Original Article

DOI: 10.5582/ddt.2022.01050

Development of a self-monitoring tool for diabetic foot prevention using smartphone-based thermography: Plantar thermal pattern changes and usability in the home environment

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SUMMARY Thermography is a well-known risk-assessment tool for diabetic foot ulcers but is not widely used in the home setting due to the influence of the complicated home environment on thermographic images. This study investigated changes in thermographic images in complicated home environments to determine the feasibility of smartphone-based thermography in home settings. Healthy volunteers (age > 20 years) were recruited and required to take plantar thermal images using smartphone-based thermography attached to a selfie stick at different times of the day for 4 days. The thermal images and associated activities and environmental factors were then analyzed using content analysis. Areas with the highest temperature on the plantar thermal images were described and categorized. Device usability was evaluated using 10-point Likert scales, with 10 representing the highest satisfaction. A total of 140 plantar thermal images from 10 participants were analyzed. In 12 classifications, the three commonest patterns based on the highest temperature location were medial arch (42.1%), whole plantar (10.7%), and forefoot and medial arch (7.9%). The medial arch pattern is most frequently seen after awakening (67.5%) compared to other time points. Device usability was rated 7.5 out of 10 on average. This study was the first to investigate the plantar thermal patterns in the home settings, and the medial arch pattern was the most common hot area, which matches previous findings in well-controlled clinical settings. Therefore, smartphone-based thermography may be feasible as a self-assessment tool in the home setting.

Keywords Diabetic foot ulcer, home monitoring, home nursing care, prevention care, self-management

1. Introduction

The diabetic foot ulcer (DFU) is one of the major complications of diabetes. It contributes to high amputation and mortality rates, presenting an enormous economic burden, both on community as well as patients and their families (*1-3*). Interim foot self-management between regular podiatry care sessions could enable timely identification and treatment of pre-ulceration signs (*1,4,5*). Foot skin-temperature monitoring is a recommended self-management tool that has proved effective in preventing DFUs, using identification of inflammation (*6*).

Over the past two decades, many skin-temperature monitoring self-management devices have been developed, including infrared dermal thermometry (*7-12*), remote temperature monitoring systems (*13,14*), and temperature sensor devices (*15-17*). Moreover, to detect problem areas typically masked by sensory neuropathy, thermographic devices can visualize skin temperature as a map, helping patients better understand their condition and thereby improve adherence (*20,21*). However, due to stringent environmental requirements and high cost, thermography is only used for diagnostic assessment in well-controlled clinical settings (*22-24*).

Recent technological advances have facilitated the development of high-quality, clinically validated (*25,26*), inexpensive smartphone-based thermography tools. We proposed a smartphone-linked thermal imaging camera (FLIR ONE Gen 3, Teledyne FLIR LLC, Wilsonville, OR) on a selfie stick as a self-assessment tool for patients at high-risk for DFUs, testing the prototype on two older adults with diabetes. One participant found the tool difficult to use due to unfamiliarity with smartphones. The other successfully self-assessed his plantar region, but showed no signs of inflammation during the study period (*27*). However, it is unclear as to the extent to which the usability concerns of patient 1 or their complex home environment impacted on the device's feasibility. Factors such as ambient temperature or the patient's daily activities could have affected the thermograms (*28,29*). Because localized areas of increased temperature serve as warning signs for latent inflammation (*30,31*), environmental factors may cause misclassification by creating variance in temperature readings. Therefore, understanding how the home environment could affect thermographs is necessary to better enable its use. Although previous studies classified plantar thermal patterns based on plantar angiosome types (*24,32*), and variations of plantar temperatures in post-exercise thermograms in a clinical setting (*33*), no study has investigated plantar thermal patterns in a home environment.

This study aimed to investigate thermographic changes in plantar temperature distributions in healthy participants to control for pathological variance, to determine whether the home environment affects the thermal images, to assess the feasibility of the use of the novel device, and to identify the minimal environment prerequisites for the use of thermography in the home environment. Furthermore, we investigated the usability of the modified device set.

