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Major Article

Evaluation of the physical performance of disposable isolation gowns

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Key Words:
Protective clothing
Body fluid
Strength
Tear
Personal protective equipment
Gown performance

Background: The threat of emerging infectious diseases has highlighted the need for effective gowns to protect health care workers and patients. Although studies identified end user issues with the physical performance of gowns, the literature that evaluates the performance is scarce. This paper represents 1 of the first efforts to investigate the physical performance of a substantial set of isolation gown models in the marketplace.

Methods: Physical performance of 20 commercial and 2 experimental disposable isolation gowns was evaluated in this study. Standard test methods were used to investigate a range of properties, including thickness, weight, tensile strength, tearing strength, and seam strength.

Results: In general, due to the differences in the fibers and methods used for the construction, large variations in the tensile, tear, and seam strength results were found. When the gowns were compared to their respective Association for the Advancement of Medical Instrumentation PB70 protection levels, no clear trend was found between protection levels and tear strength or between protection levels and seam strength, while there was a linear relationship between gowns' Association for the Advancement of Medical Instrumentation PB70 levels and their tensile strength. It was found that fabric construction significantly affects the physical performance of gowns.

Conclusions: Based on this work, a new standard, American Society of Testing and Materials International F3352, was published and has been recognized by the Food and Drug Administration. American Society of Testing and Materials International F3352 is expected to help end users in selecting the appropriate protective clothing.

BACKGROUND

The performance of personal protective equipment (PPE) in health care has received much attention from health care workers (HCWs) and the public, especially during the 2014 Ebola epidemic. Due to HCWs' familiarity with donning and doffing procedures, perceived comfort, availability of established liquid penetration classification standards, and quick and easy donning and doffing features, gowns are 1 of the most widely used pieces of PPE when providing care for patients with infectious diseases.

Viruses such as Ebola, Hepatitis B, Hepatitis C, and Human Immunodeficiency Virus spread through direct contact with blood or the body fluids of a person who is infected with that virus, or with objects (eg, bathroom surfaces, medical equipment) that have been contaminated with the infectious blood or body fluids. The virus in the blood and body fluids can enter a person's body through broken skin or unprotected mucous membranes in, for example, the eyes, nose, or mouth. Therefore, it is important to provide HCWs with PPE that fully covers the skin and clothing.[1] Gowns have been recommended by many organizations, including the Centers for Disease Control and Prevention (CDC) and World Health Organization, for use by HCWs when treating patients with Ebola virus disease during the last Ebola epidemic and COVID-19 pandemic.[1,2]

Isolation gowns are the second most frequently used type of PPE in health care after gloves. They are worn to protect HCWs during procedures and patient care activities when anticipating contact with blood, body fluids, secretions, and excretions, or when protecting the skin or clothing from contamination with antibiotic-resistant organisms that pose a transmission risk to patients.[3]

Microorganisms' movement through isolation gown fabrics depends on several factors, including the physical and chemical

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properties of the fabric, the shape and surface characteristics of the microorganisms, and the characteristics of carriers, and other factors such as physical and chemical stresses applied on the fabrics. A number of fabric and design characteristics, such as fabric and seam strength, tear strength, pore size, repellency, size, fit, thermal comfort, mobility, and interfaces can also contribute to the effectiveness of isolation gowns. Isolation gowns offer varying levels of performance depending on all of the cited properties.[4,5] When physical stresses are applied, fabric structure or points of attachments (eg, seams) can become susceptible to virus penetration. Therefore, it is important to manufacture the gown structure as durable as possible without substantially compromising other important characteristics, such as comfort.

