Efficacy of Commercial Chest Seal Adherence and Tension Pneumothorax Prevention

A Systematic Review of Quantitative Studies

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ABSTRACT

Background: Penetrating thoracic injuries account for an essential subset of battlefield and civilian injuries that result in death. Current recommendations are to use commercially available nonocclusive chest seals. We review current evidence for which chest seal(s) is likely to be the most effective in treating open pneumothoraces. Methods: A systematic review was conducted in accordance with the PRIMSA 2009 standard systematic review methodology, except where noted. The databases Pubmed, MEDLINE, CINAHL, Scopus, and gray sources were searched for all English-language, full-manuscript, experimental, quantitative studies of humans and animals concerning seal adherence or their efficacy at preventing tension pneumothoraces published between 1990 and 2020. A numerical analysis was used to provide the consensus recommendation. Results: Of 683 eligible identified articles [PubMed 528 (77.3%), Scopus 87 (12.7%), CINAHL 67 (9.8%), one (0.1%) unpublished], six (0.9%) articles were included. Synthesis of all studies' results suggests a consensus recommendation for the Hyfin Vent Chest Seal and Russell Chest Seal. These two were the most effective chest seals, as previously investigated in a quantifiable, experimental study. Conclusion: While chest seals are recommended in civilian and military prehospital medicine to improve patient survival, current evidence concerning the individual device's efficacy is limited. Further scientific, quantitative research is needed to clarify which commercially available chest seals are most effective and provide patients with penetrating chest trauma the best possible method for preventing or mitigating tension pneumothoraces.

KEYWORDS: *pneumothorax; chest seal; chest trauma; tactical combat casualty care; advanced trauma life support; systematic review*

Introduction

Penetrating thoracic injuries account for an essential subset of battlefield and civilian injuries. From 2003 to 2011, 2,048 US military members sustained combat-related, nonlethal thoracic injuries, 12.9% of which experienced an open pneumothorax.[1] Penetrating chest trauma is not confined to the battlefield. In 2011, of the 512 trauma-related deaths in Miami-Dade County, Florida, 18.6% died from potentially survivable chest injuries.[2] A study of 12 civilian mass shootings demonstrated that, of the victims who died with potentially survivable injuries, 88.9% died with chest trauma leading to respiratory impairment or tension pneumothoraces.[3] Chest trauma is not isolated to urban and combat environments. The wilderness medicine community also recognizes the importance of chest trauma in austere environments.[4,5]

For almost a century, recommendations for the management of open pneumothoraces have included specialized wound dressings due to the unique physiologic requirements of the thoracic cavity. Current recommendations are to use nonocclusive chest seals when available to improve patient survival.[6–9] The commercial market has responded, and an Internet search showed 14 commercially available occlusive and nonocclusive chest seals with conflicting marketing claims regarding their effectiveness (Table 1).

TABLE 1 *Commercially Available Chest Seals*

Nonocclusive	Occlusive
Asherman Chest Seal (Teleflex, Morrisville, NC)	H&H DualSeal Chest Seal (H&H, Ordinary, VA)
Bolin Chest Seal (H&H, Ordinary, VA)	FoxSeal (MedTrade Products LTD., Crewe, UK)
Bolin Chest Seal XL (H&H, Ordinary, VA)	Halo Chest Seal (Curaplex, Dublin, OH)
FastBreathe Thoracic Seal (FastTrack Medical Solutions, Eden Prairie, MN)	Hyfin Chest Seal (North American Rescue, Greer, SC)
Halo Vent Chest Seal (Curaplex, Dublin, OH)	SAM Non-Valved (SAM Medical, Wilsonville, OR)
Hyfin Vent Chest Seal (North American Rescue, Greer, SC)	H&H Wound Seal Kit (H&H, Ordinary, VA)
Russel Chest Seal (Tactical Medical Solutions, Anderson, SC)	
SAM with valve (SAM Medical, Wilsonville, OR)	
SAM -Valved 2.0 (SAM Medical, Wilsonville, OR)	
Sentinel Chest Seal (Prometheus Medical Ltd, Herefordshire, UK)	

The efficacy of a chest seal is directly related to its ability to improve patient mortality when used to treat penetrating chest trauma. To improve patient mortality, a chest seal needs two essential attributes, to remain physically located over a wound and to mitigate the deleterious progression of an open pneumothorax to a tension pneumothorax. These two attributes should function at the same time and remain intact when exposed to common trauma contaminants such as blood, perspiration, dirt, and fragments of tissue.

