

# Pressure at the Bowel Surface during Topical Negative Pressure Therapy of the Open Abdomen: An Experimental Study in a Porcine Model

Thordur Bjarnason · Agneta Montgomery ·  
Joanna Hlebowicz · Sandra Lindstedt ·  
Ulf Petersson

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## Abstract

**Background** Topical negative pressure (TNP) therapy is increasingly used in open abdomen management. It is not known to what extent this pressure propagates through the dressing to the bowel surface, potentially increasing the risk of bowel fistula formation. The present study in a porcine model was designed to evaluate pressure propagation.

**Methods** A commercially available TNP therapy system (ABThera/VAC) was applied in six pigs after laparotomy. Pressure sensors were placed in predetermined positions in the dressing and in the abdominal cavity and the pressure was registered at TNP settings of  $-50$ ,  $-75$ ,  $-100$ ,  $-125$ , and  $-150$  mmHg. Next, after infusing 200 ml of saline into the abdomen through a catheter, the amount of fluid drained through the system during 10 min of TNP therapy was registered. Finally, pressure was measured above and below eight layers of paraffin gauzes during TNP therapy.

**Results** Observed pressure within the outer two foams and the foam of the visceral protective layer correlated with preset TNP. The median pressure at the bowel surface was between  $-2$  and  $-10$  mmHg, regardless of preset TNP. Median fluid drainage was 95% of the infused fluid

at  $-75$  mmHg and 124% at  $-150$  mmHg. Paraffin gauzes had a limited isolating effect, reducing the pressure by 13% in median.

**Conclusions** Negative pressure reaching the bowel surface during TNP therapy with the ABThera system is limited for all TNP levels. Reduced therapy pressure does not lead to reduced pressure at the bowel surface. The system drains the abdominal cavity completely of fluid. Paraffin gauzes are of limited value as a means of pressure isolation.

## Introduction

There is an increasing trend toward managing certain surgical emergencies with open abdomen (OA) or laparostomy [1, 2]. For patients with an abdominal compartment syndrome, decompression laparotomy may be life-saving [3, 4]. Bowel edema or retroperitoneal hematoma may render abdominal closure after emergency laparotomy impossible, necessitating OA treatment. In damage control situations for trauma or in patients with abdominal sepsis, where short operation time is essential and a second-look laparotomy scheduled, OA treatment can be a feasible alternative [5, 6]. Furthermore, wound dehiscence may benefit from treatment with a temporary OA and delayed fascial closure [7].

There are several potential drawbacks associated with OA therapy, such as the risk of damage to the exposed bowel and practical difficulties associated with high fluid losses and cumbersome dressing changes [8, 9]. A large incisional hernia is often the end result due to loss of domain and adhesion formation between viscera and the abdominal wall that make primary fascial closure

T. Bjarnason (✉) · A. Montgomery · U. Petersson  
Department of Surgery, Lund University, Skåne University  
Hospital, 205 02 Malmö, Sweden  
e-mail: thordur.bjarnason@skane.se

J. Hlebowicz  
Department of Medicine, Lund University, Skåne University  
Hospital, 205 02 Malmö, Sweden

S. Lindstedt  
Department of Thoracic Surgery, Lund University,  
Skåne University Hospital, 221 85 Lund, Sweden

impossible [10]. For these reasons, it is crucial to establish temporary abdominal closure that protects the bowel and maintains abdominal domain boundaries. Topical negative pressure (TNP) therapy offers a practical way of managing the OA, avoiding many of the possible problems [11–15]. At the same time, however, concerns have been raised about using negative pressure in this setting, because of the potential risk of harmful effect of the negative pressure on the bowel wall and development of entero-atmospheric bowel fistula [16, 17]. It is not known to what extent applied TNP is spread through the dressing to the surface of the underlying bowel. The ideal TNP dressing would protect the bowel from the negative pressure while simultaneously facilitating drainage of the abdominal cavity. Abscess formation in the abdominal cavity is a common complication after bowel perforation with bacterial peritonitis. Thorough draining of the abdominal cavity, preventing collection of contaminated fluid, is therefore an important aspect of OA therapy.

