

Comparison of two ultrasonic coagulating shears in sealing pulmonary vessels

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Abstract: Ultrasonic cutting and coagulating devices have been used successfully in thoracic applications such as pulmonary resection or artery harvesting, but few studies have evaluated their use in sealing pulmonary vessels. In this study we compared two commercially available devices, Harmonic Ace+ (HAR, Ethicon Endo-Surgery, Inc., Cincinnati OH, USA) and SonoSurg (SS, Olympus America, Center Valley, PA, USA), in a canine preclinical model. There were three sections to the study: acute, survival, and ex vivo (burst pressure). Hemostasis of sealed pulmonary arteries and veins was assessed for the initial application and during a simulated hypertensive crisis, both immediately after vessel sealing and after a survival period of 30 days. Other intraoperative measures were also evaluated, including transection time, tissue sticking, tissue tags, and char on the seal. Histological evaluation was performed both after initial sealing and after the survival period. Burst pressure of sealed vessels was measured ex vivo. For both devices, hemostasis was excellent, including those measurements made under simulated hypertensive crisis. There were no differences in any of the intraoperative measures or thermal damage evaluated histologically. Wound healing was normal. The burst pressures for ex vivo vessels sealed by HAR (median 619.2 mmHg) were significantly higher than those of SS (350.3 mmHg, $P = 0.022$). Both devices displayed acceptable characteristics in sealing canine pulmonary arteries and veins. The only difference observed was that HAR produced burst pressures 76.8% greater than SS, which may lead to a lower percentage of failures in the region of physiological interest. Use of ultrasonic devices in thoracic applications provides a high rate of initial hemostasis, supraphysiological burst pressures, and durable seals that heal normally.

Keywords: ultrasonic sealing, thoracic, pulmonary vessels, burst pressure, hemostasis

Introduction

Ultrasonic cutting and coagulating devices have been used successfully in thoracic applications such as pulmonary resection or artery harvesting, but few studies have evaluated their use in sealing pulmonary vessels. Infrequent use in this area is unexpected, since ultrasonic devices, with their small size compared to surgical staplers, should be of great benefit in accessing and manipulating pulmonary arteries and veins. Lack of confidence in the ability of ultrasonic devices to seal vessels with a single application and to create strong seals may have limited their application in this area.

The energy profile delivered by an ultrasonic device is critical to the formation of a strong and durable vessel seal.¹ Building upon the foundation of basic Harmonic functionality, adaptive tissue technology has been developed to respond to varying tissue conditions by controlling the power delivered by the Harmonic Ace+ (HAR) ultrasonic shears (see Figure 1). Adaptive tissue technology monitors the instrument during use. When there is

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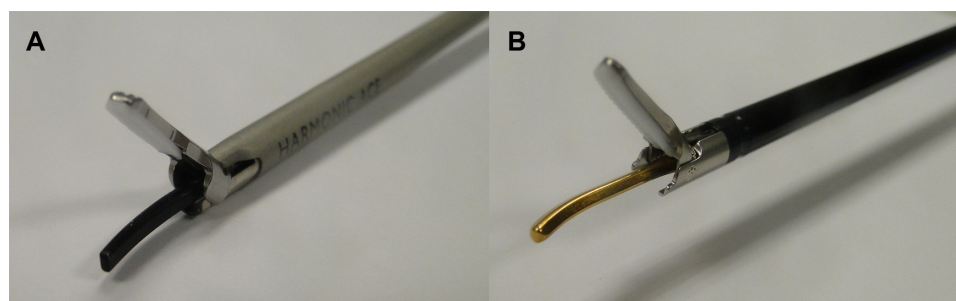


Figure 1 (A) Harmonic Ace+ shears end effector; (B) SonoSurg end effector.

little or no tissue remaining and the blade temperature begins to increase more rapidly, adaptive tissue technology provides a reduction in the power level and enhanced feedback with a change to a second activation tone. Optimal vessel sealing is achieved for each activation, without unnecessary power output that could potentially lead to thermal injury.

In this study, we evaluated the use of an improved HAR shears device with adaptive tissue technology and a new coated blade tip in sealing pulmonary vessels in a preclinical canine model. Our objectives were to determine whether HAR could effectively seal pulmonary vessels with a single activation, producing sufficiently strong seals, and whether there are any qualitative or quantitative differences between HAR and SonoSurg (SS), another commercially available ultrasonic device indicated for use in thoracic procedures.

