Benefits of innovative Exopulse Mollii full-body electric garment intervention on lower limb strength, gait speed, lower back pain, quality of life, and fatigue in a female with multiple sclerosis – a case study

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Abstract

Background: Individuals with multiple sclerosis (MS) experience a variety of neurological deficits that affect their mobility, muscle tone, sensation, and reduce their quality of life. A full-body electric garment using Exopulse Mollii device may be an innovative treatment method for symptoms management in MS.

Aims: This study aimed to investigate non-invasive Exopulse Mollii intervention on muscle strength, gait, pain, quality of life, and fatigue in a female patient with MS.

Material and methods: Verbal consent was obtained. Frequency and duration of treatment: 60 minutes, 3 times a week, for a month. Stimulation parameters: pulse width 25-175 microseconds, constant frequency current of 20 Hertz. Standardized outcome measures: Five Times Sit to Stand Test (5xSTS), Timed Up and Go Test (TUG), Visual Analogue Scale (VAS), Multiple Sclerosis Impact Scale (MSIS-29), and Modified Fatigue Impact Scale (MFIS). Data were recorded at baseline (T1) and 1 month later (T2).

Results: No side effects were reported. Compliance was 100%. Post-treatment changes were 5xSTS: 7.9 sec; TUG: 9.1 sec; VAS for pain 6 points; MSIS-29 total 29 points; MFIS total: 32 points. This patient has moved from being clinically fatigued to non-clinically fatigued within 1 month of therapy.

Conclusions: This intervention was successful and well tolerated by the patient. This single case study reported improvements across all used measures. Further studies, including pilot and randomized control trials, are warranted to investigate this promising method.

Key words

multiple sclerosis, electrical stimulation, sensory based device, advanced technology, Exopulse Mollii garment.

Introduction

Multiple sclerosis (MS) is a progressive, degenerative disease of the central nervous system that affects approximately 2.2 million people worldwide [1]. MS is associated with a variety of symptoms, including walking problems [2], muscle weakness [3], spasticity up to 84% [4], fatigue, and cognitive deficits [5]. Individuals with MS have sensory deficits, poor body schema perception, and difficulty processing movements [6]. Walking restriction is one of the most common problems in MS, with as many as 85% of people experiencing mobility issues [2].

Physiological gait requires precise coordination of the activity of many muscle groups in different phases of the gait cycle. An imbalance in tone and muscle contraction between agonists and antagonists can lead to altered gait patterns. Tripping and falls are commonly observed consequences of abnormal gait in patients with MS (PwMS), they decrease the functional activity of this group and affect their quality of life [7].

The Exopulse Mollii garment delivers electrical stimulation to 42 key muscles in the body. The primary benefits of the garment are a reduction of tone in spastic muscles, facilitation of muscle contraction in weaker muscles, and alleviation of pain. This enables a greater range of movement and leads to better motor function.

Two recent small studies in chronic stroke (n=20) and cerebral palsy (n=16) indicated some positive effects of Exopulse Mollii garment on spasticity, passive range of movement, and sensorimotor functions [8, 9]. There is very limited evidence of the potential benefits of this innovative assistive technology in the MS population. This case study aimed to investigate the benefits of the Exopulse Mollii garment on walking speed, functional muscle strength, and quality of life in a female with primary progressive MS.

Material and methods

Case description

A 27-year-old woman was diagnosed with primary progressive MS in January 2015. The assessment took place in March 2020 at a physiotherapy practice in Killaloe Co. Tipperary in Ireland. The patient signed a written consent form and was checked for contraindications for electrical stimulation. She had no prior medical or surgical history. The patient was mobilizing with the assistance of 2 elbow crutches. She reported increased tightness in lower limbs, greater on the right side, mainly in the right gastrocnemius muscle and right quadriceps, increased fatigue levels, lower back pain, slow gait, and limitations in many daily activities. She was taking Fampridine, Rituximab, and Gabapentin. She hoped to improve gait speed, reduce lower back pain, improve performance on stairs and reduce daily fatigue.

