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Monitoring wound status using multi-parameter optical fibre sensors

Submission date
18/05/2023

Recruitment status
No longer recruiting

Registration date
30/05/2023

Overall study status
Completed

Last Edited
21/03/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is estimated that 10% of people with diabetes will have a diabetic foot ulcer at some point in their lives. In general, only half of all foot ulcers in patients with diabetes will heal in 6 months. At the moment, the assessment of possible ulcer infection and checking the ulcer is healing properly can only be assessed at a clinical appointment with a healthcare professional.
If, however, we could easily monitor an ulcer away from a clinic setting it could notify the patient and clinician that either the ulcer is not healing or has become infected between clinical appointments. This alert could mean that clinicians could intervene earlier with the treatment of infection. But equally, if the ulcer is healing well, means that routine clinic appointments just for checking could be reduced.
This study is a preliminary study to see if a new type of ulcer sensor, which is made of very fine fibres (optical fibre sensors) and built into a standard dressing, can measure chemicals and gases that may be associated with ulcer healing and infection. Although the ultimate aim will be to monitor ulcers at home, in this first stage the researchers need to see whether these fibres do in fact measure what they think they should whilst on an ulcer. So, this study will take place in the diabetic foot clinic.

Who can participate?
Patients aged 18 years and over with diabetes and foot ulcers from the University Hospitals of Derby and Burton NHS Foundation Trust Diabetic Foot Clinic

What does the study involve?
The following will be conducted in addition to standard care. The OFSSWM optical probe and a sterile dressing will be placed on the largest eligible wound for up to 60 minutes. The optical probe will measure humidity, temperature, ammonia, and carbon dioxide. These will be compared with measurements from commercially available conventional sensors. Readings will be taken supine with both OFSSWM and conventional sensors. As a control, conventional measurements will also be taken in the supine position on an area of intact skin. The study will take place over an 8-week period per patient. During this time, the participants will have fortnightly visits until week 8, unless their ulcer heals before that.

What are the possible benefits and risks of participating?
Monitoring wound status remotely with optical fibre sensing will notify the patient and clinician when the wound is in an adverse state, either wound healing is not progressing or the wound is infected. This will enable clinical interventions to take place promptly but only when required, thus improving wound care and reducing the number of NHS appointments. For example, if monitoring indicates that wound healing is progressing well then this will reduce the need for specialist review and can reduce the frequency of dressing changes. On the other hand, if the wound status deteriorates rapidly, e.g. due to infection, then this will trigger an urgent specialist review, which will lead to improved outcomes, e.g., reduced admissions and amputations.
Cost savings can be made by monitoring wound status. Stratification of different wound categories (e.g. identifying wounds that are difficult to heal) will make an even more compelling case for the technology. Better wound care will result in reduced time to healing and therefore reduction in costs across all areas of diabetic foot ulcer management simply because patients will spend less time being treated.
Although there will be a higher unit cost associated with the disposable sensorised dressing and reusable electronic unit (~£4 - £9 per use compared to £2 average for current dressings), the researchers believe that this will be offset by fewer dressing changes and reduced time to healing. There will also be additional savings due to an anticipated reduction in hospital, GP and home visits and a reduced number of amputations. The device will indicate the most appropriate time to change the dressing and whether intervention is required (e.g. due to infection). A 10% reduction in costs associated with visits and admissions categories would provide a £300m annual saving to the NHS. The final product would initially concentrate on those most at risk of a non-healing wound before applying the technology to a wider population of those with chronic wounds.
Although this is the first time sensors have been applied to diabetic foot ulcers, the researchers think that any risk from the monitoring equipment is very low as the equipment has all had an independent safety review and been passed as safe.

Where is the study run from?
University Hospitals of Derby and Burton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2021 to March 2024

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
For further information please contact the diabetic foot research team on +44 (0)7384871088 or email dhft.footres@nhs.net

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
291141

Protocol serial number

IRAS 291141, CPMS 49746

Study information

Scientific Title
Monitoring diabetic foot ulcer status using the Optical Fibre Sensing System for Wound Monitoring (OFSSWM)

Acronym
OFSSWM

Study objectives
To explore the feasibility of using the Optical Fibre Sensing System for Wound Monitoring (OFSSWM) in a clinical environment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/09/2021, South East Scotland Research Ethics Committee 02 (2nd Floor, Waverly Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131 465 5473; Ruth.Fraser4@nhslothian.scot.nhs.uk), ref: 21/SS/0050

Study design
Single-centre prospective observational study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Diabetic foot ulcer

Interventions
Participants will be seen at their usual clinical setting within the UHDB diabetic foot clinic. Participants will first receive all usual best patient care including local debridement and a temporary dressing if required.

