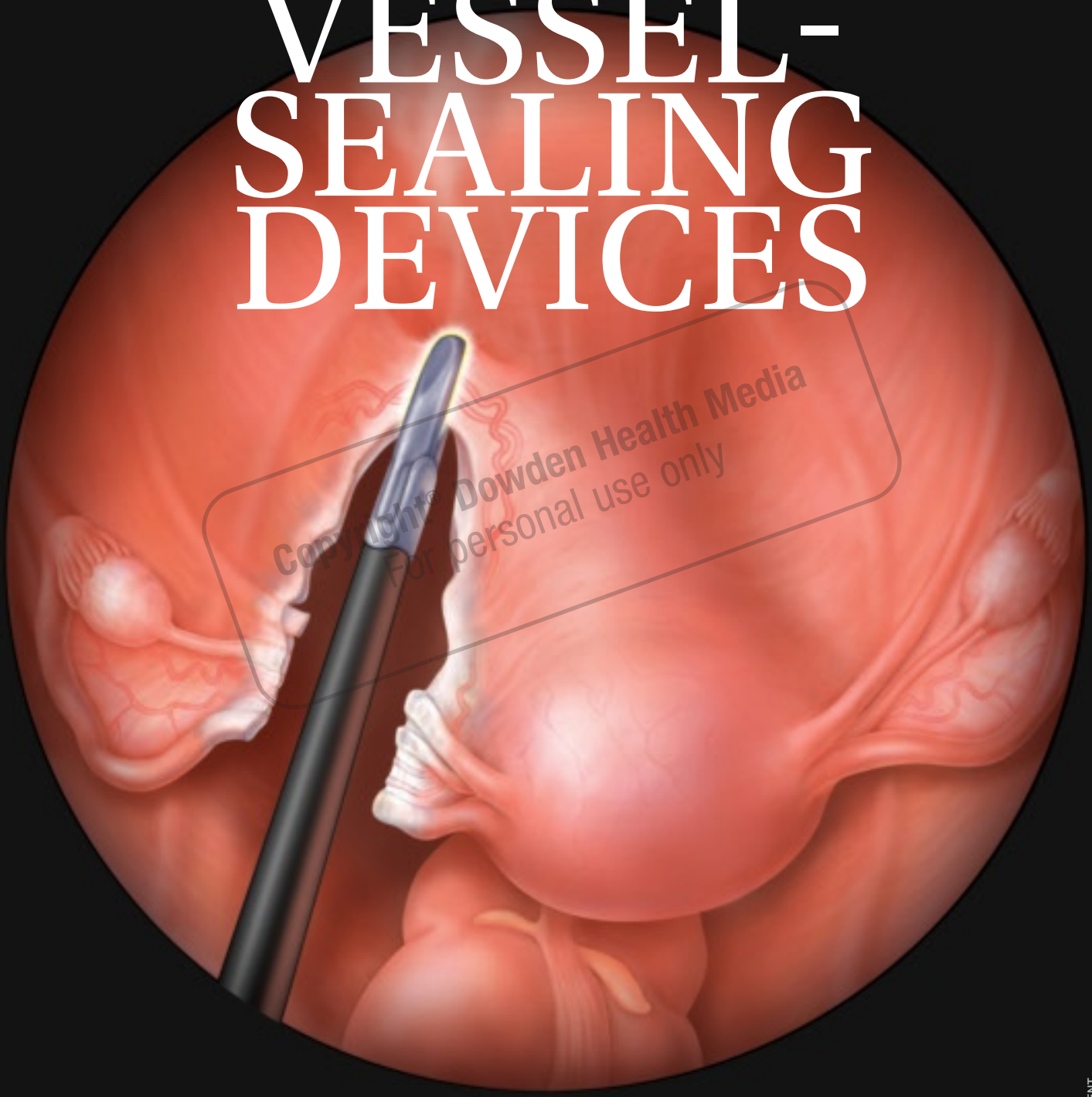
VESSEL-SEALING DEVICES



Some vessel-sealing devices apply high, uniform mechanical compression while monitoring and adjusting energy delivery to the tissue. In the process, collagen and elastin fibers in the compressed vessel walls are denatured, and cross-linking reoccurs as the tissue cools.

MAURA FLYNN FOR OBG MANAGEMENT

This overview of vessel-sealing devices for laparoscopic procedures should help you select a system that meets the particular needs of your practice

Barbara S. Levy, MD

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Dr. Levy is a consultant to Covidien (parent company of Valleylab) and to Ethicon Women's Health and Urology.

