



# Refined Diagnosis Of Diabetic Peripheral Neuropathy With Enhanced Pinprick Perception Using Novel Single-Use Precision Instrument Design And Technique

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### Cutaneous Pinprick Testing

Cutaneous pinprick testing is a routine medical procedure with applications in family practice, diabetes, neurology, oncology, anaesthesiology and ER. In particular it has ramifications for the prognosis of conditions associated with gross morbidity whose pathophysiology is dominated by small nerve fiber destruction. The pinprick deficit produced by such small fiber population loss is commonly reported to precede that of light touch and it is hypothesized, where appropriately discernible, may reflect the development of clinically critical thresholds of neuropathy not revealed by testing with other modalities. However, demonstration of so critical a development is problematic in it's early stages and this presentation represents part of a larger peer reviewed effort to address issues of clinical efficacy and infection control.

### Diabetic Peripheral Neuropathy

It is asserted that the most common peripheral neuropathy in advanced nations is diabetic peripheral neuropathy or DPN (Vinik 2002, Vinik et al 2000) which accounts for more hospitalizations than all other diabetic complications combined. Leg ulceration is remains one of the more serious complications of DPN frequently leading to amputation and for which several testing methods have been widely recommended as useful aids to prediction.

Amongst these methods convention and clinical evidence support the employment of 'large fiber' modality testing such as light touch. We would speculate however that closer scrutiny of the relevant neuropathophysiology suggests that when adequately executed pinprick may still emerge as the superior choice of testing modality. Even in the current popular climate it is regularly seen to appear in lists recommending best practice for screening (Boulton et al, 2005 and 2004), (Brown et al, 2004), (Diabetes, 2001). Medical Practice Guidelines, State Of Florida, Agency For Health Care Administration), (Perkins et al, 2001).

Observations corroborating the view that pinprick, as well as temperature perception, is carried by and targets nerve constituents typically damaged principally and initially by metabolic disorders such as diabetes are common. It is well understood that these are the small fiber - 'a' and 'c' - population, implying that the development of neuropathic ulceration is related most specifically to loss of 'protective pain' above all other modalities. The conventional notion of 'protective sensation' may lack sufficient discrimination for refined diagnosis and prognostication. Some of the findings from the 10,000 patient cohort North-West Diabetes Foot Care Study; (Abbott CA et al (2002) provide significant support, though even in this work only crude pinprick technique was employed and focus was biased towards monofilament assessment. There emerges therefore a strong case for a method to refine the stages or thresholds at which loss of 'protective sensation' becomes clinically significant.

### A refined test of pinprick should enhance the diagnostic implications of the neuropathic state.

Early diagnosis and proper management can help avoid the debilitating complications of diabetes. Recent Diabetes UK research has shown that people may have diabetes for 9-12 years before they are diagnosed. By this stage the considerable majority of patients have already developed some degree of neuropathy in which response to standard examination is distorted. The various techniques for assessing DPN are usually applied at annual check-up to reveal those patients who are at "at risk" from complications associated with DPN.

However, current techniques are crude. It is most probable that contemporary practice is insufficiently sensitive to predict the subtle loss of protective thresholds in time to implement regimes for the avoidance or critical management of complications. Pinprick stimulation is a manifestation of skin stretch and is difficult to test adequately. In patients with diabetes sensitivity loss often develops in tandem with skin weakness. In such cases, where a crude pinprick test is employed, touch modality alone is stimulated so that excessive pressure is required to achieve a pinprick stimulus. This often leads to skin penetration, reveals only extreme deficit and in all likelihood, will fail to stimulate the critical 'c' fiber population so critical in assessment of patients with DPN. A more sensitive technique to measure deficit dictates these patients require consistent augmentation of pinprick acuity in the absence of excessive application pressure.



- The 'normal' patient should be able to perceive a sharp or painful sensation even from crude devices such as a paper clip or a blunted pin. This "protective sensation" is carried in small diameter nerve fiber constituents - usually the first to degenerate in peripheral neuropathies.
- Neuropathic conditions can reduce pain perception so that testing for pinprick deficit with crude devices often requires extra or excessive application pressure to gain a response. This can generate redundant stimulation of touch and/or pressure modalities over pinprick or breach the skin.
- Therefore crude pinprick devices are more likely to be sensitive only to extreme deficit - consistent with advanced damage - implying failure to detect critically significant loss and shift scrutiny to large fibers.
- Refined pinprick testing seeks to preserve the stimulation of pain even where pre-existing deficit challenges technique and endeavors to include the especially vulnerable 'c' fibers.

