Title

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Journal

The Permanente journal, 21(1)

ISSN

1552-5767

Authors

Jones, Stephanie B
Munro, Malcolm G
Feldman, Liane S
et al.

Publication Date

2017

DOI

10.7812/tpp/16-050

Peer reviewed

Fundamental Use of Surgical Energy (FUSE): An Essential Educational Program for Operating Room Safety

Stephanie B Jones, MD; Malcolm G Munro, MD, FACOG, FRCS(c); Liane S Feldman, MD, FACS, FRCS; Thomas N Robinson, MD, MS, FACS; L Michael Brunt, MD, FACS; Steven D Schwaitzberg, MD, FACS; Daniel B Jones, MD, MS, FACS; Pascal R Fuchshuber, MD, FACS

Perm J 2017;21:16-050

E-pub: 01/13/2017

https://doi.org/10.7812/TPP/16-050

ABSTRACT

Operating room (OR) safety has become a major concern in patient safety since the 1990s. Improvement of team communication and behavior is a popular target for safety programming at the institutional level. Despite these efforts, essential safety gaps remain in the OR and procedure rooms. A prime example is the use of energy-based devices in ORs and procedural areas. The lack of fundamental understanding of energy device function, design, and application contributes to avoidable injury and harm at a rate of approximately 1 to 2 per 1000 patients in the US. Hundreds of OR fires occur each year in the US, some causing severe injury and even death. Most of these fires are associated with the use of energy-based surgical devices.

In response to this safety issue, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) developed the Fundamental Use of Surgical Energy (FUSE) program. This program includes a standardized curriculum targeted to surgeons, other physicians, and allied health care professionals and a psychometrically designed and validated certification test. A successful FUSE certification documents acquisition of the basic knowledge needed to safely use energy-based devices in the OR. By design FUSE fills a void in the curriculum and competency assessment for surgeons and other procedural specialists in the use of energy-based devices in patients.

INTRODUCTION

Adverse events caused by the use of energy-based devices in surgical operating rooms (ORs) are a daily occurrence. Millions of patient interventions occur every year in ORs and procedure suites throughout the US. Many of these invasive procedures carry a substantial risk for the patient and OR team and can lead to potentially serious complications. A large body of evidence exists on human factors underlying those risks. Many safety programs recently have been developed to address risks generated by a lack of human interaction, the increasingly challenging patient disease burden, and inadequate communications within the OR team. Heightened public awareness about safety in the OR has led to the adoption of a variety of performance-improvement programs and tools, including checklists and team training.[1] Hospitals have implemented extensive training programs, and physicians and staff are required to learn the skills needed to improve clinical outcomes and optimize patient safety.

Despite these efforts, a large gap in OR safety education and training remains on the topic of safe application of energy-based devices. From the first electrosurgical instrument invented more than 100 years ago to the most modern computer-driven device, serious harm and death of patients can result from their inappropriate use because of a lack of basic understanding of design, function, and application. Hundreds of OR fires, patient harm resulting from interference with implantable cardiac devices, and latent, life-threatening intraabdominal injuries could be avoided if this gap were addressed.[2-13]

Historical Perspective

For millennia the only available energy device for physicians was cautery. Cautery is the direct application of heat to tissue and has been used to attain hemostasis and destroy tumors since 3000 BC.[14] Approximately 100 years ago the first surgical instruments based on radiofrequency (RF) electrical energy were developed for surgical practice. The best known and one of the earliest devices successfully deployed for clinical use was developed by William T Bovie, who combined a "high-voltage" RF generator for fulguration with a lower-voltage generator designed to create a waveform that could be used to transect tissue.[15] By the end of the last century, isolated RF circuits and microprocessor-enhanced instrumentation were introduced, which have dramatically improved both safety and functionality for processes such as tissue transection and the sutureless sealing of relatively large blood vessels. Surgical and technologic innovations have generated an ever-increasing demand for, and number of, energy-based surgical devices from multiple vendors with a wide range of price and cost points.

