Validation of low-cost smartphone-based thermal camera for diabetic foot assessment

Running title: Low-cost smartphone-based thermal imaging for DFU assessment

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Structured Abstract

Aims: Infrared thermal imaging (IR) is not yet routinely implemented for early detection of diabetic foot ulcers (DFU), despite proven clinical effectiveness. Low-cost, smartphone-based IR-cameras are now available and may lower the threshold for implementation, but the quality of these cameras is unknown. We aim to validate a smartphone-based IR-camera against a high-end IR-camera for diabetic foot assessment.

Methods: We acquired plantar IR images of feet of 32 participants with a current or recently healed DFU with the smartphone-based FLIR-One and the high-end FLIR-SC305. Contralateral temperature differences of the entire plantar foot and nine pre-specified regions were compared for validation. Intra-class correlations coefficient (ICC(3,1)) and Bland-Altman plots were used to test agreement. Clinical validity was assessed by calculating statistical measures of diagnostic performance.

Results: Almost perfect agreement was found for temperature measurements in both the entire plantar foot and the combined pre-specified regions, respectively, with ICC values of 0.987 and 0.981, Bland-Altman plots' mean Δ=-0.14 and Δ=-0.06. Diagnostic accuracy showed 94% and 93% sensitivity, and 86% and 91% specificity.

Conclusions: The smartphone-based IR-camera shows excellent validity for diabetic foot assessment.

Keywords: 1 Thermal Infrared; 2 Temperature; 3 Diabetes Mellitus; 4 Diabetic Foot; 5 Foot Ulcer; 6 Smartphone

1. Introduction

Ulceration and infection are frequently occurring foot complications in people with diabetes and peripheral neuropathy, and these complications increase morbidity and mortality [1, 2]. If not treated quickly, the consequences can be devastating. Therefore, early detection of diabetic foot complications is critical. However, detection by self-examination may be impeded by health impairments related to diabetes and other comorbidities, like bad eyesight, limited mobility or social impairment [3]. An alternative is frequent examination by health professionals, but this is costly and may be meddlesome for the patient. An advanced home assessment tool to monitor the foot in people with diabetes is desirable, and for this measurement of foot skin temperature is a promising modality [4-11].

Temperature assessment is built on the notion that the heating up of the skin is a predictor for a diabetic foot ulcer (DFU) [12, 13]. Before skin breaks down, it heats up due to inflammation and enzymatic autolysis of tissue resulting from mild to moderate repetitive stresses on the foot that go unnoticed due to neuropathy [12, 13]. Such inflammation is only present in the affected side. This makes detection possible, by determining the temperature difference between the affected location and the same location on the contralateral foot. Using this principle, three randomized controlled trials have shown that diabetic foot ulceration can be prevented when contralateral foot temperature differences are monitored, followed by preventative actions when a temperature increase >2.2°C is found in specific plantar foot regions on one foot [8-10]. In addition, further research has confirmed this threshold, and additionally indicated that the most optimal cut-of value for determining urgency of treatment is a 1.35°C difference between average temperatures of the entire plantar foot [7]. Despite the promising findings from these RCTs and the clear and objectively measurable cut-off values, temperature monitoring to prevent diabetic foot ulcers is hardly used in daily practice [14].

Originally, temperature assessment in the seminal RCTs were done with simple handheld infrared thermometers [8-10]. The reason why this method is not implemented in daily foot care is not clear, but may have to do with reimbursement, a lack of confirmation of trial results in other geographical settings, and with participant barriers in the daily use of the thermometer [11]. Recent studies have exploited thermal infrared (IR) cameras. With IR, temperature profiles of the foot can be studied in more detail than with handheld thermography, and the identification of (pre-signs of) DFU may become automated with these devices, reducing the effort by the participants and the clinician to acquire and assess images [6, 7, 11, 15].

However, broad implementation of thermal assessment is still obstructed. A major reason are the costs of IR-cameras, as well as the need for complex data analysis. With newly available low-cost smartphone-based IR-cameras, the price barrier disappears and development of smartphone applications focused on DFU assessment to improve usability of data analysis and implementation in diabetes clinical practice becomes feasible [16, 17, 18]. However, it is unknown if the quality of these low-cost cameras is sufficient to reliably depict clinical outcomes. A smartphone-based IR-camera has been compared to a high-end camera in one pilot study [19]. They reported promising results, but in a small sample (5 DFUs) and only the intra- and interrater reliability was researched, with unknown cut-off points; validity and reliability of the smartphone-based IR-camera itself were not investigated. It remains therefore unknown whether this low-cost IR-camera can be safely applied for DFU detection. In this study, we aim to validate a smartphone-based IR-camera in a daily setting against high-end IR-cameras for DFU assessment.

