

Moist Bacterial Strike-through of Surgical Materials: Confirmatory Tests

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New tests consisting of modifications of the inverted Mason jar test confirm our previously reported studies which showed that woven and nonwoven surgical materials vary greatly in their ability to serve as barriers against moist bacterial strike-through. Among the woven materials, only tightly woven Pima cloth or materials treated with Quarpel waterproofing process or with polythene layer lamination was invariably resistant. However, tight-woven Pima cloth, which had been treated with Quarpel became permeable after 100 washing-sterilizing cycles. Of the nonwoven materials, single-layer nonwoven materials tended to be unevenly permeable to moist bacterial strike-through. Only the front and sleeves of nonwoven gowns reinforced with polyethelene layer were invariably resistant to moist contamination.

SURGICAL GOWNS AND DRAPES are intended to serve as barriers against the transgression of bacteria between the unsterile surfaces they cover and the sterile surgical field, whether or not they become wet during an operation.

Barrier materials used in the manufacture of surgical gowns and drapes are available as reusable woven or as disposable nonwoven materials. Woven materials are made of various grades and weaves of cotton, with or without special waterproofing treatment. As a result, they vary from those which offer no resistance to moist bacterial strike-through to those which remain totally resistant through up to 100 washing and sterilizing cycles.⁴ Nonwoven materials are made of processed cellulose fibers either alone or in combination with reinforcements of various types including polymeric films. As with the woven materials, the available nonwoven fabrics also vary from those which offer virtually no resistance to moisture or bacterial penetration to those which are resistant even under the stresses of lengthy wet surgical operations.

Despite these wide variations in the barrier effects

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of surgical materials, there are no universally accepted performance standards available to manufacturers, no altogether acceptable bench tests for quality control related to bacterial permeability, and no regulations governing the validity of promotional claims. As a result, confusion is found in all these areas.

We report on a series of bench tests which confirm the wide variations in barrier dependability between marketed surgical materials and urge for early adoption of performance standards for the materials. The new tests have also been applied to a number of new materials which have become available since our first communication.⁴ Moreover, some of the brand name drapes and gowns have changed their materials since that time.

In our previous publication we reported that during actual surgical operations, unopposed pressure or friction points of the surgical gown such as those of the surgeon's forearm, elbow, or abdominal area often transmitted bacteria from the wearer to the surgical field, especially when moist. Yet none of the prior tests used by industry had correlated friction, or stretch stresses, with moist bacterial penetration. A number of tests had been devised by manufacturers or industry-appointed laboratories to grade the penetration of moisture either by naked-eye observation of moisture beads or by bursting of the test material.⁸ Another test, the Libman-Ullrich Rodac sandwich⁵ test did, indeed, measure bacterial permeation, but the test did not replicate stresses encountered during surgical operations. The material is compressed between two Rodac plates, one of which contains a standardized bacterial culture spread. The sandwich is compressed with 100 g of pressure and is read at intervals up to 15 minutes. However, this test does not employ unopposed pressure, stretch, or shear stresses, nor do we

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believe the test is allowed to run for a long enough period.

We found that the materials which apparently passed the Libmann-Ullrich test nevertheless transmit bacteria during actual surgical use, so we devised a new test which we called the Unopposed Weight-support test using a 2 kg weight suspended in a hammock of the test material. With this test we confirmed the fact that a wide range of bacterial permeability in both woven and nonwoven materials exists.

Under the conditions of the Unopposed Weight-support test, among the woven materials, only Quarpel-treated tight-woven Pima cotton was found to be impermeable to moist bacterial strike-through. This material remained impermeable at least through 55 washings and sterilizing cycles. Ordinary muslin and untreated Pima cotton, on the other hand, permitted virtually immediate moist bacterial contamination.

Among the nonwoven gown and drape materials, only those which were reinforced or laminated with plastic or polyethylene film withstood the tests. On the strength of these findings, we recommended that the front and sleeves of nonwoven surgical gowns be reinforced with an impermeable layer in future models, in a manner similar to the reinforcements used in woven gowns, especially when the gowns and drapes would be used in lengthy, wet operations.