Topical negative pressure can be applied on the open abdomen using a “home-made” arrangement of dressings and vacuum suction, or with one of several commercially available systems. The most commonly used system on the market is the Abdominal VAC (KCI, Inc., San Antonio, TX), which is currently being replaced by a modified version, the ABThera open abdomen negative pressure therapy system (same manufacturer).

Paraffin impregnated gauze dressings, commonly used to avoid adhesions to wound tissue, may also have a pressure-isolating effect, with the paraffin acting as a barrier. Protection with paraffin gauzes could allow TNP to be safely used on an OA containing exposed bowel. In a recent study on TNP therapy after thoracic surgery, it was shown that four layers of paraffin gauze dressing reduced the delivered pressure by an average of 31 mmHg [18]. For the present experiment, it was decided to use eight layers in an attempt to ensure total coverage with paraffin and thus maximize the possible effect.

In summary, the primary aim of this experimental study was to describe the extent of pressure propagation through the dressing into the abdominal cavity at different levels of therapy pressure. Second, it was intended to measure the efficacy of the TNP system in draining fluid from the abdominal cavity and third, we sought to determine whether paraffin gauzes limit the propagation of negative pressure during TNP therapy.

## Materials and methods

The study was approved by the ethical committee on animal experiments in Malmö/Lund, Sweden.

## Animal preparation

Six domestic pigs of both genders with a median weight of 58 kg (range: 52–62 kg) were used. The animals were housed in the laboratory facilities for three to 5 days before the experiment. Preoperatively, they were fasted overnight but given free access to water. They were sedated with xylazine (0.05 mg/kg; Rompun vet., Bayer AG, Leverkusen, Germany) and ketamine (20 mg/kg; Ketaminol vet., Intervet/Merck & Co., Inc., Whitehouse Station, NJ) intramuscularly, and an intravenous (IV) line was placed in an ear vein. Anesthesia was induced with an IV injection of thiopental (5 mg/kg; Pentothal, Natrium, Hospira, Inc., Lake Forest, IL) and maintained with IV propofol (8 mg/kg/h; Propofol-Lipuro, B. Braun Melsungen AG, Melsungen, Germany) and fentanyl (0.15 mg/kg/h; Fentanyl B. Braun, B. Braun Melsungen AG, Melsungen, Germany). The animals were intubated with a 7.5 mm, cuffed endotracheal tube and mechanically ventilated (Servo 900c, Siemens, Munich, Germany) using a minute volume of 100 ml/kg, a ventilatory rate of 16/min, and a positive end-expiratory pressure of 5 cm H<sub>2</sub>O. A mixture of oxygen (O<sub>2</sub>) and nitrous oxide (N<sub>2</sub>O) was used (30/70%). One liter of buffered glucose 2.5 mg/ml was administered IV over 3 h. Depth of anesthesia was monitored by measuring heart rate and response to pain stimuli at regular intervals.

## Equipment

The ABThera open abdomen negative pressure therapy system (KCI, Inc., San Antonio, TX) was used in the experiment and is shown in Fig. 1. The vacuum pump intended to be used with the ABThera system (the ABThera negative pressure therapy unit) can only be set to a negative pressure of –100, –125, or –150 mmHg. To be able to measure the effects of TNP settings in the range of –50 to –150 mmHg, a VAC ATS Therapy Unit was used instead, along with the corresponding interface pad and tubing set (TRAC Pad).

Pressure was measured with saline-filled pressure catheters (Codman & Shurtleff, Inc., Raynham, MA) connected to an external, calibrated, custom-built pressure gauge.

