Effectiveness of Monochromatic Infrared Photo Energy and Physical Therapy for Peripheral Neuropathy: Changes in Sensation, Pain, and Balance– A Preliminary, Multi-Center Study

Wendy Volkert, MSPT
Ahmed Hassan, PT, MS
Mohamed A. Hassan, PT, MHS
Vicki L. Smock, PT
Justin P. Connor, PT
Becky McFee, PT
Shayne K. Ferguson, PT, MHS, PhD, GCS, CWS
Thomas J. Burke, PhD

Wendy Volkert is a therapist at Genesis Medical Center, 1227 E. Rusholme Street, Davenport, IA 52803 (Email: wendyvolkert@bellsouth.net).

Ahmed Hassan is a therapist at Premier Physical Therapy, 14315 S. 108th Avenue, Orland Park, IL 60462 (Email: Hassanpt@aol.com).

Mohamed A. Hassan is the owner of Premier Physical Therapy Clinics, located at 3900 W. 95th Street, Suite 7, Evergreen Park, IL 60805; 14315 S. 108th Avenue, Orland Park, IL 60462; and, 40 S. Clay Street, Suite 7 W, Hinsdale, IL 60521 (Email: Hamadah68@aol.com).

Vicki L. Smock is a therapist at Westside Retirement Village, 8616 West 10th Street, Indianapolis, IN 46234 (Email: vsmock@comcast.net).

Justin P. Connor is a therapist at Sonoma Valley Hospital, 347 Andrieux Street, Sonoma, CA 95476 (Email: connorj@svh.com).

Becky McFee is the Clinical Director of Lumina of Campbellsville, 2020 Old Hodgenville Road, Campbellsville, KY 42718 (Email: gocards@luminaky.org).

Shayne Ferguson is Director of Rehabilitation Services at Lumina of Elizabethtown, 106 Diecks Drive, Elizabethtown, KY 42701 (Email: rehdir@luminaky.org).

Thomas J. Burke is Director of Research and Clinical Affairs at Anodyne Therapy LLC, 13570 Wright Circle, Tampa, FL 33626 (Email: tburke1@qwest.net).

The authors thank Amy Spirides for her invaluable help with the statistical analysis and the figures.

This study was funded in part by Anodyne Therapy, LLC.

1

ABSTRACT. *Objective:* To evaluate the effect of monochromatic infrared photo energy (MIRE™) combined with physical therapy in reducing pain, improving sensation, and increasing balance in patients with peripheral neuropathy.

Methods: Pain [VAS scale], diminished foot sensation [Semmes Weinstein Monofilament 5.07], and balance deficits [Tinetti Assessment Tool] of 272 patients, average age 69 years, were documented before and after receiving treatments at eight physical therapy clinics.

Results: Neuropathic pain, diminished foot sensation, and balance impairments at baseline were present in 93% of patients. After an average of 18 treatments, neuropathic pain decreased by 38%, lower extremity sensory impairment improved by 77%, and balance deficits decreased by 73% [P ≤ 0.006 for all results].

Conclusions: Compared with the literature, preliminary findings suggest that MIRE™ plus manual physical therapy improves pain, balance, and sensation symptoms in patients with peripheral neuropathy, at least temporarily. *[Article copies available for a fee from The Haworth Document Delivery Service: 1-800-HAWORTH. E-mail address: <docdelivery@ haworthpress.com> Website: <http://www.HaworthPress.com> © 2005 by The Haworth Press, Inc. All rights reserved.]*

INTRODUCTION

Peripheral neuropathy [PN] defines a wide variety of symptoms due to autonomic and sensory nerve dysfunction and is estimated to affect more than 22% of all adults aged 60 to 74 (Richardson, 2002) and as many as 20 million people of all ages (Jack Miller Center for Peripheral Neuropathy, 2005). PN manifests itself as subjective paresthesias, including pain and numbness, and may result in loss of light touch and vibratory sensation as measured by the Semmes Weinstein Monofilament [SWM] and Vibratory Perception Threshold [VPT] tests, respectively.

PN results from a wide variety of causes, including traumatic injuries, chronic illness, the use of certain medications, and alcohol abuse. In addition, approximately 50% of people with diabetes mellitus have PN that is particularly debilitating and costly (Gordois et al., 2003). PN appears to be an important contributor to lower extremity ulceration [LEU] and non-traumatic amputations (Gibbons et al., 1995) and has

been reported to be the major cause of hospitalizations among people with diabetes. The annual cost of diabetic peripheral neuropathy to the US healthcare system has been growing and is estimated to be at least $37 billion (Vinik, 2002; Gordois et al., 2003). Finally, PN significantly contributes to gait and balance dysfunction, fear of falling, and falls (Richardson, 2002) and its severity can be quantified by postural instability, loss of adequate ankle strength, and diminished proprioceptive thresholds (Simoneau et al., 1994; Wallace et al., 2002; Hausdorff et al., 2001). In fact, the risk of injury from falls in elderly patients exhibiting neuropathy may exceed 50%, far more than that of the elderly population as a whole (Blaum et al., 2003).

