Department of Defense
Programmatic Overview of Chest Seal Performance – Phase II

GJ Housler[1]*, KT Curry[1], MJ Husband[1], RM McCarron[3], DG Baer[2], COL RT Gerhardt[2], DO Kennedy[1], and F Arnaud[3]

[1]U.S. Army Medical Materiel Agency (USAMMA), Fort Detrick, MD

[2]U.S. Army Institute for Surgical Research (USAISR), Fort Sam Houston, TX

[3]Naval Medical Research Center (NMRC), Silver Spring, MD

Introduction / Project Background:

Pneumothorax:

- Occurs when air leaks into the space between the pleural surfaces
- Life threatening situation when open pneumothorax develops into *tension pneumothorax (tPTx).*
- Remedy: Vented seals regulate air entry or exit through the pleural cavity to relieve tension.

Phase I study:

- In a first phase study of 17 different chest seals with optimal air flow and new material, we down-selected the best performing vented and non-vented chest seals based on adhesive properties; [2013 MHRS poster presentation]
- Kheirabadi et al. has demonstrated that only vented chest seals can prevent pneumothorax from developing into tPTx; [Kheirabadi et al 2013].

Battlefield situation:

- Exposure to extreme environmental conditions can be encountered.

Objectives:

- Evaluation of the effects of exposure at extreme hot and cold temperatures on the adhesive properties of the down-selected vented chest seals.

Results/Accomplishments:

Peeling results:

Edge Adhesion (%) as measured by peeling

Conditions	Unshaved Skin			Shaved Skin			Cold	
-19.5 ± 1.3 °C	Skin Only	Blood	Blood + Sand	Skin Only	Blood	Blood + Sand		
Product							**Average**	**SD**
Bolin chest seal™	90	86	82	97	96	90	**90**	**6**
Russell chest seal™	94	96	90	97	96	98	**95**	**3**
Fast Breathe seal™	92	84	78	95	96	88	**89**	**7**
HyFin® seal with vent	98	92	87	97	99	98	**95**	**5**
SAM® seal with valve	97	97	87	99	98	90	**94**	**5**
Average	**94.0**	**91.0**	**84.7**	**96.9**	**97.0**	**92.8**		
SD	**3.6**	**6.0**	**4.6**	**1.3**	**1.5**	**4.8**		

Conditions	Unshaved Skin			Shaved Skin			Hot	
71.5 ± 2.0 °C	Skin Only	Blood	Blood + Sand	Skin Only	Blood	Blood + Sand		
Product							**Average**	**SD**
Bolin chest seal™	87	92	77	47	91	79	**79**	**17**
Russell chest seal™	98	97	96	88	99	92	**95**	**4**
Fast Breathe seal™	89	80	84	95	99	81	**88**	**8**
HyFin® seal with vent	98	96	91	97	99	96	**96**	**3**
SAM® seal with valve	96	95	94	98	97	96	**96**	**2**
Average	**93.6**	**91.9**	**88.5**	**85.0**	**96.9**	**88.8**		
SD	**5.1**	**7.1**	**7.8**	**21.6**	**3.5**	**8.2**		

Suction results:

Detachment (%)

COLD Conditions	Unshaved Skin			Shaved Skin		
-19.5 ± 1.3 °C	Skin Only	Blood	Blood+Sand	Skin Only	Blood	Blood+Sand
Product						
Bolin chest seal™	45.0	46.3	55.0	55.0	max	25.0
Russell chest seal™	60.0	max	max	max	max	max
Fast Breathe seal™	40.0	35.0	50.0	max	65.0	max
HyFin® seal with vent	max	max	45.0	max	55.0	35.0
SAM® seal with valve	max	max	50.0	48.3	70.0	37.5
Average	**48.3**	**40.6**	**50.0**	**51.7**	**63.3**	**32.5**
SD	**10.4**	**8.0**	**4.1**	**4.7**	**7.6**	**6.6**
Hot Conditions	**Unshaved Skin**			**Shaved Skin**		
71.5 ± 2.0 °C	**Skin Only**	**Blood**	**Blood+Sand**	**Skin Only**	**Blood**	**Blood+Sand**
Product						
Bolin chest seal™	max	45.0	41.7	37.5	30.0	40.0
Russell chest seal™	max	max	max	max	max	max
Fast Breathe seal™	max	max	60.0	max	max	max
HyFin® seal with vent	max	max	52.5	max	60.0	62.5
SAM® seal with valve	max	max	53.3	48.3	35.0	55.0
Average		**45.0**	**51.9**	**42.9**	**41.7**	**52.5**
SD		**--**	**7.6**	**7.7**	**16.1**	**11.5**

