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The restorative effects of pulsed infrared light therapy on significant loss of peripheral protective sensation in patients with long-term type 1 and type 2 diabetes mellitus

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Abstract Pulsed infrared light therapy (PILT) has been shown to increase peripheral sensation in diabetic patients with diabetic peripheral neuropathy (DPN). However, most studies last for very short periods, with the subjects receiving only 6–20 treatments. The purpose of this study was to evaluate the effectiveness of an eight-week course of PILT in reversing long-standing, profound DPN in patients with type 1 and type 2 diabetes. Twenty-two subjects with a diagnosis of type 1 (n=2) or type 2 (n=20) diabetes participated in the study. PILT was administered to one foot chosen at random with the other foot serving as a within-subject control (no treatment). Patients underwent 24 treatments (3 times/week, for eight weeks) for 30 min per treatment. Changes in peripheral protective sensation (PPS) were measured using Semmes-Weinstein monofilaments (SWM) ranging from 3.7 to 6.48. PILT improved PPS even in patients with long-standing chronic neuropathies whose initial pre-study sensation was not measurable with a 200-g SWM. PILT significantly improves PPS. While the exact mechanism of action is not understood, infrared light may improve peripheral neuropathies by improving foot perfusion by stimulating nitric oxide production.

Key words Pulsed infrared light therapy • Peripheral neuropathy • Peripheral protective sensation • Loss of protective sensation • Type 1 diabetes mellitus • Type 2 diabetes mellitus • Semmes-Weinstein monofilaments • Infrared light modality • Physical therapy

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Introduction

Patients with diabetes have many pathological complications that accompany the physiological impairment of either making no insulin (type 1), or developing peripheral resistance to insulin (type 2). In either type of diabetes, the derangement of the normal insulin-to-glucose relationship makes the maintenance of euglycaemia an hour-to-hour challenge. Hypoglycaemia and hyperglycaemia are an ever-present reality in the lives of these patients. Poor control over hyperglycaemia brings with it a plethora of chronic, debilitating conditions such as neuropathic

ulcers, peripheral vascular disease, atherosclerosis, hypertension, neuropathies, nephropathies, immune system deficiencies and compromised wound healing.

Significant pharmacological interventions in the last 20 years have been helpful in assisting patients with diabetes to gain some control over hyperglycaemia. The development of ACE inhibitors, hypoglycaemic agents and long-acting insulins have been encouraging. However, hyperglycaemia, and its attendant pathological effects on organ systems, remains a chief medical concern.

Recently a new treatment, pulsed infrared light therapy (PILT), has become available. PILT represents a breakthrough as a non-pharmacological and non-invasive therapy for the treatment of neuropathies and the consequent loss of peripheral protective sensation (PPS). PILT gives patients with diabetes a hope that the loss of PPS may be prevented or reversed as long as afferent nerves in the feet and legs have not permanently stopped functioning.

A recent study by Kochman et al. [1] suggests that losses in PPS can be reversed. The authors used infrared light therapy on both type 1 (n=25) and type 2 (n=24) diabetics, who had been diagnosed with peripheral neuropathies. Treatments consisted of twelve 30-min treatments spread over 30 days. Semmes-Weinstein monofilaments (SWM) (size range: 3.22–6.45) determined the patient's improvement in PPS at three sites: great toe, fourth toe, plantar arch. After the treatments, the authors reported 100% of the patients had SWM values below 5.07 (the 10-g force monofilament commonly used in foot-screening clinics signaling the beginning of loss of protective sensation (LOPS) [2]). Their findings indicated a normal or near normal attainment of PPS, suggesting that infrared light therapy was successful in acutely reversing the loss of PPS in all subjects. Unfortunately, this study was not controlled or blinded. Additionally, the authors did not provide any clear information concerning site-specific changes due to the experimental treatment.

In a similar study, Leonard et al. [3] studied two different diabetic groups – group 1 (n=18), with an insensitivity to the 5.07 monofilament (mild to moderate LOPS); and group 2 (n=9), with a profound insensitivity to the 6.65 monofilament (severe LOPS). After testing sensitivity to the 5.07 monofilament at five separate sites, each group received 40 min of PILT, three times/week for two weeks (six total treatments) on the experimental foot and an equal number of sham treatments on the control foot. The authors reported that, after the six treatments, the number of sites sensitive to the 5.07 monofilament improved in group 1's treated foot, with no improvement in the sham-treated foot. The authors then changed the control *vs*. experimental design of their study by giving an additional six treatments of PILT to both the former sham feet and the experimental feet. When both feet received PILT during the second two-week period, the number of sites sensitive to monofilament testing improved in both feet. However, this study was unclear as to whether the patients ever achieved restoration of normal sensation i.e., were the patients able to sense a monofilament lower than the 5.07 SWM. Additionally, the authors reported that the sensitivity to the 5.07 SWM in group 2 – the more severely involved patients – did not change after either the first six treatments or the second six treatments. Sadly, the authors could not report any changes in sensitivity from the 6.65 SWM down to lower monofilaments, as they did not use any SWMs between 6.65 and 5.07. Finally, no site-specific response to PILT was reported.

