Clinical consistency of vibration sense testing: Development of a manikin great toe with embedded accelerometer for testing and training

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Article points

1. Assessment of the integrity of vibration sensation is rarely tested in the routine assessment of people with diabetes.
2. Without training or any previous exposure, VibraTip® (Bristol Robotics Laboratory) is as consistent a source of vibration as a standard tuning fork.
3. Even though VibraTip was an unfamiliar device for all of the subjects, the vibration amplitude imparted was typically greater than that imparted using a standard 128 Hz tuning fork.
4. Lack of consistency in the way devices are used are likely to be major factors in governing reliability.

Key words

- Consistency
- Neuropathy
- Reproducibility
- Vibration
- VibraTip®

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Diabetes is the most common cause of peripheral nerve damage and vibration perception is the first sensory modality affected. A standard tuning fork remains the most widely used tool for assessing vibration perception in clinical practice, however inter-operator differences in the use of this tool vary widely. The authors developed a toe manikin capable of reporting the waveform and intensity of vibration imparted to its surface. Using the manikin, the consistency of vibration applied by a group of doctors using a standard 128-Hz tuning fork, with that delivered by the same operator using VibraTip® (McCallan Medical), were compared. Despite differences in technique, the waveform generated with VibraTip was more consistent than that of the tuning fork. With both devices, however, there was considerable intra-operator variability in recorded amplitude and frequency of vibration. By providing instant feedback, the manikin toe serves as a useful training device to encourage consistency of vibration sense testing.

Loss of vibration sense has long been established as one of the earliest, and therefore one of the most important, signs of nerve damage not only in diabetes, but in other causes of peripheral neuropathy (Williamson, 1907).

The pressure of application for several gold standard vibration sources, such as the neurothesiometer and Rydel Seiffer tuning fork, is "gravity", an impractical requirement for assessment of loss of sensation over most of the foot and leg as, in a sitting or lying position, very few surfaces are truly horizontal. Therefore, optimal use of these devices as suggested by their operating instructions is largely limited to research settings.

In the clinical setting, uncalibrated tuning forks, and to a lesser extent VibraTip® (McCallan Medical), are routinely used as vibration sources. Tuning forks produce a stable frequency, albeit with harmonics, but the amplitude of the vibration and the extent to which the energy is transferred to the skin is variable. Initial amplitude, time since the tuning fork was struck, the way the stem of the device is gripped by the clinician and the pressure and angle of application all influence stimulus intensity. These variables make inter-operator differences inevitable. Intra-operator inconsistency also confounds assessment of vibration perception but, until now, this has not been easy to assess.

Aim

To objectively assess intra-operator inconsistency in the use of tuning forks and VibraTip, the authors developed a highly realistic manikin toe containing an accelerometer that reports the amplitude and frequency of vibration stimulus applied to the skin surface.

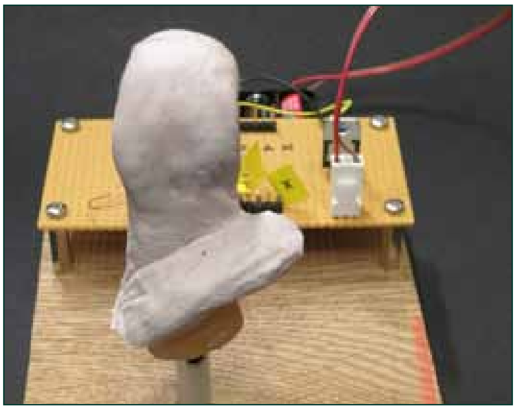
Method

To mimic as closely as possible the pattern of propagation of vibration energy throughout the toe, the authors developed a toe manikin capable of reporting the waveform and intensity of vibration imparted to its surface. The structure of the manikin was modelled as precisely as possible on human tissue.

