HOSPITAL AIR CURTAIN SYSTEMS

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ABSTRACT

Currently accepted best design practice for controlling airborne particulates in the hospital operating room rely on air flow type (laminar) and direction (down from ceiling). This is typically in the form of large arrays of laminar diffusers. These arrays are limited, or impacted, by delta T, and the need to have other ceiling mounted equipment in the operating room. An alternative is a scalable pre-engineered system that overcomes these inherent limitations. Many such systems are qualified as clean air systems by actual microbial testing.

INTRODUCTION

The modern role of air quality in the operating room (OR) was pioneered by Sir John Charnley, a British orthopedic surgeon. His rates of post-operative infection in total joint replacement patients lead Charnley to make radical changes to the aseptic and perioperative techniques in his ORs. Among these was an air distribution chamber surrounding the sterile field and the surgical staff. He developed, in conjunction with Hugh Howorth, this special system that cleaned the air, contained it, regulated its velocity, and prevented its recontamination. This became known as the Charnley-Howorth system. (Note: Any reference herein to the Charnley-Howorth system refers to the concept developed by Charnley and Howorth and its application in the OR. It does not refer to any specific device sold under that name, or to any product made by Howorth Airtech.)

At roughly the same time in the United States, Willis Whitfield, an engineer at Sandia National Labs, developed the first modern clean room. After realizing that air flow could be a primary method of controlling microscopic particles, he was able to reduce particle counts by orders of magnitude. Prior to his discovery, Class 100,000 clean rooms could be achieved only with meticulous manual cleaning techniques. After his breakthrough, Class 1000 clean rooms and better became, not only possible, but practical.

Both of these strides achieved what today we refer to as “one pass, then out.” That is, any given molecule of air (and the airborne particles they push around) is moved directly out of the clean space, never to reappear.

Charnley’s success and Whitfield’s breakthrough generated much excitement among surgeons who felt that they could now control airborne infection to a degree previously thought impractical.

Several problems became apparent. The first of these was that no one knew exactly what to expect of the Charnley-Howorth system. Charnley had statistics on the amount infection rates had dropped. But since he had made several changes at once, it was difficult to determine how much of the reduction was attributable to aseptic technique and how much to the air distribution system. Additionally, the air distribution was contained by physical barriers (typically Plexiglas panels). This created a highly restrictive environment for the surgical staff.

It was also discovered that Whitfield’s clean room methods could not be easily applied. For one, it was impractical to dedicate the layout of the room to the air distribution system. Surgeons typically disliked surgical garb that was as restrictive as the ‘bunny suit’ used in clean rooms. It was also an expensive proposition. Even worse, it was soon leaned that there was no direct corollary between the total particle count reductions achieved in a clean room, and the viable particle reductions needed in the OR. Thus, there was no way to relate standard clean room definitions to reductions in viable contamination.

Given that, it is no surprise that little remains from those two approaches today except the use of ceiling mounted laminar flow panels. It appears as if the industry believes that it is only the air flow type (laminar) and direction (down from ceiling) that made either a full clean room approach, or the Charnley-Howorth system valid in the OR. However, if we break airborne particle control down into its basics--extraction, dilution, suppression, and isolation—we can see that these approaches provide far more benefit than simply putting a random array of laminar panels in the ceiling. It is possible to come very close to a “one pass, then out” system.

One means of providing these four clean room elements, without the restriction of a Charnley-Howorth system, or the expense of a full clean room approach, is the air curtain. An air curtain system is a pre-engineered, scalable particulate reduction system that uses two differing air flow patterns to achieve its results. Some of these systems were developed around the same time that the American College of Surgeons released a proposed air cleanliness test for the OR that was based on viable particle counts. As a result, these systems were measured against this more modern standard (compared to Total Particle Reduction) and proven viable.

However, the approach used by engineers to maintain clean air in an OR during surgery has always been voluntary. Some simply add HEPA filters to the air supply. Some stick with systems designed around the Charnley-Howorth concept. Some prefer adding laminar panels in the ceiling. And some adopt the more recently developed air curtain systems. No national, or industry, standard governs their selection. Some hospitals use a mixture of these approaches.

It has thus been incumbent upon the industry to research, test, and build systems that provide a one pass, then out, benefit without the encumbrance of specialized laminar systems like Charnley-Howorth, or the equally arduous problem of building a clean room air distribution system within the OR.

BODY

Since the hospital operating room is a highly specialized environment, it is important that we define the terms and definitions that will be used in this discussion, as well as currently accepted practices.

Operating Room (OR): an enclosure specifically designed for the performance of open surgical procedures under aseptic conditions. For the purposes of this discussion, this does not include sub sterile rooms, clean supply, preoperative preparation areas, or postoperative recovery areas. While these are typically part of the surgical suite, only the OR requires the special airflow conditions described within this document.