In another study by Kochman [4], patients with a positive loss of PPS as determined with negative sensibility to the 5.07 SWM, a positive history of self-reported falls in a 3-month period, and a suspected diminution of postural balance as suggested by a fall history, were treated with PILT. Depending on their degree of LOPS, 38 patients received PILT for 30–40 min, for 6–20 (average 12) treatments. In addition, all patients participated in a balance training programme. Kochman [4] reported that all subjects had a complete restoration of PPS and that their history of falling improved to fewer falls per month with an improved Tinetti balance score. Unfortunately, this study gathered its data from a retrospective chart review design and, therefore, had no controls. Additionally, there was no accurate history available for the number of falls, making the central thesis of improved balance secondary to improved PPS as a result of PILT difficult to substantiate. Finally, it was difficult to attribute the changes in the patient's PPS to either PILT, the balance retraining that the patients received or any pharmacological intervention the patients may have received.

Finally, Prendergast et al. [5] reported that 27 patients received 10 PILT treatments each lasting 40 min over a 2-week period. These authors assessed peripheral sensibility in the feet using a Neurometer CPT (current perception threshold) diagnostic tool. After 10 PILT treatments, the authors stated that most of the patients had some level of increased sensibility in their feet. However, from the data provided, it is difficult to relate the CPT measures of improved PPS to improvements measured by the more commonly employed SWM.

In summary, there is a paucity of uniformly well designed studies providing convincing evidence that the application of PILT to diabetic patients with a loss of PPS can totally restore PPS to normal values. Additionally, most studies have based their argument that PILT improves PPS after finding a positive SWM score in only one of several sites tested. The site-specific efficacy of PILT, however, has not been reported. Moreover, there have been no controlled trials published where patients with long-term severe losses of PPS have regained normal PPS after the application of PILT. This does not imply that PILT is ineffectual for the long-term patient. Instead, it suggests that studies with a greater number of treatments

that specifically evaluate several sites are needed. Therefore, the purpose of this study is to determine if the application of eight weeks of PILT improves site-specific PPS in patients with a chronic history of type 1 and type 2 diabetes who have sustained severe losses in PPS.

Methods

Subjects

This study was reviewed and approved by the Comité Ético of the Hospital Clínico de Valencia, Valencia, España prior to the recruitment of subjects and the gathering of data.

Twenty-two patients with a clinical diagnosis of type 1 (n=2) or type 2 (n=20) diabetes mellitus participated in this study. The subjects for this study were recruited from the Asociacíon de Diabetes of Valencia, España who lived in Valencia or in the semiautonomous region of the Province of Valencia.

Subject exclusion criteria for this study included: (a) no open wounds in either lower extremity; (b) a normal haematocrit which was between 30% and 50%; (c) a normal haemoglobin which was between 9 and 18 g/dl; (d) the patient was not in acute renal failure. No attempt was made to change physician-directed pharmacological interventions that patients were receiving when they entered the study.

The research staff provided the patients with information concerning the benefits and risks associated with their participation in the study after which the prospective subjects signed a consent form and entered the study.

All subjects were interviewed concerning their medical history. Pertinent patient information consisted of: (a) years living with diabetes; (b) height, weight and body mass index (BMI); (c) current medication inventory; (d) most recent available glycosylated haemoglobin (HbA_{1c}); (e) history of a nephropathy or a retinopathy since diabetes diagnosis; (f) a standard cardiovascular risk profile evaluating hypercholesterolaemia, hypertriglyceridaemia, hypertension, smoking history and physical activity level. A summary of the anthropomorphic characteristics and other pertinent subject information is contained in Table 1.

Tests and measurements

Body mass index

BMI (kg/m^2) was measured at the beginning of the study. A BMI <24.9 was considered normal while a BMI ≥30 indicated obesity – a known risk factor for cardiovascular disease and the onset of type 2 diabetes [6].

