

Prospective randomised trial of low frequency ultrasound debridement in management of lower limb wounds

What have we learned so far?

Krysa J, Schmidt E, Thomson I, van Rij A

Emil Schmidt

Wound Care specialist

SDHB - Otago



2013 – EWMA

The Hard Ware

- Uses adjustable saline flow through a hand piece creating highly charged “bubbles”
- Antibacterial action
- Tissue selective
- Does not harm viable and fragile tissue (Tendons)
- Vasodilation and resolution of vasospasm results in increased blood flow
- Vibration of cells and the walls results in stimulation of fibroblasts, macrophages and endothelial cells to augment healing

LFUD as an Adjunctive Therapy for Chronic Wound Healing: A Systematic Review of the Literature and Meta-Analysis of Eight Randomized Controlled Trials (2013) J Voigt, M Wendelken et. Al. The International Journal of Lower Extremity Wounds10(4) 190– 199

Conclusions and Implications for Practice

- the evidence does demonstrate a short-term clinically beneficial effect of LFUD used as an adjunctive therapy on the clinical end points of complete healing and reduction in wound area size for patients presenting with venous stasis and diabetic foot ulcers
- Furthermore, there may be a longer term completing healing effect (at 6 months) of LFUD debridement in patients presenting with venous stasis ulcers.

