Differences in the Performance of Commercially Available 10-g Monofilaments

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OBJECTIVE — This independent study was designed to determine the accuracy of 10-g monofilaments manufactured and supplied by popular commercial companies.

RESEARCH DESIGN AND METHODS — A total of 160 new 10-g monofilaments (30 Semmes-Weinstein monofilaments [North Coast Medical], 30 Timesco/Sensory Testing Systems monofilaments, 50 Owen Mumford Neuropens, and 50 Bailey Instruments monofilaments) were tested using a calibrated load cell. Each monofilament was subjected to mechanical bucklings of 10 mm while the load cell detected the maximum buckling force. Longevity testing was performed on a subset of the monofilaments by subjecting them to continuous compressions until the buckling force was <9 g.

RESULTS — The accuracy of monofilaments to produce a buckling force of 10 g varies among manufacturers. Bailey Instruments and Owen Mumford filaments were the most accurate with 100% buckling within ±0.1 g of 10 g. Only 70% of the Semmes-Weinstein monofilaments from North Coast Medical buckled within ±0.1 g of 10 g. A total of 80% of Timesco filaments buckled at <8 g. Longevity tests on Bailey Instruments and Owen Mumford monofilaments demonstrated that 80% continued to buckle within 10% of 10 g after 100 compressions, but only 50% were within this range after 200 compressions. The maximum amount of recovery achieved in any monofilament occurred within 24 h.

CONCLUSIONS — Monofilaments made by either Bailey Instruments or Owen Mumford are recommended for use in clinical practice. North Coast Medical monofilaments may operate differently in the U.S. because of different environmental conditions such as differences in humidity. Timesco/Sensory Testing Systems monofilaments were neither accurate enough nor Conformity European marked to recommend their use in the U.K. Longevity and recovery testing suggest that each monofilament will survive usage on — 10 patients before needing a recovery time of 24 h before further use.

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The relationship between peripheral neuropathy and the likelihood of developing foot ulceration is well established (1–5). The incidence of foot ulceration amounts to 2–3% a year (8,905 patients in the U.S.), and as many as 15% of diabetic patients experience ulceration during their lifetime. Of those with ulceration, 6–20% will require inpatient treatment as part of their management (6–8). The cost of ulcer care for an individual is approximately $28,000 in the U.S. (8). The association between ulceration and lower-extremity amputations (LEAs) is strong (8–10), as is the association between peripheral sensory neuropathy and LEA independent of whether ulceration precedes LEA (11). In the U.K. alone, the cost of an amputation and limb fitting has been suggested to be £8,500 per patient with an estimated 4,800 amputations performed annually (12).

With as many as 30% of diabetic persons suggested to have peripheral neuropathy and the evidence of the association between neuropathy and lower-limb complications, reliable methods for assessing the extent and severity of neuropathy are required (3,13). Although nerve conduction velocities are regarded as the “gold standard” method of measuring pathological damage in peripheral nerves and are very reproducible, the time and cost of performing them preclude their use in the routine clinical environment (14,15). The measurement of vibration perception thresholds (VPTs) using the biothesiometer (Biomedical, Newbury, OH) or neurothesiometer (Scientific Laboratories Supplies) has been found to identify patients at risk for ulceration (4,16). The availability and cost of such equipment, however, may prohibit the use of objective VPT measurement in practice (13,17). The complexity of using VPTs is further increased if the VPTs are then “age corrected,” which has been deemed necessary in several studies to maximize their sensitivity in predicting patients who are at risk for future foot complications (18–20).

The use of monofilaments has been promoted by many as an easy and reliable method that discriminates between patients who are at increased risk and those who are at low risk for ulceration (21–27). However, the sensitivity of monofilaments in detecting high-risk patients varies markedly depending on the research cited. The variation in monofilament sensitivity may be a direct consequence of discrepancies in the accuracy and reliability of the monofilaments (14,17,28). In practice, these discrepancies may lead to inadequate and inappropriate screening criteria used to identify patients at risk.

Various extrinsic and intrinsic factors influence the reliability of monofilaments. Extrinsic factors include the testing procedure.
Monofilaments were then tested on a Lloyd ton, Manchester, U.K.). All of the monofilaments were tested in the open market using private funds. In total, 160 monofilaments were purchased: 30 Semmes-Weinstein monofilaments manufactured and supplied by popular companies. The results of 158 monofilaments were analyzed; the results from 2 Owen Mumford monofilaments were discounted because of gross damage caused by the manufacturer's packaging process. All monofilaments demonstrated a rapid decline in buckling force during the first 3 compressions before reaching a steady state (Fig. 1). Therefore, the first 2 compressions were disregarded for all monofilaments, and the data are means ± SD of buckling force from the last 8 consecutive tests for each monofilament. These mean values were grouped according to the amount of deviation from 10 g (Table 1). The expression of deviation allowed the comparison of monofilament performance within specified ranges.

