

Spartan Mills Blank Study

SILANE QUATERNARY AMMONIUM CHLORIDE SOLUTION

40 – DAY TEST

INTRODUCTION

The medical industry is challenged by the presence of microorganisms and the negative effects they cause. Deterioration, defacement and odors are all dramatic effects which occur from the microbial contamination of surfaces as varied as carpeting and medical non-woven fabrics. These surfaces can also act as a microbial "harbor", as most offer ideal environments for the proliferation of microorganisms that are harmful to buildings, textiles and humans. The ability to make surfaces resistant to microbial contamination has advantages in many applications and market segments. This is especially true in medical markets where many products have contributed a degree of aseptic sophistication beyond that required of consumer products.

Surfaces used in medical applications have unique microbial problems and their control is a complex task. The microbiological integrity of surfaces has been the object of numerous studies ranging from bacterial loading of carpeting to the evaluation of the barrier properties of non-woven fabrics. Test data generated with surfaces treated with the Silane Quaternary Compound (SiQuat), technology support the fact that it contributes positively to the reduction of microorganisms in the medical environment. This contribution has been part of the medical communities' actions aimed at improving the hygienic nature of their environment as they take steps towards asepsis.

HISTORY

The surgical arena provides a valuable model for illustrating the medical community's challenges with regard to asepsis. The first surgery may have occurred nearly twelve thousand years ago. Laws regarding the performance and liability of surgeons were included in the code of Hammurabi in 1700 B.C. with mention of such retribution as the surgical removal of the hand of the physician whose patient lost an eye or succumbed to the procedure.

The first use of the word inflammation appears to date back about twenty-five hundred years and is mentioned in three tablets from Assurbanipal's library. The ancient Greeks mistook infection as a "...good and natural course of events" and poured wine into wounds to help them heal. It is only coincidental that the disinfecting properties of wine are based on a chemistry very similar to that of Lister's phenol, but we come full circle when we recall that Pasteur's work on preventing wine spoilage led to Lister's theories. It was not until the last quarter of the nineteenth century, after Semmelweis had died, that Oliver Wendell Holmes had written of the risks of bacterial contamination.

The lessons learned from the historical use of sterilants and disinfectants are valuable today. The daily press has created a public frenzy by headlining even the most minor encounters with infectious diseases, resistant organisms, *E. coli* and flesh-eating bacteria. All of this attention has resulted in heightened public concern about cross contamination issues and infection control in general. This increased public awareness has sent antibacterial and antimicrobial consumer product sales soaring. It is also leading to extensive interest in the use of antimicrobial surfaces in a care facilities environment.

The desired performance of an antimicrobial treated surface is to significantly reduce levels of bacterial and fungal contamination, when compared to a similar untreated surface. Controlling and/or killing the microorganisms commonly associated with infections is a key component to maintaining an aseptic surface. Primary considerations regarding the selection of an antimicrobial are: its safety to the building occupants, that the antimicrobial activity remains unaffected by common cleaning procedures, and that the antimicrobial is not susceptible to inductive or mutative adaptation. Those surfaces that are handled by the staff, such as blankets, should also be expected to retain all of the original handling and appearance characteristics.

NOSOCOMIAL INFECTION

Nosocomial infection is a serious issue for health care facilities. According to recent articles, 1.8 million Americans contract nosocomial infection from hospitals every year. 20,000 patients died in 1998 as a direct result of nosocomial infection and 70,000 die from complications caused by infection. The cost of treating nosocomial infection in the United States is estimated at \$4.5 billion a year. Controlling infection in an environment which is contaminated by the nature of its function is difficult at best and requires a multifaceted approach.

- Will hospital blankets, protected by the SiQuat technology, end nosocomial infections? **No.**
- Will hospital blankets, protected by the SiQuat technology, reduce bacterial and fungal contamination on the blanket? **Yes.**

- Will the use of hospital blankets, protected by the SiQuat technology, be a positive step toward asepsis in the patient's immediate environment? **Yes.**
- Is the use of hospital blankets, protected by SiQuat technology, a component of practicing reasonable care? **Yes.**

BLANKET STUDIES

Spartan Mills and the Virkler Company studied blankets that were treated with the SiQuat technology and blankets that were untreated. In any environment, blankets can become a haven for bacteria. These bacteria usually represent a spectrum of Gram positive and Gram-negative organisms capable of producing infections, staining, deterioration and odors. In a hospital environment, fever and sweat are common and an excellent source of bacterial contamination. In an effort to evaluate the effects a hospital environment has on treated and untreated blankets two separate studies were undertaken. The first "simulation" study was initiated to simulate the types of exposures blankets receive when in use on a feverish patient. The second "in-use" study was initiated to determine the effectiveness of the antimicrobial on blankets when stored and used within a care facility.

