

A Comparison of the Biomechanical Performance of 3 Negative
Pressure Wound Therapy Foams

Daniel J. Gibson

Deposited 2023-09-27

Citation of published version:

Gibson, D. J. (2021). A Comparison of the Biomechanical Performance of 3
Negative Pressure Wound Therapy Foams. In *Journal of Wound, Ostomy &
Continence Nursing* (Vol. 49, Issue 1, pp. 51–58). Ovid Technologies (Wolters
Kluwer Health). <https://doi.org/10.1097/won.0000000000000833>

©2022

This work is licensed under a Attribution-NoDerivatives 4.0 International (CC BY-ND 4.0) license.





OPEN

A Comparison of the Biomechanical Performance of 3 Negative Pressure Wound Therapy Foams

Daniel J. Gibson

ABSTRACT

PURPOSE: The purpose of this study was to compare 3 foam dressings to (1) determine the biomechanical performance of existing negative pressure wound therapy (NPWT) foams and (2) to determine if a test foam is possibly suitable as an antimicrobial “white” foam alternative for use in NPWT.

DESIGN: A comparison of mechanical performance of 3 foams used for vacuum-assisted NPWT.

SUBJECTS AND SETTING: Preclinical laboratory study using an in vitro model.

METHODS: The performance of a “white” foam (polyvinyl alcohol [PVA]), an antimicrobial “black” foam (polyurethane [PU]), and an antimicrobial white foam alternative (test PVA) were tested and compared using 3 mechanically relevant criteria. First, the fluid removal rate was measured for 72 hours. Next, the pressure input was compared to the pressure directly beneath the center of the foam. Finally, the spread of negative pressure beneath the foam was measured and compared.

RESULTS: Significant differences were found in fluid removal rates; specifically, the PU foam removed fluids faster than the PVA and test PVA foams, and the currently available PVA foams performed similarly. Both the PU and test PVA foams were able to transmit the negative pressure through the center of the dressing, while the typical PVA foam began failing at 140 mm Hg, with 50% of the samples failing at 200 mm Hg. All PU replicate foams evenly distributed the pressure, while 47% to 60% of the test PVA foams and 7% of the typical PVA foams distributed pressures evenly.

CONCLUSIONS: Study findings suggest that the test PVA foam does not mechanically interfere with NPWT and performs equivalently to currently used foams. These results suggest that the test PVA may be modified and incorporated into a vacuum-assisted NPWT device. In addition, the methods employed in these experiments provide a reproducible means to compare biomechanical compatibility of various NPWT foams, dressings, and subdrape devices.

KEY WORDS: NPWT, NPWT design, NPWT dressings, NPWT testing.

INTRODUCTION

Negative pressure wound therapy (NPWT) is a popular treatment option for a variety of chronic wounds, surgical incisions, and related conditions such as enterocutaneous or enteroatmospheric fistulae.¹⁻⁸ The primary principle underlying NPWT, application of suction to a wound to promote healing, traces its roots to antiquity.¹ The technology has evolved beyond the use of dedicated people who would use their mouths to suck on open skin wounds to the use of bell jars and hand pumps, which would mitigate the unsanitary practice of wound sucking. Modern technology now employs systems that range from simple manually actuated pumps (“mechanical” NPWT) or electrically powered and control system-regulated pumps.²

The interface with the patient has likewise evolved from lips to glass jars to a flexible drape and a subdrape material (typically

a foam-based material).⁹ The flexible, airtight drape allows the system to conform to the complex surfaces of the body while enhancing the potential for customization of the area where suction is applied. However, this flexibility comes at the cost of requiring a subdrape material that can maintain a conduit between the wound and the vacuum source. In the absence of a subdrape foam, the drape would seal onto the wound in a manner comparable to the vacuum-sealing technologies employed in food preservation. In addition, a modified drape was evaluated and reported to function at lower suction pressures without a subdrape material.³ Nevertheless, the authors acknowledged this system operated at lower suction levels. The most frequent subdrape materials used in modern NPWT systems are foams, with the black polyurethane (PU) foam being the first, followed by “white” and then “green” foams. Other nonfoam materials such as cotton gauze are used, and a variety of materials are being developed and tested for possible incorporation into vacuum-assisted NPWT systems.³⁻¹¹

Research in vacuum-assisted NPWT technologies has also evaluated subdrape materials with the intention of expanding the clinical utility of this component of the NPWT system.¹¹ The first example comprised a silver-impregnated version of the black foam designed to provide antimicrobial activity. Another subdrape material is designed to maintain the potential benefits of “microdistortions” found to occur with the black foams, without the pain and potential adverse effects associated with tissue penetration and embedding when black foam remains in contact with the skin over a period of hours to days.⁴

Daniel J. Gibson, PhD, Capstone College of Nursing, University of Alabama, Tuscaloosa.

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

Correspondence: Daniel J. Gibson, PhD, Capstone College of Nursing, University of Alabama, 650 University Blvd E, Tuscaloosa, AL 35401 (dgibson1@ua.edu).

DOI: 10.1097/WON.0000000000000833

Purpose

The purpose of the experiments described in this article is to determine whether a test PVA foam dressing (Hydrofera Blue; Hollister Inc/Hydrofera, LLC, Libertyville, Illinois, and Manchester, Connecticut) might be used with vacuum-assisted NPWT devices. Specifically, I subjected a currently available polyvinyl alcohol (PVA) “white-like” foam with antimicrobial properties to early-stage laboratory testing to determine if it could provide equivalent mechanical performance to 2 currently available white foams with an ultimate goal of addressing the white foam’s lack of antimicrobial activity. I searched the literature but found no experiments describing preclinical comparisons of NPWT subdrape materials. Therefore, I developed a new approach and used it to compare foams using a bell jar–like setup, black foam, white foam, and antibacterial PVA (“purple” foam).