2. Materials and methods

2.1. Study design

In this single-centre prospective clinical study, a convenience sample of 32 consecutive participants with diabetes mellitus who visited the multidisciplinary outpatient diabetic foot clinic of Hospital Group Twente (Almelo, The Netherlands) was included. Every participant had a current, or recently healed (<4 weeks), diabetic foot ulcer. People with a major amputation (i.e. above the ankle) were excluded.

The Medical Ethical Committee Twente approved the study protocol (K17-45), and informed consent was obtained from each subject prior to the start of the study.

2.2. Materials

The smartphone-based IR-camera setup comprised the second-generation FLIR one for Android (FLIR Systems, Wilsonville, OR), a smartphone-based IR and color camera with thermal resolution 160x120 pixels, visual (color) resolution 640x480 pixels, operating temperature of 0 to 35°C, scene temperature range of –20 to 120°C, focus of 15cm to infinite, angle of view of 46°x35° and a male micro USB connector. The smartphone-based IR-camera was attached to a Motorola XT1642 Moto G4 Plus smartphone (Motorola Mobility LLC, Chicago, Il), and operated with the "Thermal camera + for FLIR One" application by Georg Friedrich (available in the Google Play Store). A mount was 3D-printed to stabilize the smartphone-based IR-camera, attached to the smartphone and mounted on a camera tripod. A black cloth was held behind the participants' feet to reduce the influence of background heat and light (Fig. 1).

The set-up for the high-end IR-camera has been extensively described elsewhere [7]. In short, it comprised a FLIR (Wilsonville, OR) SC305 thermal camera for IR and a Canon (Tokyo, Japan) Eos-40D for color, light module, thermal reference elements and foot support, mounted in a wooden box with dimensions 600x600x1.900 mm, with a light shielding extension in front. At the end of the box was an entrance for the feet with a light shielding extension, which was covered with the same black cloth, to eliminate influence of the ambient light.

2.3. Study procedures

Measurements were performed during one visit to the outpatient clinic. Participants were seated in supine position on a treatment bench with their lower legs supported by the bench and their bare feet over the edge. Their feet remained exposed to the environment for 5 minutes, to allow equilibration of foot temperature.

Two sets of plantar IR and colour images of both feet were obtained from each participant within one measurement. Measurements took 2-3 minutes, with a maximum of 5 minutes.

The first set of images was taken with the smartphone-based IR-camera setup, placed at such a distance that both feet were within the cameras' maximum field of view, for which an approximate distance of 1-meter (±25cm) was needed. The participant was instructed to hold up the black cloth behind their feet.

The second set was taken with the high-end IR-camera setup: the treatment bench was rolled towards the wooden box, and participants were asked to place their feet on support bars inside [7].

2.4. Image processing

Image acquisition in the smartphone-based IR-camera setup was done with the smartphone application. For the high-end IR setup, custom-made Matlab software (The MathWorks, Natick, MA) was used as described before [7].

Post-processing consisted firstly of delineating the boundaries of the feet in the colour images to discriminate the feet from the background using Photoshop CC 2015 (Adobe Systems, San Jose, CA). Subsequent steps were performed in Matlab, consisting of semi-automatically aligning the IR images with the corresponding delineated colour images. After alignment, the delineated colour images were used as mask for the IR images to separate foot pixels from the background.

Successive, we calculated the average temperature in the entire plantar foot and in the nine pre-specified plantar foot regions of interest. Six of these nine regions were those defined in previous studies [8-10]: hallux, first, third, and fifth metatarsal heads, metatarsocuneiform joint, and cuboid. Three additional regions of interest were identified as susceptible for DFU and were therefore added to the analyses: third and fifth toe, and lateral metatarsocuneiform joint (Fig. 2) [20]. All regions were manually annotated in the colour images with standardized circular masks 10mm in diameter. The masks on the third and fifth toe were 5mm in diameter, as these regions were smaller anatomically. The contralateral difference was calculated by subtracting the temperature of the left foot from the right foot. Measurements were excluded when the region of interest fell partially or completely outside the field of view of one of the IR-cameras, or when it was missing due to minor amputations.