The following will be conducted in addition to standard care. The OFSSWM optical probe and sterile dressing will be placed on largest eligible wound for up to 60 minutes. The optical probe will measure humidity, temperature, ammonia, and carbon dioxide. These will be compared with measurements from commercially available conventional sensors. Readings will be taken in a supine position with both OFSSWM and conventional sensors. As a control, conventional measurements will also be taken in a supine position on an intact skin area.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Device: Optical Fibre Sensing System for Wound Monitoring (OFSSWM)

Primary outcome(s)
1. Number of participants screened/consented and reasons for not participating, measured using participant consent forms at the start of each patient visit
2. Feasibility of taking measurements for each optical probe parameter (temperature, relative humidity, ammonia, and carbon dioxide) from a wound, measured using internal algorithms for data analysis and comparison with commercial measurement devices after each patient visit. The data collected will only be used to ascertain device performance and it will not be used to alter the normal care pathway of the patient.
3. Patient feedback about the use of the optical probe, collected using a survey at the end of patient participation in the study

Key secondary outcome(s))
1. Wound size measured as per normal clinical care with a Silhouette wound assessment camera (Entec Health Ltd) at the start of each patient visit
2. Incidence of secondary infection measured using baseline assessments as per the clinical protocol, e.g. assessment of ulcer infection by IDSA criteria (0 = none, 1 = mild [limited to skin and subcutaneous tissues and with inflammation limited to within 2cm of wound margin], 2 = moderate [deeper and/or with more extensive inflammation] and 3 = severe [with systemic symptoms and signs]) at the start of each patient visit
3. Pain in the area of the ulcer assessed by patient-completed 100 mm Visual Analogue Scale (VAS) at the start of each patient visit

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Patients with diabetes (according to WHO criteria) aged 18 years or over
2. At least one full-thickness ulcer below the malleolus of either foot, present for 4 weeks or more
3. Ulcer located on the sole or dorsum of the foot
4. No presence of wound necrosis, significant oedema or poor tissue viability that in the opinion of the investigator may be at risk of deterioration with the use of OFSSWM optical probe
5. At least one palpable pulse on the foot of the index limb or an Association of the British Pharmaceutical Industry (ABPI) >0.9
6. Minimum ulcer diameter of 3 mm and maximum of 35 mm
7. Able to attend clinic for four separate visits
8. Estimated glomerular filtration rate (eGFR) >20 and not receiving dialysis

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Planned revascularisation during the course of the study or within the 4 weeks preceding the start of the study
2. An ulcer of aetiology other than diabetes
3. Depth of ulcer to bone, suspected or confirmed osteomyelitis
4. Severe infection of the index ulcer in accordance with Infectious Diseases Society of America (IDSA) criteria
5. Active Charcot of the foot of the index ulcer
6. The need for negative pressure wound therapy
7. Unwilling or unable to give written informed consent
8. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, may influence the result of the trial or the participant's ability to participate in the trial
9. Wound located on the toes or between the toes
10. Wounds in a severe condition e.g. necrotic tissue and/or bleeding wounds

Date of first enrolment
18/04/2023

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust (UHDB) secondary care diabetic foot multidisciplinary clinic
Florence Nightingale Community Hospital
London Road
Derby

United Kingdom
DE1 2QY

Study participating centre
Royal Derby Hospital (nuh)
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Study participating centre
London Road Community Hospital
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Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. Once sufficient commercialisation progress has been made and intellectual property is protected, the researchers will make raw data available through the University of Nottingham Research Data Repository.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			21/03/2025	No	No
Other files			24/05/2023	No	No
Participant information sheet	version 4.0	01/11/2022	24/05/2023	No	Yes
Protocol file	version 4.1	28/03/2023	24/05/2023	No	No
Protocol file	version 4.3	20/11/2023	11/03/2024	No	No
Statistical Analysis Plan	version .06	16/09/2024	21/03/2025	No	No