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Comparison of four energy-based vascular sealing and cutting instruments: A porcine model

Benjamin Person · David A. Vivas · Dan Ruiz · Michael Talcott · James E. Coad · Steven D. Wexner

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Abstract
Aim To compare the safety and efficacy of four energy-based vascular sealing and cutting instruments.
Methods Blood vessels of various types and diameters were harvested from four pigs using four instruments: Harmonic ACE™ (Ethicon Endo-Surgery, Cincinnati, OH), LigaSure™ V and LigaSure Atlas™ (Valleylab, Inc., Boulder, CO; a division of Tyco Healthcare), and EnSeal™ vessel fusion system (SurgRx, Inc. Redwood City, CA). The diameters of the vessels, speed and adequacy of the cutting and sealing process, and bursting pressures were compared. An additional set of specimens was sealed and left in situ for up to 4 h after which the vessels were harvested and histopathologically analyzed for the degree of thermal injury.
Results The bursting pressures were significantly higher with EnSeal™ compared to all other instruments ($p < 0.0001$). The sealing process was significantly shorter with Harmonic ACE™ and significantly longer with LigaSure Atlas™ ($p < 0.0001$). The mean seal width was larger with the LigaSure Atlas™ compared to the other instruments, and it was smaller with EnSeal™ and Harmonic ACE™. Less radial adventitial collagen denaturation was present with EnSeal™ and LigaSure™ V than with the other two instruments; there were no significant differences in collagen denaturation although proximal thermal injury to the smooth muscle in the media of the vessel wall was less common with LigaSure Atlas™ than with the other instruments; however, the numbers were too small for statistical analysis.
Conclusions The bursting pressures with EnSeal™ were significantly higher than with all the other instruments. Harmonic ACE™ was the fastest sealing instrument and LigaSure Atlas™ was slowest. EnSeal™ created less radial thermal damage to the adventitial collagen of the vessels and LigaSure Atlas™ created less thermal damage to the media of the vessels. The clinical significance of these findings is unknown.

Keywords Vascular sealing · Energy-based · Bursting pressure · Thermal injury · Porcine model

Recent advances in surgical technology include the use of various energy sources for sealing, coagulating, and cutting blood vessels as opposed to performing these procedures mechanically by tying, suturing, and even clipping or stapling them. The use of energy-based instruments has become even more popular in laparoscopic surgery because the traditional techniques of surgical hemostasis (pressure, tying, suturing) are not as easily laparoscopically applied. The efficacy and reliability of various energy-based vascular sealing instruments have been reported to be equivalent to the results with metallic clips and silk ties [1–3]; however, other researchers have demonstrated that energy-based devices produced either inferior [4] or

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B. Person (✉) · D. A. Vivas · D. Ruiz · S. D. Wexner
Department of Colorectal Surgery, Cleveland Clinic,
2950 Cleveland Clinic Blvd, Weston, FL 33331, USA
e-mail: personb@ccf.org

M. Talcott
Division of Comparative Medicine, Washington University,
St. Louis School of Medicine, Washington, USA

J. E. Coad
Department of Pathology, Robert C. Byrd Health Sciences
Center of West Virginia University, PA, USA

superior [5] results compared to mechanical sealing and cutting techniques. Several other comparisons of various instruments [6–10] demonstrated a wide variety of results.

The aim of this study was to compare the safety and efficacy of four commercially available energy-based vascular sealing and cutting instruments, and to assess the histopathologic effect of each instrument with regard to the thermal effect it produced.