The American National Standards Institute/Association for the Advancement of Medical Instrumentation (AAMI) PB70:2012 "Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities" (AAMI PB70 hereafter) was established to classify gowns according to their barrier performance. However, there was no standard available that specifies the physical performance and design criteria for gowns at the time that this study was conducted.[6] AAMI PB70 specifies labeling requirements and test methods for classifying protective apparel based on their liquid barrier performance and was recognized by the Food and Drug Administration in 2004. Due to the lack of standards in the area of physical performance for isolation gowns, the American Society of Testing and Materials International's (ASTM) F23 Committee started a work item in collaboration with the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (NIOSH) to develop the minimum performance and design criteria for isolation gowns to assist end users in the correct isolation gown selection, assuring higher levels of protection than currently provided. For this purpose, the ASTM F23 Committee Work Group surveyed infection preventionists (IPs) in 2011 to determine use/wear issues, familiarity with isolation gown performance standards, and to identify compliance perceptions and problems.[7] A total of 1,498 respondents provided descriptive information regarding their use of isolation gowns and answered questions about protection levels, compliance issues, familiarity with the relevant industry standards, and garment failures. Of the total who replied, 1,354 (90%) indicated that they wore isolation gowns in their typical work activities. The majority (74%) of these 1,354 respondents reported that the type of garment (disposable or reusable) had little or no impact on their compliance, but 48% indicated that gown features could have a moderate to very high impact on their compliance. Results of the survey indicated that IPs (82%) expect and believe they achieve good protection with isolation gowns and that the fit, restriction of movement, comfort, and time to don/doff are important compliance issues to be addressed. Although most IPs reported no fit or mobility restriction issues with isolation gowns, 22% reported problems with tight fit in the shoulder area. Content analysis of open-ended questions revealed issues related to large-sized clients, neck designs, tie closures, and breathability. When 965 respondents were asked to describe the types of failures they have encountered when using isolation gowns, 436 (45%) responses described problems with puncture or tear, 303 (31%) rips and holes, 128 (13%) seam failure, and 81 (8%) worn-out fabrics. These results clearly indicated issues with the physical performance of isolation gowns used in health care settings. Thus, in this study, the primary objective was to evaluate the physical performance of isolation gowns, which is expected to significantly affect the barrier properties. Accordingly, 22 disposable isolation gown models from 6 manufacturers were evaluated for thickness, weight, tensile strength, tear strength, and seam strength. This study also provided scientific support for ASTM F23 to establish a standard specification that defines the minimum performance and design criteria for isolation gowns. Based on this study's findings, a new standard, ASTM F3352, was published and has been recognized by Food and Drug Administration.

METHODS

This study was initiated by the National Personal Protective Technology Laboratory (NPPTL) of the CDC's NIOSH in collaboration with the ASTM F23.40 committee to evaluate the physical performance with a sample of isolation gowns and to develop the minimum performance requirements for a future ASTM standard. In response to letters inviting manufacturers to participate in the isolation gown project and a 2013 Federal Register Notice,[8] manufacturers sent gowns to NPPTL for evaluation. Only gowns labeled as "isolation gowns" were included in the testing. Gowns labeled as surgical gowns, cover gowns, comfort gowns, procedure/procedural gowns, and open-back gowns were not included. All testing was conducted at the NIOSH NPPTL Morgantown, WV Laboratories. Twenty-two different single-use (disposable) isolation gown models from 6 manufacturers were voluntarily submitted. Gowns were categorized and tested according to the manufacturers' labeling claims based on AAMI PB70 barrier levels. Two gowns (#3 and #4), which did not claim any AAMI PB70 protection level, were evaluated at Level 1 protection since Level 1 is defined as the minimum level of protection for isolation gowns by AAMI PB70. However, physical performance was determined as the focus of this paper.

Twenty commercial and 2 experimental disposable isolation gowns were studied (Table 1). Standard test methods were used to evaluate the fabrics. Samples were prepared in accordance with the test methods listed. The number of test specimens specified by the standard test methods was proportionally increased to exceed the minimum of 13 specimens per fabric direction.

GOWN MODELS

Twenty gowns were manufactured using nonwoven manufacturing techniques, while 2 of the fabrics (#17 and #20) were composed of films. Nonwovens are fabric-like materials made from fibers, bonded together by a number of techniques, including chemical, mechanical, heat, or solvent treatment, while films are plastic sheet-like materials. Most of the nonwoven fabrics were composed of polypropylene fibers: 1 fabric (#3) was polypropylene coated with polyethylene, 2 fabrics (#10, #23) were polyethylene film laminated over spun bond-melt blown-spun bond polypropylene, and 1 fabric (#16) was polyethylene film laminated over spun bond polypropylene. Two of the films (#17, #20) were made of polyethylene. A variety of different seaming techniques were used from ultrasonic to heat sealing to stitching. Ties were also attached using several different techniques for different models, including ultrasonic spot welding, gluing, and taping (see Table 1).

