

# Improved foot sensitivity and pain reduction in patients with peripheral neuropathy after treatment with monochromatic infrared photo energy—MIRE

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## Abstract

The medical records of 2239 patients (mean age=73 years) with established peripheral neuropathy (PN) were examined to determine whether treatment with MIRE was, in fact, associated with increased foot sensitivity to the Semmes Weinstein monofilament (SWM) 5.07 and a reduction in neuropathic pain. The PN in 1395 of these patients (62%) was due to diabetes. Prior to treatment with MIRE, of the 10 tested sites (5 on each foot),  $7.1 \pm 2.9$  were insensitive to the SWM 5.07, and 2078 patients (93%) exhibited loss of protective sensation defined by Medicare as a loss of sensation at two or more sites on either foot. After treatment, the number of insensate sites on both feet decreased to  $2.4 \pm 2.6$ , an improvement of 66%. Of the 2078 (93%) patients initially presenting with loss of protective sensation, 1106 (53%) no longer had loss of protective sensation after treatment ( $P < .0001$ ); 1563 patients (70%) also exhibited neuropathic pain in addition to sensory impairment. Prior to treatment with MIRE, pain measured on the 11-point visual analogue scale (VAS) was  $7.2 \pm 2.2$  points, despite the use of a variety of pain-relieving therapeutic agents. After treatment with MIRE, pain was reduced by  $4.8 \pm 2.4$  points, a 67% reduction. Therefore, MIRE appears to be associated with significant clinical improvement in foot sensation and, simultaneously, a reduction in neuropathic pain in a large cohort of primarily Medicare aged, community-dwelling patients, initially diagnosed with PN. The quality of life associated with these two outcomes cannot be underappreciated.

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**Keywords:** Diabetic peripheral neuropathy; MIRE; Semmes Weinstein monofilament; Anodyne Therapy System; Monochromatic infrared photo energy

## 1. Introduction

Disturbance of skin sensation, characterized by pain, hyperesthesia, hypoesthesia, numbness, and/or tingling, is a common symptom of peripheral neuropathy (PN). Although there are many conditions in which PN is a comorbid factor, diabetes is the primary cause of PN in the Western world. Painful manifestations of PN have a

substantial adverse effect on quality of life (Galer, Gianas, & Jensen, 2000). Foot insensitivity, particularly among patients with diabetes, is highly correlated with foot wounds and nontraumatic lower extremity amputations (LEA); indeed, PN and peripheral vascular disease are the leading causes of amputations and high mortality rates among both diabetic and nondiabetic patients (Tentolouris, Al-Sabbagh, Walker, Boulton, & Jude, 2004). The prevalence of PN is extensive. Estimates suggest that 15% of the population over 40 exhibit this condition, and in those with diabetes, the rate is 29% (Gregg et al., 2004). Of concern, although 50% of these patients showed documented insensitivity to the Semmes Weinstein Monofilament

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(SWM) 5.07 at two or more of six measured plantar sites, a significant portion were asymptomatic in the sense that they had not experienced numbness, loss of feeling, painful sensations, or tingling in their feet. Thus, they did not recognize the need for foot precautions (Gregg et al., 2004).

Historically, there have been no effective treatments for improving foot sensation diminished due to PN (Diabetic Neuropathy, 1995) other than a surgical procedure championed by Dellon and others (Dellon, 2004; Wieman & Patel, 1995; Wood & Wood, 2003). However, not all patients are acceptable candidates for this surgical procedure. With this in mind, healthcare professionals vigorously encourage lower extremity ulcer (LEU) risk-reduction strategies that currently include patient education, frequent visits to their physicians, orthotics for off-loading, and accommodative foot wear. However, despite these strategies, the incidence of LEU remains at over 8% in patients with PN and loss of protective sensation (Armstrong et al., 2004). Additionally, diabetic patients with sensory loss who were assigned to therapeutic shoes do not have a significantly lower risk of reulceration compared with controls (Reiber et al., 2002).

Because chronic neuropathic pain is also a long-term complication of diabetic PN (Ziegler, 2004) and other neuropathies and has a negative impact on quality of life (Galer et al., 2000), significant research has been devoted to therapeutic options for this condition. Unfortunately, available pharmacological and other treatments for neuropathic pain have not been totally efficacious (Davies, Crombie, Lonsdale, & Macrae, 1991). Clearly, neuropathic pain is a source of frustration to affected patients and the physicians who deal with this condition on an ongoing basis.

