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The Relationship of Fabric Properties and Bacterial Filtration Efficiency for Selected Surgical Face Masks

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ABSTRACT

Surgical face masks are an important component of surgical apparel. The masks are expected to perform as barriers and provide increased protection to the patients and health care workers. In this study, the Bacterial Filtration Efficiency (BFE) of six commercially available surgical face masks was determined for two microorganisms. Fabric characteristics (weight, thickness, pore size, and resistance to synthetic blood strike through) thought to influence the barrier effectiveness were measured and the relationship between these characteristics and BFE was examined. Two challenge microorganisms, Staphylococcus aureus and Escherichia coli were evaluated in this study. For five of the six masks evaluated, the BFE against the challenge microorganism S. aureus was higher than when the challenge microorganism was E. coli. The mask with the lowest mean pore size and lowest maximum pore size had the highest BFE for both microorganisms evaluated, indicating that a relationship exists between pore size and BFE.

Keywords: surgical face masks, bacterial filtration efficiency, S. aureus, E. coli

Introduction:

Bacterial and viral diseases are spread through both airborne and blood borne pathways in the operating theater. Surgical apparel can minimize the transmission of disease. The transfer of microorganisms can be reduced because the protective surgical apparel creates a physical barrier between the infection source and the healthy individual.[1] A medical device intended to be worn by operating room personnel during surgical procedures to protect both the surgical patients and operating room personnel from transfer of microorganisms, body fluids and particulate material is identified as "Surgical Apparel" in 21 CFR, Part 878.4040. The OSHA Occupational Exposure to Blood Borne Pathogens: Final Rule (1991) mandates the principles of universal precautions, mandates performance levels, and allows employers to specify what personal protective equipment is required and when it must be used.[2, 3] Surgical face masks are an important component of surgical apparel. The masks are expected to perform as barriers and provide increased protection to the patients and health care workers. Initially, the primary purpose of the facemask was to protect the patient from being contaminated by bacteria or viral species exhaled or expelled from the health care worker. Normal activities such as sneezing, coughing, shouting, crying, breathing and speaking may release oral, dermal and nasopharyngeal bacteria that may cause post-operative infections.[4] A second purpose of the mask, that has emerged in the past decade, is the protection for the health care worker from exposure to blood borne pathogens. Skinner and Sutton have reported studies that show how surgeons commonly receive blood and/or fluid splashes to the face during operating room procedures.[5]

In the past decade, a number of publications have addressed the development and role of the surgical face mask in the operating theater, and its effectiveness in reducing post-operative infections.[5, 6, 7, 8, 9, 10] Research has shown that there are numerous other methods by which bacteria become airborne and that the microorganisms shed by the healthcare team are the most significant contaminating agents, even in correctly designed operating rooms.[5] Studies have also shown that the fit of the mask, the proper positioning and use of the mask, movement by the wearer, the length of facial hair and voice level when speaking, all have a direct bearing on its filtering efficiency.[11, 12, 13]

Although the effectiveness of the face mask for reducing surgical site infections has been controversial, a number of major organizations have published guidelines for health care workers to minimize risks of exposure which include face masks. They include the Centers for Disease Control [CDC], Association of Operating Room Nurses [AORN], Occupational Safety and Health Administration [OSHA] and the Operating Room Nurses Association of Canada [ORNAC]. AORN recommends that "all persons entering restricted areas of the surgical suite should wear mask when open sterile items and equipment are present" and that masks be worn along with protective eyewear whenever exposures to mucous membranes is reasonably anticipated.[14] The Operating Room Nurses Association of Canada (ORNAC) agree with these recommendations.[15] The CDC guidelines admit that the role of face masks in reducing the risk of surgical site infections may be more uncertain than previously thought. And yet, the same guidelines support the use of surgical face masks as personal protective equipment.

In this regard the study of the transmission of small particles and liquid aerosols through nonwoven products used in protective apparel and other filter media is of importance. This area of study, with reference to surgical face masks, is of interest as masks are now expected to act as protective barriers. In the summer of 2001, several new ASTM standards specifically relating to face masks and their evaluation (ASTM-F2101-01; ASTM-F2100-01) were approved.[16] In a draft document, published in 1998, the FDA listed 5 major categories of tests that are available for determining the barrier performance and safe use of a surgical mask. They were 1) fluid resistance, 2) filtration efficiency, 3) air exchange pressure (Delta P), 4) flammability and 5) biocompatibility testing.[17]