2. Methods

2.1. Study design and participants

This study, conducted from February to March 2021, recruited healthy adult volunteers (age > 20 years) using the snowball sampling method. Individuals with a diagnosis of angiopathy or with an existing foot wound were excluded.

2.2. Study variables and measurements

The main outcomes were changes to the participants' plantar thermographs, self-obtained by using smartphone thermography devices in their home. Data on participants' baseline characteristics, thermography-related variables, and usability-related variables were collected *via* a customized self-reported questionnaire. Participant-related characteristics included age, sex, body mass index (BMI), presence of callus(es), callus site, presence of dry skin, foot deformity, foot photos, and smoking. Thermography-related variables included the characteristics of the home environment, including ambient temperature, humidity, type of floor, use of heating devices, shoe type. This also included activities undertaken immediately before thermography such as smoking, drinking, standing, sitting, and exercising. The timing of the thermographs was determined, such as after waking, after returning home, after showering or bathing, and before bed, along with main daily activities and daily steps.

Device usability was evaluated using a questionnaire for obtaining information regarding usability-related variables, such as ease of use, adherence, and their main problems with the device, on a 10-point Likert scale (score range: 0-10, with 10 indicating the highest satisfaction with the provided device set).

This study used a modified prototype set, which included an extension cord to connect the smartphone to FLIR ONE (*27*) that enabled easier control and angle adjustment during thermography (Figure 1); FLIR ONE Gen 3-IOS thermal imaging camera [FLIR® Systems, Inc.] attached to a 100-cm selfie stick [Elecom P-SSB01RWH, Elecom Co., Ltd., Osaka, Japan] and connected to a smartphone [iPhone SE 2nd generation, Apple Inc., CA, USA] with an extension cord [F.Wave concept, F.Wave Corp., Tokyo, Japan]).

Photographs of feet were taken with a digital camera (Panasonic DMC-FX70, Panasonic Corp., Osaka, Japan). Ambient temperature and humidity were measured with Tanita TT-558 GY Thermo-Hygrometer (TANITA Corp., Tokyo, Japan). Daily steps were measured with

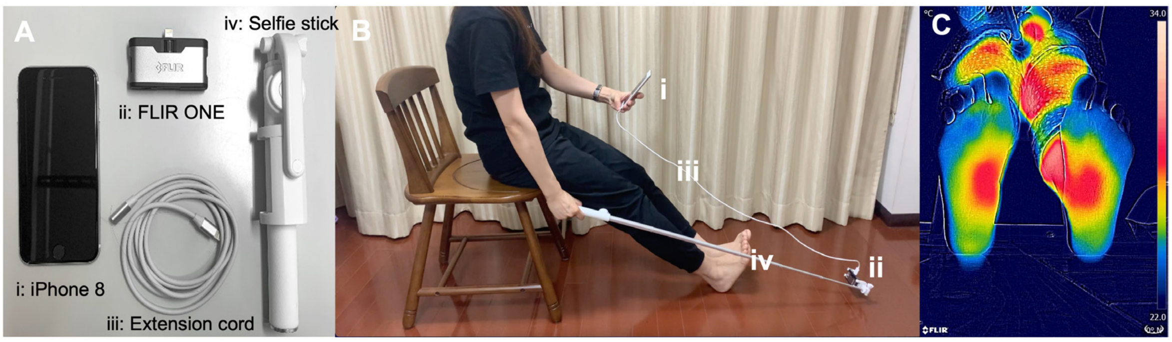

Figure 1. Demonstration of the use of the self-monitoring thermography set. The components of the set are show in picture **A**, including a smartphone (iPhone 8) (i), a smartphone-based thermography FLIR ONE (ii), an extension cord (iii) to connect the phone and the thermography, and a selfie stick (iv) to control the angle of the thermography. Picture **B** shows the demonstration of the use of the set, and the taken thermographic image (**C**).

a pedometer (OMRON HJ-325-W, Omron Co., LTD, Osaka, Japan).

