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Sensory testing in leprosy: comparison of ballpoint pen and monofilaments

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Summary The 10 g monofilament has been replaced by the ballpoint pen in routine sensory testing of nerves in leprosy control in Ethiopia. Results of sensory testing between the ballpoint pen and different monofilaments on hands and feet were compared. Ballpoint pen underdiagnosis of loss of sensation was defined to occur when the pen was felt and the monofilament was not. Differences were evaluated both for individual test points (test point level) and for the test points of extremities collectively (extremity level). An extremity (either a hand or a foot) was defined as having sensory nerve function impairment (SNFI) if a supplying nerve had SNFI, which was the case when sensation was absent in two or more test points in the area supplied by that nerve. At test point level, the percentages with ballpoint pen underdiagnosis relative to the 2, 10, 20 and 50 g monofilaments were 40, 21, 9 and 7%, respectively, in the hands, and 47, 30, 15 and 7% in the feet. Ballpoint pen underdiagnosis percentages of SNFI at extremity level were 32, 18, 8 and 9% in the hands, and 37, 26, 14 and 6% in the feet. The risk of ballpoint pen underdiagnosis appears to be higher in extremities without visible damage. In conclusion, substantial levels of underdiagnosis of sensory loss with the ballpoint pen were observed. However, the consequences for the prognosis of treatment with corticosteroids in patients with the more subtle sensation loss noted here need to be established. Development and testing of guidelines is a prerequisite for the use of the ballpoint pen.

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Introduction

In recent years, the attention given to the prevention of impairment and disability in leprosy control has increased. Nerve function impairment can, in combination with repeated injuries and misuse of hands and feet, eventually result in activity limitation and participation restriction for the affected person. Early detection of nerve function impairment is therefore a vital component of programmes for the prevention of disability. One of the earliest signs of nerve function impairment is loss of sensation in hands and feet. This paper compares ballpoint pen and nylon monofilaments as devices for detecting loss of sensation.

Sensory testing for the detection of loss of sensation was widely introduced in leprosy control programmes in the 1970s.[1] Initially, the tip of a ballpoint pen or a pencil was used. Ballpoint pens and pencils are widely available and cheap.[2,3] It is difficult, however, to train field staff so that they will always exert a standardized pressure with a ballpoint pen or pencil.[2–5]

Later in the 1970s, nylon monofilaments were advocated. These were developed in order to enable testing with a standardized and quantifiable pressure, and they proved to be a sensitive tool for detecting sensory loss.[4,6–8] There are, nevertheless, some practical difficulties in using monofilaments. Filaments may be lost or need to be replaced after they have become bent, and a test using multiple monofilaments takes more time.[7] The force exerted by monofilaments is thought to change with temperature and possibly with wear.[4] Ready-made monofilaments are relatively expensive and not always easy to obtain, but local production of handles and filaments is not too difficult. Local calibration should also be possible.[8]

In spite of different thresholds for normal sensibility in the hands and feet, a 10 g monofilament was used for both hands and feet in the field clinics of the All Africa Leprosy, Tuberculosis and Rehabilitation Training Centre (ALERT) in central Ethiopia.[1,9] The choice of only one monofilament was made because it was not considered feasible for field workers to reliably use two or more filaments.[1] In 1997, a manual from the Ethiopian Ministry of Health stated that 'Sensory testing on palms and soles should be done with a ball-point pen'.[10] The ALERT control programme was handed over to the regional governments in 1999. As a consequence, the policy of ballpoint pen testing is now applied in the clinics previously run by ALERT.

This paper is a first exploration of the consequences of replacing the 10 g monofilament by the ballpoint pen for the detection of sensory loss in leprosy patients from central Ethiopia. We report how the ballpoint pen correlates with nylon monofilaments of different weight in diagnosing loss of sensation in hands and feet. The study was conducted in field clinics of the routine ALERT leprosy control programme in the year 1998.

