Development of a New Vented Chest Seal Dressing for Treatment of Open Pneumothorax

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ABSTRACT

The most common life-threatening complications from both blunt and penetrating thoracic injury are hemothorax, pneumothorax, or a combination of both. New guidelines, set out by the Tactical Combat Casualty Care (TCCC), advises that vented chest seal dressings are used to manage open or sucking chest wounds. Designing out risk is a fundamental criterion for ensuring the optimal performance of a device is obtained that offers the casualty the greatest chance of survival. Two key areas of risk in the application of vented chest seal dressings are adhesion failure and vent failure. This study assesses a new design of vented chest seal dressing for both adhesion and vent profile. The development of this new design for a vented chest seal has been tested for adhesion and venting properties and shown to have performance criteria suitable for the treatment of open pneumothorax and design features that minimize the risk of product failure during use.

KEYWORDS: *thoracic injury; hemothorax; pneumothorax; chest seal dressing*

Introduction

Over multiple decades, combat-related thoracic trauma has been a major contributor to the morbidity and mortality of the casualties. The mechanisms of trauma can be grouped into penetrating, blunt, and blast injuries. The most common life-threatening complications from both blunt and penetrating thoracic injury are hemothorax, pneumothorax, or a combination of both. Pneumothorax is reported as the most common injury sustained in chest trauma, occurring in about 20% of patients.[1] In the late 1980s and early 1990s, a study of 3640 military casualties concluded that 10.7% were treated for chest injuries.[2] Later studies referencing conflict in Iraq and Afghanistan report 8.6% to 16% of casualties obtaining some form of chest trauma.[3]

One publication indicated that approximately 10% to 30% of patients transported to Level 1 trauma centers in the United States receive prehospital decompressive needle thoracostomies.[4] This may be a sign of the level of tension pneumothorax but is not definitive and probably excessive. A further review of military deaths reports that up to 5% of combat casualties with thoracic trauma have tension pneumothorax at the time of death.[5]

Reported data indicate that effective management of combat-related thoracic trauma is key to increasing survival. This document assesses the requirements for vented chest seal dressings and proposes a new design to mitigate existing risk factors.

Pneumothorax

Pneumothorax is defined as the presence of air or gas in the pleural cavity. The clinical impacts of this result in various degrees of collapse of the lung on the affected side. As a consequence, pneumothorax can impair oxygenation and/or ventilation. Open pneumothorax occurs in which gas enters the pleural space other than from a ruptured or lacerated lung. This can be through an open wound in the chest wall. Closed pneumothorax refers to gas accumulation in the pleural space in the absence of an open chest wound.

Tension pneumothorax is a life-threatening condition that develops when air is trapped in the pleural cavity under positive pressure. This pressure displaces the mediastinal structures, resulting in compromised cardiopulmonary function. One of the key emergency requirements once this occurs is the recognition of tension pneumothorax to help prevent death.

Current Guidelines

The August 2019 guidelines August 2019 by the TCCC[6] still uses the 2013 guideline changes for chest seal dressings and advises that "all open and/or sucking chest wounds should be treated by immediately applying a vented chest seal to cover the defect. If a vented chest seal is not available, use a nonvented chest seal." For nonvented chest seals, if the casualty develops increasing hypoxia, respiratory distress, or hypotension and a tension pneumothorax is suspected, treat by burping (the temporary removal of the dressing and resealing or by needle decompression) or removing the dressing or by needle decompression.

Design Requirements for Vented Chest Seal Dressings

Designing out risk is a fundamental criterion for ensuring the optimal performance of a device is obtained that offers the

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casualty the greatest chance of survival. When assessing key design inputs, there are many different aspects to consider, from stability of the product to chemical and biological safety, ease and intuitive use by the care provider, performance, and compliance by the casualty. Each of these different aspects may affect the outcome of the casualty either alone or in combination.

This review will focus on the performance of a newly developed vented chest seal. Assessment of the literature[7–10] and market available data identify the following key requirements for an effective vented chest seal:

1. Adhesion to skin in different conditions
2. Conformability around the chest area
3. Ability to maintain clear vents to allow release of air/gas from the pleural cavity throughout the wear time
4. Prevent ingress of air from the external environment into the pleural cavity
5. Wear time of several days if needed
6. Ability to perform as per points 1 to 5 on concave and convex anatomy
7. Work under armor or clothing without be occluded
8. Fit easily within IFAK and medical kits, potentially folded.

Analysis of the currently available vented chest seal dressings identifies different designs aimed at treating open pneumothorax. The different design features include different adhesive formulations, different number of valves/vents available, soft or hard valves/vents, location of vents/valves, and various shapes. There are several "film valve"–type chest seals. These are referred to by different names, such as flutter valves, vents, vented, etc. These all work via a similar action relying on a pressure differential to lift/collapse a thin plastic film. There are slight variations in the design of these valve systems; some are bonded around the periphery and have remote holes in the valve film, and others have incomplete bonding and the edge of the film is used as the outlet. Typically, these types of seal use a hole in the main seal with the valve part mounted to the outer face.