It was gratifying to find that some manufacturers of nonwoven surgical apparel did subsequently market such reinforced gowns and drapes. However, disposable manufacturers expressed their concern over two vexing problems. One was the concern that our Unopposed Weight-support test was unwarrantably stringent. The second was the fact that there were no universally accepted performance standards available for surgical apparel against which manufacturers could calibrate their materials. The Association of Operating Room Nurses did publish a set of standards in 1974, in which the prerequisites for barrier qualities were laid down, but these standards did not present any tests which the materials were required to pass before the property of in-use impermeability was satisfied.²

Therefore, we continued our search for a test which would assure all concerned that the materials being marketed to the surgical community would be impermeable to moist bacterial strike-through during lengthy wet surgical operations.

The tests to be described in this communication were performed upon the suggestion of members of INDA, the association of nonwoven fabrics industry. They were to determine whether the Unopposed Weight-support test was indeed too stringent, and whether less stringent tests might provide equally good evidence of in-use impermeability.

Materials Tested

Woven Materials

Materials tested included: 1) Angelica gowns. Both were 270-thread Pima Cotton, Quarpel treated,* but one was unused, while the other was subjected to over 100 washing cycles. 2) Superior Surgical Company gown, of 272-thread Pima Cotton, Liquashield treated,† and unused, 3) ordinary cotton muslin‡ used in gowns and drapes, and 4) vulcanized linen patches.§ Some were Thermopatch 270 Pima not Quarpel-treated, and others were Superior Surgical polyethylene-reinforced 270 Pima Quarpel-treated.

Nonwoven Materials

Nonwoven materials tested included: 1) Johnson and Johnson's Barrier Surgikos gown made of Spunlace nonwoven fabric, the Barrier Specialty gown made of Spunlace nonwoven fabric with front and sleeve reinforcement, and the Barrier Surgikos 450: Polyester reinforced nonwoven fabric, 2) Cenco gown, 3) Converter gown, with Scrim-reinforced tissue, 4) Curity Gown, made of Tyvek (spunbonded olefin), 5) the Superior Surgical Company's Fiber-reinforced tissue, 6) Kimberly Clark Corporation's Kimlon Gown made of fiber-reinforced tissue, 7) Spartan Healthcare gown, and 8) Vigilon Macbick gown, made of spunbonded polyethylene nonwoven fabric.

Methods

Disposable-gown manufacturers recommended that we use a bench test which was a modification of the water-resistance hydrostatic-pressure test developed in 1968 by AATCC Committee RA63, also known as

* Quarpel water-repellent treatment is a development of the U.S. Army Quartermaster Corps. It is a fluorochemical finish in combination with a pyridinium or melamine hydrophobe which produces an exceptionally durable water-repellent finish. The performance and durability of the Quarpel is partially contingent upon the quality and weave of the material to which it is applied. It is not effective if applied to loosely woven Type 140 muslin. The finish permeates every fiber as opposed to being a surface coating. Tight-woven Pima contains 270 threads per square inch. Trade names: Barbac, Liquashield. These are virtually identical materials of different manufacturers.

† According to the manufacturers, the new Liquashield material is 2 ply warp and 2 ply fill 272 threads per square inch rather than single fill, as found in the old material. In addition, the new material is fabric-singed to remove lint, protruding fibers and other matter.

‡ Type 140 muslin of corded yarns with warp of 68 and fill of 72 per inch and Class A sheeting of corded yarns with warp of 48 and fill of 52; 2.65 yards per pound.

§ Tests performed on new patches already vulcanized to gown or drape which had gone through over 100 sterilizing and washing cycles. Since the latter had been shown to be permeable, the test results could be considered valid for the vulcanized patch itself.

American National Standards Institute (ANSI) L14.265—1971. They recommended that the test be modified by using an inverted Mason jar with the test fabric fixed into the cap and four inches of water as a constant pressure head instead of a tube with a gradually increasing column of water.⁷ Our further modification was the addition of a suspension of *Serratia marcescens* to the water to lend the dimension of bacterial permeation to that of the fluid. Thus, instead of judging the leaking of fluid "at three points" with the naked eye as specified in the AATCC test, we used bacterial colony growth on agar for our endpoint. The inverted jar contained a hole above the fluid level to prevent an air lock, and the jar was placed on a rapid one-step disposable agar contact (Rodac) plate so that the fabric separated the fluid containing *Serratia marcescens* from the surface of the contact culture plate.

