

ORIGINAL ARTICLE

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# Assessment of Signs of Foot Infection in Diabetes Patients Using Photographic Foot Imaging and Infrared Thermography

Constantijn E.V.B. Hazenberg, MD,<sup>1,2</sup> Jaap J. van Netten, PhD,<sup>1</sup>  
Sjef G. van Baal, MD, PhD,<sup>1</sup> and Sicco A. Bus, PhD<sup>1,3</sup>

## Abstract

**Background:** Patients with diabetic foot disease require frequent screening to prevent complications and may be helped through telemedical home monitoring. Within this context, the goal was to determine the validity and reliability of assessing diabetic foot infection using photographic foot imaging and infrared thermography.

**Subjects and Methods:** For 38 patients with diabetes who presented with a foot infection or were admitted to the hospital with a foot-related complication, photographs of the plantar foot surface using a photographic imaging device and temperature data from six plantar regions using an infrared thermometer were obtained. A temperature difference between feet of  $>2.2^{\circ}\text{C}$  defined a “hotspot.” Two independent observers assessed each foot for presence of foot infection, both live (using the Perfusion-Extent-Depth-Infection-Sensation classification) and from photographs 2 and 4 weeks later (for presence of erythema and ulcers). Agreement in diagnosis between live assessment and (the combination of) photographic assessment and temperature recordings was calculated.

**Results:** Diagnosis of infection from photographs was specific ( $>85\%$ ) but not very sensitive ( $<60\%$ ). Diagnosis based on hotspots present was sensitive ( $>90\%$ ) but not very specific ( $<25\%$ ). Diagnosis based on the combination of photographic and temperature assessments was both sensitive ( $>60\%$ ) and specific ( $>79\%$ ). Intra-observer agreement between photographic assessments was good (Cohen’s  $\kappa=0.77$  and  $0.52$  for both observers).

**Conclusions:** Diagnosis of foot infection in patients with diabetes seems valid and reliable using photographic imaging in combination with infrared thermography. This supports the intended use of these modalities for the home monitoring of high-risk patients with diabetes to facilitate early diagnosis of signs of foot infection.

## Introduction

**D**IABETES MELLITUS IS A COMMON cause of lower extremity complications such as foot ulceration, infection, and amputation.<sup>1</sup> The prevalence of diabetes and diabetic foot complications will increase rapidly in the following decades, further increasing the patient and economic burden of the disease.<sup>2</sup> To reduce this burden, effective screening and prevention are required.<sup>2</sup> Because foot ulcers are mostly of neurogenic origin, patients do not feel trauma occurring, and therefore frequent assessment of foot status is important, both by the healthcare professional and by the patient. However, frequent (e.g., weekly) screening by a healthcare professional

would be too intrusive and costly. Self-assessment by patients is difficult or impossible, as many patients live alone, have cognitive, visual, or physical impairments, or lack knowledge about the disease. Telemedical diagnostic support in the home environment can fulfill the need for frequent foot assessment and may prove to be a missing link in the screening of patients who are at risk for diabetic foot complications.

Several telemedical approaches have been developed to support medical practice, also for the prevention and management of diabetic foot disease. Treatment of diabetic foot ulcers can be supported in the patient’s home through mobile phone and video interaction.<sup>3–6</sup> For ulcer monitoring,

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<sup>1</sup>Department of Surgery, Ziekenhuisgroep Twente, Almelo, The Netherlands.

<sup>2</sup>Department of Vascular Surgery, University Medical Centre Utrecht, Utrecht, The Netherlands.

<sup>3</sup>Department of Rehabilitation Medicine, Academic Medical Centre, University of Amsterdam, Amsterdam, The Netherlands.

imaging devices such as optical scanners have been described.<sup>7-9</sup> Our group has developed a photographic foot imaging device (PFID) to use as a home monitoring device for the early diagnosis of foot ulcers and pre-ulcerative lesions in patients with diabetes.<sup>10</sup> The PFID provides high-quality digital photographs of the plantar foot surface that can be remotely assessed by a foot specialist.<sup>10</sup> Good validity and reliability for diagnosing foot ulcers and abundant callus from photographs produced by the PFID have been proven earlier, as well as good feasibility for using this device as a home monitoring tool.<sup>11,12</sup>

