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Advanced energy systems for laparoscopic gynecology procedures

Multifunctional technology yields reliable outcomes, enhances patient safety, and increases procedure efficiency

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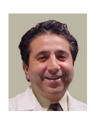

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Disclosures
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Dr McCarus serves as a consultant to Ethicon Endo-Surgery, Inc.

Dr Brill: Probably no surgical instrument defines the gynecologist more than the Kleppinger forceps, the first bipolar device used for tubal ligation. It remains an important part of our armamentarium despite thermal spread, smoke, char, tissue sticking, and inconsistent hemostasis,[1-5] shortcomings that have led to the development of newer bipolar electrosurgical devices—the LigaSure™ Vessel Sealing System, PlasmaKinetic (PK) platform, and ENSEAL®. These energy-based surgical devices offer added functionality—coagulation and cutting in a single instrument—as well as increased efficiency. These instruments offer specific features that appeal to gynecologic surgeons who have different needs and preferences. Ultrasonic energy technology has also advanced significantly, with instruments such as the Harmonic ACE®, which both cuts and coagulates at the point of impact for use in soft-tissue incisions and transections.

Despite our collective surgical experience, the comparative strengths and weaknesses of these devices have yet to be clearly established in an unbiased and reproducible fashion. Ex vivo studies have attempted to quantify the comparative effectiveness of these devices with wide variances in results, primarily based on the use of non-standardized protocols. We must await the results of well-designed in vivo studies that compare efficiency, sealing time, lateral thermal spread, smoke product, and burst pressures to define their relative use for ligating and cutting vascular tissue.

New technologies expand range of procedures

Dr Brill: As teachers, do you meet physicians who see little reason to use newer devices, given that they have had no problems with conventional bipolar devices?

Dr McCarus: Yes. If a clinician says, "I haven't had any problems

FIGURE 1

Sealing by proximal thrombus

The Kleppinger forceps create hemostasis by contraction of the vessel walls.

FIGURE 2

Sealing with electrosurgery

This seal, created by ENSEAL®, is produced through low temperature, high pressure, and pulsed energy.

Patient safety has fueled advances in instrumentation.

with the equipment I use," I ask what type of surgery he performs. The scope of electrosurgery extends beyond tubal ligation; new tools enable us to perform many procedures and manage anatomic difficulties with increased patient safety.

Dr Bertrand: The Kleppinger forceps, a wonderful device, has safety issues: lateral spread and heat generation.[6] Physicians who reject change probably do not work on involved cases that bring us close to the ureter, bowel, or bladder. Newer devices allow us to perform procedures in proximity to these vital structures and organs in a safer fashion.

Dr Brill: True: Based on fundamental biophysics of electrosurgery in living tissue, voltage is the primary cause of thermal damage. Importantly, newer bipolar ligating devices deliver low-voltage electricity to lessen thermal damage and result in more predictable spread. New devices also "communicate" with the tissue—based on changes in tissue resistance called impedance—to deliver precisely the amount of energy necessary to accomplish the task.[7]

Considerations in adopting new technology

Dr Brill: How do you decide if a new device fits into your armamentarium?

Dr Bertrand: First I determine whether the instrument marks a true scientific advance. I evaluate its ergonomics and its cost and, most importantly, whether it is safer than other devices.

Dr McCarus: Another consideration is, does the instrument provide dependable and predictable vessel hemostasis? Intraoperative bleeding is our number one practical concern. Given operating room scheduling issues and costs, I look for versatile and multifunctional equipment that will shorten procedure times.

Dr Brill: I am very concerned about the multifunctionality of a new device for tissue dissection. I assess any new energy-based device not just for thermal characteristics, but for ease of use, ability to lift, grasp, and dissect tissue, and its performance in heterogeneous desiccated, fatty, or vascular tissue.

Dr Bertrand: We should not forget the cavitational effect of Harmonic® instrumentation, in which steam accomplishes the natural plane dissection by quick and localized action, minimizing lateral thermal energy.