The 16 gown materials subjected to the test differed in fabric, and in type and amount of reinforcement and stitching. Gowns with reinforced fronts and sleeves were tested for their barrier protection in both the reinforced and nonreinforced sections. Gowns which were not reinforced were tested in analogous regions. Several gowns were tested to determine the effect of stitching and gluing on moist bacterial penetration of the seams. Also tested were two materials used for vulcanizing patches over defects in gowns and drapes.

30 Minute and 60 Minute Inverted Mason Jar Tests Using Rodac Contact Plates

As in previous tests, the standard contaminant used was a suspension of *Serratia marcescens*, 10^8 per ml. One ml was added to 500 ml sterile water. A cutting of test material was secured to the mouth of the Mason jar by a threaded metal rim.* Using sterile techniques, the jar with the test material as a cap was inverted and placed on a contact plate. The surgical gown material rested entirely upon the agar, while the metal rim of the jar fitted on the plastic rim of the plate during the test period. Thirty-minute tests were conducted to determine the amount of bacterial penetration which could occur under a constant equal force of approximately 4.9 Newtons.† An estimate of 19.4 Newtons had been previously expressed as the force exerted by a bent elbow on the sleeve material of a gown during use. Hence, the weight of the contaminated solution equaled one-fourth of the estimated stress. If materials proved to be relatively impermeable

in the 30-minute test, they were subjected to a 60-minute test.

After the test period, the plate was covered and incubated at 37° and read at 24 and 48 hours. For control purposes, the solution in the Mason jar was cultured at the end of each test to reaffirm the viability of the bacteria in the solution.

Results of the inverted Mason jar test as shown in Tables 1 and 2 generally confirmed previous results of the Unopposed Weight-support test. Although some additional fabrics were tested with the inverted Mason jar test, generally the same materials were resistant or poorly resistant to moist contamination in both tests.

A variation of the inverted Mason jar test was also carried out. Instead of the inverted jar with its test-fabric cap resting directly upon the culture plate, a pour-plate method was performed.

30 Minute Inverted Mason Jar Tests Using the Pour-Plate Technique

The inverted Mason jar containing the bacterial solution with the test material as a cap was placed in an empty Petri dish for the test period, after which liquid agar was poured into the dish. To prevent possible pull-through of liquid, the test was performed in dry empty Petri dishes as well as in Petri dishes containing 1 ml of sterile water.

Results

Woven Materials

None of the tight-woven Pima cloth gowns or drapes which were new or uncycled, or had gone through fewer than 75 washing-sterilizing cycles, were permeable to bacterial solution in 30 minutes provided they were Quarpel-treated. (Table 1). However, all of these impermeable materials became permeable in experimental periods of one minute or less after they had undergone at least 100 washing and sterilizing cycles. These results correlated well with those of the previously published Unopposed Weight-support test in which the Quarpel-treated Pima totally resisted penetration through 55 cyclings, while penetration occurred in one-sixth of the culture plates after 75 cyclings, and one-half of the culture plates at 100 cyclings. In comparison, ordinary 140 linen as well as 270 Pima cloths which had not been treated with waterproofing processes were rapidly permeable in all tests.

It is apparent that the Quarpel treatment is more critical than the tightness of the weave, as evidenced by the fact that new untreated 270-ply Pima cloth patches did not protect against bacterial permeation. Moreover, new Quarpel-treated 270 Pima patches with

* The jar lid consists of a threaded ring and a flat cap with rubber washer. The cap was replaced by a piece of gown material secured in place by the threaded ring.

† $0.5 \text{ kg H}_2\text{O} \times 9.8 \text{ m/s}^2 = 4.9 \text{ Newtons}$.

