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An Updated Perspective On The Risk Of Stray Energy Burns

OVERVIEW

With the widespread adoption of laparoscopic surgery 15 years ago, a number of studies warned of the issue of stray energy burns that resulted in serious patient morbidity and mortality. While laparoscopic surgery has expanded to treat dozens of conditions and now accounts for 5 million surgeries in the United States annually, the physics of the electro surgery have remained unchanged and stray energy burns continue to be an unquantified risk to patients.

Several organizations, including the U.S. Department of Defense (DoD) in a May 2010, Patient Safety Analysis Center publication, have called attention to this issue in recent years.[1]

Unintended burns to non-targeted tissue are often undetected and can result in serious and even lethal outcomes. Stray energy burns may account for up to 5.4 percent of laparoscopic surgery related injuries[2], or an estimated 1,350 cases annually in the United States.[3] These events may be tracked as adverse or negative outcomes, possibly affecting quality measures and reimbursement.

Current safety protocols used by 90 percent of U.S. military and civilian hospitals do not sufficiently protect against stray energy burns.[4] The introduction of laparoendoscopic single site surgery (LESS) increases the risk of stray energy burns. Technology that prevents these burns is available and cost effective.

BACKGROUND

Each year, nearly 5 million laparoscopic procedures are performed in the United States. Gallbladder removal and gynecological treatments, primarily hysterectomy, are the most common of these procedures, but others such as gastric bypass surgery and urologic procedures, are rapidly increasing in numbers. A small percentage of these patients are at risk for unintended and potentially lethal stray energy burns caused by insulation failure and capacitive coupling of the electrosurgical instruments.

It is estimated that 5.4 percent of laparoscopic surgery related injuries are caused by electrosurgical equipment. In a large prospective study conducted in 1997, there was an overall complication rate of 5.7/1000 laparoscopic procedures.[5] If stray energy burns account for 5.4 percent of these injuries, burns could be affecting 1,350 cases in the U.S. annually.

Two-thirds of stray energy burns are thought to be unobserved as they occur outside the surgeon's field of vision.[6] Patients who receive stray energy burns often present with what seem to be relatively normal postoperative symptoms: "low-grade fever, abdominal pain, and moderately elevated white blood count."[7] Patients who do not seek or respond to treatment may deteriorate rapidly, particularly if the burn has resulted in peritonitis, which has a 25 percent risk of death.

Complications of stray energy burns may be recorded as negative surgical outcomes, particularly if they result in a re-admission of the patient. Outcomes measurement is becoming standard and results in reduced reimbursements or sometimes deferred patient referrals in the case of insurers that adopt a "centers of excellence" strategy, reportedly being considered by the DoD. The U.S. Department of Health & Human Services currently measures 30-day post-surgical readmission and mortality rates for laparoscopic gallbladder surgery as well as hernia, bowel, gynecological and other surgeries.[8] The National Quality Forum considers burns from any source resulting in patient death or serious disability as one of the organization's 28 Serious Reportable Events.

Stray Energy Burns Fast Facts

- Two-thirds of laparoscopic injuries are undetected during surgery.
- Five percent of laparoscopic injuries are due to stray energy burns, accounting for as many as 1,350 cases in the United States annually.
- Stray energy burns can result even if insulation is intact prior to surgery.
- Patients with stray energy burns may not present with symptoms until a week after surgery.
- Stray energy burns may be considered an adverse event under quality monitoring and reimbursement methodology.
- Multiple organizations recommend use of active electrode monitoring to prevent stray energy burns.

UNKNOWN DANGER

During laparoscopic surgery, approximately 90 percent of the electrode is inside the patient's body but outside the surgeon's field of vision. [See figure 1.] Insulation failure or capacitive coupling can occur at any point and cause stray energy burns to unintended tissue. Because the burn is outside the field of vision and most endoscopic equipment does not have safety or warning mechanisms, the surgical team may not have knowledge of the burn at the time it occurs. Standard practice often does not include visualization of the entire region prior to closing.

