CHARACTERIZATION OF SURGICAL PLUME AEROSOLS AND ASSESSMENT OF OCCUPATIONAL EXPOSURES AMONG OPERATING ROOM PERSONNEL

by

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ABSTRACT

These studies were undertaken to increase the knowledge of characteristics of plume particles produced by surgical cutting and cauterizing instruments and to assess occupational exposure to these surgical plume particles.

Surgical plume particle characteristics measured included particle size distribution and particle number, respirable mass, active surface area, and particle-bound polycyclic aromatic hydrocarbon (pPAH) concentrations. The four surgical instruments used were an electrocautery knife, a carbon dioxide laser, a harmonic scalpel, and a neutral plasma coagulator system (i.e., Plasma Jet™). At the point of generation, geometric mean (GM) particle number concentrations ranged from 7.11E+05 particles per cubic centimeter (particles/cm^3) (geometric standard deviation (GSD): 5.68) to 7.69E+07 particles/cm^3 (GSD: 2.73). Count median diameters (CMDs) ranged from 0.034 micrometers (μm) (GSD: 1.48) to 0.095 μm (GSD: 7.99). The use of a local exhaust ventilation (LEV) control built into the electrocautery knife produced significant reductions in particle number and respirable mass concentrations. The electrocautery knife produced particles with the largest quantity of pPAHs per active surface area.

Trials using both dermal and adipose tissues were conducted to determine particle size distributions and number concentrations at the personal breathing zone (PBZ) level of a worker at the surgical table. CMDs ranged from 0.028 μm (GSD: 2.0) to 0.190 μm (GSD: 2.2). GM particle number concentrations were considerably diluted compared to the point of generation by the time they reached the PBZ, ranging from 220 particles/cm^3 (GSD: 1.9) to 108,632 particles/cm^3 (GSD: 1.33).

Exposure assessments were conducted during several surgical procedures with varying degrees of surgical plume produced through the use of an electrocautery knife or plasma jet. CMDs of particles ranged from 0.091 μm (GSD: 2.3) to 0.105 μm (GSD: 1.8) across the multiple surgeries measured. However, when the plasma jet was used for antibacterial purposes rather than cutting, particles of a smaller CMD, approximately 0.03 μm (GSD: 2.0), were measured. Peak particle number concentrations for the procedures with the greatest surgical plume concentrations produced between 96,000–134,000 particles/cm^3 at the measurement location located closest to the surgical table. LEV use dramatically decreased operating room concentrations compared to similar procedures when LEV was not used.

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Chapter 1 Introduction

Twelve million Americans are estimated to work in the health care industry, the second fastest growing sector in the nation's economy [NIOSH 2008]. From infectious diseases and latex allergies in hospitals and clinics to anesthetic waste gas exposures in operating rooms, the health care environment can present unique exposure situations to these workers. One of these unique potential occupational exposures is particulate matter, chemical, and biological exposures that make up the plume generated by energy-based cutting instruments used during surgical procedures. The widespread use of such surgical plume producing equipment, the large number of operating room personnel exposed to such plume, concerns for acute and chronic health impacts, and recommendations from organizations such as the National Institute for Occupational Safety and Health (NIOSH) and the Association of periOperative Registered Nurses (AORN) for controlling exposures all point to a need for further research into this potential occupational hazard. The overall goal of this research is to systematically characterize concentration and size properties of the plume particles produced through four common plume-producing instruments, to assess occupational exposures to the aerosols, and to elucidate practices that result in increased exposure potential.

Although limited in number and scope, past investigations have evaluated properties of particles present in surgical plume. In one way or another, these studies have each had inherent limitations including:

- the application of the cutting instrument to animal tissue rather than human tissue for plume production, which may not be fully representative of particulate matter exposure for operating room personnel

- the use of particle sampling techniques that provided limited information on particle size distribution, particularly equipment unable to characterize particles in the nano-scale size range
- the use of a single plume-producing instrument, which is often not representative of surgical procedures during which several different types of these instruments are used
- the use of a single type of tissue used to generate particles
- the lack of assessment of surgical plume particulate exposures in the personal breathing zone (PBZ) of the operating room personnel.

To more accurately determine the potential hazard posed exposures to such particles, comparative studies under controlled conditions were conducted. These studies used direct-reading instrumentation capable of measuring nano-scale particles, used human tissue, measured at both the point of particle plume generation and at the PBZ-level of a surgical table staff member, and used all of the most common energy-based cutting instruments in order to help fill the data gaps identified by these limitations. While analysis of particle plume under controlled conditions was a necessary step, evaluating personal exposures was also important in assessing the inhalation health risk for operating room personnel. Accurate assessment of exposures in terms of particle size and count concentrations using direct-reading, real-time instrumentation capable of identifying a wide size range was also conducted. Such assessment evaluated both general and activity-specific particle exposures during surgical procedures, with a goal to identify specific tasks and parameters that lead to the highest exposures.

Thus, the specific aims of this research were designed to provide a comprehensive characterization of particulate matter aerosolization and assessment of worker exposure. Particulate matter plume was generated under controlled conditions through the systematic

application of four common energy-based surgical instruments to human dermal and adipose tissue in a hospital operating room under ventilation conditions identical to those during normal surgical procedures. Assessment of the PBZ exposures of operating room personnel to surgical smoke plume using the same sizing and concentration counting instruments as the laboratory investigation was also conducted. Surgical procedures where multiple types of energy-based cutting instruments are used and tissues to which they are applied were selected to be assessed.

Specific Aim #1: Investigate the impact of energy-based cutting instrument type on characteristics of particles produced such as particle size distribution and respirable mass, particle number, active surface area, and particle-bound polycyclic aromatic hydrocarbon (pPAH) concentrations produced in the plume.

Specific Aim #2: Investigate the impact of tissue type on particle size and count concentration generated through the application of energy-based cutting instruments to two types of human tissue.

Specific Aim #3: Investigate the impact of ventilation parameters (both local exhaust and general) on the exposure potential for operating room personnel.

Specific Aim #4: Investigate the size characteristics and count concentration of surgical plume particulate matter to define the personal exposures of operating room personnel during selected surgical procedures.

Background

Based on the 1994 National Hospital Discharge Survey, the Centers for Disease Control and Prevention (CDC) and the Healthcare Infection Control Practices Advisory Committee (HICPAC) stated in their report "Guideline for the Prevention of Surgical Site Infections" that 27 million surgical procedures were performed in the United States every year at that time [Mangram, Horan et al. 1999; Kozak, DeFrances et al. 2006]. Since then, the 2010 National Hospital Discharge Survey reported that 51.4 million impatient surgery procedures were performed annually in the US [CDC 2013]. More than 234 million major surgical procedures (i.e., an intervention occurring in a hospital operating room that involves incision, excision, manipulation, or suturing of tissue that usually requires regional or general anesthesia or sedation) are estimated to be performed worldwide every year [Weiser et al., 2008]. In the surgical room, surgeons and other personnel have a variety of instrumentation available to cut and coagulate tissue during these surgical procedures. While the surgical scalpel may be the most obvious cutting instrument, several energy-based instruments have been used with regularity over the past decades. One of the most common is the electrocautery knife, a pencil with electric current running through the tip, cutting and coagulating tissues with the heat generated. Other instruments including the ultrasonic scalpel, carbon dioxide (CO_2) laser, and neutral plasma coagulator system (i.e., plasma jet) are also used. What these instruments have in common is the destruction of the tissue through the energy applied, resulting in the production of considerable quantities of surgical plume. The plume produced by these types of instruments can be an occupational hazard to operating room personnel due to the potential particle, chemical, and/or biological constituents of the plume. The respirable nature of the particles produced in the plume, the chemical by-products produced by the tissue combustion

processes, and the possible infectious agents aerosolized present concerns of potential acute and chronic health effects. [Barrett and Garber 2003; Alp, Bijl et al. 2006; Bigony 2007]

The US Occupational Safety and Health Administration (OSHA) has reported that an estimated 500,000 workers, including surgeons, nurses, anesthesiologists, and surgical technologists, are exposed to laser or electrosurgical smoke every year [OSHA 2008]. However, OSHA has not published any regulatory or enforcement standards for exposures to surgical plume. NIOSH has made the recommendation to implement engineering controls, particularly local exhaust ventilation (LEV), and work practices to control health care workers' exposures to the plume. In particular, smoke evacuators with a capture velocity of 100-150 feet per minute, high efficiency particulate air (HEPA) filters, and a suction nozzle inlet held 2 inches from the point of smoke production were recommended [NIOSH 1996]. In the 2012 edition of "Perioperative Standards and Recommended Practices", AORN also provided recommendations that exposure to electrosurgical smoke and laser plume should be minimized and removed through the use of a smoke evacuation system and/or a central wall suction system [AORN 2012].

At a minimum, workers have reported associating eye, respiratory, and mucous membrane irritation with exposure to surgical plumes. Lobraico reported that 4.4% of respondents questioned complained of throat irritation (cough or soreness/hoarseness) after exposure to laser plume. Overall, complaints of eye, nose, or throat irritation, headache, nausea, or noxious odors were reported by 10.5% of the questioned population [Lobraico, Schifano et al. 1989]. NIOSH evaluations of surgical plume have revealed higher percentages of such complaints among worker populations. In 2001, King et al. conducted a series of NIOSH health hazard evaluations (HHEs) of electrocautery plume exposures and reported health effects in three hospitals around the country. In one of these evaluations of surgical plume exposure at a Falls

Church, VA, hospital, a symptom survey questionnaire distributed to 50 operating room personnel inquired about symptoms experienced during exposure to surgical smoke. Thirty-three questionnaires were returned (66% response rate) from surgical nurses, anesthetists, and surgical technicians. Of those who responded, 51.5% reported at least one symptom that they associated with surgical smoke exposure. These included 24.2% reporting eye irritation, 18.2% reporting burning of nose or throat, 21.2% reporting headache, 24.2% reporting coughing, and 3.0% reporting nasal congestion or runny nose [NIOSH 2006b]. In an evaluation conducted at a Charlotte, NC, hospital, a similar symptom survey (92% response rate) revealed that 35.8% of those questioned reported at least one of these symptoms [NIOSH 2006a]. An evaluation conducted at a hospital in Dunedin, FL, revealed 43.7% reported at least one symptom associated with surgical smoke exposure [NIOSH 2006c].

While the concern about exposures to surgical plume has been reported for many years, large-scale, well designed epidemiological studies that define the extent of health effects associated with plume exposures are almost non-existent. In a recent study, Gates reported a multivariable analysis looking at the association between nurses' length of operating room employment (as a proxy for exposure to surgical smoke) and lung cancer risk; the authors reported that a history of working in the operating room was not associated with an increased lung cancer rate [Gates, Feskanich et al. 2007]. Smaller studies that have been performed typically focused on the risks associated with infectious bioaerosols (particularly human papillomavirus [HPV]) potentially in surgical plume rather than health effects and/or risks associated with particle exposures [Lobraico, Schifano et al. 1988; Lobraico, Schifano et al. 1989; Hallmo and Naess 1991; Gloster and Roenigk 1995].

Respiratory Effects

The effect of exposure to surgical plume is not restricted to potential infectious disease transmission. Health effects due to the inhalation of particulate matter found in plume have been investigated. Information on human health effects of exposure to surgical plume particulate matter, however, is very limited if not non-existent, as the health effects studies found in the literature are based on using animal models. It is also notable that the exposures and doses experienced by the animal models in these investigations may be considerably larger than those typically experienced by workers in an occupational environment.

In a study investigating the effects of inhalation of CO_2 laser smoke, Baggish et al. exposed 13 rats to pigskin plume. The study was conducted in three phases varying the length of exposure time: 32 minutes over the course of 4 days (phase I), 112 minutes over the course of 7 days (phase II), and 224 minutes over the course of 14 days (phase III). The animals were sacrificed and their lungs were removed, sectioned and stained. In comparison to three control rats, all phase I rats exhibited pulmonary inflammatory response, with gross and microscopic congestion. The terminal bronchioles were reportedly thickened and hypertrophic, with distension of the alveolar ducts. Phase II rats showed further accentuated features, with demonstrated emphysema. More extensive emphysema was found in Phase III rats. The authors demonstrated a proportional increase in the severity of pulmonary pathology with the duration of laser plume exposure [Baggish and Elbakry 1987].

In a follow-up study, Baggish et al. investigated the pulmonary effects filtered plume has on the rat model used previously. The study was conducted in two phases: 1) exposure to pigskin

plume that had been filtered through a smoke evacuation system with a single filter (rated to remove particles down to 0.5 micrometers (μm) in diameter) for a total 224 minutes over the course of 14 days; 2) exposure to pigskin plume filtered through a smoke evacuation system with the addition of a second filter (rated as ultra-low penetration air (ULPA), capable of removing particles as small as 0.1 μm) over the same time frame. Sectioning and staining of the sacrificed rats' lungs from phase 1 revealed similar, although less severe, pathological changes as those reported in the 1987 study. Phase 2 rats' lungs revealed no evidence of pathology and were considered comparable to control rats' lungs [Baggish, Baltoyannis et al. 1988].

Freitag et al. exposed sheep to plume produced by the application of a neodymium-doped yttrium aluminum garnet (Nd:YAG) laser to blocks of sheep bronchial tissue. The sheep were exposed to a single 10-minute smoke exposure, three 10-minute exposures, or no smoke exposures (control group). Two hours after exposure, the sheep with the single exposure showed a 28% decrease from baseline in tracheal mucus velocity (a marker for mucociliary function of the lung); in contrast, the sheep with multiple exposures had a 56% decrease from baseline. No significant changes in arterial blood pH or partial pressure of CO_2 (pCO_2) were seen, although all sheep showed mild hypoxia during the exposures. Additionally, no significant changes in white blood cell count (connoting general inflammation) were seen. Bronchiolar lavage did, however, reveal pulmonary inflammatory response [Freitag, Chapman et al. 1987].

Wenig et al. investigated the effects of Nd:YAG laser and electrocautery smoke on the rat model. Twelve rats were exposed to pigskin plume produced by either Nd:YAG laser or electrocautery knife according to the three phases of exposure time as described in the 1987 Baggish study. Exposure to the laser plume resulted in alveolar congestion, hypertrophy of blood vessels, and emphysematous changes in all exposed rats, albeit without increased severity

proportional to the exposure time. Similar effects were seen in the rats exposed to electrosurgical smoke [Wenig, Stenson et al. 1993].

Surgical Plume Particle Characteristics

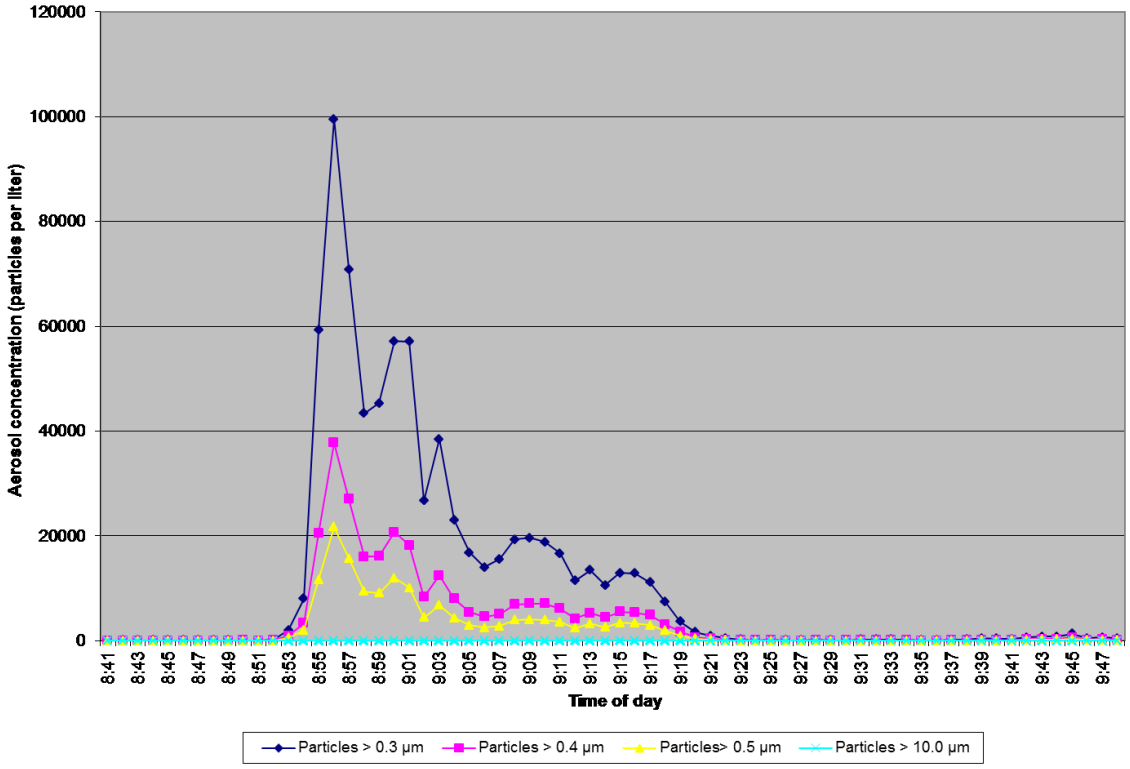
In addition to defining the respiratory effects seen in animal models exposed to surgical plume, past researchers have used a variety of methodologies to investigate different characteristics of the plume particles. These methodologies have included the use of cascade impactors, microscopy on filter samples, and some direct reading instrumentation. A substantial limitation of many methodologies used in past studies is the inability to evaluate the smallest, nano-scale size ranges potentially produced. The NIOSH investigations of electrocautery plume particle counts have been limited as a result of sampling equipment whose smallest size channel was particles with diameters between 0.3–0.4 μm; importantly, particle counts in the size range of 0.3–0.4 μm appeared to play a very prominent role in the overall percentage of particles present in plume generated during a mastectomy, suggesting particles even smaller may have been present, but were unable to be measured. See Figure 1.1 [NIOSH 2006a].

The deposition of ultrafine particles below 0.1 μm in diameter within the respiratory system has been studied which may describe the locations within the lungs where surgical plume particles of nanoscale sizes may deposit. As such, the deposition location in the lung system may impact the types of health effects experienced after surgical plume exposures.

For ultrafine particles, the main mechanism for depositing in the respiratory system is diffusion unlike larger particles which deposit through impaction, interception, and gravitational settling. According to Oberdörster et al. [2005], data from the International Commission on Radiological

Protection [1994] predicts that considerable amounts of ultrafine particles are deposited in each of the nasopharyngeal, tracheobronchial, and alveolar regions of the respiratory tract under conditions of nose breathing while at rest. While 90% of particles of 0.001 µm are expected to deposit in the nasopharyngeal region, approximately 50% of 0.020 µm sized particles are expected to deposit in the alveolar region. Percent regional deposition in the alveoli decreases as particle diameter increases. Approximately 15% of 0.020 µm sized particles deposits each in the nasopharyngeal and tracheobronchial regions [Oberdörster, Oberdörster et al. 2005; International Commission on Radiological Protection 1994]

Figure 1.1 Particle Concentration in the Periphery of an Operating Room During a Mastectomy [NIOSH 2006a].



Cascade Impactors

Nezhat et al. collected plume produced by CO_2 laser during laparoscopic endometrial surgery. The smoke that had accumulated inside the pelvic region was collected by venting it into a sterilized bag. Smoke from the bag was then drawn into a Marple Personal Cascade Impactor which separated the particles by aerodynamic diameter classes ranging from 0.2–0.5 µm to >9.8 µm onto Mylar film which were gravimetrically analyzed. The mass median aerodynamic diameter (MMAD) of particles from 32 samples collected was reported to be 0.31 µm. Samples collected in the operating room environment yielded no detectable laser plume particles [Nezhat, Winer et al. 1987].

Particle size distribution was also evaluated by Heinsohn et al. using a 10-stage low pressure cascade impactor during use of an electrocautery knife on tendon tissue. Aerosol capture was 3 cm above the source point. Most of the collected particles were <5 µm aerodynamic equivalent diameter (AED). The mode of the particle size distribution was 0.07 µm 50% effective cutoff aerodynamic diameter (ECAD) when the electrocautery knife was in the cutting mode [Heinsohn, Jewett et al. 1991]. In a follow-up study conducted in 1992, Jewett et al. found that the majority of aerosol particles sampled with a cascade impactor measured 0.42 µm AED or smaller [Jewett, Heinsohn et al. 1992].

Personal sampling for particles generated by electrocautery was conducted by Smith et al. using personal Marple cascade impactors to determine their size distribution and concentration in the personal breathing zone of the operating room personnel. A total hip replacement in a canine model was performed as the surgery. Results showed that the electrocautery produced aerosol with particle size of <1 µm AED [Smith, Yeh et al. 1992].

In a 1996 study, DesCôteaux et al. conducted experiments using a cascade impactor to describe morphology and size of plume particles produced by electrocautery knife. A portion of the study involved experiments in which smoke aspirated from the abdomen during 5 laparoscopic procedures was drawn through the impactor. Additionally, experiments were conducted whereby animal tissue samples were cauterized for 5 minutes, during which the impactor was placed in close proximity to the plume generation. The lowest impactor stage had a 50% cutoff diameter of 0.1 μm, and the highest stage was 10 μm. Morphologic information was collected by scanning electron microscopic analysis. Sampling of the plume produced in the laparoscopic procedures revealed a bi-modal distribution wherein most particle diameters ranged from 0.1 to 0.25 μm captured on the lowest stage, although a smaller proportion of particles greater than 2 μm in diameter was also identified. The experiments on the animal tissue revealed a different pattern. In comparison to the laparoscopic procedures, a greater proportion of the total particles captured were of the larger size range captured in the top three impactor tray sizes. To describe the morphological characteristics of the particles sampled during both the laparoscopic and animal tissue experiments, electron microscopy was performed. For both sets of experiments, this analysis revealed two morphological patterns: the larger particles were of a heterogenous, fragmented form resembling tissue fragments; the smaller particles were homogeneous spheres [DesCoteaux, Picard et al. 1996].

Microscopy

Kunachak et al. vaporized laryngeal papilloma specimens using a CO_2 laser in continuous mode. The plume created was captured on 0.45 μm pore-size microfilter attached to the tip of a smoke evacuator's suction hose. Microfilters were analyzed by standard scanning electron microscopy.

Results of analysis on the filters indicated that particle diameters were in the size range of 0.5–27 µm, with 70% of particles having a diameter of approximately 0.8 µm [Kunachak and Sobhon 1998].

In a study examining excimer laser plume, Taravella et al. collected plume particles using a methylcellulose filter coupled to the inlet of a smoke evacuator during two corneal ablations. The filters were held 1–2 cm from the corneal surface and analyzed using scanning electron microscopy. The count mean particle diameter was 0.22 µm, with a range of 0.13–0.42 µm [Taravella, Viega et al. 2001].

Real-time, direct reading instrumentation

Particle concentrations of electrosurgical smoke were measured by Brandon et al. [2007] using a laser particle counter during several mammoplasty-related procedures. Additionally, smoke removal devices were evaluated: one in which the smoke removal tube was attached to the electrocautery knife and three others where the exhaust tube was hand-held by the surgical assistant. With no smoke removal device, the particle count in the room, within 5 minutes after the start of electrocautery plume production, quickly rose to and remained at nearly $1x10^6$ particles per cubic foot (particles/ft^3). With an electrocautery knife-based smoke evacuation device, the average particle concentration was approximately $5x10^5$ particles/ft^3, but with peaks reaching above $1x10^6$ particles/ft^3. Use of hand-held smoke evacuation devices produced similar reduced average concentrations, with episodic spikes of higher concentrations [Brandon and Young 1997].

In an evaluation of aerosols produced during use of a harmonic scalpel, Ott et al. used a Grimm model 1106 dust monitor to conduct real-time sampling. The harmonic scalpel was applied to lean pork and beef under different tip conditions and power settings. The aerosol monitor was placed at distances from 15–30 cm from the point of tissue cutting, and collected count information for particles sized from 0.35–6.5 μm. Results indicated that 11–23 times more particles were created from fatty tissue compared to lean tissue, depending on harmonic scalpel tip type. Peak concentrations nearing $1x10^6$ particles per liter (particles/L) were measured [Ott, Moss et al. 1998].

In a 2007 study, Weld et al. wrote "at present, there is a paucity of data regarding the morphology, size and composition of surgical smoke." The objective of their study included characterizing the plume particles produced by four common laparoscopic cutting instruments within a confined space similar to laparoscopic surgery. The four different laparoscopic instruments were macroforceps, the harmonic scalpel, and floating ball and monopolar shears. Pork muscle was the tissue to which the instruments were applied. The collection tubing was placed 5 cm above the point of contact of the instrument with the tissue. An aerodynamic particle sizer and electrostatic classifier characterized the size distribution of the plume particles, and a condensation particle counter (CPC) characterized the total particle concentration. Smoke particles were also viewed by scanning electron microscope for morphologic analysis. Two distinct particle size distributions were observed for each instrument: smaller, spherical particles (geometric mean size: 67–99 nanometers (nm)) and larger irregularly shaped particles (geometric mean size: 889–1080 nm). The macroforceps and harmonic scalpel created relatively smaller number of small particles (means of $5.35x10^5$ and $6.10x10^5$ particles per cubic centimeter (particles/cm^3), respectively), while the floating ball and monopolar shears

created a larger number of small particles (means of $1.65x10^7$ and $4.4x10^7$ particles/cm^3, respectively) [Weld, Dryer et al. 2007].

Brüske-Hohlfeld et al. conducted an investigation in which they used CPCs to quantify the particle concentration in a group of operating room personnel exposed to surgical smoke from electrocautery and argon plasma tissue coagulation for a variety of surgical procedures. Results indicated very high exposure to ultrafine particles, with concentrations $>1x10^5$ particles/cm^3 for short peaks, followed by low level exposures for longer periods. The authors commented "to our knowledge the continuous size distribution of particles in surgical smoke has not been systematically studied." [Brüske-Hohlfeld, Preissler et al. 2008]

In 2011, Pierce et al. reported on a literature review of exposure characterization, health effects, and controls related to laser-generated air contaminants from medical laser applications. While the following comments were meant to describe the literature found on laser-generated particulate matter (PM) concentration and size distribution, they may well be applicable to all surgical instruments beyond lasers: "There have been too few studies, each accounting for different tissue types, laser devices, and operational parameters to draw any definitive conclusions with respect to the true range of PM diameter. Furthermore, several of these studies sampled at locations that were within centimeters of the operative site; thus, it is not clear how the size distributions measured correspond to those experienced in the breathing zone of laser operators. The generation of a more comprehensive data set that is representative of the various possible exposure scenarios is imperative for designing adequate control strategies" [Pierce, Lacey et al. 2011].

Research Design and Methods

This dissertation research was divided into two components: an investigation of the characteristics of surgical smoke under controlled-conditions (Phase I) and a field-based exposure assessment (Phase II). The Phase I controlled-conditions component was conducted to fulfill Specific Aims #1, 2, and 3 to characterize surgical plume particles generated through the application of energy-based instruments to human tissue. The Phase II field-based exposure assessment was conducted to fulfill Specific Aims #3 and 4 to assess the count concentration and size distribution of particles to which operating room personnel are exposed during selected surgical procedures using at least one, but more likely several, surgical plume-producing instruments.

Phase I

The Phase I characterization of particles present in surgical smoke was accomplished through a study utilizing direct-reading instrumentation. The instrumentation used measured several particle characteristics, including the particle count, respirable mass, active surface area, and pPAH concentrations as well as the continuous particle size distribution as the plumes are produced by different surgical instruments under controlled conditions. The research was conducted in an empty operating room at St. Joseph's Hospital Northeast Surgery Center in Fayetteville, New York. Dr. Denis Branson, a board-certified plastic surgeon employed at St. Joseph's Hospital, used four surgical cutting instruments and samples of human tissue removed from patients during previously scheduled surgeries to produce surgical smoke under controlled conditions. Tissues were collected according to a protocol approved by the Institutional Review

Board (IRB) of the Johns Hopkins Bloomberg School of Public Health and the St. Joseph's Hospital. Informed consent for the tissue donation was obtained from patients undergoing routine procedures in which tissue removed would otherwise be disposed of as medical waste.

Experimental Design

Four classes of energy-based cutting instruments were selected for this research. These instruments were selected due to their common use in surgical procedures. Each has a different method of cutting and coagulating tissue through the application of various forms of energy. Depending on the surgical procedure being performed, the type of tissue being cut or cauterized, and the needs and preferences of the surgeon, one or all of these instruments may be utilized during surgery.

The first instrument investigated was the Valleylab Force EZ™ Electrosurgical Generator, which is one of the most commonly used instruments. Also known as a 'bovie', the electrosurgical generator operates through the application of an electric current at the tip of the electrocautery pencil, or 'knife', to cut and cauterize tissue. The tip of the electrocautery knife is applied to the tissue through which the surgeon wants to cut, directing the current into that tissue and using its energy to cut or cauterize. The circuit entering the tissue at the tip of the knife exits through a grounding pad placed on the surface of the nearby skin of the patient. Two modes are available to use with this instrument: cut and coagulate, both with adjustable wattage settings. The cut mode is characterized by high voltage, but low current. The coagulate mode is characterized by high current, but low voltage, resulting in more burning which is useful for cauterization of the tissue. Thirty to forty watts is a typical level of use for both the modes of

this equipment. The zone of effect is approximately 4 millimeters in all directions into the tissue from the point of contact of the tip of the knife, although with higher power settings, the zone of effect may increase. The smaller the surface area of tissue that the electrocautery knife touches, the greater the effect as all the amount of energy is entering at the small point. One variation for the instrument is a bipolar knife tip used when working on tissue which the surgeon does not want to expose to current, such as near nerve tissue. This variation includes a forcep-shaped knife with two tips. The circuit is completed through the two tips rather than exiting through a grounding pad on the skin. The use of this instrument can be tissue dependent as, for example, adipose tissue is more resistant to current, although cutting fat tissue is a common use of the bovie [Branson 2008].

The second piece of equipment investigated was the Ethicon Endosurgery Ultracision Harmonic Scalpel. In this equipment, the tip of the scalpel probe vibrates at 55,000 hertz, producing a shearing action that is not based on the application of a current through the tip, but on the principle of cavitation. Cavitation is the formation of multitudes of minute bubbles, fragmenting the cellular and tissue structures. Since the human body is 70% water, this instrument is often used on tissue with high water content due to increased efficiency (i.e., a greater ability to form bubbles in the cellular compartments). The equipment can be run on varying intensity levels: minimum (typically a 2-3 level, often used for coagulation) and maximum (a 5 level, which has a higher cutting effect). The intensity levels describe the excursion of the harmonic scalpel tip (how far the tip extends and vibrates back and forth). A benefit in the surgeon's use of this piece of equipment is that there is no electrical stimulation of the tissue as there is with the electrocautery knife, with resultant lack of electrically-stimulated muscle twitches. Additionally, since no electrical current is applied, the temperature at the point of application of the tip to the tissue is significantly less than that of the electrocautery knife [Branson 2008].

The third instrument used in the evaluation was Plasma Surgical's Plasma Jet™ Neutral Plasma Coagulator. Rather than using electrical current or vibrational energy to cut or coagulate tissue, the Plasma Jet™ utilizes a stream of argon gas passing over an electrode in the handpiece of the unit, creating a stream of argon plasma. The effect on tissue using this instrument depends on how much argon gas is flowing, how fast the gas is flowing, and how much energy is applied to the flow of gas at the tip of the handpiece. During surgical procedures, the tip of the handpiece out of which the argon flows is brought into close proximity to the tissue. Typically the temperature at the tip is approximately 10-15,000°C. As the tip is moved away even a centimeter in distance, the temperature decreases to around 5000°C. The thermal energy introduced into the tissue, however, is not dispersed through the tissue. In fact, the dispersion of energy into the tissue is only 0.1 millimeters (mm) from the site of cutting. The Plasma Jet™ is a very efficient sterilizer and coagulator of the tissue at the site of contact, and since its effectiveness does not depend on the tissue's water content as does the harmonic scalpel, it can cut through a broad spectrum of tissue, including bone. Unlike the rest of the instruments described, the Plasma Jet is a newer technology for this application; its use in surgical operations is limited at this time as is research on its aerosol production [Branson 2008].

The fourth and final instrument included in this research was the Sharplan Silktouch Surgiplus XJ-series CO_2 laser. The laser acts on the water content in the tissue, increasing the temperature of the tissue to over 100°C, vaporizing the water component and aerosolizing the dry component as smoke. The CO_2 laser is mainly used for a cutting application in a continuous wave mode. The power used is 5–20 watts for most uses. However, tissue ablation, in which the laser is used to destroy the surface layer of skin so as to prevent its re-growth, can use a power level of 120 watts [Branson 2008].

For the trials comparing surgical instruments, particles were generated in the center of the operating room at the surgical table to replicate plume produced during an actual surgery. Ventilation parameters in the operating room were maintained as typical during a surgical procedure. Trials were conducted in which the four cutting instruments are independently applied to dermal tissue and plume measurements were made by sampling equipment either at the point of generation or in the personal breathing zone (PBZ)-level of a staff member at the surgical table. Additionally, separate but similar trials were conducted applying each of these four cutting instruments to human adipose tissue in the same manner as for the dermal tissue for measurements at the point of plume production. During each of the trials, each energy-based cutting instrument was applied to the tissue for a standardized period to produce sufficient plume. The use of these instruments by a surgeon approximated the surgical techniques and thus plume produced during actual surgeries.

Real-time sampling for particle characteristics was conducted before, during, and after plume production. For the PBZ assessment, the inlet for the sampling equipment was located approximately 2–3 feet above the point of plume production via tubing so as to best approximate the PBZ of an individual standing at an operating table, performing surgery with these tools. The sampling equipment was selected to provide characterization of a wide range of particle diameters from 10 nm to 10 µm. Little to no information is known about the characteristics of nano-scale particles produced by these cutting instruments. For this reason, the use of sampling equipment that can measure in this size range was imperative. The characterization of the particle count concentrations and size distributions was accomplished using either an MSP Model 1000XP-A Wide Range Particle Spectrometer™ (WPS™) [MSP Corporation, Shoreview, MN] or an Electrical Low Pressure Impactor (ELPI) [Dekati Ltd., Kangasala, Finland]. Additionally, handheld condensation particle counters were used at

multiple locations in the operating room to detect elevated particle concentrations throughout the room. Statistical analyses were performed to determine differences in particle characteristics based on tissue type, surgical instrument used, and exposure levels in various locations in the operating room.

Phase II

An analysis of exposure to workers under actual work conditions was undertaken to assess how the findings of the controlled laboratory studies translated to the real world. The exposure assessment component of this project was conducted at St. Joseph Hospital Northeast Surgical Center in Fayetteville, New York, where hospital administration granted access to a surgeon's operating room during surgical procedures in which the surgeon used a variety of plume-producing instruments. The surgical procedures performed that were evaluated varied in regards to the amount of surgical plume produced, but included high plume producing operations which are ideal for investigating the characteristics of surgical plume particles. All patients involved in this phase of the research provided informed consent as participants in this study.

The primary focus of this aspect of the research was to establish the magnitude and characteristics of exposure (specifically size distribution and particle count concentrations) of operating room personnel both near and further away from the site of the plume production at the operating room table. Additionally, these data were used to evaluate the appropriateness of laboratory models of surgical plume production in simulating real-world plume production.

The issue of a sterile environment on and around the operating table and its personnel must be recognized. Typically a radius of a few feet is maintained between the sterile surgical field,

surgical tool table, and personnel wearing sterile gowns, and those who are non-sterile (as would be any researchers or sampling equipment in the operating room) to minimize the chances of any surgical site becoming infected during the surgery. These restrictions presented by the operating theater introduced limitations on sampling that had some impact on the ability to conduct a personal exposure assessment. All sampling equipment was situated in a manner to ensure that sampling has no impact on the surgical procedure itself nor interfered with the proper execution of surgical care by the operating room personnel. Measurement of surgical aerosols in the operating room did not change any surgical techniques used by the surgeon.

Because of these space restrictions near the surgical table, the main sampling equipment was placed in the vicinity of the anesthesiologist's station at the head of the surgical table. Short sections of tubing for particle collection to the WPS and CPC instrument were used so that collection in or very near the PBZ of the anesthesiologist was accomplished. Direct-reading monitoring was conducted using these instruments throughout the course of the selected procedures. Handheld CPCs were also stationed throughout the room to assess particle concentration in the operating room. To provide data on background particle size and count concentration and for use as control data to the periods of time during the procedure when plume in produced, sampling was conducted prior to the start of the surgical procedures when no plume was produced. Descriptive statistics such as geometric mean, geometric standard deviation, median, and interquartile ranges of particle counts and sizes were described. Statistical analyses were performed for both the particle concentration and size distribution data to to test for differences in geometric mean particle diameter and count concentrations.

In additional, ventilation parameters in the operating room such as design, volumetric airflow in the room, and the number of air changes per hour were determined and described.

Public Health Significance

As stated previously, 500,000 workers are exposed to surgical smoke every year. [OSHA 2008] While well-designed, large scale epidemiological studies investigating the extent of health effects of these workers from plume exposure are essentially non-existent, smaller comparative studies and questionnaires have shown that at a minimum, workers have associated acute eye and respiratory irritation with exposure to surgical plume. Additionally, studies using animal models have indicated health effects as a result of exposure. At the same time, very little is known regarding characteristics of surgical plume particles and the exposures that health care workers experience during procedures in which plume is produced. This research adds critical information to the body of knowledge in this area of exposure assessment. Furthermore, studies have reported that the use of smoke evacuation devices that provide local exhaust ventilation at the point of plume generation are not routinely and consistently used in many operating rooms [Spearman, Tsavellas et al. 2007; Edwards and Reiman 2008]. Reasons for resisting using such devices have been reported to include a lack of knowledge about the potential associated health effects of exposures as well as being desensitized to the odors that accompany plume production [Ball 2001; Bigony 2007].

This research further clarifies the potential exposures experienced, assists in gaining further recognition by the health care worker community of this issue, provides impetus for use of control measures when needed, guides further development of engineering controls and surgical instruments, and, ultimately will hopefully assist in the reduction of health symptoms and concerns reported by impacted workers.

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Chapter 2 Characterization of Surgical Aerosols at the Point of Generation during Controlled Trials using Multiple Direct Reading Instruments

Abstract

An electrical low pressure impactor (ELPI), ultrafine particle counters, a mass concentration monitor, a photo-electric aerosol sensor (PAS), and a diffusion charging instrument were used to characterize surgical plume particles produced through the application of four energy-based surgical cutting instruments to human dermal tissue. Because each surgical instrument operates on a different principle for its action, the generation of plumes with distinctly different particle characteristics is possible. Direct-reading instruments were used to make real-time measurements during experimental, controlled trials of plume generation using these four surgical instruments in various configurations. Simultaneous measurements were made both at the point of generation to identify characteristics of the plume immediately upon generation as well as at two locations in the periphery of the operating room environment which may reflect exposures for healthcare workers at these locations. At the point of generation during plume production trials, geometric mean (GM) particle number concentrations produced by the instruments ranged from 7.11E+05 to 7.69E+07 particles per cubic centimeter (particles/cm^3); GM respirable mass concentrations ranged from 6.29E-02 to 1.58E+02 milligrams per cubic meter (mg/m^3). GM aerodynamic particle diameters ranged from 0.034–0.095 micrometers (μm). The use of a local exhaust ventilation (LEV) control built into one of the surgical instruments, the electrocautery knife, produced significant reductions in particle number and respirable mass concentrations, measured both at the point of generation and in the periphery of the operating room. Ratios of active surface area concentrations to total particle-bound polycyclic aromatic hydrocarbon (pPAH) concentrations revealed distinct differences in the surface chemistry, relevant to the toxicity, of the ultrafine surgical plume particles, with the electrocautery knife producing particles with the largest quantity of pPAHs per active surface area. Greater understanding of these particle characteristics as well as the effectiveness of both general and local exhaust ventilation will lead to increased understanding of occupational exposures for healthcare workers in these operating room environments.

Introduction

A variety of laser and electrical surgical instruments produce substantial aerosols during tissue cutting procedures. The US Occupational Safety and Health Administration (OSHA) has reported that an estimated 500,000 workers, including surgeons, nurses, anesthesiologists, and surgical technologists are exposed to laser or electrosurgical smoke every year [OSHA 2008]. The National Institute for Occupational Safety and Health (NIOSH) has reported that toxic gases and combustion by-products such benzene can be present in this smoke and that at high concentration can cause eye and upper respiratory irritation in health care workers exposed [NIOSH 1996].

Because of concerns of occupational exposures to these health care workers, further understanding the characteristics of these surgical plume particles can lead to a better understanding of workers' exposures to them, potential health effects from those exposures, and the effectiveness of general and local exhaust ventilation as means for controlling such exposures. Characterizations of surgical plume particle size distributions, especially down to the nanometer-sized fraction, produced by the variety of plume-producing surgical instruments available are limited.

Nezhat et al. collected plume produced by a CO_2 laser during laparoscopic endometrial surgery. The smoke that had accumulated inside the pelvic region was collected by venting it into a sterilized bag. Smoke from the bag was then drawn into a Marple Personal Cascade Impactor which separated the particles by aerodynamic diameter classes ranging from 0.2–0.5 µm to >9.8 µm. The aerosol fractions were deposited onto Mylar film and gravimetrically analyzed. The mass median aerodynamic diameter (MMAD) of particles from 32 samples collected was reported to be 0.31 µm. [Nezhat, Winer et al. 1987]

Particle size distribution of surgical plume was also evaluated by Heinsohn et al. using a 10-stage low-pressure cascade impactor during use of an electrocautery knife on tendon tissue. Aerosol was captured three centimeters above the source point. The collected particles' aerodynamic equivalent diameters (AEDs) were <5 µm, with greater than 50% of the particles captured on the 0.07, 0.14, or 0.28 µm 50% effective cutoff aerodynamic diameter (ECAD) impactor stages. The mode of the particle size distribution was 0.07 µm ECAD when the electrocautery knife was in the cutting mode [Heinsohn, Jewett et al. 1991]. In a follow-up study conducted in 1992, Jewett et al. similarly found that the aerosol particle AED sampled with a cascade impactor measured 0.42 µm or smaller, with the highest percentages of particles captured on the 0.07, 0.14, or 0.28 µm 50% ECAD impactor stages [Jewett, Heinsohn et al. 1992].

In a 1996 study, DesCôteaux et al. conducted experiments using a cascade impactor to describe morphology and size of plume particles produced by an electrocautery knife. A portion of the study involved experiments in which smoke aspirated from the abdomen during 5 laparoscopic procedures was drawn through the impactor. Additionally, experiments were conducted on animal tissue samples that were cauterized for 5 minutes, during which the impactor was placed in close proximity to the plume source. In both parts of the study, the lowest cascade impactor stage had a 50% cutoff diameter of 0.1 µm, and the highest stage of 10 µm. Sampling of the plume produced in the laparoscopic procedures revealed a bi-modal distribution wherein most particle diameters ranged from 0.1–0.25 µm captured on the lowest stage, although a smaller proportion of particles greater than 2 µm in diameter was also identified. The experiments on the animal tissue revealed a different pattern. In comparison to the laparoscopic procedures, a greater proportion of the total particles captured were of the larger size range captured in the highest three impactor trays [DesCoteaux, Picard et al. 1996].

In an evaluation of aerosols produced during use of a harmonic scalpel, Ott et al. used a Grimm model 1106 dust monitor to conduct real-time sampling. The harmonic scalpel was applied to lean pork and beef under different tip conditions and power settings. The aerosol monitor was placed at distances from 15–30 cm from the point of tissue cutting. Particle count information for aerosol fractions from 0.35–6.5 μm were collected. Results indicated that 11-23 times more particles were created from fatty tissue compared to lean tissue, depending on harmonic scalpel tip type. Peak concentrations nearing $1x10^6$ particles/L were measured [Ott, Moss et al. 1998].

In a 2007 study, Weld et al. wrote "at present, there is a paucity of data regarding the morphology, size and composition of surgical smoke." The objectives of their study included characterizing the plume particles produced by four common laparoscopic cutting instruments within a confined space similar to laparoscopic surgery. The four different laparoscopic instruments were macroforceps, the harmonic scalpel, floating ball shears, and monopolar shears, all applied to pork muscle. The aerosol collection tubing was placed 5 cm above the point of contact of the instrument with the tissue. An aerodynamic particle sizer and electrostatic classifier characterized the size distribution of the plume particles, and a condensation particle counter characterized the total particle concentration. Two particle size distributions were produced for each laparoscopic cutting instrument: smaller, spherical particles (geometric mean size: 67–99 nm) and larger irregularly shaped particles (geometric mean size: 889–1080 nm). The macroforceps and harmonic scalpel created relatively smaller number of small particles ($5.35x10^5$ and $6.10x10^5$ particles/cm^3, respectively), while the floating ball and monopolar shears created a larger number of small particles ($1.65x10^7$ and $4.4x10^7$ particles/cm^3, respectively) [Weld, Dryer et al. 2007].

Andreasson et al. [2012] recently reported on a study which identified and quantified polycyclic aromatic hydrocarbons (PAHs), primarily a result of incomplete combustion, in electrocautery smoke during peritonectomy procedures. All 16 U.S. EPA priority pollutant PAHs were detected in the smoke, with naphthalene being the most abundant. Neither the mean concentrations nor any single value concentrations exceeded available occupational exposure limits.

Study Objectives

The goal of this research was to systematically evaluate and characterize surgical plume particles aerosolized through the use of a variety of energy-based cutting and cauterizing instruments at the point of generation. The characterization focused on evaluating a number of characteristics of surgical plume particles produced at the point of generation under a number of configurations of these surgical instruments. These parameters included: particle size distribution, particle number concentration, active surface area concentration, and total particle-bound polycyclic aromatic hydrocarbon (pPAH) production. In addition to these, particle number concentrations were measured at locations in the periphery of the room during the controlled trials of the various surgical instruments, evaluating the impact that surgical instrument type has on the potential for exposure to surgical plume particles in these areas of the operating room.

In addition to evaluating plume particles at the point of generation, a goal was to evaluate the effectiveness of a local exhaust ventilation (LEV) system built into one of the surgical instruments, the electrocautery knife. While the use of LEV has been recommended as a means to control exposures to surgical plume created by instruments such as the electrocautery knife

and the CO_2 laser [NIOSH 1996], further research in the effectiveness of available LEV controls as they are commonly used is needed.

Methods

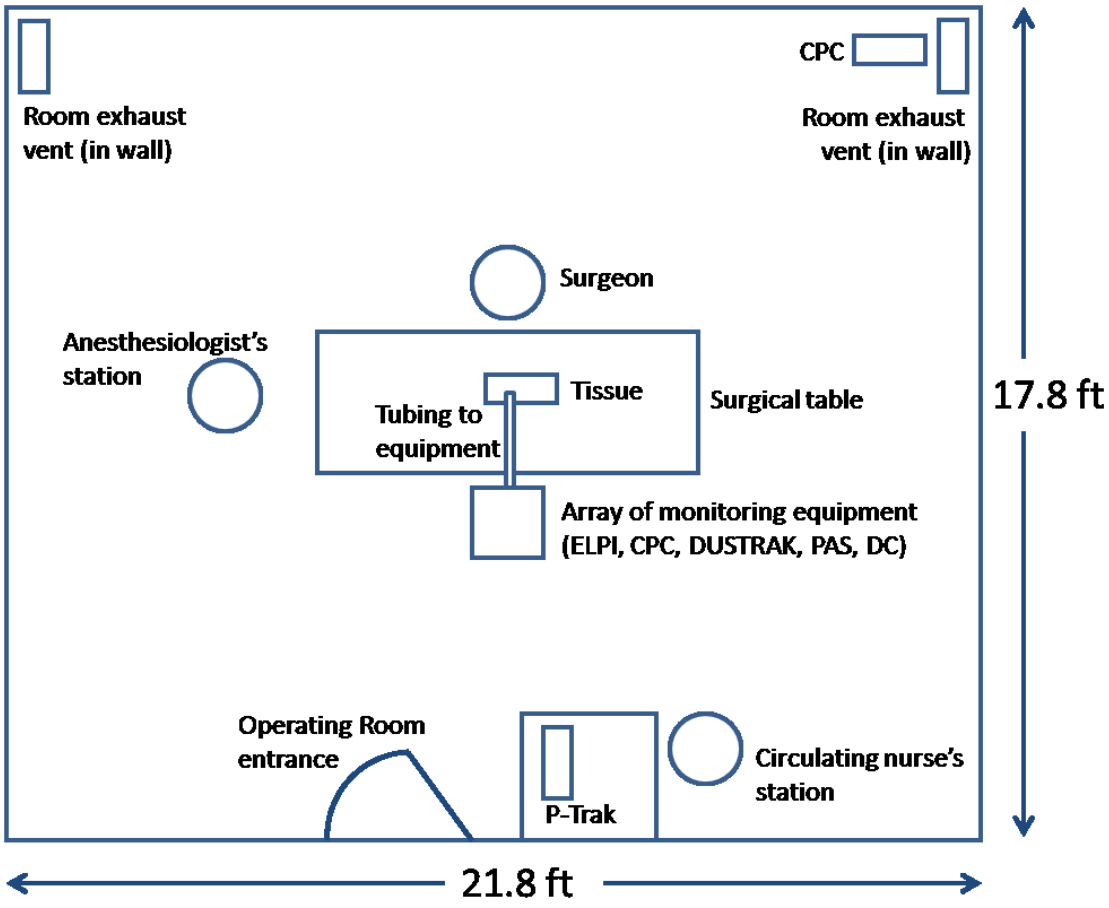
Evaluation of the characteristics of surgical plume particles at their point of generation through the application of energy-based cutting and cauterizing instruments to human dermal tissue was performed in an operating room at a surgery center in Fayetteville, New York. The operating room had been used for multiple surgical procedures prior to our study evaluations; permission was granted by hospital administration to use the operating room after the previously scheduled surgeries performed in the room were complete. After the surgical procedures had been completed, the room was cleaned, leaving the patient bed and energy-based cutting surgical instruments in the room to be used for the plume production evaluations.

All ventilation characteristics remained the same in the room during the plume production evaluations as they were during the actual surgical procedures to reflect real-world operating room conditions. The location of the air supply vents above the surgical table provided a downward laminar flow of high efficiency particulate air (HEPA)-filtered air from above the surgical table to the room's two exhaust vents, each located near the floor in the room's two corners farthest from the OR entrance. Ventilation measurements were made in the operating room using a TSI Inc. AccuBalance Plus model 8373 air capture hood and a TSI Inc. VelociCalc Plus model 8386A to measure air volume flowing through the ventilation supply registers and exhaust vents in order to calculate the number of air changes per hour (ACH) achieved in the OR.

A board-certified plastic surgeon employed at the hospital used the different instruments to human dermal tissue to produce the plume. This tissue had been collected during previous plastic surgery procedures and stored in an airtight container with a small quantity of a sterile saline solution to maintain its freshness. Typically in such surgeries, this tissue is removed and destroyed afterwards by the hospital as biological waste. Informed consent from the patient for the use of their tissue removed during the surgery was obtained prior to the surgeries. The patient's consent to use their tissue for this study did not change any aspect of the surgical procedure itself; no more or less tissue was removed than that required for the surgery. After the evaluations were conducted, the tissue was returned to the hospital's biological tissue waste stream to be destroyed. Johns Hopkins School of Public Health and the hospital IRB approval was obtained for the collection and use of the biological specimens in this manner.

For the surgical plume evaluations, the surgeon placed the tissue collected from the surgery on absorbent tissue pads in the center of the surgical table in a location which approximated the site of surgical work on a patient. Using one of four surgical plume-producing instruments included in the experimental design, the surgeon turned the instrument on and applied it to the dermal tissue. At a distance of approximately 5 cm from the point of instrument contact to the dermal tissue, the inlet of an 18-inch long non-conductive tubing was fixed to collect particles produced. The particle-collection tube led to an array of instruments situated on a mobile cart located next to the patient bed where the plume production was generated (see Figure 2.1).

Figure 2.1 Diagram of the operating room and placement of the sampling equipment



Surgical Instruments

The selected surgical instrument was applied to the tissue for one minute followed by a period of one to two minutes of no application to allow for particle clearance. The surgeon applied the instrument to the tissue using the same surgical technique that would be used during a surgical procedure. One full trial for the instrument was completed when this cycle was repeated for a total of five consecutive on/off repetitions during which continuous, real-time monitoring was conducted.

The four surgical instruments used to produce the surgical plum were: 1) CONMED System 5000™ electrosurgical generator [CONMED, Utica, NY], used in conjunction with a PlumePen™Surgical Smoke Plume Evacuating Electrosurgical Pencil with non-stick blade (also known as a bovie) and ViroVac™ Smoke Plume Evacuation System with ViroSafe® ultralow particulate air (ULPA)/carbon filter [Buffalo Filter, Lancaster, NY); 2) Plasma Jet® Neutral Plasma system (Plasma Surgical, Roswell, GA); 3) Sharplan Silktouch Surgiplus XJ-series carbon dioxide (CO_2) laser (Sharplan Lasers, Inc., Allendale, NJ); and 4) UltraCision® Harmonic Scalpel® (Ethicon Endo-Surgery Inc., Cincinnati, OH).

Four separate trials of plume production and measurement were conducted with the bovie under different operating parameters. These included a trial in the 'cut' mode at a 30 watt (W) power level and a trial in the 'coag' mode at a 30W power level. Two additional trials were conducted at these operating parameters during which the local exhaust ventilation (LEV) option (3/8 inch capture port positioned above the blade) built into the bovie was also activated. Two trials of the Plasma Jet were conducted: one in 'cut' mode where the tip of the instrument was located at the surface of the tissue at a power level of 10 and a 'coag' mode where the tip of the instrument was located 5–15 millimeters (mm) from the surface of the tissue at a power level of 10. One trial of the harmonic scalpel was conducted. One trial of the CO_2 laser was conducted at a 5W power level and a 200 mm handpiece.

Particle Measurement Equipment

Several direct reading instruments were used to fully characterize different parameters of the particles produced by the surgical instruments including: particle size distribution, particle number concentration, respirable mass concentration, active particle surface area

concentration, and total concentration of particle-bound polycyclic aromatic hydrocarbons (PAHs). A similar array of particle monitoring equipment has been utilized in other studies of ultrafine particle exposures including evaluating exposures to engineered carbon nanofibers (CNFs) at a production facility [Evans, Ku et al. 2010] and exposures to ultrafine combustion particles for firefighters [NIOSH 2010, 2013].

Because of the high concentrations of particles expected to be present at the point of plume generation and capture, a diluter filter was placed in-line after the capture of particles, but prior to measurement by the array of direct reading instruments (see Figure 2.2). This diluter prevented the measured concentrations from exceeding the upper limits of the direct reading instruments and provided a dilution factor of 28. The diluter was not needed during particle production by the harmonic scalpel.

Figure 2.2 Tissue on the surgical bed, with the black inlet tube connected to the diluter

The five pieces of monitoring equipment located on the mobile cart stationed next to the surgical table through which the sample stream was diverted included: an Electrical Low Pressure Impactor (ELPI) [Dekati Ltd., Kangasala, Finland]; a condensation particle counter (CPC) [model 3007; TSI Inc., Shoreview, MN]; a DustTrak [model 8533; TSI Inc., Shoreview, MN]; a diffusion-charging (DC) based instrument [DC 2000CE; EcoChem Analytics, League City, TX]; and a photoelectric aerosol sensor (PAS) [PAS 2000 CE; EcoChem Analytics].

The ELPI was used to provide particle number concentrations and real-time size distribution measurements of particles. The ELPI can size particles with aerodynamic diameters from 0.007—10 μm by charging particles in a corona charger. Upon entering a series of impactor collection stages, the charged particles are collected on specific stages based on their aerodynamic diameter. Electrometers at each stage measure the electric charge carried by the particles impacting that stage which can be converted to particle number concentration and size. Oiled sintered metal collection plates were used in order to minimize particle bounce. The ELPI size distribution data were collected on a per-second basis allowing for characterization of fluctuations in the particle size distributions, with an external laptop running ELPI VI 4.0 software for control and data acquisition.

The CPC was used to measure particle number concentrations. The CPC utilizes alcohol vapors that condense around particles in the sample stream, growing them to a size which can be counted by an optical detector. The CPC can count particles in a size range of 0.010–1.0 micrometers (μm) up to concentrations of 100,000 particles/cm^3. However, counting coincidence errors increase as concentrations increase beyond 100,000 particles/cm^3. The CPC was configured with logging intervals of 1 second.

Real-time particle mass estimates were measured using the DustTrak. The DustTrak simultaneously measures mass fraction concentrations corresponding to total particulate matter (PM), respirable PM, PM_1, $PM_{2.5}$, and PM_{10} fractions. The instrument uses a light scattering laser photometer, combining particle cloud and single particle detection for mass fraction measurements. The DustTrak was configured with logging intervals of 1 second.

Real-time surface area measurements were made using the DC 2000CE. The DC instrument charges all particles in the sample stream using a corona discharge and measures the current with an electrometer. The charge attachment is a surface phenomenon and therefore the measured current can be related to the particle surface area. The DC instrument was configured with logging intervals of 10 seconds.

The PAS 2000CE was used to detect particle-bound polycyclic aromatic hydrocarbons (PAHs) on ultrafine particulate matter generated through incomplete combustion. The PAS uses an excimer lamp to expose the particles to ultraviolet radiation at a wavelength such that only the aerosols coated with PAHs are ionized. These ionized aerosols are measured on a filter inside an electrometer, providing a signal proportional to the concentration of total particle-bound PAHs. The PAS instrument was configured with logging intervals of 10 seconds.

In addition to these instruments located on the mobile cart, two additional instruments were positioned in two locations in the periphery of the operating room to characterize particle concentrations. A CPC was located four feet above the floor in front of one of the exhaust vents in the far corner of the operating room opposite the entrance to the room. A P-Trak [model 8525; TSI Inc.] particle counter was located at the circulating nurse's station immediately to the right of the entrance to the operating room. A P-Trak is similar in operation to the CPC although the concentration of particles sized 0.020–1.0 μm that are reliably detected by the P-Trak is up

to 500,000 particles/cm^3. The locations of these two pieces of equipment in the periphery of the room were intended to provide information regarding the spread, concentration, and distribution of surgical plume particles to which operating room personnel would be exposed during the use of such surgical instruments at the operating room table.

Results and Discussion

Ventilation Characteristics

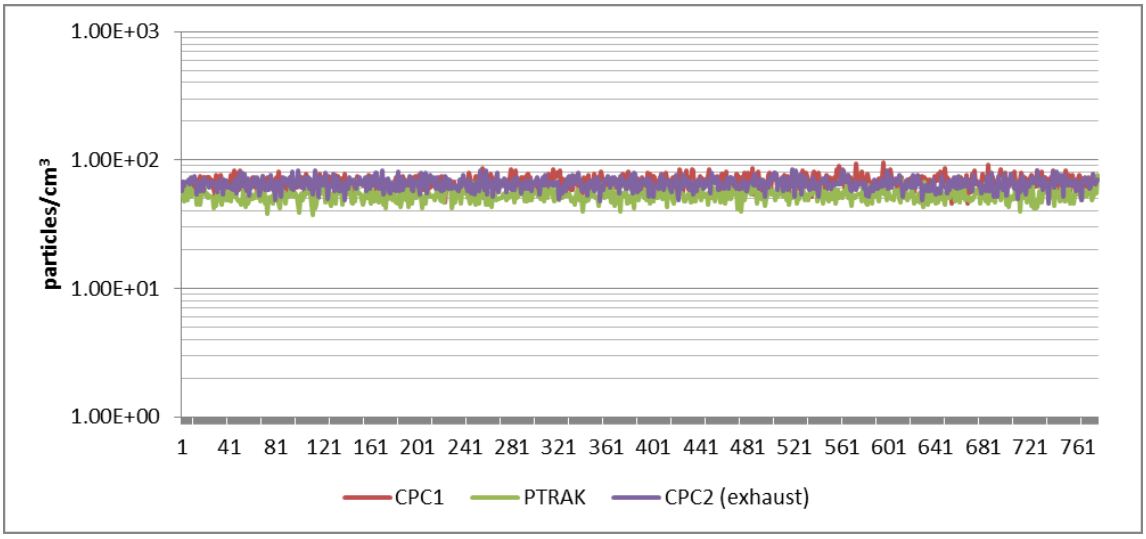
Airflow through the supply vents above the surgical table was measured to be approximately 1200 cubic feet per minute (CFM); airflow through the exhaust vents measured approximately 1300 CFM, suggesting a slight negative pressure in the room. ACH was calculated to be 20 based on measured room dimensions.

Characterization of Background

Prior to conducting the controlled trials of plume production, the two CPCs and the PTRAK were co-located side-by-side to determine background particle number concentrations in the operating room. Figures 2.3 shows the per-second time series background concentrations (n=777) calculated for the 3 particle counting instruments located side-by-side. Because of the laminar flow, HEPA-filtered air originating above the surgical table, background particle concentrations were very low (below 100 particles/cm^3), allowing increases in particle concentrations during the trials to be specifically attributed to surgical plume with little to no

background interference since no other particle-generating activities were performed at the times the trials were conducted.

Figure 2.3 Real-time Background Particle Number Concentrations - Side-by-Side

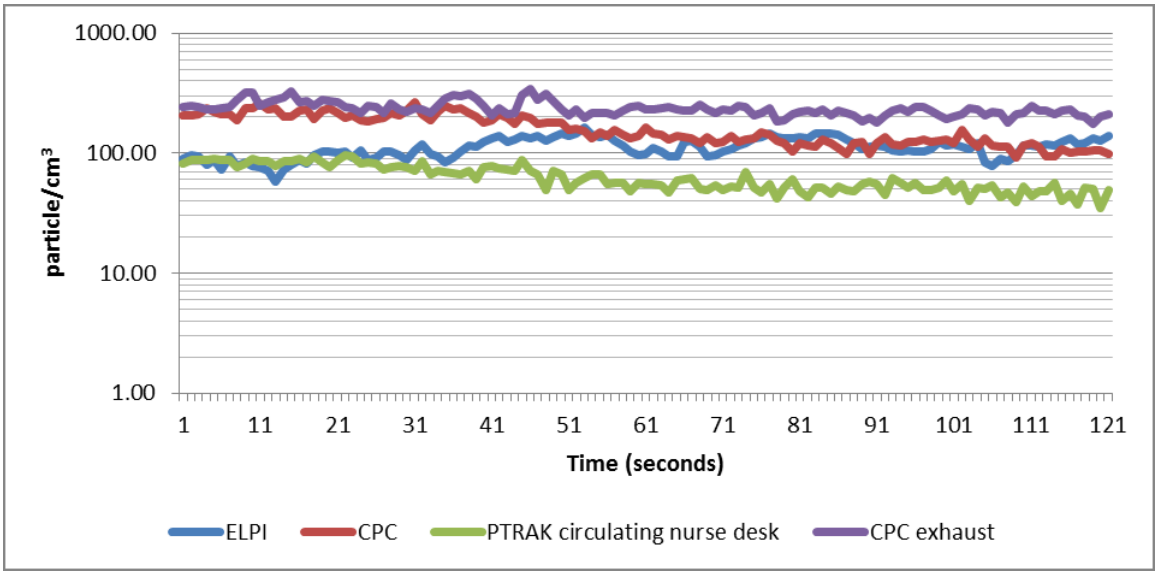


GM concentrations for the CPC1, CPC2 (exhaust), and PTRAK were 67, 65, and 53 particles/cm^3, respectively, with GSDs of 1.1 calculated for each GM. For every second of data collection, the log-transformed concentration from the PTRAK was subtracted from the log-transformed concentration from the CPC1, divided by the average of the two concentrations, and then converted to a percentage to determine the percent difference. The average percent difference over the 777 seconds between the PTRAK's concentrations compared to the CPC1's concentrations was 6.0%. Calculated in the same manner, the average percent difference between the CPC2's concentrations compared to the CPC1's concentrations was 2.9%.

Particle concentration measurements were also made to determine background concentrations in the operating room environment for the ELPI, DustTrak, CPCs, and PTRAK in the locations used during the plume production trials. Figures 2.4 shows the time-series background

concentrations (n=120). GM concentrations for the ELPI and co-located CPC were 109 and 154 particles/cm^3, respectively. The average percent difference over the 120 seconds between the ELPI's concentrations compared to the CPC's concentration was 8.4%. GM concentrations for the PTRAK was 61 particles/cm^3 and 234 particles/cm^3 for the CPC at the exhaust. Background concentrations for respirable mass were below the equipment's limit of detection.

