

Prosenex's DND: Making the Neuropathy Screening Foot Examination Truly Comprehensive in 3-5 Minutes

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Loss of protective sensation (LOPS) is one of the major causes of a visit to a podiatrist. Missed opportunity to diagnose LOPS can ultimately lead to toe and foot amputation. The major cause of LOPS is diabetic peripheral neuropathy (DPN). Approximately 7 million patients with diabetes alone have some degree of DPN.¹ Regardless of current guidelines, the feet are adequately assessed in only 12-20% of patient visits in the primary care setting. Primary care foot exams can be a leading referral source for podiatrists. Diabetes mellitus, chemotherapy, long-term antibiotic treatment, and nutritional deficiency are all etiologic factors of LOPS. Medical history and blood serum laboratory analysis do not always adequately reflect the degree of LOPS. For instance, almost 50% of newly diagnosed diabetic patients already have some LOPS.

Present LOPS assessment is based on self-administered questionnaires and well known 10 gm force monofilament application, as well as 128Hz tuning fork testing. (Michigan Neuropathy Screening Instrument)² No doubt, these examination techniques widely vary even among experienced practitioners, making longitudinal patient follow-up difficult. As a result, the American Diabetes Association task force created the Comprehensive Foot Examination and Risk Assessment.³



Admitting that a typical 15-min primary care visit does not allow practitioners to adequately evaluate a patient's feet, John D. Miller with co-authors proposed a 3-minute diabetic foot examination.⁴ This exam includes 1 minute each for the patient's history, Ipswich Touch Test and tuning fork and possibly monofilament application. Arguably, this approach may work in a fast-paced primary care setting, but not in a comprehensive podiatry setting. The need for more objective neuropathy screening is long overdue. Many patients with LOPS have no initial symptoms at all, unless they have already presented some complications to a practitioner.

The cornerstone of the comprehensive foot assessment is objective large and small fiber neuropathy screening. As a



physician, I was frequently frustrated with the inconsistency of available screening neurological examinations, especially in patients with DPN. The absence of subjective complaints and frequent late complications drove the need for an earliest possible objective screening method. The need to help a practitioner to overcome the deficiency and inconsistency of the screening foot exam was paramount.

The **Dynamic Neuroscreening Device (DND)** was conceived and designed by a physician due to the understandable disappointment of neuropathic patients not being discovered/diagnosed in a timely manner, and the absence of foot exam uniformity from one practitioner to another. One option to consider to improve the foot exam would be to

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incorporate quantitative sensory testing. Academic medicine researchers have employed QST equipment but this equipment would be expensive for field practitioners. Moreover, extensive QST studies have failed to find uniform, across-the-board thresholds for temperature (small fiber) and vibration (large fiber) sensitivity. The impracticality and ineffectiveness of these methods demanded another solution. The DND was conceived and designed based on the relative minimum difference discrimination principle, discovered by Doctor Ernst Weber in 19th century. He showed that control subjects do not sense absolute weight differences, but relative ones. The DND screens for a patient's ability to discriminate temperature and vibration stimuli.

The DND helps a practitioner to uniformly, objectively screen cold temperature sensation mediated by small

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myelinated A-delta fibers and warm temperature discrimination mediated by small myelinated C fibers in 2 degree Celsius increments in a range from 15 degrees Celsius to 40 degrees Celsius. The temperatures of the pad surfaces on the DND are changed very easily with the simple interface on the device. The temperatures change very quickly to facilitate a fast examination and they are maintained by closed loop-controlled thermoelectric coolers. In addition, objective graded large fiber function is assessed by the ability to discriminate 5 levels of vibratory stimuli, electronically mimicking a tuning fork.



As part of a complete neuro-vascular assessment I incorporate the DND to test for various stages of peripheral neuropathy. The DND has replaced my tuning fork and we are able to get reproducible screening results through testing both large and small nerve fibre functions. DND has become an integral part of the assessment. Our clinic performs between 5 and 10 full neuro-vascular assessments daily.

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The DND is indicated for neuropathy screening purposes in general care. The DND is not indicated for a threshold evaluation as some QST devices provide. The DND is very useful to compare vibration discrimination between fingers and toes, as an initial assessment. 5 amplitude modalities assure that a patient will be able comprehend at least one of them at the fingers to start, and examiners will uniformly appreciate if any discrimination sensitivity deficit exists at that level on the feet of the same patient. Prosenex has done extensive amplitude modeling of the standard tuning forks in use and matched the maximum amplitude (measured in G's) to the maximum amplitude that those tuning forks could generate.

The objective graded screening results are used to establish a patient baseline that can be monitored for both degradation and improvement during subsequent patient visits. Significant improvements in patient participation and patient compliance have been noted with use of the DND. The de-



vice is perceived by the patient to be a high tech device and objective results are more readily understood than current screening methods. Patient understanding is often easily noted when the patient can't discern a 10 degree Celsius difference on their feet, but immediately realize the drastic difference on their hands.

The DND can make the neuroscreening foot examination truly comprehensive in 3-5 minutes. The unique

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combination of two major screening modalities in one simple-to-use hand held device, makes DND truly indispensable for the screening and objective longitudinal patient follow-up. The data obtained from the screening may help to establish a need for regular patient follow-up in the podiatry office, evaluate disease progress and focus on foot appliance design.

In November 2014, Prosenex was awarded the prestigious 2014 New Hampshire High Tech Product of the Year Award in recognition of the DND's advanced technology and approach to objective graded screening. The award is presented annually by the New Hampshire High Tech Council.⁶

References

¹ Wu S, Branigan M. Diagnosing DPN. Podiatry Management. 2014;11/12:103-108

² https://www.med.umich.edu/mdrtc/profs/documents/svi/MNSI_howto.pdf.

³ Boulton AJ, Armstrong DG, Albert SF, et al; American Diabetes Association; American Association of Clinical Endocrinologists. Comprehensive foot examination and risk assessment: a report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists. Diabetes Care. 2008;31:1679-1685.)

⁴ <http://www.diabeteshub.com/clinical-reviews/article/how-to-do-a-3-minute-diabetic-foot-exam>

⁵ Hand-held Neuroscreening Device. US Patent 8579830

⁶ <http://www.nhhtc.org>

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