Control of Nanoparticle (Smoke) Inhalation in the Operating Room

Comparison of the Capture Efficiency of Three Devices

Introduction

The lack of acceptance for evacuation of surgical plume and other bioaerosols by surgeons has often resulted in discouragement of nurse's efforts to provide clean air in their work environment. There are many reasons for the surgeon's attitude and they include lack of any effective capture devices, scientific-based data, interference with surgical protocols and vision and disturbing noise volumes from the smoke evacuator pumps. Interestingly, the peri-operative nurses are often advocates for smoke removal, probably because they recognize the plume's adverse effects on their health from long-term exposure.

Aside from the oft-quoted components of smoke such as carcinogenic/mutagenic chemicals,[1] transmittable viruses[2] and contaminated body fluid present as vapor in the smoke[3] breathed by staff through ineffective face masks, we now add reports of inhaled nanoparticles that are associated with respiratory and cardiovascular diseases.[4,5] They also have been implicated in causing neurodegenerative illnesses such as Parkinsonism and Alzheimer's disease [6] and collagen diseases such as systemic lupus and rheumatoid arthritis .[7] Nanoparticles, usually in the 20-80 nanometer (nm) range, are less efficiently phagocytized by macrophages [8] and can cross the alveolar membranes, enter the circulatory and lymphatic systems[9] and translocate to distant sites such as the liver, lymph nodes and heart.[10] Those that are not well processed can result in oxidative stress resulting in cell death or induce cancers through their effect on mitochondria.[11]

Not as often discussed but still important issues for hospital risk and safety managers are the potential costs for future health-related disability and employment compensation claims based on an increased knowledge of nanoparticle-induced diseases that result from chronic exposure. This may prove to be especially problematic for administrators now that new smoke capture and evacuation system technologies allow highly efficient cleansing of operating room air. Thus, there is a need for surgical personnel, especially surgeons who are largely responsible for O.R. decisions, to be informed of such currently available devices.

Two primary methods of surgical smoke capture that are used are the "wand" and the "electrosurgical unit (ESU) "pencil." The wand, composed of a thick clear plastic tube or as an elongated cuff, either attached to or part of a 22 mm (seven-eight inch) internal

diameter (I.D.) low density polyethylene tubing, connects to a filter and source of suction capable of moving a minimum of 20-25 cubic feet per minute (CFM) of air/smoke. Once filtered and deodorized, the resultant air is returned to the operating room. Alternatively, the smoke can be removed by a central system to a remote site for processing and removal.

The ESU "pencil" is a standard monopolar electrode attached to a plastic hand grip or harness which has a built-in 5 mm (three-eight inch) I.D. coiled plastic tubing. The open end of the tubing is placed close to the site of smoke production, usually one inch from the tip of the electrode.[12] Closer placement results in interference with the surgeon's vision. The tubing diameter and the in-line ULPA filter to which it attaches before connecting to the in-wall suction, limits the air flow to three-point-five (3.5) to five-point-zero (5.0) CFM.[13] Alternatively, the tubing can be connected to a dedicated smoke evacuation system which can double the available air flow .[14]

The third recently introduced option consists of an open cell foam pad or plenum enveloped by two layers of non-porous material that is affixed close to the site of smoke generation. It has an open edge through which the smoke passes into the foam pad to a source of suction via eight (8) feet of 25 mm (1 ¼") I.D. corrugated tubing. [15]

Methods

The "Squair™" (Nascent Surgical, Model # 200-000-002, Lot # 04281102) was compared for smoke capture efficiency to the "wand" (Buffalo Filter, Model # Vacuum Hose VT 10324, Lot # 109835) and to the ESU "pencil" (Buffalo Filter, Model # PlumePen, Lot # 110301005) which was attached to ten feet of three-eights inch I.D. flexible tubing. The wand was connected to its clinical standard of eight feet of seven-eights inch I.D. smooth bore tubing. The Squair was attached to eight feet of one and one-quarter inch I.D. corrugated tubing. Both the wand and the Squair were connected to pre-filters (Nascent Surgical, Part # SQNS 10004-03) and the ULPA filters (Surgimedics, Model # ULPA-Clear, Part # 901301) which was connected to the standard surgical smoke evacuator. The ESU pencil had its three-eights inch I.D. tubing connected to an in-line filter (Buffalo Filter, lot 3061175) to trap particulates and then connected to the same smoke evacuator used for the wand and the Squair. In all cases, the evacuator was placed at its maximum setting. The target tissue used for smoke production was frozen pig skin and fat which was placed in a moist towel which covered a metal basin placed within an isolated chamber. The wand, ESU pencil and the Squair were all positioned one inch above the tissue unless stated otherwise.