Materials and methods

This study was approved by the Ethicon Endo-Surgery Institutional Animal Care and Use Committee, as conforming to the standards promulgated in the *Guide for the Care and Use of Laboratory Animals* of the Institute for Laboratory Animal Research, National Research Council.

The two ultrasonically energized devices evaluated were the 23 cm Harmonic Ace+ shears with adaptive tissue technology and a coated blade tip (model HAR23; Ethicon Endo-Surgery, Cincinnati, OH, USA) and SonoSurg scissors (Olympus America, Center Valley, PA, USA). Transections using HAR were performed at power level 3 (of 5), and transections with SonoSurg were performed at 70% power. As previously shown,² these settings provide similar frequency-amplitude products for the two devices. HAR is a hand-activated device, while SS is activated via foot pedal. Application and usage of the devices is otherwise similar.

There were three separate sections to the study: acute, survival, and ex vivo (burst pressure). In the acute study, the devices were tested in five canines undergoing video-assisted thoracoscopic surgery including the following procedures: lobectomy, esophageal mobilization, and

mediastinal lymphadenectomy. Dogs were anesthetized with propofol, acepromazine, and glycopyrrolate, intubated, and placed in right lateral recumbency. A flexible endoscope was used as a guide to reposition the endotracheal tube in order to selectively ventilate only the right side of the respiratory tract. Video-assisted thoracoscopic surgery was performed using a 12 mm Endopath Xcel trocar (Ethicon Endo-Surgery) for the camera port and 4–5 mmHg carbon dioxide insufflation. A femoral and pulmonary arterial catheter was placed to directly monitor systemic and pulmonary arterial blood pressure.

During the left cranial or caudal lobectomy, branches of the left interlobar pulmonary artery and vein were identified and isolated using laparoscopic right-angle or endoscopic dissector sponges, and the diameter of each branch was measured. The ultrasonic devices were used for coagulation and transection of these pulmonary vessels. Individual vessels larger than 5 mm in diameter, lung parenchyma, and bronchus were transected with a surgical stapler when encountered to facilitate completion of the surgical procedure. Transected vessel sites were rated and examined for hemorrhage or other complications for a minimum of 10 minutes. Following the vessel sealing, the esophagus was mobilized from its mediastinal attachments using the ultrasonic devices. Mobilization of the esophagus was continued from the diaphragm to the bifurcation of the bronchus. Finally, mediastinal lymph nodes were dissected and removed with the ultrasonic devices.

Immediately following the procedures, two animals underwent a blood pressure elevation using a vasopressor (eg, phenylephrine or vasopressin) to a systemic systolic blood pressure greater than 200 mmHg for a period of 10 minutes to mimic a simulated hypertensive crisis, and transection sites were observed for hemorrhage during this period.

At the completion of the acute phase, all pulmonary vessel seals were collected for histological evaluation in 10% neutral buffered formalin to evaluate lateral thermal damage via histology. Each vessel was trimmed, embedded in paraffin, processed

to microslide, and stained with hematoxylin and eosin. A digital slide scanner and automated telemicroscope (BA600; Motic Corporation, Hong Kong, People's Republic of China) was used to measure the linear extent of lateral thermal damage, from the base of the seal along the adventitia of the vessel to the transition to normal collagen.

In the survival study to verify durability of sealing, nine dogs underwent a similar surgical procedure with pulmonary vessel sealing, five with HAR and four with SS. All seals were evaluated intraoperatively and at 30 days postoperatively. The survival evaluation was performed just prior to death during a blood pressure challenge to simulate a hypertensive crisis. Histological assessment was performed on tissue at the vessel-sealing sites.

For burst-pressure testing, unaffected canine lungs were harvested immediately after euthanasia for an ex vivo study. Main pulmonary arterial branches were identified and isolated from the lung parenchyma. Only pulmonary arteries were utilized in this study, because they present a worst-case scenario for friability and luminal pressures compared to pulmonary veins. The isolated pulmonary arteries whose outer diameters were in the range of 1–5 mm were sealed and transected using the ultrasonic devices. These vessels were

further separated from the lung using Metzenbaum scissors and were used for burst-pressure measurement.