Several recent studies (DeLellis, Carnegie, & Burke, 2005; Kochman, 2004; Kochman, Carnegie, & Burke, 2002; Leonard, Farooqi, & Myers, 2004; Powell, Carnegie, & Burke, 2004; Prendergast, Miranda, & Sanchez, 2004) show that, at least, temporary increases in foot sensitivity, documented using either the SWM 5.07 or the Neurometer CPT sNCT, occur following the application of monochromatic near infrared photo energy (MIRE) to the feet of symptomatic diabetic patients with impaired foot sensation associated with PN. Another study showed that improvement in foot sensation resulting from MIRE treatments was associated with a substantial reduction in the incidence of new LEU among a Medicare aged population (Powell et al., 2004). Moreover, we recently reported improved foot

Table 1  
Patient demographics

	Number	Percent (%)
Patients with peripheral neuropathy	2239	
Male	1069	48
Female	1170	52
Diabetic	1395	62
Nondiabetic	844	38
Mean age±1 S.D.	73±8.4 (range 29–100)	
Mean number of sites insensate (10 maximum)	7.1±2.9	

Table 2  
Foot insensitivity to the SWM 5.07 pre- and posttreatment

	Current study		Prior study (DeLellis et al., 2005)	
Total number of patients	2239		1047	
Pretreatment sites insensate (max 10)	7.1±2.9 <sup>a</sup>		7.9±2.4 <sup>a</sup>	
Posttreatment sites insensate	2.4±2.6*		2.3±2.4*	
Mean decrease sites insensate	4.7±2.8*		5.6±2.7*	
Pretreatment patients with LOPS	2078	93%	1033	99.6%
Posttreatment patients regaining protective sensation	1106	53%	580	56.1%
Posttreatment total number of patients with LOPS	972	47%	453	43.9%
Pretreatment number of patients with all 10 sites insensate	770	34%	452	43%
Posttreatment sites insensate	3.8±3.0*		3.1±2.7*	
Mean decrease sites insensate	6.2±3.0*		6.9±2.7*	

LOPS: loss of protective sensation.

<sup>a</sup> Mean±S.D.

\*  $P<.0001$ .

sensation after MIRE in 1047 patients (790 with diabetes) for whom sensory data had been collected in the routine course of medical treatment (DeLellis et al., 2005).

The present results demonstrate improved foot sensation as well as a reduction in neuropathic pain after MIRE treatments in 2239 community-dwelling patients with PN (1395; 62% with diabetes). The improvements in foot sensitivity to the SWM 5.07 also compare favorably with those we reported previously (DeLellis et al., 2005).

## 2. Research and design methods

The insurance claims of a durable medical equipment supplier (DME) offering Anodyne Therapy System (ATS; Anodyne Therapy, Tampa, FL), an item of durable medical equipment delivering MIRE, were reviewed to obtain a list of patients who had been treated with MIRE in physicians'

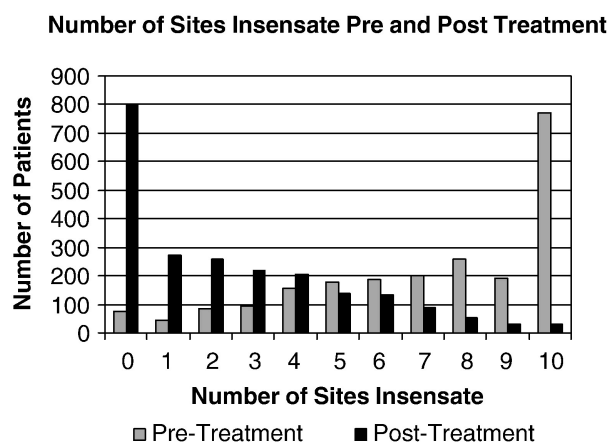


Fig. 1. Number of patients with insensate sites before (gray bars) and after (black bars) MIRE treatment.

Table 3

Foot insensitivity to the SWM 5.07 pre and posttreatment (diabetic patients compared with nondiabetic patients)

	Current study				Prior study (DeLellis et al., 2005)			
	Pre	Post	Improvement	<i>P</i> value	Pre	Post	Improvement	<i>P</i> value
All patients	7.2±2.9	2.4±2.6	4.7±2.8	<.0001	7.9±2.4	2.3±2.4	5.6±2.6	<.0001
Diabetics	7.3±2.8	2.5±2.6	4.8±2.8	<.0001	8.0±2.4	2.4±2.4	5.6±2.7	<.0001
Nondiabetics	7.0±3.1	2.3±2.6	4.6±2.8	<.0001	7.9±2.4	2.3±2.4	5.5±2.6	<.0001

