

Prospective Comparison of Four Laparoscopic Vessel Ligation Devices

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Abstract

Purpose: The merits of laparoscopic sealing devices have been poorly characterized. The purpose of this study was to compare two bipolar sealing devices [LigaSure V (LS) and Gyrus PK (GP)], an ultrasonic device [Harmonic Scalpel ACE (HS)] and a novel device using nanotechnology [EnSeal PTC (ES)].

Materials and Methods: The ability of all four 5 mm devices to seal 5 mm bovine arteries was tested under controlled temperature and humidity in accordance with manufacturer specifications. Study endpoints included lateral thermal spread, time to seal, burst pressure, smoke production and subjective (blinded review of video clips) and objective (measured using an aerosol monitor) effect upon visibility.

Results: The HS demonstrated the least thermal spread. The LS (10.0 secs) and GP (11.1 secs) had the fastest sealing times ($p < 0.001$ for both) when compared to ES (19.2 sec) and HS (14.3 sec). Mean burst pressure values were: LS 385 mm Hg, GP 290 mm Hg, ES 255 mm Hg and HS 204 mm Hg. The HS had the best subjective visibility score and the lowest objective smoke production (2.88 ppm) compared to the GP (74.1 ppm), ES (21.6 ppm) and LS (12.5 ppm), ($p < 0.01$ for all).

Conclusions: The LS has the highest burst pressure and fastest sealing time and was the highest rated overall. The HS produced the lowest thermal spread and smoke but had the lowest mean burst pressure. The GP had the highest smoke production, and variable burst pressures. Despite employing nanotechnology, the ES device was the slowest and had variable burst pressures.

Introduction

THE INTRODUCTION OF energy-based vessel sealing technologies has expanded the arsenal of potential techniques available for hemostasis during laparoscopic surgery. These devices allow for rapid sequential tissue and vessel sealing, coagulation, and transection. In addition, the efficacy of these devices has been shown to be comparable to traditional laparoscopic stapling devices and clips.^{1,2} Despite their increasing popularity and widespread use, there has been a paucity of data objectively comparing the relative safety and efficacy of each device. There are also potential disadvantages of energy-based instruments for hemostasis including lateral thermal spread, relatively high disposable cost, variable burst pressures, and the generation of smoke, vapor, and particulates which may compromise visibility.³

The purpose of this study was to compare the safety and efficacy of four energy-based technologies currently in use for dissection and hemostasis during laparoscopic surgery. Specifically this study was designed to compare vessel sealing time, burst pressure, lateral thermal spread, and laparoscopic image degradation.

Materials and Methods

The four devices compared in this study included 5 mm versions of the LigaSure V Lap System (Valleylab, Boulder, CO), Gyrus PK Tissue Management System (Gyrus Medical, Minneapolis, MN), Harmonic Scalpel ACE (Ethicon Endo-Surgery, Cincinnati, OH), and the EnSeal PTC Tissue Sealing and Hemostasis System (SurgRx, Redwood City, CA). Each device was evaluated in the following categories: (1) lateral thermal spread; (2) time to seal and cut; (3) burst pres-

sure; (4) smoke density; and (5) visibility. In this article time to seal will refer to the total time required to seal and cut the artery.

A simulated laparoscopic environment was created using a neonatal incubator to maintain temperature at 37 degrees Celsius and 98 percent humidity to approximate intraabdominal physiology encountered during laparoscopic surgery.^{4, 5} Three ports were inserted into the simulator including a 12 mm port for a 30 degree 10 mm laparoscopic camera, one port for insertion of the sealing instrument and a third port to assist in positioning and manipulation. All other openings into the simulator were sealed to prevent humidity loss, gas exchange or temperature change. All ambient light sources, except for the laparoscopic camera light, were switched off during testing.