2.3. Procedures

On the initial day of recruitment, all participants were given the device set and followed the researcher's instructions to practice obtaining thermographs. The researcher adjusted the distance between FLIR ONE and the plantar surface and marked the distance on the selfie sticker for participants to use as a reference when obtaining thermographs at home. Photographs of the participants' feet were taken, and the participants took the device set and instructions home for 1 week. Participants were required to use the device to take thermographs of their foot sole at home for 4 days, at least twice per day, including before going to bed and after waking up. Furthermore, they were required to fill out questionnaires that included items such as thermal image-associated home-environment and activities. After 4 days participants were asked to fill out another questionnaire on usability of the device.

2.4. Data analyses

Participant characteristics were summarized, and responses to the questionnaire on device usability were described as numbers and percentages. The acquired thermographic images were analyzed qualitatively as follows. Thermographic images were arranged on the time axis, including the home environment and physical activities, characteristics of thermographic patterns as descriptions of the plantar area with the highest temperature, activity-related events, and the home environment before obtaining the thermographic images were independently converted sequentially into text by two researchers. The content summarized by the two researchers was compared, and consensus was reached in cases of any disagreement. Then, content analysis was conducted to determine the relationship between the thermographic images and related variables. The core phrases were extracted as meaning units from the descriptive texts for each participant and summarized in a cross table. Thermographic patterns were then classified based on the connected phrases before them – namely, the time of thermography. Each connected phrase became a category of thermographic patterns. Thereafter, the frequency of each thermographic pattern was determined as numbers and percentages. The most frequently described thermographic patterns, overall and in each category, were counted as common patterns. Next, rare patterns were identified, and other environmental characteristics in addition to the aforementioned categories were searched in the raw data, summarized, and then qualitatively described as the environment to be avoided during thermography.

2.5. Ethical consideration

This study was approved by the Research Ethics Committee of the Graduate School of Medicine, The University of Tokyo, Tokyo, Japan (No. 2020275NI). Written informed consent was obtained from all participants before their enrolment in this study.

3. Results

3.1. Participant characteristics

Participant characteristics and information related to the home environment are shown in Table 1. Among the 10 participants (age 30.3 ± 5.6 years [mean ± SD]; BMI 21.06 ± 1.9 kg/m^2), four were male and six were female.

3.2. Representative case description

The changes in participants' thermal patterns over time during the survey period were verbally described as follows, with the thermographic pictures arranged on a

Table 1. Participants' characteristics and home settings

ID	Age	Sex	BMI (kg/m^2)	Presence of callus(es)	Pain on callus	Dry skin (Sole)	Foot deformity	Smoking behavior	Floor type	Indoor shoes
01	36	F	21.9	5th MTH on both feet	Painless	No	No	No	Wood	Socks or barefoot
02	23	M	19.6	1st toe, 2nd MTH on both feet	Painless	No	Hallux valgus on both feet	No	Wood	Barefoot
03	30	M	24.7	No	/	No	No	No	Wood	Barefoot
04	29	M	22.7	No	/	No	No	No	Carpet	Barefoot
05	27	M	19.8	No	/	No	No	No	Carpet	Barefoot
06	40	F	21.7	No	/	No	No	No	Wood	Barefoot
07	35	F	22.5	2nd MTH on both feet	Painless	No	Hallux valgus on left feet	No	Wood	Fluffy indoor boots
08	24	F	18.6	2nd MTH on both feet	Painless	No	No	No	Wood with heating	Barefoot
09	33	F	19.6	2nd MTH on both feet	Painless	No	Hallux valgus on both feet	No	Wood	Slippers
10	26		19.5	No	/	No	No	No	Wood	Socks and slippers

M, Male; F, Female; BMI, body mass index; MTH, metatarsal head.

time axis (Figure 2).

