Removal of Surgical Plume Generated by Electrosurgical Devices

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Evacuation of Surgical Plume Needs to be a Priority in All Surgical Facilities

Managers in U.S. operating rooms must comply with mandates such as those imposed by OSHA through the Blood Bourne Pathogen Rule. The cost of such regulation is reflected in the purchases of fluid management devices, safety scalpels and syringes, face shields, other related consumables and nursing time needed to implement the requirements.

Certainly, managers must prioritize these mandates...but should they do so while disregarding related rules issued by OSHA, guidelines of JCAHO, a NIOSH safety alert and the best practices recommendations of AORN? All of these entities, as well as others, advocate for evacuation of surgical plume from the operating room because of the potentially infectious elements and mutagenic/carcinogenic chemicals identified as present in the plume. It needs to be remembered that smoke is composed of vapor (liquid) and particulates released when cells are ruptured by the heated instruments used for incision and coagulation of human tissue. That body fluid (intra- and intercellular water as well as blood) contains the same potential pathogens found in blood and other fluids whose management has been carefully regulated by OSHA’s Blood Bourne Pathogen Rule. What this mandate implies is that healthcare workers need to be protected from pathogens found in blood, ascites and saline irrigation but not protected from fluids from the same body that are also present in surgical smoke which also contains carcinogenic chemicals not found in the other bodily fluids.

While the threat of splash-back of bodily fluids onto the mucus membranes of nurses is minimal with current precautions, the threat to the worker from inhaled surgical plume is definite and continuous because surgical masks offer little if any protection to the worker from inhalation of contaminated smoke.

It is not surprising, therefore, that reports of HPV (human papilloma virus) infection in the respiratory tract of doctors involved in the fulguration of venereal warts have been reported. Nor is it surprising to note that the incidence of respiratory illnesses in perioperative nurses is twice that found in the general U.S. population.

Studies indicate that poor air quality results in increased absenteeism and decreased productivity. Alternatively, efforts to improve air quality can decrease absenteeism by as much as 60% and productivity by 17%. In a 2010 report, absenteeism in Canadian nurses which was due to illness, often respiratory (25%), was as high as 9% among public sector nurses. This resulted in an overtime rate of 17.3% at a total annual cost of $660,300,000.
Perhaps a fractional decrease will be found in the operating room when surgical plume, bone dust, chemical vapors from glues and other air contaminants are removed through effective smoke capture resulting in enormous savings in manpower costs for the surgical facility. Devices capable of achieving such capture in O.R.’s have not been available so that no comparable studies regarding absenteeism have yet been reported although such a device with such a capability has been describedxxii.

Certainly, the entire principle of laminar air flow dictates that infection rates are decreased by performing surgery in a clean air environmentxxiii. Consider the “sick building syndrome”xxiv, the deaths caused by primaryxxv and secondaryxxvi cigarette smoke inhalation and studies linking inhalation of asbestos to mesotheliomaxxvii decades after the exposure and COPD caused by, “...exposure to air pollutants in the ambient air and workplace environment...”xxviii for one to appreciate both the benefits and the liabilities of clean air or the lack thereof.

The risk of litigation to hospitals by their employees based upon a disregard by the administration of the tenets of the Clean Air Act and the General Duty Clause of the OSHA Act must be considered by the Compliance Officer of the healthcare facility whose concern it is to limit such liability. These federal regulations require that the employer (hospital) provide a safe working environment for their employees including non-contaminated air to breathe. Clearly, a smoke-filled operating room which harbors irritants and potential pathogens does not qualify as a “safe working environment.” Litigation related to the absence of clean air has already been ruled on by the courts in the plaintiff’s favorxxix xxx. Minimizing such exposure is critical and possible to achieve if such a solution is currently available and hospitals fail to act on such information.

While one can readily see the need to provide unadulterated air for the O.R. team to breathe during their working hours, how can it be done in a practical way? Past and current attempts have involved trying to have a team member corral smoke, which is hot and wants to rise quickly and disperse widely, toward a 3/8” I.D. or a 7/8” I.D. tube which is connected to a suction source. Unfortunately, these devices can be tiring to hold, interfere with the surgeon’s vision, require team involvement and most significantly, are often less than effective. Smoke is still inhaled and the smell is unpleasant for the team. They, in turn, have largely given up the effort, especially when the suction source is noisy or simply ineffective. Despite these impediments to use, some hospitals, recognizing the beneficial effects of clean air for their staff, have invested in central vacuum or individual units which unfortunately often go unused except if hospital policy mandates their use by the O.R. staff.

Why the indifference of staff to the health hazards of smoke in the O.R. but not when it invades their non-professional activities? Perhaps when they say, “Smoke is not a problem in my O.R.,” what they mean is...”There are no effective smoke capture devices so why should I bother?” This is akin to the coal miner that tolerates inhalation of coal dust because there are no alternatives to his making a living. After a number of years of exposure, he goes on to develop Black Lung Diseasexxxi. Allowing smoke-filled O.R.’s is that much more inane when one recognizes that smoking is not allowed either in or outside of the hospital.
Perhaps what is needed to get the O.R. nurse to use, if not become a champion of smoke evacuation, is a device that works; that is, a product that consistently provides clean air for the operating room. By definition, such a device must be capable of at least 95% smoke capture for prolonged periods of time without interfering with the surgeon’s protocols. Further, it should be simple for the nurse or surgical tech to use or apply to the patient, frees the team from involvement during the case and doesn’t obstruct the surgeon’s vision. To date, the methods available, notably the “wand” and the “ESU pencil” both have drawbacks. The wand requires a team member to chase the plume and commonly obstructs the surgeon’s vision although it collects smoke well if kept within 1” of the smoke source\textsuperscript{xii}. The ESU pencil, while convenient, causes hand fatigue, can interfere with vision and over time, has limited smoke capture ability\textsuperscript{xxiii}. The better solution may be a new device which has been introduced at tradeshows this year\textsuperscript{xxiv} and which has none of the problems cited above. Independent testing at a leading air quality laboratory has confirmed that the product captures 99.5% of plume versus 50% by the ESU pencil\textsuperscript{xxv}. The product called, “miniSquair\textregistered,” is applied to the skin circumferentially around the wound and is connected via tubing to a suction source capable of generating a minimum of 25-35 cubic feet/minute (cfm) of air flow. 

It is barely visible beneath the surgical drape. Because of the flexibility of its cell foam core through which the smoke exits the wound, retractors can be used. If necessary, the device can be incised to lengthen the incision. It is disposed of as contaminated waste. It is made of fire retardant materials and its cost is modest. It’s called, “miniSquair\textregistered,” which denotes its shape and its promise to bring clean air back to the operating room. It is manufactured by Nascent Surgical, LLC of Eden Prairie, Minnesota and its expanded use is to be anticipated now that the device is readily available.

It promises to improve \textbf{compliance} of federal rules and guidelines which require a safe working space for employees. The improved air quality should, as shown in other environments, result in a \textbf{lower rate of absenteeism} with a subsequent \textbf{reduction in manpower costs}. Finally, the Squair should limit the potential for worker’s compensation claims for respiratory illnesses related to exposure to the contaminated air in the O.R. For example, the worker presents to the doctor for a respiratory illness. The doctor asks if there was any exposure to irritants such as smoke, chemicals, etc. The worker says, ‘Yes. I work in the operating room.” \textbf{That claim could potentially cost three times the amount of the medical charges in premiums over three years because of the impact on the “experience modification factor.”}
References


iii The Joint Commission Accreditation Program: Hospital Environment of Care. Standard EC.02.02.01, 2008.


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Olson, B. Memo from Particle Calibration Laboratory Manager, Department of Mechanical Engineering, University of Minnesota dated December 1, 2011.
This is Serious Stuff

July 29, 2015

The other day my accountant came by to “do the books” and left a sheaf of papers on my desk held together by a big metallic clip at the top. “Here are the results of my internet search for ‘clean air’ articles. You should look them over.” Naturally, since my CPA is a pretty smart guy, I did as I was told. I noted that they were brief summarized articles that were gathered together by a group called NACAA (National Association of Clean Air Agencies). It was accessed on June 26, 2015 at http://www.4cleanair.org/news.

Who knew?

It didn’t take me long to spot an article entitled, “Study Links PM 2.5 Exposure Below NAAQS to High Death Rates” dated June 3, 2015. “Researchers from the Harvard T. H. Chan School of Public Health report that both short- and long-term exposure to fine particulate matter (PM 2.5) is significantly associated with higher death rates among people over 65…The study concluded that for short-term (two-day) exposure, there is a 2.14% increase in mortality for every 10 ug./m³ increase in PM 2.5 concentrations and for long-term (annual) exposure there is a 7.52% increase in mortality for every 10 ug/m³ increase. This association held true even where PM 2.5 concentrations were less than one-third the current NAAQS (National Ambient Air Quality Standards).” Ref. Laden F, Neas LM, Dockery DW, Schwartz J. Association of Fine Particulate Matter From Different Sources With Daily Mortality in Six U.S. Cities. Environm.Hlth Perspect. 2000: 108(10); 941-947.

