

“False faith in the surgeon’s gown” revisited

by Nathan L. Belkin, PhD, Clearwater, FL

With the active participation of the Food and Drug Administration (FDA), a national standard for materials used in surgical gowns and drapes has been developed. Entitled *Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities*,¹ it allows manufacturers to identify their product’s level of resistance to penetration by viruses, blood, and/or water. Unfortunately, the tests used to define the various levels do not conform to the stresses actually occurring during “usual conditions of use.” Therefore, under the provisions of the FDA’s Medical Device Reporting regulations, it is imperative that surgeons report any “strikethrough” (a term first used by Laufman in 1975²) they experience so that a better standard may be developed.

How it all began

From the time that an operating room gown first became part of the surgeon’s armamentarium, its primary purpose was to protect the patient

from members of the surgical team. In that capacity, the garment was made of a relatively loosely woven, readily permeable, all carded cotton Type 140 (thread count) material, generically known as “muslin.”

In 1952, William C. Beck, MD, FACS, published his renowned paper, “False faith in the surgeon’s gown.”³ This article alerted the surgical community to the fact that although the “muslin” material may have been an effective barrier when dry, it lost its protective capabilities once it became wet, even when multiple layers were used.

Dr. Beck’s disclosure triggered the textile industry’s efforts to develop more satisfactory materials for this unique application. In responding to the challenge, makers of both the non-woven disposable and woven reusable gowns introduced a new generation of fabrics. Whereas manufacturers of both types of gowns made claims about their products’ performance, there was no similarity in the facts upon which those claims were predicated.

In the interim, under the leadership of Harvey R. Bernard, MD, FACS, and Dr. Beck, the American College of Surgeons Board of Governors' Committee on the Operating Room Environment (CORE) charged the entire textile industry with the responsibility of creating a test method that would simulate the stresses that they astutely described as "usual conditions of use."⁴

Emergence of HIV

With the emergence of the era of the hazards associated with the transmission of blood-borne pathogens, the primary purpose of the surgical gown suddenly changed from protecting the patient from the surgeon to protecting the surgeon from the patient as well. This meant that whatever degree of strikethrough may have been tolerated in the past no longer was acceptable.

During this early period, two clinical researchers, Drs. Shadduck⁵ and Nichols,⁶ working independently of one another, reported on the barrier effectiveness of a variety of products that were on the market. What exemplified the need for a standard test method was the fact that some of the materials that Shadduck found to be satisfactory would have failed when subjected to the challenges offered by Nichols. What is particularly noteworthy is that Shadduck, using water for the liquid, reported detecting penetration of the human immunodeficiency virus (HIV) through plastic-reinforced materials in which strikethrough was invisible.

These studies clearly confirmed the need for a meaningful test method that both the surgical community and industry could adopt for use in assessing a material's barrier effectiveness "under usual conditions of use." It was also reasonable to believe that whatever test method would be developed would measure a material's ability to resist liquid penetration at various levels. Rating the materials in this manner would be in accord with the in vitro study reported by Drs. E.J. Quebbeman and G.L. Telford.⁷ It would also facilitate the selection process mandated by the Occupational Safety and Health Administration's (OSHA's) final rule that the garments be appropriate for the "task and degree of exposure anticipated."⁸

Classification of barrier performance of surgical gowns, other protective apparel, surgical drapes, and drape accessories

Level	Test	Liquid challenge	Result*
1	AATCC 42-2000	Water	<= 4.5 g
2	AATCC 42-2000 AATCC 127-1998	Water	<=1.0 g
		Water	>=20 cm
3	AATCC 42-2000 AATCC 127-1998	Water	<=1.0 g
		Water	>=50 cm
4	ASTM F1671:2003 For surgical gowns and other protective apparel	Bacteriophage Phi-X174	Pass
	ASTM F1670:2003 For surgical drapes and other drape accessories	Surrogate blood	Pass

*All have an Acceptance Quality Level (AQL) of 4 percent.

