# Clinical Experience using NIR light therapy in subjects with Type II diabetes complaining of neuropathy

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## Abstract

### Objective

The purpose of this case report is to evaluate the effect of near infrared light therapy treatments on pain and other symptoms of diabetic peripheral neuropathy (DPN).

### Methods

The severity of neuropathy was assessed in 152 subjects in an outpatient pain clinic. Pain (VAS), a peripheral neuropathy questionnaire (PNQ), a restless leg syndrome questionnaire (RLSQ) and the Toronto Clinical Scoring System (TCSS) were used to determine the severity of symptoms. Following a mean of 18±7 light therapy treatments (20 minutes, 3 times/ week) on the lower extremities, the tests were repeated. Data were analyzed with a statistical two-sided one-sample t-test that the change from baseline in response to light therapy was zero. Data are presented as mean ± standard deviation.

### Results

Average age in the subjects was 64 ± 12 years. Baseline pain was 7.8 ± 1.5, PNQ was 58.7 ± 21.2%, RLSQ was 58.9 ± 21.1%, TCSS Left Leg was 37.0 ± 21.4% and TCSS Right Leg was almost identical at 37.1 ± 21.8%. These measures indicated that the subjects had diabetic neuropathy. Following treatments with light therapy, pain decreased by 4.4 ± 2.2 ($P<0.0001$), PNQ improved by 13.5 ± 20.9% ($P<0.0001$), RLSQ improved by 13.1 ± 22.2% ($P<0.0001$). Similarly, the TCSS increased by 28.7 ±19.9% on the right leg and by 29.7 ± 19.6% on the left leg (both $P<0.0001$).

### Conclusions

The symptoms of neuropathy improved so rapidly in some subjects that they were able to cease treatments in less than 5 weeks. Other subjects whose progress was much slower required 8 weeks or, in a few cases, more than 8 weeks to realize significant reduction of most of their neuropathy symptoms. This is likely due to the complexity of Type II diabetes and associated comorbidities. Some light therapy devices may improve the symptoms of DPN and improve quality of life.

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## Introduction

Some of the symptoms of diabetic neuropathy are numbness, a reduced ability to feel pain or temperature changes, a tingling or burning sensation, sharp pains or cramps, increased sensitivity to touch - for some people even the weight of a bed sheet can be agonizing - muscle weakness, loss of reflexes especially in the ankle, loss of balance and coordination, serious foot problems, such as ulcers, infections, deformities, and bone and joint pain (1).

Despite tight control of blood sugar, exercise and improvements in life style, these symptoms can develop, persist or worsen. There are no treatments for diabetic neuropathy although some pharmaceutical products are FDA approved and may be helpful for mitigating the symptom of diabetic nerve pain.

Persistently elevated blood glucose (EBG) underlies the pathophysiology of diabetic neuropathy and its symptoms (2). People with type II diabetes suffer from various degrees of retinopathy, coronary heart and kidney disease, gastroparesis, and stroke. Each of these can be considered to be the result of vascular injury caused, at least in part, by EBG. Simply put, low, subnormal blood flow deprives cells, including nerves, of the oxygen and glucose necessary for ATP production in mitochondria. ATP is required by cells to regulate membrane potential. Depolarized nerves send pain signals to the brain or fail to properly detect sensations.

Clearly, if one could temporarily or chronically improve blood flow, then ATP production would recover toward normal as glucose and oxygen increased at the cellular level. Pain signals related to depolarized nerves should diminish as membrane potential returns toward normal.

In fact, improved circulation to nerves might minimize or eliminate many, if not most, symptoms of diabetic neuropathy. There are several light therapy devices, (LED or laser based), cleared by the FDA for increasing circulation that should mitigate the painful symptoms in subjects with diabetic neuropathy.

This report summarizes clinical outcomes in diabetic subjects treated at one of our clinics. The subjects had previously received one or more medications but were dissatisfied with the outcomes related to their pain and/or other neuropathy symptoms or the side effects.

## Methods

Subjects who presented to our clinic with the symptoms of neuropathy were given a complete physical. A thorough medical history was obtained; if the person was diabetic (HgA1c >5.5) a Pain Self-Assessment Form was completed (Visual Analogue Scale: 0-10) as well as a Peripheral Neuropathy Questionnaire (PNQ) in which answers were converted to percentages. 0-20% = zero to mild peripheral neuropathy, 21-40% = moderate peripheral neuropathy, 41-60% = severe peripheral neuropathy, above 61% = crippling level of peripheral neuropathy; i.e. wheel chairs, bed bound, crippled. Restless Leg Syndrome (RLS) is prevalent in type II Diabetes (3) so a Restless Leg Syndrome (RLS) Questionnaire was also completed. These were also converted to percentages.