I then completed a series of experiment that compared the fluid removal rates of 2 currently marketed NPWT foams. I then compared these findings to the test foam. My next step was to determine if the negative pressure from the NPWT pump is communicated through the center of the 3 foams. Finally, I used an array of pressure sensors to determine the extent that the 2 standard foams are able to distribute the negative pressure over the area beneath the foams and to determine if test foam’s performance was comparable.

MATERIALS AND METHODS

A review of the literature revealed an approach that monitored the fluid distribution throughout the subdrape material.¹² However, this approach was limited in that it sought to only directly measure the spread of fluid throughout the subdrape

material but not its ability to remove fluid. In addition, I found that the methods used in these experiments did not measure pressure distribution beneath the subdrape. Therefore, I designed a customized set of 4 tabletop devices enabling the experiments described in this article. An aluminum frame was used to support a Delrin table with a patterned grid of holes. In one experiment, the holes were manifolded with tubes and connectors, and 50% serum was fed into the dressing from beneath to measure fluid removal rates (Figure 1). In another experiment, these holes were attached to an array of pressure sensors to measure the vacuum pressure beneath the dressing (Figure 2). All NPWT pumps and accessories are considered to be substantially equivalent by the Food and Drug Administration; therefore, I selected foams currently used in the clinical practice setting.

In all the experiments described in this article, I used the Renesys EZ Plus NPWT systems (Smith & Nephew, London, England). The performance of the NPWT pump was monitored by an in-line calibrated pressure sensor (described later). Generic in-line filters and fluid traps were directly attached to the vacuum source. I also used commercially available clinical kits with drapes, subdrape foams, and tubing (KCI, San Antonio, Texas). Three different subdrape foams were tested: (1) an antibacterial PU foam dressing, referred to here as “typical PU foam” (Granufoam Silver; KCI); (2) a PVA foam dressing, referred to here as “typical PVA foam” (WhiteFoam; KCI); and (3) an antibacterial PVA foam dressing, referred to here as “test PVA foam” (Hydrofera Blue Heavy Drainage; Hydrofera, Wilimantic, Connecticut). The subdrape foams for each group were pulled from at least 3 manufactured lots (we used at least 5 subdrape foams per lot) that were packaged and ready for sale. We acquired and tested a total of 17 typical PU foams,

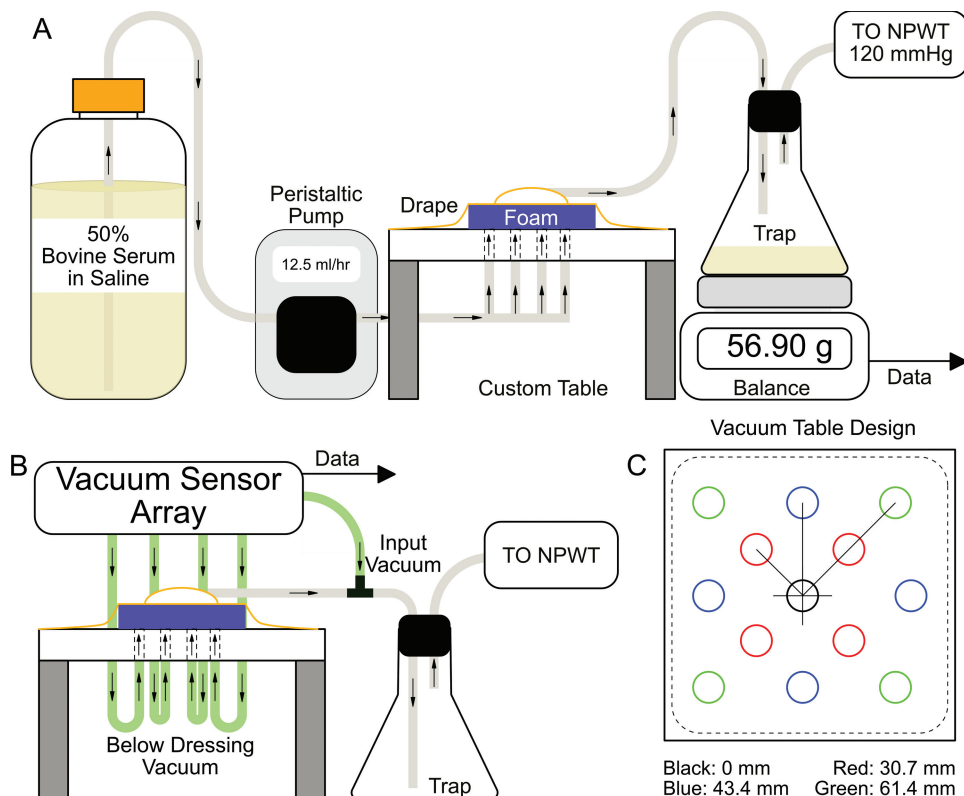


Figure 1. The fluid removal model. NPWT indicates negative pressure wound therapy.