Figure 2.4 Real-time Background Particle Number Concentrations



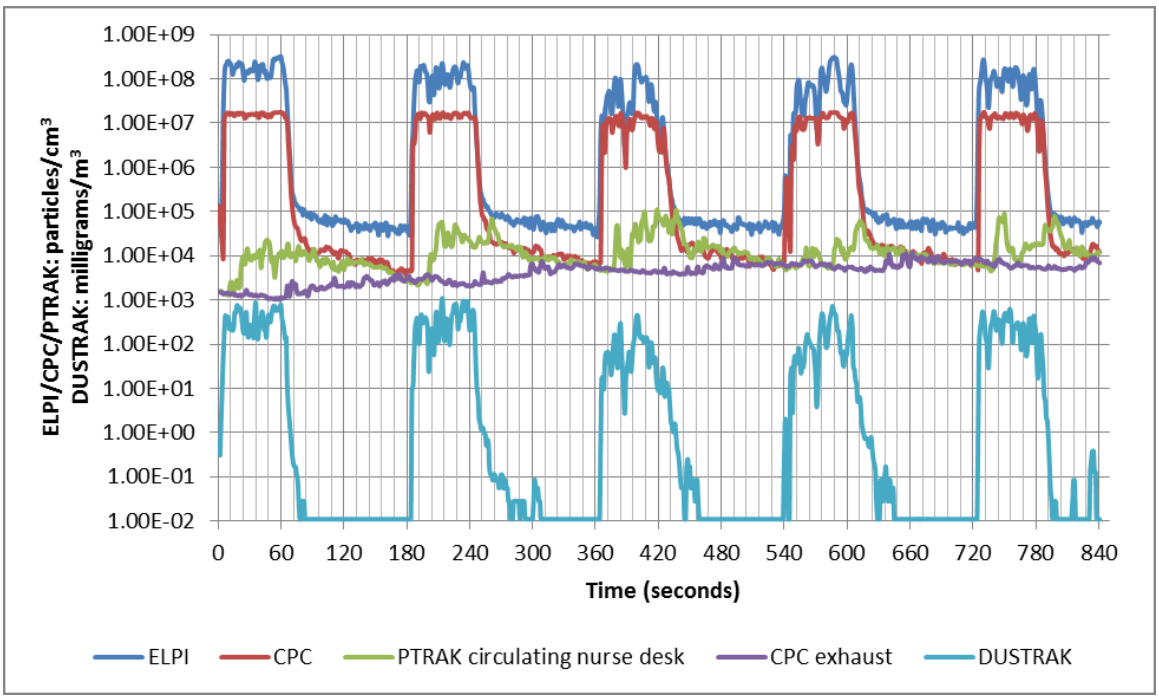
Point-of-Generation

Particle Number and Particle Mass Concentrations

Five consecutive one-minute rounds of plume generation were performed with each surgical instrument. The particle number concentrations generated were simultaneously recorded in real-time by the ELPI and a CPC at the point of generation and by a CPC and P-Trak in their respective locations in the periphery of the room. An example of these real-time measurements for one of the surgical instruments, the CO_2 laser, is shown in Figure 2.5. Also shown in the figure are the real-time respirable mass concentrations measured at the point of generation

during the five periods of plume production. Individual graphs corresponding to each of the surgical instruments and their respective configurations can be found in the Appendix as Figures A1–A8.

Figure 2.5 Particle Number and Respirable Mass Concentrations: CO_2 Laser



As can be seen in Figure 2.5, immediate increases in particle concentration were visible during each sixty-second period of plume production, often in excess of three to four orders of magnitude, with peaks reaching above 1.00E+08 particles/cm^3. An immediate and substantial drop was measured by the ELPI and CPC at the point of generation after cessation of application of the instrument to the tissue, followed by a slight decay rate through the 60–120 seconds of non-plume producing interval between each round. Peak CPC measurements at the point of generation were generally lower than those measured by the ELPI and may reflect limitations of the instrument at higher concentrations. Generally speaking, two trends were visible for the particle number concentrations in the periphery of the room, describing the distribution of

plume particles throughout the operating room. Figure 2.5 also shows that the particle counter at the circulating nurse's desk often saw periods of increased concentrations, delayed by several seconds after the initiation of plume production, and greater levels of variability in increases and decreases of particle number concentration corresponding to the plume production periods. In contrast, the particle number concentrations measured at the side of the room near the exhaust vent indicated a slow increase that did not appear to coincide with the individual plume production periods but gradually tapered off to a consistent and stable concentration typically at or after the second round of plume production. The patterns of respirable mass concentrations recorded at the point of generation by the DustTrak produced by the CO_2 laser (Figure 2.5) appeared to correlate closely with the particle number concentrations at the point of generation, with similar immediate increases and decreases to and from background level at the start and finish of each sixty-second plume production period.

In addition to overall particle number concentration, the ELPI provided size distribution data for particles produced by each of the surgical instruments. These data, along with respirable mass concentrations, are summarized for each configuration of the surgical instruments in Table 2.1.

Table 2.1 Summary of Descriptive Statistics for Plume Particles by Instrument (n=300 per instrument)

Instrument	**Count Median Diameter (μm) [GSD]**	**GM Particle Number Concentration (particles/cm^3) [GSD]**	**GM Respirable Mass Concentration (milligrams/m^3) [GSD]**
Harmonic Scalpel	0.034 [1.48]	7.11E+05 [5.68]	1.61E-01 [3.60]
CO_2 laser	0.070 [5.86]	7.69E+07 [2.73]	1.58E+02 [3.18]
Electrocautery knife (cut mode), *with LEV*	0.085 [12.37]	9.74E+05 [4.42]	1.68E+00 [12.60]
Electrocautery knife (cut mode), *without LEV*	0.095 [7.99]	7.78E+06 [3.87]	2.24E+01 [5.56]
Electrocautery knife (coag mode), *with LEV*	0.061 [9.60]	3.15E+06 [5.96]	7.95E-01 [12.21]
Electrocautery knife (coag mode), *without LEV*	0.069 [8.25]	1.30E+07 [5.44]	5.53E+00 [9.69]
Plasma Jet (cut mode)	0.041 [5.18]	1.52E+07 [3.27]	1.18E-01 [6.85]
Plasma Jet (coag mode)	0.046 [6.84]	6.16E+06 [5.18]	6.29E-02 [8.26]

The count median diameters (CMD) and GSDs were calculated to describe the size distribution of particles produced by the application of each instrument to the tissue. The shapes of the size distributions were unimodal for the particles produced by all the surgical instrument configurations tested, with the range of the CMDs from 0.034–0.095 μm and broad GSDs, particularly for the electocautery knife, reflective of the dynamic nature of the surgical plume. The harmonic scalpel produced the smallest particles at 0.034 μm CMD. The plasma jet in cut and coag modes produced particles with 0.041 and 0.046 μm CMD. The electrocautery knife in coag mode produced particles with CMD of 0.061 and 0.069 μm, with and without the use of LEV, respectively. The CO_2 laser produced particles with CMD of 0.070 μm. The electrocautery knife in cut mode produced particles with the largest CMDs of 0.085 and 0.095 μm, with and with the use of LEV, respectively.

The use of the LEV control in the electrocautery knife in both cut and coag modes resulted in GM particle size diameters that were slightly smaller, suggesting the LEV may have been

effective at capturing and removing larger sized particles, shifting the size distribution of particles released into the operating room environment slightly downward. Figure 2.6 shows the log-normal size distributions of the particles produced by the electrocautery knife, in both the cut and coag modes, with the LEV activated and off for both modes. Figure 2.7 shows the particle size distributions for the same instrument configurations on a log-probability plot with a line of best fit plotted for each configuration and approximating the particle CMD for each configuration as the line of best fit intersects the 0.5 fraction. Individual graphs of log-normal particle size distributions and log-probability plots corresponding to each of the surgical instrument configurations can be found in the Appendix as Figures A9–A16.

Figure 2.6 Particle Size Distributions: Electrocautery Knife (Cut and Coag Modes), With and Without LEV as measured by the Electrical Low Pressure Impactor (ELPI)

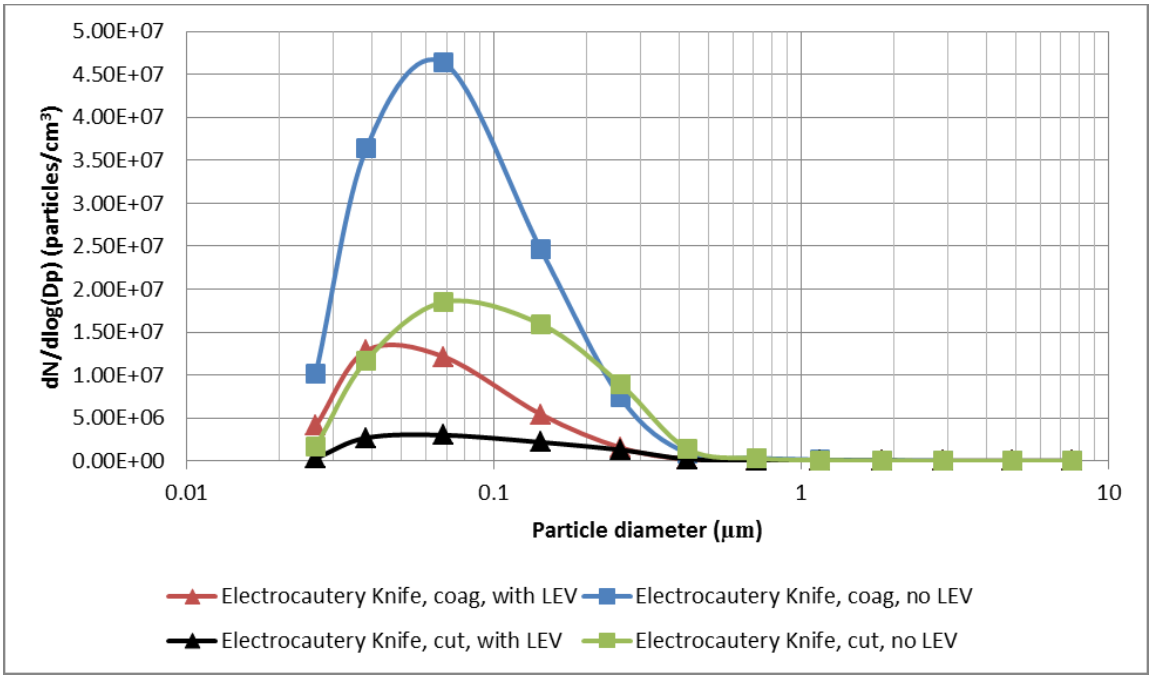
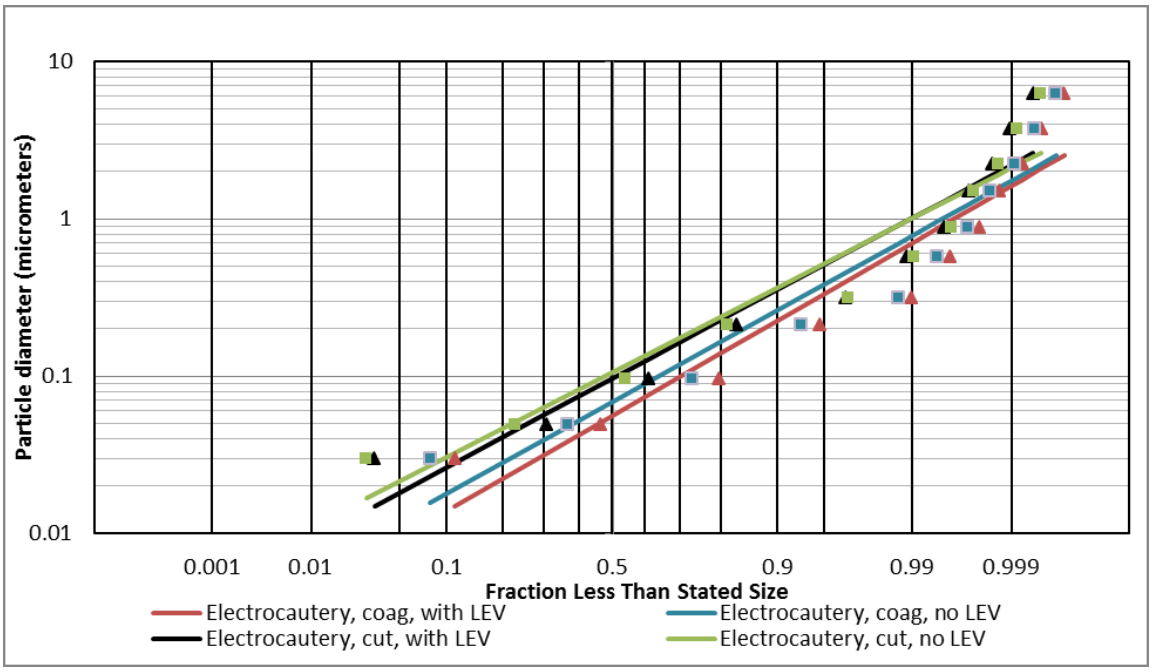
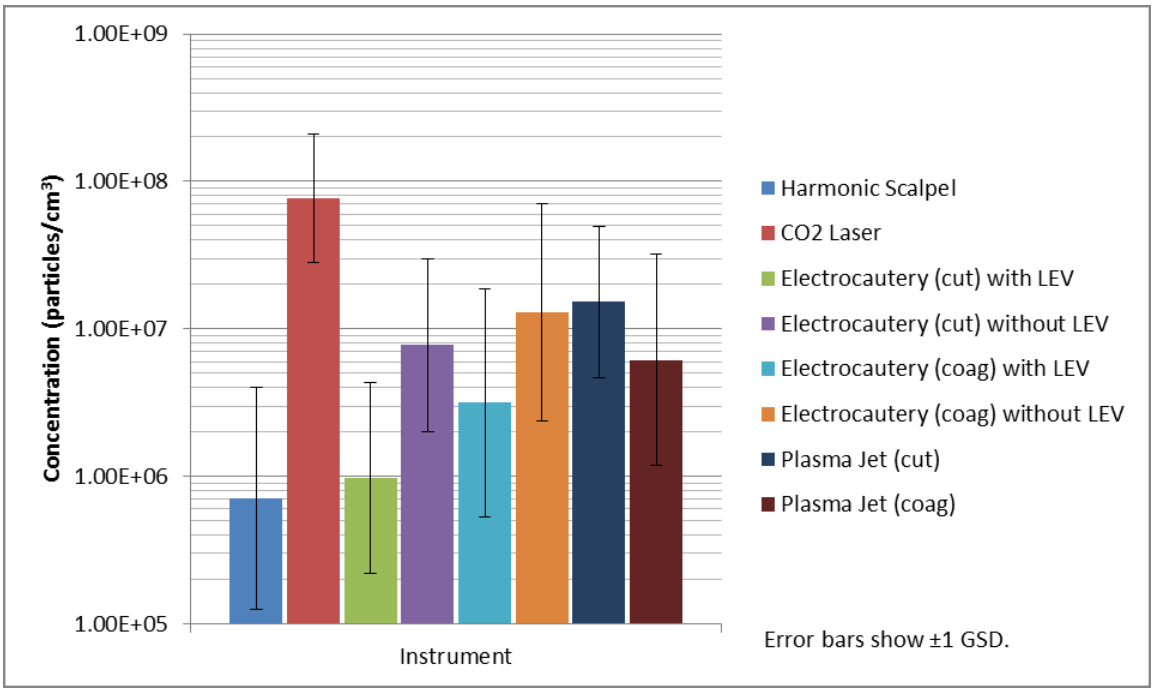


Figure 2.7 Log-Probability Plots: Electrocautery Knife (Cut and Coag Modes), With and Without LEV, as measured by the Electrical Low Pressure Impactor (ELPI)



The geometric means of the one-second particle number concentrations at the point of generation measured throughout the five sixty-second plume-generating periods (n ≈ 300 per surgical instrument) and corresponding GSD based on ELPI measurements are compared in Figure 2.8. In addition to producing the smallest sized particles, the harmonic scalpel was shown to produce the lowest number concentrations (7.11E+05 particles/cm^3) of all the instruments without the use of LEV. The instrument that produced the greatest particle number concentrations was the CO_2 laser (7.69E+07 particles/cm^3). Figure A17 in the Appendix shows the particle number concentrations for all of the instruments for each of their five plume producing rounds.

Figure 2.8 Geometric Mean Particle Number Concentrations as measured by the Electrical Low Pressure Impactor (ELPI)



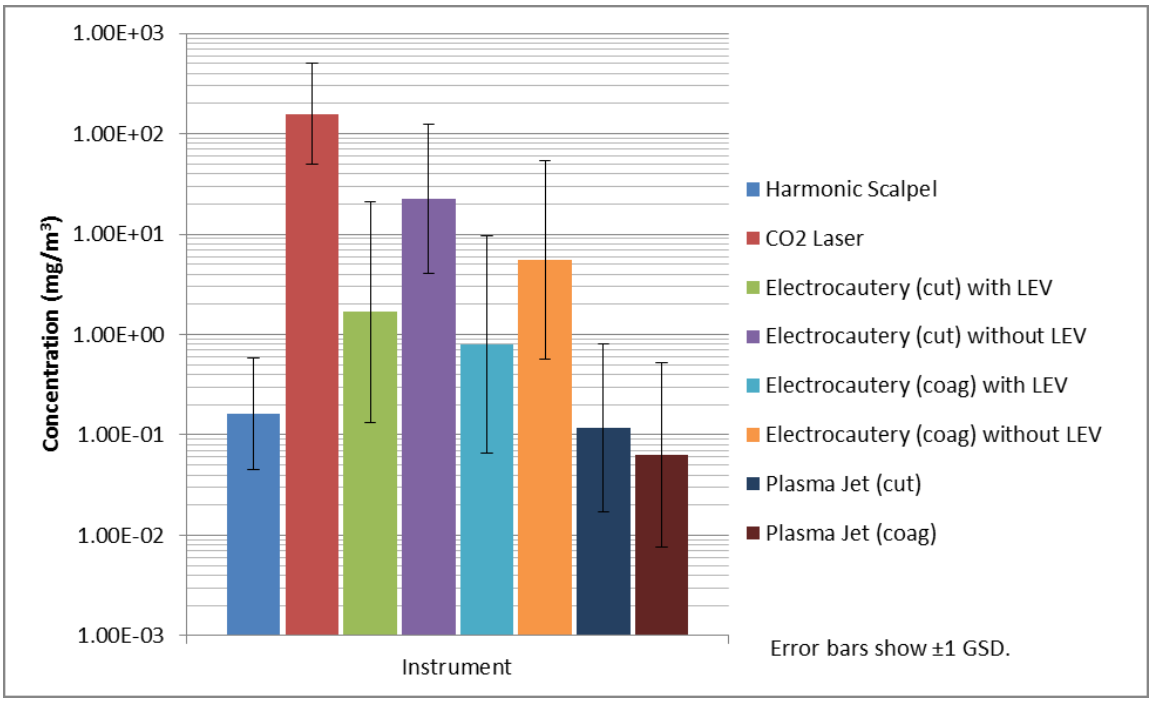
The impact of using the LEV built into the electrocautery knife is qualitatively visible when comparing the real-time concentration measurements in Figure A3 (LEV control activated) and Figure A4 (LEV control not activated). Reductions in peak concentrations were observed for both particle number and mass concentrations with the use of LEV during the plume production periods. Similar patterns of reductions were identified when the electrocautery knife was used in the coag mode with and without the LEV control (Figures A5 and A6).

The impact of the built-in LEV in the electrocautery knife can be quantitatively compared using the GM particle number concentrations calculated in both the cut and coag mode as shown in Figure 2.8. In the cut mode, the use of the LEV produced a statistically significant ($p<0.001$) 87% reduction in GM particle number concentrations from 7.78E+06 to 9.74E+05 particles/cm^3; in

the coag mode, the GM particle number concentration was significantly reduced ($p<0.001$) by 76% from 1.30E+07 particle/cm^3 without LEV use to 3.15E+06 particles/cm^3 with LEV use.

The geometric means of the one-second respirable mass concentrations measured throughout the five sixty-second plume-generating periods ($n \approx 300$ per surgical instrument) and corresponding GSD based on DustTrak measurements are listed in Table 2.1 and also compared in Figure 2.9. Because of the ultrafine size of the surgical plume particles measured, the mass of such particles can be negligible in comparison to larger fine and course-sized particles [Maynard 2003]. For the most part, the GM concentrations of respirable mass reflected patterns of particle diameter size and number concentrations produced by the different configurations of the individual surgical instruments. The harmonic scalpel, with the smallest GM particle diameter and lowest GM particle number concentration of the instrument configurations, also produced one of the lowest GM respirable mass concentrations at 1.61E-01 mg/m^3. Likewise, the CO_2 laser produced the largest GM respirable mass concentration at 1.58E+02 mg/m^3. Of all instruments, the plasma jet produced the lowest respirable mass concentrations. Reductions in respirable mass concentrations were observed when using the LEV control of the electrocautery knife in both cut and coag mode. In the cut mode, the use of the LEV produced a statistically significant ($p<0.001$) 93% reduction in GM particle mass concentrations from 2.24E+01 to 1.68E+00 mg/m^3; in the coag mode, the GM particle mass concentration was significantly reduced ($p<0.001$) by 86% from 5.53E+00 mg/m^3 without LEV use to 7.95E-01 mg/m^3 with LEV use. Figure A18 in the Appendix shows the respirable mass concentrations for all of the instruments for each individual trial.

Figure 2.9 Geometric Mean Respirable Mass Concentrations as Measured by the DustTrak



To evaluate whether the particle number concentrations measured provided predictive indications of co-located measurements of particle mass concentrations, regressions were performed for each instrument's particle number and respirable mass concentrations measured over the entire cycle of the five plume producing periods and intervals between periods. Results of regression equations and the coefficients of determination for each instrument are included in Table 2.2. As the results in the table suggest, the correlation between particle number and respirable mass concentrations varied widely from instrument to instrument.

Table 2.2 Summary of Relationship between Measured Particle Number and Particle Mass Concentrations by Surgical Instrument

Instrument	**Regression equation, Particle Number vs. Respirable Mass concentrations [R^2, Coefficient of Determination]**
Harmonic Scalpel	y = 2E-08x + 0.1031 [0.04]
CO_2 laser	y = 2E-06x + 0.4073 [0.82]
Electrocautery knife (cut mode), *with LEV*	y = 3E-06x + 0.6764 [0.55]
Electrocautery knife (cut mode), *without LEV*	y = 4E-06x + 0.1009 [0.77]
Electrocautery knife (coag mode), *with LEV*	y = 4E-07x + 0.538 [0.40]
Electrocautery knife (coag mode), *without LEV*	y = 8E-07x – 0.6521 [0.67]
Plasma Jet (cut mode)	y = 2E-08x – 0.0214 [0.55]
Plasma Jet (coag mode)	y = 5E-08x – 0.1238 [0.47]

Figures 2.10 and 2.11 show examples of graphs comparing the particle number and respirable mass concentrations in logarithmic scales for the harmonic scalpel and CO_2 laser, respectively, showing the fitted regression line as well as the regression equation and coefficient of determination (R^2) for the data. The CO^2 laser showed the greatest proportion of variation in the respirable mass concentration attributed to the particle number concentration ($R^2 = 0.822$). In contrast, the fitted regression line for the harmonic scalpel reflected a poor relationship between the measured data points ($R^2 = 0.039$). Correlations for the other surgical instruments fell between these extremes. Graphs of results from all instruments are shown in the Appendix as Figures A19–26. The introduction of the LEV control for the electrocautery knife in both cut and coag modes produced models that showed reduced correlations between the two concentration measures. This may be expected because of the size/mass biased particle removal by the LEV.

Figure 2.10 Relationship between Particle Number and Respirable Mass Concentrations for the Harmonic Scalpel as Measured by the Electrical Low Pressure Impactor (ELPI) and the DustTrak

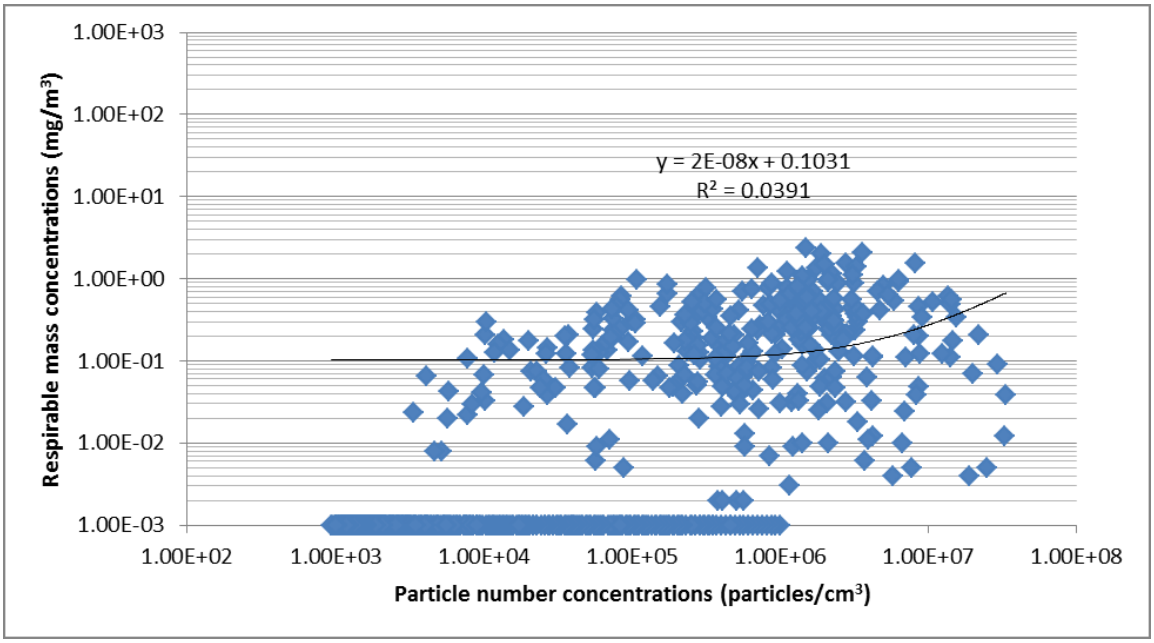
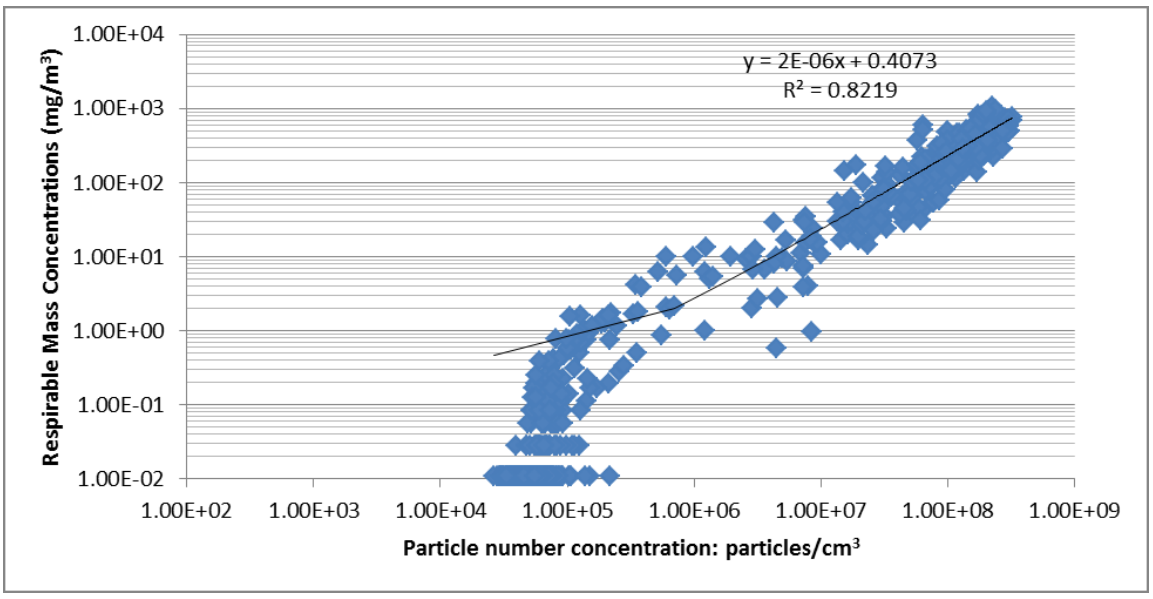


Figure 2.11 Relationship between Particle Number and Respirable Mass Concentrations for the CO_2 Laser as Measured by the Electrical Low Pressure Impactor (ELPI) and the DustTrak



Active Surface Area and Particle-bound Polycyclic Aromatic Hydrocarbon Concentrations

PAHs can be produced during incomplete combustion or from high temperature pyrolytic processes that involve carbon- and hydrogen-containing materials [Bostrom, Gerde et al. 2002]. Chetwittayachan et al. [2002] described that the combustion particles most associated with PAH adsorption are those with an aerodynamic equivalent diameter smaller than 1–2 μm. While PAHs can be found in the gas phase, those with more than four aromatic rings have high potential to adsorb onto the surface of combustion particles [Harrison, Smith et al. 1996].

Siegmann et al. [1999] reported that when such PAHs are adsorbed on the surfaces of fine particles, they can be detected with great efficiency through photoelectric particle ionization. In this process, exposure of the particle to ultraviolet (UV) light causes it to become positively electrically charged after emitting a negative photoelectron. When no PAH molecules are adsorbed onto the surface, particle photoemission is weak. However, PAH molecules adsorbed onto the particle surface absorb the UV light very efficiently, thus allowing these particles to become highly photoionized; this positive charge can then be measured by an electrometer [Ott and Siegman 2006]. Photoelectric aerosol sensors (PASs) that utilize this method have been used successfully in the past to evaluate PAHs on fine particles such as cigarette smoke aerosols [Niessner and Walendzik 1989], secondhand cigarette smoke specifically in hospitality venues before and after a smoking ban [Repace 2004], and aircraft exhaust [Childers, Witherspoon et al. 2000].

Measuring the total particle-bound PAH (pPAH) concentrations in conjunction with the active surface area (SA) concentration, measured by a diffusion charging (DC) monitor, can provide additional particle characterization. When these concentrations are measured simultaneously

and calculated in a pPAH/SA ratio, the amount of PAH mass per unit area of the active surface of the particles is quantified and creates a normalized indicator of PAHs on fine particles. The higher the pPAH/SA ratio, the greater the quantity of PAH molecules per unit surface area [Ott and Siegmann, 2006]. This ratio, therefore, is relevant to the quantity of pPAHs transported into the deepest regions of the respiratory tract [Polidori, Hu et al. 2008]. Mage [2002] suggests that particle chemistry, such as PAH adsorption, is of greater relevance to the health effects of fine particles compared to the number or mass concentrations of those particles. The pPAH/SA ratio technique has been used previously in characterizing the properties of a variety of combustion particles, including from motor vehicle exhaust [Polidori, Hu et al. 2008] and tobacco, incense, candle, cooking, wood burning, and vehicular sources [Ott and Siegmann, 2006].

Simultaneous measurements of active surface area concentrations using the DC 2000CE and total pPAH concentrations using the PAS 2000CE were made at the point of generation during the five sixty-second periods of surgical plume generation by surgical instrument configuration. The overall GM concentrations and GSDs for each were calculated and presented per surgical instrument in Figures 2.12 and 2.13. Figures A27 and A28 in the Appendix show the active surface area and total pPAH concentrations for all of the instruments on an individual trial basis. The patterns of GM active surface area concentrations for the surgical instruments was reflective of and appeared to closely follow particle number concentrations seen in Figure 2.8; such patterns between ultrafine particle number concentrations and surface area concentrations have previously been reported [Heitbrink, Evans et al. 2009; Evans, Ku et al. 2010; Dahm, Evans et al. 2013]. The highest active surface area concentrations were produced by the CO_2 laser and the lowest by the harmonic scalpel (Figure 2.12). A different pattern was observed for pPAH concentrations with the highest concentrations produced by the

electrocautery knife and the harmonic scalpel also producing the lowest concentration (Figure 2.13).

The application of the LEV control for the electrocautery knife saw a statistically significant 87% reduction ($p<0.001$) in GM SA concentrations in the cut mode and 66% in the coag mode. For GM total pPAH concentrations, these significant reductions ($p<0.001$) were 80% and 41%, for the cut and coag modes, respectively.

Figure 2.12 Geometric Mean Active Surface Area Concentrations by Surgical Instrument as Measured by the DC 2000CE

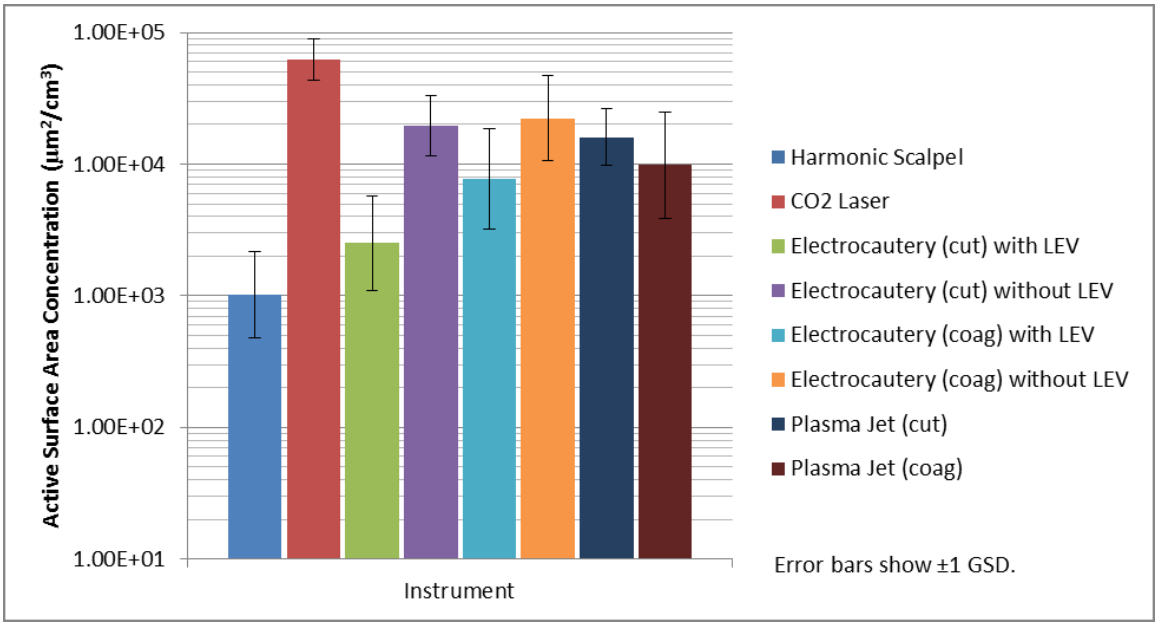
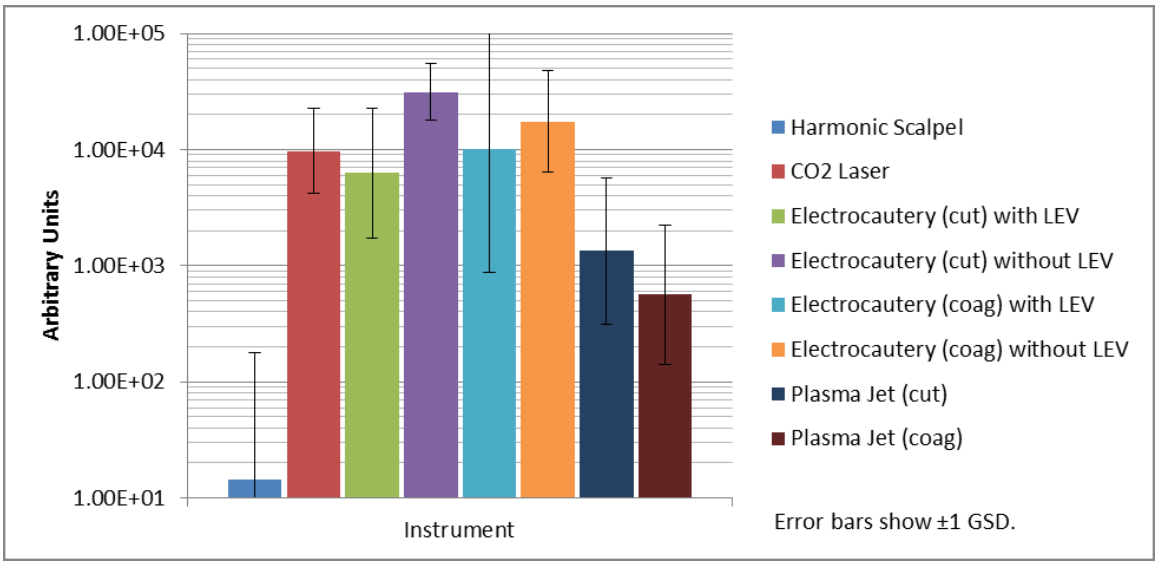


Figure 2.13 Geometric Mean Total Particle-bound PAH Concentrations by Surgical Instrument as Measured by the PAS 2000CE



Ott and Siegmann [2006] suggest two ways to calculate the pPAH/SA ratio: 1) regression analyses with the slope of the least-squares regression line yielding the pPAH/SA ratio and 2) calculation of individual ratios using the means from each averaging period. Table 2.3 shows the results from both of these types of analyses for each of the tested configurations of the surgical instruments. The slopes of the regression equations, underlined in the figure, show the ratio as determined by that method. Figures 2.14 and 2.15 show examples of graphs for two of the surgical instruments, the harmonic scalpel and CO_2 laser, respectively, with their calculated regression lines, regression equations, and coefficients of determination. Individual graphs corresponding to each of the surgical instrument configurations can be found in the Appendix as Figures A29–A33. The surface area and total particle-bound PAH concentrations showed a wide range of correlations with coefficients of determinations from 0.14 for the harmonic scalpel to 0.83 for the CO_2 laser.

Table 2.3 Comparison of pPAH/SA Calculated from Regression Equations and Ratios of Geometric Mean Concentrations by Surgical Instrument

Instrument	Regression equation, PAS vs. DC [Coefficient of Determination]	Ratio of pPAH GM/SA GM
Harmonic Scalpel	y = 0.0531x + 9.1602 [0.14]	0.09
CO_2 laser	y = 0.195x – 145.67 [0.83]	0.12
Electrocautery knife (cut mode), *with LEV*	y = 1.983x + 2379 [0.21]	0.93
Electrocautery knife (cut mode), *without LEV*	y = 0.6531x + 10,912 [0.18]	0.62
Electrocautery knife (coag mode), *with LEV*	y = 0.9304x + 5344.3 [0.17]	0.46
Electrocautery knife (coag mode), *without LEV*	y = 0.4199x + 6304.6 [0.16]	0.32
Plasma Jet (cut mode)	y = 0.0719x + 646.41 [0.09]	0.10
Plasma Jet (coag mode)	y = 0.0408x + 257.89 [0.21]	0.05

Figure 2.14 Regression Analysis for pPAH/SA: Harmonic Scalpel

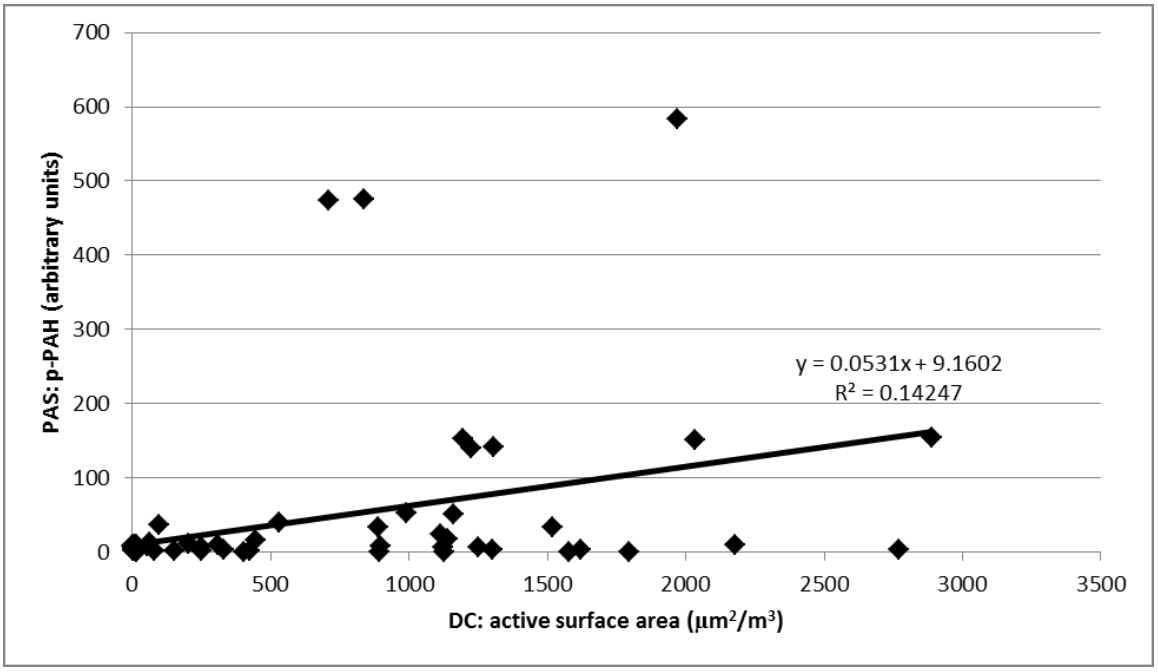
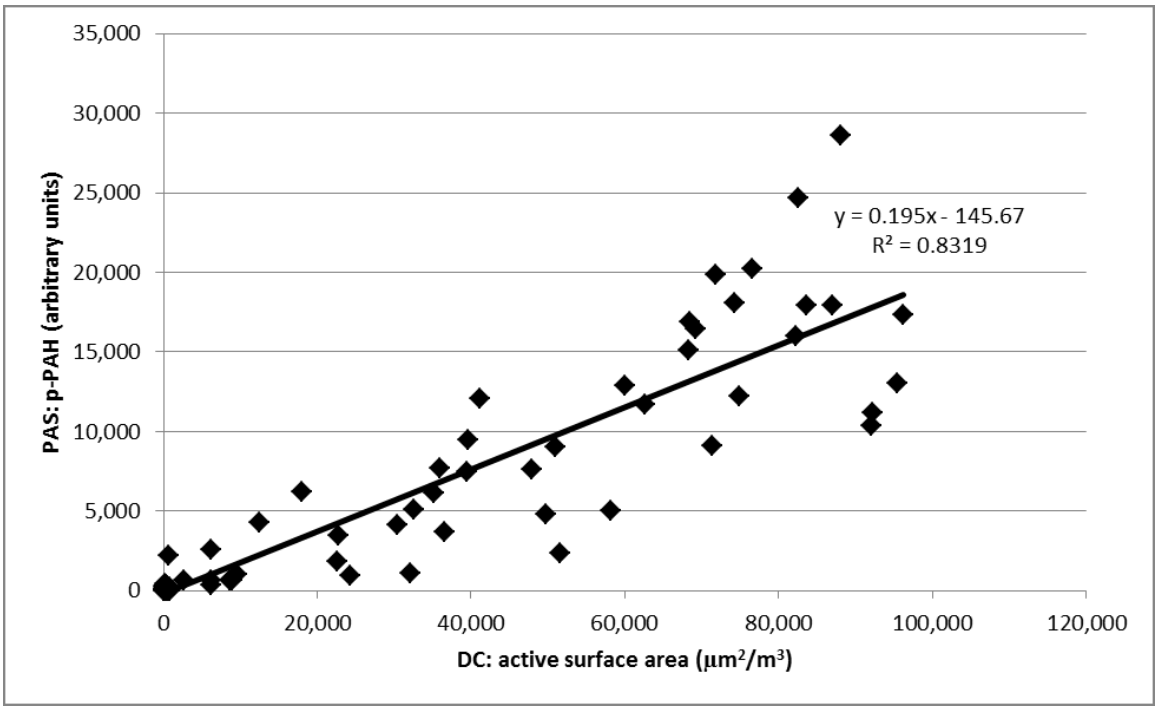


Figure 2.15 Regression Analysis for pPAH/SA: CO_2 Laser



The calculation of the pPAH/SA regression analyses and GM ratios yielded similar results. A clear difference was observed, however, between the results of the electrocautery knife and those of the other surgical instruments. The range of the slopes of the regression equations for the harmonic scalpel and plasma jet (0.04–0.07) reflected the range of calculated ratios for those two instruments (0.05–0.10) and suggested that these two instruments produced particles with low concentrations of pPAHs per unit surface area. The CO_2 laser produced particles with a slightly larger regression line slope (0.20) and ratio (0.12). The electrocautery knife, however, showed a consistent pattern of creating potentially more toxic particles than these other instruments. Without the use of LEV for the electrocautery knife, the range of regression line slopes (0.42–0.65) and calculated GM ratios (0.32–0.62) indicated considerably greater quantities of pPAHs per surface area unit compared to the other instruments. Interestingly, the use of the LEV control increased the range of slopes (0.93–1.98) and GM ratios (0.46–0.93) even further, the highest amongst all surgical instrument configurations tested. This suggests that the

control may have been less successful in capturing particles with higher ratios of pPAH concentrations to the surface area, allowing greater numbers of those particles to be released and dispersed in the operating room environment.

The relative differences observed in the pPAH/SA ratios as calculated by both methods and presumably in the potential toxicity of the particles related to pPAHs, are ultimately related to the underlying mechanism by which each instrument cuts the tissue. The harmonic scalpel, the instrument with a low PAS/DC ratio, relies on the principle of cavitation (production of microscopic bubbles within the cellular structure of the tissue) via ultrasonic vibration of the surgical tip as it's applied to the tissue. Because this principle is less likely to cause pyrolysis of the tissue compared to the other techniques, lower pPAH concentrations are presumably generated, resulting in lower pPAH per unit surface area of the aerosolized particles. In contrast, the mechanism used by the electrocautery knife is the introduction of an electrical current at the point of contact of the surgical instrument to the tissue. Such action appears to greatly increase the pyrolytic production of pPAHs and their adsorption onto the surfaces of the particles present. The higher pPAH/SA ratio in the cut mode of the electrocautery knife compared to the coag mode may reflect the fact that the cut mode uses a low voltage in a constant electrical waveform to produce maximum current concentration focusing intense heat at the site, while the coag mode uses a high voltage intermittent electrical waveform producing less heat [Covidien 2008]. The higher heat in the cut mode may therefore increase the production of pPAHs adsorbed onto the surface area of the particles.

Periphery-of-the-Room Measurements

As stated previously, patterns of particle number concentrations were observed to differ considerably between the two areas in the periphery of the operating room environment where real-time measurements were conducted during plume producing trials. Figure 2.16 shows time series measurements made at the circulating nurse's desk near the entrance to the operating room during the periods of plume production by each of the surgical instrument configurations. The concentration patterns did not necessarily closely follow the clear delineation of concentration increases and decreases as measured at the point of generation (Figure 2.5) but characterizes the exposures to surgical plume that a worker at this station would experience given similar usage of surgical instrumentation. Figure 2.17 shows the GM particle number concentrations measured at the circulating nurse's desk by surgical instrument.

Figure 2.16 Time-series Area Particle Number Concentrations at the Circulating Nurse's Desk by Surgical Instrument as Measured by a PTrak

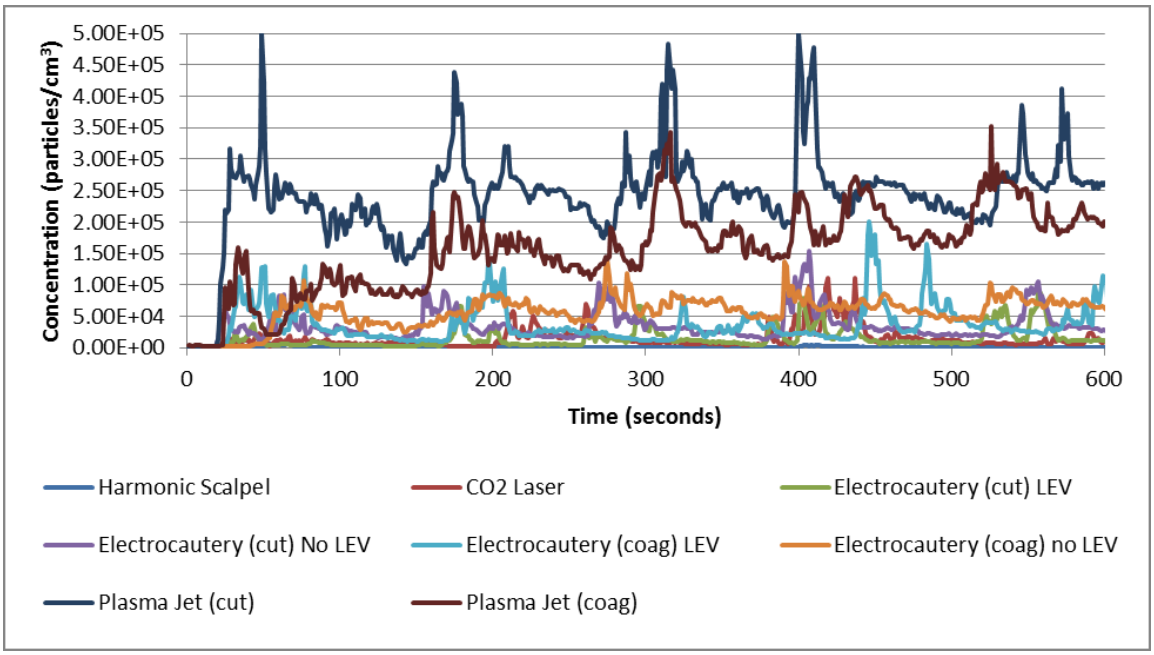
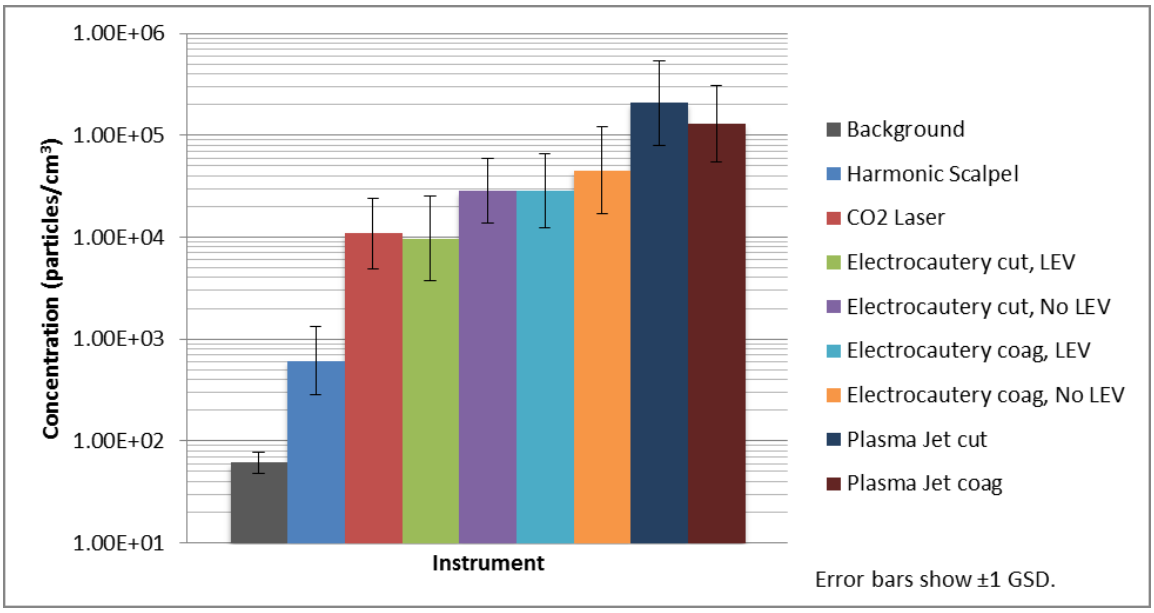


Figure 2.17 Geometric Mean Particle Number Concentrations at Circulating Nurse's Desk by Surgical Instrument as Measured by a PTrak



Compared to Figure 12.16, Figure 2.18 shows the time series of measurements made during the same periods of plume production by each of the surgical instrument configurations in the periphery of the operating room near one of the room's exhaust vents (see Figure 2.1). Similar to the measurements made at the circulation nurse's desk, concentrations are again highest for particles produced by the cut and coag modes of the plasma jet. Unlike at the circulation nurse's desk, concentrations at the far side of the room near the exhaust show only a gradual particle accumulation until an apparent equilibrium concentration is reached. The observed differences in concentration patterns speak to the airflow patterns present in the operating room. In this operating room, laminar airflow is introduced into the room above the surgical table and flows downward to the surgical table then towards the peripheries of the room. The proximity of the exhaust vents results in surgical plume concentrations in that area that are maintained and cleared in a more stable and consistent manner as compared to the area near the nurse's desk. Figure 2.19 shows the GM particle number concentrations measured near the exhaust. Peak

number concentrations reached $5x10^5$ particles/cm^3 at the circulating nurse's desk while peak concentrations less than $2x10^5$ particles/cm^3 were measured near the exhaust.

Despite the CO_2 laser producing the highest number concentrations of particles at the point of generation, surgical plume particles produced by the plasma jet (both cut and coag mode) were measured to have the highest concentrations in both of the periphery areas measured. Smaller particle size diameter and mass concentrations for particles produced by the plasma jet may account for their ability to remain aerosolized and distributed with greater ease throughout the room.

Figure 2.18 Time-series Area Particle Number Concentrations near OR Exhaust by Surgical Instrument as Measured by a CPC

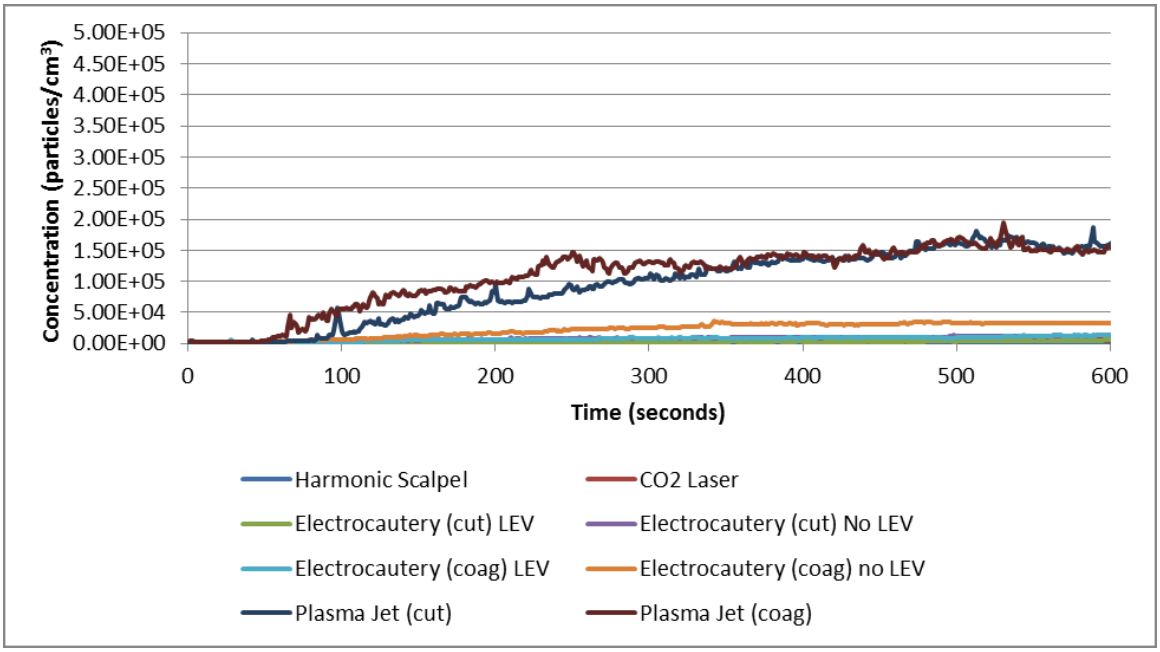
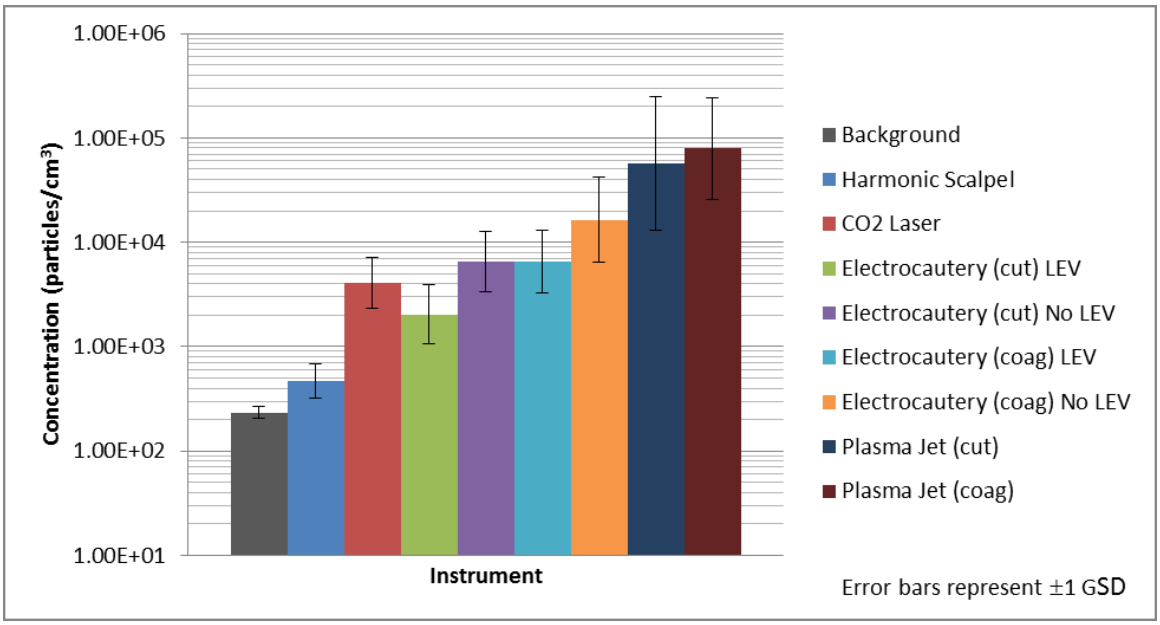


Figure 2.19 Geometric Mean Particle Number Concentrations near OR Exhaust by Surgical Instrument as Measured by a CPC



On the side of the operating room near the exhaust, the measured particle number concentrations appeared to reach equilibrium after a period of usage of all the surgical instruments. To evaluate the impact that active plume production had on the particle number concentrations at the periphery locations of the room after the initial increase in concentrations due to the first use of the instruments, GM particle number concentrations were calculated during the final three periods of plume production at the periphery locations and compared to the GM concentrations in the intervals immediately following those plume producing periods. Figures 2.20, 2.21, and 2.22 specifically show the GM concentrations for the harmonic scalpel, CO_2 laser, and plasma jet (cut mode), respectively. The percentages shown above the columns represents the GM concentration of that location as a percentage of the concentration measured at the point of generation, relative to whether it was during or after the plume production periods. Graphs showing these results for all instruments are shown in the Appendix as Figures A34–41.

At the location near the exhaust, GM concentrations in the intervals of time after the specific plume production periods were similar to the GM concentrations during the actual plume production periods. This was also the case for the GM concentrations at the circulating nurse's desk location; however, the GSD around the GM concentration at this location during plume production periods was typically larger than that in the intervals after those periods, reflective of greater concentration variability during the periods at that location. With the exception of the intervals after plume production by the harmonic scalpel ($p=0.06$), GM particle number concentrations produced by all the surgical instruments were statistically significantly higher at the circulating nurse's desk location compared to the side of the room near the exhaust ($p<0.001$). Exposures to surgical plume particles in the periphery of the room are not solely a function of the number concentrations of particles produced at the point of generation. During the plume production periods, the range of GM concentrations at the circulating nurse's desk as a percentage of the GM concentrations measured at the point of generation ranged from a low of 0.03% to a high of 3.3%. For example, while the CO_2 laser produced the highest concentrations at the point of generation, the concentrations measured at the circulating nurse's desk as a percentage relative to the point of generation were the lowest (0.03%). The wide range of percentages illustrates the difference in distribution throughout the operating room for particles produced by the various surgical instruments.

Figure 2.20 Geometric Mean Particle Number Concentrations During and After the Final Three Plume Production Periods as Measured by the ELPI, PTrak and CPC: Harmonic Scalpel

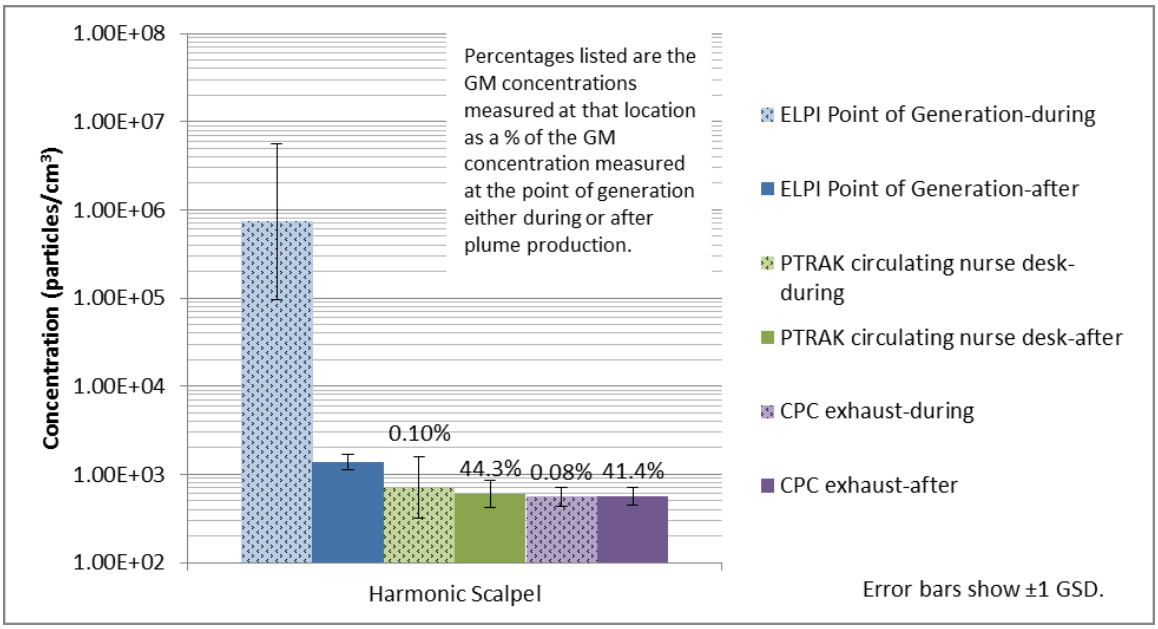


Figure 2.21 Geometric Mean Particle Number Concentrations During and After the Final Three Plume Producing Periods as Measured by the ELPI, PTrak and CPC: CO_2 Laser

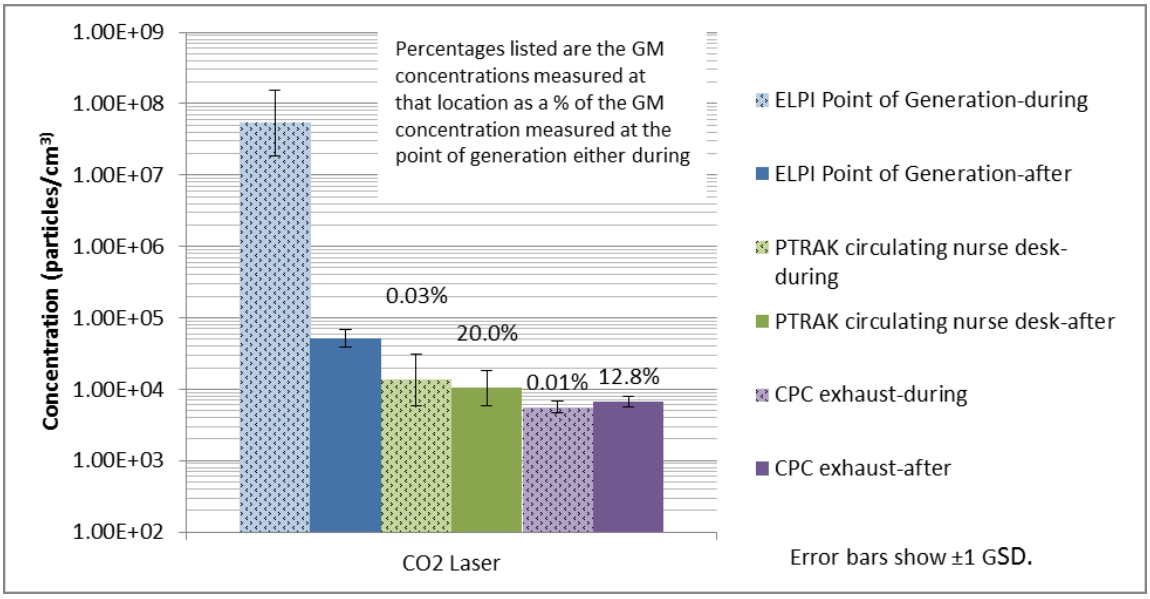
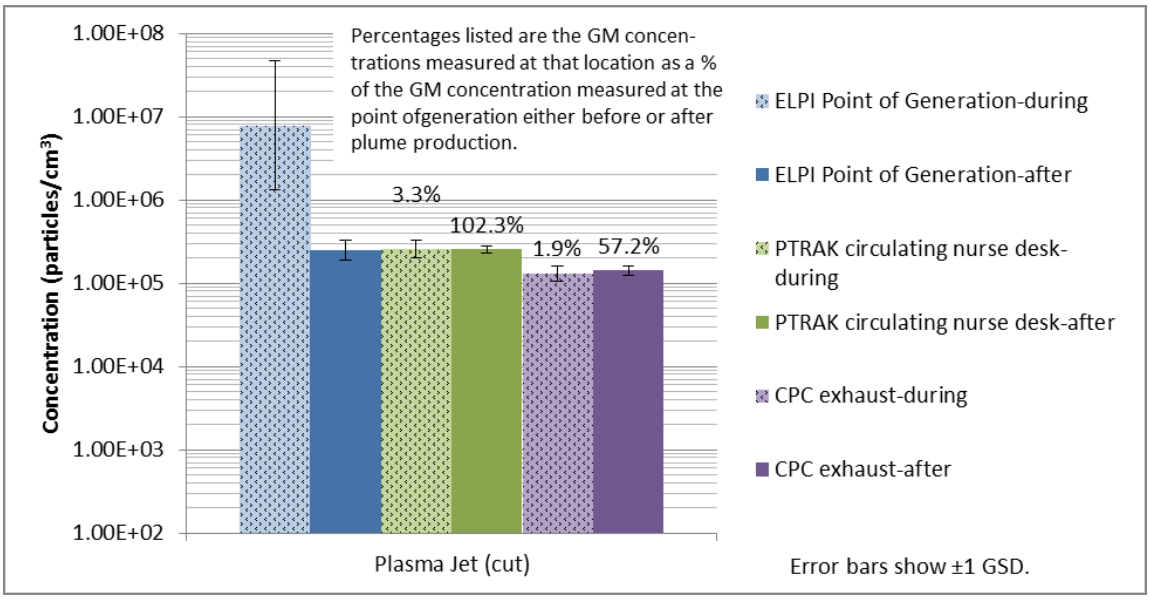


Figure 2.22 Geometric Mean Particle Number Concentrations During and After the Final Three Plume Production Periods as Measured by the ELPI, PTrak and CPC: Plasma Jet (cut)



While the general exhaust ventilation provided to the room can impact patterns of concentrations in different areas of the room, the impact of LEV used at the point of particle generation on the particle number concentrations in the periphery of the room was also investigated. Figures 2.23–2.26 specifically focus on results of measured concentrations produced by the electrocautery knife (in both cut and coag modes) with the built-in LEV control on and off. Figures 2.23 and 2.24 show the results in the two locations from the use of the electrocautery knife in cut mode with and without LEV; Figures 2.25 and 2.26 show the results in the two locations from the use of the electrocautery knife in coag mode with and without LEV. The figures show that while the use of the built-in LEV on the electocautery knife did not change the distinct pattern of increased exposures to surgical plume particles at the circulating nurse's desk as compared to the opposite side of the room near the exhaust vent, the use of the LEV control at the point of particle generation did result in a discernibly lower particle number concentration in both areas of the periphery of the room measured compared to when the LEV control was not activated.