It is well known that the substantial sensory loss associated with PN makes it very difficult for physical therapists to improve balance and reduce fall risk using conventional strategies that have proven successful in elderly patients without neuropathy. Consequently, patients with PN are taught compensatory strategies including the use of canes and walkers, and are encouraged to identify and minimize environmental hazards. However, this approach has only been able to achieve a 14-22% increase in functional activities (Richardson et al., 2001).

Although currently there is no universally effective treatment for the paresthesias associated with PN, particularly that due to chronic illnesses such as diabetes, four recent studies have demonstrated that use of monochromatic infrared photo energy therapy [MIRE™] may symptomatically improve the sensory nerve dysfunction and pain associated with diabetic or other causes of PN (Kochman et al., 2002; Leonard et al., 2004; Prendergast et al., 2004; DeLellis et al., 2005). Recently a small study in 38 patients was conducted in a hospital physical therapy geriatric inpatient department and there was a high risk of falls as well as a documented fall history in these patients with neuropathy (Kochman, 2004). After combined use of MIRE™ and physical therapy, sensation returned to the feet and lower extremities and the balance and gait abnormalities assessed by the Tinetti Screening Tool (Tinetti, 1986) improved significantly. The present study sought to determine if physical therapists in a variety of settings [hospital, out patient, and long-term care] would achieve similar results. The present report summarizes the outcomes in 272 patients with PN, following treatment with MIRE™ and adjunctive manual physical therapy, at eight physical therapy clinics in five different states.

MATERIALS AND METHODS

Patients

This summary of the clinical outcomes following combined MIRE™ and physical therapy interventions was gathered from the records of patients treated at eight physical therapy clinics, including two hospitals, two nursing homes, and four outpatient clinics. All therapists were degreed but, as might be expected, the patients in the diverse clinics (e.g., nursing homes vs. outpatient clinics) were quite different with respect to the reasons they were in a specific facility. However, all patients had PN. MIRE™ was delivered following the protocol described by Kochman (2004) for approximately 30-40 min and then several physical therapy interventions were used depending on the particular patient's needs.

As noted above, physical therapy interventions alone in neuropathy patients are unable make a significant impact on quality of life (Richardson et al., 2001). For this reason, a non-experimental, retrospective design was used in the present analysis. Furthermore, there is a strong interest by many in the health care industry in actual clinical outcomes that occur in the real world of daily practice by therapists, rather than simply in controlled, clinical studies at a university or medical center. Each facility had been using MIRE™ for at least one year and the therapists were well versed in its application. Because outpatients and inpatients have different needs and comorbid factors, we sought to determine if outcomes from the combined use of MIRE™ and physical therapy in PN would differ in different facilities. Each facility examined the records of consecutive patients with a diagnosis of PN, for whom data had been collected relative to pain, light touch, and balance deficits, before and after MIRE™ and adjunctive active physical therapy treatments. Data for a total of 272 consecutive patients form the basis of this report. Patient identifiers were removed by the staff at each facility prior to this analysis.

Measurements

Neuropathic pain was measured using the 11-point Visual Analog Scale [VAS], with a pain score of 10 being maximum pain and zero being no pain. Assessment of light touch sensation was documented objectively using the standard Semmes Weinstein Monofilament [SWM] 5.07 test. Patients were asked to respond with "Now" when they were

able to sense randomly applied pressure by this monofilament at five sites on the plantar aspect of each foot. 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 (National Diabetes Education Program, 2005). This document recommends measuring five sites on the plantar surface of the foot and use of a "forced two choice testing method," which minimizes patient bias (Sekuler et al., 1973). Finally, the technique also involves testing random sites on the feet and avoids heavily callused or active wound sites.

Balance and gait abnormalities as well as relative fall risk were assessed using the Tinetti Assessment Tool (Tinetti, 1986). This is a widely recognized objective instrument for determining balance and gait deficiencies and assessing the risk of future falls (Tinetti et al., 1998; Tinetti & Speechley, 1989). Higher Tinetti scores (maximum 28) correlate inversely with risk of falls. Individuals with Tinetti scores under 19 are considered to be at the highest risk for falls, those with scores between 19 and 23 are considered to have a moderate risk of falling, and those with scores 24 and above are considered to be at low risk for falls.