Stephanie B Jones, MD, is an Associate Professor of Anesthesia at Harvard Medical School and Vice Chair of Education and Faculty Development at Beth Israel Deaconess Medical Center in Boston, MA. E-mail: sbjones@bidmc.harvard.edu. **Malcolm G Munro, MD, FACOG, FRCS(c),** is the Director of Gynecologic Services for Kaiser Permanente, Los Angeles at the Los Angeles Medical Center in CA. E-mail: mgmunro@aol.com. **Liane S Feldman, MD, FACS, FRCS,** is a Professor of Surgery and Director of General Surgery at McGill University Health Centre in Montreal, Quebec, Canada. E-mail: liane.feldman@mcgill.ca. **Thomas N Robinson, MD, MS, FACS,** is a Professor of Surgery at the University of Colorado Denver School of Medicine in Aurora. E-mail: thomas.robinson@ucdenver.edu. **L Michael Brunt, MD, FACS,** is a Professor of Surgery, Chief of the Section of Minimally Invasive Surgery, Director of the Minimally Invasive Surgery Fellowship, and Director of the Washington University Institute for Minimally Invasive Surgery at the Washington University School of Medicine in St Louis, MO. E-mail: bruntm@wudosis.wustl.edu. **Steven D Schwaitzberg, MD, FACS,** is a Professor of Surgery and Chair of the Department of Surgery at the University of Buffalo Jacobs School of Medicine and Biomedical Sciences in NY. E-mail: schwaitz@buffalo.edu. **Daniel B Jones, MD, MS, FACS,** is a Professor of Surgery at Harvard Medical School, Vice Chair of Surgery in the Office of Technology and Innovation, and Chief of Minimally Invasive Surgical Services at Beth Israel Deaconess Medical Center in Boston, MA. E-mail: djones1@bidmc.harvard.edu. **Pascal R Fuchshuber, MD, FACS,** is an Oncologic Surgeon at the Walnut Creek Medical Center, Interregional NSQIP Physician Lead for The Permanente Federation, and Associate Professor of Surgery at the University of San Francisco-East Bay in CA. E-mail: pascal.fuchshuber@kp.org.

This large and diverse armamentarium of energy-based devices has also drastically increased the susceptibility of surgeons and other proceduralists to inadvertently cause harm to patients. The incidence of injuries related to energy-based devices during laparoscopic procedures is estimated at 1 to 2 per 1000 patients, which translates into thousands of avoidable patient injuries every year in the US alone.[4] Unrecognized bowel and major vascular injuries—mostly because of thermal energy—constitute many of these events, with serious consequent morbidity and mortality.[4,16-19]

… technical advances have not been able to close a major knowledge gap regarding the potential risks of energy-based devices in and out of the OR among the primary users: surgeons, gastroenterologists, and interventional radiologists.

In the 1970s, several cases of electrocution in the OR were published related to accidents with electrosurgical equipment.[20,21] Although dramatic and mortal injuries from electrocution are exceedingly rare in modern ORs, intestinal thermal injuries and fires caused by energy-based devices are not uncommon. In 2010, a well-known US senator succumbed to an unrecognized intestinal injury that occurred during a routine laparoscopic cholecystectomy.[22] The same year a young woman undergoing excision of a benign skin lesion on the face sustained second-degree burns from an OR fire, apparently scarring her for life.[23]

According to a recent study, laparoscopic bowel injuries occur at an overall rate of 0.85%, nearly 1 in 100 cases, of which one-third are unrecognized at the time they occur.[24] Overall mortality is 3.13% and jumps to 8% for unrecognized injuries. One-third of these injuries is directly related to the use of surgical energy-based devices.[24] Today's OR monitors and tables, anesthesia machines, and other electrical equipment are manufactured according to strict safety standards. These technical advances have not been able to close a major knowledge gap regarding the potential risks of energy-based devices in and out of the OR among the primary users: surgeons, gastroenterologists, and interventional radiologists. We must recognize that almost all the aforementioned accidents and injuries were completely preventable.