Dr Brill: When a surgeon understands the fundamental principles of energy-based surgery—and the relative strengths and weaknesses of any device in this context—it is possible to take the device to a higher level of performance, achieving otherwise impossible tissue effects. Some devices, designed simply to perform ligations, can be modified to desiccate and

Instrumentation to expand surgical options

There are 3 bipolar platforms that utilize low constant voltage, pulsed current, and impedance feedback, along with a paired ligating-cutting device. By historic sequence, the LigaSure Vessel Sealing Device (Covidien, Boulder, CO) applies a high coaptive pressure during the generation of tissue temperatures under 100ºC; hydrogen cross-links are first ruptured and then re-natured, resulting in a vascular seal that has high tensile strength. The second instrument, the PlasmaKinetic Cutting Forceps (Gyrus/ACMI/Olympus, Minneapolis, MN), lacks the compressive pressure needed to create a true vessel seal but provides efficient coagulation with visibly pulsed energy that is moderated by impedance feedback.

The third device, the EnSeal Laparoscopic Vessel Fusion System (EES, Cincinnati, OH) utilizes temperature-sensitive polymeric material (PTC) embedded with nanometer-sized spheres of carbon that automatically controls a locally regulated current, regulating temperatures at about 100º C. Desiccation with this device is facilitated by advancing an innovative "I-Blade" that provides extremely high pressure along the length of the jaw to both cut and squeeze the tissue bundle, eliminating tissue water and steam.

Using the dynamic tissue effects of mechanical energy, ultrasonic blades, and shears, tissue effects from ultrasonic energy using the Harmonic Scalpel (EES, Cincinnati, OH) are actuated by a titanium blade of variable excursion that vibrates nearly 55,500 Hz/second from an in-line piezoelectric crystal housed in the hand piece of the device. The high frequency vibration in tissue causes a low temperature protein denaturation by rupturing the hydrogen bonds of tissue proteins. Tissue cutting from cavitational fragmentation naturally evolves from the mechanical vibration and percussive effects of steam that emanates through the tissue parenchyma. Differing from the volumetric thermal tissue effects during electrosurgery, lateral thermal damage with ultrasonic energy is limited by the linear nature of energy propagation through the tip of the blade.

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Durable vessel seals can be obtained without significant thermal change to tissue.

vaporize tissue. Do you agree?

Dr McCarus: Most gynecologic surgeons don't understand the principles of energy and current flow through the path of least resistance. You've championed the term "the cognitive surgeon" to describe individuals who understand and control energy's effect on tissue and thereby regulate the procedure. Our residents and fellows must learn not just to activate an energy source to desiccate or char tissue. They need to understand the effects on the tissue and be cognizant of the ureter, bladder, and rectum, and how to prevent unwanted energy from reaching those structures. We have an exciting opportunity to teach these principles and to bring new technologies into our armamentarium.

Dr Brill: It is equally important to cognitively appreciate the technical nuances of each device, with its unique combination of software-driven energy delivery moderated by the changing resistance of tissue as it is progressively desiccated. The Gyrus is the closest cousin to the Kleppinger and therefore the most intuitive of these new devices for the gynecologic surgeon to use. LigaSure™ provides an automated click and play solution for ligating vascular tissue. More recently, the ENSEAL® also provides true vessel sealing and transection with a uniquely sophisticated combination of technological advances. Harmonic® energy, of course, is mechanical versus electrical energy, and is not regulated through impedance.

Is desiccation essential for durable seal?

Dr McCarus: Colleagues say they like to desiccate, to see charring and scarring

When we lower the voltage and decrease the amount of energy, we must be more aware of our surgical technique.

Evaluating New Energy Devices

- Reliability
- Efficiency
- Ergonomics
- Handedness
- Response to variable tissue content
- Smoke production
- Capacity to dissect
- Tissue sticking
- Tissue color
- Cost
- Degree of innovation

form on tissue. With new technology, do we really need to see desiccated tissue?

Dr Brill: At one time that preference may have been merited. Using Kleppinger forceps with a standard generator was unreliable and inconsistent. This modality does not truly seal a blood vessel but, instead, provides hemostasis through contraction of the vessel walls and the formation of a proximal thrombus (**FIGURE 1**). General surgeons, for instance, have regarded this as a completely untenable outcome in the context of high pulse-pressure vessels nearer to the heart. However, new bipolar technology seals blood vessels to withstand high systolic pressure. As a result, general surgeons have become comfortable with the use of these devices. The durable vascular seal created by newer bipolar electrosurgical devices does not cause significantly visible thermal changes. The intricate combination of low temperature, high pressure, and pulsed energy complete the sealing. Consequently, there is minimal plume, carbon formation, and tissue sticking (**FIGURE 2**).