Case 1 was a 36-year-old female participant (BMI 21.9 kg/m^2). She had painless calluses on the lateral first toe and the 5th metatarsal head (MTH) on both feet. Her home had wooden flooring; she walked barefoot at home most of the time; and kneeled on the floor sometimes. On the first day of survey, she stayed home for remote work and mostly did desk work. She arose at 6:30 in the morning, assumed Seiza (a formal position of sitting in Japan) for 18 minutes, and then took one thermograph of her feet when she experiences feet numbness. The temperature was 13.7°C, and the humidity was 36%. Thermographs showed the highest temperatures on the midfoot and heel in both feet. She then started her day of remote work, with a daylong seminar until 5:30 pm. Most of the time, she sat on the floor with a blanket to warm her legs; ambient temperature was 16.6°C, and the humidity was 36%. The thermograph obtained after sitting the whole day showed the highest temperature in the midfoot region. She took a 15-minute bath. After the bath, the highest temperature shifted from the midfoot to forefoot region; ambient temperature was 17.0°C, and the humidity was 39%. She did some stretches after the shower and went to bed, before which she felt cold; the room temperature was 17.5°C, and the humidity was 40%. The temperature on the forefoot decreased, and the midfoot region regained the highest temperature again. She walked 1,513 steps from the time she got up until she went to sleep.

3.3. Classifications of change in thermographic images

Based on the description of highest temperature of the foot plantar aspect on the thermal images, the sites of highest temperature were separated into five areas: forefoot (toe and MTH), toe, MTH, arch, and heel; 12 types of thermal patterns were classified. The representative thermal images for each thermal pattern and the illustration for each pattern are shown in Figure 3. The patterns were named based on the combination of the highest temperature areas.

The overall pattern distributions and those at different times of the day are shown in Table 2. The top three common patterns were medial arch (42.1%), whole plantar (10.7%), and forefoot and medial arch

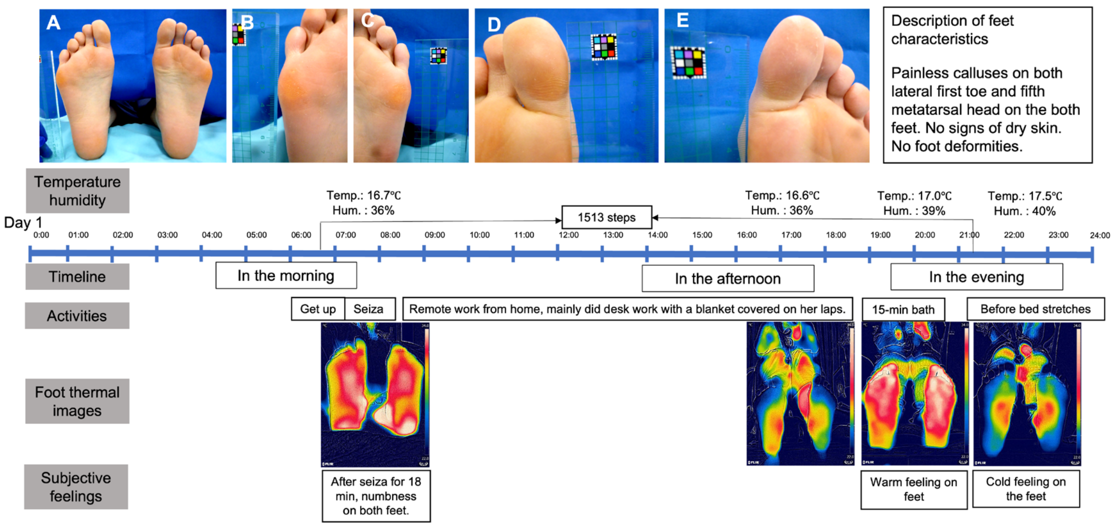

Figure 2. One example of case summary from ID1. Photos of foot plantar (**A**) and foot calluses (**B, C, D, E**) were taken before starting the survey. The descriptions of feet are shown on the right side of the foot photos. Information including temperature, time, activities before taking thermal images and subjective feelings while taking thermal images are displayed under the photos.