Initial Response

Since the 1990s, health care professionals and surgical societies both in the US and internationally began responding to these safety issues. Specific complications associated with electrosurgical devices and the risks involved in their use were described. A first attempt was made to develop practical educational and engineering solutions to the described complications.[25-29] These early studies included a survey conducted under the auspices of the American College of Surgeons to assess the complication rate associated with the use of electrosurgical devices.[30] Notably, the survey showed that most surgeons were unfamiliar with the optimal use of electrosurgical instruments and that they used inappropriately high power settings.[30] The Consortium on Electrosurgical Safety During Laparoscopy, convened in 1997, published recommendations that emphasized the acute need for training and education during residency and beyond,[31] and the Association of periOperative Registered Nurses published its recommended practices for electrosurgery in 2005.[32] Unfortunately, these important and timely initiatives had little impact on surgical practice at the time.

Fundamental knowledge about the correct use and inherent risks of energy-based devices in surgical practice as well as in radiologic and gastrointestinal interventions is still not systematically taught. In contrast to anesthesia and nursing textbooks, educational material that teaches surgeons about the risks and proper use of energy-based devices is lacking or inadequate. There is no specific requirement for surgeons to train on energy-based devices or to obtain certification that validates their knowledge of device-related safety issues.

NEEDS ASSESSMENT

In 2011 the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) developed and ran a postgraduate continuing medical education course on energy-based surgical devices. This comprehensive lecture and hands-on course was the first didactic effort designed to teach surgeons and other health care professionals the fundamentals of the use of energy-based devices in the OR and gastrointestinal endoscopy suite. An 11-item, multiple-choice, pre- and posttest encompassing critical knowledge points was administered to course participants and SAGES leadership.[33]

The survey results were sobering. The median number of correct answers was 6.5 of 11 (59%) for the SAGES leadership group. These SAGES leaders did not know how to correctly handle a fire on the patient (31%), could not identify the electrosurgical device least likely to interfere with a pacemaker (31%), did not know that thermal injury could extend beyond the jaws of a bipolar instrument (13%), and thought a dispersive electrode should be cut to fit a child (10%).[33,34] Results among course participants and surgical trainees were similar to each other.[33,34] This finding demonstrated that surgical "experts" do not necessarily have greater knowledge of energy-based surgical devices compared with nonexpert surgeons or even junior trainees. These results highlight the need to educate trainees and surgeons in the knowledge and understanding of safe and appropriate use of energy-based surgical devices.

TRAINING PROGRAM FOR ENERGY-BASED SURGICAL DEVICES

The SAGES leadership was in a unique position to recognize that a rigorous and standardized training program on energy-based devices was needed as a greater number of potentially harmful devices were introduced into routine clinical practice. The timing of this initiative could not have been more appropriate for three reasons:

1. rapid innovation in the OR and procedure suite
2. rising national awareness of OR fires
3. transformation of the relationship between industry and physicians.

Rapid innovation in the OR and procedure suite: Today's ORs and procedure suites are sophisticated computer-driven control centers of highly complex "point-of-care" delivery. Electronic medical records, anesthetic workstations, high-definition monitors, recording equipment, and a multitude of complex energy-based surgical devices can quickly overwhelm an OR team that is

potentially unfamiliar with the basic function and designs of these instruments.

Rising national awareness of OR fires: Hundreds of preventable OR fires occur every year in the US. The ingredients of this potential disaster are present every time an operation or procedure is undertaken in a patient: the presence of fuel and an oxidizer with a spark from an energy-based device. Despite the distribution of educational materials in multiple formats highlighting the dangers of OR fires, they still occur. The US Food and Drug Administration has made prevention of OR fires one of its most important patient safety goals, but there still is no common national educational program to teach fire prevention in either the OR or the procedure suite.

Transformation of the relationship between industry and physicians: Despite many changes in health care, such as industrial relationships and the implementation of regulations and barriers, the introduction of new surgical devices into the OR remains an informal process mostly governed by industry representatives. The required knowledge regarding the use of new devices is still disseminated through industry-sponsored courses or the private interaction between the industry representative and the physicians. No standards are set to determine whether a surgeon is ready and able to use the new device safely. The Physician Payments Sunshine Act, Section 6002 of The Patient Protection and Affordable Care Act of 2010[35] and other regulations have placed appropriate barriers between physicians and industry influence. However, without ready access to industry representatives, it is difficult for surgeons and nurses to learn how to use new devices. Fundamental Use of Surgical Energy (FUSE) is beginning to address important questions raised by this shift away from industry-centered instruction:

- Where will the training to master new energy-based surgical devices come from?
- How should appropriate training and certification be structured?
- Should there be a standard approach for how energy-based devices are introduced to those responsible for using and operating the equipment?
- Who will create these standards?
- Who will create a curriculum covering the function and safety profiles of new equipment?
- How will we mandate and pay for fire safety training?

