A randomised controlled trial to compare the clinical efficacy and acceptability of adjustable intermittent and continuous Negative Pressure Wound Therapy (NPWT) in a new portable NPWT system*

Martin Forlee,[1] Louis van Zyl,[2] Hein Louw,[3] Jeanne Nel,[4] Nyda Fourie,[5] Robert Hartley[6]

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Introduction

- Animal studies show that intermittent NPWT has potential to increase the rate of granulation tissue formation compared with adjustable intermittent (AI) NPWT[1]
- However, interim results from our study showed trends towards greater reductions in wound volume and area, and increases in healthy tissue with AI versus continuous therapy,[2] as well as demonstrating functionality and ease of use of a new portable NPWT system[3]*
- We present full results from the study comparing the effects of AI and continuous therapy in the management of acute, sub-acute and chronic wounds administered using the portable NPWT system* (NCT02565043)

*RENASYS◊ TOUCH system (Smith & Nephew)

Materials and methods

Patients and interventions

- An open, prospective study conducted at nine centres in South Africa (April 2015 to August 2016) in patients with acute, sub-acute and chronic wounds that would benefit from NPWT to achieve adequate wound bed preparation
- Patients were assigned to receive AI or continuous therapy for 28 days; all settings were determined according to patient need and choice of wound dressing kit and filler were at the investigator's discretion
- Wounds were assessed and imaged, and device functionality and vacuum were assessed at each dressing change (every 48 hours for gauze and every 48–72 hours for foam); adverse events were also assessed

Primary endpoint

- Time to reach readiness for closure by surgical intervention or left for closure by secondary intention
- Defined as >80% healthy granulation tissue; <5% necrotic tissue, reduction in wound area and/or depth from day 0, absence of oedema and infection

Secondary endpoints

- Included wounds ready for closure either by surgical intervention or by secondary intention within 28 days, progress towards wound closure, incidence of infection and pain scores

Statistical analysis

- Assuming a 15% drop-out rate, 80 patients were required to achieve a sample size of 68 patients
- Time to achieve readiness for closure was analysed using Kaplan-Meier estimates, with a Wilcoxon signed rank test applied to reductions in wound dimension and appearance

References

1. Morykwas MJ, et al. *Ann Plast Surg*. 1997;38:553-62; **2.** Forlee M, et al. Poster EP253 presented at the European Wound Management Association annual meeting, May 11–13, 2016; Bremen, Germany; **3.** Forlee M, et al. Poster PO590 presented at the World Union of Wound Healing Societies congress, September 25–29, 2016; Florence, Italy

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Results

- A total of 81 patients were assigned to treatment; one patient was excluded from safety and efficacy analysis and 9 more were excluded from efficacy analysis only
- Patient demographics were similar in both groups except for an increased incidence of anaemia in the continuous therapy group (13.9% vs 2.9%)
- Mean age was 61.3 and 58.6 years and mean BMI was 30.2 and 31.7 kg/m^2 in the AI and continuous therapy groups, respectively
- Overall, 74.6% of patients were treated as outpatients; wound characteristics at baseline are presented in Table 1
- Most wounds were located on the foot, ankle or lower leg in both the AI and continuous therapy groups (71.4% vs 63.9%, respectively)
- Exudate was reported for 37 patients (light [n=21]; moderate [n=13]; heavy [n=3])

Table 1. Wound characteristics at baseline

Wound charasteristics	Adjustable intermittent therapy (n=35)	Continuous therapy (n=36)
Chronic (pressure, diabetic foot and venous leg ulcers)	10 (28.6%)	14 (38.9%)
Sub-acute (includes dehisced surgical wounds)	22 (62.9%)	15 (41.7%)
Acute (surgical and traumatic)	3 (8.6%)	7 (19.4%)
Area, mean ± SD (cm^2)	23.1 ± 23.4	15.4 ± 17.3
Depth, mean ± SD (mm)	12.0 ± 11.2	11.8 ± 12.0
Volume, mean ± SD (cm^3)	29.9 ± 41.5	24.8 ± 49.4
Duration, mean ± SD (weeks)	26.8 ± 59.3	48.1 ± 206.8

Primary endpoint

- Median time to achieve the primary endpoint could not be calculated because less than 50% of patients achieved readiness for closure (n=31; 43.7%; Table 2)
  - The lower 95% confidence interval for the primary endpoint was 27 days

Table 2. Wound characteristics at end of study

Study end point	Adjustable intermittent therapy (n=35)	Continuous therapy (n=36)
Achieved readiness for closure	15 (42.9%)	16 (44.4%)
Acute	0	4 (25.0%)
Sub-acute	14 (93.3%)	10 (62.5%)
Chronic	1 (6.7%)	2 (12.5%)

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Results (cont)