Simulation Study

The first study was performed with treated and untreated blankets that were cut into 5 in. x 6 in. samples with exact weight of 5.2g per sample. Each sample was labeled and attached to a plastic bag. These samples were used to uniformly towel off the sweat from healthy male subjects after one hour of high endurance exercise. The samples were re-placed into each bag and incubated at 37° C for 3 weeks. The purpose of this testing was to simulate blanket exposure to febrile, diaphoretic patients.

Initial bacterial retrievals before incubation were performed using the BioBurden 100 (BB 100) test procedure to determine active bioload at the beginning of incubation. Each sample was cut into a 2.4g swatch of cloth that was placed in a sterile flask containing 100ml of phosphate buffer (KHaPO₄). The flask was then agitated for 30 minutes to release bacteria. After this time, the bacteria were plated into nutrient agar and incubated at 37° C. After several days, the plates were counted, and the bacteria were characterized. The results of this study show that the treated sample had 1000 CFU/cm² (colony forming units per square centimeter) of bacteria compared to the untreated sample which had three times the amount of bacteria 3000 CFU/cm² representing a 67% reduction in microorganisms on the blanket (figure 1). The types of organisms represented in the samples were *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Micrococcus* and *Bacillus*, typical skin and soil isolates.

The bacterial retrievals were repeated after 40 days of incubation at 37° C. A bioburden of 1051 CFU/g was recorded on the untreated sample while the treated sample showed a bioburden of 283 CFU/g which verified a significant (73%) reduction in microorganisms (figure 1). The rate of bioburden reduction on the treated samples shows good correlation to the samples initially tested with 1 day of incubation.

These same samples were then subjected to an odor panel of ten people. These men and women were asked to independently rate the samples based on their perceived odor and rank the level of odor on a 0 - 10 scale with 10 representing a putrid odor and 0 representing no odor. These rankings were averaged for all treated and untreated samples. The untreated samples averaged a score of 3.3 while the treated samples averaged a score of only 1.5 (figure 1). While the odor study is a qualitative test and not a quantitative measure, it does provide insight that the reduction in bioburden does significantly affect the observable odor level.

In-Use Study

The second study was performed with treated and untreated blankets that were put in use in a 24-hour care facility in North Carolina. All of the blankets were labeled with identification thread at the foot of the blanket. Black thread indicated a blanket was treated and red thread indicated a blanket was untreated. Eight of the ten blankets were

stressed by putting them into use on beds at the care facility. All of the blankets were put into service on the same day at approximately the same time. All of the blankets were removed from service when one of the test blankets was soiled by a patient (the soiled blanket was a treated blanket). All of the test blankets were individually wrapped in plastic and sent to the laboratory to initiate retrievals and testing.

Initial bacterial retrievals were performed on the stressed and nonstressed blanket samples to determine active bioload using the BB 100 test procedure. Three 2.5g swatches were cut from each blanket using aseptic techniques. The “head” sample was taken 12 inches from the top of the blanket — centered from the sides, the sample was taken 12 inches from the bottom of the blanket — centered from the sides, the “middle” sample was taken from the center of the blanket. Each sample of cloth was placed in a sterile flask containing phosphate buffer. The sample was then agitated for 30 minutes and total bacteria were retrieved on nutrient agar plates. For these samples the results are presented in the form of colony forming units per gram of blanket sample (CFU/g). Using CFU/g the percent bacterial reduction in the treated samples versus the untreated samples is calculated and reported.

