

Wound assessment within a clinical trial

Wound Management of Open Lower Limb Fracture (WOLLF RCT)

Wounds Research Network (WReN), Birmingham, 5th April 2017

Dr Julie Bruce
On behalf of WOLLF trial team

Chief Investigator: Prof Matt Costa
Health Technology Assessment Programme
(10/57/20)



Introduction



- Experiences from recent trauma surgery trial
- Open lower limb fracture
- Preliminary data – no results yet!



Lower limb fractures

- Traumatic injury of lower limb, bone exposed
- Usual care: surgical debridement, fracture stabilisation, +/- grafting, wound coverage
- Microbial contamination
- Rates of “wound infection” high – **27%** (Pollack, 2010)
- Type of dressing applied after debridement may reduce risk of infection



Negative Pressure Wound Therapy

- Increased use in NHS
- Wound exudate removed by active suction
- Little evidence for open fractures (Stannard 2009)
- Consensus document (2011) concluded that the evidence base was limited



Aim

To compare the **effectiveness** of NPWT with standard postoperative wound dressings in treatment of wounds associated with **open fractures** of lower limb



Negative Pressure Wound Therapy

Pressure (mmHg) left to the discretion of clinical team

versus



Standard Care

Dressings left to discretion of clinical team

Outcomes

Design

Multi-centre pragmatic RCT

Setting

18 Trauma Centres, UK

Sample

460 patients

Outcomes

Disability

Wound infection

Complications

QoL

Cost



Definitions

CDC

Timing

- **Deep SSI:** 30 days or 1 year with implant
- Superficial SSI: 30 days

CDC/NHSN surveillance definition of health care–associated infection and criteria for specific types of infections in the acute care setting

Teresa C. Horan, MPH, Mary Andrus, RN, BA, CIC, and Margaret A. Dudeck, MPH
Atlanta, Georgia

Am J Infect Control 2008;36:309-32.

CDC Criteria

SIP/SIS-Superficial incisional surgical site infection

A superficial incisional SSI (SIP or SIS) must meet the following criterion:

Infection occurs within 30 days after the operative procedure

and

involves only skin and subcutaneous tissue of the incision

and

patient has at least 1 of the following:

- a. purulent drainage from the superficial incision
- b. organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision
- c. at least 1 of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, *and* superficial incision is deliberately opened by surgeon and is culture positive or not cultured. A culture-negative finding does not meet this criterion.
- d. diagnosis of superficial incisional SSI by the surgeon or attending physician.

DIP/DIS-Deep incisional surgical site infection

A deep incisional SSI (DIP or DIS) must meet the following criterion:

Infection occurs within 30 days after the operative procedure if no implant¹ is left in place or within 1 year if implant is in place and the infection appears to be related to the operative procedure

and

involves deep soft tissues (eg, fascial and muscle layers) of the incision

and

patient has at least 1 of the following:

- a. purulent drainage from the deep incision but not from the organ/space component of the surgical site
- b. a deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured when the patient has at least 1 of the following signs or symptoms: fever ($>38^{\circ}\text{C}$), or localized pain or tenderness. A culture-negative finding does not meet this criterion.
- c. an abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination
- d. diagnosis of a deep incisional SSI by a surgeon or attending physician.

Data collection

Direct observation by RA at 6 weeks postoperatively

| WOLLF wound only | Yes | Yes | No |
|--|-----------------------|-------|----|
| | Anytime since surgery | Today | |
| Is the wound red and inflamed? | | | |
| Is the area around the wound swollen? | | | |
| Is the area around the wound painful or tender? | | | |
| Is there any fluid leaking from the wound? | | | |
| If yes, is the fluid | | | |
| Is the wound gaping open (dehiscent)? | | | |
| Has a surgeon deliberately opened the wound? | | | |
| Any fever of $>38^{\circ}\text{C}$ since the surgery? | | | |
| Is there any sign of abscess or infection on direct examination? | | | |
| Has a culture swab been taken from the trial wound? | | | |