Adapted from the AANSI/AAMA American National Standard: *Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.*¹

New tests

With the pressing need for a test method, an industry-driven committee of the American Society for Testing Materials (ASTM) modified one of its existing complex mechanical devices developed to determine the effectiveness of protective clothing worn by chemical workers. The group incorporated the methodology into two tests—one for liquid penetration and one for viral penetration. Both methods were first adopted as "emergency standards" and subsequently adopted as formal guidelines in 1995.^{9,10}

However, rather than the results of either test being reported on a comparative basis, each was rated on a pass/fail basis, with a "pass" predicated on the material's ability to resist penetration at a

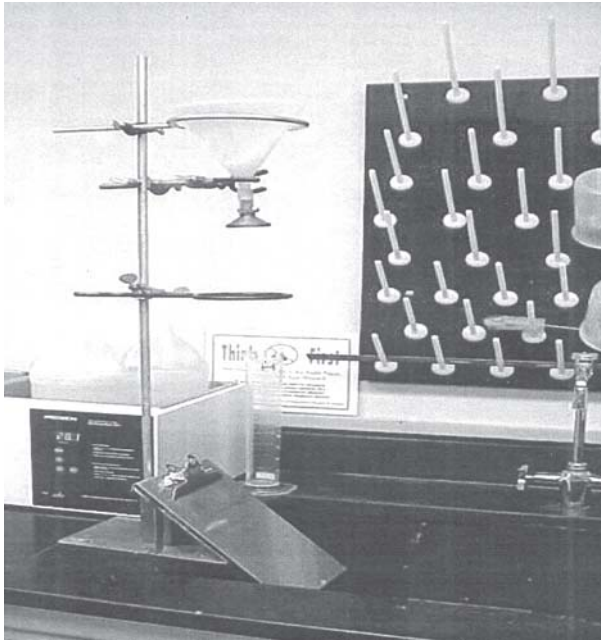


Figure 1: A spray impact penetration test (AATCC 42:2000) for level 1 materials.

level of two pounds per square inch (psi).

It should be noted that prior to the ASTM's adoption of the test methods, several reports had been published in the clinical literature indicating that the pressure exerted on surgical gowns in both in vivo and in vitro circumstances had been found to be far in excess of 2 psi.¹¹⁻¹³

The new "standard"

The American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) have recently published a "standard" that is said to provide a solution to this half-century need.¹ Entitled *Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities*, it has been adopted by the FDA, which maintains that the guidelines satisfy their need for performance requirements for these Class II medical devices. It establishes the use of four different test methods and two different liquids to classify the differences in the levels of the materials' "barrier performance."

To accommodate the need for determining a material's suitability for the "level of anticipated exposure," AAMI's Protective Barrier Committee selected two of the American Association of Textile Colorists and Chemists' (AATCC's) tests—their #42 water impact penetration test and the #127 hydrostatic head test. (It should be noted that this same AAMI group had several years earlier maintained that neither of the two tests were suitable for this purpose.)¹⁴

Thus the new standard establishes four levels of barrier effectiveness (see table, page 20).

- For Level 1, the lowest of the four, the AATCC's 42 water impact penetration test is used (see Figure 1, this page). The material's capability to resist penetration is determined by being challenged by a fixed amount of water sprayed on it while being held over an absorbent blotter (that has been weighed while dry) at a 45-degree angle. The blotter is again weighed to ascertain any increase. According to the standard, the blotter should not have gained more than 4.5 grams to be considered a Level 1 fabric.

- For Level 2, two tests can be used. One is the same AATCC test used for Level 1. An alternate test is the AATCC 127 hydrostatic head test (see Figure 2, page 22). In this test, a sample of the fabric is clamped horizontally on the bottom of a metered glass cylinder. The hydrostatic pressure is steadily increased as the height of the water in the cylinder is raised. To be acceptable for a Level 2 barrier, it must resist penetration of water when it reaches a height of 20 centimeters. When the impact penetration test is used, the weight of the blotter cannot be more than 1.0 gram.

- For Level 3, both of the AATCC tests are again used but with higher levels of resistance. However, for the impact penetration test, the weight gain of the blotter is again 1.0 gram. For the hydrostatic head test, the water level in the cylinder must be at least 50 centimeters.

- For Level 4 (see Figure 3, page 22), the ASTM's mechanical device is used for both the viral penetration (F1671 for surgical gowns) and penetration of surrogate blood (F1670 for surgical drapes). The test sample is mounted in a vertical position onto a cell that separates the challenge and a viewing port. The time and pressure protocols specify atmospheric pressure for