The results from the nonstressed blankets indicates an average of 1120 CFU/g for the untreated head samples compared to an average 280 CFU/g for the treated head samples indicating a 75% reduction in organisms on the head samples of the treated blankets. The untreated middle samples averaged 1720 CFU/g while the treated middle samples averaged 400 CFU/g indicating a 77% reduction in organisms on the middle samples of the treated blankets. The untreated toe samples averaged 800 CFU/g while the treated toe samples averaged 200 CFU/g indicating a 75% reduction in organisms on the toe samples of the treated blankets (figure 2). The reduction of bioburden on the nonstressed blanket indicates the effectiveness of the SiQuat technology in protecting hospital blankets during distribution and storage.

The results from the stressed blankets indicate bioburden levels over ten times higher than those exhibited by the nonstressed blankets. The stressed blanket samples indicated an average of 16000 CFU/g for the untreated head samples compared to an average 6600 CFU/g for the treated head samples. Comparison of the untreated blanket averages to the treated blanket averages indicates a 59% reduction in organisms on the head samples of the treated blankets. The untreated middle samples averaged 12000 CFU/g while the treated middle samples averaged 4700 CFU/g indicating a 61% reduction in organisms on the middle samples of the treated blankets. The untreated toe samples averaged 7560 CFU/g while the treated toe samples averaged 440 CFU/g indicating a 94% reduction in organisms on the toe samples of the treated blankets (figure 3). The reduction of bioburden on the stressed blanket samples indicates the effectiveness of the SiQuat technology in protecting hospital blankets during actual handling and use.

Additional Studies

There are several bioburden studies in the literature comparing fabrics treated with SiQuat technology with untreated fabrics. A study performed jointly by American Hospital Supply (now Baxter Healthcare) and Dow Corning Corporation (attachment A) generated data that is relational to the environment and microorganisms likely to be encountered by blanket use in hospital environments.

In the series of tests undertaken within the study nonwoven treated and untreated barrier drapes were tested using clinical wound and urine isolates to determine the effectiveness of The SiQuat technology in controlling the growth of microorganisms on the substrate. In this testing it was shown that SiQuat technology reduced wound isolate bacterial loading of the drape by 93.6%, 99.7% and 99.5% while reducing the urine isolate bioburden on the drape by 99.9% and 98.6% (table I).

Another series of tests was performed to show the percent of bioburden reduction on treated nonwoven fabric when the fabric was inoculated with buffered phosphate, saline and serum. The treated fabric showed a 99% reduction of *Klebsiella pneumoniae* when delivered using the buffered phosphate, 90% reduction of *Klebsiella pneumoniae* when delivered using saline and a 90% reduction of *Klebsiella pneumoniae* when delivered with serum (table II).

An important component of the patient environment within a care facility is the exposure of blanket fabric to blood. One of the test series performed within this study compared the rate of kill of treated ISO-BAC fabric on *Klebsiella pneumoniae* when it is delivered in whole blood to untreated fabrics. This test series showed that 100% of the test organisms were killed within 5 minutes of exposure to the treated fabric compared to 30 minutes for the HiLoft control (table III).

Additional surface testing compared the rate of kill of treated ISO-BAC fabric on *Klebsiella pneumoniae* when it is delivered in defibrinated blood to untreated fabrics. This test series showed that 59% of the test organisms were killed

within 30 minutes of exposure to the treated fabric and 72% were killed within 120 minutes compared to 0% kill in 120 minutes for the HiLoft control (table IV).

Preliminary tests comparing the reduction of *Staphylococcus epidermididis* applied to treated HiLoft ISO-BAC fabric compared to an untreated control when suspended in fabric showed 100% reduction in all testing (table V).

Aerosol testing showing the reduction of *Pseudomonas aeruginosa* when applied to treated ISO-BAC fabric in saline showed 100% reduction within 15 minutes in all testing (table VI).

Aerosol testing showing the reduction of *Escherichia coli* when applied to treated ISO-BAC fabric in saline showed 100% reduction within 15 minutes in all testing (table VII).

A critical concern in care facilities is the adaption of microorganisms to antimicrobials and antibiotics. Bacterial adaption testing was also performed as part of this study and clearly showed no adaption of microorganisms to SiQuat technology (table VIII).

The control of odor in a care facility is an important consideration for the comfort of patients and staff. Total accumulated ammonia testing was performed as part of the study and showed significant odor reduction when comparing SiQuat technology treated fabric to a control.