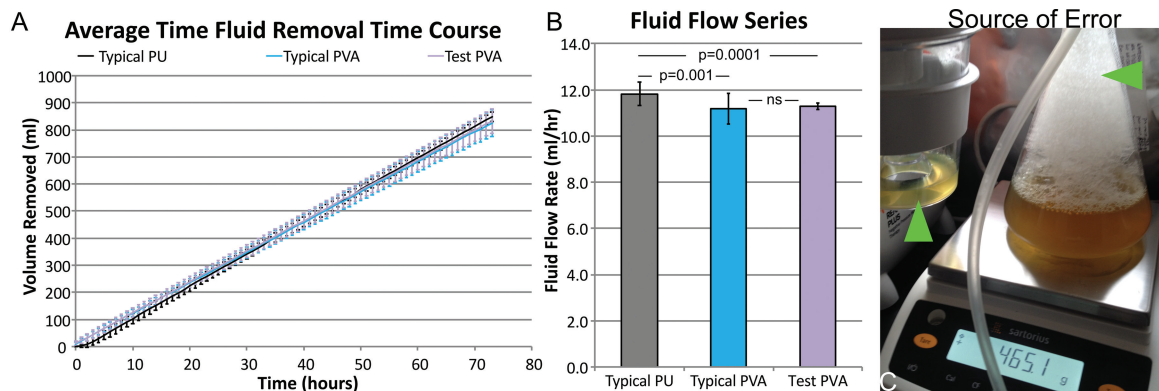


Figure 2. The vacuum distribution model. PU indicates polyurethane; PVA, polyvinyl alcohol.

15 typical PVA foams, and 20 test PVA foams. The test PVA foam was prehydrated prior to use, in accordance with the manufacturer's instructions for use. The foam was removed from its packaging and rehydrated in saturating amounts of 0.85% saline and gently wrung. The typical PU foam did not require hydration, and the typical PVA foam comes prehydrated.

Fluid Removal Model

We measured the fluid removal rate from each of the 3 foams using a 50% bovine serum diluted in 0.85% saline to simulate wound exudate/fluid.¹³ We chose 3 days; this choice was not based on clinical usage trends. Instead, it was chosen to meet laboratory constraints related to the amount of time serous fluids can be left out at room temperature prior to becoming foul. The density of each batch of 50% serum was determined by serially adding 1.0 mL (with a calibrated pipette) of the batch to a digital balance until 10 mL was added. A linear regression was run on the mass versus volume to determine that batch's density. To quantify the fluid removal rate, a fluid trap was placed on an Entris digital balance (Sartorius, Goettingen, Germany) and the balance was controlled by Signal Express through a RS-232 serial to USB connection. Mass data were collected at a frequency of 1 Hz and were then exported to Excel 2010 (Microsoft, Redmond, Washington) and downsampled from 1 sample per second to 1 sample per hour (3600:1) to display the data on a more clinically relevant time scale. The batch-specific density was then used to calculate the volume of fluid removed based on the mass of the removed fluid. A pilot study found the need to restrict the flow of the fluid in order for the experiment to last 3 days, so a peristaltic pump was used to limit the fluid withdrawal rates to 12.5 mL/h.

Vacuum Pressure Measurement Model

In order to measure the magnitude and distribution of negative pressures under the foams, an array of 13 MPX2050 pressure sensors (NXP Semiconductors Netherlands B.V., Eindhoven, the Netherlands) was used to measure the vacuum beneath the dressing, and 1 MPX2050 was placed in-line with the NPWT tubing to measure and record the input vacuum pressure. In addition to the benefit of precisely recorded input pressure, this setup enabled my team to control for slight variations from pump to pump. The pressure sensors were not directly amplified but were instead attached to an NI-9205 data acquisition unit (National Instruments, Austin, Texas) that could provide a resolution of ± 0.057 mm Hg for each sensor. Signal Express (National Instruments) was used to control the data collection and recording. The pressures were collected at a rate of 1 kHz

and then filtered with a low-pass filter in order to filter high-frequency noise, resulting in a final sampling rate of 1 Hz.

To calibrate all 14 sensors, a low-profile plastic bell jar was 3D printed in acrylonitrile butadiene styrene and the bell jar was sealed and held in place with a drape. The tubing was installed with an in-line calibrated DPG-200 digital manometer (Dwyer Instruments, Michigan City, Indiana). While the data from the sensors were being recorded, the NPWT unit was left off, then turned on, and adjusted to each of its discrete suction levels (-40 to -200 mm Hg). The actual pressure measured by the manometer at each level was used to obtain a calibration constant for each sensor (mm Hg/mV); these constants were then programmed into Signal Express, and the channel's vacuum pressure was recorded in mm Hg.

Continuous Fluid Removal Experiment

The first experiment tested the ability for the dressings to maintain negative pressures during continuous use at -120 mm Hg for 72 hours; the experiment was designed, so the NPWT system drew a surrogate wound fluid (50% serum). The purpose of this experiment was to determine whether the foam would maintain its integrity (not break apart) or become clogged by the surrogate wound fluid. This experiment was designed to evaluate the likelihood that exuding wound fluids would not accumulate under the subdrapes foam. If the test PVA foam's pores are too small, I postulated that fluid removal would be impaired, thus allowing fluid to pool under the foam and remain on or in the wound.

Vacuum Pressure Measurement Experiment

The next 2 experiments were undertaken at the 12 different vacuum levels programmed into the NPWT pump. The first experiment focused exclusively on the center of the subdrapes foam to determine if compression with application of suction might prevent the wound from receiving negative pressure. Specifically, we evaluated whether application of negative pressures would impair fluid removal by closing the pores as compared to clogging, which was evaluated in the first experiment. The second experiment focused on the distribution of pressure beneath the subdrapes foam (Figure 3). This experiment was completed because inability of the subdrapes foam to provide negative pressure over its entire area could lead to (1) regions of fluid accumulation due to a lack of enough vacuum to remove it or (2) an impairment of the vacuum-induced contraction of the wound. For each of these experiments, 14 different vacuum levels (0, -40 , -50 , -60 , -70 , -80 , -90 , -100 , -120 , -140 , -160 , -180 , -200 , and 0 mm Hg) were applied sequentially over a period of 1 minute at a time for a cumulative