TABLE 1. *Thirty-Minute Inverted Mason Jar Test Woven Material*

Material	30-Minute Bacterial Penetration
Tight-weave Pima; Quarpel-treated Barbac; new	0
	0
	0
	0
	0
	0
	0
	0
	0
Tight-weave Pima; Quarpel-treated Liquashield; new	0
	0
	0
	0
	0
Tight-weave Pima; Quarpel-treated Barbac; 100 cyclings*	+
	+
	+
	+
	+
	+
	+
	+
	+
	+
All under one minute	
Tight-weave Pima; untreated; new	+
	+
	+
	+
	+
All under 10 minutes	

* Previous studies⁴ showed that tight-weave Pima, Quarpel-treated remained impermeable for at least 75 cyclings using unopposed weight test. Type 140 muslin, used in "ordinary" gowns and drapes was not retested because it was shown to be immediately permeable using unopposed weight test as previously reported.

polyethylene backing were impermeable in all tests. Thus, it would appear that tight-woven polyethylene-backed patches are satisfactory for vulcanizing holes in woven surgical materials provided, of course, that the material being patched has retained its own impermeability.

Nonwoven Materials

Nonwoven materials used in the manufacture of disposable surgical gowns exhibited great variation in terms of their ability to prevent bacterial penetration. When the front and sleeves of the gown were reinforced with a layer of plastic film, penetration was prevented. But when the reinforcement consisted simply of another layer of the gown material as in the Kimlon gown, bacterial penetration occurred in all tests in three minutes or less.

The reinforced front and sleeve areas of the gowns

marketed under the labels Barrier Specialty, Convertor, and Spartan Healthcare were, to all intents and purposes, impermeable to bacterial penetration in both the 30-minute and 60-minute test periods. In comparison, the single-layer sections of each of these gowns were unevenly ineffective as barriers (Table 2).

Gowns made of a single layer of fabric exhibited great variations in bacterial permeation. The best performance among single-layer disposable fabrics was that of the Vigilon Macbick gown which allowed bacterial penetration in only three of ten trials. The single-layer portions of the Cenco gown, Barrier Surgikos gown, and the Curity gown, permitted penetration in 4/10, 5/10, and 9/15 trials, respectively. The Kimlon and Fashion Seal Disposable material are apparently identical, and ineffective barriers, allowing wet bacterial penetration in 100% of the tests.

The tables do not show the tests made to determine the effect of stitching and gluing upon bacterial penetration. Tests were conducted on the stitched sections of the reinforced forearm of the Barrier Specialty gown and the Spartan Healthcare gown, the stitched sleeve of the Pima gown, and the glued sleeve of the Curity gown. In all cases bacterial penetration occurred in less than 30 minutes in the seam area, whether the seam was stitched or glued, and regardless of the impermeability of the materials sewn at the seam. Hence, it would appear that seams should be limited to areas of gowns and drapes least likely to be exposed to contact stresses during surgical operations.

The Pour-plate Technique

Results of the dry pour-plate and wet pour-plate tests on selected materials were almost identical to those of all previous tests. Materials which allowed bacterial permeation during the contact agar plate tests were similarly penetrable to both the dry and wet pour-plate tests.

As shown in Table 2, all previous results were confirmed, virtually without exception, indicating that the pour-plate technique offered no advantage over the direct-contact technique in determining actual strike-through potentials for materials tested. These results also indicated that a positive culture growth by either method could be interpreted as actual permeation through the test material rather than some other mechanism of transmission of bacteria caused by the weight of the inverted Mason jar on moist agar.

Discussion

Both nonwoven and woven surgical fabrics are presently promoted as barriers to moist bacterial penetration, but our tests show wide variations in per-

TABLE 2. *Inverted Mason Jar Tests on Agar, Dry Pour Plate and Wet Pour Plate Nonwoven Materials†*

