Enhancing Diabetic Foot Ulcer Risk Assessment in the VVT Sector: The Added Value of Thermal Imaging in Periodic Screening

Master thesis

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Abstract

Introduction – Due to macrovascular and microvascular complications of diabetes mellitus (DM), there is a high risk of developing a diabetic foot ulcer (DFU). For prevention, a foot screening is performed periodically by the podotherapist. This involves assessment of peripheral arterial disease (PAD), neuropathy, pressure points and wounds. However, this screening has shortcomings. Literature shows that foot temperature is related to the risk of a DFU. Therefore, this study aimed to investigate the potential of thermal imaging of the foot temperature to enhance the risk assessment of a DFU among patients in the sector of *Verpleeg- en Verzorgingshuizen en Thuiszorg* (VVT).

Methods – In this study, 23 participants with diabetes were included and data of 15 healthy participants was used. Thermal imaging was conducted using the Optris PI 400i/PI 450i thermal camera. Basic participant characteristics, parameters of the standard foot screenings and thermal and RGB images of the dorsal and plantar side were collected. Mean temperature, temperature of different regions and angiosomes and temperature deviations within the foot were analyzed to investigate the relation with PAD and neuropathy. By subjective assessment the visibility of pressure points and ulcers on the thermal images was investigated. Statistical significance of group differences was assessed using the Independent Sample T Test, with p-values lower than 0.05 considered as statistically significant.

Results – In participants with PAD the temperature of the feet, the magnitude of the temperature deviation and the number, area and height of the peaks decreases. Neuropathy appears to have little to no influence on the mean foot temperature, but the results show a small difference in area and height of the temperature peaks in participants with neuropathy. The results suggest that regions and angiosomes can be used to further highlight temperature differences. Although subjective assessment identified pressure points in thermal images of some participants, it cannot be said with certainty that these pressure points can be detected through subjective assessment. One ulcer was clearly detected in a participant, demonstrating the potential of thermal imaging in ulcer detection.

Conclusion – Although it can be concluded from this study that PAD influences foot temperature, the large variation within groups hampers the reliability of drawing conclusions regarding the risk of DFUs based solely on thermal parameters of a one-off measurement. The premeasurement activities cannot be standardized in the setting of the VVT sector, leading to considerable variation of the temperature. However, the findings suggest that thermal imaging may be of value as an tool in addition to the standard screening, because of the information it can possibly provide about (incipient) pressure points and ulcers, but further research is needed.

1 Introduction

In 2021, around 537 million people worldwide were suffering from Diabetes Mellitus (DM) [1]. Diabetes is a chronic disease in which blood glucose levels are deregulated. This can be caused by an autoimmune response (type 1) or insulin resistance (type 2). In both types patients are suffering from increased blood glucose levels. These elevated glucose levels cause short-term and long-term consequences, one of which is the development of foot ulcers. Since these ulcers impose a significant burden on both healthcare systems and quality of life, research into prevention is necessary. This chapter first discusses the normal anatomy of the feet. Subsequently, the effects of diabetes on anatomy and physiology are explained, as well as the possible treatment of diabetic foot ulcers. This chapter also discusses the preventive screening that is carried out and how thermal imaging could contribute to this. Finally, the objectives and research questions of this study are provided.

1.1 Anatomy of the foot

In Figure 1 the bones and joints of the foot are visualised. The toes are indicated by digits (dig) 1 to 5, starting on the medial side [2, 3, 4]. In foot care the names of the bones and joints are used to indicate the locations of wounds and pressure marks on the skin.
The blood supply to the skin and superficial tissue of the feet is provided by the anterior and posterior tibial artery and the fibular peroneal artery. There are six separate regions, called angiosomes, that are fed by different branches of the three arteries. These six angiosomes can be found in Figure 2 with the associated feeding branches. Constrictions in the individual arteries therefore cause impaired blood supply and ischemia in the corresponding angiosomes [5, 6].

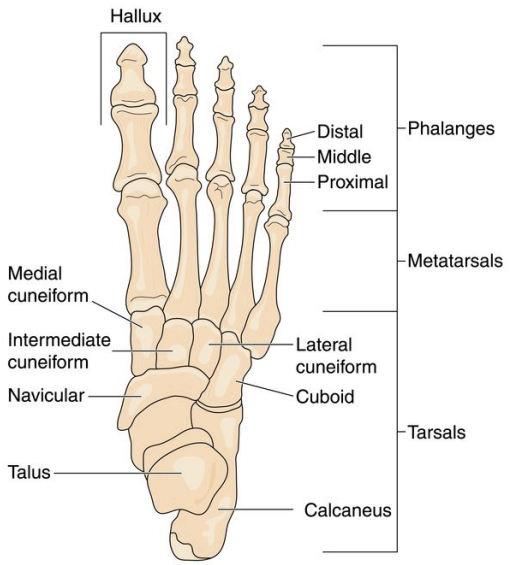


Figure 1: Anatomy of the foot. From *Elite Foot and Ankle Center. Anatomy of the foot and ankle.*

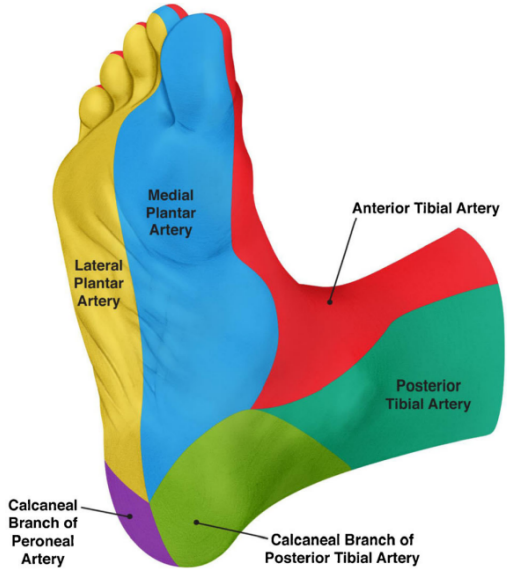


Figure 2: Angiosomes of the foot. From *Singh KP. Sharma AM. Critical limb ischemia: Current approach and future directions. Journal of Cardiovascular Translational Research, 2014.*

1.2 Complications of diabetes

If blood glucose levels are elevated for a long time, this can cause short-term and long-term complications. This study focuses on the long-term consequences. These can be divided into two categories: macro- and microvascular complications [7, 8]. Due to the increased glucose levels, the walls of the blood vessels are damaged, called atherosclerosis [9]. Inflammation of the vessel wall occurs, causing plaques to accumulate in the inner layer of the artery wall. This reduces the blood flow through the

vessels. This can, for example, cause strokes, cardiovascular diseases and peripheral arterial disease (PAD). These are macrovascular complications.
Additionaly, microvascular complications can occur. These complications arise due to alterations in blood circulation, endothelial permeability, extravascular protein accumulation and coagulation processes [10]. This affects the smaller blood vessels and nerve cells. The most common consequences of this are retinopathy, nephropathy, peripheral neuropathy and limited joint mobility syndrome [7, 8, 11].
As a result of both macro- and microvascular complications, patients with diabetes have an increased risk of developing a diabetic foot ulcer (DFU). 19-34% of patients with diabetes will develop a DFU [12].
A DFU can occur due to a (small) trauma or prolonged increased pressure on the foot, for example due to poorly fitting shoes. Neuropathy causes muscular atrophy, motor paralysis, loss of muscle reflex and decreased sweating. This leads to non-uniform pressure distribution across the feet, while reduced mobility induces an abnormal gait pattern. Due to the increased pressure on some parts of the foot, callus is formed locally. This results in even more biomechanical loading, causing subcutaneous hemorrhage and skin ulcerations [13]. In addition, neuropathy causes loss of protective sensation (LOPS), so pain sensations due to pressure points or emerging ulcers are not noticed by the patient. As a result, the wound can deteriorate rapidly.
In addition to the increased risk of wound developing, wound healing is reduced in patients with diabetes. Elevated glucose levels disrupt various functions of cells involved in wound healing. The function of macrophages is impaired, causing a chronic state of inflammation to occur in a DFU. Furthermore, immune system cells may undergo dysfunction, resulting in increased susceptibility to infections. Moreover, delayed reepithelialization occurs due to disturbed keratinocyte function. As a consequence, only 77% of DFUs heal within 1 year [14]. 40% of the patients suffering from a DFU will have to deal with a DFU again within a year and 60% within three years [12].

1.3 Treatment of a diabetic foot ulcer

DFUs can be treated by surgical debridement, glycemic control and wound offloading using orthopedic shoes or a cast [12, 15]. In addition, infections sometimes have to be treated with antibiotics and in some cases the blood supply has to be repaired through surgery, for example by a percutaneous transluminal angioplasty (PTA) or thromboendarterectomy [15]. If wound healing fails, surgical intervention such as toe, foot, or leg amputation may become necessary. Besides the decrease of quality of life of the patient, the treatment of DFUs is an intensive and expensive process. The treatment of a foot ulcer costs €5000 to €17.000 in specialized centers in Europe [16].

1.4 Periodic foot screening

The IWGDF Practical Guidelines describe the general principles of prevention, classification and treatment of diabetic foot disease [13]. According to these guidelines, patients with diabetes are screened for signs of LOPS and symptoms of PAD every 1 to 12 months, depending on the patient's risk. The following examinations are carried out during the screening:

1. Medical history (ulcers or amputations, Charcot foot, end-stage renal failure or dialysis)

2. Peripheral neuropathy assessment: a 10-g monofilament is used to test if there is loss of protective sensation. Neuropathy is diagnosed when the monofilament stimulus is not perceived in more than one of the three trials.

3. Peripheral vascular assessment: palpation of the dorsalis pedis and posterior tibial pulses of the feet. If the pulses are not palpable, ultrasound Doppler is used to check the vascular status. The Doppler measurement enables discrimination between triphasic, biphasic, and monophasic waveforms. Triphasic and biphasic patterns typically indicate the absence of PAD, whereas a monophasic waveform suggests its presence. Figure 3 shows what the different waveforms appear [17, 18]. The Doppler equipment used by the podiatrists reproduces these waveforms as different sounds.

4. Presence of spots with locally increased pressure, foot deformity or (starting) ulcers.

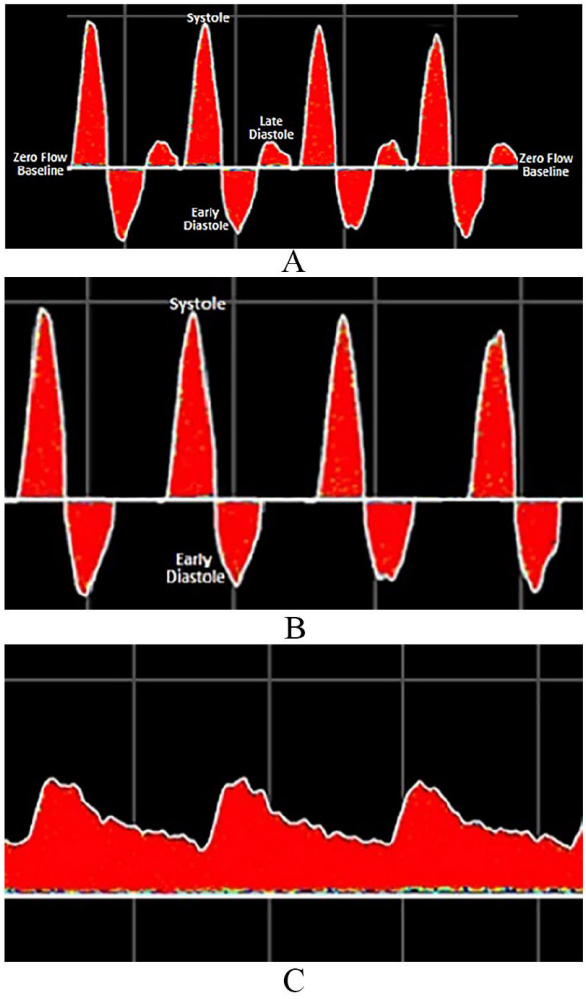


Figure 3: Triphasic (A), biphasic (B) and monophasic (C) waveforms, measured with Doppler. From *Kim WSH. Sharma A. Scissons R. et al. Interpretation of peripheral arterial and venous doppler waveforms: A consensus statement from the society for vascular medicine and society for vascular ultrasound. 2020*

Based on the screening, the patients are divided into risk categories, the Simms classification [19, 20]. In Table 1 the characteristics are given per Simms classification. Based on this Simms classification, patients are divided into four categories, called *Zorgprofielen* in Dutch. The higher the category, the more often the screening is performed and the more intensive and specialized the foot care the patient receives.
In the Netherlands, the periodic preventive screening is carried out by various institutions. If patients still live at home, the screening is done by the general practitioner or a podiatrist. When patients live in a nursing home, the periodic screening is usually carried out by the podiatrist. They are specialized in podiatry and visit patients in nursing homes and at home. In addition to the screenings, podiatrists treat patients with foot problems, provide pedicure care and are specialized in orthopedic shoes. The daily care for patients with diabetes is provided by nursing home staff. The foot care of patients with diabetes involves an ulcer team, specialized diabetes nurse and physicians.

Table 1: Simms classification

Classification	Risk	Characteristics	*Zorgprofiel*	Frequency footscreening	Foot care corresponding with classification
Simms 0	Low	No LOPS; No symptoms of PAD.	-	Once a year	Foot screening by podiatrist
Simms 1	Slightly increased	LOPS or symptoms of PAD; No signs of locally increased pressure.	1	Once every 6 months	Foot screening by podiatrist
Simms 2	High	- LOPS in combination with symptoms of PAD, or; - Symptoms of PAD in combination with signs of locally increased pressure, or; - LOPS in combination with signs of locally increased pressure, or; - LOPS in combination with symptoms of PAD and signs of locally increased pressure.	2: LOPS and/or PAD 3: LOPS and/or PAD and locally increase pressure	Once every 3 months	Foot screening and treatment plan by podiatrist, preventive foot care
Simms 3	Strongly increased	History of foot ulcer or amputation, or; Inactive Charcot-foot, or; End-stage renal disease (eGFR ¡ 15 ml/min) or renal replacement therapy.	4	Once every 1 - 3 months	Foot screening by podiatrist, specialized diabetic foot care by experts

1.5 Temperature of the diabetic foot

In addition to the examinations that are part of the screening to assess the risk of a DFU, the temperature of the feet is also a parameter that possibly offers insights into the risk of diabetic foot ulcers. Peripheral arterial disease causes impaired blood flow to the feet by damaging the vessels and nerves. In patients with PAD, stenosis occur in the vessels of the leg, resulting in impaired blood flow to the feet. Earlier research shows that the average temperature of the feet is lower in patients with PAD, due to the decrease in blood flow [21, 22, 23].

Persistent high blood sugar levels result in structural and functional alterations in the nerve microvasculature in patients with peripheral neuropathy. Previous research has shown that patients with neuropathy exhibit abnormal shunting in the tissue of the foot, which is not observed in healthy people. This shunting causes venous pressure to increase and capillary blood flow to decrease [24].

Furthermore, there is maldistribution of blood flow, caused by shunting. The total skin microcirculation is often normal or even increased, while the nutritional skin capillaries are supplied with less blood, according to previous research [24].

Other studies show that the foot temperature in diabetes patients with neuropathy is higher than in patients without neuropathy, likely caused by a persistent state of inflammation due to nerve damage [25, 26, 27, 28, 29]. Additionally, other research shows that in patients with diabetes, a decrease in pressure-induced vasodilation (PIV) occurs as a result of neuropathy [30, 31]. In healthy people, vasodilation occurs when pressure is applied to the skin to keep the tissue supplied with blood. In patients with diabetes, PIV is impaired, causing a decrease in local skin blood flow even at minimal increased local pressure.

Moreover, prior research demonstrates that wounds or inflammation in the foot can result in localized temperature elevation compared to the contralateral foot. A temperature difference of >2.2 °C between contralateral spots at the feet on consecutive days can be an early sign of the development of an ulcer [32, 33]. Another research suggests a cut-off value of >1.35 °C for the contralateral difference of the mean of the whole feet [34]. Additionally, a study of Debiec-Bak et al [25] shows that the difference between the temperature on the dorsal and plantar side is smaller in patients with diabetes and skin lesions than in healthy participants.

1.6 Measurement of the foot temperature

The temperature of the surface of the feet can be measured in different ways. A temperature difference between the two feet can be discerned by manual palpation. In addition, a hand-held thermometer can be used to determine the temperature at different spots [35]. Furthermore, there are socks available, equipped with sensors to measure the temperature in various locations [36]. Spots that are often measured using the hand-held thermometer and the sensors in the socks are the hallux, metatarsal one, three and five, the midfoot, and the heel on the plantar side [36, 37, 38]. Moreover, in some studies

mats are used that determine the temperature of the plantar side by means of sensors [39].
Tse et al [35] show that a manual measurement is less accurate and gives more false negative results than an objective temperature measurement by means of a hand-held infrared thermometer [35]. Authors of some studies using only six or eight spots, recommend more research into methods to measure more than a few spots for the prevention of DFUs [33, 34]. Thermal imaging can measure the temperature of the entire foot surface, on both the dorsal and plantar side. With a thermal camera, infrared (IR) light can be detected. IR light is emitted by all objects with a temperature above 0 K (-273.15 °C). Through radiation, heat transfer takes place from the warm object to the cold object by emitting and absorbing electromagnetic waves. The higher the temperature of an object, the more thermal radiation is emitted. Radiation takes place without contact and therefore does not require a medium for heat transfer. When the radiation hits another object, heat transfer takes place and the radition is absorbed, reflected or transmitted by the object. Infrared radiation has a wavelength between 0.78 μm and 1000 μm. The higher the temperature, the lower the wavelength. Wien's law can be employed for calculating the peak wavelength [40].

$$\text{Wien's law: } \lambda_{max} = \text{b/T}$$

Here λ_{max} is the peak wavelength, T is the absolute temperature of the object in Kelvin and b is the Wien's displacement constant (2.8977719 x10^{-3} m/K). In this study, the foot temperature is measured, which is approximately around 30 °C (303.15 K). The corresponding peak wavelength, calculated with Wien's law, is 9.559 μm.

1.7 Problems of the foot screening and possible improvements

According to previous studies into the validation of the IWGDF standard foot screening, the sensitivity to predict which diabetes patients will encounter a DFU is very high. This means that almost all patients that will develop a DFU are predicted by the screening. However, the specificity of the screening is low, resulting in a higher likelihood of patients being labeled as at risk, while they will never develop a DFU [41, 42]. Consequently, these patients receive intensive care. This situation is suboptimal in terms of efficiency and cost-effectiveness.
In the current screening according to the IWGDF standard, the macrovascular status is determined by palpation or measurement with Doppler of the dorsalis pedis artery and posterior tibial artery. However, microvascularity is not investigated, although this is a factor that is affected by prolonged elevated glucose levels and influences the development and healing of DFUs.
According to a research by Guilcher et al [18], interpreting the Doppler signal (triphasic, biphasic or monophasic) is difficult and the interpretation by different physicians is often different. Alternative methods for assessing PAD include determining the ankle brachial index or toe pressure. However, the evidence supporting their reliability is sparse [43, 44].
An additional issue associated with the existing screening protocol concerns the assessment of neuropathy during foot screening. This assessment requires understanding and cooperation from the patient to adequately tell whether the monofilament is felt under the feet. However, patients with dementia are often unable to adequately participate in this part of the screening. As a result, it is usually not possible to determine peripheral sensory loss in patients with dementia. Previous research indicates that the sensitivity and specificity of using the monofilament to determine neuropathy is not high due to this problem and no objective measurement is yet available to determine neuropathy or its implications [45].
Another shortcoming of the current screening method is the diagnosis of pressure points. In the present methodology, these pressure points are identified visually. While numerous pressure points are recognizable, there are also pressure points that are not readily discernible.
Hence, there are several points where improvements could be implemented in the existing screening method. Improvement would ensure a better distinction between patients at risk and not at risk, to accurately identifying which patients need intensive podiatric intervention to prevent a DFU and who require less intervention. The foot temperature may provide more information about feet at risk. Because the temperature of the feet is related to the vascular status [21, 22], the foot temperature could be a parameter that contributes to the correct assessment of the risk of DFUs [46, 47]. In addition

to the blood supply from the larger vessels, thermography could also be used to objectify the status of the microvasculature, which may be affected by neuropathy. Furthermore, the screening could be improved by an objective method to assess pressure points.
In short, objectifying foot temperature could enhance periodic screening if temperature, measured with thermal imaging, improves the determination of parameters in the current screening.

1.8 Objectives

The goal of this research was to investigate whether thermal imaging can be used to determine the risk of diabetic foot ulcers during the periodic screening, focussing on the geriatric sector (in Dutch: Verpleeg- en Verzorgingshuis en Thuiszorg, VVT sector). It will be determined which thermal parameters are associated with the parameters from the standard foot screening. Subsequently, it will be examined whether and in what way thermal imaging can be used in elderly care in assessment of the risk of a DFU. To achieve this goal, the following research questions are answered:

1. How is foot temperature related to diabetes, PAD and neuropathy?
    (a) How is the temperature of the dorsal and plantar side related to the factors mentioned?
    (b) How is the difference between the temperature of the dorsal and plantar side related to the factors mentioned?
    (c) How is the difference of the temperature of the two feet related to the factors mentioned?
    (d) Is division of the feet into regions useful for determining the relationship between the temperature of the feet and the factors mentioned?
    (e) Is division of the feet based on angiosomes useful for determining the relationship between the temperature of the feet and PAD?
2. How are temperature differences within the foot related to diabetes, PAD and neuropathy?
    (a) How is the distribution of temperature within the foot related to the factors mentioned?
    (b) How is the number of temperature peaks within the foot related to the factors mentioned?
3. Can pressure points be identified in the thermal images during subjective assessment?
4. Can thermal imaging be used in elderly care to improve current screening?

This research is being conducted in collaboration with Carintreggeland, a healthcare organization in the Netherlands. The results, applications and recommendations will therefore be focusing on Carintreggeland. However, most conclusions can be applied to diabetes care within the entire system of geriatric care in the Netherlands.

2 Materials and methods

To answer the questions mentioned in the chapter above, a cross-sectional study was conducted. To conduct a patient study, a non-WMO proposal was written, reviewed and approved by the domain-specific ethical committee Natural Sciences and Engineering Sciences (NES) of the University of Twente, see Appendix A. This chapter discusses the materials utilized for data collection and the data collection method, as well as the subsequent data processing procedures. The method and results for each analysis are given in the next chapter.

2.1 Inclusion and exclusion

The participants included in this study are patients living in nursing homes of Carintreggeland, Sensire and Zorgcentrum Beek en Bos. The participants are asked for informed consent to participate in the study by means of a Subject Information Sheet (Appendix B) and an Informed Consent Form (Appendix C).
Inclusion criteria are:

- 18 years or older;
- Diagnosed with diabetes;
- Being screened for the risk of a diabetic foot ulcer.

Exclusion criteria are:

- Major amputation of the foot;
- Amputation of the leg;
- Active or healing wound on the leg, above the ankle.

Additionally, data from healthy participants from a previous study is used [48].

2.2 Cameras and software

In this research, a thermal camera (Optris PI 400i / PI 450i) with accompanying software (Optris PIX connect) was used. The thermal camera has a spectral range of 8-14 μm and a thermal resolution of 0.04 K [49]. Additionally, a RGB camera (Basler acA1920-150um) with accompanying software (Pylon Viewer) is used with a wide angle lens (FUJINON HF12XA-5M). The data obtained with the thermal camera was processed using Matlab 2023b. A Matlab application designed by Dr. A. Chizari was used to create .mat files that can be analyzed by Matlab [50].

2.3 Set-up

Figure 4 shows the set-up used in this study. A device from the Bath Mat project of the BMPI department of the University of Twente was used. This device contains the two cameras. The cameras can be positioned in horizontal and vertical direction. The device containing the cameras is placed on an adjustable tripod. This tripod is placed on a metal plate, which is covered with black fabric. A stool was used to place legs, see Figure 4. This stool has two footrests in which the lower legs can be placed. Additionally, a construction is affixed to the stool, onto which a black backdrop is secured. There are two openings, facilitating the insertion of the feet. Consequently, only the plantar surfaces of the feet are depicted during the plantar measurements, while the surrounding area is hidden. The black material covering the metal plate as well as the black backdrop and the stool can be cleaned with alcohol wipes.

