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ORIGINAL ARTICLE

Prospective analysis of the sealing ability of the ENSEAL® G2 Articulating Tissue Sealer and transector on human mesenteric vessels in colorectal surgery

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Abstract
Background The sealing and transection of mesenteric vessels is a crucial step in minimally invasive colorectal surgery. We examined the sealing quality of the ENSEAL® G2 Articulating Tissue Sealer in three different articulations in mesenteric vessels.
Methods This was a prospective experimental study within a tertiary healthcare center, and 30 patients were recruited. Burst pressures for each specimen were measured as the primary outcome. Ten specimens at each of the three articulations were also histologically assessed for the quality of seal.
Results We evaluated 54 sets of specimens from 30 patients for bursting pressure, all of which were harvested and sealed in the operating room. No statistical difference was seen in burst pressures from seals recorded at no angulation, half-maximal angulation, or maximal angulation (1604, 1507, 1478 mmHg; $p = 0.07$). Histological analysis showed no statistical differences in the average vessel diameter ($p = 0.57$), lateral extent of thermal injury ($p = 0.48$), degree of vascular sclerosis, or the integrity of seal at the three articulations. No cases of intraoperative or postoperative bleeding were observed in any of the patients. Five (16.7%) of the ENSEAL® devices developed breaks in the black, heat-shrink, polyethylene covering as a result of repeated articulation and disarticulation. Electrical arcing did not appear to have occurred as a result of the break, although this was not formally examined.
Conclusions The maximum sustainable pressure in mesenteric vessels sealed with a bipolar electrothermal device is supraphysiological, and consequently, the device can be safely used at various articulations to seal vessels during colorectal surgery.

Keywords Colorectal surgery · Mesenteric vessels · ENSEAL® G2 · Laparoscopic surgery

Introduction

The increased adoption of electrothermal bipolar vessel sealing (EBVS) devices has largely facilitated the continued application of surgical techniques over the last two decades [1]. An array of these EBVS devices has been shown to be safe and perform more favorably than traditional clips and staplers [2]. Furthermore, the EBVS devices are often associated with lower costs, fewer bleeding complications, and reduced operative times than previous techniques [3–5].

The ENSEAL® tissue sealing and hemostasis system, produced by Ethicon Endo-Surgery, LLC®, is one such device and invokes millions of particles, nanometer in size, within a bipolar temperature coefficient matrix [6, 7]. Utilizing high and equal tissue compression, it creates a seal through current flow, while the blade is advanced [6, 7]. Current flow ends when temperatures exceed

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100 °C, allowing for the sealing and ligation to occur in one step [6, 7]. Animal studies comparing ENSEAL® to other bipolar devices have revealed stronger bursting pressures, decreased sealing time, and a comparable degree of lateral thermal damage when using ENSEAL® [8–10]. Furthermore, a study previously conducted at our center with human mesenteric vessels sealed with ENSEAL® revealed bursting pressures significantly higher than physiological pressures, suggesting it is safe to use ENSEAL® during colorectal procedures [1].

Recently, the Food and Drug Administration (FDA) approved a newer version of the device, the ENSEAL® G2 Articulating Tissue Sealer, which is the first articulating tissue sealer compatible within a 5-mm port [11]. This device provides a new approach to sealing tissue with its bottom-jaw technology, which is designed to deliver energy to tissue while the jaws are still open, allowing for enhanced dissection, spot coagulation, and ostomy creation [11]. Articulation also provides improved access, facilitating correct sealing [11].

Our study aimed to examine the mesenteric vessel sealing quality of this new device in three articulating positions and determine whether it is safe to use in colorectal surgery.

Materials and methods

Consecutive patients having colonic resection at a tertiary centre, with sealing of the inferior mesenteric artery (IMA) using the ENSEAL® G2 Articulating Tissue Sealer, were recruited for the study. Patients were prospectively enrolled into the study on the morning of their surgery. The study ran between June and August 2015. Informed consent was obtained from all participating patients, and protocols were followed according to ethical guidelines as outlined through institutional review board (IRB) (5828) approval.

Surgical procedures

Three colorectal surgeons performed the operations. Inferior mesenteric vessels were dissected in a medial to lateral manner, using a monopolar energy device. Once the IMA had been identified and carefully detached from surrounding structures, the bipolar ENSEAL® G2 Articulating Tissue Sealer was used to seal and transect it at its origin from the aorta. The same technique was employed for the ileocolic artery in right-sided procedures.