Most stray thermal burns are caused by two occurrences:

1. Insulation failure is the breakdown of material used to contain the electricity in the electrode. It can occur in single-use or reusable electrodes. Insulation failure can be caused by incorrect sterilization, improper handling, or normal wear and tear. Although reusable electrodes are limited to a manufacturer-specified number of uses (typically ranging from 25-50), they may be used longer, increasing the risk of insulation failure. Microscopic pin holes present the biggest hazard by concentrating the power into a small area. [See figure 2.]

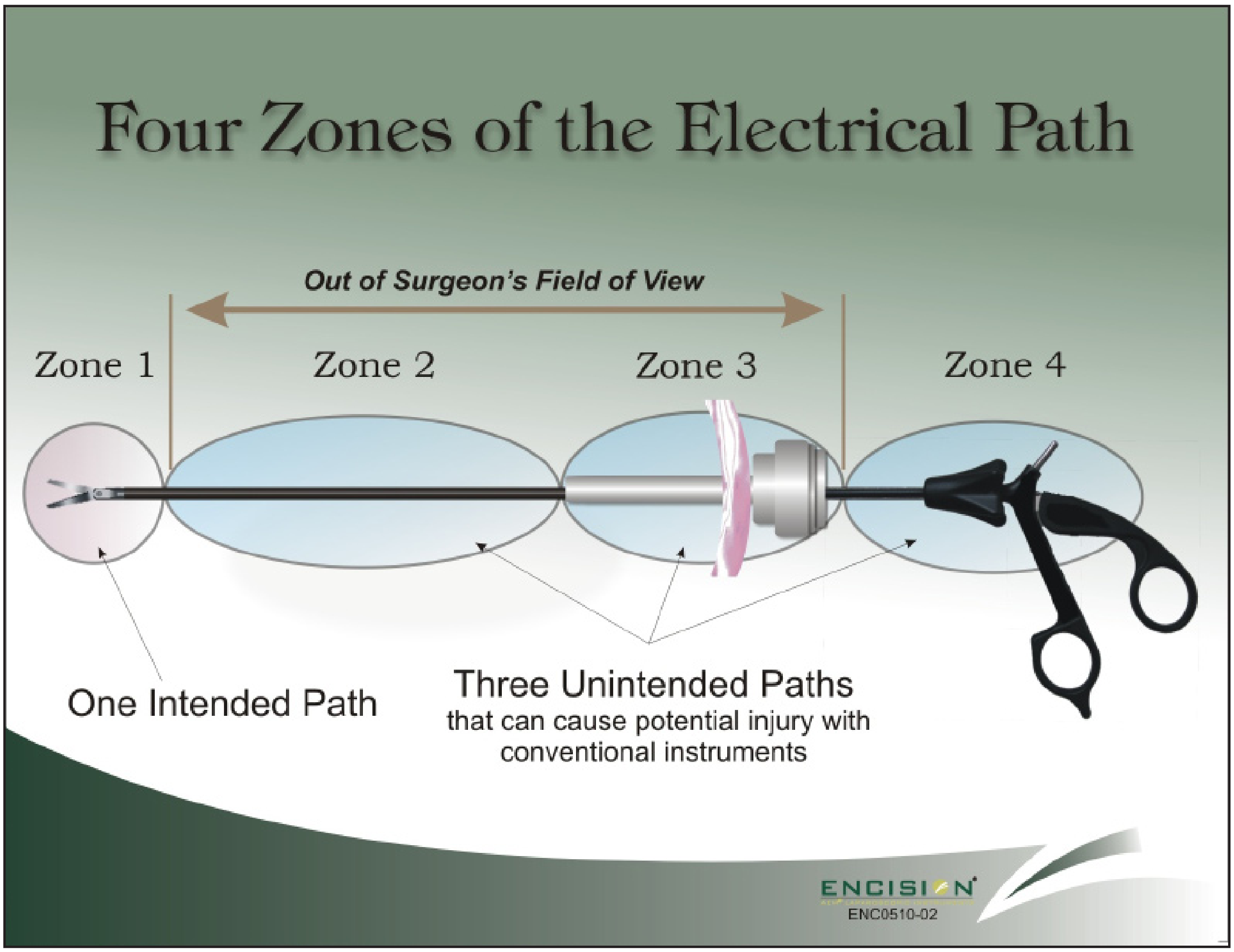

Figure 1: Stray energy is any energy that is outside of the intended electrical path. In the figure above, Zone 1 is the area at the tip of the active electrode in view of the surgeon. Zone 2 encompasses the area just outside the field of view of the surgeon to the end of the cannula. Zone 3 is the area of the active electrode covered by the cannula system. Zone 4 is the portion of the electrode and cannula that is outside the patient's body. During laparoscopy, 90% or more of the active electrode may be outside the surgeon's field of view in Zones 2, 3 and 4 where stray energy burns can occur to non-targeted tissue.

2. Capacitive coupling is another danger of laparoscopic surgery. During surgery, the current is turned rapidly on and off as needed. A rapidly alternating electrostatic field can pass from one conductor to another through a non-conductive material. In this case, the current can pass from the metal electrode through the insulation to the outer metal cannula. The energy then escapes the cannula, potentially burning surrounding tissue. The cannula does not have to be touching tissue for a burn to occur as body fluids can conduct the energy. [See figure 3.]

