Logical Application of Cutaneous Pinprick Sensibility As A Screening Device For Diabetic Peripheral Neuropathy: Overlooked, Undervalued And Critical In Redefining A Clinically Significant Threshold For Protective Sensation.

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Introduction - Cutaneous Pinprick Sensibility

It is not infrequently suggested that early diagnosis of diabetic peripheral neuropathy (DPN) is a critical part of clinical management. Early diagnosis and proper management can help avoid the debilitating complications of diabetes. Yet recent Diabetes UK research has shown that people may have diabetes for 9-12 years before they are diagnosed [1]. By this stage a considerable number of patients may have already developed some degree of neuropathy and their responses to standard examination procedures are likely to demonstrate altered nerve function. The various techniques intended to reveal patients who are at "at risk" from complications associated with DPN are usually applied at annual check-up though it is contended that current techniques are crude. It is most probable that contemporary practice is insufficiently sensitive to detect the early deficit described thus failing to predict subtle loss of protective thresholds in time to implement regimes for the avoidance or critical management of complications.

Leg ulceration remains one of the more serious complications of DPN frequently leading to amputation and for which several testing methods have been recommended widely as useful aids to prediction. Amongst these methods established convention and clinical evidence maintain the employment of 'large fiber' modality testing such as pressure/ touch and vibration and typically they are used widely. It might be speculated however that closer scrutiny of the relevant neuropathophysiology suggests that when adequately executed pinprick may still emerge as the superior choice of testing modality. The testing of cutaneous pinprick sensibility is a routine medical procedure with applications in family practice, diabetes, neurology, oncology, anesthesiology 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 larger fiber modalities such as pressure/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.

Pain As A Protective Mechanism

It might be something of a cliché and possibly the more powerful for it, that the work by Brand and Yancey "The Gift of Pain" is acclaimed as a principal medium for establishing the value of pain in providing a protective mechanism against tissue damage[2]. In context the Latin from which the term is derived, nocere, offers the

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[1] Diabetes UK. Position Statement; Early Diagnosis of Paitent With Type 2 Diabetes, 2006. http://www.diabetes.org.uk/infocentre/state/downloads/earlyid.doc

[2] Brand P and Yancey P: *The Gift of Pain: Zondervan*; Reprint edition (September 1, 1997)

translation: “To do harm”[3]. Widely quoted and almost universally venerated, the text’s standpoint on the critical role of nociception as a defining element in the maintenance of health would be difficult to refute and is compatible with the definition offered by the International Group For the Study of Pain: "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage". In principle it is reasonable to assert that in a primary role pain serves to caution the central nervous mechanism against somatic insult. This is not a function generally attributed to either pressure/touch or vibration although that is not to say the events giving rise to tissue damage cannot overlap with them. As a advance warning device however they are not the primary physiological mechanism. In the peripheral nervous system, withdrawal of an extremity from noxious stimulation is largely initiated by cutaneous nociceptors. In point of fact the CNS easily habituates to sustained neurological traffic apart from that of pain. Hence the wearer tolerates clothing whilst, to a lesser extent, the passenger endures the mild vibration of road ‘noise’. In contrast sustained exposure to a painful stimulus frequently generates an exponential curve of sensitization. In essence pain perception is a mechanism evolved to effect the preservation of normal tissue integrity whose diminution of performance must attract a concomitant potential for reciprocal endangerment of the host tissue. It is then all the more frustrating for the examining practitioner that deficit of pain perception may be a subtle but progressive affair which seems beyond conventional primary methods of assessment. According to Marks some patients will have loss of normal sensation as a result of nerve damage and hypofunction and will not be aware of their disability until injury and ulceration have occurred[4]. This apparently occult behaviour gives rise to the assertion that DPN, the most common peripheral neuropathy in advanced nations[5],[6] Vinik et al 2000) accounts for more hospitalizations than all other diabetic complications combined. It is of some import then to appreciate that the development of the potential for risk of damage does not, by necessity, represent nor require absolute abolition of pain perception rather than only a reduction. Pain sensitivity can be represented on a scale whose increments roughly equate to a proportional risk of damage. Therefore where there has occurred some degree of pain deficit examination of the affected tissues must be quantative.