What this study means to me is that:

1. Inhalation of ambient air particulates of 2.5 um size or less, which actually consist mostly of nanoparticles (also called “ultrafine particles”) takes time for its related diseases to become manifest. Although PM 2.5 primarily cause respiratory and cardiac diseases, nanoparticles only add to this list of ailments (Blog # 7).

2. Long-term exposure predisposes to premature death.
A second article indicated that this cascade of ill health can be interrupted when available protective technologies are used consistently for community-based efforts. Entitled, “Improved Air Quality Linked to Improved Children’s Health,” dated March 5, 2015 and published in The New England Journal of Medicine, related that “…researchers from the University of Southern California concluded that improved air quality is associated with statistically and clinically significant improvements in childhood lung function.”

The direct relationship between concentrations of airborne particles and respiratory mortality is documented in “Analyzing the health effects of simultaneous exposure to physical and chemical properties of airborne particles” by Pirani M, Best N, Blangiardo M, et. al. in Environ. Int. 2015; June, 79; 56-64. They reported that a consistent reduction in annual airborne particles resulted in an average annual decrease in respiratory mortality of 3.5%.

The additional effects of inhalation of PM 2.5 were detailed in a study by Woodruff TJ, Parker JD and Schoendorf RC in “Fine Particulate Matter (PM 2.5) Air Pollution and Selected Causes of Postnatal Infant Mortality in California” published in Environ. Hlth. Perspect. 2006: 114(5); 786-790. Their study reported a higher incidence of SIDS and postnatal deaths related to long-term exposure to PM 2.5.

Please note that the above articles all appear, as do hundreds of other articles about the effects of particulates on human health, in the environmental health journals while none appear in the surgical journals except for AORN J. which has shown consistent leadership in this battle to provide clean air in the country’s operating rooms. Thus, do not blame uneducated surgeons too much (a little is O.K.) for their reticence to use smoke evacuation technology; blame their journal’s editorial boards who have lacked the vision to publish data that supports efforts to prevent chronic inhalation of surgical plume by publishing articles about the topic, data that could have brought the surgeon’s attention to this topic.

Nonetheless, the “cat is out of the bag.” We know the above-mentioned relationships are true so as perioperative nurses, techs and physician advocates, do your best to educate your surgeons and work to protect both your health and that of your patients (Schultz LS. Can Efficient Smoke Evacuation Limit Aerosolization of Bacteria? AORN J. 2015; 102(1); 7-14).

DO IT!
Control of Smoke From Laser/Electric Surgical Procedures

HAZARD

During surgical procedures using a laser or electrosurgical unit, the thermal destruction of tissue creates a smoke byproduct. Research studies have confirmed that this smoke plume can contain toxic gases and vapors such as benzene, hydrogen cyanide, and formaldehyde, bioaerosols, dead and live cellular material (including blood fragments), and viruses. At high concentrations the smoke causes ocular and upper respiratory tract irritation in health care personnel, and creates visual problems for the surgeon. The smoke has unpleasant odors and has been shown to have mutagenic potential.

CONTROLS

NIOSH research has shown airborne contaminants generated by these surgical devices can be effectively controlled. Two methods of control are recommended: Ventilation and Work Practices.

VENTILATION

Recommended ventilation techniques include a combination of general room and local exhaust ventilation (LEV). General room ventilation is not by itself sufficient to capture contaminants generated at the source. The two major LEV approaches used to reduce surgical smoke levels for health care personnel are portable smoke evacuators and room suction systems.

Smoke evacuators contain a suction unit (vacuum pump), filter, hose, and an inlet nozzle. The smoke evacuator should have high efficiency in airborne particle reduction and should be used in accordance with the manufacturer's recommendations to achieve maximum efficiency. A capture velocity of about 100 to 150 feet per minute at the inlet nozzle is generally recommended. It is also important to choose a filter that is effective in collecting the contaminants. A High Efficiency Particulate Air (HEPA) filter or equivalent is recommended for trapping particulates. Various filtering and cleaning processes also exist which remove or inactivate airborne gases and vapors. The various filters and absorbers used in smoke evacuators require monitoring and replacement on a regular basis and are considered a possible biohazard requiring proper disposal.

Room suction systems can pull at a much lower rate and were designed primarily to capture liquids rather than particulate or gases. If these systems are used to capture generated smoke, users must install appropriate filters in the line, insure that the line is cleared, and that filters are disposed properly. Generally speaking, the use of smoke evacuators are more effective than room suction systems to control the generated smoke from non-endoscopic laser/ electric surgical procedures.
WORK PRACTICES

The smoke evacuator or room suction hose nozzle inlet must be kept within 2 inches of the surgical site to effectively capture airborne contaminants generated by these surgical devices. The smoke evacuator should be ON (activated) at all times when airborne particles are produced during all surgical or other procedures. At the completion of the procedure all tubing, filters, and absorbers must be considered infectious waste and be disposed appropriately. New filters and tubing should be installed on the smoke evacuator for each procedure. While there are many commercially available smoke evacuator systems to select from, all of these LEV systems must be regularly inspected and maintained to prevent possible leaks. Users shall also utilize control measures such as "universal precautions," as required by the OSHA Blood-Borne Pathogen standard.

For More Information

To obtain more information about controlling this hazard, or for information on other occupational health and safety issues, call the National Institute for Occupational Safety and Health (NIOSH) at:

1-800-35-NIOSH (1-800-356-4674)

The following reports on this topic are available free upon request from NIOSH:


*NIOSH is the Federal agency responsible for conducting research and making recommendations for preventing work-related illness and injuries. HAZARD CONTROLS are based on research studies that show reduced worker exposure to hazardous agents or activities.

Acknowledgements

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DHHS (NIOSH) Publication No. 96-128
Nanomaterials and nanoparticles: Sources and toxicity

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Abstract
This review is presented as a common foundation for scientists interested in nanoparticles, their origin, activity, and biological toxicity. It is written with the goal of rationalizing and informing public health concerns related to this sometimes-strange new science of ‘nano’, while raising awareness of nanomaterials’ toxicity among scientists and manufacturers handling them. We show that humans have always been exposed to tiny particles via dust storms, volcanic ash, and other natural processes, and that our bodily systems are well adapted to protect us from these potentially harmful intruders. The reticuloendothelial system in particular actively neutralizes and eliminates foreign matter in the body, including viruses and non-biological particles. Particles originating from human activities have existed for millennia, e.g. smoke from combustion and lint from garments, but the recent development of industry and combustion based engine transportation has profoundly increased anthropogenic particulate pollution. Significantly, technological advancement has also changed the character of particulate pollution, increasing the proportion of nanometer-sized particles - “nanoparticles” and expanding the variety of chemical compositions. Recent epidemiological studies have shown a strong correlation between particulate air pollution levels, respiratory and cardiovascular diseases, various cancers, and mortality. Adverse effects of nanoparticles on human health depend on individual factors such as genetics and existing disease, as well as exposure, and nanoparticle chemistry, size, shape, agglomeration state, and electromagnetic properties. Animal and human studies show that inhaled nanoparticles are less efficiently removed than larger particles by the macrophage clearance mechanisms in the lung, causing lung damage, and that nanoparticles can translocate through the circulatory, lymphatic, and nervous systems to many tissues and organs, including the brain. The key to understanding the toxicity of nanoparticles is that their minute size, smaller than cells and cellular organelles, allows them to penetrate these basic biological structures, disrupting their normal function. Examples of toxic effects include tissue inflammation, and altered cellular redox balance toward oxidation, causing abnormal function or cell death. The manipulation of matter at the scale of atoms, “nanotechnology”, is creating many new materials with characteristics not always easily predicted from current knowledge. Within the near limitless diversity of these materials, some happen to be toxic to biological systems, others are relatively benign, while others confer health benefits. Some of these materials have desirable characteristics for industrial applications, as nanostructured materials often exhibit beneficial properties, from UV absorbance in sunscreen to oil less lubrication of motors. A rational science-based approach is needed to minimize harm caused by these materials, while supporting continued study and appropriate industrial development. As current knowledge of the toxicology of ‘bulk’ materials may not suffice in reliably predicting toxic forms of nanoparticles, ongoing and expanded study of ‘nanotoxicity’ will be necessary. For nanotechnologies with clearly associated health risks, intelligent design of materials and devices is needed to derive the benefits of these new technologies while limiting adverse health impacts. Human exposure to toxic nanoparticles can be reduced through identifying creation-exposure pathways of toxins, a study that may some day soon unravel the mysteries of diseases such as Parkinson’s and Alzheimer’s. Reduction in fossil fuel combustion would have a large impact on global human exposure to nanoparticles, as would limiting deforestation and desertification. While ‘nanotoxicity’ is a relatively new concept to science, this review reveals the result of life’s long history of evolution in the presence of nanoparticles, and how the human body in particular has adapted to defend itself against nano particulate intruders.
December 2, 2013

Dear Dr. Schultz,

The functional analysis of ten pre-sterilization "Mini-Squair" smoke capture devices was determined by measuring the smoke capture effectiveness. Smoke was generated by cutting pork tissue using an electrosurgical pencil in a test chamber and measurements of the smoke concentrations were performed downstream in an exhaust duct using a condensation particle counter. The "Mini-Squair" was connected to a smoke evacuator pump that was turned on and off to determine its smoke capture effectiveness. Room air background concentrations were measured and subtracted. Figure 1 shows a schematic diagram of the test setup. Nascent Surgical, LLC provided all of the "Mini-Squair" smoke capture devices that were tested at the Particle Calibration Laboratory of the University of Minnesota under my direction.

