



Australian Government
Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

ANZHSN

AN INITIATIVE OF THE NATIONAL, STATE AND
TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

National Horizon Scanning Unit

Horizon scanning prioritising summary

Volume 10, Number 1:

**Temptouch[®]: Infrared thermometer device
for prevention of foot ulcers in people with
diabetes.**

September 2005



© Commonwealth of Australia 2005

This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use or use within your organisation. Apart from any use as permitted under the Copyright Act 1968, all other rights are reserved. Requests and inquiries concerning reproduction and rights should be addressed to Commonwealth Copyright Administration, Attorney General's Department, Robert Garran Offices, National Circuit, Canberra ACT 2600 or posted at <http://www.ag.gov.au/cca>

Electronic copies can be obtained from <http://www.horizonscanning.gov.au>

Enquiries about the content of this summary should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

DISCLAIMER: This summary is based on information available at the time of research and cannot be expected to cover any developments arising from subsequent improvements to health technologies. This summary is based on a limited literature search and is not a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered.

The Commonwealth does not guarantee the accuracy, currency or completeness of the information in this summary. This summary is not intended to be used as medical advice and it is not intended to be used to diagnose, treat, cure or prevent any disease, nor should it be used for therapeutic purposes or as a substitute for a health professional's advice. The Commonwealth does not accept any liability for any injury, loss or damage incurred by use of or reliance on the information.

The production of this *Horizon scanning prioritising summary* was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This *Horizon scanning prioritising summary* was prepared by Adriana Parrella, Janet Hiller and Linda Mundy from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Department of Public Health, Mail Drop 511, University of Adelaide, South Australia, 5005.

PRIORITISING SUMMARY

REGISTER ID: 000170

NAME OF TECHNOLOGY: TEMPTOUCH®

PURPOSE AND TARGET GROUP: INFRARED THERMOMETER DEVICE FOR PREVENTION OF FOOT ULCERS IN PEOPLE WITH DIABETES

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|--|-------------|
| <input type="checkbox"/> Yes | ARTG number |
| <input checked="" type="checkbox"/> No | |

TempTouch® is not currently available in Australia. The TempTouch® device was approved by the Food and Drug Administration for use in the United States in March 2005.

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓		

IMPACT SUMMARY:

Xilas Medical Inc. manufactures the TempTouch® Dermal Thermometer for measuring foot skin temperature in diabetic patients with the aim of detecting early inflammation and preventing diabetic foot ulcers.

BACKGROUND

Diabetic patients are at increased risk of peripheral vascular disease (PVD) due to reduced blood supply to the legs and feet. Patients may be asymptomatic or experience pain at movement or rest. PVD may result in leg and foot ulcers and, when severe, may lead to lower limb amputation. Diabetes accounts for almost half of all non-traumatic lower limb amputations in Australian hospitals and may also lead to further amputation as the remaining limb is at increased risk of poor circulation and ulceration (AIHW 2002).

Previous studies have suggested that an increase in foot skin temperature may be indicative of the development of foot ulcers (Armstrong et al 1997). The TempTouch® Dermal Thermometer is an

infrared, dermal thermometer intended for the intermittent measurement of foot skin surface temperature of diabetic people (Xilas Medical Inc.2005).

The TempTouch[®] (Figure 1) is a small, handheld probe designed for home use by patients. The user places the tip of the device on the skin and temperature measurements are taken automatically. If an increased temperature measurement between corresponding sites of the left- and right- foot is detected by TempTouch[®], patients are advised to alter their behaviour by reducing their level of activity and to seek a professional clinical evaluation (personal communication).



Figure 1. TempTouch[®] Device (Printed with permission, Xilas Medical, 2005)

In addition, Xilas Medical Inc. provides the TempTouch RM[®] device for patients with vision or movement disabilities. TempTouch RM[®] (Figure 2) is a bathroom scale-like device that detects temperatures across the breadth of both feet, loading the data into an on-board computer (Xilas Medical, Inc. 2005).



Figure 2 TempTouch RM[®] Device (Printed with permission, Xilas Medical, 2005)

CLINICAL NEED AND BURDEN OF DISEASE

It is estimated that approximately one million people suffer from the three types of diabetes (Type-1, Type-2 and gestational diabetes) in Australia (AIHW 2005). The Australian National Diabetes Information Audit and Benchmarking data for 2002 reported a 2.2% prevalence of current foot ulcers among adult patients attending diabetes clinics. In addition, 4.9% of patients had a past history of foot ulceration (NADC 2003). It has been estimated that 19% of people with known and newly diagnosed diabetes are at risk of foot ulcer. The majority (86.5%) of patients with a current foot ulcer had a past history of foot ulceration (NADC 2000). Also indicative of potential foot problems, peripheral vascular disease was reported in 13.5% of persons with diabetes (NADC 2003).

