Leprosy diagnosis: a device for testing the thermal sensibility of skin lesions in the field

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A handy device for testing the thermal sensibility of skin lesions has been developed and field tested in various centres in Africa and India. The instrument performed satisfactorily and its use made testing for thermal sensibility in the field practicable and straightforward. Analysis of the results of testing 260 persons, most of whom exhibited a few lesions that were characteristic of early leprosy, showed that the rate of diagnosis of sensory impairment of such skin lesions, and hence the diagnosis of leprosy, would be about 15–25% more if thermal sensibility testing using this device were added to the other tests of sensibility routinely carried out in the field. Regular use of the device in the field would help to bring more leprosy patients under treatment than at present.

Introduction

The elicitation of impaired sensibility in a suspected skin lesion ("patch") is a vital part of clinical examination of individuals suspected of having leprosy. In such cases, demonstration of impaired sensibility in a lesion clinches the diagnosis of leprosy. For this purpose, it is usual to test for the perception of pain or touch. In the later stages of the disease any method of sensibility testing can be used since by then all modalities of sensation will have been impaired. However, during the early stages, skin patches may exhibit dissociated loss of sensibility, since perception of pain or heat is impaired earlier than that of touch (*1–4*). Nevertheless, testing for impairment of thermal sensibility is not routinely carried out, even in clinics, because the recommended method (which uses test-tubes containing hot or cold water) is cumbersome and time-consuming.

The modalities of pain and thermal sensation have in common the same unmyelinated (C) and thinly myelinated (Aδ) fibre systems (*5–7*). Since infection of individual Schwann cells with *Mycobacterium leprae* is likely to be a random phenomenon, we can expect "thermal fibres" to be affected first in some cases and "pain fibres" in others. If tests for impairment of thermal sensibility are not carried out, cases that exhibit initial impairment of only this modality will not be diagnosed. However, if thermal sensibility could be tested routinely, particularly in the field, it should be possible to identify individuals with isolated impairment of this modality and treat them at this early stage.

In view of this, WHO has supported the development of a thermal sensibility tester that is suitable for use in the field. As prerequisites, such a tester should be light, easy for field personnel to carry and operate, sturdy, small, not too expensive, capable of attaining a predetermined working temperature in a short time, and not consume too much power. The first prototype of the device was field tested in Africa, Asia, and South America. Based on the results obtained, an improved second prototype was developed and field tested to a limited extent to assess its suitability, acceptability, and sturdiness. By taking into account the feedback from users of both prototypes, a third and final prototype has now been developed. A few of these have been distributed to centres in Africa and India for field testing to assess what improvements in diagnostic sensitivity are provided by thermal sensibility testing compared with that of the sensibility tests normally used in these centres. The results obtained are reported here.

The thermal sensibility tester

In the first version of the device (prototype I) a relatively sophisticated electronic head was mounted on the body of a pen torch to control the warm end to a preset temperature of 40 °C. The results of the field tests of prototype I indicated that although it was potentially useful for diagnosing early leprosy, its technical specifications, particularly the control of temperature and its robustness, had to be improved. Prototype II differed markedly from prototype I in that the temperature of the warm end was a function of the ambient temperature. By using a novel ceramic semiconductor

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Table 1: **Technical specifications for prototype III of the thermal sensibility tester**

Battery types:	Preferably rechargeable 1.2 V nickel-cadmium types; otherwise 1.5 V good quality alkaline
Battery size:	AA—R6—UM3—Mignon
Current consumption (in still air):	ca. 240 mA at an ambient temperature of 15 °C; ca. 200 mA at an ambient temperature of 25 °C; ca. 120 mA at an ambient temperature of 45 °C
Typical warm-end temperature:	45 °C at an ambient temperature of 15 °C; 50 °C at an ambient temperature of 25 °C; 60 °C at an ambient temperature of 45 °C
Recommended working temperature for examinations:	Ambient temperatures of 10–45 °C
Warm-up time:	15 seconds for ambient temperatures > 15 °C; 30 seconds for ambient temperatures < 15 °C
Recommended minimum battery voltage before recharge or change:	1 V for each battery
Dimensions:	Tip size: 7-mm diameter; Body length: 133 mm; Body diameter: 22 mm; Area of warm end exposed to the skin: 38.5 mm²
Weight:	83 g without batteries