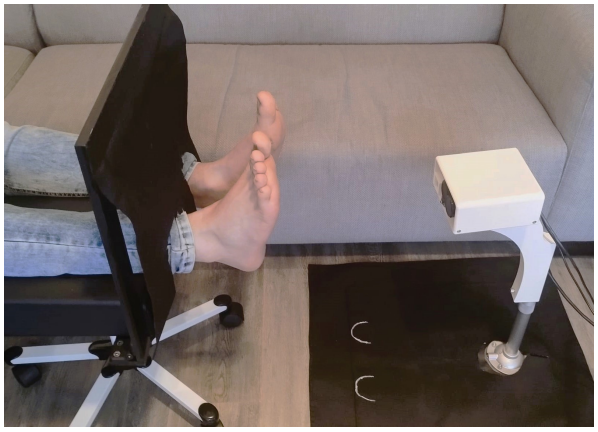


Figure 4: Set-up for measurement of the plantar side

2.4 Collected data

In this study, thermal data is compared with the data collected by the podiatrist during the periodic foot screening. This makes it possible to investigate whether thermal images and thermal parameters correspond with the data collected by the podiatrist. Because the periodic foot screening is expected to determine the risk of a DFU, the parameters and results of this screening can be used as a gold standard for diagnosing the risk of foot ulcers. The data collected consists of three components: basic characteristics, parameters and results of the periodic foot screening by the podiatrist, thermal and RGB images.

Basic characteristics

Whenever possible, the following data is collected from the patient file: age, gender, year of diagnosis, diabetes type, therapy to treat diabetes and relevant comorbidities. The basic characteristics are stored in ResearchManager.

Periodic foot screening

The podiatrist at Voetencentrum Wender is requested to provide the parameters and results of the periodic foot screening. This consists of the relevant medical history (ulcer or amputation in history, previous Charcot foot, end-stage renal failure or dialysis), symptoms of neuropathy, symptoms of PAD, presence and locations of pressure sores, position abnormalities and the presence of active ulcers. In addition, the risk profile in the Simms classification and the corresponding Zorgprofiel are collected. The parameters of the periodic foot screening are stored in ResearchManager.

Thermal and RGB images

The research data is collected at the same time as the periodic foot screening is performed by the podiatrist. The measurements involve capturing thermal images of both the dorsal and plantar sides of the feet. Furthermore, RGB images are acquired to aid in the interpretation of the thermal data. The measurement protocol is discussed in the next section.

2.5 Measurement protocol

The lens of both cameras is set to the predetermined position corresponding to the focal distance of 32 cm, so that the image resolution is optimal. During the measurements, the participant sits on a chair. Shoes and socks are asked to take off. Any plasters and bandages will be removed. The measurements start on the plantar side. For this measurement, the legs are positioned on the stool, with the heels protruding beyond the edge, as is depicted in Figure 4. The black screen is placed upwards, with the legs inserting the notches. The camera is placed 32 cm from the plantar side of the

feet. The participant is asked to pull their toes towards themselves (if possible), so that the feet are perpendicular to the camera. Thermal images and a RGB image are made of the plantar side of the feet. Subsequently, measurements are taken on the dorsal side, see Figure 5. The stool is displaced, and the feet are positioned on the plate beneath the cameras. The height of the camera tripod is set at 32 cm from the top of the feet. Thermal images and a RGB image are made of the dorsal side of the feet. After taking the images, the stool, the black material covering the metal plate as well as the black vertical background are cleaned with alcohol wipes. A step-by-step protocol can be found in Appendix D.

Figure 5: Set-up for measurement of the dorsal side

2.6 Postprocessing thermal data

Prior to conducting analyses on the thermal images, several post-processing steps must be executed, using Matlab. First, the Excel files are converted into .mat files using the Bath Mat application in Matlab, designed by dr. A. Chizari [50]. The best frame to analyze is selected manually. In this frame, the feet should be as perpendicular as possible and should not move. Subsequently, in both the dorsal and plantar images, the left and right feet are cropped separately. In the cropped images, the feet are manually segmented. The segmentation of the feet is done three times per foot to determine intraobserver variability. During segmentation, a line is drawn on the edge of the foot. On the dorsal side, the ankle is not segmented as belonging to the foot. Space between the toes does not get included in the segmentation.

2.7 Statistical analysis

Data is analyzed with the SPSS statistics software package (SPSS Statistics 29, IBM, Armonk, NY, USA). A table is created showing the basic characteristics of the participants. It is determined whether the temperature of the feet is normally distributed, using the Normality test of SPSS. For datasets following a normal distribution, the group mean values are provided. If the dataset does not adhere to a normal distribution, the median is reported. The Independent Sample T test will be applied to analyze the differences of the parameters between the groups, with p-values ≤ 0.05 considered as statistically significant.. The power of the results will be estimated with G*Power (version 3.1.9.7).

3 Analyses and results

3.1 Participants characteristics

For this study 23 participants were included. All participants were older than 18 years and have given informed consent. For the four participants with dementia, informed consent was requested from the

legal representative. In addition to the 23 participants with diabetes, thermal data from 15 healthy participants of a previous study by E. Zoetelief [48] was used. In this study, a healthy participant was defined as a participant that is not suffering from DM and has no foot wound below the ankle. It is assumed that these healthy subjects did not suffer from PAD or neuropathy. Table 2 gives the characteristics of the participants.

Table 2: Participants characteristics

	Category	Healthy subjects (15)	Subjects with diabetes (23)
Biological sex	**Men** **Women**	7 (46.7%) 8 (53.5%)	6 (26.1%) 17 (73.9%)
Age		35.6 (SD 10.5)	85.4 (SD 4.8)
Years since diagnosis			20.3 (SD 8.4)
Ulcus in medical history	No Yes		19 (82.65%) 4 (17.4%)
Amputation in medical history	No Yes		22 (95.7%) 1 (4.3%)
PAD, vascular state	No PAD, triphasic No PAD, biphasic PAD, monophasic		9 (39.1%) 9 (39.1%) 5 (21.7%)
Neuropathy	No Yes		6 (26.1%) 17 (73.9%)
Pressure spots	No Yes		2 (8.7%) 21 (91.3%)
Foot deformity [1]	No Yes		13 (56.5%) 5 (21.7%)
Wounds	No Yes		22 (95.7%) 1 (4.3%)
Simms classification	0 1 2 3		3 (13.0%) 0 (0.0%) 16 (69.6%) 4 (17.4%)

[1] Data missing of five subjects

3.2 Intraobserver variability

At first, the intraobserver variability among the segmentations was assessed. This evaluation aimed to ascertain whether analyses of manually segmented feet can be reliably compared with one another, or if excessive intraobserver variation exists when segmenting the same foot multiple times. If that is the case, it is necessary to use the average of the three segmentations for the subsequent analyses.

Method

The intraobserver variability was determined by first calculating the deviation in the number of pixels that is segmented as 'foot' for the three segmentations. This will be given in percentage of the total number of pixels. Further, the average temperature was calculated for the three segmentations per foot separately for every participant. Subsequently, the intraobserver variability was determined for every foot by calculating the standard deviation (SD) and the coefficient of variation (CV) of the temperature [51]. The coefficient of variation can be calculated with the following formula:

$$\mathrm{CV} = \sigma/\mu$$

In this formula σ is the standard deviation and μ the mean temperature of the three segmented feet. With a coefficient of variation below 0.05, the intraobserver variability is considered small [52]. With limited intraobserver variability, the segmentations exhibit minimal deviations, thereby suggesting that utilizing a single segmentation in subsequent analyses is sufficient to obtain reliable results.

Results

Table 3 shows the average difference in the number of pixels segmented as belonging to the foot between the three segmentations of the same feet, as a percentage of the total number of segmented pixels per foot.

Table 3: Difference between the number of segmented pixels

	Dorsal left	Dorsal right	Plantar left	Plantar right
Difference between the three segmentations: mean % of total number of pixels	9.22	7.68	4.41	4.53
Standard deviation of % of total number of pixels	5.01	3.60	2.70	2.82

To investigate the impact of the differences between the segmentations on the temperature, Table 4 shows the average of all participants' mean temperature per side of the foot, for all three segmentations.

Table 4: Mean temperature of the three segmentations

	Dorsal left	Dorsal right	Plantar left	Plantar right
Segmentation 1 (°C)	28.97	28.86	27.56	27.35
Segmentation 2 (°C)	28.97	28.81	27.54	27.36
Segmentation 3 (°C)	28.96	28.81	27.53	27.35

This table shows that when calculating the mean temperature of the different participants, the mean temperature of the different segmentations hardly differs.

To calculate the coefficient of variation, the mean and standard deviation for every foot were calculated. The mean temperature and SD for all participants can be found in Table 5. This table shows that the mean standard deviation of different segmentations is 0.05 °C for the dorsal side and 0.02 °C for the plantar side. The mean coefficient of variation is 0.00.

Table 5: Coefficient of variation of the mean temperature of the three segmentations

	Dorsal left	Dorsal right	Plantar left	Plantar right
Mean temperature (°C)	28.97	28.83	27.55	27.36
Mean SD (°C)	0.05	0.05	0.02	0.02
Mean CV	0.00	0.00	0.00	0.00

Based on this analysis, it can be concluded that although the number of pixels differs, this has minimal influence on the mean temperature. It was therefore decided to use only one segmentation in the following analyses. The second segmentation was selected for all analyses.

3.3 Temperature of dorsal and plantar side

Method

To analyze the differences in temperature, the mean temperature of both the dorsal and plantar side of the feet was determined by taking the mean of all segmented pixels. It was investigated whether there is a relation between the mean temperature of the feet, peripheral arterial disease, neuropathy and the Simms classification. With the temperature of the dorsal and plantar side, the difference between dorsal and plantar side and the temperature difference between both feet is calculated. It was investigated whether these values have a relation with peripheral arterial disease and neuropathy. For the analysis of the influence of neuropathy on the thermal parameters, participants with PAD have been excluded, focusing solely on the relationship with neuropathy.

Results

The results of the analyzes of the mean temperature of the dorsal and plantar sides are shown below. The mean temperature of the dorsal and plantar side is normally distributed.

Peripheral arterial disease

First, the influence of PAD on the temperature of the feet was analyzed. Figure 6 shows a box plot of the temperature per side of the foot per group. In this figure the temperature is given for the group with healthy participants and participants with diabetes with triphasic vascular state, biphasic vascular state and monophasic vascular state.

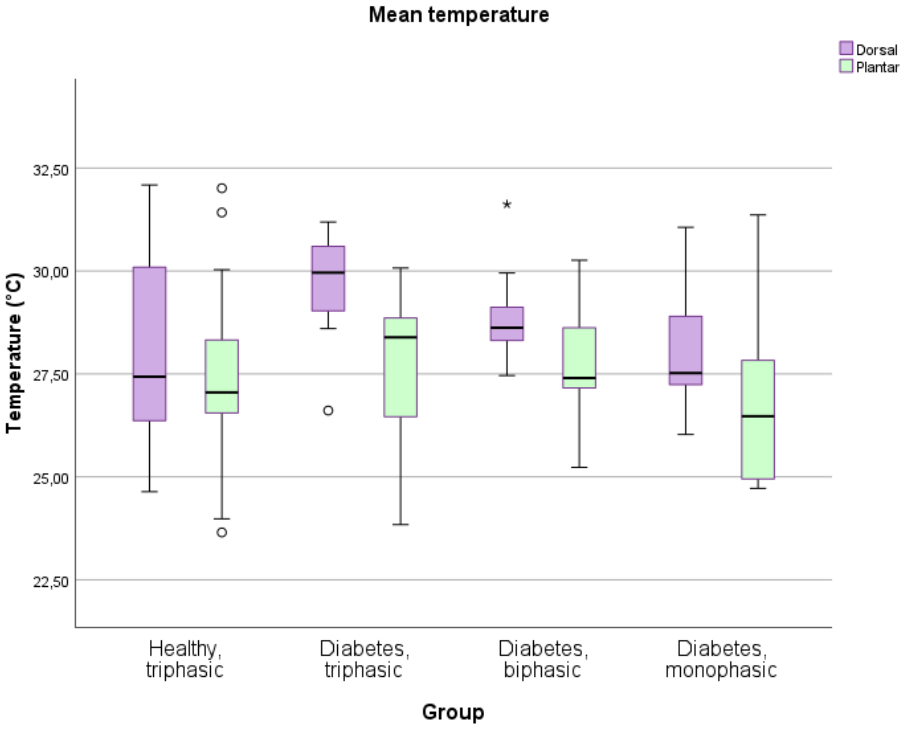


Figure 6: Box plot of the mean temperature of the feet for the groups with different vascular state

In Table 6 the temperature differences between the groups are given with the corresponding p-value, calculated with the Independent Sample T Test. None of these differences between the groups are statistically significant.

Table 6: Difference of the mean temperature between the group with different vascular states

Compared groups		Difference between mean temperature dorsal side (°C)	p-value	Difference between mean temperature plantar side (°C)	p-value
Healthy, triphasic (n=15)	**Diabetes, triphasic (n=9)**	-2.53	0.101	-1.34	0.825
Diabetes, triphasic (n=9)	**Diabetes, biphasic (n=9)**	1.34	0.279	0.99	0.899
Diabetes, triphasic (n=9)	**Diabetes, monophasic (n=5)**	2.44	0.399	1.92	0.491
Diabetes, biphasic (n=9)	**Diabetes, monophasic (n=5)**	1.10	0.399	0.93	0.575

The results show that the temperature of the feet of healthy participants is lower than the tempera-

ture of participants with diabetes without vascular disease. It is also apparent that the temperature decreases with poorer vascular status.

The box plot of Figure 7 shows the difference between the temperature of the dorsal and plantar side of the four groups. A negative value means that the plantar side has a higher temperature than the dorsal side.

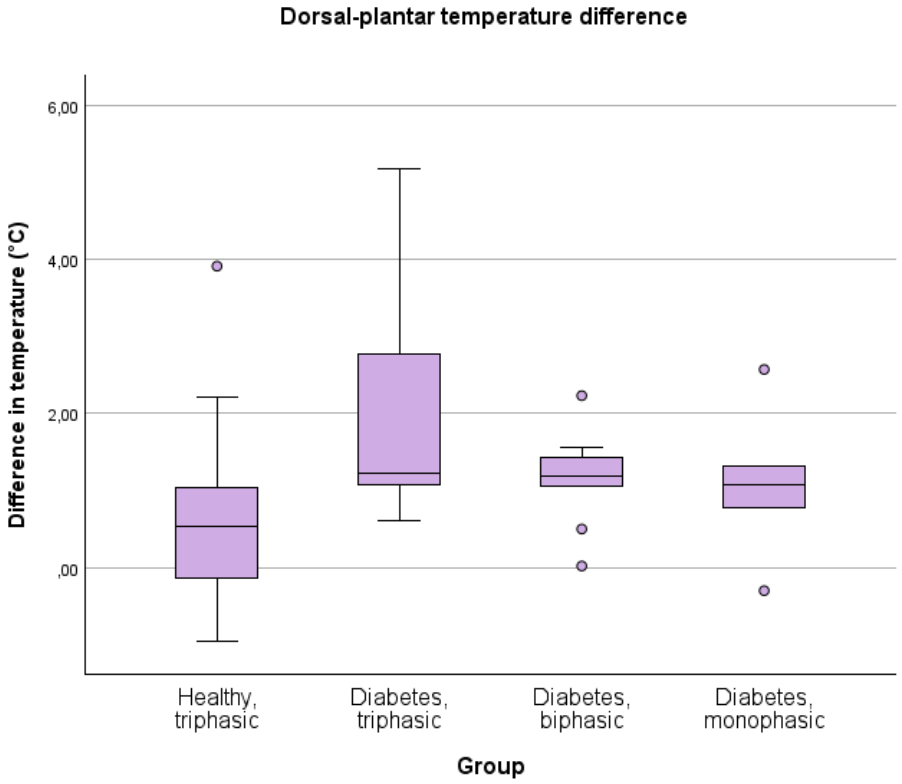


Figure 7: Box plot of the temperature difference between the dorsal and plantar side for the groups with different vascular state

There is a disparity between the dorsal-plantar temperature difference of healthy participants and participants with diabetes, while the disparity between the dorsal-plantar temperature difference of the three groups with diabetes is small. The disparity in the dorsal-plantar temperature difference between the groups are shown in Table 7, with the corresponding p-values calculated with the Independent Sample T Test.

Table 7: Disparity between the dorsal-plantar temperature difference between the group with different vascular states

Compared groups		Difference in dorsal-plantar temperature difference (°C)	p-value
Healthy, triphasic (n=15)	**Diabetes, triphasic (n=9)**	-0.68	0.038*
Diabetes, triphasic (n=9)	**Diabetes, biphasic (n=9)**	0.03	0.170
Diabetes, triphasic (n=9)	**Diabetes, monophasic (n=5)**	0.14	0.863
Diabetes, biphasic (n=9)	**Diabetes, monophasic (n=5)**	0.11	0.272

The temperature difference between the two feet per participant was examined in the four groups, to investigate the influence of PAD. Figure 8 shows the differences between the temperature of both feet for the four groups.

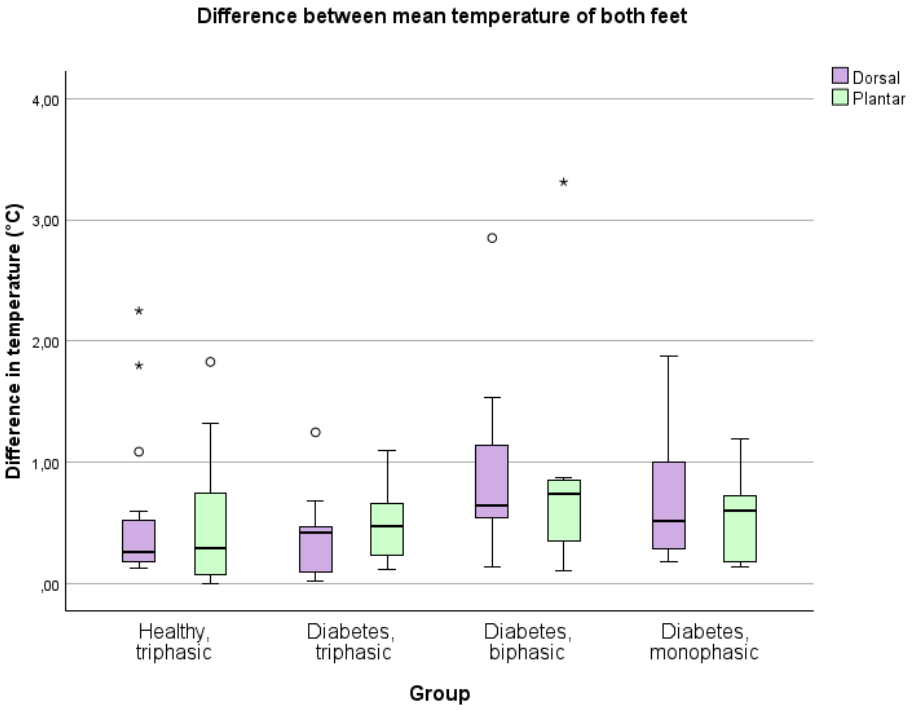


Figure 8: Box plot of the temperature difference between both feet for the groups with different vascular state

The temperature difference between the two feet is higher in participants with diabetes than in participants without diabetes. Within the group with diabetes, the difference between the temperature of both feet increases with poorer vascular status. The differences between the groups are given in Table 8, with the corresponding significance value.

Table 8: Disparity between the temperature differences between both feet for the groups with different vascular states

Compared groups		Difference between temperature difference dorsal side (°C)	p-value	Difference between temperature difference plantar side (°C)	p-value
Healthy, triphasic (n=15)	**Diabetes, triphasic (n=9)**	-0.16	0.548	-0.18	0.974
Diabetes, triphasic (n=9)	**Diabetes, biphasic (n=9)**	-0.23	0.100	-0.26	0.280
Diabetes, triphasic (n=9)	**Diabetes, monophasic (n=5)**	-0.10	0.705	-0.12	0.516
Diabetes, biphasic (n=9)	**Diabetes, monophasic (n=5)**	0.13	0.277	0.14	0.735

From this table it can be concluded that the mean temperature differences are approximately the same for the dorsal and the plantar side.

Neuropathy

In addition to the influence of peripheral arterial disease, neuropathy may also be associated to the

temperature of the feet. The temperature per group is given in Figure 9. The group without neuropathy and without PAD is limited, comprising only four participants.

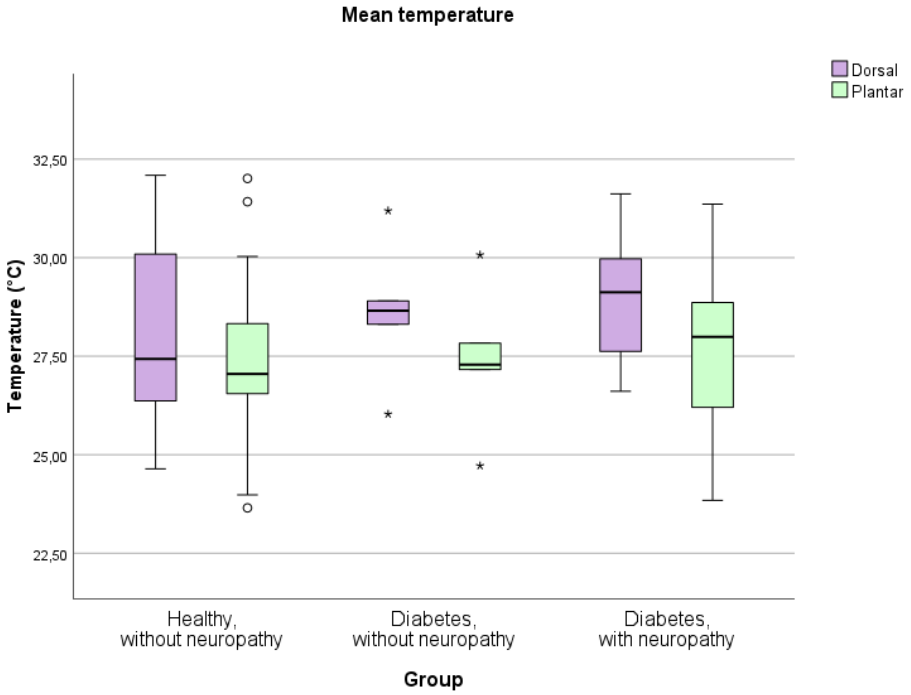


Figure 9: Box plot of the mean temperature of the feet for the groups with and without neuropathy

The differences in temperature between the three groups are given in Table 9, with the corresponding p-values, calculated with the Independent Sample T Test.

Table 9: Difference of the mean temperature between the group with and without neuropathy

Compared groups		Difference between mean temperature dorsal side (°C)	p-value	Difference between mean temperature plantar side (°C)	p-value
Healthy, without neuropathy (n=15)	**Diabetes, without neuropathy (n=4)**	1.65	0.621	1.22	0.998
Diabetes, without neuropathy (n=4)	**Diabetes, with neuropathy (n=14)**	-1.00	0.484	-1.02	0.842

It is observed that individuals with neuropathy exhibit slightly higher foot temperatures compared to those without neuropathy. However, the differences are not statistically significant.

The dorsal-plantar temperature differences are depicted in Figure 10.

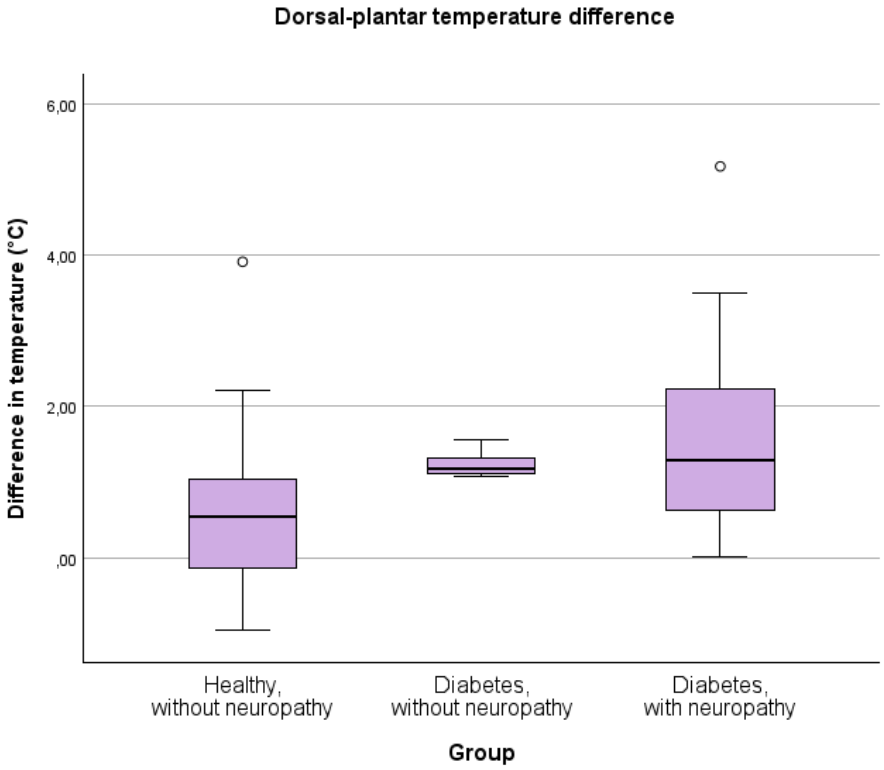


Figure 10: Box plot of the dorsal-plantar temperature differences for the groups with and without neuropathy

Participants with diabetes have a higher dorsal-plantar temperature difference than healthy participants, as was also observed in Figure 7 There is minimal variation observed between the groups with diabetes. Table 10 shows the differences between the groups, with the corresponding p-value for the significance level of the difference between the groups, calculated with the Independent Sample T Test.