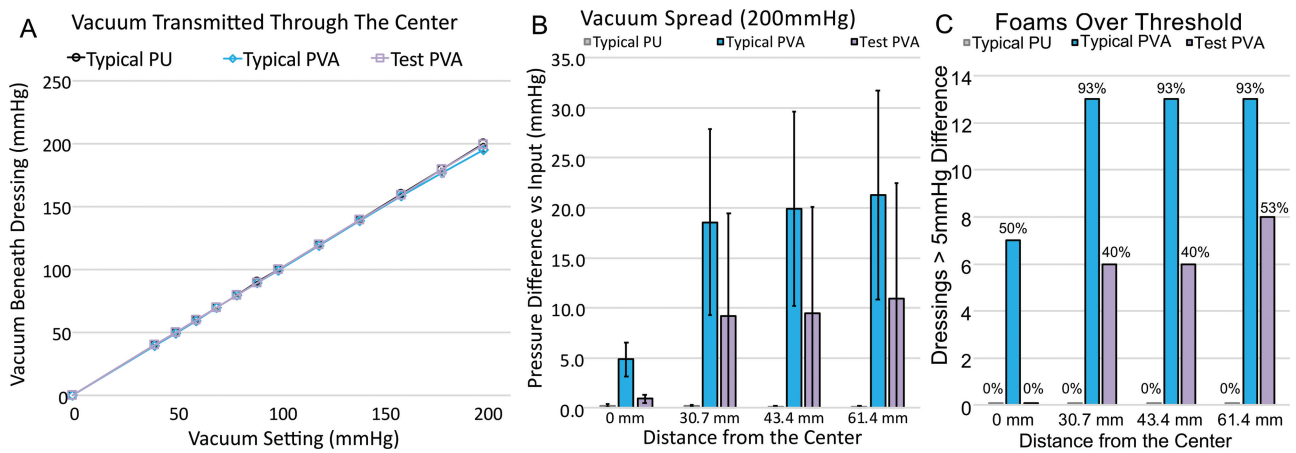


Figure 3. The vacuum measuring ports, their distances from the center, and their technical replication (1 for the center, 4 for all others). PU indicates polyurethane; PVA, polyvinyl alcohol.

test time of 14 minutes needed to apply pressure from 0 to -200 and back to 0 again. We searched the literature and the Internet but did not find an explicit margin of error considered to be clinically relevant. In a study similar to ours, Peterson and colleagues¹⁶ reported a ± 5 mm Hg at -150 mm Hg maximum margin of error for the delivery of negative pressure through the typical clinically approved PU foam. Therefore, I used this margin of error for the ability of negative pressure delivered directly beneath the center of the subdrapes foams. All experiments were performed using continuous suction due to the lack of scientific justification for testing intermittent NPWT prior to the more basic continuous mode.

DATA ANALYSIS

For the fluid removal experiments, the fluid removal rate (mL/h) was calculated for each replicate by linear regression of data recorded from the digital balance. A one-way analysis of variance (ANOVA) was used to determine if there were any differences among the 3 dressings. If any differences were found, Tukey’s Honest Significant Difference (HSD) test was used post hoc to determine which differences were statistically significant. The data from the pressure experiments were first analyzed to identify and remove statistical outliers (errors so large that they are most likely due to interference from an outside source) using the $1.5\times$ interquartile method.

Vacuum Pressure Measurement Model

To determine if the vacuum pressure was delivered under the center of the subdrapes foam, a one-way ANOVA was tested on the center data set (0 mm) separately at each pressure level applied. Any significant differences among the subdrapes foams were determined via Tukey’s HSD post hoc test. Any differences that were greater than 5 mm Hg¹⁴ were considered to be functionally significant. This same analysis approach was used to determine the vacuum at the other measurement points beyond the center, but the analysis was only applied to the maximum negative pressure (200 mm Hg) data set due to its apparent divergence at the center.

RESULTS

Results are presented using the 2 models described earlier (continuous fluid removal model and vacuum pressure

measurement model). The continuous fluid removal experiments found that no subdrapes foam failed due to clogging-impaired fluid withdrawal. Without any outliers removed, the time courses are nearly indistinguishable (not shown). Figure 4 presents data over time with outliers removed. A total of 16 typical PU foams (1 outlier), 15 typical PVA foams, and 18 test PVA foam dressings (2 outliers) remained for analysis. In a statistical comparison among the 3 tested dressings (Figure 5), a difference was found in the fluid removal rates by ANOVA ($P = 7.5 \times 10^{-4}$). Post hoc analysis revealed statistical differences occurred between the PVA subdrapes foams (typical and test) and the PU subdrapes foams ($P = .001$ for typical PVA and $P = .0001$ for test PVA). The performance of the typical and test PVA subdrapes foams was not statistically different ($P = .217$). The maximum difference in the means between the typical PVA and PU foams was quite small at $640 \mu\text{L/h}$. We also found a difference in the total volume removed between the typical PU foam and both the typical and test PVA foams. Up until hour 21, there was a significant difference among the dressings by ANOVA ($P \leq .05$ for hours 0-20, $P = .050$ at hour 21, and $P = .069$ at hour 22), with the PU subdrapes foam initially lagging behind the other 2 PVA subdrapes foams with less fluid removed. However, by the end of the 72-hour

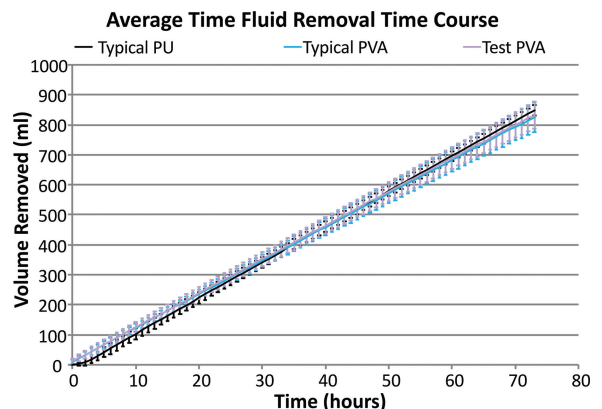


Figure 4. The fluid removal time course. PU indicates polyurethane; PVA, polyvinyl alcohol.