Little is known about the value of photographic imaging to diagnose signs of foot infection. We have experienced in an earlier study that assessment of erythema, which is one of the cardinal signs of infection, can be difficult from digital photographs, but the validity and reliability have not yet been investigated.<sup>10</sup> Increased skin temperature is another important sign of infection and can be assessed using infrared thermography. The home monitoring of foot temperatures using infrared thermometry has been shown to be effective in patients with diabetes for diagnosing signs of inflammation, which, if adequately managed, has shown to prevent foot ulcers.<sup>13-15</sup> Thermography has its limitations in assessing foot infection because it measures only one sign of infection (heat), and other conditions related to diabetes such as autonomic neuropathy or vascular disease can also affect foot temperature. Furthermore, infrared thermography may be limited in predicting severity of infection or the outcome of treatment.<sup>16</sup>

We hypothesize that the combination of photographic and temperature assessments of the foot may improve the diagnosis of diabetic foot infection from remotely accessible data. If proven effective, such tools may be helpful to monitor patients in their home environment and contribute to adequate screening of patients who are at high risk of foot disease. The aim of this study was to determine the validity and reliability of diagnosing (signs of) diabetic foot infection based on assessments from digital photographs and infrared thermography and the combination of these two.

## Subjects and Methods

### Subjects

A convenience sample of 38 patients (31 men; mean [SD] age, 65 [11] years) participated in this study. Patients were consecutive patients diagnosed with diabetes mellitus who presented at the outpatient clinic with a foot infection or who were admitted to our multidisciplinary inpatient clinic with foot-related complications (i.e., foot ulcer, necrosis or Charcot foot, with or without suspicion of foot infection). All patients were recruited between May and December 2011. Each patient signed an informed consent form before the start of the study. The study protocol was approved by the Twente medical ethics committee.

### Instrumentation

Digital photographs of the plantar surface of both feet were obtained under standardized lighting and foot positioning conditions using the PFID.<sup>10</sup> In brief, the PFID contains a camera module (featuring a charge-couple device image sensor with a resolution of 4 pixels/mm<sup>2</sup>), light sources,

mirror, glass plate, foot supports, and a computer, all contained in an ergonomically designed device (Fig. 1).<sup>10</sup> The PFID produces three images under different lighting conditions (diffuse and medially and laterally oriented, to improve perception of three-dimensional foot contours) that are automatically saved on a personal computer. Figure 2 shows examples of photographs taken of an infected and noninfected foot of a patient.

