Development of a scanner to prevent wounds in the feet of patients with diabetes.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27099

Source
NTR

Brief title
STAR (Scanner Twente Almelo Research)

Health condition

Diabetic Feet
Ulceration

Diabetische voet
Ulceratie

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: Zon-Mw (projectnumber 40-00812-98-09031)

Intervention

Outcome measures

Primary outcome

Proof of principle of the combination of modalities and software that can accurately predict (pre-signs of) ulceration in diabetic feet.

Secondary outcome

Collection of data from hyperspectral, photometric and thermal measurements, as well as live assessments, to investigate modalities and develop software for the proof of principle that is the main study parameter

Study description

Background summary

Diabetes Mellitus (DM) is one of the most common chronic diseases globally. Currently more than 382 million people are diagnosed with DM. The population and significance of DM are expected to rise even further in the future. People with DM are at risk of developing a number of disabling and life-threatening health problems, such as diabetic foot complications, including ulceration and its pre-signs (e.g. abundant callus, inflammation, fissures, blisters). Approximately 25% of patients with DM eventually develop foot ulcers. If not treated in time, the risk for (partial) lower extremity amputations or mortality increases. These devastating consequences can be prevented by early detection and timely treatment of the diabetic foot complications. This early identification strongly depends on frequent risk assessment, preferably on a daily basis, especially for high-risk patients. However, frequent assessment by healthcare professionals is costly and not always possible. Self-examination by patients is difficult and impractical, due to other complications (e.g. limited joint mobility and reduced eyesight).

An intelligent telemedicine system, which is compact, non-invasive, non-contact and user-friendly, may provide a solution for frequent assessment, which is the ultimate objective of our project. As the first step to approach this goal, an experimental setup that combined three promising imaging modalities, namely spectral imaging, infrared thermal imaging, and photometric stereo imaging, was developed and investigated. For the design of spectral imaging system, a limited number of optical bandpass filters were selected by employing an additional spectroscopy system with a spectrometer to measure regions of interest that were assessed and annotated by clinical experts. The filter selection boiled down into feature selection in machine learning technology to signify the difference between different skin status. It was found that the required number of optical filters for a spectral imaging system ranged from three to seven, depending on additional constrains.

Following, with the seven preselected filters, the spectral imaging system was built in our experimental setup in cooperation with eleven other filters that were selected based on visual inspection of the absorption spectra of the skin chromophores. To avoid possible

mechanical vibrations and to decrease the image acquisition time, a 3 × 3 cam-era array structure fitted with a sliding plate holding two 3 × 3 filter arrays was applied, instead of the traditional filter wheel structure. With the spectral images acquired, front-end pixel classifiers were designed for automatic detection of diabetic foot complications, taking image annotations based on the live assessment as the ground truth. These front-end pixel classifiers could distinguish presence or absence of diabetic foot complications with acceptable performance. How-ever, they were lack of the capability of differentiating different diabetic foot complications. Future studies on enhancing performance of the pixel classifiers and designing the back-end classifiers are needed.

With the infrared thermal imaging, the temperature difference between corresponding points on the left and right foot in the thermal images were compared to detect the risk of inflammation. As the temperature contrast between the feet and background was low, it was hard to perform the foot segmentation directly from the thermal images. To issue this, foot segmentations from digital color images were conducted for assistance. Non-rigid landmark-based registration with B-splines was applied to register the left and right foot, which helped to compare the temperature of the corresponding points on the contralateral feet. The outcomes of the thermal image analysis proved to be promising in the early detection of foot complications in patients with DM and patients who are at high risk for these complications. However, this methodology was limited to patients, for whom both feet were available in the acquired images.
With photometric stereo imaging, a feasibility study was conducted to detect diabetic foot complications. The surface curvature (derived from the reconstructed surface normal) and the reconstructed surface albedo were treated as input features to distinguish the skin regions with diabetic foot complications present or absent. The results indicated that this imaging technology was promising, although it still had some limitations to apply the photometric stereo imaging for the detection of the diabetic foot complications currently, such as the movement in patients' foot during image acquisition. To determine the potential value of this modality in the future telemedicine system, further improvement was required.

The outcomes of the studies presented in this thesis showed the feasibility of developing a telemedicine system to detect diabetic foot complications with the three imaging modalities. The studies acted as the precursors for developing such an intelligent telemedicine system, which proposed potential detection methodologies and provided the directions for the future study. Following the conclusion and recommendations of this thesis, we expect an intelligent telemedicine system suitable for measurements at the patients' homes or at health centres can be developed in the future.

Study objective

It is possible to develop a scanner that can reliably detect (pre-signs of) ulceration by hyperspectral, photometric and thermal measurements.

Study design

N/A

Intervention

A scan with hyperspectral, photometric and thermal measurements will be made from patients' feet.

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Eligibility criteria

Inclusion criteria

1. Diabetes mellitus;

2. Aged 18 years or more;

3. Diagnosed with one of the following foot problems as a consequence of diabetes:

A. Ulcer;

B. Callus;

C. Red skin;

D. Higher temperature on the skin of the foot;

E. Fissure;

F. Blister;

G. Crackle skin.

Exclusion criteria

N/A

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2011
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion

Date:	19-07-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35774
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2851
NTR-old	NTR2992
CCMO	NL36061.044.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35774

Study results

Summary results
2014 Liu C An intelligent telemedicine system for detection of diabetic foot complications. http://eprints.eemcs.utwente.nl/25219/

Liu C, Van Netten JJ, Van Baal JG, Bus SA, Van der Heijden F. Automatic Detection of Diabetic Foot Complications with Infrared Thermography by Asymmetric Analysis J Biomed Opt accepted

Van Netten JJ, Prijs M, Van Baal JG, Liu C, Van der Heijden F, Bus SA Diagnostic values for skin temperature assessment to detect diabetes-related foot complications Diab Technol Ther 2014 16:714-21

Liu C, Van Netten JJ, Klein ME, Van Baal JG, Bus SA, Van der Heijden F. Statistical analysis of spectral data: a methodology for designing an intelligent monitoring system for the diabetic foot. J Biomed Opt 2013 18:126004

Van Netten JJ, Van Baal JG, Liu C, Van Der Heijden F, Bus SA. Infrared thermal imaging for automated detection of diabetic foot complications. J Diabetes Sci Technol. 2013 7:1122-9

Liu C, Van der Heijden F, Klein M, Van Baal JG, Bus SA, Van Netten JJ. Infrared dermal thermography on diabetic feet soles to predict ulcerations: a case study. Advanced

Biomedical and Clinical Diagnostic Systems XI, Proceedings of SPIE 2013

Liu C, Van der Heijden F, Van Netten JJ. Towards surface analysis on diabetic feet soles to predict ulcerations using photometric stereo. Advanced Biomedical and Clinical Diagnostic Systems X, Proceedings of SPIE 2012

Liu C, Van der Heijden F, Klein M, Op ‘t Root T, Van Baal JG, Bus SA, Van Netten JJ. Infrared dermal thermography for automatic detection of diabetic foot complications. Nederlands Tijdschrift voor Diabetologie 2013 11:165-6