In 1999 Davis reviewed the test methods used for the evaluation of face masks effectiveness [18]. Bacterial Filtration Efficiency (BFE), both *in vivo* and *in vitro*, is a widely accepted method of evaluating face masks. In these tests, the bacteria penetrating the face masks are collected, cultured and counted to determine the number of Colony Forming Units (CFU'S) that penetrate the mask. The *in vitro* test uses positive and negative controls to determine the initial number of bacteria. The challenge bacteria are contained in a mist, which is produced by aerosolizing the bacteria with 0.1% peptone water in a nebulizer. The masks are placed directly over the opening of an Anderson sampler. The aerosol consists largely of droplets that simulate expulsion from the wearer. The current BFE tests are used with the microorganism *S. aureus*. However there are a number of microorganisms in addition to *S. aureus* that are known to cause nosocomial infections and other serious health problems. Nosocomial infections, which are defined as those infections originating in the hospital or healthcare center, occur in about 5% of all patients admitted to the hospital, with 41% being urinary tract infections, 18% surgical, and 16% respiratory.[19] Postoperative wound infections occur in up to seven percent of surgical patients and require patients to remain in the hospital an average of 7.3 extra days at an additional average cost of $3,152.[20, 21] Although a variety of pathogens are encountered in the hospital environment, a relatively limited number cause the majority of hospital infections including *Escherichia coli*, *Pseudomonas aeruginosa*, *Enterococcus faecalis*, *Candida albicans*, and *Staphylococcus aureus*.[20]

Microorganisms have varying characteristics that can influence their potential ability to penetrate the facemask material including shape, size, and their surface characteristics. A wide variety of studies have evaluated the BFE of face masks, however there have been a limited number of microorganisms evaluated in these studies.[4,22,23] Willeke, et. al reported that rod-shaped bacteria penetrate less than spherically shaped bacteria of similar size.[22] In addition, few studies have evaluated the BFE of the face masks with specifically engineered fabric characteristics

In this study, the BFE of six commercially available surgical face masks was determined for two microorganisms, *S. aureus* and *E. coli*. Fabric characteristics that influence the barrier effectiveness were measured and evaluated. Although the fit of the mask and leaks between the face and the mask interface are known to be important performance considerations, they have not been addressed in this study.

Materials and Methods:

In this study, two components of the FDA recommended areas were evaluated, 1) liquid resistance and 2) filtration efficiency. Six commercial face masks, each from a different manufacturer, were selected for evaluation (Table 1). Three of the face masks (#1-3) were three ply with a pleated construction, and three (#4-6) were molded face masks.

Properties that characterize the fabric, such as thickness, weight, and pore size, were measured in addition to the liquid resistance and bacterial filtration efficiency. These characteristics were determined in accordance with standard testing procedures (Table 2). Liquid barrier properties were measured according to ASTM F-1862-98: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood. This test method is designed to evaluate penetration of the masks by synthetic blood under high velocity. In this project varying degrees of velocity were examined to determine the influence of pressure on the level and mechanism of transmission. Velocity spray pressures of 80 mmHg, 120 mmHg, and 160 mmHg were selected.

The Bacterial Filtration Efficiency for each mask was determined in accordance with ASTM Test Method F2101-01, Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*. Two bacteria were selected for evaluation in this study, *S. aureus* and *E. coli*.

Table 1: Face masks Descriptions

Mask	Name	Description
1	Tie-on Surgical Face Mask	3-ply, pleated rayon outer web with polypropylene inner web
2	Classical Surgical Mask, Blue	3-ply, pleated cellulose polypropylene, polyester
3	Sofloop Extra Protection Mask	3-ply, pleated blended cellulosic fibers with polypropylene and polyester, ethylene methyl acrylate strip
4	Aseptex Fluid Resistant	Molded rayon and polypropylene blend with acrylic binder
5	Surgine II Cone Mask	Molded polypropylene and polyester with cellulose fibers
6	Surgical Grade Cone Style Mask	Molded polypropylene

Table 2. Test Methods and Procedures Used to Determine Facemask Properties

Description	Method Number	Title
Thickness	ASTM D1777-96	Standard Test Method for Thickness of Textile Materials
Weight	ASTM D3776 -96	Weight Per Unit Area
Pore Size	PMI Automated Perm Porometer Operation Manual, Version 6.	
Synthetic Blood Resistance	ASTM F1862-00a	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood
Bacterial Filtration Efficiency	ASTM F2101-01	Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*.

S. aureus is a gram positive cocci that is irregular in shape and often in grape like clusters. Various diseases and ailments including impetigo, toxic shock syndrome, food poisoning and pneumonia are attributed to *S. aureus*. An average coccus is about 0.5 - 1.0 µm in diameter. *E. coli* is a gram negative, rod shaped bacteria and averages 1.1 to 1.5 µm in width by 2.0 to 6.0 µm in length. *E. coli* is a leading cause of urinary tract infections.

