STUDY TITLE

Assessment of the STAL Shield as a Generic Barrier Device to Reduce on-Site spread of Pathogens during Patient Care : Testing with *Staphylococcus aureus* as the challenge

TEST ORGANISM

Staphylococcus aureus (ATCC 6538)

TEST SAMPLE IDENTITY

STAL Shield

TEST Method

Aerobiology surface/air decontamination Protocol

AUTHOR

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STUDY COMPLETION DATE

Mar/09/18

PERFORMING LABORATORY

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SPONSOR

Prodaptive Medical Innovations Ltd., Sooke, BC

STUDY NUMBER

PMI171126-01

STUDY PERSONNEL

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STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Assessment of the STAL Shield as a Generic Barrier Device to Reduce on-Site spread of Pathogens during Patient Care: Testing with *Staphylococcus aureus* as the challenge

Study Number: PMI171126-01

Protocol Number: TEM0900

Sponsor Prodaptive Medical Innovations Ltd., Sooke, BC

Testing Facility CREM Co Labs
Unit 1-2, 3403 American Drive, Mississauga, ON, Canada

TEST SUBSTANCE IDENTITY

Test Substance Name: STAL Shield

STUDY DATES
Date Sample Received: Oct/02/2017
Study initiation date: Nov/01/2017
Experimental Start Date: Nov/10/2017
Experimental End Date: Feb/23/2018
Study Completion Date: March/09/2018

I. BACKGROUND AND INTRODUCTION

CREM Co Labs' representatives first met Al Wickheim and Laura Barker of Prodaptive Medical at a scientific meeting in September 2017 to discuss the possibility of testing the STAL shield. It was agreed to first establish a proof-of-concept through some initial testing at CREM CO Labs and then submit a proper research study proposal for more formal assessment of the device.

Since the initial evaluation yielded encouraging results, a proposal to assess the device under the following three scenarios was agreed to: (a) Purging of a contaminated Foley catheter, b) Irrigation of a superficial skin wound, and c) reducing enteric pathogen spread during projectile vomiting. The findings of the testing are summarized in this report.

II. RATIONALE

While healthcare providers wear protective gear for their own safety, pathogen-containing body fluids from patients in healthcare and emergency medical services (EMS) often contaminate personnel as well as the environment by splashing and aerosolization.[1] The STAL shield, a simple

[1] Hudson, A.J. et al (2018). The Emergency Medical Service Microbiome. Appl. Environ. Microbiol. 84: https://doi.org/10.1128/AEM .02098-17.

plastic barrier designed to reduce such spread, was tested for its ability to reduce such spread of pathogens during selected medical and emergency procedures performed on-site.

SUMMARY OF RESULTS

Test Article: STAL Shield: Several samples of the shield (in their original packaging) were provided to us by the study sponsors (www.prodaptivemedical.com). A new shield was removed from its packaging just before a given test and then discarded after use as biomedical waste.

The shield is a clear plastic dome incorporating a central grommet and perforated diaphragm through which various medical instruments are introduced and secured. The Yankauer suction catheter and irrigation syringes are two such items. The shield acts to shield at-source from spray and splash-back, and acts as a stand to minimize surface contact.

The main objective of this study was to test following three applications of the shield in an experimental setting: 1) Foley catheter, 2) Wound Irrigation, and 3) Vomiting with Yankauer suction catheter.

Exposure Temperature: Ambient Temperature (22±2ºC)

TEST SYSTEM

1. Test Pathogen

Staphylococcus aureus (ATCC 6538), a Gram-positive coccus, is frequently found in the nose, respiratory tract, and on the skin. It is often positive for catalase and nitrate reduction and is a facultative anaerobe (can grow without the need for free oxygen). Although *S. aureus* is not always pathogenic, it is a common cause of skin infections including abscesses, respiratory infections such as sinusitis, and food poisoning.

As this organism is relatively easy to grow and quantify, it is frequently used as a surrogate for human pathogens in assessing devices and technologies for infection prevention and control.

2. Test Medium

The microbial growth and recovery media in this study were Tryptic Soy Broth (TSB) and Tryptic Soy Agar (TSA).

