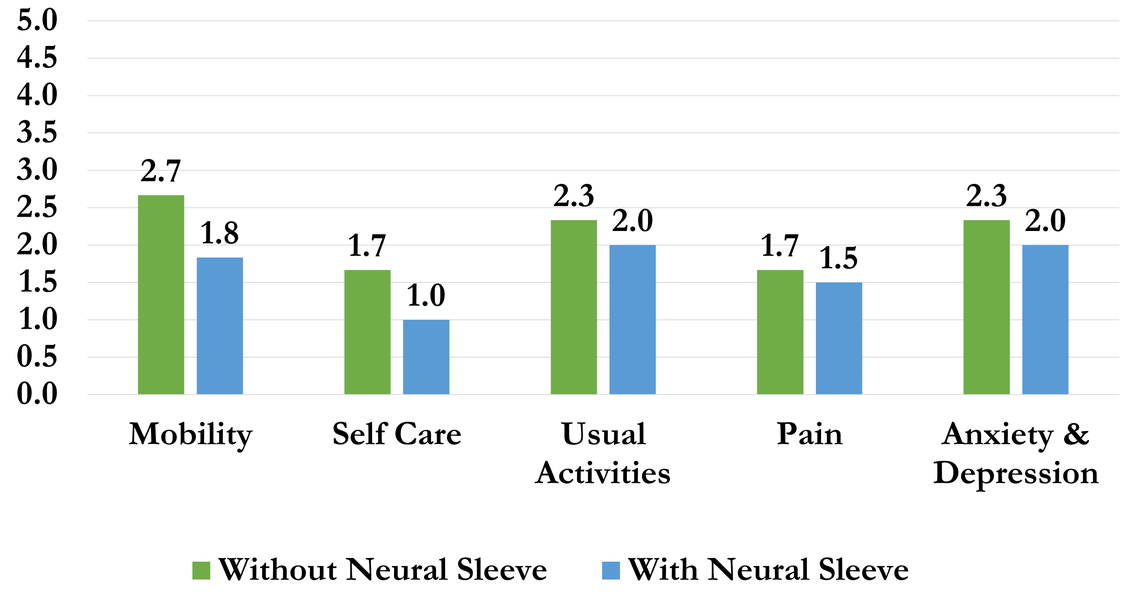

Figure 2 – Average EQ-5D Survey Response: Before and After 6 weeks of CNS Usage (n=6)

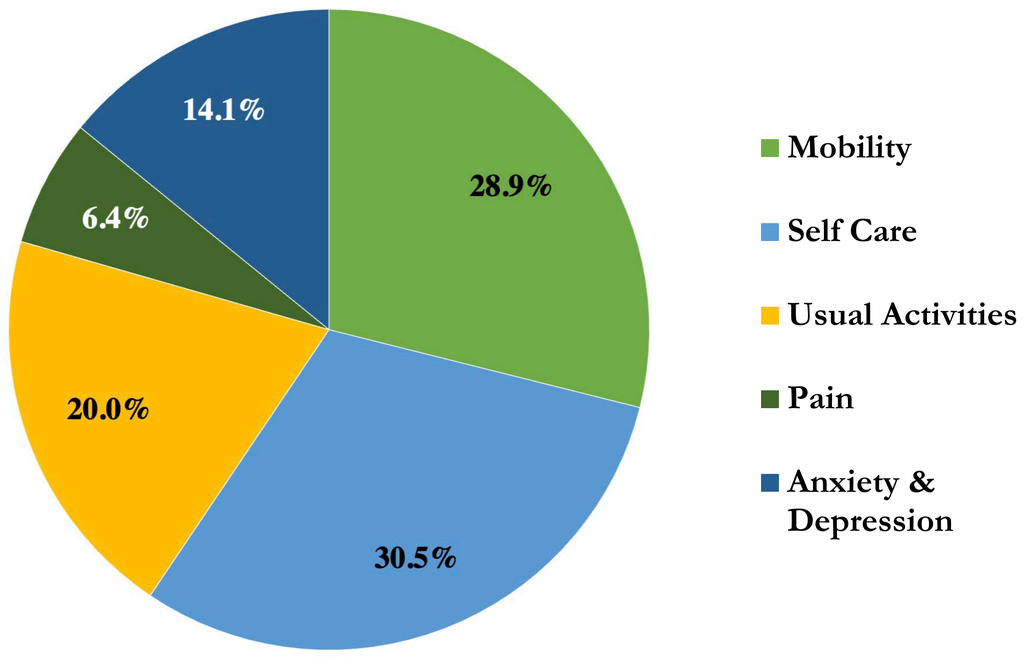

Figure 3 – Percentage Contribution to Total Increase in EQ-5D Aggregate Score

Discussion

Interpretation of Results

- The Cionic Neural Sleeve showed a significant positive impact on quality of life across several domains, including mobility, self-care, and pain/discomfort. Post-use scores indicate improved functional outcomes, particularly in mobility where severe impairments were markedly reduced.

Clinical Implications

- These findings suggest that the Cionic Neural Sleeve can be an effective intervention to enhance mobility and reduce pain, leading to overall improvements in daily functioning and quality of life in patients with mobility impairments

Conclusion

Conclusion

- The comparison of with and without Cionic Neural Sleeve use demonstrates substantial improvements in patient quality of life, particularly in enhancing mobility and improving capability to perform usual daily activities.
- Further research is recommended to explore long-term benefits and validate these findings across larger and more diverse populations. Incorporating the Cionic Neural Sleeve into treatment protocols could offer significant benefits for patients with mobility challenges.

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