Intervention

MIRE™ was delivered using the Anodyne® Therapy System [ATS]. The ATS is a super luminous diode-based monochromatic photon therapy modality (wavelength 890 nm) that was cleared by the FDA in 1994 for temporarily increasing local circulation and reducing pain (Burke, 2003). The ATS device was also the modality used in studies showing improved sensation and/or balance and reduced pain in patients with PN (Kochman et al., 2002; Leonard et al., 2004; Prendergast et al., 2004; DeLellis et al., 2005). The ATS device had been purchased by, and was in extensive use at, each study site for rehabilitation care plans covering a wide variety of pain and/or circulatory conditions including PN. These sites are among the over 3300 sites in the US using ATS for a variety of physical therapy challenges. The treatment protocol consisted of 30 to 60 minute treatments with the ATS, using four separate diode-containing therapy pads per limb, one on the medial and one on the lateral side of each lower extremity, and two on the plantar surface of the foot followed then by manual physical therapy depending on the assessed needs of the individual patient. Manual therapies included static and dynamic balance retraining, neuromuscular reeducation, strength training, and stretching of the Achilles tendon and hip flexors. Treatments were rendered three times per week for a minimum of six treatments [mean $\pm$ SD, 18 $\pm$ 10.2

treatments]. The number of treatments continued until the patient attained functional goals or until their progress plateaued at near normal levels for reduced pain, reduced fall risk, and/or improved sensation.

As part of the customary therapy protocols, clinical notes were maintained that described progress, on an interim basis, toward these goals. Additionally, at the conclusion of the treatment protocols, post-treatment data were evaluated to determine the degree of pain, the number of sites on the foot that remained insensitive to the SMW 5.07, and any residual balance deficits.

Data Analysis

Data were analyzed by paired 2-tailed t-test with a null hypothesis that the treatment protocol would have no effect on three endpoints: pain levels, foot sensation to the SWM 5.07, or balance. Significance was accepted when $P < 0.05$. All values are expressed as mean ± one standard deviation.

Data were first analyzed for all patients with PN and then separately for those with either diabetic peripheral neuropathy [DPN] or peripheral neuropathy from other causes [PNO]. Patients in both subgroups [DPN and PNO] may have exhibited impairment in one of the evaluated measures but not necessarily in all of them. Therefore, changes in each individual functional limitation were also evaluated.

Pain was analyzed only in those patients who exhibited a VAS score of four or more indicating moderate to severe pain that would be expected to result in some level of functional limitation. A total of 261 patients [96%] had pain VAS scores of four or greater prior to treatment (Acute Pain Management Guideline Panel, 1992). Changes in foot sensitivity to the SWM 5.07 were analyzed only among those patients who exhibited insensitivity at two or more sites on each foot (four or more sites on both feet). This allowed us to evaluate the possible efficacy of the combined use of both MIRE and physical therapy in those patients who had severe loss of protective sensation [LOPS], which is considered a localized illness of the foot (Centers for Medicare and Medicaid Services, 2001). A total of 257 patients [94%] had LOPS before treatment based on these CMS guidelines. Balance deficits as measured with the Tinetti Instrument, were analyzed only among those patients who exhibited a pre-treatment Tinetti score of 23 or less. A score of 23 was selected as an indication of a balance deficit because this score is 1 point below the breakpoint between "low fall risk" and "moderate fall risk" under the

Tinetti scoring system. A total of 250 patients [92%] had Tinetti scores under 24 before treatment.

RESULTS

Patient Demographics

The mean age of the patients was 69 ± 12.3 years (mean $\pm$ 1 SD; range: 33 to 100). Among the patients, 135 (50%) were male and 137 (50%) were female. In the cohort, 128 patients (47%) had a primary diagnosis of DPN and 144 (53%) exhibited PNO. The clinical deficits in pain, foot sensation, and balance in the entire 272 patient cohort, the DPN subgroup, and the PNO subgroup are also shown in Table 1. There were no differences in the two groups with respect to the severity of sensory loss, pain, or balance deficits prior to initiating this therapy

TABLE 1. Patient Demographics (Pre-Treatment)

	PNO		DPN		Total	
Patients	144	53%	128	47%	272	
Male	66	46%	69	54%	135	50%
Female	78	54%	59	46%	137	50%
Age[a]	70 ± 12.1		68 ± 12.5		69 ± 12.3	
Number of treatments	19 ± 11.6		17 ± 8.2		18 ± 10.2	
Treatment time (in minutes)	31 ± 4.1		38 ± 12		34.2 ± 9.4	
No. patients with LOPS (4 or more sites insensate out of 10)	140	97%	117	91%	257	94%
Number sites insensate (10 max)	7.2 ± 1.8		7.5 ± 1.9		7.3 ± 1.9	
No. patients VAS scale > 3	138	96%	118	92%	256	94%
VAS before treatment	7.8 ± 1.2		7.7 ± 1.1		7.7 ± 1.2	
Discomforting pain (VAS 4-6)	17	12%	14	11%	31	11%
Distressing pain (VAS 6.5-8)	100	69%	89	70%	189	69%
Horrible to excruciating pain (VAS 8.5-10)	22	15%	19	15%	41	15%
No. patients with balance impairment (Tinetti < 24)	138	96%	112	88%	250	92%
No. patients with moderate fall risk (Tinetti 19-23)	12	8%	18	14%	30	11%
No. patients with high fall risk (Tinetti 0-18)	126	88%	94	73%	220	81%

[a]Mean ± SD; PNO = Peripheral neuropathy other causes; DPN = Diabetic peripheral neuropathy; LOPS = Loss of protective sensation; VAS = Visual analogue scale.

protocol. Both groups responded to interventions in a similar manner. The time of treatment was similar in both groups [31 min in the PNO group and 38 min in the DPN group, P = NS].