The two phalanges of the great toe were made from polyester resin, cast in a mould taken from a skeleton foot, linked together with a length of polypropylene binding strip and encased in silicone rubber to simulate the resistance to movement imparted by the joint capsule (*Figure 1a–c*). A 1.5-mm thick, high fidelity, silicone rubber skin (Silastic 3483 hardness approximately Shore A 13) was made from a casting of a great toe, incorporation a toenail separately cast from polyester resin (the 3-part mold is shown in *Figure 1e*). On the inside of the skin, positioned under the pad of the great toe, an accelerometer (an electromechanical device that measures proper acceleration) connected with flexible 0.25-mm lacquer-insulated wires was secured with silicone rubber (*Figure 1d*, see arrow).

The articulated skeletal elements were positioned inside the skin and the subcuticular tissue connecting the skin surface to the skeleton created using a soft mixture of silicone rubber as above, diluted with 30% silicone fluid. The toe manikin was mounted on an 8-mm aluminium tube (*Figure 2*) and the whole assembly connected via the circuit shown to a PicoScope 2204 PC oscilloscope module (Pico Technology; *Figure 3*).

Figure 2. The toe assembly was mounted on an aluminium tube.



The PC interface allowed the waveform, amplitude and frequency of vibration imparted to the toe to be displayed on screen and captured at a set interval (3 seconds) after application of the stimulus.

With no training or preamble, junior and senior doctors (*n*=21) working on the medical admissions unit and short stay ward at the Bristol Royal Infirmary, Bristol, were asked to select either a tuning fork or VibraTip, and then to apply it five

"The toe manikin was mounted on an 8-mm aluminium tube and the whole assembly connected via the circuit shown to [an] ... oscilloscope module."

Figure 1. The authors developed a toe manikin capable of reporting the waveform and intensity of vibration imparted to its surface.

times in succession to the manikin toe, before switching to the alternative source of vibration. The procedure was repeated, allowing the amplitude and frequency of a total of ten applications from each device to be recorded per participant.

Results

None of the subjects had seen or used VibraTip before. All were familiar with a tuning fork, but only 6 of 21 subjects had used one more than once in routine practice during the previous 6 months. Nine had not assessed vibration sense on a patient at all during the previous 6 months – even though in the 6 months leading up to the trial, Trust data (held on file) indicated that 16% of patients were known to have diabetes (1701 of 10 048 emergency admissions between April and October 2013).

Almost without exception, VibraTip applied to the tip or pad of the manikin toe resulted in the oscilloscope displaying a steady, sine wave, usually of similar amplitude irrespective of how the device was held or applied to the skin. The wave pattern produced using the 128Hz tuning fork was occasionally similar to that produced by VibraTip, but more often disorganised, with harmonics and a lower amplitude overall. Not infrequently, the waveform produced by a tuning fork was almost undetectable. Typical tracings for VibraTip and tuning fork are shown (*Figure 4*).

Unexpectedly, the mean frequencies recorded from both VibraTip and tuning fork were variable, perhaps owing to complex propagation patterns of vibration through the skin and subcutaneous tissue. The amplitudes recorded were generally greater with VibraTip than tuning fork but again, there was great variability. Some clinicians produced relatively consistent results but for most, bearing in mind that standard errors of the mean rather than standard deviations are shown in *Figure 5*, intra-operator consistency was very low.

Discussion

When patients are asked whether they can feel vibration from a tuning fork, their perception is often coloured by seeing and hearing the device approaching their foot, and confused by sensing the coldness of the metal and the pressure used to apply it. People with diabetes often much want to be “normal” and even if profoundly neuropathic, may report, when asked, that they can feel vibration “a bit”.

