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OPEN LETTER

STANDUP database of plantar foot thermal and RGB images for early ulcer detection

[version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract

In this paper, we provide details of a research database consisting of 415 multispectral images (thermal and RGB images) of plantar foot from healthy (125 images) and diabetic subjects (290 images). The healthy subjects were members of two research laboratories (PRISME in France and IRF-SIC in Morocco). The second group was composed of type II diabetic patients who participated in an acquisition campaign at the Hospital Nacional Dos de Mayo in Lima, Peru, as part of a study on the early detection of ulcers in patients with diabetic foot. The purpose of this article is to describe the recruitment and acquisition protocols as well as the equipment used to help other units create similar databases. Our database was created in the context of the European STANDUP Horizon 2020 project #777661, in which eight scientific research entities and high-tech companies partnered.

Keywords

Diabetic foot, thermal imaging, medical database, research data, mobile health

This article is included in the Medical Biotechnology gateway.

Open Peer Review

Approval Status ✓ ?

	1	2
version 1 14 Jun 2022	✓ view	? view

1. **Rhys John Morris**, Cardiff and Vale University Health Board, Cardiff, UK

2. **Laith Alzubaidi**, Queensland University of Technology, Brisbane, Australia

Any reports and responses or comments on the article can be found at the end of the article.



This article is included in the Horizon 2020 gateway.



This article is included in the Marie-Sklodowska-Curie Actions (MSCA) gateway.



This article is included in the Diagnostic Imaging Technology collection.

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Competing interests: No competing interests were disclosed.

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Introduction

Disclaimer

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Background and aims of STANDUP

Diabetes is one of the most common diseases in the world, and is correlated to a high mortality index. Uncontrolled diabetes can affect several organs, namely feet, eyes, heart, kidneys, nervous system and blood vessels[1,2]. The European Horizon 2020 STANDUP #777661 project is interested in health problems that arise from diabetic foot (DF), which can be infection, ulceration or destruction of deep tissues of the foot[3]. The severity of DF can lead to hospitalization or even to lower limb amputation, resulting in substantial costs and reduced quality of life. In the majority of cases, a proper risk assessment of diabetic patients associated with diabetic foot care can significantly prevent the development of diabetic foot disorders. Currently, risk assessment for DF is based solely on neuropathy and vascular analysis. However, according to diabetes experts, further improvements are needed.

In the literature, several studies have proven that the use of temperature can be of great relevance in the early diagnosis of DF problems[4,5]. Foot temperature varies from patient to patient and depends on the surrounding temperature and the activity level. Usually, the average temperature difference between the contralateral areas of the left and right feet does not exceed 1°C. A point-to-point temperature difference greater than 2.2°C is considered abnormal and is called hyperthermia[6]. Due to neuropathic sensory loss, diabetic patients rarely feel pain and injury in the feet, especially in the early stages of the disease. Therefore, temperature elevation can be a useful indicator of foot ulceration risk. A strategy including information on hyperthermia has been shown to reduce foot ulceration by 70%[5,7].

According to 8, the temperature distribution in the thermogram of plantar foot of a healthy person is a bilateral butterfly pattern, whereas in diabetic patients, this temperature varies and shows no typical pattern as in healthy people. The cold stress test[9] is another effective method to asses thermoregulatory problems. The temperature difference before and after a cold stress is an important indicator for the early detection of diabetic neuropathy problems[10].

Within the framework of the European Horizon 2020 program, the main objective of the STANDUP #777661 project is to propose thermal solutions and technologies that could help doctors and specialists improve DF diagnosis, to detect hyperthermia at an early stage, and to develop better DF ulcer treatments using thermal information. STANDUP is a collaboration between clinicians, researchers, and industry partners. The specific research objectives of the project are:

- Developing a smartphone thermal-based system to detect hyperthermia of the plantar foot surface and to study thermal variations with time after a cold stress test in targeted regions of interest (ROI).
- Following-up on temperature, color, and 3D shape of DF ulcer along time.
- Conducting clinical trials to assess thermoregulation quality of the plantar foot surface by analyzing temperature variation in targeted ROI, and to monitor DF ulcer temperature, color, and 3D shape over time.
- Taking into account thermal factors to design new foot insoles, which will be tested in clinical trials on patients with DF ulcer.
- Associating all results produced during STANDUP to converge into advanced smartphone-based prototype and foot insoles.

