



## Advances in Vessel Sealing and Dissection with Ultrasonic Energy

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### Abstract

**Background:** Harmonic ultrasonic surgical devices, compared to conventional electrocautery, are associated with superior coagulation, less thermal damage, reduced production of surgical smoke, and improved surgical outcomes. Prior to the introduction of the Harmonic ACE+7 Shears in 2014, vessel sealing with purely ultrasonic devices was limited to vessels up to 5 mm in diameter. With the advent of Advanced Hemostasis Technology, ACE+7 was able to seal vessels up to 7 mm with high reliability and strength, and its clinical utility has been demonstrated in numerous studies. Since that time, progress in ultrasonic vessel sealing technology has enabled further advances in the use of the device, resulting in the new Harmonic 700 Shears with Advanced Hemostasis. This paper evaluates this device and compares its function to its predecessor, ACE+7.

**Methods:** Harmonic 700 was compared to ACE+7 for pad life, transection time, burst pressure and tissue sticking. Both devices were also compared for vessel sealing acutely in an *in vivo* porcine model, and in a one-month survival study.

**Results:** Harmonic 700 demonstrated significantly longer pad life, shorter transection time, higher burst pressures and less tissue sticking than ACE+7. In the acute *in vivo* study, Harmonic 700 displayed higher reliability in a simulated hypertensive crisis model. In the survival study, all seals were maintained for the duration of the postoperative period. Thermal damage remained under 2 mm lateral spread.

**Conclusion:** While advanced bipolar devices were first capable of large vessel sealing, ultrasonic devices have now surpassed them with stronger seals and meticulous dissection capabilities. The new Harmonic 700 performed as well as or better than its predecessor in benchtop and *in vivo* testing. Based on historical experience, clinical outcomes are also expected to improve.

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**Keywords:** Ultrasonic vessel sealing; Harmonic scalpel; Large vessel sealing; Hemostasis; Tissue sticking

### Introduction

Advances in Harmonic ultrasonic vessel sealing and transection technology over the past thirty years have enabled surgeons to improve the efficiency and safety of surgical procedures [1,2]. Introduced in 1990, the Harmonic scalpel uses ultrasonic energy to precisely cut and coagulate tissue allowing for simultaneous dissection and hemostasis. This device utilizes friction generated by ultrasonic vibration and clamping force to form a coagulum, effectively sealing vessels, resulting in optimal hemostasis. Compared to conventional electrocautery, Harmonic devices offer superior coagulation capabilities with lower thermal damage, decreased generation of surgical smoke, and enhanced surgical outcomes [2]. When using energy devices in surgery, unintentional injury to surrounding vital structures by means of thermal damage is a concern. One of the advantages of the Harmonic scalpel is its ability to minimize thermal spread as ultrasonic devices disperse less energy in surrounding tissue than diathermy [3-6]. Another challenge is that when such energy devices are used in laparoscopic procedures, surgical smoke can build up inside the abdominal cavity and obstruct surgical vision making it difficult for surgeons to operate. Harmonic devices, which function at lower tissue temperatures, produce a lower amount of smoke than other energy devices [7].

Advanced algorithms used in laparoscopic surgery are central for enhancing the safety, efficiency, and precision of sealing and cutting during laparoscopic surgery and other minimally invasive techniques. Earlier versions of ultrasonic instruments had a maximum vessel sealing capacity of 5 mm in diameter. Harmonic shears with Advanced Hemostasis are indicated for

sealing vessels up to 7 mm. The Advanced Hemostasis Technology provides the ability to monitor the tissue condition during use, and to modulate energy delivery to maintain optimal blade temperature. An independent rating of ten advanced energy devices, based on temperature of the device, burst pressure of sealed vessels and sealing time, gave Harmonic ACE+7 in Advanced Hemostasis mode the highest overall score [8].