Case series of 16 patients 2014 – 2015 LFUD + Silver + NPWT



Before LFUD



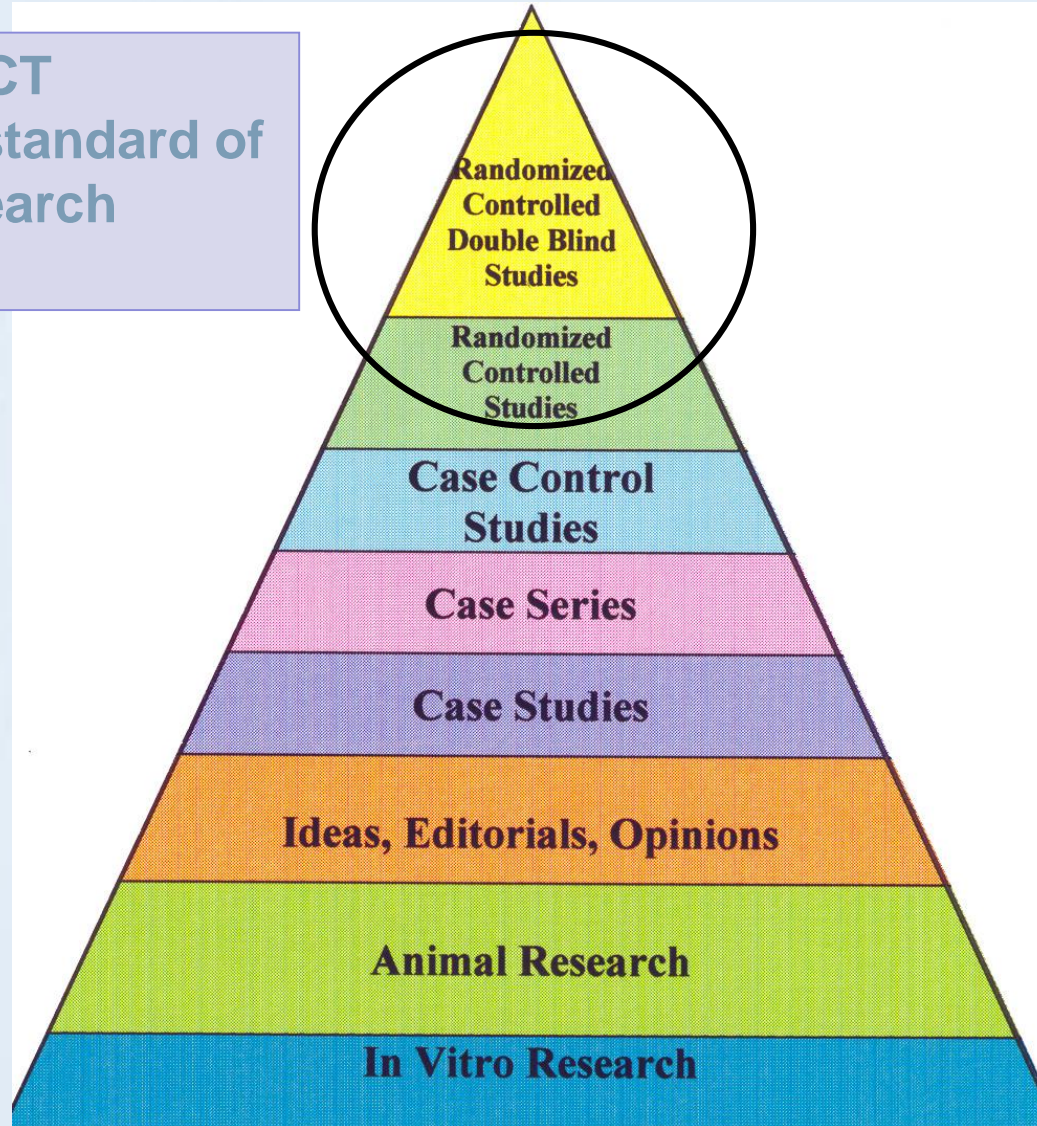
After LFUD

Case series results – encouraging

- ✓ Reduction of slough
- ✓ Reduction of exudate levels
- ✓ Reduction of odor
- ✓ Reduction in MOT debridement
- ✓ Reduction in admissions
- ✓ High percentage survival of SSG for very large ulcers

Hierarchy of evidence

RCT
The Gold standard of Research



2015

Prospective randomised trial of low frequency ultrasound debridement (LFUD) in management of lower limb wounds

- The aim of this prospective randomized study is to assess the benefit of LFUD as an adjunct in the management of acute and chronic lower limb wounds

Inclusion criteria:

- All wounds of lower limb requiring debridement

Exclusion criteria:

- Biopsy confirmed skin malignancy or vasculitis

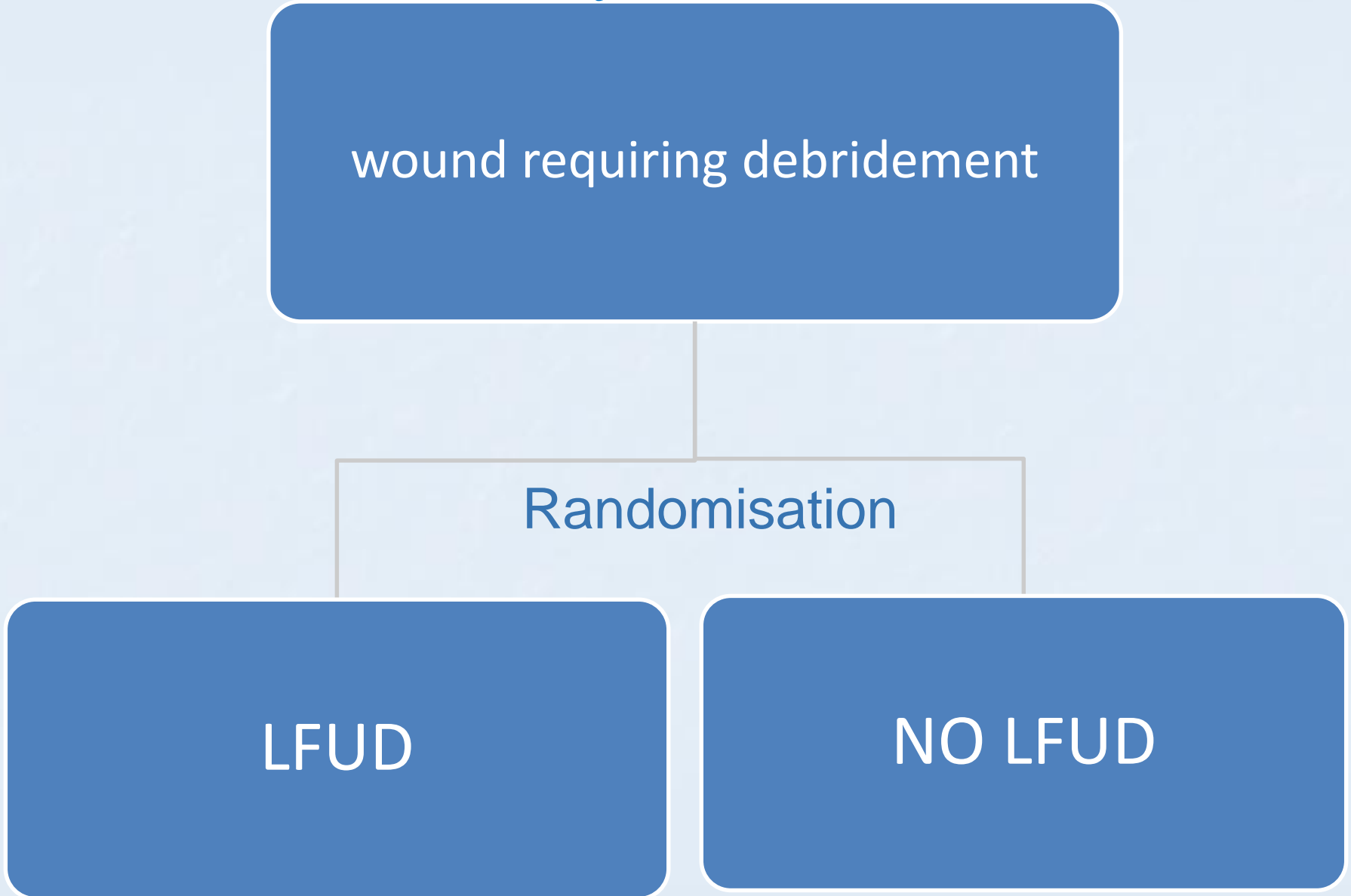
Entry into trial

wound requiring debridement

Randomisation

LFUD

NO LFUD



Primary and Secondary Outcome

Primary outcome

- time to complete wound healing
- Photograph will be assessed by 2 independent observers to confirm complete epithelialisation of the wound

Secondary outcome

- relative rate of wound healing (12, 24 and 52 weeks); length of hospital stay; operating theatre time and number of treatments
- We need 63 participant's in each arm to provide 80% power to detect a difference of 0.5 SD in

Recruitment as of 30 April 2017

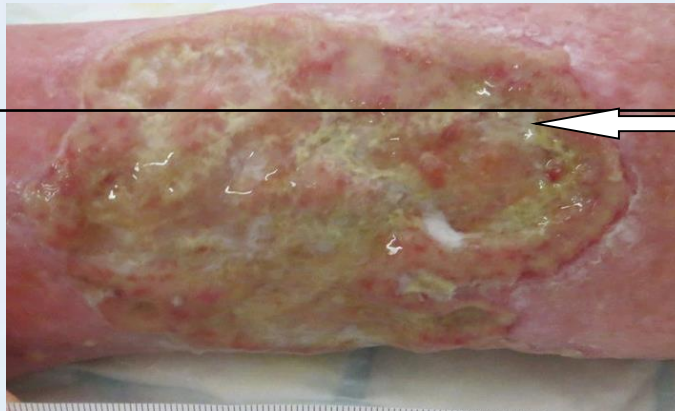
2015
236 (Total number of ulcers)
23 (Ulcers requiring Debridement)
<ul style="list-style-type: none"> • Ineligible 6/23 <ul style="list-style-type: none"> -Medical exclusion: 1 -Declined: 5 (Transport 4 & No reason given 1) • Eligible: 17/23
<ul style="list-style-type: none"> • Randomised: 17 • Healed: 10 • Not healed: 1 • Withdrawal: 6 (Amputation: 3 Deceased:3) • Ongoing: 0

2016
175 (Total number of ulcers)
43 (Ulcers requiring Debridement)
<ul style="list-style-type: none"> • Ineligible 16/43 <ul style="list-style-type: none"> -Medical exclusion: 8 -Declined: 8 (Transport & not interested) • Eligible: 27/43
<ul style="list-style-type: none"> • Randomised: 27 • Healed: 16 • Not healed:5 • Withdrawal: 2 (Medical:1 Moved away:1) • Ongoing: 4

2017
40 (Total number of ulcers)
19 (Ulcers requiring Debridement)
<ul style="list-style-type: none"> • Ineligible:4/19 <ul style="list-style-type: none"> -Declined:4 • Eligible:15/19
<ul style="list-style-type: none"> • Randomised:14 • Awaiting: 1 • Healed: 0 • Not healed: 0 • Withdrawal: 2 (Medical:2) • Ongoing: 13

