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Particulate Respirator Use for Surgical Smoke

Hazard Assessment

Laser plume and electrocautery surgical smoke generated from the use of lasers demonstrates the potential to contain airborne contaminants and can be of concern to Health Care Professionals (HCP).¹ Not only can surgical smoke generated from the use of electrocautery and lasers produce toxic gases and vapors, but it may also include bioaerosols (dead and living cell material, including blood fragments and viruses).² Collectively these can be termed laser generated airborne contaminants (LGAC).¹ Similar types of air contaminants are produced from the use of heat-producing instruments, such as electrosurgical devices, as those produced by "laser-tissue" interaction.¹ The HCP's potential level of exposure to the airborne contaminants in surgical smoke are influenced by the type of equipment used, the extent, type and infectious nature of the tissue being treated, along with the duration of the surgery and proximity of the worker to the surgical procedure area.

Negative health implications to surgery-associated HCPs with regard to surgical smoke exposure has been studied and documented.³⁻⁶ However uncertainty remains and significant gaps in study and knowledge still exist with regard to characterizing occupational exposures and in the assessment of risks to the health care worker from surgical smoke exposure.

Standards & Recommendations

The primary means for controlling laser plume and electrocautery LGAC is through effective engineering controls, such as fixed or portable smoke evacuators. In order to be effective, the inlet must be of adequate volume and within 2 inches of the surgical site.⁷ As secondary protection against the inhalation of surgical smoke, respiratory protection is recommended by certain groups, including the Association of periOperative Registered Nurses¹⁹.

Association of periOperative Registered Nurses (AORN)

AORN: 2013 Perioperative Standards and Recommended Practices, Recommended Practices for Laser Safety in Perioperative Practice Settings. Recommendation V, part c, states¹:

"Personnel should wear respiratory protection (ie, fit-tested surgical N95 filtering face piece respirator or high-filtration surgical mask) during procedures that generate surgical smoke as secondary protection against residual plume that has escaped capture by local exhaust ventilation (LEV)."

However, the statement is later clarified to say that fit tested N95 respirators are what provide reduction in airborne particles:

"Surgical and high filtration masks do not seal the face and may allow dangerous contaminants to enter the health care worker's breathing zone." And further: "Respiratory protection that is at least as protective as a fit-tested surgical N95 filtering face piece respirator should be considered for use in conjunction with LEV in disease transmissible cases (e.g., human papillomavirus) and during high-risk or aerosol transmissible diseases procedures (e.g.,tuberculosis, varicella, rubeola)." Similar recommended practices are made by AORN with regard to electrosurgery.⁸

In 2013, AORN has applied attention to and implemented an on-going education campaign focused to help increase health care worker knowledge and awareness regarding the uncertain risks related to surgical smoke exposures and is urging personal action by health care workers on their own behalf to use the controls available to reduce their exposure.⁹

Centers for Disease Control and Prevention (CDC)

Guidelines for Environmental Infection Control in Health-Care Facilities

Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) MMWR June 6, 2003 / 52(RR10);1-42¹⁰

"VI. Other Potential Infectious Aerosol Hazards in Health-Care Facilities

A. In settings where surgical lasers are used, wear appropriate personal protective equipment (PPE), including N95 or N100 respirators, to minimize exposure to laser plumes. Category IC (OSHA; 29 CFR 1910.134,139)

B. Use central wall suction units with in- line filters to evacuate minimal laser plumes. Category II

C. Use a mechanical smoke evacuation system with a high-efficiency filter to manage the generation of large amounts of laser plume, when ablating tissue infected with human papilloma virus (HPV) or performing procedures on a patient with extrapulmonary TB. Category II"

Occupational Safety and Health Administration (OSHA)

While OSHA does not have a specific standard regulating exposure to surgical smoke, they do recognize it as a hazard, and surgical smoke may therefore be subject to the general duty clause. "The general duty clause, Section 5(a)(1) of the Occupational Safety and Health Act of 1970, applies to all employers and requires each employer to provide employees with a place of employment which is free of recognized hazards that may cause death or serious physical harm." The hazards encompassed by the general duty clause may implicate specific standards, such as the respiratory protection standard (29 CFR 1910.134) and Bloodborne pathogen standard (29 CFR 1910.1030).

