

EFFECT OF A DERMATOME NEUROPOINT ACTIVATING SOCKS ON PAINFUL DIABETIC NEUROPATHY PAIN IN FEET

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INTRODUCTION:

Painful diabetic neuropathy is a common complication of diabetes and can affect many aspects of life and severely limit patients' daily functions. This condition can be difficult to treat, which frustrates both providers and patients.

Neuropathy is a common complication of diabetes, affecting up to 50% of patients. A consensus statement produced by an international meeting on the diagnosis and management of diabetic neuropathy defined it as “the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes.” There are many types of neuropathy with a variety of clinical presentations. This study focuses on one phenotype of neuropathy: painful diabetic neuropathy (PDN), specifically in the feet of the subjects. Recently, hosiery developed by Voxx Sports Inc. with dermatome and superficial nervous stimulation technology claim to reduce PDN pain in the feet of subjects. This study tested the hypothesis that wearing these Dermatome Neuropoint Socks (DNS) reduces PDN in the feet of users.

METHODS:

1000 people (Age 35-72) participated in this study after providing IRB- approved informed consent. A priori sample size estimation indicated a desired population of 36 for an effect size of 0.25. The time needed to complete 1000 assessments for

this study exceeded 6 months.

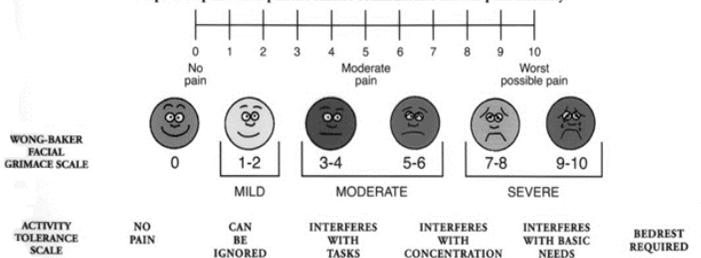
Inclusion criteria included: (a) a history of a PDN Pain Score of 4 or higher for longer a period of time exceeding 90 days (b) a confirmed diagnosis of diabetes exceeding 10 years (c) no foot condition that would limit the ability to wear the socks. (d) Regularly wore regular diabetes approved socks. Two Socks conditions were utilized for the study: DAS- Dermatome Neuropoint Socks and RDS- Regular Diabetes Socks.

Subjects were asked to complete their PDN Pain Assessment and Study Intake Form with the assistance of a Pain Management Expert. Subjects were asked to regularly wear the DAS socks for 1 week and share their findings with the Pain Management Expert upon a return visit to the clinic the following week.

The Universal Pain Assessment Tool was used for this study.

UNIVERSAL PAIN ASSESSMENT TOOL

This pain assessment tool is intended to help patient care providers assess pain according to individual patient needs. Explain and use 0-10 Scale for patient self-assessment. Use the faces or behavioral observations to interpret expressed pain when patient cannot communicate his/her pain intensity.



In order to determine average change in Pain Scores, the following statistical tests were performed:

- 2-Sample T-test to detect differences in sample means with the following parameter:
 - Ho = Null Hypothesis = $\mu_1 - \mu_2 = 0$,
 - Ha = Alternate Hypothesis = $\mu_1 - \mu_2 > 0$.
 - Difference in means = 5.119.
 - Confidence Level = 95%.
 - Level of Significance = $\alpha = 0.05$.

- Paired 2-T Test to detect any mean difference in samples of Equal number

of data points with the following parameters:

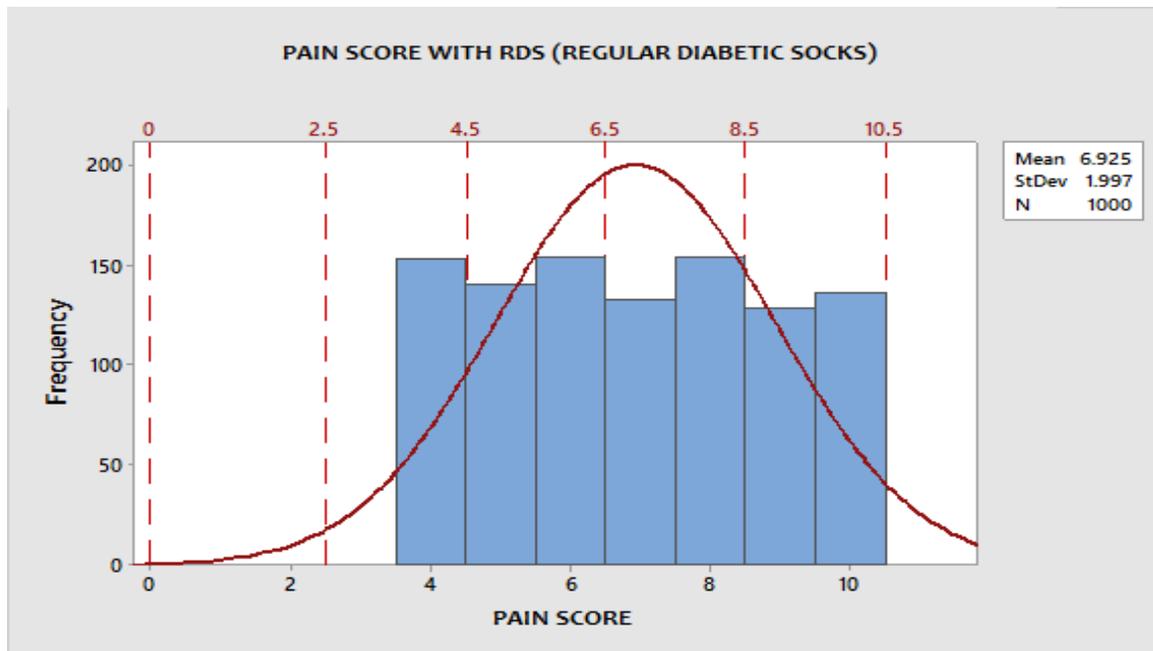
- Output for 2 Sample Paired T-test:
- Null Hypothesis = Ho = $\mu(D) = \text{Mean of Differences} = 0$.
- Alternate Hypothesis = Ha = $\mu(D) = \text{Mean of Differences} > 0$.
- Level of Confidence = 95%.
- $\alpha = 0.05$.