Project structure

STANDUP has five interrelated research work packages (WP, Figure 1) and two additional WPs (WPs 0, and 6) which focus on management, training, and ensuring impact. WP1 aims to develop a smartphone application (A1) to detect hyperthermia and to analyze thermal variation of the plantar foot surface through time.WP2 aims to create another smartphone application (A2) to assess variation of DF ulcers along time. WP3 focus on the improvement of insoles using thermal information.WP4 is dedicated to clinical trials for DF ulcer prevention and treatment using the applications (A1, A2) developed in the two previous work packages (WP1, WP2). In the last WP5, the smartphone applications will be tested in real clinical situation, and improved taking into accounts remarks from the users (medical staff, university members and patients), to result in advanced prototypes.

In this paper we focus specifically on a crucial step of the STANDUP project, which consists in creating a database of thermal and color images of the foot sole for healthy people and diabetic patients. Thermal and color images were acquired using the STANDUP protocol, *i.e.*, freehandedly with a smartphone equipped with a dedicated thermal camera that allows the simultaneous recording of a thermal image and a red-green-blue (RGB) one. To our knowledge, this database is the first multispectral database (containing thermal and color images) of diabetic patients' plantar feet surfaces.

Materials and methods

Choice of thermal camera

Camera resolution

The largest foot that we considered was 30 cm long. The vertical field of view we chose was therefore 40 cm: 30 cm to include the foot sole plus a 5 cm margin at the top and bottom of the foot. In the other direction, 40 cm was enough to contain both feet along their width (about 10 cm), including the same 10 cm margin for each foot. The field of view was then 40×40 cm² (see Figure 2).

Hyperthermia occurs one week before an ulcer. The smallest hyperthermia area is a circle of approximately 1 cm in diameter. According to Shannon's first theorem and the values used in image processing, two pixels are required to detect the smallest risk area. This means that any camera with a resolution larger than 80×80 pixels can be chosen.

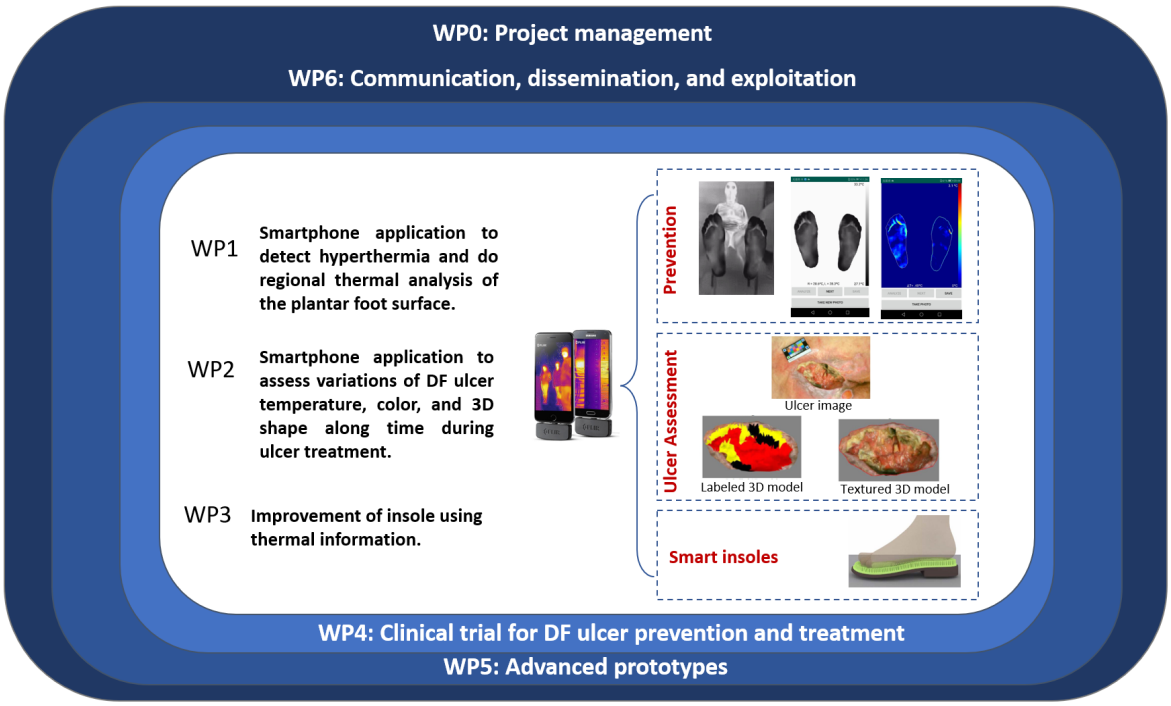


Figure 1. schematic overview showing the work packages included in the STANDUP project.