The smoke capture effectiveness was determined by measuring the smoke penetration using the following equation:

\[ \text{Pen., } \% = \frac{\text{C}_{\text{on}} - \text{C}_{\text{BG}}}{\text{C}_{\text{off}} - \text{C}_{\text{BG}}} \times 100 \]

where:
- Pen. = Smoke penetration in percent
- C_{on} = Concentration in exhaust duct with Mini-Squair turned on [#/cc]
- C_{off} = Concentration in exhaust duct with Mini-Squair turned off [#/cc]
- C_{BG} = Concentration of room air background [#/cc]

and, the smoke capture effectiveness is defined as:

\[ \text{Eff., } \% = 100 - \text{Pen., } \% \]

Table 1 provides the smoke capture effectiveness of each "Mini-Squair" device along with the average of the ten devices tested, which was found to be 98.0%.

Sincerely,

[Signature]

Bernard Olson, Ph.D.
Particle Calibration Laboratory Manager
November 21, 2011

Dear Dr. Schultz,

The functional analysis of post three-year simulated accelerated aging of the “Squair” smoke capture devices was determined by measuring their smoke capture effectiveness. Smoke was generated by vaporizing pork tissue using a CO₂ laser set at 15 watts, pulsating mode in a test chamber. Measurements of the smoke concentrations were performed downstream in an exhaust duct using a condensation particle counter with the laser turned on and off at defined intervals. In addition, room air background concentrations were measured. Figure 1 shows a schematic diagram of the test setup. Thirty (30) Squair smoke capture devices (Model # 200-000-002, Lot # 04281102) were provided by Nascent Surgical, LLC and tested at the Particle Calibration Laboratory of the University of Minnesota.

The smoke capture effectiveness was determined by measuring the smoke penetration using the following equation:

\[ \text{Pen., \%} = \left( \frac{C_{\text{on}} - C_{\text{BG}}}{C_{\text{off}} - C_{\text{BG}}} \right) \times 100 \]

where:
- \( C_{\text{on}} \) = Concentration in exhaust duct with Squair turned on [#/cc]
- \( C_{\text{off}} \) = Concentration in exhaust duct with Squair turned off [#/cc]
- \( C_{\text{BG}} \) = Concentration of room air background [#/cc]

and, the smoke capture effectiveness is defined as:

\[ \text{Eff., \%} = 100 - \text{Pen., \%} \]

Table 1 provides the smoke capture effectiveness for each of the thirty (30) Squair units. The range was from 97.9% to 100% with the average value being 99.5%.

Sincerely,

\[ \text{Bernard Olson, Ph.D.} \]

Particle Calibration Laboratory Manager
An Analysis of Surgical Smoke Plume Components, Capture, and Evacuation
LEONARD SCHULTZ, MD, FACS

ABSTRACT

Chronic exposure to surgical smoke can transmit viruses; lead to respiratory illness; and increase the risk of more serious conditions, including Alzheimer disease, collagen and cardiac diseases, and cancer. Despite this, surgical smoke plume capture and evacuation devices are often used sporadically or not at all, and do not necessarily reduce costs per procedure. In addition, the current choices for smoke plume capture are varied, and health care providers may make decisions about what type of method to use based on marketing materials rather than facts, leaving most clinicians and managers frustrated and cynical about supporting the effort to capture surgical smoke plume. This article presents current data and information that purchasing teams can use to help choose the best available technology for their practice patterns. It also provides analysis to help those responsible for choosing smoke evacuation systems make rational decisions in their quest to provide a clean, safe environment in the OR. AORN J 99 (February 2014) 289-298. © AORN, Inc, 2014. http://dx.doi.org/10.1016/j.aorn.2013.07.020

Key words: surgical smoke, plume, smoke evacuation, surgical plume capture.

Perioperative personnel using electrosurgery and other smoke-generating equipment create surgical plume daily; however, those who are exposed to plume often remain skeptical of its harmful effects, largely because many lack knowledge about these effects, and those who understand this have a difficult time convincing others to use smoke evacuation.1 In addition, the surgical literature has remained static during the past 25 years, simply restating the chemical and particulate components of the plume.1 To support the risks of inhaling surgical plume, research has relied on studies of transmission of human papilloma virus via inhaling plume,1,2 the incidence of respiratory illnesses among perioperative nurses,3 and the presence of by-products in plume that are known to produce cancer and which the National Institute for Occupational Safety and Health claims are mutagenic and carcinogenic.4,5

The environmental health literature reveals that nanoparticles, which comprise 80% of surgical smoke, are the real danger of inhaled smoke.6 These particles, also called “ultrafine particles,” are less than 100 nanometers (nm) in size (ie, 0.1 micron). Those between 20 and 80 nm are not well phagocytized by alveolar macrophages when inhaled, allowing these entities to cross the alveolar membranes by a process of translocation,
enter a person’s blood and lymphatic circulatory systems, and travel to various distant organs.7 When chronically exposed to surgical smoke, research results have indicated that individuals may be exposed to increased risk of diseases that include Parkinson disease and Alzheimer disease; collagen and cardiac diseases; and lung, breast, and prostatic cancers.8 It is this information, which has not found its way into surgical and nursing journals, that should make efficient capture and evacuation of surgical plume an OR priority. It is the purpose of this article to provide data-driven information to surgical facility personnel that will explain the options and the rationale for cost-effective purchase of available products.

BACKGROUND
The history of smoke plume or bioaerosol removal in the OR and the rationale for making the effort has been previously reported,9,10 but an explanation of terms is often needed. Smoke capture is the ability to gather the plume produced during a surgical procedure and route it to a collection site. Examples of devices that are used to capture plume include smoke evacuation suction wands and electrosurgical unit (ESU) pencils that are attached to tubing, which is, in turn, connected to smoke evacuation filters. It is commonly accepted that Wyman Stackhouse introduced the original smoke evacuator system to the OR in the mid 1980s for the purpose of collecting laser-generated smoke plume, although Stackhouse never published. His system consisted of a 6-inch hard plastic attachment that he called a wand that fit into the end of the smooth-bore tubing, sometimes called respiratory tubing because it is commonly used by anesthesia professionals in respiratory breathing circuits. The wand had a 7/8-inch internal diameter (ID) tube that was joined to 8 feet of 7/8-inch ID smooth-bore tubing attached to suction. Stackhouse established the 7/8-inch ID standard for tubing that remains the standard for adapters present on today’s filters and evacuators. Currently, wands consist of a cuffed end of 7/8-inch ID flexible tubing that is covered by a latticed screen to prevent sponges or tissue from being sucked into the tubing (Figure 1).

The ESU pencil (Figure 2) with suction evacuation tubing is a monopolar electrode pencil with a 3/8-inch ID tube attached with an orifice that can be placed at varying distances from the tip of the electrode. The tubing length can vary between 8 and 10 feet. The newest capture device available is based on cell foam technology.11 It has an open cell...
foam core sandwiched between layers of nonporous plastic to retain the smoke within the device and to prevent loss of suction power (Figure 3). It has an uncovered edge that serves as the entry site for captured smoke. The smoke then travels via a 1.25-inch ID tubing to a suction source required by all of the capture devices. The unique characteristics of these three devices are summarized in Table 1.

