A perfect 10? Why the accuracy of your monofilament matters

Matthew Young

Monofilament testing has become one of the main methods used to screen people with diabetes for increased risk of neuropathic foot ulceration. There are many different types of monofilaments in use, and although the most common is the 10-g monofilament, other available monofilaments require different force levels to bend them. This article will discuss the role of monofilaments in screening people with diabetes, and the implications of using inaccurate monofilaments.

Article points

1. The original monofilaments were the Von Frey hairs, later called Semmes-Weinstein monofilaments.
2. The modern monofilament bears little or no relation to the original versions.
3. It is important that monofilaments are used correctly; the 10-g monofilament has been chosen as the ideal screening cut-off point.
4. The consequences of inaccurate or faulty monofilaments, for both patients and respective health services, are greater than might at first be imagined.

Key words

- Monofilament
- Neuropathic foot ulcer
- Screening

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The original monofilaments were the Von Frey hairs, later called Semmes-Weinstein monofilaments, that were used for testing patients with leprosy for patchy sensory loss (Birke and Sims, 1986). The Semmes-Weinstein monofilaments are rods with a filament mounted at a 90-degree angle; these were available in full and limited sets with varied bending abilities to test for loss of pressure sensation at various levels and sites (*Figure 1*). The modern monofilament (*Figure 2*), as explained below, bears little or no relation to the original versions and thus should not be referred to as a Semmes-Weinstein monofilament. In the past, the main research tools for testing for neuropathy were the biothesiometer, which was later re-invented as the neurothesiometer (Young et al, 1993a), as well as other quantitative sensory tests, such as current perception or thermal discrimination (Masson et al, 1989), and neurophysiological tests of conduction velocity (Young et al, 1986). None of these latter tests, however, were deemed suitable for mass screening of patients as all were expensive, time-consuming, electrically powered and required a degree of technical skill. In the late 1980s, screening for sensory loss in people with diabetes was mainly performed by doctors in diabetes specialist clinics, and the preferred method was clinical examination of vibration perception, using a tuning fork and ankle reflex testing (Young et al, 1993b). The 1990s saw an explosion of research, based on the value of a number of screening methods to predict future foot ulceration. Over this time, the two most reliable methods developed were vibration perception thresholds (VPT), as measured by the neurothesiometer, and the modified neuropathy disability score (NDS) (Young et al, 1993a; 1993b; 1994). Both NDS and VPT have high discriminatory values with an excellent balance between sensitivity, the ability to pick up all or most at risk, and specificity, the ability to detect those at risk and not incorrectly label a significant number of people as being at risk incorrectly (Pham et al, 2000).

Despite these available tools, the monofilament has won the battle to become the standard screening tool for evaluating risk of foot ulceration worldwide. The

first papers on monofilament screening in people with diabetes were published in the late 1980s. Initially, cross-sectional studies such as that by Kumar et al (1991) looked at populations of people with diabetes who either did or did not have a history of foot ulceration. Failure to perceive a monofilament was associated with prior foot ulceration. These studies were followed by prospective studies in which monofilament testing was assessed to determine if it could predict future foot ulceration (Rith-Najarian et al, 1992; McGill et al, 1999; Pham et al, 2000). Although these studies have produced a variety of odds ratios for predicting the risk of future foot ulceration, all have shown a consistent benefit of monofilament screening through the ability to identify a group of patients at increased risk of neuropathic foot ulceration. Other available techniques are more likely to predict foot ulceration; monofilament testing, however, is a much more simple technique to use; people can be trained to use a monofilament in a matter of hours and with a simple yes or no proforma, the scope for observer error is reduced (see *Box 1* and *Figure 2*) (Young and Matthews, 1998). These attributes, combined with the relatively low unit cost, have ensured the widespread adoption of monofilaments as the current gold standard for first-line screening. Monofilaments perform better at predicting neuropathic ulceration when combined with other sensory testing modalities (Pham et al, 2000). However, in the UK, this is more commonly performed as part of a thorough assessment after the initial screening test. The current use of monofilaments remains largely misunderstood, as outlined below.

What do monofilaments test?

The original monofilaments came in a variety of sizes, according to the force required to bend them. The purpose of the original monofilaments was, as stated above, to allow the detection of patchy sensory loss in patients with leprosy. Even today there are papers stating that a 1-g monofilament should be used on one site and a 6-g instrument on another site in order to more accurately detect sensory loss in people with diabetes when compared with normal sensation (Bourcier et al, 2006).

The original utilisation of monofilaments does not, however, reflect their current purpose; there is a world of difference between a detectable reduction in sensation and the kind of sensory loss required to increase the risk of foot ulceration in the majority of people with diabetes. Considering nerve conduction velocities as an example, while the lower limit of normal for peroneal conduction velocities is around 40 ms^{-1}, most patients will be down to around 25 ms^{-1} before they develop ulceration (Young et al, 1986). Similarly, while age-related vibration perception thresholds are useful to determine normality (Bloom et al, 1984; Wiles et al, 1991), it is the value of 25 V that is the accepted critical threshold for foot ulceration (Boulton et al, 1986; Young et al, 1994; Pham et al, 2000).

Failure to perceive a 10-g monofilament is associated with an increased risk of foot ulceration in people with diabetes (Pham et al, 2000). These people are profoundly, not just mildly, neuropathic (Young et al, 1986).

Figure 1. An original three-force set of monofilaments. Two each of 4.17/1 g, 5.07/10 g and 6.10/75 g.

Figure 2. A modern retractable monofilament being applied to the pulp of the hallux.

Box 1. Use of the monofilament.

