

The COMPRESS Study: COMPReSSion in Excisional Surgery left to heal Secondarily

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Background

- UK DCTN training day 2013
- Groups of dermatology registrars under senior mentorship to develop trial ideas
- Choice of area of interest
- One theme compression after lower leg surgery
- Ongoing project with 4 of the team



Current team

- Professor Jane Nixon
 - Tissue Viability and Clinical Trials Research, Deputy Director at the Institute of Clinical Trials Research, Leeds
- Sarah Brown
 - Principal Statistician, Leeds CTU
- Nikki Stubbs
 - Clinical Lead, Leeds Community Healthcare wound prevention and management service
- Dr Wal Hussain
 - Consultant in Dermatology and Dermatological Surgery, Leeds
- Dr Carsten Flohr
 - Consultant Dermatologist and Senior Lecturer, St John's Institute, London, NIHR Clinical Scientist
- Shelley Dowey
 - Clinical Trials Development Manager, UK DCTN

Bandages...

- Ancient Egyptians – first compression
- Simple woven fabrics, coated
- 17th Century – French lace up stockings for ulcers
- Dog skin
- 1878 – Letter to the Lancet, Callender
- Elasticated
- 1911 – Appeared in British Pharmaceutical Codex



The hypothesis

- Lower leg surgical wounds slower to heal and at higher risk of infection
- Compression
 - reduces oedema
 - improves venous return and tissue oxygenation
 - prevents dressings from moving
 - is accessible
 - relatively low cost
 - already being used post-operatively
- Could post-operative use speed healing and reduce complications?



What existing evidence is there?

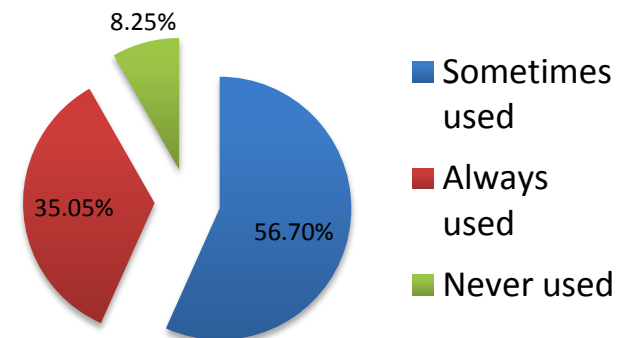
- Large Cochrane systematic review suggests that compression helps healing of chronic venous leg ulcers
 - Venous leg ulcers heal faster with compression than without
 - Specifically, multi component systems containing elastic are more effective than single component
- VenUS RCTs
 - VenUS I compares 4LB with short stretch and shows 4LB to be more clinically and cost effective
 - VenUS IV compares 4LB with 2 layer compression hosiery stockings showing them to be equally effective
- Limited case reports and series describing effect in lower leg surgical wounds
 - 10 Mohs patients given weekly Unna boots gave high satisfaction levels and no complications were reported