Single-layer Materials	30-Minute Mason Jar on Agar	30-Minute Dry Pour Plate	30-Minute Wet Pour Plate	Reinforced-layer Materials (Polyethylene Film or Polyester)	30-Minute Mason Jar on Agar	60-Minute Mason Jar on Agar
Spunlace nonwoven (Barrier Surgikos and Surgikos 450)	0 +	0	+	<i>Barrier Specialty</i> reinforced with polyethylene front	0	0
Single-layer gown	+ +	+	+		0	+
	+ 0	+	0		0	0
	0 0	0	0		0	0
Single-layer sleeve	0 0	0	0	sleeves	0	0
	+ 0	+	0		0	0
	0 +	+	+		0	0
	0 0	+	+		0	0
	+ +	0	0		0	0
Scrim reinforced tissue (Convertors) Single-layer front	+ +	+	+	<i>Convertor</i> reinforced with polyethylene front	0	0
	+ +	+	+		0	0
	0 0	+	+		0	0
	0 0	0	0		0	0
Single-layer sleeve	0	+	+	sleeves	0	0
	+ +	+	+		0	0
	+ +	+	+		0	0
	0 0	0	0		0	0
	0 0	0	0		0	0
Tyvek spunbonded olefin (Vigilon Macbick; Curity; Bard) Single-layer front	0	0	0	<i>Spartan Healthcare</i> reinforced with polyester front	0	+
	0	0	+		0	0
	+ 0	0	0		+	+
	+ 0	0	+		0	0
Single-layer sleeve	0		0	sleeves	0	+
	0		0		0	0
	0		0		0	0
	0		0		0	0
	+		0		0	0
Fiber or scrim reinforced tissue (Kimlon; Fashion Seal; Cenco; Spartan Healthcare) Single-layer front	++0+	0+0+	++0+	Kimlon reinforced with second layer same material front	+	
	++0+		0+++		+	
	++++		++00		+	
	+++0				+	
Single-layer sleeve	+++	0+0+	++0+	sleeves	+	
	+++	0+00	0+++		+	
	0++	+++0	++00		+	
	00+				+	
	+0+				+	

† Bacterial penetration.

formance between different woven and nonwoven materials.

Two separate classification panels of the Device Agency of the Food and Drug Administration—the Surgery and Plastic Surgery panel and the Hospital and General Use panel—have included surgical apparel in their list of devices. Yet until very recently neither panel has listed surgical apparel on their priority lists for devices in urgent need of standards. In March, 1978 the Surgery and Plastic Surgery Panel voted to place surgical materials in a high-priority standards category. Until now, industry has been free to supply its own

standards and its own tests, which we find do not necessarily reflect in-use performance. As a result, manufacturers could make advertising claims which were not necessarily pertinent to surgical safety, and could have been misleading to the surgeon-consumer.

Because many hospitals in the United States still use surgical gowns and drapes made of ordinary 140-thread muslin, manufacturers of disposable nonwoven apparel have felt justified in comparing the permeability of their materials with that of ordinary muslin, thereby claiming general superiority for nonwoven over all woven goods, neglecting to mention the existence of

impermeable woven materials. Published articles and advertisements often refer to the muslin gown as "standard",⁶ thereby further misleading the reader. The muslin gown is instantly permeable to moist strike-through and is certainly not standard in any sense of the word, but unfortunately, is still being used in some hospitals.

Our studies confirm our previous tests in demonstrating that nonwovens as well as wovens vary greatly in permeability, depending upon a variety of characteristics of the materials. For wovens, the weave must be tight and the fibers must be treated with a special waterproofing process known as Quarpel treatment which penetrates the fibers of the material rendering them impermeable to moist contamination. For nonwovens, the material must be combined or reinforced with a polymeric film for waterproofing. Because such impermeability serves as a heat retainer, gowns and drapes made entirely of impermeable materials would require ventilation to provide wearer comfort. From a pragmatic viewpoint, only the areas likely to get wet during a surgical operation, the front and the lower sleeves, need be made of impermeable material.

Our tests provide continuous stresses upon the fabrics for 30–60 minute periods, and therefore may be considered as being too severe since pressure upon the sleeves and front of gowns during surgical operations tends to be intermittent. Yet, our previous tests revealed a correlation between continuous unopposed stress tests and cultures actually taken during surgical procedures.

