

Statement of Purpose and Literature Review

Within the daily scope of a foot and ankle physician's practice, it is entirely common patients will present in need of interventions that can elicit pain or discomfort such as an injection or debridement. A podiatric physician has some options to manage pain during in office procedures such as the use of topical anesthetics and vapocoolant spray. Recently, there has been interest in utilizing vibratory stimulation to rouse A β fibers which reduce pain via the pain gating phenomenon. Previous studies have shown promising results in both pediatric¹ and adult² subject groups in a nonpodiatric setting. If a vibratory stimulus is able to produce a transient loss of protective sensation, then this modality may prove to be of use for painful interventions or on sensitive patients. In this study, we attempted to validate the level of effectiveness of a pedal vibratory device (Buzzy®, MMJ labs, Atlanta, GA) by way of a standard protective sensation screening protocol. As of this writing, there have been no studies performed investigating the effect of vibratory stimulation on protective

sensation. The objective of this investigation was to examine the ability of vibratory stimulation in producing a transient impairment in sensation in the feet.



"Diabetic Foot Exam and Ulcer Risk Assessment." Diabetic Foot Exam and Ulcer Risk Assessment. N.p., n.d. Web. 12 June 2016.

The Effect of Vibratory Stimulation on Protective Sensation within the Foot

Joshua A. Sebag, BA^a, Joseph D. Rundell BS^a, Tracey C. Vlahovic, DPM^b, and Robert W. Herpen DPM^b

^a4th year student, Temple University School of Podiatric Medicine, Philadelphia, PA ^bDepartment of Podiatric Medicine, Temple University School of Podiatric Medicine and Temple University Hospital, Philadelphia, PA

Methodology

- The design of this study was a prospective clinical trial using 44 volunteers at the Temple University School of Podiatric Medicine. Consent to participate in the study was obtained. No medical intervention was rendered after the test was performed. Subject Population: Inclusion criteria: Nondiabetic subjects. Exclusion criteria: skin compromise over the Buzzy® application site, history of peripheral neuropathy, fibromyalgia, or CRPS.
 - Procedure: After consent the investigator blindfolded the volunteer and assessed protective sensation using a 0.4g monofilament touching 10 points on the foot (see figure 1). The right foot was always designated to be the control side (ie without vibratory device); the control was assessed once and a second time. The left foot was assessed in the same manner after the right foot; however for one trial the Buzzy® unit would be applied over the tarsal tunnel with an aim to target the Tibial nerve distributions, and then for the second trial, placed on the dorsum of the foot with an aim to target Common peroneal nerve distributions. Volunteers were asked to reply "Yes" for each touch of the monofilament they felt. We tabulated each touch out of potentially ten touches the subject reported feeling. Instruments: Vibratory stimulation was delivered via the use of a Buzzy® XL Healthcare unit which is applied using a Velcro strap (see figure 2). A graded monofilament weight set including 0.4 gram monofilament up to 300 gram monofilament.



Differences in Stimuli Detected from Control



Graph 2 (bottom left): A comparison of monofilament stimuli by the difference in stimuli detected from the control trial with the Buzzy® over the tarsal tunnel (green) and the Buzzy over the dorsum of the foot (red).

Graph 3 (below): The overall averages of the control versus intervention groups in terms of touches felt, out of ten possible touches.

Results

<u>Graph 1 (left)</u>: The average touches of a monofilament detected by each volunteer subject.









Discussion

Utilizing the paired t test there was a significant difference found between the amount of stimuli detected between the control trial versus the intervention with the Buzzy® over the dorsum of the foot and over the tarsal tunnel. Both comparisons yielded p values of under 0.00001. Of note there is no significant difference comparing the results of the Buzzy® over the dorsum vs. the tarsal tunnel with p=0.055694

• Sensory threshold in healthy subject in the foot has been previously demonstrated the 0.4g monofilament as minimum sensory threshold³. This study has demonstrated external vibratory sensation is capable of producing a transient diminished sensation.

• The loss of protective sensation (LOPS) leading to the insensate foot is considered to be inability to detect the 5.07/10g monofilament. In preliminary trials conducted by the investigators, we were unable to demonstrate external vibration to cause a transient LOPS by the inability to detect the 10g monofilament. As such we are conflicted on whether the degree of diminished sensation we did create can be clinically significant. However, the ability to reduce sensation and perhaps act on the continuum of pain, while remaining cost effective, makes this a reasonable adjunct in podiatric clinical practice. The authors welcome further studies to determine if there are ways to optimize this modality, such as ring block type vibratory ankle sleeve, to yield more significant results. We are interested in this idea.

• The limitations of this study are as follows: Entirely healthy cohort.

<u>Figure 2:</u> Vibratory device placed over the dorsum of the foot to target Common peroneal nerve distributions & over the tarsal tunnel to target Tibial nerve distributions.



References

Canbulat Sahiner N, Inal S, Sevim Akbay A. The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety levels in children. J Perianesth Nurs. 2015;30(3):228-235. doi: 10.1016/j.jopan.2014.05.011 [doi] Baxter AL, Leong T, Mathew B. External thermomechanical stimulation versus vapocoolant for adult venipuncture pain: Pilot data on a novel device. Clin J Pain. 2009;25(8):705-710.

Jeng C, Michelson J, Mizel M. Sensory thresholds of normal human feet. Foot Ankle Int. 2000;21(6):501-4.

Acknowledgements: The authors would like to thank MMJTM Laboratories for donating the Buzzy® units utilized for this study. We also wish to thank Andy J. Meyr, DPM, FACFAS, immensely for his work on the statistical analysis and Jinsup Song, DPM, PhD for his assistance in study design.