Equipment

The Exopulse Mollii is a full-body electrical garment with 58 dry, embedded silicone electrodes (**Figure 1**). It consists of a pair of trousers, a jacket, and a detachable control unit that sends electrical signals to the user through electrodes placed on the inside of the garment. The numbers, intensity, and location of electrodes that are used during Exopulse Mollii stimulation depend on the individual's functional impairments and those muscles that require stimulation. The Exopulse Mollii garment uses constant current at a frequency of 20 Hertz with a square wave pulse shape and pulse width between 25 – 175 microseconds. The control unit is programmed individually before use and then connected to the garment. The Exopulse Mollii's mechanism is based on the well-known theory of reciprocal inhibition of the spastic muscle [10, 11].

Figure 1. Exopulse Mollii device.

Intervention

The assessment was performed at baseline (T1) by an experienced neurological physiotherapist who had previously undergone Exopulse Mollii training and had extensive experience in setting up Exopulse Mollii for various neurological patients. The activation and intensity of the selected pair of electrodes were based on the initial assessment. The settings were saved in the control unit, making it simple for the device to be used by a patient at home. The patient was instructed on how to use the Exopulse Mollii garment and to apply it for 60 minutes, 3 times a week, for a month. The patient was advised to continue everyday life activities as usual. Usability and perceived effects were monitored by a physiotherapist, through a weekly phone call. Data were collected at baseline and 1 month later (T2) by the same physiotherapist.

Outcome measures

The Five Times Sit to Stand Test (5xSTS) measures functional muscle strength in lower limbs. It requires participants to first sit on a chair with arms folded across their chest, then stand up and sit down as quickly as possible 5 times, keeping the arms folded across the chest. 5xSTS is a valid measure of muscle strength and balance in MS [12].

The Timed Up and Go (TUG) measures dynamic balance and is quantified in seconds. It requires participants to stand up from a chair, walk 3 meters, turn around, walk back, and take a seat. The TUG test showed good reliability and concurrent validity in individuals with MS [13].

The Visual Analogue Scales (VAS) were used to determine the patient's subjective feeling of pain. VAS is commonly used to assess changes in mus-

culoskeletal pain intensity and has moderate to good test-retest reliability [14]. It is a 10-point Likert scale where 0 indicated "no pain" and 10 "the worst imaginable feeling".

The Modified Fatigue Impact Scale (MFIS) was used to assess the effects of fatigue on physical, cognitive, and psychosocial functioning [15]. It is a self-report questionnaire that has good reliability [16] and validity [17] in people with MS.

The impact of MS was measured using the Multiple Sclerosis Impact Scale version 2 (MSIS-29). It is a self-report questionnaire measuring the physical (20 items) and psychological (9 items) impact of MS. The MSIS-29 has high test-retest reliability [18], good validity, and sensitivity [19] in people with MS. Scores were converted to a scale of 1 - 100 using the formula proposed by Hobart et al. [18].

Results

The patient used Exopulse Mollii garment for 1 month at home 3 times a week for an hour without reporting any adverse effects throughout the entire trial. Compliance was 100%. Improvements were reported in all outcome measures used in this case study. There was a clinically significant improvement in fatigue, a change of 32 points on the MFIS, indicating that this patient went from being clinically fatigued to non-clinically fatigued in 4 weeks. Details are reported in **Table 1**.

Table 1. Pre- and post-trial changes in all outcome measures.

Outcome measure	T1	T2	Change	% Change
5 x STS in seconds	20.73	12.76	7.97	38.4
TUG in seconds	29.09	19.97	9.12	31.4
MSIS29 physical, range 0-100	61.6	33.3	28.3	45.9
MSIS29 psychological, range 0-100	74.1	29.6	44.5	60.1
MFIS 0-84 points	68	36	32	47.1
VAS 0-10 points	6	0	6	100

Abbreviations: T1, baseline; T2, post 4 weeks; 5 x STS, five times sist to stand test; TUG, the Timed Up and Go test; MSIS29 physical, the Multiple Sclerosis Impact Scale 29, physical subscale; MSIS29 psychological, the Multiple Sclerosis Impact Scale, psychological subscale; MFIS, the Modified Fatigue Impact Scale; VAS – Verbal Analogue Scale for pain.

Discussion

This case study provides preliminary evidence of the potentially beneficial effects of the innovative Exopulse Mollii garment treatment in a person with multiple sclerosis. Improvements were found at the level of body structure and function (functional lower limb strength and lower back pain sensation), at the activity level (walking speed), and the participation level (quality of life and fatigue). These changes were apparent after 1 month of using Exopulse Mollii for an hour, 3 times a week in an individual with primary progressive MS. This case study demonstrated high

compliance to and high home usability of Exopulse Mollii treatment, which seems to be a very important factor, especially now that access to regular physiotherapy might be limited due to the COVID-19 pandemic and more people exercise at home.