Clean Room: a specialized room designed to minimize contamination. For the purposes of this paper, it refers to spaces that contain specialized air distribution equipment that micro filters the air and maintains its volume, velocity and direction specifically for the purpose of reducing and controlling airborne particulates.

Airborne Particulates: The OR environment is concerned only with viable particles (those able to cause, or carry the cause, of an infectious contamination.) These are typically biological aerosols of two types: a) microorganisms generated within the OR, and b) microorganisms introduced into the OR by means of the ventilation system.

Contamination: the seeding of a surface, or area with viable particles. This discussion is limited to contamination by airborne particulates (classified as exogenous). Airborne particulates may directly contaminate the surgical wound, or they may contaminate the surgeon's gloves or instruments and be carried into the wound indirectly.

Squames: A specific type of airborne particulate in the form of microscopic skin particles.

Surgical Site Infection (SSI): As defined by the ASHRAE HVAC Design Guide for Hospitals and Clinics, this is a pathological condition at the site of the surgical wound characterized by redness, swelling, pain, or secretions (not all of these conditions may be present). The infection may, or may not, cause a reaction in the patient such as fever. The term infection in this discussion will always mean surgical site infection.

Contamination vs. Infection: While there is no direct corollary between contamination rates and infection rates, it can be demonstrated that more viral contaminants, or contaminants in greater quantity, raise the

probability of infection. However, the ability of the surgical patient to resist infection is a factor. As such, this paper differentiates between contamination rates and infection rates.

Laminar or Laminar Flow: Specialized airflow characterized by lower velocities, higher volumes, stable directions, and low turbulence (or low mixing). ASHRAE (Chapter 33, Fundamentals) defines laminar panels, or laminar diffusers, as Type E outlets.

HEPA filters: The airflow arrangement in this discussion is independent of the method of micro-filtering air. Therefore, HEPA refers to micro filtration in a general sense, without reference to specific filter ratings such as MERV 10 or MERV 15.

Extraction: a means of removing airborne particles. Typically this is done by use of HEPA or ULPA filter. For the purposes of this paper we will include any means of removing airborne particulates from a zone as extraction.

Dilution: a means of reducing airborne particles in a space by introducing large volumes of air. This is typically expressed in ACH, or air changes per hour.

Isolation: a means of controlling contamination in a space by means of physical barriers, or through the use of air volume or pressure differentials. For example, an OR may be completely contained by walls, door, and window (physical isolation) and then use a room pressure slightly higher than the surrounding hallways to create outflow from the OR into the hallway when the doors are opened (airflow isolation) For the purposes of this paper, all isolation is airflow isolation unless stated otherwise.

Suppression: a means of controlling the path of airborne particulates in a space through the use of directional airflow.

Sterile Field: This is the zone in the OR defined as being from the horizontal plane of the surgical table to the ceiling, and bounded by the edges of the surgical table. All objects entering this zone must have been treated to achieve a sterile condition.

Air Curtain System: The details of such a system are the subject of this paper and are outlined below.

AIRFLOW AND CONTAMINATION

Maintaining sterile or ultra-clean conditions in the OR is of utmost importance. This can be aptly illustrated by the surgeon's hands. The surgeon's hands are scrubbed with germicide, then rinsed with touching a faucet, and dried with a sterile towel. Another person with equally clean hands helps the surgeon into surgical gloves. With that done, the surgeon enters the OR without lowering his/her hands, and without touching anything. In other words, once the surgeons' hands are clean, we know exactly where they are.

We rarely have the same luxury with clean air. While, like the surgeon's hands, we may clean (by means of a HEPA filter) the air before it enters the OR, once it is inside we cannot see where it goes. We have no assurance that it stays clean. In fact, it is likely that air will be contaminated when it enters the OR. Theoretically, HEPA filters of >99.7% efficiency should remove particles >.3 microns in size but these performance limits are usually measured in labs and may not be accomplished in actual applications. The ASHRAE HVAC Design Guide for Hospitals and Clinics notes that viruses are >0.3 microns in diameter, thus they cannot be reliably removed with micro filters.

Beyond that, it is also possible to inadvertently create an air flow path that actually passes air across contaminated surfaces. For example, a typical ceiling diffuser is designed to stir up air in the space. It passes a jet along the ceiling and down the walls, then displaces air near the floor. This air is lifted back up into the diffuser jet in a continual pattern of room air mixing. This is great for comfort control, but it also effectively mixes particles.