Experimental procedure

After the specimen had been removed from the patient, care was taken to dissect the mesenteric vessels to maintain integrity of the vessels. Once the ENSEAL® G2 Articulating Tissue Sealer was no longer in use by the operating surgeons for the procedure at hand, the same device, which had been used to seal the blood vessels within that patient, was used on the harvested vessel. The vessel was then sealed with the device perpendicular to the vessel (0° with no angulation), at half-maximal angulation (30° of angulation/150° to the vessel), and at maximal angulation (60° of angulation/120° to the vessel). An equal number of seals were performed at each articulating position, given the length of the vessel harvested. The sealed vessels were then transferred to the laboratory. The internal diameter was recorded for each sealed vessel at the open end. The open end was then attached by suture to the burst pressure testing device (Fig. 1). The device was used to pump 0.9% saline solution at a constant rate into the vessel. The pressure was monitored until the seal began leaking or completely burst and the highest sustained pressure was recorded (Fig. 1). Initial samples were tested to optimize the burst pressure technique and were not included within the data analysis.

Thirty additional (10 at each angulation) match-paired samples (pressure-tested burst and intact sealed vessels) were sent for histological evaluation. Diameters of the formalin-fixed vessels, lateral extent of thermal damage (sealed area), and the degree of vascular sclerosis of the vessels were examined. Finally, the integrity of the seal was measured, which was characterized as complete or intermediate depending on the totality of the seal.

Statistical analysis

All results were analyzed using SPSS software version 23.0. A one-way ANOVA was employed to compare the burst pressures, mean diameters, and lateral extent of thermal injury. Fisher's exact test was employed for comparing the degree of vascular sclerosis among the three

Fig. 1 Burst pressure apparatus—a setup of the device used to measure the burst pressure of the seals. Vessels were sealed, sutured to the device and then filled with a constant infusion of saline

articulations. Pearson's correlation was used to assess the relationship between diameter and burst pressure. A p value of 0.05 was established as clinical significance for all statistical analyses.

Results

Since operative procedures were tailored for the specific indication of the patient, some of these procedures allowed for the harvesting of multiple sets of specimens for testing. In total, 54 sets of specimens (three samples in each set) were obtained from 30 patients for evaluation by bursting pressure across the three chosen articulations (0°, 30°, and 60°). While only 30 sets of specimens were needed, we felt the additional samples added to the accuracy of our results and so they were included. Table 1 highlights the outcomes and the demographics of the patients consented for this study. Overall, the burst pressures ranged from 840 to 2390 mmHg. The mean bursting pressures at no angulation (0°), half-maximal angulation (30°), and maximal angulation (60°) were 1604, 1507, and 1478 mmHg, respectively (Table 2). A one-way analysis of variance tests revealed the differences in these mean bursting pressures not to be statistically significant ($p = 0.07$). The time it took for the seal to break was not recorded; however, vessel testing was carried out until the seal began to leak or the seal completely burst, both of which were succeeded by rapidly falling pressures. The Pearson correlation revealed a minor, but statistically significant relationship between the diameter of the vessels and the burst pressures at each of the angulations (no angulation—$r = 0.29$, $p = 0.03$; half-maximal angulation—$r = 0.29$, $p = 0.04$; maximal angulation—$r = 0.29$, $p = 0.03$; Table 3).

An additional 10 sets of specimens (three in each set) were sent for histological analysis to examine the effect of the electrocautery on the vessel itself. Factors including the vessel diameter, extent of thermal injury, degree of vascular sclerosis and integrity of seal as determined by the pathologist were examined. The maximum diameter was recorded from the open end of the vessel after the samples had been stored in formalin for a period of time. The average diameter of the samples showed no difference across the three angulations ($p = 0.57$) and was 1.82 (no angulation), 2.05 (half-maximal angulation), and 2.22 mm (maximal angulation) (Table 4). The lateral extent of thermal injury also did not vary significantly between the three articulations ($p = 0.48$). The degree of vascular sclerosis of the vessels was also assessed, according to the following criteria: 0—normal or no sclerosis; 1—mild (intimal thickening and sclerosis with <25% vascular luminal narrowing); 2—moderate (intimal thickening and sclerosis with 25–50% vascular luminal narrowing); 3—severe (intimal thickening and sclerosis with >50% vascular luminal narrowing). No differences were seen in the level of vascular sclerosis among the three groups of articulation as 77.8, 77.8, and 60.0% of vessels, respectively, had some degree of sclerosis. Finally, the integrity of the seals was assessed as either complete or incomplete and it was determined that all seals that could be analyzed across the three groups were complete (Table 4). Only 60% of the samples could be assessed for lateral extent of thermal injury and integrity of the seal. The remaining histological sections of sealed vessels were non-informative, due to technical issues related to difficulties in tissue embedding.