The OSHA Health and Safety Topics website for Laser/Electrocautery Plume states¹¹:

1910 Subpart I, Personal protective equipment [related topic page]

• 1910.134, Respiratory protection. Paragraph (a)(1) states the primary objective is to control occupational diseases caused by breathing air contaminated with harmful substances. This is to be accomplished through accepted engineering controls if feasible, or through the use of appropriate respirators. Note: Surgical masks used to prevent contamination of the patient are not certified for respiratory protection of medical employees. [related topic page]

1910 Subpart Z, Toxic and hazardous substances [related topic page]

• 1910.1030, Bloodborne pathogens. Paragraph (d)(3)(i) states the employer must supply appropriate personal protective equipment such as gloves, gowns, masks and eye protection. This standard would apply if such items become contaminated with viable bloodborne pathogens from laser smoke or plume. [related topic page]

Respirator vs. Surgical Mask

Because certain disposable filtering facepiece respirators are similar in appearance to surgical and/or procedure masks, their differences are not always well understood. However, respirators and surgical masks are very different in intended use, fit to the face, testing, and regulatory clearances and approvals. This section will highlight some of these differences, however to read a more comprehensive technical bulletin about the differences between a respirator and a surgical mask, see 3M Technical Bulletin "Respirators and Surgical Masks - A Comparison".

The biggest difference between a respirator and a surgical mask is the intended use.

Respirators are designed to help reduce the wearer's respiratory exposure to airborne contaminants such as particles, gases, and/or vapors. Particulate respirators may be used to reduce exposure to particles that are small enough to be inhaled – particles less than 100 microns (µm) in size. This includes airborne particles that may contain biological material, e.g. mold, Bacillus anthracis, Mycobacterium tuberculosis, the virus that causes SARS, Pandemic Novel Swine Origin Influenza A (H1N1) virus, etc.^{12, 13} Surgical masks do not have adequate filtering nor fitting attributes to provide respiratory protection for the wearer. And in fact, one study found that a filtering facepiece respirator provided over 27 times better protection than a procedure (laser) mask.¹⁶ Surgical masks are designed to help prevent contamination of the work environment or sterile field from large particles generated by the wearer (e.g. spit, mucous). Surgical masks may also be used to help reduce the risk of splashes or sprays of blood, body fluids, secretions and excretions from reaching the wearer's mouth and nose.^{12-14, 16-18}

If a wearer wants to reduce inhalation of smaller, inhalable particles (those smaller than 100 microns), they need to obtain and properly use a NIOSH-certified particulate respirator.

Devices which are both NIOSH approved as an N95 respirator and cleared by the FDA as a surgical mask are available and are often referred to as "surgical respirators" or, more formally, Surgical N95 NIOSH Certified Respirators.^{15, 17-18}

Summary

Research continues to be needed "to determine the factors that are associated with exposure and consequently health risks" to the health care professional related to surgical smoke.⁶

The current line of risk management strategies indicates that the primary means for controlling laser plume and electrocautery emissions is through effective engineering controls, such as smoke evacuation among other engineering controls. But if the plume cannot be controlled through these means, then the use of particulate respirators (within respiratory protection program standards) to reduce airborne particulate exposures (those that may be subject to more uncertain pathogen exposure characteristics and subsequent health implications) during laser surgery is recommended in certain situations by AORN, CDC/NIOSH and OSHA.

Definitions

(Source: America National Standard for Safe Use of Lasers in Health Care, ANSI Z136.3-2018 pg. 11-19)

Laser. A device which produces an intense, coherent, directional beam of light by stimulating electronic or molecular transitions to low energy levels. An acronym for Light Amplification by Stimulated Emission for Radiation.

Health Care Application. Use of a laser device on a patient (human or animal) by or under the supervision of a licensed practitioner, physician, dentist, veterinarian, within their scope of practice for diagnostic, preventative, aesthetic, or therapeutic purposes, where bodily structure or function is altered or symptoms are relieved. These include prescription use of the medical laser device and over the counter indications for use.

Laser generated airborne contaminants (LGAC). Airborne contaminants generated when a laser beam interacts with target materials. The materials may include, but are not limited to, plastics, metals, ceramics, glasses, wood and tissue. LGAC may be in the form of gases, vapors, organic or inorganic particulates, or aerosols, and often are a complex mixture of substances in all three states. See also: **plume.**

Plume. Gases, vapors and aerosol created by vaporization of tissue or other materials and may contain viable bacteria, viruses, cellular debris or noxious fumes.