Ankle/brachial index

Each subject's ankle/brachial index (ABI) for both the control and experimental limbs were determined prior to starting the study and at the fourth and eighth weeks of the study. The ABI was obtained after the subject rested for 15 min. ABI was determined by measuring the systolic blood pressure (SBP) in the upper extremity using a mercury column sphygmomanometer and stethoscope. A mercury column sphygmomanometer was used to cause lower extremity arterial occlusion, while a Hadeco® BiDop ES-100VII Doppler (Koven Technologies, Inc.,

Table 1 Subjects' anthropomorphic data

Age/gender	DM type	Years W/DM	Height (m^2)	Weight (kg)	BMI	Exp. foot	HbA_{1c}	Pedometer (avg miles/day)
69/F	2	11	2.4336	80	33	Right	6	None
61/F	2	12	2.3104	72	31	Left	–	None
58/M	2	12	2.3409	60	26	Right	6.6	1.9
40/M	2	12	2.7889	74	27	Right	7.2	3.9
50/F	2	13	2.7258	108	40	Left	6.5	3.2
64/M	2	13	2.6244	77	29	Right	7.4	5.4
66/F	2	14	2.4964	105	42	Left	5.5	3.9
69/F	2	15	2.5281	68	27	Right	–	None
76/F	2	17	2.5921	62	24	Left	8.8	3.8
58/F	2	17	2.4649	105	43	Left	11	2.1
55/M	2	18	3.2523	127	39	Left	8	5.5
56/F	2	18	2.5921	104	40	Right	–	1.0
73/F	2	18	2.4336	62	26	Right	8.2	1.3
70/F	2	19	2.4964	60	24	Left	6.3	2.2
65/F	2	20	2.1025	93	44	Left	–	1.7
65/F	2	20	2.4649	75	30	Right	6.7	4.3
63/F	2	20	2.4649	77	31	Right	7.7	3.5
70/F	2	21	2.1904	85	39	Left	7.8	1.5
63/M	2	24	2.6244	75	29	Right	–	3.4
68/M	2	30	2.6896	75	28	Right	6.6	1.3
38/M	1	24	3.3124	72	22	Left	7.8	4.4
35/F	1	24	2.4649	75	30	Left	6.7	3.0

12125 Woodcrest Executive Drive #220, St. Louis, MO 63141, USA) was used to locate the dorsalis pedis artery and determine the SBP reading on the dorsum of the foot. ABI was calculated by dividing the ankle SBP by the brachial SBP. Scores below 0.90 were significant for increased chances of arterial vessel disease [7, 8].

Temperature

The temperature of both feet was assessed using an Exergen® model TAT-2000C Temporal Scanner Infrared Digital Thermometer (Exergen Corporation, 51 Water Street, Watertown, MA 02472, USA). The sites that were evaluated were the same as those for monofilament testing (i.e., the pad of the great toe, plantar surface heads of the first, third and fifth metatarsals). Temperatures were recorded at these sites prior to starting the study, and at weekly intervals throughout the study.

Biothesiometer

Changes in vibratory sensation were evaluated in both the control and experimental foot using a Bio-Medical Instrument Company® Biothesiometer (Bio-Medical Instrument Company, a subdivision of Rova Co., Inc., Newbury, OH 44065, USA).

The sites tested for perception of vibration were the pad of the great toe, the lateral and plantar surfaces of the first metatarsal head, the third and fifth metatarsal heads on the plantar surfaces of the foot, the plantar surface of the heel and the distal head of the lateral malleolus of the fibula. Biothesiometer values were recorded prior to starting the study, and at weekly intervals throughout the study.

Physical activity

To assess each patient's average or usual walking activity during the study, subjects recorded two weeks of daily walking distance. Each patient was given a Sportline® pedometer (Sportline Corporation, 4 Executive Plaza, Yonkers, NY 10701, USA) and told to wear it on their belt after getting up in the morning until just before retiring to bed at night. The daily number of steps taken by the patient was recorded in an activity journal. Stride length was determined by having each patient walk a 100 foot pathway at a customary pace. Stride length was then calculated by dividing the 100 foot length of the pathway by the number of steps taken to traverse this distance. The recorded number of steps taken was multiplied by the stride length to obtain the daily traversed distance.

Monofilament assessment of peripheral protective sensation (PPS)

PPS was measured at the beginning of the study and at weekly intervals using the Weinstein Enhanced Sensory Test Foot Esthesiometer® (WEST-foot®) (Connecticut Bioinstruments, 314 West 231 Street, MS-113, Danbury, CT 06813, USA). The WEST-foot® contained several SWMs (i.e., 3.7, 4.3, 5.07, 5.7, 6.3 and 6.48) requiring manual pressures of 0.5, 2.0, 10, 50, 200 and 300 g, respectively.