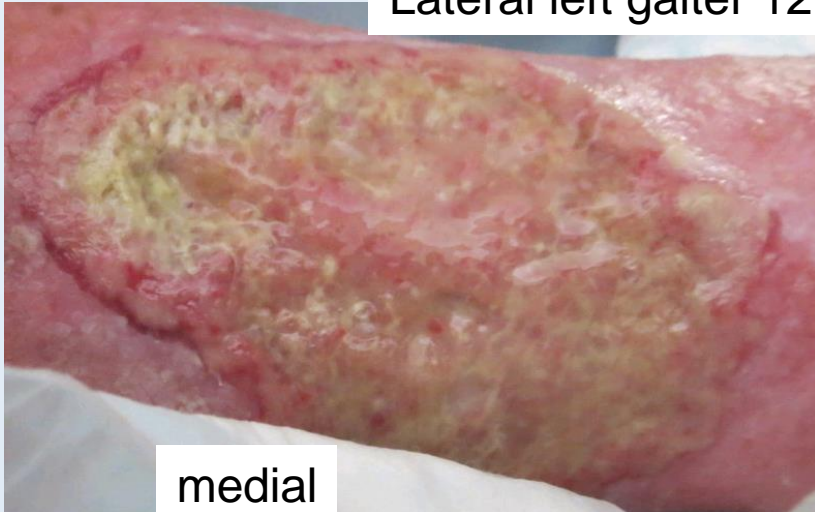
- ✚ Target 180 randomisation over 4 years (45 per each strata; Venous, Ischaemic, Neuropathic, Other)
- ✚ Aim 3.75 randomisation per month (45 per year)
- ✚ Total of 59 Randomised (63% of projected target to 31/Mar/2017)

82 year female, history of increasing very painful left leg ulcer gaiter area, now circumferential, pain 10/10, not tolerating compression, Tendon exposure

