A Novel Abdominal Negative Pressure Dressing with Automated Fluid Instillation Enhances Tissue Traction: Preclinical Evaluation in Swine

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Introduction

- Open septic abdomen management remains a significant clinical challenge, with risks of fluid imbalance, delayed fascial closure, and abdominal compartment syndrome.[1]
- Negative pressure therapy (NPT) systems have improved outcomes, but further innovation is needed to prevent fascial retraction and facilitate cleansing via an automated fluid delivery and removal system.

Purpose

- This study evaluates a novel temporary abdominal closure dressing (Novel TAC) with fluid divertor for saline instillation, compared to the current standard of care (SOC)* in a swine model.

Methods

- In accordance with federal guidelines for animal welfare,[†] eight female Yorkshire cross swine (70-110 kg) underwent midline laparotomy and were treated with SOC and Novel TAC.
- Each dressing was tested twice using -125 mmHg NPT for 15 minutes, with the addition of 500 mL saline instillation and 30-minute dwell period for the Novel TAC.
- Investigations included tissue traction (fluoroscopy), intra-abdominal pressure (via bladder pressure), core body temperature (rectal), fluid recovery (canister and dressing weights), and fluid distribution (visual/radiologic assessment).[§] After the dwell period, negative pressure was applied and fluid removed until -125mmHg was reached and stabilized (~5 minutes).

Conclusions

- This pre-clinical evaluation of the Novel TAC dressing with instillation demonstrates enhanced tissue traction and effective fluid management without compromising IAP or temperature stability when compared to the SOC.
- These findings suggest that this system may facilitate improved fluid instillation protocols and earlier fascial closure in the management of the open septic abdomen.[§]
- Further research is warranted to explore clinical translation and optimization of instillation parameters.

Reference

1. Cheatham, M.L., et al., Prospective Study Examining Clinical Outcomes Associated with a Negative Pressure Wound Therapy System and Barker's Vacuum Packing Technique. *World Journal of Surgery*, 2013. 37(9): p. 2018-2030.

Results

- The Novel TAC dressing demonstrated significant improvements in tissue traction, including 73% greater skin closure (*p<0.0001*) and 34% greater fascial closure (*p=0.0003*) [**Figure 1**].
- Intra-abdominal pressure (IAP) remained stable and well-below thresholds for intra-abdominal hypertension during negative pressure and instillation cycles [**Figure 2**].
- Core body temperature was unaffected by saline instillation, with only transient, recoverable drops in internal temperature [**Figure 3 and Figure 4**].
- Fluid recovery was highly effective, with the Novel TAC system achieving 100% recovery of instilled saline [**Figure 5**].
- Fluid distribution was observed throughout the abdomen [**Figure 6**].

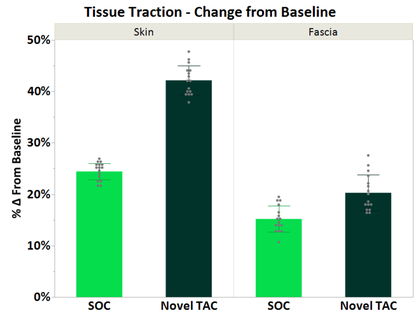

Figure 1. Novel TAC exhibited more overall tissue movement than the SOC dressing. Each dot represents a single dressing placement. There were 8 animals, and each treatment was placed twice per animal with evaluations in the superficial skin and deeper fascia (n = 16). Means ± standard deviation.

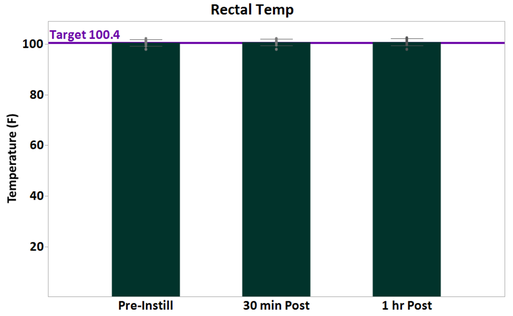

Figure 3. Results of rectal thermometer readings before, during, and after instillation of saline demonstrate that core body temperature did not decrease from target temp of 100.4 (F) after instillation of 500mL room temperature saline. Means ± standard deviation.