Five-millimeter bovine arteries were harvested and stored at -80 degrees Celsius. On the day of the study, they were thawed to room temperature and then slowly warmed to 37 degrees Celsius in a gentle water bath. Freshly thawed frozen vessels have been shown to have similar properties to fresh vessels.⁶ All testing was performed in a 15 mm Hg carbon dioxide atmosphere similar to the environment encountered during laparoscopic surgery (Fig. 1).

The lateral thermal spread was determined using a 3.5 x 0.140 inch TM99A w/1075 Puncture Probe needle thermistor (Cooper-Atkins, Middlefield, CT) placed 2 mm from the cut edge of the vessels. The maximum temperature during vessel sealing was recorded in 10 trials. Time to seal was determined in 20 applications using a standard digital stopwatch based on the device pre-programmed set endpoint as discerned from its signal output while employing manufacturer specified usage parameters.

The burst pressure was measured in 10 trials by instilling normal saline into the vessel at one end following sealing at the opposite end with the test device. Pressure was initially increased slowly until 100 mm Hg was reached to record low-pressure leakages to the nearest mm Hg. After this level

pressures were raised by 50 mm Hg every 2 minutes with a pressure monitor in series using a previously described technique⁷ until the endpoint pressures (760 mm Hg) were achieved and then maintained for 2 minutes or until the vessel leaked. If the vessel leaked at a pressure before the allotted 2 minutes, the lower pressure was recorded as the burst pressure.

The objective effect of the sealing device upon visibility was determined by measuring particulates in vapor using a laser photometer (TSI Dustrak Aerosol Monitor Model 8520) at a distance of 5 cm in 10 trials per device. This aerosol monitor incorporates a powerful vacuum that rapidly takes in all smoke produced by the sealing device for analysis (Fig. 2). The highest measurement recorded during sealing or within two seconds after completion of sealing was recorded. The effect of vessel sealing upon visibility was also subjectively assessed using digital video recorded from a laparoscope during sealing of each vessel with each device. These videos did not allow the reviewer to see the sealing device in the video images. Ten blinded reviewers reviewed the randomized videos (10 of each device) and rated the degree of visibility on a visual analog scale of 1 (no smoke) to 5 (smoke completely obscuring visibility). A subjective visibility score was calculated using the Median Test. Data was analyzed with SPSS software, version 16 (Chicago, Illinois). One-way ANOVA statistical analysis was performed for thermal spread, time to seal and burst pressure. Objective smoke density was analyzed using MANOVA statistics, and subjective smoke density was analyzed using the Median Test. P values <0.05 were considered significant.

Results

A summary of the evaluated parameters is shown in Figure 3 and Table 1. The HS demonstrated statistically lower mean thermal spread (49.9°C) compared to the GP (64.5°C;

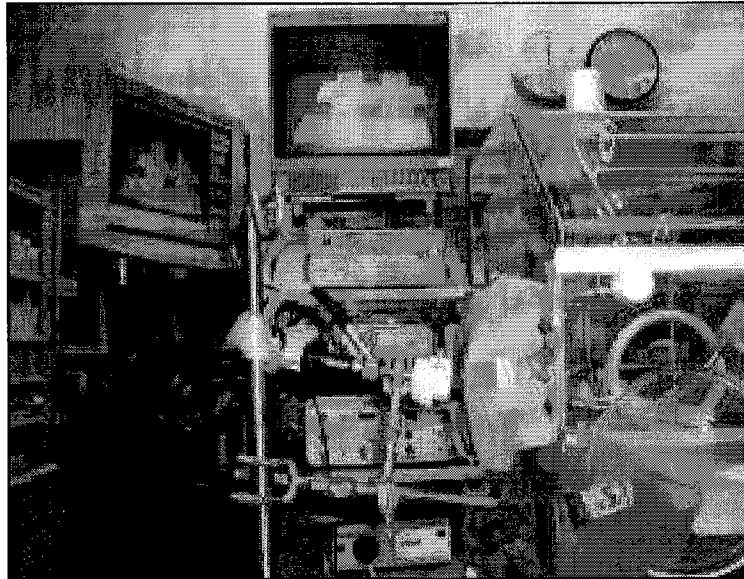


FIG. 1. Model used in testing of all devices.