Although every patient had to exhibit at least one functional limitation associated with their PN to qualify for a physical therapy plan of care, the prevalence of all three functional limitations was present in 89% of this patient cohort. It is clear that patients with PN are likely to have multiple functional limitations associated with PN. Interestingly, the functional impairments in these subgroups were substantially similar.

The pain intensity level at baseline of those with PNO was almost identical to that in patients with DPN [VAS = 7.8 for PNO, 7.2 for DPN]. The average number of sites insensitive to the SWM 5.07 was also virtually the same [7.2 PNO, 7.5 DPN]. The largest difference (although still relatively small) was the initial measure of balance deficit. The PNO group initially tested at 12.9 on the Tinetti Instrument and the DPN group tested at 14.4. However, both groups were well below the value of 19 and were clearly in the "high fall risk" category.

Changes in Neuropathic Pain Based on VAS Scale

Both the DPN and PNO groups obtained significant reductions in neuropathic pain based on the VAS scores. The mean improvement in VAS was 2.9 ± 2.0 in the PNO group [37%] and 3.0 ± 2.5 in the DPN group [39%], representing similar percentage reductions in pain level (see Table 2).

The severity of pain within each subgroup was also examined. The DPN group exhibited more than a 50% reduction in pain at both the discomforting pain level [VAS 4.0-6.0] and the horrible pain level [VAS 8.5-10.0] and a 35% reduction when pain was distressing [VAS 6.5-8.0] prior to treatment. The PNO subgroup only obtained a 17% reduction in their pain levels in the distressing level with progressively greater percentage pain reductions when the pain intensity was more severe at baseline. Although decreased pain was observed regardless of its initial severity, the greatest reduction in each subgroup and in the 272 patient cohort overall was noted in those patients who had horrible pain at baseline evaluation.

Figure 1 documents the VAS pain scores for all patients before and after treatment. Prior to treatment most of the patients experienced a pain level of 8 or more. The combination of MIRE™ and physical therapy treatment resulted in a significant decrease in VAS scores [P < 0.0001].

TABLE 2. Neuropathic Pain Pre- and Post-Treatment

	PNO (n = 139)	DPN (n = 118)	ALL (n = 257)
VAS pre-treatment	7.8 ± 1.2	7.7 ± 1.1	7.7 ± 1.2
VAS post-treatment	4.9[a] ± 1.8	4.7[a] ± 2.5	4.8[a] ± 2.2
VAS decreases	2.9 ± 2.0	3.0 ± 2.5	2.9 ± 2.2
% Pain reduction	37%	39%	38%
Horrible to excruciating pain (VAS 8.5-10)	PNO (n = 22)	DPN (n = 15)	ALL (n = 37)
VAS pre-treatment	9.3 ± 0.5	9.5 ± 0.5	9.4 ± 0.5
VAS post-treatment	5.3[a] ± 1.9	4.1 ± 3.6	4.8[a] ± 2.7
VAS decreases	4.0 ± 2.0	5.4 ± 3.8	4.6 ± 2.9
% Pain reduction	43%	57%	49%
Distressing pain (VAS 6.5-8)	PNO (n = 100)	DPN (n = 89)	ALL (n = 189)
VAS pre-treatment	7.9 ± 0.3	7.8 ± 0.5	7.8 ± 0.4
VAS post-treatment	5.0[a] ± 1.8	5.1[a] ± 2.0	5.0[a] ± 1.9
VAS decreases	2.9 ± 1.8	2.7 ± 2.0	2.8 ± 1.9
% Pain reduction	37%	35%	36%
Discomforting pain (VAS 4-6)	PNO (n = 17)	DPN (n = 14)	ALL (n = 31)
VAS pre-treatment	5.3 ± 0.8	5.4 ± 0.9	5.3 ± 0.9
VAS post-treatment	4.4[a] ± 1.9	2.5[b] ± 2.8	3.5[a] ± 2.5
VAS decreases	0.9 ± 2.0	2.9 ± 2.5	1.8 ± 2.4
% Pain reduction	17%	54%	34%

Values expressed as mean ± SD; [a]All post treatment measures are $P < 0.0001$ vs. Pre-treatment;
[b]All post-treatment measures are $P \leq 0.006$ vs. pre-treatment.

Changes in Foot Insensitivity to the SWM 5.07

Both the DPN and PNO subgroups obtained substantial improvement in the mean number of sites sensitive to the SWM 5.07 indicating improved foot sensation [see Table 3]. The mean improvement was 5.4 ± 2.8 sites, a 72% improvement compared with baseline, in the DPN subgroup and 5.8 ± 2.6 sites, an 81% improvement compared with baseline, in the PNO subgroup [both $P < 0.0001$].