Secondary endpoints

- Estimated median reduction from baseline in wound area (7.3 cm^2) and volume (11.7 cm^3) were both statistically significant ($p<0.001$; Figure 1), as was increase in median amount of healthy viable tissue (20.0%; $p<0.001$)
- By study end the amount of exudate had reduced significantly ($p<0.001$)
- Eight patients (11.3%) had signs of clinical infection at baseline that resolved during the study
- Nine patients (12.7%) developed signs of infection during the study, five of which resolved by study end
- No pain was reported at 65.3% of dressing applications for AI therapy and 90.6% for continuous therapy. At dressing removal no pain was reported at 62.7% of assessments for AI therapy and 83.3% for continuous therapy
- Both therapy modes were comfortable to wear at more than 99% of dressing changes (99.3% and 99.1% of dressing changes for AI and continuous therapy, respectively)

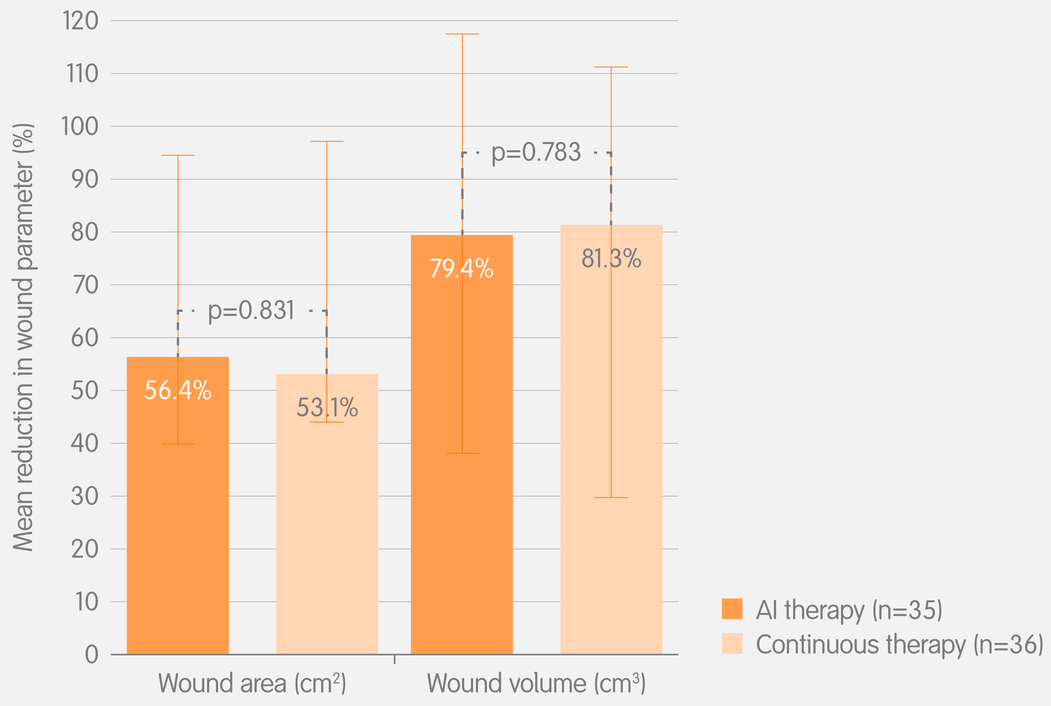

Figure 1. Mean reductions from baseline in wound area and volume ($p<0.001$ for both)

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Results (cont)

Secondary endpoints (cont)

- Use of negative pressure settings is shown in Figure 2; the most frequently selected cycle time was '10 min on' and '2 min off'