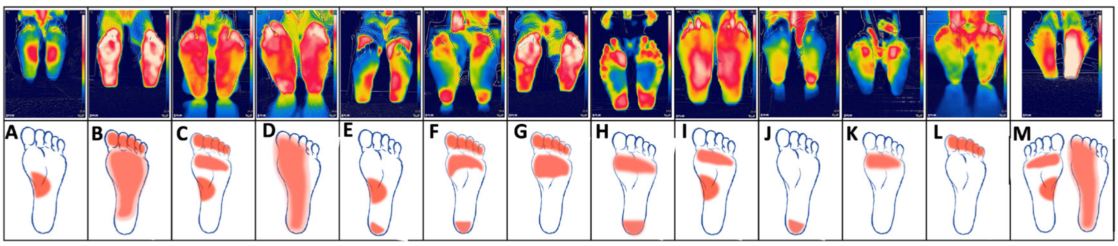

Figure 3. Representative images of thermal patterns. Patterns were named based on the highest temperature area of the plantar on the thermal images. The images on the top are representative images for each pattern, and the images on the bottoms are conceptual images where orange color indicates higher temperature. Pattern **A**: medial arch; Pattern **B**: whole plantar; Pattern **C**: forefoot and medial arch; Pattern **D**: medial plantar; Pattern **E**: medial arch and heel; Pattern **F**: forefoot and heel; Pattern **G**: forefoot; Pattern **H**: MTH (metatarsal head) and heel; Pattern **I**: MTH and medial arch; Pattern **J**: heel; Pattern **K**: MTH; Pattern **L**: toe; Pattern **M**: asymmetric.

(7.9%). Medical arch pattern was most frequently seen in the morning after getting up and staying indoors. Thermal patterns in the afternoon varied by activities. After walking, increased forefoot and medial arch (18.5%) and medial plantar (18.5) patterns were noted, whereas when remaining indoors, the medial arch had the highest temperature. In the evening, after bathing and before bed showed an increased number of whole plantar pattern (21.4%) and asymmetric patterns (22.9%).

Most of the patterns were symmetric; however, there were 16 (11.4%) asymmetric thermal images (Table 3). Half of the asymmetric thermal images were taken before bed, 18.8% were after getting up, 18% were after outdoor walking, and 12.5% were after taking a bath.

Some atypical patterns were found in different participants. A few representative thermal images are shown in Figure 4. Two were taken before bed, and one was obtained after getting up.

3.4. Results of usability evaluation

The results of questionnaires related to usability are shown in Table 4. The main problem in the use of the device set concerned the selfie stick and extension cord. One participant wrote "the selfie stick was difficult to extend". Two participants wrote "bluetooth control would be better than an extension cord". To improve adherence for self-monitoring, participants wrote "one measurement per day is preferrable", "it would be better if you can set the camera angle still because sometimes the camera angle changes easily", "having an alarm reminder would be helpful", "instead of using a selfie stick, a tripod might be better for older adults". In other suggestions, one participant wrote "being able to check on the photo prior to taking the thermograph to make sure my feet were in frame was easier. It

Table 2. Thermal pattern distribution at different times of the day

Pattern	Total	Morning N (%)	Afternoon N (%)			Evening N (%)	
		After getting up	Indoor	After outdoor walking	After biking	After bathing	Before bed
Medial arch	59 (42.1)	27 (67.5)	4 (80.0)	10 (37.0)	2 (40.0)	7 (25.0)	9 (25.7)
Whole plantar	15 (10.7)	2 (5.0)	0 (0.0)	1 (3.7)	0 (0.0)	6 (21.4)	6 (17.1)
Forefoot and medial arch	11 (7.9)	1 (2.5)	0 (0.0)	5 (18.5)	0 (0.0)	4 (14.3)	2 (5.7)
Medial plantar	8 (5.7)	3 (7.5)	0 (0.0)	5 (18.5)	0 (0.0)	0 (0.0)	0 (0.0)
Medial arch and heel	8 (5.7)	3 (7.5)	0 (0.0)	1 (3.7)	0 (0.0)	0 (0.0)	4 (11.4)
Forefoot and heel	7 (5.0)	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)	3 (10.7)	3 (8.6)
Forefoot	6 (4.3)	0 (0.0)	0 (0.0)	1 (3.7)	2 (40.0)	3 (10.7)	0 (0.0)
MTH and heel	3 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)	1 (3.6)	1 (2.9)
MTH and medial arch	2 (1.4)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.6)	0 (0.0)
Heel	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (5.7)
MTH	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.6)	0 (0.0)
Toe	1 (0.7)	0 (0.0)	1 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asymmetric	16 (11.4)	3 (7.5)	0 (0.0)	3 (11.1)	0 (0.0)	2 (7.1)	8 (22.9)
Total images	140 (100.0)	40 (100.0)	5 (100.0)	27 (100.0)	5 (100.0)	28 (100.0)	35(100.0)