Table 10: Disparity between the dorsal-plantar temperature difference between the group with and without neuropathy

Compared groups		**Difference in dorsal-plantar temperature difference (°C)**	**p-value**
Healthy, without neuropathy (n=15)	**Diabetes, without neuropathy (n=4)**	-0.63	0.405
Diabetes, without neuropathy (n=4)	**Diabetes, with neuropathy (n=14)**	-0.12	0.568

The difference in the temperature between both feet for the groups with and without neuropathy are shown in the box plot in Figure 11.

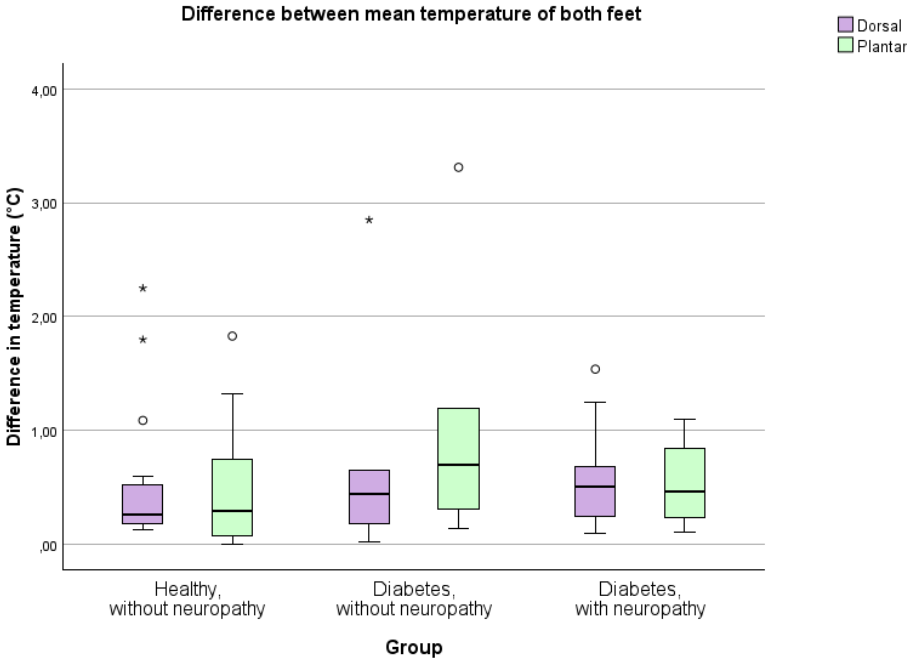


Figure 11: Box plot of the temperature difference between the both feet for the groups with and without neuropathy

Minimal difference is found between the three groups. In Table 11 the differences between the groups are given, with the significance levels.

Table 11: Disparity between the temperature differences between both feet for the groups with and without neuropathy

Compared groups		Difference between temperature difference dorsal side °C	p-value	Difference between temperature difference plantar side °C	p-value
Healthy, without neuropathy (n=15)	**Diabetes, without neuropathy (n=4)**	-0.25	0.587	0.40	0.153
Diabetes, without neuropathy (n=4)	**Diabetes, with neuropathy (n=14)**	0.00	0.596	0.23	0.369

Simms classification

In addition to the relationship with PAD and neuropathy, this study also determined whether there is a relationship between the thermal parameters and the outcome of the screening, the Simms classification. Figure 12 shows the box plot for the mean temperature for the different Simms classifications.

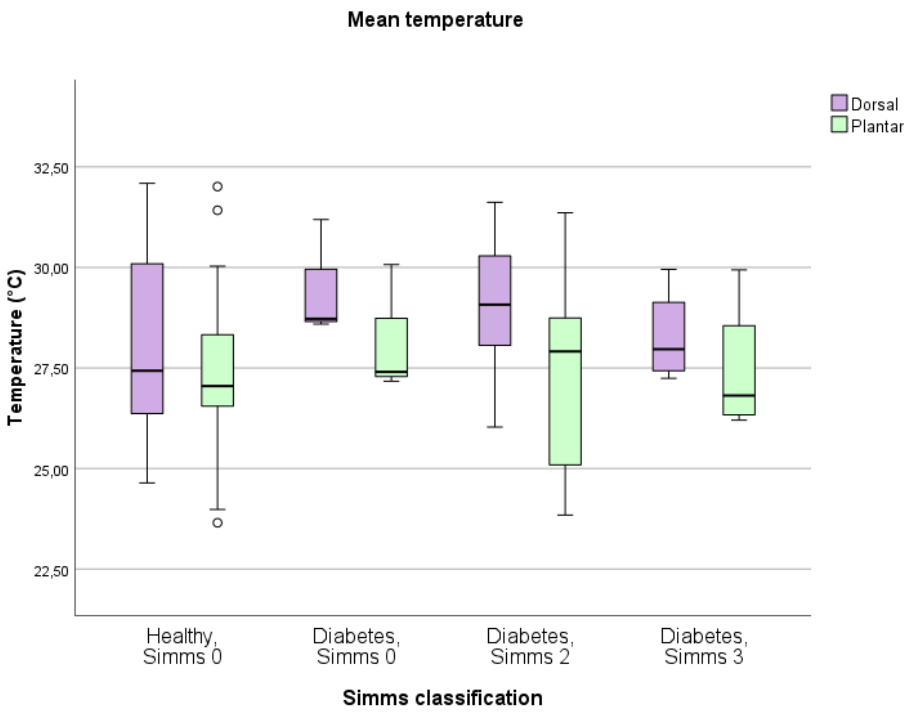


Figure 12: Box plot of the mean temperature of the feet for the groups with different Simms classification

In Table 12 the differences between the groups are given. The figure above and the table demonstrate that the temperature is lower with a higher Simms classification. As depicted in this table, no difference between the groups is statistically significant.

Table 12: Difference between the mean temperature of the groups with different Simms classification

Compared groups		Difference between mean temperature dorsal side (°C)	p-value	Difference between mean temperature plantar side (°C)	p-value
Healthy, Simms 0 (n=15)	**Diabetes, Simms 0 (n=3)**	-1.42	0.346	-0.82	0.589
Diabetes, Simms 0 (n=3)	**Diabetes, Simms 2 (n=16)**	0.41	0.690	0.77	0.573
Diabetes, Simms 0 (n=3)	**Diabetes, Simms 3 (n=4)**	1.22	0.278	0.77	0.573
Diabetes, Simms 2 (n=16)	**Diabetes, Simms 3 (n=4)**	0.82	0.302	0.00	0.994

3.4 Temperature of regions

Method

In this analysis, the foot was divided into two regions, see Figure 13. For this purpose, the foot was first rotated to a perpendicular view. Subsequently, the length of the foot is determined, after which the foot is divided into two parts, the distal region and the proximal region. This method was used to further investigate the difference between the temperature of the dorsal and plantar sides. Because the dorsal distal region is most affected by the foot screening measurements taken prior to the thermal measurements (more about this later in this report), the dorsal proximal region is selected on the dorsal side. On the plantar side, the proximal region and the distal region are analyzed separately. It was investigated whether there is a relation between the temperature difference between the regions

and peripheral arterial disease and neuropathy.

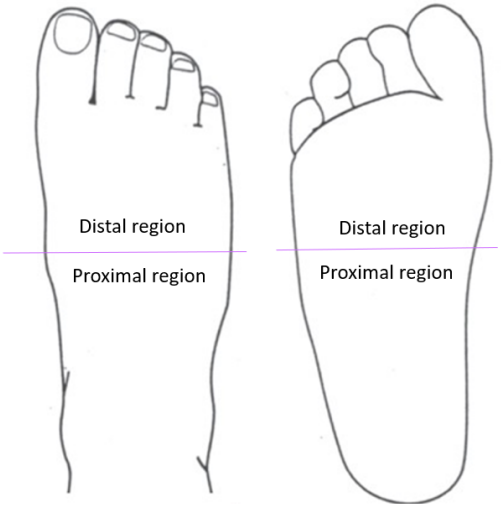


Figure 13: Division of the feet into distal and proximal region

Results

The temperature differences between the regions are normally distributed. Therefore the mean temperature is given in this analysis.

Peripheral arterial disease

Figure 14 shows the temperature difference for each combination for the four groups. In the previous analysis of the temperature difference between the total dorsal and plantar side of the foot (in Figure 14 given in the purple bar), the difference in the group with diabetes is almost the same with different vascular status. In the novel analyses, wherein the dorsal forefoot is excluded, a notable difference is observed among the various groups. The dorsal-plantar temperature difference for the groups with poorer vascular state are slightly decreased.

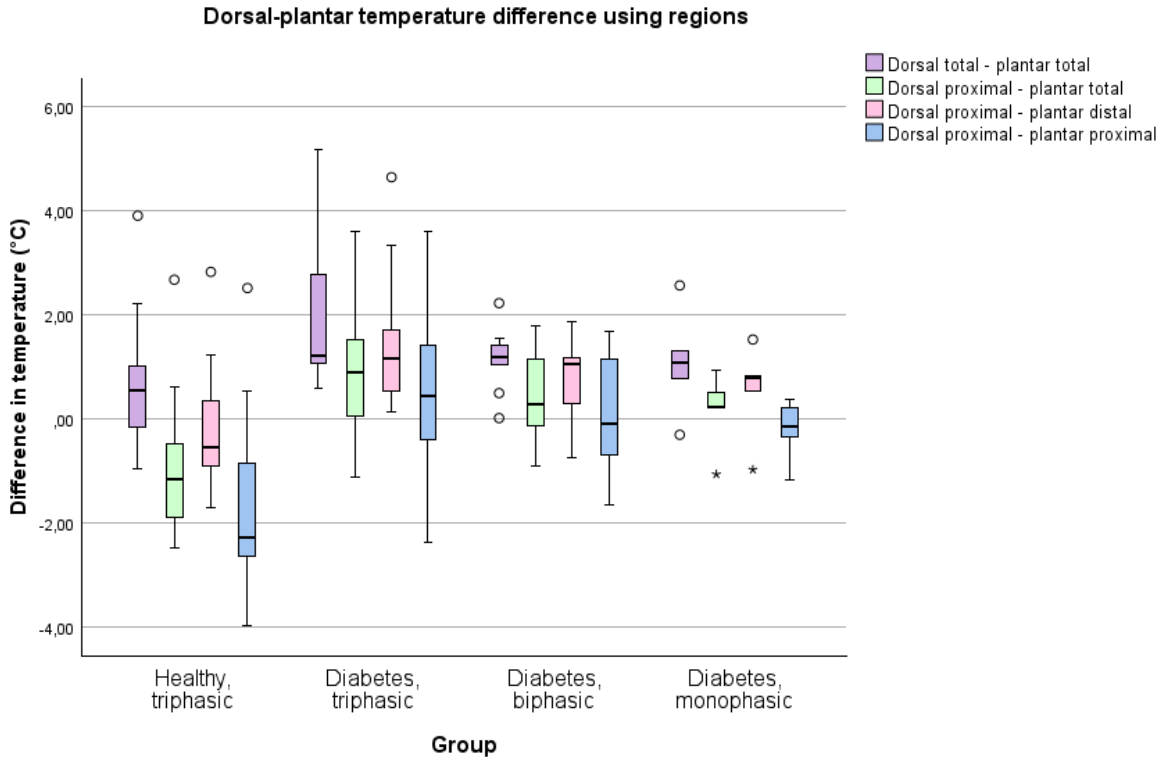


Figure 14: Box plot of the dorsal-plantar temperature differences, using the different combinations of regions for the groups with different vascular state

Table 13 shows the differences between the dorsal-plantar differences of the different groups, with the p-values calculated with the Independent Sample T Test. The difference between the healthy group and the group with diabetes and triphasic vascular status is statistically significant for all four combinations.

Table 13: Disparity between the temperature differences of the dorsal and plantar regions between the groups with different vascular state

Compared groups		Difference between dorsal tot. - plantar tot. temperature difference (°C)	p-value	Difference between dorsal prox. - plantar tot. temperature difference (°C)	p-value	Difference between dorsal prox. - plantar dist. temperature difference (°C)	p-value	Difference between dorsal prox. - plantar prox. temperature difference (°C)	p-value
Healthy, triphasic (n=15)	**Diabetes, triphasic (n=9)**	-0.68	0.038*	-2.07	0.003*	-1.71	0.004*	-2.72	0.005*
Diabetes, triphasic (n=9)	**Diabetes, biphasic (n=9)**	0.03	0.170	0.63	0.261	0.12	0.169	0.54	0.410
Diabetes, triphasic (n=9)	**Diabetes, monophasic (n=5)**	0.14	0.863	0.68	0.242	0.38	0.193	0.57	0.332
Diabetes, biphasic (n=9)	**Diabetes, monophasic (n=5)**	0.11	0.272	0.05	0.654	0.26	0.680	0.03	0.665

Neuropathy

In Figure 15 the results of the analysis of the temperature difference between dorsal and plantar side for the groups with and without neuropathy is given.

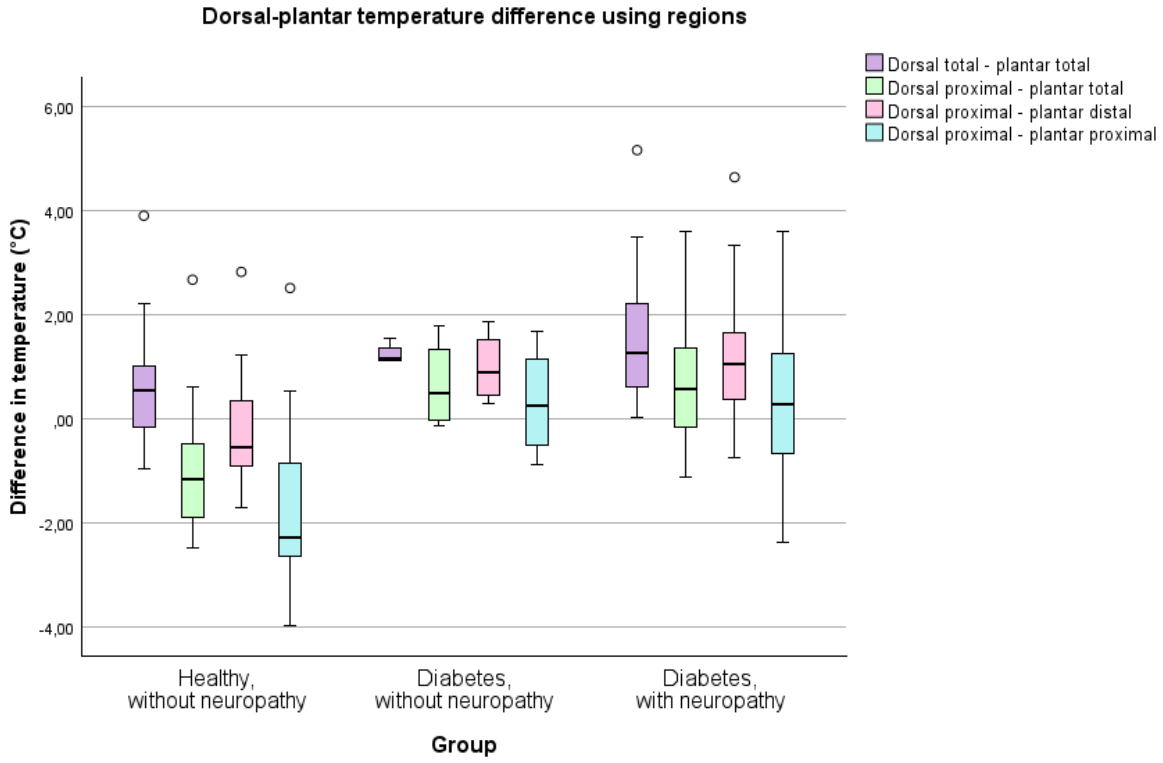


Figure 15: Box plot of the dorsal-plantar temperature differences, using the different combinations of regions for the groups with and without neuropathy

In this box plot the dorsal-plantar temperature difference hardly differs between the groups with diabetes and with and without neuropathy using the different methods to calculate the temperature difference. Table14 shows the disparity between the temperature differences between the groups, including the levels of significance.

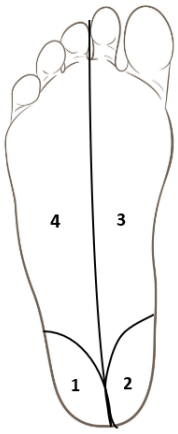
Table 14: Disparity between the temperature differences of the dorsal and plantar regions between the groups with and without neuropathy

Compared groups		Difference between dorsal tot - plantar tot. temperature difference (°C)	p-value	Difference between dorsal prox. - plantar tot. temperature difference (°C)	p-value	Difference between dorsal prox. - plantar dist. temperature difference (°C)	p-value	Difference between dorsal prox. - plantar prox. temperature difference (°C)	p-value
Healthy, without neuropathy (n=15)	**Diabetes, without neuropathy (n=4)**	-0.56	0.405	-1.60	0.043*	-1.17	0.068	-2.03	0.042*
Diabetes, without neuropathy (n=4)	**Diabetes, with neuropathy (n=14)**	-0.41	0.568	-0.11	0.893	-0.22	0.764	0.01	0.994

3.5 Temperature of angiosomes

Method

In the following analysis, the plantar side was divided in regions on the basis of angiosomes, as outlined in the Introduction, Chapter 1.1. The angiosomes have been manually segmented by the author. In Figure 16 the abbreviations of the angiosomes that are used further in this report are given. Subsequently, the mean temperature of the segmented angiosomes was calculated.



1: Lateral calcaneal branch of per.a. (LCB angiosome)
2: Medial calcaneal branch of post.tib.a. (MCB angiosome)
3: Medial plantar artery of post.tib.a. (MPA angiosome)
4: Lateral plantar artery of post.tib.a. (LPA angiosome)

Figure 16: Angiosomes of the feet

Because the angiosomes are supplied with blood by different arteries, a difference in blood supply between the different angiosomes could possibly occur in patients with peripheral arterial disease. This can cause a difference in temperature of the angiosomes. It was investigated whether there is a relationship between the temperature of one or more angiosomes, the temperature differences between the angiosomes of both feet and the vascular state.

Results

The temperature of the angiosomes is normally distributed. In Figure 17 the temperature of the angiosomes is given for the healthy group and the groups with diabetes.

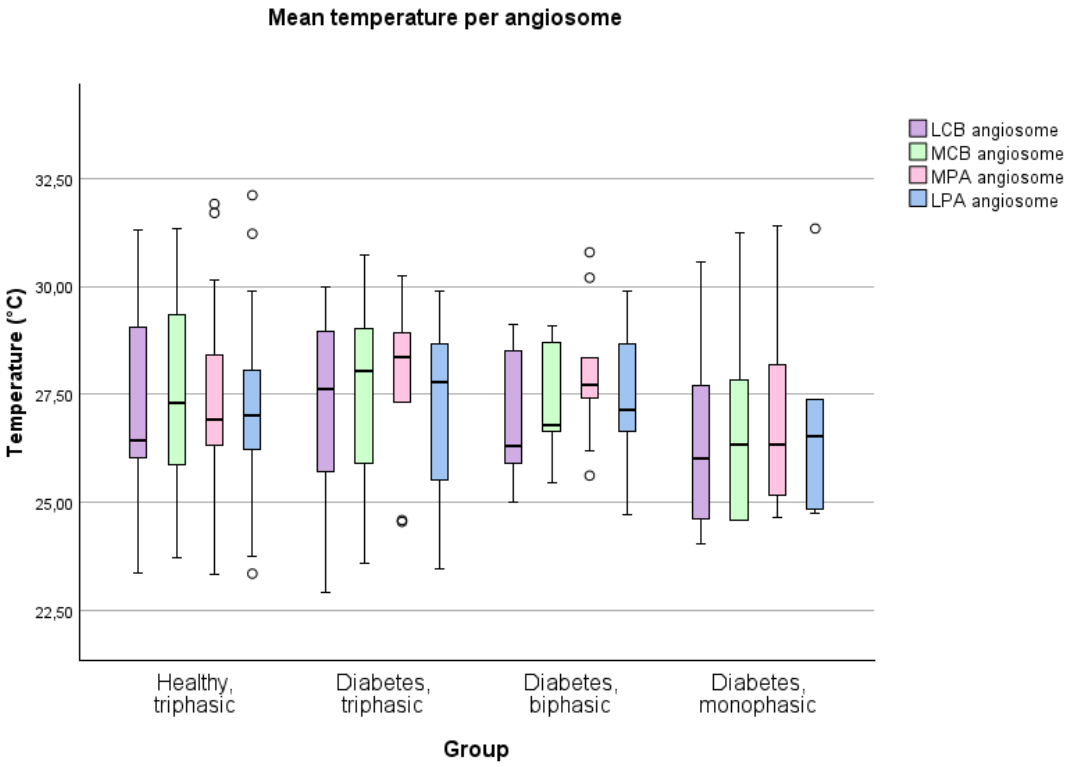


Figure 17: Box plot of the mean temperature of the angiosomes for the groups with different vascular state

In the tri- and biphasic groups there is variation between the temperature of the different angiosomes, while in the monophasic group the angiosomes have approximately the same temperature. The differences of every angiosome between the groups are given in Table 15, as well as the corresponding p-values for the differences between the groups, calculated with the Independent Sample T Test.

Table 15: Difference of mean temperature of angiosomes between the groups with different vascular state

Compared groups		Difference between mean temperature LCB angiosome (°C)	p-value	Difference between mean temperature MCB angiosome (°C)	p-value	Difference between mean temperature MPA angiosome (°C)	p-value	Difference between mean temperature LPA angiosome (°C)	p-value
Healthy, triphasic (n=15)	**Diabetes, triphasic (n=9)**	0.20	0.841	0.04	0.968	-0.51	0.618	-0.07	0.943
Diabetes, triphasic (n=9)	**Diabetes, biphasic (n=9)**	0.19	0.846	0.27	0.761	-0.11	0.900	-0.21	0.827
Diabetes, triphasic (n=9)	**Diabetes, monophasic (n=5)**	0.56	0.686	0.70	0.618	0.71	0.593	0.30	0.825
Diabetes, biphasic (n=9)	**Diabetes, monophasic (n=5)**	0.37	0.734	0.43	0.695	0.82	0.497	0.51	0.669

Figure 18 shows a visualisation of the mean temperature of every angiosome for the groups with different vascular states.

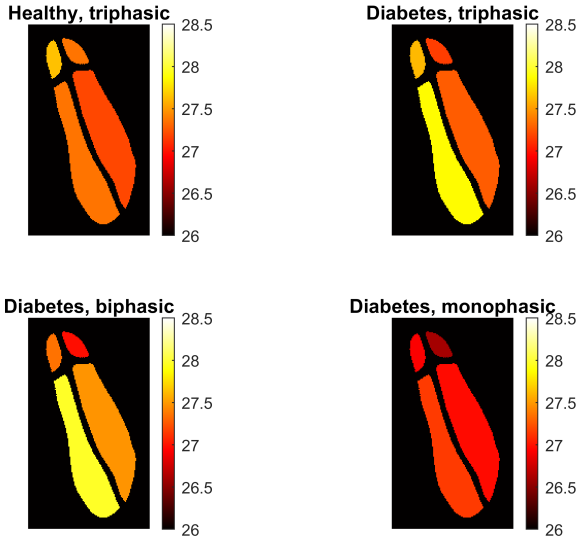


Figure 18: visualisation of the mean temperature of the angiosomes for the groups with different vascular state

In addition to the assessment of the temperature per angiosome, comparisons were made between the temperature of corresponding angiosomes of both feet. These temperature differences can be found in the box plot in Figure 19.