Through the course of the study, 5 of the 30 devices used within the procedures developed breaks within the black, heat-shrink polyethylene covering as a result of repeated articulation and disarticulation (Fig. 2). Electrical arcing did not appear to have occurred as a result of the break, but this was not examined in close detail. No cases of intraoperative or postoperative bleeding were seen as a result of using the ENSEAL G2 tissue-articulating device to seal vessels. Patients were followed up for a mean length of 9.9 months (range 8.87–13 months) during which no further complications were seen.

Discussion

Systemic evaluation of the sealing ability of EVBS devices is essential for establishing the device's efficacy and utility for the task of sealing vessels in surgical procedures. Considering the significant trend toward the use of EVBS and previous data supporting the importance, utility, and safety of the predecessor, ENSEAL® Tissue Sealer [1], we evaluated whether the newer model with the articulation feature would still maintain the same capabilities.

A previous study, looking at the surgical comfort level in using the device, the angling feature, and perceived workload in utilizing this feature, revealed that it enabled better angles of transection in tight areas and corners for mobilizing flexures, thereby reinforcing the utility of articulating energy devices for laparoscopic and robotic procedures [12]. Our study, however, is, to our knowledge, the first prospective study to reveal supraphysiological bursting pressures employing the articulating feature at three different positions (no angulation, half-maximal angulation, and maximal angulation). We also found no statistically significant difference in the sealing capabilities at the three articulations, revealing that the articulating feature can be safely employed without fear of the seal not holding firm. While a prior study did report that vessels that sealed perpendicularly using the articulation feature were 51% stronger than vessels sealed at a 45° angle, this

Table 1 Preoperative data ($n = 30$)

Characteristics	Data
Age (years), mean (SD) [range]	57.7 (±14.2) [21–80]
Gender (%)	
Male	13 (43.3)
Female	17 (56.7)
BMI(kg/m^2), mean (SD) [range]	27.3 (±5.2) [19.7–38.1]
ASA classification (%)	
I	3.6
II	67.9
III	28.5
IV	0
Preoperative diagnosis	
Benign	
Diverticular disease	14
Inflammatory bowel disease (Crohn's disease)	2
Neoplastic	
Cecal	2
Hepatic flexure	1
Sigmoid	4
Rectal	5
Anal	1
Familial adenomatous polyposis (tubular adenomas of the colon and rectum)	1
Procedures (all laparoscopic)	
Abdominal perineal resection	1
Low anterior resection	25
Hemicolectomy	3
Total proctocolectomy	1
Estimated blood loss (ml), mean (SD) [range]	264 (±709.9) [15–3500]
Length of stay (days), mean (SD) [range]	4.7 (±2.0) [2–9]
Complications	
Perioperative	2
30-Day readmission	3
Long-term	0
Mean duration of follow-up (months), mean (SD) [range]	9.90 (±1.53) [8.87–13.0]

Include sigmoid colectomies for diverticular disease and high anterior resections for sigmoid cancer

BMI body mass index, *ASA* American Society of Anesthesiologists

Table 2 Burst pressures ($n = 54$)

ENSEAL® Articulating Tissue Sealer	No angulation	Half-maximal angulation	Maximum angulation	p value
Mean burst pressure (mmHg) (range)	1604 (940–2390)	1507 (840–2320)	1478 (850–2352)	0.07

was done using the original straight sealer in comparison with the articulating one and consequently does not truly assess the quality of the articulation feature [6].

Previous studies have also shown positive correlations between vessel diameter and bursting pressure for arterial vessels [13, 14]. To determine if this would still hold true with this sealing device and to avoid the confounding variable of the angle at which the seal was made, an independent correlation between vessel diameter and bursting pressure was evaluated at each articulation. This

Table 3 Burst pressure versus diameter ($n = 54$)

ENSEAL® Articulating Tissue Sealer	Mean burst pressure (mmHg) (range)	Mean diameter (mm) (range)	Correlation coefficient	p value
No angulation	1604 (940–2390)	3.48 (1.5–7)	0.29	0.03
Half-maximal angulation	1507 (840–2320)	3.48 (1.5–6)	0.29	0.04
Maximum angulation	1478 (850–2352)	3.69 (1.5–6)	0.29	0.03

Table 4 Histological data ($n = 10$)

Characteristics	No angulation	Half-maximal angulation	Maximum angulation	p value
Mean average vessel diameter (mm)[a] (SD)	1.82 (±0.68)	2.05 (±1.10)	2.22 (±0.69)	0.57
Mean lateral extent of thermal injury (mm)[b] (SD)	0.65 (±0.28)	0.89 (±0.44)	0.64 (±0.27)	0.48
Degree of vascular sclerosis[c,d], proportion (%)	77.8%	77.8%	60.0%	–
Integrity of seal[b,e]	Complete	Complete	Complete	–