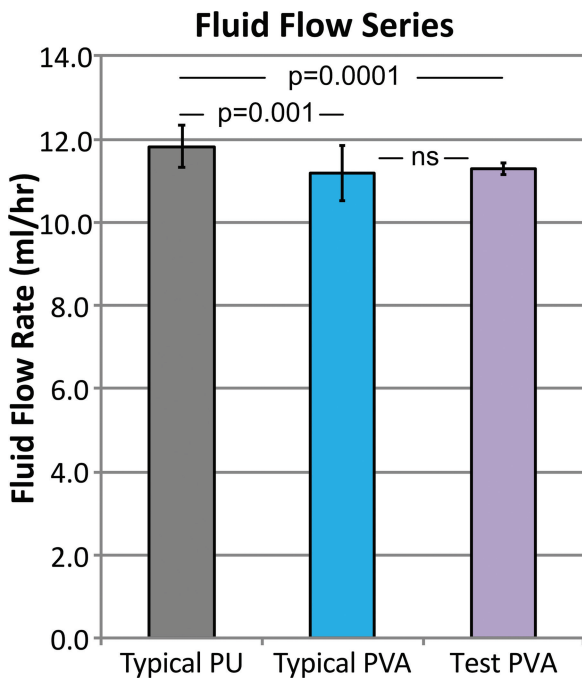


Figure 5. A comparison of the fluid removal rates. PU indicates polyurethane; PVA, polyvinyl alcohol.

period, the total fluid removed was not significantly different between the 3 test foams ($P = .297$).

Vacuum Pressure Measurement Model

As described earlier, this model was evaluated by measuring negative pressures at the center of the subdrape foams. The initial outlier screen resulted in the exclusion of 2 subdrape foams from the PU foam group (n = 15 remaining), 1 from the typical PVA foam group (n = 14 remaining), and 3 from the test PVA foam group (n = 17 remaining). Findings indicated that all subdrape foams were able to provide the tested vacuum levels beneath the center of the subdrape foam (Figure 6). Testing of the typical PVA foam yielded a maximum average difference of 4.85 mm Hg at 200 mm Hg, though one replicate in the foam group did cross the 5-mm Hg threshold beginning at

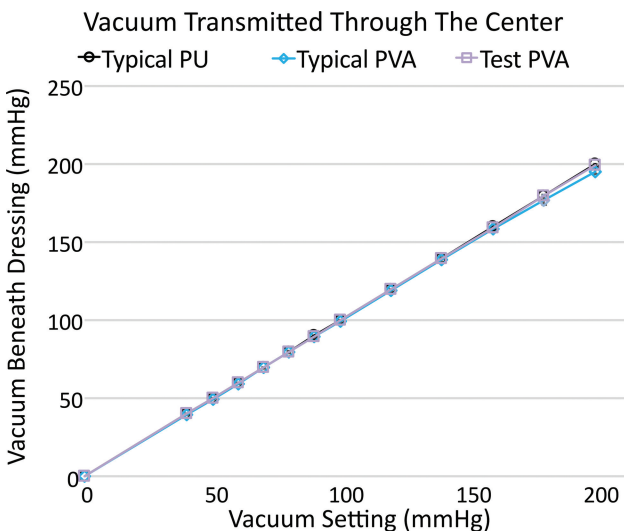


Figure 6. Vacuum delivered beneath the center of the foams. PU indicates polyurethane; PVA, polyvinyl alcohol.

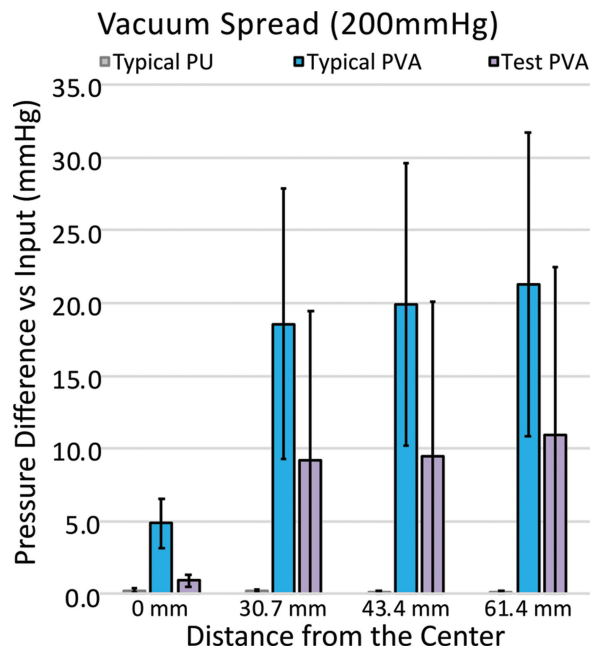


Figure 7. The distribution of the vacuum to off-center sites beneath the foams. PU indicates polyurethane; PVA, polyvinyl alcohol.

140 mm Hg. At 200 mm Hg, 7 more typical PVA foam replicates failed to deliver the NPWT to the center beneath the dressing within ± 5 mm Hg.