There is no formal training for doctors in diabetic foot care and although the various methods of assessing vibration sense are well known, there has until now been no way of assessing the intra- and inter-observer consistency and reliability of vibration stimulus application. Practitioners are currently more familiar with monofilaments to diagnose diabetic neuropathy because of their perceived

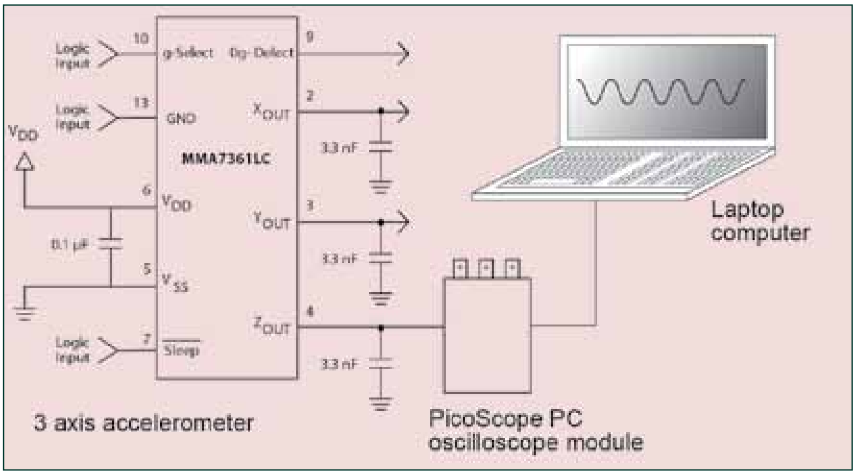


Figure 3. The toe assembly was connected via the circuit shown to a PicoScope 2204 PC oscilloscope module (Pico Technology).

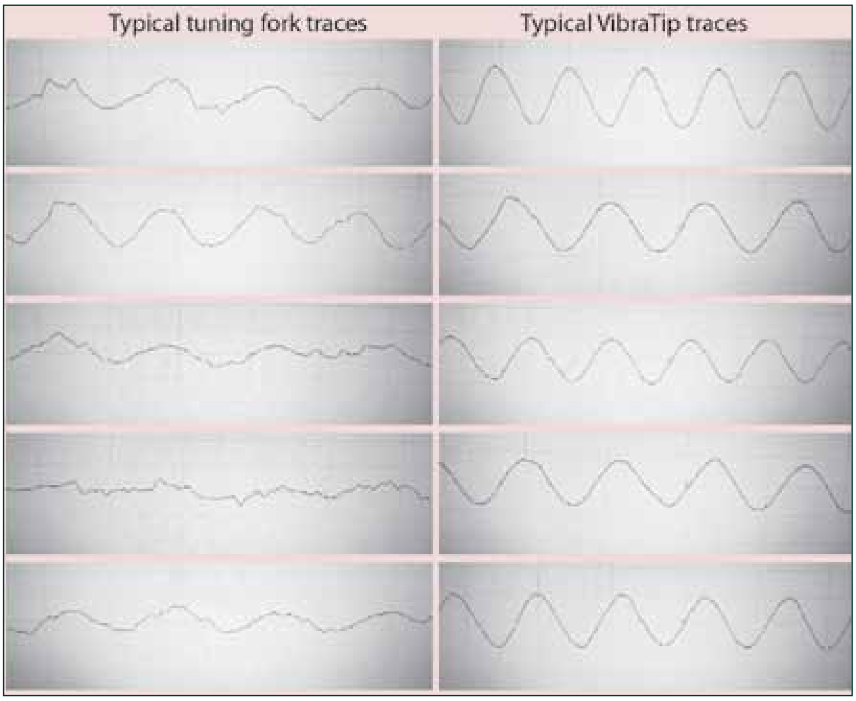


Figure 4. Typical tracings for the tuning fork and VibraTip ® (Bristol Robotics Laboratory).

reliability, compared to the 128-Hz tuning fork.

VibraTip has been selected for assessment as part of NICE's Medical Technology Evaluation Program. According to NICE's (2014) medical technology guidance scoping document: "The Committee considered that VibraTip may offer benefits to patients and to the healthcare system, in respect of ease of use, consistency of stimulus and durability. The Committee considered VibraTip may be helpful in detecting diabetic peripheral neuropathy in more patients." The Advisory Committee's draft recommendation is yet to be made; following consultation, a final recommendation will be published in December 2014.