Control of Nanoparticle (Smoke) Inhalation

To determine the effectiveness of the smoke capture devices, a test chamber and exhaust system was constructed as shown schematically in Fig. 1 to capture all of the smoke generated by cutting the tissue with the laser. The test chamber dimensions were 24 inches wide by 28 inches high by 24 inches deep. Clear Plexiglas sheets 24 inches by 24 inches by 1/8inch thick were mounted to the sides and the back of the chamber. The front of the chamber was sealed off with clear plastic wrap once the tissue sample, smoke capture device and laser were in place. This construction provided a two-inch gap at the bottom of the test chamber to allow air to flow into the chamber from all four sides. A 24 inch x 24 inch square-to-round transition was mounted to the top of the chamber and a six inch diameter exhaust duct was connected to the top of the chamber which ran vertical for 24 inches, followed by a 90 degree elbow where the exhaust duct then ran horizontal 8 feet to an external wall. An in-line blower was used to exhaust the remaining smoke and was connected to a variable voltage transformer to adjust the voltage and, therefore, the speed of the blower. The voltage was adjusted to provide a flow rate of 100 cubic feet per minute (CFM) in the exhaust duct. The flow rate was sufficient to prevent smoke from exiting the bottom of the chamber.

A sampling probe with a 0.10 inch I.D. inlet was placed in the center of the horizontal section of the duct 56 inches downstream from the vertical section to provide uniform mixing of the smoke in the duct. The probe was connected to 3/8 inch I.D. conductive tubing that ran 60 inches to a diluter with a 8.2 to 1 dilution ratio. The diluter was then connected to a condensation particle counter (CPC, model 3025, TSI, Inc., Shoreview, MN). The dilution was needed to reduce the concentration below the upper construction limit of the CPC of 10^5 particles/cc.

The smoke capture device being tested was mounted at the base of the test chamber and approximately centered front-to-back and side-to-side. It was connected to a vacuum pump (smoke evacuator Model Surgifresh Purevac Turbo, Surgimedics) using 8 feet of plastic tubing. A pre-filter (Part # SQNS 10004-03, Nascent Surgical) followed by an ULPA filter (Part # 90130, Surgimedics) was connected just upstream of the vacuum pump to remove the captured smoke.

A CO_2 laser (Model # 1030, Sharplan) was used as the heat source with an unfocused beam of 15 watts in pulsed mode of 0.5 seconds off and 1.0 seconds on. The end of the hand-piece of the laser was positioned at an angle to the tissue sample (3 ounces of pig skin/fat that was previously frozen) and one inch from its surface. The target area of the tissue sample was adjusted or it was replaced after each test to provide an unaffected area in response to the

vaporizing effects of the laser. The capture device to be tested was either mounted around or at a distance one inch away from the tissue sample and the vacuum pump suction was set to 100% unless otherwise noted. For a visual depiction, please see Figure 1.

The CPC was connected to a computer to collect the concentration data in one second intervals. The total sample time for each test was 240 seconds which was split up into sequential events as follows (see Figure 2): 1) 20 seconds used to measure room background concentration, 2) laser on cutting tissue sample for 50 seconds to measure the average smoke concentration, 3) vacuum pump to smoke capture device turned on while laser cutting for 40 seconds to measure smoke concentration not captured, 4) vacuum pump turned off while laser cutting for 30 seconds to measure the average smoke concentration a second time, 5) vacuum pump to smoke capture device turned on while laser cutting for 40 seconds to measure smoke concentration not captured a second time and 6) vacuum pump and laser turned off for 60 seconds to measure the background concentration at the end of the test. Only the last 10 second samples at the end of each event were averaged and used in the calculation of smoke capture effectiveness since some time was required after the conditions changed to reach steady-state as shown in Figure 2. This procedure was developed so that the smoke capture efficiency of the device, including background concentration subtraction, could be determined in a single test.

A scanning mobility particle sizer (SMPS, model # 3034, TSI, Inc.) was used to determine the particle size distribution of smoke generated when the laser cut the pig skin and fat tissue. Three 90 second samples were taken from the exhaust duct at the same location as that used for the CPC. Figure 3 shows the average particle size distribution and one standard deviation of the smoke generated. The program, DustFit™ (2009) was used to plot the histograms and fit the data assuming a log-normal distribution.[16] The reported number median diameter (NMD) is 33.3 nanometers (nm) with a geometric standard deviation (GSD) of 3.26. All of the smoke particles generated were in the respirable size range, being less than 500 nm in size and approximately 80% of the total particles were in the nanoparticle size range of less than 100 nm.

Results

The smoke capture effectiveness was determined by calculating the smoke penetration using the following equation:[17]

Pen., % = $[C_{on}-C_{BG}]/C_{off}-C_{BG}]*100$

Where: Pen.= Smoke penetration in percent
C_{on} = Average concentration in exhaust duct with device turned on [#/cc]
C_{off} = Average concentration in exhaust duct with device turned off [#/cc]
C_{BG} = Average concentration of room air background [#/cc]

And, the smoke capture effectiveness is defined as:

Eff., % = 100 – Pen., %

The test results for the smoke capture devices are summarized in Table 1.