Materials and methods

The purpose of the study was to determine the consequences of the replacement of the 10 g monofilament with the ballpoint pen in a routine control programme setting. The study was conducted in field clinics of the ALERT control programme. New patients, patients on MDT and patients on post-MDT surveillance were admitted to the study.

The patients were tested by one of two examiners, who were specially trained to perform sensory testing with both the ballpoint pen and the monofilaments. Part of the training was to

teach the examiners to exert a constant stimulus with the ballpoint pen, irrespective of differences in skin structures between patients. The stimulus to be exerted was the equivalent of the stimulus that the examiners experienced themselves when using a 10 g monofilament on the test points on their own hands and feet.

FILAMENTS

Sensory testing with filaments was done using ready-made, imported Semmes–Weinstein monofilaments with weights purported to be 2, 10, 50 and 300 g. In addition, in order to fill the gaps between the standard Semmes–Weinstein monofilaments, others were produced at ALERT from locally available material (nylon monofilaments of different gauges are widely used in a variety of industries and are very inexpensive), using the following method.

A standard plastic BIC pen was used to make a handle and carrying case for the monofilament. The ink tube was removed from the barrel of the pen and then also from its writing tip. In its place, a monofilament was secured in the writing tip, with an exact protrusion of 38 mm, using a strong, quick drying adhesive. At the other end of the pen a perpendicular hole was drilled through the barrel, the hole being the same diameter as the part that holds the monofilament. The monofilament was poked through this hole at right angles to the barrel of the pen. The barrel formed a handle making the testing procedure more efficient. When not in use, the monofilament was removed and put back inside the barrel of the pen for safe carriage.

Calibration of each filament was performed using an Oxford Top-loading Balance, model P1502. The maximum weight measurable on this balance was 150 g and the accuracy was to 10 mg. All filaments were tested prior to their use in the study. The method of calibration used was to place a small piece of Blu-Tack on the balance, recalibrate the balance to zero, then apply the filament perpendicularly to the scales until the filament buckled. The Blu-Tack ensured that the filament did not slide off the smooth metal surface of the balance. This was repeated 5 times for each filament and the average calculated. The length of each filament was also measured to confirm each was 38 mm long. Results for the two sets of manufactured 2 g, 10 g and 50 g filaments were 1.9 g/2.6 g, 7.7 g/8.0 g and 55 g/55 g respectively. The two sets of locally produced filaments were calibrated to 20 g/20 g, 81 g/81 g and 122 g/122 g. These filaments were also re-calibrated after the study, with the following results: 20 g initially: 17 g/17 g, 81 g: 77 g/75 g, 122 g: 109 g/121 g. This is consistent with results obtained with various commercially manufactured monofilaments, including Semmes–Weinstein monofilaments.[11]

Throughout the study, each examiner only used his own set of monofilaments, which included one monofilament for each weight. The monofilaments were not replaced during the study and there were therefore just two filaments of each weight used throughout.

EXAMINATION OF PATIENTS

Before examining a patient, the testing procedure was explained and demonstrated, and it was ensured that the procedure was fully understood. The testing procedure was as follows. With both the ballpoint pen and the monofilaments, 10 points were tested on the palms and fingers of the hands: 4 points in the area of the ulnar nerve and 6 in the area of the median nerve. On the foot each toe was tested, along with 5 points on the sole of the foot.[12] Thus, 40 points per patient were tested. Points were not tested in case of an amputation, wound or other

complication (e.g. extensive clawing). Hands and feet were examined one by one. Points on the same hand or foot were tested in random order. The patient was asked to close his eyes and to point to the spot where a stimulus was felt. A stimulus was regarded as 'felt' when the patient could point out the tested location within a range of approximately 2 cm. The patient had to point to the exact spot of the exerted stimulus for the fingertips. Points were tested only once if the stimulus was felt. If a stimulus was not felt the first time, the point was tested again after having tested some other points. In this case the result of the second test was recorded.