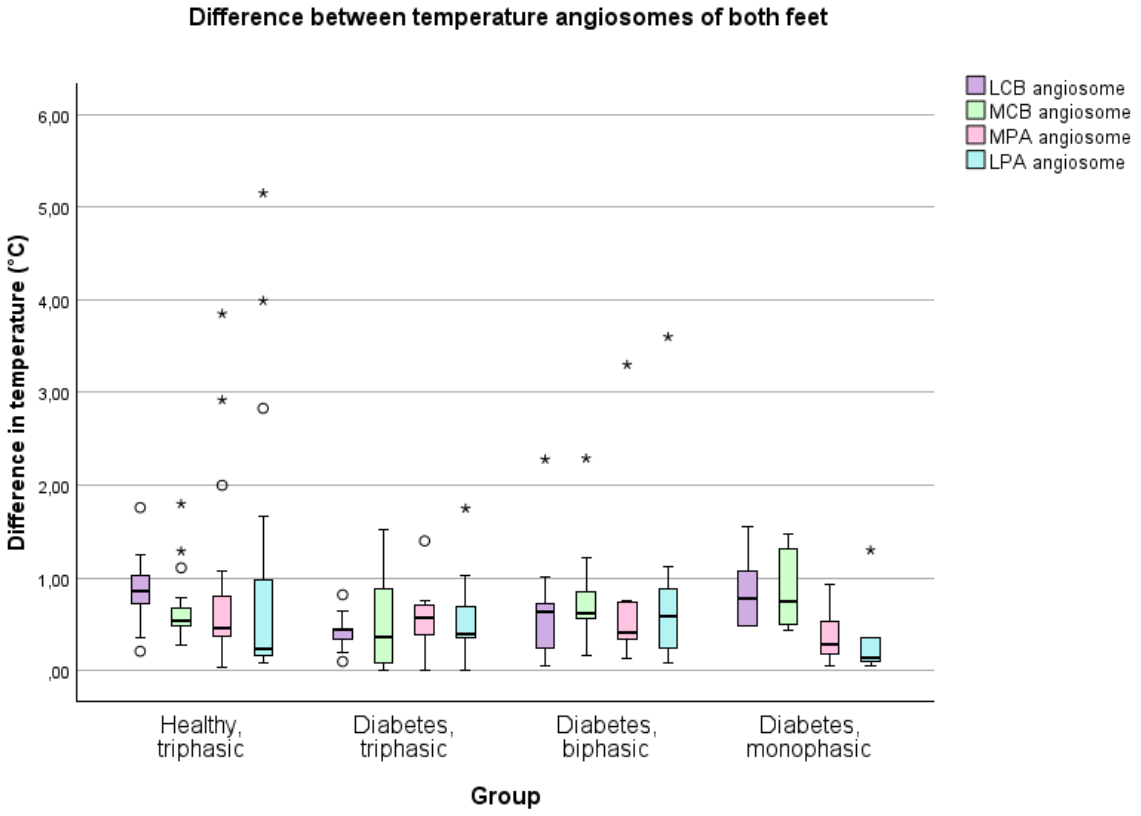


Figure 19: Box plot of the temperature differences between the angiosomes of both feet for the groups with different vascular state

The disparity between the temperature differences of the angiosomes of both feet are given in Table 16, also containing the significance levels. The disparity between the temperature difference of the LCB angiosomes in the triphasic and monophasic groups is statistically significant with a p-value of 0.012, calculated with the Independent Sample T Test.

Table 16: Disparity between the temperature difference of the angiosomes of both feet of the groups with different vascular state

Compared groups		Difference between mean temperature LCB angiosome (°C)	p-value	Difference between mean temperature MCB angiosome (°C)	p-value	Difference between mean temperature MPA angiosome (°C)	p-value	Difference between mean temperature LPA angiosome (°C)	p-value
Healthy, triphasic (n=15)	**Diabetes, triphasic (n=9)**	0.45	0.003*	0.13	0.500	0.37	0.263	0.45	0.338
Diabetes, triphasic (n=9)	**Diabetes, biphasic (n=9)**	-0.28	0.241	-0.27	0.335	-0.17	0.640	-0.27	0.515
Diabetes, triphasic (n=9)	**Diabetes, monophasic (n=5)**	-0.45	0.012*	-0.34	0.139	0.17	0.203	0.21	0.240
Diabetes, biphasic (n=9)	**Diabetes, monophasic (n=5)**	-0.17	0.626	-0.07	0.845	0.34	0.467	0.48	0.377

3.6 Temperature deviation within the foot

Method

By calculating the magnitude of the temperature deviation for both sides of the foot, it was analyzed how large the temperature differences are within the surface of the foot. The deviation from the average temperature of the foot was calculated for each pixel. Subsequently, the average of the deviation of all pixels of one foot is calculated. It was investigated whether the temperature deviations are related to the vascular state and neuropathy.

Results

The magnitude of the temperature deviation of the dorsal side is normally distributed, the magnitude of the temperature deviation of the plantar side is not. Therefore the median values are given for the plantar side.

Peripheral arterial disease

In Figure 20 the magnitude of the temperature deviation is given for the groups with different vascular states. It is observed that the magnitude of the temperature deviation of the dorsal side shows no clear trend with poorer vascular status, while the magnitude of the temperature deviation of the plantar side decreases.

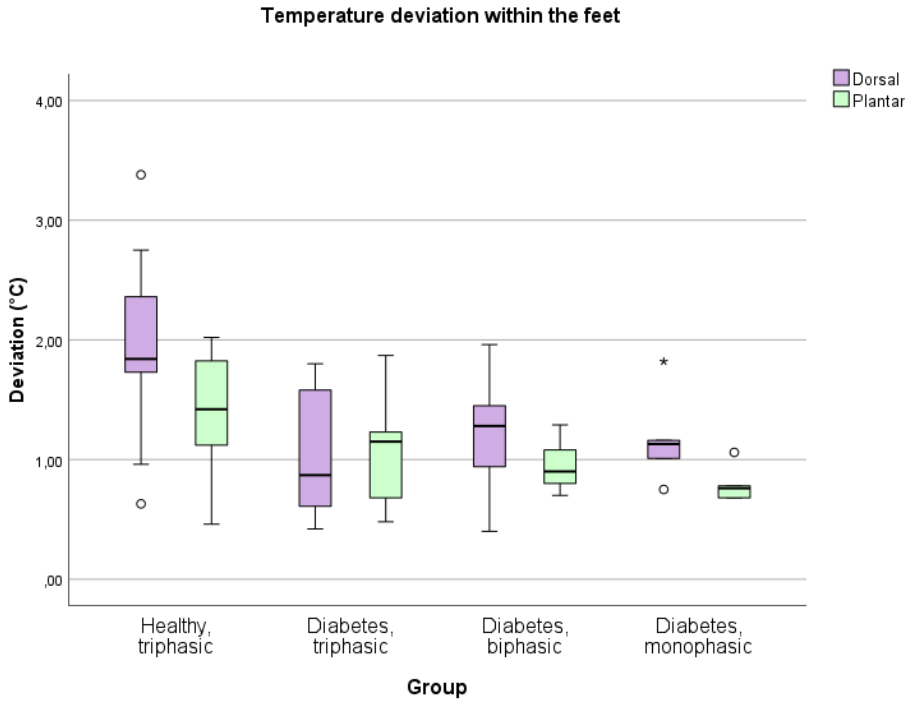


Figure 20: Box plot of the magnitude of the temperature deviation for the groups with different vascular state

The differences between the magnitude of the temperature deviation of the different groups are given in Table 17, with the corresponding p-values, calculated with the Independent Sample T Test.

Table 17: Difference of magnitude of the temperature deviation between the groups with different vascular states

Compared groups		Difference between magnitude of temperature deviation dorsal side (°C)	p-value	Difference between magnitude of temperature deviation plantar side (°C)	p-value
Healthy, triphasic (n=15)	**Diabetes, triphasic (n=9)**	0.89	0.003*	0.27	0.062
Diabetes, triphasic (n=9)	**Diabetes, biphasic (n=9)**	-0.18	0.461	0.25	0.673
Diabetes, triphasic (n=9)	**Diabetes, monophasic (n=5)**	-0.10	0.710	0.39	0.302
Diabetes, biphasic (n=9)	**Diabetes, monophasic (n=5)**	0.08	0.768	0.14	0.179

Neuropathy

In Figure 21 the magnitude of the temperature deviation is visualised for the groups with and without neuropathy (all without PAD). This figure shows a difference between the healthy group and the group with diabetes and without neuropathy. There is only a minimal difference between the two groups with diabetes.

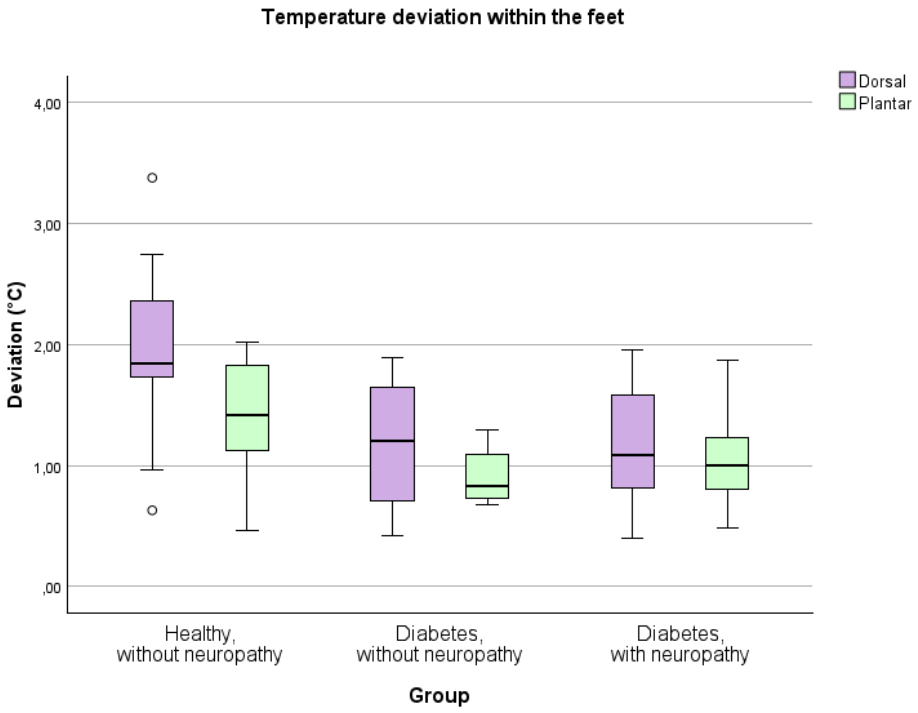


Figure 21: Box plot of the magnitude of the temperature deviation for the groups with and without neuropathy

In Table 18 the differences between the magnitude of the temperature deviation of the three groups are given with the significance levels.

Table 18: Difference of the magnitude of the temperature deviation of both feet between the group with and without neuropathy

Compared groups		Difference between magnitude of temperature deviation dorsal side (°C)	p-value	Difference between magnitude of temperature deviation plantar side (°C)	p-value
Healthy, without neuropathy (n=15)	**Diabetes, without neuropathy (n=4)**	0.78	0.058	0.58	0.068
Diabetes, without neuropathy (n=4)	**Diabetes, with neuropathy (n=14)**	0.02	0.937	-0.16	0.649

3.7 Temperature peaks

Method

To investigate whether fluctuations of the temperature on the foot surface can be caused by the implications of PAD or neuropathy, the number of peaks within the foot surface was determined. First, it was assessed whether there is noise in the image. Noise influences the determination of the number of peaks in the surface of the foot. Therefore, the images must be filtered if noise is present. A Gaussian filter is used for this. This filter is a low-pass filter, which filters the higher frequencies that comprise the noise.

The standard deviation of the filter (σ) was determined with the full width at the half maximum (FWHM). The FWHM is set at 4 pixels. A pixel has a dimension of 1205 microns (1.205 mm). By filtering with a FWHM of 4 pixels, peaks smaller than approximately 5 mm are suppressed. It was assumed that a local temperature increase caused by a pressure point or incipient wound is at least 5 mm in diameter. The σ of the Gaussian filter is calculated with the following formula [53]:

$$\sigma = \text{FWHM} \ / \ 2\sqrt{2\ ln\ 2}$$

The resulting σ for this filter with a FWHM of 4 is 1.7. The images are filtered using Matlab. After filtering, the number of temperature peaks was determined. The maximum thermal resolution of the Optris camera is 0.04 °C under optimal conditions. It was assumed that these optimal conditions were not achieved during the measurements in this study. The thermal resolution of the acquired images is therefore assumed to be 0.1 °C [54]. Hence, a peak is considered relevant when the temperature has increased by at least 0.1 °C. In addition, the area of the peaks was determined. Furthermore, the height of the peak was determined by taking the temperature value of the highest point of the peak relative to the mean temperature across the width of the foot at the location of the peak. In Figure 22 a visualisation of this calculation is given. Subsequently, it was investigated whether the amount of peaks and the mean area and height of the peaks is related to PAD or neuropathy.

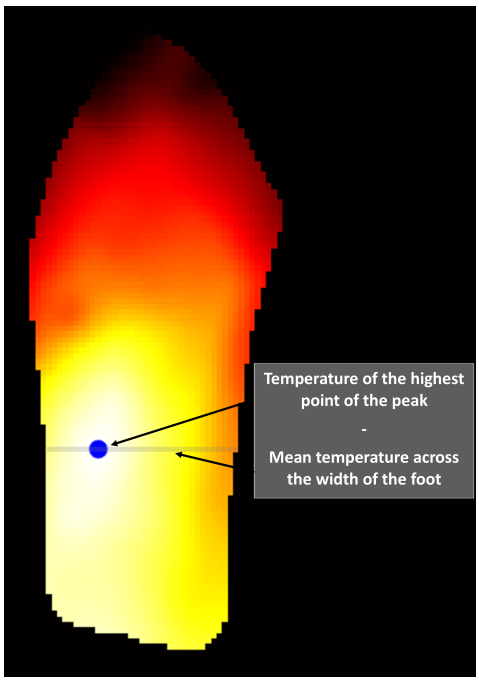


Figure 22: Visualisation of the determination of the peak height relative to the mean temperature across the width of the foot

Results

Gaussian filter

In Figure 23a a binary image shows the tops of the peaks of one of the participants before filtering. This clearly shows the amount of temperature fluctuations. Therefore, the thermal images contain noise that must be filtered to assess the temperature peaks caused by the (patho)physiology of the foot. To filter the noise, a Gaussian filter was applied to all images. In Figure 23b the tops of the peaks are shown after filtering. The noise has been removed after applying the filter.

(a) Binary image, visualising the tops of the peaks of the unfiltered image

(b) Binary image, visualising the tops of the peaks of the filtered image

Determination of the peaks

In Figure 24 the thermal images of a participant are shown with blue dots indicating the tops of the peaks. In some cases, for example in this participant's right foot on the dorsal side, there are multiple peaks indicated within an area of increased temperature, caused by temperature changes occurring within the area with elevated temperature.

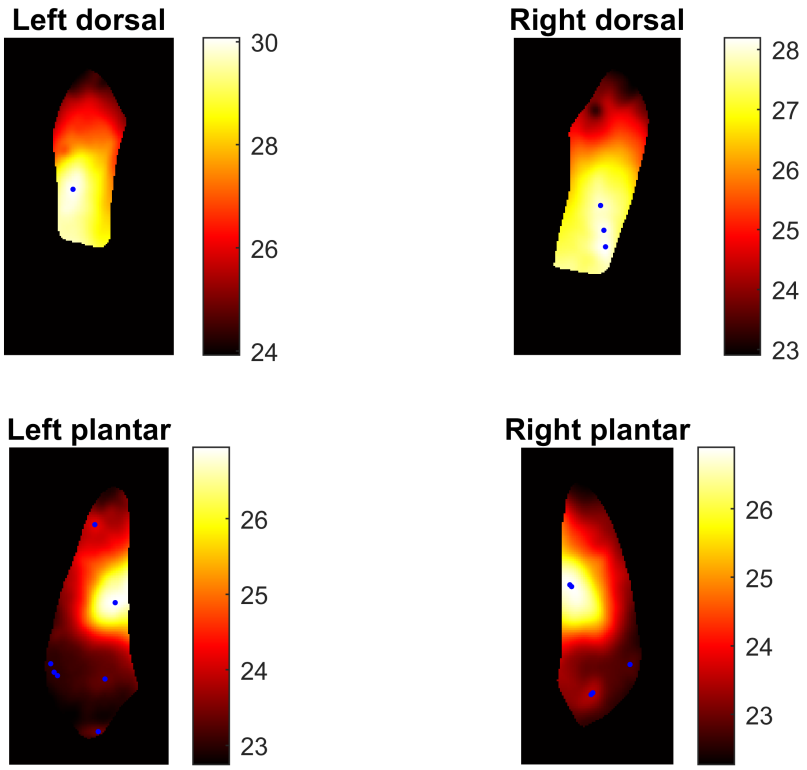


Figure 24: Visualisation of the top of the peaks after filtering

The data set of the number, area and heights of the peaks is not normally distributed. Therefore, in the following paragraphs the median is used.

Peripheral arterial disease

In Figure 25 the number of peaks for the groups with and without PAD are given in a box plot. The groups with triphasic vascular state has a decreased number of peaks on the plantar side compared to the groups with biphasic and monophasic vascular states. The number of peaks on the dorsal side shows little difference between the different groups.

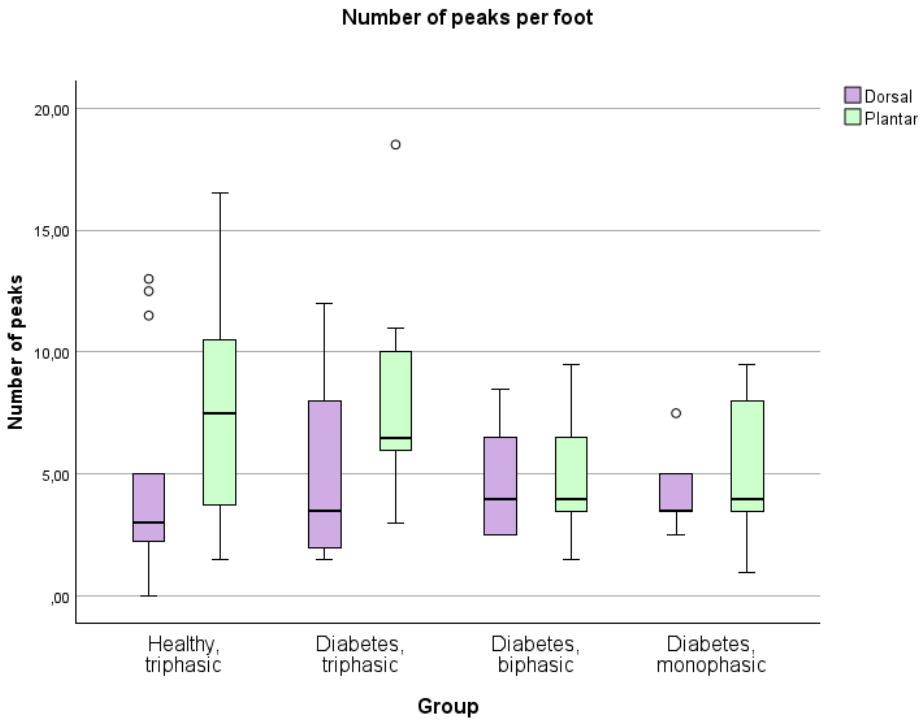


Figure 25: Box plot of the number of peaks for the groups with different vascular state

In Table 19 the differences between the number of peaks of the different groups are given with the corresponding p-values, calculated with the Independent Sample T test.

Table 19: Difference between number of peaks of the groups with a different vascular state

Compared groups		Difference in nr of peaks dorsal	p-value	Difference in nr of peaks plantar	p-value
Healthy, triphasic (n=15)	**Diabetes, triphasic (n=9)**	-0.5	0.766	1.0	0.857
Diabetes, triphasic (n=9)	**Diabetes, biphasic (n=9)**	-0.5	0.728	2.5	0.108
Diabetes, triphasic (n=9)	**Diabetes, monophasic (n=5)**	0.0	0.705	2.5	0.292
Diabetes, biphasic (n=9)	**Diabetes, monophasic (n=5)**	0.5	0.862	0.0	0.824

Figure 26 shows a box plot for the mean area of the temperature peaks of the different groups. With detoriating vascular state a decrease of the mean area of the peaks is observed.

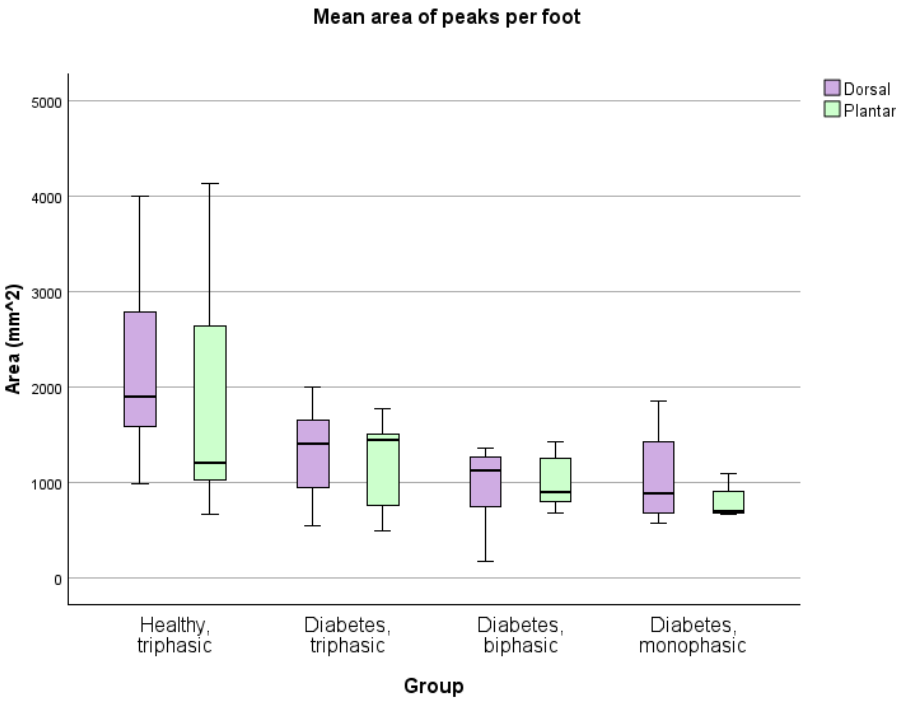


Figure 26: Box plot of the mean area of the peaks for the groups with different vascular state

In Table 20 the differences between the mean area of the peaks between the four groups are given, with the corresponding p-values.

Table 20: Difference of the mean area of the peaks between the groups with a different vascular state

Compared groups		Difference in area of peaks dorsal (mm^2)	p-value	Difference in area of peaks plantar (mm^2)	p-value
Healthy, triphasic (n=15)	**Diabetes, triphasic (n=9)**	486	0.015*	-235	0.050*
Diabetes, triphasic (n=9)	**Diabetes, biphasic (n=9)**	281	0.153	553	0.351
Diabetes, triphasic (n=9)	**Diabetes, monophasic (n=5)**	519	0.440	726	0.060
Diabetes, biphasic (n=9)	**Diabetes, monophasic (n=5)**	238	0.803	173	0.149

Figure 27 gives the box plot for the mean heights of the peaks, for the groups with different vascular state. This box plot demonstrates that with deteriorating vascular status the mean height of the peaks decreases on the plantar side.