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Do you prefer a device that is user-dependent? Or are predictable results more important to you?

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When Harry Reich performed the first laparoscopically assisted vaginal hysterectomy in 1989, he advocated the use of sutures for control of the uterine vessels. Monopolar, bipolar, and laser instruments available at that time were inherently risky to use along the pelvic sidewall because of their potential for **1)** considerable thermal energy spread beyond the area of treatment (bipolar, NG:YAG laser, monopolar) and **2)** unreliable hemostasis (CO_2 laser).

Minimally invasive surgical practice has driven meaningful advances in instrumentation and technique over the past 20 years. The constraints inherent in laparoscopic surgery, although somewhat mitigated by robotics, have generated a proliferation of technologies to obtain reliable hemostasis. Every device now on the market claims to "seal" vessels. In this article, I review the mechanism of action of these instruments and compare their strengths and weaknesses, based on high-quality scientific evidence.

Two studies highlight vessel ligation

Newcomb WL, Hope WW, Schmeizer TM, et al. Comparison of blood vessel sealing among new electrosurgical and ultrasonic devices. Surg Endosc. 2009;23:90–96.

Lamberton GR, Hsi RS, Jin DH, et al. Prospective comparison of four laparoscopic vessel ligation devices. J Endourol. 2008;22:2307–2312.

Many energy-delivery systems are available for the gynecologic surgeon; any of them can be used effectively and safely under most circumstances. Before we can make an informed choice about which system is best for our own practice, however, we need to be aware of the strengths and limitations of the systems overall (**TABLE**, page 44).

These two studies focus on the following devices:

- **Gyrus PK Tissue Management System, PKS Cutting Forceps,** and **Plasma Trissector** (all from Gyrus Medical). These are bipolar electrosurgical devices designed to deliver high current and very low voltage to tissue. Tissue impedance is continuously monitored between the jaws of the instrument, and energy delivery is adjusted accordingly. These systems deliver electrosurgical energy through a series of rapid pulses, thereby allowing the tissue to cool briefly and limiting the heating of adjacent tissue. Protein in the vessel walls is denatured and forms a coagulum, which occludes the lumen.

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TABLE Rating vessel-sealing devices: 5 measures of success

Device	Safety: Minimal thermal spread	Reliability: Efficacy on vessels ≤7 mm	Efficiency: Treatment time	Consistency: Independent of user	Utility: Multiple uses
Harmonic Scalpel	Excellent	Poor	Excellent	Poor	Excellent
Gyrus PK	Poor	Poor	Excellent	Fair	Fair
LigaSure V	Good	Excellent	Good	Excellent	Fair
EnSeal	Fair	Excellent	Poor	Excellent	Poor

These ratings were devised by the author based on data from independent studies in living tissue models.

FAST TRACK

The ideal vessel-sealing device produces minimal thermal spread, is effective on vessels ≤7 mm in diameter, works quickly, produces consistent results, and can be used multiple times

- **Harmonic Scalpel** (Ethicon EndoSurgery). This device uses a high-frequency ultrasonic transducer (55,000 cycles/second) to create mechanical vibration of one of the two jaws. The device can be used to vaporize tissue (cut) or achieve hemostasis by coagulation. As with the other devices, protein is denatured and vessels are occluded by formation of a coagulum.

  With the Harmonic Scalpel, the surgeon can adjust the amount of energy delivered to tissue by selecting any one of five available settings. Coagulation is maximized when the setting is low and tissue is under minimal tension; a high setting and maximal tissue tension, on the other hand, disrupt tissue with minimal hemostasis. Tissue effects with this device can vary strikingly, depending on how the surgeon applies it.
- **Ligamax 5 Endoscopic Multiple Clip Applier** (Ethicon). This device is a sterile, single-patient-use, 5-mm, endoscopic, multiple-clip applicator that delivers 15 medium or large titanium clips that close to 8.8 mm, the same clip size as the 10-mm applicator. Ligamax 5 has long, thin angled jaws (8.4 mm) that extend beyond vessels and ducts to improve visibility. It includes a long, 33-cm shaft for additional reach, and an anti-clip drop-ratchet mechanism for control over clip closure.
- **EnSeal Tissue Sealing and Hemostasis System** and **EnSeal PTC** (SurgRx). EnSeal utilizes nanotechnology to control the energy at the electrode–tissue interface. The jaws contain a temperature-sensitive matrix with embedded conductive carbon spherules designed to "sense" tissue characteristics. It uses extremely high jaw compression to create uniform tissue effects. It does not require a dedicated electrosurgical unit for use; an adapter can be purchased that permits use with most generators.
- **LigaSure V** (Valleylab). LigaSure is a bipolar electrosurgical device designed to deliver high current and very low voltage to tissue. It monitors tissue impedance between the jaws of the instrument and continuously adjusts the delivery of energy.