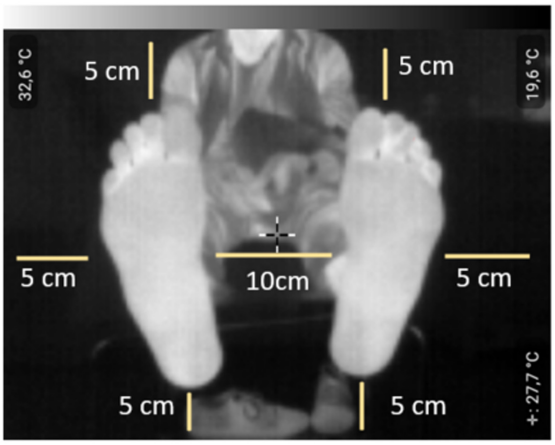


Figure 2. Margins to be respected during the acquisition of thermal images of plantar foot.

Camera sensitivity

Hyperthermia corresponds to a point-to-point temperature difference between contralateral feet higher than 2.2°C. The differential accuracy must therefore be better than 0.2°C (about 10% of the value to be evaluated).

Spectral range

For a healthy person, the mean skin temperature under normal conditions is between 33.5 and 36.9 °C[11]. Wien's law shows that the infrared radiation wavelength is around 9.5 µm. Therefore, the spectral range of the chosen camera must contain this wavelength.

In this study, we chose the FLIR ONE Pro camera. It consists of two sensors. The first is a thermal sensor that measures heat by infrared emission, characterized by a thermal image resolution of 160×120 pixels. The spectral range of the thermal sensor is 8–14 µm. FLIR ONE Pro can detect temperature differences of 0.1°C. The other sensor is a conventional 1440×1080 pixels RGB camera, designed to work in parallel with the thermal core. FLIR ONE Pro is designed to be plugged into a smartphone[12].

The FLIR ONE Pro camera software includes an alignment control technology called Multi-Spectral Dynamic Imaging (MSX)[13], allowing it to provide spatially registered RGB and thermal images. MSX increases the clarity of acquired images by integrating edge and contour details of visible light into thermal readings in real-time. This technology does not dilute the thermal image or reduce its transparency. A thermal image and an RGB image of the plantar foot surface are acquired simultaneously, as shown in Figure 3.

Recruitment and acquisition protocols

Ethical considerations

The ethical approval for the project was obtained from the Biomedical Research Ethics Committee of Hospital Nacional Dos De Mayo (No. 075-2021-CEIB-HNDM) on 10/01/2019.

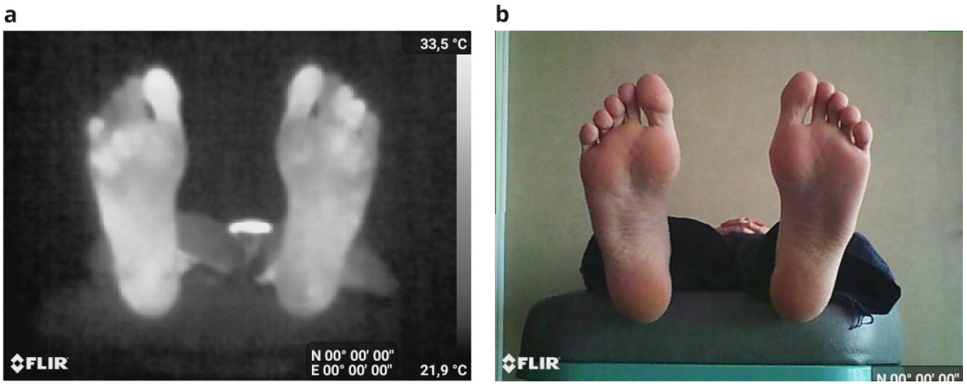


Figure 3. An acquisition example: (**a**) the thermal image and (**b**) the corresponding RGB image.

