ISSN 1855-9913

Journal of the Laser and Health Academy
Vol. 2024, No.1; www.laserandhealth.com

Repetitive Peripheral Magnetic Stimulation for Pain Management – A Case Series with a StarFormer Magnetic Stimulator

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ABSTRACT

Magnetic stimulation using the StarFormer® device was employed for pain management in four patients with chronic pain, whose average monthly VAS pain levels prior to treatment ranged from 2 to 5. No adverse events were reported during treatment or in the one-month period after treatment. All patients experienced a reduction of their pain level during the course of treatment, and a lower average monthly pain at the one-month follow-up as compared to the average monthly pain before treatment. This is consistent with the results of clinical studies performed with equivalent devices for repetitive peripheral magnetic stimulation, reflecting on the safety and effectiveness of this modality for pain management.

Key words: Magnetic stimulation, neuromodulation, pain management, chronic pain, back pain.

Article: J. LA&HA, Vol. 2024, No.1; onlineFirst.
Received: 26 August, 2024; Accepted: November 4, 2024

I. INTRODUCTION

Pain is the number one reason people seek medical attention worldwide and accounts for a significant share of health-related costs.[1] It is estimated that chronic pain is present in 28%-50% of the general population[2] and that up to 30% of chronic pain patients remain symptomatic despite undergoing medical treatment.[3] New treatment approaches are emerging in the field of pain management, including drugs and interventions with novel mechanisms of action. Among them, neuromodulatory techniques have been broadly explored in chronic pain patients. Neuromodulation is defined as a treatment (drug or procedure) that potentiates or inhibits the transmission of nerve signals, but is not the actual means of transmission itself.[3] Stimulation of peripheral nerves in different locations through neuromodulation is thought to modulate afferent input of pain signals travelling to the brainstem and subsequent higher order processing, leading to a reduction of pain sensation.[4] Repetitive peripheral magnetic stimulation (rPMS) is a non-invasive treatment method that can penetrate to deeper conductive structure with painless stimulation[5]. It can be used as a non-invasive neuromodulation technique for pain relief, via manipulation of neurotransmitter systems important to the sensation of pain.

Many studies emphasize the absence of adverse events associated with rPMS treatment[5], highlighting this method as highly tolerable and safe. Randomized controlled trials have demonstrated the effectiveness of rPMS for the reduction of musculoskeletal[6] and lower back pain[5,7] with different magnetic stimulator devices. The aim of this case series was to assess the safety and effectiveness of pain management with the StarFormer magnetic stimulator.

II. CASES

In this case series we report about treating 4 patients with chronic pain. All patients were treated in the period from March to April 2024 by the same operator, which is a healthcare professional. Before starting treatment, all patients reported their health complaint, and their basic personal information was recorded. Three patients (patient 1, patient 2 and patient 3) reported chronic pain in the lumbar area (lower back pain) and one patient (patient 4) reported chronic pain in the shoulder blade area. The patients' demographic and treatment protocol is presented in Table 1. All patients signed an informed consent form before staring treatment. The treatment consisted of 7 or 8 sessions of rPMS performed twice a week (Tables 2.-5.). The intensity of rPMS as the % of maximal stimulator output (% MSO) of each session was adjusted to the patients' tolerance level.

Patient-reported outcomes included:
- Patient's self-rated health on a vertical visual analogue scale (EQ-VAS) before treatment and after treatment completion
- Patient's self-rated VAS pain level after every session
- Patient's self-rated average VAS pain level in the month preceding treatment (reported before first session) and average VAS pain level in the month after completing the treatment (reported at the 1-month follow-up)
- Patient's self-reported adverse events during or after treatment (reported at any time and up to the 1-month follow-up)

Table 1: Basic patient demographic data and description of corresponding indication and treatment intervention.

Patient No.	Age	Sex	Indication	Intervention
1.	66	Female	Chronic pain in the lumbar area	8 sessions, StarFormer IntimaWave chair, Chronic back pain program, 2x/week
2.	67	Male	Chronic pain in the lumbar area	8 sessions, StarFormer IntimaWave chair, Chronic back pain program, 2x/week
3.	44	Male	Chronic pain in the lumbar area	7 sessions, StarFormer IntimaWave chair, Chronic back pain program, 2x/week
4.	44	Male	Chronic pain in the shoulder blade area	7 sessions, StarFormer handheld applicators, Chronic pain program, 2x/week

Table 2: Treatment protocol and patient-reported outcomes for Patient 1.