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The authors intended to systematically review the available evidence in the literature concerning chest seal adherence and the ability to prevent tension pneumothoraces in patients with penetrating chest trauma.

Research Question

The goal was to answer the following questions concerning chest seals when used to treat an open pneumothorax caused by penetrating trauma: 1) Which chest seals have superior adherence to skin as compared to other commercially available chest seals? 2) Which chest seals have a superior ability to prevent tension pneumothoraces, as compared to other commercially available chest seals?

Methods

The systematic review was conducted in accordance with the PRIMSA 2009 standards systematic review methodology, except where noted.[10] A formal protocol was not published prior to this article.

Eligibility Criteria

All English-language, full manuscript, experimental, quantitative studies of humans and animals concerning chest seal adherence or efficacy written and yet to be published or published from 1990 to 2020 were considered for the review.

To be included in this review, studies had to experimentally quantify device adherence or effectiveness at preventing tension pneumothorax-related changes when used to treat penetrating chest trauma in a human or animal model. The ability to remain physically in place can be further expanded into the device's ability to adhere to the patient's skin during initial placement, adherence over time, and readherence after temporary removal for "burping." A chest seal's effectiveness at preventing tension pneumothoraces is determined by the device's vent/valve ability and can be monitored via patient hemodynamics, intrapleural pressure, radiographs, or survivability after placement over an open pneumothorax. Publications of chest seals being used in the treatment of procedural complications, sequelae of known medical or surgical disease, or those of a descriptive nature were excluded.

Data Sources and Search Strategy

Three electronic databases MEDLINE, CINAHL and Scopus were searched using the terms ((((((((((((thoracic injuries[MeSH Terms]) OR pneumothorax) OR hemopneumothorax) OR (chest wound OR chest wounds))) AND (((Tissue Adhesives[MeSH Terms]) OR (seal OR seals)) OR (dressing OR dressings)))))) AND ("1990/01/01"[PDat]: "2020/08/31"[PDat]))))). A three-step search strategy was used in this review.

An initial limited search of MEDLINE was followed by analysis of the text words contained in the title and abstract, as well as of the index terms used to describe the articles. A second search using all identified keywords and index terms was then performed across all included databases. The reference lists of applicable reviews and all included articles were also examined for further potentially relevant studies. Gray sources such as textbooks, conference proceedings, committee reports, dissertations, websites, and clinical trial registries were searched using AccessMedicine, Defense Technical Information Center, ProQuest, and the open internet.

Study Selection and Data Collection

Studies were placed in the Rayyan QCRI (https://www.rayyan.ai/) web-based systematic review application.[11] A blinded initial screening was conducted by two investigators (RP, PA) using titles and abstracts, based on inclusion and exclusion criteria in Table 2. For example, qualitative case reports of chest seals for penetrating chest trauma and articles in which chest seals were applied for postoperative complications were excluded. A third blinded reviewer (MQ) was a tiebreaker on two articles, and one was excluded for being a qualitative review as it was an article discussing chest seal use in austere environments. A full-text review of the remaining articles by two investigators (RP, MQ) was conducted based on exclusion criteria. One study was excluded for being a qualitative update to treatment guidelines (Figure 1).