Fig. 1. **Plot showing typical warm-end temperatures as a function of the ambient temperature.**

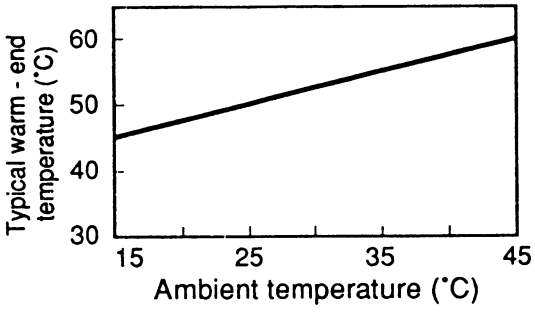


Fig. 2. **Plot showing typical battery power consumption as a function of the ambient temperature.**

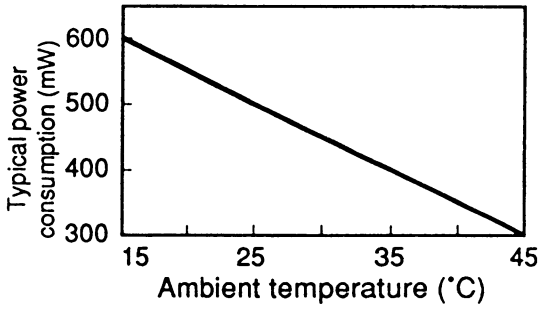


Fig. 3. **Plots showing typical battery discharge characteristics. *a*) Rechargeable "nickel–cadmium" batteries. *b*) Nonrechargeable "alkaline–manganese" batteries.**

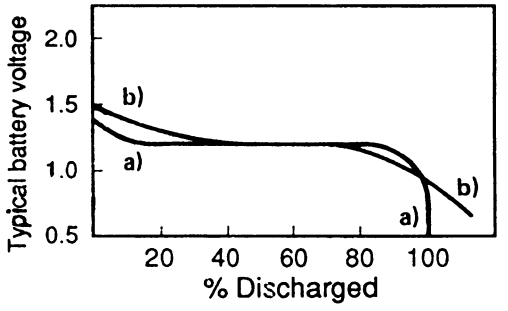
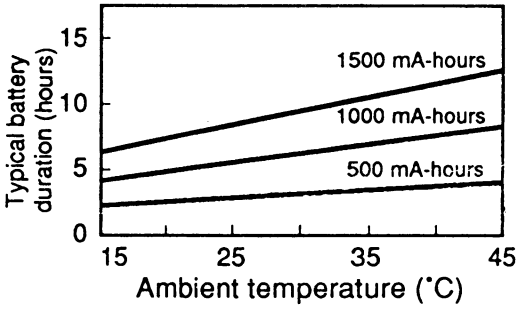


Fig. 4. **Plot showing typical battery duration at various ambient temperatures and charge capacities (a standard rechargeable battery has a capacity of 500 mA-hours, while that of a good quality alkaline battery can be up to 1500 mA-hours).**