Time point	Date	Stimulation Protocol		Average monthly pain VAS (0-10)	Patient health EQ VAS (0-100)	Pain VAS (0-10) after treatment
		Intensity (%MSO)	Duration (min)			
Before treatment	12.3.2024	/	/	5	75	/
Session 1	12.3.2024	40%	15	/	/	3-4
Session 2	15.3.2024	44%	15	/	/	3
Session 3	27.3.2024	48%	15	/	/	2
Session 4	29.3.2024	50%	15	/	/	1
Session 5	5.4.2024	54%	15	/	/	0
Session 6	9.4.2024	58%	15	/	/	0
Session 7	11.4.2024	58%	20	/	/	0
Session 8	15.4.2024	58%	20	/	80	1
1 month FU	15.5.2024	/	/	2	/	/

Table 3: Treatment protocol and patient-reported outcomes for Patient 2.

Time point	Date	Stimulation Protocol		Average monthly pain VAS (0-10)	Patient health EQ VAS (0-100)	Pain VAS (0-10) after treatment
		Intensity (%MSO)	Duration (min)			
Before treatment	12.3.2024	/	/	3	70	/
Session 1	12.3.2024	40%	15	/	/	2
Session 2	15.3.2024	44%	15	/	/	0
Session 3	27.3.2024	48%	15	/	/	0-1
Session 4	29.3.2024	50%	15	/	/	0
Session 5	5.4.2024	54%	15	/	/	0
Session 6	9.4.2024	58%	15	/	/	0
Session 7	11.4.2024	58%	20	/	/	0
Session 8	15.4.2024	58%	20	/	70	0
1 month FU	15.5.2024	/	/	0	/	/

Table 4: Treatment protocol and patient-reported outcomes for Patient 3.

Time point	Date	Stimulation Protocol		Average monthly pain VAS (0-10)	Patient health EQ VAS (0-100)	Pain VAS (0-10) after treatment
		Intensity (%MSO)	Duration (min)			
Before treatment	5.3.2024	/	/	2	77	/
Session 1	5.3.2024	36%	15	/	/	1
Session 2	7.3.2024	40%	15	/	/	1
Session 3	12.3.2024	44%	15	/	/	1
Session 4	19.3.2024	56%	15	/	/	0
Session 5	21.3.2024	56%	15	/	/	0
Session 6	27.3.2024	58%	20	/	/	1
Session 7	29.3.2024	58%	20	/	90	0
1 month FU	5.4.2024	/	/	0	/	/

Table 5: Treatment protocol and patient-reported outcomes for Patient 4.

Time point	Date	Stimulation Protocol		Average monthly pain VAS (0-10)	Patient health EQ VAS (0-100)	Pain VAS (0-10) after treatment
		Intensity (%MSO)	Duration (min)			
Before treatment	26.3.2024	/	/	2	95	/
Session 1	26.3.2024	30%	15	/	/	0
Session 2	5.4.2024	34%	15	/	/	0
Session 3	8.4.2024	38%	15	/	/	0
Session 4	15.4.2024	46%	15	/	/	0
Session 5	23.4.2024	50%	15	/	/	0
Session 6	7.5.2024	56%	15	/	/	1
Session 7	17.5.2024	56%	15	/	95	0
1 month FU	15.5.2024	/	/	1	/	/

The patients' ages ranged from 44 to 67 years. Their average monthly pain VAS preceding treatment ranged from 2 to 5. All patients reported a decrease in average monthly pain after treatment, and reported a smaller pain level after the first treatment session compared to the average pain preceding treatment. The patients' health EQ VAS at the start of treatment ranged from 70 to 95. It increased in patients 1 and 3 after the completed treatment, and was unchanged in patients 2 and 4. No adverse events were reported.

III. DISCUSSION

This case series describes pain management with StarFormer magnetic stimulation in 4 patients with chronic pain with an average monthly VAS pain in the range of 2-5. All patients reported some reduction of their pain level during the course of treatment, and a reduction of their average monthly pain after treatment at the 1-month follow-up. The patient reporting the highest level of pain at the beginning of the treatment also experienced the largest pain relief at the end of the treatment. Concomitantly with a reduction in pain, two patients rated their health higher after completing the treatment, however, no change in self-rated health occurred in the other two patients. Notably, no adverse events were detected and the treatment itself was comfortable, as it was always performed up to the patient's own tolerance level. The results of our case series are consistent with the results of clinical studies performed with equivalent devices for repetitive peripheral magnetic stimulation, reflecting on the safety and effectiveness of this modality for pain management[8].

Among the available literature regarding pain management with rPMS, some studies showed pain reduction after a single session[9-11] and some after several (up to 10) sessions[5,12,13] of rPMS. A gradual

decrease in pain VAS from the baseline after each consecutive session was also reported[5,14], with pain relief persisting up to 3 months after treatment[14]. These results indicate both short-term and long-term pain relief. Our small data set with only a 1-month follow-up is not sufficient to draw conclusion on the longevity of the observed pain relief, but we can conclude that magnetic stimulation with StarFormer is a safe and effective method for pain management in the short term.

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