(A Paired 2 sample T-test is a more efficient and offers greater statistical confidence than 2 Sample Independent T test because in the Paired T test, the deterministic ability of the test increases by accounting for more variability in conditions by considering a smaller environment of Paired data, as opposed to a Universal data set.)

RESULTS AND DISCUSSION:

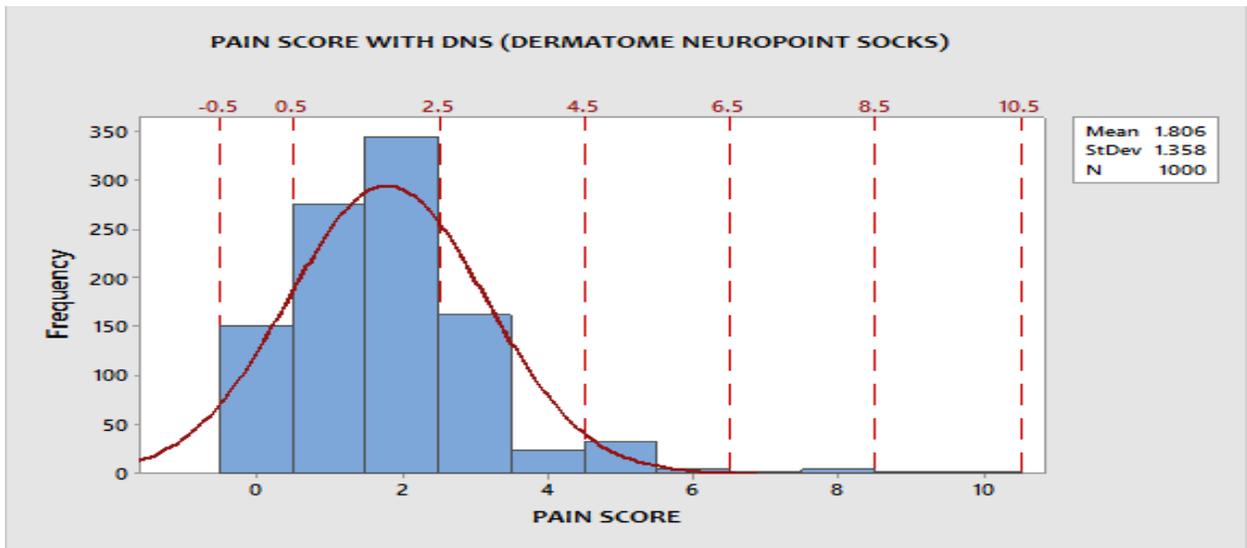
Socks condition was a significant main effect. Post-hoc analysis showed that the Pain Score was significantly lower for DNS Socks than RDS Socks.