The sealed vessels were loaded onto the burst-pressure system using iris quick connectors. The infusion for the burst pressure system was performed through a Harvard syringe pump (Harvard Apparatus, Holliston, MA, USA), operated by a computer using a custom made LabVIEW program (National Instruments, Austin, TX, USA). Burst pressures were recorded via a pressure transducer connected in line with the system. The infusion flow rate used for testing was 10 mL/minute. In case of branch leaks, the branches were closed using a clip to challenge the seal. In case of hub leak or adventitial leaks, the vessels were repositioned in the iris to challenge the seal. In the event of these leaks, the data were utilized during statistical analysis, as leaks did not impair the ability to obtain accurate burst pressures.

Normal canine systolic pulmonary arterial pressure is approximately 25 mmHg. Seals were considered successful if the burst pressure was at least 75 mmHg (ie, three times normal physiological pressure).

Results

Since the operative technique used for the acute and survival sections of the study was identical, the intraoperative results

Table 1 Results of intraoperative, survival and burst pressure testing

Measure	HAR	SS	P-value (statistical test)
Number intraoperative vessels (acute and survival)	47	40	NA
Median vessel size	3.0 mm	3.0 mm	0.815 (Mann–Whitney)
First-application hemostasis	46/47	40/40	1.000 (Fisher's exact)
Transection time	7.9 seconds	8.4 seconds	0.517 (ANOVA*)
Hemostasis during acute pressure challenge	5/5	6/6	1.000 (Fisher's exact)
Thermal damage via H&E	2.44 mm (n = 8)	3.14 mm (n = 7)	0.149 (Student's t-test)
Hemostasis during survival pressure challenge	24/24	25/25	1.000 (Fisher's exact)
Median vessel size for burst pressure	3.0 mm	3.0 mm	0.390 (Mann–Whitney)
Burst pressure \geq 75 mmHg	32/32	31/32	1.000 (Fisher's exact)
Failure rate < 75 mmHg (Weibull distribution)	1.3% (0.3%–4.8%)	5.4% (2.1%–13.4%)	NA
Median burst pressure (range)	619.2 mmHg (101.9–1753.2)	350.3 mmHg (26.8–1344.4)	0.022 (Mann–Whitney)
Mean burst pressure (SD)	631.6 mmHg (356.5 mmHg)	445.2 mmHg (305.4 mmHg)	0.028 (Student's t-test)

Note: *The ANOVA was performed on the square-root transform of the transection time using the vessel size as a covariate.

Abbreviations: HAR, Harmonic Ace+; SS, SonoSurg; NA, not applicable; ANOVA, analysis of variance; H&E, hematoxylin and eosin; SD, standard deviation.

were pooled for analysis of common measures (see Table 1). The pulmonary vessels used ranged in size from 1 to 5 mm. There was no statistical difference in the median vessel size of 3.0 mm between HAR and SS. Overall, 62% of the pulmonary vessels were arteries, and 38% were veins.

For HAR, 46 of 47 vessels (97.8%) were successfully sealed on the first application of the device, and for SS, 40 of 40 (100.0%). For both devices, no application had tissue sticking, tissue tags, char at the seal, or grossly observable mechanical or thermal injury. Both devices dissected tissue (esophageal mobilization and lymph-node dissection) acceptably. In the acute phase of the study, after simulated hypertensive crisis, with an average pulmonary systolic blood pressure of 48.5 mmHg, all five HAR seals and all six SS seals remained hemostatic. There was not a statistically significant difference in thermal damage assessed histologically between HAR and SS (Figures 2 and 3).

After the survival period of 30 days, during a simulated hypertensive crisis, with an average pulmonary systolic blood pressure of 33.6 mmHg, 100% of the HAR seals ($n = 24$) and SS seals ($n = 25$) remained hemostatic. At necropsy, gross examination showed all blood vessel pedicles were intact, with no evidence of hemorrhage or adhesions at the vessel-transection sites for both HAR and SS. Histological evaluation indicated normal wound healing, with minimal alveolar hemorrhage and mild to minimal fibrosis.

In the pulmonary vessels used for burst-pressure testing, there was no significant difference in the median sizes between HAR and SS. Comparison via Mann–Whitney test showed that the median burst pressure for HAR (619.2 mmHg) was significantly higher than SS (350.3 mmHg, $P = 0.022$). The median burst pressure for thoracic vessels sealed by HAR was 1.77 times higher than SS (Figure 4), and 24.8 times higher than normal physiological pressure (25 mmHg). A survival plot of burst pressures (Figure 5) shows that at all pressures, higher numbers of vessels remained intact for HAR compared to SS. Fitting the survival curves to a Weibull distribution indicates the HAR and SS are significantly different ($P = 0.022$), and the rate of failure below 75 mmHg is estimated to be only 1.3% for HAR compared to 5.4% for SS.

