

Validation of a Laparoscopic Ferromagnetic Technology-based Vessel Sealing Device and Comparative Study to Ultrasonic and Bipolar Laparoscopic Devices

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Introduction: Ferromagnetic heating is a new electrosurgery energy modality that has proven effective in hemostatic tissue dissection as well as sealing and dividing blood vessels and vascularized tissue. The purpose of this study was to evaluate a ferromagnetic-based laparoscopic vessel sealing device with respect to sealing and dividing vessels and vascularized tissue and to compare performance against current vessel sealing technologies.

Materials and Methods: A laparoscopic vessel sealing device, Laparoscopic FMsealer (LFM), was studied for efficacy in sealing and dividing blood vessels and comparative studies against predicate ultrasonic, Harmonic Ace + (US), and/or bipolar, LigaSure 5 mm Blunt Tip and/or Maryland (BP), devices in vivo using a swine model and in vitro for comparison of seal burst pressure and reliability. Mann-Whitney and Student *t* test were used for statistical comparisons.

Results: In division of 10 cm swine small bowel mesentery in vivo, the laparoscopic FMsealer [12.4 ± 1.8 sec (mean \pm SD)], was faster compared with US (26.8 ± 2.5 s) and BP (30.0 ± 2.7 s), $P < 0.05$ LFM versus US and BP. Blinded histologic evaluation of 5 mm vessel seals in vivo showed seal lateral thermal spread to be superior in LFM (1678 ± 433 μ m) and BP (1796 ± 337 μ m) versus US (2032 ± 387 μ m), $P < 0.001$. In vitro, seal burst strength and success of sealing 2 to 4 mm arteries were as follows (mean \pm SD mm Hg, % success burst strength > 240 mm Hg): LFM (1079 ± 494 mm Hg, 98.1% success) versus BP (1012 ± 463 , 99.0%), $P = NS$. For 5 to 7 mm arteries: LFM (1098 ± 502 mm Hg, 95.3% success) versus BP (715 ± 440 , 91.8%), $P < 0.001$ in burst strength and $P = NS$ in % success. Five 60 kg female swine underwent 21-day survival studies following ligation of vessels ranging from 1 to 7 mm in diameter ($n = 186$ total vessels). Primary seal was successful in 97%, 99% including salvage seals. There was no evidence of postoperative bleeding at sealed vessels at 21-day necropsy.

Conclusion: The Laparoscopic FMsealer is an effective tool for sealing and dividing blood vessels and vascularized tissue and compares favorably to current technologies in clinically relevant end points.

Key Words: ferromagnetic technology, vessel sealing device, vessel ligation, laparoscopic vessel sealing technologies

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The complexity of procedures performed laparoscopically has necessitated the development of more efficient and effective technologies to divide tissue and control bleeding.¹ The advent of energy-based vessel sealing technologies has expanded the arsenal of potential techniques available for hemostasis during laparoscopic surgery. In turn, this has tremendously expanded our ability to perform complex surgeries laparoscopically.

The 2 most common energy modalities employed today for sealing and dividing vascularized tissue are based on bipolar (BP) and ultrasonic (US) technology.²

Each method possesses their own pros and cons inherent to the nature of their respective mechanisms. However, no single device has been shown to be superior to the other with regard to the most common metrics of performance.^{2,3} As a result, usage of one device over the other is largely based on surgeon preference.

The FMwand (Domain Surgical, Salt Lake City, UT) is a commercially available hemostatic dissecting scalpel which uses ferromagnetic heating as its source of energy.⁴ To generate ferromagnetic heating, radiofrequency current is delivered from a generator through a conductive alloy loop and back.⁴ This loop is coated with a thin, several micron thick ferromagnetic coating material which couples to the high frequency alternating current.⁴ As the radiofrequency current passes through the loop and ferromagnetic coating, pure thermal heat is generated by magnetic hysteresis losses and Ohmic heating related to the skin effect.⁴ This technology allows for precise temperature control with rapid heating and cooling.⁴ The heat generated is restricted to the coating itself and the tissue in contact with the coating.^{5,6} No electrical energy or magnetic effects are delivered to the surrounding tissue and thus, the device remains electrically silent with regard to muscle contraction, nerve stimulation and interference with electrically sensitive equipment such as pacemakers or automatic internal defibrillators.⁷

The FMsealer was constructed by placing a ferromagnetic heating element in the jaw of a surgical vessel sealing device (Fig. 1). Tissue compression occurs between