Table 1 demonstrates that most monofilaments produced by Owen Mumford and Bailey Instruments were buckling within 0.5 g of 10 g of buckling force, with the remaining monofilaments from these batches falling within 1.0 g of deviation. Mean buckling forces were 10.1 ± 0.4 g for the Owen Mumford filaments and 9.7 ± 0.4 g for the Bailey Instruments monofilaments. Significantly fewer (76%) of the Semmes-Weinstein monofilaments manufactured by North Coast Medical buckled within 1.0 g of 10 g of force (Table 1) (P < 0.001). These filaments generally exhibited a negative deviation with most buckling forces lower than 10 g of force. The accuracy of 10-g monofilaments manufactured by popular companies was tested in the open market using private funds. In total, 160 monofilaments were purchased: 30 Semmes-Weinstein monofilaments manufactured and supplied by popular companies. The results of 158 monofilaments were analyzed; the results from 2 Owen Mumford monofilaments were discounted because of gross damage caused by the manufacturer's packaging process. All monofilaments demonstrated a rapid decline in buckling force during the first 3 compressions before reaching a steady state (Fig. 1). Therefore, the first 2 compressions were disregarded for all monofilaments, and the data are means ± SD of buckling force from the last 8 consecutive tests for each monofilament. These mean values were grouped according to the amount of deviation from 10 g (Table 1). The expression of deviation allowed the comparison of monofilament performance within specified ranges.

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Table 1— Performance of different 10-g monofilaments in laboratory testing

<table>
<thead>
<tr>
<th>Monofilament Type</th>
<th>±0.5 g</th>
<th>±1.0 g</th>
<th>±1.5 g</th>
<th>±2.0 g</th>
<th>±2.0 or more g</th>
<th>Means ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bailey Instruments</td>
<td>72</td>
<td>28</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>9.7 ± 0.4</td>
</tr>
<tr>
<td>Owen Mumford</td>
<td>69</td>
<td>31</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>10.1 ± 0.4</td>
</tr>
<tr>
<td>North Coast Medical</td>
<td>6</td>
<td>70</td>
<td>24</td>
<td>0</td>
<td>0</td>
<td>8.6 ± 0.3</td>
</tr>
<tr>
<td>Timesco/Sensory</td>
<td>0</td>
<td>10</td>
<td>10</td>
<td>33</td>
<td>47</td>
<td>8.1 ± 0.5</td>
</tr>
<tr>
<td>Testing Systems</td>
<td></td>
<td></td>
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</tbody>
</table>

Data are % or means ± SD. No significant difference was evident between Bailey Instruments and Owen Mumford monofilaments. Significantly fewer North Coast Medical and Timesco/Sensory Testing Systems monofilaments were within 1.0 g of 10 g and both had a significantly lower mean buckling force (P < 0.01).
ling forces falling to <10 g (8.6 ± 0.3 g). A similar pattern emerged with Timesco/Sensory Testing Systems monofilaments (8.1 ± 0.5 g). A total of 50% demonstrated buckling forces <8.0 g.

Figure 2 illustrates a representative sample of results from longevity tests performed on Bailey Instruments and Owen Mumford monofilaments. The results clearly show that most monofilaments remained within 10% of 10 g of buckling force after 100 continuous compressions, but by 200 compressions, only 50% of monofilaments were within this range. Most monofilaments recovered to within 10% of 10 g, although this required up to 24 h in some cases. No monofilament was found to recover to the original buckling force recorded at the beginning of the trial.

CONCLUSIONS — Monofilaments remain the most often used tool for objective screening and assessment of peripheral neuropathy and thus the evaluation of sub-sequent risk of lower-extremity complications. The use of monofilaments in practice has been supported by research that has demonstrated their capacity to identify patients at risk for ulceration (13,18,21–28). However, many researchers who have advocated the use of monofilaments have had the benefit of calibrating their monofilaments before use (22,23,28). Clinicians in practice are rarely able to access calibration equipment or procedures and have relied on the minimal data provided by manufacturers as an assurance of monofilament reliability. Because laboratory testing of monofilaments may not wholly mimic their use in practice, this study has important implications for existing research and its implementation when one considers that monofilament inaccuracies are likely to be further compounded when used on skin versus a standard stimulus such as a load cell. Furthermore, this research raises issues regarding monofilament manufacturing processes and the internal and external quality measures used to control them.

