

ADVANCES IN Electrosurgery

Safety and economic benefits for patients, surgeons and hospitals

by Ron Stoker

Although their effects can be devastating, percutaneous injuries from syringes and scalpels have historically been considered as acceptable occupational hazards by surgical personnel. Everyone knew there was potential for injury and yet there were few attempts to reduce the risk of such injuries.

Attitudes began to change when HIV (human immunodeficiency virus) was announced in 1981 and healthcare workers started looking more closely at their own safety in the operating room. In 1987, the Centers for Disease Control and Prevention (CDC) recommended the use of “Universal Precautions”,¹ which required healthcare workers to treat blood and body fluids from all patients as potentially infectious. With the passage of the Needlestick Safety and Prevention Act in 2000 and the revision of the OSHA Blood Borne Pathogen Standard of January 18, 2001, the use of appropriate barrier protection and the use of safety products were also required. Though the adoption of Universal Precautions and the use of barriers were primarily in response to the discovery of AIDS and HIV, they have aided in reducing exposure to many other serious illnesses, including hepatitis B and C.

Among healthcare settings, the operating room environment is unique. It is one of close collaboration, often under intense pressure, in the presence of a high concentration of sharp instruments and potentially infectious blood and body fluids (BBF). Several studies have shown that the skin or mucous membranes of operating room clinicians may come in contact with patient blood in as many as 50 percent of surgical procedures.^{2,3} Other studies have shown that OR personnel are at higher risk for injury as procedure time, estimated blood loss, and number of personnel in the operative field increase.⁴

While the implementation of Universal Precautions, professional society protocols and safety-engineered devices has helped decrease the incidence of injury for specific categories of sharps,⁵ available data show little change in the rate of scalpel injuries in the OR. This lack of change most likely reflects a combined failure on the part of healthcare workers to follow surgical safety protocols, inadequate design of safety devices, and a resistance to using safety-engineered scalpels. Alternatively, the lack of change in light of ever-increasing awareness and training may simply be due to the danger inherent to the sharp instrument itself. Sharps injury data collected during a seven-year period by the CDC may help support this conclusion: of 1,700 recorded injuries 19 percent occurred during safety device activation, 7 percent because the user improperly activated the safety device, and in 27 percent the user did not activate the safety feature at all.⁶

History of Electrosurgery

Surgeons have traditionally used the scalpel for skin incisions and fine subcutaneous dissection because of its precision and favorable healing profile. However, scalpel incisions result in bleeding that obscures the surgical field. The first documented applications of thermal energy for bleeding control date to the ancient Egyptians, who used hot metal cauters to stop bleeding and close amputations.

Techniques for bleeding control remained limited to heated cautery and sutures until the advent of electricity. From 1914 to 1927, the American physicist William T. Bovie developed and refined the first electrosurgical generator while working at Harvard University. It directed high frequency electrical current through a metal probe to increase temperature in the patient’s tissue directly adjacent to the probe. In 1926, the founder of modern neurosurgery, Harvey Cushing, used this device to remove a vascular myeloma from a patient’s brain. Currently, more than 17.5 million electrosurgical procedures are performed each year in the United States alone.

Though the shape of the electrosurgical generator and its accompanying handpiece has changed dramatically through the years, the fundamental design of each has not: continuous radiofrequency (RF) energy is delivered to the tissue via electrical arcing from a high-temperature, uninsulated metal probe. By adjusting the amplitude and waveform of the RF energy the function of the electrosurgical device may be changed from cutting to coagulation.

While the hemostatic capability of traditional electrosurgery (i.e. “the Bovie”) represents a major technological advance, its lack of precision and deep thermal injury profile make it impractical for routine use as a primary surgical instrument. This thermal damage produces the functional destruction of adjacent tissues, and may damage nerves and delicate vasculature. On the skin, this thermal damage increases wound scarring and results in delayed healing, and possibly increased infection rates as thermal debris may act as a “safe harbor” for bacteria. Because of these disadvantages, surgeons make skin incisions with the traditional scalpel and then use the electrosurgical device for subcutaneous dissection and bleeding control.

Advances in Electrosurgery

New advances in the electrosurgical arena have eliminated many of these disadvantages. The use of electrosurgical plasma, induced with pulsed radiofrequency (RF) energy has emerged as a method for precision dissection with simultaneous hemostasis and an improved thermal injury profile. This technology, first described as PEAK® technology, utilizes very short bursts of RF energy to induce a plasma-mediated discharge along the edge of a very thin (1050µm), flat, 99.5 percent insulated electrode.

Using electro-surgical plasma as a cutting mechanism is a novel idea. Plasma is an electrically conductive cloud that is created when RF energy contacts tissue. It is comprised of water vapor and ions (negative and positive charges) from the breakdown of tissue. This conductive plasma allows RF energy to cross at much lower levels, leading to lower operative temperatures and less thermal damage.⁷

This technology represents an evolutionary leap in radiofrequency surgical technologies, which originated with traditional electrosurgery and progressed to plasma-mediated energy devices. This technology has been commercially developed as the PEAK PlasmaBlade™ from PEAK Surgical Inc. (Palo Alto, Calif.), and is currently used in general, plastic, ENT, and OB/GYN surgeries. Preclinical studies have demonstrated the PlasmaBlade produces 60 percent less bleeding during skin incisions with equivalent scarring to a scalpel, 75 percent less thermal injury, significantly lower inflammatory cell counts, and stronger healed incision strength compared to traditional electrosurgery. Post-market clinical studies have shown that patients consume significantly less narcotics than traditional electrosurgery patients, and return to normal diet volume and activity quicker, as well. See Figure 1.