  LigaSure seals vessels by applying high, uniform mechanical compression while monitoring and adjusting energy delivery to the tissue (**FIGURE**, page 49). Collagen and elastin fibers in the compressed vessel walls are denatured; during the cool-down phase, cross-linking reoccurs, effectively creating a new, solid wall of collagen and elastin tissue. An algorithm in the generator determines optimal time and energy delivery to achieve consistent seals for vessels as large as 7 mm in diameter.

  Because this product relies heavily on the collagen and elastin content of vessels to achieve hemostasis, it works well for arteries and veins but inconsistently in tissues where the blood supply is delivered predominantly by capillaries, which have a low collagen content.

What the studies found

Newcomb and associates compared blood-vessel-sealing ability of the following devices:

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Experts talk about how they choose an energy source for laparoscopic surgery

When OBG MANAGEMENT surveyed a number of laparoscopic experts and members of our Virtual Board of Editors about their preferred energy sources for laparoscopic surgery, the responses were strikingly similar. The consensus? The best device depends on the case at hand, the skill of the surgeon, economic concerns, and other variables.

As Keith Isaacson, MD, put it, "Because tissue may be thick or thin, moist or desiccated, vascular or avascular, the ideal instrument to achieve a pure cut varies. Because a vessel may be large or small, contain a large amount of collagen or very little collagen, or be on tension or relaxed, the ideal instrument for vessel sealing also varies, depending on the surgical situation."

All of the devices are roughly equivalent, he added. "Fortunately, almost all of the commercially available energy sources that utilize bipolar radiofrequency or ultrasonic energy will perform our desired function if the surgeon understands the technology and utilizes the instruments properly."

Here is a summary of recommendations made by the experts we interviewed.

Andrew I. Brill, MD
Director of Minimally Invasive Gynecology,
California Pacific Medical Center,
San Francisco, Calif

Having been actively engaged in advanced laparoscopic surgical training for more than 20 years, I have extensive experience with all of these novel devices. I critically assess any new energy-based device for its ergonomic handedness, propensity for sticking to tissue and production of plume, ability to manipulate and dissect tissue, efficiency in desiccated or fatty tissues, discoloration of tissue by carbon, response to tissue tension, and reliability for hemostasis. Because no device is perfectly suited to all procedures, I customarily rely upon several devices to satisfy my technical needs.

All advanced bipolar energy devices—LigaSure, PK Cutting Forceps, and EnSeal—can be safely used to coagulate and cut all vascular pedicles during hysterectomy and salpingo-oophorectomy. These devices perform best when tissue tension is reduced to maximize vessel sealing. Despite the fact that these devices provide audible feedback to signal the electrosurgical endpoint, I also gauge tissue color, retraction, and the emission of steam before advancing the cutting blade.

The tapered-tip design of the PK Cutting Forceps offers some comparative advantage for fine tissue dissection, but I find that hemostasis is more consistently achieved with less thermal spread using the EnSeal or LigaSure device.

I commonly utilize the Harmonic Scalpel in lieu of any electrosurgical device, understanding that it requires more finesse to achieve equivalent results.

When I anticipate that I will need to manipulate uterine pedicles during a difficult laparoscopic hysterectomy, I employ electrosurgery using the EnSeal device for its superior tissue sealing. A 3-mm curved device by EnSeal, akin to a Pean clamp, works as an exceptionally agile instrument for hysterectomy without sacrificing hemostasis.

Only the LigaSure Advance provides both coaptive coagulation and spark cutting via an electrode on the tip of one blade; therefore, an adjunctive mechanical or energy-based device must be employed to perform culdotomy during total laparoscopic hysterectomy when EnSeal or the PK Cutting Forceps is used.