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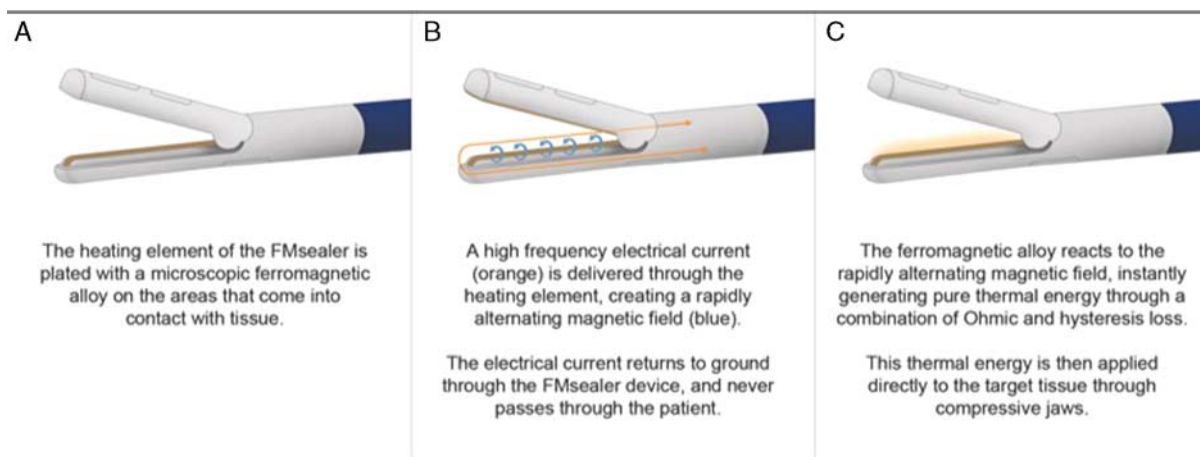


FIGURE 1. Generation of ferromagnetic heating through a novel surgical energy source.

the actively heated jaw and an opposing thermally inert surface. Heat conducts perpendicularly through the compressed tissue for sealing and dividing purposes. The versatility of a ferromagnetic energy source allows for a device that overcomes the geometrical limitations of US energy and circumvents the need for additional cutting mechanisms as seen in BP devices.

Following the development of the FMsealer, a series of experiments were conducted to compare the efficacy of ferromagnetic heating, sealing, and dividing of arteries and veins *in vitro* and *in vivo* with regard to size of vessel, speed of effect, strength of seal/burst pressure of seal, and durability in comparison with existing, commercially available US and BP devices. Compared with the US and BP vessel sealing devices, the FMsealer sealed arteries and veins *in vitro* ranging between 1 and 7 mm vessel diameter (as measured in a noncompressed naturally pressurized state) with burst pressures consistent with BP sealers and equivalent reliability of vessel seals.⁴ The FMsealer compared favorably to the other technologies in speed and efficiency as well as tissue effects including thermal spread and injury.⁴ In addition, *in vivo* survival studies confirmed the reliability of the FMsealer on arteries and veins ranging from 1 to 7 mm as well as sealing abdominal lymphatics.⁴ The FMsealer operated at cooler temperatures and had less adjacent heat transfer to surrounding tissues based in part on active cooling of the instrument.⁴

These favorable outcomes catalyzed further investigation with regards to the utility of such a device in laparoscopic surgery. The objective of this study was to evaluate common metrics of performance of a laparoscopic FMsealer as compared with the 2 most common energy modalities used today, BP and US.

MATERIALS AND METHODS

The laparoscopic FMsealer prototype was developed using a U-shaped, 15 mm long by 2.5 mm wide, heating element deployed in 1 jaw of the prototype vessel-sealing tool. The opposing jaw contains an insulated compression surface. Tissue is compressed between opposing sides and when activated, heat is transferred to the tissue from the heating element. The device was modeled in size and length after existing US and BP devices for purposes of comparative studies. This device was used throughout the

following experiments. The Harmonic Ace + as representative of US energy and LigaSure 5 mm Blunt Tip as representative of BP energy were used for purposes of comparison with other energy modalities.

