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Assessment of skin temperatures, as a predictor for infection, using infrared thermography in trauma and orthopaedic patients - A pilot study

Submission date
31/03/2023

Recruitment status
No longer recruiting

Registration date
05/05/2023

Overall study status
Completed

Last Edited
15/01/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Infection after fracture fixation (IAFF) and infected joints have great psychological and financial costs to patients, surgeons and society. Currently, there is no rapid, non-invasive, inexpensive test that can be used to facilitate diagnosis. We currently rely on blood tests and clinical examinations which can be abnormal in several conditions, leading to unnecessary tests or procedures. Infrared thermography (IRT), uses thermal images and has the potential to detect infection early, as a bedside test that could be performed in the outpatient clinic. There are huge potential benefits and savings to patients, healthcare systems and wider society from early appropriate management of infection following identification with IRT. This could reduce morbidity, mortality, and length of stay and avoid unnecessary hospital admissions (e.g. suspected infections could be discharged based on IRT from the emergency department). IRT can further reduce the number of tests/interventions for patients (e.g. IRT not suggestive of IAFF could avoid unnecessary reoperation). There could also be reduced personal costs to patients through loss of work, providing for their families and prevention of the psychological impact of infections. This study will determine whether IRT can be used to accurately identify adult patients with IAFF and septic arthritis (SA). This pilot study will inform the feasibility and design of a future larger study.

Who can participate?
Adult patients with suspected infections of large joints and wrist/ankle/hip fractures will be identified from the emergency department and clinics.

What does the study involve?
Patients will be managed as per their routine care, except for requiring a maximum of two extra hospital visits to have thermal images taken.

In this pragmatic study, thermal images will be taken during routine care (i.e. during ward stay for red, hot swollen joints; during theatre and outpatient clinics for wrist/ankle fractures). Patients will be required to expose their limb and contralateral (opposite) limb for them to equilibrate in the environment for 10 to 15 minutes, whilst resting on the bed (e.g. ankle) or

table (e.g. wrist). During this time the patient will be asked to reduce their movement and will be guided through filling in a questionnaire by a member of the research team. Thermal images will then be taken, after the acclimatisation period, at an angle of 90 degrees to the skin using a FLIR C5 camera (or similar) at the distance set by the manufacturers' instructions (e.g. 50 cm). Following fixation, wrist and ankle fractures routinely undergo follow-up with one appointment at 1 or 2 weeks and another at 4 or 6 weeks, and a third appointment at 12 weeks. The study protocol will require images immediately following surgery, in the operating room to provide a baseline temperature reading. We will invite the patients to be imaged after the operation at 1 or 2 weeks, 4, 6 12 and 24 weeks. Hip fractures will be imaged on alternate days (e.g. days 0, 2, 4 etc) whilst inpatients and during routine follow-up.

Patients attending with red, hot swollen joints will be imaged during admission and consecutive days up until washout and daily until discharge. Patients will then be pragmatically imaged during routine follow-ups, which will be directed by their surgeon. This will likely be at 1, 2, 4, 6, 12 and 24 weeks. Patients who present with a red, hot swollen joint but who do not undergo washout will be imaged during routine follow-up.

What are the possible benefits and risks of participating?
There will be the benefit of better supervision of patient management. There is evidence that patients receive better treatment when taking part in a study. Patients will have the satisfaction of being able to improve the healthcare of patients who have similar conditions in the future.

Following fixation, wrist and ankle fractures routinely undergo follow-up with one appointment at 1 or 2 weeks and another at 4 or 6 weeks, and a third appointment at 12 weeks. The study protocol will require images immediately following surgery, in the operating room to provide a baseline temperature reading. Patients will then be imaged at their routine follow-up appointments at 1 or 2 weeks, 4 or 6 weeks and 12 weeks. We will invite the patients to be imaged after the operation at 1 or 2 weeks, 4, 6, 12 and 24 weeks. Therefore patients will require two extra hospital visits (if these were not already part of their individualised routine follow-up). The importance of identifying infection early on with further data points from early thermographic images has been weighed up with the burden of the patient requiring extra visits to the hospital.

Patients will need to be managed in a removable cast or splint to allow for image capture. As per standard procedure, patients who are managed in a back slab postoperatively will have this removed at wound check at 1 or 2 weeks and their limb placed in a removable orthosis (e.g. removable cast or boot) for the duration of their immobilisation. This will be either weight-bearing or non-weight-bearing at the discretion of the surgeon as per routine practice. Casts are often removed or changed in fracture clinics for several reasons. Fractures, after being fixed with metalwork, may or may not routinely be managed with a plaster cast to support the fixation. Therefore, removing the cast for the taking of a photograph will not increase the risk of displacement.

Patients attending with red, hot swollen joints will be imaged during admission and consecutive days up until washout and daily until discharge. Patients will then be pragmatically imaged during routine follow-ups, which will be directed by their surgeon. This will likely be at 1, 2, 4, 6, 12 and 24 weeks. Patients who present with a red, hot swollen joint but who do not undergo washout will be imaged during routine follow-up. There will be a theoretically increased risk of infection due to dressing changes for photographs at both 1 and 2 weeks.

The National Institute for Clinical Excellence advises that wounds should be untouched for only 48 hours after surgery (NICE, 2020). Wound epithelisation usually is completed in 1 to 3 days in

acute wounds that are primarily closed. Therefore by one week, wounds would have sealed and the risk of infection due to dressing change would be minimal. Often, dressings are changed routinely in the fracture clinic to inspect wounds, especially if there is any leakage. Furthermore, some surgeons routinely will change the dressing and inspect wounds. During the surgical procedure, wounds will be closed using skin glue, to provide a water-tight seal, before dressing to help mitigate this potential risk.