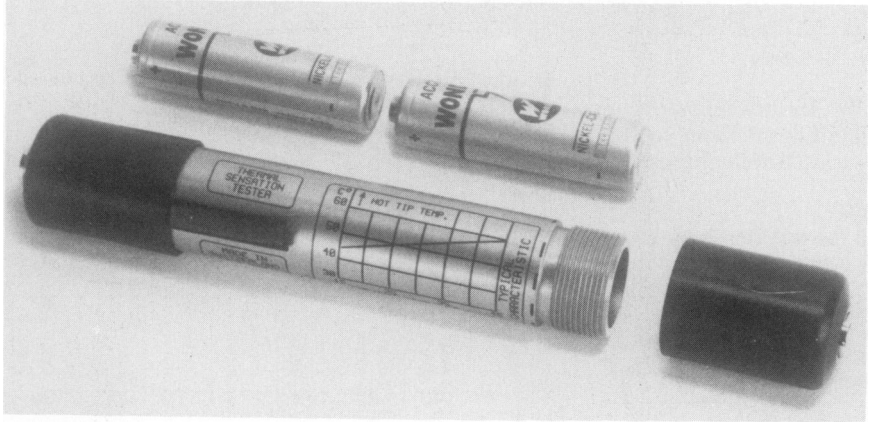


material, a heating element was produced that could control its own temperature according to the desired specification. In addition, prototype II was simpler to use, had more reliable electronics, lower power consumption, a faster warm-up time, the ability to perform under a range of ambient temperatures, and was cheaper.

Prototype III was developed from prototype II by making further improvements to the on–off switch and to the design of the warm end. In this version, the temperature of the warm end is controlled such that it is always greater than that of the skin lesion to be tested for ambient temperatures over the range 10–45°C.

The technical specifications for prototype III of the device are shown in Table 1 and Fig. 1–4. The device itself is shown in Fig. 5. Requests for further information on the device should be sent to Mr B. Stumpe (see address in footnote 2 on p. 635).

Fig. 5. **The thermal stability tester (shown with rechargeable pen torch batteries).**



Results

Data for 319 persons were received from six centres (three in Africa and three in India) that participated in the field trial of prototype III of the device. The findings on 59 persons from one centre were discarded because they were noninformative, and those for the remaining 260 persons (both males and females from practically all age groups) from the other five centres therefore form the basis of the study. Of these 260 persons, the skin lesions tested had been present in 172 for up to 1 year, in 31 for 1–2 years, and in 17 for more than 2 years. For 40 persons information on the duration of the lesions could not be determined.

The results of clinical diagnosis of the skin lesions are given in Table 2. A clinical diagnosis of tuberculoid (including borderline cases), indeterminate, or "suspicious" accounted for over 80% of the lesions. Approximately 50% the patients had one lesion, while the others had two or more. Sensibility tests were carried out on one lesion for 184 persons, on two lesions for 41, and on three for 35.

Table 2: **Clinical diagnosis of the skin lesions for 260 patients tested in the study**

Clinical diagnosis	No. of persons
"Suspicious"	51
Indeterminate	22
Tuberculoid	64
Tuberculoid (borderline)	79
Borderline	5
Lepromatous (borderline)	9
Lepromatous	29
Not recorded	1
Total	260

Sensibility tests for touch were routinely carried out in five centres, while the pinprick test for pain perception was also used in four. All three modalities of sensation were therefore tested in 210 persons only, although 260 persons were tested for thermal sensibility using the device.

The findings obtained are reported below, first using a lesion-orientated and subsequently a person-orientated approach.

Lesion-orientated approach

Pain, touch, and thermal sensibility were all tested for 263 skin lesions in 210 persons. Information on eight lesions (in six persons) was incomplete, and the analysis of the results on all three modalities of sensation is therefore based on 255 lesions in 204 persons (Table 3).

Person-orientated approach

The approach described above relates to the skin lesions themselves. Clearly when more than one lesion was tested per person that person was identified as having a sensory impairment (and hence as a case of leprosy) even if the impairment involved only one of the lesions. The data were therefore re-analysed using a person-orientated rather than lesion-orientated approach. Four of the five centres routinely used tests for pain and touch sensibility, whereas one tested only for

Table 3: **The pain, touch, and thermal sensibility status patterns of 255 skin lesions**

Pattern	Sensibility status			No. of lesions
	Pain	Touch	Thermal	
1	I[a]	I	I	132
2	I	I	N[a]	8
3	I	N	I	13
4	I	N	N	7
5	N	I	I	6
6	N	I	N	3
7	N	N	I	27
No. of lesions with impaired sensibility	160	149	178	196
Lesions with no impairment (pattern 8)	N	N	N	59
Total number of lesions tested				255

[a] I = Impaired sensibility; N = Normal sensibility.

touch sensibility to identify sensory impairment. Table 4 shows the pooled data from the four centres that used thermal sensibility tests as well as those for both pain and touch.