Or we may not account in our design for the contamination given off by the surgical staff itself. One example of such contamination is squames. Squames are shed by humans at the rate of thousands per hour. This rate can vary. For example, ASHRAE's HVAC Design Guide for Hospitals and Clinics references a study that indicates the rate to be 1000 per hour (Hambraeus 1988). Another source lists this as 42,000 per hour (Freudenberg 1994). The variance in the rate at which these squames are shed can be dependent on such factors as the subject's skin condition, and the rate of physical activity. In the OR, the important consideration is that these skin particles can contaminate the surgical wound. For example, Staphylococcus epidermis can be shed into the environment on skin scales and infect patients who have undergone prosthetic implant surgery.

The desired air flow would accomplish two things, a) it would slow the rate of air velocity across the surgical staff. Excessive velocity is a possible contributor the erosion of squames from the exposed skin of the surgical staff. This same velocity may then be high enough to cause the deposition of those particles directly into the surgical wound, or onto the instrument table. And then, b) it would actually help pull air contaminated with these particles out of the sterile field.

In short, while all equipment in the space is important in ensuring the success of a procedure, the selection, application and function of the air distribution system actually impacts the integrity of the sterile field. The VA Design Guide for Surgical Services notes, "The air supply system must be designed to minimize airborne bacteria from entering the sterile field."

The need to mitigate contamination from these two sources suggests that we consider doing more than simply introducing micro-filtered air into the OR.

One thing is to ensure proper dilution. Depending on the type of surgery being done, the ASHRAE HVAC Design Guide for Hospitals and Clinics, the ASHRAE Handbook of Fundamental, and the AIA's Guidelines for Construction and Equipment of Hospital and Medical Facilities, recommend between 15 and 25 air changes per hour (ACH). Diluting air this way reduces the particulates in the space, therefore reducing the statistical likelihood of contamination and infection.

Another thing is to isolate the OR. The ASHRAE HVAC Design Guide for Hospitals and Clinics say that the OR should have a positive pressure of between 10% and 15% of the air volume. This positive pressure should be maintained even when the room is not occupied.

The last thing is to provide directional air flow, or laminar flow. In general, laminar flow is regarded as unidirectional, non-inducing, low velocity air flow. It is currently considered best practice to bring the laminar flow in at ceiling level and out through low exhausts or returns on the wall. This flow would ideally be of low velocity. Some have suggested that velocities of less than 30 FPM at the diffuser face are optimal. Charnley had had success with velocities exceeding 100 FPM, albeit with extraordinarily high dilution rates (above 500 ACH).

Typically, all of these things can be accomplished to some degree with standard laminar panels. However, there are some drawbacks that the engineer should be aware of. While a properly designed laminar flow solution will certainly do no harm, and may do some good, a poorly designed one, or one designed without regard to its drawbacks may actually be harmful.

From the outset, the engineer should keep in mind that laminar panel were designed to be part of a system. In both the Charnley-Howorth, and Willis Whitfield systems mentioned above, the overall flow was systemic. Static in the clean space was carefully controlled. This benefits a laminar panel because it encourages even flow from the diffuser face. This makes the device less susceptible to the uneven pressure in the back pan cause by the abrupt transition from the inlet into the back pan. Additionally, both of these systems benefited from near isothermal supply conditions. True, there is some thermal loading that must be cooled in both the specialized laminar chamber Howorth designed and the clean room

Whitfield designed. However, in an environment seeing well over 100 ACH (sometimes up to 500), supply air temperatures are usually quit close to ambient. This also benefits the laminar panel as can be seen in the chart below. (Illustration 1) The other typical application is a laminar system is the entire ceiling might be devoted to laminar panels. This is helpful because, while they certainly minimize induction, laminar panels do induce. Filling the ceiling with laminar panels, or keeping the edge of the laminar flow far, far from the clean zone makes sure the induction is not allowing contamination on surfaces that must be kept clean.

These nearly ideal conditions rarely occur in the OR.

In the OR, ideal laminar flow is difficult to achieve, even under ideal conditions. The main reason for this is the large laminar array required. At 30 FPM face velocity, a 3000 CFM OR requires a 10' X 10' laminar array. (An array is a contiguous grouping of smaller laminar panels.) The first problem with this size is the lack of space for other ceiling mounted OR equipment. In an effort to keep the floor of the OR free of trip hazards, it is common to bring med gas, electrical, LAN, and other utility connections in to the room through ceiling mounted booms or columns. Providing space for these requires moving one or more panels in the array. Kept to a minimum, this probably does not represent any real disruption to the laminar flow. Complex OR's however, may require two surgical light bases, and two booms, as well as having fluorescent light fixtures within a certain distance of the surgical table. (See illustration 6) All of these disruptions in the array potentially lead to chaotic flow within the space. This chaos is minimal at velocities under 30 FPM. However, the use of large arrays with cold supply air may increase velocities to the point where the chaotic flow becomes detrimental.

