Cutaneous Pinprick Sensibility as a Screening Device

Part Two: Enhanced diagnosis of diabetic peripheral neuropathy using refined technique and dedicated single-use precision technology.

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Cutaneous pinprick sensibility testing is routinely used in neurology and diabetes. It is asserted here that the test is valuable for the prognoses of conditions with pathophysiologies dominated by small nerve fiber destruction.

Contemporary literature neglects neurological pinprick among the cutaneous modalities. Rarely is it clinically or technically reviewed for its diagnostic virtues, however, closer scrutiny of the relevant neuropathophysiology suggests that adequately executed pinprick is a logical choice.

The pinprick deficit produced by small fiber population loss is commonly reported to precede that of light touch. It may reflect the development of clinically critical thresholds of neuropathy not revealed by testing with other modalities. The following represents part of a larger peer-reviewed effort to address issues of clinical efficacy and infection control.

Nerve constituents typically damaged by metabolic disorders (eg, diabetes) are small fiber populations, implying that protective sensation (ie, focusing on larger-diameter fiber populations), as opposed to protective pain may lack sufficient discrimination for refined diagnosis and prognostication.[1-6] Pinprick data from the 10,000-patient cohort North-West Diabetes Foot Care Study corroborates this notion.[7] Where early detection of neuropathic change is considered useful, there emerges a case to redefine the stages or thresholds at which loss of protective sensation is clinically apparent.

Early diagnosis of diabetic peripheral neuropathy (DPN) is a critical part of clinical management. Combined with proper management, it may avoid debilitating diabetes complications. Yet, recent Diabetes UK research showed that people may have diabetes for 9 to12 years before they are diagnosed.[8] By this stage, many patients may develop neuropathy, and their responses to standard examination procedures are likely to demonstrate altered nerve function. Techniques to identify DPN risk factors are usually applied at annual check-ups, although it is contended that current techniques are crude and may be insufficiently sensitive to detect the early deficit. If so, we may fail to predict subtle loss of protective thresholds in time to avoid critical management of complications.

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MISCONCEPTIONS ABOUT CUTANEOUS PINPRICK MODALITY

An evidence-based approach supplies us with a reliable application in the clinical setting. Ascertaining and generating a reliable basis for description and reproduction of test conditions may eclipse established understanding, not through contradiction but rather by distraction. Some human physiology aspects cannot be quantified though preconceived models of function.

Small nerve fiber destruction is largely progressive, and therefore the deficit endured is incremental. In

order to accurately reflect typical pathophysiological function, pinprick sensitivity deficit should be discernable on an analog scale. Pain perception is a subjective affair and may vary (1) among the patient population and (2) in the same patient under differing conditions (eg, environment and emotion). Pain sensitivity is in a state of perpetual flux. We need an objective scale, intended to quantify pinprick deficit by comparison with a standard measure almost physiologically impossible except on the grossest crude scale (ie, the most common scale used in pinprick assessment). A standard measure simply does not exist. Typically, a binary or digital on-or-off approach is employed to test the patient's ability to (1) make the distinction between sharp and blunt stimuli or (2) simply recognize the presence of a painful one. This technique imposes a model of neuropathophysiological behavior that is incompatible with human function. The clinical obligation is not to demonstrate the absence of pain perception, but to reveal its early diminution. The employment of appropriate technique is key.

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STANDARDIZING IDIOSYNCRATIC SENSITIVITY

A refined pinprick test should enhance the diagnostic implications of the neuropathic state. Because cutaneous sensitivity varies among the normal population, the notion of a standardized threshold of normal perception is somewhat academic. Nonetheless, patients can reliably express subtle pain manifestations.[9] The aim of pinprick testing, in the first instance, is to detect subtle changes in deficit rather than complete obliteration. A more practical approach revolves around the old-fashioned but still-valid technique of comparison. As with the testing of motor power and reflexes, the practitioner can demonstrate even subtle clinical deficit by juxtaposing one aspect of the physiology to a comparable region. The objective is to demonstrate the presence of clinical deficit by comparing a potentially affected area to one that displays an acceptable degree of integrity. The practitioner nominates a control area (eg, proximal part of a limb or the trunk) to establish an adequate example of normal sensitivity by evoking an average response to stimulation.