2.5. Statistical analysis

Intra-class correlation coefficient (ICC(3,1)) and Bland-Altman plots were used to test agreement between smartphone-based IR-camera and the high-end IR-camera, with the second regarded as gold standard in measuring contralateral foot temperature difference [21]. Analyses were performed for the entire plantar foot, for the nine pre-specified regions combined, and for each region separately.

Clinical validity was studied by calculating the accuracy with which the smartphone-based IR-camera detected clinically meaningful outcomes. Cut-off points to detect a clinical outcome were defined, based on previous studies, as 1.35°C for the average temperature difference between the entire plantar side of both feet [7], and 2.2°C for the temperature difference between two pre-specified contralateral regions [7-10]. Validity was assessed by calculating diagnostic accuracy of the smartphone based IR-camera via its sensitivity, specificity, negative and positive predictive values, and negative and positive likelihood ratios of the clinical cut-off points, with the high-end camera as gold standard [22].

3. Results

3.1. Study population.

Characteristics of the 32 participants included are shown in Table 1. All participants had peripheral neuropathy, no participant had a major amputation, the population was predominantly male and around 67 years of age. Four participants had a recently healed DFU, all other participants had an existing DFU, most often (n=13) classified as University of Texas 1A.

3.2. Plantar foot temperature

The left-right temperature assessment of the entire plantar foot was completed for 30 participants; two were excluded because one feet partially fell out of the field of view of the high-end IR-camera. The results showed excellent reliability and a good agreement in the Bland-Altman plots (Table 2 and Fig. 3).

3.3. Regional foot temperatures

The left-right comparison of foot skin temperature in the regions of interest was possible in all participants. A total of 14 (4.8%) regions (in 8 different participants) were excluded, leaving a total of 274 regions in the 32 participants for analysis. Together, these regions showed an excellent reliability and a good agreement in the Bland-Altman plots (Table 2 and Fig. 4). The results of each region, shown in Table 3, showed similar good agreements.

4. Discussion

To bring home monitoring for diabetic foot ulcer assessment towards diabetes clinical practice, we compared plantar foot temperatures of people with diabetes acquired with a smartphone-based IR-camera and a high-end IR-camera. The resulting intra-class correlation and Bland-Altman plots of the contralateral foot temperature differences showed high agreement between the two cameras. The clinical applicability of the smartphone-based IR camera for accurate (impending) DFU detection showed a strong performance in all measures of diagnostic accuracy. Based on these results, we conclude that the smartphone-based IR-camera is as accurate as a high-end IR-camera for DFU assessment and it is thereby safe to assume that the performance results of previous research [7, 15] apply for both the high-end and smartphone-based IR-camera.

It is crucial to validate new devices before progressing to further research and implementation. This is especially important when newer devices have reduced resolution and potentially reduced accuracy, such as the smartphone-based IR camera under study here. For thermal imaging devices specifically, it was recently shown that quality and accuracy of other handheld devices varied substantially and was frequently insufficient for DFU assessment [23], even though some of these devices are being used for such assessment in daily practice. This increases the need for extensive validation of new devices, and thereby the current study, even further.

The findings of the current study show high agreement between the smartphone-based and the high-end IR-camera. Firstly, ICC values were well above the threshold (0.9) that is considered excellent agreement [21]. Second, analyses with Bland-Altman plots showed mean differences between both cameras to be very small (<0.15C), a difference that is negligible from a clinical perspective. Thirdly, and most important from a clinical perspective, in comparison with the gold standard IR-camera all measures of diagnostic accuracy were satisfactory: likelihood ratios are considered the most important for clinical decision-making [22]; the positive likelihood ratio >5 (as found in this study) indicates strong evidence, and the negative likelihood ratio found (<0.1) indicates convincing evidence [22]. Because of this, further research can aim for development of a targeted automatic IR-image evaluation application for the assessment of DFU to provide user-friendly data processing, to progress implementation of temperature monitoring for DFU assessment.

This study had various strength and limitations. A strength was the constant relative temperature (minimal spatial variation within each image) of the FLIR One, which was needed to accurately measure contralateral differences [24]. While the absolute temperature stability of the FLIR One has been shown by Klaessens et al. to fluctuate [24], this does not affect the temperature differences within one image. We suggest in future research and daily clinical practice to continue using primarily the relative temperature difference between two feet.