The study was conducted from January to March 2019 in Dos De Mayo hospital in Peru, under the supervision of Dr. H. Arbanil, responsible at the endocrinology service in HNDM, the former president of the Peruvian Society of Endocrinology, and member of biomedical research ethics committee of HNDM.

The main objective of this study was to use thermal images of the plantar foot in the prevention of diabetic ulcers at early stages. For this purpose, it was necessary to collect thermal images of the plantar foot as well as medical information measured by medical doctors.

Each volunteer participating in our clinical trial was informed of the ethical issues of the STANDUP project by a clear and informed consent form concerning the data collection and processing, the validation of the prototype which he/she read, understood, and signed.

This consent relating to the specific purpose of STANDUP project is informative, unambiguous, and freely given. It clearly defines the acquisition process, the purpose of the data collection, who will use it, and for what goal. Appropriate languages were used for each country.

Informed consent and patient details

The authors declare that this article does not contain any personal information that could lead to patients' identification. The authors declare that they have obtained a written informed consent from patients and volunteers included in the article. The authors also confirm that the personal details of the patients and volunteers have been removed.

Healthy subjects

The first acquisition campaign was conducted in the PRISME laboratory of the University of Orléans (France) in January 2017. The participants were students of the Polytech Orléans engineering school on an internship at PRISME, Ph.D. students, and PRISME staff. A total of 22 people participated in this first acquisition campaign. This group was composed of 10 women and 12 men with an average age of 25 years. It corresponds to a total of 22 multispectral images.

From December 2018 to March 2019, we organized a second acquisition campaign at the Ibn Zohr University in Agadir, Morocco. A total of 17 students and members of the IRF-SIC laboratory participated. In addition, a cold stress test acquisition campaign detailed in the second section (Figure 6) was carried out for 43 people at two different times. This gives a total of 60 people, including 25 women and 35 men with an average age of 30 years. This corresponds to a total of 103 multispectral images.

The total number of healthy multispectral images (thermal and RGB) is 125.

Recruitment protocol of healthy subjects

The criteria for recruitment were as follows: any adult volunteer without diabetes and without foot problems.

Acquisition protocol for healthy subjects

To ensure high image quality, the room conditions had to be adapted to thermal image acquisition. We conducted the acquisition campaigns in rooms that were large enough to place the equipment and provide freedom of movement for the technician and volunteers. The lighting was controlled during acquisitions. Windows were partially covered or shielded to prevent outside infrared radiation from entering the room. Temperature was controlled at 20 ± 1°C. The protocol was as follows:

- The person removes shoes and socks, and the acquisition takes place ten minutes later.
- The person reads and signs the consent agreement form.
- The data sheet is filled with the person's information.
- The person lies down on a medical bed or sits in a chair, feet at the end, upright, and 10 cm apart.
- An acquisition is made at a sufficient distance from both feet to meet the margins shown in Figure 2.

Two typical multispectral images (thermal + RGB) acquired respectively in PRISME are shown in Figure 4, and in IRF-SIC in Figure 5.

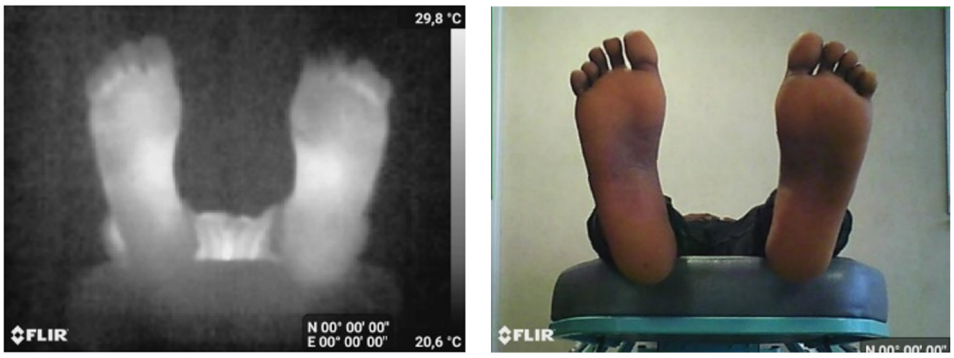


Figure 4. An example of images acquired at PRISME.