The correlation of the improvement between both studies is .98186.

offices and therapy clinics throughout the United States. The ATS delivers MIRE through therapy pads, each containing 60 superluminescent diodes (890 nm near-infrared wavelength), which are attached to a control unit, which pulses the MIRE at 292 times/s (Burke, 2003). The ATS was cleared by the FDA for use in increasing circulation and reducing pain. Prior to providing the ATS to patients for use at home, the supplier had obtained signed physician orders and therapists' clinical notes that documented the results of MIRE treatment in a clinical setting. Collectively, the data supported a diagnosis of PN in all patients; and, in all instances, the clinical notes included SWM evaluations of foot sensitivity both immediately before and shortly after a course of treatment with MIRE. Additionally, the physician orders and clinical notes also provided data regarding the severity of neuropathic pain prior to and after MIRE treatments. Charts specified the pre- and posttreatment pain on an 11-point visual analogue scale (VAS).

We used a searchable database containing a record of all claims filed, including ICD-9 coding of the underlying conditions for which the ATS had been ordered by referring physicians. The database, excluding any patient identifiers, was sorted by the DME supplier to obtain a list of all patients who had a diagnosis of PN based on ICD-9 code 357 or 782. The list was then stratified to obtain a list of those with Type 1 or 2 diabetes using ICD-9 codes 250.61 and 250.62, respectively. The period of inquiry was January 26, 2004, to November 30, 2004. In total, 2812 patients satisfied these criteria. Most patient records contained bilateral foot sensitivity data for the SWM 5.07 (at 10 sites; 5 on each foot) before and after MIRE treatment. Although all records contained data relative to improvement in foot sensation, some were not included in this analysis because (1) the SWM measurements were done at less than or more than 10 sites bilaterally, (2) the healthcare professionals used SWM other than the 5.07 SWM, or (3) they documented changes with other sensory testing devices, including the Pressure Specified Sensory Device (PSSD) or the Neuro-meter sNCT. Thus, 2239 patient records fulfilled the criteria for analysis in this report.

### 2.1. Statistics

The results were analyzed by paired two-tailed *t* test with a null hypothesis that there would be no change in sensitivity to the SWM 5.07 or neuropathic pain (either an increase or a decrease) following the use of MIRE.

Significance was accepted if  $P < .05$ . Data are expressed as mean ± 1 S.D.

### 3. Results

The mean age of the study population (1069 male; 48%) was 73 ± 8.4 years (range: 29–100; Table 1). One thousand three-hundred ninety-five patients (62%) were diagnosed with diabetic PN, and 844 patients were diagnosed with PN associated with other etiologies (PNO). The mean number of sites insensitive to the SWM 5.07 (bilaterally; maximum 10 sites for both feet) was 7.1 ± 2.9 before treatment and 2.4 ± 2.6 after treatment ( $P < .0001$ ), an improvement of 66% in foot sensation (Table 2). Prior to treatment, 2078 patients (93%) exhibited loss of protective sensation as determined by foot insensitivity to the SWM 5.07 at two or more sites on either foot. At the conclusion of the MIRE treatments in the clinic, 53% of these patients no longer exhibited loss of protective sensation ( $P < .0001$ ; Table 2).

Fig. 1 shows the number of insensate sites pre- and posttreatment in this group of patients. Prior to treatment with MIRE, most of the patients exhibited a loss sensation at 8 to 10 sites, and 73% of all patients had documented loss of sensation at 6 or more sites. After treatment, more than 60% of the patients were insensate at two sites or less, and more than 79% were insensate at four sites or less. The change in the distribution pattern of insensitivity to the SWM 5.07 graphically demonstrates the significance of the MIRE treatment effect in elderly outpatients with PN.

We also examined the data to determine whether there was a difference in the sensory responsiveness to MIRE in patients with diabetic PN as compared with those with PNO (Table 3). Both diabetic PN and PNO patients were similarly impaired prior to receiving MIRE treatment, and each group achieved the same clinical improvement in sensation ( $P < .0001$ ).