Monofilaments should be used in the following manner:

- Apply to the palm of the tester first, and then to the palm* of the patient two or three times before applying to the foot; this will allow any extra stiffness to be removed. A 10-g monofilament, after a rest, usually initially exerts a 12–13-g force, settling to 10-g by the third or fourth bend.
- Ask patient to respond "yes" if they feel the monofilament on the test site.
- Apply the monofilament perpendicular to the skin surface that is to be tested.
- Apply the monofilament until it bends by around 1 cm.
- Remove monofilament pressure and allow a couple of seconds to pass before being applying randomly to the next test site.**
- Avoid areas of callus for test sites, but include areas that are likely to ulcerate.

* *Or to another area of the hand or arm with intact sensation.*

** *There is currently much debate regarding the number and position of testing sites when using a monofilament; however, a detailed discussion is outside the remit of this article.*

Page points

1. It is important that monofilaments are used correctly; the 10-g monofilament has been chosen as the ideal screening cut-off point.
2. Monofilaments are now widely available, but free versions should be used with caution.

Detecting sensory deficits at lower levels of pressure perception loss will identify more people with early neuropathy, but will also have a major impact on the specificity of monofilament testing as a screening tool (Young and Matthews, 1998; McGill et al, 1998; McGill et al, 1999). It is for this reason that the 10-g monofilament has been chosen as the screening cut-off point and, until other levels of pressure perception are shown to be more specific, it is a 10-g detection threshold that should be aimed for. Unfortunately, a 10-g level is not always achievable.

Sources of error with monofilaments

Monofilaments need to be applied perpendicular to the skin and are not allowed to bounce, skate or skid across the surface. Monofilaments primarily test for pressure perception, so allowing them to move stimulates other skin receptors and can alter results. As mentioned previously, the original monofilaments came in a variety of forces required to bend them. Essentially, with a consistent material, the force required to bend is a function based on the thickness and the length of the monofilament, with short and fat monofilaments being stiffer than long and thin ones (McGill et al, 1998).

The original Semmes-Weinstein monofilaments were made of nylon similar to that used for fishing. They were of similar lengths and were graded by thickness, and the thickness determined the bending force. The historical term "5.07" as a descriptor for the modern 10-g monofilament has persisted in the literature, as it was the monofilament thickness that came closest to providing a 10-g bending force. However, as mathematically these monofilaments exert a force closer to 11 g, and the thickness of the newer materials is different, this should be abandoned. The nylon monofilament has problems with both temperature and humidity affecting its elastic modulus, with cold and dry conditions making it stiffer (Booth and Young, 2000). Therefore, performance of nylon monofilaments can vary from day to day, and from geographical region to region (Booth and Young, 2000).

Modern monofilaments are actually made of other polymers and not nylon at all. The modern, reputable, commercially available monofilaments should not be affected adversely by temperature or humidity. However, manufacturing tolerances need to be tight in order to ensure uniformity of thickness and length of the finished filament. Under rules of The Association of the British Pharmaceutical Industry (ABPI), any promotional materials supplied to customers must have a unit value of less than £6. For this reason, in the author's experience "free" monofilaments are often manufactured in bulk for promotional use, and can often be inaccurate (Booth and Young, 2000). In simple terms, as with most things in life, you get the quality you pay for. In the paper by Booth and Young (2000), of the sets tested, only those monofilaments manufactured and sold by Bailey Instruments (Manchester) or Owen Mumford (Oxford) in the UK were found to accurately deliver a 10-g force to bend.

As a monofilament is used, it changes its elastic modulus and will eventually plasticise and no longer deliver a consistent 10-g force, usually dropping away to lower levels. This probably occurs after approximately 100 patient equivalents in concentrated testing (Booth and Young, 2000). However, in the clinic, testing is likely to be more spaced out and some recovery occurs between sessions. Bailey Instruments and Owen Mumford recommend changing the monofilament after approximately 6 months of use, but many clinics use monofilaments much longer than this. The ultimate question is, therefore, why does this matter?

Implications of inaccurate monofilaments

If it is accepted that 10 g is the current standard level at which pressure perception loss equates to the best balance of sensitivity and specificity in primary screening of people with diabetes for the risk of future foot ulceration, then we have to use an accurate

10-g monofilament.

If the monofilament is old, or was manufactured inaccurately to require a lower force to bend, then significantly more patients will be screened as positive for increased risk of foot ulceration, resulting in increased patient anxiety, when in truth few of the people identified will actually ulcerate. This will over burden education and podiatry services, with little benefit to the person with diabetes (McGill et al, 1999).

Even if we disregard health economics, the event of the monofilament that "reads too high" is even more worrying. Such a monofilament will be felt by people with greater levels of sensory loss than would be required to expose them to increased risk of ulceration. These people will screen negative for risk of foot ulceration, but will actually be significantly at risk. They will not get foot education or preventative care and, therefore, will be left exposed to increased foot ulcer risk with no means of reducing that risk, and possibly no advice on what to do if ulceration occurs. The potential legal connotations of this scenario are serious, especially if the monofilament is not CE marked (this is a mandatory conformity mark on many products placed on the single market in the European Economic Area; it stands for *Conformité Européenne*), as it exposes the practitioner to the potential for litigation if a patient loses their leg in these circumstances.

Conclusions

The monofilament is often seen as a simple tool utilised in primary screening for foot ulceration in people with diabetes. It is, however, an engineered product with a number of factors that can influence its reliability. In clinical governance terms, users should know where a monofilament comes from, and should ensure that it is CE marked and that it consistently delivers the 10-g force it promises. The consequences of inaccurate or faulty monofilaments, for both people with diabetes and health services, are greater than might at first be imagined. ■

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Page points

1. Monofilaments should be changed after 6 months of use.
2. Clinicians using monofilaments should be vigilant and wary of inaccurate or faulty monofilaments.