Funded by NHS National Institute for Health Research

Multiple Interventions for Diabetic Foot Ulcer Treatment Trial (MIDFUT)

Nikki Dewhirst
MIDFUT Clinical Co-ordinator, Clinical Trials Research Unit, University of Leeds
Senior Vascular Research Nurse, Leeds Teaching Hospital NHS Trust

ctru University of Leeds

The Leeds Teaching Hospitals NHS NHS Trust

MIDFUT

- **Disclosure**

- ❑ This project is funded by the National Institute for Health Research HTA Programme (project number 15/08/77)

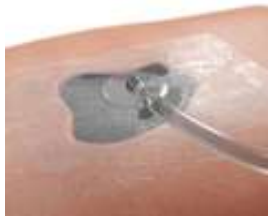
- ❑ The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR, NHS or the Department of Health.

Trial Overview

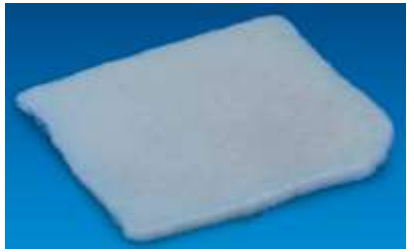
Treatment As Usual (TAU)

Hydrosurgical Debridement (HD)

Negative Pressure Wound Therapy (NPWT)



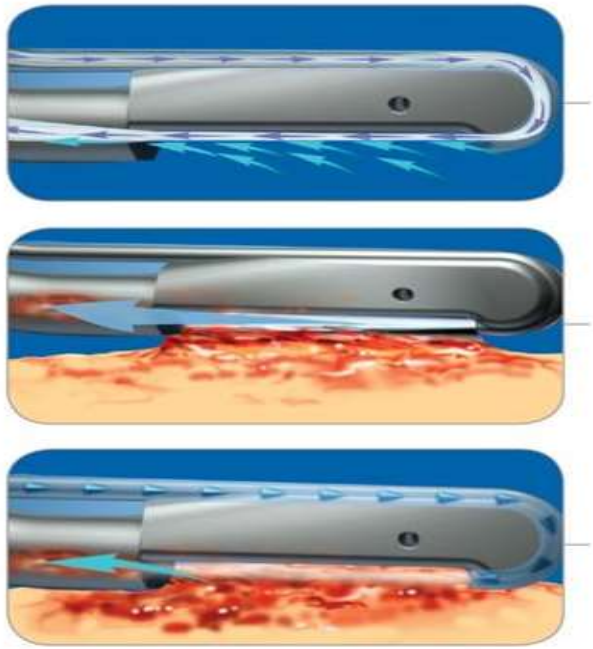
DeCellularised Dermis Allograft (DCD)



- Introduction of MDT service however DFU healing rates at 12 weeks still low
- NICE NG19 recommendation of adjuvant therapies
- NIHR funded, innovative multi-arm multi-stage adaptive design, providing an efficient platform to evaluate multiple treatment strategies under the umbrella of a single trial
- All trial adjuvant therapies are approved for NHS use & can be performed in the clinic setting
- TAU – best care through MDT DFC, as per NICE guidelines & local policy, is continued throughout the trial
- Randomised to TAU or TAU with one or a combination of adjuvant therapies
- Trial adjuvant therapies delivered at Randomisation Visit only (randomisation visit may last up to 2hrs)
- Adults, diabetic patients with a hard-to-heal, non-infected diabetic foot ulcer with no bone or joint involvement who are able & willing to receive all trial adjuvant therapies

MIDFUT

Hydrosurgical Debridement (HD)



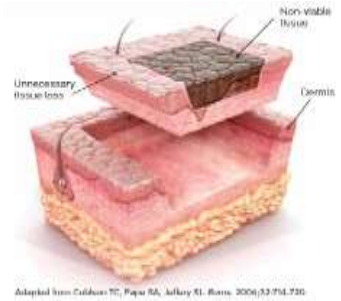
Selects
Target necrotic tissue and debris using the localised vacuum