"Hard valves" are typically premolded valve units that are bonded into the dressing. The mechanism of action of these valves varies with valve type. For example, one chest seal uses a duck bill–type valve where the pressure is controlled via the flexibility of the rubber valve, whereas an alternative chest seal uses three valves that work via displacement of an internal disc (Table 1).

The described commercially available vented chest seal designs were reviewed during the design of a new vented chest seal with a goal of further minimizing risk to the patient when treated for an open pneumothorax.

Human Physiological Data Review

Human physiological data are available for lung capacity and breathing rate, but the pressure in the pleural cavity is described as "slightly higher/lower than atmospheric pressure." Reviewing the available animal model data[8,9] gives the following physiological data, which can be used to set the performance requirements for a chest seal (Table 2).

TABLE 2 *Human Physiological Data*

Property	Value
Inspiration intrapleural pressure	–5 → –8mmHg
Exhalation intrapleural pressure	~0mmHg
Blood flow in hemopneumothorax	25mL/min (max of 226mL)
Airflow through the chest seal	200mL/5 min
Respiration rate	22–41 breaths/min

In the presence of a nonvented chest seal, the interpleural pressure rises with air accumulation in the chest cavity. As the level of pneumothorax increases, the pressures for inhalation and expiration become closer and higher. When the quantity of air is equivalent to the total lung capacity, tension pneumothorax is developed and the mean exhalation intrapleural pressure reaches ~10mmHg. Acceptance criteria for a vented chest seal can therefore be defined as shown in Table 3.

Animal models have been used to test occlusive and vented chest seals for some time. The original models used involved measuring hemodynamic stats as an indication of pneumothorax presence. More recent testing has included measurement of the intrapleural pressure as a direct indicator of pneumothorax. In all cases, the air used to create pneumothorax and the blood used to create hemopneumothorax is artificially introduced.[8,9]

Many methods have been developed for testing the vent function of vented chest seals in a laboratory environment. These methods simulate flow of both air and fluid through the chest seal at variable rates and then subsequently test for valve function. Consequently, all parameters required for the chest seal dressing are available to test in the laboratory or have been previously tested.

Methods

Adhesion

Both in vitro and in vivo studies were designed to challenge the adhesion properties of the dressing in extreme conditions in which the military are expected to operate. The environments

TABLE 1 *Comparison of Different Commercially Available Vented Chest Seal Dressings*

Chest Seal Currently on Market	Number of Vents	Type of Vent	Burp Tab	Potential Air Pathways	Vent Location	Design
Chest seal 1	3	Soft	Yes	3	Edge of dressing	Square/rectangle
Chest seal 2	3	Hard	Yes	3	Centre of dressing	Circular
Chest seal 3	4	Soft	Yes	4	Edge of dressing	Oval
Chest seal 4	1	Hard	Yes	1	Centre of dressing	Circular
Chest seal 5	1	Hard	Yes	1	Centre of dressing	Oval
Chest seal 6	4	Soft	No	4	Midway from center to edge	Square/rectangle
Chest seal 7	4	Soft	Yes	4	Midway from center to edge	Circular

TABLE 3 *Acceptance Criteria for a Vented Chest Seal*

Biological Property	Value	Chest Seal Test Criteria
Inspiration intrapleural pressure	–5 → –8mmHg	Holds –5 → –8mmHg negative pressure for ≥ 3 sec with a reservoir volume of half total lung capacity
Respiration rate	22–41 breaths/min	
Exhalation intrapleural pressure at pneumothorax	~10mmHg	Pressure <10mmHg (ideally close to 0) when air flow is at 40mL/min
Airflow through the chest seal	200mL/5 min	
Exhalation intrapleural pressure at pneumothorax	~10mmHg	Pressure <10mmHg (ideally close to 0) when air flow is at 40mL/min and blood flow is at 25mL/min
Airflow through the chest seal	200mL/5 min	
Blood flow in hemopneumothorax	25mL/min (max of 226mL)	

recreated included extreme temperature conditions representative of different global climate zones and casualties who were recently been active and in dirty environments.

In Vitro Adhesion

For the in vitro test methodology, strips of test article were cut from the chest seal dressing and adhered to a stainless-steel plate. The plate was then clamped onto a tensiometer at a 90° angle to the base. The dressing strip was then folded back on itself and clamped into an upper jaw. This creates an 180° peel test. The force to remove the dressing from the stainless-steel plate was recorded.

To recreate a sweaty environment, acidic sweat was created as per ISO 105-E04:1987(E) test method[11,12] and dosed onto the stainless-steel plate. The same procedure as described here earlier was then carried out.

To mimic sandy conditions, sand was dosed onto the stainless-steel plate and the same procedure was undertaken. Further environmental conditions were then created to recreate the sweaty sandy/dry sandy conditions that combined the use of the acidic sweat and sand as described.