Unlike the AATCC tests and those conducted by Beck and Mandeville¹ which involved simple moisture penetration as observed by the naked eye, our permeability tests are quantified by actual bacterial culture growth, and emphasize the point that bacterial penetration of gown fabric cannot necessarily be measured by visible moisture penetration. Pour-plate tests, using dry as well as wet Petri dishes, confirmed the Rodac plate contact tests.

Of the fabrics tested, 12 are presently used in surgical gowns, and to the credit of the manufacturers, since our 1975 report, at least five are now being made with reinforcement on front and sleeves with either some other relatively impermeable material, or a double layer of fabric. The mere presence of a double layer of reinforcement does not always accomplish its purpose. Reinforced areas of some gowns are not satisfactory barriers because they are not reinforced with polythene films.

Some relatively impermeable reinforced gowns can be criticized because the seams on the sleeves are in a position which makes them likely to become moistened

during an operation, others because the reinforcement on the gown front is not adequately attached to the gown proper, thus rendering it permeable to moist contamination. Our tests indicate that stitching and gluing often negate barrier properties of the reinforced gown area. Therefore, we suggest that seams be outside the areas likely to become moist in use. Bacteria may penetrate between two layers which are not adequately adherent, rendering these layers more permeable than if they had been properly adherent.

All but one of the gowns tested were fitted with stockinette cufflets which are known to be immediately permeable to fluids and bacterial penetration. In our previous communication we recommended that the cuffs of surgical gown sleeves be of more impermeable material than stockinette. It is with some gratification that we now find that one manufacturer has recently marketed a new gown with cuffs made of sleeve material shirred by Lastex[®] bands.

If our experimental results do, indeed, reflect the permeability of moistened barrier materials as it may occur during surgical operations, as we believe they do, the implications to surgeons and manufacturers alike, are significant. To surgeons who perform lengthy wet operations, our results would mean that woven gowns and drapes should be only those with sleeves and front reinforced by waterproofed tight-woven Pima cloth. An inventory system should be devised which will record the number of washing-and-sterilizing cycles a reusable gown has been through. If nonwoven gowns and drapes are used, only those with sleeves and front reinforced by an impermeable plastic layer can be considered adequate barriers.

To manufacturers, our results would mean that they should not promote nonwoven or woven materials as "barrier" material unless they are the specific types which act as actual barriers to moist bacterial strike-through according to tests recommended by specific performance standards. We believe such standards are urgently needed for surgical barrier materials.

Conclusions

A new set of tests, using modifications of the inverted Mason jar test, confirmed our previously reported studies indicating that great variations exist in the ability of surgical materials to resist moist bacterial strike-through.

Of the woven materials, Quarpel-treated tight-woven Pima cloth resisted penetration when new, but invariably became permeable after 100 washing-sterilizing cycles. Our previous studies, carried out on materials cycled varying numbers of times, showed that permea-

tion actually began after 55 cyclings, and continued to appear in more samples at 75 cyclings and in all samples after 100 cyclings. We would conclude that woven gowns with front and sleeves reinforced by Quarpel-treated tight-woven Pima cloth are safe from moist bacterial strike-through for about 75 washing-sterilizing cycles and uses.

Vulcanized patches of untreated tight-weave heavy Pima cotton were likewise permeable, while water-proofed patches reinforced with a plastic film were impermeable.

Of the nonwoven materials, the reinforced sections on the front and sleeves of some gowns remained impermeable through our tests, while others did not. This variability appeared to reflect the degree of impermeability of the reinforcing layer. Single-layer materials tended to be unevenly permeable to moist contamination. Those containing polymeric ingredients tended to be more impermeable, and those reinforced with a polythene film were totally impermeable. Therefore, we would conclude that nonwoven disposable gowns may be considered suitable for lengthy wet operations provided their front and sleeves are reinforced with a polythene film and provided the seams are properly placed.

Stitched or glued seams were permeable to moist contamination regardless of the barrier effect of the material. This was true in woven as well as nonwoven

fabrics. Therefore, we recommend that surgical gowns and drapes be designed to keep seams outside the actual surgical field.

Stockinette cufflets act as wicks and allow immediate wet bacterial penetration, but when the cuff is made of sleeve material the transmission of moisture by wicking is proportionately diminished.

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