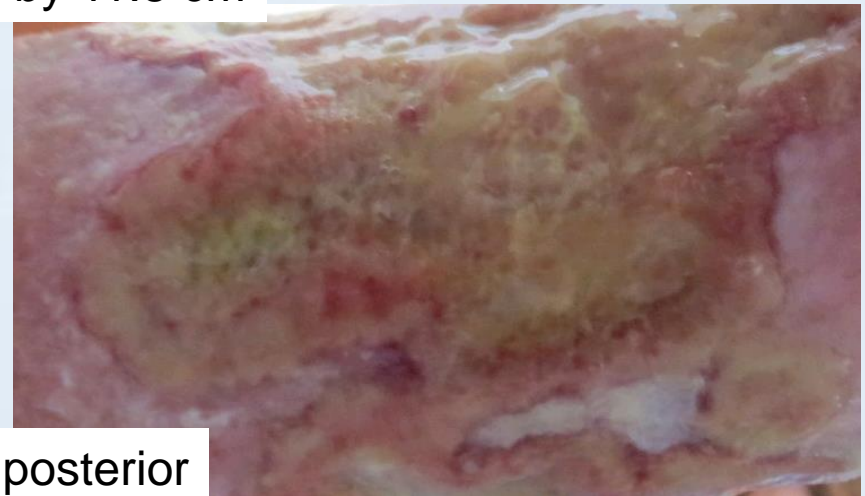


Thick, tenacious, unhealthy
Granulation tissue

Lateral left gaiter 12.2 cm by 11.8 cm

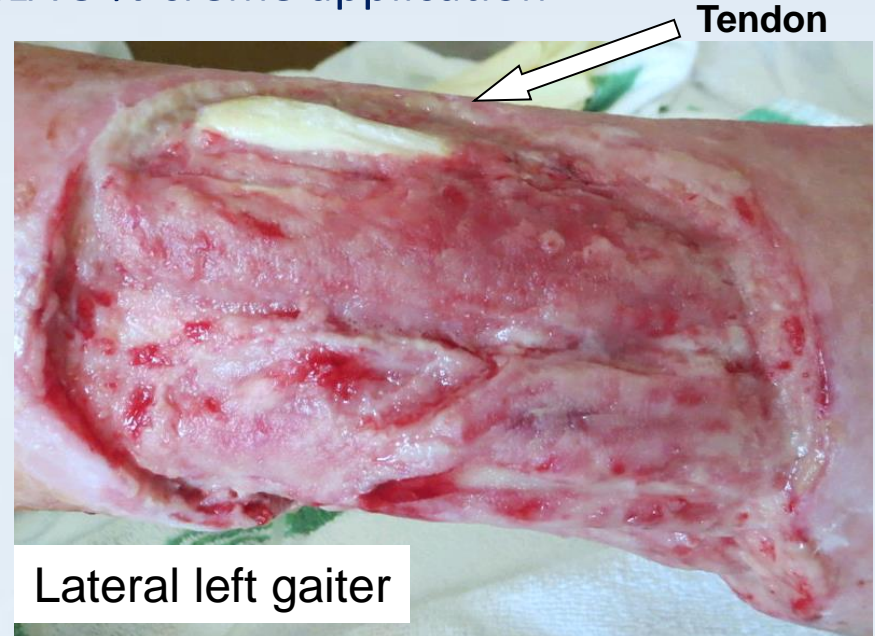


