

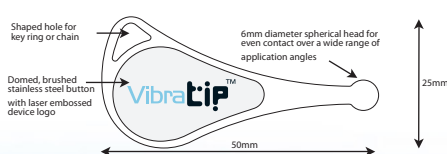
VibraTip™: a wipe-clean, pocket-sized and disposable device for testing vibration sense

Vibration sense is typically one of the first sensory modalities to be impaired as peripheral neuropathy develops

Graduated tuning forks (e.g. Reidel-Seiffer) and calibrated electronic devices (e.g. Neurothesiometer, Bio-Thesiometer and Vibrameter) are recommended to quantify the integrity of vibration sensation in trial settings. In routine clinical practice standard musicians' tuning forks are typically used as a more subjective test of vibration sense integrity.

VibraTip™ is a wipe-clean, disposable, key fob-sized device that provides a constant and reproducible source of vibration.

VibraTip™ can be applied to the skin more gently, more discretely, more consistently, more hygienically and more rapidly than a tuning fork. Vibration stimulus from VibraTip™ extends further than point pressure and is less affected by local skin characteristics such as the presence of callus. The spherical head facilitates application from any angle and its pocket size means that it is easy to carry and therefore likely to be available at the point of use. By gently touching the patient's intact skin twice with the rounded tip of VibraTip™, each time for about half a second, explaining



that 'this is touch one' and 'this is touch two' whilst randomly activating VibraTip™ on either the first or second touch, a sensitive and specific assessment of vibration perception is obtained.

Tuning forks have several drawbacks:-

- There is no general agreement about the optimal frequency of vibration
- They are cold to the touch and require pressure to impart vibration, which greatly reducing test specificity
- The Reidel-Seiffer tuning fork has to be applied perpendicular to the skin under its own weight and therefore can only be used on horizontal skin surfaces
- Because of their size and sound, tuning forks are difficult to use discretely, which leads to inappropriate cueing

- Tuning forks are difficult to carry in a pocket and have street value, both of which reduce the likelihood of them being available at the point of use
- Tuning forks are designed to produce a reference pitch rather than a specific amplitude. They vary in vibration intensity depending on how hard they are struck and how much time has elapsed since they were struck. This lead to confusion and increases the time required to make diagnoses
- As tuning forks may or may not have a foot attached to the stem, the area of skin contact can be highly variable. This significantly affects the point pressure of application
- There is no precedent for disinfecting tuning forks between patients
- Whilst the use of standard tuning forks has face validity, there are no published data related to their efficacy in clinical practice

Summary:

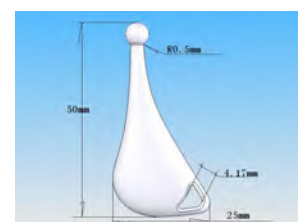
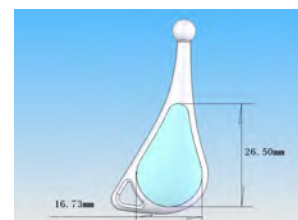
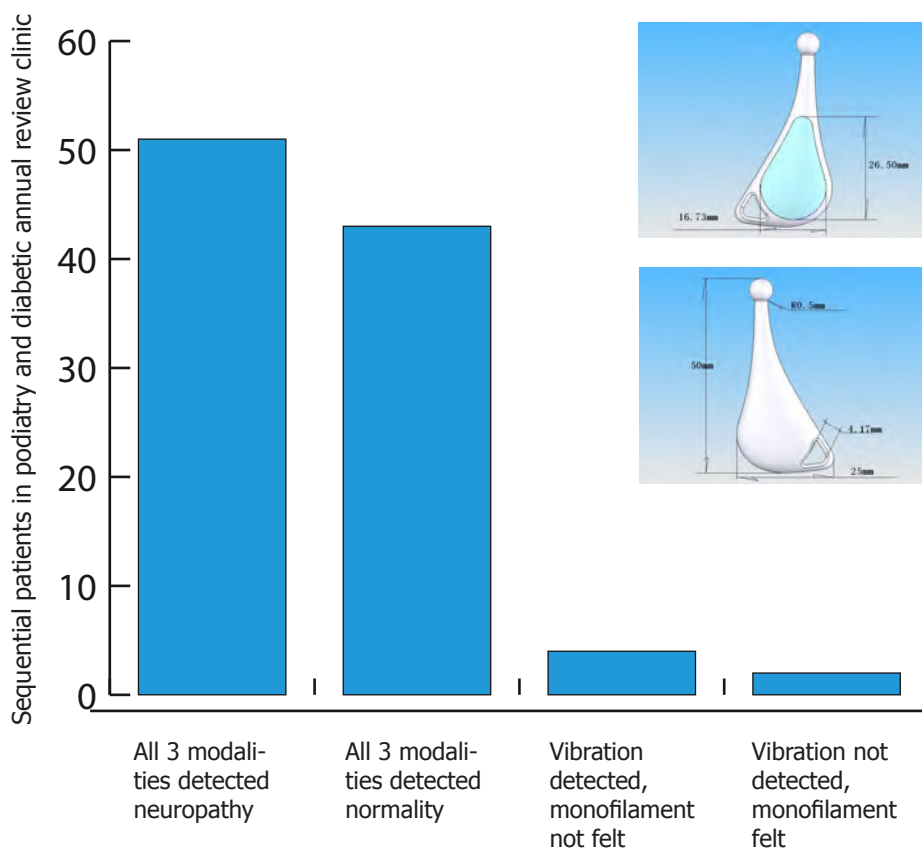
A prospective trial of 100 consecutive patients showed that VibraTip™ was as effective at detecting neuropathy as a tuning fork or monofilament.