Figure 2.23 Comparison of Particle Number Concentrations at Circulating Nurse's Desk With and Without LEV Use During Electrocautery in cut mode as Measured by a PTrak

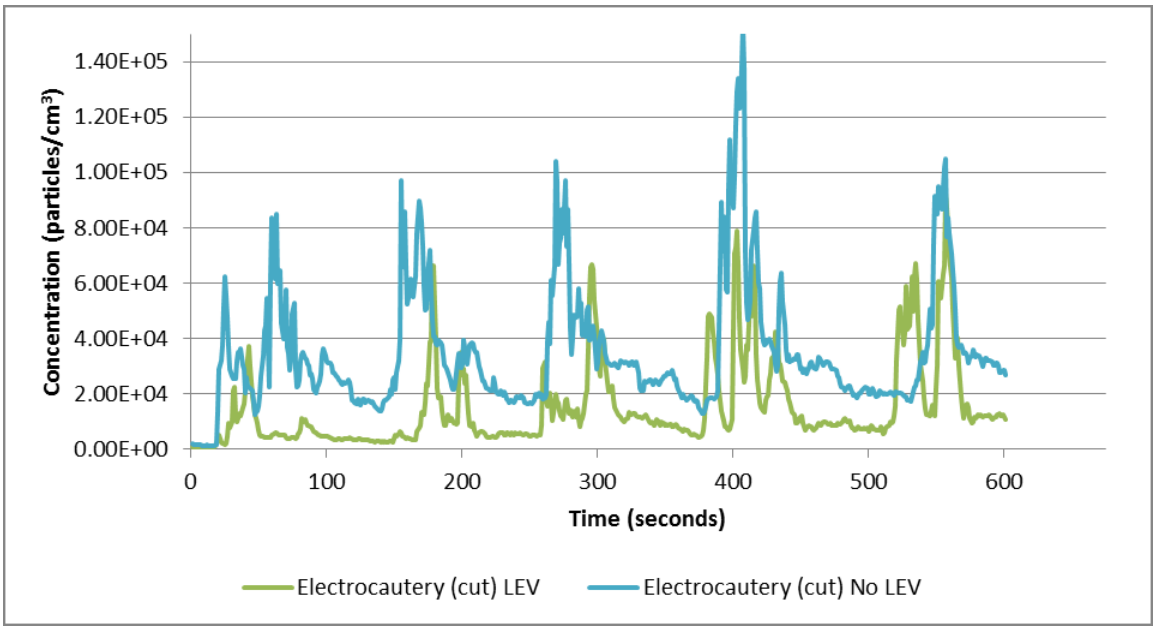


Figure 2.24 Comparison of Particle Number Concentrations near Exhaust Vent With and Without LEV Use During Electrocautery in cut mode as Measured by a CPC

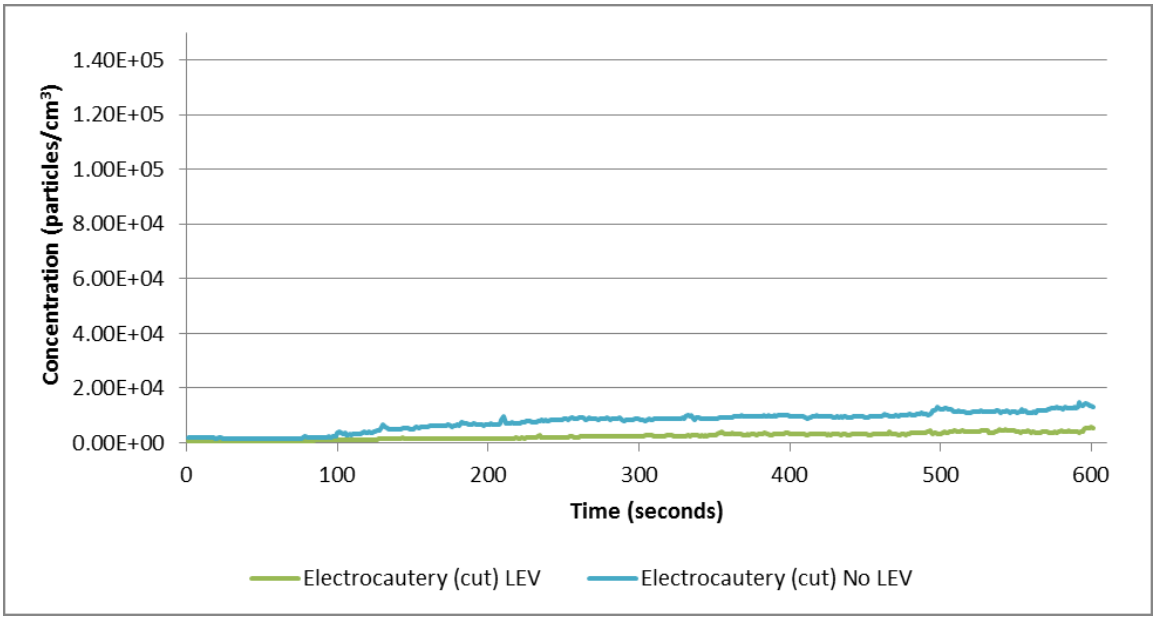


Figure 2.25 Comparison of Particle Number Concentrations at Circulating Nurse's Desk With and Without LEV Use During Electrocautery in coag mode as Measured by a PTrak

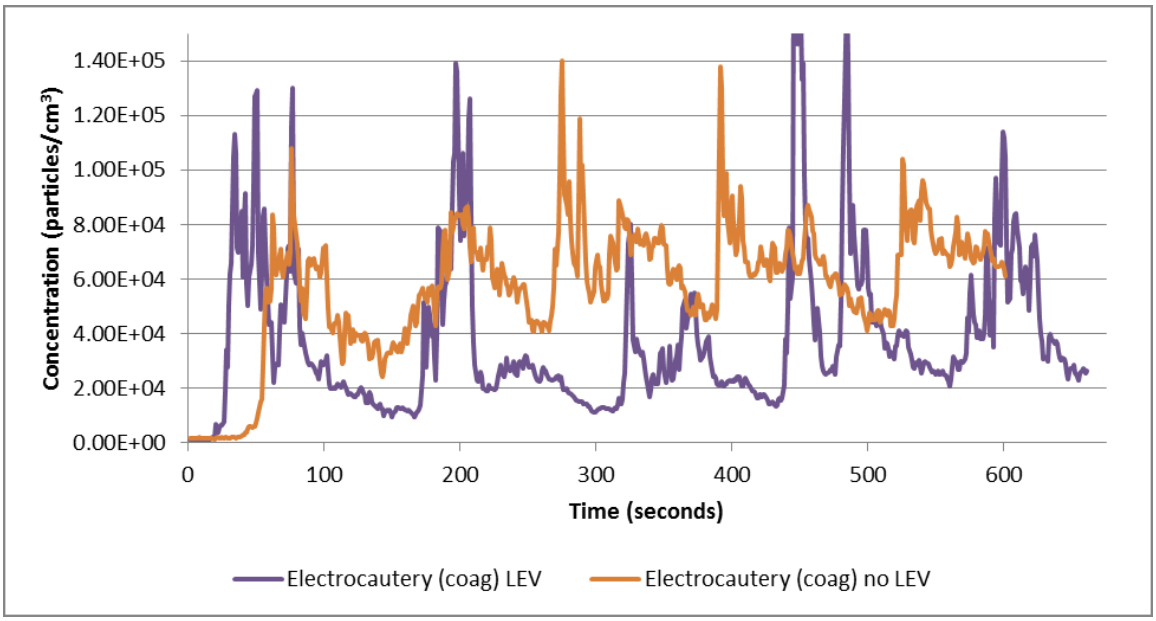
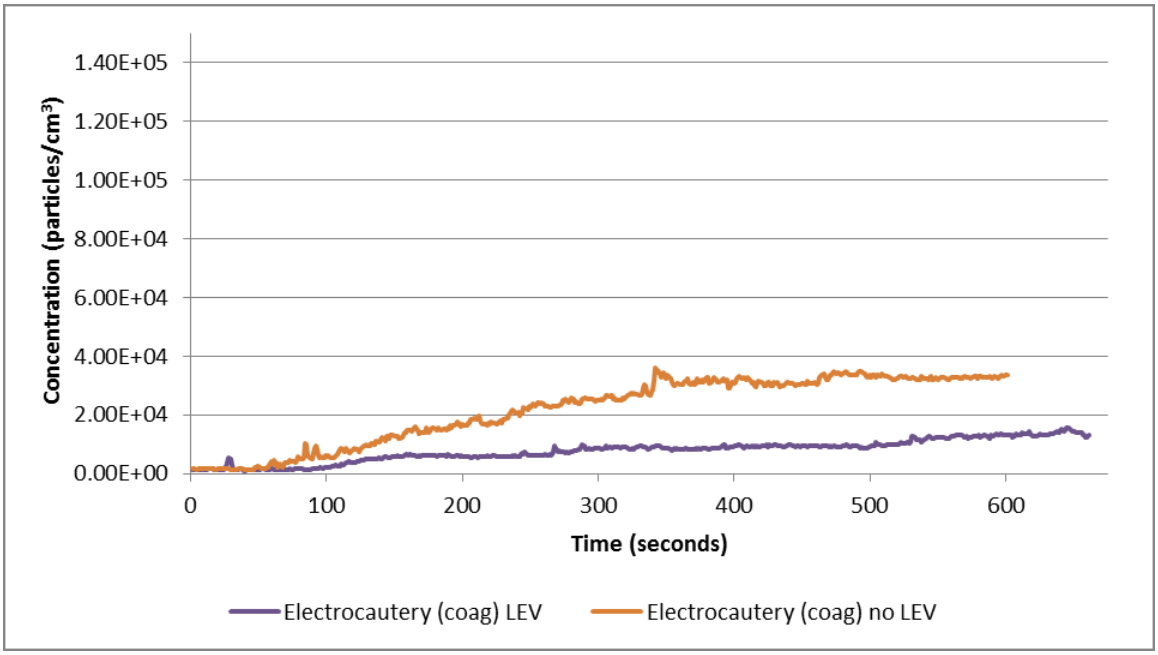


Figure 2.26 Comparison of Particle Number Concentrations Near Exhaust Vent With and Without LEV Use During Electrocautery in coag mode as Measured by a CPC



The GM and GSD of the particle number concentrations in these two areas were calculated and graphed as shown in Figures 2.27 and 2.28. The use of the LEV at the source consistently resulted in decreased GM particle number concentrations in both the circulating nurse's desk and near the exhaust. Activation of the LEV at the point of particle generation by the electrocautery knife saw a 65% statistically significant reduction ($p<0.001$) at the circulating nurse's desk in the cut mode and 37% in the coag mode compared to non-LEV use in these modes. For the location near the exhaust at the opposite side of the room, LEV use saw significant ($p<0.001$) 69% and 60% reductions in GM particle number concentrations for the cut and coag modes, respectively.

Figure 2.27 Geometric Mean Particle Number Concentrations at Circulating Nurse's Desk as Measured by a PTrak

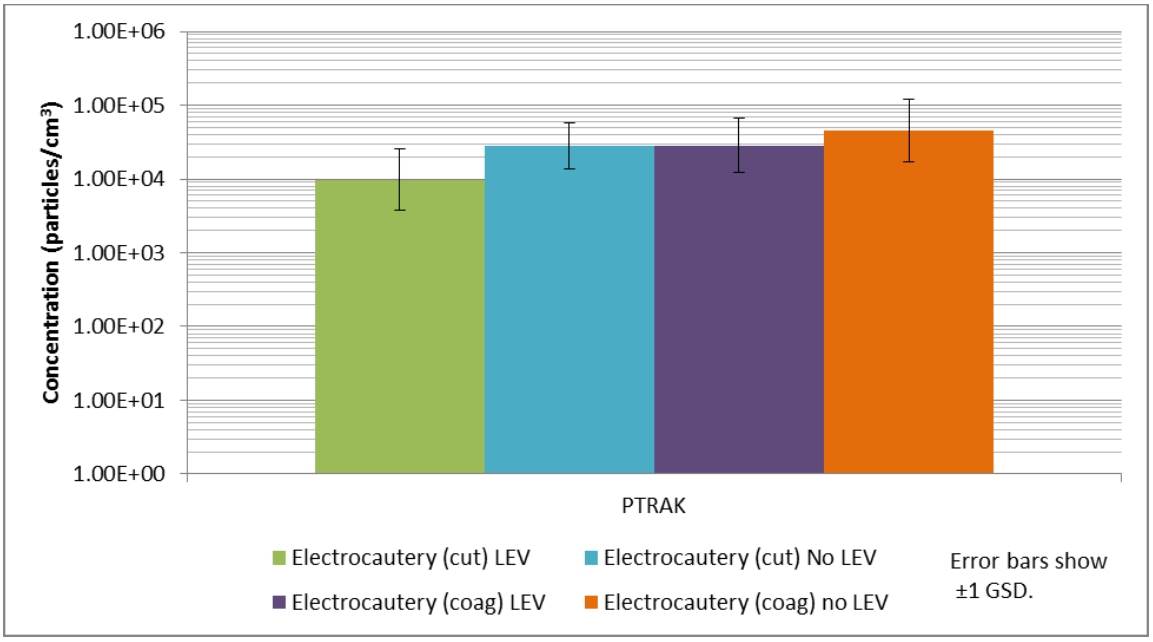
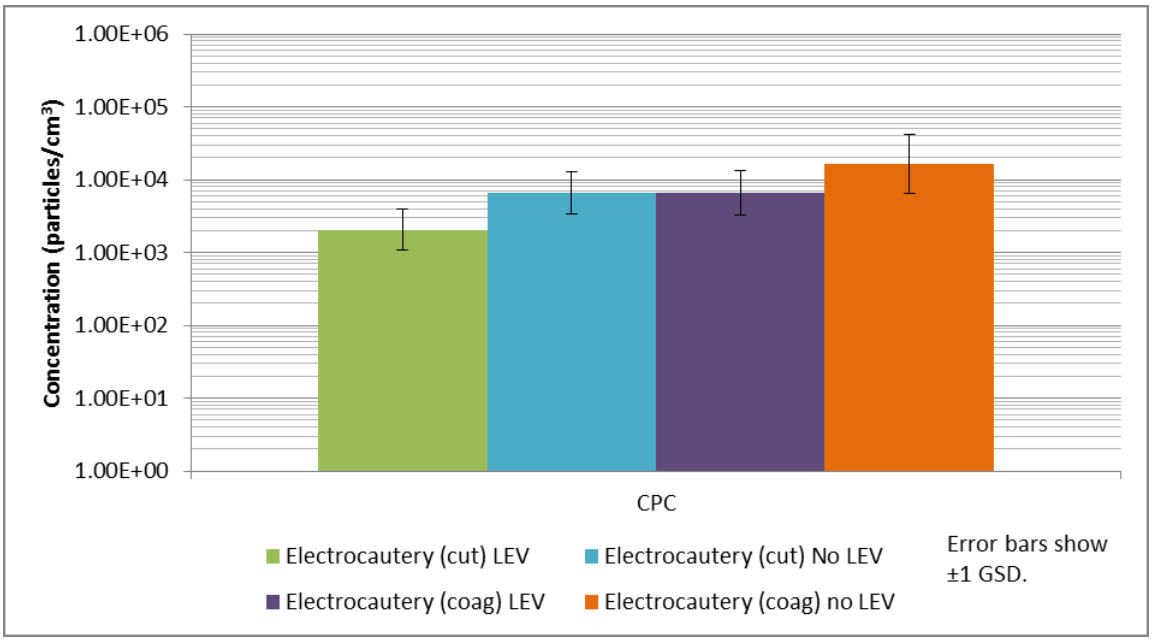


Figure 2.28 Geometric Mean Particle Number Concentrations Near Exhaust Vent as Measured by a PTrak



Conclusions

The use of multiple direct-reading instruments during the repeated controlled trials of surgical plume production allowed collection of valuable real-time data for comparing a number of characteristics of surgical plume particles. A range of size distribution and concentration values were observed based on surgical instrument type, with GM particle diameters ranging from 0.03–0.09 μm. The greatest particle number concentrations measured at the point of generation did not necessarily reflect the greatest concentrations measured in the periphery of the room as the instrument with the highest point-of-generation concentration (CO_2 laser) had the lowest percentage of those particles measured in the periphery of the room. In contrast, characteristics of particles produced by the plasma jet resulted in the highest percentage of particles from the point of generation to be measured in the periphery of the room.

Surface chemistry of the particles produced per instrument was revealed to vary widely in regards to pPAH per unit surface area, with the electrocautery knife producing the greatest concentrations of pPAH per unit surface area. This suggests that exposure to the plume of similar concentrations produced by various instruments may present different inhalation toxicity hazards to exposed health care workers.

The laminar airflow patterns provided by the general exhaust ventilation resulted in distinctly different patterns of surgical plume concentrations in the two sides of the operating room where monitoring equipment was located. Geometric mean concentrations near the entrance to the room at the circulating nurse's desk were typically statistically significantly higher than at the opposite side of the room near the exhaust.

The use of LEV with one of the surgical instruments showed significant reduction in particle number concentrations revealing the effectiveness of this particular control under the tested conditions. These reductions were in the range of 76–87% at the point of generation, 37–65% at the circulating nurse's desk, and 60–69% at the opposite side of the room. Further research is needed to ensure maximum performance of LEV to ensure that they provide the expected benefits of significant reductions in exposure potential. The electrocautery knife was the only surgical instrument tested in the controlled trials that incorporated LEV. Further research is also needed in expanding the use of such controls for other surgical instruments as well.

Several limitations in the study are acknowledged. The intent of the controlled trials of plume production was to identify plume characteristics that may impact occupational exposures in the operating room. However, conditions in the trials were reflective of one surgeon's surgical technique on the tissue, a limited selection of power levels on the surgical instruments, one operating room's ventilation system parameters, one type of human tissue, and specifically

defined intervals of application of the surgical instrument to the tissue. It is acknowledged that changes in these variables may alter how reflective these results are of all surgical plume exposure scenarios. Despite this, these results provide important contributions to illuminate differences in occupational exposure potential to surgical smoke for healthcare workers in operating room environments, with the ultimate goal of improved control and reduction of such exposures.

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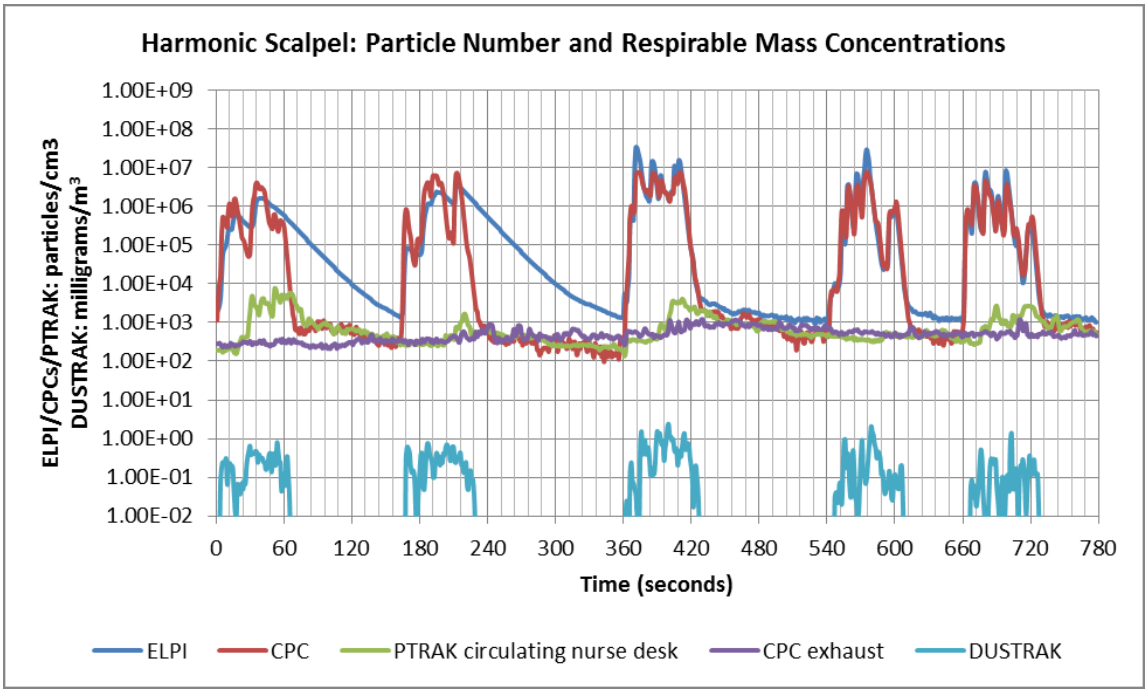
Appendix A

TABLE A1.



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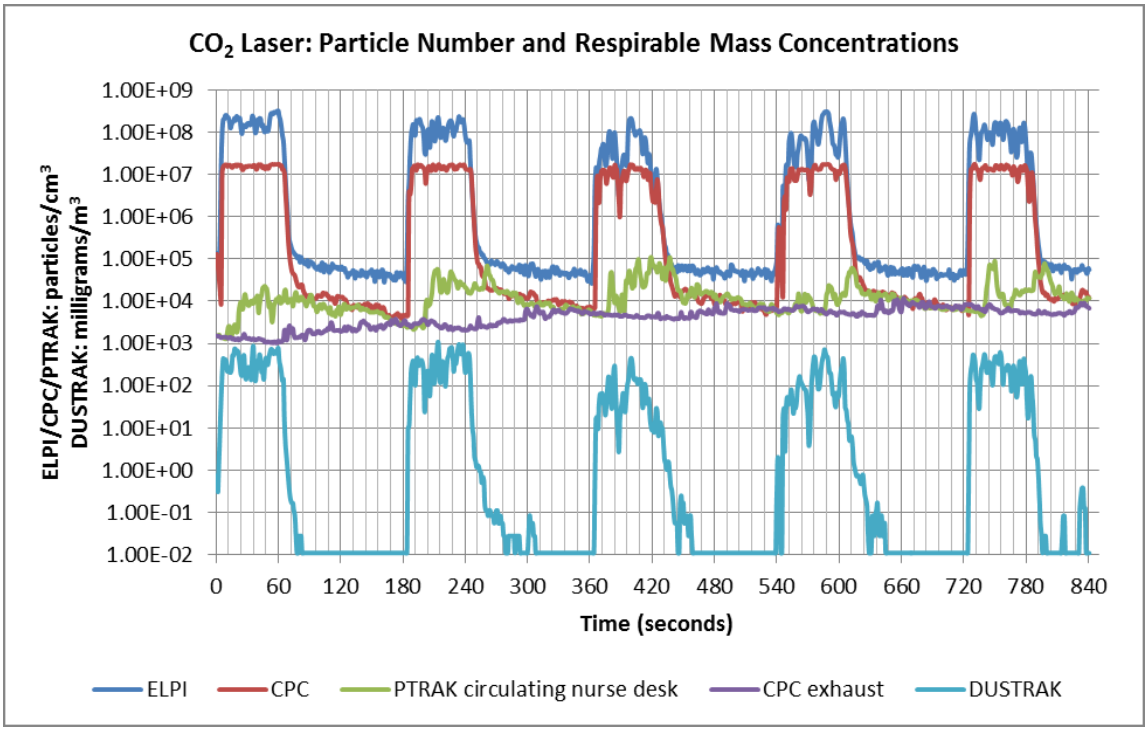

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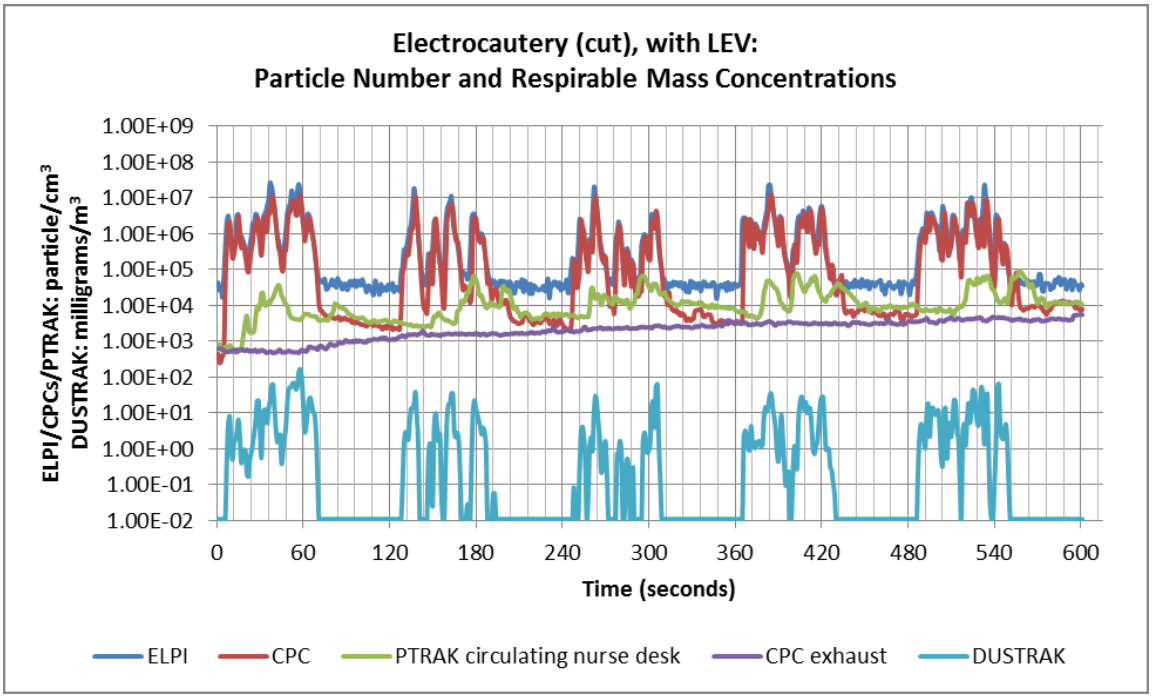

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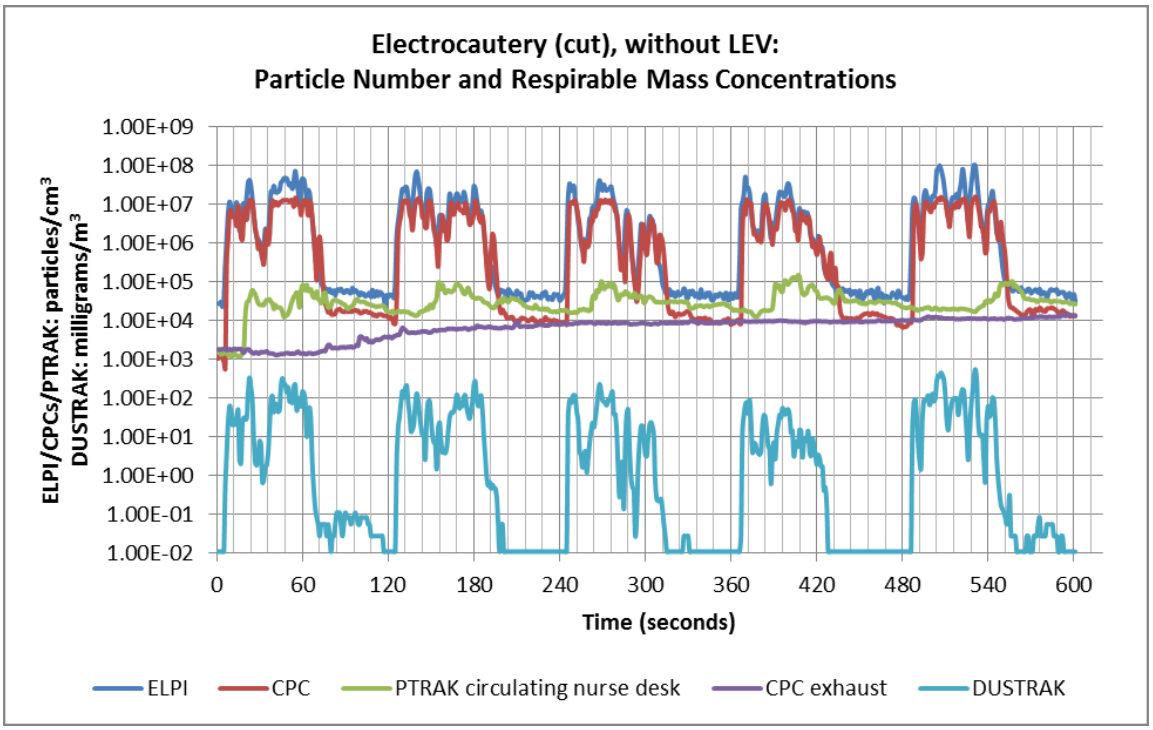

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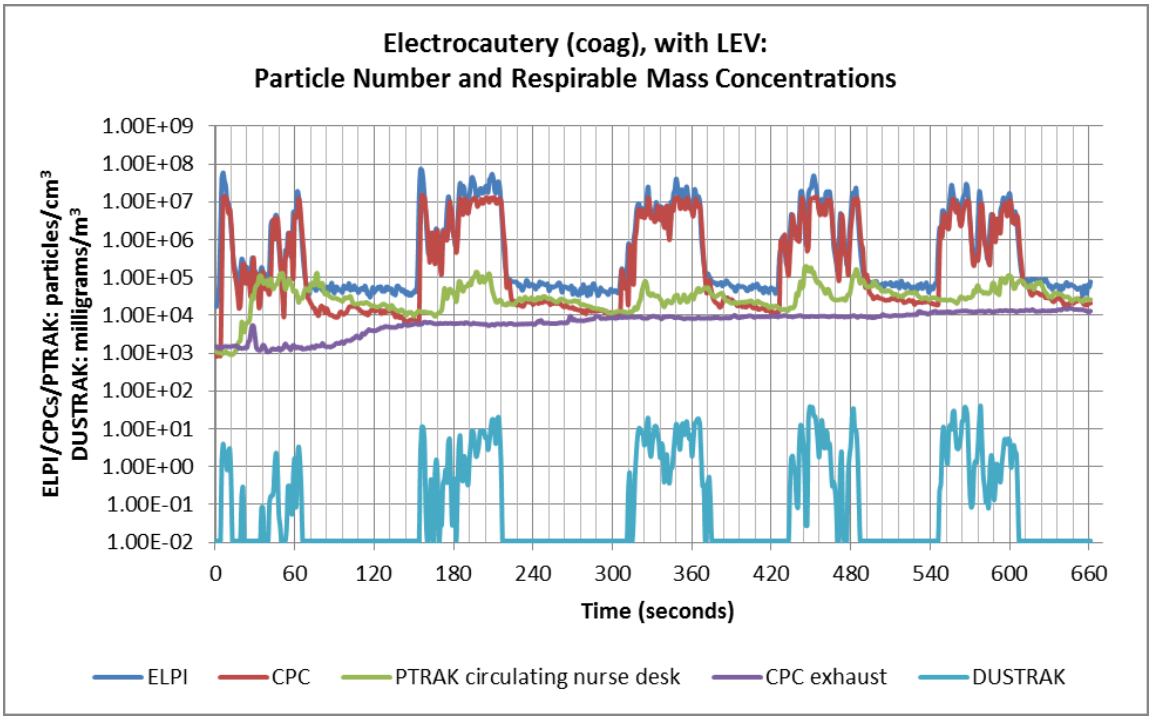

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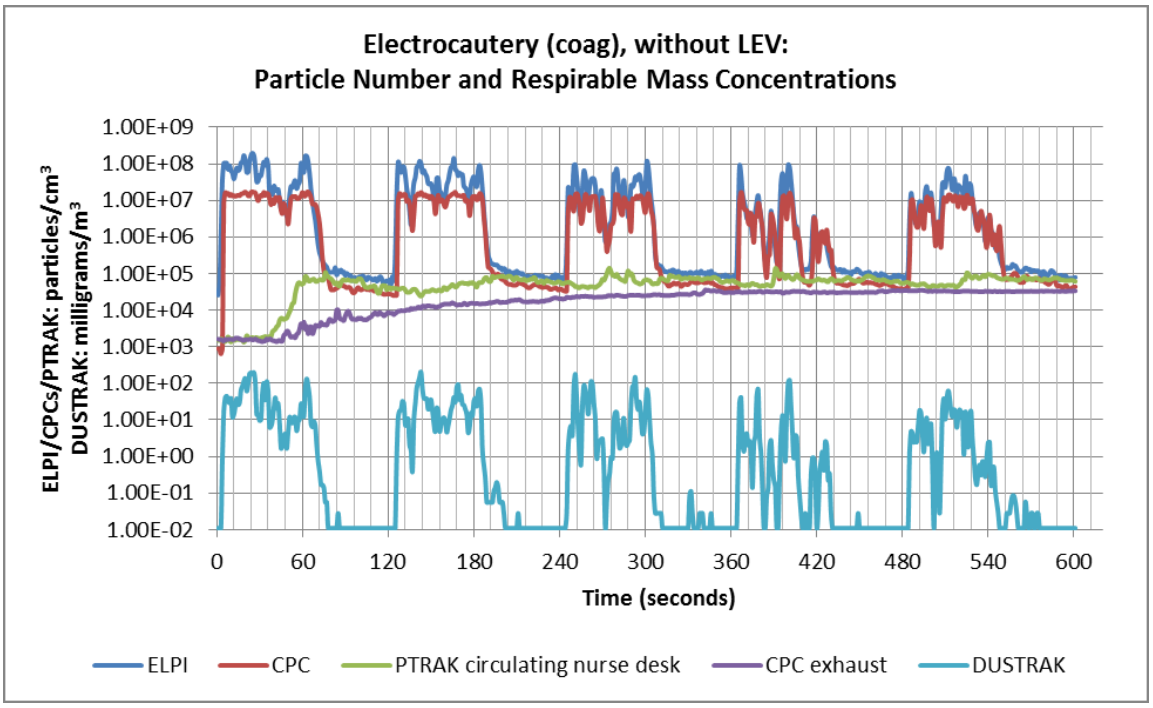

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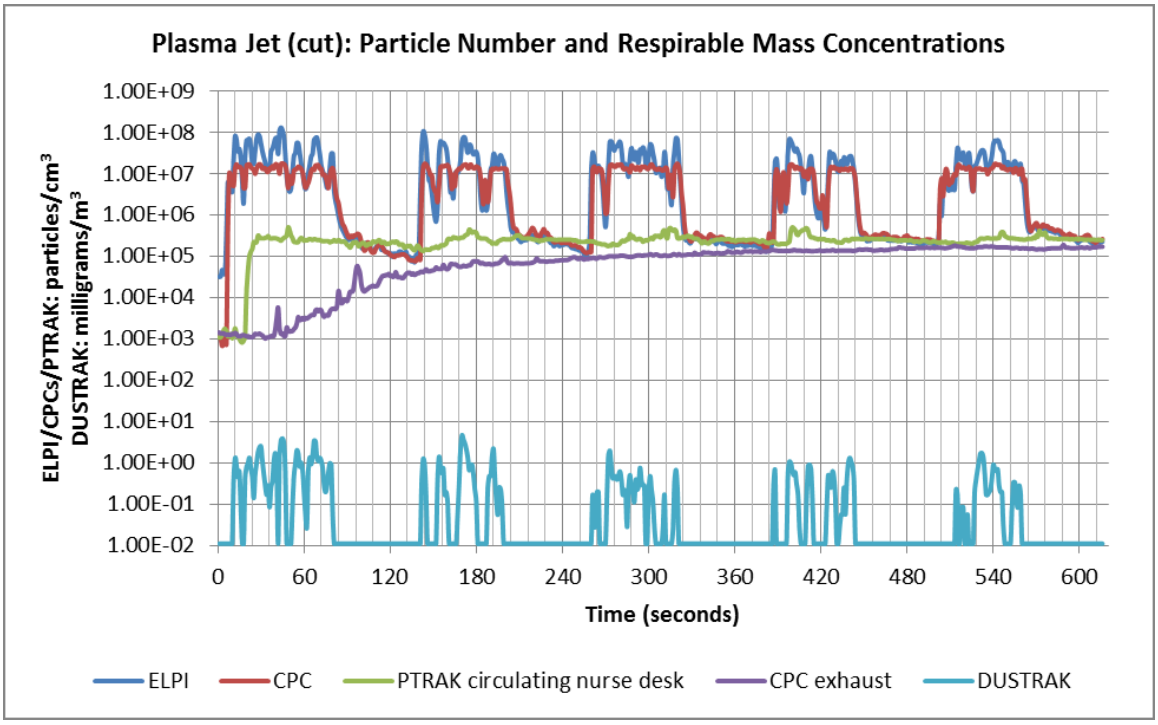

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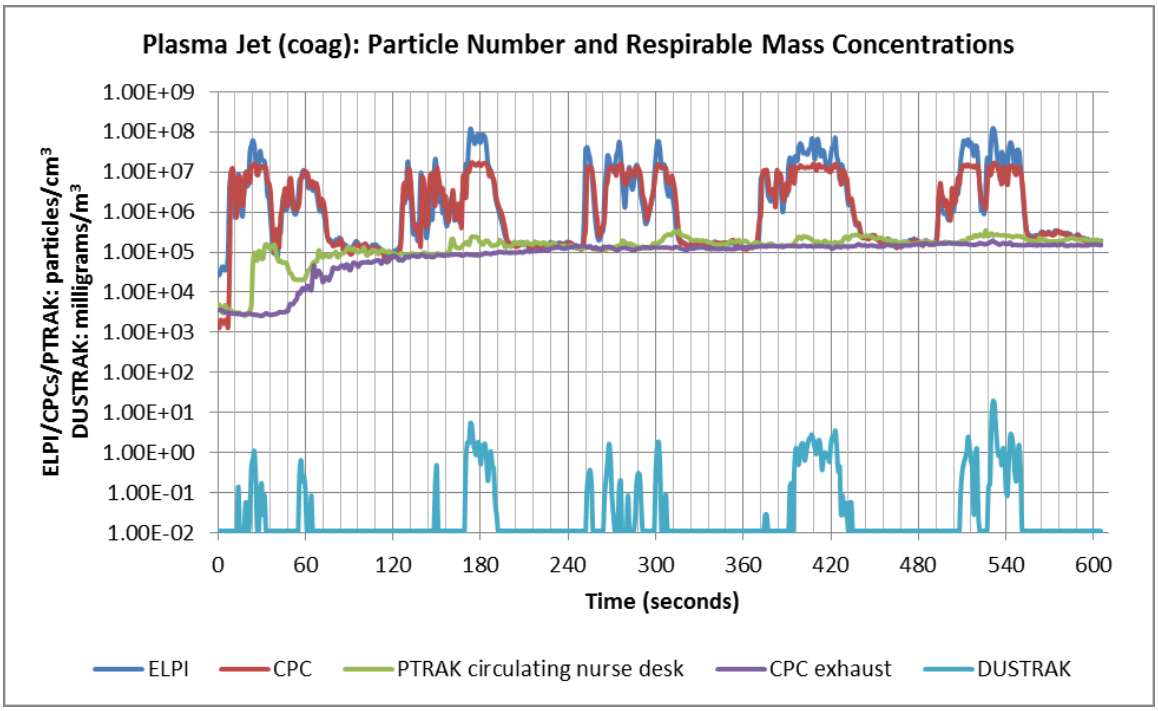

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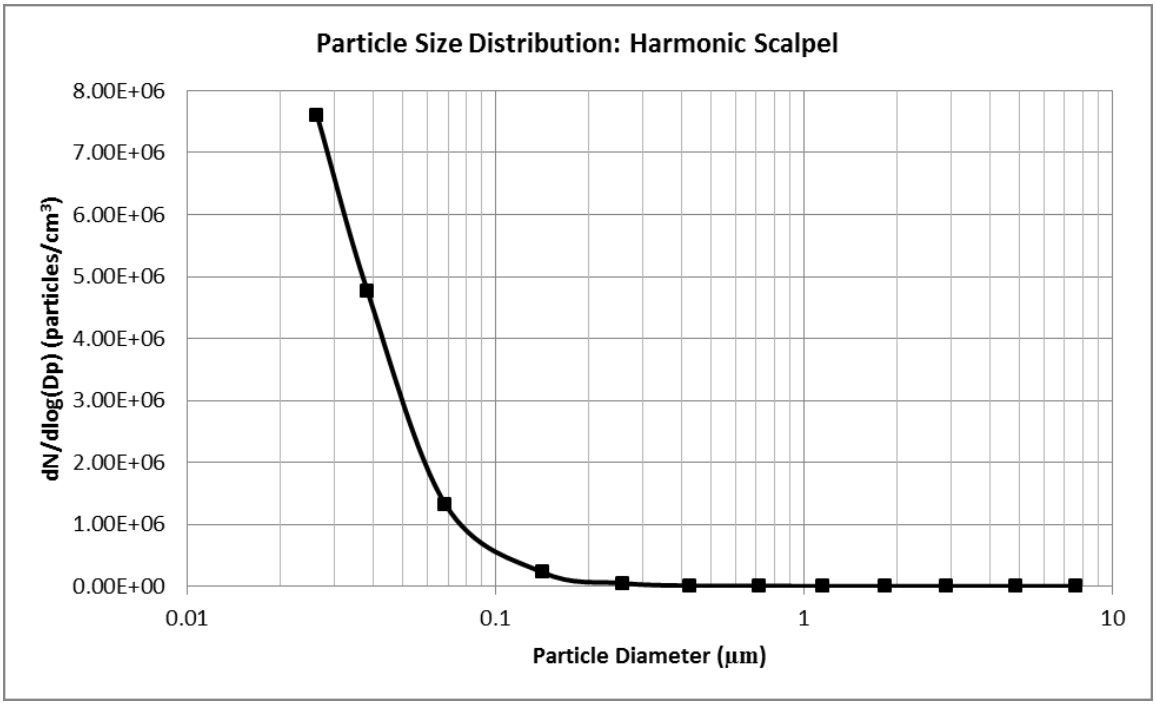

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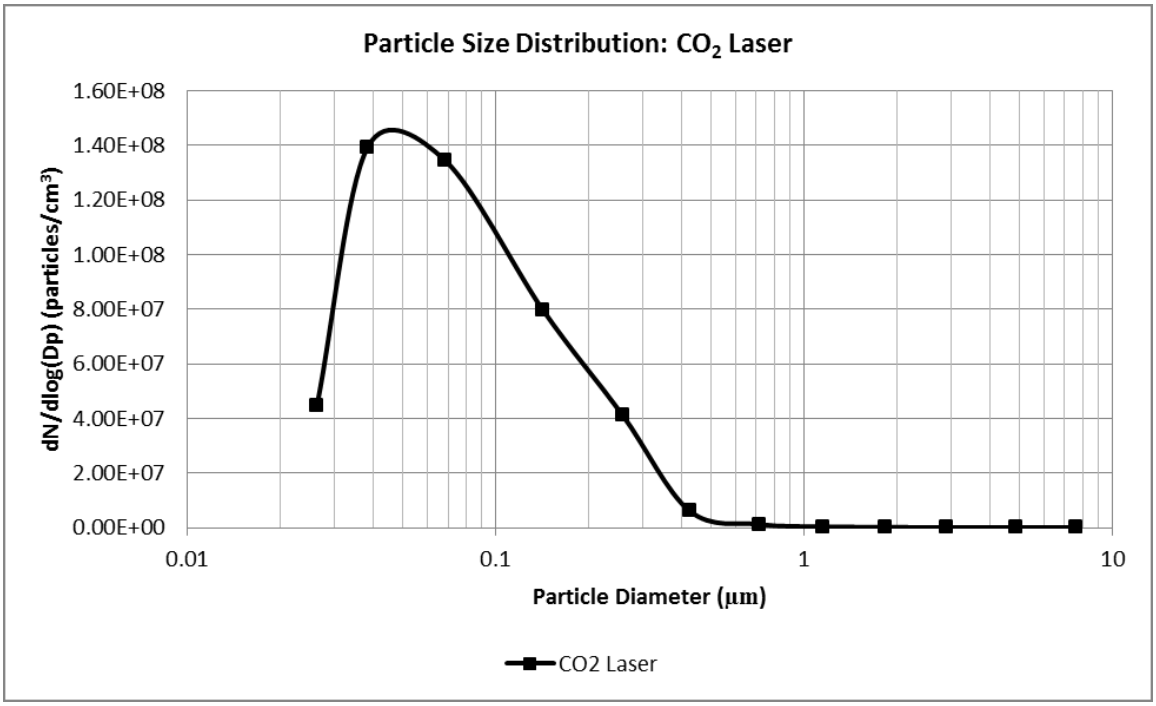


TABLE A11.

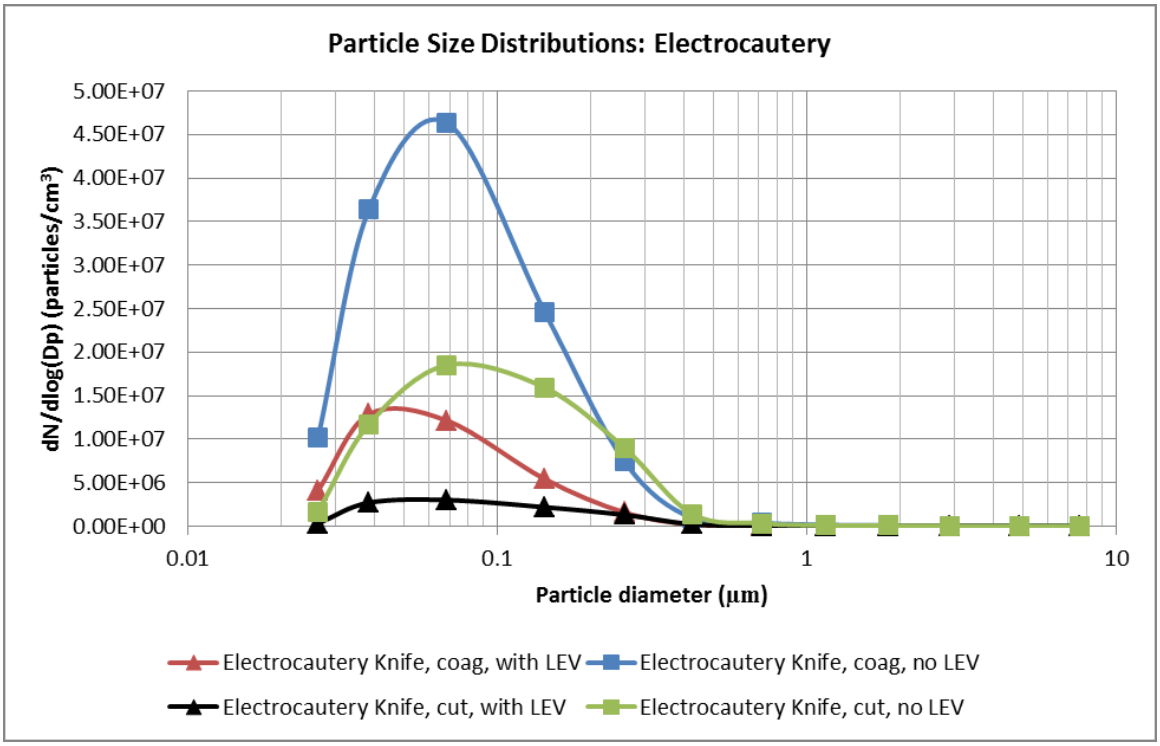


TABLE A12.

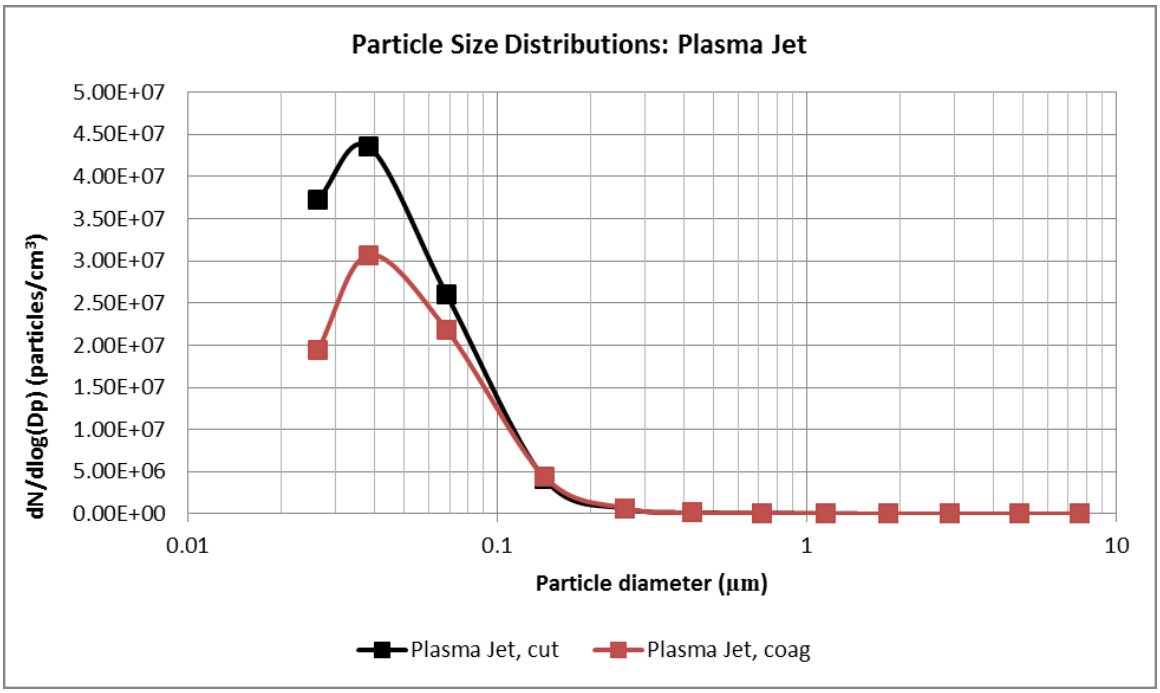


TABLE A13.

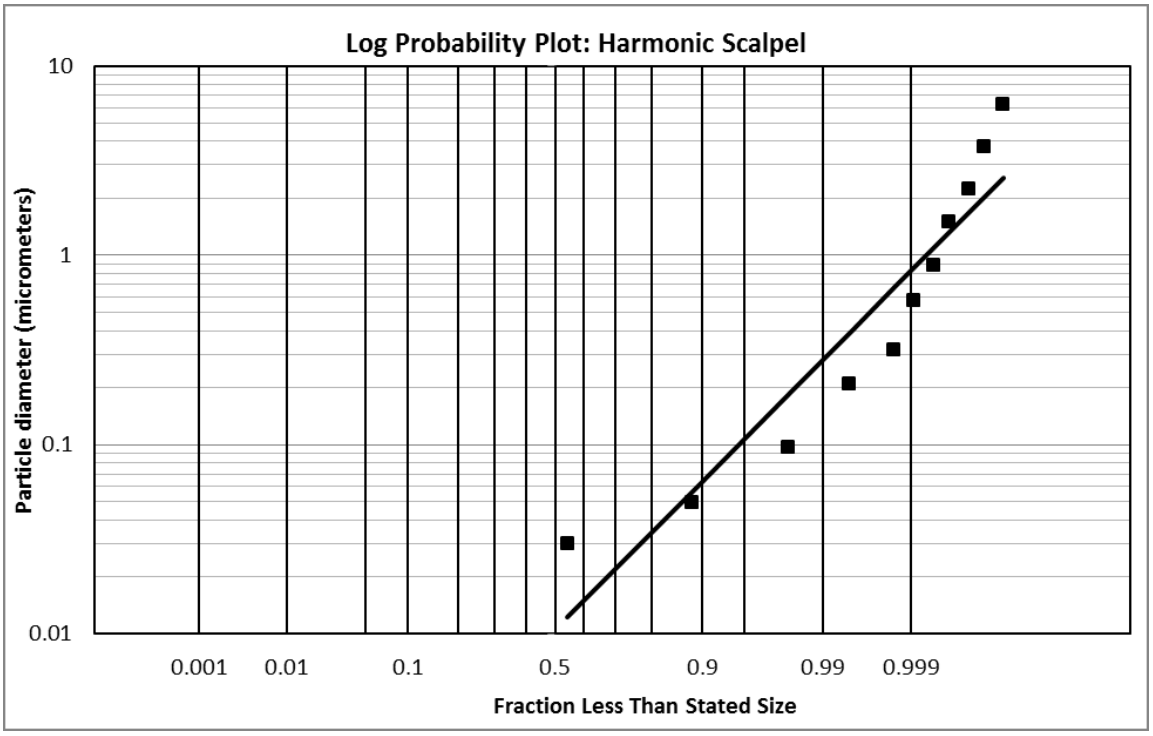
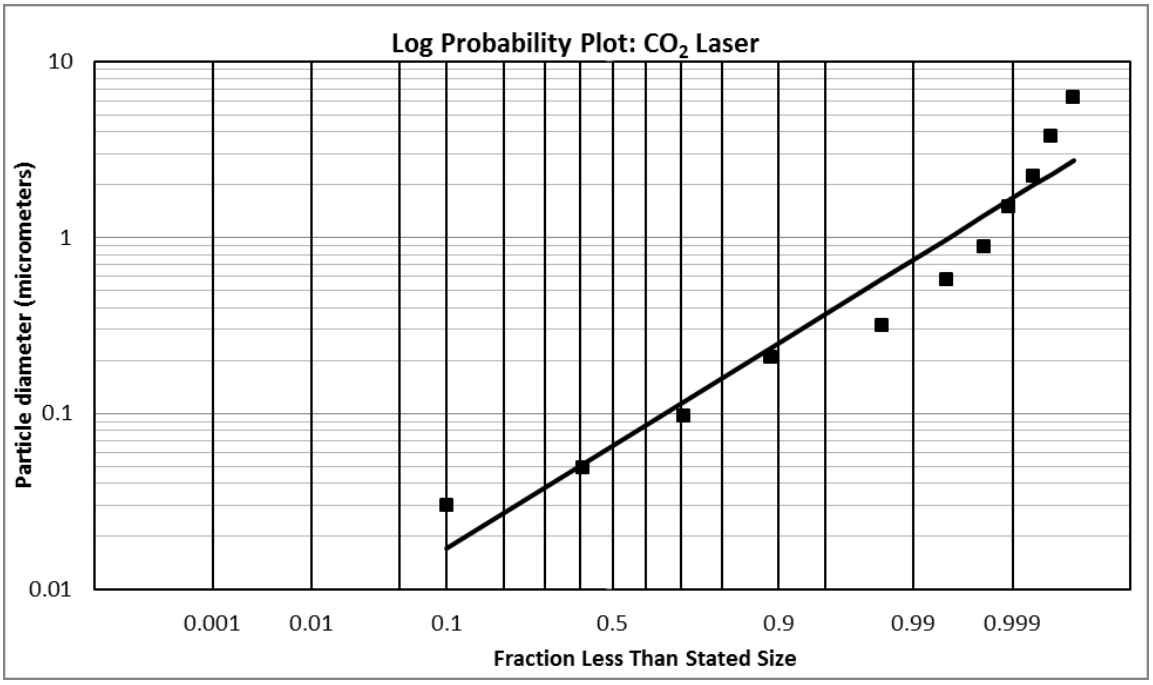


TABLE A14.



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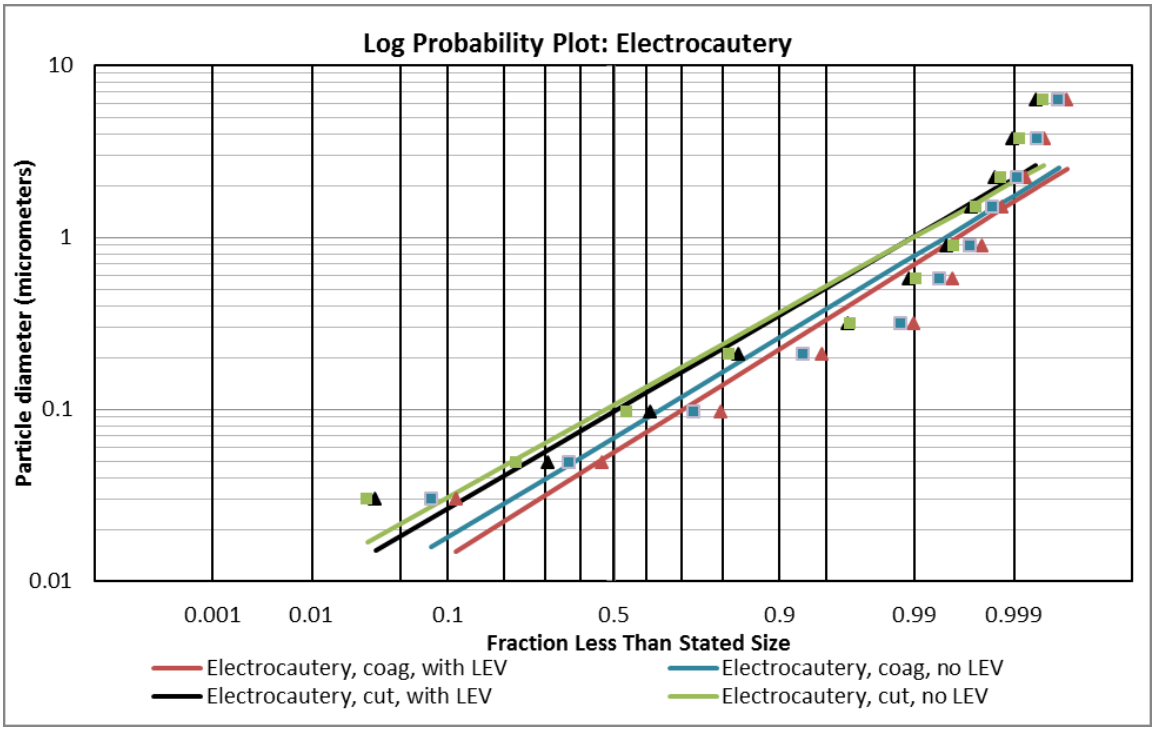


TABLE A16.

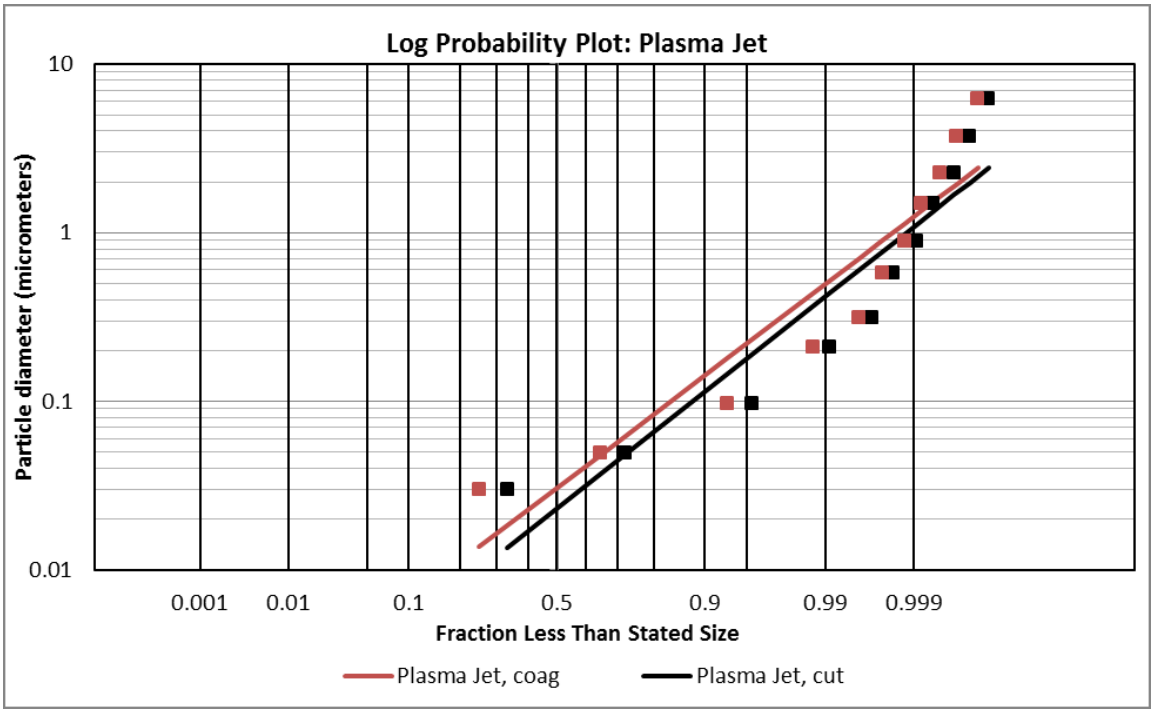


TABLE A17.