The ability to efficiently and hemostatically cut through tissue of variable mass with minimal plume, predictable thermal margins, and the retention of tissue color make the Harmonic Scalpel my first choice for laparoscopic resection of endometriosis, extensive adhesiolysis, myomectomy, cervical amputation during supracervical hysterectomy, and culdotomy during total hysterectomy. Although I have similarly utilized the unique capacity of the spatula, J-hook, and needle electrodes by Plasmacision (Gyrus) to cut tissue using bipolar electrosurgery, all have afforded less technical control, not as much hemostasis, and wider thermal margins.

Use of any energy-based device does not preclude the need for skill. Before adding any of these devices to your surgical armamentarium, appropriate training should be acquired in a skills lab using living tissue or with a laparoscopic trainer using a tissue surrogate.

Dr. Brill reports no financial relationships relevant to this review.

Jon I. Einarsson, MD, MPH

Director of Minimally Invasive Gynecologic Surgery,
Brigham and Women's Hospital,
Assistant Professor of Obstetrics,
Gynecology, and Reproductive Biology,
Harvard Medical School, Boston, Mass

I prefer the Harmonic Scalpel and a Kelly RoBi Bipolar Grasper (Karl Storz). I have been using these instruments for approximately 10 years. I use this combination for all operative laparoscopy cases, including hysterectomy, myomectomy, sacrocolpopexy, resection of endometriosis, and lysis of adhesions.

The Harmonic Scalpel is a versatile instrument that can perform dissection, cutting, and coagulation very efficiently. However, there are better vessel sealers out there, such as the LigaSure and EnSeal devices. In this era of cost containment, it is important to limit the use of multiple disposable energy sources in a single case. By adding the reusable bipolar grasper, vessel sealing becomes efficient and reliable without added cost. In addition, the bipolar grasper functions as a dissector and retractor, thereby minimizing instrument changes.

I watch the bubbles that form during desiccation with the bipolar grasper. Once these bubbles start to "die down," I know that the tissue is desiccated and safe to transect. It is important to remember that thermal spread with a traditional bipolar grasper is significant (up to 13 mm). For that reason, when I desiccate the uterine vessels with the bipolar grasper, I stay above the rim of the colpotomy ring in order to maintain a safe distance from the ureter during this step.

The Harmonic Scalpel offers several advantages over monopolar electrosurgery for cutting, such as decreased smoke formation and avoidance of complications such as insulation failure, direct coupling, and capacitative coupling.

Dr. Einarsson reports no financial relationships relevant to this review.

Carl F. Giesler, MD

Associate Professor and Director of
Minimally Invasive Surgery,
Department of Obstetrics and Gynecology,
Baylor College of Medicine,
Waco, Tex

I was introduced to laparoscopy as a resident in 1974, and have been teaching laparoscopic surgical techniques to general surgeons and gynecologists since 1988. I began performing laparoscopic hysterectomy in 1991. As an educator and trainer of other laparoscopic surgeons, I have used all available laparoscopic energy sources.

I became an early adapter and user of ultrasonic mechanical energy when it was introduced for laparoscopy in 1995, because of its safety for adjacent tissues and its single-instrument, multiple-task properties.

This energy source was originally named the Ultrasonic Coagulating Shears by Ultracision, but Ethicon EndoSurgery purchased the product in 1995 and changed its name to the Harmonic Scalpel. The current generation is called the Harmonic ACE, and I use it as my primary laparoscopic energy source for all procedures, from management of unruptured ectopic pregnancy to total laparoscopic hysterectomy and extensive adhesiolyis in previously operated abdomens.

The Harmonic ACE allows me to confidently dissect adhesions over loops of bowel, as well as over the ureter, because of its limited lateral thermal spread. It allows nearly bloodless dissection of the retroperitoneal space and space around the bladder. The cavitation effect created by the rapidly moving instrument tip (55,500 cycles/second) creates tissue separation along the areolar tissue planes, where most blood vessels are the size of capillaries and where larger blood vessels are easily identified and controlled by coaptation, coagulation, and cutting.

The protein coagulum is produced at a temperature of 54°C. The sides and back of the active blade have minimal thermal effect because tissue is not held tightly against the moving blade. Minimal char is observed because of the low tissue temperature associated with coagulum formation. Minimal sticking of tissue occurs because the rapid motion of the instrument tip dislodges the tissue.

The ease of use, multiple functions for a single instrument, tissue safety, and minimal residual traumatized tissue are the reasons I prefer the mechanical energy of the Harmonic ACE as my primary laparoscopic energy source.

