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MIDFUT
Comparing treatments for diabetic foot ulcers

Funded by NIHR

# The learnt experiences of using DeCellularised Dermis (DCD) in diabetic foot ulcers while conducting the NIHR HTA funded 'Multiple Interventions for Diabetic Foot Ulcer Treatment' (MIDFUT) Trial


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NHS Blood and Transplant

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NHS The Leeds Teaching Hospitals NHS Trust

MIDFUT

Comparing treatments for diabetic foot ulcers

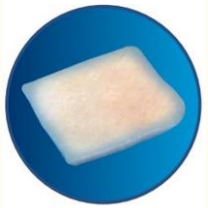
**M**ultiple **I**nterventions for **D**iabetic **F**oot **U**lcer **T**reatment

- NIHR HTA funded randomised controlled trial
- Evaluating combinations of adjuvant therapies
  - Hydrosurgical Debridement (HD)
  - Negative Pressure Wound Therapy (NPWT)
  - **DeCellularised Dermis (DCD)**
- **In difficult to heal diabetic foot ulcers**
- **In an out-patient environment.**

- Participants randomised to receive DCD
  - DFU debrided using HD
  - 1 application of DCD
  - NPWT or secondary dressing of clinician's choice.

# DeCellularised Dermis (DCD)

NHS Blood and Transplant



**dCELL® Human Dermis**

- A Decelluralised human dermal skin allograft
- Retrieved from deceased tissue donors.
- Provides a scaffold which will facilitate revascularisation and re-epithelialisation, ultimately regenerating normal skin
- Used routinely within the NHS for range of clinical indications in surgical setting
  - *burns, chronic leg ulcers, plastics & dental soft tissue reconstruction.*
- Limited use of DCD on diabetic foot ulcers (DFUs) in the UK.

## THE CHALLENGES

**Adapting the application technique to an outpatient clinic environment**

Equipment, Clinical space,
Preparing wound bed
Fenestration & Securing DCD

**Adapting the graft to wounds on the foot**

Avoiding dislodging of DCD graft
Fenestration & Securing DCD
Dressings, Offloading

**Applying the graft in conjunction with other interventions**

Hydrosurgical Debridement (HD)
Negative Pressure Wound Therapy (NPWT)

**Post application management with non-specialist and community practitioners**

Dressings, DCD appearance, Offloading

<<<<<<<<< Differing healthcare roles & levels of experience of individual interventionists >>>>>>>>>

## METHOD

Information & advice gathered from:

- NHS Blood and Transplant
- International clinical expert
- Clinical feedback from MIDFUT sites

## RESULT

- **Bespoke** written information & application guidance
- Tailored training to interventionists needs
- On going support
- Continually learning & adapting!

# Preparation

*“By failing  to prepare, you are preparing to fail”*

*Benjamin Franklyn*

- DCD needs  to be applied to a “graft ready” wound

- HD is used to debride wound “graft ready” state in the clinic setting*

**Topical anaesthesia may be required.*

## Fenestration

- Liberal fenestration allows exudate to pass through the DCD, reducing the risk of seroma or haematoma developing under the graft and causing it to lift away from the wound bed.
- Method: Use scalpel or scissors to make several perforations in the DCD before application to the wound.

## Securing

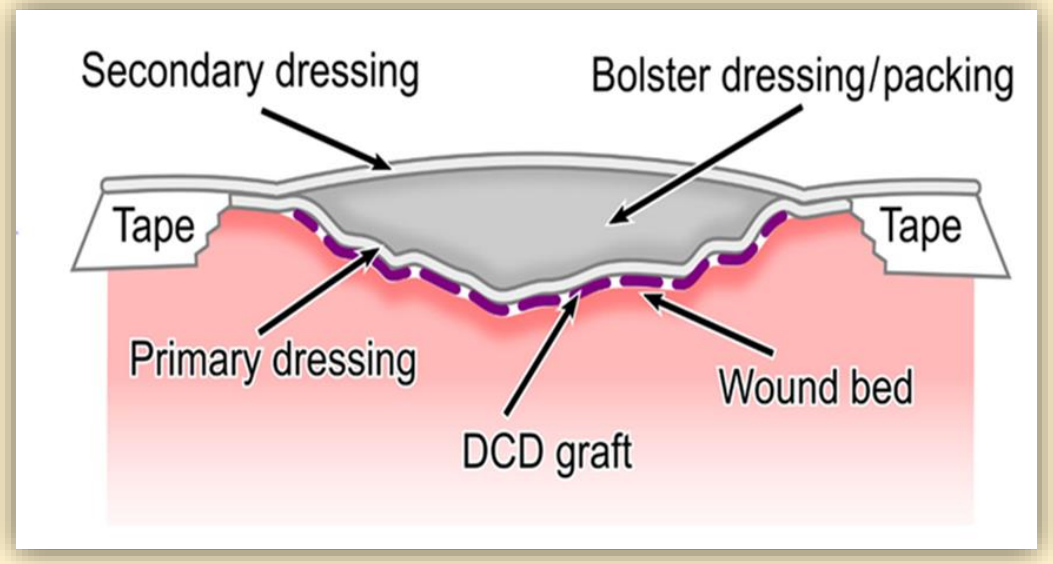
- Overlapping and securing the edges of the DCD reduces the risk of the graft being dislodged.
- Surgical glue can be used to secure DCD and can be more practical than suturing in a clinic.

## Primary Layer

- Using a suitable non-adherent primary dressing reduces the risk of removing the DCD graft during dressing changes.
- The Primary layer remains in place for first 7 days (secondary dressing changed as often as required to manage exudate).
- Primary layer requirements:
  - non-absorbent
  - non-adherent
  - non-medicated
  - permeable

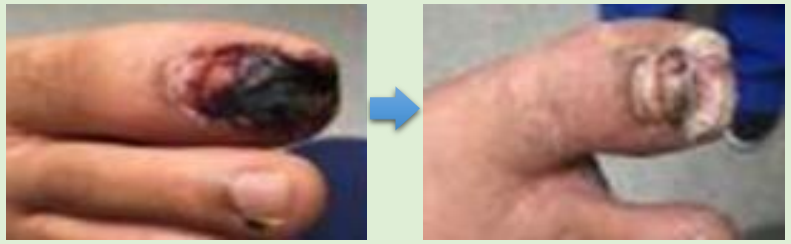
## Bolster Dressing

- Using a bolster dressing (gauze or NPWT foam) between the primary layer and secondary dressing helps to ensure the DCD graft conforms to the contours of the wound bed to optimise its adhesion.



# Aftercare

- Appropriate offloading is essential due to the risk of dislodging DCD



- If DCD is “stuck” to the wound bed: the graft has taken!

- DCD can resemble slough or eschar in the first few weeks after application.
- All clinicians and healthcare providers involved in the management of the wound need to be aware of this to avoid unnecessary debridement of the DCD for up to 4 months.

# The learnt experiences of using DeCellularised Dermis (DCD) in diabetic foot ulcers for MIDFUT Trial


**Implementation of DCD in a new clinical setting for the MIDFUT trial**

- Additional considerations by clinical teams
- New challenges for appropriate application and aftercare compared to inpatient surgical procedure.
- A robust bespoke training package developed using multiple sources of information

**DCD has been successfully adapted for use in DFUs in the out-patient clinic environment**

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If you would like more in formation about the MIDFUT Trial or dCELL® Human Dermis please contact:

midfut@leeds.ac.uk or 0113 343 1724

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