3. Preparation of Test Pathogen Suspension

To prepare a broth culture of *S. aureus* a 100 µL volume of the stock culture was added to 20 mL of TSB in a plastic tube and incubated aerobically for 24±2 h at 36±1°C.

4. Preparation of Test Inocula

Inocula for each application were prepared as follows:

a. Foley catheter
Five mL of an overnight culture was mixed with 20 mL of phosphate buffered saline (PBS)

b. Wound Irrigation
Two mL of an overnight culture was transferred to the incisions made on freshly purchased pieces of chicken leg to simulated wound irrigation

c. Yankauer suction catheter
Forty-five mL of an overnight culture was mixed with 1.5 L of PBS

TEST METHOD

1. **Preparation of Test Article**
The Shield required no special preparation for testing. Just before the test, it was removed from its original packaging and syringe or Yankauer tube was inserted into its grommet.

2. Test Procedure

All efficacy tests were performed inside CREM Co Labs' aerobiology chamber (~24 m^3). A muffin fan in the chamber was switched on during the testing to simulate air turbulence in field settings. The test system simulating each application was placed inside the chamber and tested with and without the STAL shield in place. Air samples from the chamber were collected using a programmable slit-to-agar sampler (Particle Measuring Systems, Boulder, CO; http://www.pmeasuring.com/home) @28.3 L/minute) before for 10 minutes and then right at the start of the experiment for two hours to assess the level of microbial contamination. Agar plates to collect settling airborne particles and splash contamination from the Shield were placed at, and collected from, five different locations on the floor of the chamber with a custom-built remote plate-placement and -retrieval system. Each test was repeated three times to check reproducibility of the test and for statistical analysis.

The culture plates collected from the slit sampler and the floor were incubated at 36±1°C for 18±2 hours. Colony forming units (CFU) of the test organisms were counted and percent reductions in the viability calculated.

Experimental Design

a) Background Level of Contamination

Prior to each test, a 10-minute air sample was collected from the chamber using an STA sampler to determine the initial level of microbes in it.

b) Efficacy Test

Simulated system for each application was set up inside the aerobiology chamber. Thirty five TSA plates, in groups of seven each (one as a control), were placed on the floor of the aerobiology chamber, with one set in each of the four corners and one in the center. Except the control plate, the lids of the plates were removed. Test of each application was performed with and without STAL shield separately and simultaneously the STA sampler was switched on to collect airborne microorganisms for 120 minutes.

At the end of this period, the Petri plates were retrieved, their lids replaced for incubation at the required temperature (36±1ºC) for CFU development to determine the level of microbial contamination deposited on each one. Such testing allowed us to determine the levels of airborne bacteria that could settle on the plates and calculate the percent reduction of contamination when STAL shield was in place. One plate of TSA unexposed to airborne particles in the chamber was incubated for 24 hours at 36±1ºC to check for sterility of the culture medium.

Figure 1 depicts the layout of the aerobiology chamber with the culture plate placement and retrieval system installed; all the needed supplies for this system were purchased locally from a hardware supplier.