Conclusion

The manikin toe facilitates immediate feedback on technique of vibration perception testing. It clarifies the effects of different strategies for activating and applying tuning forks, and allows users to see directly the effects of device holding pressure and application pressure and angle on vibration propagation through the toe. ■

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"The manikin toe facilitates immediate feedback on technique of vibration perception testing."

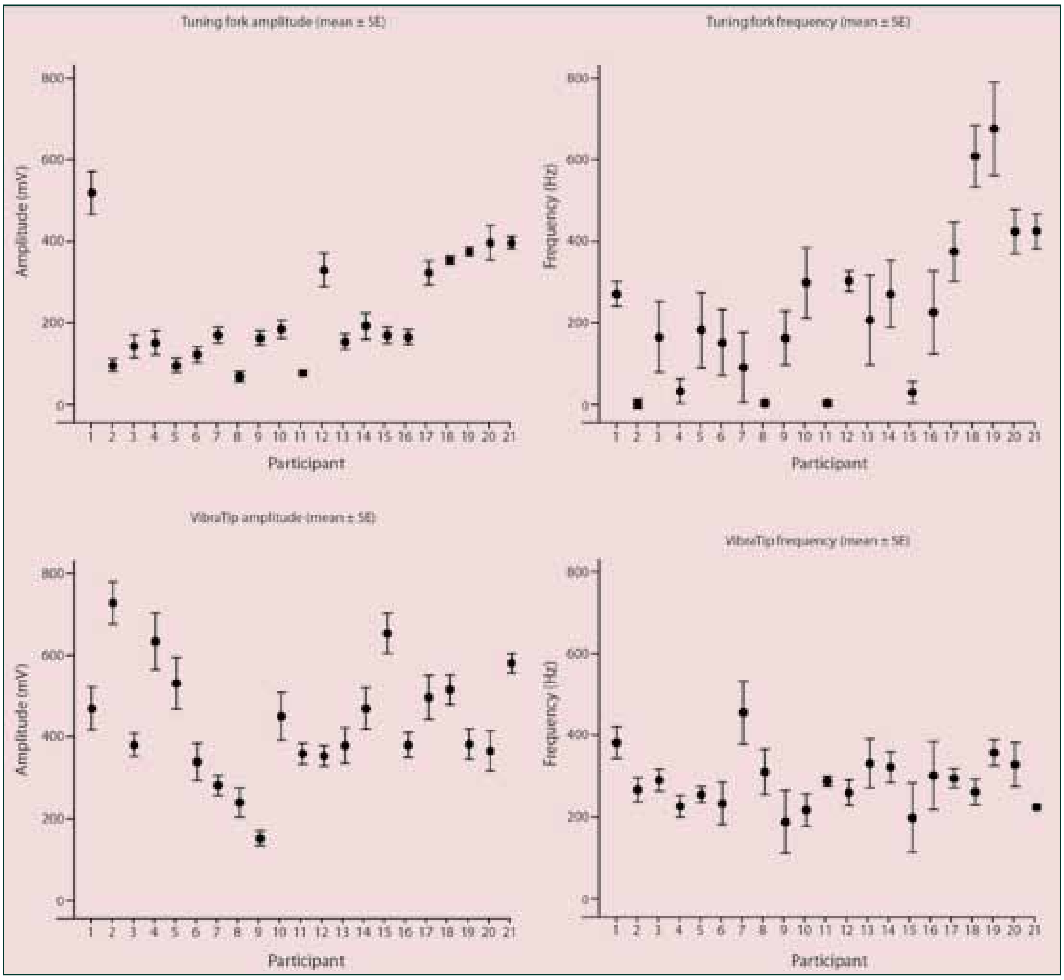

Figure 5. Four examples of intra-operator consistency (standard errors of the mean shown).