Avoiding Electrosurgical Injury During Laparoscopy
An Emerging Patient Safety Issue
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S
ince its modern introduction in the early 1970s, minimally invasive surgery has revolutionized surgical diagnosis and intervention. Minimally invasive surgery, by definition, offers patients the significant benefits of faster healing and less postoperative pain. Patients can often leave the hospital sooner and, in most cases, surgery can even be performed at an outpatient center. Convalescence is usually shorter, allowing patients to return to work and resume other activities sooner. Moreover, minimally invasive surgery is generally less expensive than open surgical procedures.

Up until the late 1980s, laparoscopic surgery—one of the most common forms of minimally invasive surgery—was mainly limited to gynecological procedures such as tubal ligation and the lysis of pelvic adhesions. The development of the micro-camera, however, opened the door to laparoscopic surgical procedures in a large number of other specialties, including urologic, general, gastrointestinal, thoracic, and orthopedic surgery. By the year 2000, laparoscopy is expected to account for 40% of urology procedures, 50% of general surgery procedures, and 70% of gynecology procedures performed in the United States.

Monopolar electrosurgery—the use of radio frequency (RF) current to cut tissue and control bleeding—has been employed effectively in open operative procedures for over 65 years. In part because of its long history of use in open surgery, it has become the most widely used cutting and coagulation technique in minimally invasive surgery, used by approximately 86% of surgeons performing laparoscopic procedures.

Though highly versatile, cost effective, and popular, monopolar laparoscopic electrosurgery can compromise patient safety under certain circumstances. For example, the surgeon may directly burn non-targeted internal organs or tissue with the tip of the active electrode, through imprecise mechanical operation of a laparoscopic instrument (i.e., “pilot error”). Perhaps more alarming, stray electrical currents emanating from the laparoscopic instruments can inadvertently burn non-targeted tissues beyond the surgeon’s limited field of vision, leading on occasion to grave complications. Such stray energy burns can occur regardless of the surgeon’s skill and judgment. Published clinical studies and case histories have
documented the very real risk of inadvertent tissue injury during laparoscopic monopolar electrosurgery, even though prevalence of the problem is currently not well defined.

Stray electrical currents may be released either through direct coupling or if the electrical insulation that coats the active electrode fails due to degradation or damage. Another electrical phenomenon known as capacitive coupling can instantaneously transfer significant amounts of stray electrical current to non-targeted tissue, causing serious burns.

Injuries arising from these stray electrical currents usually occur outside the restricted keyhole view of the laparoscope, and thus may go undetected by the surgeon. Unfortunately, symptoms of injury are usually delayed in onset for several days, thereby helping to obscure the underlying cause. The complications resulting from internal electrosurgical burn injuries compounded by delay in diagnosis and treatment can have a profound medical and economic impact on patients.

Electrosurgical burns involve a high risk of tissue necrosis and abscess formation. This can lead to perforation of internal organs, such as the bowel, resulting in bacterial contamination of the abdominal cavity (fecal peritonitis), which necessitates immediate and aggressive treatment. Even in this advanced age of antibiotics, the mortality rate from fecal peritonitis is reported to be as high as 25%.

In patients who survive such burns, the morbidity associated with the resulting complications can have serious and long-lasting physical, emotional, and financial implications. The necrosis of gastrointestinal tissue at a burn site, for example, can necessitate surgical resection of variable lengths of bowel and either temporary or permanent colostomy. Treatment is expensive and convalescence may be extended for many months, requiring long periods of time away from work.

The medicolegal and economic consequences of inadvertent and undetected burns incurred outside the surgeon's field of view are considerable, diverting healthcare resources and raising the costs of procedures and services. As evidenced by numerous legal cases, internal thermal injuries during laparoscopic surgery can be costly to the surgeons who perform these surgeries and the institutions at which they are performed.

As with any form of healthcare delivery, surgeons, biomedical engineers, risk managers, and healthcare provider organizations have a responsibility to protect patients against the potentially devastating injuries that can occur during laparoscopic electrosurgery. Several precautionary procedures and techniques have been introduced over the years by operating room staff in an attempt to reduce the incidence of stray energy release. By their very nature, however, these measures are limited in their ability to reduce the risk of electrosurgical injury to non-targeted tissues. Given the design of the instruments, the limited field of vision during laparoscopy, and the nature of the electrosurgical environment, even the most skilled surgeon may inadvertently burn a patient.

The failure to adequately address patient safety risks associated with laparoscopic electrosurgery has been compounded by the fact that at present, little if any routine maintenance and testing is performed on laparoscopic instrumentation. Unfortunately, biomedical engineers—those responsible for maintaining the integrity of electrosurgical equipment in the operating room environment—appear to have minimal awareness of the severity of the risks involved with electrosurgical burns, particularly those within the peritoneal cavity.