For the extreme temperature conditions, the test articles were conditioned at ambient room temperature (23 ± 2°C), a cold environment (at least –5°C) and a warm environment (40 ± 2°C) for 24 hours before testing. Following this conditioning period, the test articles were removed from the environmental chamber and tested within 2 minutes of removal as per the described test method.

In Vivo Adhesion

The in vivo adhesion study assessed the adhesive technology of the test article and mimicked the in vitro studies and compared active, dirty, and extreme-temperature environments.

Volunteers were selected from healthy individuals from both gender demographics. Significantly more males were recruited due to the nature of military frontline workers and the expected additional challenge of chest hair to the chest seal dressing.

Active conditions are described as sweaty skin, dirty conditions described as dirt/sand contaminated skin, and extreme-temperature environments as those at different temperatures from freezing to hot.

To validate and confirm the conditions for sweaty skin, the difference in moisture on the volunteer's skin was determined using a corneometer at three positions within the test site. Normal conditions were described as the moisture value of the skin with the volunteer at rest, whereas sweaty conditions confirmed once the skin moisture increased. For the dry conditions, volunteers at rest had the adhesive technology applied to their chest, with the side of the body noted to ensure dressings were not applied twice to the same area. After a dwell time, the adhesive technology was removed, using a handheld Mecmesin Force gauge, and the force required to peel the adhesive technology from the test area was recorded. For the sandy dry measurement, an amount of sand was applied to the chest area before application and the same test procedure was applied.

All volunteers then undertook an exercise class within a gym before the second application of the adhesive technology for evaluation in a sweaty/sweaty sandy condition. The gym session was used to establish a rise in body temperature and increased perspiration to mimic physical activity that is expected on military operations. The adhesive technology was placed onto the volunteer, on the opposite side of the initial dry sample without allowing individuals time to cool down. This was done to ensure that the body surface was sweaty, with any excess sweat being wiped off as per IFU. Corneometer readings were taken from three areas before each application of the dressings. Once the adhesive technology was applied, all volunteers underwent a cool-down period, and after a dwell time, the adhesive technology was removed, using a handheld Mecmesin Force gauge. The force required to peel the adhesive technology away from the test area recorded. For the sweaty/sandy measurement, some sand was applied to the chest area prior to adhesive technology application.

It is important to note that none of the volunteers had the area of application shaved before the adhesive technology was applied. It is not uncommon for a medic/first aid provider to have a razor in their equipment for use so shaving can take place before chest seal application. It is of huge benefit if this is not required, to save time on application.

For the environmental conditions, the adhesive technology samples were conditioned at three environment, ambient room temperature (23 ± 2°C), a cold environment (at least –5°C) and a warm environment (40 ± 2°C) for a minimum of 12 hrs. All environments were monitored via a data logged thermometer. These temperatures were the extremes of what may be seen in typical military fighting operation environments. The adhesive technology samples were placed onto a volunteer within 2 minutes of being removed from its environment for cold and warm samples. After a dwell time, the adhesive technology was removed using a handheld Mecmesin Force gauge and the force required to peel the adhesive technology away from the test area recorded. Each volunteer had all three adhesive technology conditions placed onto them in one of three positions at random; left upper chest, right upper chest, left upper back. The dwell time was consistent across all volunteer studies.

Vent Profiling

Flow/Pressure Profile

This method is designed to measure the back pressure of the vent at different air flows. The differing air flows represent varying severities of pneumothorax, which mimic the different air volumes within the pleural cavity.

To measure a flow rate/pressure profile, the output from a peristaltic pump and a pressure manometer were connected to fittings in a sealed plastic box. A 10mm hole in the top of the box represented the wound, which was covered by the test article being measured. To measure the flow rate of the decompression needle, it was sealed into the hole with butyl tape.

The airflow rate was varied from 20mL/min to 60mL/min. The system was allowed to equilibrate for 1 minute to achieve a steady state of flow/pressure. The pressure at each flow rate was recorded. Five data points were recorded.

Pressure/Flow Profile Under Military Equipment

This method is designed to measure the back pressure of the vent at different air flows under standard UK military equipment. As described, the differing air flows represent varying severities of pneumothorax, which mimic the different air volumes within the pleural cavity.