Smoke evacuation is the ability to capture the smoke generated at the surgical site and remove it to an area away from the surgical team where it can be filtered. The plume passes through a filter or filters, after which it is returned to ambient OR air. Examples of such devices are desktop suction pumps called local exhaust ventilators (Figures 4 and 5). The use of local exhaust ventilators is recommended by professional organizations and governmental health agencies. These machines are attached to ultra-low particulate (penetration) air (ULPA) filters that include activated charcoal that absorbs and deodorizes chemicals and the odors present in the plume. These ULPA filters remove 99.9995% of contaminants 0.12 microns or larger in diameter. They act to trap the larger particles present in smoke by intercepting them, and smaller particles are trapped as they diffuse in the filter. They are made from microscopically sized fibers and glass. Less commonly, surgical smoke is removed to a distant site without recirculation of the filtered air. These central evacuation systems remove the smoke directly to a remote site without using filters, and the capture device connects through tubing to a control panel that controls the flow rate (Figure 6). The capture device usually is located in a boom or tower that descends from the OR ceiling where the valves and the tubing that carries the smoke to a distant site are located.

Factors That Influence Smoke Capture
The ability to capture plume during surgery depends on several factors, including the
- distance of the device from the source of smoke production,
- power of the suction source and its ability to produce a requisite minimum volume of airflow.

<table>
<thead>
<tr>
<th>Smoke capture method</th>
<th>Average smoke capture efficiency (%)</th>
<th>Involvement by clinician</th>
<th>Possible vision obstruction</th>
<th>Possible hand fatigue</th>
<th>Disposable</th>
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</thead>
<tbody>
<tr>
<td>Wand</td>
<td>95%</td>
<td>Yes</td>
<td>Yes</td>
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<td>Yes</td>
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<tr>
<td>Electrosurgical unit pencil suction</td>
<td>51.4%</td>
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<tr>
<td>Cell foam technology</td>
<td>99.5%</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Surgimedics Surgifresh Model smoke evacuator used for suction along with the Surgifresh ultrafine particulate air filter.
internal diameter of the tubing that connects the capture device to the filter system placed in line with the suction machine, and

- amount of smoke produced during the procedure.

Factors that indirectly influence the ability to remove smoke include personnel availability, incision length, and the attitudes of the surgical team toward smoke evacuation.

Unpublished 2013 data from Olson and Schultz indicate that the 7/8-inch (22-mm) ID wand connected via tubing to a smoke evacuator and capable of generating 45 cubic feet per minute (cfm) of airflow at full power captured 99% of smoke at 1 inch from the source versus 53% when placed 3 inches from the smoke source. The importance of distance reflects the fact that heated smoke rises rapidly and disperses in all directions due to Brownian motion and available air currents. The only way to gather the smoke is to have suction airflow capable of capturing the ambient air above the dispersed smoke, which then pulls the plume toward the device.

Schultz et al showed the need to achieve a minimum airflow of 17 to 22 cfm under ideal conditions to capture smoke effectively after it has left the surgical wound. To prevent loss of smoke in the event of diminished suction, a minimum airflow of 25 to 35 cfm is recommended. This airflow needs to be calculated to include all components in the system (eg, a high-resistance filter or capture system could decrease the net airflow below effective levels).

An important but often overlooked component that can either limit or improve acceptable airflow is the ID of the system’s tubing. A tube that is too small also can be a source of an unacceptable noise level. Most evacuation tubing is either smooth bore or corrugated because tubing with these internal surfaces does not produce significant noise, whereas collapsible expansion tubing can produce a loud noise that is an unacceptable distraction to perioperative personnel. The effect of tubing diameter on airflow has been demonstrated by data from
the manufacturers of the ESU pencil that is now in common use as a smoke capture device. This product has a 3/8-inch ID tubing that is attached to a monopolar electrode. The tube orifice is located 1 to 1.5 inches from the tip of the electrode. This generates 3.5 to 5.0 cfm of airflow when connected to an in-line ULPA filter and then to the wall suction.\(^{17}\) If perioperative personnel connect this device to a dedicated smoke evacuator, however, airflow increases to 11 to 15 cfm with an accompanying improvement in capture efficiency.\(^{18}\)

Some smoke evacuation systems may use a slightly wider (eg, 25-mm or 1.2-inch ID) tubing because, given the same suction strength, the additional width can increase airflow by 5% to 10% compared with a 22-mm (7/8-inch) ID tubing (David Mulder, engineering manager, Semiconductor and Integrated Venting Solutions, Donaldson Company, Minneapolis, MN, personal communication, March 2011). Some facilities may use older suction devices that lack adequate airflow, and this larger diameter and enhanced flow can mean the difference between effective and ineffective smoke capture.

After smoke is captured, to the extent that a device’s efficiency allows, various pathways for removal (ie, evacuation) are possible. Typically, the wand or the cell foam—based devices rely on a desktop or standalone smoke evacuation unit. These usually are capable of the required 25 to 35 cfm of airflow or more. Should they only be able to generate 20 to 25 cfm of airflow, then the plume may not be able to travel more than 2 to 3 inches to the collection device. Higher flow units, however, allow movement of smoke across longer distances and provide higher capture efficiency. For example, the RN circulator can either connect the ESU pencil suction tubing to the OR wall suction or attach it directly to a dedicated smoke evacuator that, as mentioned previously, enhances its efficiency. If the RN circulator attaches the pencil suction tubing to wall suction, then an in-line ULPA filter should be used to prevent particulates from entering the tubing within the wall. Alternatively, it can be attached to a suction canister that has a high-efficiency particular air (HEPA) filter in its top entry port that can trap particulates.

Not all procedures need powerful suction (eg, laparoscopic procedures), but all procedures that produce smoke need smoke capture. Procedures that produce little smoke can be adequately serviced with an ESU pencil suction when only monopolar cautery is used. A wand or the newer cell foam—based products can capture smoke when other heat transfer devices (eg, lasers, bipolar cautery) are used. Additionally, if the patient’s incision is small (eg, 1 to 2 inches) and if the ESU pencil suction interferes with the surgeon’s vision, then the scrub person can attach a regular suction tube with or without the modified cuffed wand end to the drape near the surgical site, and this can serve as an effective method of smoke capture. A recently unpublished study showed that a suction wand is capable of efficiently capturing 95% to 99% of smoke, assuming adequate levels of suction, when the tube’s orifice is located within 2 inches of the smoke source (Olson B, Schultz L, unpublished data, 2013). In such situations, the assistants would not need to follow and capture the smoke plume and they can then devote their full attention to the surgeon’s needs.

**REASONS THAT SMOKE EVACUATION IS NOT USED**

A dismissive attitude toward the risks of smoke inhalation is often the decisive factor in choosing not to use smoke evacuation devices. Refusal by a surgeon to allow smoke evacuation is usually a reflection of

- concern that an altered protocol could negatively affect the surgical result,
- anxiety associated with any change to routines,
- a lack of knowledge about sources that recommend the removal of smoke,
- a lack of enthusiasm for smoke removal on the part of administrators or nursing personnel,
- distraction caused by the noise generated by the smoke evacuator,
unavailability of devices that achieve high efficiency capture, or

- devices that require the surgeon’s involvement.

All of these factors can be overcome by education, use of quieter smoke evacuators, and use of capture devices that remove smoke without requiring staff members to set them up. After educators and vendors present educational material to surgeons and other perioperative personnel, they often become strong advocates of the use of smoke evacuation.

Factors that affect acceptance of these units by perioperative personnel include noise levels and ease of use. Use of these units must require minimal effort because a complicated setup can be seen by clinicians as unnecessary interference with other preparation needed before surgery can begin. Staff members’ acceptance of the technology also requires cooperation from the surgeons with whom they work. In general, surgeons want no disturbance of their protocols or ability to see or access the surgical site and want a noise level that does not distract them from concentrating. Thus, ease of connecting the capture device to the ULPA filter, which is attached to a smoke evacuator that does not exceed 50 to 55 decibels, has been found to be acceptable to most clinicians.19

The heart of any effective smoke or bioaerosol collection system is the ULPA filter that traps aerosolized particles as small as 0.12 microns or 120 nm in size. Should a prefilter be part of the circuit, perhaps as a component of the ULPA filter, then some 96% of particulates as small as 0.3 microns in diameter are trapped, which in turn prolongs the useful life of the ULPA component. Such ULPA filters typically function for as many as 20 uses or for 20 to 30 hours before replacement is recommended by the manufacturer. After smoke plume is filtered, the air is then returned to the OR environment. An intermediate method of smoke evacuation is the use of smoke evacuation systems that include smoke capture devices. These devices can be used to capture smoke at the source or at a remote site and then return the filtered air to the OR environment.