The Clinically Significant Threshold for Protective Sensation

It is clear that, almost without exception, any study that has employed pinprick as part of the testing criteria for screening DPN has imposed a simple test of presence of perception of sharpness rather than degree. Whilst variations of technique have been described the general principle appears to have taken for granted that a negative finding is revealed by a failure to either discriminate between sharp and blunt or merely to identify sharp as compared to a predictably normal part of the body such as the shoulder. This is not to accurately represent the role of pinprick nor the behavior of typical pathophysiological degeneration.

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[3] Oxford English Dictionary, 2nd Ed, vol 5: 454. Oxford University Press, 1991

[4] Marks JB: The Forgotten Complication: Clinical Diabetes 23:3-4, 2005

[5] Vinik AI, Park TS, Stansberry KB, et al 2000, Diabetic neuropathies. Diabetologia; 43:957-973

[6] Vinik AI 2002, Neuropathy: New Concepts in Evaluation and Treatment South Med J 95(1):21-23

Observations corroborating the view that pain, 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[7,8,9,10,11,12]. It is well understood that these are the small fiber - 'aδ' and 'c'- population. The other tactile testing modalities such as touch (monofilament) and vibration are carried only by the large fiber populations which appear to deteriorate at a later stage. It makes for compelling speculation therefore that in tandem with it's physiological function of providing protecting against tissues damage, there is strong implication that the role of pain deficit in the development of neuropathic ulceration is a consequence of it's early occurrence compared to the modalities carried by larger fibers. In view of the progressive nature of DPN 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[13] provide significant support for this suggestion, though even in this work only crude pinprick technique was employed and focus was biased towards monofilament assessment. There emerges an argument for a method that strives to describe a point at which the patient with diabetes has become vulnerable to the effects of pain deficit. This approach would require a refinement of the stages or thresholds at which loss of "protective sensation" become clinically significant pushing them towards the right of a normal distribution curve where time runs along the 'x' axis .

Limitations to Quantification With Monofilament

The nature of testing pressure/touch is contentious. Most certainly the notion of seeking to reveal "early" deficit by focusing on testing modalities carried by large fibers would seem inconsistent with both the physiology and the pathophysiology of the nerve constituent population. Early loss of pressure/touch and the potential testing benefits it's detection might provide would be significantly preceded by deficit of pain or pinprick. In principle the clinical information to be derived from modest diminution rather than complete absence of cutaneous pinprick, when recognized, would be extensive compared with the degree of loss simultaneously demonstrable in large fibers using pressure/touch.

The attractive aspect of assessment with the Semmes-Weinstein monofilament is based on the notion of producing a degree of objective quantification through the

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[7] Brown etc al, Natural progression of Diabetic neuropathy in the Zenarestat Study population, Diabetes Care 27: 1153-1159) 2004

[8] Sosenko, J.M., Kato, M., Soto, R.A., Gadia, M.T. and Ayyar, D.R: Specific assessment of warm and cold sensitivities in adult diabetic patients. Diabetes Care,11:481-483: 1988

[9] Ziegler, D., Mayer, P. and Gries, F.A: Evaluation of thermal, pain, and vibration sensation thresholds in newly diagnosed Type 1 diabetic patients. J. Neurol. Neurosurg. Psychiatry, 51:1420-1424:1988

[10] Guy, R.J.C., Clark, C.A., Malcolm, P.N. and Watkins: P.J. Evaluation Of Thermal And Vibration Sensation In Diabetic Neuropathy. Diabetologia, 28:131-137: 1985

[11] Hendriksen PH, Oey PL, Wieneke GH, Bravenboer B, van Huffelen AC: Subclinical diabetic polyneuropathy; early detection of involvement of different nerve fibre types. J Neurol Neurosurg Psychiatry;56:509-14: 1993

[12] Said, G., Slama, G. and Selva, J: Progressive centripetal degeneration of axons in small fibre diabetic polyneuropathy. Brain,106:791-807: 1983