TABLE 2 *Inclusion and Exclusion Criteria*

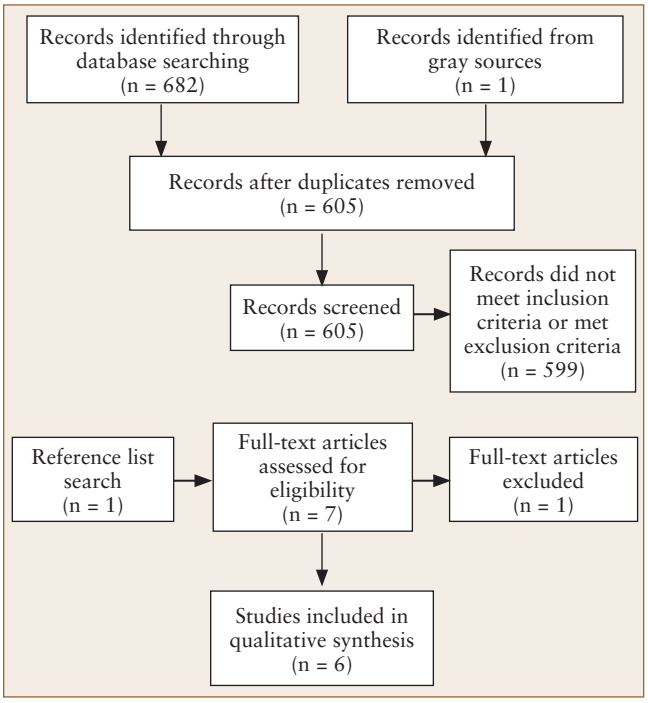
Manuscript	Published or presented in English from 1990 to 2020
Inclusion Criteria	
Type of studies	• Quantitative experimental design
Type of outcomes	• Adherence to skin • Prevention of a radiographic tension pneumothorax • Prevention of physiologic changes associated to a tension pneumothorax • Reduced mortality
Type of intervention(s) or phenomena of interest	• Adherence - Wet, dry, or soiled skin • Type of chest seal – Nonocclusive or occlusive • Medical indication – Open pneumothorax, tension pneumothorax, hemopneumothorax • Environmental conditions – Temperature, wound contaminants
Type of participants	• Animal or human adult subjects
Exclusion Criteria	
	• Case studies or articles that are purely descriptive or do not provide quantitative measurements
	• Studies of conditions caused by complications of a medical or surgical intervention
	• Studies of conditions caused by complications of an existing pathology

The included articles were reviewed, and the data extracted from each study included primary outcome, participant type, chest seals tested, method of measurement, and published results. Data collection was performed independently and unblinded for each study.

Assessment of Bias and Synthesis of Results

Scoping searches confirmed that nearly all eligible articles would not be in the form of blinded, randomized controlled trials and would have moderate risk of bias. Additionally, the heterogeneous nature of the study designs and outcome measures would prevent extensive quantitative data synthesis. For these reasons, standardized assessments of evidence quality or risk of bias were not used for the included articles. The articles are sorted by whether the primary outcome was to test adherence and vent/valve function independently of each other, or as a combined overall outcome. Results are summarized in narrative/tabular forms and the relevant methodological features are highlighted. A weighted scoring system similar to that used by Montgomery et al., to assess tourniquet performance, was

FIGURE 1 *Prisma diagram.*



used to amalgamate extremely heterogeneous data from heterogeneous studies.[12] A weighted score of one (1) to three (3) was used to score chest seal performance based on the reporting study's results. A chest seal that was reported by the original investigator to have superior performance received a score of three (3). A chest seal that was excluded from further study or deemed to have failed received a score of one (1), and a chest seal that was successful but not found to be statistically superior received a score of two (2). Each chest seal was assigned a weighted score for each of studies included in this review. A total score was calculated as a mean of each chest seal's individual scores. Chest seals that were not tested for adherence or function were given a null value and were not assigned a total score. A one-way ANOVA with Tukey posthoc testing was used to test for statistical significance of the aggregated mean weighted scores using SPSS version 26 (IBM, https://www.ibm.com/products/spss-statistics). A numerical ranking analysis was conducted using the total scores for each device to answer the objective of this study and provide consensus recommendations for overall chest seal effectiveness.

Results

Search Results and Study Characteristics

The systematic search revealed a total of 682 eligible references [PubMed 528 (77.4%), Scopus 87 (12.8%), CINAHL 67 (9.8%) and two additional studies were identified by review of the reference lists (Figure 1). Of the 533 nonduplicate articles, seven (1.0%) were initially selected for full-text review. One article was excluded during the full article review. Six (0.9%) relevant quantitative articles were found that evaluated chest seal effectiveness at treating open pneumothoraces (Table 3).

Aggregated Results

The objective of this review was to identify which chest seals are the most effective at treating open pneumothoraces secondary to penetrating trauma. Table 4 includes the characteristics of the included studies. Not all commercially available chest seals have been experimentally tested, nor did the included studies test the same chest seals (Table 5). Each chest seal's total score, weighted scores, primary outcome, sample size, and associated citation are included in Table 6.

TABLE 3 *Methodological Characteristics of Included Studies*

Characteristics	N	(%)
Study model		
Human	1	(16)
Swine	5	(83)
Study purpose		
Adherence	2	(33)
Vent/valve efficacy	1	(16)
Overall effectiveness	2	(33)
Independent investigation of adherence and vent/valve efficacy in same study	1	(16)
Year of publication		
Unpublished	1	(16)
2007–2010	1	(16)
2011–2014	2	(33)
2015–2018	2	(33)

*Percentage column does not equal 100% due to rounding.