So the second thing we have to consider is that large arrays are affected by cold air mass. Under isothermal conditions, laminar flow has a predictable downward velocity. Flow will generally continue traveling at the same velocity at which it left the diffuser face. The OR however, is rarely maintained at isothermal conditions. What is more likely is that air supplied to the space is going to be 5°F to 15°F cooler than ambient. With a small laminar array (<6 square feet) at lower delta-T, this is typical not an issue. However, with large arrays, and at higher delta-T's, velocities can increase substantially as air accelerates upon leaving the diffuser face. The explanation for this is simple and well known within our industry: colder air entering a warmer space has a tendency to sink. The rate at which it will accelerate depends upon the mass of the supply air versus the mass of ambient air. Air leaving the diffuser face at 30 FPM could accelerate to over 90 FPM by the time it crosses the patient. This is shown in the following data:

▼ **IP/METRIC DATA:** LAMINAR FLOW DIFFUSER VELOCITIES VS. AREA

	IP Data							Metric Data					
	Flow Rate	Ps	Velocity @ 6' Below Panel				NC	Flow Rate	Ps	Velocity @ 1.8m Below Panel			
			5° FΔT	10° FΔT	15° FΔT	20° FΔT				3° CΔT	6° CΔT	8° CΔT	11° CΔT
	CFM/ft²	"WG	FPM	FPM	FPM	FPM		L/s/m²	Pa	m/s	m/s	m/s	m/s
Single Panel	10	0.008	20	25	30	35	<20	51	2.0	0.10	0.13	0.15	0.18
	20	0.032	35	40	45	55	<20	101	8.0	0.18	0.20	0.23	0.28
	30	0.072	50	60	70	80	21	152	17.9	0.25	0.30	0.36	0.41
	40	0.128	65	80	95	105	25	203	31.9	0.33	0.41	0.48	0.53
15-30 ft² (1.5-3.0m²)	10	0.008	20	30	30	35	<20	51	2.0	0.10	0.15	0.15	0.18
	20	0.032	35	45	50	60	22	101	8.0	0.18	0.23	0.25	0.30
	30	0.072	50	65	80	90	26	152	17.9	0.25	0.33	0.41	0.46
	40	0.128	70	90	105	-	30	203	31.9	0.36	0.46	0.53	-
Over 30 ft² (<3m²)	10	0.008	25	30	35	40	21	51	2.0	0.13	0.15	0.18	0.20
	20	0.032	40	50	60	65	25	101	8.0	0.20	0.25	0.30	0.33
	30	0.072	60	75	90	100	29	152	17.9	0.30	0.38	0.46	0.51
	40	0.128	80	100	-	-	33	203	31.9	0.41	0.51	-	-

Illustration 1

It is not our intent to suggest that ceiling mounted laminar arrays do not work. A large amount of empirical data suggests otherwise. It is our intent to point out some of the problems inherent in this approach and to

show another solution which, while given little attention in our industry, has been proven to work, and to resolve some of these issues.

In summary, some of the concerns with large laminar arrays are: a) a conflict between the need to have a continuous group of diffusers and the need to place other OR equipment (lights, etc.) in the ceiling, b) the possibility of getting undesirable velocities as a result of the total area of the array and the room delta-T, and c) the potential drawback of installing, balancing and maintaining a large number of diffusers and/or the required HEPA filters.

ENTER THE AIR CURTAIN SYSTEM

The air curtain system was a logical technological progression of the Charnley-Howorth concept, and Willis Whitfield's work with clean rooms. As noted both of these systems use the fundamental principles of extraction, dilution, suppression, and isolation for airborne particulate control in a "one pass, then out" system. The drawback to the Charnley-Howorth concept is that it is physically restrictive; the drawback to designing an OR to be an industrial style clean room is that it is expensive. The goal of the air curtain system is to provide most of the benefits, with fewer drawbacks.

Simply stated, air curtain systems utilize two distinct types of air movement, downward laminar flow above, or nearly above the patient, with a perimeter of higher velocity air forming a 'curtain' outside the sterile field or surgical staff. The laminar flow comes from a fairly typical laminar panel; the perimeter air curtain is usually supplied through a specially designed slot, or arrangement of slots. These are specially designed because the air curtain must typically have far less velocity than a slot diffuser used for general ventilation purposes. Further, these two flows are designed to have a specific mass or velocity ratio in order to accomplish its goal.

