THE VIABILITY OF HOME TESTING FOR EARLIER DETECTION OF LOSS OF PROTECTIVE SENSATION IN PATIENTS WITH DIABETES AND ARE WE WEDDED TO THE 10G MONOFILAMENT TO DO IT?

Written by Barry Jacobs - Developer of Medipin Updated 22.06.2019

In its' 2017 position statement on diabetic neuropathy the American Diabetes Association states:

Screening for symptoms and signs of diabetic neuropathy is also critical in clinical practice, as it may detect the earliest stages of neuropathy, enabling early intervention. Although screening for rarer atypical forms of diabetic neuropathy may be warranted, DSPN and autonomic neuropathy are the most common forms encountered in practice. The strongest available evidence regarding treatment pertains to these forms.

It is true that for decades, monofilament has enjoyed the greatest body of support in terms of efficacy in predicting loss of protective sensation and certainly the strongest custom and therefore, historically, occupied an important role in routine testing. It was considered a binary fait accompli that either loss of protective sensation was present or not and that this was best determined in the simple clinical setting by a device calibrated to detect 10mg of tactile stimulation. In latter years this concept has started to give way to a more complex appreciation of diabetic peripheral neuropathology and the talk is now much more conspicuously of small and large fiber disorder and the relative virtues of their idiosyncratic detection. It is now the preserve of the learned journals to appreciate that small-fiber constituents within the peripheral nerve are those most likely to fail due to diabetes before their large counterparts and it is these than carry pinprick and temperature. The critical factor now is to recognise the role of small fiber testing in the early detection of neuropathy. It goes on to state:

Assessment should include a careful history and either temperature or pinprick sensation (small-fiber function) and vibration sensation using a 128-Hz tuning fork (large-fiber function). All patients should have an annual 10-g monofilament testing to assess for feet at risk for ulceration and amputation.

The following clinical tests may be used to assess small and large-fiber function distal to proximal:

1. *Small-fiber function: pinprick and temperature sensation*
2. *Large-fiber function: vibration perception, proprioception, 10-g mono-filament, and ankle reflexes*

The 10-g monofilament is a useful clinical tool mainly for detecting ***more advanced*** *neuropathy and identifying patients at increased risk of ulceration and amputation"*

http://care.diabetesjournals.org/content/diacare/40/1/136.full.pdf

In principle there are 2 issues in tandem; The first is the notion of home testing. Can patients reliably test themselves for clinically useful evidence of early onset diabetic peripheral neuropathy by assessing for loss of protective sensation? The second is that of the optimum modality or modalities and techniques with which they are applied to implement the first.

In developing Medipin – a single use precision instrument designed to optimize pinprick sensation without penetrating the delicate and sometimes friable skin of patients with diabetes - I was interested in seeing if it was possible to produce a clinical device that was as capable of generating as acute a sense of pinprick as possible whilst reducing the likelihood of penetrating the skin. In doing so I later became interested in the comparative virtues of the different known sensory modalities in testing for neural degeneration and the picture, though tradition might suggest otherwise, is by no means set in stone. I believe that pinprick is a more sensitive and specific instrument than other modalities in the primary care setting and might offer and extraordinary opportunity to raise patient awareness of the problem. I would also conclude that Medipin – to which I have dedicated many years in its development - is exactly the optimum device to achieve that aim.

I believe that the critical issue should not be to focus on neuropathy testing as if the various techniques and modalities are exclusive to one another.

It is very true that monofilament has to date the greatest body of support in terms of efficacy in predicting loss of protective sensation and certainly the strongest custom and therefore, historically, occupies an important role in routine testing.

Most assessment protocols for loss of protective sensation will recommend inclusion of monofilament because so much research has utilised it. Nonetheless even this test is acknowledged, like all others, to have its' limitations and there remains a healthy debate about consistency of reliability in the clinical setting.

As is often remarked in clinical education, "No one sign is pathognomonic" - in other words, never rely solely on a single clinical indicator.

Therefore, to improve reliability, the ADA recommends that, ideally, clinicians entertain the employment of more than just the one test option.

In point of fact they say that of the recommended techniques, pinprick included, insensitivity revealed even by one test alone is important and requires further assessment.

ADA Standards of Medical Care In Diabetes 2015,2016 S63-S64:

"The neurological exam recommended is designed to identify LOPS rather than early neuropathy. The clinical examination to identify LOPS is simple and requires no expensive equipment.