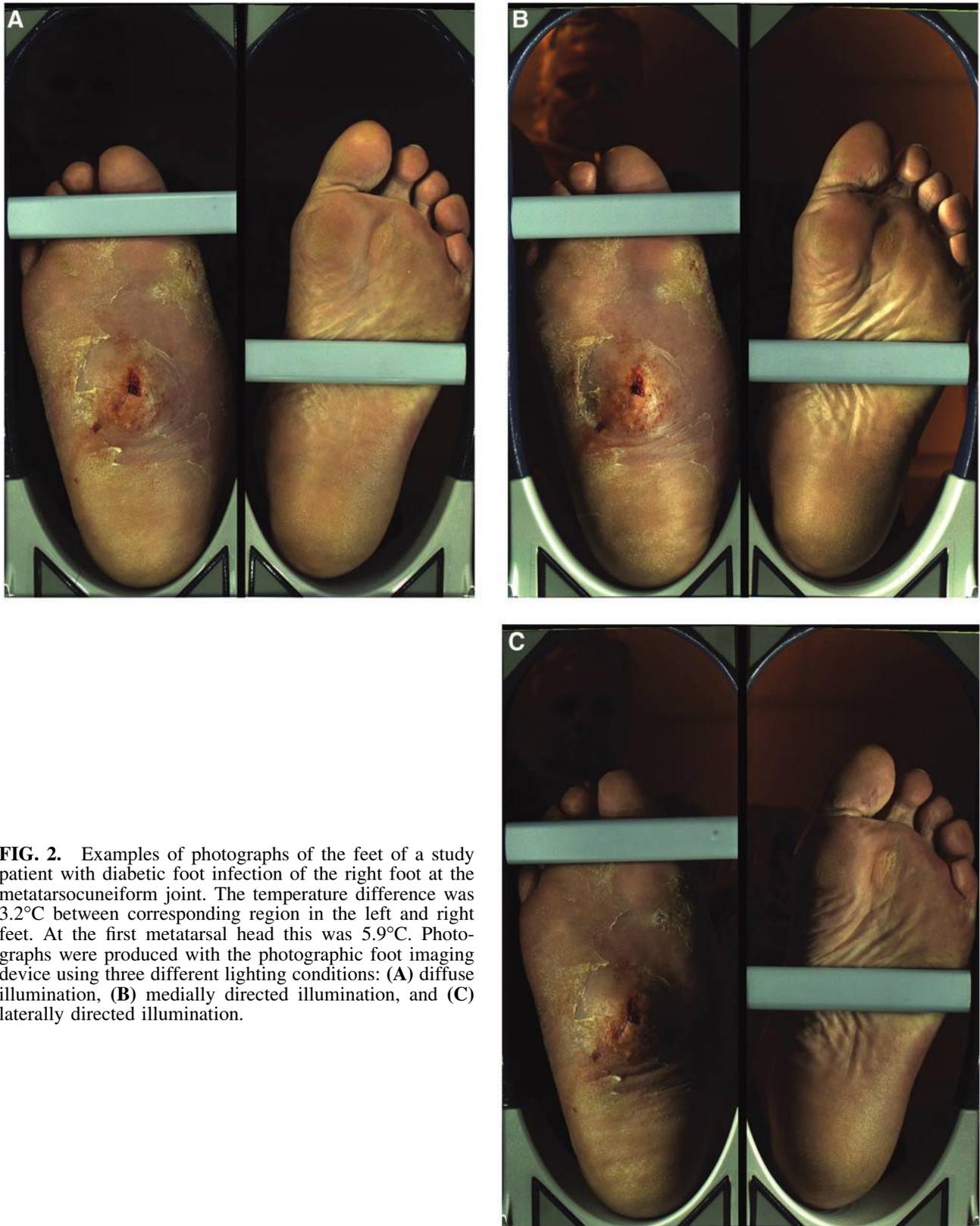
Foot skin temperatures were measured with an infrared thermometer (TempTouch®; Xilas Medical, San Antonio, TX) (Fig. 3), which is a probe designed for patients to measure subsurface temperatures on their plantar foot surface. Foot temperature is measured with 0.1°C accuracy and is displayed on a liquid crystal display on the probe.

### Protocol

Live assessment of the feet of all patients was performed by two observers, who were certified wound care specialists trained for 13 and 17 years, respectively, in diabetic foot care, and who assessed the feet independently from each other. Feet were assessed for presence of infection using the Perfusion-Extent-Depth-Infection-Sensation (PEDIS) classification criteria, where grading was based on whether signs of symptoms of infection were absent (Grade 1) or present and involved only the skin and subcutaneous tissue (Grade 2), involved deeper structures (Grade 3), or involved a systematic inflammatory response syndrome (Grade 4).<sup>17</sup> For the study, infection was classified as present with PEDIS score of grade 2 or higher. The feet were also assessed for presence of erythema, foot ulcers, abundant callus, blisters, or fissures. The clinical sign and its location on the foot were specified on paper drawings of the foot surface boundaries. Multiple observations could be made per foot. A



**FIG. 1.** The photographic foot imaging device.



**FIG. 2.** Examples of photographs of the feet of a study patient with diabetic foot infection of the right foot at the metatarsocuneiform joint. The temperature difference was  $3.2^{\circ}\text{C}$  between corresponding region in the left and right feet. At the first metatarsal head this was  $5.9^{\circ}\text{C}$ . Photographs were produced with the photographic foot imaging device using three different lighting conditions: (A) diffuse illumination, (B) medially directed illumination, and (C) laterally directed illumination.

foot ulcer was defined as a full-thickness lesion penetrating through the dermis. Abundant callus was defined as callus formation requiring treatment (i.e., sharp debridement), a blister as collection of fluid underneath the epidermis, and a fissure as a crack-like lesion of the skin. Before the study started, the two

observers assessed a patient in front of each other to discuss presence of signs of diabetic foot disease and to reach uniformity in evaluation.