Two models were developed to facilitate test experiments: *in vivo* and *in vitro*. The swine *in vivo* model was subdivided into acute, nonsurvival and chronic, survival experiments. These experiments allowed for the following end points to be evaluated: (1) Proof of the concept that ferromagnetic heating can be used for laparoscopic vessel sealing and dividing *in vivo*, (2) Comparison of clinical effectiveness to US and/or BP devices for speed of 10 cm mesentery division and histology of vessel seals to analyze the extent of adjacent tissue thermal injury, and (3) 21-day survival following surgery using the laparoscopic FMsealer ($n = 5$). The porcine *in vitro* carotid artery model was developed to compare seal burst pressure among the vessel-sealing modalities on a common platform. All *in vivo* experiments were performed by an experienced attending gastrointestinal surgeon under the direct supervision by FDA-approved personnel using good laboratory practice procedures to verify accuracy of data collection and interpretation. *In vitro* experiments were performed under the direction of the attending surgeon and PhD investigators.

In Vivo Models

Acute Nonsurvival In Vivo Animal Model

The acute nonsurvival *in vivo* studies to access proof of concept and comparison of clinical effectiveness utilized a 45-kg female swine model. Under approval from the University of Utah Institutional Animal Care and Use Committee, animals were anesthetized per protocol. The laparoscopic FMsealer was used to seal and divide *in vivo*, gastric, splenic, renal, uterine and mesenteric arteries, veins, and associated lymphatics ranging from 1 to 7 mm in diameter. Four distinct vessels were ligated and divided for each vessel size ranging from 1 to 7 mm in 1 mm increments to establish proof of concept that the ferromagnetic device could seal blood vessels.

Representative specimens of sealed arteries sealed *in vivo* were submitted for histologic evaluation. The sealed portions of the vessels were harvested, fixed in formalin, sectioned longitudinally, Hematoxylin and eosin stained, and mounted to slides for digital imaging and analysis of

thermal damage. An independent pathologist, blinded to the specific device used to seal a respective vessel, made measurements of thermal damage. Extent of adjacent vessel thermal damage was assessed by measuring the midpoint of the vessel seal down the length of sealed vessel to the end point of histologically apparent thermal damage. The end point of thermal damage was defined as when intact fibroblast cell membranes are encountered and the most distal thermally damaged cellular structures cease. In every case, the greatest amount of thermal damage is recorded to represent total thermal spread.

Laparoscopic division of small intestine mesentery was used to compare device speed and efficacy. A metric ruler was used to measure a 10 cm length of intestine mesentery equidistant from the root of the mesentery to bowel wall. Ferromagnetic, US, and BP devices were compared in speed of division of the 10 cm length of small bowel mesentery and efficacy (completeness of vessel sealing, need for rescue sealing to salvage bleeding vessels not sealed in the primary pass). Seven separate measurements were made for the FMsealer, US (at a setting 5), and BP (3 bars) devices. Time for dissection was measured from recorded video. The animals were then euthanized per protocol.

Survival In Vivo Animal Studies

Five 60-kg domestic swine were utilized in a 21-day survival study to evaluate efficacy and durability of the FMsealer in sealing and dividing 1 to 7 mm arteries and veins. Surgery was performed under sterile conditions and under the direction of the veterinary staff of the Office of Comparative Medicine at the University of Utah by the University of Utah Institutional Animal Care and Use Committee approved protocol using FDA-approved good laboratory practice procedures. All swine were anesthetized under general anesthesia. Veterinary staff regularly monitored vitals. Each animal underwent splenectomy, left nephrectomy, bilateral partial hysterectomy, and selective mesenteric vessel ligation to locate, seal and divide arteries and veins measuring 1 to 7 mm in relaxed (nonvasospasm) outer diameter along with associated lymphatics. All vessels were measured using a surgical ruler in their undisturbed state in vivo before manipulation. All sealed vessels were marked with numbered sterile mouse ear tags as fiducial markers for localization at necropsy. Vessels >7 mm (splenic and renal veins) were suture ligated as these vessels exceeded the diameter of vessel size believed to be clinically relevant for use of the sealing device. The animals were survived for >21 days under direction of the husbandry and veterinary staff of the Office of Comparative Medicine at the University of Utah. They then underwent necropsy to assess for surgical bleeding, morbidity, and mortality.

At necropsy, before euthanasia, 10 mm thick by 15 mm width vascularized tissue bundles consisting of proximal hind and fore limb muscle bundles were isolated, ligated, and divided to evaluate the performance of the laparoscopic FMsealer in dividing vascularized tissue (n = 64 sealed tissue bundles in a total of 5 animals).