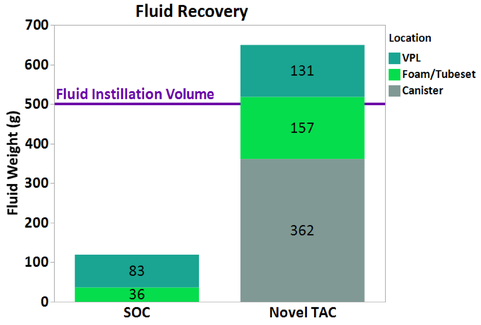

Figure 5. For SOC (no instillation), approximately 119 g of fluid was recovered overall with the majority retained in the visceral protective layer (VPL). The total volume recovered by novel TAC was 650 mL with the majority recovered in the collection canister.

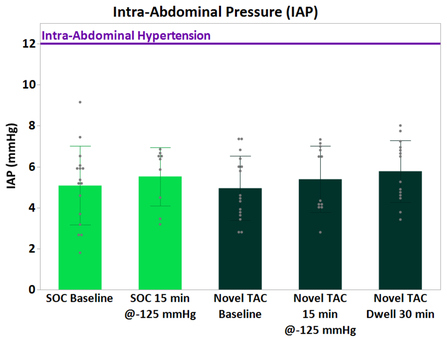

Figure 2. Intra-abdominal pressure (IAP) measurements at baseline and after 15 min of negative pressure at -125 mmHg for both SOC and Novel TAC. Novel TAC includes IAP measurements after instillation of 500 mL saline and 30 minute dwell period in the abdomen. No significant increases were observed. Means ± standard deviation.

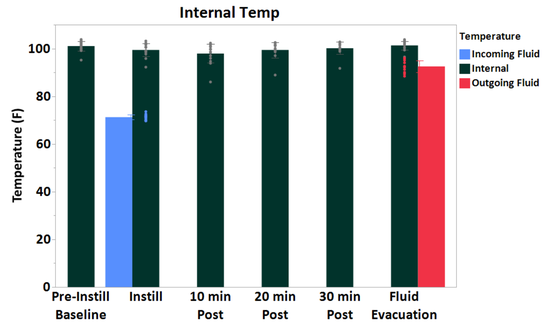

Figure 4. Average incoming fluid (blue), internal (red), and outgoing (green) fluid temperatures. The only significant difference from baseline was seen at the 10 min dwell timepoint. Means ± standard deviation.

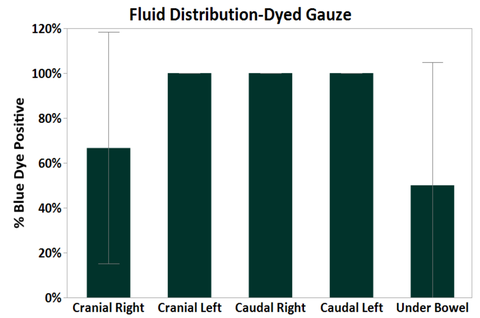

Figure 6. Fluid distribution results were determined by evaluating the presence of blue dye (Yes=100%, No=0) on gauze after a single 500 mL fluid instillation cycle.

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NOTE: Specific indications, contraindications, warnings, precautions, and safety information exist for these products and therapies, some of which may be Rx only. Please consult a clinician and product Instructions for Use prior to application.

* 3M™ AbThera™ SensaT.R.A.C.™ Open Abdomen Dressing (Solventum, St. Paul, MN).
[†]In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture.
[‡]This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs, in the amount of $34,191,124, through the Defense Health Agency Expeditionary Medicine Research and Development Program under Award No. HT94252320059. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.
[§]The novel temporary abdominal closure dressing (Novel TAC) with fluid diverter for instillation of saline into the open abdomen has not been cleared by FDA and the safety and effectiveness of this Novel TAC has not been established.
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