Five simple clinical tests (use of a 10-g monofilament, vibration testing using a 128-Hz tuning fork, tests of pinprick sensation, ankle reflex assessment, and testing vibration perception threshold with a biothesiometer), each with evidence from well conducted prospective clinical cohort studies, are considered useful in the diagnosis of LOPS in the diabetic foot.

Any of the five tests listed above could be used by clinicians to identify LOPS, although ideally two of these should be regularly performed during the screening examined normally the 10-g monofilament and one other test. One or more abnormal tests would suggest LOPS, while at least two normal tests (and no abnormal test) would rule out LOPS.")

http://care.diabetesjournals.org/content/suppl/2014/12/23/38.Supplement_1.DC1/January_Supplement_Combined_Final.6-99.pdf.

Though it might not be the primary or most fashionable choice, pinprick remains a medically useful device by which to assess sensation, especially with an instrument designed to lend itself to an easy testing scenario and utilising the very straight forward technique described by key source material cited by ADA literature

(Boulton et al, 2008, Comprehensive Foot Examination and Risk Assessment:

A report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists, Diabetes Care August vol. 31 no. 8 1679- 1685:

*"**Pinprick sensation**. Similarly, the inability of a subject to perceive pinprick sensation has been associated with an increased risk of ulceration (4). A disposable pin should be applied just proximal to the toenail on the dorsal surface of the hallux, with just enough pressure to deform the skin. Inability to perceive pinprick over either hallux would be regarded as an abnormal test result."*

http://care.diabetesjournals.org/content/31/8/1679.full.pdf+html

Pinprick sensory testing, whether in the doctors' office or home, is a very simple procedure though has, in previous studies, most probably been confounded by inconsistencies and over complication in application technique. By contrast the technique required for monofilament testing consistent with instructions published by the ADA is more complicated and whilst easy enough in the clinical setting, remains challenging to perform accurately in the home.

Testing sensation with a Medipin clearly represents the most simple and easily executed technique to perform in the home and empowers patients to participate in an important aspect of their own diabetic healthcare.

Furthermore and with regards to the question of clinical efficacy, it should be of interest that whilst not yet widely publicised, pinprick has been inadvertently overlooked despite its' very important potential.

As a testing modality for the prediction of serious diabetic complications, like the development of lower extremity ulceration, pinprick has actually been reputably demonstrated to be rather more sensitive than current fashion would suggest.

The study referenced by the ADA publication in the paragraph above **(4 – Abbott et al, 2002, The North-West Diabetes Foot Care Study: Incidence Of, And Risk Factors For New Diabetic Foot Ulceration In A Community Based Patient Cohort. *Diabet Med* 19: 377–384**) utilised a population of almost 10,000 patients.

This significant study undertaken at one of the most prolific neuropathy centres in the world, Withington, Central Manchester University Hospitals, UK, showed, surprisingly, that pinprick was even more useful for predicting the development of foot ulceration than more conventional techniques including, arguably, monofilament.

At one time, I had been a visiting lecturer at Manchester and a few years later on, when I conceived that the study group had not anticipated this outcome, was very graciously invited to spend time with the lead author to discuss their data in depth.

Typically, custom eclipsed expectations and it was gratifying to see this important finding reflected later in the ADA recommendations for sensory testing and now also represented clearly in the British Medical Association guidelines too.

With respect to the notion of home-testing itself, I would refer to the paper published by Bourcier et al (Bourcier Et Al; 2006, Diabetic Peripheral Neuropathy: How Reliable Is A Homemade 1-G Monofilament For Screening? Vol 55, No 6 / June) The Journal of Family Practice) - it was this amongst others that provided me with a platform from which to start contemplating the notion of viable self- assessment for patients.

Anecdotally, at least, I suspect it is a widely held belief that, in all probability, home-testing has been undertaken informally by patients for years though less frequently has the notion been properly explored in the literature.

In recent years the US Federal Government developed the LEAP program to promote self-management in patients with Hansens disease:

"Lower Extremity Amputation Prevention (LEAP) is a comprehensive program that can dramatically reduce lower extremity amputations in individuals with Hansen's disease or any condition that results in loss of protective sensation in the feet. LEAP was developed at the HRSA National Hansen's Disease Program in 1992."

http://www.hrsa.gov/hansensdisease/leap/index.html

This program was successful in having patients adopt a number of self care strategies including the use of monofilaments to self-assess.