[13] Abbott CA et al: The North-West diabetes foot care study: incidence of, and risk factors for, new diabetic foot ulceration in a community-based cohort. Diabet Med;19:377-384.2002

application of a reproducible, calibrated stimulus though, as is so frequently the case in the minutiae of everyday practice, takes for granted a number of issues which are merely assumptions. Aside from concerns over the lack of consistency between the multitude of monofilaments available to the practitioner, both commercially and offered free via the various pharmaceutical companies[14], it may be somewhat erroneous to assume the quantified stimulus the test offers will be perceived as universal by the patient population. Tactile sensation is an especially idiosyncratic phenomenon which is a function of and perpetually influenced by any number of factors. These include manifestations of neurological arousal embracing any variant between anxiety and relaxation though may also take account of fatigue, ambient temperature and so on. The same patient is likely to provide two or three different responses to the same test over as many occasions simply due to variation in personal circumstance. Between patients and for that matter, different practitioners, the variance will be compounded making the detection of subtle distinctions in sensitivity somewhat arbitrary. However where the application of a more extreme stimulus is utilized, one whose magnitude gravitates significantly to the right of the normal distribution curve, the practitioner is able to effect an attempt at providing sufficiently gross stimulation to eclipse subtle variations in circumstances and be more or less recognizable as uniform between individuals or for the same individual on different days. In point of fact the inability to perceive a monofilament of 5.07 represents a sensory threshold that is more than 50 times greater than normal implying that some 98% of normal sensory ability has been lost[15]. The usefulness of extreme stimulation for detecting subtle nerve damage thus becomes questionable by virtue of the advanced deficit required to fail to perceive it. Hence the 10g monofilament is probably the least of instruments suited to the detection of early deficit but perfectly adequate for consistently demonstrating unequivocal cases. Whilst the use of monofilament as a reliable device for the prediction of neuropathic ulceration has been well established in the literature it must be recognized that this predictive value is compatible only with very advanced stages of degeneration. Indeed the one disability score factor that particularly betters monofilament testing is a pre-existing history of ulceration itself[16]. So far the value of the monofilament has been only to signal advanced vulnerability which is somewhat closing the stable door after the horse has come back.

Pinprick As A Describer Of Change

The presence or absence of perception of a sharp stimulus as a simple “all or nothing” criterion is insufficient to reveal early deficit. In contrast simple recognition of a reduction in pinprick sensibility, even when early, could be critical. A redeeming feature of pinprick testing is not so much based on objective quantifiability, though quantification of sorts is possible with the use of adapted techniques[17], but the principle that it can be used to demonstrate deficit by comparison of a potentially

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[14] Lavery L: Screeing for Diabetic Neuropathy: APMA Annual Scientific Meeting: 2004

[15] Jeng C, Michelson J, Mizel M: Sensory thresholds of normal human feet: Foot Ankle Int. Jun;21(6):501-4: 2000

[16] Abbott CA, Carrington AL,Ashe H, Bath S, Every LC, Griffiths J, Hann AW, Hussein A, Jackson N, Johnson KE, Ryder CH,Torkington R,Van Ross ER,Whalley AM,Widdows P,Williamson S, Boulton AJ: 2002

[17] M.J Young, A.G.M. Boulton, A.F. Macleud, D.R.R Williams, F.H. Fonksen, Multicenter study of the prevalence of diabetic peripheral neuropathyin the U.K. Hospital clinic population. Diabetologia, (36), 150-54: 1993

affected area to one which is expected to display an acceptable degree of integrity elsewhere on the same subject. Findings are based upon the distinctions made by the patient between these areas thereby dispensing with the need to compare to a predetermined marker. Extraneous circumstances will be of little consequence as they will be constant for the same patient, on the same day, who is always comparing to themselves. All that is required of the patient is to recognize a difference in acuity of the pinprick stimulus. Visual analogue scales have shown patients to be capable of demonstrating remarkable consistency in identifying subtle distinctions in pain severity.[18]. By use of a simple comparison between affected and normal areas of skin patients are permitted to express even the earliest and most subtle differences freely. Adaptations to technique, such as those routinely employed by neurologists, can also be utilized to further refine this mode of assessment for test sensitivity, accuracy and reproducibility.

Screening For Diabetic Peripheral Neuropathy

As sensitive methods for monitoring progression of DPN examination, procedures that exclude pinprick from the tactile modalities are likely to be inadequate. It is unsurprising that even in the current popular climate pinprick is regularly seen to appear in lists recommending best practice for screening[19],[20],[21],[22],[23],[24] though, it is suggested, remains largely neglected by the health provider community. There seems satisfactory evidence to effect a more reflective and potentially effective approach simply by drawing upon the resources of evidence based physiology and revisiting with a more objective viewpoint some of the existing literature.