The percent BFE was determined as described in the test method for *S. aureus*, and modified for *E. coli*. The *S. aureus* was obtained from American Type Culture Collection #6538 and *E. coli* was obtained from UGA Microbiology Department. Tryptic Soy Agar was the media used and Peptone water (Difco Dehydrated 500 grams-Lot #1361000) was used as the diluting agent as needed for the test method. Positive and negative controls were completed for each replication as directed in the test method. Using the positive control, it was determined that a challenge delivery rate of 2200 +/- 500 viable particles per test was required. This was achieved by diluting the bacterial stock solution to the appropriate bacterial concentration. The rate was determined by the results of the positive control plates when the aerosol is collected in the six-stage viable particle cascade impactor, with no test specimen clamped into the test system. The exposed plates were placed in an incubator at 37°C for 24 hours. The CFU's for each plate were counted using the Protocol Bacteria Colony Counter, Synopitcs Corporation, V 2.05. The filtration efficiency percentages were calculated using the equation provided in the test method:

$$100\,(C-T) / C = \%BFE$$

where C = average plate count total for test controls and T = plate count total for test sample.

Results and Discussion

The fabric characterization results for the three face masks are presented in Table 3. The pleated masks had lower pore size means than the molded masks. Mask #3 had the lowest mean pore size, 16.9µm, followed by Mask #2 with a mean pore size of 19.29µm, and Mask #1 had the highest pore size of the pleated masks at 23.97 µm. The mean pore size of the molded masks were significantly higher ranging from 31.72 µm (Mask #6) to 51.0 µm (Mask #5). Although thickness was not significantly different for the masks, the basis weight ranged from 58.567 gm/m^2 (Mask #2) to 164.405 gm/m^2 for Mask #6. The molded masks (#4, 5 & 6) were significantly higher in weight than the pleated masks (#1, 2 & 3).

The percent Bacterial Filtration Efficiency for each mask and bacteria are presented in Table 4. For 5 of the 6 masks (not Mask #4), the BFE values were higher when tested with *E. coli* than for *S. aureus*. This was expected as the size and shape of the microorganisms differ and *E. coli* is larger and rod shaped when compared with *S. aureus*. *S. aureus* ranges in size from 0.5 to 1.0 microns and is round in shape. *E. coli* is rod shaped and averages 1.1 to 1.5 µm in width by 2.0 to 6.0 µm in length.

Mask #3 had the highest %BFE for *S. aureus* and the second highest %BFE for *E. coli* and the lowest mean pore size of the face masks examined here. This indicates a relationship between pore size and BFE and further testing should be completed to investigate this relationship.

Mask #3, also had the lowest maximum pore size of 27.19 µm. This is a critical parameter to measure as this indicates the largest pore detected in the sample and therefore particles may be transmitted through this opening, hence reducing the BFE. When considering the mean pore size and the maximum pore size for face Masks #1 and #2, their order from highest to lowest is reversed for these two parameters. Although Mask #2 had a lower mean pore size than Mask #1, the maximum pore size was greater than that of Mask #1. This may help explain why the BFE for the masks is not in the same order as the mean pore size. Mask #2 had a slightly lower BFE for *E. coli* (98.53%) and *S. aureus* (88.18%) than did

Table 3: Face Mask Material Characteristics- thickness, weight, pore size, Resistance to Blood

Mask	Thickness mm	Weight gm/m^2	Pore Size µm		Synthetic Blood Resistance (% Passed)		
			Mean	Max.	80 mm Hg	120 mm Hg	160 mm Hg
1	0.3345	66.908	23.97	41.74	70	0	0
2	0.2339	58.657	19.29	43.27	100	100	50
3	0.4417	95.775	16.90	27.19	100	100	100
4	0.6137	140.828	35.06	87.74	0	0	0
5	0.3607	145.760	51.00	146.60	0	0	0
6	0.4742	164.405	31.72	92.12	0	0	0

Table 4. Face Mask Bacterial Filtration Efficiency - Mean and (Standard Deviation)

Mask	***S. aureus*** **- % BFE**	***E. coli*** **- % BFE**
1	91.09 (0.08)	98.53 (0.01)
2	88.18 (0.04)	97.26 (0.01)
3	92.19 (0.03)	99.34 (0.01)
4	90.72 (0.03)	99.10 (0.01)
5	84.82 (0.01)	95.74 (0.03)
6	86.4 (0.05)	99.73 (0.00)

Mask #1 (*E. coli*, 97.26%; *S. aureus* 88.18%). The % BFE for Mask #4 for *S. aureus* was higher than for Mask #2, which was unexpected since the mean and maximum pore size for Mask #2 was lower.

CONCLUSIONS

The BFE of six surgical face masks has been measured by challenges from two microorganisms, *S. aureus* and *E. coli*. Although there were no significant differences between the face masks, the bacterium did have a significant influence on the facemask performance. The BFE for 5 of the 6 masks exposed to E. *coli* was higher than when exposed to *S. aureus*. This was likely due to the size and shape of the bacteria. *S. aureus* is round and ranges in size from 0.5mm to 0.1 mm. *E. coli* is rod shaped and is larger, with size ranging from 1.1 to 1.5 μm in width and from 2.0 to 6.0 μm in length. Continuing studies with different microorganisms and face masks with varied characteristics will provide additional information on those factors that influence facemask barrier performance. In addition, the relationship between the mean pore size, the maximum pore size and the pore size distribution with BFE performance should also be examined.

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