However the program leader, CAPT John Figarola, Chief Rehabilitation and Education Branch, National, Hansen's Disease Programs, 1770 Physicians Park Drive, Baton Rouge, LA 70816 told me in the strongest terms last year and to paraphrase, that any form of self monitoring, including that intended to detect neuropathy, was of critical importance and that he lamented the cessation of funding for the program.

In point of fact another study **(Lavery et al 2004, Home Monitoring of Foot Skin Temperatures to Prevent Ulceration, Diabetes Care, Volume 27, Number 11, November)** http://care.diabetesjournals.org/content/27/11/2642.full) provides further useful evidence for home testing. However, instead of the more conventional tests mentioned previously the authors have instead employed temperature, though, in this case, measured on the skin for elevation by inflammation secondary to infection.

So what of the role of pinprick?

Interestingly, when tested as a modality of perception, temperature happens to examine the same nerve constituents as those stimulated by pinprick and has been recommended for use in routine neuropathy testing: **Mayo Clinic, Patient Care and Health Info, Diabetic Neuropathy, Tests and Diagnosis accessed March 2016**; http://www.mayoclinic.org/diseases-conditions/diabetic-neuropathy/basics/tests-diagnosis/con-20033336

Whilst it is true that monofilament remains the most prolifically explored and recognised of all the tests for reliability in diabetic sensory testing, it is something of a self-perpetuating custom that helps keep it so. As with all medical testing it is far from perfect and a more satisfactory level of detection sensitivity in this field remains elusive. In point of fact the best predictor for development of an ulcer is a pre-existing one or a medical history of it.

Even monofilament is just not as good as we'd like and research to prefect sensory testing remains keen.

Therefore there is excellent evidence to support the notion that, whilst pinprick might not be the most fashionable or well known testing modality, a test that looks at the nerve fibers stimulated by it or by temperature can enjoy a robustly justifiable role in the home testing setting.

Rather than be dismissed for its relative obscurity, pinprick should be embraced as a clinically useful tool in helping patients with diabetes to monitor themselves for loss of protective sensation.

I am also most aware that virtually all health care professionals I have encountered working and studying in this area express the view that anything that alters foot self-care behavior in diabetes has got to be a good thing. It is for this reason that we have also developed a web site www.healthyfeetclub.com promoting diabetic foot health.

We believe that this, in addition to the Smartphone app being developed, will massively encourage education and better self care practice and all the undoubted benefits that come with it.

Furthermore a mobile app will also provide an excellent platform to garner data with which to study and drive a large-scale home-use patient centered program, which could attract even traditionally difficult to reach sectors of the population across the United States

(Shantanu N et al 2014; How Do Mobile Phone Diabetes Programs Drive Behavior Change? Evidence From a Mixed Methods Observational Cohort Study, Diabetes Educator, Volume 40, Number 6, November/December pp 806-819 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4492449/

Such a study is long overdue and might conceivably transform the world of diabetic self-management.

Finally I would like to offer a brief few thoughts regarding the Wartenberg wheel.

Whilst I appreciate the attraction of a device that appears to promote consistency I am more persuaded by the adaptation of conventional neurological pinprick testing which utilizes the patient as their own control.

This is predominantly a technique for the clinician but is a simple yet remarkably sophisticated adaption of conventional technique where an area of 'normal' sensation is established and compared to the periphery, in this case the foot, with multiple repetitive applications.

Medipin is an FDA listed, dedicated device which has been in regular use by US Doctors for many years, as well has having been employed successfully in quite a number of international medical studies.

It is an all-plastic precision instrument which I designed to avoid skin puncture whilst, simultaneously, significantly heightening stimulation at lower application pressures by exploiting neural lateral inhibition.

A specially faceted and blunted point is situated within a surrounding annular component that serves to both micro stretch the skin and create an artificial center surround field.

In the clinical setting however the technique is quite different to that in the home and the product of much experience in neurological environments rather than endocrinology ones.

The testing technique is one of continuous repetitive application using multiple contacts with the patients' skin around the same locality. Normally pinprick can be quite a haphazard affair because nerve receptors in the skin are distributed randomly and the practitioner might use quite inconsistent pressure.