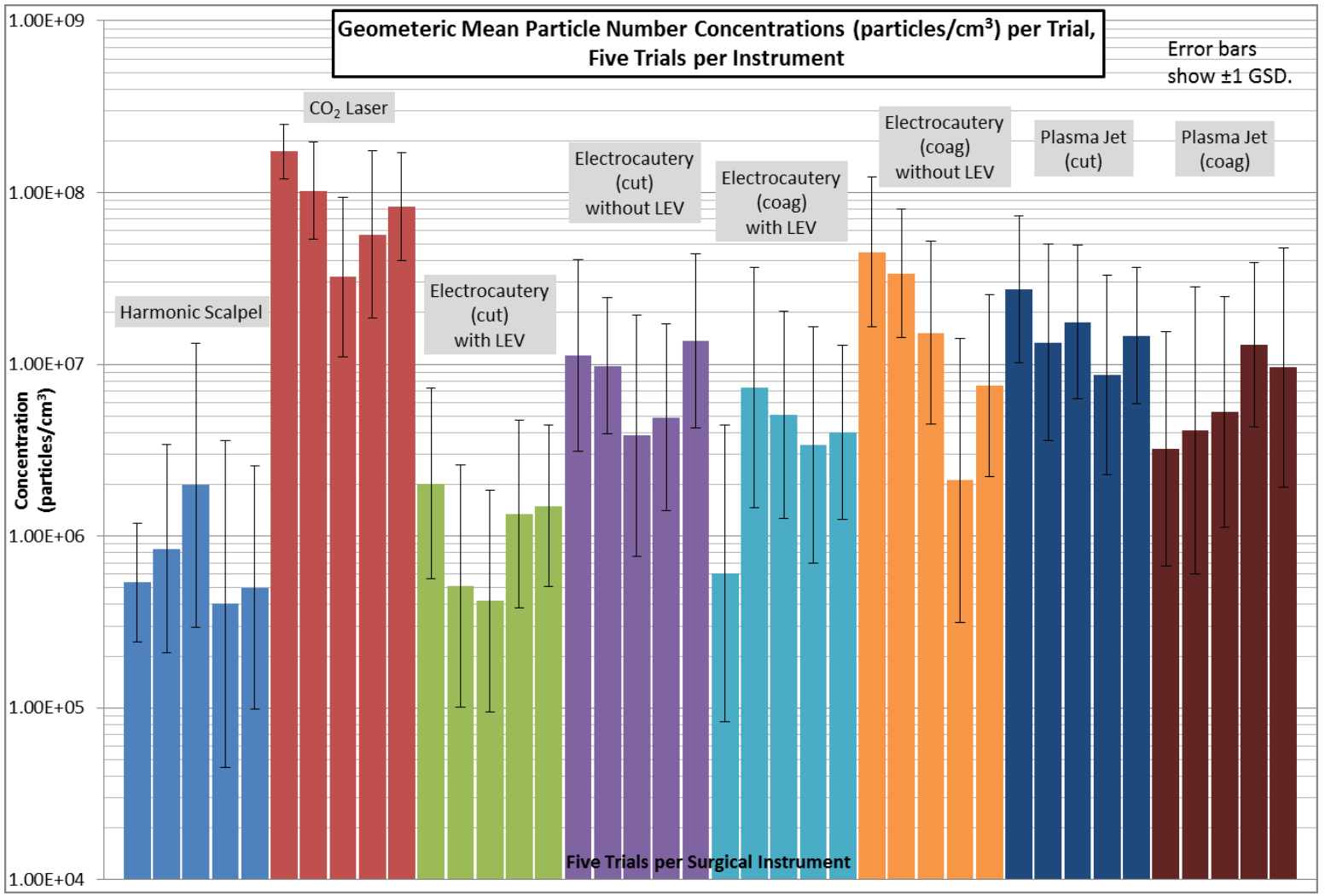

Geometeric Mean Particle Number Concentrations (particles/cm³) per Trial, Five Trials per Instrument
Error bars show ±1 GSD.
1.00E+09
1.00E+08
1.00E+07
1.00E+06
1.00E+05
1.00E+04
Concentration (particles/cm³)
Harmonic Scalpel
CO2 Laser
Electrocautery (cut) with LEV
Electrocautery (cut) without LEV
Electrocautery (coag) with LEV
Electrocautery (coag) without LEV
Plasma Jet (cut)
Plasma Jet (coag)
Five Trials per Surgical Instrument

TABLE A18.

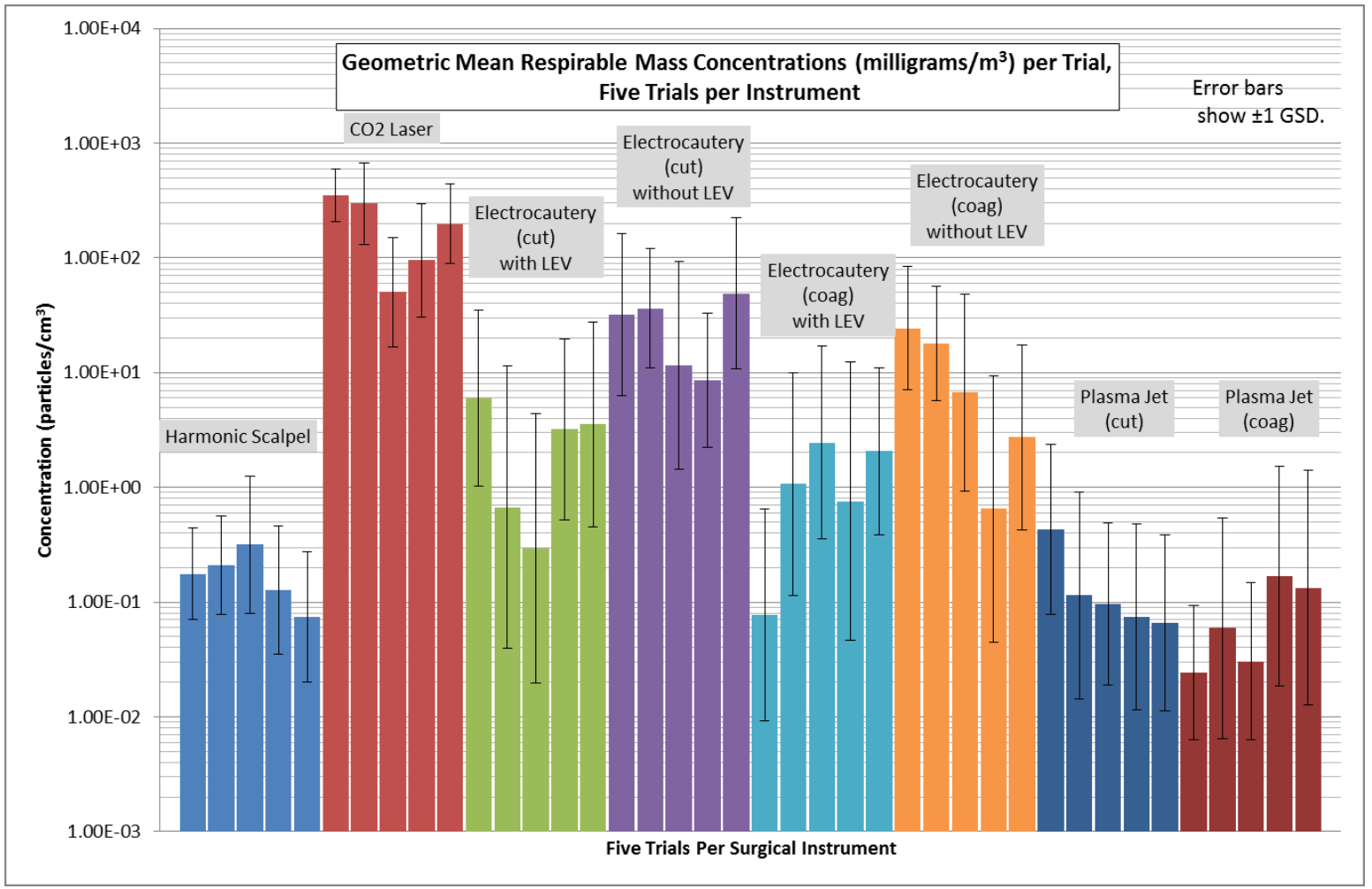

Geometric Mean Respirable Mass Concentrations (milligrams/m³) per Trial, Five Trials per Instrument
Error bars show ±1 GSD.
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
1.00E-02
1.00E-03
Concentration (particles/cm³)
Harmonic Scalpel
CO2 Laser
Electrocautery (cut) with LEV
Electrocautery (cut) without LEV
Electrocautery (coag) with LEV
Electrocautery (coag) without LEV
Plasma Jet (cut)
Plasma Jet (coag)
Five Trials Per Surgical Instrument

TABLE A19.

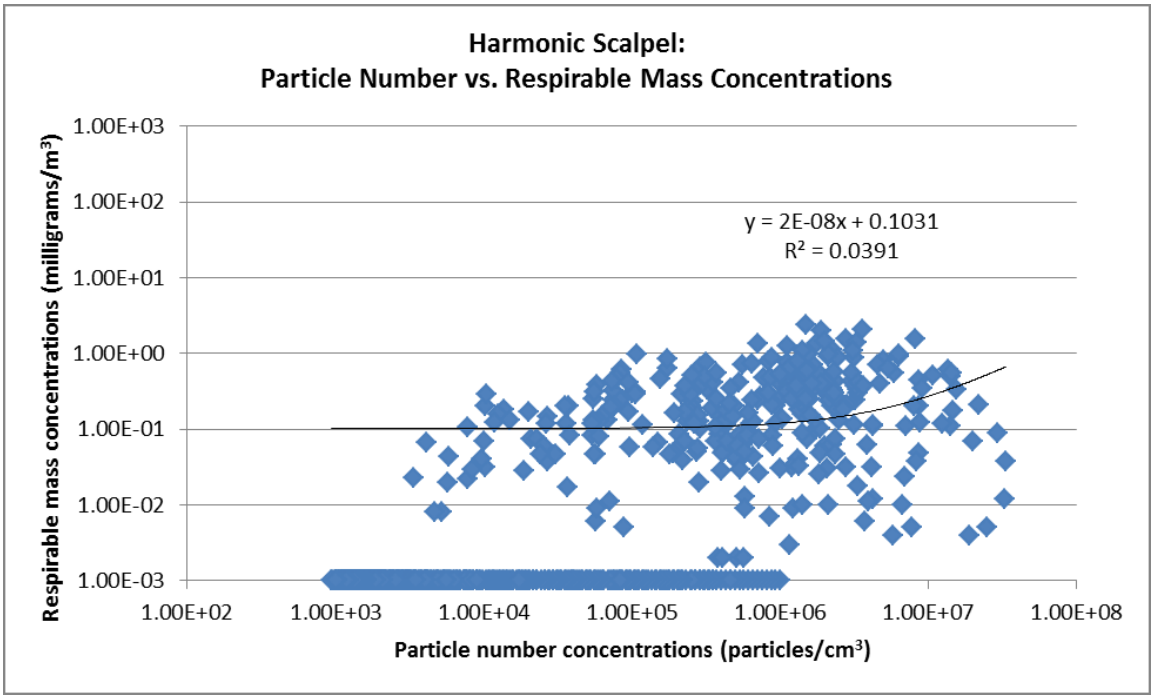


TABLE A20.

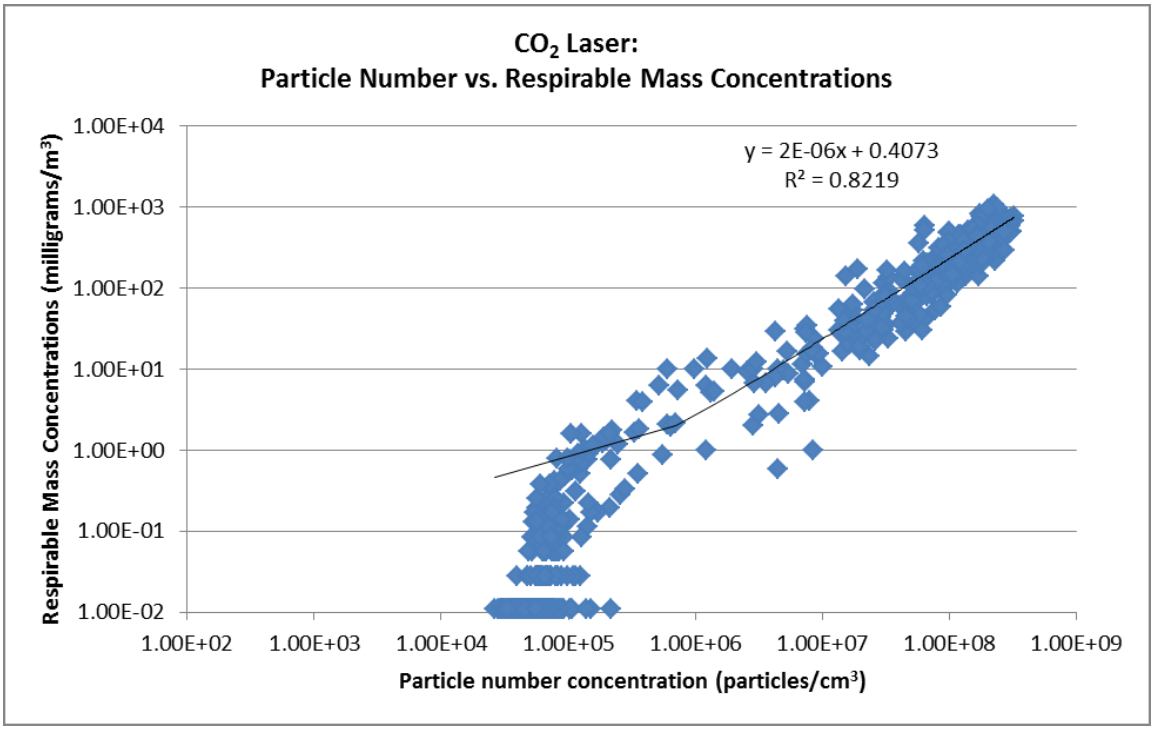


TABLE A21.

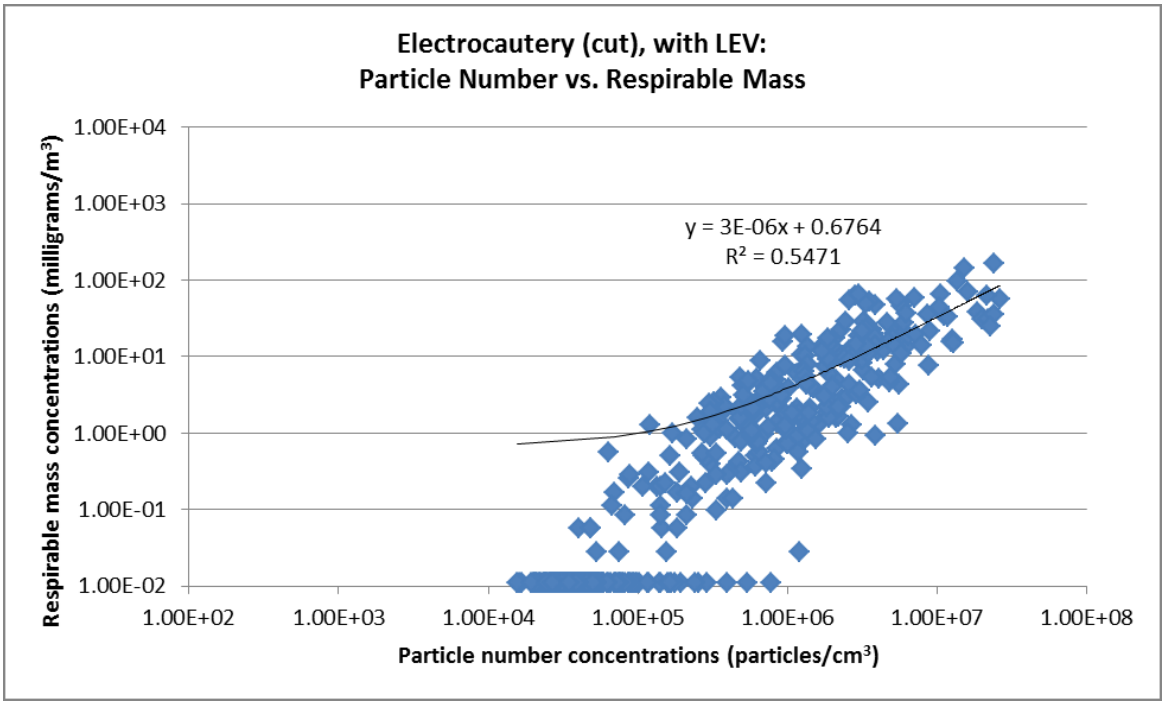


TABLE A22.

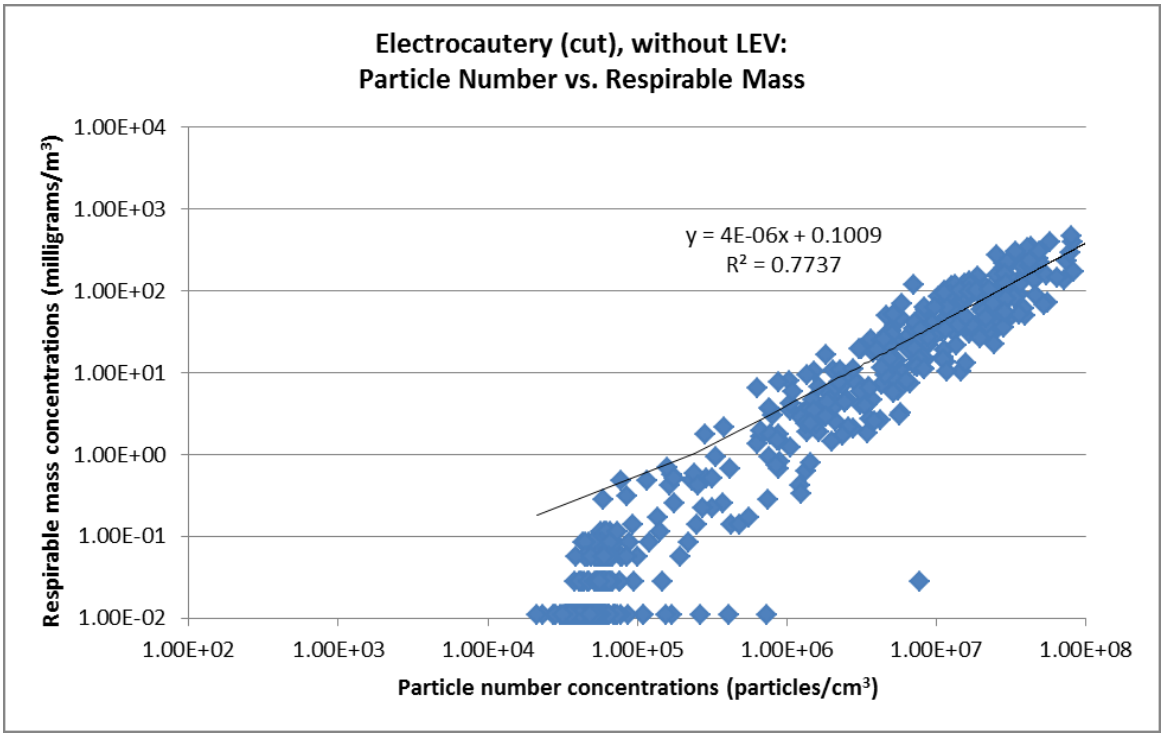
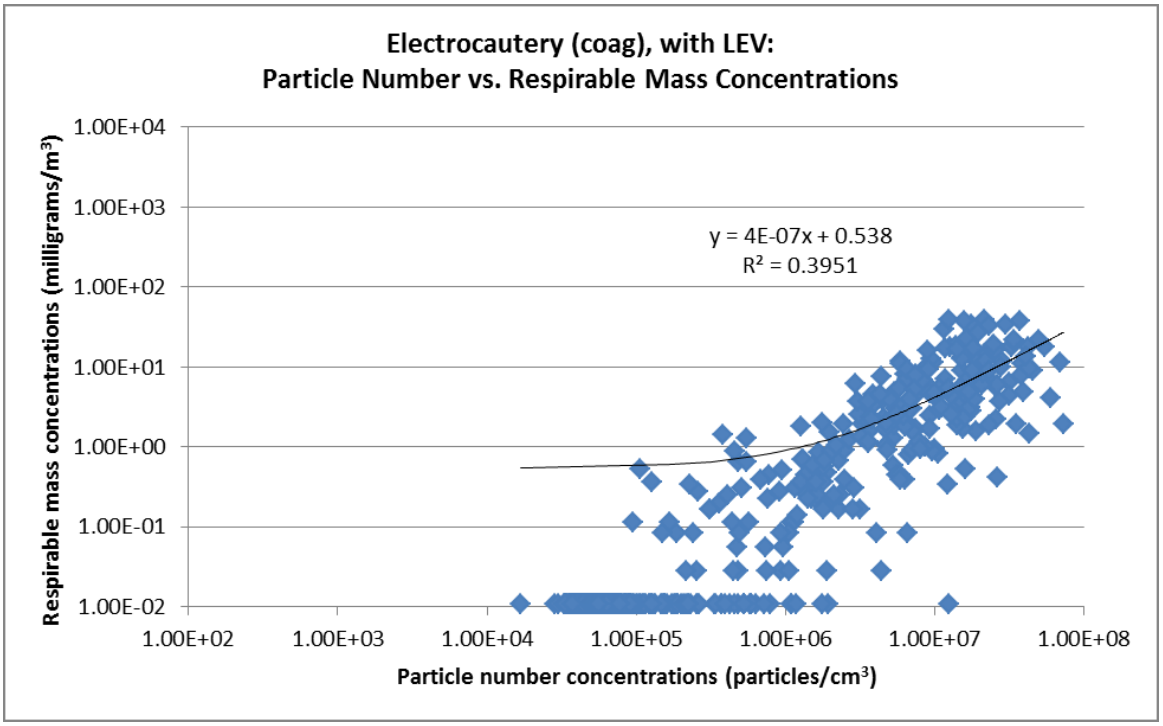


TABLE A23.



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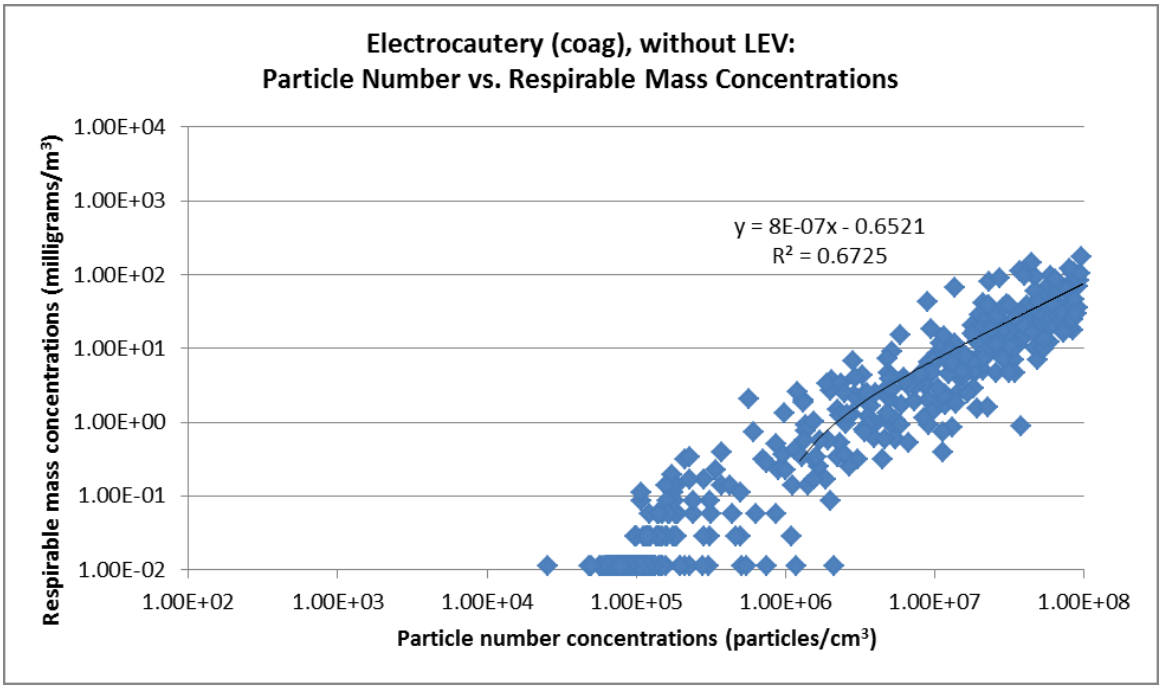

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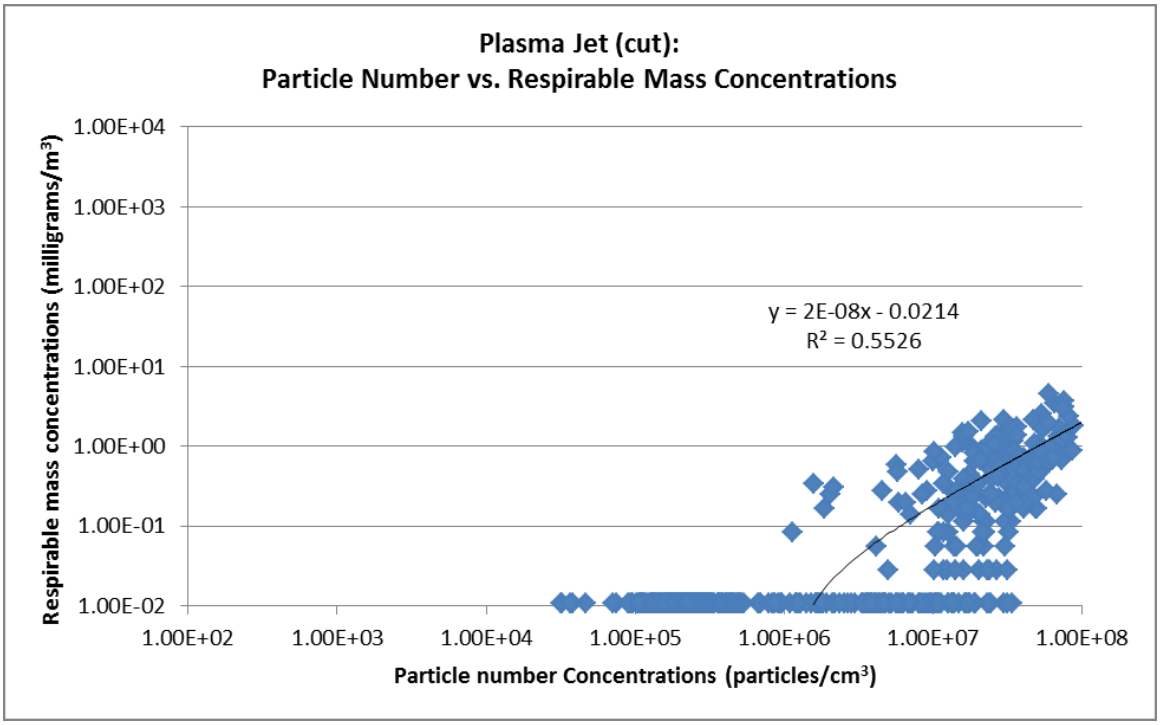


TABLE A26.

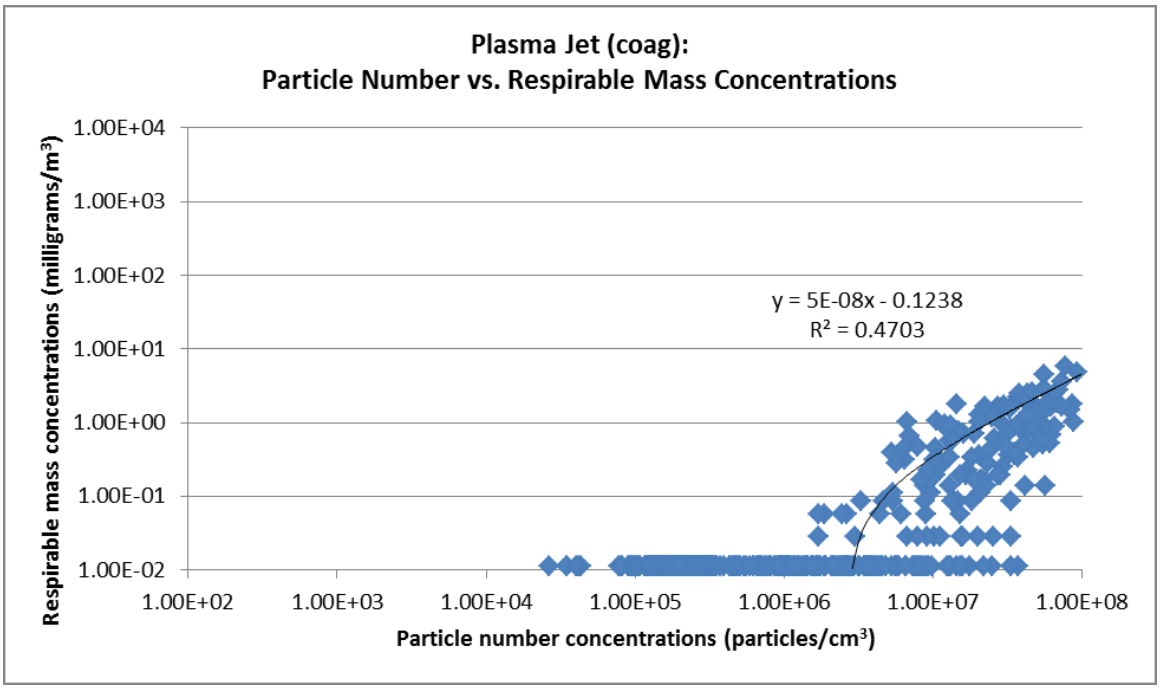


TABLE A27.

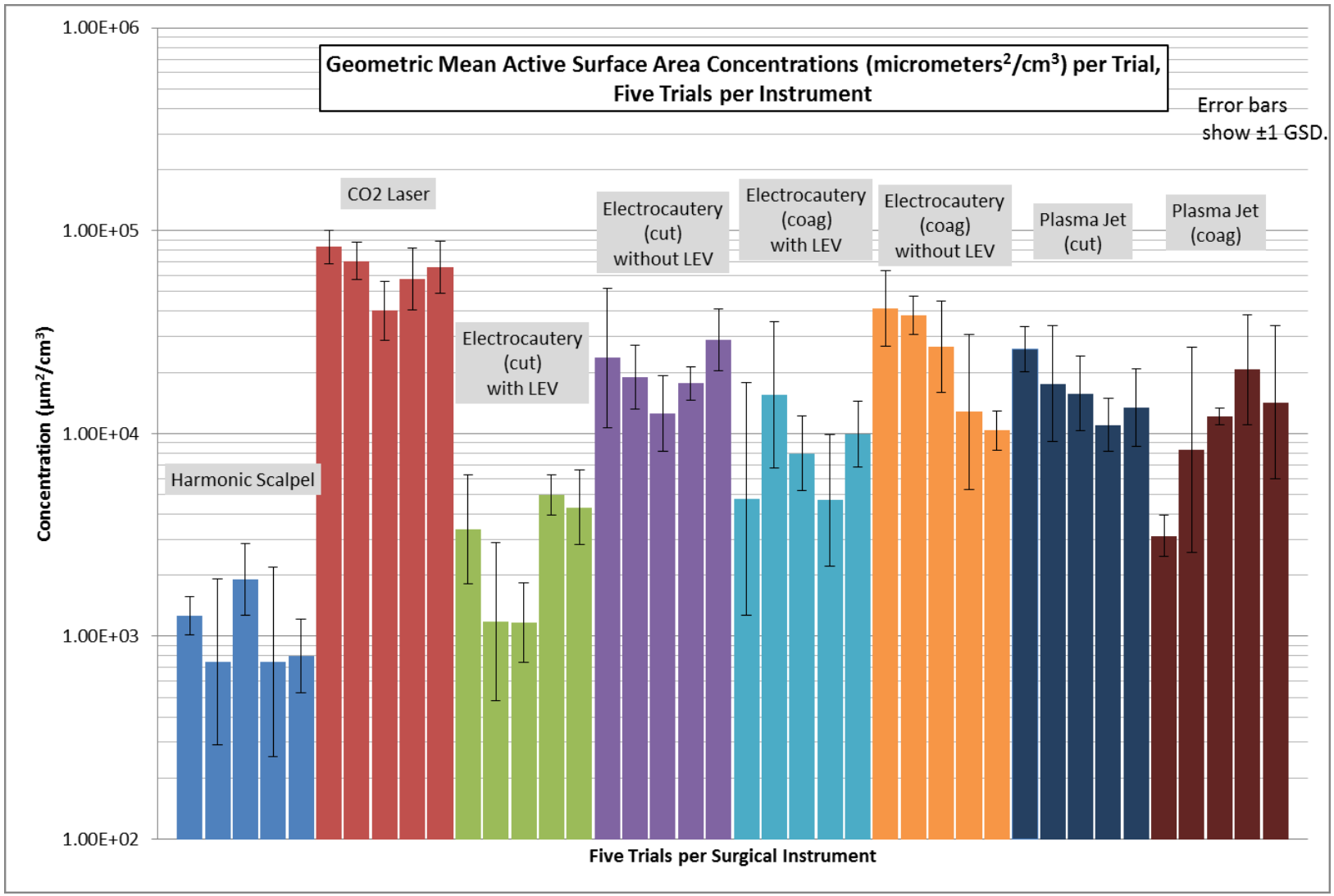

Geometric Mean Active Surface Area Concentrations (micrometers²/cm³) per Trial, Five Trials per Instrument
Error bars show ±1 GSD.
1.00E+06
1.00E+05
1.00E+04
1.00E+03
1.00E+02
Concentration (µm²/cm³)
Harmonic Scalpel
CO2 Laser
Electrocautery (cut) with LEV
Electrocautery (cut) without LEV
Electrocautery (coag) with LEV
Electrocautery (coag) without LEV
Plasma Jet (cut)
Plasma Jet (coag)
Five Trials per Surgical Instrument

TABLE A28.

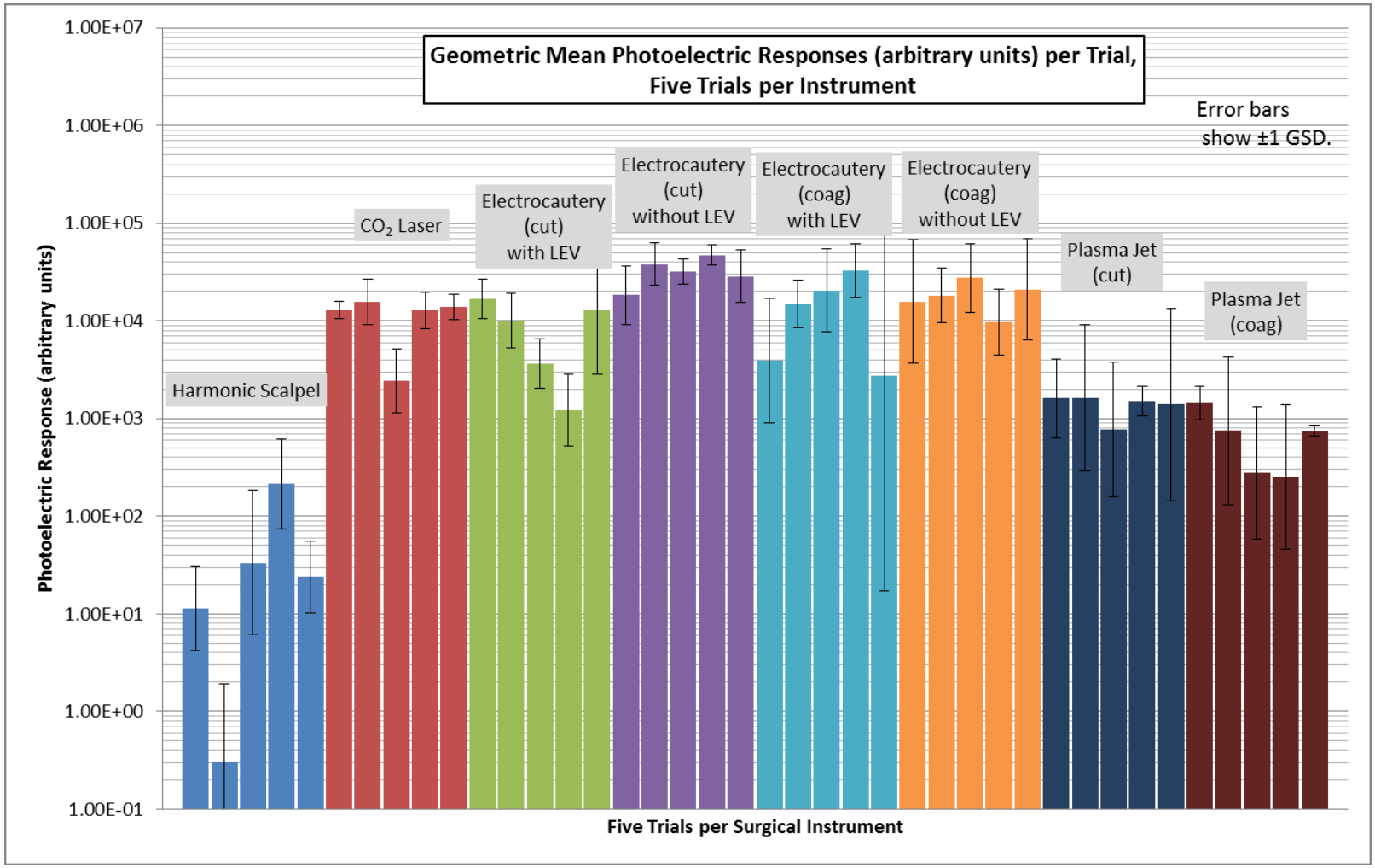

Geometric Mean Photoelectric Responses (arbitrary units) per Trial, Five Trials per Instrument
Error bars show ±1 GSD.
Photoelectric Response (arbitrary units)
1.00E+07
1.00E+06
1.00E+05
1.00E+04
1.00E+03
1.00E+02
1.00E+01
1.00E+00
1.00E-01
Harmonic Scalpel
CO2 Laser
Electrocautery (cut) with LEV
Electrocautery (cut) without LEV
Electrocautery (coag) with LEV
Electrocautery (coag) without LEV
Plasma Jet (cut)
Plasma Jet (coag)
Five Trials per Surgical Instrument

TABLE A29.

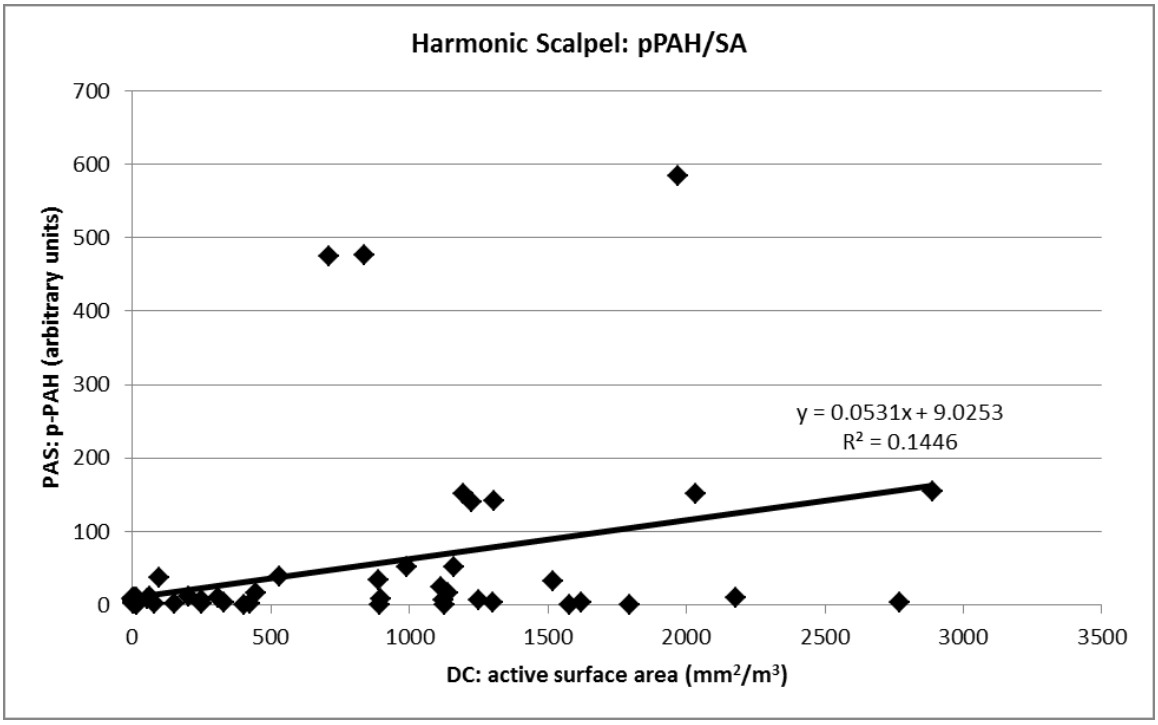


TABLE A30.

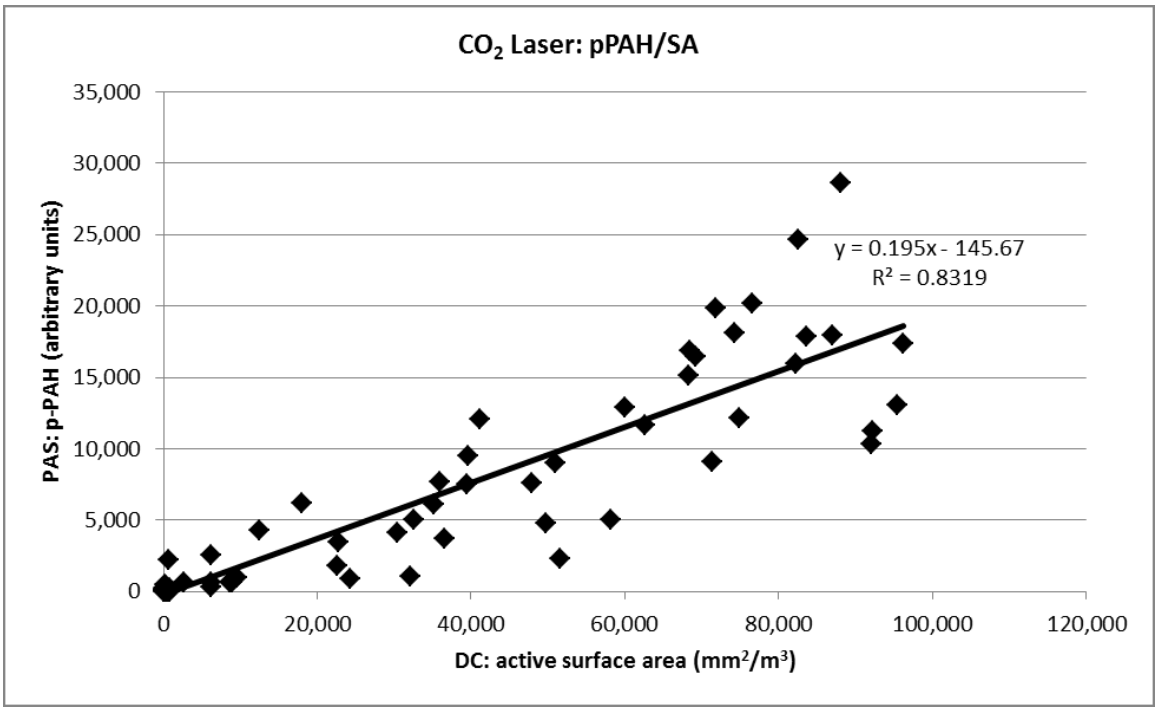


TABLE A31.

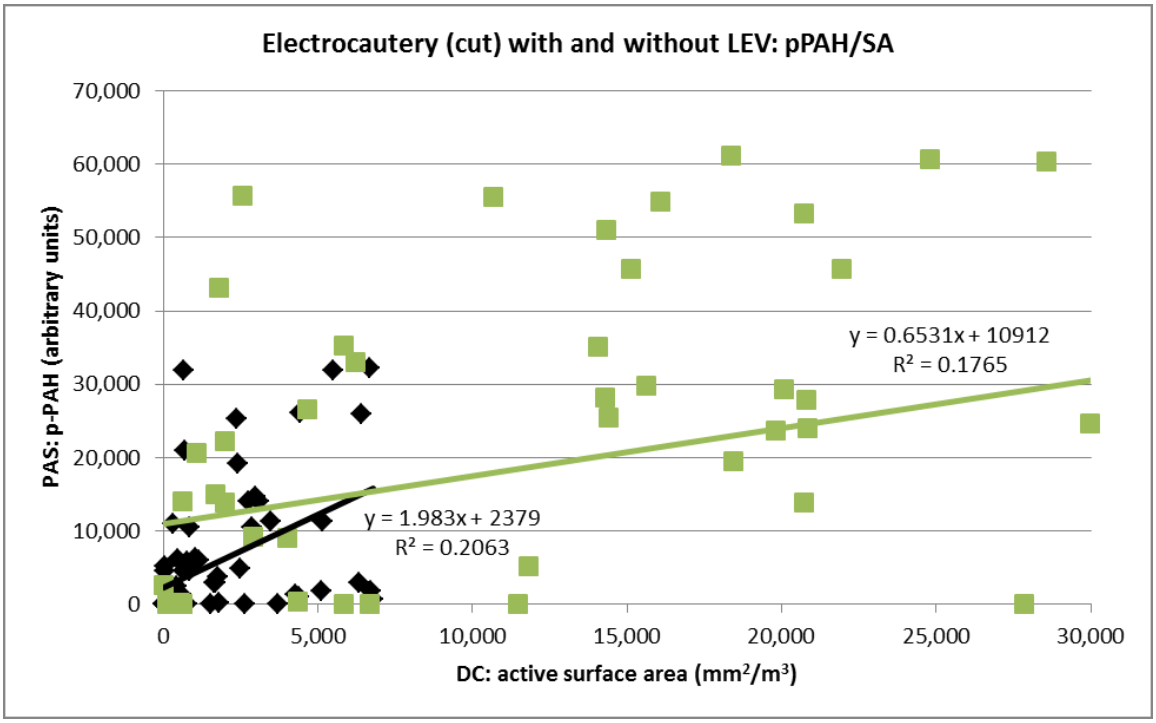


TABLE A32.

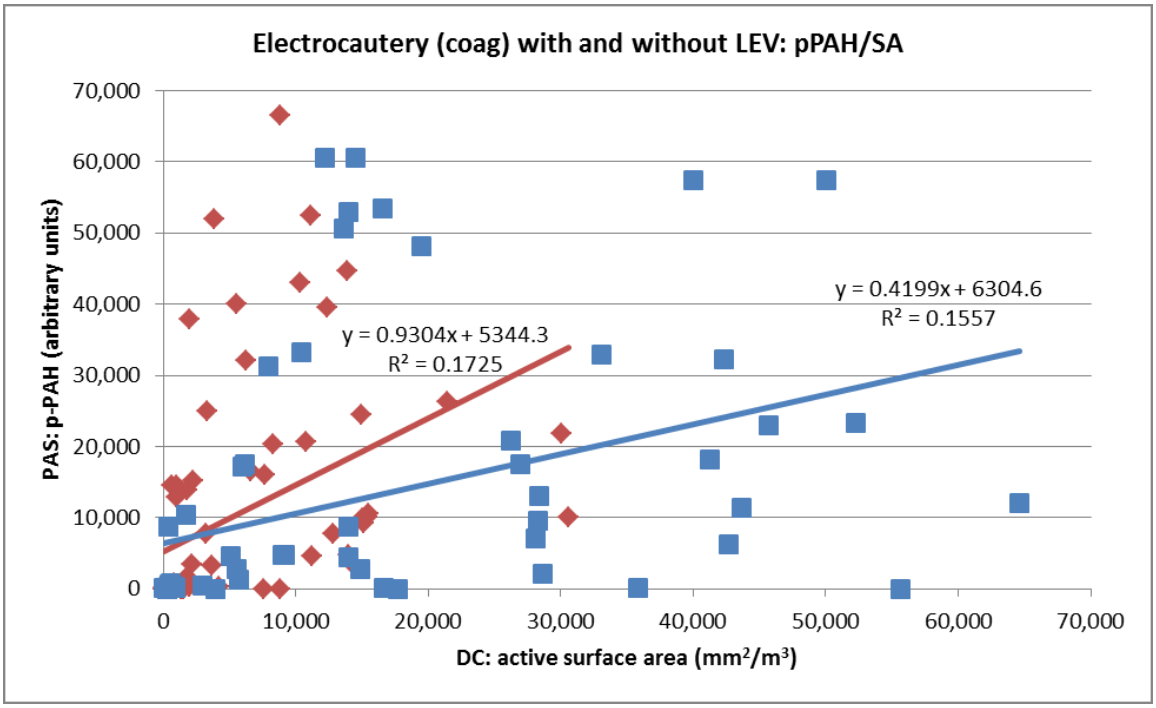


TABLE A33.

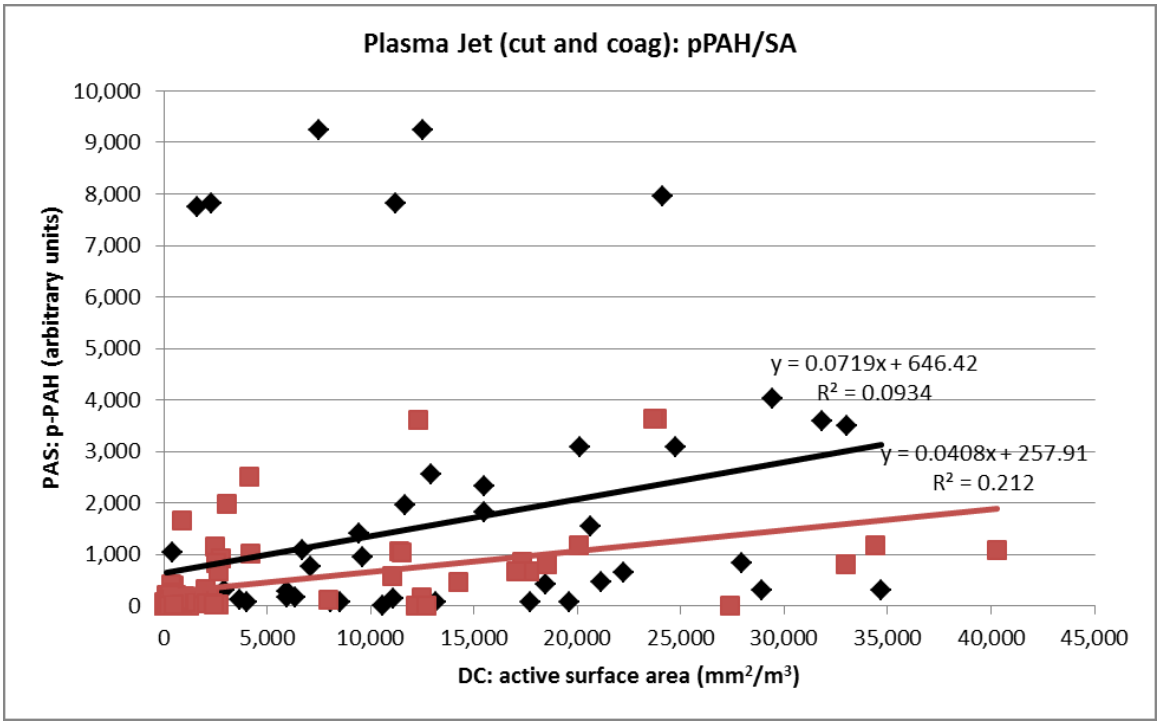
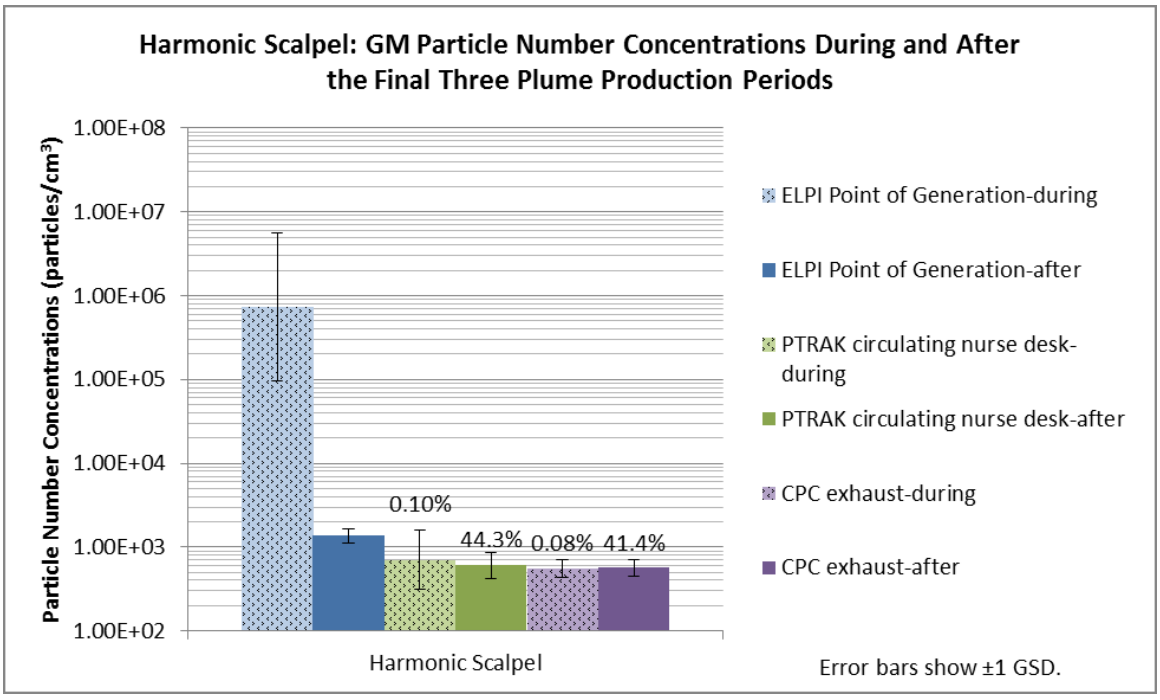


TABLE A34.



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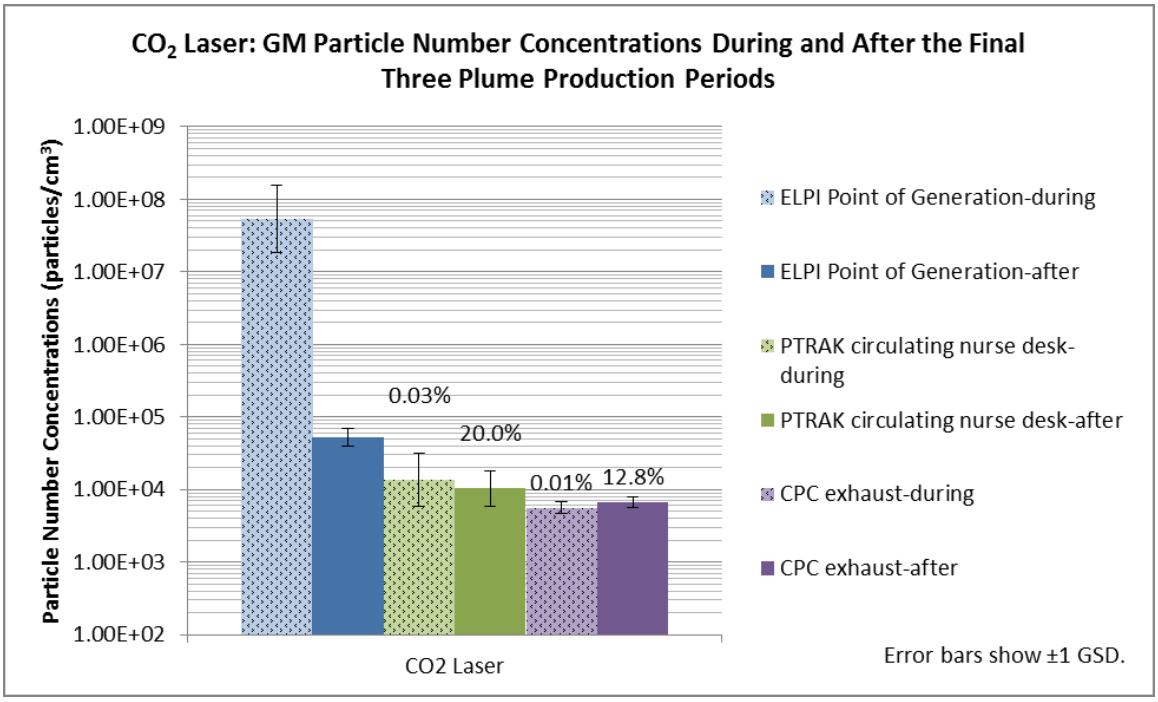

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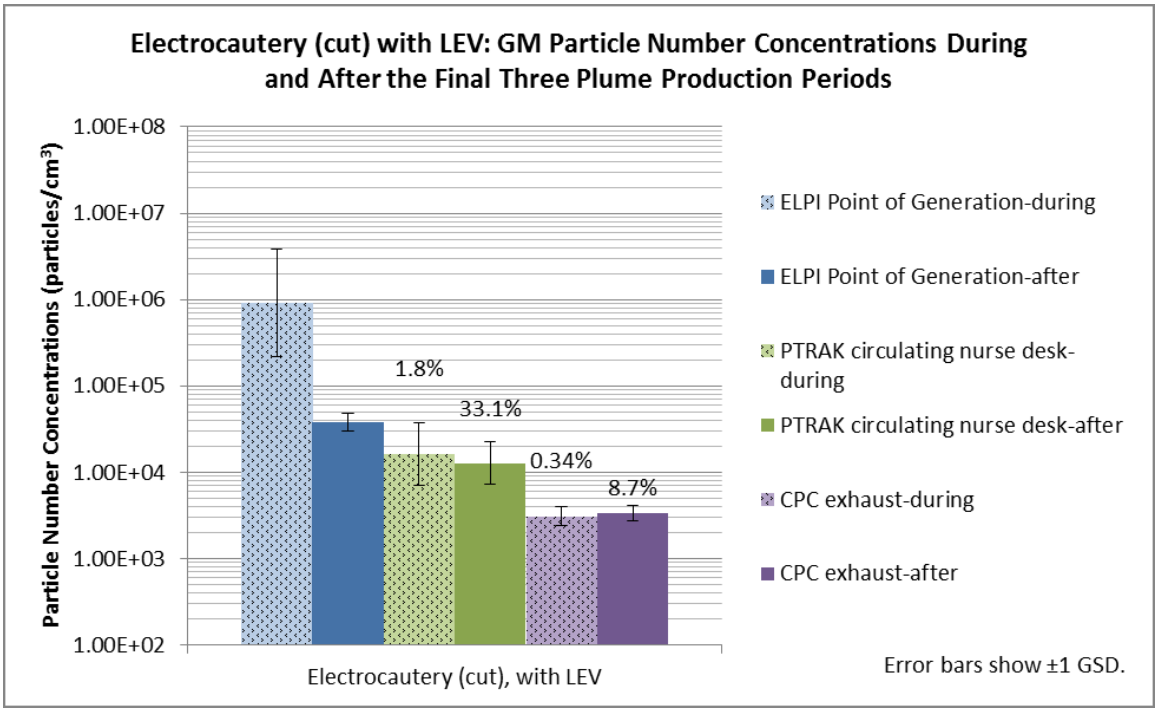
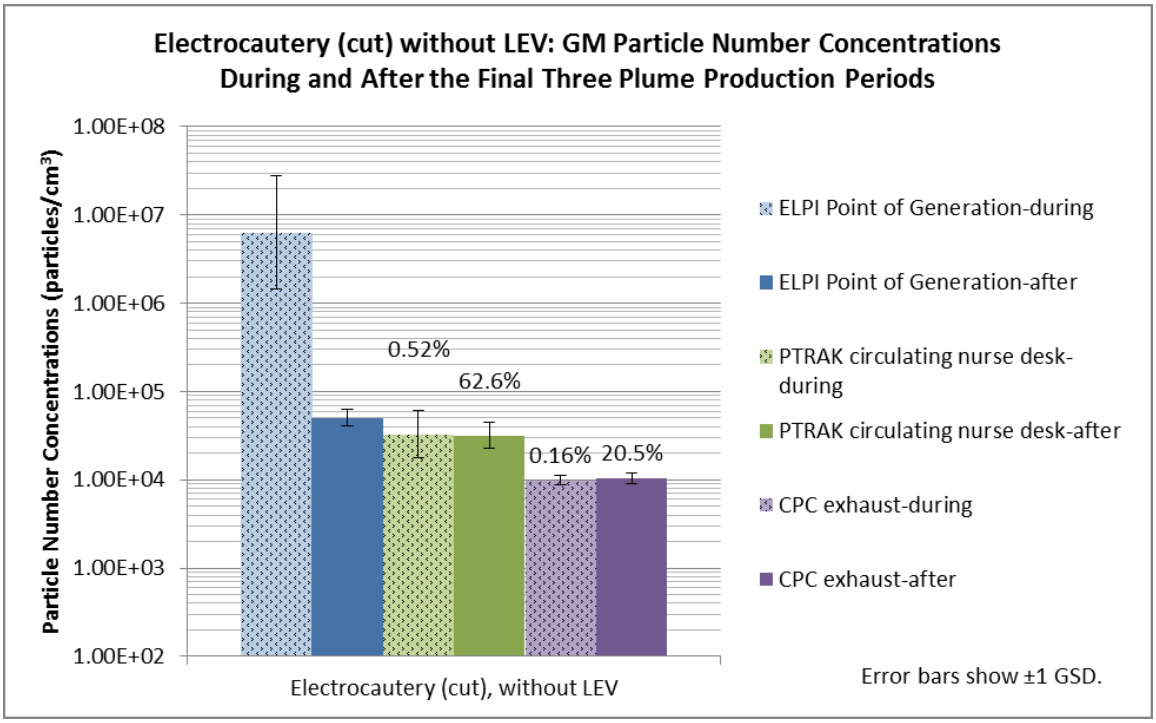


TABLE A37.



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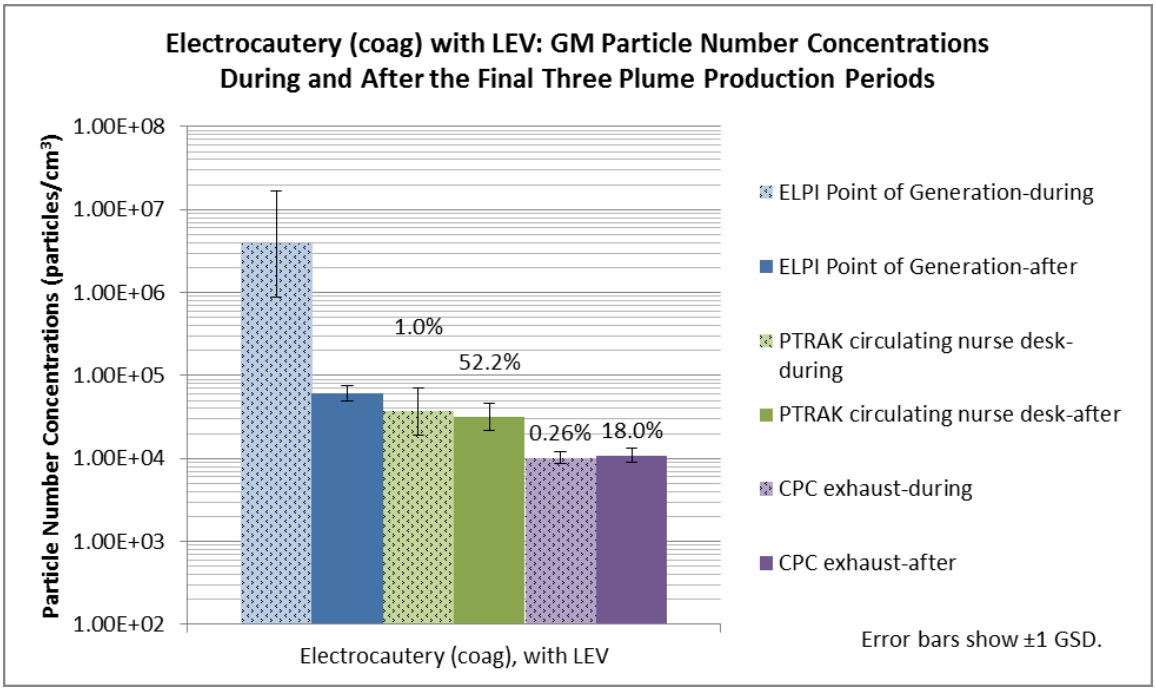
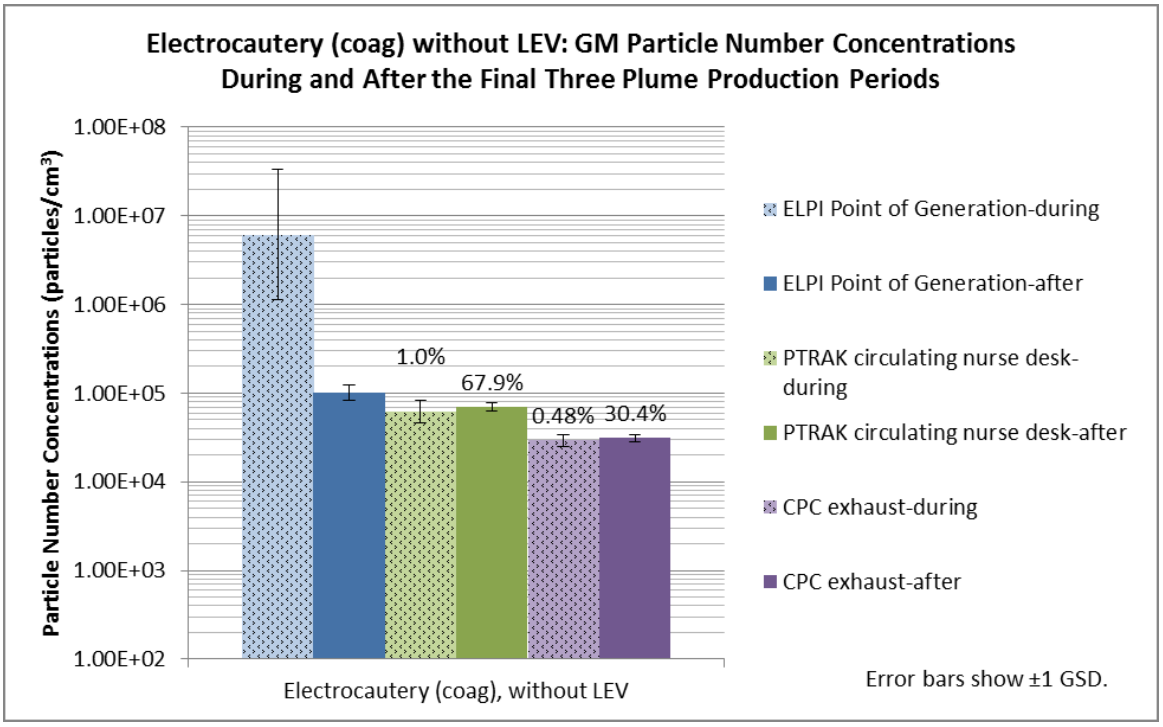


TABLE A39.