Survey results

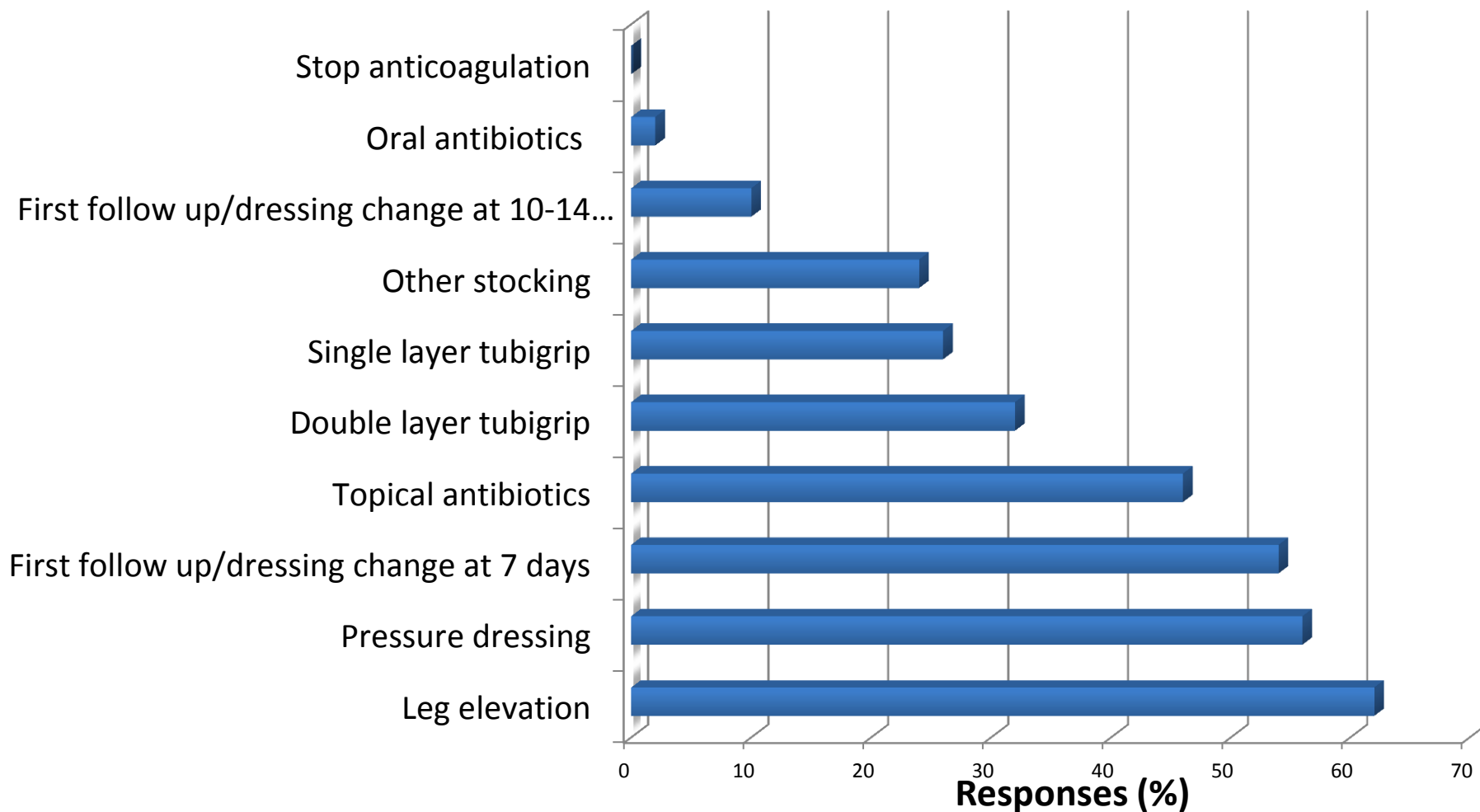
- Survey of 109 dermatologists in the British Society of Dermatology Surgery (BSDS):
 - Majority leave lower leg wounds to heal secondarily if primary closure is not possible
 - 0-20 per month, average 5.4
 - 57% of operators use compression sometimes, indicating clinical equipoise
 - Other elements of practice vary greatly
 - Duration, antibiotic use, type of compression
- 60% expressed willingness to participate in potential trial

Practice if primary closure not possible	Results (%)
Leave to heal secondarily with a purse string or other suture	57%
Leave to heal secondarily	48%
Repair with a skin graft or flap	36%
Refer to plastics/another specialty	6%

Compression Use



Which of the following would you typically do for a patient with a secondary intention wound on the lower leg?



(Other stockings – Velband/4 layer/3 layer)

For whom would you routinely consider post-operative compression?

- Indications varied (%)
 - All where wound healing may be impaired (60)
 - All patients (32)
 - Those at higher risk of complications (31)
 - Larger defects > 3cm (31)
 - Elderly (28)
 - Primary closures (16)
 - Secondary closures (27)
 - Grafts (22)



Research Question

Does compression, as an adjunct to standard care, compared to standard care alone improve time to healing of secondary intention wounds after excision of skin cancer below the knee?

Trial overview

- Open, parallel group randomised controlled trial
- Secondary care patients
- Skin cancers on the lower limb
- Secondary intention healing
- Standard wound care
- Compression immediately postoperatively

Inclusion Criteria

- Patients who have a planned excision of skin cancer with healing by secondary intention on the lower limbs (above ankle and below knee)
- Aged over 18 years
- Ankle Brachial Pressure Index (ABPI) of greater than or equal to 0.8 measured by Doppler Sonography

Exclusion Criteria

- Wounds closed by primary closure, skin graft, or flap
- Individuals with one or more contraindications to compression;
 - history of thrombosis
 - arteritis obliterans stage III and IV of the lower limbs (IPS<0.6)
 - micro-angiopathy
 - decompensated heart failure
 - phlegmatia coerulea dolens
 - recent cellulitis
- Unable to comply with compression therapy

Intervention

- Compression as an adjunct to standard care versus standard care alone
- Identify eligible (equivalent) compression options through:
 - focus groups
 - a review of the leg ulcer trials and systematic review evidence, including consideration of effectiveness and compliance

Potential confounders

Various factors affecting healing

- **Surgical**

- *Wound size*
 - Stratified for in ulcer trials, cut off 5cm
- *Use of purse string sutures*
 - Used by 57% of skin surgeons surveyed
 - Difficult to control for (suture size, tension etc.)
 - Recent evidence from a small trial showed no clear benefit