Table 7 provides each chest seal's scores concerning their performance in adherence or vent/valve function. Table 6 includes more data points for each device tested as compared to Table 7 because it has expanded varying experimental iterations found within the included studies.

Four studies tested adherence as a primary outcome. Of the chest seals tested, the FastBreathe Thoracic Seal (Fast Track Medical Solutions LLC, www.fasttrackmedicalsolutions.com, Hyfin Vent Chest Seal (North American Rescue, www.narescue.com), and SAM Chest With Valve Seal (SAM Medical, www.sammedical.com) had equally superior performance (mean 3, standard deviation (SD) 0) (Table 7).

Three studies tested the device's ability to avoid predefined tension pneumothorax-related parameters as a primary outcome. Of the chest seals tested, the Asherman Chest Seal (Teleflex Medical, www.teleflex.com), Russell Chest Seal (Prometheus Medical Ltd., www.prometheusmedical.co.uk), and Sentinel Chest Seal (Prometheus Medical Ltd, www.prometheusmedical.co.uk) had equally superior performance (Mean 3, SD 0) (Table 7).

To synthesize the results across the heterogeneous studies, answer the research questions, and provide a consensus statement, an overall score was calculated for each device. Chest seals not tested for both adherence and vent/valve function were not eligible to be recommended. There were no statistically significant differences between the chest seal's total score as determined by a one-way ANOVA [$F(5,26) = 1.288$, $p = 0.299$] with $\alpha = 0.05$ due to a limited data set. Ordinal ranking analysis of all the total scores suggests a consensus recommendation for the Hyfin Vent Chest Seal and the Russell Chest Seal, both with total scores of 2.75, as being the most effective chest seals previously investigated in a quantifiable, experimental study (Table 7).

Adherence

Supinksi et al. was the only adherence study conducted on human participants and, despite being unpublished, has been

TABLE 4 *Data Extracted from Included Studies*

Authors, Year	Primary Outcome	Model	A Priori of Outcome	Independent Variable(s)	Independent Variable(s) Details	Results	
						Superior Performance	Inferior Performance
Kheirabadi et al., 2017[16]	Combined efficacy of CS treating OHPNX, preventing TPNX	Swine	DCR 20% MAP, 20% CO, or 30% MVO_2; INC 1mmHg IPP or 30% PAP	**Skin:** shaved, clean, dried **Thorax:** air, blood **Wound:** active bleeding tract	**AI:** 0.25L **BI to wound tract:** 50mL	HYVCS, RCS, SCS	BCS, SCSV
Arnaud et al., 2016[14]	CS adhesiveness after storage at varying temperatures	Swine	% attached after peeling, vertical force	**Skin:** clean, bloody, sand, dry, shaven, unshaven **Storage:** ambient, cold, or hot	Horizonal peeling Vertical pull	HYVCS, FBTS, RCS, SCSV	ACS, BCS, BCSXL, SCS
Kotora et al., 2013[19]	Vent/valve efficacy of CS treating OHPNX, preventing TPNX	Swine	DCR 20% HR or MAP	**Thorax:** air, blood	**AI:** 60mL **BI to thorax:** 10% total volume	No significant difference	N/A
Kheirabadi et al., 2013[20]	Vent vs. nonvented CS efficacy treating OPNX preventing TPNX	Swine	1mmHg IPP plus ≥ 4 of 5: DCR 20% MAP, 20% CO, 20% TV, or 30% MVO2; ICR 30% PAP	**Thorax:** air	**AI:** 0.2L	BCS	HACS
Supinski et al., 2012[13]	CS adherence and readherence after burping	Human	CS % TSA, loss of adhesion within 1 cm of wound	**Skin:** perspiration, body hair, contaminants	**Skin:** perspiration, burp dressing	ACS, BCS, HACS, HYCS, RCS, SCSV	SCS, WSK
Arnaud et al., 2008[17]	CS vent/valve efficacy treating OPNX preventing TPNX and CS adhesion	Swine	**Vent/Valve:** DCR 20% HR or MAP **Skin:** scored on a scale of 0 (poor) to 3 (good)	**Skin:** dry, blood soiled **Thorax:** air, blood	**AI:** 60mL **BI to thorax:** 240mL	**Vent/Valve:** ACS, BCS **Adherence:** BCS	**Blood soiled skin:** ACS