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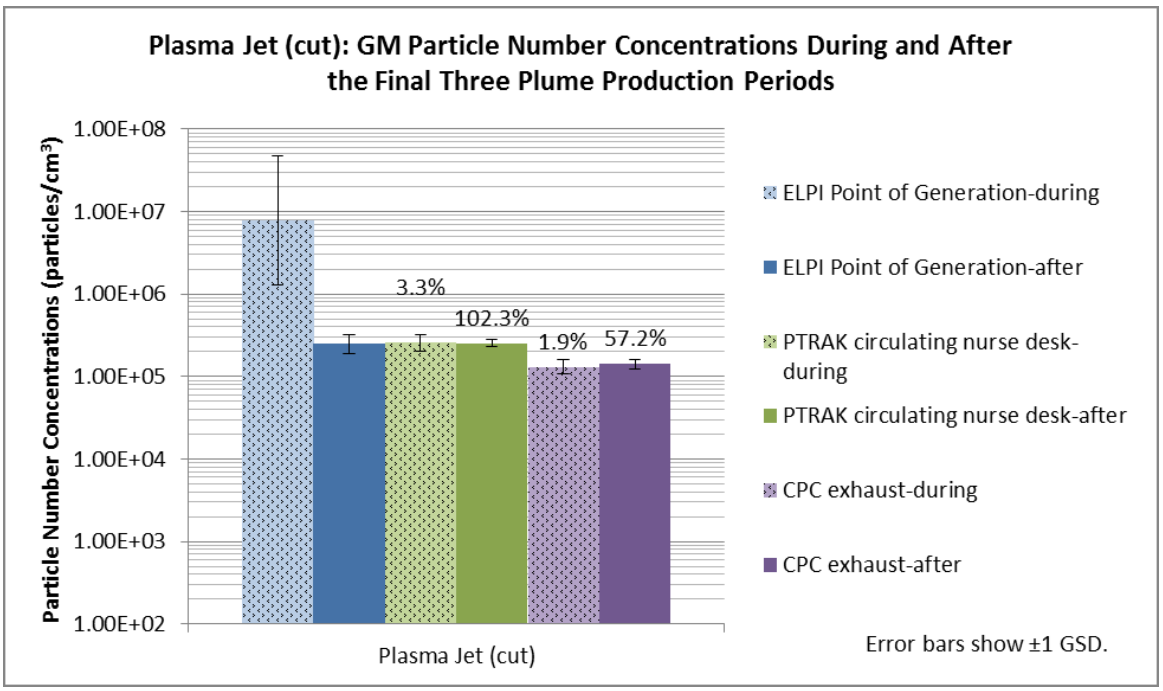
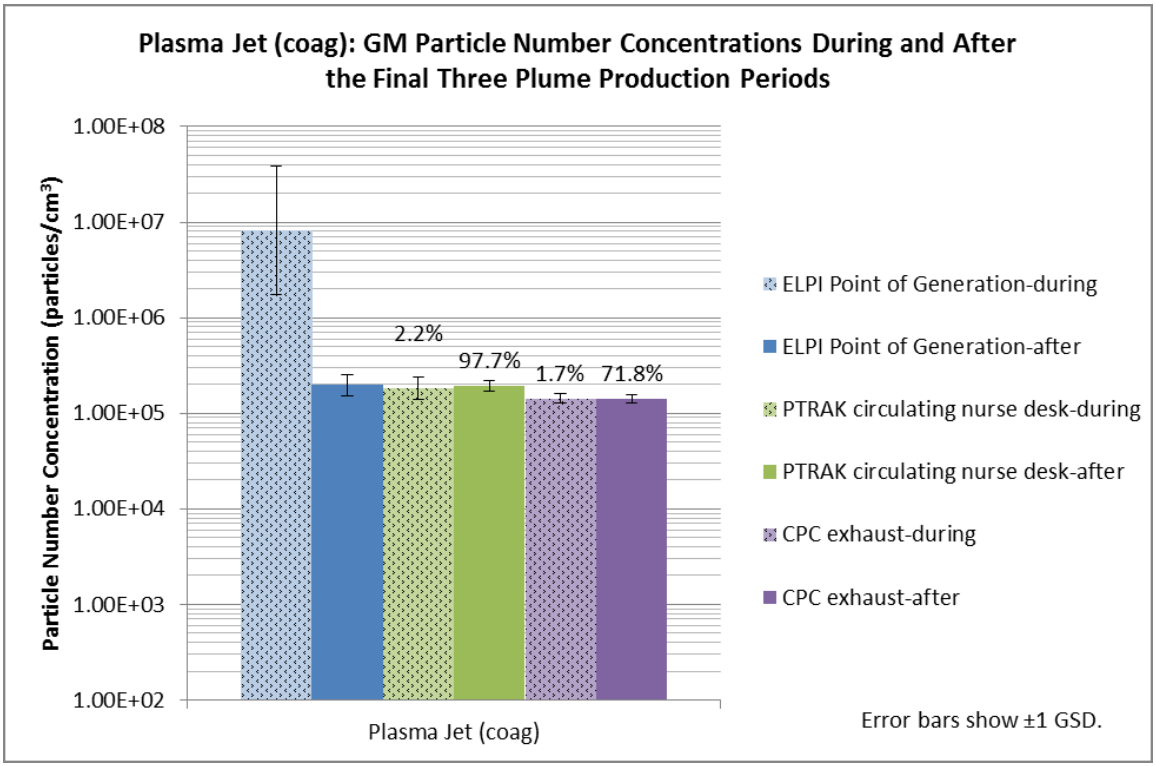


TABLE A41.


Plasma Jet (coag): GM Particle Number Concentrations During and After the Final Three Plume Production Periods
Particle Number Concentration (particles/cm³)
1.00E+08
1.00E+07
1.00E+06
1.00E+05
1.00E+04
1.00E+03
1.00E+02
2.2%
97.7%
1.7%
71.8%
Plasma Jet (coag)
ELPI Point of Generation-during
ELPI Point of Generation-after
PTRAK circulating nurse desk-during
PTRAK circulating nurse desk-after
CPC exhaust-during
CPC exhaust-after
Error bars show ±1 GSD.

Chapter 3 Personal Breathing Zone Exposures to Surgical Aerosols Produced during Controlled Trials of Application of Energy-Based Surgical Instruments to Dermal and Adipose Tissue

Abstract

A wide-spectrum particle spectrometer (WPS) and ultrafine particle counters were used to characterize personal breathing zone (PBZ) exposures to surgical plume particles produced through the use of four energy-based surgical cutting instruments to human dermal and adipose tissue. These instruments included a harmonic scalpel, a CO_2 laser, an electrocautery knife, and a plasma coagulator system. The use of these instruments during surgical procedures can produce the potential for inhalation of ultrafine plume particles by healthcare workers, including surgeons and nursing staff, present in the operating room environment. Because each surgical instrument uses a different mechanism for its cutting/coagulating/shearing action, the creation of distinctly different plume particle characteristics generated during the application of each instrument to different types of human tissue is expected. Direct-reading, real-time measurements were made during experimental, controlled trials of plume generation using these four surgical instruments in various configurations. Measurements were made at the surgical table of an operating room at a position that would represent the PBZ of a surgeon or surgeon's assistant. Geometric mean (GM) particle number concentrations produced by the four surgical instruments ranged from 220 to 108,632 particles per cubic centimeter (particles/cm^3) at the point of the personal breathing zone (PBZ) of a surgeon standing at the surgical table. Amongst the instruments tested, the Plasma Jet produced the greatest concentrations of plume particles in the PBZ of a staff member at the surgical table and the harmonic scalpel produced the lowest. All of the instruments produced ultrafine particles measured in the PBZ, with most instruments producing particles with count median diameters (CMDs) in the range of 0.082–0.190 µm, while the harmonic scalpel produced the very finest particles with CMDs in the range of 0.028–0.038 µm. Greater understanding of these particle characteristics will lead to increased understanding of occupational exposures for healthcare workers in these operating room environments.

Introduction

The Centers for Disease Control and Prevention (CDC) and the Healthcare Infection Control Practices Advisory Committee (HICPAC) stated in their report "Guideline for the Prevention of Surgical Site Infections" that 27 million surgical procedures are performed in the United States every year [Mangram, Horan et al. 1999; Kozak, DeFrances et al. 2006]. During many of these procedures, energy-based cutting instruments produce substantial aerosols from the cutting of tissues during the surgeries. The US Occupational Safety and Health Administration (OSHA) has reported that an estimated 500,000 workers, including surgeons, nurses, anesthesiologists, and surgical technologists are exposed to laser or electrosurgical smoke every year [OSHA 2008]. Surgeons and other personnel have several surgical instruments available to cut and cauterize tissue during these surgical procedures. While the surgical scalpel may be the most obvious cutting instrument, several energy-based instruments have been used with regularity over the past decades. One of the most common is the electrocautery knife, a pencil with electric current running through the tip which cuts and coagulates with the heat generated. Other instruments used include ultrasonic scalpels and lasers, as well as more recently introduced instruments such as the plasma jet. These instruments all destory the tissue through the energy applied, resulting in the production of considerable quantities of surgical plume. The plume produced by these types of instruments has the potential to be an occupational hazard to operating room personnel due to the particles produced and a variety of possible chemical and biological constituents. The respirable nature of the particles produced in the plume, the chemical by-products produced by the tissue combustion process, and the possible infectious agents aerosolized present concerns of potential acute and chronic health effects [Barrett and Garber 2003; Alp, Bijl et al. 2006; Bigony 2007].

Understanding the characteristics of these surgical plume particles will lead to a better understanding of workers' exposures to them and the potential health effects from those exposures. Characterization of surgical plume particle size distributions and differences related down to the variety of plume-producing surgical instruments available is limited. The International Social Security Association Section on Prevention of Occupational Risks in Health Services recently summarized the published data regarding the health hazards linked to surgical plume. In discussing surgical plume particle composition, the authors state that "one of the unknown elements is the nanoparticle fraction [of the smoke], which has certainly not been sufficiently evaluated, and for which we currently do not know the effects" [Eickmann, Falcy et al. 2011].

Researchers have reported using a variety of methodologies to investigate different characteristics of the plume particles. These methodologies have included the use of cascade impactors, microscopy on filter samples, and some direct reading instrumentation. A substantial limitation of many methodologies used in past studies is the inability to evaluate the smallest, nano-scale size ranges potentially produced as well as the evaluation of those particles within the personal breathing zone (PBZ) of those closest to the source of plume production.

Few studies have been published comparing the characteristics of plume particles produced by the variety of plume-generating surgical instruments used by surgeons. In one study, Weld et al. [2007] stated "at present, there is a paucity of data regarding the morphology, size, and composition of surgical smoke." The authors of the study reported on plume particles produced by four common laproscopic cutting instruments within a confined space similar to laparoscopic surgery, reporting size distribution and number concentrations of particles produced by the different surgical instruments. Similarly, Kim et al [2012] compared surgical plume specifically

produced by various laparoscopic dissectors and reported their effects on the obstruction of laparoscopic visibility. Fitzgerald et al. [2012] compared analyses of volatile hydrocarbon concentrations produced by ultrasonic scalpels and electrocautery knives in human laparoscopic surgeries, comparing both with concentrations of those compounds found in cigarette smoke.

The goal of this evaluation was to systematically characterize surgical plume particles in the PBZ of the individual(s) closest to the source of plume production in an operating room using a variety of plume producing surgical instruments on human tissue types. Because of concerns about sterility and space that are inherent around the surgical table during actual procedures, instrumentation designed to characterize surgical plume exposures cannot easily be introduced into the PBZ of surgeons or surgeons' assistants. This has made it difficult to characterize the size and concentrations of surgical plume particles which those individuals are respiring. Therefore, these surgical plume evaluations undertaken as a part of this investigation were designed to replicate real-world surgical conditions as closely as possible in terms of operating room environment, surgical techniques and instruments, and the use of human tissue.

Methods

Evaluation of the characteristics of surgical plume particles generated through the use of energy-based cutting and cauterizing instruments on human tissue was performed in operating rooms at a surgery center in Fayetteville, New York. These operating rooms had been used for multiple surgical procedures for a large portion of the day prior to the evaluations; permission was granted by hospital administration to use the operating rooms after the previously scheduled surgeries performed in those rooms were complete for that day. After the surgical

procedures had been completed, the rooms were cleaned, leaving the patient bed and cutting/cauterizing instruments in the room to be used for the plume production evaluations.

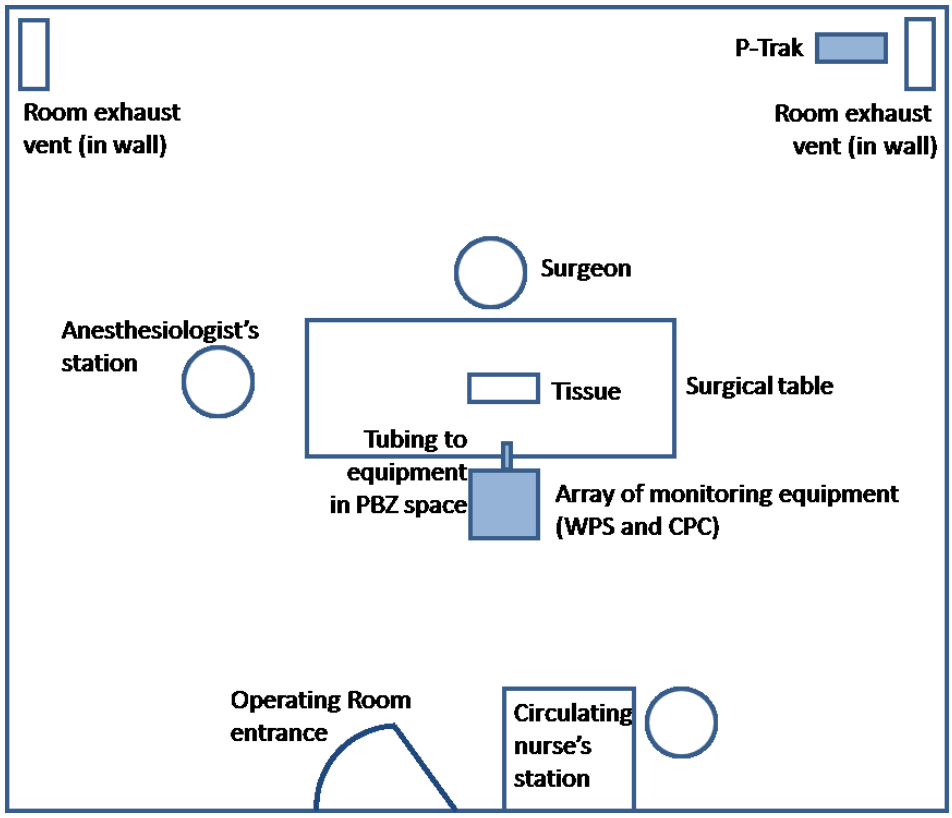
All room ventilation characteristics during the plume production evaluations were identical to those during the actual surgical procedures to reflect real-world operating room conditions. Ventilation measurements were made in the operating room using a TSI Inc. AccuBalance Plus model 8373 air capture hood and a TSI Inc. VelociCalc Plus model 8386A to measure air volume flowing through the ventilation supply registers and exhaust vents in order to calculate the number of air changes per hour (ACH) achieved in the OR. The location of the supply registers above the surgical table provide a downward laminar flow of high efficiency particulate air (HEPA) filtered air from above the surgical site to the room's two exhaust vents, each located near the floor in the room's corners farthest from the OR entrance. Measurements were also made to confirm that the rooms were maintained under positive pressure as designed.

A board-certified plastic surgeon employed at the hospital produced the surgical plume through the use of the surgical instruments to human dermal and adipose tissue. This tissue was collected during plastic surgery procedures that the surgeon had performed previously in the day and stored in an airtight container with a small quantity of a sterile saline solution to maintain its freshness. Typically in such surgeries, this tissue is removed and destroyed afterwards by the hospital as biological waste. Prior to the start of these surgeries, the surgeon received informed consent from the patient for the use of their tissue removed during the surgery for the plume production evaluations later that day. The patient's response to the request to use their tissue for this study purposes did not change any aspect of the surgical procedure itself; no more or less tissue was removed than that required for the surgery. After the plume production evaluations were conducted that day, the tissue was returned to the

hospital's biological tissue waste stream to be destroyed. Hospital and JHSPH IRB approval was obtained for the collection and use of the biological specimens in this manner.

The surgeon placed the tissue collected from prior surgery on absorbent tissue pads in the center of the surgical table in a location that approximated the site of surgical work on a patient. Using one of four surgical plume-producing instruments described below, the surgeon applied the instrument to the tissue using the same surgical technique that would be used during a surgical procedure. Because these instruments are often applied in a short, intermittent, and sporadic manner during surgeries, a similar design was incorporated in the experimental plume production design. For each specific instrument applied to a tissue type, 20 consecutive sampling periods were conducted by the monitoring equipment whose inlets were located in what would be the PBZ space of an individual working at the surgical table (see Figure 3.1). Each sampling period lasted 30 seconds. For the first five seconds of each sampling period, the surgeon applied the instrument to the tissue to create a plume of particles simulating that formed during a surgery. After completing 20 sampling periods using one instrument on one type of tissue, plume production was ceased and the particle concentrations were allowed to return to background level (approximately at or below 100 particles/cm^3) before a new round of 20 sampling periods using a different instrument on a fresh area of the tissue was conducted.

Figure 3.1 Layout of the Operating Room and Placement of the Sampling Equipment



The number of sampling periods required for comparison of the plume characteristics produced by the different cutting instrument was determined through sample size calculations. Several variables were needed for such calculations: variability of the mean particle diameters, the expected difference between the two means, the significance level (alpha, set at 0.05), and the power (beta, set at 0.80). While little is known about the variability of mean particle diameter to be expected, a study conducted by Weld et al. (2007) comparing the count median diameter of particles produced by four laparoscopic cutting instruments reported geometric mean particle diameter as well as the geometric standard deviations. The difference between the geometric mean particle diameter of the particles <500 nm produced by the harmonic scalpel and the floating ball (an electrocautery-like device) was 1.6 nm. The average geometric standard

deviation was 1.75. [Weld, Dryer et al. 2007] Using these data as estimates of the expected variables yielded the following sample size:

$n = 2/d^2 * C_{p,power}$ (where d = expected difference/standard deviation)
$n = 2/(1.6/1.75)^2 * C_{0.05, 80\%}$
$n = 2/(0.91)^2 * 7.9$
n = 19 sample trials per cutting instrument per tissue

Particle Measurement Equipment

A wide-range particle spectrometer (WPS) model 1000XP-A (MSP Corp., Shoreview, MN) and a handheld condensation particle counter (CPC) model 3007 (TSI Inc., Shoreview, MN) were co-located to characterize size distributions and particle number concentrations of surgical plume particles in what would be the PBZ of a surgeon or surgeon's assistant standing at the surgical table. Short lengths of non-conducting tubing (approximate length: 30 cm) were added to the instruments' inlets; the tubes' particle-collecting inlets were 41 cm above and offset by 41 cm from the point of plume production on the table and were 120 cm in height above the floor of the operating room.

The WPS uses a combination of laser light scattering, differential mobility analysis, and condensation particle counting to size and count airborne particles. The output parameters for the WPS included 12 bins of particle sizes from 0.010–0.500 µm using its differential mobility analyzer and 24 bins of particle sizes from 0.350–10 µm using its laser particle spectrometer. To scan through these particle size bins, the WPS operates on a 30-second sampling period, followed by a 15-second wait time before the scan of the next sampling period started. Additionally, the CPC co-located with the WPS counted particles measuring 0.010–1.0 µm in size in concentrations up to 100,000 particles/cm^3, with a logging interval of 60 seconds. A P-Trak®

ultrafine particle counter (TSI Incorporated, Shoreview, MN) was also used in the periphery of the room at a location in the far corner opposite the entrance and near one of the room's exhaust vents for additional particle number concentration characterization. The P-Trak® counts particles measuring 0.020–1.0 μm in size, ranging in concentrations up to 500,000 particles/cm^3. The CPC and the P-Trak were configured with logging intervals of 60 seconds.

Surgical Instruments

Four classes of energy-based cutting instruments were used in the evaluation. The extent of use of these instruments in surgical operating rooms across the country varies. Each has a different method of cutting, coagulating, and cauterizing tissue through the application of various forms of energy. Depending on the surgical procedure being performed, the type of tissue being cut or cauterized, and the needs and preferences of the surgeon, one or all of these instruments may be utilized during surgery.

The Valleylab Force EZ™ Electrosurgical Generator (Covidien, Boulder, CO), also known as a bovie and one of the most commonly used instruments that produce surgical plume, employs an electric current at the tip of the handpiece. As this tip is applied to tissue, the electric current enters the tissue and creates a circuit, exiting a grounding pad placed on the surface of the patient's skin near the surgical point. Cut and coagulation modes are available to use with this instrument, each having adjustable wattage settings. The cut setting uses a low voltage with constant electrical waveform to produce maximum current concentration, focusing intense heat at the site and resulting in tissue vaporization. The coagulation mode uses a high voltage with intermittent electrical waveform, producing less heat and resulting in a coagulum rather than tissue vaporization [Covidien 2008].

The Plasma Jet® Neutral Plasma Coagulator system (Plasma Surgical, Roswell, GA) utilizes a low-flow stream of argon gas that passes over electrodes in the handpiece of the unit. This creates a stream of high energy argon plasma, a mixture of ionized gas atoms and electrons [Plasma Surgical Limited 2009]. The effects on tissue by the stream of argon plasma depend on the quantity and speed of argon gas and how much energy is being applied into the gas at the tip of the handpiece. During surgical procedures, the argon flow at the tip of the hand piece is brought in close proximity to the tissue, with differing effects dependent on the distance of the tip from the tissue surface. Tissue shrinkage and coagulation occurs at a distance of 1 cm or more, while vaporization and cutting of the tissue occurs with contact of the tissue by the tip. The thermal and kinetic energy introduced into the tissue penetrates to a typical depth of less than 0.5 millimeters from the site of contact. [Plasma Surgical Limited 2009]

The UltraCision® Harmonic Scalpel® (Ethicon Endo-Surgery Inc., Cincinnati, OH) produces high-frequency mechanical energy to vibrate at 55,000 hertz to create a shearing and coagulating action on soft tissue [Ethicon Endosurgery 2012]. A benefit in the surgeon's use of this piece of equipment is that there is no electrical stimulation of the tissue as there is with the electrocautery knife, with resultant lack of electrically-stimulated muscle twitches. Additionally, since no electrical current is applied, the temperature at the point of application of the tip to the tissue is considerably less than that of the electrocautery knife. [Branson 2008]

The Sharplan Silktouch Surgiplus XJ-series CO_2 laser (Sharplan Lasers, Inc., Allendale, NJ) produces a beam with a wavelength of 10.6 µm which is strongly absorbed by the water content in the tissue, increasing the temperature of the tissue resulting in coagulation and tissue vaporization (Dagan J 1984).

Initial acquisition and analysis of data from the WPS was performed using WPS Commander™ software, version 2.5 [MSP Corp., Shoreview, MN]. Initial acquisition and analysis of data from the P-Trak was performed using Trak-PRO™ software, version 4.2.0.15, while Aerosol Instrument Manager® software, version 8.1.0.0, was used for data originating from the CPCs. [TSI Incorporated, Shoreview, MN]. Statistical analysis was performed using Intercooled Stata, version 9 [StataCorp LP, College Station, TX].

Data Analysis

Descriptive statistics such as count median diameter (CMD) and geometric standard deviation (GSD) of size distribution of PBZ particles were calculated for the particle plume produced by each instrument on dermal and adipose tissue. The first of each of the 20 trials per instrument were not used in the analyses because of a short lag time observed in production of particles and measurement by the instrument. T-tests for difference in means were performed to determine if statistically significant differences exist between the CMDs of particles produced by each cutting instrument between the two tissues and between various instruments on each tissue type. Similarly, tests for differences in means for particle count concentrations were performed for the various instruments and tissue types as well as between concentrations at the surgical table and at the periphery of the operating room.

Results and Discussion

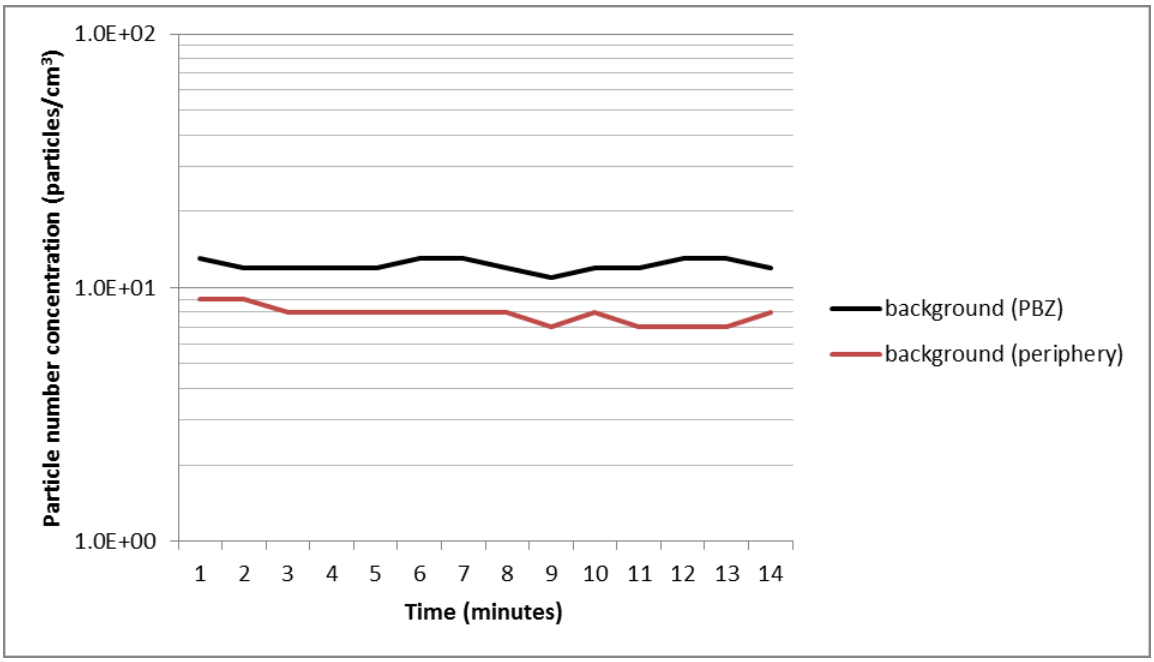
Ventilation Characteristics

The ACH achieved in the room during which sampling was conducted on the dermal tissue was 23.5 ACH; exhaust exceeded supply by approximately 200 cubic feet per minute (CFM) and provided a negative pressure environment in the room compared to the adjacent corridor. The ACH achieved in the room during which sampling was conducted on the adipose tissue was 21.3 ACH; in this case, supply exceeded exhaust by approximately 200 cfm, ensuring a positive pressure environment in the room compared to the adjacent corridor.

Characterization of Background

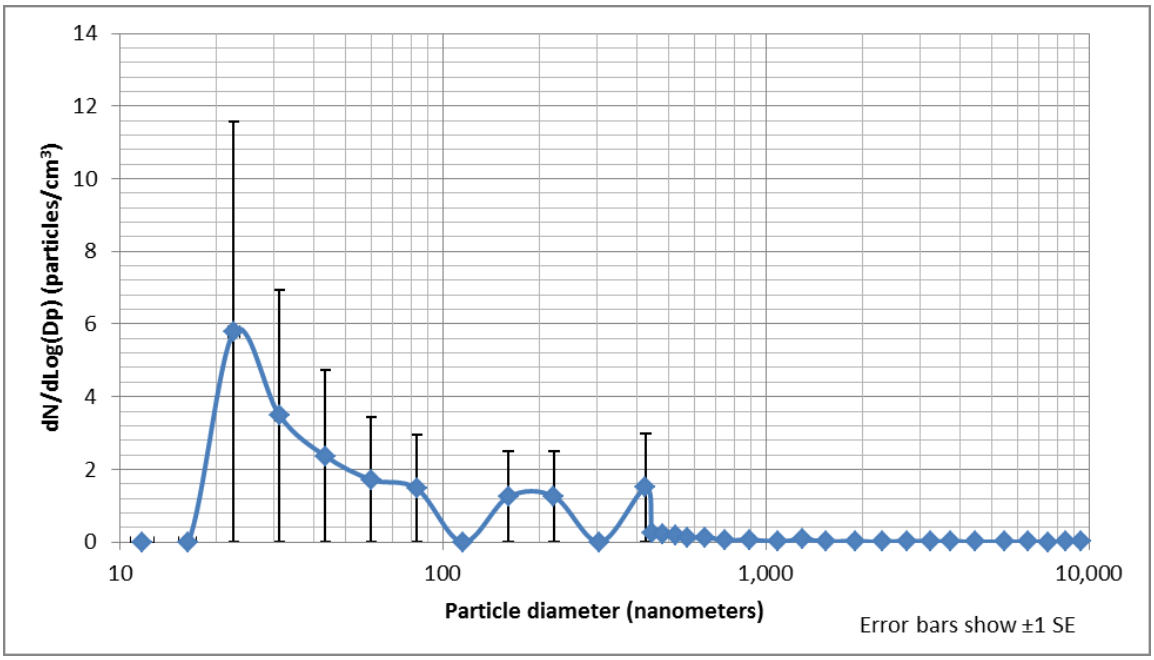
Prior to the start of experimental plume production, a round of 20 sampling periods was performed to determine background airborne particle concentrations and sizes. Because of the introduction of HEPA-filtered air from supply registers located above the surgical table, very few particles of any size were recorded during these sampling periods. The geometric mean (GM) particle number concentration recorded in the PBZ area at the surgical table was 12 particles/cm^3 [GSD: 1.05] while it was 8 particles/cm^3 [GSD: 1.09] in the periphery of the room. See Figure 3.2 for real-time particle number concentration measurements during fourteen minutes of sampling in the PBZ and periphery of the operating room. While the difference between these two concentrations was very small, a paired t-test performed for difference in mean concentrations of the two areas did show a statistically significant difference [$p<0.001$].

Figure 3.2 Background Particle Number Concentrations in the PBZ at the Surgical Table and in the Area at the Periphery of the Room as Measured by a CPC and PTrak



Measurement of size distribution of the background particles in the PBZ area at the surgical table showed a small particle diameter peak was recorded at 0.023 µm and a count median diameter (CMD) of 0.062 µm (geometric standard deviation [GSD]: 3.02). See Figure 3.3 for the size distribution of background aerosols averaged over 19 trials.

Figure 3.3 Average Particle Size Distribution of Background Aerosols as Measured using a WPS

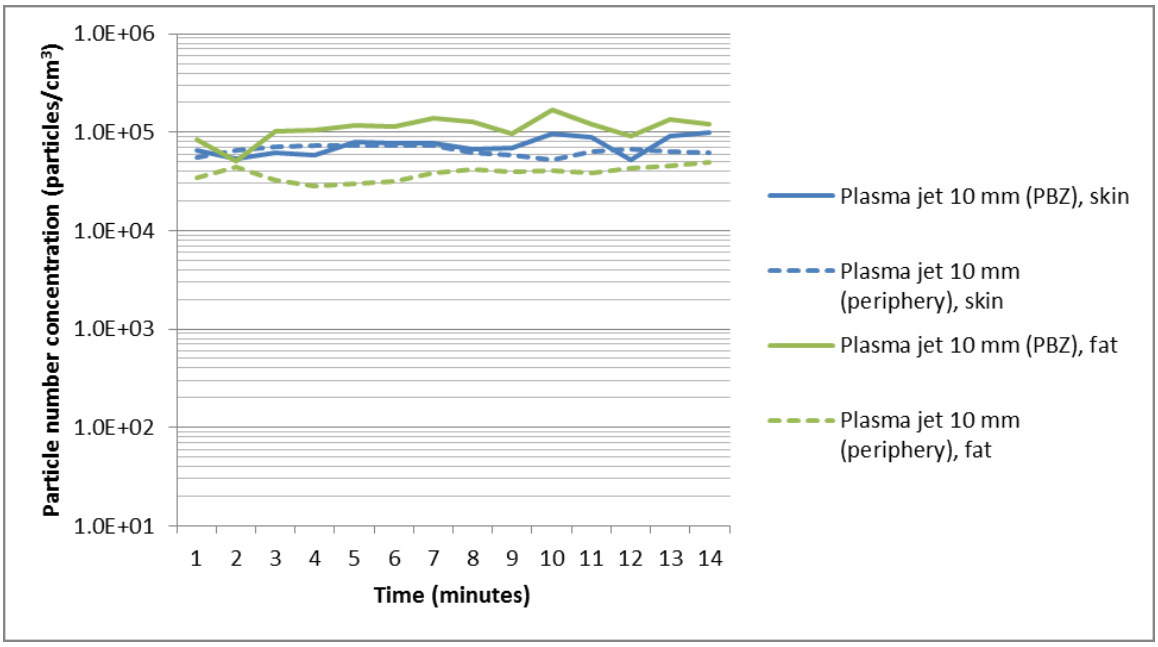


Plasma Jet

The Plasma Jet can be manipulated by the surgeon to create the desired effect on the tissue. While the surgeon can choose multiple power levels for the instrument, the surgeon selected a power level of 40 for the plume generation as being a representative level typically used for dermal and adipose tissue. In addition to power level selection, the distance of the plasma jet from the tissue is also important to produce the desired effect. Plume production was performed with the tip of the instrument close to the skin surface as well as at 10 mm away from the surface. Placement of the tip of the instrument close to the skin surface is typical for tissue cutting via vaporization while placement 10 mm from the surface is typical when tissue coagulation is desired.

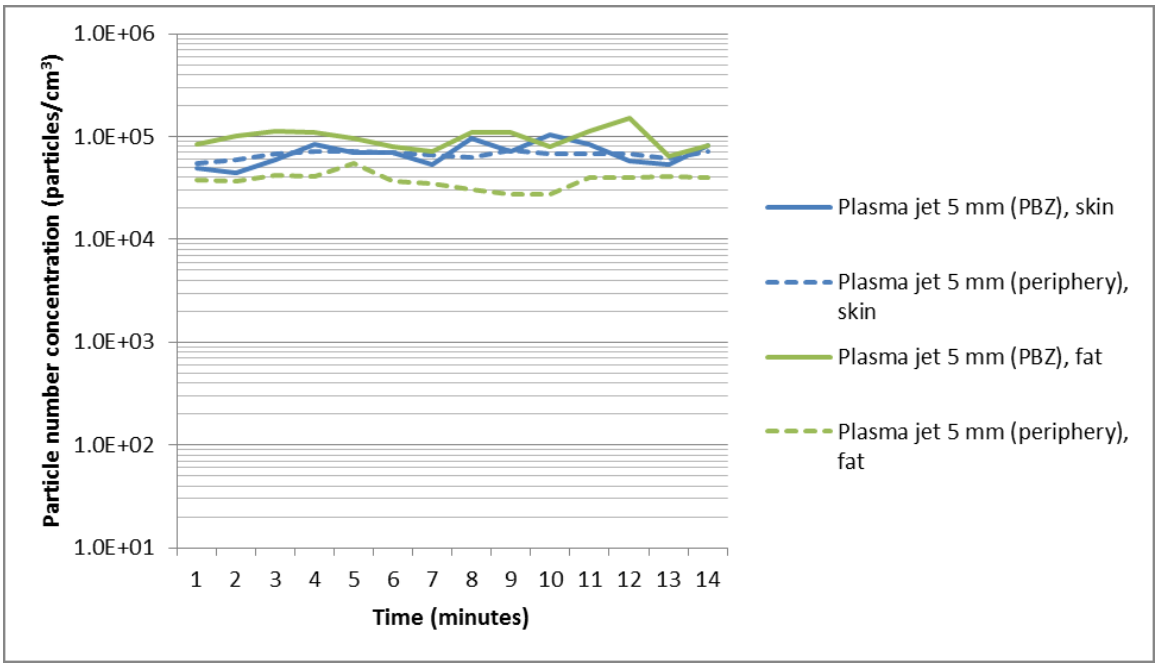
During coagulation procedures with the plasma jet, the GM PBZ particle number concentrations were 72,572 particles/cm^3 from dermal tissue and 108,632 particles/cm^3 from adipose. Figure 3.4 shows real-time particle number concentrations produced during coagulation mode.

Figure 3.4 Particle Number Concentrations in the PBZ and Periphery of the Room Produced by the Plasma Jet (coag mode) on Dermal and Adipose Tissues as Measured using a CPC



With the Plasma Jet in the cut mode, the GM particle number concentration in the PBZ was 67,995 particles/cm^3 using the Plasma Jet during for dermal tissue compared to 95,159 particles/cm^3 for adipose tissue. Figure 3.5 shows the particle number concentrations produced during cutting mode.

Figure 3.5 Particle Number Concentrations in the PBZ and Periphery of the Room Produced by the Plasma Jet (cut mode) on Dermal and Adipose Tissue as Measured using a CPC



Figures 3.6–3.7 and 3.8–3.9 show the average particle size distribution and log probability plots of surgical plume particles produced by the Plasma Jet in the coagulation mode on dermal and adipose tissue, respectively. Figures 3.10–3.11 and 3.12–3.13 show the distribution and log probability plots produced by the Plasma Jet in the cut mode on the same tissue types. All trials produced similar particle size distributions. CMDs for the coag mode on dermal and adipose tissue were 0.088 µm (GSD: 2.1) and 0.090 (GSD: 2.2), respectively; for the cut mode on dermal and adipose tissue, they were 0.082 µm (GSD: 1.9) and 0.115 µm (GSD: 2.6). Peaks in the size distribution were found to be at 0.115 µm for both tissues in coag mode and 0.115 for dermal tissue and 0.160 µm for adipose tissue in the cut mode.

Figure 3.6 Particle Size Distribution Plot of Surgical Plume Produced from Dermal Tissue by Plasma Jet (coag mode) as Measured Using a WPS

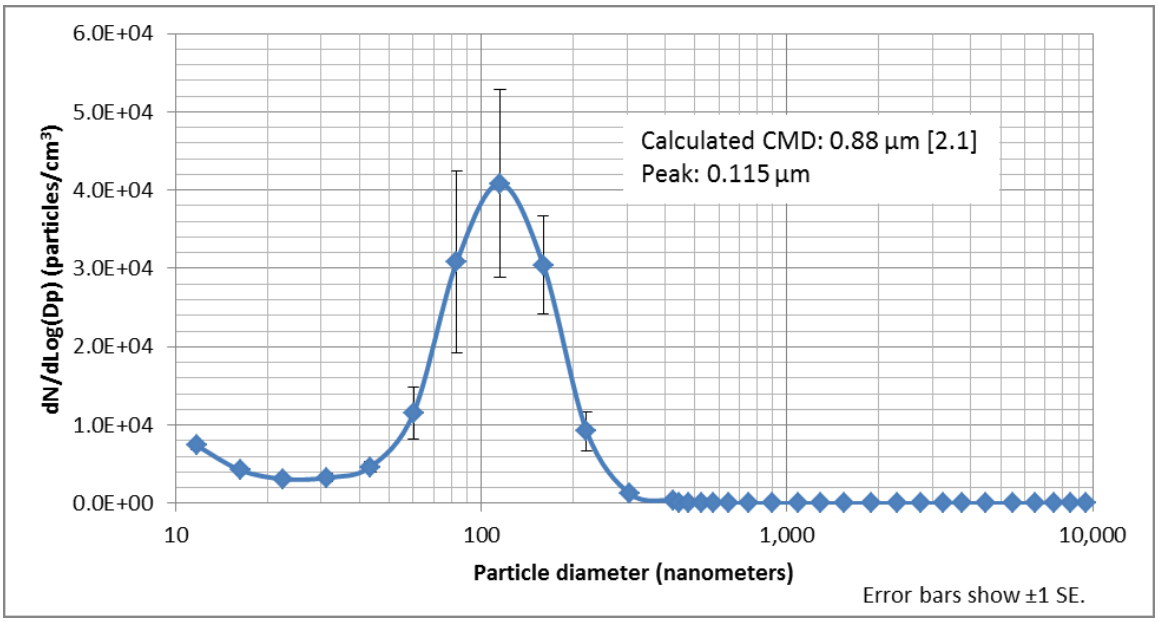


Figure 3.7 Log-Probability Plot of Surgical Plume Produced from Dermal Tissue by Plasma Jet (coag mode) as Measured Using a WPS

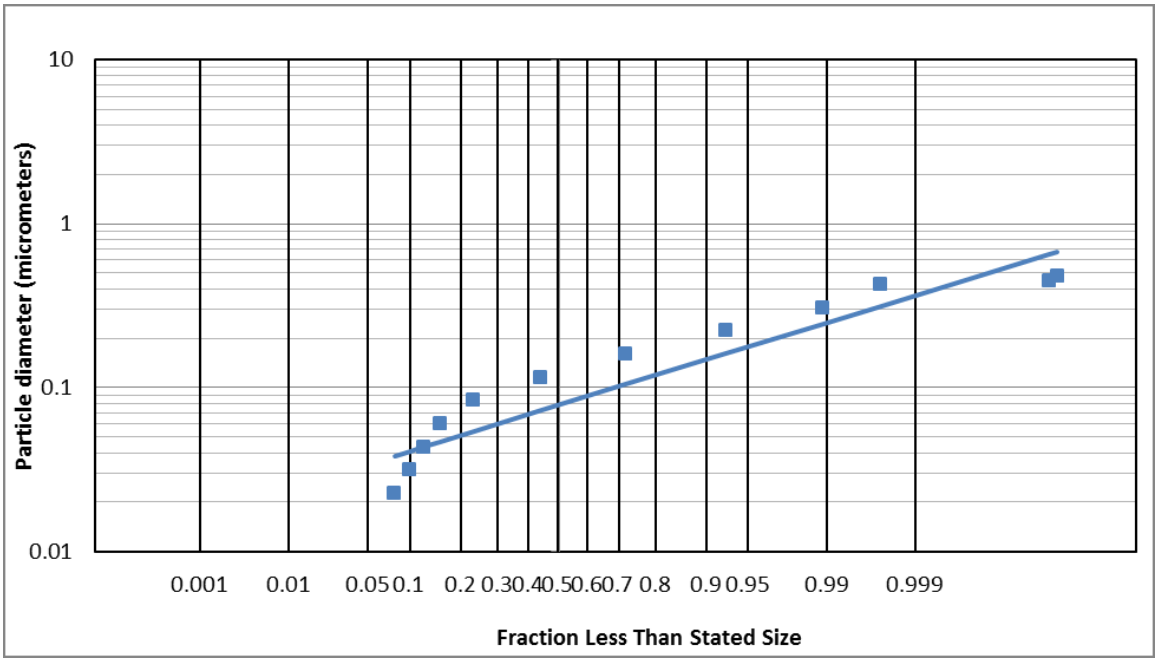


Figure 3.8 Average Particle Size Distribution Plot of Surgical Plume Produced from Adipose Tissue by Plasma Jet (coag mode) as Measured Using a WPS

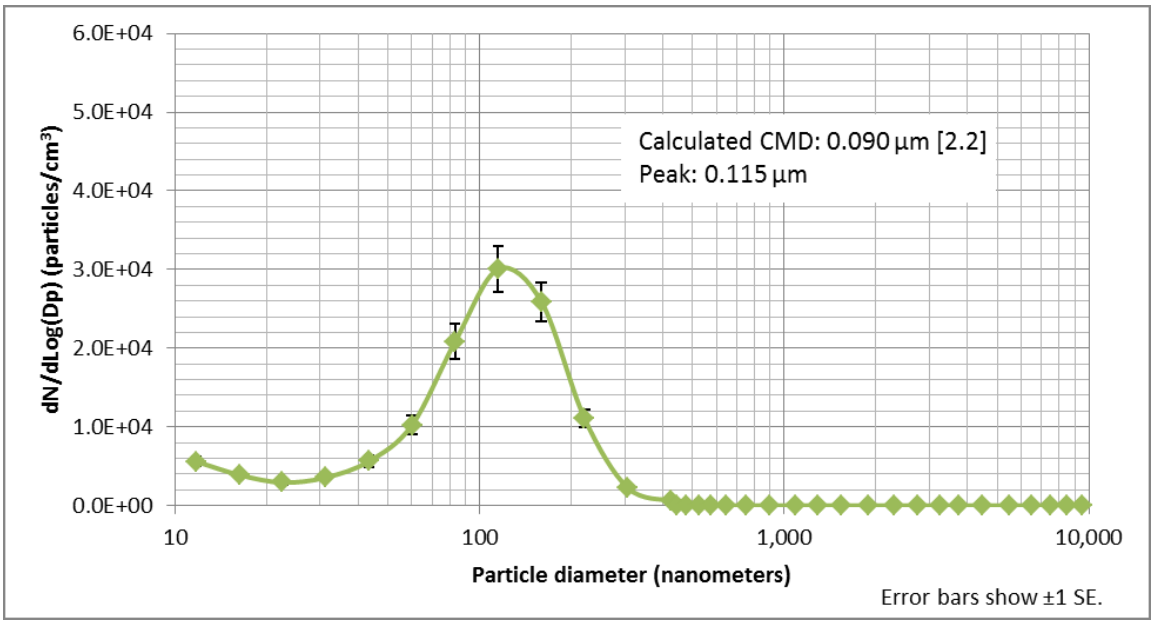


Figure 3.9 Log-Probability Plot of Surgical Plume Produced from Adipose Tissue by Plasma Jet (coag mode) as Measured Using a WPS

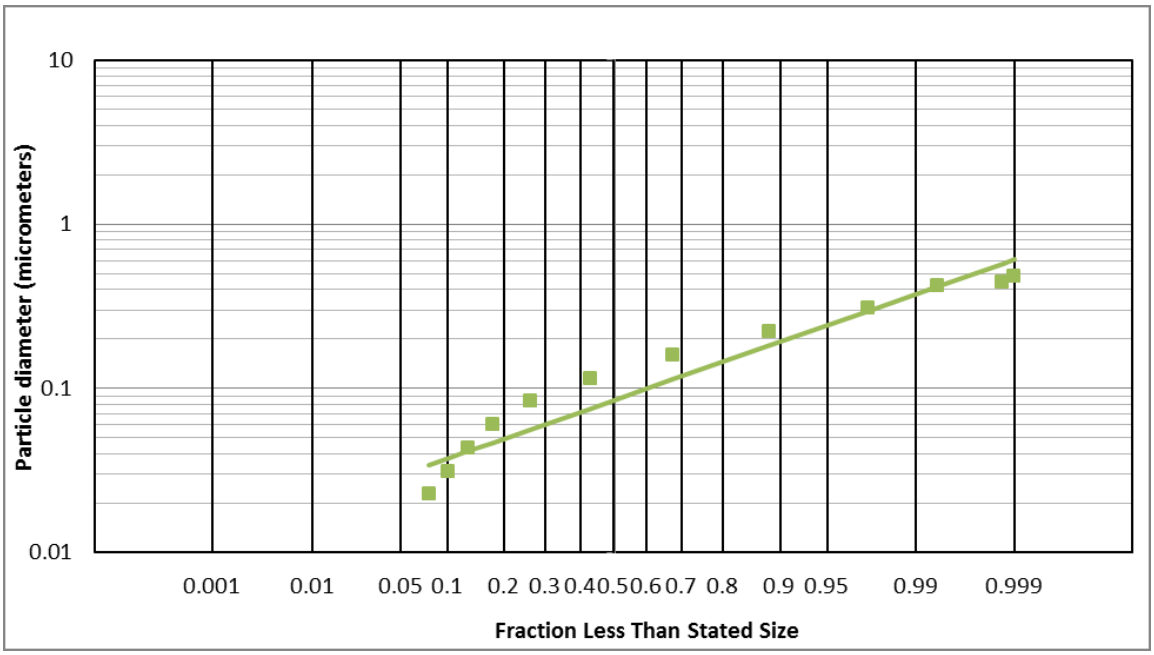


Figure 3.10 Average Particle Size Distribution Plot of Surgical Plume Produced from Dermal Skin by Plasma Jet (cut mode) as Measured Using a WPS

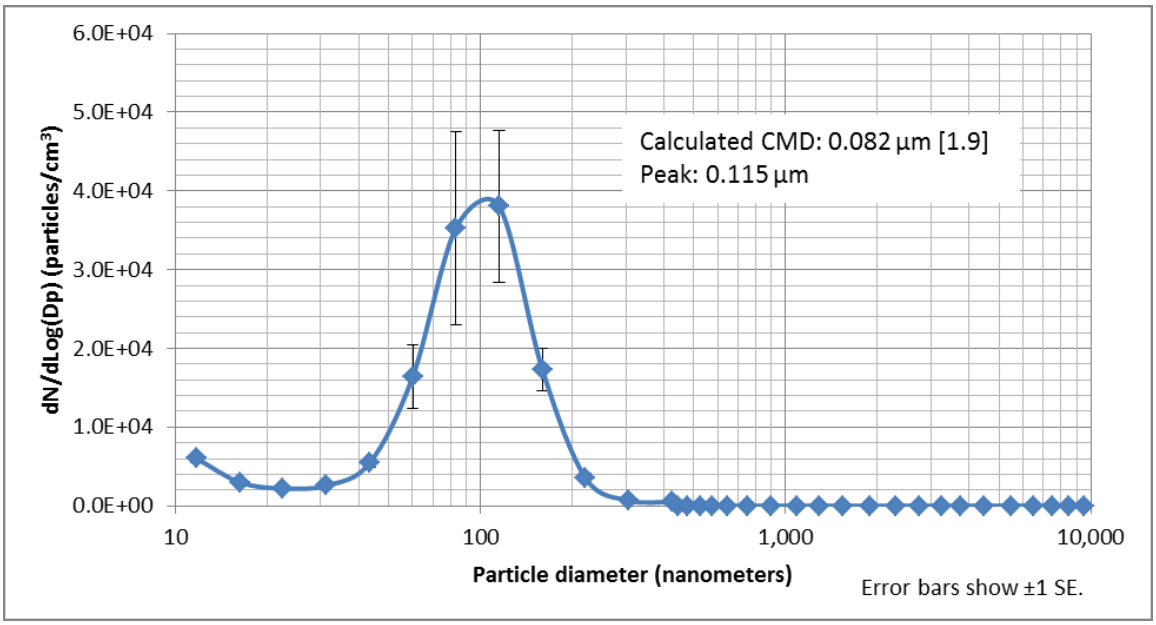


Figure 3.11 Log-Probability Plot of Surgical Plume Produced from Dermal Tissue by Plasma Jet (cut mode) as Measured Using a WPS

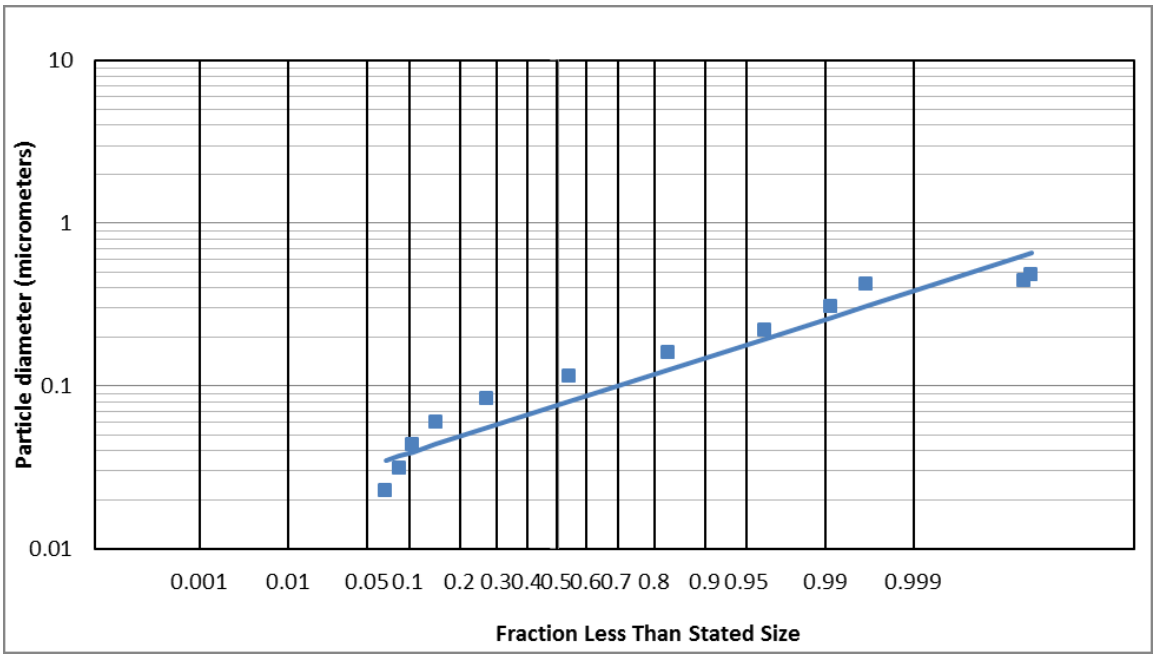


Figure 3.12 Average Particle Size Distribution Plot of Surgical Plume Produced from Adipose Tissue by Plasma Jet (cut mode) as Measured using a WPS

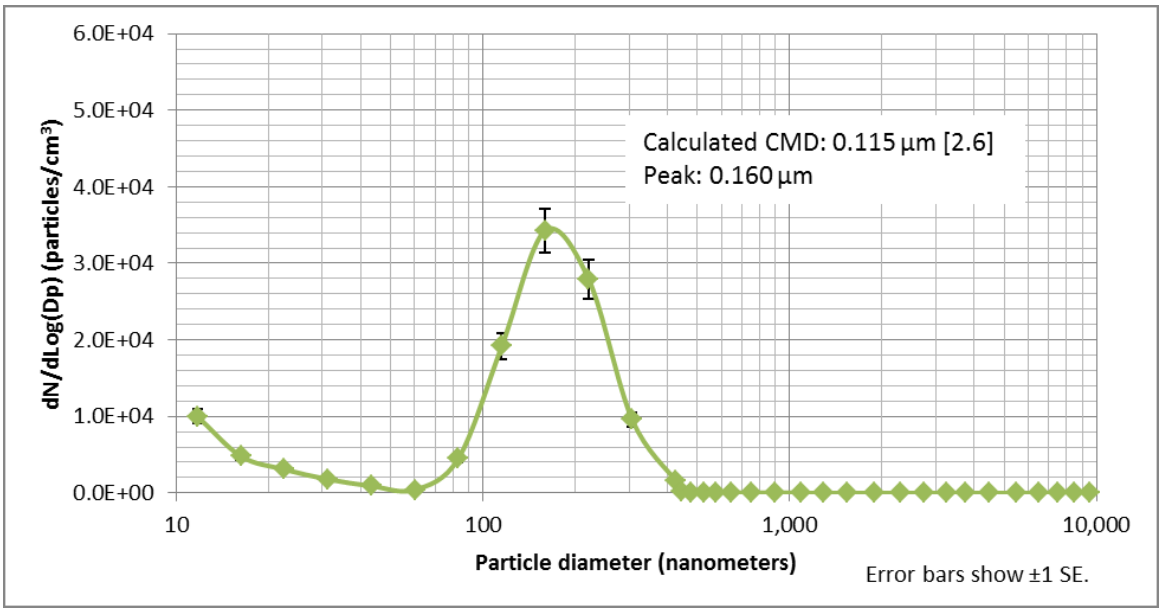
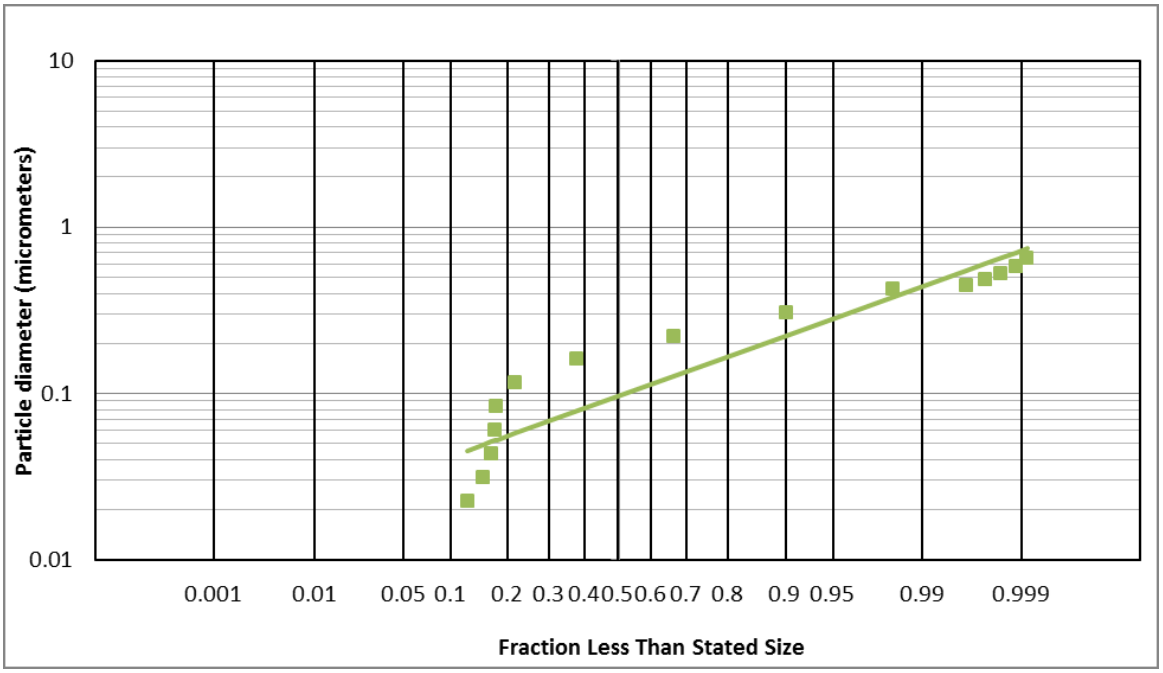


Figure 3.13 Log-Probability Plot of Surgical Plume Produced from Adipose Tissue by Plasma Jet (cut mode) as Measured using a WPS



Electrocautery Knife

Similar to the Plasma Jet, the electrocautery knife, also known as a bovie, can be used in both a cut mode and a coagulation mode. Because of differing voltages and waveforms produced during these modes, evaluations of plume production by the bovie under both modes were conducted. The bovie was operated at 30 watts (W) during its use on the dermal tissue and 40W during its use on adipose based on the surgeon's recommendation of typical use during a surgery. Using the bovie in coag mode on the dermal tissue, the GM particle number concentration measured by the CPC in the PBZ was 10,149 particles/cm^3 compared to 3,602 particles/cm^3 for adipose. For the bovie in cut mode, the mean PBZ concentrations were 4,884 particles/cm^3 for dermal tissue and 282 particles/cm^3 for adipose. See Figures A1 and A2 in the Appendix for real-time particle concentrations during use of the bovie in coag and cut modes, respectively. Figures A3 (a and b) and A4 (a and b) in the Appendix show the average particle size distribution and log probability plots of surgical plume particles produced by the bovie in coag mode on dermal and adipose tissue, respectively. Figures A5 (a and b) and A6 (a and b) show the average particle size distribution and log probability plots of the particles produced by the bovie in cut mode on dermal and adipose tissue, respectively. While particle number concentrations produced by the instrument from the two tissues differed considerably, all produced peaks at similar diameter sizes. CMDs for the coag mode on dermal and adipose tissues were 0.129 µm (GSD: 2.4) and 0.116 µm (GSD: 2.13), respectively; for the cut mode on dermal and adipose tissues, they were 0.190 µm (GSD: 2.2) and 0.088 µm (GSD: 3.11). Peak concentrations were found to be at 0.160 µm for both tissues in coag mode, and 0.221 µm for dermal tissue and 0.160 µm for adipose tissue in cut mode.

CO_2 Laser

For the trials using the CO_2 laser, a power level of 5W was selected as representative for use with these tissue types. The GM particle number concentration measured by the CPC in the PBZ was 4,362 particles/cm^3 from dermal tissue compared to 5,375 particles/cm^3 from adipose. See Figure A7 in the Appendix for a depiction of the real-time particle number concentration measurements during use of this instrument. Figures A8 (a and b) and A9 (a and b) show the average particle size distribution and log probability plots of surgical plume particles produced by the CO_2 laser at this setting on dermal and adipose tissue, respectively. Similar to the Plasma Jet and electrocautery knife, the CO_2 laser produced peaks of similar mean diameters. CMDs for the CO_2 laser used on dermal and adipose tissue were calculated to be 0.086 µm (GSD: 2.9) and 0.091 µm (GSD: 2.96), respectively. Peak concentrations were measured at 0.160 µm for both tissues.

Harmonic Scalpel

The maximum level was selected as the power setting for the harmonic scalpel use on the two tissue types. The GM particle number concentrations in the PBZ at the surgical table produced by the harmonic scalpel were amongst the lowest of the four instruments, at 220 particles/cm^3 from dermal tissue and 457 particles/cm^3 from adipose. See Figure A10 in the Appendix for real-time particle number concentration measurements during use of this instrument. Figures A11 (a and b) and A12 (a and b) show the average particle size distribution and log probability plots of surgical plume particles produced by the harmonic scalpel at this setting on dermal and adipose tissue, respectively. Unlike the Plasma Jet, electrocautery knife, and CO_2 laser, the harmonic

scalpel produced peaks at smaller diameter sizes with wider size distributions. CMDs for the harmonic scalpel on dermal and adipose tissues were 0.028 µm (GSD: 2.0) and 0.038 µm (GSD: 3.8), respectively. Peak concentrations were observed at 0.023 µm and 0.016 µm for the dermal and adipose tissue, respectively.

Summary of comparisons

Table 3.1 provides descriptive statistics for the GM particle number concentrations measured in the PBZ at the surgical table and at the periphery of the room. Table 3.2 shows size distribution statistics for each instrument and tissue types.

