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Ensuring Safety in the Operating Room – The “Fundamental Use of Surgical Energy” (FUSE) Program

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Introduction

Operating rooms can be dangerous places as harm to both patients and operators can occur in many different ways. Although most people understand that patients in operating rooms undergo risky, highly complex, and potentially life-threatening procedures, they seem much less aware that operating rooms have many potentially harmful energy devices used by anesthesiologists, surgeons, and nurses. Malfunction or misapplication of these devices can endanger the well-being of both the patient and the operator.

Anesthesiologists and nurses have been aware of this possibility for many decades. In 1979 Chambers and Saha reported a cardiac arrest due to electrocution in a young patient undergoing laparotomy (1). The patient died because of a faulty electrical switch in the operating table. An EKG monitor with a direct earth ground created an electrical circuit that included the patient and resulted in the electrocution. Although this design has been abandoned in favor of isolated electrical systems, and every electrical device in the operating room must comply with numerous safety requirements, injuries from electrical devices continue to occur. As recently as 2010 Wills et al. reported a case of electroshock injury to a nurse in a modern operating room.(2) These few publications helped create awareness and have led to safer standards and technologies for the typical electrical systems used in operating rooms, including EKG machines, anesthesia monitors, operating room

tables, electrical outlets and switches. These publications also appear to have been largely ignored by surgeons who relied on their anesthesia colleagues and allied health personnel to address them. The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has developed the “Fundamental Use of Surgical Energy™” (FUSE) program to address this knowledge gap and contribute to a safer operating room environment.

The “Fundamental Use of Surgical Energy” Program – FUSE

Historical perspective and creation of the concept:

Devices that apply energy to tissue therapeutically have been in use for millennia. Cautery, the direct application of heat to tissue, has been in use since 3000 BC to destroy tumors and achieve hemostasis (3). At the beginning of the 20th century William T Bovie invented an instrument in which high-frequency alternating current (radiofrequency electrosurgery) was used to achieve effects similar to a knife, but in addition could coagulate tissue while cutting through it. (4) It was introduced into surgical practice by Harvey W Cushing and remains the most widely used energy-based device today with very little modification of its basic principles. In the 1940's, bipolar devices were introduced, with innovations such as the incorporation of cutting blades and real-time impedance measurement into bipolar instruments appearing over the next few decades.

After this relatively slow pace of innovation, the last two decades have seen an explosion in the type and availability of energy devices used by physicians of all specialties. Fueled by the minimally invasive “revolution” which required new devices for tissue dissection and efficient control of larger vessels without suturing, there is now a vast array of devices that apply energy to tissues in clinical use throughout the world across all surgical specialties and operative approaches - open, laparoscopic, robotic and endoscopic. These devices use a variety of energy sources: electric current at radiofrequency wave-length, mechanical energy at ultrasonic wave-length and microwave energy. Without question these technical innovations have enabled the advances in minimally invasive surgery, endoscopic interventional techniques and percutaneous approaches to diseases that have greatly enhanced our ability to treat patients. However, this technological boon has also created a dizzying multitude of energy device platforms, configurations, generators, cost points and vendors, and this complexity has increased the potential for injury.

Today's surgeon encounters complex energy systems to be used after a short introduction by a specific vendor without any incentive or need to understand the fundamental principles of function and safety of the device. Clearly, there is a need for an educational program to address this gap. With the rapid increase in number, types, and forms of energy applications to tissue, the wide variety of indications and devices and the complex environment in which they are used, the risk for complications and harm to both to patients and operators has become part of daily practice.