The examiners saw the patients for the first time, and did not have access to patient record cards and previous sensory testing results. For each patient, all tests were carried out by the same examiner. This choice was made because change of examiners might lead to loss of concentration by the patient, and might introduce bias due to inter-observer variation. The points were first tested with the ballpoint pen and then, in order to find the threshold for sensation, with the monofilaments. This order was chosen to minimize bias in the results of tests carried out by one examiner: prior knowledge of the monofilament threshold for sensation may introduce bias in ballpoint pen test results, and the ballpoint pen is more susceptible to bias than the monofilaments. The first monofilament used was the one thought to be closest to the actual threshold for most points on the hand or foot involved. Heavier or lighter monofilaments were subsequently used until the threshold was identified. This procedure, which gives priority to efficiency in determining the threshold, may also involve bias. The choice for this procedure was also made because we judged maintaining the patient's concentration to be essential.

ANALYSIS

The test results with monofilaments and the ballpoint pen were compared for individual test points (test point level). Monofilament testing was regarded as the 'gold standard'. The occurrence of underdiagnosis of absence of sensation with the ballpoint pen was determined relative to the monofilaments. For each monofilament, the percentage ballpoint pen underdiagnosis was defined as the percentage of points where the ballpoint pen was felt at those points where that monofilament was not felt. The occurrence of overdiagnosis of absence of sensation with the ballpoint pen was also determined relative to the monofilaments. In this case, the percentage ballpoint pen overdiagnosis refers to the percentage of points where the ballpoint pen was not felt at the points where the monofilament was felt.

Underdiagnosis and overdiagnosis are terms that are used here in comparison with different monofilaments. Clearly, it was expected that the ballpoint pen would be less sensitive than the fine monofilaments (2 g and 10 g) and would miss or underdiagnose mild degrees of sensory loss shown up by these filaments. On the other hand, compared with the 300 g monofilament, which only detects gross sensory loss, the ballpoint pen would be expected to be more sensitive and thus detect moderate degrees of sensory loss, overdiagnosing it in comparison with this filament.

Nerve function impairment may involve deficiencies in sensory function, motor function, sweating and blood flow. In this study, only sensory nerve function impairment (SNFI) was investigated. This was done for hands and feet separately (extremity level), as follows. For each nerve, two or more points had to be tested. A hand was diagnosed to have SNFI if sensation was absent in two or more points supplied by the median, and/or two or more points supplied by the ulnar nerve. A foot was diagnosed with SNFI if two or more points were without sensation. Apart from the restriction to sensory loss only, these definitions for SNFI

follow the ALERT guidelines for diagnosing impairment of nerve functioning.[12] Diagnoses of SNFI were based only on test results of points that were tested with both the ballpoint pen and the monofilaments. Similar definitions for underdiagnosis and overdiagnosis of SNFI were used at extremity level, as have been described above for the test point level.

Finally, this paper investigates factors that may possibly influence the underdiagnosis of absence of sensation with the ballpoint pen as compared to the monofilament assessments. Factors considered are location of the test point (fingers versus palm, toes versus sole), supplying nerve (hands only: ulnar or median nerve), the presence of visible damage and the examiner who conducted the tests. In the analysis, a point on the hand or foot was associated with visible damage if there was any clawing, absorption, wound or open crack on the hand or foot involved.

A complication in the analysis is that results of sensory testing in points on the same foot or on the same hand that are supplied by the same nerve are not statistically independent. For instance, if the ballpoint pen is not felt at a test point on a certain foot, then one can suspect impairment in the nerve of that foot. This increases the chance that the ballpoint pen is not felt at other points on that same foot as well. Standard logistic regression assumes that all observations (in this case test results) are statistically independent. It can therefore not be used to derive confidence intervals for odds ratios for ballpoint pen underdiagnosis frequencies for the factors under consideration. Instead, we applied a procedure that takes into account the interdependencies in test results: logistic regression using the GEE-method (Generalized Estimating Equations; the package SAS, release 8.0, was used). 13 In this procedure, we applied a compound symmetry error structure for the clusters.

The collected patient information further includes type of leprosy, age, gender and WHO disability grading (assessed using the 10 g monofilament).