Materials and methods

Four 40–45 kg domestic pigs (Oakhill Genetics, Ewing, IL) were sedated with Telazol (4 mg/kg), ketamine (2 mg/kg) and xylazine (2 mg/kg) intramuscularly, intubated, and maintained under general anesthesia using Isoflurane (2–4%). The study was conducted in accordance with the guidelines set forth by the *Guide for the Care and Use of Laboratory Animals* [11], and was approved by the Washington University animal studies committee. Following surgical isolation using blunt/sharp dissection, blood vessels of various types (peripheral, visceral, arteries, and veins) and diameters were harvested using four instruments: Harmonic ACE™ (Ethicon Endo-Surgery, Cincinnati, OH), LigaSure™ V and LigaSure Atlas™ (Valleylab, Inc. Boulder, CO; a division of Tyco Healthcare Group) and EnSeal™ vessel fusion system (SurgRx, Inc. Redwood City, CA). The diameters of the vessels, speed and adequacy of the cutting and sealing process, and bursting pressures were compared. The diameters of the vessels were measured in vivo before application of the instruments. The speed of the sealing process was measured with a standard digital stopwatch. Since with the LigaSure instruments, the sealing process is separate from the cutting act, the time measured was the time elapsed to the termination of the sealing cycle as indicated by a longer beep. The adequacy of the seal was graded as follows: 1 – no seal; 2 – oozing that required additional intervention; 3 – oozing that stopped spontaneously; 4 – dry seal. The bursting pressure of the sealed end of the vessel was measured with a specialized saline infusion machine manufactured specifically for this experiment (Fig. 1): the open end of the harvested vessel segment was secured to the insertion tool with a silk tie; normal saline solution was infused at a constant rate into the vessel, and the pressure was digitally recorded and displayed on the controller readout. The highest recorded pressure measurement before the sealed end of the vessel burst was determined as the bursting pressure. If a segment had side branches identified during the pressure measurement, that specimen was disqualified and excluded from the analysis.

An additional set of specimens was sealed and left in situ for approximately 2 h (range: 0.5–4 h) after which the vessels were harvested and histopathologically analyzed for the seal quality and thermal injury. Each specimen was embedded in an individual paraffin block. The blocks were faced and four 5 μm sections were prepared equidistant across the entire seal's width. All sections were hematoxylin and eosin stained for evaluation. Each vascular seal was assessed for the following parameters: perpendicular width of tissue seal (Fig. 2); contacting artery wall layers forming tissue seal (Fig. 3a); radius of adventitial collagen denaturation proximal to tissue seal (Fig. 3b); presence of tissue homogenization (cellular/tissue architecture loss) in tissue seal (Fig 4a); presence of gas formation (tissue boiling) in tissue seal (Fig. 4b); presence of tissue arterial wall dissection in tissue seal (Fig. 5); presence of blood pockets in tissue seal; and injury to the smooth muscle in the proximal media.

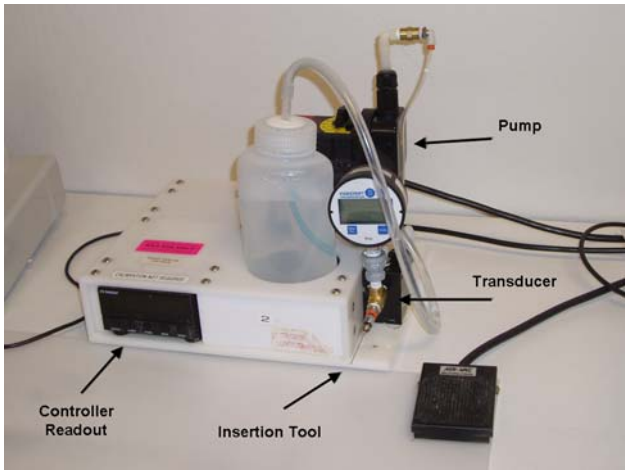


Fig. 1 Burst pressure-measuring machine

Statistical analysis was performed using GraphPad Instat™, GraphPad software V2.04 (San Diego, CA), using Student's *t*-test and analysis of variance (ANOVA) when appropriate.

Results

The number of specimens harvested with each device, diameters of vessels, quality and speed of the seal, and bursting pressures are summarized in Table 1. Individual comparisons of the speed of the sealing process and bursting pressures are summarized in Table 2. The diameters of the vessels harvested with Harmonic ACE™ were significantly smaller than the diameters of vessels harvested with LigaSure Atlas™ ($p = 0.0006$). This difference depicts a selection bias since we deliberately chose larger vessels to be sealed with LigaSure Atlas™ and smaller vessels to be sealed with Harmonic ACE™ according to the recommendations of the manufacturers of