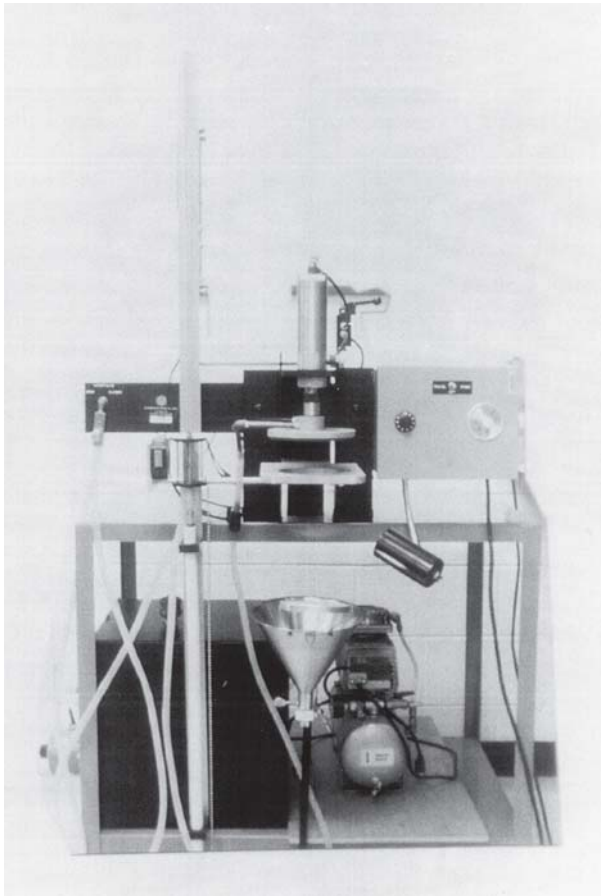


Figure 2: The AATCC's 127:1998 hydrostatic head test for levels 2 and 3 materials.

five minutes, followed by 2.0 psi for one minute and atmospheric pressure again for 54 minutes. The test is terminated if penetration occurs before or after 60 minutes. (It should be noted that the standard makes no mention of the level of protection that a "pass" provides.)

Interpreting the results

For Levels 1, 2, and 3, the results of the water impact penetration tests must stand on their merit because there is no known way of correlating them to a level of pressure.

For the hydrostatic head test used for Levels 2 and 3, difference in the level of pressure is

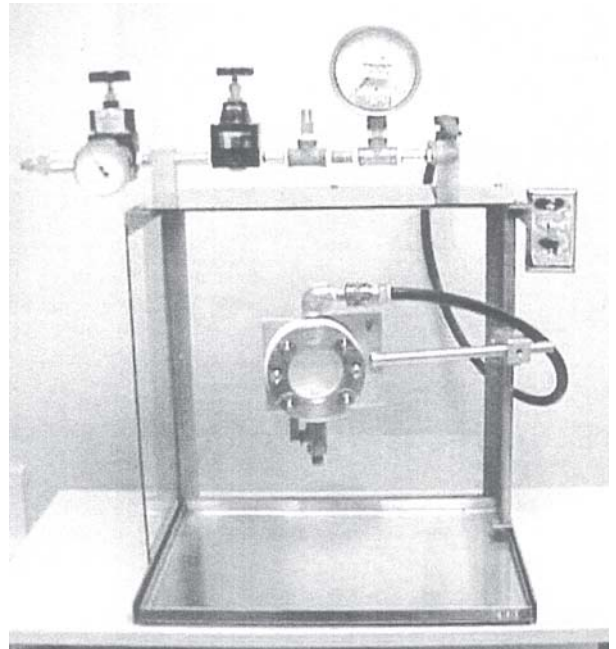


Figure 3: Synthetic blood and bacteriophage test (ASTM 1670 and ASTM 1671:2003), for level 4 materials.

known. For Level 2, the equivalent in the psi is 0.20; for Level 3, the equivalent in psi is 0.73.

The question that logically follows is how can the barrier effectiveness of a material that is awarded a pass (at 2 psi) when tested with the ASTM's device reasonably be compared to the psi of the Levels 2 and 3? Unfortunately, they cannot.

Surface tension

Surface tension is defined in the document as the "intermolecular forces acting on the molecules at the free surface of a liquid. Surface tension affects the degree to which a liquid can wet a material (that is to say, the lower the surface tension, the more easily the liquid wets a material's surface)."¹³

Surface tension is measured by a unit of dynes per centimeter. Whereas water used in both of the AATCC tests measures around 72 dynes/cm, blood is around 42 dynes/cm. (It is viscosity that makes blood thicker than water.) This means that liquids, such as blood, that have a low surface tension can

penetrate fabrics more readily than those with a higher surface tension, such as water.

Thus, in terms of interpreting the results of the tests for Levels 1, 2, and 3, they do *not* mean that under “usual conditions of use,” they would protect against penetration of blood.