Testing the distribution of the negative pressure beneath the subdrape foams revealed that major differences were seen at other locations away from the center (Figures 7 and 8). First, the ANOVA results indicated significant differences among the dressings ($P < 1.5 \times 10^{-6}$), with the PU foam emerging as different from the other 2 foams. The pressure differences between the input negative pressure and the negative pressure

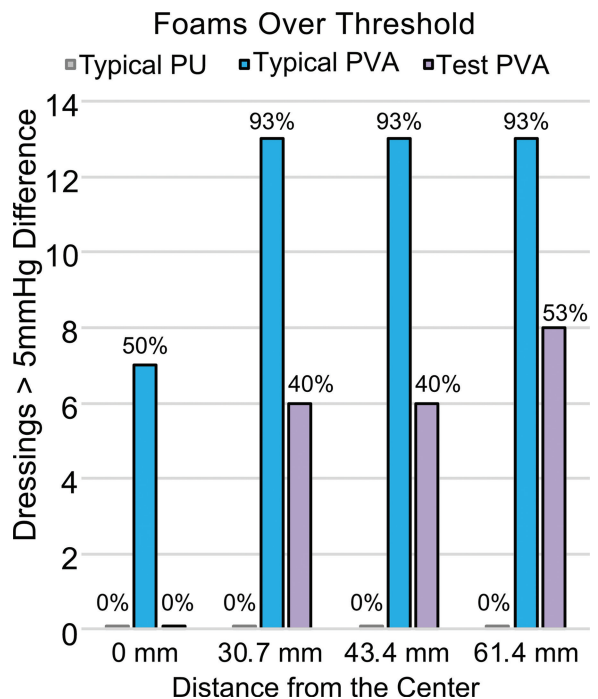


Figure 8. The number of foams with vacuum losses of more than 5 mm Hg. PU indicates polyurethane; PVA, polyvinyl alcohol.

measured beyond the center varied highly among both the typical and test PVA foams (Figure 7). Between the 2 PVA-based foams, the test foam was closer to the input pressure than the typical foam (30.7 mm, $P = .013$; 43.4 mm, $P = .008$; 61.4 mm, $P = .014$) at all distances by an average of 10.0 mm Hg. The data from both PVA-based dressings had a high degree of variance (large error bars). Using the performance threshold of ± 5 mm Hg to perform a secondary analysis, it was found that the source of variance could be attributable to the number of dressings that had a difference greater than 5 mm Hg compared to the 200 mm Hg level that was set (Figure 8). Nearly half of the test PVA foam dressings (range, 40%-53%) had pressure differences greater than 5 mm Hg beyond the center, while all but one typical PVA foam (13/14 foams; 93%) exceeded this threshold.

DISCUSSION

I completed a set of experiments using 2 models designed to compare 3 subdrapes foams used in vacuum-assisted NPWT and found differences in the fluid removal rates. The key differences were found between the PU and PVA foams. The differences were statistically significant, but the overall magnitude of the difference was less than 1 mL/h and is not expected to be clinically significant. The ability to measure such small, but clinically insignificant, differences is primarily due to the sensitivity of the sensors and balance used.

Unexpectedly, while 1000 mL of 50% serum was used for the fluid removal experiment, none of the final removed volumes totaled 1000 mL. A minor portion of the volume remained within the source bottle, the tubing, table, and dressing. I found that the majority of lost fluid was due to foaming in the weighed fluid trap, which led to it being carried out of that trap and into the final, protective prepump trap (Figure 9). I believe this difference also accounts for the flow rates all being under the 12.5-mL/h flow rate set by the peristaltic pump. Improvements in future experiments could include the addition of an equal mass of antifoaming agent to the trap, the addition of filter within the trap, or the use of a taller trap with shorter internal vacuum input tubing.

Analysis of findings also revealed that the typical PU foam had less fluid removed in the first 22 hours than that by the PVA foams. This is probably attributable to the fact that the PU foam was dry to begin with. The PU foam does not require hydration before use according to the instructions for use, while the typical PVA foam comes prehydrated. The test PVA foam was prehydrated, per its instructions for use, so that it matched its materially most relevant equivalent. Otherwise, I found both PVA foams are very hard to the touch when dry. The initial fluid drawn into the dressing in the early stages first had to fill the void space in the PU foams, whereas both PVA-based foams were hydrated (one came prehydrated, the other had to be manually hydrated). I hypothesize that this difference is not clinically relevant since the fluid entering the dressing and/or tubing would still be removed from the wound. Future experiments seeking to improve the test method for side-by-side comparability that incorporates a priming phase that ensured the entire system was fluid filled prior to beginning the comparison are needed.

The results from the vacuum pressure measurement model indicate the negative pressure beneath the center of the foam

Source of Error

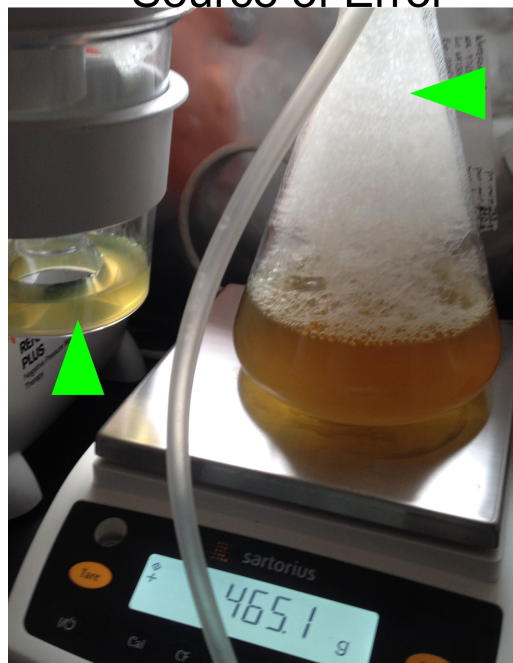


Figure 9. An identified source of error in the fluid removal experiments.

was the same for all 3 foams and reflected the suction setting on the vacuum. However, the typical and test PVA foams had some replicates that exceeded 5-mm Hg pressure difference, suggesting that they were not as consistent as the PU foam. The center of the dressing was also where the drape tubing interface was centered. In other reports using a single pressure monitor, black foam and gauze were compared in an in vivo porcine skin wound model.¹⁴ This model found that the black foam (PU, just like the foam in the present report) had a maximum standard deviation of 5 mm Hg while gauze had a maximum of 1.4 mm Hg difference. The addition of a wound contact layer lessened the error with the black foam and increased it in the gauze, but all remained within 5 mm Hg of the input pressure. We anticipate the differences between our results with the PU foam and those of Malmsjö and colleagues¹⁴ could arise either from the rigid nature of our table compared to the wound bed or from a possible effect on the in-wound pressure sensor tube utilized in the in vivo experiments.