We also scored the severity of neuropathy in each leg using the Toronto Clinical Scoring System (TCSS) (4). The maximum score in a patient with no symptoms is 74 (100%). The following are the results of the severity of neuropathy in 152 subjects. The subjects were then offered treatment with a FDA cleared near infrared LED device (HealthLight PN LLC, Reno, NV 89523). The protocol was explained and informed consent was obtained. Treatments were on the foot and calf of each leg for 20 minutes 3 times/week. The PN and RLS symptoms and the Toronto scores were re-assessed after 6 treatments to determine if there were any improvements in the interim period. These were re-evaluated again following the completion of all treatments.

## Statistics

Data were analyzed with a statistical two-sided one-sample t-test that the change from baseline in response to light therapy was zero. Data are presented as mean ± standard deviation.

## Results

Type II diabetes is more prominent in adults. Average age of our subjects was 64 ± 12 years. Baseline pain was high; 7.8 ± 1.5, PNQ was low; 58.7 ± 21.2%, RLSQ was also low; 58.9 ± 21.1%. The TCSS Left Leg was Low; 37.0 ± 21.4% and TCSS Right Leg was almost identical

at 37.1 ± 21.8%. These subjects exhibited the symptoms of neuropathy.

Following a mean of 18 treatments, pain decreased by 4.4 ± 2.2 (P<0.0001), PNQ improved by 13.5 ± 20.9% (P<0.0001) and the RLSQ improved by 13.2 ± 22.2% (P<0.0001). Similarly, the TCSS increased by 28.7 ±19.9% on the right leg and by 29.7 ± 19.6% on the left leg (both P<0.0001). The symptoms of neuropathy improve so rapidly in some subjects that they were able to cease treatments in less than 5 weeks. Other subjects whose progress was much slower required 8 weeks or, in a few cases, more than 8 weeks to have resolution most of their neuropathy symptoms. This is likely due to the complexity of Type II diabetes and comorbidities.

The box plot for pain is presented in the diagrams.The line in the box is the median. The closer to the middle of the box the median is, the less asymmetric the data are. If the median is in the upper part of the box, the data are skewed to the top and have a tail to the bottom of the graph. If the median is in the lower part of the box, then the data are skewed to the bottom of the figure with a long tail to the top. Asterisks that appear below or above the lines extending from the box can be considered outliers.

An analysis was done by linear regression to see if there was a trend in change from baseline with increasing numbers of treatments. The mean number of treatments was 18.05 (SD=7.334) with median of 15, (~5 weeks); range 7, 44. The change from baseline Pain or PNQ did not have a relationship with the number of treatments with P=0.668 and P=0.294, respectively. This means that in most subjects treated 3 times a week for 20 minutes each time, the lowest pain level achievable would be approximately 3.7 and that more treatments may not improve this or the PNQ symptoms. It would be interesting to determine if treatments for longer than 20 minutes or more often than 3 times a week, or both, would improve these results.

However, RLSQ, TCSS Left, and TCSS Right did have a statistically significant relationship with the number of treatments with P=0.006, P=0.021, and P=0.007, respectively. The change in RLSQ was improved by about 0.8% for each additional treatment. The TCSS Left was increased by about 0.57% for each additional treatment and TCSS Right was increased by about 0.65% for each

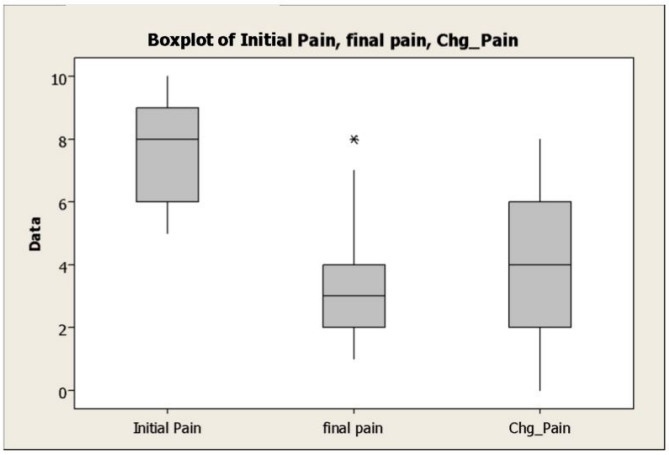


**Figure 1. Box Plots of Initial Pain, Final Pain and Change from Baseline Pain.** Initial pain is skewed high (most subjects had clinically significant pain) but both final pain and change from baseline appear to be nearly symmetric in response to HealthLight™ treatments.

