Seven Reasons to Reconsider Monofilament Testing for Loss of Protective Sensation

(LOPS)

The use of the 10 gram Semmes-Weinstein monofilament test for the identification of LOPS in patients with diabetic peripheral neuropathy (DPN) has been a widespread practice throughout medicine for decades. Few would argue that it is the most commonly used method of neurological risk stratification for this patient population. This is especially important as DPN is acknowledged as the essential precursor to most diabetic foot complications (Fig.1). Ideally, results of the test are used to implement risk mitigation strategies with the goal of amputation prevention.

In light of recent insights derived from advances in our understanding, the case can be made that the usefulness of this test is ambiguous at best. Although some may argue that years of research support its use, there remains a lack of evidence demonstrating a reduction in diabetic foot complications or amputation rates as a result of performing this exam.

A summary of six well-established shortcomings of the test are enumerated below. A seventh potentially intrinsic flaw based on current research completes the list.

1. **Manufacturing Defects**: The exam and all the research done supporting its use is predicated on the device consistently applying 10 grams of pressure to the skin of the foot. Research on new monofilaments has shown poor standardization of force application among various manufacturers (1).
2. **Material Fatigue:** The nylon material used in the device will fatigue with use (2). This fact will result in monofilaments being used past their useful service life as there is currently no standard method of testing or calibrating the device.
3. **Climactic Effects:** Nylon is susceptible to changes in its stiffness depending on atmospheric humidity and temperature (3). The resulting effect is variation from the 10 gram pressure application required for accurate testing.
4. **Technique Variability:** One standardized clinical testing protocol has yet to be adopted by all providers. A lack of standardization in technique calls into question the applicability of test results. This is especially concerning as the test is used across a wide spectrum healthcare providers in countries around the globe. For example, Japanese researchers have found the 2 gm monofilament more effective in their patient population than the traditional 10 gram device (4).
5. **Skin Variability**: Skin on the plantar aspect of the foot varies in thickness and is susceptible to the development hyperkeratotic lesions which can result in false positive test results. Recommendations to perform the test on non-callused skin are a practical solution to this problem however it is impossible to know if this is done consistently.

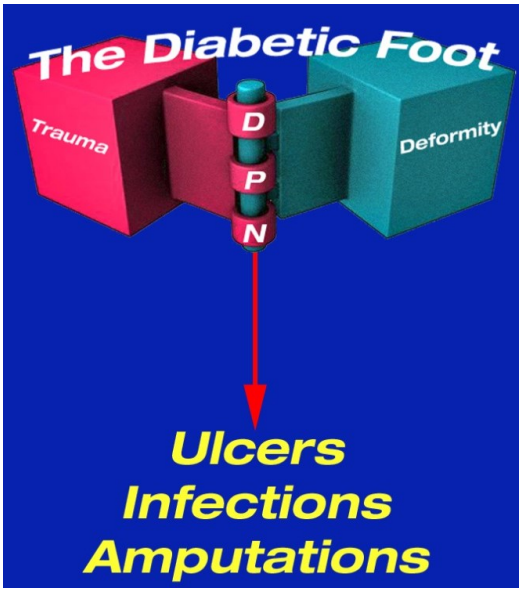

Fig. 1. DPN, trauma, and deformity conspire to precipitate most diabetic foot complications. DPN can be viewed as the critical axis point of this pathological triad.

6. Poor Interrater Reliability: The test provides ambiguous results and poor interrater reliability even when done correctly (5). Family Medicine physicians have recently called into question exactly how useful the device is at identifying diabetic patients with LOPS (6).

7. A Large Fiber Test for a Small Fiber Deficit: Monofilament testing under ideal conditions assesses light touch by applying pressure to the skin of the foot. Light touch is mediated mostly by large fiber encapsulated nerve receptors and a few small nerve fiber mechanoreceptors (Fig. 2). For decades, providers have been advised by researchers and expert consensus to accept this as a valid "proxy" test for LOPS (7). LOPS, more accurately interpreted as a loss of pain sensation, is a small nerve fiber function mediated by specialized free nerve endings known as nociceptors. This leads one to question whether a test assessing a mostly large fiber nerve function can imply a loss of small fiber nerve function. Although there is thought to be some correlation between the two, it is difficult to make a direct comparison. For example, nerve conduction velocity (NCV) testing, acknowledged as the "Gold Standard" for diagnosing neuropathy, tells us nothing about small fiber nerve function. This lack of direct correlation is heightened in light of recent research demonstrating that small fiber neuropathy (SFN) precedes large fiber neuropathy in the feet of diabetic patients (8).

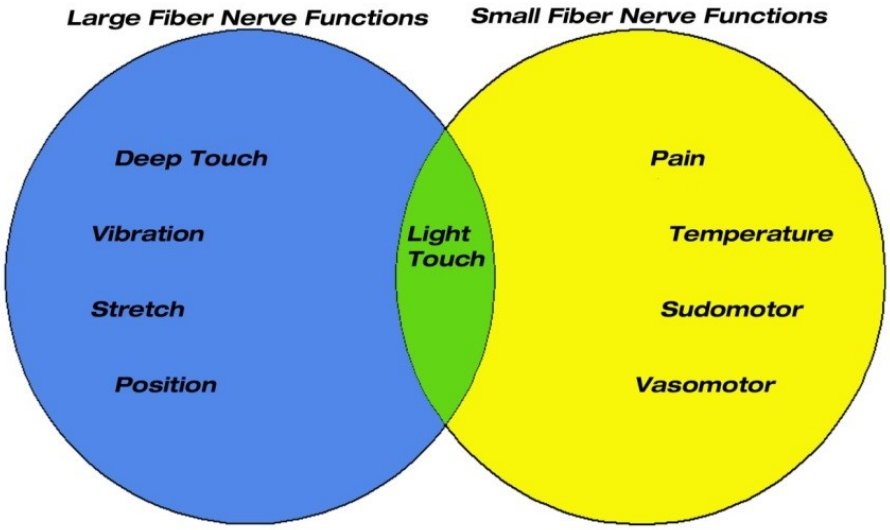

Fig. 2. Large and small nerve fiber functions in the skin of the foot. Note that pain perception resides on the small fiber side and light touch is the only shared function.

Given these facts, the argument can be made that there is an intrinsic flaw in the test itself. Although not commonly discussed in the literature, providers have no doubt seen its impact over the years in the false negatives elicited by the test. The most glaring examples are those patients who will "pass" the monofilament exam while failing to react to a sharp stimulus or complain of pain when presenting with a full-thickness foot ulcer. In these cases, patients most likely are passing the exam with their intact large fiber nerve receptors. Although these may be exceptions, periodic false negatives combined with the errors induced by the above noted confounding variables lead one to reconsider the validity of the test as medicine moves into the 21st century. Ultimately providers should consider whether LOPS as diagnosed by the monofilament is effective at further reducing diabetic foot complications.

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