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Major Article

Barrier resistance of double layer isolation gowns

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Key Words:
Double layer gown
Isolation settings
Personal protective equipment

Background: Isolation gowns are one of the crucial pieces of personal protective equipment (PPE) to prevent the migration of microorganisms and body fluids from patients to health care personnel and vice versa. Underperforming isolation gowns in terms of fluid resistance, could potentially put lives in danger. Wearing multiple layers of isolation gowns could theoretically increase the fluid penetration resistance. This study investigates if 2-layer lower barrier level isolation gowns meet the barrier effectiveness requirements of a single higher barrier level isolation gown.

Methods: Three commonly used ANSI/AAMI Level 2 isolation gown models were selected and tested in single layer and double layer configurations in accordance with ANSI/AAMI PB70 requirements.

Results: Total of 240 experiments were conducted to analyze the effects of gown model, fabric region, and the number of gown layers on AATCC 127 and AATCC 42 test results. In regard to AATCC 42, there was a significant difference among the different gown models, and the number of gown layers. Similar to AATCC 42 results, there was a significant difference among the different gown models, and the number of gown layers for AATCC 127; additionally, the gown regions was also significantly different.

Conclusion: Test results demonstrated that the double layer isolation gown configurations do not always provide equal fluid penetration resistance as required for a single Level 3 isolation gown using the standard test methods specified in ANSI/AAMI PB70.

BACKGROUND

Isolation precautions are vital to prevent spreading infectious diseases such as, Hepatitis B (HBV), Hepatitis C (HCV), AIDS (HIV), Ebola virus disease and the coronavirus disease 2019 (SARS-CoV-2). Health care personnel (HCP) are at the frontline in terms of risk of infection and death, and heavily rely on the barrier resistance of the personnel protective equipment (PPE) that they use in addition to other infection prevention measures applied by their organizations. As of April 9, 2020, the coronavirus disease 2019 (COVID-19) pandemic had resulted in 9,282 HCP infections, and among those 27 deaths, in the United States alone.[1] Significant efforts have been employed to develop new materials and manufacturing techniques to meet consumers' design needs and improve barrier protection in recent years. Isolation gowns are one of the main elements of PPE for protecting HCP, patients, and visitors from infectious pathogens. There are many types of isolation gowns in the marketplace which offer varying barrier resistance to blood or other body fluids. Isolation gowns are generally classified as disposable or reusable, however, mainly disposable gowns are used in the US health care in contrast to Europe.[2] The building materials and design of the isolation gowns determine the barrier effectiveness. Disposable isolation gowns are typically constructed of nonwoven materials, which are made of a wide range of synthetic fibers or in combination with other materials such as plastic films.[3] The ANSI/AAMI PB70[4] standard is currently used to classify gowns according to the liquid barrier performance. The AAMI PB70 standard includes 3 standard tests to evaluate the barrier effectiveness of surgical gowns and isolation gowns. Based on the results of these standardized tests, 4 levels of barrier performance are defined, with Level 1 being the lowest level of protection, and Level 4 being the highest level of protection (Table 1). The requirements for the design and construction of surgical and isolation gowns are based on the anticipated location and degree of liquid contact, given the expected conditions of use. ANSI/AAMI PB70 identifies certain areas of isolation gowns as critical zones. The critical zones

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Table 1
ANSI/AAMI PB 70:12 levels of barrier protection

Level	Test	Result	Expected barrier effectiveness
1	AATCC 42 (Spray Impact Test)	≤4.5 g.	Minimal water resistance
2	AATCC 42 AATCC 127 (Hydrostatic Head Test)	≤1 g. ≥20 cm H_20	Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)
3	AATCC 42 AATCC 127	≤ 1 g. ≥50 cm H_20	Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)
4	ASTM F1670 *(Synthetic Blood Test for Drapes and Drape Accessories Only)* ASTM F1671 *(Bacteriophage Test for Surgical and Isolation Gowns)*	Pass Pass	Blood and viral penetration resistance

include those areas where direct contact with blood, body fluids, and/or other potentially infectious materials is most likely to occur. According to the standard, for isolation gowns the whole garment is considered a critical zone which includes the seams, but excludes the cuffs, hems, and bindings.[3]

AAMI TIR 11 is a technical guidance that provides considerations for selecting the protection level of PPE based on the anticipated exposure to potentially infectious fluids.[5] Some of the factors important to assessing the risk of exposure in health care facilities include source, modes of transmission, pressures and types of contact, and duration and type of tasks. According to the guidance, level 1–3 gowns could be used when minimal to moderate fluid exposures are expected such as, simple biopsies, ear, nose, and throat procedures, as well as mastectomies, gastrointestinal, arthroscopic orthopedic, and endoscopic urological procedures. Thus, identifying the expected fluid amount and duration of exposure has great importance when selecting the appropriate gown.