Testing

The evaluated fabric characteristics included thickness, weight, tensile strength, tear strength, and seam strength. The fabric basis weight (mass) for all fabrics was measured in accordance with the

Table 1
Isolation gown descriptions

AAMI level	Gown ID	Fiber composition	Structure	Laminated	Seam type	Tie attachment
1	1	Polypropylene	SMS	No	Ultrasonic	Ultrasonic
1	2	Polypropylene	SMS	No	Heat sealed	Glued
1	3	Polypropylene/Polyethylene	SMS polypropylene coated with polyethylene	No	Sewn seam	Glued
1	4	Polypropylene	SMS	No	Sewn seam	Sewn
1	13	Polypropylene	SMS	No	Ultrasonic	Ultrasonic
1	21	Polypropylene	SMS	No	Heat sealed	Glued
2	5	Polypropylene	SMS	No	Ultrasonic	Ultrasonic
2	6	Polypropylene	SMS	No	Heat sealed	Glued
2	7	Polypropylene	SMS	No	Heat sealed	Glued
2	14	Polypropylene	SMS	No	Ultrasonic	Ultrasonic
2	18	Polypropylene	SMS	No	Heat sealed	Glued
2	22	Polypropylene	SMS	Yes	Heat sealed	Glued
3	8	Polypropylene	SMS	No	Heat sealed	Glued
3	9	Polypropylene	SMS	No	Ultrasonic	Glued
3	10	Polypropylene/Polyethylene	Polyethylene film laminated over SMS polypropylene	Yes	Heat sealed	Glued
3	11	Polypropylene	SMS	No	Heat sealed	Glued
3	15	Polypropylene	SMS	No	Ultrasonic	Ultrasonic
3	19	Polypropylene/Polyethylene	Polyethylene film laminated over spunbond polypropylene	Yes	Heat sealed	Glued
3	23	Polypropylene	SMS	Yes	Heat sealed	Glued
4	16	Polypropylene	Polyethylene film laminated over spunbond polypropylene	Yes	Heat sealed	Double sided taped
4	17	Polyethylene	Film	No	Heat sealed	Double sided taped
4	20	Polyethylene	Film	No	Heat sealed	Glued

AAMI, Association for the Advancement of Medical Instrumentation; *SMS*, spun bond-melt blown-spun bond.

ASTM D3776 Standard Method for Mass per Unit Area of a Woven Fabric.[9] A Scientech SA210 laboratory balance (USA), accurate to 0.0001 g, was used to determine the weight. Thirty-two specimens from different gowns and various locations on the gowns were tested for each gown model, and the average, standard deviation, maximum, and minimum values were calculated (Table 2). Fabric tensile strength, tearing strength, and seam strength were measured by Instron 5565A (Instron Norwood) using the standard test methods: ASTM D5034 Breaking Strength of Nonwoven Fabrics, ASTM D5733 Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure, and ASTM D1683 Failure in Sewn Seams of Woven Apparel Fabrics, respectively.[10–12] Fifteen specimens in the machine direction (MD) and 24 specimens in the cross-machine direction (CMD) were tested for breaking strength test. Sixteen specimens in MD and 16 specimens in CMD were tested for tearing resistance. Specimens were cut from multiple locations of multiple gowns. Sixteen shoulder seam specimens and 16 arm seam specimens were used for ASTM D1683 seam strength test. All fabric testing was conducted at 21 ± 3°C and 50 ± 5% relative humidity.

Analysis

Table 2 lists the descriptive statistics for tensile and tear test results in both MD and CMD. The tensile maximum load (in Newtons) value, which is the maximum force applied to the fabric carried to rupture, was normalized by dividing it by the cross-sectional area (fabric thickness x fabric width). Tearing strength and seam strength values were reported as maximum forces (in Newtons) required to continue a tear started in the fabric or break the seam, respectively. Strain values show the ratio of the extension of the fabric to the length of the material prior to stretching, expressed as percentages. A linear regression of the data is also shown using the least-squares method to illustrate the trend between the AAMI PB70 level and the bulk density, which is the density of the gown fabric. All of the analyses were conducted using Microsoft Excel.

RESULTS

Tensile strength

Table 2 shows the breaking load (N), tensile strength (breaking load per area, N/m^2), and tensile strain (%) for each gown model. Box plots, generated from data that exclude the outliers, are shown in Figure 1. Tensile strength values show a wide range of distribution within each gown model and within each AAMI PB70 level.