Connecticut Bioinstruments, Inc., the manufacturer of the WEST-foot®, states that when testing a patient for PPS, the following procedure should be followed. "The monofilament should be held close to the surface of the foot and the person testing should slowly touch the monofilament to the test site with the monofilament perpendicular to the site. Sufficient pressure should be applied to achieve a 50% curved deformation of the monofilament and within a 2-second period slowly withdraw the monofilament. If the patient detects the contact, for example, of the 10-gram monofilament 50% of the time without any false trials being introduced, then the tester can document that this monofilament is the threshold of the patient's PPS. If, however, the patient detects the presence of the 10-gram monofilament in 100% of the trials but never reports the presence of the next smaller monofilament (2-gram), the PPS for that patient is somewhere in between 10-grams and 2-grams." They recommend adding the numerical values of the two monofilaments together and dividing by two to obtain a reasonable approximation of the patient's real PPS. In the case of the 10-g and the 2-g monofilament example, the PPS would be evaluated to be 6. Using this system for measurement of PPS, the clinician can use the WEST-foot® to determine 11 different possible levels of PPS (see Table 2).

Table 2 WEST-foot® Esthesiometer evaluation table of peripheral protective sensation

Monofilament (g force)	#	Comments
0.25	1	Normal PPS
0.5	2	Normal PPS
1.25	3	Measurable neuropathy
2.0	4	Reduced protective sensation
6	5	Borderline loss of protective sensation
10	6	Borderline loss of protective sensation
30	7	Loss of protective sensation
50	8	Loss of deep pressure sensation
125	9	Profoundly insensitive
200	10	Profoundly insensitive
200+	11	Anaesthetic

This methodology was used in determining the subjects' PPS. With the subject's eyes closed and with their head turned in another direction, the monofilaments were touched to the subject's foot with sufficient pressure to give a 50% bend of the monofilament for approximately 1.0–1.5 s. In a random fashion, the spectrum of monofilaments were applied to the pad of the great toe and to the first, third and fifth metatarsal heads of both the control and the experimental feet avoiding the most heavily callused portions of the feet. During the weekly testing, each site was tested three to five times. When the subject first consistently felt the pressure of the monofilament, they indicated this by saying "yes". One member of the research team performed the monofilament tests on all subjects and was unaware which foot was the experimental and which foot was the control.

Treatment application

Once all medical histories and preliminary measurements were completed, one foot was randomly designated as the experimental foot (received PILT), while the contralateral foot acted as the within-subject control (received no treatment).

Pulsed infrared light therapy (PILT)

The unit delivering the PILT to the experimental foot was a RevitaMed® Infrared Light Therapy RL-1001SP device (Sports Medicine Technologies/Revitamed Therapeutic Systems, 19401

Fig. 1 RevitaMed units and pad placement on a patient

N. Cave Creek Road, Suite #28, Phoenix, AZ 85024, USA). Gallium-arsenide light-emitting diodes (LEDs) delivered infrared light at a wavelength of 880 nm and visible red light at a wavelength of 650 nm. The PILT unit was connected to a neoprene pad (19.5X12.0X0.5 cm) into which was embedded an array of LEDs. The LED array was arranged in six rows of 5 LEDs emitting infrared light at 880 nm alternating with five rows of 4 LEDs emitting visible red light at a wavelength of 650 nm. This pattern permitted a total of 50 LEDs to be evenly dispersed throughout the treatment neoprene pad area.

The RevitaMed® Unit provides seven different frequency settings dispersing light from the lowest setting of 1 at 73 Hz up to a setting of 7 at 4672 Hz. Each increase in the setting is a doubling of the frequency i.e., a setting of 2 is equal to a frequency of 146 Hz and a setting of 3 is equal to a frequency of 292 Hz. In this study, each subject received on the experimental foot PILT at a setting of 4, which was equal to a frequency of 584 Hz, for 30 min, 3 times per week, for eight weeks.

PILT was delivered by placing one neoprene pad on the volar surface of the foot and one neoprene pad on the dorsum of the foot effectively encompassing the entire foot from the toes to the heel. These pads were held in place by two Velcro straps (see Fig. 1).

Statistical analysis

A paired t-test was used to evaluate all measures for significant pre to post changes for all data, excepting the PPS data. Significance for each measure was accepted at $p<0.05$. Values were expressed as mean±SEM. The statistical package SigmaStat was used for evaluation of the data.