Misconceptions about cutaneous pinprick modality

Western scientific medicine strives to be consistent with an evidence based approach. Only when pursued under these conditions can the data we derive qualify for reliable application in the clinical setting. However, the drive to ascertain and generate a reliable basis for description and reproduction of test conditions occasionally eclipses

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[18] Kelly AM: The minimum clinically significant difference in visual analogue scale pain score does not differ with severity of pain. Emerg Med J:18:205–207. 2001

[19] Diabetes (2001)Medical Practice Guidelines, State Of Florida,Agency For Health Care Administration

[20] Boulton AJ,Vinik AI,Arezzo JC, Bril V, Feldman EL, Freeman R, Malik RA, Maser RE, Sosenko JM, Ziegler D: Diabetic Neuropathies: A statement by the American Diabetes Association, Diabetes Care 28:956-962

[21] Boulton AJ, Malik RA,Arezzo JC, Sosenko JM.2004, Diabetic Somatic Neuropathies, Diabetes Care 27:1458-1486, June

[22] Brown MJ, Bird SJ,Watling S, Kaleta H, Hayes L, Eckert S, Foyt HL; Zenarest study. etc al: Natural progression of Diabetic neuropathy in the Zenarestat Study population, Diabetes Care 27: 1153-1159: 2004

[23] Perkins B, Zinman B, Olaleye D, Bril V Simple Screening Tests for Peripheral Neuropathy in the Diabetes Clinic. Diab Care Feb; 24 (2): 250-256: 2001

[24] Jacobs B, Lewis D, 2003 Value Of Pinprick In Finding Peripheral Neuropathy In Diabetes Mellitus Patients;World Family Doctor Association,WONCA Europe Regional Conference, Ljubljana, 18-21 June,.
(Poster)

established understanding, not through contradiction but rather, by distraction. In essence some aspects of human physiology are simply not easily quantified though attempts to inflict preconceived models of function rapidly corrupt our understanding of the very phenomenon under scrutiny.

Small nerve fiber destruction is largely progressive and therefore the deficit endured is incremental. In effect, in order to accurately reflect typical pathophysiological function, pinprick sensitivity deficit should be discernable on an analogue scale though this is an especially difficult phenomenon to quantify as patients are all too idiosyncratic. Perception of pain is a grossly subjective affair and may vary not only amongst the patient population but within the same patient under differing conditions of context such as environment and emotion. Pain sensitivity is in a state of perpetual flux which renders the imposition of an objective scale intended to quantify pinprick deficit by comparison to some 'standard or normal measure' almost physiologically impossible except on the grossest crude scale. This very difficulty dictates practice therefore and the crude scale is the commonest in use in current research involving pinprick assessment - the standard measure simply doesn't exist. Typically a 'binary' or 'digital – on or off' approach is employed where the patient is directed to make the distinction between sharp and blunt stimuli or simply to admit the presence of a painful one. This technique therefore clouds logic by imposing a model of neuropathophysiological behavior that is incompatible with human function. The detection of early or subtle fiber population loss is imperative for optimum management. Therefore the clinical obligation is not to demonstrate the absence of pain perception but to reveal it's early diminution and the employment of appropriate technique is key.

Standardizing Idiosyncratic Sensitivity

A refined test of pinprick should enhance the diagnostic implications of the neuropathic state. As established above, it is essential to appreciate that individual cutaneous sensitivity typically varies amongst the normal population which renders the notion of an apparently, objectively determined, standardized threshold of normal perception somewhat academic. Nonetheless appropriate techniques have demonstrated patients to be reliable witnessess in the expression of subtle manifestations in pain.[25] 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. In short the object of the exercise is to demonstrate the presence of clinical 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. A nominated control area such as the proximal part of a limb or the trunk is recruited by the practitioner to establish for the patient an adequate and acceptable example of normal sensitivity by evoking an 'average' response to stimulation.

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[25] Price DD, Bush FM, Long S, Harkins SW. A comparison of pain measurement characteristics of mechanical visual analogue and simple numerical rating scales, Pain. 1994 Feb;56(2):217-26.