In Vitro Model

A computerized test apparatus that automates burst strength testing and reporting after sealing of vessels was developed. This allowed a large number of arteries to be evaluated in identical circumstances by the different technologies. Bench tests were performed on fresh (< 48 h old and refrigerated to 38°F) 2 to 7 mm commercially harvested

swine arteries. The outer diameter of each vessel was measured with a caliper after manipulating the vessel to its native tubular shape rather than measuring the diameter of the vessel in its flattened shape so as to more accurately measure the true diameter of the vessel. Each vessel to be sealed was sectioned at 1½" length. One end of the artery was fitted over a 16 Ga stub adaptor and clamped to create a seal for pressure testing. The distal end of the vessel was then sealed using the recommended settings for each instrument as follows: LigaSure 5 mm Blunt Tip (3 bars); FMsealer (min setting 3). Upon sealing, each vessel segment was submerged in a saline bath while connected by Luer-lock connector to an automated syringe pump which, under computer control, allowed gradual injection of air to the point of burst of the seal while simultaneously monitoring pressure with an in line strain gauge pressure sensor. Data acquisition and plotting were performed using a multichannel A/D converter (NI USB-6009, National Instruments, Austin, TX), plotting time versus pressure at 0.1-second intervals. The data acquisition module and gauge had been previously calibrated to NIST-traceable standards. The peak burst pressure was automatically derived. BP energy will seal vessels 4 to 7 mm to a higher burst pressure and with more success as compared with US energy.^{8,9} As the burst strength and reliability performance of the laparoscopic FMsealer most closely resembled that of the BP device, the US device was omitted from comparison in the burst pressure and reliability studies.

Comparisons between devices were made using the mean value of burst pressure based upon the following criteria: fail (seal burst < 120 mm Hg), marginal (120-240 mm Hg), and pass (> 240 mm Hg). Multiple measurements were taken (N > 100) for each device.

Statistics

Student *t* test was used for statistical comparisons for data with a Gaussian distribution (burst strength testing, speed of mesenteric division, and thermal spread). Mann-Whitney was used for statistical comparisons of non-parametric data (burst strength reliability, objective tissue effects).

RESULTS

Proof of Concept

The laparoscopic ferromagnetic device (FMsealer) was able to seal and divide arteries (mesenteric, gastric, renal, splenic, femoral, and carotid) ranging from 1 to 7 mm in diameter in a live swine model. These data are not shown as each vessel size in this range were successfully sealed and divided in vivo up to 7 mm arteries and veins. The FMsealer was clinically effective across the entire range of artery and vein diameters.

Tissue Thermal Effects

A comparison of thermal heating peak temperature of the laparoscopic FMsealer compared with the BP and US devices is shown in Figure 2. During a single continuous activation to seal and divide a 5-mm carotid artery, the peak external temperature of the FMsealer (92°C) and BP device (83°C) were significantly lower than that of the US device (235°C). In histologic measurements of extent of thermal injury to adjacent tissue, the FMsealer showed less thermal damage to adjacent vessel wall compared with US