During 1999–00 a total of 3,404 amputations of lower extremities and/or limbs were performed for patients with diabetes (AIHW 2002, p68). Males with diabetes were more than twice as likely to have a lower extremity amputation than females. Hospitalisation for diabetes-related amputation increases with age. The average length of hospital stay for diabetes-related lower extremity amputation was 27.5 days (AIHW 2002, p68).

DIFFUSION

The TempTouch[®] is intended for home use and such would be made available to patients on an individual basis. Although the device is not yet available in Australia, the manufacturer intends to release TempTouch[®] into the Australian market in the near future (personal communication, Xilas Medical, Inc. representative).

COMPARATORS

Assessment of the diabetic patient's feet should include the detection of peripheral neuropathy, vascular disease, deformities which may predispose to ulceration, identification of active lesions (ulceration or infection in particular) and the observation of gait and footwear (Campbell et al 2000).

Simple testing of touch, pain, temperature, vibration sense and ankle jerks can be performed by the clinician, however vibration sense can be better assessed quantitatively with a biothesiometer. The presence of protective sensation can be determined by use of the Semmes-Weinstein monofilament. The Semmes-Weinstein monofilament delivers 10 g pressure and is recommended for identifying "at risk" feet as those which fail to register the pressure at one or more testing sites on the plantar surface (Campbell et al 2000).

EFFECTIVENESS AND SAFETY ISSUES

A randomised controlled trial by Lavery et al (2004) assessed the use of the TempTouch[®] in a group of diabetic patients considered at high risk of foot complications (level II intervention evidence). High-risk patients were defined as having a history of foot ulceration or a previous lower-extremity amputation or with peripheral sensory neuropathy and a loss of protective sensation. There were no significant differences between patient characteristics (age, duration of diabetes, severity of neuropathy or diabetic risk category) assigned to standard treatment (n=44) group or the TempTouch[®] intervention group (n=41). Patient follow up was six months and included a podiatry evaluation every 10-12 weeks.

Both groups received standard care consisting of therapeutic footwear, education and foot evaluation by a podiatrist every 10-12 weeks. It is not stated whether the podiatrist was blinded to the intervention group however the treating physician was blinded to treatment group. In addition, the intervention group used the TempTouch[®] probe to measure temperature on the sole of the foot in the morning and evening. Six predetermined sites were measured on each foot and temperatures were recorded in a log book. The patients were advised to contact a nurse if the temperatures between the left and right sites differed $>4^{\circ}\text{F}$ ($\sim 2.2^{\circ}\text{C}$) and to reduce mobility in the following days until temperature differences decreased to $<2.2^{\circ}\text{C}$.

Patient outcomes are reported in Table 1. There were significantly ($p=0.01$, OR 10.3, 95%CI 1.2, 85.3) fewer foot complications in patients who monitored their feet with the TempTouch[®] compared to the patients in the standard therapy group. Two patients in the standard therapy group developed infections and required foot amputations. There were no infections, fractures or

amputations in the patients using the TempTouch[®]. The patient in the TempTouch[®] intervention group who developed a foot ulcer failed to contact her health care provider over 21 consecutive days when there were temperature differences >2.2°C recorded.

Although these results suggest effectiveness, they may be influenced by patients changing activity levels in the TempTouch[®] and/or seeking a clinical evaluation by the study nurse when temperature differences were noted. There were a total of seven patients who dropped out of the study: three in the standard therapy group and four in the TempTouch[®] group.

Table 1. Patient Outcomes

Outcomes	Standard therapy (n=44)	Standard therapy + TempTouch [®] (n=41)
Foot ulceration	7/44 (15.9%)	1/41 (2.4%)
Charcot fracture	2/44 (4.5%)	0/41 (0%)
Total	9/44 (20.5%)	1/41 (2.4%)

The manufacturer has conducted a further (unpublished) study (level III-2 intervention evidence) of 180 patients with a follow-up period of 15 months (personal communication, Xilas Medical Inc. representative, commercial in confidence). The three treatment arms included a standard therapy group, TempTouch[®] therapy group and a structured foot evaluation group. The standard therapy group received therapeutic shoes and insoles, patient education and regular foot evaluations by a physician every eight weeks. The TempTouch[®] therapy group received standard therapy plus home temperature assessment with the TempTouch[®]. The structured foot evaluation group performed a structured foot evaluation to identify local signs of tissue injury, redness, discoloration, swelling, and local warmth twice a day in addition to receiving standard therapy. These patients were also given used a hand mirror to better visualise their feet if required. Significantly lower diabetic foot complications were reported in the TempTouch[®] group compared to the two other groups (personal communication, Xilas Medical Inc. representative, commercial in confidence).