### Disadvantages of Crude Testing

- Failure of prognosis
- Patient Compliance - Complacency
- 'High risk' patients could be better managed
- Fails to cater for innovative clinical intervention such as new drug management

### What Needs to be Achieved?

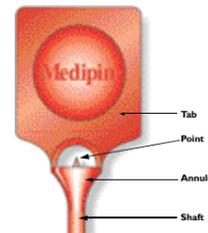
- A Method to apply a more acute pinprick stimulus without using increased force of application
- A Method to stimulate even the 'c' fiber population
- This will provide a more sensitive and possibly earlier indication of clinically significant deficit

### Advantages of Refining the Stage at which loss of 'Protective Sensation' becomes Clinically Significant:

- Refined identification of patients 'at risk'
- Subtler monitoring of deficit management
- Earlier definition of deficit in undiagnosed cases

### The Single Use Protected Neurological Pin

This program motivated the development of a dedicated single use precision technology designed to enhance the clinical sensitivity of cutaneous pinprick testing. It is proposed that this has been achieved by the manipulation of multiple factors influencing acuity perception and consistency. The resulting device can now be injection molded for multiple production and has been named Medipin



The Medipin - magnified x 16

The instrument consists of a short faceted point, acutely delineated by its surfaces and edges and inclined to stretch rather than penetrate the skin surface, within an annular apparatus that encircles the point with a perimeter of dull stimulation.

By stretching the skin and contrasting the sharp stimulus of this highly demarcated point with that of the annulus, it is possible to emphasize the neurological phenomenon of Lateral Inhibition where functional connections are formed in the Central Nervous System to highlight differences between areas of sensation. At each application Medipin generates a focused and well-defined 'Centre Surround' field effect, which augments the acuity of pinprick stimulation and is designed to achieve 'c' fiber stimulation.

The annulus also serves to standardize point penetration and improve test consistency.

In short the combination of acuity and reproducibility enhances test sensitivity. This high sensitivity also means less application pressure is required to cause stimulation than in regular devices and the limitation to point penetration provided by the annulus renders cross infection from accidental liberation of bodily fluids significantly less likely.

### Method - Appropriate Technique For Application Of The Medipin Instrument

#### Standardizing Idiosyncratic sensitivity

It is essential to appreciate that individual cutaneous sensitivity typically varies amongst the normal population. This renders the notion of an apparently, objectively determined, standardized threshold of normal perception somewhat academic. A more practical approach is to demonstrate deficit by comparison of a potentially affected area to one which is expected to display an acceptable degree of integrity elsewhere on the same subject. Invoking responses to continuous comparison between the two territories by consistently asking the patient to make distinctions between them permits the expression of very early, subtle, though potentially critical, distinctions in sensitivity. This is described as the Continuous, Pinprick Comparison Method (CPC).

### Instructions

- 1 Break tab to expose point, avoiding contact with fingers.
- 2 Grasp device between thumb and index finger lightly enough to permit slight axial slippage.

3 Apply to the skin surface at a perpendicular, making several quick applications around the same locality - repeated application diminishes standard deviation error and promotes 'average' stimulation.

Press firmly but carefully, using a controlled, repetitive, percussive contact. Avoid high amplitude or 'stabbing' actions as skin penetration should never be regarded as 'impossible'.

- 4 To prevent re-use, destroy point by compressing against a hard surface and/ or dispose of in a biohazard container.

Always observe sharps policy

### Results

Combining novel technique and instrument design provides enhanced test sensitivity and accuracy, which has been corroborated by preliminary field-testing. Initial impressions from health care professionals dealing with peripheral neuropathy have been very favorable. Patients with diabetes mellitus tolerated Medipin very well. Nurses found the technique easy to learn. Demonstration of sensory deficit appears reliable.

Medipin has also been evaluated and approved by the following institutions:

- Manchester Royal Infirmary, UK
- Dept of Neurophysiology, National Hospital for Neurology and Neurosurgery, UK
- Charing Cross Neurology Department, UK
- Massachusetts Institute of Technology, USA
- John Radcliffe Hospital, Oxford, UK
- Cornell University Medical College, New York, USA
- New York University Medical Centre, New York, USA

### Conclusions

Clinicians now have a tool that has been designed specifically for the job, significantly reduces fear of cross or self-infection, promotes standardization and accuracy of routine pinprick testing, and is easy to apply.

### Medipin Promotes:

1. Test Sensitivity - Acuity and Reproducibility
  - Rapid Application in 1<sup>st</sup> Care setting
  - Earlier Diagnosis of significant deficit
  - Closer Monitoring
  - Cost efficient management
2. Advanced Infection Control - Skin penetration and disposability

### Subjects Utilizing Medipin in Progress

- Prediction of neuropathic ulceration in amputees - Manchester Royal Infirmary UK
- Pin-prick method to evaluate the delivery of lidocaine - Massachusetts Institute of Technology, USA

### Subjects Focusing on Medipin for Future Study

- Microneurographic assessment of 'C' fiber stimulation efficiency
- Reproducibility - interpractitioner reliability/consistency
- Neuropathic Sensitivity - Utilizing the Continuous, Pinprick Comparison Method compared with application by other devices and techniques

More information regarding this approach can be found on the world wide web at: [WWW.Medipin.net](http://WWW.Medipin.net)

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