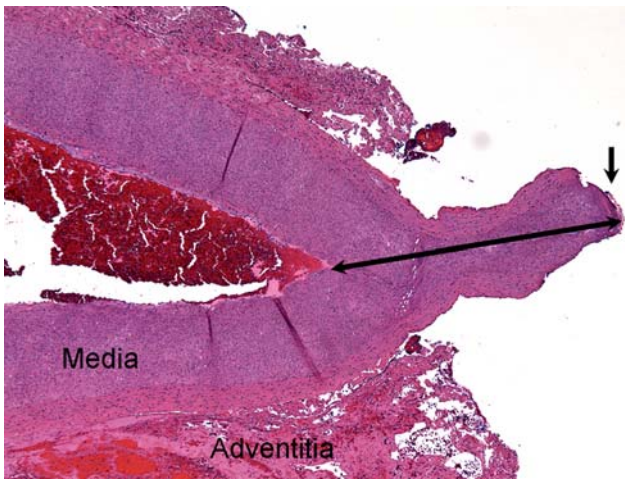


Fig. 2 The anatomy of the vascular seal. Short arrow: The cut end of the vessel; long arrow: the width of the seal covering the length of vascular wall "welding"; the length of the seal was measured from the cut end of the vessel to the point where the two walls of the vessel separated from each other

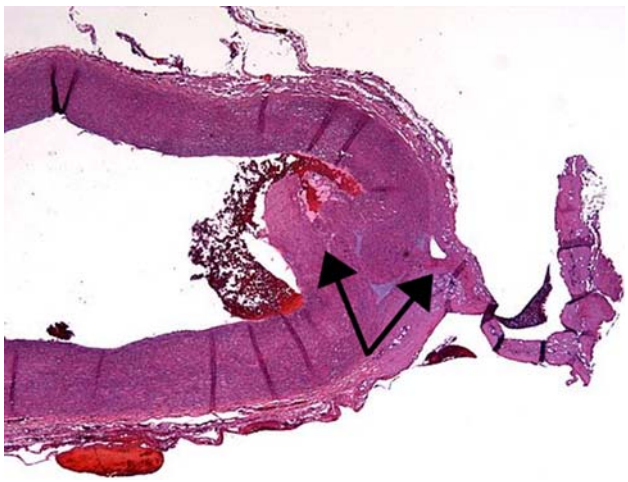


Fig. 5 Arterial wall dissection. At the seal site, the media is dissected from the adventitia at the seal site, reflected back into the lumen and the seal primarily utilizes adventitia tissue (LigaSure^{TM} V)

Fig. 3 Denatured adventitial collagen proximal to the sealed end. Radius of denatured adventitial collagen proximal to tissue seal is seen to variable degrees. More limited (Fig. 3a; arrow denotes denaturation boundary) and more extensive (Fig. 3b; arrows denote denatured layer) adventitial collagen denaturation is illustrated (LigaSure Atlas^{TM})

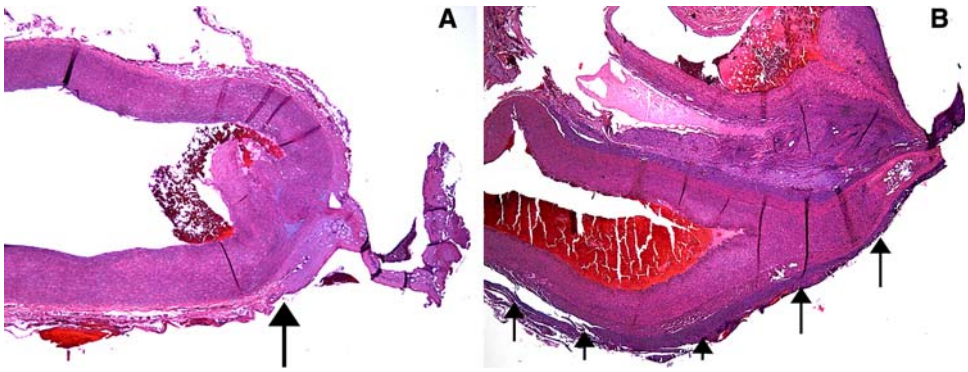
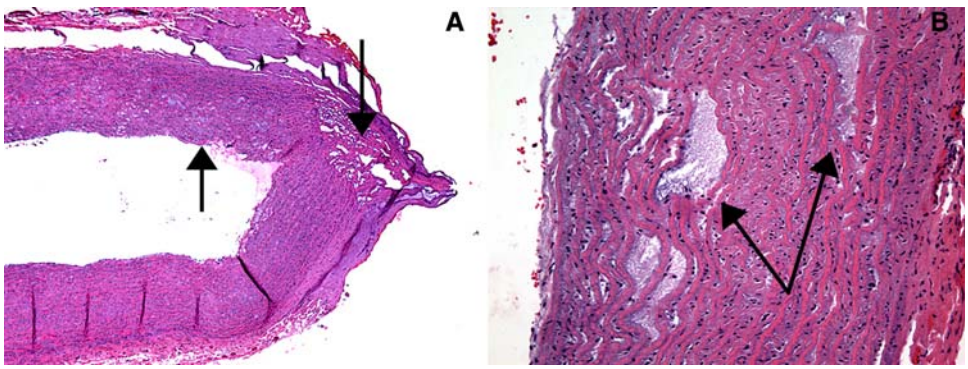