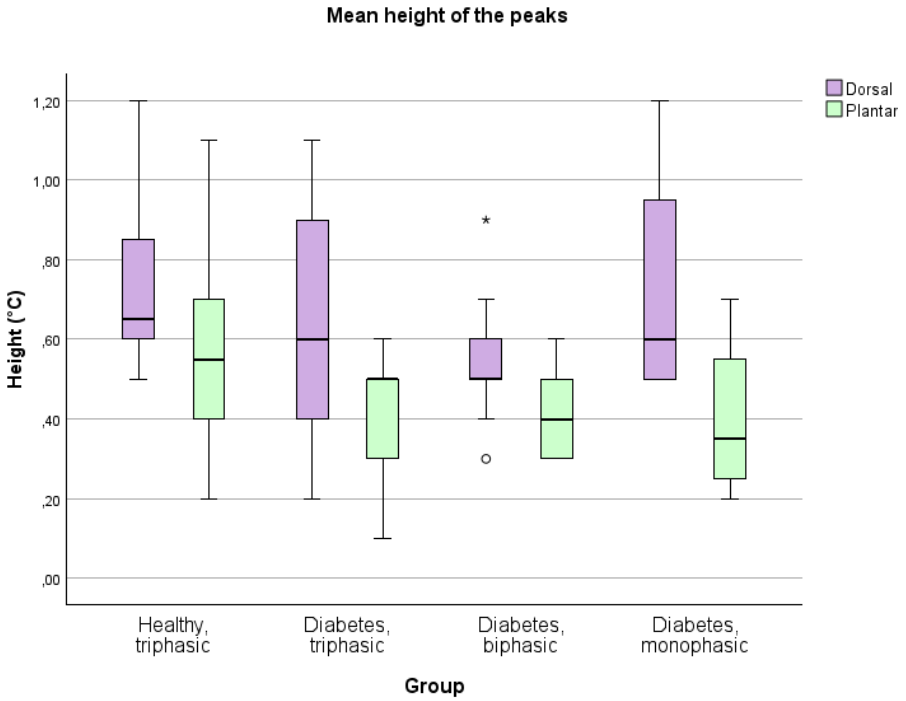


Figure 27: Box plot of the mean height of the peaks for the groups with different vascular state

Table 21 gives the differences between the mean height of the peaks between the different groups, with the corresponding p-value.

Table 21: Difference of mean height of the peaks between the groups with a different vascular state

Compared groups		Difference in height of peaks dorsal (°C)	p-value	Difference in height of peaks plantar (°C)	p-value
Healthy, triphasic (n=15)	**Diabetes, triphasic (n=9)**	0.05	0.449	0.10	0.062
Diabetes, triphasic (n=9)	**Diabetes, biphasic (n=9)**	0.10	0.502	0.10	0.653
Diabetes, triphasic (n=9)	**Diabetes, monophasic (n=5)**	0.00	0.624	0.20	0.712
Diabetes, biphasic (n=9)	**Diabetes, monophasic (n=5)**	-0.10	0.241	0.10	0.416

Neuropathy

Subsequently, it was examined whether neuropathy has a relationship with the number of peaks. In Figure 28 a box plot is given with the number of peaks for the groups with and without neuropathy. The number of peaks on the dorsal side differs minimally. On the plantar side, a difference between the groups is observed, where the group with diabetes and without neuropathy has the least peaks, while the healthy group and the group with neuropathy have more peaks.

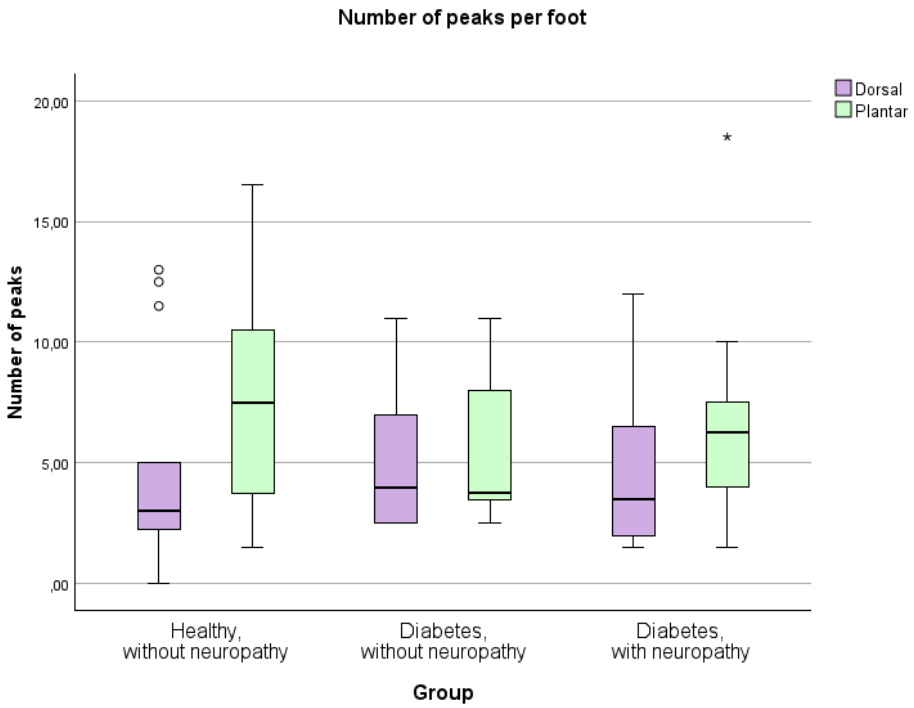


Figure 28: Box plot of the number of peaks per foot for the groups with and without neuropathy

Table 22 gives the differences of the number of peaks for the groups with and without neuropathy, with the corresponding p-values.

Table 22: Difference of number of peaks between the groups with and without neuropathy

Compared groups		Difference in nr of peaks dorsal	p-value	Difference in nr of peaks plantar	p-value
Healthy, without neuropathy (n=15)	**Diabetes, without neuropathy (n=4)**	-1.0	0.787	3.75	0.316
Diabetes, without neuropathy (n=4)	**Diabetes, with neuropathy (n=14)**	0.5	0.672	-2.5	0.519

Figure 29 shows a box plot for the mean area of the peaks for the groups with and without neuropathy. In participants with neuropathy, a higher mean area on both the dorsal and plantar side is observed compared to the groups with diabetes and without neuropathy.

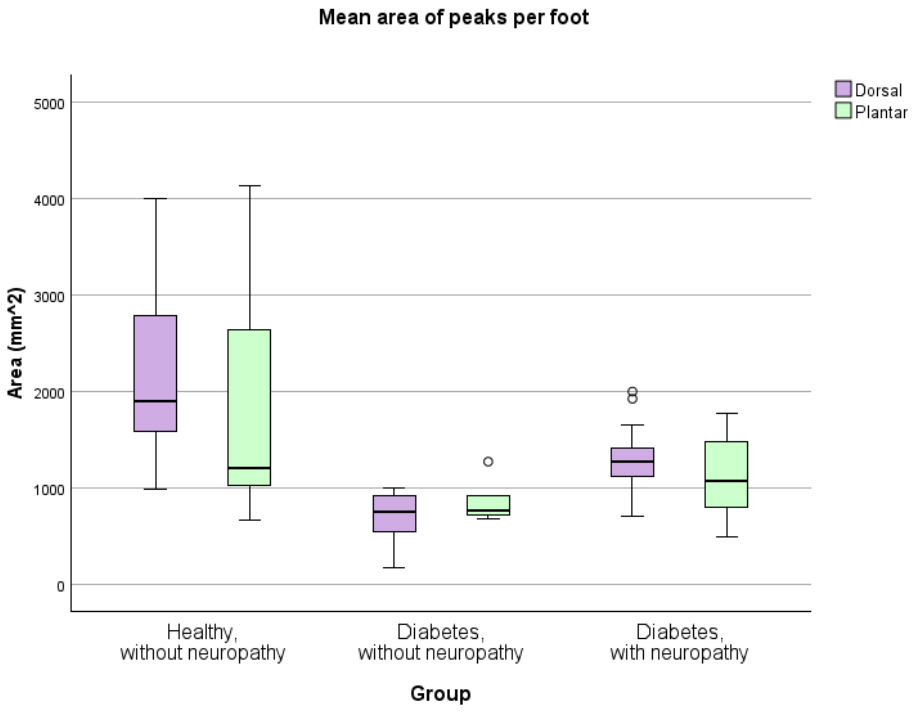


Figure 29: Box plot of mean area of the peaks for the groups with and without neuropathy

Table 23 gives the differences between the mean area of the peaks for the groups with and without neuropathy, with the corresponding p-values.

Table 23: Difference of the mean area of the peaks between the groups with and without neuropathy

Compared groups		**Difference in area of peaks dorsal (mm^2)**	**p-value**	**Difference in area of peaks plantar (mm^2)**	**p-value**
Healthy, without neuropathy (n=15)	**Diabetes, without neuropathy (n=4)**	1141	<0.001*	473	0.004*
Diabetes, without neuropathy (n=4)	**Diabetes, with neuropathy (n=14)**	-526	0.005*	-330	0.076

Figure 30 shows the box plot of the mean height of the peaks for the groups with and without neuropathy. A small difference of the mean height is seen on both side. The mean height of the peaks on the dorsal side is lower in the groups with diabetes and lowest in the group with neuropathy.

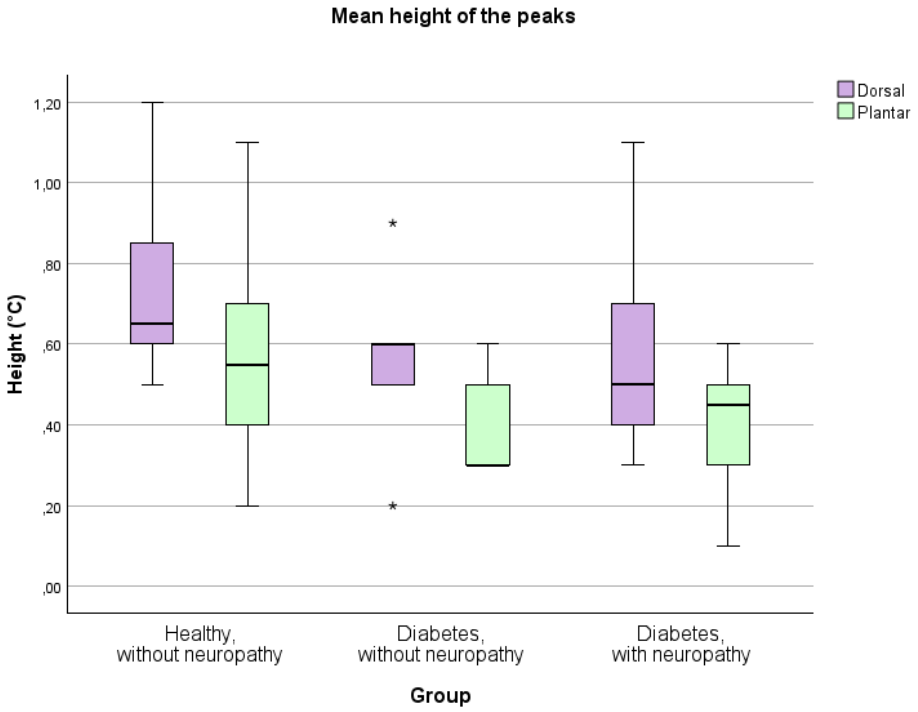


Figure 30: Box plot of the mean height of the peaks for the groups with and without neuropathy

In Table 24 the differences between the mean height of the peaks for the different groups are given with the corresponding p-values.

Table 24: Difference of the mean height of the peaks between the groups with and without neuropathy

Compared groups		Difference in height of peaks dorsal (°C)	p-value	Difference in height of peaks plantar (°C)	p-value
Healthy, without neuropathy (n=15)	**Diabetes, without neuropathy (n=4)**	0.05	0.196	0.30	0.063
Diabetes, without neuropathy (n=4)	**Diabetes, with neuropathy (n=14)**	0.10	0.750	-0.15	0.536

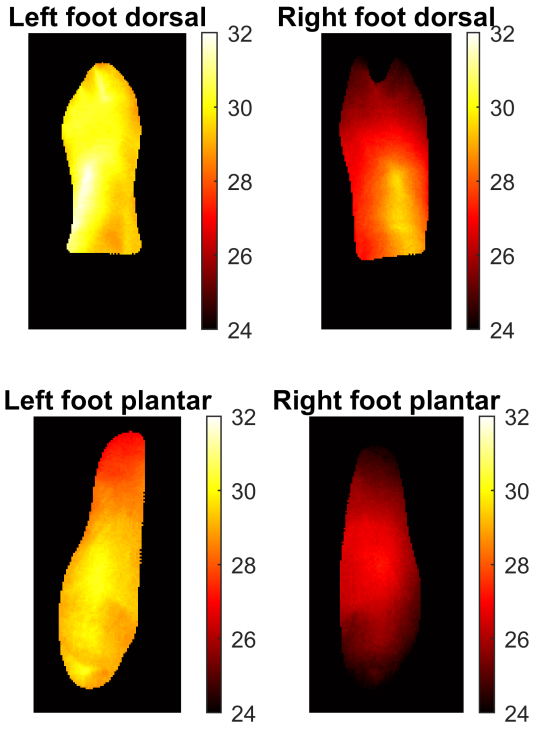
3.8 Subjective assessment of the images

Method

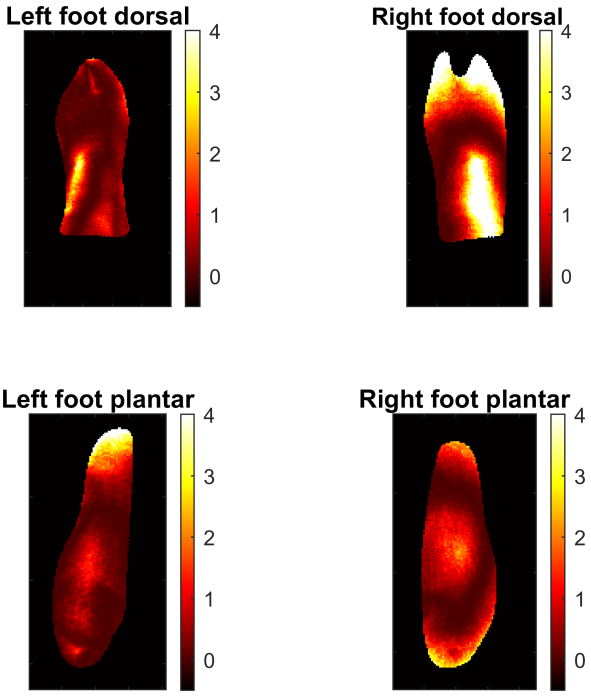
Finally, a subjective assessment was performed by the author. The original thermal images, images with the quadratic deviation from the mean and images with contour lines with a thermal resolution of 0.5 °C were subjectively assessed by the author. It was investigated whether the parameters discussed above can also be assessed during subjective assessment. Furthermore, the images were examined to see whether the pressure points and ulcers indicated in the screening reports are deflected in the thermal images and whether the various ways of displaying the thermal images can make pressure spots or ulcers more prominent visible.

Results

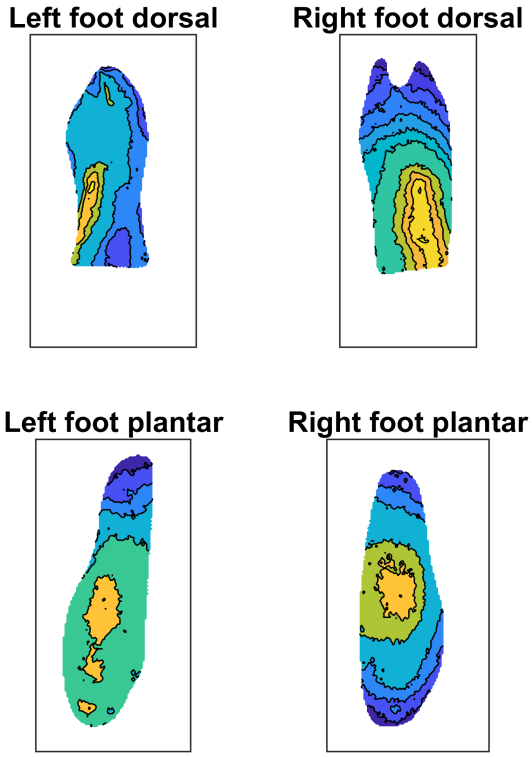
The original thermal image, the image with the quadratic deviation from the mean and the contour image of the participants where notable deviations were observed during the author's subjective assessment are shown in Figure 31 to 40. In addition, the pressure spots that were indicated in the foot screening are also visualised in the figures as a reference.



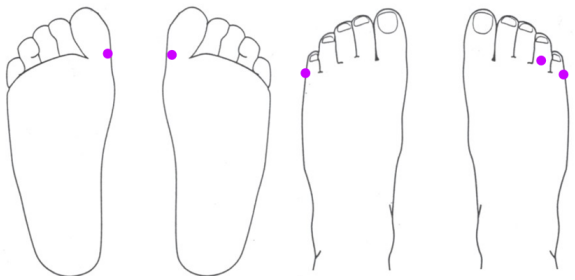
(a) Original thermal image



(b) Quadratic deviation from the mean



(c) Contour image

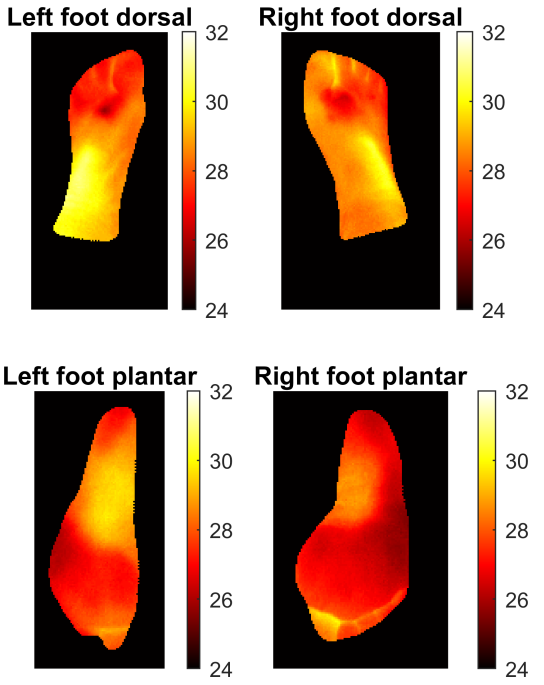


(d) Pressure points

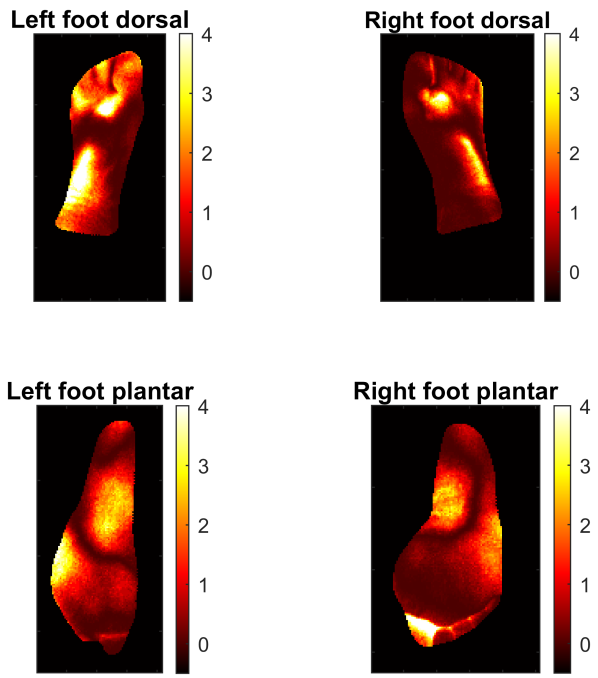
Figure 31: Subjective assessment of participant 1. Biphasic, no neuropathy

In Figure 31 it was observed that the left foot is much warmer than the right foot. This participant was not diagnosed with PAD or neuropathy. There was also no history of an ulcer or amputation. It is therefore unclear why there is a large temperature difference between the two feet. The pressure

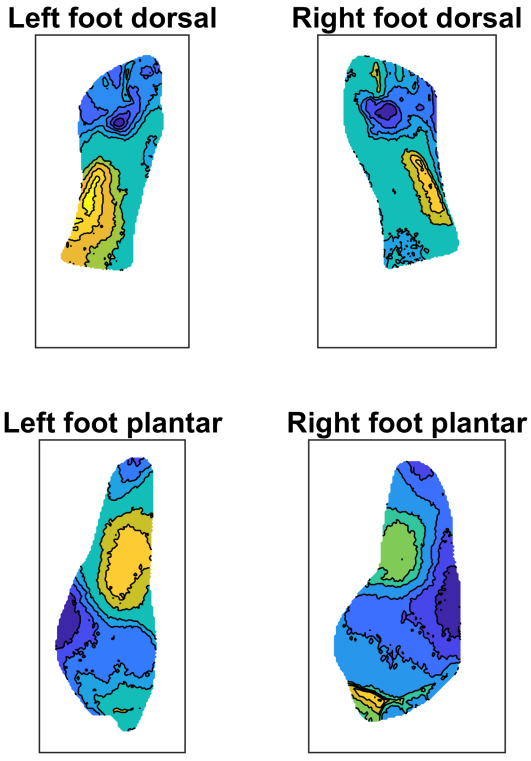
spots reported in the screening are not found in the (edited) thermal images.



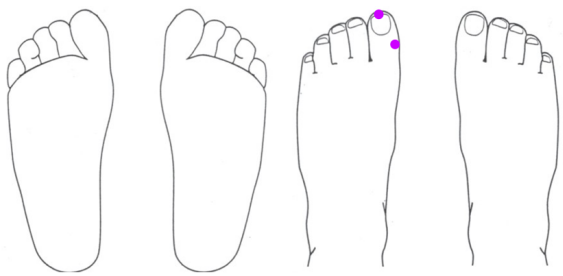
(a) Original thermal image



(b) Quadratic deviation from the mean



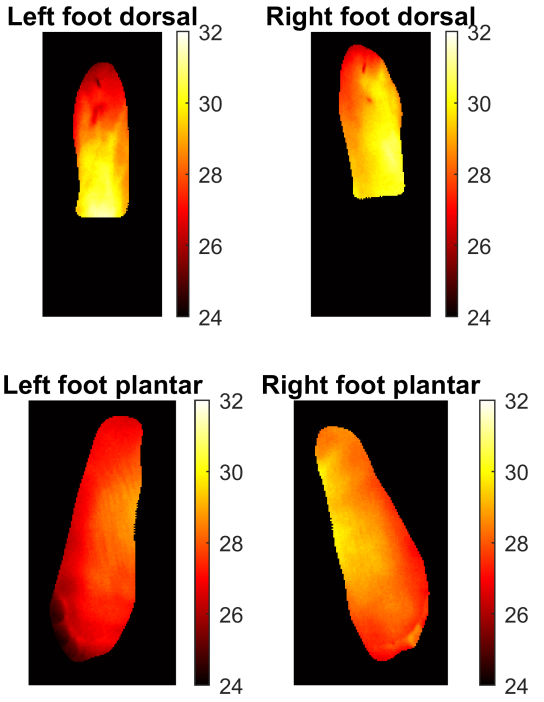
(c) Contour image



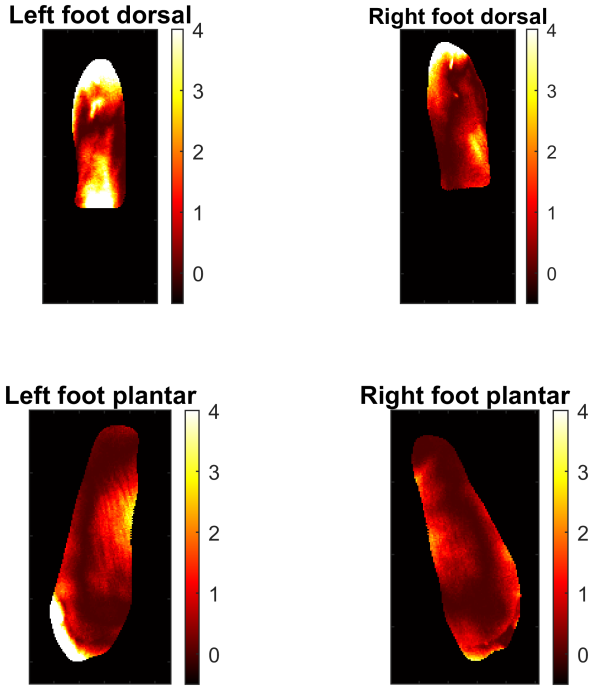
(d) Pressure points

Figure 32: Subjective assessment of participant 2. Biphasic, neuropathy

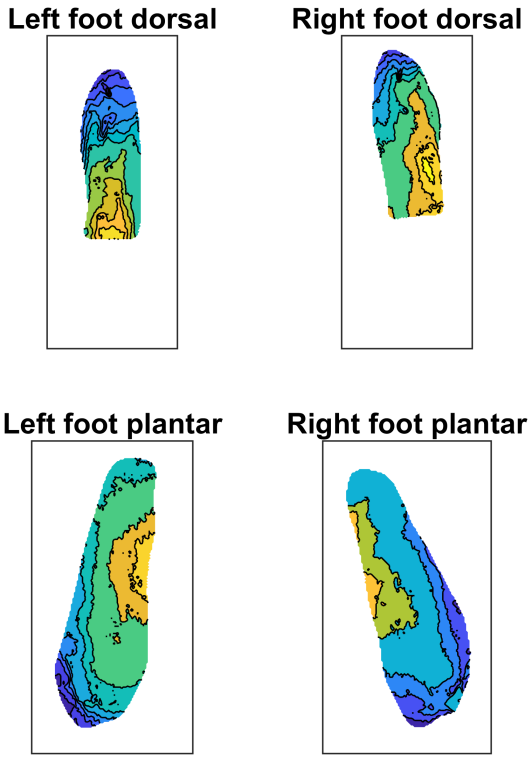
Figure 32 shows that dig 1 of both feet has a higher temperature on the plantar side. There were pressure spots on the dorsal side of dig 1 of the left foot.