Inspection of the initial PPS values revealed a large heterogeneity in the severity of the PPS amongst the specific sites (i.e., great toe, and first, third and fifth metatarsals) both within each foot and between the treated and untreated foot. For example, in one patient's treated foot, all four PPSs were <5.07, while in the untreated foot three of the four PPSs were >5.07. In contrast, another patient's treated foot had three of four PPSs >5.07, but in the untreated foot only one of four PPSs was >5.07. As previous research suggests that PILT is more effective with severe LOPS [1, 3, 4], it was felt that this great diversity in PPS would confound any within (i.e., site comparisons) or between foot statistical comparisons. Hence, the site-specific monofilament data for each treated and control foot were evaluated separately. In addition, for each site, the subjects were divided into two categories: those whose initial PPS in the treated foot was greater than 10 g (insensate), and those whose initial PPS in the treated foot was less than or equal to 10 g (sensate). A paired t-test was used to evaluate pre to post changes for each measure. However, as making multiple comparisons requires the p values to be corrected by dividing the p value by the number of comparisons, the significance level was set at $p<0.0125$ (i.e., 0.05 divided by four – the number of t-tests done for each site).

Results

Descriptive information

Descriptive information (e.g., BMI and physical activity) is presented in Table 1. Of the 22 patients in this study, 45% (n=10) had BMIs over 30, ranging from 31 to 44. The remaining 55% (n=12) had BMIs ≤30, ranging from 30 to 22. Only 7 subjects walked more than 10 000 steps per day, indicating their physical activity was adequate for reducing body weight and improving insulin sensitivity [9]. The remaining 15 were only mildly engaged in physical activity and never met the goal of 10 000 steps per day.

ABI

The initial mean ABI of the treated foot was 0.97±0.04. After eight weeks of treatment, the final mean ABI was 0.97±0.03. The difference between the pre and post values was deemed non-significant (p=0.94).

Similar results were obtained for the control foot – the pre-mean was 0.94±0.03 and the post-mean was 0.97±0.03. This change was also non-significant (p=0.33).

Temperature and biothesiometer

Across all sites for all subjects, there were no significant changes in temperature of the control or treated foot, or in the perception of vibratory sensation secondary to the application of PILT.

Monofilaments (PPS)

Great toe

Before PILT, the PPS of the great toe of the treated foot was 39.6±13.6 g. After PILT the PPS had decreased to 3.4±1.3 g (p=0.011). During the same time, the untreated

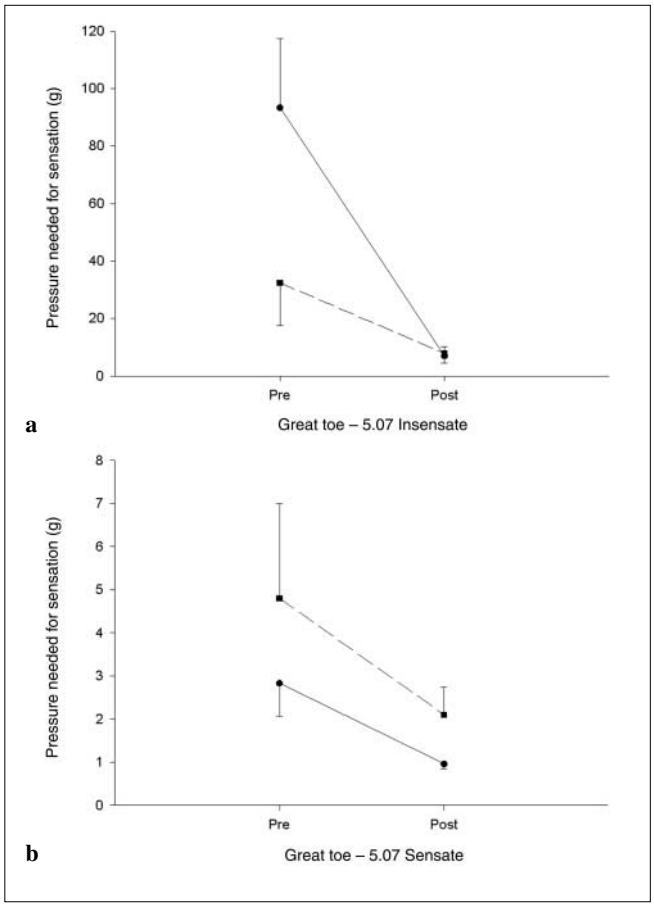

Fig. 2a, b Pre- to post-changes in the great toe's PPS following PILT for both the insensate (n=9) and sensate (n=13) groups. The solid line represents the treated foot PPS and the broken line represents the untreated foot PPS. Values are means±SEM