Most studies that have used monofilaments to categorize individuals according to risk status have used Semmes-Weinstein filaments (21–28). Rith Najarian et al. (22) detailed the results of calibration. They found up to 10% of variation in Semmes-Weinstein monofilaments. The present study has found considerably greater variation in these monofilaments. This degree of variation may explain the discrepancies in odds ratios (from 2.5 to 18) cited in the key research that has analyzed the use of monofilaments to determine the risk status of patients (22,26,31). In addition, the rapid decline in recorded buckling force during the first 3 compressions may also influence screening results. The results of this study suggest that all monofilaments should be test bounced twice (e.g., on the clinician’s hand) before use on the area to be tested.

Further research may be required to ascertain the extent to which differences in accuracy of monofilaments affect their sensitivity and specificity to detect high-risk patients and also whether the detection of 10 g of buckling force is the level at which protective sensation is preserved. If at this stage we regard 10-g monofilaments as the most appropriate, then the results of this study imply that centers using North Coast Medical or Timesco/Sensory Testing Systems monofilaments may be producing far too many false-positive results (i.e., they may be categorizing patients as insensate who are in fact sensate).

McGill et al. (28) highlighted the effect of misdiagnosing sensate patients as insensate in their work on monofilaments. That research showed that a minor reduction in the specificity of monofilament testing resulted in 388 patients incorrectly recruited for specialist education and intervention. The outcome in clinical provision was reported to amount to >800 h of intensive education and >1,600 podiatry treatments. The research stressed the importance of this finding in the light of the fact that limitations in health care resources are typical of almost all health care systems. Furthermore, from an ethical perspective, the effect of potentially inappropriate education and treatment strategies that patients may be subjected to if misdiagnosed should not be overlooked.

The differences in accuracy found between monofilaments produced by the various manufacturers may be explained by differences in the physical and/or chemical properties of the material from which the monofilaments are made. Previous research has demonstrated the effect of varying monofilament lengths on buckling forces (17). A monofilament is mathematically represented by a circular column. The buckling force of a circular column depends not only on its length but also on the radius of the column and the modulus of elasticity of the filament material (29). The results of this study could be due to alterations in the chemical composition of the monofilaments produced by the various manufacturers versus any significant differences in their physical characteristics. Numerous nylon polymers may be used in the manufacture of monofilaments, all with differing properties that could cause the monofilament to behave differently under the same environmental conditions (30). This may account for the differences in performance between the monofilaments manufactured in the U.K. and U.S. in this study. However, the composition of the material and the environmental conditions under which the monofilaments were produced are not provided in the product literature supplied with each monofilament or on request from the manufacturers. Further studies are therefore required to con-
firm whether environmental conditions have a significant effect on monofilament performance.

Although the quality control measures that are adopted within an organization cannot be commented on, all monofilaments (except the Timesco/Sensory Testing Systems monofilaments) have the Conformity European (CE) mark awarded by the Medical Devices Agency (which consists of U.K. Department of Health agents responsible for implementing the Medical Devices Directive of the European Union, 1993). The CE mark indicates that a product satisfies the requirements essential for it to be considered fit for its intended purpose (33). For devices used diagnostically to monitor physiological processes, the CE mark may be awarded only if the devices are assessed by an external notified body. The nature of this assessment, however, can be chosen by the manufacturer and may simply be an audit of the production quality assurance system rather than an assessment of the quality of the product itself (33). One could argue that the level of inaccuracy exhibited by some manufacturers’ monofilaments is sufficient to inappropriately diagnose patients. We hope therefore that the results of this study will produce better communication between the notified bodies of competent authorities and the manufacturers to address the quality measures by which monofilaments are currently assessed.

The performance exhibited by Bailey Instruments and Owen Mumford monofilaments in the longevity tests has important implications for their use in clinical practice. If 100 compressions are regarded as equivalent to testing 10 sites on 10 patients, then >1 monofilament should be used in clinics in which >10 patients are assessed or screened per day. The laboratory testing of monofilaments used continuous compressions, which may not entirely mimic the procedure when using monofilaments on patients. Therefore, further long-term clinician-based studies are needed to confirm how many monofilament tests may be performed on patients before they become inaccurate, the subsequent recovery time they require, and the point at which monofilaments can no longer recover and thus need replacing. However, 12% of monofilaments required up to 24 h to recover after continuous use, and we advise that monofilaments should be left for 24 h after patient testing sessions to ensure optimum recovery.

Clinicians, health researchers, and national and international regulatory bodies have the combined responsibility to ensure that the skills, techniques, and equipment used on patients are based on evidence regarding their reliability and efficacy. Monofilaments remain a useful screening and assessment tool to identify the extent and severity of peripheral neuropathy, and their use has the capacity to affect the incidence and prevalence of ulceration and lower-limb complications. The quality of the monofilaments produced by manufacturers is of paramount importance if the true potential of monofilaments as a simple but effective tool is to be fully investigated and realized.

References
23. Sosenko JM, Kato M, Soto R, Bild DE: Comparison of quantitative sensory thresh-