CS, chest seal; OPNX, open pneumothorax, OHPNX, open hemopneumothorax; TPNX, tension pneumothorax; CO, cardiac output; HR, heart rate; IPP, intrapleural pressure; MAP, mean arterial pressure; MVO_2, mixed venous oxygen saturation; PAP, pulmonary arterial pressure; TV, tidal volume; AI, air increments; BI, blood increments; ACS, Asherman Chest Seal; BCS, Bolin Chest Seal; BCSXL, Bolin Chest Seal XL; FBTS, FastBreathe Thoracic Seal; HACS, Halo Chest Seal; HYCS, Hyfin Chest Seal; HYVCS, Hyfin Vent Chest Seal; RCS, Russell Chest Seal; SCSV, SAM Chest Seal with Valve; SCS, Sentinel Chest Seal; WSK, H&H Wound Seal Kit; TSA, total surface area; DCR, decrease of; ICR, increase of.

TABLE 5 *Commercially Available Chest Seal Experimental Testing Frequency*

Number of Studies Testing Each Chest Seal			
Adherence (Nonocclusive)		**Prevention of Tension Pneumothorax (Nonocclusive)**	
Asherman Chest Seal	3	Asherman Chest Seal	1
Bolin Chest Seal	3	Bolin Chest Seal	2
Bolin Chest Seal XL	1	Bolin Chest Seal XL	0
FastBreathe Thoracic Seal	1	FastBreathe Thoracic Seal	0
Hyfin Vent Chest Seal	2	Hyfin Vent Chest Seal	2
Russell Chest Seal	2	Russell Chest Seal	1
SAM Chest Seal with Valve	3	SAM Chest Seal with Valve	2
Sentinel Chest Seal	3	Sentinel Chest Seal	2
Adherence (Occlusive)		**Prevention of Tension Pneumothorax (Occlusive)**	
Halo Chest Seal	1	Halo Chest Seal	1
Hyfin Chest Seal	1	Hyfin Chest Seal	0
H&H Wound Seal Kit	1	H&H Wound Seal Kit	0

previously cited in multiple publications, to include the Committee for Tactical Combat Casualty Care treatment and device recommendations.[13–16] Research manuscripts from Arnaud et al. in 2008 and 2016, and Kheirabadi et al. in 2017, tested adherence on swine models with varying designs.[14,16,17]

Supinksi et al. tested the adherence of eight chest seals on healthy, human volunteers with a simulated wound to their chest and back.[13] Supinksi et al. simulated combat conditions and wound contaminants with exercise, canned condensed milk, and sand. A randomized chest seal was centered over the wound and remained in place for 30–40 minutes before being visually evaluated for separation from the skin. Supinksi et al. then evaluated readherence after a simulated wound "burping."[13] Arnaud et al.'s 2008 study[17] assessed the adherence of two chest seals on a swine model by placing a randomized chest seal over a surgically created open pneumothorax surrounded by dry or blood-soiled skin. Arnaud et al.[17] recorded the force needed to separate the chest seal from the swine skin using a 0-3 scale described by Khan and Peh.[18] Arnaud et al.'s 2016 study[14] focused on the adherence of seven chest seals on uninjured swine skin after being stored at ambient (20–22°C), cold (–19.5 ± 1.3°C), or hot (71.5 ± 2.0°C) temperatures.[14] After storage at either cold or hot temperatures, the randomized chest seals were allowed to return to ambient temperature then affixed to skin that was either clean dry shaven, clean dry unshaven, unshaven covered in blood, unshaven covered in dry sand, or unshaven covered with blood and sand.

Supinksi et al. evaluated each chest seal based on percent adherence and whether the devices exhibited loss of adhesion within

TABLE 6 *Weighted Scoring of Chest Seals Tested for Both Adherence and Vent/Valve Function*