Excises
Ablate nonviable tissue with maximum precision

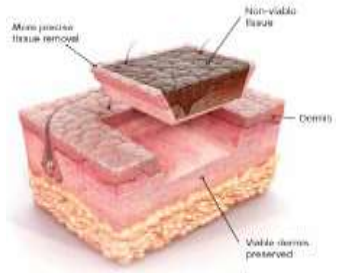
Evacuates
Remove debris and slough while preserving viable tissue

Precision to Preserve

Conventional Surgical excusion



Hydrosurgical excusion



HD has been shown to be as effective as formal theatre surgical debridement in wound healing outcomes *.

* Caputo, W.J., et al., *A prospective randomised controlled clinical trial comparing hydrosurgery debridement with conventional surgical debridement in lower extremity ulcers.* International Wound Journal, 2008. **5**(2): p. 288-294.

Hydrosurgical Debridement (HD)

- Portable console, suitable for use in clinic setting
- Full training available
- Console can be supplied for duration of trial
- Handsets single use – sourced by recruitment site direct from manufacturer (cost neutral to site)
- Incidentals - Bag Saline / Receptacle (bucket)
- Well tolerated by patients - pain risk assessment as per sharp debridement
- Consider bleed risk
- Local approvals – New Invasive Procedures / Infection Prevention & Control / Clinical Engineering checks

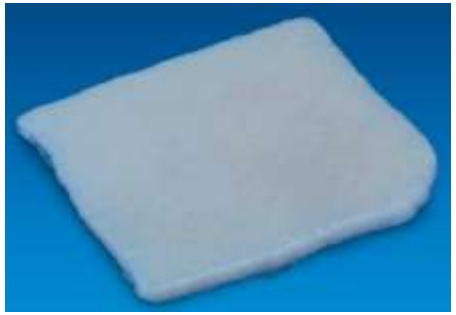
Infection Prevention & Control Concerns: Aerosol

- ➢ Slight increase/similar to other procedures
- ➢ Contained within 1 meter radius
- ➢ Transient, settles after 5 mins

- ✓ Normal lavage precautions
- ✓ Room/bay size – at least 1 meter clearance
- ✓ Cover irregular surfaces with plastic
- ✓ PPE (gown/splash mask)
- ✓ Normal cleaning procedures

MIDFUT

DeCellularised Dermis Allograft (DCD)

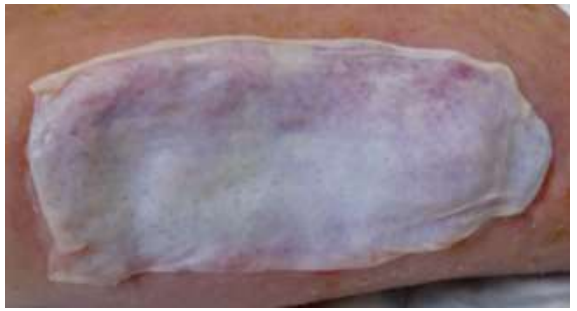


Decelluralised dermal skin allograft

- Harvested from deceased tissue donors
- Produced from split thickness skin grafts (epidermis and upper part of the dermis)
- All epidermal and cellular components from the dermis are removed
- Integrates into the wound bed replacing lost dermal tissue
- Provides a scaffold into which recipient's cells can grow
- Used in plastics & burns - available via NHS supplies
- Lowest risk category for disease transfer (none reported in 60yrs)
- Low risk of allergic reaction to antibiotic & reagents used for processing and storage (none reported)
- Available in different sizes

MIDFUT

DeCellularised Dermis Allograft (DCD)

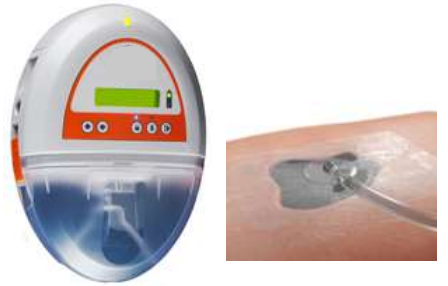


- DCD Grafts & training provided free of charge for MIDFUT trial
- Secure storage at Room Temperature (0 to 40^{o}C), 2 year shelf life
- Graft Tracking Log - 30 year archiving
- Primary dressing – non-adherent, non-absorbent, permeable, non-medicated
- DCD Graft can resemble slough in the first few weeks following application