Injury and harm from electrosurgical devices in laparoscopic surgery is estimated to occur at a rate of 1-2 per 1000 patients. (5) These complications include unrecognized bowel injuries and major vascular injuries.(6,7) Although vascular injuries declare themselves through the presence of unexpected bleeding, unrecognized thermal injuries to the intestine during

laparoscopic surgery are difficult to detect and therefore particularly dangerous, with a significant associated mortality.(8,9)

Over 600 operating fires occur each year in the United States with 2-3 mortalities each year. (11) These injuries are potentially preventable and most of them are associated with the use of surgical energy devices. In over 90% the reported ignition source is an electrosurgical device. As a proportion of all surgical claims, those related to fires have increased from less than 1% of all surgical claims during 1985-1989 to 4.4% between the 2000 and 2009, representing a greater than 5-fold increase.(10) The scope of harm from fires and thermal injuries is comparable to more publicized safety issues like retained foreign objects (0.7-1 per 1000 abdominal operations) and wrong-site surgery (1 in 9000 cases) (12,13)

In response to this safety issue, individual surgeons, health care professionals and surgical societies both nationally and internationally have tried to increase our understanding of the fundamental properties of electrosurgical instruments. (14,15,16,17,18) These pioneers raised awareness of the specific complications associated with electrosurgical devices and the risks involved in their use, particularly in laparoscopy. This early work included a survey sponsored by the American College of Surgeons to assess the complication rate associated with the use of electrosurgical devices, showing that the majority of respondents reported inappropriately high power settings when using electrosurgical instruments (19). In 1998, the Society of Laparoendoscopic Surgery publicized the need for better education of surgeons on the safe use of laparoscopic monopolar electrosurgical devices. (20) Similarly, the Association of periOperative Registered Nurses (AORN) has published recommendations on the safe use of energy devices in electrosurgery, but without a comprehensive review of all devices and without an assessment component. (21)

Despite these early attempts to make surgeons aware of the potential threat from energy devices used every day in the operating room, the general understanding among surgeons about the correct use and inherent dangers of energy devices has remained very poor. Compared to anesthesia and nursing textbooks, standard surgical textbooks provide little relevant information. Training on new energy devices is not standardized, with almost all training on a particular device delivered by a sales representative or an industry sponsored course. In preparation for a postgraduate course addressing surgical energy devices given at the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) in 2011, a pretest consisting of 11 multiple-choice questions was given to 48 society leaders. The pretest included items addressing fundamental principles of electrosurgery as well as safety issues with a variety of energy-based devices. On initial administration of the test the median number of correct answers was 6.5 or 59%. The range of correct answers was 3 to 11. Thirty-one percent of the participants did not know how to handle an operating room fire involving a patient; 31% could not identify the energy device least likely to interfere with a pacemaker; 13 % did not know about thermal spread of bipolar instruments; and 10% would have cut a dispersive electrode (return pad) to fit a child. (22) Only 35% knew the correct nomenclature for electrosurgical device function and only 20% were able to describe the generator output. When surveyed, few surgeons consider themselves “expert” on the energy-based devices they use every day, and the most common source of knowledge about these devices (42%) came from industry sales representatives or an industry-sponsored course.

(23) These results suggest that surgeons in practice may have a relatively poor understanding of the potential safety issues of commonly used surgical energy devices and that training has been provided mostly by industry.

In summary, multiple factors have coalesced in the field of energy-based surgical devices, including the laparoscopic revolution, the rapid expansion of surgical energy technologies and the identification of operating room fires as an important safety issue. Where will the training to master these devices come from? Who will create a curriculum covering their functioning and safety profiles? How should we offer appropriate training and certification? What is the standard procedure when a surgeon or a nurse is suddenly faced with unfamiliar equipment? How will we mandate and pay for fire safety training? Should there be a standard approach for how energy devices get introduced into the hands of surgeons? Who will create these standards? A nationwide, non-industry, multidisciplinary educational program with validated assessment in surgical energy-based devices could address this knowledge and certifications gap and potentially contribute to a safer operating room environment. (24)

The FUSE educational curriculum and certification

In October 2010, SAGES created the FUSE (Fundamental Use of Surgical Energy) program to address this gap (Figure 1). Working in partnership with AORN, AAGL (American Association of Gynecologic Laparoscopists), and the AUA (American Urologic Association), the FUSE task force includes general surgeons with a variety of subspecialty practices, nurses, anesthesiologists, engineers, and gynecologists. As with the two other SAGES “Fundamentals” programs (FLS, or Fundamentals of Laparoscopic Surgery™, and FES, or Fundamentals of Endoscopic Surgery™), FUSE includes two components: a standardized curriculum for surgeons and allied health care professionals of all specialties, and a certification test that meets high psychometric and accreditation standards. Success on the test will result in FUSE certification, documenting the basic knowledge that underlies the safe use of energy-based devices in the operating room.