Figure 6. The control module of a central smoke evacuation system accepts the evacuator tubing, and the smoke is conveyed to a remote site through a conduit located in the tower and the ceiling. Photograph printed with permission from Nascent Surgical, LLC.
evacuation is where a ULPA filter has been incorporated into a tower or boom in the ceiling directly over the OR bed. An example of this is the unit manufactured by Berchtold (Charleston, South Carolina), during the use of which, the smoke passes through the filter that is within the boom and the suction source is remote. The smoke is then removed from the room after filtration.

Another variation of a central smoke evacuation system transports the contaminated smoke plume, which is vented directly off-site without the use of a filter. At that site, the plume enters a collection tank where particulates of all sizes are washed down a drain connected to the sewer system. These units are powered by a turbine that generates the suction needed to provide smoke removal for all ORs within a facility. With this method, no filters are needed except an occasional HEPA filter that traps whatever particulates might possibly escape the collection tank. These HEPA filters remove 99.97% of particles 0.3 microns in diameter or larger and are made from similar materials and trap particles by the same mechanisms as do ULPA filters.13 These systems do not allow for any plume to re-enter the OR suite after processing. As shown in Table 2, nanoparticle penetration of ULPA filters increases as airflow increases to levels that are used clinically.20 Specifications for ULPA filters were determined at airflow rates that mimic breathing rates, which are approximately one-tenth those used for smoke evacuation.21 Analysis of the data indicates continued rebreathing by perioperative team members of nanoparticles derived from smoke, which argues for central disposal of captured plume. Desktop to central smoke evacuation systems are compared in Table 3. Further, should a central system be installed, the capital outlay can be recaptured within one to two years by avoiding replacement of ULPA filters. After the capital costs are returned, the per-use cost of evacuation is reduced to the cost of the capture device alone (Table 4).

<table>
<thead>
<tr>
<th>TABLE 2. Ultra-low Particulate Air Filter Particle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suction power setting</td>
</tr>
<tr>
<td>Specified 50%</td>
</tr>
<tr>
<td>100%</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>TABLE 3. Comparison of Smoke Evacuation Techniques</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desktop units</td>
</tr>
<tr>
<td>Noise based on manufacturer’s published specifications</td>
</tr>
<tr>
<td>Airflow</td>
</tr>
<tr>
<td>Nanoparticle capture</td>
</tr>
<tr>
<td>Uses ultra-low particulate air filters</td>
</tr>
</tbody>
</table>

dB = decibel; cfm = cubic feet per minute.

a Desktop units: Stryker Medical: 22 cfm with 7/8-inch tubing; Buffalo Filter: 44 cfm with 7/8-inch tubing; Surgimedics: 55 cfm with 1 1/3-inch tubing.
b Central evacuation units: Bechtold Corp: 30 cfm with 7/8-inch tubing; Central Vacuum system: 45 cfm with 7/8-inch tubing.
c Decibel units: Buffalo Filter: 49 dB to 62 dB; Stryker Neptune II: 55 dB; Bechtold Central system: 49 dB to 60 dB; Central Vacuum system: 50 dB to 55 dB.
Ambulatory Takeaways

Smoke Evacuation in an Ambulatory Surgery Center

More complex and longer procedures are being performed in ambulatory surgery centers, and this equates to more surgical smoke being produced. Reasons for not evacuating surgical smoke typically center around how the device affects the surgical procedure because they can be noisy, take up space, and obstruct the surgeon’s view. However, because exposure to surgical smoke can be as toxic as exposure to cigarettes and other carcinogens,1 the decision should focus on protecting all surgical team members and patients.

A systematic process should be conducted to choose smoke evacuation products. In addition to surgeon preference, important variables to consider include type and length of procedure, visibility at the surgical field, and amount of smoke produced. Another consideration is cost—standardizing products can help keep costs down. It is important to include surgeons in product selection to help ensure compliance, and industry partners are key in product selection, support, and subsequent education.

There are many new products available for surgical smoke evacuation, including an integrated electrosurgical unit pencil with smoke evacuation tubing, although the expense may be difficult to justify in centers in which minimally invasive procedures are primarily performed. Centralized smoke evacuation systems are ideal in inpatient facilities in which multiple open procedures are performed, but this option may not be practical or cost effective in an ambulatory surgery center setting. Using in-line filters with standard suction is an inexpensive way of evacuating surgical smoke in the ambulatory setting. In addition, evacuating smoke within 1 inch of the surgical incision and using a 7/8-inch corrugated tubing can be effective, although noise may be a limiting factor. Additional options include using an electrosurgical unit pencil adapter in which the pencil snaps into an adapter integrated with smoke evacuation tubing.

During laparoscopic procedures, surgical smoke often is evacuated because of poor visibility at the surgical field. Pausing and venting smoke to room air when visibility is compromised exposes surgical team members to surgical plume. There are several options available to evacuate laparoscopic-produced smoke. Some do not require suction or a smoke evacuator because intra-abdominal pressure vents smoke through a filter before it is introduced into the OR.

A key factor in deciding what smoke evacuation method to use is the effectiveness of the method. If perioperative personnel can see or smell smoke, then the method being used is either not appropriate or not working correctly. When collecting baseline data on compliance with evacuating surgical smoke, evaluation of appropriate procedures for which to use smoke evacuation, multidisciplinary evaluation of products, education, implementation, and data collection on compliance and continued sustainability would be a meaningful process improvement project.

Terri Link, MPH, RN, CNOR, CIC, is an ambulatory education specialist at AORN, Inc. Ms Link has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.

CONCLUSION

Surgical plume evacuation requires a more robust discussion than simply talking about dry eyes, a sore throat, or respiratory illnesses. There needs to be a greater awareness that the smoke and vapor contain the same contaminants as blood or other potentially infectious materials and that smoke potentially can transmit bacteria and viruses when inhaled. Whereas regulations about bloodborne pathogen transmission protect team members from blood and body fluid contamination, they do not regulate the use of smoke evacuation or protect perioperative nurses and surgeons from inhalation of surgical plume. In addition to posing an inhalation risk, research may demonstrate the possibility that smoke plume is a source of wound contamination. The ideal smoke evacuation system to protect surgical team members and patients is one that captures as much surgical smoke as possible and evacuates it to a remote site without recirculation of that air into the OR. Smoke evacuation systems must be tested and documented to be high quality and cost effective.

TABLE 4. Surgical Smoke Capture System and Central Suction Financial Analysis Tool

<table>
<thead>
<tr>
<th>Surgical facility smoke evacuation needs</th>
<th>ESU pencil system</th>
<th>Cell foam—based smoke capture system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of ORs</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Procedures per day per room</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Operating days per year</td>
<td>260</td>
<td>260</td>
</tr>
<tr>
<td>Percentage of open procedures</td>
<td>60%</td>
<td>60%</td>
</tr>
<tr>
<td>Capital equipment costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central suction turbine</td>
<td>$152,487</td>
<td></td>
</tr>
<tr>
<td>OR equipment per OR</td>
<td>$2,500</td>
<td></td>
</tr>
<tr>
<td>Tubing and fixtures</td>
<td>$28,200</td>
<td></td>
</tr>
<tr>
<td>Disposables costs per procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrosurgical unit pencil</td>
<td>$37.50</td>
<td>$0</td>
</tr>
<tr>
<td>ULPA filters</td>
<td>$23.25</td>
<td>$0</td>
</tr>
<tr>
<td>Cell foam—based surgical smoke capture system unit</td>
<td>$37.50</td>
<td>$0</td>
</tr>
<tr>
<td>Disinfectant</td>
<td>$0.25</td>
<td></td>
</tr>
<tr>
<td>Initial training costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central vacuum</td>
<td>$3,000</td>
<td></td>
</tr>
<tr>
<td>Module</td>
<td>$500</td>
<td></td>
</tr>
<tr>
<td>Annual servicing costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central vacuum</td>
<td>$1,000</td>
<td></td>
</tr>
<tr>
<td>Module</td>
<td>$500</td>
<td></td>
</tr>
<tr>
<td>Financing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bank interest (monthly)</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Repayment period (mo)</td>
<td>1 (up-front cost paid in full)</td>
<td></td>
</tr>
<tr>
<td>Monthly cost to hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amortized capital equipment and training expense</td>
<td>$234,187</td>
<td>$0</td>
</tr>
<tr>
<td>Open procedure disposables expense</td>
<td>$31,590</td>
<td>$19,630</td>
</tr>
<tr>
<td>Servicing expense</td>
<td>$150</td>
<td></td>
</tr>
<tr>
<td>Total monthly cost to hospital for term of loan</td>
<td>$31,590</td>
<td>$253,967</td>
</tr>
<tr>
<td>Total monthly cost to hospital after repayment</td>
<td>$31,590</td>
<td>$19,780</td>
</tr>
<tr>
<td>Payback period (mo)</td>
<td>18.8</td>
<td></td>
</tr>
</tbody>
</table>

ESU = electrosurgical unit; ULPA = ultra-low particulate air.

a Suggested average retail pricing from ESU “pencil” distributors, from Central Vacuum central smoke evacuation system distributors, and from Nascent Surgical, LLC. Final actual prices are proprietary and subject to individual hospital-company negotiation.

b Currently showing up-front costs paid in full on installation.
References


Leonard Schultz, MD, FACS, is CEO and chairman, Nascent Surgical, LLC, Eden Prairie, MN, and a former clinical assistant professor of surgery, Department of Surgery, University of Minnesota, Minneapolis, MN. As chairman of the board and an employee of Nascent Surgical, Dr Schultz has declared an affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.
Can Efficient Smoke Evacuation Limit Aerosolization of Bacteria?