It has become clear to all involved that perhaps the best solution is a national, multidisciplinary educational program, independent of industry that includes a validated assessment. Only in this way can we address the baseline knowledge gap as well as prepare for the introduction of new devices in a way that maximizes efficacy, efficiency, and, most importantly, patient safety.

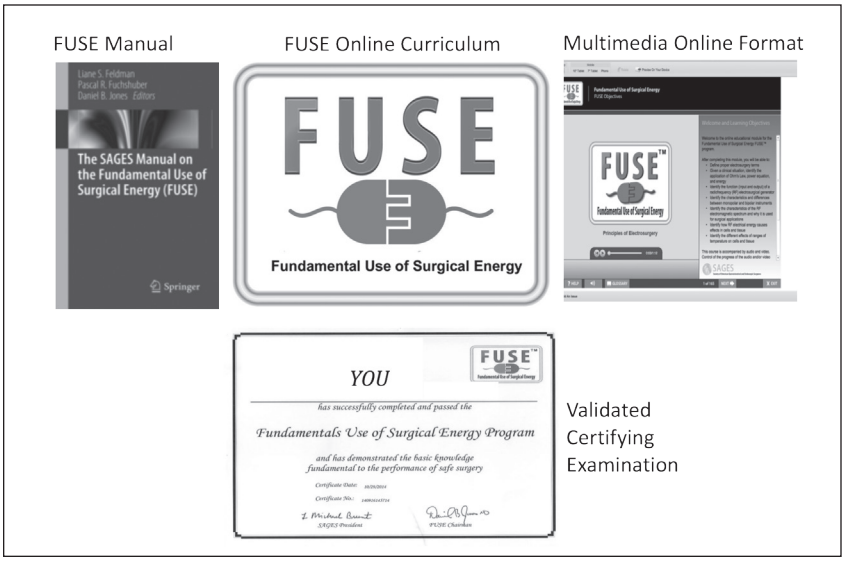

Figure 1. Fundamental Use of Surgical Energy (FUSE) educational program components: Manual, online curriculum, multimedia online format, and certifying examination.[a]

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[a] The educational program was developed through multidisciplinary cooperation.

SAGES = Society of American Gastrointestinal and Endoscopic Surgeons.

Ten Sections of the Fundamental Use of Surgical Energy Online Curriculum[1]

1. Fundamentals of electrosurgery
2. Mechanisms and prevention of adverse events with electrosurgery
3. Monopolar devices
4. Bipolar devices
5. Radiofrequency for soft-tissue ablation
6. Endoscopic devices
7. Ultrasonic energy devices
8. Microwave energy systems
9. Energy-based devices in pediatric surgery
10. Integration of energy systems with other devices.

1. Surgical fundamentals online didactics [Internet]. Los Angeles, CA: Society of American Gastrointestinal and Endoscopic Surgeons; 2002-2016 [cited Aug 11]. Available from: www.fusedidactic.org.

FUNDAMENTAL USE OF SURGICAL ENERGY EDUCATIONAL PROGRAM

The FUSE educational program was created by SAGES in partnership with the Association of periOperative Registered Nurses, the American Association of Gynecologic Laparoscopists, and the American Urologic Association. Members of the FUSE team include a variety of general and subspecialty surgeons, nurses, anesthesiologists, gynecologists, and engineers.