We compared the foot sensitivity data that we previously collected reported on 1047 patients (DeLellis et al., 2005) with PN to determine the degree of correlation between the

Table 4

Patients reporting significant pain pre- and posttreatment

	Pre	Post	Improvement	Percent improvement (%)
All patients	1563	33	1530	98
Diabetic	979	23	956	98
Nondiabetic	584	10	574	98

Table 5  
Changes in pain on the 11-point VAS

	Pre	Post	Improvement	P value	Percent improvement (%)
All patients	7.2±2.2	2.4±2.1	4.8±2.4	<.0001	67
Diabetic	7.1±2.2	2.4±2.2	4.7±2.5	<.0001	66
Nondiabetic	7.3±2.1	2.5±2.1	4.8±2.3	<.0001	66

results of that study and of the present study. The correlation of the sensory improvement values between the two studies was .98186; clearly, the results of the two studies are virtually identical (Tables 2 and 3).

Interestingly, although the patients exhibited severe sensory impairment as measured by the SWM 5.07 (mean=7.1±2.9 of 10 sites insensitive), 1563 patients or 70% also exhibited neuropathic pain (Table 4). Physician notes (verified by analysis of clinical records) showed that 98% of patients initially reporting neuropathic pain obtained substantial reduction in their pain after treatment. Mean pain as reported on the 10-point VAS was 7.2±2.2 immediately prior to MIRE treatment. After MIRE treatment, the mean pain level was reported to be 2.4±2.1, a mean reduction of 4.8 points, or 67% (Table 5). From a descriptive standpoint, the mean pain level was reduced from “distressing” to “mild.” As is the case for changes in foot sensitivity after MIRE (Table 2), there was no significant difference between the initial level of pain or in pain reduction between the diabetic PN and PNO patients (Table 5).

The clinical records of the patients with PNO were quite detailed and showed that the pretreatment pain continued to be a complaint of these patients despite the fact that more than 62% were taking one or more prescription medications (anticonvulsants, antidepressants, and/or opiates) in an unsuccessful effort to reduce their neuropathic pain. Of the remaining patients, 13% had continued to experience significant levels of neuropathic pain despite the use of topical analgesics (e.g., capsaicin cream, Lidocaine patches, and Biofreeze), physical therapy, nerve blocks, and over-the-counter pain medications. Additionally, the duration of

Table 6  
Descriptive characteristics of nondiabetic patients

Total	844	
Duration (months)	mean=70; range, 0.5 to 1020	
Etiology		
Idiopathic neuropathy	558	(66%)
Inflammatory and toxic neuropathies	36	(4%)
Mononeuritis	65	(8%)
All other	185	(22%)
Total reporting ineffective prescription drugs <sup>a</sup>	521	(83%)
Total reporting ineffective other treatments <sup>b</sup>	110	(17%)

<sup>a</sup> One or more antidepressants, anticonvulsants, opioids.

<sup>b</sup> More than one of the following: topical analgesics, over-the-counter analgesics, physical therapy, and nerve block injections.

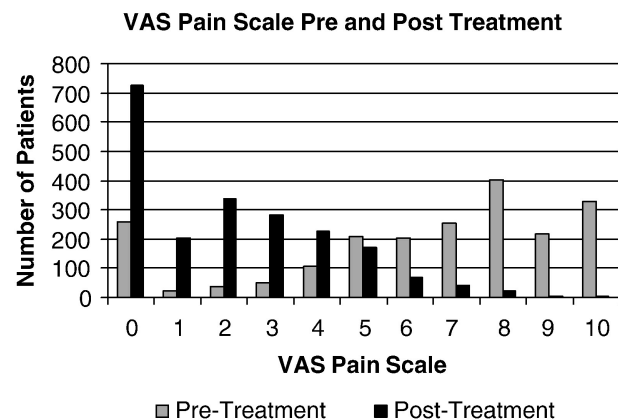


Fig. 2. Number of patients with pain levels on VAS scale before (gray bars) and after (black bars) MIRE treatment.

the PNO was significant, with a mean duration of 70 months (range, 0.5 to 1020 months; Table 6).

Fig. 2 shows the 11-point VAS reported pre- and posttreatment in this group of patients. After treatment with MIRE, more than half of the patients initially reporting high degrees of neuropathic pain reported pain levels of two or less. Additionally, 30% of patients initially reporting pain reported no pain at all after MIRE treatments. The change in the distribution pattern of pain intensity graphically demonstrates the significance of the MIRE treatment effect in this patient population.

#### 4. Discussion

Until recently, sensory impairments associated with PN, particularly due to diabetes, were thought to be progressive and irreversible. Several groups have employed a surgical technique, tarsal tunnel decompression surgery, with very favorable outcomes in selected patients with neuropathy (Dellon, 2004; Wieman & Patel, 1995; Wood & Wood, 2003). The present results confirm a recent report in a similarly large group of patients (1047) that improvement can occur in a very real world study population (i.e., community-dwelling patients with PN) treated in routine clinical practice with MIRE (DeLellis et al., 2005). These data support other published studies relative to the effectiveness of MIRE treatments for PN (Kochman, 2004; Kochman, Carnegie, & Burke, 2002; Leonard et al., 2004; Prendergast et al., 2004; Powell et al., 2004).