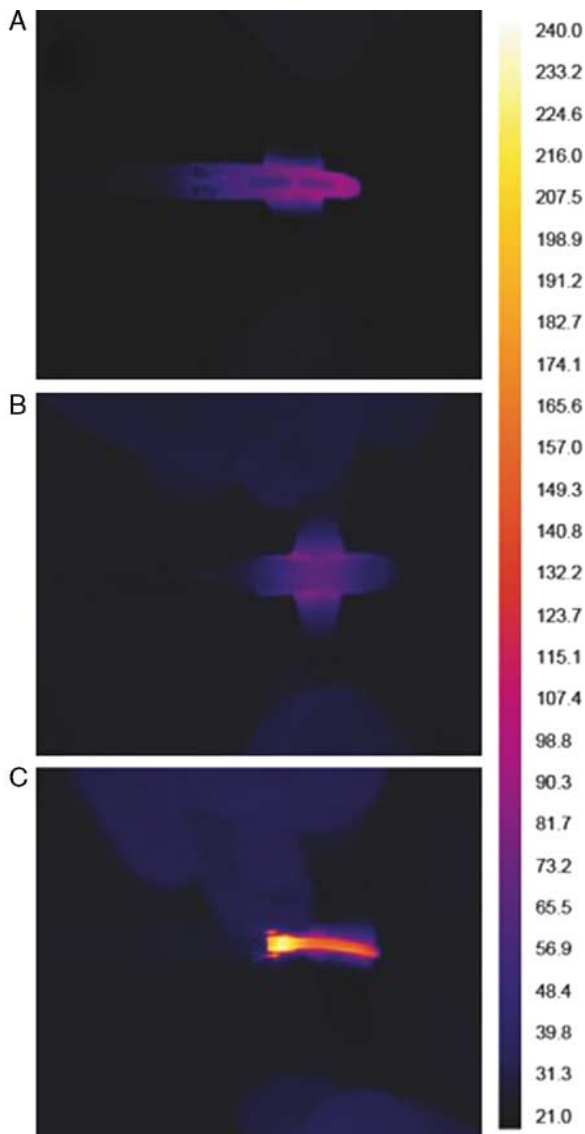


FIGURE 2. Thermal heating profile of the laparoscopic FMsealer compared with the bipolar and ultrasonic devices using infrared heat camera. Ferromagnetic sealer (A), Bipolar sealer (B), Ultrasonic sealer (C).

TABLE 1. Histologic Measurement of Lateral Thermal Spread of Sealed Vessels

	Laparoscopic Ferromagnetic FMsealer	Laparoscopic Ultrasonic (Harmonic Ace +)*	Laparoscopic Bipolar (LigaSure 5 mm Blunt Tip)†
Mean (µm)‡	1678	2032	1796
SD (µm)	433	387	337
Sealed vessels (n)	33	42	63
P-value FM vs. other		0.0004	0.14

*Power setting 5 was used for the Harmonic Ace + .
 †Power setting 3 was used for the LigaSure 5 mm Blunt Tip.
 ‡Values were determined by averaging the maximum amount of thermal damage on each vessel seal.
 FM indicates ferromagnetic.

energy and equivalent to BP. This is shown in Figure 3 and Table 1.

Speed of Mesentery Division

The FMsealer was superior to US and BP energy sources in speed of 10cm mesentery division (mean ± SD s): FMsealer (12.43 ± 1.8 s), US (20.50 ± 2.46 s), BP (30.01 ± 2.65 s) ($P \leq 0.01$, FM vs. US or BP). Data shown are speed of mesenteric division to achieve complete hemostasis of divided mesenteric vessels. This is summarized in Table 2.

Sealed Vessel Burst Pressure and Reliability

Data showing burst pressure and efficacy of sealing arteries 2 to 4 mm and 5 to 7 mm in diameter using the laparoscopic FMsealer versus BP device are shown in Table 3, respectively. Data from the sealing of swine carotid arteries were as follows: (mean ± SD mm Hg, % success sealing burst strength > 240 mm Hg). The laparoscopic FMsealer sealed vessels 5 to 7 mm to a higher burst pressure and with more success: Laparoscopic FMsealer (1098 ± 502 mm Hg, 95.3% success) versus BP (715 ± 440, 91.8%). For swine carotid arteries measuring 2 to 4 mm the laparoscopic FMsealer sealed to equivalent burst pressure and equivalent success: Laparoscopic FMsealer (1079 ± 494 mm Hg, 98.1% success) versus BP (1012 ± 463, 99.0%).

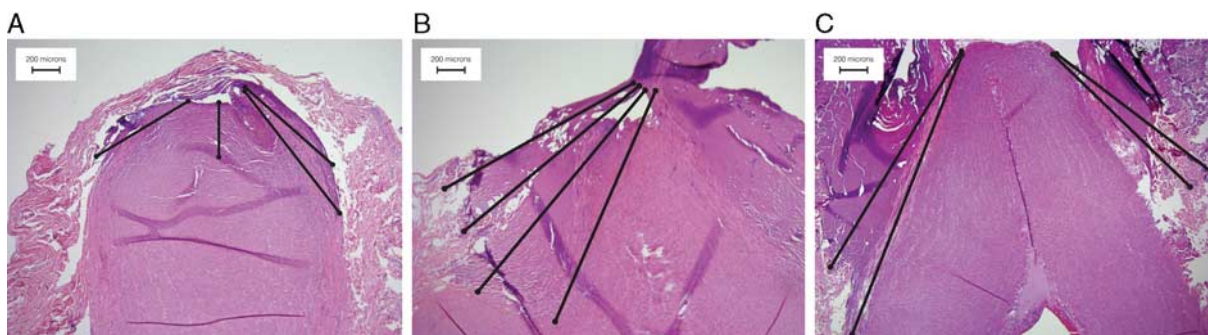


FIGURE 3. Representative 5-mm swine carotid arteries sealed in vitro. Ferromagnetic sealer (A), Bipolar sealer (B), Ultrasonic sealer (C).