Best practices for training

Dr Brill: This method of sealing, with its unique tissue effects and absence of visual effects, requires surgeons to think differently. Is it helpful first to work on inanimate models?

Dr McCarus: Certainly. And then we move on to animate models in laboratory sessions. But real learning occurs when you're under the supervision of a proctor or attending at table side.

Dr Bertrand: Again, surgeons must understand energy. Otherwise, they may feel comfortable only with complete desiccation, characterized by a lot of smoke, char, and heat.

Dr Brill: Yes, when we lower the voltage and decrease the amount of energy, we have to be more aware of our surgical technique to ensure durable seals. Success depends on best practices and physician awareness of the strengths and weaknesses of each energy modality. As teachers, do you start your learners with the same device regardless of the procedure?

Dr McCarus: I present all instruments and ensure that students understand the strengths and weaknesses of each. I leave it up to them to decide which instrument works best in their hands.

Dr Bertrand: I evaluate the expertise of my student and also consider the procedure. Gyrus PK Cutting Forceps are suitable for surgeons who wish to move on to more advanced technology and have experience using the Kleppinger device. It is closest to a Kleppinger in terms of how it works. The surgeon grabs the tissue and then coagulates it before cutting with the centrally set mechanical blade. For an adnexa, I typically select an ENSEAL® device. Among other features, I use this technology because it regulates temperature production within the jaws of the instrument. By not allowing the temperatures to exceed ~100°C, I get not only reliable hemostasis, but a noticeable reduction in char and tissue stickiness.

Dr McCarus: I think we tend to teach our students the instrument with which we are most comfortable. After my initial introduction of the array of devices, I don't pull out different ones on every case. It's not cost-effective.

Issues of device choice

Dr Brill: Which instruments do you prefer for different surgical procedures?

Dr McCarus: I choose Harmonic®, primarily for its ability to simultaneously cut, coagulate, and dissect tissue. I seldom use bipolar devices, but when I do, I use ENSEAL®, particularly when transecting larger vessels.

Dr Bertrand: I've become interested in the ENSEAL® technology because it produces only ~1 mm of spread. By offsetting the positive and negative electrodes, the flow of current is limited to within the jaws. It allows me to get close to surrounding structures without fear of excessive thermal spread.

Dr Brill: Dr Bertrand, you mentioned the characteristics of ENSEAL® that attract you most: local regulation of current and temperature. Additionally, you also noted that the minimal thermal spread is a consequence of low temperature and that the current is uniquely channeled between the jaws, which prevents stray energy. Can you tell the difference between a seal-and-cut done with ENSEAL® versus the other devices?

Dr Bertrand: Yes, I can. Its small thermal margins are noticeable. The results are very similar to those obtained with the Harmonic® device.

Dr Brill: My use of equipment has evolved with the technologic development of devices. First, the Gyrus PK platform, with its pulsed, low-voltage energy, provides continuous tissue impedance feedback.[8] Second, LigaSure™ allows the surgeon to close the automated device on a vascular pedicle; the appropriate amount of energy required to seal tissue is applied, with effects regulated by impedance feedback, leading to reliable hemostasis.[7] Both Ligasure™ and Gyrus provide Haney Clamp–like instrumentation, which is effective in securing pedicles for vaginal hysterectomy. And most recently, the ENSEAL® device provides temperature control with a unique electrode configuration and composition that heats tissue at a low temperature while under extremely high compressive force to produce a durable vascular seal. It is for these reasons that ENSEAL® is my technology of choice for vessel sealing. For jobs that require fine dissection, I too rely on Harmonic® technology.

Best practices: Safe and effective use of technology

Dr Brill: Given the technical advances provided by ENSEAL®, how do you actualize the promise of this technology?

Dr McCarus: I first apply light tissue compression and visualize the I-Blade. I then bring the I-Blade to the tissue, activate the energy, and slowly advance it under direct visualization to ensure control of the instrument. When using low voltage, compression is key to creating durable vessel seals.

Dr Bertrand: I place the jaws on the pedicle and squeeze it, much as I would apply a Haney clamp. I then rotate the jaws so I have a clear vision of the I-Blade and can bring it down onto the compressed tissue. As the tissue becomes denatured, the I-Blade slides more easily. There are actually 2 ways to deliver energy, Single Tap and Double Tap. Single Tap is a 15-second cycle which will tell me when the tissue has reached 450 ohms or complete coagulation has been reached. Double Tap is a 2-minute cycle, which does not confirm this tissue impedance. I have transitioned to the Double Tap mode, primarily based on my comfort with the visual and tactile cues that the technology provides.