More than half of the patients who were initially diagnosed with loss of protective sensation (53%) obtained at least a temporary return of protective sensation, which compares favorably with the results that we reported previously in 1047 patients (56%; DeLellis et al., 2005). Even those patients with the most severe sensory dysfunction (all 10 sites insensitive to the SWM 5.07) obtained significant sensory improvement (6.2±3.0 sites were sensed after MIRE). Again, this result compares favorably with previous results that demonstrated 6.9±2.7 sites sensed after



MIRE in patients who were initially totally insensate to the SWM 5.07 (DeLellis et al., 2005). This result occurred irrespective of the etiology of the PN because there was no significant difference in the response of the patients with diabetic PN as compared with those with PNO. Thus, the results of this analysis demonstrate that sensory loss associated with PN, even when it has advanced to and beyond simply the loss of protective sensation, is not necessarily irreversible.

These data also demonstrate that neuropathic pain is closely associated with impaired sensation to the SWM 5.07 because 70% of the patients exhibited both manifestations of PN. Ninety-eight percent of patients reported having a “significant reduction in pain” after MIRE, as verified through the review of the clinical notes. We know of no other intervention that is as successful for patients with PN.

Of importance, the etiology of the PN was not a determining factor of whether the patients responded to treatment. There was no significant difference in the response of the diabetic PN and PNO patients, either in terms of pain reduction or increased sensation to the SWM 5.07. The clinical history for the PNO patients showed that the mean duration of their pain was 70 months and that, prior to treatment with MIRE, 62% of the patients continued to exhibit clinically significant symptomatic pain despite taking anticonvulsants, antidepressants, and/or opiate analgesics. These data on the relative ineffectiveness of medications for neuropathic pain are not surprising because a recent survey of physicians, experienced in treating neuropathic pain, noted that only a minority would rate the results of these medications as either excellent or good (Davies et al., 1991).

These observations and the conclusions derived must be analyzed in the context of certain limitations in our design. For example, there was no control group against which the results of this study were measured. However, when a disease such as diabetic PN is known to be progressive and irreversible, use of historical controls from published literature may be appropriate (Sima & Laudadio, 1996). In the case of diabetic PN, there have been no reports of either spontaneous reversal of this condition or efficacy of any nonsurgical intervention (Diabetic Neuropathy, 1995; Prendergast et al., 2004). In fact, two published randomized control trials have shown that 4 weeks of either thrice or biweekly sham photo energy treatment did not result in any improvement in the ability to detect the SWM 5.07 by patients with diabetic PN (Leonard et al., 2004; Zinman et al., 2004). Additionally, the present data were obtained from the records of patients who all exhibited some improvement in their neuropathic symptoms. Therefore, although we cannot generalize these results to all patients with PN, we can conclude that these 2239 patients, similarly to the 1047 patients on whom we reported previously, obtained objective improvement in foot sensation to the SWM 5.07 after treatment with MIRE.

Furthermore, we confirm that insensitivity to the SWM 5.07 is often associated with neuropathic pain, and in the

group of patients that were treated with MIRE, improved foot sensation resulting from MIRE treatment was paralleled by significant reductions in neuropathic pain. Importantly, in the PNO patients, significant pain reductions were apparent despite a long history of chronic pain unrelieved by conventional prescription or OTC medications and other interventions.

