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Group 11
Non-Invasive Stimulation

Efficacy of Percutaneous Electrical Neurostimulation in the Management of Diabetic Peripheral Neuropathic Pain

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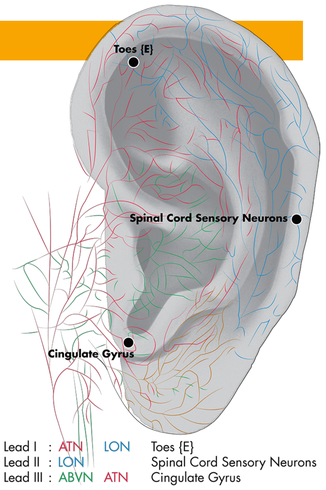
INTRODUCTION

Painful diabetic neuropathy is a common phenotype of peripheral neuropathy due to diabetes, affecting up to a third of the general diabetic population. The aim of this study was to assess the efficacy of percutaneous electrical neuro-stimulation (PENS) in treating and relieving patients suffering from painful complications of diabetes.

METHODS

A double-blind, randomized, placebo-controlled longitudinal trial enrolled 40 subjects with pain due to peripheral neuropathy caused by type 2 diabetes mellitus. Patients with pain duration of 4 months involving the lower extremities were randomly assigned to receive either standard (A) or variable-frequency (B) auricular PENS treatment, or a sham device, for 12 weeks, on a week-on week-off basis. Visual analogue scale (VAS) on 10 cm was used to assess pain, while severity of peripheral neuropathy was estimated through the vibration perception test (VPT) and the overall neuropathy limitation scale (ONLS). Insomnia and anxiety/mood severities were assessed by means of, respectively, the insomnia severity index (ISI) and the Hamilton anxiety rating scale (HAM-A). These 5 measures were repeated each week, alternating between installation and removal of the treatment device. Patients were encouraged to come back and complete the 6 treatments.

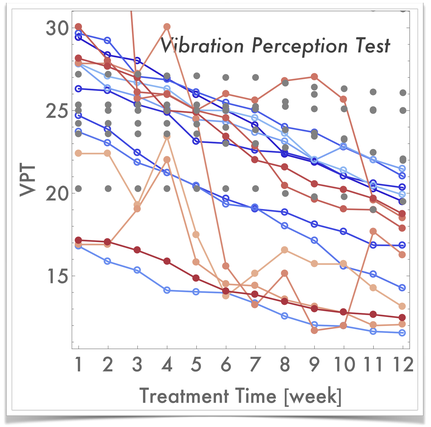


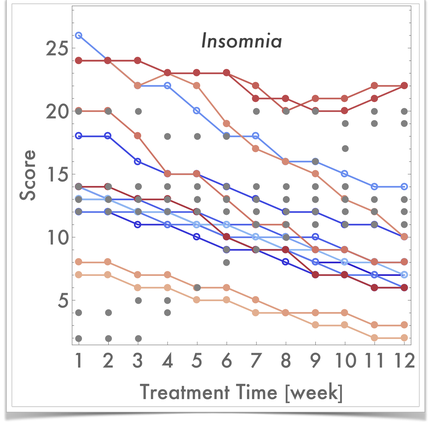
RESULTS

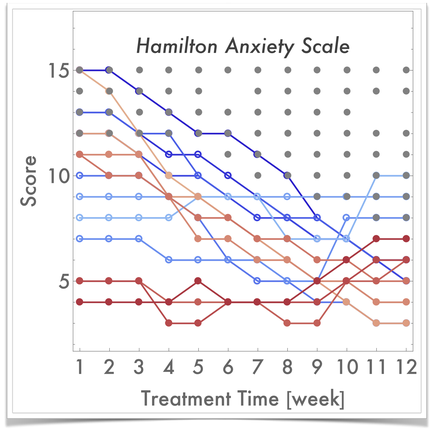
Population size dwindled from initial 40 to 24 subjects (8 with A, 7 with B) remaining after 12 weeks. VAS, VPT, ONLS and HAM-A measures decreased with statistical significance for all 15 individuals in comparison with 9 placebo-treated patients (p-value << 0.01). E.g, pain scores were found to linearly reduce with time from 6.8 ± 0.7 to 5.4 ± 0.3 over the complete study period with placebo, whereas treatments A and B allowed quadratic reductions from 7.4 ± 0.8 to 3.9 ± 0.3 and 7.3 ± 1.4 to 2.9 ± 0.3, respectively. ISI also exhibited overall significant decrease ($p < 0.01$) for PENS groups in comparison with a raise of insomnia values for the control group. Analgesic requirements decreased by 80% for both treatment groups and only by 7% with placebo. No adverse events were found.

