

# Do barrier drapes reduce surgical site infections?

by Nathan L. Belkin, PhD

The intensity of the pressures to control and contain health care costs is accompanied by the need for the surgical community to consider the cost-to-benefit ratio of practices that have become ingrained in surgical technique. Such practices continue to be performed even though they may not influence the outcome of the procedure. One of these practices is the use of barrier surgical drapes.

## *Barrier drapes and SSI*

The use of surgical gowns and drapes evolved as a standard of practice more than a century ago. Their main function was to protect the sterile field from microbial invasion. It was in 1939 that Devenish and Miles first questioned the effectiveness of the readily permeable material of which the surgical gowns were made.<sup>1</sup> Having observed that blood and saline were penetrating the sleeve to the skin of the forearm, they reasoned that bacteria from the forearm could similarly pass from the surgeon to the patient. As a solution, it was suggested that the sleeves be made of a fabric that had been treated with a rubber coating on both sides. Although this rendered the material to be impervious, its use was not generally adopted because of its discomfort.

Subsequently in 1952, William C. Beck, MD, FACS, warned the surgical community that although the material that was being used for the gowns and drapes may have been considered to be a satisfactory bacteriological barrier when it was dry, it lost that capability once it became wet.<sup>2</sup>

For some time thereafter, most operations were still performed with gowns and drapes made of the traditional, readily permeable material. Lacking scientific evidence to justify the use of a more expensive barrier fabric, the community awaited the publication of a study to support its use.

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The results of the first published study were reported by Joseph D. Moylan, MD, FACS, in 1980. His findings indicated that whereas the rate of infection with reusable nonbarrier materials was 4.42 percent, the incidence of a surgical site infection (SSI) with the disposable barrier fabrics was reduced to 1.98 percent.<sup>3</sup>

However, Dr. Moylan subsequently acknowledged that “additional matched clinical studies are necessary so that with better understanding of barrier characteristics, laboratory bench tests can be correlated to wound infection rates.”<sup>4</sup>

Nevertheless, although the study’s findings were not conclusive, their use mushroomed the use of the barrier-quality disposable products. In addition to igniting the heated reusable versus disposable controversy, their use was further skewed by a reimbursement system that made any single-use disposable a profit generator, as this item was reimbursed at cost plus patient charge. Thus, the concern for the patient’s welfare and the possibility of reducing the incidence of a surgical wound infection were totally overshadowed.

## *Sources of infection*

The major contributing factors to the incidence of SSI have been described by Harold Laufman, MD, PhD, FACS, as the “5 Ds” and defined as follows<sup>5</sup>:

- Discipline of the surgeon
- Defense mechanism of the patient
- Drugs (prophylactic antibiotics)

- Design of the surgical suite
- Devices, of which surgical gowns and drapes are but one category of the hundreds of items used.

Thus, those cases that are performed on body sites that are considered “clean” should have a low risk of infection because they would come primarily from contamination external to the body (exogenous). Therefore, if barrier materials were to be expected to have the greatest effect on reducing infections, it would be in those procedures.

The largest and most frequently cited study that reports rates of infection in class I clean procedures is the analysis done by Peter J. E. Cruse, MB, FACS, FRCS. This most comprehensive study covered a period of 10 years with all the procedures performed with gowns and drapes made of “usual cotton.” Particularly noteworthy is that of the 47,054 clean procedures with gowns and drapes both made of a nonbarrier reusable material, the incidence of SSI was 1.5 percent.<sup>6</sup>

In a commentary on the preoperative measures to prevent complications, Dr. Cruse stated the following:

In the final analysis, two factors determine the development of infection: the dose of contamination and the resistance of the patient. Resistance depends most on adequate nutrition. Contamination can be introduced from exogenous sources such as the surgeon’s hands or air and droplet contamination or it can be endogenous, originating from the patient’s bowel flora, urinary tract, biliary tract and elsewhere. Endogenous contamination is far more important than all the exogenous factors combined yet paradoxically, the aseptic religion is aimed at the satan of exogenous contamination.<sup>7</sup>

### ***Defining a barrier***

Up to this time, although manufacturers of both reusable and disposable fabrics made claims about the barrier capabilities of their products, the results of their proprietary tests could not be correlated. 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 challenged industry to develop a test method that would simulate the stresses to which a material would be subjected under what they astutely de-

scribed as “usual conditions of use.”<sup>8</sup>

With the emergence of the era of preventing the hazards associated with the transmission of bloodborne pathogens, whatever “strikethrough” of materials that may have been tolerated in the past was no longer acceptable. With a pressing need for a test, a standard was established under the auspices of the American National Standards Institute and the Association for Advancement of Medical Instrumentation.<sup>9</sup>

The standard classifies a barrier’s performance capability at four levels, three that are tested with water. Barrier drapes, on the other hand, must be made of a class IV fabric that is required to pass a test when challenged by surrogate blood and at a level of pressure of two pounds per square inch.<sup>10</sup>

### ***Protection for the patient***

What was not considered in requiring this level of protection for the patient are the advances in surgical technique and changes in the marketplace that may antique the need for a drape to be made of an expensive class IV barrier fabric. For example, consider the following:

- If the surgical gown protects the surgeon, it simultaneously protects the patient from the surgeon. This being the case, from whom or what does the class IV barrier-quality drape protect the patient?

