A pilot study on closed porcine incisions of a novel low-cost, solid-state NPWT device

Stephen Davis1, Jie Li1, Joel Gil1, Jose Valdes1, Michael Solis1, Alexander Higa1
John S. Buan2, PhD, Jeffery Ustin3, MD and Robin Martin4, PhD

1University of Miami Miller School of Medicine Department of Dermatology & Cutaneous Surgery P.O. Box 016250 (R-250) Miami, Florida 33101, USA
2 Aatru Medical, LLC 1301 East 9th Street, 27th Floor Cleveland, Ohio 44114, USA
3 Aatru Medical, LLC Cleveland and UH Cleveland Medical Center 11100 Euclid Ave, Cleveland, Ohio, 44106 USA
4 Robin Martin PhD Scientific Consulting, 3 Manor Farm Barns, Foggathorpe, YO86PZ, UK

Background: Randomized studies have shown that Negative Pressure Wound Therapy (iNPWT) reduces surgical site infections (SSI) or surgical site complications (SSC), by around 50%. However, the expense of single-use electromechanical pumps (EMP) (US$250-500) may limit the cost effectiveness of iNPWT. This pilot study tested a novel, low-cost-of-manufacture, non-electrical device that uses solid-state oxygen management technology (OxMT) to create and sustain a vacuum in an iNPWT dressing.

Methods: The study was conducted in pigs (n=2) using 12 stapled incision wounds (38mm long, 10mm depth) per animal. All wounds were covered with the same (pre-weighed) iNPWT dressing (length 5cm) connected either to the OxST device or a conventional EMP. Wounds (3) were harvested for each of the OxMT and EMP systems on days 1, 3, 5 and 7 for: total bacterial burden, H&E histology and exudate handling. Pressure sensors were connected to each of the (12) OxMT dressings.

Results: Over the duration of the study mean negative pressure across all OxMT dressings was -81.1 mmHg (n=9, lost 3 sensors). Exudate in the iNPWT dressings was minimal (mean 0.3015 mL n=24). Histological analysis was similar for new epithelial growth, epithelial thickness, white cell infiltration, granulation tissue and angiogenesis. Total bacterial counts for the OxMT treated wounds were significantly lower over the 7 days than the EMP treated wounds, with the difference at day 7 being approximately 1.5 log 10.

Discussion: This preliminary study on porcine incisions demonstrates that a novel, low cost iNPWT device and dressing system, utilizing a solid-state oxygen management technology, delivers comparable negative pressure therapy to existing electrical devices. Additionally, there are indications that the OxMT technology may have a beneficial effect on limiting bacterial viability in the wound.

EMP – PICO NPWT pump Smith & Nephew Inc
OxMT – Aatru iNPWT system – Aatru Medical LLC