The flow profile of the test articles was measured under the following conditions:

- Under British standard issue equipment
- Under British standard issue equipment and body armor

Pressure/Flow Profile With Vents Partially Blocked

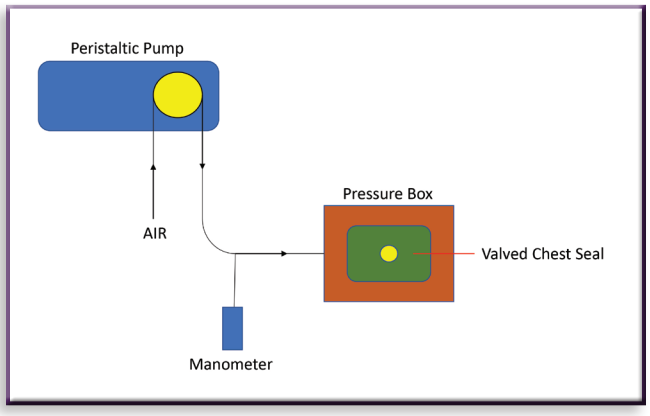
This method is designed to measure the back pressure of the vent at different air flows when half the vents are blocked. The blocked vents represent conditions whereby blood and exudate loss through the wound may congeal within the valve system. As described here, the differing air flows represent varying severities of pneumothorax that mimic the different air volumes within the pleural cavity.

To simulate the partial blockage within the vents, 50% of the vent area was occluded with tape (see Figure 1).

Flow/Valve Function Over the Full Wear Time

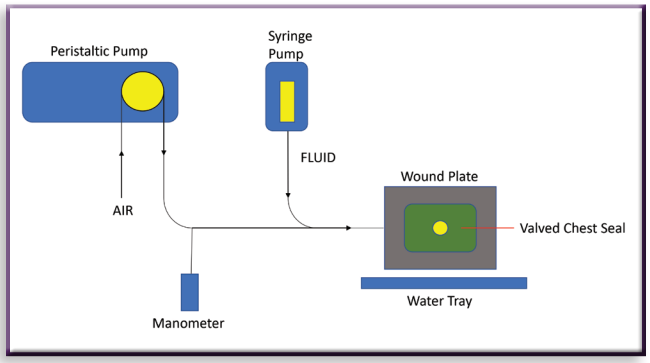
This method is designed to assess the functionality and performance of the test article over a 48-hour wear time.

FIGURE 1 *Schematic of experimental equipment.*



The vent performance was assessed over a 48-hour period whereby both air and fluid flow out of the wound and through the vent system was simulated. The test article was applied to a flat wound model plate at 37°C, and air/fluid was supplied through the flow port. Solution A was supplied at 25mL/min using a syringe pump, and air was supplied using an aquarium pump. The air/fluid flow was oscillated using an electrical plug timer to simulate the open/closed valve action every 15 minutes. The valve performance was measured periodically during the test using a Mityvac hand pump testing for both retention of negative pressure and no retention of positive pressure (see Figure 2).

FIGURE 2 *Schematic of experimental equipment.*



Channel Failure on Concave and Convex Surfaces

The test articles were evaluated for contour performance by applying them to both concave and convex wound model plates and checking for vent function using the Mityvac hand pump. Attempts to introduce creases/channels into the valve film were conducted by manually forcing the valve film to channel.

Results

In Vitro Adhesion

The in vitro data are summarized as an average of the overall results for each condition (Figure 3).

The adhesion data for the test article under different environmental conditions indicate that the adhesive characteristics of the test article are not adversely affected by temperature, and to some degree a warmer environment may increase adhesion (Figure 4).

The adhesion data for the test article, when applied to surfaces ranging from dry to sweaty conditions, show an impact on the adhesion profile when used on sweaty (diaphoretic) skin. The adhesion profile dropped by approximately 50% due to the moisture on the test surface. However, the data demonstrate that there is a relatively high adhesion force even when applied under these conditions (Figure 5).

The adhesion data for the test article, when applied to surfaces that are dirty, both dry and sweaty, indicate that there is very little difference between these two conditions. The data are comparable to data for Figure 4 for dry clean conditions, suggesting that contamination of dirty on the skin has no detrimental effect on the adhesion profile of the test article.

In Vivo Adhesion

The in vivo data are summarized as an average of the overall results for each condition with standard deviations.

FIGURE 3 *Adhesion data of test article under different environmental conditions (ambient room temperature (23 ± 2°C), a cold environment (at least –5°C) and a warm environment (40 ± 2°C).*