Results

A total of 69 patients were enrolled in this study: 42 males (61%) and 27 females (39%). The mean age of the patients was 35 years (range 9–77). Nine patients (13%) were PB and 58 (87%) were MB. The type of leprosy was not recorded for two patients. Ten patients (15%) had no impairment, 17 (25%) had WHO impairment grade 1 and 41 (60%) WHO impairment grade 2. The WHO score was not recorded for 1 patient.

ABSENCE OF SENSATION AND PRESENCE OF SNFI

Complications such as wounds and amputations prohibited sensory testing in 61 points. Due to various other reasons, 75 points were missed with either the ballpoint pen, or the monofilaments, or both. Thus, in total 1354 points on the hands and 1270 points on the feet were tested with both ballpoint pen and monofilaments. The diagnosis of SNFI could not be made for both the ulnar and median nerve of one hand and for eight feet because of insufficient numbers of points tested. This leaves 137/138 hands and 130/138 feet for which diagnoses of SNFI could be made.

Table 1 summarizes the absence of sensation (test point level) and SNFI (extremity level). Frequencies of absence of sensation and presence of SNFI decreased with increasing monofilament weight. Because many hands and feet have partial loss of sensation, the percentage of extremities with impairment is always higher than the percentage of test points

Table 1. Numbers and percentages of test points on hands and feet with absence of sensation as diagnosed with monofilaments and the ballpoint pen (test point level), and associated numbers and percentages of hands and feet with sensory nerve function impairment (extremity level, SNFI)

		Monofilament (g)							Ballpoint pen
		2	10	20	50	81	122	300	
Hands									
Test point level ($n = 1354$)	no.	466	336	285	252	220	204	187	281
	%	34	25	21	19	16	15	14	2
Extremity level ($n = 137$)	no.	69	56	50	45	37	34	33	47
	%	50	41	36	33	27	25	24	34
Feet									
Test point level ($n = 1270$)	no.	956	706	558	485	443	416	386	508
	%	75	56	44	38	35	33	30%	40%
Extremity level ($n = 130$)	no.	113	96	79	71	64	61	57	71
	%	87	74	61	55	49	47	44	55

with impairment. The frequencies of absence of sensation and SNFI on ballpoint pen in hands and feet were in between those obtained with the 20 g and 50 g monofilaments.

UNDERDIAGNOSIS AND OVERDIAGNOSIS WITH THE BALLPOINT PEN

Table 2 and Figure 1 show that percentages of ballpoint pen underdiagnosis of absence of sensation and SNFI decreased with increasing monofilament weight. Figure 1 also shows that, in contrast, overdiagnosis increased with increasing filament weight.

Relative to the 10 g monofilament, the frequency of ballpoint pen underdiagnosis of absence of sensation was 21% for points on the hands and 30% for points on the feet. These frequencies were below 10% from the 20 g monofilament onwards for the hands and from the 50 g monofilament onwards for the feet. Frequencies of ballpoint pen underdiagnosis of absence of sensation and of SNFI were more or less similar (the difference was at most 4%, except for the 2 g monofilament).

Ballpoint pen overdiagnosis of absence of sensation and SNFI was very uncommon for the monofilaments of 2 and 10 g for both hands and feet (Figure 1). Relative to the 50 g

Table 2. Ballpoint pen underdiagnosis: frequency of presence of sensation on ballpoint pen amongst points on hands and feet without sensation on the monofilament involved (test point level), and frequency of absence of sensory nerve function impairment (SNFI) on ballpoint pen amongst hands and feet with SNFI as diagnosed with the monofilament (extremity level)

	Monofilament (g)				
	2	10	20	50	81
Hands					
Test point level ($n = 1354$)	185/466 (40%)	69/336 (21%)	27/285 (9%)	17/252 (7%)	8/220 (4%)
Extremity level ($n = 137$)	22/69 (32%)	10/56 (18%)	4/50 (8%)	4/45 (9%)	1/37 (3%)
Feet					
Test point level ($n = 1270$)	449/956 (47%)	209/706 (30%)	86/558 (15%)	35/485 (7%)	15/443 (3%)
Extremity level ($n = 130$)	42/113 (37%)	25/96 (26%)	11/79 (14%)	4/71 (6%)	1/64 (2%)