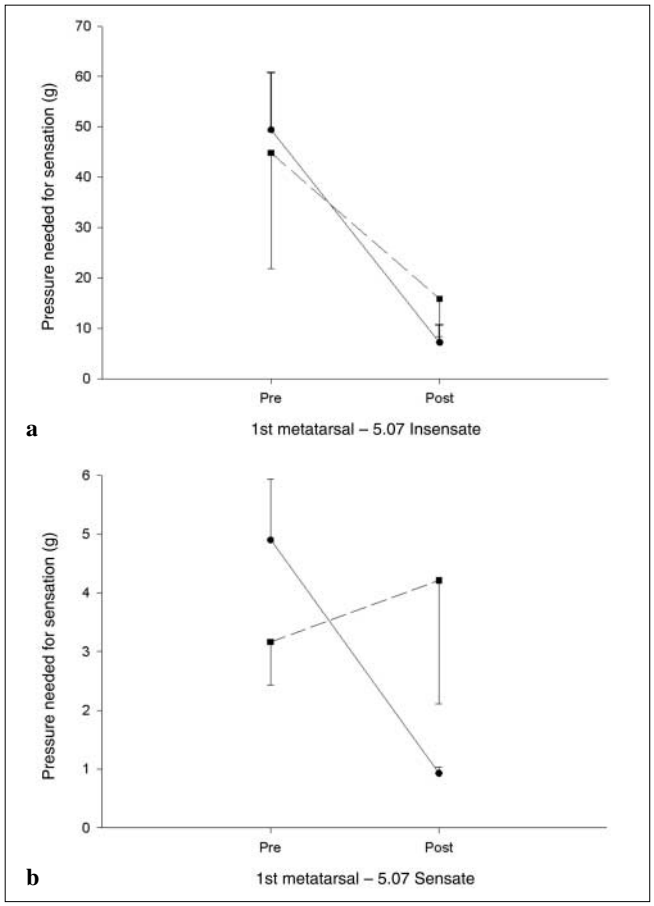

Fig. 3a, b Pre- to post-changes in the first metatarsal's PPS following PILT for both the insensate (n=8) and sensate (n=14) groups. The solid line represents the treated foot PPS and the broken line represents the untreated foot PPS. Values are means±SEM

foot PPS went from 15±6.3 g to 4.3±1.4 g. This change, however, was not significant (p=0.077).

Figure 2 illustrates the results of sensate and insensate sub-divisions for the great toe. The PPS of the treated foot of the insensate group (n=9) showed a significant (p=0.006) mean decrease of 86.3±23.6 g. On the other hand, the PPS of the untreated foot non-significantly (p=0.134) decreased (24.6±5.1 g) (Fig. 2a). For the sensate treated foot (n=13), the PPS had a decrease of 1.9±0.7 g, which approached significance (p=0.026), while the untreated foot had a non-significant (p=0.223) decrease of 2.8±2.2 g (Fig. 2b).

First metatarsal

The results for the first metatarsal were similar to those of the great toe. The pre-PILT PPS of the treated foot was 21.1±6.2 g. Post-PILT PPS decreased to 3.2±1.4 g (p=0.004). During the same time, the untreated foot PPS had a non-significant (p=0.181) decrease from 18.3±9.1 g to 8.4±3.2 g.

Figure 3a shows that the insensate treated foot PPS (n=8) significantly decreased (p=0.006, 42.2±10.9 g). While the PPS of the insensate untreated foot had a non-significant (p=0.149) decrease of 28.9±7.8 g. Likewise, the sensate (n=14) treated foot PPS significantly decreased (p=0.002, 3.9±1.0 g), while the untreated foot non-significantly (p=0.658) increased (1.1±2.3 g) (Fig. 3b).

Third metatarsal

Similar to the first metatarsal and great toe, the PPS at the third metatarsal following PILT was decreased (p=0.01). The treated foot started at 18.2±5.7 g and fell to 6.1±1.7 g. In contrast, the untreated foot PPS had a non-significant (p=0.105) drop from 21.0±5.6 g to 10.3±2.7 g.