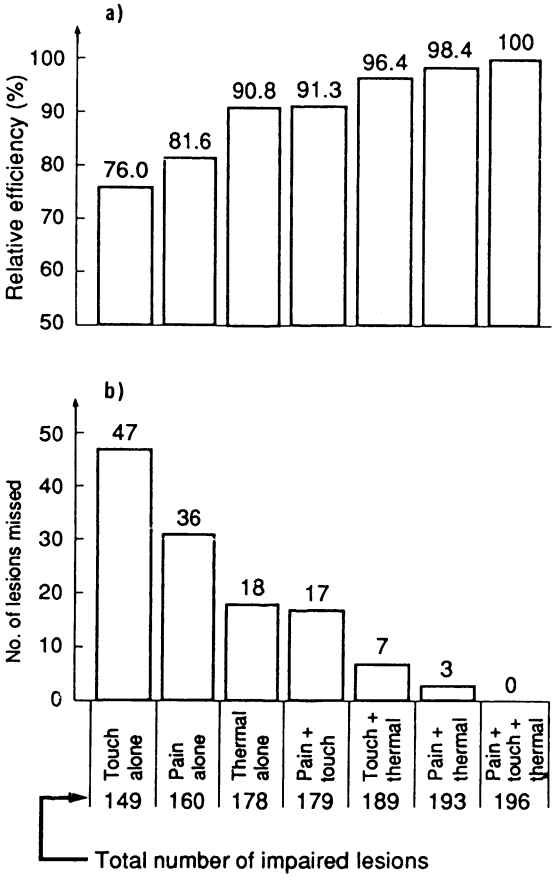
Table 4: **The pain, touch, and thermal sensibility status patterns of 204 persons in the study**

Pattern	Sensibility status of any or all lesions			No. of persons
	Pain	Touch	Thermal	
1	I[a]	I	I	102
2	I	I	N[a]	6
3	I	N	I	11
4	I	N	N	6
5	N	I	I	4
6	N	I	N	3
7	N	N	I	24
Total number of persons with impaired sensibility	125	115	141	156
Persons with no impairments (pattern 8)	N	N	N	48
Total number of persons tested				204

[a] I = Impaired sensibility; N = Normal sensibility.

The ability of tests for the different modalities of sensory loss and their combinations to act as indicators of early lepromatous lesions is shown in Fig. 6, while the ability of tests for the different modalities of sensory loss and their combinations to identify early cases of leprosy is shown in Fig. 7.

Fig. 6. ***a*) Relative efficiency of tests for touch, pain, and thermal sensibility when the total number of impaired lesions found by all three tests combined (196) was set at 100%. *b*) Distribution of the number of skin lesions missed by testing for various modalities of sensibility.**

