

Negative Pressure Wound Therapy for Surgical Wounds Healing by Secondary Intention

Catherine Arundel, Research Fellow, on behalf of the SWHSI-2 Trial Team

This project is funded by the National Institute for Health Research Health Technology Assessment Programme (project number 17/42/94).
The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Systematic Review Evidence

Dumville et al (2015)¹

- Found two small RCTs comparing NPWT with standard care for SWHSI (combined total n = 69).
- Trial 1 compared NPWT with an alginate dressing in participants with a groin SWHSI following arterial surgery (n=49)
- Trial 2 compared NPWT with silicone dressing in participants who had undergone pilonidal sinus excision (n=20)

	Median Time to Healing
Trial 1	NPWT group (57 days, range 25 to 115) Alginate dressing group (104 days, range 57 to 175)
Trial 2	NPWT group (84 days, range 34 to 349) Dressing group (93 days range 43 to 264)

!! Caution in interpretation of these findings is recommended **!!**

- Unclear how the analysis was undertaken.
- There is no rigorous RCT evidence for the clinical effectiveness of NPWT in the treatment of SWHSI
 - Potential benefits and harms remain uncertain.

Systematic Review Evidence

Dumville et al (2013)²

- Found one RCT comparing NPWT with dressings for SWHSI following diabetic foot amputation (n=77)

Median Time to Healing

NPWT group (n=43, 56 days, range 26 to 92)

dressing group (n=33, 77 days, range 40 to 112)

!! Caution in interpretation of these findings is recommended **!!**

DFU study included patients with adequate foot perfusion (not representative of DFU patients)

DFU study was commercially funded and so at risk of performance bias

Previous Research Evidence

Programme Grant for Applied Research (PGfAR): RP-PG-0609-10171³

- Treating SWHSI can be costly to the NHS
 - Initial cost estimated to be £1060 per wound before treatment costs (estimated range £441 – £1,323 per month)
- Negative pressure use has been rapidly increasing
 - We estimate prevalence of SWHSI to be 4.1 per 10,000 population
 - On the basis of time to healing observed in our cohort study we expect >89,000 receive NPWT for SWHSI per year
- Our PGfAR included economic modelling of NPWT effectiveness for SWHSI using cohort data
 - This identified NPWT may not be clinically or cost effective as a treatment for SWHSI
 - If RCT evidence corresponds to modelling evidence cessation of NPWT would have direct health benefits of between 719 and 16,400 Quality Adjusted Life Years per year*

*conditional on the findings of a future trial and their successful implementation.

Beyond SWHSI...

Diabetic Foot Ulcers

- Two studies found that NPWT resulted in faster healing
 - 1) N=162; 56% NPWT vs 39% Standard dressings⁴
 - 2) N=335; 43.2% NPWT vs 28.9% Moist Wound Therapy⁵
- One study (n=368) found no significant difference in time to wound closure when NPWT or usual dressings were used⁶.

Surgical Site Infection

- Two studies found that NPWT reduced SSI
 - 1) N = 876; 4.6% NPWT vs 9.2% Standard dressings⁷
 - 2) N=123; 9.7% NPWT vs 31.1 Standard dressing (p=0.0003)⁸
- One study (n=1548) found no evidence of a difference in deep SSI rate at 30days: 5.8% NPWT vs 6.7% Standard dressings⁹

Beyond SWHSI...

Subcutaneous Abdominal Wounds (n=507)¹⁰

- Time to wound closure was significantly shorter for the NPWT group compared with conventional wound therapy : 36.1 days vs 39.1 days
- Wound closure rate at 42 days was higher with NPWT compared to conventional wound therapy:35.9% vs 21.5%

Lower Limb Fractures (n=460)¹¹

- No statistically significant difference in disability score between the NPWT and standard dressing groups

References

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- 11) Costa et al. Effect of Negative Pressure Wound Therapy vs Standard Wound Management on 12-Month Disability Among Adults With Severe Open Fracture of the Lower Limb: The WOLLF Randomized Clinical Trial. *JAMA* 2018; 319(22): 2280-88

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The Importance of Supporting SWHSI-2 Recruitment

Catherine Arundel, Research Fellow, on behalf of the SWHSI-2 Trial Team

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“But we know it works...”

- Only anecdotal evidence that NPWT improves time to SWHSI healing
- Treatment being used in clinical practice without high quality evidence to support
- NHS spending needs to be supported by evidence
 - May become difficult to support continued use if evidence still remains inconsistent or limited
- SWHSI-2 offers the opportunity to obtain much needed robust evidence which confirms (or refutes) the anecdotal evidence

The Importance of Evidence Based Practice

- Treatment being used in clinical practice without high quality evidence to support
- Evidence based wound care improves outcomes for patients
- Patient care needs to be supported by evidence
 - Want to be sure we are doing our best for the patient
 - Difficult to support continued use if evidence still remains inconsistent or limited

Patient Right to Research Participation

- “Patients and participants are the foundation of clinical research. Without them research can’t happen and healthcare can’t improve” (Department of Health and Social Care¹)
- Patients should be encouraged and enabled to explore research opportunities and make informed decisions about participation in research
 - The patient’s choice!
- A benefit for you and your institution
 - Evidence shows clinically research-active hospitals have better patient care outcomes.

1) Saving and Improving Lives: The Future of UK Clinical Research Delivery 23.03.2021 <https://www.gov.uk/government/publications/the-future-of-uk-clinical-research-delivery/saving-and-improving-lives-the-future-of-uk-clinical-research-delivery>

How Can I Help?