The FUSE curriculum content was first delivered as a postgraduate course at the SAGES meeting in 2011 and 2012. The material was expanded into a textbook on surgical energy and safety (The FUSE manual), published in 2012 (25) and an online multimedia curriculum completed in late 2012.

The curriculum includes 10 sections:

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 systems
8. Microwave energy systems
9. Energy-based devices in pediatric surgery
10. Integration of energy systems with other medical devices

The content focuses on the fundamental principles required for safe and effective use of devices. For example, section 1, Fundamentals of Electrosurgery, includes the types of currents used, correct nomenclature, explanation of physics such as Ohm's law as it is applied to electrosurgery, electrosurgical generators, differences in "coag" and "cut" waveforms, monopolar versus bipolar systems, isolated versus ground-referenced systems, active and dispersive electrodes, physical effects of temperature and alternating current on cells and tissue, resistive heating, and the different tissue effects (desiccation versus coagulation versus fulguration). Section two focuses on the safe use of electrosurgical devices, including direct and capacitive coupling, insulation failure, and prevention and response to operating room fires. A similar emphasis on fundamental principles and safe application is used in the sections on specific devices, including monopolar, bipolar, radiofrequency ablation, microwave and endoscopic devices. Additional sections deal with the special considerations for use of energy devices in pediatric patients and when used in patients carrying other medical devices such as pacemakers. For illustration, Figure 2 shows a page of the "Integration of energy systems with other medical devices" chapter of the FUSE Manual. The manual contains supplemental "Hands-On" chapters describing how to set up "live" stations for demonstration and teaching surgical energy principles and safe practice. Figure 3 shows an example of a FUSE manual hands-on chapter. The online curriculum includes the essential content of the FUSE Manual in an electronic multimedia self-assessment format with multiple choice test questions eligible for CME and CEU. An example of a "page" from the online curriculum is shown in Figure 4.

Successful completion of the FUSE program, including assessment, will lead to certification. SAGES is following a test development process that complies with the legal and technical requirements for professional certification. This included a "job task analysis" where psychometricians lead 15 FUSE content experts in a systematic process to define the competencies required to use energy devices safely. The results describe the breadth and depth of knowledge and skills that must be covered by the certification exam in order for it to be deemed valid, reliable, and legally defensible. This was used to create test objectives for the exam. For each section of the curriculum, between 2 and 20 objectives were identified, for a total of 63 objectives. For example, for Section 1, "Fundamentals of Electrosurgery", objectives include "Identify the function (input and output) of an electrosurgical (RF) generator" and "Identify how radiofrequency electrical energy causes effects in cells and tissue". For section 2 "Mechanisms and Prevention of Adverse Events with Electrosurgery", objectives include "Identify circumstances, mechanisms, and prevention of dispersive electrodes-related injury" and "Identify circumstances which promote OR fires and identify prevention strategies". Test objectives help ensure that the knowledge measured by the exam is the same knowledge that is required for safe practice in the operating room. SAGES leaders, along with selected members of AORN and AAGL, participated in development of the test blueprint by ranking each objective and by

determining the number of test items to be written. Competencies that emphasize the fundamental principles of energy devices, their electrosurgical safety and the integration of energy systems with other devices were viewed as most important for the FUSE assessment. Beta testing of the program and assessment are underway and will serve as the basis for any revisions of the certification exam and to determine the passing score range. The final program including the online curriculum and certification is expected to be launched in late 2013.