The tensile strengths of AAMI PB70 Level 1 gowns and Level 2 gowns were very similar (statistically nonsignificant), while AAMI PB70 Level 3 gown models demonstrate slightly higher (statistically significant with $P < 10^{-13}$) strength values. Three gown models, classified as AAMI PB70 Level 4 protection, did not show a clear trend. This can be attributed to the constructional difference between these 2 gowns (#17 and #20) and the other gown in the group (#16). Gowns #17 and #20, with relatively lower tensile strength values, were made of films, while the rest of the gown models were made of nonwoven structures. When the tensile strain values are examined, it is evident that these 2 gowns (#17 and #20) show very high levels of extension due to their unique structure. Nonwoven fabrics are made from fibers, bonded together by chemical, mechanical, heat, or solvent treatment, while plastic films are used alone or in combination with nonwoven fabrics in the construction of isolation gowns (frequently at the expense of thermal comfort) when a higher degree of protection is required. It should be noted that the test method used for the measurement of tensile strength in this study is mostly used for nonwoven fabrics and may not be applicable for film products. However, for comparison purposes, the same test methods were used in this study. Thus, these 2 gown models were treated as outliers and removed from the data set when more in-depth analysis was conducted, which is reported later in this paper.

The properties of nonwoven fabrics differ widely from one another because of the wide variety of available fibrous raw materials and many possible methods of locking or bonding the basic fibrous

Table 2
Descriptive statistics of the physical characteristics

AAMI level	Gown ID	Thickness (mm)		Weight (g/m^2)		Tensile strength–Max load (N)						Tensile strength/area (10^{-6} x N/m^2)						Tensile strain (%)					
						MD				CMD						MD				CMD			
		Ave	SD	Ave	SD	Ave	SD	Max	Min	Ave	SD	Max	Min	Ave	SD	Max	Min	Ave	SD	Max	Min	Ave	SD	Max	Min
1	1	19.4	0.01	24.1	1.1	61	8.0	69	44	46	2.5	50	41	3.1	0.4	3.6	2.3	2.4	0.1	2.6	2.1	30	1.4	32	28	44	16	73	26
1	2	17.2	0.01	24.3	1.0	59	3.2	64	55	35	2.7	40	30	3.4	0.2	3.7	3.2	2.0	0.2	2.3	1.7	40	3.6	46	34	57	6	67	44
1	3	22.8	0.02	40.8	1.8	49	3.3	54	42	35	3.3	40	29	2.1	0.1	2.4	1.8	1.5	0.1	1.8	1.3	65	12.2	80	42	66	14	89	33
1	4	19.2	0.02	19.6	1.3	64	3.8	71	59	48	4.4	56	39	3.3	0.2	3.7	3.1	2.5	0.2	2.9	2.0	59	4.6	66	51	80	10	98	61
1	13	18.8	0.01	21.5	0.9	66	4.2	73	60	41	3.3	46	33	3.5	0.2	3.9	3.2	2.2	0.2	2.5	1.7	57	5.0	64	51	77	10	94	55
1	21	18.6	0.01	24.7	1.5	70	2.0	73	66	41	3.1	45	35	3.8	0.1	3.9	3.6	2.2	0.2	2.4	1.9	47	2.8	51	43	57	6	67	47
2	5	18.2	0.01	20.3	0.9	53	3.4	58	47	33	1.1	35	31	2.9	0.2	3.2	2.6	1.8	0.1	1.9	1.7	45	4.0	53	40	61	5	71	52
2	6	26.0	0.03	26.4	1.1	65	6.5	74	55	50	3.5	55	44	2.5	0.3	2.8	2.1	1.9	0.1	2.1	1.7	40	3.6	47	35	57	4	66	51
2	7	17.0	0.01	22.5	1.0	56	5.3	64	45	38	3.3	43	31	3.3	0.3	3.8	2.6	2.2	0.2	2.5	1.8	67	9.4	79	51	97	16	119	67
2	14	18.2	0.01	20.9	1.0	63	3.1	67	58	40	5.2	49	32	3.5	0.2	3.7	3.2	2.2	0.3	2.7	1.7	54	3.4	60	48	78	13	107	56
2	18	21.8	0.01	29.4	1.0	80	5.2	87	68	59	4.3	68	52	3.7	0.2	4.0	3.1	2.7	0.2	3.1	2.4	47	4.4	56	39	61	6	73	49
2	22	24.0	0.01	27.3	1.2	74	5.1	83	66	49	4.1	55	44	3.1	0.2	3.5	2.7	2.1	0.2	2.3	1.8	43	3.8	50	35	59	7	73	49
3	8	24.0	0.01	34.2	1.5	100	4.1	106	94	75	3.1	82	70	4.2	0.2	4.4	3.9	3.1	0.1	3.4	2.9	44	2.6	48	39	60	3	65	55
3	9	29.6	0.02	47.9	1.4	110	4.1	116	103	74	3.3	79	67	3.7	0.1	3.9	3.5	2.5	0.1	2.7	2.3	39	1.9	43	37	58	4	68	49
3	10	22.0	0.01	44.6	1.3	92	6.2	103	79	64	7.3	78	47	4.2	0.3	4.7	3.6	2.9	0.3	3.6	2.2	57	4.9	65	47	75	11	95	51
3	11	25.8	0.01	35.0	1.2	110	5.4	119	103	73	5.4	83	63	4.3	0.2	4.6	4.0	2.8	0.2	3.2	2.4	49	2.2	53	46	63	7	79	53
3	15	32.0	0.02	44.0	1.4	134	5.1	142	125	89	5.1	102	79	4.2	0.2	4.4	3.9	2.8	0.2	3.2	2.5	54	2.9	58	49	78	7	97	64
3	19	12.0	0.01	29.7	1.0	56	1.8	59	51	36	3.1	42	29	4.6	0.2	4.9	4.3	3.0	0.3	3.5	2.4	65	4.5	74	57	66	9	85	53
3	23	24.6	0.01	23.2	1.0	63	3.7	70	59	43	3.7	51	37	2.6	0.2	2.9	2.4	1.8	0.2	2.1	1.5	46	4.7	55	40	61	6	74	52
4	16	24.4	0.03	42.9	1.9	75	6.6	87	65	68	10.1	85	45	3.1	0.3	3.6	2.7	2.8	0.4	3.5	1.8	53	4.8	62	45	62	11	79	39
4	17	6.0	0.00	23.7	1.1	32	0.6	33	31	25	3.1	29	19	5.3	0.1	5.5	5.2	4.2	0.5	4.8	3.1	198	11.2	215	179	399	104	500	140
4	20	10.0	0.00	28.7	1.0	32	1.8	35	29	24	2.4	29	20	3.2	0.2	3.5	2.9	2.4	0.2	2.9	2.0	153	15.9	180	125	269	121	457	111