The encouraging news is that the problem of stray energy burns can be significantly reduced or eliminated if the proper safety protocols are followed. The most comprehensive and
effective solution to stray energy risks appears to be a technology known as active electrode monitoring or AEM. This patient protection device addresses both the insulation failure and capacitive coupling phenomena by casting a virtual safety net around the unpredictable electrical environment present during laparoscopic electrosurgery. By eliminating stray energy risks—which are to a large extent beyond the surgeon’s immediate control—surgeons can concentrate instead on mastering their laparoscopic surgery techniques. Through better training and the use of simple, cost-effective safety protocols such as active electrode monitoring, surgeons and their patients can continue to reap the benefits of laparoscopic electrosurgery while avoiding some of its more serious potential complications.
Over the past 25 years, there has been a significant conversion in surgical practice from open procedures to the use of fibroscopic instrumentation in minimally invasive surgery wherever feasible. Until quite recently, however, minimal access or “keyhole” surgery was mostly limited to gynecological surgery, and then generally only in tubal ligation and the lysis of pelvic adhesions. In the late 1980s, the development of a micro-camera that could project images displayed on a video monitor resulted in a rapid acceptance and expansion of minimally invasive surgery to a wider range of gynecological procedures and to several other specialties, including urologic and gastrointestinal surgery. Today, for example, 90% of elective and 50% of emergency gall bladder surgeries are performed laparoscopically. According to an informal study conducted by the Society of Laparoendoscopic Surgeons, laparoscopy will account for an estimated 40% of urology procedures, 50% of general surgery procedures, and 70% of gynecology procedures performed in the United States by the year 2000.

When used appropriately, minimally invasive surgery offers many benefits to patients compared with traditional open surgery. Since the procedure is less disruptive to tissues, patients generally recover faster with less pain, fewer wound problems, and less scarring. Studies have shown that patients recovering from laparoscopic surgery experience less severe postoperative pulmonary function difficulties than those recovering from open surgery.

Patients are frequently discharged from the hospital soon after minimally invasive procedures. Indeed, in many cases, surgery can be performed at outpatient centers. Convalescence following such procedures is usually shorter, allowing patients to return to work and to perform other activities sooner. In fact, several studies have shown that 95% of patients are discharged within 24–48 hours of laparoscopic cholecystectomy and over 90% return to work or normal activities within two weeks postoperatively. Patients subjected to open surgical cholecystectomy, by contrast, generally remain in the hospital for 4–7 days and require 4–7 weeks of post-discharge convalescence. Due to the decreased recovery time and quicker return to work associated with laparoscopic keyhole surgery, the costs to patients and healthcare insurers are considerably less than with open surgery.
Monopolar Electrosurgery
Monopolar electrosurgery has been used successfully in open operative procedures for over 65 years to control bleeding. In part because of this long history, it has become the most widely used surgical technique for cutting and coagulation in laparoscopic surgical procedures. In a recently published survey, 86% of surgeons reported that they employed monopolar electrosurgery in laparoscopic procedures.\(^{14}\) Its popularity, however, is not simply a function of its long availability—the versatility and preferability of monopolar electrosurgical techniques have been amply demonstrated in a very wide range of surgical settings.\(^{15-17}\)

Monopolar electrosurgery has traditionally been used primarily as a method of hemostasis during surgery. The technique gets its name from the single electrode used to deliver electrical energy from the current generator to the patient. A concentrated electrical current is delivered from the tip of the electrode to targeted tissues, causing a burn that stops bleeding. With this technique, the electricity
then disperses and flows harmlessly through the patient, to be returned to the electrosurgical unit (ESU) via a large return electrode pad attached to the patient's skin at a remote location. Several surgical functions have been facilitated using monopolar electrosurgery. By varying the voltage, current, or waveform of the electrical energy delivered by the electrode, surgeons can cut tissue cleanly (a “pure cut”), coagulate tissue to stop bleeding, or produce a “blended cut” that combines these two functions. Finally, a dispersed coagulation mode known as fulguration allows coagulation of diffuse bleeding, which may be desirable when operating on highly vascular tissues. This range of surgical modes, in addition to superior efficacy for coagulation, makes monopolar electrosurgery the dominant and most advantageous minimally invasive surgery technique.

**Alternatives to Monopolar Electrosurgery**

Other minimally invasive techniques such as bipolar electrosurgery, laser light surgery, and the harmonic scalpel are available for tissue dissection and the cautery of blood vessels for hemostasis. These techniques, however, have somewhat limited clinical efficacy and have not become widely utilized by surgeons, who generally prefer monopolar electrosurgery. In a recently published survey, for example, only 12% of surgeons reported using bipolar electrosurgery and 2% reported using laser energy.14

Bipolar electrosurgery uses an instrument on which both the active and return electrodes are mounted, delivering energy to tissues between the two electrodes. While bipolar electrosurgery can be superior to monopolar electrosurgery for certain neurosurgical and ophthalmic applications involving a “wet surgical field,” and includes only a minimal amount of the patient's tissue as part of the electrical circuit, the monopolar technique is preferred by most surgeons because of the range of procedures it allows them to perform.7 Unlike monopolar electrosurgery, bipolar electrosurgery is not an effective method for making a “pure cut.” Furthermore, the bipolar technique cannot be used to stop bleeding over a large area. In order to achieve hemostasis in bipolar surgery, it is necessary to grasp tissue between both the active and return electrodes—this may be difficult with dense tissues.18–20

Monopolar electrosurgery is also currently preferred by surgeons for laparoscopic procedures over alternative surgical tools such as laser light and the harmonic scalpel. These instruments are more expensive and they have limited applications. Lasers, for example, do not coagulate blood as well as electrosurgery.21 Although lasers can be used with some degree of success in spray or topical coagulation, they are ineffective for deep hemostasis. The contact neodymium Nd:YAG laser, in particular, has been shown to be less efficient in tissue excision and to cause more tissue damage and blood loss than monopolar electrosurgery.15,16 The harmonic scalpel technique is not very effective in either superficial or deep coagulation.17 (See Appendix A for a cost and efficacy comparison of the various laparoscopic cutting and coagulation techniques.)