We cannot totally discount physician or therapist bias, because the SWM 5.07, while broadly accepted and objective, is only a patient-blinded test. Additionally, all of the patients knew that they were receiving active treatment. However, it is exceedingly unlikely that the more than 1000 evaluators in testing more than 2239 patients systematically misinterpreted the sensitivity to the SWM before and after MIRE treatment. Similarly, the effectiveness of MIRE treatments in improving sensitivity to the SWM 5.07, as reported in a recent double-blinded, placebo-controlled RCT, lessens the likelihood that the present results were due to evaluator bias (Leonard et al., 2004). Other testing modalities, namely, PSSD (Aszmann & Dellon, 1998) and the Neurometer (Pitei, Watkins, Stevens, & Edmonds, 1994), are currently being used to detect discrete changes in skin sensation impaired due to PN that cannot be determined with the SWM 5.07. Nevertheless, the SWM 5.07 is the most commonly used test to determine loss of protective sensation resulting from PN. It is highly sensitive (between 85% and 100%) and specific (between 34% and 100%) based on the number of sites tested and the testing methodology (Mayfield & Sugarman, 2000). Additionally, SWM data have been correlated with abnormal nerve conduction velocity outcomes, especially with more severe nerve impairment (Perkins, Olaleye, Zinman, & Brill, 2001). Like all tests in which the patient is an active participant, the accuracy of the SWM is dependent upon communication from an alert, cooperative, and responsive patient (Mayfield & Sugarman, 2000). To maximize the validity of the test results, those performing the SWM tests were given case report forms adapted from Feet Can Last a Lifetime (Feet Can Last a Lifetime, 2005). This document recommends measuring five sites on the plantar surface of the foot and the use of a “forced two choice testing method,” which minimizes patient bias (Sekuler, Nash, & Armstrong, 1973). Finally, the technique also involves random testing sites on the feet and avoids heavily callused or active wound sites.

It is obvious that changes in pain are difficult to objectively measure and are subject possibly to placebo effect. The 11-point VAS has been widely validated (Flandry, Hunt, Terry, & Hughston, 1991) and is not subject to evaluator bias because it is reported by the patient. The extent of the reduction in reported pain by the patients in this study (67%) substantially exceeds the reported minimal level of detectable change (1.3 to 1.6 points on the VAS), which is considered clinically relevant (Gallagher, Bijur, Latimer, & Silver, 2002). Moreover, the VAS pain reduction exceeded 3.0, which has been reported to be a clinically important difference in pain severity corresponding to

patient's perception of adequate analgesic control (Lee, Hobden, Stiell & Wells, 2003). Zinman et al. (2004) examined the placebo effect of 12 sham treatments with low-intensity laser therapy delivered over 6 weeks and noted an approximately 20% reduction in pain ( $6.9 \pm 1.7$  to  $5.4 \pm 1.9$ ). The patients in the present study had a similar level of initial pain ( $7.2 \pm 2.2$ ), but they reported more than three times the pain relief (67%) reported by the sham treated patients in the Zinman et al. study, making it very unlikely that the present results are due to a placebo effect. Lastly, the large number of patients (1563) with neuropathic pain whose pain decreased in this study would also tend to discount a placebo effect.

## 5. Conclusion

MIRE treatments are associated with a substantially improved foot sensation, assessed by the SWM 5.07, and a robust reduction in neuropathic pain that had been previously unresponsive to other interventions (both  $P < .0001$ ) in a cohort of 2239 patients initially diagnosed with PN. The improvements in foot sensation to the SWM 5.07 are remarkably similar (correlation = .98186) to our previous analysis of 1047 patients (DeLellis et al., 2005). Overall, the magnitude and consistency of these results and those from other studies using MIRE (Kochman, 2004; Kochman et al., 2002; Leonard et al., 2004; Prendergast et al., 2004; Powell et al., 2004) show that sensory disturbances associated with PN are not necessarily progressive and irreversible and that this condition can be effectively treated noninvasively with a high degree of patient safety.

This reported advancement in the treatment of sensory disturbances associated with PN has enormous potential to affect health care in other ways. For example, it would seem likely that a secondary outcome after the restoration of sensation would be a reduction in the incidence of LEU, consequent amputations, and high morbidity, particularly among patients with diabetic PN. One study reported a 1.5% annual incidence of LEU after symptomatic improvement in foot sensation to the SWM 5.07 through the use of MIRE (Powell et al., 2004). This represents more than an 80% reduction in the 35-week incidence rate (8%) recently reported by Armstrong et al. (2004) in patients with diabetic PN who had been prescribed accommodative footwear and were under the ongoing care of physicians. Additionally, at least where MIRE is used in conjunction with appropriate physical therapy, there is a significant improvement in balance and a substantial reduction in the number of falls in elderly patients (Kochman, 2004). The improved sensation during MIRE in patients who have a significant fall history may allow physical therapy interventions to be more effective. Because of the high reported costs of PN and its devastating sequelae (Gordois, Scuffham, Shearer, Oglesby, & Tobian, 2003; Harrington, Zagari, Corea, & Klitenic, 2000; Hogan, Dall, & Nikolov, 2003; Shearer,

Scuffham, Gordois, & Oglesby, 2003), the use of MIRE in patients can be expected to improve their quality of life and simultaneously offer significant cost savings to the U.S. and international healthcare systems.

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