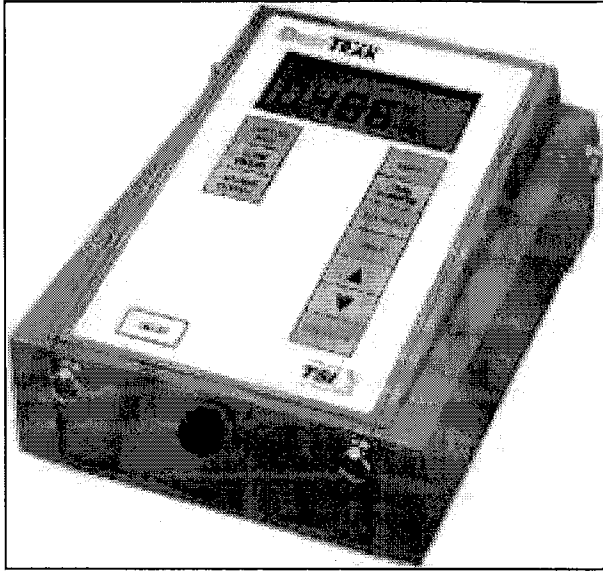


FIG. 2. TSI Dustrak Aerosol Monitor Model 8520.

In comparing the burst pressures between devices the GP was noted to produce an extremely wide variation in sealing with some vessels sealed to the maximum burst pressure while other vessels leaked immediately (0-760 mm Hg range). Due to this extreme variability of vessel sealing recorded with the GP there was no statistically significant difference between devices (Figure 4). Mean values for each device were: LS 385 mm Hg, GP 290 mm Hg, ES 255 mm Hg and HS 204 mm Hg (Table 1). Seventy percent of LS devices had burst pressures above 250 mm Hg, while this value was 40 percent with all three other instruments.

In comparing the objective amount of particulates produced during vessel sealing the HS had the least amount of smoke produced while the GP produced the greatest amount of smoke. The HS (mean 2.88 ppm) had significantly lower particulate production than the GP (mean 74.1 ppm, $p < 0.0001$) and the ES (mean 21.6 ppm, $p < 0.0001$), but was similar to the LS (mean 12.5 ppm, $p = 0.11$). When blinded reviewers compared the effect of particulates and vapor production, the HS had the best visibility with a median visibility score of 105 ($p < 0.001$). The GP had the worst subjective visibility score of 291 ($p < 0.001$). The subjective visibility scores of the LS and ES devices were statistically similar with medians of 191 and 213, respectively.

$p = 0.001$), but was similar to the LS (55.5°C , $p = 0.651$) and the ES device (58.9°C ; $p = 0.073$).

The time to seal was fastest for the LS device and slowest for the HS. Sealing times for the LS (10.0 sec) and GP instruments (11.1 sec) were statistically faster when compared to ES (19.2 sec) or HS (14.3 sec; p for both < 0.001). Time to seal is device dependent and programmed into the auto-feedback mechanism for the LS, GP, and ES devices.

Discussion

Although there are many laparoscopic vessel sealing and transection devices on the market there have been few head to head prospective comparisons of these commonly used devices. There are recent published studies comparing more than two devices although these comparisons were performed as open surgical procedures^{8, 9} or as part of industry-sponsored trials with subsequent potential inherent bi-