Protecting an Entire Medical Environment

In January 1990, just prior to the scheduled opening of a major hospital and cancer research institute on the campus of Ohio State University, a major water pipe froze and ruptured at the roof level of the building. All twelve floors of the completely furnished building were flooded with an estimated 500,000 gallons of water. The water flowed down stairwells, elevator shafts, utility service shafts and spread out over and under each floor. Water moving over the floors wicked up into the wallboard and insulation and soaked the carpeted areas in offices, patient rooms and hallways. The water running on the under-surface of floors dropped onto the acoustical ceiling tile below. In some areas the weight of the water broke the acoustical tile insets and the water fell onto upholstered furnishings and equipment below.

Microbial sampling began early in the restoration process, and by day seven the facility was developing a distinct musty odor. By week three there were gross fungal colonies on exposed surfaces and behind vinyl wall coverings. The lower floors were most visually contaminated with active fungal growth on most surfaces. Microbial sampling retrieved >2800 colony forming units of fungus per cubic meter of air on most floors of the facility.

Due to the sensitive use of the structure, a microbial contamination prevention plan using the SiQuat technology. This treatment was used as an on-site application to reduce microbial populations and continuously maintain them at very low levels.

The facility is presently free of odor and has a new appearance unaffected by the extensive application of a surface antimicrobial. Re-evaluation for airborne fungi and surface microbial contamination have continued yearly. Levels have remained consistently below 7 colony forming units per cubic meter on all floors throughout the facility. A recent 5-year evaluation of infection data was conducted in 1996 with results superior to other cancer hospitals. Since then the Cover Shield technology has been used to control microbial contamination in numerous hospitals, heart institutes and care facilities.

Summary

The In-use study on Spartan Mills blankets correlates well with the simulated study undertaken earlier in the year. Both studies clearly show that blankets protected by the SiQuat technology have a significantly lower

bioburden and will present less of a risk in the patient environment. Historical data generated by American Hospital Supply and Dow Corning Corporation support these findings.

These data generated by university, medical and industrial laboratories represent some of the most extensive microbiological work ever performed on antimicrobial treated substrates for use in the medical community. The control of the microorganisms is impressive and provides numerous benefits.

- Prevents blanket staining due to mold and mildew growth that occurs on damp blankets prior to laundering.
- Controls blanket deterioration due to microbial growth that occurs on blankets during storage.
- Controls odors caused by bacteria and fungus normally found in blankets.
- Provides 3 times more protection from bacteria and fungus than an untreated blanket.

Spartan Mills blankets, protected by the SiQuat technology, clearly provide an added step towards asepsis for the health care environment.

Bacterial Bio-Burden and Odor Studies on Stressed Blankets							
#	Description	Average Odor Perception Studies ₁ (0-10)	Bacterial Retrieval Studies ₂				Pass/Fail
			Average Total CFU/g		Average % Reduction		
			Day 1	Day 40	Day 1	Day 40	
1	Untreated	3.3	1500	1051	0%	0%	Fail
2	Treated	1.5	500	283	66%	73%	Pass

Figure 1

Bacterial Bio-Burden Studies on Non-Stressed Blankets				
#	Description	Bacterial Retrieval Studies		
		Average Total CFU/g	Average % Reduction	Pass/Fail
1	Untreated Head	1120	-	Fail
2	Treated Head	280	75%	Pass
3	Untreated Middle	1720	-	Fail
4	Treated Middle	400	77%	Pass
5	Untreated Toe	800	-	Fail
6	Treated Toe	200	75%	Pass

Figure 2

Bacterial Bio-Burden Studies on Stressed Blankets			
#	Description	Bacterial Retrieval Studies	
		Average Total CFU/g	Pass/Fail
1	Untreated Head	16000	Fail
2	Treated Head	6600	Pass
3	Untreated Middle	12000	Fail