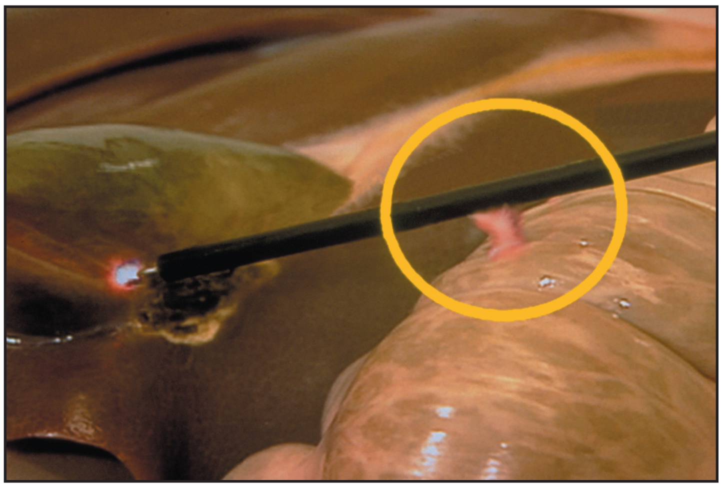

Figure 2: Insulation failure occurs when insulation on instruments breaks down and leaks currents leading to burns on nearby tissue.

Figure 3: Capacitive coupling occurs when electrical current is induced from the active electrode to nearby conductive material through intact insulation.

SINGLE-PORT ACCESS INCREASES RISKS

The use of laparoendoscopic single-site surgery (LESS), also known as single-port endoscopic surgery, has grown steadily in the three years since its introduction due to refinement and modification of equipment. The use of this technique is expected to continue to grow due to patient requests for cosmesis and the relative ease in surgeon training.

The use of a single port for endscopic surgery increases the risk of stray thermal burns in three ways:[9] [See figure 4.]

1. Instrument clashing: Multiple instruments are inserted through a single port, causing the instruments to cross and contact each other. This phenomenon, called “sword fighting,” increases the chances of capacitive coupling and insulation failure.
2. Decreased field of vision: Single port access prevents surgeons from panning back with the camera to view the location of instruments in relationship to patient organs, decreasing and even eliminating the opportunity to check for stray energy burns.
3. Weakened insulation: Advanced rotating/articulating instruments may be particularly sensitive to capacitive coupling or insulation failure due to thinner outer insulation at the point where the instrument bends.