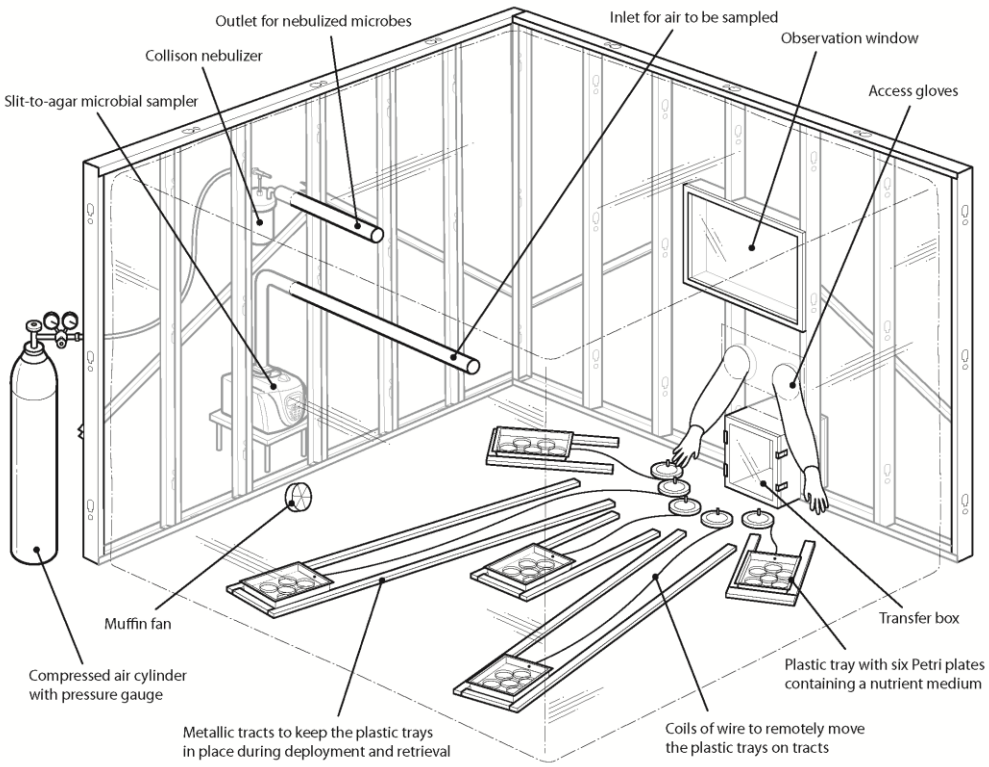

Figure 1: Aerobiology chamber with the entire Petri plate deployment set-up. Plastic trays with the Petri plates could be placed on metal tracts and remotely and individually moved with cables to five locations on the floor of the chamber.

The procedure for each application of medical device was as follows:

1) **Foley catheter**
For testing Foley catheter purging, Shield was connected to the base of the syringe, the syringe was connected to the Foley Catheter. Five mL of an overnight culture of *S. aureus* was mixed with 20 mL of sterile PBS. The Shield was held with two fingers and pushed toward the base of the syringe (Figure 2). For testing Foley catheter purging without the Shield, the syringe was connected to the Foley catheter directly and was held with two figures.

Figure 2: Set up for testing Foley catheter

2) **Wound Irrigation**
An incision was created on a chicken leg just before the testing to simulate a wound (Figure 3). For testing wound irrigation with the Shield, it was connected to the middle of the base of the syringe and the wound was irrigated/washed with 60

mL of sterile PBS (3x20 mL). For testing without the Shield, the syringe was used to irrigate/wash the wound with 60 mL of sterile PBS (3x20 mL).

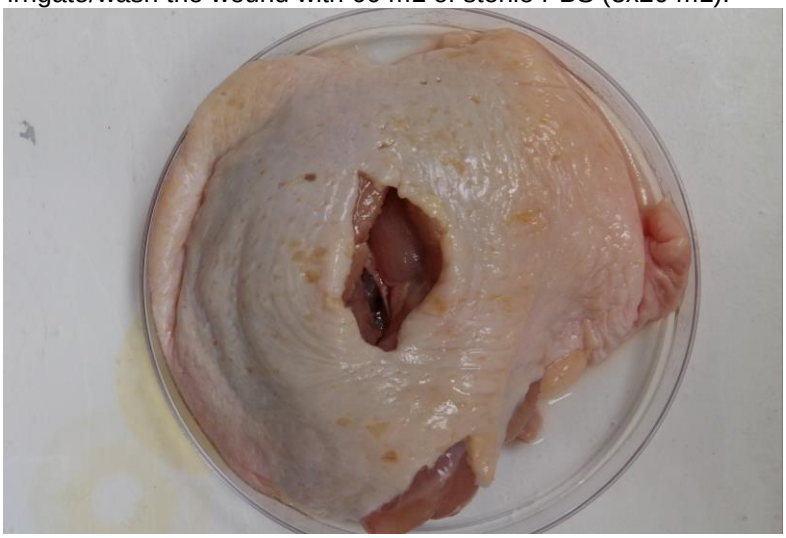

Figure 3: Experimental set up to simulate wound irrigation

3) Projectile Vomiting

In order to simulate projectile vomiting by a patient (Figure 4), a rubber hot water bottle was filled with 1955 mL of PBS and 45 mL of an overnight culture of *S. aureus*. The outlet of the rubber was connected to a Mannequin head, made from white Styrofoam, through a tube (1/2" ID x 5/8" OD HH SKU# 8610-611)