References

- 1) ANSI Z136.3-2018: American National Standard for Safe Use of Lasers in Health Care. Washington, DC: American National Standards Institute: 2018.
- 2) Association of periOperative Registered Nurses. Recommended Practices for Laser Safety in Perioperative Practice Settings. Denver, CO: AORN; 2013:147-148.
- 3) Champault G, Taffinder N, Ziol M, Riskalla H, Catheline JMC. Cells are present in the smoke created during laparoscopic surgery. British Journal of Surgery. 1997;84(7):993-995.
- 4) Baggish MS, Polesz BJ, Joret D, Williamson P, Refai A. Presence of human immunodeficiency virus DNA in laser smoke. Lasers in Surgery and Medicine. 1991;11(3):197-203.
- 5) Ediger MN, Matchette LS. In vitro production of viable bacteriophage in a laser plume. Lasers in Surgery and Medicine. 1989;9(3):296-299.
- 6) Jennifer S. Pierce, Steven E. Lacey, Julia F. Lippert, Ramon Lopez, & John E. Frank (2011): Laser-Generated Air Contaminants from Medical Laser Applications: A State-of-the-Science Review of Exposure Characterization, Health Effects, and Control, Journal of Occupational and Environmental Hygiene, 8:7, 447-466.
- 7) National Institute of Occupational Safety and Health. Control of Smoke From Laser/Electric Surgical Procedures-HC11. NIOSH Hazard Control. Available at: http://www.cdc.gov/niosh/docs/hazardcontrol/hc11.html.
- 8) Association of periOperative Registered Nurses. Recommended Practices for Electrosurgery in Perioperative Practice Settings. Denver, CO: AORN; 2013:134-135.
- AORN Management of Surgical Smoke Tool Kit: https://www.aorn.org/guidelines/clinical-resources/tool-kits/management-of-surgical-smoke-tool-kit Accessed June 4, 2019.
- Sehulster L, Chinn RY, Arduino MJ, et al. Guidelines for Environmental Infection Control in Health-Care Facilities. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR Recomm Rep. 2003;52(RR10):1-42.
- 11) Occupational Safety and Health Administration. Laser/Electrosurgery Plume: Safety and Health Topics. Safety and Health Topics. 2008. Available at: https://www.osha.gov/SLTC/laserelectrosurgeryplume/. Accessed June 4, 2019.
- 12) Brosseau LM, Berry Ann R. N-95 Respirators and Surgical Masks. CDC NIOSH Science Blog. 2009. Available at: http://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/. Accessed June 4, 2019.
- 13) Brosseau LM. Update on Respirators and Surgical Masks Review of Literature (2007 2010). 2010. Available at: http://www.nationalacademies.org/hmd/~/media/Files/Activity%20Files/PublicHealth/PPECurrentResearch/2010-JUN-3/Bros. Accessed June 4, 2019.
- 14) Oberg T, Brosseau LM. Surgical mask filter and fit performance. American Journal of Infection Control. 2008;36(4):276-282.
- 15) Center for Devices and Radiological Health. Guidance Documents (Medical Devices and Radiation-Emitting Products)

 Guidance for Industry and FDA Staff: Surgical Masks Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA. Available
 at: http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/uc m072549.htm.
 Accessed June 4, 2019.
- 16) Derrick, J.L., Li, P.T.Y., Tang, S.P.Y., Gomersall, C.D. (2006). Protecting staff against airborne viral particles: in vivo efficiency of laser masks. Journal of Hospital Infection, 64, 278-281.
- 17) Zhuang, Z., and Viscusi, D. (2011). Respiratory protection for workers handling engineered nanoparticles. CDC NIOSH Science Blog, December 7, https://blogs.cdc.gov/niosh-science-blog/2011/12/07/resp-nano/.
- 18) Benson, S.M., Novak, D.A., Ogg, M.J. (2013). Proper use of surgical N95 respirators and surgical masks in the OR. AORN Journal, 97(4), 458-470.
- 19) Association of periOperative Registered Nurses. Guidelines for Perioperative Practice: Surgical Smoke Safety. AORN eGuidelines, Denver, CO.

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