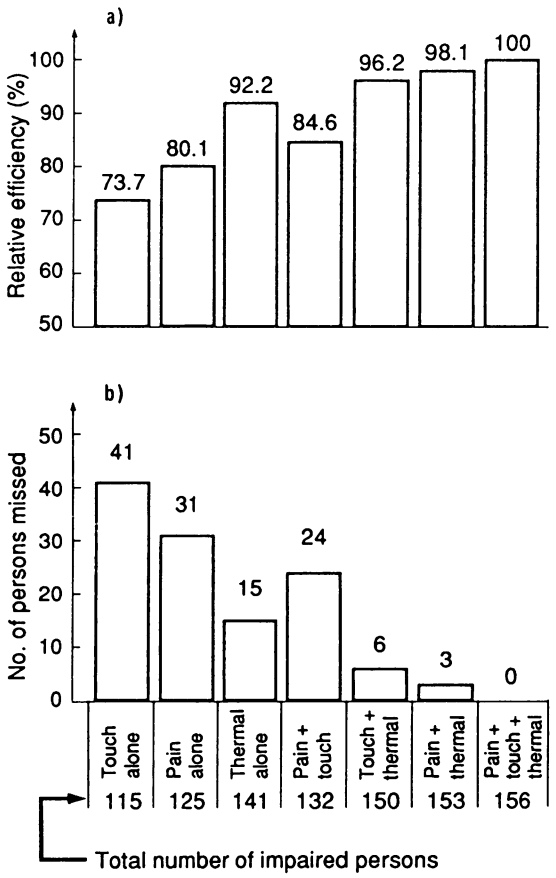


Discussion

Successful leprosy control depends on effective multidrug therapy (*8–10*) and early diagnosis of all cases. The present study was therefore carried out to find answers to the following questions. (1) To what extent would the addition of thermal sensibility testing (using the device described) increase the rate of diagnosis of leprosy in the field by identifying cases of isolated impairment of thermal sensibility in skin lesions? (2) Is it feasible to use the device for this purpose in the field?

The device was therefore tested by different

Fig. 7. *a)* **Relative efficiency of tests for touch, pain, and thermal sensibility when the total number of impaired persons found by all three tests combined (156) was set at 100%.** *b)* **Distribution of the number of impaired persons missed by testing for various modalities of sensibility.**



persons in various parts of the world under a variety of field conditions in a multicentre trial in which participants were requested to carry out thermal sensibility testing in addition to the other sensibility tests that they routinely used in the field. The results obtained indicate that the use of a practicable procedure to test the thermal sensibility of skin lesions, in addition to the other methods of sensibility testing routinely used in the field, could improve the rate of diagnosis of leprosy and bring more patients under effective treatment.

Performance of the thermal sensibility tester

All the investigators reported that the prototype III of the tester performed satisfactorily. It was easy to carry and its use made thermal sensibility testing simple and feasible in the field. The dimensions of the warm end (diameter, 7 mm; area, 38.5 mm^2) made it suitable for testing all but the smallest lesions. Power consumption was not excessive, and ordinary leak-proof pen torch cells, which were available in most of the centres, needed to be changed only after testing 50–70 persons, depending on the type of battery and the ambient temperature. However, at low ambient temperatures ($\leq$10–15 °C) the device took longer to warm up and the drain on the batteries was heavy, making it difficult for some types to deliver the current needed. This problem can be solved by using rechargeable cells, which in any case, are to be preferred for reasons of cost and other considerations. Use of rechargeable batteries increases the purchase price by approximately US$ 25 (the cost of a battery charger, two sets of two rechargeable batteries, and a battery checker). The thermal sensibility tester itself costs about US$ 35. However, a set of rechargeable batteries can be charged over 500 times, i.e., two sets of such batteries can be used for over 50 000 examinations at the rate of 50 examinations per charge. The cost of electricity to charge the batteries 1000 times (approximately US$ 2) together with that of the charger and battery checker amount to US$ 27, and hence the cost per examination is only US$ 0.00054. In contrast, if nonrechargeable batteries are used (cost: US$ 1.00 per set) and 70 examinations are obtained per set, the cost per examination is approximately US$ 0.014. Thus, the use of rechargeable batteries enables the cost to be reduced by a factor of about 26, as well as markedly reducing the problem of waste disposal of the used batteries.

When the tester was used at ambient temperatures greater than 40 °C, difficulties were experienced since the temperature difference between the "cold" and "warm" ends (the basis of the test) was then not always easy for patients to distinguish.

Advantages of using thermal sensibility testing

Although it might be expected that use of thermal sensibility tests would increase the number of individuals with impaired thermal sensibility who are identified, previously there was no way of quantifying this figure.

