Clinical assessment of a simplified single use NPWT device*

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Background

The purpose of this study was to evaluate a prototype of a new device that has been developed to provide Negative Pressure Wound Therapy (NPWT) in a radically simplified format. The new device differs significantly from previous NPWT devices in that it is light weight and eliminates the need for a canister. The pump is capable of delivering 80mmHg (nominal) to the wound surface and an airlock layer in the dressing maintains open airflow and allows even distribution of negative pressure across the dressing. An additional absorbent layer moves exudate away from the wound and the top film allows one-way transpiration of exudate vapor.

Pre-clinical studies have confirmed its ability to function consistent with larger, multi-use NPWT devices with respect to pressure transmission to the wound bed, tissue contraction and changes in blood flow[1].

The study

The purpose of the study was to validate the performance of the single use NPWT system in a clinical setting. This was a 20 patient non-comparative study with a maximum treatment period of 14 days. The study was conducted in 2 sites in South Africa, the investigators were Professor Hudson and Dr Kevin Adams (Academy of Plastic surgery, Capetown) and Dr Adriaan van Huyssteen (Panorama Mediclinic, Capetown).

Patients were enrolled into the study with the following wounds:

- Hip or knee replacement surgery where the incision was high risk for a wound healing complication
- Moderate to highly exuding trauma wounds
- Skin grafts

The primary objective was to assess overall clinician acceptability of the NPWT device and functional performance.

Secondary objectives were clinical outcomes relating to the wound and surrounding skin and patient outcomes (Pain and acceptability).

Methods

The study protocol was reviewed and approved by the South African Medical Association Research Ethics Committee (SAMAREC) prior to the study commencing and patient informed consent was taken from all patients prior to their participation in the study.

A total of 20 patients were recruited into the study from the two centres between 3rd August 2010 and 19th November 2010. There were 9 (45%) male and 11 (55%) female patients with a mean age of 55.2 years (range 27-79). The mean BMI was 30.9Kg/m^2 (range 21.8-44.3). Sixteen (80%) patients had surgical wounds, two (10%) patients had traumatic wounds and two (10%) patients received meshed split thickness skin grafts (STSG).

Assessments

Initial assessments were made of patient demographics, medical history and details of surgical procedure and wound assessment. Daily assessments of the device functionality (interventions required, maintenance of vacuum, dressing seal, alarm) were conducted, photographs taken and wound assessments were made at each dressing change over the 14 day treatment period (level of exudate, wound infection and clinical signs of infection, condition of surrounding skin and level of wound pain).

Results[2]

For the primary objective a clinician satisfaction rating of 95% very satisfied/satisfied was obtained with the performance of the device at the end of the treatment period (see figure 1).

The mean study duration was 10.7 days and the mean dressing wear time per individual patient was 4.6 days ranging from 7.7 for patients with no exudate at baseline, to 3.5 days for patients with moderate exudate. Figure 2 shows the ease of use assessment ratings and Figure 3 shows the wound progress assessments at the study discontinuation.

The vacuum was reported as being maintained in 191 (90%) of 212 assessments. The battery was functioning in 209 (99%) of 212 assessments.

There was no damage caused to the wound on removal of device at 98% of dressing changes and only 2% incident of slight damage. There was no damage to the surrounding skin on removal of device in the majority (91%) of cases with 7% slight damage and 2% severe damage.

There were no non-serious adverse device effects. There was one adverse device effect observed in the study which was detailed as small blister like lesions around the wound associated with removal of the fixation strips.

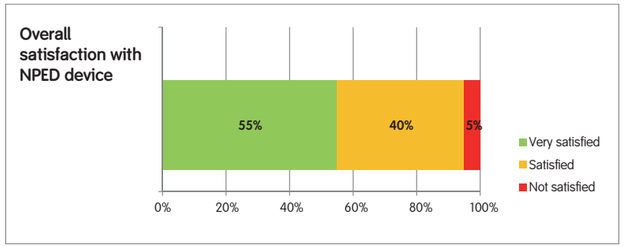


Figure 1

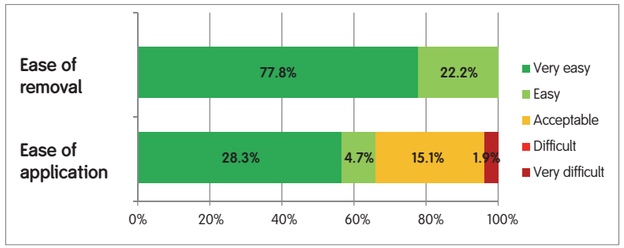


Figure 2

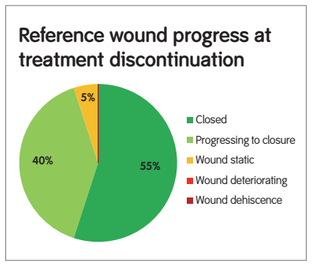


Figure 3

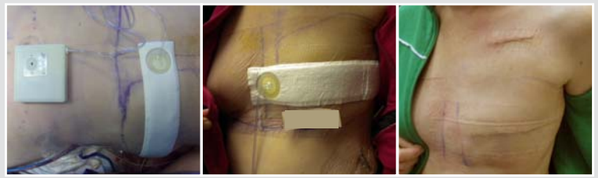
Patient outcome objective	%
Single use NPWT system* rated acceptable to patient	**100%**
Patient comfortable during wearing single use NPWT system*	**99%**
No pain at single use NPWT system* dressing application	**93%**
No pain on single use NPWT system* dressing removal	**89%**

Table 1

Discussion

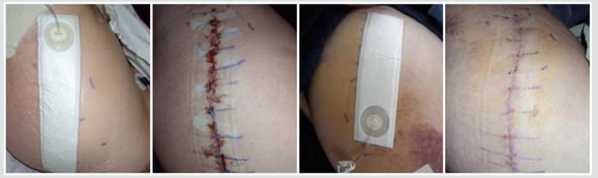
This was the first clinical study performed on this single use NPWT system. Patient and clinician satisfaction were high and no new risks were identified. The expected reduced costs, ease of use and increase mobility of patients using this single use NPWT system, may enable existing NPWT benefits to be available to greater proportion of those patients who would benefit from NPWT.

Figure 4: Case study 1.01 – Breast surgery



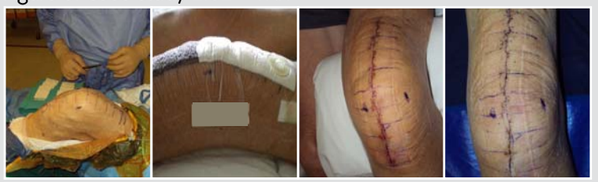
Day 0 Day 5 Day 11

Figure 5: Case study 2.01 – THR



Day 1 Day 3 Day 5 Day 10

Figure 6: Case study 2.02 – TKR



Day 0 Day 4 Day 6 Day 13

References

1. Poster SAWC 2011 Assessment of a simplified NPWT device in pre-clinical studies, E Huddleston
2. Smith & Nephew data on file reference (OR-DOF/012-14)

*"PICO" Single Use Negative Pressure Wound Therapy System – Smith & Nephew Wound Management, St. Petersburg, Florida. 510k pending with FDA.

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