*Number of images varies between participants. **N (%): Number (percentage of the total images). MTH: metatarsal head

Table 3. Asymmetric thermal pattern distribution at different times of the day

Items	Total	Morning N (%)	Afternoon N (%)	Evening N (%)	
		After getting up	After outdoor walking	After bathing	Before bed
Asymmetric patterns in total	16	3 (18.8)	3 (18.8)	2 (12.5)	8 (50.0)
Right medial arch and left medial arch and heel	2			1 (50)	1 (50)
Right toe and medial arch and heel and left toe and medial arch	2				2 (100)
Right medial plantar and left medial arch	1		1 (100)		
Left medial plantar	1			1 (100)	
Left medial arch and heel	1				1 (100)
Right forefoot and heel and left heel	1	1 (100)			
Left 5th MTH	1				1 (100)
Right forefoot and heel and left whole plantar	1				1 (100)
Right MTH and left medial arch	1	1 (100)			
Right forefoot and left medial arch	1	1 (100)			
Right heel	1				1 (100)
Right forefoot and left lateral plantar	1		1 (100)		
Left foot medial arch	1		1 (100)		
Right medial arch and left whole plantar	1				1 (100)

*Number of images varies between participants. **N (%): Number (percentage of the total pattern number).

Table 4. Results of questionnaires related to usability

Questions	Scores* N (%)**								
	0–2	3	4	5	6	7	8	9	10
How easy do you find this device set to use?					2 (20)	3 (30)	3 (30)	2 (20)	
Do you think you can use this device to assess your feet every day?		2 (20)	2 (20)	2 (20)	2 (20)			2 (20)	

*Scale from 0 to 10, and 10 is the highest level in satisfaction and agreement. **N (%): Number and percentage of all answers.

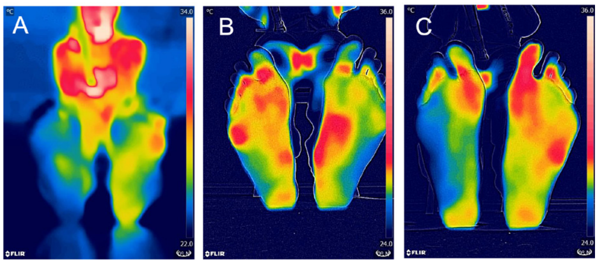

Figure 4. Atypical thermal patterns. A. thermal pattern before bed; **B.** thermal pattern after getting up; **C.** thermal pattern before bed. Thermal images are from different participants.

might be helpful for people with vision problems". All participants could use the device at least once per day during the survey (data not shown).

4. Discussion

This study is the first to investigate thermographic patterns at different times of the day in a home environment to provide information for the use of a novel self-assessment tool for people with diabetes. Thermal images from healthy participants were summarized into mainly 12 symmetric and 16 asymmetric patterns. The commonest pattern, the medial arch pattern, is mostly like to be seen immediately after getting up and indicates that the morning might be the best time for plantar self-assessment.

