Pre-clinical assessment of a simplified NPWT device*  

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**Introduction**  

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 NPWT device (referred to as simplified NPWT) is lightweight, single use and needs no eschar preparation. This device is therefore ideally suited for delivery of NPWT to outpatients, patients at home and patients who do not want to have restricted mobility.

Pre-clinical studies were undertaken in an established porcine model to determine whether the device functioned in the same way as larger, conventional NPWT devices, prior to testing in a 20 patient non-comparative clinical trial (reported separately). Experiments were designed to test some of the key mechanical and biological properties of a NPWT system: pressure transmission to the wound bed, tissue contraction and altered patterns of blood flow.

**Methods**  

Experiments were performed using a porcic peripheral wound model (n=8). Full thickness circular wounds were created (6cm wide by 2cm deep) on the back. Wound cavities were filled with either polyurethane foam or gauze according to clinical recommendations for use, or left unfilled. Wounds were then covered with either the simplified NPWT dressings or a standard NPWT drape and wound drain combination (Charlenk-Jeter method) and connected either directly to a prototype pump (simplified NPWT device) or a conventional NPWT device (Figure 1). Devices were programmed to deliver negative pressure at -80mmHg. The following measurements were taken during application of NPWT for each dressing-device combination:

**Tissue contraction**  

Eight ink marks were tattooed around the margins of each wound with the aid of a template, at a defined distance from the wound edge. To calculate the area of the wound, the distance across the open wound between opposite marks was recorded and the area calculated in mm².

**Blood flow measurement**  

Micronuclear blood flow was measured during therapy using laser Doppler velocimetry, with a multichannel Periflux System 5000 (Perimed, Sweden) and 0.5-mm filament probes which were placed into muscle tissue at distances of 0.5cm and 2.5cm from the wound edge.

**Blood flow probes**  

Pressure probes

**Results**  

**Pressure measurement**  

To measure negative pressure at the wound bed during therapy, the tip of a saline-filled pressure catheter was sutured to the bottom of the wound (Figure 2). The pressure catheter was connected to a custom built pressure gauge on which there pressure at the bottom of the wound could be monitored.

**Simplified NPWT system (device & dressing with no filler)**  

- Blood flow probes
- Pressure probes

**Figure 2. Schematic of wound showing positions of laser doppler filament probes and pressure probes in the wound, in order to measure blood flow and wound bed pressure during therapy.**

**Figure 3.** Blood flow measurements for the simplified NPWT system (device & dressing with no filler) compared to conventional NPWT systems.

**Figure 4. The effects of a new simplified NPWT system on blood flow changes (0.5cm from wound edge) compared to conventional NPWT systems.**

**Discussion**  

The new simplified NPWT device has been tested for some of the key functional properties of NPWT systems: delivery of negative pressure to the wound bed, tissue contraction and changes in patterns of blood flow, in a pre-clinical defect model. The evidence from these studies shows that the simplified NPWT device behaves in a similar fashion to existing conventional, multi-use, electrical powered NPWT devices. The simplified NPWT device is able to deliver negative pressure to the wound bed either with or without foam gauze filters; it is able to control wound tissue, and is able to set up the same characteristic patterns of blood flow seen with other NPWT devices. It follows therefore that subject to deployment on wounds of modest size and exudate flow, the new single-use, simplified NPWT device is predicted to deliver similar clinical results to conventional NPWT devices.

**References**  