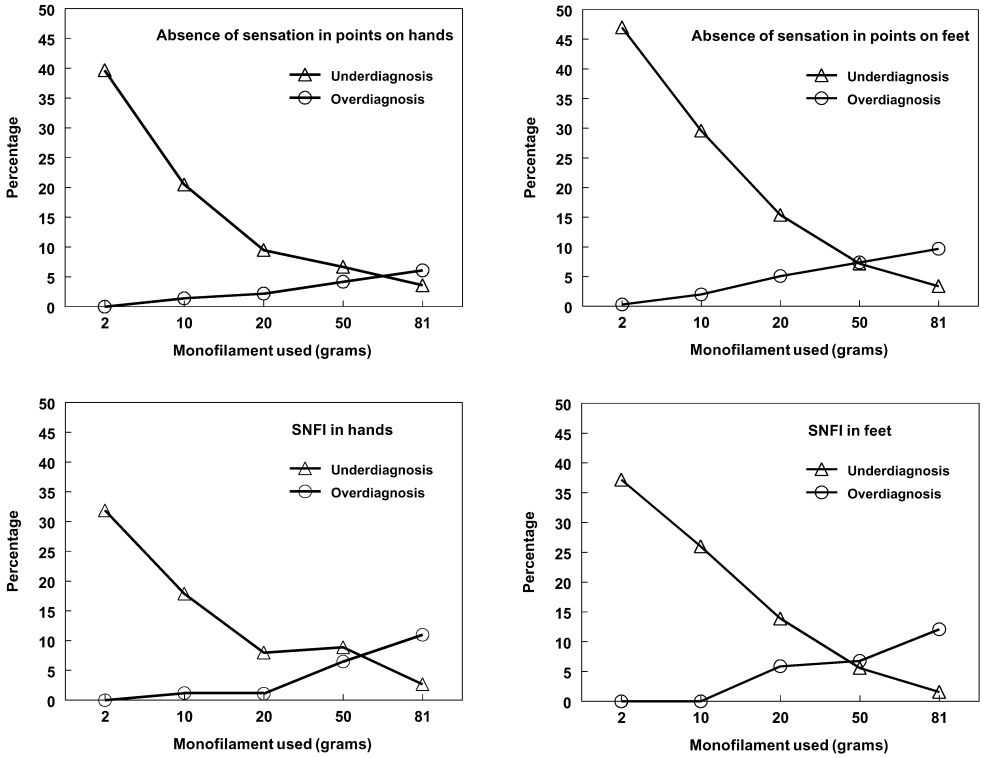

Figure 1. Percentages of underdiagnosis and overdiagnosis of absence of sensation (test point level) and presence of sensory nerve function impairment (SNFI, extremity level) in hands and feet with ballpoint pen relative to monofilaments of different weights.

monofilament, the ballpoint pen overdiagnosis percentages of both absence of sensation and SNFI were still below 10%.

FACTORS INFLUENCING BALLPOINT PEN UNDERDIAGNOSIS

In this analysis, monofilaments from 2 to 81 g are considered. Logistic regression with GEE did not show statistically significant differences in ballpoint pen underdiagnosis for the comparison of median versus ulnar nerve, fingers versus palm (except for the 2 g monofilament), toes versus sole, and of the two examiners. In both hands and feet, ballpoint pen underdiagnosis was more frequent in points without visible damage for all monofilaments, than when visible damage was present (Table 3). Nevertheless, the odds ratios were only statistically significant for the two lightest monofilaments for the feet. Nerve damage is likely to be less advanced in extremities without visible damage, which may cause the ballpoint pen to be felt in points where the lightest monofilaments are not felt. This would support the hypothesis of a higher risk of ballpoint pen underdiagnosis in extremities without visible damage. Indeed, in this study sensory impairment was less severe in the absence of visible damage for both hands and feet. This was shown by considering points without sensation on the 2 g monofilament: test results with heavier monofilaments were compared for these points in the presence and absence of visible