Although, selection of an appropriate gown depends on anticipated fluid exposure, it may be based on the availability of a gown at the specific level of protection within the healthcare institution. During times of pandemics or product recalls, PPE shortages could occur.[6-8] When gowns with higher levels of protection are not available, HCP may resort to wearing gowns with lower levels of protection. This study aims to investigate if wearing a double layer of lower level (Level 2) isolation gown provides an equal degree of protection as wearing a single higher level of (Level 3) of protection, when institutions only have lower level isolation gowns in their inventories. Hypothetically adding multiple layers could increase the barrier effectiveness. The thicker and denser fabric construction could potentially decrease the fluid penetration. The fluid penetration though fabric pores depends on physicochemical properties of fabric, characteristics of the fluid, and other factors such as physical, chemical, and thermal stresses that are applied to the fabric. One of the important parameters that defines how fast and deep the fluid travel through the fabric is the external pressure exerted on the fabric surface by the fluid. Having multiple layers could help increasing the fluid penetration resistance since first garment layer could absorb the initial impact pressure of the fluid and decrease the external fluid pressure effect. The AATCC 42 test tool could be useful for measuring this effect, since the test is designed to quantify the impact penetration of water.

There are several studies that show benefits of double-gloving, as demonstrated by Guo et al where they provided evidence of advantages of using double layer glove configuration compared to single layer.[9] In addition, previous National Institute for Occupational Safety and Health (NIOSH) research showed the benefit of double gloving in terms of glove-gown interface barrier efficacy.[10] Although double-gloving is not directly related to wearing multiple layer gowns, since generally double-gloving is considered advantageous if a puncture or imperfection potentially occurs or exists in the first layer, where both layers of gloves are expected to be impervious to fluid, it is worth to mention, because double-gloving could be thought as an evidence-based justification for wearing multiple layer isolation gowns.

METHODS

An experimental laboratory study was designed to investigate the impact of double layer gown configuration on the fluid resistance provided by the system using isolation gowns. Three commonly used (labeled as A, B, and C) ANSI/AAMI Level 2 isolation gown models were selected and tested in single layer and double layer configurations in accordance with ANSI/AAMI PB70 requirements. ANSI/AAMI PB70 requires testing the gown critical zones using AATCC 42[11] and AATCC 127[12] standard test methods. All of the gown models had a medium weight multilayer nonwoven fabric design and heat-sealed seams. Some of the other specifications of the gowns are listed in the Table 2.

The AATCC 42 (Water Resistance: Impact Penetration Test) determines the ability of a material to resist water penetration under spray impact. The test sample is clamped over preweighed blotter paper at a 45° angle and 500 mL of water is released from a spray head. The total water penetration is calculated and reported in grams by subtracting the weight of the dry blotter paper from the weight of the blotter paper after the test. Higher weights in grams represent lower water resistance. According to ANSI/AAMI PB70, this testing should be conducted on samples taken from the critical zones, which correspond to the entire gown for the isolation gowns, including sleeve seams and points of attachments. Ten specimens from 2 of the critical zones (chest-continuous regions and sleeve seams) were tested for 3 isolation gown models. In total, 120 AATCC 42 tests were conducted.

The AATCC 127 (Water Resistance: Hydrostatic Pressure Test) determines the ability of a material to resist water penetration under increasing water pressure. The test sample is clamped in place, and the hydrostatic pressure is increased at a rate of 60 mbar/min until visible penetration of water droplets is observed. Thus, higher hydrostatic pressure represents higher water resistance. Similar to AATCC 42, 10 specimens from 2 of the critical zones (chest-continuous regions and sleeve seams) were tested for 3 isolation gown models. In total, 120 AATCC 127 tests were conducted.