Total Score (Mean of Scores)	Score	Outcome Description	n =	Citation
Asherman Chest Seal				
1.833	3	Adherence to dry swine skin	12	17
	1	Adherence to blood soiled swine skin	12	17
	2	Adherence to human skin with simulated wounds	10	13
	1	Adherence against horizontal forces at ambient temperatures	3*	14
	1	Adherence against vertical forces at ambient temperatures	3*	14
	3	Valve efficacy	12	17
Bolin Chest Seal				
2.5	3	Adherence to dry swine skin	12	17
	3	Adherence to blood soiled swine skin	12	17
	3	Adherence to human skin with simulated wounds	36	13
	2	Adherence against horizontal forces at varying temperatures	36*	14
	2	Adherence against vertical forces at varying temperatures	36*	14
	3	Valve efficacy preventing tension pneumothorax	12	17
	3	Valve efficacy preventing tension pneumothorax	8	19
	1	Chest seal efficacy at combined adherence and vent capability with bleeding wound	4	16
Hyfin Vent Chest Seals				
2.75	3	Adherence against horizontal forces at varying temperatures	36*	14
	3	Adherence against vertical forces at varying temperatures	36*	14
	3	Vent efficacy preventing tension pneumothorax	8	18
	2	Chest seal efficacy at combined adherence and vent capability with bleeding wound	6	16
Russell Chest Seal				
2.75	2	Adherence to human skin with simulated wounds	8	13
	3	Adherence against horizontal forces at varying temperatures	36*	14
	3	Adherence against vertical forces at varying temperatures	36*	14
	3	Chest seal efficacy at combined adherence and vent capability with bleeding wound	6	16
SAM Chest Seal with Valve				
2.2	2	Adherence to human skin with simulated wounds	8	13
	3	Adherence against horizontal forces at varying temperatures	36*	14
	3	Adherence against vertical forces at varying temperatures	36*	14
	3	Vent efficacy preventing tension pneumothorax	8	18
	1	Chest seal efficacy at combined adherence and vent capability with bleeding wound	4	16
Sentinel Chest Seal				
1.8	1	Adherence to human skin with simulated wounds	15	13
	1	Adherence against horizontal forces at ambient temperatures	3*	14
	1	Adherence against vertical forces at ambient temperatures	3*	14
	3	Vent efficacy preventing tension pneumothorax	8	18
	3	Chest seal efficacy at combined adherence and vent capability with bleeding wound	6	16

*Sample size not clearly stated by author; estimates or averages provided.

1 cm of the simulated wound 30–40 minutes after application.[13] After recording the initial results, Supinksi et al. readhered the device after a simulated "burping" and once again evaluated for percent adherence or damage to the dressing.[13] In 2016, Arnaud et al. tested for chest seal adherence when challenged by horizontal and vertical forces.[14] Resistance to horizontal forces was assessed by measuring the percentage of the chest seal still adhered after a manual rubbing force was applied to the edges of the chest seal. A novel dual syringe system with a quantifiable vertical pulling force was used to assess each device's resistance to vertical forces. The force needed to separate the device from the skin, up to 20 mL of syringe vacuum, was recorded.

Supinksi et al. reported a statistically significant improvement in adhesion of the SAM Chest Seal With Valve and Bolin Chest Seal (H&H Medical Corporation, www.hhmedcorp.com) as compared to the Sentinel Chest Seal and the H&H Wound Seal Kit (H&H Medical Corporation, www.hhmedcorp.com).[13] Supinksi et al. found no statistically significant difference in adherence between the Asherman Chest Seal, Bolin Chest Seal, Halo Chest Seal (Curaplex, www.curaplex.com), Hyfin Chest Seal, Russell Chest Seal, and SAM Chest Seal With Valve.[13] However, Supinksi et al. concluded the "SAM [with valve] and Bolin Chest Seal performed better," due to lower rates of adhesion failure within 1 cm of the wound.[13] Supinksi et al. further concluded that neither the Sentinel Chest Seal or the H&H Wound Seal Kit should be kept in military inventory based on their statistically significant poor performance.[13] In 2008, Arnaud et al. reported that on dry skin, the Asherman and Bolin Chest Seal performed similarly, but the Bolin Chest Sealperformed statistically better on blood-soiled skin.[17] In 2016, Arnaud et al. reported no significant difference in adhesion between the FastBreathe Thoracic Seal, Hyfin Vent Chest Seal, Russell Chest Seal, and SAM Chest Seal With Valve at all temperatures.[14]

TABLE 7 *Tested Chest Seals Performance by Study*

	Adherence				Vent/Valve Function			
	Count	Sum	Mean	SD	Count	Sum	Mean	SD
Hyfin Vent Chest Seal	1	3	3	0	2	5	2.5	0.707
Russell Chest Seal	2	5	2.5	0.707	1	3	3	0
Bolin Chest Seal	3	8	2.667	0.577	3	7	2.333	1.155
SAM Chest Seal With Valve	2	6	3	0	2	2	2	1.414
Asherman Chest Seal	3	4	1.333	0.577	1	3	3	0
Sentinel Chest Seal	2	2	1	0	2	3	3	0
Halo Chest Seal	1	2	2	0	1	2	1	0
Bolin Chest Seal XL	1	1	1	0	—	—	—	—
FastBreathe Thoracic Seal	1	3	3	0	—	—	—	—
H&H Wound Seal Kit	1	1	1	0	—	—	—	—