4	Treated Middle	4700	61%	Pass
5	Untreated Toe	7560	-	Fail
6	Treated Toe	440	94%	Pass

TABLE I: Results Clinical Isolate Control ² Antimicrobial Treated Nonwovens		
Sample	Microorganism	Percent Reduction
Untreated ¹ Treated Innoculum	<i>Citerobacter diversus</i>	14.3 93.6 0
	Wound Isolate	
Untreated Treated Innoculum	<i>Pseudomonas aeruginosa</i>	28.3 99.9 0
	Urine Isolate	
Untreated Treated Innoculum	<i>Staphylococcus aureus</i>	0 99.7 0
	Wound Isolate	
Untreated Treated Innoculum	<i>Escherichia coli</i>	11.6 98.6 0
	Urine Isolate	
Untreated Treated Innoculum	<i>Proteus mirabilis</i>	0 99.5 0
	Wound Isolate	
¹ Sonatara Fabric ² Dow Corning CTM 0923		

TABLE II: Results Fluid Compatibility Tests Antimicrobial Treated ISOBAC Fabric			
Percent Reduction ¹ with 15 minute contact			
Sample	Buffered Phosphate	Saline	Serum
Untreated Linen	8	0	0
Untreated Sontara Nonwoven	0	0	0
Treated Sontara	99+	90+	90+
¹ Modified AATCC method 100 using test fluids <i>Klebsiella pneumoniae</i> statistically significant at the 95% confidence level			

TABLE III: Results Surface Testing of Whole Blood and Bacteria ¹			
Sample (Surface)	Contact Time (Minutes)	# of Organisms per MI.	% Reduction
A) Green Surgical Linen	0 1 3 5 30 60 120	6550 4750 3750 400 200	- 27 43 94 97 97 98

		200 100	
B) Non-Woven Tablecover from J&J Laparotomy Pack	0 1 3 5 30 60 120	22,100 20,800 15,300 2,800 550 700 200	- 6 31 87 98 97 99
C) HiLoft Untreated Control	0 1 3 5 30 60 120	10,450 8650 8900 200 0 0 0	- 17 15 98 100 100 100
D) HiLoft with Antimicrobial – ISOBAC Fabric	0 1 3 5 30 60 120	12,500 5000 5700 0 0 0 0	- 60 54 100 100 100 100

¹Innoculum: 90% whole fresh rabbit blood contaminated with *Klebsiella pneumoniae* ATCC 4352

TABLE IV: Results Surface Testing of Defibrinated Blood and Bacteria ¹			
Sample (Surface)	Contact Time (Minutes)	# of Organisms per MI.	% Reduction
A) Green Surgical Linen	0 1 3 5 30 60 120	8750 9300 8700 8850 9900 10,350 10,850	- 0 0 0 0 0 0
B) Non-Woven Tablecover from J&J Laparotomy Pack	0 1 3 5 30 60 120	14,050 17,450 13,750 13,400 15,350 16,450 17,800	- 0 2 5 0 0 0
C) HiLoft Untreated Control	0 1 3 5 30 60 120	13,650 14,150 13,600 14,000 13,750 14,600 16,850	- 0 0 0 0 0 0
D) HiLoft with Antimicrobial – ISOBAC Fabric	0 1 3 5 30 60 120	14,900 15,400 14,400 12,400 6050 5650 4200	- 0 3 17 59 62 72

¹Innoculum: 90% defibrinated sheep blood contaminated with *Klebsiella pneumoniae* ATCC 4352

TABLE V: Results Preliminary Tests Comparing the Reduction in Count of <i>Staphylococcus epidermidis</i> applied to HiLoft ISOBAC Compared to the Untreated Control						
Bacteria Suspended in	Count/0.1 ml.(x10 ⁶)	Swatch Wetted	Repl.	Count/ml (x10 ³)		Percent Reduction
				Control	Treated	
Clark-Lubs Kh ₂ PO ₄	1.46	Clark-Lubs	1 2	198 201	0 0	100 100
Acta Sweat	1.48	Acta Sweat	1 2	209 214	0 0	100 100

TABLE VI: Results – Aerosol Test
ISOBAC Control of *Pseudomonas aeruginosa* in Saline

		Count/ml. (x10 ³ at each dwell interval)					
Media No.	Repl.	0	1/4 HR	1/2 HR	1 HR	2 HRS	3 HRS
Control ²	1	114	120	102	136	122	126
	2	115	101	91	107	112	113
	3	98	116	116	110	92	121
Av.		109	112	103	118	109	120
ISOBAC Level A	1	11	0	0	0	0	0