The FUSE program has three main components (Figure 1): 1) A standardized educational curriculum that is online-based and free of charge (Figure 2); 2)

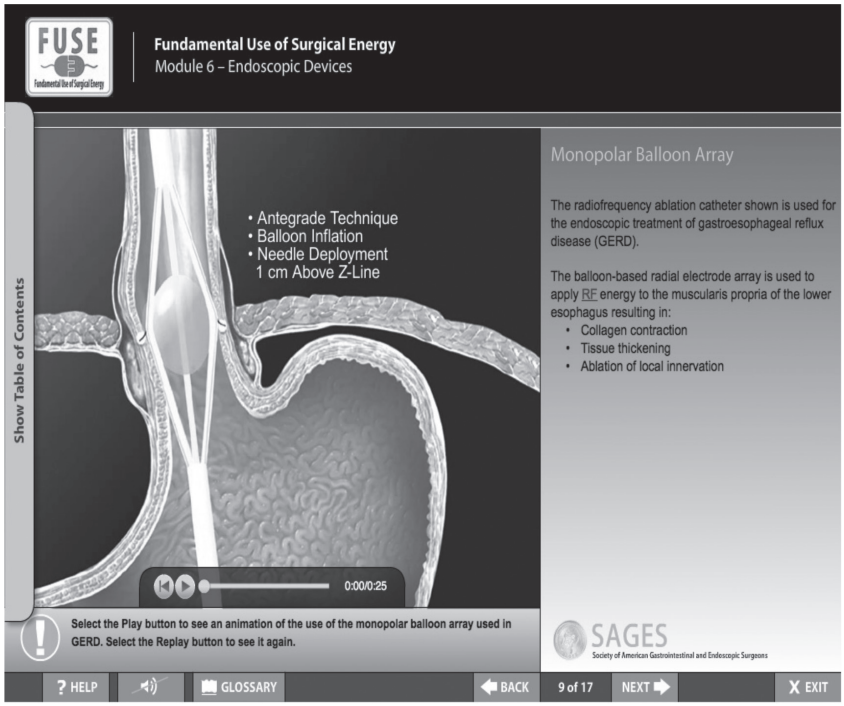

Figure 2. Example from Fundamental Use of Surgical Energy (FUSE) online curriculum: Module 6 – Endoscopic Devices.

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continuing medical education credits or continuing education units that can be obtained as part of the online curriculum for a small fee; and 3) a high-stakes certification examination that meets rigorous psychometric and accreditation standards.

This voluntary, validated, and proctored examination is administered at one of the many test centers across the nation. Successful completion of this test provides verification that the participant has the basic knowledge necessary to safely use energy-based devices in the OR and/or procedure room. If the participant fails the test, it can be retaken without additional charge. *The SAGES Manual on the Fundamental Use of Surgical Energy (FUSE)*, a handbook published in 2012, is an additional offline resource.[36]

Table 1. Example of educational objectives from sections 1 & 2 used to develop online curriculum and the certification examination

Section	Objective
1	Fundamentals of electrosurgery
1.1	Define proper electrosurgery terms
1.2	Given a clinical situation, identify the application of the Ohm law, power equation, and energy
1.3	Identify the function (input and output) of an electrosurgical (RF) generator
1.4	Identify the characteristics of monopolar and bipolar instruments and the differences between them
1.5	Identify the characteristics of the RF electromagnetic spectrum and why it is used for surgical applications
1.6	Identify how RF electrical energy causes effects in cells and tissue
1.7	Identify the different effects of ranges of temperature on cells and tissue
2	Mechanisms and prevention of adverse events with electrosurgery
2.1	Identify general patient protection measures for setup and settings for the electrosurgical unit
2.2	Identify various mechanisms whereby electrosurgical injuries may occur
2.3	Identify circumstances, mechanisms, and prevention of dispersive electrode-related injury

RF = radiofrequency.

The FUSE online curriculum[37] includes ten sections that teach the basic principles underlying energy-based surgical devices and the application of those principles to safe and effective use of the devices (see Sidebar: Ten Sections of the Fundamental Use of Surgical Energy Online Curriculum). For example, Section 1, Fundamentals of Electrosurgery, starts with the basic physics concepts, nomenclature, and the difference between "cut" and "coag" (coagulation), monopolar vs bipolar RF instrumentation, and active vs dispersive electrodes. The different tissue effects—desiccation, coagulation, and fulguration—achieved by the physical effects of temperature and alternating current on cells and tissue are explained, laying the groundwork for a discussion of specific energy applications. Section 2 describes a crucial safety issue, current diversion in the form of direct and capacitive coupling and insulation failure, as well as prevention and response to OR fires. A similar format emphasizing core principles and safe application is used in the subsequent device sections: monopolar RF, bipolar RF, ultrasonic energy, RF ablation, microwave, and devices designed for use in the alimentary tract. Special considerations for use of energy-based devices in pediatric patients and in patients with other medical devices, most notably cardiac implantable electronic devices, are addressed as well. The FUSE manual also contains supplemental hands-on chapters describing in detail how to set up "live" demonstration and teaching stations.[36]