After live assessment, the researcher instructed the patient to put his or her feet in the PFID, and photographs of the foot

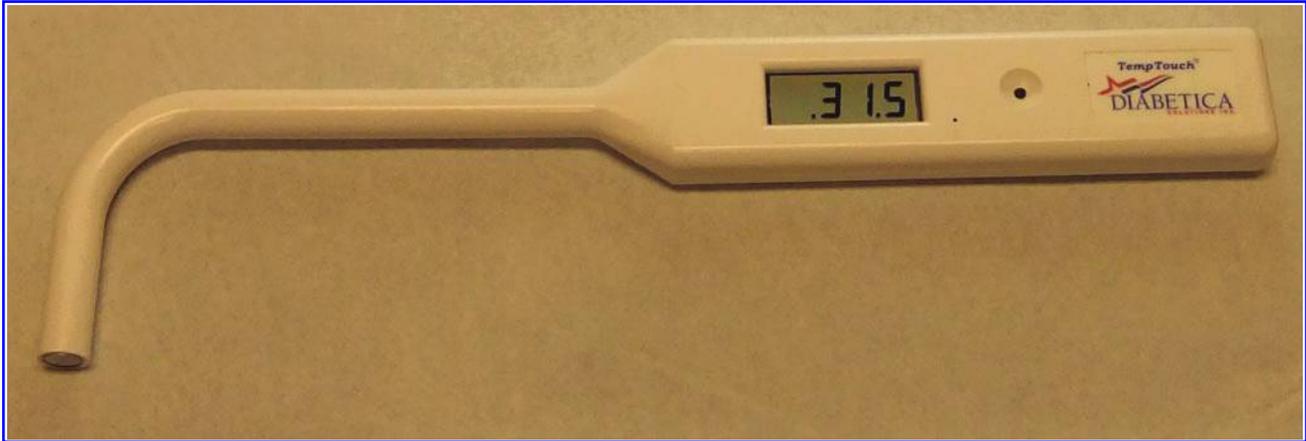


FIG. 3. The infrared thermometer (TempTouch).

were taken. The researcher subsequently measured foot temperature at six plantar regions on each foot using the TempTouch thermometer: hallux, first, third, and fifth metatarsal heads, metatarsocuneiform joint, and cuboid.<sup>15</sup> Measured temperatures and foot location were entered in a clinical report form. All assessments (live, photographic, and temperature) were carried out before any treatment of any infection present (e.g., antibiotics, sharp debridement) was initiated.

At 2 weeks and again at 4 weeks after inclusion of 10 subsequent patients, the same two observers who performed the live assessment assessed the photographs of the feet of these 10 patients, again independently from each other. To reduce the chance of photographic memory and reporting bias, the photographs were randomly ordered and mixed with photographs of the feet of 10 patients with a variety of (or absence of) foot problems that were assessed in a previous study. Photographs were assessed using the IrfanView