Table 3.1 Geometric Mean Particle Number Concentrations (particles/cm^3) and Geometric Standard Deviations (GSD) of Surgical Plume Produced by Surgical Instrument and Tissue Type in the PBZ of the Surgeon and at the Room Periphery as Measured using a CPC and PTrak (n=19 trials per instrument)

	Dermal		**Adipose**	
	PBZ GM Concentration (particles/cm^3) [GSD]	**Periphery GM Concentration (particles/cm^3) [GSD]**	**PBZ GM Concentration (particles/cm^3) [GSD]**	**Periphery GM Concentration (particles/cm^3) [GSD]**
Plasma Jet (coag)	72,572 [1.24]	64,797 [1.12]	108,632 [1.33]	38,178 [1.18]
Plasma Jet (cut)	67,995 [1.30]	66,517 [1.09]	95,159 [1.25]	37,238 [1.20]
Electrocautery knife (coag)	10,149 [1.53]	17,726 [1.15]	3,602 [1.38]	2,083 [1.19]
Electrocautery knife (cut)	4,884 [1.75]	8,805 [1.17]	282 [1.36]	146 [1.24]
CO_2 laser	4,362 [1.40]	13,704 [1.21]	5,375 [1.11]	3,060 [1.12]
Harmonic scalpel	220 [1.92]	541 [1.88]	457 [2.98]	51 [1.49]

Table 3.2 Descriptive Statistics for Surgical Plume Particle Size Distributions by Instrument and Tissue Type as Measured using a WPS (n=19 trials per instrument)

	Dermal	**Adipose**
	CMD (μm) [GSD]	**CMD (μm) [GSD]**
Plasma Jet (coag)	0.088 [2.1]	0.090 [2.2]
Plasma Jet (cut)	0.082 [1.9]	0.115 [2.6]
Electrocautery knife (coag)	0.129 [2.4]	0.116 [2.1]
Electrocautery knife (cut)	0.190 [2.2]	0.088 [3.1]
CO_2 laser	0.086 [2.9]	0.091 [3.0]
Harmonic scalpel	0.028 [2.0]	0.038 [3.8]

Paired t-tests for difference in means of the PBZ particle number concentrations were performed for each combination of pairs of instruments. For the dermal tissue, all differences in PBZ particle number concentration were found to be statistically significant except the electrocautery knife (cut mode) vs. the CO_2 laser [p=0.58] and the Plasma Jet (cut vs. coag modes) [p=0.35]. Findings were similar for adipose tissue. All differences in PBZ particle number concentration were found to be statistically significant except the electrocautery knife (cut mode) vs. the harmonic scalpel [p=0.11] and the Plasma Jet (cut vs. coag modes) [p=0.26]. Mean PBZ particle number concentrations produced by use of each instrument on dermal tissue were determined to be statistically significantly different than concentrations produced by the instrument when used on adipose tissue.

The instrument that generated by far the highest particle number concentrations when applied to both types of tissues was the Plasma Jet in both the cut and coag modes. Exposures to surgical plume particles produced by the Plasma Jet and measured in the PBZ area of a surgical

table staff were 200–330 times greater than those produced by the harmonic scalpel, depending on tissue and instrument mode. Electrocautery produced PBZ concentrations up to 46 times greater than the harmonic scalpel, while the CO_2 laser produced concentrations up to 20 times greater, depending on tissue type.

See Figures 3.14 and 3.15 for real-time particle number concentrations produced by the surgical instruments on dermal and adipose tissue in the PBZ of the surgical table staff and at the periphery of the room during plume production. See Figures A13 and A14 in the Appendix for graphs of particle number concentrations in the periphery of the room.

Figure 3.14 Particle Number Concentrations Produced by Selected Surgical Instruments on Dermal Tissue in the PBZ of the Surgical Table Staff as Measured using a CPC

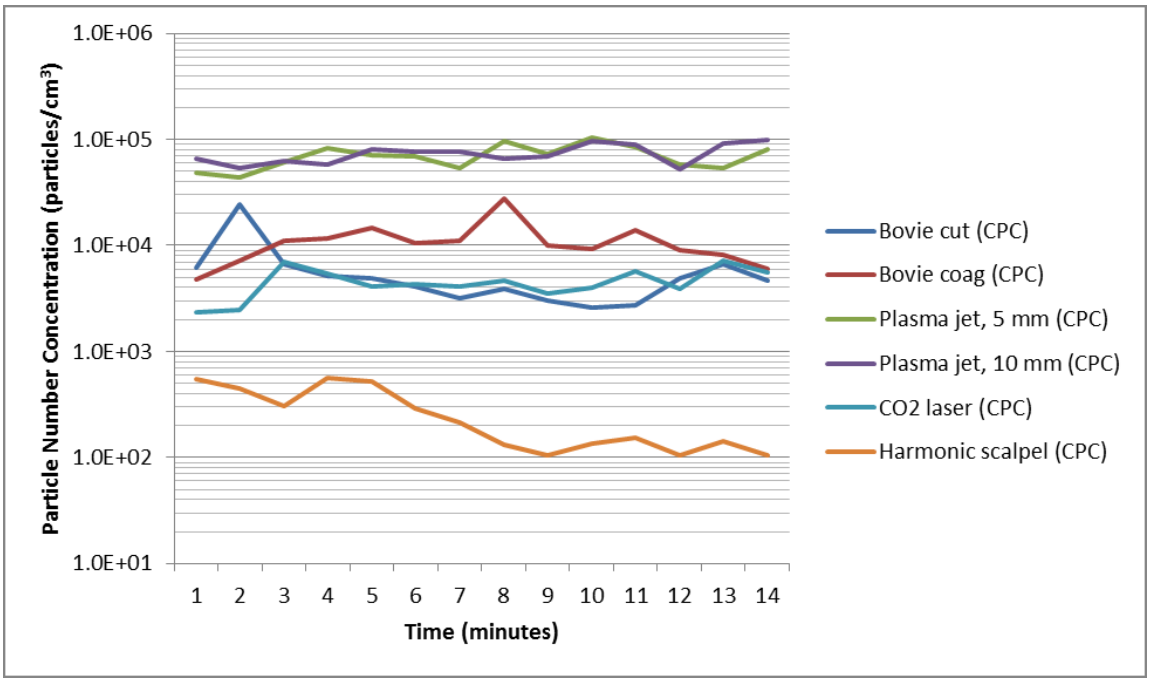
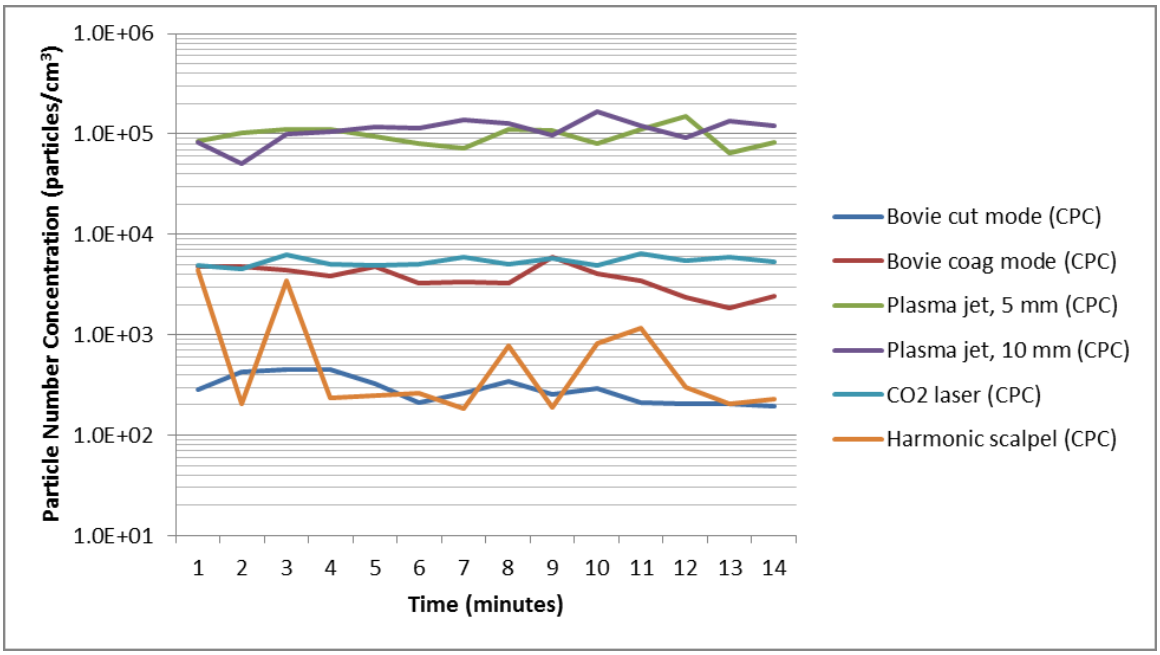


Figure 3.15 Particle Number Concentrations Produced by the Surgical Instruments on Adipose Tissue in the PBZ of the Surgical Table Staff as Measured using a CPC



Paired t-tests were performed to evaluate differences in means of log-transformed PBZ and periphery particle number concentrations for each instrument and tissue type. Differences between mean concentrations measured in the two areas of the room were found to be statistically significant for all surgical instruments and tissue combinations except for the Plasma Jet applied to dermal tissue in the cut and coag modes [p=0.72 and p=0.14, respectively]. However, a clear trend was observed when comparing the concentrations in the two areas. Despite the hypothesis that proximity to the plume source would generate the highest particle number concentrations, the particle number concentrations in the PBZ of the surgical table staff during the dermal tissue processing were found to be significantly less or not significantly different than those measured at the periphery of the room near the exhaust vent. In contrast, however, the particle number concentrations in the PBZ of the surgical table staff produced from the adipose tissue were all significantly higher than those measured near the exhaust in the periphery of the room. It is unlikely that the change in tissue type is the cause of such a

trend. It is suggested that the positive or negative environments produced by the general ventilation played a pivotal role in the increase or decrease in concentrations when comparing the two areas. The operating room in which the experimental setup for the dermal tissue was conducted was determined to be under negative pressure caused by greater exhaust than supply into the room. This would create a distinct pattern of airflow from above the surgical table towards the exhaust vent, carrying with it the plume particles at the point of production and the resultant higher concentrations near the exhaust vent. However, the operating room in which the experimental setup for the adipose tissue was conducted was determined to be under positive pressure caused by a greater quantity of airflow supplied into the room than exhausted from the two exhaust vents. Current ventilation guidelines call for operating rooms to be under positive pressure compared to the outer corridor. In this situation, we would expect a different airflow pattern in which supplied air would not just be exhausted through the vents but also flow towards the outer corridor. Under this scenario, the particle concentrations near the exhaust vent were significantly lower than at the surgical table suggesting that airflow towards the door of the operating was carrying a substantial quantity of surgical plume particles with it toward that area. This scenario has ramifications for the exposure potential of workers such as the circulating nurse whose station was located near the door.

When comparing PBZ size distribution data for particles produced by the various surgical instruments, the intent was to investigate the full spectrum of particle diameters down to as low as 0.010 μm (i.e., 10 nanometers). The data showed that three instruments (Plasma Jet, electrocautery knife, and CO_2 laser) produced particle distributions with CMDs in the range of 0.082–0.190 μm. Size distribution plots for these instruments showed single peaks near their respective CMDS, but also slight upward trends in the very smallest particle size bins. This was true particularly for the CO_2 laser. The harmonic scalpel, however, produced particles with the

smallest CMDs in the range of 0.028–0.038 μm. Unlike the other three instruments which apply varying degrees of elevated temperatures to the tissue to achieve the desired cutting or coagulating effect, the harmonic scalpel uses an instrument tip that vibrates at high-frequency. The rupture of tissue cells through the process of cavitation may account for aerosolized particles with the smaller CMDs but also far fewer numbers of particles aerosolized through this process compared to the other surgical instruments.

Conclusions

The primary goal of this research was to elucidate characteristics of surgical plume particles that enter in the personal breathing zone of operating room staff at the surgical table closest to the point of surgical plume production. The use of direct reading instruments to quantify and compare exposures to such particulate matter produced by a variety of common energy-based cutting and cauterizing surgical instruments was particularly helpful in capturing real-time exposure data at this location. The magnitude of exposures to surgical plume appears to vary greatly, particularly based on the choice of surgical instrument used. Amongst the instruments tested, the Plasma Jet produced the greatest concentrations of plume particles in the PBZ of a staff member at the surgical table and the harmonic scalpel produced the lowest. All of the instruments produced ultrafine particles measured in the PBZ, with most instruments producing particles with CMDs in the range of 0.082–0.190 μm, while the harmonic scalpel produced the very finest particles with CMDs in the range of 0.028–0.038 μm. The general ventilation in the room is also an important determinant in the exposure for individuals in the operating room. In particular, the pressure differential in the room (either positive or negative in relation to the adjacent corridor) played a role in where greater concentrations of plume particles may be

distributed in the operating room, thereby impacting the exposure levels of staff in the periphery of the room. It is recognized that hospital operating rooms are typically kept under positive pressure for infection control purposes and is not a ventilation factor that can or should be modified because of the importance of these practices. The health impact on operating room staff members respiring surgical plume particles in this size range at the concentrations measured multiple times a day on a daily basis is unclear, however, and requires further research. Despite this uncertainty, the use of controls such as local exhaust ventilation at the point of production can be an effective tool to reduce exposures to these particles for staff working within the operating room environment.

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Appendix A

FIGURE A1. Particle number concentrations measured in the PBZ and periphery of the room produced by the bovie in the coag mode on skin and fat

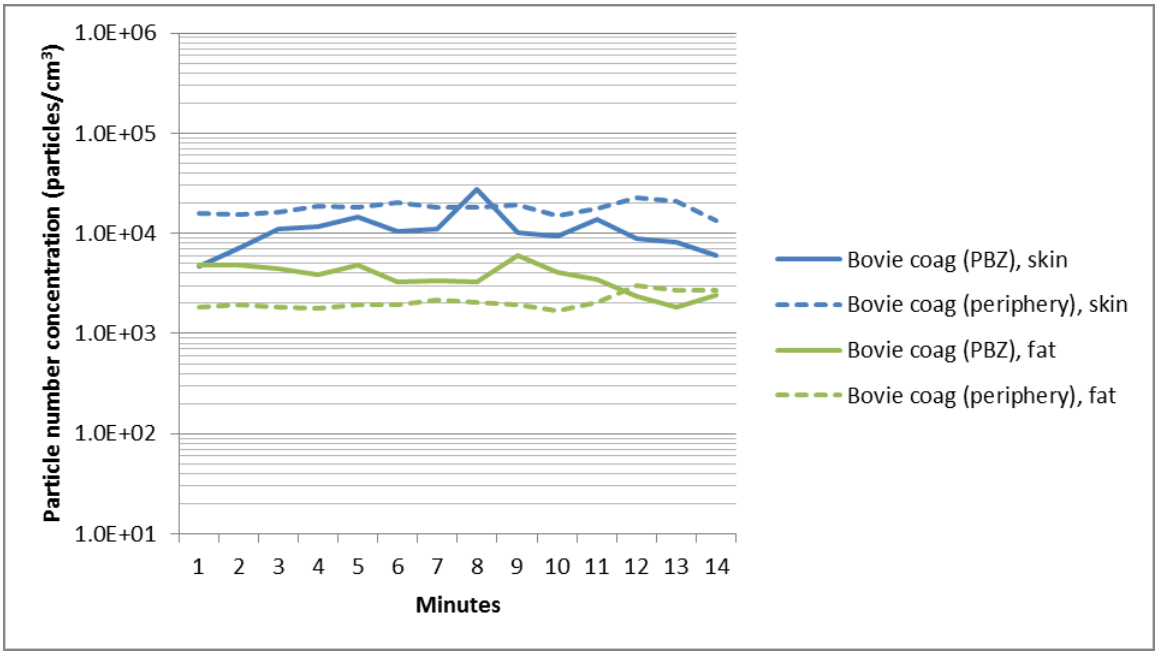


FIGURE A2. Particle number concentrations measured in the PBZ and periphery of the room produced by the bovie in the cut mode on skin and fat

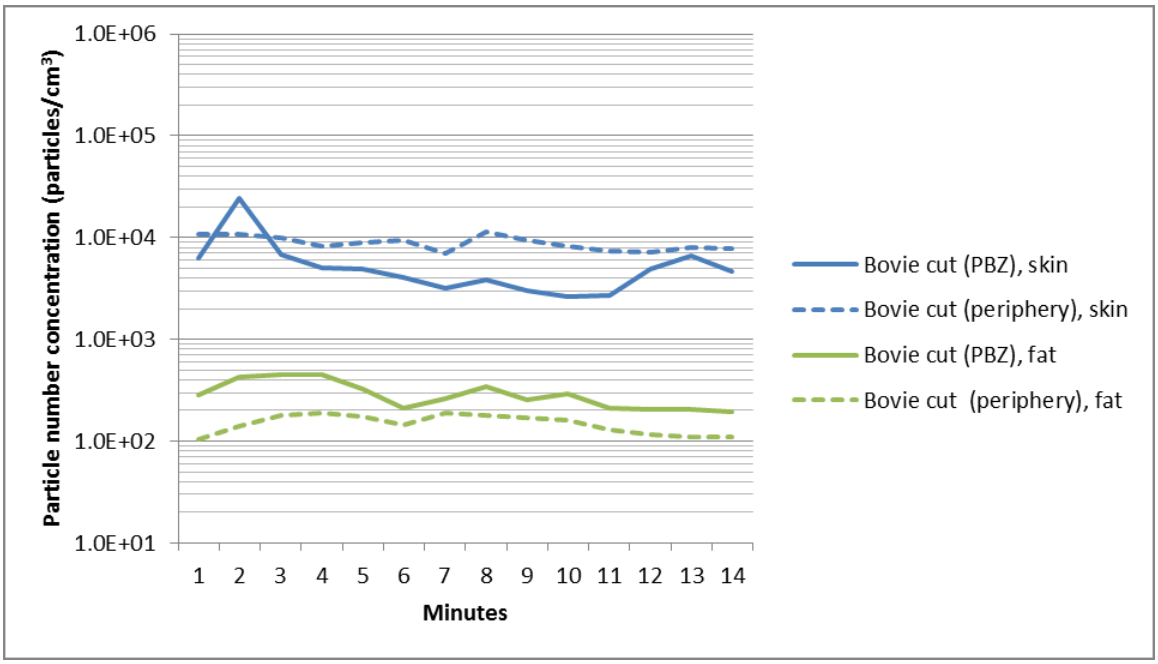
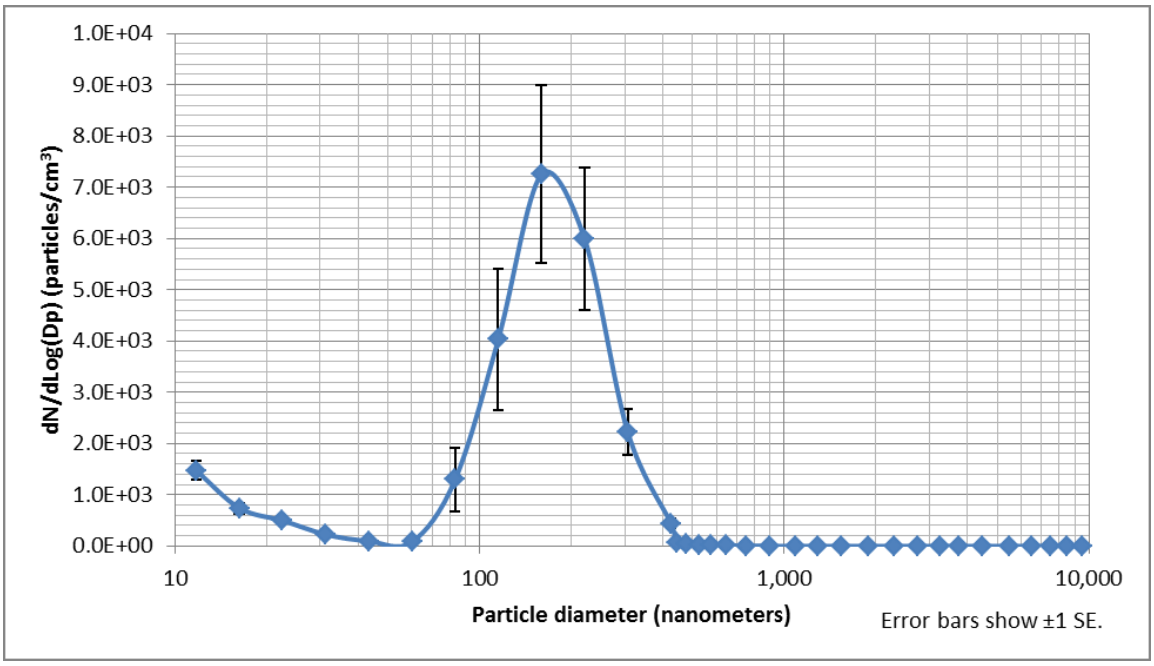


FIGURE A3 (a and b). Average particle size distribution and log probability plots of surgical plume produced from skin by bovie (coag mode): Calculated CMD: 0.129 µm [2.4]; Peak: 0.160 µm

A3 a) Size distribution plot



A3 b) Log probability plot

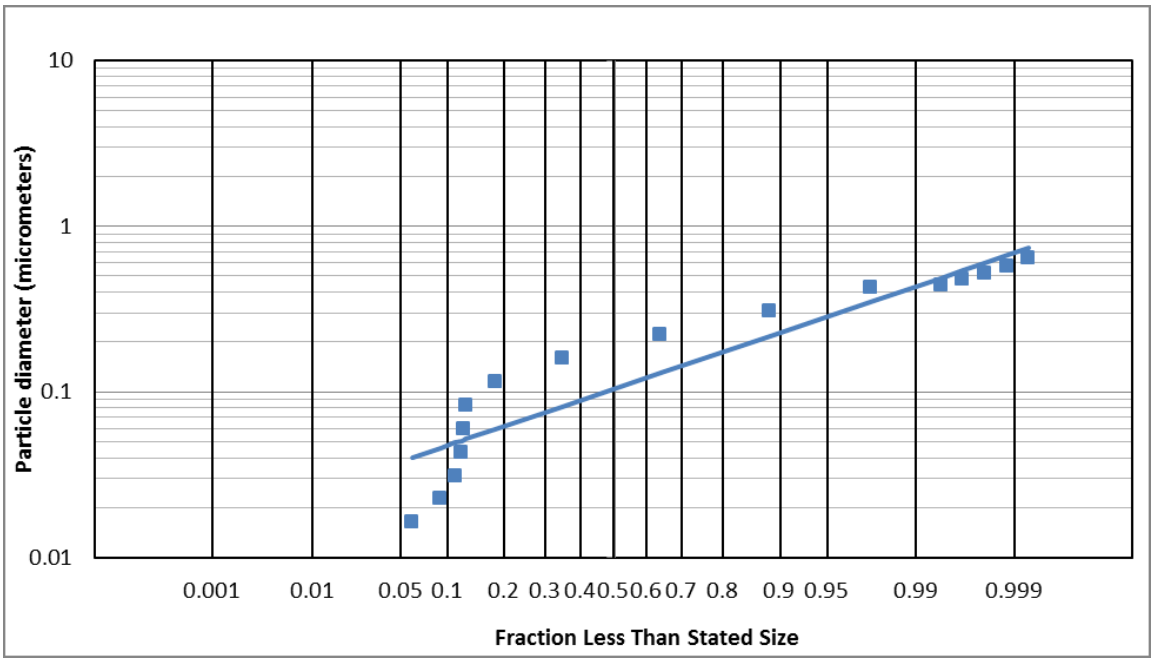
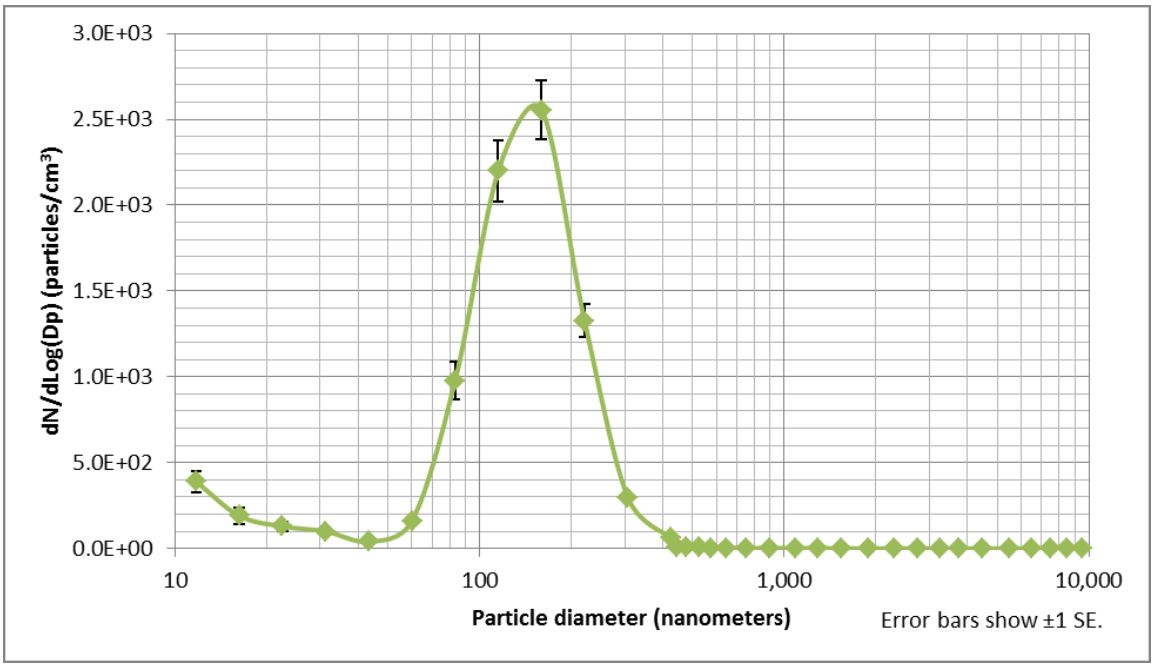


FIGURE A4 (a and b). Average particle size distribution and log probability plots of surgical plume produced from fat by bovie (coag mode): Calcuated CMD: 0.116 [2.13]; Peak: 0.160 µm

A4 a) Size distribution plot



A4 b) Log probability plot

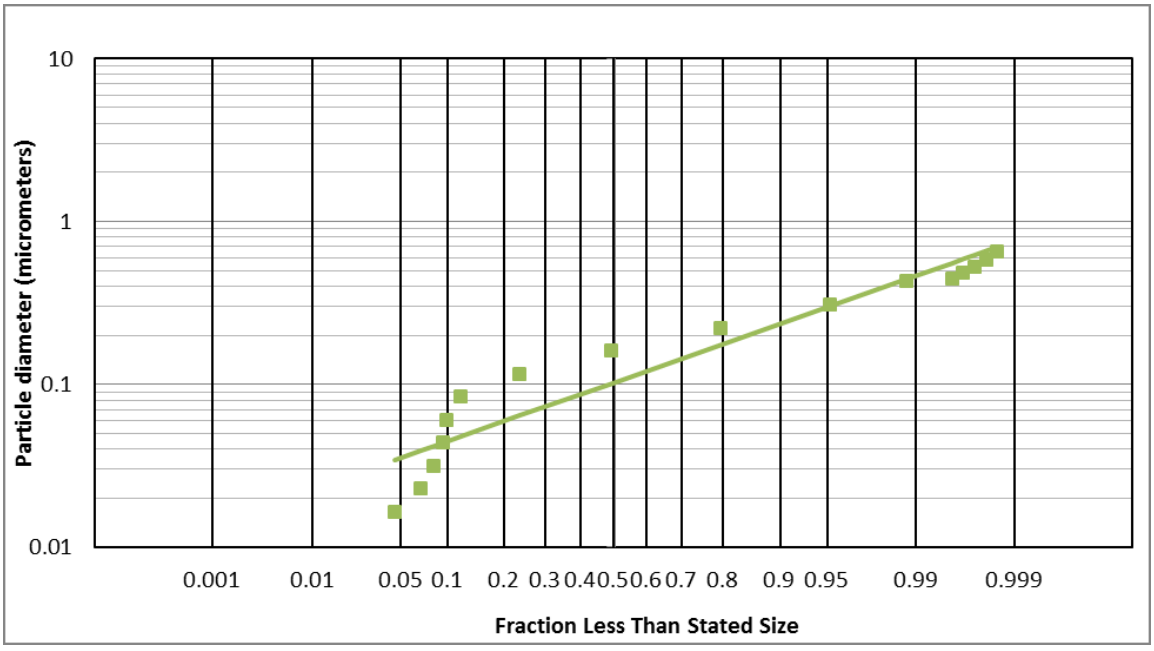
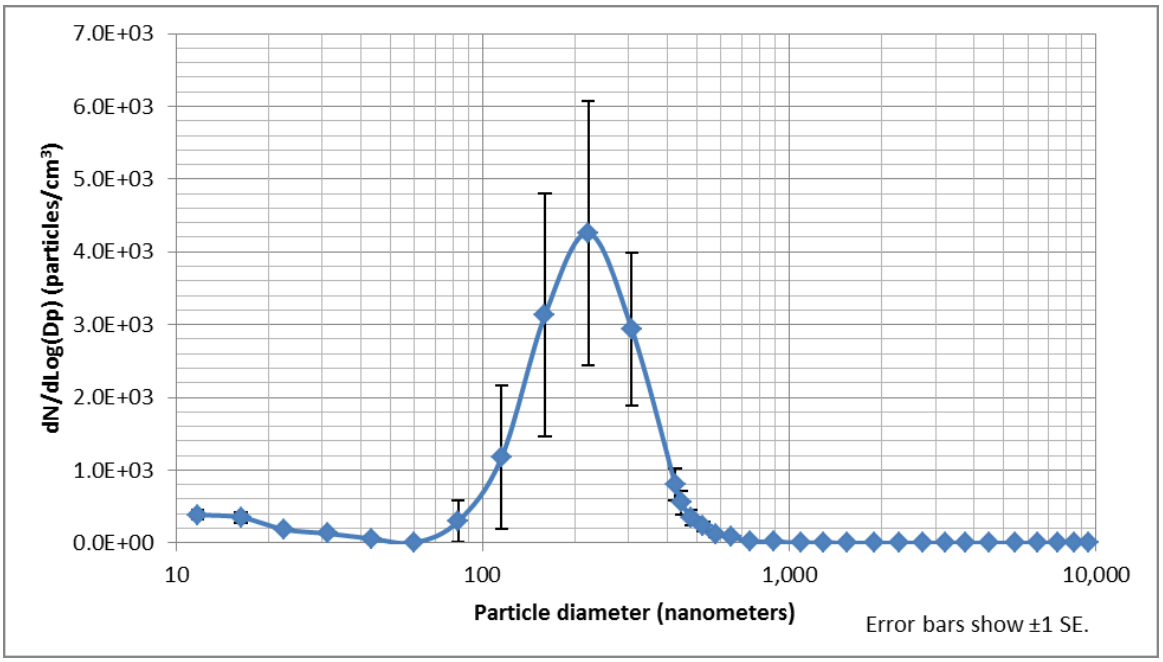


FIGURE A5 (a and b). Average particle size distribution and log probability plots of surgical plume produced from skin by bovie (cut mode): Calculated CMD: 0.190 µm [2.2]; Peak: 0.221 µm

A5 a) Size distribution plot



A4 b) Log probability plot

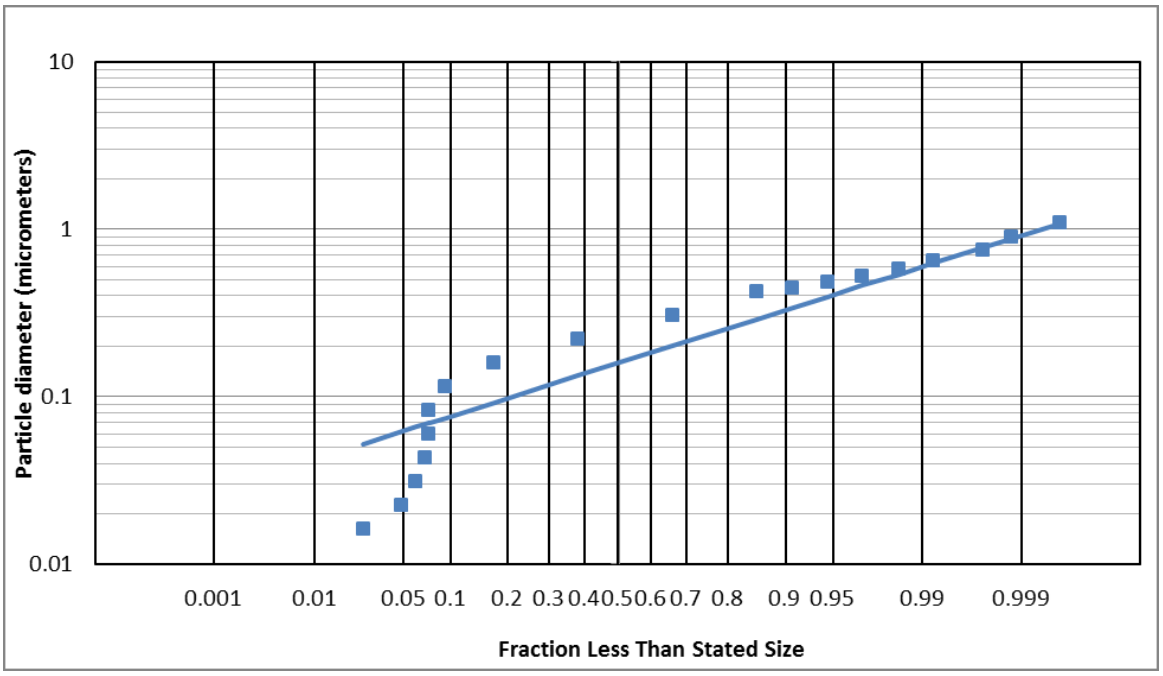
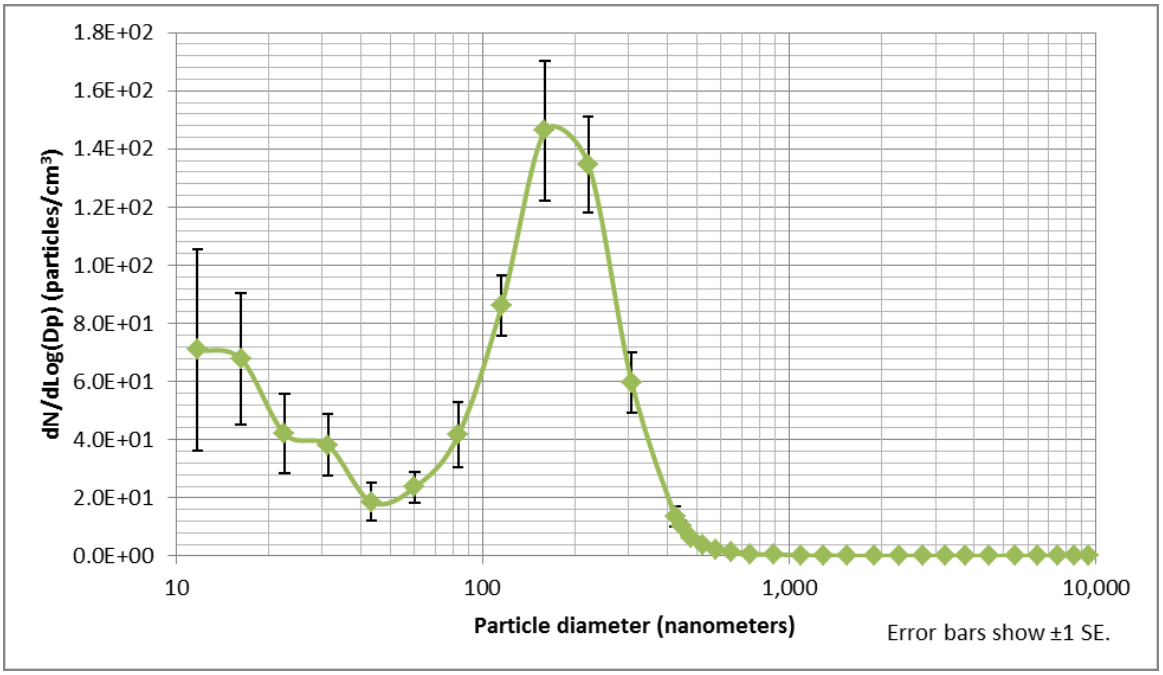


FIGURE A6 (a and b). Average particle size distribution of surgical plume produced from fat by bovie (cut mode): CMD: 0.088 µm [3.11]; Peak: 0.160 µm

A6 a) Size distribution plot



A6 b) Log probability plot

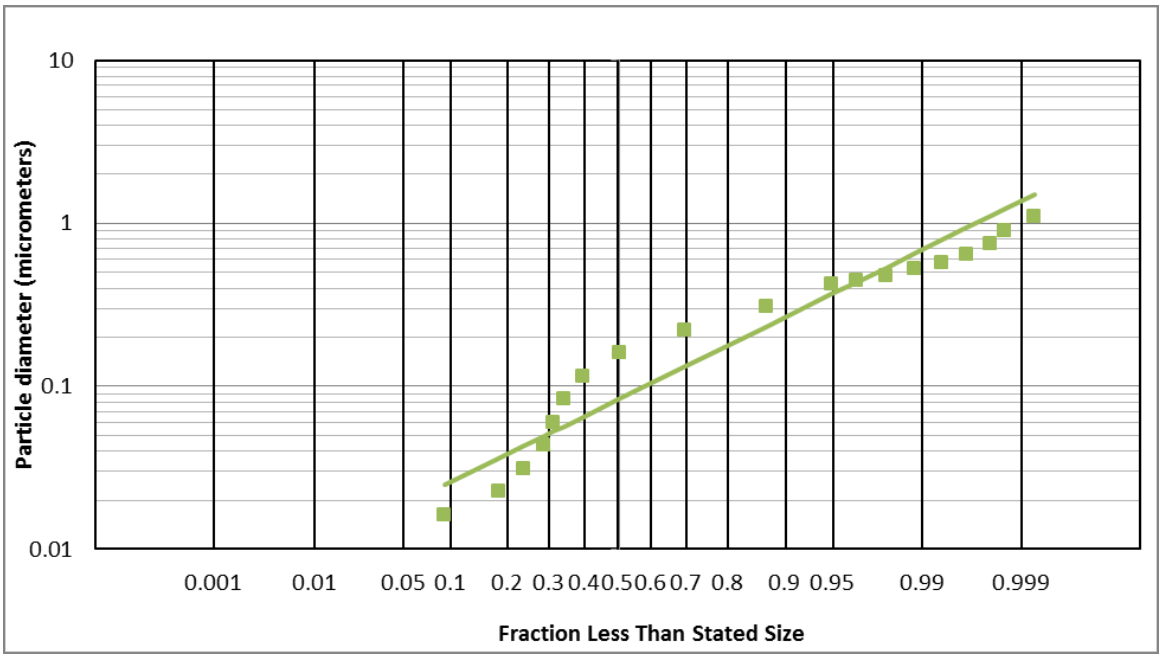


FIGURE A7. Particle number concentrations measured in the PBZ and periphery of the room produced by the CO_2 laser on skin and fat

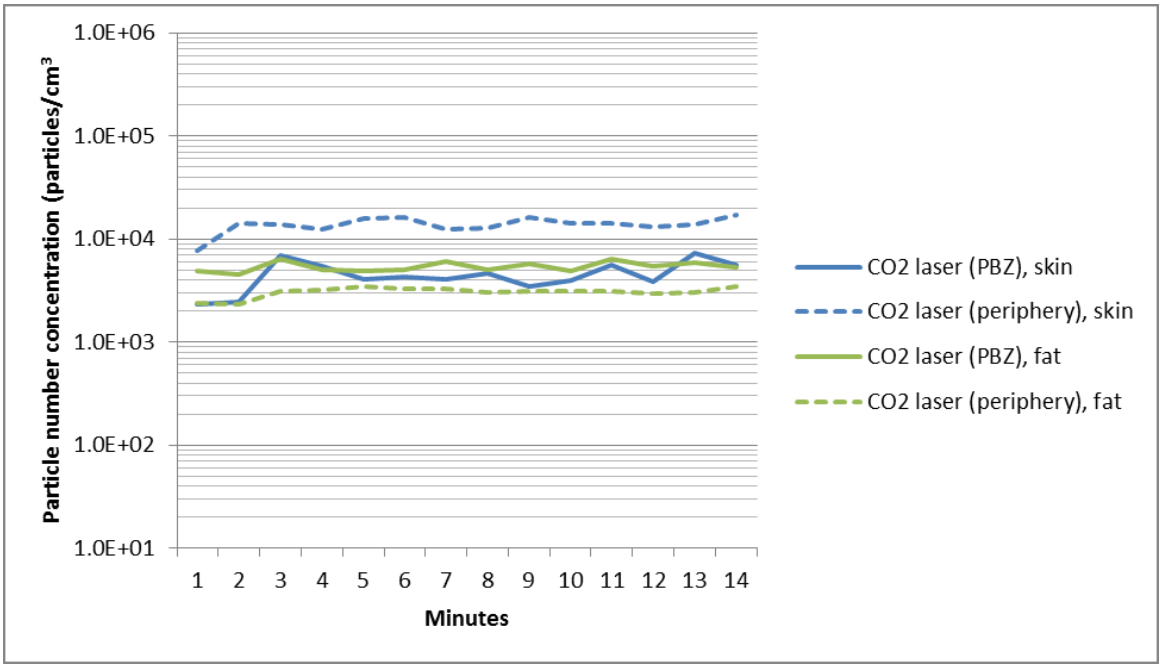
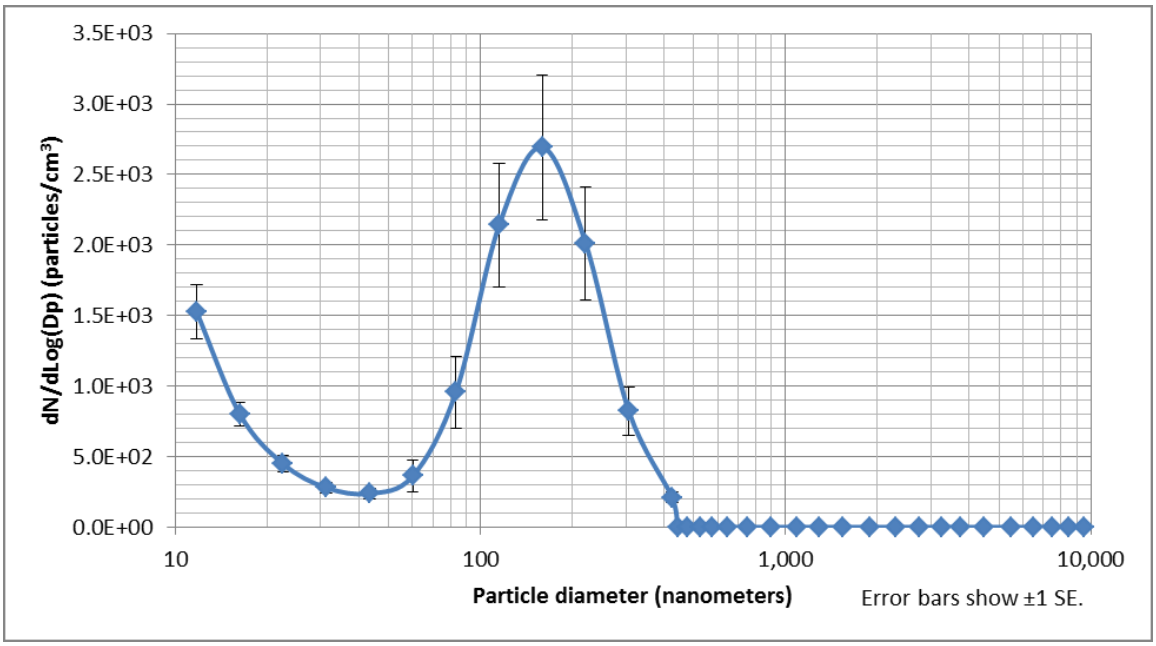


FIGURE A8 (a and b). Average particle size distribution of surgical plume produced from skin by CO_2 laser, 5W continuous wave, 125 mm handpiece: Calculated CMD: 0.086 µm [2.9]; Peak: 0.160 µm

A8 a) Size distribution plot



A8 b) Log probability plot

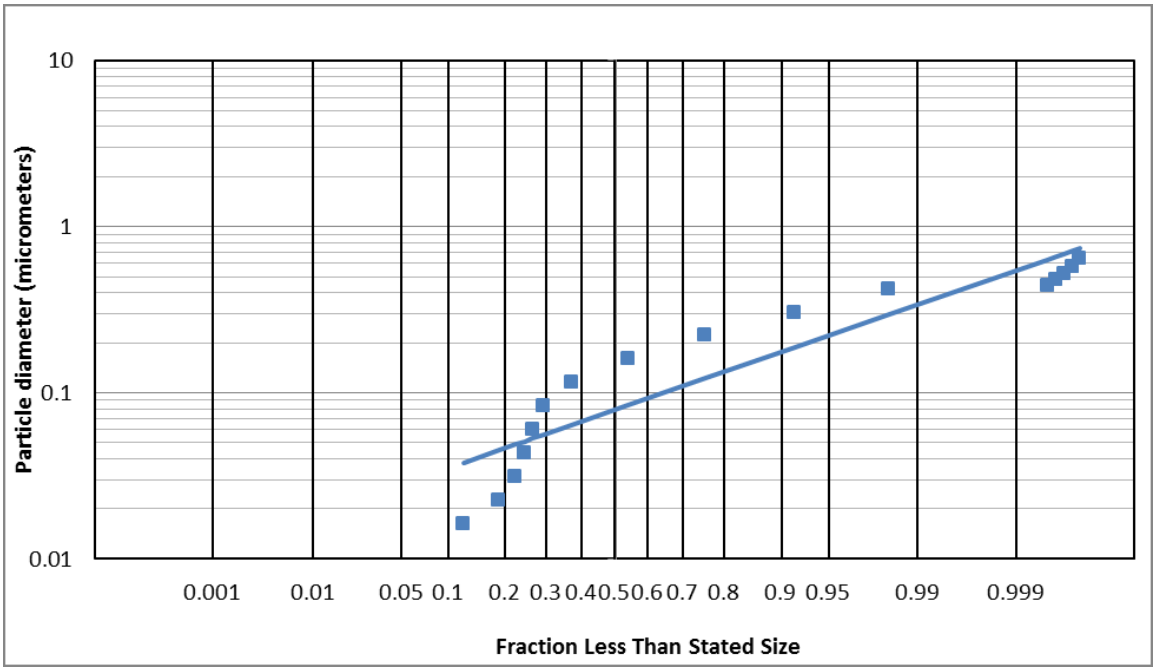
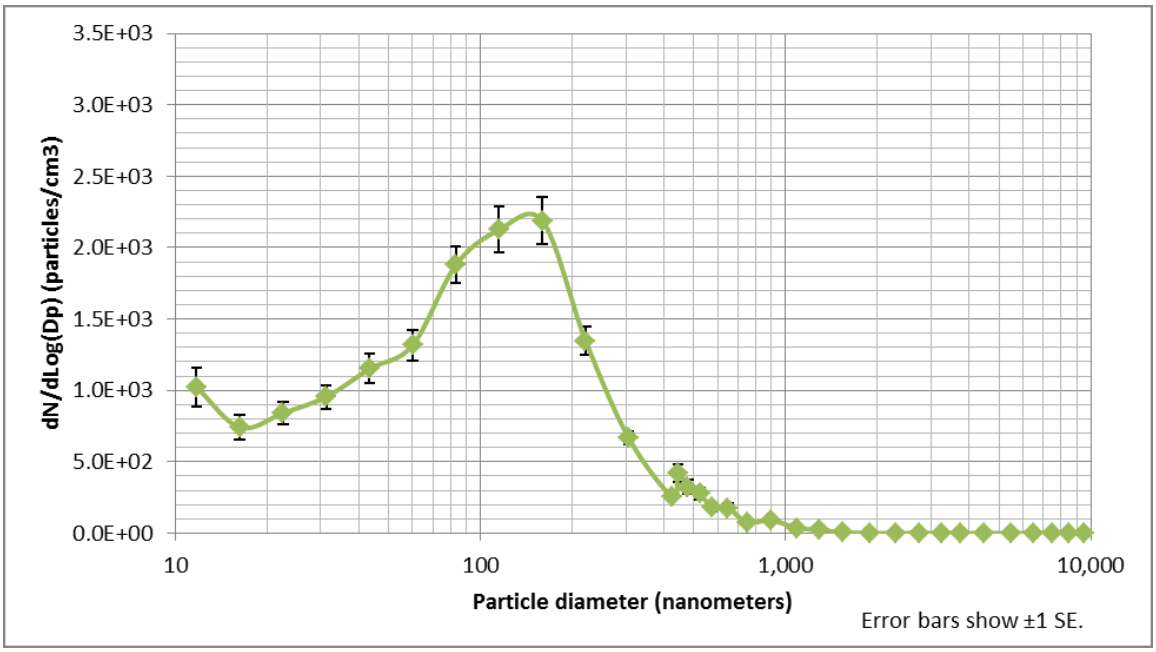


FIGURE A9 (a and b). Average particle size distribution of surgical plume produced from skin and fat by CO_2 laser, 5W continuous wave, 125 mm handpiece: Calculated CMD: 0.091 [2.96]; Peak #1: 0.160 µm

A9 a) Size distribution plot



A9 b) Log probability plot

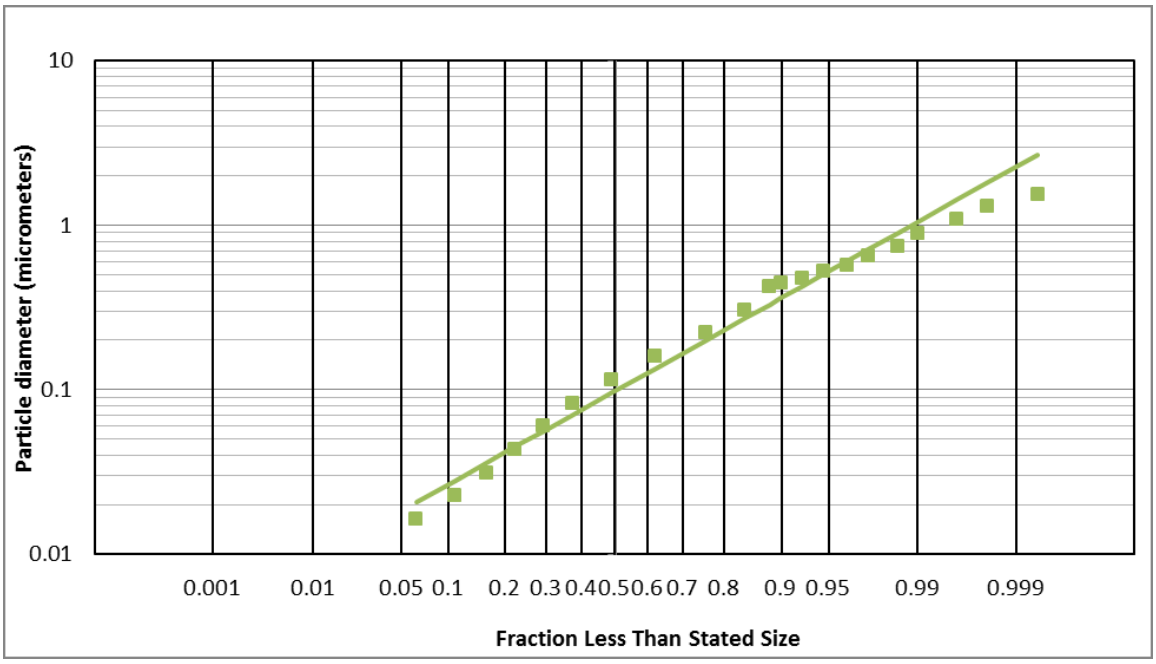


FIGURE A10. Particle number concentrations measured in the PBZ and periphery of the room produced by the harmonic scalpel on skin and fat

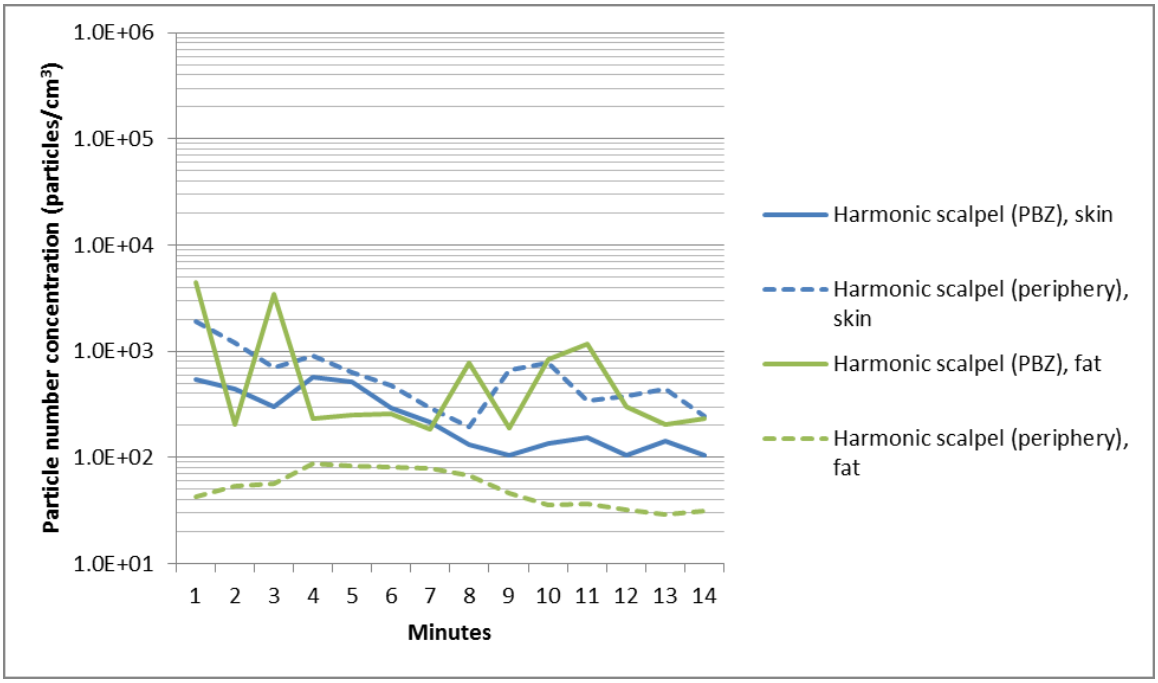
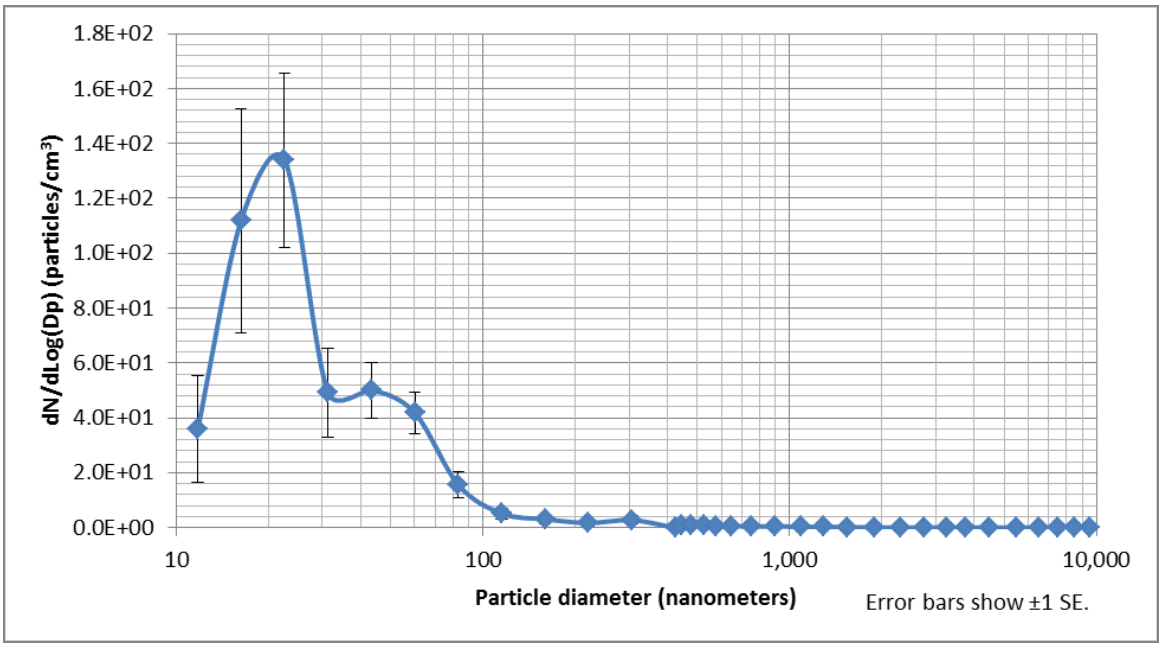


FIGURE A11 (a and b). Average particle size distribution of surgical plume produced from skin by harmonic scalpel: Calculated CMD: 0.028 µm [20]; Peak: 0.023 µm

A11 a) Size distribution plot



A11 b) Log probability plot

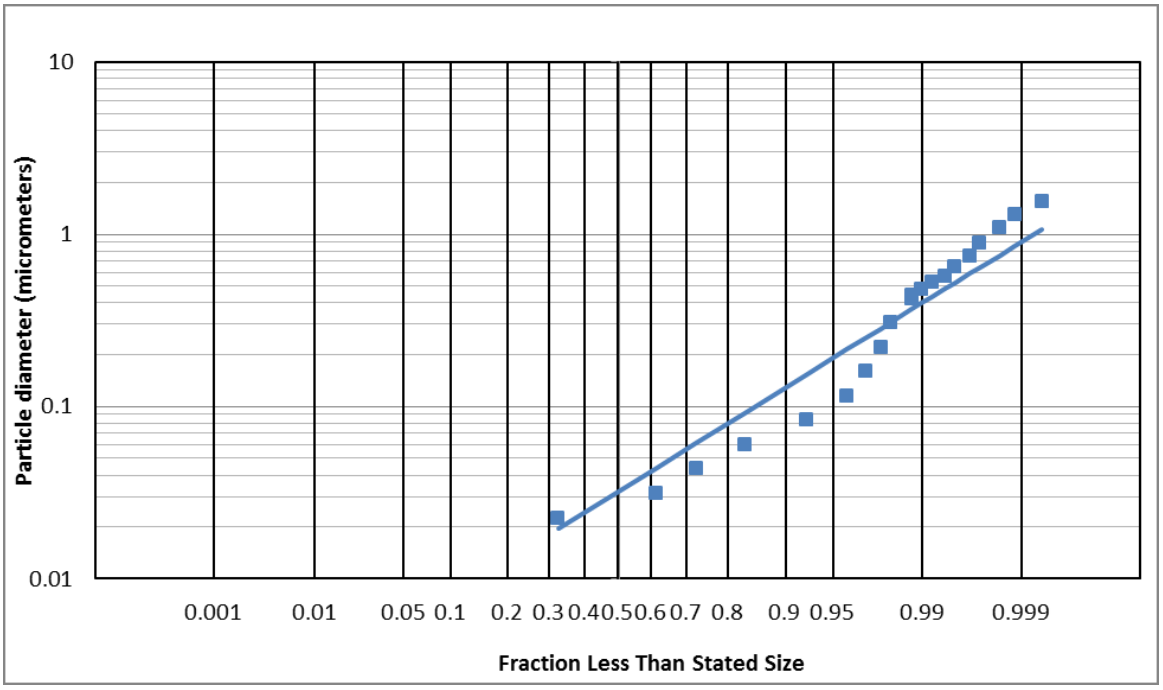
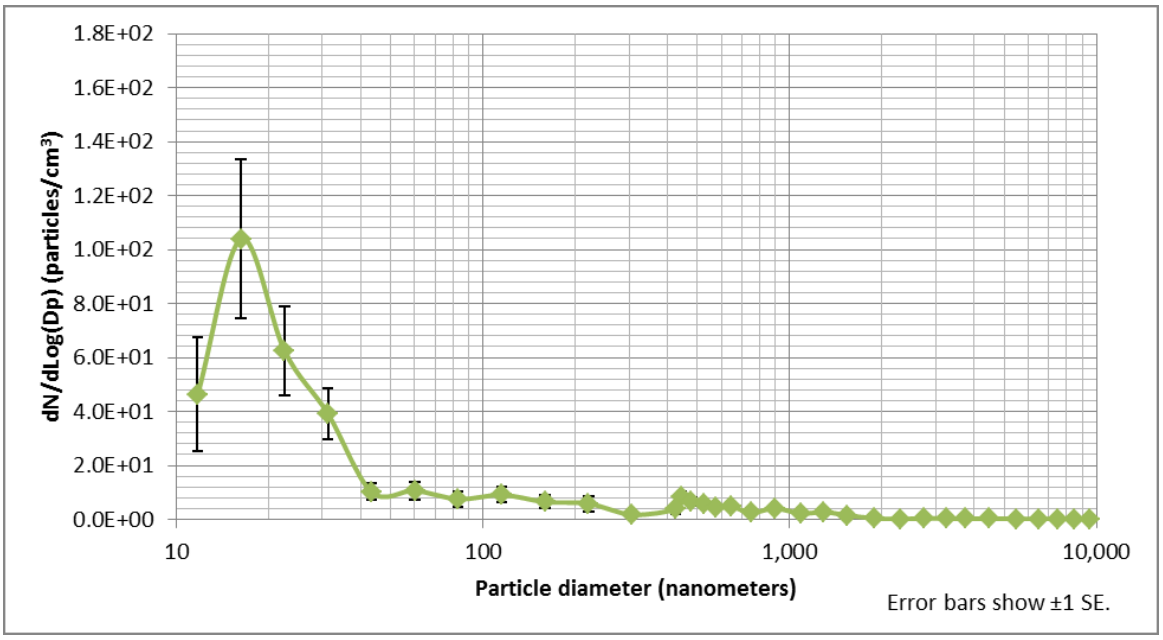


FIGURE A12 (a and b). Average particle size distribution of surgical plume produced from skin and fat by harmonic scalpel: Calculated CMD: 0.038 [3.8]; Peak: 0.016

A12 a) Size distribution plot



A12 b) Log probability plot

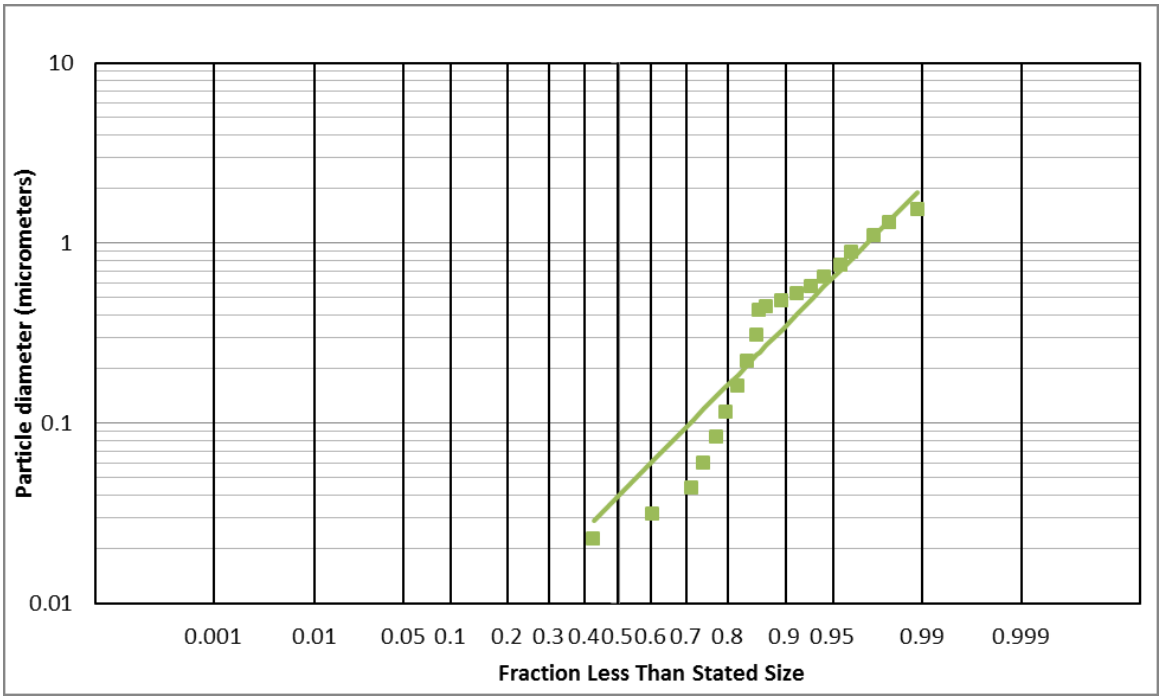


FIGURE A13. Particle number concentrations produced by the surgical instruments on dermal tissue in the periphery of the operating room

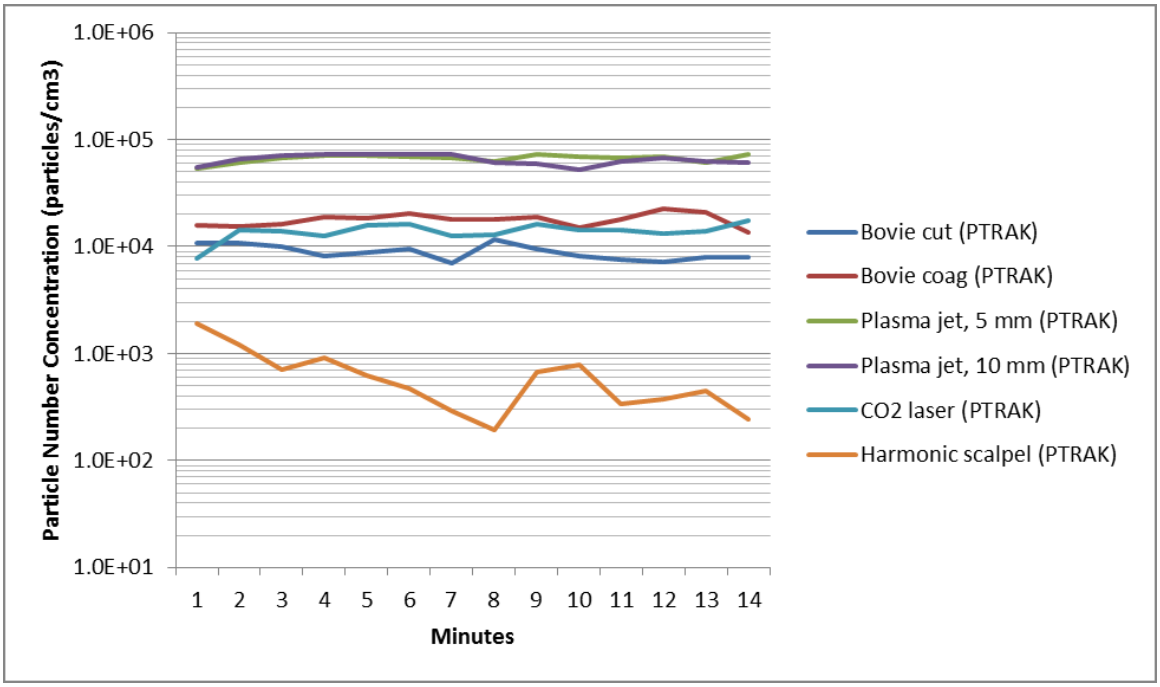
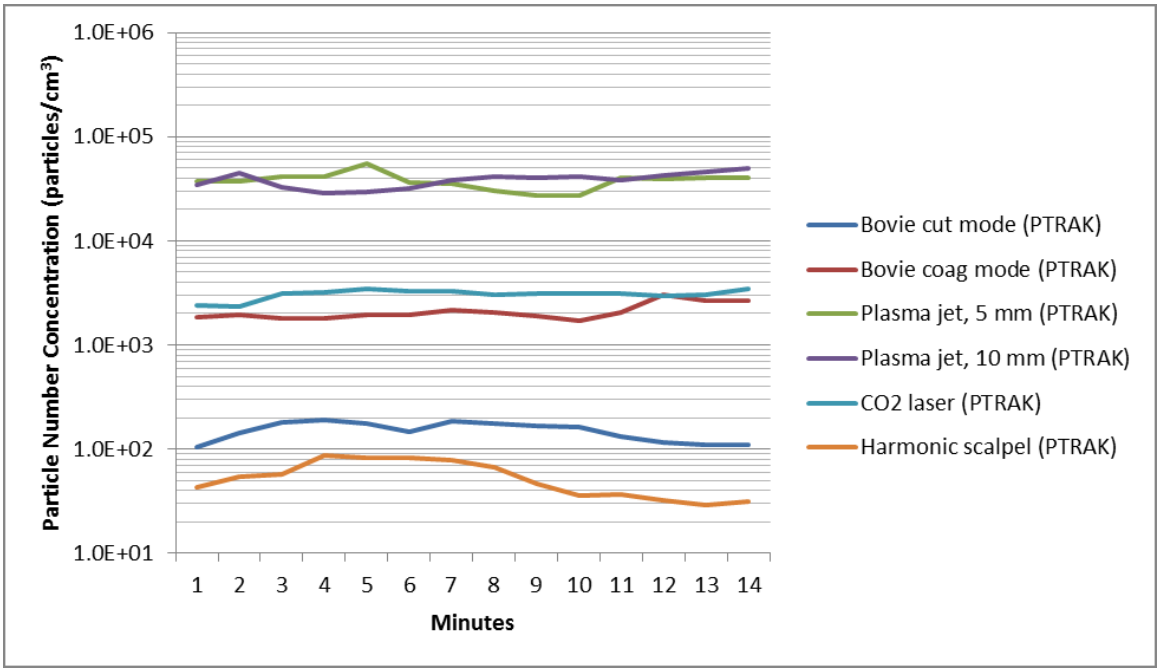


FIGURE A14. Particle number concentrations produced by the surgical instruments on adipose tissue in the periphery of the room



Chapter 4 Assessment of Airborne Surgical Plume Particles and Exposures to Operating Room Personnel during Selected Surgical Procedures

Abstract

The use of energy-based instruments to cut and cauterize tissue during surgical procedures produces a plume of particulate matter in the operating room environment. Concerns of health hazards associated with operating room personnel's exposure to such particulate matter have prompted the need for additional exposure characterizations. The aims of this study were to characterize the number concentration and size distribution characteristics of such particles produced during several surgical procedures in a hospital operating room environment. Surgical plume particles were measured using a wide-spectrum particle spectrometer (WPS) to characterize size distribution of particles and condensation particle counters (CPCs) and a PTrak ultrafine particle counter to measure concentrations of particles. Measurements were made in a hospital operating room during surgical procedures that varied in the types and extent of use of energy-based instruments for cutting and cauterizing tissue. Real-time CPC, PTrak, and WPS measurements of number concentrations and particle size distributions were collected in the area of the anesthesiologist's work station at the head of the patient near the site of surgical plume production. CPC and PTrak measurements were also made at points on the periphery of the operating room to assess exposures for operating room personnel further from the site of surgical plume production. During the surgeries, particles were produced through the use of two energy-based instruments, an electrocautery knife (bovie) and a Plasma Jet™ neutral coagulator system, on human dermal and adipose tissue. Local exhaust ventilation (LEV) at the point of plume production was used during some of the procedures providing substantial reduction in particle number concentrations in the room during its use. General room ventilation provided a fairly rapid decline in particle concentrations after last use of the plume producing instruments. Use of the bovie and plasma jet to cut or cauterize during the surgeries produced peaks of particles with count median diameter around 0.09–0.11 micrometers; use of the plasma jet for its antibacterial purposes produced peaks with smaller CMD around 0.03 micrometers. This study adds to the understanding of occupational exposures to surgical plume particles produced

through the use of such instruments and the benefits of controls such as LEV and general exhaust ventilation in controlling exposures observed in these procedures.