Table 3. Ballpoint pen underdiagnosis: results of logistic regression using GEE for presence of sensation on ballpoint pen in points without sensation on monofilament as outcome, and presence of visible damage as predictor, for monofilaments of different weight

		Monofilament (g)				
	Visible damage	2	10	20	50	81
		Odds ratios (95% confidence intervals)				
Hands	Yes (baseline)	1	1	1	1	1
	No	1.8 (1.0–3.3)	1.2 (0.6–2.6)	2.0 (0.8–5.2)	1.9 (0.6–6.2)	3.0 (0.6–15.1)
Feet	Yes (baseline)	1	1	1	1	1
	No	3.5 (1.9–6.4)	2.4 (1.3–4.7)	1.3 (0.6–3.0)	1.3 (0.5–3.3)	1.5 (0.5–4.3)

damage (logistic regression with use of GEE was applied; all odds ratios were statistically significant).

Discussion

This paper investigates how the ballpoint pen relates to monofilaments of different weights at two levels: diagnosis of absence of sensation at the individual test point level, and diagnosis of sensory nerve function impairment in hands and feet (extremity level: SNFI). An attempt was also made to investigate factors that influence differences in the outcomes at test point level. To date, little attention has been paid to these factors in the literature.

COMPARISON AT TEST POINT LEVEL AND EXTREMITY LEVEL FOR THE HANDS AND FEET

The results of tests with the ballpoint pen and monofilaments should be interpreted with caution. For most filaments, identical test results were obtained with ballpoint pen in 90% or more of test points. These results were not shown because the relevance of this finding is limited: test results with ballpoint pen and monofilaments were bound to be identical in many test points because there was often either little or no loss of sensation, or extensive loss of sensation (see Table 1). For this reason, we concentrated in our analysis on absence of sensation that is not identified by the ballpoint pen (ballpoint pen underdiagnosis). The second focus was on false diagnosis of absence of sensation with the ballpoint pen (ballpoint overdiagnosis).

Taking monofilament testing as the gold standard, levels of ballpoint pen underdiagnosis were substantial. For instance, relative to the 10 g monofilament which was previously used at ALERT, the percentages of underdiagnosis of absence of sensation with ballpoint pen were 21% for points on the hands and 30% for points on the feet. This finding and the other results from Table 2 imply that the examiners did not succeed in exerting a constant '10 g monofilament stimulus' with the ballpoint pen, despite their dedication and specific training for this study. Patterns of underdiagnosis of absence of sensation and of SNFI (extremity level) were quite similar (Table 2). Our findings indicate a risk of postponement of the detection of loss of nerve function in patients when the ballpoint pen is used instead of the monofilament. However, it is also true that the ballpoint pen test is less likely to lead to overdiagnosis of new sensory loss, as may occur with a much more sensitive test.[9]

Percentages of ballpoint pen overdiagnosis of absence of sensation and of SNFI (extremity level) were generally low in both hands and feet: up to 50 g, overdiagnosis percentages were below 10% in both hands and feet.

LOCALLY PRODUCED MONOFILAMENTS

It should be pointed out that Table 1 and Figure 1, as well as the re-calibration data, suggest that the locally produced monofilaments have performed very reasonably in comparison with the Semmes–Weinstein monofilaments. Bell-Krotoski and Buford[5] pointed out that top-loading scales do not measure the dynamic characteristics of filament testing and are not sensitive enough for calibration purposes, but their study looked particularly at testing near the threshold of touch sensation (weights of less than 100 mg). The high degree of precision of filament weights is not of major importance in this study and we believe that the top-loading scale is a reasonable instrument for comparing different monofilaments. The advantage of monofilaments, wherever they are manufactured is that they give reproducible results when used by skilled examiners, as has been amply demonstrated by Bell-Krotoski and her colleagues. A practical matter is that Semmes–Weinstein monofilaments are difficult to obtain in many countries outside of the United States.

