Wound Management with Adjustable Intermittent or Continuous Negative Pressure Wound Therapy: Interim Results from a Randomised Controlled Trial

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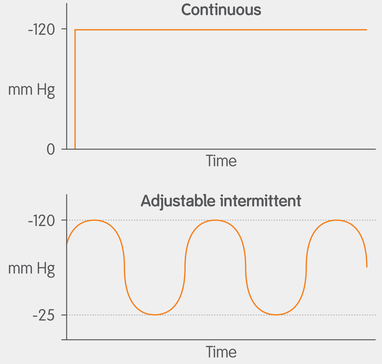
Background

- Negative Pressure Wound Therapy is effective in treating acute, subacute and chronic wounds
- Animal studies[1] suggest intermittent therapy has potential for faster granulation tissue compared to continuous therapy

Hypothesis

Variable intermittent mode Negative Pressure Wound Therapy heals wounds faster than continuous mode



Note: The 'adjustable intermittent' setting used cycled between a 'high' set point (typically -120mmHg) and a 'low' set point of -25mmHg. Pressure was never reduced to 0mmHg as with historic delivery of 'intermittent' NPWT

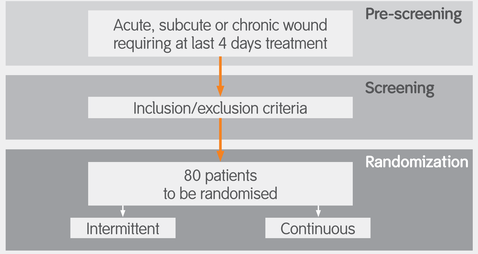
Aims

- To assess the safety and efficacy of the new RENASYS® TOUCH device
- To compare the efficacy of variable intermittent versus continuous Negative Pressure Wound Therapy

Methods

Overview

Prospective, randomized, open-label, multicentre trial



Inclusion/exclusion criteria

Key inclusion criteria

- Pt > 18yo
- Acute or subacute or chronic wound that would benefit from NPWT
- Expected minimum 4 days treatment needed

Key exclusion criteria

- Necrotic tissue or > 25% slough
- Untreated infection, osteomyelitis
- Malignancy
- Anastomotic sites, exposed blood vessels
- Fistula

Primary and secondary endpoints

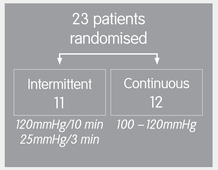
Primary endpoint:

Time to reach point where wound ready to be closed by surgery or 2^0 intention

- *Criteria:*
  - Granulation tissue > 80%
  - Necrotic tissue < 5%
  - Wound area and depth appropriate
  - No oedema/infection

Secondary endpoint:

- % of wounds ready for closure at 28 days
- Wound progression
- Wound pain



- Web based electronic randomization
- Patients treated up to 28 days
- Foam fillers: changed every 48-72 hrs, no less than 3 x/week
- Gauze fillers: initial change at 48 hrs, then 2-3x per week
- Wound assessment at each dressing change

Results

Demographics

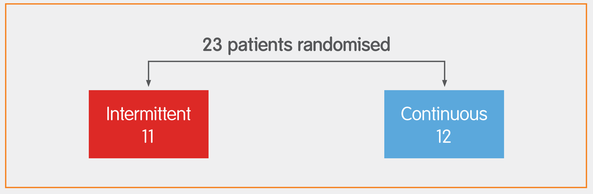
	Intermittent (n=11)	Continuous (n=12)	Overall (n=23)	P-value
Age (years)	66.1 (49 – 79)	60.8 (24 – 83)	63.3 (24 – 83)	0.347
BMI (kg/m^2)	29.1 (21.9 – 36.6)	29.6 (19.8 – 40.1)	29.3 (19.8 – 40.1)	0.843
Diabetes	9 (81.8%)	8 (66.7%)	17 (73.9%)	

There were no apparent patient demographic differences between the two groups

Wound characteristics

	Intermittent (n=11)	Continuous (n=12)	Overall (n=23)	P-value
Wound area (cm^2)	16.1 (8 – 121)	14.5 (4.7 – 71.5)	16.1 (4.7 – 121)	0.662
Wound depth (mm)	5 (0.5 – 29)	4.5 (2 – 25)	5 (0.5 – 29)	0.859
Wound volume (cm^3)	11.8 (0.8 – 147.6)	11.5 (3.3 – 60.5)	11.8 (0.8 – 147.6)	0.481

There were no apparent differences in wound characteristics between the two groups



Overall impact of NPWT

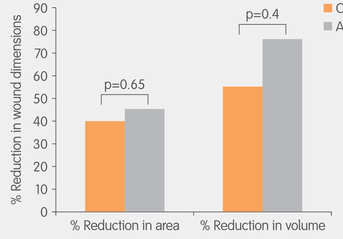
- Significant overall reduction in wound volume and area throughout therapy
- Significant increase in healthy tissue
- 2/23 patients reached 'ready for closure' by the end of the 28 day live phase.

	Overall (n=23)	P-value
% reduction in area	42.6 (-45.8 – 100)	p<0.001
Per week (cm^2)	17.3 (-17 – 102.1)	
% reduction in volume	65.2 (-47.9 – 100)	p<0.001
Per week (cm^3)	26.9 (-12 – 111.6)	
% increase of healthy/viable tissue	15% (-65 – 100)	p=0.013
Pain during wear(on scale 0-10)	99.1% reported both therapies as comfortable	

Comparison of continuous and adjustable intermittent

A number of trends were observed between continuous and adjustable intermittent NPWT

	Intermittent (n=11)	Continuous (n=12)	P-value
Patients achieving "ready for closure"	1 (9.1%)	1 (8.3%)	0.812
% increase in healthy/viable tissue	50 (-65 – 100)	10 (-40 – 55)	0.098
Pain during wear (on scale 0-10)	1.2 (0 – 9)	1.7 (0 – 8)	0.010



Compared to continuous pressure, use of adjustable intermittent resulted in the following trends:

- Increased healthy/viable tissue (NS)
- Reduction in wound volume (NS)
- Reduced pain sensation during wear (p=0.01)

Conclusions

- Whilst a number of non-significant trends between therapies were observed on the limited interim data, these need to be investigated further during the remainder of the trial
- Limitation: Interim study with small numbers

Reference:

1. Morykwas *et al.* Ann Plast Surg. 1997 Jun;38:553-62

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