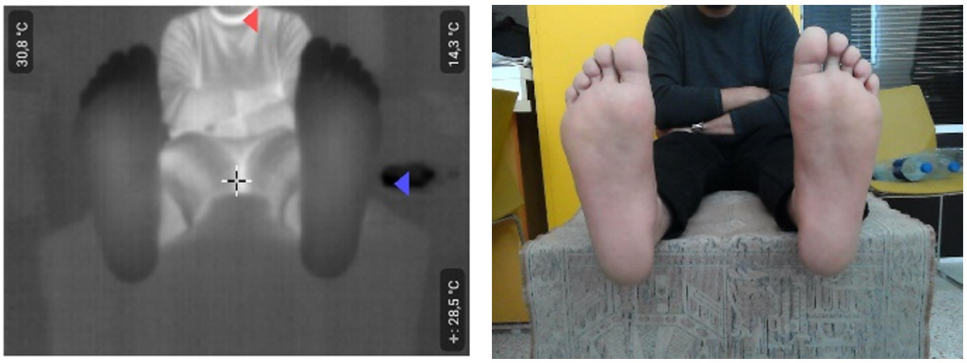


Figure 5. An example of images acquired at IRF-SIC.

Diabetic subjects

The image database of people with diabetes was acquired at the Hospital Nacional Dos de Mayo (HNDM) in Lima, Peru from 14 January, 2019, to 9 March 9. The approval (Number 075-2021-CEIB-HNDM) of this study by the ethics committee of the HNDM occurred on January 10, 2019. A total of 145 diabetic patients participated in this acquisition campaign. It was performed under the supervision of nurses and medical doctors. The thermal stress test was applied. For each subject, we obtained a pair of multispectral images (thermal + RGB). Thus, a total of 290 pair images for diabetic subjects, 91 women and 54 men with an average age of 63 years was collected.

Recruitment protocol of diabetic subjects

The subjects in HNDM were diabetic patients who have a regular examination in the diabetes department. We excluded patients with ulcers, partial or total amputations from this campaign.

Acquisition protocol for diabetic subjects

The objective of this campaign conducted in HNDM was to conduct a cold stress test for all subjects in order to perform a correlation study between thermal and medical into. This test consists in immersing the patient's feet in cold water at 15°C for one minute[9,14]. The campaign was performed in a north-facing room with small windows and controlled luminosity. The average temperature in the room was 20°C with a variation of less than 1°C. The acquisition protocol was as follows:

- The person removes shoes and socks, and the acquisition takes place ten minutes later.
- The person reads and signs the consent agreement form (Figure 6a).
- Complete the data sheet with the person's information.
- The person lies down on a medical bed and places his/her feet on the end of the medical bed, in an upright position and 10 cm apart. The distance between the camera and the feet is chosen so that the feet are completely visible in the image, as shown in Figure 2. The first acquisition (thermal and color images) at time T0 is performed (Figure 6b).
- The patient is asked to sit in a chair. Each foot is inserted into a plastic bag. The feet are then immersed in cold water at 15°C for one minute (Figure 6c).
- The patient lifts his feet, the plastic bags are removed and a waiting time of 10 min is respected before a second thermal and color acquisition corresponding to the time T10 is performed (Figure 6d).



Figure 6. Cold stress test protocol. a) Signature of the consent form (the two persons on the left side). **b**) First acquisition at time T0. **c**) Immerse both feet one minute in water at 15°C. (**d**) Second acquisition at time T10 10 min later.

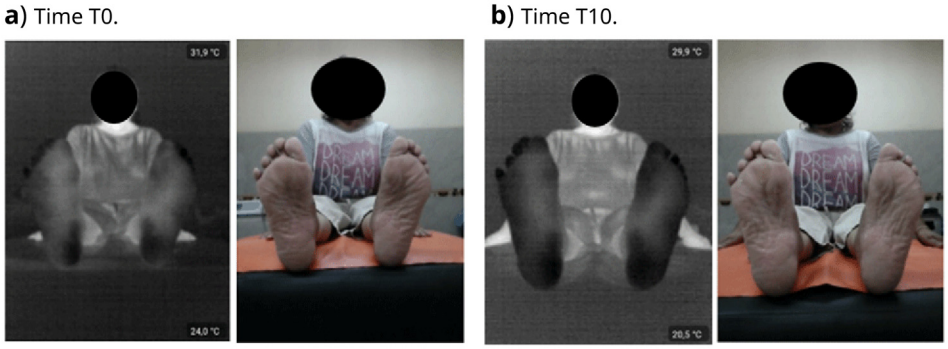


Figure 7. Example of a diabetic patient without ulcer or amputation (Dos De Mayo Hospital). First (thermal and RGB) image acquisition at T0 (**a**) and second (thermal and RGB) acquisition at T10 (**b**). We can see that feet are colder at time T10 than time T0.