Dr. Giesler serves as a speaker for Ethicon EndoSurgery.

Cheryl Iglesia, MD

Director, Urogynecology and Reconstructive Pelvic Surgery,
Washington Hospital Center,
Associate Professor, Departments of ObGyn and Urology,
Georgetown University, Washington, DC.
Member, OBG MANAGEMENT Board of Editors

I prefer the Harmonic ACE for straight-stick laparoscopic hysterectomy cases and the PK Cutting Forceps for robotic hysterectomy and sacrocolpopexy.

The Harmonic ACE is fast and has little thermal spread; the PK Cutting Forceps is the only energy source available with reticulating arms for the robot.

I have been using the Harmonic ACE for more than 10 years and the PK Cutting Forceps since 2006.

Dr. Iglesia reports no financial relationships relevant to this review.

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Keith Isaacson, MD
Director of Minimally Invasive Gynecologic Surgery and Infertility,
Director of the AAGL/SRS Fellowship in Minimally Invasive Gynecologic Surgery,
Newton Wellesley Hospital,
Associate Professor of Obstetrics, Gynecology, and Reproductive Biology,
Harvard Medical School, Boston, Mass

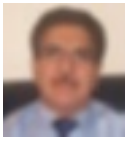
I have used every bipolar and harmonic tool that is commercially available, including the recently released EnSeal. I like them all. The tools I have chosen were selected in conjunction with our purchasing department and determined to be the optimal tools for the lowest cost and highest efficiency. Our goal is to use as few disposables as possible, but to be as efficient as possible.

The instruments I utilize most frequently are the reusable 5-mm bipolar instruments from Karl Storz (RoBi) and ERBE Medical. The RoBi set includes a variety of tips, ranging from a dissecting Maryland-type tip to a flat, broad-based tip similar to the Kleppinger design. These are all plugged into the ERBE VIO generator. With this assortment of tools, I can seal a vessel of almost any size, whether it be thin-walled, such as a large vein, or a thick-walled artery.

To cut tissue, I prefer the Harmonic Scalpel and the bipolar Laparoscopic Spatula (Gyrus). I use the Harmonic Scalpel during laparoscopic hysterectomy, and the Spatula during laparoscopic myomectomy. Both devices cut tissue well while simultaneously sealing small vessels.

I have been using these instruments for approximately 10 years.

Dr. Isaacson reports that he is a consultant for Karl Storz in hysteroscopy.



Noor Ahmed, MB, ChB, MD
Consultant Gynecologist,
Dundee, Scotland.
Member, OBG MANAGEMENT Virtual Board of Editors

I am a consultant gynecologist with an interest in fertility, endometriosis surgery, and general gynecologic surgery. Most of my surgical work is performed laparoscopically or vaginally.

My first experience with vessel-sealing technology was in 2000, when I began using the LigaSure Max for difficult vaginal hysterectomies. I was impressed by its ability to clamp and seal and, in later versions, its ability to cut, as well. Since then, I have been using various versions of LigaSure vessel- and tissue-sealing technology for many gynecologic procedures.

I have had some exposure to other vessel- and tissue-sealing technologies, but prefer LigaSure because:

1. It provides an experience similar to that of conventional clamp, cut, and suture through the control offered by its unique combination of pressure and energy, creating vessel and tissue fusion that does not rely on a proximal thrombus and produces minimal thermal spread.
2. The feedback-controlled response system automatically discontinues energy delivery when sealing is complete.
3. It works with clamps of various sizes and shapes, using the same hardware (generator) and saving money and space. Moreover, the nursing staff has to develop familiarity with one machine only.

For laparoscopic procedures, I use LigaSure Lap, LigaSure Atlas Sealer/Divider and, most commonly, the 5-mm LigaSure V Sealer/Divider.

Dr. Ahmed reports no financial relationships relevant to this review.

Michael Kirwin, MD
General Obstetrics and Gynecology, Freehold, NJ.
Member, OBG MANAGEMENT Virtual Board of Editors

With advanced laparoscopic cases, particularly hysterectomy, I use the Harmonic Scalpel and PK Cutting Forceps. I have used the Harmonic Scalpel regularly for approximately 4 years, and it works well for dissection and, particularly, for transecting the cervix in supracervical cases.

Over the past year, I have also begun to use the Gyrus forceps, especially when I expect to encounter larger vessels that require coagulation. Both instruments can be used in 5-mm ports. Both seem relatively reliable and easy for the OR team to use. I would hope that an articulation feature can be added in the future.