The biggest differences in the experiments using the vacuum pressure measurement model occurred at regions beyond the center of the subdrape foam, where nearly half of the test PVA foam and 93% of the typical PVA foams exceeded the 5-mm Hg difference. The ability of the negative pressure to be communicated to the sensor port directly beneath the subdrape foam requires a good connection through the thickness of the dressings alone. In order to do the same for the off-center ports, out to the edge of the dressing, the dressing must have good “horizontal” connections through the body of the dressing or along its outer surfaces. Visually, it is clear the typical PU foam is well connected horizontally, as there is more void space than foam material. This openness may have allowed the PU foam to better communicate the negative pressure to all areas tested beneath the dressing. In

contrast, the PVA foams were more dense and therefore less internally connected. At weaker negative pressures, both PVA foams were able to distribute the negative pressure, but as the pressure increased, the suction level measured at the peripheral ports would cease increasing with increasing input levels. I hypothesize that at the higher negative pressure, the PVA foams would collapse and close the pores, effectively “vacuum sealing” those regions. It is important to note that these regions remain under negative pressure, but they do so at lower levels than the pump setting.

With current PVA foams, higher pressures are needed to obtain flow rates equivalent to those of PU foams. Our data suggest that the central port does not become sealed off and would still enable fluid removal. However, it is uncertain whether these increased suction levels have unanticipated consequences as our data have found. Whether the observed sealing is internal collapse of the foam itself or a sealing of the foam against the experimental equipment’s surface is not known. In addition, it is not known if the same sealing occurs on the wound surface in vivo. The moistness and pliancy of the wound surface cast doubt on the ability of the PVA to seal the wound surface (due to the incompressibility of water), but the possibility of an internal collapse of the dressing remains. Additional in vitro studies with more biological materials are needed to determine if this is an inherent limitation of PVA foams.

In the negative pressure distribution experiments, the worst performing subdrape foam (a single replicate for a typical PVA) had a maximum difference of 37.0 mm Hg and occurred at the furthest point (61.4 mm) at 200 mm Hg. Nevertheless, this worst-case scenario foam still had 163.0 mm Hg of negative pressure. Whether this is clinically significant or not is not clear, as there is not any precise quantitative relation between the negative pressure experienced by the wound at any given point and clinical outcomes.

Considering the outcomes of these experiments collectively, all 3 subdrape foams were able to continuously withdraw biological fluids and could distribute negative pressure to the area beneath the dressings. The largest differences found appeared to be due to the material type of the dressing; the PU-based dressing was able to more rapidly withdraw fluids and to better distribute the negative pressure (suction). For the 2 PVA-based foams, the performance was more dictated by dressing-to-dressing (batch) variance. The PVA-based foams did not have the full negative pressure provided over the whole treated area, which may explain the clinical observation that the PVA foams are more “gentle.” However, the differences in tactile properties between the PU and PVA might also be a consequence of the PU and PVA having different material properties.

The typical PU and PVA foam dressings are currently used with vacuum-assisted NPWT. The test PVA foam has not been marketed for use with negative pressure, though it is used successfully in clinical practice as an external dressing for use in local management of wounds such as pressure injuries, donor sites, venous stasis ulcers, arterial ulcers, diabetic ulcers, abrasions, lacerations, superficial burns, postsurgical incisions, and other external wounds inflicted by trauma since 2005.¹⁵ There is emerging case report evidence of the use of the test PVA foam within NPWT treatments, though in at least one of these cases, another foam dressing was placed over the test PVA, directly into contact with the drape.¹⁶⁻¹⁸

STRENGTHS AND LIMITATIONS

The models described herein provided a method for consistent and reproducible preclinical testing of subdrape NPWT foams, which may aid in the economic development of novel NPWT technologies. The use of 50% serum very closely models wound fluids and their fluid properties. The continuous measurement system was able to identify differences in starting hydration and to provide an evidentiary log over a 72-hour period. The system was capable of continuing well beyond that time frame as well, limited only by the amount of data storage space.

A hard plastic table was used to model the wound surface; differences that arise due to deformation of tissue would not be captured by this preclinical model. Future development might include the use of a silicone-based “table,” which would also allow for testing on nonflat surfaces. Additionally, the fluid flow rate and pressure beneath the subdrape foams were measured independently. Future studies may enable the combined study of fluid removal rates, center pressure, and pressure distribution simultaneously, making the model more biologically relevant.

CONCLUSIONS

The data obtained from the fluid removal model demonstrate that the test PVA is equivalent to 2 currently approved NPWT foams in its ability to remove biological fluids when used in an NPWT system. The vacuum pressure measurement model revealed that the test foam had vacuum levels beneath the center of the foam that were equivalent to 2 current NPWT foams, but that beyond the center, the PU foam was best at distributing negative pressure, followed by the test PVA foam, and the typical PVA foam doing the worst. These results support the advancement of the test PVA foam to clinical testing and potential use in patients undergoing vacuum-assisted NPWT.