Seen as a cross-section of an OR, a CFD (computational fluid dynamics) model of the air flow in an air curtain system looks like this:

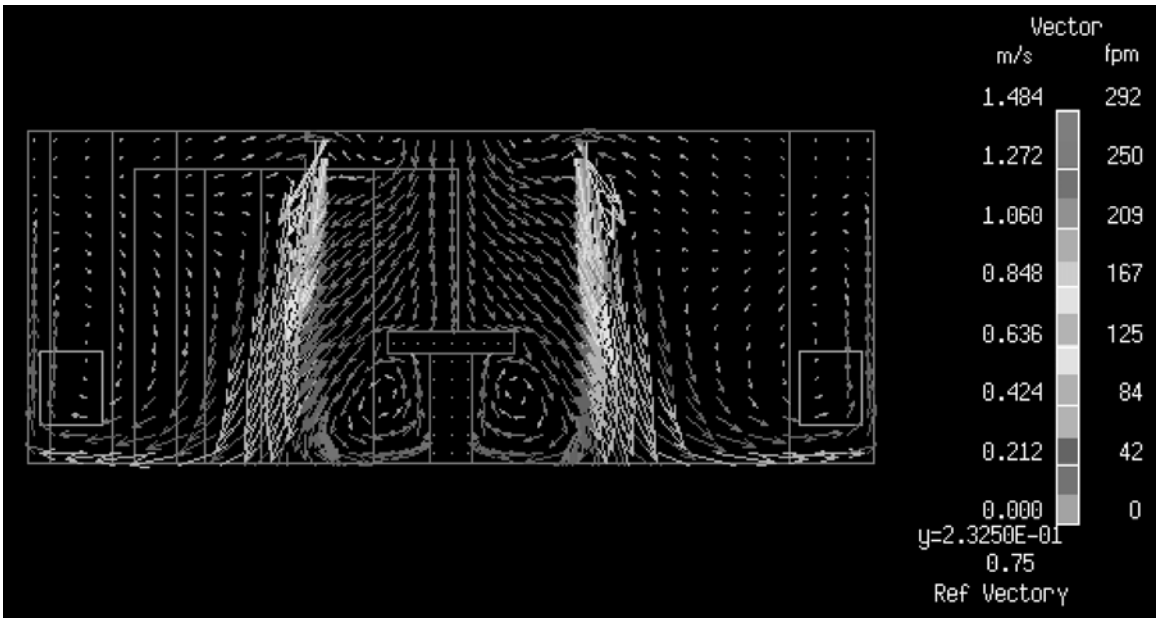

Illustration 2

Seen as a ceiling view of the OR, a typical air curtain system looks like this:

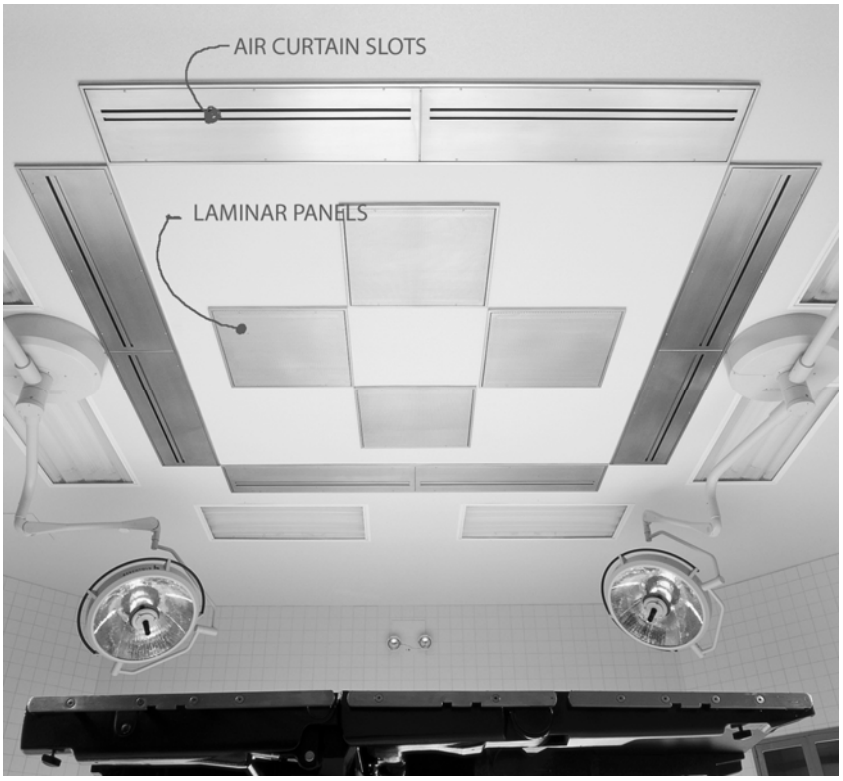

Illustration 3

(Note: The word “curtain” in an air curtain system makes it sound as if the only purpose of the perimeter air flow is to act as a protective barrier. As you will see in the discussion that follows, it does much more than that. However, we will hold to the industry convention of calling it an air curtain.)

