Wound Management of Open Lower Limb Fracture: The WOLLF Trial

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WOLLF
Wound Management of Open Lower Limb Fractures

Chief Investigator: Prof Matt Costa
Background

- Open lower limb fractures at high risk of microbial contamination
- Rates of infection high – **27%** (Pollack, 2010)
- Usual management: early lavage, surgical debridement, fracture stabilisation +/- bone grafting, wound coverage
- Antibiotic prophylaxis
Negative Pressure Wound Therapy

• NPWT removes wound exudate by active suction
• Changes the bacterial environment, increases oxygenation
• Little evidence for open fractures (Stannard 2009)
• Consensus document (2011) concluded that the evidence base was limited
• Increased use in NHS
Aim of trial

To compare the **effectiveness** and **cost-effectiveness** of NPWT with standard postoperative wound dressings in treatment of wounds associated with **open fractures** of lower limb.
## Overview

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Multi-centre, randomised controlled trial (RCT)</th>
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</thead>
<tbody>
<tr>
<td>Setting</td>
<td>18 Trauma Centres, UK</td>
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<tr>
<td>Sample size</td>
<td>460 patients</td>
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<tr>
<td>Interventions</td>
<td>Standard care vs. Negative Pressure Wound Therapy</td>
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<tr>
<td>Outcomes</td>
<td>Disability Rating Index, SSI, reoperation, QoL, costs</td>
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</tbody>
</table>
Participants

**Inclusion criteria**

- Aged 16 years or older
- Present within 72 hours of injury
- Open fracture of the lower limb: Gustilo & Anderson 2, 3 or 3+

**Exclusion criteria**

- Cannot undergo general anaesthesia /surgery
- Unable to adhere to trial procedures or complete questionnaires
Outcomes

Primary outcome

- Disability Rating Index (DRI)* at 12 months
- VAS, gross movement scale, suitable for different #’s
- Scale: no difficulty __________________ great difficulty  
  e.g. walking, climbing stairs, running etc.

Secondary outcomes

- Surgical site infection @6 weeks, 12 months (Deep SSI)
- Wound healing
- Quality of life – SF-12 & EQ-5D
- Resource use

## Wound assessment
### Observation at 6 weeks postoperatively

### Section 2—Trial wound complications

1. After surgery, have any of the following wound complications occurred in relation to the trial wound? *Please go through each, with the patient and tick all that apply.*  
*Please ignore pin site infections if the fracture was treated with an external fixator.*

<table>
<thead>
<tr>
<th>WOLLF wound only</th>
<th>Anytime since surgery</th>
<th>Symptoms present today</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the wound red and inflamed?</td>
<td></td>
<td></td>
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<tr>
<td>Is the area around the wound swollen?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Is the area around the wound painful or tender?</td>
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<tr>
<td>Is there any fluid leaking from the wound?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>If yes, is the fluid pus or cloudy yellow?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Is the wound gaping open (dehisced?)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a surgeon deliberately opened the wound?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any fever of &gt;38°C since the surgery?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there any sign of abscess or infection on direct examination?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has a culture swab been taken from the trial wound?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If a culture swab was taken from the trial wound, please confirm:

Organism: ........................................ Date taken (dd/mm/yyyy) □ □ □ □ □ □
WOLLF Data Collection

Surgery

Consent

X-rays

6 weeks

3 months  6 months  9 months  12 months

Postoperative assessment
Wound complications Etc.

Patient Questionnaires
Disability Rating Index
EQ-5D / SF12
Wound / other complications
Health economics

Baseline Questionnaire
Disability Rating Index
EQ-5D / SF12
Wound / other complications
Health economics

Independent assessment of images
Tissue Viability Nurse
Senior Clinical Researcher

X-rays
Status
Recruitment closed 10\textsuperscript{th} Dec 2015, n=460

![Graph showing recruitment progress over time, with expected and consented participants milestone points.]
Example images
6 weeks postoperatively – photos by RAs

Images removed
Challenges

Data collection
- Good relationships with patients, long hospitalisations
- Patients traumatised
- All consented for images – patient involvement!
- Challenging to use scale if external fixator
- Overall adhered to protocol

Data management
- Range 1 - 10 images x 460 patients
- Good visual indicator
- Used to supplement decisions re wound infection

Follow-up ongoing.....
Thanks to:

Amy Verdon, Tissue Viability Specialist,
University Hospitals Coventry & Warwickshire
- Upper & lower limb trauma

- Closed surgical incisions, \( N=2000 \)

**WE NEED:**

Major Trauma Centres
Independent Assessment Panel

[WHIST@ndorms.ox.ac.uk](mailto:WHIST@ndorms.ox.ac.uk)

OR

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