Importantly, at the conclusion of therapy, the patients with DPN had only 2.1 ± 2.9 sites [total for both feet] insensitive to the SWM 5.07. This degree of improvement indicated that most patients no longer exhibited LOPS as defined by CMS. The results were somewhat more impressive in the PNO group where the average number of sites insensitive to the SWM 5.07 was only 1.4 ± 2.1 [total for both feet] at the conclusion of

FIGURE 1. Pain before (gray bars) and after (solid bars) combined treatment with MIRE™ and physical therapy.
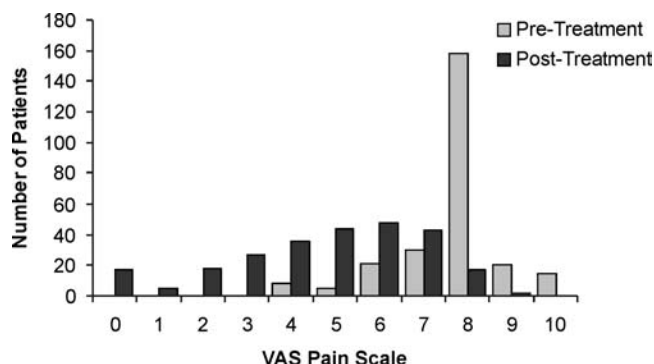

TABLE 3. Foot Sensitivity to the SWM 5.07 Pre- and Post-Treatment

	PNO (n = 140)	DPN (n = 117)	Total (n = 257)
Pre-treatment sites insensate (max 10 sites)	7.2[a] ± 1.8	7.5 ± 1.9	7.3 ± 1.9
Post-treatment sites insensate	1.4[b] ± 2.1	2.1[a] ± 2.9	1.7[a] ± 2.5
Mean decrease sites insensate	5.7[b] ± 2.6	5.4 ± 2.8	5.6 ± 2.7
% Improvement in foot sensation	81%	72%	77%

[a]Mean ± SD; [b]All post-treatment measures are P < 0.0001 vs. pre-treatment.

therapy. The absence of LOPS after therapy was a significant improvement [P < 0.0001] compared with baseline.

Figure 2 demonstrates the number of insensitive sites to the SWM 5.07 prior to and after treatment in 257 patients with LOPS as reflected by being insensitive to the SWM at four or more sites at baseline evaluation. The results clearly demonstrate that there was a significant decrease [P < 0.0001] in the number of insensate sites among the entire population.

Changes in Balance Impairment and Fall Risk Based on Tinetti Scores

Patients with either DPN or PNO demonstrated a substantial, improvement in their balance and a reduced fall risk after receiving treatment. The mean Tinetti score improvement (see Table 4) was 9.0 ± 3.8 points in the DPN subgroup and 10.5 ± 2.8 points in the PNO subgroup

FIGURE 2. Sensitivity (number of insensate sites on both feet) to the SWM 5.07 before (gray bars) and after (solid bars) treatments.
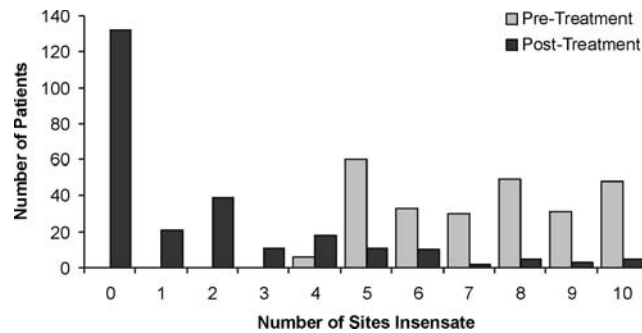

TABLE 4. Balance Impairments (Tinetti Scores) Pre- and Post-Treatment

Patients (with Tinetti < 24 at baseline)	PNO (n = 138)	DPN (n = 112)	ALL (n = 250)
Tinetti pre-treatment	12.9[a] ± 4.1	14.2 ± 4.1	13.5 ± 4.1
Tinetti post-treatment	23.4[b] ± 3.1	23.2[b] ± 3.2	23.3[b] ± 3.1
Mean increase	10.5 ± 2.8	9.0 ± 3.8	9.8 ± 3.4
% Improvement	81%	63%	73%
Moderate fall risk (19-23)	PNO (n = 12)	DPN (n = 18)	ALL (n = 30)
Tinetti pre-treatment	20.6 ± 0.9	20.9 ± 1.6	20.8 ± 1.3
Tinetti post-treatment	26.0[b] ± 1.9	24.8[b] ± 2.5	25.3[b] ± 2.3
Mean increase	5.4 ± 2.2	3.9 ± 3.0	4.5 ± 2.8
% Improvement	26%	19%	22%
High fall risk (0-18)	PNO (n = 126)	DPN (n = 94)	ALL (n = 220)
Tinetti pre-treatment	12.2 ± 3.4	13.0 ± 3.1	12.5 ± 3.3
Tinetti post-treatment	23.2[b] ± 3.1	22.9[b] ± 3.3	23.1[b] ± 3.2
Mean increase	11.0 ± 2.3	10.0 ± 3.2	10.5 ± 2.8
% Improvement	90%	76%	85%
	PNO	DPN	ALL
No. of patients with low fall risk after Tx	87	61	148
% Low fall risk after Tx	63%	54%	59%
No. of patients with moderate fall risk after Tx	38	41	79
% Moderate fall risk after Tx	28%	37%	32%
No. of patients with high fall risk after Tx	13	10	23
% of patients with high fall risk after Tx	9%	9%	9%