CONCERNS	ACTIONS	
Accidental dislodging of graft at dressing changes	Primary dressing undisturbed for first 7days	Patient/RHCP information letters
Accidental debridement DCD graft	Avoid debridement for 4 months	Patient/RHCP information letters
Accidental dislodging of graft due to shearing/friction	Optimise off loading (standard care) Optional - secure graft with surgical glue +/- sutures	Patient/RHCP information letters
Allergic reaction - Low risk - nil reported	Rinsing of DCD graft before application Monitor patients post application	Assess/exclude high risk patients

MIDFUT

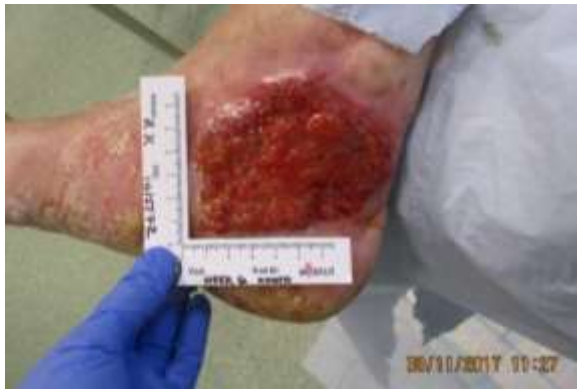
Negative Pressure Wound Therapy (NPWT)



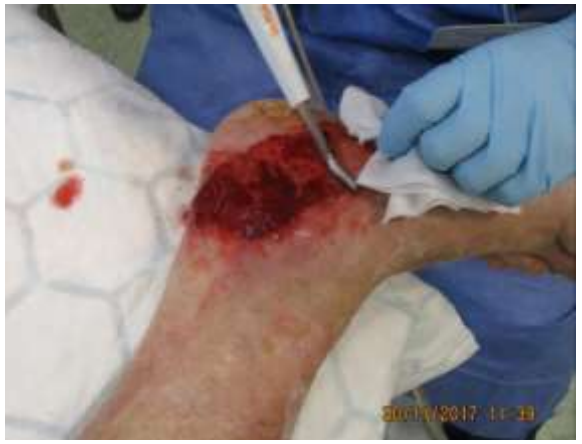
- Portable NWPT devices with removable canister, constant pressure
- Not disposable NPWT where dressing act as reservoir
- Pumps can be provided for trial duration
- Full training available
- Consumables - cost neutral to Trust
- Black foam – recommended for chronic & load bearing wounds
- Continued for 2 weeks – changed at least weekly (can be extended as standard care)
- Primary wound contact layer required when used with DCD graft
- Consider falls risk

