Neufit System and the Neubie Device

Impact of Treatment with the Neubie Direct Current Device VS TENS Alternating Current Device on Diabetic Peripheral Neuropathy

Treating Diabetic Peripheral Neuropathy

Diabetic peripheral neuropathy (DPN) is a common complication in both type 1 and 2 diabetes, affecting approximately 60-70% of people with diabetes. DPN causes pain, numbness, and sensory disturbances, primarily in feet and hands. Traditionally, drug therapies have been the main treatment for DPN, which are associated with multiple side effects and do not result in any improvement in DPN. One potential alternative treatment is electrical stimulation (e-stim). E-stim is non-invasive, has few side effects and contraindications, and no known drug interactions.

E-Stim for Treating DPN

E-stim used for DPN has been found to improve pain, motor function, and sensory deficit symptoms, and improve microcirculation and vascularity. To date, there are a limited number of clinical studies that have investigated using e-stim for DPN. Many have used transcutaneous e-stim (TENS), which employs low frequency alternating current (AC), and have seen some effectiveness for pain associated with neuropathy. There is evidence that higher frequency AC e-stim is significantly more effective than TENS at ameliorating other symptoms like motor function and numbness. Higher frequency stimulation can be a challenge to use if the device runs AC, as the intensity causes a co-contraction, making it difficult for patients to perform any movement. However, this issue can be mitigated by the use of higher frequency direct current (DC) electrical stimulation devices. The research on DC devices is more limited, as it is traditionally more difficult to get into the body safely due to charge build up, however recent technologic advances have made them safer and more useful in clinical practice.

The Neubie - High Frequency Direct Current Device

- Imitates action potentials of both the peripheral and central nervous systems, which the body uses for communication with virtually all parts of the body.
- Unlike traditional direct current devices, it includes an additional "carrier" waveform that dissipates heat and charge buildup, allowing for higher-intensity direct current stimulation without irritation.
- Allows for active movement and optimal eccentric contractions to generate neuromuscular adaptations, improved performance of complex dynamic movements, and faster recovery of muscle contractility and functional abilities.

TENS - Low Frequency Alternating Current Device

- Current is foreign to the nervous system - does not imitate action potentials.
- Commonly used for e-stim treatments, but has limitations in application for functional movement due to excessive tension and co-contractions affecting movement quality.
- Primarily used for short-term pain management or fatiguing hypertonic muscles.

The Study

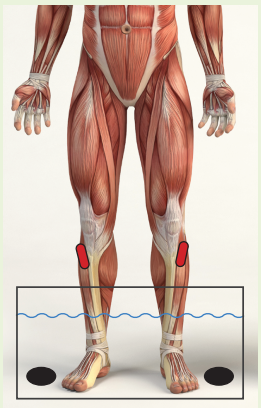
The goal of the study was to evaluate the effectiveness of treatments with two different non-invasive types of e-stim (DC vs AC), to determine if they could offer substantial relief and improvement in neuropathic symptoms for DPN patients. The devices compared were the Neubie (DC) and TENS (AC).

LOCATION — 13 EMG Certified and Approved Hands-On Diagnostics Physical Therapy Centers Across the US

150 PARTICIPANTS	52% MALE 48% FEMALE	74 AVERAGE AGE	1 TCNS All with a minimum score of 1 on the Toronto Clinical Neuropathy Scale.
DESIGN	2X PER WEEK FOR 6 WEEKS	PT exercises + 20 min footbath treatment with Neubie or TENS	

MEASUREMENTS

- Measurements taken pre- & post-intervention protocol (baseline and 6 weeks treatment with Neubie or TENS, respectively)
- Toronto Clinical Neuropathy Scale (Neuropathy Severity Score)
- Two-Point Discrimination (how close together a patient can feel two separate point)
- Vibration Sense Time (how long after stimulus a vibration can be sensed)
- Visual Analog Pain Scale (reported pain score)
- Electromyography (EMG - determines muscle response to nerve stimulation)
  - Distal Latency (time from stimulus on nerve to response)
  - Amplitude (muscle tension as measured by # of motor units being recruited by a stimulus and how frequently they are activated)
- Nerve Conduction Velocity (Speed of electrical impulse moving through a nerve)
- EMG and Nerve Conduction was measured in nerves associated with lower limb motor control (M) and sensory (S).
  - Dominant Tibial (Motor)
  - Dominant Fibular (Motor and Sensory)
  - Dominant Sural (Motor)



RUBBER ELECTRODES FLOATING IN WATER
STICKY ELECTRODES
WATER BATH

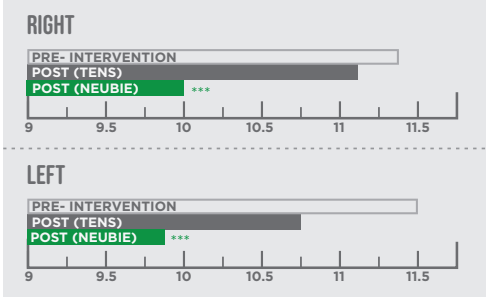
STATISTICAL ANALYSIS

The effect of the two variables (Neubie and TENS) on all outcome measures was determined using the statistical method Analysis of Covariance (ANCOVA). A p value of <0.05 was considered statistically significant. Any data that was statistically significant is visually represented with *'s in the results section - the greater the number of stars, the more statistically significant the finding."

The Results

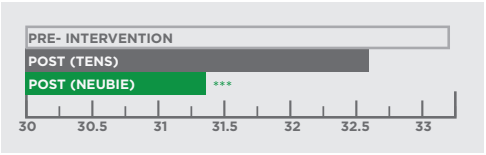
1 Toronto Clinical Neuropathy Scale (TCNS)

Higher score = more severe neuropathy symptoms. Neubie treatment significantly decreased score (p<0.001***) while TENS treatment did not.