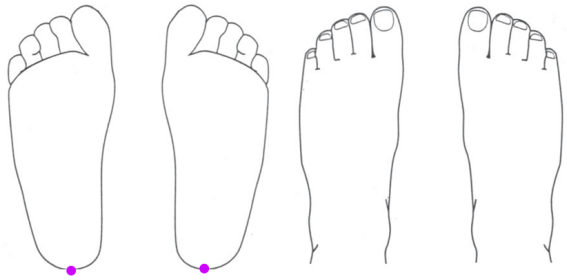
(a) Original thermal image



(b) Quadratic deviation from the mean



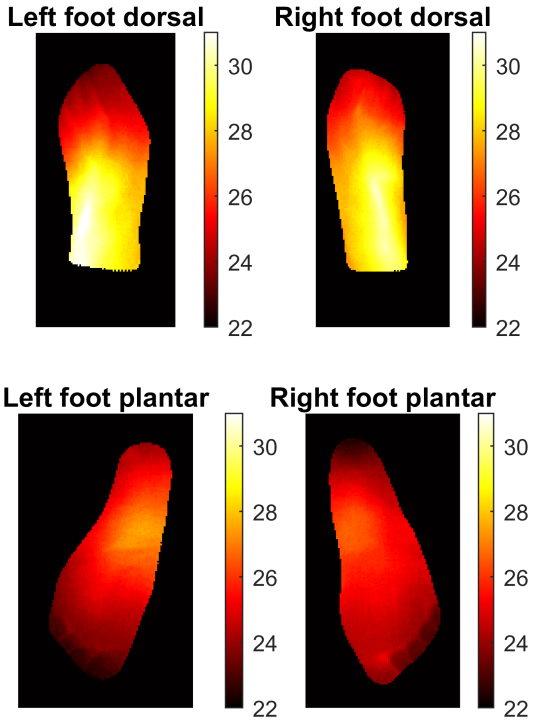
(c) Contour image



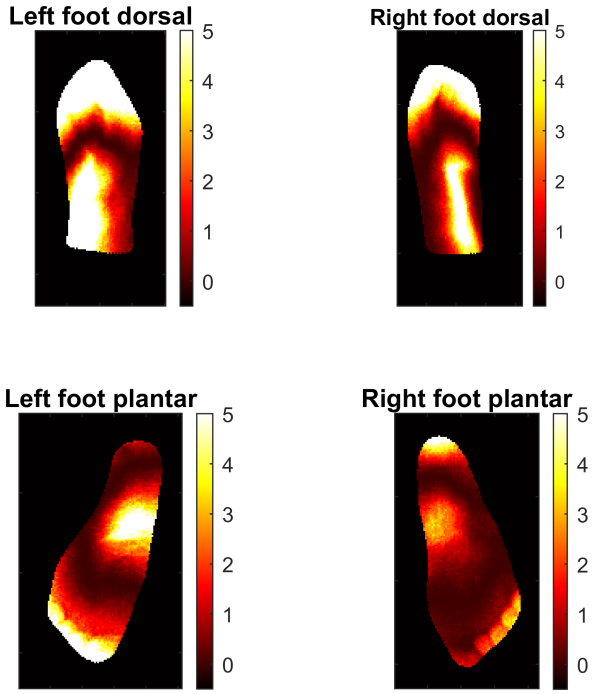
(d) Pressure points

Figure 33: Subjective assessment of participant 11. Monophasic, no neuropathy

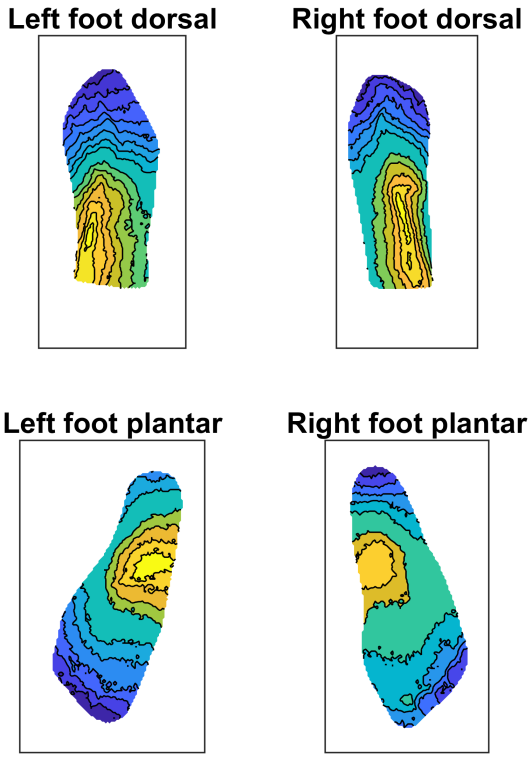
Figure 33 shows a higher temperature of dig 3 of the right foot on the plantar side. The screening results offer no indication as to what might be causing this rise in temperature.



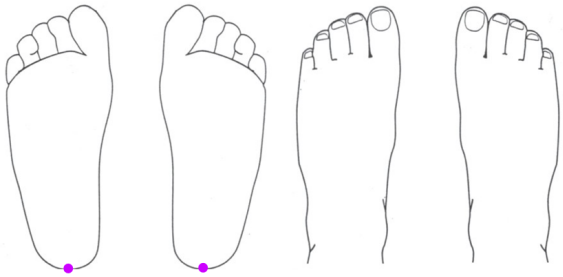
(a) Original thermal image



(b) Quadratic deviation from the mean



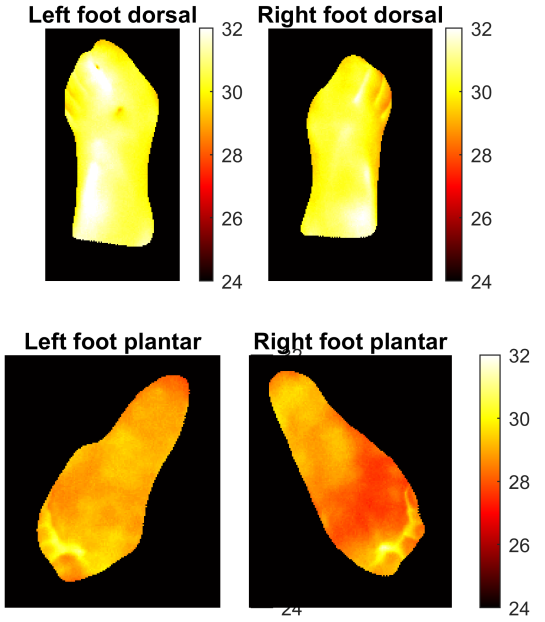
(c) Contour image



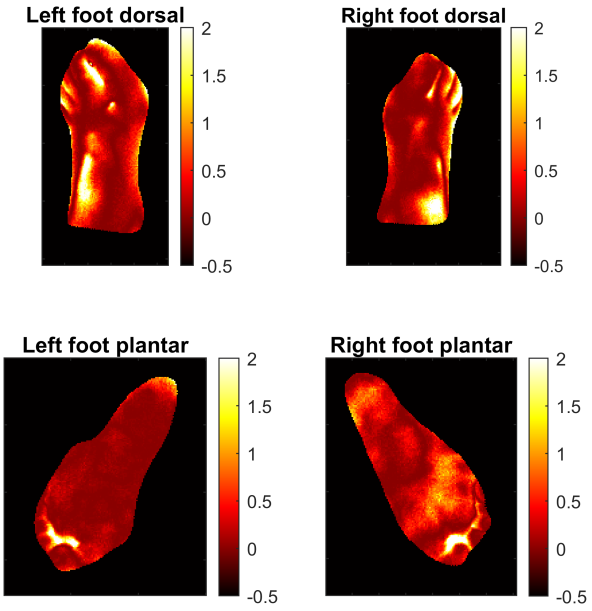
(d) Pressure points

Figure 34: Subjective assessment of participant 13. Monophasic, neuropathy

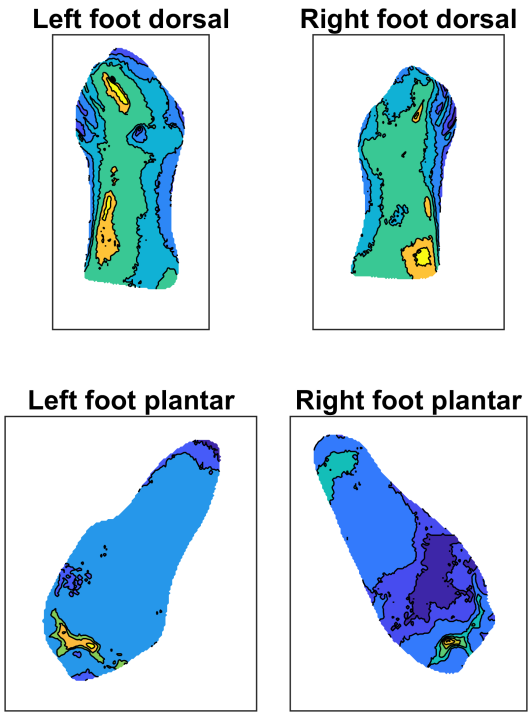
Figure 34 shows a higher temperature of dig 1 of the right foot on the plantar side. In the screening report there was no pressure spot or ulcer reported at this spot.



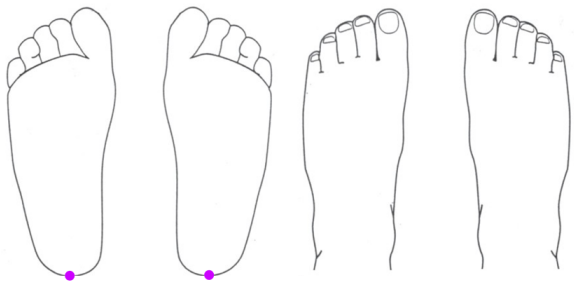
(a) Original thermal image



(b) Quadratic deviation from the mean



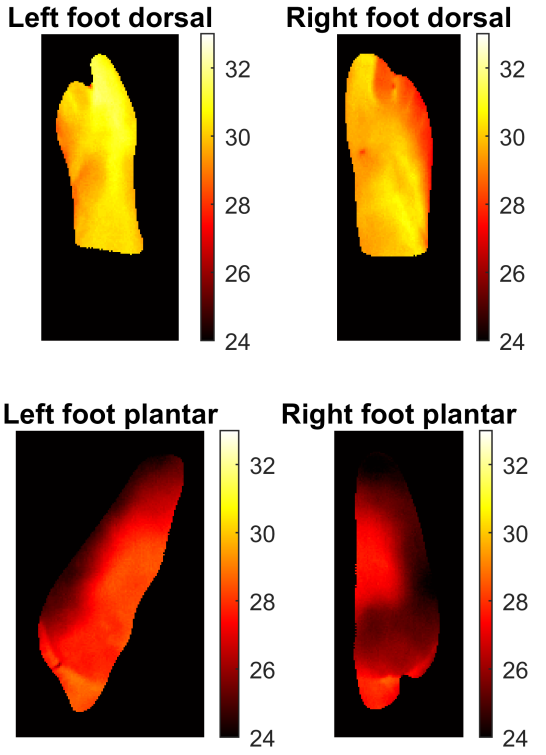
(c) Contour image



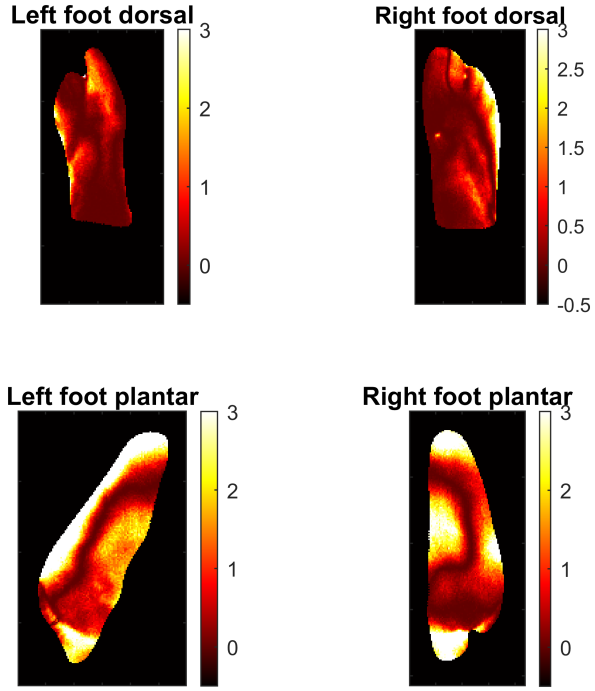
(d) Pressure points

Figure 35: Subjective assessment of participant 15. Triphasic, neuropathy

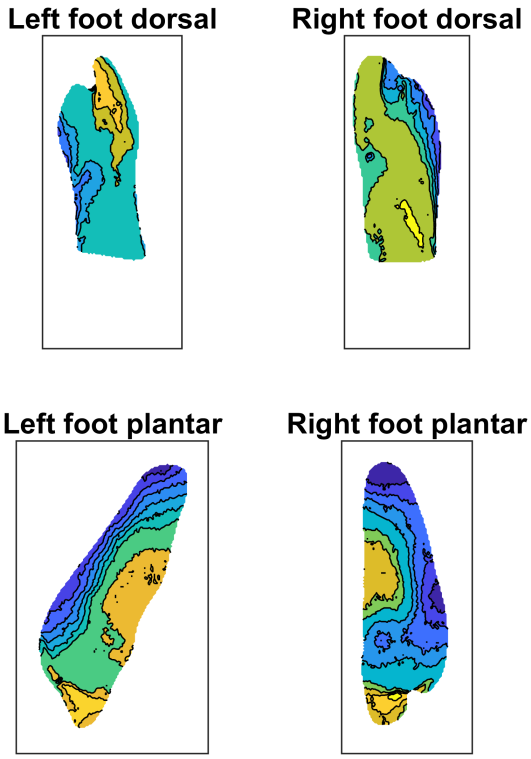
Figure 35 illustrates a cold spot observed on the dorsal aspect of the left foot. There is no indication for a pressure spot or ulcer. In addition, there is a difference in the temperature distribution of the plantar side between the left and right foot.



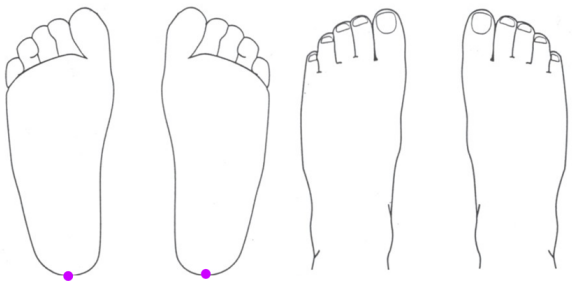
(a) Original thermal image



(b) Quadratic deviation from the mean



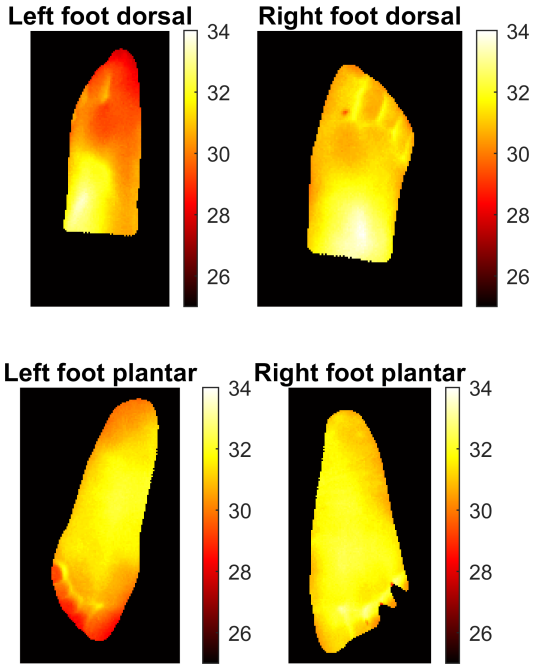
(c) Contour image



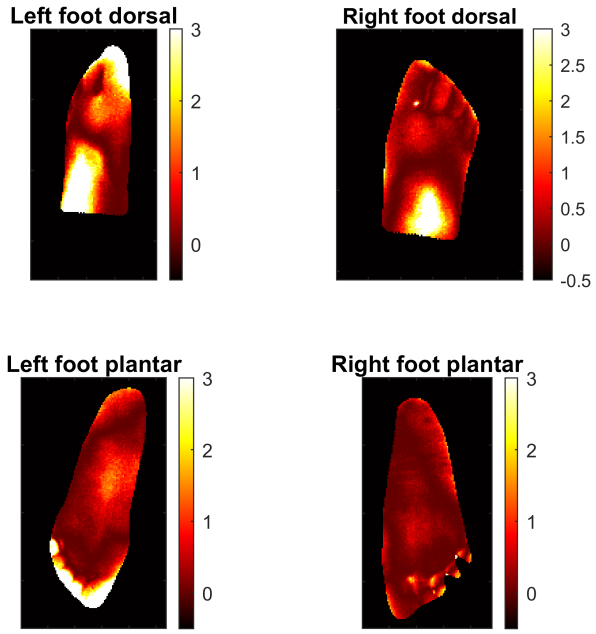
(d) Pressure points

Figure 36: Subjective assessment of participant 18. Triphasic, neuropathy

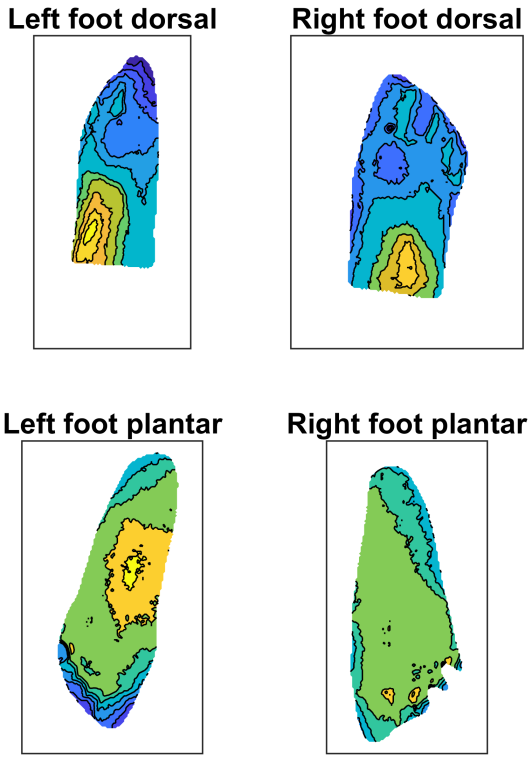
Figure 36 shows an increased temperature in right and left dorsal dig 1. No pressure spots or ulcers are indicated here.



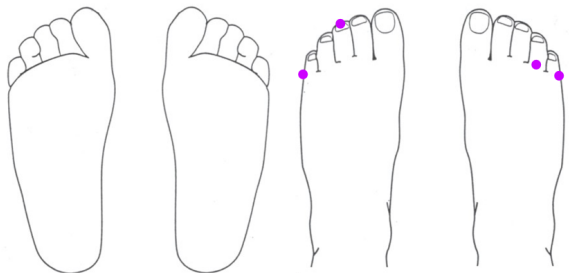
(a) Original thermal image



(b) Quadratic deviation from the mean



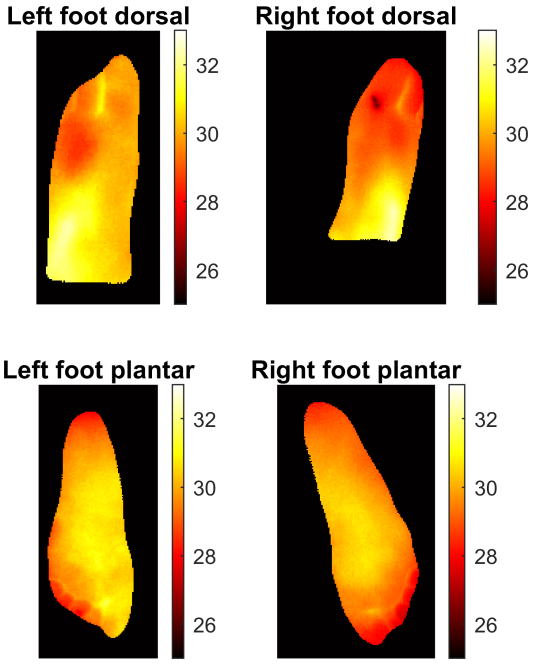
(c) Contour image



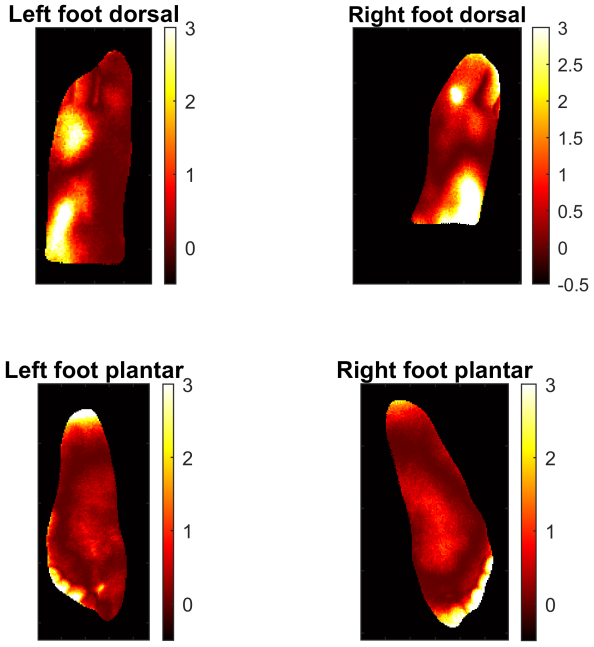
(d) Pressure points

Figure 37: Subjective assessment of participant 20. Triphasic, neuropathy

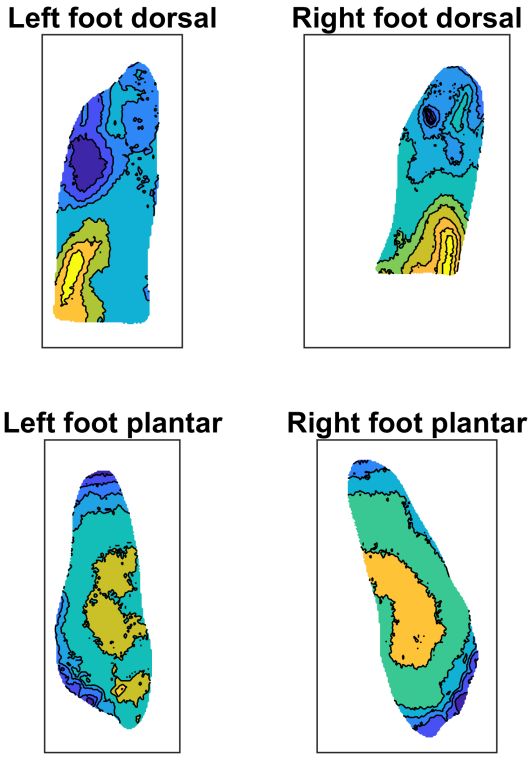
In Figure 37, there are little warm spots on the heel of the plantar side of the right foot. No pressure spots or ulcers are indicated here. These warmer spots are not clearly visible on the contour images.



