

VESTEX RESEARCH SUMMARY

TITLE: Cross-Over Trial to Determine the Efficacy of Antimicrobial Surgical Scrubs

ABSTRACT

Bearman et al conducted a randomized clinical trial to determine the effectiveness of Vestex, breathable, antimicrobial, fluid barrier scrub uniform attire for reducing the bacterial burden on scrub attire worn by health care workers in an intensive care unit (ICU) setting. Cultures (N = 3,324) taken at the beginning and end of the shifts included garment cultures taken from the abdominal and leg pockets of the scrub attire. The researchers found a highly statically significant ($p= 0.0002$) 4-7 log reduction in the number of methicillin-resistant *Staphylococcus aureus* (MRSA) colony forming units (CFUs) on antimicrobial scrub attire compared to traditional non-protective scrub attire worn by nurses on both the leg and abdominal area at the beginning and end of shifts. Due to low baseline prevalence of Vancomycin-resistant *Enterococcus* (VRE) and gram-negative rods, the researchers found no differences in the number of CFUs of these microorganisms. No skin sensitization or irritation was reported by study participants. The authors conclude that an extension of a horizontal (Infection Control) strategy includes apparel bioburden reduction with scrubs protected by Vestex technologies. The Vestex scrubs were associated with decreased MRSA apparel microbial bioburden. When bundled with known infection prevention strategies such as hand hygiene, Vestex impregnated apparel may limit the bacterial burden of the inanimate environment. For settings with high rates of hospital-acquired infections with drug-resistant pathogens such as MRSA, the use of Vestex apparel may be a useful adjunct to other infection prevention measures.

CITATION

Bearman GM, Rosato A, Elam K, et al. A crossover trial of antimicrobial scrubs to reduce methicillin-resistant *Staphylococcus aureus* burden on healthcare worker apparel. *Infect Control Hosp. Epidemiol.* 2012;33:268–275.

TITLE: Making the Case for Textiles with a Dual Mechanism of Action

ABSTRACT

Bearman et al [study listed above] documented the effectiveness an active barrier textile, with a dual mechanism of action of both fluid repellency and antimicrobial attributes, for reducing the bacterial burden on hands and scrub attire worn by healthcare workers (HCWs) in an intensive care unit (ICU) setting. The researchers concluded that “When bundled with known infection prevention strategies such as hand hygiene, antimicrobial impregnated apparel may limit the bacterial burden of the inanimate environment... and may be a useful adjunct to other infection prevention measures.” When an antimicrobial is combined with fluid repellency there is an additive effect. The role of the fluid barrier is consistent with the CDC/HICPAC Guideline for Disinfection and Sterilization in Healthcare Facilities (2008), which states that organic matter in the form of serum, blood, pus, or fecal or lubricant material can interfere with the antimicrobial activity of disinfectants. The bioburden reduction results of Hardwick’s study [study listed below] correlates with the findings of Bearman and colleagues.

In contrast, textiles with an antimicrobial alone have been shown to be ineffective, which is consistent with the findings of Boutin. Similar to Boutin, Burden et al compared the bacterial contamination of 2 different types of antimicrobial scrub attire with traditional nonprotective scrub attire. One type of antimicrobial scrub attire was made from polyester microfiber embedded with an antimicrobial chemical, the second from a polyester/cotton blend embedded with two proprietary chemicals and silver. The researchers found that at the end of an 8-hour work day, wearing the antimicrobial only scrub attire did not decrease bacterial or antibiotic-resistant microbial contamination of the HCWs’ scrub attire. In another study conducted by Gross et al, contamination rates were taken from newly developed silver thread-hybrid clothing and compared to contamination rates of standard clothing, in an emergency medical setting. No significant difference in the extent of microbial contamination was detected between the two materials.

These studies suggest that the presence of a fluid barrier, the type of fabric, the active antimicrobial ingredient, the onset of action, kill time, and nonleaching characteristics of the fabric and technology should be carefully assessed to ensure effectiveness and safety.

CITATION:

Amber H. Mitchell Making the Case for Textiles with a Dual Mechanism of Action. *Infect. Control Hosp. Epidemiol.* 2015 doi:10.1017/ice.2014.92.

TITLE: Fabric Challenge Assays: new standards for the evaluation of the performance of textiles treated with antimicrobial agents

ABSTRACT

This in-vitro study validates the findings of Bearman's work with Breathable, Antimicrobial, Fluid Barrier attire. The experimental model simulates three potential methods of fabric colonization, splatter, aerosol and direct contact to assess the performance of fabrics with an Antimicrobial alone, Fluid Barrier alone as well as Breathable, Antimicrobial, Fluid Barrier fabric relative to an untreated control fabric. The research identifies the dual mechanism of action of breathable, antimicrobial, fluid barrier fabrics noting that the combination of an organo-silane antimicrobial agent and a hydrophobic barrier chemistry provides an additive effect when combined together and results in a higher reduction of MRSA on the fabric than does either the antimicrobial or fluid barrier alone. The researchers assert that, established standard laboratory testing protocols do not address the real-world transmission mechanisms encountered by fabrics during normal use in a hospital environment or as the CDC Disinfection and Sterilization Guidelines suggest, organic material from secretions and body fluids interferes with or forms a complex that reduces antimicrobial activity or is overwhelmed by the amount of the contaminant on fabrics that do not contain a fluid barrier.