To the best of our knowledge, this is the first study reporting the effects of Exopulse Mollii treatment in MS. There is some available evidence of the positive effects of Exopulse Mollii treatment in stroke and cerebral palsy. Recent research conducted by Palmcranz et al. (2020), investigated the benefits of Exopulse Mollii garment treatment in chronic (>12 months) stroke survivors [8]. Exopulse Mollii garment was set up individually for 20 patients who presented with spasticity and hemiplegia after stroke. The authors reported a perceived positive effect on functioning in 60% of the patients included in the study. The most commonly reported improvements were related to a reduction in muscle tone (n=9), improved gait pattern function (n=7), and voluntary movement in the upper extremity (n=6). In relation to spasticity, the authors observed a significant decrease in a neural component of the wrist flexors, however, manual assessments of the upper and lower limbs using the Modified Ashworth Scale (MAS) showed no positive change. On the other hand, Hedin et al. (2020) [9], reported a significant reduction in muscle tone assessed with MAS after 1 and 6 months of using Exopulse Mollii garment in a population with Cerebral Palsy. Discrepancies in reporting changes in spasticity may be due to the specificity of the outcome measures used to evaluate the changes. The MAS has low accuracy in diagnosing reflex-mediated resistance to passive stretch and cannot differentiate between the active neural component and the passive elastic component. More robust studies with comparison groups are warranty to explore the potential benefits of Exopulse Mollii for spasticity, as it may be an alternative approach to more expensive pharmacological (baclofen) or surgical interventions. It is also worth noting that the long-term effects of Exopulse Mollii on spasticity may be different in progressive conditions, such as MS or Parkinson's disease, than in non-progressive conditions and need to be further investigated.

This case study reports a clinically significant improvement in the level of perceived fatigue after a month of using the Exopulse Mollii garment. The patient began treatment with a score greater than 38 points on the MFIS, indicating clinically significant fatigue [20], and the score reduced by more than 50% over 1 month. Anecdotally, subjective reports from other Exopulse Mollii users suggest that Mollii makes arms and legs feel "lighter" and therefore easier to move. The movement then becomes effortless and economical. Between 75%-95% of patients with MS experience fatigue, and up to 69% of these patients consider it one of the most disabling features of MS [21]. Ziemssen, (2009) [22], reported that fatigue is a primary determinant of poor quality of life and can affect people both physically and mentally. This particular case study provides initial data on the beneficial effects of Exopulse Mollii on fatigue levels in patients with MS.

This case study describes real changes in two standard functional tests (5xSTS and TUG). The 5xSTS measures the functional strength of the lower limbs and is easy to use in clinical practice in comparison to isokinetic dynamometry. Isokinetic dynamometry is considered the 'gold standard' of strength testing tools but is less accessible in clinical practice. In our case study, the 5xSTS score changed by 38.4% after Exopulse Mollii intervention and exceeded the > 25% change that can be considered a genuine change in MS [12]. Similarly, there was a 31.4% change in TUG time, exceeding the 31% mark of a real change for this test in the MS population, as reported by Nilsagard, (2007) [23]. Such data needs to be interpreted with extreme caution due to the exploratory nature of the study design and the lack of a control group.

This study has many limitations and is far away from a robust design, but our intention was to

conduct a simple and exploratory case study that explored the feasibility of a hybrid treatment approach, where the assessment was conducted in clinical practice, but the treatment was delivered at the patients' home. At the time of COVID-19, where access to regular sessions with a rehabilitation team is limited and a hands-on approach is not favorable, this case may provide an alternative and effective method of treating individuals. More evidence is emerging on the positive effects of augmenting rehabilitation robotics and advanced technologies [24-27]. Many of these devices can be used at home, are easily disinfected, and provide a high degree of therapy.

Conclusions

This case study demonstrated an innovative approach to treating MS patients with an individually programmed full-body electrical Exopulse Mollii garment at home. Preliminary data has shown improvement across all three domains of the International Classification of Functioning (ICF). High compliance and home usability are additional benefits during Covid. Further research, including a pilot study and a randomized control trial, is needed to explore the feasibility and significance of the effects of this innovative treatment in the MS population.

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