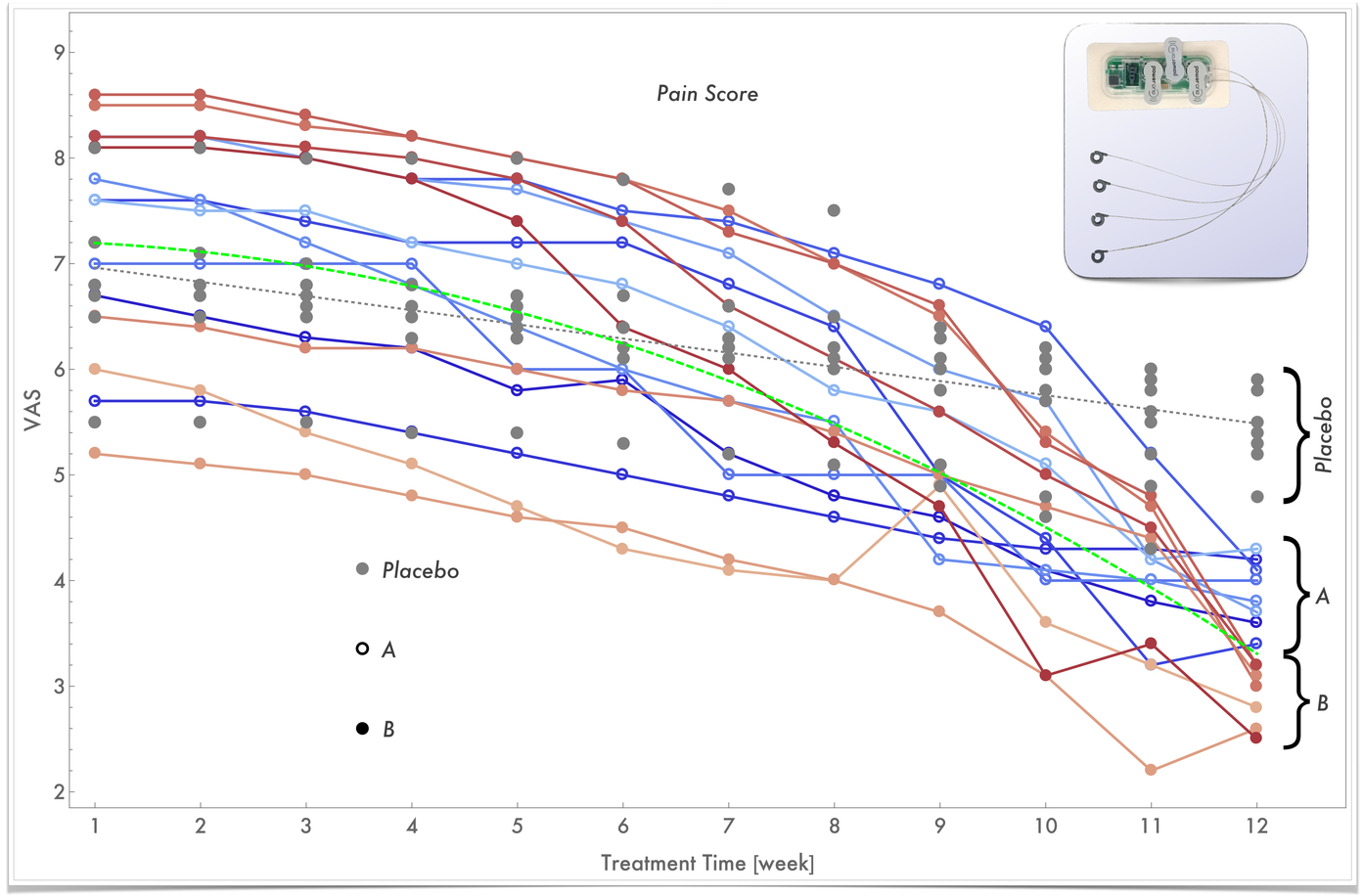
CONCLUSION

Active PENS treatments improved the neuropathic pain symptoms in all patients who completed the 12 weeks. Their resilience in participating may explain this success. In addition to decreased extremity pain, PENS improved physical activity, sense of well-being, and sleep quality while reducing the need for analgesics.









	Placebo		Group A		Group B	
Gender	F (4/9)	M (5/9)	F (6/8)	M (2/8)	F (2/7)	M (5/7)
Age	55.7 ± 7.6		57.6 ± 6.5		59.6 ± 7.1	
BMI	23.6 ± 1.1		23.3 ± 1.6		24.3 ± 0.4	
Treatment	Before No 1	After No 6	Before No 1	After No 6	Before No 1	After No 6
Pain VAS	[6.2 – 7.3]	[5.2 – 5.7]	[6.6 – 8.1]	[3.6 – 4.1]	[6.0 – 8.6]	[2.7 – 3.2]
VPT	[22.9 – 35.5]	[22.0 – 33.7]	[22.3 – 29.3]	[15.1 – 21.1]	[17.1 – 37.9]	[12.8 – 18.3]
Insomnia	[7.5 – 15.9]	[11.1 – 16.3]	[11.3 – 19.2]	[6.0 – 10.5]	[10.3 – 24.3]	[2.7 – 18.2]
ONLS	[3.1 – 4.2]	[4.0 – 4.8]	[2.4 – 3.8]	[0.9 – 1.8]	[1.1 – 4.3]	[1.0 – 1.0]
HAM-A	[12.8– 14.1]	[9.2 – 13.3]	[8.5 – 13.2]	[4.6 – 8.4]	[5.0 – 13.0]	[3.7 – 6.3]

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