[a] Max diameter was recorded after samples had been stored in formalin

[b] Only 60% of samples were assessed as remaining histological sections of sealed end were uninformative due to technical issues (specifically related to difficulties in tissue embedding)

[c] Scores for degree of sclerosis were assigned by the pathologist according to the following criteria [0—normal or no sclerosis; 1—mild (intimal thickening and sclerosis with <25% vascular luminal narrowing); 2—moderate (intimal thickening and sclerosis with 25–50% vascular luminal narrowing); 3—severe (intimal thickening and sclerosis with >50% vascular luminal narrowing); proportion represents the % of samples that presented with any degree of sclerosis not identified as 0]

[d] Sample size was too small to compare proportions across groups

[e] Quality of seal was assessed as either complete or incomplete

Fig. 2 ENSEAL® device breaks—repeated articulation and disarticulation of the device can result in a break where part of the shaft where current flows arches out

revealed statistically significant but weak to moderate correlations at each of the three articulations. Most importantly, our study was able to successfully seal vessels up to 7 mm in diameter.

Vessel diameters as measured histologically (Table 4) were slightly less than what had been measured in samples that had been burst (Table 2), which we believe to be a consequence of formalin fixation leading to a decrease in tissue size [1]. Lateral thermal damage showed no differences with the angling feature and is comparable to what has been previously reported [1, 10, 15–17]. The tunica adventitia also exhibited the most extensive thermal injury, which extended much further than in the tunica media. Of note, larger diameter vessels also exhibited more lateral thermal injury, which is also supported by prior work [10, 15–17]. Measurement, however, was confounded by multiple factors notably suboptimal embedding, tangential sectioning, tissue fragmentation, and arbitrary identification of the edge of the seal. While only 60% of the samples could be evaluated for both the average vessel diameter and the integrity of the seal, due to technical issues involving difficulties with tissue embedding, those assessed had a complete seal, irrespective of the angle of articulation used to create the seal. As evidenced by the supraphysiological burst pressures, this reaffirms the notion that the seal is intact and strong enough to maintain physiological pressures within the human body in any angle the seal is created using the tissue-articulating device.

Five of the 30 devices used in the study developed breaks in the shaft after articulation and repeated disarticulations. To our knowledge, this is the first time breaks have been reported in electrothermal bipolar vessel sealing devices. The manufacturers of the device state that the black, heat-shrink polyethylene does not serve as an electrical insulator for the end-effector and instead is used to reduce reflection. We did not see any electrical arcing from the device. However, we believe this will have to be explored further to ensure no harm is done to the patient, if the surgeon remains unaware of a break in the shaft insulation.

Two intraoperative complications were seen in this study. One patient experienced massive blood loss (3500 ml), which

occurred when the tumor was dissected from underlying attachments and the internal iliac vein was injured as a result of this dissection. The ENSEAL® device was neither a direct or indirect cause of this. Another patient suffered a splenic injury (splenic capsular tear) due to traction of the splenic flexure of the colon, and here too, the device was not involved in the complication. Finally, three patients returned within 30 days because of abdominal pain, wound infection, or anastomotic leak; all of which, once again, were not a by-product of using the tissue-articulating device throughout the respective procedures. No cases of intraoperative or postoperative bleeding were seen as a consequence of the device failing to seal the blood vessels. With a mean follow-up of 9.9 months, no late complications were observed in any of the patients.

Limitations of this study include its non-randomized nature; the small sample size of patients enrolled; a lack of a head-to-head comparison with other EBVS devices (including its predecessor, the ENSEAL® G2 Straight Tissue Sealer); and the use of 0.9% saline solution (as opposed to blood) to determine bursting pressures. Furthermore, only arteries, not veins, were considered for this study; burst pressures were checked only at one time point (immediately after the seal); and the length of time the pressure could be sustained was not examined here.

Conclusions

Sealing of mesenteric vessels can be safely performed using the ENSEAL® G2 Articulating Tissue Sealer and produces supraphysiological burst pressures with minimal levels of thermal damage. Potential breaks developing as a result of articulation and disarticulation must be examined further for potential electrical arcing effects.

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Compliance with ethical standards

Conflict of interest This study was financially supported through an investigator-initiated Grant (#100263) from Ethicon Endo-Surgery, LLC. (subsidiary of Johnson & Johnson). Authors do not have any competing financial interests.

Ethical approval This study was approved by the Institutional Review Board committee of Advocate Lutheran General Hospital (IRB#5828).

Informed consent Informed consent was obtained from all patients participating in this study.

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