Summary

The Fundamental Use of Surgical Energy program by SAGES has multiple components: a comprehensive educational curriculum on the principles and safety of surgical and endoscopic energy devices available as a postgraduate course, a comprehensive manual and an online multimedia CME approved program; and a psychometrically sound high-stakes examination for physicians that can be used for maintenance of certification. Future developments of the FUSE program will include specific modules tailored to individual energy devices. These modules will be developed in collaboration with industry to provide standardized education for the safe and appropriate use of current and new energy devices. This will ensure that FUSE continues on its mission to fill the unmet curricular, regulatory, safety and competency assessment needs that exist for the use of energy devices in patients by surgeons, endoscopists, anesthesiologists and nurses.

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Figure 1.

Fundamental Use of Surgical Energy – FUSE Program Logo (copyright with SAGES)

12. Integration of Energy Systems with Other Medical Devices

Stephanie B. Jones and Marc A. Rozner

Electromagnetic interference (EMI) from medical equipment may originate from multiple sources and interfere with implantable electronic devices in the patient [1]. Such implanted devices include cardiac implantable electronic devices (CIED), i.e., pacemakers and implantable defibrillators; deep brain, spinal cord, vagal nerve and sacral nerve (bladder) stimulators; implantable infusion pumps and cochlear implants. The scope of this discussion is limited to CIED.

It is estimated that over three million patients are currently treated with conventional pacemakers for bradycardia pacing, and approximately 750,000 are implanted in the United States yearly, according to industry sources. Greater than 300,000 patients have implanted defibrillators (ICD), which provide high-voltage therapy for ventricular tachycardia/fibrillation as well as conventional pacing for bradycardia. The Heart Rhythm Society estimates that more than 10,000 ICDs are implanted per month, with an expected prevalence of 670,000 by 2020. Many of the CIEDs, whether or not high-voltage therapy is present, have a pacing lead designed to activate the left ventricle (called cardiac resynchronization therapy (CRT) or biventricular (BiV) pacing) for the patient who has significant cardiomyopathy. EMI can be generated by many devices in the operating room and elsewhere within the hospital. These include monopolar electrosurgical and endoscopic devices, radiofrequency ablation (RFA) systems, electrocardiographic monitors, fluid and blood warmers, MRI and CT scanners, and peripheral nerve stimulators. Ultrasonic shears generate mechanical rather than electromagnetic energy and are therefore safe to use in the presence of implantable devices. One must remember, however, that any energy device has the potential to cause damage, particularly to surrounding structures (Fig. 12.1).

Multiple factors determine the effects of EMI on CIED, which include the distance between the energy source and CIED leads and how the

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Fig. 12.2. Preoperative (*left panel*) and postoperative (*right panel*) “strength-duration” plots of pacing output and capture thresholds from an 82.5 kg, 48-year-old woman with hypertrophic obstructive cardiomyopathy who underwent a paraspinal sarcoma excision in the prone position, where both standard monopolar and argon beam devices were used and who had a one blood volume (5.5 L) transfusion. In a strength-duration plot, any combination of pacing pulse amplitude and width in the non-shaded area would be expected to provide ventricular capture. In the *left panel* , the “+” (1.5 V, 1.0 ms) was the recommended setting by the programmer to conserve battery energy, the “X” (2.5 V, 0.6 ms) was the presenting output, and the “*” (5 V, 1.0 ms) was the setting upon presentation to the operating room. In the *right panel* , the pacing threshold has increased several-fold, likely due to effects from EMI and the volume resuscitation. The “+” and the “X” (recommended pacing output and the current output—5 V, 1.0 ms) overlaid each other. The “*” (2.5 V, 0.6 ms) was the initial presenting output and is now clearly inadequate. (Courtesy of M. Rozner, PhD, MD, Houston, TX).

[4] is an obvious factor, as more wiring in the heart increases the surface area available to detect EMI. Thus, dual chamber pacemakers (Fig. 12.3) are more likely than single chamber pacemakers to have problems with EMI. The distance between anode and cathode is also relevant. In a unipolar lead, the anode is the pacemaker case itself, with the cathode at the tip of the lead. This creates more lead distance over which electrical signal may be detected. By contrast, a bipolar lead tip contains both anode and cathode, creating a very small electrically active area. Fortunately, the majority of current pacemakers and all ICDs utilize bipolar sensing leads.