Algorithm

*infected
yes / no*

Outcomes

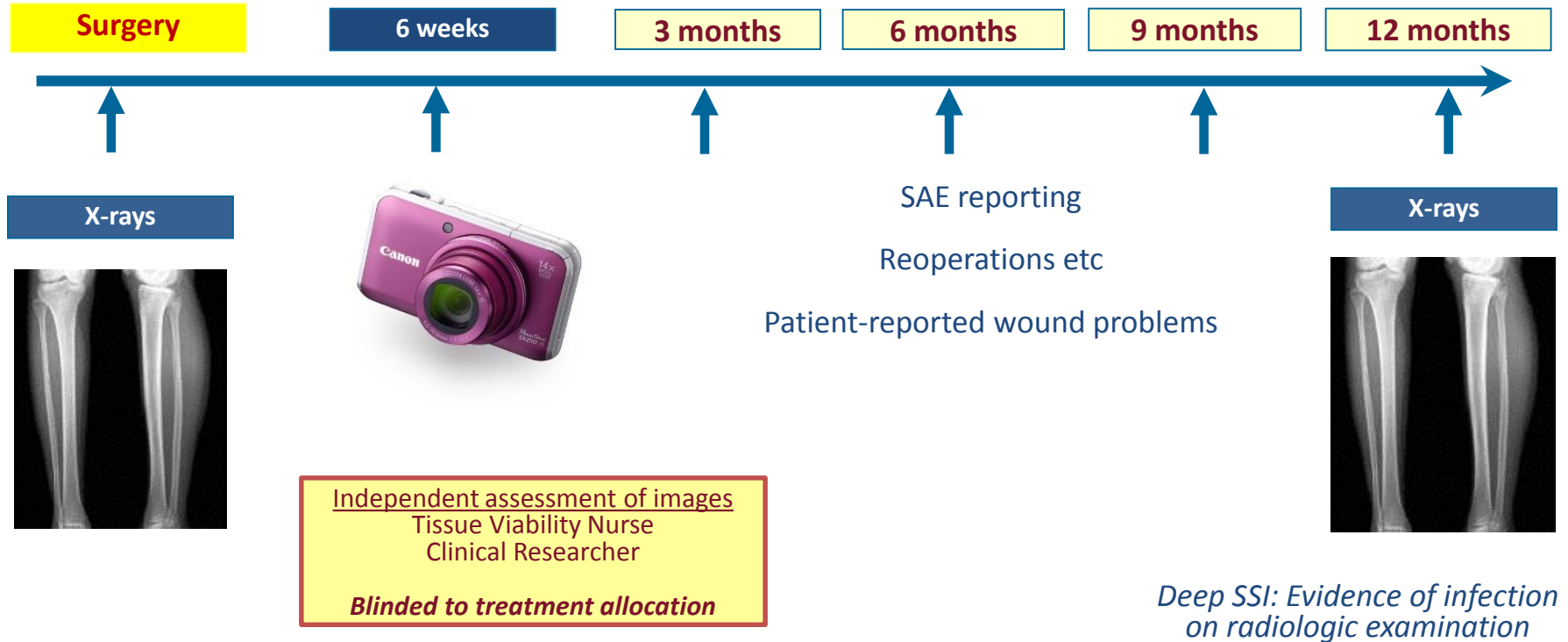
Photographs

- Novel
- A useful addition?

Wound healing

- Limited literature on open fractures
- Secondary outcome @6 weeks:
 - RA: “does the wound look fully healed?”
 - “does the patient think that their wound has healed?”

Data Collection



Preliminary findings: Superficial SSI @6 weeks

All participants

| CDC Superficial SSI Wound characteristics | % Yes |
|--|-------------------------|
| Wound infected | 68 / 460 (14.8%) |

| Photographs | % Yes |
|----------------|-------------------------|
| Wound infected | 58 / 355 (16.3%) |

Preliminary findings: Wound healing @6 weeks

All participants

| Wound healing | % Healed |
|-----------------|-------------------|
| Photograph | 184 / 355 (51.8%) |
| Patient opinion | 204 / 460 (44.3%) |

Level of agreement – yes / no

Cohen's kappa

| 2 independent assessors | kappa statistic |
|-------------------------|-----------------|
| Wound infected | 0.63 |
| Wound healed | 0.80 |

| Value of kappa | Strength of agreement |
|----------------|-----------------------|
| <0.20 | Poor |
| 0.21-0.40 | Fair |
| 0.41-0.60 | Moderate |
| 0.61-0.80 | Good |
| 0.81-1.00 | Very good |

Interpretation of kappa (Landis & Koch, 1977)

Using photographs

- ~80% return rate
- Feasible - long hospitalisations
- High participant consent rates
- Data storage >1500 images
- Highlighted extent of injury

Life-changing injuries – images removed

Qualitative interviews

- Photographs useful addition
- Acute injury – no chance to adjust
- Technological preference for VAC – “being cleaned”
- Dressing changes often distressing
- 5 year follow-up ongoing
- **RCT findings soon.....**



University Hospitals **NHS**
Coventry and Warwickshire
NHS Trust

Warwick
Medical School
CLINICAL TRIALS UNIT



Thank you
julie.bruce@warwick.ac.uk