SRYAHWA PUBLICATIONS

Open Access Journal of Nursing
ISSN: 2639-1783 | Volume 6, Issue 2, 2023
https://doi.org/10.22259/2639-1783.0602003

RESEARCH ARTICLE

Determination of Smoke Particulates and Formaldehyde Removal from the Surgical Site by a Smoke Evacuator

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Received: 12 September 2023 Accepted: 26 September 2023 Published: 03 October 2023
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Abstract

Background: Modern smoke evacuators are equipped with high-efficiency filters capable of capturing particulates generated by electrosurgery. However, the efficacy of an evacuator also depends upon the design of the device that captures the smoke. This study was performed to evaluate the removal of particulates and formaldehyde in smoke at the surgical site by the Megadyne Smoke Evacuator and Telescoping Smoke Evacuator Pencil.

Methods: Electrosurgery was performed on *ex vivo* porcine liver in an operating room setting. Peak levels of $PM_{2.5}$, PM_{10}, total particles and formaldehyde were monitored at 30 cm above the electrosurgical site, i.e., at the level of the surgeon's head. Measurements were made and compared with the smoke evacuator turned on and off.

Results: Use of the smoke evacuator reduced levels of $PM_{2.5}$, PM_{10}, total particles and formaldehyde at the surgical site by over 99% ($p<0.001$).

Conclusion: The combination of the Megadyne Smoke Evacuator and Telescoping Smoke Evacuator Pencil effectively removed smoke from the region where particulates and formaldehyde are most concentrated. By lowering the concentration of particulates and volatile organic compounds at the surgical site, the Megadyne Smoke Evacuator can help to improve air quality in the operating room and respiratory comfort of the staff.

Keywords: Smoke, Plume, Evacuation, Particulates, Formaldehyde.

1. Introduction

Surgical smoke is an airborne byproduct of all forms of electrosurgery, comprised of vapor and suspended particles. Recently the characterization and handling of surgical smoke has garnered attention by not only healthcare regulatory bodies but also state legislatures, as concerns grow regarding its potential negative impacts.[1] Surgical smoke has been shown to contain carcinogenic substances, has the ability to irritate the respiratory tract, can produce unpleasant odors, and may transmit disease, potentially posing health risks to operating room (OR) staff.[2, 3] In addition, surgical smoke can decrease the visibility of the surgical field, impeding visualization, technique, and precision with risk of prolonging operative times.[4, 5]

The concentration of small particulate matter is commonly measured by average particle diameter in two groups: particles less than or equal to 10 µm (PM_{10}) and particles less than or equal to 2.5 µm ($PM_{2.5}$). According to the US EPA, $PM_{2.5}$ has the most deleterious effects, and causal or likely causal relationships have been established between short- and long-term exposure to $PM_{2.5}$ and diseases of the respiratory, cardiovascular, and nervous systems, as well as cancer and overall mortality.[6] Since 1971, the National Ambient Air Quality Standards have set guidelines for exposure to particulate matter, with both average annual (12 µg/m^3) and 24-hour (35 µg/m^3) limits.[7]

Particles generated by electrosurgery were shown

Citation: Mordechai G. Sadowsky, Shawn K. Horner, Jeffrey W. Clymer, Crystal D. Ricketts. Determination of Smoke Particulates and Formaldehyde Removal from the Surgical Site by a Smoke Evacuator. Open Access Journal of Nursing. 2023;6(2): 15-20.

to have a mean diameter of 0.07 μm,[8, 9] while ultrasonic scalpel by-products had particle diameters ranging from 0.35 to 6.5 μm.[10-13] Particle concentrations in an operating theatre have been shown to range from a preoperative baseline of 2,000 particles per liter up to 35,000 particles per liter with the use of electrosurgical devices.[5]