[a]Mean ± SD; [b]All post-treatment measures are P < 0.0001 vs. Pre-treatment; Tx = treatment.

representing percentage improvements of 63% and 81%, respectively [both P < 0.0001].

Thus, whereas both subgroups had significant increases in both raw Tinetti scores and percentage improvement, the PNO group obtained approximately a 30% higher percentage improvement than did the DPN group.

Prior to treatment, the average Tinetti score was well below the breakpoint [19 points] for high fall risk [12.9 ± 4.1 in the PNO group and 14.2 ± 4.1 in the DPN group]. Tinetti scores increased substantially in each group and overall after therapy. Importantly, at the conclusion of the treatment protocol, the average Tinetti score in both the PNO and the DPN groups was just over 23 points. This is very close to the value of 24 that, in the Tinetti scoring system, is where patients have been determined to have a low fall risk. Thus, there was a significant improvement in balance and a concomitant reduction in fall risk. The data were also analyzed with respect to the fall risk based on the initial impairment in the Tinetti scores. The greatest percentage reduction in fall risk in both the PNO and DPN subgroups occurred among those who were at high fall risk [P < 0.0001]. At the conclusion of the therapy interventions, only 9% of the patients [23 of 250] remained at a high risk for falls [9% or 13 of 138 patients in the PNO group and 9% or 10 of 112 in the DPN group], compared with 88% [220 of 250] at baseline evaluation [126 in the PNO group and 94 in the DPN group]. Additionally, 59% of patients [148 of 250] who were either at moderate or high risk for falls at baseline were at low risk for falls after receiving MIRE™ and physical therapy.

Figure 3 is a graphic representation of the dispersion of the Tinetti scores in the patient population prior to and after treatment. Prior to treatment, 50% of the patients scored in the 12 to 15 range, substantially below the high fall risk score of 19 on the Tinetti scale. After treatment, the 50% of the patients had scores from 23 to 26, indicating that most patients were now categorized as "low fall risks" [24 and above]. Thus, there was a significant decrease in fall risk in the vast majority of patients regardless of the level of their impairment prior to treatment.

DISCUSSION

It was hypothesized that the use of MIRE™ and adjunctive manual physical therapy would reduce neuropathic pain, improve foot sensation, and reduce fall risk [by improving balance] in patients with PN from diabetes or other causes. The results confirmed this hypothesis. The

analysis also demonstrates that the prevalence and extent of functional limitations [pain, foot insensitivity, and balance deficits] experienced by patients with PN are substantially similar regardless of whether the PN is due to diabetes or other causes and that the therapeutic approach employed resulted in similarly improved outcomes. Finally, the improved outcomes using the treatment protocol were significant and very similar regardless of the etiology of the PN. Because all patients received both MIRE™ and adjunctive manual physical therapy, it is impossible to attribute these improvements more so to either MIRE™ alone or the manual therapy alone. However, several inferences can be drawn from a review of the literature. First, there are no reports demonstrating that any non-surgical intervention other than MIRE™, including manual physical therapy alone, is able to improve foot insensitivity to the SWM 5.07. Therefore, it is likely that these results occurred because physical therapists included MIRE™ as a component of treatment. Recent studies have documented the effect of MIRE™ treatment alone on foot insensitivity to the SWM 5.07 resulting from DPN and/or PNO (Kochman et al., 2002; Leonard et al., 2004; Prendergast et al., 2004; DeLellis et al., 2005). Improvements were noted after six treatments with MIRE™ alone and further improvement occurred with 10-12 treatments. It is not surprising therefore that six or more treatments [mean 18] in this cohort of patients were accompanied by improved sensation in the lower extremities. These results were unlikely to be due to a placebo effect. Leonard et al. (2004) looked closely at the possible placebo effect of MIRE on restoration of sensation by using identical units that did not emit photo energy. DPN patients on placebo devices did not improve.