## Experimental procedure

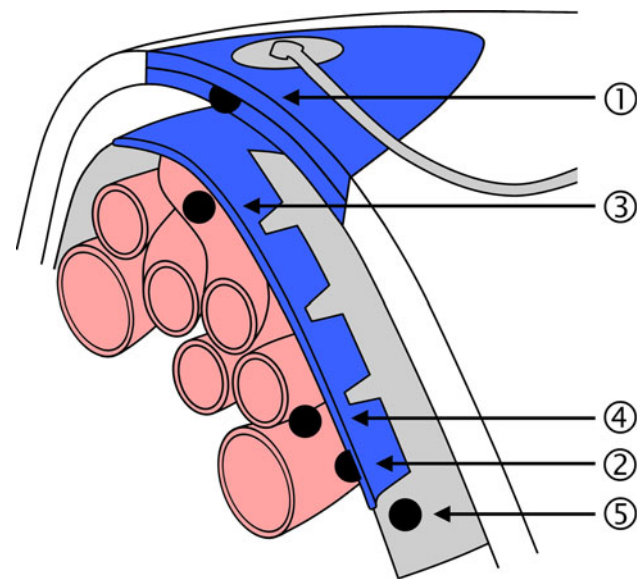
A 30 cm midline incision was performed. A suprapubic urinary catheter was inserted. Another catheter was placed in the pelvis for saline infusion. The visceral protective layer (VPL) was trimmed down to cover the entire inside area of the abdominal wall (about 30 × 35 cm). Five pressure catheters were inserted through the abdominal wall and connected to the pressure gauge. The tips of the catheters



**Fig. 1** ABThera open abdomen negative pressure therapy system. 1 A visceral protective layer (ABThera open abdomen dressing): a polyurethane foam with six radiating foam extensions enveloped in a polyethylene sheet with small fenestrations to be placed within the abdominal cavity between the viscera and the abdominal wall. 2 Two polyurethane foams (ABThera perforated foam) for placement on top of the visceral protective layer between the wound edges. 3 Self-adhesive polyethylene drapes (ABThera drape) for air-tight coverage of the wound. 4 A tubing set with an interface pad (ABThera tubing set) to be attached onto an opening in the drapes and connected to the vacuum source. 5 A vacuum source (ABThera negative pressure therapy unit) delivering adjustable, calibrated negative pressure, not shown in picture

were positioned as shown in Fig. 2. Catheter positions were secured with a suture where necessary. The fenestrations of the VPL are close together, and exact positioning of the catheter tips in relation to the fenestrations was not possible to obtain in a practical way. Care was taken to place the catheters without tension and in such a way that the tips would not penetrate a fenestration. The dressing was secured in position by suturing the lateral part of the foam arms to the abdominal wall. Two polyurethane foams were cut to fit between the wound edges (about  $11 \times 25$  cm) and placed on top of each other above the VPL. The area was covered with self adhesive drapes and connected to the negative pressure unit via the interface pad.

The pressure was measured in each position at five different TNP settings:  $-50$ ,  $-75$ ,  $-100$ ,  $-125$ , and  $-150$  mmHg. The registered pressure was the mean value of three consecutive readings. The pressure was allowed to neutralize before changing to a different TNP setting. The positions of the pressure sensors were confirmed when the VPL was removed.



**Fig. 2** Positions of pressure sensors. 1 Centrally above the visceral protective layer, between the two polyurethane foams, 5 cm cranially of the interface pad. 2 Laterally within a foam extension on the right side, 15 cm from the center of the dressing. 3 Centrally between the visceral protective layer and the viscera. 4 Laterally between the visceral protective layer and the viscera, under the upper right foam arm, 15 cm from the center of the dressing. 5 Laterally, between the visceral protective layer and the abdominal wall, 15 cm from the center of the dressing

A total of 200 ml of physiological saline (9 g/l) was infused into the abdominal cavity through the pelvic catheter, and the TNP was set to  $-75$  mmHg. After 10 min, the drained volume was registered. The pressure was allowed to neutralize and the procedure then repeated at a TNP setting of  $-150$  mmHg. At the end of the experiment the abdominal cavity was inspected for any remaining fluid.