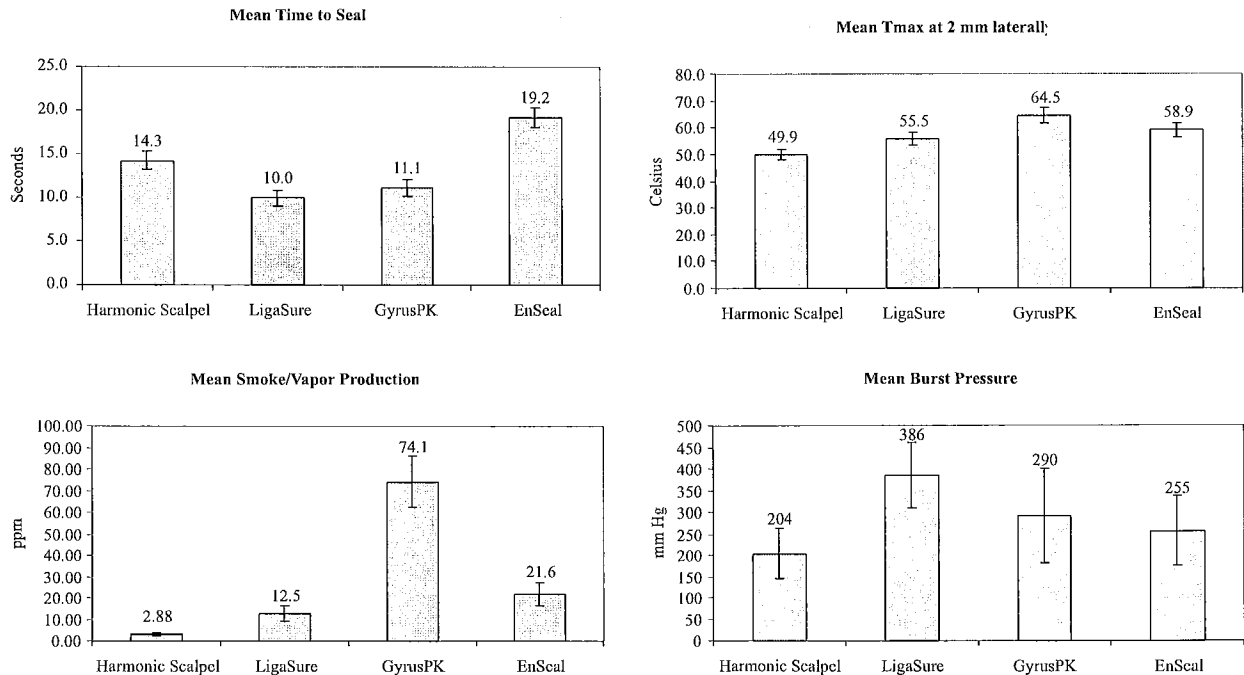


FIG. 3. Summary of the evaluated parameters for the four hemostatic methods.

TABLE 1. SUMMARY OF THE EVALUATED PARAMETERS FOR THE FOUR HEMOSTATIC METHODS

	<i>Harmonic sScalpel</i>	<i>LigaSure</i>	<i>Gyrus PK</i>	<i>EnSeal</i>	<i>P Value</i>
Thermal spread (Mean Tmax)	49.9 ± 1.8	55.5 ± 2.4	64.5 ± 2.7	58.9 ± 2.6	<0.001 (HS vs. GP)
Time to seal (sec)	14.3 ± 1.0	10.0 ± 0.9	11.1 ± 1.0	19.2 ± 1.1	<0.0001 (LS and GP vs. Group)
Smoke/vapor (ppm)	2.88 ± 0.6	12.5 ± 3.6	74.1 ± 11.9	21.6 ± 5.6	<0.0001 (Group vs. GP)
Median subjective visibility ^a	105	191	291	213	<0.0001 (HS vs. Group)
Mean burst pressure (mm Hg)	204 ± 59	385 ± 76	290 ± 110	255 ± 80	0.48
% Burst pressure >150 mm Hg	50	80	50	50	

^aSubjective visibility was calculated by Median Test.

ases.¹⁰ To our knowledge, this is the first independent laparoscopic comparison between all four devices.