FIGURE 3. Tinetti scores before (gray bars) and after (solid bars) treament.
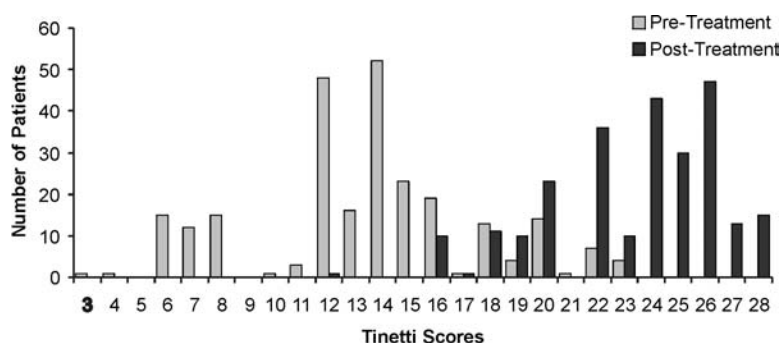
Second, there are no published reports indicating that manual physical therapy alone is able to substantially reduce pain associated with PN. It may, in fact, be extremely difficult to engage patients with neuropathic pain in a physical therapy program that would otherwise be easily implemented in patients without pain. The patients in this analysis had significant pain at baseline. Furthermore, neuropathic pain syndromes such as those in this group of patients are not sympathetically mediated and therefore do not usually respond to sympathetic blockade through manual mobilization (The Merck Manual of Diagnosis and Therapy, 2005). Despite these problems, participation by patients in the active physical therapy treatment protocol may have been easier for the clinicians to implement because of the coincidental use of MIRE™ due to the reduction in pain and the improved sensation in the lower extremities. Accordingly, we tentatively conclude that the treatment protocol, which included MIRE™ and manual physical therapy, was associated with a substantial reduction in neuropathic pain.

Historically, physical therapy interventions designed to reduce the number of falls in elderly patients, particularly those with distal neuropathy, have resulted in minimal success (Hill-Westmoreland et al., 2002; Hageman & Thomas, 2002) although a manual physical therapy protocol without MIRE™ has been reported to have some beneficial effects on balance (Richardson et al., 2001). None of these reports included an analysis of changes in gait and balance using a Tinetti or similar test(s). Because we have been unable to locate any literature showing changes in Tinetti scores of patients with PN following treatment with manual physical therapy alone, we conclude that it was the comprehensive therapy protocol employed for the patients treated in this report that substantially increased their balance and reduced their risk of falls.

We also recognize the limitations of a post-treatment analysis, specifically that these data were based upon a review of patients' charts. There was no control arm comparing the possible effect of MIRE™ alone or physical therapy interventions alone in each patient. However, historical evidence in the published literature suggests that physical therapy alone will do little to improve quality of life issues in patients with PN and we could find no ethical justification for re-confirming in our patients, by use of another randomized control trial of physical therapy alone, what others have reported. The previous failures are probably because PN patients continue to experience neurological deficits in sensation, balance and/or pain. With the growing evidence that MIRE™ can restore sensation in patients with peripheral neuropathy (Kochman

et al., 2002; Leonard et al., 2004; Prendergast et al., 2004; DeLellis et al., 2005), it seemed reasonable to combine MIRE™ and physical therapy to determine if a combination of approaches could elicit a better outcome in patients than would physical therapy alone.

Furthermore, because the SWM is an objective test, historical controls may be appropriate since the sensory loss in DPN patients is generally thought to be progressive and irreversible (Sima & Laudio, 1996). There are no pharmacologic treatments for sensory loss associated DPN making MIRE™ an impressive therapeutic intervention for therapists. Although we did not examine the concomitant use of psychoactive drugs, pain medications, and other intrinsic or extrinsic risks for falling, there were no changes in pain medications or psychoactive drugs reported to the investigators during this short study protocol. However, the possibility does exist that this might have occurred in some patients and cannot be completely ruled out.

Lastly, the study protocol did not permit us to analyze the proportion of improvements that were attributable to physical therapy alone and those related to the increases in foot sensation alone resulting from the use of MIRE™. Future studies should consider the use of other types of controls to determine the relative effectiveness of the combination of MIRE™ with physical therapy compared with physical therapy alone. Because patients are heterogeneous, perhaps a trial of outcomes using physical therapy alone, followed by MIRE™ and physical therapy together, would be a useful protocol design.

In conclusion, MIRE™ when used in conjunction with manual physical therapy is able to significantly reduce pain, improve foot sensation, and improve balance and gait thus reducing an objective fall risk in patients exhibiting PN, at least temporarily. Of interest, as noted in this chart review, the benefit of combined physical therapy and MIRE™ was shown in the majority of patients with neuropathy, irrespective of whether this was due primarily to diabetes or other causes and despite the fact that treatments were rendered in either an outpatient clinic, in a hospital, or in a nursing home.

REFERENCES

Acute Pain Management Guideline Panel (1992). *Acute Pain Management: Operative or Medical Procedures and Trauma: Clinical Practice Guidelines*. AHCPR Pub No. 92-0032, Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, US Department of Health and Human Services.

Blaum, C. S., Ofstedal, M. B., Langa, K. M., & Wray, L. A. (2003). Functional outcomes in older Americans with diabetes mellitus. *Journal of the American Geriatric Society, 51*, 745-753.

Burke, T. J. (2003). 5 Questions-and answers-about MIRE treatment. *Advances in Skin and Wound Care, 16*, 369-371.