A cost evaluation was included in the above study and included the cost of clinic visits, procedures, therapeutic shoes and insoles, temperature devices, medications, diagnostic studies, hospitalisations, and supplies used by patients in the three treatment groups. Preventive care costs were higher and ulcer care costs were lower in the TempTouch[®] group, compared to the two other intervention groups (personal communication, Xilas Medical Inc. representative, commercial in confidence). It is not clear whether this evaluation will be published.

COST IMPACT

The TempTouch[®] costs \$US 150 and is indicated for home use.

Diabetes-related foot problems are costly as they constitute the most common reason for hospital admission for people with diabetes, and are associated with a high rate of recurrence, morbidity and mortality.

A study conducted in 1994 estimated that the hospitalisation cost, in Australia, for a diabetic foot ulcer was \$AUD 12,474, while outpatient treatment of an ulcer by a specialist foot care team was 85% less. (Campbell et al 2000). The costs associated with lower-limb amputation are estimated at double these costs although the actual cost items are not included (Campbell et al 2000).

It is likely that a reduction in the number of foot ulcers and diabetes-related foot complications and the subsequent morbidity and adverse outcomes such as amputation would produce a significant cost savings.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

The authors of both studies presented in this prioritising summary include clinical advisors and employees of Xilas Medical, Inc.

CONCLUSION:

Diabetes in Australia is a significant public health issue. The detection, monitoring and treatment of diabetes may result in considerable costs to patients and public health expenditure. In particular, there is a current emphasis on promoting home monitoring systems in the management of chronic conditions such as diabetes and in reducing associated public health costs. The TempTouch[®] device may provide an additional tool for diabetic patients in managing foot complications, especially in rural situations and may save a number of amputations.

HEALTHPACT ACTION:

This device is designed for home use and as such is unlikely to be funded by the public health system in Australia. Therefore it is recommended that this technology be archived.

LIST OF STUDIES INCLUDED

TOTAL

Total number of studies	
Level II intervention evidence	1
Level III-2 intervention evidence (unpublished)	1

SOURCES OF FURTHER INFORMATION:

AIHW (2002). *Diabetes: Australian facts 2002* [Internet]. Australian Institute of Health and Welfare. Available from: <http://www.aihw.gov.au/publications/cvd/daf02/daf02-c04.pdf> [Accessed 18th May 2005].

AIHW (2005) *Diabetes* [Internet] Available from: <http://www.aihw.gov.au/diabetes/index.cfm> [Accessed 18th May 2005].

Armstrong, D. G. & Lavery, L. A. (1997). 'Predicting neuropathic ulceration with infrared dermal thermometry', *J Am Podiatr Med Assoc*, 87 (7), 336-337.

Armstrong, D. G., Lavery, L. A. et al (1997). 'Infrared dermal thermometry for the high-risk diabetic foot', *Phys Ther*, 77 (2), 169-175; discussion 176-167.

Armstrong, D. G., Lavery, L. A. et al (2003). '2003 William J. Stickel Silver Award. Skin temperatures as a one-time screening tool do not predict future diabetic foot complications', *J Am Podiatr Med Assoc*, 93 (6), 443-447.

Campbell, L. V., Graham, A. R. et al (2000). 'The lower limb in people with diabetes. Position statement of the Australian Diabetes Society', *Med J Aust*, 173 (7), 369-372.

Colman, P. G. & Beischer, A. D. (2000). 'Lower-limb amputation and diabetes: the key is prevention', *Med J Aust*, 173 (7), 341-342.

Lavery, L. A., Higgins, K. R. et al (2004). 'Home monitoring of foot skin temperatures to prevent ulceration', *Diabetes Care*, 27 (11), 2642-2647.

NADC (National Association of Diabetes Centres) 2003. *ANDIAB 2002. Australian National Diabetes Information Audit & Benchmarking*. Canberra: National Association of Diabetes Centres.

NADC (National Association of Diabetes Centres) 2000. *ANDIAB 2000. Australian National Diabetes Information Audit & Benchmarking*. Canberra: National Association of Diabetes Centres.

Xilas Medical Inc. (2005) *XILAS Medical, Inc. - Products* [Internet] Available from: <http://www.xilas.com/products-TempTouch.html> [Accessed 18th May 2005].

SEARCH CRITERIA TO BE USED:

Amputation/ statistics & numerical data

Diabetic Foot/economics/physiopathology/prevention & control/surgery

Diabetic Foot/etiology/ prevention & control/ surgery

Podiatry

Skin Temperature