Measurable levels of several volatile organic compounds (VOCs) including acrylamide, acetaldehyde, benzene, and formaldehyde have been identified in surgical smoke.[14] Formaldehyde specifically has been measured in surgical smoke from electrosurgery, argon beam, and ultrasonic dissection, with the highest levels occurring in electrosurgery.[14] The World Health Organization (WHO) recommends that levels of formaldehyde not exceed a threshold value of 0.1 mg/m^3 over a period of 30 minutes.[15]

Unsurprisingly, the highest concentration of smoke is at the surgical site, as ventilation in the typical OR quickly disperses smoke and gradually removes it from the vicinity, with the airflow directed away from the operating table.[16] Although the standard personal protective equipment (PPE) of surgical masks is effective at filtering respiratory droplets, these masks are not designed to, nor are they effective at filtering smaller particles in the PM_{10} and $PM_{2.5}$ ranges.[17, 18] Therefore, in order to protect patients and staff against smoke created by electrosurgical devices, the use of smoke evacuators is strongly recommended by the Association of periOperative Registered Nurses and The U.S. National Institute for Occupational Safety and Health.[19, 20]

The Megadyne Smoke Evacuation System was designed to address the issue of surgical smoke exposure in the operating environment for doctors and OR staff. The smoke evacuator has technology designed to make it quieter, easy to use and maintain a high flow rate which allows for an effective method of collecting and filtering smoke.[21, 22] The Megadyne Smoke Evacuator uses ultra-low particulate air (ULPA) filters that remove molecular odors and completely block particles as small as 50 nm and is 99.9999% effective down to 20 nm.[22] Although the efficacy of air filters is well documented, there are relatively few studies examining the functional smoke capture of smoke evacuators and measurement of smoke components. This study was conducted to determine the reduction of formaldehyde and particulate matter at the surgical site with use of a smoke evacuator in a controlled benchtop model.

2. Methods

2.1 Experimental Setup

This preclinical study was conducted with an *ex vivo* porcine liver model. An adhesive return electrode was placed underneath a fresh porcine liver, while monopolar electrosurgical energy was applied to the top surface without sharp penetration of the liver capsule. The applications were performed by a single operator, a physician experienced with monopolar technology, to minimize variability.

Each test run consisted of 30 seconds of application of monopolar energy with the pencil electrode applied directly to the surface of the liver in three bursts of 10 seconds each, moving the electrode to a new location with each burst. Particulate matter and formaldehyde concentrations were measured via a monitor placed 30 cm above the liver surface to approximate the distance of the primary surgeon's head during surgery, as the primary surgeon typically is exposed to the highest amount of smoke[16]. Ten runs were conducted with the smoke evacuator turned off or on for a total of twenty runs, with a new stainless steel electrode blade replaced after each run. In between runs, a small fan was used to clear the testing site of any residual surgical smoke. The entire procedure was filmed, with the video recording centered on the air quality monitor to allow for accurate recording of baseline and peak readings.

2.2 Devices and Settings Used for Testing

Electrosurgery was performed using a Telescoping Smoke Evacuator Pencil (251010J, Ethicon, Inc., Cincinnati OH) with a stainless-steel blade (0312 SS 2.5", Ethicon, Inc.) connected to a Megadyne Electrosurgical Generator (MEGEN1, Ethicon, Inc.) [23] and a Megadyne Smoke Evacuator (MESE1, Ethicon, Inc., Figure 1). The electrosurgical unit was set to Coag mode at 40W, as previous research has demonstrated this results in increased smoke production.[24] $PM_{2.5}$, PM_{10}, total particle count and formaldehyde were measured using a Temtop Air Quality Monitor (M2000, Temtop, Shanghai, China).

The smoke evacuator was set to its highest level of evacuation (Open Level 5, approximately 100 liters per minute) with a time dwell of 15 seconds (Level 4), for which period the smoke evacuator continues to withdraw air after the end of electrosurgical application. For both conditions of the smoke evacuator turned on and off, the blade was maintained in the vicinity of the electrosurgery site for 15 seconds after application. Testing was conducted in a pre-

clinical laboratory operating room to mimic the conditions of a clinical operating room. Room air flow was measured at 1600 cubic feet per minute, approximately 3 room air changes per hour.

