

Monochromatic Infrared Photo Energy and DPN

Taken collectively, clinical studies indicated that MIRE treatments are associated with increased sensation in the foot.

BY NEIL GOLDBERG, MD

Diabetic peripheral neuropathy (DPN) is a common complication of diabetes.¹ Foot insensitivity resulting from DPN is highly correlated with foot wounds, and it is recognized as a leading cause of amputations and high mortality rates among diabetic patients.² Chronic pain is often another manifestation of DPN and has been reported to have a significantly negative impact on quality of life.³

Historically, available pharmacological and other treatments for neuropathic pain have not been totally acceptable. There have been no effective treatments for improving foot sensation in patients with DPN, which has been thought to be progressive and irreversible.^{4,5} Lower extremity ulcer (LEU) risk reduction strategies have included patient education, frequent physician visits, orthotics for off-loading and accommodative foot wear. Despite these strategies, the incidence of LEUs remains at >8% incidence/year for patients with DPN and loss of protective sensation.⁶ DPN continues to be a source of morbidity, mortality, frustration and concern to patients and physicians.

The etiology of DPN is not well understood and may well be multifaceted.⁷ One of the primary causative factors appears to be reduced endoneural blood flow and consequent hypoxia.^{8,9} Research is ongoing to determine whether agents that improve microcirculation might impact the progression or reversal of DPN.⁷

Several recently published studies report that at least temporary increases in foot sensitivity and reductions in neuropathic pain may be achieved through the application of monochromatic near infrared photo energy (MIRE, Anodyne Therapy System, Tampa, Fla).¹⁰⁻¹⁶ This device is noninvasive, and published trials report it was well tolerated by patients.

MIRE TECHNOLOGY

The Anodyne Therapy System delivers MIRE through therapy arrays, each containing 60 superluminescent diodes (890 nanometers, near infrared wave-

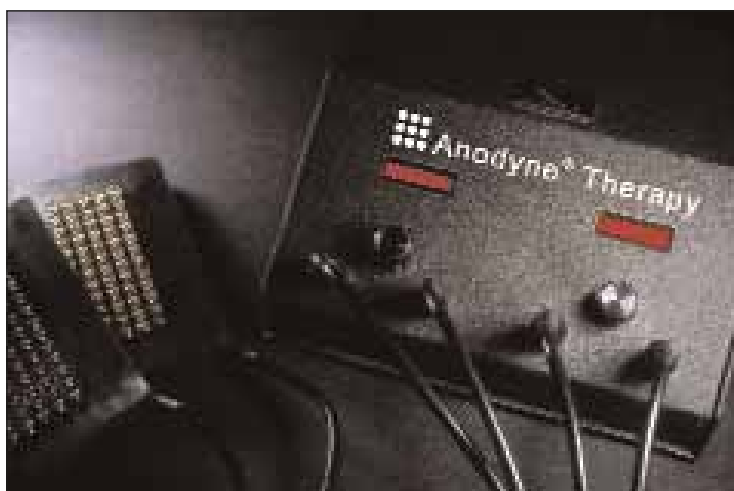


Figure 1. The Anodyne Therapy System delivers MIRE through therapy arrays, each containing 60 superluminescent diodes (890 nanometers, near infrared wavelength). These diode arrays are attached to a control unit that pulses the MIRE at 292 times/second.

length). These diode arrays are attached to a control unit that pulses the MIRE at 292 times/second.¹⁷ The therapy arrays are placed in direct contact with the skin to temporarily increase local microcirculation. The ability of photo energy to increase microcirculation, possibly through the release of nitric oxide, has been documented in clinical literature.¹⁸

Photo energy increases microcirculation, possibly through the release of nitric oxide.

During the past 3 years, there has been increased professional awareness and published evidence concerning the use of MIRE for DPN (Table 1). Below are summaries of clinical studies that have either been published or accepted for publication:

- Noble et al examined the effects of MIRE on medial nerve function in a randomized, controlled trial of 40 healthy patients.¹⁰ The investigators concluded that MIRE improved nerve function in the medial nerve ($P<.05$). While the population was healthy, this clinical trial showed that MIRE was able to improve nerve function, which may be relevant to its reported effectiveness in the treatment neural dysfunction

associated with DPN.