LEONARD SCHULTZ, MD

ABSTRACT

Preventing surgical site infections requires knowledge of the sources of wound contamination. One possible source of wound contamination is bacteria aerosolized in diathermy plume (ie, surgical smoke). This study used an experimental model of porcine tissue embedded with Serratia marcescens to determine the extent of viable bacteria present in surgical plume. The results showed that only blended current electrosurgery, not laser plume or coagulation electrosurgery, contains viable bacteria. Further, the study revealed that placing a suction device near the electrosurgical site reduced the number of aerosolized viable bacteria. Therefore, evacuating the electrosurgical plume may help reduce contamination of the surgical wound. Nurses may wish to advocate for the use of air suction devices as one way to protect patients from surgical site infections.

Key words: diathermy plume, electrosurgical smoke, surgical site infections, surgical smoke evacuation, bacterial aerosols.

Surgical site infections (SSIs) are the second leading cause of health care—associated infections (HAIs). Many attempts at prevention have been evaluated, such as preoperative bathing, various times for hair removal or not at all, chemicals for surgical hand antisepsis, different antibiotic protocols, and controlled airflow in the OR. Despite these efforts, preventing the first step in infection, that of contamination, remains elusive. One obvious possibility of a source of wound contamination is diathermy plume (ie, surgical smoke), which is common to most surgeries. Surgical plume is defined as the bioaerosol created by electrosurgery, lasers, and high-powered drills and saws. Surgical plume has been shown to contain live viruses and bacteria, toxic chemicals, and particulates, as well as the patient’s own potentially contaminated body fluid in the form of blood and vapor. If surgical plume serves as a transfer vehicle for bacteria, then effective prevention could potentially lessen the economic impact of SSIs.

RESEARCH QUESTION/HYPOTHESIS

To fulfill the purpose of this research, an independent third-party team of bacteriology experts developed a laboratory model that allowed live bacteria to consistently exist in surgical plume. After they created that model, the team worked to answer the following question: Could such bacteria be made to disperse and aerosolize in surgical plume? Finally, if they determined that the model caused such dispersal, the team needed to answer another question: Could the use of a smoke capture and evacuation system capable of documented 98% to 100% smoke capture efficiency prevent or significantly decrease such dispersal?

STATEMENT OF SIGNIFICANCE TO NURSING

Nanoparticles that comprise 80% of surgical plume (L Schultz, unpublished data, 2013) can cross the alveolar membrane and

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proceed to distant internal sites and become associated with multiple systemic diseases. The ability to capture surgical plume effectively suggests the potential benefit to patients by reducing the chance for wound contamination.

LITERATURE REVIEW

Surgical site infections impose a staggering cost to our economy and to patients. Estimates for the treatment of SSIs in the United States average $25,546 per patient, for a total cost approaching $1.6 billion annually. A recent study cited the cost of HAIs as $147 billion annually in both the total cost of all HAIs, which includes causes such as catheter infections, sepsis, pneumonia, and urinary tract infections, as well as SSIs annually in both

- direct costs (eg, buildings, consultations, devices, equipment/technology, food, labor [eg, laundry, environmental control, administration], medications, procedures, supplies, testing [eg, laboratory, radiographic], utilities) and
- indirect costs (eg, home care costs, forgone leisure time, lost or diminished wages and worker productivity on the job for the patient and family members, morbidity [ie, both short-term and long-term], mortality, travel costs, spent time by family and friends for hospital visits).

Costs related to direct care of HAIs approached $45 billion per year.

Causes of SSIs

Multiple contributory causes of SSIs have been identified. These causes include

- a source for bacteria from a remote site in the patient (eg, lungs, urinary tract),
- vascular catheter contamination,
- malnutrition, or
- a compromised immune system.

The first two causes require seeding of bacteria from a remote site to the wound. Direct contamination of the wound also may occur in cases of intra-abdominal infection or bowel resection. In general, the most useful practice to reduce wound infection rates is to use laparoscopy, in which manipulations are accomplished through a trocar, or to place a protective barrier over the exposed wound margins. Both of these methods suggest the need for protection of open wound margins with a nonporous barrier. Two studies demonstrated decreased infection rates when plastic barriers (eg, trocars used during laparoscopy, nonporous sheets used during open surgery) were used to protect the wound opening from airborne contamination and manipulation of the wound that occurs by hand and with surgical instruments.

To make SSI prevention even more difficult, modern surgical techniques, improved home care, high inpatient costs, and new third-party payer rules contribute to the early discharge of pa-

Modern surgical techniques, improved home care, high inpatient costs, and new third-party payer rules contribute to the early discharge of patients, which may result in delayed recognition of infection.
be diagnosed that is far along in the process. Such costs are now being borne by the hospital and the health care practitioners because of a 2010 ruling by the Department of Health and Human Services, which no longer allows payment for complications for which readmission occurs within 30 days of original discharge. The need to determine the initiating cause and identify a method of preventing wound infection is now a major priority for all health care facilities and practitioners because such additional cost burdens could prevent hospitals from providing sustained community care. If a major contributory cause, such as surgical plume serving as the transfer vehicle for bacteria, is delineated, then effective prevention could lessen the economic impact of SSIs.

METHODS AND MATERIALS

An independent third-party team of bacteriology experts at Biotest Laboratories, Inc, Brooklyn Park, Minnesota, a subsidiary of Steris Corporation, Mentor, Ohio, independently developed the protocol, performance of the experiments, and tabulation of the results in response to questions given to them by the author. A series of three experiments was performed.

- In the first experiment, they developed the model that allowed bacteria to aerosolize from the target tissue (ie, porcine skin and fat) after vaporization with blended electrosurgery current.
- The second experiment was used to determine whether the carbon dioxide (CO₂) laser could duplicate the bacterial dispersion.
- In the third experiment, they compared the effects of coagulation and blended electric current, with and without suction, on bacterial aerosolization.

*Serratia marcescens* (ATCC 3880 lot number 247-26-4) was selected as the test bacteria for these experiments. The initial population was $1.7 \times 10^{10}$ colony-forming units (CFU)/0.1 mL, which was prepared as a suspension to a concentration of approximately $2.4 \times 10^2$ CFU/0.1 mL. The test tissue was a 3-oz segment of porcine skin and fat that had been irradiated with a gamma dose of 10.9 to 13.5 kilogray to achieve sterility.

Culture plates were made for air sampling from trypticase soybean agar and the culture plates used for wall and floor sampling of the enclosure as well as media plates from trypticase soybean agar and lecithin polysorbate 80. This was added to offset possible growth inhibition by the sodium hypochlorite solution that they used to clean the enclosure surfaces. The culture and media plates were placed at four quadrants around the target tissue.

All experiments were performed in a polymethyl methacrylate (ie, transparent thermoplastic) enclosure, henceforth referred to as the “glove box,” which measured 30” wide by 48” long by 30” high. One end of the long axis of the box had a loading air lock, which measured 12” wide by 14” long by 12” high. The air lock was separated from the glove box by a partition, which they opened to the box after they closed the door to the outside air. Sterile gloves were worn so that they could transfer the material aseptically from the air lock to the box and also maintain an aseptic environment within the chamber.

The following pieces of equipment were used for the experiments:

- Mega Power® Electrosurgical Generator, S/N 13910001, Ref. 1000, from Megadyne, Draper, Utah;
- Sharplan CO₂ Laser (model #1030) from Sharplan, Newport, Australia;
- PureVac™ Turbo Smoke Evacuator System (model #906150) with a ULPA-Clear™ filter (part #901301) from Surgimedics, San Antonio, Texas; and
- miniSQUAIR® Surgical Smoke Evacuation System (part #SQ20012-01, lot #04151304) and SQUAIR® Small Capture Device (model #200-000-001, lot #04281104) from Nascent Surgical, LLC, Eden Prairie, Minnesota.

