

Gowns and drapes for the “level of exposure anticipated”

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The use of surgical gowns and drapes evolved as a standard of practice a century ago.¹ Their primary purpose was to protect the sterile surgical zones from microbial invasion. For the most part, the items were made of a loosely woven, readily permeable, reusable fabric generically known as muslin.

It was not until 1952 that Beck alerted the surgical community to the fact that while the material may have been considered an acceptable bacteriological barrier when dry, it lost its barrier capability once it became wet even when multiple layers were used.² This proved to be the turning point that triggered research into developing more satisfactory materials for this unique application.

It was also during this period that another segment of the textile industry made its presence known, namely, nonwoven, disposable material that was intended to be used once and thrown away. The new generation of materials ignited the heated controversy between reusable and disposable material that completely overshadowed the concern for the patient's welfare and the influence that either might have on the incidence of a surgical site infection (SSI).

Although improved materials were available in both reusable and single-use qualities, for a decade thereafter most hospitals continued to use products made of the traditional, readily permeable, reusable material. Some health care providers simply incorporated the new, more expensive “barrier” quality materials into their gowning and draping practices with the thought that they would perhaps protect their patients from another possible portal of entry for exogenous contamination. However, the popularity of the single-use products mushroomed dramatically when skewed by the provisions of a reimbursement system that permitted all single-use items to be charged to the patient on a cost-plus basis. In addition, having thus been viewed as revenue generators by hospital administrators, whatever clinical benefit to be derived from their use was totally obscured by their financial effects.

Barrier materials and SSI

The latest edition of the Centers for Disease Control and Prevention (CDC) *Guidelines for the Prevention of Surgical Site Infections* cites a number of studies that have been conducted to demonstrate the influence that gowns and drapes made

of the new barrier-quality materials had over the incidence of SSI. However, they state that “there are limited data that can be used to understand the relationship of gown or drape characteristics with SSI risk,” and that “the wide variation in the products and study design make interpretation of the literature difficult.”³ As observed by Birenbaum, their position could well be attributable to the fact that because both the gowns and drapes were made of barrier-quality materials, it is impossible to determine whether it was the gowns, the drapes, or the combination of the two that provided the benefit.⁴

Gown’s protective role

The emergence of the era of the hazards associated with the transmission of blood-borne pathogens dramatically altered the role of the surgeon’s gown. Whereas it had initially been used to protect the patient from the surgeon, its protective capability now focused on protecting the surgeon from the patient.

As mandated by the Occupational Safety and Health Administration’s (OSHA’s) Final Standard on Occupational Exposure to Bloodborne Pathogens and the use of Personal Protective Equipment (PPE), the need for and the function of the surgeons’ gown are now givens.⁵ OSHA’s mandate for its use states that its selection is to be made based on “the duration of time which the protective equipment will be used” and for the “level of exposure anticipated.”

Nevertheless, whether it be for gowns or drapes, the results of the only test methods that the textile industry has developed for testing a material’s “barrier” effectiveness are reported on a pass/fail basis, thereby characterizing it as being impervious or liquid-proof.^{6,7}

It should be noted that although OSHA’s final rule makes no mention of or reference to the surgical drape, the textile industry’s tests have classified it as an item of “protective clothing.”^{8,9} Interestingly enough, the Food and Drug Administration’s code of federal regulations describes the drape as a “protective patient covering...that includes a plastic wound protector that may adhere to the skin around a surgical incision or be placed in a wound to cover its exposed edges....”¹⁰

Be that as it may, reporting the effectiveness of a barrier-quality material on a pass/fail basis liter-

ally prohibits surgeons from selecting the quality of protective products that they believe is required for themselves and their patients for the “level of exposure anticipated,” or what Bernard and Beck referred to as the “usual conditions of use.”¹¹

Questions to answer

What seems to have been overlooked in these rules are the advances made in surgical techniques over the past decade and the variances in draping practices that have accompanied them. For example:

1. With the trend toward small incisions and minimally invasive procedures, how vital is the need for both the gowns and drapes to be made of materials that “pass” the textile industry’s tests for maximum effectiveness?

2. Last year, an estimated 65 percent of surgical procedures performed in hospitals were done on an outpatient basis. That number is expected to increase another 28 percent in the next five years. In addition, there is the corresponding increase that has been projected for the number of procedures performed in physicians’ offices and freestanding ambulatory surgery centers.¹² In these settings, how vital is the need for both the gowns and drapes to be made of costly barrier-quality materials that pass the industry tests?

3. A survey of draping practices found that almost two-thirds of the respondents reported using incise drapes.¹³ If an incise drape is used, why is it necessary for the entire patient drape to be made of barrier-quality material?

4. If the surgical drape is to be considered “protective clothing” for the patient, why shouldn’t its selection be predicated on the same basis as the surgical gown, that is, on the “level of exposure anticipated?”

Influences on SSI

Cruise has astutely observed that, “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.”¹⁴ Laufman more succinctly identified the major contributing factors to the incidence of SSI and defined them as the “5 Ds”:

1. Discipline of the surgeon.
2. Defense mechanisms of the patient.
3. Drugs—prophylactic antibiotics.

4. Design of the surgical suite.
 5. Devices—of which surgical gowns and drapes are but one category of the hundreds of items used.¹⁵

An excellent example of what might be considered the enhancement of defense mechanisms is the recent report in which an international collaboration of 70 investigators in 10 countries concluded that for patients undergoing major operations, supplemental oxygen had the potential to protect them against the incidence of surgical wound infections.¹⁶

A recently published editorial on prevention of surgical wound infections concluded, “The best strategy for preventing not only wound infections but also other complications will involve staff of all types working together during surgery, in the recovery room and postoperatively.”¹⁷

Summary

Today, the intensity of the pressures to not only control but to reduce costs prohibits the luxury of perpetuating any practice simply because “that’s the way we’ve always done it.” Rather it mandates an assessment of the cost-effectiveness of every practice from the perspective of its influence on the outcome of the surgical procedure.

The need for surgeons’ gowns and drapes to be made of a barrier-quality material was first viewed as a reasonable practice. Subsequently, it was assumed that data had been developed to support that need. Actually, their worthiness has yet to be demonstrated through unbiased, statistically valid, conclusive research.¹⁸ Under the circumstances, it could be said that their cost-effectiveness is predicated on what has been described as “anecdotal experience and commercial interests rather than scientific studies.”¹⁹

The question at hand, therefore, is not one of the cost-effectiveness of reusable versus disposable drapes and gowns, but rather one of the surgical community being able to select the products they believe are commensurate with the “level of exposure anticipated” and “under usual conditions of use.” □

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