In this study four different devices currently on the market were compared. These devices employ different energies and monitoring techniques to seal tissue. Each device uses a different feedback mechanism and regulates the bipolar waveform based on manufacturer specifications. Closing the grasping end of the electro-surgery device completes a bipolar circuit. Energy is then delivered in a high-voltage and low-current burst to seal the vessel. This is combined with a feedback mechanism from the energy source to determine the quantity of tissue being sealed and the strength of the current is adjusted accordingly.¹¹

The HS uses a high-frequency ultrasonic transducer with a microprocessor-controlled generator to detect changes in the feedback acoustic pattern. Vessel coagulation is then performed in a similar method to electro-surgery by tamponading the vessel and then sealing with a denatured protein coagulum while using ultrasonic vibration to denature hydrogen bonds.^{12, 13} The GP and LS both use bipolar electrical energy and pressure to melt collagen and elastin in vessel walls to form a seal. The LS device utilizes continuous energy while the GP uses pulsed energy.¹¹ The ES device also uses bipolar electrical energy but employs a nanotechnology feedback mechanism to reduce thermal spread by changing the energy required for sealing in response to tissue characteristics. The manufacturer calls this, "Smart Elec-

trode Technology," adjusting the energy administered to nanometer-sized areas of the sealed vessel in an effort to reduce thermal spread and aerosol production.¹⁴

Of the electro-surgical instruments the LS devices are among the most closely examined to date. In a well-designed open study, Hruby and coworkers found a high burst pressure with the LS and a rapid sealing time.⁸ The LS device was compared to two ultrasonic devices and a prototype plasmakinetic trisector and was found to be the overall best device. The best sealing was seen with the LS device and the poorest with the HS, similar to the results obtained in the current study. The mean arterial burst pressure for arteries was 536 mm Hg and time to seal for vessels 3.1–5.0 mm was 5.7 sec. All vessels employed in our study were 5 mm in diameter and this may have contributed to the lower burst pressures observed. Vessel size limitations for the ultrasonic HS instruments range between 3 and 5 mm depending on instrument and technique used but risk of failure is possible with mean burst pressures ranging from 338–908 mm Hg.^{9, 12}

Although the GP had fast sealing times, 3 of 10 trials had a completely open lumen following transection and 50% leaked below 50 mm Hg. These findings mirror those reported by Pietrow et al. where renal arteries greater than 5 mm did not reliably seal.¹⁵ In a comparison of the LS and GP sealing devices used in small, medium and large arteries, Carbonell and associates found the GP system had lower burst pressures when compared to the LS system with comparable thermal spread,¹¹ consistent with our data.

The HS had consistently lower burst pressures in our study but had the least smoke production and lateral thermal spread. The burst pressures with the HS and with all devices were lower than some burst pressures reported in previous studies. Clements et al reported HS burst pressures higher (mean 908 mm Hg for 5 mm vessels) than our study.¹² Person et al. also reported higher burst pressures with the ES and the LS¹⁰. In the current study 5 mm vessels were intentionally selected as this measurement was close to the maximum size criteria for most devices in order to accentuate differences between them. This may have contributed to the lower observed burst pressures. Size limitation for the ultrasonic HS instruments range between 3 and 5 mm depending on instrument and technique used, but risk of failure is possible.^{9, 12} Size limitations for vessel sealing by the GP were previously described by Pietrow et al.¹⁵ Furthermore burst pressures may have been lower in the absence of blood and clotting factors inside the vessels acting to facilitate vessel sealing.¹⁶

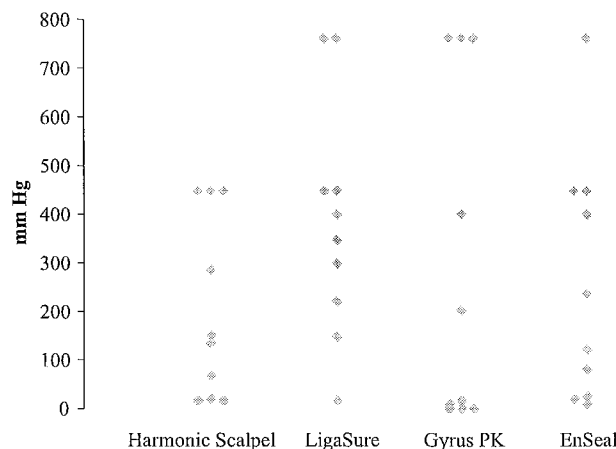


FIG. 4. Vessel burst pressures by device type.