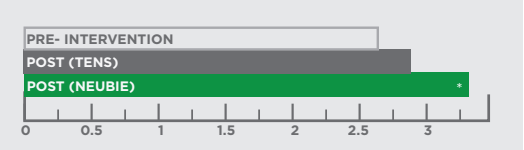
2 Two-Point Discrimination

Smaller distance = better sensitivity and discrimination. Neubie treatment significantly decreased distance (p<0.001***) while TENS did not.



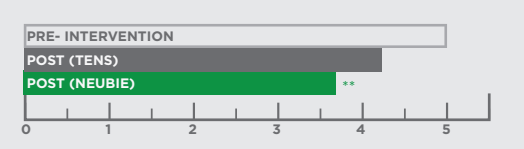
3 Vibration Sense Time

Longer time = better vibration sense. Neubie treatment significantly increased sensation time (p=0.022*) but TENS did not.



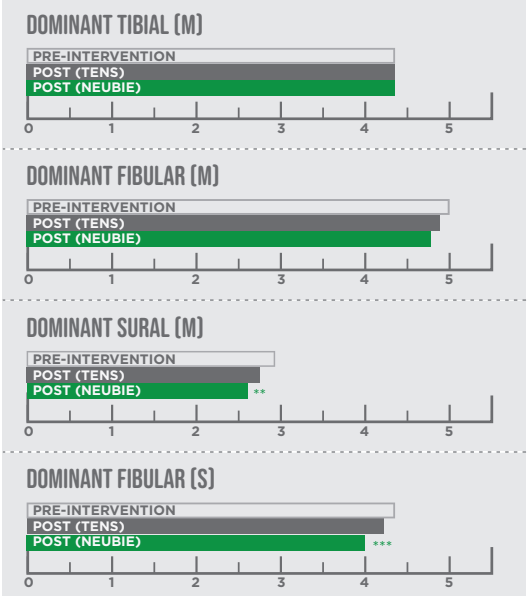
4 Reported Pain

Lower score = less pain. Neubie treatment significantly decreased reported pain (p=0.009**) but TENS did not.



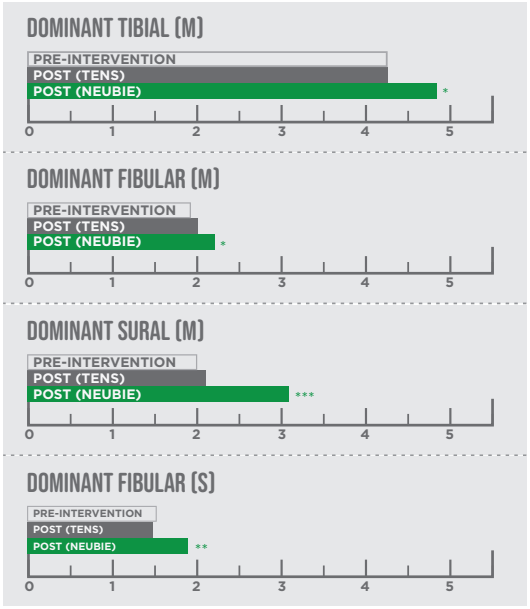
5 Distal Latency

Time from stimulus to response - shorter time is considered a better response. Neubie treatment significantly decreased time in 2/4 nerves measured (Dominant Sural (M) - p=0.003**; Dominant Fibular (S) - p>0.001***) whereas TENS treatment showed no significant difference in time in any nerve measured.



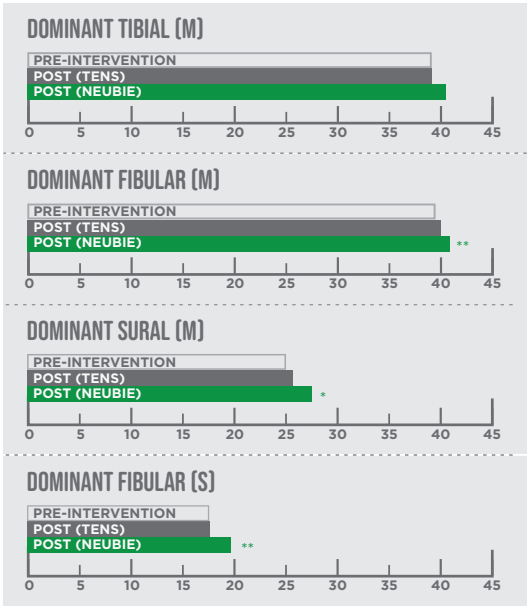
6 Amplitude

of motor units being recruited & how frequently they are activated - higher # = more units. Neubie treatment significantly increased amplitude in 4/4 nerves measured (Dominant Tibial (M) - p=0.019*; Dominant Fibular (M) - p=0.02*; Dominant Fibular (S) - p=0.006**; Dominant Sural (M) - p=<0.001***)



7 Nerve Conduction Velocity

Higher velocity = faster speed of electrical impulse moving through a nerve. Neubie treatment significantly increased conduction in 3/4 nerves measured (Dominant Fibular (M) - p=0.006**; Dominant Sural (M) - p=0.013*; Dominant Fibular (S) - p=0.001**) whereas TENS treatment showed no significant difference in speed in any nerve measured.



CONCLUSION

Overall, DPN treatment with the Neubie resulted in significant improvements to all outcome measures, whereas TENS showed no significant difference to any outcome measure. These results objectively demonstrate that treatment with the Neubie provides superior therapeutic benefits for patients with DPN compared to TENS. These findings can inform future therapeutic strategies and may prompt further research to understand the specific mechanisms underlying the observed benefits of Neubie treatment for neuropathy and related conditions.