Table 2
Gown descriptions and physical properties

Manufacturer and model #	ID	ANSI/AAMI PB70 level	Seam type	Thickness (mm)	Weight (g/m^2)
Medline (NONLV240)	A	Level 2	Heat Sealed	0.18	25.9
Medline (NONLV200)	B	Level 2	Heat Sealed	0.172	20.8
Cardinal Health (AT4437-BD)	C	Level 2	Heat Sealed	0.18	22.4

Table 3.
Descriptive Statistics for AATCC 42 and AATCC 127

			AATCC 42		AATCC 127	
Model	Gown region	Number of layers	Mean (g)	Std. Deviation (g)	Mean (cm H_20)	Std. deviation (cm H_20)
A	Continuous	Single	0.28	0.09	35.53	9.33
		Double	0.03	0.01	57.55	2.93
	Seam	Single	0.31	0.10	35.69	3.11
		Double	0.03	0.01	51.46	2.02
B	Continuous	Single	0.72	0.56	33.53	7.38
		Double	0.02	0.01	42.49	7.19
	Seam	Single	0.57	0.31	28.35	2.99
		Double	0.02	0.01	38.03	6.04
C	Continuous	Single	0.45	0.13	33.62	5.83
		Double	0.04	0.01	43.51	6.05
	Seam	Single	0.41	0.41	25.39	4.11
		Double	0.01	0.01	40.09	4.43

RESULTS

In total, 240 experiments were conducted to analyze the effects of gown model (A, B, C), gown region (continuous and seams), and the number of gown layers (one and two) on AATCC 42 and AATCC 127 test results. Two, distinct $3 \times 2 \times 2$ analyses of variances (ANOVAs) were used to examine the effect of each of the independent variables on AATCC 127 and AATCC 42 individually. Descriptive statistics of AATCC 127 and AATCC 42 test results for each gown, gown region, and number of gown layers are shown in the Table 3. Figures 1 (AATCC 42) and 2 (AATCC 127) depict the mean plots corresponding to each cell in the design.

In regard to AATCC 42, 2 of the main effects were significant. There was a significant difference among the different models, $F(2,108) = 5.57$, $P = .005$, $n_p^2 = 0.09$ (gown A, M = 0.16 g; gown B, M = 0.33 g; and gown C, M = 0.23 g). The main effect of the number of gown layers was also significant, $F(1,108) = 109.05$, $P < .001$, $n_p^2 = 0.50$ (single layer, M = 0.46; double layer, M = 0.02). There was not a significant difference among the different gown regions, $P = .44$, (continuous fabric, M = 0.26 g; seams, M = 0.22 g). This may be attributed to the fact that entire gown seams were constructed using heat sealing and AATCC 42 tests the water penetration for a single contact. Only the 2-way interaction between gown model and the number of layers was significant, $F(2,108) = 6.50$, $P = .002$, $n_p^2 = 0.11$—given a slightly different pattern of differences between single and double layering as a function of gown model.

In regard to AATCC 127, each of the main effects was significant. There was a significant difference among the different models, $F(2,108) = 38.65$, $P < .001$, $n_p^2 = 0.42$ (gown A, M = 45.06 cm H_2O; gown B, M = 35.60 cm H_2O; and gown C, M = 35.65 cm H_2O). There was a significant difference among the different gown regions, $F(1, 108) = 20.12$, $P < .001$, $n_p^2 = 0.16$ (continuous fabric, M = 41.04 cm H_2O; seams, M = 36.50 cm H_2O). The main effect of the number of gown layers was also significant, $F(1,108) = 178.26$, $P < .001$, $n_p^2 = 0.62$ (single layer, M = 32.01 cm H_2O; double layer, M = 45.52 cm H_2O). The 3-way interaction was not significant. Similar to AATCC 42, only the 2-way interaction between gown model and the number of layers was significant, $F(2,108) = 7.83$, $P = .001$, $n_p^2 = 0.13$—given a slightly different pattern of difference between single and double layering as a function of gown model.