In terms of particulate control, an air flow system in an ideal operating room would accomplish the following:

> It would control velocity at the operating table level. Some have theorized that that laminar flow impinges on the wound site. (Lewis 1993) The idea is that high velocities erode squames from the exposed skin area of the surgical staff and deposit the particles into the wound. However, high velocities are not an inherent part of a laminar flow system. Chanley-Howorth used high velocities, but only because they also use phenomenally high ACH. It is possible to have laminar flow with lower velocities. ASHRAE Standard 170 (P), suggests that lower velocities are better. This is probably correct. An ideal system would control velocities at table level. This level is important for two reasons: a) if the thermal plume (created by heat from the patient, the open wound, the surgical staff, and the equipment) helps protect the wound from impinging particles (Memarzadeh, Maning 2005), then velocities at table level are the most important to consider. And, b) hypothermia can lead to increased incidences of SSI’s. (Sessler, Lenhardt 1996). Since there is a direct relationship between air velocity and hypothermia, a reduction in velocity at table level is potentially beneficial to the patient.

As noted in the discussion above, large laminar arrays cannot be depended upon to produce a table velocity that relates to initial face velocity. An air curtain system behaves differently. In an air curtain system, the laminar area is typically much smaller than the area defined by the perimeter curtain. As the

lower (relative to the curtain) velocity air exits the laminar panels, the relatively higher velocity of the air curtain begins pulling the laminar flow outward. As the laminar flow expands to fill this zone, it must, by necessity, slow down. This mitigates any tendency of the laminar flow to accelerate due to cold mass effect. The net result is the ability to maintain velocities at the table level very close to what they are at the diffuser face.

An example of a typical air curtain velocity profile is shown in the following illustration:

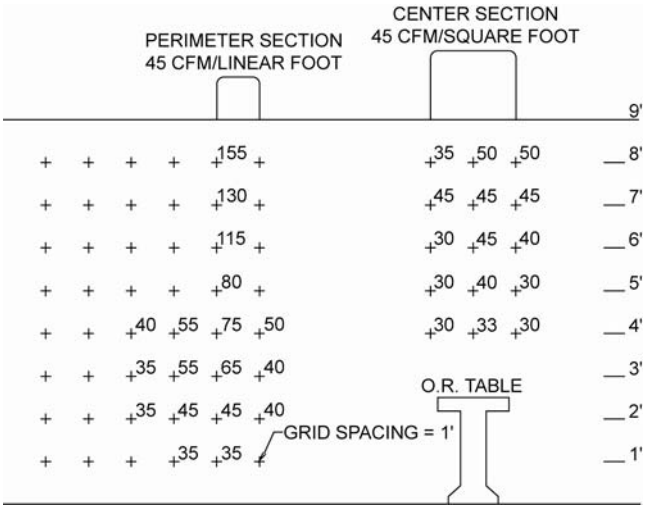

Illustration 4

It would extract particles from the sterile area. As noted, we must deal with two types of contamination from airborne particulates: those introduced by the air distribution system and those introduced by the room occupants. HEPA filtration addresses only those particulates pulled into the air handler. It is important to also address those particulates stirred up by (resuspension, or created by (bio-aerolized by), the surgical staff and patient. ASHRAE's HVAC Design Guide for Hospitals and Clinics notes. "air flow should be purposefully directed from clean (beginning at the wound site) outward to less clean (low and at the room perimeter)" As shown by the velocity profile in Illustration 2 above, the air curtain enforces this type of flow.

It would enforce dilution rates in the space. One of the drawbacks to large laminar arrays is the need to break them up in order to have places to mount other ceiling mounted equipment. This has a tendency to create pockets of uneven flow in the space. This has the potential to create recirculation with resulting pockets of aging air. As air ages, it can concentrate airborne particulates, thus effectively reducing the benefits of dilution. By forcing the outward distribution of air from the laminar panels, this effect is mitigated, thus enforcing the desired dilution rate.

It would enforce isolation in the space. As noted, ASHRAE recommends isolating the OR by means of a pressure differential. This ensures outflow from the OR into the less clean surrounding area when the OR doors are opened. The air curtain has the same affect around the sterile area. It pulls the air within the space into the curtain, entrains it, and then exhausts it outward to await being finally exhaust out of the space. Particulates thus pulled from out of the sterile area are prevented from reentering by the curtain until they enter the exhaust ductwork. (It is from this last function that the air curtain gets its name.) Of course, to do this, the curtain would have to carry a sustainable velocity to below table level (below the sterile field). This is shown in Illustration 4 above.

DISCUSSION

Breaking down the air curtain system into its fundamentals shows it to function on the same principles as a clean room. However, the advantage of this technology over John Charnley and Hugh Howorth's original concept is that it is not physically obtrusive. From the perspective of that concept, the air curtain performs part of the function of the Plexiglas barriers: containing and defining the primary flow, and preventing the entrainment of airborne particles. The advantage of the air curtain over simply constructing the OR as a clean room is that it covers a smaller area, and should thus be less expensive to install, operate, and maintain. Its advantages over a large laminar array are discussed above.