Again, the insensate treated foot PPS (n=10) had a significant decrease (p=0.006) of 68.7±21.1 g, while the PPS of the insensate untreated foot had a non-significant decrease (p=0.058) of 34.8±16.0g (Fig. 4a). In contrast, the sensate (n=12) treated foot PPS non-significantly (p=0.671) decreased (0.8±2.0 g), and the untreated foot increased (7.3±3.6 g, p=0.069) (Fig. 4b).

Fifth metatarsal

The pre-PILT PPS of the treated foot at the fifth metatarsal was 10.9±2.4 g. Post-PILT PPS decreased to 2.5±4.7 g (p=0.002). During the same time, the untreated foot PPS

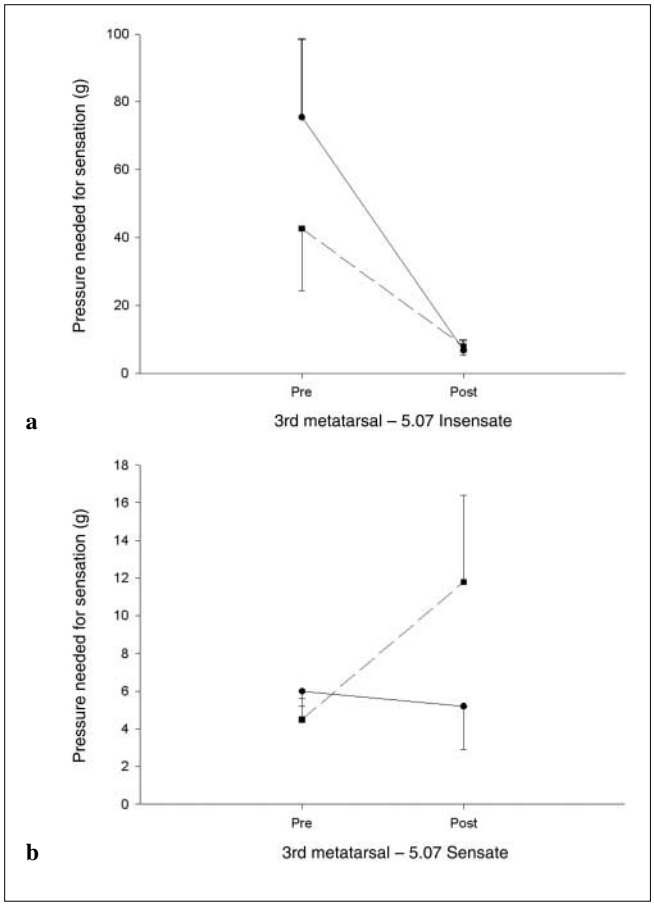

Fig. 4a, b Pre- to post-changes in the third metatarsal's PPS following PILT for both the insensate (n=10) and sensate (n=12) groups. The solid line represents the treated foot PPS and the broken line represents the untreated foot PPS. Values are means±SEM

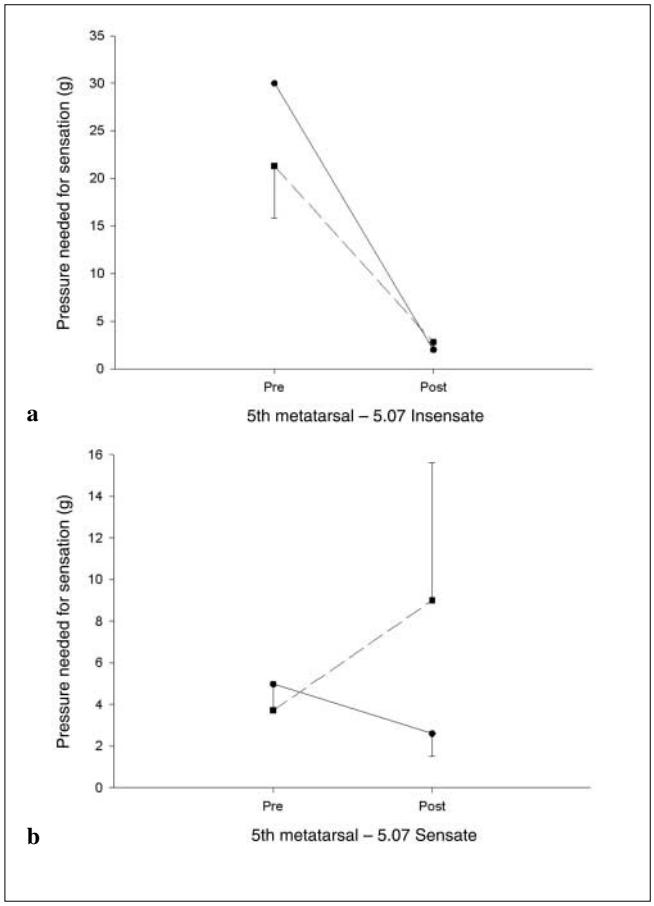

Fig. 5a, b Pre- to post-changes in the fifth metatarsal's PPS following PILT for both the insensate (n=6) and sensate (n=16) groups. The solid line represents the treated foot PPS and the broken line represents the untreated foot PPS. Values are means±SEM

had a non-significant (p=0.749) decrease from 8.5±2.3 g to 7.3±3.0 g.