Dr Brill: You both emphasize the importance of visualizing tissue effects as you advance the I-Blade. To reiterate, what separates this device from others is not

Compression is key to maximizing seal strength.

When you “follow the bubbles,” tissue becomes easier to cut.

Understanding the energy principles behind laparoscopic gynecology surgery

BIPOLAR ELECTROSURGERY

A high-frequency alternating current applied to living tissue by an active electrode flows through the tissue by pathways offering the least resistance and return to an opposing electrode. The flow of electrons or electrical current (I) is set in motion and sustained by electromotive force termed voltage (V) to complete the circuit across the difference in electrical potential between the 2 electrodes. Greater voltage produces greater thermal necrosis.

Thermal injury correlates to the maximum tissue temperature, total volume of heated tissue, rate of temperature rise, and duration of temperature elevation. If living tissue is heated to above 50ºC for a sufficient duration of time, irreversible damage occurs; cellular water evaporates at 90ºC (desiccation); cell walls rupture at 100ºC (vaporization); and tissue begins to carbonize and char at 250ºC. The temporal relationship between tissue temperature and thermal injury is nonlinear owing to the complex effects of conduction and convection on the entire process.

Practically speaking, thermal effects can be moderated by altering the power setting, the type of output current (cut vs blend vs coag), the electrode dwell time, the proximity of the tissue to the active electrode, and the current density (ie, electrode surface area). The behavior of electricity in living tissue is generally governed by Ohm’s law: V=I x R. Derivatively, current is directly proportional to voltage and inversely proportional to resistance (R). To complete a circuit, force or voltage must increase as resistance increases.

Power is keyed into an electrosurgical generator as watts (W), corresponding to the rate of work being performed. The relationship between voltage and resistance is restated by the derivation of power, W=I x V, and by using Ohm’s law, W=I2 x R and W=V2/R; at any particular power setting (W) using a conventional electrosurgery generator, higher R as with desiccation, fat, or char will drive higher output V to maintain the desired tissue end point.

ULTRASONIC SURGERY

This type of surgery owes its efficacy to the fact that ultrasound travels easily through water, which makes up roughly 80% of all soft tissue. High-intensity focused ultrasound transfers a significant amount of energy to targeted tissue, causing a rise in temperature.

Coagulation with ultrasound requires coaptation of blood vessels; H+ bonds are broken; and protein in the cells is denatured. Denatured protein forms a sticky coagulum. Internal tissue heat generated from friction then seals or welds vessel walls. Simultaneous cutting and coagulation takes place at a lower temperature than in electrosurgery with minimal lateral thermal spread.

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just the tremendous pressure that occurs with advancing the I-Blade, but also the fact that so little water remains in the pedicle when the cut is completed. I’ve developed a visual pathway for using the ENSEAL® device. I grasp a typical tissue pedicle. I then activate the energy and advance the I-Blade about halfway, which begins to compress the tissue. I always stop at that point and, while applying energy, wait for the visual clue of bubbles that appear once the tissue has been denatured and the seal is complete. At that point, I advance the I-Blade, typically at a rate of 1 mm per second, to follow the wave of bubbles. Using this method with the ENSEAL® device, I have never had a problem with hemostasis for ligating and cutting vascular pedicles.

Dr McCarus: Have you noticed that when you “follow the bubbles,” tissue becomes somewhat easier to cut?

Dr Brill: Absolutely. Normal collagen is very dense and relatively difficult to manipulate. Denatured collagen becomes soft like butter. With the ENSEAL®

device, you get feedback about resistance, further letting you know that the pedicle is ready to be cut.

The ENSEAL® device comes either as a round-tipped 5-mm device or as a curved 3-mm device that looks like a curved surgical clamp. Do you prefer one over the other? Do you use them differently?

Dr McCarus: I use the ENSEAL® Trio exclusively. It is very comfortable to use and is effective on large vascular bundles, and for separating the leaves of the broad ligament or opening the bladder flap. Its curved shape is similar to the Harmonic ACE®.

Dr Bertrand I have used both. I usually use the larger device for the adnexa. When I want a curved tool for advanced dissection, I use Harmonic ACE®.