Valve/Vent Efficacy

Kotora et al.[19] and Arnaud et al.'s 2008 study[17] used the same swine model and physiologic parameters of a 20% decrease in mean arterial pressure or a 20% increase in heart rate from baseline to signify the development of a tension pneumothorax and therefore valve/vent failure.[17,19] In both studies, the swine were prepared in the same fashion by surgically creating an open pneumothorax into the pleural cavity and inserting a catheter into the pleural space, through which air and blood were systematically injected. It is at this point that the two studies experimental designs began to differ. Arnaud et al. placed one of their two randomized chest seals over the open chest wound, and its edges were securely taped to the swine's skin to ensure full adherence.[17] Kotora et al. placed one of their three randomized chest seals over the wound without additional securing efforts.[19] Arnaud et al. and Kotora et al. then injected air into the intrapleural space in 60mL increments to a maximum of 50mL/kg in an attempt to induce the predefined tension pneumothorax-related changes.[17,19] After a successful iteration involving air injections, both studies performed a follow-on trial by adding blood to the intrapleural space. Arnaud et al. removed 240mL of fresh blood, and Kotora et al. removed 10% of the total circulatory volume from their swine.[17,19] After the blood was injected into the intrapleural cavities, to create hemopneumothoraces, air injections in 60mL increments up to 50mL/kg were once again initiated.

Arnaud et al. reported no statistically significant difference between the Asherman Chest Seal and Bolin Chest Seal, as they both prevented the tension pneumothorax related-changes equally well, regardless of whether the hemopneumothorax was present.[17] Kotora et al. reported that the Hyfin Vent Chest Seal, SAM Chest Seal With Valve, and Sentinel Chest Seal all prevented any tension pneumothorax related changes with or without the presence of a hemopneumothorax equally well and with no significant difference.[19]

Valve/Vent Efficacy and Adherence: Occlusive versus Nonocclusive Chest Seals

In 2017, Kheirabadi et al. studied chest seals as a complete functional unit, requiring both essential attributes of effectiveness to work in union.[16] The study used a swine model with a surgically-created open hemopneumothorax and an actively bleeding wound tract. The chest seals were assessed for their ability to avoid tension pneumothorax-related physiology, defined by the authors as an increase of intrapleural pressure by 1 mm Hg, 30% rise of pulmonary arterial pressure, 30% fall in mixed venous oxygen saturation, or a 20% fall of the mean arterial pressure or cardiac output.

Kheirabadi et al. surgically created an open pneumothorax with two percutaneous catheters, one of which reemerged within the wound tract to simulate an actively bleeding wound.[16] The second catheter allowed air and blood to be injected into the pleural cavity. Approximately 10% of the swine's total blood volume was then withdrawn and injected into its pleural cavity. The area around the wound was shaved, cleaned, and dried in preparation for one of the five randomized chest seals to be placed over the open wound, with the valve or vent directly overlying the open wound. Air and blood were injected into the pleural space and wound tract in 0.25 L and 50 mL increments, respectively, every 10 minutes. The injections continued until either 2 L of air, which was the approximate total lung capacity of the swine, was injected into the intrapleural space, the chest seal detached from the wound, or the study-defined tension pneumothorax criteria occurred.

Kheirabadi et al. reported that the Hyfin Vent Chest Seal, Russell Chest Seal, and Sentinel Chest Seals' vents allowed blood and air to escape the intrapleural space, preventing failure. They also reported that blood clots blocked the valve mechanisms on the Bolin Chest Seal and SAM Chest Seal With Valve after the "leakage of a few milliliters of blood."[16] After becoming occluded, the adhesive capabilities of the Bolin Chest Seal and SAM Chest Seal With Valve were eventually overwhelmed by the increasing intrapleural pressure, and they were excluded from further study. During two of the six iterations with the Hyfin Vent Chest Seal, adhesion failed on one side, creating a functional three-sided dressing. Kheirabadi et al. reported that the Bolin Chest Seal and SAM Chest Seal With Valve failed, and the Hyfin Vent Chest Seal, Russell Chest Seal, and Sentinel Chest Seal as being equally successful.[16]