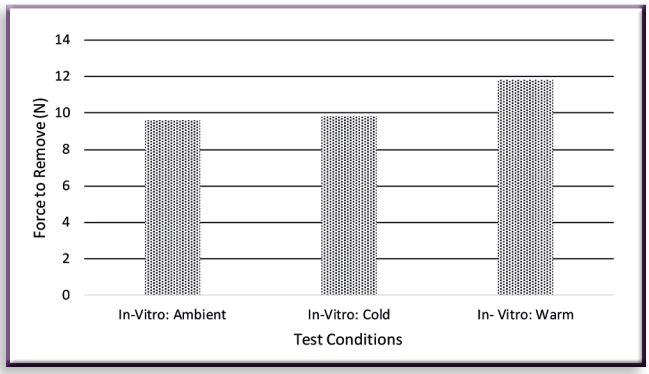


FIGURE 4 *Adhesion data of test article under dry and sweaty conditions.*

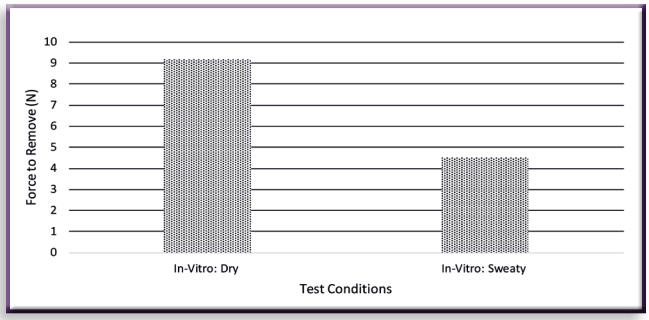
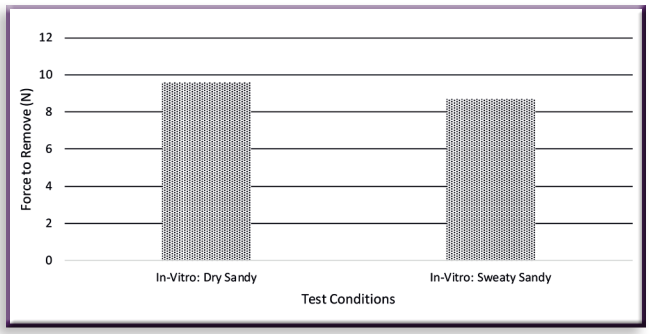


FIGURE 5 *Adhesion data of test article under dirty, dry, and sweaty conditions.*



In assessing the increase in skin moisture content through sweat, the corneometer results on average increased by a value of 73, with the lowest recording increase being 47 and the highest increase being 107. The corneometer measures the change in the dielectric constant due to skin surface hydration changing the capacitance of a precision capacitor. The measurement can detect even slightest changes in the hydration level. This supports that the exercise that took place increased perspiration (Figure 6).

The adhesion data for the adhesive technology when applied to surfaces that are dirty, both dry and sweaty, indicate that there is very little difference between all conditions, dirty, clean or sweaty dirty, sweaty clean when applied to human volunteers. There is a large standard deviation, which may reflect the differences in skin related to age, sex, and natural oils (Figure 7).

FIGURE 6 *Adhesion data of adhesive technology under dirty, dry, and sweaty conditions on human volunteers. Summary of all individuals assessed irrespective of body hair coverage.*

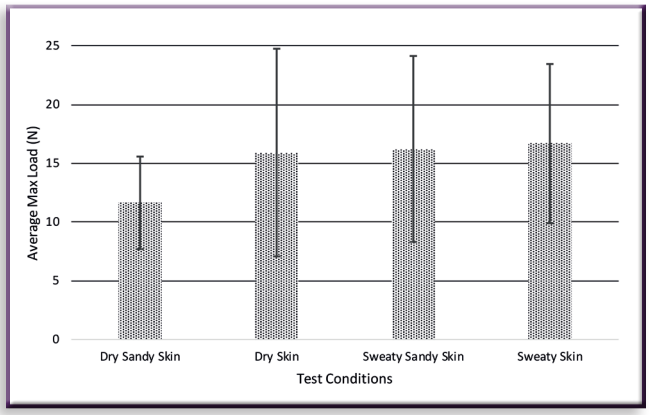
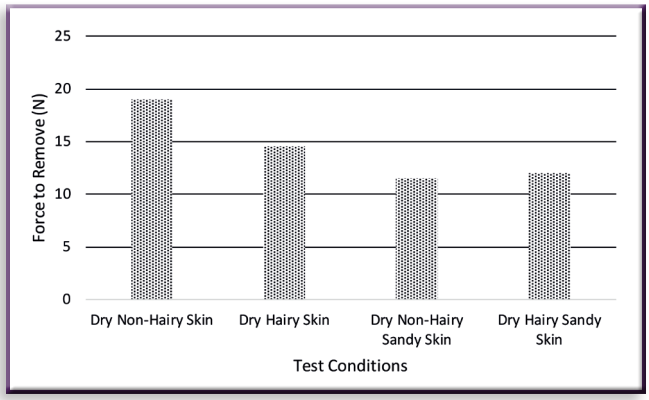
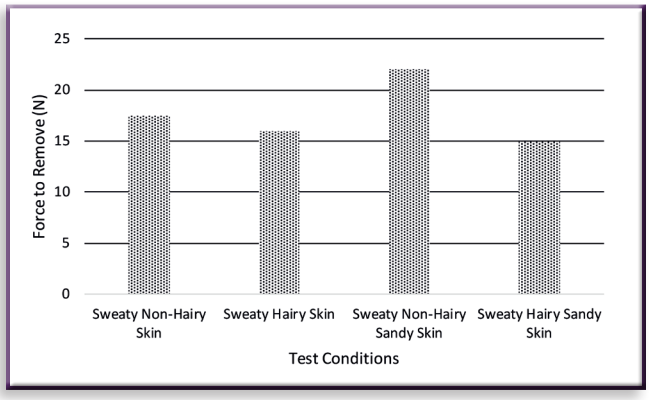


FIGURE 7 *A more in-depth analysis of Figure 6, whereby the hairiness of the volunteers' test site is assessed. Note that more individuals were male, so the level of hairy test sites was higher than that in the female group.*





The data within Figure 7 indicate that for all groups and conditions, the adhesion level was still very high. There appears to be a trend in dry clean and sweaty dirty conditions to hair affecting the adhesion profile of the adhesive technology, but this reduction in adhesion did not result in the adhesive technology falling off (Figure 8).