Max - indicates that there was no detachment and the syringe was pulled to its maximum without detachment

The number indicates at which % of the maximum pulling detachment occurred

This table also indicates the incidence of detachment

Breaching (%)

COLD Conditions	Unshaved Skin			Shaved Skin		
-19.5 ± 1.3 °C	Skin Only	Blood	Blood+Sand	Skin Only	Blood	Blood+Sand
Product						
Bolin chest seal™	n/a	60.0	70.0	n/a	n/a	n/a
Russell chest seal™	n/a	n/a	n/a	n/a	n/a	n/a
Fast Breathe seal™	n/a	n/a	n/a	n/a	n/a	n/a
HyFin® seal with vent	n/a	n/a	n/a	n/a	n/a	n/a
SAM® seal with valve	n/a	n/a	n/a	n/a	n/a	n/a
Average	**--**	**60.0**	**70.0**	**--**	**--**	**--**
SD	**--**	**--**	**--**	**--**	**--**	**--**
Hot Conditions	**Unshaved Skin**			**Shaved Skin**		
71.5 ± 2.0 °C	**Skin Only**	**Blood**	**Blood+Sand**	**Skin Only**	**Blood**	**Blood+Sand**
Product						
Bolin chest seal™	n/a	70.0	70.0	n/a	n/a	n/a
Russell chest seal™	n/a	n/a	n/a	n/a	n/a	n/a
Fast Breathe seal™	n/a	n/a	n/a	n/a	n/a	n/a
HyFin® seal with vent	n/a	n/a	n/a	n/a	n/a	n/a
SAM® seal with valve	n/a	n/a	n/a	n/a	n/a	n/a
Average	**--**	**70.0**	**70.0**	**--**	**--**	**--**
SD	**--**	**--**	**--**	**--**	**--**	**--**

n/a indicate that there was no breaching

The number indicates at which % of the maximum pulling breaching occured

This table also indicates the incidence of breaching

Overall:

Product	Seal Particularity	Skin Condition	COLD				HOT				Remarks
			Removing of backing	Resistance to Peeling	Resistance to Suction	Easiness of removal	Removing of backing	Resistance to Peeling	Resistance to Suction	Easiness of removal	
Bolin chest seal™	Valves are centered	**Unshaved**	Easy	Variable: good to poor (B)	Medium to good	Easy	Easy	Variable good to poor	Good	Easy	Seal tended not to adhere to skin when hair is long
		Shaved		Variable: good to poor (B)	Medium to good	Easy		Variable medium to poor	Good	Easy	Seal and adhesive tended to separate a little
New Bolin chest seal™	Valves are aligned	**Unshaved**	Easy	Good	Good	Easy	Easy	Variable good to medium	Good	Easy; Seal separate from glue	Seal and adhesive separated to the vent
	bigger flap	**Shaved**		Good; adhevise cover separate from seal	Good	Medium to Easy		Good	Good	Easy	
Russell chest seal™	No flap	**Unshaved**	Hard	Good	Good	Medium	Hard	Good	Medium to good	Medium	Seal streched on removal
		Shaved		Good	Good	Medium		Good	Good	Easy to medium (B)	
New Russell chest seal™	New plastic backing;	**Unshaved**	Easy	Good		Easy	Easy	Good		Easy to medium (B)	
	No flap	**Shaved**		Good		Easy to medium (B+S)		Good		Easy to medium (B)	
Fast Breathe seal™	One flap; fabic seal	**Unshaved**	Easy	good to poor (B+S)	Medium to good	Easy to Medium	Easy	Good	Good	Easy to medium (B)	Left glue on the skin
		Shaved		Good	Good	Medium to hard; little glue left on skin		Good	Good	Easy to medium (B)	Glue retracted (melted) from hot seal
New Fast Breathe seal™	Two flaps;	**Unshaved**	Easy	Medium	Good	Medium	Easy	Good	Medium to good	Medium	Left glue on the skin
	New seal cover	**Shaved**		Good	Good	Medium; little glue on skin		Good	Good	Medium	
HyFin® seal with vent		**Unshaved**	Easy	Good to medium(B)	Medium to good	Easy	Easy	Good	Good	Medium to Hard	Glue retracted (melted) from hot seal
		Shaved		Good	Good	Easy to medium; glue left on skin		Good	Good	Medium; glue left on skin	
SAM® seal with valve		**Unshaved**	Medium to Easy	Good	Good	Hard; glue left on skin	Easy	Good	Good	Hard; glue left on skin	Glue retracted (melted) from hot seal
		Shaved		Good	Good	Hard; glue left on skin		Good	Good	Hard; glue left on skin	

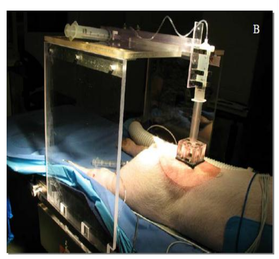
Evaluation Methods:

Swine Skin Model Adhesion Experimentation:

- Quantitative measurements for the detachment of the seal from the pig skin using:

  - *Peeling technique:* Percent adherence of the horizontal unbound portion of the seal that started detaching from the skin.

  - *Suction techniques:* Detachment level: fluid displaced for the seal to detach without breaking the air tight sealing. Breaching level: fluid displaced for compromising the airtight sealing.



Temperature exposure:

● Cold:

18.5 ± 1.9 hours at -19.5 ± 1.3 ºC

● Hot:

17.7 ± 1.5 hours at 71.5 ± 2.0 ºC

Technology:

Down-selected vented seals:

- Vented chest seal
  - 5 non-vented seals considered for testing

	Bolin™ CS	Fast Breathe™ CS	Russell™ CS	SAM® CS	Hyfin® CS
Original					
Modified					
Valve/vent	Protruding 3-ball valves	Protruding Multichannel	Flat middle Vent	Protruding Valve	Flat side Vent

Conclusions:

- Adhesion of vented seals to skin were maintained after an average exposure of 18 hours at extreme temperatures of hot (71.5 ºC) or cold (-19.5 ºC). Adhesion was slightly less for the Bolin™ chest seal; this was attributed to coarse swine hair.
- Exposure to hot temperature had a tendency to "melt" the adhesives causing glue to remain on the skin; in particular for the SAM® chest seal, Hyfin® chest seal, and Fast Breathe™ chest seal. Seal removal was very difficult in these cases.
- Other qualitative characteristics may be considered for more specific down-selection.

Project Future:

- Live-animal experimental hemodynamic/respiratory physiology testing will assess the valve/vent type for best performance of vented seals. This will be conducted at USAISR.

The opinions of the authors and mention of company names, trade names, or commercial products does not constitute endorsement or recommendation for use by the Federal Government, Navy, or Department of Defense. Study funded by the 6.7 Defense Health Program, work unit number A1267, and USAMMA. Animal experiments were performed using a study protocol that was reviewed and approved by the Walter Reed Army Institute of Research/Naval Medical Research Center Institutional Animal Care and Use Committee.

***Contractor, Allied Technologies and Consulting, LLC.**