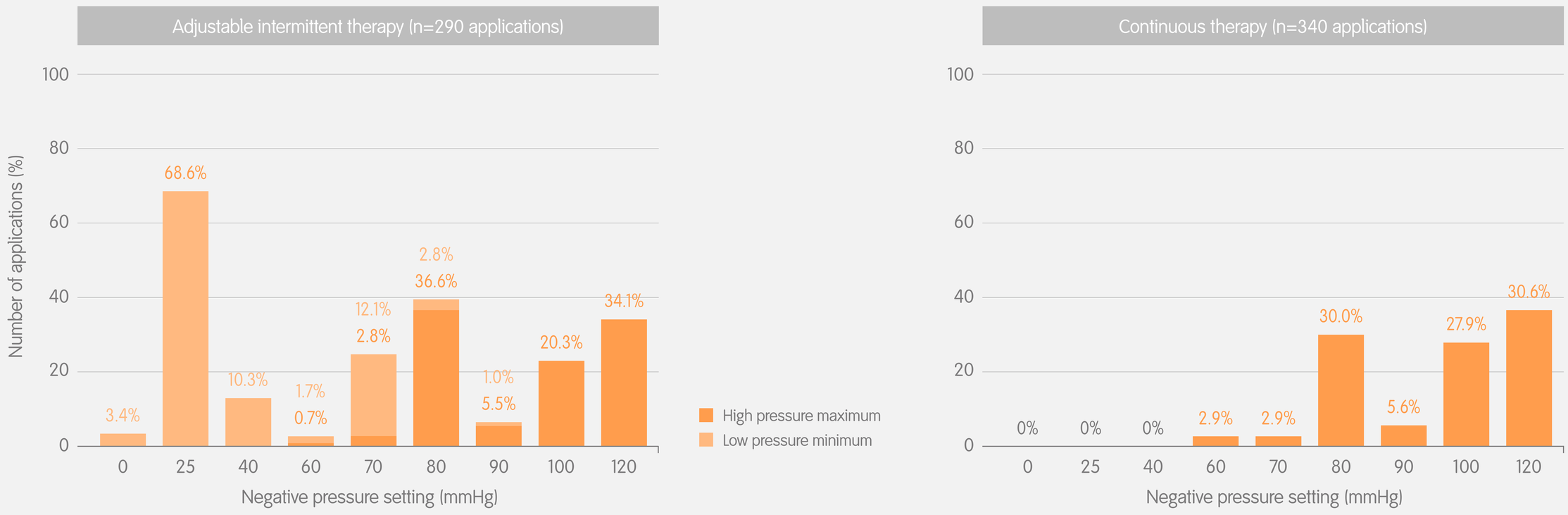

Figure 2. Pressure settings used for AI and continuous therapy during the study

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Results (cont)

Secondary endpoints (cont)

- Clinician acceptability of device functionality was >90% for all parameters assessed (Figure 3)

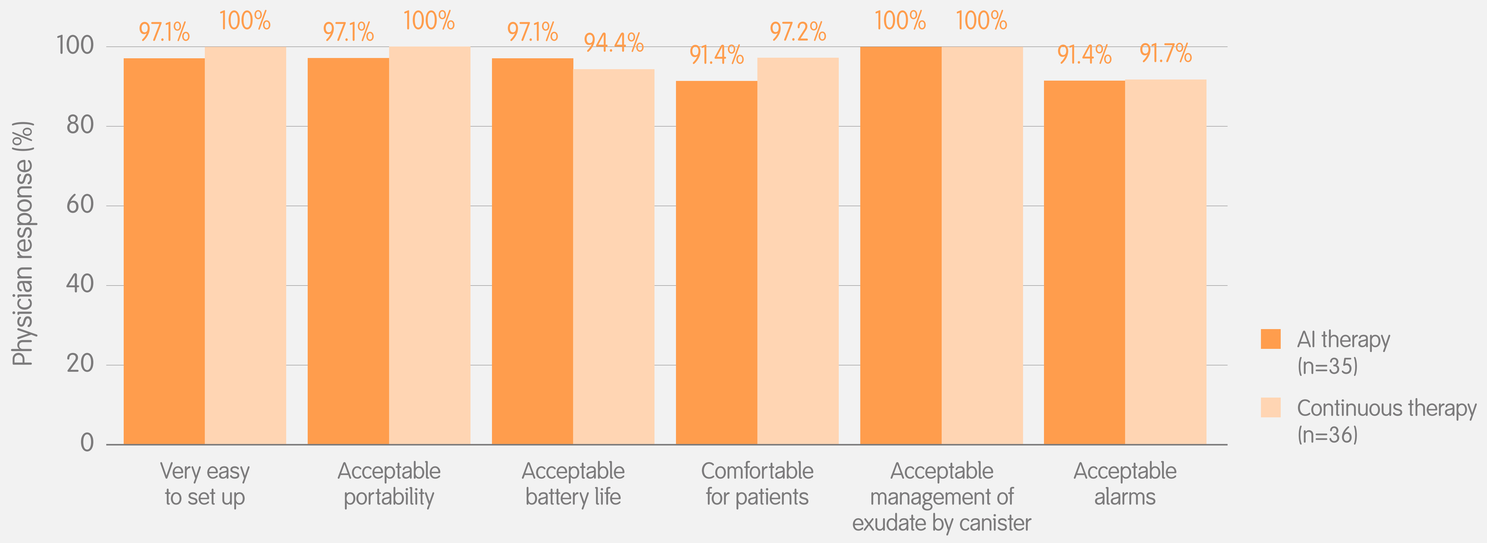

Figure 3. Clinician ratings of device functionality by treatment group

Safety

- A similar proportion of patients in each group reported adverse events (AEs); 48.8% and 46.2% in the AI and continuous therapy groups, respectively
- Twelve device-related AEs occurred: pain (n=6), blistering (n=2), excess exudate (n=2), device deficiency (n=1) and broken skin (n=1)
- The incidence of serious AEs was <10% and none were device related

Conclusions

- The device* was effective at managing all types of wound using both therapeutic modes as shown by a statistically significant decrease in estimated wound area and volume
  - Statistically significant improvements in the amount of healthy viable tissue and exudate levels were also achieved with both AI and continuous therapy
- Although the primary study endpoint could not be calculated, a mean reduction in wound area of 54.8% was achieved over the 4-week study period
- Most wounds were on a healing trajectory at study end; therefore, a longer follow-up period may have revealed difference between the two groups

Acknowledgements

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For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

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