Monopolar electrosurgery is clearly the dominant cutting and coagulation technique for minimally invasive surgery, with several advantages over alternative modalities. As with all surgical techniques, however, it is accompanied by certain risks that can increase morbidity, and in certain circumstances, even mortality.
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During open surgery, the surgeon operates in a relatively unrestricted space and generally has a full view of the exposed active electrode as well as the operative field and surrounding tissues. In this situation, the surgeon is usually immediately aware of an unintended burn and can apply treatment to avoid serious complications. The direct manipulation of instruments and internal tissues during open surgery allows maximum control by the surgical team with the result that unintentional electrosurgical tissue burns are rare.

During laparoscopic monopolar electrosurgery, by contrast, the view of the surgical field is constricted. The surgeon operates from the exterior of the patient’s body usually using 14-inch (35 cm) remote instrumentation. The manipulation of instruments and tissue is based on magnified images of a 1.5-inch (4 cm) field, relayed from a micro-camera connected to the laparoscope and displayed on a video monitor. The very nature of the surgical environment—in which the active electrode is in close proximity to other conductive instruments and to tissue—may result in stray electrical current being transmitted to unseen tissue off the extended shaft of the remote laparoscopic instruments. While the laparoscope provides a detailed view of the tip of the active electrode, up to 90% of the presumably insulated part of the electrode may be beyond the surgeon’s view at any one time.\textsuperscript{22} Since the surgeon cannot directly or readily observe a burn that occurs outside the surgical field, unreliable indicators—such as interference on the video monitor or loss of power to the electrode tip—provide the only warning that a thermal injury may have occurred. Unaware that electrical currents may be dangerously straying, the surgeon cannot intervene to prevent injury, let alone treat such injury immediately following its causation.\textsuperscript{23–25}

The stray currents that can cause patient injury outside the laparoscope’s view may occur via direct coupling, insulation failure, or capacitive coupling. Direct coupling occurs when the active electrode touches another metal instrument within the abdomen, transferring energy to the second instrument and possibly injuring tissue with which it comes in contact. For example, the active electrode touches the laparoscope, which then touches and burns the bowel or other organs.

Insulation failure occurs when the insulated shaft of the electrode—designed to protect

\textbf{Unintentional Tissue Burns at Non-Targeted Sites}
against the release of stray electrical current—becomes compromised due to excessive voltage, abuse, wear and tear, poor handling, or mechanical accident. Insulation breakdown can occur cumulatively over time or can take place during a single laparoscopic procedure or during disinfection and sterilization procedures.\textsuperscript{7,26} The breakdown along the unseen shaft of an activated electrode can allow electrical current to leak into surrounding non-targeted tissues, causing unobserved damage (See Figure 1). Paradoxically, small cracks are more dangerous than large breaks because the current is more focused, and is therefore more likely to produce a burn.\textsuperscript{7,17,22}

The risk of insulation failure is exacerbated by the fact that biomedical engineers in most facilities do not maintain or test laparoscopic instruments as a matter of routine. More typically, these instruments are used until they fail, and then are discarded. Given the potential for stray energy to escape from these instruments through insulation failure, the real question is whether these instruments will fail safely or in a manner that injures a patient.

Electrosurgical burns can also result from the phenomenon of capacitive coupling, which occurs when electrical current is induced from the active electrode to nearby conductive material, despite intact insulation. During electrosurgery, the charge on the active electrode switches from highly positive to highly negative at a very high frequency. The rapidly varying electrical field around the active electrode is only partially impeded by electrical insulation and creates stray electrical currents by alternately attracting and repelling ions in surrounding body tissue. Currents transferred in this way in nearby tissue can cause irreversible damage. The movement of electrically charged ions in capacitively coupled tissue can cause currents that can heat tissue sufficiently to produce a burn (See Figure 2).\textsuperscript{7,22,27}

Due to the well-recognized phenomena of direct coupling, insulation failure, and capacitive coupling, surgeons performing laparoscopic monopolar electrosurgery can seriously burn non-targeted tissues outside the surgical field, despite their best skill and effort. Patients who suffer such unintended electrosurgical injuries can develop painful and costly complications, resulting in subsequent emergency surgeries, extended hospital stays, long-term convalescence, and potentially life-threatening infections.
Complications Resulting from Unintentional Tissue Burns

Complications resulting from accidental, unsuspected thermal injuries can have significant adverse medical impacts on patients, including organ damage and vessel hemorrhage, perforation, and peritonitis. If not detected expeditiously, any of these conditions can result in significant morbidity or even death. Fecal peritonitis, resulting from the contamination of the abdominal cavity by bacteria from a bowel perforation, is the most feared complication of thermal injury, with a mortality rate estimated at 25%.

In a worst-case (but not atypical) scenario, a patient with a severe, but undetected, thermal injury to the bowel leaves the hospital asymptomatic. The patient returns to the local emergency room or outpatient clinic a few days postoperatively with a low-grade fever and complaining of increasingly severe abdominal pain. Abdominal x-ray films are negative for free air (a pathognomonic sign of gastrointestinal tract perforation), and laboratory tests may show a moderate increase in white blood cells suggesting inflammation or infection. The patient is placed on antibiotics but does not respond. Instead, the signs of advanced peritonitis—high-grade fever and severe abdominal pain—develop in due course and emergency exploratory surgery is performed. The surgery reveals extensive necrosis of the bowel with perforation and seepage of fecal contents into the abdominal cavity. Extensive areas of severe infection and inflammation—diffuse purulent peritonitis—are observed in the abdominal cavity. Wide debridement and resection of the intestine are performed with colostomy. The patient is placed on aggressive intravenous antibiotic therapy only to die in seven days from septicemia (blood poisoning).