Fig. 4 Gas vapor formation. Gas vapor formation is present within the media adjacent to the seal (Harmonic ACE^{TM})



these instruments. There was no significant difference in the quality of the seal among the four devices. The bursting pressures were significantly higher with EnSeal^{TM} compared to all other instruments ($p < 0.0001$). There was no difference in the bursting pressures among the other three instruments; furthermore, the lowest mean bursting pressure that was recorded in the entire cohort of specimens was more than three times higher than normal systolic pressure. The sealing process was significantly shorter with Harmonic ACE^{TM} and significantly longer with LigaSure Atlas^{TM} ($p < 0.0001$) compared to the other instruments.

All the histological findings are summarized in Table 3. The seal's width was larger with LigaSure Atlas^{TM} and smaller with EnSeal^{TM} and Harmonic ACE^{TM}. Radial adventitial collagen denaturation was less

Table 1 Summary of the evaluated parameters

Instrument	No. of specimens	Vessel diameter (mm)	Quality of seal[#]	Speed of seal (sec)	Burst pressure (mmHg)
EnSeal™	50	4.1 ± 1.5	3.98	4.1 ± 0.9	678 ± 184[†]
LigaSure™ V	55	3.8 ± 1.6	3.93	5.2 ± 2.1	380 ± 135
LigaSure Atlas™	27	4.8 ± 0.6*	3.78	7.9 ± 2.2	489 ± 270
Harmonic ACE™	52	3.3 ± 1.0*	4	3.3 ± 1.0	435 ± 321

*$p = 0.0006$; [#]p = NS; [†]$p < 0.0001$

Table 2 Comparison of the significance of results of the speed of sealing processes and bursting pressures

Comparison	Speed of seal	Burst pressure
EnSeal versus LigaSure V	NS	<0.0001
EnSeal versus Harmonic ACE	0.03	0.0015
EnSeal versus LigaSure Atlas	<0.0001	0.0094
LigaSure V versus Harmonic ACE	0.0031	NS
LigaSure V versus LigaSure Atlas	0.0043	NS
Harmonic ACE versus LigaSure Atlas	<0.0001	NS

The numbers are p values of each individual comparison; NS: not significant

common with EnSeal™ and LigaSure™ V than with the other two instruments; EnSeal™ caused somewhat less collagen denaturation than LigaSure™ V. Proximal thermal injury to the smooth muscle in the media of the vessel wall was least common with LigaSure Atlas™; however analysis with this instrument was performed only on three of the four specimens since one of the specimens lacked sufficient tissue proximal to the sealed end. Thermal injury to the smooth muscle in the vessel's media was most common with EnSeal™ (present in four out of the five specimens). In the specimens treated with LigaSure™ V and Harmonic ACE™, this finding was present in three out of the four specimens. Gas pockets depicting tissue boiling were most commonly observed in specimens treated with Harmonic ACE™.