Introduction

The Centers for Disease Control and Prevention (CDC) and the Healthcare Infection Control Practices Advisory Committee (HICPAC) stated in their report "Guideline for the Prevention of Surgical Site Infections" that 27 million surgical procedures are performed in the United States every year based on the 1994 National Hospital Discharge Survey [Mangram, Horan et al. 1999; Kozak, DeFrances et al. 2006]. The 2010 National Hospital Discharge Survey reported that 51.4 million impatient surgery procedures were performed in the US [CDC 2013]. More than 234 million major surgical procedures (i.e., an intervention occurring in a hospital operating room that involves incision, excision, manipulation, or suturing of tissue that usually requires regional or general anesthesia or sedation) are estimated to be performed worldwide every year [Weiser, Regenbogen et al. 2008]. Surgeons and other surgical personnel have a variety of instrumentation available to cut and cauterize tissue during these surgical procedures. While the surgical scalpel may be the most obvious cutting instrument, several energy-based instruments have been used with regularity over the past decades depending on the needs and choice of the surgeon. One of the most common of these instruments is the electrocautery knife, also known as a bovie. The electrocautery knife is a blade-like pencil with electric current running through the tip that allows for cutting and coagulating tissue with the heat generated. Other similar instruments used include ultrasonic scalpels and lasers, as well as more recently introduced instruments such as the Plasma Jet™ neutral coagulation system. These instruments all destroy tissue through the energy applied, resulting in the production and aerosolization of surgical

plume into the operating room environment. The plume produced by these types of instruments has the potential to be an occupational hazard to operating room personnel due to the particles themselves and a variety of possible associated chemical and biological constituents. The respirable nature of the particles produced in the plume, the chemical by-products produced by the tissue combustion process, and the possible infectious agents aerosolized present concerns of potential acute and chronic health effects [Barrett and Garber 2003; Alp, Bijl, et al. 2006; Bigony 2007].

The US Occupational Safety and Health Administration (OSHA) has reported that an estimated 500,000 workers, including surgeons, nurses, anesthesiologists, and surgical technologists are exposed to laser or electrosurgical smoke every year [OSHA 2008]. However, OSHA has not published any regulatory or enforcement standards for exposures to surgical plume. The National Institute for Occupational Safety and Health (NIOSH) has made the recommendation to implement engineering controls, particularly local exhaust ventilation (LEV), and work practices to control health care workers' exposures to the plume. In particular, high efficiency particulate air (HEPA) filters and a suction nozzle inlet held 2 inches from the point of smoke production were recommended [NIOSH 1996]. In the 2012 edition of "Perioperative Standards and Recommended Practices", the Association of periOperative Registered Nurses (AORN) also provided recommendations that exposure to electrosurgical smoke and laser plume should be minimized and removed through the use of a smoke evacuation system and/or a central wall suction system [AORN 2012].

Reports in the scientific literature of characterizations of surgical plume particle number concentrations generated during surgical procedures performed in hospital operating rooms are limited. Brandon and Young [1997] reported measuring particle concentrations of

electrosurgical smoke using a laser particle counter during several mammoplasty-related procedures. Additionally, smoke removal devices were evaluated: one in which the smoke removal tube was attached to the electrocautery knife and three others where the tube was hand-held by the surgical assistant. With no smoke removal device, the particle count in the room, within 5 minutes after the start of the electrocautery plume production, quickly rose to and remained at nearly $1x10^6$ particles per cubic foot (particles/ft^3) from a baseline of 60,000 particles/ft^3. With an electrocautery knife-based smoke evacuation device, the average particle concentration fell to below $5x10^5$ particles/ft^3, but with peaks reaching above $1x10^6$ particles/ft^3. Hand-held smoke evacuation devices also produced similar lower average concentrations (i.e., general reductions of particle concentration greater than 50%), with episodic spikes of higher concentrations [Brandon and Young 1997]. No information was provided on ventilation characteristics in the operating room evaluated.

Hansen et al. investigated the impact of ultra-clean laminar air flow systems in operating rooms on ultrafine particle counts during surgical procedures [Hansen, Krabs et al. 2005]. A P-Trak™ ultrafine particle counter was used to measure ultrafine particles (<0.100 μm in diameter) near the operative field in hospital rooms with ultra-clean laminar airflow ventilation systems. The ultrafine particle counts (median and range) for ten operations using electrical coagulation were 940 and 117–40,000 particles/cm^3 compared to 1 and 0–62 particles/cm^3 for 95 operations where no electrical coagulation was performed [Hansen, Krabs et al. 2005]. The authors suggested that their findings of quick reductions in ultrafine particle counts for operations with electrical coagulation were a result of the laminar air flow systems with which these operating rooms were equipped [Hansen, Krabs et al. 2005].

Brüske-Hohlfeld et al. conducted an investigation using condensation particle counters (CPCs) to quantify the particle concentrations of surgical smoke generated from electrocautery and argon plasma tissue coagulation during six surgical procedures of different types including hemihepatectomy, mesh hernia repair, and laparoscopic appendectomy [Brüske-Hohlfeld, Preissler, et al., 2008]. CPCs were placed near the surgical table with the intake suction tube corresponding roughly to the personal breathing zone (PBZ) of personnel at the surgical table. Results indicated very high exposure for surgeons and close assisting operating staff to particles sized 0.010–1 μm with concentrations greater than $1x10^5$ particles/cm^3 of air for short peaks, followed by low level exposures for longer periods. Maximum concentrations were measured as high as $4.9x10^5$ particles/cm^3; however, these concentrations above $1x10^5$ particles/cm^3 could not be considered reliable due to instrument limitations. The use of a filter system during the laparoscopic appendectomy resulted in mean and peak particle concentrations of only 74 and 379 particles/cm^3. The authors commented "To our knowledge, the continuous size distribution of particles in surgical smoke has not been systematically studied" [Brüske-Hohlfeld, Preissler, et al. 2008].

Andreasson et al. analyzed particle concentrations during peritonectomy and colon/rectal cancer surgical procedures in which an electrocautery knife generated plume. Particle concentrations in the PBZ of surgeons and in the operating room environment were measured using a P-Trak® ultrafine particle counter. The authors compared the concentrations of airborne plume particles during peritonectomies (i.e., dissections of parietal and visceral peritoneum) during which surgeons used a reusable electro-surgical pencil set at a high voltage of 200/300 watts (W) to standard colon/rectal cancer surgeries during which surgeons used electro-surgical pieces set at 50/70 W. The median cumulative level of ultrafine particles was higher in the peritonectomy procedures for both PBZ (9.3×10^6 particles per milliliter per hour

[particles/ml/hr]) and area samples (2.6 x 10^6 particles/ml/hr) compared to the standard colon/rectal cancer surgery control group (4.8 x 10^5 and 3.9 x 10^4 particles/ml/hr). The median PBZ maximum concentrations recorded were 5.2 x 10^5 and 4.7 x 10^4 particles/ml/hr for peritonectomy and control groups, respectively [Andreasson, Anundi, et al. 2009].

The International Social Security Association Section on Prevention of Occupational Risks in Health Services recently reported on the published data regarding the hazards linked to surgical plume. With regard to surgical plume particle composition, the authors of the report, "Surgical Smoke: Risks and Preventive Measures", reference the two previous studies and state "One of the unknown elements is the nanoparticle fraction [of the smoke], which has certainly not been sufficiently evaluated, and for which we currently do not know the effects" [Eickmann U, Falcy M, et al. 2011].

The purpose of this paper is to address these concerns by adding to the body of knowledge with characterizations of surgical plume particles during surgical procedures to include: 1) particle number concentrations in various areas of the operating room environment; 2) comparisons of surgeries with and without use of a hand-held smoke evacuation device; and 3) size distribution characteristics that include the nanoparticle size fraction down to 0.010 μm in diameter.

Methods

Evaluation of surgical plume exposures in hospital operating rooms was conducted at a surgery center in Fayetteville, New York. A single board-certified plastic surgeon employed at the hospital performed all procedures in which measurements of particle number concentration and size distribution were made using several real-time direct-reading instruments. Informed patient

consent was received by the surgeon for permission to conduct air sampling during the selected surgical procedures. Four types of surgical procedures were selected for study based on differences in the use of energy-based cutting instruments as well as expected quantities of surgical plume particles produced.

During the surgical procedures evaluated, two surgical instruments produced the surgical plume in the operating room environment. The first was the Valleylab Force EZ™ Electrosurgical Generator (Covidien, Boulder, CO). Also known as a bovie and one of the most commonly used instruments that produce surgical plume, the electrosurgical generator applies electric current at the tip of the handpiece. As this tip is applied to tissue, the electric current enters the tissue and creates a circuit, exiting a grounding pad placed on the surface of the patient's skin near the surgical point. Cut and coagulation modes are available to use with this instrument, each having adjustable wattage settings. The cut setting uses a low voltage, constant electrical waveform to produce maximum current concentration, focusing intense heat at the site and resulting in tissue vaporization. The coagulation mode uses a high voltage, intermittent electrical waveform, producing less heat and resulting in a coagulum rather than tissue vaporization [Covidien 2008].

The second instrument used was Plasma Surgical's Plasma Jet®neutral plasma coagulator system (Plasma Surgical, Roswell, GA). Rather than introducing an external electrical current to cut or coagulate tissue as with electrosurgical techniques, the Plasma Jet utilizes a low-flow stream of argon gas that passes over electrodes in the handpiece of the unit. This creates a stream of high energy argon plasma, a mixture of ionized gas atoms and electrons [Plasma Surgical Limited 2009]. The tissue effects of the stream of argon plasma depends on the quantity and velocity of argon gas flowing and how much energy is transferred to the gas at the tip of the handpiece.

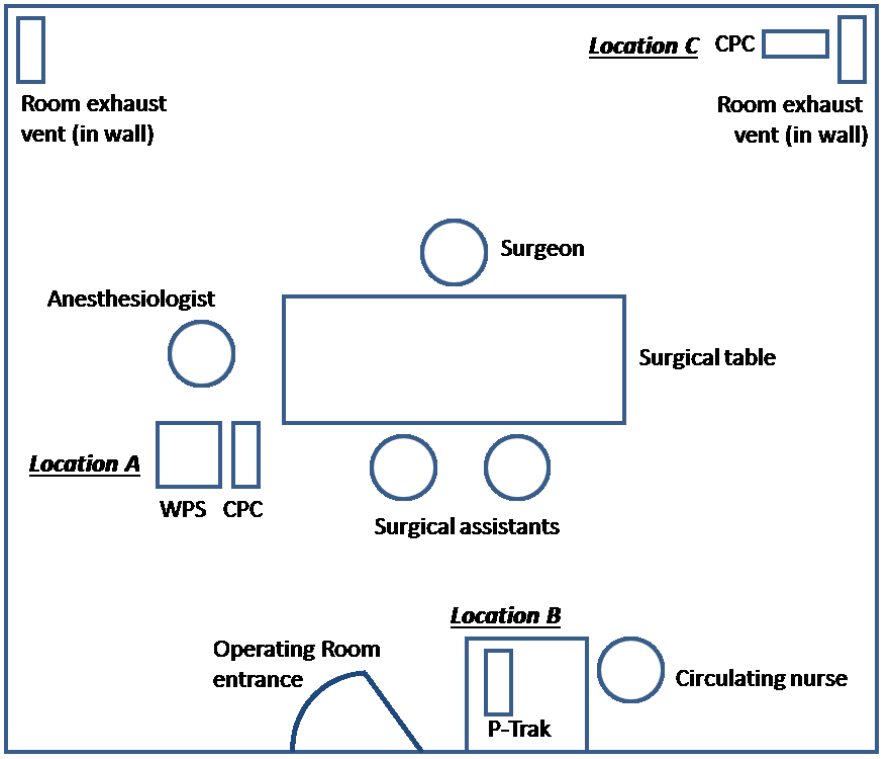
During surgical procedures, the argon flow at the tip of the hand piece is brought in close proximity to the tissue, with differing effects dependent on the distance of the tip from the tissue surface. Tissue shrinkage and coagulation occurs at a distance of 1 cm or more, with vaporization and cutting of the tissue occurring with contact of the tissue by the tip. The thermal and kinetic energy introduced into the tissue penetrates to a typical depth of less than 0.5 mm from the site of contact [Plasma Surgical Limited 2009].

Instrumentation used to measure particle number concentrations in the operating room environment included two TSI Inc. handheld condensation particle counters (CPC) model 3007 and a TSI Inc. P-Trak® ultrafine particle counter (TSI Incorporated, Shoreview, MN). The model 3007 CPCs count particles measuring 0.010–1.0 µm in size in concentrations up to 100,000 particles/cm^3. The P-Trak® counts particles measuring 0.020–1.0 µm in size, ranging in concentrations up to 500,000 particles/cm^3. The CPCs and the P-Trak were configured with logging intervals of 60 seconds each in which they would measure the particle number concentrations for 60 seconds and provide an average for that minute. In addition to the particle counters located in the operating room, an MSP Corp. Wide-Range Particle Spectrometer (WPS) model 1000XP-A was utilized to characterize size distributions of surgical plume particles (MSP Corporation, Shoreview, MN). The WPS uses a combination of laser light scattering, differential mobility analysis, and condensation particle counting to size and count airborne particles.

Placement of the real-time direct reading instrumentation was standardized so the monitoring locations for each instrument were the same for every surgical procedure. While exposures to surgical smoke are expected to be greatest for individuals working at the surgical table, concerns for maintaining the sterility of the surgical field required the placement of measuring equipment

outside of the immediate surgical area. For all procedures, the WPS and a CPC were co-located in the vicinity of the anesthesiologist's workstation at the head of the patient, designated Location A on Figure 4.1. Short lengths of non-conductive tubing from the intake ports of the instruments allowed collection of the particles in the vicinity of the PBZ of the seated anesthesiologist. The P-Trak was located approximately 4 feet above the floor on a circulating nurse's work station in the periphery of the OR near the door, designated Location B. During the first two surgical procedures monitored, only one CPC was available for use and was located at the anesthesiologist's station. For the other procedures, a second CPC was available and located approximately three feet above the floor in the far corner of the room in front of one of the room's two exhaust vents, designated Location C. See Figure 4.1 for a representation of instrumentation locations in the operating room.

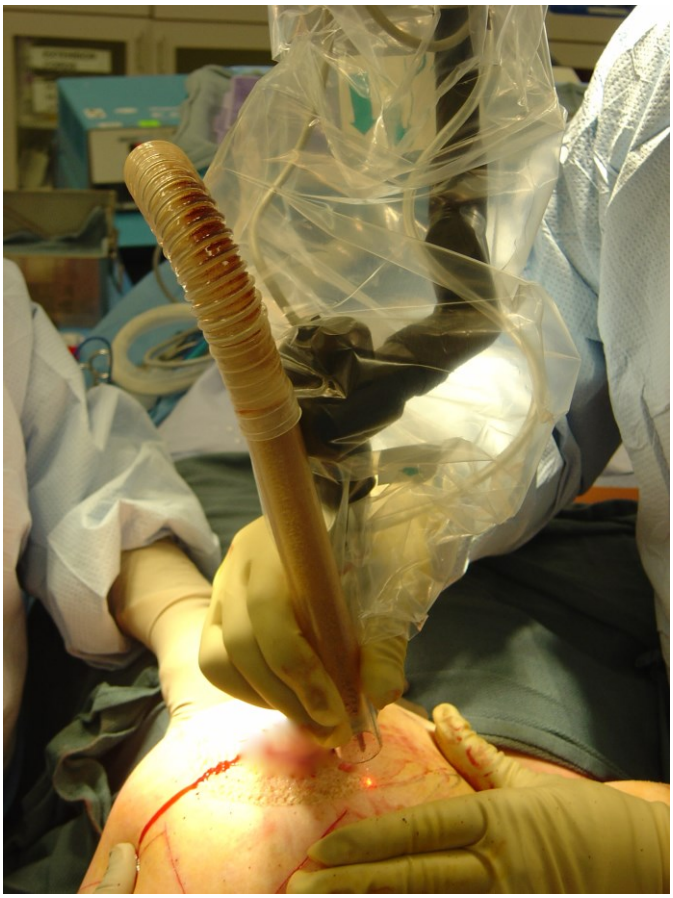
Figure 4.1 Schematic Diagram of a Surgical Table, Operating Room Personnel, and Sampling Equipment Location within the Operating Room



Ventilation measurements were made in the operating room following monitored surgical procedures to characterize the ventilation and airflow parameters in the operating room. After surgical procedures had been completed in the rooms where monitoring occurred, a TSI Inc. AccuBalance Plus model 8373 air capture hood and a TSI Inc. VelociCalc Plus model 8386A were used to measure air volume flowing through the ventilation supply registers and exhausts in order to calculate the number of air changes per hour (ACH) achieved in the OR. The location of the supply registers above the surgical table provide a downward laminar flow of high efficiency particulate air (HEPA) filtered air from above the surgical site to the room's two exhaust vents, each located near the floor in the room's corners farthest from the OR entrance. Measurements were also made to confirm the rooms were maintained under positive pressure as designed.

A surgical smoke evacuator, Buffalo Filter Plume Safe smoke evacuation system model 1202, was available in the OR and used according to needs as determined by the surgeon. See Figure 4.2 for a photograph of this evacuation system being used during a surgery with a carbon dioxide laser generating surgical plume particles.

Figure 4.2 Photograph of Surgical Plume Particles Captured Using LEV during a Surgical Procedure



When used during the surgeries monitored, a surgical assistant held the evacuation system's 18 mm diameter tubing at a distance of a few inches (typically, 2–3 inches) from the point of surgical plume production to evacuate smoke from the surgical area.

Initial acquisition and analysis of data originating from the WPS was performed using WPS Commander™ software, version 2.5 [MSP Corp., Shoreview, MN]. Initial acquisition and analysis of data originating from the P-Trak was performed using Trak-PRO™ software, version 4.2.0.15, while Aerosol Instrument Manager® software, version 8.1.0.0, was used for data originating from the CPCs. [TSI Incorporated, Shoreview, MN]. Statistical analysis was performed using Intercooled Stata, version 9 [StataCorp LP, College Station, TX].

Data analyses were conducted to characterize number concentrations of aerosolized plume particles in various regions of the operating room during the selected surgical procedures. These regions included locations where operating room personnel commonly worked in order to characterize the extent to which surgical plume exposure varied within the room. Data from the CPCs and P-Trak were log-transformed for statistical analysis to approximate a normal distribution. Descriptive statistics such as geometric mean number concentration, geometric standard deviation, and the range of number concentrations were calculated from those data points collected between the initiation of plume production through the end of plume production in that procedure plus 10 minutes. Correlation coefficients were calculated to determine the strength of correlation between concentrations of airborne particles in the various regions of the room; paired t-tests were conducted to determine if there were statistically significant differences in the concentrations recorded at these locations.

Results and Discussion

An enumeration of the surgical procedures evaluated and several associated parameters are presented in Table 4.1. Two of the surgical procedures, the brachioplasty and the thighplasty, are each treated as two separate procedures in the tables given that nearly identical but consecutive surgical work was performed on each of the two extremities (i.e., arm 1 and arm 2, or leg 1 and leg 2) with a definitive break of surgical work and plume production between them. During each of these two surgeries, the surgeon chose to use local exhaust ventilation (LEV) during the surgical work on the first extremity while declining to use LEV during surgical work on the second extremity. Data on type and length of surgical procedure, room ventilation parameters, types of plume-producing equipment, and use of evacuation instruments are included.

Table 4.1 Surgical Procedures Monitored for Determination of Surgical Smoke Concentration

Procedure	**Length of Procedure (minutes)**	**Calculated Room ACH**	**Use of LEV**	**Plume Producing Equipment Used**
Brachioplasty 1	50	23.6	Yes	Bovie and PlasmaJet®
Brachioplasty 2	48	23.6	No	Bovie and PlasmaJet®
Thighplasty 1	82	21.3	Yes	Bovie and PlasmaJet®
Thighplasty 2	89	21.3	No	Bovie and PlasmaJet®
Breast augmentation	74	21.3	No	Bovie and PlasmaJet®
Necrotic tissue removal	17	23.6	No	Bovie

Table 4.2 presents summary descriptive statistics for particle number count for the CPC(s) and P-Trak instruments, including mean number concentrations and geometric standard deviations (GSDs) as well as minimum and maximum number concentrations for each of the procedures. Table 4.3 presents the count median diameters (CMDs) and GSDs for both the periods of time over the plume production during each surgery as well as at specific points in time during each surgery.

Table 4.2 Descriptive Statistics for Particle Number Concentrations (particles/cm^3) by Surgery Type and Location in OR as Measured using CPCs (Locations A and C) and a PTrak (Location B)

Procedure	**Location A Geometric Mean Concentration [GSD] (range)**	**Location B Geometric Mean Concentration [GSD] (range)**	**Location C Geometric Mean Concentration [GSD] (range)**
Brachioplasty 1 (LEV used)	1,817 [2.85] (149–7,435)	917 [4.75] (17–12,982)	N/A
Brachioplasty 2 (no LEV use)	16,140 [6.10] (23–96,443)	8,499 [5.86] (54–53,435)	N/A
Thighplasty 1 (LEV used)	3,277 [3.92] (32–15,918)	1,114 [3.54] (23–4,556)	3,460 [4.20] (46–20,933)
Thighplasty 2 (no LEV use)	23,913 [4.92] (26–134,324)	13,267 [7.57] (2–71,748)	21,669 [5.35] (35–136,400)
Breast augmentation (no LEV use)	230 [3.78] (11–3,941)	245 [3.89] (8–6,813)	232 [3.78] (10–2,802)
Necrotic tissue removal (no LEV use)	1,875 [3.22] (246–10,560)	890 [2.17] (183–2,934)	N/A

Table 4.3 Descriptive Statistics for Particle Size Distribution (Count Median Diameters and Geometric Standard Deviations) by Surgery Type at Location A as Measured using a WPS

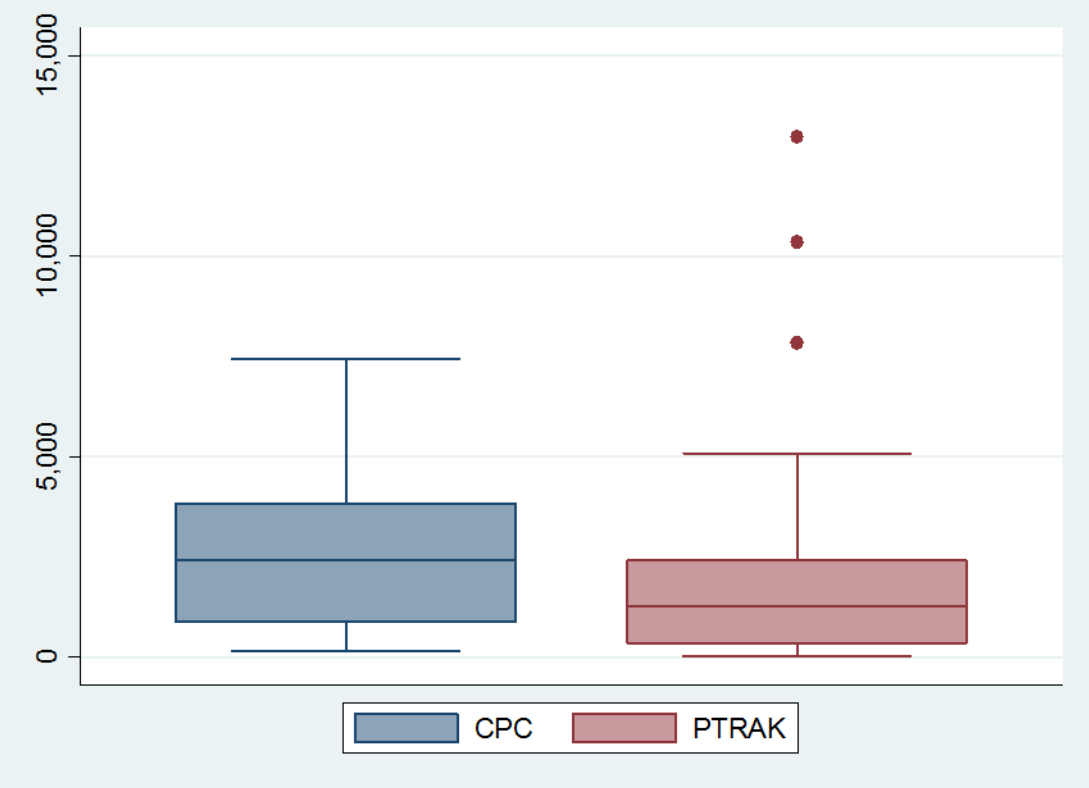
	Averaged over Procedure (or) Point-in-Time during Plume Generation	**Count Median Diameter (μm) [GSD]**
Brachioplasty 1 (LEV)	Averaged over Procedure	0.035 [2.53]
Brachioplasty 2 (no LEV)	Averaged over Procedure	0.105 [1.8]
Thighplasty 1 (LEV)	Averaged over Procedure	0.042 [2.50]
Thighplasty 2 (no LEV)	Averaged over Procedure	0.091 [2.33]
Breast augmentation (no LEV)	Point-in-Time after Plasma Jet use for cutting/cauterizing purposes	0.098 [2.00]
Breast augmentation (no LEV)	Point-in-Time after Bovie use	0.099 [2.36]
Breast augmentation (no LEV)	Point-in-Time after Plasma Jet use for antibacterial purposes	0.035 [2.02]
Necrotic tissue removal (no LEV)	Point-in-Time after Bovie use	0.092 [2.02]

Brachioplasties

During surgical work that included the use of both the electrocautery knife and Plasma Jet on arm 1 of the brachioplasty procedure, the surgeon's assistant held the LEV tubing within a few inches of the point of plume production. During the surgical work on arm 1, the GM particle number concentration at location A near the surgical table was 1,817 particles/cm^3 (GSD: 2.85) compared to 917 particles/cm^3 (GSD: 4.75] at the nurse's station at the periphery of the operating room near its entrance door. While the geometric mean number concentration was expectedly higher at location A, a higher peak concentration was detected at location B during this same sampling time period. Whether this peak concentration was a result of surgical plume at a higher concentration in this area or a result of other particle generating activity is unknown.

The correlation coefficient calculated, 0.744, indicates a fairly strong degree of correlation between the concentrations measured at these two locations during the surgical plume production on arm 1 of the brachioplasty. A paired t-test of the log-transformed data indicated, however, that there was a statistically significant difference in the mean number concentration between the two areas ($p<0.01$]. See Figure 4.3 for boxplot charts of the concentrations measured by the two instruments.

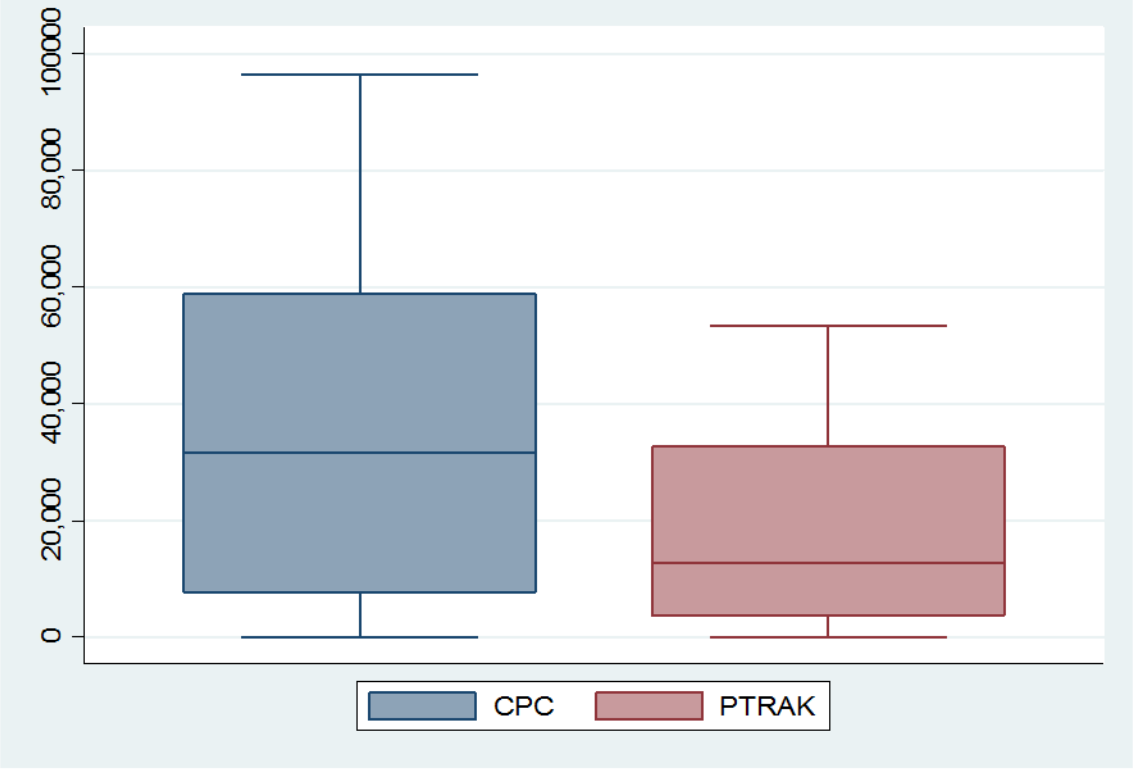
Figure 4.3 Particle Number Concentrations (y axis: particles/cm^3) Measured by the CPC (Location A) and P-Trak (Location B) During Brachioplasty 1 Using LEV



During the surgical work on arm 2 of the brachioplasty procedure, which did not include the use of LEV, the geometric mean number concentration at location A near the surgical table was

measured at 16,140 particles/cm^3 (GSD: 6.10) compared to 8,499 particles/cm^3 (GSD: 5.86) at location B. During surgical work which included the use of either the bovie or plasma jet on arm 2, both the geometric mean particle number and peak particle number concentrations were higher at location A than location B. The correlation coefficient between the concentrations measured at these two locations was 0.902, indicating a very strong degree of correlation. A paired t-test indicated, however, that there was a statistically significant difference in the mean particle number concentration between the two areas ($p<0.01$). See Figure 4.4 for boxplot charts of the concentrations measured by the two instruments.

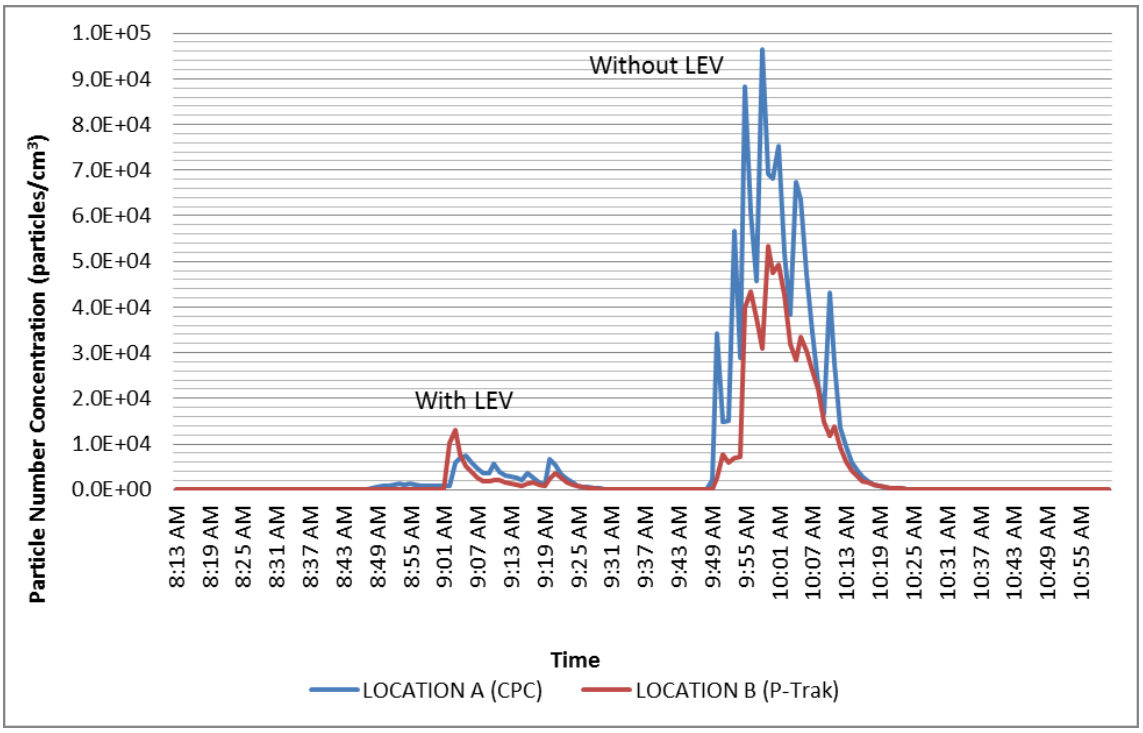
Figure 4.4 Particle Number Concentrations (y axis: particles/cm^3) Measured by the CPC (Location A) and P-Trak (Location B) During Brachioplasty 2 Without Using LEV



While LEV was used during the periods of plume production on arm 1 of the brachioplasty, no LEV was used during periods of plume production from the use of the bovie and plasma jet on arm 2. As a result, mean particle number concentrations increased considerably from arm 2 compared to arm 1 in both areas of the operating room during periods of plume production. Compared to a geometric mean of 1,817 particles/cm^3 (GSD: 2.85) during the surgical plume production on arm 1 when LEV was used, geometric mean particle number concentration at location A increased to more than 16,100 particles/cm^3 (GSD: 6.10) when no LEV was used on arm 2. Peak number concentration at this location reached more than 96,400 particles/cm^3 compared to 7,400 particles/cm^3 when LEV was used. Similarly, compared to a geometric mean of 917 particles/cm^3 (GSD: 4.75) during plume production on arm 1 when LEV was used, geometric mean particle number concentration at location B increased to 8,500 particles/cm^3 (GSD: 5.86). Peak number concentration at location B reached more than 53,400 particles/cm^3 without the use of LEV compared to 12,900 particles/cm^3 with LEV. Compared with the use of no exposure control during the second brachioplasty, the use of LEV reduced the geometric mean particle number concentration during the first brachioplasty by 89% at both locations A and B in the operating room. Furthermore, the LEV reduced peak particle number concentrations by 93% at location A and 76% at location B.

Figure 4.5 shows real-time measurements of particle number concentrations at locations A and B through the time periods of both LEV use and non-use during the brachioplasty. The time period of bovie/plasma jet use with LEV on arm 1 corresponds to 08:57–09:20 A.M.; the time period of bovie/plasma jet use without LEV on arm 2 corresponds to 09:48–10:09 A.M. The reduction in peak particle number concentrations in both locations due to LEV use is readily observed.

Figure 4.5 Airborne Particle Number Concentrations (particles/cm^3) During Brachioplasties With and Without LEV Use as Measured by a CPC and PTrak



Figures 4.6 and 4.7 show the size distribution of particles produced during plume production on arms 1 (with LEV used) and 2 (no LEV used), respectively. Times of increased particle concentrations corresponded directly with the use of plume-producing equipment during the brachioplasty.

Figure 4.6 Airborne Particle Size Distribution by Time at Location A During Brachioplasty 1 (With LEV), as Measured by the WPS

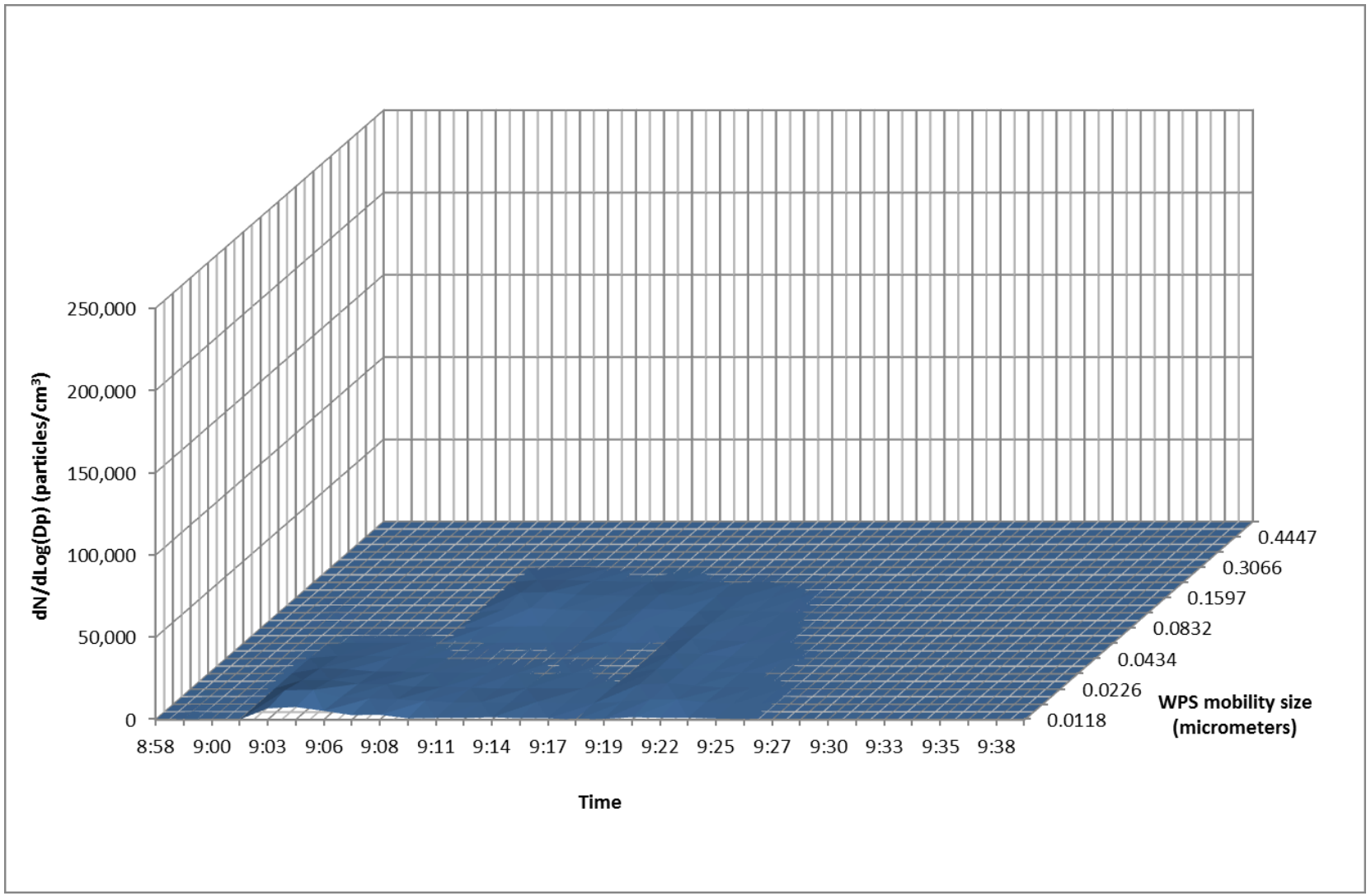


Figure 4.7 Airborne Particle Size Distribution by Time at Location A during Brachioplasty 2 (Without LEV), as Measured by the WPS

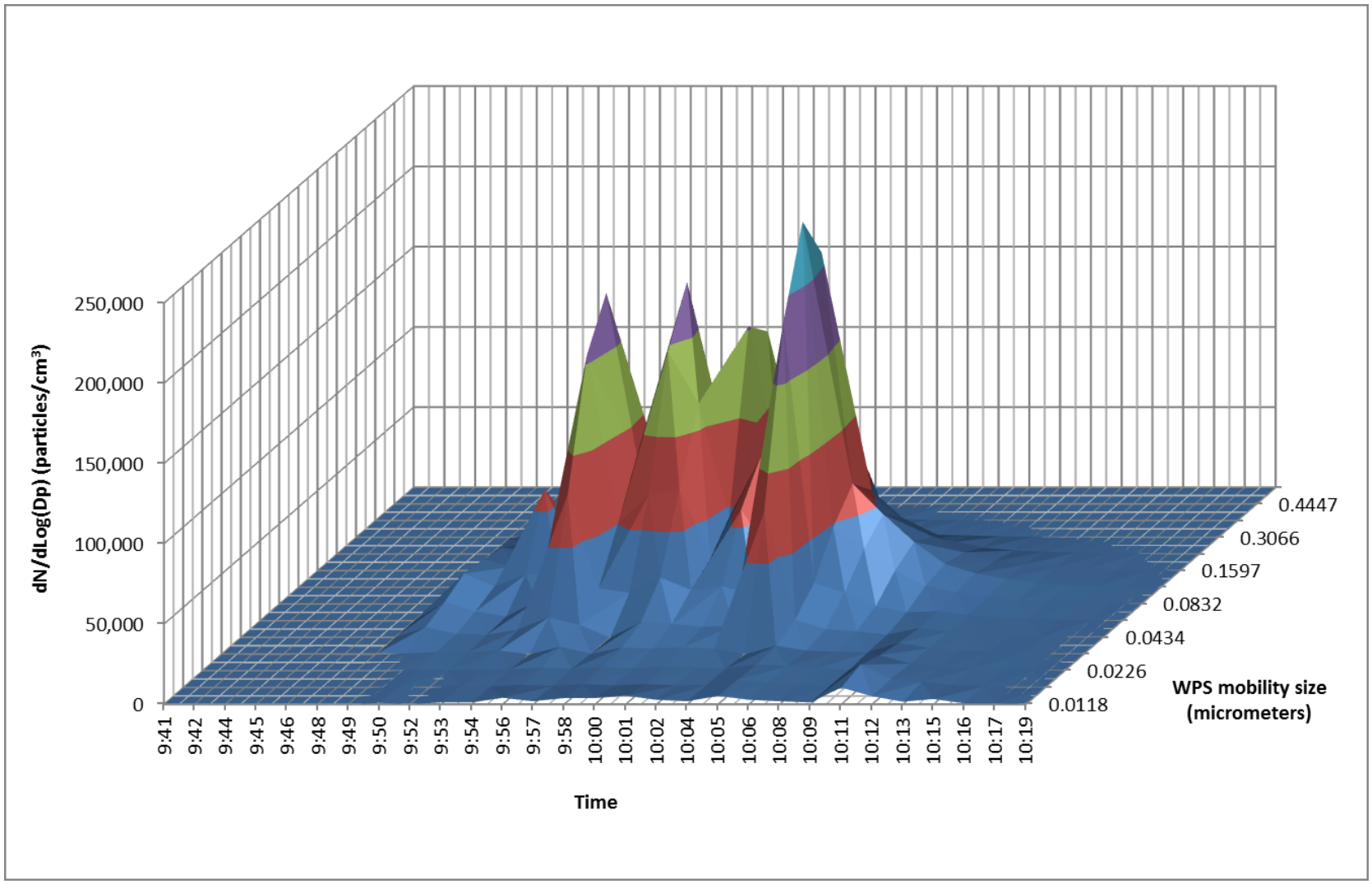
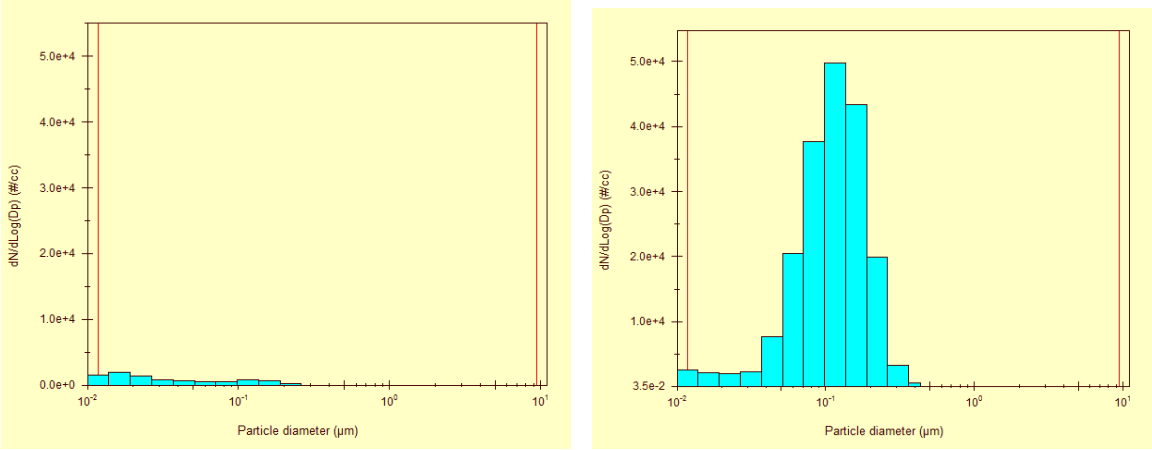


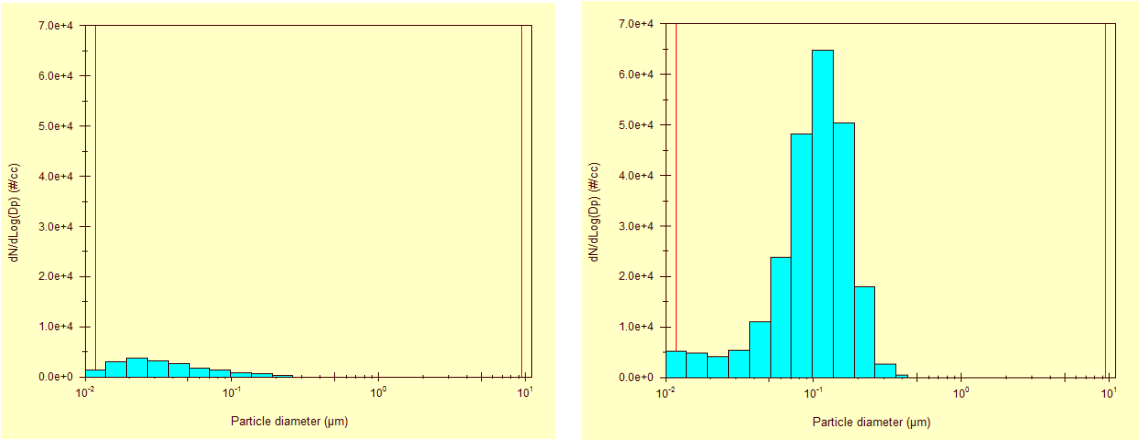
Figure 4.8 show histograms of the size distributions of particles measured at Location A, averaged over the periods of plume production during arm 1 and 2, respectively. Figure 4.8 (left) shows a low level concentration across the spectrum of sizes with no discernible major peaks when LEV was used. The count median diameter (CMD) of the particle size distribution was 0.035 µm, with geometric standard deviations (GSD) of 2.53. In contrast, the size selective WPS sampling shown in Figure 4.8 (right) shows a sharp peak in particles produced with a mobility particle diameter slightly larger than 0.1 µm, with a CMD of 0.105 µm (GSD: 1.8) when no LEV was used.

Figure 4.8 Comparison of Average Size Distributions of Surgical Plume Particles During Brachioplasties With LEV Use (left) and Without LEV Use (right) as Measured by the WPS



Figures 4.9 shows particle size distributions for single points in time (chosen as representative points in time during plume production) during work on arm 1 (9:21 A.M) and arm 2 (10:05 A.M.), reflecting the averages shown in Figure 4.8. As above, figure 4.9 (left) shows no discernable peak, with a CMD of 0.034 (GSD: 2.06). Figure 4.9 (right) shows a single peak in the distribution with a CMD of 0.095 µm (GSD: 1.91).

Figure 4.9 Comparison of Average Size Distributions of Surgical Plume Particles at Specific Points in Time During Brachioplasties With LEV use (left, 09:21 A.M.) and Without LEV Use (right, 10:05 A.M.) as Measured by the WPS

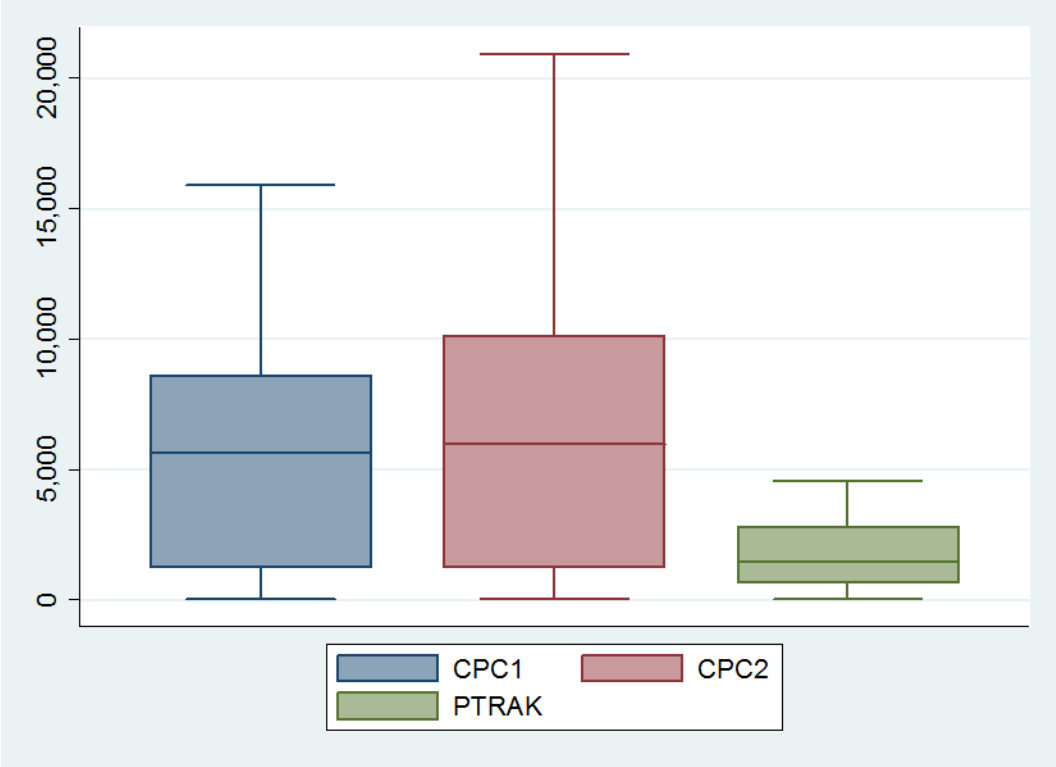


Thighplasties

During surgical work on leg 1 of the thighplasty procedure that included the use of both the bovie and plasma jet, the surgeon's assistant used LEV during plume production. Of the three locations measured, location B near the door registered the lowest geometric mean (1,114 particles/cm^3 [GSD: 3.54]) and peak (4,556 particles/cm^3) number concentrations during the period of plume production. While location A was closest to the point of plume production (GM: 3,277 particles/cm^3 [GSD: 3.92]; peak: 15,918 particles/cm^3), location C near the exhaust register had a higher geometric mean (3,460 particles/cm^3 [GSD: 4.20]) and peak (20,933 particles/cm^3) number concentration. Correlation coefficients between the concentrations in all areas of the operating room showed very strong relationships: 0.971 between locations A and C; 0.931 between locations A and B; and 0.960 between locations B and C. Paired t-tests indicated that there was no statistically significant difference in the mean number concentrations between locations A and C (p=0.2655); however, statistically significant

differences were found between locations A and B ($p<0.001$) and locations B and C ($p<0.001$). See Figure 4.10 for boxplot charts of the concentrations measured by the three instruments.

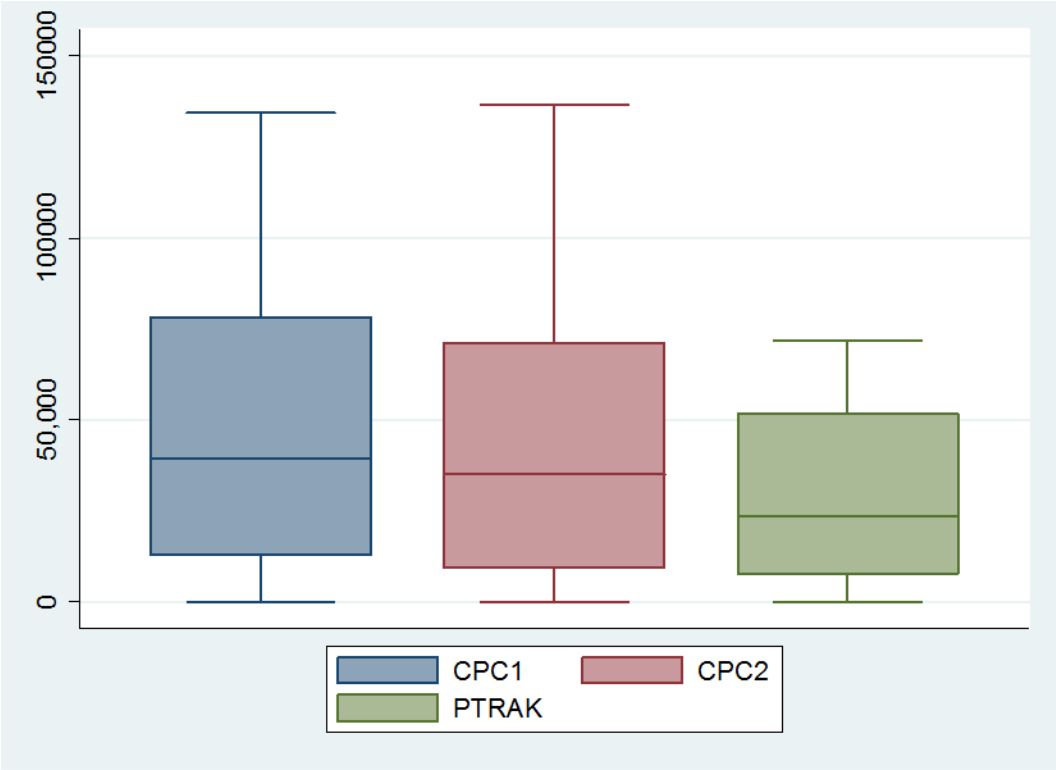
Figure 4.10 Boxplots of Particle Number Concentrations (y axis: particles/cm^3) Measured by the CPC (Location A), PTRAK (Location B), and CPC2 (Location C) During Thighplasty 1, With LEV Use



During the surgical work on leg 2 of the thighplasty procedure which did not use LEV, the geometric mean number concentration at location A near the surgical table was 23,913 particles/cm^3 (GSD: 4.92) [peak: 134,324 particles/cm^3] compared to 21,669 particles/cm^3 (GSD: 5.35) [peak: 136,400 particles/cm^3] at location C near the exhaust register. Of the three locations measured, location B near the door had the lowest geometric mean (13,267 particles/cm^3 [GSD: 7.57]) and peak (71,748 particles/cm^3) number concentrations during the

sampling period. Correlation coefficient between concentrations measured at these locations showed a very strong positive relationship between locations A and C (0.958) and less strong positive relationships between locations A and B (0.786) and locations B and C (0.826). As was the case during sampling of leg 1 of the thighplasty, paired t-tests indicated that there was no statistically significant difference in the mean number concentrations between locations A and C ($p=0.1203$); however, statistically significant differences were found between locations A and B ($p<0.001$) and locations B and C ($p<0.002$). See Figure 4.11 for boxplots of the concentrations measured by the three instruments.

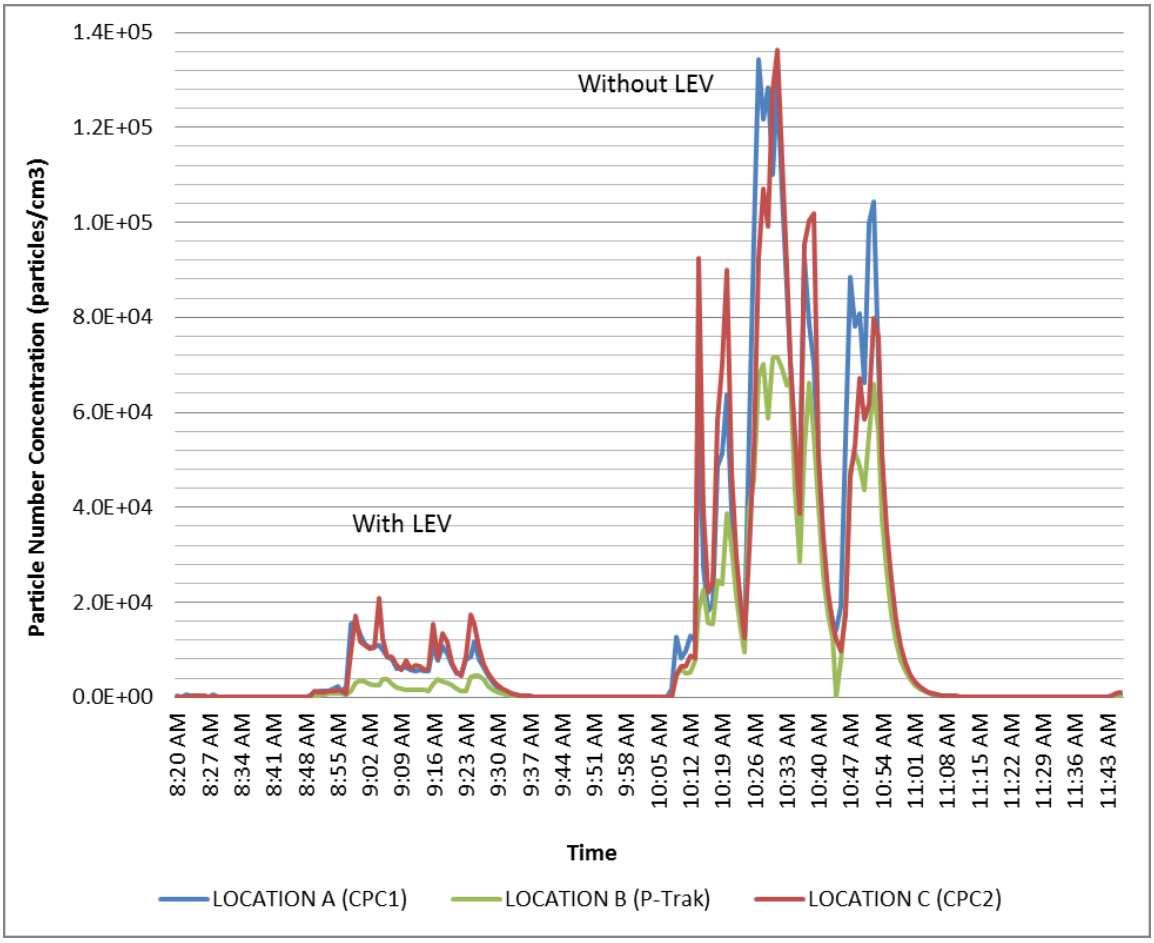
Figure 4.11 Boxplots of Particle Number Concentrations (y axis: particles/cm^3) Measured by the CPC1 (Location A), CPC2 (Location C), and PTRAK (Location B) During Thighplasty 2, Without LEV Use



While LEV was used during the periods of plume production on leg 1 of the thighplasty, no LEV was used on leg 2. As a result, mean particle number concentrations increased substantially in all areas of the operating room monitored during periods of plume production from leg 2 to leg 1. Compared to a geometric mean of 3,277 particles/cm^3 (GSD: 3.92) during the surgical plume production on leg 1 when LEV was used, geometric mean particle number concentration at location A increased to more than 23,900 particles/cm^3 (GSD: 4.92) when no LEV was used on leg 2. Peak number concentration at this location reached more than 134,300 particles/cm^3 compared to 15,900 particles/cm^3 when LEV was used. Similarly, geometric mean particle number concentration at location B increased from 1,114 particles/cm^3 (GSD: 3.54) with LEV to 13,260 particles/cm^3 (GSD: 7.57) without LEV. Peak number concentration at location B reached more than 71,700 particles/cm^3 without the use of LEV compared to 4,500 particles/cm^3 with LEV. For location C, use of LEV reduced geometric mean concentrations from 21,669 particles/cm^3 (GSD: 5.35) to 3,460 particles/cm^3 (GSD: 4.20) and peak concentrations from 136,400 particles/cm^3 to 20,900 particles/cm^3. Compared with no LEV use during the second thighplasty, LEV use reduced the geometric mean particle number concentration during the first thighplasty by 86%, 92%, and 84% at locations A, B, and C, respectively. Furthermore, the LEV reduced peak particle number concentrations by 88% at location A, 94% at location B, and 85% at location C.