The new Harmonic 700 (Figure 1, 2) has undergone new design enhancements to provide improved delivery of energy. This advanced energy device utilizes an innovative algorithm to administer the optimal amount of energy during tissue sealing and transection which regulates the temperature of the blade, potentially offering improved protection for both the tissue and the surrounding vital structures. While a Harmonic device itself becomes warm during activation, the actual thermal damage incurred during vessel sealing is generally less than that of advanced bipolar devices [9]. This difference is helpful when dissecting near vital structures, such as nerves. Additionally, the two-piece tissue pad to which the blade is opposed has been redesigned to be a single piece. This enables surgeons to take full bites of tissue, all the way to the distal portion of the jaw.

The objective of this work was to evaluate this new ultrasonic energy device, the Harmonic 700, for its effectiveness in sealing vessels, hemostatic performance, thermal damage, and overall useability in benchtop analyses and preclinical surgical models and compare it to its predecessor, the ACE+7.

## Methods

All *in vivo* procedures were reviewed, and animals approved for use by the Ethicon Institutional Animal Care and Use Committee in compliance with the US Animal Welfare Act Regulations (9CFR, Parts 1, 2 & 3) and the Guide for the Care and Use of Laboratory Animals of the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

The devices evaluated were the new HARMONIC™ 700 5-mm Diameter Shears with Advanced Hemostasis (HAR723/736/745) and the previous version of this device, the HARMONIC ACE™+7 5-mm Diameter Shears with Advanced Hemostasis (HARH23/36/45), both manufactured Ethicon, Inc., Cincinnati Ohio.

### Pad Life

Device pad life was determined as the number of activations before pad failure while sealing porcine jejunum. Prior to the test activations, a preconditioning cycle was performed with a 30-second-long activation with the device jaws open. Activations were performed at Power Level 5 on 15 devices per leg. Activation of the device extended three seconds beyond the point at which the tissue was transected. Based on the median failure cycle of ACE+7, a suspension point for stoppage of testing was set at 510 cycles.

### Transection time

For power level 5, transection speed was evaluated by sealing and cutting porcine jejunum under minimal tension, waiting 15 sec between transections. For power level 3, transection speed was evaluated by sealing and cutting 3 mm to 5 mm (measured round) porcine carotid vessels under tension and insufflation.

### Burst pressure

Burst pressure was determined *via* insufflation of porcine carotid vessels 5 mm to 7 mm diameter (measured flat) that had been sealed using Advanced Hemostasis mode for Harmonic 700 and compared

to previously published results for ACE+7 [10]. Vessels were sealed and cut without tension or insufflation.

### Acute *in vivo* study

For *in vivo* tests, the 23, 36 and 45 cm versions of Harmonic 700 were compared to the same respective lengths of ACE+7. A total of 180 vessels were sealed in 36 domestic swine for each of the two devices. Sealing and transection of a variety of blood vessels and blood vessel pedicles were performed in an acute porcine model. Endpoints were based on seal hemostasis at initial transection (first pass hemostasis), hemostasis after a hypertensive condition (blood pressure challenge), and thermal spread of carotid artery seals *via* histology. Blood vessels and blood vessel pedicles up to 5 mm in external diameter were transected using the Min/Max setting, and vessels and vessel pedicles up to 7 mm in external diameter using the Advanced Hemostasis setting. Seal integrity was assessed immediately after device application, and after a blood pressure challenge where the systolic blood pressure was elevated to  $\geq 200$  mmHg for a minimum of at least 10 min. Hemostasis was evaluated using the Siegel Hemostasis Likert scale [11]. Following completion of the sealing tests, the animals were euthanized, and the carotid artery seals collected. Seals were histologically processed and microscopically evaluated for lateral thermal damage. The caudal sides of porcine carotid artery seals were immersion-fixed in formalin solution, trimmed, processed histologically using H&E staining, and thermal damage measured by observation of adventitial collagen denaturation.

### Sticking

Sticking was analyzed as the total of all sticking occurrences categorized as mild, moderate or severe. Harmonic was applied to porcine carotid, epigastric, gastroepiploic, inferior mesenteric, ovarian pedicle, renal, splenic and uterine vessels, using power levels 3, 5 or Advanced Hemostasis mode as appropriate for the vessel.