The adhesion data for the adhesive technology under different environmental conditions indicate that the adhesive characteristics of the adhesive technology are not adversely affected by temperature, and to some degree a warmer environment may increase adhesion (Figure 9).

FIGURE 8 *Adhesion data of adhesive technology under different environmental conditions on human volunteers: ambient room temperature (23 ± 2°C), a cold environment (at least –5°C), and a warm environment (40 ± 2°C).*

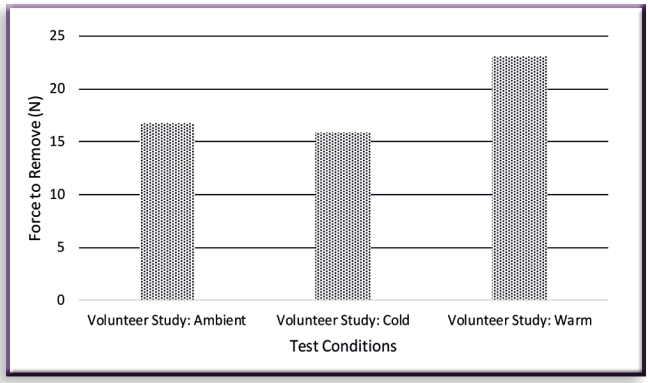
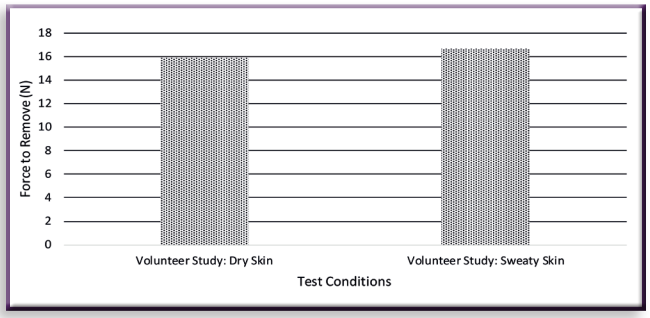


FIGURE 9 *Adhesion data of adhesive technology under dry and sweaty conditions on human volunteers.*



When assessed on healthy volunteers, the increase in moisture on and within the skin does not appear to have any detrimental effect on the adhesive profile of the adhesive technology (Figure 10).

The data for dirty skin under dry and sweaty conditions also showed no detrimental effect on the adhesive properties of the adhesive technology.

Vent Profiling

Flow/Pressure Profile With and Without Vents Partially Blocked

The data within (Figure 11) indicate that even with half the vents occluded, the new design of test article allows effective use of the vent system. The increased air volume within the pleural cavity does result in a slight increase in back pressure caused by the vents but does not cause the vents to fail.

Pressure/Flow Profile Under Military Equipment

The data within (Figure 12) indicates that the vent system continues to operate effectively under equipment and armor, when applied under predicted normal conditions. The increased air volume within the pleural cavity does result in a slight increase in back pressure caused by the vents, as does the application of the armor and equipment over the test article.

Flow/Valve Function Over the Full Wear Time

The ability of the vent to hold a negative pressure over 3 seconds and not hold positive pressure was assessed over a 48-hour period at various timepoints; at no point did the dressing function fail.

FIGURE 10 *Adhesion data of adhesive technology under dirty, dry, and sweaty conditions on human volunteers.*

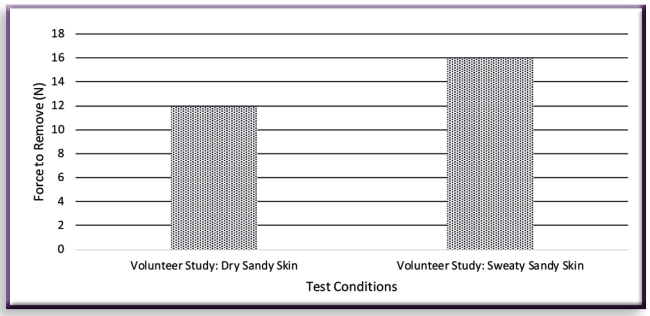


FIGURE 11 *Back pressure of vent unhindered and occluded with varying levels of airflow.*