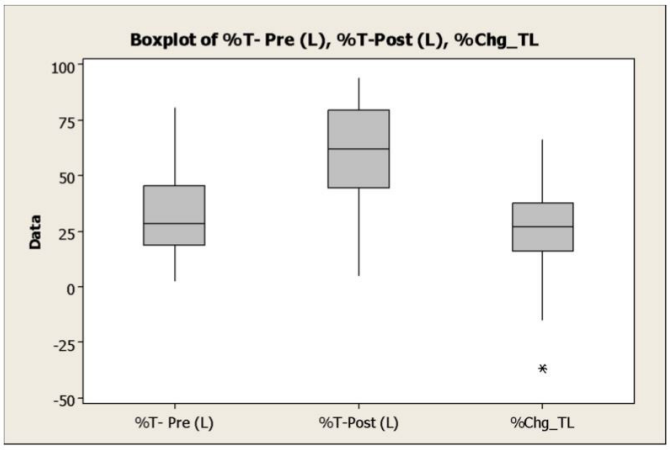


**Figure 2. Box Plots of %T-Pre(L), %T-Post (L) and Change from Baseline TCSS Left.** The baseline TCSS Left is skewed low, indicating that the majority of subjects had more symptomatic problems but both final and change from baseline following HealthLight™ treatment appear to be nearly symmetric. In other words, despite the severity of symptoms in some subjects on their left leg, improvements after light therapy were similar to those with less severe symptoms.

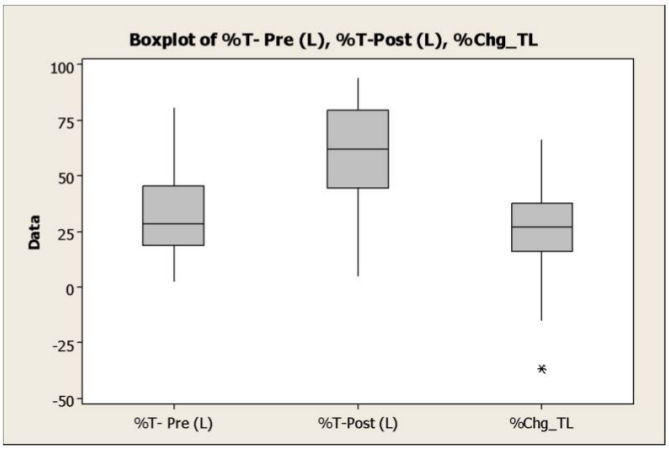


**Figure 3. Box Plots of %T-Pre(R), %T-Post (R) and Change from Baseline TCSS Right.** These data indicate that there was more variance in the right leg than the left leg (figure 2). NIR treatments improved (% change) by about 25% in both legs .

additional treatment. These data should be interpreted cautiously because there are a small number of patients who received many treatments that have large impact on the slope of the linear relationship. Nevertheless, in our clinic the majority of subjects treated with HealthLight™ have significant improvement of their neuropathy symptoms in less than 20 treatments.

## Discussion

The symptoms of diabetic neuropathy are varied. Each alone affects quality of life and is costly to the health care system. This becomes an even more serious problem when several symptoms occur simultaneously. Not surprisingly, patients often seek alternatives to conventional medical treatments for these diabetic neuropathy symptoms.

Our clinics treat a variety of painful conditions. This case report summarizes our results in our subjects who initially presented with painful symptoms related to diabetes. They also scored well below average in a PNQ, a RLSQ and in the TCSS. One might not be impressed by a low score in one of these tests at baseline but all 3 tests indicated the likelihood that this was indeed symptomatic, painful, diabetic neuropathy. We never claim to treat neuropathy itself nor does the company that provided the light therapy. Claiming to treat symptoms, such as pain, is within the clearance of the device we used.

Pain, as well as the troublesome symptoms accompanying restless leg, improved in these subjects. The treatment of the affected limbs took only 20 minutes making the thrice weekly visits to our clinic acceptable by both subjects as well as our clinic staff. Compliance was excellent. There are over 26 million people with diabetes and many, if not most, will develop neuropathy symptoms, specifically pain, that may be lessened by medical care offered by healthcare professionals treating pain, including Podiatrists, Chiropractors and Physical Therapists.

Collectively, an approximately 30-40 % improvement in diabetic neuropathy symptoms was seen when this medical device was used on the symptomatic lower extremities. HealthLight™ is cleared to increase circulation. As mentioned above, this could improve nerve function by restoring a presumably reduced blood flow caused by EBG. One mechanism may involve increased release of nitric oxide from hemoglobin (5).

This is an observational study only and any conclusions must be tempered because no subjects were either left untreated or were treated with a placebo device. Nevertheless, in the real world, unlike during clinical trials where there are several exclusion criteria, some subjects complaining of diabetic neuropathy symptoms may be helped by treatments that include light therapy.

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