Discussion

Pulmonary vessels may be divided using an endostapler, but difficulty in exposing or accessing vessels with a stapling device makes use of a small, precise ultrasonic scalpel more attractive. HAR has been shown in nonthoracic applications to produce lower levels of inflammation,³ promote faster wound healing,⁴ and decrease the risk of neurophysiological damage⁵ compared to electrosurgery. Ultrasonic devices have become popular in thoracic applications for such uses as pulmonary dissection,^{6–10} artery harvesting,^{11–13} and sealing the thoracic duct.¹⁴ However, few studies have examined the use of ultrasonically energized

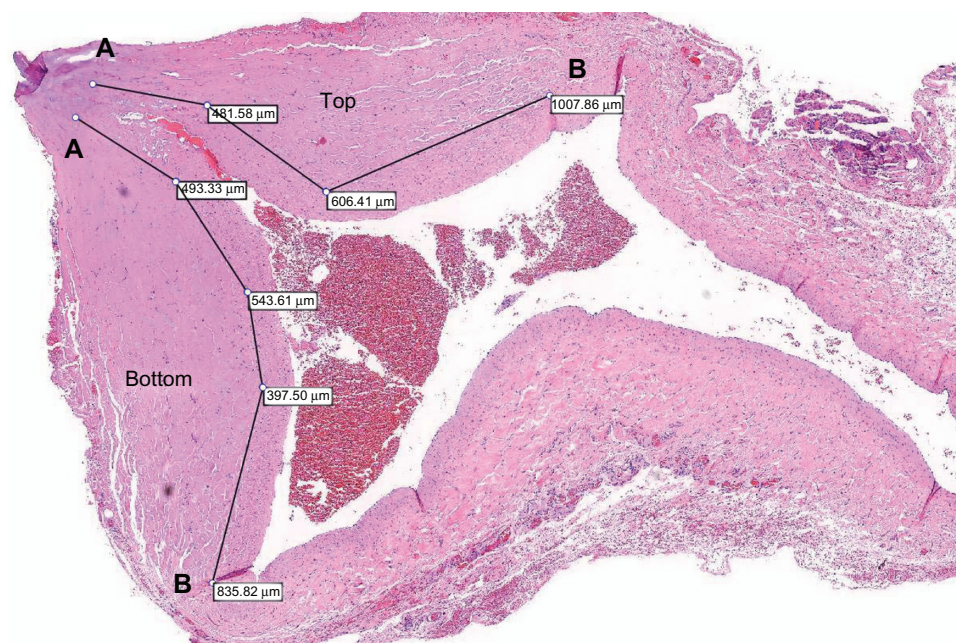


Figure 2 (A and B) Histologic (hematoxylin and eosin) section of pulmonary artery transected with Harmonic Ace+. Thermal damage within the adventitial collagen is measured from the base of the seal (A) to the transition to normal collagen (B).