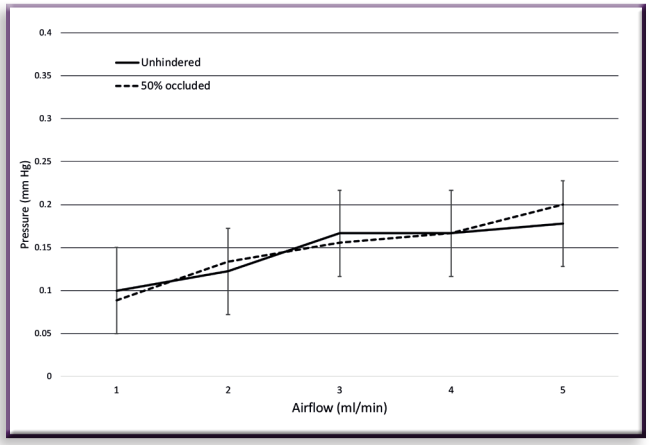
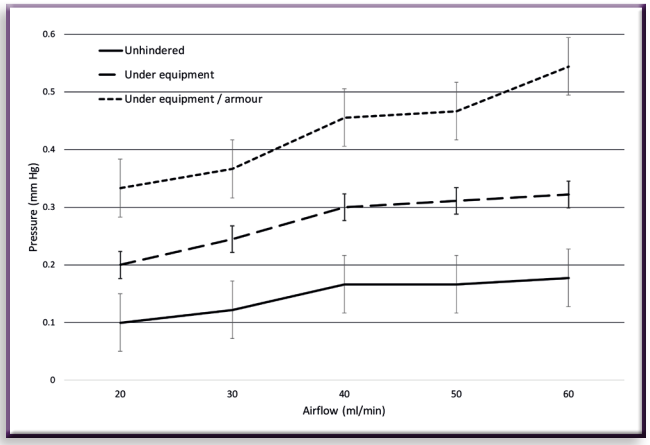


FIGURE 12 *Back pressure of vent unhindered and under standard UK military equipment and armor.*



Channel Failure on Concave and Convex Surfaces

When applied to both concave and convex surfaces, the ability of the vent to hold a negative pressure over 3 seconds and not hold positive pressure was assessed; at no point did the dressing function fail.

Discussion

The main complication associated with the use of an open pneumothorax dressing is the development of tension pneumothorax.[14] The use of a vented chest seal dressing may prevent this from occurring. To ensure the design of the vented chest seal dressing is optimal and reduces the risk of further complications related to product failure, two key elements of

the design features are the adhesion profile and the vent design. As reported in the introduction, there are several dressing designs on the market currently, which use different technologies. A new dressing design has been developed with the objective of trying to minimize potential failings observed and reported with existing dressing.[8]

With respect to adhesion profiling of the adhesive technology used within the new vented chest seal design, the data within this study indicate that the adhesive characteristics are capable of adhering to skin under all austere conditions. These conditions included below-freezing conditions, ambient conditions, and very hot conditions, representative of the different global environmental zones. The results show that over all these conditions, there is minimal difference in the ability for the design to adhere, even suggesting that in hotter climates the adhesive properties may increase. The adhesive technology within the product helps reduce the risk of failure during use, in that it maintains the product in place over the wear time, allowing the casualty to obtain further medical assistance and evacuation. The adhesive technology also minimizes the risk of blood leakage finding a pathway under the adhesive skin contact layer, which may further result in product failure.

When subjected to dirty skin, sweaty skin, hairy skin, and a combination of each condition, both in vitro and in vivo testing demonstrated that the adhesion technology within the new design still functions. This is also a key design feature, as often this type of injury and medical intervention are under conditions that would create such an environment. It is still advisable to clean the area around the wound before product application, but the results indicate that when not viable, the performance of the new design operates as intended.

Only acidic sweat was tested; alkaline sweat adhesion testing was not assessed. Alkaline sweat is created from the use of alkaline soaps. However, due to the environment that this testing was intended for, alkaline sweat will not be a factor. Soldiers in the field will rarely have use of washing facilities and, therefore, will not create alkaline sweat. The mean pH of sweat is 5.5, with a range of 4.3 to 7.1.[13]

The ability to adhere to within in vivo environments and not rely on in vitro data is an important criterion in the development of a product because human skin/tissue behaves differently from in vitro substitutes.

Maintaining the product in place is the first key element of the new design. The second key element is the vent functionality. The new design has three zones, with each zone having eight vents. In total, there are 512 pathways for air and fluid to escape from the dressing. This design feature allows the dressing to be placed at any angle (360° orientation), making it intuitive during application. Physically, any expelled blood and exudate from the wound would follow a path related to gravity. If over time the blood congeals and restricts the movement of air through the lower vents, there are a significant number of other vents that still operate, as demonstrated within the valve profiling analysis. Using a vented chest seal with two or fewer vents potentially increases the likelihood of complications if one or more of the vents is obstructed.

Data within this study demonstrate that even under standard UK military equipment and armor, the vent system is not occluded. However, it should still be advised to be cautious about overtightening of straps, etc., which may ultimately cause full occlusion.