When conducting a preoperative evaluation of a patient with an existing

CIED, a standard approach should be used. Much of the information presented below has been derived from the American Society of Anesthesiologists (ASA) Practice Advisory for the Perioperative

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Fig. 12.3. Dual chamber pacemaker

Management of Patients with CIED: Pacemakers and Implantable Cardioverter-Defibrillators [5] and the Consensus Statement from the Heart Rhythm Society [6] . It should be kept in mind that both of these documents represent practice advisories and expert opinion; neither is a guideline, indicating an insufficient number of adequately controlled studies on which to base recommendations.

First, one needs to determine if the patient has a CIED. Although this may seem obvious, such information may be missed when preparing a patient for an urgent or emergent procedure. A thorough history and physical exam will help verify the presence of a pacemaker or ICD generator and the indication for device placement. The determination of pacing dependence (which could be present in any CIED patient) as well as the presence of a high-voltage device (ICD) serves to identify those patients who will have the greatest potential for harm from typical EMI effects. Absolute pacing dependence refers to the patient who has no underlying ventricular systoles, owing to either sinoatrial or atrioventricular nodal disease. Functional pacing dependence refers to the patient who will suffer hemodynamic embarrassment at any system failure to sense/pace the myocardium in an optimal fashion. Ideally, the patient will have an identification card on hand in order to easily establish the type of device. In the absence of such, a chest X-ray can reveal identifying codes [7] . If surgical urgency allows for more investigative time, medical records pertaining to CIED placement, function and evaluation should be obtained. Without these records or a reliable history from the patient, it may not be possible to ascertain

Fig. 12.7. Illustration of undesired electrocautery current path crossing the CIED system. (Original illustration courtesy of Mark Trankina, MD, Birmingham, AL).

tissue, a capacitor is created which increases the risk of EMI. An additional mechanism for the creation of EMI relates to the fact that the arcing (active electrode not in direct contact with the tissues) actually demodulates the frequency of the electrocautery current, defeating the existing CIED electrical filtering system.

Similar principles should be employed when performing coagulation and desiccation of large volumes of tissue that is a characteristic of RFA. The CIED should be kept out of the current path, and contact between the pulse generator and leads should be avoided. Patients in whom RFA is chosen as an alternative to surgery due to significant comorbid conditions likely have a higher prevalence of CIED than average. In one study published by Skonieczki in the *European Journal of Radiology*, fifteen percutaneous RFA procedures were performed in patients with CIED. One device was found to have been reprogrammed from VOO to VVI mode (which likely represents an electrical reset), with no inhibition noted, and another showed four episodes of pacemaker inhibition and increased atrial rate, although this effect was believed to be clinically insignificant [13]. No damage to CIED was revealed by postprocedure interrogation, and the authors concluded that RFA could be safely performed in these patients with appropriate perioperative

Fig. 12.8. (a , b) Comparison of placement of a circumferential ablation catheter for treatment of Barrett's esophagus with that of a transesophageal echocardiography probe. Note proximity to heart and therefore any CIED that may be present.

planning. However, in some circumstances, an electrical reset can require replacement of the generator.

Endoscopic devices employ EMI emitting energy sources as well. For lower gastrointestinal procedures, this is probably of lesser concern. However, for procedures occurring in the esophagus or stomach or possibly the transverse colon, one needs to be mindful of the presence of CIED (Fig. 12.8). Stretta, a proprietary device used to treat gastroesophageal reflux, is a monopolar device. The BARRX device, an instrument used in the treatment of Barrett's esophagus, is bipolar, but during the procedure the electrodes are in very close

proximity to the heart. Even more worrisome, such procedures may be taking place in busy free-standing endoscopy centers with little in the

Figure 2.