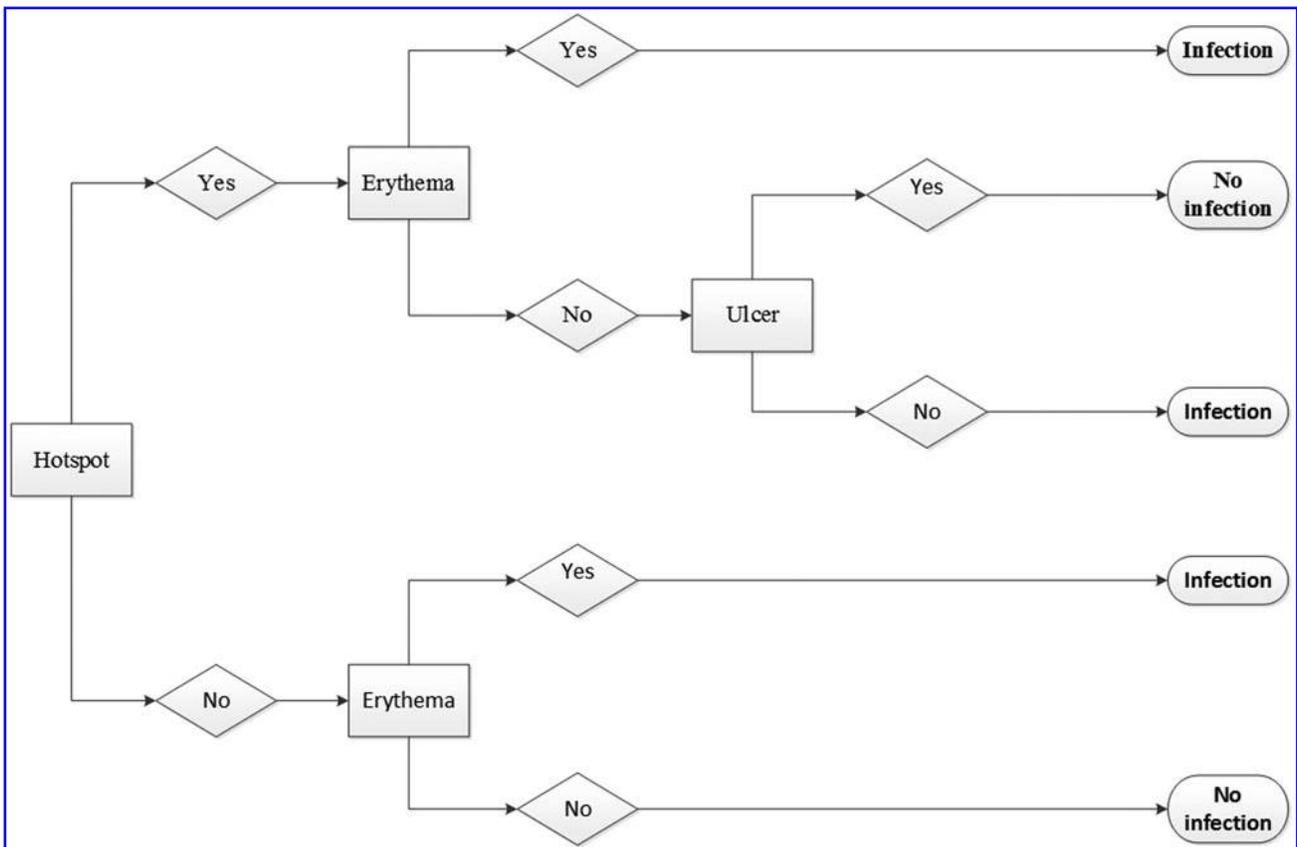


FIG. 4. Algorithm used for the diagnosis of infection based on the combination of photographic and temperature assessments. In this algorithm, infection is defined based on a sequence of observations in a hierarchical order: presence (or absence) of a hotspot from temperature measurements, erythema on the photograph, and an ulcer on the photograph.

TABLE 1. NUMBER OF OBSERVATIONS PER CLINICAL SIGN OF FOOT DISEASE FOR THE 75 FEET OF 38 PATIENTS ASSESSED LIVE AND FROM PHOTOGRAPHS

	<i>Infection (PEDIS)</i>	<i>Erythema</i>	<i>Ulcer</i>	<i>Abundant callus</i>	<i>Blister</i>	<i>Fissure</i>	<i>Absence of signs<sup>a</sup></i>
Live assessment							
Observer 1	21	17	36	12	3	1	24
Observer 2	20	18	33	34	5	4	16
Photographic assessment 1							
Observer 1	—	14	35	15	2	1	24
Observer 2	—	11	37	24	5	3	21
Photographic assessment 2							
Observer 1	—	12	36	11	3	1	24
Observer 2	—	6	32	27	4	4	21

Each clinical sign could be observed more than once on the same foot, and multiple signs could be observed per foot.

<sup>a</sup>Absence of any sign in the whole foot.

PEDIS, Perfusion-Extent-Depth-Infection-Sensation.

(Wiener Neustadt, Austria) graphic viewer version 3.99 (www.irfanview.com). Observation of any clinical sign and its location on the foot were entered on paper drawings of the foot surface boundaries.

#### Data analysis

As reference for the diagnosis of erythema from the photographic images, observations during live assessment were used. As reference for the diagnosis of infection, the PEDIS score from the live assessment was used. A temperature difference of  $>2.2^{\circ}\text{C}$  measured between corresponding regions in the left and right foot, defined the warmer region as a “hotspot” (i.e., sign of infection). Intra-observer agreement between live and photographic assessment for the diagnosis of erythema and between PEDIS and a hotspot for presence of infection was determined based on calculated sensitivity, specificity, and positive predictive and negative predictive values.

To explore the value of combining photographic and thermographic methods for the diagnosis of foot infection, agreement with PEDIS was computed using the algorithm shown in Figure 4. This algorithm uses three types of observations in a hierarchical order to define foot infection: hotspot, erythema, and foot ulcer. Types of observations and their hierarchical order were defined based on a trial and error experiment to obtain the best balance in sensitivity and specificity values.