- Allow your patients to be approached for recruitment to SWHSI-2
 - Including those you think it will and won't work for
 - Put your treatment preferences and anecdotal thoughts on NPWT aside
- Encourage your patients to participate in SWHSI-2
- Get involved with the study team
 - Consider becoming an Associate PI (if trainee or working in a non research role)
- Encourage your colleagues to support the study
 - We have lots of tools to help with this!

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Surgical Wounds Healing by Secondary Intention Trial – 2

A pragmatic, multicentre, randomised controlled trial to assess the clinical and cost effectiveness of negative pressure wound therapy versus usual care for surgical wounds healing by secondary intention (SWHSI-2)

Professor Ian Chetter, Chief Investigator, on behalf of the SWHSI-2 Trial Team

Inclusion Criteria

- Aged 16 years or over
- Has an acute SWHSI deemed appropriate and ready to receive NPWT or wound dressing treatment
- Not deemed to be malnourished
- Willing and able to give informed consent and provide follow-up data

Exclusion Criteria - Wound

- Chronic wounds non-surgical in origin (e.g. pressure ulcers or foot ulcers)
- Current wound has previously been, or is currently being, treated with NPWT
- Planned delayed primary closure of the wound
- Patient or wound is contraindicated to receiving NPWT

Exclusion Criteria - Patient

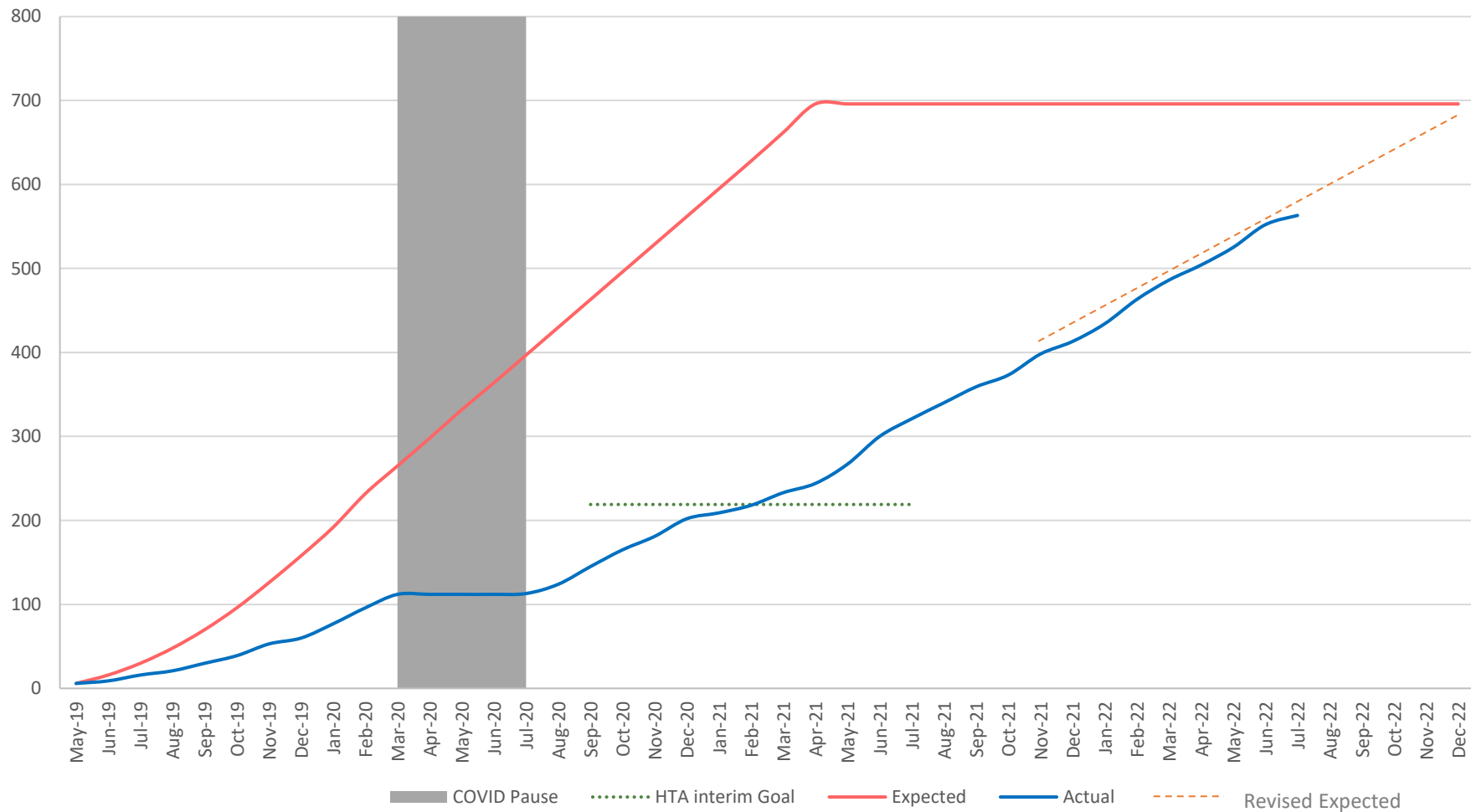
- Life expectancy of less than 6-months
- Has an active systemic infection at baseline
- Has inadequate haemostasis or patient is at risk of bleeding
- Currently participating in another wound research study, where the primary outcome time point has not yet been reached

Study Status - Sites

26 sites open to
recruitment



Study Status



563 participants recruited

198 confirmations of healing

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