- **Patient**

- *Diabetes*
 - ABPI variability
- *Oedema*
- *Venous eczema*



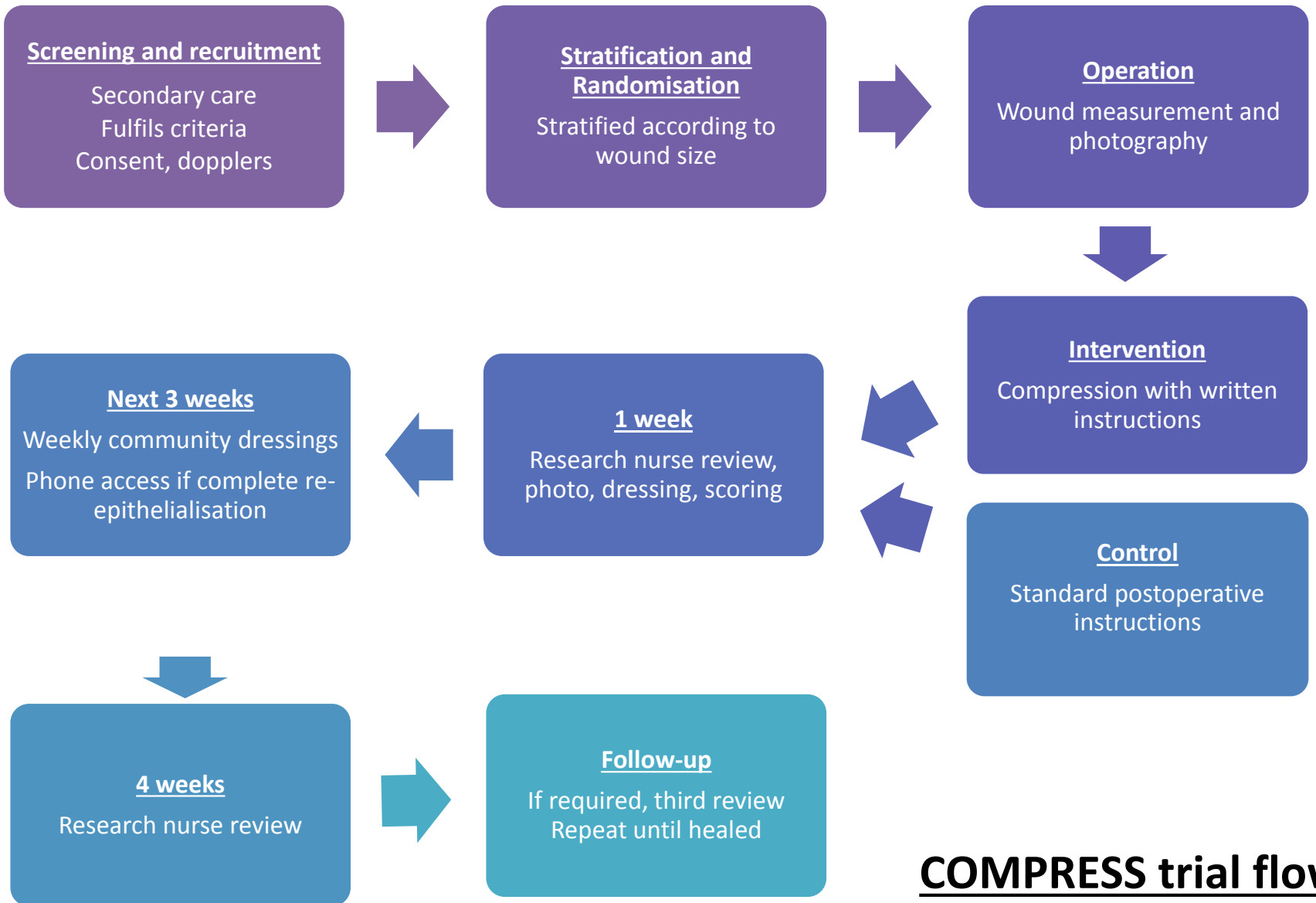
Outcomes

Primary

- Time to wound healing
 - defined as time from the date of surgery to the date complete re-epithelialisation observed

Secondary

- Rate of reduction in wound area as measured by percentage change in surface area
- Incidence of wound infection
- Compliance
- Patient reported quality of life
- Cost effectiveness



COMPRESS trial flow chart

Pilot work

- With the help of UK DCTN themed research call award we are planning and developing an HTA grant application by:
 - **Conducting focus groups**
 - to clarify potential barriers to recruitment, understanding of randomisation and suitability of interventions
 - **Undertaking a survey**
 - to better understand the current care pathway in relation to frequency and location of dressing changes
 - **Recruiting and following up a cohort** of 50 patients who fulfil trial eligibility
 - to assess time to healing



Why are we excited about this project?

- Practical, relevant question
- Clinical equipoise
- Simple intervention
- Short duration trial
 - could engage dermatology trainees particularly
- Far-reaching benefits whether shown to be useful or not
 - Reduced antibiotic use
 - Cost implications
 - Direct patient benefit

Thank you

We welcome questions and
particularly comments and
suggestions