Figure 4.12 shows real-time measurements of particle number concentrations at locations A, B, and C through the time periods of both LEV use and non-use during the brachioplasty. The time period of bovie/plasma jet use with LEV on arm 1 corresponds to 08:48–09:27 A.M.; the time period of bovie/plasma jet use without LEV on arm 2 corresponds to 10:07–10:55 A.M. The substantial reduction in peak particle number concentrations in all locations due to LEV use is readily observed.

Figure 4.12 Airborne Particle Concentrations (particles/cm^3) During Thighplasties With and Without LEV Use as Measured by the CPCs and PTrak



Figures 4.13 and 4.14 show the size distributions for particles associated with procedures on each leg, respectively. Figures 4.15 and 4.16 show the average particle size distributions for the periods of plume production on leg 1 and 2.

Figure 4.13 Airborne Particle Size Distribution by Time at Location A During Thighplasty 1 (With LEV), as Measured by the WPS

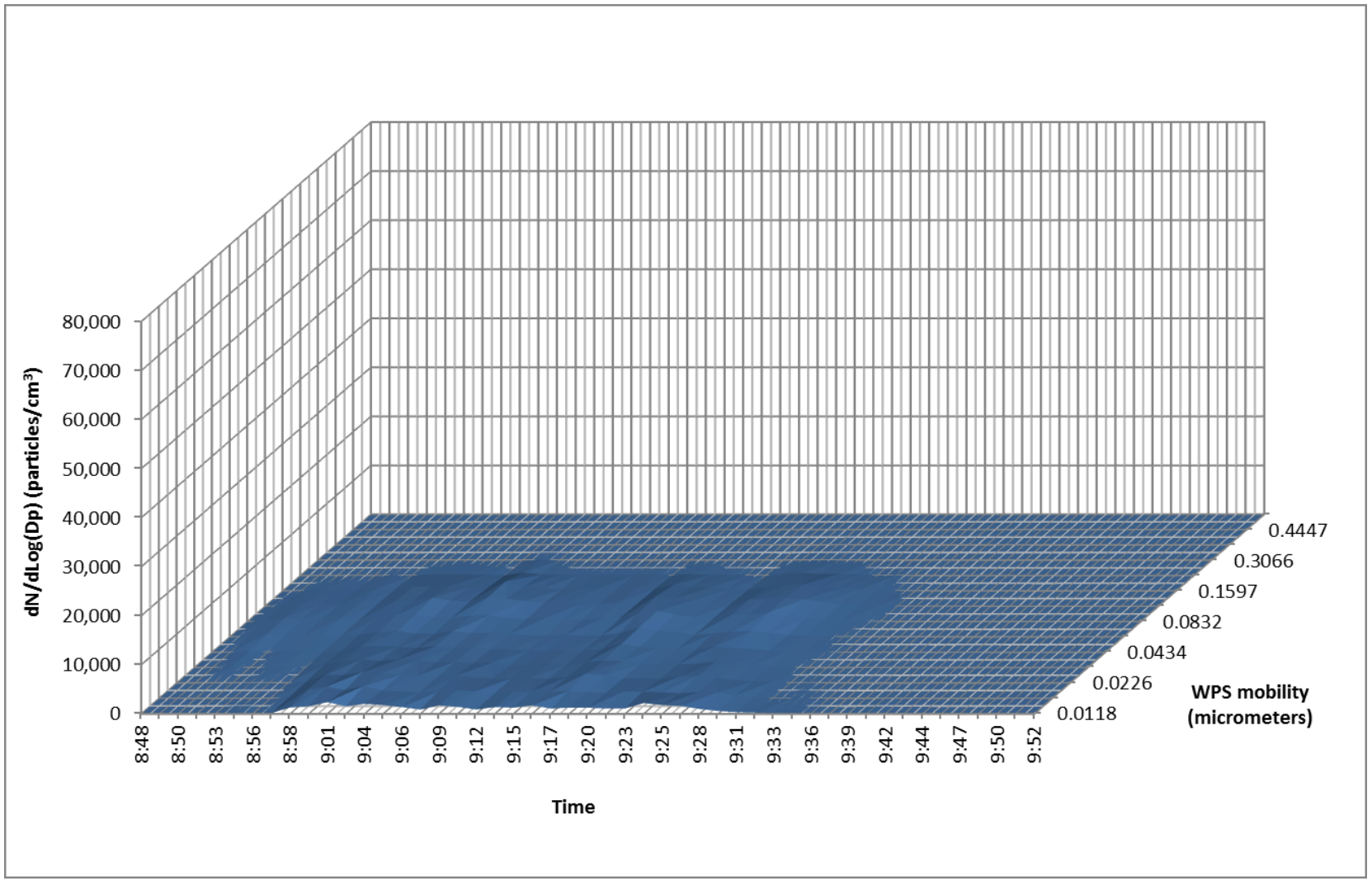
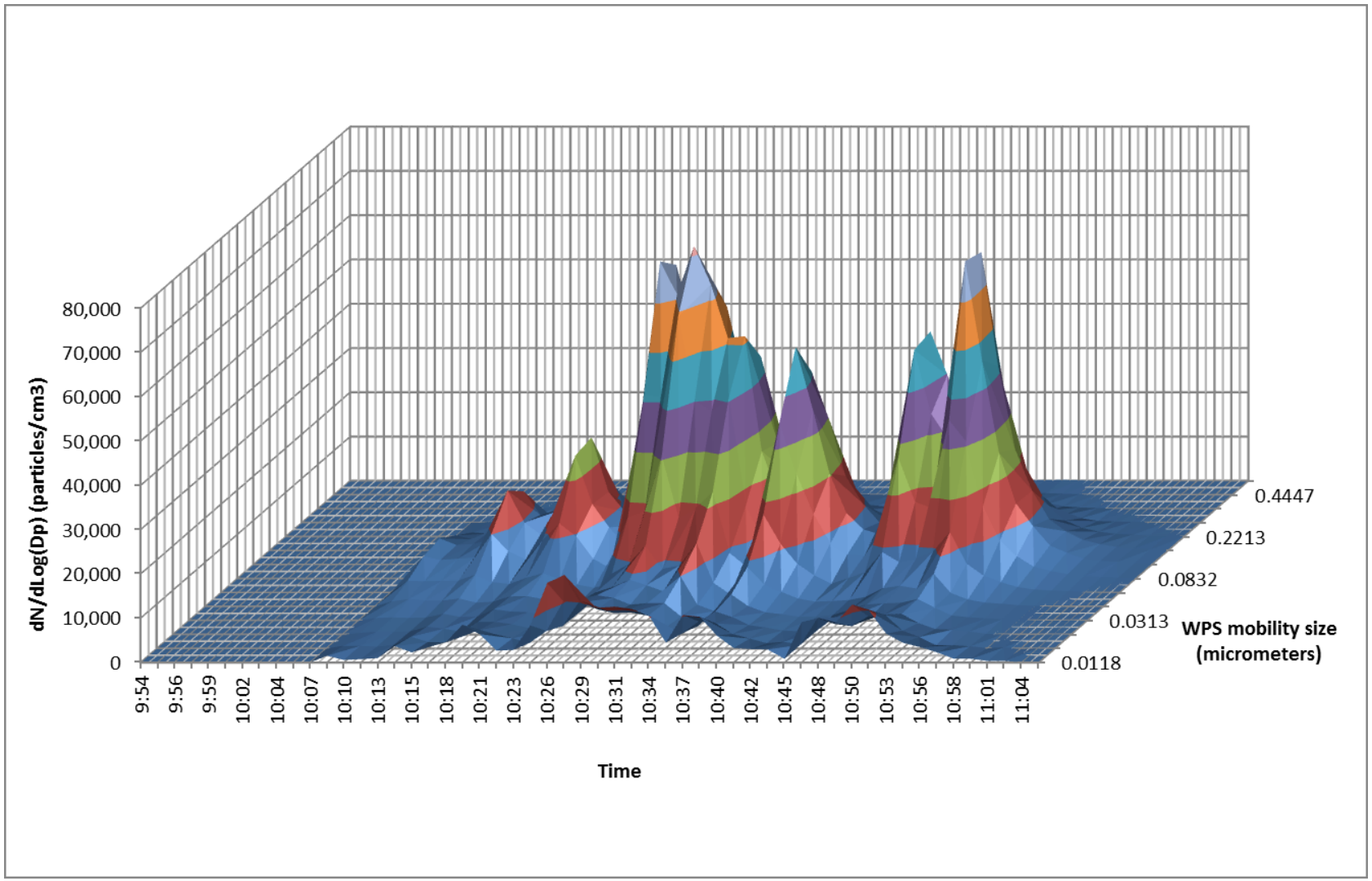


Figure 4.14 Airborne Particle Size Distribution by Time at Location A of Thighplasty 2 (Without LEV), as Measured by the WPS



Similar to the particle size distributions observed during the brachioplasties, a single major peak in particles sized slightly larger than 0.1 µm in diameter was measured during the thighplasties. The average size distribution during the thighplasty with LEV had a CMD of 0.042 (GSD: 2.5) as seen in Figure 4.15 (left). The average size distribution during the thighplasty without LEV use had a CMD of 0.091 µm (GSD: 2.33) as shown in Figure 4.15 (right). Similarly, this pattern is visible at specific points in time during active plume production during each portion of the surgery. At 10:29 A.M. during the leg 2 portion of the surgery, a distribution with CMD of 0.084 µm (GSD: 2.15) was visible (Figure 4.16, right) during the thighplasty without LEV; no peak was present at 9:02 A.M. when LEV was being used (Figure 4.16, left).

Figure 4.15 Average Particle Size Distribution of Surgical Plume Particles During Thighplasties, With LEV Use (left) and Without LEV Use (right), as Measured by the WPS

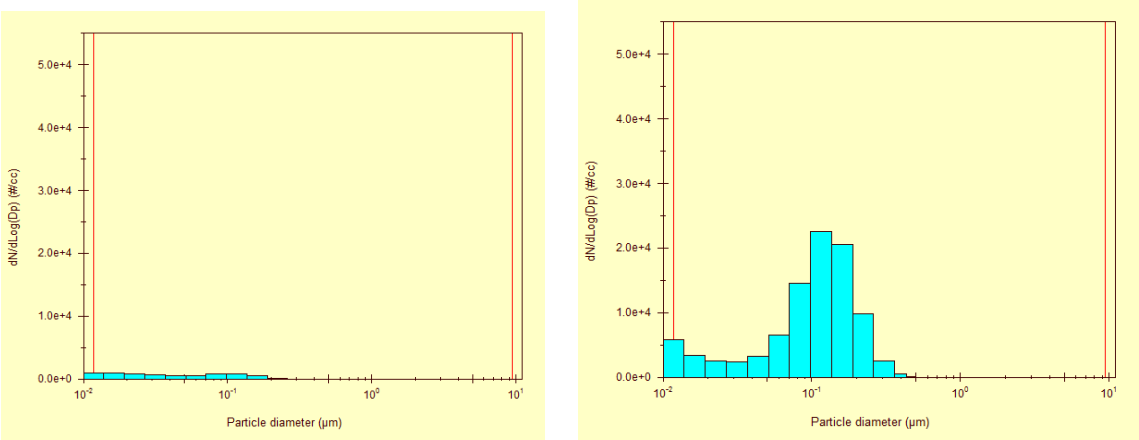
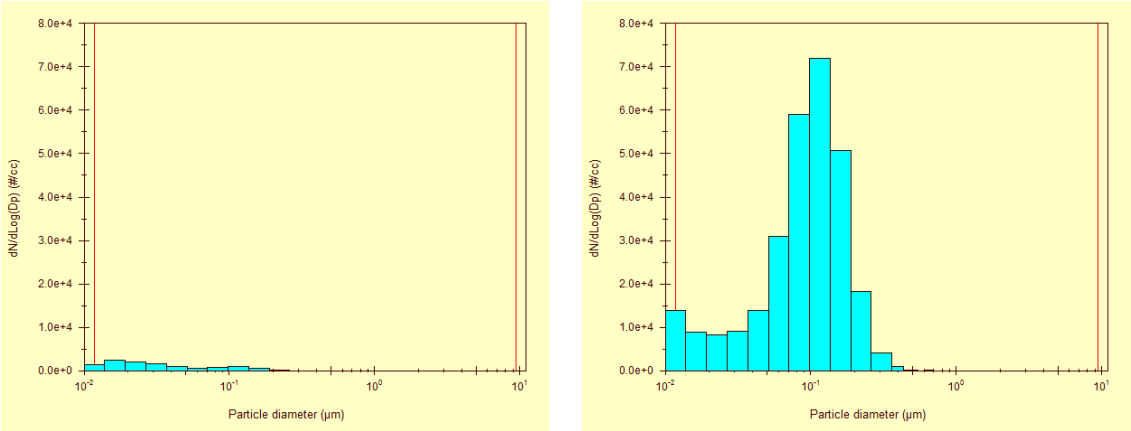


Figure 4.16 Comparison of Particle Size Distributions of Surgical Plume Particles at Specific Points in Time During Thighplasties, With LEV Use (left, 09:02 A.M.) and Without LEV Use (right, 10:29 A.M.)



Breast Augmentation

At various points during the surgical work for the breast augmentation procedure, intermittent use of both the bovie and plasma jet occurred. Power settings for the bovie were 40W (cut)/40W (coag). For the plasma jet, a 70 setting was used for cutting and coagulating tissue; the setting was lowered when the surgeon used the plasma jet to treat the dermal tissue for antibacterial purposes. The lengths of time in which the surgeon used either the bovie or the plasma jet were typically only seconds long rather than the repeated and sustained use of plume producing instruments experienced during the brachioplasties and thighplasties. The geometric mean particle number concentration at Location A near the surgical table during the breast augmentation was measured at 230 particles/cm^3 (GSD: 3.78) [peak: 3,941 particles/cm^3] compared to 245 particles/cm^3 (GSD: 3.89) [peak: 6,813 particles/cm^3] at location B near the door and 232 particles/cm^3 (GSD: 3.78) [peak: 2,802 particles/cm^3] at location C near the exhaust register. Calculated correlation coefficients showed a very strong positive relationship between the concentrations in locations A and C (0.917); less strong positive relationships were

observed between locations A and B (0.834) and between locations B and C (0.699). Paired t-tests indicated that there were no statistically significant differences in the mean number concentrations between any of the pairs of locations: A and C (p=0.8826); A and B (p=0.5413); and B and C (p=0.7055). See Figure 4.17 for boxplots of the concentrations measured by the three instruments.

Figure 4.17 Boxplots of Particle Number Concentrations (y axis: particles/cm^3) Measured by the CPC1 (Location A), CPC2 (Location C), and PTRAK (Location B) During Breast Augmentation, Without LEV Use

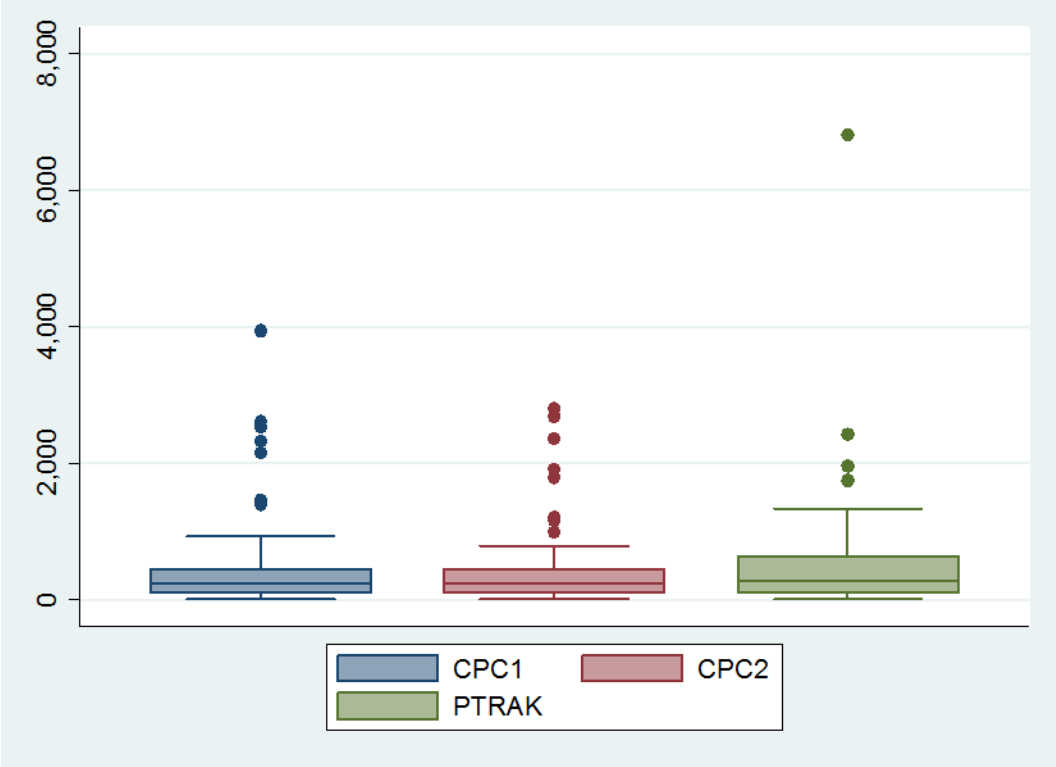


Figure 4.18 shows real-time measurements of particle number concentrations at locations A, B, and C through the time period of surgical work on the breast augmentation procedure. Unlike the brachioplasty and thighplasty procedures which had more sustained bovie and Plasma Jet use, these instruments were only used in short and intermittent pulses during this procedure.

The time period during which the bovie and Plasma Jet were used corresponds to 02:17–03:02 P.M. The highest peaks in particle number concentration measured at any of the locations corresponded to the two instances (02:57 P.M. and 03:02 P.M.) when the surgeon used the Plasma Jet for its antibacterial properties rather than to cut the tissue. At these times, the Plasma Jet was swept across the surface of the dermal breast tissue at a lower setting for a more sustained period of time compared to when it was used to cut or coagulate tissue.

Figure 4.18 Airborne Particle Concentration (particles/cm^3) During Breast Augmentation, Without LEV Use as Measured by the CPCs and PTrak

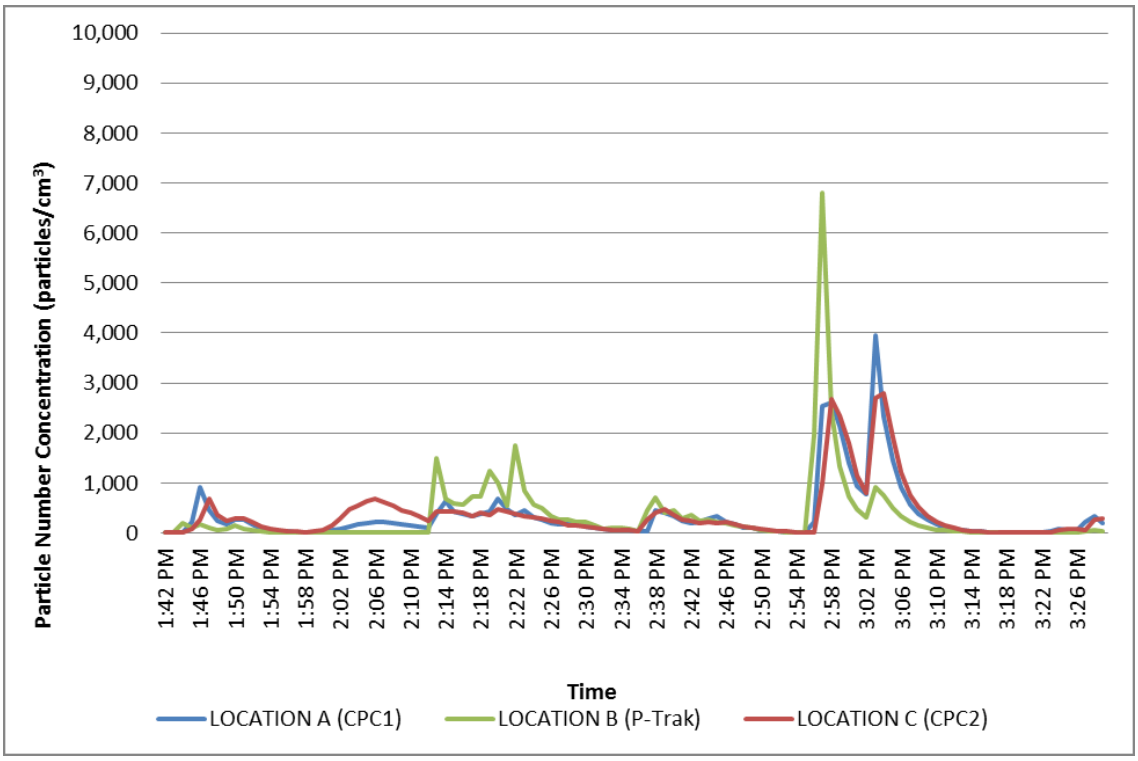


Figure 4.19 shows the size distribution of particles produced during the surgery from the time immediately before the production of surgical plume through the last instance of plume production in the surgery.

Figure 4.19 Airborne Particle Size Distribution by Time at Location A During Breast Augmentation, Without LEV Use, as Measured by the WPS

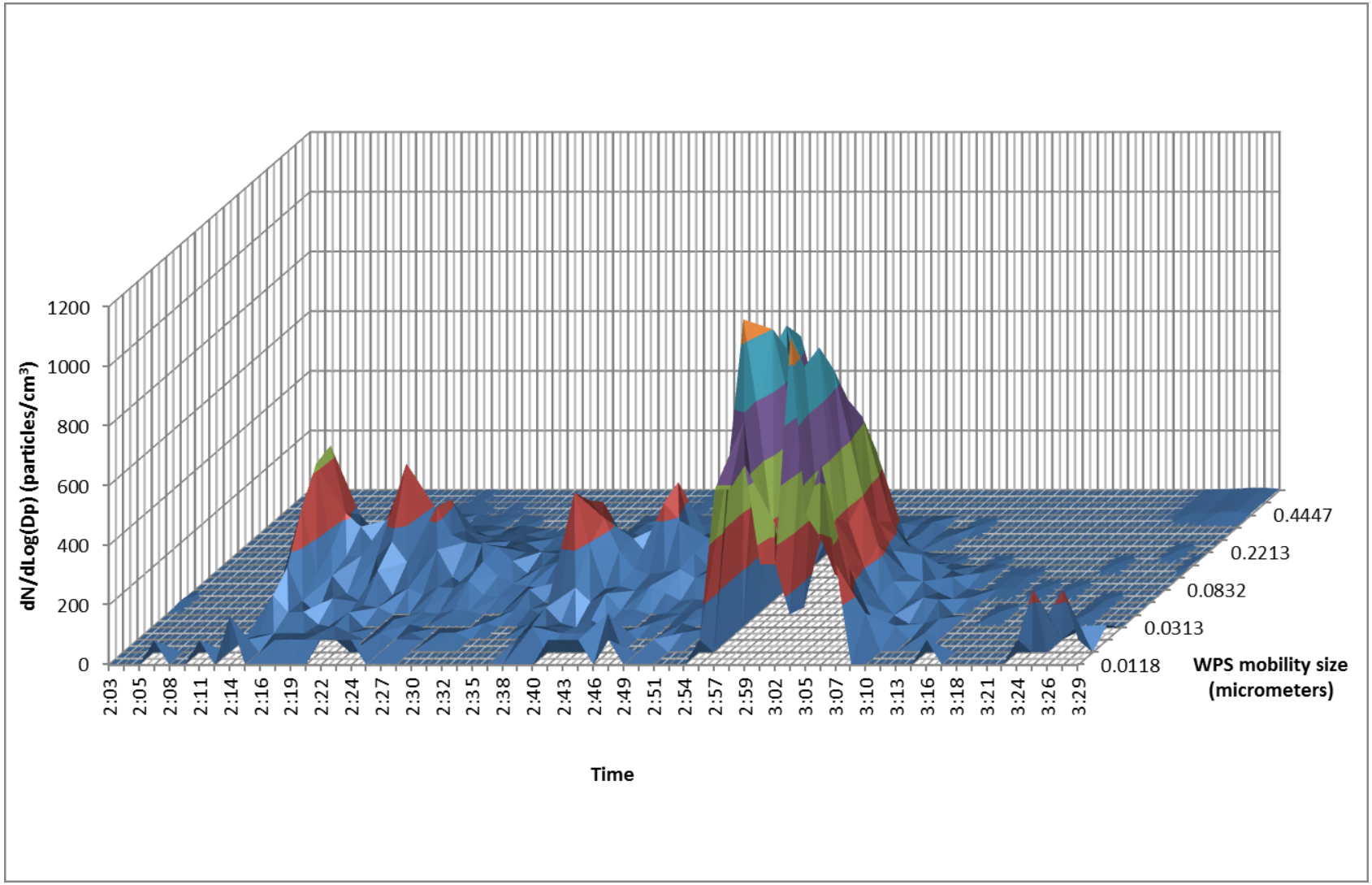


Figure 4.24 shows particle size distributions at specific points in time during the surgery. These points in time were selected to correspond with periods of plume production during the surgery. Figure 4.24(a) represents a measurement collected at 2:20 P.M., after two instances of short bursts of Plasma Jet use at a higher setting for cutting and coagulating. Figure 4.24(b) represents a measurement collected at 2:43 P.M., after several instances of shorts bursts of bovie use. Figure 4.24(c) represents a measurement collected at 2:58 P.M., after a more sustained use of the Plasma Jet at a lower setting for antibacterial purposes. Each measurement revealed a single major peak as shown in the Figures. CMDs describing particle size distributions were 0.098 μm (GSD: 2.00) and 0.099 μm (GSD: 2.36) for the measurements during cutting/coagulating tissue by Plasma Jet and bovie, respectively (Figures 4.20a and b). However, a shift to a smaller diameter particle size was observed during the measurement of plume particles after using the Plasma Jet for antibacterial purposes. For this distribution, the CMD was 0.035 μm (GSD: 2.02) (Figure 4.20c). Peak number concentration during the antibacterial use of the Plasma Jet was at least two times that of the other two measurements for bovie use and cutting using the Plasma Jet. Figure 4.24(d) shows the average size distribution of particles measured throughout the surgery. No identifiable peak can be observed, with similar concentrations of particles in sizes ranging from 0.01–0.11 μm; CMD of the size distribution was 0.044 μm (GSD: 2.45).

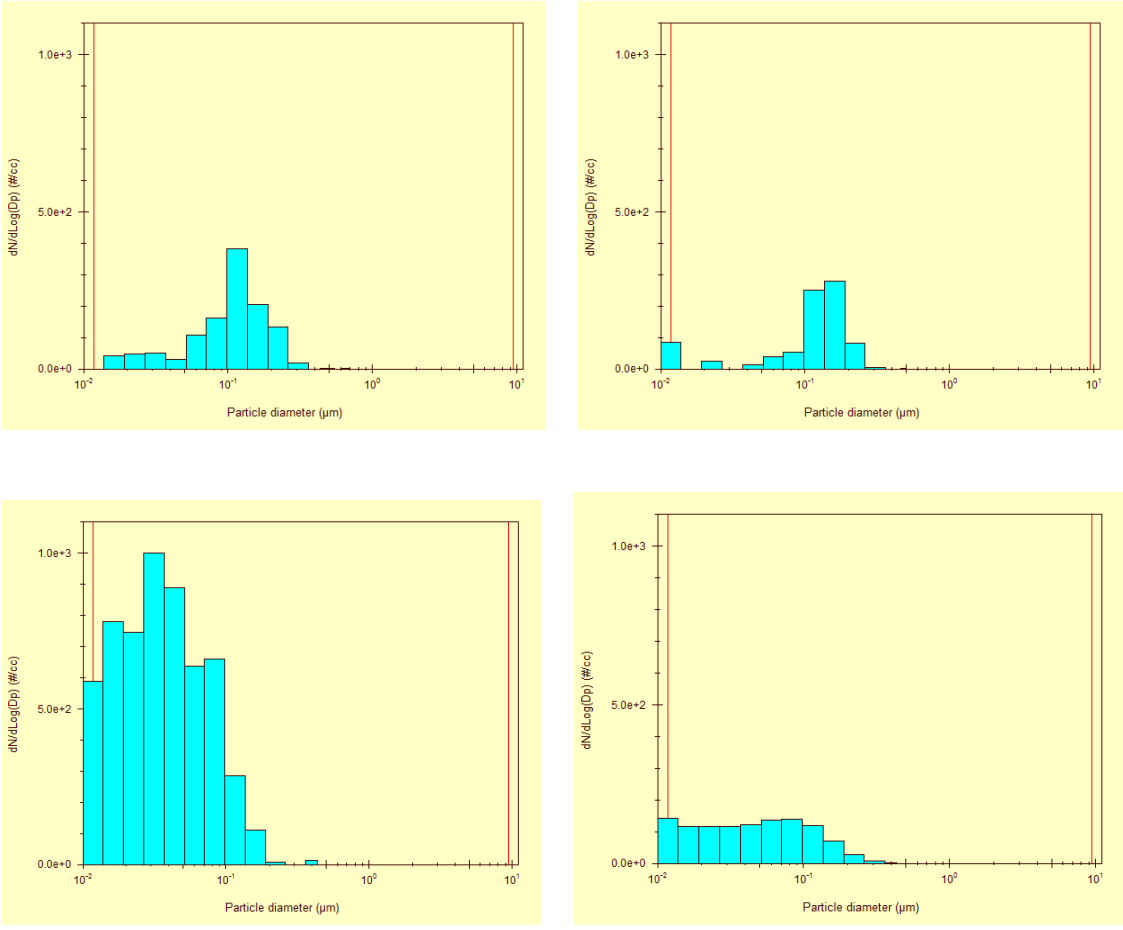
Figure 4.20 Particle Size Distributions of Surgical Plume Particles, as Measured by the WPS

a) [upper left] at a Specific Point in Time During Breast Augmentation Using the Plasma Jet, Cut Mode (2:20 P.M.)

b) [upper right] at a Specific Point in Time During Breast Augmentation Using the Electrocautery Knife, Cut Mode, (2:43 P.M.)

c) [lower left] at a Specific Point in Time During Breast Augmentation Using Plasma Jet, Antibacterial Use (2:58 P.M.)

d) [lower right] averaged During Breast Augmentation (2:17-3:12 P.M.)



Removal of Necrotic Tissue

During the surgical work for the removal of necrotic tissue surrounding a patient's nipple, the bovie was the sole energy-based instrument used for cutting and cauterizing. During the course of the procedure, the bovie was only used twice, approximately four minutes apart, and for periods of approximately 20 seconds each. The geometric mean number concentration at location A near the surgical table was measured at 1,857 particles/cm^3 (GSD 3.22) [peak: 10,560 particles/cm^3] compared to 890 particles/cm^3 (GSD: 2.17) [peak: 2,934 particles/cm^3] at location B near the door. The correlation coefficient calculated showed a strong positive relationship between the concentrations in the two locations (0.856). Paired t-tests indicated, however, that there was a statistically significant difference in the mean number concentrations between locations A and B (p=0.0005). See Figure 14.21 for boxplots of the concentrations measured by the two instruments.

Figure 4.21 Boxplots of Particle Number Concentrations (y axis: particles/cm^3) Measured by the CPC (Location A) and PTRAK (Location B) During Necrotic Tissue Removal

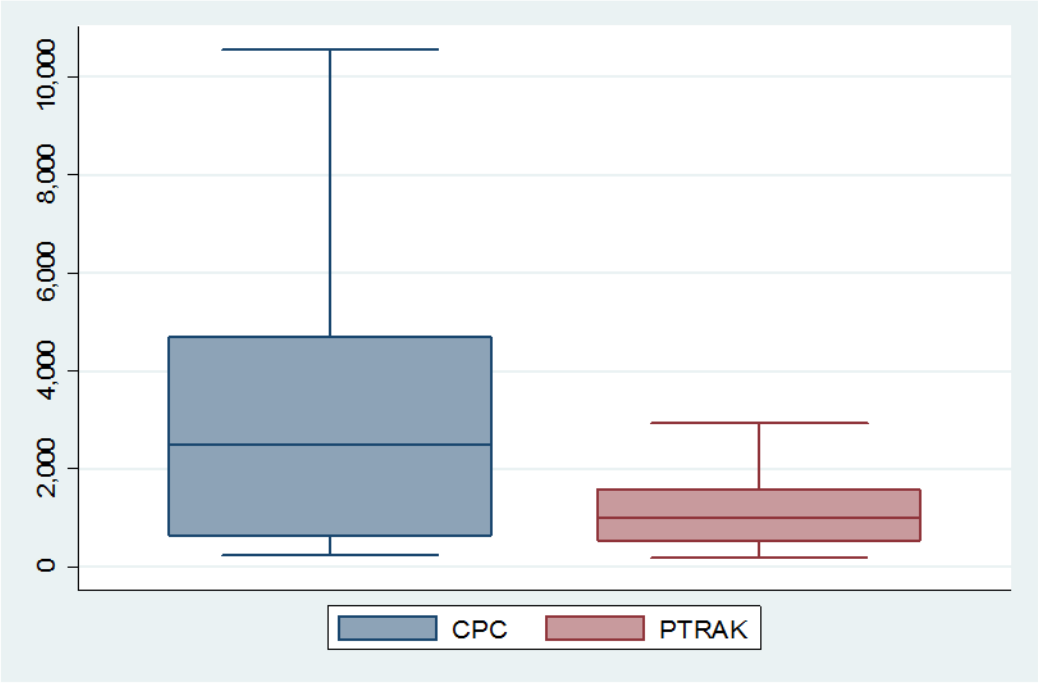


Figure 4.22 shows real-time measurements of particle number concentrations at locations A and B through the time period of surgical necrotic tissue removal. The time period during which the bovie was used corresponds to 12:33–12:37 P.M., with a twenty-second pulse of bovie use at the start and finish of that time frame. Peaks in particle number concentration can be seen at those two times predominantly at location A and only slightly at location B. Activities outside the time range when the bovie was used may have caused increases in particle number concentrations at those times. At 12:22 P.M., additional draping was unfolded and draped above the patient's head near location A; this additional draping was removed around 12:50 P.M. Increases in particle number concentration at these times are, therefore, most likely due to these activities rather than being reflective of increased surgical plume particles.

Figure 4.22 Airborne Particle Concentrations (y axis: particles/cm^3) During Necrotic Tissue Removal Including Plume Production (12:33-12:37 P.M.), as Measured by a CPC and PTrak

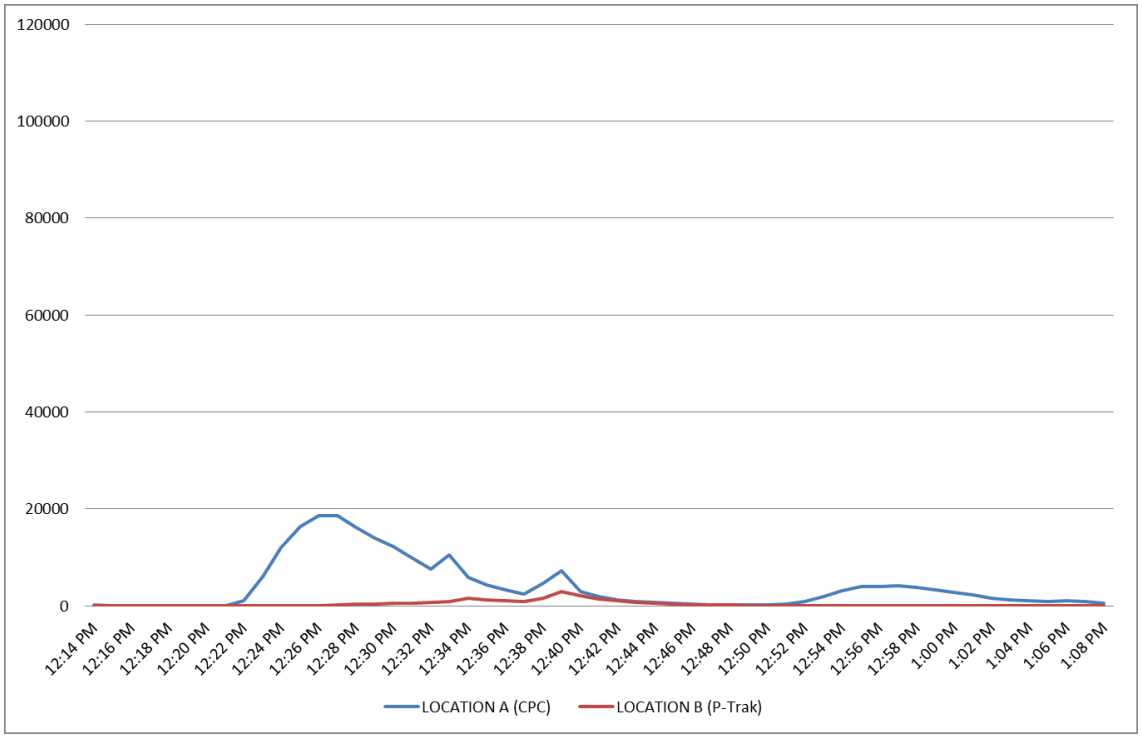


Figure 4.23 shows the particle size distribution during the necrotic tissue removal procedure from the time immediately before the first plume production through the end of the procedure. At the beginning of this period from 12:26–12:38 P.M., decreasing concentrations of the smallest particles can be observed. Presence of these particles precedes surgical plume production and reflects particles aerosolized from the draping of the patient. Peaks of the number of particles of larger diameters can be observed at the two points in time during the surgery when the bovie was used and surgical plume was produced.

Figure 4.23 Airborne Particle Size Distribution by Time at Location A During Necrotic Tissue Removal Without LEV Use, as Measured by the WPS

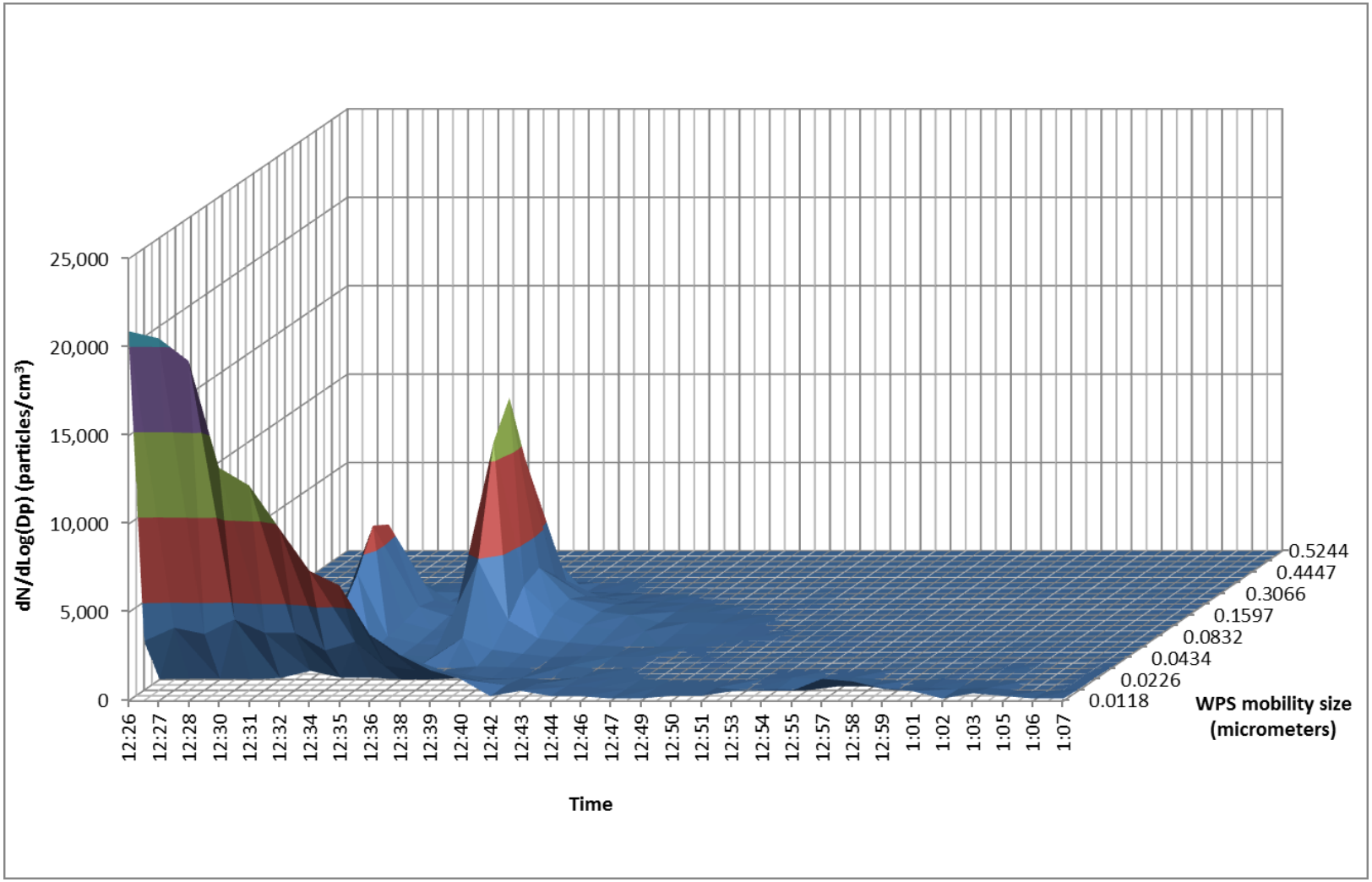
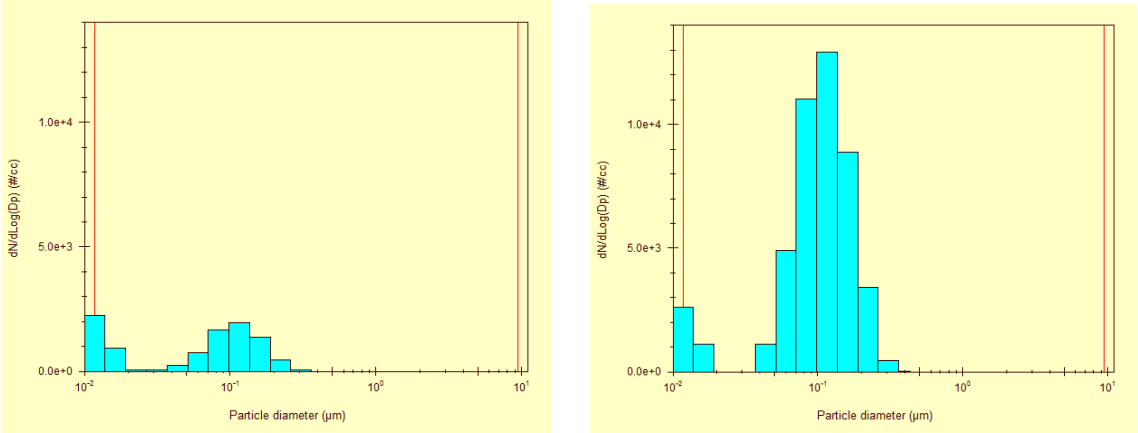


Figure 4.24 (left) shows the average size distribution of particles from throughout the surgery (CMD: 0.054 µm; GSD: 2.87), heavily influenced by particles generated by the draping. Figure 4.24 (right) shows the size distribution at 12:38 P.M., immediately after one of the 20-second bursts of bovie use. The CMD of particle number size distribution was 0.092 µm (GSD: 2.02), similar to that seen in the other surgical procedures after surgical plume production.

Figure 4.24 Average Particle Size Distribution of Surgical Plume Particles During Necrotic Tissue Removal (left) and at a Specific Point in Time (right, 12:38 P.M.)



Conclusions

Continuous particle number concentrations and particle size distributions were measured throughout several plastic surgery procedures with varied use of surgical plume producing instruments. While each of the surgical procedures was different, several important findings were documented. Particle number concentrations measured at various locations in the operating room showed that the level of occupational exposures to surgical plume may reflect work location in the room itself. During a procedure with higher levels of surgical plume produced such as the thighplasty, concentrations near the surgical table at the anesthesiologist

station were significantly higher than at the circulating nurse's station at the periphery of the room near the door; however, there was no significant difference in particle concentrations near the surgical table compared to the periphery of the far side of the room near the exhaust vents, reflecting the flow of air from the supply registers above the surgical table to the exhaust vents. Air changes rates of 21–24 per hour were measured in the operating rooms where these procedures took place. Ventilations rates such as these provided fairly rapid reductions in even the highest surgical plume concentrations measured near the surgical table back to near background levels typically within approximately 10–15 minutes of the last time point of surgical plume production.

Measurement of particle number concentrations during procedures in which LEV was used showed the effectiveness of the LEV at capturing and reducing concentrations of particles to near background levels during plume production compared to procedures in which no LEV was used, greatly reducing the exposure to surgical plume of employees in the operating room. The use of LEV achieved reductions in geometric mean particle number concentrations up to 89% near the surgical table, 92% near the circulating nurse's desk, and 84% on the side of the room near the exhaust. For peak particle number concentrations, these reductions were up to 93% near the surgical table, 94% near the circulating nurse's desk, and 85% on the side of the room near the exhaust.

Particle number size distributions were characterized and showed that bovie and plasma jet use for cutting and cauterizing produced particles with CMDs consistently centered around 0.09 µm (GSD: 2.3) to 0.11 µm (GSD: 1.8); however, when the plasma jet was used for antibacterial purposes, particles of a smaller CMD around 0.03 µm (GSD: 2.0) were produced. The confirmation of particles of this size distribution yields important information as to the ease of

respirability of these surgical plume particles into the deepest regions of the lungs. While the concentrations of inhaled surgical plume particles that induce health impacts during repeated, full-shift, and daily exposures is currently unknown, the study demonstrates the significant impact that the introduction of LEV at the point of plume production can have on the concentrations to which workers in all areas of the operating room are exposed.

Limitations in the study are acknowledged in that only a small number of varied procedures were measured in one hospital location, they were performed by a single board-certified surgeon, and they may not be reflective of all possible surgical plume exposures. However, it adds to and reinforces similar results from the limited scientific literature in this area. These results further the understanding of surgical plume particles produced through energy-based cutting and cauterizing instruments and the occupational exposures to those particles, while providing additional information on the effectiveness of controls such as general exhaust and LEV on those exposures.

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Chapter 5 Conclusions

Summary of Findings

The three studies presented in this dissertation provide new insights into particle characteristics produced by a variety of surgical cutting and cauterizing instruments as well as occupational exposures resulting from such plume production. The first study presents information comparing several plume characteristics measured at the point of plume production during controlled trials. The second study focuses on resultant differences in particle characteristics at the personal breathing zone level of an individual working at the surgical table during controlled trials to more closely represent true occupational exposure levels. The final study describes the results of exposure assessments during selected plastic surgery procedures.

The study presented in Chapter 2 provides novel evidence of differences in ultrafine particle plume characteristics such as particle size distributions and number, respirable mass, and active surface area concentrations. Particle size distributions measured at the point of generation ranged from the smallest (CMD: 0.034 μm; GSD: 1.48) generated by the harmonic scalpel to the largest (CMD: 0.095 μm; GSD: 7.99) generated by the electrocautery knife. GM particle number concentrations produced by the instruments ranged from 7.11E+05 particles/cm^3 (GSD: 5.68) produced by the harmonic scalpel to 7.69E+07 particles/cm^3 (GSD: 2.73) produced by the CO_2 laser. The instruments that produced the lowest GM respirable mass concentrations, the harmonic scalpel and the Plasma Jet, were also those that were shown to have the smallest particle size diameters; the range of observed GM respirable mass concentrations was 6.29E-02 mg/m^3 (GSD: 8.26) [Plasma Jet] to 1.58E+02 mg/m^3 (GSD: 3.18) [CO_2 laser]. While occupational hazards may depend on aspects such as particle number and respirable mass concentrations,

the research showed that the toxicity of particles based on particle-bound compounds such as polycyclic aromatic hydrocarbons differs with those produced by the electrocautery knife having higher quantities of such compounds per active surface area compared to particles produced by the other instruments. The use of a local exhaust ventilation control built into one of the instruments, the electrocautery knife, was shown to produce significant reductions in particle number and respirable mass concentrations, measured both at the point of generation and in the periphery of the operating room.

Chapter 3 identified surgical plume characteristics relevant to actual occupational exposures as they were measured at the level of the personal breathing zone of an individual standing at the surgical table closest to where the plume was generated by the various instruments tested on both human dermal and adipose tissue. Particle size distributions measured at this location reflected those seen when measured at the point of production, indicating this characteristic changes only minimally as it travels from the point of production to the PBZ of an individual standing at the surgical table. The harmonic scalpel produced the smallest CMDs, 0.028 µm (GSD: 2.0) and 0.038 µm (GSD: 3.8), for dermal and adipose tissue respectively. The electrocautery knife produced the largest CMDs in the range of 0.129 µm (GSD: 2.4) to 0.190 µm (GSD: 2.2) for dermal tissue and 0.088 µm (GSD: 3.1) to 0.116 µm (GSD: 2.1) for adipose tissue. Particle number concentrations were considerably diluted by the time they reached the PBZ compared to those measured the point of generation; however the harmonic scalpel still produced the lowest GM concentrations, 220 particles/cm^3 (GSD: 1.92), compared to 108,632 particles/cm^3 (GSD: 1.33) for the Plasma Jet, which may present the greatest exposure concern if based on particle number concentration alone.

In contrast to the studies in Chapters 2 and 3, the data in Chapter 4 represents real-world exposure measurements. These assessments were conducted during surgical procedures in which the electrocautery knife and Plasma Jet were used to varying extents. The results indicate that the controlled trials well represent the conditions measured during actual surgeries. CMDs of particles measured during use of the Plasma Jet and electrocautery knife ranged from 0.91 µm (GSD: 2.3) to 0.105 µm (GSD: 1.8) across the multiple surgeries measured. However, when the Plasma Jet was used for antibacterial purposes rather than cutting, particles of a smaller CMD, approximately 0.03 µm (GSD: 2.0), were measured. The confirmation of particles of this size distribution yields important information as to the ease of respirability of these surgical plume particles into the deepest regions of the lungs. Peak particle number concentrations for the procedures with the greatest concentrations produced between 96,00 and 134,000 particles/cm^3 at the measurement location located closest to the surgical table. LEV use during the highest plume producing procedures resulted in substantial decreases in operating room particle concentrations.

Strengths and Limitations

Strengths of the study included the use of aerosol monitoring equipment that measured a wide range of aerosol size distributions, measurements in multiple locations of the operating room, the use of human tissue for plume generation, and surgical cutting techniques used by the surgeon that approximated how he uses the cutting instruments in real surgeries. However, several limitations were also inherent in this study of surgical plume particles, as alluded to in previous chapters. Studies of both the controlled trials of plume generation and the selected surgical procedures monitored took place in one hospital with one surgeon conducting all

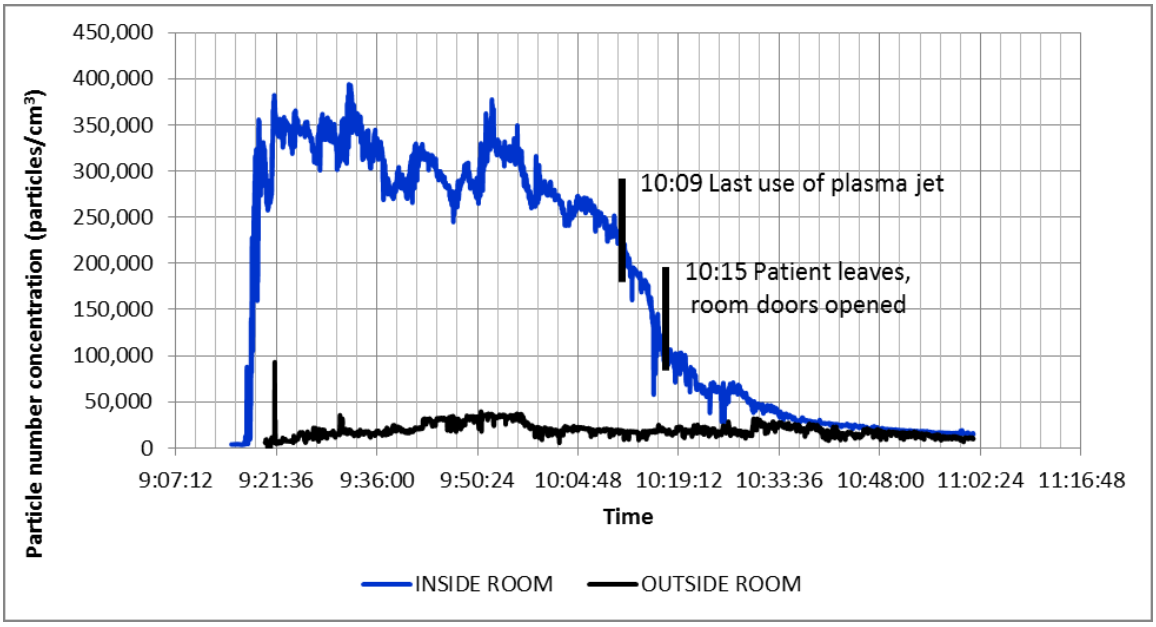
procedures. Surgical technique may differ between surgeons and OR ventilation parameters at other hospitals may differ than those observed in this location, both of which may impact plume characteristics compared to those observed in this study. Additionally, for each of the surgical instruments assessed, a wide variety of variations can be changed, including the tool tip for some of the surgical instruments and the power levels used by the surgeon for various needs in the surgery. For purposes of this work, commonly used variations were selected for evaluation for each instrument, but may not be completely representative of results with altered variables for each instrument. Finally, tissue types such as muscle were not included in the study which may produce particles with differing characteristics compared to dermal and adipose tissue.

Future Studies

A variety of areas exist for future study of occupational surgical plume exposures. While this study focused on exposures to surgical plume particles in a hospital operating room environment, there is the need for future studies to focus on the potential for exposures in non-hospital operating room locations. Because these surgical instruments can also be used during procedures in surgeons' private operating suites often located in office environments rather than in hospitals, exposures may differ drastically in these locations, particularly due to different general ventilation requirements in hospital operating rooms versus these office space locations. Preliminary measurements were made also at the private office practice offsite from the hospital maintained by the surgeon who conducted the procedures studied in Chapters 2–4. General ventilation in this room was provided by a typical residential heating, ventilating, and air conditioning (HVAC) unit that provided little filtration of supply air compared to the HEPA filtration provided in the operating room environment and considerably reduced number of

ACH. Particle number concentrations were measured both in the treatment room as well as outside of the room during a treatment in which the surgeon used the Plasma Jet on low level on the facial dermal tissue of a client for cosmetic purposes rather than to cut or cauterize tissue. Peak particle number concentrations reached nearly 400,000 particles/cm^3, far higher than the highest peak of 136,400 particles/cm^3 measured during the surgical procedures monitored in the hospital operating room. Additionally, the concentrations of airborne particles appeared to be sustained at these concentrations for a longer period of time compared to the hospital operating room environment. See Figure 5.1 for a depiction of the real-time particle number concentrations measured during this treatment procedure. Because of the inherent differences in these two environments, further exposure assessment research is needed for locations that do not provide the general ventilation of a hospital operating room as exposures could be increased as a result of this variable.

Figure 5.1 Real-time Particle Number Concentrations During a Treatment Procedure in a Non-Hospital Treatment Office as Measured by CPCs



The particulate exposures experienced by operating room personnel are only one component of the potential health hazard associated with plume. The potential biological component of plume, namely viable and infectious bacteria and viruses, are an important consideration as well. Hallmo et al. [1991] reported on a case of laryngeal papillomatosis with human papilloma virus (HPV) DNA contracted by a laser surgeon. Calero et al. [2003] also concluded that a case of laryngeal papillomatosis was occupationally related after a virologic analysis showed high probability of a correlation between the case and occupational exposure to HPV DNA. More recently, Rioux et al. [2013] reported on two cases of HPV-16 positive oro-pharyngeal squamous cell carcinomas diagnosed in laser surgeons after having long-term occupational exposures to laser plumes. The possibility of microbiologic aerosols in the plume has been investigated; viral HPV DNA has been found to be present in surgical plume produced by CO_2 laser. [Garden, O'Banion et al. 1988; Sawchuck, Weber et al. 1989; Kashima, Kessis et al. 1991]. Additionally, bovine papilloma virus collected in plume produced by CO_2 laser has been shown to transmit fibropapillomas in inoculated cattle. [Garden, O'Banion et al. 2002]. However, an assay to determine the viability and infectivity potential of HPV virions in surgical plume is currently not readily available. Further research in the development of such an assay would prove valuable in assessing potential infectious exposures for this virus. In spite of the lack of such an assay, techniques for assessing the possible exposure of operating room personnel should be pursued. Such techniques must demonstrate the presence of intact viral particles, important when considering the possibility of infectivity, rather than simply viral DNA and they must demonstrate that personnel are being exposed by the inhalation route of transmission.

In addition to the potential biological components in surgical plume, concerns of chemical compounds produced through the combustion process have been expressed. In a recent study, Fitzgerald et al. compared analyses of potentially carcinogenic or irritant volatile hydrocarbon concentrations produced by ultrasonic scalpels and electrocautery knives in human laparoscopic surgeries, and compared them both with concentrations of those compounds found in cigarette smoke and urban city air control samples. Results suggested that both electrocautery and ultrasonic dissection were significantly lower in concentrations of these compounds compared to cigarette smoke. Ultrasonic dissection produced non-significantly lower concentrations of these compounds compared to electrocautery, with concentrations produced by the ultrasonic scalpel similar to those of city air. Despite lower levels, the authors comment that cumulative exposures may still pose a risk. [Fitzgerald, Malik et al. 2012]

As part of the controlled trials of plume generation for this study, we collected preliminary data on chemical combustion by-products that are produced by the various surgical instruments included in our study. Air samples were collected using Summa® canisters at the point of generation during the use of the four different surgical instruments and analyzed for the presence of a variety of volatile hydrocarbons. See Table 5.1 for a summary of results of compounds detected. Concentrations of benzene and propene were the highest among the compounds detected and were generally higher in plume produced by electrocautery and Plasma Jet compared to the CO_2 laser and harmonic scalpel. The use of a hand-held LEV appeared to considerably reduce these concentrations as well. Ambient air concentrations in the operating room for these compounds were also measured via Summa® canisters. See Table 5.2 for a summary of these concentrations during plume production trials. The Summa® canisters were placed three feet away from the surgical smoke generation in the operating room (i.e., 'OR table'); 15 feet away from the surgical smoke generation (i.e., 'nurse desk'); and

in a control operating room where no surgical plume was generated (i.e., 'OR #2'). Flow rate was set at approximately 0.05 liters per minute with a 30 minutes sampling time per canister. With the exception of isopropyl alcohol, very few compounds were detected at these locations. While these results are preliminary, they do point to future work that can be undertaken to better characterize personal exposures to chemical combustion by-products that may significantly differ by surgical instrument and ventilation parameters.

Concluding Remarks

The research conducted points to a potential occupational exposure which requires further investigation to assess the magnitude of exposures and the range of potential health effects. While the minimum concentrations of inhaled surgical plume particles experienced during repeated, full-shift, and daily exposures required to induce health impacts is currently unknown and requires further research, the study results indicate the primary importance of implementation and proper use of a control in limiting occupational exposures to surgical plume particles during surgical procedures. The types of local exhaust ventilation controls studied are recommended to prevent future exposures, particularly with the surgical instruments that were shown to generate the highest concentrations of surgical aerosols.

Table 5.1 Summary of Volatile Hydrocarbon Concentrations (ppb) Measured at the Point of Production During Use of Various Surgical Instruments, With and Without Use of LEV

	Electrocautery		**Plasma Jet**		**CO_2 laser**	**Harmonic scalpel**	**LEV on**		**Control**
Analyte	**cutting**	**coagulating**	**cutting**	**coagulating**	**cutting**	**cutting**	**electrocautery**	**Plasma Jet**	**hallway**
1,3-Butadiene	780	2,700	1,100	71	320	6	<LOD	<LOD	<LOD
2-Butanone	22	98	140	120	20	1	<LOD	<LOD	<LOD
2-Hexanone	<LOD	<LOD	16	25	<LOD	<LOD	<LOD	<LOD	<LOD
Acetone	95	240	290	230	48	13	3	3	2
Benzene	140	1,400	2,400	1,600	85	3	<LOD	<LOD	<LOD
Chloromethane	79	46	<LOD	<LOD	41	<LOD	<LOD	<LOD	<LOD
Cyclohexane	<LOD	12	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
Ethylbenzene	23	68	350	100	12	<LOD	<LOD	<LOD	<LOD
Heptane	30	120	57	52	<LOD	<LOD	<LOD	<LOD	<LOD
Hexane	43	160	86	57	<LOD	<LOD	<LOD	<LOD	<LOD
Isopropyl Alcohol	120	150	<LOD	<LOD	<LOD	37	57	21	10
m & p-Xylene	<LOD	17	67	22	<LOD	<LOD	<LOD	<LOD	<LOD
Methylene Chloride	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	4	<LOD
o-Xylene	<LOD	<LOD	36	13	<LOD	<LOD	<LOD	<LOD	<LOD
Propene	2,900	3,700	3,400	2,600	960	11	<LOD	<LOD	<LOD
Styrene	30	100	11	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
Toluene	87	370	1,400	450	39	1	<LOD	<LOD	<LOD

Table 5.2 Summary of Results of Volatile Hydrocarbon Concentrations (ppb) Measured in Ambient Air in Operating Rooms during Use of Various Surgical Instruments Without LEV Use

	Electrocautery			**Plasma Jet**		**CO_2 laser**	**Harmonic scalpel**		**Control**
Analyte	**OR table**	**nurse desk**	**nurse desk**	**OR table**	**nurse desk**	**OR table**	**OR table**	**nurse desk**	**OR#2**
1,3-Butadiene	<LOD	<LOD	<LOD	<LOD	<LOD	3	<LOD	<LOD	<LOD
Acetone	<LOD	8	<LOD	9	<LOD	10	8	<LOD	<LOD
Carbon Disulfide	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	2	<LOD
Isopropyl Alcohol	150	410	570	250	1,100	270	160	500	87
Methylene Chloride	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	3	<LOD
Propene	<LOD	<LOD	<LOD	<LOD	<LOD	7	<LOD	<LOD	<LOD

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Curriculum Vitae

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