ACKNOWLEDGMENTS

The author conducted this research via a contract with Hollister Inc, which distributed one of the products subject herein. The product’s manufacturer, Hydrofera, LLC, sponsored Dr Gibson’s effort for composition and costs of publication. The sponsors chose the pressure distribution pattern beneath the dressing that they would like to be measured and manufactured the pressure table and supports. They did not have a role in the design of the measurement routine, conduct of the research, or data analysis. The sponsors did not write the manuscript but were allowed to review it for accuracy pertaining to comments made about the sponsors or their intents.

KEY POINTS

- ▶ All 3 foams (PVA and PU) were capable of drawing continuous 50% serum for 72 hours, and all 3 foams delivered expected vacuum levels beneath the center of the dressing.
- ▶ The typical PU foam had the least impact on vacuum delivery and distribution.
- ▶ The typical and test PVA foams lost some negative pressure delivered to the off-center locations.
- ▶ Different foam materials influence delivery of negative pressure (suction) during NPWT.

REFERENCES

- Miller C. The history of negative pressure wound therapy (NPWT): from "lip service" to the modern vacuum system. *J Am Coll Clin Wound Spec.* 2012;4(3):61-62. doi:10.1016/j.jccw.2013.11.002.
- Crumley C. Single-use negative pressure wound therapy devices: a technologic analysis. *J Wound Ostomy Continence Nurs.* 2021;48(3):195-198. doi:10.1097/WON.0000000000000761.
- Nuutila K, Yang L, Broomhead M, Proppe K, Eriksson E. Novel negative pressure wound therapy device without foam or gauze is effective at -50 mmHg. *Wound Repair Regen.* 2019;27(2):162-169. doi:10.1111/wrr.3.
- Kane BJ, Younan G, Helm D, et al. Controlled induction of distributed microdeformation in wounded tissue via a microchamber array dressing. *J Biomed Mater Res A.* 2010;95A(2):333-340. doi:10.1002/jbm.a.32840.
- Shankaran V, Brooks M, Mostow E. Advanced therapies for chronic wounds: NPWT, engineered skin, growth factors, extracellular matrices. *Dermatol Ther.* 2013;26(3):215-221. doi:10.1111/dth.12050.
- Cristescu I, Vilciciu D, Safta F, et al. Use of collagen scaffolds in conjunction with NPWT for the care of complex wounds: clinical report. *Key Eng Mater.* 2017;745:91-100. doi:10.4028/www.scientific.net/KEM.745.91.
- Menn ZK, Lee E, Klebuc MJ. Acellular dermal matrix and negative pressure wound therapy: a tissue-engineered alternative to free tissue transfer in the compromised host. *J Reconstr Microsurg.* 2012;28(2):139-144. doi:10.1055/s-0031-1289167.
- de Haas LEM, Gardien KLM, van Trier AJM, Vloemans AFPM, Buis DR. The use of Integra in extensive full-thickness scalp burn involving the skull in a child. *J Craniofac Surg.* 2019;30(3):888-890. doi:10.1097/SCS.0000000000005375.
- Arnold-Long M, Johnson R, Reed L. Negative pressure wound therapy overlay technique with collagen dressings for nonhealing wounds. *J Wound Ostomy Continence Nurs.* 2010;37(5):549. doi:10.1097/WON.0b013e3181eda751.
- Anesäter E, Borgquist O, Torbrand C, et al. The use of a rigid disc to protect exposed structures in wounds treated with negative pressure wound therapy: effects on wound bed pressure and microvascular blood flow. *Wound Repair Regen.* 2012;20(4):611-616. doi:10.1111/j.1524-475X.2012.00801.x.
- Malmsjö M, Lindstedt S, Ingemansson R, Gustafsson L. Use of bacteria- and fungus-binding mesh in negative pressure wound therapy provides significant granulation tissue without tissue ingrowth. *ePlasty.* 2014;14:e3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3899807>. Accessed September 4, 2019.
- Wiegand C, Springer S, Abel M, Ruth P, Hipler U-C. Differences in fluid distribution during negative pressure wound therapy (NPWT) in a large-pored PU-foam dressing, drainage film, and a specialized NPWT dressing system. *Wound Med.* 2014;6:22-25. doi:10.1016/j.wndm.2014.09.004.
- Trengove NJ, Langton SR, Stacey MC. Biochemical analysis of wound fluid from nonhealing and healing chronic leg ulcers. *Wound Repair Regen.* 1996;4(2):234-239. doi:10.1046/j.1524-475X.1996.40211.x.
- Malmsjö M, Ingemansson R, Martin R, Huddleston E. Negative-pressure wound therapy using gauze or open-cell polyurethane foam: similar early effects on pressure transduction and tissue contraction in an experimental porcine wound model. *Wound Repair Regen.* 2009;17(2):200-205. doi:10.1111/j.1524-475X.2009.00461.x.
- Webb M. Use of bacteriostatic foam composed of polyvinyl alcohol (PVA) with Methylene Blue and Gentian Violet (pigment-complexed PVA sponge) to decrease colony count in large infected peri-anal wound. *J Wound Ostomy Continence Nurs.* 2009;36(3):1.
- Peterson DJ. Effectively managing infected wounds with Hydrofera Blue™ and negative pressure wound therapy. <https://www.researchgate.net/publication/242519971>. Published 2005. Accessed September 10, 2019.
- Smith APS, Whittington K, Frykberg RG, de Leon JM. Negative pressure wound therapy. In: *Chronic Wound Care: The Essentials e-Book*. Malvern, PA: HMP; 2018:195-224. <https://www.cwc-essentials.com>. Accessed September 17, 2019.
- Regner JL, Forestiere MJ, Munoz-Maldonado Y, et al. Comparison of a standardized negative pressure wound therapy protocol after midline celiotomy to primary skin closure and traditional open wound vacuum-assisted closure management. *Baylor Univ Medl Center Proc.* 2018;31(1):25-29. doi:10.1080/08998280.2017.1400312.