AAMI, Association for the Advancement of Medical Instrumentation; *CMD*, cross-machine direction; *MD*, machine direction.

webs. The selection of fiber type, binder system, technique, and equipment used in their manufacture determines their characteristics. For isolation gowns, in addition to the cost, manufacturers consider the classification requirements of AAMI PB70 protection levels when designing their fabrics.

The AAMI PB70 standard defines barrier performance levels. AAMI PB70 relies upon 4 standard test methods to classify the barrier effectiveness of surgical gowns, isolation gowns, and surgical drapes (Table 3). Based on the results of these standardized tests, 4 levels of barrier performance were defined, with Level 1 being the lowest level of protection and Level 4 being the highest level of protection.

As can be seen in Table 3, when a higher protection level is required, the pass or fail criteria for the gowns are more difficult to achieve. To increase the protection level of the gowns, manufacturers have to increase the fabric density (bulk density) or use other methods, such as coating or laminating. Bulk density is 1 of the important characteristics for nonwovens, which directly or indirectly impacts the physical performance of gowns. Bulk density can be calculated by dividing the fabric weight by the fabric thickness. At Level 4 protection, manufacturers occasionally prefer using completely different structures (films) in order to pass the challenging viral penetration resistance test, instead of increasing the bulk density of the nonwoven structure.

Figure 2 shows the average bulk density for each gown model and the average bulk density per AAMI PB70 Level. As can be seen from the figure, there is a linear relationship between the AAMI PB70 level of gowns and the bulk density, with an R value of 0.85. A weaker linear relationship between the tensile strength/area and AAMI PB70 levels was also observed, with R = 0.37 in MD and R = 0.57 in CMD. Also, when the same analysis was conducted after the exclusion of all of the structurally different gowns (#3, #10, #19, #16, #17, and #20), the R value was found to be 0.68 and 0.69 for MD and CMD, respectively.

Tear strength

Tear strength is 1 of the important fabric characteristics for isolation gown users, as it shows the resistance of the fabrics to the forces that occur due to rips, tears, and snags. Figure 3 shows the tearing force for each of the gown models in MD and CMD. Due to the differences in the materials and manufacturing methods (eg, spun bond-melt blown-spun bond, lamination, films) used for the construction of the gowns, there was a large variation in the tear strength values. No clear relationship was found between each AAMI PB70 level and the tear strength values. However, with the exclusion of laminated gowns (#10, #19, #23, and #16) and film gowns (#17 and #20), the tearing force increases as the AAMI PB70 protection level increases.