### Survival study

A survival porcine study was conducted to evaluate initial ligation and transection of vessels and vessel pedicles up to 7 mm in diameter. Seal durability was tested after a minimum 21-day survival period and a simulated hypertensive crisis. A total of 24 domestic female swine were used with 12 treated with the Harmonic 700 and 12 with ACE+7. Intra-abdominal vessels and vessel pedicles associated with specific surgical procedures (i.e., splenectomy and nephrectomy,) were ligated and sealed in all animals. Additionally, all animals had one carotid artery (either right or left) ligated and sealed. After a minimum of 21 days postoperatively, all pigs underwent a chronic seal durability assessment under simulated hypertensive crisis. Animals were then euthanized and necropsied. At necropsy, all seals were assessed for evidence of bleeding (chronic or acute hemorrhage), adequacy of tissue healing, presence of adhesions with the surrounding tissues and any other changes indicative of possible intraoperative damage (thermal and/or mechanical) to adjacent tissues.

### Statistics

Statistical comparisons for continuous data were performed using Student's t-test for normal data or Mann-Whitney for non-normal data. Comparisons for proportions used Fisher's exact test. All statistical comparisons used an alpha of significance of 0.05.

## Results

### Pad life

ACE+7 achieved a median pad life of 20 cycles, while Harmonic



**Figure 1:** Harmonic™ 700 5-mm diameter Shears with Advanced Hemostasis.

700 had a median of at least 510 activations, i.e., the suspension point ( $p < 0.001$ ). Hence the median pad life of Harmonic 700 was at least 24 times longer than that of ACE+7.

**Transection time**

Harmonic 700 transected 10% faster than ACE+7 at Power Level 3 on porcine carotid vessels and 31% faster at Power Level 5 on porcine jejunum.

**Burst pressure**

Median burst pressures for Harmonic 700 in Advanced Hemostasis mode were higher than historical values for ACE+7, and 15 times as high as a normal systolic pressure of 120 mmHg.

**Sticking**

Harmonic 700 had 93% less total sticking than ACE+7, and exhibited no severe sticking in over 1000 applications.

**Acute in vivo study**

There was no significant difference for first-pass hemostasis between Harmonic 700 and ACE+7, with both devices providing over 99% sealing success. However, for the blood pressure challenge, Harmonic 700 provided a significantly higher success rate. The failure rate was reduced from 2.4% for ACE+7 to 0.5% for Harmonic 700, a 79% reduction. There was no difference in lateral thermal damage between the devices, with both producing less than 2 mm of lateral thermal damage as assessed by adventitial collagen denaturation.

**Survival study**

In the survival study, both devices provided high rates for initial hemostasis and hemostasis after the simulated hypertensive crisis at 22 to 28 days postoperatively, with no failures observed for Harmonic 700. Pathology assessment after necropsy showed gross healing responses at each treatment site location were similar between the two devices and were minimal to mild, typical and as expected after the survival period (Table 1).

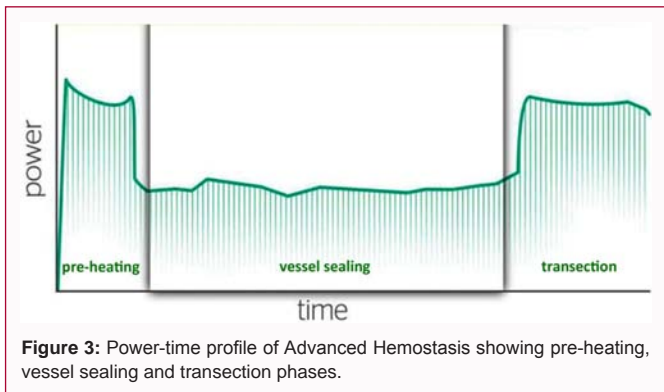
**Discussion**

Harmonic devices have demonstrated improved patient outcomes for operating time, length of stay, intraoperative blood loss, drainage volume, postoperative pain, and overall complications compared to conventional techniques [2].