The insensate treated foot PPS (n=6) dramatically (p<0.00016) decreased (28.0±0.9 g) (Fig. 5a), while the PPS of the insensate untreated foot had a near significant (p=0.015) decrease of 18.5±5.1 g. The sensate (n=16) treated foot PPS, however, significantly (p=0.006) decreased (2.3±0.8 g), while the untreated foot non-significantly (p=0.147) increased (5.3±3.7 g) (Fig. 5b).

Discussion

Patients with diabetes mellitus suffer from a variety of pathologies, including advancing atherosclerosis, poor immune defence, blindness, reduced kidney function and peripheral neuropathy in the hands and feet leading to the loss of PPS. Accompanying the loss of PPS is the development of the co-morbidities of occult infections and wounds. Diabetes is singularly the most common cause of therapeutic amputation of gangrenous limbs in the United States [10].

Although recent pharmacological advances have made the management of diabetes easier, the loss of PPS has been more difficult to treat. A new therapy, PILT, has recently been shown to effectively reduce pain [3] and improve neuropathies by partially restoring PPS [1, 3, 4]. PILT is also credited with improving balance [4], and assisting chronic wounds to close [11]. Additionally, Thomasson [12] reports improvements in tendonitis, capsulitis and myofascial pain.

The subjects in this study were volunteers with chronic diabetes mellitus (11+ years since diagnosis). The average age was 63 years for the patients with type 2 diabetes, and 37 years for the patients with type 1 diabetes. The HbA1c data on these subjects indicated that only 8 out of the 22 were in good control. The rest were clearly not managing their blood sugars closely. None of these patients had nephropathies, and only one of the patients reported sustaining a retinopathy. None of them reported having had neuropathic ulcers since the time of their diagnosis with diabetes mellitus.

The single most important piece of information to come out of this controlled study is the fact that PILT improved the PPS of all subjects at all of the sites evaluated. There were only four instances (one great toe, one first metatarsal, and two third metatarsals) where subjects failed to obtain a SWM sensibility below the 5.07 monofilament (10 g pressure). For each of these four instances, the subjects experienced an improvement in PPS from not being able to detect the 300-g monofilament pressure at the study's inception to being able to detect an applied force using the 30-g monofilament at the study's completion. This was at least a 10-fold increase in sensation. This finding is in contrast to the report of Leonard et al. [3], who found that highly insensate individuals did not regain sensitivity to the 5.07 monofilament after 12 treatments. On the other hand, the current findings are in agreement with those of Kochman et al. [1]. Unfortunately, Kochman et al. [1] did not provide site specificity for their results, so it is unknown whether or not sensation was restored in just one or in all of the locations evaluated. Nevertheless, as the subjects in this study received 24 treatments, it is suggested that PILT can restore sensation (i.e., PPS <10 g) to all individuals if the treatments are continued for an extended period.

Conclusions

PILT, when administered for 30 min/day for three days per week for eight weeks, is a viable non-invasive treatment for chronic and profound losses in PPS in patients with long-standing diabetes mellitus. The mechanism of action is not well understood, but is probably due to an increased perfusion and vascularisation of the foot secondary to the increased cellular production of nitric oxide.

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Abbreviations *PILT*, pulsed infrared light at a wavelength of 880 nm and visible near-infrared light at a wavelength of 650 nm delivered at a frequency of 584 Hz; *PPS*, peripheral protective sensation, the normal sensory perception of light touch that people without neuropathic disease can feel; *SWM*, Semmes-Weinstein monofilament, a common clinical tool used to assess the level of discrimination of light touch; *LOPS*, loss of protective sensation, the patient's loss of discriminating light touch usually beginning at a pressure greater than or equal to 10 g of pressure; *ABI*, ankle/brachial index, the systolic blood pressure determined at the dorsalis pedis artery divided by the systolic blood pressure determined at the brachial artery producing a valueless decimal fraction indicating the degree of arterial disease present.

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