Although death is, of course, the most catastrophic complication of undetected burns to the bowel during laparoscopy, significant morbidity is associated with undetected burns and can present healthcare providers with extremely difficult patient management challenges. Patients recovering from the reparative resection of the intestine may require stents or colostomies to maintain gastrointestinal continuity. Parenteral nutrition is frequently necessary for up to 10 days after surgery while awaiting the return of bowel function. Oral intake of solid nutrients may be impossible for up to 20 days.

The morbidity associated with undetected burns can also have serious long-term financial and psychological impacts on
patients and their families. Recurrent infections and painful adhesions requiring additional hospitalizations and surgery are common long-term complications for these patients. Prolonged treatment can be expensive and convalescence may be extended for many months, requiring long periods of time away from work or normal activities.7,29–32

The seriousness and long-term impact of complications arising from unintended tissue burns during laparoscopy are further illustrated in the following case histories.

Case: A 38-year-old nurse was seen by a gynecologist for left lower quadrant pain. The patient’s surgical history included wedge resection of the left ovary for endometriosis. The gynecologist made a diagnosis of pelvic adhesions of the ovary and performed diagnostic laparoscopy. Monopolar electrosurgery was used to cauterize adhesions from the ovary to the pelvic side wall. The electrosurgical generator power setting was 30 watts and the electrode was activated for approximately five seconds. The patient was considered sufficiently well to be discharged from the hospital on the same day of the surgery. On the seventh postoperative day, however, the patient became quite ill and was admitted to the emergency room with a low-grade fever and slightly elevated white blood count. Free air was found in the abdomen by CT scan and the consulting gastroenterologist suggested that the patient was suffering a possible complication of laparoscopy. An exploratory laparotomy revealed “multiple necrotic areas” in the distal ileum that resembled “burns.” Several areas of the colon appeared “compromised” and one area showed perforation. Peritonitis was localized to the right lower quadrant. Microscopic examination of the small bowel showed “focal full-thickness necrosis.” Examination of the large intestine revealed “areas of mucosal ulceration and full-thickness wall necrosis.” Forty centimeters—almost 16 inches—of the ileum were removed during surgery and a temporary colostomy was performed. After the laparotomy, the patient developed a wound infection requiring treatment. The patient subsequently underwent surgery to close the colostomy, and was sufficiently well to return to normal activities six months after the initial laparoscopy.29,30

Case: A 79-year-old woman underwent laparoscopic surgery for gall bladder removal. No bowel injury was noted during the surgery. The colon was, in fact, not observed by the surgeon at any time during the procedure. The patient was discharged from the hospital two days postoperatively, asymptomatic. She collapsed and died, however, four days after discharge. Upon autopsy, examination of the abdominal cavity revealed extensive soiling of the peritoneal cavity with fecal material and generalized peritoneal inflammation. The source of the leakage of bowel contents was found to be two perforations in the transverse colon. Diffuse peritonitis was determined to be the cause of death. The pathologist concluded that the histological appearance of the perforated tissue suggested “coagulative necrosis consistent with thermal injury.”33

Undetected thermal injury should be suspected in patients who present with symptoms suggesting organ perforation or peritonitis following laparoscopic monopolar electrosurgery. The exact prevalence of injury to the intestines or other organs as a result of stray electrical current, however, cannot be ascertained for several reasons. Unlike injuries that occur within the visible surgical field, stray current injuries are generally not immediately visible at the time of surgery. Since the surgeon cannot directly observe the burn, unreliable indicators—such as interference on the video monitor and/or loss of power at the tip of the electrode—provide the only warning that a thermal injury may have occurred.22,34,35
Further, clinically significant symptoms of the complications of thermal burns are often delayed—sometimes for several days after the initial surgery—placing a patient at risk of delayed diagnosis and treatment.\(^3,28,36\) Patients suffering from complications of thermal burns often initially present with symptoms markedly similar to far less serious conditions. With the exception of a slightly elevated white blood count, laboratory tests are frequently unremarkable in these patients.\(^36\) Patients with minor thermal injuries may respond well to oral antibiotics and the exact cause of their symptoms may never be determined.

Another challenge in determining the prevalence of stray energy burns is that these injuries are sometimes mistakenly diagnosed as puncture wounds from the insertion of the trocar or as lacerations caused by surgical pilot error in manipulating the laparoscopic instruments. The histological features of tissues injured by burns are unique, however, differing markedly from those observed with puncture injury and laceration. Ironically, the diagnosis of thermal injury is often not made by pathologists, those most qualified to discern the difference between a burn and a puncture/laceration.\(^12,14\) Moreover, the injured areas may be compromised by secondary infection making the identification of the primary cause difficult;\(^29\) or the microscopic examination of the tissue may not be sufficient to detect coagulative necrosis. In many cases, the physician performing the diagnosis may not be fully aware of the unique histological characteristics of thermal injury; complications attributable to stray energy burns may therefore be underreported and underappreciated.\(^7\)

Nevertheless, case histories and survey results suggest that the problem is prevalent enough to cause substantial concern, especially given the severity of the complications when it does arise. A survey conducted at the American College of Surgeons (ACS) meeting in 1993 to investigate electrosurgical complications and surgical techniques during laparoscopy indicated that surgeons are quite aware of the danger of thermal injury to patients. Of the 506 surgeons polled, 86% acknowledged the potential for hazardous complications beyond the laparoscope’s field of view during use of intact, fully insulated monopolar electrosurgical instruments. Eighteen percent of the participating surgeons reported that they had personally experienced complications in patients due to capacitive coupling or insulation failure during laparoscopy, and a majority (54%) reported that they knew other surgeons whose patients had experienced such complications.\(^14\)