However this technique of gentle repetition entirely changes the stimulation by establishing an 'average' response via a neural phenomenon called 'wind-up' or summation which has been much explored and demonstrated. Very quickly the patient experiences an 'averaging out' of the stimulus and can then use this sensation for comparison with other parts of their body.

A "normal and sensitive area", assumedly unaffected by neuropathy such as the wrist or shoulder, can be nominated, by the doctor and for the patient, to be an arbitrary 5 out of 10, allowing them to express, verbally, a relatively quantitative comparison in the potentially affected one.

It doesn't matter if one clinician is more forceful than a colleague performing the test at another time. The test only compares the patient to themselves. Whatever the strength of application "5 out of 10" is always 5 out of 10. The patient becomes their own control and they can use the "normal" or "control" area" to compare the sensitivity in an affected one like their feet.

The doctor would ask: " if the normal area is 5 out of 10, what would you say is the foot?" Essentially, this is a very simple adaptation of technique that employs "like for like" comparison and patient feedback in an analogue form. It produces what may be described as a "Verbal Analogue Scale" and these kind of feedback techniques have been employed in a number of clinical settings for many years.

I have long sought to explore this adaptation of neurological technique further in a dedicated study for diabetic neuropathy. I believe it has the potential to provide evidence for a very simple technique that converts a currently relatively crude test into a sophisticated device for subtle depiction of a patient's neuropathic status undertaken easily, rapidly and inexpensively in the clinical setting.

It might well be a candidate for providing a most useful quantitative measure of neurogenic progression and in the future I would welcome views on collaboration.

To summarise;

1. Home testing for diabetic neuropathy has excellent potential to transform self-management strategy of the diabetic foot in the USA and elsewhere.

2. Whilst pinprick has not been the historic primary choice of testing modality for diabetic neuropathy, as much though fashion and neglect rather than appropriate scrutiny it remains, nonetheless, acknowledged as a potent, justifiably efficacious and ADA recommended test.

3. Pinprick sensation testing using the technique recommended in the ADA's guidelines and performed with a Medipin, is probably the easiest test for patients to do in the home.

4. As an afterthought - if the spirit of ADA assessment were to be taken to the fullest degree the optimum scenario for home testing would be to offer the patient an option to perform a pinprick test with Medipin with the addition of a simple disposable monofilament test or instructions for the 'Ipswich Touch Test' which has been shown to be as efficacious as the monofilament and requires no extra equipment at all: (Rayman G, Vas PR, Baker N, et al. The Ipswich Touch Test: a simple and novel method to identify inpatients with diabetes at risk of foot ulceration. *Diabetes Care*. 2011;34:1517-1518)

(For further technical information in detail regarding the neurophysiology of pinprick as a modality, modified testing technique and of the Medipin device itself - clinicians please see below)

Further notes for the clinician – Neurophysiology in more detail

Pinprick as a useful testing modality
The monofilament is widely considered a gold standard for detecting diabetic peripheral neuropathy.

It uses the modality of light touch carried by large fiber neural constituents and studies consistently demonstrate significant specificity for DPN.

However large fibers appear more resistant to damage than their smaller and poorly myelinated counterparts, appearing to resist the deleterious effects of diabetes for longer.

Therefore large fiber testing is SPECIFIC for DPN but probably not as SENSITIVE as that of small fibers.

So in Diabetic Peripheral or Polyneuropathy, cutaneous pinprick sensation, carried by small fiber constituents (small fiber neuropathy) deteriorates early by comparison to touch, as tested by the monofilament (large fiber neuropathy).

Interestingly vibration, by virtue of the comparatively delicate and resource extravagant microphysiology that carries it, also deteriorates early on but despite it's large fibers.

In contrast to both pinprick and light touch, it appears to degenerate so dramatically over relatively short periods that it may offer better SENSITIVITY but less SPECIFICITY.

Surprisingly, then despite it's small, poorly protected fibers pinprick seems to resist deterioration a little longer and unlike vibration, is less vulnerable to the typical effects of physiological aging.

Pinprick has the potential to offer a level of SPECIFICITY not available from vibration and SENSITIVITY not available from light touch. This has been supported by good quality research – though sometimes by default and hence is included in the guidelines.