DISCUSSION

According to the AATCC 42 impact penetration results, fluid resistance of A, B, and C continuous region samples were increased about 89%, 97%, and 91%, respectively, when comparing single versus double layer configuration. However, the AATCC 127 hydrostatic resistance test resulted in about 62%, 26%, and 29% increase in the fluid resistance, respectively. These results could be attributed to prolonged high-pressure water contact in the AATCC 127 test, in contrast to the single water spray in the AATCC 42, in which the outer fabric layer could resist the initial water impact causing the water to lose its initial impact energy resulting in a small number of droplets reaching the second inner layer. Although, there was an increase in the resistance performances of all models, most of the time double layer configurations of these Level 2 gowns were not able to provide a degree of protection equal to a Level 3 of ANSI/AAMI PB70 gown.

ANSI/AAMI PB70 specifies for Level 2 gowns maximum 1 g of weight gain when tested according to AATCC 42 and minimum 20 cm H_2O hydrostatic resistance when tested according to AATCC 127 (Table 1). Gowns need to achieve a minimum of 50 cm H_2O hydrostatic resistance in order to meet the Level 3 protection level. Two of the gown models, B and C, failed to meet the minimum AATCC 127 requirements for Level 3, while gown model A met this requirement,

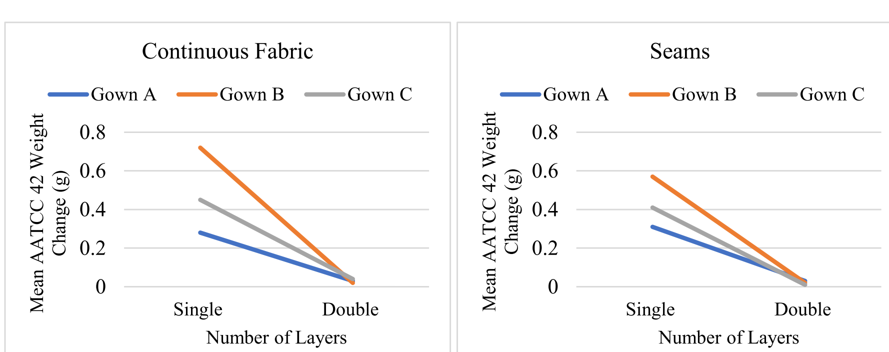

Fig 1. AATCC 42 plot of means as a function of gown model, gown region, and number of layers.

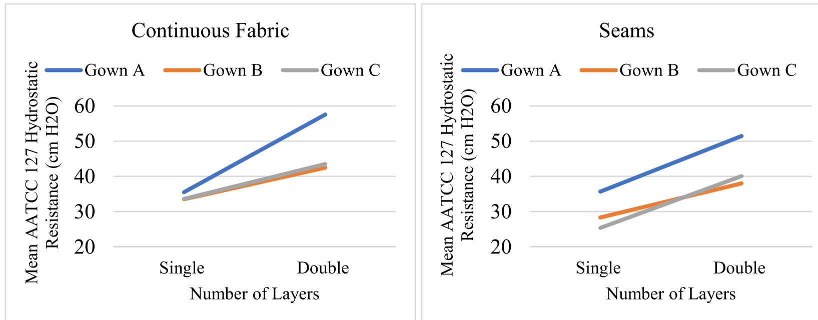

Fig 2. AATCC 127 plot of means as a function of gown model, gown region, and number of layers.

in the double layer configuration. However, although the average value of AATCC 127 of gown model A met the minimum requirement for Level 3 gowns, it was observed that 3 of the ten fabric samples resulted in less than 50 cm H_2O of hydrostatic resistance. The ANSI/AAMI PB70 standard requires manufacturers to implement a quality system that rejects lots with a failure rate greater than or equal to 20% at least 90% of the time. This is known as the Rejectable Quality Level (RQL). Based on this requirement, it may be required that we test more samples to make a clear conclusion on gown model A.

CONCLUSIONS

This study investigated if double layering Level 2 isolation gowns could provide an equal degree of fluid resistance with wearing one Level 3 gown. Three ANSI/AAMI PB70 Level 2 isolation gowns were tested based on the standard, in single- and double-layer configurations. Test results demonstrated that the double layer isolation gown configurations do not always provide equal fluid penetration resistance as required for a single Level 3 isolation gown using the standard test methods specified in ANSI/AAMI PB70.

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DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the National Institute for Occupational Safety and Health (NIOSH). Mention of any product name or depiction of product does not constitute endorsement by NIOSH.

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