A study report published in 1994 by the Physician Insurers Association of America (PIAA) revealed that 615 patient injury claims were filed as a result of injuries incurred during laparoscopic procedures over a four-year period. A majority of the medical malpractice insurance member firms in the United States responded to the survey (31 out of 44). The most common injuries reported were to the bile duct; other injury claims were attributable to perforation of the bowel, small intestine, and liver, and injuries to hepatic ducts, arteries, and veins. Additional surgery commonly followed, but was generally delayed since the injuries were not detected during the initial laparoscopic procedure. For 11% of the injured patients, postoperative complications compounded by late diagnosis ultimately resulted in death. While the PIAA study report did not quantify the percentage of laparoscopic surgical injury claims attributable to stray energy problems (as opposed to trocar punctures or instrument lacerations, for example), these data warrant serious concern when taken together with the aforementioned ACS data.\(^37\)
Medicolegal and Economic Issues

Patient injuries from burns incurred during laparoscopic monopolar electrosurgery have potentially enormous medicolegal and economic consequences to medical institutions, healthcare professionals, and insurers. Hospital risk managers, hospital insurers, physician insurers, and surgeons have a strong incentive to protect themselves and their institutions from the financial and legal risks associated with such injuries.

At the 1995 meeting of the Society of Laparoendoscopic Surgeons, 13% of members surveyed indicated that they currently had one or more malpractice cases in litigation that involved a laparoscopic electrosurgical procedure. Not surprisingly, the increasing number and scope of malpractice claims citing injury during laparoscopic surgery has prompted the formation of a special Laparoscopic Litigation Group within the Association of Trial Lawyers of America. This group has taken the position that injury resulting from stray electrosurgical current during electrosurgery provides a strong case for malpractice suits. According to one of the group’s founders, surgeons and hospitals may be targeted both for specific surgical errors as well as for simply using electrosurgery tools and instruments that allowed stray current to injure a patient.

Physician insurance companies also have begun to recognize the risk that minimally invasive monopolar electrosurgical procedures pose to surgeons. In response to the rising number of malpractice claims, some malpractice insurers have increased their rates by 15–20% for surgeons who perform these procedures. In a more proactive approach, several physician insurance companies now offer no-cost, accredited post-graduate training courses in electrosurgery and risk management for their members who use laparoscopic electrosurgery. Some malpractice insurance companies have reduced their rates by as much as 7% for surgeons who have attended these training sessions.

Several recent malpractice cases underscore the point that unintentional thermal injury can be very costly for surgeons who perform minimally invasive electrosurgery. In a 1992 Minnesota case, for example, a 31-year-old woman claimed that her surgeon’s negligence during the cauterization of endometrial tissue resulted in the perforation of her colon. As a result of the perforation and subsequent
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Contamination of the abdominal cavity, the woman developed a severe infection and required two colostomies in order to repair the damage. The woman was awarded $2.8 million by the jury, including almost $2 million for “pain, disability, disfigurement, embarrassment, and emotional distress.” The remaining award was for “past and future medical expenses and lost earnings” that were expected to be associated with her disability.31

In the previously discussed case involving the 38-year-old nurse who suffered complications from laparoscopic monopolar electrosurgery to dissect pelvic adhesions, a malpractice suit was brought against the gynecologist. The Florida jury found the gynecologist liable for medical negligence and awarded the victim $551,891—$51,891 for past medical expenses, $300,000 for past pain and suffering, and $200,000 for future pain and suffering.30 Two of the surgeon’s expert witnesses testified that bowel ischemia resulting from stray energy burns coincidental to the monopolar electrosurgery caused the damage.

In 1994, a Washington woman sued her surgeon following the laparoscopic removal of her gallbladder. Although the surgeon had previously performed only 10 cholecystectomies and had a total of eight hours of advanced training in laparoscopic electrosurgery, he assured his patient that there was absolutely no risk involved in minimally invasive electrosurgery. The operating room record indicated that throughout the surgery, the video monitor registered “electrical interference” that “made continuing the procedure extremely difficult.” Seven days after the procedure, the patient was found during open surgery to have a high-grade stricture of the common hepatic duct. The injury required repeated surgeries for repair and dilation of the duct. The surgeon’s own expert witness testified that the injury was most likely the result of electrosurgical burns to the hepatic duct during the periods of “electrical interference.” It took the jury less than one hour to conclude that the surgeon was negligent in causing the injury and to award the victim $250,000.32

These examples represent just a small cross-section of the malpractice cases filed as a result of electrosurgical burns. The number of cases that have actually gone to trial is likely dwarfed by the number of cases in which surgeons and/or insurance companies have settled claims out of court.

Professional and Public Awareness

The medicolegal problems associated with stray energy burns during laparoscopic monopolar electrosurgery will most likely escalate, considering both the trend toward these types of surgical procedures and the increased attention paid to this issue by trial lawyers, insurance companies, professional organizations, and the popular press.

Healthcare professionals are becoming increasingly aware of the need to address the issue of unintentional burns that go undetected in minimally invasive monopolar electrosurgery, as illustrated by the previously mentioned ACS and PIAA surveys.14 Nursing organizations are also beginning to recognize the danger of tissue burns during laparoscopic electrosurgery. In its recently published recommended practices for minimal access electrosurgery, the Board of Directors of the Association of Operating Room Nurses (AORN) recognized the risk of capacitively coupled electrical currents during laparoscopic electrosurgery and the associated risk of severe—and possibly fatal—burns to patients. The guidelines recommend that practices to reduce such risks be employed, including increased vigilance by perioperative nursing staff and strict adherence to equipment manufacturers’ instructions.42

Furthermore, an article by the editor of the AORN Journal has also warned members of
Institutional Review Boards (IRBs) and perioperative nurses of the potential danger to patients of severe burns from the coupling of electrical current when electrosurgery is used in minimally invasive procedures. The editor reminded perioperative nurses that, as the front-line “guardians of surgical patients,” it is their responsibility to control the surgical environment and be fully aware of the hazards of laparoscopic electrosurgery. Two monthly publications directed to operating room decision makers—OR Manager and Surgical Services Management—have devoted in-depth articles to the “overlooked” hazards of laparoscopic electrosurgery, and have recommended precautionary steps to protect against risks of patient injury.

