Identification of standard tests for assessing barrier performance of surgical gowns and drapes has been an illusive goal. Although surgical procedures have been described as early as 1653 when the illustrated surgical methodology for craniotomy was published,1 documentation of the use of surgical gowns has had to be determined by paintings and photographs. One of the first depictions of the use of surgical gowns appears in an 1889 oil painting by Thomas Eakins displaying a surgical theater in the University of Pennsylvania.2

Most of the early research on barrier materials was performed by Dr William Beck. In 1952, Beck3 published his classic paper “False Faith in the Surgeon’s Gown and Surgical Drape,” demonstrating that cotton cloth when wet transports bacteria from a nonsterile to a sterile area.

In 1963, Beck and Carlson4 defined an aseptic barrier as a “material placed between an aseptic area, such as an operative incision, and areas which harbor microorganisms with the purpose of preventing the spread of bacteria into the sterile zone.” Beck’s work demonstrated that the wicking action of the cotton drapes was so great that microorganisms traveled almost instantaneously in both directions through these materials.

After World War II, Quarpel (Quartermaster Corp, Philadelphia, Pa), an extremely fine, all-pima cotton treated with a water-repellent finish, became available to the health care market. Research published in 19675 demonstrated that wearing surgical attire constructed of this cloth reduced bacterial transfer.

In the 1960s, single-use gowns and drapes were introduced. The initial products—odoriferous, noisy, and undrapable—were often rejected by surgeons. Product improvements gradually led to a greater acceptance. In 1975, research by Harold Laufman6 demonstrated that not all woven and nonwoven material was impermeable to moist contamination for equal periods of time.

In 1980, Moylan and Kennedy7 reported a reduction in postoperative infection after the adoption of a single-use, spun-bonded olefin gown-and-drape system.

In 1981, the Association for the Advancement of Medical Instrumentation (AAMI) authorized formation of the Aseptic Barriers Committee to develop a standard for aseptic barrier material for surgical gowns and drapes. Dr Beck co-chaired the committee with Margaret Huth-Meeker, RN, BSN, CNOR, from the Association of Operating Room Nurses. Also participating were Harold Laufman PhD, MD, and Nathan L. Belkin, PhD, along with representatives of producers, users, and the Food and Drug Administration. At the time, the Mason jar test, developed by the International Nonwovens Disposables Association, was used to demonstrate liquid penetration resistance. The test was crude and failed to win committee support.

In 1983, the AAMI Standards Board determined that the process was stalemated and discontinued the effort. One of the principal difficulties was the lack of a standard test method to determine barrier properties of various products.

In 1990, AAMI authorized a technical information report (TIR) on the selection and use of surgical gowns and drapes. The TIR, an AAMI Standards Board publication that addresses a particular aspect of medical technology, is released to provide information needed immediately by the industry and related professions. A TIR is not subject to the same formal process as a standard but is approved for distribution by a technical committee and the AAMI Standards Board.
In 1991, the Occupational Safety and Health Administration’s Final Standard on Occupational Exposure to Blood-Borne Pathogens and the Use of Personal Protective Equipment, addressed surgical gowns and the need to identify their barrier properties. The report stated that selection of a protective garment should be made on the basis of “the duration of time which the protective equipment will be used” and the “level of exposure anticipated.”

In 1994, AAMI published “Selection of Surgical Gowns and Drapes in Health Care Facilities.” This TIR referenced 2 recently approved American Society for Testing Materials (ASTM) Emergency Standards: ES21-92, to establish the barrier property of gowns and drapes, and ES22-92, to determine the passage of viruses through the fabric. The document also addressed other important characteristics of gown and drape materials, such as strength, comfort, and drapability, and provided a grid to be used as a guide for collecting information in an evaluation.

In 1995, the ASTM tests received final approval: ASTM F1670-98 (formerly ES21-92), Standard Test Method for Resistance of Material Used in Protective Clothing to Penetration by Synthetic Blood, used to determine the ability of a material to resist the penetration of synthetic blood under constant pressure. Time and temperature are specified at 6 minutes, 2.0 psi for 1 minute, and atmospheric pressure for 54 minutes. The test is terminated if visible liquid penetration occurs before or at 60 minutes. This is a pass/fail screening test. Materials that pass ASTM F1670-98 should then be subjected to ASTM F1671-97h, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration (formerly ES22-92). This test, designed to model penetration of viruses, determines the ability of a material to resist the penetration of microorganisms under constant contact. Specifications for time and temperature are the same as those designed for ASTM F1670-98.

In 1998, the AAMI Standards Board authorized the establishment of a committee to work on a standards document titled “Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.” That document, still in development, is intended to establish a barrier performance classification system for protective apparel and drapes used in health care facilities and to provide guidance to manufacturers.

All these efforts, and the Association of periOperative Registered Nurses Recommended Practices for Gowns and Drapes, have been directed toward providing health care users with the information needed to make a gown selection that will provide the wearer better protection from the patient’s blood and body fluids and provide the patient better protection from infection. In today’s cost-conscious health care environment, it is essential to provide appropriate protection for the individual procedure with the most cost-effective product. Although there are single-use and multiple-use materials that pass ASTM F1671 and resist liquid and viral penetration, it is not necessary to use such products in all procedures. Surgical procedures involve varying levels of splashing, leaning, and pressure.

To assist in further classifying drapes and gowns according to lesser levels of protection, 2 American National Standards Institute tests have been identified. The hydrostatic pressure test, ANSI–127, challenges a sample of material with a column of water by increasing the height of water in the column. The test is terminated when water droplets penetrate the material. The higher the hydrostatic pressure before strike-through, the more resistant the material is to strike-through.

The water resistance (impact penetration) test, ASTM 42, examines the ability of a material to resist water penetration exposed to spray contact. Material is placed over a piece of blotter paper that is angled at 45°. A measured amount of water is released through a funnel at a specified distance from the sample. The blotter paper is weighed at the completion of the test. The lower the weight gain of the blotter, the more resistant the material is to penetration. ASTM 42 and ASTM 127 have been used by the industry for many years to demonstrate barrier effectiveness of surgical materials to perioperative staff and managers. Although the tests appear impressive in a laboratory setting, lack of industry agreement on results that would establish barrier properties of specific materials has made it impossible to classify barrier materials. Nevertheless, test results may be used to compare products.

As examined in Belkin, the question becomes how a user selects a barrier product considering the level of exposure anticipated and the expected condition of use. At this point in time, users should select products that pass ASTM 1671 when they expect exposure to large amounts of blood and body fluids and procedures involving significant pressing and cleaning. For procedures involving lesser amounts of exposure, products with lesser protection may be appropriate. In most practice settings, users make these choices on the basis of the scheduled procedure, the anticipated length of the procedure, and their knowledge of the individual surgeon’s technique.

References