Surgical procedures are optimized by the improved dissection techniques with simultaneous cut and coagulation occurring at lower temperatures without electric currents passing through the body providing a safer surgery [6]. Prior to the introduction of ACE+7, only advanced bipolar devices, such as LigaSure or Enseal, were capable of sealing vessels greater than 5 mm in diameter. With the introduction of ACE+7, which maintained the superior dissection characteristics of Harmonic ACE+, ultrasonic shears could seal vessels up to and including 7 mm, when using the device in Advanced Hemostasis mode [10,12-14]. Additionally, the new Advanced Hemostasis



**Figure 2:** Closeup of the Harmonic 700 end effector.



**Figure 3:** Power-time profile of Advanced Hemostasis showing pre-heating, vessel sealing and transection phases.

**Table 1:** Summary of comparisons of Harmonic 700 vs. ACE+7.

Measure	Harmonic 700	ACE+7	p-value
Pad Life: No. Activations (median)	≥ 510 cycles	20 cycles	<0.001
<b>Transection time (median)</b>			
Power Level 3	6.67 s	7.37 s	0.029
Power Level 5	6.02 s	7.88 s	<0.001
<b>Burst Pressure (median)</b>			
Advanced Hemostasis	1894 mmHg	1294 mmHg*	NA
Sticking (percentage)			
Total	0.64% (8/1247)	8.80% (109/1242)	<0.001
Severe	0.00% (0/1247)	5.40% (67/1242)	<0.001
Acute Study	99.80%	99.10%	0.218
First-pass Hemostasis	(586/587)	(582/587)	
Acute Study	99.50%	97.60%	0.007
Blood Pressure Challenge	(583/586)	(568/582)	
Lateral Thermal Damage (mean)	1.89 ± 0.47 mm	1.89 ± 0.47 mm	1.000
Survival Study			
First-pass Hemostasis	100% (313/313)	99.70% (341/342)	1.000
Survival Study			
End of Study Seal Durability	100%	100%	1.000

mode responsible for 7 mm sealing provided increased strength and confidence when used with smaller vessels.

The Technology of Advanced Hemostasis mode, which allows for the sealing of 7 mm vessels, is based on the careful control of power based upon monitoring of tissue conditions (Figure 3). In the first phase, elevated power of the ultrasonic blade quickly heats the tissue and drives off most of the water. As the tissue reaches an appropriate moisture content, the power drops down and remains relatively constant for the longest phase of the cycle; this is where the bulk of the sealing occurs. When this stage is complete, the power is ramped up so that the tissue can be quickly dissected during the final phase. The relatively long vessel sealing phase at low power allows mobility and increased adhesion of the collagen fibers, providing strong seals

even with large diameter vessels.

Advanced Hemostasis mode was also used in Harmonic HD1000i. For this device, a longer 'Maryland'-type blade was incorporated to provide greater dissecting ability [15,16]. Based on the blade length, the resonant ultrasonic frequency was lowered from 55 kHz to approximately 50 kHz, necessitating appropriate changes in the Advanced Hemostasis mode parameters. However, it was observed that if the device were run without tissue in the jaws (so-called 'abuse mode'), the pad against which the blade presses would on occasion melt. The Adaptive Tissue Technology that controls the energy delivery was adjusted so that the maximum blade temperature reached by an updated device, Harmonic H1100, would not exceed the melting point of the pad [17,18]. The new Harmonic 700 incorporates this same temperature-limiting algorithm, and results show that the median pad life of Harmonic 700 is at least 24 times longer than that of ACE+7.

There have been over thirty published clinical studies using ACE+7 or HD1000i, involving a total of more than 4000 subjects. Specialties evaluated include breast, colorectal, general, gynecology, head & neck, hepatobiliary, thoracic and urology. Notable among these is a series of studies evaluating ultrasonic vessel sealing in pulmonary lobectomy [19-23]. In the final study of this series, ACE+7 was found to effectively seal pulmonary artery branches up to and including vessels 7 mm in diameter, at a success rate equivalent to endostaplers, with an absence of postoperative bleeding. Although ACE+7 may be perceived as a high-cost item, a study found that in gastrectomy, its use was associated with the use of fewer ligating clips and less blood loss, resulting in overall comparable costs [24].