Dr. Kirwin reports no financial relationships relevant to this review.

- Gyrus 5-mm PKS Cutting Forceps
- Gyrus Plasma Trissector
- Harmonic Scalpel
- EnSeal Tissue Sealing and Hemostasis System
- LigaSure V, using the LigaSure Generator (Valleylab)
- LigaSure V, using the Force Triad Generator (Valleylab)
- Ligamax 5 Endoscopic Multiple Clip Applier.

The authors assessed mean seal times and burst pressures. Used on medium and large vessels, the Harmonic Scalpel and Gyrus products had significant failure rates: 8% to 22% for the Harmonic Scalpel and 41% to

92% for the pulsed, bipolar Gyrus systems.

The shortest sealing times for medium to large vessels were achieved with the LigaSure V using the Force Triad Generator. The Gyrus systems were the fastest devices when vessels were 2 to 3 mm in diameter.

There were no seal failures with the Ligamax, EnSeal, or LigaSure products.

Second study involved repeated applications

Lamberton and colleagues tested 5-mm laparoscopic devices under controlled temperature and humidity using a laparoscopic simulator, focusing on the following systems:

- LigaSure V
- Gyrus PK
- Harmonic Scalpel
- EnSeal Tissue Sealing and Hemostasis System.

The authors used 5-mm bovine arteries to assess sealing time, burst pressure, lateral thermal spread, and smoke production, as well as both subjective and objective effects on visibility.

Each device was used 10 times to determine burst pressure, lateral thermal spread, visibility, and smoke production. The devices were applied 20 times to measure time to seal, based on the devices' preprogrammed endpoints.

The Harmonic Scalpel produced the lowest thermal spread and least smoke, but also had the lowest mean burst pressure.

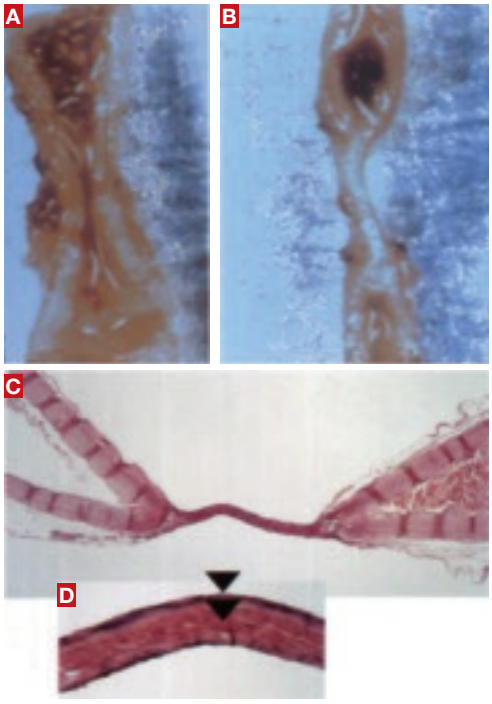
The Gyrus PK generated the most smoke and had variable burst pressure. Although it had the fastest sealing times, in three of 10 trials there was a completely open arterial lumen following transection. In addition, 50% of applications involved burst pressures below 50 mm Hg.

Maximum temperatures 2 mm from the device were 49.9°C for the Harmonic Scalpel, 55.5°C for LigaSure, 58.9°C for EnSeal, and 64.5°C for Gyrus PK.

LigaSure was the highest-rated device overall, with the highest burst pressure and fastest sealing time.

EnSeal was the slowest and had variable burst pressures.

FIGURE How energy-based vessel-sealing works



(**A**) When the carotid artery of an animal model was sealed using a standard bipolar forceps, the lumen remained open and a proximal thrombus developed. (**B**) When LigaSure was used, the artery was fused and the lumen obliterated with one 5-second application. (**C** and **D**) When a renal artery was sealed with LigaSure, the lumen of the vessel walls fused completely.

Clinical implications of the trials

These studies—neither of which was industry-sponsored—suggest that larger vessels cannot be controlled consistently and effectively using the Harmonic Scalpel or Gyrus systems. The Harmonic Scalpel is most user-dependent.

So what's the bottom line? In the end, according to Andrew Brill, MD, past president of AAGL, "it's not the wand, it's the magician."

FAST TRACK

Two studies found the Harmonic Scalpel to be the most user-dependent device