2.3 Statistical Analysis

For statistical comparisons, the increases in the peak over baseline values were compared between the conditions of having the smoke evacuator turned on or off using a Kruskal-Wallis test. An alpha value of 0.05 was considered as the level of significance. All statistical analysis was performed with Minitab, Version 17 (Minitab, State College, PA).

3. Results

For each of the four parameters ($PM_{2.5}$, PM_{10}, particles, formaldehyde), the difference between the baseline and peak value of the ten runs was determined for both the condition of having the smoke evacuation on and the condition of having the smoke evacuation off. Since the $PM_{2.5}$, PM_{10}, and particles measurements were frequently at the maximum value, i.e., censored, when the smoke evacuation was off, statistical comparisons were performed using a non-parametric test.

Via the Kruskal-Wallis test, each comparison between the conditions of having the smoke evacuator off or on was significantly different with $p < 0.001$ (Table 1, Figure 2). Percent reduction of the parameter was determined as the difference between the medians with smoke evacuation off and on divided by the median for the smoke evacuation off. In the case of formaldehyde, where the median value with smoke evacuation on was 0.0, the value used for smoke evacuation on was 0.001 mg/m^3, i.e., the resolution of the meter. As the $PM_{2.5}$, PM_{10}, and particles measurements were right-censored, the percent reductions represent minimum values; for these parameters the actual percent reduction is greater than shown.

Table 1. *Medians for each parameter with smoke evacuation off and on.*

Parameter	Evacuation Off (n=10)	Evacuation On (n=10)	p-value	Percent Reduction
$PM_{2.5}$ (µg/m^3)	996.6	2.4	<0.001	99.8%
PM_{10} (µg/m^3)	995.5	3.4	<0.001	99.7%
Particles (count/liter)	1444877	3135	<0.001	99.8%
Formaldehyde (mg/m^3)	0.206	0.0	<0.001	99.5% *

* Using 0.001 mg/m^3 (the resolution of the meter) as the value for Evacuation On.

Figure 1. *The Megadyne Smoke Evacuator and Telescoping Smoke Evacuator Pencil.*

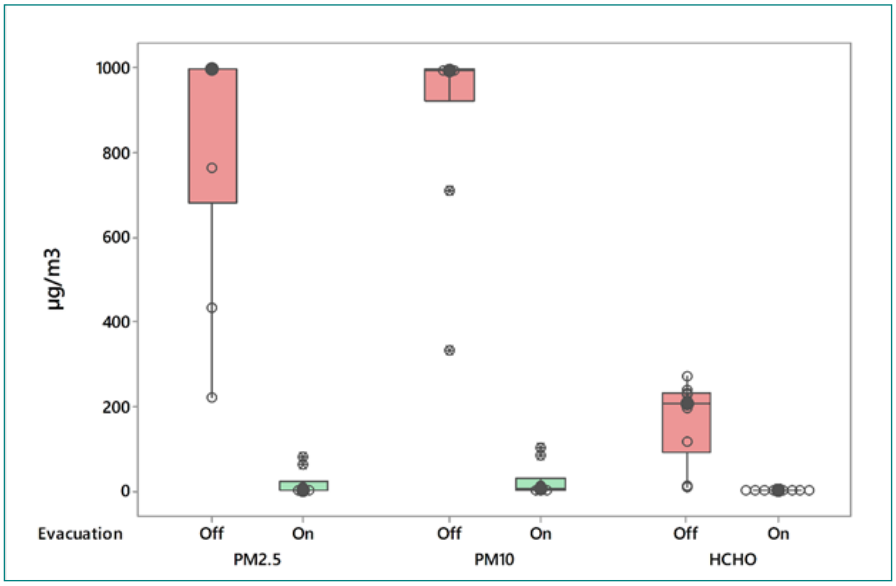

Figure 2. *Boxplot of PM2.5, PM10 and formaldehyde (HCO) levels in µg/m3 showing medians (gray), interquartile boxes, individual points (circles), and outliers (crossed circles) for smoke evacuation off (red) and on (green).*