REPRODUCIBILITY IN TESTING – THE 'AVERAGE' RESPONSE

One of the major flaws in any clinical diagnosis is test consistency. Cutaneous pinprick assessment is particularly vulnerable to the variables that promote test inconsistency. Among these is the random distribution of nociceptors in the skin, strength of stimulation used per application, and sensitization to the stimulus depending on the period for which the stimulation is maintained. There is a simple solution for reducing this natural standard deviation: make multiple applications over a predetermined area such as the periphery or a dermatome.[10] Repetitious applications level stimulation to an average where minor variations in application pressure and contact location become statistically diminished. This technique is simple to perform and rapid — taking perhaps seconds at a time. Immediately, the practitioner has established an adequate example of normal sensitivity in the nominated control region. The test area should be addressed. Continuous comparison between the two territories is established by asking the patient to make distinctions between them. This permits the expression of early subtle, though potentially critical, distinctions in sensitivity and is described as the Continuous Pinprick Comparison Method (CPC). The technique can precisely gauge an area of deficit and plot progression of the condition, possibly in response to management, simply by mapping out subtle loss rather than by determining absence of pain perception.

CRUDE PINKPICK STIMULUS

Pinprick stimulation is a manifestation of skin stretch rather than sharpness and is difficult to test adequately. Ironically, the sharper the point, the less the skin is disturbed in a fashion that activates cutaneous mechanoreception (Ruffini/SAII afferents) to report nociception. In patients with diabetes, sensitivity loss often develops in tandem with skin weakness and, when a crude pinprick test is employed, touch modality alone is stimulated so that excessive pressure is required to achieve a pinprick stimulus. This may lead to skin penetration and reveals only extreme sensory loss. A more sensitive technique to measure deficit dictates that these patients require consistent augmentation of pinprick acuity in the absence of excessive application pressure while simultaneously promoting test application reproducibility. Conditions dictating optimum performance for pinprick include

innovation of a dedicated instrument intended to achieve best practice and is still compatible with the everyday clinical setting. In summary, the aims of this program for enhanced cutaneous pinprick test were expressed by:

- Rapid application in the primary care setting;
- Refined diagnosis of significant deficit through the achievement of neurophysiologically enhanced pinprick stimulus;
- Earlier definition and diagnosis of clinically significant thresholds at reduced application pressures;
- Examination to include A-delta and C-nerve fiber constituents;
- Promotion of test reproducibility with more reliable monitoring of neuropathic progression; and
- Improvement of infection control issues.

This program motivated the development of a single-use precision technology designed to enhance the clinical sensitivity of cutaneous pinprick testing. It is proposed that this has been achieved by manipulating multiple factors that influence acuity perception and consistency. The resulting device is an 80-mm disposable instrument that can be injection-molded for multiple production and described for the purposes of the US Food Drug Administration as the Single-Use Protected Neurological Pin. For more public dissemination, it has been named Medipin (Figure 1) (in the United States, marketed by US Neurologicals, Kirkland, Wash, in the United Kingdom, Mastermedica Limited, Worcestershire, UK).

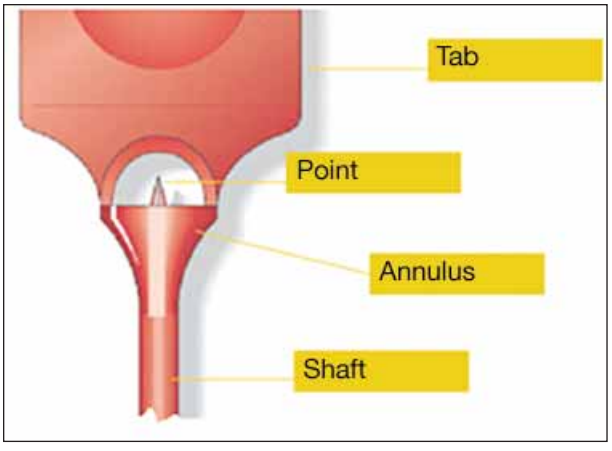

Figure 1. The Medipin is an 80-mm disposable instrument.