The VPL was removed and  $10 \times 30$  cm sheets of paraffin gauze dressing (Jelonet, Smith & Nephew, London, England) in eight layers were placed on top of the bowel, directly underneath the two subcutaneous foams. Pressure catheters were positioned at two locations: (1) on the small bowel surface under the paraffin gauzes, 5 cm cranially of the interface pad, and (2) above the paraffin gauzes directly under the subcutaneous foams, 5 cm cranially of the interface pad. Measurements were then carried out for each of the five different pressure settings in the same manner as described above. At the end of the experiment the positions of the sensors were confirmed.

When the measurements were completed, the animals were euthanized with an IV administration of 80 mEq of potassium chloride.

#### Statistics

Statistical analysis was done with SPSS Statistics 17.0 (SPSS Inc., Chicago, IL) software. Results are presented as

median and range unless otherwise stated. Spearman's rank correlation coefficient ( $\rho$ ) was used for calculating correlations, and Wilcoxon's signed rank test was used for comparing paired observations. Differences were regarded as statistically significant when the  $P$  value was  $< 0.05$ .

## Results

### Pressure measurements

The pressure registrations for the five different negative pressure settings at each of the five sensor positions (Fig. 2) are summarized in Fig. 3.

#### Sensor positions 1 and 2

The pressure between the two subcutaneous foams (position 1) and within the foam extension laterally (position 2) is shown in detail in Fig. 4. The observed pressure correlated significantly with the TNP setting of the negative pressure unit for all animals ( $\rho \geq 0.900$ ,  $P \leq 0.037$ ). The median observed pressure was over 75% of the applied TNP at all settings. Correct position of the pressure sensors was confirmed at the end of the experiment.

#### Sensor position 3

Between the VPL and the viscera centrally (position 3), the median values of the observed pressure at the five different TNP settings varied between  $-3$  and  $-10$  mmHg (Fig. 3). The lowest measured pressure varied between  $-10$  and

$-15$  mmHg. The observed pressures did not correlate significantly with the applied TNP, except in animal number six ( $\rho = 0.949$ ,  $P = 0.014$ ). Correct position of the pressure sensors was confirmed at the end of the experiment.