Figure 1.



The PlasmaBlade is not inherently sharp, and unlike traditional electrosurgical devices, it remains relatively cool to the touch while in operation. Therefore, when a surgeon has completed an incision and sets the instrument down, the risk of unintentional cuts or burns to the surgeon and other OR personnel is eliminated. See Figure 2.

The following PlasmaBlade tissue dissection surgical devices are FDA-cleared and commercially available:

- ▶ The PlasmaBlade 4.0, which is designed to be used to cut through all types of soft tissue, including skin, fat and muscle;
- ▶ The PlasmaBlade Needle, which has a fine needlepoint tip and is specifically designed for ultra-precise surgical procedures;
- ▶ The PlasmaBlade EXT, which is designed for use in surgical procedures requiring an extended-reach tip.

Figure 2.



Each of the PlasmaBlade tissue dissection devices above are used in conjunction with the PULSAR Generator, which supplies the pulsed waveforms that produce plasma-mediated electrical discharges from the PlasmaBlade. Because the RF energy is provided through a highly insulated cutting electrode, the PlasmaBlade cuts at much lower average temperature than that of conventional electrosurgery, and can be as low as 50 degrees Centigrade, which is dramatically less than traditional electrosurgery. In contrast, traditional electrosurgical devices use continuous RF energy and uninsulated electrodes to cut and coagulate tissue in excess of 300 degrees Centigrade. See Figure 3.

Figure 3.



The PlasmaBlade provides surgeons with a single device that offers:

- ▶ the precision of a traditional scalpel;
- ▶ the bleeding control of traditional electrosurgical technology;
- ▶ minimal thermal injury to adjacent tissue;
- ▶ the ability to quickly and easily cut through all types of soft tissue, including skin, fat and muscle in a wet or dry surgical field.

Improved surgical outcomes

The use of electrical plasma to effect the incisions and coagulation of blood combines the advantages of the scalpel's cutting precision and conventional electrosurgery's coagulation capability, while minimizing collateral thermal damage. These advantages have been shown to result in stronger healed wound strength, equivalent scarring to a scalpel, reduced serous drainage, and lower inflammatory cell counts in healing incisions.

Reduced bleeding

Surgeons require the ability to make precise incisions and yet need a sound method of controlling bleeding during surgery to minimize blood loss and maintain adequate visualization of the surgical field. The PlasmaBlade is the first electrosurgical device to deliver both features in a single system.⁸

Surgical site infections

Surgical site infections (SSIs) are serious operative complications that occur in approximately 2 percent of surgical procedures and account for some 20 percent of healthcare-associated infections. A recent study utilizing the 2005 Healthcare Cost and Utilization Project National Inpatient Sample (HCUP NIS) examined the impact of SSIs on length of stay and cost. On a national average, the average SSI extended length of inpatient stay by 9.7 days and increased cost by \$20,842 per admission.⁹

The cooler operating temperature and improved thermal injury profile of the PlasmaBlade may help reduce the incidence of surgical site infections. Specifically, reducing the amount of necrotic surgical debris and inflammatory response, in conjunction with the reduced narcotic use and faster return to normal activity, may present a distinct advantage over traditional electrosurgical devices in decreasing SSI incidence. Although the prevention of surgical site infections is complex and multifactorial, the PlasmaBlade may further help post-operative outcomes in this regard.

OR safety

The PlasmaBlade cuts tissue via a relatively low temperature mechanism—lowering the potential for inadvertent burns during use—and produces little to no carcinogenic surgical smoke compared to traditional electrosurgery.¹⁰ Additionally, because the PlasmaBlade may be used for the skin incision it eliminates the possibility of blood and body fluid (BBF) exposure from a scalpel injury.

Operating room scalpel injuries present a significant expense to hospitals. Recent data on the cost of occupational BBF exposure from sharps injuries date to 2007 when the CDC published an analysis of four U.S. healthcare facilities. Examining the direct and indirect costs to manage exposure, with an average frequency of 9.4 scalpel injuries per year for a 700-bed hospital results in a minimum cost of \$3,534 per year, assuming all patients were of unknown infection status and there was no resulting mechanical injury.^{11,12}

It is reasonable to conclude that the actual cost of scalpel injuries may be much higher. For example, a prominent hospital in Milwaukee recently shared that their estimated cost to manage scalpel-related injuries is nearly \$10,000 per incident.¹³

OR efficiency

The fast cutting action of the PlasmaBlade coupled with improved incisional bleeding control provides for greater surgical efficiency, as well. The surgeon is able to cut with precision and coagulate without repeatedly switching tools—this may shorten the amount of time needed for a given procedure. See figure 4.

Figure 4.



Conclusion

The PlasmaBlade represents an important advance in electrosurgery, offering the cutting precision of a scalpel and the coagulation capability of traditional electrosurgery with minimal thermal injury. It may offer significant safety and economic benefits for patients, surgeons and hospitals.

Given the risks of injury, infection exposure, and the costs associated with the traditional scalpel, the introduction of safer alternatives is desirable. It is only feasible, however, if those alternatives offer surgeons functionality and handling equivalent or superior to the traditional surgical instruments they use now. The PlasmaBlade tissue dissection device is the first instrument to provide this functionality and safety benefit that may facilitate a much sought after reduction in OR scalpel injuries.

For more information on the PlasmaBlade contact the manufacturer, PEAK Surgical Inc., at 650.331.3020 or visit the company's Web site at www.peak surgical.com. †

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