Dr Brill: I use both devices, but I prefer the smaller curved device. As noted, it is more ergonomic and feels similar to normal surgical instrumentation, and it provides good mobilization of tissue planes. But again it begs the question, would you have a first-time user begin with a 5- or 3-mm device using this technology?

Dr Bertrand: Wanting to minimize blood loss, I would pick the larger device.

Dr McCarus: I'm not sure there is a difference as far as hemostasis. They both seem very effective. Again, I would teach a first-time user the proper technique for what I'm most comfortable with, the Trio.

Dr Brill: You've taught an entire generation of surgeons about ultrasonic surgery. How does the Harmonic ACE® fit into this picture?

Dr McCarus: The ENSEAL® is similar to Harmonic ACE® as far as minimizing lateral thermal spread and ensuring adequate coagulation.[9-11] The Harmonic ACE® has built its reputation on its superior multifunctionality and precision. It can be technique-sensitive, which makes the learning curve slightly longer than that associated with the ENSEAL® device. However, when mastered, Harmonic® performs like no other. I appreciate the fact that ENSEAL® can achieve coagulation at lower temperatures than other bipolar instruments. It likens itself to Harmonic® as far as tissue effects. At the end of the day, it truly depends on what the student values in terms of device qualities.

Dr Brill: Dr Bertrand, do you use the Harmonic ACE® as well?

Dr Bertrand: I do. Dr McCarus trained me to be a Harmonic® user with first-generation Harmonic® shears. With the advent of the Harmonic ACE®, this technology has become easier to use: You clamp it, click it, and it does the work for you.

I use the ENSEAL® on the adnexa. When I perform the peritoneal separation and open the right round ligament, I use the Harmonic ACE®. Its cavitational effect with the active blade on high power precisely dissects the bladder peritoneum. It causes very little, if any, lateral tissue effect. I also like to use it to amputate the cervix, using a drilling technique.

Dr McCarus: It's difficult for many people to understand that, with Harmonic® technology, achieving hemostasis depends on tissue density and tissue tension. You have to be involved with the instrument for proper performance. On vascular bundles, the technique has always been to clamp and relax tension. But that is not always intuitive in handling tissue. Variables such as the power setting, blade edge, and tissue tension and density must be evaluated. When I'm near vital structures—the ureter, bladder, or bowel—or I have an endometriosis, adhesion, or distortion, I need to be in control of the energy. Harmonic® and ENSEAL® provide this control.

Dr Brill: Ultimately, we must make choices. We can have only so many tools in a box. Based on our experience, preferences, and

Variables such as the power setting, blade edge, and tissue tension and density must be evaluated.

The days of clamp-cut-tie are gone.

skill levels, we will gravitate toward one modality or another for surgical dissection. I am very comfortable having both the ENSEAL® device and the Harmonic ACE® in my operating room for my cases and for my teaching.

Whenever I need to dissect near vital structures—for example, during laparoscopic myomectomy or excision of endometriosis—monitoring tissue color and temperature are important, and I always use the Harmonic ACE®. On the other hand, if I'm performing a hysterectomy and I'm concerned about the tenacity and strength of the vascular pedicles, and am having to mobilize and manipulate the uterus, I will take out my ENSEAL® device, which provides excellent hemostasis and minimizes thermal effects. What do you use in your OR?

Dr McCarus: We are very fortunate to have these choices. We all remember when our options were much more limited. I try to use one energy source, Harmonic®, for all my cases, but there are times when it is limited—eg, large tortuous vessels or anatomy that requires increased tissue tension and retraction. Harmonic® energy is still the most versatile hand instrument allowing predictable tissue effects when coagulating and cutting across the IP and uterine ovarian ligaments, acquiring colpotomies, excision of endometriosis, appendectomy, and myomectomy.

Dr Bertrand: Most of the time I'm proctoring or preceptoring, I use the 2 instruments interchangeably. I use the ENSEAL® device as a bipolar cutter for the adnexa, and I use the Harmonic ACE® for the bladder, colpotomy, or amputation, depending on whether I'm doing a total or a supracervical hysterectomy.

Dr McCarus: The goal is safe surgery, to think about what we are doing to tissue and minimize adverse effects. Do we really need to desiccate where there are vital structures? The days of clamp-cut-tie or desiccate-cut are gone. Gaining control over the energy and moderating tissue effects is key.

Dr Brill: Just as a shielded trocar does not preclude proper technique for trocar insertion, low-energy devices do not preclude the need for fundamentally correct technique that respects anatomy. ■

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