The non-clinical press has recently begun to bring the possibility of serious injury during minimally invasive electrosurgery to wider attention. An article in the technology section of Modern Health Care discussed surgeons’ fear that surgical accidents will occur increasingly as electrical tools are used more frequently in minimally invasive surgery.

Reaching even the general public, a front-page article in the Houston Post ran with the headline, “Fast, Cheap Surgery Can Also Be Risky: Complications Stem From Flaws in Laparoscopy.”

Even so, minimally invasive surgery remains an extremely valuable diagnostic and therapeutic procedure. The many medical attributes of its use are unquestioned, and clinicians and patients should have the benefit of this important surgical technique whenever appropriate. The danger of serious or fatal thermal injury during laparoscopic monopolar electrosurgery, however, must be minimized in order to protect patients and reduce medicolegal risk to healthcare institutions and healthcare professionals.
Several measures intended to reduce the risk of internal thermal injury during laparoscopic monopolar electrosurgery have been adopted by surgeons and healthcare facilities, albeit to varying degrees. Certainly, better training of medical personnel in the use of electrosurgical equipment and better understanding of the physics and hazards of electricity can reduce the rate of electrosurgical complications, particularly those attributable to direct thermal injury (i.e., pilot error). Several studies, in fact, have substantiated this proposition. \(^{10,46,47}\) One study found that 22% of laparoscopic surgeons who had completed a two-day introductory laparoscopy training seminar—but received no additional training—reported complications during minimal access electrosurgery. Only 5% of surgeons who received additional training in laparoscopy, however, reported complications. \(^{47}\)

Unfortunately, there are currently no universally enforced or professionally endorsed guidelines for the training and credentialing of electrosurgical staff members. This fact is reflected in the results of an informal survey conducted at a meeting of the Society of Laparoscopic Surgeons, in which 86% of surgeons stated that they currently worked in a facility that did not require credentialing, and 50% indicated that they had no formal training in electrosurgery. \(^{38}\)

A recent issue of *Health Devices* suggested that a clinical credentialing and privileging policy be put into place by hospitals for surgeons and perioperative nurses who perform electrosurgery. \(^{25}\)

While improved training and credentialing can help ameliorate electrosurgical complications relating to improper technique, these efforts alone cannot fully address the safety risks associated with stray electrical current. Other measures that have been suggested include specific training of technical personnel, visual examination of electrodes for insulation breakdown, the use of disposable electrodes, prohibiting the use of hybrid (plastic-metal) cannulas or plastic anchors with all-metal cannulas, and adopting the use of bipolar electrosurgery. To some degree, improved adherence to these measures may decrease the incidence of electrosurgical injury; their effectiveness, however, is limited, because insulation failure and capacitive coupling are dependent largely on the very nature of the minimally invasive electrosurgical environment. Only a change in that environment can eliminate the risk of electrosurgical injury. Another remedy that has been proposed—using lower power and lower voltage settings on the...
Electrosurgical equipment—tends to compromise the very effectiveness of the electrosurgery and may place the patient at risk.

Proper maintenance and testing of instruments by biomedical engineers has been proposed as one of the best approaches to reduce the risk of inadvertent tissue burns during laparoscopic monopolar electrosurgery due to insulation breakdown. Currently, there are no accepted standards or protocols for such maintenance or testing, even though it is widely recognized that laparoscopic instruments—which are generally used until they fail—may possess defects that can lead to insulation failure. The current lack of testing and maintenance probably stems from the fact that most biomedical engineers would appear to be unaware that the stray energy problem exists or that it can produce significant injury.

Clearly, pre-use testing and routine maintenance of instruments could help reduce the risk of insulation failure. Conventional, visual examination methods may not be sufficient, however. Normal wear and improper handling can damage the electrode insulation. Such defective insulation can go unnoticed, even during careful visual examination prior to a procedure. Furthermore, even if the insulation is intact prior to surgery, damage from contact with sharp instruments, such as the edges of the trocar cannula, can impair electrode insulation during the procedure. The electrode insulation is stressed by the voltage differences created across it—over time, especially with high voltage use, this electrical stress can cause insulation failure. In short, no degree of vigilance in pre-use testing of electrodes will completely eliminate the risk that intraoperative insulation failure will occur.

The cumulative breakdown of insulation can be averted by using disposable electrodes, provided strict protocols for disposal of electrodes are followed to prevent the possibility of reuse. Even when used only once, however, disposable electrodes can be damaged prior to or during electrosurgery, resulting in failure. Disposable active electrodes also tend to have thinner insulation than reusable electrodes, making them more susceptible to capacitive coupling and insulation failure.