FACTORS INFLUENCING DIAGNOSIS OF SENSORY LOSS AND BALLPOINT PEN UNDERDIAGNOSIS

For all monofilaments, ballpoint pen underdiagnosis was more frequent in points on hands and feet without visible damage. However, statistical significance was reached only for points on the feet, and only when the two lightest monofilaments were used. Important differences in ballpoint pen underdiagnosis according to location of the test points on hands and feet and between the examiners were not demonstrated. Larger studies may shed more light on factors that may influence ballpoint pen underdiagnosis.

More frequent ballpoint pen underdiagnosis in extremities without visible damage can be conceived to be a true risk. This is because nerve function impairment is likely to be less advanced in such extremities, which implies that the ballpoint pen is prone to be felt—'more underdiagnosis'—in points where the lightest monofilaments are not felt. Ballpoint pen testing results may also involve a certain degree of examiner bias, because the examiner may consciously or unconsciously adjust the pressure applied to extremities with visible damage to elicit his/her anticipated test result. In any case, the observed differences are of concern because they themselves suggest that ballpoint pen underdiagnosis is most frequent in extremities that look healthiest and for which preventive action could be most promising.

The role of callus was not evaluated systematically in our study group. Tentative exploration of this issue suggested that ballpoint pen underdiagnosis was more frequent on skin with pronounced callus for the monofilaments of 20 g and heavier. This was the case for both hands and feet. These findings suggest that the examiners unconsciously pressed the ballpoint pen harder on callused skin, despite attempts not to do so. This observation and our considerations regarding visible damage illustrate that it is difficult always to exert a fixed stimulus with the ballpoint pen. For callused skin, apparent absence of sensation may be due to lack of elasticity of the skin rather than loss of nerve function, and thresholds for light touch sensation are known to be higher compared with soft skin.[14]

BALLPOINT PEN VERSUS MONOFILAMENTS: A REFLECTION

The present study improves our understanding of the behaviour of the ballpoint pen as compared to the monofilaments in sensory testing. Our results confirm previous work[8] showing that that absence of sensation as diagnosed with monofilaments can be missed with the ballpoint pen. However, it remains unclear how serious the observed extent of ballpoint pen underdiagnosis is in the context of prevention of impairment and disability. The reverse, the low extent of ballpoint pen overdiagnosis of sensory loss is a point in favour of the use of the ballpoint pen.

It is of concern that ballpoint pen underdiagnosis may be more frequent in points on hands and feet without visible damage. However, it is unclear whether corticosteroid treatment will improve the prognosis of nerve function impairment when the diagnosis is based only on sensory loss that is established with light monofilaments but not with the ballpoint pen. There is evidence that this is not the case.[15] The possibility that patients with sensory loss to light monofilaments only and without other signs of nerve function impairment are relatively rare, should also not be discounted. Still, silent neuropathy requiring corticosteroid treatment can show sensory loss alone. Other signs that may lead to the diagnosis of nerve function impairment and initiation of corticosteroid treatment include recent changes in voluntary muscle testing (VMT) results, pain or tenderness on palpation of a nerve trunk, and a skin reaction in a patch overlying a major nerve trunk or eye.[12]

Whatever device is used, light touch sensory testing remains a crude way of establishing changes in sensation. In our opinion, it is essential that patients are asked about their own perception of 'feeling changes' to support sensory testing. Well developed clinical skills are essential to perform sensory testing in a meaningful way. Our study illustrates the difficulty in exerting a fixed, constant stimulus with the ballpoint pen. This implies that strict guidelines on the use of the ballpoint pen need to be developed and tested if the detection of new sensory loss in routine control programmes is going to rely on this instrument. Little is known about the response to sensory tests with the ballpoint pen on callused skin, although guidelines have been suggested for the use of monofilaments.[14] The actual implications of replacing monofilaments by the ballpoint pen for prevention of impairment and disability can only be determined through further field trials.

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