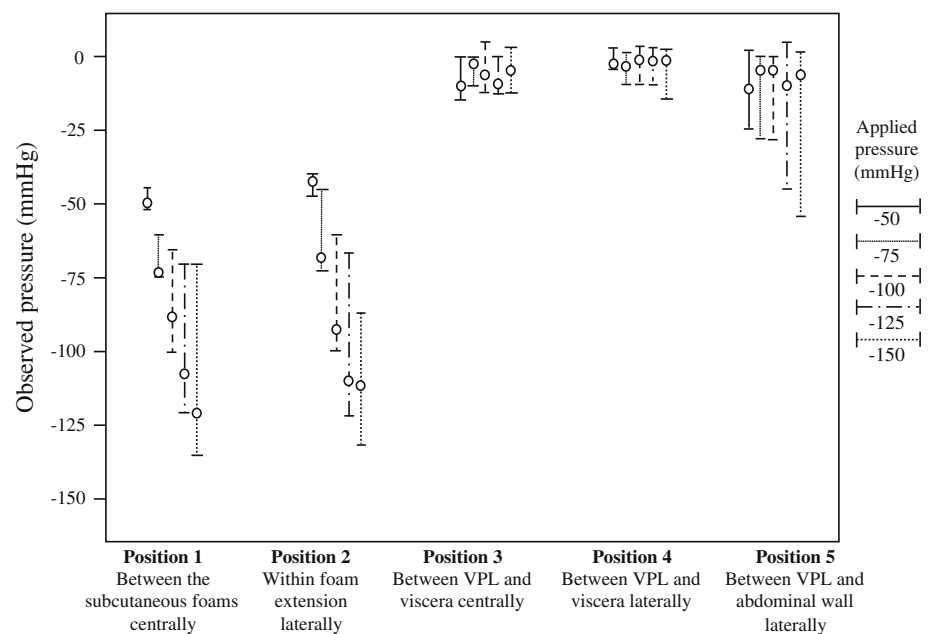
#### Sensor position 4

Between the VPL and the viscera laterally (position 4), the median values varied between  $-2$  and  $-5$  mmHg (Fig. 3). The lowest measured pressure varied between  $-5$  and  $-15$  mmHg. The observed pressure correlated significantly with the applied TNP for animals one, two, and five ( $\rho = 0.900$ ,  $0.894$ , and  $0.949$ ;  $P = 0.037$ ,  $0.041$ , and  $0.014$ , respectively) but not for the others. Correct position of the pressure sensor was confirmed at the end of the experiment.

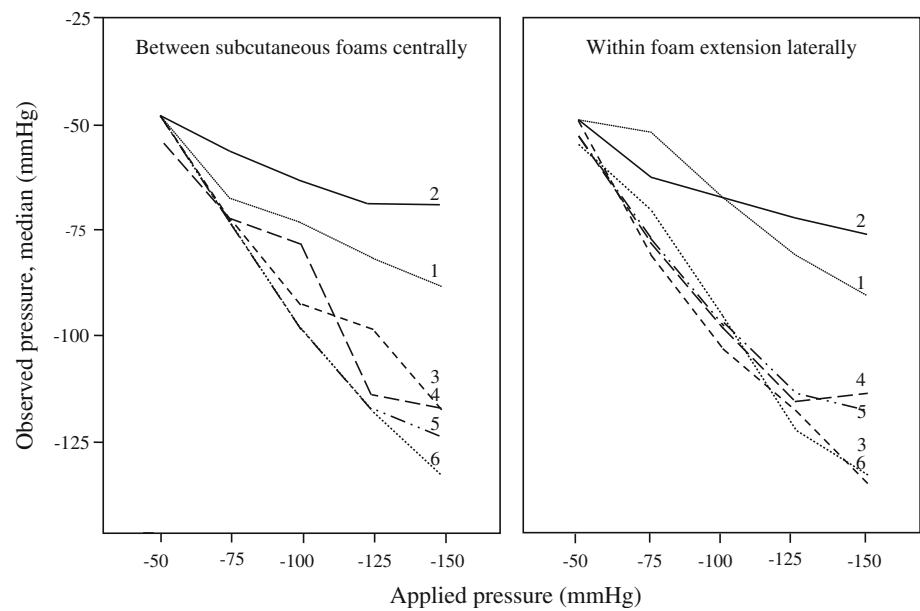
#### Sensor position 5

Between the VPL and the abdominal wall laterally (position 5) the median values varied between  $-5$  and  $-12$  mmHg for the different TNP settings. The minimal values varied between  $-2$  and  $-60$  mmHg (Fig. 3). The observed pressure correlated significantly with the applied TNP for animals three and six ( $\rho = 0.975$ ,  $P = 0.005$  and  $\rho = 1.000$ , respectively) but not for the others. Animals five and six differed from the others with an observed pressure between  $-25$  and  $-60$  mmHg, compared to the median pressure of  $-5$  to  $-12$  mmHg. In both of these cases the pressure catheter tips were found to be dislodged (medially toward the subcutaneous foams in one and toward a fenestration of a foam extension in the other).

**Fig. 3** Observed pressure (median and range) at sensor positions 1–5 for each topical negative pressure (TNP) setting. VPL visceral protective layer



**Fig. 4** Pressure between the two subcutaneous foams centrally and within a foam extension laterally. Results for all six animals are shown for each TNP setting



In all other cases, the position of the pressure sensor was found to be correct.