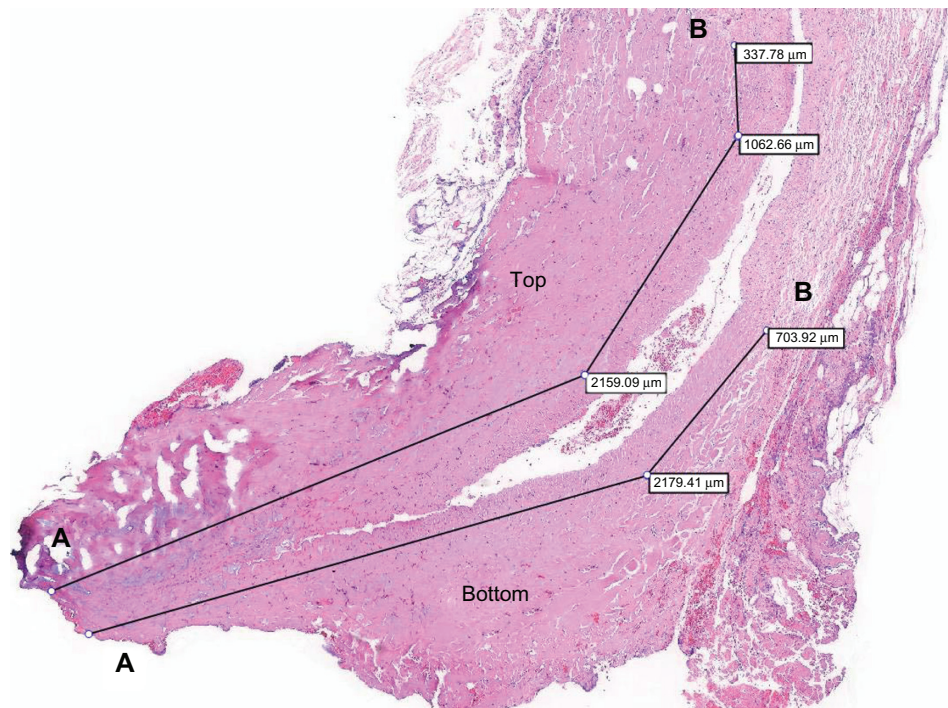


Figure 3 (A and B) Histologic (hematoxylin and eosin) section of pulmonary artery transected with SonoSurg. Thermal damage within the adventitial collagen is measured from the base of the seal (A) to the transition to normal collagen (B).

devices in the ligation of pulmonary vessels and evaluated the long-term durability of vessel sealing.

One early study examined application of the Harmonic Ace shears in sealing and dividing pulmonary vessels in pig, followed by a 1- to 6-week survival period.¹⁵ Mean pulmonary artery pressure was 13 mmHg under anesthesia, compared to a mean systemic pressure of 50 mmHg. Although Harmonic Ace is only intended to seal vessels with a diameter of 5 mm or less, vessels up to 9 mm in diameter were evaluated. At a power setting of 5, there were no seal failures in pulmonary arteries 5 mm or less, or veins 7 mm or less. Using Harmonic Ace, permanent seals were achieved on all vessels tested,

except for one 7 mm and one 9 mm vessel. By 6 weeks, sealed-vessel histology was consistent with normal wound healing. It was concluded that the Harmonic Ace could reliably seal and divide pulmonary vessels 4 mm and smaller.

A second study evaluated pulmonary vessel division with Harmonic Ace shears both in a preclinical model and clinically.¹⁶ In the preclinical model in pig, all burst pressures of sealed pulmonary arteries were greater than 75 mmHg. Clinically, Harmonic Ace was used to divide pulmonary vessels secured with a single ligation in 20 patients. Sealing was performed on 43 pulmonary arteries and 13 veins, ranging in size from 2 to 5 mm. Only two early failures were observed,

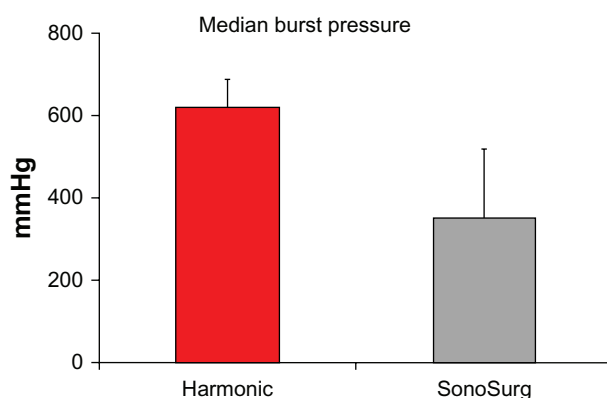


Figure 4 Median burst pressure of Harmonic Ace+ and SonoSurg. **Note:** Error bars represent the 95% confidence interval of the median.

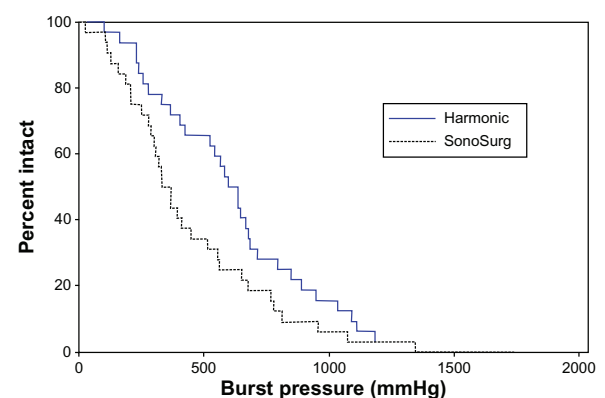


Figure 5 Vessels remaining intact at increasing pressures for Harmonic Ace+ and SonoSurg.

which were related to positioning of the vessels within the jaws of the device. No other intraoperative or postoperative bleeding was observed in any patient.