Importantly, fully functioning insulation alone is not sufficient to prevent thermal injury. Capacitive coupling can occur with both reusable and disposable electrodes even when the insulation surrounding the active electrode is intact. Certain protective measures have been suggested to mitigate the likelihood of patient injury from capacitive coupling. For example, the avoidance of hybrid (plastic-metal) cannulas or plastic anchors with all-metal cannulas somewhat reduces the possibility that any stray current flow resulting from capacitive coupling will cause serious complications. When all-metal cannulas are used, currents that are capacitively coupled to the cannula can flow off through the patient’s abdominal wall with little risk of injury. When hybrid cannulas or plastic anchors are used, by contrast, capacitively coupled currents—without another path of least resistance—may arc to tissues adjacent to the cannula, causing serious burns.

The use of low-power/low-voltage settings on electrosurgical equipment has also been proposed as another way to reduce electrosurgical mishaps, as injuries are more frequently associated with high-power surgical modes. In some clinical situations, however, high-power surgical modes such as fulguration are essential. Indeed, the risk of patient injury can actually be increased by the use of low-power settings, which are less effective at coagulating. If ineffective coagulation results in uncontrolled bleeding, the surgeon has no alternative but to return to high-power settings. In this emergency situation, where achieving hemostasis becomes urgent, the opportunity for patients to be injured by stray current or inadvertent surgeon error is inevitably increased.
In summary, the procedures and techniques suggested in this section to reduce the risk of electrosurgical injury with monopolar equipment are of limited utility, given the problems of insulation failure and capacitive coupling. Adherence to these procedures and techniques, while helpful, will not reduce the risk of burns to non-targeted tissues to a satisfactory level. Even the most skilled surgeon, following the strictest safety procedures, may inadvertently burn non-targeted tissue during laparoscopic electrosurgery due to the nature of the electrosurgical environment. Alternative methods of performing minimally invasive surgery—such as bipolar electrosurgery, laser light, and the harmonic scalpel—can reduce the risk of tissue burns to non-targeted tissues, but these techniques have gained extremely limited acceptance due to their reduced range of application. An alternative technological solution to the problem of electrical burns to non-targeted tissues is needed so that patient safety during this popular and clinically effective surgical technique may be better ensured.
Because tissue burns to non-targeted sites are due largely to the surgical environment during laparoscopic monopolar electrosurgery, improvements in user skill and training and biomedical engineering protocols to inspect equipment for insulation integrity alone cannot eliminate the problem. This situation requires a technological solution that prevents tissue burns by modifying the electrosurgical environment itself.

Such a technological solution should meet a number of criteria. First and foremost, it should completely eliminate the chance of inadvertent tissue injury due to stray electrical currents from insulation failure or capacitive coupling. Its presence should be transparent to the surgeon, requiring little additional training and few adjustments in procedures or surgical methods. It should require little capital investment and be cost effective to use over time. Finally, it should overcome the current deficiencies in maintenance and testing of laparoscopic instruments by ensuring that when such instruments do fail, they fail safely.

In fact, a newly available technology meets these criteria and thus provides a solution to the problem of unintended tissue burns to non-targeted sites during laparoscopic monopolar electrosurgery. This technology—active electrode monitoring (AEM)—uses a combination of added electrical insulation and conductive shielding in addition to an electronic current monitoring system. The added electrical insulation and conductive shielding absorb any stray currents released through faulty insulation. Moreover, the conductive shielding is electrically connected to the return electrode of the electrosurgical unit, allowing capacitively coupled currents to flow off harmlessly. In the event that any stray energy reaches potentially dangerous levels, the active electrode monitoring circuit interrupts the flow of energy from the electrosurgical unit and sounds an alarm.

The Emergency Care Research Institute (ECRI), a non-profit research agency that reviews and tests medical devices, conducted a thorough study in 1995 of the potential dangers of monopolar laparoscopic electrosurgery and the safety precautions that can be taken to mitigate or eliminate these risks. In its independent laboratory tests on the only currently available active electrode monitoring system, ECRI found this system to successfully and safely prevent stray energy leakage and tissue injury at unintended sites. After comparing this technique with other suggested protective
measures such as electrode inspection and the avoidance of high electrosurgical power settings, the ECRI report concluded that active electrode monitoring offers the highest available level of protection against patient injury due to insulation failure and capacitive coupling, and recommended that this system be used as the best means to promote electrosurgical safety.\textsuperscript{25}

Active electrode monitoring has also been recognized in leading medical journals, such as the \textit{Journal of Reproductive Medicine} and \textit{Gynaecological Endoscopy}, and by professional societies, for its contributions to the safe and effective application of monopolar laparoscopic electrosurgery.\textsuperscript{23,50} In its recommendations on methods of preventing possible complications of minimally invasive electrosurgery, the American Association of Gynecological Laparoscopists has urged surgeons to consider using active electrode monitoring.\textsuperscript{19}

The development of active electrode monitoring appears to have provided a safe and effective solution to eliminate the stray energy problems associated with monopolar laparoscopic electrosurgery. Given its ready availability, cost effectiveness, and capacity for unobtrusive incorporation into the surgeon’s regular routine, failure to employ such a technology, along with improved training and accreditation and biomedical engineering safety protocols, appears unacceptable.
Conclusion

Minimally invasive monopolar electrosurgery continues to be used in a greater number of procedures in a wider array of surgical specialties due to its versatility and effectiveness. With this expanded use, a significant population of patients are currently and will continue to be at risk for unintended burns to non-targeted tissues resulting from stray energy release due to direct coupling, insulation failure, or capacitive coupling.

The potential consequences of such burns to patients—including emergency surgeries, extended hospital stays, long-term convalescence, severe and sometimes fatal infections—are significant. Failure to adequately address the underlying etiology with appropriate safety protocols and technology also incurs heavy direct and indirect financial penalties for the healthcare system at large, and for the surgeons who perform these surgeries and the institutions where they practice.