PREVENTING STRAY ENERGY BURNS

Ninety percent of U.S. hospitals use visual inspection and/or electrical scans of endoscopic equipment as their standard safety protocol to prevent stray energy burns. There is evidence to show that these inspections are inadequate.

One study randomly tested 1,438 instruments in 33 hospitals and found that 18.6 percent had insulation failures. The average instrument had 1.8 defects, with one-third of the defects on the part of the instrument that would be inside the patient’s body but outside the surgeon’s field of view.[10] In addition, these methods do not fully protect patients from stray energy burns in three key ways:

- Visual inspections do not detect microscopic tears. The same study found that 57 percent of insulation breaks could not be seen with the naked eye.[11] These tears are potentially the most lethal because they concentrate escaping energy, creating a higher likelihood of burns.
- Visual inspections and electrical scans do not detect wearing insulation that may crack or break during surgery, releasing stray energy and causing a burn.
- Visual inspections and electrial scans cannot detect or prevent burns caused by capacitive coupling.

Figure 4: Crossed instruments resulting in cross coupling of electrosurgical energy.

In short, the current protocols being utilized by nearly all hospitals cannot detect or prevent stray energy burns during surgery.

Recognizing this shortcoming, several organizations have recommended the use of active electrode monitoring. This technology works in a similar manner as a ground fault circuit interrupter that is required in every kitchen and bathroom today. Like a GFCI, active electrode monitoring senses imbalance in the current flowing down the laparoscopic instrument and back to the generator and, if there is any imbalance, it instantaneously trips the circuit to shut off the power.

In the May 2010 patient safety alert, the DoD included use of automatic sensors in its recommendations. The Society of Laparoendoscopic Surgeons[12] and the Association of Perioperative Registered Nurses[13] also have included use of this technology as a recommended practice to address unintended burns to patients. Instruments employing active electrode monitoring are similar in pricing to standard instrumentation and can be substituted during standard replacement cycles at no extra cost.

Case Study: Gwinnett Hospital System

Gwinnett Hospital System in Lawrenceville, Georgia, converted all of its laparoscopic instrumentation to active electrode monitoring following an in-depth review of the potential for stray energy burns by a multi-disciplinary surgical task force. “Active electrode monitoring is the only technology recognized by ECRI/Health Devices that we, as perioperative management, could have used that would allow us to say we had done everything in our power to protect that patient during the time he or she spent in our OR,” said Vangie Dennis, RN, CNOR, CMLSO, clinical manager for procedural nursing.

References

1 Hoerner, Paul Lt Col., Department of Defense Patient Safety Analysis Center Alert. 2010; Issue 12.

2 Physician Insurers Association of America, Laparoscopic Injury Study. 2000, p. 13.

3 Based on prospective study by Jansen. See reference 5.

4 Consultation with active electrode monitoring manufacturer: Encision.

5 Jansen, F.W., et al. British Journal of Obstetrics and Gynaecology. 1997.

6 PIAA Study, p. 12.

7 Harrell, G.J., et al., AORN Journal, 1998.

8 Hospitalcompare.hhs.com

9 Morris, Franklin Jr., M.D., et al. Dangers of Single Port Access: Unseen and Unsuspected. Presentation to Texas Endosurgery Institute. Sept. 2010

10 Frei R. Safety Study of Laparoscopic Instrument Rings Alarm Bells. General Surgery News. 2005: Vol. 32, No. 8, p. 17.

11 Ibid.

12 Voyles, R.C., MD, MS, and Tucker, R.D., PhD, MD. Safe Use of Electrosurgical Devices During Minimally Invasive Surgery. Laparoscopy Today. 2006: 16-20.

13 Association of Perioperative Registered Nurses, 2004 Standards, Recommended Practices, and Guidelines: 2004.