

# TENS and EMS Treatment for Diabetic Peripheral Neuropathy

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## ABSTRACT

**Context** • Diabetic peripheral neuropathy (DPN) is a common complication occurring in both type 1 and type 2 diabetics. DPN may result in foot ulceration or lower-limb amputation.

**Objective** • This case was undertaken to evaluate the efficacy of ReBuilder® therapy in the treatment of diabetic peripheral neuropathy.

**Methods** • The case report is based on 3 selected patients, 2 males and 1 female. Each patient continued being managed by his/her primary care physician. No changes

to allopathic medicine or diet were advised by our team. In addition to the allopathic therapy, we added ReBuilder® therapy, low level light therapy, vibration therapy and supplementation. The treatment period ranged from 17 to 20 weeks.

**Conclusion** • The data presented here show promise for future, larger, controlled studies on the use of ReBuilder® devices for the treatment of diabetic peripheral neuropathy pain. (*Altern Ther Health Med.* 2022;28(6):57-59)

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## INTRODUCTION

Diabetic peripheral neuropathy (DPN) is a common complication occurring in both type 1 and type 2 diabetics. DPN may result in foot ulceration or lower-limb amputation. High blood glucose can damage nerves, or starve them, of oxygen and nutrients, by affecting the blood vessels and capillaries that feed them. Terminal sensory axons in the periphery are the most effected, leading to the ‘stocking and glove’ pattern of DPN.<sup>1</sup> It is estimated that 30-50% of patients with DPN experience neuropathic pain.<sup>2</sup> This burning pain is often spontaneous and although continuous, the feet may be insensate to touch.

Current treatment approaches for managing DPN include glycemic control, pain medications such as antidepressants and serotonin and norepinephrine reuptake inhibitors (SNRIs), and additionally for type 2 diabetics, lifestyle modifications of diet and exercise. Multiple studies, as reviewed by Cohen et al.<sup>3</sup> on the use of medications have been published, however, researchers consider only a 30%

reduction in pain intensity to be ‘meaningful.’<sup>4</sup> Complimentary and alternative therapies for reducing DPN pain include the use of dietary supplements including, B vitamins, vitamin D, alpha-lipoic acid and acetyl-L-carnitine, acupuncture, yoga and transcutaneous electrical nerve stimulation (TENS).<sup>5</sup>

There is great interest in non-pharmacological treatment approaches for DPN. External electrotherapy such as, pulsed dose electrical stimulation, high-frequency muscle stimulation, and frequency-modulated electromagnetic neural stimulation, have been studied.<sup>6</sup> Our interest is the new generation of TENS units, the ReBuilder® device. ReBuilder® is an FDA registered device and approved as a 510K pre-amendment version TENS (transcutaneous electrical stimulator) and an electronic muscle stimulator (EMS).<sup>7</sup> This handheld, battery-powered nerve stimulator delivers an electronic impulse, replicating the wave form and frequency of healthy peripheral nerve signals, to specific pain regions, thereby alleviating symptoms of pain, burning pain, tingling and painful numbness. We utilized the ReBuilder® device on three patients with DPN.

## CASE PRESENTATIONS

All patients came to our integrative medicine clinic seeking better pain management of their DPN.

Patient A is a 69 year-old male. He was diagnosed with type 2 diabetes and had a history of poor circulation, hypertension, and elevated cholesterol. Patient A presented

with neuropathy symptoms including sharp/stabbing pain, throbbing pain, and burning pain in lower extremities bilaterally. These conditions had inhibited the patient's ability to sleep and interfere with daily activities. Symptoms are worse at night and post-activity.

Patient B is an 82 year-old male. He was diagnosed with type 2 diabetes and had a history of poor circulation, hypertension, prostate cancer, and polio in childhood. Patient B had limited mobility and was confined to a wheelchair. Patient B presented with neuropathy symptoms including imbalance, swelling, painful numbness, tingling, tiredness, and dead feeling in lower extremities bilaterally. These conditions had inhibited the patient's mobility, independence, and quality of life. Symptoms worsen following periods of activity.

Patient C is a 70 year-old female. She was diagnosed with type 2 diabetes and had a history of poor circulation, arthritis in hands and feet, herniated disc, spinal stenosis, and degenerative disc disease. Family history included diabetes leading to amputation. The patient presented with neuropathy symptoms including painful numbness, tingling, painful burning, sharp/stabbing pain, dead feeling, imbalance, and sores. These complaints inhibited her mobility. Symptoms worsen with activity and long periods of standing. Rest and elevation of feet improve symptoms.

### Exam

Each patient received a neurological exam and consulting that included lower extremity reflexes, standard muscle strength grading, and Romberg's test to assess balance. The general appearance of the foot was noted, specifically focusing on the following: onychomycosis, cyanosis, petechiae, and the evidence of hair growth. The following seven stimuli were used order to determine extent of loss in sensation:

- Cold sensation—a refrigerated steel reflex hammer handle.
- Pinwheel—a standard pinwheel.
- Cool sensation—a TIP THERM® tool.
- Vibration—a 128 hz tuning fork.
- Sharp and dull sensation was tested using a Medi Tip device.
- 10g monofilament was used to measure light touch.
- Heat—a standard hairdryer was used for 2 seconds approx. one inch from the skin surface.

All the above stimuli were graded by the patient on a scale of 0-10. All stimuli were administered on normal unaffected tissue to establish a baseline. If the stimulus was felt, it became the baseline unit of 10 out of a possible 10 score. The stimuli were then applied to the affected area and the patient rated the intensity of stimuli on a scale of 0-10. Scores were then added and calculated out of a possible 70. An overall percentage was then calculated based on results.