Pulmonary vessels are less muscular and more elastic than systemic vessels, so specific testing must be performed to ensure adequate sealing and durability. The pulmonary artery is very fragile,¹⁷ and poses a higher risk of intraoperative bleeding than the pulmonary vein, which can be adequately sealed via stapling, hence we focused on arteries in this study. Blood pressures in pulmonary vessels are lower than in the systemic circulation, approximately 25 mmHg. The burst-pressure criterion should therefore be lower, and we used 75 mmHg (three times the normal pressure) as our minimum criterion for success.

In this study we evaluated the improved HAR shears device with adaptive tissue technology and a coated blade for the first time in a canine preclinical model and compared it to another commercially available ultrasonic device, SS. The pulmonary artery diameter of canine is closely related in size to the pulmonary artery diameter of humans. Pulmonary tissue manipulation is also similar between canine and human. For this reason, an energy instrument targeting 1–5 mm vessels in canine is directly related to human pulmonary vasculature.

Both HAR and SS had a high rate of sealing on the first application, with no evidence of tissue sticking, tissue tags, or char on the seal. Median thermal damage width evaluated histologically was less for HAR than SS, although not significantly so. The seals produced by both devices were durable, and there was no evidence of leakage under a blood pressure challenge either immediately after surgery, or at the end of a 30-day survival period. For the HAR device, burst pressures of all vessels tested were higher than the 75 mmHg criterion and the median burst pressure was 619.2 mmHg, 24.8 times greater than the normal physiological pressure of 25 mmHg. While in all other sealing characteristics tested, the two devices were not different, HAR produced a significantly greater median burst pressure, 76.8% higher than that of SS.

A limitation of this study is that it was performed in a canine model. Although canine and human pulmonary arteries contain similar amounts of collagen and elastin, canine pulmonary artery has more collagen than elastin,¹⁸ while human pulmonary artery has more elastin than collagen.¹⁹ For bipolar vessel sealing, burst pressure has been linked to the collagen–elastin ratio.²⁰ If this same correlation were to hold for ultrasonic sealing, then one might expect that the burst pressures observed in canine pulmonary artery

would be greater than those in human pulmonary artery. However, the window of safety is so great that a slight decrease in mean burst pressure would have a negligible effect on the failure rate at physiological pressures. Furthermore, the differences between devices observed in this study should be similar in other animal models.

Previous studies in nonpulmonary applications have shown that a previous version of HAR and SS were essentially equivalent in sealing characteristics.^{2,21} The difference in the current study between HAR shears and SS may in part be due to the incorporation of adaptive tissue technology into the Harmonic platform. This technology provides the system with the ability to monitor the thermal condition of the blade end effector and to identify conditions correlative with excessive waste thermal energy, namely, rapid increases in heat flux into the blade from action directly against the tissue pad rather than against tissue. When minimal tissue remains in the jaw, an audible tone provides feedback to the user, and the generator decreases its power output. This intelligent technology reduces unnecessary power output that could potentially lead to excess thermal injury. Additionally, the new, more lubricious, coated blade tip for the HAR shears may provide for a more uniform tissue division that may, in part, account for the difference between HAR and SS in this study.

Based on the results of this study, HAR shears with adaptive tissue technology provides the ability to seal pulmonary vessels similar to SS, although it achieves much higher burst pressures. Together with previous studies on Harmonic Ace, to which HAR with adaptive tissue technology represents a step improvement, there is now mounting preclinical and clinical evidence that this ultrasonic device can provide strong, durable vessel sealing in pulmonary arteries and veins. Surgeons can be confident that pulmonary vessels of 5 mm diameter and less can be sealed by HAR with a single application, and will stay sealed even under extreme physiological conditions.

Conclusion

In this preclinical study, both HAR and SS ultrasonic devices successfully sealed pulmonary vessels in the 1–5 mm range with little thermal damage, and vessels sealed by these devices were durable over a 30-day survival period in canines. While both devices produced seals with supraphysiologic burst pressures, HAR seals had significantly higher burst pressures than those of SS. Based on the high burst pressures achieved and low level of leakage expected at physiological blood pressures, the new Harmonic Ace+ device provides confidence of successful usage in pulmonary vessel sealing and other thoracic applications.

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Disclosure

Devanathan Raghavan, Duan Broughton, Courtney E Henderson, and Jeffrey W Clymer are employees of Ethicon Endo-Surgery, Inc. John A Howington is a paid consultant of Ethicon Endo-Surgery, Inc.

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