Thermal patterns at different times of the day and activities prior to the thermal imaging were recorded. We found that the change of thermal patterns is less likely to be affected by activities rather than the time that the thermal images were taken, and thermal patterns in the morning are most consistent compared with those at other times of the day, possibly because of skin blood-flow changes caused by activities (*28*). Skin blood flow is sufficiently relevant as one of the primary factors influencing thermography. Skin blood flow is related to the autonomic nervous system, which controls vasoconstriction and vasodilatation of the capillary vessels to maintain homeostasis. Therefore, other factors such as physical activity may directly correlate with skin blood flow (*29*). In the clinical settings, acclimation time is usually set before taking the thermal images (*31*). However, it could be difficult when considering thermography as a daily assessment tool. Therefore, thermography after getting up is associated with minimal activities, which could provide the most stable and consistent images for the evaluation of the risk of diabetic foot ulcers.

The medial arch pattern is the commonest thermal pattern, with a 42.1% of the thermographic images belonging to this category and was most frequently seen after getting up (67.5%) and staying indoors (80%). This pattern has previously been called the bilateral butterfly pattern and is considered a normal pattern that indicates an overlapping area supplied by the medial plantar and lateral plantar arteries (*34*). This butterfly pattern has been confirmed in 50% (*34*) and 46.9% (*32*) of healthy participants in two studies that investigated plantar thermographic patterns in well-controlled environments. The results suggest that thermal images obtained in the morning can obtain the same information as in a well-controlled environment (*33*).

Nonetheless, 11.4% of thermal patterns from different healthy participants were asymmetric. Asymmetric or low temperature on one side of the foot is usually an indicator of peripheral artery disease in people with diabetes (*36*). However, it was found in healthy participants in this study, which suggested that assessment based on a single thermal image is insufficient to judge the risk of DFUs; thus, assessment of plantar thermal images on a regular basis is more reliable. Assessment of a single foot might generate information bias.

Atypical thermal patterns showed a hotspot on the MTH and heel areas with asymmetric patterns. Hotspot is a sign of early inflammation, and most previous studies used algorithms that relied on a comparison between temperatures in the same region of interest, *e.g.*, MTH, on both feet (*10-13*). This study showed that, in the home environment, many patterns could be mistaken as danger signs, since they also exist in healthy participants. Certain situations should be avoided before taking a thermographic image of the soles such as immediately after waking and showering. Moreover, the algorithm for studies used thermometry, temperature sensors, and thermal mats that could not be applied to smartphone-thermography and which are easily mistaken and cause unnecessary concerns (*23*). Normal patterns are usually restored in the morning, suggesting that if a suspicious hotspot shows on the thermographic image, another one should be obtained the following morning to check whether the hotspot has disappeared. If it does disappear, then it may likely have resulted from activities rather than inflammation. If it does not disappear, then patients could then contact health care professionals or visit them for further examination.

All participants gave a high score on the ease of using the thermography set. However, some improvement is required. Most relate to remembering to use daily and how to take a clear thermographic image. For people who do not have an ulcer, the requirement of taking daily plantar thermal images may be a burden (*37*). To improve adherence, a daily reminder seems to be an easy approach. To improve the user friendliness, personalized adjustment is needed for the use of the thermography set.

This study had several noticeable limitations. First, only 10 participants from a younger healthy population with a low BMI were included. Older adults with diabetes or higher BMI might show different thermal patterns (*24*). Second, all participants had a similar lifestyle of limited home environments and activities; accordingly, it is unclear whether people with more complicated lifestyles would have similar results; this needs to be further investigated. Finally, this study was conducted over a short time period. Therefore, the seasonal effect on the results of this study should be confirmed.

In conclusion, this study provided information for the feasibility of a novel self-assessment tool using smartphone-based thermography in the home setting. When using thermography for foot assessment in a home setting, assessment immediately after waking is the most preferred for reliable evaluation. To avoid false positives and unnecessary concerns, daily self-assessments and communication with trained healthcare professionals on abnormal patterns on consecutive days are recommended. This easy-to-use and relatively inexpensive tool may have high clinical value and help empower people with diabetes for foot self-care.

Funding: This work was supported by JSPS KAKENHI Grant Number JP 20K10780.

Conflict of Interest: The authors have no conflicts of interest to disclose.

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Received June 23, 2022; Revised August 1, 2022; Accepted August 19, 2022.

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Released online in J-STAGE as advance publication August 25, 2022.