Intra-observer agreement between the first and second photographic assessment for diagnosis of erythema was calculated using Cohen’s  $\kappa$ , where  $\kappa < 0.20$  represents poor, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 good, and 0.81–1.00 very good agreement.<sup>18</sup> Inter-observer agreement for the diagnosis of infection based on PEDIS was also calculated using Cohen’s  $\kappa$ .

#### Results

Twenty-one patients were recruited from our inpatient clinic, and 17 were enrolled from our outpatient clinic. In total, 75 feet in these 38 patients were assessed; one patient had unilateral amputation above the ankle. In one patient it was impossible to measure skin temperature because of technical problems. In the remaining 36 patients who were analyzed for foot temperature, the mean maximum temper-

ature difference measured between any pair of corresponding left and right foot regions was  $4.4^{\circ}\text{C}$  (range,  $1.3$ – $9.2^{\circ}\text{C}$ ; SD  $2.0^{\circ}\text{C}$ ). A hotspot was found in 30 patients.

Table 1 shows the number of observations per clinical sign of foot disease per observer for the live assessment and for both photographic assessments. During live assessment, infection (PEDIS) was scored 21 and 20 times, erythema 17 and 18 times, ulcer 36 and 33 times, abundant callus 12 and 34 times, and absence of signs 24 and 16 times by Observer 1 and Observer 2, respectively. Observer 1 missed two live assessments of two admitted patients, because of his absence on 1 day. In the photographic assessment of these two patients, an ulcer and erythema was scored in one patient, and absence of signs of foot disease was scored in the other. Observer 2 missed seven live assessments (one inpatient and six outpatient clinic patients) because of his absence on 3 days. In the photographic assessments of these seven patients, absence of signs of foot disease was scored in four patients, compared with erythema in three.

Table 2 shows the agreement per observer for the diagnosis of infection between live assessment (PEDIS) and the

TABLE 2. AGREEMENT BETWEEN LIVE ASSESSMENT AND THE COMBINATION OF PHOTOGRAPHIC AND THERMOGRAPHY ASSESSMENT FOR PRESENCE OF DIABETIC FOOT INFECTION

<i>Live assessment (PEDIS)</i>	<i>Combination of photographic and thermography assessment</i>	
	<i>Present</i>	<i>Absent</i>
Observer 1 <sup>a</sup>		
Present	14	6 <sup>b</sup>
Absent	3 <sup>c</sup>	11
Observer 2 <sup>d</sup>		
Present	11	7 <sup>b</sup>
Absent	2 <sup>c</sup>	8

<sup>a</sup>Observer 1 missed two live assessments.

<sup>b</sup>False-negative observations.

<sup>c</sup>False-positive observations.

<sup>d</sup>Observer 2 missed seven live assessments and missed a Perfusion-Extent-Depth-Infection-Sensation (PEDIS) score on one occasion.

TABLE 3. SENSITIVITY, SPECIFICITY, AND POSITIVE AND NEGATIVE PREDICTIVE VALUES FOR THE DIAGNOSIS OF DIABETIC FOOT INFECTION THROUGH (THE COMBINATION OF) PHOTOGRAPHIC IMAGING AND INFRARED THERMOGRAPHY

	<i>Sensitivity (%)</i>	<i>Specificity (%)</i>	<i>Positive predictive value (%)</i>	<i>Negative predictive value (%)</i>
Observer 1				
Live (erythema) versus photographic (erythema)	57	86	73	76
Live (PEDIS) versus thermography (hotspot)	90	21	62	60
Live (PEDIS) versus combination (algorithm)	70	79	83	65
Observer 2				
Live (erythema) versus photographic (erythema)	50	87	80	62
Live (PEDIS) versus thermography (hotspot)	94	10	65	50
Live (PEDIS) versus combination (algorithm)	61	80	85	53

PEDIS, Perfusion-Extent-Depth-Infection-Sensation.

combination of photographic and temperature assessments as determined by the algorithm. False-negative outcomes (six for Observer 1, seven for Observer 2) were mainly recordings of a hotspot without diagnosis of erythema at a location where an ulcer was present. False-positive outcomes (three for Observer 1, two for Observer 2) were recordings of a hotspot and diagnosis of erythema at a location where a foot ulcer but not infection (PEDIS) was present (Observer 1) or recordings of a hotspot but no infection (PEDIS) for Observer 2. Choosing larger temperature differences than 2.2°C to define a hotspot (i.e., 3.2°C, 4.2°C, or 5.2°C) did not improve agreement with live assessment.