Seam strength

The gown seam strength is very important, especially when a smaller size of a gown than required is selected. Several different seaming techniques are used in the construction of isolation gowns, depending on the need. AAMI PB70 defines the entire isolation gown as the critical zone. Thus, the gown seams are required to pass the criteria set by AAMI PB70 for liquid and viral penetration for continuous regions. In this study, 2 of the gowns had sewn seams (#3 and #4), 6 gowns had ultrasonic seams (#1, #5, #9, #13, #14, and #15), and fourteen gowns had heat-sealed seams. Figure 4 shows the arm and shoulder seam strength. There was no significant relationship between the seam types, AAMI PB70 levels, and seam strength. It should be noted that most of the heat-sealed gowns had fabric slippage at the jaws that the samples were mounted on: there

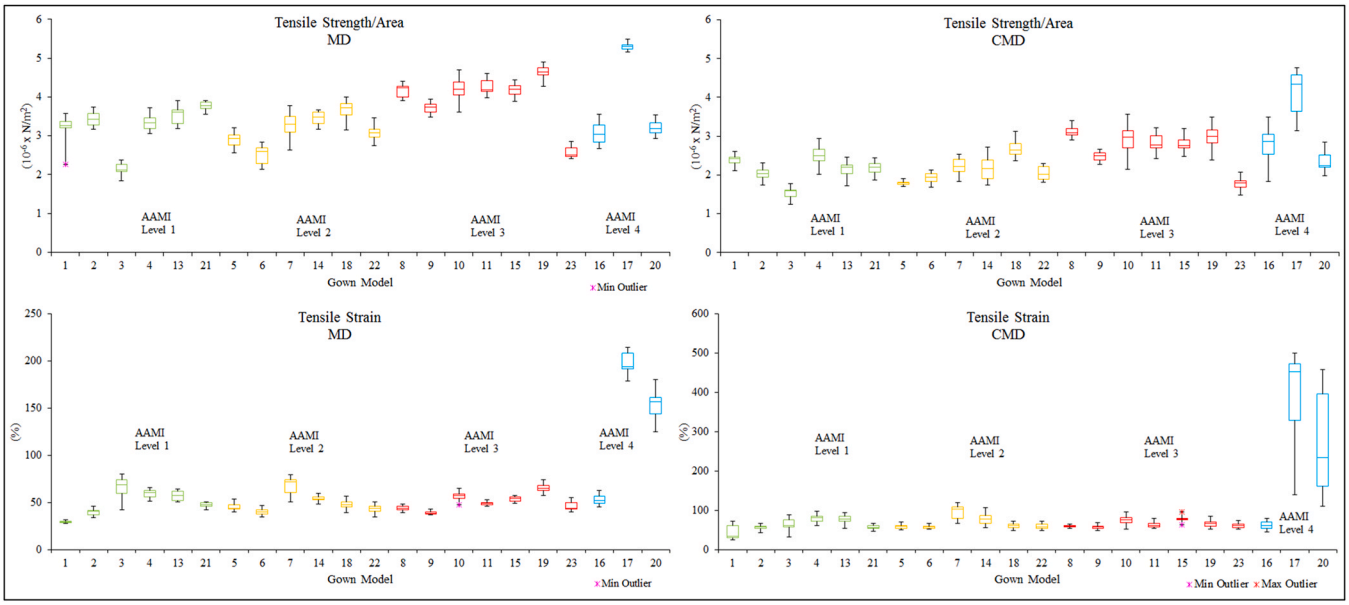

Fig. 1. Box plots for the first and third quartiles of tensile strength/area and strain.

Table 3
ANSI/AAMI PB70:12 classification of the barrier performance of surgical gowns, other protective apparel, surgical drapes, and drape accessories[6]

Level*	Test	Liquid challenge	Pass/fail criteria†	Expected barrier effectiveness
1	AATCC 42 Impact Penetration‡	Water	≤4.5 g	Minimal water resistance (some resistance to water spray)
2	AATCC 42 Impact Penetration	Water	≤1.0 g	Low water resistance (resistance to water spray and some resistance to water penetration under constant contact with increasing pressure)
	AATCC 127 Hydrostatic Pressure§	Water	≥20 cm	
3	AATCC 42 Impact Penetration	Water	≤1.0 g	Moderate water resistance (resistance to water spray and some resistance to water penetration under constant contact with increasing pressure)
	AATCC 127 Hydrostatic Pressure	Water	≥50 cm	
4	ASTM F1670 Synthetic Blood Penetration Test (for surgical drapes)**	Synthetic blood	No penetration	Blood and viral penetration resistance (59 min at ambient pressure and 1 min at 2 psi)
	ASTM F1671 Viral Penetration Test (for surgical and isolation gowns)††	Bacteriophage phi-X174	No penetration	