The three zones of vents have also been designed to prevent any channeling of the outer vent layer from the inner central opening to the outer vent area on flat, concave, or convex surface or being created when folded within the IFAK or medical kit. Channeling within existing formats of commercially available chest seal dressing may result in the product permanently venting, resulting in the casualty requiring further medical attention due to external pressure/air entering the pleural cavity space.

Conclusion

The recommended application of a vented chest seal in managing open pneumothorax by the TCCC[6] is intended to provide the casualty with the optimal at-point care and increase the likelihood of survival. It is, therefore, critical during the design and development process of such products to introduce design features that help support this objective and do not introduce further risks. The development of this new design for a vented chest seal has been tested for adhesion technology and venting properties and shown to have performance criteria suitable for the treatment of open pneumothorax and design features that have the potential to minimize risk of product failure during use.

Conflict of Interest

All authors are employees of Medtrade Products Ltd, Crewe, UK.

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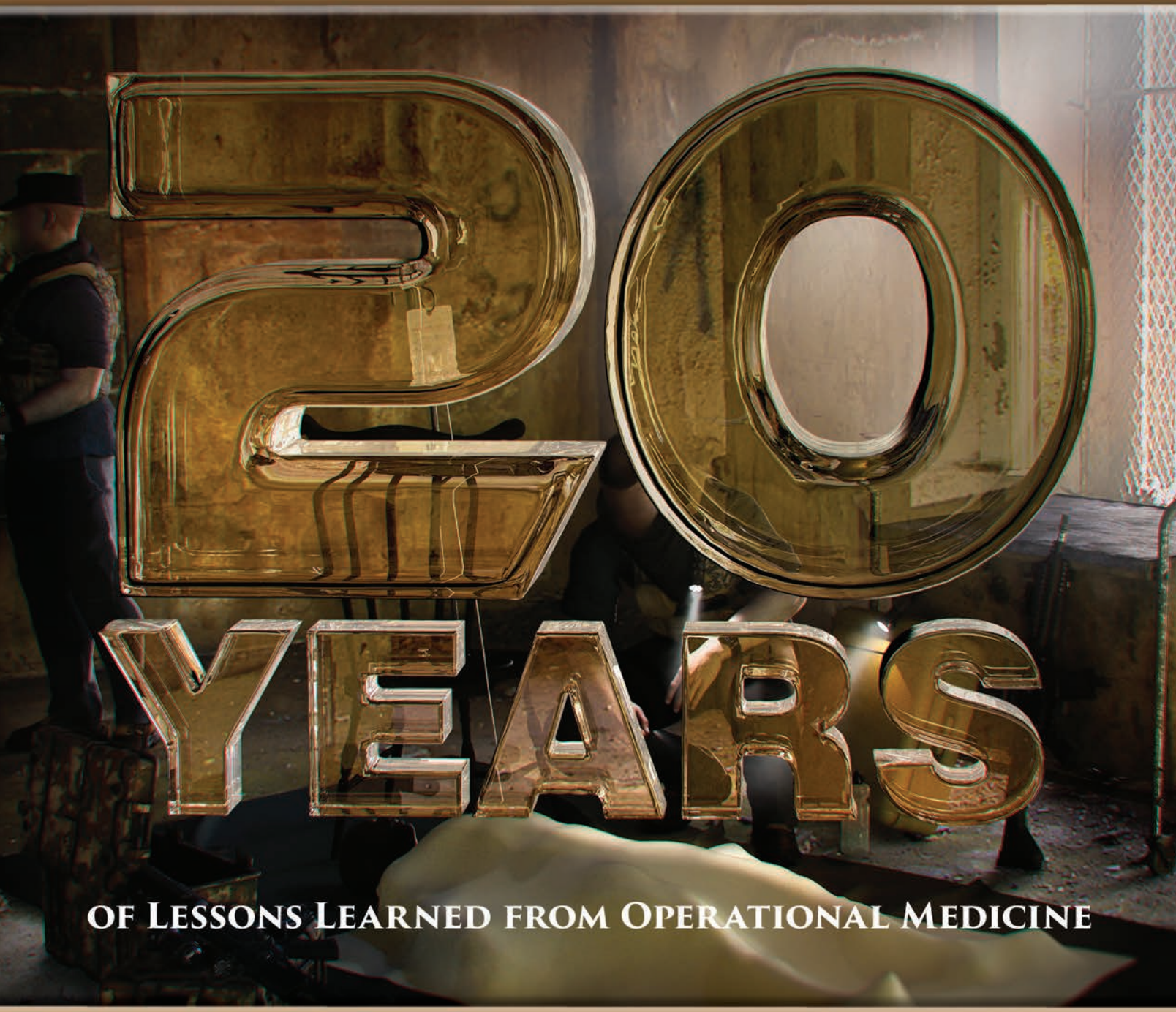

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