**Experiment 1**

For the initial microorganism dispersal study, the researchers used the glove box after its interior was cleaned with sterile, low-lint wipes impregnated with a sporicidal solution of 1:50 sodium hypochlorite. All required media plates were passed from the air lock to the enclosure to maintain sterility. This included the

- air impact plates and the M Air T® air sampler impact device (Millipore Filter Corporation, Bedford, Massachusetts),
- sterile instruments and bacteria container with micropipettes and tips for seeding the bacteria on the porcine tissue,
- sterile monopolar electrode,
- sterile towels, and
- sterile capture devices.

The electrode wire, electrosurgical unit dispersive pad, and capture device tubing were passed out of the enclosure to their external connections through small side holes in the back wall, with the holes then closed over with tape to preserve isolation of the box contents. Four high-efficiency particulate air filters exited the top of the enclosure at its corners to allow air to enter the box when suction was applied.

Sterile towels were moistened with sterile saline and used them to create a basin 2 inches high with the electrosurgical unit dispersive pad at its base and the tissue placed over the dispersive pad. The RODACT™ (Replicate Organism...
Detection and Counting media plates (Becton, Dickinson and Company, Franklin Lakes, New Jersey) was placed 1 to 2 inches from and at four quadrants around the tissue leaning up against the towels (Figure 1). One air sampling plate was placed within the M Air T air sampler impact device, which was 2.5 feet from the target tissue.

The Serratia marcescens suspension was mixed, previously prepared with Pseudomonas isolation agar to ensure a known population, by vortexing for a minimum of 30 seconds and micropipetting 0.1 mL onto the meat surface. This was then allowed to stand for five minutes.

The electrosurgical generator was activated with a foot switch and applied the electrode’s blade to the impregnated meat continuously for 90 seconds. Settings included coagulation at 220 watts and cutting/blend at 220 watts. Surgical plume was allowed to permeate the chamber for each setting and set the air sampler intake at 300 L/min. Before and after completion of the two electrosurgical periods, they collected the plates and cultured them under standard conditions at 25°C (77°F) for three days before calculating colony counts.

**Experiment 2**

The researchers used the same methods and materials as in experiment 1, except that the Sharplan CO₂ laser, set at 20 watts pulsed mode, was used at 30 and 60 seconds. Samples were taken at these intervals with and without the use of capture devices attached to suction using an ultra-low-velocity jet evacuator system. Samples were collected from the glove box, which was used to create a sterile environment. Samples were taken at 5 Petri dishes with sterile agar placed within the glove box. (M Air T is a registered trademark of Millipore Filter Corporation, Bedford, MA. RODAC is a trademark of Becton, Dickinson and Company, Franklin Lakes, NJ.)

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**Figure 1.** Illustration of the transparent thermoplastic enclosure (ie, glove box). The porcine tissue embedded with Serratia marcescens is in the center of the well, surrounded in four quadrants by sterile RODAC™ agar-filled plates. The M Air T® air sampler in the right side of the box has a sterile RODAC plate on its top to sample any air or smoke present in the box. (M Air T is a registered trademark of Millipore Filter Corporation, Bedford, MA. RODAC is a trademark of Becton, Dickinson and Company, Franklin Lakes, NJ.)
particulate air filter and 45 cubic feet per minute airflow. The capture devices were placed on the rim of the towel basin with the attached suction turned on during the entire period of vaporization.

Experiment 3
The researchers used the same methods and materials as in experiment 1 in all aspects except that they used SQUAIR and miniSQUAIR capture devices on suction with their placement the same as seen in Figure 1. Only electrosurgery was used because lasing in experiment 2 failed to show any dispersion of bacteria.

RESULTS
The results of experiment 1, tabulated in Table 1, indicated that viable bacteria were present on plates 2 and 3, which they had placed in quadrants around the tissue vaporized with a cutting blended current. Viable bacteria were not present when coagulation alone was used. No colonies grew on the walls or floor of the glove box or in the air sampler. The results of experiment 2, tabulated in Table 2, indicate that no growth of viable bacteria was present at any site at any period of time after lasing. The results of experiment 3, tabulated in Table 3, show extensive bacterial growth in the Petri dish placed on top of the air sampler and decreased colonies in two of the four-quadrant Petri dishes. Plates 1 and 2 were far enough away from the SQUAIR and miniSQUAIR suction devices so that no protection against contamination was afforded these Petri dish sites. Protection was afforded only those sites (eg, plates 3 and 4) that were close to the miniSQUAIR and SQUAIR devices. Distance from the suction source no doubt played a role in these results.

DISCUSSION
The results indicate that live bacteria can exist in surgical plume that is produced with a blended electrosurgical current but not with the CO₂ laser or with pure coagulation electrosurgery at designated power settings. Previous studies have shown the laser’s ability to sterilize contaminated wounds, suggesting that the degree of heat transfer at higher temperatures determines the viability of bacteria that are exposed to the device. The culture results suggest that contamination of unprotected simulated wound margins can occur. Further, while such contamination can be significantly lessened with the use of high-efficiency smoke capture devices that are powered by effective suction, contamination cannot be prevented with current technology. Aerosolization of bacteria, however, can be prevented by such methods. Further, such aerosolization suggests a possible method for contamination of OR surfaces far from the operative site.

Table 1. Tabulated Results of Experiment 1: Colony-Forming Units Present

<table>
<thead>
<tr>
<th>Sample Designation</th>
<th>Colony-Forming Units of <em>Serratia marcescens</em> Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (before inoculation and cauterization)</td>
<td>5 0 6 0 7 0 8 0</td>
</tr>
<tr>
<td>Blended cutting mode</td>
<td>1A 0 2A 4 3A 8 4A 0</td>
</tr>
<tr>
<td>Coagulation mode</td>
<td>1B 0</td>
</tr>
<tr>
<td>Coagulation mode</td>
<td>2B 0</td>
</tr>
</tbody>
</table>

Table 2. Tabulated Results of Experiment 2—No Growth on Laser-Produced Samples

<table>
<thead>
<tr>
<th>Test setup</th>
<th>T = 0 Seconds</th>
<th>T = 30 Seconds</th>
<th>T = 60 Seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RODAC Plates</td>
<td>Air Samples</td>
<td>Tissue Samples*</td>
</tr>
<tr>
<td>SQUAIR® Small Capture Device</td>
<td>0 0 &lt;2</td>
<td>0 0 &lt;2</td>
<td>0 0 &lt;2</td>
</tr>
<tr>
<td>miniSQUAIR® Surgical Smoke Evacuation System</td>
<td>0 0 &lt;2</td>
<td>0 0 &lt;2</td>
<td>0 0 &lt;2</td>
</tr>
<tr>
<td>No device</td>
<td>0 0 &lt;2</td>
<td>0 0 &lt;2</td>
<td>0 0 &lt;2</td>
</tr>
</tbody>
</table>

*Sample with "<" sign indicates 0 colony-forming units were recovered. The stated value reflects the correction factor used during the testing.

The miniSQUAIR and SQUAIR are registered trademarks of Nascent Surgical LLC, Eden Prairie, Minnesota. RODAC is a trademark of Becton, Dickinson and Company, Franklin Lakes, New Jersey.
The data in this study indicate that the miniSQUAIR, because of its high capture efficiency of 99.5%, is potentially capable of preventing contaminated surgical plume from contacting material surfaces while still arguing for a direct covering of exposed wound margins during open surgery (L Schultz, unpublished data, 2013). The results of experiment 3 show the effectiveness of blended current to disperse the bacteria and the effectiveness of capture-suction technology to prevent bacterial aerosolization and to decrease contamination in areas closest to the capture devices. This technology may now be considered as a potentially beneficial method of infection control in the OR.

**STUDY LIMITATIONS**

The primary limitation of the study is that it is a laboratory simulation without inclusion of clinical material. Whether the glove box mirrors a surgical field is beyond the scope of this study.

**RECOMMENDATIONS FOR CLINICAL PRACTICE**

The literature review and the study results provide validation and strong reasons for including routine smoke evacuation in surgical practice. The ability of evacuation to prevent bacterial aerosolization and to diminish local dispersal suggests a vital potential protection for the surgical patient.