AAMI, Association for the Advancement of Medical Instrumentation; *ANSI*, American National Standards Institute; *AQL*, acceptable quality level; *RQL*, rejectible quality level.
*In order of increasing protection.
†Sampling requirement outlined in ANSI/AAMI PB70:2012 is to assure a 4% AQL and 20% RQL per critical zone.
‡American Association of Textile Chemists and Colorists (AATCC) 42 Water Resistance: Impact Penetration test determines the ability of a material to resist water penetration under spray impact.
§AATCC 127 Water Resistance: Hydrostatic Pressure test determines the ability of a material to resist water penetration under constant contact with increasing pressure.
**American Society of Testing and Materials International (ASTM) F1670 standard test method for resistance of materials used in protective clothing to penetration by synthetic blood evaluates the resistance of a material to synthetic blood penetration.
††ASTM F1671 standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system determines the resistance of a material to viral penetration.

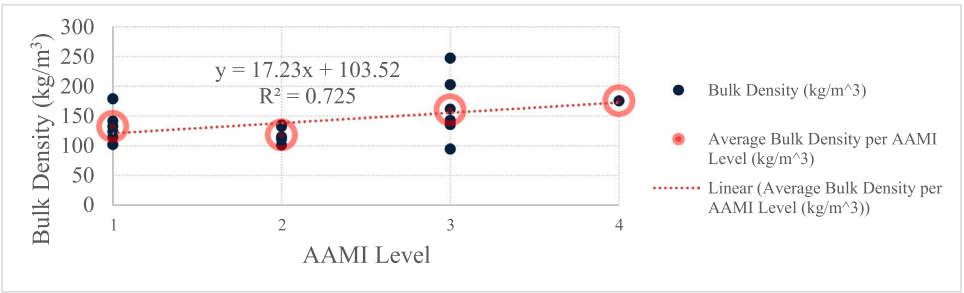

Fig. 2. Bulk density of gowns with different AAMI PB70 levels.

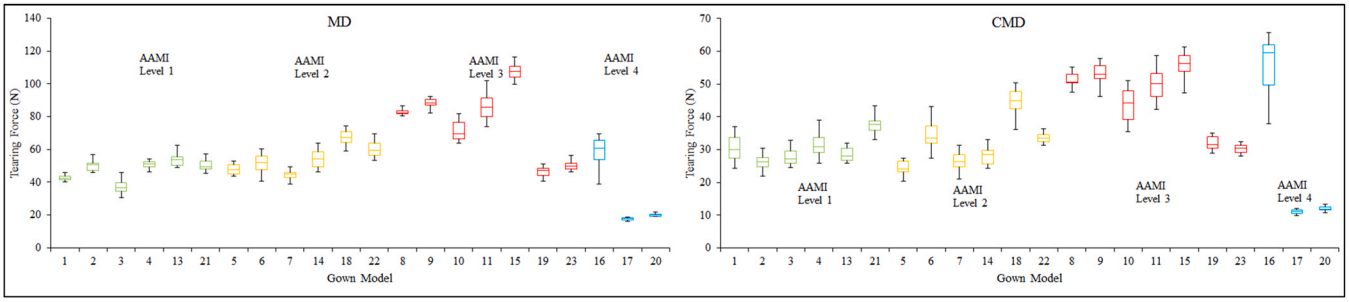

Fig. 3. Tear strength of isolation gown models.