However, air curtain systems have physical properties which push their advantages beyond air flow. The first of these is that such systems are scalable. As noted above, making a laminar array larger may affect velocity profiles because of the mass of cold air. In a scalable system like an air curtain system, the perimeter grows in proportion to the center laminar, thus maintaining the same overall effect.

While the details vary from one manufacturer to another (based on their exact air curtain velocity profile), a basic scalable system works like this: The total room air volume is determined. This can be based on ACH requirements, or by the cooling load required. Of the total room volume, 2/3 goes to the perimeter air curtain; the remaining 1/3 goes to the laminar panels. If the perimeter is to have multiple inlets, each inlet should be balanced to receive a part of the airflow proportional the length of the perimeter it serves. If the laminar is multiple panels, each panel should be balanced to receive a part of the airflow proportional to its part of the total laminar area.

Next you need a ratio of air curtain slot length to laminar area. Again, the details of this vary from manufacturer to manufacturer, but a typical system breaks down so that the total lineal slot length is double the laminar square area. A check of this should show that the CFM per square foot of the laminar is equal to the CFM per lineal foot of the slot.

This scalability lets designers of operating rooms select a system confidently. They know that no matter what size system they need, it will work the same as whichever system, or systems, the manufacturer actually tested.

Another important aspect of the air curtain system is the open ceiling space between the laminar panel and the perimeter air curtain. Modern OR's are becoming increasingly equipment intensive places. And a great amount of that equipment is now wired or piped through ceiling mounted booms. Since an air curtain system does not have to devote its entire ceiling area to laminar panels, this open space can be used to mount some of this equipment without sacrificing the airflow parameters. This is shown in a typical installation illustrated on the next page:

Illustration 6

Another advantage of the air curtain system is for the air balancer and scrub team. Small systems can have two inlets, one for the perimeter and one for the center. Even very large systems may require as few as four inlets. This makes it far easier and less expensive for the balancer than large laminar arrays that may require more then a dozen inlets (one per panel). Likewise, it is less work for the scrub team who prepares the OR for its first use (as well as any subsequent cleanings). The typical 10 X10 large laminar array described above may have 240 square feet of plenum surface to be cleaned. This, compared to 160 square feet for a 10 X 10 air curtain system.

MAINTAINING AIR CLEANLINESS

However, the chief advantage of a scalable system is that it allows a manufacturer to qualify a design, with the designer of the OR able to pick a variation on that design knowing that it uses the same physics. This mitigates the need to qualify all of the dozens of variations possible. But how should the manufacturer qualify their design?

The large general acceptance of downward laminar flow is partly based on years of data gathered in hospital operating rooms. While no standard existed saying just how clean OR air should be, the number and variety of tests done indicated that downward laminar flow at the very least did no harm, and at best actually provided some benefit to the patient. However, at one time a standard for actually measuring air cleanliness in the OR during surgery was proposed.

The standard is called “Definition of surgical microbiologic clean air.” It was written and proposed by CORE, the Committee on Operating Room Environment (Willis Whitfield, et al, 1976), as convened by the American College of Surgeons. The committee acknowledged the value of Federal Standard 209B, which provided definitions for clean rooms; but their research showed the needs of the OR to be different, thus requiring a different standard. They noted “since there is no consistent ration between viable airborne particulates (microbially inhabited) and the nonviable ones…Federal Standard 209B has not provided adequate definitions.”

The standard noted several important things about its own definition. It defined viable particles as "independently airborne particles of variable size which contain or transport microorganisms which produce colonies on culture media." They also noted that testing should include observations and recordings of temperature, humidity, ACH, and pressure differential. However, the two things that differentiate this standard are the methods of measuring viable particles, and the definition of clean air classes. Specifically it noted, "counts (of viable particles) are to be taken during periods of normal work activity at a location that will yield the viable particle count of the air as it approaches the location of the actual site of work and/or equipment used in the work." It then required a minimum sample of 30 cubic feet of air. Class 1 air would not exceed one viable particle per cubic foot. Class 5 would not exceed five viable particles per cubic foot.

In summary, the committee saw no consistent ratio between viable particles and total particles, and the concluded that Federal Standard 209B did not apply in the OR. Further, they realized that air cleanliness must be based on the actual conditions found in the OR and wanted tests that emulated those conditions as closely as possible. Lastly, their results are based simply on catching and counting microbes. They were not beholden to any particular air flow pattern. This opened the door for ways of maintaining air cleanliness in the OR that went beyond traditional laminar systems.