1. Test protocol

Patients were tested for peripheral neuropathy using VibraTip™, a 10g monofilament and a 128Hz tuning fork. The order in which the three methods were used was determined by block randomisation. The six different orders in which the tests could be completed were allocated prior to the start of the study in blocks of 12. In each case, testing involved gently applying the stimulus to either the patient's left or right foot in 5 different places, each time on two occasions ("first time" and "second time"), for about one second, then asking the patient whether they felt the stimulus on the first or second occasion, saying 'this is the first', and 'this is the second'. On one of the two occasions, randomly, the damped tuning fork will be applied (i.e. without vibration), the VibraTip™ without activating it or the monofilament held near the foot but not applied.

2. Results

The results for the non-vibrating presentation of VibraTip™ showed no patients who thought they could feel vibration when no such vibration was being applied. Several patients reported feeling 'some' or 'slight' vibration when the non-vibrating tuning fork was applied.



Comparison of VibraTip™, 128Hz tuning fork and 10g monofilament

2010 Peripheral neuropathy bedside testing

VibraTip™ v.s. monofilament

For the monofilament 53 patients were able to feel the sensation, of which 51 were the same as the vibratip results. This gave a Kappa value of 0.879 which indicates very good agreement and is identical to the agreement seen between the tuning fork and the monofilament in this set of patients.





INSTRUCTIONS FOR USE

The device is presented in non-sterile packaging

Preparation

1. Open packaging containing the VibraTip™ device
2. Remove VibraTip™ from packaging and check for damage
3. Test VibraTip™ by briefly depressing the activation button and confirm that the device vibrates
4. Clean VibraTip™ by wiping with an alcohol swab

Application

1. Hold VibraTip™ gently between thumb and index finger
2. Gently touch the patient's intact skin twice, each time for about 1 second, with the rounded tip of VibraTip™, explaining that 'this is touch one' and 'this is touch two'. Randomly activate VibraTip™ on either the first or second touch
3. Ask the patient which of the two touches was associated with vibration
4. Clean VibraTip™ between uses with an alcohol swab

Precautions

- VibraTip™ should only be applied to intact skin
- VibraTip™ should not be applied to mucosal surfaces
- VibraTip™ should not be inserted into the urethra, ear or other body cavities
- VibraTip™ should be kept away from the eye
- Do not allow alcohol from cleaning swabs or other liquids to seep into the battery compartment of VibraTip™
- Do not immerse VibraTip™ into liquid at any time as permanent damage is likely to result
- VibraTip™ should not be placed in a microwave oven or autoclave
- Always dispose of VibraTip™ safely

Patent Application GB0814968.4 and PCT/GB2009/001993

VibraTip is a trademark of University Hospitals Bristol NHS Foundation Trust, UK registered Trade Mark Application No. 2514506