Images at times T0 and T10 are shown in Figure 7.

Scientific papers that used this database

- "A joint snake and atlas-based segmentation of plantar foot thermal images"

  DOI: 10.1109/IPTA.2017.8310081

- "A comparison of active contour prior shape segmentation methods: application to diabetic plantar foot thermal images " https://csitcp.net/abstract/9/94csit04

- "On the segmentation of plantar foot thermal images with Deep Learning " DOI: 10.23919/EUSIPCO.2019.8902691

- Diabetic foot thermal image segmentation using Double Encoder-ResUnet (DE-ResUnet)

DOI:10.1080/03091902.2022.2077997

- Segmentation of Plantar Foot Thermal Images Using Prior Information

DOI: https://doi.org/10.3390/s22103835

- "Segmentation of plantar foot thermal images: application to diabetic foot diagnosis" DOI: 10.1109/IWSSIP48289.2020.9145167

Data availability

Due to the sensitive nature of the data, images are currently only available internally to our partners of the STANDUP #777661 project. It is also worth mentioning that the database will be publicly available on https://www.standupproject.eu/home/fr once the research project is achieved on June 30, 2023.

The project website (https://www.standupproject.eu/home/fr) contains the coordinator's contact; however, interested parties are advised to contact the project's coordinator or the corresponding author (doha.bouallal@uiz.ac.ma) for further information to apply for data access.

Acknowledgements

We would like to thank all our colleagues from both universities of Orleans and Ibn Zohr who participated in our acquisition campaigns. We would also like to thank all the medical staff from the HNDM in Peru who accompanied us during the whole study and took care of the patients during the acquisition of the images. A special thanks to patients.

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Publisher Full Text
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Reviewer Report 09 September 2024

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Laith Alzubaidi
Queensland University of Technology, Brisbane, Queensland, Australia

This is the review report for the following letter " STANDUP database of plantar foot thermal and RGB images for early ulcer detection."

The topic is a very interesting and life-saving project with big potential. I have several questions to improve it.
1- The dataset is not provided, but it says it will be available by the 30th of June. This is important to open the door for new research areas.
2- what is exactly the function of the smartphone app? Is it only to take the image? Do you need the app to analyze the input image? Can we have the camera do the job without the smartphone?
3- Can this application work in any situation, indoor or outdoor?
4- is there any evidence for the accuracy of the smartphone
5- can the smartphone work with a different camera company, or it has to be with FLIR ONE?

Is the rationale for the Open Letter provided in sufficient detail? (Please consider whether existing challenges in the field are outlined clearly and whether the purpose of the letter is explained)
Partly

Does the article adequately reference differing views and opinions?
Yes

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language? (Please consider whether all subject-specific terms, concepts and abbreviations are explained)

Partly

Where applicable, are recommendations and next steps explained clearly for others to follow? (Please consider whether others in the research community would be able to implement guidelines or recommendations and/or constructively engage in the debate)
Partly

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 28 July 2022

https://doi.org/10.21956/openreseurope.15883.r29547

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Rhys John Morris
Cardiff and Vale University Health Board, Cardiff, UK

The article describes a search database, and is successful in doing so. The images and details of the protocol are all helpful in understanding the data that have been acquired. I have answered 'no' to 'Does the article adequately reference differing views and opinions?' because the initial literature review is short and does not provide any critique of using thermal images to assess effects of diabetes on feet, though as this is only a description of the database that may not be necessary.

Is the rationale for the Open Letter provided in sufficient detail? (Please consider whether existing challenges in the field are outlined clearly and whether the purpose of the letter is explained)
Yes

Does the article adequately reference differing views and opinions?
No

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language? (Please consider whether all subject-specific terms, concepts and abbreviations are explained)

Yes

Where applicable, are recommendations and next steps explained clearly for others to follow? (Please consider whether others in the research community would be able to implement guidelines or recommendations and/or constructively engage in the debate)
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Vascular assessment and therapies.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.