In 2013, Kheirabadi et al. compared the efficacy of an occlusive chest seal and a nonocclusive chest seal for the treatment of open pneumothoraces.[20] Chest seal effectiveness was determined by their ability to prevent the predefined tension pneumothorax-related changes. Kheirabadi et al. defined those changes as an intrapleural pressure change greater than 1 mm Hg and at least four of the following five findings: 30% increase in pulmonary artery pressure, 30% decrease in mixed venous oxygen saturation, 20% decrease in tidal volume, 20% decrease in mean arterial pressure, or 20% decrease in cardiac output.[20]

Kheirabadi et al. surgically created an open pneumothorax and a catheter was placed percutaneously into the intrapleural cavity to facilitate the injection of air and intrapleural pressure monitoring.[20] One of the two randomized chest seals was then placed over the open pneumothorax after 5 minutes in the open atmosphere. Every 5 minutes, 200mL of air was injected into the intrapleural space, and data were recorded until either the study-defined criteria were met, or the volume of air injected into the intrapleural space equaled the total lung capacity of the swine. At the completion of the iteration, the presence or absence of a tension pneumothorax was confirmed with a radiograph.

All iterations with the nonvented Halo Chest Seal resulted in failure and the development of a tension pneumothorax.[20] All iterations with the vented Bolin Chest Seal were a success, even when the maximum volume of air had been reached.[20]

Discussion

This study's key finding was a paucity of quantitative experimental design research focusing on chest seal adherence and ability to prevent tension pneumothorax following penetrating trauma. Of 682 eligible references, only six met review inclusion criteria: 595 did not assess adherence or vent/valve function; 32 involved indications other than penetrating chest trauma; and 8 were qualitative and narrative. Additional review complications for determining which chest seals have superior adherence and ability to prevent tension pneumothorax development were heterogeneity in study methods and reported outcomes, the use of swine in five of the laboratory studies, and the absence of relevant clinical trial data.

This review and synthesis of the limited data identified the Hyfin Vent Chest Seal and Russell Chest Seal, both nonocclusive chest seals, as being the recommended chest seals. This was the recommendation by consensus of the reviewed studies for the treatment of open pneumothoraces. It is unknown whether these two chest seals would remain as the top performers if *all* commercially available devices were tested across *all* the relevant studies. While the Hyfin Vent Chest Seal lost adherence in Kheirabadi et al.'s 2017 study, its ability to continue functioning as a three-sided dressing and preventing the predetermined tension pneumothorax-related criteria led to it being considered a success.[16] It is for this reason that it is still considered eligible to be included in the consensus recommendation.

Study Limitations

There were limitations within all the included studies. Supinski et al. was the only study with human participants.[13] Swine hair and skin differ from human hair and skin enough to create a significant limitation. The relatively shorter, stiffer, and more coarse hairs of the swine may affect how any device adheres to unshaven skin. The thicker and less pliable swine skin may affect how an adhesive device remains adhered to a moving chest wall. Swine do not perspire, and regardless of the investigator's intent, real battlefield and prehospital conditions are not easily reproduced during simulation. Kheirabadi et al.'s 2017 study was the only study to simulate bleeding into the wound tract, which could be seen as a limitation within this study or a limitation of the other five studies that lacked a bleeding wound tract.[16] The authors of this review felt that blood moving through the chest seal is a possibility under combat conditions and therefore that the Kheirabadi et al. study provided realistic conditions.[16]

Study heterogeneity preventing meta-analysis and the lack of clinical trials available for review are also limitations of this analysis. The review methodology had limitations, including the inability to present quantitative summaries of results given the studies' heterogeneity, as well as the use of a fundamental comparative analysis as compared with a formal, previously validated method of analysis. The paucity of literature on this topic over the past 28 years prevented the inclusion of every commercially available chest seal. Despite these limitations, the search strategy was quite broad. It allowed for the identification of a full spectrum of topics relevant to chest seals over an extensive time period. It also critically evaluated the methodology of eligible studies and did not incorporate results from studies with inappropriate design or phenomena of interest.

Conclusion

Although chest seals are recommended in civilian and military prehospital medicine to improve patient survival, current evidence concerning the efficacy of these devices is limited. Further experimental, quantitative research is needed to clarify which commercially available chest seals are the most effective and provide patients the best possible chance for survival.

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Disclosures

The authors report no conflict of interests.

Author Contributions

RP conducted the initial literature search. RP, A., and LB developed the study design and methods. RP, MQ, PA, and LB conducted the data collection, analysis, interpretation. RP wrote the initial manuscript. MQ, PA, and LB provided critical revisions.

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