The patients experienced sensory testing with the ReBuilder® device and ReBuilder® electrode mitts. The ReBuilder® unit was turned on while mitts were applied to the

plantar aspect of the affected feet. The patient was then advised to report when a sensation was felt. The goal for this test was to determine whether a stimulus could be felt below a level of 5 or less. The higher above 5, the greater the loss of function.

A standard pulse oximeter was used to check oxygen saturation at the great toe. Surface temperature was measured using a standard laser thermometer. The temperature of the anterior surface of the forearm and the dorsum of the foot were compared, for possible temperature differences. Skin temperature of the hands and feet were tested with a standard FLIR thermal camera. The FLIR thermal camera offers accurate quantitative and in-depth measurement of temperatures. By measuring emitted thermal radiation, a function of surface temperature, and turn this radiation into thermal images under various color formats available within the camera. Using this image, it is possible to identify abnormal thermal patterns or defects.<sup>8</sup> If the patient has adequate blood flow, there should be no more than a 2-degree Fahrenheit difference.

### Treatment Protocol

Each patient continued being managed by his/her primary care physician. No changes to allopathic medicine or diet were advised by our team. In addition to the allopathic therapy, we added ReBuilder® therapy, low level light therapy, vibration therapy and supplementation. The treatment period ranged from 17 to 20 weeks. Each patient followed the same protocol described below:

- ReBuilder® therapy twice per day at 30 minutes duration for 90 days (approximately). The ReBuilder is a highly specialized therapy device, unlike a common TENS unit. It utilizes a patented waveform which automatically adjusts to each patient's specific needs to eliminate pain.
- Low level Light therapy, which brings about a photochemical reaction in the cell. This can induce biostimulation, increase collagen synthesis, reduce oxidative stress, increase cell oxygen consumption and increased production of anti-inflammatory cytokins.<sup>9</sup> Duration was 60 seconds per session, twice per day. The therapy settings were 12.5 watts of 808 nm.
- Vibration therapy with a Medi-Rub® 2000 Plus. Vibration therapy is known to increase blood flow, thereby increasing oxygen and nutrient distribution.<sup>10</sup> Duration was 30 minutes at patient's preferred speed/intensity, twice per day.
- Alpha lipoic acid 600 mg, twice per day.
- L-Arginine 1400 mg once per day.
- A-Calm topical cream with L-Arginine for vasodilation. The cream was applied in the evening. N-Calm topical was applied in the morning for the purposes of analgesia.

The patients returned within approximately 90 days for re-evaluation. All abnormal results from the first exam were rechecked and graded. After the 90-day re-exam patients were advised to continue with their treatment at twice per day for the duration of the 12-month treatment window.

**Table 1.** Patient evaluation data

Assessment	Patient A			Patient B			Patient C		
Thermal Imaging	Adequate circulation Profusion to extremities			Severe ischemia in lower extremities Left markedly worse			Slight ischemia LL Adequate circulation and profusion LR		
Reflex	1+ bilateral			1+ bilateral			1+ bilateral		
Muscle	Full resistance Bi			Full resistance Bi			Full resistance Bi		
Extremity Temperature (Fahrenheit degrees)		Upper	Lower		Upper	Lower		Upper	Lower
	Left	92	88	Left	82	82	Left	83	81
	Right	92	88	Right	83	86	Right	82	82
Pulse Oximeter	Left	Right	Left	Right	Not Available				
	97%	98%	95%	95%					
Sway Test	Negative			Positive			Positive		
ReBuilder® Mitt (Lower Extremities)	Left	Right	Left	Right	Left	Right	Left	Right	
	NS	Level 8	NS	NS	Level 8	Level 8	Level 8	Level 8	
Neuropathy Severity Evaluation Score (Loss in Sensation)	Left	Right	Left	Right	Left	Right	Left	Right	
	27%	30%	43%	43%	75%	75%	75%	75%	
Treatment Duration	20 weeks			17 weeks			18 weeks		
Neuropathy Re-evaluation (improvement)	Left	Right	Left	Right	Left	Right	Left	Right	
	1%	100%	40%	33%	55%	68%	55%	68%	

**Abbreviations:** LL, Lower Left; LR, Lower Right; UL, Upper Left; UR, Upper Right; Bi, Bilaterally; NS, No Sensation.

## DISCUSSION

Treatment duration for peripheral neuropathy ranges from 12 to 18 months. Patient compliance with a long treatment plan is a concern. Patient A, Patient B and Patient C underwent the described treatment for a period of 20, 17 and 18 weeks respectively. At the beginning of treatment, each patient underwent a neuropathy severity evaluation, and at the end each was re-evaluated. Although each patient self-reported improvement of symptoms, the comparison between baseline and post-treatment scores, shows marked improvement (See Table 1).

## Limitations

Evaluations rely heavily on patient interpretation of sensations and pain, thus, scientific objective scoring is not possible. All patients presented were previously diagnosed with type 2 diabetes, therefore there is no comparison between different forms of diabetes. Multiple variables were used on these patients, without control groups, therefore, we do not know if the success of the treatment was solely due to the use of ReBuilder®. Another element or the specific combination of elements in the treatment protocol may be the reason for the improvement seen in these patients.

## CONCLUSION

The data presented here show promise for future, larger, controlled studies on the use of ReBuilder® devices for the treatment of diabetic peripheral neuropathy pain. All three patients saw significant improvement in a relatively short treatment duration. The use of ReBuilder® devices should be considered as an adjunct therapy when DPN pain is not well managed by allopathic treatment.

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