The HS had consistently lower burst pressures in our study but with no complete failures to seal. This is likely due to our decision to create an environment that would be consistent among all the instruments studied. We simply used each device at its preprogrammed start setting. The HS can be adjusted for better sealing by increasing the preprogrammed ultrasonic energy time by manually decreasing the setting from three to one on the power unit and subsequently greatly increasing the sealing time. Bubenik et al. found that by leaving the power setting at three they were only able to reliably seal vessels 4.5 mm in size or smaller.¹⁷

Despite employing nano particles to "sense" tissue characteristics, the ES device demonstrated lateral thermal spread similar to the other bipolar devices. Smoke production and burst pressure were also similar and time to seal was statistically longer. In contrast to this study and other previously reported studies, Person et al. found the ES device to have the overall best performance including fastest sealing time, highest burst pressure and thermal spread.¹⁰ In this study however, the thermal spread was determined using histologic changes that may be less sensitive for thermal spread, there was a wide variation in size of vessels tested, and the study was funded by the maker of the ES device.

All devices tested resulted in temperatures 2 mm away from tissue that were greater than 40 degrees C and hence should be used with caution next to vital structures like the neurovascular bundle. The GP markets a Vapor Pulse Coagulation, pulse-off periods, theoretically to allow for cooling to occur at the tissue site and decrease the thermal spread. This feature did not decrease the amount of the thermal spread in our study and in fact GP had higher temperatures than the other tested devices but was only statistically greater when compared to the HS. In a study evaluating the thermal spread produced by the GP, the PlasmaKinetic instrument had damage ranging from 2.7–4.7 mm from the cut surface with a mean of 3.6 mm.¹⁵ This is consistent with the high temperatures observed in our study at 2 mm.

In the majority of studies comparing electrosurgical devices an open surgical technique was employed.^{2, 8–11, 18–21} This limits the degree to which temperature and humidity can be controlled and may change the degree of smoke production compared with the humid closed space of the laparoscopic environment. The current study is the first to use both objective and subjective data to measure smoke production in a laparoscopic environment controlling for humidity and temperature. The closed space of the abdominal cavity combined with the increased humidity tends to exacerbate the effect of particulates and vapor in the air, increasing condensation and deteriorating the video image.³ Surgical smoke has long been a concern to the surgeon. Laser aerosolized HPV virus has been associated with virus transmission and breathing cautery smoke may pose risks similar to breathing second hand cigarette smoke.²² Surgical smoke is potentially detrimental to both the laparoscopic surgeon and patient by limiting visualization, lengthening procedure time, adding time for cleaning the camera lens and by potentially aerosolizing harmful viruses.²² Clearly in this study the GP instrument had the largest subjective and objective degradation of video image, while the HS had the least. There was no significant difference observed between the LS, HS, and ES devices.

Potential limitations with this model include vessels without blood and an ex vivo experimental model. This, however, allowed for identical comparisons between each device that could not have been controlled for with an in vivo model. This ex vivo model did allow temperature to be controlled at 37 degrees Celsius and humidity at 98 percent to fully simulate the laparoscopic environment. It is unknown whether blood inside vessels would alter smoke production, however, a recent paper by Phillips and colleagues demonstrated that intraluminal contents may significantly effect burst pressures.¹⁶

Conclusion

The LS had the best overall performance with the highest burst pressure, fast sealing time, low thermal spread, and low smoke production. The HS had the lowest thermal spread and smoke production, but was slow and had the lowest mean burst pressure. The GP had a fast sealing time, but the highest smoke production, variable and sometimes extremely low burst pressure. The ES had the slowest sealing time and variable burst pressures.

Disclosure Statement

No competing interests exist.

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Abbreviations and Acronyms:

LS = LigaSure V

GP = Gyrus PK

HS = Harmonic Scalpel ACE

ES = EnSeal PTC