#### Fluid drainage

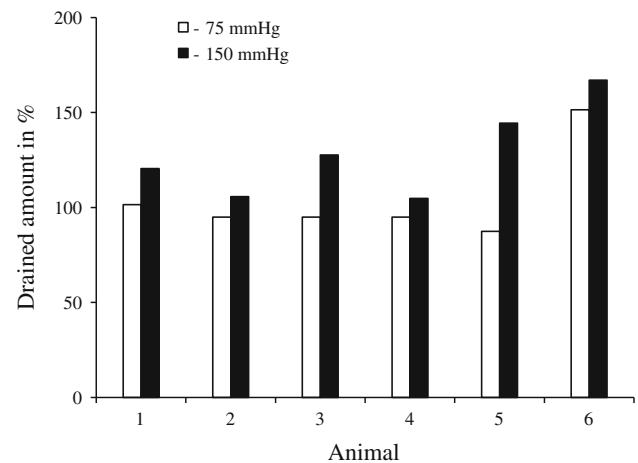
After 10 min of therapy with a TNP of  $-75$  mmHg, 95% (88–152%) of the infused 200 ml of saline had been drained from the abdominal cavity (median, range). With the TNP set to  $-150$  mmHg, the drained amount corresponded to 124% (105–167%) of the infused volume (Fig. 5). This difference was statistically significant (Wilcoxon;  $P = 0.028$ ). No residual fluid was seen in the abdominal cavity at the end of the experiment in any of the animals.

#### Isolating effect of paraffin gauze

Pressure reduction by eight layers of paraffin gauze (Fig. 6) was statistically significant only at a TNP setting of  $-125$  mmHg (Wilcoxon;  $P = 0.041$ ). The median pressure reduction was 13% and the maximal single measurement was a reduction of 28%.

#### Discussion

Managing the OA with TNP therapy has several potential advantages. If correctly applied, the innermost layer of the dressing shields the bowel, prevents evisceration (loss of domain), and prevents adhesions of the viscera to the abdominal wall. The negative pressure helps to remove wound fluid and debris, reduces bacterial load, and counteracts retraction of the wound edges [19–21]. These

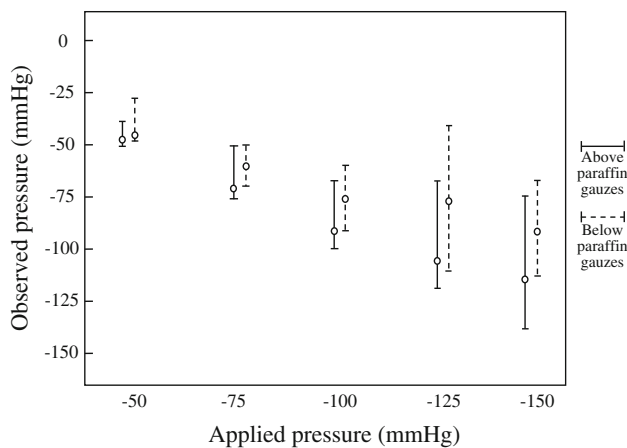


**Fig. 5** Fluid drainage from the abdominal cavity, shown for each of the six animals. Drained amount is expressed as a percentage of the volume previously infused through a pelvic catheter

factors help create a closed, physiological wound environment and contribute to subsequent fascial closure. By continuously removing excess wound fluid, frequent, time-consuming dressing changes can, in many cases, be avoided, leading to reduced nursing workload and improved patient comfort.

There are, however, ongoing discussions among surgeons whether the use of TNP in OA treatment is safe in terms of fistula development [16, 17]. The risk of bowel injury and fistula formation is inherent in open abdomen therapy itself, with the bowel exposed to desiccation, potentially harmful wound fluids, manipulation during dressing changes, and friction against the dressing. In addition, in patients where OA therapy is warranted, multiple morbidities such as bowel ischemia, infections, and/or





**Fig. 6** Isolating effect of paraffin gauze in eight layers. Median pressure and range is shown for each TNP setting

multiple organ failure commonly exist, which increases the risk of injury or fistula formation even further. Different techniques of managing the OA may influence the risk of fistula formation differently. In a recently published meta-analysis [22], where different temporary abdominal closure methods were compared, the V.A.C. technique was not associated with a higher risk of fistula formation. Existing studies are different with regard to underlying pathology, age, and co-morbidity of the patients included, as well as criteria for OA therapy and management with TNP. Consequently, it is difficult to interpret whether the development of fistula is caused by or coincides with TNP therapy [22–24]. If TNP therapy is to be regarded as an independent risk factor for fistula formation, the applied negative pressure must to some extent reach the bowel surface and cause tissue damage.