More device quality control measurements of this smartphone-based IR-camera have been tested by Klaessens et al. and were concluded to be a good alternative to high-end cameras for routine clinical measurements [24]. Therefore, these measurements were excluded in this study. These measurements include among others: stability, repeatability, temperature gradient and temperature in relation to the object distance.

Another strength of the smartphone-based IR-camera used in this study is the colour-camera that is incorporated within the device, less than one centimetre apart from its IR-camera. This can be used to delineate the feet from the background, even when (for example) the toes are on room temperature. The geometric transformation needed for this delineation depends on the viewing angles between the IR and colour cameras. With them being so close to each other, only a minimal transformation is necessary. This also means that both colour and IR-images are available in one device. With diagnostic accuracy of colour images only recently found to be sub-optimal [25], it has been suggested that this combination is an important step forward in diabetic foot telemedicine [25]. The current smartphone-based IR-camera provides this combination.

Measurements in the toe region and central of the foot were specifically added because these are susceptible for DFU [20] even though these were not used in previous studies [8-10]. It was hypothesized that with the accuracy of the IR camera, it should be possible to validly assess the temperature of the lesser toes in more detail than with spot thermometers or other devices. While this was feasible, the smaller toes showed a lesser performance and agreement compared to the rest. However, we expect this to be primarily the result of a geometrical transformation error, as described in the previous paragraph. This error mainly occurred in the toes, because of a common angulation between the toes and the plantar side of the feet. With almost all of the results in the toe region still in the range of good agreement, we think it is safe to conclude that the smartphone-based IR-camera is valid for all regions.

Another limitation of our study concerned the support of the foot at the cuboid region, and (in some cases) also the lesser toes, in the high-end IR-camera setup against the set-up. This contact with the setup might have influenced the temperature of the foot. In the smartphone-based IR-camera setup, the feet were placed just over the edge of the research bench to avoid contact with any object that might influence foot temperature.

A limitation within participant selection was that all of them were under care for a DFU and no developing ulcers or feet that were ulcer-free for longer periods of time were measured. While we do not expect any differences in performance of the smartphone-based IR-camera in this population, it might be useful in future research to validate the camera also for this population specifically.

A final limitation was the manual annotation of regions of interest on the measurements of both the high-end and the smartphone-based IR-camera. This was needed because no validated programs or applications currently exist for reliable automatic annotation. By doing it all manually, each annotation could be carefully checked by the researcher. However, this method is susceptible to human error and despite checking, it cannot be ruled out that minor differences in contralateral annotation occurred. By visually checking each annotation for accuracy and with the high agreement found, it is not expected that this has had a major influence on the results.

As stated before, we can now assume that the results of studies with high-end IR-cameras (e.g. [6, 7, 11, 15]) also apply to this smartphone-based IR-camera. However, the performance of high-end IR-cameras are only tested in the clinic setting, with participants under treatment. The next step is to test the predictive value of IR-cameras in peoples home.

For home implementation, an important development would be the creation of specific acquisition and automatic assessment algorithms for the smartphone application to assess the IR images. Such an application is firstly needed to move the smartphone camera from a research towards a clinical setting, as it enhances usability by non-technicians. Different approaches of such applications are being developed already, such as an application in which the thermal images are shared with a specialist for evaluation [16], or an application with automatic evaluation a server or in a standalone application [17, 18]. For automatic evaluation, our suggestion would be to evaluate the entire feet instead of certain specific regions. This becomes possible, because a thermal map of the entire feet is available with IR-imaging. This may reduce the chance of missing a critical spot with impending ulceration. This approach is similar to automated comparison as done using high-end IR cameras [26].To do so the smartphone application should accurately register and align the contralateral feet surfaces for a pixel-by-pixel comparison of the left and right foot. We suggest averaging with the neighbouring pixels to minimize registration errors.

Another aspect in future development of smartphone-based IR cameras is the possibility to monitor other aspects of the foot, rather than the plantar side alone. Compared to for example the Bath-mat that has been recently developed for DFU assessment [27], smartphone-based IR cameras can also monitor the medial, lateral and dorsal side of the foot. With around 50% of foot ulcers not developing on the plantar side [20], this is a clinically relevant addition. Future research should investigate possibilities to measure temperature around the foot, for example by validating a dorsal temperature view including contralateral comparison of regions, or by creating 3D thermal images of the whole foot.