medial

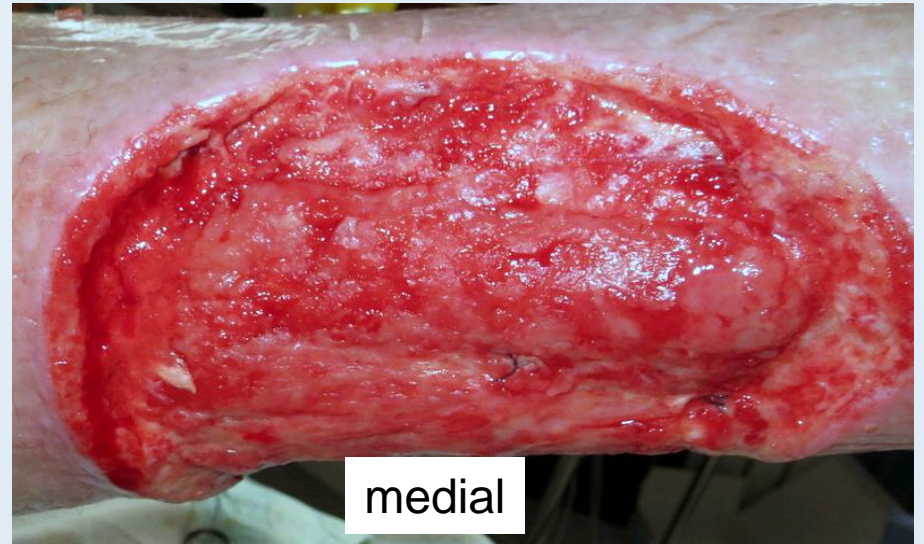
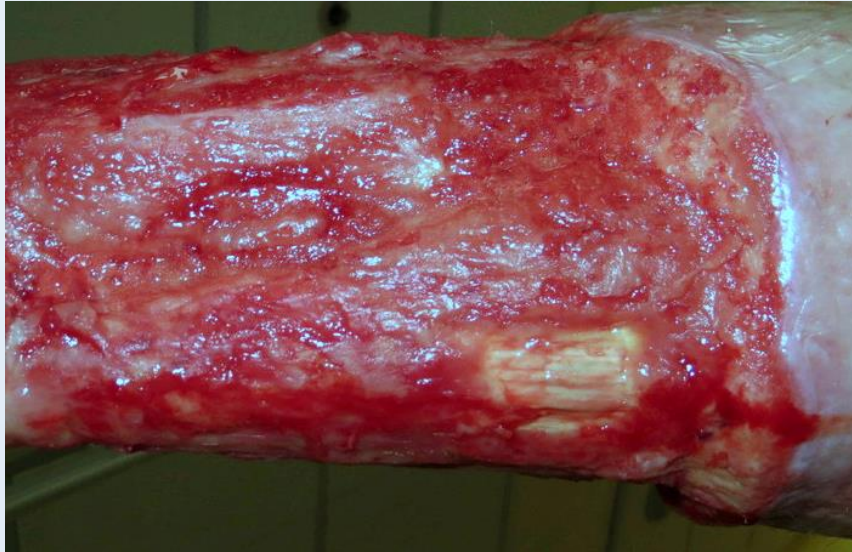
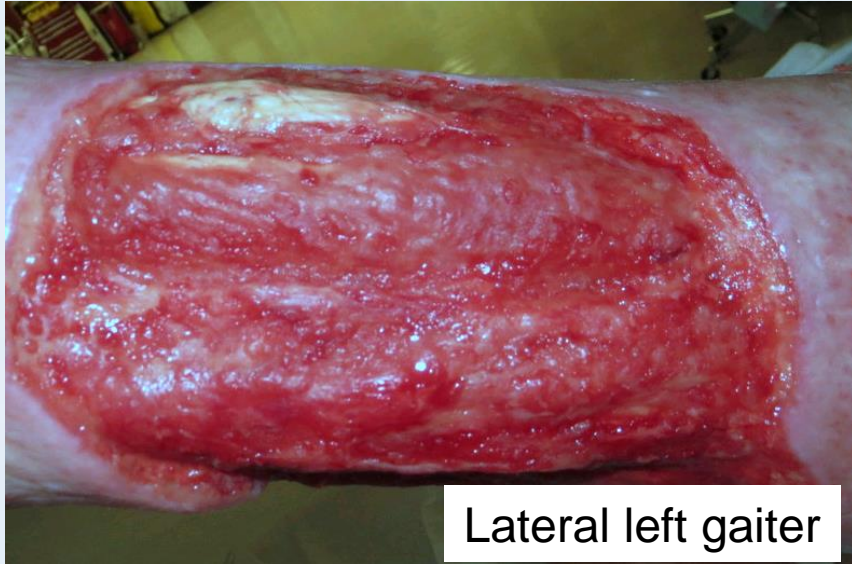