Case Study 1

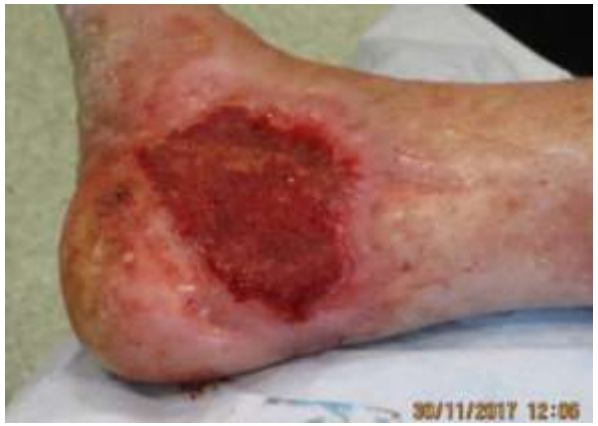
Prior to HD



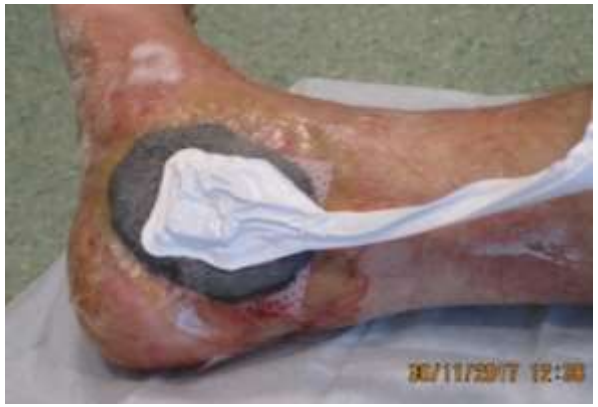
HD in action



Well tolerated by patient!



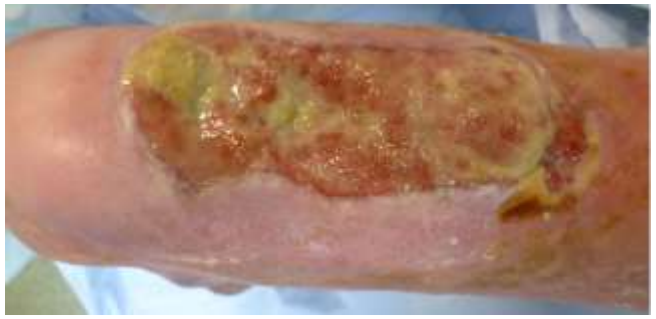
Post HD



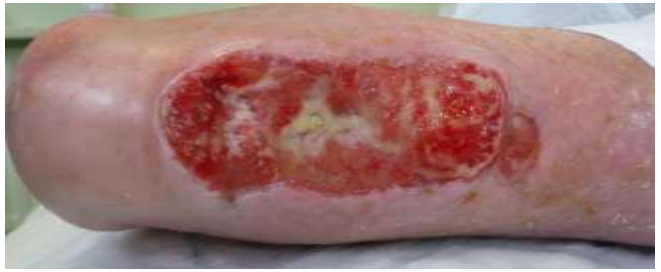
NPWT applied

Case Study 2

Prior to HD



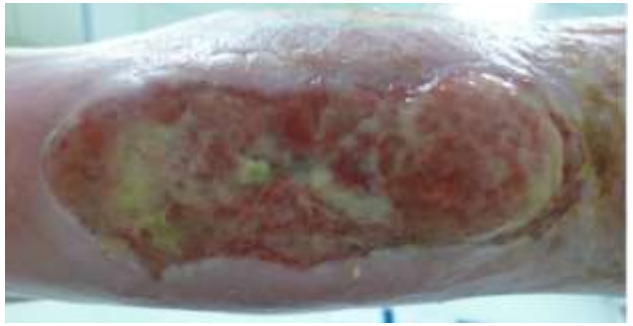
Post HD



Immediately following DCD application

8 days after application

40 days post application



Current Trial Status

- HRA approval gained May 2017 (amendment July 2017)
- Trial opened for recruitment in Leeds August 2017
  - 22 patients registered
  - 9 patients randomised
- 9 sites now open
    - 44 patients Registered overall
    - 19 Patients Randomised overall
- 4 sites plan to open Q2 2018
- New sites welcomed

MIDFUT

Comparing treatments for diabetic foot ulcers

midfut@leeds.ac.uk

Rachael Gilberts - Trial Co-ordinator (CTRU)

R.M.Gilberts@leeds.ac.uk

0113 343 1724

Chief Investigator: Mr David Russell
Scientific Lead: Prof Jane Nixon
Statisticians: Sarah Brown; Myka Ransom
Trial Managers: Rachael Gilberts, Dr Catherine Fernandez

Data Manager: Howard Collier
Clinical Coordinators: Dr Elizabeth McGinnis; Nikki Dewhirst
Statistical Consultants: Prof Linda Sharples; Dr James Wason