Page examples of the FUSE manual, chapter "Integration of Energy Systems With Other Medical Devices" (24)

Hands-On Demonstration
Art and Science of MonopolarElectrosurgery
“Case studies” of metal-to-metal arcing and single port cannula surgery.
Outlined by Dr. Randy Voyles

Enhanced “artful” application of monopolarelectrosurgery occurs only after a period of continued real-time study in animate *in vivo* models. The models outlined in the previous chapter with steak on a dispersive electrode are useful for outlining concepts and poorly understood principles. For example, the novice surgeon can demonstrate the various tissue effects of concentration of current at various wattages. Further demonstrations outlined how current can be inadvertently concentration at unintended sites through inadvertent direct coupling, insulation failure, or induced/capacitive coupling. Enhanced art forms occur as a function of insightful study.

Two further demonstrations are useful to outline understanding of concepts.

Demonstration 1: Direct coupling to staple line generates 1000 degrees C

To outline the maximum effect of concentrated current, a staple (from either a paper stapler or preferably from one of the mechanical stapling devices) is straightened and one half of the length is inserted into the steak on the dispersive electrode as in the previously outlined model. The surgical electrode is the activated (open circuit) and held near enough to the staple to allow continuous arcing with “coag” mode at 40-60 watts power. In short order, the staple will melt and disintegrate. Do you understand the biophysics of this demonstration? Do you “see” maximum current density with maximum thermal change that can be generated in a laparoscopic setting with monopolarelectrosurgery?

A more telling model of the same demonstration can be accomplished in the operating room. After the end of colon resection, take the resected colon and place it on a dispersive electrode. Arrange the colon so that the surgical electrode approximates the “end staple” of the transected bowel (figure one); activate the electrode so that there is a continuous arc to the staple (figure 2); be careful to observe the disintegration of the staple with an explosion of “staple shrapnel” (figure 3) as the high levels of heat cause instant boiling of the tissue in association with the staple line (figure

Now reflect back on a capillary ooze at a stapled anastomosis. Be careful using energy on the staple line (or near clips) as the same demonstration can be effected with a resultant anastomotic failure in 3 to 5 days.

Demonstration 2: Amplified electrosurgical risk of stray current with single port surgery

Use the same model outlined in the previous chapter(simulation of the abdominal cavity) but use a single port technology to introduce the closely aligned instruments. Do several tasks:

- 1) Introduce a surgical electrode alongside a laparoscope. Demonstrate how readily the active electrode can contact the laparoscope and deliver energy to an unintended site. (*Notice how the instruments are in closer proximity one to another than with conventional port technology.*)
- 2) Introduce the instrument with known defective insulation. Is it apparent that the chance for injury has been enhanced by single port introduction?
- 3) Activate the electrode open circuit (not touching tissue) and advance another inactive electrode through alongside the active electrode. Advance the “inactive electrode” to near the steak and observe the stray “induced” current onto the “inactive” electrode. Change the ESU output from 20 to 100 watts coag and observe the qualitative differences in induced currents. Now do the same with cut current (low voltage with very little induced current).

Figure 3.

Examples of the FUSE manual Hands-On Demonstration chapter (24)

Fundamental Use of Surgical Energy

Module 2 – Mechanisms and Prevention of Adverse Events

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Unintended Activation

0:00/0:20

Unintentional Activation of the Electrode

Unintended and unrecognized activation is common cause of active electrode-related happen with any electrosurgical instrument

Two precautions should be followed to red of inadvertent activation:

- Return the [active electrode](#) to a safe the operating field after each use (fo replace the "pencil" in its holster
- Beware of creating an injury out of th view, especially during laparoscopic

Special care should also be taken when tw electrosurgical systems are in use simulta avoid unintentional activation of the wrong

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Figure 4.
Screenshot of the FUSE online program

Table 1

Example of educational objectives used to develop online curriculum and certification exam

	FUSE Blueprint
	Final - September 1, 2011
1	Fundamentals of Electrosurgery
1.1	Define proper electrosurgery terms.
1.2	Given a clinical situation, identify the application of Ohms 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 electrodes-related injury.