Standard Medium Squair Smoke Capture Device

The smoke capture effectiveness of the standard medium Squair for seven tests is given in Table 1. The average efficiency was found to be 99.0% with a standard deviation of 1.3%. A photograph of the device in the test chamber is shown in Figure 4.

Standard Medium Squair Smoke Capture Device Post Three-Year Simulated Accelerated Ageing Tests

The smoke capture effectiveness of thirty standard medium Squair units that underwent simulated 3 year accelerated ageing tests is given in Table 2. The average efficiency was found to be 99.5% with a standard deviation of 0.4%.

ESU Smoke Capture Device With In-Line Filter And Evacuator Set To Simulate Wall Suction

The smoke capture effectiveness of the ESU “pencil” for tests is given in Table 3. The average Control of Nanoparticle (Smoke) Inhalation
efficiency was found to be 45.5% with a standard deviation of 28%. A photograph of the device in the test chamber is shown in Figure 5. The ESU was connected to an in-line ULPA filter with additional 3/8 inch extension tubing attached to the other end of the filter with the free end attached to the evacuator set at 50% power to simulate wall suction.

ESU Smoke Capture Device

The smoke capture effectiveness of the ESU for three tests is given in Table 4 where the

tubing attached to the ESU device was connected directly to the evacuator which was set at 100% power. The average efficiency was found to be 74.4% with a standard deviation of 4.9%.

Wand Smoke Capture Device

The smoke capture effectiveness of the wand for four tests is given in Table 5. The average efficiency was found to be 100% with a standard deviation of 0.1%. A photograph of the device in the test chamber is shown in Figure 6.

The smoke capture effectiveness of the wand was tested at three sampling distances from the tissue sample of 1 inch, 2 inches and 3 inches as shown in Table 6. The effectiveness decreased significantly when going from 2 to 3 inches from the source of smoke.

Discussion

As noted, Figure 3, which shows the size of the smoke components, supports previous data that the majority of particles within surgical plume are less than 0.1 micron (um) in diameter, and are small enough to be inhaled to the alveolar level. From there, they can migrate to all parts of the body to exert their cumulative effects.

Data from the Squair, both before (Table 1) and after ageing simulation (Table 2) are consistent with very tight standard deviations (1.3% and 0.4% respectively). Such results indicate that ageing, which simulates actual shelf life where one month in the chamber equals one year on the shelf, supports the usefulness of such testing to allow an expiration date on the label and is a measure of the Squair's functional reliability over time.

Table 3 data shows that the ESU "pencil," as currently used with an in-line filter connected to wall suction, is relatively less effective than other methods. This is documented by its large standard deviation of 28%. Conversely, much better performance for the "pencil" is achieved when a dedicated smoke evacuator is substituted for the in-line filter and wall suction. The function of the device compared to the Squair, however, remains significantly lower ($p<0.01$).

Table 5 and 6 clearly show the effectiveness of the wand connected by a length of 7/8 inch tubing to a smoke evacuator, especially when the opening is within 1-2 inches from the smoke source. When the distance is increased to 3 inches, function decreases precipitously to 53.8% reflecting the dispersive effect of heat and the Brownian motion of the smoke's molecules. This requirement of the wand to stay close to the heat source shows its usefulness for small incisions where smoke is produced over short distances and the tubing can be fixated to the drape adjacent to the incision. Its use for longer incisions where smoke is more widely

dispersed is more limited since adequate help to keep the wand close to the plume does not often exist in today's operating room.

Removal of the smoke and other bioaerosols from the operating room environment has been an ongoing effort since the introduction of electrosurgical devices but has been difficult to achieve because of the physical characteristics of smoke. The principles involved in smoke capture efficiency, namely closeness to the smoke source and the amount of air flow per minute which is directly related to suction power, have made it difficult to capture smoke through a small diameter tube, as is the current clinical standard with the ESU pencil.

In order to keep the opening of the 3/8 inch tubing close enough to the smoke, the surgeon may have to lengthen the incision to see the tip of the monopolar electrode. At times, hand fatigue from holding the bulky handle for prolonged periods of time may occur. Further, the "pencil" cannot be used to collect smoke produced with other methods of tissue vaporization and coagulation such as bipolar, laser and harmonic technologies. These issues combine to limit the use of smoke capture technology entirely, increasing the risk of exposure to operating room personnel of the harmful contents in surgical smoke.

In contrast, the cell foam-based plenum, once applied, needs no further clinical involvement. Its adequate surface area allows for near-total smoke capture provided that suction power provides the required air flow per minute.

Conclusion

Three methods of smoke evacuation used in the clinical setting were evaluated. All were tested under laboratory conditions similar to operating room protocols. Each method had varying degrees of efficiency with described examples of clinical advantages and disadvantages for their use. Each method can find use in the operating room depending upon the degree of smoke and/or bioaerosol produced, cost and personal preference. The newly available device based on cell foam technology sandwiched between two nonporous layers, exhibited near perfect efficiency (99.0%) making it the most effective smoke capture system tested.

Comparing surgical smoke capture devices

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