Reproducibility In Testing – The 'Average' Response

One of the major flaws in any form of clinical diagnosis is test consistency either between practitioners or even by the same practitioner under differing conditions. Cutaneous pinprick assessment is particularly vulnerable to the variables that promote test inconsistency. Amongst these are the random distribution of nociceptors in the skin. Another is the strength of stimulation used per application as well as sensitization to the stimulus depending on the period for which the stimulation is maintained. A simple solution for reducing this natural standard deviation can be achieved by making multiple applications over a predetermined area such as the periphery or a dermatome[26]. Repetitious applications 'level' out 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 for the patient an adequate and acceptable example of normal sensitivity in the nominated control region the 'test' area should be addressed. 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). The technique can be used to 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 altogether.

The Single Use Protected Neurological Pin – A Teleological device

Pinprick stimulation is a manifestation of skin stretch rather than sharpness per se 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 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 can lead to skin penetration and reveals only extreme sensory loss . A more sensitive technique to measure deficit dictates these patients require consistent augmentation of pinprick acuity in the absence of excessive application pressure whilst simultaneously promoting test application reproducibility. In essence the expression of the conditions dictating optimum performance for pinprick testing describe criteria for the innovation of a dedicated instrument intended to achieve best practice whilst remaining compatible with the everyday clinical setting. In summary the aims of this program for enhanced cutaneous pinprick test were expressed by the following:

- Rapid application in the primary Care setting
- Refined diagnosis of significant deficit through the achievement of neurophysiologically enhanced pinprick stimulus

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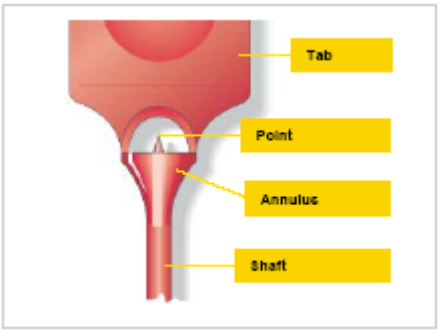
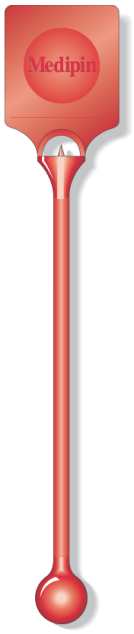
[26] Frisso A Potts, MD. Peripheral Neuropathy. Merck Medicus, Best Practice of Medicine; 2001 April;
http://merck.micromedex.com/index.asp?page=bpm_brief&article_id=BPM01NE12

- Earlier definition and diagnosis of clinically significant thresholds at reduced application pressures
- Examination to include ‘aδ’ and ‘c’ nerve fiber constituents
- Promotion of test reproducibility with more reliable monitoring of neuropathic progression
- Improvement of infection control issues

This program therefore 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 is an 80mm disposable instrument which can now be injection molded for multiple production and described for the purposes of the FDA as ‘The Single Use Protected Neurological Pin’. For more public dissemination it has been named Medipin.





Actual Size

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 are formed in the Central Nervous System to highlight differences between areas of sensation [27]. At each application the device generates a focused and well-defined 'Center-Surround' field effect, comparable to that occurring in visual phenomena, which augments the acuity of pinprick stimulation[28] [29]. This augmentation is an innovation intended to achieve ‘c’ fiber stimulation though this has yet to be verified.

Anecdotally patients report a frequent pattern of stimulation which consists 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’ responses respectively though further study is needed to confirm the hypothesis. In short 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 than in other methodologies whilst limitation to point

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[27] Deprtment of Physiology, Berkeley University, Ca, USA. “Lateral Inhibition” http://totoro.berkeley.edu/teaching/AA_teaching_aids.html

[28] Robert M. Berne. Principles of Physiology, 2001 Jan; Chpts. 6 - 9, 12-14 pub Mosby.

[29] Ebner FF, Armstrong-James MA. Intracortical processes regulating the integration of sensory information, Prog Brain Res. 1990;86:129-41.

penetration, imposed by seating it within the annular structure, is intended to render cross infection from accidental liberation of bodily fluids less probable. The annulus also serves to 'shield' the practitioner from the point during application and offers a little more protection against accidental so called 'needle-stick' injury. The annulus is therefore a design component which serves to promote test consistency though standardizing point penetration as well as infection control.

It is noteworthy that a similar solution for standardizing point penetration was discovered in the field of immunology where a comparable design was developed with the intention of producing a consistent set of pinpricks, though in that case, with the express intention of penetrating the skin surface to investigate allergy. In this design a narrower point achieves penetration of the skin whereas Medipin adopts a wider point base and more favorable point height to annular radius ratio in order to prevent it [303132]. Despite these precautions it should be noted that skin penetration should never be regarded with complacency and that disposal remains key to appropriate infection control.