Centers for Medicare and Medicaid Services, Decision Memorandum CAG-00059, October 2001.

DeLellis, S., Carnegie, D. H., & Burke, T. J. (2005). Improved sensitivity in patients with peripheral neuropathy after treatment with monochromatic infrared energy. *Journal of the American Podiatric Medical Association, 95*, 143-147.

Gibbons, G. W., Marcaccio, E. J., & Habershaw, G. M. (1995). Management of the diabetic foot. Vascular Surgery: Theory and Practice. Callow A. D., Ernst C. B. N. (Eds). Appleton and Lange, Stamford, CT, 167-178.

Gordois, A., Scuffham, P., Shearer, A., & Oglesby, A. (2003). The health care costs of peripheral neuropathy for people with diabetes in the U.S. *Diabetes Care, 26*, 1790-1795.

Hageman, P. A., & Thomas, V. S. (2002). Gait performance in dementia: The effects of a 6-week resistance training program in an adult day-care setting. *International Journal of Geriatric Psychiatry, 17*, 329-334.

Hausdorff, J. M., Rios, D. A., & Edelberg, H. K. (2001). Gait variability and fall risk in community-living older adults: A 1-year prospective study. *Archives of Physical Medicine and Rehabilitation, 82*, 1050-1056.

Hill-Westmoreland, E. E., Soeken, K., & Spellbring, A. M. (2002). A meta-analysis of fall prevention programs for the elderly: How effective are they? *Nursing Research, 51*, 1-8.

Jack Miller Center for Peripheral Neuropathy, University of Chicago (2005). *http://millercenter.uchicago.edu/learnaboutpn/index.shtml*. Accessed on March 28, 2005.

Kochman, A., Carnegie, D., & Burke, T. (2002). Symptomatic reversal of peripheral neuropathy in diabetic patients. *Journal of the American Podiatric Medical Association, 92*, 125-130.

Kochman, A. B. (2004). Restoration of sensation, improved balance and gait and reduction in falls in elderly patients with use of monochromatic infrared photo energy and physical therapy. *Journal of Geriatric Physical Therapy, 27*, 18-21.

Leonard, D. R., Farooqi, M. H., & Myers, S. (2004). Restoration of sensation, reduced pain, and improved balance in subjects with diabetic peripheral neuropathy: A double-blind, randomized, placebo-controlled study with monochromatic near-infrared treatment. *Diabetes Care, 27*, 168-172.

National Diabetes Education Program. Feet Can Last a Lifetime: *http://www.ndep.nih.gov/diabetes/pubs/Feet_HCGuide.pdf*. Accessed on March 28, 2005.

Prendergast, J. J., Miranda, G., & Sanchez, M. (2004). Reduced sensory impairment in patients with peripheral neuropathy. *Endocrine Practice, 10*, 24-30.

Richardson, J. K. (2002). Factors associated with falls in older patients with diffuse polyneuroapthy. *Journal American Geriatric Society, 50*, 1767-1773.

Richardson, J. K., Sandman, D., & Vela, S. (2001). A focused exercise regimen improves clinical measures of balance in patients with peripheral neuropathy. *Archives of Physical Medicine and Rehabilitation, 8*, 205-209.

Sekuler, R., Nash, D., & Armstrong, R. (1973). Sensitive, objective procedure for evaluating response to light touch. *Neurology, 23*, 1282-1291.

Sima, A. A., & Laudio, C. (1996). Design of controlled clinical trials for diabetic peripheral polyneuropathy. *Seminars in Neurology, 16*, 187-191.

Simoneau, G. C., Ulbrecht, J. S., Derr, J. A., Becker, M. B., & Cavanagh, P. R. (1994). Postural instability in patients with diabetic sensory neuropathy. *Diabetes Care, 17*, 1411-1421.

The Merck Manual of Diagnosis and Therapy, Neuropathic Pain; M. H. Beers & M. D. Berkow (Eds), Section 14, Chapter 167, 17th edition. *http://www.merck.com/ mrkshared/mmanual/section14/chapter167/167d.jsp.* Accessed on March 29, 2005.

Tinetti, M. E. (1986). Performance-oriented assessment of mobility problems in elderly patients. *J Am Geriatr Soc, 34*, 119-126.

Tinetti, M. E., & Speechley, M. (1989). Preventions of falls among the elderly. *New England Journal of Medicine, 320*, 10055-10059.

Tinetti, M. E., Speechley, M., & Ginter, S. F. (1998). Risk factors among elderly persons living in the community. *New England Journal of Medicine, 319*, 1701-1707.

Vinik, A. I. (2002). Neuropathy: New Concepts in Evaluation & Treatment. *Southern Medical Journal, 95*, 21-23.

Wallace, C., Reiber, G. E., LeMaster, J., Smith, D. G., Sullivan, K., Hayes, S., & Vath, C. (2002). Incidence of falls, risk factors for falls, and fall-related fractures in individuals with diabetes and a prior foot ulcer. *Diabetes Care, 25*, 1983-1986.