In principle, therefore, sharp stimulation is an obvious choice to compliment the monofilament when testing for LOPS. It should be able provide us with the SENSITIVITY that light touch cannot but with more reliable SPECIFICITY than that provided by a tuning fork.

The Modified Technique

On a more neurophysiological note, pain is also a device intended to protect against insult - a function not usually attributed to modalities of touch, pressure or vibration. Indeed, unlike touch, pain is not a modality to which the individual easily habituates.

Yet the human condition easily becomes used to the stimulation otherwise caused by clothing and hair.

It may be cliché—and possibly the more powerful for it—that he Gift of Pain by Brand and Yancey is acclaimed as a principal medium for establishing the value of pain to provide a protective mechanism against tissue damage.

As a testing modality pinprick sensation can be exploited for its sensitivity, reliability and if the technique is correct, for subtle specificity.

Most of the time - in fact nearly always - pinprick is relegated or dismissed clinically because it is used only in a binary, "on or off" fashion asking – “is this sharp or blunt” or “can you feel this?” ‘All or nothing’ is bound to provide many false negative results because sensory loss is incremental.

Essentially, where pinprick perception has diminished, patients can still report a stimulus though there is no facility to express magnitude.

The patient is asked only IF they can feel not HOW MUCH. In consequence pinprick only appears insensitive to neuropathy by virtue of it being applied to the wrong question.

By contrast, Continuous Pinprick Comparison, or CPC, is our recommended technique where the stimulus is applied in a novel way to promote both sensitivity and specificity.

There can be no standardized neuropathy threshold superimposed upon the patient – especially in the early stages of damage.

Everyone’s perception is idiosyncratic and state-dependent. Therefore we can detect subtler, earlier deficit by using the second rule of clinical examination – comparison.

The principle behind CPC is to introduce a reliable “control” stimulus where the subject is himself or herself, made the control.

Typically, when testing for DPN, the patient is assessed for sensory deficit in that part of the peripheral nervous system potentially most vulnerable to the effects of metabolic destruction – their extremities and especially the feet and toes.

The idea is to establish a level of “normal” sensitivity for them in a remote area of skin supposedly unaffected by pathology against which the examiner can then compare the extremity.

Verbal feedback can then be used to express differences between the two and patients can be very sensitive to small distinctions.

Why Use Medipin?

It is critical to try to generate as acute a sense of sharpness as possible without increasing the risk of skin penetration.

For decades, since the work of the likes of De Castillo, Katz, Miledi and others, we have understood the neurophysiology of these stimuli. Pinprick is not truly about physical sharpness at all.

A hypodermic needle is very sharp – a blade really – and as such and in the right hands can be almost painless.

On the other hand sharp stimulation acuity is all about skin stretch and contact demarcation of the point and it's surfaces of contact.

Medipin is an FDA listed, dedicated device which has been in regular use by US Doctors for many years, as well has having been employed successfully in quite a number of international medical studies.

It utilizes a well demarcated but blunted pyramidal point in order to this phenomenon.

As well as being intended to reduce the risk of skin penetration this stretching will heighten the sense of pinprick.

This is then augmented by the surrounding annulus in which the point is situated that creates a perimeter of duller sensation to exploit the cortical phenomenon of lateral neural inhibition.

Lateral inhibition, is the phenomenon that supresses information form areas of perception bordering those that more vividly garner cortical stimulation to evoke discrete boundaries and delineations.

This is the same phenomenon that fools us in optical illusions and is exploited here by positioning Medipin's well demarcated point at the center of an area of duller stimulation created by the annulus.

Effectively the device is intended to generate a localized center surround field effect which further enhances the sharp element at its' center whilst surrounding neurons are inhibited to further augment perception of the point.

This means more acute stimulation at lesser contact pressure.

The annulus also serves to protect the clinician from the point itself so that even if there has been an accident, the risk of self-inflicted needle stick is rendered very improbable.

Infection control is also a little easier because, even if there is not a sharps bin handy the point can be destroyed easily by simple compression against a robust surface.

Medipin is an all-plastic device and pretty harmless really but intended to be all the more efficacious for it.

For further information on Medipin please see www.medipin.net

For further information on the home-testing version of Medipin, the Diabetic Toes Test, which contains 12 Medipins for monthly self testing now available for doctors to provide to their patients please see www.diabetictoestest.com