Figure 4: Experimental set up to simulate vomiting

The pressure on the rubber bag was adjusted to eject the vomiting liquid around one meter away from the mouth. Two pulses of pressure on the rubber were applied to eject around 1 L of the vomitus.

STUDY ACCEPTANCE CRITERIA

No product acceptance criterion was specified for this range-finding study.

RESULTS

We tested the STAL Shield inside an aerobiology chamber for flushing of Foley catheters, flushing/irrigation of incisions made on pieces of fresh chicken meat, and also reduce the dispersal of fluid during projectile vomiting. Bacterial culture plates were strategically placed on the floor of the aerobiology chamber to detect contamination from splashes and a slit-to-agar sampler was run for two hours (@28.3 L/minute) to assess aerial spread. After incubation, bacterial colonies were counted and percent reductions in contamination calculated. For each scenarios, three tests were conducted without and with the STAL Shield. The results of the testing are reported here in three different sections:

Scenario a) Foley catheters

The suspension of *S. aureus* for contaminating the catheters contained $3x10^9$ CFU. As can be seen from the data summarized in Table 1, the Shield could reduce the airborne and surface contamination of the test pathogen by >99% (>2 $\log_{10}$).

Table 1. CFU in Petri plates after 24 hours of incubation from test . LB=Left Bottom, LT= Left Top, RB=Right Bottom, RT=Right Top, MC=Center.

Sample Name	CFU with STAL Shield			CFU without STAL Shield/		
	Test #1	Test #2	Test #3	Test #1	Test #2	Test #3
CFU on agar plates from STA machine after 2 hrs of exposure	3	16	2	5291	1227	8022
CFU/m^3 of air	0.88	4.71	0.589	1558	361	2362
LB1	2	0	2	85	10	168
LB2	0	1	0	83	16	173
LB3	0	0	0	95	18	325
LB4	0	0	0	57	13	209
LB5	0	0	0	62	18	163
LB6		1	0		27	172
RB1	1	0	2	300	10	2470
RB2	0	0	1	289	21	1983
RB3	0	1	0	191	28	733
RB4	0	0	2	272	9	761
RB5	0	0	1	206	17	1208
RB6		1	0		15	511
LT1	0	1	0	60	9	106
LT2	1	1	0	88	17	148
LT3	0	2	0	78	11	147
LT4	0	0	0	66	16	98
LT5	0	1	1	81	19	101
LT6		0	0		14	140
C1	0	0	0	92	9	163
C2	0	0	0	72	12	154
C3	0	0	0	77	24	224
C4	0	0	1	78	16	157
C5	0	0	0	79	15	162
C6		0	0		17	175
RT1	1	0	1	85	16	146
RT2	0	0	0	66	17	161
RT3	0	1	0	78	9	212
RT4	0	0	0	70	13	161
RT5	0	0	0	80	15	181
RT6		0	0		21	205
Mean and Standard Deviation	0.125±0.338	0.333±0.546	0.310±0.604	111.60±73.349	15.7333±4.939	390.567±548.523
Mean and Standard Deviation CFU/m^2	40±100	66.7±109.3	73.3±135.37	111.6±73.35	3146.7±1004.724	78113.3±113330.9
Percent Reduction in Air: 99.5±0.73				**Percent Reduction on Surface: 99.20±1.15**		

Scenario b) Wound Flushing/Irrigation

The suspension of *S. aureus* for contaminating the wound for irrigation/flushing had $1.2x10^9$ CFU. The wounds were separately flushed without and with the Shield mounted on a 60 mL irrigation syringe. The results for this scenario are summarized in Table 2. The Shield could reduce the spread of airborne spread of the test pathogen by 95.8±4.87% and surface contamination by 90.44±2.11%.