Where is the study run from:
Hull University Teaching Hospitals NHS Trust (HUTH) (UK)

When is the study starting and how long is it expected to run for:
July 2021 to January 2024

Who is funding the study:
Trauma & Orthopaedic Research Fund, HUTH (UK)

Who is the main contact:
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
317991

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 317991

Study information

Scientific Title
Assessment of skin temperatures, as a predictor for infection, using infrared thermography in trauma and orthopaedic patients - A pilot study

Acronym
IRTO

Study objectives

This observational study proposes to define the normal thermographic skin temperature following wrist/ankle/hip fracture fixation and in patients who present to hospital with red, hot swollen joints. Infection after fracture fixation (IAFF) and infected joints have great psychological and financial costs to patients, surgeons and society. Currently there is no rapid, non-invasive, inexpensive test that can be used to facilitate diagnosis. Infrared thermography (IRT), uses thermal images, and has the potential to detect infection early, as a bedside test that could be performed in the outpatient clinic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/10/2022, Health and Care Research Wales (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB; +44 2920230457; HCRW.approvals@wales.nhs.uk), ref: 22/EE/0250

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Thermographic skin temperatures of patients presenting to the hospital with red, hot swollen joints and of wrists, ankles and hips after fracture fixation.

Interventions
This is a study of 12 months duration.
Following wrist and ankle fixation, patients will be imaged after the operation, and at 1 or 2 weeks, 4, 6, 12 and 24 weeks.
Following hip fixation, patients will be imaged whilst an inpatient and during routine follow-up.
Patients attending with red, hot swollen joints will be imaged during admission and consecutive days up until washout and daily until discharge. Patients will then be pragmatically imaged during routine follow-ups, which will be directed by their surgeon. This will likely be at 1, 2, 4, 6, 12 and 24 weeks. Patients who present with a red, hot swollen joint but who do not undergo washout will be imaged during routine follow-up.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Infrared thermography using FLIR T540 camera

Primary outcome measure
1. Skin temperature (Tsk) values for wound healing relative to the unaffected contralateral (opposite) limb following wrist, ankle and hip fracture fixation measured using infrared thermography (IRT) at baseline, 1 or 2 weeks, 4, 6, 12 and 24 weeks for wrist and ankle fractures. Hip fractures will be imaged on alternate days (e.g. days 0, 2, 4 etc) whilst inpatients and during routine follow-up.
2. Tsk values in those patients who go on to develop IAFF or wound-healing problems measured using IRT at baseline, 1 or 2 weeks, 4, 6, 12 and 24 weeks for wrist and ankle fractures. Hip fractures will be imaged on alternate days (e.g. days 0, 2, 4 etc) whilst inpatients and during routine follow-up.
3. Tsk values in patients with a red, hot swollen joint(s) relative to the unaffected contralateral (opposite) limb measured using IRT imaged during admission and consecutive days up until washout and daily until discharge. Patients will then be pragmatically imaged during routine follow-ups, which will be directed by their surgeon. This will likely be at 1, 2, 4, 6, 12 and 24 weeks.
4. Feasibility, operational protocols and numbers required for a larger, follow-up study power calculations, cost estimates and qualitative assessment at conclusion of the study

Secondary outcome measures
1. Define Tsk reference values in orthopaedic populations over the time frame Tsk returns to normal measured using IRT across the whole duration of the study, at 1 or 2 weeks, 4, 6, 12 and 24 weeks and during routine follow-up
2. Confirm or refute whether contralateral (opposite) Tsk temperatures during fracture healing follow a similar pattern to the fractured limb as previously suggested measured using IRT across the whole duration of the study at 1 or 2 weeks, 4, 6, 12 and 24 weeks and during routine follow-up
3. To store and analyse data in a way compatible with an Artificial Intelligence/machine learning (advanced data analytical methods) model measured using qualitative assessment at the conclusion of the study
4. To establish the effect of fracture severity and comorbidity on Tsk IRT readings in orthopaedic patients measured using questionnaires across the study duration
5. To establish the effect of wound length on Tsk IRT readings measured using clinical measurement with a ruler at 24 weeks
6. To determine whether thermographic Tsk differences exist in those patients who go on to develop septic arthritis (infected joints), versus other conditions e.g. crystal arthropathy (crystals in the joint), and cellulitis (infected skin) measured using IRT and recorded diagnoses in patient medical records at 24 weeks

Overall study start date
01/07/2021

Completion date

31/01/2024

Eligibility

Key inclusion criteria
1. Wrist fractures treated with volar plate
2. Ankle fractures treated with plate and screws
3. Neck of femur fractures treated with dynamic hip screw or arthroplasty
3. Patients with painful, red, hot, swollen joints (shoulder, elbow, wrist, hip, knee and ankle) attending the emergency department or who have been admitted

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Aged <18 years old
2. Prior fixation to ipsilateral or contralateral ROI (Region of Interest)
3. Concurrent skin condition over ROI
4. Peripheral neuropathy or vasculopathy
5. Pathological Fracture
6. Inflammatory Arthropathy
7. Open fracture
8. Concomitant injuries or other joints or limbs affected
9. Skin conditions affecting the ipsilateral or contralateral region of interest
10. Conditions that will prevent the participant from having capacity, giving consent or following instructions

Date of first enrolment
30/04/2023

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
England

United Kingdom

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Trauma & Orthopaedic Research Fund, Hull University Teaching Hospitals

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/01/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1		12/04/2023	No	Yes
Protocol file	version 1.1		12/04/2023	No	No
HRA research summary			28/06/2023	No	No