The active element of this 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, formed in the central nervous system, highlight differences between areas of sensation.[11] At each application, the device generates a focused and well-defined center-surround field effect, comparable with that occurring in visual phenomena. This effect augments the acuity of pinprick stimulation[12,13] and is an innovation intended to achieve C-nerve fiber stimulation, although this has yet to be verified.

Anecdotally, patients report a frequent pattern of stimulation consisting of an initial sharp stimulation followed by a deeper more persistent sensation. Current understanding of nociceptor behavior is consistent with this representing A-delta and C-nerve fiber responses respectively, though further study is needed. The combination of acuity and reproducibility is intended to enhance test sensitivity. This high sensitivity also suggests that less application pressure is required to generate adequate stimulation versus other methodologies. Limitation to point penetration, imposed by seating it within the annular structure, is intended to render cross infection from accidental liberation of bodily fluids. The annulus also serves to shield the practitioner from the point during application and offers more protection against accidental needle-stick injury. The annulus design serves to promote test consistency through standardizing point penetration as well as infection control.

A similar solution for standardizing point penetration was discovered in the immunology field. A comparable design was developed to produce consistent pinpricks to penetrate the skin surface and investigate allergy. In this design, a narrower point achieves penetration of the skin, whereas the Medipin adopts a wider point base and a more favorable point height to annular radius ratio to prevent it.[14-16] Despite these precautions, skin penetration should never be regarded with complacency, and disposal remains key to appropriate infection control.

PRACTICAL APPLICATION

Observations were drawn from routine practice and modifications were made during its development. A textured shaft to facilitate handling was incorporated. Surgeons felt that consistency was a matter of light grip and minimal skin contact so that axial slippage was possible during its application. A later innovation was the snap-off tab, designed to protect the point prior to

application and negate restoration of the device afterwards, dissuades inexperienced clinicians from attempting to reuse a disposable device on multiple occasions.

With this last view in mind and the perpetual possibility of micropenetration, European practitioners addressed the frequent lack of sharps disposal containers. They destroyed the device's point by compressing it against a hardened usually metallic, surface. The point was designed to collapse without breaking off from the main body of the instrument and can therefore be rendered reasonably safe. In the United States, this design is less advantageous because sharps disposal facilities are not a common issue, however, it remained an advantage over metal-based devices where the clinician might not have a choice.

The device has been assessed, somewhat informally, at several reputable institutions worldwide, and it is currently engaged in clinical studies. It has also been used quite extensively in the primary care setting. In all cases, consultation guided application and was supported by specific directions:

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 angle, making several quick applications around the same locality. Repeated application diminishes standard deviation error and promotes average stimulation. Press firmly but carefully, using controlled, repetitive, percussive contact. Avoid high amplitude or stabbing actions as skin penetration should never be regarded as impossible.

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

RESULTS

Initial impressions from health care professionals diagnosing and treating peripheral neuropathy have been favorable. Patients with diabetes tolerated the device and technique very well, and nurses found the technique easy to learn. Demonstration of sensory deficit appears reliable between practitioners, and further study is indicated on this approach.[17,18]

The pertinent pathophysiology strongly suggests that cutaneous pinprick testing should be the primary choice of modality. Although frequently misunderstood or neglected, an appropriate clinical approach that offers clinicians access to enhanced efficacy in the early diagnosis of diabetic peripheral neuropathy is easily achieved. In combining an easy-to-apply, single-use technology with physiologically corroborated, evidence-based technique, we move toward the promotion of test standardization and accuracy of routine pinprick testing and simultaneously reducing fear of cross or self-infection. ■

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