This failure is all the more remarkable given the relatively recent solution of an allied problem—skin burns at the site of the return electrode pad during open monopolar electrosurgery, caused by high currents flowing through the skin with inadequately attached return electrodes. As awareness increased, education and improved vigilance greatly reduced these skin burns, along with the introduction and adoption of innovative technology—return electrode monitoring—to the point where these injuries are now virtually obsolete.

Even if one postulates that the incidence of stray energy burns is relatively low, the severity of the injuries when the problem does occur is significant. Reasonable prudence and economics dictate that cost effective and easily implementable safety technologies such as active electrode monitoring, along with improved clinical training and credentialing practices, and biomedical engineering safety protocols, be adopted sooner rather than later. Surgeons, nurses, OR managers, biomedical engineering directors, hospital risk managers, and healthcare insurers all share a responsibility for patients’ well-being and safety. As such, they all have an ethical obligation to protect patients from potential injury by continuously evaluating and adopting new practices and technologies that can help them fulfill this obligation.
## Appendix A: Cost and Efficacy Comparison*

<table>
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<tr>
<th>Surgical Energy</th>
<th>Efficacy</th>
<th>Safety</th>
<th>Hospital Costs</th>
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<tr>
<td></td>
<td>Cut</td>
<td>Coag</td>
<td>Capital</td>
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<tr>
<td>Unmonitored Monopolar Electrosurgery</td>
<td>∗∗∗ ∗∗∗ ∗∗∗ ∗∗∗</td>
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</tr>
<tr>
<td>Monopolar Electrosurgery with AEM &amp; REM</td>
<td>∗∗∗ ∗∗∗ ∗∗∗ ∗∗∗</td>
<td>Yes</td>
<td>Exists</td>
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<td>in O R</td>
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<tr>
<td>Bipolar Electrosurgery</td>
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<td>Exists</td>
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<td></td>
<td></td>
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<td>in O R</td>
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<tr>
<td>Laser</td>
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<tr>
<td>Harmonic Scalpel</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>$13,900</td>
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* minimally effective
  ∗ ∗ ∗ ∗ highly effective

AEM — active electrode monitoring
REM — return electrode monitoring

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**Notes:** The dollar figures quoted were generated in 1996 and may not represent current pricing.
Avoiding Electrosurgical Injury During Laparoscopy

**Glossary**

**Active electrode**  Device that directs electrical current to the surgical site to achieve the desired surgical effect. The energy is then diffused and captured by the return electrode’s large surface area. The active electrode can be in the form of simple probes, cutting blades, clamps, or scissors.

**Active electrode monitoring (AEM)**  A technology designed to prevent stray energy along the length of a laparoscopic instrument. When connected to a monitoring electronic unit, stray energy will be detected and burns to the patient will be prevented.

**Bipolar electrosurgery**  Electrosurgery technique in which current flows between two electrodes mounted on the same instrument and positioned around tissue to create a surgical effect. Current passes from one electrode, through the desired tissue, to another electrode, thus completing the circuit without entering any other part of the patient’s body.

**Capacitive coupling**  Creation of varying electrical currents in tissues surrounding an insulated electrode due to variations in the electrode's electrical field as the electrode's voltage changes. Capacitive coupling is reduced by increasing the thickness, not the quality, of the electrode's insulating layer.

**Coagulation (electrosurgical)**  The use of electrical energy to stop bleeding by thickening and clotting blood.

**Current**  Flow of electricity through a conductor due to an electrical voltage; akin to water flow through a pipe.

**Desiccation**  Stopping the blood flow from a discrete bleeder using electrical energy.

**Direct coupling**  Occurs when the active electrode touches another metal instrument, thereby transferring energy to the second instrument and possibly injuring tissue with which it comes in contact.

**Electrosurgery**  Cutting and coagulation of body tissue with high-voltage current conducted to the surgical site by active electrodes (either monopolar or bipolar). Radio frequency current is used to avoid tissue and muscle stimulation.

**Electrosurgical unit**  The instrument that generates and controls the electrical power used in electrosurgery; includes a generator, foot- and/or hand-control devices, and an electrical cord.

**Fulguration**  Stopping diffuse blood flow over a large area by using an arc of electrical sparks that are transmitted through the air from the electrode to the tissue.

**Generator**  Instrument that produces high-voltage current.

**Hemostasis**  Stopping blood flow. Electrical energy is frequently used during surgery for hemostasis.
Insulation failure  Damage to the insulation barrier, allowing the current to flow outside of the planned electrical pathway.

Laparoscope  Optical instrument used to view the peritoneal cavity through small openings in the abdominal wall.

Minimally invasive surgery  Surgery that does not require the larger and open incisions of traditional surgery.

Monopolar electrosurgery  Electrosurgery in which current flows to the surgical site by a single active electrode and is returned to the electrosurgical unit by a remote return electrode.

Return electrode  A large pad attached to the patient’s skin through which electrical energy is returned to the electrosurgical unit.

Return electrode monitoring (REM)  A technology incorporating a “split” conductive surface patient return electrode which can measure impedance at the interface between patient tissue and the patient return electrode itself and avoid tissue burns (“pad burns”).

Shielding  Protective sheath, used in conjunction with a monitoring device, to prevent electrosurgical energy from burning a patient at an undetected site out of view of the laparoscope.

Trocar cannula  A tubular instrument inserted through a patient’s abdominal wall (in the case of laparoscopy), through which the laparoscope and other surgical instruments are inserted.

Voltage  The electrical “pressure” that drives electrical current through a conductor; akin to water pressure in a pipe.
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