The FUSE curriculum includes an optional structured interactive benchtop simulation component that is available on demand from SAGES. This goal-directed, hands-on training session has been shown to improve learning and retention of key knowledge points in surgical trainees three months after the session.[38] It also includes a novel virtual reality-based simulation station.[39]

The FUSE curriculum was designed to provide surgeons with the knowledge

they need to pass the FUSE certifying examination. The curriculum and examination underwent a development process specifically designed to meet the stringent design and validation requirements for professional certification.[40] Psychometricians conducted an iterative process with 15 FUSE content experts, defining the competencies to be taught and tested. A total of 72 learning objectives were identified for the entire curriculum, 2 to 20 per section. Table 1 lists the objectives from Sections 1 and 2. Leaders from SAGES, the Association of periOperative Registered Nurses, and the American Association of Gynecologic Laparoscopists were used to rank each objective, which in turn helped determine the number of test items for each objective on the written examination. Draft versions of the examination underwent further iterative scrutiny by the FUSE committee, and beta testing was completed in April 2014. The FUSE certification test is now available to all health care professionals at 30 national and international FUSE test centers. More than 400 practicing surgeons and residents are certified.

Until standard mandatory surgical education curricula address the teaching of safe use of energy devices, FUSE remains one of the most comprehensive voluntary options for surgical training program administrators to add this essential component of surgical teaching to their curriculum. The FUSE program office at SAGES[a] welcomes any request to establish FUSE testing centers at individual hospitals and teaching institutions and will guide you through the process.

CONCLUSION

The FUSE program was developed to provide a standardized educational tool for all physicians and staff who interface in the OR and procedural and interventional suites to bridge a knowledge gap in best-practice use of energy devices. It encompasses the safe and appropriate use of the most common energy devices employed in the operative and endoscopic field, as well as their contribution to OR fire risk and impact on implantable electronic devices. FUSE is the first educational tool of its kind that addresses patient and OR team safety for energy devices.

Ongoing development will ensure that the FUSE program will continue to evolve and fill the curricular, regulatory, safety, and competency assessment needs that exist for the use of energy devices by surgeons, endoscopists, anesthesiologists, and nurses worldwide. ❖

[a] Contact Jessica Mischna, FUSE Program Manager, SAGES, 11300 W Olympic Blvd, Suite 600, Los Angeles, CA 90064; phone: 310-437-0544 extension 139; fax: 310-437-0585; e-mail: jessica@fuseprogram.org.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

Acknowledgments

Fundamental Use of Surgical Energy (FUSE) is funded by unrestricted educational grants to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) FUSE Consortium Education Fund from the SAGES Educational & Research Foundation, Los Angeles, CA; Covidien (now Medtronic Minimally Invasive Therapies), Minneapolis, MN; and Olympus America Inc, Center Valley, PA. All authors are members of the SAGES FUSE Task Force.

The authors would like to thank Jessica Mischna, Sallie Matthews, Brenda Castaneda, and Carla Bryant from the SAGES headquarters for their invaluable support of the FUSE program and the members of the SAGES FUSE Task Force for their contributions.

Kathleen Louden, ELS, of Louden Health Communications provided editorial assistance.

How to Cite this Article

Jones SB, Munro MG, Feldman LS, et al. Fundamental use of surgical energy (FUSE): An essential educational program for operating room safety. Perm J 2017;21:16-050. DOI: https://doi.org/10.7812/TPP/16-050.

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Necessary Conditions

The conditions necessary for the surgeon are four: first, he should be learned; second, he should be expert; third, he must be ingenious; and fourth, he should be able to adapt himself … Let the surgeon be bold in all things, and fearful in dangerous things.

— Guy de Chauliac, 1300-1368, French physician and surgeon