TABLE 2. Comparison of Speed and Efficacy of Sealing and Division of a 10 cm Section of Small Bowel Mesentery In Vivo

	Laparoscopic Ferromagnetic FMsealer	Laparoscopic Ultrasonic (Harmonic Ace +)†	Laparoscopic Bipolar (LigaSure 5 mm Blunt Tip)‡
Mean (s)	12.43	20.50*	30.01*
SD (s)	1.80	2.46	2.65
Max (s)	15.03	24.54	33.44
Min (s)	10.97	17.32	25.65
Success/ number§	7/7	7/7	7/7

†Power setting 5 was used for the Harmonic Ace +.

‡Power setting 3 was used for the LigaSure 5 mm Blunt Tip.

§Success as defined by complete mesentery division without bleeding.

* $P < 0.01$ Ferromagnetic versus ultrasonic or bipolar, and ultrasonic versus bipolar.

Survival Studies

One hundred eighty-six vessels ranging in size from 1 to 7 mm (Table 4) were sealed in total among the 5 swine in the > 21-day survival study. Vessel types sealed were typical of splenectomy, left nephrectomy, bilateral hysterectomy, and selective ligation of mesenteric arteries, veins, and lymphatics. Initial sealing failed in 6 arteries ranging from 4 to 7 mm yielding a 96.8% primary seal rate. Five of the 6 vessel seal failures were successfully resealed with a single application of the FMsealer yielding a 99.5% overall successful seal rate. One vessel required suture ligation for failure of rescue seal and inadequate remaining vessel length to attempt additional rescue seals.

TABLE 3. In Vitro Comparison of Burst Pressure and Efficacy of Sealing Arteries of Varying Size (Laparoscopic FMsealer vs. Laparoscopic Bipolar)

	Ferromagnetic	Bipolar
Burst pressure and efficacy of 2 to 4 mm in vitro sealed swine arteries		
Average	1079	1012
SD	494	463
Max	2252	1938
Min	41	135
N	107	101
Passing (> 240 mm Hg)	105 (98.1%)	100 (99.0%)
Marginal (120-240 mm Hg)	1 (0.9%)	1 (1.0%)
Fail (< 120 mm Hg)	1 (0.9%)	1 (0.0%)
Burst pressure and efficacy of 5-7 mm in vitro sealed swine arteries		
Average	1098	715
SD	502	440
Max	2218	1837
Min	93	45
n	107	110
Passing (> 240 mm Hg)	102 (95.3%)	101 (91.8%)
Marginal (120-240 mm Hg)	4 (3.7%)	8 (7.3%)
Fail (< 120 mm Hg)	1 (0.9%)	1 (0.9%)

As the burst strength and reliability performance of the FMsealer most closely resembled that of the bipolar device, data showing comparison of burst pressure and reliability by different vessel size were done for the FMsealer and bipolar only, omitting the ultrasonic device from this comparison.

 $P = 0.33$ ferromagnetic versus bipolar. $P = NS$ ferromagnetic versus bipolar. $P < 0.001$ ferromagnetic versus bipolar. $P = NS$ ferromagnetic versus bipolar.**TABLE 4.** Distribution of Arteries and Veins Sealed During In Vivo Survival Study

Vessel Diameter (mm)	Arteries	Veins
1	33	21
2	31	33
3	13	14
4	11	8
5	3	4
6	4	5
7	4	2
Total	99	87

Sealed and divided vessels during 21-day survival study on 5 swine. Each animal underwent splenectomy, left nephrectomy, bilateral hysterectomy, and selective mesenteric vein and artery ligation.

All 5 animals survived to postoperative day 21 without any observed morbidity or mortality. 186 of 186 numbered mouse ear tag fiducial markers were located. No animals showed signs of early or delayed intraperitoneal hemorrhage (no hematoma, hematin staining of adjacent tissues) from any sealed vessel site. All sealed vessels were secure. No lymphoceles or ascites were appreciated indicating successful ligation of lymphatics in association with sealed arteries and veins.

The FMsealer was successful in ligating and dividing the vascularized fore and hind limb 1 cm thick muscle bundles in all cases without bleeding ($n = 64$ sealed tissue bundles in a total of 5 animals).