Scenario c) Reducing Pathogen spread during Projectile Vomitting

Testing for this scenario proved unexpectedly challenging. Several experimental designs were attempted to simulate projectile vomitting and obtain realistic and reproducible data. This was not possible in the time and resources available for this investigation. The leads gathered in this study may be helpful in the construction of a better set-up to test this scenario.

DISCUSSION

The STAL Shield proved to be highly effective in reducing pathogen spread by air and by splashes during two of the three scenarios tested in this study. The findings of the third scenario were inconclusive due to the challenge of constructing a suitable experimental set-up.

The Sponsors were most help to us throughout this project and provided technical input as well as materials as and when we needed them. That assistance proved highly crucial in the completion of this innovative project, which required the development of a unique set of test protocols.

The findings of this investigation reinforce the usefulness of the STAL Shield as a relatively simple and inexpensive device to significantly reduce the spread of pathogen contamination by air and via environmental surfaces. The device can also cut down the risk of contamination of PPE worn by medical and EMS personnel while providing patient care. The on-site reduction in pathogen contamination constitutes the primary barrier in infection prevention and control (IPAC), thereby reducing the need for more extensive environmental decontamination.

Wounds to be flushed/irrigated may or may not be infected. However, even fresh and uninfected wounds also pose a threat from blood-borne pathogens. Therefore, the Shield could reduce the spread of such pathogens as well.

While we assessed only a limited number of applications of the Shield, it has a much greater potential in IPAC. Further, additional studies would be needed with other classes of pathogens such as viruses and, eventually, assessing the performance of the Shield in actual field use.

Such information would better inform infection preventionists of reduced field-relevant potential of environmental contamination and also reductions in the amounts of chemicals used for decontamination, thereby adding further to environmental and workplace safety.

Table 2. Wound irrigation/washing. CFU in Petri plates after 24 hours of incubation from test on contaminated Petri plates. LB=Left Bottom, LT= Left Top, RB=Right Bottom, RT=Right Top, MC=Center.

Sample Name	With STAL CFU			Without STAL CFU		
	Test #1	Test #2	Test #3	Test #1	Test #2	Test #3
CFU on agar plates from STA machine after 2 hrs of exposure	1	0	2	33	5	21
CFU/m^3 of air	0.294	0	0.59	9.71	1.47	6.18
LB1	0	1	0	27	37	14
LB2	0	2	0	53	6	11
LB3	0	8	0	49	10	18
LB4	0	0	0	41	4	17
LB5	2	1	1	30	2	11
LB6	35	3	0	29	4	15
RB1	3	21	0	65	23	118
RB2	18	9	4	103	60	69
RB3	12	6	3	109	41	52
RB4	10	24	3	114	26	78
RB5	3	11	4	122	31	50
RB6	19	14	4	156	36	44
LT1	0	0	14	3	0	1
LT2	0	0	0	3	306	3
LT3	0	0	0	2	2	3
LT4	0	0	2	2	1	5
LT5	0	0	1	3	0	1
LT6	0	1	0	3	0	7
C1	0	0	0	4	3	9
C2	2	0	1	6	20	12
C3	0	0	1	5	12	9
C4	0	0	0	3	16	20
C5	1	0	0	17	7	10
C6	0	0	0	17	48	13
RT1	1	0	1	3	5	2
RT2	0	2	1	3	0	1
RT3	1	1	1	2	1	6
RT4	0	0	0	1	17	2
RT5	0	2	0	1	0	0
RT6	0	1	2	3	0	2
Average and Standard Deviation CFU	3.655±6.415	3.655±6.416	1.483±2.760	32.633±43.621	23.933±54.838	20.100±27.192
Average and Standard Deviation CFU/m^2	737.93±1598.3	713.3±1283.16	286.7±554.2	6731.034±8958.4	4786.7±11315.3	4020.0±5586.2
Percent Reduction on Air: 95.8±4.87				Percent Reduction on Surface: 90.44±2.11		