posterior

3rd treatment with LFUD - EMLA 5 % crème application



4th treatment with LFUD - EMLA 5 % crème + NPWT





SSTG in MOT 3 wks. after start of treatment,
Acticoat flex + NPWT



Patient	Treatment	Outcome
82 year female, history of increasing very painful left leg ulcer gaiter area, now circumferential, pain 10/10, not tolerating compression, Tendon exposure	LFUD treatment group,, LFUD done for 3 weeks twice a week, NPWT, SSG after several treatments with EMLA + LA Xylocaine	95 % healed skin graft, able to wear compression stockings class 1, lives independently again

10 days after SSG



Posterior



Lateral left gaiter

What have we learned so far?

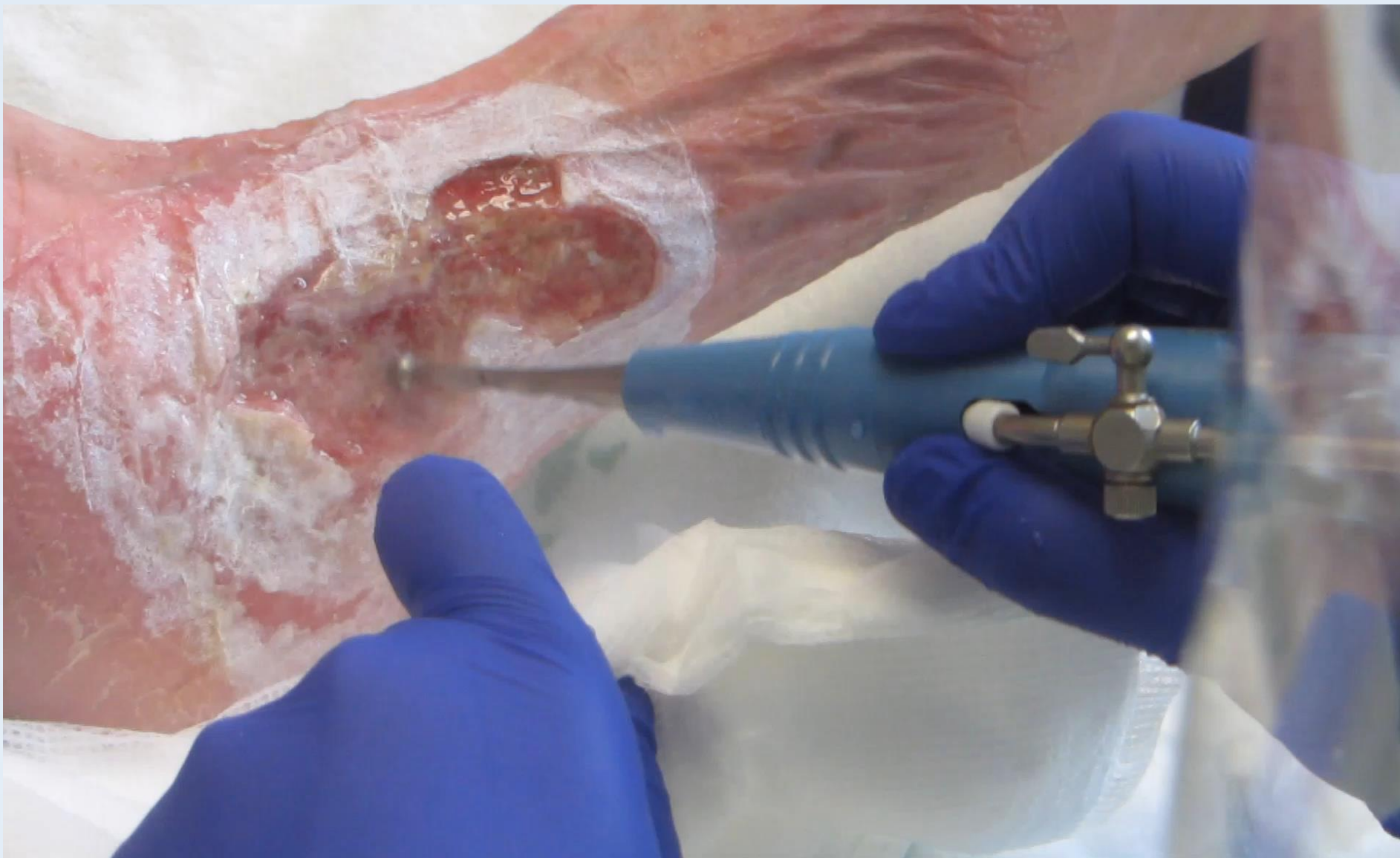


The Clinical Research Nurse

What would we do without Sue



Listen to my journey
Saturday 0950



Each wound is LFUD debrided

Before and after debridement



Photographed before and after debridement



Digital imaging and tracking is done using Silhouette Connect system

Adequate Pain management

- Pain management is important
- Technique related
- Setting of water flow and amplitude

Topical EMLA

Topical Lignocaine

- Adjunct Analgesia
- Regular pain medication
- Entonox



CONSENT FORM

The **ASCEND** study: A study to investigate
Clinical Effect of Nexagon to treat slow healing
ulcers

Request for interpreter (please circle)

English	I wish to have an interpreter.
Maori	E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhakapekeha korero.
Cook Island	Ka inangaro au i tetahi tangata uri reo.
Fijian	Au gadreva me dua e vakadewa vosa vei au.
Niuean	Fia manako au ke fakaaoga e tetahi kupa.
Samoan	Ou te manako e fa'aaoga e tetahi kupa.
Tokelaun	

Otago District Health Board

Pouari Hauora-ā-rohe ki Ōtago

Patient Information Sheet

The **ASCEND** study: A study to investigate
Clinical Effect of Nexagon to treat
ulcers

Introduction

You are invited to take part in a research study
Nexagon®, which may be able to improve the
healing of your slow healing ulcer.

Your participation in this study is voluntary. You
do not have to take part in the study. You can
stop at any time. You will not be penalised for
not taking part in the study.

The details of the research study that you are
invited to take part in are set out in this information sheet. You should read this information sheet carefully.

ALERT - CLINICAL

See iPM

PATIENT NAME:

NHI:

TRIAL RECRUITMENT DATE:

TRIAL CLOSE OUT DATE:

TITLE:

A Randomized, Prospective, Double-blind, Placebo-controlled
Dose-escalation, Single-centre Study of the Safety and
Effect of Nexagon® in the Treatment of Participants with
Diabetic Foot Ulcers

CONTACT DETAILS:

PI (Principal Investigator): Emil Schmidt

Custodial Account Code Request Form

Can you please set up the following custodial account code:

Project Title: The **ASCEND** study: A study to investigate the Safety and Clinical Effect
of Nexagon to treat slow healing Diabetic foot ulcers

Group: Surgery

Effective From: 15.09.09

Emil Schmidt

Clinical Study Costing Template

Completed by the Researcher with input from a Business Analyst

Title of Research

Principal Investigator

Research Nurse

ODHB Service

Location for research

Date to commence / finish

Number of patients

Funding per patient

(Less 12.5% GST)

Total

Mr Emil Schmidt

Wendy H

021 47705

4747681

Count Code:

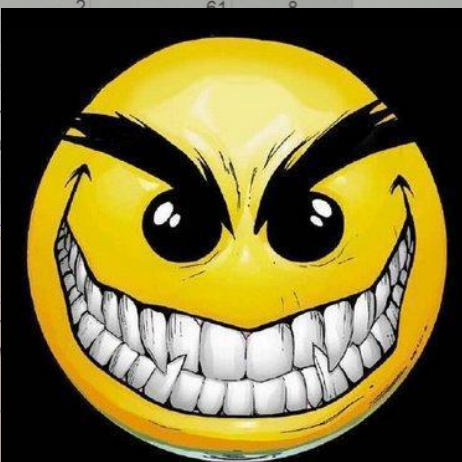
Researcher:

Manager:

BA:

480.00

	No Hours	Hourly rate	Number of patients	Total Cost
Preparation (ethics etc. Recommend \$2500)				2500
Research Nurse set up per patient	6	37	8	1776
Research Nurse per patient	30	37	8	8880
Nurse Specialist				976
Consultant				1560
Plaster technician				1440
Orthotics				2440
Sub Total				572.00
Consumables per patient (eg Pharmacy)				
Allevyn dressings, Tapes,				3200
Total contact cast				2400
Sub Total				600.00



SECTION 2

Departmental / Group Level Approval

Full costs to the DHB or DSM have been identified:

☐ Yes

☐ Not Applicable (attach explanation)

Researcher please complete and attach an appropriate costing template

ODHB Support Services (Radiology Pharmacy)

☐ Yes

Researcher please complete

Implications Request Form:

Researcher please complete and attach an appropriate costing template. Issues reviewed and approved by Group Manager. Confirmation of the availability and cost of ODHB resources external to ODHB, Radiology, Pharmacy.

SECTION 1

Overview of Intended Research

Researcher please complete and attach an appropriate costing template. Any assistance with the Clinical Research Approval procedure contact the Health Research Office on 474 7007 or extn 5085.

ASCEND Study - A Study of Safety and clinical effect of Nexagon to treat slow healing Diabetic foot ulcers

Project ID:

SECTION 4

Departmental / Group Level Approval to Commence Research

Researcher please complete

Researcher please complete and attach an appropriate costing template. Approved by the appropriate individuals.

☐ Yes ☐ No

Researcher please complete and attach an appropriate costing template. Subject to verification of final Ethics Approval all required for documentation is complete

☐ Yes ☐ No

Researcher please complete and attach an appropriate costing template. Where appropriate University of Otago the research process has been completed

☐ Yes ☐ No

Researcher please complete and attach an appropriate costing template. Indemnity covered by:

ACC ☐ (Declaration A Marked for your information)

Company ☐ (Contracts reviewed and recommended for signing by ODHB)

University ☐ The research is a student project or is externally funded research and University policies will apply.

Transport to hospital



- Organising transportation for hospital visits
- No funding in the budget
- Arrangement with red cross

Huge Time commitment

- Asking to commit to LFUD treatments – 6 times in 3 weeks
- 1-2 hrs per visit for treatment and dressing
- Contacting participants for follow up visits
- Taking photos at 4, 8, 12, 24, 52 weeks
- Data collection on adverse events for one year

We love - Randomization Day



Recruitment takes longer than we planned

Does LFUD make a difference?



I am not allowed to be bias
Will tell you in 3 years

Thank you!

The image features the words "Thank you!" in a playful, hand-drawn style. The letters are thick and outlined in black. The word "Thank" is in the top row, with "T" in orange, "h" in orange with red wavy lines, "a" in green with black dots, "n" in purple with vertical lines, and "k" in orange with red wavy lines. The word "you!" is in the bottom row, with "y" in green with black dots, "o" in pink with black dots, and "u!" in blue with black dots. There are four flowers: a blue one with a purple center above the "k", a blue one with a purple center above the "u", a pink one with a yellow center below the "h", and a blue one with a purple center below the "y". The exclamation mark is blue with a green dot. The background is white.



Benefits

- One need to have an excellent and flexible research nurse
- Identified areas of inadequate treatment
- Management and care improvements
- Increased the ulcer management profile within the district nursing team, PHO's and Rest homes
- Closer links with Primary Health Care Providers
- Closer link to the clinical trial research unit in Auckland
- Personal development
- Database of patients with leg ulcers