DISCUSSION

Advances in electrosurgical technology have driven the complexity of procedures that can now routinely be accomplished laparoscopically. This increasing complexity, in turn, drives the need for further technological advances. This is most notably seen in advanced laparoscopic procedures where obligate electrosurgical instruments are needed to achieve reliable and rapid hemostasis while dissecting, sealing, and dividing vascularized tissue, and simultaneously minimizing collateral damage to surrounding tissues.^{2,10}

Current technologies, US and BP, still possess non-trivial shortcomings including limitations in geometry, shape, efficiency of dissection, adjacent tissue damage, and ergonomics. Despite numerous studies comparing these devices, there is no clear evidence to support the use of either in preference over the other.^{2,11} This is because to date, no single device has been shown to be superior to another in all categories of performance.^{2,3,11}

The use of ferromagnetic heating to dissect and coagulate tissue is a new energy modality born out of this cycle. Application of ferromagnetic technology as a dissecting tool, the FMwand, has resulted in a surgical device that delivers a near instantaneous "on" effect with rapid cooling, minimal collateral damage, and excellent first pass hemostasis.^{5,6} Furthermore, the FMwand has been shown to be superior with respect to tissue distortion, ease and speed when compared with monopolar electrosurgical devices.¹²

Inspired by this new technology, a prototype of a vessel-sealing tool was developed, the FMsealer.⁴ Proof of concept and comparative studies have demonstrated superiority of the FMsealer as compared with US and BP devices in an initial device suitable for open surgical

applications.⁴ On the basis of this favorable outcome, a series of experiments were designed to investigate the FMsealer in the laparoscopic setting. In vivo and in vitro models were used to study proof of concept and comparative performance parameters of the laparoscopic FMsealer compared with predicate US and BP devices.

The laparoscopic FMsealer proved effective using live in vivo swine models, in which abdominal, femoral, and carotid arteries ranging from 1 to 7 mm in diameter were successfully sealed and divided. The laparoscopic FMsealer compared favorably to the other technologies in speed and efficiency as well as tissue effects including thermal spread and injury. Compared with the US and BP vessel-sealing devices, the laparoscopic FMsealer sealed vessels with clinically reliable burst pressures consistent with the other technologies presently available. In addition, survival studies confirmed the reliability seen in the in vitro bench-top vessel-sealing burst pressure and reliability model both in the initial use of the laparoscopic FMsealer on vessels ranging from 1 to 7 mm in diameter and durability of the seal in the survival in vivo studies with no evidence of intraperitoneal bleeding at 21-day necropsy in a total of 186 separate arteries and veins.

In addition to measurable benefits in tissue sealing and dividing performance in this animal model, ferromagnetic technology offers additional theoretical advantages. First, there are few constraints as to size, length, and geometry of the technology as is the case with US technologies. The open and laparoscopic FMsealer can be configured to specific uses including longer, larger jawed instruments for open abdominal applications, shorter and narrower designs for fine tissue dissection such as head and neck surgery, and curved platforms for use in laparoscopic and pelvic surgery, including urologic, gynecologic, and rectal operations. In this regard, the FMsealer resembles the existing BP platforms. Second, the FMsealer has the ergonomic advantage of allowing for separate sealing and division and omits the addition of a separate cutting mechanism needed in existing BP platforms. Third, there is no electrical energy conducted to the patient so the device remains electrically silent with regard to muscle contraction or nerve stimulation and interference with electrical monitoring or electrically sensitive equipment like pacemakers or automatic internal defibrillators.⁷ Finally, as the FMsealer does not pass electrical current through the tissue, it can be expected to work across staple lines or in the vicinity of other metallic objects such as clips, similar to that of US technologies but unlike BP technologies.

As the data presented here represent the proof of concept work and initial validation of efficacy in vivo and in vitro using a porcine model, the utility of this energy platform in the clinical setting in humans remains to be determined.

CONCLUSIONS

Ferromagnetic technology through a novel ferromagnetic alloy-coated heating element is a highly effective and efficient technology for thermal sealing and dividing blood vessels and vascularized tissue. An initial prototype of a laparoscopic sealing instrument utilizing ferromagnetic heating compared favorably to commercially available products based on US and BP technologies. Development of ferromagnetic vessel-sealing technology for this application shows great promise with possible distinct clinical advantages over existing technologies, particularly in the laparoscopic setting.

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