FIGURE 1, CHART1



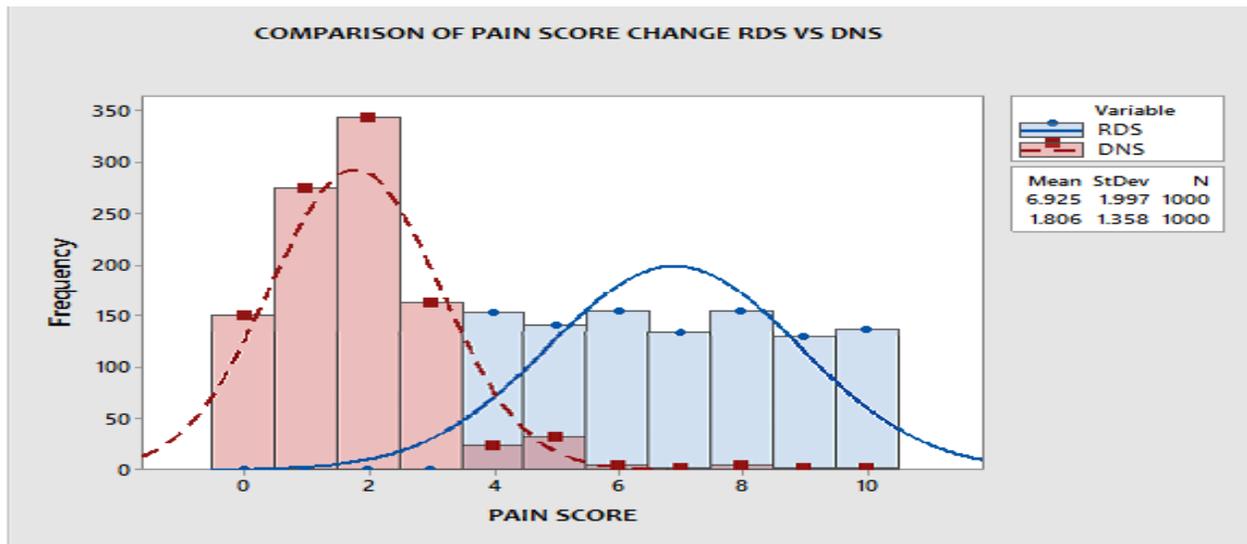
Pain Group	0	1-2	3-4	5-6	7-8	9-10
No of Subjects	0	0	153	295	287	265
Percentage of Subjects	0	0	15.3%	29.5%	28.7%	26.5%
Average Change/Drop in Pain Scores	0	0	2	5.12	5.13	5.12
Percentage Drop	0	0	20%	51.2%	51.3%	51.2%

FIGURE 2, CHART 2



Pain Group	0	1-2	3-4	5-6	7-8	9-10
No of Subjects	150	619	186	36	5	4
Percentage of Subjects	15%	61.9%	18.6%	3.6%	0.5%	0.4%
Average Change/Drop in Pain Scores	6.81	5.11	5.12	5.13	0	0
Percentage Drop	68.1%	51.1%	51.2%	51.3%	0%	0%

FIGURE 3, CHART 3



Overall Change Groups	Net Improvement	Net Deterioration	No Improvement(No Change)
Number of Subjects	941	13	46
Percent of subjects	94.1%	1.3%	4.6%

CHART 4

Amount of Drop/Change	Number of Subjects respective to the Drop	Percentage of subjects
1 or 10%	18	1.8%
2 or 20%	61	6.1%
3 or 30%	113	11.3%
4 or 40%	136	13.6%
5 or 50%	145	14.5%
6 or 60%	143	14.3%
7 or 70%	147	14.7%
8 or 80%	122	12.2%
9 or 90%	39	3.9%
10 or 100%	17	1.7%

DISCUSSION:

On Subjects using the RDS, the mean Pain Score was 6.925, with 100% of subjects greater than 4 on the Pain Scale.

FIGURE 1, CHART 1

The Mean Pain Score with the DNS is 1.806 with 95.5% of subjects with a Pain Score of less than 4. *FIGURE 2 CHART 2*

The results show that 1.3% of the subjects actually had an increase on the Pain Scale and 4.6% of subjects are no change in pain.

FIGURE 3, CHART 3

A deeper look at the test group indicates that 76.9% of the subjects had a Pain Score of 2 or less with DNS. This suggests that 100% of the subjects were at a Pain Score that “Interfered with Tasks” using the RDS, and after 1 week of wearing the DNS 76.9% had a Pain Score that “Can Be Ignored”.

The result show and statistically significant decrease in the Pain Score with the DNS across all levels.

FIGURE 1, CHART 1, FIGURE 2 CHART 2, FIGURE 3, CHART 3, CHART 4

CONCLUSION:

Painful Diabetic Neuropathy is a type of nerve damage can afflict patients that have diabetes and can have a significant impact on day-to-day living. The most common damage of the nerves is experienced in the patients’ legs and feet.

Symptoms include tingling, burning, numbness and pain in the regions that are affected. Patients have reported the pain being similar to a burning, electrical or stabbing sensation. According to the American Diabetes Association, Diabetic Neuropathy is chronic and progressive and it greatly affects all aspects of a patients’ life including; mood, sleep, self-worth, independence, ability to work, and interpersonal relationships. This study looked at the efficacy of Dermatome Neuropoint Socks (DNS) developed by Voxx Sports Inc. and their ability to reduce PDN foot pain in a test group of 1000 patients.

The initial findings are promising as over 95% of the subjects saw a significant reduction in pain after 1 week of usage when compared to a Regular Diabetic Sock. (RDS)

The initial testing also shows that 76.9% of pain scores using the Universal Pain Scale were reduced to 2 or lower, correlating to pain that “Can be Ignored”. This was reduced from 100% of the pain scores being 4 or higher, or “Pain that Interferes with Tasks”.

The initial data and testing with the DNS supplied by Voxx Sports Inc. shows promise in offering PDN patients an alternative for pain management. This phenomenon needs to be further studied on a longer period of time to see if there are long term benefits of the DNS socks.