Sensitivity, specificity, and positive and negative predictive values for the diagnosis of (signs of) foot infection through (the combination of) photographic and temperature assessment are shown in Table 3. For the assessment of erythema on photographs, sensitivity was <60%, and specificity was >85% in both observers. For diagnosis of infection through a hotspot, sensitivity was >90%, and specificity was <25% in both observers. The diagnosis of infection through the combination of photographic and temperature assessment (i.e., the algorithm as shown in Figure 1) resulted in a sensitivity of >60% and a specificity of >79% for both observers.

Intra-observer agreement between the two photographic assessments for diagnosis of erythema was good for Observer 1 ( $\kappa=0.77$ ) and moderate for Observer 2 ( $\kappa=0.52$ ). Inter-observer agreement for the diagnosis of infection using PEDIS in the live assessment was moderate ( $\kappa=0.44$ ).

## Discussion

The aim of this study was to determine the validity and reliability of diagnosing (signs of) diabetic foot infection from photographic imaging and infrared thermography. The findings show low sensitivity with high specificity and positive and negative predictive values for the diagnosis of erythema as sign of infection using digital photographs. In contrast, high sensitivity scores with low specificity and moderate positive and negative predictive values were found for the diagnosis of infection through hotspots as sign of infection using infrared thermography. Combining photographic and temperature assessment, and including information on ulceration obtained from photographs, greatly improved the balance of sensitivity and specificity and also

improved the positive predictive value in the diagnosis of diabetic foot infection. These results show that photographic or temperature assessments alone are either not sensitive or not specific enough for the diagnosis of diabetic foot infection, but the combination of modalities gives acceptable outcomes.

The results show that if photographic foot imaging or infrared thermography would be used separately as a home monitoring tool for the early diagnosis of signs of diabetic foot infection, diagnosis would be underestimated (in the case of photographic imaging) or overestimated (in the case of thermography). In both cases this is undesirable because the first may result in lack of required treatment for what is a severe foot problem (i.e., false-negative cases), whereas the second would result in many unjustified and unnecessary referrals (i.e., false-positive cases), which may lead to overexpenditure of clinical resources and an unnecessary burden for the patient. The false-negative observations found when combining the modalities were mainly observations of a hotspot without erythema at a location where a foot ulcer was present. In other words, these ulcers were considered infected during live assessment, but the absence of erythema observed from photographs resulted in a false-negative observation according to the algorithm. The wider range of possibilities to assess presence of infection during live assessment (e.g., smell and touch) may potentially explain these false-negative observations. The consequences are, however, acceptable for these cases because patients would still be referred for treatment based on the ulcer seen on the photographs. This emphasizes the advantage of combining the two modalities for the diagnosis of infection. Another advantage compared with using only thermography is that photographic imaging allows the diagnosis of other pre-ulcerative lesions such as abundant callus or blisters in addition to signs of foot infection.<sup>11</sup>

No earlier published data were found for the use of digital photography to diagnose diabetic foot infection. In studies on patients without diabetes, agreement scores between photographic and live assessments for presence of infection (i.e., cellulitis, erythema, or infection) vary widely, with reported sensitivity ranging from 32% to 71%, specificity from 27% to 91%,<sup>19–21</sup> and Cohen's  $\kappa$  from 0.12 to 0.92.<sup>21–24</sup> Skin temperature monitoring of the diabetic foot was previously shown to be an effective tool for early diagnosis of inflammation, resulting in a significant reduction in the incidence of

ulceration in high-risk patients.<sup>13–15</sup> Additionally, it has been used to monitor neuropathic ulcer healing<sup>25</sup> and the acute Charcot foot.<sup>26</sup> To our best knowledge, this is the first study that examined the validity and reliability of the combined use of photographic imaging and infrared thermography for the diagnosis of diabetic foot infection.