Discussion

The use of sophisticated energy sources for dissection and hemostasis has greatly advanced and facilitated complex laparoscopic procedures. Due to their mode of action, traditional monopolar and bipolar cautery devices generate significant heat and result in inconsistent vessel sealing with substantial thermal spread and charring [3]. These drawbacks prompted the development of more advanced instruments such as the ultrasonic shears and feedback-monitored bipolar forceps. The desired end result of the action of every energy-based sealing/cutting instrument is the same regardless of the energy employed: a safely sealed vessel with minimal collateral thermal damage. The mode of action of ultrasonic instruments such as the Harmonic ACE™ is based on an active blade that vibrates at 55,500 Hz, which creates simultaneous coagulation and cutting of tissues. These instruments operate in lower temperatures and cause less smoke and charring due to the fact that electrical current is absent; however, the Harmonic ACE™ is recommended only for sealing vessels of up to 5 mm in diameter [12]. The LigaSure™ instruments utilize a high-current, low-voltage bipolar radiofrequency (RF) energy, in combination with a feedback-controlled response system that automatically delivers and disrupts the power according to the composition and impedance of the tissue between the jaws of the instrument [13]. These instruments can seal vessels of up to and including 7 mm in diameter. The EnSeal™ tissue sealing and hemostasis system (SurgRx, Inc. Redwood City, CA) is one of the newer products

Table 3 Histopathology findings

Instrument	Seal width (mm) [mean (range)]	Denatured adventitial collagen (mm) [mean (range)]	Wall layer dissection (%)	Gas formation (%)	Blood pockets (%)	Proximal wall injury
EnSeal™	1.0 (0.1–2.4)	0.1 (0.0–0.6)	60	60	40	4/5
LigaSure™ V	1.8 (0.5–3.4)	0.4 (0.0–1.4)	100	75	25	3/4
LigaSure Atlas™	2.5 (1.6–3.7)	1.5 (0.5–2.8)	75	75	25	1/3*
Harmonic ACE™	0.9 (0.6–1.4)	1.0 (0.1–2.0)	50	100	0	3/4

*One specimen had insufficient tissue proximal to the seal

%: the percentage of the specimens in which each finding was observed

available for sealing blood vessels. It is a bipolar instrument that combines a high-compression jaw with a tissue-dynamic energy delivery mechanism. Due to the configuration and composition of the jaws of the instrument, each tissue type within the jaws receives a different energy dose that is constantly changing as the tissue is being sealed and its impedance changes. The instrument has an I-shaped blade, which is advanced as the tissue is being sealed, simultaneously cutting the sealed tissue [14]. This instrument is also recommended for vessels of up to and including 7 mm in diameter.

The results of the current experiment showed that all four instruments were efficacious and safe in sealing and cutting blood vessels. All four instruments created good seals with supraphysiological bursting pressures. Vessels sealed with EnSeal™ had statistically significantly higher bursting pressures compared to all the other instruments; however, even the lowest bursting pressures that were recorded were in the supraphysiological range, which makes the clinical significance of these differences unclear.

All four vascular seal groups showed variable degrees of histologic heterogeneity. This heterogeneity in the tissue seals precluded definitive determination of a primary representative histology for each device and their subsequent comparison. This heterogeneity may be due to inherent differences in the individual treated vessel walls (muscle/elastic media composition, wall thickness, vessel location, vessel diameter, for example), operator experience, device design, and/or other factors. Comparisons of acute cell injury (<4 h in vivo) are also limited as the cytological manifestations of cell/tissue injury do not fully develop for 36–48 h post in vivo treatment. The preliminary data suggest that the LigaSure™ instruments create a wider tissue seal compared to the other instruments; the EnSeal™ device caused variably less denaturation of the adventitial collagen, which may indicate lower temperatures in the outer layers of the vessels, but it appears to potentially have more thermal injury to the proximal inner layers of the vessels. Superheated tissue, as indicated by the presence of gas pockets, was more commonly observed in the specimens that were treated with the Harmonic ACE™. This finding indicates that, in spite of operating in lower temperatures, ultrasonic energy can create substantial tissue heat.

Within the seal region, local disruption of the vessel wall appeared similar with all four instruments. As the histological evaluation of nonsurvival study tissues for thermal injury is limited, 7-day acute and 30-day subacute follow-up studies are necessary to confirm, better characterize, and understand the apparent immediate thermal injury patterns associated with these devices. The clinical significance and implications of these immediate histological changes (<4 hour in vivo survival) cannot be determined with certainty.

Disclosures

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–Dr. Talcott is a consultant and owns stock at SurgRx Inc.

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