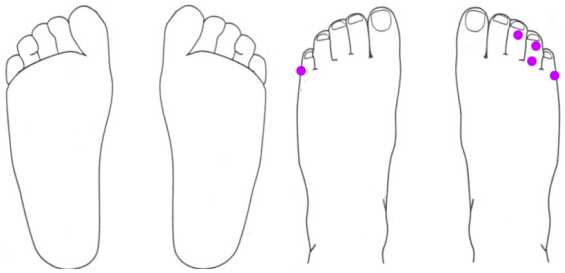
(a) Original thermal image



(b) Quadratic deviation from the mean



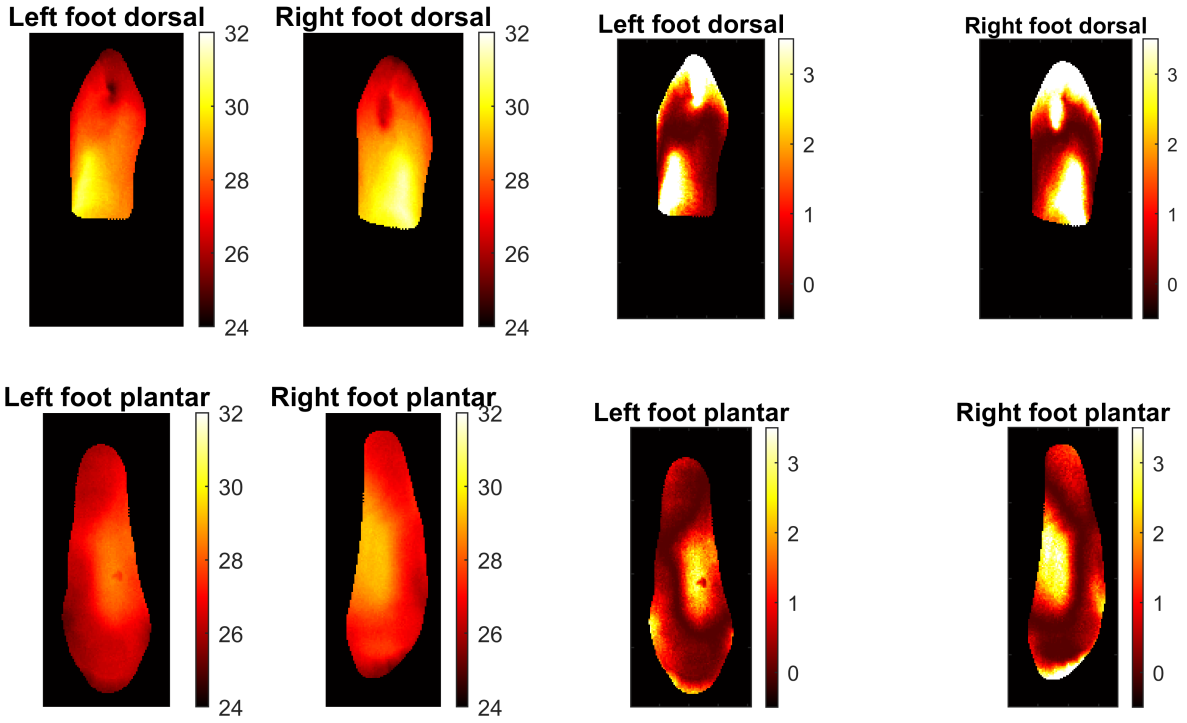
(c) Contour image



(d) Pressure points

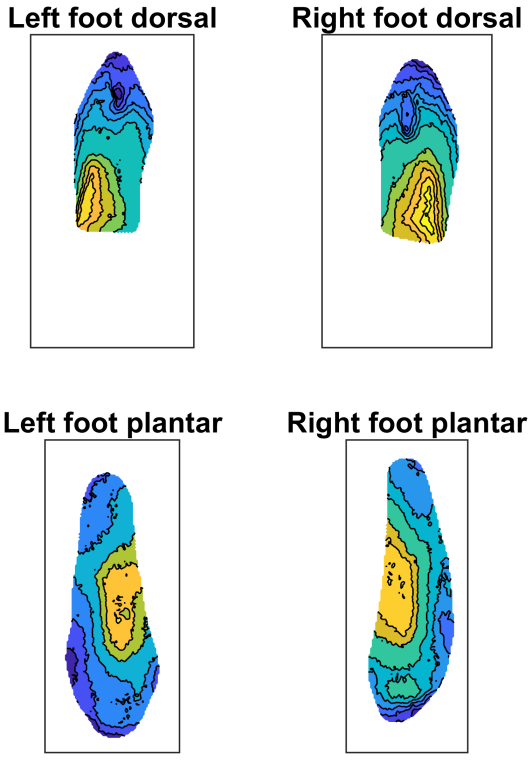
Figure 38: Subjective assessment of participant 21. Biphasic, neuropathy

Figure 38 shows an increased temperature on the plantar side of dig 1 of the left foot. There are no pressure spots or ulcers indicated on this location.

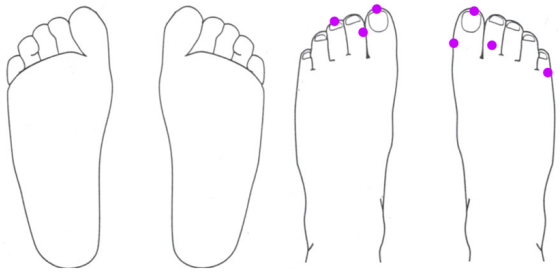


(a) Original thermal image

(b) Quadratic deviation from the mean



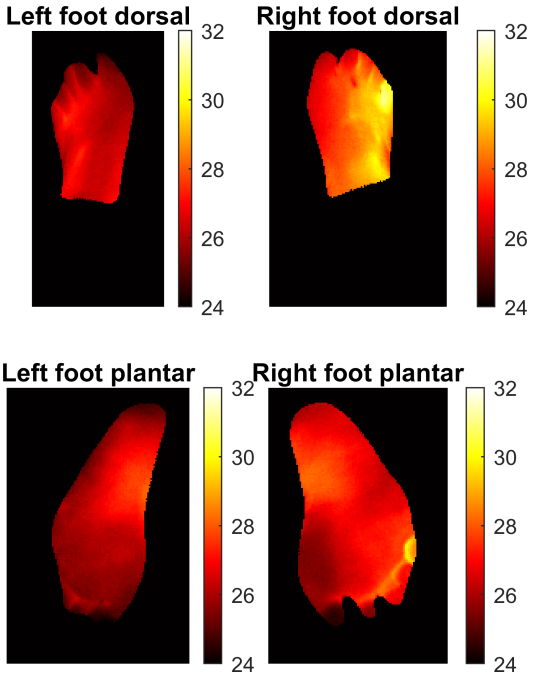
(c) Contour image



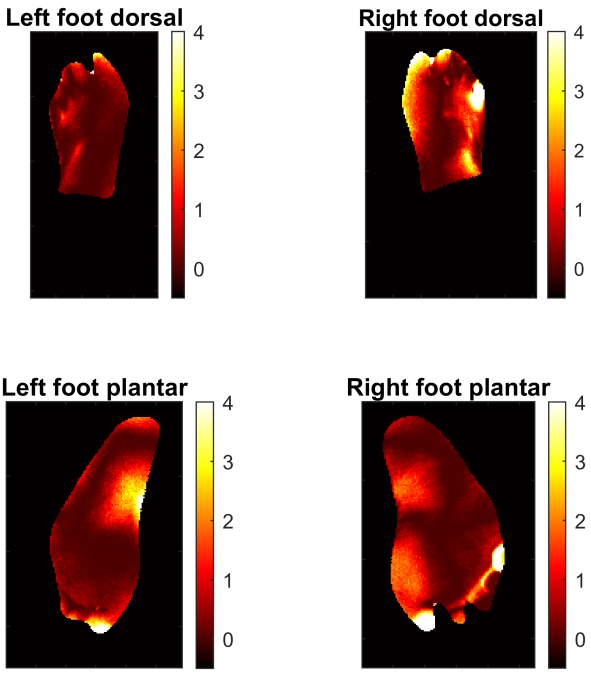
(d) Pressure points

Figure 39: Subjective assessment of participant 23. Biphasic, no neuropathy

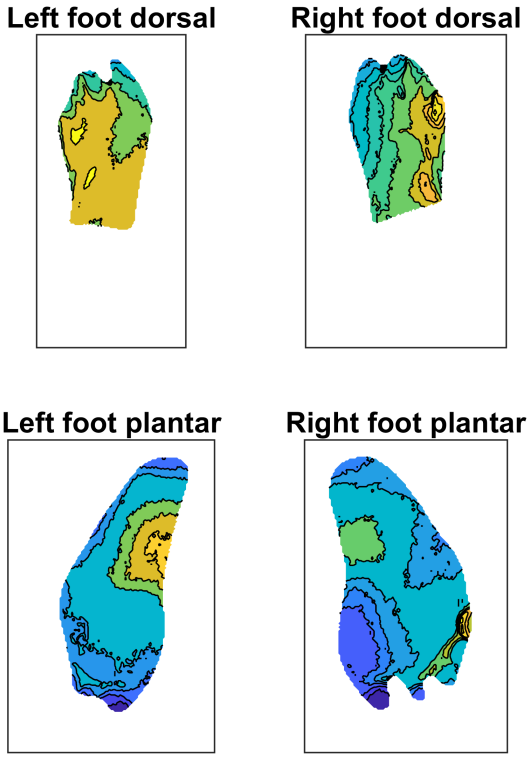
In Figure 39 it was observed that using the contour image with thermal resolution of 0.5 °C, a warmer spot on the forefoot on the plantar side of the right foot is more visible than in the original image. No explanation was given for the increased temperature at this spot.



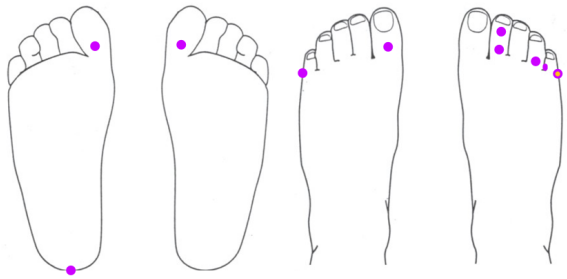
(a) Original thermal image



(b) Quadratic deviation from the mean



(c) Contour image



(d) Pressure points

Figure 40: Subjective assessment of participant 24. Monophasic, neuropathy

Figure 40 shows an elevated temperature on dig 5 of the right foot, both on the dorsal and plantar side. An ulcer is located on the dorsal side of dig 5. There is also a colder spot on dig 2 of the right foot on the dorsal side. A pressure spot is indicated here, but the other pressure spots indicated on the feet are not reflected in the images.

4 Discussion

This study aimed to investigate whether thermal imaging can be of value in determining the risk of a DFU in the context of the VVT sector. The previous chapter showed the results of this research. This chapter discusses the results to answer the research questions, given in Chapter 1.8, the limitations of this study and provides suggestions for further research.

Subjects characteristics

When comparing the group of healthy participants and the group of participants with diabetes, there is a difference in age between the two groups (Table 2). The percentage of women in the group with diabetes is also higher than in the healthy group. Within the group with diabetes, there are only five participants with PAD. In addition, the majority has neuropathy and most participants are diagnosed with pressure points. Most participants are classified as Simms classification 2, while classification 0 and 3 are less represented. Classification 1 is not represented at all. The distribution of the group of participants categorized under Simms classification 1 to be smaller compared to other classifications is observed in a earlier study [55].

Intraobserver variability

Between the different segmentations of a foot, there is variation in the number of pixels identified as part of the foot, particularly on the dorsal side. This arises from the challenge of precisely discerning the transition of the dorsal side of the foot to the ankle. It was observed that the differences in number of segmented pixels has minimal influence on the mean temperature. The intraobserver variability of the determination of the mean temperature is therefore low. For the other analyzes in this study, only one segmentation was used, so the intraobserver variability was not calculated for these parameters.
The interobserver variability was not determined in this study. Because the intraobserver variability demonstrates a significant disparity between the number of segmented pixels per segmented foot, it is expected that there may also be considerable interobserver variability during segmentation. However, the analysis in this study showed that the influence of deviations in segmentation on the mean temperature of the foot is small. Nonetheless, no conclusions can be drawn about the expected interobserver variability of the other parameters, because only a single segmentation was used for the other analyses.

Mean temperature

A difference is observed in foot temperature between the group of healthy participants and participants with diabetes without vascular disease. This indicates that even though clear diabetes complications have not yet been detected, the vascular status and the physiology of the feet are indeed deteriorating. The results of the group with diabetes showed that with poorer vascular status, the temperature decreases. Chin et al [22] confirm this in their research. They found a small temperature difference between participants with different vascular states. A study of Staffa et al [23] also concludes this. In their study the temperature of the feet was measured before and after a percutaneous transluminal angioplasty (PTA) in patients with PAD. The results showed that restoring the blood supply through the PTA increased the temperature of the feet on average by 0.4 °C. This indicates that the degree of occlusion of the vessels by PAD and the blood supply influences the temperature of the feet. In participants with biphasic or monophasic vascular state, the blood supply is deteriorated due to the damage to the vessels, affecting the blood flow in macro peripheral and micro peripheral arteries. This causes the temperature to decrease [21, 22, 23].
The analyzes of the influence of neuropathy on foot temperature are limited by the low number of participants without neuropathy. However, the results show that the temperature is slightly higher on both sides in the group with neuropathy. This increase in temperature could be caused by the persisted state of inflammation, due to nerve damage [28, 29]. The previously mentioned research by Ilo et al [21] also concluded that patients with neuropathy have a higher mean temperature of the feet compared to the control group without neuropathy. Other studies also draw this conclusion [26, 56].
In addition to the factors PAD and neuropathy, it was investigated whether foot temperature is directly related to the outcome of the screening, the Simms classification. The temperature appears to decrease with a higher Simms classification. This suggests that the temperature change caused by PAD plays

a major role in the foot temperature of patients in Simms classification 3.
Although there appears to be a relationship between foot temperature and PAD and neuropathy, there is a lot of variation within the groups. As a result, cut-off values cannot be established and used, and the diagnosis of PAD or neuropathy based on one thermal image is not possible.

Temperature differences between both feet

The difference between the temperature of both feet is slightly higher in participants with biphasic and monophasic vascular status. The research of Ilo et al [21] shows a mean temperature difference between the both feet of patients with angiopathy of 0.9 °C (SD 0.8 °C) for the dorsal side and 0.8 °C (SD 0.6 °C) for the plantar side. These larger temperature differences are not clearly reflected in our results, despite the slight decrease in temperature we found. This same study of Ilo et al [21] concluded that the group with neuropathy showed large temperature differences between both feet, which is not reflected in our results.
Previous studies often show an increase in temperature difference between both feet when there is an ulcer or inflammation present. In the study population of this research, there is only one participant with an ulcer. The difference in temperature between both feet could potentially be a parameter used to detect the presence of pressure points and (emerging) wounds. However, more extensive research is needed to determine whether this parameter would also be useful in the setting of the VVT sector when thermal imaging is used to objectify the presence of pressure points and wounds.

Temperature differences between dorsal and plantar side

The disparity between the temperature difference between the dorsal and plantar sides in the groups with deteriorated vascular status, suggested in the study by Ilo et al [21], is slightly reflected in our study by the analysis of the different regions on the dorsal and plantar side. However, drawing conclusions based on the temperature difference between the dorsal and plantar side is not possible due to the large variation within the groups.
The analysis of temperature difference between the dorsal and plantar side of the participants with and without neuropathy shows that there seems not to be a difference between the groups, nor when the regions of the distal and proximal regions are used to determine the disparity. Research of Papanas et al [26] into the differences in temperature in diabetes patients with and without neuropathy also draw this conclusion. They found a higher temperature on both the dorsal and plantar sides, but neither the dorsal nor plantar side increase in temperature more than the other side. This is in line with the expectations that the microcirculation on both the dorsal and plantar sides is equally affected by the consequences of neuropathy.
In this study, the division of the foot into distal and proximal regions was only used to exclude the artifacts caused by the Doppler measurement. Whether dividing the feet in (more) regions is also useful for data from subjects where no artifacts occur due to Doppler measurements, needs to be investigated.

Temperature differences between angiosomes

Furthermore, this research examined the differences between the temperature of the angiosomes in the groups with different vascular status. Earlier research suggests the forefoot to has a higher temperature in patients with diabetes and PAD than in patients with diabetes without PAD [57, 58]. This increase in temperature of the forefoot is not clearly reflected in the results of this study, although the temperature of the MPA and LPA angiosomes is slightly higher compared to the temperature of the LCB and MCB angiosomes, especially in the biphasic group. The results show differences between the groups with different vascular state in the comparison of the temperature of every angiosome between both feet. The statistical test indicates that there is a significant disparity in the temperature of the LCB angiosome of both feet between the triphasic and monophasic groups. The interpretation of the temperature of the angiosomes is limited by the lack of information about the location of any stenosis. In some cases, this information is entirely unknown, and sometimes it is known in the hospital but not disclosed to the nursing home. The author has found no previous research addressing the comparison between the temperature of the angiosomes of the left and right foot.
The results from the analysis of the angiosomes in this study indicate that utilizing different regions

based on angiosomes can possibly provide information about the vascular status of the feet, but information about the location of the stenosis is necessary to interpret the temperature differences between the angiosomes. In this study, the angiosomes were determined based on previous research by McCallum et al [5]. In other studies, the angiosomes were determined differently [59].

Temperature deviations within the foot

This research indicates that within the group with diabetes, deterioration of the vascular status shows a small decrease in the magnitude of the temperature deviation of the plantar side, in comparison to the group with triphasic vascular state. The number of peaks, the mean area of the peaks and the height of the peaks on the plantar side also decreases with a poorer vascular status.
The decrease in the magnitude of temperature deviation within the foot and the decrease of the height of the peaks in participants with deteriorated vascular status may be caused by a decrease in overall foot temperature due to reduced blood flow. The decrease of the magnitude of the temperature deviation could also be caused by skin abnormalities. One of the consequences of diabetes is the increase in calluses and dry skin [13]. For instance, the presence of calluses may result in reduced thermal emission. In this study, no information was collected about the status of the skin and the amount of calluses. More studies, which also take into account the thickness of the skin and the amount of calluses, are needed to draw conclusions about the relationship between the magnitude and the number and height of the temperature deviations and the factors PAD and neuropathy.
The decrease of the mean area of the peaks in participants with biphasic and monophasic vascular state may indicate that there are more smaller peaks occurring in patients with PAD. This could be caused by poorly or unevenly perfused tissue and skin, showing more small temperature peaks. [24].
Neuropathy also appears to influence the area of the peaks, but due to the low number of participants without neuropathy, no conclusions can be drawn from this. However, it does seem worthwhile to further expand the analysis of the area and height of the peaks, as there are indications that these are influenced by PAD and possibly neuropathy. Ideally, the magnitude of the temperature deviation and the number, area and height of peaks would also be compared to the pressure points, as these may induce local temperature changes. Additionally, examining local areas exhibiting decreased temperature could provide valuable insights into their potential relation with pressure points, due to the decrease in pressure-induced vasodilation as a result of neuropathy [30, 31].

Subjective assessment

While the subjective assessment was solely conducted by the author and thus remains unilateral, it holds significance for the research presented in this report. This research is aimed at the possible application of thermal imaging in the VVT sector. Given the limited use of advanced technologies, low academic backgrounds among users and the absence of resources and expertise to employ and interpret complex technology, it is crucial for the generated images to be easily interpretable and utilizable in this environment.
The subjective assessment shows that most pressure points reported in the screening cannot be found in the thermal images. Other spots with abnormal temperatures depicted in the thermal images cannot be explained by the pressure points or wounds that are reported in the screening. Because determining the pressure points in the standard screening is a subjective method, it's possible that these spots with deviating temperature could be pressure points that were not identified during the screening. However, no conclusion can be drawn about this based on the available information. In the images of participant 24 it is clearly visible that ulcers do result in temperature differences that can be observed subjectively on the thermal images. The wound of participant 24 was also observable without the use of a thermal camera. However, it might be feasible to identify early-stage wounds resulting from pressure points that are not yet visually detectable by using a thermal camera. Nonetheless, in this group of participants there was no case reported in which an incipient, non-open wound was present.
The analysis of the mean temperature shows that a lower temperature appears to be related to peripheral arterial disease. However, for example, participant 1 deviates from this. This participant shows a large temperature difference between both feet, while no PAD was reported. Previous research of E. Zoetelief [48] indicates that the foot temperature can fluctuate significantly on a daily basis due to various internal and external factors. Hence, it appears impossible to draw conclusions about ulcer development risk factors based solely on foot temperature measurements from a single day.

Although no new, relevant information for answering the research questions in this study was observed in the images by the subjective assessment, this part does indicate that image processing can cause certain temperature differences to stand out that are poorly visible in the original images. The contour images, in particular, accentuate local high and low temperature spots and may therefore be useful when thermal imaging is used at the bedside. The quadratic deviation maps strongly highlight large deviations from the mean temperature. The drawback of this method is that it is no longer clear whether the temperature is lower or higher than the mean due to squaring.

Usability in the VVT sector

While collecting and analyzing the data in this study, it became clear that in this environment it is impossible to apply a standardized situation before making the images. The target group often has physical and cognitive limitations and the healthcare providers involved have little technical knowledge. An important condition for the usability of thermal imaging in this sector is that the technique must produce good results easily and with minimal adjustments to the situation or environment. The findings of this study suggest that the use of thermography, as investigated in this study, does not appear to add value to periodic screening due to the absence of a standardized setting and environment. However, the findings provide reason to believe that thermography might potentially contribute to the prevention or objectivation of diabetic foot ulcers in different ways, as suggested in this chapter.

Limitations

This study has a number of limitations. First, this study is limited by the low number of participants included. Due to this low number, it is impossible to draw conclusions with certainty. The power of the analysis of the mean temperature between the group with biphasic and monophasic vascular state is 0.117 (mean 28.98, SD 1.27 for the biphasic group, mean 28.15, SD 1.92 for the monophasic group). The power of this analysis is therefore very low.
Furthermore, neuropathy was diagnosed in almost all participants, which means that in the analysis of the influence of vascular disease on the parameters of the thermal images, not only participants with only PAD and without neuropathy could be analyzed, which may also imply that neuropathy influences these results. The analysis of the relationship between neuropathy and the mean temperature has a power of 0.129 (mean 28.62, SD 1.64 for the group without neuropathy and mean 29.26, SD 1.40 for the group with neuropathy). Thus, this analysis exhibits low statistical power. The power of the other analyzes conducted is also limited, due to the low number of participants. According to the power calculation, a minimum of 168 participants is required for a power of 0.95 with the mentioned means and standard deviations.
Furthermore, taking the thermal images was complicated by the conditions in which the measurement protocol was carried out. For example, not all feet are depicted perpendicularly, which means that the entire foot surface is not always measured. This was mainly caused by the immobility of the participants. In addition, the ambient room temperature varies among measurements. The premeasurement conditions varied strongly per participant. Due to the physical and cognitive status of the participants and the time-efficient planning pursued by the podiatrists during the measurement moments, it was usually not possible to take the thermal images prior to the standard foot screening and to ensure all participants to be in the same condition for a while. As a result, the images will be influenced by the activities prior to the measurements. In this study, it was not recorded which premeasurement activities the participants carried out. However, these limitations also appear when thermal imaging is applied outside a study context in the VVT sector. It therefore demonstrates that thermal imaging in this environment is constrained by the circumstances.
As mentioned earlier, in some participants particularly the distal part of the dorsal side is influenced by the Doppler measurement prior to the thermal imaging.
Besides thermal images, RGB images were taken during the measurement moments. The images obtained were not easily interpretable due to a lack of lighting and were therefore not used in the analyses.
Various postprocessing steps were taken to prepare the data for analysis. These were performed manually. Low intraobserver variability was found in mean temperature, but all segmentations were performed by the same researcher. This causes subjectivity of the results.
The assumptions of minimum dimension and minimum temperature increase used to determine the

characteristics of the Gaussian filter and the relevance of the peaks in this study are somewhat arbitrary, because there is still insufficient evidence regarding the area of an incipient pressure spot or wound and the magnitude of temperature increase. This may result in missing peaks that could be relevant.
Moreover, the parameters of the standard screening often cannot be determined objectively. Although the screening is performed by professional podiatrists, some parameters are subject to subjectivity and interobserver variability. The vascular status is determined based on the Doppler measurement. However, the outcome of this measurement (the audible pulsation) must still be interpreted by the podiatrist. Additionally, although determining the pressure points is done with care, it is prone to subjectivity. There is currently no objective measuring instrument available for determining pressure points. Finally, performing the examination with the monofilament only determines symptoms of neuropathy, but it cannot objectively determine nerve damage. Diagnosing neuropathy is especially difficult in patients who have poor hearing or understanding (e.g. due to dementia). However, the participants in this study are often patients with hearing complaints or cognitive decline.
In addition to the limitations of the results of standard screening, interpreting the results is also hampered by the lack of clinical background information. For many participants, no or only limited medical information was recorded in the patient file of the elderly institution. This is caused by a lack of information provided from the hospital to other institutions. Requesting this information is often difficult due to (privacy) legislation. Relevant information would, for example, indicate in which vessel stenosis exists as a result of PAD. This could expand and improve the interpretation of the consequences of PAD on the temperature of the feet and angiosomes.