CITATION:

M. Hardwick, T. Walsh, and M. Cotton Fabric Challenge Assays: New Standards for the Evaluation of the Performance of Textiles Treated with Antimicrobial Agents Pesticide Formulations and Delivery Systems: 32nd Volume

TITLE Fluid Barrier Protective Performance of VTT-003 (Vestex)

ABSTRACT

A safe and effective barrier device can protect both the patient and HCW from the transfer of microorganisms or bodily fluids during procedures and is important in preventing infections. Studies report HCW and patient textiles providing better protection when a finish possessing fluid repellency and antimicrobial properties is applied. We studied the VTT003 finish to determine if VTT003 is suited for protecting HCW and patients from contaminants encountered in the health care setting. Textiles treated with the VTT003 finish passed all five standard tests for evaluating products for use in the health care setting. AATCC 42 – Water Resistance, AATCC Test Method 127 Hydrostatic Pressure, ASTM ES-21-1992, Resistance of Protective Clothing to Synthetic Blood, ISO/13795-3:2001 Dry Bacterial Penetration, ISO13795-4:2001 Wet Bacterial Penetration

CITATION

Elam, K. Walsh, T, Society of Healthcare Epidemiology of American

TITLE: Human Safety of VTT-003 (Vestex)

ABSTRACT

HCWs may also acquire infections from or transmit infections to patients, other personnel, household members, or other community contacts." The use of an effective barrier such as an antimicrobial treated textile worn by HCWs may protect them from both the transfer of microorganisms or possible contamination from trauma procedures. The purpose of this study was to assess the safety of antimicrobial treated textiles by in vivo and in vitro methods on both human skin and cell lines. Textiles impregnated with the Vestagen antimicrobial passed both standard tests for evaluating the safety of products used in the health care setting. Although further testing of Vestagen's antimicrobial is warranted, the results of this study show that the textiles do not exhibit cytotoxic effects on the epidermis of the wearer. Therefore it is plausible that due to their safety, textiles with Vestagen's antimicrobial impregnation may reduce the transmission of contaminants, and pathogens for HCWs in the ED.

CITATION

Elam, K. Walsh, T. Emergency Nurses Association



VESTEX® Claims Script April 1, 2016



This document is intended to be used for consistent Claims messaging. Claims and Attributes to Fabric can be used in any public-facing documents or messages.

MECHANISM	CLAIM	ATTRIBUTES TO FABRIC
		<i>FDA Class I exempt devices with EPA verification – (Pre-510k clearance)</i>
FLUID BARRIER	<p>1. Apparel Protected by VESTEX is designed and constructed as active barrier protective apparel.</p> <p>2. Apparel Protected by VESTEX are worn by healthcare personnel to ...</p> <p>A. Serve as a physical barrier to:</p> <p>B. Inhibit the migration of liquid through the surface of the fabric, to include:</p> <p>C. Repel liquids from the surface of the fabric, to include:</p> <p>D. Prevent soak through the fabric, to include:</p>	<p>To guard healthcare personnel and patients from the transfer of microorganisms, blood, body fluids and other potentially infectious materials (OPIM).</p> <p>... the transfer of body fluids, particulate matter, microorganisms</p> <p>...splatters, spills, body fluids</p>
ANTIMICROBIAL: LABORATORY ACTIVITY		
ANTIMICROBIAL: CLINICAL USE	A study done in an Intensive Care Unit showed that VESTEX “was associated with a 4-7 mean log reduction in MRSA burden” compared to control scrubs.	<p>Apparel protected by VESTEX are impregnated with an EPA Registered antimicrobial agent to:</p> <ul style="list-style-type: none"> inhibit the growth of bacteria on the fabric protect the fabric from the growth of microorganisms (bacteria/fungi) on the fabric
DURABILITY	When processed according to manufacturer’s care instructions, VESTEX apparel is reusable through 50 wash, dry cycles. They are manufactured and distributed as non-sterile scrubs that are intended to be processed by healthcare facilities, contract healthcare laundries or at home.	
DISCLAIMERS	The ability of VESTEX to kill microbes on the fabric surface has not been shown to correlate with any clinical event or to be able to reduce patient infections. Clinical studies to evaluate reduction in infection have not been performed for this device.	