An interesting and important finding from the study was that the inter-observer agreement for the live diagnosis of infection using PEDIS was only moderate ( $\kappa=0.44$ ). These outcomes are not unprecedented because a previous telemedicine study in vascular surgery showed that onsite surgeons disagreed about the presence of erythema or cellulitis in approximately one-third of inpatients who had undergone peripheral bypass surgery or amputation or who were admitted for wound healing problems.<sup>21</sup> This may question either the use of the PEDIS system as the “gold standard” reference for the live assessment of diabetic foot infection or the skills of the involved clinicians to accurately use this classification system. Apparently, the diagnosis of infection is difficult on which to reach agreement, which limits the establishment of suitable references for studies. Other authors have confirmed this for the diagnosis of signs of infection in diabetic foot ulcers,<sup>27</sup> and two systematic reviews on the clinical examination and diagnostic testing of infected diabetic foot ulcers concluded that infection in diabetic foot ulcers cannot be reliably identified using clinical assessment.<sup>28,29</sup>

The implications for clinical practice are that a usable set of tools is available in a semiautomated and remote setup for the early diagnosis of (signs of) diabetic foot infection. Assessment of other signs than infection using photographic imaging has previously been shown to be valid and reliable, and implementing a system like the PFID as a home monitoring tool has been shown to be feasible.<sup>11,12</sup> Therefore, these tools allow a complete and remote assessment of important (pre-) signs of diabetic foot disease. The next step would be to assess the (cost-) effectiveness of this setup in comparison with usual care for early diagnosis and prevention of foot complications in high-risk diabetes patients. Little is known regarding the costs of implementation of both systems, although over time the technology used is becoming available at lower prices, and the systems can be managed without the need of much support. If the system proves to be cost-effective in these studies and implementation in the daily care of the high-risk diabetic patient is feasible for the given healthcare setting, a major reduction in patient burden and healthcare costs for diabetic foot disease can be expected as well as improvements in patient autonomy and quality of life.

This study has some limitations. First, imaging using the PFID is limited to the plantar surface of the foot, whereas approximately 50% of all ulcers seen in specialized centers may occur on the dorsal or lateral foot surface or in-between toes.<sup>30</sup> In addition, the temperature measurements are also primarily focused on the plantar foot surface considering the design of the thermometer and earlier reports on these measurements.<sup>14</sup> Because in all cases of diagnosed infection in the current study the infection was present on the plantar side of the foot (in some cases also dorsal) and because this study was on validity and reliability and not on efficacy, assessing only the plantar foot in the study sufficed. However, we cannot draw conclusions from the results for infection that occurs on the dorsal side of the foot or in between toes. Photographic systems and infrared thermometers that also

image or measure the dorsal and lateral side of the foot are needed to obtain a more complete analysis of the diabetic foot. Second, the method of comparing foot temperatures between the left and right foot is limited in cases of foot amputation, as one patient in our study showed. Future work should focus on finding reliable methods to define hotspots if only one foot is present. Third, the study was limited to the assessment of signs of foot infection. Other cardinal signs of diabetic foot disease were beyond the scope of this study. Diabetic foot ulcers and pre-ulcerative lesions can be diagnosed in a valid and reliable manner using the PFID,<sup>11</sup> and local or diffuse diabetic foot complications, or absence thereof, can be properly discriminated using infrared thermal imaging.<sup>31</sup> However, other important signs such as gangrene or nail folds should receive special attention in future research because early detection of these signs is important for improved prognosis of the disease. Finally, the results may be specific to the two observers, both certified and experienced wound consultants, who performed all assessments. Both observers have a long-standing experience in daily foot care of diabetic foot patients, and both have experience in assessing digital photographs of diabetic feet. In our clinical setting, these wound consultants would be the specialists of choice to perform remote assessments when these tools would be implemented in clinical practice, which supports their involvement in the current study. Nevertheless, generalizability of the results to other healthcare professionals may be limited.

In conclusion, the present study demonstrates the validity and reliability, and with that the potential value, of using photographic imaging in combination with infrared thermography for the diagnosis of foot infection in diabetes patients. As a result, this combination of modalities may hold promise as a home-monitoring system, with the opportunity for remote assessment of high-risk diabetic feet. Deploying such a system could facilitate the early diagnosis of (signs of) foot infection and also other important (pre-) signs of diabetic foot disease, which may prove in future studies to be effective in preventing more devastating consequences.

#### Author Disclosure Statement

No competing financial interests exist.

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Address correspondence to:  
*Constantijn E.V.B. Hazenberg, MD, MSc*  
*Department of Vascular Surgery*  
*University Medical Centre Utrecht*  
*P.O. Box 85500*  
*3508 GA Utrecht, The Netherlands*  
*E-mail: c.e.v.b.hazenberg@umcutrecht.nl*