For clinical practice, the smartphone-based IR camera tested in this study is already commercially available, which makes it possible for clinics or people to obtain the camera and monitor their feet. The promising outcomes on the validity of the smartphone-based IR camera bring implementation of this advanced monitoring tool much closer to daily clinical practice.

5. Conclusion

The low-cost smartphone-based thermal infrared camera showed excellent reliability and validity for the assessment of temperature differences between contralateral feet in people with diabetic foot complications. For this reason, the smartphone based IR-camera can be used as assessment tool for monitoring and preventing diabetic foot ulcers in daily clinical practice.

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8. Figures and tables with legends

Table 1: Participant characteristics

Characteristic	N=32
Gender (male : female)	24:8
Age (years) (mean ± SD)	67±12
(Previous) Ulcer Location	
Hallux	9
Digitus 2-5	8
Metatarsal heads	16
Midfoot or heel	8
Charcot foot	1
Affected side (left : right : both)	19:7:6
Diabetes mellitus type (1 : 2 : unknown)	1:29:2
University of Texas classification	
0 (no DFU<4 weeks)	4
1 (A : B-D)	13:4
2 (A : B-D)	4:5
3 (A : B-D)	0:2
Note: DFU= Diabetic Foot Ulcer	

Table 2: Main temperature assessment results of entire plantar foot and all nine regions on the plantar foot combined.

	Entire plantar foot	Nine pre-specified regions combined
Count [n=]	30	274
ICC(3,1)	0.987	0.981
Bland- Altman		
Mean difference	-0.14	-0.06
Limits of agreement	-1.0 to 0.75	-1.4 to 1.3
Sensitivity	94%	93%
Specificity	86%	91%
LLR+	6.56	10.86
LLR-	0.07	0.07
Positive predictive value	0.88	0.90
Negative predictive value	0.92	0.95
Note: LLR= likelihood ratio		

Table 3: Temperature assessment results of all nine regions on the plantar foot separate.

Region	Hallux	Dig 3	Dig 5	MTP 1	MTP 3	MTP 5	Midfoot	Midfoot lateral	Cuboid
Count [n=]	28	28	28	32	32	30	32	32	32
ICC(3,1)	0.991	0.973	0.929	0.992	0.993	0.984	0.972	0.989	0.969
Bland- Altman									
Mean difference	-0.02	-0.02	-0.06	-0.01	-0.07	-0.07	-0.06	-0.07	-0.18
Negative LoA	-1.2	-1.6	-2.5	-1.1	-1.1	-1.4	-1.4	-0.89	-1.4
Positive LoA	1.2	1.6	2.4	1.1	0.93	1.3	1.3	0.75	1.0
Sensitivity	94%	93%	91%	95%	94%	93%	91%	100%	88%
Specificity	90%	64%	94%	92%	86%	100%	95%	96%	96%
LLR+	9.4	2.6	15.45	12.31	6.61	~	19.09	23	21
LLR-	0.06	0.11	0.10	0.06	0.06	0.07	0.10	0	0.13
PPV	0.94	0.72	0.91	0.95	0.90	1	0.91	0.90	0.88
NPV	0.90	0.90	0.94	0.92	0.92	0.94	0.95	1	0.96

Note: "Midfoot" indicates the metatarsocuneiform joint.

LoA= Limits of Agreement; LLR= likelihood ratio; PPV= Positive predictive value; NPV= Negative predictive value; MTP = Metatarsophalangeal joint; ~=divided by zero

9. Figure Legends

Figure 1: Smartphone with underneath a FLIR One IR-camera connected. They are placed within the 3D printed mount for tripod fixation. On the screen is a thermal infrared foot image visible of a participant while holding a black cloth.

Figure 2: Annotation order with respective region of interest size portrayed on a grayscale healthy foot thermal image taken with the high-end IR-camera setup. From 1 to 9: Hallux, dig 3, dig 5, MTP 1, MTP 3, MPT 5, lateral midfoot, central midfoot and cuboid.

Figure 3: Intra-class correlation and Bland-Altman plot for the average plantar foot temperatures

Figure 4: Intra-class correlation and Bland-Altman plot for all regional foot temperatures. Every region is numbered according to the numbering in Fig. 2. Outliers in the Bland-Altman plot all concern the two toe regions (digitus 3 (1 outlier in 28) and digitus 5 (5 outliers in 28).