- Leonard et al reported the effectiveness of MIRE treatments delivered to 27 patients with DPN in a randomized controlled trial where each patient served as their own control as active and sham (heat only) treatments were delivered to alternate limbs.¹¹ Six and 12 active MIRE treatments resulted in improved sensation to the Semmes Weinstein Monofilament (SWM) 5.07 (10 g) ($P<.02$ and $P<.001$, respectively) in those who were able to sense the 6.65 SWM (300 g) but not the SWM 5.07 at baseline. Six placebo treatments did not improve sensitivity to the SWM 5.07. When six active treatments were later administered, subjects did improve sensitivity to the SWM 5.07 ($P<.002$). The authors also reported significant reductions in neuropathic symptom scores using the Michigan Neuropathy Screening Instrument, reductions in neuropathic pain and improved balance ($P<.05$).

- Prendergast et al reported electrophysical changes in myelinated and unmyelinated nerve fiber function resulting from 10 MIRE treatments delivered to 27 consecutive patients diagnosed with DPN.¹² Twenty-six patients (96%) exhibited improvement (mean 61%; $P<.0001$), and 59% of patients experienced a return to normal nerve responsiveness in all three nerve groups. Within the specific nerve fibers, MIRE treatment resulted in statistically significant improved function

TABLE 1. EVIDENCE CONCERNING THE USE OF MIRE FOR DPN

Journal	(Reference)	n	Study Type	Endpoints
<i>J Amer Pod Med Assn</i>	(13)	49	Prospective, open label	Quantitative Monofilaments, Hot/Cold Discrimination
<i>Endocrine Practice</i>	(12)	27	Prospective, open label	Pretreatment control group, Neurometer, CPT/sNCT
<i>Diabetes Care</i>	(11)	27	Randomized, double-blind, placebo controlled	SWM; VAS Pain; MNSI; Balance
<i>J of Geriatric Physical Therapy</i>	(14)	38	Prospective, open label	SWM; Tinetti Gait and Balance; Actual Falls
<i>Advances in Skin and Wound Care</i>	(15)	8	Retrospective, questionnaire	Incidence of new wounds; time of healing
<i>J Amer Pod Med Assn</i>	(16)	1,047	Prospective, chart review	SWM

in large myelinated ($P < .001$), small myelinated ($P < .02$), but not small unmyelinated nerve fibers ($P < .423$). Ten patients who had received conventional management of their diabetes and DPN for an average of 27 months prior to receiving MIRE treatment had showed no improvement in nerve function. However, these patients subsequently improved with MIRE treatment ($P < .002$).

Kochman used discreet SWM testing and reported that mean sensory improvement after MIRE was 85%.

- Kochman and colleagues reported the results of 12 MIRE treatments on 49 consecutive patients with DPN, loss of protective sensation and impaired hot/cold sensation.¹³ One hundred percent of patients obtained protective sensation based on SWM monofilament testing ($P < .0001$). Forty patients (81%) had improvement in hot/cold temperature discrimination. Kochman used discreet SWM testing and reported that the mean sensory improvement after MIRE was 85% (from the ability to sense a 20-g monofilament on average to the ability to feel a 3-g monofilament; $P < .0001$).

- Kochman reported a second study of 38 consecutive patients that related to improvement in foot sensation to the SWM 5.07 after 12 treatments with MIRE.¹⁴ After treatment, all limbs exhibited protective sensation to the SWM 5.07 monofilament. Additionally, every patient exhibited improved balance and gait as measured on the Tinetti scale (mean 10 point gain; 93% improvement) and reported falls decreased from 98 in a 3-month period preceding treatment to only 4 in the 3 months after treatment ($P < .0001$ for all results).

- Powell et al reported on 68 Medicare-aged patients, initially impaired due to DPN, to determine whether restoration of sensation through MIRE treatments would reduce the incidence of foot ulcers.¹⁵ After a mean duration of 12.5 months treatment with a home MIRE system, the reported incidence of new foot wounds was 1.5% compared to the published incidence in the Medicare population of 7.3% ($P < .0001$). This represented a 79% reduction in the expected annual incidence of diabetic foot wounds among this population.

- A study in press by DeLellis et al reported on the treatment effect of MIRE in 1,047 patients with DPN

(790 with diabetes).¹⁶ These researchers reported a 71% improvement in foot sensitivity to the SWM ($P < .0001$).

CONCLUSIONS

The reported clinical studies, including one in press, examine the effectiveness of MIRE for DPN in more than 1,200 patients. When considered individually, each of these studies may be subject to design limitations. Collectively, they suggest that MIRE treatments are associated with increases in foot sensation in patients with DPN. Given reported safety of MIRE, the high cost and morbidity of DPN, and the absence of a currently satisfactory alternative pattern of care, this approach may be of interest to affected patients and their physicians. ■

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