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A prospective randomised pilot study comparing the effectiveness of Suprathel versus the standard of care dressing sterilised Hypafix for split-thickness skin graft donor sites in older patients

Submission date
31/01/2024

Recruitment status
No longer recruiting

Registration date
15/04/2024

Overall study status
Completed

Last Edited
24/06/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Human skin undergoes many changes as it ages, making optimal wound healing in the older (aged over 65 years) often more challenging for the treating clinical care team. The extended time taken to heal wounds, the prolonged patient discomfort and the greater number of appointments often required before wounds heal in older patients come at an increased cost to the NHS when compared to the skin of younger patients.
The aim of this study is to evaluate the healing properties of a new type of synthetic dressing (Suprathel) compared to the current dressing used (sterilised Hypafix) to see which facilitates faster healing of skin donor sites in older patients who have undergone a split-thickness skin graft procedure at the St Andrew's Centre for Plastic Surgery & Burns, Chelmsford. Both dressings are licenced to be used on donor sites, but older patients often have problems healing and therefore the aim is to find out which dressing heals the wounds quicker, therefore improving patient care.

Who can participate?
Patients aged 65-100 years of age attending St Andrew's Centre for Plastic and Burns, Broomfield Hospital, Chelmsford, who are scheduled to undergo a mixed-depth skin graft

What does the study involve?
Participants undergo the skin graft procedure as part of standard-of-care treatment and following they will be randomly allocated (by a sealed envelope allocation) to either receive the Suprathel dressing or the standard-of-care Hypafix dressing to treat and heal the skin graft wound. In accordance with standard clinical practice, participants are then asked to return to the hospital to have the wound healing assessed at 1, 2 and 3 weeks after the skin graft and then fortnightly until the wound has healed. The researchers do not expect the wounds to heal any slower with this dressing than the current dressing that is used. At these appointments the

researchers will take pictures of the wound sites (to give a visual documentation of how the wounds improve and scarring visible), measure the extent of healing, redress the wounds as required, assess if there is evidence of any infection to the tissue and gauge the level of pain and discomfort they are experiencing. There will be a final clinic appointment 13 weeks after the original surgery, where this process will be repeated.

What are the possible benefits and risks of participating?
The researchers do not foresee any risks from taking part in this study. Both wound dressings (Hypafix and Suprathel) have been extensively used in clinical practice. The only disadvantage of taking part could be the additional time taken (20 minutes) to undergo the informed consent process. The researchers do not foresee any personal benefit that will arise from taking part in this study. It is hoped the study will enable the researchers to further optimise wound healing in more older patients.

Where is the study run from?
St Andrew's Centre for Plastic Surgery & Burns (UK)

When is the study starting and how long is it expected to run for?
February 2020 to July 2023

Who is funding the study?
1. Mid and South Essex NHS Foundation Trust (UK)
2. PolyMedics Innovations GmbH (Germany)

Who is the main contact?
David Cussons, david.cussons@nhs.net

Contact information

Type(s)
Public, Scientific

Contact name
Dr David Cussons

Contact details
Broomfield Hospital
Court Road
Chelmsford
United Kingdom
CM1 7ET
+44 (0)1245 362000
david.cussons@nhs.net

Type(s)
Principal investigator

Contact name
Mr David Barnes

Contact details

Broomfield Hospital
Court Road
Chelmsford
United Kingdom
CM1 7ET
+44 (0)1245 362000
david.barnes9@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
258208

Study information

Scientific Title
Suprathel versus Hypafix in the management of split-thickness donor site wounds in the elderly: a randomised controlled trial

Study objectives
Suprathel dressings are no worse than Hypafix dressings for the management of split-thickness skin graft wounds in the elderly

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/06/2020, East of England - Essex Research Ethics Committee (The Old Chapel Royal, Standard Place , Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8106; essex.rec@hra.nhs.uk), ref: 19/EE/0336

Primary study design
Interventional

Study design
Prospective randomized unblinded non-inferiority trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Split thickness donor site wounds

Interventions
Eligible patients will be randomized (blinded using a sealed envelope system) to receive either Suprathel or the current dressing mainly used sterilized Hypafix to their graft site wound as part of the study. Participants (as with normal clinical practice) will return to the treatment centre weekly for their graft site healing to be assessed. There will be no additional visits expected for any of the patients. Healing will be clinically determined once 95% re-epithelization of the graft site skin has been accomplished.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Time to donor site 95% healed (in days), by visual assessment of total surface area re-epithelialised, confirmed and verified with photographs

Key secondary outcome(s)
1. Pain and itch measured using visual analogue scale at 1 week, 2 weeks, and weekly until healed
2. Scar outcome, including colour, relief, vascularity, pliability, and thickness, assessed by patient and observer using Patient and Observer Scar Assessment Scale (POSAS) v2 at the time of healing and week 13

Completion date
01/07/2023

Eligibility

Key inclusion criteria
1. 65 to 100 years of age
2. Undergoing less than 2% Total Body Surface Area (TBSA) split skin grafting
3. Able to provide informed consent to the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Patients without the above age range
2. Any allergy to either of the dressings used in the study
3. Patients with any medical condition such as immunosuppression, poorly controlled diabetes or peripheral vascular disease predisposing to altered wound healing

Date of first enrolment
26/01/2022

Date of final enrolment
22/03/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Broomfield Hospital
Court Road
Broomfield
Chelmsford
United Kingdom
CM1 7ET

Sponsor information

Organisation
Mid and South Essex NHS Foundation Trust

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Mid and South Essex NHS Foundation Trust

Funder Name
PolyMedics Innovations GmbH

Results and Publications

Individual participant data (IPD) sharing plan

The anonymised datasets generated during the current study will be available upon request from David Cussons (david.cussons@nhs.net). Individual photographs can be reviewed with the author on special arrangement, depending on the level of consent obtained from individual patients at the time of photographic recording.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/10/2024	24/06/2025	Yes	No