Practical Application

A number of observations were drawn from routine practice and the instrument was modified during it's development accordingly. A textured shaft to facilitate handling in a manner preferred by British neurologists was incorporated. They felt that, in particular, consistency was also a matter of light grip and minimal skin contact so that axial slippage along the instrument was possible during it's application. This remains a fashion above all though appears useful for some practitioners. A later innovation was the inclusion of the snap-off tab. This was designed to protect the point prior to application and negate restoration of the device afterwards and was intended to dissuade inexperienced clinicians from attempting to re-use a disposable device on multiple occasions. With this last view in mind and the perpetual possibility of micro-penetration it is useful to appreciate that European practitioners were keen to address the frequent experience of finding themselves in a location lacking a sharps disposal container. Rather than leave the task in progress or put the used device in a pocket they were inclined to exploit the facility to destroy the point by compressing it against a hardened, usually metallic, surface. The point was designed to collapse down without breaking off from the main body of the instrument and can therefore be rendered reasonably 'safe'. In the US this design aspect seemed to represent less of an advantage since failure to provide sharps disposal facilities was not a common issue though remained an advantage over metal based devices where the clinician might be deprived of choice.

The one factor that appeared of least concern to practitioners was sterilization. Not withstanding the notion that an injection molded device reaches fantastic temperatures

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[30] Perrin LF, Dechamp C, Deviller P, Joly P. Reproducibility of skin tests. A comparative study of the Pepys prick test and the Morrow-Brown needle and their correlation with the serum IgE level. Clinical Allergy. 1984; 14:581-8

[31] Adinoff AD, Rosloniec DM, McCall LL, Nelson HS. A comparison of six epicutaneous devices in the performance of immediate hypersensitivity skin testing. J. Allergy Clin Immunol 1989; 84:168-74

[32] Demoly P, Bousquet J, Manderscheid JC, Dreborg S, Dhivert H, Michel FB. Precision of skin prick and puncture tests with nine methods, J Allergy Clin Immunol 1991. 88:758-62.

during manufacture there appeared no eclipsing drive amongst clinical staff to keep the device sterile during storage. The explanation was a common sense one in that it is something of a cliché amongst microbiologists that the human skin is one of the more "filthy" object known to medical science. It simply teams with microbes and it is a fatuous notion to propose that a device intended to make multiple points of application with the subject should retain it's sterile status after first contact. Further, some authorities speculated that where skin penetration is the singular intention, such as for venepuncture, sterility is justified whilst a 'clinically clean' device intended to remain on the skin surface is the less likely of the two to attract invasion from opportunistic microorganisms.

The device has been assessed, somewhat informally, at a number of institutions of repute around the globe and is currently engaged for applications in clinical studies at some them. It has also been utilized quite extensively in the primary care setting. In all cases application was guided by consultation and supported by specific directions as follows:

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

Initial impressions from health care professionals dealing with peripheral neuropathy have been very favorable. Patients with diabetes mellitus 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 [33] [34].

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[33] Jacobs B, Lewis D. Value of pinprick in finding peripheral neuropathy in diabetes mellitus patients.
Poster presented at the World Family Doctor Association, WONCA Europe Regional Conference. June 18-21, 2003.Ljubljana, Slovenia.

[34] Jacobs B, Lewis D. Refined Diagnosis Of Diabetic Peripheral Neuropathy With Enhanced Pinprick Perception Using Novel Single-Use Precision Instrument Design And Technique. Abstract/Poster Presentation at Global Diabetic Foot Conference 2006,. March 23-25, Los Angeles, Ca, USA.

Conclusions

The pertinent pathophysiology strongly suggests that cutaneous pinprick testing should be the primary choice of modality for early diagnosis of diabetic peripheral neuropathy. It is a test frequently undertaken in erratum however though an appropriate clinical approach is easily achieved. The development of this device in tandem with logical technique has led to the view that clinicians now have an instrument intended to enhance the diagnostic value of cutaneous pinprick testing. In combining an easy to apply, single-use technology which has been designed specifically for the job with physiologically corroborated, evidence-based technique it has been possible to move towards the promotion of test standardization and accuracy of routine pinprick testing whilst simultaneously reducing fear of cross or self-infection.

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