Several other large-scale studies (i.e., more than 100 subjects) have evaluated ultrasonic devices capable of sealing 7-mm vessels. In a study of laparoscopic liver resection of more than 600 patients, use of ACE+7 or HD1000i was associated with safe outcomes, while removing the need for intraoperative drain placement [25]. In a retrospective study of thoracoscopic procedures in over 900 subjects, HD1000i demonstrated low rates of blood loss and complications in lobectomies and segmentectomies [26]. In a study of over 400 patients demonstrating decreased complications with the use of an Enhanced Recovery after Surgery (ERAS) protocol during open and laparoscopic liver resection, HD1000i was chosen for performing the parenchymal transection [27]. In a study of more than 1000 subjects undergoing laparoscopic appendectomy, use of ACE+7 provided shorter operative time, lower pain scores and a lower rate of postoperative ileus compared to conventional techniques [28]. HD1000i has been shown to provide acceptable outcomes in a variety of urologic surgical procedures *via* a retrospective review of 105 subjects [29]. Recently, in a smaller study of breast reconstruction with extended latissimus dorsi flap, ACE+7 was shown to significantly reduce the rate of seroma, operative time, and intraoperative bleeding compared to conventional techniques [30].

While the use of energy devices provides convenience for surgeons, there is concern regarding inadvertent damage to the adjacent tissues particularly from ultrasonic devices. Several studies, however, have shown that monopolar electrosurgery exhibits greater thermal damage than Harmonic devices [6,31,32]. Many studies have shown that Harmonic technology with its minimal thermal spread can reduce postoperative complications and pain [2]. In addition, the new updated thermal management system was designed to reduce Harmonic blade temperatures. This change may also reduce the

chance of inadvertent injury to nearby structures. In the current study there was no difference in lateral thermal damage between ACE+7 and Harmonic 700, with both producing less than 2 mm of damage.

Surgical smoke is caused by the thermal destruction of tissue when using energy-generating devices during surgical procedures. Tissue heated by energy devices to temperatures of at least 100°C can cause cells to burst and smoke to disperse throughout the operating room [33]. It is generally accepted that inhaling particulate matter found in surgical smoke can cause adverse effects on health [34-36]. Research has shown that there are fewer VOCs in surgical smoke produced by ultrasonic devices [37].

In an age of rapidly developing surgical technology combined with the desire for faster, less painful, and safer surgery, the need for constant evaluation and reconfiguration of current surgical tools is crucial. Harmonic 700 is an example of this concept through enhanced modulation of energy delivery. The Harmonic 700 has produced a variety of improved metrics for effective use and this study has demonstrated these benefits in preclinical testing. The factors that were studied were a chosen conglomeration of specific feedback obtained clinically in the operating room and previous measures of effectiveness of advanced energy devices [8].

Factors that were significantly improved for Harmonic 700 relative to its predecessor, ACE+7, include longer pad life, reduced transection time, increased burst pressure, less tissue sticking, and more durable vessel seals. Increased burst pressure and more durable seals in elevated blood pressure subjects may provide additional security to the patient and the surgeon postoperatively. With reduced transection time and sticking, surgical procedures can be more fluid and efficient, allowing decreased operative times and a reduction in iatrogenic injury from incidental tissue damage. These improvements in speed, efficiency and strength have been achieved without a negative impact on the thermal properties of Harmonic 700. Lateral thermal damage to tissue remains low, at less than 2 mm.

Based on the history of improved patient outcomes from the use of Harmonic technology, it is anticipated that the advances demonstrated in this preclinical study of Harmonic 700 will lead to continued improved clinical outcomes. Future clinical studies are needed to confirm these benefits.

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