**RECOMMENDATIONS FOR FUTURE RESEARCH**

The next logical step would be to perform a double-blind study to determine the effect of high-efficiency smoke capture on the

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**Table 3. Tabulated Results of Experiment 3—Effectiveness of Tools to Prevent Aerosolization**

<table>
<thead>
<tr>
<th>Sample Designation</th>
<th>Baseline Testing: No Device, No Smoke Generation</th>
<th>SQUAIR® Small Capture Device With Smoke Generation</th>
<th>miniSQUAIR® Surgical Smoke Evacuation System With Smoke Generation, First Trial</th>
<th>miniSQUAIR® Surgical Smoke Evacuation System With Smoke Generation, Second Trial</th>
<th>No Device, Smoke Generation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Air impact plates</td>
<td>Air impact plates</td>
<td>Air impact plates</td>
<td>Air impact plates</td>
<td>Air impact plates</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>NTNC*</td>
</tr>
<tr>
<td></td>
<td>RODAC™ plates surrounding tissue</td>
<td>RODAC plates surrounding tissue</td>
<td>RODAC plates surrounding tissue</td>
<td>RODAC plates surrounding tissue</td>
<td>RODAC plates surrounding tissue</td>
</tr>
<tr>
<td>Tray 1</td>
<td>0</td>
<td>15</td>
<td>37</td>
<td>127</td>
<td>67</td>
</tr>
<tr>
<td>Tray 2</td>
<td>0</td>
<td>43</td>
<td>103</td>
<td>183</td>
<td>21</td>
</tr>
<tr>
<td>Tray 3</td>
<td>0</td>
<td>19</td>
<td>15</td>
<td>2</td>
<td>32</td>
</tr>
<tr>
<td>Tray 4</td>
<td>0</td>
<td>54</td>
<td>22</td>
<td>12</td>
<td>41</td>
</tr>
<tr>
<td>Average</td>
<td>0.0</td>
<td>32.8</td>
<td>44.3</td>
<td>81.0</td>
<td>40.3</td>
</tr>
<tr>
<td></td>
<td>RODAC plates used to test walls and floor</td>
<td>RODAC plates used to test walls and floor</td>
<td>RODAC plates used to test walls and floor</td>
<td>RODAC plates used to test walls and floor</td>
<td>RODAC plates used to test walls and floor</td>
</tr>
<tr>
<td>Side 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Side 2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Side 3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Side 4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Side 5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>15</td>
</tr>
<tr>
<td>Average</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

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*NTNC (i.e., too numerous to count) is any count greater than 300 colony-forming units for this size plate. The count has been estimated at 463 colony-forming units.

rate of SSIs in a variety of surgical specialties. The potential savings to the nation’s health care bill should add impetus to the initiation of such a clinical study. Aside from the clinical studies that could proceed from this research, the model could be used for studying the viability and dispersal of viruses and other bacterial entities after exposure to various surgical instruments such as bipolar cauterity and harmonic energy.

Other studies that could extend from the observation that effective smoke evacuation can limit aerosolization of bacteria could be those of OR surfaces after use of such technology in open surgical procedures. An ultimate question needs to be answered: If contamination were decreased or eliminated, what effect would that have on the cost of infection control materials and practices?

CONCLUSION
Standard bacteriological methods have been used to establish a laboratory model that allows live bacteria to exist in surgical plume. That model was used to show that effective smoke capture and evacuation can limit local dispersal and aerosolization of the bacteria tested. The effect that such smoke removal may have on the infection rate of open surgical wounds is yet to be determined.

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Editor’s notes: Mega Power is a registered trademark of Megadyne, Draper, Utah. PureVac™ and ULPA-Clear™ are trademarks of Surgimedics, San Antonio, Texas. miniSQUAIR® and SQUAIR®

www.aornjournal.org
References


Leonard Schultz, MD, is the chief executive officer and chairman of Nascent Surgical, LLC, and a clinical assistant professor of surgery (retired) in the Department of Surgery at the University of Minnesota, Minneapolis. As the chief executive officer of Nascent Surgical LLC, manufacturer of the Squair and miniSquair, Dr Schultz has declared an affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.
The same innovative designers of the first smoke evacuation method patented for laparoscopic procedures, now bring you the miniSQUAIR® for **open** surgical procedures.

**Nearly twice as effective as current smoke evacuation methods.**

**Proven Benefits to Surgeons**

- No Intraoperative Involvement
- Low Profile Does Not Obstruct Vision
- Allows Use Of Retractors
- Does Not Disturb Operative Protocols

*99.5% of surgical plume is captured with ETO Sterilization and 90.6% with Gamma Sterilization. University of Minnesota Department of Mechanical Engineering Particle Calibration Laboratory. Bernard Olson, Ph.D., Manager. Dtd. Nov. 21 and 30, 2011, and Oct. 18 and Dec. 2, 2013.*

U.S. patents: 6,942,650; Additional patents pending.
Why Perioperative Nurses Want the miniSQUAIR®

The miniSQUAIR® is almost unnoticeable after surgical drape is applied.

Adoption of the miniSQUAIR® Solves Multiple Challenges

Materials Management
• Cost neutral
• Reduces inventory (one size fits all)
• Self contained
• Ordered by a single part number

Occupational Health and Safety
• Twice as effective as current methods
• O.R. staff have twice the incidence of respiratory illness when compared to the general population
• Surgical smoke contains mutagenic and carcinogenic substances
• Fire retardant (UL 94 RH-1)
• Clean air has been proven to reduce absenteeism
• Currently used surgical masks do not protect from inhalation of nanoparticles

Sterile Components
Plenum with polyurethane cell foam core and polyethylene "skin"
Proprietary polypropylene "transition" adapter
25 mm I.D. x 96" corrugated LDPE/EVA tubing
Part Number: SQ20012-01

Non-Sterile Components
25 mm I.D. x 72" corrugated LDPE/EVA tubing
Proprietary pre-filter (96.4% BFE)
Proprietary adapters.
Part Number: SQNS 20018-01

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miniSQUAIR® Frequently Asked Questions

1. **Is this product registered and approved by the Food and Drug Administration (FDA)?**

   Yes to both questions. It is approved as a 510 (k) product and classified as a Class II sterile device.

2. **How do I apply the miniSQUAIR®?**

   Complete the surgical prep and dry. If you use a surgical barrier drape, apply that next; if not, then remove the white “release paper” and apply the miniSQUAIR® to the skin (or drape). Pass the end of the tubing to the circulating nurse for attachment to the ULPA filter or directly to the suction source. Complete the sterile field with towels and/or drapes as per protocol.

3. **Can I use retractors as needed?**

   Yes, everything from simple springs and rakes to heavy “ring” retractors can be used. As long as there is exposed cell foam, the product will continue to capture smoke.

4. **Can I use wall suction for the miniSQUAIR® as I do for the ESU?**

   No. Wall suction will not provide the volume of air flow needed to effectively capture the smoke which is 25-35 cfm.

5. **Can small biopsy specimens or sponges be sucked into the miniSQUAIR®?**

   No. The reticulated foam, because of the small “cell” size, will not allow unwanted removal of tissue or sponges. In fact, particulates such as hair, dust or fabric debris from masks or caps will be trapped by the cell foam core of the miniSQUAIR®.

6. **Can moistened lap sponges interfere with removal of the plume?**

   That is not likely, but it is best to avoid covering the edge of the open cell foam. The smoke will not pass through wet towels if used to cover the edges of an incision.
7. **What if body fluids or saline irrigation gets sucked up by the miniSQUAIR®?** Will the fluids prevent bioaerosol capture?

No. The miniSQUAIR® is non-porous to fluids as well as to smoke, so both will be carried to the source of suction. To prevent damage to the in-line filter(s) by the fluid, attach the hose to dual non-collapsible canisters or to a fluid-bioaerosol management system. If canisters are needed, you will also need an additional length of 25 mm I.D. tubing to connect the second canister to a surgical suction; wall suction will not provide enough air flow.

8. **Why use the wider 1 1/4” tubing instead of the standard 7/8” tubing?**

The tubing we have provided for use allows greater air flow than the standard tubing. The enhanced flow is one of the reasons why the miniSQUAIR® does a superior job of smoke capture while also increasing the efficiency of your surgical suction.

9. **Is the miniSQUAIR® “fireproof?”**

No, but it has been specially treated with fire retardant to earn a UL94RH-1 rating. This means that should it be set on fire, the device will self-extinguish.

10. **Why was it constructed with a cell foam core?**

The core allows no significant resistance to air flow while providing an excellent pathway for the removal of surgical plume, bone dust and chemical odors.

11. **What if I have additional questions? With whom and how can I contact a person knowledgeable about the product?**

Nascent Surgical is happy to put you in touch with an experienced clinician. Please call 952-345-1112 or e-mail info@nascentsurgical.com. We will promptly respond to your inquiry.
• Apply parallel to and within 1” of intended incision
• Can be applied to the skin or surgical drapes
• Will adhere to any body contour

Anterior Midline

Posterior Midline

Hip (anterior or lateral incision)

Breast

Breast with Local Excision

Knee
Placement Guide for the miniSQUAIR®

- Right Subcostal
- Thoraco-Abdominal
- Mid-Sternotomy
- Thoracotomy
- Suprapubic (Pfannenstiel) Incision
- Perineal (2 Positions)
- Perianal (2 Positions)