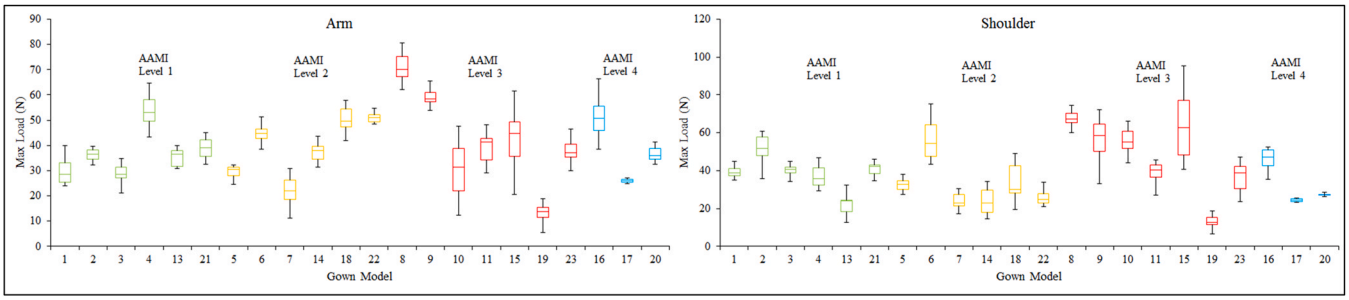

Fig. 4. Arm and shoulder seam strengths.

was no seam failure, but there was fabric rupture. Therefore, the values may not reflect the actual seam strength performance.

CONCLUSIONS

In general, due to the differences in the fibers/methods used for the construction of the gowns, large variations in gown tensile, tear, and seam strength results were found in this study. When the gowns were compared regarding their AAMI PB70 protection levels, no clear trend was found between AAMI PB70 levels and tear strength or between AAMI PB70 level and seam strength, while there was a linear relationship between the AAMI PB70 level and the tensile strength. Bulk density (packing density) was found to be an important nonwoven fabric characteristic, as there was a strong linear relationship between the AAMI PB70 level and bulk density of fabrics.

The study findings are limited to the gown models tested and the variability of the test methods. The isolation gowns evaluated in this study were estimated to represent over 80% of the gowns (by market share) in the marketplace in the United States between 2010 and 2020. In the industry, various fibers, fabric production methods, and seaming techniques are used to construct isolation gowns. These constructional properties significantly affect the physical properties. The fiber type and the manufacturing method directly affect the test results for tensile strength or strain and tear resistance or strain. In this study, there are general trends toward stronger gowns as the AAMI PB70 level increases; however, due to the interaction between the fiber composition, fabric structure, use of lamination, seam type, fabric weight, and fabric thickness, some of the tested gowns (eg, film gowns) achieve higher AAMI PB70 levels even though they demonstrate a lower physical performance. Since these parameters were not controlled in this study and gowns present a wide range of characteristics, the study illustrates the combined effect of the fabric characteristics on the physical performance. No direct relationship was observed between each parameter and physical performance due to the uncontrolled sample design.

AAMI PB70 requires a different test method for isolation gowns to be classified as Level 4 compared to Level 1 through Level 3 for barrier resistance. The same tests (AATCC 42 and AATCC 127 water resistance tests) are required for Level 1 through 3 with increasingly more stringent pass or fail criteria, while Level 4 gowns are subjected to completely different test methods for the classification (ASTM F1671 viral penetration resistance test). AAMI PB70 Level 1, 2, and 3 isolation gown testing requirements only use water as a challenge. Because the surface tension of water is much higher than that of bacteriophage suspension (0.072 vs 0.042 N/m), the solvent may penetrate through fabrics more readily than water. Therefore, no correlation can be made between AATCC water resistance tests (AATCC 42 and AATCC 127) and ASTM F1671 viral penetration tests. Consequently, gowns with completely different structural parameters could be selected for the construction of Level 4 gowns. Therefore, a strong relationship may not be found between all of the AAMI PB70 levels and physical performance. The study findings were shared with the ASTM F23 Protective Clothing and Equipment Committee and a new standard that defines the minimum performance criteria was established based on the shared data. The new standard specification (ASTM F3352)[13] defines the minimum performance criteria for isolation gowns and includes tensile strength, tear strength, and seam strength requirements. This standard is expected to help end users in selecting the appropriate protective clothing. Furthermore, it could lead to the improvement of the physical performance of isolation gowns.

It is important to have products that have consistent physical performance properties. However, it may not be easy or necessary to have similar strength properties for all of the gown materials at the different protection levels on the market, as this will be design-restrictive. However, it is important to have a certain baseline physical performance for all of the gowns sold on the market, which is based on the user's need. Manufacturers, distributors, infection

preventionists, purchasing agents, and those who involve in the gown selection process should become familiar with the new standard (ASTM F3352). Also, hospitals should consider purchasing gowns that claim conformance to ASTM F3352, which specifies the minimum physical performance criteria and other important requirements, such as labeling, design, and safety requirements.

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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), Centers for Disease Control and Prevention (CDC). Mention of any company or product does not constitute endorsement by NIOSH, CDC.

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