4. Discussion

This study demonstrates that the Megadyne Smoke Evacuator removes over 99% of some of the potentially harmful components of surgical smoke: particulate matter and formaldehyde. Although the study was conducted with a benchtop model in a preclinical laboratory, the experimental setup was designed to best approximate the conditions of an actual operating room while maintaining reproducible and repeatable test conditions. Various tissue types have been shown to produce different volumes of smoke plume, the primary component of which is water vapor. Previous work has demonstrated that electrosurgical treatment of liver produces the largest amount of particulate matter, supporting the use of porcine liver in this study.[24]

Although during a surgical procedure exposure to a high concentration of surgical smoke lasts only for a brief time, our simulations showed that the $PM_{2.5}$ levels at the surgical site frequently rose to greater than 1000 µg/m^3, markedly above the recommended 24-hour average limit of 35 µg/m^3. Use of smoke evacuation lowered the median $PM_{2.5}$ level to 2.4 µg/m^3, well below the long-term average limit of 12 µg/m^3. For formaldehyde, the median concentration reached 0.206 mg/m^3, over twice the level recommended by the WHO, while with smoke evacuation turned on, median levels were reduced to less than 1 µg/m^3, at least two orders of magnitude below the threshold level. Considering that other VOC's are cleared along with formaldehyde, there may be improvement in respiratory comfort, if not a demonstrable health benefit for the OR staff with use of the smoke evacuator.

Several recent studies have examined the efficacy of other smoke evacuation products, with a range of results. During spinal surgery, electrosurgical smoke evacuation was evaluated using two different devices: a flat, broad suction pad adjacent to the site (miniSQUAIR, Nascent Surgical Inc.), and a smoke evacuation pencil (Valleylab, Medtronic). Reduction of average smoke level of ultrafine particles (0.02 to 1.0 µm) was 59.7% and 44.1% for the pad and pencil, respectively.[25] Use of a smoke evacuation pencil (Buffalo Filter SnapEvac, Conmed) during canine orthopedic surgery decreased particle concentrations by 56.4%.[26] In open cholecystectomy, a smoke evacuation pencil (Valleylab, Medtronic) reduced particulates by 58%.[27] During spinal surgery, a smoke evacuation pencil (Neptune E-SEP, Stryker Surgical Technologies) decreased $PM_{2.5}$ peak levels in the room by approximately 82%.[28] A pre-clinical study showed reduction of $PM_{2.5}$ from use of another commercial smoke pencil (SW12200, Shinmed) of 93%.[29] During pediatric tonsillectomy, a smoke evacuation pencil (Neptune E-SEP) lowered particulate levels by 93.8%.[30] To the best of our knowledge, no other studies have evaluated removal of formaldehyde by smoke evacuation pencils.

Despite the demonstrated efficacy of smoke evacuator filters and the lack of efficacy of standard surgical masks at particulate filtration, smoke evacuators are not commonly used in the operating room.[31] Many smoke evacuation systems are quite loud, which may contribute to slow adoption.[32] However, the Megadyne Smoke Evacuator has been shown to address this concern with significantly reduced noise production compared to other evacuators.[21, 22]

The present study builds on previous work demonstrating that not only is the Megadyne Smoke Evacuator quieter, but also has higher air flow rates. [21] The results of this study demonstrate that air flow is effectively removed from the surgical site by the clearance of smoke particulates. Future work is needed to confirm these results in a clinical setting, as well as compare smoke component clearance between different market devices.

5. Conclusion

The Megadyne Smoke Evacuator removes more than 99% of small particulate matter and formaldehyde from the surgical field, potentially improving the comfort of the staff, and the air quality in the OR.

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