In the study, the routine tests for light touch and pinprick pain identified 132 persons (Table 4: patterns 1–6) with sensory impairment and 72 (patterns 7 and 8) with no such impairment. The results of thermal sensibility testing carried out using the device we have described indicated that 24 of these 72 persons (33%) did, in fact, have impaired (thermal) sensibility (pattern 7). Inclusion of thermal sensibility testing thus led to a substantial increase in the rate of diagnosis (from 132 to 156, i.e., by about 18%). It therefore appears that the rate of leprosy diagnosis could be increased by about 10–20% by including thermal sensibility testing along

with the other diagnostic tests routinely used in the field for this disease.

Comparison of the relative efficacy of touch and thermal sensibility testing indicates that, of the 156 persons who exhibited sensory loss, only 115 (73.7%) were identified by testing for perception of touch, whereas by testing for thermal sensibility 141 persons (90.4%) were identified, i.e., an increase in the rate of diagnosis of 16.7% (Table 4). It should also be noted that of the 150 persons identified with impairment of light touch or thermal sensibility (patterns 1–3 and 5–7), isolated loss of light touch sensibility was exhibited only by nine individuals (patterns 2 and 6), while this modality was intact in as many as 35 (patterns 3 and 7).

The pinprick pain perception test is commonly used in the field to identify sensory impairment in lesions suspected to be due to leprosy. Comparison of the relative efficacy of pinprick and thermal sensibility tests indicates that of the 156 persons who exhibited loss of one or other of all these modalities, 125 (80.1%) had lost perception of pain, whereas 141 persons (90.4%) exhibited impaired thermal sensibility. Furthermore, the data in Table 4 indicate that 12 persons had lost only perception of pinprick pain (patterns 2 and 4), while 28 exhibited only loss of thermal sensibility (patterns 5 and 7). Use of thermal sensibility testing alone would not have detected the former 12 cases, while the pinprick test alone would not have detected the latter 28. Also, a substantial number of lesions that were negative in pinprick tests, i.e., no loss of pain, exhibited impaired thermal sensibility. The pinprick test, which has the merit of being extremely cheap and simple to perform, should nevertheless continue to be used.

Conclusion

The results of this multicentre field trial indicate that the addition of thermal sensibility testing increased the relative efficiency of leprosy diagnosis by up to 25%, depending on which combination of tests was used. The prototype III of the thermal sensibility tester is therefore a suitable instrument for use in the field for this purpose.

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Résumé

Diagnostic de la lèpre: appareil pour évaluer la sensibilité thermique des lésions cutanées sur le terrain

Un appareil pratique pour évaluer la sensibilité thermique a été mis au point et essayé dans cinq centres antilépreux. Ce petit instrument de la taille d'un stylo, qui fonctionne sur piles, possède une sonde de 7 mm de diamètre. Lorsque le contact est mis, la sonde est portée à 60° en 15 secondes environ. La température est réglée par un élément semi-conducteur, spécialement conçu à cette fin.

Les résultats des essais ont montré que l'appareil est robuste, qu'il fonctionne de façon satisfaisante et qu'il permet d'évaluer facilement la sensibilité thermique sur le terrain. Les essais ont été menés en Afrique et en Inde sur un total de 260 sujets des deux sexes et de tous âges. Parmi les personnes examinées figuraient des lépreux confirmés, qui présentaient un nombre variable de lésions cutanées plus ou moins anciennes, ainsi que des cas "suspects". Outre la sensibilité thermique, on a évalué également la sensibilité à la douleur et au toucher.

L'analyse des résultats obtenus chez les sujets examinés, dont la plupart ne présentaient que quelques lésions lépreuses, montre qu'il y a eu augmentation du taux de diagnostic des pertes de sensibilité au niveau des lésions cutanées, et par voie de conséquence du taux de diagnostic de la lèpre. On a calculé que l'évaluation de la sensibilité thermique à l'aide de cet appareil, jointe aux autres tests de sensibilité couramment pratiqués sur le terrain, améliorait de 15 à 25% le taux de diagnostic de la lepre. L'utilisation régulière de cet appareil sur le terrain devrait donc amener un plus grand nombre de lépreux à recevoir le traitement dont ils ont besoin.

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