In the present study, applied TNP was found to conduct well through the outer subcutaneous foams and along a foam extension of the VPL. At these locations, the observed pressure correlated statistically with the preset therapy pressure, with all observed values corresponding to more than 75% of the applied pressure. This demonstrates that a significant negative pressure is maintained within the foam, and it is reasonable to believe that fluid reaching the foam will be drained by the negative pressure.

The negative pressure observed at the bowel surface was substantially reduced, compared to the preset values, for all TNP settings, indicating that the visceral protective layer effectively isolates the bowel from the negative pressure. The lowest single measurement at the bowel surface was  $-15$  mmHg. It is unclear if this level of negative pressure at the bowel surface is harmless or not. Further studies are necessary to determine whether low-magnitude negative pressure can cause tissue damage if applied over long periods to vulnerable bowel due to, e.g., existing ischemia, bowel dilatation, new anastomoses, or infections. The

observed pressure at the bowel surface did not correlate with the level of applied TNP. In other words, reducing the therapy pressure from the  $-125$  mmHg, which is the level recommended by the manufacturer, would not lead to reduced pressure at the bowel surface.

The negative pressure under the abdominal wall outside the VPL was minimal in four of the six pigs. In two animals, however, pressure between  $-25$  and  $-60$  mmHg was observed. This may have been a normal variation between individual animals but, as described previously, the pressure catheter tips were found to be slightly dislodged in both cases, which could be another explanation for the findings. The results indicate that negative pressure outside the VPL diminishes rapidly with increased distance from the wound edges. Further investigation with radially placed pressure sensors would be necessary in order to describe this in more detail.

Intra-abdominal fluid was effectively drained with the ABThera system at both  $-75$  and  $-150$  mmHg TNP. Frequently, more fluid was drained than the infused amount, indicating transudation of fluid from the peritoneum during the treatment (in this setting without peritoneal inflammation). In all cases, we found the abdominal cavity to be free of fluid after 10 min of treatment with the higher pressure setting. A TNP setting of  $-150$  mmHg might therefore be suggested for a more complete drainage of the abdominal cavity, potentially minimizing the risk of intra-abdominal collections of fluid and debris that could lead to abscess formations.

The study showed a modest isolating effect of the paraffin gauzes, statistically significant only at TNP of  $-125$  mmHg. The median pressure reduction was 13% and the maximal single measurement was 28%. This must be considered insufficient to protect underlying bowel from applied topical negative pressure. Paraffin gauzes or other non-adherent dressings may, however, have a protective effect by preventing adhesions between the foam and underlying tissue and thus reducing the risk of tearing during dressing changes. These dressings are an alternative in the management of an adherent OA, when the VPL cannot be applied because of adherence between the bowel and the abdominal wall (frozen abdomen) and continued TNP therapy is desirable. Topical negative pressure has also been used in the treatment of established entero-atmospheric fistulae [25, 26], mostly with the intention of keeping the surrounding wound clean and free from fistula secretion. In these cases, a non-adherent dressing was used to cover the bowel surface surrounding the fistulae before TNP was applied.

In summary, the results from this study show that the visceral protective layer of the ABThera dressing effectively isolates the viscera from TNP during OA treatment in healthy pigs. It was found that TNP with the ABThera

system thoroughly drains fluid from the abdominal cavity, and that paraffin gauzes are of limited value as a means of pressure isolation.

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