At that time, at least one air distribution manufacturer in the United States was working on an air curtain design, and at least one other would soon follow. Since CORE did not make any presumptions about air flow patterns this manufacturer was able to test their system according to this emerging standard. When they did, they learned that their system met the cleanest class of air under the definition. Here is a sample of the test data:

Procedure: Open Reduction/Internal Fixation of Left Tibia — Date: October 15, 1980
Temperature: 70° F — R.H.53%
6 - 8 People in Room — Much Activity

Gross Particle Count (Royco or Climette)			Anderson Sampler At O.R. Table			Anderson Sampler Outside Clean Field		
	5.0	0.5						
Time	**Micron**	**Micron**	**Time**	**Stage**	**Colonies**	**Time**	**Stage**	**Colonies**
7:59 AM	498	7767	8:16 AM	1	0	8:16 AM	1	38
8:17 AM	291	8727	8:46 AM	2	0	8:46 AM	2	7
8:28 AM	165	35474		3	0		3	4
8:38 AM	170	10878		4	2		4	8
8:55 AM	142	10135		5	1		5	8
9:05 AM	121	19787		6	2		-	-
			Total	**1-6**	**5**	**Total**	**1-6**	**65**
9:15 AM	182	19965		1	0	8:53 AM	1	6
9:25 AM	146	24566		2	2	9:26 AM	2	7
9:35 AM	163	4136		3	2		3	4
				4	0		4	4
				5	6		5	3
				6	2		6	0
			Total	**1-6**	**12**	**Total**	**1-6**	**24**

Average size distribution per stage: 1-9.8U, 2-6.2U, 3-3.8U, 4-2.2U, 5-0.9U, e6-0.9U

This representative sampling was one of five tests done on October 15 and 16, 1980 at Tucson Medical Center. It also reflects the data collected on January 20 and 21, 1981 at University Medical Center (also in Tucson) when an additional eight tests were conducted, this time with a comparison to a (then) state of the art horizontal laminar flow system. The two things that become immediately obvious from this data are that

the system meets the definition of Class 1 microbiological clean air. And that air inside the perimeter air curtain was kept much cleaner than the air exhausted through the curtain into the periphery of the room. This is exactly what was predicted by the air velocity profiles illustrated above.

The second manufacturer to enter this arena had similar results. They opted to conduct their tests in a mock surgical environment in order to prevent any risk to actual surgical patients. But they held to the definition proposed by CORE and substantiated the fact that air curtain systems were viable.

CONCLUSION

Laminar panel arrays have their place in the OR. It would be difficult given their history, and their general acceptance in the industry, to conclude that they do not have some usefulness. Certainly in OR's where the amount of airflow needed keeps them to a size that prevents cold air mass effect, or where the surgical procedure is not protracted, or the patients are not generally regarded to be at risk for nosocomial infection, they offer a useful, inexpensive means of providing proper air flow in the OR.

This is not meant to propose a technology change just for the sake of doing so. True, OR's have become far more sophisticated, technically advanced places in the past 50 years. But that does not mean that air flow solutions that were applicable then are invalid now.

On the other hand, technology advances in the OR now means that our industry must find a way to share the ceiling space (and the even more crowded plenum space above it) with new equipment. It is no longer possible to devote the entire ceiling above the sterile field to laminar panels. Likewise, we also can't assume that air distribution methods, like simply placing a laminar array in the ceiling, that were never specifically tested to any air cleanliness standard specific to viable particles should be the basis for our designs What we have is a definition based on viable particles, and conditions specific to the OR environment. It would be unwise not to consider the importance of the work done by CORE, and the resulting "Definition of surgical microbiological clean air."

Manufacturers in the industry have discovered better ways maintaining proper air flow in the OR. The air curtain systems produced as a result have both empirical data and decades of application to back up their effectiveness.

One important caveat is that these systems are not just a slot diffuser coupled with a laminar flow panel. The proper physics needed to set up the dynamic relationship between the two cannot be ignored. But as shown above, manufacturers with the proper knowledge, and testing facilities, can produce viable systems for application in the field.

It is not just technical advances in the OR that should point us down this road. Airborne particulates and their resulting contamination are more likely to lead to an infection when: a) a large foreign body is implanted in the patient, b) the patient has a suppressed immune system, and c) the quantity and virulence of the contamination is overwhelming to the patient. (Laufman, et al. 1999) With an aging population, we face more implant surgery than ever before. With AIDS, as well as various treatments for cancers, increases in hepatitis, etc, we are seeing increased number of patients with weakened immune systems. And with the ineffective use of prophylactic antibiotics, we now have "super" viruses and bacteria whose virulence is potentially deadly. We need better particulate control systems in our OR's. Air curtain systems are a way to accomplish that. Their superiority of an array of laminar panels should be given consideration in many operating rooms being designed today.

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