Functional and Safety Assessment of Smart Textile Neurostimulation Sleeve Garments: A Pre-Clinical Study

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INTRODUCTION

Neurostimulation delivers electrical pulses to modulate neuromuscular activity [1]. It is widely used for applications ranging from pain management to rehabilitation. Conventional practice relies on manually positioned hydrogel electrodes, which, while effective, can cause skin sensitization and irritation during frequent or prolonged use [2]. These limitations have motivated the development of reusable textile electrodes [3] that can be seamlessly integrated into washable garments, offering potential improvements in comfort, usability, and cost-effectiveness. This pre-clinical safety and feasibility study evaluated smart textile calf-sleeve neurostimulation garments (Smart Ongoing Circulatory Compression, SOCC) designed to activate ankle flexor and extensor muscles to enhance venous return and potentially reduce the risk of deep vein thrombosis (DVT), in healthy adults.

MATERIALS AND METHODS

20 healthy participants (Veritas REB# 3395, 12 male, 8 female) completed functional testing using lower-leg neurostimulation sleeves with stainless-steel textile electrodes covered with medical-grade hydrogel pads. The garments incorporated fully textile-based circuitry with embedded interconnects, eliminating the need for external wiring. Electrodes were positioned over the tibialis anterior (TA) and gastrocnemius (GAS) muscles. Outcome measures included electrode-skin impedance, detection threshold (DT), motor threshold (MT), and current intensity at 20% maximum voluntary contraction (MVC). DT is the minimum current amplitude needed to sense electrical stimulation, while MT is the minimum current amplitude needed to initiate movement of the ankle [1,3]. Participants also rated stimulation comfort and perceived intensity [1,3]. Short-term testing was performed on all participants (n=20), while long-term testing (at 0, 2, 4, and 6 hours) was performed on a subset of the participants (n=10; 5 male, 5 female).

RESULTS AND DISCUSSION

Initial impedance averaged 2732 ± 752 Ω (TA) and 3306 ± 646 Ω (GAS). No statistically significant difference in impedance occurred over 6 hours ($p>0.05$). Stimulation parameters (Fig 1) were also consistent over time DT averaged 6.71 ± 2.76 mA (TA) and 5.40 ± 1.57 mA (GAS); MT averaged 22.15 ± 5.91 mA (TA) and 25.95 ± 6.16 mA (GAS); 20% MVC current values averaged 27.75 ± 7.51 mA (TA) and 29.45 ± 7.80 mA (GAS). Comfort ratings also remained favourable throughout (stimulation comfort: 2.8–3.1/7, garment comfort: 1.95–2.50/7; 1 = very comfortable, 7 = very uncomfortable).

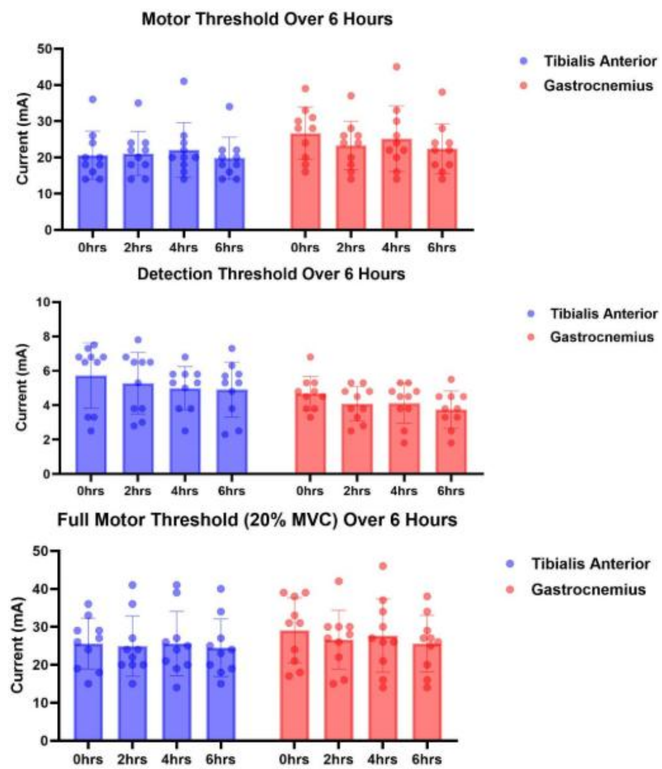

Fig 1 Sensorimotor response for 6 hours of use, with no statistically significant difference.

CONCLUSIONS

The garments demonstrated stable stimulation performance and high user comfort for at least 6 hours of wear in typical adults. These findings confirm safety and functional performance, supporting progression to external clinical trials in targeted patient population.

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