- With the trend toward small incisions and minimally invasive procedures, how vital is it to use a drape made of a class IV barrier fabric that has been challenged by surrogate blood?

- A survey of draping practices found that almost two-thirds of respondents use incise drapes.<sup>11</sup> If, as Dr. Laufman has stated, “the area that particularly requires impermeability is the area around the fenestra, or the peri-incisions area,”<sup>12</sup> why is it necessary for the drape to be made of the most expensive class IV barrier-quality materials?

- If a drape is to be considered an item of protective clothing for the patient, should it not be chosen based on the same factors (that is, the level of exposure anticipated for the patient) that were used to choose the surgeon’s gown?

- Data released by the American Hospital Association indicate that 16,700,000 (61%) of the 27,200,000 surgical procedures reported for 1997 were performed in hospitals on an outpatient ba-

sis.\*<sup>13</sup> With an increasing number of procedures also being performed in office surgery centers and freestanding ambulatory surgery centers, how vital is it for drapes to be made of the most expensive and costly class IV barrier-quality materials?

### Conclusion

The Centers for Disease Control and Prevention (CDC) maintains that “There are limited data that can be used to understand the relationship of gown or drape characteristics with SSI risk. The wide variation in products and study designs make interpretation of the literature difficult.”<sup>14</sup>

The CDC’s position is further supported by a recently published review of experimental, clinical, and epidemiological studies of gowns and drapes in which the authors concluded that the studies were “of limited relevance because of methodological flaws and product improvements.”<sup>15</sup>

The fact of the matter is that there is no real, empirical evidence demonstrating the influence of patient drapes made of a class IV barrier-quality fabric on the outcome of a surgical procedure. As Ronald L. Nichols, MD, FACS, has observed, “A practice cannot be justified on the basis of anecdotal experience or commercial interests; it must be evaluated by its influence on the outcome of surgical procedures and supported by scientific facts.”<sup>16</sup>

As evidenced by a review of the literature, the need for an unbiased, statistically valid conclusive research on the influence of barrier drapes on SSI remains. Until such data become available, the need cannot be indisputably defended. Q

### References

1. Devenish EA, Miles AA. Control of staphylococcus in an operating theater. *Lancet*. 1939;1:1088.
2. Beck WC, Collette TS. False faith in the surgeon’s gown and surgical drape. *Am J Surg*. 1952;83:125-126.

**\*Author’s note:** I recently became aware of a report issued by the Centers for Disease Control and Prevention (CDC) indicating that of the total of approximately 72,000,000 surgical procedures performed in 1996, 31,500,000 were ambulatory. However, the CDC’s report states, “Figure does not meet standard of reliability or precision.” As this statistic represents a tremendous difference from the cited figures from the American Hospital Association in this article, I will supply the reference: Center for Disease Control and Prevention. *Ambulatory and In-Patient Procedures in the United States, 1996*. Atlanta, GA: CDC; 1998:1-39.

3. Moylan JD, Kennedy B. The importance of gown and drape barriers in the prevention of wound infection. *Surg Gynecol Obstet*. 1980;151:465-470.
4. Moylan JA. Clinical evaluation of gown-and-drape barrier performance. *Bull Am Coll Surg*. 1982;67(5):8-12.
5. Laufman HA. The control of operating room infections: Discipline, defense mechanisms, drugs, design and devices. *Bull N Y Acad Med*. 1978;54:465-483.
6. Cruse PJE, Foord R. The epidemiology of wound infection: A 10-year prospective study of 62,939 wounds. *Surg Clin North Am*. 1980;60:27-40.
7. Cruse PJE. Preparing the patient for operation. *Bull Am Coll Surg*. 1981;66:16-25.
8. Bernard HR, Beck WC. Operating room barriers: Idealism, practicality and the future. *Bull Am Coll Surg*. 1975;60(9):16.
9. American National Standards Institute/Association for the Advancement of Medical Instrumentation. *Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities*. Arlington, VA: AAMI; 2003. ANSI/AAMI PB70
10. Belkin NL. “False faith in the surgeon’s gown” revisited. *Bull Am Coll Surg*. 2005;60(4):19-56.
11. In benchmarking, draping shows big variations [editorial]. *OR Manager*. 1997;13:1,8.
12. Laufman HA. Surgical barrier materials product information vs. controlled evidence. *Bull Am Coll Surg*. 1982;67(5):13.
13. Chicago Health Forum. *Hospital Statistics*. Chicago, IL: American Hospital Association; 2003.
14. Mangram AJ, Horan TC, Pearson ML, et al. Guideline for prevention of surgical infection, 1999: Hospital Infection Control Practices Advisory Committee. *Infect Control Hosp Epidemiol*. 1999;20:250-278.
15. Rutala WA, Weber DJ. A review of single-use and reusable gowns and drapes in health care. *Infect Control Hosp Epidemiol*. 2001;22:248-257.
16. Nichols RL. Postoperative wound infection. *N Engl J Med*. 1982;307:1701-1702.

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