Further perspectives

The purpose of this study was to investigate the predictive value of thermal imaging in assessing the risk of a diabetic foot ulcer. This study, which focused on making a one-off thermal image by an employee in elderly care and of the feet of patients with physical and cognitive limitations, appears to show that thermal imaging is not suitable for this application in the manner that was investigated. However, the results from this study provide grounds for several other research directions.
The results indicate that a single measurement does not provide added information on the risk of wounds compared to current screening. However, this study does demonstrate that ulcers are indeed visible in thermal images. Additionally, pressure points were identified in some participants on the thermal images. This suggests that thermal imaging in the context of elderly care may provide information about pressure points and incipient wounds that are not yet visible to the naked eye. In addition, the use of a thermal camera for objective assessment and determination of wound severity in this sector should be investigated [32, 33, 60]. Analyzing the area and height of the peaks could potentially contribute to this. In this regard, the method used in this study could be improved and expanded by optimizing the filter and determining, for example, the volume of the peaks.
Furthermore, the analyzes performed in this study could be expanded with several other analyzes to conduct a more comprehensive investigation into the influence of PAD and neuropathy on foot temperature. For example, the analysis of the temperature over the midline of the foot might provide different information [61]. Additionally, the analysis of the different regions can be expanded. Our study only used two regions to investigated the difference between dorsal and plantar side. When the foot is divided into different regions in different ways, the temperature of the regsions, the magnitude of the temperature deviation and the number of peaks could be examined. This may potentially enable the more precise detection of temperature disparities among regions compared to methods using the mean temperature measurement of the entire foot.
Although this study does not yet give significant results, the difference between the dorsal and plantar sides may contribute to the diagnosis in patients where the vascular status cannot be properly determined on the basis of the Doppler measurement or the palpation of the pulsations. Besides, if usable RGB images are available, these images could also be used together with the thermal images to detect possible color differences, for example on the locations of wounds or pressure points.
The results of this study indicate that foot temperature is related to PAD, although the findings of this method demonstrate large variations within the groups. Other methods to objectify PAD using thermal imaging can be investigated in the future to achieve a better objective assessment of the foot temperature. Previous research suggests that thermal imaging after mechanical or thermal stress provides useful information about vascularization [62].

This study showed that the temperature in the feet was also influenced in biphasic participants, while a biphasic vascular signal is not identified as peripheral arterial disease. Because blood supply has a major impact on the risk of developing a DFU and wound healing, it may also be important, based on the outcomes of this study, to include biphasic vascular status as a risk factor. Additionally, it is difficult to discern the difference between triphasic, biphasic, and monophasic vascular signals with the current measuring method. The results of this study indicate a need for further investigation into the extent to which a biphasic vascular status should be considered as a risk factor and how this can be reliably measured during screening.
Furthermore, other research could focus on designing a neural network, using thermal, RGB and clinical parameters to ultimately estimate the risk of developing a DFU. Recent research has given promising results in this regard, but new research should investigate to what extent this is applicable in predicting DFUs in elderly people in the non-standardized environment of the elderly care [63].

In short, although the results of this study do not give reason to expect that thermal imaging can partially or completely replace the standard screening for the prevention of DFUs, it is important to assess the applicability of technologies in this sector of elderly care. The environment of this sector is different from the (academic) situation of hospitals, which requires extensive research into the applicability of techniques in this sector. The need to properly implement technologies in elderly care is high, due to the increase in the number of elderly people and the decrease in the number of available employees in healthcare. This study contributed to this goal by investigating the use of thermal imaging in the VVT sector.

5 Conclusions

Based on the results given and discussed before, a number of conclusions can be drawn. Peripheral arterial disease appears to influence the temperature of the feet. The temperature, magnitude of temperature deviations within the foot and the number, area and height of the peaks decreases in patients with PAD. Neuropathy appears to have little to no influence on the mean foot temperature, but the results show a small difference in area and height of the temperature peaks in participants with neuropathy.

The utilization of distinct regions in the foot and the segmentation of the foot based on angiosomes appear to provide more information regarding temperature differences.

However, due to the large variation within the groups, no reliable conclusions can be drawn about the risk of DFUs based on thermal parameters. The thermal images are influenced by the activities prior to thermal imaging. In elderly care it is not possible to standardize patient preparation protocols before conducting thermal imaging. Hence, it is concluded that a single thermal measurement is not appropriate in geriatric care for estimating the risk of a diabetic foot ulcer.

Some pressure points can be detected through subjective assessment of the thermal images, while others are not visible in the thermal images. The analysis of pressure points in this study was limited by the lack of a reliable objective method to determine pressure points in the current standard screening method. However, the ulcer in the collected data was clearly evident.

The findings of this study suggest that thermal imaging may be of value as an predictive tool in addition to the standard screening, because of the information it can provide about (incipient) pressure points and ulcers, but further research is needed. This study contributed to research aimed at the implementation of technology in the VVT sector, by investigating the applicability of thermal imaging in this setting.

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Appendices

A Ethical review

UNIVERSITY OF TWENTE.

Natural Sciences & Engineering Sciences (NES)

230607 REQUEST FOR ETHICAL REVIEW

Request nr:	230607	Intro form:	7 - Introduction
Researcher:	Keurhorst, J.A. (M-TM)	Middle form:	7 - Natural Sciences & Engineering Sciences (NES)
Supervisor:	Kappert, K.D.R. (TNW-BMPI)	Outro form:	5 - Submission
Reviewer:	Rouwkema, J. (ET-EOST)		
Status:	Positive advice by Reviewer		
Date of application:	03-11-2023		
Request version:	1		

0. GENERAL

0.1. Personal details

Student/employee number: s1802453
Initials: J.A.
First name: Alieke
Last name: Keurhorst
Email : j.a.keurhorst@student.utwente.nl
Education/department:
Faculty:

0.2. Project title

Admendment to 'Thermography to improve the diabetic foot screening'

0.3. Summary

Amendment to application no. 230474 with amendment no. 230555: In the previous application that has already been approved, thermography for this study is carried out during the screening by the podiatrist or within a week after this screening of clients living in a nursing home. I would like to change this: in this study, participants will be scanned during or within a week after a podiatrist's visit to the nursing home, or during the visit of people who do not live in a nursing home and come to the podiatry clinic for the screening.

Rationale: Patients with diabetes have an increased risk of foot ulcers due to neuropathy, reduced blood supply and other symptoms of diabetes. Preventive care is necessary to prevent foot ulcers. Therefore, patients with diabetes undergo a foot screening by a podiatrist at least once a year to assess the risk of a foot ulcer and to scale up preventive care if necessary. Because there are more and more patients with diabetes and the cost of a foot ulcer is high, it is important to improve the foot screening where possible, to prevent ulcers.
Objectives: Literature shows that changes in the surface temperature of the feet are associated with the risk of developing diabetic foot ulcers. The periodic diabetic foot screening does not yet contain an objective measure of the temperature of the feet. The objective of this study is to investigate the correlation between the temperature of the feet, measured by an infrared thermography camera, and the parameters and outcome of the standard foot screening. This can be used to determine whether infrared thermography can improve

the foot screening by objectifying the temperature and whether certain parameters (for example pulsations or doppler measurement of the a. dorsalis pedis and a. posterior tibilias; pressure points; signs of inflammation) from the screening can be correlated to the thermographic parameters (for example difference mean temperature of both feet; difference highest temperature with collateral location; difference temperature dorsal and plantar), to give information about the risk of ulcers.
Design: Diagnostic research
Methods: A group of around 60 patients with diabetes,
will be included in the study. These patients undergo the standard foot screening by the podiatrist. At the same moment as the standard foot screening is performed or within one week after the screening,
thermographic and RGB images are made of the top and bottom of both feet. This is a total of four images and it takes a maximum of 5 minutes. The patient only needs to sit on the chair.
The images will be analyzed, whereby the mean and highest temperature of the dorsal and plantar sides will be determined. These parameters are compared with the parameters obtained from the standard foot screening and the
outcome of this standard foot screening.

0.4. Start date (estimated) and end date (estimated) for your research project

Start date: 04-11-2023

End date: 10-07-2024

0.5. If additional researchers (students and/or staff) will be involved in carrying out this research, please name them: [Please include full name and email]

Full name	Email

0.6. In which context will you conduct this research?

Master's thesis

0.7. Please select your supervisor

Kappert, K.D.R. (TNW-BMPI)

0.8. Please select an ethical committee

Natural Sciences & Engineering Sciences (NES)

1. SIMILAR RESEARCH

1.1. Is this research connected to a research project previously assessed by the NES Ethics Committee?

No

2. RESEARCH INVOLVING SECONDARY DATA

2.1. Will you be using existing (secondary) data pertaining to individuals or groups?

Yes

2.2. Please provide a brief description of the data or documents that you plan to use and from which source these are obtained?

Basic characteristics such as age, gender, year of diagnosis, diabetes type, therapie, Barthel index, relevant comorbidities --> obtained from patient record or in a quastionaire, asked from the participant
Parameters from the standard foot screening: -> obtained from Voetencentrum Wender, they perform the standard foot screening

2.3. Does the (secondary) dataset contain information (or a combination of information) that can be traced back to specific individuals?

No

3. HUMAN SUBJECTS

3.1. Does your research involve human subjects?

Yes
Yes
N ~ 60
Inclusion criteria:
- 18 years or older
- Diagnosed with diabetes
- Being screened for risk of diabetic foot ulcers
- Has given informed consent or informed consent has been given by the responsible person in case of legal incapacity
Exclusion criteria:
- Major amputation of the foot
- Amputation of the leg
- Active or healing wound on the leg, above the ankle

3.2. Is the research considered to be medical research?

Yes
Yes, in this study an imaging technology is used to improve the screening (diagnosis) for the risk of diabetic feet.
It is not expected to require a non-WMO statement because the technology is not invasive, has no risks and requires very little time and effort from the subjects.

3.3. Please explain what selection procedure will take place, in relation to the intended study population

The selection of the participants is done by looking at which patients are scheduled for the standard foot screening. Informed consent is requested from these patients and it is checked whether they meet the inclusion and exclusion criteria.

3.4. Please explain the size (n) of your study population (e.g. powercalculation)

During a visit to a health organization where foot screenings are performed by the podiatrist, or on a screening day at the podiatrists clinic, approximately 6 to 8 patients are screened. In the time of my master's
thesis, it is expected to be able to screen and analyse approximately 60 patients.

3.5. Are participants completely free to participate in the research and can they withdraw at any time, without giving reasons?

Yes

3.6. Will participants be screened to reduce the risks of adverse effects of the research?

No
There is no risk of adverse effects.

3.7. Is there a risk of unexpected findings which might have implications for the subject, due to the used methods/ equipment?

No

3.8. Is there any risk of injury or high burden for the participant? Does the equipment used pose any danger to the participants.

No

3.9. Are participants briefed and do they sign informed consent before participation?

Yes

3.9.1. Upload Information Brochure and Consent Form

PIF_en_InformedConsent_versie3.pdf

3.10. Is deception taking place?

No

3.11. Are the requirements with regard to anonymity and privacy satisfied as stipulated in the University's data privacy impact assessment?

Yes
No name, address details, contact details or other traceable information are stored.

4. ANIMAL SUBJECTS

4.1. Does your research involve animal subjects?

No

5. ANIMAL MATERIAL

5.1. Does your research include the use of animal material?

No

6. HUMAN MATERIAL

6.1. Does your research include the use of human material?

No

7. PLANT MATERIAL

7.1. Does your research include the use of plant material?

No

8. GENETICALLY-MODIFIED CELLS OR ORGANISMS

8.1. Does your research include the use of genetically-modified cells or organisms?

No

9. 'DUAL USE' RESEARCH

9.1. Can your research be classified as 'dual use' research, with potential applications in for instance military or police technology?

No

10. OWNERSHIP OF DATA

10.1. Is ownership of the research data or freedom to publish results, limited in any way by a collaboration or contract with an external (commercial) party?

Yes

10.2. Is this research project conducted in collaboration with a commercial party or performed under any kind of contract?

Yes
This study is being carried out in collaboration with Voetencentrum Wender and

the healthcare institutions where they perform the foot screenings, such as Carintreggeland.

10.3. Is there any payment (e.g. cash, goods, reimbursements) connected with this research, either to the researchers, the research group or the University, with the exception of non-profit funding agencies?

No

10.4. Are the research data and results fully owned by the University?

Yes

10.5. Are the results free to be published open access?

Yes

11. CONFLICT OF INTEREST

11.1. Does your research include the use of data (either new or existing) the collection and analysis of which might conflict with the interests of the individuals, groups or organizations to which these data pertain?

No

12. IMPACT ON THE ENVIRONMENT

12.1. Does your research, the aim of your research outcome or technology have an impact on the environment?

No

13. OTHER POTENTIAL ETHICAL ISSUES

13.1. Do you anticipate any other ethical issues in your research project that have not been previously noted in this application?

No

14. CLOSURE

14.1. I have answered all questions truthful and complete

Yes

15. COMMENTS

Rouwkema, J. (ET-EOST) (07-11-2023 11:12) :

As the amendment does not raise any ethical concerns, a positive advice for the amended application can be given.

16. CONCLUSION

Status: Positive advice by Reviewer

B Subject Information Sheet

Proefpersonen informatie formulier

De inzet van thermografie bij de voetscreening bij patiënten met diabetes

Inleiding
Geachte heer/mevrouw,

Deze brief gaat over het onderzoek 'De inzet van thermografie bij de voetscreening bij patiënten met diabetes'. U bent uitgenodigd om deel te nemen aan dit onderzoek. In deze brief wordt uitgelegd wat het doel van het onderzoek is en hoe het in zijn werk gaat. Het is veel informatie. U kunt bij vragen altijd contact opnemen met de onderzoeker, de contactgegevens staan onderaan deze brief. De onderzoeker zal voor het uitvoeren van het onderzoek de informatie nog met u doorlopen en eventuele vragen beantwoorden.

Wat is het doel van het onderzoek?
Het doel van het onderzoek is bepalen of thermografische beelden behulpzaam zijn bij het inschatten van het risico op een voetulcus en of het de voetscreening zou kunnen verbeteren. Hieronder vindt u meer informatie over de techniek thermografie bij patiënten met diabetes.

Wat is de achtergrond van het onderzoek?
Om te voorkomen dat u een wond aan de voet krijgt, wordt er periodiek een screening uitgevoerd door de podotherapeut. Aan de hand van deze voetscreening wordt bepaald hoe groot het risico op een wond is en welke preventieve zorg nodig is om wonden zo goed mogelijk te voorkomen. Uit onderzoek blijkt dat verandering van de temperatuur van de voeten een aanwijzing kan zijn van een verhoogde kans op een wond aan de voet. De temperatuur van het oppervlak van de voeten kan gemeten worden door middel van thermografie. Hierbij wordt met een infrarood camera beelden gemaakt van de voeten, waarna bijvoorbeeld de gemiddelde temperatuur van de voeten bepaald kan worden. Ook kan bijvoorbeeld het verschil tussen de temperatuur van beide voeten of kleine locaties op de voet met een verhoogde temperatuur in beeld gebracht worden.

Hoe verloopt het onderzoek?
Wanneer u deelneemt aan het onderzoek, zullen bij u eenmalig met een thermografische camera en een gewone camera beelden gemaakt worden van de voeten. U gaat daarbij eerst op een stoel of bed zitten met de benen recht voor u, zodat er beelden van de onderkant van de voeten gemaakt kunnen worden. Daarna gaat u zitten of staan met beide voeten op de grond, waarbij beelden van de bovenkant van de voeten gemaakt worden.

Het maken van de beelden vindt plaats tijdens of binnen een week na de normale voetscreening die bij u uitgevoerd wordt door de podotherapeut van Voetencentrum Wender. Het maken van de beelden neemt ongeveer 5 tot 10 minuten in beslag.
Naast de thermografische beelden worden de gegevens van de uitgevoerde voetscreening bij Voetencentrum Wender opgevraagd. Ook worden basisgegevens* opgevraagd vanuit het dossier van uw zorginstelling/organisatie, of wanneer u niet in een zorginstelling woont worden deze gegevens door middel van een vragenlijst van uzelf verkregen. Dit is nodig om de resultaten van de thermografische beelden goed te kunnen duiden.

De beelden en gegevens die tijdens het onderzoek worden verzameld, zullen gebruikt worden voor wetenschappelijk onderzoek en kunnen gepubliceerd worden door middel van een verslag en/of wetenschappelijk(e) artikel(en).

** De gegevens die wij opvragen zijn: leeftijd, geslacht, jaar van diagnose diabetes, type diabetes, therapie i.v.m. diabetes, Barthel index, comorbiditeiten.*

Wanneer kunt u meedoen?
U dient tenminste 18 jaar te zijn om deel te nemen aan dit onderzoek. U kunt niet mee doen wanneer u een amputatie van een uw gehele voet of been hebt ondergaan, of als u een actieve (rood en warm) wond op uw been hebt (boven de enkel).

Wat zijn de voor- en nadelen?
Er zijn geen fysieke, juridische of economische risico's verbonden aan uw deelname aan dit onderzoek. De thermografische beelden hebben geen invloed op de behandelingen en de zorg die u ontvangt en worden alleen door de onderzoekers gebruikt voor het onderzoek.
Met uw deelname aan dit onderzoek helpt u de onderzoekers om meer inzicht te krijgen in de toegevoegde waarde van thermografie bij patiënten met diabetes.

Deelname aan het onderzoek
Uw deelname is geheel vrijwillig en u kunt uw deelname op elk gewenst moment stoppen of weigeren dat uw gegevens voor het onderzoek worden gebruikt, zonder opgave van redenen.

Wat gebeurt er met uw gegevens en de beelden?
Uw privacy is beschermd. De verkregen beelden, de gegevens van de voetscreening en de basisgegevens die nodig zijn om de beelden goed te interpreteren, worden anoniem gemaakt en opgeslagen op de beveiligde schijf van de vakgroep Biomedical Phototonic Imaging (BMPI) van de Universiteit Twente. De beelden en gegevens worden 15 jaar bewaard. In rapporten en publicaties over het onderzoek kan niemand achterhalen dat het over u gaat.

Heeft u vragen?
Bij vragen kunt u contact opnemen met de onderzoekers via de contactgegevens hieronder. Als u vragen heeft over uw rechten als onderzoeksdeelnemer, informatie wilt inwinnen, vragen wilt stellen of eventuele zorgen over dit onderzoek wilt bespreken met iemand anders dan de onderzoeker(s), kunt u contact opnemen met de secretaris van de Ethics Committee Natural Sciences en Engineering Sciences van de Universiteit Twente via ethicscommittee-nes@utwente.nl.

Dit onderzoeksproject is beoordeeld en goedgekeurd door de ethische commissie Natural Sciences and Engineering Sciences (NES) van de Universiteit van Twente.

Hoe geeft u toestemming voor het onderzoek?
U krijgt informatie over het onderzoek via deze brief. Daarnaast legt de onderzoeker het onderzoek aan u uit en beantwoordt uw vragen. Daarna vertelt u de onderzoeker of u de informatie begrijpt en of u wel of niet mee wil doen. Wilt u meedoen? Dan vult u het toestemmingsformulier in dat u bij deze informatiebrief vindt. U en de onderzoeker krijgen allebei een getekende versie van dit toestemmingsformulier.

Hartelijk bedankt voor uw tijd.

Studiecontactgegevens voor verdere informatie:

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C Informed Consent Form

Toestemmingsformulier

U ontvangt een kopie van dit toestemmingsformulier

Vink de juiste vakjes aan	Ja	Nee
Deelnemen aan dit onderzoek		
- Ik heb de onderzoeksinformatie gelezen en begrepen, of deze is aan mij voorgelezen. Ik heb vragen kunnen stellen over het onderzoek en mijn vragen zijn naar tevredenheid beantwoord.	□	□
- Ik geef vrijwillig toestemming om deel te nemen aan dit onderzoek en begrijp dat ik kan weigeren vragen te beantwoorden en dat ik me op elk moment kan terugtrekken uit het onderzoek, zonder dat ik hiervoor een reden hoef op te geven.	□	□

- Ik begrijp dat deelname aan dit onderzoek betekent dat:
  - beelden van de onder- en bovenzijde van mijn voeten worden gemaakt met een thermografische en normale camera.
  - basisgegevens voor het onderzoek worden opgevraagd bij mij of mijn zorginstelling/organisatie en anoniem worden opgeslagen en gebruikt.
  - de gegevens van de voetscreening door Voetencentrum Wender anoniem aan de onderzoekers worden verstrekt.
	□	□

Gebruik van de informatie in dit onderzoek		
- Ik begrijp dat de informatie die ik verstrek en zal worden verkregen, zal worden gebruikt voor wetenschappelijk onderzoek en wellicht gepubliceerd zal worden door middel van een of meerdere wetenschappelijke artikelen.	□	□
- Ik begrijp dat de persoonlijke informatie die over mij wordt verzameld en die mij kan identificeren, zoals (bijv. mijn naam of waar ik woon), niet wordt gedeeld buiten het onderzoeksteam.	□	□
Toekomstig gebruik en hergebruik van de informatie door anderen		
- Ik geef toestemming om de beelden en gegeven die verkregen worden anoniem te archiveren op de beveiligde schijf van de vakgroep BMPI van de Universiteit van Twente, zodat deze kunnen worden gebruikt voor toekomstig onderzoek.	□	□

_____	_____	_____
Naam deelnemer	Handtekening	Datum

In te vullen in geval van wilsonbekwaamheid van deelnemer

_____	_____	_____
Ingevuld door (naam)	Geboortedatum	Relatie tot deelnemer

In te vullen door de onderzoeker

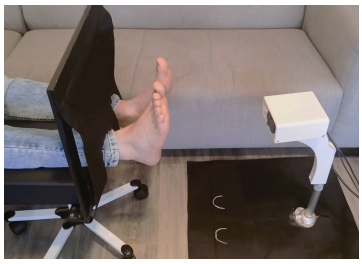
- Ik heb het informatieblad laten lezen en uitgelegd aan de potentiële deelnemer en, naar mijn beste vermogen, ervoor gezorgd dat de deelnemer begrijpt waar hij vrijwillig mee instemt.

_____	_____	_____
Naam onderzoeker	Handtekening	Datum

D Measurement protocol

Materials

- Laptop or computer
- Thermal camera: Optris PI 400i / PI 450
- RGB camera: Basler acA1920-150 μm
- Wide angle lens: FUJINON HF6XA-5M
- Software thermal camera: Optris PIX connect
- Software RGB camera: Pylon Viewe
- Black backdrop
- Black base plate
- Tripod
- Stool with notches for the legs
- Chair
- Measuring tape
- Disinfectant



(a) Measurement of the plantar side

(b) Measurement of the dorsal side

Measurement protocol

1. **Plantar measurement, see Figure 41a**

(a) Turn on all systems and cameras. Focus the lenses of both cameras to the predetermined setting;

(b) Have the participant sit on a chair, without shoes or socks, with the legs placed horizontally on the stool;

(c) Remove all plasters and bandages;

(d) Place both feet in dorsiflexion (as close to 90 degrees to the legs as possible), side by side on the stool. The calves rest on the stool and the heels do not;

(e) Set up the black backdrop;

(f) Place the camera at 32 cm from the plantar side of the feet, so that both feet are fully in view, in the middle of the two feet, on the same height as the heels;

(g) Take a thermal image and a RGB image of both feet;

(h) Remove the black background around the legs, remove the stool;

2. **Dorsal measurement, see Figure 41b**

(a) Have the participant sit with the feet placed 3 centimeters apart on the black base plate;

(b) Place the camera at a distance of 32 cm above the dorsal side of the feet;

(c) Take a thermal image and a RGB image of both feet at the same time;

(d) Disinfect the black surface plate, the stool and the black backdrop.