The “critical zone”

The ANSI/AAMI standard defines the “critical zone” as an “area of protective apparel or surgical drape where direct contact with blood, body fluids and otherwise potentially infectious material is most likely to occur.”¹³

One of those areas of the surgical gown in which “leakage” is known to have occurred is at the gown/glove interface. It was first reported by Laufman in 1975¹ and more recently by Drs. Meyer and Beck.¹⁵ Nevertheless, it is in the list of exclusions as one of the items that the standard does *not* cover.¹³

In response to an inquiry of the FDA about the exclusion, the agency said that AAMI’s Barrier Committee “excluded this subject because the ‘Standard’ is for the barrier properties of the gown and drapes, especially in the critical zone, and it is not possible to determine how an individual would select a gown that assured him that there would not be a potential problem with this interface.”¹⁶

What is particularly noteworthy is that both researchers proposed solutions to this problem area, none of which have been pursued commercially to this day.

Another omission


It should be noted that the standard classifies the patient drape as an item of protective clothing. In so doing, it specifies the inclusion of a barrier-quality material in the critical zone. However, the committee failed to consider the widespread use of plastic incise drapes and the advent of minimally invasive surgical procedures that preclude the need of a costly barrier material.

Conclusion

Webster’s *New World Dictionary* (Second College Edition, 1988) defines a standard as “something established for use as a rule or basis for comparison....” What the ANSI/AAMI standard does is assess a barrier material’s effectiveness using four different tests for liquid resistance for four different levels, three different challenges, and

then expresses the results in three totally unrelated ways, including a meaningless pass/fail.

As succinctly stated in the document, the standard was developed with the intent of satisfying the “Food and Drug Administration’s requirements for premarket notification (Section 510(k)) and medical device reporting” and to be “used mainly by device manufacturers in qualifying, classifying, and labeling the barrier performance of their products.”

The new standard is only a beginning. Until the design and construction of the gown/glove interface area is changed, the barrier effectiveness of the surgeon’s gown will be compromised, even if the material has been awarded a “pass.” Change will come only if you and your operating room staff report (as per regulations) every observed strikethrough. Until then, don’t put “false faith” in your gown’s protective capability. 

References

1. Association for the Advancement of Medical Instrumentation: *Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities, ANSI/AAMI PB 70:2003*. Arlington, VA: AAMI, 2003.
2. Laufman HA, Eudy WW, Vandervoot AM: Strikethrough of moist contamination by woven and nonwoven surgical materials. *Ann Surg*, 181:857-862, 1978.
3. Beck WC, Collette TA: False faith in the surgeon’s gown and surgical drape. *Ann Surg*, 85:125-126, 1952.
4. Bernard HR, Beck WC: Operating room barriers: Idealism, practicality and the future. *Bull Am Coll Surg*, 60(9):16, 1975.

continued on page 56

Dr. Belkin retired in 1991 after 40 years in research and development of surgical textiles.



THE SURGEON'S GOWN, from page 23

5. Shadduck PD, Tyler DS, Lyerly HX, et al: Commercially available surgical gowns do not prevent penetration by HIV-1. In: *Surgical Forum, Volume XLI*. Chicago, IL: American College of Surgeons, pages 77-80, 1990.
6. Smith JC, Nichols RJ: Barrier efficacy of surgical gowns. *Arch Surg*, 26:756-761, 1991.
7. Quebbemen EJ, Telford GL, Hubbard S, et al: In-use evaluation of surgical gowns. *Surg Gynecol & Obstet*, 174:369-375, May 1992.
8. Occupation Safety and Health Administration: Occupational exposure to bloodborne pathogens: Final rule. *Federal Register*, 56, 64040-64182, Dec. 6, 1991.
9. American Society for Testing Materials: *Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration to Synthetic Blood*, F1670-95. West Conshohocken, PA: ASTM, 1995.
10. American Society for Testing Materials: *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*. F1671-97b. West Conshohocken, PA: ASTM, 1997.
11. Altman, KW, et al: Transmural surgical gown pressure measurements in the operating theatre. *Am J Infect Cont*, 19:147-155, June 1991.
12. Smith, JW, Tate WA, Yazdani S, et al: Determination of surgeon-generated gown pressures during various surgical procedures in the operating room. *Am J Infect Cont*, 23(4):237-246, August 1993.
13. Telford GL, Quebbeman EJ: Assessing the risk of blood exposure in the operating room. *Am J Infect Cont*, 21:351-356, December 1993.
14. Association for the Advancement of Medical Instrumentation: *Technical Information Report, Selection of Surgical Gowns and Drapes in Health Care Facilities*, AAMI TIR 11. Arlington, VA: AAMI, 1994.
15. Meyer KK, Beck WC: Gown-glove interface: A possible solution to the danger zone. *Infect Cont and Hosp Epidem*, 16:488-490, August 1995.
16. Personal communication, C.S. Lin, Office of Device Evaluation, FDA, Rockville, MD, October 5, 2004.